WHA70/2017/REC/1



WORLD HEALTH ORGANIZATION

# SEVENTIETH WORLD HEALTH ASSEMBLY

GENEVA, 22–31 MAY 2017

RESOLUTIONS AND DECISIONS ANNEXES

> GENEVA 2017

## **ABBREVIATIONS**

Abbreviations used in WHO documentation include the following:

| FAO  | <ul> <li>Food and Agriculture</li> <li>Organization of the United</li> </ul> | UNAIDS – Joint United Nations Programme<br>on HIV/AIDS               |
|------|--|--|
|      | Nations  | UNCTAD – United Nations Conference on                                |
| IAEA | <ul> <li>International Atomic Energy</li> </ul>                              | Trade and Development  |
|      | Agency   | UNODC – United Nations Office on Drugs                               |
| IARC | <ul> <li>International Agency for Research</li> </ul>                        | and Crime  |
|      | on Cancer  | UNDP – United Nations Development                                    |
| ICAO | <ul> <li>International Civil Aviation</li> </ul>                             | Programme  |
|      | Organization   | UNEP – United Nations Environment                                    |
| IFAD | – International Fund for   | Programme  |
|      | Agricultural Development   | UNESCO – United Nations Educational,                                 |
| ILO  | - International Labour Organization  | Scientific and Cultural  |
|      | (Office)   | Organization   |
| IMF  | – International Monetary Fund  | UNFPA – United Nations Population Fund                               |
| IMO  | - International Maritime   | UNHCR – Office of the United Nations High                            |
| IOM  | Organization   | Commissioner for Refugees<br>UNICEF – United Nations Children's Fund |
| IOM  | <ul> <li>International Organization for<br/>Migration</li> </ul>             | UNIDO – United Nations Industrial                                    |
| INCB | <ul> <li>International Narcotics Control</li> </ul>                          | Development Organization   |
| INCD | Board  | UNRWA – United Nations Relief and Works                              |
| ITU  | <ul> <li>International Telecommunication</li> </ul>                          | Agency for Palestine Refugees in                                     |
| 110  | Union  | the Near East  |
| OECD | <ul> <li>Organisation for Economic</li> </ul>                                | WFP – World Food Programme   |
| 0202 | Co-operation and Development   | WIPO – World Intellectual Property                                   |
| OIE  | <ul> <li>World Organisation for Animal</li> </ul>                            | Organization   |
|      | Health   | WMO – World Meteorological   |
| РАНО | – Pan American Health  | Organization   |
|      | Organization   | WTO – World Trade Organization                                       |
|      |  |  |

The designations employed and the presentation of the material in this volume do not imply the expression of any opinion whatsoever on the part of the Secretariat of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Where the designation "country or area" appears in the headings of tables, it covers countries, territories, cities or areas.

## PREFACE

The Seventieth World Health Assembly was held at the Palais des Nations, Geneva, from 22 to 31 May 2017, in accordance with the decision of the Executive Board at its 139th session.<sup>1</sup>

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<sup>&</sup>lt;sup>1</sup> Decision EB139(11) (2016).

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# AGENDA<sup>1</sup>

## PLENARY

- 1. Opening of the Health Assembly
  - 1.1 Appointment of the Committee on Credentials
  - 1.2 Election of the President
  - 1.3 Election of the five Vice-Presidents, the Chairmen of the main committees, and establishment of the General Committee
  - 1.4 Adoption of the agenda and allocation of items to the main committees
- 2. Report of the Executive Board on its 139th and 140th sessions
- 3. Address by Dr Margaret Chan, Director-General
- 4. Post of Director-General
  - 4.1 Procedures for the conduct of the election
  - 4.2 Appointment of the Director-General
  - 4.3 Contract of the Director-General
- 5. [deleted]
- 6. Executive Board: election
- 7. Awards
- 8. Reports of the main committees
- 9. Closure of the Health Assembly

<sup>&</sup>lt;sup>1</sup> Adopted at the second plenary meeting.

## **COMMITTEE A**

- 10. Opening of the Committee<sup>1</sup>
- 11. Programme and budget matters
  - 11.1 Overview of financial situation: Programme budget 2016–2017
  - 11.2 Proposed programme budget 2018–2019
- 12. Preparedness, surveillance and response
  - 12.1 Health emergencies
    - The Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme
    - WHO response in severe, large-scale emergencies
    - Research and development for potentially epidemic diseases
    - Health workforce coordination in emergencies with health consequences
  - 12.2 Antimicrobial resistance
  - 12.3 Poliomyelitis
    - Poliomyelitis update
    - Polio transition planning
  - 12.4 Implementation of the International Health Regulations (2005)
  - 12.5 Review of the Pandemic Influenza Preparedness Framework
- 13. Health systems
  - 13.1 Human resources for health and implementation of the outcomes of the United Nations' High-Level Commission on Health Employment and Economic Growth
  - 13.2 Principles on the donation and management of blood, blood components and other medical products of human origin
  - 13.3 Addressing the global shortage of, and access to, medicines and vaccines
  - 13.4 Evaluation and review of the global strategy and plan of action on public health, innovation and intellectual property

<sup>&</sup>lt;sup>1</sup> Including election of Vice-Chairmen and the Rapporteur.

- 13.5 Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination
- 13.6 Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products
- 13.7 Promoting the health of refugees and migrants
- 14. Communicable diseases
  - 14.1 Global vaccine action plan
  - 14.2 Global vector control response
- 15. Noncommunicable diseases
  - 15.1 Preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018
  - 15.2 Draft global action plan on the public health response to dementia
  - 15.3 Public health dimension of the world drug problem
  - 15.4 Outcome of the Second International Conference on Nutrition
  - 15.5 Report of the Commission on Ending Childhood Obesity: implementation plan
  - 15.6 Cancer prevention and control in the context of an integrated approach
  - 15.7 Strengthening synergies between the World Health Assembly and the Conference of the Parties to the WHO Framework Convention on Tobacco Control
  - 15.8 Prevention of deafness and hearing loss
- 16. Promoting health through the life course
  - 16.1 Progress in the implementation of the 2030 Agenda for Sustainable Development
  - 16.2 The role of the health sector in the Strategic Approach to International Chemicals Management towards the 2020 goal and beyond
  - 16.3 Global Strategy for Women's, Children's and Adolescents' Health (2016–2030): adolescents' health

## 17. Progress reports

#### Noncommunicable diseases

- A. WHO global disability action plan 2014–2021: better health for all people with disability (resolution WHA67.7 (2014))
- B. Addressing the challenges of the United Nations Decade of Action for Road Safety (2011–2020): outcome of the second Global High-level Conference on Road Safety – Time for Results (resolution WHA69.7 (2016))
- C. Towards universal eye health: a global action plan 2014–2019 (resolution WHA66.4 (2013))

#### **Communicable diseases**

- D. Eradication of dracunculiasis (resolution WHA64.16 (2011))
- E. Global strategy and targets for tuberculosis prevention, care and control after 2015 (resolution WHA67.1 (2014))
- F. Global technical strategy and targets for malaria 2016–2030 (resolution WHA68.2 (2015))

#### Promoting health through the life course

- G. Public health impacts of exposure to mercury and mercury compounds: the role of WHO and ministries of public health in the implementation of the Minamata Convention (resolution WHA67.11 (2014))
- H. Strategy for integrating gender analysis and actions into the work of WHO (resolution WHA60.25 (2007))

#### Health systems

- I. Progress in the rational use of medicines (resolution WHA60.16 (2007))
- J. Regulatory system strengthening for medical products (resolution WHA67.20 (2014))
- K. Strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage (resolution WHA68.15 (2015))

#### Preparedness, surveillance and response

- L. Smallpox eradication: destruction of variola virus stocks (resolution WHA60.1 (2007))
- M. Enhancement of laboratory biosafety (resolution WHA58.29 (2005))
- 20.3 Special arrangements for settlement of arrears

#### **COMMITTEE B**

- 18. Opening of the Committee<sup>1</sup>
- 19. Health conditions in the occupied Palestinian territory, including east Jerusalem, and in the occupied Syrian Golan
- 20. Financial matters
  - 20.1 WHO mid-term programmatic and financial report for 2016–2017, including audited financial statements for 2016
  - 20.2 Status of collection of assessed contributions, including Member States in arrears in the payment of their contributions to an extent that would justify invoking Article 7 of the Constitution
  - 20.3 [transferred to Committee A]
  - 20.4 Scale of assessments for 2018–2019
  - 20.5 [deleted]
  - 20.6 [deleted]
- 21. Audit and oversight matters
  - 21.1 Report of the External Auditor
  - 21.2 Report of the Internal Auditor
- 22. Staffing matters
  - 22.1 Human resources: annual report
  - 22.2 Report of the International Civil Service Commission
  - 22.3 Amendments to the Staff Regulations and Staff Rules
  - 22.4 Report of the United Nations Joint Staff Pension Board
  - 22.5 Appointment of representatives to the WHO Staff Pension Committee
- 23. Management, legal and governance matters
  - 23.1 Overview of WHO reform implementation
  - 23.2 Governance reform: follow-up to decision WHA69(8) (2016)

<sup>&</sup>lt;sup>1</sup> Including election of Vice-Chairmen and the Rapporteur.

- 23.3 Engagement with non-State actors
  - Criteria and principles for secondments from nongovernmental organizations, philanthropic foundations and academic institutions
- 23.4 Proposed Infrastructure Fund (consolidating the Real Estate Fund and IT Fund)
- 23.5 [deleted]
- 24. Collaboration within the United Nations system and with other intergovernmental organizations

# LIST OF DOCUMENTS

| A70/1 Rev.2       | Agenda <sup>1</sup>   |
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| A70/2             | Report of the Executive Board on its 139th and 140th sessions                                       |
| A70/3             | Address by Dr Margaret Chan, Director-General, to the Seventieth World Health Assembly              |
| A70/4             | Post of Director-General<br>Note by the Legal Counsel <sup>2</sup>                                  |
| A70/5             | Post of Director-General<br>Contract of the Director-General <sup>3</sup>                           |
| A70/6             | Overview of financial situation: Programme budget 2016–2017   |
| A70/7             | Proposed programme budget 2018–2019   |
| A70/7 Add.1 Rev.1 | Draft resolution: Programme budget 2018–2019  |
| A70/8             | Report of the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme |
| A70/9             | Health emergencies<br>WHO response in severe, large-scale emergencies                               |
| A70/10            | Research and development for potentially epidemic diseases  |
| A70/11            | Health workforce coordination in emergencies with health consequences                               |
| A70/12            | Antimicrobial resistance  |
| A70/13            | Improving the prevention, diagnosis and clinical management of sepsis                               |
| A70/14            | Poliomyelitis   |
| A70/14 Add.1      | Polio transition planning <sup>4</sup>  |
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<sup>&</sup>lt;sup>1</sup> See page ix.

<sup>&</sup>lt;sup>2</sup> See Annex 6.

<sup>&</sup>lt;sup>3</sup> See Annex 1.

<sup>&</sup>lt;sup>4</sup> See Annex 7.

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| A70/15       | Implementation of the International Health Regulations (2005)<br>Annual report on the implementation of the International Health<br>Regulations (2005)           |
|--------------|--|
| A70/16       | Implementation of the International Health Regulations (2005)<br>Global implementation plan <sup>1</sup>   |
| A70/17       | Review of the Pandemic Influenza Preparedness Framework <sup>2</sup>   |
| A70/18       | Human resources for health and implementation of the outcomes of the United Nations' High-Level Commission on Health Employment and Economic Growth <sup>3</sup> |
| A70/19       | Principles on the donation and management of blood, blood components and other medical products of human origin  |
| A70/20       | Addressing the global shortage of, and access to, medicines and vaccines   |
| A70/21       | Evaluation and review of the global strategy and plan of action on public health, innovation and intellectual property   |
| A70/22       | Follow-up of the report of the Consultative Expert Working Group on<br>Research and Development: Financing and Coordination                                      |
| A70/23       | Member State mechanism on substandard/spurious/falsely-<br>labelled/falsified/counterfeit medical products <sup>4</sup>  |
| A70/23 Add.1 | Review of the Member State mechanism on<br>substandard/spurious/falsely-labelled/falsified/counterfeit medical<br>products                                       |
| A70/23 Add.2 | Financial and administrative implications for the Secretariat of decisions proposed for adoption by the Health Assembly <sup>5</sup>                             |
| A70/24       | Promoting the health of refugees and migrants <sup>6</sup>   |
| A70/25       | Global vaccine action plan   |

- <sup>2</sup> See Annex 8.
- <sup>3</sup> See Annex 2.
- <sup>4</sup> See Annex 12.
- <sup>5</sup> See Annex 14
- <sup>6</sup> See Annex 4.

<sup>&</sup>lt;sup>1</sup> See Annex 9.

| A70/26 Rev.1 and<br>A70/26 Rev.1 Add.1 | Global vector control response <sup>1</sup>  |
|--|--|
| A70/26 Rev.1 Add.2                     | Financial and administrative implications for the Secretariat of resolutions proposed for adoption by the Health Assembly <sup>2</sup>                           |
| A70/27                                 | Preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018 <sup>3</sup> |
| A70/28                                 | Draft global action plan on the public health response to dementia <sup>4</sup>  |
| A70/29                                 | Public health dimension of the world drug problem  |
| A70/30                                 | Outcome of the Second International Conference on Nutrition  |
| A70/31                                 | Report of the Commission on Ending Childhood Obesity: implementation plan <sup>5</sup>   |
| A70/32                                 | Cancer prevention and control in the context of an integrated approach   |
| A70/33                                 | Strengthening synergies between the World Health Assembly and the<br>Conference of the Parties to the WHO Framework Convention on<br>Tobacco Control             |
| A70/34                                 | Prevention of deafness and hearing loss  |
| A70/35                                 | Progress in the implementation of the 2030 Agenda for Sustainable Development  |
| A70/36                                 | The role of the health sector in the Strategic Approach to<br>International Chemicals Management towards the 2020 goal and<br>beyond <sup>6</sup>                |
| A70/36 Add.1                           | Financial and administrative implications for the Secretariat of decisions proposed for adoption by the Health Assembly <sup>7</sup>                             |

- <sup>2</sup> See Annex 14.
- <sup>3</sup> See Annex 3.
- <sup>4</sup> See Annex 10.
- <sup>5</sup> See Annex 11.
- <sup>6</sup> See Annex 13.
- <sup>7</sup> See Annex 14.

<sup>&</sup>lt;sup>1</sup> See Annex 5.

## SEVENTIETH WORLD HEALTH ASSEMBLY

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| A70/38       | Progress reports  |
| A70/39       | Health conditions in the occupied Palestinian territory, including east Jerusalem, and in the occupied Syrian Golan   |
| A70/40       | WHO mid-term programmatic and financial report for 2016–2017, including audited financial statements for 2016   |
| A70/41       | Status of collection of assessed contributions, including Member<br>States in arrears in the payment of their contributions to an extent that<br>would justify invoking Article 7 of the Constitution |
| A70/42       | Scale of assessments for 2018–2019  |
| A70/43       | Report of the External Auditor  |
| A70/44       | Report of the Internal Auditor  |
| A70/45       | Human resources: annual report  |
| A70/46       | Report of the International Civil Service Commission  |
| A70/47       | Amendments to the Staff Regulations and Staff Rules   |
| A70/48       | Report of the United Nations Joint Staff Pension Board  |
| A70/49       | Appointment of representatives to the WHO Staff Pension<br>Committee  |
| A70/50       | Overview of WHO reform implementation   |
| A70/50 Add.1 | Overview of WHO reform implementation<br>Leadership and management at WHO: evaluation of WHO reform,<br>third stage   |
| A70/50 Add.2 | Overview of WHO reform implementation<br>WHO's performance in countries   |
| A70/51       | Governance reform: follow-up to decision WHA69(8) (2016)  |
| A70/51 Add.1 | Financial and administrative implications for the Secretariat of decisions proposed for adoption by the Health Assembly <sup>1</sup>  |
| A70/52       | Engagement with non-State actors  |

<sup>1</sup> See Annex 14.

| A70/53 | Engagement with non-State actors<br>Criteria and principles for secondments from nongovernmental<br>organizations, philanthropic foundations and academic institutions  |
|--------|---|
| A70/54 | Proposed Infrastructure Fund (consolidating the Real Estate Fund and IT Fund)   |
| A70/55 | Collaboration within the United Nations system and with other intergovernmental organizations   |
| A70/56 | External and internal audit recommendations: report on implementation   |
| A70/57 | Review of the Pandemic Influenza Preparedness Framework<br>Collaboration with the Secretariat of the Convention on Biological<br>Diversity and other relevant international organizations   |
| A70/58 | Overview of financial situation: Programme budget 2016–2017<br>WHO mid-term programmatic and financial report for 2016–2017,<br>including audited financial statements for 2016<br>Report of the Programme, Budget and Administration Committee of<br>the Executive Board to the Seventieth World Health Assembly                       |
| A70/59 | Proposed programme budget 2018–2019<br>Report of the Programme, Budget and Administration Committee of<br>the Executive Board to the Seventieth World Health Assembly   |
| A70/60 | Status of collection of assessed contributions, including Member<br>States in arrears in the payment of their contributions to an extent that<br>would justify invoking Article 7 of the Constitution<br>Report of the Programme, Budget and Administration Committee of<br>the Executive Board to the Seventieth World Health Assembly |
| A70/61 | Report of the External Auditor<br>Report of the Programme, Budget and Administration Committee of<br>the Executive Board to the Seventieth World Health Assembly  |
| A70/62 | Report of the Internal Auditor<br>Report of the Programme, Budget and Administration Committee of<br>the Executive Board to the Seventieth World Health Assembly  |
| A70/63 | Human resources: annual report<br>Report of the Programme, Budget and Administration Committee of<br>the Executive Board to the Seventieth World Health Assembly  |
| A70/64 | Overview of WHO reform implementation<br>Report of the Programme, Budget and Administration Committee of<br>the Executive Board to the Seventieth World Health Assembly   |

## SEVENTIETH WORLD HEALTH ASSEMBLY

| A70/65                | Proposed Infrastructure Fund (consolidating the Real Estate Fund and<br>IT Fund)<br>Report of the Programme, Budget and Administration Committee of<br>the Executive Board to the Seventieth World Health Assembly |  |
|-----------------------|--|--|
| A70/66                | Committee on Credentials   |  |
| A70/67                | Special arrangements for settlement of arrears   |  |
| A70/68                | First report of Committee A  |  |
| A70/69                | Second report of Committee A   |  |
| A70/70                | Election of Members entitled to designate a person to serve on the Executive Board   |  |
| A70/71                | First report of Committee B  |  |
| A70/72                | Third report of Committee A  |  |
| A70/73                | Fourth report of Committee A   |  |
| A70/74                | Second report of Committee B   |  |
| A70/75                | Fifth report of Committee A  |  |
| A70/76                | Third report of Committee B  |  |
| A70/77                | Sixth report of Committee A  |  |
| A70/78                | Fourth report of Committee B   |  |
| Information documents |  |  |
| A70/INF./1            | Awards   |  |
| A70/INF./2            | Proposed programme budget 2018–2019<br>Proposed increase in assessed contributions   |  |
| A70/INF./3            | WHO presence in countries, territories and areas: 2017 report  |  |
| A70/INF./4            | Voluntary contributions by fund and by contributor, 2016   |  |
| A70/INF./5            | Financing of category 6 and cost recovery mechanisms: current practices and proposed way forward   |  |
| A70/INF./6            | Better value, better health<br>Towards a strategy and plan for value for money for WHO   |  |

## **Diverse documents**

| A70/DIV./1 Rev.1 | List of delegates and other participants         |
|------------------|--|
| A70/DIV./2       | Guide for delegates to the World Health Assembly |
| A70/DIV./3       | List of decisions and resolutions                |
| A70/DIV./4       | List of documents                                |

## OFFICERS OF THE HEALTH ASSEMBLY AND MEMBERSHIP OF ITS COMMITTEES

#### President

Professor Veronika SKVORTSOVA (Russian Federation)

## Vice-Presidents

Mr Nandi Tuaine GLASSIE (Cook Islands) Dr Fawziya ABIKAR NUR (Somalia) Dr Arlindo NASCIMENTO DO ROSARIO (Cabo Verde) Mr Patrick PENGEL (Suriname) Mr CHOE Myong Nam (Democratic People's Republic of Korea)

#### Secretary

Dr Margaret CHAN, Director-General

#### **Committee on Credentials**

The Committee on Credentials was composed of delegates of the following Member States: Angola; Belarus; Italy; Japan; Lithuania; Mali; Myanmar; Panama; Paraguay; South Sudan; Yemen.

Chairman: Mr Hiroyuki YAMAYA (Japan) Vice-Chairman: Mr Augusto Rosa NETO (Angola)

Secretary: Mr Xavier DANEY, Senior Legal Officer

#### **General Committee**

The General Committee was composed of the President and Vice-Presidents of the Health Assembly and the chairmen of the main committees, together with the delegates of the following Member States: China, Cuba, Djibouti, Dominican Republic, France, Guinea, Kyrgyzstan, Malawi, Maldives, Malta, Mozambique, Norway, Philippines, Rwanda, Togo, United Kingdom of Great Britain and Northern Ireland, and United States of America.

Chairman: Professor Veronika SKVORTSOVA (Russian Federation) Secretary: Dr Margaret CHAN, Director-General

#### MAIN COMMITTEES

Under Rule 33 of the Rules of Procedure of the World Health Assembly, each delegation is entitled to be represented on each main committee by one of its members.

### **Committee A**

Chairman: Dr Hanan Mohamed AL-KUWARI (Oatar)

- **Vice-Chairmen:** Dr Mohammad Anwar HUSNOO (Mauritius)<sup>1</sup> and Mr Philip DAVIES (Fiji)
- **Rapporteur:** Mr Ioannis BASKOZOS (Greece)

Secretary: Mr Ian ROBERTS, Coordinator, Library and Information Networks for Knowledge

#### **Committee B**

**Chairman:** Dr Molwyn JOSEPH (Antigua and Barbuda)

Vice-Chairmen: Mr Mario MIKLOSI (Slovakia) and Dr SLAMET (Indonesia)

Rapporteur: Dr NGUYEN MANH CUONG (Viet Nam)

Secretary: Dr Clive ONDARI, Coordinator, Safety and Vigilence

## **REPRESENTATIVE OF THE EXECUTIVE BOARD**

Dr Raymond BUSUTTIL (Malta)

<sup>&</sup>lt;sup>1</sup> Replaced by Mr Anandrao Hurree (Mauritius) at the opening of the third meeting of Committee A.

**RESOLUTIONS AND DECISIONS** 

## RESOLUTIONS

## WHA70.1 Arrears in payment of contributions: Somalia

The Seventieth World Health Assembly,

Having considered the request of Somalia (see Annex to the present resolution) in respect of its outstanding contributions of US\$ 451 014, and noting payment of US\$ 4650 in respect of 2016, and the commitment given to make a further payment of US\$ 4650 in respect of 2017;

Having also considered the request of Somalia to reschedule payment of this balance of US\$ 446 364 over the period 2018–2037;

Noting also that this request did not comply fully with the requirements of resolution WHA54.6 (2001) as to timing and procedure,

1. DECIDES to restore Somalia's voting privileges at the Seventieth World Health Assembly on the following conditions:

Somalia shall pay its outstanding arrears of assessed contributions, totalling US\$ 446 364 over 20 years from 2018 to 2037 as set out below, in addition to making payment of its annual assessment for the current year;

| Year  | US\$    |
|-------|---------|
| 2018  | 22 318  |
| 2019  | 22 318  |
| 2020  | 22 318  |
| 2021  | 22 318  |
| 2022  | 22 318  |
| 2023  | 22 318  |
| 2024  | 22 318  |
| 2025  | 22 318  |
| 2026  | 22 318  |
| 2027  | 22 318  |
| 2028  | 22 318  |
| 2029  | 22 318  |
| 2030  | 22 318  |
| 2031  | 22 318  |
| 2032  | 22 318  |
| 2033  | 22 318  |
| 2034  | 22 318  |
| 2035  | 22 318  |
| 2036  | 22 318  |
| 2037  | 22 322  |
| TOTAL | 446 364 |

2. FURTHER DECIDES that, in accordance with Article 7 of the Constitution, Somalia's voting privileges shall be automatically suspended if it does not meet the requirements laid down in paragraph 1 above;

3. REQUESTS the Director-General to report to the Seventy-first World Health Assembly on the prevailing situation;

4. FURTHER REQUESTS the Director-General to communicate this resolution to the Government of Somalia.





Jamhuuriyadda Federasika Soomaaliya Srgada Jooglada Soomaliyeed ee Qaramada Midoobay ee Caneva

جمهورية المومان الفيارانية ابتلة الدامة لجنوررية الصومان بنكب الأمم الفتاة بيقيف ويقرىانات المقاصصة بسويسر

THE FEDERAL REPUBLIC OF SCHALLS

Permanent Mission of the Federal Republic of Semalla to the United Nations Office at Geneva and other International Organizations in Switzerland

Ref: SPM/UNOG/003479/17

Geneva May 22, 2017

The Permanent Mission of the Federal Republic of Somalia to the United Nations Office and Other international organizations in Switzerland presents its complements to the World Health organization and has the honor to acknowledge that due to the prolonged civil war the Federal Republic of Somalia cives membership fees arrears amounting USD 451,014.00 up to an including 2016 to WHO. In order to settle the arrears we commit ourselves to pay at the present USD 9,300.00 being 2016 and 2017 and the balance in installments for the coming 20 years, as has been practice to other countries.

We call the member states and the WHO Secretariat to support our request.

The Permanent Mission of the Federal Republic of Somalia to the United Nations office and other International Organizations in Switzerland avails itself of this opportunity to renew to the World Health Organization in Geneva. The assurance of its highest and distinguished consideration.

Mrs. Margaret Chan Director General World Health Organization Avenue Appia 20 1211 Geneva 27, Switzerland



64, rue de Mariffrota 1201 Genava (b. 14. (0)227315450 & +4. (0)227316402, genevamission@mia.gov.sc

(Fourth plenary meeting, 23 May 2017 – Committee A, first report)

## WHA70.2 Appointment of the Director-General

The Seventieth World Health Assembly,

On the nomination of the Executive Board,

APPOINTS Dr Tedros Adhanom Ghebreyesus as Director-General of the World Health Organization.

(Fifth plenary meeting, 23 May 2017)

## WHA70.3 Contract of the Director-General

The Seventieth World Health Assembly,

I

Pursuant to Article 31 of the Constitution and Rule 107 of the Rules of Procedure of the World Health Assembly,

APPROVES the contract establishing the terms and conditions of appointment, salary and other emoluments for the post of Director-General, as amended;<sup>1</sup>

Π

Pursuant to Rule 110 of the Rules of Procedure of the World Health Assembly,

AUTHORIZES the President of the Seventieth World Health Assembly to sign this contract in the name of the Organization.

(Fifth plenary meeting, 23 May 2017)

## WHA70.4 Expression of appreciation to Dr Margaret Chan

The Seventieth World Health Assembly,

Expressing its profound gratitude to Dr Margaret Chan for her extraordinary leadership of the World Health Organization during the period 2007–2017;

Commending her dedication to partnership and evidence-based approaches to public health, and her drive towards organizational effectiveness, and transparency and accountability;

Paying tribute to her unwavering efforts and skilful stewardship to ensure the prominence of health on national and global political agendas;

Recognizing her resilience in overcoming unprecedented global public health challenges encountered during the course of her tenure;

<sup>1</sup> See Annex 1.

Acclaiming her tireless commitment to improve the health of all peoples around the world,

DECLARES Dr Margaret Chan Director-General Emeritus of the World Health Organization as from the date of her retirement.

(Fifth plenary meeting, 23 May 2017)

### WHA70.5 Programme budget 2018–2019

The Seventieth World Health Assembly,

Having considered the Proposed programme budget 2018–2019;<sup>1</sup>

Having noted the report of the Programme, Budget and Administration Committee of the Executive Board to the Seventieth World Health Assembly;<sup>2</sup>

Welcoming the work being conducted to identify efficiencies in the area of management and administration;

Considering the continuing increase in the volume of tasks assigned by WHO's governing bodies to the Director-General, including the recent creation of the WHO Health Emergencies Programme;

Conscious of the necessity to prioritize and, in a context of limited resources, to concentrate such resources on those programmes that have the greatest impact on public health, or where WHO has a significant comparative advantage, as agreed by the Member States;

Stressing that proposed increases above the level of the approved Programme budget 2018–2019 should be requested only when necessary for the purpose of the Organization's mandated activities and after all possible steps have been taken to finance such increases through savings, efficiencies and prioritization,

1. APPROVES the programme of work, as outlined in the Proposed programme budget 2018–2019;

2. APPROVES the budget for the financial period 2018–2019, under all sources of funds, namely, assessed and voluntary contributions of US\$ 4421.5 million;

3. ALLOCATES the budget for the financial period 2018–2019 to the following categories and other areas:

- (1) Communicable diseases US\$ 805.4 million;
- (2) Noncommunicable diseases US\$ 351.4 million;
- (3) Promoting health through the life course US\$ 384.3 million;

<sup>6</sup> 

<sup>&</sup>lt;sup>1</sup> Document A70/7.

<sup>&</sup>lt;sup>2</sup> Document A70/59.

- (4) Health systems US\$ 589.5 million;
- (E) WHO Health Emergencies Programme US\$ 554.2 million;
- (6) Corporate services/enabling functions US\$ 715.5 million;

Other areas:

- Polio eradication (US\$ 902.8 million), Tropical disease research (US\$ 50.0 million), and Research in human reproduction (US\$ 68.4 million) totalling US\$ 1021.2 million; and
- Outbreak and crisis response and scalable operations, which is subject to the eventdriven nature of the activities concerned and, as such, does not have a budget requirement;
- 4. **RESOLVES** that the budget will be financed as follows:
  - by net assessments on Member States adjusted for estimated Member State non-assessed income, for a total of US\$ 956.9 million;
  - from voluntary contributions, for a total of US\$ 3464.6 million;

5. FURTHER RESOLVES that the gross amount of the assessed contribution for each Member State shall be reduced by the sum standing to their credit in the Tax Equalization Fund; that this reduction shall be adjusted in the case of those Members that require staff members to pay income taxes on their WHO emoluments, taxes which the Organization reimburses to said staff members; and that the amount of such tax reimbursements is estimated at US\$ 31.8 million, resulting in a total assessment on Members of US\$ 988.7 million;

6. DECIDES that the Working Capital Fund shall be maintained at its existing level of US\$ 31 million;

7. AUTHORIZES the Director-General to use the assessed contributions together with the voluntary contributions, subject to the availability of resources, to finance the budget as allocated in paragraph 3, up to the amounts approved;

8. FURTHER AUTHORIZES the Director-General, where necessary, to make budget transfers among the six categories, up to an amount not exceeding 5% of the amount allocated to the category from which the transfer is made. Any such transfers will be reported in the statutory reports to the respective governing bodies;

9. FURTHER AUTHORIZES the Director-General, where necessary, to incur expenditures in the Outbreak and crisis response and scalable operations area, subject to availability of resources;

10. FURTHER AUTHORIZES the Director-General, where necessary, to incur expenditures in the Polio, Tropical disease research, and Research in human reproduction components of the budget beyond the amount allocated for those components, as a result of additional governance and resource mobilization mechanisms, as well as their budget cycle, which inform the annual/biennial budgets for these special programmes, subject to availability of resources;

11. REQUESTS the Director-General:

(1) to submit regular reports on the financing and implementation of the budget as presented in document A70/7 and on the outcome of the financing dialogue, the strategic allocation of flexible resources and the results of the coordinated resource mobilization strategy, through the Executive Board and its Programme, Budget and Administration Committee, to the World Health Assembly;

(2) to submit regular reports on the availability of resources and expenditures under the budget areas of Outbreak and crisis response and scalable operations, and Polio, together with the special programmes of the Tropical disease research, and Research on human reproduction areas;

(3) to provide additional information on the prioritization process and a plan, including details of the activities that should be discontinued, in preparation for the Thirteenth General Programme of Work, through the Executive Board and its Programme Budget and Administration Committee, to the Seventy-first World Health Assembly;

(4) to control costs and seek efficiencies, and to submit regular reports with detailed information on savings and efficiencies as well as an estimation of savings achieved.

(Eighth plenary meeting, 26 May 2017 – Committee A, second report)

# WHA70.6 Human resources for health and implementation of the outcomes of the United Nations' High-Level Commission on Health Employment and Economic Growth<sup>1</sup>

The Seventieth World Health Assembly,

Having considered the report on human resources for health and implementation of the outcomes of the United Nations' High-Level Commission on Health Employment and Economic Growth;<sup>2</sup>

Reaffirming resolution WHA69.19 (2016) on the global strategy on human resources for health: workforce 2030, in which the Health Assembly adopted WHO's Global Strategy on Human Resources for Health: Workforce 2030, including its strong call to engage across public and private sectors and stakeholders including government, education and training institutions, employers and health workers' organizations in order to coordinate an intersectoral health and social workforce agenda towards achieving a fit-for-purpose workforce for the 2030 Agenda;

Recalling resolution WHA63.16 (2010) on the WHO Global Code of Practice on the International Recruitment of Health Personnel, which adopted the Global Code, and the Global Code's recognition that an adequate and accessible health workforce is fundamental to an integrated and effective health system, and to the provision of health services, bearing in mind the necessity of mitigating the negative effects of health personnel migration on the health systems of developing countries;

<sup>&</sup>lt;sup>1</sup> See Annex 14 for the financial and administrative implications for the Secretariat of this resolution.

<sup>&</sup>lt;sup>2</sup> Document A70/18.

Recalling also previous Health Assembly resolutions aimed at strengthening the health workforce;<sup>1</sup>

Further recalling the United Nations General Assembly resolutions in 2015 (resolution 70/183) and 2016 (resolution 71/159) that, respectively, requested the establishment of the United Nations' High-Level Commission on Health Employment and Economic Growth (hereinafter "the Commission") and welcomed the Commission's report;

Underlining that investing in the health and social workforce has multiplier effects that enhance inclusive economic growth, both locally and globally, and that it contributes to the ambition of the 2030 Agenda for Sustainable Development and to progress towards achieving the Sustainable Development Goals, including Goal 1 (End poverty in all its forms everywhere), Goal 3 (Ensure healthy lives and promote well-being for all at all ages), Goal 4 (Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all), Goal 5 (Achieve gender equality and empower all women and girls), Goal 8 (promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all), and Goal 10 (Reduce inequality within and among countries) and exploiting the interlinkages between the Goals and their targets;

Acknowledging that twenty-first century health challenges related to demographic, socioeconomic, environmental, epidemiological and technological changes will require a health and social workforce that is fit for purpose for the provision of integrated people-centred health and social services across the continuum of care;

Recalling decision EB140(3) (2017) which, inter alia, welcomed the report of the High-Level Commission on Health Employment and Economic Growth, and its task of lending the necessary political, intersectoral and multistakeholder momentum, through the elaboration of 10 recommendations and the identification of five immediate actions, in order to guide and stimulate the creation of health and social sector jobs as a means to advance inclusive economic growth and social cohesion;

Underscoring that skilled and motivated health and social sector workers are integral to building strong and resilient health systems, and underlining the importance of adequate workforce investments to meet needs in respect of universal health coverage and to develop core capacities under the International Health Regulations (2005), including the capacity of the domestic health workforce to ensure preparedness for and response to public health threats;

Recognizing the need to substantially expand and transform health financing and the recruitment, development, education and training, distribution and retention of the health and social workforce;

Recognizing also the need to substantially increase the protection and security of health and social workers and health facilities in all settings, including acute and protracted public health emergencies and humanitarian settings,

<sup>&</sup>lt;sup>1</sup> Resolutions WHA64.6 (2011) on health workforce strengthening, WHA64.7 (2011) on strengthening nursing and midwifery, WHA65.20 (2012) on WHO's response, and role as the health cluster lead, in meeting the growing demands of health in humanitarian emergencies, WHA66.23 (2013) on transforming health workforce education in support of universal health coverage, WHA67.19 (2014) on strengthening of palliative care as a component of comprehensive care throughout the life course, WHA67.24 (2014) on follow-up of the Recife Political Declaration on Human Resources for Health: renewed commitments towards universal health coverage, and WHA68.15 (2015) on strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage.

1. ADOPTS "Working for Health": the ILO, OECD and WHO five-year action plan for health employment and inclusive economic growth  $(2017-2021)^1$  as a mechanism for coordinating and advancing the intersectoral implementation of the Commission's recommendations and immediate actions in support of WHO's Global Strategy on Human Resources for Health: Workforce 2030;

2. URGES all Member States to act forthwith on the Commission's recommendations and immediate actions, with the support of WHO, ILO and OECD,<sup>2</sup> as appropriate and consistent with national contexts, priorities and specificities;

3. INVITES international, regional, national and local partners and stakeholders responsible for health, social and gender matters, and for foreign affairs, education, finance and labour, to engage in and support the implementation of the Commission's recommendations and the five-year action plan for health employment and inclusive economic growth (2017–2021) as a whole;

4. **REQUESTS** the Director-General:

(1) to collaborate with Member States, upon request, with agencies in other relevant sectors, and with partners, in implementing the Commission's recommendations and immediate actions as elaborated in the five-year action plan for health employment and inclusive economic growth (2017–2021), including to:

(a) strengthen the progressive development and implementation of national health workforce accounts;

(b) strengthen the relevance, effectiveness and implementation of the WHO Global Code of Practice on the International Recruitment of Health Personnel, including by continuously fostering bilateral and multilateral dialogue and cooperation to promote mutuality of benefits deriving from the international mobility of health workers;

(c) catalyse the scale-up and transformation of professional, technical and vocational education and training, including inter-professional education, particularly in communityand health systems-based settings, and stimulate investments in creating decent health and social jobs with the right skills, in the right numbers and in the right places, particularly in countries facing the greatest challenges in attaining universal health coverage and in implementing the Global Strategy on Human Resources for Health: Workforce 2030;

(2) to coordinate and work with ILO, OECD and other relevant sectors, agencies and partners to develop their joint capacity to support Member States, upon request, in this agenda, including with respect to:

(a) the establishment of an inter-agency data exchange and online knowledge platform on the health and social workforce, respecting personal confidentiality and relevant data protection laws, that progressively brings together data and information from multiple agencies, sectors and sources to advance health and social labour market data, analysis, accountability, monitoring and tracking, as an open-access, electronic, and real-time web-based resource, building on the progressive implementation and reporting of national health workforce accounts; and

<sup>&</sup>lt;sup>1</sup> See Annex 2.

<sup>&</sup>lt;sup>2</sup> And, where applicable, regional economic integration organizations.

(b) the establishment of an international platform on health worker mobility for transparent intersectoral policy dialogue, exchange and collective action in order to achieve a sustainable health and social workforce, maximize mutual benefits, promote ethical recruitment and mitigate adverse effects arising from such mobility;

(3) to utilize the Global Health Workforce Network as a mechanism to engage stakeholders in the implementation of the five-year action plan for health employment and inclusive economic growth (2017–2021);

(4) to explore intersectoral and innovative financing mechanisms necessary for advancing implementation of the five-year action plan for health employment and inclusive economic growth (2017–2021);

(5) to accelerate progress in health workforce monitoring with the application of national health workforce accounts, and ensure the appropriate number, competency and equitable distribution of health workers;

(6) to submit a regular report to the Health Assembly on progress made in implementing the five-year action plan for health employment and inclusive economic growth (2017–2021), aligned with reporting on the Global Strategy on Human Resources for Health: Workforce 2030.

(Ninth plenary meeting, 29 May 2017 – Committee A, third report)

## WHA70.7 Improving the prevention, diagnosis and clinical management of sepsis<sup>1</sup>

The Seventieth World Health Assembly,

Having considered the report on improving the prevention, diagnosis and clinical management of sepsis;<sup>2</sup>

Concerned that sepsis continues to cause approximately six million deaths worldwide every year, most of which are preventable;

Recognizing that sepsis as a syndromic response to infection is the final common pathway to death from most infectious diseases worldwide;

Considering that sepsis follows a unique and time-critical clinical course, which in the early stages is highly amenable to treatment through early diagnosis and timely and appropriate clinical management;

Considering also that infections that may lead to sepsis can often be prevented through appropriate hand hygiene, access to vaccination programmes, improved sanitation and water quality and availability, and other infection prevention and control best practices; and that forms of septicaemia associated with nosocomial infections are severe, hard to control and have high fatality rates;

<sup>&</sup>lt;sup>1</sup> See Annex 14 for the financial and administrative implications for the Secretariat of this resolution.

<sup>&</sup>lt;sup>2</sup> Document A70/13.

Recognizing that while sepsis itself cannot always be predicted, its ill effects in terms of mortality and long-term morbidity can be mitigated through early diagnosis and appropriate and timely clinical management;

Recognizing also the need to improve measures for the prevention of infections and control of the consequences of sepsis due to inadequate infection prevention and control programmes, insufficient health education and recognition in respect of early sepsis, inadequate access to affordable, timely and appropriate treatment and care, and insufficient laboratory services, as well as the lack of integrated approaches to the prevention and clinical management of sepsis;

Noting that health care-associated infections represent a common pathway through which sepsis can place an increased burden on health care resources;

Considering the need for an integrated approach to tackling sepsis that focuses on prevention, early recognition through clinical and laboratory services, and timely access to health care, including intensive care services, with reliability in the delivery of the basics of care, including intravenous fluids and the timely administration of antimicrobials, where indicated;

Acknowledging that: (i) the inappropriate and excessive use of antimicrobials contributes to the threat of antimicrobial resistance; (ii) the global action plan on antimicrobial resistance adopted in resolution WHA68.7 (2015),<sup>1</sup> as well as resolution WHA67.25 (2014), urged WHO to accelerate efforts to secure access to effective antimicrobials and to use them responsibly and prudently; (iii) sepsis represents the most vital indication for the responsible use of effective antimicrobials for human health; (iv) in the absence of appropriate and timely clinical management, including effective antimicrobial therapy for infections, including sepsis, may be a major contributor to the increasing threat of antimicrobial resistance; (vi) the incidence of some resistant pathogens may be reduced by the use of appropriate vaccines; and (vii) immunocompromised patients are most at risk from very serious forms of septicaemia;

Recognizing that many vaccine-preventable diseases are major contributors to sepsis, and reaffirming resolution WHA45.17 (1992) on immunization and vaccine quality, which urged Member States, inter alia, to integrate cost-effective and affordable new vaccines into national immunization programmes in countries where this is feasible;

Recognizing also the importance of strong, functional health systems, which include organizational and therapeutic strategies in order to improve patient safety and outcomes from sepsis of bacterial origin;

Further recognizing the need to prevent and control sepsis, to increase timely access to correct diagnosis and to provide appropriate treatment programmes;

Also recognizing the advocacy efforts of stakeholders, in particular through existing activities held every year on 13 September<sup>2</sup> in many countries, to raise awareness regarding sepsis,

<sup>&</sup>lt;sup>1</sup> See document WHA68/2015/REC/1, Annex 3.

<sup>&</sup>lt;sup>2</sup> See document A70/13, paragraph 11: civil society organizations promote a World Sepsis Day on 13 September.

#### 1. URGES Member States:<sup>1</sup>

(1) to include prevention, diagnosis and treatment of sepsis in national health systems strengthening in the community and in health care settings, according to WHO guidelines;

(2) to reinforce existing strategies or develop new ones leading to strengthened infection prevention and control programmes, including by strengthening hygienic infrastructure, promoting hand hygiene, and other infection prevention and control best practices, clean childbirth practices, infection prevention practices in surgery, improvements in sanitation, nutrition and delivery of clean water, access to vaccination programmes, provision of effective personal protective equipment for health professionals and infection control in health care settings;

(3) to continue in their efforts to reduce antimicrobial resistance and promote the appropriate use of antimicrobials in accordance with the global action plan on antimicrobial resistance,<sup>2</sup> including the development and implementation of comprehensive antimicrobial stewardship activities;

(4) to develop and implement standard and optimal care and strengthen medical countermeasures for diagnosing and managing sepsis in health emergencies, including outbreaks, through appropriate guidelines with a multisectoral approach;

(5) to increase public awareness of the risk of progression to sepsis from infectious diseases, through health education, including on patient safety, in order to ensure prompt initial contact between affected persons and the health care system;

(6) to develop training for all health professionals on infection prevention and patient safety, and on the importance of recognizing sepsis as a preventable and time-critical condition with urgent therapeutic need, and of communicating with patients, relatives and other parties using the term "sepsis" in order to enhance public awareness;

(7) to promote research aimed at innovative means of diagnosing and treating sepsis across the lifespan, including research for new antimicrobial and alternative medicines, rapid diagnostic tests, vaccines and other important technologies, interventions and therapies;

(8) to apply and improve the use of the International Classification of Diseases system to establish the prevalence and profile of sepsis and antimicrobial resistance, and to develop and implement monitoring and evaluation tools in order to focus attention on and monitor progress towards improving outcomes from sepsis, including the development and fostering of specific epidemiologic surveillance systems, and to guide evidence-based strategies for policy decisions related to preventive, diagnostic and treatment activities and access to relevant health care for survivors;

(9) to engage further in advocacy efforts to raise awareness of sepsis, in particular through supporting existing activities held every year on 13 September in Member States;<sup>3</sup>

<sup>&</sup>lt;sup>1</sup> And, where applicable, regional economic integration organizations.

<sup>&</sup>lt;sup>2</sup> See document WHA68/2015/REC/1, Annex 3.

<sup>&</sup>lt;sup>3</sup> See document A70/13, paragraph 11: civil society organizations promote a World Sepsis Day on 13 September.

2. REQUESTS the Director-General:

(1) to develop WHO guidance including guidelines, as appropriate, on sepsis prevention and management;

(2) to draw attention to the public health impact of sepsis, including by publishing a report on sepsis describing its global epidemiology and impact on the burden of disease, and identifying successful approaches for integrating the timely diagnosis and management of sepsis into existing health systems, by the end of 2018;

(3) to support Member States, as appropriate, to define standards and establish the necessary guidelines, infrastructures, laboratory capacity, strategies and tools for reducing the incidence of, mortality from and long-term complications of sepsis;

(4) to collaborate with other organizations in the United Nations system, partners, international organizations and other relevant stakeholders in enhancing access to quality, safe, efficacious and affordable types of treatments for sepsis, and infection prevention and control, including immunization, particularly in developing countries, while taking into account relevant existing initiatives;

(5) to report to the Seventy-third World Health Assembly on the implementation of this resolution.

(Ninth plenary meeting, 29 May 2017 – Committee A, fourth report)

# WHA70.8 Status of collection of assessed contributions, including Member States in arrears in the payment of their contributions to an extent that would justify invoking Article 7 of the Constitution

The Seventieth World Health Assembly,

Having considered the report on the status of collection of assessed contributions, including Member States in arrears in the payment of their contributions to an extent that would justify invoking Article 7 of the Constitution, and special arrangements for settlement of arrears;<sup>1</sup>

Having noted the report of the Programme, Budget and Administration Committee of the Executive Board to the Seventieth World Health Assembly;<sup>2</sup>

Noting that, at the time of opening of the Seventieth World Health Assembly, the voting rights of Central African Republic, Comoros, Guinea-Bissau, Somalia and Ukraine were suspended, and that such suspension shall continue until the arrears of the Member States concerned have been reduced, at the present or future Health Assemblies, to a level below the amount that would justify invoking Article 7 of the Constitution;

<sup>&</sup>lt;sup>1</sup> Document A70/41.

<sup>&</sup>lt;sup>2</sup> Document A70/60.

Noting that Equatorial Guinea, Gambia, Grenada, and South Sudan were in arrears at the time of the opening of the Seventieth World Health Assembly to such an extent that it was necessary for the Health Assembly to consider, in accordance with Article 7 of the Constitution, whether the voting privileges of those countries should be suspended at the opening of the Seventy-first World Health Assembly,

**DECIDES**:

(1) that, in accordance with the statement of principles set out in resolution WHA41.7 (1988), if, by the time of the opening of the Seventy-first World Health Assembly, Equatorial Guinea, Gambia, Grenada, and South Sudan are still in arrears in the payment of their contributions to an extent that would justify invoking Article 7 of the Constitution, their voting privileges shall be suspended as from the said opening;

(2) that any suspension that takes effect as set out in paragraph (1) above shall continue at the Seventy-first World Health Assembly and subsequent Health Assemblies, until the arrears of Equatorial Guinea, Gambia, Grenada, and South Sudan have been reduced to a level below the amount that would justify invoking Article 7 of the Constitution;

(3) that this decision shall be without prejudice to the right of any Member to request restoration of its voting privileges in accordance with Article 7 of the Constitution.

(Ninth plenary meeting, 29 May 2017 – Committee B, first report)

## WHA70.9 Scale of assessments for 2018–2019

The Seventieth World Health Assembly,

Having considered the report of the Director-General,<sup>1</sup>

ADOPTS the scale of assessments of Members and Associate Members for the biennium 2018–2019 as set out below.

| Members and<br>Associate Members | WHO scale<br>for 2018–2019<br>% |
|----------------------------------|---------------------------------|
| Afghanistan                      | 0.0060                          |
| Albania                          | 0.0080                          |
| Algeria                          | 0.1610                          |
| Andorra                          | 0.0060                          |
| Angola                           | 0.0100                          |
| Antigua and Barbuda              | 0.0020                          |
| Argentina                        | 0.8920                          |
| Armenia                          | 0.0060                          |
| Australia                        | 2.3371                          |
| Austria                          | 0.7201                          |
| Azerbaijan                       | 0.0600                          |

<sup>1</sup> Document A70/42.

| Members and<br>Associate Members         | WHO scale<br>for 2018–2019<br>% |
|--|---------------------------------|
| Bahamas                                  | 0.0140                          |
| Bahrain                                  | 0.0440                          |
| Bangladesh                               | 0.0100                          |
| Barbados                                 | 0.0070                          |
| Belarus                                  | 0.0560                          |
| Belgium                                  | 0.8851                          |
| Belize                                   | 0.0010                          |
| Benin                                    | 0.0030                          |
| Bhutan                                   | 0.0010                          |
| Bolivia (Plurinational State of)         | 0.0120                          |
| Bosnia and Herzegovina                   | 0.0130                          |
| Botswana                                 | 0.0140                          |
| Brazil                                   | 3.8232                          |
| Brunei Darussalam                        | 0.0290                          |
| Bulgaria                                 | 0.0450                          |
| Burkina Faso                             | 0.0040                          |
| Burundi                                  | 0.0010                          |
| Cabo Verde                               | 0.0010                          |
| Cambodia                                 | 0.0040                          |
| Cameroon                                 | 0.0100                          |
| Canada                                   | 2.9211                          |
| Central African Republic                 | 0.0010                          |
| Chad                                     | 0.0050                          |
| Chile                                    | 0.3990                          |
| China                                    | 7.9212                          |
| Colombia                                 | 0.3220                          |
| Comoros                                  | 0.0010                          |
| Congo                                    | 0.0060                          |
| Cook Islands                             | 0.0010                          |
| Costa Rica                               | 0.0470                          |
| Côte d'Ivoire                            | 0.0090                          |
| Croatia                                  | 0.0990                          |
| Cuba                                     | 0.0650                          |
| Cyprus                                   | 0.0430                          |
| Czechia                                  | 0.3440                          |
| Democratic People's Republic of<br>Korea | 0.0050                          |
| Democratic Republic of the Congo         | 0.0080                          |
| Denmark                                  | 0.5840                          |
| Djibouti                                 | 0.0010                          |
| Dominica                                 | 0.0010                          |
| Dominican Republic                       | 0.0460                          |
| Ecuador                                  | 0.0670                          |
| Egypt                                    | 0.1520                          |
| El Salvador                              | 0.0140                          |
| Equatorial Guinea                        | 0.0100                          |

| Members and<br>Associate Members | WHO scale<br>for 2018–2019<br>% |
|----------------------------------|---------------------------------|
| Eritrea                          | 0.0010                          |
| Estonia                          | 0.0380                          |
| Ethiopia                         | 0.0100                          |
| Fiji                             | 0.0030                          |
| Finland                          | 0.4560                          |
| France                           | 4.8592                          |
| Gabon                            | 0.0170                          |
| Gambia                           | 0.0010                          |
| Georgia                          | 0.0080                          |
| Germany                          | 6.3892                          |
| Ghana                            | 0.0160                          |
| Greece                           | 0.4710                          |
| Grenada                          | 0.0010                          |
| Guatemala                        | 0.0280                          |
| Guinea                           | 0.0020                          |
| Guinea-Bissau                    | 0.0010                          |
| Guyana                           | 0.0020                          |
| Haiti                            | 0.0030                          |
| Honduras                         | 0.0080                          |
| Hungary                          | 0.1610                          |
| Iceland                          | 0.0230                          |
| India                            | 0.7370                          |
| Indonesia                        | 0.5040                          |
| Iran (Islamic Republic of)       | 0.4710                          |
| Iraq                             | 0.1290                          |
| Ireland                          | 0.3350                          |
| Israel                           | 0.4300                          |
| Italy                            | 3.7482                          |
| Jamaica                          | 0.0090                          |
| Japan                            | 9.6802                          |
| Jordan                           | 0.0200                          |
| Kazakhstan                       | 0.1910                          |
| Kenya                            | 0.0180                          |
| Kiribati                         | 0.0010                          |
| Kuwait                           | 0.2850                          |
| Kyrgyzstan                       | 0.0020                          |
| Lao People's Democratic Republic | 0.0030                          |
| Latvia                           | 0.0500                          |
| Lebanon                          | 0.0460                          |
| Lesotho                          | 0.0010                          |
| Liberia                          | 0.0010                          |
| Libya                            | 0.1250                          |
| Lithuania                        | 0.0720                          |
| Luxembourg                       | 0.0640                          |
| Madagascar                       | 0.0030                          |

| Members and<br>Associate Members | WHO scale<br>for 2018–2019<br>% |
|----------------------------------|---------------------------------|
| Malawi                           | 0.0020                          |
| Malaysia                         | 0.3220                          |
| Maldives                         | 0.0020                          |
| Mali                             | 0.0030                          |
| Malta                            | 0.0160                          |
| Marshall Islands                 | 0.0010                          |
| Mauritania                       | 0.0020                          |
| Mauritius                        | 0.0120                          |
| Mexico                           | 1.4351                          |
| Micronesia (Federated States of) | 0.0010                          |
| Monaco                           | 0.0100                          |
| Mongolia                         | 0.0050                          |
| Montenegro                       | 0.0040                          |
| Morocco                          | 0.0540                          |
| Mozambique                       | 0.0040                          |
| Myanmar                          | 0.0100                          |
| Namibia                          | 0.0100                          |
| Nauru                            | 0.0010                          |
| Nepal                            | 0.0060                          |
| Netherlands                      | 1.4821                          |
| New Zealand                      | 0.2680                          |
| Nicaragua                        | 0.0040                          |
| Niger                            | 0.0020                          |
| Nigeria                          | 0.2090                          |
| Niue                             | 0.0010                          |
| Norway                           | 0.8491                          |
| Oman                             | 0.1130                          |
| Pakistan                         | 0.0930                          |
| Palau                            | 0.0010                          |
| Panama                           | 0.0340                          |
| Papua New Guinea                 | 0.0040                          |
| Paraguay                         | 0.0140                          |
| Peru                             | 0.1360                          |
| Philippines                      | 0.1650                          |
| Poland                           | 0.8411                          |
| Portugal                         | 0.3920                          |
| Puerto Rico                      | 0.0010                          |
| Qatar                            | 0.2690                          |
| Republic of Korea                | 2.0391                          |
| Republic of Moldova              | 0.0040                          |
| Romania                          | 0.1840                          |
| Russian Federation               | 3.0882                          |
| Rwanda                           | 0.0020                          |
| Saint Kitts and Nevis            | 0.0010                          |
| Saint Lucia                      | 0.0010                          |
| Saint Vincent and the Grenadines | 0.0010                          |
| Samoa                            | 0.0010                          |

| Members and<br>Associate Members                        | WHO scale<br>for 2018–2019<br>% |
|---|---------------------------------|
| San Marino  | 0.0030                          |
| Sao Tome and Principe                                   | 0.0010                          |
| Saudi Arabia  | 1.1461                          |
| Senegal   | 0.0050                          |
| Serbia  | 0.0320                          |
| Seychelles  | 0.0010                          |
| Sierra Leone  | 0.0010                          |
| Singapore   | 0.4470                          |
| Slovakia  | 0.1600                          |
| Slovenia  | 0.0840                          |
| Solomon Islands   | 0.0010                          |
| Somalia   | 0.0010                          |
| South Africa  | 0.3640                          |
| South Sudan   | 0.0030                          |
| Spain   | 2.4431                          |
| Sri Lanka   | 0.0310                          |
| Sudan   | 0.0100                          |
| Suriname  | 0.0060                          |
| Swaziland   | 0.0020                          |
| Sweden  | 0.9561                          |
| Switzerland   | 1.1401                          |
| Syrian Arab Republic                                    | 0.0240                          |
| Tajikistan  | 0.0040                          |
| Thailand  | 0.2910                          |
| The former Yugoslav Republic of<br>Macedonia            | 0.0070                          |
| Timor-Leste   | 0.0030                          |
| Togo  | 0.0010                          |
| Tokelau   | 0.0010                          |
| Tonga   | 0.0010                          |
| Trinidad and Tobago                                     | 0.0340                          |
| Tunisia   | 0.0280                          |
| Turkey  | 1.0181                          |
| Turkmenistan  | 0.0260                          |
| Tuvalu  | 0.0010                          |
| Uganda  | 0.0090                          |
| Ukraine   | 0.1030                          |
| United Arab Emirates                                    | 0.6040                          |
| United Kingdom of Great Britain and<br>Northern Ireland | 4.4632                          |
| United Republic of Tanzania                             | 0.0100                          |
| United States of America                                | 22.0000                         |
| Uruguay   | 0.0790                          |
| Uzbekistan  | 0.0230                          |
| Vanuatu   | 0.0010                          |
| Venezuela (Bolivarian Republic of)                      | 0.5710                          |
| Viet Nam  | 0.0580                          |

| Members and<br>Associate Members | WHO scale<br>for 2018–2019<br>% |
|----------------------------------|---------------------------------|
| Yemen                            | 0.0100                          |
| Zambia                           | 0.0070                          |
| Zimbabwe                         | 0.0040                          |
| Total                            | 100.0000                        |
|                                  |                                 |

(Ninth plenary meeting, 29 May 2017 – Committee B, first report)

#### WHA70.10 Salaries of staff in ungraded posts and of the Director-General

The Seventieth World Health Assembly,

Noting the recommendations of the Executive Board with regard to remuneration of staff in ungraded posts and of the Director-General,

1. ESTABLISHES the salaries of Assistant Directors-General and Regional Directors at US\$ 174 373 gross per annum, with a corresponding net salary of US\$ 130 586;

2. ESTABLISHES the salary of the Deputy Director-General at US\$ 192 236 gross per annum, with a corresponding net salary of US\$ 142 376;

3. ESTABLISHES the salary of the Director-General at US\$ 241 276 gross per annum, with a corresponding net salary of US\$ 172 069;

4. DECIDES that those adjustments in remuneration shall take effect on 1 January 2017.

(Tenth plenary meeting, 31 May 2017 – Committee B, second report)

# WHA70.11 Preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018<sup>1</sup>

The Seventieth World Health Assembly,

Having considered the report on preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018;<sup>2</sup>

Recalling resolutions WHA66.10 (2013) on the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, and WHA69.6 (2016) on responses to specific assignments in preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable diseases; United Nations General Assembly resolutions 66/2 (2011) on the Political Declaration of the High-level Meeting, 68/300 (2014) on the outcome document of the high-level meeting of the General Assembly

<sup>&</sup>lt;sup>1</sup> See Annex 14 for the financial and administrative implications for the Secretariat of this resolution.

<sup>&</sup>lt;sup>2</sup> Document A70/27.

on the comprehensive review and assessment of the progress achieved in the prevention and control of non-communicable diseases, 69/313 (2015) on the Addis Ababa Action Agenda, and 70/1 (2015) on the 2030 Agenda for Sustainable Development; and United Nations Economic and Social Council resolutions 2013/12, 2014/10, 2015/8 and 2016/5 on the United Nations Inter-Agency Task Force on the Prevention and Control of Non-communicable Diseases,

1. ENDORSES the updated Appendix 3 to the global action plan for the prevention and control of noncommunicable diseases 2013–2020;<sup>1</sup>

2. NOTES the workplan for the global coordination mechanism on the prevention and control of noncommunicable diseases covering the period 2018-2019;<sup>1</sup>

3. URGES Member States:<sup>2</sup>

(1) to continue to implement resolutions WHA66.10 (2013) on the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases and WHA69.6 (2016) on responses to specific assignments in preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable diseases; United Nations General Assembly resolutions 66/2 (2011) on the Political Declaration of the High-level Meeting, 68/300 (2014) on the outcome document of the high-level meeting of the General Assembly on the comprehensive review and assessment of the progress achieved in the prevention and control of non-communicable diseases, 69/313 (2015) on the Addis Ababa Action Agenda, and 70/1 (2015) on the 2030 Agenda for Sustainable Development; and United Nations Economic and Social Council resolutions 2013/12, 2014/10, 2015/8 and 2016/5 on the United Nations Inter-Agency Task Force on the Prevention and Control of Non-communicable Diseases, taking into account the updated Appendix 3 to the global action plan for the prevention and control of noncommunicable diseases 2013–2020;

(2) to support the preparation at the national, regional and international levels for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018;

4. REQUESTS the Director-General to submit a report on preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018, to the Seventy-first World Health Assembly in 2018, through the Executive Board.

(Tenth plenary meeting, 31 May 2017 – Committee B, fourth report)

<sup>&</sup>lt;sup>1</sup> See Annex 3.

<sup>&</sup>lt;sup>2</sup> And, where applicable, regional economic integration organizations.

# WHA70.12 Cancer prevention and control in the context of an integrated approach<sup>1</sup>

The Seventieth World Health Assembly,

Having considered the report on cancer prevention and control in the context of an integrated approach;<sup>2</sup>

Acknowledging that, in 2012, cancer was the second leading cause of death in the world with 8.2 million cancer-related deaths, the majority of which occurred in low- and middle-income countries;

Recognizing that cancer is a leading cause of morbidity globally and a growing public health concern, with the annual number of new cancer cases projected to increase from 14.1 million in 2012 to 21.6 million by 2030;

Aware that certain population groups experience inequalities in risk factor exposure and in access to screening, early diagnosis and timely and appropriate treatment, and that they also experience poorer outcomes for cancer; and recognizing that different cancer control strategies are required for specific groups of cancer patients, such as children and adolescents;

Noting that risk reduction has the potential to prevent around half of all cancers;

Aware that early diagnosis and prompt and appropriate treatment, including pain relief and palliative care, can reduce mortality and improve the outcomes and quality of life of cancer patients;

Recognizing with appreciation the introduction of new pharmaceutical products based on investment in innovation for cancer treatment in recent years, but noting with great concern the increasing cost to health systems and patients;

Emphasizing the importance of addressing barriers in access to safe, quality, effective and affordable medicines, medical products and appropriate technology for cancer prevention, detection, screening diagnosis and treatment, including surgery, by strengthening national health systems and international cooperation, including human resources, with the ultimate aim of enhancing access for patients, including through increasing the capacity of health systems to provide such access;

Recalling resolution WHA58.22 (2005) on cancer prevention and control;

Recalling also United Nations General Assembly resolution 66/2 (2011) on the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, which includes a road map of national commitments from Heads of State and Government to address cancer and other noncommunicable diseases;

Recalling further resolution WHA66.10 (2013) endorsing the global action plan for the prevention and control of noncommunicable diseases 2013–2020, which provides guidance on how Member States can realize the commitments they made in the Political Declaration of the High-level

<sup>&</sup>lt;sup>1</sup> See Annex 14 for the financial and administrative implications for the Secretariat of this resolution.

<sup>&</sup>lt;sup>2</sup> Document A70/32.

Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, including those related to addressing cancer;

Recalling in addition United Nations General Assembly resolution 68/300 (2014) on the Outcome document of the high-level meeting of the General Assembly on the comprehensive review and assessment of the progress achieved in the prevention and control of non-communicable diseases, which sets out the continued and increased commitments that are essential in order to realize the road map of commitments to address cancer and other noncommunicable diseases included in the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, including four time-bound national commitments for 2015 and 2016;

Mindful of the existing monitoring tool that WHO is using to track the extent to which its 194 Member States are implementing these four time-bound commitments to address cancer and other noncommunicable diseases, in accordance with the technical note<sup>1</sup> published by WHO on 1 May 2015 pursuant to decision EB136(13) (2015);

Mindful also of the WHO Framework Convention on Tobacco Control;

Also mindful of the Sustainable Development Goals of the 2030 Agenda for Sustainable Development, specifically Goal 3 (Ensure healthy lives and promote well-being for all at all ages) with its target 3.4 to reduce, by 2030, premature mortality from noncommunicable diseases by one third, and target 3.8 on achieving universal health coverage;

Appreciating the efforts made by Member States<sup>2</sup> and international partners in recent years to prevent and control cancer, but mindful of the need for further action;

Reaffirming the global strategy and plan of action on public health, innovation and intellectual property;

Reaffirming also the rights of Member States to the full use of the flexibilities in the WTO Agreement on Trade-related Aspects of the Intellectual Property Rights (TRIPS) to increase access to affordable, safe, effective and quality medicines, noting that, inter alia, intellectual property rights are an important incentive in the development of new health products,

1. URGES Member States,<sup>2</sup> taking into account their context and institutional and legal frameworks, as well as national priorities:

(1) to continue to implement the road map of national commitments for the prevention and control of cancer and other noncommunicable diseases included in United Nations General Assembly resolutions 66/2 (2011) on the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases and 68/300 (2014) on the Outcome document of the high-level meeting of the General Assembly on the comprehensive review and assessment of the progress achieved in the prevention and control of non-communicable diseases;

(2) to implement also the four time-bound national commitments for 2015 and 2016 set out in the Outcome document, in preparation for a third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018,

<sup>&</sup>lt;sup>1</sup> Available at http://www.who.int/nmh/events/2015/technical-note-en.pdf?ua=1 (accessed 19 May 2017).

<sup>&</sup>lt;sup>2</sup> And, where applicable, regional economic integration organizations.

taking into account the technical note published by WHO on 1 May 2015, which sets out the progress indicators that the Director-General will use to report to the United Nations General Assembly in 2017 on the progress achieved in the implementation of national commitments, including those related to addressing cancer, taking into account cancer-specific risk factors;

(3) to integrate and scale up national cancer prevention and control as part of national responses to noncommunicable diseases, in line with the 2030 Agenda for Sustainable Development;

(4) to develop, as appropriate, and implement national cancer control plans that are inclusive of all age groups; that have adequate resources, monitoring and accountability; and that seek synergies and cost-efficiencies with other health interventions;

(5) to collect high-quality population-based incidence and mortality data on cancer, for all age groups by cancer type, including measurements of inequalities, through population-based cancer registries, household surveys and other health information systems in order to guide policies and plans;

(6) to accelerate the implementation by States Parties of the WHO Framework Convention on Tobacco Control; and, for those Member States that have not yet done so, to consider acceding to the Convention at the earliest opportunity, given that the substantial reduction of tobacco use is an important contribution to the prevention and control of cancer; and to act to prevent the tobacco industry's interference in public health policy for the success of reducing the risk factors of noncommunicable diseases;

(7) to promote the primary prevention of cancers;

(8) to promote increased access to cost-effective vaccinations to prevent infections associated with cancers, as part of national immunization schedules, based on national epidemiological profiles and health systems' capacities, and in line with the immunization targets of the global vaccine action plan;

(9) to develop, implement and monitor programmes, based on national epidemiological profiles, for the early diagnosis of common cancers, and for screening of cancers, according to assessed feasibility and cost-effectiveness of screening, and with adequate capacity to avoid delays in diagnosis and treatment;

(10) to develop and implement evidence-based protocols for cancer management, in children and adults, including palliative care;

(11) to collaborate by strengthening, where appropriate, regional and subregional partnerships and networks in order to create centres of excellence for the management of certain cancers;

(12) to promote recommendations that support clinical decision-making and referral based on the effective, safe and cost-effective use of cancer diagnostic and therapeutic services, such as cancer surgery, radiation and chemotherapy; and to facilitate cross-sectoral cooperation between health professionals, as well as the training of personnel at all levels of health systems;

(13) to mobilize sustainable domestic human and financial resources and consider voluntary and innovative financing approaches to support cancer control in order to promote equitable and affordable access to cancer care;

(14) to promote cancer research to improve the evidence base for cancer prevention and control, including research on health outcomes, quality of life and cost-effectiveness;

(15) to provide pain relief and palliative care in line with resolution WHA67.19 (2014) on the strengthening of palliative care as a component of comprehensive care throughout the life course;

(16) to anticipate and promote cancer survivor follow-up, late effect management and tertiary prevention, with the active involvement of survivors and their relatives;

(17) to promote early detection of patients' needs and access to rehabilitation, including in relation to work, psychosocial and palliative care services;

(18) to promote and facilitate psychosocial counselling and aftercare for cancer patients and their families, taking into account the increasingly chronic nature of cancer;

(19) to continue fostering partnerships between government and civil society, building on the contribution of health-related nongovernmental organizations and patient organizations, to support, as appropriate, the provision of services for the prevention and control, treatment and care of cancer, including palliative care;

(20) to work towards the attainment of Sustainable Development Goal 3, target 3.4, reiterating the commitment to reduce, by 2030, premature mortality from cancer and other noncommunicable diseases by one third;

(21) to promote the availability and affordability of quality, safe and effective medicines (in particular, but not limited to, those on the WHO Model List of Essential Medicines), vaccines and diagnostics for cancer;

(22) to promote access to comprehensive and cost-effective prevention, treatment and care for the integrated management of cancers including, inter alia, increased access to affordable, safe, effective and quality medicines and diagnostics and other technologies;

#### 2. **REQUESTS** the Director-General:

(1) to develop or adapt stepwise and resource-stratified guidance and tool kits in order to establish and implement comprehensive cancer prevention and control programmes, including for the management of cancers in children and adolescents, leveraging the work of other organizations;

(2) to collect, synthesize and disseminate evidence on the most cost-effective interventions for all age groups, and support Member States<sup>1</sup> in the implementation of these interventions; and to make an investment case for cancer prevention and control;

(3) to strengthen the capacity of the Secretariat both to support the implementation of cost-effective interventions and country-adapted models of care and to work with international partners, including IAEA, to harmonize the technical assistance provided to countries for cancer prevention and control;

<sup>&</sup>lt;sup>1</sup> And, where applicable, regional economic integration organizations.

(4) to work with Member States,<sup>1</sup> and collaborate with nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions as defined in the Framework of Engagement with Non-State Actors in order to develop partnerships to scale up cancer prevention and control, and to improve the quality of life of cancer patients, in line with Sustainable Development Goals 3 (Ensure healthy lives and promote well-being for all at all ages) and 17 (Strengthen the means of implementation and revitalize the global partnership for sustainable development);

(5) to strengthen collaboration with nongovernmental organizations, private sector entities, academic institutions and philanthropic foundations, as defined in WHO's Framework for Engagement with Non-State Actors, with a view to fostering the development of effective and affordable new cancer medicines;

(6) to provide technical assistance, upon request, to regional and subregional partnerships and networks, including, where appropriate, support for the establishment of centres of excellence to strengthen cancer management;

(7) to develop, before the end of 2019, the first periodic public health- and policy-oriented world report on cancer, in the context of an integrated approach, based on the latest available evidence and international experience, and covering the elements of this resolution, with the participation of all relevant parts of WHO, including IARC, and in collaboration with all other relevant stakeholders, including cancer survivors;

(8) to enhance the coordination between IARC and other parts of WHO on assessments of hazards and risks, and on the communication of those assessments;

(9) to prepare a comprehensive technical report to the Executive Board at its 144th session that examines pricing approaches, including transparency, and their impact on the availability and affordability of medicines for the prevention and treatment of cancer, including any evidence of the benefits or unintended negative consequences, as well as incentives for investment in research and development on cancer and in innovation of these measures, as well as the relationship between inputs throughout the value chain and price setting, financing gaps for research and development on cancer, and options that might enhance the affordability and accessibility of these medicines;

(10) to synchronize the periodic report on progress made in implementing this resolution with, and integrate it into, the monitoring and report timeline of the prevention and control of noncommunicable diseases, set out in resolution WHA66.10.

(Tenth plenary meeting, 31 May 2017 – Committee B, fourth report)

## WHA70.13 Prevention of deafness and hearing loss<sup>1</sup>

The Seventieth World Health Assembly,

Having considered the report on prevention of deafness and hearing loss;<sup>2</sup>

Recognizing that 360 million people across the world live with disabling hearing loss, a total that includes 32 million children and nearly 180 million older adults;

Acknowledging that nearly 90% of the people with hearing loss live in low- and middle-income countries, which often lack resources and strategies to address hearing loss;

Concerned by the persistent high prevalence of chronic ear diseases, such as chronic suppurative otitis media, which lead to hearing loss and may cause life-threatening complications;

Acknowledging the significance of work-related, noise-induced hearing loss, in addition to issues related to recreational and environmental noise-induced hearing loss;

Aware that unaddressed hearing loss is linked with cognitive decline and contributes to the burden of depression and dementia, especially in older adults;

Noting the significant impact of ear diseases and hearing loss on the development, ability to communicate, education, livelihood, social well-being and economic independence of individuals, as well as on communities and countries;

Aware that most of the causes of hearing loss are avoidable with preventive strategies; that the interventions available are both successful and cost-effective; but that, despite this, most people with ear diseases and hearing loss do not have access to suitable services;

Recalling resolution WHA48.9 (1995) on prevention of hearing impairment, and resolution WHA58.23 (2005) on disability, including prevention, management and rehabilitation;

Recalling also the *World report on disability 2011*, which recommends investment in improved access to health services, rehabilitation and assistive technologies and the WHO global disability action plan 2014–2021,<sup>3</sup> based on that report's recommendations;

Mindful of the Sustainable Development Goals in the 2030 Agenda for Sustainable Development, specifically Goal 3 (Ensure healthy lives and promote well-being for all at all ages) with its target 3.8 on achieving universal health coverage, which implicitly recognizes the need for persons with disabilities to have access to good-quality health care services, and recognizing that the targets of Goal 4 (Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all) explicitly mention persons with disabilities, and that unaddressed hearing loss greatly hinders their education and academic outcomes;

Appreciating the efforts made by Member States and international partners in recent years to prevent hearing loss, but mindful of the need for further action,

<sup>&</sup>lt;sup>1</sup> See Annex 14 for the financial and administrative implications for the Secretariat of this resolution.

<sup>&</sup>lt;sup>2</sup> Document A70/34.

<sup>&</sup>lt;sup>3</sup> See document WHA67/2014/REC/1, Annex 3.

1. URGES Member States, taking into account their national circumstances:

(1) to integrate strategies for ear and hearing care within the framework of their primary health care systems, under the umbrella of universal health coverage, by such means as raising awareness at all levels and building political commitment and intersectoral collaboration;

(2) to collect high-quality population-based data on ear diseases and hearing loss in order to develop evidence-based strategies and policies;

(3) to establish suitable training programmes for the development of human resources in the field of ear and hearing care;

(4) to ensure the highest possible vaccination coverage against rubella, measles, mumps and meningitis, in line with the immunization targets of the global vaccine action plan 2011–2020, and in accordance with national priorities;

(5) to develop, implement and monitor screening programmes for early identification of ear diseases, such as chronic suppurative otitis media and hearing loss in high-risk populations, including infants, young children, older adults and people exposed to noise in occupational and recreational settings;

(6) to improve access to affordable, cost-effective, high-quality, assistive hearing technologies and products, including hearing aids, cochlear implants and other assistive devices, as part of universal health coverage, taking into account the delivery capacity of health care systems in an equitable and sustainable manner;

(7) to develop and implement regulations for the control of noise in occupational settings, at entertainment venues and through personal audio systems, as well as for the control of ototoxic medicines;

(8) to improve access to a variety of ways of communicating through promoting alternative methods of communication, such as sign language and captioning;

(9) to work towards the attainment of Sustainable Development Goal 3 (Ensure healthy lives and promote well-being for all at all ages) and Goal 4 (Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all) in the 2030 Agenda for Sustainable Development, with special reference to people with hearing loss;

2. **REQUESTS** the Director-General:

(1) to prepare a world report on ear and hearing care, based on the best-available scientific evidence;

(2) to develop a toolkit as well as provide the necessary technical support for Member States in collecting data, planning national strategies for ear and hearing care, specifying how prevention of hearing loss can be integrated into other health care programmes, raising awareness, screening for hearing loss and ear diseases, and organizing training in and provision of assistive technologies;

(3) to intensify collaboration with all stakeholders with the aim of reducing hearing loss due to recreational exposure to noise through the development and promotion of safe-listening standards, screening protocols and software applications to promote safe-listening and information products;

(4) to undertake advocacy through World Hearing Day on 3 March each year, with a different theme every year;

(5) to report on progress in the implementation of the present resolution to the World Health Assembly.<sup>1</sup>

(Tenth plenary meeting, 31 May 2017 – Committee B, fourth report)

# WHA70.14 Strengthening immunization to achieve the goals of the global vaccine action plan<sup>2</sup>

The Seventieth World Health Assembly,

Having considered the report on the global vaccine action plan;<sup>3</sup>

Recalling resolutions WHA65.17 (2012) and WHA68.6 (2015) on the global vaccine action plan; and resolution WHA67.23 (2014) on health intervention and technology assessment;

Welcoming the declaration by the International Expert Committee for Documenting and Verifying Measles, Rubella and Congenital Rubella Syndrome Elimination, that the Member States in the Region of the Americas have achieved the interruption of endemic transmission of both rubella and measles viruses,<sup>4</sup> in 2015 and 2016, respectively;

Welcoming the validation of the elimination of maternal and neonatal tetanus in all districts in all 11 Member States of the South-East Asia Region;

Having considered the 2016 assessment report from the Strategic Advisory Group of Experts on immunization on the implementation of the global vaccine action plan and progress towards its stated strategic objectives and goals;<sup>5</sup>

Noting that although many countries have achieved the 2015 goals of the global vaccine action plan, and that others are making substantial progress, indicating that while the goals and targets are ambitious, they are achievable, the 2016 assessment report from the Strategic Advisory Group of Experts on immunization concluded that progress is not on track and that only one of the six mid-decade targets of the action plan was met;

Noting the progress made on the introduction of new vaccines and the impact that these vaccines have at the individual level and, when high vaccination rates are achieved, at the population

<sup>&</sup>lt;sup>1</sup> The Executive Board agreed that the long-term reporting requirements of the present resolution should be included in the forward-looking planning schedule of expected agenda items, established by decision WHA69(8) (2016). See document EB139/2016/REC/1, summary record of the Executive Board at its 139th session, second meeting.

<sup>&</sup>lt;sup>2</sup> See Annex 14 for the financial and administrative implications for the Secretariat of this resolution.

<sup>&</sup>lt;sup>3</sup> Document A70/25.

<sup>&</sup>lt;sup>4</sup> See document CD55/INF/10, Rev.1.

<sup>&</sup>lt;sup>5</sup> The full 2016 SAGE Assessment Report of the Global Vaccine Action Plan is available at: http://www.who.int/entity/immunization/global\_vaccine\_action\_plan/SAGE\_GVAP\_Assessment\_Report\_2016\_EN.pdf (accessed 23 January 2017).

level, in reducing morbidity and/or mortality from vaccine-preventable diseases, such as pneumonia, diarrhoea and cervical cancer;

Concerned that at the mid-point of the Decade of Vaccines (2011–2020), progress toward the goals of the global vaccine action plan to eradicate polio, eliminate measles and rubella, eliminate maternal and neonatal tetanus, and increase equitable access to affordable, life-saving vaccines is too slow; and recognizing that middle-income countries, in particular, have faced specific challenges with the introduction of new vaccines;

Noting that although Member States in all six WHO regions have measles elimination goals, and that three regions have rubella elimination goals, additional efforts should be invested to reach measles and rubella elimination;

Recognizing the important contribution of vaccines and immunization to: improving the health of populations; achieving the ambitious Sustainable Development Goals; ensuring outbreak preparedness and response, including in respect of outbreaks involving emerging pathogens; and tackling antimicrobial resistance;

Recognizing that strong health systems and integrated routine immunization programmes that are well coordinated across other relevant sectors contribute to achieving immunization goals and targets, and universal health coverage;

Recognizing the significant progress achieved towards polio eradication and the significant contribution of the polio-related assets, human resources and infrastructure, which should be transitioned effectively, to the strengthening of national immunization and health systems;

Recognizing the need for enhanced international cooperation aimed at, in a sustainable manner, strengthening the capacities of developing countries to achieve the goals of the global vaccine action plan,

1. URGES Member States:<sup>1</sup>

(1) to demonstrate stronger leadership and governance of national immunization programmes by:

(a) increasing the effectiveness and efficiency of national immunization programmes, as an integrated part of strong and sustainable health care systems;

(b) allocating adequate financial and human resources to immunization programmes according to national priorities;

(c) strengthening national processes and advisory bodies for independent, evidence-based, transparent advice, including on vaccine safety and effectiveness, such as health intervention and technology assessments and/or National Immunization Technical Advisory Groups working in collaboration with national regulatory authorities;

(d) strengthening mechanisms to monitor and efficiently manage vaccination programme funds at all levels;

<sup>&</sup>lt;sup>1</sup> And, where applicable, regional economic integration organizations.

(e) making up-to-date and accurate information on the effectiveness and safety of vaccines publicly available;

(f) strengthening systems to monitor and deal with adverse events following immunization;

(g) promoting awareness-raising campaigns on immunization, underlining public health benefits and vaccine safety and effectiveness;

(h) strengthening the immunization systems, procedures and policies that are necessary to achieve and sustain high immunization coverage;

(i) reviewing periodically, through the National Immunization Technical Advisory Groups or equivalent independent groups, the progress made, including immunization coverage, lessons learned and possible solutions for dealing with remaining challenges;

(j) continuing to report on progress to the regional committees, as urged in resolution WHA65.17;

(2) to ensure use of up-to-date data including, where possible, sex-disaggregated data on immunization coverage to guide strategic and programmatic decisions that protect at-risk populations and reduce disease burden;

(3) to strengthen and sustain surveillance capacity by investing in disease detection and notification systems, routine analysis and data reporting systems;

(4) to expand immunization services beyond infancy to cover the whole life course, as appropriate, guided by evidence, including on the burden of disease, cost effectiveness, budget impact assessment and system capacities, and using the most appropriate and effective means of reaching the other age groups and high-risk populations with immunization and integrated health services;

(5) to strengthen international and national actions to ensure the application of the International Health Regulations (2005), which aim to prevent, protect against, control and provide a public health response to the international spread of diseases;

(6) to mobilize domestic financing, as appropriate, in order to sustain the immunization gains achieved through the support from the Global Polio Eradication Initiative and the GAVI Alliance;

(7) to continue to strengthen international cooperation to achieve the goals of the global vaccine action plan, including by enhancing sustainable, national and regional manufacturing capacity for affordable vaccines and technologies through collaboration and exchange, as appropriate;

2. **REQUESTS** the Director-General:

(1) to continue supporting countries to achieve regional and global vaccination goals;

(2) to advocate in national and international forums in support of the urgency and value of accelerating the pace of progress toward achieving the goals of the global vaccine action plan

by 2020, including addressing the nine recommendations made by the Strategic Advisory Group of Experts on immunization in their 2016 mid-term review of the global vaccine action plan;

(3) to ensure that accountability mechanisms for monitoring global and regional vaccine action plans are fully implemented;

(4) to support Member States in strengthening National Immunization Technical Advisory Group or equivalent mechanisms cooperating with regulatory authorities to inform national decisions based on national context and evidence to achieve national immunization goals;

(5) to collaborate with all key partners, including civil society organizations, in order to assess how their work complements national routine immunization systems and the implementation of costed national immunization plans and targets;

(6) to continue working with all partners to support research, development and production of vaccines against new and re-emerging pathogens;

(7) to continue to strengthen the WHO prequalification programme and provide technical assistance to support developing countries in capacity building for research and development, technology transfer, and other upstream to downstream vaccine development and manufacturing strategies that foster proper competition for a healthy vaccine market;

(8) to continue working with all parties to support use of joint procurements and other mechanisms to increase efficiency, cost–effectiveness and sustainability of vaccine supply;

(9) to continue working with all parties to support research and development, especially in developing countries, for supply chain innovations and vaccine-administration technologies to increase the efficiency of vaccine delivery, as appropriate;

(10) to cooperate with, as appropriate, international agencies, in accordance with their respective mandates, donors, vaccine manufacturers and national governments<sup>1</sup> in order to overcome barriers to timely and adequate access to affordable vaccines of assured quality for all, and to implement effective preventive measures for the protection of health workers, including in public health emergencies of international concern and in the specific context of humanitarian crises;

(11) to report to the Seventy-third World Health Assembly, through the Executive Board, on the epidemiological aspects and feasibility of, and potential resource requirements for, measles and rubella eradication, taking into account the assessment of the Strategic Advisory Group of Experts on immunization;

(12) to continue to monitor progress annually and to report to the Health Assembly, through the Executive Board, as a substantive agenda item in 2020 and 2022 on the achievements made against the 2020 global vaccine action plan goals and targets.

(Tenth plenary meeting, 31 May 2017 – Committee A, fifth report)

<sup>&</sup>lt;sup>1</sup> And, where applicable, regional economic integration organizations.

# WHA70.15 Promoting the health of refugees and migrants<sup>1</sup>

The Seventieth World Health Assembly,

Having considered the report on promoting the health of refugees and migrants,<sup>2</sup> and following decision EB140(9) (2017);

Recalling resolution WHA61.17 (2008) on the health of migrants and reaffirming the healthrelated commitments made within the New York Declaration for Refugees and Migrants;<sup>3</sup>

Recalling the need for international cooperation to support countries hosting refugees, and recognizing the efforts of the countries hosting and receiving large populations of refugees and migrants,

1. NOTES WITH APPRECIATION the framework of priorities and guiding principles to promote the health of refugees and migrants;<sup>4</sup>

2. URGES Member States,<sup>5</sup> in accordance with their national context, priorities, and legal frameworks:

(1) to consider promoting the framework of priorities and guiding principles to promote the health of refugees and migrants, as appropriate, at global, regional and country levels including using it to inform discussions among Member States and partners engaged in the development of the global compact on refugees and the global compact for safe, orderly and regular migration;

(2) to identify and collect evidence-based information, best practices and lessons learned in addressing the health needs of refugees and migrants in order to contribute to the development of a draft global action plan on promoting the health of refugees and migrants;

(3) to strengthen international cooperation on the health of refugees and migrants in line with paragraphs 11 and 68 and other relevant paragraphs of the New York Declaration for Refugees and Migrants;

(4) to consider providing necessary health-related assistance through bilateral and international cooperation to those countries hosting and receiving large populations of refugees and migrants;

#### 3. **REQUESTS** the Director-General:

(1) to use the framework of priorities and guiding principles to promote the health of refugees and migrants in order to increase advocacy at all levels to promote the health of refugees and migrants, as appropriate;

<sup>&</sup>lt;sup>1</sup> See Annex 14 for the financial and administrative implications for the Secretariat of this resolution.

<sup>&</sup>lt;sup>2</sup> Document A70/24.

<sup>&</sup>lt;sup>3</sup> See United Nations General Assembly resolution 71/1 (2016).

<sup>&</sup>lt;sup>4</sup> See Annex 4.

<sup>&</sup>lt;sup>5</sup> And, where applicable, regional economic integration organizations.

(2) to develop, reinforce and maintain the necessary capacities to provide health leadership and to provide support to Member States and partners in promoting the health of refugees and migrants, in close collaboration with the International Organization for Migration, UNHCR, other international organizations and relevant stakeholders, and avoiding duplication;

(3) to identify best practices, experiences and lessons learned on the health of refugees and migrants in each region, in order to contribute to the development of a draft global action plan on the health of refugees and migrants to be considered for adoption by the Seventy-second World Health Assembly, and to report thereon to the Health Assembly;

(4) to submit to the Seventy-first and Seventy-second World Health Assemblies a report on progress made in implementing this resolution.

(Tenth plenary meeting, 31 May 2017 – Committee A, fifth report)

# WHA70.16 Global vector control response: an integrated approach for the control of vector-borne diseases<sup>1</sup>

The Seventieth World Health Assembly,

Having considered the report on global vector control response;<sup>2</sup>

Appreciating the work of the Secretariat in developing, through broad consultation with Member States and members of the global health community, a comprehensive draft global vector control response 2017-2030, which served as the basis for the report;<sup>2</sup>

Acutely aware of the burden and threat of vector-borne diseases to individuals, families and societies throughout the world, and the influence of social, demographic and environmental factors, including climate change and other climate- and weather-related factors, and increasing vector resistance to insecticides and the spread of mosquitoes and other vectors to unaffected areas;

Recognizing the need for cooperation to prevent, detect, report on and respond to outbreaks of vector-borne diseases so as to avoid a public health emergency of international concern under the International Health Regulations (2005);

Noting the recent gains that have been made against malaria, onchocerciasis, lymphatic filariasis, Chagas disease and others, as well as previous failures and existing challenges, and that lessons learned could be used for other vector-borne diseases;

Recognizing the need for an integrated, comprehensive approach to vector control that will enable the setting and achievement of disease-specific national and global goals, and that will contribute to the attainment of the Sustainable Development Goals, to addressing the social determinants of health and to tackling health inequities;

<sup>&</sup>lt;sup>1</sup> See Annex 14 for the financial and administrative implications for the Secretariat of this resolution.

<sup>&</sup>lt;sup>2</sup> Document A70/26 Rev.1.

Deeply concerned by the current limited capacity and capability for vector control globally, and in particular the acute shortage in public health and development programmes of personnel with skills in public health entomology,

1. WELCOMES the strategic approach for integrated global vector control and response, as articulated in the report<sup>1</sup> and its Annex;<sup>2</sup>

2. URGES Member States:<sup>3</sup>

(1) to develop or adapt, as appropriate, existing national vector control strategies and operational plans in alignment with the strategic approach for integrated global vector control and response, as summarized in the report,<sup>1</sup> and consistent with the International Health Regulations (2005);

(2) to build and sustain, as appropriate, adequate human-resource (especially public health entomology), infrastructural and institutional capacity and capability at all levels of government and across all relevant sectors, based on a vector control needs assessment;

(3) to promote basic research on vectors and their transmission of pathogens, and applied research on vector control tools, including biological tools, technologies and approaches to evaluate their impact on disease, socioeconomic development, human populations and the environment; and to assess how to integrate them with vaccines, medicines and other interventions;

(4) to promote collaboration in line with the "One Health" approach and the integrated vector and communicable disease approach, as appropriate, across all levels and sectors of government, including municipality and local administrative structures, and with the engagement and mobilization of communities through organized stakeholder groups;

(5) to strengthen national and subnational capacity, as appropriate, for vector surveillance, forecasting and intervention monitoring, including for vector pesticide resistance and for the impact of pesticides on environmental and human health, and to integrate the information generated into public health surveillance systems;

(6) to strengthen and engage in cross-border and regional collaboration by means that include networks in line with the International Health Regulations (2005) in order to build adequate capacity for prevention, surveillance, control and response for vector-borne diseases;

(7) to collaborate, as appropriate, with international, regional, national and local institutions and non-State actors from relevant sectors to support and contribute to the implementation of WHO's strategic approach for integrated global vector control and response;

#### 3. **REQUESTS** the Director-General:

(1) to continue to develop and disseminate normative guidance, policy advice and implementation guidance that provides support to Member  $States^2$  to reduce the burden and

<sup>&</sup>lt;sup>1</sup> Document A70/26 Rev.1.

<sup>&</sup>lt;sup>2</sup> See Annex 5.

<sup>&</sup>lt;sup>3</sup> And, where applicable, regional economic integration organizations.

threat of vector-borne diseases, including to strengthen human-resource capacity and capability for effective locally adapted sustainable and ethically sensitive vector control;

(2) to continue to promote research on vector-borne disease systems and development of innovative products, methods, tools, technologies and approaches, and to support the generation of evidence-based knowledge on their safety, efficacy and impact on disease, socioeconomic development, human populations and the natural environment;

(3) to review and provide technical guidance on the ethical aspects and issues associated with the implementation of new vector control approaches in order to develop mitigating strategies and solutions;

(4) to undertake a review of the ethical aspects and related issues associated with vector control implementation that will include social determinants of health, in order to develop mitigating strategies and solutions to tackle health inequities;

(5) to disseminate widely, and update as appropriate, technical guidance on integrated vector control for all relevant vector-borne diseases, especially as new evidence-based knowledge becomes available for improved and novel products, tools, technologies and approaches;

(6) to strengthen the capacities and capabilities of the Secretariat at the global, regional and country levels and ensure that all relevant parts of the Organization across all three levels are actively engaged to lead a coordinated global effort that includes collaboration with other bodies of the United Nations system and other intergovernmental agencies for better implementation of vector control;

(7) to develop, in consultation with Member States and through regional committees, as appropriate, regional action plans aligned with WHO's technical guidance on vector control, including the priority activities as described in the report;<sup>1</sup>

(8) to provide support to countries to develop and/or update national vector control and vector-borne disease control strategies aligned to the strategic approach for integrated global vector control and response and, as appropriate, to other ongoing communicable disease control strategies and emergency responses to outbreaks;

(9) to monitor the implementation of the strategic approach for integrated global vector control and response, and report back on its impact and the progress made towards the milestones and targets at the Seventy-fifth, Eightieth and Eighty-fifth World Health Assemblies.

(Tenth plenary meeting, 31 May 2017 – Committee A, sixth report)

<sup>&</sup>lt;sup>1</sup> Document A70/26 Rev.1.

# **DECISIONS**

# WHA70(1) Composition of the Committee on Credentials

The Seventieth World Health Assembly appointed a Committee on Credentials consisting of delegates of the following Member States: Angola, Belarus, Cambodia, Italy, Japan, Lithuania, Mali, Myanmar, Panama, Paraguay, South Sudan and Yemen.

(First plenary meeting, 22 May 2017)

## WHA70(2) Election of officers of the Seventieth World Health Assembly

The Seventieth World Health Assembly elected the following officers:

| President:       | Professor Veronika Skvortsova (Russian Federation)  |
|------------------|---|
| Vice-Presidents: | Mr Nandi Tuaine Glassie (Cook Islands)<br>Dr Fawziya Abikar Nur (Somalia)<br>Dr Arlindo Nascimento do Rosario (Cabo Verde)<br>Mr Patrick Pengel (Suriname)<br>Mr Choe Myong Nam (Democratic People's Republic of Korea) |
|                  |   |

(First plenary meeting, 22 May 2017)

# WHA70(3) Election of officers of the main committees

The Seventieth World Health Assembly elected the following officers of the main committees:

| Committee A: | Chairman | Dr Hanan Mohamed Al-Kuwari (Qatar)     |
|--------------|----------|--|
| Committee B: | Chairman | Dr Molwyn Joseph (Antigua and Barbuda) |

(First plenary meeting, 22 May 2017)

The main committees subsequently elected the following officers:

| Committee A: | Vice-Chairmen | Dr Mohammad Anwar Husnoo <sup>1</sup> (Mauritius)<br>Mr Philip Davies (Fiji) |
|--------------|---------------|--|
|              | Rapporteur    | Mr Ioannis Baskozos (Greece)   |

<sup>&</sup>lt;sup>1</sup> Replaced by Mr Anandrao Hurree (Mauritius) at the opening of the third meeting of Committee A.

| Committee B: | Vice-Chairmen | Mr Mario Miklosi (Slovakia)<br>Dr Slamet (Indonesia) |
|--------------|---------------|--|
|              | Rapporteur    | Dr Nguyen Manh Cuong (Viet Nam)                      |

(First meetings of Committees A and B, 22 and 25 May 2017, respectively)

#### WHA70(4) Establishment of the General Committee

The Seventieth World Health Assembly, after considering the recommendations of the Committee on Nominations, elected the delegates of the following 17 countries as members of the General Committee: China, Cuba, Djibouti, Dominican Republic, France, Guinea, Kyrgyzstan, Malawi, Maldives, Malta, Mozambique, Norway, Philippines, Rwanda, Togo, United Kingdom of Great Britain and Northern Ireland, and United States of America.

(First plenary meeting, 22 May 2017)

#### WHA70(5) Adoption of the agenda

The Seventieth World Health Assembly adopted the provisional agenda prepared by the Executive Board at its 140th session, with the deletion of four items and the exclusion of one supplementary item, and the transfer of one item from Committee B to Committee A.

(Second plenary meeting, 22 May 2017)

#### WHA70(6) Post of Director-General

The Seventieth World Health Assembly, having considered the report on the post of Director-General contained in document A70/4, decided:

- (1) to use a paper-based voting system for the appointment of the Director-General;
- (2) to implement the proposals outlined in the Table in document A70/4;

(3) to adopt the amendments to the Rules of Procedure of the World Health Assembly contained in Annex 4 to document A70/4 in accordance with Rule 119 of the Rules of Procedure of the World Health Assembly.<sup>1</sup>

(Second plenary meeting, 22 May 2017)

## WHA70(7) Verification of credentials

The Seventieth World Health Assembly recognized the validity of the credentials of the following delegations: Afghanistan, Albania, Algeria, Andorra, Angola, Antigua and Barbuda, Argentina, Armenia, Australia, Austria, Azerbaijan, Bahamas, Bahrain, Bangladesh, Barbados, Belarus, Belgium, Belize, Benin, Bhutan, Bolivia (Plurinational State of), Bosnia and Herzegovina, Botswana, Brazil, Brunei Darussalam, Bulgaria, Burkina Faso, Burundi, Cabo Verde, Cambodia,

<sup>&</sup>lt;sup>1</sup> See Annex 6.

Cameroon, Canada, Central African Republic, Chad, Chile, China, Colombia, Comoros, Congo, Cook Islands, Costa Rica, Côte d'Ivoire, Croatia, Cuba, Cyprus, Czech Republic, Democratic People's Republic of Korea, Democratic Republic of the Congo, Denmark, Djibouti, Dominica, Dominican Republic, Ecuador, Egypt, El Salvador, Equatorial Guinea, Eritrea, Estonia, Ethiopia, Fiji, Finland, France, Gabon, Gambia, Georgia, Germany, Ghana, Greece, Grenada, Guatemala, Guinea, Guinea-Bissau, Guyana, Haiti, Honduras, Hungary, Iceland, India, Indonesia, Iran (Islamic Republic of), Iraq, Ireland, Israel, Italy, Jamaica, Japan, Jordan, Kazakhstan, Kenya, Kiribati, Kuwait, Kyrgyzstan, Lao People's Democratic Republic, Latvia, Lebanon, Lesotho, Liberia, Libya, Lithuania, Luxembourg, Madagascar, Malawi, Malaysia, Maldives, Mali, Malta, Marshall Islands, Mauritania, Mauritius, Mexico, Monaco, Mongolia, Montenegro, Morocco, Mozambique, Myanmar, Namibia, Nauru, Nepal, Netherlands, New Zealand, Nicaragua, Niger, Nigeria, Norway, Oman, Pakistan, Palau (Republic of), Panama, Paraguay, Peru, Philippines, Poland, Portugal, Qatar, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Rwanda, Saint Kitts and Nevis, Saint Vincent and the Grenadines, Samoa, San Marino, Sao Tome and Principe, Saudi Arabia, Senegal, Serbia, Seychelles, Sierra Leone, Singapore, Slovakia, Slovenia, Solomon Islands, Somalia, South Africa, South Sudan, Spain, Sri Lanka, Sudan, Suriname, Swaziland, Sweden, Switzerland, Syrian Arab Republic, Tajikistan, Thailand, The former Yugoslav Republic of Macedonia, Timor-Leste, Togo, Tonga, Trinidad and Tobago, Tunisia, Turkey, Turkmenistan, Tuvalu, Uganda, Ukraine, United Arab Emirates, United Kingdom of Great Britain and Northern Ireland, United Republic of Tanzania, United States of America, Uruguay, Uzbekistan, Vanuatu, Venezuela (Bolivarian Republic of), Viet Nam, Yemen, Zambia, Zimbabwe.

(Third plenary meeting, 22 May 2017 and seventh plenary meeting, 24 May 2017)

# WHA70(8) Election of Members entitled to designate a person to serve on the Executive Board

The Seventieth World Health Assembly, after considering the recommendations of the General Committee, elected the following as Members entitled to designate a person to serve on the Executive Board: Benin, Brazil, Georgia, Iraq, Italy, Japan, Sri Lanka, Swaziland, United Republic of Tanzania, Zambia.

(Ninth plenary meeting, 29 May 2017)

## WHA70(9) Poliomyelitis: polio transition planning<sup>1</sup>

The Seventieth World Health Assembly, having considered the updated report on polio transition planning,<sup>2</sup> decided:

(1) to acknowledge that the active role taken by the Office of the Director-General in directing and leading this process is of key importance;

(2) to emphasize the critical and urgent need to maintain and pursue eradication efforts in polio-endemic countries and to sustain surveillance in countries through polio eradication certification, and the importance of ensuring that the Global Polio Eradication Initiative is fit for purpose, with adequate levels of qualified staff;

<sup>&</sup>lt;sup>1</sup> See Annex 14 for the financial and administrative implications for the Secretariat of this decision.

<sup>&</sup>lt;sup>2</sup> Document A70/14 Add.1.

(3) to acknowledge that the ramp-down of the Global Polio Eradication Initiative has started and highlight the need for WHO to strategically manage the resulting impact on WHO human resources and other assets;

(4) to note the ongoing process of developing a post-certification strategy that will define the essential polio functions needed to sustain eradication and maintain a polio-free world;

(5) to highlight the need for WHO to work with all relevant stakeholders on options for ensuring effective accountability and oversight after eradication in the post-certification strategy;

(6) to note with great concern the reliance on the Global Polio Eradication Initiative's funding of WHO at global, regional and country levels, involving many WHO programme activities, and the financial, organizational and programmatic risks that this reliance entails for WHO, including risks for the sustainability of WHO's capacity to ensure effective delivery in key programmatic areas and to maintain essential continuing functions;

(7) to note also the list of Secretariat actions to be implemented by the end of 2017, as referred to in document A70/14 Add.1, in particular in relation to the development of a comprehensive WHO strategic action plan on polio transition;<sup>1</sup>

- (8) to urge the Director-General:
  - (a) to make polio transition a key priority for the Organization at its three levels;

(b) to ensure that the development of the WHO strategic action plan on polio transition is guided by an overarching principle of responding to country needs and priorities, including by participating in and supporting Global Polio Eradication Initiative country transition planning;

(c) to mainstream best practices from polio eradication into all relevant health interventions and build capacity and responsibility for ongoing polio eradication functions and assets in national programmes, while maintaining WHO's capacity to provide norms and standards for post-eradication planning and oversight;

(d) to explore innovative ways for mobilizing additional funding for the period 2017–2019 in order to mitigate the possible impact of the ramp-down of the Global Polio Eradication Initiative, including on the longer-term sustainability of key assets that are currently financed by the Global Polio Eradication Initiative, and to update Member States on this work, through a dedicated session at the forthcoming financing dialogue;

(9) to request the Director-General:

(a) to develop a strategic action plan on polio transition by the end of 2017, to be submitted for consideration by the Seventy-first World Health Assembly, through the Executive Board at its 142nd session, that:

<sup>&</sup>lt;sup>1</sup> See Annex 7.

(i) clearly identifies the capacities and assets, especially at country and, where appropriate, community levels, that are required to:

- sustain progress in other programmatic areas, such as: disease surveillance; immunization and health systems strengthening; early warning, emergency and outbreak response, including the strengthening and maintenance of core capacities under the International Health Regulations (2005);
- maintain a polio-free world after eradication;
- (ii) provides a detailed costing of these capacities and assets;

(b) to present to the Seventy-first World Health Assembly a report on the efforts to mobilize funding for transitioning capacities and assets that are currently financed by the Global Polio Eradication Initiative into the programme budget, to enable the Seventy-first World Health Assembly to provide guidance for the development of the programme budget for the biennium 2020–2021 and the Thirteenth General Programme of Work on a realistic basis;

(c) to report regularly on the planning and implementation of the transition process to the Health Assembly, through the Regional Committees and the Executive Board.

(Ninth plenary meeting, 29 May 2017 – Committee A, third report)

# WHA70(10) Review of the Pandemic Influenza Preparedness Framework<sup>1</sup>

The Seventieth World Health Assembly, having considered the report on the 2016 Pandemic Influenza Preparedness (PIP) Framework Review Group and the report of the Secretariat on collaboration with the Secretariat of the Convention on Biological Diversity and other relevant international organizations,<sup>2</sup> decided:

(1) to recall WHO's mandate as the directing and coordinating authority on international health work, and its role under the International Health Regulations (2005) in global outbreak alert and response in respect of public health crises;

(2) to reaffirm the importance of the PIP Framework in addressing present or imminent threats to human health from influenza viruses with pandemic potential, and emphasize its critical function as a specialized international instrument that facilitates expeditious access to influenza viruses of human pandemic potential, risk analysis and the expeditious, fair and equitable sharing of vaccines and other benefits;

(3) to emphasize the importance of prioritizing and supporting global pandemic influenza preparedness and response, including through the strengthening of domestic seasonal influenza virus surveillance, manufacturing and regulatory capacities, and international coordination and collaboration through WHO's Global Influenza Surveillance and Response System to identify and share influenza viruses with pandemic potential rapidly;

<sup>&</sup>lt;sup>1</sup> See Annex 14 for the financial and administrative implications for the Secretariat of this decision.

<sup>&</sup>lt;sup>2</sup> Documents A70/17 (Annex) and A70/57.

(4) to acknowledge the critical role of Global Influenza Surveillance and Response System in the identification, risk analysis and sharing of influenza viruses with human pandemic potential in order to allow rapid development of diagnostics, vaccines and medicines;

(5) to recognize the significant progress on the rate of conclusion of the Standard Material Transfer Agreements 2, and on the rate of collection of partnership contributions, and the need to maintain progress, as well as the continued need to ensure timely payments by influenza vaccine, diagnostic and pharmaceutical manufacturers using the Global Influenza Surveillance and Response System;

(6) to recognize the ongoing consultations and collaboration between WHO and the secretariat of the Convention on Biological Diversity and other relevant international organizations;

(7) to commend the useful recommendations of the 2016 PIP Framework Review Group;<sup>1</sup>

(8) to request the Director-General:

(a) to take forward expeditiously the recommendations in the report of the 2016 PIP Framework Review Group;

(b) regarding the 2016 PIP Framework Review Group's recommendations concerning seasonal influenza and genetic sequence data, to conduct a thorough and deliberative analysis of the issues raised, including the implications of pursuing or not pursing possible approaches, relying on the 2016 PIP Framework Review and the expertise of the PIP Advisory Group, and transparent consultation of Member States and relevant stakeholders, including the Global Influenza Surveillance and Response System;

(c) to continue supporting the strengthening of regulatory capacities and carrying out burden-of-disease studies, which are fundamental foundations for pandemic preparedness;

(d) to continue encouraging manufacturers and other relevant stakeholders to engage in PIP Framework efforts, including, where applicable, by entering into Standard Material Transfer Agreements 2 and by making timely annual PIP Partnership Contributions;

(e) to request the External Auditor to perform an audit of PIP Partnership Contribution funds in line with the Review Group's recommendation to provide: (1) assurances that the Financial Regulations of the World Health Organization have been appropriately applied in the use of funds and that the financial information reported is accurate and reliable; and (2) recommendations to further increase the transparency of reporting on the linkages between expenditure and technical impact;

(f) to continue consultations with the secretariat of the Convention on Biological Diversity and other relevant international organizations, as appropriate;

(g) to report to the Seventy-first World Health Assembly, on progress in implementing this decision, including by indicating the status of the response to the recommendations

<sup>&</sup>lt;sup>1</sup> See Annex 8.

contained in the report of the 2016 PIP Framework Review Group, and to make recommendations on further action.

(Ninth plenary meeting, 29 May 2017 – Committee A, third report)

## WHA70(11) Implementation of the International Health Regulations (2005)

The Seventieth World Health Assembly, having considered the report on implementation of the International Health Regulations (2005): global implementation plan,<sup>1</sup> mindful of the legally binding nature of the International Health Regulations (2005), recalling country ownership and WHO's leadership in the implementation of the International Health Regulations (2005), and aware of the urgency of their implementation, decided:

- (1) to take note of the report contained in document A70/16; and
- (2) to request the Director-General:

(a) to develop, in full consultation with Member States, including through the regional committees, a draft five-year global strategic plan to improve public health preparedness and response, based on the guiding principles contained in Annex 2 of document A70/16,<sup>2</sup> to be submitted for consideration and adoption by the Seventy-first World Health Assembly, through the Executive Board at its 142nd session;

(b) to continue to pursue and strengthen efforts to support Member States in the full implementation of the International Health Regulations (2005), including through building their core public health capacities.

(Ninth plenary meeting, 29 May 2017 – Committee A, fourth report)

# WHA70(12) Health conditions in the occupied Palestinian territory, including east Jerusalem, and in the occupied Syrian Golan<sup>3</sup>

The Seventieth World Health Assembly, taking note of the report by the Director-General requested in decision WHA69(10) (2016),<sup>4</sup> decided to request the Director-General:

(1) to report on progress in the implementation of the recommendations contained in the report by the Director-General, based on field monitoring, to the Seventy-first World Health Assembly;

(2) to provide support to the Palestinian health services, including through capacity-building programmes and the development of strategic plans for investments in specific treatment and diagnostic capacities locally;

<sup>&</sup>lt;sup>1</sup> Document A70/16.

<sup>&</sup>lt;sup>2</sup> See Annex 9.

<sup>&</sup>lt;sup>3</sup> See Annex 14 for the financial and administrative implications for the Secretariat of this decision.

<sup>&</sup>lt;sup>4</sup> Document A70/39.

(3) to provide health-related technical assistance to the Syrian population in the occupied Syrian Golan;

(4) to continue providing the necessary technical assistance in order to meet the health needs of the Palestinian people, including prisoners and detainees, in cooperation with the efforts of the International Committee of the Red Cross, as well as the health needs of handicapped and injured people;

(5) to support the development of the health system in the occupied Palestinian territory, including the development of human resources, with a particular focus on strengthening primary care and integrating provision of mental health services into primary care services, together with a focus on health prevention and integrated disease management; and to advise donors on how to best support these activities; and

(6) to ensure the allocation of human and financial resources in order to achieve these objectives.

(Ninth plenary meeting, 29 May 2017 – Committee B, first report)

# WHA70(13) WHO mid-term programmatic and financial report for 2016–2017, including audited financial statements for 2016

The Seventieth World Health Assembly, having considered the WHO mid-term programmatic and financial report for 2016–2017, including audited financial statements for 2016;<sup>1</sup> and having noted the report of the Programme, Budget and Administration Committee of the Executive Board to the Seventieth World Health Assembly,<sup>2</sup> decided to accept the WHO mid-term programmatic and financial report for 2016–2017, including audited financial statements for 2016.

(Ninth plenary meeting, 29 May 2017 – Committee B, first report)

## WHA70(14) Report of the External Auditor

The Seventieth World Health Assembly, having considered the report of the External Auditor to the Health Assembly;<sup>3</sup> and having noted the report of the Programme, Budget and Administration Committee of the Executive Board to the Seventieth World Health Assembly,<sup>4</sup> decided to accept the report of the External Auditor to the Health Assembly.

(Ninth plenary meeting, 29 May 2017 – Committee B, first report)

<sup>&</sup>lt;sup>1</sup> Document A70/40.

<sup>&</sup>lt;sup>2</sup> Document A70/58.

<sup>&</sup>lt;sup>3</sup> Document A70/43.

<sup>&</sup>lt;sup>4</sup> Document A70/61.

#### WHA70(15) Appointment of representatives to the WHO Staff Pension Committee

The Seventieth Health Assembly nominated the alternate members, Dr Naoko Yamamoto of the delegation of Japan and Dr Gerardo Lubin Burgos Bernal of the delegation of Colombia, as members for the remainder of their terms of office until May 2019.

The Health Assembly nominated Dr Asad Hafeez of the delegation of Pakistan, Dr Papa Amadou Diack of the delegation of Senegal and Dr Alan Ludowyke of the delegation of Sri Lanka as alternate members of the WHO Staff Pension Committee for three-year terms until May 2020.

(Tenth plenary meeting, 31 May 2017 – Committee B, second report)

#### WHA70(16) Infrastructure Fund

The Seventieth World Health Assembly, having considered the report on proposed Infrastructure Fund (consolidating the Real Estate Fund and IT Fund);<sup>1</sup> having noted the report of the Programme, Budget and Administration Committee of the Executive Board to the Seventieth World Health Assembly;<sup>2</sup> noting the financing requirements for infrastructure needs, comprising investments in both real estate and information technology, as described in document A70/54; and noting the existing financing arrangements for the Real Estate Fund, in accordance with resolution WHA63.7 (2010) on the Capital Master Plan and decision WHA69(18) (2016) on real estate: update on the Geneva buildings renovation strategy, which provide for US\$ 25 million per biennium for real estate needs, decided:

(1) to approve the renaming of the Real Estate Fund as the Infrastructure Fund;

(2) to approve also the extension of the purposes of the Infrastructure Fund (formerly Real Estate Fund) to include information technology investments, as approved by the IT Board, in addition to the approved purposes defined under resolution WHA23.14 (1970) on Real Estate Fund, while maintaining and reporting on real estate and information technology investments as separate sub-accounts;

(3) to authorize the Director-General to allocate, by the end of each biennium, at least US\$ 15 million, as available, for information technology investment needs within the Infrastructure Fund;

(4) to request the Director-General to establish separate sub-accounts to maintain the segregation between the Real Estate and the information technology investment funds within the Infrastructure Fund;

<sup>&</sup>lt;sup>1</sup>Document A70/54.

<sup>&</sup>lt;sup>2</sup> Document A70/65.

(5) to further request the Director-General to report to the Executive Board at its future sessions both on the implementation of the information technology and real estate funds included in the Infrastructure Fund, and on the financing of the Fund.

(Tenth plenary meeting, 31 May 2017 – Committee B, second report)

# WHA70(17) Global action plan on the public health response to dementia<sup>1</sup>

The Seventieth World Health Assembly, having considered the draft global action plan on the public health response to dementia 2017–2025,<sup>2</sup> decided:

(1) to endorse the global action plan on the public health response to dementia 2017-2025;<sup>3</sup>

(2) to urge Member States<sup>4</sup> to develop, as soon as practicable, ambitious national responses to the overall implementation of the global action plan on the public health response to dementia 2017-2025;

(3) to request the Director-General to submit a report on progress made in implementing this decision to the Seventy-third, Seventy-sixth and Seventy-ninth World Health Assemblies.

(Tenth plenary meeting, 31 May 2017 – Committee B, third report)

# WHA70(18) Public health dimension of the world drug problem<sup>1</sup>

The Seventieth World Health Assembly, having considered the report of the Secretariat on the public health dimension of the world drug problem,<sup>5</sup> decided:

(1) to welcome the progress made in strengthening and expanding existing cooperation on the public health-related aspects of the world drug problem, including the signing of the Memorandum of Understanding between WHO and UNODC in February 2017;

(2) to recognize the need for intensified efforts to support Member States, upon request, in addressing and countering the world drug problem in accordance with a comprehensive, integrated and balanced approach;

(3) to request the Director-General to continue efforts to improve the coordination and collaboration of WHO with UNODC and the International Narcotics Control Board, within their existing mandates, in addressing and countering the world drug problem;

(4) to further request the Director-General to report on the implementation of this decision to the Seventy-first, Seventy-third and Seventy-fifth World Health Assemblies, and to continue to

<sup>&</sup>lt;sup>1</sup> See Annex 14 for the financial and administrative implications for the Secretariat of this decision.

<sup>&</sup>lt;sup>2</sup> Document A70/28, Annex.

<sup>&</sup>lt;sup>3</sup> See Annex 10.

<sup>&</sup>lt;sup>4</sup> And, where applicable, regional economic integration organizations.

<sup>&</sup>lt;sup>5</sup> Document A70/29.

keep the Commission on Narcotics Drugs, considering its treaty-based mandates, appropriately informed of relevant programmes and progress.

(Tenth plenary meeting, 31 May 2017 – Committee B, third report)

# WHA70(19) Report of the Commission on Ending Childhood Obesity: implementation plan<sup>1</sup>

The Seventieth World Health Assembly, recalling, inter alia, the WHO Comprehensive Implementation Plan on Maternal, Infant and Young Child Nutrition, resolution WHA69.9 (2016) on ending inappropriate promotion of foods for infants and young children, resolution WHA66.10 (2013) on follow-up to the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, which includes the WHO global action plan for the prevention and control of noncommunicable diseases 2013–2020, and the accountability and monitoring framework of the FAO/WHO Second International Conference on Nutrition (Rome, 19–21 November 2014); and having considered the report of the Commission on Ending Childhood Obesity: implementation plan,<sup>2</sup> decided:

(1) to welcome the implementation plan to guide further action on the recommendations included in the report of the Commission on Ending Childhood Obesity;<sup>3</sup>

(2) to urge Member States to develop national responses, strategies and plans to end infant, child and adolescent obesity,<sup>4</sup> taking into account the implementation  $plan;^3$ 

(3) to request the Director-General to report to the Health Assembly periodically on progress made towards ending childhood obesity, including on the implementation plan,<sup>3</sup> as part of existing reporting in respect of nutrition and noncommunicable diseases.

(Tenth plenary meeting, 31 May 2017 – Committee B, fourth report)

# WHA70(20) Strengthening synergies between the World Health Assembly and the Conference of the Parties to the WHO Framework Convention on Tobacco Control<sup>1</sup>

The Seventieth World Health Assembly, having considered the report by the Secretariat on strengthening synergies between the World Health Assembly and the Conference of the Parties to the WHO Framework Convention on Tobacco Control,<sup>5</sup> and having noted decision FCTC/COP7(18) (2016) adopted by the Conference of the Parties to the WHO Framework Convention on Tobacco Control, decided:

<sup>&</sup>lt;sup>1</sup> See Annex 14 for the financial and administrative implications for the Secretariat of this decision.

<sup>&</sup>lt;sup>2</sup> Document A70/31.

<sup>&</sup>lt;sup>3</sup> See Annex 11.

<sup>&</sup>lt;sup>4</sup> As defined in Annex 11, paragraph 1, footnote 5.

<sup>&</sup>lt;sup>5</sup> Document A70/33.

(1) to note with appreciation the report presented by the President of the Conference of the Parties to the Framework Convention on Tobacco Control;<sup>1</sup>

(2) to invite the Conference of the Parties to the Framework Convention on Tobacco Control to direct the secretariat of the Framework Convention to provide a report on the outcomes of each future session of the Conference to the following session of the Health Assembly, for information purposes and as part of the documentation provided to the Health Assembly under the agenda item on the prevention and control of noncommunicable diseases;

(3) to request the WHO Director-General, pursuant to decision WHA69(13) (2016), to continue to provide regular reports for information purposes to the Conference of the Parties to the Framework Convention on Tobacco Control on resolutions and decisions of the Health Assembly relevant to the implementation of the Framework Convention.

(Tenth plenary meeting, 31 May 2017 – Committee B, fourth report)

# $WHA70(21) \qquad Member State mechanism on substandard and falsified medical products^2$

The Seventieth World Health Assembly, having considered the report of the fifth meeting of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products and resolution WHA65.19 (2012),<sup>3</sup> decided:

(1) to endorse the definitions as set out in Appendix 3 to the Annex to document A70/23;<sup>4</sup>

(2) to request the Director-General to replace the term "substandard/spurious/ falsely-labelled/falsified/counterfeit medical products" with "substandard and falsified medical products" as the term to be used in the name of the Member State mechanism and in all future documentation on the subject of medical products of this type.

> (Tenth plenary meeting, 31 May 2017 – Committee A, fifth report)

# WHA70(22) Progress in the implementation of the 2030 Agenda for Sustainable Development<sup>1</sup>

The Seventieth World Health Assembly, having considered the report on progress in the implementation of the 2030 Agenda for Sustainable Development,<sup>5</sup> decided to request the Director-General to continue to report every two years, as requested in resolution WHA69.11 (2016), on health in the 2030 Agenda for Sustainable Development, including on the strengthening of

<sup>&</sup>lt;sup>1</sup> Document A70/33, Annex.

<sup>&</sup>lt;sup>2</sup> See Annex 14 for the financial and administrative implications for the Secretariat of this decision.

 $<sup>^{3}</sup>$  See document A70/23 and document WHA65/2012/REC/1, and in particular the footnote in the first paragraph of the Annex to the resolution.

<sup>&</sup>lt;sup>4</sup> See Annex 12.

<sup>&</sup>lt;sup>5</sup> Document A70/35.

emergency and essential surgical care and anaesthesia as a component of universal health coverage, as requested in resolution WHA68.15 (2015).

(Tenth plenary meeting, 31 May 2017 – Committee A, sixth report)

# WHA70(23) The role of the health sector in the Strategic Approach to International Chemicals Management towards the 2020 goal and beyond<sup>1</sup>

The Seventieth World Health Assembly, having considered the report on the role of the health sector in the Strategic Approach to International Chemicals Management towards the 2020 goal and beyond,<sup>2</sup> decided:

(1) to approve the road map to enhance health sector engagement in the Strategic Approach to International Chemicals Management towards the 2020 goal and beyond;<sup>3</sup>

(2) to request the Director-General to report to the Seventy-second World Health Assembly on progress made in implementing the road map, and at the Seventy-fourth World Health Assembly to report further on progress, as well as on actions undertaken by the Secretariat to update the road map in the light of the outcome of the intersessional process to prepare recommendations regarding the Strategic Approach and the sound management of chemicals and waste beyond 2020.<sup>4</sup>

(Tenth plenary meeting, 31 May 2017 – Committee A, sixth report)

#### WHA70(24) Selection of the country in which the Seventy-first World Health Assembly would be held

The Seventieth World Health Assembly, in accordance with Article 14 of the Constitution, decided that the Seventy-first World Health Assembly would be held in Switzerland.

(Tenth plenary meeting, 31 May 2017)

<sup>&</sup>lt;sup>1</sup> See Annex 14 for the financial and administrative implications for the Secretariat of this decision.

<sup>&</sup>lt;sup>2</sup> Document A70/36.

<sup>&</sup>lt;sup>3</sup> See Annex 13.

<sup>&</sup>lt;sup>4</sup> See resolution WHA69.4 (2016), paragraph 2(10).

# ANNEXES

### ANNEX 1

## **Contract of the Director-General**<sup>1</sup>

#### [A70/5, Annex – 24 April 2017]

THIS CONTRACT is made this twenty-third day of May of the year two thousand and seventeen between the World Health Organization (hereinafter called the Organization) of the one part and Dr Tedros Adhanom Ghebreyesus (hereinafter called the Director-General) of the other part.

#### WHEREAS

(1) It is provided by Article 31 of the Constitution of the Organization that the Director-General of the Organization shall be appointed by the World Health Assembly (hereinafter called the Health Assembly) on the nomination of the Executive Board (hereinafter called the Board) on such terms as the Health Assembly may decide; and

(2) The Director-General has been duly appointed by the Health Assembly at its meeting held on the twenty-third day of May of the year two thousand and seventeen for a period of five years.

NOW THIS CONTRACT WITNESSETH and it is hereby agreed as follows,

I. (1) The Director-General shall serve from the first day of July of the year two thousand and seventeen until the thirtieth day of June of the year two thousand and twenty-two, on which date the appointment and this Contract shall terminate.

(2) Subject to the authority of the Board, the Director-General shall exercise the functions of chief technical and administrative officer of the Organization and shall perform such duties as may be specified in the Constitution and in the rules of the Organization and/or as may be assigned to him or her by the Health Assembly or the Board.

(3) The Director-General fully commits to the responsible management and appropriate stewardship of WHO's resources, including financial resources, human resources and physical resources, in an efficient and effective manner to achieve the Organization's objectives; an ethical culture, so that all Secretariat decisions and actions are informed by accountability, transparency, integrity, and respect; equitable geographical representation and gender balance in staff appointments and in accordance with Article 35 of the Constitution of the World Health Organization; follow-up of recommendations from the Organization's internal and external audits, and timeliness and transparency of official documentation.

(4) The Director-General shall be subject to the Staff Regulations of the Organization in so far as they may be applicable to him or her. In particular he or she shall not hold any other administrative post, and shall not receive emoluments from any outside sources in respect of activities relating to the Organization. He or she shall not engage in business or in any employment or activity that would interfere with his or her duties in the Organization.

<sup>&</sup>lt;sup>1</sup> See resolution WHA70.3.

(5) The Director-General, during the term of this appointment, shall enjoy all the privileges and immunities in keeping with the office by virtue of the Constitution of the Organization and any relevant arrangements already in force or to be concluded in the future.

(6) The Director-General may at any time give six months' notice of resignation in writing to the Board, which is authorized to accept such resignation on behalf of the Health Assembly; in which case, upon the expiration of the said period of notice, the Director-General shall cease to hold the appointment and this Contract shall terminate.

(7) The Health Assembly shall have the right, on the proposal of the Board and after hearing the Director-General and subject to at least six months' notice in writing, to terminate this Contract for reasons of exceptional gravity likely to prejudice the interests of the Organization.

II. (1) As from the first day of July of the year two thousand and seventeen the Director-General shall receive from the Organization an annual salary of two hundred and forty-one thousand, two hundred and seventy-six United States dollars, before staff assessment, resulting in a net salary (to be paid monthly) of one hundred and seventy-two thousand, and sixty-nine United States dollars per annum or its equivalent in such other currency as may be mutually agreed between the parties to this Contract.

(2) In addition to the normal adjustments and allowances authorized to staff members under the Staff Rules, the Director-General shall receive an annual representation allowance of twenty-one thousand United States dollars or its equivalent in such other currency as may be mutually agreed between the parties to this Contract, to be paid monthly commencing on the first day of July of the year two thousand and seventeen. The representation allowance shall be used at his or her discretion entirely in respect of representation in connection with his or her official duties. He or she shall be entitled to such reimbursable allowances as travel allowances and removal costs on appointment, on subsequent change of official station, on termination of appointment, or on official travel and home leave travel.

III. The terms of the present Contract relating to rates of salary and representation allowance are subject to review and adjustment by the Health Assembly, on the proposal of the Board and after consultation with the Director-General, in order to bring them into conformity with any provision regarding the conditions of employment of staff members which the Health Assembly may decide to apply to staff members already in the service.

IV. If any question of interpretation or any dispute arises concerning this Contract that is not settled by negotiation or agreement, the matter shall be referred for final decision to the competent tribunal provided for in the Staff Rules.

WHEREUNTO we have set our hands the day and year first above written.

.....

.....

Dr Tedros Adhanom Ghebreyesus Director-General Professor Veronika Skvortsova President of the Seventieth World Health Assembly

# ANNEX 2

# Working for health

# Five-year action plan for health employment and inclusive economic growth (2017–2021)<sup>1</sup>

[A70/18, Annex – 15 May 2017]

| Summary                                |   |  |  |  |
|--|---|--|--|--|
| One vision:                            | Accelerate progress towards universal health coverage and attaining the goals of the 2030 Agenda for Sustainable Development by ensuring equitable access to health workers within strengthened health systems  |  |  |  |
| Two goals:                             | Invest in both the expansion and transformation of the global health and social workforce   |  |  |  |
| Three agencies:                        | International Labour Organization (ILO), Organisation for Economic Cooperation and Development (OECD) and the World Health Organization (WHO)   |  |  |  |
| Four Sustainable<br>Development Goals: | Ensure healthy lives and promote well-being for all at all ages (Goal 3);<br>Ensure inclusive and equitable quality education and promote lifelong<br>learning opportunities for all (Goal 4); Achieve gender equality and<br>empower all women and girls (Goal 5); and Promote sustained, inclusive<br>and sustainable economic growth, full and productive employment and<br>decent work for all (Goal 8) |  |  |  |
| Five workstreams:                      | To facilitate the implementation of intersectoral approaches and country-driven action and catalyse sustainable investments, capacity-<br>building and policy action: (1) advocacy, social dialogue and policy dialogue; (2) data, evidence and accountability; (3) education, skills and jobs; (4) financing and investments; and (5) international labour mobility.                                       |  |  |  |

<sup>&</sup>lt;sup>1</sup> See resolution WHA70.6.

#### 1. Background

1. In its report entitled Working for health and growth: investing in the *health workforce*, the High-Level **Commission on Health Employment** and Economic Growth ("the Commission") proposed 10 recommendations and five immediate actions to transform the health and social workforce for the achievement of the 2030 Agenda for Sustainable Development.<sup>1</sup> Implementation of these will require game-changing interventions and action by Member States, led by ministries of health, education, employment and finance, as well as the international community.

2. Dismantling the long-held belief that investment in the health workforce is a drag on the economy, the Commission found that health workforce investments coupled with the right policy action could unleash enormous socioeconomic gains in quality education, gender equality, decent work, inclusive economic growth, and health and well-being. This paradigm shift provides new political impetus for Member States to implement WHO's global strategy on human resources for health: Workforce  $2030^2$  adopted by the Sixty-ninth World Health Assembly in May 2016.<sup>3</sup>

**The High-Level Commission on Health Employment and Economic Growth** was established by the United Nations Secretary-General on 2 March 2016 in response to United Nations General Assembly resolution 70/183 on Global Health and Foreign Policy: Strengthening the Management of International Health Crises adopted on 17 December 2015.

The Commission was chaired by H.E. President of France, Mr François Hollande, and H.E. President of South Africa, Mr Jacob Zuma; and co-chaired by Dr Margaret Chan, Director-General of the World Health Organization, Mr Ángel Gurría, Secretary-General of the Organisation for Economic Co-operation and Development and Mr Guy Ryder, Director-General of the International Labour Organization. The Commission launched its report on the margins of the United Nations General Assembly in New York on 20 September 2016.

The Commission's report was welcomed by the United Nations General Assembly at its seventy-first session.<sup>1</sup> The General Assembly urged Member States to consider its recommendations, "including the development of intersectoral plans and investment in education and job creation in the health and social sectors" with the aim of "contributing to global inclusive economic growth and the creation of decent jobs and achieving universal health coverage".

The Executive Board of the World Health Organization at its 140th session in January 2017 considered and welcomed the Commission's report. It requested the Director-General of WHO to work with Member States to adopt measures focusing on the key recommendations.

<sup>&</sup>lt;sup>1</sup> High-Level Commission on Health Employment and Economic Growth. Working for health and growth: Investing in the health workforce. Geneva: World Health Organization; 2016 (http://www.who.int/hrh/com-heeg/reports, accessed 5 April 2017).

<sup>&</sup>lt;sup>2</sup> Available at: http://www.who.int/hrh/resources/pub\_globstrathrh-2030/en/ (accessed 5 April 2017).

<sup>&</sup>lt;sup>3</sup> Resolution WHA69.19 (2016).

3. The Commission identifies the health and social sectors<sup>1</sup> as a major and growing source of employment, and as strategic areas for investment that translate into more decent work opportunities than most other industries and sectors, particularly for women and young people.<sup>2</sup> As populations grow and change, it is estimated that the demand for health workers will almost double by 2030 with the expected creation of around 40 million new health worker jobs, primarily in upper-middle and high-income countries.<sup>3</sup> Each health and social worker job is supported on average by at least two additional jobs in other occupations in the broader health economy, offering the potential for job creation in and beyond the health and social sectors. Few economic sectors present opportunities for steady growth in decent work, especially in light of large potential job losses in other economic sectors due to rapid technological advances and the changing organization of production and work.<sup>4</sup>

4. However, the projected growth in jobs takes place alongside the potential shortfall of 18 million health workers if universal health coverage is to be achieved and sustained by 2030, primarily in lowand middle-income countries as envisaged in WHO's global strategy on human resources for health. Without targeted interventions, the situation in resource-constrained settings could be further exacerbated by increased labour mobility towards countries with the greatest demands, thereby undermining already vulnerable health systems. Investing in the quality of jobs in terms of working conditions, labour protection and rights at work is the key to retaining health workers where they are needed.

5. The Commission called for immediate, bold and game-changing interventions to challenge the status quo and alter the projected trends in the health and social workforce. Achieving a sustainable health and social workforce is an intersectoral pursuit that requires coordinated leadership and action across the sectors of government responsible for finance, labour, education, health, social affairs and foreign affairs, as well as close collaboration with employers' and health workers' organizations, professional associations and other key stakeholders. Ten recommendations and five immediate actions (Table 1) are proposed in the pursuit of the Sustainable Development Goals.

<sup>&</sup>lt;sup>1</sup> Note that the five-year action plan includes all occupations that contribute towards improved health and well-being in the health and health-related social care sectors, and thus refers to the health and social workforce engaged in health care in all its deliverables.

<sup>&</sup>lt;sup>2</sup> Investing in the care economy: a gender analysis of employment stimulus in seven OECD countries, March 2016. Brussels: International Trade Union Confederation; 2016 (http://www.ituc-csi.org/CareJobs, accessed 5 September 2016).

<sup>&</sup>lt;sup>3</sup> Liua JX, Goryakin Y, Maeda A, Bruckner TA, Scheffler RM. Global health workforce labor market projections for 2030. Policy Research Working Paper. Report number WPS7790. Washington, DC: World Bank; 2016 (http://documents.worldbank.org/curated/en/546161470834083341/Global-health-workforce-labor-market-projections-for-2030, accessed 5 April 2017).

<sup>&</sup>lt;sup>4</sup> See Report of the ILO's Director-General: The future of work centenary initiative. Conference paper. 104<sup>th</sup> International Labour Conference, 2015 (http://www.ilo.org/ilc/ILCSessions/104/reports/reports-to-theconference/WCMS\_369026/lang--en/index.htm, accessed 5 April 2017) and The Learning Generation: Investing in Education for a Changing World. International Commission on Financing Global Education Opportunity. September 2016. (http://report.educationcommission.org/wp-content/uploads/2016/09/Learning\_Generation\_Full\_Report.pdf, accessed 30 November 2016).

# Table 1. Recommendations and immediate actions from the High-Level Commission on Health Employment and Economic Growth

| Reco                              | mmendations   | Immediate actions by<br>March 2018   |
|-----------------------------------|---|--|
|                                   | 1. Stimulate investments in creating decent health sector jobs, particularly for women and youth, with the right skills, in the right numbers and in the right places.  | A. Secure commitments, foster<br>intersectoral engagement and<br>develop an action plan                        |
|                                   | 2. Maximize women's economic participation and foster their<br>empowerment through institutionalizing their leadership,<br>addressing gender biases and inequities in education and the health  | <ul><li>B. Galvanize accountability, commitment and advocacy</li><li>C. Advance health labour market</li></ul> |
| force                             | labour market, and tackling gender concerns in health reform processes.   | data, analysis and tracking in all countries   |
| alth work                         | 3. Scale up transformative, high-quality education and life-long learning so that all health workers have skills that match the health needs of populations and can work to their full potential.   | D. Accelerate investment in transformative education, skills and job creation                                  |
| Transforming the health workforce | 4. Reform service models concentrated on hospital care and focus instead on prevention and on the efficient provision of high-quality, affordable, integrated, community-based, people-centred primary and ambulatory care, paying special attention to underserved areas.  | E. Establish an international platform on health worker mobility   |
| Transforn                         | 5. Harness the power of cost-effective information and communication technologies to enhance health education, people-centred health services and health information systems.   |  |
|                                   | 6. Ensure investment in the International Health Regulations (2005) core capacities, including skills development of national and international health workers in humanitarian settings and public health emergencies, both acute and protracted. Ensure the protection and security of all health workers and health facilities in all settings.     |  |
|                                   | 7. Raise adequate funding from domestic and international sources, public and private where appropriate, and consider broad-based health financing reform where needed, to invest in the right skills, decent working conditions and an appropriate number of health workers.   |  |
| Enabling change                   | 8. Promote intersectoral collaboration at national, regional and<br>international levels; engage civil society, unions and other health<br>workers' organizations and the private sector; and align<br>international cooperation to support investments in the health<br>workforce, as part of national health and education strategies and<br>plans. |  |
| Enŝ                               | 9. Advance international recognition of health workers' qualifications to optimize skills use, increase the benefits from and reduce the negative effects of health worker migration, and safeguard migrants' rights.   |  |
|                                   | 10. Undertake robust research and analysis of health labour markets, using harmonized metrics and methodologies, to strengthen evidence, accountability and action.   |  |

6. There is no one path to effective implementation of the Commission's recommendations and immediate actions. To be effective, the implementation of the Commission's recommendations must be driven by Member States and be aligned and integrated with national and regional priorities and

related agendas on health, social protection, employment and economic growth across sectors. Policies and action must be implemented through continuous social dialogue with representatives of employers and health and social workers. Current and future trends and needs must be anticipated and taken into account to ensure equity and inclusivity, such as demographic and epidemiological changes, migration flows, climate change, inequities in access to health services, technological advancements and socioeconomic transitions. Investments must be coupled with a transformative agenda and the right policies to ensure that they result in achieving the right skills for the right jobs, in the right places.

7. ILO, OECD and WHO organized the High-Level Ministerial Meeting on Health Employment and Economic Growth (Geneva, 14 and 15 December 2016) and presented for a first round of consultation a draft plan for how the three agencies can support their Member States in translating the recommendations of the Commission into action. WHO's Executive Board at its 140th session in January 2017 in turn requested the Director-General in decision EB140(3) to finalize the five-year action plan in time for the Seventieth World Health Assembly in May 2017 – in collaboration with ILO, OECD and relevant regional and specialized entities and in consultation with Member States.

8. Two rounds of open consultation have informed the development of this action plan, with more than 60 contributions both before (25 October–11 November 2016) and after (15 December 2016–17 February 2017) the High-Level Ministerial Meeting on Health Employment and Economic Growth. The draft action plan was also discussed with more than 80 representatives of permanent missions to the United Nations in Geneva through an information session on 9 February 2017. The contributions highlight the breadth of Member States and stakeholders across sectors that are actively working towards adopting and implementing the Commission's recommendations at national, regional and international levels.

#### **Objectives of the five-year action plan**

9. The five-year action plan is a joint intersectoral programme of work across ILO, OECD and WHO that is critical to supporting Member States in the effective implementation of the Commission's recommendations in line with WHO's global strategy on human resources for health. With the aim of supporting and facilitating country-driven implementation, it sets out how the three agencies will work with Member States and key stakeholders as they translate the Commission's recommendations into action in line with national, regional and global plans and strategies. As such, the action plan is a good example of the type of collaborative partnerships between international agencies that are needed to support Member States in realizing the 2030 Agenda.

10. The action plan does not prescribe the actions of Member States or key stakeholders required to implement the Commission's recommendations. Rather, it sets out the deliverables that ILO, OECD and WHO will generate in order to respond to the expected demands and requests of Member States, employers' and workers' organizations and other key stakeholders. Where applicable and requested by Member States, the organizations could engage in technical cooperation, convening and coordination, capacity development, research, facilitating investments and financing, and normative guidance.

11. The specific objectives of the five-year action plan are to:

(a) facilitate Member States' implementation of intersectoral, collaborative and integrated approaches and country-driven action that advance the Commission's recommendations and immediate actions in line with WHO's global strategy on human resources for health; and

(b) catalyse and stimulate predictable and sustainable investments, institutional capacity-building, and transformative policy action and practice in the health and social

workforce, with special consideration to priority countries where universal health coverage and the Commission's recommendations are least likely to be attained.<sup>1</sup>

#### Approach

12. The leadership and stewardship roles of Member States and other key stakeholders are critical to implementation of the Commission's recommendations in line with WHO's global strategy on human resources for health and guided by resolution WHA69.19 (2016) adopting that strategy and the United Nations General Assembly's resolution 71/159 (2016) on Global health and foreign policy: health employment and economic growth. All stakeholders have a critical role to play and must work together across sectors of education, health, labour, finance and foreign affairs to invest in and transform current health workforce models to be sustainable and fit-for-purpose.

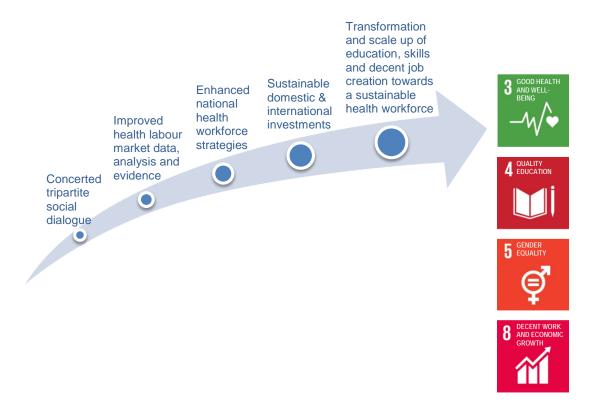
13. Country ownership, all-of-government approaches, social dialogue and outreach to other partners are essential foundations for the implementation of the Commission's recommendations. With this action plan ILO, OECD and WHO, together with other partners and global initiatives working on relevant goals of the 2030 Agenda (for example, for quality education, youth employment, gender equality, and sustainable business) can support and facilitate country-driven action.

14. By joining forces ILO, OECD and WHO will be better able to work with Member States in the formulation of comprehensive, intersectoral and integrated national health workforce strategies. Using their convening power and drawing on their data and analytical work, the three organizations can facilitate concerted tripartite social dialogue<sup>2</sup> and improved health labour market data and evidence, which are critical to the formulation of a new generation of national health workforce strategies and the mobilization of domestic and international resources to implement these (Figure 1). Investments coupled with the transformation and expansion of education, skills and decent job creation will contribute towards a sustainable health workforce and, in doing so, achieve socioeconomic dividends across Goals 3, 4, 5 and 8.

<sup>&</sup>lt;sup>1</sup> Priority countries were defined by the Commission's report as countries where universal health coverage and the Commission's recommendations are least likely to be attained. Criteria will be developed by the organizations which could be used by Member States to determine eligibility to access enhanced, targeted support.

<sup>&</sup>lt;sup>2</sup> Social dialogue includes all types of negotiation, consultation or simply exchange of information between, or among, representatives of governments, employers and workers, on issues of common interest relating to economic and social policy.





15. The five-year action plan demonstrates how ILO, OECD and WHO will respond to each recommendation with a number of deliverables at the national, regional and global levels that will support Member States in translating these recommendations into action, and also realize related goals of WHO's global strategy on human resources for health and the global strategic directions for strengthening nursing and midwifery.<sup>1</sup> The deliverables will be organized through five workstreams that respond to the available global strategies and recommendations, with priorities set for each year through operational planning processes (Table 2).

| Table 2. Workstreams mapped to global strategies and recommendations |
|--|
|--|

| Workstreams   | Commission's<br>recommendations<br>and immediate<br>actions | WHO's<br>global<br>strategy's<br>objectives | Strategic<br>directions for<br>strengthening<br>nursing and<br>midwifery<br>thematic areas |
|---|---|---|--|
| 1. Advocacy, social dialogue and policy dialogue.<br>Galvanizing political support and momentum and<br>building intersectoral commitment at the global, regional<br>and national levels, and strengthening social dialogue<br>and policy dialogue for investments and action. | 1–10, A, B  | 1, 2, 3, 4                                  | 2, 4   |

<sup>&</sup>lt;sup>1</sup> WHO. Global strategic directions for strengthening nursing and midwifery 2016–2020. Geneva: World Health Organization; 2016 (http://www.who.int/hrh/nursing\_midwifery/global-strategy-midwifery-2016-2020/en/, accessed 5 April 2017).

| Workstreams   | Commission's<br>recommendations<br>and immediate<br>actions | WHO's<br>global<br>strategy's<br>objectives | Strategic<br>directions for<br>strengthening<br>nursing and<br>midwifery<br>thematic areas |
|---|---|---|--|
| 2. Data, evidence and accountability. Strengthening data and evidence through implementation of the national health workforce accounts and the Global Health Labour Market Data Exchange; enhancing accountability through monitoring, review and action; and strengthening knowledge management. | 10, C   | 3, 4  | 1, 2   |
| 3. Education, skills and jobs. Accelerating the implementation of intersectoral national health workforce strategies designed to achieve a sustainable health workforce.  | 1–6, D  | 1, 2, 3                                     | 1, 3   |
| 4. <b>Financing and investments.</b> Supporting Member<br>States in catalysing sustainable financing for increased<br>investments in health and social workforces through<br>financing reforms and increased domestic and<br>international resources.   | 7, D  | 1, 2, 3                                     | 4  |
| 5. <b>International labour mobility.</b> Facilitating policy dialogue, analysis and institutional capacity-building to maximize mutual benefits from international labour mobility.   | 9, E  | 1–4   |  |

16. Activities integral to each workstream include: analysis and research, advice on norms and international labour standards, technical cooperation, coordination, knowledge management, institutional capacity-building and catalytic resource mobilization. Operational plans will be produced including programmatic details on: the activities towards achieving implementation of deliverables; targets; timeframes; qualitative and quantitative metrics for monitoring and evaluation; the specific roles of each agency; collaboration with stakeholders; and resource requirements at national, regional and international levels.

17. There are important interconnections between the workstreams that will be factored into the technical design and operational planning. For example, stimulating investments in creating decent health sector jobs must be connected to efforts to transform and expand education and life-long learning, take into account reforms in service delivery, and be appropriately financed.

#### 1. Key principles

18. The implementation of the five-year action plan will follow the key principles of:

(a) supporting the achievement of the 2030 Agenda for Sustainable Development;

(b) being guided by United Nations General Assembly resolutions, World Health Assembly resolutions, normative frameworks and instruments, and International Labour Standards;

(c) being country-led and driven, with the agencies working in close consultation with governments, employers and workers' organizations as well as other key partners at the country, regional and global levels;

(d) focusing on making an impact and achieving tangible results at the country level and in key sectors;

(e) combining immediate action and longer-term strengthening of laws, policies and institutions;

(f) making full use of institutional mandates, strengths and value-added activities across three agencies without duplication; including utilizing existing initiatives, knowledge platforms, networks and lessons learned, particularly those related to education and skills, gender equality, youth employment and decent work, health emergencies amongst others; and

(g) harnessing and building on credible data and analysis to monitor progress and impact at the national, regional and global levels.

#### 2. Key cross-cutting considerations

19. Key cross-cutting considerations that underpin the five-year action plan and approach include the following:

(a) **Labour market approach.** A labour market approach will be applied in health and social workforce analysis, action and investments, taking full consideration of the dynamics and drivers across sectors (Figure 2). This approach includes analysis of the education sector, pre-service education systems, available workforce pool (for example, demographics, skills and distribution), life-long learning systems (for example, continuing professional development and continuing education), employment, and workforce investments against current and future population health and social care needs. A suite of appropriate policies, reforms, regulatory frameworks and incentives may be required to address labour market and public failures identified through labour market analysis.

(b) **Coherence and coordinated action across sectors.** Coordinated intersectoral analysis, action and investments across education, health, social, labour, finance, and foreign affairs sectors are critical to effective progress. Policy coherence and alignment across sectors are also essential.

(c) **Decent work.** Health and social workforce investments and interventions must strive towards ensuring decent work for all available and future jobs across the health economy. Attention must be paid to improving working conditions, job security and occupational health and safety as well as the effective recognition and application of labour rights.

(d) **Gender equality.** Gender equality will be mainstreamed as a cross-cutting goal in gender-transformative investments and actions for the health and social workforces. Gender inequalities must be analysed and redressed; an example is women's provision of unpaid care in the absence of social protection and skilled care workers. Women should be appropriately represented in social dialogue mechanisms. Sex-disaggregated data should be strengthened and used; and gender analysis should be undertaken as an integral part of labour market analysis. National health workforce strategies, policies and investments that address identified gender biases and inequalities should be developed and strengthened, including gender-sensitive considerations regarding women's security, working conditions and mobility.

(e) **Youth empowerment.** Opportunities to improve the quality of education, education opportunities, human capital, decent work and career pathways for youth will be maximized. Young people and people from vulnerable and disadvantaged communities, including indigenous communities should be empowered.

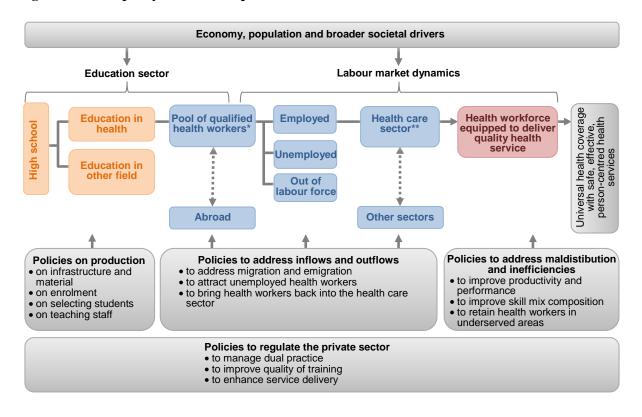
(f) **Social dialogue.** Social dialogue between governments, employers and workers as well as other relevant health sector stakeholders will be strengthened as a fundamental process in health and social workforce policy development. Social dialogue facilitates consensus building and contributes positively to health sector reforms and is particularly important in times of structural change.

(g) **Needs-based, fit-for-purpose health and social workforce.** Health and social workforce investments and actions must respond to the current and future needs of populations not only for universal health coverage, but also global health security. Policies should take into account demographic changes, technological changes, inequities in access to health and social services, and socioeconomic transitions. The workforce should be geared towards the social determinants of health, health promotion, disease prevention, primary care and people-centred, integrated, community-based services (including all types of health and social sector workforce). Coherent public action with partnerships with a range of stakeholders is urgently required to develop labour market policies conducive to stimulating demand for a sustainable health workforce, particularly in underserved areas.

(h) **Maximize available opportunities and reinforce linkages with existing initiatives.** Existing opportunities and mechanisms across agencies will be utilized to the greatest extent possible through available projects, collaborations and initiatives, and strengthening international, South–South and triangular cooperation to streamline efforts towards the implementation of the five-year action plan.

(i) **Sustainability.** Reforms and improved use and management of existing financing opportunities will be advocated and supported. Sustainable financing strategies for health workforce investments must be expanded, including general budget, progressive taxation, social health insurance, earmarked funds, and the private sector.

(j) **Public health and protracted emergencies, and humanitarian settings.** Special consideration should also be given to the specificities of the health labour market and challenges in the education and training of health workers, decent work, and the protection and security of health workers in public health, protracted emergencies and humanitarian settings.



#### Figure 2. Public policy levers to shape health labour markets

\* Supply of qualified health and social workforce willing to work

\*\* Demand for health and social workforce in the health and health-related social care sectors

#### Coordinating implementation of the five-year action plan

20. ILO, OECD and WHO will oversee and coordinate the implementation of the five-year action plan (Table 3) through regular decision-making meetings at the senior management level; a Steering Committee of the three organizations is being established for that purpose. Working under the direction of the Steering Committee, a joint Technical Secretariat will be responsible for developing annual operational plans, ensuring effective implementation, communications and knowledge management, stakeholder management, consultative processes, monitoring and evaluation, and reporting. Expertise across the three organizations will be organized into the five workstreams to design and implement the technical strategy required to implement the action plan at national, regional and global levels. A high-level Advisory Committee will provide strategic input and political support.

21. Effective implementation of the five-year action plan will require intersectoral and multistakeholder engagement and collaboration. Regular consultative processes with Member States and key stakeholders will be embedded into the implementation process of the five-year action plan to facilitate input and technical exchange. ILO, OECD and WHO will explore engagement with key stakeholders across sectors at global, regional and national levels as an integral part of conducting their work and drawing on available institutional capacities to derive added value in implementing the action plan in the most effective and efficient way. A website will be established as an online knowledge platform to strengthen intersectoral knowledge management, coordination, analysis, and dissemination of evidence and best practice to inform intersectoral plans, actions and investments.

22. The Global Health Workforce Network,<sup>1</sup> coordinated by WHO at the request of Member States, will serve as a mechanism across all workstreams to engage other United Nations agencies, organizations and stakeholders across sectors in the implementation process of the five-year action plan at national, regional and global levels.

23. With the exception of a limited number of deliverables which can be achieved through existing programmes with available institutional resources, additional resources will be required by ILO, OECD and WHO to achieve the deliverables articulated in this action plan.

#### Monitoring, evaluation and reporting

24. As described in the Commission's report, success will be measurable by the extent to which progress is achieved on the relevant targets and indicators for Sustainable Development Goals 3, 4, 5 and 8. Process metrics including qualitative and quantitative measures will be developed as part of annual operational plans for regular monitoring, evaluation and reporting.

25. The first report on the operationalization of the immediate actions and the five-year action plan will be submitted in September 2017 for consideration by the United Nations General Assembly at its seventy-second session, as requested in its resolution 71/159. Annual progress reports, with formal reporting on performance against the five-year action plan, will be submitted to the Health Assembly, aligned with reporting on the implementation of WHO's global strategy on human resources for health.

| Cross-cutting<br>immediate actions | Deliverables  | Lead <sup>a</sup>    | Partner |
|------------------------------------|---|----------------------|---------|
| (2017–March 2018)                  | 1. Commitments and expressions of support by the governing bodies of ILO, OECD, WHO, partner organizations and international decision-making forums secured.  | ILO,<br>OECD,<br>WHO |         |
|                                    | 2. Recommendations of the Commission adopted in regional and national forums.   | ILO,<br>OECD,<br>WHO |         |
|                                    | 3. Conclusions of the ILO Tripartite Sectoral Meeting on<br>Improving Employment and Working Conditions in Health<br>Services (Geneva, 24–28 April 2017) and the 4th Global Forum<br>on Human Resources for Health (Dublin, 13–17 November 2017)<br>support implementation of the Commission's recommendations in<br>line with WHO's global strategy on human resources for health. | ILO,<br>WHO          | OECD    |
|                                    | 4. An online knowledge platform established to strengthen<br>intersectoral knowledge management, coordination, analysis, and<br>dissemination of evidence and best practice to inform health and<br>social workforce plans, actions and investments.  | ILO,<br>OECD,<br>WHO |         |

#### Table 3. Five-year action plan deliverables<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> See http://www.who.int/hrh/network/en/ (accessed 11 April 2017).

<sup>&</sup>lt;sup>2</sup> Supporting documents from the consultation exercises and frequently asked questions are available on the WHO website at: http://who.int/hrh/com-heeg/action-plan-annexes/en/.

| Recommendations   | Deliverables   | Lead <sup>a</sup>    | Partner      |
|---|--|----------------------|--------------|
| 1. Stimulate<br>investments in<br>creating decent<br>health sector jobs,  | 1.1 Capacity of governments, employers' associations and trade<br>unions and other key stakeholders in the health and social sectors<br>strengthened to establish dialogue mechanisms and engage in<br>social dialogue processes.  | ILO                  |              |
| particularly for<br>women and youth,<br>with the right skills,<br>in the right numbers<br>and in the right  | 1.2 Development of international, regional and national tripartite dialogue across health, education, finance and labour sectors supported as a step towards strengthening or producing national health workforce strategies.  | ILO                  | OECD,<br>WHO |
| places.   | 1.3 Labour market, gender and fiscal space analysis supported<br>and institutional capacity strengthened for the development of<br>policy options to inform national health workforce strategies,<br>financing reforms and investments.  | WHO                  | ILO,<br>OECD |
|   | 1.4 Development and implementation of national health<br>workforce strategies, medium-term fiscal frameworks and<br>investments supported with technical assistance and institutional<br>capacity-building to ensure decent work, gender-transformative<br>approaches, and current and future sustainable health workforce.  | WHO                  | ILO,<br>OECD |
|   | 1.5 Alignment of domestic resources and official development assistance with national health workforce strategies and investments facilitated.   | WHO                  |              |
| 2. Maximize<br>women's economic<br>participation and<br>foster their<br>empowerment<br>through<br>institutionalizing<br>their leadership,<br>addressing gender<br>biases and inequities<br>in education and the | 2.1 Gender-transformative <sup>1</sup> global policy guidance developed<br>and regional and national initiatives accelerated to analyse and<br>overcome gender biases and inequalities in education and the<br>health labour market across the health and social workforce (for<br>example, increasing opportunities for formal education,<br>transforming unpaid care and informal work into decent jobs,<br>equal pay for work of equal value, decent working conditions and<br>occupational safety and health, promoting employment free from<br>harassment, discrimination and violence, equal representation in<br>management and leadership positions, social protection/child<br>care, and elderly care). | ILO,<br>OECD,<br>WHO |              |
| health labour<br>market, and<br>tackling gender<br>concerns in health<br>reform processes.  | 2.2 Gender-transformative policy development and implementation capacity to overcome gender biases and inequalities in education and the health labour market supported.   | ILO,<br>WHO          |              |

<sup>&</sup>lt;sup>1</sup> Gender-transformative approaches seek to re-define women's and men's gender roles and relations to promote gender equality and achieve positive development outcomes by transforming unequal gender relations in order to promote shared power, control of resources, decision-making, and support for women's empowerment.

| Recommendations  | Deliverables  | Lead <sup>a</sup> | Partner      |
|--|---|-------------------|--------------|
| 3. Scale up<br>transformative,<br>high-quality   | 3.1 Transform and expand education and lifelong learning and intersectoral coordination integrated in the development and implementation of health workforce strategies.  | WHO               | ILO,<br>OECD |
| education and<br>life-long learning so<br>that all health<br>workers have skills<br>that match the   | 3.2 Massive scale-up of socially accountable and transformative professional, technical and vocational education and training supported with technical cooperation, institutional capacity-building and financing.  | WHO               | ILO          |
| health needs of<br>populations and can<br>work to their full<br>potential.   | 3.3 Professional, technical and vocational education, training<br>and lifelong learning systems strengthened for health and social<br>occupations (including community-based health workers) to<br>achieve integrated people-centred care.  | WHO               | ILO,<br>OECD |
|  | 3.4 Develop skills assessment tools and approaches to evaluate<br>the skills of the health and social workforce, including assessment<br>of skills mix, shortages and mismatches to support greater<br>alignment of skills with jobs and integrated people-centred care.  | OECD              | ILO,<br>WHO  |
| 4. Reform service<br>models concentrated<br>on hospital care and<br>focus instead on<br>prevention and on  | 4.1 Governance, regulation, accreditation and quality-<br>improvement mechanisms improved and supported with guidance<br>and institutional capacity-building to ensure safe, ethical,<br>effective and people-centred practice that protects the public's<br>interests and rights.  | WHO,<br>ILO       |              |
| the efficient<br>provision of<br>high-quality,<br>affordable,<br>integrated,   | 4.2 Guidance developed for provision of interprofessional education and organization of multidisciplinary care, including recommendations on skills mix and competencies to achieve integrated people-centred care.   | WHO               | OECD         |
| community-based,<br>people-centred<br>primary and<br>ambulatory care,<br>paying special<br>attention to<br>underserved areas.  | 4.3 Evidence and guidance developed on practices to ensure an adequate proportion of the workforce in primary health care appropriately distributed to achieve equitable access in underserved areas and for marginalized groups (for example, recruitment practices, education methods, professional development opportunities, and incentive structures). | ILO,<br>WHO       | OECD         |
| 5. Harness the<br>power of<br>cost-effective<br>information and<br>communication<br>technologies to<br>enhance health<br>education,<br>people-centred<br>health services and<br>health information<br>systems. | 5.1 Efficacy and efficiency of information and communication<br>tools with a target product profile that could enhance health<br>worker education, people-centred health services and health<br>information systems mapped, reviewed and disseminated for<br>national adoption.   | WHO               |              |
| 6. Ensure<br>investment in the<br>International Health<br>Regulations (2005)   | 6.1 Workforce strategies for full implementation of the<br>International Health Regulations (2005), emergency and disaster<br>risk management and response capacity integrated into national<br>health workforce and emergency strategies and supported.  | WHO               | ILO          |
| core capacities,<br>including skills<br>development of<br>national and   | 6.2 Evidence and guidance on metrics, methodologies, practices, reporting and information systems that improve the security and protection of health workers in all settings strengthened, including humanitarian and emergency settings.   | WHO               |              |

| Recommendations  | Deliverables   | Lead <sup>a</sup> | Partner      |
|--|--|-------------------|--------------|
| international health<br>workers in<br>humanitarian<br>settings and public<br>health emergencies,<br>both acute and<br>protracted. Ensure<br>the protection and<br>security of all health<br>workers and health<br>facilities in all<br>settings. | 6.3 Capacities of high-risk countries to protect occupational<br>health and safety of health and emergency aid workers<br>strengthened.  | WHO               | ILO          |
| 7. Raise adequate<br>funding from<br>domestic and<br>international   | 7.1 National health workforce strategies and global, regional and national institutional financing reforms that identify and commit adequate budgetary resources for investments in transformative education, skills and job creation developed and supported.   | WHO               | ILO          |
| sources, public and<br>private where<br>appropriate, and<br>consider<br>broad-based health   | 7.2 Sustainable financing for expanding and transforming the health and social workforce expanded, particularly for countries where universal health coverage and the Commission's recommendations are least likely to be attained.  | WHO               | ILO          |
| broad-based health<br>financing reform<br>where needed, to<br>invest in the right<br>skills, decent  | 7.3 Mechanisms to track the alignment of official development<br>assistance for education, employment, gender, health and skills<br>development with national health workforce strategies<br>strengthened.   | WHO               | OECD         |
| working conditions<br>and an appropriate<br>number of health<br>workers.   | 7.4 Tools and methodologies to analyse health and social workforce productivity, performance and wages reviewed and advanced.  | WHO               | ILO,<br>OECD |
| 8. Promote<br>intersectoral<br>collaboration at<br>national, regional<br>and international   | 8.1 The Global Health Workforce Network engaged to support<br>coordination, alignment and accountability for WHO's global<br>strategy on human resources for health and implementation of the<br>Commission's recommendations with international, regional and<br>national stakeholders.   | WHO               | ILO,<br>OECD |
| levels; engage civil<br>society, unions and<br>other health<br>workers'<br>organizations and<br>the private sector;<br>and align<br>international<br>cooperation to  | 8.2 Intersectoral collaboration and coordination for the implementation of national health workforce strategies strengthened and capacity developed among relevant ministries (for instance, health, social, labour, education, finance, and gender), professional associations, labour unions, civil society including women's civil society organizations, employers, the private sector, local government authorities, education and training providers and other constituencies. | ILO,<br>WHO       |              |
| support investments<br>in the health<br>workforce, as part<br>of national health<br>and education<br>strategies and plans.   | 8.3 Global health initiatives ensure that all grants and loans<br>include an assessment of health workforce implications and align<br>contributions with implementation of national health workforce<br>strategies beyond disease-specific in-service training and<br>incentives.  | WHO               |              |

| Recommendations  | Deliverables   | Lead <sup>a</sup>    | Partner      |
|--|--|----------------------|--------------|
| 9. Advance<br>international<br>recognition of health<br>workers'<br>qualifications to<br>optimize skills use,<br>increase the benefits<br>from and reduce the<br>negative effects of<br>health worker<br>migration, and<br>safeguard migrants' | <ul> <li>9.1 Platform established to maximize benefits from international health worker mobility through: <ul> <li>(a) improved monitoring of labour mobility; building on the success of the OECD/WHO EURO/Eurostat collaborative work and with a progressive international scale-up and implementation of the National Health Workforce Accounts;</li> <li>(b) strengthened evidence analysis, knowledge exchange and global public goods on mobility, recognition of qualifications, remittances, resource transfers, good practices and policies.</li> </ul> </li> </ul> | ILO,<br>OECD,<br>WHO |              |
| rights.  | 9.2 Existing instruments, such as the WHO Global Code of<br>Practice on the International Recruitment of Health Personnel and<br>ILO Conventions on Migrant Workers, strengthened and<br>implementation supported; and policy dialogue facilitated for new<br>innovations and voluntary commitments that maximize mutual<br>benefits informed by lessons from other international instruments.   | ILO,<br>OECD,<br>WHO |              |
|  | 9.3 Management of health worker migration improved to ensure mutuality of benefits through institutional capacity-building to governments, employers, workers and other relevant stakeholders in countries of both source and destination.   | ILO,<br>WHO          | OECD         |
| 10. Undertake robust research and  | 10.1 Health workforce monitoring, financing and accountability reports produced.   | WHO                  | ILO,<br>OECD |
| analysis of health<br>labour markets,<br>using harmonized<br>metrics and   | 10.2 Implementation of national health workforce accounts and disaggregated reporting supported and institutional capacity for implementation strengthened.  | WHO                  | ILO,<br>OECD |
| methodologies, to<br>strengthen evidence,<br>accountability and  | 10.3 An interagency global data exchange on the health labour market with harmonized metrics and definitions established and maintained.   | WHO                  | ILO,<br>OECD |
| action.  | 10.4 A health workforce research agenda established, research<br>methodologies advanced, and evidence base expanded for decent<br>work and effective health labour market interventions that<br>optimize the socioeconomic returns on health workforce<br>investments.   | WHO                  | ILO,<br>OECD |

<sup>a</sup> The agency or agencies designated as the lead in the action plan will hold or share responsibility for leading the coordination and implementation of the deliverable. The agency or agencies designated as partners will take a supportive role in contributing specific inputs towards the deliverable.

## ANNEX 3

## Preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018<sup>1</sup>

[A70/27, Annexes 1 and 3 – 18 May 2017]

#### UPDATED APPENDIX 3 TO THE GLOBAL ACTION PLAN FOR THE PREVENTION AND CONTROL OF NONCOMMUNICABLE DISEASES 2013–2020

#### What is Appendix 3?

1. Appendix 3 is a part of the global action plan for the prevention and control of noncommunicable diseases 2013–2020.<sup>2</sup> It consists of a menu of policy options and cost-effective interventions to assist Member States in implementing, as appropriate for national context (without prejudice to the sovereign rights of nations to determine taxation among other policies), actions to achieve the nine voluntary global targets for the prevention and control of noncommunicable diseases. They are presented under the six objectives of the global action plan. The list of interventions is not exhaustive but is intended to provide information and guidance on the effectiveness and cost-effectiveness of population-based and individual interventions based on current evidence, and to serve as the basis for future work to develop and expand the evidence base. Countries are implementing the global action plan, as appropriate for the national context, and Appendix 3 has been used in the development and prioritization of national action plans.

#### Why update Appendix 3?

2. Appendix 3 has been updated at the request of Member States, to take into consideration the new evidence that has emerged of cost-effectiveness and the new WHO recommendations that have been issued since the adoption of the global action plan in 2013; and also to refine the existing formulation of some interventions based on lessons learned from the use of the first version. The global action plan ends in 2020, and any future updates will be considered as part of the development of any subsequent global strategies for noncommunicable diseases.

#### What has changed?

3. The menu of options listed for objectives 1 (raising the priority accorded to noncommunicable diseases), 2 (strengthening leadership and governance), 5 (research) and 6 (monitoring and evaluation) are process-related recommendations and have not changed. Within objectives 3 (risk factors) and 4 (health systems), in the updated Appendix 3, there are now a total of 86 interventions and overarching/enabling actions, representing an expansion from the original list of 62. This increase is

<sup>&</sup>lt;sup>1</sup> See resolution WHA70.11.

<sup>&</sup>lt;sup>2</sup> See document WHA66/2013/REC/1, Annex 4.

due to the greater availability of scientific evidence and to the need to disaggregate some previous interventions (such as "reduce salt intake") into more clearly defined and implementable actions.

4. As in the original Appendix 3, a select number of interventions, considered to be the most costeffective and feasible for implementation, are identified in bold text. In the updated Appendix 3, 16 interventions are listed in bold,<sup>1</sup> as compared to 14 in the original version, and the method for identifying such interventions has been modified.<sup>2</sup> Other interventions, for which cost-effectiveness analysis by the WHO's Choosing interventions that are cost-effective (WHO-CHOICE) project could be completed, are listed in descending order of cost-effectiveness.<sup>3</sup> Interventions that are mentioned in WHO's guidelines and technical documents where WHO-CHOICE analysis has not been able to be conducted are also listed. Care needs to be taken when interpreting these lists; for example, the absence of WHO-CHOICE analysis does not necessarily mean that an intervention is not costeffective, affordable or feasible – rather, there were methodological or capacity reasons for which the WHO-CHOICE analysis could not be completed. The economic analyses in the technical annex,<sup>4</sup> upon which this list is based, give an assessment of cost-effectiveness ratio, health impact and the economic cost of implementation. These economic results present a set of parameters for consideration by Member States, but it must be emphasized that such global analyses should be accompanied by analyses in the local context. Other WHO tools, such as the OneHealth Tool,<sup>5</sup> are available to help individual countries cost specific interventions in their national context.

#### The importance of non-financial considerations

5. Cost-effectiveness analysis is a useful tool but it has limitations and should not be used as the sole basis for decision-making. When selecting interventions for the prevention and control of noncommunicable diseases, consideration should be given to effectiveness, cost-effectiveness, affordability, implementation capacity, feasibility, according to national circumstances, and impact on health equity of interventions, and to the need to implement a combination of population-wide policy interventions and individual interventions.

6. Critical non-financial considerations that may affect the feasibility of certain interventions in some settings are set out in a new column in the updated Appendix 3. Many of the interventions for the prevention and control of noncommunicable diseases involve multisectoral benefits and costs that need to be taken into account, and examples of the multisectoral aspects of these interventions are outlined in Appendix 5 to the global action plan. It was not possible to provide an equity rating for each intervention, given the importance of context, but, in general, population-based interventions, including fiscal policies and environmental changes, show the most potential to reduce inequalities in

<sup>&</sup>lt;sup>1</sup> With an average cost-effectiveness ratio of  $\leq$ I\$ 100/disability-adjusted life-year averted in low and lower-middle income countries. The international dollar (I\$) is a hypothetical unit of currency that has the same purchasing power parity that the United States dollar had in the United States at a given point in time.

<sup>&</sup>lt;sup>2</sup> The listing of interventions in bold text in this updated Appendix 3 is based on economic analyses only. Critical non-financial considerations that may affect the feasibility of certain interventions in some settings are set out in a new column in the updated Appendix 3.

<sup>&</sup>lt;sup>3</sup> Based on cost-effectiveness ratio in low and middle income settings.

<sup>&</sup>lt;sup>4</sup> The draft technical annex is available in the WHO discussion paper dated 25 July 2016 on the draft updated Appendix 3, and information on the process to update the Appendix, are available at: http://who.int/ncds/governance/appendix3-update-discussion-paper/en/ (accessed 3 May 2017).

<sup>&</sup>lt;sup>5</sup> http://www.who.int/choice/onehealthtool/en/ (accessed 3 May 2017).

the prevention and control of noncommunicable diseases.<sup>1</sup> Individual interventions, especially those involving education and awareness campaigns, are most likely to widen inequalities and should be accompanied by measures to assess and address other barriers to behaviour change. For any intervention, the impact on health inequalities needs to be considered and evaluated, in order to ensure that policies are effective across all population groups.<sup>2</sup>

#### **Technical annex**

7. Based on feedback from experts and Member States, this updated Appendix 3 is accompanied by a technical annex.<sup>3</sup> The annex provides more detailed information about the methodology used to identify and analyse interventions, and presents the results of the economic analysis separately for low and lower-middle income, and upper-middle and high income countries. The Secretariat will explore options to provide an interactive web-tool, to enable users to compare and rank the information according to their own needs. The detailed description of the WHO-CHOICE methods for these analyses, including the assumptions, strength of evidence and the individual studies used to inform the development of models for each intervention, will be published separately as peer-reviewed scientific papers, which will be publicly available through open access.

|                              | Menu of policy options  | Critical non-financial<br>considerations <sup>a</sup> | WHO tools <sup>b</sup>   |
|------------------------------|---|---|--|
| OBJI                         | ECTIVE 1  |   |  |
| Overarching/enabling actions | <ul> <li>Raise public and political awareness,<br/>understanding and practice about prevention<br/>and control of NCDs</li> <li>Integrate NCDs into the social and<br/>development agenda and poverty alleviation<br/>strategies</li> <li>Strengthen international cooperation for<br/>resource mobilization, capacity-building,<br/>health workforce training and exchange of<br/>information on lessons learned and best<br/>practices</li> </ul> |   | <ul> <li>WHO global status<br/>report on NCDs 2014</li> <li>WHO fact sheets</li> <li>Noncommunicable<br/>diseases country<br/>profiles (2014)</li> <li>IARC GLOBOCAN<br/>2008</li> </ul> |
| Overal                       | • Engage and mobilize civil society and the private sector as appropriate and strengthen international cooperation to support implementation of the action plan at global, regional and national levels   |   |  |
|                              | • Implement other policy options in objective 1   |   |  |

<sup>&</sup>lt;sup>1</sup> See for example: http://www.euro.who.int/\_\_data/assets/pdf\_file/0003/247638/obesity-090514.pdf; http://www.euro.who.int/\_\_data/assets/pdf\_file/0005/247640/tobacco-090514.pdf?ua=1; and http://www.euro.who.int/\_\_data/assets/pdf\_file/0003/247629/Alcohol-and-Inequities.pdf (accessed 3 May 2017).

<sup>&</sup>lt;sup>2</sup> For example, accompanying tobacco price increases with smoking cessation support for the poor, and ensuring food product reformulation involves the entire product range and not just the more expensive options.

<sup>&</sup>lt;sup>3</sup> The draft technical annex is available in the WHO discussion paper dated 25 July 2016 on the draft updated Appendix 3, which is available at http://who.int/ncds/governance/appendix3-update/en/ (accessed 10 October 2016). It was updated after the 140th session of the Executive Board, before the Seventieth World Health Assembly.

|                              | Menu of policy options   | Critical non-financial considerations <sup>a</sup> | WHO tools <sup>b</sup>   |
|------------------------------|--|--|--|
| OBJ                          | ECTIVE 2   | -  | •  |
| Overarching/enabling actions | <ul> <li>Prioritize and increase, as needed, budgetary allocations for prevention and control of NCDs, without prejudice to the sovereign right of nations to determine taxation and other policies</li> <li>Assess national capacity for prevention and control of NCDs</li> <li>Develop and implement a national multisectoral policy and plan for the prevention and control of NCDs through multistakeholder engagement</li> <li>Implement other policy options in objective 2 to strengthen national capacity, leadership, governance, multisectoral action and partnerships for prevention and control of noncommunicable diseases</li> </ul>  |  | <ul> <li>United Nations<br/>Secretary-General's<br/>Note A/67/373</li> <li>NCD country capacity<br/>survey tool</li> <li>Online NCD MAP Tool<br/>for developing,<br/>implementing and<br/>monitoring national<br/>multisectoral action<br/>plans</li> </ul>  |
| OBJ                          | ECTIVE 3   |  |  |
| тов                          | ACCO USE   |  |  |
| Overarching/enabling actions | <ul> <li>For the Parties to the WHO Framework<br/>Convention on Tobacco Control<br/>(WHO FCTC):</li> <li>Strengthen the effective implementation of<br/>the WHO FCTC and its protocols</li> <li>Establish and operationalize national<br/>mechanisms for coordination of the<br/>WHO FCTC implementation as part of<br/>national strategy with specific mandate,<br/>responsibilities and resources</li> <li>For the Member States that are not Parties to<br/>the WHO FCTC:</li> <li>Consider implementing the measures set out<br/>in the WHO FCTC and its protocols, as the<br/>foundational instrument in global tobacco<br/>control</li> <li>Increase excise taxes and prices on</li> </ul> |  | <ul> <li>The WHO FCTC, its guidelines and its Protocol to Eliminate Illicit Trade in Tobacco Products</li> <li>MPOWER capacity-building modules to reduce demand for tobacco, in line with the WHO FCTC (2011–2014)</li> <li>MPOWER policy measures (2009)</li> <li>WHO reports on the global tobacco epidemic (2008, 2009, 2011, 2012, 2015)</li> <li>Assessing the national</li> </ul> |
|                              | tobacco products   |  | <ul> <li>capacity to implement<br/>effective tobacco<br/>control policies (2011)</li> <li>Technical resource for<br/>country implementation<br/>of the WHO Framework<br/>Convention on Tobacco<br/>Control Article 5.3<br/>(2012)</li> </ul>   |

|  | Menu of policy options  | Critical non-financial considerations <sup>a</sup> | WHO tools <sup>b</sup>  |
|--|---|--|---|
|  |   |  | <ul> <li>WHO tobacco tax<br/>simulation model<br/>(TaXSiM) (2014)</li> </ul>  |
|  |   |  | <ul> <li>WHO technical manual<br/>on tobacco tax<br/>administration (2010)</li> </ul>   |
|  |   |  | <ul> <li>IARC Handbook of<br/>Cancer Prevention/<br/>Volume 12 (2008),<br/>Volume 13 (2009),<br/>Volume 14 (2011)</li> </ul>        |
|  | • Implement plain/standardized packaging<br>and/or large graphic health warnings on<br>all tobacco packages   |  | <ul> <li>Plain packaging of<br/>tobacco products:<br/>evidence, design and<br/>implementation (2016)</li> </ul>                     |
| is available <sup>c</sup>                  | <ul> <li>Enact and enforce comprehensive bans on<br/>tobacco advertising, promotion and<br/>sponsorship</li> <li>Eliminate exposure to second-hand<br/>tobacco smoke in all indoor workplaces,</li> </ul> |  | <ul> <li>Banning tobacco<br/>advertising, promotion<br/>and sponsorship – What<br/>you need to know<br/>(2013)</li> </ul>           |
| WHO-CHOICE analysis available <sup>c</sup> | public places, public transport   |  | <ul> <li>Making your city<br/>smoke-free: brochure<br/>(2011) and workshop<br/>package (2013)</li> </ul>                            |
| ино-сн                                     |   |  | <ul> <li>Smoke-free movies:</li> <li>from evidence to action</li> <li>third edition (2016)</li> </ul>                               |
| Δ  |   |  | <ul> <li>Protect people from<br/>tobacco smoke: smoke-<br/>free environments<br/>(2011)</li> </ul>                                  |
|  |   |  | <ul> <li>A guide to tobacco-free<br/>mega events (2009)</li> </ul>  |
|  | <ul> <li>Implement effective mass media<br/>campaigns that educate the public about<br/>the harms of smoking/tobacco use and<br/>second hand smoke</li> <li>Dravide cost ecourd effective and</li> </ul>  |  | <ul> <li>Policy<br/>recommendations on<br/>protection from<br/>exposure to second-<br/>hand tobacco smoke</li> </ul>                |
|  | • Provide cost-covered, effective and<br>population-wide support (including brief<br>advice, national toll-free quit line services)<br>for tobacco cessation to all those who want<br>to quit             |  | <ul> <li>(2007)</li> <li>Strengthening health<br/>systems for treating<br/>tobacco dependence in<br/>primary care (2013)</li> </ul> |

|  | Menu of policy options  | Critical non-financial considerations <sup>a</sup>   | WHO tools <sup>b</sup>  |
|--|---|--|---|
| WHO-CHOICE analysis<br>not available       | <ul> <li>Implement measures to minimize illicit trade<br/>in tobacco products</li> <li>Ban cross-border advertising, including<br/>using modern means of communication</li> <li>Provide mcessation for tobacco cessation to<br/>all those who want to quit</li> </ul>   |  | <ul> <li>Training for tobacco<br/>quit line counsellors:<br/>telephone counselling<br/>(2014)</li> <li>Developing and<br/>improving national toll-<br/>free tobacco quit line<br/>services (2011)</li> <li>Confronting the<br/>tobacco epidemic in a<br/>new era of trade and<br/>investment<br/>liberalization (2012)</li> </ul> |
| HAR  | MFUL USE OF ALCOHOL   |  |   |
| <b>Overarching/enabling actions</b>        | <ul> <li>Implement the WHO global strategy to reduce harmful use of alcohol through multisectoral actions in the recommended target areas</li> <li>Strengthen leadership and increase commitment and capacity to address the harmful use of alcohol</li> <li>Increase awareness and strengthen the knowledge base on the magnitude and nature of problems caused by harmful use of alcohol by awareness programmes, operational research, improved monitoring and surveillance systems</li> </ul> |  | <ul> <li>Global strategy to<br/>reduce the harmful use<br/>of alcohol (2010)<br/>(WHA63.13)</li> <li>WHO global status<br/>report on alcohol and<br/>health (2014)</li> <li>WHO fact sheets and<br/>policy briefs on<br/>harmful use of alcohol</li> </ul>  |
| WHO-CHOICE analysis available <sup>c</sup> | <ul> <li>Increase excise taxes on alcoholic beverages</li> <li>Enact and enforce bans or comprehensive restrictions on exposure to alcohol advertising (across multiple types of media)</li> <li>Enact and enforce restrictions on the physical availability of retailed alcohol (via reduced hours of sale)</li> </ul>   | <ul> <li>Requires an effective system for tax administration and should be combined with efforts to prevent tax avoidance and tax evasion</li> <li>Requires capacity for implementing and enforcing regulations and legislation</li> <li>Formal controls on sale need to be complemented by</li> </ul> | <ul> <li>WHO implementation<br/>toolkit for the global<br/>strategy to reduce the<br/>harmful use of alcohol<br/>(2017)</li> <li>Resource book on<br/>alcohol taxation (2017)</li> </ul>  |

|  |  | Critical non-financial  |   |
|--|--|---|---|
|  | Menu of policy options   | considerations <sup>a</sup>   | WHO tools <sup>b</sup>  |
|  |  | actions addressing<br>illicit or informally<br>produced alcohol                                 |   |
| ailable <sup>c</sup>                       | • Enact and enforce drink-driving laws and blood alcohol concentration limits via sobriety checkpoints                                 | <ul> <li>Requires allocation of<br/>sufficient human<br/>resources and<br/>equipment</li> </ul> |   |
| WHO-CHOICE analysis available <sup>c</sup> | <ul> <li>Provide brief psychosocial intervention for<br/>persons with hazardous and harmful alcohol<br/>use</li> </ul>                 | <ul> <li>Requires trained<br/>providers at all levels<br/>of health care</li> </ul>             | <ul> <li>Manuals for the<br/>alcohol, smoking and<br/>substance involvement<br/>screening test<br/>(ASSIST) and the<br/>ASSIST-linked brief<br/>interventions (2011)</li> </ul> |
| WHO-C                                      |  |   | <ul> <li>Brief intervention for<br/>hazardous and harmful<br/>drinking: a manual for<br/>use in primary care<br/>(2001)</li> </ul>  |
|  | • Carry out regular reviews of prices in relation to level of inflation and income   |   |   |
| O-CHOICE analysis not available            | • Establish minimum prices for alcohol where applicable  |   | <ul> <li>WHO implementation<br/>toolkit for the global<br/>strategy to reduce the<br/>harmful use of alcohol<br/>(2017)</li> </ul>  |
| nalysis n                                  | • Enact and enforce an appropriate minimum age for purchase or consumption of alcoholic beverages and reduce density of retail outlets |   |   |
| HOICE a                                    | • Restrict or ban promotions of alcoholic beverages in connection with sponsorships and activities targeting young people              |   | <ul> <li>mhGAP intervention<br/>guide 2.0 (2016)</li> </ul>   |
| WHO-CI                                     | • Provide prevention, treatment and care for alcohol use disorders and comorbid conditions in health and social services               |   |   |
|  | • Provide consumer information about, and label, alcoholic beverages to indicate, the harm related to alcohol                          |   |   |
| UNH  | EALTHY DIET  |   |   |
| ing/<br>ctions                             | • Implement the global strategy on diet, physical activity and health  |   | <ul> <li>Global strategy on diet,<br/>physical activity and<br/>health (2004)</li> </ul>  |
| Overarching/<br>enabling actions           | • Implement the WHO recommendations on<br>the marketing of foods and non-alcoholic<br>beverages to children                            |   | <ul> <li>WHO Set of<br/>recommendations on the<br/>marketing of foods and<br/>non-alcoholic beverages<br/>to children (2010)</li> </ul>   |

|  | Menu of policy options   | Critical non-financial considerations <sup>a</sup>   | WHO tools <sup>b</sup>   |
|--|--|--|--|
|  |  |  | <ul> <li>Framework for<br/>implementing the set of<br/>recommendations on<br/>the marketing of foods<br/>and non-alcoholic<br/>beverages to children<br/>(2012)</li> </ul> |
|  | • Reduce salt intake through the reformulation of food products to contain less salt and the setting of target levels for the amount of salt in foods and meals  | <ul> <li>Requires multisectoral<br/>actions with relevant<br/>ministries and support<br/>by civil society</li> </ul> | <ul> <li>WHO nutrient profile<br/>model(s) for regulating<br/>marketing food and<br/>non-alcoholic<br/>beverages to children</li> </ul>                                    |
|  | • Reduce salt intake through the<br>establishment of a supportive<br>environment in public institutions such as<br>hospitals, schools, workplaces and nursing<br>homes, to enable lower sodium options to              |  | <ul> <li>Report of the<br/>Commission on Ending<br/>Childhood Obesity<br/>(2016)</li> </ul>  |
| 3  | <ul><li>be provided</li><li>Reduce salt intake through a behaviour</li></ul>   |  | <ul> <li>WHO e-Library of<br/>Evidence for Nutrition<br/>Actions (eLENA)</li> </ul>  |
| ailable                                    | change communication and mass media campaign   |  | <ul> <li>Fact sheet on healthy<br/>diet</li> </ul>   |
| WHO-CHOICE analysis available <sup>c</sup> | <ul> <li>Reduce salt intake through the implementation of front-of-pack labelling</li> <li>Eliminate industrial <i>trans</i>-fats through the development of legislation to ban their use in the food chain</li> </ul> | <ul> <li>Regulatory capacity<br/>along with<br/>multisectoral action is<br/>needed</li> </ul>                        | <ul> <li>Interventions on diet<br/>and physical activity:<br/>what works: summary<br/>report (2009)</li> </ul>   |
| -CHOICI                                    | <ul> <li>Reduce sugar consumption through effective taxation on sugar-sweetened beverages</li> </ul>   |  | <ul> <li>Guideline: sodium<br/>intake for adults and<br/>children (2012)</li> </ul>  |
| онм  |  |  | <ul> <li>Guideline: potassium<br/>intake for adults and<br/>children (2012)</li> </ul>   |
|  |  |  | <ul> <li>SHAKE the salt habit:<br/>technical package for<br/>salt reduction (2016)</li> </ul>  |
|  |  |  | <ul> <li>Guideline: sugars<br/>intake for adults and<br/>children (2015)</li> </ul>  |
|  |  |  | <ul> <li>Fiscal policies for diet<br/>and the prevention of<br/>noncommunicable<br/>diseases (2016)</li> </ul>   |

|                               | Menu of policy options  | Critical non-financial considerations <sup>a</sup> | WHO tools <sup>b</sup>  |
|-------------------------------|---|--|---|
|                               | • Promote and support exclusive breastfeeding<br>for the first 6 months of life, including<br>promotion of breastfeeding  |  | <ul> <li>Global strategy for<br/>infant and young child<br/>feeding (2003)</li> </ul>   |
|                               |   |  | <ul> <li>International Code of<br/>Marketing of Breast-<br/>milk Substitutes (1981)</li> </ul>  |
|                               |   |  | <ul> <li>Evidence for the ten<br/>steps to successful<br/>breastfeeding (1998)</li> </ul>   |
|                               |   |  | <ul> <li>Marketing of breast-<br/>milk substitutes:<br/>national<br/>implementation of the<br/>international code:<br/>status report (2016)</li> </ul>      |
|                               |   |  | <ul> <li>Baby-friendly hospital<br/>initiative: revised,<br/>updated and expanded<br/>for integrated care<br/>(2009)</li> </ul>                             |
| e                             | • Implement subsidies to increase the intake of fruits and vegetables   |  | <ul> <li>Five keys to a healthy<br/>diet (2016)</li> </ul>  |
| CHOICE analysis not available | • Replace <i>trans</i> -fats and saturated fats with unsaturated fats through reformulation, labelling, fiscal policies or agricultural   |  | <ul> <li>Fruit and vegetables for<br/>health (2004)</li> </ul>  |
|                               | <ul><li>policies</li><li>Limiting portion and package size to reduce energy intake and the risk of</li></ul>  |  | <ul> <li>Population-based<br/>approaches to<br/>childhood obesity<br/>prevention (2012)</li> </ul>  |
| WHO-CHOICE a                  | <ul> <li>overweight/obesity</li> <li>Implement nutrition education and counselling in different settings (for example, in preschools, schools, workplaces and hospitals) to increase the intake of fruits and vegetables</li> </ul> |  | <ul> <li>Essential nutrition<br/>actions: improving<br/>maternal, newborn,<br/>infant and young child<br/>health and nutrition<br/>(2013)</li> </ul>        |
| L .                           | • Implement nutrition labelling to reduce total energy intake (kcal), sugars, sodium and fats   |  | <ul> <li>Planning guide for<br/>national<br/>implementation of the<br/>Global Strategy for<br/>Infant and Young Child<br/>Feeding (2007)</li> </ul>         |
|                               |   |  | <ul> <li>School policy<br/>framework:<br/>implementation of the<br/>WHO global strategy<br/>on diet, physical<br/>activity and health<br/>(2008)</li> </ul> |
|                               |   |  |   |

|   |  | Critical non-financial  |  |
|---|--|---|--|
|   | Menu of policy options   | considerations <sup>a</sup>   | WHO tools <sup>b</sup>   |
|   |  |   | <ul> <li>Development of a<br/>framework on the<br/>nutrition-friendly<br/>schools initiative<br/>(2006)</li> </ul>   |
|   | • Implement mass media campaign on healthy diets, including social marketing to reduce the intake of total fat, saturated fats, sugars and salt, and promote the intake of fruits and vegetables |   | <ul> <li>Prioritizing areas for<br/>action in the field of<br/>population-based<br/>prevention of childhood<br/>obesity (2012)</li> </ul>                    |
| PHYS  | SICAL INACTIVITY   |   | ·  |
|   | • Implement the global strategy on diet, physical activity and health  |   | <ul> <li>Global<br/>recommendations on<br/>physical activity for<br/>health (2010)</li> </ul>  |
| actions                                       |  |   | <ul> <li>Report of the<br/>Commission on Ending<br/>Childhood Obesity<br/>(2016)</li> </ul>  |
| Overarching/enabling actions                  |  |   | <ul> <li>Interventions on diet<br/>and physical activity:<br/>what works: summary<br/>report (2009)</li> </ul>   |
| Overarchi                                     |  |   | <ul> <li>WHO global strategy<br/>on diet, physical<br/>activity and health: a<br/>framework to monitor<br/>and evaluate<br/>implementation (2008)</li> </ul> |
|   |  |   | <ul> <li>Physical activity<br/>technical package<br/>(Draft)</li> </ul>  |
| HOICE<br>wailable <sup>c</sup>                | • Provide physical activity counselling and referral as part of routine primary health care services through the use of a brief intervention   | <ul> <li>Requires sufficient,<br/>trained capacity in<br/>primary care</li> </ul> |  |
| WHO-CHOICE<br>analysis available <sup>c</sup> | • Implement public awareness and<br>motivational communications for physical<br>activity, including mass media campaigns<br>for physical activity behavioural change                             |   |  |

|                                   | Menu of policy options  | Critical non-financial considerations <sup>a</sup>   | WHO tools <sup>b</sup>  |
|-----------------------------------|---|--|---|
|                                   | • Ensure that macro-level urban design<br>incorporates the core elements of residential<br>density, connected street networks that<br>include sidewalks, easy access to a diversity   | <ul> <li>Requires involvement<br/>and capacity of other<br/>sectors apart from<br/>health</li> </ul> | <ul> <li>Guide for population-<br/>based approaches to<br/>increasing levels of<br/>physical activity (2007)</li> </ul>   |
|                                   | of destinations and access to public transport  |  | <ul> <li>Prioritizing areas for<br/>action in the field of<br/>population-based<br/>prevention of childhood<br/>obesity (2012)</li> </ul>   |
| not available                     | • Implement whole-of-school programme that<br>includes quality physical education,<br>availability of adequate facilities and<br>programs to support physical activity for all  |  | <ul> <li>Population-based<br/>approaches to<br/>childhood obesity<br/>prevention (2012)</li> </ul>  |
| alysis                            | <ul><li> Provide convenient and safe access to</li></ul>  |  | <ul> <li>School policy<br/>framework (2008)</li> </ul>  |
| WHO-CHOICE analysis not available | quality public open space and adequate<br>infrastructure to support walking and cycling   |  | <ul> <li>Promoting physical<br/>activity in schools: an<br/>important element of a<br/>health-promoting<br/>school (2007)</li> </ul>  |
| МН                                |   |  | <ul> <li>Quality physical<br/>education policy<br/>package (2014)</li> </ul>  |
|                                   | <ul> <li>Implement multi-component workplace<br/>physical activity programmes</li> <li>Promotion of physical activity through<br/>organized sport groups and clubs,<br/>programmes and events</li> </ul>                    |  | <ul> <li>Preventing<br/>noncommunicable<br/>diseases in the<br/>workplace through diet<br/>and physical activity<br/>(2008)</li> </ul>  |
| OBJ                               | ECTIVE 4  |  |   |
|                                   | • Integrate very cost-effective<br>noncommunicable disease interventions into<br>the basic primary health care package with<br>referral systems to all levels of care to<br>advance the universal health coverage<br>agenda |  | <ul> <li>Implementation tools:</li> <li>WHO package of<br/>essential<br/>noncommunicable<br/>(PEN) disease<br/>interventions for<br/>primary health care in<br/>low-resource settings<br/>(2013)</li> </ul> |

|                              | Menu of policy options   | Critical non-financial considerations <sup>a</sup>   | WHO tools <sup>b</sup>  |
|------------------------------|--|--|---|
|                              | Explore viable health financing mechanisms<br>and innovative economic tools supported by<br>evidence   |  | <ul> <li>WHO model list of<br/>essential medicines</li> </ul>   |
|                              | <ul> <li>Scale up early detection and coverage,<br/>prioritizing very cost-effective high-impact<br/>interventions including cost-effective<br/>interventions to address behavioural risk<br/>factors</li> </ul>   |  | <ul> <li>Scaling-up the capacity<br/>of nursing and<br/>midwifery services to<br/>contribute to the<br/>Millennium<br/>Development Goals</li> </ul> |
| ictions                      | • Train the health workforce and strengthen<br>the capacity of health systems, particularly at<br>the primary care level, to address the<br>prevention and control of noncommunicable<br>diseases  |  | <ul> <li>Scaling up action<br/>against<br/>noncommunicable<br/>diseases: How much<br/>will it cost? (2011)</li> </ul>                               |
| Overarching/enabling actions | • Improve the availability of the affordable<br>basic technologies and essential medicines,<br>including generics, required to treat major<br>noncommunicable diseases, in both public<br>and private facilities   |  | <ul> <li>Health systems<br/>financing: the path to<br/>universal coverage<br/>(2010)</li> </ul>   |
| Overarc                      | • Implement other cost-effective interventions<br>and policy options in objective 4 to<br>strengthen and orient health systems to<br>address noncommunicable diseases and risk<br>factors through people-centred health care<br>and universal health coverage  |  |   |
|                              | • Develop and implement a palliative care<br>policy, including access to opioids<br>analgesics for pain relief, together with<br>training for health workers   |  |   |
|                              | • Expand the use of digital technologies to increase health service access and efficacy for NCD prevention, and to reduce the costs in health care delivery  |  |   |
| CAR                          | DIOVASCULAR DISEASE AND DIABETES   |  |   |
|                              | <ul> <li>Drug therapy (including glycaemic control for diabetes mellitus and control of hypertension using a total risk<sup>1</sup> approach) and counselling to individuals who have had a heart attack or stroke and to persons with high risk (≥ 30%) of a fatal and non-fatal cardiovascular event in the next 10 years</li> </ul> | <ul> <li>Feasible in all resource<br/>settings, including by<br/>non-physician health<br/>workers</li> </ul> | <ul> <li>Global atlas on<br/>cardiovascular disease<br/>prevention and control<br/>(2011)</li> </ul>  |
|                              |  |  |   |

<sup>&</sup>lt;sup>1</sup> Total risk is defined as the probability of an individual experiencing a cardiovascular disease event (for example, myocardial infarction or stroke) over a given period of time, for example 10 years.

|  | Menu of policy options  | Critical non-financial considerations <sup>a</sup>   | WHO tools <sup>b</sup>  |
|--|---|--|---|
|  | <ul> <li>Drug therapy (including glycaemic control for diabetes mellitus and control of hypertension using a total risk approach) and counselling to individuals who have had a heart attack or stroke and to persons with moderate to high risk (≥ 20%) of a fatal and non-fatal cardiovascular event in the next 10 years</li> </ul>          | <ul> <li>Applying lower risk<br/>threshold increases<br/>health gain but also<br/>increases<br/>implementation cost</li> </ul> | <ul> <li>WHO ISH<br/>cardiovascular risk<br/>prediction charts</li> <li>Guidelines for primary<br/>health care in low-<br/>resource settings (2012)</li> </ul>  |
| WHO-CHOICE analysis available <sup>c</sup> | • Treatment of new cases of acute myocardial infarction <sup>1</sup> with either: acetylsalicylic acid, or acetylsalicylic acid and clopidogrel, or thrombolysis, or primary percutaneous coronary interventions (PCI)  | <ul> <li>Selection of option<br/>depends on health<br/>system capacity</li> </ul>  |   |
| OICE an                                    | • Treatment of acute ischemic stroke with intravenous thrombolytic therapy  | <ul> <li>Needs capacity to<br/>diagnose ischaemic<br/>stroke</li> </ul>  | <ul> <li>A global brief on<br/>hypertension (2013)</li> </ul>   |
| WHO-CH                                     | <ul> <li>Primary prevention of rheumatic fever and rheumatic heart diseases by increasing appropriate treatment of streptococcal pharyngitis at the primary care level</li> <li>Secondary prevention of rheumatic fever and rheumatic heart disease by developing a register of patients who receive regular prophylactic penicillin</li> </ul> | <ul> <li>Depending on<br/>prevalence in specific<br/>countries or sub-<br/>populations</li> </ul>                              | <ul> <li>Consolidated guidelines<br/>on the use of<br/>antiretroviral drugs for<br/>treating and preventing<br/>HIV infection: what's<br/>new (2015)</li> <li>HEARTS technical<br/>package for<br/>cardiovascular disease<br/>management in primary<br/>health care (2016)</li> </ul> |
| t not                                      | • Treatment of congestive cardiac failure with angiotensin-converting-enzyme inhibitor, beta-blocker and diuretic   |  |   |
| WHO-CHOICE analysis not<br>available       | <ul> <li>Cardiac rehabilitation post myocardial<br/>infarction</li> </ul>   |  |   |
|  | • Anticoagulation for medium-and high-risk<br>non-valvular atrial fibrillation and for mitral<br>stenosis with atrial fibrillation  |  |   |
| VHO-C                                      | • Low-dose acetylsalicylic acid for ischemic stroke   |  |   |
| Λ  | • Care of acute stroke and rehabilitation in stroke units   |  |   |

<sup>&</sup>lt;sup>1</sup> Costing assumes hospital care in all scenarios.

|   | Menu of policy options   | Critical non-financial<br>considerations <sup>a</sup>   | WHO tools <sup>b</sup>  |
|---|--|---|---|
| DIAI  | BETES  |   |   |
| WHO-CHOICE analysis<br>available <sup>c</sup> | <ul> <li>Preventive foot care for people with diabetes<br/>(including educational programmes, access<br/>to appropriate footwear, multidisciplinary<br/>clinics)</li> <li>Diabetic retinopathy screening for all<br/>diabetes patients and laser photocoagulation<br/>for prevention of blindness</li> <li>Effective glycaemic control for people with<br/>diabetes, along with standard home glucose<br/>monitoring for people treated with insulin to<br/>reduce diabetes complications</li> </ul>   | <ul> <li>Requires systems for<br/>patient recall</li> </ul>   | <ul> <li>Guidelines for primary<br/>health care in low-<br/>resource settings (2012)</li> <li>Global report on<br/>diabetes (2016)</li> </ul>   |
| WHO-CHOICE analysis not<br>available          | <ul> <li>Lifestyle interventions for preventing type 2 diabetes</li> <li>Influenza vaccination for patients with diabetes</li> <li>Preconception care among women of reproductive age who have diabetes including patient education and intensive glucose management</li> <li>Screening of people with diabetes for proteinuria and treatment with angiotensin-converting-enzyme inhibitor for the prevention and delay of renal disease</li> </ul>  |   |   |
| CAN   | CER  |   |   |
| WHO-CHOICE analysis available <sup>c</sup>    | <ul> <li>Vaccination against human<br/>papillomavirus (2 doses) of 9–13 year old<br/>girls</li> <li>Prevention of cervical cancer by screening<br/>women aged 30–49, either through: <ul> <li>visual inspection with acetic acid<br/>linked with timely treatment of pre-<br/>cancerous lesions</li> <li>pap smear (cervical cytology) every<br/>3–5 years linked with timely<br/>treatment of pre-cancerous lesions</li> <li>human papillomavirus test every<br/>5 years linked with timely treatment<br/>of pre-cancerous lesions</li> </ul> </li> </ul> | <ul> <li>Visual inspection with acetic acid is feasible in low resource settings, including with non-physician health workers</li> <li>Pap smear requires cytopathology capacity</li> <li>Requires systems for organized, population-based screening and quality control</li> </ul> | <ul> <li>National cancer control programmes core capacity self-assessment tool (2011)</li> <li>Guidelines for primary health care in low-resource settings (2012)</li> <li>Cancer control: knowledge into action, six modules (2008)</li> </ul> |

|  | Menu of policy options   | Critical non-financial considerations <sup>a</sup>  | WHO tools <sup>b</sup>   |
|--|--|---|--|
| WHO-CHOICE analysis available <sup>c</sup> | <ul> <li>Treatment of cervical cancer stages I and II with either surgery or radiotherapy +/- chemotherapy</li> <li>Treatment of breast cancer stages I and II with surgery +/- systemic therapy</li> <li>Screening with mammography (once every 2 years for women aged 50–69 years) linked with timely diagnosis and treatment of breast cancer</li> <li>Treatment of colorectal cancer stages I and II with surgery +/- chemotherapy and radiotherapy</li> </ul> | <ul> <li>Requires systems for<br/>organized, population-<br/>based screening and<br/>quality control</li> </ul> | <ul> <li>Comprehensive<br/>cervical cancer control:<br/>A guide to essential<br/>practice – Second<br/>edition (2014)</li> <li>WHO position paper on<br/>mammography<br/>screening (2014)</li> <li>Cryosurgical equipment<br/>for the treatment of<br/>precancerous cervical<br/>lesions and prevention<br/>of cervical cancer<br/>(2012)</li> <li>Monitoring national<br/>cervical cancer<br/>prevention and control<br/>programmes (2013)</li> <li>Use of cryotherapy for<br/>cervical intraepithelial<br/>neoplasia (2011)</li> <li>Global atlas of<br/>palliative care at the<br/>end of life (2014)</li> <li>Planning and<br/>implementing palliative<br/>care services: a guide<br/>for programme<br/>managers (2016)</li> </ul> |
|  | • Basic palliative care for cancer: home-based<br>and hospital care with multi-disciplinary<br>team and access to opiates and essential<br>supportive medicines  | <ul> <li>Requires access to<br/>controlled medicines<br/>for pain relief</li> </ul>                             | - Guidelines on the<br>pharmacological<br>treatment of persisting<br>pain in children with<br>medical illnesses<br>(2012)  |
| WHO-CHOICE<br>analysis not available       | <ul> <li>Prevention of liver cancer through hepatitis B immunization</li> <li>Oral cancer screening in high-risk groups (for example, tobacco users, betel-nut chewers) linked with timely treatment</li> <li>Population-based colorectal cancer screening, including through a faecal occult blood test, as appropriate, at age &gt;50, linked with timely treatment</li> </ul>   |   | <ul> <li>Practices to improve<br/>coverage of the<br/>hepatitis B birth dose<br/>vaccine (2013)</li> </ul>   |

|   | Menu of policy options  | Critical non-financial considerations <sup>a</sup> | WHO tools <sup>b</sup>  |
|---|---|--|---|
| CHR   | ONIC RESPIRATORY DISEASE  |  |   |
| WHO-CHOICE analysis<br>available <sup>c</sup> | <ul> <li>Symptom relief for patients with asthma with inhaled salbutamol</li> <li>Symptom relief for patients with chronic obstructive pulmonary disease with inhaled salbutamol</li> <li>Treatment of asthma using low dose inhaled beclometasone and short acting beta agonist</li> </ul>   |  | <ul> <li>Guidelines for primary<br/>health care in low-<br/>resource settings (2012)</li> <li>Selected pollutants:<br/>WHO guideline for<br/>indoor air quality<br/>(2010)</li> <li>WHO air quality<br/>guidelines for particular<br/>matter, ozone, nitrogen,<br/>dioxide and sulphur<br/>dioxide (2005)</li> </ul>                            |
| WHO-CHOICE analysis<br>not available          | <ul> <li>Access to improved stoves and cleaner fuels<br/>to reduce indoor air pollution</li> <li>Cost-effective interventions to prevent<br/>occupational lung diseases, for example,<br/>from exposure to silica, asbestos</li> <li>Influenza vaccination for patients with<br/>chronic obstructive pulmonary disease</li> </ul>   |  | <ul> <li>WHO guidelines for<br/>indoor air quality:<br/>Household fuel<br/>combustion (2014)</li> <li>Outline for the<br/>development of<br/>national programmes<br/>for elimination of<br/>asbestos-related<br/>diseases (2014)</li> </ul>   |
| OBJ   | ECTIVE 5  |  |   |
| Overarching/enabling actions                  | <ul> <li>Develop and implement a prioritized national research agenda for noncommunicable diseases</li> <li>Prioritize budgetary allocation for research on noncommunicable disease prevention and control</li> <li>Strengthen human resources and institutional capacity for research</li> <li>Strengthen research capacity through cooperation with foreign and domestic research institutes</li> <li>Implement other policy options in objective 5 to promote and support national capacity for high-quality research, development and innovation</li> </ul> |  | <ul> <li>Prioritized research<br/>agenda for the<br/>prevention and control<br/>of noncommunicable<br/>diseases 2011</li> <li>Research for universal<br/>health coverage: World<br/>Health Report 2013</li> <li>Global strategy and<br/>plan of action on public<br/>health, innovation and<br/>intellectual property<br/>(WHA61.21)</li> </ul> |

|                              | Menu of policy options   | Critical non-financial considerations <sup>a</sup> | WHO tools <sup>b</sup>   |
|------------------------------|--|--|--|
| OBJI                         | ECTIVE 6   |  |  |
|                              | • Develop national targets and indicators<br>based on global monitoring framework and<br>linked with a multisectoral policy and plans  |  | <ul> <li>Noncommunicable<br/>diseases progress<br/>monitor 2015</li> </ul>                       |
|                              | • Strengthen human resources and institutional capacity for surveillance and monitoring and evaluation   |  | <ul> <li>Global monitoring<br/>framework</li> </ul>  |
|                              | • Establish and/or strengthen a comprehensive noncommunicable disease surveillance   |  | <ul> <li>Verbal autopsy<br/>instrument</li> </ul>  |
| tions                        | <ul> <li>system, including reliable registration of<br/>deaths by cause, cancer registration, periodic<br/>data collection on risk factors and<br/>monitoring national response</li> <li>Integrate noncommunicable disease<br/>surveillance and monitoring into national<br/>health information systems</li> <li>Implement other policy options in<br/>objective 6 to monitor trends and<br/>determinants of noncommunicable diseases<br/>and evaluate progress in their prevention and<br/>control</li> </ul> |  | <ul> <li>STEPwise approach to<br/>surveillance</li> </ul>  |
| ling act                     |  |  | <ul> <li>Global Tobacco</li> <li>Surveillance System</li> </ul>                                  |
| Overarching/enabling actions |  |  | <ul> <li>Global Information<br/>System on Alcohol and<br/>Health</li> </ul>                      |
|                              |  |  | <ul> <li>Global database on the<br/>Implementation of<br/>Nutrition Action<br/>(GINA)</li> </ul> |
|                              |  |  | <ul> <li>Global school-based<br/>student health survey,<br/>ICD-10 training tool</li> </ul>      |
|                              |  |  | <ul> <li>Service Availability<br/>and Readiness (SARA)<br/>assessment tool</li> </ul>            |
|                              |  |  | <ul> <li>IARC GLOBOCAN<br/>2008</li> </ul>   |

<sup>a</sup> Cost-effectiveness alone does not imply the feasibility of an intervention in all settings. This column highlights some of the critical non-financial aspects that should be taken into account when considering the suitability of interventions for specific contexts.

<sup>b</sup> An up-to-date list of WHO tools and resources for each objective can be found at: http://www.who.int/nmh/ncd-tools/en/ (accessed 10 October 2016).

 $^{c}$  Interventions in bold font are those with an average cost-effectiveness ratio of  $\leq$ I\$100/DALY averted in low and lower-middle income countries.

#### WORKPLAN FOR THE GLOBAL COORDINATION MECHANISM ON THE PREVENTION AND CONTROL OF NONCOMMUNICABLE DISEASES COVERING THE PERIOD 2018–2019

1. This workplan sets out the activities of the global coordination mechanism on the prevention and control of noncommunicable diseases, including those of time-bound Working Groups, covering the period 2018–2019. The workplan takes into account the terms of reference for the global coordination mechanism,<sup>1</sup> the workplans covering the periods 2014–2015<sup>2</sup> and 2016–2017,<sup>3</sup> the global action plan for the prevention and control of noncommunicable diseases 2013–2020,<sup>4</sup> the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases,<sup>5</sup> the Outcome document of the high-level meeting of the General Assembly on the comprehensive review and assessment of the progress achieved in the prevention and control of non-communicable diseases,<sup>6</sup> and the 2030 Agenda for Sustainable Development.

2. This workplan takes into consideration the 2030 Agenda for Sustainable Development and the need to enhance multisectoral and multistakeholder advocacy, engagement and action that supports whole-of-government approaches across sectors beyond health and whole-of-society approaches engaging all sectors of society, in order to achieve the noncommunicable disease-related targets of the Sustainable Development Goals.

3. During the implementation of this workplan, account will be taken of: the evaluations mentioned in paragraphs 16 and 17 of document EB140/27; the Outcome document to be adopted at the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018; and outcomes adopted at other relevant high-level meetings, forums and events convened by the United Nations General Assembly as part of the systematic follow-up and review of the implementation of the 2030 Agenda for Sustainable Development at the global level.<sup>7</sup>

4. As with the previous two workplans, this workplan is organized around five objectives, in line with the five functions of the global coordination mechanism stated in its terms of reference. It will be implemented between January 2018 and December 2019 in line with the time frame of the Programme budget 2018–2019 and the budgetary provisions related to the activities of the global coordination mechanism included in that programme budget. This workplan will be fully integrated into programme area 2.1 (noncommunicable diseases) of the Programme budget 2018–2019, which will be operationalized through Programme Area Network 2.1, in accordance with established operating procedures.

<sup>&</sup>lt;sup>1</sup> Document A67/14 Add.1, Annex, Appendix 1.

<sup>&</sup>lt;sup>2</sup> Document A67/14 Add.3 Rev.1.

<sup>&</sup>lt;sup>3</sup> Document A68/11, Annex 3.

<sup>&</sup>lt;sup>4</sup> Endorsed by the Sixty-sixth World Health Assembly in resolution WHA66.10 (2013).

<sup>&</sup>lt;sup>5</sup> Adopted by the United Nations General Assembly in resolution 66/2 (2011).

<sup>&</sup>lt;sup>6</sup> Adopted by the United Nations General Assembly in resolution 68/300 (2014).

<sup>&</sup>lt;sup>7</sup> Adopted by the United Nations General Assembly in resolution 70/299 (2016).

5. As with the workplan covering the period 2016–2017, and in line with the scope and purpose of the global coordination mechanism, the third workplan covering the period 2018–2019 aims to facilitate and enhance the coordination of activities, multistakeholder engagement and action across sectors at the local, national, regional and global levels, in order to contribute to the implementation of the global action plan for the prevention and control of noncommunicable diseases 2013–2020, while avoiding duplication of efforts, using resources in an efficient and results-oriented way, and safeguarding WHO and public health from any undue influence by any form of real, perceived or potential conflicts of interest.<sup>1</sup>

#### **OBJECTIVES AND ACTIONS**

Objective 1. Advocate for and raise awareness of the urgency of implementing the global action plan for the prevention and control of noncommunicable diseases 2013–2020, and mainstream the prevention and control of noncommunicable diseases in the international development agenda.

Action 1.1: Continue the implementation and development of the global communications campaign launched in 2016, with a focus on achieving the noncommunicable disease-related targets of the Sustainable Development Goals and realizing the commitments to prevent and control noncommunicable diseases, as agreed by Member States.<sup>2</sup>

Action 1.2: Raise awareness of the need to accelerate action to strengthen national responses to noncommunicable diseases by facilitating and enhancing the coordination of activities, multistakeholder engagement and actions across sectors by participants in the global coordination mechanism at high-level political forums.

Action 1.3: Conduct at least one dialogue to facilitate and enhance the coordination of activities, multistakeholder engagement and action across sectors at the local, national, regional and global levels, to support Member States in realizing their commitments to address noncommunicable diseases.

# Objective 2. Disseminate knowledge and share information based on scientific evidence and/or best practices regarding implementation of the global action plan for the prevention and control of noncommunicable diseases 2013–2020.

Action 2.1: Continue to facilitate the exchange of information on noncommunicable disease-related research and its translation, identify barriers to research generation and translation, and facilitate innovation in order to enhance the knowledge base for ongoing national, regional and global action.

Action 2.2: Curate a resource library through the portal<sup>3</sup> of the global coordination mechanism by the end of 2018, which will include relevant and appropriate materials that promote multisectoral and multistakeholder action on noncommunicable diseases.

<sup>&</sup>lt;sup>1</sup> Document A67/14 Add.1, Annex, Appendix 1, paragraph 1.

<sup>&</sup>lt;sup>2</sup> See United Nations General Assembly resolutions 66/2 (2011) and 68/300 (2014).

<sup>&</sup>lt;sup>3</sup> See http://www.gcmportal.org/ (accessed 2 May 2017).

Action 2.3: Support knowledge dissemination and information sharing, including through communities of practice and webinars to support the implementation of the global action plan for the prevention and control of noncommunicable diseases 2013–2020 at the national, regional and global levels.

Action 2.4: Develop and disseminate an annual activity report describing progress made in the implementation of the workplan.

# Objective 3. Provide a forum to identify barriers and share innovative solutions and actions for the implementation of the global action plan for the prevention and control of noncommunicable diseases 2013–2020 and to promote sustained actions across sectors.

Action 3.1: Establish at least one working group to recommend ways and means of encouraging Member States and non-State actors to realize the commitments made to prevent and control noncommunicable diseases through multisectoral and multistakeholder approaches.

Action 3.2: Conduct at least one meeting of participants in the global coordination mechanism to facilitate and enhance the coordination of activities, multistakeholder engagement and action across sectors at the local, national, regional and global levels.

# Objective 4. Advance multisectoral action by identifying and promoting sustained actions across sectors that can contribute to and support the implementation of the global action plan for the prevention and control of noncommunicable diseases 2013–2020.

Action 4.1: Establish strategic roundtables aimed at supporting governments in strengthening their whole-of-government approaches across sectors beyond health and whole-of-society approaches engaging all sectors of society, in collaboration with relevant WHO technical units, the United Nations Inter-Agency Task Force on the Prevention and Control of Non-communicable Diseases, and other stakeholders, as appropriate.

Action 4.2: Work with relevant WHO technical units and the United Nations Inter-Agency Task Force in efforts to meet the requests by Member States to implement the recommendations of the WHO working groups of the global coordination mechanism.

Action 4.3: Continue to contribute to an integrated initiative, in collaboration with relevant WHO technical units and offices, the United Nations Inter-Agency Task Force and other stakeholders, that ensures an appropriate, coordinated and comprehensive response to provide support to Member States that are committed to making fast-track progress towards achieving the nine voluntary global targets for noncommunicable diseases by 2025, and the noncommunicable disease-related targets of the Sustainable Development Goals by 2030.

# Objective 5. Identify and share information on existing and potential sources of finance and cooperation mechanisms at the local, national, regional and global levels for implementation of the global action plan for the prevention and control of noncommunicable diseases 2013–2020.

Action 5.1: Continue to promote the implementation of the approach that WHO will have developed to register and publish contributions of non-State actors to the achievement of the nine voluntary targets for noncommunicable diseases.

Action 5.2: Map and publish the commitments made by participants in the global coordination mechanism to implement the global action plan for the prevention and control of noncommunicable diseases 2013–2020.<sup>1</sup>

Action 5.3: Establish an ongoing dialogue to explore the feasibility of establishing voluntary innovative financing mechanisms and partnerships<sup>2</sup> to develop and implement national noncommunicable disease responses through multisectoral and multistakeholder approaches.

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<sup>&</sup>lt;sup>1</sup> See document A67/14 Add.1, Annex, Appendix 1, paragraph 22.

<sup>&</sup>lt;sup>2</sup> In accordance with Sustainable Development Goal 17 (Strengthen the means of implementation and revitalize the global partnership for sustainable development).

#### ANNEX 4

## Framework of priorities and guiding principles to promote the health of refugees and migrants<sup>1</sup>

[A70/24, Annex – 17 May 2017]

#### A. INTRODUCTION AND PURPOSE

To achieve the aim of the 2030 Agenda for Sustainable Development – to leave no one behind – and the health-related commitments outlined in the New York Declaration for Refugees and Migrants,<sup>2</sup> it is imperative that the health needs of refugees and migrants are adequately addressed in the global compact on refugees and the global compact for safe, orderly and regular migration, to be endorsed in 2018.

This framework was requested in January 2017 by the Executive Board at its 140th session,<sup>3</sup> to be considered during the Seventieth World Health Assembly. The purpose of this framework is threefold:

(a) to inform discussions among Member States and partners engaged in the development of the global compact on refugees and the global compact for safe, orderly and regular migration to ensure that the health aspects of refugees and migrants are adequately addressed;

(b) to serve as a foundation for the development of a draft global plan of action on the health of refugees and migrants, which is planned to be submitted to the Seventy-second World Health Assembly in 2019;

(c) to provide a resource for consideration by Member States in addressing the health needs of refugees and migrants, in alignment with the Sustainable Development Goals and other global and regional policy frameworks as appropriate to each country's context and priorities.

#### **B.** SCOPE

This framework describes a number of overarching guiding principles and priorities to promote the health of refugees and migrants, building on existing instruments and resolutions<sup>4</sup> including a strategy and action plan for refugee and migrant health in the WHO European Region<sup>5</sup> and resolution CD55.R13 (2016) on the health of migrants adopted by Member States at the sessions of the WHO Regional Committee for the Americas/Directing Council in September 2016. The framework

<sup>&</sup>lt;sup>1</sup> See resolution WHA70.15.

<sup>&</sup>lt;sup>2</sup> Adopted by the United Nations General Assembly in resolution 71/1 (2016).

<sup>&</sup>lt;sup>3</sup> See decision EB140(9).

<sup>&</sup>lt;sup>4</sup> See document A70/24, paragraphs 11–13.

<sup>&</sup>lt;sup>5</sup> Strategy and action plan for refugee and migrant health in the WHO European Region (http://www.euro.who.int/ \_\_data/assets/pdf\_file/0004/314725/66wd08e\_MigrantHealthStrategyActionPlan\_160424.pdf, accessed 3 May 2017).

recognizes the urgent need for the health sector to address more effectively the impact of migration and displacement on health. The framework seeks to contribute to improving global public health by addressing the health of refugees and migrants in an inclusive, comprehensive manner and as part of holistic efforts to respond to the health needs of the overall population in any given setting. It is designed to promote the right to health, in accordance with humanitarian principles, international human rights obligations, including refugee law<sup>1</sup> and relevant international and regional instruments.<sup>2</sup> It also aims to support actions to minimize vulnerability to ill-health and to address the social determinants of health by promoting refugees' and migrants' ability to access promotive, preventive, curative and palliative health services. This framework acknowledges that laws, regulations and policies governing access to health services and financial protection for health by refugees and migrants vary across countries and are determined by national laws, policies and priorities.

#### C. GUIDING PRINCIPLES

1. The right to the enjoyment of the highest attainable standard of physical and mental health. Refugees and migrants have the fundamental right, as do all human beings, to the enjoyment of the highest attainable standard of health, without distinction of race, religion, political belief, economic or social condition.<sup>3</sup> Furthermore, States parties to the 1951 Convention relating to the Status of Refugees shall accord to refugees lawfully staying in their territory the same treatment as accorded to their host country nationals,<sup>4</sup> with respect to public relief and social security, which may include access to health services.

2. **Equality and non-discrimination.** The right to the enjoyment of the highest attainable standard of health should be exercised through non-discriminatory, comprehensive laws, and policies and practices including social protection.

3. **Equitable access to health services.** Equitable access to health promotion, disease prevention and care should be provided for migrants, subject to national laws and practice, without discrimination on the basis of gender, age, religion, nationality or race;<sup>5</sup> and in accordance with the international law for refugees.<sup>1</sup> The health of refugees and migrants should not be considered separately from the health of the overall population. Where appropriate, it should be considered to include refugees and migrants into existing national health systems, plans and policies, with the aim of reducing health inequities and to achieve the Sustainable Development Goals.

4. **People-centred, refugee- and migrant-, and gender -sensitive health systems.** Health systems should be refugee- and migrant-, and gender-sensitive, and people-centred, with the aim of delivering culturally, linguistically and gender- and age-responsive services.<sup>6</sup> While the legal status of

<sup>&</sup>lt;sup>1</sup> 1951 Convention relating to the Status of Refugees.

<sup>&</sup>lt;sup>2</sup> Such as the International Covenant on Economic, Social and Cultural Rights (1966) and the humanitarian principles.

<sup>&</sup>lt;sup>3</sup> As declared in the preamble to the Constitution of the World Health Organization. Also, the International Covenant on Economic, Social and Cultural Rights, Article 2.2 and Article 12, recognizes the right of everyone to the enjoyment of the highest attainable standard of physical and mental health without discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.

<sup>&</sup>lt;sup>4</sup> 1951 Convention relating to the Status of Refugees, Articles 23 and 24.

<sup>&</sup>lt;sup>5</sup> See resolution WHA61.17 (2008) on the health of migrants.

<sup>&</sup>lt;sup>6</sup> WHO. Health of migrants –the way forward – report of a global consultation. Madrid, Spain, 3–5 March 2010. Geneva: World Health Organization; 2016.

refugees<sup>1</sup> and migrants<sup>2</sup> is different, their health needs may be similar to or vary greatly from those of the host population. They may have been exposed to distress, torture and sexual and gender-based violence associated with conflict or their movements and may have had limited access to preventive and curative services before arrival in the host country. All of these factors may result in additional health care needs that require specific health responses.

5. **Non-restrictive health practices based on health conditions.** The health conditions experienced by refugees and migrants should not be used as an excuse for imposing arbitrary restrictions on their freedom of movement; or for employing stigmatization, deportation or other forms of discriminatory practices. Safeguards should be in place for health screening to ensure non-stigmatization, privacy and dignity, and the screening procedure should be carried out based on informed consent and to the benefit of both the individual and the public. It should also be linked to accessing risk assessment, treatment, care and support.

6. Whole-of-government and whole-of-society approaches. Addressing the complexity of migration and displacement should be based on values of solidarity, humanity and sustainable development. The health sector has a key role to play in ensuring that the health aspects of migration and displacement are considered in the context of broader government policy and in engaging and coordinating with other sectors, including civil society, the private sector, refugees' and migrants' associations and the affected populations themselves, to find joint solutions that benefit the health of refugees and migrants.

7. **Participation and social inclusion of refugees and migrants.** Health policies, strategies and plans and interventions across the migration and displacement cycle and in countries of origin, transit, and destination should be participatory, so that refugees and migrants are involved and engaged in relevant decision-making processes.

8. **Partnership and cooperation.** Managing large movements of refugees and migrants in a humane, sensitive, compassionate and people-centred manner is a shared responsibility.<sup>3</sup> Greater partnership and international cooperation among countries, the United Nations system including WHO, IOM and UNHCR, and other stakeholders, is essential to assist countries in addressing the health needs of refugees and migrants; and to ensure harmonized and coordinated responses. WHO, in collaboration with other relevant international organizations, has a lead role to coordinate and promote refugees' and migrants' health on the international agenda.

#### **D. PRIORITIES**

To promote the health of refugees and migrants, the following priorities could be considered:

1. Advocate mainstreaming refugee and migrant health in the global, regional and country agendas and contingency planning. Special attention should be given to promote and monitor the health of refugees and migrants, as part of efforts to achieve the Sustainable Development Goals. Efforts should also be made to ensure that the health aspects of refugees and migrants are included in the global compact on refugees and the global compact for safe, orderly and regular migration.

<sup>&</sup>lt;sup>1</sup> The international legal framework applicable to refugees includes the 1951 Convention relating to the Status of Refugees and its 1967 Protocol, and relevant resolutions and conclusions of international bodies relating to the rights of refugees in respect of health, including the conclusions adopted by the Executive Committee of UNHCR.

<sup>&</sup>lt;sup>2</sup> At the international level, there is no universally accepted definition of the term "migrant".

<sup>&</sup>lt;sup>3</sup> New York Declaration for Refugees and Migrants, paragraph 11.

2. **Promote refugee- and migrant-sensitive health policies, legal and social protection and programme interventions** that incorporate a public health approach and that can provide equitable, affordable and acceptable access to essential health promotion, disease prevention, and high-quality health services, including palliative care for refugees and migrants. This may require modifying or improving regulatory and legal frameworks to address the specific health needs of these populations, consistent with applicable national and international laws.

3. Enhance capacity to address the social determinants of health<sup>1</sup> to ensure effective health responses and health protection in countries of origin, transit and destination. This includes improving basic services such as water, sanitation, housing and education. Priority should be given to implement a Health in All Policies approach to promote health equality for refugees and migrants. This will require joint and integrated action and coherent public policy responses involving multisectoral collaboration such as the health, social, welfare and finance sectors, together with the education, interior and development sectors.

4. **Strengthen health monitoring and health information systems** in order to: assess and analyze trends in refugees' and migrants' health, disaggregate health information by relevant categories, as appropriate; conduct research; and identify, collate and facilitate the exchange of experiences and lessons learned among Member States, and generate a repository of information on relevant experiences in the affected countries.

5. Accelerate progress towards achieving the Sustainable Development Goals including universal health coverage by promoting equitable access to quality essential health services, financial risk protection, and access to safe, effective, quality and affordable essential medicines and vaccines for all (target 3.8), including refugees and migrants. This may require strengthening and building the capacities and resilience of health systems. As a part of these efforts, priority should also be given to developing sustainable financial mechanisms to enhance social protection for refugees and migrants, and to strengthen the implementation of the WHO Global Code of Practice on the International Recruitment of Health Personnel.<sup>2</sup>

6. **Reduce mortality and morbidity among refugees and migrants through short- and long-term public health interventions**, aimed at saving lives and promoting the physical and mental health of refugees and migrants. Rapid and effective emergency and humanitarian responses is essential to saving lives and relieving suffering, but longer-term planning for more systematic development-oriented approaches to ensure the continuity and sustainability of the response should begin early. Priority should be given to efforts to enhance local capacity to address public health issues such as communicable and noncommunicable diseases, with an emphasis on disease prevention, for example through vaccination. Vaccines should be provided for refugees and migrants in an equitable manner, with a systematic, sustainable, non-stigmatizing approach. As vaccination is a health intervention that requires a continuum of follow-up until the full schedule is completed, there must be cooperation among the countries of origin, of transit and of destination.

7. **Protect and improve the health and well-being of women, children and adolescents living in refugee and migrant settings.** Priority should be given to the provision of essential health services such as: a minimum initial service package for reproductive health, sexual and reproductive health information and services; maternal health care including emergency obstetric services, pre- and postnatal care; prevention, treatment, care and support for sexually transmitted infections including

<sup>&</sup>lt;sup>1</sup> See resolution WHA62.14 (2009).

<sup>&</sup>lt;sup>2</sup> The Code was adopted by the Sixty-third World Health Assembly through resolution WHA63.16 (2010).

HIV, and specialized care for survivors of sexual violence, as well as supporting for child health activities.

8. **Promote continuity and quality of care** delivered by public and private institutions and providers, non-State actors and other service providers for refugees and migrants, in particular for persons with disabilities, people living with HIV/AIDS, tuberculosis, malaria, mental health and other chronic health conditions as well as those with physical trauma and injury. It is important to ensure that adequate information on continuity of care is provided and is adhered to, especially during mobility, and particularly for the management of chronic health needs. Access to adequate mental health care, including at reception and through referrals to appropriate secondary services, should be provided. Priority should be given to ensuring that children have access to specific care and psychological support, which takes into account the fact that they experience and deal with stress differently than adults do.

9. **Develop, reinforce and implement occupational health safety measures** in work places where refugees and migrant workers are employed, in order to prevent work injuries and fatal accidents. Provide information and training to educate refugee and migrant workers about occupational health and safety risks in hazardous occupations. Refugee and migrant workers should have equal access to treatment of work-related injuries and disability, rehabilitation and death compensation according to national contexts.

10. **Promote gender equality and empower refugee and migrant women and girls** including through recognizing gender differences, roles, needs and related power structures among all relevant stakeholders and mainstreaming gender into humanitarian responses, and longer-term policy development and interventions. Also consider implementing the recommendations of the High-Level Commission on Health Employment and Economic Growth (2016), which call for tackling gender concerns in the health reform process and the health labour market.

11. **Support measures to improve communication and counter xenophobia** by making efforts to dispel fears and misperceptions among refugee, migrant and host populations on the health impacts of migration and displacement; and share accurate information on the impact of refugees and migrants on the health of local communities and health systems, as well as to acknowledge the contribution of refugees and migrants to society. Provide appropriate, accurate, timely and user-friendly information on the health services available in countries of origin, transit and destination to refugees and migrants.

12. Strengthen partnerships, intersectoral, intercountry and interagency coordination and collaboration mechanisms to achieve synergies and efficiency, including within the United Nations system, with IOM and UNHCR in particular, and with other stakeholders working towards improving the health of refugees and migrants; strengthen the humanitarian–development nexus to enhance better coordination between humanitarian and development health actors; and foster the exchange of best practices and lessons learned on the health of refugees and migrants among relevant actors. Also strengthen resource mobilization for flexible and multiyear funding to enable countries and communities to respond to both the immediate and the medium/longer-term health needs of refugees and migrants; identify gaps and innovative financing to ensure a more effective use of resources.

## ANNEX 5

## Global vector control response 2017–2030<sup>1</sup>

[A70/26 Rev.1 – 19 May 2017]

[Paragraphs 1–12 described the background to the global vector control response, including the challenges it is designed to meet and the process of its development.]

#### The global vector control response 2017–2030 in brief<sup>2</sup>

13. The global vector control response aims to support the implementation of a comprehensive approach to vector control that will enable the setting and achievement of disease-specific national and global goals and contribute to attainment of the Sustainable Development Goals. It also aims to support countries in mounting coherent and coordinated efforts to counter the increasing burden and threat of vector-borne diseases.

14. The document provides strategic guidance to countries and development partners for urgent strengthening of vector control as a fundamental approach to preventing disease and responding to outbreaks. This objective calls for significant enhancement of vector control programming, supported by increased numbers of technical staff, stronger monitoring and surveillance systems, and improved infrastructure. The vision of this response is a world free of human suffering from vector-borne diseases, with the aim of reducing the burden and threat of vector-borne diseases through effective locally adapted and sustainable vector control. The response sets an ambitious target of at least 75% reduction in mortality and 60% reduction in case incidence due to vector-borne diseases globally by 2030 relative to 2016, with epidemics prevented in all countries in line with Sustainable Development Goal 3. Interim milestones have been set, with reductions in mortality of at least 30% by 2020 and at least 50% by 2025, and reductions in morbidity of at least 25% and 40% over the same time periods.

15. The response comprises two foundational elements: (1) enhanced human, infrastructural and health systems capacity and capability for vector control and vector surveillance within all locally relevant sectors, and (2) increased basic and applied research to underpin optimized vector control, and innovation for development of new tools, technologies and approaches.

16. **Enhance vector control capacity and capability.** Formulating an inventory of the human, infrastructural, institutional and financial resources available and making an appraisal of existing organizational structures for vector control are essential first steps. Career structures in vector control within national and subnational programmes must be evaluated. Opportunities to attract resources from beyond the health sector should be explored, including staffing arrangements that involve collaboration and time-sharing. Where the number of human resources is inadequate, efforts should be

<sup>&</sup>lt;sup>1</sup>See resolution WHA70.16.

<sup>&</sup>lt;sup>2</sup> The full document can be accessed on the WHO website at http://www.who.int/malaria/global-vector-control-response (accessed 13 March 2017).

made to recruit and train staff from across sectors in the field of vector management and control and more broadly in public health, epidemiology and programme management.

17. **Increase basic and applied research, and innovation.** Vector control must be evidence-based to ensure local appropriateness and generate impact data required to justify continued investment in implementation. Basic research is urgently needed to understand better those aspects of vectors that influence interactions with human beings and pathogen transmission, such as biology, behaviour and environment. The results of such research should inform the development of innovative approaches and interventions. Applied research is also needed to assess effectiveness and optimize delivery of interventions. A research agenda that prioritizes strategic areas for attention should be defined by the national vector-borne disease control programme, in collaboration with relevant partners. This agenda should serve to guide research and academic institutions in aligning their work, help to avoid gaps or overlap, and assist in identifying additional external resources to support priority work.

18. Action is required in four key areas (pillars) to attain effective locally adapted and sustainable vector control. These four areas are aligned with the key elements of an integrated vector management approach.

19. Pillar 1. Strengthen inter- and intrasectoral action and collaboration. For maximum impact and efficiency, collaboration with non-health sectors must be enhanced, along with improved coordination of activities within the health sector such as water, sanitation and hygiene initiatives. National vector control programmes should become an integral part of national development strategies on poverty reduction and resilience to climate change, as well as regional development cooperation strategies. Engagement with ministries of agriculture, education, environment, finance, housing, tourism, transport and water is especially important. Municipality and local administrative structures can contribute to improving vector control services, enhance community engagement and mobilization, and create towns and cities more resilient to climate change. Collaboration will require strong political commitment and resources from central government with respective ministerial strategic plans to reflect adequately contributions to vector control. An interministerial taskforce should be established and funded appropriately to conduct the necessary coordination activities. The initial task should be to coordinate an assessment of national vector control capacity and needs, if that has not recently been done. An appraisal of the partnership landscape will help to identify all the existing and potential resources available to support vector control. Strategies need to be adapted to country-specific social determinants.

20. **Pillar 2. Engage and mobilize communities.** Given the major role of communities in the prevention, control and elimination of vector-borne diseases, the success and sustainability of vector control interventions require coordination between many stakeholders but especially depend on harnessing local knowledge and skills. Communities need to be mobilized to take responsibility for and implement vector control and surveillance actions through appropriate participatory community-based approaches. Strategies for engaging communities should be built upon research, behavioural situation analyses, monitoring and evaluation of engagement, and long-term sustainability.

21. **Pillar 3. Enhance vector surveillance and monitoring and evaluation of interventions.** As the capacity of vectors to transmit pathogens and their susceptibility to vector control measures can vary by species, location and time, depending on local environmental factors, vector control must be implemented on the basis of up-to-date local data. Vector surveillance should be routinely conducted at representative sites in areas where vector-borne diseases are endemic as well as those with conditions favourable for transmission. Linkage with epidemiological and health intervention coverage or usage data is essential. This information should be used to inform sound decision-making

for policy, planning and implementation of vector control and assist in early responses to the build-up of vector populations before outbreaks occur.

22. **Pillar 4. Scale up and integrate tools and approaches.** A key action to maximize the public health impact of vector control is the deployment and expansion of tools and approaches appropriate to the epidemiological and entomological context. Each vector control intervention that is selected for use in a particular setting should be applied to a high standard of quality and at optimal coverage. One tool can have multiple effects against several vectors and diseases. In some settings, an approach using multiple vector control interventions can have greater impact in reducing transmission or disease burden than use of one intervention alone. Core interventions may need to be supplemented with additional tools in order to meet specific challenges such as insecticide resistance. Integrated strategies should also be applied to reduce vector habitats by altering the domestic environment, for instance by improving water supply so as to prevent household-level storage, or to prevent access of vectors to human dwellings by installing screening on house entry points.

23. Three enabling factors are needed to implement the response: (1) country leadership; (2) advocacy, resource mobilization and partner coordination; and (3) regulatory, policy and normative support. Achievement of the targets and milestones set out in this response will need significant investment from both international and domestic sources to strengthen vector control capacity and capability, research and innovation, cross-sectoral coordination, community involvement, and surveillance and monitoring systems. It is estimated that full implementation of the priority activities defined for the interim period 2017-2022 will require an annual investment of US\$ 330 million. This equates to an average of US\$ 0.05 per person per year at risk from at least one vector-borne disease, with variation by burden and risk as well as other local factors such as income level. This represents a maximum value as it is assumed that over time adequate and well-trained local workforces will expand to undertake surveillance and coordination functions. The figures exclude both the cost of vector control commodities and their deployment, and research and innovation implementation costs. Required resource costs were estimated using WHO's tools for cost-effectiveness and strategic planning and cost assumptions.<sup>1</sup> These costs for workforce, coordination and surveillance represent a relatively modest investment in relation to implementation of core interventions, such as insecticide-treated nets (US\$ 1.27 per person protected per year), indoor residual spraying (US\$ 4.24 per person protected per year), and community-based activities for dengue prevention (estimated to exceed US\$ 1.00 per person protected per year). Accurate estimates of resource requirements and costs are expected to be made through comprehensive vector control needs assessments at country and subnational levels.

#### **ROLE OF THE SECRETARIAT**

24. In line with WHO's core functions, the Secretariat will continue to set and disseminate normative guidelines, policy advice and implementation guidance to support regional and country actions. It will provide, on request, support to Member States in implementing the global vector control response and provide guidance in reviewing and updating national vector control strategies.

25. The Secretariat will ensure that its policy-setting process responds to changing vector control needs and that its global technical guidance is regularly updated by incorporating information about innovative tools, technologies and approaches that are proven to be safe, effective and of public health

<sup>&</sup>lt;sup>1</sup>Cost–effectiveness and strategic planning (WHO-CHOICE), available at http://www.who.int/choice/en/# (accessed 14 March 2017).

value with due consideration of ethical issues and impact on the natural environment. Expert groups will be convened as necessary to address key issues related to policy development.

26. The Secretariat will strengthen its own capacities and capabilities at the global, regional and country levels so that it is better positioned to lead a coordinated global effort. It will continue to coordinate activities across related programmes and initiatives of the Organization, including the WHO Health Emergencies Programme, the International Health Regulations (2005), and the R&D blueprint for action to prevent epidemics. It will also provide support to initiatives on advocacy, resource mobilization and partner coordination.

27. The Secretariat will promote the generation of research and knowledge that is required to accelerate progress towards a world free of human suffering from vector-borne diseases. It will monitor implementation of the response and regularly evaluate progress towards the interim milestones and the targets for 2030.

#### ACTION BY THE HEALTH ASSEMBLY

28. This paragraph contained one draft resolution, which was adopted by the Health Assembly as resolution WHA70.16.

#### Appendix

#### OVERVIEW OF TECHNICAL ELEMENTS OF THE GLOBAL VECTOR CONTROL RESPONSE 2017–2030

**Vision:** A world free of human suffering from vector-borne diseases

**Aim:** Reduce the burden and threat of vector-borne diseases through effective locally adapted and sustainable vector control

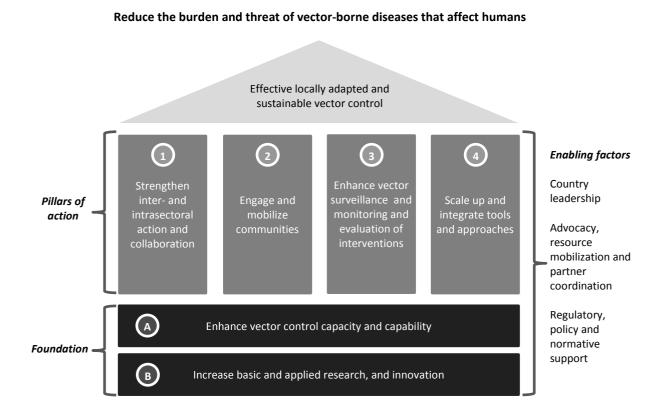
| Goals  | Milestones      |   | Targets          |
|--|-----------------|---|------------------|
|  | 2020            | 2025  | 2030             |
| Reduce mortality due to vector-borne diseases globally relative to 2016            | By at least 30% | By at least 50%                               | By at least 75%  |
| Reduce case incidence due to<br>vector-borne diseases globally relative<br>to 2016 | By at least 25% | By at least 40%                               | By at least 60%  |
| Prevent epidemics of vector-borne diseases <sup>a</sup>                            | _               | In all countries without transmission in 2016 | In all countries |

<sup>a</sup> Rapid detection and curtailment of outbreaks to prevent spread beyond the country.

#### RATIONALE

- Major vector-borne diseases of humans include malaria, dengue, lymphatic filariasis, Chagas disease, onchocerciasis, leishmaniasis, chikungunya, Zika virus disease, yellow fever, Japanese encephalitis and schistosomiasis. Other vector-borne diseases are of local importance in specific areas or populations, such as tick-borne diseases.
- These diseases account for around 17% of the estimated global burden of communicable diseases and disproportionately affect poorer populations. They impede economic development through direct medical costs and indirect costs such as loss of productivity and tourism.
- Social, demographic and environmental factors strongly influence transmission patterns of vector-borne pathogens, with major outbreaks of dengue, malaria, chikungunya, yellow fever and Zika virus disease since 2014.
- Most vector-borne diseases can be prevented by vector control, if it is implemented well. Major reductions in the incidence of malaria, onchocerciasis and Chagas disease have been largely due to strong political and financial commitment.
- For other vector-borne diseases, vector control has not yet been used to its full potential or had maximal impact. This situation can be reversed by realigning programmes to optimize the delivery of interventions that are tailored to the local context.
- This response calls for improved public health entomology (and malacology) capacity and capability, a well-defined national research agenda, better coordination within and between sectors, community involvement in vector control, strengthened monitoring systems and novel interventions with proven effectiveness.

#### **Response framework**



## **PRIORITY ACTIVITIES FOR 2017–2022<sup>1</sup>**

1. National and regional vector control strategic plans developed or adapted to align with the global vector control response.

2. National vector control needs assessment conducted or updated and resource mobilization plan developed, including for outbreak response.

3. National entomology and cross-sectoral workforce appraised and enhanced to meet identified requirements for vector control.

4. Relevant staff from health ministries or supporting institutions trained in public health entomology.

5. National and regional institutional networks to support training and/or education in public health entomology and technical support established and functioning.

6. National agenda for basic and applied research on entomology and vector control established and/or progress reviewed.

<sup>&</sup>lt;sup>1</sup> To be revised and updated for the subsequent period of 2023–2030.

7. National interministerial task force for multisectoral engagement in vector control established and functioning.

8. National plan for effective community engagement and mobilization in vector control developed.

9. National vector surveillance systems strengthened and integrated with health information systems to guide vector control.

10. National targets for protection of at-risk population with appropriate vector control aligned across vector-borne diseases.

## ANNEX 6

# **Post of Director-General**

[A70/4 and Annex 4 – 24 April 2017]

### PROPOSALS TO IMPROVE THE EFFICIENCY OF PAPER-BASED VOTING IN THE HEALTH ASSEMBLY AND CONSEQUENT NEED FOR PROCEDURAL AMENDMENTS<sup>1</sup>

|     | Proposal   | Is amendment of the Rules of Procedure of the World<br>Health Assembly or of the Guiding Principles for the<br>Conduct of Elections by Secret Ballot required?  |
|-----|--|---|
| (1) | Delegations are called to vote<br>simultaneously at six voting stations set<br>up in front of each of the six seating<br>blocks in the Assembly Hall at the Palais<br>des Nations.<br>Delegations are called to vote in the order<br>they are seated in the six seating blocks.  | Yes.<br>The Guiding Principles for the Conduct of Elections by<br>Secret Ballot require that members shall be called in turn<br>to vote in the required alphabetical order of their names,<br>beginning with the name of a Member which shall have<br>been drawn by lot and that the call shall be made in<br>English, French, Russian and Spanish.   |
| (2) | One teller and one legal officer are<br>positioned at each of the six voting<br>stations. The legal officer distributes one<br>ballot paper to each representative having<br>come to the voting station at which he/she<br>is positioned and records the distribution<br>of a ballot paper to the respective<br>delegation on a sheet of paper.  | Yes.<br>Rule 78 of the Rules of Procedure of the World Health<br>Assembly provides that, where a ballot is required,<br><u>two</u> tellers appointed by the President from among the<br>delegations present shall assist in the counting of votes.<br>The Guiding Principles for the Conduct of Elections by<br>Secret Ballot refer to the ballot box in the <u>singular</u><br>throughout. |
| (3) | After each Member entitled to vote has<br>inserted its ballot paper in the ballot box,<br>the six tellers positioned at the voting<br>stations carry the ballot boxes to the<br>rostrum and place them on three tables.<br>At each table, two tellers will then open<br>the two ballot boxes placed on each table,<br>count the votes and record the result on a<br>sheet prepared for this purpose by the<br>Secretariat. | Yes.<br>As for (2) above.   |
| (4) | One teller at each table carries the result<br>sheet to a fourth table where the result of<br>the vote will be recorded onto the<br>appropriate WHO form.  | Yes.<br>As for (2) above.   |

 $<sup>^{1}</sup>$  The amendments, which are now to be implemented following the adoption of decision WHA70(6), are set out below.

# Text of amended Rules of Procedure of the World Health Assembly and of amended Guiding Principles for the Conduct of Elections by Secret Ballot

#### **Rules of Procedure**

|                    | Rule 78   |
|--------------------|---|
|                    | Elections shall normally be held by secret ballot.<br>Subject to the provisions of Rule 108, and in the absence<br>of any objection, the Health Assembly may decide to<br>proceed without taking a ballot on an agreed candidate or<br>list of candidates. Where a ballot is required, two or<br>more tellers appointed by the President from among the<br>delegations present shall assist in the counting of votes.   |
| Guiding Principles |   |
|                    | 1. Before voting begins, the President shall hand to the tellers appointed by him the list of Members entitled to vote and the list of candidates. For the elections of Members entitled to designate persons to serve on the Executive Board or of the Director-General, the list of candidates shall include only those nominations submitted to the World Health Assembly in accordance with the procedure laid down in Rules 100 and 108 respectively of the Rules of Procedure of the World Health Assembly. |
|                    | 3. The tellers shall satisfy themselves that the ballot box or ballot boxes is/are empty and, having locked it/them, shall hand the key/keys to the President.  |
|                    | 4. Except as otherwise determined by the Health Assembly, Members shall be called in turn to vote in the required alphabetical order of their names, <sup>1</sup> beginning with the name of a Member which shall have been drawn by lot. The call shall be made in English, French, Russian and Spanish.   |
|                    | 7. When the ballot box or ballot boxes has/have been opened, the tellers shall count the number of ballot papers. If the number is not equal to that of the voters, the President shall declare the vote invalid and another ballot shall be held.  |
|                    | 9. One of the tellers shall then read aloud the names<br>which are on the ballot paper. The number of votes<br>obtained by each of the candidates mentioned shall be<br>written opposite their names by one of the other tellers<br>on a document drawn up for this purpose.  |

<sup>&</sup>lt;sup>1</sup> Under Rule 72 of the Rules of Procedure of the World Health Assembly.

## ANNEX 7

## **Poliomyelitis: polio transition planning**

[A70/14 Add.1, Annex - 19 May 2017]

# List of Secretariat actions between 1 June and 31 December 2017<sup>1</sup>

#### Active high-level oversight at all three levels of the Organization

- Detailed briefing on polio transition to the Director-General-elect immediately after the Seventieth World Health Assembly, highlighting the corporate risks that polio transition presents, as well as the need for regular communication to external stakeholders.
- Sustained oversight by the Office of the Director-General of the Organization-wide polio transition planning and management of risks.
- Meeting in Geneva of the 16 WHO Representatives concerned, and of regional and headquarters staff in order to discuss progress of the country transition plans, combined with a mission briefing, third or fourth quarter, 2017.
- Discussion of polio transition during the regional committees 2017 in the African, South-East Asia and Eastern Mediterranean regions.
- Development of a dedicated polio transition planning webpage on the WHO website where detailed data on the following: WHO polio transition risks and process; the country-level polio transition planning process; and Global Polio Eradication Initiative partnership polio transition process will be made available, and regularly updated.
- Active support for a designated team within the Office of the Director-General tasked with the development of the strategic action plan and options by end 2017.

#### Coordinated human resources planning and budget management

- Quarterly planning dashboards on transition human resources and national transition to be developed and shared on polio transition planning webpage.
- Human resource plans for staff retention, re-training and career transition to be developed and shared and coordinated between headquarters and the three regions concerned.
- Communication plans and products to be developed and shared, for both internal and external audiences.

<sup>&</sup>lt;sup>1</sup> See decision WHA70(9).

- Programme areas to explore the use of operational planning for the Programme budget 2018–2019 to revise budget needs, and develop financing strategies to cover increased budgets.
- Discussions initiated across the Organization to ensure advance planning for development of the Programme budget 2020–2021, ensuring that polio transition needs are taken into consideration.

#### Development of a strategic action plan and options – by end 2017

- Collect more precise details on a prioritized set of "programmatic risks" that would have the biggest public health impact; coordinate with all relevant departments and programme areas.
- Identify the critical gaps that would be left by the decrease in polio budgets, and eventual closure of Global Polio Eradication Initiative, and prioritize the gaps that need to be closed urgently.
- Develop a timeline and specific options for dealing with the gaps covering the areas of human resources, financing, coordination, and policy.
- Develop an implementation and monitoring framework that can be tracked.

# ANNEX 8

# **Report of the 2016 PIP Framework Review Group**<sup>1</sup>

[A70/17, Annex – 10 April 2017]

<sup>&</sup>lt;sup>1</sup> See decision WHA70(10).

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# Preface

The risk of another influenza pandemic is ever-present but its timing and impact is unpredictable. Advance planning and preparedness is key to mitigating the adverse outcomes of future influenza pandemics. This includes building capacity to detect and respond to a public health emergency of international concern.

In 2011,WHO and Member States set up the Pandemic Influenza Preparedness (PIP) Framework as a novel international instrument to strengthen the sharing of influenza viruses with human pandemic potential while increasing the preparedness of developing countries, and their access to vaccines and other pandemic related supplies in the event of a pandemic. All players – WHO, Member States, industry, civil society and other stakeholders – came together with a common purpose to better prepare the world to respond to the next pandemic and reduce uncertainty in our collective ability to share viruses and the benefits.

It has been five years since the PIP Framework was signed; while such new and complex initiatives take time to operationalise, it is now timely to review progress as to whether the PIP Framework has both achieved what was intended and continues to remain relevant looking forward.

As the world faces an increasing number of public health threats with international impact (e.g. Middle East respiratory syndrome coronavirus (MERS-CoV), Ebola virus disease and Zika virus), global solidarity is more important than ever to address critical policy, operational and capacity barriers ahead of an emergency. The PIP Framework offers helpful insights for the sharing of other pathogens that require a rapid response and the equitable sharing of benefits. However, it is the view of the PIP Framework Review Group that the PIP Framework will only remain relevant if viruses continue to be shared and the need for clarification around the sharing of genetic sequence data and benefits is rapidly addressed. In addition, linkages to other efforts to strengthen capacity building (e.g. the International Health Regulations (2005)) and to increase influenza vaccine production are improved to maximise the impact of resources leveraged by the PIP Framework. In order to ensure the PIP Framework remains sustainable and maintains the interest of all major players, it is important that its delivery of results is regularly measured and widely communicated.

Dr Christine Kaseba-Sata (Chair), Dr Theresa Tam (acting Chair)

PIP Review Group

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# Glossary

| AFRO       | WHO Regional Office for Africa  |
|------------|---|
| AMRO       | WHO Regional Office for the Americas  |
| CDC        | U.S. Centers for Disease Control and Prevention                                   |
| CNBG       | China National Biotec Group   |
| COP        | Conference of the Parties   |
| CVV        | Candidate vaccine virus   |
| DDBJ       | DNA Data Bank of Japan  |
| ECN        | WHO Emergency Communications Network  |
| ECSPP      | WHO Expert Committee on Specifications for Pharmaceutical Preparations            |
| EMRO       | WHO Regional Office for the Eastern Mediterranean                                 |
| ENA        | European Nucleotide Archive   |
| EQAP       | WHO External Quality Assessment Project for the detection of influenza virus      |
| LQAF       | type A by polymerase chain reaction   |
| EU         |   |
| EURO       | European Union  |
|            | WHO Regional Office for Europe  |
| FAO        | Food and Agriculture Organization of the United Nations<br>Flu Informed Decisions |
| FluID      |   |
| GAP        | Global Action Plan for Influenza Vaccines   |
| GDP        | Gross domestic product  |
| GHSA       | Global Health Security Agenda   |
| GIP        | WHO Global Influenza Programme  |
| GISAID     | Global Initiative on Sharing All Influenza Data                                   |
| GISN       | Global Influenza Surveillance Network   |
| GISRS      | Global Influenza Surveillance and Response System                                 |
| GSD        | Genetic sequence data   |
| GSK        | GlaxoSmithKline   |
| HQ         | Headquarters  |
|            | Institutional development plan  |
| IHR (2005) | International Health Regulations (2005)   |
| INSDC      | International Nucleotide Sequence Database Collaboration                          |
| IRD        | Influenza Research Database   |
|            | Influenza viruses with human pandemic potential                                   |
| IVTM       | Influenza Virus Traceability Mechanism  |
| MAT        | Mutually agreed terms   |
| MERS-CoV   | Middle East respiratory syndrome coronavirus                                      |
| MOP        | Meeting of the Parties  |
| NIC        | National Influenza Centre   |
| NRA        | National regulatory authority   |
| OIE        | World Organisation for Animal Health  |
| PAHO       | Pan American Health Organization  |
| PC         | Partnership Contribution  |
| PCR        | Polymerase chain reaction   |
| PHEIC      | Public health emergency of international concern                                  |
| PIC        | Prior informed consent  |
| PIP        | Pandemic Influenza Preparedness   |
| PIP BM     | PIP biological materials  |
| PIRM       | WHO Pandemic Influenza Risk Management  |
| PSC        | Programme support costs   |
|            |   |

| SAGE<br>SARS<br>SDG | Strategic Advisory Group of Experts on Immunization<br>Severe acute respiratory syndrome<br>UN Sustainable Development Goal |
|---------------------|---|
| SEARO               | WHO South-East Asia Regional Office   |
| SMTA                | Standard material transfer agreement  |
| SWOT                | Strengths, weaknesses, opportunities and threats  |
| TEWG                | Technical Expert Working Group on Genetic Sequence Data   |
| TWG                 | Technical Working Group on the Sharing of Influenza Genetic Sequence Data   |
| TIPRA               | Tool for Influenza Pandemic Risk Assessment   |
| UN                  | United Nations  |
| UNICEF              | United Nations Children's Fund  |
| WPRO                | WHO Regional Office for the Western Pacific   |
| WHO                 | World Health Organization   |
| WHO CC              | WHO Collaborating Centre  |
| WHO ERL             | WHO Essential Regulatory Laboratory   |
| WHO H5RL            | WHO H5 Reference Laboratory   |

# **Executive Summary**

Global health security has become an international priority over the past decade, with the recognition that infectious diseases know no borders in a world of shifting populations and vastly expanded international travel. While the 2003 severe acute respiratory syndrome (SARS) outbreak provided a wake-up call, the specific global risks posed by influenza were highlighted by the re-emergence of influenza A(H5N1) in 2003 and the influenza A(H1N1) pdm09<sup>1</sup> pandemic in 2009. Almost a century after the deadly 1918 influenza pandemic swept the world with devastating consequences, the Report of the Review Committee on the Functioning of the International Health Regulations (2005) (IHR (2005)) in relation to the 2009 A(H1N1) outbreak concluded that the world remained "ill-prepared" to respond to a severe influenza pandemic and that "tens of millions" of people would be at risk of dying.<sup>2</sup>

After the influenza A(H5N1) outbreak in 2003, it became clear that an effective response to an influenza pandemic required closer international collaboration. Such collaboration not only needed to cover the sharing of information and of influenza viruses with human pandemic potential (IVPP), but also the distribution of the benefits that flow from such cooperation, including influenza vaccines and other medical products. Negotiations started on the creation of a new system and four years later, in 2011, an international instrument, the Pandemic Influenza Preparedness (PIP) Framework,<sup>3</sup> was set up by 194 Member States.<sup>4</sup> From the start, strong engagement with stakeholders – including Member States, industry and civil society – has been crucial to the implementation of the PIP Framework. Successful implementation of the PIP Framework remains as critical as ever given the continual emergence of new influenza viruses and the ever-present potential of a pandemic.

The PIP Framework aims to balance virus sharing with benefit sharing on an equal footing. Advances in vaccine, antiviral and diagnostic technology alone are not enough to protect a world against a pandemic. Whereas access to health services and products remains unequal around the world, the influenza virus is indiscriminate and all countries can be equally at risk. Consequently, it is vital that the influenza products produced through the rapid sharing of viruses are available to the most vulnerable populations in the time of a pandemic.

Viruses are shared through the Global Influenza Surveillance and Response System (GISRS) of 152 laboratories, including 143 National Influenza Centres (NICs) spread across 113 Member States, six WHO Collaborating Centres for Reference and Research on Influenza (WHO CCs), four WHO Essential Regulatory Laboratories (WHO ERLs), and 13 WHO H5

(http://apps.who.int/gb/ebwha/pdf\_files/WHA64/A64\_10-en.pdf, accessed 20 September 2016).

<sup>&</sup>lt;sup>1</sup> Influenza A(H1N1)pdm09 is the virus responsible for the 2009 influenza pandemic that was declared the first Public Health Emergency of International Concern under the International Health Regulations (2005).

<sup>&</sup>lt;sup>2</sup> Implementation of the International Health Regulations (2005), Report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009, Report by the Director-General. Geneva: World Health Organization; 2011 (A64/10;

<sup>&</sup>lt;sup>3</sup> Pandemic influenza preparedness framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011 (http://www.who.int/influenza/pip/en/, accessed 19 September 2016).

<sup>&</sup>lt;sup>4</sup> Agenda item 13.1. Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits. Sixty-fourth World Health Assembly. Geneva: World Health Organization; 2011 (WHA64.5; http://apps.who.int/gb/ebwha/pdf\_files/WHA64/A64\_R5-en.pdf, accessed 21 September 2016).

Reference Laboratories (WHO H5RLs).<sup>1,2</sup> The Standard Material Transfer Agreement 1 (SMTA1), contained in Annex 1 to the PIP Framework, is a binding contract that establishes the conditions under which GISRS laboratories exchange PIP biological materials (PIP BM) among themselves.

The PIP Framework's benefit sharing aspect occurs in two ways: SMTA2s and Partnership Contribution (PC).<sup>3</sup> Non-GISRS entities, such as manufacturers or academic institutions, who receive physical virus samples sign an STMA2, a legally binding agreement to provide products such as vaccines, antivirals and diagnostics in the event of a pandemic. Influenza vaccine, pharmaceutical and diagnostic manufacturers who use GISRS also pay annual PC funds totalling US\$ 28 million, which are used to bolster pandemic Preparedness and Response.

## The first review of the PIP Framework

At the start of this Review, the PIP Framework had been implemented for five years. This first review was provided for under section 7.4.2 of the PIP Framework, which states that the PIP Framework and its Annexes should be reviewed by 2016 "with a view to proposing revisions reflecting developments as appropriate, to the World Health Assembly in 2017, through the Executive Board".

The PIP Framework Advisory Group (the "Advisory Group") met in a Special Session on 13-14 October 2015 with Member States, industry and other stakeholders, and recommended that an independent group of experts be established to review implementation of the PIP Framework.<sup>4</sup> The Director-General convened the Review Group, consisting of eight experts with wide-ranging expertise, covering all WHO regions and with a good gender balance. As part of its terms of reference, the Review Group was asked to focus on three questions:<sup>5</sup>

1. What are the achievements since the PIP Framework was adopted?

2. Has implementation of the PIP Framework improved global pandemic influenza preparedness, including inter-pandemic surveillance, and capacity to respond?

3. What are the challenges, and possible ways of addressing them?

The Review Group was appointed in December 2015. In addition to analysing the sharing of influenza viruses with human pandemic potential (IVPP) through GISRS, the collection of PC

<sup>&</sup>lt;sup>1</sup> Global Influenza Surveillance and Response System (GISRS). In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/gisrs\_laboratory/en/, accessed 20 October 2016).

<sup>&</sup>lt;sup>2</sup> Outside GISRS there are also influenza laboratories authorized and designated by a Member State to provide PIP BM to GISRS. These laboratories are either in Member States that do not have a NIC or are additional laboratories carrying out certain roles usually performed by NICs.

<sup>&</sup>lt;sup>3</sup> Pandemic influenza preparedness framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011 (http://www.who.int/influenza/pip/en/, accessed 19 September 2016), Annex 2 and section 6.14.

<sup>&</sup>lt;sup>4</sup> PIP Framework Advisory Group. Special session of the Pandemic influenza preparedness (PIP) Framework Advisory Group, 13-14 October 2015, Geneva, Switzerland. Report to the Director-General. Geneva: World Health Organization; 2015 (http://www.who.int/influenza/pip/advisory\_group/ag\_spec\_session\_report.pdf, accessed 24 September 2016).

and its implementation through five Areas of Work, the signing of SMTA2s, and the governance of the PIP Framework, the Review Group also looked at other key contextual and implementation issues including: the handling of genetic sequence data (GSD) under the PIP Framework; linkages with other programmes or instruments (specifically the Global Action Plan for Influenza Vaccines (GAP),<sup>1</sup> the IHR (2005),<sup>2</sup> the implementation of the Nagoya Protocol<sup>3</sup>); interactions with key partners in the PIP Framework, including industry, civil society and other stakeholders; and collateral benefits that may have resulted from implementation of the PIP Framework.

During 2016, the Review Group met several times face to face at WHO Headquarters in Geneva and held a number of teleconferences. To inform its deliberations, the Review Group actively sought input from WHO staff, Member States and many key stakeholders, including representatives of GISRS, industry, civil society organizations, and relevant databases. This engagement took place through individual interviews, written submissions, an electronic open consultation process that included questions for response, and two open consultation meetings at WHO Headquarters. Following several of the Review Group meetings, the Review Group held debriefing and question/answer sessions for Member States at WHO Headquarters that were open to all stakeholders and the public via a live webcast on the WHO website.<sup>4</sup>

The main report begins with an introduction to the PIP Framework and its component parts, followed by a brief description of the Review Group's Method of Work. The remainder of the report presents the Review Group's Findings and Recommendations. This Executive Summary summarizes the main Findings and reproduces all the Recommendations.

## **Findings and Recommendations**

### **Overarching analysis**

### Summary of Findings:

The Review Group found that the PIP Framework is a bold and innovative tool for pandemic influenza preparedness, is being well implemented, and that the principle of the PIP Framework of placing virus sharing and benefit sharing on an equal footing remains relevant today. The implementation of the PIP Framework has led to greater confidence and predictability in the global capacity to respond to an influenza pandemic. The PIP Framework's success is due in part to the regular, committed engagement by WHO and Member States with key stakeholders including industry, civil society, and others. However, while there are regular reports on the implementation of the PIP Framework, the various elements could be better brought together to give a clearer picture of overall progress.

<sup>&</sup>lt;sup>1</sup> Global Action Plan for Influenza Vaccines (GAP). In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza\_vaccines\_plan/en/, accessed 22 September 2016).

<sup>&</sup>lt;sup>2</sup> International Health Regulations (2005), 2<sup>nd</sup> ed. Geneva: World Health Organization; 2008 (http://apps.who.int/iris/bitstream/10665/43883/1/9789241580410\_eng.pdf, accessed 22 September 2016).

<sup>&</sup>lt;sup>3</sup> The Nagoya Protocol on Access and Benefit-sharing. In: Convention on Biological Diversity [website]. Montreal: Convention on Biological Diversity, United Nations; 2011 (https://www.cbd.int/abs/, accessed 4 October 2016).

<sup>&</sup>lt;sup>4</sup> PIP Framework Review Group. 2016 Review of the PIP Framework, PIP Review Group Meeting Reports. In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.uka.int/influenza/sip/2016, review/meetings/ap/, assessed 20, Sastember 2016).

<sup>(</sup>http://www.who.int/influenza/pip/2016-review/meetings/en/, accessed 20 September 2016).

It is also clear that there are key issues that must urgently be addressed for the PIP Framework to remain relevant, including the issue of how GSD should be handled under the PIP Framework, and whether or not the PIP Framework could be expanded to include seasonal influenza, or indeed be used as a model for the sharing of other pathogens.

#### **Recommendations:**

1. WHO should develop a comprehensive evaluation model, including overall success metrics for the Pandemic Influenza Preparedness (PIP) Framework for annual reporting. Such reporting should include an infographic that illustrates the status of overall progress in implementing the PIP Framework to allow for greater clarity on progress towards pandemic preparedness and response.

2. WHO should regularly and more effectively communicate the objectives and progress in the implementation of the PIP Framework to Members States, Global Influenza Surveillance and Response System (GISRS) laboratories, industry, civil society, and other stakeholders. In particular, it should better communicate:

a. Progress against the comprehensive evaluation model;

b. Partnership Contribution implementation measures; these should be highlighted in regular Advisory Group reports and post-meeting briefings so that progress is more visible and clearly recognized;

c. Communication and transparency should be enhanced around issues such as selection of countries to receive Partnership Contribution implementation support for improved understanding of the PIP Framework among Member States;

d. The significance of stakeholder voluntary contributions, and in-kind Member States' commitments, including support and maintenance of GISRS through provision of routine running costs of laboratories.

3. The Director-General should undertake a study to determine the implications and desirability of including seasonal influenza viruses in the PIP Framework.

4. The PIP Framework is a foundational model of reciprocity for global public health that could be applied to other pathogens; however, the current scope of the PIP Framework should remain focused on pandemic influenza at this time.

5. Member States should agree the timing of the next review of the PIP Framework, which should be before the end of 2021.

#### Virus Sharing

#### Summary of Findings:

GISRS has expanded in scope and been strengthened since the PIP Framework was adopted in 2011, and provides significant benefits to Member States, including risk assessment, candidate vaccine viruses (CVVs), diagnostic kits, reagents, training, capacity building and other expertise. Virus sharing via GISRS generally works well. However, despite a prompt and comprehensive response to the emergence of the H7N9 strain in 2013, there has since been a reduced sharing of IVPP from some countries. At the Advisory's Group request, the Secretariat is studying the reasons for this reduced sharing.

GISRS collaborates closely with the animal sector to conduct risk assessment and develop CVVs; these links between the human and animal sectors are especially important when the sharing of human viruses is delayed, and include relationships with the Food and Agriculture Organization of the United Nations (FAO), the World Organisation for Animal Health (OIE), and the OFFLU (the joint OIE-FAO network of animal influenza experts).

Although the Influenza Virus Traceability Mechanism (IVTM) is vital in tracking the sharing of viruses, and thereby triggering the PIP Framework's benefit sharing mechanisms, it is not consistently used by all laboratories.

#### **Recommendations:**

6. The Review Group welcomes the PIP Framework Secretariat's study of the reasons for the recent decline in the sharing of influenza viruses with human pandemic potential. The Advisory Group should, as a priority, follow-up on the results of this study in order to ensure the timely sharing of all viruses.

7. Given the recent decline in the sharing of influenza viruses with human pandemic potential, WHO should continue to provide technical operational guidance and training for National Influenza Centres to ensure that they are fully aware of their roles as agreed in the Standard Material Transfer Agreement 1, the effective use of the Influenza Virus Traceability Mechanism, and the importance of appropriate sharing of all PIP biological materials and genetic sequence data.

8. WHO should provide clarification to GISRS laboratories on the interpretation of the terms "timely" and "as feasible" with respect to the sharing of PIP biological materials from all cases of A(H5N1) and other influenza viruses with human pandemic potential (section 5.1.1 of the PIP Framework).

9. Although genetic sequence data do not fully substitute for the physical virus, in cases where it is not possible to ship PIP biological materials rapidly, genetic sequence data should, if available, be shared immediately.

10. The WHO Global Influenza Programme should strengthen contacts and linkages with, and processes between, the GISRS system and non-GISRS laboratories and other networks.

11. WHO, GISRS, the Food and Agricultural Organization of the United Nations, the World Organisation for Animal Health, the OFFLU and others should collaboratively establish guidance for GISRS and animal laboratories to strengthen their relationships and enhance surveillance and risk assessment of influenza viruses at the animal-human interface.

### Genetic Sequence Data

### Summary of Findings:

Due to the complexities of its handling under the PIP Framework, GSD was not included in the definition of PIP BM when the PIP Framework was set up. Thus, while the sharing of viruses is tracked via the IVTM, the sharing of GSD is not, and therefore does not trigger specific benefit sharing under the PIP Framework. However, as technology advances, GSD is becoming increasingly critical in influenza research, and can in some cases substitute for physical samples for pandemic risk assessment and the development of commercial products. Therefore, clarity is urgently required on the handling of GSD under the PIP Framework.

Some good progress has already been made by the Advisory Group in examining possible approaches to handling GSD under the PIP Framework. A key challenge has been the lack of agreement on what should be traced. Options could include tracking access to GSD or tracking the commercial products developed using such data. Transparency in both the sharing and traceability of GSD is crucial in order to identify any resulting benefit that should be shared.

There are a range of players involved in the discussion of how to handle GSD and diverse views about the optimal traceability and monitoring system. It is clear from the Review Group's interviews and wider discussions that there also remains some confusion among stakeholders as to the potential options for future sharing of GSD.

### **Recommendations:**

12. The Director-General should request Member States to consider amending the definition of PIP biological materials in section 4.1 of the PIP Framework to include genetic sequence data.

13. The Director-General should request Member States to consider clarifying Annex 4, section 9, which currently states that "The WHO GISRS laboratories will submit genetic sequences data to GISAID and Genbank or similar databases in a timely manner consistent with the Standard Material Transfer Agreement", by amending it to:

"The WHO GISRS laboratories will submit genetic sequences data to one or more publicly accessible database of their choice in a timely manner consistent with the Standard Material Transfer Agreement".

14. The Director-General should request Member States to consider updating and correcting the statement in section 5.2.2 of the PIP Framework, which currently states "Recognizing that greater transparency and access concerning influenza virus genetic sequence data is important to public health and there is a movement towards the use of public-domain or public-access databases such as Genbank and GISAID respectively;"

### by amending it to:

"Recognizing that greater transparency and access concerning influenza virus genetic sequence data is important to public health and use is made of publicdomain or public-access databases such as GenBank and/or GISAID, respectively;" 15. It is critical that the PIP Framework adapts to technological developments, and that the Advisory Group produces with urgency recommendations to clarify the handling of genetic sequence data. The Advisory Group should consider asking WHO Collaborating Centres to report on how genetic sequence data are actually handled, with a view to providing information about the operational realities in GISRS in relation to the acquisition, sharing and use of such data, to inform the Advisory Group's recommendations on the optimal handling of genetic sequence data under the PIP Framework.

16. The Director-General should enlist the support of Member States to ensure that influenza virus genetic sequence data remain publicly accessible in sustainable databases, to enable timely, accurate and accessible sharing of these data for pandemic risk assessment and rapid response.

17. Noting that genetic sequence data may be generated from many entities outside of GISRS, and that there are diverse views on the optimal traceability and monitoring mechanism, the Advisory Group should give consideration to broadening and deepening engagement with all stakeholders.

### Benefit Sharing

### Standard Material Transfer Agreement 2 (SMTA2)

### Summary of Findings:

The SMTA2s signed so far have secured access to approximately 350 million doses of pandemic vaccine to be delivered in real time during an influenza pandemic. However, PIP Framework options for SMTA2 commitments from manufacturers of other pandemic products (such as diagnostics, syringes, etc.) are too narrow, and need to include a wider choice of commitments.

Good progress on securing prequalified vaccines and antivirals has been achieved through the PIP Framework Secretariat's strategic approach of prioritizing agreements with large companies with prequalified vaccines before moving on to negotiations with medium to small companies. In order to facilitate negotiations of SMTA2s, the PIP Framework Secretariat has developed tools<sup>1</sup> that outline the technical requirements, such as prequalification, export procedures and regulatory approvals, which must be fulfilled by signatories to SMTA2s.

<sup>&</sup>lt;sup>1</sup> Frequently asked questions about Standard Material Transfer Agreements 2. In: World Health Organization [website]. Geneva: World Health Organization; 2016

<sup>(</sup>http://www.who.int/influenza/pip/benefit\_sharing/smta2\_FAQs.pdf, accessed 26 September 2016).

The regularity and high quality of communication between the PIP Framework Secretariat and industry and other stakeholders has helped to facilitate the conclusion of SMTA2s. On the few occasions when negotiations have been complicated or have stalled, the PIP Framework Secretariat has successfully implemented the stepwise approach recommended by the Advisory Group to progress towards conclusion of the agreements.<sup>1</sup>

The fulfilment of SMTA2 agreements at the time of a pandemic outbreak will be critical to pandemic response. Member States with in-country influenza vaccine production capacity need to recognize the SMTA2 commitments of the manufacturer(s) into their pandemic influenza response plans.

### **Recommendations:**

18. The PIP Framework Secretariat should improve communication of progress and achievements in securing SMTA2s by better highlighting the rationale and prioritization strategy for concluding these agreements, and clarifying the intended use of the antivirals, vaccines and other products secured through these agreements.

19. The PIP Framework Secretariat should develop, for consideration by the Advisory Group, and ultimate decision-making by Member States, an approach to include the provision of financial contributions, specimen collection and processing materials as options for category B SMTA2 commitments in Annex 2.

20. The Director-General should consider requesting that Member States remove section 6.9 in the PIP Framework on pandemic influenza preparedness vaccine stockpiles, since it is no longer relevant.

21. The Director-General should request Member States with in-country vaccine production capacity to commit to allow manufacturers to release to WHO on a real-time basis, pandemic vaccines and other products secured by WHO under SMTA2s.

22. WHO should rapidly finalize and communicate the Interim Pandemic Influenza Risk Management (PIRM) Framework, which will provide clarity on the implementation of the switch from seasonal to pandemic vaccine production.

### Partnership Contribution collection

### Summary of Findings:

The involvement of industry in the collaborative development<sup>2</sup> of the PC formula has achieved its strong buy-in, and has resulted in early contribution payments being made in 2012, and the

<sup>&</sup>lt;sup>1</sup> PIP Framework Advisory Group. Meeting of the Pandemic Influenza Preparedness Framework (PIPF) Advisory Group, 15-16 October 2015, Geneva, Switzerland, Report to the Director-General. Geneva: World Health Organization; 2015 (http://www.who.int/influenza/pip/ag\_meetingreport\_october2015.pdf, accessed 22 September 2015), paragraph 8.

<sup>&</sup>lt;sup>2</sup> Partnership Contribution Standard Operating Procedures June 2015. Geneva: World Health Organization; 2015 (http://www.who.int/influenza/pip/benefit\_sharing/pc\_collection\_sop.pdf?ua=1, accessed 24 September 2016), page 5, Annex 2.

collection of 96%<sup>1</sup> of the overall funds due for 2013 and 2014. However, not all companies pay their contributions by the expected deadline, which is of concern since the PC mechanism relies on all stakeholders fulfilling their obligations.

Several industry representatives have highlighted as an issue that the fluctuation in the amount of PC they are asked to pay each year poses budgetary challenges, and they would prefer to pay a set amount.<sup>2</sup> Consistent with the recommendation of the Advisory Group in April 2016,<sup>3</sup> industry has begun a consultative process to review the PC formula, working with all relevant industry sectors (vaccine, diagnostics and pharmaceuticals) and the PIP Framework Secretariat.<sup>4</sup>

A survey of GISRS running costs was undertaken for this Review: the estimates from 41 laboratories are that their total annual running costs alone are approximately US\$ 39 million. Although this figure is preliminary, and should be studied further, this indicates that total running costs for the whole of the GISRS system are likely to have increased from the 2010 estimate.

### **Recommendations:**

23. The Advisory Group should consider updating the 2010 estimate of GISRS running/operating costs, as input to a revision of the Partnership Contribution formula calculation, in collaboration with industry, to facilitate the timely payment of Partnership Contribution, and its sustainability as a financing mechanism for implementation of the PIP Framework.

24. Given the successful use, following a recommendation by the Advisory Group, of a stepwise approach for the agreement of SMTA2s, the Advisory Group should consider developing a similar escalation response to underpayment, late payment or default of Partnership Contribution.

### Partnership Contribution implementation

### Summary of Findings:

Since PC funds began to be distributed in 2014, the implementation of the PC mechanism has allowed countries to develop multi-year plans and has fostered sustained and meaningful capacity building in priority countries in each of the five Areas of Work for Preparedness (Laboratory and Surveillance; Burden of Disease; Regulatory Capacity building; Planning for

(http://apps.who.int/iris/bitstream/10665/246229/1/WHO-OHE-PED-2016.01-eng.pdf, accessed 24 September 2016).

<sup>&</sup>lt;sup>1</sup> Calculation based on data in Pandemic Influenza Preparedness Framework, Partnership Contribution Annual Report 2015. Geneva: World Health Organization; 2016

<sup>&</sup>lt;sup>2</sup> PIP Framework Review Group. Report of the Third Meeting of the Pandemic Influenza Preparedness (PIP) Framework 2016 Review Group. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/2016-review/meeting30march\_1april.pdf, accessed 4 October 2016).

<sup>&</sup>lt;sup>3</sup> PIP Framework Advisory Group. Meeting of the Pandemic Influenza Preparedness Framework Advisory Group, 19-22 April 2016, Geneva, Switzerland. Report to the Director-General. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/ag\_april2016\_MeetingRpt.pdf?ua=1, accessed 24 September 2016).

<sup>&</sup>lt;sup>4</sup> PIP Framework Secretariat, World Health Organization, unpublished data, October 2016.

Deployment; and Risk Communication). A Response fund has also been established for use by WHO at the time of a pandemic outbreak.

However, expenditure does not always keep pace with collection, leading to a mistaken perception among some stakeholders that either additional Preparedness funds are not needed or that work plans are failing to be implemented according to planned timeframes.

The PIP Framework Secretariat communicates regularly about the achievements and challenges of PC implementation. Nevertheless, stakeholders regularly raise specific issues with WHO concerning: (1) dissatisfaction that PC funds continue to be collected while the Response funds are left untouched, which seemingly indicates a lack of understanding that the Response Fund is a contingency fund to enable rapid response at the start of a pandemic, and that the value of the Response funds is far below what will be needed at the time of a pandemic outbreak; (2) the basis on which recipient priority countries are selected, even though the criteria and process for selection have been published,<sup>1</sup> though this could indicate the desire of certain countries to be put on this list; and (3) a lack of understanding of how PC funds are building capacity in countries to increase preparedness for pandemic influenza.

### **Recommendations:**

25. The Advisory Group should consider for inclusion in the 2018-2022 Partnership Contribution Implementation Plan, the development of process measures to enable better monitoring of progress for key Areas of Work.

26. The Advisory Group should request regular financial reports and audits and ensure that appropriate financial accountability mechanisms are in place; it should also request the PIP Framework Secretariat to illustrate how the Partnership Contribution Response funds will be severely inadequate in a pandemic.<sup>2</sup>

### Governance

### Summary of Findings:

The PIP Framework has a well-functioning governance structure that oversees how the PIP Framework is operationalized. It has benefited from strong commitment at each of WHO's three levels: Headquarters; Regional Offices; and Country Offices. The Advisory Group continues to play a key role in effective governance by providing impartial, committed, and pragmatic oversight and guidance, representing its independent deliberations. However, AG members usually leave after completing individual terms of three years, meaning that there can be gaps in knowledge continuity.

<sup>&</sup>lt;sup>1</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Implementation Plan 2013-2016. Geneva: World Health Organization; 2015

<sup>(</sup>http://www.who.int/influenza/pip/pip\_pcimpplan\_update\_31jan2015.pdf?ua=1, accessed 20 September 2016), pages 9-11.

<sup>&</sup>lt;sup>2</sup> See Recommendation 2(b) of this report, which states: "WHO should regularly and more effectively communicate the objectives and progress in the implementation of the PIP Framework to Members States, Global Influenza Surveillance and Response System (GISRS) laboratories, industry, civil society, and other stakeholders. In particular, it should better communicate:

b. Partnership Contribution implementation measures; these should be highlighted in regular Advisory Group reports and post-meeting briefings so that progress is more visible and clearly recognized."

Although the AG's Annual Reports<sup>1</sup> to the Director-General and the Director-General's Biennial Reports<sup>2</sup> to the World Health Assembly are comprehensive and well-received, the formats and contents differ, leading to inefficient preparation of information.

Some GISRS members, notably WHO CCs, feel there should be greater interaction between themselves, the Advisory Group, and the PIP Framework Secretariat, including in the setting up of technical working groups and the subsequent selection of experts. The regular, direct contact that occurs between the Advisory Group and industry/civil society groups might also be helpful if it included GISRS representatives.

An objective of the PIP Framework (section 2) is to strengthen GISRS, and the geographical reach, scope and functioning of GISRS has expanded since 2011. However, the leadership of this network remains largely informal, with the system being coordinated through WHO's Global Influenza Programme (GIP). The lack of a formalized leadership structure from within GISRS has led to the absence of recognized representation for the entire GISRS network in PIP Framework operations.

Under the 2016 reform of WHO's work in health emergency management, all WHO's work in emergencies was brought under a new Health Emergencies Programme, including the Secretariat of the PIP Framework.<sup>3</sup> WHO's commitment to the PIP Framework remains unchanged by this internal reorganization. The PIP Framework Secretariat is significantly dependent on close collaboration with many technical units of WHO, especially GIP, which is the technical influenza unit that coordinates GISRS, which in turn underpins the implementation of the PIP Framework.

### **Recommendations:**

27. The Director-General should consider options for retaining continuity and knowledge in the Advisory Group, including members being able to serve a second term of flexible duration.

28. The structure of the Advisory Group's Annual Reports to the Director-General and the Director-General's Biennial Reports to the World Health Assembly should be harmonized to simplify reporting.

29. The PIP Framework Secretariat and Advisory Group should broaden and deepen engagement with civil society to a greater number of participating organizations.

30. Noting the critical role of the WHO Collaborating Centres in the GISRS network, the Advisory Group should undertake more regular engagement with the WHO Collaborating Centres and other key GISRS laboratories, including when setting up technical working groups.

<sup>&</sup>lt;sup>1</sup> PIP Framework Advisory Group Reports. In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/pip\_meetings\_consultations/en/, accessed 22 September 2016).

<sup>&</sup>lt;sup>2</sup> Ibid.

<sup>&</sup>lt;sup>3</sup> Reform of WHO's work in health emergency management, WHO Health Emergencies Programme, Report by the Director-General. In: World Health Organization [website]. Geneva: World Health Organization; 2016 (A69/30; http://apps.who.int/gb/ebwha/pdf\_files/WHA69/A69\_30-en.pdf, accessed 22 September 2016).

31. The Director-General should address the issue of the lack of a formalized representation for the GISRS network, and encourage the WHO Global Influenza Programme and GISRS to establish such representation as soon as possible.

32. The Director-General should ensure that any internal reorganization of WHO departments under the new Health Emergencies Programmes should ensure that the activities of GISRS and the PIP Framework remain closely aligned and integrated with the WHO Global Influenza Programme to ensure stronger scientific and technical leadership in the implementation of the PIP Framework.

33. The Director-General should continue to make available the necessary human and financial resources to implement the growing activities of the PIP Framework and the Recommendations of this Review.

### Linkages with WHO programmes and other legal instruments

### **Global Action Plan for Influenza Vaccines**

### Summary of Findings:

There are important synergies between the PIP Framework and the GAP programme.<sup>1,2</sup> This includes the encouragement of technology transfers and capacity building for burden of disease studies, regulatory authorities and risk communications. However, technology transfer agreements are currently not being obtained through SMTA2s.

The November 2016 review of GAP will be available to feed into an assessment of which aspects of GAP (burden of disease studies, technical guidance to new vaccine manufacturers, vaccine deployment, or logistics), might be continued as part of the PIP Framework's implementation of PC.

The quantity of pandemic influenza vaccines secured by the PIP Framework, as well as global vaccine production capacity (including new vaccine capacity available through the GAP programme) currently remain insufficient to meet anticipated global demand at the time of an influenza pandemic.

### **Recommendation:**

34. The PIP Framework Advisory Group should consider lessons learned from the Global Action Plan for Influenza Vaccines (GAP), which closes in November 2016, to identify any aspects that would support implementation of the PIP Framework.

<sup>&</sup>lt;sup>1</sup> The objectives of the GAP programme centre around increasing influenza vaccine manufacturing capacity for developing countries, and include an increase in the manufacture and use of seasonal vaccine, an increase in vaccine production capacity for pandemic vaccine, and relevant research and development. The GAP was developed by WHO together with public health and academic experts, vaccine manufacturers and funding agencies from developed and developing countries. The third and final GAP consultation will take place in November 2016.

<sup>&</sup>lt;sup>2</sup> Global Action Plan for Influenza Vaccines (GAP). In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza\_vaccines\_plan/en/, accessed 22 September 2016).

### International Health Regulations (2005)

### Summary of Findings:

PIP Framework PC funds may have additional benefits in improving IHR (2005)<sup>1</sup> core capacities, especially in the areas of laboratory and surveillance capacity. However, since PC funds only began to be distributed in 2014, data on the relationship between PC implementation funds and IHR (2005) core capacities are not yet available. An analysis of PC funds' impact on IHR (2005) core capacities could be undertaken in the next review of the PIP Framework.

### **Recommendation:**

35. Activity under the PIP Framework should be undertaken with the provisions of the International Health Regulations (2005) (IHR (2005)) in mind, and capacity building efforts should be aligned, supportive and complementary to those under the IHR (2005). This could be addressed by closer interaction at all three levels of WHO regarding implementation of the IHR (2005) and the PIP Framework to maximise synergies and efficiencies.

### Nagoya Protocol to the Convention on Biological Diversity

### Summary of Findings:

The PIP Framework is a multilateral access and benefit sharing instrument that appears to be consistent with the objectives of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity.<sup>2</sup> The intergovernmental negotiation of the PIP Framework established rules for access to IVPP and sharing of benefits; by contrast, the implementation of the Nagoya Protocol may introduce uncertainty in relation to the sharing of influenza viruses, since numerous bilateral transactions could be required to be negotiated, which could delay the access to viruses. As more countries put in place domestic legislation to implement the Nagoya Protocol, the urgency increases to resolve this uncertainty and reduce the risk to global health security.

The public health implications of the implementation of the Nagoya Protocol are not yet widely understood. While the WHO Secretariat is producing a report to clarify these implications, better knowledge, understanding and awareness of the Protocol are required in the public health sector.

The Nagoya Protocol does not expressly identify a mechanism to recognize an instrument under its Article 4(4). The Review Group understands that an authoritative, formal and internationally credible entity such as the Meeting of the Parties (MOP) or World Health Assembly could make a decision that the PIP Framework constitutes a specialized international

<sup>&</sup>lt;sup>1</sup> International Health Regulations (2005), 2<sup>nd</sup> ed. Geneva: World Health Organization; 2008 (http://apps.who.int/iris/bitstream/10665/43883/1/9789241580410\_eng.pdf, accessed 22 September 2016).

<sup>&</sup>lt;sup>2</sup> The Nagoya Protocol on Access and Benefit-sharing. In: Convention on Biological Diversity [website]. Montreal: Convention on Biological Diversity, United Nations; 2011 (https://www.cbd.int/abs/, accessed 4 October 2016).

instrument for pandemic influenza preparedness and response. In this case, the decision should facilitate fulfilment of the PIP Framework's access and benefit sharing objectives by ensuring that all countries would handle IVPP in the same way. IVPP access and sharing would be covered for Nagoya Protocol purposes by the PIP Framework, and therefore not require bilateral agreements on a case-by-case basis.

### **Recommendation:**

36. The PIP Framework should be considered as a specialized international instrument to clarify the implementation of the Nagoya Protocol in relation to pandemic influenza preparedness and response:

- The December 2016 Meeting of the Parties of the Nagoya Protocol provides an opportunity to consider recognizing the PIP Framework as a specialized international instrument for pandemic influenza preparedness and response. In the view of the Review Group, it would serve the aims of the PIP Framework if the Meeting of the Parties took up this opportunity.
- Further, the 2017 World Health Assembly should address the recognition of the PIP Framework as a specialized international instrument under the Nagoya Protocol.

## Chapter 1: Introduction and background

Ensuring the health security of all people is an overarching concern in public health today. The tremendous increase in international travel over the last 40 years or so means that diseases are no longer contained by geography alone. Health security became a prominent aspect of global health after the severe acute respiratory syndrome (SARS) outbreak in 2003, the reemergence of influenza A(H5N1) beginning in 2003 and 2004, and the influenza A(H1N1) pdm09<sup>1</sup> pandemic in 2009. In 2011, the Report of the Review Committee on the Functioning of the International Health Regulations (2005) (IHR (2005)) in relation to the 2009 pandemic of influenza A(H1N1) concluded that the world was "ill-prepared" to respond to a severe influenza pandemic and that "the unavoidable reality is that tens of millions of people would be at risk of dying in a severe pandemic".<sup>2</sup> These events taught the world a valuable lesson – an effective response to an outbreak of an infectious pathogen that can easily cross borders can only ever come about through close collaboration and information-sharing between countries.

After the re-emergence of influenza A(H5N1) with human pandemic potential, some developing countries were concerned that despite contributing virus samples to the Global Influenza Surveillance and Response System (GISRS) network of public health laboratories that collect, monitor and share influenza viruses, they were unable to afford vaccines and other medical products developed as a result of sharing viruses. It became clear that a new system was needed that lifted barriers to virus sharing among scientists, industry and countries, while ensuring that the products of such sharing could be fairly and easily accessed by those who need them most.

After four years of negotiation, this new system was embodied in the Pandemic Influenza Preparedness (PIP) Framework<sup>3</sup> – an international instrument set up by 194 WHO Member States in 2011<sup>4</sup> that brought together countries, industry and civil society to ready the world's defences and strengthen its capacity to respond to an influenza pandemic. The PIP Framework does this by facilitating the sharing between countries of influenza viruses with human pandemic potential (IVPP), in order to develop antivirals, vaccines and diagnostics, while ensuring fair and equitable access to these products across the world. The PIP Framework also seeks to increase capacity for pandemic preparedness in all countries, and prioritizes support to those most in need. A fundamental tenet of the PIP Framework is that the sharing of viruses and benefits takes place on an equal footing, balancing public health and economic interests in a win-win model based on the principle of reciprocity (see Figure 1.1). The PIP Framework

(http://apps.who.int/gb/ebwha/pdf\_files/WHA64/A64\_10-en.pdf, accessed 20 September 2016).

<sup>&</sup>lt;sup>1</sup> Influenza A(H1N1)pdm09 is the virus responsible for the 2009 influenza pandemic that was declared the first Public Health Emergency of International Concern under the International Health Regulations (2005).

<sup>&</sup>lt;sup>2</sup> Implementation of the International Health Regulations (2005), Report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009, Report by the Director-General. Geneva: World Health Organization; 2011 (A64/10;

<sup>&</sup>lt;sup>3</sup> Pandemic influenza preparedness framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011 (http://www.who.int/influenza/pip/en/, accessed 19 September 2016).

<sup>&</sup>lt;sup>4</sup> Agenda item 13.1. Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits. Sixty-fourth World Health Assembly. Geneva: World Health Organization; 2011 (WHA64.5; http://apps.who.int/gb/ebwha/pdf\_files/WHA64/A64\_R5-en.pdf, accessed 21 September 2016).

allows effective coordination without the need constantly to rewrite the rule book, which would cause delays that can be devastating to public health during a fast-moving pandemic.

Viruses are shared through the 152 GISRS laboratories, including 143 National Influenza Centres (NICs) spread across 113 Member States, six WHO Collaborating Centres (WHO CCs) for Reference and Research on Influenza, four WHO Essential Regulatory Laboratories (WHO ERLs), and 13 WHO H5 Reference Laboratories (WHO H5RLs).<sup>1,2</sup> The Standard Material Transfer Agreement 1 (SMTA1), contained in Annex 1 to the PIP Framework, is a binding contract that establishes the conditions under which GISRS laboratories exchange PIP biological materials (PIP BM) among themselves. With the advent of technology to sequence and analyse genetic sequence data (GSD), an increasing proportion of viruses are shared electronically through their genetic sequences, although GSD is not included in the definition of PIP BM.

The PIP Framework's benefit sharing aspect occurs in two ways: Partnership Contribution (PC) funds and Standard Material Transfer Agreement 2s (SMTA2s). Influenza vaccine, pharmaceutical and diagnostic manufacturers who use GISRS pay annual PC funds totalling US\$ 28 million, which are used to bolster pandemic Preparedness and Response. Non-GISRS entities, such as manufacturers or academic institutions, who receive physical virus samples sign an STMA2, a legally binding agreement to provide products such as vaccines, antivirals and diagnostics in the event of a pandemic.

### Why is the Framework being reviewed now?

This first review of the PIP Framework (the "Review") was provided for under section 7.4.2 of the PIP Framework, which states that the PIP Framework and its Annexes should be reviewed by 2016 "with a view to proposing revisions reflecting developments as appropriate, to the World Health Assembly in 2017, through the Executive Board".

The PIP Framework Advisory Group (the "Advisory Group") met in a Special Session on 13-14 October 2015 to seek views from Member States, industry and other stakeholders on the review. The outcome of that meeting was a recommendation that a small, independent group of experts be established to review implementation of the PIP Framework using a transparent and inclusive approach.<sup>3</sup> In response, the Director-General convened the Review Group, consisting of eight experts with wide-ranging expertise and from across all WHO regions. The Review Group was charged with answering the following questions:<sup>4</sup>

<sup>&</sup>lt;sup>1</sup> Global Influenza Surveillance and Response System (GISRS). In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/gisrs\_laboratory/en/, accessed 20 October 2016).

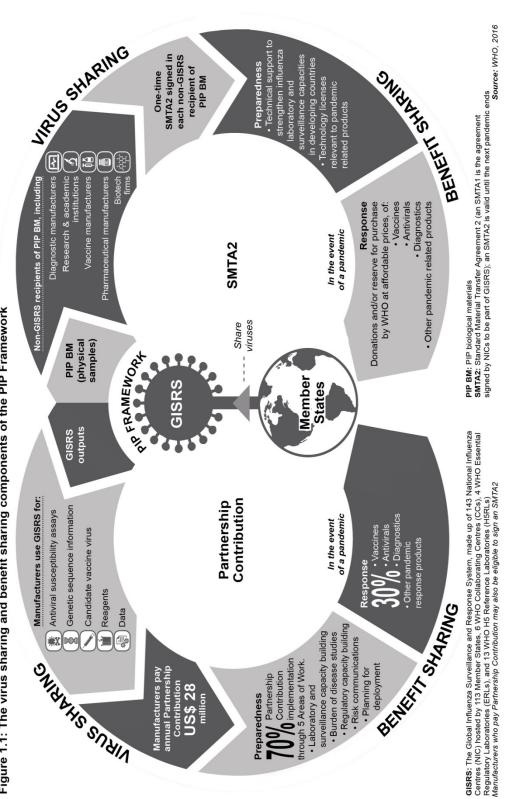
<sup>&</sup>lt;sup>2</sup> Outside GISRS there are also influenza laboratories authorized and designated by a Member State to provide PIP BM to GISRS. These laboratories are either in Member States that do not have a NIC or are additional laboratories carrying out certain roles usually performed by NICs.

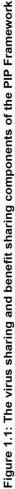
<sup>&</sup>lt;sup>3</sup> PIP Framework Advisory Group. Special session of the Pandemic influenza preparedness (PIP) Framework Advisory Group, 13-14 October 2015, Geneva, Switzerland. Report to the Director-General. Geneva: World Health Organization; 2015 (http://www.who.int/influenza/pip/advisory\_group/ag\_spec\_session\_report.pdf, accessed 24 September 2016).

1. What are the achievements since the PIP Framework was adopted?

2. Has implementation of the PIP Framework improved global pandemic influenza preparedness, including inter-pandemic surveillance, and capacity to respond?

3. What are the challenges, and possible ways of addressing them?





## Chapter 2: Method of Work

The Advisory Group's Special Session on 13-14 October 2015 sought views from Member States, industry and other stakeholders on the terms of reference and direction of the Review. Following the meeting, the Advisory Group reported to the Director-General, with recommendations on the organization, process, scope and terms of reference for the Review.<sup>1</sup>

The Review Group was appointed in December 2015, and held four face-to-face meetings between March 2016 and September 2016 at WHO Headquarters in Geneva. These meetings were preceded by two teleconferences, in January and February 2016. The Review Group held deliberative sessions, open only to members of the Review Group and the WHO Review Group Secretariat. In addition, representatives of Member States were invited to attend a debriefing and question/answer session following the February 2016 teleconference and the March 2016, June 2016 and August/September 2016 meetings. These sessions were open to all stakeholders and the public via a live webcast on the WHO website.<sup>2</sup> In addition, the Review Group Chair, Dr Christine Mwelwa Kaseba-Sata, presented an update of the Review Group's work at the Sixty-ninth World Health Assembly on 25 May 2016.<sup>3</sup>

The methods of work of the Review Group are detailed in Appendix II and summarized briefly as follows. The Review Group began its work by conducting a systematic analysis of the PIP Framework, highlighting areas considered not to be functioning effectively and possible reasons for this. The Review Group reviewed key documents, including reports relating to the work of the Advisory Group, implementation of the PIP Framework, and a study on the implementation of the Nagoya Protocol.

To inform its deliberations, the Review Group actively sought input throughout the review from Member States and representatives of GISRS, industry, civil society organizations (s), relevant databases and other stakeholders, through both interviews and an electronic open consultation process that included questions for response. On 30 March 2016 and 29 August 2016, as part of Review Group meetings, open consultations were held at WHO HQ, with Member States, civil society and other stakeholders. Overall, the Review Group conducted 40 interviews with key informants; received several written submissions from Member States, industry, civil society, databases, and other stakeholders; examined other initiatives underway to protect global public health; and sought information from WHO staff at HQ and Regional Offices.

<sup>&</sup>lt;sup>1</sup> Ibid.

<sup>&</sup>lt;sup>2</sup> PIP Framework Review Group. 2016 Review of the PIP Framework, PIP Review Group Meeting Reports. In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/2016-review/meetings/en/, accessed 20 September 2016).

<sup>&</sup>lt;sup>3</sup> Dr Christine Mwelwa Kaseba-Sata, Review Group Chair. Update of the Review Group's work at the Sixty-ninth World Health Assembly. Committee A, Wednesday 25 May 2016, Late Session. In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/mediacentre/events/2016/wha69/webstreaming/en/, accessed 29 September, 2016).

The Review Group provided its final Report to the Director-General in October 2016, for transmission to the WHO Executive Board in January 2017 and the World Health Assembly in May 2017.

## Chapter 3: Overarching Analysis

In this report, the Review Group responds to its terms of reference to:<sup>1</sup>

1 Discuss achievements of the PIP Framework

2. Discuss whether implementation of the PIP Framework improved global pandemic influenza preparedness, including inter-pandemic surveillance, and capacity to respond

3. Discuss possible challenges and ways of addressing them.

This chapter addresses the first two points by taking an overarching perspective on the PIP Framework as a whole and the overall achievements (see Figure 3.1) and challenges; subsequent chapters 4 - 8 address the third point by considering achievements and challenges associated with specific elements of the PIP Framework and the ways in which challenges might be addressed.

<sup>&</sup>lt;sup>1</sup> PIP Framework Advisory Group. Special session of the Pandemic influenza preparedness (PIP) Framework Advisory Group, 13-14 October 2015, Geneva, Switzerland. Report to the Director-General. Geneva: World Health Organization; 2015 (http://www.who.int/influenza/pip/advisory\_group/ag\_spec\_session\_report.pdf, accessed 24 September 2016).

### Figure 3.1 Top 10 achievements of the PIP Framework



### 3.1 An innovative approach to improving pandemic preparedness

### Key Findings

Finding 1: The PIP Framework, which was negotiated through an extensive intergovernmental process, is valued as a bold and innovative tool for pandemic influenza preparedness. It demonstrates that the balance of virus sharing and benefit sharing on an equal footing is a successful approach for improving pandemic influenza preparedness, which contributes to strengthening global health security.

Finding 2: The PIP Framework has improved global influenza pandemic preparedness through more reliable access to viruses, and its ongoing efforts in securing increased, realtime access to vaccines and antivirals in the event of an influenza pandemic. It has also improved preparedness by funding capacity building in priority countries with limited or no national ability to detect, monitor and share novel influenza viruses, and by ensuring that there is a reserved Response Fund for response. Through these activities, there is confidence and greater predictability in the global capacity to respond to an influenza pandemic as well as in the equity of that response.

Finding 3: The PIP Framework is a model within which Member States engage transparently and effectively, via WHO, with different stakeholders, including industry and civil society. WHO regularly brings industry and civil society to the table with Member States to operationalise different aspects of the PIP Framework and engages them at key decision making points. Given their varied perspectives, these stakeholders provide critical input that contribute to the success of the PIP Framework.

Finding 4: The ongoing risk assessment by GISRS of seasonal influenza viruses and periodic risk assessment of other zoonotic influenza viruses to ascertain pandemic potential provide key benefits for countries in strengthening core capacities for seasonal influenza response and pandemic preparedness.

Finding 5: While there is regular reporting on individual aspects of the PIP Framework, as provided for in sections 7.2.5 and 7.4.1, these elements are not currently brought together in a comprehensive evaluation model, and thus it is challenging for different stakeholders to gain a comprehensive picture of overall progress.

Finding 6: Contributions made to the PIP Framework could be given more visible recognition and acknowledgement, including the significant support by Member States for their GISRS laboratories. Such recognition could build on the PIP Framework Secretariat's existing practice of formally acknowledging PC payments.

The PIP Framework took an innovative approach to engaging stakeholders, especially industry, in a way that had not previously been achieved in public health. It brought key players in public and private health care together in a partnership that was challenging to negotiate, but has proven successful.

### **3.2** Ensuring the relevance of the PIP Framework

Finding 7: The principles of the PIP Framework, especially that of placing virus sharing and benefit sharing on an equal footing, remain as relevant today as they were five years ago, given the unique threat that the ever-changing influenza virus presents for public health, and the increasing number of health emergencies, such as the Ebola virus disease and Zika virus outbreaks.

Finding 8: Maintaining the contribution of the PIP Framework, and demonstrating the benefits of pandemic influenza preparedness, is especially important as countries with several competing health priorities usually focus their attention on current local disease threats and therefore may be unprepared for an influenza pandemic. The PIP Framework must continue to demonstrate its contribution towards increasing global health security in the context of a wider landscape of public health interventions in order to remain relevant to policymakers, government, industry and intergovernmental organizations.

Finding 9: Currently, the PIP Framework does not specify the timing of subsequent reviews. To ensure the continued relevance and optimal impact of the PIP Framework, regular review of its functioning is needed. There is a need for Member States to indicate how often future reviews should take place.

Finding 10: An increasingly urgent concern among Member States and other stakeholders has been how to address the impact of new technology, particularly relating to the handling of GSD under the PIP Framework.

While the text of the PIP Framework was formulated in a manner that was as forwardthinking as possible, it also reflects a particular political, scientific, technological and economic point in time. Preparing the world for an influenza pandemic remains a critical mission and it is important that the PIP Framework retains its relevancy by adapting to the ever-changing landscape of global health.

Global health, especially in relation to infectious pathogens, has become increasingly framed in the context of health security, where the various initiatives and key players extend beyond the health sector to include humanitarian actors, development agencies, UN agencies, and communities. The financing landscape is also wider, with funding for pandemics now including the new World Bank's Pandemic Emergency Facility.<sup>1</sup>

The PIP Framework must also accommodate advances in technology that may change the way influenza viruses are shared or lead to the development of new products. These changes can include new methods of laboratory analysis, changes in influenza vaccine production technology, and novel communication technologies, as well as developments in the use of the genetic sequences of influenza viruses.

<sup>&</sup>lt;sup>1</sup> Pandemic Emergency Facility: Frequently Asked Questions. In: The World Bank [website]. Geneva: World Bank; 2016 (http://www.worldbank.org/en/topic/pandemics/brief/pandemic-emergency-facility-frequentlyasked-questions, accessed 26 October 2016).

### **3.2.1** Discussion on expanding the PIP Framework to seasonal influenza

Finding 11: The Review Group received wide-ranging views from key informants, including Member States, industry and civil society, on this complex and challenging issue, with strong views both for and against including seasonal influenza under the PIP Framework. The implications of including seasonal influenza need to be studied further.

The PIP Framework states in its scope (section 3.2) that the PIP Framework "does not apply to seasonal influenza viruses". Such inclusion was considered but seasonal influenza viruses were not included in the final text of the PIP Framework. In reality, however, seasonal and pandemic influenza viruses exist as a continuum, involving humans, birds and other animals. Each of the novel IVPP is due to the continuously evolving nature of the virus, which can reassort with other influenza viruses. This is known as "antigenic shift"<sup>1</sup> and can rapidly lead to new viruses with pandemic potential.

The overwhelming majority of viruses shared through GISRS are seasonal viruses – annually, 28,000 seasonal viruses are shared with WHO CCs.<sup>2</sup> These viruses undergo "antigenic drift"<sup>3</sup> through mutation, often requiring an update of the viruses in the seasonal vaccine. Moreover, this "drift" can be significant leading to more virulent seasonal viruses. The bulk of GISRS work is based on seasonal risk assessment, virus characterisation, the development of candidate vaccine viruses (CVVs), reagents and diagnostic kits, and vaccine virus recommendations for the seasonal vaccine. This is of critical importance to manufacturers and countries. Moreover, robust seasonal vaccine production is vital for pandemic vaccine production since the same facilities are used. Such facilities must be robust if there is to be a rapid and timely switch from seasonal vaccine to pandemic vaccine production at the right time.<sup>4</sup>

<sup>&</sup>lt;sup>1</sup> According to the U.S. Centers for Disease Control and Prevention (CDC), "Antigenic shift is an abrupt, major change in the influenza A viruses, resulting in new hemagglutinin and/or new hemagglutinin and neuraminidase proteins in influenza viruses that infect humans. Shift results in a new influenza A subtype or a virus with a hemagglutinin or a hemagglutinin and neuraminidase combination that has emerged from an animal population that is so different from the same subtype in humans that most people do not have immunity to the new (e.g. novel) virus". How the Flu Virus Can Change: "Drift" and "Shift". Atlanta, GA: Centers for Disease Control and Prevention; 2016 (http://www.cdc.gov/flu/about/viruses/change.htm, accessed 19 September 2016).

<sup>&</sup>lt;sup>2</sup> Global Influenza Programme, World Health Organization, unpublished data, October 2016.

<sup>&</sup>lt;sup>3</sup> The U.S. CDC further defines antigenic drift as "small changes in the genes of influenza viruses that happen continually over time as the virus replicates." How the Flu Virus Can Change: "Drift" and "Shift". Atlanta, GA: Centers for Disease Control and Prevention; 2016 (http://www.cdc.gov/flu/about/viruses/change.htm, accessed 19 September 2016).

<sup>&</sup>lt;sup>4</sup> Influenza Vaccine Response during the Start of a Pandemic, Report of a WHO Informal Consultation held in Geneva, Switzerland, 29 June-1 July 2015. Geneva: World Health Organization; 2016 http://apps.who.int/iris/bitstream/10665/207751/1/WHO\_OHE\_PED\_GIP\_2016.1\_eng.pdf, accessed 20 September 2016).

It should be noted that in the implementation of the PIP Framework's PC mechanism, the value of seasonal vaccine production is the basis on which each of the vaccine producers using GISRS determines its "sales band", which in turn is the determining factor for calculating the amount each company is asked by WHO to contribute.

The distinction between seasonal and pandemic viruses can present challenges. This becomes particularly evident when a virus – such as the influenza A(H1N1) – causes a severe epidemic in a country well after the original pandemic has been declared over. This happened in May 2016 in Fiji, when influenza A(H1N1) caused several deaths in pregnant women,<sup>1</sup> well after the pandemic had been declared over.

However, expanding the PIP Framework to include seasonal influenza would lead to a significant increase in workload for GISRS laboratories if seasonal viruses were tracked in the same way as IVPP. The benefit sharing aspect would also need to be addressed.

### **3.2.2 Improved communication about the PIP Framework**

Finding 12: Some stakeholders do not clearly understand key aspects of the PIP Framework, including priority country selection for PC implementation and the progress that is being achieved in PC-funded projects. While WHO and the Advisory Group already engage in regular, transparent communication with stakeholders, these gaps in understanding need to be addressed by enhancing communication about key aspects of the PIP Framework, its implementation and achievements.

The implementation of the PIP Framework would benefit from as wide an understanding as possible. Although the PIP Framework Secretariat communicates frequently through face-to-face meetings, teleconferences and newsletters, and the WHO's PIP Framework website,<sup>2</sup> the turnover of staff within Member State permanent missions in Geneva, WHO Regional Offices and stakeholder organizations leads to a loss of institutional memory, which means that they become less well engaged with the PIP Framework.

Communication about the importance of the PIP Framework for public health should also target a wider range of civil society organizations, since a lack of understanding about the seriousness of influenza can have wider impacts on health.

<sup>&</sup>lt;sup>1</sup> Fiji Health & Nutrition Cluster. Bulletin #8: Covering Period 6 May-13 June, 2016. In: Fiji Ministry of Health and Medical Services [website] Toorak: Fiji Ministry of Health and Medical Services; 2016 (http://www.health.gov.fj/wp-content/uploads/2016/03/20160613\_HNC\_Bulletin8\_final.pdf, accessed 4 October 2016).

<sup>&</sup>lt;sup>2</sup> Pandemic Influenza Preparedness (PIP) Framework. In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/en/, accessed 20 September 2016).

### **3.3 Applying the PIP Framework to other pathogens**

Finding 13: The success of the PIP Framework in ensuring better and more equitable access to viruses, vaccines, antivirals and diagnostics, has led some stakeholders to propose that the PIP Framework be expanded to include other infectious pathogens, whereas others have suggested applying the principles of the PIP Framework as a model.

Finding 14: Expanding the current PIP Framework to pathogens other than influenza viruses, as the 2016 report of the UN High Level Panel on the Global Response to Health Crises<sup>1</sup> has recommended, would be a very complicated process and may threaten its viability; no other disease has a system in which a network of public health laboratories and industry have such a long-standing interdependence.

Finding 15: Using the principles of the PIP Framework as a model for equity and reciprocity in other diseases, as recommended by the 2016 report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response,<sup>2</sup> is likely to be more feasible than expanding its scope, although this is still likely to be challenging.

The success of the PIP Framework has led some to consider how lessons from its implementation could be applied to other diseases. Some reports have gone as far as suggesting that the PIP Framework itself be expanded. The UN High Level Panel on the Global Response to Health Crises, which published its report in January 2016, recommended that "The WHO convenes its Member States to re-negotiate the Pandemic Influenza Preparedness Framework with a view to including other novel pathogens, making it legally binding, and achieving an appropriate balance between obligations and benefits, in accordance with the principles of the 2010 Nagoya Protocol to the Convention on Biological Diversity".<sup>3</sup>

In the view of this Review Group, while the PIP Framework could serve as an effective model, an expansion of the PIP Framework itself to include other pathogens would be very challenging. A more pragmatic approach is reflected in the 2016 report of the IHR (2005) Review Committee, which recommended that WHO and States Parties should "consider using the PIP Framework or similar existing agreements as a template for creating new agreements or other infectious agents that have caused, or may potentially cause, [public health emergencies of international concern] PHEICs. These agreements should be based

<sup>&</sup>lt;sup>1</sup> Protecting Humanity from Future Health Crises, Report of the High-level Panel on the Global Response to Health Crises, Recommendation 15. United Nations General Assembly, 9 February 2016. New York: United Nations; 2016 (A/70/723; http://www.un.org/ga/search/view\_doc.asp?symbol=A/70/723, accessed 20 September; 2016).

<sup>&</sup>lt;sup>2</sup> Implementation of the International Health Regulations (2005), Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response, Report by the Director-General, 13 May 2016. Geneva: World Health Organization; 2016 (A69/21; http://apps.who.int/gb/ebwha/pdf\_files/WHA69/A69\_21-en.pdf?ua=1, accessed 20 September 2016).

<sup>&</sup>lt;sup>3</sup> Protecting Humanity from Future Health Crises, Report of the High-level Panel on the Global Response to Health Crises, Recommendation 15. United Nations General Assembly, 9 February 2016. New York: United Nations; 2016 (A/70/723; http://www.un.org/ga/search/view\_doc.asp?symbol=A/70/723, accessed 20 September; 2016).

on the principle of balancing the sharing of samples and data with benefit sharing on an equal footing".<sup>1</sup>

Balancing the interests of different stakeholders to ensure equity in public health is complex. That the PIP Framework was the first global agreement of its kind has much to do with the uniqueness of the influenza virus itself – it mutates frequently and, because of the need for updated seasonal influenza vaccines, has a continuous product cycle, which therefore results in a consistent income stream for manufacturers, as well as a high quality production line that allows manufacturers to be ready to switch from seasonal to pandemic vaccine production. There is also a strong, established network of laboratories in GISRS, monitoring influenza, which provided the foundation for the PIP Framework.

However, for most new and emerging pathogens, there is no established laboratory network that regularly shares samples and expertise with an associated established vaccine (or other product) production capacity. Thus, while the sharing of viruses and benefits on an equal footing could be applied to other pathogens, using the PIP Framework as a template is likely to present significant implementational and operational challenges.

### **Recommendations: Overarching**

1. WHO should develop a comprehensive evaluation model, including overall success metrics for the Pandemic Influenza Preparedness (PIP) Framework for annual reporting. Such reporting should include an infographic that illustrates the status of overall progress in implementing the PIP Framework to allow for greater clarity on progress towards pandemic preparedness and response.

2. WHO should regularly and more effectively communicate the objectives and progress in the implementation of the PIP Framework to Members States, Global Influenza Surveillance and Response System (GISRS) laboratories, industry, civil society, and other stakeholders. In particular, it should better communicate:

a. Progress against the comprehensive evaluation model;

b. Partnership Contribution implementation measures; these should be highlighted in regular Advisory Group reports and post-meeting briefings so that progress is more visible and clearly recognized;

c. Communication and transparency should be enhanced around issues such as selection of countries to receive Partnership Contribution implementation support for improved understanding of the PIP Framework among Member States;

d. The significance of stakeholder voluntary contributions, and in-kind Member States' commitments, including support and maintenance of GISRS through provision of routine running costs of laboratories.

<sup>&</sup>lt;sup>1</sup> Implementation of the International Health Regulations (2005), Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response, Report by the Director-General, 13 May 2016. Geneva: World Health Organization; 2016 (A69/21; http://www.accessed.com/access

http://apps.who.int/gb/ebwha/pdf\_files/WHA69/A69\_21-en.pdf?ua=1, accessed 20 September 2016).

3. The Director-General should undertake a study to determine the implications and desirability of including seasonal influenza viruses in the PIP Framework.

4. The PIP Framework is a foundational model of reciprocity for global public health that could be applied to other pathogens; however, the current scope of the PIP Framework should remain focused on pandemic influenza at this time.

5. Member States should agree the timing of the next review of the PIP Framework, which should be before the end of 2021.

## Chapter 4: Virus sharing

## 4.1 Overview

### Key Findings

Finding 16: The GISRS virus sharing system generally works well and is expanding to cover more geographical regions. Between 2011 and 2016, the number of NICs has increased from 136 to 143, the number of WHO H5RLs from 12 to 13; the number of WHO CCs remained at six and the number of WHO ERLs at four. At an operational level, there are platforms for the rapid exchange of information and strong interactions between different organizations. The WHO Shipping Fund Project ("Shipping Fund") has increased laboratories' ability to share viruses.

Finding 17: The PIP Framework (Annex 4) sets out guiding principles for the terms of reference for the WHO GISRS laboratories; assessment of whether those terms of reference are fulfilled is carried out through self-assessment by GISRS laboratories and surveys of NICs. The evidence is that laboratories comply with their SMTA1 obligations.

Finding 18: The Review Group's discussions with key informants from laboratories indicated that they were unclear on how to interpret the definition of "timely" and "representative" with respect to the sharing of PIP BM and GSD, and on the meaning of "as feasible" with regard to the sharing of all cases of A(H5N1) and other IVPP in section 5.1.1 of the Framework.

Finding 19: GISRS provides significant benefits, including conducting critical risk assessment, and providing vaccine viruses and vaccine virus recommendations, diagnostic kits, reagents, reference viruses, expertise, training and capacity building. The laboratory capacity developed for influenza appears to have had collateral benefits for other pathogens, such as Middle East respiratory syndrome coronavirus (MERS-CoV).<sup>1</sup> The Review Group found, however, that there are some barriers (including political, regulatory and logistical) to the provision of reagents and diagnostic kits to some laboratories.

Finding 20: The GISRS self-assessment also revealed weaknesses, such as gaps in geographic coverage (particularly in Africa and the Middle East) along with insufficient national funding and a lack of prioritization of influenza surveillance.<sup>2</sup>

Finding 21: There are enduring links between GISRS and non-GISRS laboratories, especially those from the animal sector. However, some informants felt that there should be stronger linkages between the GISRS and non-GISRS parts of the system.

Finding 22: GISRS collaborates closely with the Food and Agriculture Organization of the United Nations (FAO), the World Organisation for Animal Health (OIE), and the OFFLU (the

<sup>&</sup>lt;sup>1</sup> Self-assessment of the WHO Global Influenza Surveillance and Response System (GISRS), Report to the Advisory Group. Geneva: World Health Organization; 2014 (http://www.who.int/influenza/pip/virus\_sharing/gisrs\_self\_assessment.pdf, accessed 19 September 2016),

<sup>(</sup>http://www.who.int/influenza/pip/virus\_sharing/gisrs\_self\_assessment.pdf, accessed 19 September 2016), section 4.1.

<sup>&</sup>lt;sup>2</sup> *Ibid.,* section 4.2.

joint OIE-FAO network of animal influenza experts) to conduct risk assessment and development of CVVs. In some cases, where viruses from human infections are not shared (or their sharing is delayed) due to export controls, political hesitancy, or other reasons, animal viruses have been used for risk assessment and CVV development. However, there is a lack of clarity over when to share animal samples to GISRS, which could be improved.

Finding 23: In the event of an influenza pandemic, GISRS will face a surge of samples to process, and concerns have been raised that the network could become overwhelmed. WHO has provided guidance to prepare for this contingency, including prioritization of virus samples to be forwarded to WHO CCs for further analysis and development of CVVs.<sup>1</sup> This guidance proved valuable during the 2009 A(H1N1) pandemic, and it will be necessary to maintain or improve it as necessary, and continue to make it publicly available.

Finding 24: Following the recent launch of the Tool for Influenza Pandemic Risk Assessment (TIPRA),<sup>2</sup> there is an opportunity for WHO to work with Member States that have GISRS laboratories to strengthen risk assessment capacities for pandemic influenza.

Given the rapidly evolving nature of influenza and the potential threat it poses as a pandemic-prone disease, a robust, global system for sharing influenza viruses is vital to surveillance, preparedness and response. Monitoring global influenza virus evolution and spread helps public health officials perform risk assessment studies and identify potential pandemic viruses, while virus samples and genetic sequence information are indispensable for developing the diagnostics, vaccines and pharmaceuticals needed to detect, prevent and treat illness.

GISRS performs many of these functions and is the backbone of the PIP Framework. For more than 60 years a global network of public health laboratories, known as the Global Influenza Surveillance Network (GISN), had been collecting and monitoring influenza viruses. Its name was changed to GISRS when the PIP Framework was adopted in 2011, to reflect an expanded role for the network. This role is established in the SMTA1, in Annex 1 to the PIP Framework, which is a binding contract that sets out the conditions under which laboratories in GISRS exchange influenza viruses with human pandemic potential among themselves.

GISRS laboratories track the evolution of influenza viruses, providing vital risk assessment (see Box 4.1) and early warning to Member States, for instance through monthly risk assessment summaries.<sup>3</sup> Although the PIP Framework (section 3) is limited to IVPP, the GISRS network handles all human influenza viruses and some animal influenza viruses that present a threat to humans (e.g. H3N2v and H5, H7, H9). All influenza viruses that are

<sup>&</sup>lt;sup>1</sup> WHO checklist for influenza pandemic preparedness planning. Geneva: World Health Organization; 2005 (WHO/CDS/CSR/GIP/2005.4; http://www.who.int/influenza/resources/documents/FluCheck6web.pdf, accessed 19 September 2016).

<sup>&</sup>lt;sup>2</sup> Tool for Influenza Pandemic Risk Assessment (TIPRA), Version 1 Release. Geneva: World Health Organization; 2016 (WHO/OHE/PED/GIP/2016.2; http://apps.who.int/iris/bitstream/10665/250130/1/WHO-OHE-PED-GIP-2016.2-eng.pdf, accessed 4 October 2016).

<sup>&</sup>lt;sup>3</sup> Monthly Risk Assessment Summary, Influenza at the Human-Animal Interface. In: World Health Organization [website]. Geneva: World Health Organization; 2011 to 2016 (http://www.who.int/influenza/human\_animal\_interface/HAI\_Risk\_Assessment/en/, accessed 20 September 2016).

relevant for seasonal vaccines or pandemic preparedness should enter the GISRS network through an appropriate channel.

The GISRS network provides significant benefits to Member States and others, including specialist informal consultation on the improvement of influenza vaccine virus selection,<sup>1</sup> guidance on switching from seasonal to pandemic vaccine production,<sup>2</sup> training courses, specialist conferences for NICs, and increased collaborative scientific publications, such as on how WHO makes its vaccine virus recommendations.<sup>3</sup> In some cases, the GISRS network has also been leveraged to respond to threats from non-influenza pathogens (e.g. for surveillance of respiratory syncytial virus (RSV))<sup>4</sup> and some GISRS laboratories routinely detect other pathogens, such as measles and polio.<sup>5</sup>

NICs form the core of GISRS. They are responsible for gathering "clinical specimens from patients suspected to be infected with" IVPP, acting "as a collection point for virus isolates of suspected" IVPP, conducting preliminary testing, and shipping "within one week, clinical specimens and/or viruses" among other duties.<sup>6</sup> Member States, through their NICs, are required to "provide PIP biological materials from all cases [of IVPP], as feasible" within one week to a WHO CC or WHO H5RL "of the originating Member State's choice".<sup>7</sup>

The WHO CCs conduct detailed analyses of IVPP, including "typing and subtyping", virus isolation, "detailed antigenic and genetic analyses", and "antiviral susceptibility testing" among other tasks.<sup>8</sup> A key function of WHO CCs is the selection and creation of CVVs. A CVV is a virus that has been altered from the wild type<sup>9</sup> to make it more suitable for the

<sup>3</sup> Ampofo W, Azziz-Baumgartner E, Bashir U, Cox NJ, Fasce R, Giovanni M, et al. Strengthening the influenza vaccine virus selection and development process: Report of the 3<sup>rd</sup> WHO Informal Consultation for Improving Influenza Vaccine Virus Selection held at WHO headquarters, Geneva, Switzerland, 1-3 April 2014. Vaccine. 2014;36:4368-82. doi: 10.1016/j.vaccine.2015.06.090.

<sup>4</sup> World Health Organization. WHO informal consultation on surveillance of respiratory syncytial virus on the WHO Global Influenza Surveillance and Response System (GISRS) platform, 25–27 March 2015. Wkly Epidemiol Rec. 2016;91:1 (http://www.ncbi.nlm.nih.gov/pubmed/26753193, accessed 19 September 2016).

<sup>5</sup> Self-assessment of the WHO Global Influenza Surveillance and Response System (GISRS), Report to the Advisory Group. Geneva: World Health Organization; 2014 (http://www.who.int/influenza/pip/virus\_sharing/gisrs\_self\_assessment.pdf, accessed 19 September 2016).

<sup>6</sup> Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011 (http://www.who.int/influenza/pip/en/, accessed 21 September 2016), Annex 5, National Influenza Centres, Core Terms of Reference, B. Laboratory and related activities.

<sup>7</sup> *Ibid.,*,section 5.1.1.

<sup>8</sup> *Ibid.,* Annex 5, WHO Collaborating Centres for Influenza, Core Terms of Reference, B. Laboratory analyses and related activities.

<sup>9</sup> Wild type viruses are those in the field, naturally occurring in humans or animals. They are not modified or reassorted like many vaccine viruses.

<sup>&</sup>lt;sup>1</sup> For example, 4th WHO Informal Consultation on Improving Influenza Vaccine Virus Selection. In: World Health Organization [website]. Geneva: World Health Organization; 2015

<sup>(</sup>http://www.who.int/influenza/vaccines/virus/4thmtg\_improve\_vaccine\_virus\_selection/en/,

accessed 19 September 2016).

<sup>&</sup>lt;sup>2</sup> World Health Organization. Influenza vaccine response during the start of a pandemic, Report of a WHO Informal Consultation held in Geneva, Switzerland, 29 June-1 July 2015. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/207751/1/WHO\_OHE\_PED\_GIP\_2016.1\_eng.pdf, accessed 19 September 2016).

production of vaccines, while retaining antigenic similarity.<sup>1</sup> This typically means: (1) attenuating (or weakening) the virus so it does not cause severe illness; (2) ensuring that it grows well in eggs and cell culture; and (3) ensuring that it still triggers the appropriate immune response.<sup>2</sup> Because they form the basis for vaccines, available and effective CVVs are critical both for the efficacy of seasonal vaccines and for a robust response to an influenza pandemic. WHO CCs are required to share widely all information gathered, along with CVVs and reagents.<sup>3</sup> Between 1 August 2014 and 31 July 2015, WHO CCs characterized 123 IVPP coming from five countries (Bangladesh, Canada, China, Egypt, and the United States of America).<sup>4</sup>

WHO H5RLs are responsible for some of the same tasks as WHO CCs, but for a particular subset of influenza viruses with hemagglutinin antigen H5.<sup>5</sup> WHO ERLs are tasked with "developing, regulating and standardizing influenza vaccines", most significantly by developing CVVs<sup>6</sup> and preparing reference reagents to standardize influenza vaccines.<sup>7</sup>

Box 4.1. Tool for Influenza Pandemic Risk Assessment (TIPRA)<sup>8</sup>

A central function of GISRS as a whole is to provide the data necessary for countries to develop an effective and meaningful response.<sup>9</sup> Using this information along with other sources, according to the PIP Framework (section 6.2.3) it is the responsibility of the WHO Secretariat to "make available to all Member States, in a rapid, systematic and timely way,

<sup>3</sup> Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011 (http://www.who.int/influenza/pip/en/, accessed 21 September 2016), Annex 5, WHO Collaborating Centres for Influenza, Core Terms of Reference, B. Laboratory analyses and related activities.

<sup>4</sup> PIP Framework Advisory Group. Pandemic Influenza Preparedness Framework ("PIP Framework") Advisory Group annual report to the Director-General under PIP Framework section 7.2.5: 2015 Annual Report. Geneva: World Health Organization; 2015 (http://www.who.int/influenza/pip/ag\_annual\_report\_2015.pdf, accessed 20 September 2016), page 17.

<sup>5</sup> Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011 (http://www.who.int/influenza/pip/en/, accessed 21 September 2016), Annex 5, WHO H5 Reference Laboratories, Core Terms of Reference, B. Laboratory and other activities.

<sup>6</sup> *Ibid.,* Annex 5, WHO Essential Regulatory Laboratories.

<sup>7</sup> *Ibid.,* Annex 5, WHO Essential Regulatory Laboratories, Core Terms of Reference, B. Laboratory and related activities.

<sup>8</sup> Tool for Influenza Pandemic Risk Assessment (TIPRA). In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/areas\_of\_work/human\_animal\_interface/tipra/en/, accessed 20 October 2016).

<sup>9</sup> Pandemic influenza preparedness framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011 (http://www.who.int/influenza/pip/en/, accessed 19 September 2016), section 6.2.1.

<sup>&</sup>lt;sup>1</sup> Antigenically similar viruses are those that induce equivalent antibody responses, as measured by serological tests.

<sup>&</sup>lt;sup>2</sup> Making a Candidate Vaccine Virus (CVV) for a HPAI (Bird Flu) Virus. In: Centers for Disease Control and Prevention [website]. Atlanta: National Center for Immunization and Respiratory Diseases, U.S. Centers for Disease Control and Prevention; 2016 (http://www.cdc.gov/flu/avianflu/candidate-vaccine-virus.htm, accessed 19 September 2016).

pandemic risk assessments". Recognizing the need for a specific risk assessment tool, the TIPRA has been developed to support a timely and updatable risk assessment for IVPP.<sup>1</sup> The tool focuses on a virus's qualitative pandemic potential, as evaluated by experts, based on different virus elements that are known to affect transmissibility and severity. It seeks to answer the question: What is the risk of sustained human-to-human transmission of the virus? To evaluate this risk it assesses two components: what is the likelihood of sustained human-to-human transmission of the virus; and what is the impact to the human population if the virus acquires sustained human-to-human transmissibility? Triggers for using the TIPRA may be epidemiological (for example, emergence of human cases of a non-seasonal or animal influenza virus) or virological (for example, studies in laboratory animals indicating that the virus has the capability to transmit to uninfected animals by either direct contact or respiratory droplets).<sup>2</sup>

The costs of virus sharing can be challenging for some laboratories. Started in 2005, the WHO Shipping Fund provides funding for the shipment by NICs (and in some cases other national influenza laboratories) of seasonal and pandemic virus specimens to WHO CCs and WHO H5RLs.<sup>3</sup> Since 2015, PC contributions have financed the entire cost of the Shipping Fund. Beyond covering shipping costs, the Shipping Fund has also been used to streamline shipment procedures and to provide WHO technical and logistical support for shipping infectious substances.<sup>4</sup> From 1 August 2015 to 31 July 2016, the Shipping Fund was used to facilitate 213 shipments of seasonal and pandemic influenza viruses.<sup>5</sup>

### 4.2 Virus sharing metrics

### Key Findings

Finding 25: While the sharing of PIP BM initially increased after adoption of the PIP Framework, a decline has been noted over the past two years. The September 2014 GISRS self-assessment showed that the response to the emergence of the influenza A(H7N9) strain in 2013 was prompt and comprehensive, but virus sharing has declined since then.<sup>6</sup> Overall, there has been a reduced sharing of IVPP from some countries. As requested by the Advisory Group, WHO is undertaking a study to understand the reasons for, and the significance of, this decline; this report is due to be provided to the Advisory Group in October 2016.

<sup>&</sup>lt;sup>1</sup> TIPRA is based on the US CDC's Influenza Risk Assessment Tool tool: http://www.cdc.gov/flu/pandemic-resources/tools/risk-assessment.htm.

<sup>&</sup>lt;sup>2</sup> Tool for Influenza Pandemic Risk Assessment (TIPRA), Version 1 Release. Geneva: World Health Organization; 2016 (WHO/OHE/PED/GIP/2016.2; http://apps.who.int/iris/bitstream/10665/250130/1/WHO-OHE-PED-GIP-2016.2-eng.pdf, accessed 4 October 2016).

<sup>&</sup>lt;sup>3</sup> Shipping and logistics activity. In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/gisrs\_laboratory/logistic\_activities/en/, accessed 19 September 2016).

<sup>&</sup>lt;sup>4</sup> Ibid.

<sup>&</sup>lt;sup>5</sup> PIP Framework Secretariat, World Health Organization, unpublished data, October 2016.

<sup>&</sup>lt;sup>6</sup> Self-assessment of the WHO Global Influenza Surveillance and Response System (GISRS): Report to the Advisory Group. Geneva: World Health Organization; 2014 (http://www.who.int/influenza/pip/virus\_sharing/gisrs\_self\_assessment.pdf, accessed 19 September 2016), section 4.1.

Despite the growth of the GISRS network and the assistance with shipping, there has been a worrying decline in virus sharing within GISRS since its peak of 370 IVPP between 1 August 2012 and 31 July 2013. The PIP Framework Advisory Group pointed out this trend at its April 2016 meeting:

While the sharing of PIP biological materials initially increased after adoption of the PIP Framework, recent data point to a decreasing trend in IVPP virus sharing. Detailed figures for H5N1, H7N9, H10N8 and H9N2 illustrated how in some specific countries the number of viruses shared was considerably lower than the number of confirmed human cases during 2011-16.<sup>1</sup>

Figure 4.1 shows virus sharing with WHO CCs for part of 2016.

WHO and Influenza Virus Traceability Mechanism (IVTM) data show that:

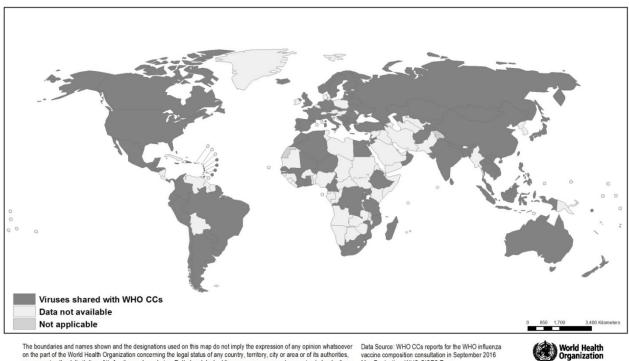
- From 1 August 2014 to 31 July 2015, the IVTM recorded 156 shipments of IVPP from WHO CCs and WHO ERLs, 92 of which went to non-GISRS laboratories.<sup>2</sup> This represents a 71% drop in recorded IVPP sharing as compared with the previous year.<sup>3</sup>
- From 1 August 2015 through 31 July 2016, IVTM recorded the sharing of 84 IVPP from WHO CC's. Of these, 47 were shared with non-GISRS laboratories.<sup>4</sup>
- From March 2011 to February 2016, 79 CVVs were shared with GISRS laboratories and an additional 174 with non-GISRS laboratories.<sup>4</sup>
- In the one year period from March 2015 to February 2016, eight CVVs were shared with two GISRS laboratories and 13 CVVs were shared with eight non-GISRS laboratories.<sup>5</sup>

<sup>&</sup>lt;sup>1</sup> PIP Framework Advisory Group. Meeting of the Pandemic Influenza Preparedness Framework Advisory Group, 19-22 April 2016, Geneva, Switzerland. Report to the Director-General. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/ag\_april2016\_MeetingRpt.pdf?ua=1, accessed 24 September 2016), paragraph 56.

<sup>&</sup>lt;sup>2</sup> PIP Framework Advisory Group. Pandemic Influenza Preparedness Framework ("PIP Framework") Advisory Group Annual Report to the Director-General Under PIP Framework section 7.2.5, 2015 Annual Report. Geneva: World Health Organization; 2015 (http://www.who.int/influenza/pip/ag\_annual\_report\_2015.pdf, accessed 20 September 2016), page 9.

<sup>&</sup>lt;sup>3</sup> *Ibid.*, page 9.

<sup>&</sup>lt;sup>4</sup> Global Influenza Programme, World Health Organization, unpublished data, October 2016.



# Figure 4.1: Countries, areas and territories sharing viruses with WHO CCs from February to September 2016

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsover Data Source: WHO CCS reports for the WHO influenza on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, for which there may not yet be full agreement. WHO CCS reports for the WHO GISRS Team World Health Organization of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement. WHO CCS reports for the WHO GISRS Team World Health Organization O WHO 2016. All rights reserved

During an outbreak, representative samples from each geographical location and point in time are critical to effective risk assessment and other GISRS activities. The decrease in virus sharing thus poses a potentially serious challenge to the PIP Framework's objective of improving pandemic influenza preparedness and response.

As requested by the Advisory Group, WHO is carrying out a study into the reasons for, and significance of, the decline in virus sharing and its impact on the PIP Framework's objectives.

Information from the WHO Global Influenza Programme (GIP) (which coordinates WHO's work on both pandemic and seasonal influenza, including overseeing GISRS) and interviews with key informants highlighted several areas where greater clarity might benefit virus sharing: a lack of understanding among NICs that sharing IVPP GSD does not replace the sharing of physical materials; different interpretations of the phrasing of the PIP Framework's requirement that all IVPP should be shared "as feasible"; export procedures that can be complex and involve Ministries other than Health; national concerns about a loss of control and sovereign rights; and uncertainty in countries with both a NIC and a WHO CC over whether sharing only between these two laboratories is enough to fulfil a literal interpretation of the PIP Framework's requirements, thereby not requiring the international sharing envisioned under the PIP Framework.

While the WHO study will help more fully to understand the apparent recent decline in virus sharing, implementation of the PIP Framework is putting in place many of the foundations needed to resume an upward trend. Capacity building activities funded under the PC's Laboratory and Surveillance work plans are targeting 43 priority countries to improve their

national ability to detect and share novel influenza viruses (see chapter 6, section 6.3.2.1). The PC investments are also improving countries' abilities to monitor evolution in IVPP and perform risk assessments.

### 4.3 Influenza Virus Traceability Mechanism

### Key Findings

Finding 26: Consistent use of the IVTM among GISRS laboratories is vital for ensuring transparency and advancing the PIP Framework's goal of equitable benefit sharing.

Finding 27: IVTM recordkeeping is sporadic among NICs because many deal primarily and routinely with seasonal influenza viruses, whereas the IVTM is used specifically for specimens with pandemic potential. Many NICs therefore have had little exposure to this tool in day-to-day operations. While WHO CCs use the tool consistently, NICs generally fail to enter shipments of PIP BM. This appears to stem from a lack of knowledge, and training on the use of the IVTM could help address this problem.

The IVTM is a publicly accessible online tool for tracking IVPP "into, within, and out of" the GISRS network.<sup>1</sup> This information is used: by WHO to identify users of GISRS who are subject to signing SMTA2s; by Member States to see how the viruses they share are being used; and by other stakeholders to see how GISRS enhances pandemic influenza preparedness. The system relies on consistent reporting of the transfer and receipt of IVPP by GISRS laboratories.

Knowing who is receiving IVPP is vital for the PIP Framework's benefit sharing system as well as for its goal of transparency. Prior to the IVTM, Member States did not have a tracking system to inform them how the viruses they shared were subsequently passed on. The IVTM contains more than 1,000 records of IVPP and more than 1,100 shipment records, representing 19 influenza virus subtypes.<sup>2</sup> Transactions are meant to be recorded both when specimens are sent and when they are received. However, in practice many NICs fail to record their outgoing shipments, leaving WHO CCs retroactively to enter this information. This practice eliminates an important safeguard of data integrity and increases the workload on WHO CCs.

In discussions with GISRS laboratories, it became clear to the Review Group that an important reason for this failure was a lack of knowledge among NICs of the IVTM and the expectations for when it should be used. IVPP make up a relatively small proportion of total influenza virus specimens shared so IVPP procedures, such as the IVTM, are not routine for many NICs.

<sup>&</sup>lt;sup>1</sup> Pandemic influenza preparedness framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011 (http://www.who.int/influenza/pip/en/, accessed 19 September 2016), section 5.3.1.

<sup>&</sup>lt;sup>2</sup> Influenza Virus Traceability Mechanism [website]. Geneva: World Health Organization; 2016 (https://extranet.who.int/ivtm/, accessed 10 June 2016).

### **Recommendations: Virus Sharing**

6. The Review Group welcomes the PIP Framework Secretariat's study of the reasons for the recent decline in the sharing of influenza viruses with human pandemic potential. The Advisory Group should, as a priority, follow-up on the results of this study in order to ensure the timely sharing of all viruses.

7. Given the recent decline in the sharing of influenza viruses with human pandemic potential, WHO should continue to provide technical operational guidance and training for National Influenza Centres to ensure that they are fully aware of their roles as agreed in the SMTA1, the effective use of the Influenza Virus Traceability Mechanism, and the importance of appropriate sharing of all PIP biological materials and genetic sequence data.

8. WHO should provide clarification to GISRS laboratories on the interpretation of the terms "timely" and "as feasible" with respect to the sharing of PIP biological materials from all cases of A(H5N1) and other influenza viruses with human pandemic potential (section 5.1.1 of the PIP Framework).

9. Although genetic sequence data do not fully substitute for the physical virus, in cases where it is not possible to ship PIP biological materials rapidly, genetic sequence data should, if available, be shared immediately.

10. The WHO Global Influenza Programme should strengthen contacts and linkages with, and processes between, the GISRS system and non-GISRS laboratories and other networks.

11. WHO, GISRS, the Food and Agricultural Organization of the United Nations, the World Organisation for Animal Health, the OFFLU and others should collaboratively establish guidance for GISRS and animal laboratories to strengthen their relationships and enhance surveillance and risk assessment of influenza viruses at the animal-human interface.

## Chapter 5: Genetic Sequence Data

### Key Findings

Finding 28: Due to the complexities of how best to handle GSD under the PIP Framework, GSD was not included in the definition of PIP BM in section 4.1. Technological developments mean that GSD can increasingly provide critical supplementary information and, in some cases, substitute for physical samples during pandemic risk assessment and the development of commercial products. Many IVPP sequences are already being shared; what is not currently clear under the PIP Framework is how GSD sharing should trigger benefit sharing, and what the trigger should be. Therefore, clarity is urgently required on the handling of GSD under the PIP Framework to ensure that it is guided by the same principles as the sharing of PIP BM.

Finding 29: There is confusion over language in the PIP Framework (Annex 4, section 9), which can read that WHO GISRS laboratories should submit genetic sequences to both the Global Initiative on Sharing All Influenza Data (GISAID) (Epiflu<sup>TM</sup>) database and the GenBank database, rather than submitting to only one database if desired.

Finding 30: Some good progress has already been made by the Advisory Group on examining possible approaches to handling GSD under the PIP Framework, as requested by Member States in section 5.2.4.<sup>1</sup> A key challenge has been the lack of agreement on what should be traced. Options could include tracking access to GSD or tracing the commercial products developed using GSD. Transparency in both the sharing and traceability of GSD is crucial in order to identify any resulting benefit that should be shared.

Finding 31: Among stakeholders involved in the discussions around the handling of GSD, there are diverse views on how a traceability and monitoring system might best work. It was clear from the Review Group's interviews and wider discussions that there remains some confusion as to potential options for future data sharing and operating procedures.

Finding 32: WHO CCs have a key role in collating IVPP GSD through GISRS. Their understanding of the realities of how GSD is shared via GISRS will be critical in informing the ongoing deliberations about the optimal handling of GSD under the PIP Framework.

Finding 33: It is crucial for GISRS to have access to sustainable databases to enable uploading and timely sharing of sequence data, such as the rapid sharing of influenza *A*(H7N9) by China.

<sup>&</sup>lt;sup>1</sup> PIP Framework Advisory Group. Meeting of the Pandemic Influenza Preparedness Framework Advisory Group, 19-22 April 2016, Geneva, Switzerland. Report to the Director-General. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/ag\_april2016\_MeetingRpt.pdf?ua=1, accessed 24 September 2016), paragraph 53.

### 5.1 Overview

GSD is important for surveillance and risk assessment because the sequences can reveal specific genetic changes in circulating influenza viruses that have been associated with pathogenicity and human-to-human transmission. GSD is also used to study influenza virus evolution, and segments of GSD can be used to design primers and probes for diagnostics. While GSD cannot fully substitute for physical virus samples in many areas, such as product development (mostly due to regulatory requirements), GSD is increasingly being used to develop several new types of vaccines without the need for physical virus.

GSD and physical materials are dealt with differently under the PIP Framework (see Figure 5.1). GSD is not included in the definition of PIP BM in section 4.1, and there is no mechanism (trigger) to operationalise the requirement for benefit sharing from GSD. Thus, there is a dissonance between the way the PIP Framework treats GSD and the reality in which it is used by scientists. This dissonance, if not resolved soon, could threaten the relevance of the PIP Framework since the sharing of GSD largely operates outside the virus sharing and benefit sharing rules of the PIP Framework.

The expectations on the sharing of IVPP GSD are laid out in Annex 5 of the PIP Framework. The core terms of reference of WHO CCs state that they should "upload available haemagglutinin, neuraminidase, and other gene sequences, of A(H5) and other influenza viruses with pandemic potential to a publicly accessible database in a timely manner but no later than three months after sequencing is completed".

The main genetic sequence databases that store influenza GSD include: GISAID's EpiFlu<sup>™</sup> database,<sup>1</sup> GenBank, the European Nucleotide Archive (ENA),<sup>2</sup> the DNA Data Bank of Japan (DDBJ)<sup>3</sup> (GenBank, ENA and DDBJ participate in the International Nucleotide Sequence Database Collaboration (INSDC)),<sup>4</sup> OpenFluDB,<sup>5</sup> and Influenza Research Database (IRD).<sup>6</sup>

Member States and GISRS laboratories can choose the database or databases they want to use. Nevertheless, there remains some ambiguity over language in the PIP Framework (Annex 4, section 9), specifically over whether WHO GISRS laboratories should submit genetic sequences to both the GISAID (Epiflu<sup>™</sup>) database and the GenBank database, or to only one database if desired: the guiding principles for the development of terms of reference for GISRS laboratories state that "The WHO GISRS laboratories will submit genetic

<sup>&</sup>lt;sup>1</sup> EpiFlu<sup>™</sup> Database. In: GISAID [website]. Bonn: GISAID; 2016 (http://platform.gisaid.org/epi3/frontend#13da29, accessed 29 September 2016).

<sup>&</sup>lt;sup>2</sup> European Nucleotide Archive. In: European Nucleotide Archive [website]. Hinxton, UK: European Bioinformatics Institute (EMBL-EBI); 2016 (http://www.ebi.ac.uk/ena, accessed 29 September 2016).

<sup>&</sup>lt;sup>3</sup> Introduction of DDBJ. In: DNA Data Bank of Japan [website]. Shizuoka: DNA Data Bank of Japan; 2016 (http://www.ddbj.nig.ac.jp/intro-e.html, accessed 29 September 2016).

<sup>&</sup>lt;sup>4</sup> International Nucleotide Sequence Database Collaboration. In: INSDC [website]. Hinxton, UK: INSDC; 2016 (http://www.insdc.org/, accessed 29 September 2016).

<sup>&</sup>lt;sup>5</sup> OpenFlu Database. In: OpenFlu [website]. Lausanne: Swiss Institute of Bioinformatics; 2016 (http://openflu.vital-it.ch/browse.php, accessed 29 September 2016).

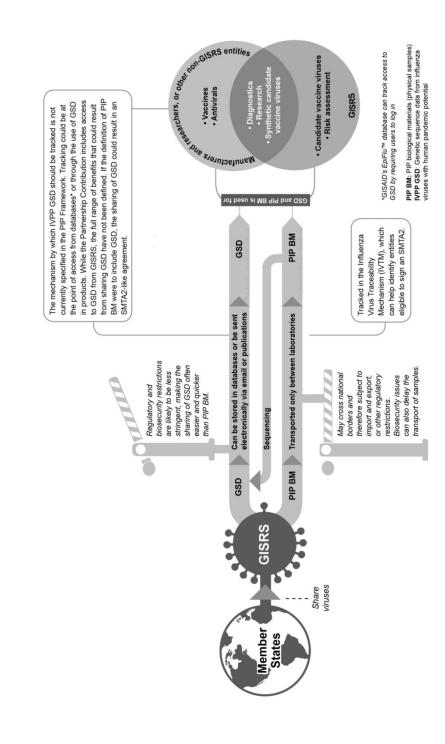
<sup>&</sup>lt;sup>6</sup> Influenza Research Database. In: Influenza Research Database [website]. Washington, DC: Influenza Research Database; 2016 (https://www.fludb.org/brc/home.spg?decorator=influenza, accessed 29 September 2016).

sequences data to GISAID and Genbank or similar databases in a timely manner consistent with the Standard Material Transfer Agreement." The WHO CCs provide scientific oversight and, as noted by the Advisory Group in October 2014, "most GISRS laboratories use GISAID".<sup>1</sup>

While the IVTM tracks the sharing of PIP BM, resulting in SMTA2s being signed, there is no equivalent tracking (and therefore currently no benefit sharing mechanism) for GSD. This means that sequences that are shared are not tracked in the IVTM and that the benefits from such sharing of sequences are not covered under an SMTA2. When the PIP Framework (section 5.2.4) was agreed, Member States, recognizing that further work was needed, requested "the Director-General to consult the Advisory Group on the best process for further discussion and resolution of issues relating to the handling of" GSD for IVPP.

Since June 2013, the Advisory Group has been conducting technical work to better understand the issues related to GSD in order to advise the Director-General.

<sup>&</sup>lt;sup>1</sup> PIP Framework Advisory Group. Meeting of the Pandemic influenza preparedness (PIP) Framework Advisory Group, 21-24 October 2014, Geneva, Switzerland. Report to the Director-General. Geneva: World Health Organization; 2014 (http://www.who.int/influenza/pip/advisory\_group/oct2014\_mr\_consolidated.pdf?ua=1, accessed 24 September 2016), paragraph 29.





#### 5.1 Advisory Group's work on GSD

The Advisory Group's work on GSD began in June 2013 when GISAID requested clarification on the use of IVPP GSD under the PIP Framework.<sup>1</sup> In October 2013, the Advisory Group established the Technical Expert Working Group on Genetic Sequence Data (TEWG), tasked with assessing the "scientific, technical, operational and intellectual property implications" as well as "any other significant implications" of the shift from physical IVPP to IVPP GSD.<sup>2</sup>

The TEWG published its final report in October 2014, examining current uses of GSD, potential regulatory and intellectual property issues, the feasibility of monitoring and tracing GSD, and biosecurity and biosafety implications.<sup>3</sup> In particular, it became apparent that a system for equitably sharing the benefits arising from GSD would need to take into account the unique characteristics of GSD and the way in which they are shared. Because easy and rapid sharing of GSD is needed for timely risk assessment, scientific research and product development, the TEWG recognized that "it is essential that any [benefit sharing] mechanisms do not slow down the sharing of genetic sequence data".<sup>4</sup>

After considering the TEWG report, and following consultation with database providers and other stakeholders, in October 2014 the Advisory Group formulated a recommendation to the Director-General on the best process to discuss further and resolve the issues related to the handling of IVPP GSD under the PIP Framework. The Advisory Group recommended a process to identify "the optimal characteristics of a system for the handling of IVPP GSD under the PIP Framework". To that end, the Advisory Group: (1) established a second expert group, the Technical Working Group on the Sharing of Influenza Genetic Sequence Data (TWG) to consider the optimal data sharing system, and; (2) commissioned a paper to consider possible benefit sharing options.<sup>5</sup>

In June 2016, the TWG issued its final report, which identified optimal characteristics of a data sharing system, and included some options within those characteristics.<sup>6</sup> These covered such aspects as: expectations to submit IVPP GSD; timeliness of submission; ensuring

(http://www.who.int/influenza/pip/advisory\_group/twg\_doc.pdf?ua=1, accessed 22 September 2016).

<sup>&</sup>lt;sup>1</sup> GSD Timeline, Process for handling Genetic Sequence Data under the PIP Framework. In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/entity/influenza/pip/advisory\_group/GSD\_timeline.pdf?ua=1, accessed 22 September 2016).

<sup>&</sup>lt;sup>2</sup> PIP Framework Advisory Group, Technical Expert Working Group (TEWG) on Genetic Sequence Data. Final Report to the Advisory Group. Geneva: World Health Organization; 2014 (http://www.who.int/influenza/pip/advisory\_group/PIP\_AG\_Rev\_Final\_TEWG\_Report\_10\_Oct\_2014.pdf, accessed 22 September 2016), page 2.

<sup>&</sup>lt;sup>3</sup> Ibid.

<sup>&</sup>lt;sup>4</sup> *Ibid.*, page 3.

<sup>&</sup>lt;sup>5</sup> PIP Framework Advisory Group. Meeting of the Pandemic Influenza Preparedness Framework Advisory Group, 21-24 October 2014, Geneva, Switzerland. Report to the Director-General. Geneva: World Health Organization; 2014 (http://www.who.int/influenza/pip/pip\_ag\_oct2014\_meetingreport\_final\_7nov2014.pdf, accessed 22 September 2016), paragraph 32.

<sup>&</sup>lt;sup>6</sup> PIP Framework Advisory Group, Technical Working Group (TWG) on the sharing of influenza genetic sequence data. Optimal Characteristics of and Influenza Genetic Sequence Data Sharing System under the PIP Framework. Geneva: World Health Organization; 2016 (http://www.uka.int/influenza/cin/cat/inser/ croup/twg. doe.pdf2us\_1\_accessed 22 September 2016)

quality; completeness of metadata; ease of access/use; sustainability/security of the system; source identification; and support to the regulatory process. The Review Group has heard concerns about the breadth and depth of engagement with stakeholders, in particular database providers, during the working group process.

On the benefit sharing system, the Advisory Group requested the PIP Framework Secretariat to develop a paper discussing benefit sharing mechanisms for IVPP GSD, and in particular options for monitoring use of IVPP GSD.<sup>1</sup> The paper identified two main types of monitoring: upstream and downstream. Upstream monitoring systems "are implemented at the point at which IVPP GSD is distributed and accessed" (e.g. when a sequence is downloaded from a database).<sup>2</sup> Downstream monitoring, on the other hand, is undertaken "after [IVPP GSD] has been shared and used to research and develop end-products".<sup>3</sup>

At its April 2016 meeting, based on the work to then, the Advisory Group discussed key principles that should underpin the balance of virus sharing and benefit sharing for GSD.<sup>4</sup> At its October 2016 meeting the Advisory Group considered the range of operational tools for the handling of GSD, as well as a strategy for the next steps.

#### **Recommendations: Genetic Sequence Data**

12. The Director-General should request Member States to consider amending the definition of PIP biological materials in section 4.1 of the PIP Framework to include genetic sequence data.

13. The Director-General should request Member States to consider clarifying Annex 4, section 9, which currently states that "The WHO GISRS laboratories will submit genetic sequences data to GISAID and Genbank or similar databases in a timely manner consistent with the Standard Material Transfer Agreement", by amending it to:

"The WHO GISRS laboratories will submit genetic sequences data to one or more publicly accessible database of their choice in a timely manner consistent with the Standard Material Transfer Agreement".

14. The Director-General should request Member States to consider updating and correcting the statement in section 5.2.2 of the PIP Framework, which currently states "Recognizing that greater transparency and access concerning influenza virus genetic sequence data is important to public health and there is a movement towards the use of public-domain or public-access databases such as Genbank and GISAID respectively;"

<sup>&</sup>lt;sup>1</sup> Best Process to Handle Genetic Sequence Data from Influenza Viruses with Human Pandemic Potential (IVPP GSD) under the PIP Framework, Options to monitor the use of genetic sequence data from influenza viruses with human pandemic potential (IVPP GSD) in end-products. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/advisory\_group/gsdoptionspaper\_revised.pdf, accessed 22 September 2016).

<sup>&</sup>lt;sup>2</sup> *Ibid.*, page 4.

<sup>&</sup>lt;sup>3</sup> *Ibid.*, page 6.

<sup>&</sup>lt;sup>4</sup> PIP Framework Advisory Group. Meeting of the Pandemic Influenza Preparedness Framework Advisory Group, 19-22 April 2016, Geneva, Switzerland. Report to the Director-General. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/ag\_april2016\_MeetingRpt.pdf?ua=1, accessed 24 September 2016), paragraph 53.

by amending it to:

"Recognizing that greater transparency and access concerning influenza virus genetic sequence data is important to public health and use is made of public-domain or public-access databases such as GenBank and/or GISAID, respectively;"

15. It is critical that the PIP Framework adapts to technological developments, and that the Advisory Group produces with urgency recommendations to clarify the handling of genetic sequence data. The Advisory Group should consider asking WHO Collaborating Centres to report on how genetic sequence data are actually handled, with a view to providing information about the operational realities in GISRS in relation to the acquisition, sharing and use of such data, to inform the Advisory Group's recommendations on the optimal handling of genetic sequence data under the PIP Framework.

16. The Director-General should enlist the support of Member States to ensure that influenza virus genetic sequence data remain publicly accessible in sustainable databases, to enable timely, accurate and accessible sharing of these data for pandemic risk assessment and rapid response.

17. Noting that genetic sequence data may be generated from many entities outside of GISRS, and that there are diverse views on the optimal traceability and monitoring mechanism, the Advisory Group should give consideration to broadening and deepening engagement with all stakeholders.

## Chapter 6: Benefit sharing

### 6.1 Standard Material Transfer Agreement 2

#### Key Findings

Finding 34: By October 2016, four SMTA2s had been signed with vaccine manufacturers, one with a diagnostics manufacturer, and 47 with academic and research institutions.<sup>1,2</sup> These agreements have secured access to approximately 350 million<sup>3</sup> doses of pandemic influenza vaccine to be delivered in real time during an influenza pandemic. Further, two million<sup>4</sup> antiviral treatment courses have been secured. Although some institutions have not yet been contacted to sign an SMTA2 and some negotiations are still under way, the Review Group considers that there has been good progress. The PIP Framework Secretariat has focused on addressing SMTA2s with those companies that offer the biggest gains – the agreements signed by October 2016 had already significantly improved WHO's future access to pandemic vaccine doses, antivirals and other products for distribution to countries in need should an influenza pandemic occur.

Finding 35: Good progress on securing prequalified vaccines and antivirals has been achieved through the PIP Framework Secretariat's strategic approach of prioritizing agreements with large companies with pregualified vaccines before moving on to negotiations with medium to small companies. Some Member States have queried whether the labour-intensive process of signing SMTA2s with small and medium companies is worth the resources required given the relatively modest additional volume of vaccines or other products secured. However, the PIP Framework's principle of fairness and equity in benefit sharing requires that all non-GISRS recipients of PIP BM sign an SMTA2 with WHO and provide benefits based on their nature and capacities. This principle is valued and WHO recognizes the importance of treating manufacturers equitably and of maintaining that goal despite the diminishing returns of additional products secured. The PIP Framework Secretariat has already made considerable effort to familiarise small and medium companies with the collateral benefits that are available, such as increased understanding of requirements for WHO prequalification status. The Review Group is of the opinion that the PIP Framework Secretariat, with support from the Advisory Group, should continue to take steps to prepare companies better for the SMTA2 negotiations.

Finding 36: The regularity and high quality of communication between the PIP Framework Secretariat and industry and other stakeholders has helped to facilitate the conclusion of SMTA2s. On several occasions when negotiations have been complicated or have stalled, the PIP Framework Secretariat has successfully implemented the stepwise approach recommended by the Advisory Group to progress towards conclusion of the agreements in a

<sup>&</sup>lt;sup>1</sup> Standard Material Transfer Agreements 2 (SMTA2). In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/benefit\_sharing/smta2\_signed/en/, accessed 19 October 2016).

<sup>&</sup>lt;sup>2</sup> PIP Framework Secretariat, World Health Organization, unpublished data, October 2016.

<sup>&</sup>lt;sup>3</sup> Ibid.

<sup>&</sup>lt;sup>4</sup> Ibid.

timely manner.<sup>1</sup> There is nevertheless a perception that some eligible entities are not signing SMTA2s. The stepwise approach recognizes that a delicate balance needs to be maintained with the companies that are not facilitating completion of the negotiations; if these manufacturers are denied access to PIP BM because of failing to sign an SMTA2, this could be detrimental to public health.

Finding 37: Although SMTA2s were designed to be broad enough to accommodate a range of commitments, by October 2016 no companies had agreed to provide technology transfer. This is most likely because not many eligible manufacturers have patented technologies that could be made available for licence through WHO.

Finding 38: PIP Framework options for SMTA2 commitments from manufacturers of other pandemic products (such as diagnostics, syringes, etc.) are too narrow, and need to include a wider choice of commitments other than diagnostic materials that may not be beneficial in the case of a future influenza pandemic.

Finding 39: In November 2013, at the request of WHO, the Strategic Advisory Group of Experts on Immunization (SAGE) reviewed its 2007 recommended policies for the establishment and use of influenza A(H5N1) vaccine stockpiles during a pandemic. Recognizing the immediate access to pandemic vaccine production secured by the SMTA2 agreements under the PIP Framework and the unchanged global epidemiology of influenza A(H5N1) among other factors, SAGE recommended that WHO should no longer create a stockpile of influenza A(H5N1) vaccine. Instead, WHO should ensure immediate access to pandemic vaccines under the PIP Framework.<sup>2,3</sup> This decision is not reflected in the PIP Framework (section 6.9).

Finding 40: Member States with in-country influenza vaccine production capacity need to include the SMTA2 requirements of the manufacturer(s) into their pandemic influenza response plans. It is essential that Member States ensure that the manufacturers can fulfil their SMTA2 commitments to provide WHO with real time access to pandemic vaccines and allow the export of these vaccines to other countries.

Finding 41: In order to facilitate negotiations of SMTA2s, the PIP Framework Secretariat has developed tools<sup>4</sup> that outline the technical requirements, such as prequalification, export procedures and regulatory approvals that must be fulfilled by signatories to SMTA2s.

- <sup>3</sup> World Health Organization. Meeting of the Strategic Advisory Group of Experts on immunization, November 2013 – conclusions and recommendations. Wkly Epidemiol Rec. 2014;89:1-20 (http://www.who.int/wer/2014/wer8901.pdf, accessed 16 September 2016), page 10.
- <sup>4</sup> Frequently asked questions about Standard Material Transfer Agreements 2. In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/benefit\_sharing/smta2\_FAQs.pdf, accessed 26 September 2016).

<sup>&</sup>lt;sup>1</sup> PIP Framework Advisory Group. Meeting of the Pandemic Influenza Preparedness Framework (PIPF) Advisory Group, 15-16 October 2015, Geneva, Switzerland, Report to the Director-General. Geneva: World Health Organization; 2015 (http://www.who.int/influenza/pip/ag\_meetingreport\_october2015.pdf, accessed 22 September 2015), paragraph 8.

<sup>&</sup>lt;sup>2</sup> PIP Framework Advisory Group. Annual report from the Advisory Group to the Director-General. Geneva: World Health Organization; 2014 (http://www.who.int/influenza/pip/ag\_annual\_report\_2014.pdf, accessed 20 September 2016), section 3.5.

Finding 42: WHO has published a report on the rapid and timely switch<sup>1</sup> from seasonal vaccine to pandemic vaccine production, and the 2013 Interim Pandemic Influenza Risk Management (PIRM) Framework is being finalized.

SMTA2s ensure the availability and predictability of access to pandemic influenza vaccines, antivirals and other products at the time of a pandemic. SMTA2s are valid until the end of the next pandemic. There are three categories of SMTA2, corresponding to the different users of PIP BM. Category A are vaccine and antiviral manufacturers, category B are manufacturers of other products such as diagnostics test kits, and category C are academic and research institutions.

Under the concluded category A SMTA2s, it is expected that a total of 350 million<sup>2</sup> doses of pandemic vaccines from real time production will be donated or reserved for purchase by the WHO at affordable prices, representing 7 – 10% of global production capacity.<sup>3,4</sup> In addition, two million<sup>5</sup> treatment courses of antiviral medicine have been committed, with a further eight million courses reserved for purchase by WHO at affordable prices.<sup>6</sup> The manufacturer Roche does not enter into SMTA2s as it does not use PIP BM but it has since 2005 voluntarily donated antiviral treatment courses for a WHO "rapid response stockpile". There were an estimated five million treatment courses from Roche in the stockpile in October 2016.<sup>7</sup> Among the category C research and academic entities that have entered into SMTA2s, almost half have offered to provide a benefit to WHO; these institutions are asked to consider but are not required to provide a benefit. Among these offers, the most common commitment selected up to October 2016 had been benefit sharing in the areas of improving laboratory and surveillance capacity; the PIP Framework Secretariat is working with WHO CCs and WHO Regional Offices to implement the training offers.

The first SMTA2 agreement with a vaccine manufacturer was signed in October 2012. As of 23 September 2016, four out of 32 vaccine manufacturers have signed SMTA2s, including two large multinational manufacturers: GlaxoSmithKline (GSK) (which also produces

<sup>&</sup>lt;sup>1</sup> Influenza Vaccine Response during the Start of a Pandemic, Report of a WHO Informal Consultation held in Geneva, Switzerland, 29 June-1 July 2015. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/207751/1/WHO\_OHE\_PED\_GIP\_2016.1\_eng.pdf, accessed 20 September 2016).

<sup>&</sup>lt;sup>2</sup> PIP Framework Secretariat, World Health Organization, unpublished data, October 2016.

<sup>&</sup>lt;sup>3</sup> Partridge J, Kieny MP. Global production capacity of seasonal influenza vaccine in 2011. Vaccine. 2012;31:728-31. doi: 10.1016/j.vaccine.2012.10.111.

<sup>&</sup>lt;sup>4</sup> Pandemic Influenza Preparedness Framework Partnership Contribution 2013-2016, Gap Analyses. Geneva: World Health Organization; 2013 (http://www.who.int/influenza/pip/pip\_pc\_ga.pdf, accessed 22 September 2016).

<sup>&</sup>lt;sup>5</sup> PIP Framework Secretariat, World Health Organization, unpublished data, October 2016.

<sup>&</sup>lt;sup>6</sup> Standard Material Transfer Agreement 2 between Glaxo Group Limited and WHO. In: World Health Organization [website]. Geneva: World Health Organization; 2012 (http://www.who.int/influenza/pip/benefit\_sharing/gsk\_smta2\_dec\_2012.pdf, accessed 22 September 2016).

<sup>&</sup>lt;sup>7</sup> Supporting pandemic preparedness. In: Roche [website]. Basel: Hoffman-La Roche; 2016 (http://www.roche.com/content/sustainability/what\_we\_do/for\_patients/access\_to\_healthcare/making\_innovation\_ accessible/tamiflu\_corpres.htm, accessed 26 September 2016).

antivirals) and Sanofi Pasteur.<sup>1</sup> The two other SMTA2 signatories are Serum Institute of India (the largest developing country manufacturer) and China National Biotec Group (CNBG), a leading biotechnology company in China.<sup>2</sup> Eight other vaccine manufacturers have formally submitted benefit sharing proposals and thus are in formal negotiations.<sup>3</sup> At the time of a pandemic, a decision will have to be made for vaccine producers to switch from seasonal to pandemic vaccine production (see Box 6.1). One category B SMTA2 has been signed with Quidel Corporation, and formal negotiations are taking place with one multinational company.<sup>4</sup> A total of 47 agreements<sup>5</sup> have been signed with category C research or academic institutions.

# Box 6.1 Decision mechanisms for switching from seasonal to pandemic vaccine production

Influenza vaccine production facilities cannot produce pandemic vaccines at the same time as seasonal vaccines. Once risk assessment has indicated the start of an influenza pandemic, a decision has to be taken on whether and how to "switch" from seasonal vaccine to pandemic vaccine production, invoking the SMTA2 arrangements. A pandemic may be breaking out in one part of the world while elsewhere seasonal influenza is still circulating and/or manufacturers are mid-cycle in fulfilling contracts for the production of seasonal vaccines.<sup>6</sup> Countries may also experience a pandemic at different times and with different levels of severity. So the decision to switch is a complex and time-sensitive process requiring the interaction and cooperation of many different public and private sector organizations, including WHO, GISRS, industry, Ministries of Health, providers of CVVs and regulatory agencies.<sup>7</sup>

In June-July 2015, WHO held an informal consultation to develop a global cooperative, riskmanagement approach to influenza vaccine response at the start of a pandemic. This consultation identified a number of key challenges, including the potentially severe public health consequences of switching to pandemic vaccine production either too early or too late.<sup>8</sup> A premature decision to stop seasonal vaccine production may compromise seasonal vaccine availability and increase seasonal deaths; a late switch may delay response and

<sup>&</sup>lt;sup>1</sup> Standard Material Transfer Agreements 2 (SMTA2). In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/benefit\_sharing/smta2\_signed/en/, accessed 19 October 2016).

<sup>&</sup>lt;sup>2</sup> WHO concludes SMTA2 with Chinese vaccine manufacturer CNBG. Pandemic Influenza Preparedness Framework eNewsletter [Internet]. July 2016. Geneva: World Health Organization; 2016 (http://us8.campaign-archive1.com/?u=c35eb4938c7246655f6384192&id=5b4741cf8b, accessed 26 September 2016).

<sup>&</sup>lt;sup>3</sup> PIP Framework Secretariat, World Health Organization, unpublished data, October 2016.

<sup>&</sup>lt;sup>4</sup> Ibid.

<sup>&</sup>lt;sup>5</sup> Ibid.

<sup>&</sup>lt;sup>6</sup> PIP Framework Advisory Group. Pandemic Influenza Preparedness Framework ("PIP Framework") Advisory Group annual report to the Director-General under PIP Framework section 7.2.5, 2015 Annual Report. Geneva: World Health Organization; 2015 (http://www.who.int/influenza/pip/ag\_annual\_report\_2015.pdf, accessed 20 September 2016), page 8.

<sup>&</sup>lt;sup>7</sup> Influenza vaccine response during the start of a pandemic: Report of a WHO informal consultation held in Geneva, Switzerland, 29June-1 July 2015. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/207751/1/WHO\_OHE\_PED\_GIP\_2016.1\_eng.pdf, accessed 19 September 2016).

increase the severity of a pandemic. Each stage of the complex vaccine development and manufacturing process presents the potential for a bottleneck or a delay, thereby creating a "domino effect" that can undermine a timely switch from seasonal vaccine production to pandemic vaccine production. For example, CVV development, reagent production, clinical trials, regulatory approvals and attaining adequate vaccine yields are all key sequential steps in the timeline of pandemic vaccine production.<sup>1</sup> Competing Advance Purchase Agreements between manufacturers and governments for seasonal vaccines may also affect WHO's SMTA2 real-time access to vaccines at the beginning of the pandemic if manufacturers must first fulfil those contractual obligations.

Since the 2015 consultation, work has focussed on completing an Operational Framework for Pandemic Vaccine Response<sup>2</sup> and finalizing the 2013 Interim PIRM Framework, which will also address pandemic vaccine response. In July 2016 a second WHO informal consultation was held. While the key outcomes had not yet been published in October 2016, they included an update to the Operational Framework for Pandemic Vaccine Response, a recommendation to finalize the Interim PIRM Framework, the formation of working groups to solve the current bottleneck issues related to production and regulation, the formation of a policy group to identify the key the principles of a decision to switch from seasonal to pandemic production, and a recommendation that a specialist committee be formed, involving GISRS experts, industry, civil society and other relevant stakeholders, to advise WHO in real time on the practical issues involved in switching from seasonal vaccine to pandemic vaccine production in the event of a pandemic declaration or emerging pandemic threat.

WHO's strategy for Category A SMTA2s has been to focus on securing access to pandemic vaccines from large companies with an existing WHO prequalified vaccine. To ensure standards and safety concerns are met, UN organizations (such as WHO and UNICEF) can only accept prequalified vaccines. As the pandemic vaccine can only be produced when the novel pandemic strain arrives, all companies wanting to supply vaccine to WHO will have to prequalify their new vaccine. If a company has already previously prequalified an influenza vaccine (either seasonal or pandemic) then the time needed to prequalify a new pandemic vaccine when an outbreak occurs will usually be very much shorter. This is why the PIP Framework Secretariat encourages companies to prequalify a seasonal vaccine or a mock-up pandemic vaccine in advance of the next pandemic. As of October 2016, seven<sup>3</sup> manufacturers of influenza vaccines had a prequalified vaccine. All the SMTA2 signatories had a prequalified vaccines. As of October 2016, the Chinese vaccine manufacturing firms were all working to prequalify their seasonal vaccines.

Negotiations of SMTA2s are complex and lengthy, involving full-time staff or consultants, and so far WHO has successfully maximized the impact of the SMTA2 benefit sharing mechanism by initially focussing on the largest vaccine manufacturers. Additional effort and resources, such as travel and technical briefings, are required to finalize negotiations with medium and smaller manufacturers, as these manufacturers are usually less familiar with the

<sup>&</sup>lt;sup>1</sup> Ibid.

<sup>&</sup>lt;sup>2</sup> Ibid.

<sup>&</sup>lt;sup>3</sup> WHO Prequalified vaccines. In: World Health Organization [website]. Geneva: World Health Organization; 2016 (https://extranet.who.int/gavi/PQ\_Web/, accessed 26 September 2016).

technical requirements under the SMTA2 and for them an SMTA2 can represent a significant extra cost. If a company has only produced vaccines for its domestic market then as part of the SMTA2 negotiations it often needs to be informed about WHO prequalification, the UN vaccine procurement process, the requirements for exporting biological products,<sup>1</sup> labelling for export markets, and the need to license the vaccine in the recipient market. To this end, WHO has carried out a range of communications involving outreach and company briefings to improve knowledge about SMTA2s and the implications of benefit sharing.<sup>2</sup> Development of guidelines and protocols might assist smaller manufacturers to facilitate the process. In addition, companies can also communicate directly with the technical officers from the WHO Prequalification team, who are best placed to answer questions concerning packaging and labelling, shipping etc. However, it is difficult to see how the SMTA2 process can be completed significantly faster with smaller firms given all the complexities involved.

The PIP Framework Secretariat has approached medium sized manufacturers on a regional basis, as these companies have common profiles and issues.

Manufacturers with small production volumes can face additional challenges. The cost of achieving WHO prequalification status may not be perceived to bring any benefits if a company has no plans to export influenza vaccines, even though securing WHO prequalification could potentially open up new business markets. In addition, domestic manufacturers with government contracts accounting for the whole of their vaccine production capacity need to determine how to provide 10% of their production to meet SMTA2 requirements. For example, government contract holders may allow 10% of the vaccine reserved for them to be released to WHO, or companies may need to scale up production, which could increase costs and resources for some firms. This suggests the potential need for greater flexibility in the commitments required from small and medium sized manufacturers.

With category B diagnostic companies, WHO faces an additional challenge as the PIP Framework limits the donate/reserve option to just diagnostic kits. As there is no certainty as to which types of diagnostic kits will be useful in a future influenza pandemic, WHO risks signing SMTA2s for products that will not be needed. More benefit-sharing options could be made available for category B companies, such as supply of ancillary pandemic equipment (syringes, needles and applicators etc.), as well as materials needed for surveillance such as specimen collection and processing materials, in order to maximize the benefits from this category.

The need for technological support through the PIP Framework may increase after GAP ends in November 2016, and it may be necessary to put more effort into these wider SMTA2 options. Four of the GAP-supported companies are now producing vaccines and a further

<sup>&</sup>lt;sup>1</sup> PIP Framework Advisory Group. Annual report from the Advisory Group to the Director-General. Geneva: World Health Organization; 2014 (http://www.who.int/influenza/pip/ag\_annual\_report\_2014.pdf, accessed 20 September 2016), section 3.1.

<sup>&</sup>lt;sup>2</sup> WHO Executive Board Resolution 138/21. Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits: Report by the Director-General. Geneva: World Health Organization; 2016 (http://apps.who.int/gb/ebwha/pdf\_files/EB138/B138\_21-en.pdf, accessed 22 September 2016), paragraph 15.

five are expected to have capacity by 2019, but the sustainability of these early stage manufacturers is expected to require further technological support.<sup>1</sup>

Since the PIP Framework was adopted, there have been some cases of companies delaying entering into an SMTA2 or not offering reasonable benefit sharing commitments despite being in receipt of PIP BM. In October 2015, in response to negotiations that were not progressing in a timely manner, the Advisory Group recommended to the Director-General that "where manufacturers engaged in SMTA2 negotiations maintain manifestly unreasonable positions, the PIP Framework Secretariat should use a stepwise approach" to remind them that access to PIP BM must be suspended to entities that do not have an SMTA2 with WHO.<sup>2</sup> The stepwise approach starts with informal and formal communications with industry and manufacturers' associations but can then escalate to involve PIP Framework Secretariat dialogue with host governments and direct interventions by WHO senior officials with the manufacturer's senior management. In recognition of the impact it could have on public health, only as a last resort will a company be cut off from access to PIP BM if all of the steps are exhausted and negotiations do not progress. The stepwise approach has already assisted negotiations with two manufacturers.

Looking ahead, there are still considerable gaps in the communication to a wider audience of the progress that has been achieved through SMTA2s. Better communication about benefit sharing and the associated processes will also help to ameliorate some of the criticisms of the SMTA2 system, including addressing the increasingly high costs to the PIP Framework Secretariat of concluding SMTA2s, given the diminishing returns of agreements with small and medium manufacturers and non-manufacturers.

#### **Recommendations: SMTA2s**

18. The PIP Framework Secretariat should improve communication of progress and achievements in securing SMTA2s by better highlighting the rationale and prioritization strategy for concluding these agreements, and clarifying the intended use of the antivirals, vaccines and other products secured through these agreements.

19. The PIP Framework Secretariat should develop, for consideration by the Advisory Group, and ultimate decision-making by Member States, an approach to include the provision of financial contributions, specimen collection and processing materials as options for category B SMTA2 commitments in Annex 2.

20. The Director-General should consider requesting that Member States remove section 6.9 in the PIP Framework on pandemic influenza preparedness vaccine stockpiles, since it is no longer relevant.

<sup>&</sup>lt;sup>1</sup> Grohmann G, Francis DP, Sokhey J, Robertson J. Challenges and successes for the grantees and the Technical Advisory Group of WHO's influenza vaccine technology transfer initiative. Vaccine. In press. doi: 10.1016/j.vaccine.2016.07.047.

<sup>&</sup>lt;sup>2</sup> PIP Framework Advisory Group. Meeting of the Pandemic Influenza Preparedness Framework (PIPF) Advisory Group: 15-16 October 2015, Geneva, Switzerland: Report to the Director-General. Geneva: World Health Organization; 2015 (http://www.who.int/influenza/pip/ag\_meetingreport\_october2015.pdf, accessed 22 September 2015), paragraph 8.

21. The Director-General should request Member States with in-country vaccine production capacity to commit to allow manufacturers to release to WHO on a real-time basis, pandemic vaccines and other products secured by WHO under SMTA2s.

22. WHO should rapidly finalize and communicate the Interim Pandemic Influenza Risk Management (PIRM) Framework, which will provide clarity on the implementation of the switch from seasonal to pandemic vaccine production.

#### 6.2 Partnership Contribution collection

#### Key Findings

Finding 43: The involvement of industry in the collaborative development<sup>1</sup> of the PC formula has achieved strong buy-in, and has resulted in early contribution payments being made in 2012, and the collection of 96%<sup>2</sup> of the overall funds due for 2013 and 2014.

Finding 44: Collection of PC is a continuing challenge, however, as not all companies pay their contributions by the expected deadline, and a few have not paid in full. This is of concern since the PC mechanism relies on all stakeholders fulfilling their obligations. Unlike a contractual SMTA2, the PC system is not legally binding and there are no enforcement mechanisms available to WHO beyond skilful negotiation and the potential embarrassment for a company of public exposure. However, Member States have signed up to the PIP Framework and can hold their companies to account to fulfil these obligations.

Finding 45: Issues of concern that could adversely affect the PC process were identified. Some civil society organizations and industry representatives consider that not all entities qualifying to make contributions actually do so in practice, resulting in a perception of inequity. Some companies (mostly manufacturers of diagnostic products) that make infrequent use of GISRS, perceive unfairness in the requirement to make annual contributions, even though their product sales continue to benefit from past access to the network.

<sup>&</sup>lt;sup>1</sup> Partnership Contribution Standard Operating Procedures June 2015. Geneva: World Health Organization; 2015 (http://www.who.int/influenza/pip/benefit\_sharing/pc\_collection\_sop.pdf?ua=1, accessed 24 September 2016), page 5, Annex 2.

<sup>&</sup>lt;sup>2</sup> Calculation based on data in Pandemic Influenza Preparedness Framework, Partnership Contribution Annual Report 2015. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/246229/1/WHO-OHE-PED-2016.01-eng.pdf?ua=1, accessed 24 September 2016).

Finding 46: Several industry representatives have highlighted as an issue that the fluctuation in the amount of PC they are asked to pay each year poses budgetary challenges, and they would prefer to pay a set amount.<sup>1</sup> Consistent with the recommendation of the Advisory Group in April 2016, industry has begun a consultative process to review the PC formula, working with all relevant industry sectors (vaccine, diagnostics and pharmaceuticals) and the PIP Framework Secretariat.<sup>2</sup>

Finding 47: A survey of GISRS running costs was undertaken for this Review: the estimates from a sample of 41 laboratories indicates that GISRS total running costs are likely to have increased since 2010, and should be estimated more accurately (see Box 6.2 and Table 6.2).

By July 2016, 30 of the 32 contributor companies identified in 2013,<sup>3</sup> and 38 of the 42 identified in 2014,<sup>4</sup> had made their PC payments. The PC funds collected as of 2 March 2016 are shown in Table 6.1. The shortfall shown for 2015 is mostly accounted for by a payment from one major contributor that was not received by WHO until after that date.

|                | 2012            | 2013            | 2014            | 2015            |
|----------------|-----------------|-----------------|-----------------|-----------------|
| Entities       | 163             | 194             | 250             | 256             |
| contacted      |                 |                 |                 |                 |
| Questionnaire  | 43              | 89              | 102             | 90              |
| responses      |                 |                 |                 |                 |
| Contributors   | 24              | 32              | 42              | 39              |
| identified     |                 |                 |                 |                 |
| Funds received | US\$ 18 121 000 | US\$ 27 538 586 | US\$ 26 964 062 | US\$ 18 813 522 |
|                |                 |                 |                 |                 |

Table 6.1: Partnership Contribution collection (2012-2015) (at 2 March 2016)<sup>1,2</sup>

Pandemic Influenza Preparedness Framework, Partnership Contribution Annual Report 2014. Geneva: World Health Organization; 2015.

<sup>2</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Annual Report 2015. Geneva: World Health Organization; 2016.

There are challenges for both industry and WHO regarding collection of the PC funds. Some companies find it difficult to pay the contributions in a single payment so they are permitted to pay in instalments.<sup>5</sup> Contributors have also raised concerns about invoices arriving late in the financial year, the budgeting challenges that flow from the fluctuations in the required annual

2015PCCollectionResults1APR2016.pdf?ua=1, accessed 24 September 2016).

<sup>&</sup>lt;sup>1</sup> PIP Framework Review Group. Report of the Third Meeting of the Pandemic Influenza Preparedness (PIP) Framework 2016 Review Group. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/2016-review/meeting30march\_1april.pdf, accessed 4 October 2016).

<sup>&</sup>lt;sup>2</sup> PIP Framework Secretariat, World Health Organization, unpublished information, October 2016.

<sup>&</sup>lt;sup>3</sup> Provisional agenda item 8.2, Executive Board 138<sup>th</sup> session. Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits, Report by the Director-General. Geneva: World Health Organization; 2016 (EB138/21; http://apps.who.int/gb/ebwha/pdf\_files/EB138/B138\_21-en.pdf?ua=1, accessed 22 October 2016), paragraph 16.

<sup>&</sup>lt;sup>4</sup> PIP Framework Secretariat, World Health Organization, unpublished data, October 2016.

<sup>&</sup>lt;sup>5</sup> 2015 PIP Partnership Contribution (PC) Collection, Results as of 1 April 2016. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/benefit\_sharing/

contributions from each individual company, and the continuing inclusion of 2009, together with the three most recent years, in the calculation of the four-year average.<sup>1,2</sup>

From WHO's perspective, there is often no response to the questionnaire, with replies from less than half of the entities contacted. Those replies are often slow to arrive and do not always include the necessary information for applying the formula, such as the "sales band" selection. Specifically, each company is asked to place itself in one of 23 bands, based on the average annual influenza product sales figure. Each band has an associated "weight" that, together with the sum of band weights for all entities, is required for the formula that calculates an individual company's PC.<sup>3</sup> This means that the PIP Framework Secretariat cannot issue invoices until it has received adequate information from all the contributing organizations.

There is a cash-flow problem every year because the timing of receipt of PC funds is not well-aligned with the timetable for deciding and implementing the associated PC influenza preparedness work plans; any delays in payments by contributors further exacerbate this problem.<sup>4</sup> For example, implementation of work plans and distribution of the 2016 PC funds had to be made in several tranches due to several contributions from manufacturers not being received by the end of 2015.<sup>5</sup> In April 2016, the Advisory Group recommended that the Director-General explore mechanisms to advance funds to the Secretariat for preparedness projects based on projected contributions and that the PIP Framework Secretariat continue to explore, in consultation with industry, "modification and simplification" of the collection process.<sup>6</sup> In addition, as the collection of PC funds operates on an annual cycle, some WHO Regional Offices said this can complicate efforts to make programmes sustainable, leading some regions to call for longer-term funding and/or forecasting.

When the PIP Framework was negotiated, it was decided that the total annual amount of PC should be equivalent to 50% of the running costs of the GISRS, based on 2010 costs of approximately US\$ 56.5 million.<sup>7</sup> However, it was also stated that such running costs "may change over time and the partnership contribution will change accordingly".<sup>8</sup>

- <sup>5</sup> *Ibid.*, paragraphs 33 and 34.
- <sup>6</sup> *Ibid.*, paragraphs 36 and 37.

<sup>&</sup>lt;sup>1</sup> PIP Framework Advisory Group. Meeting of the Pandemic Influenza Preparedness Framework Advisory Group, 19-22 April 2016, Geneva, Switzerland. Report to the Director-General. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/ag\_april2016\_MeetingRpt.pdf?ua=1, accessed 24 September 2016), paragraph 34.

<sup>&</sup>lt;sup>2</sup> Pandemic Influenza Preparedness Framework: Distribution of Partnership Contribution among companies. Geneva: World Health Organization; 2013 (http://www.who.int/influenza/pip/pc\_distribution.pdf?ua=1, accessed 24 September 2016), section III B.

<sup>&</sup>lt;sup>3</sup> *Ibid.*, pages 5 and 6.

<sup>&</sup>lt;sup>4</sup> PIP Framework Advisory Group. Meeting of the Pandemic Influenza Preparedness Framework Advisory Group, 19-22 April 2016, Geneva, Switzerland. Report to the Director-General. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/ag\_april2016\_MeetingRpt.pdf?ua=1, accessed 24 September 2016), paragraph 34.

<sup>&</sup>lt;sup>7</sup> Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011 (http://www.who.int/influenza/pip/en/, accessed 24 September 2016), section 6.14.3, footnote 1.

<sup>&</sup>lt;sup>8</sup> *Ibid.* section 6.14.3, footnote 1.

The Review Group requested that the PIP Framework Secretariat conduct a brief survey of GISRS laboratories to obtain estimated 2016 running costs, and to determine to what extent they may have changed since 2010 (see Box 6.2).

#### Box 6.2: GISRS running costs survey, June - September 2016

The Secretariat sent a survey to all GISRS laboratories including WHO CCs (6), NICs (143), WHO H5RLs laboratories (13) and WHO ERLs (4), noting that some laboratories provide dual functions.<sup>1</sup> Responses were received from only 41 laboratories, and only 19 provided complete datasets. The data provided had several limitations which made analysis difficult; it should be noted, that most responses were estimates of costs only, that data was often incomplete, and that in some cases the validity/accuracy of the data needed to be checked.

The estimated cost from only 41 laboratories totalled US\$ 39 million, indicating that GISRS total running costs most likely exceed the 2010 estimate of US\$ 56.5 million.

Given that WHO ERLs charge for their services, it was decided that their costs would not be included in this estimate. As running costs are different for WHO CCs, NICs and WHO H5RLs, they were grouped separately. Costs were then expressed as an average cost per laboratory (see Table 6.2) for each category and the 2016 total running costs then approximated for each category and then combined to reach an estimated overall total of US\$ 122 million.

There may be several reasons to explain why the running costs for GISRS have increased since 2010. The first estimate was based on little information, on only a few institutions, and did not contain all the running costs; for example, costs associated with training, accreditation, utilities, depreciation of equipment and in-kind contributions were not included. There are more laboratories in the GISRS network now than in 2011. Moreover, general costs and salaries would be expected to increase over the last five to six years. Industry's costs would also have increased over that time and while the Member State contribution to GISRS labs is a significant global investment and benefit, this contribution varies and is not equal among Member States.

| Institution | Number of labs<br>responding to<br>survey* | Average cost per<br>laboratory | Number of labs in GISRS | Estimated total cost              |
|-------------|--|--------------------------------|-------------------------|-----------------------------------|
| WHO CC      | 4  | US\$ 10 875 769                | 5**                     | US\$ 54 million                   |
| NIC         | 13   | US\$ 411 195                   | 143                     | US\$ 58 million                   |
| WHO H5RL    | 2  | US\$ 737 000                   | 14**                    | US\$ 10 million***                |
| TOTAL       |  |                                |                         | Approximately<br>US\$ 122 million |

\* While 41 labs responded to the survey only 19 provided complete and reliable datasets; WHO ERLs are not included.

\*\* Note that the WHO CC for studies on the ecology of influenza in animals and birds has been added to the WHO H5RL group for averaging purposes as its costs were significantly lower than the WHO CCs working on seasonal and pandemic viruses, and similar to the data provided by a WHO H5RL.

\*\*\* The dataset is too small to be meaningful and the average is likely to be exaggerated.

<sup>&</sup>lt;sup>1</sup> PIP Framework Review Group Secretariat, World Health Organization, unpublished data, October 2016.

Some stakeholders have suggested that the total PC should be linked to economic indicators, such as the gross domestic product (GDP) of the country in which the manufacturer is based. Industry representatives are working on some proposals for changes to the method for calculating the PC in order to improve stability and predictability and will submit these to WHO.

#### **Recommendations: Partnership Contribution collection**

23. The Advisory Group should consider updating the 2010 estimate of GISRS running/operating costs, as input to a revision of the Partnership Contribution formula calculation, in collaboration with industry, to facilitate the timely payment of Partnership Contribution, and its sustainability as a financing mechanism for implementation of the PIP Framework.

24. Given the successful use, following a recommendation by the Advisory Group, of a stepwise approach for the agreement of SMTA2s, the Advisory Group should consider developing a similar escalation response to underpayment, late payment or default of Partnership Contribution.

#### 6.3 Partnership Contribution implementation

#### Key Findings

Finding 48: Since funds began to be distributed in 2014, the implementation of the PC benefit sharing mechanism has been transparent and well-aligned with the Partnership Contribution Implementation Plan 2013-2016, which has been extended, following a recommendation by the Advisory Group to the Director-General, to 2017.<sup>1,2</sup> These PC resources have allowed countries to develop multi-year plans and have fostered sustained and meaningful capacity building.

Finding 49: Implementation of capacity development in each of the five Areas of Work (Laboratory and Surveillance; Burden of Disease; Regulatory Capacity building; Planning for Deployment; and Risk Communication) in priority countries started in 2014, with targets now due to be achieved by the end of 2017. Satisfactory progress has generally occurred although some regions have been delayed by necessary shifts in focus to outbreaks such as Ebola virus disease and Zika virus. Good progress has been made in supporting countries to improve capacity to detect and monitor novel influenza viruses, in burden of disease studies, risk communication, and the development of regulatory capacity. There has been some delay in the area of deployment capacity and there is now increased focus on national deployment plans.

<sup>&</sup>lt;sup>1</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Implementation Plan 2013-2016. Geneva: World Health Organization; 2015

<sup>(</sup>http://www.who.int/influenza/pip/pip\_pcimpplan\_update\_31jan2015.pdf?ua=1, accessed 20 September 2016), pages 9-11.

<sup>&</sup>lt;sup>2</sup> PIP Framework Advisory Group. Meeting of the Pandemic Influenza Preparedness Framework Advisory Group, 19-22 April 2016, Geneva, Switzerland. Report to the Director-General. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/ag\_april2016\_MeetingRpt.pdf?ua=1, accessed 22 September 2016), paragraph 45.

Finding 50: Expenditure does not always keep pace with collection, leading to a mistaken perception among some stakeholders that either additional PC Preparedness funds are not needed or that work plans are failing to be implemented according to planned timeframes. This risks an erosion of support among the entities making PC payments and an unwillingness to make further contributions.

Finding 51: The PIP Framework Secretariat communicates regularly about the achievements and challenges of PC implementation. Nevertheless, stakeholders regularly raise specific issues with WHO concerning: (1) dissatisfaction that PC funds continue to be collected while the Response funds are left untouched, which seemingly indicates a lack of understanding that this is a contingency fund to enable rapid response at the start of a pandemic, and that the amount of the Response funds is far below what will be needed at the time of a pandemic outbreak; (2) the basis on which recipient priority countries are selected, even though the criteria and process for selection have been published,<sup>1</sup> though this could indicate the desire of certain countries to be put on this list; and (3) a lack of understanding of how PC funds are building capacity in countries to increase preparedness for pandemic influenza.

Finding 52: The second Gap Analysis (the assessment of gaps and needs, as well as PC strengths, weaknesses, opportunities and threats (SWOT)) to be carried out by the PIP Framework Secretariat will inform the Director-General's proposal to the WHO Executive Board on the proportional split of PC funds between Preparedness and Response, which currently stands at 70:30, respectively.

Finding 53: Industry and Member States remain highly interested in understanding the decision-making process for PC implementation, and providing input as appropriate. WHO Regional Offices, too, have requested opportunities for PC implementers to discuss lessons learned, and would like to be more engaged in planning, implementation and monitoring. However, it should be noted that WHO Regional Offices are invited to participate in all Advisory Group meetings.

Finding 54: PC implementation Areas of Work, especially Burden of Disease studies, Regulatory Capacity and Planning for Deployment, are fundamental for the introduction of seasonal influenza vaccine programmes, which in turn provide the critical foundations for pandemic preparedness.

Finding 55: Several WHO Regional Offices raised the issue of the limited PIP Framework funding that is available for staff costs involved in implementation of PIP Framework activities. The current operating principle is that the percentage used for WHO staff should be kept as low as possible to ensure that the maximum amount of PC funds goes to activities implemented by countries. Other sources of funds may be appropriate to assist with staffing costs, and the PIP Framework (section 6.14.3.1) does encourage other donors generally to provide additional funds.

The funds raised through PC collection are allocated and spent in line with decisions taken by Member States through the WHO Executive Board. An amount not exceeding 10% of total contributions is allocated to fund the operation of the PIP Framework Secretariat, which

<sup>&</sup>lt;sup>1</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Implementation Plan 2013-2016. Geneva: World Health Organization; 2015 (http://www.who.int/influenza/

pip/pip\_pcimpplan\_update\_31jan2015.pdf?ua=1, accessed 20 September 2016), pages 9-11.

manages the implementation of the PIP Framework.<sup>1</sup> The balance is then split proportionately 70:30<sup>2</sup> between pandemic Preparedness activities and the PIP Response funds, with the indirect costs of WHO administrative support identified transparently as Programme Support Costs (PSC). A summary of total allocations relating to 2012-2015 PC is shown in Table 6.3 (receipts as of 30 June 2016).

|                              |                           | *              | A                |
|------------------------------|---------------------------|----------------|------------------|
| Table 6.3: Total Partnership |                           | (0040 004E \   | 1 = -100 = 0.010 |
| Lanie 6 3. Lotal Partnersnin | Lontribuition allocations | (/())/=/()/5 ) |                  |
|                              |                           |                |                  |

| Total Partnership  | Allocations     |                 |                      |                |
|--------------------|-----------------|-----------------|----------------------|----------------|
| Contribution funds | Preparedness**  | Response        | PIP Framework Progra |                |
| received           |                 |                 | Secretariat          | Support Costs  |
| US\$ 92 800 499    | US\$ 51 738 331 | US\$ 23 416 948 | US\$ 8 212 433       | US\$ 9 432 786 |

\* Year of invoice. \*\*Includes funds not yet allocated to specific Preparedness activities.

<sup>1</sup> Partnership Contribution Implementation Portal, Budget 2012-2016. In: World Health Organization (https://extranet.who.int/pip-pc-implementation/). Geneva: World Health Organization; 2016.

#### 6.3.1 Response

The Response funds are held in a reserve account that accumulates over time so that financial resources are immediately available to WHO at the time of a pandemic outbreak. A set of Guiding Principles was developed by the Advisory Group, in consultation with industry and other stakeholders, as the basis for the Director-General's decisions on how to use the Response funds.<sup>3</sup> For example, it is expected that funds will be needed to distribute the pandemic influenza vaccines donated through the SMTA2s and to purchase the additional products that manufacturers have agreed to make available at affordable prices.

#### 6.3.2 Preparedness

Under the Partnership Contribution Implementation Plan (2013-2016), the Preparedness funds are allocated across five Areas of Work: Laboratory and Surveillance; Burden of Disease; Regulatory Capacity building; Planning for Deployment; and Risk Communication.<sup>4</sup> The activities selected for support under these five areas are directly linked to the findings of the 2013 Gap Analyses, which assessed where capacity building was most urgently needed to strengthen global pandemic preparedness.<sup>5</sup> For each Area of Work there is a list of priority countries for action; regions were closely consulted in the selection of these countries, and the PIP Framework Partnership Contribution Implementation Plan 2013-2016 details the

<sup>3</sup> Ibid.

<sup>4</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Implementation Plan 2013-2016. Geneva: World Health Organization; 2015

(http://www.who.int/influenza/pip/pip\_pcimpplan\_update\_31jan2015.pdf?ua=1, accessed 22 September 2016).

<sup>&</sup>lt;sup>1</sup> *Ibid.*, page 6.

<sup>&</sup>lt;sup>2</sup> Guiding Principles for use of PIP Partnership Contribution "Response" Funds. In: World Health Organization [website]. Geneva: World Health Organization; 2014 (http://www.who.int/influenza/pip/guiding\_principles\_pc\_response\_funds.pdf?ua=1, accessed 21 September 2016), paragraph 2(b).

<sup>&</sup>lt;sup>5</sup> Pandemic Influenza Preparedness Framework Partnership Contribution 2013-2016 Gap Analyses. Geneva: World Health Organization; 2013 (http://www.who.int/influenza/pip/pip\_pc\_ga.pdf?ua=1, accessed 22 September 2016).

country selection process for each Area of Work.<sup>1</sup> Since Laboratory and Surveillance capacity building would receive the majority of PC funds, a more detailed process of selection was undertaken (see Box 6.3).

#### Box 6.3: Selection of countries for Laboratory and Surveillance capacity building<sup>2</sup>

Regional lists of potential priority countries were created through technical assessment of influenza-specific laboratory and surveillance country capacity, using factors identified by the Advisory Group. These were: country development status; IHR (2005) core capacity implementation; country needs for influenza epidemiological and laboratory surveillance; and A(H5N1) vulnerability.

WHO Regional Offices refined these lists by taking into account additional elements including: the political situation of countries in the region, notably whether a country is in a complex emergency; ongoing donor funding and investments in a country; absorptive capacity of a country; country population size; geographical location of a country in the region/sub-region (notably for island states); level of interest within a country/Ministry of Health to work in influenza; ability of a country to build on existing capacities to produce influenza surveillance data that could be shared with neighbouring countries.

Regions prioritized countries according to their ability to receive PC funds to strengthen capacities to detect and monitor influenza outbreaks, and to share information on influenza, particularly through GISRS. The lists of recommended countries were then sent to the Director-General, via the Advisory Group.

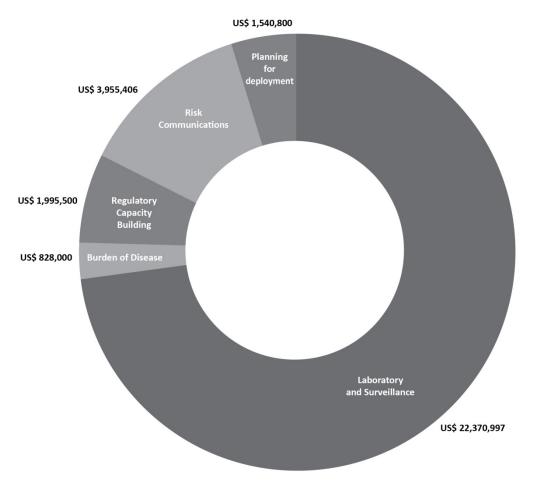
During 2014, more than 50 work plans were developed across WHO. The first tranches of funding went out in in April 2014 and by August 2014 some US\$ 17.4 million had been distributed to WHO HQ, Regional Offices and Country Offices to implement approved preparedness activities in the five areas.<sup>3</sup> By the end of 2015 the total PC funds distributed had reached approximately US\$ 31 million, with Laboratory and Surveillance accounting for around 70% of the distributions (see Figure 6.1).<sup>4</sup>

<sup>&</sup>lt;sup>1</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Implementation Plan 2013-2016. Geneva: World Health Organization; 2015 (http://www.who.int/influenza/pip/ pip\_pcimpplan\_update\_31jan2015.pdf?ua=1, accessed 22 September 2016), pages 9-11.

<sup>&</sup>lt;sup>2</sup> Ibid.

<sup>&</sup>lt;sup>3</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Annual Report 2015. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/246229/1/WHO-OHE-PED-2016.01eng.pdf?ua=1, accessed 22 September 2016), page 8.

<sup>&</sup>lt;sup>4</sup> *Ibid.*, page 4.



#### Figure 6.1: Distribution of Preparedness funds by area of work (end December 2015)

<sup>1</sup>. Pandemic Influenza Preparedness Framework, Partnership Contribution Annual Report 2015. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/246229/1/WHO-OHE-PED-2016.01-eng.pdf?ua=1, accessed 22 September 2016), page 65.

PC Preparedness funds are distributed against approved work plans and expenditure (i.e. actual spending) is tracked and reported across WHO. This has shown that expenditure of PC funds has not always kept up with funds' distribution. Over the five Areas of Work, the proportion of distributed money (i.e. as shown in Figure 6.1) that had actually been spent by the end of 2015 for the different Areas of Work was: Laboratory and Surveillance (80%); Burden of Disease (76%); Regulatory Capacity building (56%); Planning for Deployment (44%); and Risk Communication (85%).<sup>1</sup> The overall expenditure rate for Preparedness for 2014 and 2015 combined was 77%.<sup>2</sup>

Although the five Areas of Work have guided PC implementation so far, WHO recognizes that additional work areas may become relevant and more low and middle-income countries than are currently supported will need PC support in the future.<sup>3</sup> The Partnership

<sup>&</sup>lt;sup>1</sup> *Ibid.*, page 67.

<sup>&</sup>lt;sup>2</sup> Ibid., page 65.

<sup>&</sup>lt;sup>3</sup> *Ibid.*, page 52.

Contribution Implementation Plan 2013-2016 has been extended to the end of 2017<sup>1</sup> while a new Gap Analysis is carried out to review progress in the existing Areas of Work and to define possible future Areas of Work. All this information will feed into the development of a new PC high level implementation plan. Aligned with this, the current 70:30<sup>2</sup> split of PC funds between Preparedness and Response has also been extended by one year to the end of 2017 and will, if appropriate, be revised in the new plan according to any recommendations from the Director-General and the WHO Executive Board that are ratified by Member States at the 2017 World Health Assembly.

Progress towards agreed implementation targets is monitored closely every six months using a set of indicators for each Area of Work in order to register achievements against initial baseline conditions.<sup>3</sup> The targets set in the Partnership Contribution Implementation Plan 2013-2016 have been extended, with the Plan, to the end of 2017.<sup>4</sup> A detailed update on performance, as measured by the indicators, has been published annually by WHO in a Partnership Contribution Annual Report, starting for 2014.<sup>5,6</sup>

A summary of the main achievements under the five Areas of Work to end-2015 is presented in Table 6.4. Tables 6.5 - 6.10 present data for individual Areas of Work. While there are more recent data from 2016 for some of these indicators, different reporting periods mean that not all of Areas of Work have more recent data than the end of 2015; thus, to show progress in each Area of Work across the same period of time, the data used comes from the 2015 Partnership Contribution Annual Report.

<sup>&</sup>lt;sup>1</sup> PIP Framework Advisory Group. Meeting of the Pandemic Influenza Preparedness Framework Advisory Group, 19-22 April 2016, Geneva, Switzerland. Report to the Director-General. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/ag\_april2016\_MeetingRpt.pdf?ua=1, accessed 22 September 2016), paragraph 45.

<sup>&</sup>lt;sup>2</sup> This proportional split is after 10% of total PC income is allocated to the PIP Framework Secretariat.

<sup>&</sup>lt;sup>3</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Annual Report 2015. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/246229/1/WHO-OHE-PED-2016.01eng.pdf?ua=1, accessed 22 September 2016), page 11.

<sup>&</sup>lt;sup>4</sup> PIP Framework Secretariat, World Health Organization, unpublished information, October 2016.

<sup>&</sup>lt;sup>5</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Annual Report 2014. Geneva: World Health Organization; 2015 (http://apps.who.int/iris/bitstream/10665/161369/1/ WHO\_HSE\_PED\_GIP\_PIP\_2015.2\_eng.pdf?ua=1&ua=1, accessed 22 September 2016).

<sup>&</sup>lt;sup>6</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Annual Report 2015. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/246229/1/WHO-OHE-PED-2016.01-eng.pdf?ua=1, accessed 22 September 2016).

|   | 2014  | 2015  |
|---|---|---|
| Laboratory and<br>Surveillance capacity-<br>building <sup>2,3</sup> | 21 capacity indicators were<br>defined to measure progress<br>towards outputs and outcomes.<br>Baseline data were collected in<br>the 43 countries prioritized for<br>support in this area.   | Established and functioning<br>event-based surveillance for<br>influenza in 12 of the 43 PIP<br>priority countries.<br>128 countries worldwide shared<br>virus <sup>4</sup> with WHO CCs, WHO<br>H5RLs and WHO ERLs.  |
|   |   | <ul><li>66 countries consistently<br/>reported epidemiological data to<br/>regional or global platforms.</li><li>114 countries consistently<br/>reported virological data to a</li></ul>  |
|   |   | regional or global platform.<br>103 countries participated in the<br>WHO External Quality<br>Assessment Project for the<br>detection of influenza virus type<br>A by polymerase chain reaction<br>(EQAP) and scored 100%.   |
| Burden of Disease   | Seven countries participated in a<br>training to learn how to develop<br>national disease burden<br>estimates using a new WHO<br>manual.  | 40 countries, including 19 PIP<br>PC priority countries, are<br>estimating the burden of<br>influenza using WHO<br>methodology and technical<br>support.<br>Three PIP priority countries<br>completed robust national<br>burden of influenza estimates. <sup>5</sup><br>Six countries are piloting the<br>WHO economic burden tool. |
| Regulatory<br>capacity-building                                     | Work started to revise the<br>expedited review procedure to<br>facilitate licensing of pre-qualified<br>antivirals and vaccines.  | WHO collaborative procedure for accelerated regulatory approval of influenza products adopted by 14 countries. <sup>6</sup>   |
|   | The new Collaborative procedure<br>to address assessment and<br>accelerated national registration<br>of WHO-prequalified<br>pharmaceutical products and<br>vaccines was developed and<br>endorsed by the Expert<br>Committee on Specifications for<br>Pharmaceutical Preparations<br>(ECSPP) in October 2014. | 14 of 16 priority countries<br>assessed for regulatory capacity.  |

# Table 6.4: Highlights for 2014 and 2015 in the five Preparedness Areas of Work $\int_{1}^{1}$

|                         | 2014   | 2015   |
|-------------------------|--|--|
| Planning for Deployment | Model agreements between<br>WHO and recipient countries of<br>pandemic products were drafted.  | PIPDEPLOY tool to improve<br>deployment of influenza products<br>to countries was developed. |
| Risk Communications     | municationsSignificant training materials<br>were developed, translated and<br>published online.17 target countries<br>risk communication<br>and/or workshops. |  |
|                         |  | The ECN has a roster of 150 people able to be deployed to health emergencies worldwide.      |

<sup>1</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Annual Report 2015. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/246229/1/WHO-OHE-PED-2016.01-eng.pdf?ua=1, accessed 22 September 2016), page 8.

<sup>2</sup> Data from regional and global databases.

<sup>3</sup> Achievements for Laboratory & Surveillance at WHO Headquarters level were made with funds from PIP Partnership Contribution and other donors.

<sup>4</sup> Refers to seasonal and pandemic potential influenza viruses.

<sup>5</sup> Costa Rica, Chile and Egypt.

<sup>6</sup> United Rep. of Tanzania, Uganda, Ethiopia, Ghana, Kenya, Mozambique, Burkina Faso, Cameroon, Benin, Mali, Armenia, Sri Lanka, Bhutan, and Myanmar.

<sup>7</sup> Barbados, Cambodia, Dominica, Egypt, Kazakhstan, Kenya, Republic of Moldova, Mongolia, Nepal, Saint Lucia, Saint Vincent and the Grenadines, Senegal, Sudan, Turkey, Ukraine, Uzbekistan, Vietnam.

#### 6.3.2.1 Area of work: Laboratory and Surveillance<sup>1</sup>

The majority of activities in this Area of Work are under the responsibility of the Regional Offices that work through Country Offices to strengthen capacities for laboratory and surveillance where they are needed most. At the Regional level, the emphasis is placed on: 1) strengthening national capacities to detect respiratory disease outbreaks due to novel influenza virus (Output 1); and 2) strengthening national capacities to monitor trends in circulating influenza viruses (Output 2). In 2014, a total of 11 capacity indicators were defined to assess progress in national capacity to detect, monitor and share novel influenza viruses, and to judge the overall sustainability of the system in the 43 priority countries. Baseline data were collected from these priority countries in August 2014.

<sup>&</sup>lt;sup>1</sup> *Ibid.*, pages 4, 8, 12-14, and 33–34.

At the global level, 10 capacity indicators focus on strengthening collaboration through the sharing of information and viruses with an emphasis on improving the quality of the GISRS system (Output 3). These global indicators reflect all 196 Member States that provide information on influenza viruses to the WHO global databases, Flu Informed Decisions (FluID) and FluNet, including the 43 priority countries. Together with the 11 indicators mentioned above, this makes a total of 21 capacity indicators for laboratory and surveillance. By the end of 2015, the number of PIP countries reporting to FluNet had increased from 26 to 30, and to FluID from five to 11.

Tables 6.5 and 6.6 present an overview as measured against indicators for the three Outputs, followed by summaries of progress in these areas.

|                       |                      |                 |                |                        | 1 |
|-----------------------|----------------------|-----------------|----------------|------------------------|---|
| Table 6.5: Laboratory | y and Surveillance i | ndicators for O | utputs 1 and 2 | 2 at the national leve |   |

Outcome: The capacity to detect and monitor influenza epidemics is strengthened in developing countries that have weak or no capacity.

| Support to WHO regions and countries  |           |        |        |  |
|---|-----------|--------|--------|--|
| Output indicators   | Baseline* | Target | Status |  |
| <b>Detention capacity (43 PIP priority countries)</b><br>Number of countries with an established and functioning<br>event-based surveillance system | 8         | 43     | 12     |  |
| Monitoring capacity capacity (43 PIP priority countries)<br>Number of countries able to consistently report and analyze<br>virological data         | 26        | 35     | 30     |  |
| Number of countries able to consistently report and analyze epidemiological data  | 5         | 17     | 9      |  |

<sup>1</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Annual Report 2015. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/246229/1/WHO-OHE-PED-2016.01-eng.pdf?ua=1, accessed 22 September 2016), page 13.

\* 31 Aug 2014.

#### Summary of progress

Overall, good progress has been made across all regions in improving capacity to detect and monitor novel influenza viruses, share information about these viruses and sustain these actions over time.

- The 43 priority countries are distributed across six WHO Regional Offices as follows: WHO Regional Office for Africa (AFRO) (11 countries), WHO Regional Office for the Americas (AMRO)/Pan American Health Organization (PAHO) (8 countries), WHO Regional Office for the Eastern Mediterranean (EMRO) (7 countries), WHO Regional Office for Europe (EURO) (6 countries), WHO South-East Asia Regional Office (SEARO) (6 countries) and WHO Regional Office for the Western Pacific (WPRO) (5 countries).
- Not all priority countries are directly funded by PIP PC but they do benefit from training and workshops funded at the Regional and HQ levels of WHO. This means that countries may report full or partial capacity for an indicator where they have been suported indirectly, i.e. not through PIP PC funded work plans.

- AMRO, WPRO and EURO are expected to meet their country-level targets for the output indicators based on data collection round three in February 2016.
- AFRO, EMRO and SEARO have faced serious challenges to PIP PC implementation including outbreaks of Ebola virus disease, Yellow fever and Cholera (AFRO), civil unrest and refugee crisises (EMRO), and staff turnover and reagent/equipment challenges (SEARO). These regions may struggle to reach their targets by 2017 but are still expected to improve capacity based on the data collection round three in February 2016.

#### Table 6.6: Laboratory and Surveillance indicators for Output 3 at the global level

 Outcome: The capacity to detect and monitor influenza epidemics is strengthened in developing countries that have weak or no capacity.

 Output indicators

| Output indicators  | Baseline*       | Target        | Status |
|--|-----------------|---------------|--------|
| <b>Sharing capacity (global)</b><br>Number of countries that participate in EQAP and score 100%  | 109             | 120           | 103    |
| Number of countries sharing virus with WHO CCs, H5<br>Reference Laboratories and Essential Regulatory<br>Laboratories at least once a year in the past two years | 90              | 108           | 128    |
| Number of countries consistently reporting epidemiological data to regional or global platforms  | 55              | 71            | 66     |
| Number of countries which consistently report virological data to a global platform  | 108             | 124           | 114    |
| <sup>1</sup> Pandemic Influenza Preparedness Framework, Partnership Contribu   | tion Annual Rep | oort 2015. Ge | eneva: |

World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/246229/1/WHO-OHE-PED-2016.01eng.pdf?ua=1, accessed 22 September 2016), page 33.

\* 31 Aug 2014

#### Summary of progress

Overall, good progress has been made at the global level with workshops and training regularly provided in WHO regions and countries.

- For the WHO External Quality Assessment Project for the detection of influenza virus type A by polymerase chain reaction (EQAP) indicator, there will be fluctuations in the number of participating laboratories scoring 100%. This reflects staff turnover in national laboratories and the need continuously to train laboratory technicians to maintain high quality use of polymerase chain reaction (PCR) to detect influenza viruses. The target for this indicator may need to be revised to capture the reality of training laboratory staff in countries. An appropriate target may be, for example, "no fewer than 100 countries participating and scoring 100%".
- The results for sharing viruses with WHO CCs are positive and reflect the success of the influenza virus Shipping Fund (see chapter 4, section 4.1), which was established to improve sharing capacity for influenza viruses and clinical specimens.

 Results for global reporting of both epidemiological and virological data are positive and targets are expected to be met by the end of 2017. The results reflect improvements to make data entry easier when using the WHO/GIP global databases, FluNet (for epidemiological data) and FluID (for virological data).

#### 6.3.2.2 Area of Work: Burden of Disease<sup>1</sup>

Robust information on the national burden of disease for influenza is needed so that governments can decide whether to prioritize seasonal influenza prevention and control, including expansion of seasonal vaccine production capacity, which in turn is needed for pandemic vaccine preparedness. PC funds have supported GIP to develop tools for estimating the disease and economic burden of seasonal influenza. The biggest challenge in developing national burden of disease estimates is the lack of country-level data, which are often incomplete. In particular, robust data on influenza morbidity including hospitalization relies on laboratory confirmation, which is often unavailable in low income countries. Specific data are also needed on high risk groups and on the country-specific direct medical costs and indirect costs from loss of productivity. Considerable further work is needed to develop tools to estimate the cost-effectiveness of specific influenza interventions and to guide policy decisions on when and where to use seasonal vaccine. The goal is to create a global platform holding regularly updated global and regional data, economic data, and risk factor information for use in national influenza policy planning. Table 6.7 shows progress against this Area of Work's output indicators.

#### Outcome: National policy-makers will have influenza disease burden data needed for informed decision-making and prioritization of health resources Baseline Status Target All six WHO regions develop regional representative On track NA 6 burden of disease data to guide developing countries' policy-making Output 1: Derive regionally representative influenza 0 19 3\* disease burden estimates from selected countries Number of countries supported by Partnership Contribution with disease burden estimates by 2016 Output 2: Derive a global estimate of influenza disease 0 December On track burden estimates from selected countries Global 2016 estimate of influenza disease burden derived from national estimates purchased <sup>1</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Annual Report 2015. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/246229/1/WHO-OHE-PED-2016.01-

#### Table 6.7: Burden of Disease Output indicators

eng.pdf?ua=1, accessed 22 September 2016), page 36.

Costa Rica, Chile and Egypt have estimates pending publication in peer-reviewed journals. A further 12 countries are finalizing estimates

<sup>&</sup>lt;sup>1</sup> *Ibid.*, pages 8 and 37-38.

#### Summary of progress

Overall good progress has been made in this Area of Work as a result of training workshops in countries and the Burden of Disease Expert Advisory Group for influenza, which was convened in 2014 to provide advice and support to countries carrying out influenza burden estimation. This group holds monthly teleconferences and by September 2016 had held two face-to-face meetings. There is also good synergy with the WHO economic burden of disease tool. This tool is being piloted in four PIP priority countries (Chile, Costa Rica, Lao PDR and Indonesia), plus two others. Process indicators may be helpful to track the amount of work that is going into the estimation process from WHO's side.

- By September 2016, 40 countries (including 19 PIP priority countries for this Area of Work) were engaged in estimating the burden of influenza using WHO methodology and technical support; three countries (Costa Rica, Chile and Egypt) had completed their burden of disease estimates.
- A workshop was held in July 2016 to bring together countries involved in the estimation process to share challenges, solutions and preliminary results. As a result of the workshop, more robust national estimates are expected to be produced by the end of 2016.
- The targets are expected to be met by the end of 2017. There have been some delays on certain inputs to the global burden of influenza estimation process (i.e. global mortality estimates) resulting from delays in finding the right organizations to contract for the estimates.

#### **6.3.2.3** Area of Work: Regulatory Capacity Building<sup>1</sup>

Non-vaccine-producing countries that do not have appropriately developed regulatory systems will be unable to ensure that incoming vaccines are swiftly approved for use in the event of a pandemic. During the 2009 A(H1N1) pandemic, lack of a common regulatory approval process hampered influenza product registration in over half of the countries that received donated pandemic A(H1N1) vaccines.<sup>2</sup> The outputs and targets for this Area of Work seek to address the regulatory gaps in countries that were unable to follow relevant WHO guidance documents for product registration (see Table 6.8). PC is being used by the WHO Essential Medicines and Health Products Department to strengthen regional/sub-regional/national regulatory systems in the regulation of influenza products and their national approval.

<sup>&</sup>lt;sup>1</sup> *Ibid.*, pages 8 and 40-42.

<sup>&</sup>lt;sup>2</sup> Main operational lessons learnt from the WHO Pandemic Influenza A(H1N1) Vaccine Deployment Initiative. WHO: Geneva; 2010 (http://www.who.int/influenza\_vaccines\_plan/resources/ h1n1\_vaccine\_deployment\_initiaitve\_moll.pdf, accessed 4 October 2016).

#### Table 6.8: Regulatory Capacity Building Output indicators

Outcome: Countries with weak or no regulatory capacity will be able to regulate influenza products including vaccines, antivirals and diagnostics, and to accelerate national approval of these commodities in case of an influenza pandemic

1

| or these commodities in ease of an initidenza paracini  |          | r              |                              |
|---|----------|----------------|------------------------------|
|   | Baseline | Target         | Status                       |
| By 2016, at least 16 countries will have improved<br>their regulatory capacity to oversee influenza<br>products including vaccines, antivirals and<br>diagnostics and to accelerate national approval<br>registration of these commodities in caser of an<br>influenza pandemic   | NA       | At least<br>16 | On track                     |
| Output 1: Develop guidelines on regulatory<br>preparedness of non-vaccine producing countries<br>that enable them to expedite approval of influenza<br>vaccines used in national immunization<br>programmes<br>Regulatory preparedness guidelines endorsed by the<br>WHO Expert Committee on Biologicals Standardization<br>(ECBS)                                      | 0        | 1              | Awaiting ECBS<br>endorsement |
| Output 2: NRA capacity to regulate influenza<br>products including vaccines, antivirals and<br>diagnostics is strengthened<br>Number of countries which developed regulatory<br>capacity to oversee influenza products including<br>vaccines, antivirals and diagnostics in case of pandemic<br>as per the WHO NRA assessment and IDP elaboration<br>and implementation | 0        | 16*            | 1**                          |
| Output 3: Regulatory processes to accelerate<br>approval of influenza vaccines, antivirals and<br>diagnostics during a public health emergency are<br>incorporated into deployment plans for pandemic<br>influenza products<br>Number of countries with a common approach for<br>accelerated regulatory approval of influenza products in<br>a public health emergency  | 0        | 48***          | 14****                       |

<sup>1</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Annual Report 2015. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/246229/1/WHO-OHE-PED-2016.01-eng.pdf?ua=1, accessed 22 September 2016), page 39.

\* Democratic Republic of the Congo, Ethiopia, Ghana, Kenya, United Republic of Tanzania, Uganda, Bolivia, Haiti, Pakistan, Sudan, Armenia, Georgia, Nepal, Sri Lanka, Cambodia, Lao PDR.

\*\* The NRA of 14 of 16 PIP priority countries were assessed. One country has acceptable capacity in the three areas of assessment: regulatory systems, marketing authorization and pharmacovigilance. Implementation of Institutional Development Plans (IDP) started in 14 of the 16 PIP countries. Enhancing regulatory capacity is a long-term investment and impact data is not yet available.

\*\*\* Democratic Republic of Congo, Ethiopia, Ghana, Kenya, United Republic of Tanzania, Uganda, Mozambique, Cote d'Ivoire, South Africa, Angola, Burkina Faso, Gambia, Cameroon, Benin, Central African Republic, Guinea, Malawi, Mali, Bolivia, Haiti, Honduras, Nicaragua, Guyana, Peru, Pakistan, Sudan, Afghanistan, Yemen, Iraq, Morocco, Armenia, Georgia, Rep. of Moldova, Kazakhstan, Kyrgyzstan, Tajikistan, Nepal, Sri Lanka, Bangladesh, Bhutan, Myanmar, TimorLeste, Cambodia, Lao PDR, Kiribati, Mongolia, Philippines, Papua New Guinea.

\*\*\*\* United republic of Tanzania, Uganda, Ethiopia, Ghana, Kenya, Mozambique, Burkina Faso, Cameroon, Benin, Mali, Armenia, Sri Lanka, Bhutan and Myanmar.

#### Summary of progress

Overall progress has been made in this Area of Work but the three outputs are closely linked and futhermore are designed to support countries at different stages of national regulatory authority (NRA) development. Since Outputs 2 and 3 require country buy-in, (i.e. countries committing to implementing institutional development plans (IDPs) and adopting the WHO collaborative approach), WHO spends time and money on workshops, training and advocacy, which go unreported due to the results-based indicators assigned to these outputs. Process indicators might be helpful to allow monitoring of the outputs at a more granular level.

- Guidelines have been produced on regulatory preparedness to assist non-vaccine producing countries to expedite approval of seasonal vaccines and/or pandemic vaccines deployed by a UN agency. The WHO Expert Committee on Biological Standardization approval is expected by October 2016 and the target for Output 1 is due to be met by the end of 2016.
- WHO is working with 16 priority countries to address critical gaps in regulatory systems and two other functions deemed essential for countries that procure vaccines through UN agencies: marketing authorization and pharamcovigilance. Progress has been made for this output, namely WHO has assessed 14 countries to identify gaps in these three critical areas. IDPs are in place in these countries to fix these gaps. The two remaining priority countries were due to be assessed by the end of 2016 and IDPs also put into place. By October 2016, only one of the 16 priority countries had met the "desired capacity" for regulatory preparedness in all three critical areas and it is unlikely that the remaining 15 countries will reach this stage by the end of 2017. Nonetheless progress has been made in moving countries from "below critical capacity" for regulatory capacity and into "acceptable capacity" as a result of in-country training activities.
- 14 out of 48 target countries have adopted the WHO common approach for accelerated regulatory approval of influenza products in a public health emergency. Acceptance of the WHO common approach is voluntary for countries, and is one of several options to improve regulatory capacity. Progress in this area has been made by holding advocacy workshops in SEARO and developing an addendum to the collaborative procedure to cover vaccines for emergency use. It is unlikely that all 48 target countries will adopt the collaborative procedure by 2017 but WHO continues to raise the profile of the collaborative procedure for pharmaceutical products and vaccines. A regional workshop in the WPRO region is due to take place by the end of 2016.

#### 6.3.2.4 Area of Work: Planning for Deployment<sup>1</sup>

System bottlenecks and lack of coordination between the large number of different organizations involved in deployment can severely delay the distribution and use of pandemic vaccines and other public health products at the time of an outbreak. In addition,

<sup>&</sup>lt;sup>1</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Annual Report 2015. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/246229/1/WHO-OHE-PED-2016.01eng.pdf?ua=1, accessed 22 September 2016), pages 8 and 45.

low resourced countries need to be in a "ready" mode in order to receive and make optimal immediate use of an initial limited supply of pandemic vaccines and antivirals. Simulation exercises can be used to test operational deployment systems across countries and responding support agencies in a combined response. PC funds have helped to develop and test the PIPDEPLOY simulation tool, which is designed for countries to identify and help correct bottlenecks and failure points in vaccine delivery in public health emergencies. Table 6.9 shows progress against this Area of Work's output indicators.

#### Table 6.9: Planning for Deployment Output indicators

| Outcome: Plans for deployment of pandemic supplies includes vaccines, antivirals and diagnostics, will be developed and regularly updated  |          |        |   |  |  |
|--|----------|--------|---|--|--|
|  | Baseline | Target | Status                                      |  |  |
| Output 1: A common approach to manage<br>deployment operations is developed and shared<br>with stakeholders and deployment partners<br>A common deployment approach is developed with<br>multiple deployment stakeholder endorsement | 0        | 1      | Draft available                             |  |  |
| Number of training and simulation exercises with deployment stakeholders   | 0        | 8      | Simulation<br>exercise set for<br>mid-2016* |  |  |
| Output 2: Country deployment readiness systems<br>are simplified and updated<br>Model country recipient agreement is revised and<br>updated  | 0        | 1      | In process                                  |  |  |
| Countries and partners accessing web-based planning tools  | 0        | 16     | Pending tools                               |  |  |

<sup>1</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Annual Report 2015. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/246229/1/WHO-OHE-PED-2016.01-eng.pdf?ua=1, accessed 22 September 2016), page 44.

\* This simulation exercise was still pending as of 26 October 2016.

#### Summary of progress

Overall this Area of Work has been delayed despite considerable work on developing the PIPDEPLOY simulation tool. National deployment plans are expected to be the focus of further development in 2016, with some process measures enabling progress to be monitored.

- For Output 1, a draft document on a common approach to manage deployment operations has been developed for endorsement by deployment stakeholders.
- The PIPDEPLOY simulation tool is delayed. The tool was expected to go live in early 2016 but the complexity of technological difficulties were underestimated, delaying the tool's release. By the end of 2017, two or three simulation exercises are expected to be conducted with deployment stakeholders.
- For Output 2, the model country recipient agreement has been streamlined and updated. It will need to be adjusted for specific public health emergency circumstances as emergencies arise. The web-based planning tools have not yet

been developed. To support their development, current national deployment plans for the 16 target countries are being assessed and appropriate tools will be developed to fill any gaps identified in the plans.

• The 16 target countries for planning for deployment are the same as those for regulatory capacity building, creating a synergy between the linked activities of product registration and product deployment in countries.

#### 6.3.2.5 Area of Work: Risk Communications<sup>1</sup>

Effective risk communication is important for avoiding misinformation and panic that can hamper public health interventions. As was learned in 2014 and 2015, during the international response to Ebola virus disease in West Africa, national and international capacity for risk communication is a crucial element of effective emergency response. In this context, PC funds have been used to target the 30 priority countries, as well as supporting the global WHO Emergency Communications Network (ECN). A wide range of guidelines, tools, curricula and materials have been developed to build skills in pandemic influenza risk communication. These materials have been distributed through the WHO website, iLearn and through a contact database of more than 1,000 training participants. Materials to train journalists in responsible reporting during pandemic influenza have been finalized and sub-regional media workshops held. Simulation and "table-top" exercises hosted in eight countries were used to build and test risk communication capacity. Table 6.10 shows progress against this Area of Work's output indicators.

| pandemic influenza communications  |          |        |                         |  |
|--|----------|--------|-------------------------|--|
|  | Baseline | Target | Status                  |  |
| Output 1: Access to risk communications training<br>and platforms is increased enabling all countries<br>to respond more effectively to a potential<br>influenza pandemic<br>Tools and web-based risk communications training<br>material accessible to Member States in all language<br>versions by December 2015 | 0        | 194    | Available in<br>English |  |
| Number of registered users of online material  | 0        | 500    | 513                     |  |
| Number of trainings completed on IHR risk communications training website*   | 0        | 200    | 96                      |  |
| Output 2: Risk communications capacity is<br>established in priority countries with little or no<br>capacity<br>Targeted Member States will have benefitted from<br>IHR risk communications programme by end of 2016   | 0        | 30     | 17                      |  |

Outcome: Global risk communications capacities are strengthened with a specific focus on

#### Table 6.10: Risk Communication Output indicators

<sup>&</sup>lt;sup>1</sup> *Ibid.*, pages 8 and 47.

| Output 3: Global Emergency Communications<br>Network (ECN) operationalized to provide support<br>to countries before, during and after public health<br>emergencies<br>Proportion of requests for risk communications surge<br>support responded to within 72 hours by WHO in<br>2015/16 | 0 | 80% | 100% |  |  |
|--|---|-----|------|--|--|
| <sup>1</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Annual Report 2015. Geneva: World Health Organization; 2016, (http://apps.who.int/iris/bitstream/10665/246229/1/WHO-OHE-PED-2016.01-eng.pdf?ua=1, accessed 22 September 2016), page 46.                 |   |     |      |  |  |

#### Summary of progress

Overall this Area of Work has made good progress towards its targets and has exceeded expectations for Output 3 by meeting the target early. Work needs to continue to include all 30 priority countries in risk communications training and to make training materials available in languages other than English.

- Good progress has been made towards providing access to risk communication training, with introductory materials available in all UN languages and Portuguese and a wide range of more advanced materials available in English. Limitations of the material dissemination through iLearn, the WHO website, and contact lists will be addressed through the launch of www.openWHO.org platform, scheduled in October 2016. The new platform will facilitate access and a much wider dissemination and use of these training materials, and will enable better tracking of user numbers and feedback. With this platform, the target set for completed online training is likely to be met or exceeded by the end of 2017.
- The target of establishing risk communications capacity in the 30 priority countries is expected to be met by the end of 2017. Priority countries that are inaccessible for face-to-face training interventions will be supported through training initiatives hosted on the platform and supported through mentoring activities.
- Development of the ECN has met its target to provide support to countries before, after and during public health emergencies. By October 2016, this network had a roster of 150 staff, consultants, partners, government experts and officials able to be deployed for pandemic communications within 72 hours. The ECN is a benefit across WHO's Health Emergencies Programme because its capacities are available to all public health emergency operations, creating synergies between PIP and other areas. Regular deployment of trainees also ensures that existing capacity is maintained and exercised.

#### **Operational challenges**

Influenza pandemic preparedness activities naturally overlap with other public health initiatives and specifically with other influenza efforts. On the positive side, this means that PC funded programmes can produce collateral benefits, creating efficiencies and aligning with and providing support to other programmes. However, there is also the potential for duplication of effort if careful and detailed co-planning and monitoring are not performed. All influenza preparedness activities also have to deal with the reality that regions have

competing priorities and influenza is not high on policy makers' agendas all the time; in the case of the PIP Framework this contributes to variability across regions and countries in PC implementation.

There will always be a necessary balance between rapid disbursement of funds and the need for quality control of work plans. While WHO has been conservative in disbursement, attempts have also been made to streamline this process. However, as mentioned in chapter 6 section 6.2 (PC collection), the misalignment between the time period when PC funds are received and when they need to be distributed to work plans has been exacerbated by late payments from contributors and by some non-payments. Until this issue is addressed it will continue to have a knock-on impact in terms of delaying the start of work plans and hindering pandemic preparedness.

The PIP Framework Secretariat has commissioned an external independent evaluation of PC implementation, which is due to take place from October 2016 to April 2017. It will:

- Evaluate the progress of each Area of Work towards achieving the target outputs and outcomes set out in the high level Partnership Contribution Implementation Plan 2013-2016;<sup>1</sup>
- Measure the short, medium and longer term impact generated by each of the Areas
  of Work to determine how these have helped prepared the global community for
  pandemic influenza;
- Identify lessons learnt that can improve the management of PIP PC funds in the future.

#### **Recommendations: Partnership Contribution implementation**

25. The Advisory Group should consider for inclusion in the 2018-2022 Partnership Contribution Implementation Plan, the development of process measures to enable better monitoring of progress for key Areas of Work.

26. The Advisory Group should request regular financial reports and audits and ensure that appropriate financial accountability mechanisms are in place; it should also request the PIP Framework Secretariat to illustrate how the Partnership Contribution Response funds will be severely inadequate in a pandemic.<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Implementation Plan 2013-2016. Geneva: World Health Organization; 2015

<sup>(</sup>http://www.who.int/influenza/pip/pip\_pcimpplan\_update\_31jan2015.pdf?ua=1, accessed 22 September 2016).

<sup>&</sup>lt;sup>2</sup> See Recommendation 2(b) of this report, which states: "WHO should regularly and more effectively communicate the objectives and progress in the implementation of the PIP Framework to Members States, Global Influenza Surveillance and Response System (GISRS) laboratories, industry, civil society, and other stakeholders. In particular, it should better communicate:

b. Partnership Contribution implementation measures; these should be highlighted in regular Advisory Group reports and post-meeting briefings so that progress is more visible and clearly recognized."

### Chapter 7: Governance

#### Key Findings

Finding 56: Although it is relatively new, the PIP Framework overall has a well-functioning governance structure that oversees how the PIP Framework is operationalized. It has benefited from strong commitment at each of WHO's three levels: HQ; Regional Offices; and Country Offices.

Finding 57: The Advisory Group continues to play a key role in effective governance by providing impartial, committed, and pragmatic oversight and guidance, representing its independent deliberations.

Finding 58: The intended composition of the Advisory Group has been achieved in practice, with a good balance of skills and representation of the regions. The engagement of WHO Regional Offices in Advisory Group meetings has benefited all participants – and Regions should be encouraged to increase their participation. Where expert evidence and situational analysis has been required, the Advisory Group has initiated the establishment by the Director-General of technical and expert working groups on GSD.

Finding 59: The value of the Advisory Group has been enhanced by members' familiarity with the issues and the expertise that has developed over time. However, the fixed three-year term for Advisory Group members, with extensions only for a further full three-year term, means that the membership of the Advisory Group is usually completely renewed every three years. This regular turnover brings benefits in terms of fresh inputs from new members but also risks the loss of institutional memory with the exit of experienced members.

Finding 60: Based on evidence provided to the Review Group, since 2011 the Advisory Group's recommendations to the PIP Framework Secretariat and to the Director-General have been acted upon. The Advisory Group's Annual Reports and the Director-General's Biennial Reports have been completed and delivered on time and made available as publications on the PIP Framework website. The Director-General has reported each year on the PIP Framework to the WHO Executive Board and the World Health Assembly; therefore, Member States are well apprised of its actions and progress. However, harmonising the prescribed content of the Advisory Group Annual Reports and the Director-General's Biennial Reports would improve efficiency.

Finding 61: The regularity and transparency of communication and engagement between the Advisory Group and Member States, industry and civil society organizations was recognized and appreciated by a number of key informants interviewed by the Review Group. That said, only a relatively small number of civil society organizations engage consistently with the Secretariat; this may be because others are unclear about the relevance of the PIP Framework for their work. The Secretariat could reach out to a wider community of civil society groups in order to broaden and deepen engagement, which would bring new perspectives that could benefit the PIP Framework.

Finding 62: Some GISRS members, notably WHO CCs, feel there should be greater interaction between themselves, the Advisory Group, and the PIP Framework Secretariat,

including in the setting up of technical working groups. It might also be helpful if the regular, direct contact that occurs between the Advisory Group and industry and civil society organizations also included GISRS technical experts. However, it is important to note that the PIP Framework Secretariat and Advisory Group have had consistent engagement from only one or two civil society organizations.

Finding 63: An objective of the PIP Framework is to strengthen GISRS, and geographical reach, scope and functioning of GISRS has expanded; however, the leadership of this network remains largely informal and the system is coordinated through GIP. The lack of a formalized leadership structure from within GISRS has led to the absence of recognized representation for the entire GISRS network in PIP Framework operations.

Finding 64: Under the 2016 reform of WHO's work in health emergency management, all WHO's work in emergencies was brought under a new Health Emergencies Programme, including the PIP Framework Secretariat.<sup>1</sup> WHO's commitment to the PIP Framework remains unchanged by this internal reorganization. The PIP Framework Secretariat is significantly dependent on close collaboration with many technical units of WHO, especially the GIP. The GIP is the technical influenza unit that coordinates GISRS, which underpins the implementation of the PIP Framework. Thus any internal reorganization would need to ensure that the GIP technical input remains closely aligned with the PIP Framework Secretariat and informs its implementation.

Finding 65: The Review Group was advised that resources and staffing are stretched in many areas, at all three levels of WHO (HQ, Regional Offices and Country Offices) and across many areas of activity, such as virus sharing, PC implementation, and in the PIP Framework Secretariat's work with companies on the prequalification of vaccines. Some of this Review's Recommendations will require additional resources, for example to produce the studies that have been called for.

#### 7.1 PIP Framework Advisory Group

The implementation of the PIP Framework is overseen by the World Health Assembly with advice from the Director-General, who also promotes implementation of the PIP Framework within WHO and among relevant WHO-related entities.<sup>2</sup> An independent Advisory Group, appointed by the Director-General, is the "third pillar" of the PIP Framework's Governance and Review structure.<sup>3</sup> It provides expert monitoring and evaluation of implementation of the PIP Framework, with evidence-based reporting, assessment and recommendations to the Director-General on the functioning of the PIP Framework. The Advisory Group does not

<sup>&</sup>lt;sup>1</sup> Reform of WHO's work in health emergency management, WHO Health Emergencies Programme,

Report by the Director-General. In: World Health Organization [website]. Geneva: World Health Organization; 2016 (A69/30; http://apps.who.int/gb/ebwha/pdf\_files/WHA69/A69\_30-en.pdf, accessed 22 September 2016).

<sup>&</sup>lt;sup>2</sup> Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011 (http://www.who.int/influenza/pip/en/, accessed 21 September 2016), section 7.1.

<sup>&</sup>lt;sup>3</sup> Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits: report of the Advisory Group. Report by the Director-General. In: World Health Organization [website]. Geneva: World Health Organization; 2011 (EB130/18; http://apps.who.int/gb/ebwha/pdf\_files/EB130/B130\_18-en.pdf?ua=1, accessed 21 September 2016), paragraph 2.

itself engage in administrative functions.<sup>1</sup> When considered necessary, the Advisory Group can recommend that the Director-General set up a technical or expert working group to provide evidence an analysis on a specific issue, such as the handling of IVPP GSD under the PIP Framework.<sup>2</sup>

Since its first meeting in November 2011,<sup>3</sup> the Advisory Group has convened twice a year at WHO HQ, Geneva. Reports of these meetings are published on the PIP Framework website, including recommendations to the Director-General. Member States' Permanent Missions in Geneva are briefed immediately after the meetings. Each Advisory Group meeting also includes an interaction with industry and other stakeholders to hear their views on the implementation of the PIP Framework. A PIP Framework e-Newsletter is published every two months to keep all stakeholders informed of events and new publications; regular teleconferences are held with industry and civil society groups for direct contact.

The 18 members of the Advisory Group are drawn from three Member States in each WHO region and are selected to provide a skill mix of internationally recognized policy makers, public health experts and technical experts in the field of influenza.<sup>4</sup> The standard duration of appointment is three years, with members eligible to serve for two appointments. Members of the original Advisory Group all served until 2015 to maintain stability during the early years of PIP Framework implementation. Starting in 2015, one third of the Advisory Group (i.e. six of the 18 members) has been renewed each year after completing a three-year appointment, in line with the terms of reference.<sup>5</sup> This pattern of staggered renewal over three years aims to preserve the continuity and institutional memory of the Advisory Group. The mix of geographical and skills is maintained when membership of the group changes.

Every April, the PIP Framework Secretariat puts considerable effort into educating the six new members of the group but the rotation means that at some meetings the most experienced members have only been on the Advisory Group for two years. The Review Group was encouraged to consider how an appropriate balance could be maintained between the positive impact of new members and the importance of institutional memory and continuity. While there would be ways to introduce more flexibility into the lengths of term served, many of these approaches would make it difficult to maintain the Advisory Group's geographic and skills mix that is required by the PIP Framework.

<sup>&</sup>lt;sup>1</sup> Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011 (http://www.who.int/influenza/pip/en/, accessed 21 September 2016), section 7.1.2(iii).

<sup>&</sup>lt;sup>2</sup> Handling Genetic Sequence Data under the PIP Framework. In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/advisory\_group/gsd/en/, accessed 20 September 2016).

<sup>&</sup>lt;sup>3</sup> Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits: report of the Advisory Group, Report by the Director-General. In: World Health Organization [website]. Geneva: World Health Organization; 2011 (EB130/18; http://apps.who.int/gb/ebwha/pdf\_files/EB130/B130\_18-en.pdf?ua=1, accessed 22 September 2016), paragraph 2.

<sup>&</sup>lt;sup>4</sup> Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011 (http://www.who.int/influenza/pip/en/, accessed 21 September 2016), Annex 3, Advisory Group, Terms of Reference, section 3.1.

<sup>&</sup>lt;sup>5</sup> *Ibid.* Annex 3, Advisory Group, Terms of Reference, section 3.2.

The Advisory Group presents an Annual Report to the Director-General describing progress and challenges to the PIP Framework's implementation. The report covers seven areas:<sup>1</sup> necessary technical capacities of WHO GISRS; operational functioning of WHO GISRS; WHO GISRS influenza pandemic preparedness priorities, guidelines and best practices (e.g. vaccine stockpiles, capacity building); increasing and enhancing surveillance for A(H5N1) and other IVPP; the IVTM; the sharing of influenza viruses and access to vaccines and other benefits; use of financial and non-financial contributions. The first separate Partnership Contribution Annual Report was published in April 2015.<sup>2</sup>

Every two years the Director-General presents a Biennial Report to inform the World Health Assembly, through the WHO Executive Board, about the status and progress in five areas of PIP Framework activity:<sup>3</sup> laboratory and surveillance capacity; global influenza vaccine production capacity; the status of agreements entered into with industry, including information on access to vaccines, antivirals and other pandemic material; the financial report on the use of the PC; the experience arising from the use of the definition of PIP BM. All Annual Reports and Biennial Reports are available on the PIP Framework website.<sup>4</sup>

The subjects to be covered by the Annual Reports and Biennial Reports are specified in the PIP Framework and do not currently map well onto each other (see Table 7.1);<sup>5</sup> this creates considerable additional work for the PIP Framework Secretariat when preparing the documents.

The PIP Framework also sets funding limits for WHO's own PIP Framework implementation related costs. The PIP Framework Secretariat is funded through an amount not exceeding 10% of total PC funds<sup>6</sup> and a maximum of up to 20% of PC work plan funds can be used for staff in the regions. As a result, resources and staffing are stretched in many areas at all three levels of WHO work (HQ, Regional Offices and Country Offices), including for administering virus sharing, PC implementation, and in the GIP team working with companies on the prequalification of vaccines. Some of this Review's Recommendations will require additional resources, for example to produce the studies that have been called for.

<sup>4</sup> PIP Framework Advisory Group. PIP Framework Advisory Group Reports. In: World Health Organization [website]. Geneva: World Health Organization; 2016

(http://www.who.int/influenza/pip/pip\_meetings\_consultations/en/, accessed 22 September 2016).

<sup>&</sup>lt;sup>1</sup> *Ibid.* section 7.2.5.

<sup>&</sup>lt;sup>2</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Annual Report 2014. Geneva: World Health Organization; 2015

<sup>(</sup>http://apps.who.int/iris/bitstream/10665/161369/1/WHO\_HSE\_PED\_GIP\_PIP\_2015.2\_eng.pdf?ua=1&ua=1, accessed 22 September 2016).

<sup>&</sup>lt;sup>3</sup> Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. Geneva: World Health Organization; 2011 (http://www.who.int/influenza/pip/en/, accessed 21 September 2016), section 7.4.1.

<sup>&</sup>lt;sup>5</sup> http://www.who.int/influenza/pip/pip\_pcimpplan\_update\_31jan2015.pdf?ua=1, accessed 22 September 2016), page 6. The sequences in this table are out of numeric and alphabetical order as they follow that of the source publications.

<sup>&</sup>lt;sup>6</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Implementation Plan 2013-2016. Geneva: World Health Organization; 2015 (http://www.who.int/influenza/pip/pip\_pcimpplan\_update\_31jan2015.pdf?ua=1, accessed 22 September 2016), page 6.

|                    | Director-General's Biannual<br>Report (section 7.4.1)   | Advisory Group Annual Report (section 7.2.5<br>and Annex 3, section 2.6) <sup>1</sup>  |  |  |
|--------------------|---|--|--|--|
| Virus<br>Sharing   | (i) Laboratory and Surveillance<br>capacity   | <ul> <li>(f) The sharing of influenza viruses and access to vaccines and other benefits</li> <li>(e) The IVTM</li> <li>(a) Necessary technical capacities of WHO GISRS</li> <li>(b) Operational functioning of WHO GISRS</li> <li>(c) WHO GISRS influenza pandemic preparedness priorities, guidelines and best practices (e.g. vaccine stockpiles, capacity building)</li> <li>(d) Increasing and enhancing surveillance for A(H5N1) and other influenza viruses with human pandemic potential</li> </ul> |  |  |
|                    | (v) The experience arising from the use of the definition of PIP BM   |  |  |  |
| Benefit<br>Sharing | (ii) Global influenza vaccine<br>production capacity  | (f) The sharing of influenza viruses and access to vaccines and other benefits   |  |  |
|                    | (iii) Status of agreements entered<br>into with industry including<br>information on access to vaccines,<br>antivirals and other pandemic<br>material |  |  |  |
|                    | (iv) Financial report on the use of the PC  | (g) Use of financial and non-financial contributions   |  |  |

## **Table 7.1: PIP Framework Reporting Requirements**

## 7.2 Oversight of GISRS

The PIP Framework (Annexes 4 and 5) sets out core and specific guiding principles for the terms of reference for the different types of GISRS laboratories – WHO CCs, WHO NICs, WHO H5RLs and WHO ERLs. These terms of reference cover general operational requirements as well as PIP-specific clauses. All GISRS laboratories are under a system of continuous review by GIP to assess whether they are meeting their terms of reference; for example, WHO CCs are reviewed every four years.

NICS are sovereign national facilities with responsibilities as members of GISRS and under the PIP Framework but there is no contractual relationship and no payments for specific aspects of their PIP Framework and seasonal influenza work. Oversight by WHO of this voluntary network, for instance of their use of the IVTM, is therefore limited. The timeliness of the NICs' sharing of viruses with WHO CCs is key to any assessment their performance. Such sharing underpins the six-monthly WHO consultations that analyse the GISRS influenza virus surveillance data and issues recommendations on the composition of the influenza vaccines for the following influenza season. Among their tasks, these meetings review the antigenic and genetic characteristics of seasonal viruses and viruses presenting a pandemic threat such as A(H7N9), A(H5), A(H9) and other subtypes or variant influenza viruses detected and analysed by GISRS laboratories. They also review the need for the

<sup>&</sup>lt;sup>1</sup> Section 7.2.5 and Annex 3, section 2.6 of the PIP Framework provide the same text.

development of new CVVs for pandemic preparedness purposes.<sup>1</sup> There are also regular updates on influenza virus global surveillance that show surveillance activity by region and the number of times updates are posted,<sup>2,3</sup> all of which provides monitoring of the NICs' performance.

The PIP Framework Secretariat meets the WHO CC and WHO ERL directors every February and September at the vaccine virus selection meetings and works closely with GISRS. However, GISRS laboratories have had only limited involvement in the development of the high level PC implementation plans for capacity building for laboratories and surveillance. GISRS representatives also expressed to the Review Group their wish to have greater and regular engagement with the Advisory Group, along the same lines at that arranged for industry and civil society. Some concerns were also expressed about the selection of experts for the technical working groups.

An objective of the PIP Framework is to strengthen GISRS, and since 2011 the geographical reach, scope and functioning of GISRS has expanded; however, the leadership of this network remains largely informal and the system is coordinated through the GIP. The lack of a formalized leadership structure from within GISRS has led to the absence of recognized representation for the entire GISRS network in PIP Framework operations.

#### **Recommendations: Governance**

27. The Director-General should consider options for retaining continuity and knowledge in the Advisory Group, including members being able to serve a second term of flexible duration.

28. The structure of the Advisory Group's Annual Reports to the Director-General and the Director-General's Biennial Reports to the World Health Assembly should be harmonized to simplify reporting.

29. The PIP Framework Secretariat and Advisory Group should broaden and deepen engagement with civil society to a greater number of participating organizations.

30. Noting the critical role of the WHO Collaborating Centres in the GISRS network, the Advisory Group should undertake more regular engagement with the WHO Collaborating Centres and other key GISRS laboratories, including when setting up technical working groups.

<sup>&</sup>lt;sup>1</sup> WHO Consultation and Information Meeting on the Composition of Influenza Virus Vaccines for the Northern Hemisphere 2016-2017. In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/vaccines/virus/recommendations/consultation201602/en/, accessed 22 September 2016).

<sup>&</sup>lt;sup>2</sup> For example, Influenza update – 272. In: World Health Organization [website]. Geneva: World Health Organization; 2016

<sup>(</sup>http://www.who.int/influenza/surveillance\_monitoring/updates/latest\_update\_GIP\_surveillance/, accessed 22 September 2016).

<sup>&</sup>lt;sup>3</sup> FluNet Summary. In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/gisrs\_laboratory/updates/summaryreport, accessed 22 September 2016).

31. The Director-General should address the issue of the lack of a formalized representation for the GISRS network, and encourage the WHO Global Influenza Programme and GISRS to establish such representation as soon as possible.

32. The Director-General should ensure that any internal reorganization of WHO departments under the new Health Emergencies Programmes should ensure that the activities of GISRS and the PIP Framework remain closely aligned and integrated with the WHO Global Influenza Programme to ensure stronger scientific and technical leadership in the implementation of the PIP Framework.

33. The Director-General should continue to make available the necessary human and financial resources to implement the growing activities of the PIP Framework and the Recommendations of this Review.

# Chapter 8: Linkages with WHO programmes and other legal instruments

Maximizing the impact of the PIP Framework requires looking beyond the specific scope of the agreement to the complex legal and institutional environment in which it operates. Aspects of the PIP Framework's mandate overlap with those of other legal instruments and WHO programmes. Three in particular – the GAP,<sup>1</sup> the IHR (2005),<sup>2</sup> and the Nagoya Protocol to the Convention on Biological Diversity<sup>3</sup> ("Nagoya Protocol") – intersect with the PIP Framework's scope (see Table 8.1).

The risk of an influenza pandemic is also relevant for the several major global health security initiatives to understand how to equip the world more generally against future emergencies. One of the most high-profile is the Global Health Security Agenda (GHSA),<sup>4</sup> an effort by countries, international organizations, and civil society to enhance the capacity of the world to prevent, detect, and rapidly respond to infectious disease threats. The GHSA has 11 Action Packages, some of which support pandemic preparedness, including on zoonotic disease, immunization, national laboratory systems, and real-time surveillance.<sup>5</sup> The third UN Sustainable Development Goal (SDG) is to ensure healthy lives and promote well-being for all at all ages. Its targets include the access to safe, effective, quality and affordable antivirals and vaccines for all, support for the research and development of antivirals and vaccines, and to strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks.<sup>6</sup>

| Торіс                            | PIP Framework | IHR (2005) | GAP | Nagoya |
|----------------------------------|---------------|------------|-----|--------|
| Improve pandemic<br>preparedness | $\checkmark$  | ~          | ~   |        |
| Improve pandemic response        | $\checkmark$  | ~          | ~   |        |

 Table 8.1: Summary of linkages between the PIP Framework the IHR (2005), GAP and

 Nagoya Protocol

<sup>&</sup>lt;sup>1</sup> Global Action Plan for Influenza Vaccines (GAP). In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza\_vaccines\_plan/en/, accessed 22 September 2016).

<sup>&</sup>lt;sup>2</sup> International Health Regulations (2005), 2<sup>nd</sup> ed. Geneva: World Health Organization; 2008 (http://apps.who.int/iris/bitstream/10665/43883/1/9789241580410\_eng.pdf, accessed 22 September 2016).

<sup>&</sup>lt;sup>3</sup> The Nagoya Protocol on Access and Benefit-sharing. In: Convention on Biological Diversity [website]. Montreal: Convention on Biological Diversity, United Nations; 2011 (https://www.cbd.int/abs/, accessed 22 September 2016).

<sup>&</sup>lt;sup>4</sup> Global Health – CDC and the Global Health Security Agenda. In: Centers for Disease Control and Prevention [website]. Atlanta, GA: Centers for Disease Control and Prevention; 2016 (http://www.cdc.gov/globalhealth/security/index.htm, accessed 21 September 2016).

<sup>&</sup>lt;sup>5</sup> Global Health Security Agenda: Action Packages. In: Centers for Disease Control and Prevention [website]. Atlanta, GA: Centers for Disease Control and Prevention; 2016 (http://www.cdc.gov/globalhealth/security/actionpackages/default.htm, accessed 21 September 2016).

<sup>&</sup>lt;sup>6</sup> Sustainable Development Goals. In: Sustainable Development Knowledge Platform, United Nations Department of Economic and Social Affairs [website]. New York: United Nations; 2016 (https://sustainabledevelopment.un.org/?menu=1300, accessed 21 September 2016).

| Торіс   | PIP Framework  | IHR (2005)  | GAP | Nagoya   |
|---|--|-------------|-----|----------|
| Sharing of biological<br>materials, including<br>viruses                  | Section 5.1.1<br>Annex 5 terms of reference for<br>NICs, WHO CCs |             |     | <b>√</b> |
| Sharing of public health information                                      | Section 5.1.3 (ii)<br>Annex 5                                    | Article 6.2 |     |          |
| Regulatory capacity building  | Section 6.7  |             | ~   |          |
| Increase access to vaccine  | Sections 6.9, 6.10, 6.11<br>Annex 2, SMTA2                       |             | ~   |          |
| Strengthen laboratory and surveillance Capacities                         | Section 6.6<br>Section 6.14.4                                    | Annex 1     |     |          |
| Develop influenza vaccine production capacity                             | Section 6.13<br>Annex 2, SMTA2 Article 4.1 A5,<br>A6             |             | ~   |          |
| Technology transfer   | Section 6.13,<br>Annex 2, SMTA2 Article 4.1A5,<br>A6             |             | ~   |          |
| Access to products,<br>technology and<br>information & benefit<br>sharing | $\checkmark$   |             | ✓   | ~        |

## 8.1 Global Action Plan for Influenza Vaccines<sup>1</sup>

## Key Findings

Finding 66: There are important synergies between the PIP Framework and the GAP programme.<sup>2</sup> They include the encouragement of technology transfers and capacity building for burden of disease studies, regulatory authorities and risk communications. However, technology transfer agreements are currently not being obtained.

Finding 67: The November 2016 review of the GAP will be available to feed into an assessment on what aspects of the GAP (burden of disease studies/ technical guidance to new vaccine manufacturers/vaccine deployment/ logistics), might be continued as part of the PC implementation under the PIP Framework, and where these needs exist.

Finding 68: The quantity of pandemic influenza vaccines secured by the PIP Framework, as well as global vaccine production capacity, including new vaccine capacity available through the GAP, currently remain insufficient to meet anticipated global demand at the time of an influenza pandemic.

<sup>&</sup>lt;sup>1</sup> Global Action Plan for Influenza Vaccines (GAP). In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza\_vaccines\_plan/en/, accessed 22 September 2016).

<sup>&</sup>lt;sup>2</sup> The GAP was developed by WHO together with public health and academic experts, vaccine manufacturers and funding agencies from developed and developing countries. The third and final GAP consultation will take place in November 2016.

Some aspects of the PIP Framework intersect with those of other WHO programmes. GAP, which was set up in 2006 and further refined in 2011. Its objectives were increasing influenza vaccine manufacturing capacity for developing countries, and focused on an increase in the manufacture and use of seasonal vaccine, an increase in vaccine production capacity for pandemic vaccine, and relevant research and development.<sup>1,2</sup>

Since GAP's inception, WHO has invested approximately US\$ 50 million and countries and other bodies have contributed nearly US\$ 1 billion.<sup>3</sup> GAP funds have been used to support 14 manufacturers.<sup>4</sup> As a result, between 2007 and 2017, the capacity to produce approximate additional 600 million doses of pandemic influenza was made possible by the GAP.<sup>5</sup> In several cases, partnership with large pharmaceutical companies has facilitated vaccine production. By 2018/19, GAP-supported companies are expected to have expanded pandemic influenza vaccine capacity by a total of up to one billion doses.

The GAP's ten-year mandate ends in November 2016, and the Review Group has considered how the work of the programme could continue to be supported after its closure, for example through burden of disease studies or the provision to GAP-supported countries of technical assistance on vaccine manufacturing, registration and distribution. Where GAP-targeted vaccine manufacturers are still in the process of establishing themselves, PC funds could be used to strengthen their progress towards achieving sustainable seasonal and pandemic vaccine production capacity, including through training programmes and expert consultants. Such a proposal would benefit from discussions with established manufacturers to build support and collaboration. The SMTA2 mechanism could also be leveraged to fund such training if there were flexibility over the SMTA2 options for come categories of participants, such as diagnostic companies and category C entities. Along these lines, the PIP Framework Secretariat is assessing the introduction of laboratory and surveillance training as an option that category C SMTA2 contributors could support in order to complement PC Preparedness investment.

## **Recommendation: Global Action Plan for Influenza Vaccines**

34. The PIP Framework Advisory Group should consider lessons learned from the Global Action Plan for Influenza Vaccines, which closes in November 2016, to identify any aspects that would support implementation of the PIP Framework.

<sup>&</sup>lt;sup>1</sup> Global Action Plan for Influenza Vaccines (GAP). In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza\_vaccines\_plan/en/, accessed 21 September 2016).

<sup>&</sup>lt;sup>2</sup> Global action plan for influenza vaccines, GAP projects: capacity enhancement and technology transfer in developing countries. In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza\_vaccines\_plan/objectives/projects/en/, accessed 21 September 2016).

<sup>&</sup>lt;sup>3</sup> Grohmann G, Francis DP, Sokhey J, Robertson J. Challenges and successes for the grantees and the Technical Advisory Group of WHO's influenza vaccine technology transfer initiative. Vaccine. In press. doi: 10.1016/j.vaccine.2016.07.047.

<sup>&</sup>lt;sup>4</sup> Ibid.

## 8.2 International Health Regulations (2005)<sup>1</sup>

## Key Findings

Finding 69: PIP Framework PC funds may have collateral benefits in improving IHR (2005) core capacities, especially in the areas of laboratory and surveillance capacity. However, since PC funds only began to be distributed in 2014, data on the relationship between PC funds and IHR (2005) core capacities are not yet available. An analysis of PC funds' impact on IHR (2005) core capacities could be undertaken in the next review of the PIP Framework.

The IHR (2005) are a legally binding instrument by which Member States "prevent, protect against, control and provide a public health response to the international spread of disease".<sup>2</sup> Among other provisions, they require countries to ensure core capacities, such as laboratory and surveillance capacity, to detect, prevent and respond to an outbreak.<sup>3</sup> States Parties to the IHR (2005) are likely to consider a case of human influenza with a new subtype as a potential PHEIC, and to notify WHO and share public health information related to such an event. An influenza pandemic is likely to be a PHEIC, as the 2009 pandemic was.

While discussions of the linkages between the PIP Framework and the IHR (2005) often focus on the synergies between the two instruments, there are also important differences. The IHR (2005)'s provisions are only legally binding on States Parties,<sup>4,5</sup> and not on industry or other stakeholders. WHO collaborates with industry and other players in the implementation of the IHR (2005), but these actors are not legally obliged to adhere to the IHR (2005).

The PIP Framework encourages the sharing of physical samples between countries, while the IHR (2005) do not. The PIP Framework explicitly sets up a balance between virus sharing and benefit sharing, to ensure that commercial interest is balanced with equity in access to public health. While the IHR (2005) has provisions to encourage the rapid and timely sharing of data and other information, it does not have the PIP Framework's specific benefit sharing provisions – in the IHR (2005), the sharing of information and data is also the benefit, since this allows Member States and organizations such as WHO to detect disease more rapidly, alert populations at risk and implement public health actions earlier.

There are points of synergy between the IHR (2005) and the PIP Framework. Both were created to strengthen global health security by preparing the world to be able to detect and respond to health emergencies. Although the PIP Framework is specific to pandemic

<sup>&</sup>lt;sup>1</sup> Strengthening health security by implementing the International Health Regulations (2005), About IHR. In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/ihr/en/, accessed 24 September 2016).

<sup>&</sup>lt;sup>2</sup> International Health Regulations (2005), 2<sup>nd</sup> ed. Geneva: World Health Organization; 2008 (http://apps.who.int/iris/bitstream/10665/43883/1/9789241580410\_eng.pdf, accessed 22 September 2016).

<sup>&</sup>lt;sup>3</sup> *Ibid.*, Annex 1.

<sup>&</sup>lt;sup>4</sup> States Parties are States that are legally bound by the provisions of the IHR (2005). As of October 2016, the regulations have 196 States Parties.

<sup>&</sup>lt;sup>5</sup> States Parties to the International Health Regulations (2005). In: World Health Organization [website]. WHO: Geneva; 2016 (http://www.who.int/ihr/legal\_issues/states\_parties/en/, accessed 4 October 2016).

influenza, both instruments have a common goal of supporting low-resource countries in building capacity to detect disease.

Indeed, IHR (2005) core capacities informed the initial process in the selection of countries for PC implementation. The Gap Analyses,<sup>1</sup> undertaken in 2013 to determine the most critical gaps in capacity for pandemic influenza preparedness and response, used the IHR (2005) core capacity indicators as a starting point, particularly for laboratory and surveillance capacity, to identify countries to be targeted for PC implementation funds. For instance, the scoring methodology for a country's capacity for "detection" of novel viruses included IHR (2005) indicator 3.2.1, which measures "event-based surveillance".<sup>2</sup>

It is likely that implementation of the PIP Framework, through capacity building in countries, has had a positive impact in helping countries establish IHR (2005) core capacities. However, it is important to note that these benefits may be challenging to pin down since the PC implementation funds strengthen only influenza laboratory and surveillance capacity, whereas the IHR (2005) core capacities relate to surveillance and laboratory capacity for all emerging health threats.

#### **Recommendation: International Health Regulations**

35. Activity under the PIP Framework should be undertaken with the provisions of the International Health Regulations (2005) (IHR (2005)) in mind, and capacity building efforts should be aligned, supportive and complementary to those under the IHR (2005). This could be addressed by closer interaction at all three levels of WHO regarding implementation of the IHR (2005) and the PIP Framework to maximise synergies and efficiencies.

## 8.3 Nagoya Protocol to the Convention on Biological Diversity<sup>3</sup>

Finding 70: The PIP Framework is a multilateral access and benefit sharing instrument that appears to be consistent with the objectives of the Nagoya Protocol.

Finding 71: The intergovernmental negotiation of the PIP Framework established rules for access to IVPP and sharing of benefits; by contrast, the implementation of the Nagoya Protocol may introduce uncertainty in relation to the sharing of influenza viruses, since numerous bilateral transactions could be required to be negotiated, which could delay the access to viruses. The European Union (EU) has already recognized the PIP Framework as a specialized instrument with respect to pandemic influenza, although other countries that have created legislation to implement the Nagoya Protocol have not taken this step yet. As

<sup>&</sup>lt;sup>1</sup> Pandemic Influenza Preparedness Framework Partnership Contribution 2013-2016: Gap Analyses. Geneva: World Health Organization; 2013 (http://www.who.int/influenza/pip/pip\_pc\_ga.pdf, accessed 22 September 2016), page 11.

<sup>&</sup>lt;sup>2</sup> Checklist and indicators for monitoring progress in the development of IHR Core Capacities in States Parties. Geneva: World Health Organization; 2013 (WHO/HSE/GCR/2013.2; http://apps.who.int/iris/bitstream/10665/84933/1/WHO\_HSE\_GCR\_2013.2\_eng.pdf, accessed 4 October 2016).

<sup>&</sup>lt;sup>3</sup> In January 2016, the WHO Executive Board requested the Director-General undertake a study on the public health implications of implementation of the Nagoya Protocol. The Review Group's Findings have benefited from updates and data from that process.

more countries put in place domestic legislation to implement the Nagoya Protocol, the urgency increases to resolve this uncertainty and reduce the risk to global health security.

Finding 72: The public health implications of the implementation of the Nagoya Protocol are not widely understood. While the WHO Secretariat is producing a report to clarify these implications, better knowledge, understanding and awareness of the Protocol is required in the public health sector.

Finding 73: The Nagoya Protocol does not expressly identify a mechanism to recognize an instrument under its Article 4(4). An authoritative, formal and internationally credible entity such as the Meeting of the Parties (MOP) or World Health Assembly could make the decision that the PIP Framework constitutes a specialized international instrument for pandemic influenza preparedness and response. This decision would facilitate fulfilment of the PIP Framework's access and benefit sharing objectives by ensuring that all countries would handle IVPP in the same way. IVPP access and sharing would be covered for Nagoya Protocol purposes by the PIP Framework, and therefore not require bilateral agreements on a case-by-case basis.

The Convention on Biological Diversity<sup>1</sup> is a treaty among 196 states parties,<sup>2</sup> with three main objectives: (1) conserving biological diversity, (2) ensuring that biological resources are used sustainably and (3) the "fair and equitable sharing of the benefits arising out of the utilization of genetic resources". The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity <sup>3</sup> is designed to help implement the Convention on Biological Diversity's third objective. It requires states to create a legal and regulatory environment that ensure benefits of genetic resources are shared equitably among states (particularly with countries of origin) and within states (indigenous or local communities who supply knowledge).

In January 2016, the WHO Executive Board asked the WHO Secretariat to explore the public health implications of the implementation of the Nagoya Protocol. In response, the WHO Secretariat commissioned a study focused on the impact of the Nagoya Protocol in two areas: (1) pathogen sharing broadly, including GSD and (2) the PIP Framework and GISRS, including options for "improved harmonization between the Nagoya Protocol and PIP Framework, in the context of the ongoing PIP Framework 2016 Review".<sup>4</sup> The Nagoya Protocol's provisions overlap considerably with the access and benefit sharing system under the PIP Framework. Of particular interest is whether the PIP Framework is a specialized instrument under the Nagoya Protocol.

<sup>&</sup>lt;sup>1</sup> Convention on Biological Diversity. In: Convention on Biological Diversity [website]. Montreal: Convention on Biological Diversity, United Nations; 2016 (https://www.cbd.int/convention/, accessed 22 September 2016).

<sup>&</sup>lt;sup>2</sup> States Parties to the Convention on Biological Diversity are not automatically bound by the Nagoya Protocol, but must rather ratify that agreement separately. As of 4 October 2016, the Nagoya Protocol had 78 states parties.

<sup>&</sup>lt;sup>3</sup> The Nagoya Protocol on Access and Benefit-sharing. In: Convention on Biological Diversity [website]. Montreal: Convention on Biological Diversity, United Nations; 2011 (https://www.cbd.int/abs/, accessed 4 October 2016).

<sup>&</sup>lt;sup>4</sup> Terms of Reference, Production of a study on how the implementation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity might affect the sharing of pathogens and the potential public health implications. Geneva: World Health Organization; 2016 (http://www.who.int/entity/influenza/pip/2016-review/NagoyaStudyTORs.pdf, accessed 22 September 2016).

The Nagoya Protocol requires a would-be user of a genetic resource to obtain "prior informed consent" (PIC) from the provider. This will typically require negotiation between each party to reach "mutually agreed terms" (MAT) for the sharing of benefits. Like the Nagoya Protocol, the PIP Framework creates an access and benefit sharing system, but narrowly tailored to influenza viruses with human pandemic potential. The Nagoya Protocol recognizes that such agreements may exist, carving out an exception:

Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.<sup>1</sup>

Were virus sharing within GISRS to be subjected to both Nagoya's PIC and MAT obligations (which might require negotiating terms for each virus sample) as well as the requirements of the PIP Framework, it would risk duplication and substantially slow down the sharing of viruses within the GISRS network. For instance, the Review Group heard concerns that requiring vaccine manufacturers to negotiate PIC and MAT with each originating country for individual CVVs could increase the cost and complexity of vaccine development, slowing development and in some cases resulting in less useful end products. So far, no instrument has been officially declared a "specialized instrument" under Nagoya and it remains unclear whether designation of the PIP Framework as a "specialized instrument" is accomplished by the States Parties collectively, e.g. through the Conference of the Parties (COP) to the Convention on Biological Diversity MOP to the Nagoya Protocol, by individual states through their implementing legislation, or by some other mechanism. Thus far, the COP and MOP have taken no action in this regard. And while the EU, in its legislation implementing the Nagoya Protocol, has recognized the PIP Framework as a specialized instrument,<sup>2</sup> other States Parties have not yet done so.

For the time being, the Review Group heard from key informants that there is still a lack of awareness of the Nagoya Protocol and that this is becoming an issue in pathogen sharing. For example, EU countries are seeking to abide by the protocol but have run into difficulties when they send pathogens to recipient states that are not familiar with the requirements of the protocol.

#### **Recommendation: Nagoya Protocol**

36. The PIP Framework should be considered as a specialized international instrument to clarify the implementation of the Nagoya Protocol in relation to pandemic influenza preparedness and response:

<sup>&</sup>lt;sup>1</sup> Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity. Montreal: Convention on Biological Diversity, United Nations; 2011 (https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf, accessed 22 September 2016), Article 4, paragraph 4.

<sup>&</sup>lt;sup>2</sup> Regulation (EU) No. 511/2014 of the European Parliament and of the Council if 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. In: Official Journal of the European Union. Strasbourg: European Parliament; 2014 (L 150/59; http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32014R0511&from=EN), paragraph 16.

- The December 2016 Meeting of the Parties of the Nagoya Protocol provides an opportunity to consider recognizing the PIP Framework as a specialized international instrument for pandemic influenza preparedness and response. In the view of the Review Group, it would serve the aims of the PIP Framework if the Meeting of the Parties took up this opportunity.
- Further, the 2017 World Health Assembly should address the recognition of the PIP Framework as a specialized international instrument under the Nagoya Protocol.

## **Appendix I: REVIEW GROUP MEMBERS**

## Professor William Kwabena Ampofo

Head of Virology Department, Noguchi Memorial Institute for Medical Research, University of Ghana, Accra, Ghana

Prof William Ampofo holds the position of Associate Professor and Head of the Virology Department of the Noguchi Memorial Institute for Medical Research (NMIMR) at the University of Ghana in Accra, Ghana.

Prof Ampofo has held research fellowships at the NMIMR and headed its Department of Electron Microscopy and Histopathology. His work has focused on molecular and serological investigations of viral infections and anti-viral interventions.

Prof Ampofo is a member of the Academic Board at the University of Ghana's College of Health Sciences and of the Ghana Field Epidemiology and Laboratory Training Program Steering Committee of the School of Public Health. He also participates in the National Steering Committee for the IHR (2005) at Ghana's Ministry of Health and in the Ministry's National Technical Coordinating Committee for Ebola Virus Disease. He is a member of Ghana's National Ebola Emergency Operations Center.

Prof Ampofo has been a temporary advisor and consultant to WHO, including in support of the Ebola virus disease response, and is a former member of WHO's SAGE Working Group on Influenza Vaccines and Immunization. He recently chaired WHO's PIP Framework Advisory Group. He is a member of the WHO GAP Advisory Group and served as an advisor to the WHO IHR Emergency Committee for Ebola virus disease.

## Dr Christine Mwelwa Kaseba-Sata (Chair)

#### Former WHO Goodwill Ambassador against Gender-based Violence, Zambia

Dr Christine Mwelwa Kaseba-Sata, is a renowned Zambian specialist in obstetrics and gynaecology. She has practiced as a physician at the University Teaching Hospital in Lusaka for more than 25 years, and lectured for the past 15 years at the University of Zambia, School of Medicine.

Dr Kaseba-Sata has broad experience in the area of sexual and reproductive health, from sexually transmitted infections including HIV/AIDS, to family planning, comprehensive abortion care, and malaria in pregnancy, reproductive health cancers, emergency obstetrics and newborn care.

Dr Kaseba-Sata is a committed advocate for improving maternal and newborn health and addressing issues around gender-based violence, and was appointed WHO's Goodwill Ambassador against Gender-based Violence from October 2012 to October 2014.

## Dr Frances McGrath

## Chief Advisor, Office of the Chief Medical Officer, Ministry of Health, New Zealand

Dr McGrath is a specialist public health physician, currently serving as the Chief Advisor in the Office of the Chief Medical Officer in the Ministry of Health, New Zealand. In this capacity, Dr McGrath advises ministers and colleagues on public health strategy and issues and, as required, serves as a key advisor on emergencies such as infectious disease outbreaks, notably the 2009 influenza pandemic, and the health impacts of contaminated environmental sites.

Dr McGrath has post-graduate qualifications and comprehensive experience in public health, public policy and senior management in many different parts of the health sector, including as Acting Director of Public Health, senior health advisor to a number of Ministers of Health, and has represented New Zealand at a number of meetings of the World Health Assembly, and at Regional Committee Meetings of the Western Pacific Region of WHO. She has worked in developing countries including Central America, Thailand, and worked for a year in the Cook Islands Ministry of Health.

Dr McGrath previously worked as a General Practitioner in rural and high need areas in New Zealand.

## Dr Talat Mokhtari-Azad

#### Director, Iranian National Influenza Center

Dr Mokhtari-Azad has a degree in Veterinary Medicine from Tehran University, a Master of Public Health (MPH) and Ph.D. degree in Virology (1982) from Tehran University of Medical Sciences, and specialization degree in Clinical Medical Laboratory Sciences (1991) from the Iran University of Medical Sciences.

Dr Mokhtari-Azad is Professor of Virology and head of the Virology Department in the School of Public Health, Tehran University of Medical Sciences. Since 1985, she has been the Director of the NIC and since 2006 the head of the National Measles/Rubella laboratory. She has wide-ranging experience in research and higher education and has supervised MSc and Ph.D. students in different virology fields especially in sero-epidemiology, isolation and molecular diagnostics. She is currently a member of the National Influenza Committee and National Vaccination Committee in Iran. She serves as a temporary advisor with WHO on influenza vaccine composition.

#### Ms Johanne Newstead

#### Head of Food Policy, Public Health Directorate, Department of Health, United Kingdom

Ms Newstead is a UK civil servant with broad experience in public health and internationally. She currently heads the food policy work in the Department of Health in London, leading the work with the food industry, in particular on reducing obesity.

Prior to that she spent six years on pandemic flu preparedness and health security for the UK, much of that on the global issues both in the EU, within the WHO European Region, and more widely with WHO and other global partners. She led the UK delegation throughout the

PIP Framework negotiations, and chaired the WHO European Region meeting in the later stages of negotiations.

Ms Newstead has also led the Department of Health biotechnology policy development for England. She has worked at the Organisation for Economic Co-operation and Development and for five years represented the UK interests there on health, science and technology.

## Dr Theresa Tam (acting Chair)

Assistant Deputy Minister, Infectious Disease Prevention and Control Branch, Public Health Agency of Canada

Dr Theresa Tam is the Deputy Chief Public Health Officer of the Public Health Agency of Canada (the "Agency"). In this role, she provides support to Canada's Chief Public Health Officer in day-to-day activities and responding to public health issues of high importance to Canadians.

She is also the Assistant Deputy Minister responsible for the Infectious Diseases Prevention and Control Branch at the Agency. In this role Dr Tam oversees Agency activities aimed at making Canadians less vulnerable to impacts of infectious diseases. This includes surveillance, laboratory diagnostics, science research, policy development and national leadership for a wide range of infectious disease threats. Dr Tam has previously provided senior leadership on key Agency initiatives and programmes on immunization, respiratory infections, health emergency preparedness and response; public health at Canada's borders and on public conveyances; laboratory biosecurity; public health workforce, surveillance and other infrastructure capacities; and implementation of the IHR (2005).

Dr Tam is a paediatric infectious disease specialist and field epidemiologist with extensive experience in the management of outbreaks and complex health emergency situations, including the SARS outbreak; A(H1N1) influenza pandemic; and Ebola virus disease outbreak in West Africa. She has served as an international expert on a number of WHO committees and international missions, including the first WHO Influenza Pandemic Task Force. She has also served as a WHO consultant on multiple international missions related to influenza and polio eradication in Bangladesh.

## Dr Viroj Tangcharoensathien

#### Senior Advisor, International Health Policy Program, Ministry of Public Health, Thailand

Dr Viroj Tangcharoensathien is a senior expert in Health Economics at the Ministry of Public Health, Thailand, and advisor to its International Health Policy Program, where he also heads the research hub for the Asia Pacific Observatory. He supports the implementation of universal health coverage in a number of countries. Trained in medicine, he served for nine years in rural district hospitals in a poor province of Thailand and received the 'Best Rural Doctor' award in 1986 from the Thai Medical Association.

In 1990 he received a PhD in health planning and financing at the London School of Hygiene & Tropical Medicine. He won the Woodruff Medal in 1991 for his PhD thesis on community health financing and the Edwin Chadwick Medal in 2011 for his contributions to improve health systems in the interests of the poor. He has published 155 scientific articles.

Dr Tangcharoensathien chaired the negotiations of the WHO Global Code of Practice on the International Recruitment of Health Personnel, adopted by the Sixty-third World Health Assembly.

## Prof Dr Makarim Wibisono

## Chairman, Governing Board of Indonesia Council of World Affairs

Prof Makarim Wibisono is a former Indonesian Ambassador and Permanent Representative to the United Nations in New York and Geneva. He served as Director-General for Foreign Affairs Economic Relations (2000-2002), and Director for Multilateral Economic Cooperation (1993-1994) of the Indonesian Ministry of Foreign Affairs. As Director-General for Asia Pacific and Africa (2002-2004), he helped finalize the Bali Concord II which created the Association of Southeast Asian Nations (ASEAN). He led the Indonesian Delegation to the Senior Officials Meetings of ASEAN, ASEAN+3, ASEAN Regional Forum (ARF) and Asia-Pacific Economid Cooperation (APEC). He has been the UN Special Rapporteur on the Occupied Palestinian Territory Since 1967, and General Coordinator of Europalia Indonesia, Ministry of Education and Culture, Republic of Indonesia.

He is the Chairman of the Governing Board of the Indonesian Council on World Affairs, Advisor to the National Commission of Human Rights, and Senior Advisor on International Affairs to the Speaker of the House of Representatives of Indonesia.

Prior to his post as Executive Director at the ASEAN Foundation, Prof Wibisono was Senior Advisor on International Cooperation to the Minister of Health of Indonesia. He also served as President of the UN Economic and Social Council and the UN Conference on Trade and Development. In addition, Prof Wibisono has served as a member and advisor to various UN Task Forces.

Prof Wibisono is a lecturer at the National Defense Institute, Paramadina University, Atma Jaya Catholic University, the University of Al Azhar, Indonesia and Gadjah Mada University. Prof Wibisono holds a Master's degree in International Political Economy and a PhD in Political Science from Ohio State University, USA. He also has an M.A. in International Relations from Johns Hopkins University, USA.

## **Appendix II: DETAILED METHODS OF WORK**

## **Appointment of the Review Committee**

The PIP Framework Advisory Group met in Special Session, 13-14 October 2015, shortly before the Review Group was convened, to seek views from Member States, industry, civil society and other stakeholders on the terms of reference and direction of the Review. The Advisory Group Report from the Special Session provided advice and recommendations to the WHO Director-General on the conduct of the Review, including four guiding principles: independence and impartiality; transparency; engagement with Member States and stakeholders; and an iterative process.<sup>1</sup>

In response, the Director-General convened the Review Group and appointed eight members to the Review Group. In line with the Advisory Group's recommendations,<sup>2</sup> members were selected to provide a skill mix of internationally recognized policy makers, public health experts and technical experts in the field of influenza, and included two former members of the Advisory Group. All six WHO regions were represented and there was a good gender balance. The Review Group members are listed in Appendix I.

The Review Group selected Dr Kaseba-Sata as Chair, and Dr Tam served as acting Chair for the August meeting onwards. The Review Group has been supported by a dedicated Review Group Secretariat at WHO.

#### Meetings

The Review Group held four meetings at WHO HQ in Geneva: 30 March–1 April 2016; 9–11 May 2016; 27 June–1 July 2016; and 29 August–2 September 2016. The Review Group also held two meetings via teleconference: 7 January 2016 and 19 February 2016. Reports of all these meeting were published on the WHO website.<sup>3</sup> Multiple consultations took place among the Review Group and the Review Group Secretariat by means of email exchanges.

Representatives of Member States were invited to attend a debriefing and question session at WHO HQ in Geneva following the February 2016 teleconference and the March 2016, June 2016 and August 2016 Review Group meetings. These sessions were open to all stakeholders and the public via a live webcast on the WHO website.<sup>4</sup>

24 September 2016).

<sup>&</sup>lt;sup>1</sup> PIP Framework Advisory Group. Special session of the Pandemic influenza preparedness (PIP) Framework Advisory Group, 13-14 October 2015, Geneva, Switzerland. Report to the Director-General. Geneva: World Health Organization; 2015 (http://www.who.int/influenza/pip/advisory\_group/ag\_spec\_session\_report.pdf, accessed

<sup>&</sup>lt;sup>2</sup> Ibid.

<sup>&</sup>lt;sup>3</sup> PIP Framework Review Group. 2016 Review of the PIP Framework, PIP Review Group Meeting Reports. In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenzo/pip/2016 review/meetings/on/\_second\_20\_Sectomber 2016)

On 30 March 2016 and 29 August 2016, as part of Review Group meetings, the Review Group held open consultations at WHO HQ, Geneva, with Member States, civil society and other stakeholders, and these open sessions were also webcast live on the WHO website.<sup>1</sup> Participants were invited to make statements, ask questions and submit written memoranda at each open session.

In addition, the Review Group Chair, Dr Kaseba-Sata, presented an update of the Review Group's work at the Sixty-ninth World Health Assembly on 25 May 2016, which was also available via a live web stream.<sup>2</sup>

#### Information gathering

The Review Committee interviewed and/or received written inputs from key informants including Member States and representatives of GISRS, industry, civil society, relevant databases and other stakeholders. Overall, the Review Group conducted 40 interviews with key informants and received several written submissions. These key informants are listed in the Acknowledgements.

The Review Group reviewed key documents and reports including PIP Framework Advisory Group meeting reports;<sup>3</sup> the Advisory Group Annual Reports to the Director-General;<sup>4</sup> the Director-General's Biennial Reports on the PIP Framework to the WHO Executive Board;<sup>5</sup> the Partnership Contribution 2014 and 2015 Annual Reports;<sup>6,7</sup> the October 2014 final report of the TEWG;<sup>8</sup> the 2016 final report of the TWG;<sup>9</sup> the draft 2016 WHO study on the impact of

<sup>1</sup> Ibid.

<sup>2</sup> Dr Christine Mwelwa Kaseba-Sata, Review Group Chair. Update of the Review Group's work at the Sixty-ninth World Health Assembly. Committee A, Wednesday 25 May 2016, Late Session. In: World Health Organization [website]. Geneva: World Health Organization: 2016 (http://www.who.int/mediacentre/events/2016/wha69/

webstreaming/en/, accessed 29 September 2016).

<sup>3</sup> PIP Framework Advisory Group. PIP Framework Advisory Group Reports. In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/pip\_meetings\_consultations/ en/, accessed 22 September 2016).

4 Ibid.

5 Ibid.

<sup>6</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Annual Report 2014. Geneva: World Health Organization; 2015 (http://apps.who.int/iris/bitstream/10665/161369/1/ WHO\_HSE\_PED\_GIP\_PIP\_2015.2\_eng.pdf?ua=1&ua=1, accessed 24 September 2016).

<sup>7</sup> Pandemic Influenza Preparedness Framework, Partnership Contribution Annual Report 2015. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/246229/1/WHO-OHE-PED-2016.01eng.pdf?ua=1, accessed 24 September 2016).

<sup>8</sup> PIP Framework Advisory Group, Technical Expert Working Group (TEWG) on Genetic Sequence Data. Final Report to the PIP Advisory Group. Geneva: World Health Organization; 2014 (http://www.who.int/influenza/pip/

advisory\_group/PIP\_AG\_Rev\_Final\_TEWG\_Report\_10\_Oct\_2014.pdf?ua=1, accessed 19 October 2016).

<sup>9</sup> PIP Framework Advisory Group, Technical Working Group (TWG) on the sharing of influenza genetic sequence data. Optimal Characteristics of and Influenza Genetic Sequence Data Sharing System under the PIP Framework. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/ advisory\_group/twg\_doc.pdf?ua=1, accessed 22 September 2016).

the Nagoya Protocol implementation on public health; and the Report of a 2015 WHO informal consultation on influenza vaccine response during the start of a pandemic.<sup>1</sup>

The Review Group actively sought input from Member States and other stakeholders. To this end, the Permanent Missions to the UN Office in Geneva and other relevant organizations were contacted by email and invited to contribute their views on the PIP Framework. The WHO website for the Review also published specific Review Group questions separately for Member States and stakeholders, with a request for responses and views on any other aspects of the implementation of the PIP Framework.<sup>2</sup>

During its deliberations the Review Group interviewed the Director-General, programme directors, technical and other staff and representatives of WHO Regional Offices. The key WHO informants are listed in Acknowledgements. The Review Group members received technical briefings on various aspects of the PIP Framework including: (1) SMTA 2 negotiations, (2) GISRS and virus sharing, (3) PC collection and implementation, (4) GSD. While operating independently, the Review Group sought information and requested the development of written technical documents from the PIP Framework Secretariat and the Review Group Secretariat. The Review Group also asked for clarification of issues that arose during the information-gathering and report-writing periods. WHO staff provided written responses to questions posed by the Review Group and spoke informally and openly with Review Group members.

The WHO Secretariat provided an overview of the progress of the GAP, linkages between the GAP and the PIP Framework, and how the work of the GAP could be continued after the GAP ended.

#### Assessment and development of recommendations

The Review Group began its work by conducting a thorough analysis of the PIP Framework and its implementation milestones and challenges. Review Group members established three sub-groups to cover the questions outlined in the terms of reference as they related to: 1) Virus Sharing, including GSD; 2) Benefit Sharing; and 3) Governance and Linkages with other instruments. Each of the sub-groups developed relevant questions and identified key informants to be interviewed whose input might inform the Review and the subsequent development of practical and feasible recommendations.

The Review Group conducted a SWOT analysis of various aspects of PIP Framework implementation, including virus sharing and GSD, SMTA2s, PC collection and implementation, governance, and linkages with other instruments such as the Nagoya Protocol, the IHR (2005) and the GHSA. This analysis assisted in identifying factors that promoted or inhibited successful implementation of the PIP Framework, as well as desirable outcomes and draft recommendations. Following a strategic analysis of each draft recommendation, preliminary recommendations were developed and subsequently refined.

<sup>&</sup>lt;sup>1</sup> Influenza vaccine response during the start of a pandemic: Report of a WHO informal consultation held in Geneva, Switzerland 29 June-1 July 2015. Geneva: World Health Organization; 2016 (http://apps.who.int/iris/bitstream/10665/207751/1/WHO\_OHE\_PED\_GIP\_2016.1\_eng.pdf, accessed 19 September 2016).

<sup>&</sup>lt;sup>2</sup> 2016 Review of the PIP Framework, Questions to Member States, Questions to Stakeholders. In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/2016-review/en/, accessed 19 October 2016).

The Review Group's Preliminary Findings were circulated to Member States and published on the WHO website for response, dated 19 August 2016.<sup>1</sup>

## **Review of recommendations**

The Review Group provided its final Report to the Director-General in November 2016 for transmission to the WHO Executive Board in January 2017 and the World Health Assembly in May 2017.

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<sup>&</sup>lt;sup>1</sup> PIP Framework Review Group 2016, Preliminary Findings. In: World Health Organization [website]. Geneva: World Health Organization; 2016 (http://www.who.int/influenza/pip/2016-review/pip\_review\_group\_prelim\_findings.pdf?ua=1, accessed 19 October 2016).

## ANNEX 9

## Draft five-year global strategic plan to improve public health preparedness and response 2018–2022: guiding principles<sup>1</sup>

[A70/16, Annex 2 – 18 May 2017]

## Background

In document EB140/14 (draft global implementation plan for the recommendations of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response) the Secretariat stated that it would give great importance to drafting a five-year global strategic plan for public health preparedness and response, to be submitted to the Seventy-first World Health Assembly in May 2018, through the Executive Board at its 142nd session in January 2018.

## Scope

The five-year global strategic plan will comprise guiding principles and strategic orientations for sustained implementation of the International Health Regulations (2005), with the aim of strengthening capacities at the global, regional and country levels to prepare, detect, assess and respond to public health emergencies with the potential for international spread.

## Guiding principles

The five-year global strategic plan will be developed on the basis of 12 interrelated guiding principles.

## 1. Consultation

The development of the plan will follow a consultative process from May to November 2017, which will comprise specific technical consultations, web-based consultations with Member States, regional technical consultations, and at least one information session for focal points from permanent missions to the United Nations Office at Geneva. The draft plan will be presented to the Executive Board at its 142nd session in January 2018 for submission to the Seventy-first World Health Assembly in May 2018.

## 2. Country ownership

Building and sustaining capacity for health security and public health emergency preparedness and response is the primary responsibility of national governments. In this process, governments take into account their national health, social, economic, security and political contexts to develop and implement adequate capacities at national and subnational level.

<sup>&</sup>lt;sup>1</sup> See decision WHA70(11).

## 3. WHO leadership and governance

The WHO Health Emergencies Programme will lead the development and implementation of the five-year global strategic plan for public health preparedness and response. The WHO Secretariat will report on progress to the governing bodies, as part of regular reporting on the application and implementation of the International Health Regulations (2005).

## 4. Broad partnerships

Many countries require technical support to assess and enhance their capacities for health security and public health emergencies preparedness. Many global partners support countries in the field of health security and public health emergencies. As decided by the Fifty-eighth World Health Assembly, WHO will cooperate and coordinate its activities, as appropriate, with the following: United Nations, International Labour Organization, Food and Agriculture Organization, International Atomic Energy Agency, International Civil Aviation Organization, International Maritime Organization, International Committee of the Red Cross, International Federation of Red Cross and Red Crescent Societies, International Air Transport Association, International Shipping Federation, and *Office International des Epizooties.*<sup>1</sup> Cooperation with other relevant non-State actors and industry associations will also be considered.

## 5. Intersectoral approach

Responding to public health security threats requires a multisectoral, coordinated approach, (for example with agriculture, transport, tourism, and finance sectors). Many countries already have health coordination platforms or mechanisms in place, such as the "One Health" approach. The five-year global strategic plan will emphasize the importance of planning for public health preparedness across multiple sectors.

## 6. Integration with the health system

The Ebola virus disease outbreak has put both health security and health system resilience high on the development agenda. Integrating the core capacities required by the International Health Regulations (2005) with the essential public health functions will mutually reinforce health security and health systems, leading to resilient health systems.

## 7. Community involvement

Effective emergency preparedness can only be achieved with the active participation of local governments, civil society organizations, local leaders, and individual citizens. Communities must take ownership of their preparedness and strengthen it for emergencies that range in scale from local or national events to pandemics and disasters.

## 8. Focus on fragile context: "we are only as strong as our weakest link"

While the WHO Health Emergencies Programme is supporting all countries in their preparation for and response to public health risks and emergencies, the initial focus will be on a set of priority

<sup>&</sup>lt;sup>1</sup> Resolution WHA58.3 (2005). Revision of the International Health Regulations. Available at: http://apps.who.int/gb/ebwha/pdf\_files/WHA58-REC1/english/Resolutions.pdf (accessed 1 May 2017).

countries in fragile situations.<sup>1</sup> The identification of priority countries will take into account an assessment of national core capacities and other risk assessments, for example using the INFORM methodology.<sup>2</sup>

#### 9. Regional integration

Building on the five-year global strategic plan, WHO regional offices will develop regional implementation plans, taking into account existing regional frameworks and mechanisms, such as: Integrated Disease Surveillance and Response – a strategy of the Regional Office for Africa,<sup>3</sup> the Asia Pacific Strategy for Emerging Diseases – a common strategic framework for the regions of South-East Asia and the Western Pacific,<sup>4</sup> Health 2020 – a policy framework and strategy for the European Region,<sup>5</sup> the Regional Assessment Commission for the International Health Regulations (2005) established by the Regional Committee for the Eastern Mediterranean,<sup>6</sup> and other regional approaches.

## **10.** Domestic financing

For long-term sustainability, the budgeting and financing of core capacities required by the International Health Regulations (2005) should be supported at least in part from domestic resources. WHO will work with countries to encourage the allocation of domestic financial resources to the national action plans for the development and maintenance of the core capacities for surveillance and response. In countries that require substantial external resources the WHO Secretariat will provide support for strengthening the institutional mechanisms for coordinating international cooperation, based on the principles of effective development cooperation (country ownership, focus on results, inclusive partnerships, transparency and accountability).<sup>7</sup>

## 11. Linking the five-year global strategic plan with requirements under the International Health Regulations (2005)

The five-year global strategic plan will propose strategic directions in relation to the relevant IHR requirements for States Parties and for WHO, as well as voluntary operational and technical aspects that are not a requirement under the International Health Regulations (2005).

<sup>&</sup>lt;sup>1</sup> See document "UPDATE | WHO Health Emergencies Programme: progress and priorities. Financing dialogue. 31 October 2016" for the list of priority countries. Available at: http://www.who.int/about/financesaccountability/funding/financing-dialogue/whe-update.pdf?ua=1 (accessed 1 May 2017).

<sup>&</sup>lt;sup>2</sup> INFORM Index for Risk Management is a tool for understanding the risk of humanitarian crises and disasters. Available at: http://www.inform-index.org/Portals/0/InfoRM/INFORM%20Global%20Results%20Report% 202017%20FINAL%20WEB.pdf?ver=2016-11-21-164053-717 (accessed 1 May 2017).

<sup>&</sup>lt;sup>3</sup> http://www.afro.who.int/health-topics/integrated-disease-surveillance (accessed 28 September 2017).

<sup>&</sup>lt;sup>4</sup> http://www.wpro.who.int/emerging\_diseases/documents/docs/ASPED\_2010.pdf?ua=1 (accessed 1 May 2017).

<sup>&</sup>lt;sup>5</sup> http://www.euro.who.int/\_\_data/assets/pdf\_file/0011/199532/Health2020-Long.pdf?ua=1 (accessed 1 May 2017).

<sup>&</sup>lt;sup>6</sup> http://applications.emro.who.int/docs/RC62\_Resolutions\_2015\_R3\_16576\_EN.pdf?ua=1 (accessed 1 May 2017).

<sup>&</sup>lt;sup>7</sup> Global Partnership for Effective Development Cooperation – principles. (Available at:

http://effectivecooperation.org/about/principles/. Accessed 1 May 2017.)

## 12. Focus on results, including monitoring and accountability

The five-year global strategic plan will have its own monitoring framework, including indicators and timelines, which will be developed through the consultative process, and used for annual reporting on progress to the Health Assembly.

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## ANNEX 10

## Global action plan on the public health response to dementia 2017–2025<sup>1</sup>

[A70/28, Annex – 3 April 2017]

## **OVERVIEW OF THE GLOBAL SITUATION**

1. Dementia is an umbrella term for several diseases that are mostly progressive, affecting memory, other cognitive abilities and behaviour, and that interfere significantly with a person's ability to maintain the activities of daily living. Alzheimer disease is the most common form of dementia and may contribute to 60–70% of cases. Other major forms include vascular dementia, dementia with Lewy bodies, and a group of diseases that contribute to frontotemporal dementia. The boundaries between different forms of dementia are indistinct and mixed forms often coexist.

2. In 2015, dementia affected 47 million people worldwide (or roughly 5% of the world's elderly population), a figure that is predicted to increase to 75 million in 2030 and 132 million by 2050. Recent reviews estimate that globally nearly 9.9 million people develop dementia each year; this figure translates into one new case every three seconds. Nearly 60% of people with dementia currently live in low- and middle-income countries and most new cases (71%) are expected to occur in those countries.<sup>2,3</sup>

3. Crucially, although age is the strongest known risk factor for the onset of dementia, it is not an inevitable consequence of ageing. Further, dementia does not exclusively affect older people, with young onset dementia (defined as the onset of symptoms before the age of 65 years) accounting for up to 9% of cases.<sup>4</sup> Some research has shown a relationship between the development of cognitive impairment and lifestyle-related risk factors that are shared with other noncommunicable diseases. These risk factors include physical inactivity, obesity, unbalanced diets, tobacco use and harmful use of alcohol as well as diabetes mellitus and mid-life hypertension. Other potentially modifiable risk factors more specific to dementia include mid-life depression, low educational attainment, social isolation and cognitive inactivity. Additionally, non-modifiable genetic risk factors exist that increase a person's risk of developing dementia.<sup>5</sup> There is also evidence suggesting that overall more women develop dementia than men.<sup>3</sup>

<sup>&</sup>lt;sup>1</sup> See decision WHA70(17).

<sup>&</sup>lt;sup>2</sup> WHO. The epidemiology and impact of dementia: current state and future trends. Geneva: World Health Organization; 2015, Document WHO/MSD/MER/15.3, available at

http://www.who.int/mental\_health/neurology/dementia/dementia\_thematicbrief\_epidemiology.pdf (accessed 8 March 2017).

<sup>&</sup>lt;sup>3</sup> Prince M, Wimo A, Guerchet M, Ali GC, Wu Yutzu, Prina M. World Alzheimer Report 2015. The global impact of dementia: an analysis of prevalence, incidence, cost and trends. London: Alzheimer's Disease International; 2015.

<sup>&</sup>lt;sup>4</sup> Alzheimer's Disease International and WHO. Dementia: a public health priority. Geneva: World Health Organization; 2012 (http://www.who.int/mental\_health/publications/dementia\_report\_2012/en/, accessed 8 March 2017).

<sup>&</sup>lt;sup>5</sup> Loy CT, Schofield PR, Turner AM, Kwok JBJ. Genetics of dementia. Lancet. 2014;383(9919):828-40. doi:http://dx.doi.org/10.1016/S0140-6736(13)60630-3.

4. Dementia is a major cause of disability and dependency among older people worldwide, having a significant impact not only on individuals but also on their carers, families, communities and societies. Dementia accounts for 11.9% of the years lived with disability due to a noncommunicable disease.<sup>1</sup> In light of the improved life expectancy globally, this figure is expected to increase further.

5. Dementia leads to increased costs for governments, communities, families and individuals, and to loss in productivity for economies.

- In 2015, dementia costs<sup>2</sup> were estimated at US\$ 818 billion, equivalent to 1.1% of global gross domestic product, ranging from 0.2% for low- and middle-income countries to 1.4% for high-income countries. By 2030, it is estimated that the cost of caring for people with dementia worldwide will have risen to US\$ 2 trillion, a total that could undermine social and economic development globally and overwhelm health and social services, including long-term care systems specifically.<sup>3</sup>
- People with dementia and their families face significant financial impact from the cost of health and social care and from reduction or loss of income. In high-income countries, the costs related to dementia are shared between informal care (45%) and social care (40%). In contrast, in low- and middle-income countries social care costs (15%) pale in comparison to informal care costs.<sup>3</sup> The expected disproportionate increase in dementia in low- and middle-income countribute further to increasing inequalities between countries and populations.

6. Currently, the gap is wide between the need for prevention, treatment and care for dementia and the actual provision of these services. Dementia is underdiagnosed worldwide, and, if a diagnosis is made, it is typically at a relatively late stage in the disease process. Long-term care pathways (from diagnosis until the end of life) for people with dementia are frequently fragmented if not entirely lacking. Lack of awareness and understanding of dementia is often to blame, resulting in stigmatization and barriers to diagnosis and care. People with dementia are frequently denied their human rights in both the community and care homes. In addition, people with dementia are not always involved in decision-making processes and their wishes and preferences for care are often not respected.

7. WHO and the World Bank estimate a need by 2030 for 40 million new health and social care jobs globally and about 18 million additional health workers, primarily in low-resource settings, in order to attain high and effective coverage with the broad range of necessary health services. In addressing dementia, expanding the health and social care workforce with appropriate skill mixes as well as available interventions and services will be essential to prevent, diagnose, treat and care for people with dementia.

<sup>&</sup>lt;sup>1</sup> Prince M, Albanese E, Guerchet M, Prina M. World Alzheimer Report 2014. Dementia and risk reduction: an analysis of protective and modifiable risk factors. London: Alzheimer's Disease International; 2014 (http://www.alz.co.uk/research/WorldAlzheimerReport2014.pdf, accessed 8 March 2017).

<sup>&</sup>lt;sup>2</sup> Direct medical and social care costs and costs of informal care.

<sup>&</sup>lt;sup>3</sup> Prince M, Wimo A, Guerchet M, Ali GC, Wu Yutzu, Prina M. World Alzheimer Report 2015. The global impact of dementia: an analysis of prevalence, incidence, cost and trends. London: Alzheimer's Disease International; 2015.

## VISION, GOALS AND CROSS-CUTTING PRINCIPLES

## Vision

8. The vision of the global action plan on the public health response to dementia is a world in which dementia is prevented and people with dementia and their carers live well and receive the care and support they need to fulfil their potential with dignity, respect, autonomy and equality.

## Goal

9. The goal of the global action plan is to improve the lives of people with dementia, their carers and families, while decreasing the impact of dementia on them as well as on communities and countries.

## **Cross-cutting principles**

10. The global action plan is grounded in the following seven cross-cutting principles.

(a) **Human rights of people with dementia.** Policies, plans, legislation, programmes, interventions and actions should be sensitive to the needs, expectations and human rights of people with dementia, consistent with the Convention on the Rights of Persons with Disabilities and other international and regional human rights instruments.

(b) **Empowerment and engagement of people with dementia and their carers.** People with dementia, their carers and organizations that represent them should be empowered and involved in advocacy, policy, planning, legislation, service provision, monitoring and research of dementia.

(c) **Evidence-based practice for dementia risk reduction and care.** Based on scientific evidence and/or best practice, it is important to develop strategies and interventions for dementia risk reduction and care that are person-centred, cost-effective, sustainable and affordable, and take public health principles and cultural aspects into account.

(d) **Multisectoral collaboration on the public health response to dementia.** A comprehensive and coordinated response to dementia requires collaboration among all stakeholders to improve prevention, risk reduction, diagnosis, treatment and care. Achieving such collaboration requires engagement at the government level of all relevant public sectors, such as health (including alignment of existing noncommunicable disease, mental health and ageing efforts), social services, education, employment, justice, and housing, as well as partnerships with relevant civil society and private sector entities.

(e) Universal health and social care coverage for dementia. Designing and implementing health programmes for universal health coverage must include financial risk protection and ensuring equitable access to a broad range of promotive, preventive, diagnostic and care services (including palliative, rehabilitative and social support) for all people with dementia and their carers.

(f) **Equity.** All efforts to implement public health responses to dementia must support gender equity and take a gender-sensitive perspective, keeping in mind all vulnerabilities specific to each national context, consistent with the 2030 Agenda for Sustainable Development, which recognizes that people who are vulnerable, including people with disabilities, older people and migrants, must be empowered.

(g) **Appropriate attention to dementia prevention, cure and care.** Steps to realize this focus include using existing knowledge and experience to improve prevention, risk reduction, care and support for people with dementia and their carers and generation of new knowledge towards finding disease-modifying treatments or a cure, effective risk reduction interventions and innovative models of care.

## ACTIONS AND TARGETS FOR MEMBER STATES, THE SECRETARIAT AND INTERNATIONAL, REGIONAL AND NATIONAL PARTNERS

11. Effective implementation of the global action plan on the public health response to dementia will require actions by Member States, the Secretariat and international, regional, national and subnational partners. Depending on national context, these partners include but are not limited to:

- development agencies, including international multilateral agencies (for example, OECD, United Nations development agencies and the World Bank), regional agencies (for example, regional development banks), subregional intergovernmental agencies and bilateral development aid agencies;
- academic institutions and research agencies, including the network of WHO collaborating centres for mental health, ageing, disability, human rights and social determinants of health, and other related networks;
- civil society, including people with dementia, their carers and families and associations that represent them, and other relevant organizations;
- the private sector, health insurance, and the media.

12. The roles of these four groups often overlap and can include multiple actions cutting across the areas of governance, health and social care services, promotion of understanding and prevention in dementia, and information, evidence and research. Country-based assessments of the needs and capacities of different partners will be essential to clarify the roles and actions of stakeholder groups.

13. Targets included in this global action plan are defined for achievement globally. Each Member State can be guided by these global targets when setting its own national targets, taking into account national circumstances. Each Member State will also decide how these global targets should be adapted for national planning, processes (including data collection systems), policies and strategies.

14. The global action plan recognizes that each Member State faces specific challenges in implementing these action areas and therefore suggests a range of proposed actions that each Member State will need to adapt to the national context.

## Action areas

15. The global action plan comprises **seven action areas**, which form the underlying structural framework:

- 1. Dementia as a public health priority
- 2. Dementia awareness and friendliness
- 3. Dementia risk reduction
- 4. Dementia diagnosis, treatment, care and support
- 5. Support for dementia carers
- 6. Information systems for dementia
- 7. Dementia research and innovation

#### Action area 1: Dementia as a public health priority

16. Given the range of the population affected directly or indirectly by dementia and the complexity of this condition, dementia requires a whole-of-government, broad, multistakeholder, public health approach. Such an approach will lead to a comprehensive response from the health and social care system (both public and private) and other government sectors, and will engage people with dementia and their carers and other relevant stakeholders and partners.

17. **Rationale.** The development and coordination of policies, legislation, plans, frameworks and integrated programmes of care through a comprehensive, multisectoral approach will support the recognition, and address the complex needs, of people with dementia within the context of each country. This approach is in line with the principle of universal health coverage and the standards outlined in the Convention on the Rights of Persons with Disabilities.

18. **Global target 1:** 75% of countries will have developed or updated national policies, strategies, plans or frameworks for dementia, either stand-alone or integrated into other policies/plans, by 2025.<sup>1</sup>

## PROPOSED ACTIONS FOR MEMBER STATES

19. Develop, strengthen and implement national and/or subnational strategies, policies, plans or frameworks that address dementia, whether as separate instruments or integrated into other planned actions for noncommunicable diseases, mental health, ageing, and disability (or equivalent). These undertakings should give consideration to equity, dignity and the human rights of people with dementia and support the needs of carers, in consultation with people with dementia and other relevant stakeholders.

20. Promote mechanisms to monitor the protection of the human rights, wishes and preferences of people with dementia and the implementation of relevant legislation, in line with the objectives of the Convention on the Rights of Persons with Disabilities and other international and regional human rights instruments. These mechanisms include safeguards for concepts such as legal capacity, self-determination, supported decision-making, and power of attorney, and for protection against exploitation and abuse in institutions as well as in the community.

<sup>&</sup>lt;sup>1</sup> The global target indicators and means of verification are provided in the Appendix to this Annex.

21. Set up a focal point, unit or functional division responsible for dementia or a coordination mechanism within the entity responsible for noncommunicable diseases, mental health or ageing within the health ministry (or equivalent body), in order to ensure sustainable funding, clear lines of responsibility for strategic planning, implementation, mechanisms for multisectoral collaboration, service evaluation, monitoring and reporting on dementia.

22. Allocate sustainable financial resources that are commensurate with the identified service need and human and other resources required to implement national dementia plans and actions, and set up mechanisms for tracking expenditures on dementia in health, social and other relevant sectors such as education and employment.

## **ACTIONS FOR THE SECRETARIAT**

23. Offer technical support, tools and guidance to Member States, and strengthen national capacity in:

- leadership within health ministries and other relevant sectors for the development, strengthening and implementation of evidence-based national and/or subnational strategies or plans and associated multisectoral resource planning, budgeting and tracking of expenditure on dementia;
- evaluating and implementing evidence-based options that suit Member States' needs and capacities and assessing the health impact of public policies on dementia by supporting national and international partners and establishing or strengthening national reference centres, WHO collaborating centres and knowledge-sharing networks;
- coordinating programmes on dementia with those on related noncommunicable diseases, ageing, mental health and health systems, and with service delivery and processes to ensure maximum synergy and optimal use of existing and new resources.

24. Compile and share knowledge and best practices on existing policy documents dealing with dementia, including codes of practice and mechanisms to monitor the protection of human rights and implementation of legislation, consistent with the Convention on the Rights of Persons with Disabilities and other international and regional human rights instruments.

25. Promote and support collaboration and partnerships with countries at international, regional and national levels for multisectoral action in the response to dementia and aligning these with the principle of universal health coverage. Collaboration and partnerships should include all relevant sectors: health, justice and social services sectors, civil society, people with dementia, carers and family members, and organizations in the United Nations system, United Nations interagency groups and intergovernmental organizations.

## PROPOSED ACTIONS FOR INTERNATIONAL, REGIONAL AND NATIONAL PARTNERS

26. Create and strengthen associations and organizations of people with dementia, their families and carers, and foster their collaboration with existing disability (or other) organizations as partners in the prevention and treatment of dementia.

27. Motivate and actively engage in dialogue between associations representing people with dementia, their carers and families, health workers and government authorities in reforming health and social laws, policies, strategies, plans and programmes relevant to dementia, while paying explicit attention to the human rights of people with dementia and their carers as well as their empowerment, engagement and inclusion.

28. Support the development and application of national dementia policies, legislation, strategies and plans, and the creation of a formal role and authority for people with dementia and their carers to influence the process of designing, planning and implementing policies, laws and services related to dementia.

## Action area 2: Dementia awareness and friendliness

29. There is a common misconception that dementia is a natural and inevitable part of ageing rather than a disease process, resulting in barriers to diagnosis and care. The lack of understanding also causes fear of developing dementia and leads to stigmatization and discrimination. Furthermore, people with dementia are frequently denied their human rights in both the community and care homes.

30. Dementia-awareness programmes should: foster an accurate understanding of dementia and its various subtypes as clinical diseases; reduce stigmatization and discrimination associated with dementia; educate people about the human rights of people with dementia and the Convention on the Rights of Persons with Disabilities; enhance the general population's ability to recognize early symptoms and signs of dementia; and increase the public's knowledge of risk factors associated with dementia, thereby promoting healthy lifestyles and risk reduction behaviour in all.

31. A dementia-friendly society possesses an inclusive and accessible community environment that optimizes opportunities for health, participation and security for all people, in order to ensure quality of life and dignity for people with dementia, their carers and families. Shared key aspects of dementia-friendly initiatives include safeguarding the human rights of people with dementia, tackling the stigmatization associated with dementia, promoting a greater involvement of people with dementia in society, and supporting families and carers of people with dementia. The concept of dementia-friendly initiatives should take into account the fact that a significant number of older people are living alone and are sometimes very isolated.

32. Dementia-awareness campaigns and dementia-friendly programmes that are tailored to the cultural contexts and particular needs of a community can promote enhanced health and social outcomes that reflect the wishes and preferences of people with dementia, as well as improve the quality of life for people with dementia, their carers and the broader community.

33. **Rationale.** Increasing public awareness, acceptance and understanding of dementia and making the societal environment dementia-friendly will enable people with dementia to participate in the community and maximize their autonomy through improved social participation.

34. **Global target 2.1:** 100% of countries will have at least one functioning public awareness campaign on dementia to foster a dementia-inclusive society by 2025.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> The global target indicator and means of verification are provided in the Appendix to this Annex.

35. **Global target 2.2:** 50% of countries will have at least one dementia-friendly initiative to foster a dementia-inclusive society by 2025.<sup>1</sup>

## PROPOSED ACTIONS FOR MEMBER STATES

36. In collaboration with people with dementia, their carers and the organizations that represent them, the media and other relevant stakeholders, organize national and local public health and awareness campaigns that are community- and culture-specific. This cooperative action will improve the accuracy of the general public's knowledge about dementia, reduce stigmatization, dispel myths, promote early diagnosis, and emphasize the need for gender- and culturally-appropriate responses, recognition of human rights and respect for the autonomy of people with dementia.

37. Support changing all aspects of the social and built environments, including the provision of amenities, goods and services, in order to make them more inclusive and age- and dementia-friendly, promoting respect and acceptance in a manner that meets the needs of people with dementia and their carers and enables participation, safety and inclusion.

38. Develop programmes, adapted to the relevant context, to encourage dementia-friendly attitudes in the community and the public and private sectors that are informed by the experiences of people with dementia and their carers. Target different community and stakeholder groups, including but not limited to: school students and teachers, police, ambulance, fire brigades, transport, financial and other public service providers, education and faith-based organizations, and volunteers.

## **ACTIONS FOR THE SECRETARIAT**

39. Offer technical support to Member States in strengthening global, regional and national capacity:

- to engage and include people with dementia, their carers and organizations that represent them in decision-making within WHO's own processes and on issues that concern them;
- for the selection, formulation, implementation and dissemination of best practices for awareness-raising and reduction of stigmatization and discrimination towards people with dementia.

40. Building upon the WHO Global Network of Age-friendly Cities and Communities and its dedicated website,<sup>1</sup> integrate and link dementia-friendly initiatives by documenting and evaluating existing dementia-friendly initiatives in order to identify evidence of what works in different contexts and disseminate this information.

41. Promote awareness and understanding of dementia, the human rights of people with dementia and the role of families and/or other carers as well as maintain and strengthen partnerships with organizations representing people with dementia and their carers.

42. Develop guidance for Member States on how to implement, monitor and evaluate dementia-friendly initiatives.

<sup>&</sup>lt;sup>1</sup> https://extranet.who.int/agefriendlyworld/ (accessed 8 March 2017).

## PROPOSED ACTIONS FOR INTERNATIONAL, REGIONAL AND NATIONAL PARTNERS

- 43. Encourage all stakeholders to:
  - raise awareness of the magnitude of the social and economic impact of dementia;
  - include people with dementia, their carers and families in all aspects of developing and strengthening services that support the autonomy of people with dementia;
  - protect and promote human rights of people with dementia and support their carers and their families;
  - redress the inequities in vulnerable populations.

44. Ensure that people with dementia are included in activities of the wider community and foster cultural, social and civic participation by enhancing their autonomy.

45. Share in the development and implementation of all relevant programmes to raise awareness about dementia and make communities more dementia-friendly and -inclusive.

#### Action area 3: Dementia risk reduction

46. Growing evidence suggests an interrelationship between dementia on one side and noncommunicable disease and lifestyle-related risk factors on the other. These risk factors include physical inactivity, obesity, unbalanced diets, tobacco use, harmful use of alcohol, diabetes mellitus and mid-life hypertension. In addition, other potentially modifiable risk factors are more specific to dementia and include social isolation, low educational attainment, cognitive inactivity and mid-life depression. Reducing the level of exposure of individuals and populations to these potentially modifiable risk factors, beginning in childhood and extending throughout life, can strengthen the capacity of individuals and populations to make healthier choices and follow lifestyle patterns that foster good health.

47. There is growing consensus that the following measures are protective and can reduce the risk of cognitive decline and dementia: increasing physical activity, preventing and reducing obesity, promotion of balanced and healthy diets, cessation of tobacco use and the harmful use of alcohol, social engagement, promotion of cognitively stimulating activities and learning as well as prevention and management of diabetes, hypertension, especially in mid-life, and depression.

48. **Rationale.** By improving the capacity of health and social care professionals to provide evidence-based, multisectoral, gender and culturally-appropriate interventions to the general population, educate about and proactively manage modifiable risk factors for dementia that are shared with other noncommunicable diseases, the risk of developing dementia can be reduced or its progression delayed.

49. **Global target 3:** The relevant global targets defined in the Global action plan for prevention and control of noncommunicable diseases 2013–2020 and any future revisions are achieved for risk reduction and reported.<sup>1</sup>

## PROPOSED ACTIONS FOR MEMBER STATES

50. Link dementia with other programmes, policies and campaigns on noncommunicable disease risk reduction and health promotion across relevant sectors by promoting physical activity, healthy and balanced diets. Specific actions include weight management for obese individuals, cessation of tobacco use and the harmful use of alcohol, formal education and mentally stimulating activities as well as lifelong social engagement in line with the principle of balancing prevention and care.

51. Develop, deliver and promote evidence-based, age-, gender-, disability- and culturally sensitive interventions and training to health professionals, especially within the primary health care system, to improve knowledge and practices of such staff, and proactively manage modifiable dementia risk factors when conducting counselling about risk reduction. Routinely update these interventions as new scientific evidence becomes available.

## **ACTIONS FOR THE SECRETARIAT**

52. Linking to the actions specified in the global action plan for the prevention and control of noncommunicable diseases 2013–2020, offer technical support and strengthen global, regional and national capacities and capabilities to:

- raise awareness of the links between dementia and other noncommunicable diseases;
- integrate the reduction and control of modifiable dementia risk factors into national health-planning processes and development agendas;
- support the formulation and implementation of evidence-based, multisectoral interventions for reducing the risk of dementia.

53. Strengthen the evidence base and share and disseminate evidence to support policy interventions for reducing potentially modifiable risk factors for dementia by providing a database of available evidence on the prevalence of those risk factors and the consequences of reducing them.

## PROPOSED ACTIONS FOR INTERNATIONAL, REGIONAL AND NATIONAL PARTNERS

- 54. Encourage all stakeholders to engage in activities to:
  - promote and mainstream population health strategies that are age-inclusive, gender-sensitive and equity-based at national, regional and international levels in order to support a socially active lifestyle that is physically and mentally healthy for all, including people with dementia, their carers and families;

<sup>&</sup>lt;sup>1</sup> See document WHA66/2013/REC/1, Annex 4, available at http://apps.who.int/gb/ebwha/pdf\_files/WHA66-REC1/A66\_REC1-en.pdf#page=87, accessed 20 September 2017.

- take particular actions that have been shown to reduce the risk of dementia, particularly during mid-life;
- support national efforts for prevention and control of noncommunicable diseases in general and dementia in particular, for example, through exchange of information on evidence-based best practices and dissemination of research findings.

## Action area 4: Dementia diagnosis, treatment, care and support

55. Dementia is associated with complex needs and high levels of dependency and morbidity in its later stages, requiring a range of health and social care, including long-term-care services. People with dementia are also less likely to be diagnosed for comorbid health conditions, which, when left untreated, can cause faster decline, and to receive the care and support they need to manage them. The services that they require include case-finding, diagnosis, treatment (including pharmacological and psychosocial), rehabilitation, palliative/end-of-life care and other support such as home help, transport, food and the provision of a structured day with meaningful activities.

56. People with dementia should be empowered to live in the community and to receive care aligned with their wishes and preferences. To ensure that people with dementia can maintain a level of functional ability consistent with their basic rights, fundamental freedoms and human dignity, they need integrated, person-centred, accessible, affordable health and social care, including long-term care. Long-term care covers all activities, whether these are provided by health, social or palliative care services or result from a dementia-friendly environment. Palliative care is a core component of the continuum of care for people living with dementia from the point of diagnosis through to the end of life and into the bereavement stages for families and carers. It provides physical, psychosocial and spiritual support for people with dementia and their carers including support with advance care planning.

57. The global action plan proposes some principles for organizing and developing health and social care, including long-term care systems for dementia. Providing sustainable care across the continuum from diagnosis to the end of life requires: timely diagnosis; the integration of dementia treatment and care into primary care; coordinated continuity of health and social care including long-term care between different providers and system levels, multidisciplinary collaboration and active cooperation between paid and unpaid carers. Planning responses to and recovery from humanitarian emergencies must ensure that individual support for people with dementia and community psychosocial support are widely available.

58. Adequately trained and qualified workforces are required to provide these interventions. The continuity of care between different care providers, multiple sectors and system levels and active collaboration between paid and unpaid carers are crucial, from the first symptoms of dementia until the end of life. Integrated, evidence-based, person-centred care is required in all settings where people with dementia live, ranging from their homes, the community, assisted-living facilities and nursing homes to hospitals and hospices. The skills and capacity of the workforce and services are often challenged by the complex needs of people with dementia.

59. **Rationale.** The needs and preferences of people with dementia can be met and their autonomy from diagnosis to the end of life respected through integrated, culturally appropriate, person-centred, community-based health, psychosocial, long-term care and support and, where appropriate, the inputs of families and carers.

60. **Global target 4:** In at least 50% of countries, as a minimum, 50% of the estimated number of people with dementia are diagnosed<sup>1</sup> by 2025.<sup>2</sup>

## PROPOSED ACTIONS FOR MEMBER STATES

61. Develop a pathway of efficient, coordinated care for people with dementia that is embedded in the health and social care system (including long-term care), to provide integrated, person-centred care as and when it is required. The pathway should provide quality care and management that integrates multiple services, including primary health care, home care, long-term care, specialist medical care, rehabilitation and palliative services, household help, food and transport services, other social welfare services and meaningful activities, into a seamless bundle that enhances the capacity and functional ability of people with dementia.

62. Build the knowledge and skills of general and specialized staff in the health workforce to deliver evidence-based, culturally-appropriate and human rights-oriented health and social care, including long-term care services for people with dementia. (Mechanisms may include teaching the core competences of dementia diagnosis, treatment and care in undergraduate and graduate medical and paramedical training, and continuing training programmes for all health and social care professionals, in collaboration with key stakeholders such as regulatory bodies.) Earmark budgets and resources for in-service training for these professionals, or include such budgets and resources in specific programmes.

63. Improve the quality of care towards the end of life by: recognizing advanced dementia as a condition requiring palliative care; promoting awareness about advanced care planning for all people living with dementia to document their wishes for the end of their life; using validated end-of-life pathways and ensuring that people with dementia have their values and preferences respected and are cared for in their place of choice; and providing training for health care professionals and palliative care specialists.

64. Systematically shift the locus of care away from hospitals towards community-based care settings and multidisciplinary, community-based networks that integrate social and health systems and provide quality care and evidence-based interventions.

65. Enhance access to a range of person-centred, gender-sensitive, culturally-appropriate and responsive services including liaison with local nongovernmental organizations and other stakeholders in order to provide information that empowers people with dementia to make informed choices and decisions about their care. Respect their rights and preferences and foster active collaboration between the person with dementia, their families and carers and service providers from the first symptoms through to the end of life.

## **ACTIONS FOR THE SECRETARIAT**

66. Offer technical support to Member States for documenting and sharing best practices of evidence-based service delivery and care coordination, and provide support to Member States in developing dementia care pathways in line with the principle of universal health coverage.

<sup>&</sup>lt;sup>1</sup> All people who are diagnosed should receive appropriate post-diagnostic health and social care.

<sup>&</sup>lt;sup>2</sup> The global target indicator and means of verification are provided in the Appendix to this Annex.

67. Develop and implement guidelines, tools and training materials, such as model training curricula, covering core competencies relating to dementia for health and social care workers in the field. Provide support to Member States in the formulation of human resource strategies for dementia, including the identification of gaps, specific needs and training requirements for health and social care workers as well as graduate and undergraduate education about integrated provision of long-term care that is person-centred from diagnosis to the end of life.

68. Provide guidance on strengthening the implementation of the dementia component of the WHO Mental Health Gap Action Programme<sup>1</sup> to enhance capabilities of existing human resources and train more staff, and on improving the ability to provide quality care and evidence-based interventions through primary health care.

# PROPOSED ACTIONS FOR INTERNATIONAL, REGIONAL AND NATIONAL PARTNERS

69. Support people with dementia and their families and carers, for example, by developing evidence-based, user-friendly information and training tools concerning dementia and available services to allow timely diagnosis and enhance the continued provision of long-term care, or by setting up national helplines and websites with information and advice at local levels.

70. Support the training of health and social care personnel to provide evidence-based treatment and care for people with dementia, by developing training relevant to needs, supporting teaching institutions in revising the contents of curricula so as to place greater emphasis on dementia, and ensuring that people with dementia are engaged, as appropriate, in the development and provision of education and training.

71. Promote community-based rehabilitation as an effective strategy to enable and support people with dementia in preserving their autonomy and rights and ensuring that the person with dementia remains at the centre of all discussions on diagnosis, treatment and care.

#### Action area 5: Support for dementia carers

72. Carers can be defined by their relationship to the person with dementia and their care input. Many dementia carers are relatives or extended family members, but close friends, neighbours and paid lay persons or volunteers can also take on responsibilities for caring. Carers are involved in providing "hands-on" care and support for people with dementia or play a significant role in organizing the care delivered by others. Carers often know the person with dementia well, and therefore are likely to have knowledge of and information about the person with dementia that is crucial for developing effective personalized needs-based treatment and care plans. Carers should therefore be considered essential partners in the planning and provision of care in all settings according to the wishes and needs of the person with dementia.

73. It should be noted that being a carer for someone with dementia may affect the carer's physical and mental health and well-being and social relationships. Health systems must consider both the substantial need of people with dementia for help from others and its significant impact on carers and families, including economic impact. Carers should have access to support and services tailored to their needs in order effectively to respond to and manage the physical, mental and social demands of their caring role.

<sup>&</sup>lt;sup>1</sup> See http://www.who.int/mental\_health/mhgap/en/ (accessed 8 March 2017).

74. **Rationale.** The creation and implementation of means to deliver multisectoral care, support and services for carers will help to meet the needs of carers, and prevent a decline in their physical and mental health and social well-being.

75. **Global target 5:** 75% of countries provide support and training programmes for carers and families of people with dementia by 2025.<sup>1</sup>

## PROPOSED ACTIONS FOR MEMBER STATES

76. Provide accessible and evidence-based information, training programmes, respite services and other resources tailored to the needs of carers to improve knowledge and caregiving skills, such as coping with challenging behaviour, to enable people with dementia to live in the community and to prevent stress and health problems for their carers.

77. Provide training programmes for health care and social care staff for the identification and reduction of stress and burn-out of carers.

78. Develop or strengthen protection of carers, such as social and disability benefits, policies and legislation against discrimination, for example in employment, and support them beyond their caregiving role in all settings.

79. Involve carers in the planning of care, with attention being given to the wishes and preferences of people with dementia and their families.

#### ACTIONS FOR THE SECRETARIAT

80. Build evidence on and articulate the importance of carers in the lives of people with dementia, while raising awareness about the disproportionate effect on women, and offer technical support to Member States by monitoring trends in availability of carer-support services. Provide support to Member States in developing evidence-based information, training programmes and respite services for carers, using a multisectoral approach, and foster outcome measurement.

81. Facilitate access to affordable, evidence-based resources for carers to improve knowledge and skills, reduce emotional stress and improve coping, self-efficacy and health by making use of information and communication technologies such as Internet and mobile phone technologies (for instance, WHO iSupport<sup>2</sup>), for education, skills training and social support.

# PROPOSED ACTIONS FOR INTERNATIONAL, REGIONAL AND NATIONAL PARTNERS

82. Increase awareness of the involvement, and its consequences, of carers and families in the lives of people with dementia, protecting them from discrimination, supporting their ability to continue their caregiving in a gender-sensitive manner, and empowering carers with opportunities to develop self-advocacy skills to be able to meet specific challenges in accessing health and social care, including long-term care services.

<sup>&</sup>lt;sup>1</sup> The global target indicator and means of verification are provided in the Appendix to this Annex.

<sup>&</sup>lt;sup>2</sup> WHO iSupport: e-programme for caregivers of people living with dementia (http://www.who.int/mental\_health/neurology/dementia/isupport/en/, accessed 8 March 2017).

83. Assist in carrying out appropriate training programmes: for carers and families to enhance knowledge and caregiving skills across the progression of dementia; and on a person-centred approach to promote respect and well-being.

## Action area 6: Information systems for dementia

84. Systematic, routine population-level monitoring of a core set of dementia indicators provides the data needed to guide evidence-based actions to improve services and to measure progress towards implementing national dementia policies. By building and/or strengthening information systems for dementia, the functional trajectories of people with dementia, their carers and families can be improved. However, this will require significant changes, while respecting existing regulatory frameworks, to the routine collection, recording, linkage and disaggregation for the sharing of health and administrative data of each encounter of a person with dementia with the health and social care system.

85. **Rationale.** Systematic monitoring and evaluation of the usage of health and social care systems can provide the best available evidence for policy development and service delivery, and can improve prevention and the accessibility and coordination of care for people with dementia across the continuum, from risk reduction to the end of life.

86. **Global target 6:** 50% of countries routinely collect a core set of dementia indicators through their national health and social information systems every two years by 2025.<sup>1</sup>

## **PROPOSED ACTIONS FOR MEMBER STATES**

87. Develop, implement and improve, as needed, national surveillance and monitoring systems, including registers that are integrated into existing health information systems, in order to improve availability of high-quality, multisectoral data on dementia. Enable access to health and social care data and map available services and resources at national and regional levels in order to improve service delivery and coverage across the care continuum from prevention through risk reduction to the end of life.

88. Update or create supportive policy or legislation pertaining to the measurement, collection and sharing of data on health and social care for dementia and integrate this information routinely into national health information systems so as to facilitate routine reporting on dementia.

89. Collect and use the necessary data on epidemiology, care and resources relating to dementia in the country in order to implement relevant policies and plans.

#### **ACTIONS FOR THE SECRETARIAT**

- 90. Offer technical support to Members States as they:
  - develop and/or reform national data collection systems, including health information systems, in order to strengthen multisectoral dementia data collection;

<sup>&</sup>lt;sup>1</sup> The global target indicator and means of verification are provided in the Appendix to this Annex.

• build national capacity and resources for systematic collection, analysis and use of dementia-specific data through development of targets and indicators that account for national circumstances, yet are aligned as closely as possible with indicators and targets of the global monitoring framework.

91. Develop a core set of indicators in line with this action plan and provide guidance, training and technical assistance on capturing information and facilitating the use of these data to monitor outcomes. WHO's Global Dementia Observatory provides the mechanism to monitor systematically and facilitate the use of data from these core indicators, offering a platform for the exchange of data and knowledge in order to support evidence-based service planning, sharing of best practices and strengthening of both policies on dementia and health and social care systems.

92. Offer technical support to Member States in generating and providing information for monitoring of global, regional and national targets as required, through the Global Dementia Observatory.

# PROPOSED ACTIONS FOR INTERNATIONAL, REGIONAL AND NATIONAL PARTNERS

93. Provide support to Member States and the Secretariat in developing tools and strengthening capacity for surveillance and information systems that: capture data on core indicators on dementia; monitor usage of health and social care and support services for people with dementia, carers and families; and enable an assessment of trends over time.

94. Advocate the involvement of people with dementia and their families and carers in the creation, collection, analysis and use of data on dementia.

#### Action area 7: Dementia research and innovation

95. If the incidence of dementia is to be reduced and the lives of people with dementia are to be improved, research and innovation are crucial, as is their translation into daily practice. It is important not only that funding and appropriate infrastructures for dementia research and innovation are available but also that mechanisms are in place that assist appropriate recruitment of people with dementia, their families and carers into research studies. Research and development costs are higher for dementia than other therapeutic areas, because of lower success rates, longer development times, and low recruitment rates into trials; this disproportion discourages investment in this area. Research is needed to find a cure for dementia, but research is equally needed into prevention, risk reduction, diagnosis, treatment and care, including the disciplines of social science, public health and implementation research.

96. Collaboration among and between Member States and relevant stakeholders, with a particular focus on strengthening North–South, South–South and triangular cooperation, to implement a global dementia research agenda, will increase the likelihood of effective progress globally towards better prevention, diagnosis, treatment and care for people with dementia.

97. There is a growing interest in, and call for, the use of innovative health technologies in prevention, risk reduction, early diagnosis, treatment, care and support relating to dementia. These innovations aim to improve knowledge, skills and coping mechanisms in order to facilitate and support the daily lives of people with dementia and their carers while meeting, in particular, identified needs in an evidence-based and age-, gender- and culturally-sensitive manner.

98. **Rationale.** The successful implementation of research into dementia aligned with identified research priorities and social and technological innovations can increase the likelihood of effective progress towards better prevention, diagnosis, treatment and care for people with dementia.

99. Global target 7: The output of global research on dementia doubles between 2017 and 2025.<sup>1</sup>

## PROPOSED ACTIONS FOR MEMBER STATES

100. Develop, implement and monitor the realization of a national research agenda on prevention, diagnosis, treatment and care of people with dementia in collaboration with academic and research institutions; this work could be stand-alone or integrated into related research programmes that focus on filling gaps in evidence to support policy or practice. Strengthen research capacity for academic collaborations on national priorities for research into dementia by engaging relevant stakeholders, including people with dementia. Relevant steps may include: improving research infrastructure for dementia and related fields, enhancing competence of researchers to conduct high-quality research, and establishing centres of excellence for research into dementia.

101. Increase investment in dementia research and innovative health technologies and improve research governance as an integral component of the national response to dementia. In particular, allocate budgets to promote projects that: support collaborative national and international research; promote sharing of and open access to research data; generate knowledge on how to translate what is already known about dementia into action; and support the retention of the research workforce.

102. Foster the development of technological innovations that, in terms of design and evaluation, respond to the physical, psychological and social needs of people with dementia, their carers or people at risk of developing dementia; these innovations include but are not limited to diagnosis, disease monitoring and assessment, assistive technologies, pharmaceuticals and new models of care or forecasting/modelling techniques.

103. Following the national ethical requirements for research, promote equitable opportunities and access for people with dementia and their carers to be part of clinical and social research that concerns them.

#### **ACTIONS FOR THE SECRETARIAT**

104. Draw up a global research agenda and work together with Member States to strengthen and build capacity in the area of dementia research by incorporating it in national and subnational policies and plans relating to dementia. Advocate increased investment in dementia research, capacities, methods and collaboration in the fields of biomedical and social sciences research, inter alia, through a network of WHO collaborating centres, countries from all WHO regions, and civil society organizations.

105. Engage relevant stakeholders, including people with dementia and their organizations, in the development and promotion of a global dementia research programme; facilitate global networks for research collaboration; and carry out multisectoral research related to the burden of disease, dementia risk reduction, treatment, care, policy and service evaluation. Promote international cooperation and intercountry exchange of research expertise, policy and practice through the systematic mapping of national investments in research and outputs of that research.

<sup>&</sup>lt;sup>1</sup> The global target indicator and means of verification are provided in the Appendix to this Annex.

106. Support the inclusion of technological innovation in national and subnational policies and plans on dementia and offer technical support to Member States in developing and strengthening the provision of assistive and innovative technologies to maximize the functional ability of people with dementia, particularly in resource-poor settings.

# PROPOSED ACTIONS FOR INTERNATIONAL, REGIONAL AND NATIONAL PARTNERS

107. Support Member States and the Secretariat, where appropriate, by collaborating in setting priorities for dementia research, promoting increased governmental investment, mobilizing and increasing financial support, and disseminating research findings in user-friendly language to policy-makers, the public, people with dementia, their carers and families.

108. Advocate the engagement of people with dementia and their carers in applied research, clinical trials and the evaluation of new technologies that take account of the different physiology, needs and preferences of people with dementia and their carers.

109. Assist in the implementation and evaluation of innovative technologies, community-based service delivery structures and new dementia care concepts. Promote the use of information and communications technology to improve programme implementation, health outcomes, health promotion, monitoring and reporting and surveillance systems, and to disseminate, as appropriate, information on affordable, cost-effective, sustainable and high-quality interventions, best practices and lessons learned in the field of dementia.

110. Strengthen national capacity for research, development and innovation, for all aspects of dementia prevention, risk reduction, treatment and care in a sustainable and cost-effective manner, including the strengthening of institutional capacity and the creation of research fellowships and scholarships.

#### Appendix

### INDICATORS FOR MEASURING PROGRESS TOWARDS THE DEFINED TARGETS OF THE GLOBAL ACTION PLAN ON THE PUBLIC HEALTH RESPONSE TO DEMENTIA AND MEANS OF VERIFICATION

The indicators offer measures to meet a subset of the information and reporting needs that Member States require to be able to monitor the progress and outcome of their dementia policies and programmes adequately. Given that targets are voluntary and global, each Member State is not necessarily expected to achieve all the specific targets but can contribute to a varying extent towards reaching them jointly. As indicated under action area 6 of the global action plan, the Secretariat will provide guidance, training and technical support to Member States, upon request, on the development of national information systems for capturing data on dementia indicators. WHO's Global Dementia Observatory provides the mechanism to monitor and facilitate the use of data through a platform for exchanging data and knowledge in order to support evidence-based service planning, sharing of best practices, and strengthening of dementia policies as well as health and long-term care systems. The aim is to build on existing information systems rather than creating new or parallel systems. Baselines for each target will be established early during the implementation phase of the global action plan.

| Action area 1: Dementia as a p     | Action area 1: Dementia as a public health priority   |  |
|------------------------------------|---|--|
| Global target                      | 75% of countries will have developed or updated national policies, strategies, plans or frameworks for dementia, either stand-alone or integrated into other policies/plans, by 2025.   |  |
| Indicator                          | Existence of an operational national policy, strategy, plan or framework for<br>dementia, either a stand-alone instrument specific for dementia or<br>integrating dementia into other relevant policies, plans or strategies (for<br>instance, on mental health, ageing, noncommunicable diseases and<br>disability).                                 |  |
|                                    | For countries with a federated system, the indicator will refer to the availability of dementia policies or plans for 50% or more of the states or provinces within the country.  |  |
| Means of verification              | Physical availability of the policy or plan that incorporates the suggested range of cross-cutting principles and areas to be adapted by Member States, depending on national context.  |  |
| Comments/assumptions/<br>rationale | Policies or plans on dementia may be stand-alone or integrated into other<br>health, ageing or disability policies or plans. "Operational" means that the<br>national policy, strategy, plan or framework is being used and implemented<br>in the country, and has funds, resources and instructions allocated to<br>implement it.                    |  |
|                                    | Many policies and plans that are older than 10 years may not reflect recent<br>developments in evidence-based practice for treatment and care of people<br>with dementia and international human rights standards. The key principles<br>of dementia care will be in line with the cross-cutting principles and<br>actions of the global action plan. |  |

| Action area 2: Dementia awareness and friendliness |  |
|--|--|
| Global target                                      | 2.1 100% of countries will have at least one functioning public awareness campaign on dementia to foster a dementia-inclusive society by 2025.   |
|  | 2.2 50% of countries will have at least one dementia-friendly initiative to foster a dementia-inclusive society by 2025.   |
| Indicator  | <u>2.1</u> Existence of at least one mass media dementia awareness-raising programme/campaign (run nationwide for example, on television and radio, in print media and/or on billboards for at least three weeks) in the past year/during the most recent survey period.   |
|  | 2.2 Existence of at least one dementia-friendly initiative and/or age-friendly initiative specifically targeting dementia to foster a dementia-inclusive society by 2025.  |
| Means of verification                              | Inventory of currently implemented dementia-awareness campaigns and dementia/age-friendly initiatives, described project by project.   |
| Comments/assumptions/<br>rationale                 | Raising awareness and changing the social and physical environment are<br>both important. Raising awareness on an individual basis through<br>campaigns will not necessarily result in greater social inclusion in the way<br>that programmes designed for changes to physical and social environments<br>can.   |
|  | Awareness-raising campaigns may – and preferably should – cover both<br>universal, population-level strategies (for example, mass media campaigns<br>against dementia stigmatization and discrimination) and those aimed at<br>locally-identified vulnerable groups (for example, the elderly, women,<br>people with low educational attainment, high-risk populations such as |

| Action area 2: Dementia awareness and friendliness |  |
|--|--|
|  | smokers and ethnic minorities). Key aspects of these campaigns include:<br>fostering an accurate understanding of dementia and its various subtypes as<br>clinical diseases; reducing stigmatization and discrimination associated<br>with dementia; improving knowledge about the human rights of people<br>with dementia and the Convention on the Rights of Persons with<br>Disabilities; enhancing the general population's ability to recognize early<br>symptoms and signs of dementia; and increasing the public's knowledge of<br>risk factors associated with dementia, thereby promoting healthy lifestyles<br>and risk reduction behaviour in all.  |
|  | The media play a key role in shaping knowledge, opinions and behaviours,<br>and can be extremely powerful in influencing both individuals and<br>policy-makers regarding dementia awareness and understanding. As a<br>result, mass media dementia campaigns should become a key component of<br>raising dementia awareness.   |
|  | A "dementia-friendly" society is one that has an inclusive and accessible<br>community environment that optimizes opportunities for health, participation<br>and security for all people, in order to ensure quality of life and dignity for<br>people with dementia and their families and carers. Shared key aspects of<br>dementia-friendly initiatives include: safeguarding the human rights of<br>people with dementia; tackling the associated stigmatization; promoting a<br>greater involvement of people with dementia and their carers in society; and<br>supporting people with dementia to continue to live independent and<br>fulfilling lives in their own communities as well as providing support to their<br>carers and families. The choice of a broad indicator (namely, the existence of<br>at least one dementia-friendly initiative) is intended to maximize the impact<br>across a broad range of outputs. The successful implementation of<br>dementia-friendly initiatives requires a multisectoral approach involving<br>governments, civil society and the private sector. |

| Action area 3: Dementia risk reduction |   |
|--|---|
| Global target                          | The relevant global targets defined in, and in keeping with, the Global action plan for prevention and control of noncommunicable diseases 2013–2020 and any future revisions are achieved. |
| Indicator                              | A 10% relative reduction in prevalence of insufficient physical activity  |
|  | A 30% relative reduction in prevalence of current tobacco use in persons aged 15 years and older  |
|  | At least a 10% relative reduction in the harmful use of alcohol, as appropriate, within the national context  |
|  | A halt in the rise in diabetes and obesity  |
|  | A 25% relative reduction in the prevalence of raised blood pressure or contain the prevalence of raised blood pressure according to national circumstances                                  |
|  | A 25% relative reduction in overall mortality from cardiovascular diseases, cancer, diabetes or chronic respiratory diseases  |

|                                    | Indicators as currently defined in Appendix 2 of the Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020. <sup>1</sup>  |
|------------------------------------|---|
| Means of verification              | Reporting to WHO's governing bodies as provided for in the Global action plan for prevention and control of noncommunicable diseases 2013–2020  |
| Comments/assumptions/<br>rationale | There is growing consensus that the following measures are protective and<br>can reduce the risk of cognitive decline and dementia: reduction of physical<br>inactivity and obesity, cessation of tobacco use and the harmful use of<br>alcohol, prevention and management of diabetes, and hypertension. |
|                                    | Six of the nine voluntary global targets in the Global action plan for prevention and control of noncommunicable diseases 2013–2020 have been identified as being able to have a positive influence on dementia risk reduction.   |

| Action area 4: Dementia diagnosis, treatment, care and support |   |
|--|---|
| Global target  | In at least 50% of countries, as a minimum, 50% of the estimated number of people with dementia are diagnosed by 2025.                                  |
| Indicator  | The number of people with dementia in a population who accessed the health and/or social care system and received a diagnosis of dementia (all-causes). |
| Means of verification  | Numerator: number of people with dementia in a country who have presented to services and received a dementia diagnosis.                                |
|  | Denominator: estimated population-based prevalence of dementia for a country as calculated by WHO as part of the Global Dementia Observatory.           |
| Comments/assumptions/<br>rationale                             | Data may be derived from administrative sources, electronic records and registries. This will be a relative, globally combined measure.                 |
|  | All people who are diagnosed should receive appropriate care and support from health and social care services.  |

| Action area 5: Support for dementia carers |   |
|--|---|
| Global target                              | 75% of countries provide support and training programmes for carers and families of people with dementia by 2025.   |
| Indicator                                  | At least one national or several subnational, functioning, support or training programmes are available for carers. |
| Means of verification                      | Inventory of currently implemented programmes for carers.   |

<sup>&</sup>lt;sup>1</sup> See document WHA66/2013/REC/1, Annex 4, available at http://apps.who.int/gb/ebwha/pdf\_files/WHA66-REC1/A66\_REC1-en.pdf#page=87, accessed 20 September 2017.

| Comments/assumptions/<br>rationale | Functional programmes are defined as having dedicated financial and<br>human resources, an implementation plan and documented evidence of<br>progress or impact.   |
|------------------------------------|--|
|                                    | Types of programmes or support for carers can include respite care, counselling, and educational training on subjects such as care techniques, non-verbal communication and patient–carer relationship development.                                  |
|                                    | For countries with a federated system, the indicator will refer to the availability of at least one provincial or state-wide service or programme with complete geographical coverage for 50% or more of the states or provinces within the country. |

| Action area 6: Information systems for dementia |   |
|---|---|
| Global target                                   | 50% of countries routinely collect a core set of dementia indicators through their national health and social information systems on which they report every two years by 2025.   |
| Indicator                                       | Core set of identified and agreed dementia indicators routinely collected<br>and reported every two years (yes/no).   |
| Means of verification                           | Routine reporting and submission of a core dementia indicator set to the Global Dementia Observatory every two years.   |
| Comments/assumptions/<br>rationale              | Core dementia indicators include those relating to specified targets of this action plan, together with other essential indicators of health and social system policies and resources. The data need to be disaggregated by sex and age. Where needed, surveys can also be used to complement data from routine information systems. The Secretariat will advise countries on a set of core indicators on dementia for which data can be collected from Member States as part of the activities of the Global Dementia Observatory. |

| Action Area 7: Dementia research and innovation |  |
|---|--|
| Global target                                   | The output of global research on dementia doubles between 2017 and 2025.   |
| Indicator                                       | Number of published articles on dementia research (defined as a research article published in an indexed and peer-reviewed journal).                       |
| Means of verification                           | Centrally-conducted literature search, stratified by country of origin, every two years.   |
| Comments/assumptions/<br>rationale              | The indicator measures the output of research related to dementia as defined by national published research studies in indexed and peer-reviewed journals. |
|   | Data will be collected, analysed and reported by WHO on a global and regional basis (as part of the work of WHO's Global Dementia Observatory).            |

# LINKS TO OTHER GLOBAL ACTION PLANS, STRATEGIES AND $\mathsf{PROGRAMMES}^1$

- Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, available at: http://www.un.org/ga/search/view\_doc.asp?symbol=A/66/L.1
- Comprehensive mental health action plan 2013–2020, available at: http://apps.who.int/gb/ebwha/pdf\_files/WHA66-REC1/A66\_REC1-en.pdf#page=106
- Global action plan for the prevention and control of noncommunicable disease 2013–2020, available at: http://apps.who.int/gb/ebwha/pdf\_files/WHA66-REC1/A66\_REC1-en.pdf#page=130
- WHO global disability action plan 2014–2021, available at: http://apps.who.int/gb/ebwha/pdf\_files/WHA67-REC1/A67\_2014\_REC1-en.pdf#page=112
- PAHO. Strategy and plan of action on dementias in older persons, available at: http://www.paho.org/hq/index.php?option=com\_docman&task=doc\_download&gid=31496&Ite mid=270&lang=en
- Global strategy and action plan on ageing and health (2016–2020), available at: http://apps.who.int/gb/or/ (document WHA69/2016/REC/1, Annex 1)
- Sustainable Development Goals, available at: http://www.who.int/topics/sustainabledevelopment-goals/en/
- WHO. Measuring the age-friendliness of cities: a guide to using core indicators, available at: http://www.who.int/kobe\_centre/publications/AFC\_guide/en/

# LIST OF OTHER DOCUMENTS THAT ARE LINKED TO THE GLOBAL ACTION PLAN ON THE PUBLIC HEALTH RESPONSE TO DEMENTIA<sup>1</sup>

- WHO Mental Health Gap Action Programme. Diagnosis of dementia, available at: http://www.who.int/mental\_health/mhgap/evidence/dementia/q6/en/
- WHO iSupport: e-programme for caregivers of people living with dementia, available at: http://www.who.int/mental\_health/neurology/dementia/isupport/en/
- WHO. Mental health atlas 2014, available at: http://www.who.int/mental\_health/evidence/atlas/mental\_health\_atlas\_2014/en/
- WHO assessment instrument for mental health systems (AIMS), Version 2.2, available at: http://www.who.int/mental\_health/evidence/WHO-AIMS/en/
- WHO. Service availability and readiness assessment, available at: http://www.who.int/healthinfo/systems/sara\_introduction/en/

<sup>&</sup>lt;sup>1</sup> All websites accessed 8 March 2017.

- WHO QualityRights toolkit, available at: http://www.who.int/mental\_health/policy/quality\_rights/en/
- WHO. Global age-friendly cities: a guide (2007), available at: http://www.who.int/ageing/ publications/Global\_age\_friendly\_cities\_Guide\_English.pdf
- WHO. Tobacco use knowledge summaries: tobacco use and dementia, available at: http://www.who.int/tobacco/publications/mental\_health/dementia\_tks\_14\_1/en/
- Reports of the WHO global forums on innovation for ageing populations (Kobe, Japan, 10–12 December 2013 and 7–9 October 2015), available at: http://www.who.int/kobe\_centre/publications/GFIAP\_report.pdf; http://www.who.int/kobe\_centre/ageing/innovation-forum/gfiap2\_report/en/; and http://www.who.int/kobe\_centre/publications/gfiap\_report/en/
- WHO. World report on ageing and health, 2015, available at: http://www.who.int/ageing/ events/world-report-2015-launch/en/

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## ANNEX 11

# Implementation plan to guide further action on the recommendations included in the Report of the Commission on Ending Childhood Obesity<sup>1</sup>

#### [A70/31, Annex – 27 March 2017]

1. The Sustainable Development Goals,<sup>2</sup> adopted by the United Nations General Assembly in resolution 70/1 (2015), identify prevention and control of noncommunicable diseases as one of the health challenges in the 2030 Agenda for Sustainable Development. Among the risk factors for noncommunicable disease, overweight and obesity are particularly concerning and have the potential to negate many of the health benefits that have contributed to increased life expectancy. The global action plan for the prevention and control of noncommunicable diseases 2013–2020<sup>3</sup> calls for a halt in the rise in obesity among adolescents, and the comprehensive implementation plan on maternal, infant and young child nutrition<sup>4</sup> sets a target of no increase in childhood overweight by 2025. Yet the prevalence of obesity in infants, children and adolescents<sup>5</sup> is rising around the world and many children who are not yet obese are overweight and on the pathway to obesity. Renewed action is therefore urgently needed if these targets are to be met.

2. Almost three quarters of the 42 million children under 5 years of age who are overweight and obese live in Asia and Africa.<sup>6</sup> In countries where prevalence of overweight and obesity is plateauing, there are growing economic and health inequities, and rates of obesity continue to increase among people with low socioeconomic status and minority ethnic groups. Obesity can affect a child's immediate health, educational attainment and quality of life. Children with obesity are very likely to remain so as adults and are at risk of developing serious noncommunicable diseases. Despite the rising global prevalence of overweight and obesity, awareness of the magnitude and consequences of childhood obesity is still lacking in many settings, particularly in countries where undernutrition is common and prevention of childhood obesity may not be seen as a public health priority. As countries undergo rapid socioeconomic and/or nutrition transition, they face a double burden, in which inadequate nutrition and excessive weight gain may coexist, in the same household and even in the

<sup>&</sup>lt;sup>1</sup> See decision WHA70(19).

<sup>&</sup>lt;sup>2</sup> https://sustainabledevelopment.un.org/sdgs (accessed 6 March 2017).

<sup>&</sup>lt;sup>3</sup> Endorsed by the Health Assembly in resolution WHA66.10 (2013) on Follow-up to the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases; see document WHA66/2013/REC/1, Annex 4 for the text of the action plan.

<sup>&</sup>lt;sup>4</sup> Endorsed by the Health Assembly in resolution WHA65.6 (2012) on Comprehensive implementation plan on maternal, infant and young child nutrition; see document WHA65/2012/REC/1, Annex 2 for the text of the implementation plan.

<sup>&</sup>lt;sup>5</sup> The Convention on the Rights of the Child defines children as those below the age of 18 years. WHO defines adolescents as those between 10 and 19 years of age. In global surveys, overweight and obesity in persons aged 18 years and over is reported as adult data. Therefore, in this context, childhood obesity refers to all children under 19 years of age, including adolescents, with body mass index-for-age more than 3 standard deviations above the WHO child growth median for children less than 5 years of age, and more than 2 standard deviations above the WHO growth reference median for children aged 5–19 years.

<sup>&</sup>lt;sup>6</sup> UNICEF, WHO, The World Bank Group. Levels and trends in child malnutrition: UNICEF-WHO-World Bank joint child malnutrition estimates (2016 edition), available at: http://www.who.int/nutgrowthdb/estimates2015/en/ (accessed 6 March 2017).

same individuals. Children who have been undernourished, either in utero or in early childhood, are at particular risk of becoming overweight and obese if then faced with an obesogenic environment, that is, one that promotes high energy intake and sedentary behaviour. An individual's biological and behavioural responses to such an environment can be strongly influenced by developmental or life course factors from before conception and across generations, as well as by peer pressure and social norms.

3. Recognizing that progress in tackling obesity in infants, children and adolescents has been slow and inconsistent, the Director-General established the Commission on Ending Childhood Obesity in 2014 to review, build upon, and address gaps in, existing mandates and strategies in order to prevent infants, children and adolescents from developing obesity. The aim is to reduce the risk of morbidity and mortality due to noncommunicable diseases, lessen the negative psychosocial effects of obesity in both childhood and adulthood, and reduce the risk of the next generation developing obesity.

4. Having reviewed the scientific evidence,<sup>1</sup> consulted with more than 100 Member States and considered nearly 180 online comments, the Commission finalized its report, which contained a comprehensive, integrated package of recommendations to address childhood obesity.<sup>2</sup> The report presents the rationale for these recommendations and provides the background for this implementation plan. The Commission called for governments to take leadership and for all stakeholders to recognize their moral responsibility in acting on behalf of the child to reduce the risk of obesity by recognizing the importance of remedying obesogenic environments, taking a life course approach and improving or addressing the treatment of children who are already obese.

5. In 2016, the Sixty-ninth World Health Assembly adopted decision WHA69(12) in which it requested the Director-General to develop, in consultation with Member States,<sup>3</sup> an implementation plan guiding further action on the recommendations included in the report of the Commission.

6. The resulting plan comprises two sections. The first sets out the aim, scope and guiding principles of the implementation plan. The second defines the actions needed to end childhood obesity in the specific areas of (I) leadership; (II) the set of six recommendations of the Commission; (III) monitoring and accountability; (IV) key elements for successful implementation; and (V) roles and responsibilities of stakeholders.

## **IMPLEMENTATION PLAN**

#### Aim and scope

7. This implementation plan builds on the recommendations and accompanying rationales in the report of the Commission on Ending Childhood Obesity and aims to guide Member States and other partners on the actions needed to implement these recommendations. It recognizes that Member States face different challenges with respect to all forms of malnutrition. The plan acknowledges variations in constitutional frameworks among Member States, differences in the sharing of responsibility

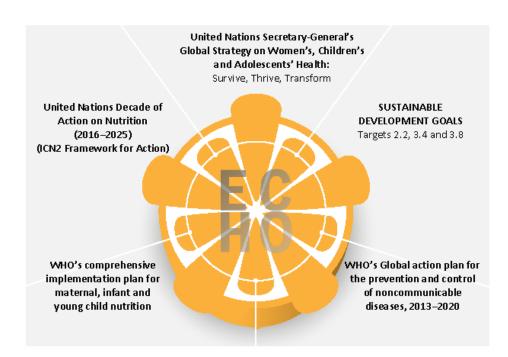
<sup>&</sup>lt;sup>1</sup> WHO. Consideration of the evidence on childhood obesity for the Commission on Ending Childhood Obesity: Report of the ad hoc working group on science and evidence for ending childhood obesity. Geneva: World Health Organization; 2016.

<sup>&</sup>lt;sup>2</sup> Commission on Ending Childhood Obesity. Report of the Commission on Ending Childhood Obesity. Geneva: World Health Organization; 2016, available at: http://apps.who.int/iris/bitstream/10665/204176/ 1/9789241510066\_eng.pdf?ua=1 (accessed 6 March 2017).

<sup>&</sup>lt;sup>3</sup> And, where applicable, regional economic integration organizations.

between levels of government, and variance in the public health policies already in place in different countries. Actions to end childhood obesity should be integrated into existing policies and programmes across diverse domains at all levels. The goal to end childhood obesity aligns with the objectives of the 2030 Agenda for Sustainable Development, such as the targets of the Sustainable Development Goals that call for an end to malnutrition in all its forms (target 2.2), a reduction in premature mortality from noncommunicable diseases (target 3.4), ensuring universal health coverage (target 3.8), as well as contributing to quality education (Goal 4) and reduced inequalities within and among countries (Goal 10). If Member States take prompt and comprehensive action to prevent and treat childhood obesity, then other health initiatives, including those to improve maternal, child and adolescent health, nutrition and physical activity, will be further strengthened, thus contributing to broader targets for health and well-being. This synergy provides an additional focus for concentrating efforts for long-term impact. Figure 1 depicts how ending childhood obesity can draw together and add value to different strategies such as the United Nations Secretary-General's Global Strategy for Women's, Children's and Adolescents' Health, the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, and the United Nations Decade of Action on Nutrition (2016–2025), and so contribute to improving the health and well-being of this and the next generation of children.

#### Figure 1. Ending childhood obesity contributes to several other strategies



#### **Guiding principles**

8. In its report the Commission on Ending Childhood Obesity identified the following guiding principles, which underpin this implementation plan.

(a) **The child's right to health.** Government and society have a moral and legal responsibility to act on behalf of, and in the best interest of, the child to reduce the risk of obesity by protecting children's rights to health and food. A comprehensive response for tackling childhood obesity is consistent with the universal acceptance of the rights of the child

to a healthy life as well as the obligations assumed by State Parties to the Convention on the Rights of the Child. $^1$ 

(b) **Government commitment and leadership.** Governments need to accept primary responsibility for taking action and implementing effective policies on behalf of the children they are ethically bound to protect. A failure to act will have major health, well-being, social and economic consequences.

(c) A whole-of-government approach. Prevention and treatment of obesity require a wholeof-government approach in which policies across all sectors systematically consider health outcomes. Avoiding harmful health impacts can help all sectors to achieve their goals. Current approaches are clearly insufficient and additional coordinated intervention is needed if the targets to halt the rise in obesity in children, adolescents and adults are to be achieved.<sup>2</sup> For example, the education sector plays a crucial role in providing education about nutrition and health, increasing the opportunities for physical activity and promoting healthy school environments. Agriculture and trade policies and the globalization of the food system affect food affordability, availability and quality at national and local levels. Urban planning and design, and transport planning, all have direct consequences on opportunities for physical activity and access to healthy foods. Intersectoral governmental structures, such as a high-level inter-ministerial task force for child and adolescent health that includes childhood obesity as one of its tasks, can identify mutual interests and facilitate coordination, collaboration and exchange of information through coordinating mechanisms.

(d) **A whole-of-society approach.** The complexity of obesity calls for a comprehensive approach that involves, in addition to all levels of government, other actors, such as parents, carers, civil society, academic institutions, philanthropic foundations and the private sector. Moving from policy to action to prevent and reverse childhood obesity demands a concerted effort and active engagement of all sectors of society at the local, national, regional and global levels, with appropriate attention paid to conflicts of interest. Joint ownership and shared responsibility are essential for effective interventions to have reach and impact.

(e) **Equity.** Governments should ensure equitable coverage of interventions, particularly for excluded, marginalized or otherwise vulnerable population groups, who are at high risk both of malnutrition in all its forms and of developing obesity. Obesity and its associated morbidities erode potential improvements in social and health capital, and increase inequity and inequality. The social determinants of health mean that these population groups often have poor access to healthy foods, safe places for physical activity and preventive health services and support. Attention needs to be given to ensuring that interventions are developed in ways that are acceptable and culturally sensitive.

(f) Aligning with the global development agenda. The Sustainable Development Goals call for an end to malnutrition in all its forms (target 2.2) and a reduction in premature mortality from noncommunicable diseases (target 3.4). Reducing childhood obesity will also contribute to universal health coverage (target 3.8), quality education (Goal 4) and reduced inequalities

<sup>&</sup>lt;sup>1</sup> United Nations Convention on the Rights of the Child, Committee on the Rights of the Child. General comment No. 15 (2013) on the right of the child to the enjoyment of the highest attainable standard of health (art. 24), para. 47; document CRC/C/GC/15.

<sup>&</sup>lt;sup>2</sup> Resolution WHA66.10 (2013) on Follow-up to the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, and resolution WHA65.6 (2012) on Comprehensive implementation plan on maternal, infant and young child nutrition.

(Goal 10). Integrating ending childhood obesity into national development and financing frameworks for the Sustainable Development Goals will ensure a response from all sectors.

**Integration into a life course approach.** The Commission has highlighted the need to (g) reduce the risk of childhood obesity by action even before conception. Integrating interventions to prevent and treat childhood obesity into existing WHO and other initiatives, using a life course approach, will offer additional benefits for longer-term health.<sup>1</sup> These initiatives include the United Nations Secretary-General's Global Strategy for Women's, Children's and Adolescents' Health, the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, the Rome Declaration on Nutrition adopted at the Second International Conference on Nutrition (Rome, 19–21 November 2014) and the United Nations Decade of Action on Nutrition (2016–2025). Several other strategies and implementation plans of WHO and other bodies in the United Nations system related to optimizing maternal, infant, young child and adolescent nutrition and health exist that are highly relevant to key elements of a comprehensive approach to prevention of obesity. Relevant principles and recommendations can be found in related documents providing guidance throughout the life-course. Initiatives to address childhood obesity should be integrated within these existing areas of work and build upon them to help children to realize their fundamental right to health and improve their well-being, while reducing the burden on the health system.

(h) **Accountability.** Political and financial commitment is imperative in combating childhood obesity. A robust mechanism and framework are needed to monitor policy development, implementation and outcomes, thus facilitating the accountability of governments and non-State actors for the commitments they make.

(i) **Universal health coverage.** Sustainable Development Goal target 3.8 calls for the achievement of universal health coverage through integrated health services that enable people to receive a continuum of health promotion, disease prevention, diagnosis, treatment and management, over the course of a lifetime.<sup>2</sup> As such, access to and coverage of interventions for the prevention of overweight and obesity and the treatment of children already obese and those who are overweight and on the pathway to obesity, should be considered important elements of universal health coverage.

### ACTIONS NEEDED TO END CHILDHOOD OBESITY

9. The Commission proposed six sets of recommendations to tackle the obesogenic environment and interventions at critical time points in the life course for the prevention of obesity and the treatment of children who are already obese.

10. Effective implementation of the recommendations will require political commitment and leadership as well as capacities to deliver the required interventions and effective monitoring of accountabilities of different stakeholders. The framework is illustrated in Figure 2.

<sup>&</sup>lt;sup>1</sup> The Minsk Declaration: the life-course approach in the context of Health 2020, available at: http://www.euro.who.int/\_\_data/assets/pdf\_file/0009/289962/The-Minsk-Declaration-EN-rev1.pdf?ua=1 (accessed 6 March 2017).

 $<sup>^{2}</sup>$  As also expressed in United Nations General Assembly resolution 69/132 on global health and foreign policy.

#### Figure 2. Action framework for ending childhood obesity



11. In advance of a global strategy, WHO's regional offices developed several strategies and action plans that address some aspects of the recommendations below.<sup>1</sup> These instruments can be integrated and further strengthened, where necessary, by alignment with the recommendations of the Commission on Ending Childhood Obesity.

12. A multisectoral approach will be essential for sustained progress. The following sections provide guidance on the necessary actions that Member States must consider, and the supportive actions by other stakeholders, in order to achieve the aims of this implementation plan. In recognition of the policies already in place in some Member States, and the differing prevalence rates of malnutrition in all its forms, Member States are encouraged to prioritize actions in a step-wise approach according to local context, drivers of obesity and opportunities to intervene.

# I. PROVIDE LEADERSHIP FOR COMPREHENSIVE, INTEGRATED, MULTISECTORAL ACTION

#### Rationale

13. Governments bear the ultimate responsibility for ensuring their citizens have a healthy start in life. Preventing childhood obesity requires the coordinated contributions of all governmental sectors and institutions contributing to policy development and implementation. National strategic leadership includes establishing the governance structures across a variety of sectors that are necessary to manage the development and implementation of laws, policies and programmes. Resources need to be dedicated to policy implementation and workforce capacity strengthening. National leadership is also necessary to manage engagement with non-State actors, such as nongovernmental organizations, the

<sup>&</sup>lt;sup>1</sup> WHO Regional Office for Europe. European food and nutrition action plan 2015–2020. Copenhagen: WHO Regional Office for Europe; 2015; WHO Regional Office for South-East Asia. Strategic action plan to reduce the double burden of malnutrition in the South-East Asia Region 2016–2025. Delhi: WHO Regional Office for South-East Asia; 2016; PAHO. Plan of action for prevention of obesity in children and adolescents. Washington DC: Pan American Health Organization; 2014; WHO Regional Office for the Western Pacific. Action plan to reduce the double burden of malnutrition in the Western Pacific Region (2015–2020). Manila: WHO Regional Office for the Western Pacific; 2015.

private sector and academic institutions, in order to successfully implement, monitor and evaluate the impact of programmes, activities and investments.

14. Table 1 proposes actions to be taken by Member States to implement the recommendation of the Commission on the roles and responsibilities of Member States. Some countries may already have implemented some of these policies and can build upon and strengthen these.

| Recommended roles and<br>responsibilities outlined<br>by the Commission  | Steps to be taken by Member States   |
|--|--|
| (a) Take ownership, provide<br>leadership and engage political<br>commitment to tackle childhood<br>obesity over the long term.  | <ul> <li>Ensure regular contact with parliamentarians to consolidate high-level commitment to prevention of childhood obesity.</li> <li>Conduct regular high-level policy dialogues on childhood obesity.</li> <li>Mobilize sustainable resources to tackle childhood obesity.</li> <li>Prepare a budget and legislation or regulatory instrument to implement key interventions to reduce childhood obesity.</li> </ul> |
| (b) Coordinate contributions of<br>all government sectors and<br>institutions responsible for<br>policies, including, but not limited<br>to: education; food and<br>agriculture; commerce and<br>industry; development; finance<br>and revenue; sport and recreation;<br>communication; environmental<br>and urban planning; transport and<br>social affairs; and trade. | Establish or expand an existing multisectoral group, comprising relevant<br>government agencies, to coordinate policy development, implementation<br>of interventions, monitoring and evaluation across the whole of<br>government, including accountability systems.  |
| (c) Ensure data collection on<br>body mass index-for-age of<br>children – including for ages not<br>currently monitored – and set<br>national targets for childhood<br>obesity.  | Set national or local, time-bound targets for reductions in childhood<br>obesity and monitoring mechanisms that include body mass index-for-<br>age in addition to other appropriate <b>measures</b> , disaggregated by age, sex<br>and socioeconomic status.  |
| (d) Develop guidelines,<br><b>recommendations</b> or policy<br>measures that appropriately<br>engage relevant sectors –<br>including the private sector, where<br>applicable – to implement actions,<br>aimed at reducing childhood<br>obesity.  | Establish mechanisms to coordinate the engagement of non-State actors<br>and hold them to account in the implementation of interventions.<br>Establish clear mechanisms/policies for the management of conflicts of<br>interest.   |

## II. RECOMMENDATIONS OF THE COMMISSION

#### Rationale

15. No single intervention can halt the advance of the epidemic of obesity. To challenge childhood obesity successfully requires countering the obesogenic environment and addressing vital elements in the life course through coordinated, multisectoral action that is held to account.

16. Member States already have some relevant programmes in place that provide guidance on diet and physical activity at population level, in settings such as schools and child care, and throughout the life course. The recommendations of the Commission highlight the urgent need to add additional elements for prevention and treatment of obesity that will contribute to the achievement of a range of targets for maternal, infant, young child and adolescent health.

17. The prevalence of childhood obesity, the risk factors that contribute to this issue, and the political and economic situations differ between Member States. The actions recommended below are designed to allow countries to assess which package of integrated interventions may best be implemented in their particular settings. Section IV details how to prioritize actions and develop a step-wise approach to implementation in order to support governments in realizing these actions. Some tools and resources are available at both global and regional levels to support Member States in developing policies and interventions and in implementing, monitoring and evaluating them.

18. The tables below outline examples of actions that Member States may consider taking in order to implement the six recommendations of the Commission. Interventions to tackle childhood obesity can be integrated into and build upon existing national plans, policies and programmes.

# **1.** Actions to implement comprehensive programmes that promote the intake of healthy foods and reduce the intake of unhealthy foods and sugar-sweetened beverages by children and adolescents (Table 2)

## Rationale

19. An obesogenic environment is one that promotes high-energy intake and physical inactivity, including sedentary behaviour. This includes foods and opportunities for physical activity that are available, affordable, accessible and marketed, and social norms in relation to food and physical activity. Children and families need to be empowered to make healthier choices about diet and physical activity. Knowledge underlying choices of healthy food and physical activity will be undermined if there are conflicting messages, both through marketing in the media and in settings where children gather. Voluntary measures or self-regulation commonly have limited value unless there is active government involvement in establishing the standards and the time frame for achievement, and in determining sanctions for non-compliance. Voluntary approaches and self-regulation can also impede progress if they are used to defer effective regulation. Enabling the choice of a healthy lifestyle needs healthy foods and opportunities for physical activity to be readily available and affordable to all members of society; it also requires that less advantaged children, who are at particular risk of obesity, are fully engaged in the intervention.

| Recommendations of the<br>Commission   | Steps to be taken by Member States  |  |  |  |
|--|---|--|--|--|
| 1.1 Ensure that appropriate and<br>context-specific nutrition<br>information and guidelines for<br>both adults and children are<br>developed and disseminated in a<br>simple, understandable and<br>accessible manner to all groups in<br>society. | Inform the population about childhood overweight and obesity and consequences for health and well-being.  |  |  |  |
|  | Update, as necessary, guidance on the prevention of childhood obesity through the consumption of a healthy diet throughout the life course.   |  |  |  |
|  | Ensure that food-based dietary guidance is disseminated in an accessible manner for children, carers, school staff and health professionals.  |  |  |  |
|  | Develop and implement evidence-based, public education campaigns<br>about what constitutes a healthy diet and the need for it and for physical<br>activity, which are appropriately funded and sustained over time. |  |  |  |

| Recommendations of the<br>Commission  | Steps to be taken by Member States   |  |  |  |  |
|---|--|--|--|--|--|
| 1.2 Implement an effective tax on sugar-sweetened beverages.  | Analyse the administration and impact of a tax on sugar-sweetened beverages.   |  |  |  |  |
|   | Levy an effective tax on sugar-sweetened beverages according to WHO's guidance.  |  |  |  |  |
| 1.3 Implement the set of recommendations on the marketing of foods and non-   | Assess the impact of legislation, regulation and guidelines to tackle the marketing of unhealthy foods and non-alcoholic beverages to children, where required.  |  |  |  |  |
| alcoholic beverages to children <sup>1</sup><br>to reduce the exposure of children<br>and adolescents to, and the power<br>of, the marketing of unhealthy | Adopt, and implement effective measures, such as legislation or<br>regulation, to restrict the marketing of foods and non-alcoholic beverages<br>to children and thereby reduce the exposure of children and adolescents<br>to such marketing.             |  |  |  |  |
| foods.  | Establish mechanisms to effectively enforce implementation of legislation or regulation on the marketing of foods and non-alcoholic beverages to children.   |  |  |  |  |
| 1.4 Develop nutrient profiles to identify unhealthy foods and beverages.  | Establish a national nutrient-profiling model to regulate marketing, taxation, labelling and provision in public institutions, based on WHO's regional or global nutrient-profile models. <sup>2</sup>   |  |  |  |  |
| 1.5 Establish cooperation<br>between Member States to reduce<br>the impact of cross-border<br>marketing of unhealthy foods and<br>beverages.              | beverages to children through WHO regional committees and other  |  |  |  |  |
| 1.6 Implement a standardized global nutrient-labelling system.  | At the international level, work through the Codex Alimentarius<br>Commission to develop a standardized system of food labelling, to<br>support health literacy education efforts through mandatory labelling for<br>all pre-packaged foods and beverages. |  |  |  |  |
|   | At the domestic level, adopt mandatory laws and regulations for nutrition labelling.   |  |  |  |  |
| 1.7 Implement interpretive<br>front-of-pack labelling, supported  | Consider undertaking pre-market/consumer testing of interpretive front-<br>of-pack labelling, based on a nutrient-profile model.   |  |  |  |  |
| by public education of both adults<br>and children for nutrition literacy.  | Adopt, or develop as necessary, a mandatory interpretive front-of-pack<br>labelling system based on the best available evidence to identify the<br>healthfulness of foods and beverages.   |  |  |  |  |
| 1.8 Require settings such as<br>schools, child-care settings,<br>children's sports facilities and<br>events to create healthy food                        | Set standards for the foods that can be provided or sold in child-care settings, schools, children's sports facilities and at events (see also recommendations 4.9 and 5.1) based on a national nutrient-profile model.                                    |  |  |  |  |
| environments.   | Apply such food laws, regulations and standards in catering services for   |  |  |  |  |

<sup>&</sup>lt;sup>1</sup> Endorsed by the Health Assembly in resolution WHA63.14 (2010) on Marketing of food and non-alcoholic beverages to children; see also document WHA61/2008/REC/1, Annex 3.

<sup>&</sup>lt;sup>2</sup> See: PAHO nutrient profile model, available at: http://iris.paho.org/xmlui/handle/123456789/18621; WHO Regional Office for Europe nutrient profile model, available at: http://www.euro.who.int/\_\_data/assets/pdf\_file/0005/270716/ Nutrient-children\_web-new.pdf?ua=1; Technical Meeting on the Regional Adaptation of the WHO Nutrient Profile Model to the Western Pacific Region, available at: http://iris.wpro.who.int/bitstream/handle/10665.1/13410/RS-2015-GE-52-PHL-eng.pdf; Nutrient profiling: report of a technical meeting, 2010, available at:

http://www.who.int/nutrition/publications/profiling/WHO\_IASO\_report2010.pdf?ua=1 (all accessed 6 March 2017).

| Recommendations of the<br>Commission                               | Steps to be taken by Member States   |  |  |  |
|--|--|--|--|--|
|  | existing school, child-care and other relevant settings.   |  |  |  |
| 1.9 Increase access to healthy foods in disadvantaged communities. | Involve actors and resources outside the health system to improve<br>access, availability and affordability of nutritious foods at a sustained<br>scale in disadvantaged communities (for instance, through incentives to<br>retailers and zoning policies). |  |  |  |
|  | Establish regulations and standards for social support programmes based<br>on national and international dietary guidelines.   |  |  |  |
|  | Incentivize local production of fruit and vegetables, such as urban agriculture.   |  |  |  |

# 2. Actions to implement comprehensive programmes that promote physical activity and reduce sedentary behaviours in children and adolescents (Table 3)

#### Rationale

20. Physical activity declines from the age of school entry and low physical activity is rapidly becoming a social norm. Yet, physical activity is known to reduce the risk of diabetes, cardiovascular disease and cancers and to improve children's ability to learn, their mental health and well-being. Moreover, childhood experience can influence lifelong physical activity behaviours.

| Recommendations of the<br>Commission   | Steps to be taken by Member States   |  |  |  |  |
|--|--|--|--|--|--|
| 2.1 Provide guidance to children<br>and adolescents, their parents,<br>carers, teachers and health<br>professionals on healthy body<br>size, physical activity, sleep<br>behaviours and appropriate use of<br>screen-based entertainment.  | Develop and implement evidence-based, targeted and appropriately<br>funded, public education campaigns on the importance of physical<br>activity.  |  |  |  |  |
|  | Update existing materials, as necessary, to include guidance on physical activity throughout the life course.  |  |  |  |  |
|  | Disseminate guidance on physical activity to children, carers, school staff and health professionals in an accessible manner.  |  |  |  |  |
|  | Use peer education and whole-of-school initiatives to influence the physical activity behaviours of children and social norms.   |  |  |  |  |
| 2.2 Ensure that adequate<br>facilities are available on school<br>premises and in public spaces for<br>physical activity during<br>recreational time for all children<br>(including those with disabilities),<br>with the provision of<br>gender-friendly spaces where<br>appropriate. | Provide, in collaboration with other sectors (such as urban planning and transportation) and stakeholders, safe facilities, resources and opportunities for all children to be physically active during recreational time. |  |  |  |  |

#### Table 3. Recommendation 2 of the Commission and steps to be taken by Member States

# **3.** Actions to integrate and strengthen guidance for noncommunicable disease prevention with current guidance for preconception and antenatal care, to reduce the risk of childhood obesity (Table 4)

#### Rationale

21. The risk of obesity can be passed from one generation to the next and maternal health can influence fetal development and the risk of a child becoming obese. The care that women receive before, during and after pregnancy has profound implications for the later health and development of their children. Current guidance for preconception and antenatal care focuses on the prevention of maternal and fetal undernutrition. Given changing exposures to obesogenic environments, guidelines are needed that address malnutrition in all its forms (including excessive energy intake) and the risk of subsequent development of obesity in the offspring. Interventions to tackle childhood obesity risk factors also prevent other adverse pregnancy outcomes<sup>1</sup> and so contribute to improving maternal and newborn health.

| Recommendations of the<br>Commission   | Steps to be taken by Member States   |
|--|--|
| 3.1 Diagnose and manage<br>hyperglycaemia and gestational<br>hypertension.   | Ensure that screening for hypertension and hyperglycaemia are included<br>in antenatal care.   |
| 3.2 Monitor and manage<br>appropriate gestational weight<br>gain.  | Ensure that measurement of weight and gestational weight gain are included in antenatal care.  |
| <ul> <li>3.3 Include an additional focus<br/>on appropriate nutrition in<br/>guidance and advice for both<br/>prospective mothers and fathers<br/>before conception and during<br/>pregnancy.</li> <li>3.4 Develop clear guidance and<br/>support for the promotion of good<br/>nutrition, healthy diets and<br/>physical activity, and for avoiding<br/>the use of and exposure to<br/>tobacco, alcohol, drugs and other<br/>toxins.</li> </ul> | Ensure that diet and nutrition counselling is included in antenatal care.<br>Include information on the association between prospective parents' diet,<br>physical activity and health behaviours and the risk of childhood obesity<br>in the curriculum of health care providers.<br>Disseminate guidance and provide support for healthy diet and physical<br>activity to prospective parents whom preconception or antenatal care<br>may not reach. |

#### Table 4. Recommendation 3 of the Commission and steps to be taken by Member States

<sup>&</sup>lt;sup>1</sup> Temel S, van Voorst SF, Jack BW, Denktas S, Steegers EA. Evidence-based preconceptional lifestyle interventions. Epidemiol Rev. 2014;36:19-30.

# 4. Actions to provide guidance on, and support for, healthy diet, sleep and physical activity in early childhood to ensure children grow appropriately and develop healthy habits (Table 5)

### Rationale

22. The first years of life are critical in establishing good nutrition and physical activity behaviours that reduce the risk of developing obesity. Exclusive breastfeeding for the first six months of life, followed by the introduction of appropriate complementary foods, is core to optimizing infant development, growth and nutrition and may also be beneficial for postnatal weight management in women. Current global guidance for infant and young child feeding primarily targets undernutrition. It is also important to consider the risks created by unhealthy diets in infancy and childhood.

| Recommendations of the<br>Commission  | Steps to be taken by Member States   |  |  |  |  |
|---|--|--|--|--|--|
| 4.1 Enforce regulatory measures<br>such as the International Code of<br>Marketing of Breast-milk<br>Substitutes and subsequent World<br>Health Assembly resolutions.  | Ensure that legislation and regulations on the marketing of breast-missubstitutes adhere to all the provisions in the International Code Marketing of Breast-milk Substitutes and subsequent related Heat Assembly resolutions.  |  |  |  |  |
| 4.2 Ensure all maternity<br>facilities fully practice the Ten<br>Steps to Successful Breastfeeding.   | Establish regulations for all maternity facilities to practice the Ten Steps to Successful Breastfeeding. Build or enhance assessment systems to regularly verify maternity facilities' adherence.   |  |  |  |  |
| 4.3 Promote the benefits of<br>breastfeeding for both mother and<br>child through broad-based<br>education to parents and the<br>community at large.  | Include information on the benefits of breastfeeding for promoting<br>appropriate infant growth and health and for reducing the risk of<br>childhood obesity in guidance for parents and public communications.  |  |  |  |  |
| 4.4 Support mothers to<br>breastfeed, through regulatory<br>measures such as maternity leave,<br>facilities and time for<br>breastfeeding in the work place.  | Ratify ILO Convention 183 and enact legislation mandating all the provisions of ILO Recommendation 191 on maternity leave and provision of time and facilities in the work place for breastfeeding.  |  |  |  |  |
| 4.5 Develop regulations on the<br>marketing of complementary<br>foods and beverages, in line with<br>WHO recommendations, to limit<br>the consumption of foods and<br>beverages high in fat, sugar and<br>salt by infants and young children. | Assess the impact of legislation, regulations and guidelines to address<br>the marketing of complementary foods for infants and young children,<br>where required.<br>Adopt and implement effective measures, such as legislation or<br>regulation, to restrict the inappropriate marketing of complementary<br>foods for infants and young children.<br>Establish mechanisms to enforce effectively and monitor<br>implementation of legislation or regulation on the marketing of<br>complementary foods for infants and young children. |  |  |  |  |

#### Table 5. Recommendation 4 of the Commission and steps to be taken by Member States

| Recommendations of the<br>Commission  | Steps to be taken by Member States   |  |  |  |  |
|---|--|--|--|--|--|
| 4.6 Provide clear guidance and<br>support to carers to avoid specific<br>categories of foods<br>(e.g. sugar-sweetened milks and<br>fruit juices or energy-dense,<br>nutrient-poor foods) for the<br>prevention of excess weight gain. | Include the following in guidance on infant and young child feeding:<br>(1) the introduction of appropriate complementary foods, avoiding<br>use of added sugar or sweeteners; (2) responsive feeding to encoura<br>infants and young children to eat a wide variety of healthy foo<br>(3) which foods and beverages are high in sugar, fat and salt and sho<br>not be given to infants and young children; (4) appropriate portion sin<br>for children of different ages.   |  |  |  |  |
| 4.7 Provide clear guidance and<br>support to caregivers to encourage<br>the consumption of a wide variety<br>of healthy foods.  | Train community health workers or peer support groups to support appropriate complementary feeding.  |  |  |  |  |
| 4.8 Provide guidance to<br>caregivers on appropriate<br>nutrition, diet and portion size for<br>this age group.   |  |  |  |  |  |
| 4.9 Ensure only healthy foods,<br>beverages and snacks are served<br>in formal child-care settings or<br>institutions.  | Set mandatory nutrition standards for foods and beverages provided<br>(including meals) or sold (including vending machines and school<br>shops) in public and private child-care settings or institutions.<br>Implement such food laws, regulations and standards into catering<br>services for existing child-care and other relevant settings.  |  |  |  |  |
| 4.10 Ensure food education and<br>understanding are incorporated<br>into the curriculum in formal<br>child-care settings or institutions.   | Develop nutrition, food and health education curricula jointly between<br>education and health sectors. Train teachers in curriculum delivery.<br>Integrate nutrition and health education components, including practical<br>skills, developed in collaboration with the education sector, into the core<br>curriculum.   |  |  |  |  |
| 4.11 Ensure physical activity is<br>incorporated into the daily routine<br>and curriculum in formal<br>child-care settings or institutions.   | Set standards for physical activity in child-care settings.<br>Provide guidance to carers on the provision of safe and developmentally-<br>appropriate physical activity, active play and active recreation for all<br>children.   |  |  |  |  |
| 4.12 Provide guidance on<br>appropriate sleep time, sedentary<br>or screen-time, and physical<br>activity or active play for the<br>2–5 years of age group.   | Develop guidance on physical activity for children under 5 years of age,<br>including age-appropriate activities and ideas to support and encourage<br>participation in physical activity at home and in the community all year<br>round.<br>Develop guidelines on appropriate sleep time and use of screen-based<br>entertainment by children and adolescents (see recommendation 2.1) and<br>ideas to avoid sedentary activities, including avoiding excessive screen-<br>time, and to model regular physical activities for families.   |  |  |  |  |
| 4.13 Engage whole-of-community<br>support for carers and child-care<br>settings to promote healthy<br>lifestyles for young children.  | Conduct public awareness campaigns and disseminate information to<br>increase awareness of the consequences of childhood obesity.<br>Promote the benefits of physical activity for both carers and children<br>through broad-based education to carers and the community at large.<br>Promote communication and community participation to raise awareness<br>and create an enabling environment and social demand for policy action<br>to improve diet and physical activity in children.<br>Identify community champions/leaders/civil society organizations to<br>work with, and ensure community representation. |  |  |  |  |

# 5. Actions to implement comprehensive programmes that promote healthy school environments, health and nutrition literacy and physical activity among school-age children and adolescents (Table 6)

#### Rationale

23. Children and adolescents are highly susceptible to the marketing of unhealthy foods and beverages, and the need to protect children from such marketing has been recognized.<sup>1</sup> Peer pressure and perceptions of ideal body image also influence children's attitudes to diet and physical activity. Adolescents in particular are exposed to influences and market forces different from those bearing on younger children and families. It is unfortunate that a significant number of school-age children are not in formal education, as the compulsory school years provide an easy entry point to engage this age group and embed healthy eating and physical activity habits for lifetime prevention of obesity. To be successful, programmes to improve the nutrition and physical activity of children and adolescents need to engage various stakeholders and ensure that conflicts of interest, such as those that can arise when the food and beverage industry is involved in such programmes, do not undermine progress. The active engagement of the education sector and integration of activities into health-promoting school initiatives, will help to ensure the success of such programmes and improve school attainment. Older children and adolescents, as well as their community, need to be engaged in the development and implementation of interventions to reduce childhood obesity.<sup>2</sup>

| Recommendations of the<br>Commission   | Steps to be taken by Member States   |
|--|--|
| <ul> <li>5.1 Establish standards for<br/>meals provided in schools, or<br/>foods and beverages sold in<br/>schools that meet healthy<br/>nutrition guidelines.</li> <li>5.2 Eliminate the provision or<br/>sale of unhealthy foods, such as<br/>sugar-sweetened beverages and<br/>energy-dense, nutrient-poor<br/>foods, in the school environment.</li> </ul> | Set mandatory nutrition standards for foods and beverages provided<br>(including meals) or sold (including vending machines and school shops)<br>in the public and private school environment.<br>Implement such food laws, regulations and standards into catering<br>services for existing school and other relevant settings. |
| 5.3 Ensure access to potable water in schools and sports facilities.   | Ensure all school and sports facilities provide free access to safe drinking water.  |
| 5.4 Require inclusion of<br>nutrition and health education<br>within the core curriculum of<br>schools.  | Develop nutrition, food and health education curricula jointly between<br>education and health sectors. Train teachers in curriculum delivery.<br>Integrate nutrition and health education components, including practical<br>skills, developed in collaboration with education sector, into the core<br>curriculum.             |
| 5.5 Improve the nutrition literacy and skills of parents and carers.   | Work with schools and communities to deliver skills through community classes/groups.  |

#### Table 6. Recommendation 5 of the Commission and steps to be taken by Member States

<sup>&</sup>lt;sup>1</sup> United Nations Committee on the Rights of the Child, General comment No. 15 (2013) on the right of the child to the enjoyment of the highest attainable standard of health (art. 24), 17 April 2013, document CRC/C/GC/15.

<sup>&</sup>lt;sup>2</sup> School policy framework. Implementation of the WHO global strategy on diet, physical activity and health. Geneva: World Health Organization; 2008.

| Recommendations of the<br>Commission  | Steps to be taken by Member States                                     |
|---|--|
| 5.6 Make food preparation classes available to children, their parents and carers.  |  |
| 5.7 Include quality physical<br>education in the school<br>curriculum and provide adequate<br>and appropriate staffing and<br>facilities to support this. | Set standards for quality physical education in the school curriculum. |

# 6. Actions to provide family-based, multicomponent services on lifestyle weight management for children and young people who are obese (Table 7)

#### Rationale

24. When children are already overweight or obese, weight management to reduce body mass index-for-age and to reduce or prevent obesity-related morbidities will improve current and future health outcomes. Primary health-care services are important for the early detection and management of obesity and its associated complications. Regular growth monitoring at the primary health care facility or at school provides an opportunity to identify children at risk of becoming obese. The mental health needs of children who are overweight or obese, including issues of stigmatization and bullying, need to be given special attention.

| Recommendations of the<br>Commission   | Steps to be taken by Member States   |
|--|--|
| 6.1 Develop and support<br>appropriate weight management<br>services for children and  | Implement a context-appropriate multicomponent weight management<br>protocol that covers diet, physical activity and psychosocial support<br>services tailored to children and families. |
| adolescents who are overweight<br>or obese that are family-based,<br>multicomponent (including                                     | Align services with existing clinical guidelines and clearly configure the roles of primary health care providers for effective multidisciplinary work.                                  |
| nutrition, physical activity and<br>psychosocial support) and<br>delivered by multiprofessional<br>teams with appropriate training | Educate and train concerned primary health care providers in identification and management of childhood obesity and associated stigmatization.   |
| and resources, as part of universal health coverage.   | Include childhood weight management services as part of universal health coverage.   |

| Table 7. Recommendation | 6 of the | Commission | and stens to b | ne taken hv | Member States |
|-------------------------|----------|------------|----------------|-------------|---------------|
| Table 7. Recommendation | 0 of the | Commission | and steps to t | Je taken Dy | Member States |

# III. MONITORING AND ACCOUNTABILITY FOR EFFECTIVE PROGRESS (TABLE 8)

25. Monitoring can serve to sustain awareness of the problem of childhood obesity and is necessary to track progress in the development, implementation and effectiveness of interventions. Governments are understandably wary of increasing the burden of reporting on their commitments. Several monitoring mechanisms currently exist that countries could draw upon and integrate into a comprehensive national monitoring framework for childhood obesity. These include the Indicators and a Monitoring Framework for the Sustainable Development Goals, the United Nations Secretary-General's Independent Accountability Panel for the updated Global Strategy for Women's, Children's

and Adolescents' Health, the Global Monitoring Framework for Noncommunicable Diseases, the Global Monitoring Framework for Maternal, Infant and Young Child Nutrition<sup>1</sup> and the Framework to Monitor and Evaluate Implementation of the Global Strategy on Diet, Physical Activity and Health.<sup>2</sup>

26. Member States do not want unnecessarily to increase the reporting burden. Thus, a second phase of work is required to identify all relevant existing indicators and reporting mechanisms that can be harnessed for monitoring implementation and to develop technical advice and tools for monitoring and accountability that take this into consideration. The Secretariat will develop a framework for evaluating progress on the implementation plan, which will define baselines, indicators and responsible sectors. It should also provide specific examples of the roles of different sectors/ministries in supporting a whole-of-government response to prevention and treatment of childhood obesity.

## Table 8. Recommendations of the Commission on monitoring and accountability and steps to be taken by Member States

| Recommendations of the<br>Commission   | Steps to be taken by Member States   |
|--|--|
| Establish monitoring systems<br>to provide evidence of the<br>impact and effectiveness of<br>interventions in reducing the<br>prevalence of childhood<br>obesity and use data for policy<br>and implementation<br>improvement. | Ensure weight and height of children are regularly measured in all<br>primary care settings with adequate quality control.<br>Establish monitoring systems to provide evidence of the impact<br>and effectiveness of interventions in achieving their policy goals<br>and use data for policy and implementation improvement.  |
| Develop an accountability<br>mechanism that encourages<br>participation of<br>nongovernmental<br>organizations and academic<br>institutions in accountability<br>activities.   | Establish coordinating mechanisms for the involvement of non-<br>State actors in monitoring and accountability activities aligned<br>with the accountability mechanisms for the Sustainable<br>Development Goals, the Global Strategy on Women's, Children's<br>and Adolescents' Health, the United Nations Decade of Action on<br>Nutrition (2016–2025), Global Monitoring Framework on the<br>Prevention and Control of Noncommunicable Diseases and the<br>associated set of progress indicators. |

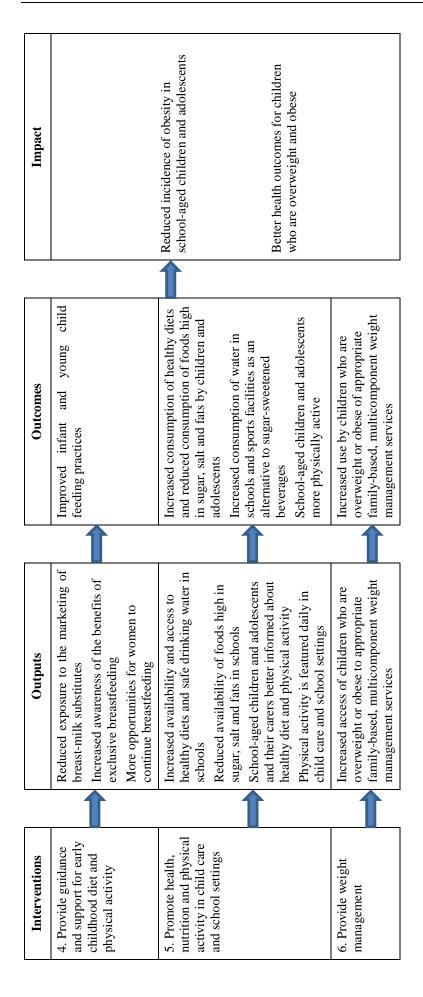
27. The logic model presented in Figure 3 provides guidance to Member States in identifying shortand medium-term outcomes in order to define specific indicators to measure determinants in a standardized manner.

<sup>&</sup>lt;sup>1</sup> See decision WHA68(14) (2015) on Maternal, infant and young child nutrition: development of the core set of indicators and document WHA68/2015/REC/1, Annex 7.

<sup>&</sup>lt;sup>2</sup> WHO global strategy on diet, physical activity and health: a framework to monitor and evaluate implementation. Geneva: World Health Organization; 2008.

| Impact        | Lower incidence and prevalence of<br>childhood obesity<br>Lower prevalence of health conditions<br>associated with childhood obesity<br>Reduced prevalence of obesity in<br>young children<br>Reduced incidence of obesity in<br>school-aged children and adolescents<br>Better health outcomes and well-being<br>for children who are overweight and | opese   |  |  |  |
|---------------|---|---|--|--|--|
| Outcomes      | Increased consumption of healthier<br>diets<br>Reduced consumption of sugar-<br>sweetened beverages and unhealthy<br>diets  | Increased physical activity in children<br>and adolescents<br>Reduced sedentary time and screen-<br>time and adequate sleep in children and<br>adolescents  | Reduced exposure of fetus to risk<br>factors for childhood obesity<br>Reduced proportion of low-birth-<br>weight and large-for-gestational-age<br>infants  |  |  |
|               |   |   |  |  |  |
| Outputs       | Improved understanding of nutrition<br>information<br>An effective tax on sugar-sweetened<br>beverages<br>Reduced exposure of children to<br>marketing of foods and non-alcoholic<br>beverages<br>Increased access to healthy food<br>choices, particularly in disadvantaged<br>communities   | Improved knowledge and<br>understanding of benefits of physical<br>activity by teachers, carers and children<br>All children have access to facilities<br>and opportunities for physical activity<br>during recreation time and can use<br>them | Improved diagnosis and management<br>of hyperglycaemia and gestational<br>hypertension<br>Prospective parents better informed on<br>healthy diet, physical activity and<br>avoidance of exposure to tobacco,<br>alcohol, drugs and toxins before and<br>during pregnancy |  |  |
|               |   |   |  |  |  |
| Interventions | 1. Promote the intake<br>of healthy foods   | 2. Promote physical activity  | 3. Provide<br>preconception and<br>pregnancy care  |  |  |

Figure 3. Logic model for childhood obesity prevention interventions



28. Strong commitments must be accompanied by strong implementation systems and well-defined accountability mechanisms for effective progress in preventing childhood obesity. A whole-of-society approach offers the best opportunity for tackling childhood obesity. Both governments and other actors, notably civil society, can hold each other and private-sector entities to account in order to ensure that they adopt policies and comply with standards.<sup>1</sup>

29. Governments bear primary responsibility for setting the policy and regulatory framework for the prevention of childhood obesity at the country level. A whole-of-government approach requires that a clear chain of responsibility and accountability is established and that relevant institutions, tasked with developing or implementing interventions, are held accountable for the performance of those tasks. This can be facilitated through the development of a policy and action planning matrix. The matrix (see Figure 4) could serve as a tool for ensuring whole-of-government accountability, through: a clear delineation of the actions and the actors, and the tasks, outputs or outcomes that an actor is accountable for; monitoring of the actions; and processes for holding parties to account, including legal processes, regulatory arrangements, economic incentives, and market-based and media-based approaches.

30. Civil society can play a critical role in bringing social, moral and political pressure on governments to fulfil their commitments.<sup>2</sup> Ending childhood obesity should form part of civil society's agenda for advocacy and accountability. Improving coordination of civil society organizations and strengthening their capacity to monitor effectively, and ensure accountability for, commitments made is vitally important. Governments may consider providing opportunities for formal participation by civil society in the policy-making, implementation and evaluation process, as well as ensuring mutual accountability and transparency.

31. The private sector can play a role in tackling childhood obesity, with appropriate consideration of their core business, but additional accountability strategies are often necessary. Risks of conflicts of interest need to be identified, assessed and managed in a transparent and appropriate manner when engaging with non-State actors. Codes of conduct and independently audited assessments of compliance with government oversight are therefore important.

<sup>&</sup>lt;sup>1</sup> Swinburn B, Kraak V, Rutter H, Vandevijvere S, Lobstein T, Sacks G, et al. Strengthening of accountability systems to create healthy food environments and reduce global obesity. Lancet. 2015;385:2534-45.

<sup>&</sup>lt;sup>2</sup> Huang TTK, Cawley JH, Ashe M, Costa SA, Frerichs LM, Zwicker L, et al. Mobilisation of public support for policy actions to prevent obesity. Lancet. 2015;385:2422-31.

| Actions<br>(recommendations of<br>the Commission)           | Identify specific actions/sets of actions to be addressed<br>↓   |  |
|---|--|--|
| Actors  | Who will formulate the policy or action for implementation?<br>Who will implement the policy/action? [separate question]<br>Are there other relevant actors, and, if so, who are they?<br>I  |  |
| Allocation of responsibility<br>for tasks and outcomes      | What will each of the relevant actors be held accountable for? For example:<br>formulating a policy/programme<br>implementing a policy/programme<br>complying with the policy<br>achieving measurable progress towards the ultimate (or an appropriate<br>intermediate) policy objective<br>collecting and analysing data disaggregated by key determinants such as<br>sex, age, socioeconomic level and education<br><b>Q</b> |  |
| Monitoring  | Who will monitor the tasks or actions which the actors are being held accountable for?   |  |
| Holding to account<br>(accountability relationships)        | Who will hold the actors (that is, those who formulate the policy and actions for implementation) to account?<br>Who will hold the actors that implement the actions to account?<br>Who will hold other relevant actors to account?<br>I   |  |
| Monitoring indicators<br>(process, outputs and<br>outcomes) | What indicators provide measures of the actions for which actors are being held accountable?   |  |
| Tools and processes for<br>holding to account               | How will the actors be held to account for their performance?  |  |

## Figure 4. Policy and action planning matrix for monitoring and accountability

## IV. KEY ELEMENTS FOR SUCCESSFUL IMPLEMENTATION

32. In implementing actions for ending childhood obesity, consideration should be given to certain elements, as highlighted by the Commission in its report.

## Prioritization

33. Regions, countries and national subregions may have differing childhood obesity prevalence and socioeconomic distribution, as well as different economic and health service capacity. They may also have a mix of nutrition conditions that have to be simultaneously addressed, including overweight, undernutrition and micronutrient deficiencies. An analysis that takes into account prevalence data by key determinants of health, such as gender, age, socioeconomic level and ethnicity, combined with a prioritization exercise, can help governments to choose combinations and the order of implementation of interventions that will effectively redress childhood obesity. Interventions that have the capacity to generate revenue, such as taxation of sugar-sweetened beverages, may assist governments in meeting the cost of implementation. Various prioritization tools exist that can guide this process.<sup>1</sup> Synergistic interventions and combinations that enable the healthy choice to become the easier choice, interventions that have the benefit of stimulating population-wide discussion, and education on childhood obesity all can prove effective in raising public awareness and building support for legislation and regulation. Ensuring the involvement of relevant stakeholders in the prioritization exercise and policy development, with attention to potential conflicts of interest, is also important. All countries are invited to take action to prevent and control childhood overweight, even at very low prevalence levels, as the epidemic is evolving quickly.

#### Awareness, communication and education

34. Values and norms influence the perception of healthy or desirable body weight, especially for children. Communication to improve knowledge, correct misperceptions and ensure that communities support and participate in policies and interventions that encourage behaviour change is vital. Peer education and whole-of-community initiatives can engage children, adolescents, families and individuals in designing together new approaches to preventing and tackling obesity, empowering them to act but more importantly creating a demand and support for services and interventions. Capacity-building programmes to teach health care providers and community health workers additional skills in communications and education are also critical for effective programme implementation.

35. Evidence-based mass-media campaigns based on integrated marketing principles, and implemented at appropriate scale and with suitable frequency, should be conducted in order to justify and gain support for a wider programme of action. Such approaches have been shown to be important for changing perceptions, attitudes and intentions, and for promoting community discussions about obesity, physical activity and healthy diets. Such campaigns and programmes can also be targeted, for example, at parents and carers.

#### Mobilization of resources

36. Governments and stakeholders need resources to implement actions and to find innovative approaches for domestic and international financing. Taxation of sugar-sweetened beverages could generate revenue for programmes against childhood obesity, although due regard must be given to avoiding or managing conflicts of interest.

37. To ensure long-term impact, sustainable domestic and international resources are needed for implementing the recommendations of the Commission.

#### **Capacity-building**

38. Strengthening institutional capacity and providing appropriate training to health care workers, child-care and school staff are also essential for the successful implementation of the recommendations of the Commission. In addition, both capacity and capability are also needed to support the design, implementation, evaluation and enforcement of population-based policies, such as taxation of sugar-sweetened beverages and restriction of the marketing of foods and non-alcoholic beverages to children.

<sup>&</sup>lt;sup>1</sup> Prioritizing areas for action in the field of population-based prevention of childhood obesity: a set of tools for Member States to determine and identify priority areas for action. Geneva: World Health Organization; 2012.

39. Networks can provide support for countries committed to implementing specific activities as well as building capacity through platforms for sharing experience and exchanging policies between Member States.

## V. ROLES AND RESPONSIBILITIES OF STAKEHOLDERS

40. Successful implementation of further action on the recommendations of the Commission requires the committed input, focus and support of numerous agencies besides Member States (see section II). The Commission identified the following stakeholder groups with specific roles and responsibilities.

#### WHO Secretariat

41. Momentum must be maintained. The Secretariat will lead and convene high-level dialogue within the United Nations system and with and between Member States. Its aim will be to fulfil the commitments made in the 2030 Agenda for Sustainable Development, the Political Declaration of the High-level Meeting of United Nations General Assembly on the Prevention and Control of Non-communicable Diseases, the Rome Declaration on Nutrition and other relevant global and regional policy frameworks through the actions detailed by the Commission on Ending Childhood Obesity in its report.

42. Using its normative function, both globally and through its network of regional and country offices, WHO can provide technical assistance by developing or building on guidelines, tools and standards in order to put the recommendations of the Commission and other relevant WHO mandates into effect at country level. The Secretariat can disseminate guidance for implementation, monitoring and accountability, and monitor and report on progress to end childhood obesity.

#### Actions

(a) Collaborate with other bodies in the United Nations system whose mandates encompass nutrition and childhood obesity, in particular FAO, UNDP, UN Habitat, UNICEF and WFP.

(b) Institutionalize a cross-cutting and life course approach to ending childhood obesity across all relevant technical areas in WHO headquarters, regional and country offices.

(c) Develop, in consultation with Member States, guidelines for engaging constructively with the private sector for the prevention of childhood obesity.

(d) Strengthen capacity to provide technical support for action to end childhood obesity at global, regional and national levels, by for example:

(i) building legal and regulatory capacity, by means including workshops and courses in collaboration with other government sectors;

(ii) developing guidelines on obesity risk prevention during antenatal care, on physical activity for pregnant women and young children, and on appropriate sleep time and screen use by children and adolescents;

(iii) providing technical support and tools to Member States, as requested, through the establishment of multisectoral committees or task forces, for instance, in order to support the implementation of the recommendations of the Commission;

(iv) offering a platform to enable cooperation between Member States with similar priorities for implementation of the recommendations.

(e) Support international agencies, national governments and relevant stakeholders in turning existing commitments into relevant actions to end childhood obesity at global, regional and national levels.

(f) Promote collaborative research on ending childhood obesity with a focus on the life course approach.

(g) Encourage innovative means of financing implementation of strategies for prevention of childhood obesity, with due attention to conflicts of interest.

(h) Report on global progress in ending childhood obesity.

#### **International organizations**

43. Cooperation between international organizations including entities in the United Nations system can promote global and regional partnerships and networks for advocacy, resource mobilization, capacity-building and collaborative research. The United Nations Inter-agency Task Force on the Prevention and Control of Non-communicable Diseases can support Member States in tackling childhood obesity.

#### Actions

(a) Cooperate to build capacity and support respective Member States in tackling childhood obesity.

(b) Incorporate prevention of childhood obesity into country-level programmes in the United Nations Development Assistance Framework.

(c) Provide support for the development and dissemination of guidance on healthy diet and physical activity.

(d) Collaborate with organizations in the United Nations system dealing with nutrition to review current practices on the delivery of food and nutrition programmes and ensure that the programmes contribute to the prevention of childhood obesity.

(e) Partner with governments to implement interventions to end childhood obesity, through for example the United Nations Inter-agency Task Force on the Prevention and Control of Noncommunicable Diseases, the United Nations Network for Scaling Up Nutrition and the WHO-UNDP Global Joint Programme to activate National Responses to Noncommunicable Diseases, which can support implementation of the recommendations of the Commission.

#### Nongovernmental organizations

44. Although governments build policy frameworks, in some countries the tasks of developing nutrition information and education campaigns, implementing programmes, and monitoring and holding actors to account for commitments made may be shared between government and civil society. Social movements can engage members of the community and provide a platform for advocacy and action.

#### Actions

(a) Raise the profile of prevention of childhood obesity through advocacy and dissemination of information.

(b) Motivate consumers to demand that governments support healthy lifestyles and that the food and non-alcoholic beverage industry provide healthy products and do not market unhealthy foods and beverages to children.

(c) Call on governments to create the legal and regulatory frameworks needed to implement recommendations to end childhood obesity.

(d) Contribute to the development and implementation of a mechanism for monitoring and accountability.

#### The private sector

45. The private sector is not a homogeneous entity and includes the agricultural food production sector, the food and beverage industry, retailers, catering companies, sporting-goods manufacturers, advertising and recreation businesses, and the media, among others. It is, therefore, important to consider the level of governmental engagement with entities in the private sector whose activities could have a positive or negative impact on childhood obesity. Governments need to engage constructively with the private sector to encourage implementation of government-determined and government-led policies and interventions.

Some private sector initiatives exist that have the potential to reduce childhood obesity. These 46. need to be encouraged where they are supported by an evidence base and do not have coincident negative impacts, such as delaying more effective regulation. As many companies operate globally, international collaboration between their different arms is vital. However, attention must also be given to local and regional entities and artisans. Although some cooperative relationships with industry have led to some encouraging outcomes related to diet and physical activity, others have been seen to shift responsibility from the food and beverage industry to the consumer and to be intended to improve the company's image in the community. Initiatives by the food manufacturing industry to reduce the content of fat, sugar and salt and portion sizes of processed foods, and to increase the production of innovative, healthy and nutritious choices, could accelerate health gains worldwide if implemented widely. Multinational companies should apply consistent approaches to labelling and marketing across their entire global portfolios so as to ensure that actions are global and do not differ between countries. In doing so, multinational companies should apply the highest standards to which their products are subjected. However, engagement between governments and the private sector needs to be health-goal oriented, transparent and accountable and to pay particular attention to managing potential conflicts of interest.<sup>1</sup>

#### Actions

(a) Support the production of, and facilitate access to, foods and non-alcoholic beverages that contribute to a healthy diet.

<sup>&</sup>lt;sup>1</sup> Addressing and managing conflicts of interest in the planning and delivery of nutrition programmes at country level, available at: http://www.who.int/nutrition/events/2015\_conflictsofinterest\_nut\_programmes/en/ (accessed 6 March 2017).

(b) Facilitate access to, and participation in, physical activity.

### **Philanthropic foundations**

47. Philanthropic foundations are uniquely placed to make significant contributions to global public health and can also engage in monitoring and accountability activities.

### Actions

(a) Recognize childhood obesity as endangering child health and educational attainment with long-term consequences and thus address this important issue.

(b) Mobilize funds to support research, capacity-building, service delivery, and monitoring and accountability.

#### Academic institutions and health professional associations

48. Academic institutions can contribute to prevention and control of childhood obesity through studies on biological, behavioural and environmental risk factors and determinants, and the effectiveness of interventions on each of these. Associations of health professionals have an important role in raising public awareness of the immediate and long-term consequences of childhood obesity to health and well-being and advocate implementation of effective interventions. They can also provide support for health professional training and contribute to monitoring and accountability.

#### Actions

(a) Raise the profile of prevention and treatment of childhood obesity through the dissemination of relevant information and its incorporation into appropriate curricula at all levels (pre- and post-graduate).

(b) Fill gaps in knowledge through research that is free from commercial interests in order to provide evidence to support policy implementation.

(c) Support and evaluate monitoring and accountability activities.

## CONCLUSIONS

49. Childhood obesity undermines the physical, social and psychological well-being of children and is a known risk factor for adult obesity and noncommunicable diseases. There is an urgent need to act now to improve the health of this and the next generation of children. Overweight and obesity cannot be solved through individual action alone. Comprehensive responses are needed to create healthy environments that can support individuals in making healthy choices grounded on knowledge and skills related to health and nutrition. These responses require government commitment and leadership, long-term investment and engagement of the whole of society to protect the rights of children to good health and well-being. Progress can be made if all actors remain committed to working together towards a collective goal of ending childhood obesity.

## ANNEX 12

## Fifth meeting of the Member State mechanism on substandard/ spurious/falsely-labelled/falsified/counterfeit medical products<sup>1</sup>

[A70/23, Appendix 3 – 20 March 2017]

## WHO MEMBER STATE MECHANISM ON SUBSTANDARD/SPURIOUS/FALSELY-LABELLED/FALSIFIED/COUNTERFEIT (SSFFC) MEDICAL PRODUCTS

## WORKING DEFINITIONS

### **INTRODUCTION**

1. At the fourth meeting of the Member State mechanism on SSFFC medical products held on 19 and 20 November 2015, the decision was taken<sup>2</sup> to establish a working group on refining the working definitions of SSFFC medical products,<sup>3</sup> based on those currently used by the WHO global surveillance and monitoring system. This decision followed comments received from Member States with reference to the working definitions document circulated on the MedNet platform in 2015, which have been consolidated in the present paper.

## Scope

2. This working group seeks to achieve a simplified common global understanding and provide clarity of what is meant by the term "SSFFC medical product" to Member States and all other stakeholders; and to recommend a definition of what constitutes a SSFFC medical product to the fifth meeting of the Member State mechanism.

3. In this sense, in the terms of reference set out in resolution WHA65.19  $(2012)^4$  it was stated in the relevant footnote that "The Member State mechanism shall use the term "substandard/spurious/ falsely-labelled/falsified/counterfeit medical products" until a definition has been endorsed by the governing bodies of WHO. Previous discussions between Member States show that there would be a consensus among them to accept the use of the term "falsified" for the purposes of the work carried out within the Member State mechanism. Should consensus among Member States be achieved, the term "SSFFC" could, therefore, be replaced by that agreed by them.

4. It is not intended to propose, or affect in any way, national and/or regional legislation either in existence or that may be drafted in the future by Member States and/or regional organizations relating

<sup>&</sup>lt;sup>1</sup> See decision WHA70(21).

<sup>&</sup>lt;sup>2</sup> See document A/MSM/4/10.

<sup>&</sup>lt;sup>3</sup> A medical product is defined as a medicine, vaccine or in vitro diagnostic (paragraph 3 document A/SSFFC/WG/5) and it may also include medical devices at an appropriate time in the future.

<sup>&</sup>lt;sup>4</sup> See document WHA65/2012/REC/1.

to SSFFC medical products. No matter which terms are adopted by each Member State, it is important to have a clear understanding about the terms and their correlation with the working definitions adopted by the Member State mechanism.

### Methodology

5. The classification of reports of SSFFC medical products to WHO permits a more thorough and accurate comparison and analysis of reports, separating substandard medical products from those that are deliberately/fraudulently making a misrepresentation (spurious, falsely-labelled, falsified or counterfeit) and those that are unregistered/unlicensed in the country of marketing (see Figure).

Figure. Classification of medical products to be used by the WHO global surveillance and monitoring system and the Member State mechanism

| SUBSTANDARD  | UNREGISTERED/<br>UNLICENSED   | FALSIFIED   |
|--|---|---|
| Also called "out of<br>specification", these are<br>authorized medical<br>products that fail to meet<br>either their quality<br>standards or their<br>specifications, or both. | Medical products that<br>have not undergone<br>evaluation and/or<br>approval by the NRRA for<br>the market in which they<br>are marketed/distributed<br>or used, subject to<br>permitted conditions<br>under national or regional | Medical products that<br>deliberately/fraudulently<br>misrepresent their<br>identity, composition or<br>source. |
|  | regulation and legislation.   |   |

6. The classification table shown in the Figure above sets out three separate and mutually exclusive classifications of medical products reported to the WHO global surveillance and monitoring system.

7. For the purpose of this document and the classifications below, Authorized medical products means medical products in compliance with national and regional regulations and legislation. NRRAs can, according to national or regional regulations and legislation, permit the marketing or distribution of medical products with or without registration/license.

(a) Substandard medical products

Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or their specifications, or both.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup>When the authorized manufacturer deliberately fails to meet these quality standards or specifications due to misrepresentation of identity, composition, or source, then the medical product should be considered "falsified".

#### (b) Unregistered/unlicensed medical products

Medical products that have not undergone evaluation and/or approval by the NRRA for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

These medical products may or may not have obtained the relevant authorization from the national/regional regulatory authority of its geographical origin.

### (c) Falsified medical products

Medical products that deliberately/fraudulently misrepresent their identity, composition or source.

Any consideration related to intellectual property rights does not fall within this definition.

Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration, reproduction of an authorized medical product or the manufacture of a medical product that is not an authorized product.

"Identity" shall refer to the name, labelling or packaging or to documents that support the authenticity of an authorized medical product.

"Composition" shall refer to any ingredient or component of the medical product in accordance with applicable specifications authorized/recognized by NRRA.

"Source" shall refer to the identification, including name and address, of the marketing authorization holder, manufacturer, importer, exporter, distributor or retailer, as applicable.

Medical products should not be considered as falsified solely on the grounds that they are unauthorized for marketing in any given country.

## **Intellectual property rights**

8. The terms of reference of the Member State mechanism on SSFFC medical products expressly exclude the protection of intellectual property rights from the mandate of the mechanism and, therefore, the same criteria shall be used in the definitions to be used in its deliberations and work. The term "counterfeit" is now usually defined and associated with the protection of intellectual property rights. For reference purposes, the definitions of "trademark counterfeit goods"<sup>1</sup> and pirated copyright goods<sup>2</sup> are included as defined under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

<sup>&</sup>lt;sup>1</sup> "Trademark counterfeit goods: goods, including packaging, bearing without authorization a trademark that is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation."

<sup>&</sup>lt;sup>2</sup> "Pirated copyright goods: any goods that are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production, and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation."

9. In the context of medical products, the term "falsified" appears to adequately include all the various types of deliberate misrepresentation of a medical product in such a way which enables the specific exclusion of intellectual property rights.

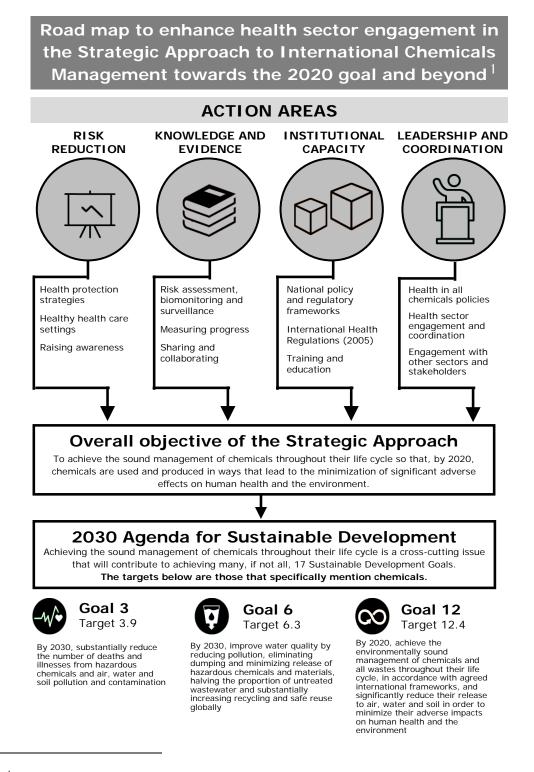
#### **Conclusion and recommendation**

10. This document is not intended to be an exhaustive examination of legal texts and definitions, but; rather, it is meant to start the process of simplifying the current terminology in use by the WHO global surveillance and monitoring system and the Member State mechanism from a public health perspective.

11. Based on the deliberation of the working group it is recommended that the Member State mechanism replace the use of "substandard/spurious/falsely-labelled/falsified/counterfeit medical products" with "substandard and falsified medical products", as the term to be used in its name and in all future documentation on the subject of medical products of this type.

## ANNEX 13

[A70/36, Annex - 4 May 2017]



<sup>1</sup> See decision WHA70(23).



RISK REDUCTION

MS

Actions focused on risk management by and within the health sector, including health protection strategies, regulating chemicals, public education, and sharing information and best practices.

#### **HEALTH PROTECTION** STRATEGIES



health promotion and protection strategies and programmes for the life cycle of high-priority chemicals, particularly for vulnerable populations.

Actively engage in and support the implementation of the chemicals- and wasterelated multilateral environmental agreements, particularly health protective aspects. Support ratification and implementation of the Minamata Convention on Mercury and build capacity to assess and address health impacts of mercury exposure in line with resolution WHA67.11 (2014).



wно

MS

Collaborate to identify and promote reduced-risk alternatives, taking into account the life cycle of substances and products, including waste, and promoting the use of these alternatives.

Provide guidance on the prevention of negative health impacts from specific chemicals of concern

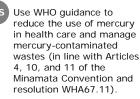
Finalize guidelines on the prevention and management of lead poisoning Implement forthcoming guidelines, and phase out paints containing

lead by 2020 as per the objectives of the Global Alliance to Eliminate Lead Paint

#### **HEALTHY HEALTH** CARE SETTINGS

Provide guidance for health care settings to promote and facilitate the use of safer alternatives and sound management of health care waste, drawing on relevant guidance from WHO and others, such as that adopted under multilateral environmental agreements.

Develop and implement awareness campaigns for health care workers about chemicals of concern and established best practices for safe chemicals management within the health sector, including occupational, patient/community and environmental impacts in health care settings.



### RAISING AWARENESS





All Promote communication of relevant information, including training, on chemicals used in products and processes, to enable informed decision-making by all actors throughout the product life cycle, and to promote safer alternatives

> Publish and use articles on chemicals-related health sector issues in peerreviewed health care, medical, toxicology and other related journals, including those of professional bodies.



All

WHO Sec Support development of the health-related components of the Strategic Approach information clearing house.

Document experiences with and effectiveness of various awareness-raising, riskreduction actions and prevention strategies and share this information with others

Outcome:

Improved health, in both the short and the long term and for future generations, through the reduction of risk to health from exposure to chemicals throughout their life cycle, including as waste, resulting from increased health protection activities by the health sector at the national, regional and international level, as well as from greater interest and awareness within the health sector and in the general community.

<sup>†</sup> Actions that are within the mandate of WHO and also contribute to increasing the capacity of the secretariat of the Strategic Approach to support activities related to the health sector in line with resolution WHA69.4. For actions with more than one lead actor, this note applies only to the WHO Secretariat's role.

All: all stakeholders; MS: Member States; WHO Sec: WHO Secretariat.

### **KNOWLEDGE AND EVIDENCE**

Actions focused on filling gaps in knowledge and methodologies for risk assessment based on objective evidence, increasing biomonitoring and surveillance, estimating the burden of disease from chemicals, and measuring progress.

SHARING AND

COLLABORATING

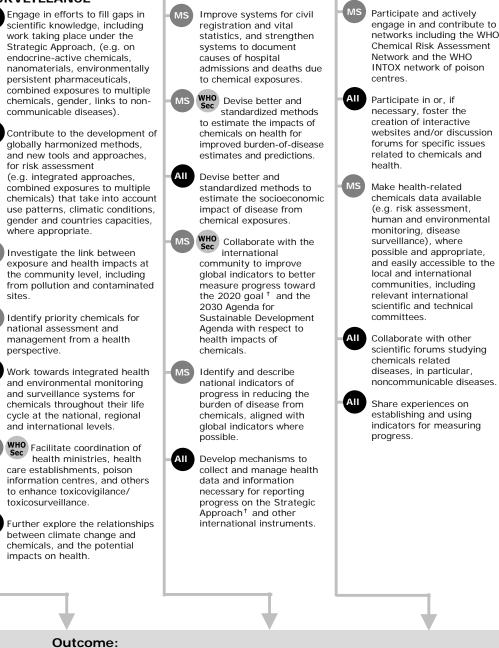
#### **RISK ASSESSMENT**, **BIOMONITORING AND** SURVEILLANCE

A 11

All

sites

#### MEASURING PROGRESS





All

Enhanced engagement of the health sector in cooperative efforts to fill current gaps in knowledge and methodologies for risk assessment, biomonitoring, surveillance, estimating the burden of disease, and measuring progress. This includes greater participation in networks and development of new cooperative mechanisms, as necessary, to facilitate knowledge sharing and collaboration within the health sector on specific technical issues.

## INSTITUTIONAL CAPACITY

Actions to strengthen national institutional capacities to address health threats from chemicals, including in response to chemical incidents and emergencies.

#### NATIONAL POLICY AND REGULATORY FRAMEWORKS

Identify gaps and support stronger national policy and regulatory frameworks to address the health impacts of chemicals throughout the life cycle of chemicals with a focus on the 11 basic elements set out in paragraph 19 of the Strategic Approach's orientation and guidance document.

Contribute to international efforts to develop tools and guidance for developing national frameworks, such as the IOMC Toolbox.

All

Establish health-based guidelines for water, air, soil, food, products, and occupational exposure, drawing on WHO norms, standards and guidelines, as appropriate, and participating in their development.

Support implementation of the Globally Harmonized System of Classification and Labelling of Chemicals, coordinating internationally, where appropriate.

Support regulations to prevent discharge of toxic chemicals and advocate appropriate recovery and recycling technology, as well as safe storage and disposal, in line with resolutions WHA63.25 and WHA63.26 (2010), and relevant multilateral environmental agreements.

Support stronger monitoring of production, transport, use and releases of hazardous chemicals and waste, and promote regional and international cooperation with a view to enhancing compliance with existing regulations and preventing illegal traffic.

#### INTERNATIONAL HEALTH REGULATIONS (2005)

Establish/strengthen core capacities for chemical incident and emergency preparedness, detection and response, including: chemical event surveillance, verification, notification, risk assessment and communication, and inspection capacities at ports of entry.

Continue to develop and enhance tools, guidance and other support to countries, in order to strengthen core capacities for chemical incidents and emergencies, and promote awareness among all stakeholders.

WHO Sec Establish an international health workforce to be mobilised to respond to chemical emergencies, e.g. contribute to a WHO roster of experts for chemical incidents and emergencies.

Strengthen existing, and establish new poison centres and networks, coordinating as necessary to achieve the objective of all countries having access to a poison information service.

Develop or enhance regional networks to coordinate, strengthen and share existing laboratory capacity.

Improve communication and collaboration between national focal points for the International Health Regulations (2005), the Strategic Approach, and chemicals- and waste-related multilateral environmental agreements to leverage synergies, e.g. need for risk assessment, surveillance, laboratory capacity and reporting.

## TRAINING AND EDUCATION



Disseminate training materials for targeted audiences (e.g. nongovernmental organisations, government officials, teachers, medical professionals, and health care workers) on specific topics (e.g. assessing and monitoring health risks, gathering evidence, diagnosing and treating health disorders, chemical safety awareness, and labelling).

All Enhance curricula in medical schools and other academic institutions to address the health impacts of chemicals, with an emphasis on toxicology and occupational and public health, and encourage residencies. fellowships, or specializations; encourage inclusion of curricula in other academic programmes that would promote safe and sustainable chemistry (e.g. Safer by Design).

WHO Sec Provide a portal of WHO training materials on chemicals and health as a contribution to the Strategic Approach information clearing house.<sup>†</sup>

All Link health professional associations with academic environmental health or risk analysis groups and institutions to strengthen engagement on and knowledge of chemicals management issues.



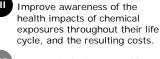
#### Outcome:

Increased capacity and resilience of health systems in order to address all aspects of chemical safety.

## LEADERSHIP AND COORDINATION

Actions to promote the inclusion of health considerations in all chemicals policies, engagement of the health sector in chemicals management activities at the national, regional and international levels, and engagement of the health sector with other sectors.

#### HEALTH **IN ALL CHEMICALS** POLICIES



Promote inclusion of health priorities in chemicals policies, gap analyses, profiles, implementation plans and strategies, at all levels, including for the 2030 Agenda for Sustainable Development.

Pursue additional initiatives to mobilize financial resources for the health sector, including for WHO, for the sound management of chemicals and waste.



AII

All

Organize high-level briefing sessions on chemicals and health for politicians and senior officials at the national, regional and international levels. \*

Strengthen the chemicals component of national, regional and international health and environmental processes, including at the highest levels.



Include gender and equity as a component in all policies strategies and plans for the sound management of chemicals and waste.

#### HEALTH SECTOR ENGAGEMENT AND COORDINATION

Nominate a health ministry contact point for issues related to chemicals and health including implementation of this road map, and establish a national chemicals and health network. WHO Establish a global chemicals and health network, with links AII to existing subregional, regional and international networks, to facilitate health sector implementation of this road map (including participation in the Strategic Approach †). Participate in and promote the inclusion of health sector **A**11 priorities in the intersessional process to prepare recommendations regarding the Strategic Approach and the sound management of All chemicals and waste beyond 2020. Participate actively in decision making and support strengthening of national policy and regulatory frameworks relevant for chemicals and health. AII MS Engage in national, regional, and international chemicals forums, including for Strategic Approach emerging policy issues and other issues of concern as well as for noncommunicable diseases. Implement the strategy for strengthening the engagement of the health sector in the implementation of the Strategic Approach and promote it to others.

#### **ENGAGEMENT WITH OTHER SECTORS AND STAKEHOLDERS**

MS Participate in and encourage the development of sustainable, effective and operational multisectoral coordination networks to maximize collective efforts, as envisaged by the Strategic Approach. Facilitate inclusion and active participation of all relevant sectors and stakeholders in chemicals management throughout the life cycle, at all levels, while recognizing the shared leadership of the health and environment sectors. Highlight the multisectoral impact that health investments can have on economies and communities. Build capacity within the health sector for multisectoral engagement and look for opportunities to share information, harmonize and leverage efforts of networks in other sectors Actively engage in relevant regional and international negotiations, including those related to multilateral environmental agreements, development financing and technical cooperation, and, where possible and appropriate, establish a standing item to discuss issues relating to the health sector



#### Outcome:

ΔII

Increased awareness and integration of health considerations and engagement of the health sector in chemicals management activities at the national, regional and international levels, including engagement with other sectors, leading to an increased profile and priority for the global sound management of chemicals throughout their life cycle.

## ANNEX 14

# Financial and administrative implications for the Secretariat of resolutions and decisions adopted by the Health Assembly

**Resolution WHA70.6** Human resources for health and implementation of the outcomes of the United Nations' High-Level Commission on Health Employment and Economic Growth Link to the general programme of work and programme budget A. 1. Outcome(s) in the Twelfth General Programme of Work, 2014–2019 and output(s) in the Programme budget 2016–2017 to which this resolution will contribute. Twelfth General Programme of Work, 2014–2019 outcome(s): Policies, financing and human resources are in place to increase access to people-centred, integrated health services. **Programme budget 2016–2017 output(s):** Output 4.2.2. Health workforce strategies oriented towards universal health coverage implemented in countries. The action plan will also support outputs across other categories, for example: Output 1.1.1. Increased capacity of countries to deliver key HIV interventions through active engagement in policy dialogue, development of normative guidance and tools, dissemination of strategic information, and provision of technical support; Output 2.1.3. Countries enabled to improve health care coverage for the management of cardiovascular diseases, cancer, diabetes and chronic respiratory diseases and their risk factors through strengthening health systems; Output 3.3.2. Countries enabled to integrate and monitor gender, equity and human rights in national health policies and programmes; Output 3.5.1. Countries enabled to assess health risks and develop and implement policies, strategies or regulations for the prevention, mitigation and management of the health impacts of environmental and occupational risks; Output 5.1.1. Implementation and monitoring of the International Health Regulations (2005) at country level and training and advice for Member States in further developing and making use of core capacities required under the Regulations; Output 6.1.1. Effective WHO leadership and management in accordance with leadership priorities. 2. Brief justification for considering the resolution, if there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017.

Not applicable.

#### 3. Estimated time frame (in years or months) for implementation of any additional deliverables.

The five-year action plan for health employment and inclusive economic growth covers the period 2017–2021 and provides further support towards the implementation of the Global Strategy on Human Resources for Health: Workforce 2030, adopted by the Sixty-ninth World Health Assembly in resolution WHA69.19 (2016).

The action plan is consistent with the Organization's response to the Sustainable Development Goals. It incorporates a broad-based approach that impacts Goals 3, 4, 5, 8 and 17.

The action plan will be implemented in collaboration with Member States, ILO, OECD and relevant regional and specialized entities. It focuses on instruments of change and enabling factors, such as: intersectoral action involving multiple stakeholders; strengthening health systems for universal health coverage; respect for equity and human rights; sustainable finance; scientific research and innovation; and monitoring and evaluation. Its implementation will make contributions across the category/programme areas of communicable diseases, noncommunicable diseases, promoting health through the life course and the WHO Health Emergencies Programme.

#### B. Budgetary implications

#### 1. Estimated total cost to implement the resolution , in US\$ millions:

US\$ 70.0 million (over the five years), of which US\$ 45.0 million would be for WHO.

The indicative budget for staff and activities reflects the combination of country work and global public goods in the action plan. Key actions on the intersectoral agenda and global public goods, integrating the recommendation of the Joint Inspection Unit of the United Nations System for WHO to mainstream full and productive employment and decent work into its programme, will engage the regional offices and headquarters. Focused work on education and employment is anticipated in the 15–20 countries where progress towards universal health coverage is furthest behind. About 50% of the WHO costs will resource staffing and activities at the regional and country levels.

#### 2.a. Estimated additional budgetary requirements in the current biennium, in US\$ millions:

US\$ 1 million.

The additional activities and deliverables in the remaining six months of the biennium are feasible within the category 4 budget space.

#### 2.b. Resources available during the current biennium

Resources available in the current biennium to fund the implementation of the resolution , in US\$ millions:

US\$ 0.5 million in category 4, output 4.2.2, to implement the priority activities in the remaining six months of the biennium.

- Extent of any financing gap, in US\$ millions: US\$ 0.5 million.
- Estimated resources, not yet available, which would help to close any financing gap, in US\$ millions:

WHO, ILO and OECD will jointly coordinate resource mobilization in support of the action plan.

#### 3. Estimated additional budgetary requirements in 2018–2019 (if relevant), in US\$ millions:

US\$23.0 million, to be accommodated within the Proposed programme budget 2018–2019.

#### Has this been included in the Programme budget 2018-2019?

The five-year action plan, developed in consultation and collaboration with Member States, ILO, OECD and relevant regional and specialized agencies over the period December 2016–April 2017, will be accommodated within the Proposed programme budget 2018–2019, supported by additional resource mobilization activities.

#### 4. Estimated additional budgetary requirements in future bienniums (if relevant), in US\$ millions:

US\$ 21.0 million.

**Resolution WHA70.7** Improving the prevention, diagnosis and management of sepsis

#### A. Link to the General Programme of Work and the Programme budget

1. Please indicate to which outcome in the Twelfth General Programme of Work, 2014–2019 and to which output in the Programme budget 2016–2017 this resolution will contribute .

Twelfth General Programme of Work, 2014–2019, category 3, outcome: increased access to interventions for improving health of women, newborns, children and adolescents; category 4, outcome: policies, financing and human resources are in place to increase access to people-centred, integrated health services; category 5, outcome: increased capacity of countries to build resilience and adequate preparedness to mount a rapid, predictable and effective response to major epidemics and pandemics.

Programme budget 2016–2017, outputs: 3.1.1; 3.1.2; 3.1.4; 3.1.6; 4.2.3; and 5.2.2.

2. Please provide a short justification for considering the resolution, if there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017.

Not applicable.

**3.** Please indicate the estimated implementation time frame (in years or months) for any additional deliverables.

4.5 years.

#### B. Budgetary implications for implementation of additional deliverables

1. Current biennium – estimated, additional budgetary requirements, in US\$ millions:

None.

- (i) Please indicate the level of available resources to fund the implementation of the proposed resolution in the current biennium, in US\$ millions:
  - How much are the resources available to fund the proposed resolution in the current biennium?

US\$ 0.40 million (in-kind staff contribution across regional offices and WHO headquarters).

- How much would the financing gap be?
   US\$ 1.68 million.
- What are the estimated resources, not yet available, if any, which would help to close the financing gap?

Zero.

2018–2019 (if required): estimated budget requirements, in US\$ millions:

#### Level Activities Total Staff 1.20 1.20 Country offices 0.00 **Regional offices** 1.35 0.48 1.83 2.00 Headquarters 1.20 0.80 5.03 Total 2.55 2.48 Future bienniums beyond 2018-2019 (if required) - estimated budgetary requirements, in 3. **US\$ millions:** US\$ 5.03 million. **Resolution WHA70.11** Preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018 Link to the general programme of work and programme budget A. 1. Outcome(s) in the Twelfth General Programme of Work, 2014–2019 and output(s) in the Programme budget 2016-2017 to which this resolution will contribute . Twelfth General Programme of Work, 2014–2019 outcome(s): Increased access to interventions to prevent and manage noncommunicable diseases and their risk factors. **Programme budget 2016–2017 output(s):** Output 2.1.1. Development and/or implementation of national multisectoral policies and plans to prevent and control noncommunicable diseases accelerated. 2. Brief justification for considering the resolution, if there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017. Not applicable. Estimated time frame (in years or months) for implementation of any additional deliverables. 3. The resolution will be implemented in June 2017. The predominance of activities and deliverables in preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018, will occur in 2017-2018. In order to ensure full delivery of the results of the meeting, work may continue into 2019. The workplan for the global coordination mechanism on the prevention and control of noncommunicable diseases covers the biennium 2018–2019. B. **Budgetary implications** 1. Estimated total cost to implement the resolution , in US\$ millions: US\$ 12.3 million. 2.a. Estimated additional budgetary requirements in the current biennium, in US\$ millions: Budgetary requirements for implementation during 2017 are estimated at US\$ 2.5 million. This can already be accommodated within the existing budget ceiling.

2.

US\$ 5.03 million.

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|    | <ul> <li>Resources available in the cumulation millions:</li> </ul>  | urrent biennium to   | fund the implementati  | on of the decision , in U   |  |  |  |
|----|--|--|--|---|--|--|--|
|    | Level  | Staff  | Activities   | Total   |  |  |  |
|    | Country offices  | 0  | 0  | 0   |  |  |  |
|    | Regional offices   | 0  | 0  | 0   |  |  |  |
|    | Headquarters   | 1.6  | 0.9  | 2.5   |  |  |  |
|    | Total  | 1.6  | 0.9  | 2.5   |  |  |  |
| •  | <ul> <li>Estimated resources, not ye millions:</li> <li>Not applicable.</li> <li>Estimated additional budgetary</li> </ul>   |  |  |   |  |  |  |
|    | Level  | Staff  | Activities   | Total   |  |  |  |
|    | Country offices  | 0  | 0  | 0   |  |  |  |
|    | Regional offices   | 0  | 0  | 0   |  |  |  |
|    | Headquarters   | 6.2  | 3.6  | 9.8   |  |  |  |
|    | Total  | 6.2  | 3.6  | 9.8   |  |  |  |
| ŀ. | Has this been included in the Payes.         Yes.         Estimated additional budgetary         Estimated budget requirements i         the third High-level Meeting         Non-communicable Diseases in 2 | y <b>requirements in fu</b><br>n future bienniums a<br>of the General<br>2018 and the global c | ture bienniums (if release<br>the to be determined in<br>Assembly on the Proportion of the | line with requirements af<br>revention and Control<br>workplan 2018–2019. |  |  |  |
|    | *  |  | n the context of an integ  | rated approach  |  |  |  |
| 4. | Link to the general programme  |  | -  |   |  |  |  |
| •  | Outcome(s) in the Twelfth General Programme of Work, 2014–2019 and output(s) in the Programme budget 2016–2017 to which this resolution will contribute .  |  |  |   |  |  |  |
|    | Twelfth General Programme of Work, 2014–2019 outcome(s):   |  |  |   |  |  |  |
|    | Increased access to interventions to prevent and manage noncommunicable diseases and their risk factors;   |  |  |   |  |  |  |
|    | Additionally related to:   |  |  |   |  |  |  |
|    | Increased vaccination coverage for hard-to-reach populations and communities;  |  |  |   |  |  |  |
|    | Increased access to interventions for improving health of women, newborns, children and adolescents;   |  |  |   |  |  |  |

Gender, equity and human rights integrated into the Secretariat's and countries' policies and programmes;

Reduced environmental threats to health;

- All countries have comprehensive national health policies, strategies and plans updated within the last five years;
- Policies, financing and human resources are in place to increase access to people-centred, integrated health services;
- Improved access to, and rational use of, safe, efficacious and quality medicines and health technologies;
- All countries have properly functioning civil registration and vital statistics systems.

Programme budget 2016–2017 output(s):

Output 2.1.3. Countries enabled to improve health care coverage for management of cardiovascular diseases, cancer, diabetes and chronic respiratory diseases and their risk factors through strengthening health systems.

Additionally related to:

Output 1.5.1. Implementation and monitoring of the global vaccine action plan, with emphasis on strengthening service delivery and immunization monitoring in order to achieve the goals for the Decade of Vaccines;

Output 3.1.2. Countries enabled to implement and monitor integrated strategic plans for newborn and child health, with a focus on expanding access to high-quality interventions to improve early childhood development and end preventable newborn and child deaths from pneumonia, diarrhoea and other conditions;

Output 3.1.3. Countries enabled to implement and monitor effective interventions to cover unmet needs in sexual and reproductive health;

Output 3.3.1. Gender, equity and human rights integrated in WHO's institutional mechanisms and programme deliverables;

Output 3.5.1. Countries enabled to assess health risks and develop and implement policies, strategies or regulations for the prevention, mitigation and management of the health impacts of environmental and occupational risks;

Output 4.1.1. Improved country governance capacity to formulate, implement and review comprehensive national health policies, strategies and plans (including multisectoral action, and "health in all policies" and equity policies);

Output 4.2.1. Equitable integrated, people-centred service delivery systems in place in countries and public-health approaches strengthened;

Output 4.2.2. Health workforce strategies oriented towards universal health coverage implemented in countries;

Output 4.3.3. Improved quality and safety of medicines and other health technologies through norms, standards and guidelines, strengthening of regulatory systems, and prequalification.

- Brief justification for considering the resolution, if there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017. Not applicable.
- 3. Estimated time frame (in years or months) for implementation of any additional deliverables. It is proposed to implement the resolution from June 2017 to December 2023.

B. Budgetary implications

1. Estimated total cost to implement the resolution , in US\$ millions:

US\$ 63.0 million.

2.a. Estimated additional budgetary requirements in the current biennium, in US\$ millions:

No additional costs to be accommodated within the approved programme budget for the current biennium.

- 2.b. Resources available during the current biennium
  - Resources available in the current biennium to fund the implementation of the resolution , in US\$ millions:

| Level            | Staff | Activities | Total |
|------------------|-------|------------|-------|
| Country offices  | 0.4   | 0.9        | 1.3   |
| Regional offices | 1.9   | 3.0        | 4.9   |
| Headquarters     | 1.2   | 1.9        | 3.1   |
| Total            | 3.5   | 5.8        | 9.3   |

– Extent of any financing gap, in US\$ millions:

There is no financing gap for the current biennium.

- Estimated resources, not yet available, which would help to close any financing gap, in US\$ millions: Not applicable.
- 3. Estimated additional budgetary requirements in 2018–2019 (if relevant), in US\$ millions:

| Level            | Staff | Activities | Total |
|------------------|-------|------------|-------|
| Country offices  | 1.0   | 3.3        | 4.3   |
| Regional offices | 3.3   | 4.8        | 8.1   |
| Headquarters     | 2.7   | 4.0        | 6.7   |
| Total            | 7.0   | 12.1       | 19.1  |

Has this been included in the Proposed programme budget 2018–2019? Yes.

4. Estimated additional budgetary requirements in future bienniums (if relevant), in US\$ millions:

Estimated budget requirements for cancer control in biennium 2020–2021 are US\$ 20.1 million and in biennium 2022–2023 are US\$ 21.1 million, each with a 5% increase each biennium from 2018–2019. These estimated budget requirements will be taken into account during subsequent proposed programme budgets.

| Res | olution WHA70.13 Prevention of deafness and hearing loss  |  |  |
|-----|---|--|--|
| А.  | Link to the general programme of work and the programme budget  |  |  |
| 1.  | Please indicate to which impact and outcome in the Twelfth General Programme of Work, 2014–2019 and which output in the Programme budget 2016–2017 this resolution will contribute .                                      |  |  |
|     | Twelfth General Programme of Work 2014–2019: Impacts: reducing premature mortality from noncommunicable diseases; and preventing death, illness and disability arising from emergencies; outcome: 2.4; and output: 2.4.2. |  |  |

2. If there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017, please provide a justification for giving consideration to the resolution.

Not applicable.

3. What is the proposed timeline for implementation of this resolution?

From 2017 to 2021.

If the timeline stretches to future programme budgets, please ensure that further information is provided in the costing section.

| B. Budgetary implications of implementation of the resolution  |  |                                    |                             |  |  |  |
|--|--|------------------------------------|-----------------------------|--|--|--|
| 1. Current biennium: estimated budgetary requirements, in US\$ million   |  |                                    |                             |  |  |  |
| Level  | Staff  | Activities                         | Total                       |  |  |  |
| Country offices  | 0.100  | 0.150                              | 0.250                       |  |  |  |
| Regional offices   | 0.300  | 0.125                              | 0.425                       |  |  |  |
| Headquarters   | 1.000  | 0.500                              | 1.500                       |  |  |  |
| Total  | 1.400  | 0.775                              | 2.175                       |  |  |  |
| within the current p<br>Yes.   | dget requirement in respec<br>rogramme budget? (Yes/No   | )                                  | e resolution fully included |  |  |  |
| <ul> <li>How much is finat<br/>US\$ 1.7 million.</li> <li>What are the gaps<br/>US\$ 0.475 million.</li> <li>What action is pro<br/>The gap will be add</li> </ul> | ons for the budget in the cur<br>need in the current biennium<br>?<br>oposed to close these gaps?<br>dressed through coordinated r<br>ole financing by voluntary com | n?<br>esource mobilization efforts | s, including the financing  |  |  |  |
| 2. Next biennium: estim  | mated budgetary requireme  | ents, in US\$ million              |                             |  |  |  |
| Level  | Staff  | Activities                         | Total                       |  |  |  |
| Country offices  | 0.20   | 0.75                               | 0.95                        |  |  |  |
| Regional offices   | 0.60   | 0.50                               | 1.10                        |  |  |  |
| Headquarters   | 1.50   | 1.35                               | 2.85                        |  |  |  |
| Total  | 2.30   | 2.60                               | 4.90                        |  |  |  |
| <ul> <li>How much is curr<br/>US\$ 1.7 million.</li> <li>What are the fina<br/>US\$ 3.2 million.</li> <li>What action is pro-</li> </ul>                           | ons for the budget in the nex<br>ently financed in the next b<br>ncing gaps?<br>oposed to close these gaps?<br>dressed through coordinated r                         | iennium?                           | s, including the financing  |  |  |  |

| Reso | <b>Strengthening immunization to achieve the goals of the global vaccine action plan</b>  |
|------|---|
| А.   | Link to the general programme of work and programme budget  |
| 1.   | Outcome(s) in the Twelfth General Programme of Work, 2014–2019 and output(s) in the Programme budget 2016–2017 to which this resolution will contribute .   |
|      | Twelfth General Programme of Work, 2014–2019 outcome(s):  |
|      | Increased vaccination coverage for hard-to-reach populations and communities.   |
|      | Programme budget 2016–2017 output(s):<br>Output 1.5.1. Implementation and monitoring of the global vaccine action plan, with emphasis on<br>strengthening service delivery and immunization monitoring in order to achieve the goals for the Decade<br>of Vaccines;   |
|      | Output 1.5.2. Intensified implementation and monitoring of measles and rubella elimination strategies facilitated;  |
|      | Output 1.5.3. Target product profiles for new vaccines and other immunization-related technologies, as well as research priorities, defined and agreed, in order to develop vaccines of public health importance and overcome barriers to immunization.   |
| 2.   | Brief justification for considering the resolution, if there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017. Not applicable.   |
| 3.   | Estimated time frame (in years or months) for implementation of any additional deliverables.<br>The resolution would be implemented during 2017–2021. The Sixty-fifth World Health Assembly in resolution WHA65.17 (2012) requested the Director-General to report annually, through the Executive Board, to the Health Assembly, until the Seventy-first World Health Assembly, on progress towards achievement of global immunization targets. As the Secretariat will report on the finalization of the global vaccine action plan (final assessment, monitoring and evaluation) in 2021, activities will need to be carried out until then.   |
| B.   | Budgetary implications  |
| 1.   | Estimated total cost to implement the resolution, in US\$ millions:   |
|      | US\$ 258 million (from 2017 to 2021).   |
| 2.a. | Estimated additional budgetary requirements in the current biennium, in US\$ millions:  |
|      | US\$ 7 million.   |
|      | This additional budgetary requirement is needed to cover new activities that have arisen over the course of the biennium, including: supporting the implementation of the WHO research and development blueprint for action to prevent epidemics, facilitating the implementation of malaria vaccine pilot projects; strengthening surveillance for measles and other vaccine-preventable diseases, even as resources available through the Global Polio Eradication Initiative decline; and providing support to countries not eligible for support from the GAVI Alliance in accessing new and underutilized vaccines and strengthening their immunization programmes, including the maintenance and expansion of the vaccine product, price and procurement database, and establishing a vaccine demand/supply exchange forum. The sum of US\$ 7 million includes costs for staff, procurement and consultant contracts for technical support. |

- 2.b. Resources available during the current biennium
  - Resources available in the current biennium to fund the implementation of the resolution , in US\$ millions:

None.

- Extent of any financing gap, in US\$ millions:

Implementing activities as requested in the resolution would require an estimated amount of US\$ 7 million for the remainder of the biennium.

- Estimated resources, not yet available, which would help to close any financing gap, in US\$ millions:
   Some fundraising activities would be implemented after adoption of the resolution to cover the funding gap. Several partners have already expressed interest in increasing their investments in the areas mentioned in the resolution.
- 3. Estimated additional budgetary requirements in 2018–2019 (if relevant), in US\$ millions:

#### US\$ 73 million.

Additional budgetary requirement is needed to cover new activities, for example, in relation to the WHO research and development blueprint for action to prevent epidemics, and malaria vaccine pilot projects. Strengthening surveillance for measles and other vaccine-preventable diseases is key to achieving the goals of the global vaccine action plan and requires additional budget and resources. A plan is needed to secure the necessary investments by countries to sustain immunization during polio transition and to continue and enhance support to countries that transition out of support from the GAVI Alliance, in order to mitigate any risk to sustaining effective immunization programmes when polio funding decreases.

Has this been included in the Proposed programme budget 2018–2019?

As far as possible, these costs will be accommodated within the Programme budget 2018–2019.

- 4. Estimated additional budgetary requirements in future bienniums (if relevant), in US\$ millions:
  - US\$ 178 million for biennium 2020–2021.

#### **Resolution WHA70.15** Promoting the health of refugees and migrants

| А. | Link to the general programme of work and programme budget |  |
|----|--|--|
|    |  |  |

1. Outcome(s) in the Twelfth General Programme of Work, 2014–2019 and output(s) in the Programme budget 2016–2017 to which this resolution will contribute .

Twelfth General Programme of Work, 2014–2019 outcome(s):

Currently there is no specific outcome on migration in the Twelfth General Programme of Work, 2014–2019.

Programme budget 2016–2017 output(s):

There is no specific outcome on migration in the Programme budget 2016–2017. However, the Organization has linked its current activities on health and migration to outputs 4.2.1 (equitable integrated, people-centred service delivery systems in place in countries and public-health approaches strengthened) and 4.2.3 (countries enabled to improve patient safety and quality of services, and patient empowerment within the context of universal health coverage) in the Programme budget 2016–2017.

2. Brief justification for considering the resolution, if there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017.

The resolution is linked to proposed outputs in programme area 4.2.1 of the Proposed programme budget 2018–2019. That said, decision EB140(9) (2017) requests, inter alia, the Director-General to prepare, in full consultation and cooperation with Member States, and, where applicable, regional economic integration organizations, and in cooperation with IOM, UNHCR and other relevant stakeholders, a draft framework of priorities and guiding principles to promote the health of refugees and migrants, to be considered by the Seventieth World Health Assembly, and a global plan of action on the health of refugees and migrants to be considered by the Seventy-second World Health Assembly. It also requests the Director-General to conduct situation analysis and to ensure that the health aspects of refugees and migrants are adequately addressed in the global compact on refugees and the global compact for safe, orderly and regular migration, to be submitted to the United Nations General Assembly in 2018.

3. Estimated time frame (in years or months) for implementation of any additional deliverables. 2.5 years.

B. Budgetary implications

1. Estimated total cost to implement the resolution , in US\$ millions:

The cost between June 2017 and December 2019 is US\$ 4.36 million.

The cost beyond this would be subject to the global plan of action on the health of refugees and migrants that will be developed, for consideration at the Seventy-second World Health Assembly.

2.a. Estimated additional budgetary requirements in the current biennium, in US\$ millions:

US\$ 0.54 million.

- 2.b. Resources available during the current biennium
  - Resources available in the current biennium to fund the implementation of the resolution , in US\$ millions:

Zero.

- Extent of any financing gap, in US\$ millions:

US\$ 0.54 million.

Estimated resources, not yet available, which would help to close any financing gap, in US\$ millions:
 Zero.

3. Estimated additional budgetary requirements in 2018–2019 (if relevant), in US\$ millions:

US\$ 3.82 million.

| Level            | Staff | Activities | Total |
|------------------|-------|------------|-------|
| Country offices  | 0.00  | 0.10       | 0.10  |
| Regional offices | 1.20  | 0.50       | 1.70  |
| Headquarters     | 1.57  | 0.45       | 2.02  |
| Total            | 2.77  | 1.05       | 3.82  |

Has this been included in the Proposed programme budget 2018–2019?

This has been included in the Proposed programme budget 2018–2019 in terms of deliverables for 2018–2019: the specific details of those deliverables and the work are under discussion with Member States. This is due to the fact that this is a new area of work for WHO based on the framework of priorities and principles to promote the health of refugees and migrants that is being developed, at the request of the Executive Board.

4. Estimated additional budgetary requirements in future bienniums (if relevant), in US\$ millions:

Not applicable – budgetary requirements will be estimated when the framework and the global plan of action are developed in 2018.

**Resolution WHA70.16** Global vector control response: an integrated approach for the control of vectorborne diseases

#### A. Link to the general programme of work and programme budget

1. Outcome(s) in the Twelfth General Programme of Work, 2014–2019 and output(s) in the Programme budget 2016–2017 to which this resolution will contribute .

Twelfth General Programme of Work, 2014–2019 outcome(s):

- Increased access to first-line antimalarial treatment for confirmed malaria cases;
- Increased and sustained access to essential medicines for neglected tropical diseases;
- Increased intersectoral policy coordination to address the social determinants of health;
- Reduced environmental threats to health;
- All countries have comprehensive national health policies, strategies and plans updated within the last five years;
- Policies, financing and human resources are in place to increase access to people centred, integrated health services;
- Improved access to, and rational use of, safe, efficacious and quality medicines and health technologies;
- All countries have the minimum core capacities required by the International Health Regulations (2005) for all-hazard alert and response;
- Increased capacity of countries to build resilience and adequate preparedness to mount a rapid, predictable and effective response to major epidemics and pandemics;
- Countries have the capacity to manage public health risks associated with emergencies;
- Greater coherence in global health, with WHO taking the lead in enabling the many different actors to play an active and effective role in contributing to the health of all people.

Programme budget 2016–2017 output(s):

Output 1.3.1. Countries enabled to implement evidence-based malaria strategic plans, with focus on effective coverage of vector control interventions and diagnostic testing and treatment, therapeutic efficacy and insecticide resistance monitoring and surveillance through capacity strengthening for enhanced malaria reduction;

Output 1.3.2. Updated policy recommendations, strategic and technical guidelines on vector control, diagnostic testing, antimalarial treatment, integrated management of febrile illness, surveillance, epidemic detection and response for accelerated malaria reduction and elimination;

Output 1.4.1. Implementation and monitoring of the WHO road map for neglected tropical diseases facilitated;

Output 1.4.2. Implementation and monitoring of neglected tropical disease control interventions facilitated by evidence-based technical guidelines and technical support;

Output 1.4.3. New knowledge, solutions and implementation strategies that respond to the health needs of disease-endemic countries developed.

- Brief justification for considering the resolution, if there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017. Not applicable.
- 3. Estimated time frame (in years or months) for implementation of any additional deliverables.
  13 years and 6 months. The strategic time frame is from July 2017 to December 2030, to align with the 2030 Agenda for Sustainable Development.
- B. Budgetary implications
- 1. Estimated total cost to implement the resolution , in US\$ millions:

US\$ 53.18 million (staff: US\$ 29.34 million; activities: US\$ 23.84 million).

Total for 2017-2030, in US\$ millions

| Level                              | Staff | Activities | Total |
|------------------------------------|-------|------------|-------|
| Country, intercountry and regional | 22.03 | 17.22      | 39.25 |
| Global                             | 7.31  | 6.62       | 13.93 |
| Total                              | 29.34 | 23.84      | 53.18 |

2.a. Estimated additional budgetary requirements in the current biennium, in US\$ millions:

US\$ 1.00 million (staff: US\$ 0.55 million; activities: US\$ 0.45 million).

The additional deliverables will be accommodated within the existing budget ceilings for the category in the current biennium.

- 2.b. Resources available during the current biennium
  - Resources available in the current biennium to fund the implementation of the resolution , in US\$ millions:

There are no funds currently available to fund implementation of the resolution.

- Extent of any financing gap, in US\$ millions:
  - US\$ 1.00 million
- Estimated resources, not yet available, which would help to close any financing gap, in US\$ millions: Resources will be mobilized for the current biennium through mobilization of voluntary contributions.

3. Estimated additional budgetary requirements in 2018–2019 (if relevant), in US\$ millions:

US\$ 7.98 million (staff: US\$ 4.38 million; activities: US\$ 3.60 million).

Total for 2018–2019, in US\$ millions

| Level                              | Staff | Activities | Total |
|------------------------------------|-------|------------|-------|
| Country, intercountry and regional | 3.28  | 2.60       | 5.88  |
| Global                             | 1.10  | 1.00       | 2.10  |
| Total                              | 4.38  | 3.60       | 7.98  |

Has this been included in the Proposed programme budget 2018–2019?

The cost related to implementing this resolution in the biennium 2018–2019 will be accommodated within the overall budget in the Proposed programme budget 2018–2019.

### 4. Estimated additional budgetary requirements in future bienniums (if relevant), in US\$ millions:

The estimated cost to implement the resolution for 2020–2030 is US\$ 44.20 million (staff: US\$ 24.41 million; activities: US\$ 19.79 million) assuming no change in currency exchanges.

Total for 2020–2030, in US\$ millions

| Level                              | Staff | Activities | Total |
|------------------------------------|-------|------------|-------|
| Country, intercountry and regional | 18.34 | 14.29      | 32.63 |
| Global                             | 6.07  | 5.50       | 11.57 |
| Total                              | 24.41 | 19.79      | 44.20 |

| Dec | ision WHA70(9) Poliomyelitis: polio transition planning  |
|-----|--|
| А.  | Link to the general programme of work and programme budget   |
| 1.  | Outcome(s) in the Twelfth General Programme of Work, 2014–2019 and output(s) in the Programme budget 2016–2017 to which this decision will contribute .  |
|     | Twelfth General Programme of Work, 2014–2019 outcome(s):   |
|     | No cases of paralysis due to wild or type-2 vaccine-related poliovirus globally.   |
|     | Programme budget 2016–2017 output(s):  |
|     | Output 5.5.4. Polio legacy workplan finalized and under implementation globally.   |
| 2.  | Brief justification for considering the decision, if there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017. Not applicable.  |
| 3.  | Estimated time frame (in years or months) for implementation of any additional deliverables.<br>The WHO strategic polio transition action plan and options is due to be developed by the end of 2017 and<br>presented for consideration by the Executive Board at its 142nd session in January 2018. The strategic<br>action plan will be further developed and refined for the Seventy-first World Health Assembly in<br>May 2018. The timeline for implementation of the plan (and the cost) will be included in the strategic<br>action plan.   |
| В.  | Budgetary implications   |
| 1.  | Estimated total cost to implement the decision, in US\$ millions:  |
|     | Developing the strategic action plan and options, with costing, by the end of 2017 for submission the Seventy-first World Health Assembly through the 142nd session of the Executive Board will require dedicated staff resources at WHO estimated to be as follows: at headquarters, one P6, one P5 and one P4 staff member, and one G5 support staff member for 7 months (for the remainder of 2017), and a P5 staff member in the Regional Office for the Eastern Mediterranean and the Regional Office for Africa, and a half-time P4 staff member in the Regional Office for South-East Asia. The 2017 cost for staff is US\$ 1.06 million. |
|     | The same staff complement will be required for the first 6 months of 2018, at a cost of US\$ 0.89 million.   |
|     | Operational costs for meetings and documentation in 2017 are estimated to be US\$ 0.03 million.  |
|     | The total estimated 13-month cost is therefore US\$ 1.98 million.  |
|     | In-kind support from staff in Polio Eradication and related programmes (for example, the WHO Health Emergencies Programme and Immunization, Vaccines and Biologicals) and country offices will also be required but is not costed. This estimate is based partly on the resources that have been required up to now to coordinate transition planning.   |

- 2.a. Estimated additional budgetary requirements in the current biennium, in US\$ millions:As stated in section B.1, the costs during 2017 will amount to US\$ 1.09 million; however, these will be accommodated within the Programme budget 2016–2017 envelope.
- 2.b. Resources available during the current biennium
  - Resources available in the current biennium to fund the implementation of the decision , in US\$ millions:

Funds to implement the decision are likely to be found within existing resources.

- Extent of any financing gap, in US\$ millions: None.
- Estimated resources, not yet available, which would help to close any financing gap, in US\$ millions: Not applicable.
- 3. Estimated additional budgetary requirements in 2018–2019 (if relevant), in US\$ millions:

The cost to deliver and continue to refine the strategic action plan and options in the first 6 months of 2018 is estimated to be US\$ 0.89 million for the headquarters and regional staff members outlined in section B.1.

Has this been included in the Proposed programme budget 2018–2019?

The planning for achievement of the deliverables is an ongoing process but as far as possible, the costs will be included within the approved Programme budget 2018–2019. The cost of implementation of the strategic action plan and options will be included in the report that will be submitted to the Executive Board at its 142nd session and the Seventy-first World Health Assembly.

4. Estimated additional budgetary requirements in future bienniums (if relevant), in US\$ millions: To be determined in the strategic action plan and options.

**Decision WHA70(10)** Review of the Pandemic Influenza Preparedness Framework

- A. Link to the general programme of work and programme budget
- 1. Outcome(s) in the Twelfth General Programme of Work, 2014–2019 and output(s) in the Programme budget 2016–2017 to which this decision will contribute .

Twelfth General Programme of Work, 2014–2019 outcome(s): Not applicable.

Programme budget 2016–2017 output(s):

Not applicable.

2. Brief justification for considering the decision, if there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017.

The Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits contributes to outcomes E.1 and E.2 of the WHO Health Emergencies Programme.

Member States are considering the report of the 2016 PIP Framework Review Group. The PIP Framework, section 7.4.2, notes that the Framework and its Appendices will be reviewed by 2016 with a view to proposing revisions reflecting developments as appropriate, to the World Health Assembly in 2017, through the Executive Board.

3. Estimated time frame (in years or months) for implementation of any additional deliverables. Up to 30 months.

| В.   | Budgetary implications  |
|------|---|
| 1.   | Estimated total cost to implement the decision, in US\$ millions:   |
|      | US\$ 2.91 million.  |
| 2.a. | Estimated additional budgetary requirements in the current biennium, in US\$ millions:  |
|      | Undertaking the activities outlined in the decision is estimated to require an additional US\$ 0.84 million of financing in 2017. Because the PIP Framework sits outside the programme budget, implementing the decision can be accommodated without increasing the budget space. |
| 2.b. | Resources available during the current biennium   |
|      | <ul> <li>Resources available in the current biennium to fund the implementation of the decision , in US\$ millions:</li> <li>None.</li> </ul>   |
|      | <ul> <li>Extent of any financing gap, in US\$ millions:</li> <li>US\$ 0.84 million.</li> </ul>  |
|      | <ul> <li>Estimated resources, not yet available, which would help to close any financing gap, in US\$ millions:<br/>None.</li> </ul>  |
| 3.   | Estimated additional budgetary requirements in 2018–2019 (if relevant), in US\$ millions:   |
|      | US\$ 2.07 million.  |
|      | Has this been included in the Proposed programme budget 2018–2019?<br>The PIP Framework sits outside the programme budget.  |
| 4.   | Estimated additional budgetary requirements in future bienniums (if relevant), in US\$ millions:<br>Not applicable.   |

| Dec | Decision WHA70(12) Health conditions in the occupied Palestinian territory, including east Jerusalem,<br>and in the occupied Syrian Golan   |  |  |
|-----|---|--|--|
| А.  | Link to the general programme of work and programme budget  |  |  |
| 1.  | Outcome(s) in the Twelfth General Programme of Work, 2014–2019 and output(s) in the Programme budget 2016–2017 to which this decision will contribute .   |  |  |
|     | Twelfth General Programme of Work, 2014–2019 outcome(s):<br>All outcomes in the Twelfth General Programme of Work, 2014–2019 would be covered in the work to be<br>undertaken.                            |  |  |
|     | Programme budget 2016–2017 output(s):<br>All outputs in the Programme budget 2016–2017 output would be covered in the work to be undertaken.  |  |  |
| 2.  | Brief justification for considering the decision, if there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017. Not applicable. |  |  |
| 3.  | Estimated time frame (in years or months) for implementation of any additional deliverables.<br>One year (May 2017–May 2018).   |  |  |

- B. Budgetary implications
- 1. Estimated total cost to implement the decision , in US\$ millions:

Total: US\$ 10.11 million (staff: US\$ 3.86 million; activities: US\$ 6.25 million).

2.a. Estimated additional budgetary requirements in the current biennium, in US\$ millions:

Total: US\$ 6.48 million (staff: US\$ 2.25 million; activities: US\$ 4.23 million) to be accommodated within the existing programme budget envelope.

- 2.b. Resources available during the current biennium
  - Resources available in the current biennium to fund the implementation of the decision , in US\$ millions:

US\$ 1.39 million.

- Extent of any financing gap, in US\$ millions:
   Funding will continue to be sought through voluntary contributions, including the strategic response plan for the occupied Palestinian territory.
- Estimated resources, not yet available, which would help to close any financing gap, in US\$ millions: Not applicable.
- 3. Estimated additional budgetary requirements in 2018–2019 (if relevant), in US\$ millions:

Total: US\$ 3.63 million (staff: US\$ 1.61 million; activities: US\$ 2.02 million).

Has this been included in the Proposed programme budget 2018–2019? Yes.

4. Estimated additional budgetary requirements in future bienniums (if relevant), in US\$ millions:

Not applicable.

Decision WHA70(17) Global action plan on the public health response to dementia

- A. Link to the General Programme of Work and the Programme budget
- 1. Please indicate to which outcome in the Twelfth General Programme of Work, 2014–2019 and to which output in the Programme budget 2016–2017 this decision will contribute .

Twelfth General Programme of Work, 2014–2019, category 2, outcome: increased access to services for mental health and substance use disorders. Programme budget 2016–2017, outputs 2.2.1 (countries' capacity strengthened to develop and implement national policies, plans and information systems in line with the comprehensive mental health action plan 2013–2020) and 2.2.2 (countries with technical capacity to develop integrated mental health services across the continuum of promotion, prevention, treatment and recovery).

2. Please provide a short justification for considering the decision, if there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017.

The Programme budget 2018–2019 includes a regional office deliverable on providing guidance and support to countries in the region to develop and implement national policies/plans/strategies for dementia; and a headquarters deliverable on establishing a global dementia observatory and assisting Member States in developing and implementing dementia strategies.

| 3.  | Please indicate the estimated implementation time frame (in years or months) for any additional deliverables.  |
|-----|--|
|     | Eight years for the duration of the global action plan on the public health response to dementia.  |
| В.  | Budgetary implications for implementation of additional deliverables   |
| 1.  | Current biennium – estimated, additional budgetary requirements, in US\$ millions:   |
|     | Covering July to December 2017:  |
|     | Total US\$ 1.33 million (staff US\$ 0.70 million, activities US\$ 0.63 million).   |
|     | At headquarters: one person (100%) at grade P2, one person (75% of one full-time equivalent) at grade P4, one person (25% of one full-time equivalent) at P5, with international expertise in public health and dementia, and one person providing administrative support (50% of one full-time equivalent) at grade G5. |
|     | At regional level: an international expert in public health and dementia with knowledge of the needs in their region (50% of one full-time equivalent) at grade P4 in each region.   |
| (i) | Please indicate the level of available resources to fund the implementation of the proposed decision in the current biennium, in US\$ millions:  |
|     | <ul> <li>How much are the resources available to fund the proposed decision in the current biennium?</li> <li>US\$ 0.11 million.</li> </ul>  |
|     | - How much would the financing gap be?   |
|     | US\$ 1.22 million.   |
|     | - What are the estimated resources, not yet available, if any, which would help to close the financing gap?  |
|     | US\$ 0.08 million (a grant expected from the European Commission).   |
| 2.  | 2018–2019 (if required): estimated budget requirements, in US\$ millions:  |
|     | US\$ 5.30 million (staff US\$ 2.80 million, activities US\$ 2.50 million).   |
| 3.  | Future bienniums beyond 2018–2019 (if required) – estimated budgetary requirements, in US\$ millions:  |
|     | Biennium 2020–2021: US\$ 5.30 million (staff US\$ 2.80 million, activities US\$ 2.50 million).   |
|     | Biennium 2022–2023: US\$ 5.30 million (staff US\$ 2.80 million, activities US\$ 2.50 million).   |
|     | Biennium 2024–2025: US\$ 5.30 million (staff US\$ 2.80 million, activities US\$ 2.50 million).   |
|     | Total: US\$ 15.90 million (staff US\$ 8.40 million, activities US\$ 7.50 million) for the three bienniums.   |

| Dec | <b>Decision WHA70(18)</b> Public health dimension of the world drug problem   |  |  |
|-----|---|--|--|
| A.  | Link to the general programme of work and programme budget  |  |  |
| 1.  | Outcome(s) in the Twelfth General Programme of Work, 2014–2019 and output(s) in the Programme budget 2016–2017 to which this decision will contribute . |  |  |
|     | Twelfth General Programme of Work, 2014–2019 outcome(s):  |  |  |
|     | Increased access to key interventions for people living with HIV;   |  |  |
|     | Increased access to services for mental health and substance use disorders;   |  |  |
|     | Improved access to, and rational use of, safe, efficacious and quality medicines and health technologies.   |  |  |

Programme budget 2016–2017 output(s):

Output 1.1.1. Increased capacity of countries to deliver key HIV interventions through active engagement in policy dialogue, development of normative guidance and tools, dissemination of strategic information, and provision of technical support;

Output 1.1.2. Increased capacity of countries to deliver key hepatitis interventions through active engagement in policy dialogue, development of normative guidance and tools, dissemination of strategic information, and provision of technical support;

Output 2.2.3. Expansion and strengthening of country strategies, systems and interventions for disorders caused by alcohol and other psychoactive substance use enabled;

Output 4.3.1. Countries enabled to develop or update, implement, monitor and evaluate national policies on better access to medicines and other health technologies; and to strengthen their evidence-based selection and rational use.

- Brief justification for considering the decision, if there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017. Not applicable.
- 3. Estimated time frame (in years or months) for implementation of any additional deliverables. June 2017–May 2022 (5 years).

B. Budgetary implications

1. Estimated total cost to implement the decision , in US\$ millions: US\$ 12.85 million.

Biennium 2016–2017: US\$ 1.35 million Biennium 2018–2019: US\$ 5.75 million Biennium 2020–2021: US\$ 5.75 million Total: US\$ 12.85 million

2.a. Estimated additional budgetary requirements in the current biennium, in US\$ millions: US\$ 1.35 million.

With the following additional deliverables, scaling up WHO–UNODC–INCB collaboration responding to increased country needs with effective coordination and implementation mechanisms, US\$ 0.3 million can be accommodated within the existing ceiling budget.

- 2.b. Resources available during the current biennium
  - Resources available in the current biennium to fund the implementation of the decision , in US\$ millions:

US\$ 0.3 million.

- Extent of any financing gap, in US\$ millions: US\$ 1.05 million.
  - Cost: US\$ 1.35 million
  - Available resources: US\$ 0.30 million

Financing gap: US\$ 1.05 million.

- Estimated resources, not yet available, which would help to close any financing gap, in US\$ millions:
   US\$ 1.05 million.
- 3. Estimated additional budgetary requirements in 2018–2019 (if relevant), in US\$ millions:

US\$ 5.75 million.

Has this been included in the Proposed programme budget 2018–2019? Yes.

4. Estimated additional budgetary requirements in future bienniums (if relevant), in US\$ millions:

US\$ 5.75 million.

| Dec | <b>Decision WHA70(19)</b> Report of the Commission on Ending Childhood Obesity: implementation plan  |  |  |
|-----|--|--|--|
| А.  | Link to the general programme of work and programme budget   |  |  |
| 1.  | Outcome(s) in the Twelfth General Programme of Work, 2014–2019 and output(s) in the Programme budget 2016–2017 to which this decision will contribute .  |  |  |
|     | Twelfth General Programme of Work, 2014–2019 outcome(s):   |  |  |
|     | Outcomes of category 2, programme area noncommunicable diseases.   |  |  |
|     | Programme budget 2016–2017 output(s):  |  |  |
|     | Output 2.1.1. Development and/or implementation of national multisectoral policies and plans to prevent and control noncommunicable diseases accelerated;  |  |  |
|     | Output 2.1.2. Countries enabled to implement strategies to reduce modifiable risk factors for noncommunicable diseases (tobacco use, diet, physical inactivity and harmful use of alcohol), including the underlying social determinants;  |  |  |
|     | Output 2.1.3. Countries enabled to improve health care coverage for the management of cardiovascular diseases, cancer, diabetes and chronic respiratory diseases and their risk factors through strengthening health systems;  |  |  |
|     | Output 2.1.4. Monitoring framework implemented to report on the progress made on the commitments contained in the Political Declaration of the High-Level Meeting of the United Nations General Assembly on the Prevention and Control of Non-communicable Diseases and in the WHO global action plan for the prevention and control of noncommunicable diseases 2013–2020.  |  |  |
| 2.  | Brief justification for considering the decision, if there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017. Not applicable.  |  |  |
| 3.  | Estimated time frame (in years or months) for implementation of any additional deliverables.<br>It is proposed to implement the decision from January 2018 to December 2023.   |  |  |
|     | The Secretariat will lead coordination of the development of a monitoring and evaluation framework to enable periodic reporting on global progress on the implementation of recommendations of the Commission on Ending Childhood Obesity and to provide guidance to Member States on the development and strengthening of national-level monitoring, evaluation and accountability. These activities would be carried out during the biennium 2018–2019.  |  |  |
|     | A set of relevant policy briefs and implementation guides will be developed and disseminated to support capacity-building at regional and country offices in 2018–2019. This will enhance support for Member States' implementation of existing and new innovative approaches to tackle childhood obesity. Technical work will be conducted to close the gaps in knowledge and practice on methods and monitoring systems to measure key behaviours and body weight in children aged under 5 years and those aged 5–17 years. Technical support and capacity-building through regional hubs and networks will be established in 2018–2019. |  |  |

| B.   | Budgetary implications  |   |   |  |                                    |
|------|---|---|---|--|------------------------------------|
| 1.   | Estimated total cost to implement the decision , in US\$ millions:<br>US\$ 12.61 million.   |   |   |  |                                    |
| 2.a. | Estimated additional budgetary re<br>None.  | equirements in the cu   | rrent biennium, in US\$ 1   | nillions:  |                                    |
| 2.b. | Resources available during the cu   | rrent biennium  |   |  |                                    |
|      | <ul> <li>Resources available in the cumillions:</li> <li>Zero.</li> </ul>   | irrent biennium to f  | fund the implementation   | n of the decision , in   | US\$                               |
|      | <ul> <li>Extent of any financing gap, in Zero.</li> </ul>   | US\$ millions:  |   |  |                                    |
|      | <ul> <li>Estimated resources, not yet ava<br/>Not applicable.</li> </ul>  | ailable, which would  | help to close any financir  | ig gap, in US\$ millions:  |                                    |
| 3.   | Estimated additional budgetary re   | equirements in 2018-  | -2019 (if relevant), in US  | \$ millions:   |                                    |
|      | Level   | Staff   | Activities  | Total  |                                    |
|      | Country offices   | 0.2   | 0.3   | 0.5  |                                    |
|      | Regional offices  | 0.3   | 0.5   | 0.8  |                                    |
|      | Headquarters  | 1.1   | 1.6   | 2.7  |                                    |
|      | Total   | 1.6   | 2.4   | 4.0  |                                    |
|      | Has this been included in the Prop<br>Yes.  | posed programme bu  | dget 2018–2019?   |  |                                    |
| 4.   | Estimated additional budgetary re   | equirements in future   | bienniums (if relevant),  | in US\$ millions:  |                                    |
|      | Estimated budget requirements for<br>Childhood Obesity in biennium<br>US\$ 4.41 million, each with a<br>budget requirements will be ta<br>Allocations would support contin<br>recommendations of the Commis<br>guidance to Member States. | a 2020–2021 are U<br>5% increase each b<br>aken into account<br>uued assessment of gl | S\$ 4.2 million and in<br>iennium from that of 2<br>during subsequent prop<br>lobal and national progre | biennium 2022–202<br>018–2019. These estir<br>posed programme buc<br>ss on implementation of | 3 are<br>nated<br>lgets.<br>of the |

| Deci | Decision WHA70(20) Strengthening synergies between the World Health Assembly and the Conference of the Parties to the WHO Framework Convention on Tobacco Control   |  |
|------|---|--|
| А.   | Link to the general programme of work and programme budget  |  |
| 1.   | Outcome(s) in the Twelfth General Programme of Work, 2014–2019 and output(s) in the Programme budget 2016–2017 to which this decision will contribute .   |  |
|      | Twelfth General Programme of Work, 2014–2019 outcome(s):  |  |
|      | Outcomes of category 2, programme area noncommunicable diseases.  |  |
|      | Programme budget 2016–2017 output(s):   |  |
|      | Output 2.1.1. Development and/or implementation of national multisectoral policies and plans to prevent and control noncommunicable diseases accelerated;   |  |
|      | Output 2.1.2. Countries enabled to implement strategies to reduce modifiable risk factors for noncommunicable diseases (tobacco use, diet, physical inactivity and harmful use of alcohol), including the underlying social determinants. |  |
| 2.   | Brief justification for considering the decision, if there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017. Not applicable.                                 |  |
| 3.   | Estimated time frame (in years or months) for implementation of any additional deliverables.<br>Indefinite.   |  |
| B.   | Budgetary implications  |  |
| 1.   | Estimated total cost to implement the decision , in US\$ millions:<br>Zero  |  |
| 2.a. | Estimated additional budgetary requirements in the current biennium, in US\$ millions:<br>None.   |  |
| 2.b. | Resources available during the current biennium   |  |
|      | <ul> <li>Resources available in the current biennium to fund the implementation of the decision , in US\$ millions:</li> <li>Zero.</li> </ul>   |  |
|      | <ul> <li>Extent of any financing gap, in US\$ millions:</li> <li>Zero.</li> </ul>   |  |
|      | <ul> <li>Estimated resources, not yet available, which would help to close any financing gap, in US\$ millions:<br/>Not applicable.</li> </ul>  |  |
| 3.   | Estimated additional budgetary requirements in 2018–2019 (if relevant), in US\$ millions:<br>Zero   |  |
|      | Has this been included in the Proposed programme budget 2018–2019?<br>Not applicable.   |  |
| 4.   | Estimated additional budgetary requirements in future bienniums (if relevant), in US\$ millions:<br>Zero.   |  |

| Deci | sion WHA70(21) Member State mechanism on substandard and falsified medical products  |
|------|--|
| А.   | Link to the general programme of work and programme budget   |
| 1.   | Outcome(s) in the Twelfth General Programme of Work, 2014–2019 and output(s) in the Programme budget 2016–2017 to which this decision will contribute .  |
|      | Twelfth General Programme of Work, 2014–2019 outcome(s):   |
|      | Improved access to, and rational use of, safe, efficacious and quality medicines and health technologies.  |
|      | Programme budget 2016–2017 output(s):<br>Output 4.3.3. Improved quality and safety of medicines and other health technologies through norms, standards and guidelines, strengthening of regulatory systems, and prequalification.  |
| 2.   | Brief justification for considering the decision, if there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017. Not applicable.  |
| 3.   | Estimated time frame (in years or months) for implementation of any additional deliverables.   |
|      | Three months (June–August 2017), if the decision is adopted by the Health Assembly. The WHO website would be updated: to reflect the endorsement of the definitions as set out in Appendix 3 to the Annex to document A70/23; and the term "substandard/spurious/falsely-labelled/falsified/counterfeit medical products" would be replaced with "substandard and falsified medical products" in the name of the Member State Mechanism. |
| B.   | Budgetary implications   |
| 1.   | Estimated total cost to implement the decision, in US\$ millions:  |
|      | Zero cost implication.   |
| 2.a. | Estimated additional budgetary requirements in the current biennium, in US\$ millions:   |
|      | Zero cost implication.   |
| 2.b. | Resources available during the current biennium  |
|      | <ul> <li>Resources available in the current biennium to fund the implementation of the decision , in US\$ millions:</li> <li>Zero cost implication.</li> </ul>   |
|      | •  |
|      | <ul> <li>Extent of any financing gap, in US\$ millions:</li> <li>Not applicable.</li> </ul>  |
|      | <ul> <li>Estimated resources, not yet available, which would help to close any financing gap, in US\$ millions:<br/>Not applicable.</li> </ul>   |
| 3.   | Estimated additional budgetary requirements in 2018–2019 (if relevant), in US\$ millions:  |
|      | Zero cost implication.   |
|      | Has this been included in the Proposed programme budget 2018–2019?   |
|      | Not applicable.  |
| 4.   | Estimated additional budgetary requirements in future bienniums (if relevant), in US\$ millions:   |
|      | Not applicable.  |
|      |  |

| Decis | <b>Decision WHA70(22)</b> Progress in the implementation of the 2030 Agenda for Sustainable Development  |  |
|-------|--|--|
| A.    | Link to the general programme of work and programme budget   |  |
| 1.    | Outcome(s) in the Twelfth General Programme of Work, 2014–2019 and output(s) in the<br>Programme budget 2016–2017 to which this decision will contribute .<br>Twelfth General Programme of Work, 2014–2019 outcome(s):<br>Not applicable.<br>Programme budget 2016–2017 output(s):<br>Not applicable.  |  |
| 2.    | <b>Brief justification for considering the decision, if there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017.</b> At the time the current Twelfth General Programme of Work 2014–2019 and the Programme budget 2016–2017 were considered and approved, the Sustainable Development Goals had not been finalized, so they could not be included in the result structure. |  |
| 3.    | <b>Estimated time frame (in years or months) for implementation of any additional deliverables.</b><br>Progress to be reviewed and reported thereon every third year starting in 2018 until 2030.  |  |
| B.    | Budgetary implications   |  |
| 1.    | <b>Estimated total cost to implement the decision , in US\$ millions:</b><br>Zero cost implication.  |  |
| 2.a.  | <b>Estimated additional budgetary requirements in the current biennium, in US\$ millions:</b><br>Zero cost implication.  |  |
| 2.b.  | Resources available during the current biennium  |  |
|       | <ul> <li>Resources available in the current biennium to fund the implementation of the decision , in US\$ millions:<br/>Zero cost implication.</li> <li>Extent of any financing gap, in US\$ millions:<br/>Not applicable.</li> <li>Estimated resources, not yet available, which would help to close any financing gap, in US\$ millions:<br/>Not applicable.</li> </ul>  |  |
| 3.    | Estimated additional budgetary requirements in 2018–2019 (if relevant), in US\$ millions:<br>Zero cost implication.<br>Has this been included in the Proposed programme budget 2018–2019?<br>Not applicable.   |  |
| 4.    | <b>Estimated additional budgetary requirements in future bienniums (if relevant), in US\$ millions:</b><br>Not applicable.   |  |

| Deci | Decision WHA70(23) The role of the health sector in the Strategic Approach to International Chemicals<br>Management towards the 2020 goal and beyond   |  |
|------|--|--|
| A.   | Link to the general programme of work and programme budget   |  |
| 1.   | Outcome(s) in the Twelfth General Programme of Work, 2014–2019 and output(s) in the Programme budget 2016–2017 to which this decision will contribute .  |  |
|      | Twelfth General Programme of Work, 2014–2019 outcome(s):   |  |
|      | Reduced environmental threats to health.   |  |
|      | Programme budget 2016–2017 output(s):  |  |
|      | Output 3.5.1. Countries enabled to assess health risks and develop and implement policies, strategies or regulations for the prevention, mitigation and management of the health impacts of environmental and occupational risks;  |  |
|      | Output 3.5.2. Norms and standards established and guidelines developed for environmental and occupational health risks and benefits associated with, for example, air and noise pollution, chemicals, waste, water and sanitation, radiation, nanotechnologies and climate change;       |  |
|      | Output 3.5.3. Public health objectives addressed in implementation of multilateral agreements and conventions on the environment and in relation to the proposed sustainable development goals and the post-2015 development agenda.   |  |
| 2.   | Brief justification for considering the decision, if there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017. Not applicable.  |  |
| 3.   | Estimated time frame (in years or months) for implementation of any additional deliverables.<br>13 years, January 2018–December 2030.  |  |
| B.   | Budgetary implications   |  |
| 1.   | Estimated total cost to implement the decision, in US\$ millions:  |  |
|      | The road map to enhance health sector engagement in the Strategic Approach to International Chemicals Management towards the 2020 goal and beyond includes both current ongoing activities and new activities. The estimated cost of implementing the new activities is US\$ 52 million. |  |
| 2.a. | Estimated additional budgetary requirements in the current biennium, in US\$ millions:   |  |
|      | Zero.  |  |
| 2.b. | Resources available during the current biennium  |  |
|      | <ul> <li>Resources available in the current biennium to fund the implementation of the decision , in US\$ millions:</li> </ul>   |  |
|      | Not applicable. No increase in the Secretariat's level of activity on chemicals management in the current biennium is proposed.  |  |
|      | <ul> <li>Extent of any financing gap, in US\$ millions:</li> <li>Not applicable.</li> </ul>  |  |
|      | - Estimated resources, not yet available, which would help to close any financing gap, in US\$ millions:   |  |

Not applicable.

 Estimated additional budgetary requirements in 2018–2019 (if relevant), in US\$ millions: US\$ 8 million, comprising US\$ 1.8 million at headquarters plus US\$ 6.2 million at regional office level. This would provide for one additional staff member at headquarters, and would bring the staffing levels up to one post for each of the six regional offices, the majority of which currently have a fraction of one post for this function. The remainder of the increase is activity costs for headquarters and the six regional offices. Has this been included in the Proposed programme budget 2018–2019? As far as possible, the cost related to implementing this decision in the biennium 2018–2019 will be accommodated within the overall budget in the Proposed programme budget 2018–2019.
 Estimated additional budgetary requirements in future bienniums (if relevant), in US\$ millions: US\$ 8 million per biennium from 2020 to 2030, that is, US\$ 44 million.