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Committee on the Environment, Public Health and Food Safety

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COMPROMISE AMENDMENTS 1 - 42

Draft report
Pernille Weiss
(PE753.470v01-00)

Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC

Proposal for a directive
(COM(2023)0192 – C9-0143/2023 – 2023/0132(COD))

COMPROMISE AMENDMENT 1 - (ARTICLE 1)
replacing amendments 383-405
Supported by
EPP, S&D, RE, Greens/EFA, Left

Proposal for a directive
Article 1 – paragraph 1

Text proposed by the Commission	*Unchanged text included in the compromise*
1. This Directive lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of medicinal products for human use.	1. This Directive lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of medicinal products for human use.

Proposal for a directive
Article 1 – paragraph 2

Text proposed by the Commission	*Amendment*
2. This Directive shall apply to medicinal products for human use intended to be placed on the market.	2. This Directive shall apply to medicinal products for human use intended to be placed on the market ***in Member States***.

Proposal for a directive
Article 1 – paragraph 3

Text proposed by the Commission	*Unchanged text included in the compromise*
3. In addition to the products referred to in paragraph 2, Chapter XI shall also apply to starting materials, active substances, excipients and intermediate products.	3. In addition to the products referred to in paragraph 2, Chapter XI shall also apply to starting materials, active substances, excipients and intermediate products.

Proposal for a directive
Article 1 – paragraph 4

Text proposed by the Commission	*Amendment*
4. In cases where, taking into account all its characteristics, a product falls within	4. In cases where, taking into account all its characteristics, a product falls within

the definition of a 'medicinal product' and within the definition of a product covered by other Union law and there is a conflict between this Directive and other Union law, the provisions of this Directive shall prevail.	the definition of a 'medicinal product' and within the definition of a product covered by other Union law and there is a conflict between this Directive and other Union law, the provisions of this Directive shall prevail. ***In cases where, taking into account all its characteristics, questions arise as to the regulatory status of a substance or a product, the competent authority or, in the case of a centralised marketing authorisation the Agency shall consult with other relevant advisory and regulatory bodies with a view to reaching a decision on the regulatory status. In any decision on such question, the competent authority or the Agency shall make public the views of other authorities or bodies consulted.***

Proposal for a directive
Article 1 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Directive shall not apply to:	5. The Directive shall not apply to:
(a) medicinal products prepared in a pharmacy in accordance with a medical prescription for an individual patient ('magistral formula');	(a) medicinal products prepared in a pharmacy in accordance with a medical prescription for an individual patient ('magistral formula');
(b) medicinal product prepared in a pharmacy in accordance with a pharmacopoeia and intended to be supplied directly to the patients served by the pharmacy in question ('officinal formula');	(b) medicinal product prepared in a pharmacy in accordance with a pharmacopoeia and intended to be supplied directly to the patients served by the pharmacy in question ***or to another pharmacy which intends to supply the medicinal product directly to the patient*** ('officinal formula');
(c) investigational medicinal product as defined in Article 2, paragraph 5, of Regulation (EU) No 536/2014.	(c) investigational medicinal product as defined in Article 2, paragraph 5, of Regulation (EU) No 536/2014.
	(c a) medicinal product prepared in advance, in duly justified cases, by the pharmaceutical department of a hospital ('hospital formula'), supplied on medical prescription to one or several patients by

the hospital's pharmaceutical department.

Proposal for a directive
Article 1 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Medicinal products referred to in paragraph 5, point (a), may be prepared in duly justified cases in advance by a pharmacy serving a hospital, on the basis of the estimated medical prescriptions within that hospital for the following seven days.	6. Medicinal products referred to in paragraph 5, point (a) ***and (b)***, may be prepared in duly justified cases in advance by a pharmacy serving a hospital, on the basis of the estimated medical prescriptions within that hospital for the following seven days***, or when duly justified based on the stability of the product within a different time limit***.

Proposal for a directive
Article 1 – paragraph 7

Text proposed by the Commission	*Amendment*
7. Member States shall take the necessary measures to develop the production and use of medicinal products derived from substances of human origin coming from voluntary unpaid donations.	7. Member States shall take the necessary measures to develop the production and use of medicinal products derived from substances of human origin coming from voluntary unpaid donations ***in accordance with rules established under on [Regulation (EC) repealing Directives 2002/98/EC and 2004/23/EC]***.

Proposal for a directive
Article 1 – paragraph 8

Text proposed by the Commission	*Unchanged text included in the compromise*
8. This Directive and all Regulations referred to therein shall be without prejudice to the application of national legislation prohibiting or restricting the use of any specific type of substance of human origin or animal cells, or the sale, supply or use of medicinal products containing, consisting of or derived from these animal cells or substances of human origin, on	8. This Directive and all Regulations referred to therein shall be without prejudice to the application of national legislation prohibiting or restricting the use of any specific type of substance of human origin or animal cells, or the sale, supply or use of medicinal products containing, consisting of or derived from these animal cells or substances of human origin, on

grounds not dealt with in the aforementioned Union law. The Member States shall communicate the national legislation concerned to the Commission.	grounds not dealt with in the aforementioned Union law. The Member States shall communicate the national legislation concerned to the Commission.
Proposal for a directive **Article 1 – paragraph 9**	
Text proposed by the Commission	*Unchanged text included in the compromise*
9. The provisions of this Directive shall not affect the powers of the Member States' authorities either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions.	9. The provisions of this Directive shall not affect the powers of the Member States' authorities either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions.

COMPROMISE AMENDMENT 2 (ARTICLE 2)
replacing amendments 30-37; 412-474

Supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a directive
Article 2 - paragraph 1

Text proposed by the Commission	*Amendment*
By way of derogation from Article 1(1), only this Article shall apply to advanced therapy medicinal products prepared on a non-routine basis in accordance with the requirements set in paragraph 3 and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient ('advanced therapy medicinal products prepared under hospital exemption').	By way of derogation from Article 1(1), only this Article shall apply to advanced therapy medicinal products prepared a non-routine basis in accordance with the requirements set in paragraph 3 and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner ***and, where relevant, a hospital pharmacist***. ***To meet the criteria of 'non-routine basis', the exemption shall be made only*** in order to comply with an individual medical prescription for a custom-made product ***to meet the special need of*** an individual patient ('advanced therapy medicinal products prepared under hospital exemption').

Proposal for a directive
Article 2 - paragraph 2 -subparagraph 1

Text proposed by the Commission	*Unchanged text included in the compromise*
The manufacturing of an advanced therapy medicinal product prepared under hospital exemption shall require an approval by the competent authority of the Member State ('hospital exemption approval'). Member States shall notify any such approval, as well as subsequent changes, to the Agency.	The manufacturing of an advanced therapy medicinal product prepared under hospital exemption shall require an approval by the competent authority of the Member State ('hospital exemption approval'). Member States shall notify any such approval, as well as subsequent changes, to the Agency.

Proposal for a directive
Article 2 - paragraph 2 - subparagraph 2

Text proposed by the Commission	*Amendment*
The application for a hospital exemption	The application for a hospital exemption

approval shall be submitted to the competent authority of the Member State where the hospital is located.	approval shall be submitted to the competent authority of the Member State where the hospital is located. ***The application shall include evidence on quality, safety and expected efficacy of the advanced therapy medicinal products prepared under hospital exemption.***

Proposal for a directive
Article 2 - paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall ensure that advanced therapy medicinal products prepared under hospital exemption comply with ***the requirements*** equivalent to the good manufacturing practices and traceability for advanced therapy medicinal products referred to in Articles 5 and 15 of Regulation (EC) No 1394/2007[69] respectively, and with pharmacovigilance requirements equivalent to those provided for at Union level pursuant to [revised Regulation (EC) No 726/2004].	3. Member States shall ensure that advanced therapy medicinal products prepared under hospital exemption comply with ***the good pharmacy preparation practices that are adapted to hospital processes while still*** equivalent to the good manufacturing practices and traceability for advanced therapy medicinal products referred to in Articles 5 and 15 of Regulation (EC) No 1394/2007 [1] respectively, and with pharmacovigilance requirements equivalent to those provided for at Union level pursuant to [revised Regulation (EC) No 726/2004]. ***This shall include site inspections as well as traceability and pharmacovigilance plans and the evaluation of the preclinical and clinical data generated by the applicant.***

Proposal for a directive
Article 2 - paragraph 4

Text proposed by the Commission	*Amendment*
4. Member States shall ensure that data on the use, safety and the efficacy of advanced therapy medicinal products prepared under hospital exemption is collected and reported by the hospital exemption approval holder to the competent authority of the Member State at least annually. The competent authority of the Member State shall review such data	4. Member States shall ensure that data on the use, safety and the efficacy of advanced therapy medicinal products prepared under hospital exemption***, as well as any relevant data from patient follow-up for a sufficient period of time after the administration of the product,*** is collected and reported by the hospital exemption approval holder to the competent authority

[1] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 1).

and shall verify the compliance of advanced therapy medicinal products prepared under hospital exemption with the requirements referred to in paragraph 3.	of the Member State at least annually. ***The data shall be collected and reported in a structured and standardized way that enables robust, reliable and comparable results and conclusions.*** The competent authority of the Member State shall review such data and shall verify the compliance of advanced therapy medicinal products prepared under hospital exemption with the requirements referred to in paragraph 3. ***Competent authorities shall ensure that scientific and regulatory advice is provided to non-profit and academic institutions in order to ensure appropriate reporting mechanisms.***

Proposal for a directive
Article 2 - paragraph 5

Text proposed by the Commission	*Unchanged text included in the compromise*
5. If a hospital exemption approval is revoked due to safety or efficacy concerns the competent authority of the Member States that approved the hospital exemption shall inform the Agency and the competent authorities of the other Member States.	5. If a hospital exemption approval is revoked due to safety or efficacy concerns the competent authority of the Member States that approved the hospital exemption shall inform the Agency and the competent authorities of the other Member States.

Proposal for a directive
Article 2 - paragraph 6

Text proposed by the Commission	*Amendment*
6. The competent authority of the Member State shall transmit the data related to the use, safety and efficacy of an advanced therapy medicinal product prepared under the hospital exemption approval to the Agency annually. The Agency shall, in collaboration with the competent authorities of Member States and the Commission, set up and maintain a repository of that data.	6. The competent authority of the Member State shall transmit the data related to the use, safety and efficacy of an advanced therapy medicinal product prepared under the hospital exemption approval to the Agency annually. The Agency shall, in collaboration with the competent authorities of Member States and the Commission, set up and maintain ***via regular updates*** a repository of that data ***as well as of information on the authorisation, suspension or withdrawal of hospital exemption approvals, which shall be updated regularly***. ***The repository shall be publically available except personal data and commercially***

confidentail information.

Proposal for a directive
Article 2 - paragraph 7

Text proposed by the Commission	*Amendment*
7. The Commission shall adopt implementing acts to specify the following:	7. The Commission shall adopt implementing acts to specify the following:
(a) details of the application for the approval of hospital exemption referred to in paragraph 1, second subparagraph, including the evidence on quality, safety and efficacy of the advance therapy medicinal products prepared under hospital exemption for the approval and the subsequent changes;	
(b) the format for collection and reporting of data referred to in paragraph 4;	(b) the format for collection and reporting of data referred to in paragraph 4;
(c) the modalities for the exchange of knowledge between hospital exemption approval holders within the same Member State or different Member States;	(c) the modalities for the exchange of knowledge between hospital exemption approval holders within the same Member State or different Member States;
	(c a) the modalities of guidance for academic and other not-for-profit entities through the requirements of the hospital exemption clause.
(d) the modalities for preparation and use of advanced therapy medicinal products under hospital exemption on a non-routine basis.	
Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).
	The Commission shall by [OP please insert the date = 24 months after the date of entering into force of this Directive] adopt delegated acts in accordance with Article 215 to establish:
	(a) details of the application for the approval of hospital exemption referred to in paragraph 1, second subparagraph, including the evidence on quality, safety and efficacy of the advance therapy medicinal products prepared under hospital exemption for the approval and the subsequent changes;
	(b) the modalities for harmonised implementation of the preparation and use of advanced therapy medicinal products under hospital exemption on a non-routine basis;

Proposal for a directive
Article 2 - paragraph 8

Text proposed by the Commission	*Amendment*
8. The Agency shall provide to the Commission a report on the experience acquired with the hospital exemption approvals on the basis of contributions from Member States and the data referred to in paragraph 4. The first report shall be provided three years after [OP please insert the date =18 months after the date of entering into force of this Directive] and then every five years thereafter.	8. The Agency shall provide to the Commission a report on the experience acquired with the hospital exemption approvals on the basis of contributions from Member States and the data referred to in paragraph 4. ***The report shall be made publicly available.*** The first report shall be provided three years after [OP please insert the date =18 months after the date of entering into force of this Directive] and then every five years thereafter.

Proposal for a directive
Article 2 – paragraph 8 a (new)

Text proposed by the Commission	*Amendment*
	8 a. By way of derogation of paragraph 1, Member States may authorise the cross-border exchange of advanced therapy medicinal products prepared under hospital exemption in justified cases of medical need and in the absence of other solutions for the individual patient. A second medical practitioner and a hospital pharmacist in the receiving Member State shall be designated for the exclusive professional responsibility of the use and collection of follow-up data for the product. Information about the cross-border exchange shall be submitted to the competent authorities of both Member States, and shall be shared in the public repository referred to in paragraph 6 by the competent authority of the Member State of origin of the product.

COMPROMISE AMENDMENT 3 - (ARTICLE 3)
replacing amendments 475-482

Supported by
EPP, S&D, RE, ECR, Greens/EFA, Left

Proposal for a directive
Article 3 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
1. A Member State may, in order to fulfil special needs, exclude from the scope of this Directive medicinal products supplied in response to a bona fide unsolicited order, prepared in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility. However, in such case Member States shall encourage healthcare professionals and patients to report data on the safety of the use of such products to the competent authority of the Member State in accordance with Article 97.	1. A Member State may, in order to fulfil special needs, exclude from the scope of this Directive medicinal products supplied in response to a bona fide unsolicited order, prepared in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility***, or prepared in accordance with the specifications of a competent authority***. However, in such case Member States shall encourage ***and establish channels for*** healthcare professionals and patients to report data on the safety of the use of such products to the competent authority of the Member State in accordance with Article 97.

Or. en

Proposal for a directive
Article 3 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Unchanged text included in the compromise*
For allergen medicinal products supplied in accordance with this paragraph, the competent authorities of the Member State may request the submission of relevant information in accordance with Annex II.	For allergen medicinal products supplied in accordance with this paragraph, the competent authorities of the Member State may request the submission of relevant information in accordance with Annex II.

Proposal for a directive
Article 3 – paragraph 2

Text proposed by the Commission	*Unchanged text included in the compromise*
2. Without prejudice to Article 30 of [revised Regulation (EC) No 726/2004], Member States may temporarily authorise the use and distribution of an unauthorised medicinal product in response to a suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm.	2. Without prejudice to Article 30 of [revised Regulation (EC) No 726/2004], Member States may temporarily authorise the use and distribution of an unauthorised medicinal product in response to a suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm.

Or. en

Proposal for a directive
Article 3 – paragraph 3

Text proposed by the Commission	*Unchanged text included in the compromise*
3. Member States shall ensure that marketing authorisation holders, manufacturers and healthcare professionals are not subject to civil or administrative liability for any consequences resulting from the use of a medicinal product otherwise than for the authorised therapeutic indications or from the use of an unauthorised medicinal product, where such use is recommended or required by a competent authority in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm. Such provisions shall apply whether or not a national or a centralised marketing authorisation has been granted.	3. Member States shall ensure that marketing authorisation holders, manufacturers and healthcare professionals are not subject to civil or administrative liability for any consequences resulting from the use of a medicinal product otherwise than for the authorised therapeutic indications or from the use of an unauthorised medicinal product, where such use is recommended or required by a competent authority in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm. Such provisions shall apply whether or not a national or a centralised marketing authorisation has been granted.

Or. en

Proposal for a directive
Article 3 – paragraph 4

Text proposed by the Commission	*Unchanged text included in the compromise*
4. Liability for defective products, as provided for by [Council Directive	4. Liability for defective products, as provided for by [Council Directive

85/374/EEC[2] – OP please replace reference by new instrument COM(2022) 495 when adopted], shall not be affected by paragraph 3.

85/374/EEC[3] – OP please replace reference by new instrument COM(2022) 495 when adopted], shall not be affected by paragraph 3.

[2] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States, concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).

[3] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States, concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).

COMPROMISE AMENDMENT 4 - DEFINITIONS (ARTICLE 4)
replacing amendments AMs 38-52; 483-530; 533-537; 540-547
Supported by
EPP, S&D, RE, Greens/EFA, Left

Proposal for a directive
Article 4 – paragraph 1 – point 2 – point d

Text proposed by the Commission	*Unchanged text included in the compromise*
(d) chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis;	(d) chemical, e.g. elements naturally occurring chemical materials and chemical products obtained by chemical change or synthesis;

Proposal for a directive
Article 4 – paragraph 1 – point 4

Text proposed by the Commission	*Amendment*
(4) 'starting material' means any material from which an active substance is manufactured or extracted;	(4) 'starting material' means any material from which an active substance is manufactured or extracted;

Proposal for a directive
Article 4 – paragraph 1 – point 11

Text proposed by the Commission	*Amendment*
(11) 'non-clinical' means a study or a test conducted in vitro, in silico, or in chemico, or a non-human in vivo test related to the investigation of the safety and efficacy of a medicinal product. Such test may include simple and complex human cell-based assays, microphysiological systems including organ-on-chip, computer modelling, other non-human or human biology-based test methods, and animal-based tests;	(11) 'non-clinical' means a study or a test conducted in vitro***, ex vivo***, in silico, or in chemico, or a non-human in vivo test related to the investigation of the safety and efficacy of a medicinal product. Such test may include simple and complex human cell-based assays, microphysiological systems including organ-on-chip, computer modelling ***and other in silico methods***, other non-human or human biology-based test methods, ***including aquatic egg models as well as***

	invertebrate species, and animal-based tests;

Proposal for a directive
Article 4 – paragraph 1 – point 22

Text proposed by the Commission	*Amendment*
(22) 'antimicrobial' means any medicinal product with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals ***and*** antifungals;	(22) 'antimicrobial' means any medicinal product with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals**,** antifungals ***and antiprotozoals***;

Proposal for a directive
Article 4 – paragraph 1 – point 26

Text proposed by the Commission	*Amendment*
(26) 'combination of a medicinal product with a product other than a medical device' means a combination of a medicinal product with a product other than a medical device (as defined by Regulation (EU) 2017/745) and where the two are intended for use in the given combination in accordance with the summary of product characteristics;	(26) 'combination of a medicinal product with a product other than a medical device' means a combination of a medicinal product with a product other than a medical device (as defined by Regulation (EU) 2017/745 and ***Regulation (EU) 2017/746***) ***and*** where the two are intended for use in the given combination in accordance with the summary of product characteristics

Proposal for a directive
Article 4 – paragraph 1 – point 28

Text proposed by the Commission	*Unchanged text included in the compromise*
(28) 'vaccine' means any medicinal product that is intended to elicit an immune response for prevention, including post exposure prophylaxis, and for treatment of diseases caused by an infectious agent;	(28) 'vaccine' means any medicinal product that is intended to elicit an immune response for prevention, including post exposure prophylaxis, and for treatment of diseases caused by an infectious agent;

Proposal for a directive
Article 4 – paragraph 1 – point 29

Text proposed by the Commission	*Amendment*
"gene therapy medicinal product" means a medicinal product***, except vaccines against infectious diseases, that contains or consists of***:	"gene therapy medicinal product" ***means a type 1 or type 2 medicinal product;***

Proposal for a directive
Article 4 – paragraph 1 – point 29a (new)

Text proposed by the Commission	*Amendment*
	"type 1 gene therapy medicinal product" means a medicinal product, that contains or consists of a substance or a combination of substances that edit the host genome in a sequence-specific manner or that contain or consists of cells subjected to such modification;

Proposal for a directive
Article 4 – paragraph 1 – point 29b (new)

Text proposed by the Commission	*Amendment*
	"type 2 gene therapy medicinal product" means a medicinal product, except vaccines against infectious diseases, that contains or consists of a recombinant or synthetic nucleic acid used in or administered to human beings with a view to regulating, replacing or adding a genetic sequence that mediates its effect by transcription or translation of the transferred genetic materials or that contain or consists of cells subjected to these modifications;

Proposal for a directive
Article 4 – paragraph 1 – point 29 – point a

Text proposed by the Commission	*Amendment*
(a) a substance or a combination of substances ***intended to*** edit the host genome in a sequence-specific manner or that contain or consists of cells subjected to such modification; or „	***deleted***

Proposal for a directive
Article 4 – paragraph 1 – point 29 – point b

Text proposed by the Commission	*Amendment*
(b) a recombinant or synthetic nucleic acid used in or administered to human beings with a view to regulating, replacing or adding a genetic sequence that mediates its effect by transcription or translation of the transferred genetic materials or that contain or consists of cells subjected to these modifications;	***deleted***

Proposal for a directive
Article 4 – paragraph 1 – point 30 a (new)

Text proposed by the Commission	*Amendment*
	(30a) 'platform technology' means a technology or collection of technologies that is comprehensive, well-characterised, reproducible and used to support the development, manufacturing process, quality control, or testing of medicinal products or their components that rely on prior knowledge and are established under the same underlying scientific principles

Proposal for a directive
Article 4 – paragraph 1 – point 30 b (new)

Text proposed by the Commission	*Amendment*
	(30b) 'platform technology master file'

	means a document, prepared by the owner of the platform technology, that contains data of a platform technology for which the underlying scientific principles, under which the platform technology is established, have reasonable scientific certainty to remain unchanged across products and to apply regardless of components added to the platform for a medicinal product;

Proposal for a directive
Article 4 – paragraph 1 – point 31 – point a

Text proposed by the Commission	*Amendment*
(a) a method involving an industrial process which includes pooling of donations; or	(a) a method involving an industrial process which includes pooling of donations***, for purposes beyond processing of SoHOs for concentrates or pathogen inactivation***; or

Proposal for a directive
Article 4 – paragraph 1 – point 31 – point b

Text proposed by the Commission	*Unchanged text included in the compromise*
(b) a process that extracts an active ingredient from the substance of human origin or transforms the substance of human origin by changing its inherent properties;	(b) a process that extracts an active ingredient from the substance of human origin or transforms the substance of human origin by changing its inherent properties;

Proposal for a directive
Article 4 – paragraph 1 – point 33

Text proposed by the Commission	*Amendment*
(33) 'environmental risk assessment' means the evaluation of the risks to the environment, or risks to public health, posed by the release of the medicinal product in the environment from the use and disposal of the medicinal product and the identification of risk prevention, limitation and mitigation measures. For medicinal product with an antimicrobial	(33) 'environmental risk assessment' means the evaluation of the risks to the environment, or risks to public health, posed by the release of the medicinal product in the environment from the ***manufacturing,*** use and disposal of the medicinal product and the identification of risk prevention, limitation and mitigation measures. For medicinal product with an

mode of action, the ERA also encompasses an evaluation of the risk for antimicrobial resistance selection in the environment due to the manufacturing, use and disposal of that medicinal product;	antimicrobial mode of action, the ERA also encompasses an evaluation of the risk for antimicrobial resistance selection in the environment due to the manufacturing, use and disposal of that medicinal product;

Proposal for a directive
Article 4 – paragraph 1 – point 34

Text proposed by the Commission	*Amendment*
(34) 'antimicrobial resistance' means the ability of a micro-organism to survive or to grow in the presence of a concentration of an antimicrobial agent that is usually sufficient to inhibit or kill that micro-organism;	(34) 'antimicrobial resistance' means the ability of a micro-organism to survive or to grow in the presence of a concentration of an antimicrobial agent that is usually ***or was in the past*** sufficient to inhibit or kill that micro-organism;

Proposal for a directive
Article 4 – paragraph 1 – point 53

Text proposed by the Commission	*Unchanged text included in the compromise*
(53) 'micro, small and medium-sized enterprises' means micro, small and medium-sized enterprises as defined in Article 2 of Commission Recommendation 2003/361/EC[72] ;	(53) 'micro, small and medium-sized enterprises' means micro, small and medium-sized enterprises as defined in Article 2 of Commission Recommendation 2003/361/EC[72];

Proposal for a directive
Article 4 – paragraph 1 – point 70

Text proposed by the Commission	*Amendment*
(70) 'public service obligation' means to ***guarantee*** permanently an adequate range of medicinal products to meet the requirements of a specific geographical	(70) 'public service obligation' means to ***ensure*** permanently an adequate range of medicinal products to meet the requirements of a specific geographical

area and to deliver the supplies requested within a very short time over the whole of the area in question.

area and to deliver the supplies requested within a very short time over the whole of the area in question.

Proposal for a directive
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend the definitions in paragraph 1, points (2) to (6), (8), (14), (16) to ***(31),*** in the light of technical and scientific progress and taking into account definitions agreed at Union and international level without extending the scope of the definitions.	2. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend the definitions in paragraph 1, points (2) to (6), (8), (14), (16) to ***(28) and (30)*** in the light of technical and scientific progress and taking into account definitions agreed at Union and international level without extending the scope of the definitions.

COMPROMISE AMENDMENT 5 (ARTICLE 5)
replacing amendments 548 - 549
Supported by
EPP, S&D, RE, Greens/EFA, Left

Proposal for a directive
Article 5 – paragraph 1

Text proposed by the Commission	*Unchanged text included in the compromise*
1. A medicinal product shall be placed on the market of a Member State only when a marketing authorisation has been granted by the competent authorities of a Member State in accordance with Chapter III ('national marketing authorisation') or a marketing authorisation has been granted in accordance with [revised Regulation (EC) No 726/2004] ('centralised marketing authorisation').	1. A medicinal product shall be placed on the market of a Member State only when a marketing authorisation has been granted by the competent authorities of a Member State in accordance with Chapter III ('national marketing authorisation') or a marketing authorisation has been granted in accordance with [revised Regulation (EC) No 726/2004] ('centralised marketing authorisation').

Proposal for a directive
Article 5 – paragraph 2

Text proposed by the Commission	*Unchanged text included in the compromise*
2. When an initial marketing authorisation has been granted in accordance with paragraph 1, any development concerning the medicinal product covered by the authorisation such as additional therapeutic indication, strengths, pharmaceutical forms, administration routes, presentations, as well as any variations of the marketing authorisation shall also be granted an authorisation in accordance with paragraph 1 or be included in the initial marketing authorisation. All those marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the marketing authorisations applications under Articles 9 to 12, including as regards the expiry of the regulatory data protection period for	2. When an initial marketing authorisation has been granted in accordance with paragraph 1, any development concerning the medicinal product covered by the authorisation such as additional therapeutic indication, strengths, pharmaceutical forms, administration routes, presentations, as well as any variations of the marketing authorisation shall also be granted an authorisation in accordance with paragraph 1 or be included in the initial marketing authorisation. All those marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the marketing authorisations applications under Articles 9 to 12, including as regards the expiry of the regulatory data protection period for

applications using a reference medicinal product.	applications using a reference medicinal product.
	Or. en

COMPROMISE AMENDMENT 6 (ARTICLE 6)
replacing amendments 53; 550-562
Supported by
EPP, S&D, RE, Greens/EFA, Left

Proposal for a directive
Article 6 – paragraph 1

Text proposed by the Commission	*Unchanged text included in the compromise*
1. In order to obtain a marketing authorisation, an electronic marketing authorisation application shall be submitted to the competent authority concerned in a common format. The Agency shall make available such format after consultation with the Member States.	1. In order to obtain a marketing authorisation, an electronic marketing authorisation application shall be submitted to the competent authority concerned in a common format. The Agency shall make available such format after consultation with the Member States.
	Or. en

Proposal for a directive
Article 6 – paragraph 2

Text proposed by the Commission	*Unchanged text included in the compromise*
2. The marketing authorisation application shall include the particulars and documentation listed in Annex I, submitted in accordance with Annex II.	2. The marketing authorisation application shall include the particulars and documentation listed in Annex I, submitted in accordance with Annex II.
	Or. en

Proposal for a directive
Article 6 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. A marketing authorisation may be granted for a medicinal product on the basis of an active substance master file, an additional quality master file or a platform

technology master file where this exists and is referred to in the application.

Or. en

Proposal for a directive
Article 6 – paragraph 3

Text proposed by the Commission	*Unchanged text included in the compromise*
3. The documents and information concerning the results of the pharmaceutical and non-clinical tests and the clinical studies referred to in Annex I shall be accompanied by detailed summaries in accordance with Article 7 and supportive raw data.	3. The documents and information concerning the results of the pharmaceutical and non-clinical tests and the clinical studies referred to in Annex I shall be accompanied by detailed summaries in accordance with Article 7 and supportive raw data.

Or. en

Proposal for a directive
Article 6 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The risk management system referred to in Annex I shall be proportionate to the identified risks and the potential risks of the medicinal product, and the need for post-authorisation safety data.	4. The risk management system referred to in Annex I shall be proportionate to the identified risks and the potential risks ***to human health or the environment*** of the medicinal product, and the need for post-authorisation safety data.

Or. en

Proposal for a directive
Article 6 – paragraph 5 – subparagraph 1

Text proposed by the Commission	*Unchanged text included in the compromise*
The marketing authorisation application for a medicinal product that is not authorised in the Union at the time of entry into force of this Directive and for new therapeutic indications, including paediatric indications, new pharmaceutical forms, new strengths and new routes of administration of authorised medicinal products which are protected either by a supplementary	The marketing authorisation application for a medicinal product that is not authorised in the Union at the time of entry into force of this Directive and for new therapeutic indications, including paediatric indications, new pharmaceutical forms, new strengths and new routes of administration of authorised medicinal products which are protected either by a supplementary

protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a patent which qualifies for the granting of the supplementary protection certificate, shall include one of the following:	protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a patent which qualifies for the granting of the supplementary protection certificate, shall include one of the following:
(a) the results of all studies performed and details of all information collected in compliance with an agreed paediatric investigation plan;	(a) the results of all studies performed and details of all information collected in compliance with an agreed paediatric investigation plan;
(b) a decision of the Agency granting a product-specific waiver pursuant to Article 75(1) of [revised Regulation No (EC) 726/2004];	(b) a decision of the Agency granting a product-specific waiver pursuant to Article 75(1) of [revised Regulation No (EC) 726/2004];
(c) a decision of the Agency granting a class waiver pursuant to Article 75(2) of [revised Regulation No (EC) 726/2004];	(c) a decision of the Agency granting a class waiver pursuant to Article 75(2) of [revised Regulation No (EC) 726/2004];
(d) a decision of the Agency granting a deferral pursuant to Article 81 of [revised Regulation No (EC) 726/2004];	(d) a decision of the Agency granting a deferral pursuant to Article 81 of [revised Regulation No (EC) 726/2004];
(e) a decision of the Agency taken in consultation with the Commission pursuant to Article 83 of [revised Regulation No (EC) 726/2004] to temporarily derogate from the provision referred to in points (a) to (d) above in case of health emergencies.	(e) a decision of the Agency taken in consultation with the Commission pursuant to Article 83 of [revised Regulation No (EC) 726/2004] to temporarily derogate from the provision referred to in points (a) to (d) above in case of health emergencies.
	Or. en

Proposal for a directive
Article 6 – paragraph 5 – subparagraph 2

Text proposed by the Commission	*Unchanged text included in the compromise*
The documents submitted under points (a) to (d) shall, cumulatively, cover all subsets of the paediatric population.	The documents submitted under points (a) to (d) shall, cumulatively, cover all subsets of the paediatric population.
	Or. en

Proposal for a directive
Article 6 – paragraph 5 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	In the absence of a paediatric investigation plan according to point (a), or where in this regard a comparative study was not carried out, a justification shall be submitted and where relevant also evidence obtained from post-marketing long-term studies.

Or. en

Proposal for a directive
Article 6 – paragraph 6

Text proposed by the Commission	*Unchanged text included in the compromise*
6. The provisions of paragraph 5 shall not apply to medicinal products authorised under Articles 9, 11, 13, Articles 125 to 141 and medicinal products authorised under Articles 10 and 12 which are not protected either by a supplementary protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a patent which qualifies for the granting of the supplementary protection certificate.	6. The provisions of paragraph 5 shall not apply to medicinal products authorised under Articles 9, 11, 13, Articles 125 to 141 and medicinal products authorised under Articles 10 and 12 which are not protected either by a supplementary protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a patent which qualifies for the granting of the supplementary protection certificate.

Or. en

Proposal for a directive
Article 6 – paragraph 7 – subparagraph 1

Text proposed by the Commission	*Unchanged text included in the compromise*
7. The marketing authorisation applicant shall demonstrate that the principle of replacement, reduction and refinement of animal testing for scientific purposes has been applied in compliance with Directive 2010/63/EU with regard to any animal study conducted in support of the application.	7. The marketing authorisation applicant shall demonstrate that the principle of replacement, reduction and refinement of animal testing for scientific purposes has been applied in compliance with Directive 2010/63/EU with regard to any animal study conducted in support of the application.

Or. en

Proposal for a directive
Article 6 – paragraph 7 – subparagraph 2

Text proposed by the Commission	*Amendment*
The marketing authorisation applicant shall not carry out animal testing in case scientifically satisfactory non-animal testing methods are available.	The marketing authorisation applicant shall not carry out animal testing in case scientifically satisfactory non-animal testing methods are available. ***Where scientifically satisfactory non-animal testing methods are not available, applicants that use animal testing shall ensure that the principle of replacement, reduction and refinement of animal testing for scientific purposes has been applied in compliance with Directive 2010/63/EU with regard to any animal study conducted for the purpose of supporting the application.***

[No AMs on art 7 and 8]

COMPROMISE AMENDMENT 9 (ARTICLES 9-13)
replacing amendments 563-573
Supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a directive
Article 9

Text proposed by the Commission	*Unchanged text included in the compromise*
9. By way of derogation from Article 6(2), the applicant for a marketing authorisation for a generic medicinal product shall not be required to provide to the competent authorities the results of non-clinical tests and of clinical studies if equivalence of the generic medicinal product with the reference medicinal product is demonstrated.[...]	9. By way of derogation from Article 6(2), the applicant for a marketing authorisation for a generic medicinal product shall not be required to provide to the competent authorities the results of non-clinical tests and of clinical studies if equivalence of the generic medicinal product with the reference medicinal product is demonstrated.[...]

Or. en

Proposal for a directive
Article 10 – paragraph 1

Text proposed by the Commission	*Amendment*
In cases where the medicinal product does not fall within the definition of a generic medicinal product or has changes in strength, pharmaceutical form, route of administration or therapeutic indications, compared to the reference medicinal product, the results of the appropriate non-clinical tests or clinical studies shall be provided to the competent authorities to the extent necessary to establish a scientific bridge to the data relied upon in the marketing authorisation for the reference medicinal product, and to demonstrate the safety and efficacy profile of the hybrid medicinal product.	In cases where the medicinal product does not fall within the definition of a generic medicinal product or has changes in strength, pharmaceutical form, route of administration or therapeutic indications, compared to the reference medicinal product, the results of the appropriate non-clinical tests or clinical studies shall be provided to the competent authorities to the extent necessary to establish a scientific bridge to the data relied upon in the marketing authorisation for the reference medicinal product, and to demonstrate the safety and efficacy profile of the hybrid medicinal product. ***The Agency shall adopt guidelines on the appropriate tests and clinical studies for marketing authorisation of hybrid medicinal products.***

Or. en

Proposal for a directive
Article 11 – title

Text proposed by the Commission	*Unchanged text included in the compromise*
Applications concerning biosimilar medicinal products	Applications concerning biosimilar medicinal products

Or. en

Proposal for a directive
Article 11 – paragraph 1

Text proposed by the Commission	Unchanged text included in the compromise
For a biological medicinal product that is similar to a reference biological medicinal product (‘biosimilar medicinal product’), the results of appropriate comparability tests and studies shall be provided to the competent authorities. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex II and the related detailed guidelines. The results of other tests and studies from the reference medicinal product's dossier shall not be provided.	For a biological medicinal product that is similar to a reference biological medicinal product (‘biosimilar medicinal product’), the results of appropriate comparability tests and studies shall be provided to the competent authorities. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex II and the related detailed guidelines. The results of other tests and studies from the reference medicinal product's dossier shall not be provided.

Or. en

Or. en

Proposal for a directive
Article 12 – paragraph 1

Text proposed by the Commission	*Amendment*
In cases where a biosimilar medicinal product has changes in strength, pharmaceutical form, route of administration or therapeutic indications, compared to the reference biological medicinal product (‘bio-hybrid’), the results of the appropriate non-clinical tests or clinical studies shall be provided to the	In cases where a biosimilar medicinal product has changes in strength, pharmaceutical form, route of administration or therapeutic indications, compared to the reference biological medicinal product (‘bio-hybrid’), the results of the appropriate non-clinical tests or clinical studies shall be provided to the

competent authorities to the extent necessary to establish a scientific bridge to the data relied upon in the marketing authorisation for the reference biological medicinal product, and to demonstrate the safety or efficacy profile of the biosimilar medicinal product.	competent authorities to the extent necessary to establish a scientific bridge to the data relied upon in the marketing authorisation for the reference biological medicinal product, and to demonstrate the safety or efficacy profile of the biosimilar medicinal product. ***The Agency shall adopt guidelines on the appropriate tests and clinical studies for marketing authorisation of bio-hybrid medicinal products.***
	Or. en

Proposal for a directive
Article 13 – paragraph 1

Text proposed by the Commission	*Amendment*
In cases where no reference medicinal product is or has been authorised for the active substance of the medicinal product concerned**,** the applicant shall, by way of derogation from Article 6(2), not be required to provide the results of non-clinical tests or clinical studies if the applicant can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Union for the same therapeutic use and route of administration and for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex II. In that event, the test and trial results shall be replaced by appropriate bibliographic data in the form of scientific literature.	In cases where no reference medicinal product is or has been authorised for the active substance of the medicinal product concerned, the applicant shall, by way of derogation from Article 6(2), not be required to provide the results of non-clinical tests or clinical studies if the applicant can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Union the same therapeutic use and route of administration and for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex II. In that event, the test and trial results shall be replaced by appropriate bibliographic data in the form of scientific literature. ***A justification shall be provided with regard to the relevance of this literature for the medicinal product.***
	Or. en

[No AMs on art 14]

COMPROMISE AMENDMENT 10 (ARTICLES 15 & 16)
replacing amendments 54-58, 574-581

Supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a directive
Article 15 – title

Text proposed by the Commission	*Amendment*
Fixed dose combination medicinal product**,** platform ***technologies*** and multi-medicinal product packages	Fixed dose combination medicinal product, platform ***marketing authorisation*** and multi-medicinal product packages

Proposal for a directive
Article 15 – paragraph 1

Text proposed by the Commission	*Unchanged text included in the compromise*
1. Where justified for therapeutic purposes, a marketing authorisation may be granted for a fixed dose combination medicinal product.	1. Where justified for therapeutic purposes, a marketing authorisation may be granted for a fixed dose combination medicinal product.

Or. en

Proposal for a directive
Article 15 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
Where justified for therapeutic purposes, a marketing authorisation may***, in exceptional circumstances,*** be granted for a medicinal product comprised of a fixed component and a variable component that is pre-defined in order to, where appropriate, target different variants of an infectious agent or, where necessary, to tailor the medicinal product to characteristics of an individual patient or a group of patients ***(‘***platform ***technology’)***.	Where justified for therapeutic purposes, a marketing authorisation may be granted for a medicinal product comprised of a fixed component and a variable component that is pre-defined in order to, where appropriate, target different variants of an infectious agent or, where necessary, to tailor the medicinal product to characteristics of an individual patient or a group of patients ***(‘***platform ***marketing authorisation’)***.

Proposal for a directive
Article 15 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Unchanged text included in the compromise*
An applicant that intends to submit an application for a marketing authorisation for such a medicinal product shall seek, in advance, the agreement concerning the submission of such application by the competent authority concerned.	An applicant that intends to submit an application for a marketing authorisation for such a medicinal product shall seek, in advance, the agreement concerning the submission of such application by the competent authority concerned.

Or. en

Proposal for a directive
Article 15 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Unchanged text included in the compromise*
Where justified for public health reasons and when the active substances cannot be combined within a fixed dose combination medicinal product, a marketing authorisation may, in exceptional circumstances, be granted to a multi-medicinal product package.	Where justified for public health reasons and when the active substances cannot be combined within a fixed dose combination medicinal product, a marketing authorisation may, in exceptional circumstances, be granted to a multi-medicinal product package.

Or. en

Proposal for a directive
Article 15 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Unchanged text included in the compromise*
An applicant that intends to submit a an application for a marketing authorisation for such a medicinal product shall seek, in advance, the agreement concerning the submission of such application by the competent authority concerned.	An applicant that intends to submit a an application for a marketing authorisation for such a medicinal product shall seek, in advance, the agreement concerning the submission of such application by the competent authority concerned.

Or. en

Article 16 – paragraph 1

Text proposed by the Commission	*Amendment*
1. A marketing authorisation shall be required for radionuclide generators, kits, and radionuclide precursors, unless they are used as starting material, active substance or intermediate of radiopharmaceuticals covered by a marketing authorisation under Article 5(1).	1. A marketing authorisation shall be required for radionuclide generators, kits ***for radiopharmaceutical preparations ('kits')***, and radionuclide precursors, unless they are used as starting material, active substance or intermediate of radiopharmaceuticals covered by a marketing authorisation under Article 5(1).

COMPROMISE AMENDMENT 12 (ARTICLE 17)
replacing amendments 582-597

Supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Article 17 – paragraph 1 - point a

Text proposed by the Commission	*Amendment*
(a) an antimicrobial stewardship plan as referred to in Annex I;	(a) an antimicrobial stewardship ***and access*** plan as referred to in Annex I;

Article 17 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. The competent authority of the Member State shall, following the granting of a marketing authorisation, make publicly available the documents referred to in paragraph 1.

Proposal for a directive
Article 17 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The competent authority ***may*** impose obligations on the marketing	2. ***The competent authority shall review the information submitted***

authorisation holder if it finds the risk mitigation measures contained in the antimicrobial stewardship plan unsatisfactory.	***according to paragraph 1 point b.*** The competent authority ***shall*** impose obligations on the marketing authorisation holder if it finds the risk mitigation measures contained in the antimicrobial stewardship ***and access*** plan unsatisfactory.
	Or. en

Proposal for a directive
Article 17 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The marketing authorisation holder shall ensure that the pack size of the antimicrobial corresponds to the usual posology and duration of treatment.	3. ***The marketing authorisation holder shall ensure, wherever possible, that the antimicrobial may be dispensed per unit in a number corresponding to the quantities corresponding to the duration of treatment. If an antimicrobial cannot be dispensed per unit,*** the marketing authorisation holder shall ensure that the pack size of the antimicrobial corresponds to the usual posology and duration of treatment.

COMPROMISE AMENDMENT 13 (ARTICLE 18)
replacing amendments 598-601; ITRE 13-15

Supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a directive
Article 18 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
As part of the assessment, in accordance with Article 29, of the integral combination of a medicinal product and a medical device the competent authorities shall assess the benefit-risk balance of the integral combination of a medicinal product and a medical device, taking into account the suitability of the use of the medicinal product together with the medical device.	As part of the assessment, in accordance with Article 29, of the integral combination of a medicinal product and a medical device the competent authorities shall assess the benefit-risk balance of the integral combination of a medicinal product and a medical device, taking into account the suitability of the use of the medicinal product together with the medical device***, where relevant particularly for paediatric patients, including aspects such as storage, assembly, cleanliness, and the technique required for application or intake***. Or. en

COMPROMISE AMENDMENT 14 (ARTICLES 19-21)
replacing amendments 602-606

Supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

[COM text as CA]

COMPROMISE AMENDMENT 15 - ENVIRONMENTAL RISK ASSESSMENT (ARTICLE 4, PARA 1, POINT 41, ARTICLE 22 AND ARTICLE 47, PARA 1 POINT D)
replacing amendments 59-68, 80-81, 531, 532, 607-652, 758-766

Supported by
EPP, S&D, RE, Greens/EFA, Left

Article 4 – paragraph 1 – point 41 [COMPROMISE is the COM TEXT)

Text proposed by the Commission	*Unchanged text included in the compromise*
(41) 'benefit-risk balance' means an evaluation of the positive therapeutic effects of the medicinal product in relation to the risks referred to in point (35)**,** subpoint (a);	(41) 'benefit-risk balance' means an evaluation of the positive therapeutic effects of the medicinal product in relation to the risks referred to in point (35), subpoint (a);

Article 22

Article 22 – paragraph 1

Text proposed by the Commission	*Amendment*
1. When preparing the environmental risk assessment ('ERA') to be submitted pursuant to Article 6(2), the applicant shall take into account the scientific guidelines on the environmental risk assessment of medicinal products for human use as referred to in paragraph ***6***, or provide the reasons for any divergence from the scientific guidelines to the Agency or, as appropriate to the competent authority of the Member State concerned, in a timely manner. Where available, the applicant shall take into account existing ERAs performed under other Union legislation.	1. When preparing the environmental risk assessment ('ERA') to be submitted pursuant to Article 6(2), the applicant shall take into account the scientific guidelines on the environmental risk assessment of medicinal products for human use as referred to in paragraph ***5***, or provide the ***duly justified*** reasons for any divergence from the scientific guidelines to the Agency or, as appropriate to the competent authority of the Member State concerned, in a timely manner. Where available, the applicant shall take into account existing ERAs performed under other Union legislation.

Article 22 – paragraph 2 – introductory part

Text proposed by the Commission	*Unchanged text included in the compromise*
2. The ERA shall indicate whether the medicinal product or any of its ingredients or other constituents is one of the following substances according to the criteria of Annex I to the Regulation (EC) No 1272/2008:	2. The ERA shall indicate whether the medicinal product or any of its ingredients or other constituents is one of the following substances according to the criteria of Annex I to the Regulation (EC) No 1272/2008:

Article 22 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Unchanged text included in the compromise*
or are endocrine active agents.	or are endocrine active agents.

Article 22 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The applicant shall also include in the ERA risk mitigation measures to avoid or where it is not possible, limit emissions to air, water and soil of pollutants listed in Directive 2000/60/EC, Directive 2006/118/EC, Directive 2008/105/EC and Directive 2010/75/EU. The applicant shall provide detailed explanation that the proposed mitigation measures are appropriate and sufficient to address the identified risks to the environment.	3. The applicant shall also include in the ERA risk mitigation measures to avoid or where it is not possible, limit emissions to air, water and soil of pollutants listed in Directive 2000/60/EC, Directive 2006/118/EC, Directive 2008/105/EC and Directive 2010/75/EU ***during the manufacture, use and disposal of the medicine***. The applicant shall provide detailed explanation that the proposed mitigation measures are appropriate and sufficient to address the identified risks to the environment. ***When necessary, it shall also include information on available techniques and on the techniques that will be used to reduce the discharges and emissions of the medicinal product, in particular those occurring in manufacturing effluents before these effluents leave the manufacturing sites.***

Article 22 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The ERA for antimicrobials shall include an evaluation of the risk for antimicrobial resistance selection in the environment due to the ***entire***	4. The ERA for antimicrobials shall include an evaluation of the risk for antimicrobial resistance selection in the environment due to the ***entire***

manufacturing ***supply chain inside and outside*** the Union, use and disposal of the antimicrobial taking into account, where relevant, the existing international standards that have established predicted no effect concentration (PNECs) specific for antibiotics.	manufacturing ***supply chain inside and outside*** the Union, use and disposal***, including by healthcare professionals and patients,*** of the antimicrobial taking into account, where relevant, the existing international standards that have established predicted no effect concentration (PNECs) specific for antibiotics.

Or. en

Proposal for a directive
Article 22 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. By ... [12 months after the date of entry into force of this Directive], the Commission shall, after having consulted the Agency, the European Environmental Agency (EEA), and the ECDC, issue guidelines on how to conduct the ERA for antimicrobials other than antibiotics.

Article 22 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Agency shall draw up scientific guidelines in accordance with Article 138 of [revised Regulation No (EC) 726/2004], to specify technical details regarding the ERA requirements for medicinal products for human use. Where appropriate, the Agency shall consult the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) ***and*** the European Environmental Agency (EEA) on the drafting of these scientific guidelines.	5. The Agency shall draw up scientific guidelines in accordance with Article 138 of [revised Regulation No (EC) 726/2004], to specify technical details regarding the ERA requirements for medicinal products for human use. Where appropriate, the Agency shall consult the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA)***,*** the European Environmental Agency (EEA)***, the European Centre of Disease Control (ECDC) and other relevant stakeholders, including drinking water and wastewater operators,*** on the drafting of these scientific guidelines.

Article 22 – paragraph 6 – subparagraph 1

Text proposed by the Commission	*Unchanged text included in the compromise*
The marketing authorisation holder shall update the ERA with new information without undue delay to the relevant competent authorities, in accordance with Article 90(2), if new information pertaining to the assessment criteria referred to in Article 29 becomes available and could lead to a change of the conclusions of the ERA. The update shall include any relevant information from environmental monitoring, including monitoring under Directive 2000/60/EC, from eco-toxicity studies, from new or updated risk assessments under other Union legislation, as referred to in paragraph 1, and environmental exposure data.	The marketing authorisation holder shall update the ERA with new information without undue delay to the relevant competent authorities, in accordance with Article 90(2), if new information pertaining to the assessment criteria referred to in Article 29 becomes available and could lead to a change of the conclusions of the ERA. The update shall include any relevant information from environmental monitoring, including monitoring under Directive 2000/60/EC, from eco-toxicity studies, from new or updated risk assessments under other Union legislation, as referred to in paragraph 1, and environmental exposure data.

Article 22 – paragraph 6 – subparagraph 2

Text proposed by the Commission	*Amendment*
For an ERA conducted prior to [OP please insert the date = 18 months after the date of entering into force of this Directive], the competent authority shall request the marketing authorisation holder to update the ERA if missing information has been identified for medicinal products potentially harmful to the environment.	For an ERA conducted prior to [OP please insert the date = 18 months after the date of entering into force of this Directive], the competent authority shall request the marketing authorisation holder to update the ERA ***to include risk mitigation measures as referred to in paragraph 3. The competent authority shall also request the marketing authorisation holder to update the ERA*** if missing information has been identified for medicinal products potentially harmful to the environment.

Article 22 – paragraph 7

Text proposed by the Commission	*Amendment*
7. For medicinal products referred to in Articles 9 to 12, the applicant may refer to ERA studies conducted for the reference medicinal product when preparing the ERA.	7. For medicinal products referred to in Articles 9 to 12, the applicant may refer to ERA studies conducted for the reference medicinal product when preparing the ERA ***and shall provide any other data and the scientific guidelines as referred to in the***

first paragraph.

Article 22 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7 a. The outcome of the assessment of the ERA, including the data submitted by the marketing authorisation holder, shall be made publicly available by the Agency or, as appropriate, by the competent authority of the Member State.

Article 22 – paragraph 7 b (new)

Text proposed by the Commission	*Amendment*
	7 b. When making public the information on the ERA, including the antimicrobial stewardship and access plan referred to in Article 17, the competent authority shall delete any information of a commercially confident nature.

Article 47

Article 47 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) the environmental risk assessment is incomplete or insufficiently substantiated by the applicant or if the risks identified in the environmental risk assessment have not been sufficiently addressed by the applicant;	(d) the environmental risk assessment is incomplete or insufficiently substantiated, ***and the reason for the incomplete nature of the ERA is not duly justified and substantiated*** by the applicant, or if the risks identified in the environmental risk assessment have not been sufficiently addressed by the applicant ***or by the risk mitigation measures by the applicant, in accordance Article 22 (3) of this Directive;***

Article 47 – paragraph 1 – point d, second subparagraph

Text proposed by the Commission	*Amendment*
	For medicinal products where the reference medicinal product received its first marketing authorisation before 30 October 2005, the national marketing

authorisation may be refused if the view is taken that the environmental risk assessment is incomplete or insufficiently substantiated and they can be identified as potentially harmful to the environment.

COMPROMISE AMENDMENT 16 (ARTICLE 23)
replacing amendments 69-71, 653-668

Supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Article 23 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
By [OP please insert the date = ***30*** months after the date of the entry into force of this Directive] the Agency shall, after consultation with the competent authorities of the Member States, the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA), establish a programme for the ERA to be submitted in accordance with Article 22 of the medicinal products authorised before 30 October 2005 that have not been subject to any ERA and that the Agency has identified as potentially harmful to the environment in accordance with paragraph 2.	By [OP please insert the date = ***24*** months after the date of the entry into force of this Directive] the Agency shall, after consultation with the competent authorities of the Member States***, the European Centre for Disease Prevention and Control (ECDC)***, the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA), establish a programme for the ERA to be submitted in accordance with Article 22 of the medicinal products authorised before 30 October 2005 that have not been subject to any ERA and that the Agency has identified as potentially harmful to the environment in accordance with paragraph 2.

Proposal for a directive
Article 23 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Unchanged text included in the compromise*
This programme shall be made publicly available by the Agency.	This programme shall be made publicly available by the Agency.

Proposal for a directive
Article 23 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Agency shall set the scientific criteria for the identification of the medicinal products as potentially harmful to the environment and for the prioritisation of their ERA, using a risk based approach. For this task, the Agency may request from marketing authorisation holders the submission of relevant data or information.	2. The Agency shall set the scientific criteria for the identification of the medicinal products as potentially harmful to the environment and for the prioritisation of their ERA, using a risk based approach. For this task, the Agency ***shall consult relevant stakeholders, including actors managing residues from medicinal products and their production in the environment and*** may request from marketing authorisation holders the submission of relevant data or information.

Or. en

Proposal for a directive
Article 23 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The marketing authorisation holders for medicinal products identified in the programme referred to in paragraph 1 shall submit the ERA to the Agency. The outcome of the assessment of the ERA including the data submitted by the marketing authorisation holder shall be made publicly available by the Agency.	3. The marketing authorisation holders for medicinal products identified in the programme referred to in paragraph 1 shall submit the ERA to the Agency. The outcome of the assessment of the ERA including the data ***and a summary of ERA studies and their results as*** submitted by the marketing authorisation holder shall be made publicly available by the Agency.

Or. en

Proposal for a directive
Article 23 – paragraph 4

Text proposed by the Commission	*Unchanged text included in the compromise*
4. Where there are several medicinal products identified in the programme referred to in paragraph 1 that contain the same active substance and that are expected to pose the same risks to the environment, the competent authorities of the Member States or the Agency shall encourage the marketing authorisation holders to conduct joint studies for the ERA, to minimise unnecessary duplication	4. Where there are several medicinal products identified in the programme referred to in paragraph 1 that contain the same active substance and that are expected to pose the same risks to the environment, the competent authorities of the Member States or the Agency shall encourage the marketing authorisation holders to conduct joint studies for the ERA, to minimise unnecessary duplication

of data and use of animals.	of data and use of animals.

COMPROMISE AMENDMENT 17 (ARTICLE 24)
replacing amendments 72-74, 669-674, ITRE 16-18

Supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a directive
Article 24 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Agency shall, in collaboration with the competent authorities of the Member States, set-up an active substance based review system of ERA data ('ERA monographs') for authorised medicinal products. An ERA monograph shall include a comprehensive set of physiochemical data, fate data and effect data based on an assessment of a competent authority.	1. The Agency shall, in collaboration with the competent authorities of the Member States, set-up an active substance based review system of ERA data ('ERA monographs') for authorised medicinal products ***and publicise relevant information about this system***. An ERA monograph shall include a comprehensive set of physiochemical data, fate data and effect data based on an assessment of a competent authority.

Proposal for a directive
Article 24 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The setting-up of the system of ERA monographs shall be based on a risk-based prioritisation of active substances.	2. The setting-up of the system of ERA monographs shall be based on a risk-based prioritisation of active substances ***and data requirements***.

Proposal for a directive
Article 24 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Agency in cooperation with the competent authorities of the Member States shall conduct a proof-of-concept pilot of ERA monographs to be completed within ***three years*** after entering into force of this	4. The Agency in cooperation with the competent authorities of the Member States shall conduct a proof-of-concept pilot of ERA monographs to be completed within ***30 months*** after entering into force of this

Directive.	Directive***, while taking into account outcomes from relevant Union initiatives with regard to animal testing.***

COMPROMISE AMENDMENT 18 - SPECIFIC DOSSIER REQUIREMENTS OTHER THAN RISK MANAGEMENT PLAN AND ERA (ARTICLES 25-27) AND ADAPTED DOSSIER REQUIREMENTS (ARTICLE 28)
replacing amendments AMs 75-78; 675-694

Supported by
EPP, S&D, RE, Greens/EFA, Left

Article 25 - COM text proposed as compromise

Article 26

Proposal for a directive
Article 26 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Marketing authorisation applicants may, instead of submitting the relevant data on an active substance other than a chemical active substance, or on other substances present or used in the manufacture of a medicinal product, required in accordance with Annex II, rely on an additional quality master file, an additional quality master file certificate granted by the Agency in accordance with this Article ('additional quality master file certificate'), or a certificate confirming that the quality of that substance is suitably controlled by the relevant monograph of the European Pharmacopeia.	Marketing authorisation applicants may, instead of submitting the relevant data on an active substance other than a chemical active substance, or on other substances present or used in the manufacture of a medicinal product**,** required in accordance with Annex II, rely on an additional quality master file, an additional quality master file certificate granted by the Agency in accordance with this Article ('additional quality master file certificate'), or a certificate confirming that the quality of that substance is suitably controlled by the relevant monograph of the European Pharmacopeia.

Article 26 – paragraph 3 – point b

Text proposed by the Commission	*Amendment*
(b) additional quality master files for which a certificate may be used in order to provide specific information on the quality of a substance present or used in the manufacture of a medicinal product;	(b) additional quality master files for which a certificate may be used in order to provide specific information on the quality of a substance***, preparation or other material*** present or used in the manufacture of a medicinal product***, including cell therapies and gene therapies***;

Article 26 a (new)

Text proposed by the Commission	*Amendment*
	Article 26a
	Additional platform technology master files
	1. Marketing authorisation applicants may, instead of submitting the relevant data related to a platform technology, rely on an additional platform technology master file or an additional platform technology master file certificate granted by the Agency in accordance with this Article ('additional platform technology master file certificate').
	2. Article 25(1) to (5), (7) and (8) shall also apply mutatis mutandis to additional platform technology master file certification.
	3. To adequately describe the platform technology master file, appropriate information as laid down in scientific guidelines published by the Agency shall be provided.
	4. The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement this Directive by specifying:
	(a) the rules governing the content and format of the application for an additional platform technology master file certificate;
	(b) additional platform technology master files for which a certificate may be used in order to provide specific information on the platform technology on the basis of which a substance present or used in the manufacture of a medicinal product is manufactured;
	(c) the rules for the examination of applications for making publicly available of additional platform technology master file certificates;
	(d) the rules for introducing changes to the additional platform technology master file and the certificate;
	(e) the rules on access for competent authorities of the Member State to the additional platform technology master file and its assessment report;

(f) the rules on access for marketing authorisation applicants and marketing authorisation holders relying on a additional platform technology master file certificate to the additional platform technology master file and to the assessment report.

5. The Agency shall develop and publish scientific guidelines on the requirements for an additional platform technology master file.

6. If requested by the Agency, the manufacturer of a substance present or used in the manufacturing of a medicinal product for which an application for an additional platform technology master file certificate has been submitted or the additional platform technology master file certificate holder shall undergo an inspection to verify the information contained in the application or the master file.

If the holder of the additional platform technology master file refuses to undergo such an inspection, the Agency may suspend or terminate the application for the additional platform technology master file certificate.

Article 27

Article 27 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
If a colour used in medicinal product is removed from the Union list of authorised food additives, on the basis of the scientific opinion of the European Food Safety Authority ('EFSA'), the Agency shall, on the request of the Commission or on its own initiative, without undue delay issue a scientific opinion as regards the use of the colour concerned in medicinal product, taking into account the opinion of the EFSA ***if relevant***. The opinion of the Agency shall be adopted by the Committee for Medicinal Products for Human Use.	If a colour used in medicinal product is removed from the Union list of authorised food additives, on the basis of the scientific opinion of the European Food Safety Authority ('EFSA'), the Agency shall, on the request of the Commission or on its own initiative, without undue delay issue a scientific opinion as regards the use of the colour concerned in medicinal product, taking into account the opinion of the EFSA. The opinion of the Agency shall be adopted by the Committee for Medicinal Products for Human Use.

Or. en

Article 27 – paragraph 5

Text proposed by the Commission	*Amendment*
5. If a colour has been removed from the Union list of authorised food additives for reasons that do not require an EFSA opinion, the Commission shall decide on the use of the colour concerned in medicinal products and, where applicable, include it in the list of colours permitted for use in medicinal products referred to in paragraph 3. The Commission ***may***, in such cases, request the opinion from the Agency.	5. If a colour has been removed from the Union list of authorised food additives for reasons that do not require an EFSA opinion, the Commission shall decide on the use of the colour concerned in medicinal products and, where applicable, include it in the list of colours permitted for use in medicinal products referred to in paragraph 3. The Commission ***shall***, in such cases, request the opinion from the Agency.

Article 28

Article 28 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6 a. The Commission shall submit a report on the application of adapted frameworks to the European Parliament and the Council of the European Union.

The first report shall be provided five years after [OP please insert the date =18 months after the date of entering into force of this Directive] and then every five years thereafter.

COMPROMISE AMENDMENT 19 - NATIONAL MAS - GENERAL PROVISION AND MAS VALID IN ONE MS (ARTICLE 29-33)
replacing amendments AMs 695-703

Supported by
EPP, S&D, RE, Greens/EFA, Left

Article 29

Article 29 – paragraph 1 – point a

Text proposed by the Commission	*Unchanged text included in the compromise*
(a) shall verify whether the particulars and documentations submitted in support of the application comply with Articles 6 and 9 to 14 ('validation'), and examine whether the conditions for issuing a marketing authorisation set out in Articles 43 to 45 are complied with;	(a) shall verify whether the particulars and documentations submitted in support of the application comply with Articles 6 and 9 to 14 ('validation'), and examine whether the conditions for issuing a marketing authorisation set out in Articles 43 to 45 are complied with;

Article 29 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the competent authority of the Member State considers that the marketing authorisation application is incomplete, or contains critical deficiencies that may prevent the evaluation of the medicinal product it shall inform the applicant accordingly and shall set a time limit for submitting the missing information and documentation. If the applicant fails to provide the missing information and documentation within the time limit set, the application shall be considered to have been withdrawn.	3. Where the competent authority of the Member State considers that the marketing authorisation application is incomplete, or contains critical deficiencies that may prevent the evaluation of the medicinal product it shall inform the applicant accordingly and shall set a time limit for submitting the missing information and documentation. If the applicant fails to provide the missing information and documentation within the time limit set, the application shall be considered to have been withdrawn ***by default.***

Article 29 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
The competent authority of the Member State shall summarise the deficiencies in writing. On this basis, the competent authority of the Member State shall inform the applicant accordingly and set a time limit to address the deficiencies. The application shall be suspended until the applicant addresses the deficiencies. If the applicant fails to address those deficiencies within the time limit set by the competent authority of the Member State, the application shall be considered as withdrawn.	The competent authority of the Member State shall summarise the deficiencies in writing. On this basis, the competent authority of the Member State shall inform the applicant accordingly and set a ***reasonable*** time limit to address the deficiencies. The application shall be suspended until the applicant addresses the deficiencies. If the applicant fails to address those deficiencies within the time limit set by the competent authority of the Member State, the application shall be considered as withdrawn ***by default***.

Article 29 – paragraph 4a (new)

Text proposed by the Commission	*Amendment*
	4a. When making public the information on the ERA and the antimicrobial stewardship and access plan referred to in Article 17, the competent authority shall delete any information of a commercially confident nature.

Article 30 - COM text proposed as compromise

Article 31 - No AMs tabled

Article 32 - COM text proposed as compromise

COMPROMISE AMENDMENT 20 - DECENTRALISED MAS PROCEDURE (ARTICLES 33-34)
replacing amendments AMs 703-710, ITRE 19-21

Supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Article 33 - COM text proposed as compromise

Article 34

Article 34 – paragraph 3

Text proposed by the Commission	*Amendment*

3. ***The applicant shall inform all the competent authorities of all Member States of its application at the time of submission.*** The competent authority of a Member State may request for justified public health reasons to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the decentralised procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay.	3. ***The reference Member State competent authority shall inform the Coordination group for decentralised and mutual recognition procedures of an application, which shall notify the competent authorities of all Member States.*** The competent authority of a Member State may request for justified public health reasons to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the decentralised procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay.

Article 34 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
The competent authority of the reference Member State for the decentralised procedure shall summarise the deficiencies in writing. On this basis, the competent authority of the reference Member State for the decentralised procedure shall inform the applicant and the competent authorities of the Member States concerned accordingly and set a time limit to address the deficiencies. The application shall be suspended until the applicant addresses the deficiencies. If the applicant fails to address those deficiencies within the time limit set by the competent authority of the reference Member State for the decentralised procedure, the application shall be considered as withdrawn.	The competent authority of the reference Member State for the decentralised procedure shall summarise the deficiencies in writing. On this basis, the competent authority of the reference Member State for the decentralised procedure shall inform the applicant and the competent authorities of the Member States concerned accordingly and set a time limit to address the deficiencies. The application shall be suspended until the applicant addresses the deficiencies. If the applicant fails to address those deficiencies within the time limit set by the competent authority of the reference Member State for the decentralised procedure, the application shall be considered as withdrawn ***by default***.

COMPROMISE AMENDMENT 21 - MUTUAL RECOGNITION OF MAS (ARTICLES 35-36)
replacing amendments AMs 711-718, ITRE 22, ITRE 23

Supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Article 35 - COM text proposed as CA

Article 36

Article 36 – paragraph 4

Text proposed by the Commission	*Amendment*
4. ***The applicant shall inform the competent authorities of all Member States of its application at the time of submission.*** The competent authority of a Member State may request for justified public health reasons to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the mutual recognition procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay.	4. ***The reference Member State competent authority shall inform the Coordination group for decentralised and mutual recognition procedures of an application, which shall notify the competent authorities of all Member States.*** The competent authority of a Member State may request for justified public health reasons to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the mutual recognition procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay.

COMPROMISE AMENDMENT 22 - COORDINATION OF NATIONAL MA (ARTICLES 37-42)
replacing amendments AMs 719-723

Supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Article 37

Article 37 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
The coordination group shall be composed of one representative per Member State appointed for a renewable period of three years. ***Member States may appoint an***	The coordination group shall be composed of one representative per Member State ***and one representative from patients' organisations*** appointed for a renewable

alternate for a renewable period of three years. Members of the coordination group may arrange to be accompanied by experts.	period of three years. ***Alternates may be appointed*** for a renewable period of three years. Members of the coordination group may arrange to be accompanied by experts.

[No AMs were tabled on Articles 38-41]

Article 42

Article 42 – paragraph 1 – subparagraph 5

Text proposed by the Commission	*Amendment*
The Commission shall send the draft decision to the competent authorities of the Member States and the applicant or the marketing authorisation holder.	The Commission shall send the draft decision to the competent authorities of the Member States and the applicant or the marketing authorisation holder ***and make the decision, including the justification, publicly available***.

COMPROMISE AMENDMENT 23 - RESULTS OF EXAMINATION OF NATIONAL MA APPLICATIONS (ARTICLES 43-46)
replacing amendments AMs 79; 724-757, ITRE 24

Supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Article 43

Article 43 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The competent authorities of the Member States shall, without undue delay, make publicly available the national marketing authorisation together with the summary of product characteristics, the package leaflet as well as any conditions established in accordance with Articles 44, 45 and any obligations imposed subsequently in accordance with Article 87, together with any deadlines for the fulfilment of those conditions and obligations for each medicinal product that	3. The competent authorities of the Member States shall, without undue delay, make publicly available the national marketing authorisation together with the summary of product characteristics, the package leaflet*, **the antimicrobial stewardship and access plan and special information requirements referred to in Article 17 (1a (new)*** as well as any conditions established in accordance with Articles ***17,*** 44, 45 and any obligations imposed subsequently in accordance with

they have authorised.	Article 87, together with any deadlines for the fulfilment of those conditions and obligations for each medicinal product that they have authorised.

Article 43 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The competent authority of the Member State may consider and decide upon additional evidence available, independently from the data submitted by the marketing authorisation holder. On that basis, the summary of product characteristics shall be updated if the additional evidence has an impact on the benefit-risk balance of a medicinal product.	4. The competent authority of the Member State may consider and decide upon additional evidence available, independently from the data submitted by the marketing authorisation holder. On that basis, the summary of product characteristics shall be updated if the additional evidence has an impact on the benefit-risk balance of a medicinal product. ***The competent authority shall inform the marketing authorization holder of its decision, including the grounds for this decision, without unnecessary delay.***

Article 43 – paragraph 5

Text proposed by the Commission	*Unchanged text included in the compromise*
5. The competent authorities of the Member States shall draw up an assessment report and make comments on the file as regards the results of the pharmaceutical and non-clinical tests, the clinical studies, the risk management system, the environmental risk assessment and the pharmacovigilance system of the medicinal product concerned.	5. The competent authorities of the Member States shall draw up an assessment report and make comments on the file as regards the results of the pharmaceutical and non-clinical tests, the clinical studies, the risk management system, the environmental risk assessment and the pharmacovigilance system of the medicinal product concerned.

Article 44

Article 44 – paragraph 1 – subparagraph 1 – point g

Text proposed by the Commission	*Amendment*
(g) in case of medicinal products for which there is substantial uncertainty as to the surrogate endpoint relation to the expected health outcome, where appropriate and relevant for the benefit-risk balance, a post-authorisation obligation to substantiate the clinical benefit;	(g) in case of medicinal products for which***, on duly justified grounds described in the assessment report,*** there is substantial uncertainty as to the surrogate endpoint relation to the expected health outcome, where appropriate and relevant for the benefit-risk balance, ***with particular attention to new active substances and therapeutic indications,*** a post-

	authorisation obligation to substantiate the clinical benefit;

Article 44 – paragraph 1 – subparagraph 1 – point h

Text proposed by the Commission	*Unchanged text included in the compromise*
(h) to conduct post-authorisation environmental risk assessment studies, collection of monitoring data or information on use, where identified or potential concerns about risks to the environment or public health, including antimicrobial resistance need to be further investigated after the medicinal product has been marketed;	(h) to conduct post-authorisation environmental risk assessment studies, collection of monitoring data or information on use, where identified or potential concerns about risks to the environment or public health, including antimicrobial resistance need to be further investigated after the medicinal product has been marketed;

Article 45 - COM text proposed as CA

Article 46 - COM text proposed as CA

Note: AMs related to Article 47 included in CA 15 on Environmental Risk Assessment

COMPROMISE AMENDMENT 24 - SPECIFIC REQUIREMENTS FOR PAEDIATRIC MEDICINAL PRODUCTS (ARTICLES 48-49)
replacing amendments AMs 767-768

Supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Article 48 - no AMs tabled

Proposal for a directive
Article 49 – paragraph 2

Text proposed by the Commission	*Amendment*
2. If the application complies with all the measures contained in the agreed completed paediatric investigation plan and if the summary of product characteristics reflects the results of studies conducted in compliance with that agreed paediatric investigation plan, the competent authority	2. If the application complies with all the measures contained in the agreed completed paediatric investigation plan and if the summary of product characteristics reflects the results of studies conducted in compliance with that agreed paediatric investigation plan, the competent authority

of the Member State shall include within the marketing authorisation a statement indicating compliance of the application with the agreed completed paediatric investigation plan.	of the Member State shall include within the marketing authorisation a statement indicating compliance of the application with the agreed completed paediatric investigation plan. ***The competent authority shall make the conclusions of the assessment regarding compliance with paediatric investigation plan publicly available.***

COMPROMISE AMENDMENT 25 - PRESCRIPTION STATUS (ARTICLES 50 TO 55)
replacing amendments AMs 82, 83, 769-795

Supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Article 50 - no AMs tabled

Article 51

Article 51 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) is an ***antimicrobial; or***	(e) is an ***antibiotic or any other antimicrobial for which there is an identified risk of antimicrobial resistance; or***

Article 51 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) contains an active substance which are persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, or persistent, mobile and toxic, or very persistent and very mobile for which medical prescription is required as risk minimisation measure with regard to the environment, unless the use of the medicinal product and the patient safety require otherwise.	(f) contains an active substance ***adjuvants or any other ingredients or constituent part*** which are persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, or persistent, mobile and toxic, or very persistent and very mobile for which medical prescription is required as risk minimisation measure with regard to the environment, unless the use of the medicinal product and the patient safety require otherwise.

Article 51 – paragraph 1a (new)

Text proposed by the Commission	*Amendment*
	The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to add further antimicrobial products that shall be subject to prescription status where the Agency has identified a risk of antimicrobial

resistance.

Proposal for a directive
Article 51 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States may set additional conditions on the prescription of antimicrobials, restrict the validity of medical prescription and limit the quantities prescribed to the amount required for the treatment or therapy concerned or submitting certain antimicrobial medicinal products to special medical prescription or restricted prescription.	2. Member States may set additional conditions on the prescription of antimicrobials, restrict the validity of medical prescription and limit the quantities prescribed to the amount required for the treatment or therapy concerned ***by authorising the use of pre-cut blister units*** or submitting certain antimicrobial medicinal products to special medical prescription or restricted prescription.

Proposal for a directive
Article 51 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. A prescription for antibiotic products shall be subject to the following conditions:
	(a) be limited to the amount required for the treatment or therapy concerned;
	(b) only be prescribed for a limited duration to cover the period of risk when used as prophylaxis;
	(c) in case a diagnostic test has not been performed, a justification shall be required.

Article 51 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2 b. Member States shall, wherever possible, provide for per unit prescription and dispensing for the treatment or therapy concerned.

Article 51 – paragraph 4 – point c a (new)

Text proposed by the Commission	*Amendment*
	The risk of antimicrobial resistance, including any mitigating measures in this regard, from use of the product

Article 51 – paragraph 5 – point b

Text proposed by the Commission	*Amendment*
(b) other circumstances of use that it has specified.	***deleted***

Articles 52-54 - no AMs tabled

Article 55 - COM text is proposed as compromise.

COMPROMISE AMENDMENT 26 - OBLIGATION AND LIABILITY OF THE MAH (ARTICLES 56-59)
replacing amendments AMs 84-87; 796-850; 854, 855, 1242-1244, 1602

Supported by
EPP, S&D, RE, Greens/EFA, Left

Article 56 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Unchanged text included in the compromise*
The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate and continued supplies of that medicinal product to wholesale distributors, pharmacies or persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.	The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate and continued supplies of that medicinal product to wholesale distributors, pharmacies or persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.

Article 56 – paragraph 4

Text proposed by the Commission	*Unchanged text included in the compromise*
4. The marketing authorisation holder	4. The marketing authorisation holder

shall, at all stages of manufacturing and distribution ensure that the starting materials and ingredients of the medicinal products and the medicinal products themselves comply with the requirements of this Directive and, where relevant, the [revised Regulation (EC) No 726/2004] and other Union law and shall verify that such requirements are met.	shall, at all stages of manufacturing and distribution ensure that the starting materials and ingredients of the medicinal products and the medicinal products themselves comply with the requirements of this Directive and, where relevant, the [revised Regulation (EC) No 726/2004] and other Union law and shall verify that such requirements are met.

Article 56 - other paragraphs --> COM text proposed as Compromise amendment

Article 57

Article 57 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority ***or*** publicly funded body, in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support**.**	1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority**,** publicly funded body ***or philanthropic or non-for profit organisation or fund, irrespective of its geographic location, and any indirect financial support received from any public authority or publicly funded body of the Union or its Member States*** in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.

Article 57 – paragraph 2 – point a – point ii

Text proposed by the Commission	*Amendment*
(ii) the ***public authority or publicly funded body*** that provided the financial support referred to in point (i);	(ii) the ***entity*** that provided the financial support referred to in point (i);

Article 57 – paragraph 2 – point a – point iii a (new)

Text proposed by the Commission	*Amendment*
	(iii a) Where relevant, any independent legal entity from which it obtained a

	license in relation to, or acquired, the medicinal product in its previous phases of development, and at which stage of the research and development process. The marketing authorisation holder shall, to the extent possible, include in the report information on funding received according to paragraph 1 of this article specific to the relevant medicinal product.

Article 57 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Commission ***may*** adopt implementing acts to lay down the principles and format for the information to be reported pursuant to paragraph 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	6. The Commission ***shall*** adopt implementing acts to lay down the principles and format for the information to be reported pursuant to paragraph 2***, no later than 12 months after the date of entering into force of this Directive***. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).

Article 57 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. The Agency shall provide on its website the links to the information communicated to the Agency in accordance with paragraphs 2 and 3, sorted, where relevant, by medicine and by Member State.

Article 58

Article 58 – paragraph 1

Text proposed by the Commission	*Unchanged text included in the compromise*
1. The marketing authorisation holder shall, when necessary, ensure the traceability of an active substance, starting material, excipient or any other substance intended or expected to be present in a medicinal product at all stages of manufacturing and distribution.	1. The marketing authorisation holder shall, when necessary, ensure the traceability of an active substance, starting material, excipient or any other substance intended or expected to be present in a medicinal product at all stages of manufacturing and distribution.

Article 58 – paragraph 4

Text proposed by the Commission	*Unchanged text included in the compromise*
4. The marketing authorisation holder and its suppliers shall have in place systems and procedures to identify the other natural or legal persons to whom products referred to in paragraph 2 have been supplied. This information shall, upon request, be made available to the competent authorities.	4. The marketing authorisation holder and its suppliers shall have in place systems and procedures to identify the other natural or legal persons to whom products referred to in paragraph 2 have been supplied. This information shall, upon request, be made available to the competent authorities.

Article 59

Article 59 – paragraph 1

Text proposed by the Commission	*Unchanged text included in the compromise*
Where medicinal products are authorised for a paediatric indication following completion of an agreed paediatric investigation plan and those medicinal products have already been marketed with other therapeutic indications, the marketing authorisation holder shall, within two years of the date on which the paediatric indication is authorised, place the medicinal product on the market taking into account the paediatric indication in all Member States where the medicinal product is already placed on the market.	Where medicinal products are authorised for a paediatric indication following completion of an agreed paediatric investigation plan and those medicinal products have already been marketed with other therapeutic indications, the marketing authorisation holder shall, within two years of the date on which the paediatric indication is authorised, place the medicinal product on the market taking into account the paediatric indication in all Member States where the medicinal product is already placed on the market.

Article 60 - no AMs tabled

Article 61 - no AMs tabled

COMPROMISE AMENDMENT 27 - PRODUCT INFORMATION AND LABELLING (ARTICLES 62-79)
replacing amendments AMs 90-101; 856-889; 892-932; 934-988

Supported by
EPP, S&D, RE, Greens/EFA

Article 62 - no AMs tabled

Article 63

Article 63 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States may decide that the package leaflet shall be made available ***in paper format or electronically***, ***or*** both. In the absence of such specific rules in a Member State, a package leaflet in paper format ***shall be included*** in the packaging of a medicinal product. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients.	3. Member States may decide that ***for individual products, categories of products or for all products,*** the package leaflet shall be made available both ***in paper format and electronically or electronically only***. ***In the latter case, this decision shall be made only following a consultation of patients, carers and other relevant stakeholders.*** In the absence of such specific rules in a Member State, a package leaflet ***shall be made available electronically and be included*** in paper format in the packaging of a medicinal product. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients ***as well as written and designed in a clear and understandable way***.

Article 63 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. If a Member State has decided that the package leaflet is only to be made available electronically, patients shall be made aware of their right to a printed copy of the package leaflet.

Article 63 – paragraph 3 b (new)

Text proposed by the Commission	*Amendment*
	3b. If a Member State decides that the package leaflet shall be made available electronically, a paper package leaflet in addition to the electronic format may be made available on a voluntary basis by the marketing authorisation holder in addition to the electronic package leaflet.

Article 63 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. By way of derogation from paragraph 3, where the medicinal product is intended for dispensation and administration by a qualified healthcare professionals rather than for self-administration by the patient, the package leaflet may be made available only in electronic format.

Article 63 – paragraph 5

Text proposed by the Commission	Amendment
5. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend paragraph 3 by making mandatory the electronic version of the package leaflet. That delegated act shall also establish the patient's right to a printed copy of the package leaflet upon request and free of charge. The delegation of powers shall apply as of [OP please insert the date = five years following 18 months after the date of entering into force of this Directive].	***deleted***

Article 63 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies.	6. ***By ... [12 months after the date of entry into force of this Directive],*** the Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies.

Article 63 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6 a. The Agency shall make available a system to accommodate the electronic product information after consultation with Member States and the relevant stakeholders. The system shall be available at the latest by [24 months after entry into force of this Directive].

Article 63 – paragraph 7

Text proposed by the Commission	*Amendment*
7. ***Where*** the package leaflet ***is made available*** electronically, the individual right to privacy shall be ensured. Any technology giving access to the information shall not allow the identification or tracking of individuals, nor shall it be used for commercial purposes.	7. ***When accessing*** the package leaflet electronically, the individual right to privacy shall be ensured. Any technology giving access to the information shall ***ensure the protection of personal data in line with Regulation (EU) 2016/679 and Directive 2002/58/EC and shall*** not allow the identification***, profiling*** or tracking of individuals, nor shall it be used for commercial purposes ***including advertising and marketing activities***.

Article 64

Article 64 – paragraph 3

Text proposed by the Commission	*Amendment*
3. ***The package leaflet shall reflect the results of consultations*** with target patient groups to ensure that ***it*** is legible, clear and easy to use.	3. ***Following a consultation*** with target patient groups ***and other relevant stakeholders, the Commission shall adopt guidelines*** to ensure that ***the package leaflet*** is legible, clear and easy to use.

Article 65 - COM text as CA

Article 66

Article 66 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The particulars laid down in Annex IV shall appear on immediate packagings other than those referred to in the paragraphs 2 and 3.	1. The particulars laid down in Annex IV shall appear on immediate packagings other than those referred to in the paragraphs 2 and 3 ***and shall allow, at the request of the national competent authorities, single dispensation, particularly in the event of a shortage or major public health issue.***

Article 66 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. Each single dose of the blister pack shall include the following labelling particulars:
	(a) the name of the medicinal product followed by its strength and pharmaceutical form;
	(b) a data matrix code in which the following information is encoded:
	(i) the Global Trading Index Number (GTIN)
	(ii) the expiry date;
	(iii) the batch number.

Article 67

Article 67 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
Medicinal products not subject to prescription shall not bear the safety features referred to in Annex IV, unless, by way of exception, they have been listed in accordance with the procedure referred to in paragraph 2, second subparagraph, point (b).	Medicinal products not subject to prescription shall not bear the safety features referred to in Annex IV, unless, by way of exception, they have been listed in accordance with the procedure referred to in paragraph 2, second subparagraph, point (b)***, or where the marketing authorisation holder chooses to do so voluntarily***.

Article 67 – paragraph 7 a (new)

Text proposed by the Commission	*Amendment*
	7a. For the purpose of patient safety, Member States may decide that medicinal products imported or distributed in parallel shall be repackaged in new outer packaging.

<u>Article 68 - no AMs tabled</u>

Article 69

Proposal for a directive
Article 69 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The marketing authorisation holder shall ensure availability of educational material to healthcare professionals, ***including through medical sales representatives as referred to in Article 175(1), point (c),*** regarding the appropriate use of diagnostic tools, testing or other diagnostic approaches related to antimicrobial-resistant pathogens, that may inform on the use of the antimicrobial.	1. The marketing authorisation holder shall ensure availability of educational material to healthcare professionals, regarding the appropriate use of diagnostic tools, testing or other diagnostic approaches related to antimicrobial-resistant pathogens, that may inform on the use of the antimicrobial. ***Any informational material must be compatible with the summary of product characteristics.***

Article 69 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
Member States ***may decide*** that the awareness card ***shall be*** made available in paper format or electronically***, or both***. ***In the absence of such specific rules in a Member State, an awareness card in paper format shall be included in the packaging of an antimicrobial.***	Member States ***shall ensure*** that the awareness card ***is*** made available in paper format or ***both in paper format and*** electronically ***in the packaging of an antimicrobial.***

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Proposal for a directive
Article 69 – paragraph 3 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	Members States shall introduce appropriate disposal systems for antimicrobials in the community setting, and inform the general public on the correct disposal methods for antimicrobial.

Article 69 – paragraph 3a (new)

Text proposed by the Commission	*Amendment*
	3a. The Commission is empowered to adopt implementing acts laying down further standards for the awareness card after consulting the Agency. Those

implementing acts shall be adopted through the advisory procedure.

Article 70 - no AMs tabled

Article 71 - COM text proposed as CA

Article 72 - no AMs tabled

Article 73

Article 73 – paragraph 1

Text proposed by the Commission	*Amendment*
The outer packaging and the package leaflet may include symbols or pictograms designed to clarify certain information set out in Articles 64(1) ***and 65*** and other information compatible with the summary of product characteristics that is useful for the patient, to the exclusion of any element of a promotional nature.	The outer ***packaging, the immediate*** packaging and the package leaflet may include symbols or pictograms designed to clarify certain information set out in Articles 64(1)***, 65 and 69*** and other information compatible with the summary of product characteristics that is useful for the patient, to the exclusion of any element of a promotional nature.

Article 74

Article 74 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The competent authorities of the Member State may also grant a full or partial exemption to the obligation that the labelling and the package leaflet must be in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State. For the purpose of multi-language packages, Member States may allow the use on the labelling and package leaflet of an official language of the Union that is commonly understood in the Member States where the multi-language package is marketed.	4. The competent authorities of the Member State may also grant a full or partial exemption to the obligation that the labelling and the package leaflet must be in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State. ***When a competent authority grants a full or partial exemption to the language requirements that apply to the label or package leaflet, the patients' right to a printed copy in the official language or official languages of the Member State shall be guaranteed upon request and free of charge.*** For the purpose of multi-language packages, Member States may allow the use on the labelling and package leaflet of an official language of the Union that is commonly understood in the Member States where the multi-language package is

marketed.

Article 75 - COM text proposed as CA

Article 76 - no AMs tabled

Article 77

Proposal for a directive
Article 77 – paragraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(a a) the wording on prudent use and safe disposal of antimicrobials;

Article 78 - no AMs tabled

Article 79 - no AMs tabled

COMPROMISE AMENDMENT 40 - REGULATORY PROTECTION, UNMET MEDICAL NEEDS AND REWARDS FOR PAEDIATRIC MEDICINAL PRODUCTS (ARTICLES 81-83 AND 58A-B (NEW) AND 206, PARA 2, POINT EA (NEW), AND 11, 44 A (NEW), 47, 50, 50 A, 52, 53, 54, 55, 56 , 57, 59)

replacing amendments AMs 8, 10-16; 19, 88, 89; 104 -115; 132; 164-166; 210; 218; 219; 230-241; 246-250; 252-261; 267; 851-853; 1004-1209; 1341-1348; 1577, ITRE 4; ITRE 11; ITRE 25-ITRE 49

Supported by
EPP, S&D, RE, Greens/EFA, Left

Article 81

Article 81 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The regulatory data protection period shall be ***six*** years from the date when the marketing authorisation for that medicinal product was granted in accordance with Article 6(2). For marketing authorisations that belong to the same global marketing authorisation the period of data protection shall start from the date when the initial marketing authorisation was granted in the Union.	1. The regulatory data protection period shall be ***seven*** years ***and six months*** from the date when the marketing authorisation for that medicinal product was granted in accordance with Article 6(2). For marketing authorisations that belong to the same global marketing authorisation the period of data protection shall start from the date when the initial marketing authorisation was granted in the Union.

Article 81 – paragraph 2 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) 24 months, where the marketing authorisation holder demonstrates that the conditions referred to in Article 82(1) are fulfilled within two years, from the date when the marketing authorisation was granted or, within three years from that date for any of the following entities:	***Deleted***
(i) SMEs within the meaning of Commission Recommendation 2003/361/EC;	
(ii) entities not engaged in an economic activity ('not-for-profit entity'); and	
(iii) undertakings that, by the time of	

granting of a marketing authorisation, have received not more than five centralised marketing authorisations for the undertaking concerned or, in the case of an undertaking belonging to a group, for the group of which it is part, since the establishment of the undertaking or the group, whichever is earliest.

Article 81 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) six months, where the marketing authorisation applicant demonstrates at the time of the initial marketing authorisation application that the medicinal product addresses an unmet medical need as referred to in Article 83;	(b) ***12*** months, where the marketing authorisation applicant demonstrates at the time of the initial marketing authorisation application that the medicinal product addresses an unmet medical need as referred to in Article 83;

Article 81 – paragraph 2 – subparagraph 1 – point c

Text proposed by the Commission	*Unchanged text included in the compromise*
(c) six months, for medicinal products containing a new active substance, where the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency;	(c) six months, for medicinal products containing a new active substance, where the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency;

Article 81 – paragraph 2 – subparagraph 1 – point ca (new)

Text proposed by the Commission	*Amendment*
	(ca) six months, where the marketing authorisation holder demonstrates that a significant share of research and development, including preclinical and clinical, related to the medicinal product has been done within the Union and at least in part in collaboration with public entities, including University Hospital Institutes, centres of excellence or bioclusters in the Union.

Article 81 – paragraph 2 – subparagraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) 12 months, where the marketing authorisation holder obtains, during the data protection period, an authorisation for an additional therapeutic indication for which the marketing authorisation holder has demonstrated, with supporting data, a significant clinical benefit in comparison with existing therapies.	***deleted***

Article 81 – paragraph 2 – subparagraph 3

Text proposed by the Commission	*Amendment*
The prolongation referred to in the first subparagraph, point (d), may only be granted once.	***Deleted***

Article 81 - paragraph 2 - subparagraph 4 (new)

Text proposed by the Commission	*Amendment*
	By [OP please insert the date =12 months after the date of entering into force of this Directive] the Commission shall adopt a delegated act setting out the procedural aspects and criteria related to point ca (new) in accordance with the procedure referred to in Article 215.

Article 81 – paragraph 4 (new)

Text proposed by the Commission	*Amendment*
	The regulatory protection referred to in paragraphs 1 and 2 shall not exceed eight years and six months.

Article 82

Text proposed by the Commission	*Amendment*
[...]	***Deleted***

Article 83

Paragraphs 1 & 2: Unchanged Commission text

Article 83 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004].	3. Where the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies referred to in ***paragraph 1 of*** Article 162 of [revised Regulation (EC) No 726/2004] ***and the stakeholders referred to in paragraph 2 of Article 162.***

Article 85 a (new)

Text proposed by the Commission	*Amendment*
	Article 85a
	Non-interference of intellectual property rights
	1. The procedures and decisions in Article 85 shall be considered by Member States as regulatory or administrative procedures which, as such, are independent from the enforcement of intellectual property rights.
	2. The protection of intellectual property rights shall not be a valid ground to

refuse, suspend, delay, withdraw or revoke decisions referred to in Article 85.

3. Paragraphs 1 and 2 shall apply without prejudice to the Union and national legislation relating to the protection of intellectual property.

Article 58 a (new)

Text proposed by the Commission	*Amendment*
	Article 58a
	Obligation to submit an application for pricing and reimbursement in all Member States
	1. The marketing authorisation holder shall, upon request by a Member State in which the marketing authorisation is valid, in good faith and within the limits of its responsibilities submit an application for pricing and reimbursement for the medicinal product and, where relevant, negotiate. In case of a positive decision to permit the marketing of the medicinal product according to Directive 89/105/EEC, the obligation in article 56(3) to ensure appropriate and continued supply to cover the needs of patients in that Member State shall apply. The application for pricing and reimbursement for the medicinal product shall be submitted no later than 12 months from the date when the Member State made its request, or within 24 months from that date for any of the following entities:
	(i) SMEs;
	(ii) entities not engaged in an economic activity ('not-for-profit entity'); and
	(iii) undertakings that, by the time of granting the marketing authorisation, have received not more than five centralised marketing authorisations for

the undertaking concerned or, in the case of an undertaking belonging to a group, for the group of which it is part, since the establishment of the undertaking or the group, whichever is earliest.

The deadlines in the first subparagraph shall be prolonged by six months following the notification of the marketing authorisation holder to the competent authority. The marketing authorisation holder shall in such cases state the reasons for the delay. The marketing authorisation holder shall notify that it fulfilled the obligations set out in the first subparagraph through the EU Access to Medicines Notification System provided for in Article 58b.

2. For the purposes of paragraph 1 of this Article, Member States shall make either their request or a notification that their request will be made at a later date within one year of the granting of a marketing authorisation. This shall be notified in the EU Access to Medicines Notification System provided for in Article 58b, and for a notification that a request will be made at a later date be accompanied by a justification. Following the filing for pricing and reimbursement by the marketing authorisation holder, Directive 89/105/EEC shall apply. Where a Member State has not complied with the time limits laid down in Directive 89/105/EEC, the obligation on the marketing authorisation holder set out in this Article shall be considered to be fulfilled in that Member State.

3. By way of derogation from paragraph 1, the marketing authorisation holder for a designated orphan medicinal product or for an advanced therapy medicinal product may choose instead to fulfill the obligations set out in paragraph 1 only in the Member States where the relevant patient population has been identified.

4. Following agreement between a Member State and a marketing authorisation holder, timelines that are different from those set out in paragraphs 1 and 2 may apply. A Member State may choose, after making a request in accordance with paragraph 1, to issue a product-specific waiver after which the obligation to submit an application shall be considered to be fulfilled in that Member State.

5. The Commission shall adopt a delegated act in accordance with Article 215 to specify criteria for the exemption of products from the obligations set out in this article based on the nature of the product or its market. The delegated act shall provide clarity to developers regarding the application of exemptions, and set out requirements related to impartiality and transparency in decisions of the implementing acts set out in this article.

After consultation with the Agency, the Commission shall adopt by means of implementing acts a list of products to be exempted from the obligations set out in this Article. The inclusion of a medicinal product in that list shall where relevant take into account circumstances related to regulatory and reimbursement procedures pertaining to particular products, or to the administration of a medicinal product in most Member States being impracticable. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).

6. Where a marketing authorisation is transferred to a different legal entity before the end of the period referred to in paragraph 1, the obligations shall be transferred to the new marketing authorisation holder.

7. The Commission shall by means of implementing acts establish a conciliation

mechanism to facilitate discussions between applicants and Member States to resolve potential disputes related to the process for submission of applications for pricing and reimbursement and with respect to the timelines set out in Directive 89/105/EEC.

In the event of continued disagreement between an applicant and a Member State regarding the fulfilment of the obligations set out in this Article, the Commission shall be empowered to issue a legally binding Commission decision following an opinion of the Agency.

8. The provisions of this Article shall not prevent a marketing authorisation holder from submitting an application for pricing and reimbursement and placing a medicinal product on the market of a Member State without a Member State having made a request in accordance with paragraph 1.

Article 58 b (new)

Text proposed by the Commission	*Amendment*
	Article 58b
	EU Access to Medicines Notification System
	1. The Commission shall set up and maintain an electronic notification system for the notification of compliance with the obligations set out in Article 58a. The EU Access to Medicines Notification System shall be interoperable with other relevant Union-wide data repositories for medicinal products.
	2. The marketing authorisation holder shall use the EU Access to Medicines Notification System to notify their compliance with the obligations set out in Article 58a. In the Member States where the marketing authorisation is valid, the national competent authority

shall use the EU Access to Medicines Notification System to indicate that the marketing authorisation holder has fulfilled its obligations set out in Article 58a.

3. By ... [3 years following the date of entry into force of this Directive], the Commission shall adopt implementing acts to establish technical and organisational requirements. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).

5. By ... [5 years after the date of entry into force of this Directive], the Commission shall assess the feasibility of extending the EU Access to Medicines Notification System to other areas of the process for pricing of medicinal products as set out in Directive 89/105/EEC and, if appropriate, adopt implementing acts to establish this extended system. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).

Anonymized data, aggregated to the Member State level, from the Notification System may be made public for the purpose of reporting on access in Article 86a.

Article 206 – paragraph 2 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) non-compliance with the obligations laid down in Article 58a shall be subject to the imposition of effective, proportionate and dissuasive financial penalties.

Recital 11

Text proposed by the Commission	*Amendment*
(11) The Directive should work in synergy with the Regulation to enable	(11) The Directive should work in synergy with the Regulation to enable

innovation and promote competitiveness of the Union pharmaceutical industry, in particular SMEs. In this respect a balanced system of incentives is proposed that rewards innovation especially in areas of unmet medical need ***and*** innovation that reaches patients and improves access across the Union. To make the regulatory system more efficient and innovation-friendly the Directive also aims at reducing administrative burden and simplifying procedures for undertakings.	innovation and promote competitiveness of the Union pharmaceutical industry, in particular ***of*** SMEs**.** In this respect a balanced system of incentives is proposed that rewards innovation especially in areas of unmet medical need**,** innovation that reaches patients and improves access across ***the Union and innovation that stems from development in*** the Union. To make the regulatory system more efficient and innovation-friendly the Directive also aims at reducing administrative burden and simplifying procedures for undertakings.

Recital 44 a (new)

Text proposed by the Commission	*Amendment*
	(44 a) In order to increase the availability of medicines and contribute to reducing access inequalities within the Union, the marketing authorisation holders of medicinal products should submit an application for pricing and reimbursement in Member States upon request.

Recital 47

Text proposed by the Commission	*Amendment*
(47) To ensure dialogue among all actors in the medicines lifecycle, discussions on policy issues related to the application of the rules related to prolongation of regulatory data protection ***for market launch*** shall take place in the Pharmaceutical Committee. The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.	(47) To ensure dialogue among all actors in the medicines lifecycle, discussions on policy issues related to the application of the rules related to prolongation of regulatory data protection shall take place in the Pharmaceutical Committee. The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.

Recital 50

Text proposed by the Commission	*Amendment*
(50) The establishment of a criteria-based definition of 'unmet medical need' is required to incentivise the development of medicinal products in therapeutic areas that are currently underserved. To ensure that	(50) The establishment of a criteria-based definition of 'unmet medical need' is required to incentivise the development of medicinal products in therapeutic areas that are currently underserved. To ensure that

the concept of unmet medical need reflects scientific and technological developments and current knowledge in underserved diseases, the Commission should specify ***and update using implementing acts,*** the criteria of satisfactory method of diagnosis, prevention or treatment, 'remaining high morbidity or mortality', 'relevant patient population' following scientific assessment by the Agency. The Agency will seek input from a broad range of authorities or bodies active along the lifecycle of medicinal products in the framework of the consultation process established under the [revised Regulation (EC) No 726/2004] and also take into account scientific initiatives at EU level or between Member States related to analysing unmet medical needs, burden of disease and priority setting for research and development. The criteria for 'unmet medical need' can be subsequently used by Member States to identify specific therapeutic areas of interest.	the concept of unmet medical need reflects scientific and technological developments and current knowledge in underserved diseases, ***and prevents extensions of data protection not in line with this objective due to unclear interpretation of 'unmet medical need',*** the Commission should specify the criteria of satisfactory method of diagnosis, prevention or treatment, 'remaining high morbidity or mortality', **'**relevant patient population' following scientific assessment by the Agency. The Agency will seek input from a broad range of authorities or bodies active along the lifecycle of medicinal products in the framework of the consultation process established under the [revised Regulation (EC) No 726/2004] and also take into account scientific initiatives at EU level or between Member States related to analysing unmet medical needs, burden of disease and priority setting for research and development. The ***Agency should also seek input from other relevant stakeholders, including relevant patient populations. The*** criteria for 'unmet medical need' can be subsequently used by Member States to identify specific therapeutic areas of interest, ***but need not have any automatic effect on Member States' decisions on pricing and reimbursement of medicinal products which should take into account other factors, notably the Health Technology Assessment, than the definition established under this Directive***.
Recital 50 a (new)	
Text proposed by the Commission	*Amendment*
	(50a) The concept of morbidity in the definition of 'unmet medical need' should encompass a multiplicity of factors. Morbidity should be understood to include aspects of quality of life of patients, a high burden of disease and treatment and the inability to perform daily life activities. Therefore, the assessment of 'unmet medical need' should take into account relevant patient experience data.
Recital 52	

Text proposed by the Commission	*Amendment*
(52) For the ***initial*** marketing authorisation application for medicinal products containing a new active substance, the submission of clinical trials that include as a comparator an evidence-based existing treatment should be incentivised, in order to foster the generation of comparative clinical evidence that is relevant and can accordingly support subsequent health technology assessments and decisions on pricing and reimbursement by Member States.	(52) For the marketing authorisation application for medicinal products containing a new active substance, the submission of clinical trials that include as a comparator an evidence-based existing treatment should be incentivised, in order to foster the generation of comparative clinical evidence that is relevant and can accordingly support subsequent health technology assessments and decisions on pricing and reimbursement by Member States. ***National competent authorities and the Agency should promote, when possible, the use of comparative studies when giving regulatory advice prior to marketing authorization for medicinal products that compare the new active substance to the existing treatment.***

Recital 53

Text proposed by the Commission	*Amendment*
(53) A marketing authorisation holder should ensure the appropriate and continuous supply of a medicinal product throughout its lifetime ***irrespective of whether that medicinal product is covered by a supply incentive or not***.	(53) A marketing authorisation holder should***, within its responsibilities,*** ensure the appropriate and continuous supply of a medicinal product throughout its lifetime.

Recital 54

Text proposed by the Commission	*Amendment*
(54) Micro, small and medium-sized enterprises ('SMEs'), not-for-profit entities or entities with limited experience in the Union system should benefit from additional time to ***market*** a medicinal product in the Member States where the marketing authorisation is valid ***for the purposes of receiving additional regulatory data protection***.	(54) Micro, small and medium-sized enterprises ('SMEs'), not-for-profit entities or entities with limited experience in the Union system should benefit from additional time to ***submit an application for pricing and reimbursement for*** a medicinal product in the Member States where the marketing authorisation is valid***, and where a Member State has requested it***.

Recital 55

Text proposed by the Commission	*Amendment*
(55) ***When applying the provisions on market launch incentives,*** marketing authorisation holders and Member States should do their utmost to achieve a mutually agreed supply of medicinal products in accordance with the needs of the Member State concerned, without unduly delaying or hindering the other party from enjoying its rights under this Directive.	(55) Marketing authorisation holders and Member States should do their utmost to achieve a mutually agreed supply of medicinal products in accordance with the needs of the Member State concerned, without unduly delaying or hindering the other party from enjoying its rights under this Directive.

Recital 56

Text proposed by the Commission	*Amendment*
(56) Member States have the possibility to waive the condition of launch in their territory for the purpose of the prolongation of data protection for market launch. This can be done through a statement of non-objection to prolong the period of regulatory data protection. This is expected to be the case particularly in situations where launch in a particular Member State is materially impossible or because there are special reasons why a Member State wishes that launch take place later.	***deleted***

Recital 57

Text proposed by the Commission	*Amendment*
(57) The ***issuing of documentation from*** the Member States ***as regards the prolongation of data protection for the purpose of supply of medicinal products in all Member States where a marketing authorisation is valid, in particular the waiver to the conditions for such prolongation,*** does not affect at any time the powers of the Member States as regards the supply, setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes. ***Member States do not waive the possibility to***	(57) The ***application for pricing and reimbursement in*** the Member States does not affect at any time the powers of the Member States as regards the supply, setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes.

request release or supply of the product concerned at any time before, during or after the prolongation of the data protection period.

Recital 59

Text proposed by the Commission	*Amendment*
(59) A Member State that considers that the conditions of supply have not been met for its territory should provide a reasoned statement of non-compliance at the latest in the Standing Committee on Medicinal Products for Human Use procedure of the variation linked to the provision of the relevant incentive.	***deleted***

COMPROMISE AMENDMENT 42 - (ARTICLES 80, 84, 85, 86 AND 86A (NEW)
replacing amendments AMs 102; 103; 116-120; 989-1003; 1210 - 1241; 1245 -1340; 1349-1352; ITRE 50

Supported by
EPP, S&D, RE, Greens/EFA, Left

Article 80

Article 80 - paras 1 to 3 - Commission text as a proposal

Article 80 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. The period referred in paragraph 2 shall be extended by an additional period of one year, where the marketing authorization holder obtains, during the data protection period referred to in Article 81, an authorisation for an additional therapeutic indication , provided that significant clinical benefit in comparison with existing therapies has been demonstrated by the marketing authorisation holder with supporting data. This extension may only be granted once.

Article 80 – paragraph 4

Text proposed by the Commission	*Amendment*
4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by a relevant authority in the Union to a party ***to address a public health emergency,*** the data and market protection shall be suspended with regard to that party insofar as the compulsory licence requires, and during the duration period of the compulsory licence.	4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted ***under conditions laid out in Union law and with the respect of international agreements*** by a relevant ***Member State*** authority in the Union to a party the data and market protection shall be suspended with regard to that party insofar as the compulsory licence requires, and during the duration period of the compulsory licence ***in the Member State(s) where the compulsory license has been granted***.

Article 80 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The marketing authorisation holder for the medicinal product for which a compulsory licence has been granted shall be informed of the decision without delay.

Article 84
Article 84 – paragraph 1 – introductory part

Text proposed by the Commission	*Unchanged text included in the compromise*
1. A regulatory data protection period of four years shall be granted for a medicinal product with respect to a new therapeutic indication not previously authorised in the Union, provided that:	1. A regulatory data protection period of four years shall be granted for a medicinal product with respect to a new therapeutic indication not previously authorised in the Union, provided that:

Article 84 – paragraph 1 – point a

Text proposed by the Commission	*Unchanged text included in the compromise*
(a) adequate non-clinical or clinical studies were carried out in relation to the therapeutic indication demonstrating that it is of significant clinical benefit, and	(a) adequate non-clinical or clinical studies were carried out in relation to the therapeutic indication demonstrating that it is of significant clinical benefit, and

Article 84 – paragraph 1 – point b

Text proposed by the Commission	*Unchanged text included in the compromise*
(b) the medicinal product is authorised in accordance with Articles 9 to 12 and has not previously benefitted from data protection, or 25 years have passed since the granting of the initial marketing authorisation of the medicinal product concerned.	(b) the medicinal product is authorised in accordance with Articles 9 to 12 and has not previously benefitted from data protection, or 25 years have passed since the granting of the initial marketing authorisation of the medicinal product concerned.

Article 84 – paragraph 3

Text proposed by the Commission	*Unchanged text included in the compromise*
3. During the data protection period referred to in paragraph 1, the marketing authorisation shall indicate that the medicinal product is an existing medicinal product authorised in the Union that has been authorised with an additional therapeutic indication.	3. During the data protection period referred to in paragraph 1, the marketing authorisation shall indicate that the medicinal product is an existing medicinal product authorised in the Union that has been authorised with an additional therapeutic indication.

Article 85

Article 85 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
Patent rights, or supplementary protection certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted] shall not be regarded as infringed when ***a reference medicinal product is used*** for the ***purposes*** of:	Patent rights, or supplementary protection certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted] shall not be regarded as infringed when ***necessary studies, trials and other activities are conducted*** for the ***purpose*** of:

Article 85 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) studies, trials and other activities conducted to generate data for an application, for:	***deleted***

Article 85 – paragraph 1 – point a – point i

Text proposed by the Commission	*Amendment*
(i) a marketing authorisation ***of generic, biosimilar, hybrid or bio-hybrid medicinal products and for*** subsequent variations;	(i) ***obtaining*** a marketing authorisation ***and*** subsequent variations;

Article 85 – paragraph 1 – point a – point ii

Text proposed by the Commission	*Amendment*
(ii) health technology assessment as defined in Regulation (EU) 2021/2282;	(ii) ***conducting a*** health technology assessment as defined in Regulation (EU) 2021/2282;

Article 85 – paragraph 1 – point a – point iii

Text proposed by the Commission	*Amendment*
(iii) pricing and reimbursement**.**	(iii) ***obtaining*** pricing and reimbursement ***approval;***

Article 85 – paragraph 1 – point a – point iii c (new)

Text proposed by the Commission	*Amendment*
	(iii a) and the subsequent practical requirements associated with such activities.

Article 85 – paragraph 1 - suparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
The activities conducted exclusively for the purposes set out in ***point (a)***, ***may*** cover the submission of the application for a marketing authorisation and the offer, manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers. This exception shall not cover the placing on the market of the medicinal products resulting from such activities.	The activities conducted exclusively for the purposes set out ***in the first subparagraph***, ***shall*** cover ***as relevant*** the submission of the application for a marketing authorisation and the offer, manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers. This exception shall not cover the placing on the market of the medicinal products resulting from such activities.

Article 86

Proposal of a Directive
Article 86 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Where an application for marketing authorisation, includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Article 13, paragraphs 1 and 2 of [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted].	Where an application for marketing authorisation, includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Article 13, paragraphs 1 and 2 of [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted].

Article 86 a (new)

Text proposed by the Commission	*Amendment*
	Article 86a
	Reporting on access to medicinal products
	1. The Commission, in collaboration with the Member States, shall develop indicators to measure access to medicinal products within the EU. These indicators shall be evidence-based, measurable, and regularly reviewed to reflect the evolving healthcare landscape within the EU.
	The Commission shall publish a report assessing access to medicinal products and barriers to improving access in each Member State as well as on an aggregated Union level. The report shall be publically available.
	Based on the report, the Commission shall create a dedicated website with easily accessible information on the access indicators and access to medicinal products in the Union, intended for the general public and relevant stakeholders.
	The report shall be drawn up for the first time by [OP: Please insert date of the end of the second year after the date of entry into force of this Directive] and every five years thereafter.

COMPROMISE AMENDMENT 37 - POST-MARKETING AUTHORISATION MEASURES (ARTICLES 87-95)
replacing amendments AMs 121; 1353-1367

Supported by
EPP, S&D, RE, Greens/EFA, Left

Article 87

Article 87 – paragraph 1– point c – subparagraph 1

Text proposed by the Commission	*Amendment*
(c) to conduct a post-authorisation environmental risk assessment study, collection of monitoring data or information on use, if there are concerns about the risks to the environment or public health, including antimicrobial resistance, due to an authorised medicinal product, or related active substance.	(c) to conduct a post-authorisation environmental risk assessment study, collection of monitoring data or information on use, if there are concerns about the risks to the environment or public health, including antimicrobial resistance, due to an authorised medicinal product, or related active substance. ***Where the post-authorisation environmental risk assessment study concerns an antimicrobial, it shall include relevant and comparable data on the volume of sales and the use per types of antimicrobial medicinal products The Agency shall cooperate with Member States and with other Union agencies to analyse those data and shall publish an annual report. The Agency shall take into account those data when adopting any relevant guidelines and recommendations.***

Proposal for a directive
Article 87 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
The imposition of such an obligation shall be duly justified, notified in writing, and shall include the objectives and timeframe for submission and conduct of the study.	The imposition of such an obligation shall be duly justified, notified in writing, and shall include the objectives and timeframe for submission and conduct of the study. ***Information on imposed post-authorisation studies shall be noted in the product's European Public Assessment Report and a database of the competent authority.***

Article 89 - COM text proposed as CA

Article 90 - no AMs tabled

Article 91 - no AMs tabled

Article 92

Article 92 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The procedures for examination of applications for variations shall be proportionate to the risk and impact involved. Those procedures shall range from procedures that allow implementation only after approval based on a complete scientific assessment to procedures that allow immediate implementation and subsequent notification by the marketing authorisation holder to the competent authority. Such procedures may also include updates by the marketing authorisation holder of their information held in a database.	3. The procedures for examination of applications for variations shall be proportionate to the risk and impact involved. Those procedures shall range from procedures that allow implementation only after approval based on a complete scientific assessment to procedures that allow immediate implementation and subsequent notification by the marketing authorisation holder to the competent authority. Such procedures may also include updates by the marketing authorisation holder of their information held in a database. ***Where deemed justified by the Agency, accelerated assessment procedures shall also be foreseen for variations which are of major interest from the point of view of public health.***

Article 93 - no AMs tabled

Article 94
Article 94 – paragraph 1

Text proposed by the Commission	*Amendment*
1. On the basis of relevant paediatric clinical studies received in accordance with Article 45(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council[76] , the competent authorities of the Member States may vary the marketing authorisation of the medicinal product concerned accordingly and update the summary of product characteristics and	1. On the basis of relevant paediatric clinical studies received in accordance with Article 45(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council[76] , the competent authorities of the Member States may***, following a consultation of the marketing authorisation holder,*** vary the marketing authorisation of the medicinal product

package leaflet of the medicinal product concerned. The competent authorities shall exchange information regarding the studies submitted and, as appropriate, their implications for any marketing authorisations concerned.	concerned accordingly and update the summary of product characteristics and package leaflet of the medicinal product concerned. The competent authorities shall exchange information regarding the studies submitted and, as appropriate, their implications for any marketing authorisations concerned.

Article 95 - no AMs tabled

COMPROMISE AMENDMENT 28 - GENERAL PHARMACOVIGILANCE PROVISIONS (ARTICLES 96-101) AND TRANSPARENCY AND COMMUNICATIONS (ARTICLES 102-104) AND RECORDING AND REPORTING OF SUSPECTED ADVERSE REACTIONS (ARTICLE 105-106)
replacing amendments AMs 122; 1368-1390

Supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Article 96

Article 96 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Member States shall operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks and their participation in the Union pharmacovigilance activities.	Member States shall operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks and their participation in the Union pharmacovigilance activities ***including the pharmacovigilance of the post-authorisation safety and efficacy long-term studies in children, including where relevant data from the off-label use of the product.***

Article 97Article 97 – paragraph 1 – point e a (new)

Text proposed by the Commission	*Amendment*
	(e a) facilitate the protection of patients in relation to adverse events through the development and implementation of plans for safe administration and handling of medicinal products, which may include the use of digital medication safety systems in hospitals and ambulatory care settings.

Articles 98 to 100 - no AMs tabled

Article 101 - COM text proposed as CA

Article 102

Article 102 – paragraph 1 – point b b (new)

Text proposed by the Commission	*Amendment*
	(b b) The outcome of the assessment of the ERA, including the data submitted by the marketing authorisation holder, in accordance with Article 22(7a new) and Article 29 (4a (new));

Article 102 – paragraph 1 – point d a (new)

Text proposed by the Commission	*Amendment*
	(d a) Where relevant, information related to antimicrobials, in accordance with Article 17(2) and Article 29 (4a (new));;

Article 102 – paragraph 1 – point d b (new)

Text proposed by the Commission	*Amendment*
	(d b) Where relevant, the awareness card with information on antimicrobial resistance and the appropriate use and disposal of antimicrobials;

Article 102 – paragraph 1 – point d c (new)

Text proposed by the Commission	*Amendment*
	(d c) periodic safety update reports;

Proposal for a directive
Article 102 – paragraph 1 – point d d (new)

Text proposed by the Commission	*Amendment*
	(d d) information on the shortage status of medicinal products as referred to in Article 121(1)(b) of [revised Regulation (EC) No 726/2004];

Article 103 - no AMs tabled

Article 104 - COM text proposed as CA

Article 105

Article 105 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Marketing authorisation holders shall not refuse to consider reports of suspected adverse reactions received electronically or by any other appropriate means from patients or healthcare professionals.	2. Marketing authorisation holders shall not refuse to consider reports of suspected adverse reactions received electronically or by any other appropriate means from patients***, carers or other relevant persons, such as family members,*** or healthcare professionals.

Article 106

Article 106 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Each Member State shall record all suspected adverse reactions that occur in its territory and that are brought to its attention from healthcare professionals and patients. This shall include all authorised medicinal products and medicinal products used in accordance with Article 3, paragraphs 1 or 2. Member States shall involve patients and healthcare professionals, as appropriate, in the follow-up of any reports they receive in order to comply with Article 97(1), points (c) and (e).	Each Member State shall record all suspected adverse reactions that occur in its territory and that are brought to its attention from healthcare professionals and patients. This shall include all authorised medicinal products and medicinal products used in accordance with Article 3, paragraphs 1 or 2. Member States shall involve patients and healthcare professionals, as appropriate, in the follow-up of any reports they receive in order to comply with Article 97(1), points (c) and (e)***, and shall seek to inform directly those stakeholders that reported a suspected adverse drug reaction on decisions taken in relation to the safety of the medicinal product***.

Article 106 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Member States shall ensure that reports of suspected adverse reactions arising from an error associated with the use of a medicinal product that are brought to their attention are made available to the Eudravigilance database and to any authorities, bodies, organisations or institutions, responsible for patient safety within that Member State concerned. They shall also ensure that the authorities responsible for medicinal products within	5. Member States shall ensure that reports of suspected adverse reactions arising from an error***, including those*** associated with the use***, administration, and dispensation*** of a medicinal product***, by professionals,*** that are brought to their attention are made available to the Eudravigilance database and to any authorities, bodies, organisations or institutions, responsible for patient safety within that Member State concerned. They

that Member State are informed of any suspected adverse reactions brought to the attention of any other authority within that Member State. These reports shall be appropriately identified in the forms referred to in Article 102 of [revised Regulation (EC) No 726/2004]**.**	shall also ensure that the authorities responsible for medicinal products within that Member State are informed of any suspected adverse reactions brought to the attention of any other authority within that Member State. These reports shall be appropriately identified in the forms referred to in Article 102 of [revised Regulation (EC) No 726/2004]
Article 106 – paragraph 5 a (new)	
Text proposed by the Commission	*Amendment*
	5 a. Reports of adverse reactions arising from incorrect administration or dispensation of a medicinal product shall be available in the Eudravigilance database and shall be included in periodic safety update reports. Where relevant, Member States shall take corrective action to achieve high standards of medication safety in healthcare settings after consultation of healthcare professionals and other relevant stakeholders.

COMPROMISE AMENDMENT 29 - PERIODIC SAFETY UPDATE REPORTS (ARTICLES 107-112) AND SIGNAL DETECTION (ARTICLE 113) AND URGENT UNION PROCEDURE (ARTICLE 114-116) AND SUPERVISION OF POST-AUTHORISATION SAFETY STUDIES (ARTICLE 117-121) AND IMPLEMENTATION, GUIDANCE AND REPORTING (ARTICLE 122-124)
replacing amendments AMs 1391-1406

Supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Article 107 - COM text proposed as CA, except the following:
Proposal for a directive
Article 107 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3 a. The Agency or the national competent authorities, as appropriate, shall make publicly available the reports referred to in paragraph 1 points (a) and (b).

Article 108 - COM text proposed as CA

Articles 109 to Article 111 no AMs tabled

Article 112 - COM text proposed as CA

Articles 113 to 116 - no AMs tabled

Article 117 - COM text proposed as CA

Articles 118 - 119 - no AMs tabled

Article 120 - COM text proposed as CA

Articles 121 - 122 - no AMs tabled

Article 123

Article 123 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The Agency shall, in cooperation with competent authorities of the Member States and other interested parties, draw up:	The Agency shall, in cooperation with competent authorities of the Member States and other interested parties, ***including those referred to in Article 162 of [revised Regulation (EC) No 726/2004],*** draw up:

Proposal for a directive
Article 123 – paragraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(a a) guidance for national competent authorities on the effective inclusion of patients and healthcare professionals in the data collection and communication of the risks of medicinal products within the pharmacovigilance activities;

COMPROMISE AMENDMENT 30 - Homeopathic medicinal products and traditional herbal medicinal products (ARTICLES 125-141)
replacing amendments AMs 154; 194; 538; 539; 1407-1429; 1461

Supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Article 4 – paragraph 1 – point 62

Text proposed by the Commission	*Amendment*
(62) 'homeopathic ***medicinal*** product' means a medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the by the pharmacopoeias currently used officially in the Member States;	(62) 'homeopathic product' means a medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the by the pharmacopoeias currently used officially in the Member States;

Chapter X – title

Text proposed by the Commission	*Amendment*
Homeopathic ***medicinal*** products and traditional herbal medicinal products	Homeopathic products and traditional herbal medicinal products

Article 125

Text proposed by the Commission	*Amendment*
*Registration or authorisation of homeopathic **medicinal** products*	*Registration or authorisation of homeopathic products*
1. Member States shall ensure that homeopathic ***medicinal*** products manufactured and placed on the market in the Union are registered in accordance with Articles 126 and 127 or authorised in accordance with Article 133(1), except where such homeopathic ***medicinal*** products are covered by a registration or	1. Member States shall ensure that homeopathic products manufactured and placed on the market in the Union are registered in accordance with Articles 126 and 127 or authorised in accordance with Article 133(1), except where such homeopathic products are covered by a registration or authorisation granted in

authorisation granted in accordance with national legislation on or before 31 December 1993. In case of registrations, Chapter III, Sections 3 and 4, and Article 38, paragraphs 1, 2 and 3 shall apply.	accordance with national legislation on or before 31 December 1993. In case of registrations, Chapter III, Sections 3 and 4, and Article 38, paragraphs 1, 2 and 3 shall apply.
2. Member States shall establish a simplified registration procedure referred to in Article 126 for the homeopathic ***medicinal*** products.	2. Member States shall establish a simplified registration procedure referred to in Article 126 for the homeopathic products.

Article 126

Text proposed by the Commission	*Amendment*
*Simplified registration procedure for homeopathic **medicinal** products*	*Simplified registration procedure for homeopathic products*
1. Homeopathic ***medicinal*** products that satisfy all of the following conditions may be subject to a simplified registration procedure:	1. Homeopathic products that satisfy all of the following conditions may be subject to a simplified registration procedure:
(a) they are administered orally or externally;	(a) they are administered orally or externally;
(b) no specific therapeutic indication appears on the labelling of the ***medicinal*** product or in any information relating thereto;	(b) no specific therapeutic indication appears on the labelling of the ***homeopathic*** product or in any information relating thereto;
(c) there is a sufficient degree of dilution to guarantee the safety of the ***medicinal*** product.	(c) there is a sufficient degree of dilution to guarantee the safety of the ***homeopathic*** product.
For the purposes of point (c), the ***medicinal*** product may not contain either more than one part per 10000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active substances whose presence in an allopathic ***medicinal*** product results in the obligation to submit a doctor's prescription.	For the purposes of point (c), the ***homeopathic*** product may not contain either more than one part per 10000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active substances whose presence in an allopathic ***homeopathic*** product results in the obligation to submit a doctor's prescription.

The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend the first subparagph, point (c), in order to take account of scientific progress.	The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend the first subparagph, point (c), in order to take account of scientific progress.
At the time of registration, Member States shall determine the prescription status for the dispensing of the homeopathic ***medicinal*** product.	At the time of registration, Member States shall determine the prescription status for the dispensing of the homeopathic product.
2. The criteria and rules of procedure provided for in Article 1(10), point (c), Article 30, Chapter III, Section 6, Articles 191, 195 and 204 shall apply by analogy to the simplified registration procedure for homeopathic ***medicinal*** products, with the exception of the proof of therapeutic efficacy.	2. The criteria and rules of procedure provided for in Article 1(10), point (c), Article 30, Chapter III, Section 6, Articles 191, 195 and 204 shall apply by analogy to the simplified registration procedure for homeopathic products, with the exception of the proof of therapeutic efficacy.

Article 127

Text proposed by the Commission	*Amendment*
Application requirements for simplified registration	*Application requirements for simplified registration*
An application a simplified registration may cover a series of homeopathic ***medicinal*** products derived from the same homeopathic stock or stocks. The following shall be included with the application in order to demonstrate, in particular, the pharmaceutical quality and the batch-to-batch homogeneity of the homeopathic ***medicinal*** products concerned:	An application a simplified registration may cover a series of homeopathic products derived from the same homeopathic stock or stocks. The following shall be included with the application in order to demonstrate, in particular, the pharmaceutical quality and the batch-to-batch homogeneity of the homeopathic products concerned:
(a) the scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered;	(a) the scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered;
(b) a dossier describing how the homeopathic stock or stocks are obtained and controlled, and justifying their homeopathic use, on the basis of an	(b) a dossier describing how the homeopathic stock or stocks are obtained and controlled, and justifying their

adequate bibliography;	homeopathic use, on the basis of an adequate bibliography;
(c) the manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentisation;	(c) the manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentisation;
(d) the manufacturing authorisation for the homeopathic ***medicinal*** product concerned;	(d) the manufacturing authorisation for the homeopathic product concerned;
(e) the copies of any registrations or authorisations obtained for the same homeopathic ***medicinal*** product in other Member States;	(e) the copies of any registrations or authorisations obtained for the same homeopathic product in other Member States;
(f) one or more mock-ups of the outer packaging and the immediate packaging of the homeopathic ***medicinal*** products to be registered;	(f) one or more mock-ups of the outer packaging and the immediate packaging of the homeopathic products to be registered;
(g) the data concerning the stability of the homeopathic ***medicinal*** product.	(g) the data concerning the stability of the homeopathic product.

Article 128

Text proposed by the Commission	*Amendment*
*Application of decentralised and mutual recognition procedures to homeopathic **medicinal** products*	*Application of decentralised and mutual recognition procedures to homeopathic products*
1. Article 38, paragraphs 4 and 6, Articles 39 to 42 and 95 shall not apply to the homeopathic ***medicinal*** products referred to in Article 126.	1. Article 38, paragraphs 4 and 6, Articles 39 to 42 and 95 shall not apply to the homeopathic products referred to in Article 126.
2. Chapter III, Sections 3 to 5, shall not apply to the homeopathic ***medicinal*** products referred to in Article 133(2).	2. Chapter III, Sections 3 to 5, shall not apply to the homeopathic products referred to in Article 133(2).

Article 129

Text proposed by the Commission	*Amendment*
*Labelling of homeopathic **medicinal** products*	*Labelling of homeopathic products*
Homeopathic ***medicinal*** products, with the exception those referred to in Article 126(1), shall be labelled in accordance with the provisions of Chapter VI and shall be identified by a reference on their labels, in clear and legible form, to their homeopathic nature.	Homeopathic products, with the exception those referred to in Article 126(1), shall be labelled in accordance with the provisions of Chapter VI and shall be identified by a reference on their labels, in clear and legible form, to their homeopathic nature.

Article 130

Text proposed by the Commission	*Amendment*
*Specific requirements for labelling of certain homeopathic **medicinal** products*	*Specific requirements for labelling of certain homeopathic products*
1. The labelling and, where appropriate, the package insert for homeopathic ***medicinal*** products referred to in Article 126(1) in addition to the clear mention of the words 'homeopathic ***medicinal*** product', shall bear the following, and no other, information:	1. The labelling and, where appropriate, the package insert for homeopathic products referred to in Article 126(1) in addition to the clear mention of the words 'homeopathic product', shall bear the following, and no other, information:
(a) the scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia used in accordance with Article 4(62);	(a) the scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia used in accordance with Article 4(62);
(b) name and address of the registration holder and, where appropriate, of the manufacturer;	(b) name and address of the registration holder and, where appropriate, of the manufacturer;
(c) method of administration and, if necessary, route of administration;	(c) method of administration and, if necessary, route of administration;
(d) pharmaceutical form;	(d) pharmaceutical form;
(e) expiry date, in clear terms (month, year);	(e) expiry date, in clear terms (month, year);
(f) contents of the sales presentation;	(f) contents of the sales presentation;
(g) special storage precautions, if any;	(g) special storage precautions, if any;
(h) a special warning if necessary for the medicinal product;	(h) a special warning if necessary for the medicinal product;
(i) manufacturer's batch number;	(i) manufacturer's batch number;
(j) registration number;	(j) registration number;
(k) 'homeopathic ***medicinal*** product without approved therapeutic indications';	(k) 'homeopathic product without approved therapeutic indications';
(l) a warning advising the user to consult a doctor if the symptoms persist.	(l) a warning advising the user to consult a doctor if the symptoms persist.
As regards the first subparagraph, point (a), if the homeopathic ***medicinal*** product is composed of two or more stocks, the scientific names of the stocks on the labelling may be supplemented by an invented name.	As regards the first subparagraph, point (a), if the homeopathic product is composed of two or more stocks, the scientific names of the stocks on the labelling may be supplemented by an invented name.

2. Notwithstanding paragraph 1, Member States may require the use of certain types of labelling in order to show:	2. Notwithstanding paragraph 1, Member States may require the use of certain types of labelling in order to show:
(a) the price of the homeopathic ***medicinal*** product;	(a) the price of the homeopathic product;
(b) the conditions for refunds by social security bodies.	(b) the conditions for refunds by social security bodies.

Article 131

Text proposed by the Commission	*Amendment*
*Advertising of homeopathic **medicinal** products*	*Advertising of homeopathic products*
1. Chapter XIII shall apply to homeopathic ***medicinal*** products.	1. Chapter XIII shall apply to homeopathic products.
2. By derogation from paragraph 1, Article 176(1) shall not apply to ***medicinal*** products referred to in Article 126(1).	2. By derogation from paragraph 1, Article 176(1) shall not apply to ***homeopathic*** products referred to in Article 126(1).
However, only the information specified in Article 130(1) may be used in the advertising of such homeopathic ***medicinal*** products.	However, only the information specified in Article 130(1) may be used in the advertising of such homeopathic products.

Article 132

Text proposed by the Commission	*Amendment*
*Exchange of information on homeopathic **medicinal** products*	*Exchange of information on homeopathic products*
Member States shall communicate to each other all the information necessary to guarantee the quality and safety of homeopathic ***medicinal*** products manufactured and marketed within the Union, and in particular the information referred to in Articles 202 and 203.	Member States shall communicate to each other all the information necessary to guarantee the quality and safety of homeopathic products manufactured and marketed within the Union, and in particular the information referred to in Articles 202 and 203.

Article 133

Text proposed by the Commission	*Amendment*
Other requirements for homeopathic	*Other requirements for homeopathic*

medicinal *products*	*products*
1. Homeopathic ***medicinal*** products other than those referred to in Article 126(1) shall be granted a marketing authorisation in accordance with Articles 6 and 9 to 14 and labelled in accordance with Chapter VI.	1. Homeopathic products other than those referred to in Article 126(1) shall be granted a marketing authorisation in accordance with Articles 6 and 9 to 14 and labelled in accordance with Chapter VI.
2. A Member State may introduce or retain in its territory specific rules for the non-clinical tests and clinical studies of homeopathic ***medicinal*** products other than those referred to in Article 126(1), in accordance with the principles and characteristics of homeopathy as practised in that Member State.	2. A Member State may introduce or retain in its territory specific rules for the non-clinical tests and clinical studies of homeopathic products other than those referred to in Article 126(1), in accordance with the principles and characteristics of homeopathy as practised in that Member State.
In this case, the Member State concerned shall notify the Commission of the specific rules in force.	In this case, the Member State concerned shall notify the Commission of the specific rules in force.
3. Chapter IX shall apply to homeopathic ***medicinal*** products, with the exception of those referred to in Article 126(1). Chapter XI, Chapter XII, Section 1, and Chapter XIV shall apply to homeopathic ***medicinal*** products.	3. Chapter IX shall apply to homeopathic products, with the exception of those referred to in Article 126(1). Chapter XI, Chapter XII, Section 1, and Chapter XIV shall apply to homeopathic products.

Recital 4

Text proposed by the Commission	*Amendment*
(4) This revision focuses on provisions relevant to achieve its specific objectives; therefore it covers all but provisions concerning falsified medicines, homeopathic and traditional herbal medicines. Nevertheless, for the sake of clarity, it is necessary to replace Directive 2001/83/EC of the European Parliament and of the Council with a new Directive. The provisions on falsified medicines, homeopathic ***medicines*** and traditional herbal medicines are therefore maintained in this Directive without changing their substance compared to previous harmonisations. However, in view of the changes in the governance of the Agency, the Herbal Committee is replaced by a working group.	(4) This revision focuses on provisions relevant to achieve its specific objectives; therefore it covers all but provisions concerning falsified medicines, homeopathic ***products*** and traditional herbal medicines. Nevertheless, for the sake of clarity, it is necessary to replace Directive 2001/83/EC of the European Parliament and of the Council1 with a new Directive. The provisions on falsified medicines, homeopathic ***products*** and traditional herbal medicines are therefore maintained in this Directive without changing their substance compared to previous harmonisations. However, in view of the changes in the governance of the Agency, the Herbal Committee is replaced by a working group.

Recital 24

Text proposed by the Commission	*Amendment*
(24) It is therefore necessary to introduce a requirement for new medicinal products or when developing paediatric indications of already authorised products covered by a patent or a supplementary protection certificate to present either the results of studies in the paediatric population in accordance with an agreed paediatric investigation plan or proof of having obtained a waiver or deferral, at the time of filing a marketing authorisation application or an application for a new therapeutic indication, new pharmaceutical form or new route of administration. However, in order to avoid exposing children to unnecessary clinical trials or due to the nature of the medicinal products, that requirement should not apply to generics or similar biological medicinal products and medicinal products authorised through the well-established medicinal use procedure, nor to homeopathic ***medicinal*** products and traditional herbal medicinal products authorised through the simplified registration procedures of this Directive.	(24) It is therefore necessary to introduce a requirement for new medicinal products or when developing paediatric indications of already authorised products covered by a patent or a supplementary protection certificate to present either the results of studies in the paediatric population in accordance with an agreed paediatric investigation plan or proof of having obtained a waiver or deferral, at the time of filing a marketing authorisation application or an application for a new therapeutic indication, new pharmaceutical form or new route of administration. However, in order to avoid exposing children to unnecessary clinical trials or due to the nature of the medicinal products, that requirement should not apply to generics or similar biological medicinal products and medicinal products authorised through the well-established medicinal use procedure, nor to homeopathic products and traditional herbal medicinal products authorised through the simplified registration procedures of this Directive.

Herbal Medicinal Product

Article 134 - COM text proposed as CA

Articles 135 - 138 - no AMs tabled

Article 139 - COM text proposed as CA

Article 140

Article 140 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the user should consult a doctor or a qualified healthcare practitioner if the symptoms persist during the use of the traditional herbal medicinal product or if	(b) the user should consult a doctor or a qualified healthcare practitioner if the symptoms persist during the use of the traditional herbal medicinal product or if

adverse effects ***not mentioned in the package leaflet*** occur***.***	adverse effects occur***; and***

Article 140 – paragraph 2 – subparagraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(b a) consult a doctor or a qualified healthcare practitioner for information about possible contraindications or pharmacological interactions with other medications.

Article 140 – paragraph 3

Text proposed by the Commission	*Amendment*
3. In addition to the requirements set out in Chapter XIII, any advertisement for a traditional herbal medicinal product registered under this Section shall contain the following statement: Traditional herbal medicinal product for use in specified therapeutic indication(s) exclusively based upon long-standing use.	3. In addition to the requirements set out in Chapter XIII, any advertisement for a traditional herbal medicinal product registered under this Section shall contain the following statement: Traditional herbal medicinal product for use in specified therapeutic indication(s) exclusively based upon long-standing use***.*** ***For more information, consult a healthcare professional.***

Article 141 - COM text proposed as CA

COMPROMISE AMENDMENT 31 - Manufacturing and import (ARTICLES 142-161)
replacing amendments AMs 123; 1430-1445, ITRE 51 - ITRE 54

Supported by
EPP, S&D, RE, Greens/EFA, Left

Article 142
Proposal for a directive
Article 142 – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) preparation, dividing up, changes in packaging or presentation where these processes are carried out, solely for retail supply, by pharmacists in dispensing pharmacies or by persons legally authorised in the Member States to carry out such processes; or	(a) preparation, dividing up, changes in packaging or presentation where these processes are carried out, solely for retail ***and hospital*** supply, by pharmacists in dispensing pharmacies or by persons legally authorised in the Member States to carry out such processes; or

Article 143 - COM text proposed as CA

Articles 144 to 146 - no AMs tabled

Article 147

Article 147 – paragraph 1 – subparagraph 1 – point j a (new)

Text proposed by the Commission	*Amendment*
	(ja) use an appropriate wastewater treatment system;

Article 147 – paragraph 1 – subparagraph 1 – point j b (new)

Text proposed by the Commission	*Amendment*
	(j b) comply with relevant risk mitigation measures identified in accordance with Article 22.

Article 148

Article 148 – paragraph 9

Text proposed by the Commission	*Amendment*
9. Where relevant, competent authorities of the Member State supervising the central and decentralised	9. Where relevant, competent authorities of the Member State supervising the central and decentralised

sites ***may*** liaise with the competent authority of the Member State responsible for the supervision of the marketing authorisation.	sites ***shall*** liaise with the competent authority of the Member State responsible for the supervision of the marketing authorisation.

Articles 149 to 158 - no AMs tabled

Article 159 - COM text proposed as CA

Article 160

Article 160 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The Commission may adopt ***implementing*** acts in accordance with Article ***214(2)*** to supplement this Directive by specifying:	The Commission may adopt ***delegated*** acts in accordance with Article ***215*** to supplement this Directive by specifying:

Article 160 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(b a) measures to reduce the negative impact on the environment posed by the manufacturing of medicinal products.

Article 161 - no AMs tabled

COMPROMISE AMENDMENT 32 - WHOLESALE DISTRIBUTION AND SALE AT A DISTANCE (ARTICLES 162-174)
replacing amendments AMs 124-127; 1446-1460

Supported by
EPP, S&D, RE, Greens/EFA, Left

Article 162 - no AMs tabled

Article 163

Article 163 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The competent authority of the Member State concerned shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to an authorisation to engage in activity as a wholesaler in medicinal products ("wholesale distribution authorisation"). The wholesale distribution authorisation shall indicate the premises, the medicinal products and the wholesale distribution operations for which it is valid.	1. The competent authority of the Member State concerned shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to an authorisation to engage in activity as a wholesaler in medicinal products ("wholesale distribution authorisation"). The wholesale distribution authorisation shall indicate the premises, the ***categories of*** medicinal products and the wholesale distribution operations for which it is valid.

Articles 164 and 165 - no AMs tabled

Article 166

Article 166 – paragraph 1 – point d

Text proposed by the Commission	*Unchanged text included in the compromise*
(d) supply, including by financial transaction, medicinal products only to persons who are themselves wholesale distribution authorisation holders or who are authorised or entitled to supply medicinal products to the public;	(d) supply, including by financial transaction, medicinal products only to persons who are themselves wholesale distribution authorisation holders or who are authorised or entitled to supply medicinal products to the public;

Article 166 – paragraph 1 – point l

Text proposed by the Commission	*Unchanged text included in the compromise*
(l) continuously guarantee the appropriate and continued supply of an adequate range of medicinal products to meet the requirements of a specific geographical area, and deliver the supplies requested over the whole of the area in question, within a reasonable timeframe, which shall be defined in the national legislation;	(l) continuously guarantee the appropriate and continued supply of an adequate range of medicinal products to meet the requirements of a specific geographical area, and deliver the supplies requested over the whole of the area in question, within a reasonable timeframe, which shall be defined in the national legislation;

Article 166 – paragraph 1 – point m

Text proposed by the Commission	*Amendment*
(m) cooperate with marketing authorisation holders and competent authorities of the Member States on the security of supply.	(m) cooperate with ***all relevant stakeholders, including*** marketing authorisation holders and competent authorities of the Member States on the security of supply.

Article 167

Article 167 – paragraph 2

Text proposed by the Commission	*Unchanged text included in the compromise*
2. The wholesale distributors of a medicinal product placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.	2. The wholesale distributors of a medicinal product placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.

Article 168Article 168 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. For all supplies of medicinal products to a person authorised or entitled to supply medicinal products to the public	1. For all supplies of medicinal products to a person authorised or entitled to supply medicinal products to the public

in the Member State concerned, the authorised wholesaler must ***enclose*** a document that makes it possible to ascertain the following:	in the Member State concerned, the authorised wholesaler must ***provide*** a document***, which may be submitted in electronic format,*** that makes it possible to ascertain the following:

Article 169 - no AMs tabled

Article 170 - no AMs tabled

Article 171 - no AMs tabled

Article 172

Article 172 – paragraph 1 – introductory part

Text proposed by the Commission	*Unchanged text included in the compromise*
1. Without prejudice to national legislation prohibiting the offer for sale at a distance of prescription medicinal products to the public by means of information society services, Member States shall ensure that medicinal products are offered for sale at a distance to the public by means of services as defined in Directive (EU) 2015/1535 of the European Parliament and of the Council[78] laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services under the following conditions:	1. Without prejudice to national legislation prohibiting the offer for sale at a distance of prescription medicinal products to the public by means of information society services, Member States shall ensure that medicinal products are offered for sale at a distance to the public by means of services as defined in Directive (EU) 2015/1535 of the European Parliament and of the Council[78] laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services under the following conditions:

Proposal for a directive
Article 172 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the natural or legal person offering the medicinal products is authorised or entitled to supply medicinal products to the public, also at a distance, in accordance with national legislation of the Member State in which that person is established;	(a) the natural or legal person offering the medicinal products is authorised or entitled to supply medicinal products to the public, also at a distance, in accordance with national legislation of the Member State in which that person is established ***and complies, where applicable, with the conditions referred to in paragraph 2 of this Article;***

Article 173 - no AMs tabled

Article 174 - no AMs tabled

COMPROMISE AMENDMENT 33 - ADVERTISING (ARTICLE 175-187)
replacing amendments AMs 128; 129; 1462-1524

Supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Article 175
Article 175 – paragraph 1 – subparagraph 2 – point e

Text proposed by the Commission	*Amendment*
(e) the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind***, except when their intrinsic value is minimal***;	(e) the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind;

Article 176

Article 176 – paragraph 3 – point b a (new)

Text proposed by the Commission	*Amendment*
	(b a) shall not induce to an excessive or abusive use of the medicinal product.

Proposal for a directive
Article 176 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Any form of advertising that aims to highlight negatively another medicinal product shall be prohibited. Advertising that suggests that a medicinal product is safer or more effective than another medicinal product shall also be prohibited**,** unless demonstrated and supported by the summary of product characteristics.	4. Any form of advertising that aims to highlight negatively another medicinal product shall be prohibited. Advertising that suggests that a medicinal product is safer or more effective than another medicinal product shall also be prohibited, unless demonstrated and supported by the summary of product characteristics ***for the relevant indications and patient population.***

Article 177

Proposal for a directive
Article 177 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*

	(b a) are antibiotics or antimicrobials for which there is an identified risk of antimicrobial resistance as referred to in Article 51(1a).

Article 177 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Medicinal products may be advertised to the general public where, by virtue of their composition and purpose, they are intended and designed for use without the intervention of a ***medical practitioner*** for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.	2. Medicinal products may be advertised to the general public where, by virtue of their composition and purpose, they are intended and designed for use without the intervention of a ***healthcare professional*** for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.

Article 177 – paragraph 3

Text proposed by the Commission	*Unchanged text included in the compromise*
3. Member States shall be entitled to ban, on their territory, advertising to the general public of medicinal products the cost of which may be reimbursed.	3. Member States shall be entitled to ban, on their territory, advertising to the general public of medicinal products the cost of which may be reimbursed.

Article 177 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The prohibition contained in paragraph 1 shall not apply to vaccination campaigns ***carried out by the industry and*** approved by the competent authorities of the Member States.	4. The prohibition contained in paragraph 1 shall not apply to vaccination campaigns approved by the competent authorities of the Member States.

Article 178

Article 178 – paragraph 1 – point b – point ii

Text proposed by the Commission	*Amendment*
(ii) the information necessary for correct use of the medicinal product;	(ii) the information necessary for correct use ***and disposal*** of the medicinal product;

Article 178 – paragraph 1 – point b – point iii

Text proposed by the Commission	*Amendment*
(iii) an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be.	(iii) an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be***, and to consult a medical practitioner or a pharmacist for extended information***.

Article 178 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. The Commission shall adopt delegated acts to specify requirements in relation to direct and indirect advertising of medicinal products through social media and other media platforms and product placements by celebrities and influencers.

Proposal for a directive
Article 179 – paragraph 1 – point h

Text proposed by the Commission	*Amendment*
(h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;	(h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural ***or not chemical***;

Article 180 - COM text proposed as CA

Article 181 - no AMs tabled

Article 182 - no AMs tabled

Article 183

Article 183 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to	1. Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to

such persons ***unless they are inexpensive and relevant to the practice of medicine or pharmacy***.	such persons.

Article 184 - no AMs tabled

Article 185

Article 185 – paragraph 1 – point b

Text proposed by the Commission	*Unchanged text included in the compromise*
(b) any supply of samples shall be in response to a written request, signed and dated, from the persons qualified to prescribe or supply medicinal products;	(b) any supply of samples shall be in response to a written request, signed and dated, from the persons qualified to prescribe or supply medicinal products;

Article 185 – paragraph 1 – point g

Text proposed by the Commission	*Amendment*
(g) no samples of medicinal products containing substances classified as psychotropic or narcotic within the meaning of international conventions may be supplied**.**	(g) no samples of medicinal products containing substances classified as ***antibiotic,*** psychotropic or narcotic within the meaning of international conventions may be supplied.

Article 186

Article 186 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall ensure that there are adequate and effective methods to monitor the advertising of medicinal products. Such methods, ***which may*** be based on a system of prior vetting, shall in any event include legal provisions under which persons or organisations regarded under national law as having a legitimate interest in prohibiting any advertisement inconsistent with this Chapter, may take legal action against such advertisement, or bring such advertisement before the competent authority of the Member State either to decide on complaints or to initiate appropriate legal proceedings.	1. Member States shall ensure that there are adequate and effective methods to monitor the advertising of medicinal products. ***At least for advertisements targeted at the general public,*** such methods ***shall*** be based on a system of prior vetting, ***and*** shall in any event include legal provisions under which persons or organisations regarded under national law as having a legitimate interest in prohibiting any advertisement inconsistent with this Chapter, may take legal action against such advertisement, or bring such advertisement before the competent authority of the Member State either to decide on complaints or to initiate

appropriate legal proceedings.

Proposal for a directive
Article 186 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. Member States shall set up and maintain a national transparency register of transfers of value regarding the advertising activities referred to in Articles 175, 177, 180, 182, 183, 184 and 185, targeting persons qualified to prescribe medicinal products. The Commission shall on its website publish a listing referring to all national registries.

Or. en

Proposal for a directive
Article 186 – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	4 b. The national registries referred to in paragraph 4a shall include at least the following information:
	(a) the name of the marketing authorisation holder;
	(b) the name of a person qualified to prescribe medicinal products;
	(c) medicinal product concerned;
	(d) type of advertising activity, referred to in Article 175 paragraph 1 points (b) to (g) and Article 184;
	(e) monetary value.

Or. en

Proposal for a directive
Article 186 – paragraph 4 c (new)

Text proposed by the Commission	*Amendment*

4 c. Marketing authorisation holders shall use the national transparency register referred to in paragraph 4a to submit information referred to in paragraph 4b in relation to each person qualified to prescribe medicinal products in respective Member State where such activity takes place.

Or. en

Proposal for a directive
Article 186 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The paragraphs 1 to ***4*** shall not exclude the voluntary control of advertising of medicinal products by self-regulatory bodies ***and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or administrative proceedings referred to in paragraph 1***.	5. The paragraphs 1 to ***4c*** shall not exclude the voluntary control of advertising of medicinal products by self-regulatory bodies.

Or. en

Proposal for a directive
Article 187 – paragraph 2 – point d a (new)

Text proposed by the Commission	*Amendment*
	(d a) report activities in national registries, as laid down in Article 186 (4c).

Or. en

COMPROMISE AMENDMENT 34 - SUPERVISION AND CONTROLS (ARTICLES 188-194)
replacing amendments AMs 130; 1525-1541

Supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Article 188

Article 188 – paragraph 5 – introductory part

Text proposed by the Commission	*Amendment*
5. Where the competent authority of the Member State considers it necessary, in particular where there are grounds for suspecting non-compliance with the rules of this Directive, including with the principles of good manufacturing practice and good distribution practices, referred to in Articles 160 and 161, it may have its official representatives carry out the measures referred to in paragraph 1, second subparagraph at the premises or on the activities of:	5. Where the competent authority of the Member State considers it necessary, in particular where there are grounds for suspecting non-compliance with the rules of this Directive, including with the principles of good manufacturing practice and good distribution practices, referred to in Articles 160 and 161, ***or based on a risk assessment,*** it may have its official representatives carry out the measures referred to in paragraph 1, second subparagraph at the premises or on the activities of:

Article 188 – paragraph 5 – point d

Text proposed by the Commission	*Amendment*
(d) distributors of medicinal products or active substances located in third countries;	(d) distributors of medicinal products or ***manufacturers or distributors of*** active substances located in third countries;

Article 188 – paragraph 15 a (new)

Text proposed by the Commission	*Amendment*
	15a. The Agency shall draw up guidelines on the use of the Union database.

Article 189

Article 189 – paragraph 1 – subparagraph 2 – point c

Text proposed by the Commission	*Unchanged text included in the*

	compromise
(c) the competent authority of the Member State receiving the request agrees that there are other reasonable grounds such as training of inspectors, sharing of good practice, for conducting a joint inspection.	(c) the competent authority of the Member State receiving the request agrees that there are other reasonable grounds such as training of inspectors, sharing of good practice, for conducting a joint inspection.

Articles 190 and 191 - no AMs tabled

Article 192 - COM text proposed as CA

Article 193

Article 193 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where, in the interests of public health, the laws of a Member State so provide, the competent authorities of the Member State may require the marketing authorisation holder for medicinal products derived from human blood or human plasma to submit samples from each batch of the bulk or the medicinal product for testing by an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose before being released into free circulation, unless the competent authorities of another Member State have previously examined the batch in question and declared it to be in conformity with the approved specifications. Member States shall ensure that any such examination is completed within 60 days of the receipt of the samples.	2. Where, in the interests of public health, the laws of a Member State so provide, the competent authorities of the Member State may require the marketing authorisation holder for medicinal products derived from human blood or human plasma to submit samples from each batch of the bulk or the medicinal product for testing by an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose before being released into free circulation, unless the competent authorities of another Member State have previously examined the batch in question and declared it to be in conformity with the approved specifications. ***In such a case the declaration of conformity issued by another Member State shall be recognised.*** Member States shall ensure that any such examination is completed within 60 days of the receipt of the samples.

Article 194

Proposal for a directive
Article 194 – title

Text proposed by the Commission	*Amendment*
Processes for the preparation of medicinal products derived from ***human blood or*** human ***plasma***	Processes for the preparation of medicinal products derived from ***substances of*** human ***origin***

Proposal for a directive
Article 194 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall take all necessary measures to ensure that the manufacturing and purifying processes used in the preparation of medicinal products derived from ***human blood or*** human ***plasma*** are properly validated, attain batch-to-batch consistency and guarantee, insofar as the state of technology permits, the absence of ***specific viral contamination***.	1. Member States shall take all necessary measures to ensure that the manufacturing and purifying processes used in the preparation of medicinal products derived from ***substances of*** human ***origin*** are properly validated, attain batch-to-batch consistency and guarantee, insofar as the state of technology permits, the absence of ***relevant risks for the human health, including contaminations***.

Article 194 – paragraph 2

Text proposed by the Commission	*Amendment*
2. To this end manufacturers shall notify the competent authorities of the Member States of the ***method*** used to ***reduce or eliminate pathogenic viruses liable to be transmitted by medicinal products derived from*** human ***blood or human plasma***. The competent authority of the Member State may submit samples of the bulk or the medicinal product for testing by a State laboratory or a laboratory designated for that purpose, either during the examination of the application pursuant to Article 29, or after a marketing authorisation has been granted.	2. To this end manufacturers shall notify the competent authorities of the Member States of the ***methods*** used to ***ensure the quality and safety of the substances of*** human ***origin, as described in Regulation (EU) No [SoHO Regulation]***. The competent authority of the Member State may submit samples of the bulk or the medicinal product for testing by a State laboratory or a laboratory designated for that purpose, either during the examination of the application pursuant to Article 29, or after a marketing authorisation has been granted.

COMPROMISE AMENDMENT 35 - RESTRICTIONS OF MARKETING AUTHORISATIONS (ARTICLES 195-199)
replacing amendments AMs 131; 1542-1561, ITRE 55, ITRE 56

Supported by
EPP, S&D, RE, Greens/EFA, Left

Article 195

Article 195 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend**,** revoke or vary a marketing authorisation if a serious risk to the environment or public health has been identified and not sufficiently addressed by the marketing authorisation holder.	2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend, revoke or vary a marketing authorisation if a serious risk to the environment or public health has been identified and not sufficiently addressed by the marketing authorisation holder ***and if the risks cannot be mitigated via conditions specified in Articles 44(h) or 87(c) following a decision of suspension or modification. Any such decision shall take into account the clinical benefits of the medicinal product and the needs of patients, including alternative treatments available.***

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Article 196

Article 196 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) a serious risk to the environment or to public health via the environment has been identified and not sufficiently addressed by the marketing authorisation holder.	(f) a serious risk to the environment or to public health via the environment has been identified and not sufficiently addressed by the marketing authorisation holder ***via conditions specified in Articles 44(h) or 87(c). Any such decision shall also take into account the clinical benefits of the medicinal product and the needs of patients, including alternative treatments***

available.

Article 197 - COM text proposed as CA

Article 198 - no AMs tabled

Article 199 - no AMs tabled

COMPROMISE AMENDMENT 36 - General provisions (ARTICLES 200-208)
replacing amendments AMs 133-137; 1562-1576; 1578-1594

Supported by
EPP, S&D, RE, Greens/EFA, Left

Article 200

Article 200 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
The competent authority of the Member State may process personal health data from sources other than clinical studies to support their public health tasks and, in particular, the evaluation and monitoring to medicinal products, for the purpose of improving the robustness of the scientific assessment or verifying claims of the applicant or marketing authorisation holder.	The competent authority of the Member State may process personal health data from sources other than clinical studies***, including real world data,*** to support their public health tasks and, in particular, the evaluation and monitoring to medicinal products, for the purpose of improving the robustness of the scientific assessment or verifying claims of the applicant or marketing authorisation holder.

Article 200 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ensure that adequate financial resources are available to provide the staff and other resources necessary for the competent authorities to carry out the activities required by this Directive and [revised Regulation (EC) No 726/2004].	2. Member States shall ensure that adequate financial resources are available to provide the staff and other resources***, including appropriate digital infrastructure,*** necessary for the competent authorities to carry out the activities required by this Directive and [revised Regulation (EC) No 726/2004].

Article 201

Article 201 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States, in applying this Directive, shall ensure that when questions arise with regard to the regulatory status of a medicinal product, in relation to their link to substances of human origin as referred to in Regulation (EU) No [SoHO Regulation], the competent authorities of	1. Member States, in applying this Directive, shall ensure that when questions arise with regard to the regulatory status of a medicinal product, in relation to their link to substances of human origin as referred to in Regulation (EU) No [SoHO Regulation], the competent authorities of

the Member States shall consult the relevant authorities established under that Regulation.	the Member States shall consult the ***Agency and the*** relevant authorities established under that Regulation.

Article 201 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. The Commission, in applying this Directive, in order to improve regulatory certainty and cross-sectoral cooperation it shall where deemed necessary, organise joint meetings between the Agency and the relevant advisory and regulatory bodies established under other Union legislation to assess emerging trends and questions on the regulatory status of products and to find agreement on common regulatory status principles. The summaries and conclusions of these joint meetings shall be made publicly available, including the opinions and conclusions of each of the respective bodies.

Article 202 - no AMs tabled

Article 203 - no AMs tabled

Article 204 - no AMs tabled

Article 205 - no AMs tabled

Article 206

Article 206 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. When determining the type and level of penalties to be imposed in case of infringements, the competent authorities of the Member States shall give due regard to all relevant circumstances of the specific infringement and to the following:
	(a) the nature, gravity and extent of the infringement;

(b) the repetitive or singular character of the infringement;

(c) where appropriate, the intentional or negligent character of the infringement;

(d) any action taken by the infringing party to mitigate or remedy the damage caused;

(e) the level of cooperation with the competent authorities, in order to remedy the infringement and mitigate the possible adverse effects of the infringement;

Article 207

Article 207 – title

Text proposed by the Commission	*Amendment*
Collection of unused or expired medicinal products	Collection ***and management*** of unused or expired medicinal products

Article 207 – paragraph 1

Text proposed by the Commission	*Amendment*
Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired.	Member States shall ensure that appropriate collection ***and management*** systems are in place for medicinal products that are unused or have expired ***and that the collected medicinal products are managed properly without any technically avoidable leakage to the environment***.

Article 207 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. By ... [18 months after the date of entry into force of this Directive], Member States shall draw up national plans including measures designed to:
	(a) monitor the rates of correct and incorrect disposal of unused and expired medicinal products;
	(b) inform the general public about the environmental risks associated with incorrect disposal of medicinal products,

	in particular those that contain substances referred to in Article 22(2);
	(c) inform healthcare professionals about the environmental risks associated with incorrect disposal of unused or expired medicinal products, in particular those that contain substances referred to in Article 22(2);
	(d) increase the rate of correct disposal of unused or expired medicinal products; and
	(e) designate public and/or private actors responsible for the collection systems referred to in paragraph 1.

Article 207 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. The national plans shall be submitted to the Commission.

Article 208

Article 208 – paragraph 1

Text proposed by the Commission	*Amendment*
1. In order to guarantee independence and transparency, the Member States shall ensure that members of staff of the competent authority responsible for granting authorisations, rapporteurs and experts concerned with the authorisation and surveillance of medicinal products have no financial or other interests in the pharmaceutical industry that could affect their impartiality. These persons shall make an annual declaration of their financial interests.	1. In order to guarantee independence and transparency, the Member States shall ensure that members of staff of the competent authority responsible for granting authorisations, rapporteurs and experts concerned with the authorisation and surveillance of medicinal products have no ***direct or indirect*** financial or other interests in the pharmaceutical industry that could affect their impartiality ***and their independence***. These persons shall make an annual declaration of their financial interests ***and update them annually and whenever necessary***. ***The declaration shall be made available upon request.***

Article 208 – paragraph 2

Text proposed by the Commission	*Amendment*
2. In addition, the Member States	2. In addition, the Member States

shall ensure that the competent authority makes publicly available its rules of procedure and those of its committees, agendas for its meetings and records of its meetings, accompanied by decisions taken, details of votes and explanations of votes, including minority opinions.	shall ensure that the competent authority makes publicly available its rules of procedure and those of its committees***, including their working groups and expert groups***, agendas for its meetings and records of its meetings, accompanied by decisions taken, details of votes and explanations of votes, including minority opinions.

COMPROMISE AMENDMENT 38 - SPECIFIC PROVISIONS CONCERNING CYPRUS, IRELAND, MALTA AND THE UNITED KINGDOM IN RESPECT OF NORTHERN IRELAND (ARTICLES 209-212) AND FINAL PROVISIONS (ARTICLES 213-221)
replacing amendments AMs 138-140; 1595-1601; 1603

Supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Article 209 to Article 213 - no AMs tabled

Article 214

Article 214 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The rules of procedure ***of*** the Standing Committee on Medicinal Products shall be made publicly available.	4. The rules of procedure***, lists of participating entities of its meetings, agendas for its meetings and records of its meetings, accompanied by decisions taken, and, where applicable, details of votes and explanations of votes, including minority opinions,*** of the Standing Committee on Medicinal Products shall be made publicly available.

Article 215 - TO BE REVISED AT LATER STAGE

Article 216

Article 216 – paragraph 1

Text proposed by the Commission	*Amendment*

By [OP please insert the date = 10 years following 18 months after the date of entering into force of this Directive], the Commission shall present a report to the European Parliament and the Council on the application of this Directive, including an assessment of the fulfilment of its objectives and the resources required to implement it.	By [OP please insert the date = 10 years following 18 months after the date of entering into force of this Directive], the Commission shall present a report to the European Parliament and the Council on the application of this Directive, including an assessment of the fulfilment of its objectives and the resources required to implement it***, including regarding the revised framework for regulatory data protection periods***. ***1a. By [OP please insert the date =2 years after the date of entering into force of this Directive], the Commission shall publish a report to the European Parliament and Council evaluating the appropriateness of the framework of homeopathic products, notably aspects of public health and patient protection.*** ***The report shall, where appropriate, be accompanied by a legislative proposal.***

Article 217 - COM text is proposed as compromise

Article 218 - COM text is proposed as compromise

Article 219 - COM text is proposed as compromise

Article 220 and 221 - no AMs tabled

COMPROMISE AMENDMENT 39 - ANNEXES I - VIII
replacing amendments AMs 141; 142; 890; 891; 933; 1604-1636

Supported by
EPP, S&D, RE, Greens/EFA, Left

Annex I

Annex I – point 21 – point a – introductory part

Text proposed by the Commission	*Amendment*
a) an antimicrobial stewardship plan which shall in particular outline:	a) an antimicrobial stewardship ***and access*** plan which shall in particular outline:

Proposal for a directive
Annex I – point 21 – point a – point ii a (new)

Text proposed by the Commission	*Amendment*
	(ii a) information about measures to strategy to promote access, including proposed production chain capacity;

Annex I – point 21 – point a – point ii d (new)

Text proposed by the Commission	*Amendment*
	(ii d) information about measures to ensure marketing approvals are received for key territories in a timely manner; and

Annex I – point 21 – point a – point ii e (new)

Text proposed by the Commission	*Amendment*
	(ii e) information about measures to monitor effectiveness of stewardship and access.

Annex II - COM text is proposed as compromise

Annex III - COM text as compromise

Annex IV

Annex IV – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the name of the medicinal product, including in Braille, followed by its strength and pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults; where the medicinal product contains up to three active substances, the international non-proprietary name (INN) shall be included, or, if one does not exist, the common name;	(a) the name of the medicinal product, including in Braille, followed by its strength and pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults; where the medicinal product contains up to three active substances, the international non-proprietary name (INN) shall be included, ***unless it is already part of the name of the medicinal product,*** or, if one does not exist, the common name;

Annex IV – paragraph 1 – point j

Text proposed by the Commission	*Amendment*
(j) specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products***, where appropriate,*** as well as reference to any appropriate collection system in place;	(j) specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products as well as reference to any appropriate collection system in place;

Proposal for a directive
Annex IV – paragraph 1 – point g a (new)

Text proposed by the Commission	*Amendment*
	(g a) for antimicrobials, a warning that improper use and unsafe disposal of the medicinal product contributes to antimicrobial resistance;

Annex V

Annex V – paragraph 1 – point 6 – point f

Text proposed by the Commission	*Amendment*
(f) special precautions for disposal of a ***used*** medicinal product or waste materials derived from such medicinal product***, if appropriate***. In case of antimicrobial medicinal products in addition to the precautions a warning that inappropriate disposal of the medicinal product contributes to antimicrobial resistance**.**	(f) special precautions for disposal of a medicinal product or waste materials derived from such medicinal ***product as well as any designated collection system in place.*** In case of antimicrobial medicinal products in addition to the precautions a warning that inappropriate disposal of the medicinal product contributes to

antimicrobial resistance***;***

Annex VI

Annex VI – paragraph 1 – point 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) a key information section reflecting the results of consultations with patients' organisations to ensure that the leaflet is legible, clear and easy to use;

Annex VI – paragraph 1 – point 4 – point b

Text proposed by the Commission	*Amendment*
(b) the method and, if necessary, route of administration;	(b) the method and, if necessary, route of administration, ***and where relevant a description of the measuring or delivery device, as well as the relevant individual steps of medicine preparation and administration;***

Annex VI – paragraph 2 (new)

Text proposed by the Commission	**Amendment**
	The package leaflet may also contain information on the importance of therapeutic adherence and available support for adherence in the Member State.

COMPROMISE AMENDMENT 41 - RECITALS (EXCEPT: RECITALS 4, 11, 24, 44 A (NEW), 47, 50, 50 A, 52, 53, 54, 55, 56, 57AND 59)

replacing amendments 1-7, 9, 17-18, 20-29, 143-153; 155-163; 167-193; 195-209; 211-217; 220-229; 242-245; 251; 262-266; 268-382; ITRE 1-3; ITRE 5-10; ITRE 12

Supported by
EPP, S&D, RE, Greens/EFA, Left

Proposal for a directive
Recital 2

Text proposed by the Commission	*Amendment*

(2) The most recent comprehensive revision took place between 2001 and 2004 while targeted revisions on post-authorisation monitoring (pharmacovigilance) and on falsified medicines were adopted subsequently. In the almost 20 years since the last comprehensive revision, the pharmaceutical sector has changed and has become more globalised, both in terms of development and manufacture. Moreover, science and technology have evolved at a rapid pace. However, there continues to be unmet medical needs, i.e. diseases without or only with suboptimal treatments. Moreover, some patients may not benefit from innovation because medicines may be unaffordable or not placed on the market in the Member State concerned. There is also a greater awareness of the environmental impact of medicines. More recently, the COVID-19 pandemic has stress tested the framework.

(2) The most recent comprehensive revision took place between 2001 and 2004 while targeted revisions on post-authorisation monitoring (pharmacovigilance) and on falsified medicines were adopted subsequently. In the almost 20 years since the last comprehensive revision, the pharmaceutical sector has changed and has become more globalised, both in terms of development and manufacture. Moreover, science and technology have evolved at a rapid pace. However, there continues to be unmet medical needs, i.e. diseases without or only with suboptimal ***or highly burdensome*** treatments***, or with treatments targeting only sub-populations of a disease***. Moreover, some patients may not benefit from innovation because medicines may be unaffordable or not placed on the market in the Member State concerned. There is also a greater awareness of the environmental impact of medicines. More recently, the COVID-19 pandemic has stress tested the framework.

Proposal for a directive
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2 a) This Directive should contribute to the implementation of the One Health Approach, stressing the well-established interconnectedness between human, animal, and ecosystem health and the need to include those three dimensions when addressing public health threats. Environmental stress and degradation, including biodiversity loss, contribute to the transmission of diseases between, and diseases burdens of, humans and animals. In addition, pollution from active pharmaceutical ingredients negatively affects the quality of waters and ecosystems, posing risks to public health globally.

Recital 3

Text proposed by the Commission	*Amendment*
(3) This revision is part of the implementation of the Pharmaceutical strategy for Europe and aims to promote innovation, in particular for unmet medical needs, while reducing regulatory burden and the environmental impact of medicines; ensure access to innovative and established medicines for patients, with special attention to enhancing security of supply and addressing risks of shortages, taking into account the challenges of the smaller markets of the Union; and create a balanced and competitive system that keeps medicines affordable for health systems while rewarding innovation.	(3) This revision is part of the implementation of the Pharmaceutical strategy for Europe and aims to promote innovation, in particular for unmet medical needs, while reducing regulatory burden and the environmental impact of medicines; ***create an attractive environment for research, development and manufacturing of medicines in the Union;*** ensure access***, including affordability,*** to innovative and established medicines for patients, with special attention to enhancing security of supply and addressing risks of shortages, taking into account the challenges of the smaller markets of the Union; and create a balanced and competitive system that keeps medicines affordable for health systems ***and patients*** while rewarding innovation.

Recital 3 a (new)

Text proposed by the Commission	*Amendment*

	(3 a) In parallel of this revision, the Union should strengthen the European pharmaceutical ecosystem to accelerate research and development of a new medicinal product and support innovation through the establishment of public-private partnerships, the multiplication of University Hospital Institutes, centres of excellence and bioclusters.

Recital 3 b (new)

Text proposed by the Commission	*Amendment*
	(3 b) ***A range of EU programmes can be used to fund pharmaceutical research projects, such as Horizon Europe, InvestEU, EU4Health, cohesion policy and the Digital Europe programme. The Union should prioritize in its research agenda also participation in cross-country collaboration enabling transnational research to meet public health needs.***

Recital 6

Text proposed by the Commission	*Amendment*
(6) The regulatory framework for medicinal products use should also take into account the needs of the undertakings in the pharmaceutical sector and trade in medicinal products within the Union, without jeopardising the quality, safety and efficacy of medicinal products.	(6) The regulatory framework for medicinal products ***for human*** use should also take into account the needs of the undertakings in the pharmaceutical sector and trade in medicinal products within the Union, without jeopardising the quality, safety and efficacy of medicinal products.

Recital 8

Text proposed by the Commission	*Amendment*
(8) This revision maintains the level of harmonisation that has been achieved. Where necessary and appropriate, it further reduces the remaining disparities, by laying down rules on the supervision and control of medicinal products and the rights and duties incumbent upon the competent authorities of the Member States with a view to ensuring compliance with legal requirements. In the light of experience	(8) This revision maintains the level of harmonisation that has been achieved. Where necessary and appropriate, it further reduces the remaining disparities, by laying down rules on the supervision and control of medicinal products and the rights and duties incumbent upon the competent authorities of the Member States with a view to ensuring compliance with legal requirements. In the light of experience

gained on the application of the Union pharmaceutical legislation and the evaluation of its functioning, the regulatory framework need to be adapted to scientific and technological progress, the current market conditions and economic reality within the Union. Scientific and technological developments induce innovation and development of medicinal products, including for therapeutic areas where there is still unmet medical need. To harness these developments, the Union pharmaceutical framework should be adapted to meet scientific developments such as genomics, accommodate cutting edge medicinal products, e.g. personalised medicinal products and technological transformation such as data analytics, digital tools and the use of artificial intelligence. These adaptations also contribute to competitiveness of the Union pharmaceutical industry.	gained on the application of the Union pharmaceutical legislation and the evaluation of its functioning, the regulatory framework need to be adapted to scientific and technological progress, the current market conditions and economic reality within the Union. Scientific and technological developments induce innovation and development of medicinal products, including for therapeutic areas where there is still unmet medical need. To harness these developments, the Union pharmaceutical framework should be adapted to meet scientific developments such as genomics, accommodate cutting edge medicinal products, e.g. personalised medicinal products***, novel health treatments*** and technological transformation such as data analytics, digital tools and the use of artificial intelligence. These adaptations also contribute to competitiveness of the Union pharmaceutical industry.

Recital 8a(new)

Text proposed by the Commission	***Amendment***
	(8a) This Directive should aim to enhance the Union's open strategic autonomy with regard to its public health objectives. Increasing the number of EU-based clinical trials and the local production of active pharmaceutical ingredients would support a more resilient and sustainable European health ecosystem.

Recital 9

Text proposed by the Commission	*Amendment*
(9) Medicinal products for rare diseases and for children, should be subject to the same conditions as any other medicinal product concerning their quality, safety and efficacy, for example for what concerns the marketing authorisation procedures, quality and the	(9) Medicinal products for rare diseases and for children, should be subject to the same conditions as any other medicinal product concerning their quality, safety and efficacy, for example for what concerns the marketing authorisation procedures, quality and the

pharmacovigilance requirements. However, specific requirements also apply to them considering their unique characteristics. Such requirements, which are currently defined in separate legislations, should be integrated in general pharmaceutical legal framework in order to ensure clarity and coherency of all the measures applicable to these medicinal products. Furthermore, as some medicinal products authorised for use in children are authorised by the Member States, specific provisions should be integrated in this Directive.	pharmacovigilance requirements. However, specific requirements also apply to them considering their unique characteristics. Such requirements, which are currently defined in separate legislations, should be integrated in general pharmaceutical legal framework in order to ensure clarity and coherency of all the measures applicable to these medicinal products. Furthermore, as some medicinal products authorised for use in children are authorised by the Member States, specific provisions should be integrated in this Directive. ***Effort should be made to address encountered problems of medicinal products for children, such as failure to timely accomplish the paediatric clinical studies and obtain data required for marketing authorization, which results in significant delay of approval in children compared to adults.***

Recital 11 a (new)

Text proposed by the Commission	*Amendment*
	(11a) This Directive should be consistent with the Union's objectives with regard to promotion of research, innovation, digitalization, trade, international development and industrial competitiveness.

Recital 12

Text proposed by the Commission	*Amendment*
(12) The definitions and scope of Directive 2001/83/EC should be clarified in order to achieve high standards for the quality, safety and efficacy of medicinal products and to address potential regulatory gaps, without changing the overall scope, due to scientific and technological developments, e.g. low-	(12) The definitions and scope of Directive 2001/83/EC should be clarified in order to achieve high standards for the quality, safety and efficacy of medicinal products and to address potential regulatory gaps, without changing the overall scope ***or affecting national competences in this regard,*** due to

volume products, bedside-manufacturing or personalised medicinal products that do not involve an industrial manufacturing process.

scientific and technological developments, e.g. low-volume products, bedside-manufacturing or personalised medicinal products that do not involve an industrial manufacturing process.

Recital 13

Text proposed by the Commission	*Amendment*
(13) To avoid the duplication of requirements for medicinal products in this Directive and in the Regulation, the general standards in regards to quality, safety ***and*** efficacy of medicinal products laid down in this Directive shall be applicable to medicinal products covered by national marketing authorisation and also to medicinal products covered by centralised marketing authorisation. Therefore, the requirements for an application for medicinal product are valid for both, also the rules on prescription status, product information, regulatory protection and rules on manufacturing, supply, advertising, supervision and other national requirements shall be applicable to medicinal products covered by centralised marketing authorisation.	(13) To avoid the duplication of requirements for medicinal products in this Directive and in the Regulation, the general standards in regards to quality, safety***,*** efficacy ***and environmental risk*** of medicinal products laid down in this Directive shall be applicable to medicinal products covered by national marketing authorisation and also to medicinal products covered by centralised marketing authorisation. Therefore, the requirements for an application for medicinal product are valid for both, also the rules on prescription status, product information, regulatory protection and rules on manufacturing, supply, advertising, supervision and other national requirements shall be applicable to medicinal products covered by centralised marketing authorisation.

Recital 15

Text proposed by the Commission	*Amendment*
(15) In order to take account both of the emergence of new therapies and of the growing number of so-called 'borderline' products between the medicinal product sector and other sectors, certain definitions and derogations should be modified, so as to avoid any doubt as to the applicable legislation. With the same objective of clarifying situations when a product fully falls within the definition of a medicinal product and also meet the definition of other regulated products, the rules for medicinal products under this Directive apply. Furthermore, to ensure the clarity of applicable rules, it is also appropriate to	(15) In order to take account both of the emergence of new therapies and of the growing number of so-called 'borderline' products between the medicinal product sector and other sectors, certain definitions and derogations should be modified, so as to avoid any doubt as to the applicable legislation. ***In cases when there still exists unclarity of the regulatory status of a product, the competent authorities or the Agency and the relevant advisory bodies responsible for other regulatory frameworks, namely medical devices and substances of human origin should engage in consultations. In such cases,***

improve the consistency of the terminology of the pharmaceutical legislation and clearly indicate the products excluded from the scope of this Directive.	***the compendium referred to in Regulation (EU) No [reference to be added after adoption cf. COM(2022)338 final] should be consulted, where relevant. If after consulting the compendium, there remains doubt about the regulatory status the relevant bodies should further consult to determine the regulatory status. The Commission and the Member States should facilitate the cooperation between the Agency, national competent authorities and advisory bodies established by other Union legislation. The opinions and the recommendations of the Agency and the relevant advisory bodies on the regulatory status of the product should be made publicly available after the consultations have taken place.*** With the same objective of clarifying situations when a product fully falls within the definition of a medicinal product and also meet the definition of other regulated products, the for medicinal products under this Directive apply. Furthermore, to ensure the clarity of applicable rules, it is also appropriate to improve the consistency of the terminology of the pharmaceutical legislation and clearly indicate the products excluded from the scope of this Directive.

Recital 16

Text proposed by the Commission	*Unchanged text included in the compromise*
(16) The new definition for a substance of human origin (SOHO) by the [SoHO Regulation] covers any substance collected from the human body in whatever manner, whether it contains cells or not and regardless of whether it meets the definition of 'blood', 'tissue' or 'cell', for example human breast milk, intestinal microbiota and any other SoHO that may be applied to humans in the future. Such substances of human origin, other than tissues and cells, may become SoHO derived medicinal products, other than ATMPs, when the SoHO is subject to an	(16) The new definition for a substance of human origin (SOHO) by the [SoHO Regulation] covers any substance collected from the human body in whatever manner, whether it contains cells or not and regardless of whether it meets the definition of 'blood', 'tissue' or 'cell', for example human breast milk, intestinal microbiota and any other SoHO that may be applied to humans in the future. Such substances of human origin, other than tissues and cells, may become SoHO derived medicinal products, other than ATMPs, when the SoHO is subject to an

industrial process involving systematisation, reproducibility and operations performed on a routine basis or batch-wise resulting in a product of standardised consistency. When a process concerns extraction of an active ingredient from the SoHO, other than tissues and cells, or a transformation of a SoHO, other than tissues and cells, by changing its inherent properties, this should also be considered a SoHO derived medicinal product. When a process concerns concentrating, separating or isolating elements in the preparation of blood components, this should not be considered as changing their inherent properties.	industrial process involving systematisation, reproducibility and operations performed on a routine basis or batch-wise resulting in a product of standardised consistency. When a process concerns extraction of an active ingredient from the SoHO, other than tissues and cells, or a transformation of a SoHO, other than tissues and cells, by changing its inherent properties, this should also be considered a SoHO derived medicinal product. When a process concerns concentrating, separating or isolating elements in the preparation of blood components, this should not be considered as changing their inherent properties.

Recital 18

Text proposed by the Commission	*Amendment*
(18) Advanced therapy medicinal products that are prepared on a non-routine basis according to specific quality standards, and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient, should be excluded from the scope of this Directive whilst at the same time ensuring that relevant Union rules related to quality and safety are not undermined ('hospital exemption'). Experience has shown that there are great differences in the application of hospital exemption among Member States. To improve the application of hospital exemption this Directive introduces measures for collection, reporting of data as well as review of these data yearly by the competent authorities and their publication by the Agency in a repository. Furthermore, the Agency should provide a report on the implementation of hospital exemption on the basis of contributions from Member States in order to examine whether an adapted framework should be	(18) Advanced therapy medicinal products that are prepared on a non-routine basis according to specific quality standards, and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner ***and hospital pharmacist***, in order to comply with an individual medical prescription for a custom-made product for an individual patient, should be excluded from the scope of this Directive whilst at the same time ensuring that relevant Union rules related to quality and safety are not undermined ('hospital exemption'). Experience has shown that there are great differences in the application of hospital exemption among Member States .. To improve ***and harmonise*** the application of hospital exemption this Directive introduces measures for collection, reporting of data as well as review of these data yearly by the competent authorities and their publication by the Agency in a repository. Furthermore, the Agency should provide a report on the implementation of hospital exemption on the basis of contributions from Member States in order to examine

established for certain less complex ATMPs ***that have been developed and used under the hospital exemption***. When an authorisation for the manufacturing and use of an ATMP under hospital exemption is revoked because of safety concerns, the relevant competent authorities shall inform the competent authorities of other Member States.

whether an adapted framework should be established for certain less complex ATMPs. When an authorisation for the manufacturing and use of an ATMP under hospital exemption is revoked because of safety concerns, the relevant competent authorities shall inform the competent authorities of other Member States. ***Competent authorities should support academic institutions and other non-profit entities through the requirements of the hospital exemption clause.***

Recital 18 a (new)

Text proposed by the Commission	*Amendment*
	(18a) The Agency should establish a programme with the objective to guide academic and other not-for-profit entities through the centralised marketing authorisation procedure. That programme should be able to draw on results of the Agency's pilot programme for enhanced support to academic and non-profit developers of advanced therapy medicinal products, started in September 2022.

Recital 19

Text proposed by the Commission	*Unchanged text included in the compromise*
(19) This Directive should be without prejudice to the provisions of Council Directive 2013/59/Euratom[41] **,** including with respect to justification and optimisation of protection of patients and other individuals subject to medical exposure to ionising radiation. In the case of radiopharmaceuticals used for therapy, marketing authorisations, posology and administration rules have to notably respect that Directive's requirements that exposures of target volumes are to be individually planned, and their delivery appropriately verified taking into account	(19) This Directive should be without prejudice to the provisions of Council Directive 2013/59/Euratom[41], including with respect to justification and optimisation of protection of patients and other individuals subject to medical exposure to ionising radiation. In the case of radiopharmaceuticals used for therapy, marketing authorisations, posology and administration rules have to notably respect that Directive's requirements that exposures of target volumes are to be individually planned, and their delivery appropriately verified taking into account

that doses to non-target volumes and tissues are to be as low as reasonably achievable and consistent with the intended therapeutic purpose of the exposure.

that doses to non-target volumes and tissues are to be as low as reasonably achievable and consistent with the intended therapeutic purpose of the exposure.

Recital 20

Text proposed by the Commission	*Amendment*
(20) In the interest of public health, a medicinal product should only be allowed to be placed on the market in the Union when the marketing authorisation has been granted to the medicinal product, and its quality, safety ***and*** efficacy have been demonstrated. However, exemption should be provided from this requirement in situations characterised by an urgent need to administer a medicinal product to address the specific needs of a patient, or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation that could cause harm. In particular, to fulfil special needs, Member States should be allowed to exclude from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility. Member States should be also allowed to temporarily authorise the distribution of an unauthorised medicinal product in response to a suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm.	(20) In the interest of public health, a medicinal product should only be allowed to be placed on the market in the Union when the marketing authorisation has been granted to the medicinal product, and its quality, safety***,*** efficacy ***and environmental risk*** have been demonstrated. However, exemption should be provided from this requirement in situations characterised by an urgent need to administer a medicinal product to address the specific needs of a patient, or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation that could cause harm. In particular, to fulfil special needs, Member States should be allowed to exclude from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility. Member States should be also allowed to temporarily authorise the distribution of an unauthorised medicinal product in response to a suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm.

Recital 22 a (new)

Text proposed by the Commission	*Amendment*
	(22 a) Particular attention should be given to the composition of clinical trials to ensure gender based equity and comprehensive clinical data.

Recital 26

Text proposed by the Commission	*Unchanged text included in the compromise*
(26) In order to reward the compliance with all the measures included in the agreed paediatric investigation plan, for products covered by a supplementary protection certificate, if relevant information on the results of the studies conducted is included in the product information, a reward should be granted in the form of a six month extension of the supplementary protection certificate created by [Regulation (EC) No 469/2009 of the European Parliament and of the Council[42] - OP please replace reference by new instrument when adopted].	(26) In order to reward the compliance with all the measures included in the agreed paediatric investigation plan, for products covered by a supplementary protection certificate, if relevant information on the results of the studies conducted is included in the product information, a reward should be granted in the form of a six month extension of the supplementary protection certificate created by [Regulation (EC) No 469/2009 of the European Parliament and of the Council[42] - OP please replace reference by new instrument when adopted].

Recital 27

Text proposed by the Commission	*Amendment*
(27) Certain particulars and documentation that are normally to be submitted with an application for a marketing authorisation should not be required if a medicinal product is a generic medicinal product or a similar biological medicinal product (biosimilar) that is authorised or has been authorised in the Union. Both generic and biosimilar medicinal products are important to ensure access of medicinal products to a wider patient population and create a competitive internal market. In a joint statement authorities of the Member States confirmed that the experience with approved biosimilar medicinal products over the past 15 years has shown that in terms of efficacy, safety and immunogenicity they are comparable to their reference medicinal product and are therefore interchangeable and can be used instead of its reference product (or vice versa) or replaced by another biosimilar of the same reference product.	(27) Certain particulars and documentation that are normally to be submitted with an application for a marketing authorisation should not be required if a medicinal product is a generic medicinal product or a similar biological medicinal product (biosimilar) that is authorised or has been authorised in the Union. Both generic and biosimilar medicinal products are important to ensure access of medicinal products to a wider patient population ***at more affordable prices*** and create a competitive internal market. In a joint statement authorities of the Member States confirmed that the experience with approved biosimilar medicinal products over the past 15 years has shown that in terms of efficacy, safety and immunogenicity they are comparable to their reference medicinal product and are therefore interchangeable and can be used instead of its reference product (or vice versa) or replaced by another biosimilar of the same reference product.

Recital 30

Text proposed by the Commission	*Amendment*
(30) Regulatory decision-making on the development, authorisation and supervision of medicines may be supported by access and analysis of health data, including real world data i.e. health data generated outside of clinical studies**,** where appropriate. The competent authorities should be able to use such data, including via the European Health Data Space interoperable infrastructure.	(30) Regulatory decision-making on the development, authorisation and supervision of medicines may be supported by access and analysis of health data, including real world data i.e. health data generated outside of clinical studies where appropriate. The competent authorities should be able to use such data, including via the European Health Data Space interoperable infrastructure. ***Data generated via in silico methods, such as computational modelling and simulation, molecular modelling, mechanistic modelling, digital twin and artificial intelligence, where appropriate, could also be used to support regulatory***

decision making.

Recital 31

Text proposed by the Commission	*Amendment*
(31) Directive 2010/63/EU of the European Parliament and of the Council[43] lays down provisions on the protection of animals used for scientific purposes based on the principles of replacement, reduction and refinement. Any study involving the use of animals, which provides essential information on the quality, safety and efficacy of a medicinal product, should take into account those principles of replacement, reduction and refinement, where they concern the care and use of live animals for scientific purposes, and should be optimised in order to provide the most satisfactory results whilst using the minimum number of animals. The procedures of such testing should be designed to avoid causing pain, suffering, distress or lasting harm to animals and should follow the available EMA and ICH guidelines. In particular, the marketing authorisation applicant and the marketing authorisation holder should take into account the principles laid down in Directive 2010/63/EU, including, where possible, use new approach methodologies in place of animal testing. These can include but are not limited to: in vitro models, such as microphysiological systems including organ-on-chips, (2D and 3D-) cell culture models, organoids and human stem cells-based models; in silico tools or read-across models.	(31) Directive 2010/63/EU of the European Parliament and of the Council***[1]*** lays down provisions on the protection of animals used for scientific purposes based on the principles of replacement, reduction and refinement. Any study involving the use of animals, which provides essential information on the quality, safety and efficacy of a medicinal product, should take into account those principles of replacement, reduction and refinement, where they concern the care and use of live animals for scientific purposes, and should be ***only used as necessary and be*** optimised in order to provide the most satisfactory results whilst using the minimum number of animals***. The marketing authorisation applicant should not carry out animal tests in case scientifically satisfactory non-animal testing methods are available. Where scientifically satisfactory non-animal testing methods are not available, applicants that use animal testing should ensure that the principle of replacement, reduction and refinement of animal testing for scientific purposes has been with regard to any animal study conducted for the purpose of supporting the application***. The procedures of such testing should be designed to avoid causing pain, suffering, distress or lasting harm to animals and should follow the available EMA and ICH guidelines. In particular, the marketing authorisation applicant and the marketing authorisation holder should take into account the principles laid down in Directive 2010/63/EU, including, where possible, use new approach methodologies in place of animal testing. These can include but are not limited to: in vitro models, such as microphysiological systems including organ-on-chips, (2D and 3D-) cell culture models, organoids and human stem cells-based models; in silico

	tools or ***grouping and*** read-across***, aquatic egg*** models ***as well as invertebrate species***.
	[1] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

Recital 32

Text proposed by the Commission	*Amendment*
(32) Procedures should be in place to facilitate joint animal testing, wherever possible, in order to avoid unnecessary ***duplication of*** testing using live animals covered by Directive 2010/63/EU. Marketing authorisation applicants and marketing authorisation holders should make all efforts to reuse animal study results and make the results obtained from animal studies publicly available. For abridged applications marketing authorisation applicants should refer to the relevant studies conducted for the reference medicinal product.	(32) Procedures should be in place to facilitate joint animal testing, wherever possible, in order to avoid unnecessary testing using live animals covered by Directive 2010/63/EU. Marketing authorisation applicants and marketing authorisation holders should make all efforts to reuse animal study results and make the results obtained from animal studies publicly available. For abridged applications marketing authorisation applicants should refer to the relevant studies conducted for the reference medicinal product.

Recital 34 a (new)

Text proposed by the Commission	*Amendment*
	(34a) Where the environmental risk assessment is incomplete or insufficiently substantiated for a medicinal product authorised before 30 October 2005, the national marketing authorisation may be refused. However, due consideration of avoiding the restriction of patient access to such products should be taken before any decision on revocation.

Recital 44

Text proposed by the Commission	*Amendment*
(44) As regards access to medicinal products, previous amendments to the	(44) As regards access to medicinal products, previous amendments to the

Union pharmaceutical legislation have addressed this issue by providing for accelerated assessment of marketing authorisation applications or by allowing conditional marketing authorisation for medicinal products for unmet medical need. While these measures accelerated the authorisation of innovative and promising therapies, these medicinal products do not always reach the patient and patients in the Union still have different levels of access to medicinal products. Patient access to medicinal products depends on many factors. Marketing authorisation holders are not obliged to market a medicinal product in all Member States; they may decide not to market their medicinal products in, or withdraw them from, one or more Member States. National pricing and reimbursement policies, the size of the population, the organisation of health systems and national administrative procedures are other factors influencing market launch and patient access.	Union pharmaceutical legislation have addressed this issue by providing for accelerated assessment of marketing authorisation applications or by allowing conditional marketing authorisation for medicinal products for unmet medical need. While these measures accelerated the authorisation of innovative and promising therapies ***in some areas***, ***some public health priorities are still unaddressed and*** these medicinal products do not always reach the patient and patients in the Union still have different levels of access to medicinal products. Patient access to medicinal products depends on many factors. Marketing authorisation holders are not obliged to market a medicinal product in all Member States; they may decide not to market their medicinal products in, or withdraw them from, one or more Member States ***often due to commercial reasons .*** National pricing and reimbursement policies, the size of the population, the organisation of health systems and national administrative procedures are other factors influencing market launch and patient access. ***In addition, a complex regulatory environment and associated administrative burden may prevent SMEs, research institutes and academic institutions developing promising innovative treatments from applying for conditional market authorization.***

Proposal for a directive
Recital 45

Text proposed by the Commission	*Amendment*
(45) Addressing unequal patient access and affordability of medicinal products has become a key priority of the Pharmaceutical Strategy for Europe, as also highlighted by Council conclusions[45] and a resolution of the European Parliament[46] . Member States called for revised mechanisms and incentives for	(45) Addressing unequal patient access and affordability of medicinal products has become a key priority of the Pharmaceutical Strategy for Europe, as also highlighted by Council conclusions***[1]*** and a resolution of the European Parliament***[2]***. Member States called for revised mechanisms and incentives for

development of medicinal products tailored to the level of unmet medical need, while ensuring health system sustainability, patient access and availability of affordable medicinal products in all Member States.	development of medicinal products tailored to the level of unmet medical need, while ensuring health system sustainability, patient access and availability of affordable medicinal products in all Member States. ***Monitoring and evaluating access to medicines at a Union level is important to understand the results achieved through incentives.***

Recital 46 a (new)

Text proposed by the Commission	*Amendment*
	(46a) Member States apply diverse procedures and measures in the pricing and reimbursement of medicinal products. Those procedures and measures significantly affect access to medicinal products, especially with regard to the speed at which access is achieved. Likewise, Member States apply specific procedures and measures pertaining to the promotion of competition from generic and biosimilar medicinal products. Having regard to Member State competences, and recognising the disparities which can be observed in access to medicines across the Union, the exchange of best practice among national competent authorities in that area should be given greater priority. In that regard, the Commission should play a distinct role in facilitating the exchange of best practices.

Recital 48

Text proposed by the Commission	*Amendment*
(48) While pricing and reimbursement decisions are a Member State competence, the Pharmaceutical Strategy for Europe announced actions to support cooperation of Member States to improve affordability. The Commission has transformed the group of National Competent Authorities on Pricing and Reimbursement and public	(48) While pricing and reimbursement decisions are a Member State competence, the Pharmaceutical Strategy for Europe announced actions to support cooperation of Member States to improve affordability. ***While the price paid within a given Member State reflects the preference of a national health system, more coordination***

healthcare payers (NCAPR) from an ad-hoc forum to a continuous voluntary cooperation with the aim to exchange information and best practices on pricing, payment and procurement policies to improve the affordability and cost-effectiveness of medicines and health system's sustainability. The Commission is committed to stepping up this cooperation and further supporting information exchange among national authorities, including on public procurement of medicines, while fully respecting the competences of Member States in this area. The Commission may also invite NCAPR members to participate in deliberations of the Pharmaceutical Committee on topics that may have an impact on pricing or reimbursement policies, such as the market launch incentive.	***on pricing and procurement could contribute to more equal and timely access to medicines, including for Member States with lower purchasing power. The Commission may support initiatives such as the Beneluxa Initiative on Pharmaceutical Policy and the Valletta Declaration.*** The Commission has transformed the group of National Competent Authorities on Pricing and Reimbursement and public healthcare payers (NCAPR) from an ad-hoc forum to a continuous voluntary cooperation with the aim to exchange information and best practices on pricing, payment and procurement policies to improve the affordability and cost-effectiveness of medicines and health system's sustainability. The Commission is committed to stepping up this cooperation and further supporting information exchange among national authorities, including on public procurement of medicines, while fully respecting the competences of Member States in this area. ***The Commission should issues guidance on how to best implement 'most economically advantageous tender' ('MEAT' criteria) in public procurement, which aims to ensure the best value for money rather than looking at the lowest price criteria alone.*** The Commission may also invite NCAPR members to participate in deliberations of the Pharmaceutical Committee on topics that may have an impact on pricing or reimbursement policies, such as the market launch incentive. ***Joint procurement should aim not to have detrimental impact on access to medicines for countries not taking part in the procurement.***

Recital 49

Text proposed by the Commission	*Amendment*
(49) Joint procurement, whether within a country or across countries, can improve access, affordability, and security of supply of medicines, in particular for smaller countries. Member States interested in joint	(49) Joint procurement, whether within a country or across countries, can improve access, affordability, and security of supply of medicines, in particular for smaller countries. Member States interested in joint

procurement of medicines can make use of Directive 2014/24/EU[47] , which sets out purchasing procedures for public buyers, the Joint Procurement Agreement[48] and the proposed revised Financial Regulation[49] . Upon request from the Member States the Commission may support interested Member States by facilitating coordination to enable access to medicines for patients in the Union as well as information exchange, in particular for medicines for rare and chronic diseases.	procurement of medicines can make use of Directive 2014/24/EU[47] , which sets out purchasing procedures for public buyers, the Joint Procurement Agreement[48] and the proposed revised Financial Regulation[49] . Upon request from the Member States the Commission may support interested Member States by facilitating coordination to enable access to medicines for patients in the Union as well as information exchange, in particular for medicines for rare and chronic diseases. ***In the event of joint procurement of medicinal products as a medical countermeasure in cases of serious cross-border threats to health, the provisions of Regulation (EU) 2022/2371 of the European Parliament and of the Council[49a] apply***.

Recital 51 a (new)

Text proposed by the Commission	*Amendment*
	(51 a) Repurposing of off-patent medicines to develop new therapeutic options should be supported as it can expand access in an affordable manner, providing significant benefits to patients;

Recital 58

Text proposed by the Commission	*Amendment*
(58) An alternative way of demonstrating supply relates to the inclusion of medicinal products in a positive list of medicinal products covered by the national health insurance system in accordance with Directive 89/105/EEC. The related negotiations between companies and the Member State should be conducted in good faith.	(58) An alternative way of demonstrating supply relates to the inclusion of medicinal products in a positive list of medicinal products covered by the national health insurance system in accordance with Directive 89/105/EEC. The related negotiations between companies and the Member State should be conducted in good faith, ***and all parties should adhere to the deadlines set out in Directive 89/105/EEC***.

Recital 58 a (new)

Text proposed by the Commission	*Amendment*
	(58a) Cross-border healthcare is an important pathway for patients to access medicinal products that might otherwise not be available to them. To support access to medicinal products, in particular in the case of small patient populations such as for paediatric or rare diseases which are often disadvantaged when it comes to access to medicines, or where the administration of a medicine requires special competences or infrastructure, the full implementation of Directive 2011/24/EU of the European Parliament and of the Council[1a] should be supported. It is important to consider in that regard all alternative paths of making available medicinal products to patients. Competent authorities of the Member States should therefore utilise the NCAPR to exchange and share best practice regarding the implementation of cross-border access agreements and negotiations.

Recital 61

Text proposed by the Commission	*Amendment*
(61) When a compulsory licence has been granted by a relevant authority in the Union ***to tackle a public health emergency***, regulatory data protection may, if still in force, prevent the effective use of the compulsory licence as they impede the authorisation of generic medicinal products, and thus access to the medicinal products needed to address the crisis. For this reason, data and market protection should be suspended when a compulsory licence has been issued ***to tackle a public health emergency.*** Such a suspension of the regulatory data protection should be allowed only in relation to the compulsory licence granted and its beneficiary. The suspension shall comply with the objective, the territorial scope, the duration and the	(61) When a compulsory licence has been granted ***under conditions laid out in Union law and with the respect of international agreements by a relevant authority in the Union*** , regulatory data protection may, if still in force, prevent the effective use of the compulsory licence as they impede the authorisation of generic medicinal products, and thus access to the medicinal products needed to address the crisis. For this reason, data and market protection should be suspended. Such a suspension of the regulatory data protection should be allowed only in relation to the compulsory licence granted and its beneficiary. The suspension shall comply with the objective, the territorial scope, the

subject matter of the granted compulsory licence.

duration and the subject matter of the granted compulsory licence.

Recital 62

Text proposed by the Commission	*Amendment*
(62) The suspension of the regulatory data protection should be granted only for the duration of the compulsory licence. A 'suspension' of data and market protection ***in cases of public health emergency*** shall mean that data and market protection shall produce no effect in relation to the particular licensee of the compulsory licence while that compulsory licence is in effect. When the compulsory licence ends, the data and market protection shall resume their effect. The suspension should not result in an extension of the original duration.	(62) The suspension of the regulatory data protection should be granted only for the duration of the compulsory licence ***in the Member State(s) where the compulsory license has been granted***. A 'suspension' of data and market protection ***in accordance to a compulsory licence granted under conditions laid out in Union law and with the respect of international agreements by a relevant authority in the Union*** shall mean that data and market protection shall produce no effect in relation to the particular licensee of the compulsory licence while that compulsory licence is in effect. When the compulsory licence ends, the data and market protection shall resume their effect. The suspension should not result in an extension of the original duration.

Recital 63

Text proposed by the Commission	*Unchanged text included in the compromise*
(63) It is currently possible for applicants for marketing authorisation of generic, biosimilar, hybrid and bio-hybrid medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals for those medicinal products during the term of protection of the patent or Supplementary Protection Certificate (SPC) of the reference medicinal product, without this being considered patent or SPC infringement. The application of this limited exemption is however fragmented across the Union and it is considered necessary, in order to facilitate the market entry of generic, biosimilar, hybrid and bio-hybrid medicinal products that rely on a reference	(63) It is currently possible for applicants for marketing authorisation of generic, biosimilar, hybrid and bio-hybrid medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals for those medicinal products during the term of protection of the patent or Supplementary Protection Certificate (SPC) of the reference medicinal product, without this being considered patent or SPC infringement. The application of this limited exemption is however fragmented across the Union and it is considered necessary, in order to facilitate the market entry of generic, biosimilar, hybrid and bio-hybrid medicinal products that rely on a reference

medicinal product, to clarify its scope in order to ensure a harmonised application in all Member States, both in terms of beneficiaries and in terms of activities covered. The exemption must be confined to conduct studies and trials and other activities needed for the regulatory approval process, health technology assessment and pricing reimbursement request, even though this may require substantial amounts of test production to demonstrate reliable manufacturing. During the term of protection of the patent or SPC of the reference medicinal product, there can be no commercial use of the resulting final medicinal products obtained for the purposes of the regulatory approval process.	medicinal product, to clarify its scope in order to ensure a harmonised application in all Member States, both in terms of beneficiaries and in terms of activities covered. The exemption must be confined to conduct studies and trials and other activities needed for the regulatory approval process, health technology assessment and pricing reimbursement request, even though this may require substantial amounts of test production to demonstrate reliable manufacturing. During the term of protection of the patent or SPC of the reference medicinal product, there can be no commercial use of the resulting final medicinal products obtained for the purposes of the regulatory approval process.

Recital 64

Text proposed by the Commission	*Amendment*
(64) It will allow, inter alia, to conduct studies to support pricing and reimbursement as well as the manufacture or purchase of patent protected active substances for the purpose of seeking marketing authorisations during that period, contributing to the market entry of generics and biosimilars on day one of loss of the patent or SPC protection.	(64) It will allow ***all necessary steps to support timely access to generic medicines***, inter alia, to conduct studies to support pricing and reimbursement as well as the manufacture or purchase of patent protected active substances for the purpose of seeking marketing authorisations during that period, contributing to ***the timely market entry of medicinal products, in particular*** the market entry of generics and biosimilars on day one of loss of the patent or SPC protection.

Recital 65

Text proposed by the Commission	*Amendment*
(65) The competent authorities should refuse the validation for an application for a marketing authorisation referring to data of a reference medicinal product only on the basis of the grounds set out in this Directive. The same applies to any decision to grant, vary, suspend, restrict or revoke the marketing authorisation. The competent authorities cannot base their decision on	(65) ***The timely availability of generic and biosimilar medicinal products were highlighted as priorities by Council conclusions[1a] and a resolution of the European Parliament[2a]*** .The competent authorities should refuse the validation for an application for a marketing authorisation referring to data of a reference medicinal product only on the

any other grounds. In particular, those decisions cannot be based on the patent or SPC status of the reference medicinal product.	basis of the grounds set out in this Directive. The same applies to any decision to grant, vary, suspend, restrict or revoke the marketing authorisation. The competent authorities cannot base their decision on any other grounds. In particular, those decisions cannot be based on the patent or SPC status of the reference medicinal product. ***It is therefore appropriate to explicitly prohibit this practice.***
	1a Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States. Council Conclusions on Access to medicines and medical devices for a Stronger and Resilient EU
	2a European Parliament resolution of 2 March 2017 on EU options for improving access to medicine

Recital 65 a (new)

Text proposed by the Commission	*Amendment*
	(65 a) The One Health Approach is needed in order to address antimicrobial resistance, one of the most significant, current health threats. It is estimated that more than 35 000 people in the EU/EEA and more than 1.2 million people globally die each year as a direct consequence of an infection due to bacteria resistant to antibiotics[1a]. High levels of cooperation are required across sectors and globally; this Directive puts in place coordinated action order to ensure prevention and minimisation of environmental risk assessment throughout the supply chain, use and disposal, awareness raising among patients, consumers and healthcare professionals and prudent and responsible use of antimicrobials;
	[1a] 4 Murray, C.J.L., Ikuta, K.S., Sharara, F., et al. 'Global burden of bacterial antimicrobial resistance in 2019: a

systematic analysis', Lancet, Vol. 399, No 10325, pp. 629-655:

Recital 66

Text proposed by the Commission	*Amendment*
(66) In order to address the challenge of antimicrobial resistance, antimicrobials should be packaged in quantities that are appropriate for the therapy cycle relevant for that product and national rules on antimicrobial subject to prescription ensure that they are dispensed in a way that corresponds to the quantities described by the prescription.	(66) In order to address the challenge of antimicrobial resistance, antimicrobials should be packaged in quantities that are appropriate for the therapy cycle relevant for that product***, including where possible the per unit dispensing,*** and national rules on antimicrobial subject to prescription ensure that they are dispensed in a way that corresponds to the quantities described by the prescription. ***Dispensing the exact number of units needed could help address antimicrobial resistance as well as environmental impact.***

Recital 67

Text proposed by the Commission	*Amendment*
(67) The provision of information to healthcare professionals and to patients on the appropriate use, storage and disposal of antimicrobials is a joint responsibility of marketing authorisation holders and of Member States ***who*** should ensure appropriate collection system for all medicinal products.	(67) The provision of information to healthcare professionals and to patients on the appropriate use, storage and disposal of antimicrobials is a joint responsibility of marketing authorisation holders and of Member States***. Member States*** should ensure appropriate collection ***and disposal*** system for all medicinal products.

Recitial 67 a (new)

Text proposed by the Commission	*Amendment*
	Pharmacists and other health care professionals should play a role in antimicrobial stewardship, including advising on the prudent use of antibiotics and other antimicrobials, as well as their correct disposal.

Recital 68

Text proposed by the Commission	*Amendment*
(68) While this Directive restricts the use of antimicrobials by setting ***certain categories of*** antimicrobials under prescription status, due to the growing antimicrobial resistance in the Union, competent authorities of the Member States should consider further measures ***for example*** expanding the prescription status of antimicrobials or the mandatory use of diagnostic tests before prescription. Competent authorities of the Member States should consider such further measures according to the level of antimicrobial resistance in their territory and the needs of patients.	(68) While this Directive restricts the use of antimicrobials by setting ***antibiotics and antimicrobials with an identified risk of resistance*** under prescription status, due to the growing antimicrobial resistance in the Union, competent authorities of the Member States should consider further ***a number of*** measures***, including*** expanding the prescription status of antimicrobials***, restricting the use of certain antimicrobials to the use in hospitals, mandatory training of healthcare professionals on the environmental impact of medicines use and stewardship regarding the use of antimicrobials,*** or the mandatory use of diagnostic tests before prescription. ***Member States should also ensure that measures are in place to safeguard the prescription for antibiotic products from influence by any form of economic incentive provided directly or indirectly to persons who prescribe medicinal products, given the risks associated with antimicrobial resistanceand for avoiding risks to the environment, in line with the European Union Strategic Approach to Pharmaceuticals in the Environment. Additionally, the combined use of several antimicrobial active substances may represent a particular risk with respect to the development of antimicrobial resistance. Such combined use should therefore only be prescribed in exceptional cases where the benefit-risk balance of the combination is favorable***. Competent authorities of the Member States should ***promote the availability of rapid diagnostic tests in the Member States and should*** consider such further measures according to the level of antimicrobial resistance in their territory and the needs of patients.

Recital 69

Text proposed by the Commission	*Amendment*
(69) The pollution of waters and soils with pharmaceutical residues is an emerging environmental problem, and there is scientific evidence that the presence of those substances in the environment from their manufacturing, use and disposal poses a risk to the environment and public health. The evaluation of the legislation showed that strengthening of existing measures to reduce the impact of medicinal products' lifecycle on the environment and public health is required. Measures under this ***Regulation*** complement the main environmental legislation, in particular the Water Framework Directive (2000/60/EC[50]), the Environmental Quality Standard Directive (2008/105/EC[51]) the Groundwater Directive (2006/118/EC[52]), the Urban Wastewater Treatment Directive (91/271/EEC[53]), the Drinking Water Directive (2020/2184[54]) ***and*** the Industrial Emissions Directive (***2010/75/EU***[55]).	(69) The pollution of waters and soils with pharmaceutical residues is an emerging environmental problem, and there is scientific evidence that the presence of those substances in the environment from their manufacturing, use and disposal poses a risk to the environment and public health. The evaluation of the legislation showed that strengthening of existing measures to reduce the impact of medicinal products' lifecycle on the environment and public health is required. Measures under this ***Directive*** complement the main environmental legislation, in particular the Water Framework Directive (2000/60/EC***[1]***), the Environmental Quality Standard Directive (2008/105/EC***[2]***) the Groundwater Directive (2006/118/EC***[3]***), the Urban Wastewater Treatment Directive (91/271/EEC***[4]***), the Drinking Water Directive (2020/2184***[5]*****,** the Industrial Emissions Directive (***2010/75/EU) and the Waste Framework Directive (2008/98/EC***[18a]).

Recital 69 a (new)

Text proposed by the Commission	*Amendment*
	(69 a) Emissions of active substances during manufacturing can be a threat to the environment and public health. Therefore, environmental risks should be assessed and addressed through the entire lifecycle of medicinal products, starting from manufacturing, through use and to disposal.

Recital 69 b (new)

Text proposed by the Commission	*Amendment*
	(69 b) Unitary packaging of medicines, in particular in hospital pharmacies, could where this packaged and distributed in bulk result in a decrease of packaging materials used and thereby contribute to environmental footprint of medicines, including its waste. It may also contribute to mitigating medicine shortages and antimicrobial resistance. The use of single dose unit containing all relevant information, in hospital environment, could furthermore represent an improvement in the risk of medication errors and therefore increase patient protection. Member States should promote the use of unit dose pre-cut blisters in hospital environment and, progressively, in dispensing pharmacies, when necessary.

Recital 69 c (new)

Text proposed by the Commission	*Amendment*
	(69 c) The use of pharmaceuticals in human and veterinary medicines, including antimicrobials, has increased their concentrations in many environmental reservoirs such as soils, sediments and waterbodies in the past 20 years, and the environmental concentration is likely to increase further as the population grows and ages. The discharge of pharmaceuticals into the environment may not only harm ecosystems and wildlife, but may also undermine the effectiveness of these same pharmaceuticals. The chemical and metabolic stability of certain pharmaceuticals means that up to 90 % of their active substances are released into the environment in their original form after use.

Recital 70

Text proposed by the Commission	*Unchanged text included in the compromise*
(70) Marketing authorisation applications for medicinal products in the Union should include an Environmental Risk Assessment (ERA) and risk mitigation measures. If the applicant fails to submit a complete or sufficiently substantiated environmental risk assessment or they do not propose risk mitigation measures to sufficiently address the risks identified in the environmental risk assessment, the marketing authorisation should be refused. The ERA should be updated when new data or knowledge about relevant risks become available.	(70) Marketing authorisation applications for medicinal products in the Union should include an Environmental Risk Assessment (ERA) and risk mitigation measures. If the applicant fails to submit a complete or sufficiently substantiated environmental risk assessment or they do not propose risk mitigation measures to sufficiently address the risks identified in the environmental risk assessment, the marketing authorisation should be refused. The ERA should be updated when new data or knowledge about relevant risks become available.

Recital 70 a (new)

Text proposed by the Commission	*Amendment*
	(70 a) In exceptional cases where the ERA is incomplete due to missing data and this can be duly justified and substantiated by the marketing authorisation holder the medicinal product should still be able to be placed on the market for reasons in the interest of public health, and with certain post-authorisation conditions and obligations. Where a medicinal product has been authorised and the ERA is incomplete for the reason above, the marketing authorisation holder should submit the completed ERA in the timeline agreed with the authorities and deliver upon any other post authorisation obligations.

Recital 71

Text proposed by the Commission	*Amendment*
(71) Marketing authorisation applicants should take into account environmental risk assessment procedures of other EU legal frameworks that may apply to chemicals dependent on their use. Further to this Regulation, there are four main	(71) Marketing authorisation applicants should take into account environmental risk assessment procedures of other EU legal frameworks that may apply to chemicals dependent on their use. Further to this Regulation, there are four main

other frameworks: (i) Industrial chemicals (REACH, (Regulation (EC) No 1907/2006); (ii) Biocides (Regulation (EC) No 528/2012); (iii) Pesticides (Regulation (EC) No 1107/2009); and (iv) Veterinary medicines (Regulation (EU) 2019/6)). As a part of the Green Deal, the Commission has proposed a 'one-substance one-assessment' (OS-OA) approach for chemicals , in order to increase the efficiency of the registration system, reduce costs and unnecessary animal testing.	other frameworks: (i) Industrial chemicals (REACH, (Regulation (EC) No 1907/2006); (ii) Biocides (Regulation (EC) No 528/2012); (iii) Pesticides (Regulation (EC) No 1107/2009); and (iv) Veterinary medicines (Regulation (EU) 2019/6)). As a part of the Green Deal, the Commission has proposed a 'one-substance one-assessment' (OS-OA) approach for chemicals , in order to increase the efficiency of the registration system, reduce costs and unnecessary animal testing. ***The ERA covers the risks associated with production. Compliance with relevant Union and Member State legislation in terms of environmental protection at the stage of manufacturing should generally be considered as a relevant risk mitigation measure in terms of production. This should also apply for production in third countries with a level of environmental protection equivalent to that of the Union. More environmentally friendly pharmaceuticals would contribute positively to human health.***

Recital 72

Text proposed by the Commission	*Amendment*
(72) The emissions and discharges of antimicrobials to the environment from manufacturing sites may lead to antimicrobial resistance ("AMR"), which is a global concern regardless where the emissions and discharges take place. Therefore, the ERA scope should be extended to cover the risk of AMR selection during the entire life cycle of antimicrobials, including manufacturing.	(72) The emissions and discharges of antimicrobials to the environment from manufacturing sites may lead to antimicrobial resistance ("AMR"), which is a global concern regardless where the emissions and discharges take place. Therefore, the ERA scope should be extended to cover the risk of AMR selection during the entire life cycle of antimicrobials, including manufacturing. ***At the date of adoption of this Directive, for the purpose of the ERA, there is not a scientifically agreed method to measure antimicrobial resistance other than for antibiotic resistance. The Commission should therefore issue guidelines on how to conduct ERAs for AMR selection for microbials other than bacteria after consulting the EMA, the European***

Centre for Disease Prevention and Control (ECDC) and the European Environment Agency.

Recital 74 a (new)

Text proposed by the Commission	*Amendment*
	(74 a) According to the Aarhus Convention, the public has a right to obtain information on environmental matters, including on the ERA of a pharmaceutical product.

Recital 93

Text proposed by the Commission	*Amendment*
(93) To optimise the use of resources for both applicants for marketing authorisation and competent authorities and avoid duplication of assessment of chemical active substances of medicinal products, marketing authorisation applicants should be able to rely on an active substance master file certificate or a monograph of the European Pharmacopeia, instead of submitting the relevant data as required in accordance with Annex II. An active substance master file certificate may be granted by the Agency when the relevant data on the active substance concerned is not already covered by a monograph of the European Pharmacopeia or by another active substance master file certificate. The Commission should be empowered to establish the procedure for the single assessment of an active substance master file. To further optimise the use of resources, the Commission should be empowered to allow use a certification scheme also for additional quality master files i.e. for active substances other than chemical active substances, or for other substances present or used in the manufacture of a medicinal product, required in accordance with Annex II, e.g. in case of novel excipients, adjuvants,	(93) To optimise the use of resources for both applicants for marketing authorisation and competent authorities and avoid duplication of assessment of chemical active substances of medicinal products ***which includes cell and gene therapies***, marketing authorisation applicants should be able to rely on an active substance master file certificate or a monograph of the European Pharmacopeia, instead of submitting the relevant data as required in accordance with Annex II. An active substance master file certificate may be granted by the Agency when the relevant data on the active substance concerned is not already covered by a monograph of the European Pharmacopeia or by another active substance master file certificate. The Commission should be empowered to establish the procedure for the single assessment of an active substance master file. To further optimise the use of resources, the Commission should be empowered to allow use ***of*** a certification scheme also for additional ***master files, including*** quality master files***,*** i.e. for active substances other than chemical active substances, or for other substances present or used in the manufacture of a medicinal product, required in accordance

radiopharmaceutical precursors and active substance intermediates, when the intermediate is a chemical active substance by itself or used in conjugation with a biological substance.	with Annex II, e.g. in case of novel excipients, adjuvants, ***raw materials, viral vectors and other starting materials, growth media,*** radiopharmaceutical precursors and active substance intermediates, when the intermediate is a chemical active substance by itself or used in conjugation with a biological substance***, as well as for raw materials and starting materials used for manufacturing of cell therapy and gene therapy***.

Recital 100

Text proposed by the Commission	*Unchanged text included in the compromise*
(100) It is necessary to take account of changes arising as a result of international harmonisation of definitions, terminology and technological developments in the field of pharmacovigilance.	(100) It is necessary to take account of changes arising as a result of international harmonisation of definitions, terminology and technological developments in the field of pharmacovigilance.

Recital 101

Text proposed by the Commission	*Amendment*
(101) The increasing use of electronic networks for communication of information on adverse reactions to medicinal products marketed in the Union is intended to allow competent authorities to share the information at the same time.	(101) The increasing use of electronic networks for communication of information on adverse reactions to medicinal products marketed in the Union is intended to allow competent authorities to share the information at the same time. ***In that regard, Member States should seek to inform directly those stakeholders who report adverse reactions in case there exists any update on the safety profile of the products.***

Recital 109

Text proposed by the Commission	*Amendment*
(109) There may be cases where manufacturing or testing steps of medicinal products need to take place in sites close to patients, for example advanced therapy medicinal products with short shelf-life. In such cases, these manufacturing or testing steps may need to be decentralised to multiple sites to reach patients across the Union. When the manufacturing or testing steps are decentralised, they should be carried out under the responsibility of the qualified person of an authorised central site. The decentralised sites should not require a separate manufacturing authorisation from the one granted to the relevant central site but should be registered by the competent authority of the Member State in which the decentralised site is established. In the case of medicinal products containing, consisting or derived from autologous SoHO, the decentralised sites have to be registered as a SoHO entity as defined in and pursuant to [SoHO Regulation] for the activities of donor review and eligibility assessment, donor testing and collection, or just for collection in the case of products manufactured for autologous use.	(109) There may be cases where manufacturing or testing steps of medicinal products need to take place in sites close to patients, for example advanced therapy medicinal products with short shelf-life. In such cases, these manufacturing or testing steps may need to be decentralised to multiple sites to reach patients across the Union. When the manufacturing or testing steps are decentralised, they should be carried out under the responsibility of the qualified person of an authorised central site***. Additionally, in order to ensure smooth functioning of decentralised sites under this framework with the activities relevant for other Union legal frameworks, competent authorities of Member States supervising the decentralised site should coordinate their acitivities and supervisory tasks with the relevant authorities responsible for the supervision of the manufacturing or testing activities under other Union acts***. The decentralised sites should not require a separate manufacturing authorisation from the one granted to the relevant central site but should be registered by the competent authority of the Member State in which the decentralised site is established. In the case of medicinal products containing, consisting or derived from autologous

	SoHO, the decentralised sites have to be registered as a SoHO entity as defined in and pursuant to [SoHO Regulation] for the activities of donor review and eligibility assessment, donor testing and collection, or just for collection in the case of products manufactured for autologous use.

Recital 123 a (new)

Text proposed by the Commission	*Amendment*
	(123 a) Pharmacists and other health care professionals have an important role in primary care, particularly to compound, dispense and sell medicinal products that patients need, to provide advice on their proper use and possible adverse effects and to support patients suffering of acute and chronic illnesses. In a hospital environment, hospital pharmacists set up pharmaceutical consultations and designate personalised pharmaceutical plans, in cooperation with other health professionals, patients and carers. Hospital pharmacists and community pharmacists could play a significant role in the use of electronic package leaflets, as well as for understanding the information contained in paper leaflets.

Recital 124

Text proposed by the Commission	*Amendment*
(124) Rules should be laid down as to how the labelling and package leaflets are to be presented.	(124) Rules should be laid down as to how the labelling and package leaflets are to be presented. ***The package leaflet should be easily legible, clearly comprehensible and indelible by users, including especially the target patient groups. Patient leaflets are in the category of consultative reading which means that relevant information should be found without reading the whole leaflet. For readability and legibility, the package leaflet can benefit from a typographic hierarchy and a legible typeface. Design choices should primarily serve function and readability, rather than aesthetics.***

Recital 125

Text proposed by the Commission	*Amendment*
(125) The provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information.	(125) ***Sharing accurate information with the general public in order to promote trust in science and the regulatory system and supporting health literacy of patients and consumers is crucial. When relevant, competent authorities should also share up to date information with healthcare professionals, including pharmacists, and the scientific community.*** The provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information.

Recital 127

Text proposed by the Commission	*Amendment*
(127) The use of electronic and technological possibilities other than paper package leaflets can facilitate access to medicinal products, medicinal products distribution and should always guarantee equal or better quality of information to all	(127) The use of electronic and technological possibilities other than paper package leaflets***, which is complementary to the paper leaflets which are crucial for patients with limited digital health literacy,*** can facilitate access to medicinal

patients compared to the paper form of product information.	products, medicinal products distribution and should always guarantee equal or better quality of information to all patients compared to the paper form of product information. ***Ensuring the protection of personal data pursuant to Regulation 2016/679 and prevention of the identification, profiling or tracking of individuals is necessary in this regard.***

Recital 128

Text proposed by the Commission	*Amendment*
(128) Member States have varying levels of digital literacy and internet access. In addition, patient and healthcare professional needs may differ. It is therefore necessary that Member States have a discretion on the adoption of measures enabling the electronic provision of product information while ensuring that no patient is left behind, taking into account the needs of different age categories and the different levels of digital literacy in the population, and making sure that product information is easily accessible to all patients***. Member States should progressively allow the possibility for*** electronic product information, while ensuring full compliance with the rules on protection of personal data, and ***adhere*** to harmonised standards developed at EU level.	(128) Member States have varying levels of digital literacy and internet access. In addition, patient and healthcare professional needs may differ. It is therefore necessary that Member States have a discretion on the adoption of measures enabling the electronic provision of product information while ensuring that no patient is left behind, taking into account the needs of different age categories and the different levels of digital literacy in the population, and making sure that product information is easily accessible to all patients. ***A package leaflet should be made available electronically and be included in paper format, except where the Member State, following a consultation, decides to make only the electronic product information available. E***lectronic product information ***should be available in*** full compliance with the rules on protection of personal data, and ***adhere*** to harmonised standards developed at EU level. ***The information in digital format should be easily accessible to all patients. Based on the findings from hospital pilots, the obligation to provide a paper leaflet should be lifted for medicinal products not intended for self-administration by the patient.***

Recital 129

Text proposed by the Commission	*Amendment*
(129) ***Where*** Member States ***decide that***	(129) Member States ***should make*** the

the package leaflet ***should be made*** available ***in principle only*** electronically***,*** they should also ensure that a paper version of the package leaflet is to be made available on demand and without additonal cost to patients. ***They*** should also ensure that the information in digital format is easily accessible to all patients, for instance by including in the outer packaging of the product a digitally readable barcode, which would direct the patient to the electronic version of the package leaflet.	package leaflet available electronically ***and in paper format, except where the Member State decides to make only the electronic product information available. Where the package leaflet is only available electronically, Member States*** should also ensure that a paper version of the package leaflet is to be made available on demand and without additonal cost to patients. They should also ensure that the information in digital format is easily accessible to all patients, for instance by including in the outer packaging of the product a digitally readable barcode, which would direct the patient to the electronic version of the package leaflet**..**

Recital 130

Text proposed by the Commission	*Amendment*
(130) The use of multi-language packages can be a tool for access to medicinal products, in particular for small markets and in public health emergencies. Where multi-language packages are used, Member States may allow the use on the labelling and package leaflet of an official language of the Union that is commonly understood in the Member States where the multi-language package is marketed.	(130) The use of multi-language packages can be a tool for access to medicinal products, in particular for small markets and in public health emergencies. Where multi-language packages are used, Member States may allow the use on the labelling and package leaflet of an official language of the Union that is commonly understood in the Member States where the multi-language package is marketed. ***While electronic medicinal product information can facilitate their redistribution between Member States, language requirements on labels can remain a challenge. The granting of an exemption to the requirement for an official language, as well as the obligation to use the international non-proprietary name for medicinal products not intended for self-administration by the patient, in addition to providing electronic product information, could improve the availability of medicinal products and enable easier redistribution between Member States.***

Recital 131

Text proposed by the Commission	*Amendment*
(131) To ensure a high level of transparency of public support to the research and development of medicinal products, the reporting of public contribution for the development of a particular medicinal product should be a requirement for all medicines. Given however the practical difficulty to identify how indirect public funding instruments, such as tax advantages, have supported a particular product, the reporting obligation should only concern the direct public financial support, such as direct grants or contracts. Therefore, the provisions of this Directive ensure, without prejudice to the rules on the protection of confidential and personal data, transparency regarding ***any direct*** financial support received from any public authority or public body to carry out any activities for the research and development of medicinal products.	(131) To ensure a high level of transparency of public support to the research and development of medicinal products, the reporting of public contribution for the development of a particular medicinal product should be a requirement for all medicines. Given however the practical difficulty to identify ***in third countries*** how indirect public funding instruments, such as tax advantages, have supported a particular product, the reporting obligation ***on financial support from entities outside of the Union*** should only concern the direct public financial support, such as direct grants or contracts. Therefore, the provisions of this Directive ensure, without prejudice to the rules on the protection of confidential and personal data, transparency regarding financial support received from any public authority or public body ***or philanthropic or non-for profit organisation or fund*** to carry out any activities for the research and development of medicinal products.

Recital 135 a (new)

Text proposed by the Commission	*Amendment*
	Clear, impartial and independent information from healthcare professional to the public about a medicinal product and its correct use can play an important role in informing citizens and combatting misinformation, notably during health emergencies such as the COVID-19 pandemic. Member States should ensure that the ability of healthcare professionals to share clear, impartial and independent information, whether in a direct conversation with a patient or in broader communication, should not be hindered.

Recital 136

Text proposed by the Commission	*Amendment*
(136) Advertising of medicinal products should aim at disseminating objective and unbiased information about the medicinal product. For that purpose, it is expressly forbidden highlight negatively another medicinal product or to suggest that advertised medicinal product might be safer or more effective than another medicinal product**.** Comparison of medicinal products should only be allowed if such information is listed in the summary of product characteristics of the medicinal product being advertised. This prohibition covers any medicinal product, also biosimilars, and therefore it would be misleading to refer in the advertising, that a biosimilar medicinal product would not be interchangeable with the original biological medicinal product or another biosimilar from the same original biological medicinal product. Additional strict rules about negative and comparative advertising of competitor medicinal products will prohibit claims that can mislead persons qualified to prescribe, administer or supply them.	(136) Advertising of medicinal products should aim at disseminating objective and unbiased information about the medicinal product. For that purpose, it is expressly forbidden highlight negatively another medicinal product or to suggest that advertised medicinal product might be safer or more effective than another medicinal product. Comparison of medicinal products should only be allowed if such information is listed in the summary of product characteristics ***for the relevant indications and patient population*** of the medicinal product being advertised. This prohibition covers any medicinal product, also biosimilars, and therefore it would be misleading to refer in the advertising, that a biosimilar medicinal product would not be interchangeable with the original biological medicinal product or another biosimilar from the same original biological medicinal product. Additional strict rules about negative and comparative advertising of competitor medicinal products will prohibit claims that can mislead persons qualified to prescribe, administer or supply them.

Recital 138 a (new)

Text proposed by the Commission	*Amendment*
	(138 a) Patients and consumers are increasingly exposed to the promotional practices of using celebrities to advertise medicinal products due to the global reach of social media. The Commission should assess the exposure and impact of pharmaceutical advertising and promotions online, and adopt specific rules to regulate such advertising and promotional practices.

Recital 139 a (new)

Text proposed by the Commission	*Amendment*
	(139 a) Even minimal inducement may result in bias decisions in regard to prescription behaviour of physicians. Therefore, to avoid conflict of interest, Member States should maintain a transparency register of transfer of value regarding advertising activities which target persons qualified to prescribe medicinal products. The Commission should establish a web portal to list all national registers of transfers of value to persons qualified to prescribe medicinal products.

Recital 145

Text proposed by the Commission	*Amendment*
(145) In order to ensure uniform conditions for the implementation of this ***Regulation***, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[66] .	(145) In order to ensure uniform conditions for the implementation of this ***Directive***, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council***[1]***.

[66] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning

mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Recital 149

Text proposed by the Commission	*Amendment*
(149) In order to supplement or amend certain non-essential elements of this Directive, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of specifying the procedure for examination of application of active substance master file certificate, the publication of such certificates, the procedure for changes to the active substance master file and its certificate, access to the active substance master file and its assessment report; specifying additional ***quality*** master files to provide information on a constituent of a medicinal product, the procedure for examination of application of a quality master file certificate, the publication of such certificates, the procedure for changes to the ***quality*** master file and its certificate, and access to the ***quality*** master file and its assessment report; determining the situations in which post-authorisation efficacy studies may be required; specifying the categories of medicinal products to which a marketing authorisation subject to specific obligations could be granted and specifying the procedures and requirements for granting such a marketing authorisation and for its renewal; specifying exemptions to variation and the categories in which variations should be classified and establishing procedures for the examination of applications for variations to the terms of marketing authorisations as well as specifying conditions and procedures for cooperation with third countries and international organisations for examination of applications for such variations. It is of particular importance that the Commission carry out appropriate	(149) In order to supplement or amend certain non-essential elements of this Directive, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of specifying the procedure for examination of application of active substance master file certificate, the publication of such certificates, the procedure for changes to the active substance master file and its certificate, access to the active substance master file and its assessment report; specifying additional master files to provide information on a constituent of a medicinal product, the procedure for examination of application of a quality master file certificate ***or a platform technology master file certificate***, the publication of such certificates, the procedure for changes to the master file and its certificate, and access to the master file and its assessment report; determining the situations in which post-authorisation efficacy studies may be required; specifying the categories of medicinal products to which a marketing authorisation subject to specific obligations could be granted and specifying the procedures and requirements for granting such a marketing authorisation and for its renewal; specifying exemptions to variation and the categories in which variations should be classified and establishing procedures for the examination of applications for variations to the terms of marketing authorisations as well as specifying conditions and procedures for cooperation with third countries and international organisations for examination of applications for such variations. It is of particular importance that the Commission carry out appropriate

consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[67] . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[67] . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

European Parliament
2019-2024

Committee on the Environment, Public Health and Food Safety

2023/0131(COD)

14.03.2024

COMPROMISE AMENDMENTS
1 - 58

Draft report
Tiemo Wölken
(PE756.131v01-00)(PE756.132v01-00)(PE756.133v01-00)(PE756.134v01-00)(PE756.135v01-00)(PE756.136v01-00)(PE756.137v01-00)(PE756.138v01-00)

Laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006

Proposal for a regulation
(COM(2023)0193 – C9-0144/2023 – 2023/0131(COD))

COMPROMISE AMENDMENT 1 - SUBJECT MATTER (ARTICLE 1)
replacing amendments 516-520

supported by
EPP, S&D, RE, Greens/EFA, ECR, ID, Left

Proposal for a regulation
Article 1 – paragraph 1

Text proposed by the Commission	*Amendment*
This Regulation lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union level, establishes rules and procedures at Union and at Member State level relating to the security of supply of medicinal products and lays down the governance provisions of the European Medicines Agency ('the Agency') established by Regulation (EC) No 726/2004 which shall carry out the tasks relating to medicinal products for human use that are laid down in this Regulation, Regulation (EU) No 2019/6 and other relevant Union legal acts.	This Regulation lays down Union procedures for the authorisation, supervision and pharmacovigilance of medicinal products for human use at Union level, establishes rules and procedures at Union and at Member State level relating to the ***monitoring and management of shortages and critical shortages and the*** security of supply of medicinal products and lays down the governance provisions of the European Medicines Agency ('the Agency') established by Regulation (EC) No 726/2004 which shall carry out the tasks relating to medicinal products for human use that are laid down in this Regulation, Regulation (EU) No 2019/6 and other relevant Union legal acts.

Or. en

COMPROMISE AMENDMENT 2 - CENTRALLY AUTHORISED MEDICINAL PRODUCTS (ARTICLE 3) AND MEMBER STATE AUTHORISATION OF GENERICS OF CENTRALLY AUTHORISED MEDICINAL PRODUCTS (ARTICLE 4)
replacing amendments 576-587, ITRE 46-47

supported by
EPP, S&D, RE, Greens/EFA, ECR, ID, Left

Proposal for a regulation
Article 3 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of marketing authorisation in accordance with this Regulation is in the interest of patients' health at Union level, including as regards antimicrobial resistance and medicinal products for public health emergencies;	(a) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of marketing authorisation in accordance with this Regulation is in the interest of patients' health at Union level, including as regards antimicrobial resistance and medicinal products for public health emergencies;

Proposal for a regulation
Article 4 – Title

Text proposed by the Commission	*Amendment*
Member State authorisation of generics of centrally authorised medicinal products	Member State authorisation of generics of centrally authorised medicinal products

Proposal for a regulation
Article 4 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
A generic medicinal product of a reference medicinal product authorised by the Union may be authorised by the competent authorities of the Member States in accordance with [revised Directive 2001/83/EC] under the following conditions:	A generic medicinal product of a reference medicinal product authorised by the Union may be authorised by the competent authorities of the Member States in accordance with [revised Directive 2001/83/EC] under the following conditions:

Proposal for a regulation
Article 4 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the application for marketing authorisation is submitted in accordance with Article 9 of [revised Directive 2001/83/EC];	(a) the application for marketing authorisation is submitted in accordance with Article 9 of [revised Directive 2001/83/EC];

Proposal for a regulation
Article 4 – paragraph 2

Text proposed by the Commission	*Amendment*
Point (b), first subparagraph, shall not apply to those parts of summary of product characteristics and package leaflet referring to indications, posologies, pharmaceutical forms, methods or routes of administration or any other way in which the medicinal product may be used which were still covered by a patent or a supplementary protection certificate for medicinal products at the time when the generic medicinal product was marketed and where the applicant for the generic medicinal product has requested not to include this information in their marketing authorisation.	Point (b), first subparagraph, shall not apply to those parts of summary of product characteristics and package leaflet referring to indications, posologies, pharmaceutical forms, methods or routes of administration or any other way in which the medicinal product may be used which were still covered by a patent or a supplementary protection certificate for medicinal products at the time when the generic medicinal product was marketed and where the applicant for the generic medicinal product has requested not to include this information in their marketing authorisation.

COMPROMISE AMENDMENT 3- SUBMISSION OF APPLICATIONS FOR MARKETING AUTHORISATIONS (ARTICLE 5)
replacing amendments 35; 588-590

supported by
EPP, S&D, RE, Greens/EFA, ECR, ID, Left

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. An applicant shall agree with the Agency the submission date of an application for a marketing authorisation.	2. An applicant shall agree with the Agency the submission date of an application for a marketing authorisation.

Proposal for a regulation
Article 5 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Within 20 days of receipt of an application, the Agency shall check whether all the information and documentation required in accordance with Article 6 have been submitted, that the application does not contain critical deficiencies that may prevent the evaluation of the medicinal product and decide whether the application is valid.	5. Within 20 days of receipt of an application, the Agency shall check whether all the information and documentation required in accordance with Article 6 have been submitted, that the application does not contain critical deficiencies ***as defined in guidelines established under paragraph 7*** that may prevent the evaluation of the medicinal product and decide whether the application is valid.

COMPROMISE AMENDMENT 4 - CENTRALISED MARKETING AUTHORISATIONS (ARTICLE 6)
replacing amendments 36-38; 591-621, ITRE 48-51

supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a regulation
Article 6 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
The documentation shall include a declaration to the effect that clinical trials carried out outside the Union meet the ethical requirements of Regulation (EU) No 536/2014. Those particulars and documentation shall take account of the unique, Union nature of the authorisation requested and, otherwise than in exceptional cases relating to the application of the law on trademarks pursuant to Regulation (EU) 2017/1001 of the European Parliament and of the Council[66] , shall include the use of a single name for the medicinal product. The use of a single name does not exclude the use of additional qualifiers where necessary to identify different presentations of the medicinal product concerned.	The documentation shall include a declaration to the effect that clinical trials carried out outside the Union meet the ethical requirements of Regulation (EU) No 536/2014. Those particulars and documentation shall take account of the unique, Union nature of the authorisation requested and, otherwise than in exceptional cases relating to the application of the law on trademarks pursuant to Regulation (EU) 2017/1001 of the European Parliament and of the Council[66] , shall include the use of a single name for the medicinal product. The use of a single name does not exclude***:***
	(a) the use of additional qualifiers where necessary to identify different presentations of the medicinal product concerned; ***and***
	(b) the use of identified versions of the summary of product characteristics as referred to in Article 62 of [Revised Directive] in situations where elements of the product information are still covered by patent law or supplementary protection certificates for medicinal products.
[66] Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark (OJ L 154, 16.6.2017, p. 1).	[66] Regulation (EU) 2017/1001 of the European Parliament and of the Council of 14 June 2017 on the European Union trade mark (OJ L 154, 16.6.2017, p. 1).

Proposal for a regulation
Article 6 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
For medicinal products that are likely to offer an exceptional therapeutic advancement in the diagnosis, prevention or treatment of a life-threatening**,** seriously debilitating or serious and chronic condition in the Union, the Agency may, following the advice of the Committee for Medicinal Products for Human Use regarding the maturity of the data related to the development, offer to the applicant a phased review of complete data packages for individual modules of particulars and documentation as referred to in paragraph 1.	For medicinal products that are likely to offer an exceptional therapeutic advancement in the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic ***or are expected to be of major interest from the point of view of public health or for conditions with no authorised alternatives*** in the Union, the Agency may, following the advice of the Committee for Medicinal Products for Human Use regarding the maturity of the data related to the development, offer to the applicant a phased review of complete data packages for individual modules of particulars and documentation as referred to in paragraph 1.

Proposal for a regulation
Article 6 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Where appropriate, the application may include an active substance master file certificate or an application for an active substance master file or any other quality master file certificate or application as referred to in Article 25 of [revised Directive 2001/83/EC].	4. Where appropriate, the application may include an active substance master file certificate or an application for an active substance master file or any other quality master file certificate or application as referred to in Article 25 of [revised Directive 2001/83/EC].

Proposal for a regulation
Article 6 – paragraph 5 – subparagraph 2

Text proposed by the Commission	*Amendment*
The marketing authorisation applicant shall not carry out animal tests in case scientifically satisfactory non-animal testing methods are available.	The marketing authorisation applicant shall not carry out animal tests in case scientifically satisfactory non-animal testing methods are available. ***The Agency shall in its annual report highlight key observations and best practices in the replacement, reduction and refinement of animal testing submitted by applicants.***

Proposal for a regulation
Article 6 – paragraph 6 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall ensure that the opinion of the Committee for Medicinal Products for Human	The Agency shall ensure that the opinion of the Committee for Medicinal Products for Human

Use is given within 180 days after receipt of a valid application. In the case of a medicinal product for human use containing or consisting of genetically modified organisms, the opinion of that Committee shall take into account the evaluation of the environmental risk assessment in accordance with Article 8.	Use is given within 180 days-after receipt of a valid application. In the case of a medicinal product for human use containing or consisting of genetically modified organisms, the opinion of that Committee shall take into account the evaluation of the environmental risk assessment in accordance with Article 8.

COMPROMISE AMENDMENT 5 - ENVIRONMENTAL RISK ASSESSMENT
(ARTICLES 7; 8; 9)
replacing amendments 39; 40; 622-633

supported by
EPP, S&D, RE, Greens/EFA, ID, Left

Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Without prejudice to Article 22 of [revised Directive 2001/83/EC], the marketing authorisation application of a medicinal product for human use containing or consisting of genetically modified organisms as defined in Article 2(2) of Directive 2001/18/EC shall be accompanied by an environmental risk assessment identifying and evaluating potential adverse effects of the genetically modified organisms on human health and the environment.	1. Without prejudice to Article 22 of [revised Directive 2001/83/EC], the marketing authorisation application of a medicinal product for human use containing or consisting of genetically modified organisms as defined in Article 2(2) of Directive 2001/18/EC shall be accompanied by an environmental risk assessment identifying and evaluating potential adverse effects of the genetically modified organisms on human ***and animal*** health**,** and the environment.

Proposal for a regulation
Article 7 – paragraph 4 – introductory part

Text proposed by the Commission	*Amendment*
4. Articles 6 to 11 of [revised Directive 2001/18/EC] as well as Articles 4 to 13 of Directive 2009/41/EC shall not apply to operations related to the supply and clinical use, including the packaging and labelling, distribution, storage, transport, preparation for administration, administration, destruction or disposal of medicinal products containing or consisting of genetically modified organisms, with the exception of their manufacture, in any of the following cases:	4. Articles 6 to 11 of [revised Directive 2001/18/EC] as well as Articles 4 to 13 of Directive 2009/41/EC shall not apply to operations related to the supply and clinical use, including the packaging and labelling, distribution, storage, transport, preparation for administration, administration, destruction or disposal of medicinal products containing or consisting of genetically modified organisms, with the exception of their manufacture, in any of the following cases:

Proposal for a regulation
Article 7 – paragraph 5 – subparagraph 1

Text proposed by the Commission	*Amendment*
In the cases referred to in paragraph 4, Member States shall implement appropriate measures to minimise foreseeable negative environmental impacts resulting from the intended or unintended release of the medicinal products containing or consisting of genetically modified organisms into the environment.	In the cases referred to in paragraph 4, Member States shall implement appropriate measures to minimise foreseeable negative environmental impacts resulting from the intended or unintended release of the medicinal products containing or consisting of genetically modified organisms into the environment.

Proposal for a regulation
Article 8 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) identification and characterisation of hazards for the environment, animals and for human health;	(b) identification and characterisation of hazards for the environment, animals and for human health ***throughout the lifecycle of the medicine, including manufacturing.*** ***For the purpose of this point, 'hazards for human health' include the risks to the health of human beings other than the treated patient as the risk to the treated patient shall be assessed as part of the benefit-risk assessment of the medicinal product;***

Proposal for a regulation
Article 8 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) risk minimisation strategies proposed to address identified risks including specific containment measures to limit contact with the medicinal product.	(e) risk minimisation ***and mitigation*** strategies proposed to address identified risks including specific containment measures to limit contact with the medicinal product.

Proposal for a regulation
Article 9 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
The applicant shall submit an environmental risk assessment referred to in Article 7(1) to the Agency.	The applicant shall submit an environmental risk assessment referred to in Article 7(1) to the Agency

Proposal for a regulation
Article 9 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
The Committee for Medicinal Products for Human Use shall assess the environmental risk assessment.	The Committee for Medicinal Products for Human Use shall assess the environmental risk assessment, ***and where necessary consult the ad-hoc Environmental Risk Assessment Working Party referred to in Article 150***.

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. In case of first-in-class medicinal products or when a novel question is raised during the assessment of the submitted environmental risk assessment, the Committee for Medicinal Products for Human Use, or the rapporteur, shall carry out necessary consultations with bodies Member States have set up in accordance with Directive 2001/18/EC. They ***may*** also consult with relevant Union bodies. Details on the consultation procedure shall be published by the Agency at the latest by [OJ:12 months after the date of entry into force of this Regulation].	2. In case of first-in-class medicinal products or when a novel question is raised during the assessment of the submitted environmental risk assessment, the Committee for Medicinal Products for Human Use, or the rapporteur, shall carry out necessary consultations with bodies Member States have set up in accordance with Directive 2001/18/EC. They ***shall*** also consult with relevant Union bodies. Details on the consultation procedure shall be published by the Agency at the latest by [OJ:12 months after the date of entry into force of this Regulation].

COMPROMISE AMENDMENT 6 - COMMITTEE ASSESSMENT OF AN APPLICATION FOR A MARKETING AUTHORISATION (ARTICLE 10)
replacing amendments 41; 634-641

supported by
EPP, S&D, RE, Greens/EFA, ECR, ID, Left

Proposal for a regulation
Article 10 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where within 90 days of the validation of the marketing authorisation application and during the assessment the Committee for Medicinal Products for Human Use considers that the submitted data are not of sufficient quality or maturity to complete the assessment, the assessment can be terminated. The Committee for Medicinal Products for Human Use shall summarise the deficiencies in writing. On this basis, the Agency shall inform the applicant accordingly and set a time limit to address the deficiencies. The application shall be suspended until the applicant addresses the deficiencies. If the applicant fails to address those deficiencies within the time limit set by the Agency, the application shall be considered as withdrawn.	2. Where within 90 days of the validation of the marketing authorisation application and during the assessment the Committee for Medicinal Products for Human Use considers that the submitted data are not of sufficient quality or maturity to complete the assessment, the assessment can be terminated. The Committee for Medicinal Products for Human Use shall summarise the deficiencies in writing. On this basis, the Agency shall inform the applicant accordingly and set a ***reasonable*** time limit to address the deficiencies. The application shall be suspended until the applicant addresses the deficiencies. If the applicant fails to address those deficiencies within the time limit set by the Agency, the application shall be considered as withdrawn ***by default***.

COMPROMISE AMENDMENT 7 - COMMITTEE OPINION (ARTICLE 12)
replacing amendments 42-48; 642-650

supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a regulation
Article 12 – paragraph 4 – point g

Text proposed by the Commission	*Amendment*
(g) where appropriate, details of any recommended obligation to conduct post-authorisation efficacy studies where concerns relating to some aspects of the efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been marketed. Such an obligation to conduct such studies shall be based on the delegated acts adopted pursuant to Article 21 while taking into account the scientific guidance referred to in Article 123 of [revised Directive 2001/83/EC];	(g) where appropriate, details of any recommended obligation to conduct post-authorisation efficacy studies where concerns relating to some aspects of the efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been marketed. Such an obligation to conduct such studies shall be based on the delegated acts adopted pursuant to Article 21 while taking into account the scientific guidance referred to in Article 123 of [revised Directive 2001/83/EC] ***and the consultation process in accordance with Article 162 of this Regulation***;

Proposal for a regulation
Article 12 – paragraph 4 – point h

Text proposed by the Commission	*Amendment*
(h) where appropriate, details of any recommended obligation to conduct any other post-authorisation studies to improve the safe and effective use of the medicinal product;	(h) where appropriate, details of any recommended obligation to conduct any other post-authorisation studies***, including post-authorisation treatment optimisation studies,*** to improve the safe and effective use of the medicinal product;

Proposal for a regulation
Article 12 – paragraph 4 – point i

Text proposed by the Commission	*Amendment*
(i) in case of medicinal products for which there is ***substantial*** uncertainty as to the surrogate endpoint relation to the expected health outcome, where appropriate and relevant for the benefit-risk balance, a post-authorisation obligation to substantiate the	(i) in case of medicinal products for which there is ***a detailed justification submitted to the Agency as to the grounds of*** uncertainty as to the surrogate endpoint relation to the expected health outcome, where appropriate and relevant for the benefit-risk

clinical benefit;	balance, ***with specific attention given to new active substances and therapeutic indications,*** a post-authorisation obligation to substantiate the clinical benefit:

Proposal for a regulation
Article 12 – paragraph 4 – point j a (new)

Text proposed by the Commission	*Amendment*
	(j a) where appropriate any justified reasoning for granting marketing authorisation pursuant to Article 18, 19 and 30 of this Regulation;

Proposal for a regulation
Article 12 – paragraph 4 – point m

Text proposed by the Commission	*Amendment*
(m) where appropriate, to carry out medicinal product-specific validation studies to replace animal-based control methods with non-animal-based control methods.	(m) where appropriate, to carry out medicinal product-specific validation studies to replace animal-based control methods with non-animal-based control methods***;***

Proposal for a regulation
Article 12 – paragraph 4 – point m a (new)

Text proposed by the Commission	*Amendment*
	(ma) a stewardship and access plan in accordance with Article 17 of [revised Directive 2001/83/EC] and special information requirements in accordance with Article 69 of that Directive for any antimicrobials, as well as any other obligations imposed on the marketing authorisation holder;

Proposal for a regulation
Article 12 – paragraph 4 – point m b (new)

Text proposed by the Commission	*Amendment*
	(mb) where applicable, a reasoning as to whether the medicinal product satisfies the criteria of Article 83 of [revised Directive 2001/83/EC] regarding medicinal products addressing an unmet medical need.

COMPROMISE AMENDMENT 8 - COMMITTEE DECISION ON MARKETING AUTHORISATION (ARTICLE 13)
replacing amendments 49-51; 651-655

supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Within 12 days of receipt of the opinion of the Committee for Medicinal products for Human Use the Commission shall submit to the Standing Committee on Medicinal Products for Human Use referred to in Article 173(1) a draft of the decision on the application**.**	Within 12 days of receipt of the opinion of the Committee for Medicinal products for Human Use the Commission shall submit to the Standing Committee on Medicinal Products for Human Use referred to in Article 173(1) a draft of the decision on the application.

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 5

Text proposed by the Commission	*Amendment*
Where the draft decision differs from the opinion of the Agency, the Commission shall provide a detailed explanation of the reasons for the differences.	Where the draft decision differs from the opinion of the Agency, the Commission shall provide a detailed explanation of the reasons for the differences ***and make that information publicly available.***

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 6

Text proposed by the Commission	*Amendment*
The Commission shall send the draft decision to the Member States and the applicant.	The Commission shall send the draft decision ***and the accompanying reasoning referred to in the fifth subparagraph*** to the Member States and the applicant.

Proposal for a regulation
Article 13 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Agency shall disseminate the documents referred to in Article 12(4), points (a) to (e), together with any deadlines laid down pursuant to paragraph 1, first	4. The Agency shall disseminate the documents referred to in Article 12(4), points (a) to (e), ***and, where relevant, the documents referred to in Article 12(4), points (f) to (mb),***

subparagraph.	together with any deadlines laid down pursuant to paragraph 1, first subparagraph.

COMPROMISE AMENDMENT 9 - WITHDRAWAL AND REFUSAL OF A CENTRALISED MARKETING AUTHORISATION (ARTICLE 14 AND ARTICLE 15)
replacing amendments 52; 656-672

supported by
EPP, S&D, RE, Greens/EFA, Left

Article 14 is COM proposal

Proposal for a regulation
Article 15 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) the environmental risk assessment is incomplete or insufficiently substantiated by the applicant or if the risks identified in the environmental risk assessment have not been sufficiently addressed by the applicant;	(d) the environmental risk assessment is incomplete or insufficiently substantiated by the applicant or if the risks identified in the environmental risk assessment have not been sufficiently addressed by the ***risk mitigation measures proposed by the applicant in accordance with Article 22(3) of [revised Directive 2001/83/EC];***

COMPROMISE AMENDMENT 10 - MARKETING AUTHORISATIONS (ARTICLE 16)
replacing amendments 53-55; 673-683

supported by
EPP, S&D, RE, Greens/EFA, Left

Proposal for a regulation
Article 16 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall immediately publish the assessment report on the medicinal product for human use and the reasons for its opinion in favour of granting marketing authorisation, after deletion of any information of a commercially confidential nature.	The Agency shall immediately publish the assessment report on the medicinal product for human use and the reasons for its opinion in favour of granting marketing authorisation, after deletion of any information of a commercially confidential nature ***following a notification to relevant patient organisations. The Agency shall ensure the readability, clarity and comprehensibility of European public assessment report summaries***.

Proposal for a regulation
Article 16 – paragraph 3 – subparagraph 2 – indent 2

Text proposed by the Commission	*Amendment*
– a summary of environmental risk assessment studies and their results as submitted by the marketing authorisation holder and the assessment of the environmental risk assessment and the information referred to in Article 22(5) of [revised Directive 2001/83/EC] by the Agency.	– ***the complete*** environmental risk assessment ***submitted to the*** Agency by the marketing authorisation ***applicant as well as*** a summary of environmental risk assessment studies and their results as submitted by the marketing authorisation holder and the assessment of the environmental risk assessment and the information referred to in Article 22(5) of [revised Directive 2001/83/EC] by the Agency.

Proposal for a regulation
Article 16 – paragraph 3 – subparagraph 2 – indent 2 a (new)

Text proposed by the Commission	*Amendment*
	– ***for antimicrobials, all information referred to in Article 17 of and Annex I to [revised Directive 2001/83/EC] as well as any other obligations imposed on the marketing authorisation holder.***

Proposal for a regulation
Article 16 – paragraph 4 – subparagraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) a potential or actual shortage in that Member State in accordance with Article 116(1), point (d); and its reasons for such action under points (a) and (b) in accordance with Article 24, as well as any other reason relating to precautionary actions with regard to quality, safety, efficacy and the environment.	(c) a potential or actual shortage in that Member State in accordance with Article 116(1), point (d); and its reasons for such action under points (a) and (b) in accordance with Article 24, as well as any other reason relating to precautionary actions with regard to quality, safety, efficacy and the environment.

COMPROMISE AMENDMENT 11 - VALIDITY AND RENEWAL OF MARKETING AUTHORISATIONS (ARTICLE 17)
replacing amendments 56-61; 684-696

supported by
EPP, S&D, RE, Greens/EFA, ECR, ID, Left

Proposal for a regulation
Article 17 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Without prejudice to paragraph 2, a marketing authorisation for a medicinal product shall be valid for an unlimited period.	1. Without prejudice to paragraph 2, a marketing authorisation for a medicinal product shall be valid for an unlimited period.

Proposal for a regulation
Article 17 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
Where the validity of the marketing authorisation is limited to five years**,** the marketing authorisation holder shall apply to the Agency for a renewal of the marketing authorisation at least nine months before the marketing authorisation ceases to be valid.	Where the validity of the marketing authorisation is limited to five years The marketing authorisation holder shall apply to the Agency for a renewal of the marketing authorisation at least nine months before the marketing authorisation ceases to be valid.

Proposal for a regulation
Article 17 – paragraph 2 – subparagraph 3

Text proposed by the Commission	*Amendment*
Where a renewal application has been submitted in accordance with the second subparagraph, the marketing authorisation shall remain valid until a decision is adopted by the Commission in accordance with Article 13.	Where a renewal application has been submitted in accordance with the second subparagraph, the marketing authorisation shall remain valid until a decision is adopted by the Commission in accordance with Article 13.

Proposal for a regulation
Article 17 – paragraph 2 – subparagraph 4

Text proposed by the Commission	*Amendment*
The marketing authorisation may be renewed on the basis of a re-evaluation by the Agency of the benefit-risk balance. Once renewed, the marketing authorisation shall be valid for an unlimited period.	The marketing authorisation may be renewed on the basis of a re-evaluation by the Agency of the benefit-risk balance. Once renewed, the marketing authorisation shall be valid for an unlimited period.

COMPROMISE AMENDMENT 12 - MARKETING AUTHORISATIONS GRANTED IN EXCEPTIONAL CIRCUMSTANCES (ARTICLE 18)
replacing amendments 62; 697-704

supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a regulation
Article 18 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. In exceptional circumstances where, in an application under Article 6 of [revised Directive 2001/83/EC] for a marketing authorisation of a medicinal product or a new therapeutic indication of an existing marketing authorisation under this Regulation, an applicant is unable to provide comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use, the Commission may, by derogation to Article 6, grant an authorisation under Article 13, subject to specific conditions, where the following requirements are met:	1. In exceptional circumstances where, in an application under Article 6 of [revised Directive 2001/83/EC] for a marketing authorisation of a medicinal product or a new therapeutic indication, of an existing marketing authorisation under this Regulation, an applicant is unable to provide comprehensive data on the efficacy and safety***, and, where missing, on the environmental risk*** of the medicinal product under normal conditions of use, the Commission may, by derogation to Article 6, grant an authorisation under Article 13, subject to specific conditions, where the following requirements are met:

Proposal for a regulation
Article 18 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
The maintenance of the authorised new therapeutic indication and the validity of the marketing authorisation granted in accordance with paragraph 1 shall be linked to the reassessment by the Agency of the conditions referred to in paragraph 1 after two years from the date when the new therapeutic indication was authorised or the marketing authorisation was granted, and thereafter at a risk-based frequency to be determined by the Agency and specified by the Commission in the marketing authorisation.	The maintenance of the authorised new therapeutic indication**,** and the validity of the marketing authorisation granted in accordance with paragraph 1 shall be linked to the reassessment by the Agency of the conditions referred to in paragraph 1 after two years from the date when the new therapeutic indication**,** was authorised or the marketing authorisation was granted, and thereafter at a risk-based frequency to be determined by the Agency and specified by the Commission in the marketing authorisation.

Proposal for a regulation
Article 18 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
This reassessment shall be conducted on the basis of an application by the marketing	This reassessment shall be conducted on the basis of an application by the marketing

authorisation holder to maintain the authorised new therapeutic indication or renew the marketing authorisation under exceptional circumstances.	authorisation holder to maintain the authorised new therapeutic indication or renew the marketing authorisation under exceptional circumstances.

Proposal for a regulation
Article 18 – paragraph 2 – subparagraph 2 a (new)

Text proposed by the Commission	*Amendment*
	Where specific conditions referred to in paragraph 1, point (c), are not fulfilled within the timeframe given by the Agency or the marketing authorisation holder does not provide duly justified reasons for not fulfilling the conditions, the Commission may suspend, revoke or vary the marketing authorisation by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 173(2).

COMPROMISE AMENDMENT 13 - CONDITIONAL MARKETING AUTHORISATION (ARTICLE 19)
replacing amendments 63-68; 705-732

supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a regulation
Article 19 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
In duly justified cases, to meet an unmet medical need of patients, as referred to in Article 83(1), point (a), of [revised Directive 2001/83/EC], a conditional marketing authorisation or a new conditional therapeutic indication to an existing marketing authorisation authorised under this Regulation may be granted by the Commission to a medicinal product that is likely to address the unmet medical need in accordance with Article 83(1), point (b), of [revised Directive 2001/83/EC], prior to the submission of comprehensive clinical data provided that the benefit of the immediate availability on the market of that medicinal product outweighs the risk inherent in the fact that additional data are still required.	In duly justified cases, to meet an unmet medical need of patients, as referred to in Article 83(1), point (a), of [revised Directive 2001/83/EC], a conditional marketing authorisation or a new conditional therapeutic indication to an existing marketing authorisation authorised under this Regulation may be granted by the Commission to a medicinal product that is likely to address the unmet medical need in accordance with Article 83(1), point (b), of [revised Directive 2001/83/EC], prior to the submission of comprehensive clinical data provided that the benefit of the immediate availability on the market of that medicinal product outweighs the risk inherent in the fact that additional data are still required.

Proposal for a regulation
Article 19 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
In emergency situations, a conditional marketing authorisation or a new conditional therapeutic indication referred to in the first subparagraph may be granted also where comprehensive non-clinical or pharmaceutical data have not been supplied.	In emergency situations**,** a conditional marketing authorisation or a new conditional therapeutic indication referred to in the first subparagraph may be granted also where comprehensive non-clinical or pharmaceutical data have not been supplied.

Proposal for a regulation
Article 19 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Conditional marketing authorisations or a new conditional therapeutic indication referred to in paragraph 1 may be granted only if the benefit-risk balance of the medicinal product is favourable and the applicant is likely to be able to provide comprehensive data.	2. Conditional marketing authorisations or a new conditional therapeutic indication referred to in paragraph 1 may be granted only if the benefit-risk balance of the medicinal product is favourable and the applicant is likely to be able to provide comprehensive data.

Proposal for a regulation
Article 19 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Conditional marketing authorisations or a new conditional therapeutic indication granted pursuant to this Article shall be subject to specific obligations. Those specific obligations and, where appropriate, the time limit for compliance shall be specified in the conditions to the marketing authorisation. Those specific obligations shall be reviewed annually by the Agency for the first three years after granting the authorisation and every two years thereafter.	3. Conditional marketing authorisations or a new conditional therapeutic indication, granted pursuant to this Article shall be subject to specific obligations, Those specific obligations***, in particular for ongoing or new studies as referred to in paragraph 4 of this Article***, and, where appropriate the time limit for compliance shall be specified in the conditions to the marketing authorisation. Those specific obligations shall be reviewed annually by the Agency for the first three years after granting the authorisation and every two years thereafter.

Proposal for a regulation
Article 19 – paragraph 4

Text proposed by the Commission	*Amendment*
4. As part of the specific obligations referred to in paragraph 3, the marketing authorisation holder of a conditional marketing authorisation granted pursuant to this Article	4. As part of the specific obligations referred to in paragraph 3, the marketing authorisation holder of a conditional marketing authorisation granted pursuant to this Article

shall be required to complete ongoing studies, or to conduct new studies, with a view to confirming ***that*** the ***benefit-risk balance is favourable***.	shall be required to complete ongoing studies, or to conduct new studies ***in accordance with Article 20***, with a view to confirming the that the benefit-risk balance is favourable**.**

Proposal for a regulation
Article 19 – paragraph 6

Text proposed by the Commission	*Amendment*
6. By way of derogation from Article 17(1), an initial conditional marketing authorisation granted pursuant to this Article shall be valid for one year, on a renewable basis for the first three years after granting the authorisation and every two years thereafter.	6. By way of derogation from Article 17(1), an initial conditional marketing authorisation granted pursuant to this Article shall be valid for one year, on a renewable basis for the first three years after granting the authorisation and every two years thereafter.

Proposal for a regulation
Article 19 – paragraph 7 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Where specific conditions referred to in paragraph 3 are not fulfilled within the timeframe given by the Agency or the marketing authorisation holder does not provide duly justified reasons for not fulfilling the conditions, the Commission may suspend, revoke or vary the marketing authorisation by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 173(2).

Proposal for a regulation
Article 19 – paragraph 8 – point b

Text proposed by the Commission	*Amendment*
(b) the procedures and requirements for granting a conditional marketing authorisation, for its renewal, ***and*** for adding a new conditional therapeutic indication to an existing marketing authorisation.	(b) the procedures and requirements for granting a conditional marketing authorisation, for its renewal, for adding a new conditional therapeutic indication to an existing marketing authorisation***, and for the withdrawal, suspension or revocation of the conditional marketing authorisation***.

Proposal for a regulation
Article 19 – paragraph 8 a (new)

Text proposed by the Commission	*Amendment*
	8 a. The Agency shall publish in the database referred to in Article 138(1)(n) the list of conditional marketing authorisations, together with the following information:
	(a) specific obligations to be fulfilled by the marketing authorisation holder;
	(b) timelines for compliance with specific obligations;
	(c) any delays by the marketing authorisation holder regarding the fulfilment of obligations and the reasons for it;
	(d) any actions on the conditional marketing authorisation taken in accordance with Article 56.

COMPROMISE AMENDMENT 14 - POST-AUTHORISATION STUDIES (ARTICLE 20 AND 21)
replacing amendments 69-71 ; 733-739

supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a regulation
Article 20 – paragraph 1 – subparagraph 1 – introductory part

Text proposed by the Commission	*Amendment*
After the granting of a marketing authorisation, the Agency may consider that it is necessary that the marketing authorisation holder:	After the granting of a marketing authorisation, the Agency may consider that it is necessary that the marketing authorisation holder:

Proposal for a regulation
Article 20 – paragraph 1 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) conducts a post-authorisation safety study if there are concerns about the risks of an authorised medicinal product. If the same concerns apply to more than one medicinal product, the Agency shall, following consultation with the Pharmacovigilance Risk Assessment Committee, encourage the marketing authorisation holders concerned to conduct a joint post-authorisation safety study;	(a) conducts a post-authorisation safety study if there are concerns about the risks of an authorised medicinal product If the same concerns apply to more than one medicinal product, the Agency shall, following consultation with the Pharmacovigilance Risk Assessment Committee, encourage the marketing authorisation holders concerned to conduct a joint post-authorisation safety study;

Proposal for a regulation
Article 20 – paragraph 1 – subparagraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) conducts a post-authorisation treatment optimisation study when the optimal usage of medicinal product was not previously established.

Proposal for a regulation
Article 20 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
If this obligation would apply to several medicinal products, the Agency shall encourage the marketing authorisation holders concerned to conduct a joint post authorisation environmental risk assessment study.	If this obligation would apply to several medicinal products, the Agency shall encourage the marketing authorisation holders concerned to conduct a joint post authorisation environmental risk assessment study.

Proposal for a regulation
Article 20 – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
Where the Agency considers that any of the post-authorisations studies referred to in points (a) to ***(c)*** is necessary, it shall inform the marketing authorisation holder thereof in writing, stating the grounds for its assessment and shall include the objectives and timeframe for submission and conduct of the study.	Where the Agency considers that any of the post-authorisations studies referred to in points (a) to ***(ca)*** is necessary, it shall inform the marketing authorisation holder thereof in writing, stating the grounds for its assessment and shall include the objectives and timeframe for submission and conduct of the study.

Proposal for a regulation
Article 20 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Where the opinion of the Agency confirms the need for any of the post-authorisation studies referred to in paragraph 1, points (a) to ***(c)***, to be carried out, the Commission shall vary the marketing authorisation, by means of implementing acts, adopted pursuant to Article 13 to include the obligation as a condition of the marketing authorisation unless the Commission returns the opinion to the Agency for further consideration. For obligations under paragraph 1, points (a) and (b), the marketing authorisation holder shall update the risk management system accordingly.	4. Where the opinion of the Agency confirms the need for any of the post-authorisation studies referred to in paragraph 1, points (a) to ***(ca)***, to be carried out, the Commission shall vary the marketing authorisation, by means of implementing acts, adopted pursuant to Article 13 to include the obligation as a condition of the marketing authorisation unless the Commission returns the opinion to the Agency for further consideration. For obligations under paragraph 1, points (a) and (b), the marketing authorisation holder shall update the risk management system accordingly.

COMPROMISE AMENDMENT 15 - ARTICLE 22A (NEW) AND 23
replacing amendments 72, 740-741

supported by
EPP, S&D, RE, Greens/EFA, ECR, ID, Left

Proposal for a regulation
Article 23 – paragraph 1

Text proposed by the Commission	*Amendment*
The granting of a marketing authorisation shall not affect the civil or criminal liability of the manufacturer or of the marketing authorisation holder pursuant to the applicable national law in Member States.	The granting of a marketing authorisation shall not affect the civil or criminal liability of the manufacturer or of the marketing authorisation holder pursuant to the applicable national law in Member States.

No other AMs tabled on other paragraphs of these Articles

COMPROMISE AMENDMENT 16 - SUSPENSION AND WITHDRAWAL (ARTICLE 24)
replacing amendments 73-78, 742-755

supported by
EPP, S&D, RE, Greens/EFA, Left

Proposal for a regulation
Article 24 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
In addition to the notification made pursuant to Article 116, the marketing authorisation holder shall notify the Agency without undue delay of any action they take to suspend the marketing of a medicinal product, to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation or not to apply for the renewal of a marketing authorisation, together with ***the reasons*** for such action.	In addition to the notification made pursuant to Article 116, the marketing authorisation holder shall notify the Agency without undue delay of any action they take to suspend the marketing of a medicinal product, to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation or not to apply for the renewal of a marketing authorisation, together with ***a detailed reasoning*** for such action.

Proposal for a regulation
Article 24 – paragraph 1 – subparagraph 2 – point f

Text proposed by the Commission	*Amendment*
(f) a serious risk to the environment or to public health via the environment has been identified and not sufficiently addressed by the marketing authorisation holder.	(f) a serious risk to the environment or to public health via the environment has been identified and not sufficiently addressed by the marketing authorisation holder~~.~~

Proposal for a regulation
Article 24 – paragraph 1 – subparagraph 2 – point f a (new)

Text proposed by the Commission	*Amendment*
	(f a) commercial reasons .

Proposal for a regulation
Article 24 – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
Where the action referred to in the first subparagraph is to withdraw a medicinal product from the market, the marketing authorisation holder shall provide information on the impact of such withdrawal on patients who are already being treated.	Where the action referred to in the first subparagraph is to withdraw a medicinal product from the market, the marketing authorisation holder shall provide information on the impact of such withdrawal on patients who are already being treated**.**

Proposal for a regulation
Article 24 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3 a. In the cases referred to in paragraph 1 point (f), the Agency shall immediately inform the Commission that is to be responsible for informing the relevant national and Union authorities. Where relevant, national authorities shall forward the information to drinking water and wastewater operators.

Proposal for a regulation
Article 24 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Where the marketing authorisation holder intends to permanently withdraw the marketing authorisation for a critical medicinal product, the marketing authorisation holder shall, prior to the notification referred to in paragraph 1, offer, on reasonable terms, to transfer the marketing authorisation to a third	4. Where the marketing authorisation holder intends to permanently withdraw the marketing authorisation for a critical medicinal product, the marketing authorisation holder shall, prior to the notification referred to in paragraph 1, offer, on reasonable terms, to transfer the marketing authorisation to a third

party that has declared its intention to place that critical medicinal product on the market, or to use the pharmaceutical non-clinical and clinical documentation contained in the file of the medicinal product for the purposes of submitting an application in accordance with Article 14 of [revised Directive 2001/83/EC].	party that has declared its intention to place that critical medicinal product on the market, or to use the pharmaceutical non-clinical and clinical documentation contained in the file of the medicinal product for the purposes of submitting an application in accordance with Article 14 of [revised Directive 2001/83/EC].

Proposal for a regulation
Article 24 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. The Agency may decide to extend obligations set in paragraph 4 in justified cases to a specific non-critical medicinal product on a case-by-case basis.

Proposal for a regulation
Article 24 – paragraph 4 b (new)

Text proposed by the Commission	*Amendment*
	4b. The marketing authorisation holder from which the marketing authorisation has been transferred to a third party shall notify the Agency of the transfer as soon as possible. The information regarding the transfer provided shall be made publicly available.

COMPROMISE AMENDMENT 17 - DUPLICATE MAS (ARTICLE 25)
replacing amendments 79, 756-758

supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a regulation
Article 25 – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
As soon as the relevant patent or supplementary protection certificate referred to in point (a) expires, the marketing authorisation holder shall withdraw the initial or duplicate marketing authorisation.	As soon as the relevant patent or supplementary protection certificate referred to in point (a) expires, the marketing authorisation holder shall ***without undue delay*** withdraw the initial or duplicate marketing

authorisation.

Proposal for a regulation
Article 25 – paragraph 1 – subparagraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) if one of its indications or pharmaceutical forms is protected by a patent or a supplementary protection certificate in one or more Member States;	(a) if one of its indications or **,** pharmaceutical forms**,** is protected by a patent or a supplementary protection certificate in one or more Member States;

Proposal for a regulation
Article 25 – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
As soon as the relevant patent or supplementary protection certificate referred to in point (a) expires, the marketing authorisation holder shall withdraw the initial or duplicate marketing authorisation.	As soon as the relevant patent or supplementary protection certificate referred to in point (a) expires, the marketing authorisation holder shall withdraw the initial or duplicate marketing authorisation

No AMs tabled on other paragraphs

COMPROMISE AMENDMENT 18 - COMPASSIONATE USE (ARTICLE 26) AND REQUEST FOR OPINION ON SCIENTIFIC MATTERS (ARTICLE 27)
replacing amendments 80; 81; 759-772

supported by
EPP, S&D, RE, Greens/EFA, ECR, ID, Left

Proposal for a regulation
Article 26 – paragraph 2

Text proposed by the Commission	*Amendment*
2. For the purposes of this Article, 'compassionate use' shall mean making a medicinal product belonging to the categories referred to in Article 3, paragraphs 1 and 2 available for compassionate reasons to a group of patients with a chronically or seriously debilitating disease ***or*** whose disease is considered to be life-threatening, and who cannot be treated satisfactorily by an	2. For the purposes of this Article, 'compassionate use' shall mean making a medicinal product belonging to the categories referred to in Article 3, paragraphs 1 and 2 available for compassionate reasons to a ***single*** or group of patients with a chronically or seriously debilitating disease whose disease is considered to be life-threatening***, treatment resistant, or causing psychological distress or***

authorised medicinal product. The medicinal product concerned must either be the subject of an application for a marketing authorisation in accordance with Article 6 or the submission of such application is imminent, or it must be undergoing clinical trials in the same indication.	***in palliative care***, and who cannot be treated satisfactorily by an authorised medicinal product. The medicinal product concerned must either be the subject of an application for a marketing authorisation in accordance with Article 6 or the submission of such application is imminent, or it must be undergoing clinical trials in the same indication.

Proposal for a regulation
Article 26 – paragraph 3

Text proposed by the Commission	*Amendment*
3. When applying paragraph 1, the Member State shall notify the Agency.	3. When applying paragraph 1, the Member State shall notify the Agency, ***which shall make the notification publicly available.***

Proposal for a regulation
Article 26 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
When compassionate use is envisaged by a Member State, the Committee for Medicinal Products for Human Use, after consulting the manufacturer or the applicant, may adopt opinions on the conditions for use, the conditions for distribution and the patients targeted. The opinions shall be updated where necessary.	When compassionate use is envisaged by a Member State**,** the Committee for Medicinal Products for Human Use, after consulting the manufacturer or the applicant, may adopt opinions on the conditions for use, the conditions for distribution and the patients targeted. The opinions shall be updated where necessary.

Proposal for a regulation
Article 26 – paragraph 4 – subparagraph 2

Text proposed by the Commission	*Amendment*
In the preparation of the opinion, the Committee for Medicinal Products for Human Use may request information and data from marketing authorisation holders and from developers and may engage with them in preliminary discussions. The Committee may also make use of health data generated outside of clinical studies, where available, taking into account the reliability of those data.	In the preparation of the opinion, the Committee for Medicinal Products for Human Use may request information and data from marketing authorisation holders and from developers and may engage with them in preliminary discussions. The Committee may also make use of health data generated outside of clinical studies, ***including real world data,*** where available, taking into account the reliability of those data.

Proposal for a regulation
Article 26 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Agency shall keep an up-to-date	6. The Agency shall keep an up-to-date

list of the opinions adopted in accordance with paragraph 4 and shall publish it on its website.	list of the opinions adopted in accordance with paragraph 4 and shall publish it ***in the database referred to in Article 138 paragraph 1 (n)*** on its website.

Proposal for a regulation
Article 26 – paragraph 10

Text proposed by the Commission	*Amendment*
10. The Agency ***may*** adopt detailed guidelines laying down format and content of notifications referred to in paragraphs 3 and 5, and data exchange under this Article.	10. The Agency ***shall*** adopt detailed guidelines laying down format and content of notifications referred to in paragraphs 3 and 5, and data exchange under this Article.

No AMs tabled on other paragraphs

COM text is compromise for Article 27

COMPROMISE AMENDMENT 19 - ARTICLES 28 AND 29 (REGULATORY DATA PROTECTION)
replacing amendments 773-777

supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a regulation
Article 29 – paragraph 1

Text proposed by the Commission	*Amendment*
Without prejudice to the law on the protection of industrial and commercial property, medicinal products for human use which have been authorised in accordance with this Regulation shall benefit from the periods of regulatory protection set out in Chapter VII of [revised Directive 2001/83/EC].	Without prejudice to the law on the protection of industrial and commercial property, medicinal products for human use which have been authorised in accordance with this Regulation shall benefit from the periods of regulatory protection set out in Chapter VII of [revised Directive 2001/83/EC]. ***The applicable periods of regulatory protection shall be published and updated where appropriate by the Commission in the Union Register of Medicinal Products.***

COMPROMISE AMENDMENT 20 - ARTICLES 30-37 (TEMPORARY EMERGENCY MARKETING AUTHORISATIONS)
replacing amendments 82-87; 778-819

supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a regulation
Article 30 – paragraph 1

Text proposed by the Commission	*Amendment*
During a public health emergency, the Commission may grant a temporary emergency marketing authorisation ('TEMA') for medicinal products intended for the treatment, prevention or medical diagnosis of a serious or life-threatening disease or condition which are directly related to the public health emergency, prior to the submission of the complete quality, non-clinical, clinical data and environmental data and information..	During a public health emergency**,** the Commission may grant a temporary emergency marketing authorisation ('TEMA') for medicinal products intended for the treatment, prevention or medical diagnosis of a serious or life-threatening disease or condition which are directly related to the public health emergency, prior to the submission of the complete quality, non-clinical, clinical data and environmental data and information.

Proposal for a regulation
Article 30 – paragraph 3

Text proposed by the Commission	*Amendment*
An application for a temporary emergency marketing authorisation shall be submitted in accordance with Articles 5 and 6.	An application for a temporary emergency marketing authorisation shall be submitted in accordance with Articles 5 and 6.

Proposal for a regulation
Article 31 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
A temporary emergency marketing authorisation may be granted only after the recognition of a public health emergency at Union level in accordance with Article 23 of Regulation (EU) 2022/2371 of the European Parliament and of the Council[67] and where the following requirements are met:	A temporary emergency marketing authorisation may be granted only after the recognition of a public health emergency at Union level in accordance with Article 23 of Regulation (EU) 2022/2371 of the European Parliament and of the Council[67] and where the following requirements are met:

Proposal for a regulation
Article 31 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) there is no other satisfactory method of treatment, prevention or diagnosis authorised or sufficiently available in the Union or, if such method is already available, the temporary emergency marketing authorisation of the medicinal product will contribute to address the public health emergency;	(a) there is no other satisfactory method of treatment, prevention or diagnosis authorised or sufficiently available in the Union or, if such method is already available, the temporary emergency marketing of the medicinal product**,** will contribute to address the public health emergency;

Proposal for a regulation
Article 31 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) based on the scientific evidence available, the Agency issues an opinion concluding that the medicinal product could be effective in treating, preventing or diagnosing the disease or condition directly related to the public health emergency, and the known and potential benefits of the product outweigh the known and potential risks of the product, taking into consideration the threat posed by the public health emergency.	(b) based on the scientific evidence available, the Agency issues an opinion concluding that the medicinal product could be effective in treating, preventing or diagnosing the disease or condition directly related to the public health emergency, and the known and potential benefits of the product outweigh the known and potential risks of the product, taking into consideration the threat posed by the public health emergency.

Proposal for a regulation
Article 32 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Agency shall ensure that the scientific opinion of the Committee for Medicinal Products for Human Use is given without undue delay, taking into account, the recommendation of the Emergency Task Force referred to in Article 38(1), second subparagraph. For the purpose of issuing its opinion, the Agency may consider any relevant data on the medicinal product concerned.	1. The Agency shall ensure that the scientific opinion of the Committee for Medicinal Products for Human Use is given without undue delay, taking into account, the recommendation of the Emergency Task Force referred to in Article 38(1), second subparagraph. For the purpose of issuing its opinion, the Agency may consider any relevant data on the medicinal product concerned ***in addition to the evidence submitted in the applicant's dossier***.

Proposal for a regulation
Article 32 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall review any new evidence provided by the developer, the Member States or the Commission, or any other evidence that comes to its attention, in particular evidence that might influence the benefit-risk balance of the medicinal product concerned.	The Agency shall ***without undue delay*** review any new evidence provided by the developer, the Member States or the Commission, or any other evidence ***of*** that comes to its attention ***in addition to and in the context of evidence submitted by the developer*** , in particular evidence that might influence the benefit-risk balance of the medicinal product concerned.

Proposal for a regulation
Article 32 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall transmit without undue delay to the Commission the scientific opinion and its updates and any recommendations on the temporary emergency marketing authorisation.	3. The Agency shall transmit without undue delay to the Commission the scientific opinion and its updates and any recommendations on the temporary emergency marketing authorisation. ***The scientific opinion and information on the application on the use of temporary emergency marketing authorisation shall be made publicly available by the Agency.***

Proposal for a regulation
Article 33 – paragraph 2

Text proposed by the Commission	*Amendment*

2. On the basis of the scientific opinion of the Agency referred to in paragraph 1, the Commission shall set specific conditions with respect to the temporary emergency marketing authorisation, in particular the conditions for manufacturing, use, supply and safety monitoring and the compliance with related good manufacturing, and pharmacovigilance practices. If necessary, the conditions may specify the batches of the medicinal product concerned by the temporary emergency marketing authorisation.	2. On the basis of the scientific opinion of the Agency referred to in paragraph 1, the Commission shall set specific conditions with respect to the temporary emergency marketing authorisation, in particular the conditions for manufacturing, use, supply and safety monitoring and the compliance with related good manufacturing, and pharmacovigilance practices. If necessary, the conditions may specify the batches of the medicinal product concerned by the temporary emergency marketing authorisation, ***after consultation with the applicant or marketing authorisation holder***.

Proposal for a regulation
Article 33 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Specific conditions may be set to require the completion of ongoing studies or to conduct new studies to ensure the safe and effective use of the medicinal product or minimise its impact on the environment. A time limit for the submission of those studies shall be set.	3. Specific conditions may be set to require the completion of ongoing studies or to conduct new studies to ensure the safe and effective use of the medicinal product or minimise its impact on the environment. A time limit for the submission of those studies shall be set.

Proposal for a regulation
Article 33 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Those specific conditions and, where appropriate, the time limit for compliance shall be specified in the conditions to the marketing authorisation and shall be reviewed annually by the Agency.	4. Those specific conditions and, where appropriate, the time limit for compliance shall be specified in the conditions to the marketing authorisation and shall be reviewed annually by the Agency.

Proposal for a regulation
Article 34 – paragraph 1

Text proposed by the Commission	*Amendment*
The temporary emergency marketing authorisation shall cease to be valid when the Commission terminates the recognition of a public health emergency in accordance with Article 23(2) and (4) of Regulation (EU) 2022/2371.	The temporary emergency marketing authorisation shall cease to be valid when the Commission terminates the recognition of a public health emergency in accordance with Article 23(2) and (4) of Regulation (EU) 2022/2371

Proposal for a regulation
Article 35 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
b) it is appropriate to protect public health	b) it is appropriate to protect public health

Article 36
Proposal for a regulation
Article 36 – paragraph 1

Text proposed by the Commission	*Amendment*
The marketing authorisation holder of an authorisation in accordance with Article 33 may submit an application in accordance with Articles 5 and 6 in order to obtain an authorisation in accordance with Articles 13, 16 or 19.	The marketing authorisation holder of an authorisation in accordance with Article 33 may submit an application in accordance with Articles 5 and 6 in order to obtain an authorisation in accordance with Articles 13, 16 or 19 ***based on the pre-agreed timelines established with the Agency***.

Proposal for a regulation
Article 36 – paragraph 2

Text proposed by the Commission	*Amendment*
For the purpose of regulatory data protection, the temporary emergency marketing authorisation and any subsequent marketing authorisation, as referred to in subparagraph 1, shall be considered as part of the same global marketing authorisation.	For the purpose of regulatory data protection, the temporary emergency marketing authorisationand any subsequent marketing authorisation, as referred to in subparagraph 1, shall be considered as part of the same global marketing authorisation.

Proposal for a regulation
Article 37 – paragraph 1

Text proposed by the Commission	*Amendment*
When the temporary marketing authorisation of a medicinal product is suspended or revoked for reasons other than the safety of the medicinal product, or if that temporary emergency marketing authorisation ceases to be valid, Member States may, in exceptional circumstances, allow for a transitional period, the supply of the medicinal product to patients who are already being treated with it.	When the temporary marketing authorisation of a medicinal product is suspended or revoked for reasons other than the safety of the medicinal product, or if that temporary emergency marketing authorisation ceases to be valid, Member States may, in exceptional circumstances, allow for a transitional period, the supply of the medicinal product to patients who are already being treated with it. ***In such cases, the Member State shall inform the Agency about the application of the***

transitional period. Conditions for manufacturing, use, supply and safety monitoring and the compliance with related good manufacturing, and pharmacovigilance practices shall continue to apply during that period.

COM text proposed as CA on paragraphs not listed.

COMPROMISE AMENDMENT 21 - URGENT SAFETY AND EFFICACY RESTRICTIONS AND UPDATE OF MAS RELATED TO SCIENTIFIC DEVELOPMENTS (ARTICLES 44 AND 45)
replacing amendments 95; 955-958

supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a regulation
Article 44 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
If, in the event of a risk to public health, the marketing authorisation holder takes urgent safety or efficacy restrictions on their own initiative, the marketing authorisation holder shall immediately inform the Agency.	If, in the event of a risk to public health, the marketing authorisation holder takes urgent safety or efficacy restrictions on their own initiative, the marketing authorisation holder shall immediately inform the Agency.

Proposal for a regulation
Article 44 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
In the event of a risk to public health, the Commission may vary the marketing authorisation to impose urgent safety or efficacy restrictions on the marketing authorisation holder.	In the event of a risk to public health the Commission may vary the marketing authorisation to impose urgent safety or efficacy restrictions on the marketing authorisation holder.

Proposal for a regulation
Article 45 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
The marketing authorisation holder shall without undue delay inform the Agency and the Commission of any prohibition or restriction imposed on the marketing authorisation holder or any entity in contractual relationship with the marketing authorisation holder by the competent authorities of any country in which the medicinal product is marketed and of any other new information	The marketing authorisation holder shall without undue delay inform the Agency and the Commission of any prohibition or restriction imposed on the marketing authorisation holder or any entity in contractual relationship with the marketing authorisation holder by the competent authorities of any country in which the medicinal product is marketed and of any other new information

which might influence the evaluation of the benefits and risks of the medicinal product concerned. The information shall include both positive and negative results of clinical trials or other studies in all indications and populations, whether or not included in the marketing authorisation, as well as data on the use of the medicinal product where such use is outside the terms of the marketing authorisation.

which might influence the evaluation of the benefits and risks of the medicinal product concerned. The information shall include both positive and negative results of clinical trials or other studies in all indications and populations, whether or not included in the marketing authorisation, as well as data on the use of the medicinal product where such use is outside the terms of the marketing authorisation.

Proposal for a regulation
Article 45 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency may at any time request the marketing authorisation holder to submit data demonstrating that the benefit-risk balance remains favourable. The marketing authorisation holder shall answer fully and ***promptly*** any such request. The marketing authorisation holder shall also respond fully and within the time limit set ***to*** any request of a competent authority regarding the implementation of any measures previously imposed, including risk minimisation measures.	The Agency may at any time request the marketing authorisation holder to submit data demonstrating that the benefit-risk balance remains favourable. The marketing authorisation holder shall answer fully and ***within the time limit set to*** any such request. The marketing authorisation holder shall also respond fully and within the time limit set any ***such*** request of a competent authority regarding the implementation of any measures previously imposed, including risk minimisation measures.

Article 46 - no AMs

Proposal for a regulation
Article 47 – paragraph 1

Text proposed by the Commission	*Amendment*
1. An application for variation of a centralised marketing authorisation by the marketing authorisation holder shall be made electronically in the formats made available by the Agency, unless the variation is an update by the marketing authorisation holder of their information held in a database.	1. An application for variation of a centralised marketing authorisation by the marketing authorisation holder shall be made electronically in the formats made available by the Agency, unless the variation is an update by the marketing authorisation holder of their information held in a database. ***The electronic format shall include a baseline sequence in regards to the Common Technical Document (CTD).***

COMPROMISE AMENDMENT 22 - SCIENTIFIC OPINION FROM NOT PROFIT ENTITIES FOR REPURPOSING OF AUTHORISED MEDICINAL PRODUCTS (ARTICLE 48)
replacing amendments 97-100, 959-975

supported by
EPP, S&D, RE, Greens/EFA, ECR, ID, Left

Proposal for a regulation
Article 48 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
An entity not engaged in an economic activity ('not-for-profit entity') may submit to the Agency or to a competent authority of the Member State substantive non-clinical or clinical evidence for a new therapeutic indication ***that is expected to fulfil an unmet medical need***.	An entity not engaged in an economic activity ('not-for-profit entity') may submit to the Agency or to a competent authority of the Member State substantive non-clinical or clinical evidence for a new therapeutic indication.

Proposal for a regulation
Article 48 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
The Agency may, at the request of a Member State, the Commission, or on its own initiative and on the basis of all available evidence make a scientific evaluation of the benefit-risk of the use of a medicinal product with a new therapeutic indication ***that concerns an unmet medical need.***	The Agency may, at the request of a Member State, the Commission, or on its own initiative and on the basis of all available evidence***, including any additional evidence that may be submitted by the marketing authorisation holders of the medicinal products concerned,*** make a scientific evaluation of the benefit-risk of the use of a medicinal product with a new therapeutic indication.

Proposal for a regulation
Article 48 – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
The opinion of the Agency shall be made publicly available and the competent authorities of the Member States shall be informed.	The opinion of the Agency shall be made publicly available and the competent authorities of the Member States ***and the marketing authorisation holder*** shall be informed.

Proposal for a regulation
Article 48 – paragraph 2

Text proposed by the Commission	*Amendment*
2. In cases where the opinion is favourable, marketing authorisation holders of the medicinal products concerned shall submit	2. In cases where the opinion is favourable, marketing authorisation holders of the medicinal products concerned shall submit

a variation to update the product information with the new therapeutic indication.	a variation to update the product information with the new therapeutic indication.

Proposal for a regulation
Article 48 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Article 81(2), point (c) of [revised Directive 2001/83/EC] shall not apply for variations under this Article.	***deleted***

COMPROMISE AMENDMENT 23 - RESPONSIBILITY OF SUPERVISORY AUTHORITIES (ARTICLES 51-55)
replacing amendments 976-978

supported by
EPP, S&D, RE, Greens/EFA, Left

Proposal for a regulation
Article 52 – paragraph 2 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) to lend its assistance by participating in a joint inspection with the supervisory authority of the site. In that case the supervisory authority leads the inspection and the follow up thereof. After completion of the inspection, the supervisory authority grants the relevant good manufacturing practice (GMP) certificate and enters the certificate in the Union database; or	(a) to lend its assistance by participating in a joint inspection with the supervisory authority of the site ***to assess the respect of the good manufacturing practice (GMP) as well as any practices relating to the environmental and worker safety***. In that case the supervisory authority leads the inspection and the follow up thereof. After completion of the inspection, the supervisory authority grants the relevant good manufacturing practice (GMP) certificate and enters the certificate in the Union database; or

Proposal for a regulation
Article 53 – paragraph 2

Text proposed by the Commission	*Amendment*
2. In cooperation with the Agency, the Commission ***may*** adopt detailed guidelines laying down the principles applicable to those international inspection programmes.	2. In cooperation with the Agency, the Commission ***shall*** adopt detailed guidelines laying down the principles applicable to those international inspection programmes. ***The guidelines shall include rules on impartially, independence and conflict of interest of inspectors.***

COMPROMISE AMENDMENT 24 - ACTION ON CONDITIONAL MAS (ARTICLE 56)
replacing amendments 979-982

supported by
EPP, S&D, RE, Greens/EFA, Left

Proposal for a regulation
Article 56 – paragraph 1

Text proposed by the Commission	*Amendment*
Where the Agency concludes that a holder of a marketing authorisation granted in accordance with Article 19, including a new therapeutic indication granted referred to Article 19, failed to comply with the obligations laid down in the marketing authorisation, the Agency shall inform the Commission accordingly.	Where the Agency concludes that a holder of a marketing authorisationgranted in accordance with Article 19, including a new therapeutic indication granted referred to Article 19, failed to comply with the obligations laid down in the marketing authorisation, the Agency shall inform the Commission accordingly.

Proposal for a regulation
Article 56 – paragraph 2a (new)

Text proposed by the Commission	*Amendment*
	2a. Where the marketing authorisation holder fails to comply with the obligation in the post-authorisation studies laid down in Article 20 the Commission may adopt a decision to vary, suspend, or revoke that marketing authorisation in accordance with the procedure laid down in Article 13.

COMPROMISE AMENDMENT 25 - SCIENTIFIC ADVICE (ARTICLE 58) AND PARALLEL SCIENTIFIC ADVICE (ARTICLE 59)
replacing amendments 105; 106; 983-1003

supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Article 58

Proposal for a regulation
Article 58 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
Such advice can also be requested for medicinal products referred to in Articles 83 and 84 of [revised Directive 2001/83/EC].	Such advice can also be requested for medicinal products referred to in Articles 83 and 84 of [revised Directive 2001/83/EC].

Proposal for a regulation
Article 58 – paragraph 2

Text proposed by the Commission	*Amendment*
2. In the preparation of the scientific advice referred to in paragraph 1 and upon request by undertakings or, as relevant, not-for-profit entities that requested the scientific advice, the Agency may consult experts of the Member States with clinical trial or medical device expertise or the expert panels designated in accordance with Article 106(1) of Regulation (EU) 2017/745.	2. In the preparation of the scientific advice referred to in paragraph 1 and upon request by undertakings or, as relevant, not-for-profit entities that requested the scientific advice, the Agency may consult experts of the Member States with clinical trial or medical device expertise or the expert panels designated in accordance with Article 106(1) of Regulation (EU) 2017/745.

Proposal for a regulation
Article 58 – paragraph 3

Text proposed by the Commission	*Amendment*
3. In the preparation of the scientific advice referred to in paragraph 1 ***and in duly justified cases,*** the Agency may consult authorities established in other Union legal acts as relevant for the provision of the scientific advice in question ***or*** other public bodies established in the Union, ***as applicable***.	3. In the preparation of the scientific advice referred to in paragraph 1 the Agency may consult authorities established in other Union legal acts as relevant for the provision of the scientific advice in question, other public bodies established in the Union, ***in particular those listed in Article 162 of this Regulation or other bodies, as applicable or in duly justified cases public bodies established in third countries***

Proposal for a regulation
Article 58 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Agency shall include in the European public assessment report the key areas of the scientific advice once the corresponding marketing authorisation decision has been taken in relation to the medicinal product, after deletion of any information of a commercially confidential nature.	4. The Agency shall include in the European public assessment report the key areas of the scientific advice ***as well as a detailed log of the pre-submission activities of the medicinal product, including the names of the experts involved,*** once the corresponding marketing authorisation decision has been taken in relation to the medicinal product, after deletion of any information of a commercially confidential nature. ***This report shall be made publicly available.***

Proposal for a regulation
Article 58 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The Agency shall, to the greatest extent possible, ensure that there is a separation between those responsible for providing scientific advice to a given medicinal product developer and those subsequently responsible for the evaluation of the marketing authorisation application for the same medicinal product.
	The Agency shall ensure that at least one of the two rapporteurs for a marketing authorisation application has not taken part in any pre-submission activities concerning the medicinal product. The reasons for any exceptions shall be documented and published with the European Public Assessment Report and recorded in the summary minutes of the meetings in accordance with Article 147(2).

Article 59

Proposal for a regulation
Article 59 – paragraph 2

Text proposed by the Commission	*Amendment*
2. In case of medicinal products involving a medical device, undertakings or, as relevant, not-for-profit entities may request scientific advice as referred to in Article 58(1) in parallel with the consultation of the expert panels referred to in Article 61(2) of	2. In case of medicinal products involving a medical device, undertakings or, as relevant, not-for-profit entities may request scientific advice as referred to in Article 58(1) in parallel with the consultation of the expert panels referred to in Article 61(2) of

Regulation (EU) 2017/745.

Regulation (EU) 2017/745.

COMPROMISE AMENDMENT 26 - PRIME (ARTICLE 60)
replacing amendments 107-109; 1004-1039

supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a regulation

Article 60 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The Agency may offer enhanced scientific and regulatory support, including as applicable consultation with other bodies as referred to in Articles 58 and 59 and accelerated assessment mechanisms, for certain medicinal products that, based on preliminary evidence submitted by the developer fulfil the following conditions:	1. The Agency may offer enhanced scientific and regulatory support, including as applicable consultation with other bodies as referred to in Articles 58 and 59 and accelerated assessment mechanisms, for certain medicinal products that, based on preliminary evidence submitted by the developer fulfil ***at least one*** of the following conditions:

Article 60 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) are orphan medicinal products and are likely to address a high unmet medical need as referred to in Article 70(1);	(b) are orphan medicinal products and are likely to address a high unmet medical need as referred to in Article 70(1);

Proposal for a regulation

Article 60 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) are expected to be of major interest from the point of view of public health, in particular as regards therapeutic innovation, taking into account the early stage of development, or antimicrobials with any of the characteristics mentioned in Article 40(3).	c) are expected to be of major interest from the point of view of public health, in particular as regards therapeutic innovation, taking into account the early stage of development, or antimicrobials with any of the characteristics mentioned in Article 40(3) ***or provided for in the 'WHO priority pathogens list for R&D of new antibiotics', specifically those listed as priority 1 (critical) or priority 2 (high), or***

	taking into account as a priority any equivalent list of priority pathogens adopted at Union level.

Proposal for a regulation
Article 60 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency may stop the enhanced support if it is established that the medicinal product will not address the identified unmet medical need to the anticipated extent.	3. The Agency may stop the enhanced support if it is established that the medicinal product will not address the identified unmet medical need to the anticipated extent.

Proposal for a regulation
Article 60 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The compliance of a medicinal product with the criteria set out in Article 83 of [revised Directive 2001/83/EC] shall be assessed on the basis of the relevant criteria, independently of whether it has received priority medicinal product support under this Article.	4. The compliance of a medicinal product with the criteria set out in Article 83 of [revised Directive 2001/83/EC]***/*** shall be assessed on the basis of the relevant criteria, independently of whether it has received priority medicinal product support under this Article.

Proposal for a regulation
Article 60 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. Where a priority medicinal product benefits from enhanced scientific and regulatory support from the Agency, the European public assessment report shall include a specific section on the Agency's pre-submission activities, and information on the key areas of the scientific advice and regulatory support provided and on the follow-up by the requester, including corresponding information and data which show that the conditions for the PRIME scheme have been fulfilled.

COMPROMISE AMENDMENT 27 - SCIENTIFIC RECOMMENDATION AND DECISION ON REGULATORY STATUS (ARTICLES 61 AND 62)
replacing amendments 1040-1050

supported by
EPP, S&D, RE, Greens/EFA, Left

Article 61

Proposal for a regulation

Article 61 - paragraph 1 - subparagraph 1

Text proposed by the Commission	*Amendment*
For products under development which may fall within the categories of medicinal products to be authorised by the Union listed in Annex I, a developer or a competent authority of the Member States may submit a duly substantiated request to the Agency for a scientific recommendation with a view to determining on scientific grounds whether the concerned product is potentially a 'medicinal product', including an 'advanced therapy medicinal product' as defined in Article 2 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council[71].	For products under development which may fall within the categories of medicinal products to be authorised by the Union listed in Annex I, a developer or a competent authority of the Member States may submit a duly substantiated request to the Agency for a scientific recommendation with a view to determining on scientific grounds whether the concerned product is potentially a 'medicinal product', including an 'advanced therapy medicinal product' as defined in Article 2 of Regulation (EC) No 1394/2007 of the European Parliament and of the Council[71]. ***The Agency may rely on the relevant expertise of working parties and pools of experts when making its recommendation.***
[71] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).	[71] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).

Proposal for a regulation
Article 61 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
When forming the recommendation referred to in paragraph 1, the Agency shall consult, where appropriate, relevant advisory or regulatory bodies established in other Union legal acts in related fields. In the case of products which are based on substances of	When forming the recommendation referred to in paragraph 1, the Agency shall consult, where appropriate ***and where there is a doubt of the regulatory status of a product under development*** , relevant advisory or regulatory bodies established in other Union legal acts in

human origin, the Agency shall consult the Substances of Human Origin (SoHO) Coordination Board as established in Regulation (EU) No [reference to be added after adoption cf. COM(2022)338 final].

related fields. In the case of products which are based on substances of human origin, the Agency shall ***first consult the compendium referred to in Regulation (EU) No [reference to be added after adoption cf. COM(2022)338 final] and where necessary, conduct joint meetings with*** the Substances of Human Origin (SoHO) Coordination Board as established in Regulation (EU) No [reference to be added after adoption cf. COM(2022)338 final].

Proposal for a regulation
Article 61 – paragraph 2 – subparagraph 3

Text proposed by the Commission	*Amendment*
The Agency shall publish ***summaries of*** the recommendations delivered in accordance with paragraph 1, after deletion of all information of a commercially confidential nature.	The Agency shall publish the recommendations delivered in accordance with paragraph 1, after deletion of all information of a commercially confidential nature.
	For transparency purposes, the respective opinions and conclusions of the Agency and the relevant advisory bodies on the regulatory status of the product shall be made publicly available after the consultations, and where applicable, joint meetings, have taken place.

Article 62

Proposal for a regulation
Article 62 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
In the case of duly substantiated disagreement with the Agency's recommendation, in accordance with Article 61(2), a Member State may request the Commission to decide whether the product is a product referred to in Article 61(1).	In the case of duly substantiated disagreement with the Agency's ***scientific*** recommendation, in accordance with Article 61(2), a Member State may request the Commission to decide whether the product is a product referred to in Article 61(1).

Proposal for a regulation
Article 62 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission may ask the Agency for clarifications or refer the recommendation	2. The Commission may ask the Agency ***and the relevant advisory or regulatory bodies***

back to the Agency for further consideration where a Member State's substantiated request raises new questions of a scientific or technical nature or on its own initiative.	***involved in the delivery of the scientific recommendation*** for clarifications or refer the recommendation back to the Agency for further consideration where a Member State's substantiated request raises new questions of a scientific or technical nature or on its own initiative.

Proposal for a regulation
Article 62 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The decision of the Commission referred to in paragraph 1 shall be adopted by means of implementing acts, in accordance with the examination procedure referred to in Article 173(2), taking into account the scientific recommendation of the Agency.	3. The decision of the Commission referred to in paragraph 1 shall be adopted by means of implementing acts, in accordance with the examination procedure referred to in Article 173(2), taking into account the scientific recommendation of the Agency ***and other advisory bodies***.

COMPROMISE AMENDMENT 28 - CHAPTER VIII PHARMACOVIGILANCE (ARTICLE 101, ARTICLE 103)
replacing amendments: AM 1367-1376

supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a regulation
Article 101 – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
The Eudravigilance database shall contain information on suspected adverse reactions in human beings arising from use of the medicinal product within the terms of the marketing authorisation as well as from uses outside the terms of the marketing authorisation, and on those occurring in the course of post-authorisation studies with the medicinal product or associated with occupational exposure.	The Eudravigilance database shall contain information on suspected adverse reactions in human beings arising from use of the medicinal product within the terms of the marketing authorisation as well as from uses outside the terms of the marketing authorisation, ***including errors of medication,*** and on those occurring in the course of post-authorisation studies with the medicinal product or associated with occupational exposure.

Proposal for a regulation
Article 101 – paragraph 2 – subparagraph 5

Text proposed by the Commission	*Amendment*
The Agency shall ensure that healthcare professionals and the public have appropriate levels of access to the Eudravigilance database, and that personal data is protected. The Agency shall work together with all stakeholders, including research institutions, healthcare professionals, and patient and consumer organisations, in order to define the 'appropriate level of access' for healthcare professionals and the public to the Eudravigilance database.	The Agency shall ensure that healthcare professionals and the public have appropriate levels of access to the Eudravigilance database, and that personal data is protected ***in line with the EU data protection and privacy legislation***. The Agency shall work together with all stakeholders, including research institutions, healthcare professionals, and patient and consumer organisations, in order to define the 'appropriate level of access' for healthcare professionals and the public to the Eudravigilance database.

Proposal for a regulation
Article 101 – paragraph 2 – subparagraph 6

Text proposed by the Commission	*Amendment*
The data held on the Eudravigilance database shall be made publicly available in an	The data held on the Eudravigilance database shall be made publicly available in an

aggregated format together with an explanation of how to interpret the data.	aggregated ***and anonymised*** format together with an explanation of how to interpret the data.

Proposal for a regulation
Article 103 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	The periodic safety update reports shall, in addition, be made publicly available in the web-portal referred to in Article 135(1)(n).

COMPROMISE AMENDMENT 29 - CHAPTER VIII PHARMACOVIGILANCE (ARTICLE 104, ARTICLE 105, ARTICLE 109, ARTICLE 111, ARTICLE 112)
replacing amendments: AM 129-133, 1377-1395

supported by
EPP, S&D, Greens/EFA, ECR, Left

Proposal for a regulation
Article 104 – paragraph 1 – subparagraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a European medicines web-portal for the dissemination of information on medicinal products authorised or to be authorised in the Union. By means of that portal, the Agency shall make public the following:	The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a European medicines web-portal for the dissemination of information on medicinal products authorised or to be authorised in the Union. By means of that portal, the Agency shall make public the following***. The dedicated web-portal shall be set up in accordance with Directive (EU) 2016/2102 of the European Parliament and of the Council[1a]***: _____ ***[1a] Directive (EU) 2016/2102 of the European Parliament and of the Council of 26 October 2016 on the accessibility of the websites and mobile applications of public sector bodies (OJ L 327, 2.12.2016, p. 1).***

Proposal for a regulation
Article 104 – paragraph 1 – subparagraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) ***a summary of*** the risk management plans for medicinal products authorised in accordance with this Regulation;	(c) the risk management plans for medicinal products authorised in accordance with this Regulation ***and the accompanying summaries of the risk management plans***;

Proposal for a regulation
Article 104 – paragraph 1 – subparagraph 1 – point h

Text proposed by the Commission	*Amendment*
(h) the initiation of the procedure provided for in Article 41(2), and Articles 114, 115 and 116 of [revised Directive 2001/83/EC], the active substances or medicinal products concerned and the issue being addressed, any public hearings pursuant to that procedure and information on how to submit information and to participate in public hearings;	(h) the initiation of the procedure provided for in **[**Article 41(2)**] in this Regulation**, and Articles 114, 115 and 116 of [revised Directive 2001/83/EC], the active substances or medicinal products concerned and the issue being addressed, any public hearings pursuant to that procedure and information on how to submit information and to participate in public hearings;

Proposal for a regulation
Article 104 – paragraph 1 – subparagraph 1 – point i

Text proposed by the Commission	*Amendment*
(i) conclusions of assessments, recommendations, opinions, approvals and decisions taken by the Agency and its Committees under this Regulation and [revised Directive 2001/83/EC]***, unless it is required that this information is made public by the Agency by other means;***	(i) conclusions of assessments***,*** ***obligations for post-marketing studies***, recommendations, opinions, approvals and decisions taken by the Agency and its Committees under this Regulation and [revised Directive 2001/83/EC]**.**

Proposal for a regulation
Article 104 – paragraph 1 – subparagraph 1 – point j

Text proposed by the Commission	*Amendment*
(j) conclusions of assessments, recommendations, opinions, approvals and decisions taken by the coordination group, the competent authorities of the Member States and the Commission in the framework of the procedures set out in Articles 16, 106, 107 and 108 of this Regulation and of Chapter IX, Sections 3 and 7 of [revised Directive	(j) conclusions of assessments, recommendations, opinions, approvals***,*** ***obligations deriving from the conditional marketing authorisations*** and decisions taken by the coordination group, the competent authorities of the Member States and the Commission in the framework of the procedures set out in Articles 16, 106, 107 and

2001/83/EC].	108 of this Regulation and of Chapter IX, Sections 3 and 7 of [revised Directive 2001/83/EC].

Proposal for a regulation
Article 104 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
The ***summaries*** referred to in point (c) shall include a description of any additional risk minimisation measures.	The ***risk management plans*** referred to in point (c) shall include a description of any additional risk minimisation measures ***and distribution/implementation plans***.

Proposal for a regulation
Article 104 – paragraph 2

Text proposed by the Commission	*Amendment*
2. In the development and review of the web portal, the Agency shall consult relevant stakeholders, including patient and consumer groups, healthcare professionals and industry representatives.	2. In the development and review of the web portal, the Agency shall consult relevant stakeholders, including patient and consumer groups, healthcare professionals***, not-for-profit entities*** and industry representatives.

Proposal for a regulation
Article 104 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a register of environmental risk assessment studies conducted for the purpose of supporting an environmental risk assessment for medicinal products authorised in the Union***, unless such information is made public in the Union by different means***.	The Agency shall, in collaboration with the Member States and the Commission, set up and maintain a register of environmental risk assessment studies conducted for the purpose of supporting an environmental risk assessment for medicinal products authorised in the Union.

Proposal for a regulation
Article 104 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
Information in such register shall be publicly available, unless restrictions are necessary to protect commercially confidential information. For the purpose of setting up such register, the Agency may request marketing authorisation	Information in such register shall be publicly available ***and easily accessible on the Agency's website***, ***and includes as a minimum the information reported in Annex II - Section 1.6 of [revised Directive 2001/83/EC]***

holders and competent authorities to submit results of any such study already completed for products authorised in the Union within [OP please add the date = 24 months after the date of application of this Regulation].	unless restrictions are necessary to protect commercially confidential information. For the purpose of setting up such register, the Agency ***shall, where not already received,*** request marketing authorisation holders and competent authorities to submit results of any such study already completed for products authorised in the Union within [OP please add the date = 24 months after the date of application of this Regulation].

Proposal for a regulation
Article 105 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall, in consultation with the Commission, Member States and ***interested*** parties, draw up a detailed guide regarding the monitoring of medical literature and the entry of relevant information into the Eudravigilance database.	3. The Agency shall, in consultation with the Commission, Member States and ***their relevant authorities, as well as other relevant*** parties***, including experts from academia***, draw up a detailed guide regarding the monitoring of medical literature and the entry of relevant information into the Eudravigilance database.

Proposal for a regulation
Article 109 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Agency and the European ***Monitoring Centre for*** Drugs ***and Drug Addiction*** shall exchange information that they receive on the abuse of medicinal products including information related to illicit drugs.	2. The Agency and the European Drugs ***Agency*** shall exchange information that they receive on the abuse of medicinal products including information related to illicit drugs.

Proposal for a regulation
Article 111 – paragraph 1

Text proposed by the Commission	*Amendment*
The Agency and the Member States shall cooperate to continuously develop	The Agency and the Member States shall cooperate to continuously develop

pharmacovigilance systems capable of achieving high standards of public health protection for all medicinal products, regardless of the routes of marketing authorisation, including the use of collaborative approaches, to maximise use of resources available within the Union.	pharmacovigilance systems***, including those that record adverse events including medication errors, processes and standards for medication safety,*** capable of achieving high standards of public health protection for all medicinal products, regardless of the routes of marketing authorisation, including the use of collaborative approaches, to maximise use of resources available within the Union.

Article 112 - COM text is compromise

COMPROMISE AMENDMENT 31 - CHAPTER X AVAILABILITY AND SECURITY OF SUPPLY OF MEDICINAL PRODUCTS
(ARTICLES 116 AND 117)
replacing amendments: AM 137-140, 1463-1508, ITRE 88-90

supported by
EPP, S&D, RE, Greens/EFA, Left

Proposal for a regulation
Article 116 – para 1 - introductory part

Text proposed by the Commission	*Amendment*
1. The marketing authorisation holder of a medicinal product in possession of a centralised marketing authorisation or a national marketing authorisation ('the marketing authorisation holder') shall notify the competent authority of the Member State where the medicinal product has been placed on the market and, in addition, the Agency for a medicinal product covered by a centralised marketing authorisation (these are referred to in this Chapter as 'the competent authority concerned') of the following:	1. The marketing authorisation holder of a medicinal product in possession of a centralised marketing authorisation or a national marketing authorisation ('the marketing authorisation holder') shall notify ***and explain the reasons to*** the competent authority of the Member State where the medicinal product has been placed on the market and, in addition, the Agency for a medicinal product covered by a centralised marketing authorisation (these are referred to in this Chapter as 'the competent authority concerned') of the following:

Proposal for a regulation
Article 116 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) its decision to temporarily suspend the marketing of a medicinal product in that Member State no less than six months before the start of the temporary suspension of supply of that medicinal product into the market of a given Member State by the marketing authorisation holder;	(c) its decision to temporarily suspend the marketing of a medicinal product in that Member State ***as soon as possible and*** no less than six months the start of the temporary suspension of supply of that medicinal product into the market of a given Member State by the marketing authorisation holder;

Proposal for a regulation
Article 116 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) a temporary disruption in supply of a medicinal product in a given Member State, of an expected duration of in excess of two weeks or, based on the demand forecast of the marketing authorisation holder no less than six months before the start of such temporary disruption of supply or, if this is not possible and where duly justified, as soon as they become aware of such temporary disruption, to allow the Member State to monitor any potential or actual shortage in accordance with Article 118(1).	(d) a ***foreseeable*** temporary disruption in supply of a medicinal product in a given Member State, of an expected duration of in excess of two weeks or, based on the demand forecast of the marketing authorisation holder ***and national competent authorities, where available, as soon as possible*** no less than six months before the start of such temporary disruption of supply or, if this is not possible and ***unforeseeable*** where duly justified, as soon as they become aware of such temporary disruption, to allow the Member State to monitor any potential or actual shortage in accordance with Article 118(1).

Proposal for a regulation
Article 117 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The marketing authorisation holder as defined in Article 116(1) shall have in place and keep up to date a shortage prevention plan, for any medicinal product placed on the market. To put in place the shortage prevention plan, the marketing authorisation holder shall include the minimum set of information set out in Part V of Annex IV and take into account the guidance drawn up by the Agency according to paragraph 2.	1. ***By ... [18 months after the date of entry into force of this Regulation],*** the marketing authorisation holder as defined in Article 116(1) shall have in place and keep up to date a shortage prevention plan, for any medicinal product placed on the market. To put in place the shortage prevention plan, the marketing authorisation holder shall include the minimum set of information set out in Part V of Annex IV and take into account the guidance drawn up by the Agency according to paragraph 2. ***The shortage prevention plan shall be made available upon request by the Agency or the competent national authority of the Member State where the medicinal product has been placed on the market***.

Proposal for a regulation
Article 117 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Agency, in collaboration with the working party referred to in Article 121(1)***, point (c), shall*** draw up guidance to marketing authorisation holders as defined in Article 116(1) to put in place the shortage prevention plan.	2. The Agency ***shall***, in collaboration with the working party referred to in Article 121(1) ***and after consultation with the Healthcare Professionals' Working Party (HPWP) and the Patients' and Consumers' Working Party (PCWP),*** draw up guidance to marketing authorisation holders as defined in Article 116(1) to put in place the shortage prevention plan.

COMPROMISE AMENDMENT 32 - CHAPTER X AVAILABILITY AND SECURITY OF SUPPLY OF MEDICINAL PRODUCTS
(ARTICLES 118, 119, 120)
replacing amendments: AM 141-144, 1509-1534, ITRE 91-93

supported by
EPP, S&D, RE, Greens/EFA, Left

Proposal for a regulation
Article 118 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Based on the reports referred to in Articles 120(1) and 121(1), point (c), information referred to in Articles 119, 120(2) and 121 and the notification made pursuant to Article 116(1), points (a) to (d), the competent authority concerned as referred to in Article 116(1) shall continuously monitor any potential or actual shortage of those medicinal products.	Based on the reports referred to in Articles 120(1) and 121(1), point (c), information referred to in Articles 119, 120(2) and 121 ***of this Regulation*** and the notification made pursuant to Article 116(1), points (a) to (d), ***of this Regulation,*** the competent authority concerned as referred to in Article 116(1) ***of this Regulation*** shall continuously monitor any potential or actual shortage of those medicinal products ***through their national IT surveillance systems or data bases and send the information to the Agency without undue delay***.

Proposal for a regulation
Article 118 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. On the basis of the information provided pursuant to article 121(2), point (f), the Agency should monitor and assess any actions foreseen or taken by a Member State to mitigate a shortage at national level with regards to their impact on the availability and supply of medicinal products at European level.

Proposal for a regulation
Article 118 – paragraph 2

Text proposed by the Commission	*Amendment*
2. For the purposes of paragraph 1, the competent authority concerned as defined in Article 116(1) may request any additional information from the marketing authorisation holder as defined in Article 116(1). In particular, it may request the marketing authorisation holder to submit a shortage mitigation plan in accordance with Article 119(2), a risk assessment of impact of suspension, cessation or withdrawal in accordance with Article 119(3), or the shortage prevention plan referred to in Article 117. The competent authority concerned ***may*** set a deadline for the submission of the information requested.	2. For the purposes of paragraph 1, the competent authority concerned as defined in Article 116(1) may request any additional information from the marketing authorisation holder as defined in Article 116(1). In particular, it may request the marketing authorisation holder to submit a shortage mitigation plan in accordance with Article 119(2), a risk assessment of impact of suspension, cessation or withdrawal in accordance with Article 119(3), or the shortage prevention plan referred to in Article 117***]***. The competent authority concerned ***shall*** set a deadline for the submission of the information requested.

Proposal for a regulation
Article 120 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Wholesale distributors and other persons or legal entities that are authorised or entitled to supply medicinal products authorised to be placed on the market of a Member State pursuant to Article 5 of [revised Directive 2001/83/EC] to the public ***may*** report a shortage of a given medicinal product marketed in the Member State concerned to the competent authority in that Member State.	1. Wholesale distributors and other persons or legal entities that are authorised or entitled to supply medicinal products authorised to be placed on the market of a Member State pursuant to Article 5 of [revised Directive 2001/83/EC] to the public ***shall*** report a shortage of a given medicinal product marketed in the Member State concerned to the competent authority in that Member State. ***In addition, wholesale distributors shall submit regular information on the available stocks of the medicines they supply to the competent***

authority.

Proposal for a regulation
Article 120 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. When a marketing authorisation holder notifies a temporary disruption in supply of a medicinal product, wholesale distributors as well as other persons or legal entities that are authorised or entitled to supply medicinal products shall provide information requested in a timely manner to the Agency, the competent authority in a Member State, and the relevant marketing authorisation holder for the reasons of the temporary disruption in supply of the product in a Member State.

Proposal for a regulation
Article 120 – paragraph 2

Text proposed by the Commission	*Amendment*
2. For the purposes of Article 118(1), where relevant, upon request from the competent authority concerned as defined in Article 116(1), entities including other marketing authorisation holders as defined in Article 116(1), importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public shall provide any information requested in a timely manner.	2. For the purposes of Article 118(1), where relevant, upon request from the competent authority concerned as defined in Article 116(1), entities including other marketing authorisation holders as defined in Article 116(1), importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public shall provide any information requested in a timely manner.

COMPROMISE AMENDMENT 33 - CHAPTER X AVAILABILITY AND SECURITY OF SUPPLY OF MEDICINAL PRODUCTS (ARTICLE 121)
replacing amendments: AM 145-147, 1535-1564, ITRE 94-98

supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a regulation

Article 121 – paragraph 1 – point -a (new)

Text proposed by the Commission	*Amendment*
	(-a) collect and assess the information on potential and actual shortages provided by marketing authorisation holders, importers, manufacturers and suppliers of medicinal products or active substances, wholesale distributors, healthcare professionals, patients and consumers and other persons or legal entities that are authorised or entitled to supply medicinal products to the public;

Proposal for a regulation
Article 121 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) publish information on actual shortages of medicinal products, ***in cases in which*** that competent authority has assessed the shortage, on a publicly available website;	(b) publish information ***and regularly update*** on actual shortages of medicinal products, that competent authority has assessed the shortage on a publicly available ***and user-friendly*** website ***and ensure such information, including regarding available alternatives, has been proactively communicated to representatives of healthcare professionals and patients***; ***competent authorities shall as soon as possible inform the Agency of any measure foreseen or taken at national level to mitigate the shortage or expected shortage.***

Proposal for a regulation
Article 121 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(b a) create a system allowing patients to report shortages of medicinal products and request from pharmacies supplying hospitals and hospital pharmacies, to electronically communicate data on available stock of the respective medicinal product, in order to avert or mitigate an imminent or existing supply shortage relevant to the supply of a medicinal product.

Proposal for a regulation
Article 121 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(c a) address recommendations to health professionals on the alternative medicinal products to use to pursue treatments in the event of shortages;

Proposal for a regulation
Article 121 – paragraph 1 – point c e (new)

Text proposed by the Commission	*Amendment*
	(c b) consider the use of appropriate regulatory measures to mitigate the shortage.

Proposal for a regulation
Article 121 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. After the expansion of the ESMP referred to in article 122 (6) and for the purpose of articles 118 (1), and 121 (2), point (a), competent authorities of the Member States shall set up national IT systems which are interoperable with the ESMP and allow for the automated exchange of information with the ESMP while avoiding duplication of reporting.

Proposal for a regulation
Article 121 – paragraph 2 – point f

Text proposed by the Commission	*Amendment*
(f) inform the Agency of any actions foreseen or taken by that Member State to mitigate the shortage at national level.	(f) inform the Agency of any actions foreseen or taken by that Member State to mitigate the shortage at national level ***without undue delay***.

Proposal for a regulation
Article 121 – paragraph 5 – point a

Text proposed by the Commission	*Amendment*
(a) report to the Agency on any information received from the marketing authorisation holder as defined in Article 116(1) of the medicinal product concerned or from other actors pursuant to Article ***120(2)***;	(a) report to the Agency on any information received from the marketing authorisation holder as defined in Article 116(1) of the medicinal product concerned or from other actors pursuant to Article ***120(1b) and (2)***;

Proposal for a regulation

Article 121 – paragraph 5 – point d

Text proposed by the Commission	*Amendment*
(d) inform the Agency of any actions foreseen or taken by that Member State in accordance with points (b) and (c) and report on any other actions taken to mitigate or resolve the critical shortage in the Member State, as well as the results of these actions.	(d) inform the Agency of any actions foreseen or taken by that Member State in accordance with points (b) and (c) and report on any other actions taken to mitigate or resolve the critical shortage in the Member State, as well as the results of these actions, ***without undue delay***.

Proposal for a regulation
Article 121 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Member States may request that the MSSG provide further recommendations, referred to in Article 123(4).	6. The Member States may request that the MSSG provide further recommendations, referred to in Article 123(4). ***Where Member States that take an alternative course of action not in line with the recommendations of the MSSG at national level, they shall share the reasons for doing so with the MSSG in a timely manner.***

COMPROMISE AMENDMENT 34 - CHAPTER X AVAILABILITY AND SECURITY OF SUPPLY OF MEDICINAL PRODUCTS - NATIONAL WEBSITES (ARTICLE 121A (NEW))
replacing amendments: 1565 -1566

supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a regulation
Article 121 a (new)

Text proposed by the Commission	*Amendment*
	Article 121a
	National websites on medicines shortages
	The website referred to in article 121 paragraph 1(b) shall include at least the following information:
	(a) trade name of the medicinal product and international non-proprietary name, for interoperability purposes;
	(b) the therapeutic indication for the medicinal product in shortage;
	(c) reasons of the shortages and mitigation measures taken to address the shortage;

(d) the start and expected end dates of the shortage;

(e) other relevant information for healthcare professionals and patients, including information about therapeutic alternatives available.

COMPROMISE AMENDMENT 35 - CHAPTER X AVAILABILITY AND SECURITY OF SUPPLY OF MEDICINAL PRODUCTS
(ARTICLE 122, ARTICLE 123)
replacing amendments: AM 148, 149, 1567-1606, ITRE 99-102

supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a regulation
Article 122 – paragraph 1

Text proposed by the Commission	*Amendment*
1. For the purposes of Article 118(1), the Agency may request additional information from the competent authority of the Member State, through the working party referred to in Article 121(1), point (c). The Agency ***may*** set a deadline for the submission of the information requested.	1. For the purposes of Article 118(1) ***and 118(1a)(new)***, the Agency may request additional information from the competent authority of the Member State, through the working party referred to in Article 121(1), point (c). The Agency ***may*** set a deadline for the submission of the information requested.

Proposal for a regulation
Article 122 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. For the purpose of Article 118 (1a) (new) and based on the information provided pursuant to articles 121 (1), point (d), and 121 (2), the Agency shall assess the actions taken or foreseen by a Member State to mitigate a shortage at national level with regards to any potential or actual negative impacts of these actions on the availability and security of supply in another Member State and at European level.
	The Agency shall inform the Member State in question of its assessment in a timely manner and the MSSG and the Member States potentially or actually impacted through the single point of contact working party referred to in Article 3(6) of Regulation (EU) 2022/123. The Agency shall also inform the Commission of its assessment.

Proposal for a regulation
Article 122 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. For the purpose of identifying the medicinal products for which the shortage cannot be resolved without EU coordination pursuant to paragraph 2, the Agency may consult market authorisation holders and other relevant stakeholders.

Proposal for a regulation
Article 122 – paragraph 4 – introductory part

Text proposed by the Commission	*Amendment*
4. For the purposes of fulfilling the tasks referred to in Articles 118(1), 123 and 124, the Agency shall ensure the following, in consultation with the working party referred to in Article 121(1), point (c):	4. For the purposes of fulfilling the tasks referred to in Articles 118(1), 123 and 124, the Agency shall ensure the following, in consultation with the working party referred to in Article 121(1), point (c) ***and in consultation with the Patients Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP) and other relevant stakeholders.***

Proposal for a regulation
Article 122 – paragraph 6

Text proposed by the Commission	*Amendment*
6. For the purposes of implementing this Regulation, the Agency shall expand the scope of the ESMP. The Agency shall ensure that***,*** ***where relevant,*** data is interoperable between the ESMP, Member States' IT systems and other relevant IT systems and databases, without duplication of reporting.	6. For the purposes of implementing this Regulation, the Agency shall expand the scope of the ESMP. The Agency shall ensure that data and is interoperable between the ESMP, Member States' IT systems and ***where relevant, with*** other relevant IT systems and databases, without duplication of reporting.

Proposal for a regulation
Article 123 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The MSSG shall review the status of the critical shortage whenever necessary and shall update the list when it considers that a medicinal product needs to be added or that the critical shortage has been resolved based on the report pursuant to Article 122(5).	2. The MSSG shall review the status of the critical shortage whenever necessary and shall update the list when it considers that a medicinal product needs to be added or that the critical shortage has been resolved based on the report pursuant to Article 122(5). ***The MSSG may recommend monitoring forecasts of supply and demand for medicinal products for human use in the Union and monitoring of available stocks in the whole supply chain.***

Proposal for a regulation
Article 123 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The MSSG ***may*** provide recommendations on measures to resolve or to mitigate the critical shortage, in accordance with the methods referred to in Article 122(4), point (d), to relevant marketing authorisation holders, the Member States, the Commission, the representatives of healthcare professionals or other entities.	4. The MSSG ***shall, without undue delay***, provide recommendations on measures to resolve or to mitigate the critical shortage in accordance with the methods referred to in Article 122(4), point (d), to relevant marketing authorisation holders, the Member States, the Commission, the representatives of healthcare professionals or other entities.

Proposal for a regulation
Article 123 – paragraph 4 – subparagraph 1a (new)

Text proposed by the Commission	*Amendment*
	Member States, within the MSSG, may decide to activate the "Voluntary Solidarity Mechanism for medicines" to
	(a) notify a critical shortage of a medicinal product at national level to other Member States and the Commission,
	(b) identify, with the support of the Agency, the availabilities of the medicinal product in other Member States,
	(c) organise, with the support of the Agency, meetings with the issuing Member States, the donating part and other relevant parties to discuss operational requirements,
	(d) request the activation of the Union Civil Protection Mechanism to coordinate and logistically support the voluntary transfer of medicines.

COMPROMISE AMENDMENT 36 - CHAPTER X AVAILABILITY AND SECURITY OF SUPPLY OF MEDICINAL PRODUCTS
(ARTICLE 124, ARTICLE 125, ARTICLE 126)
replacing amendments: AM 150-154, 1607-1632, ITRE 103-104

supported by
EPP, S&D, RE, Greens/EFA, Left

Proposal for a regulation
Article 124 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
For the purposes of this paragraph, the Agency ***may*** set a deadline for the submission of the information requested.	For the purposes of this paragraph, the Agency ***shall*** set a deadline for the submission of the information requested.

Proposal for a regulation
Article 124 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall establish within its web-portal referred to in Article 104 a publicly available webpage that provides information on actual critical shortages of medicinal products ***in cases in which*** the Agency ***has assessed the shortage and has provided*** recommendations to healthcare professionals and patients. This webpage shall also provide references to the lists of actual shortages published by the competent authorities of the Member State pursuant to Article 121(1), point (b)**.**	3. The Agency shall establish within its web-portal referred to in Article 104 a publicly available ***and user-friendly*** webpage that provides information on ***all*** actual critical shortages of medicinal products***, including the reasons for the shortages. After assessing the shortages,*** the Agency ***shall provide*** recommendations to healthcare professionals and patients. ***The webpage shall include the information described in paragraph 3a of this Article in addition to the list of Member States affected by each shortage.*** This webpage shall also provide references to the lists of actual shortages published by the competent authorities of the Member State pursuant to Article 121(1), point (b), the ESMP and ***include, to the extent possible, information from other relevant sources and databases identified by the Agency and include reference to alternative treatment options or products and appropriate communication.***

Proposal for a regulation
Article 125 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) provide any additional information that the Agency may request;	(a) provide any additional information that the Agency may request***, including regular information on the available stocks of medicines***;

Proposal for a regulation
Article 125 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) take into account the recommendations referred to in Article 123(4);	(c) take into account the recommendations referred to in Article 123(4);

Proposal for a regulation
Article 125 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) inform the Agency of the end date of the critical shortage**.**	(f) inform the Agency of the end date of the critical shortage ***without undue delay;***

Proposal for a regulation
Article 126 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. The Commission shall take the appropriate steps to address any concerns raised by the assessment of the Agency referred to in Article 122 (1a) (new).

COMPROMISE AMENDMENT 37 - CHAPTER X AVAILABILITY AND SECURITY OF SUPPLY OF MEDICINAL PRODUCTS - SECURITY OF SUPPLY (ARTICLE 127, ARTICLE 128, ARTICLE 129)
replacing amendments: AM 155-157, 1633-1649, ITRE 105-106

supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a regulation
Article 127 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The competent authority of the Member State shall identify critical medicinal products in that Member State, using the methodology set out in Article 130(1), point	1. The competent authority of the Member State shall***, after consultation with healthcare professionals and patient organisations,*** identify critical medicinal

(a).

products in that Member State, using the methodology set out in Article 130(1), point (a).

Proposal for a regulation
Article 127 – paragraph 3

Text proposed by the Commission	*Amendment*
3. For the purposes of the identification of critical medicinal products referred to in paragraph 1, the competent authority of the Member State may request relevant information including the shortage prevention plan referred to in Article 117 from the marketing authorisation holder as defined in Article 116(1).	3. For the purposes of the identification of critical medicinal products referred to in paragraph 1, the competent authority of the Member State may request relevant information including the shortage prevention plan referred to in Article 117 from the marketing authorisation holder as defined in Article 116(1).

Proposal for a regulation
Article 128 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The marketing authorisation as defined in Article 116(1) ***authorisation*** shall be responsible for providing correct, not misleading, and complete information as requested by the competent authority concerned as defined in Article 116(1) and shall have the duty to cooperate and to disclose on their own motion any relevant information without undue delay to that competent authority and to update the information as soon as that information becomes available.	2. The marketing authorisation ***holder*** as defined in Article 116(1) shall be responsible for providing correct, not misleading, and complete information as requested by the competent authority concerned as defined in Article 116(1) and shall have the duty to cooperate and to disclose on their own motion any relevant information without undue delay to that competent authority and to update the information as soon as that information becomes available.

Proposal for a regulation
Article 129 – paragraph 1

Text proposed by the Commission	*Amendment*
For the purposes of Article 127(4) and Article 130(2), point (c), and Article 130(4), point (c), where relevant, upon request from the competent authority concerned as defined in Article 116(1), entities including other marketing authorisation holders as defined in Article 116(1), importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public shall provide	For the purposes of Article 127(4) and Article 130(2), point (c), and Article 130(4), point (c), where relevant, upon request from the competent authority concerned as defined in Article 116(1), entities including other marketing authorisation holders as defined in Article 116(1), importers and manufacturers of medicinal products or active substances and relevant suppliers of these, wholesale distributors, stakeholder representative associations or other persons or legal entities that are authorised or entitled to supply medicinal products to the public shall provide

any information ***requested in a timely manner***.	any information ***by the deadline set by the Agency and provide updates whenever necessary.***

COMPROMISE AMENDMENT 38 - CHAPTER X AVAILABILITY AND SECURITY OF SUPPLY OF MEDICINAL PRODUCTS
(ARTICLE 130, ARTICLE 131)
replacing amendments: AM 158 - 161, 1650 -1681

supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a regulation
Article 130 – paragraph 1 – subparagraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The Agency shall, in collaboration with the working party referred to in Article 121(1), point (c), ensure the following:	The Agency shall, in collaboration with the working party referred to in Article 121(1), point (c), ensure the following:

Proposal for a regulation
Article 130 – paragraph 1 – subparagraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) develop a common methodology to identify critical medicinal products, including the evaluation of vulnerabilities with respect to the supply chain of those medicines, in consultation***, where appropriate,*** with relevant stakeholders;	(a) develop a common methodology to identify critical medicinal products, including the evaluation of vulnerabilities ***and the availability of appropriate alternatives*** with respect to the supply chain of those medicines, in consultation with ***the Patients Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP), as well as other*** relevant stakeholders;

Article 130 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
The Agency shall publish the information referred to in points (b), (c) and (d) on a dedicated webpage on its web-portal.	The Agency shall publish the information referred to in points (b), (c) and (d) on a dedicated webpage on its web-portal.

Proposal for a regulation
Article 130 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the marketing authorisation holder of	(b) the marketing authorisation holder of

the medicinal product, including the shortage prevention plan, referred to in Article 117;	the medicinal product, including the shortage prevention ***and mitigation*** plan, referred to in Article 117 ***and 119(2)***;

Proposal for a regulation
Article 130 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Following the adoption of the Union list of critical medicinal products in accordance with Article 131, the Agency shall report to the MSSG on any relevant information received from the marketing authorisation holder pursuant to Article 133 and the competent authority of the Member State in accordance with Article 127, paragraphs 7 and 8.	5. Following the adoption of the Union list of critical medicinal products in accordance with Article 131, the Agency shall ***assess and*** report to the MSSG on any relevant information received from the marketing authorisation holder pursuant to Article 133 and the competent authority of the Member State in accordance with Article 127, paragraphs 7 and 8.

Proposal for a regulation
Article 130 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6 a. Following the request by a Member State to use the Voluntary Solidarity Mechanism referred to in Article 132(4a), the Agency shall provide assistance to the MSSG and may:
	(a) confirm that the conditions are met to launch the Voluntary Solidarity Mechanism;
	(b) notify the members of the MSSG of the launch of the Voluntary Solidarity Mechanism;
	(c) request from the members of the MSSG relevant information within a specific time-limit;
	(d) put the issuing country in contact with those Member States able to support them;
	(e) organise meetings with the issuing Member States, the donating party and other relevant concerned parties;
	(f) request the activation of the Union Civil Protection Mechanism to coordinate and logistically support the voluntary transfer of medicines.

Proposal for a regulation
Article 131 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Following the reporting referred to in Article 130, paragraph 2, second subparagraph, and Article 130(5), the MSSG shall consult the working party referred to in Article 121(1), point (c). Based on this consultation, the MSSG shall propose a Union list of critical medicinal products authorised to be placed on the market of a Member State pursuant to Article 5 of [revised Directive 2001/83/EC] and for which coordinated Union level action is necessary ("the Union list of critical medicinal products").	1. Following the reporting referred to in Article 130, paragraph 2, second subparagraph, and Article 130(5), the MSSG shall consult the working party referred to in Article 121(1), point (c)***, and the Patients Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP) and Industry Standing Group (ISG)***. Based on this consultation, the MSSG shall propose a Union list of critical medicinal products authorised to be placed on the market of a Member State pursuant to Article 5 of [revised Directive 2001/83/EC] and for which coordinated Union level action is necessary ("the Union list of critical medicinal products").

Proposal for a regulation
Article 131 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The MSSG ***may*** propose updates to the Union list of critical medicines to the Commission, where necessary.	2. The MSSG ***shall*** propose updates to the Union list of critical medicines to the Commission, where necessary.

COMPROMISE AMENDMENT 39 - CHAPTER X AVAILABILITY AND SECURITY OF SUPPLY OF MEDICINAL PRODUCTS
(ARTICLE 132, ARTICLE 133)
replacing amendments: AM 162; 163; 1682 - 1696

supported by
EPP, S&D, RE, Greens/EFA, Left

Proposal for a regulation
Article 132 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Following the adoption of the Union list of critical medicinal products pursuant to Article 131(3), in consultation with the Agency and the working party referred to in Article	1. Following the adoption of the Union list of critical medicinal products pursuant to Article 131(3), in consultation with the Agency and the working party referred to in Article

121(1), point (c), the MSSG may provide recommendations, in accordance with the methods referred to in Article 130(1), point (d), on appropriate security of supply measures to marketing authorisation holders as defined in Article 116(1), the Member States, the Commission or other entities. Such measures may include recommendations on diversification of suppliers ***and*** inventory management.	121(1), point (c), the MSSG may provide recommendations, in accordance with the methods referred to in Article 130(1), point (d), on appropriate security of supply measures to marketing authorisation holders as defined in Article 116(1), the Member States, the Commission or other entities. Such measures may include recommendations on ***manufacturing capacity, on reorganisation of manufacturing capacity,*** diversification of suppliers***,*** inventory management***, establishment of minimum safety stock and if necessary, redistribution of available stock among Member States under the voluntary solidarity mechanism to address urgent needs***, ***as well as pricing and procurement mechanisms and measures and where appropriate the use of regulatory flexibilities without lowering safety and efficacy standards.***

Proposal for a regulation
Article 132 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. The MSSG shall coordinate the Voluntary Solidarity Mechanism to allow Member States to request assistance in obtaining stocks of a medicine during critical shortages. The MSSG shall specify the procedures and criteria to launch the Voluntary Solidarity Mechanism in consultation with the Member States, the Agency and the Commission.

Proposal for a regulation
Article 132 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	1b. Following the update of the Union list of critical medicinal products, the MSSG shall assess the shortage prevention plan of the medicinal products present on the list.

Proposal for a regulation
Article 133 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) take into account the recommendations referred to in Article 132(1);	(c) take into account the recommendations referred to in Article 132(1);

COMPROMISE AMENDMENT 40 - CHAPTER X AVAILABILITY AND SECURITY OF SUPPLY OF MEDICINAL PRODUCTS
(ARTICLE 134)
replacing amendments: AM 164; 165; 1698 -1718

supported by
EPP, S&D, RE, Greens/EFA, Left

Proposal for a regulation
Article 134 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The Commission ***may, where it considers it appropriate and necessary***:	1. The Commission ***shall***:

Proposal for a regulation
Article 134 – paragraph 1 – point -a (new)

Text proposed by the Commission	*Amendment*
	(-a) take all necessary action within its limits of the powers conferred on it, with a view to mitigating critical shortages of medicinal products;

Proposal for a regulation
Article 134 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) inform the MSSG of those measures taken by the Commission.	(b) inform the MSSG of those measures taken by the Commission.

Proposal for a regulation
Article 134 – paragraph 1 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) develop guidelines to ensure that national initiatives on stockpiling are proportionate to the needs and do not create undesirable consequences, such as supply shortages, in other Member States;

Proposal for a regulation
Article 134 – paragraph 1 – point c b (new)

Text proposed by the Commission	*Amendment*
	(cb) develop, within the framework of the Public Procurement Directive 2014/24/EU[1] c,

guidelines to support public procurement practices in the pharmaceutical field, in particular with regard to the implementation of the most economically advantageous tender (MEAT) criteria in order to establish remedies against single-winner, price-only tenders.

[1 c] Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94 28.3.2014, p. 65).

Proposal for a regulation
Article 134 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. The Commission shall work with the European Centre for Disease prevention and Control on building reliable forecasts of potential threats and potential shortages.

Proposal for a regulation
Article 134 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission, taking into consideration the information or the opinion, referred to in paragraph 1, or MSSG recommendations, may decide to adopt an ***implementing*** act to improve security of supply**.** The ***implementing*** act may impose contingency stock requirements of active pharmaceutical ingredient or finished dosage forms, or other relevant measures required to improve security of supply, on marketing authorisation holders, wholesale distributors or other relevant entities.	2. The Commission, taking into consideration the information or the opinion, referred to in paragraph 1, or MSSG recommendations, may decide to adopt a ***delegated*** act to improve security of supply, ***while allowing Member States to adopt or maintain legislation ensuring a higher degree of protection against medicine shortages, in respect of the commitments taken in the framework of the 'Voluntary Solidarity Mechanism'.*** The ***delegated*** act may impose contingency stock requirements of active pharmaceutical ingredient or finished dosage forms, or other relevant measures required to improve security of supply, on marketing authorisation holders, wholesale distributors or other relevant entities.

Proposal for a regulation
Article 134 – paragraph 3

Text proposed by the Commission	*Amendment*
3.The ***implementing*** act referred to in paragraph 2 shall be adopted in accordance with the examination procedure referred to in Article ***173(2)***	3. The ***delegated*** act referred to in paragraph 2 shall be adopted in accordance with the procedure referred to in Article ***175.***

COMPROMISE AMENDMENT 41 - CHAPTER XI EUROPEAN MEDICINES AGENCY (ARTICLE 138)

replacing amendments: AM 167-172, 1720-1744

supported by
EPP, S&D, RE, Greens/EFA, Left

Articles 135-137 no AMs

Proposal for a regulation

Article 138 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall provide the Member States and the institutions of the Union with the best possible scientific opinion on any question relating to the evaluation of the quality, safety ***and*** efficacy of medicinal products for human use, veterinary medicinal products, which is referred to it in accordance with the Union legal acts relating to medicinal products for human use or veterinary medicinal products.	The Agency shall provide the Member States and the institutions of the Union with the best possible scientific opinion on any question relating to the evaluation of the quality, safety***,*** efficacy ***and environmental risk*** of medicinal products for human use, veterinary medicinal products, which is referred to it in accordance with the Union legal acts relating to medicinal products for human use or veterinary medicinal products.

Proposal for a regulation

Article 138 – paragraph 1 – subparagraph 2 – introductory part

Text proposed by the Commission	*Amendment*
The Agency, acting particularly through its Committees, shall carry out the following tasks:	The Agency, acting particularly through its Committees ***and working groups***, shall carry out the following tasks:

Proposal for a regulation

Article 138 – paragraph 1 – subparagraph 2 – point a a (new)

Text proposed by the Commission	*Amendment*
	(a a) the Agency, after consulting with relevant national authorities and national bodies responsible for pricing and reimbursement in accordance with Article 162 and the health technology coordination group established by Article 3 of Regulation (EU) 2021/2282, shall develop harmonised standards for the design of scientific studies for marketing authorisation holders.

Proposal for a regulation

Article 138 – paragraph 1 – subparagraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) coordinating the scientific evaluation of the quality, safety ***and*** efficacy of medicinal products for human use, which are subject to Union marketing authorisation procedures;	(a) coordinating the scientific evaluation of the quality, safety***,*** efficacy ***and environmental risk*** of medicinal products for human use, which are subject to Union marketing authorisation procedures;

Proposal for a regulation
Article 138 – paragraph 1 – subparagraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) coordinating the scientific evaluation of the quality, safety and efficacy of veterinary medicinal products, which are subject to Union marketing authorisation procedures in accordance with Regulation (EU) 2019/6 and the performance of other tasks set out in Regulation (EU) 2019/6 and Regulation (EC) 470/2009;	(b) coordinating the scientific evaluation of the quality, safety and efficacy of veterinary medicinal products, ***and advice on methodological aspects relating to their trials and the use of affected clinical trial results for regulatory purposes,*** which are subject to Union marketing authorisation procedures in accordance with Regulation (EU) 2019/6 and the performance of other tasks set out in Regulation (EU) 2019/6 and Regulation (EC) 470/2009;

Proposal for a regulation

Article 138 – paragraph 1 – subparagraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) transmitting on request and making publicly available assessment reports, summaries of product characteristics, labels ***and*** package leaflets for the medicinal products for human use;	(c) transmitting on request and making publicly available assessment reports, summaries of product characteristics, ***periodic safety update reports,*** labels***,*** package leaflets ***and AMR awareness cards, where applicable,*** for the medicinal products for human use;

Proposal for a regulation

Article 138 – paragraph 1 – subparagraph 2 – point n

Text proposed by the Commission	*Amendment*
(n) creating a database on medicinal products for human use, to be accessible to the general public, and ensuring that it is updated, and managed independently of pharmaceutical companies; the database is to facilitate the search for information already authorised for package leaflets; it is to include a section on medicinal products for human use authorised for the treatment of children; the information provided to the general public is to be worded in an appropriate and comprehensible manner;	(n) creating a ***user-friendly*** database on medicinal products for human use, to be accessible to the general public, and ensuring that it is updated, and managed independently of pharmaceutical companies; the database is to facilitate the search for information already authorised for package leaflet, ***and for other documents deemed relevant by the Agency***; it is to include a section on medicinal products for human use authorised for the treatment of children; the information provided to the general public is to be worded in an appropriate and comprehensible manner;

Proposal for a regulation

Article 138 – paragraph 1 – subparagraph 2 – point zc

Text proposed by the Commission	*Amendment*
(zc) establishing a mechanism of consultation of authorities or bodies active along the life cycle of medicinal products for human use for exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency;	(zc) establishing a mechanism of consultation of authorities or bodies active along the life cycle of medicinal products for human use for exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency***, notably with the SoHO Coordination Board, Medical Devices Coordination Group, Coordination Group on***

	the Health Technology Assessment and national pricing and reimbursement authorities;

Proposal for a regulation

Article 138 – paragraph 1 – subparagraph 2 – point ze

Text proposed by the Commission	*Amendment*
(ze) cooperating with EU decentralised agencies and other scientific authorities and bodies established under Union law, notably the European Chemicals Agency, the European Food Safety Authority, the European Centre for Disease Prevention and Control and the European Environment Agency as regards the scientific assessment of relevant substances, exchange of data and information and development of coherent scientific methodologies, including replacing, reducing or refining animal testing, taking into account the specificities of the assessment of medicinal products;	(ze) cooperating with EU decentralised agencies and other scientific authorities and bodies established under Union law, notably the European Chemicals Agency, the European Food Safety Authority, the European Centre for Disease Prevention and Control and the European Environment Agency as regards the scientific assessment of relevant substances, exchange of data and information and development of coherent scientific methodologies, including replacing, reducing or refining animal testing, ***and where possible prioritising replacement strategies such for example as non-animal in vitro and silico approaches,*** taking into account the specificities of the assessment of medicinal products;

Proposal for a regulation

Article 138 – paragraph 1 – subparagraph 2 – point zl a (new)

Text proposed by the Commission	*Amendment*
	(zla) where scientific guidelines are provided, the Agency shall ensure that such guidelines are kept up-to-date and based on the latest scientific developments.

Article 138 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*

The database provided for in paragraph 1, point (n), shall include all medicinal products for human use authorised in the Union together with the summaries of product characteristics, the package leaflet ***and*** the information shown on the labelling. Where relevant, it shall include the electronic links to the dedicated webpages where the marketing authorisation holders have reported the information pursuant to Article 40(4), point (b), and Article 57 of [revised Directive 2001/83/EC].	The database provided for in paragraph 1, point (n), shall include all medicinal products for human use authorised in the Union together with the summaries of product characteristics, ***European product assessment reports, periodic safety update reports, where applicable documentation related to received scientific advice, environmental risk assessment reports,*** the package leaflet***,*** the information shown on the labelling***, awareness cards in case of antimicrobials, post-marketing obligations related to the medicinal product, , shortage prevention and, where relevant, mitigation plans, and information in which Member States is the product placed on the market and other documents deemed relevant by the Agency***. Where relevant, it shall include the electronic links to the dedicated webpages where the marketing authorisation holders have reported the information pursuant to 40(4), point (b) and Article 57 f [revised Directive 2001/83/EC].

Proposal for a regulation

Article 138 – paragraph 2 – subparagraph 2 – point b a (new)

Text proposed by the Commission	*Amendment*
	(b a) marketing authorisation holders shall electronically submit to the agency information on which Member States the medical products for human use authorised in the Union have been placed.

Proposal for a regulation

Article 138 – paragraph 2 – subparagraph 3

Text proposed by the Commission	*Amendment*
Where ***appropriate,*** the database shall also include references to clinical trials currently being carried out or already completed, contained in the clinical trials database	Where ***applicable,*** the database shall also include references to clinical trials currently being carried out or already completed, contained in the clinical trials database

provided for in Article 81 of Regulation (EU) No 536/2014.

provided for in Article 81 of Regulation (EU) No 536/2014.

COMPROMISE AMENDMENT 42 - CHAPTER XI EUROPEAN MEDICINES AGENCY

(ARTICLE 139, ARTICLE 142, ARTICLE 143)

replacing amendments: AM 173-176, 1745-1773

supported by
EPP, S&D, RE, Greens/EFA, Left

Article 139 COM text as proposal

Art 140 no ams

Art 141 no ams

Proposal for a regulation

Article 142 – paragraph 1 – point l

Text proposed by the Commission	*Amendment*
(l) a Secretariat, which shall provide technical, scientific and administrative support to all bodies of the Agency and ensure appropriate coordination between them, and which shall provide technical and administrative support for the coordination group referred to in Article 37 of [revised Directive 2001/83/EC] and ensure appropriate coordination between it and the Committees. It shall also undertake the work required of the Agency under the procedures for the assessment and preparations of decisions for paediatric investigation plans, waivers, deferrals or orphan designations.	(l) a Secretariat, which shall provide technical, scientific and administrative support to all bodies of the Agency and ensure appropriate coordination between them, and which shall provide technical and administrative support for the coordination group referred to in Article 37 of [revised Directive 2001/83/EC] and ensure appropriate coordination between it and the Committees. It shall also ***ensure implementation of all transparency commitments and*** undertake the work required of the Agency under the procedures for the assessment and preparations of decisions for paediatric investigation plans, waivers, deferrals or orphan designations.

Proposal for a regulation

Article 143 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
In addition, two representatives of patients' organisations, one representative of doctors' organisations and one representative of veterinarians' organisations, all with voting rights, shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission which includes appreciably more names than there are posts to be filled. The list drawn up by the Commission shall be forwarded to the	In addition, two representatives of patients' organisations, one representative of doctors***' organisations , one representative of pharmacists***' organisations and one representative of veterinarians' organisations, all with voting rights, shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission which includes appreciably more names than there are posts to be filled.

European Parliament, together with the relevant background documents. As quickly as possible, and at the latest within three months of notification, the European Parliament may submit its views for consideration to the Council, which shall then appoint these representatives to the Management Board.

The list drawn up by the Commission shall be forwarded to the European Parliament, together with the relevant background documents. As quickly as possible, and at the latest within three months of notification, the European Parliament may submit its views for consideration to the Council, which shall then appoint these representatives to the Management Board.

Proposal for a regulation

Article 143 – paragraph 1 – subparagraph 3

Text proposed by the Commission	*Amendment*
The members of the Management Board shall be appointed in such a way as to guarantee the highest levels of specialist qualifications, a broad spectrum of relevant expertise and the broadest possible geographic spread within the European Union.	The members of the Management Board shall be appointed in such a way as to guarantee the highest levels of specialist qualifications, a broad spectrum of relevant expertise***,*** and the broadest possible geographic spread within the European Union.

Proposal for a regulation

Article 143 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
All parties represented in the Management Board shall make efforts to limit turnover of their representatives, in order to ensure continuity of the work of the Management Board. All parties shall aim to achieve a balanced representation ***between men and women*** on the Management Board.	All parties represented in the Management Board shall make efforts to limit turnover of their representatives, in order to ensure continuity of the work of the Management Board. All parties shall aim to achieve a ***gender*** balanced representation on the Management Board.

Proposal for a regulation

Article 143 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The term of office for members and their alternates shall be four years. That term shall be extendable.	4. The term of office for members and their alternates shall be four years. That term shall be extendable ***once consecutively***.

COMPROMISE AMENDMENT 43 - CHAPTER XI EUROPEAN MEDICINES AGENCY

(ARTICLES 144, 145, 146)

replacing amendments: AM 1774-1789

supported by
EPP, S&D, Greens/EFA, ECR, ID, Left

Articles 144 and 145 - COM TEXT as CA

Proposal for a regulation

Article 146 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4 a. Representatives from patients' organisations serving as members or alternate members on scientific committees shall be eligible for reimbursement of expenses incurred in the execution of their duties as representatives, financed through the Agency budget, in accordance with the financial rules applicable to the Agency.

Proposal for a regulation

Article 146 – paragraph 8 – subparagraph 1

Text proposed by the Commission	*Amendment*

The scientific committees and any working parties and scientific advisory groups established in accordance with this Article shall in general matters establish contacts, on an advisory basis, with parties concerned with the use of medicinal products for human use, in particular patient and consumer organisations and healthcare professionals' associations. For that purpose working groups of patient and consumer organisations and healthcare professionals' associations shall be established by the Agency. They shall ensure a fair representation of healthcare professionals, patients and consumers covering a wide range of experience and disease areas, including orphan, paediatric and geriatric diseases and advanced therapy medicinal products, and a broad geographical range.	The scientific committees and any working parties and scientific advisory groups established in accordance with this Article shall in general matters establish contacts, on an advisory basis, with parties concerned with the use of medicinal products for human use, in particular patient and consumer organisations***,*** ***including paediatric representatives,*** and healthcare professionals' associations. For that purpose working groups of patient and consumer organisations and healthcare professionals' associations shall be established by the Agency. They shall ensure a fair representation of healthcare professionals, patients and consumers covering a wide range of experience and disease areas, including orphan, paediatric and geriatric diseases and advanced therapy medicinal products, and a broad geographical range.

COMPROMISE AMENDMENT 44 - CHAPTER XI EUROPEAN MEDICINES AGENCY

(ARTICLE 147)

replacing amendments: AM 177-182, 1790-1798

supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Proposal for a regulation

Article 147 – title

Text proposed by the Commission	*Amendment*
Conflict of interest	***Independence and*** Conflict of interest

Proposal for a regulation

Article 147 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Members of the Management Board, members of the committees, rapporteurs and experts shall not have financial or other interests in the pharmaceutical industry which could affect	Members of the Management Board, members of the committees, rapporteurs and experts shall not have financial or other interests in the pharmaceutical industry which could affect

their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. All indirect interests which could relate to this industry shall be entered in a register held by the Agency which is accessible to the public, on request, at the Agency's offices.	their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. All indirect interests which could relate to this industry shall be entered in a register held by the Agency which is accessible to the public, on request, at the Agency's offices.

Proposal for a regulation

Article 147 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
The Agency's code of conduct shall provide for the implementation of this Article ***with particular reference to the acceptance of gifts***.	The Agency's code of conduct shall provide for the implementation of this Article.

Proposal for a regulation

Article 147 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Members of the Management Board, members of the committees, rapporteurs and experts who participate in meetings or working groups of the Agency shall declare, at each meeting, any specific interests which could be considered to be prejudicial to their independence with respect to the items on the agenda. These declarations shall be made available to the public.	2. Members of the Management Board, members of the committees, rapporteurs and experts who participate in meetings or working groups of the Agency shall declare, at each meeting, any specific interests which could be considered to be prejudicial to their independence ***or impartiality*** with respect to the items on the agenda. These declarations shall be made available to the public. ***Where the Agency decides that a declared interest constitutes a conflict of interest, that representative shall not take part in any discussions or decision-making, or obtain any information concerning that item of the agenda. Such declarations of representatives and the decision of the Commission shall be recorded in the summary minutes of the meeting.***

Proposal for a regulation

Article 147 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Executive Director after leaving the service, shall continue to be bound by the duty to behave with integrity and discretion as regards the acceptance of certain appointments or benefits and if intending to engage in an occupational activity, whether gainful or not, within two years of leaving the service shall inform the Management Board for approval. The Management Board shall, in principle, prohibit them, during the 12 months after leaving the service, from engaging in lobbying or advocacy vis-à-vis staff of the European Institutions and Agencies for their business, clients or employers on matters for which they were responsible during the last three years in the service.

Proposal for a regulation

Article 147 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. Patients, clinical experts and other relevant experts shall declare any financial and other interests relevant to the joint work in which they are due to participate. Such declarations and any actions taken as a result shall be recorded in the summary minutes of the meeting and in the outcome documents of the joint work in question.

Proposal for a regulation

Article 147 – paragraph 2 c (new)

Text proposed by the Commission	*Amendment*
	2 c. The Agency shall make available the rules of procedure, agendas, minutes and

members of the Management Board, committees, working parties and advisory committees on its website.

COMPROMISE AMENDMENT 45 - CHAPTER XI EUROPEAN MEDICINES AGENCY

(ARTICLE 148, ARTICLE 149, ARTICLE 150, ARTICLE 151, ARTICLE 152, ARTICLE 153)

replacing amendments: AM 183-186; 1799-1840

supported by
EPP, S&D, RE, Greens/EFA, Left

Art 148 and 149 COM text as compromise proposal

Proposal for a regulation

Article 150 – title

Text proposed by the Commission	*Amendment*
Scientific working parties and scientific advisory groups	Scientific working parties***, ad-hoc working groups*** and scientific advisory groups

Proposal for a regulation

Article 150 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Committee for Human Medicinal Products shall establish for the evaluation of specific types of medicinal products or treatments, working parties with scientific expertise in the fields of pharmaceutical quality, methodologies, non-clinical and clinical evaluations.	The Committee for Human Medicinal Products shall establish for the evaluation of specific types of medicinal products or treatments, working parties with scientific expertise in the fields of pharmaceutical quality, methodologies, non-clinical and clinical evaluations.

Proposal for a regulation

Article 150 – paragraph 2 – subparagraph 3

Text proposed by the Commission	*Amendment*
The Committee ***may*** establish an Environmental Risk Assessment working party	The Committee ***shall*** establish an ***ad-hoc*** Environmental Risk Assessment working party

and other scientific working parties, as necessary.	and other scientific working parties, as necessary.

Proposal for a regulation

Article 150 – paragraph 3 – subparagraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(b a) fulfillment of conflict of interest requirements referred to in Article 147

Proposal for a regulation

Article 150 – paragraph 3 – subparagraph 2

Text proposed by the Commission	*Amendment*
The majority of the members of the working parties shall consist of experts from the competent authorities of the Member States. Where appropriate, the Committee for Human Medicinal Products may, following consultation with the Management Board, set a minimum number of experts from the competent authorities in a working party.	The majority of the members of the working parties shall consist of experts from the competent authorities of the Member States**.** Where appropriate, the Committee for Human Medicinal Products may, following consultation with the Management Board, set a minimum number of experts from the competent authorities in a working party.

Article 150 – paragraph 3a (new)

Text proposed by the Commission	*Amendment*
	Representatives of patients, caregivers, clinicians and academia shall be included as members of the working parties as appropriate.

Article 150 – paragraph 5a (new)

Text proposed by the Commission	*Amendment*
	The Agency shall establish the following ad-hoc working groups:

(a) an ad-hoc working group on Advanced Therapy Medicinal Products;

(b) an ad hoc working group on Orphan Medicinal Products;

(c) an ad-hoc working group on Paediatric Medicinal Products

Article 151 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
Where necessary, for the nomination of other experts the Agency ***may*** publish a call for expression of interest after endorsement by the Management Board of the necessary criteria and fields of expertise, in particular to ensure a high level of public health and animal protection.	Where necessary, for the nomination of other experts the Agency ***shall*** publish a call for expression of interest after endorsement by the Management Board of the necessary criteria and fields of expertise, in particular to ensure a high level of public health and animal protection.

Proposal for a regulation

Article 152 – paragraph 2 – subparagraph 2

Text proposed by the Commission	*Amendment*
The person concerned, or their employer, shall be remunerated in accordance with [a scale of fees to be included in the financial arrangements established by the ***Management Board/mechanism under the new fee legislation***].	The person concerned, or their employer, shall be remunerated in accordance with [a scale of fees to be included in the financial arrangements established by the ***EMA fees Regulation 2022/0417***].

Proposal for a regulation

Article 153 – paragraph 1

Text proposed by the Commission	*Amendment*
At the request of the Commission, the Agency shall, in respect of authorised medicinal products for human use, collect any available information on methods that Member States'	At the request of the Commission, the Agency shall, in respect of authorised medicinal products for human use, collect any available information on methods that Member States'

competent authorities use to determine the added therapeutic value that any new medicinal product for human use provides.	competent authorities use to determine the added therapeutic value that any new medicinal product for human use provides. ***The Agency shall, in collaboration with patient organisations and healthcare professionals, draw up guidelines for the determination of added therapeutic value.***

COMPROMISE AMENDMENT 46 - CHAPTER XI EUROPEAN MEDICINES AGENCY

(ARTICLE 154, ARTICLE 158, ARTICLE 162, ARTICLE 163, ARTICLE 164)

replacing amendments: AM 187, 1841-1858, ITRE 107

supported by
EPP, S&D, RE, Greens/EFA, ECR, ID, Left

Proposal for a regulation

Article 154 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Activities relating to the assessment of marketing authorisation applications, subsequent variations, pharmacovigilance, to the operation of communications networks and to market surveillance shall be under the permanent control of the Management Board in order to guarantee the independence of the Agency. This shall not preclude the Agency from charging fees to marketing authorisation holders for performing these activities by the Agency on the condition that its independence is strictly guaranteed.	4. Activities relating to the assessment of marketing authorisation applications, subsequent variations, pharmacovigilance, to the operation of communications networks and to market surveillance shall be under the permanent control of the Management Board in order to guarantee the independence of the Agency. This shall not preclude the Agency from charging fees to marketing authorisation holders for performing these activities by the Agency on the condition that its independence is strictly guaranteed ***in accordance with provisions laid down in Article 147***.

Art 155-57 No Ams

Art 159 No AMs

Art 160 No AMs

Art 161 No ams

Proposal for a regulation

Article 162 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Agency ***may*** extend the consultation process to patients, medicine developers, healthcare professionals, industries or other stakeholders**,** as relevant.	2. The Agency ***shall*** extend the consultation process to patients, medicine developers, healthcare professionals, industries or other stakeholders as relevant**.**

Proposal for a regulation

Article 163 – paragraph 1

Text proposed by the Commission	*Amendment*
The Management Board shall, in agreement with the Commission, develop appropriate contacts between the Agency and the representatives of the industry, consumers and patients and the healthcare professions. These contacts may include the participation of observers in certain aspects of the Agency's work, under conditions determined beforehand by the Management Board, in agreement with the Commission.	The Management Board shall, in agreement with the Commission, develop appropriate contacts between the Agency and the representatives of the industry, consumers and patients and the healthcare professions**,** ***including through the Patients Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP) and Industry Standing Group (ISG)***. These contacts may include the participation of observers in certain aspects of the Agency's work, under conditions determined beforehand by the Management Board, in agreement with the Commission.

Proposal for a regulation

Article 164 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Agency shall ensure that micro, small and medium-sized enterprises ('SMEs') and not-for-profit entities are offered a support scheme.	1. The Agency shall ensure that micro, small and medium-sized enterprises ('SMEs')**,** ***not-for profit entities*** are offered a support scheme.

Proposal for a regulation

Article 164 – paragraph 5

Text proposed by the Commission	*Amendment*
5. For not-for-profit entities, the Commission shall adopt specific provisions clarifying the definitions, establishing waivers, reductions or deferrals of fees, as appropriate, in accordance with the procedure referred to in Article 10 and Article 12 of [revised Regulation (EC) No 297/95].	5. For ***not-for profit entities*** the Commission shall adopt specific provisions clarifying the definitions, establishing waivers, reductions or deferrals of fees, as appropriate, in accordance with the procedure referred to in Article 10 and Article 12 ***and Annex V*** of [revised Regulation (EC) No 297/95].

COMPROMISE AMENDMENT 47 - CHAPTER XI EUROPEAN MEDICINES AGENCY

(ARTICLE 165, ARTICLE 166, ARTICLE 167, ARTICLE 168, ARTICLE 169, ARTICLE 170)

replacing amendments: AM 188-192, 1859 - 1871, ITRE 108

supported by
EPP, S&D, RE, Greens/EFA, Left

Proposal for a regulation

Article 165 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. Sufficient resources shall be allocated to the Agency to ensure appropriate implementation of its transparency obligations and commitments.

Proposal for a regulation

Article 166 – paragraph 1

Text proposed by the Commission	*Amendment*
1. To support its public health tasks and in particular the evaluation and monitoring medicinal products or the preparation of regulatory decisions and scientific opinions, the Agency may process personal health data, from sources other than clinical trials, for the purpose of improving the robustness of its scientific assessment or verifying claims of the applicant or marketing authorisation holder in the context of the evaluation or supervision of medicinal product.	1. To support its public health tasks and in particular the evaluation and monitoring medicinal products or the preparation of regulatory decisions and scientific opinions, the Agency may process personal health data, from sources other than clinical trials, ***including real world data*** for the purpose of improving the robustness of its scientific assessment or verifying claims of the applicant or marketing authorisation holder in the context of the evaluation or supervision of medicinal product. ***The Agency shall put in place sufficient, effective and specific technical and organisational measures to safeguard the fundamental rights and***

interests of data subjects in line with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725, including but not limited to clear and targeted data minimisation policies, state-of-the-art anonymisation and pseudonymisation requirements.

Proposal for a regulation

Article 166 – paragraph 1 – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	Such data shall in particular include personal electronic health data as defined in Regulation (EU) .../... [draft EHDS Regulation 2022/0140(COD)], data from the Eudravigilance database, clinical data, and where applicable , data from monitoring studies on the use, effectiveness and safety of medicinal products intended for treatment, prevention, or the diagnosis of disease, including health data provided by public authorities..

Proposal for a regulation

Article 166 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Agency may consider and decide upon additional evidence available, independently from the data submitted by the marketing authorisation applicant or marketing authorisation holder. On that basis, the summary of product characteristics shall be updated if the additional evidence has an impact on the benefit-risk balance of a medicinal product.	2. The Agency may consider and decide upon additional evidence available, independently from the data submitted by the marketing authorisation applicant or marketing authorisation holder. On that basis, the summary of product characteristics shall be updated if the additional evidence has an impact on the benefit-risk balance of a medicinal product. ***Such update shall only take place after the consultation with the marketing authorisation applicant or marketing authorisation holder concerned. Marketing authorisation applicants and marketing authorisation holders shall have***

	the opportunity to respond within a reasonable timeline set by the Agency. Marketing authorisation applicants and marketing authorisation holders may submit to the Agency questions and shall be offered the opportunity of an explanation to any proposed update to the summary of product characteristics as appropriate. The reasons for the conclusions reached shall be included in the final opinion.

Proposal for a regulation
Article 167 – paragraph 2

Text proposed by the Commission	*Amendment*
For the purposes of the first subparagraph, the Agency shall actively identify and implement cybersecurity best practices adopted within Union institutions, bodies, offices and agencies for preventing, detecting, mitigating, and responding to cyber attacks.	For the purposes of the first subparagraph, the Agency shall actively ***take measures to ensure its compliance with a high common level of cybersecurity*** adopted within Union institutions, bodies, offices and agencies, identify and implement ***up-to-date*** cybersecurity best practices for preventing, detecting, mitigating, and responding to cyber attacks.

Proposal for a regulation

Article 168 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001 and Directive (EU) 2019/1937 of the European Parliament and of the Council[85] , and existing national provisions ***and practices in the Member States*** on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the commercially confidential information and trade secrets of natural or legal persons in accordance with Directive (EU) 2016/943 of the European Parliament and of	1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001 and Directive (EU) 2019/1937 of the European Parliament and of the Council[85] , and existing national provisions on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the commercially confidential information and trade secrets of natural or legal persons in accordance with Directive (EU) 2016/943 of the European Parliament and of

the Council[86] , including intellectual property rights.	the Council[86] , including intellectual property rights.

Proposal for a regulation

Article 168 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Paragraphs 1, 2 and 3 do not affect the rights and obligations of the Commission, the Agency, Member States or other actors identified in this Regulation with regard to the exchange of information and the dissemination of warnings, nor do they affect the obligations of the persons concerned to provide information under criminal law.	4. Paragraphs 1, 2 and 3 do not affect the rights and obligations of the Commission, the Agency, Member States or other actors identified in this Regulation with regard to the exchange of information and the dissemination of warnings, nor do they affect the obligations of the persons concerned to provide information under criminal law.

Proposal for a regulation

Article 169 – paragraph 1 – subparagraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) as regards special categories of personal data, is strictly necessary and subject to appropriate safeguards, which may include pseudonymisation.	(b) as regards special categories of personal data, is strictly necessary and subject to appropriate safeguards, which may include pseudonymisation ***requirements and techniques, data minimisation measures, specific organisational measures and access controls on a 'need to know' basis and other appropriate measures, confidentiality requirements, and fundamental rights of data subjects as set out in Regulations (EU) 2016/679 and (EU) 2018/1725***.

Proposal for a regulation

Article 170 – paragraph 3

Text proposed by the Commission	*Amendment*
3. On the occasion of every second evaluation, there shall be an assessment of the results achieved by the Agency having regard	3. On the occasion of every second evaluation, there shall be an assessment of the results achieved by the Agency having regard

to its objectives, mandate, governance and tasks, including an assessment of whether the continuation of the Agency is still justified with regard to these objectives, mandate, governance and tasks. This assessment shall also include the experience acquired as a result of the operation of the procedures laid down in this Regulation and in Chapter III, Sections 4 and 5 of [revised Directive 2001/83/EC] on the basis of input from Member States and the Coordination group referred to in Article 37 of [revised Directive 2001/83/EC].	to its objectives, mandate, governance and tasks, including an assessment of whether the continuation of the Agency is still justified with regard to these objectives, mandate, governance and tasks. This assessment shall also include the experience acquired as a result of the operation of the procedures laid down in this Regulation and in Chapter III, Sections 4 and 5 of [revised Directive 2001/83/EC] on the basis of input from Member States and the Coordination group referred to in Article 37 of [revised Directive 2001/83/EC].

COMPROMISE AMENDMENT 48 - CHAPTER VI - ORPHAN MEDICINAL PRODUCTS (ARTICLES 71 AND 72) replacing AMs 118-124; 1154-1279, ITRE 66-80

supported by
EPP, S&D, RE, Greens/EFA, ECR, ID, Left

Proposal for a regulation
Article 71 - paragraph 1

Text proposed by the Commission	*Amendment*
Where an orphan marketing authorisation is granted and without prejudice to intellectual property law, the Union and the Member States shall not grant a marketing authorisation or extend an existing marketing authorisation, for the same therapeutic indication, in respect of a similar medicinal product for the duration of market exclusivity set out in paragraph 2.	Where an orphan marketing authorisation is granted and without prejudice to intellectual property law, the Union and the Member States shall not grant a marketing authorisation or extend an existing marketing authorisation, for the same therapeutic indication, in respect of a similar medicinal product for the duration of market exclusivity set out in paragraph 2.

Proposal for a regulation
Article 71 – paragraph 2 – point a

Text proposed by the Commission	*Amendment*
(a) nine years for orphan medicinal products other than those referred to in points (b) and (c);	(a) nine years for orphan medicinal products other than those referred to in points (b) and (c);

Proposal for a regulation
Article 71 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
(b) ***ten*** years for orphan medicinal products addressing a high unmet medical need	(b) ***eleven*** years for orphan medicinal products addressing a high unmet medical need

as referred to in Article 70;

as referred to in Article 70;

Proposal for a regulation
Article 71 – paragraph 2 – point c

Text proposed by the Commission	*Amendment*
(c) ***five*** years for orphan medicinal products which have been authorised in accordance with Article 13 of [revised Directive 2001/83/EC].	(c) ***four*** years for orphan medicinal products which have been authorised in accordance with Article 13 of [revised Directive 2001/83/EC].

Proposal for a regulation
Article 71 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The submission, validation and assessment of the application for the marketing authorisation and granting the marketing authorisation for a generic or biosimilar product to the reference medicinal product ***for which market exclusivity has expired***, shall not be prevented by the market exclusivity of a similar product to the reference medicinal product.	5. The submission, validation and assessment of the application for the marketing authorisation and granting the marketing authorisation for a generic or biosimilar product to the reference medicinal product, shall not be prevented by the market exclusivity of a similar product to the reference medicinal product.

Proposal for a regulation
Article 71 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The market exclusivity of the orphan medicinal product shall not prevent the submission, validation ***and*** assessment of an application for a marketing authorisation for a similar medicinal product, including generics and biosimilars, where the remainder of the duration of the market exclusivity is less than two years.	6. The market exclusivity of the orphan medicinal product shall not prevent the submission, validation***,*** assessment of an application for ***and granting of*** a marketing authorisation for a similar medicinal product, including generics and biosimilars, where the remainder of the duration of the ***initial*** market exclusivity is less than two years.

Proposal for a regulation
Article 72 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The periods of market exclusivity referred to in Article 71, paragraph 2, points (a) and (b), shall be prolonged by 12 months, where the orphan marketing authorisation holder can demonstrate that the conditions referred to in Article 81(2),	***deleted***

point (a), and Article 82(1) [of revised Directive 2001/83/EC] are fulfilled.

The procedures set out in Articles 82(2) to (5) [of revised Directive 2001/83/EC] shall accordingly apply to the prolongation of market exclusivity.

COMPROMISE AMENDMENT 49 - CHAPTER VII - PAEDIATRIC MEDICINAL PRODUCTS (ARTICLES 74 TO 98) replacing AMs 125-128; 1284-1366, ITRE 81

supported by
EPP, S&D, RE, Greens/EFA, ECR, Left

Article 74

Proposal for a regulation

Article 74 – paragraph 2 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) following the acceptance by the Agency of a justified request from an applicant in accordance with paragraph 3.	(b) following the acceptance by the Agency of a ***duly*** justified request from an applicant in accordance with paragraph 3.

Proposal for a regulation

Article 74 – paragraph 3

Text proposed by the Commission	*Amendment*
3. When it is not possible, on the basis of scientifically justified reasons, to have a complete paediatric development plan in accordance with the timing given in Article 76(1) an applicant may submit a justified request to the Agency to utilise the procedure mentioned in paragraph 2. The Agency has 20 days to accept or refuse the request and shall immediately inform the applicant and state the reasons for refusal.	3. When it is not possible, on the basis of scientifically justified reasons, to have a complete paediatric development plan in accordance with the timing given in Article 76(1) an applicant may submit a ***duly*** justified request to the Agency to utilise the procedure mentioned in paragraph 2. The Agency has 20 days to accept or refuse the request and shall immediately inform the applicant and state the reasons for refusal.

Article 75

Proposal for a regulation

Article 75 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) that the specific medicinal product or class of medicinal products is likely to be ineffective or unsafe in part or all of the paediatric population;	(a) that the specific medicinal product or class of medicinal products is likely to be ineffective or unsafe in part or all of the paediatric population;

Proposal for a regulation

Article 75 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) that the disease or condition for which the specific medicinal product or class is intended occurs only in adult populations, unless when the product is directed at a molecular target that on the basis of existing scientific data, is responsible for a different disease or condition in the same therapeutic area in children than the one for which the specific medicinal product or class of medicinal products is intended for in the adult population;	(b) that the disease or condition for which the specific medicinal product or class is intended occurs only in adult populations, unless ***when*** the ***product is directed at a*** molecular target ***or due to its mechanism of action*** on the basis of existing scientific data, ***is responsible for*** a different disease or condition in the same therapeutic area in children than the one for which the specific medicinal product or class of medicinal products is intended for in the adult population;

Proposal for a regulation

Article 75 – paragraph 3

Text proposed by the Commission	*Amendment*
3. On the basis of the experience acquired as a result of the operation of this Article or of scientific knowledge the Commission is empowered to adopt delegated acts in accordance with Article 175 to amend the grounds for granting a waiver detailed in paragraph 1.	***deleted***

Proposal for a regulation

Article 75 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	1 a. The Agency shall, after consultation with the Commission and relevant interested parties, draw up guidelines for the application of this Article.

Article 76

Proposal for a regulation

Article 76 – paragraph 1

Text proposed by the Commission	*Amendment*
1. A paediatric investigation plan or an application for waiver shall be submitted to the Agency with a request for agreement, except in duly justified cases, before the initiation of safety and efficacy clinical studies so as to ensure that a decision on use in the paediatric population of the medicinal product concerned can be given at the time of the marketing authorisation or other application concerned.	1. A paediatric investigation plan or an application for waiver shall be submitted to the Agency with a request for agreement, except in duly justified cases, before the initiation of safety and efficacy clinical studies so as to ensure that a decision on use in the paediatric population of the medicinal product concerned can be given at the time of the marketing authorisation or other application concerned.

Art 77 COM proposal as compromise

Art 78 COM proposal as compromise

Art 79 No AMs tabled

Art 80 COM proposal as compromise

Article 81

Proposal for a regulation

Article 81 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The length of the deferral shall be specified in a decision of the Agency and shall not exceed five years.	3. The length of the deferral shall be specified in a decision of the Agency and shall ***be substantiated by scientific and technical reasoning or by considerations pertaining to public health and*** not exceed five years.

Art 82 COM proposal as compromise

Art 83 no AMs tabled

Article 84

Proposal for a regulation

Article 84 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1 a. The procedure foreseen in paragraph 1 shall also apply when the applicant updates the elements of an initial paediatric investigation plan submitted in accordance with Article 74(2).

Proposal for a regulation

Article 84 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
If, following the decision agreeing the paediatric investigation plan referred to in Article 77, paragraphs 1, 2 and 4, or on the basis of the updated paediatric investigation plan received in accordance with Article 77(3), the Agency, on the base of new scientific information available, considers that the agreed plan or any of its elements are no longer appropriate, it shall request the applicant ***to*** propose changes to the paediatric investigation plan.	If, following the decision agreeing the paediatric investigation plan referred to in Article 77, paragraphs 1, 2 and 4, or on the basis of the updated paediatric investigation plan received in accordance with Article 77(3), the Agency, on the base of new scientific information available, considers that the agreed plan or any of its elements are no longer appropriate, it shall request***, based on detailed scientific grounds, that*** the applicant propose changes to the paediatric investigation plan.

Art 85 COM proposal as compromise

Art 86 COM proposal as compromise

Article 87

Proposal for a regulation

Article 87 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. Within the timelines for adoption of a decision foreseen in Articles 77, 78, 80, 81, 82 and 84, the Agency shall transmit its scientific conclusions to the applicant.

Proposal for a regulation

Article 87 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2 b. Where marketing authorisation applicants or marketing authorisation holders disagree with the scientific conclusions, they may respond within 20 days following receipt by providingdetailed grounds and evidence for re-examination.
	The Agency shall assess the request for re-examination and may request more information from the marketing authorisation applicant or marketing authorisation holder in this process.
	Within 30 days following receipt of a request for re-examination, the Agency shall confirm its scientific conclusions or commence a re-examination where deemed justified.

Article 88

Proposal for a regulation

Article 88 – paragraph 1

Text proposed by the Commission	*Amendment*
Where a paediatric investigation plan, agreed in accordance with the provisions of Article 77, paragraphs 1, 2 and 4, is discontinued, the applicant shall notify the Agency of its intention to discontinue the conduct of the paediatric investigation plan and provide the reasons for such discontinuation no less than six months before the discontinuation.	Where a paediatric investigation plan, agreed in accordance with the provisions of Article 77, paragraphs 1, 2 and 4, is discontinued, the applicant shall notify the Agency of its intention to discontinue the conduct of the paediatric investigation plan and provide the reasons for such discontinuation no less than six months before the discontinuation ***or as soon as possible***.

Article 89 No AMs tabled

Art 90 No AMs tabled

Article 91

Proposal for a regulation

Article 91 – paragraph 3

Text proposed by the Commission	*Amendment*
3. When products are authorised in accordance with the provisions of this Regulation, the Commission may update the summary of product characteristics and package leaflet, and may vary the marketing authorisation accordingly.	3. When products are authorised in accordance with the provisions of this Regulation, the Commission may update the summary of product characteristics and package leaflet, and may vary the marketing authorisation accordingly***, including regarding information on dosage accuracy***.

Art 92 No AMs tabled

Art 93 No AMs tabled

Article 94

Proposal for a regulation

Article 94 – paragraph 2 – subparagraph 3

Text proposed by the Commission	*Amendment*
If for justified scientific reasons it is not possible to submit the summary of the result of	If for justified scientific reasons it is not possible to submit the summary of the result of

the trial within 6 months it shall be submitted to the EU database at the latest within twelve months after the trial has ended. The justification for the delay needs also to be submitted in the EU database.	the trial within 6 months it shall be submitted to the EU database at the latest within twelve months after the trial has ended. The justification for the delay needs also to be submitted in the EU database.

Art 95 COM prop

Art 96 COM proposal

Art 97 No AMs

Art 98 COM proposal

COMPROMISE AMENDMENT 50 - CHAPTER I - ARTICLE 2 - DEFINITIONS
replacing AMs 30-34, 521-539; 546-575, ITRE 40-45

supported by
EPP, S&D, RE, Greens/EFA, ECR, ID, Left

Proposal for a regulation
Article 2 – paragraph 2 – point 4

Text proposed by the Commission	*Amendment*
(4) 'orphan medicine sponsor' means any legal or natural person, established in the Union, who submitted an application for or has been granted an orphan designation by a decision referred to in Article 64(4);	(4) 'orphan medicine sponsor' means any legal or natural person, established in the Union, who submitted an application for or has been granted an orphan designation by a decision referred to in Article 64(4);

Proposal for a regulation
Article 2 – paragraph 2 – point 7

Text proposed by the Commission	*Amendment*
(7) 'significant benefit' means a clinically relevant advantage or a major contribution to patient care of an orphan medicinal product if such an advantage or contribution benefits a ***substantial*** part of the target population;	(7) 'significant benefit' means a clinically relevant advantage or a major contribution to patient care of an orphan medicinal product if such an advantage or contribution benefits a ***relevant*** part of the target population;

Proposal for a regulation
Article 2 – paragraph 2 – point 8 – point a

Text proposed by the Commission	*Amendment*
(a) greater efficacy than an authorised medicinal orphan medicinal product in a ***substantial*** part of the target population;	(a) eater efficacy than an authorised medicinal orphan medicinal product in a ***relevant*** part of the target population;

Proposal for a regulation
Article 2 – paragraph 2 – point 8 – point b

Text proposed by the Commission	*Amendment*
(b) greater safety than an authorised medicinal product in a ***substantial*** part of the target population;	(b) greater safety than an authorised medicinal product in a ***relevant*** part of the target population;

Proposal for a regulation
Article 2 – paragraph 2 – point 12

Text proposed by the Commission	*Amendment*
(12) 'shortage' means a situation in which the supply of a medicinal product that is authorised and placed on the market in a Member State does not meet the demand for that medicinal product in that Member State.	(12) 'shortage' means a situation in which the supply of a medicinal product that is authorised and placed on the market in a Member State does not meet the demand for that medicinal product in that Member State ***whatever the cause***.

Proposal for a regulation
Article 2 – paragraph 2 – point 13

Text proposed by the Commission	*Amendment*
(13) 'critical shortage in the Member State' means a shortage of a medicinal product, for which there is no appropriate alternative medicinal product available on the market in that Member State, and that shortage cannot be resolved.	(13) 'critical shortage in the Member State' means a shortage of a medicinal product, for which there is no appropriate medicinal product alternative available on the market in that Member State, and that shortage cannot be resolved.

Proposal for a regulation
Article 2 – paragraph 2 – point 14 a (new)

Text proposed by the Commission	*Amendment*
	(14 a) 'demand' means the request for a medicinal product by a healthcare professional or patient in response to clinical need; the demand is satisfactorily met when the medicinal product is acquired in appropriate time and in sufficient quantity to allow continuity of provision of the best care to patients;

Proposal for a regulation
Article 2 – paragraph 2 – point 14 b (new)

Text proposed by the Commission	*Amendment*
	(14b) 'supply' means the total volume of stock of a given medicinal product that is placed on the market by a marketing authorisation holder or a manufacturer;

COMPROMISE AMENDMENT 51 - CHAPTER IX - REGULATORY SANDBOX (ARTICLES 113 TO 115); ARTICLE 2 – PARAGRAPH 2 – POINT 10; RECITALS 132A TO 133; RECITAL 135

replacing AMs 25; 442-455, ITRE 27-30 (rec 132a-133); AMs 27; 462-464; ITRE 32 (rec 135); AMs 540-545 (Art2-para2-point10); AMs 134; 1396-1462, ITRE 82-87 (Art 113-115)

supported by
EPP, S&D, RE, Greens/EFA, Left

Proposal for a regulation

Recital 132 a (new)

Text proposed by the Commission	*Amendment*
	(132 a) To better facilitate patient' access to innovative medicines, it is appropriate to establish common rules for the testing and authorisation of innovative medicinal products and innovative technologies related to such products that, due to their exceptional nature or characteristics, are expected to not completely fit the EU medicines regulatory framework.

Proposal for a regulation

Recital 132 b (new)

Text proposed by the Commission	*Amendment*
	(132 b) On duly justified grounds, regulatory sandboxes may be set up when it is not possible to develop the medicinal product or category of

products in compliance with the requirements applicable to medicinal products due to scientific or regulatory challenges arising from characteristics or methods related to the product, and those characteristics or methods positively and distinctively contribute to the quality, safety or efficacy of the medicinal product or category of products, or provide a major advantage contribution to patient access to treatment.

Proposal for a regulation

Recital 132 c (new)

Text proposed by the Commission	*Amendment*
	(132 c) The objectives of the possibility to establish regulatory sandboxes under this Regulation are the following: for the Agency and national competent authorities to increase their understanding of technical and scientific developments, to allow developers in a controlled environment to test and develop innovative medicinal products and related technologies that are not fitting the current regulatory framework, as agreed with the competent authorities, and to identify possible future adaptations of the legal framework for the authorisation of medicinal products in the Union.

RECITAL 133

Proposal for a regulation

Recital 133

Text proposed by the Commission	*Amendment*
(133) Regulatory sandboxes can provide the opportunity for advancing regulation through proactive regulatory learning, enabling regulators to gain better regulatory knowledge and to find the best means to regulate innovations based on real-world evidence, especially at a very early stage of development	(133) Regulatory sandboxes can provide the opportunity for advancing regulation through proactive regulatory learning, enabling regulators to gain better regulatory knowledge and to find the best means to regulate innovations based on real-world evidence, especially at a very early stage of development

of a medicinal product, which can be particularly important in the face of high uncertainty and disruptive challenges, as well as when preparing new policies. Regulatory sandboxes provide a structured context for experimentation, enable where appropriate in a real-world environment the testing of innovative technologies, products, services or approaches – at the moment especially in the context of digitalisation or the use of artificial intelligence and machine learning in the life cycle of medicinal products from drug discovery, development to the administration of medicinal products – for a limited time and in a limited part of a sector or area under regulatory supervision ensuring that appropriate safeguards are in place. In its conclusions of 23 December 2020 the Council has encouraged the Commission to consider the use of regulatory sandboxes on a case-by-case basis when drafting and reviewing legislation.

of a medicinal product, which can be particularly important in the face of high uncertainty and disruptive challenges, as well as when preparing new policies. ***SMEs and startups should also have the possibility to utilise regulatory sandboxes where they can, as relevant, contribute with their knowhow and experience.*** Regulatory sandboxes ***can*** provide ***controlled frameworks which, by providing*** a structured context for experimentation, enable where appropriate in a real-world environment the testing of innovative technologies, products, services or approaches – at the moment especially in the context of digitalisation or the use of artificial intelligence and machine learning in the life cycle of medicinal products from drug discovery, development to the administration of medicinal products – for a limited time and in a limited part of a sector or area under regulatory supervision ensuring that appropriate safeguards are in place. ***They allow the authorities tasked with implementing and enforcing the legislation to exercise on a case-by-case basis a degree of flexibility in relation to testing innovative medicines, for the benefit of bringing these products to patients without compromising the standards of quality, safety and efficacy. The regulatory sandbox should in principle allow the Agency to assess if an adapted framework for the medicinal product in question is appropriate and should be developed. Given that the regulatory sandbox should not continue indefinitely, upon its completion the medicinal product in question should, if appropriate, be regulated through an adapted framework.*** In its conclusions of 23 December 2020 the Council has encouraged the Commission to consider the use of regulatory sandboxes on a case-by-case basis when drafting and reviewing legislation..

RECITAL 135

Proposal for a regulation

Recital 135

Text proposed by the Commission	*Amendment*
(135) The establishment of a regulatory sandbox should be based on a Commission Decision following a recommendation of the Agency. Such decision should be based on a detailed plan outlining the particularities of the sandbox as well as describing the products to be covered. A regulatory sandbox should be limited in duration and may be terminated at any time based on public health considerations. The learning stemming from a regulatory sandbox should inform future changes to the legal framework to fully integrate the particular innovative aspects into the medicinal product regulation. Where appropriate, adapted frameworks may be developed by the Commission on the basis of the results of a regulatory sandbox.	(135) The establishment of a regulatory sandbox should be based on a Commission Decision following a recommendation of the Agency. Such decision should be based on a detailed ***and comprehensive*** plan outlining the particularities of the sandbox as well as describing the products to be covered. A regulatory sandbox should be limited in duration and may be terminated at any time based on public health considerations. The learning stemming from a regulatory sandbox should inform future changes to the legal framework to fully integrate the particular innovative aspects into the medicinal product regulation. Where appropriate, adapted frameworks may be developed by the Commission on the basis of the results of a regulatory sandbox.

ARTICLE 2 – PARAGRAPH 2 – POINT 10

Proposal for a regulation

Article 2 – paragraph 2 – point 10

Text proposed by the Commission	*Amendment*
(10) ‘regulatory sandbox’ means a regulatory framework during which it is possible to develop, validate and test in a controlled environment innovative or adapted regulatory solutions that facilitate the development and authorisation of innovative products which are likely to fall in the scope of this Regulation***,*** pursuant to a specific plan and for a limited time under regulatory supervision.	(10) ‘regulatory sandbox’ means a regulatory framework during which it is possible to develop, validate and test in a controlled environment innovative or adapted regulatory solutions that facilitate the development and authorisation of innovative products which are likely to fall in the scope of this Regulation ***but for which there is an absence of existing adapted rules for development and authorisation,*** pursuant to a specific plan and for a limited time under regulatory supervision..

Article 113

Proposal for a regulation

Article 113 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
(1) The Commission may set up a regulatory sandbox pursuant to a specific sandbox plan, based on a recommendation of the Agency and pursuant to the procedure set out in paragraphs 4 to 7, where all the following conditions are met;	(1) The Commission may set up ***on a case-by-case basis*** a regulatory sandbox pursuant to a specific sandbox plan, based on a recommendation of the Agency and pursuant to the procedure set out in paragraphs 4 to 7, where all the following conditions are met;

Proposal for a regulation

Article 113 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) it is not possible to develop the medicinal product or category of products in compliance with the requirements applicable to medicinal products due to scientific or regulatory challenges arising from characteristics or methods related to the product;	(a) it is not possible to develop the medicinal product or category of products in compliance with the requirements applicable to medicinal products due to scientific or regulatory challenges arising from characteristics or methods related to the product;

Proposal for a regulation

Article 113 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Agency shall monitor the field of emerging medicinal products and may request information and data from marketing authorisation holders, developers, independent experts and researchers, and representatives of healthcare professionals and of patients and may engage with them in preliminary discussions.	3. The Agency shall monitor the field of emerging medicinal products and may request information and data from marketing authorisation holders, developers, independent experts and researchers, and representatives of healthcare professionals and of patients and may engage with them in preliminary discussions***, where appropriate referring to***

the consultation mechanism provided in Article 162.

Proposal for a regulation

Article 113 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
Where the Agency considers it appropriate to set up a regulatory sandbox for medicinal products which are likely to fall under the scope of this Regulation, it shall provide a recommendation to the Commission. The Agency shall list eligible products or category of products in that recommendation and shall include the sandbox plan referred to in paragraph 1.	Where the Agency considers it appropriate to set up a regulatory sandbox for medicinal products which are likely to fall under the scope of this Regulation ***but for which there is the absence of existing adapted rules for development and authorisation***, it shall provide a recommendation to the Commission. The Agency shall list eligible products or category of products in that recommendation and shall include the sandbox plan referred to in paragraph 1.

Proposal for a regulation

Article 113 – paragraph 5

Text proposed by the Commission	*Amendment*
5. The Agency shall be responsible for developing a sandbox plan based on data submitted by developers of eligible products and following appropriate consultations. The plan shall set out clinical, scientific and regulatory justification for a sandbox, including the identification of the requirements of this Regulation, [revised Directive 2001/83/EC] and Regulation (EC) 1394/2007 that cannot be complied with and a proposal for alternative or mitigation measures, where appropriate. The plan shall also include a proposed timeline for the duration of the sandbox. Where appropriate, the Agency shall also propose measures in order to mitigate any possible distortion of market conditions as a consequence of establishing a regulatory.	5. The Agency shall be responsible for developing a sandbox plan based on data submitted by developers of eligible products and following appropriate consultations ***including, where relevant, with patients, academia, HTA bodies, healthcare professionals or developers***. The plan shall set out clinical, scientific and regulatory justification for a sandbox, including the identification of the requirements of this Regulation, [revised Directive 2001/83/EC]**,** Regulation (EC) 1394/2007 that cannot be complied with and a proposal for alternative or mitigation measures, where appropriate. The plan shall also include a proposed timeline for the duration of the sandbox. Where appropriate, the Agency shall also propose measures in order to mitigate any possible distortion of market

conditions as a consequence of establishing a regulatory.

Proposal for a regulation

Article 113 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The Commission shall, by means of ***implementing*** acts, take a decision on the set up of a regulatory sandbox taking into account the recommendation of the Agency and the sandbox plan pursuant to paragraph 4. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 17***3(2).***	6. The Commission shall, by means of ***delegated*** acts, take a decision on the set up of a regulatory sandbox taking into account the recommendation of the Agency and the sandbox plan pursuant to paragraph 4. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 17***5***.

Proposal for a regulation

Article 113 – paragraph 8 – subparagraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) it is appropriate to protect public health.	(b) it is appropriate to protect public health ***or the environment***.

Proposal for a regulation

Article 113 – paragraph 9

Text proposed by the Commission	*Amendment*
9. Where after the Decision to establish the regulatory sandbox in accordance with paragraph 6, risks to health are identified but these risks can be fully mitigated by the adoption of supplementary conditions, the Commission may**,** after consultation of the Agency, amend its decision by means of implementing acts. The Commission may also prolong the duration of a regulatory sandbox by means of implementing acts. Those ***implementing*** acts shall be adopted in	9. Where after the Decision to establish the regulatory sandbox in accordance with paragraph 6, risks to health are identified but these risks can be fully mitigated by the adoption of supplementary conditions, the Commission may **,** after consultation of the Agency, amend its decision by means of implementing acts. The Commission may also, ***on the basis of duly justified reasoning and evidence from the Agency***, prolong the duration of a regulatory sandbox by means of ***delegated*** acts. Those implementing acts shall

accordance with the examination procedure referred to in Article 173(2).

be adopted in accordance with the examination procedure referred to in Article 173(2).

Article 114

Proposal for a regulation

Article 114 – paragraph 2

Text proposed by the Commission	*Amendment*
2. A medicinal product developed as part of a regulatory sandbox may be placed on the market only when authorised in accordance with this Regulation. The initial validity of such authorisation shall not exceed the duration of the regulatory sandbox. The authorisation may be prolonged at the request of the marketing authorisation holder	2. A medicinal product developed as part of a regulatory sandbox may be placed on the market only when authorised in accordance with this Regulation. The initial validity of such authorisation shall not exceed the duration of the regulatory sandbox. The authorisation may, ***upon justified recommendation by the Agency***, be prolonged at the request of the marketing authorisation holder**.**

Proposal for a regulation

Article 114 – paragraph 3

Text proposed by the Commission	*Amendment*
3. In duly justified cases, the marketing authorisation of a medicinal product developed under the regulatory sandbox may include derogations from the requirements set out in this Regulation and [revised Directive 2001/83/EC]. Those derogations may entail adapted, enhanced, waived or deferred requirements. Each derogation shall be limited to what is apt and strictly necessary to attain the objectives pursued, duly justified and specified in the conditions to the marketing authorisation.	3. In duly justified cases, the marketing authorisation of a medicinal product developed under the regulatory sandbox may include derogations from the requirements set out in this Regulation and [revised Directive 2001/83/EC]. ***Any derogation from the requirements in context of the sandbox shall ensure that the level of patient safety and protection of public health and ethical principles are upheld*** Those derogations may entail adapted, enhanced, waived or deferred requirements. Each derogation shall be limited to what is apt and strictly necessary to attain the objectives pursued, duly justified and specified in the conditions to the marketing authorisation**.**

Article 115

Proposal for a regulation

Article 115 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
Where such mitigation is not possible or proves to be ineffective, the development and testing process shall be suspended without delay until an effective mitigation takes place.	Where such mitigation is not possible or proves to be ineffective, the development and testing process shall be suspended without delay until an effective mitigation takes place. ***If no effective mitigation plan can be provided the Agency shall end the sandbox without undue delay.***

Proposal for a regulation

Article 115 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The Agency with input from Member States shall submit annual reports to the Commission on the results from the implementation of a regulatory sandbox, including good practices, lessons learnt and recommendations on their setup and, where relevant, on the application of this Regulation and other Union legal acts supervised within the sandbox. These reports shall be made publicly available by the Commission.	4. The Agency with input from Member States shall submit annual reports to the Commission on the results from the implementation of a regulatory sandbox, including ***a breakdown on the number of sandboxes granted, trends on medicinal products eligible for a regulatory sandbox,*** good practices, ***difficulties encountered***, lessons learnt, ***reflections on possible future adaptations to the regulatory framework*** and recommendations on their setup and, where relevant, on the application of this Regulation and other Union legal acts supervised within the sandbox. These reports ***as well as lay summaries*** shall be made publicly available by the Commission.

COMPROMISE AMENDMENT 52 - CHAPTER III - INCENTIVES FOR THE DEVELOPMENT OF 'PRIORITY ANTIMICROBIALS' (ARTICLES 39A (NEW), 39B (NEW) (INITIALLY TABLED AS AMS INTRODUCING ARTICLES 40A AND 40B NEW), 40 TO 43; RECITALS 77-84, ARTICLE 180, PARA 13)

replacing AMs 11, 12, 15-20, 88-94, 195, 326-332, 334-335, 349-380; 820-954, 1903-1905; ITRE 17-19; ITRE 52-62

supported by
EPP, S&D, RE, Greens/EFA, ECR

Article 39a (new)

Proposal for a regulation
Article 39a (new)

Text proposed by the Commission	*Amendment*
	Article 39a
	Milestone payment reward scheme
	1. An antimicrobial shall be considered a 'priority antimicrobial' if preclinical and clinical data underpin a significant clinical benefit with respect to antimicrobial resistance and it has at least one of the following characteristics:
	(a) it represents a new class of antimicrobials;
	(b) its mechanism of action is distinctly different from that of any authorised antimicrobial in the Union;
	(c) it contains an active substance not previously authorised in a medicinal product in the Union that addresses a multi-drug resistant organism and serious or life-threatening infection. In the scientific assessment of the criteria referred to in the first subparagraph, and in the case of antibiotics, the Agency shall take into account the 'WHO priority pathogens list for R&D of new antibiotics', or an equivalent list established at Union level.
	2. The Commission, in consultation with the Agency shall award milestone payments and support to potential priority antimicrobial products addressing the priority pathogens referred to in paragraph 1. The milestone payments shall be financed through resource matching by the Commission, including within the framework of Article 12 paragraph 2(b)(i) of Regulation (EU) 2021/695 and

Regulation (EU) 2021/522[1].

The Commission shall adopt delegated acts in accordance with Article 175 to set the criteria for the awarding of milestone payments, including payments for the completion of pre-specified development stages and criteria, taking into account the costs of the development of that stage and the anticipated costs of the next stage of development.

The awarding of milestone payments shall be contingent on legal commitments to use the payments:

(a) to further develop the priority antimicrobial ;

(b) to apply for a marketing authorisation in accordance with this Regulation;

(c) to conduct antimicrobial stewardship and access plans as referred to in Article 17 of [revised Directive]; and where relevant

(d) to apply for the joint procurement agreement referred to in Article 39b.

3. The priority antimicrobial shall also be subject to joint clinical assessment in accordance with Article 7(2)(a) of Regulation 2021/2282.

4. A developer who benefits from milestone payments under this Article shall not be eligible to avail of a transferable exclusivity voucher in accordance with Article 40 of this Regulation.

Proposal for a regulation
Article 39b (new)

Text proposed by the Commission	*Amendment*
	Article 39b
	Subscription model for the joint procurement of antimicrobials
	1. The Commission and any of the Member States may engage, as contracting parties, in a joint procurement procedure conducted pursuant to Article 165(2) of Regulation (EU,

[1] within Budget 2024 - Section III - Commission- Chapter 0606 - EU4Health Programme

Euratom) 2018/1046 with a view to the advance purchase of antimicrobials.

2. A joint procurement procedure as referred to in paragraph 1 shall be preceded by a Joint Procurement Agreement between the parties determining the practical arrangements governing the subscription model system and other procedures including the length of the subscription contract and the possibility of the parallel procurement.

3. The joint procurement agreement shall take the form of a multi-year subscription and include the following conditions:

- ***(a) delinkage or partial delinkage of funding from the volume of sales of the antimicrobial;***
- ***(b) commitment to continuous and sufficient supply in pre-agreed quantities;***
- ***(c) commitment to the stewardship and access plans as referred to in Article 17 of [revised Directive] ;***
- ***(d) commitment to the environmental risk assessment as referred to in Article 22 of [revised Directive];***
- ***(e) submission of a global access plan to supply third countries in critical need, including through development partners or voluntarily licensing.***

4. Participation in the joint procurement procedure is open to all Member States and third countries, including the European Free Trade Association States and Union candidate countries, as well as the Principality of Andorra, the Principality of Monaco, the Republic of San Marino and the Vatican City State, by way of derogation from Article 165(2) of Regulation (EU, Euratom) 2018/1046.

5. The Commission shall inform the European Parliament about procedures concerning the joint procurement of antimicrobials and, upon request, grant access to the contracts that are concluded as a result of those procedures, subject to the adequate protection of business secrecy, commercial relations and the interests of the Union. The Commission shall communicate information to the European Parliament

regarding sensitive documents in accordance with Article 9(7) of Regulation (EC) No 1049/2001.

Proposal for a regulation
Article 40

Text proposed by the Commission	*Amendment*
Article 40	*Article 40*
Granting the right to a transferable data exclusivity voucher	*Granting the right to a transferable data exclusivity voucher*
1. Following a request by the applicant when applying for a marketing authorisation, the Commission may, by means of implementing acts, grant a transferable data exclusivity voucher to a 'priority antimicrobial' referred to in ***paragraph 3***, under the conditions referred to in paragraph 4 based on a scientific assessment by the Agency.	1. Following a request by the applicant for a marketing authorisation***, made before the marketing authorisation is granted***, the Commission may, by means of implementing acts, grant a transferable data exclusivity voucher to a 'priority antimicrobial' referred to in ***Article 39a, paragraph 1***, under the conditions referred to in paragraph 4 based on a scientific assessment by the Agency.
2. The voucher referred to in paragraph 1 shall give the right to its holder to ***an*** additional 12 months of data protection for one authorised medicinal product.	2. The voucher referred to in paragraph 1 shall give the right to its holder to ***a maximum of*** additional 12 months of data protection for one authorised medicinal product.
3. An antimicrobial shall be considered 'priority antimicrobial' if preclinical and clinical data underpin a significant clinical benefit with respect to antimicrobial resistance and it has at least one of the following characteristics:	***2a. By means of delegated acts, the Commission shall set up eligibility of pathogens to the protection periods referred to in paragraph 2 in accordance with the WHO priority pathogens list or an equivalent established at Union level, with 12 months of data protection for authorised product ranked 'critical', 9 months for those ranked 'high' and 6 months for those ranked 'medium'.***
(a) it represents a new class of antimicrobials;	
(b) its mechanism of action is distinctly different from that of any authorised antimicrobial in the Union;	
(c) it contains an active substance not previously authorised in a medicinal product in the Union that addresses a multi-drug resistant organism and serious or life threatening infection.	
In the scientific assessment of the criteria referred to in the first subparagraph, and in the case of antibiotics, the Agency shall take into account the 'WHO priority pathogens list for R&D of new antibiotics', or an equivalent	4. To be granted the voucher by the Commission, the applicant shall:
	(a) demonstrate capacity ***and ensure the*** supply ***of*** the priority antimicrobial in sufficient quantities for the expected needs of the Union market, ***as defined in a contract with the Authority;***
	(b) provide information on all direct financial support ***and indirect financial support in accordance with Article 57 of [Revised***

list established at Union level.	***Directive]*** received for research related to the development of the priority antimicrobial;
4. To be granted the voucher by the Commission, the applicant shall:	
(a) demonstrate capacity ***to*** supply the priority antimicrobial in sufficient quantities for the expected needs of the Union market;	
(b) provide information on all direct financial support received for research related to the development of the priority antimicrobial.	***(ba) submit the stewardship and access plan as referred to in Annex I of [revised Directive 2001/83/EC],***
	(bb) submission of a global access plan to supply third countries in critical need, including through development partners or voluntarily licensing.
Within 30 days after the marketing authorisation is granted, the marketing authorisation holder shall make the information referred to in point (b) accessible to the public via a dedicated webpage and shall communicate, in a timely manner the electronic link to that webpage to the Agency.	Within 30 days after the marketing authorisation is granted, the marketing authorisation holder shall make the information referred to in point (b) accessible to the public via a dedicated webpage and shall communicate, in a timely manner the electronic link to that webpage to the Agency.
	5. The priority antimicrobial shall be added to the list of antimicrobials which are to be reserved for treatment of certain infections in humans and added to the Unions list as established via Commissions implementing regulation C(2022) 50.

Proposal for a regulation
Article 41

Text proposed by the Commission	*Amendment*
Article 41 *Transfer and use of the voucher*	*Article 41* *Transfer and use of the voucher*
1. A voucher may be used to extend the data protection for a period of 12 months of the priority antimicrobial or another medicinal product authorised in accordance with this Regulation of the same or different marketing authorisation holder.	1. A voucher may be used to extend the data protection for a period of 12, ***9 or 6*** months of the priority antimicrobial or another medicinal product authorised in accordance with this Regulation of the same or different marketing authorisation holder.
A voucher shall only be used once and in relation to a single centrally authorised medicinal product and only if that product is within its first four years of regulatory data protection.	A voucher shall only be used once and in relation to a single centrally authorised medicinal product and only if that product is within its first four years of regulatory data protection. ***The voucher shall not be used for a product which already benefited from maximum regulatory data protection period as set in Article 81 of [revised Directive 2001/83/EC]***
A voucher may only be used if the marketing authorisation of the priority antimicrobial for which the right was initially granted has not been withdrawn.	

2. To use the voucher, its owner shall apply for a variation of the marketing authorisation concerned in accordance with Article 47 to extend the data protection.

3. A voucher may be transferred to another marketing authorisation holder and shall not be transferred further.

4. A marketing authorisation holder to whom a voucher is transferred shall notify the Agency of the transfer within 30 days, stating the value of the transaction between the two parties. The Agency shall make this information publicly available.

A voucher may only be used if the marketing authorisation of the priority antimicrobial for which the right was initially granted has not been withdrawn

2. To use the voucher, its owner shall apply for a variation of the marketing authorisation concerned in accordance with Article 47 to extend the data protection.

3. A voucher may be transferred to another marketing authorisation holder ***once*** and shall not be transferred further.

3a. The monetary value paid for the transfer of the voucher shall be directed to the Authority, which shall in yearly instalments transfer the amount to the marketing authorisation holder, in order to ensure the manufacturing capacity and supply of the priority antimicrobial. The Commission shall adopt delegated acts in accordance with Article 175 to set up the framework for the conditions and functioning of annual instalments.

4. A marketing authorisation holder to whom a voucher is transferred shall notify the Agency of the transfer within 30 days, stating the value of the transaction between the two parties. The Agency shall make this information publicly available.

Proposal for a regulation
Article 42

Text proposed by the Commission	*Amendment*
Article 42 *Validity of the voucher*	*Article 42* *Validity of the voucher*
1. A voucher shall cease to be valid in the following cases:	1. A voucher shall cease to be valid in the following cases:
(a) where the Commission adopts a decision in accordance with Article 47 to extend the data protection of the receiving medicinal product; (b) where it is not used within ***5*** years ***from the date it was granted***.	(a) where the Commission adopts a decision in accordance with Article 47 to extend the data protection of the receiving medicinal product; (b) where it is not used within ***four*** years ***after the conditions set out in Article 41 have been fulfilled by the seller***.
2. The Commission may revoke the voucher ***prior to its transfer*** as referred to in Article	2. The Commission may revoke the voucher as referred to in Article 41(3) if a request for

41(3) if a request for supply, procurement or purchase of the priority antimicrobial in the Union has not been fulfilled.

3. Without prejudice to patent rights, or supplementary protection certificates[34], if a priority antimicrobial is withdrawn from the Union market prior to expiry of the periods of market and data protection laid down in Articles 80 and 81 of [revised Directive 2001/83/EC], those periods shall not prevent the validation, authorisation and placing on the market of a medicinal product using the priority antimicrobial as a reference medicinal product in accordance with Chapter II, Section 2 of [revised Directive 2001/83].

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[34] Regulation (EC) No 469/2009 of the European Parliament and of the Council, (OJ L 152, 16.6.2009, p. 1).

supply, procurement or purchase of the priority antimicrobial in the Union has not been fulfilled. ***To protect the buyer from damage resulting from a possible revocation of a voucher after the transfer, seller and buyer shall make contractual liability arrangements.***

3. Without prejudice to patent rights, or supplementary protection certificates[34], if a priority antimicrobial is withdrawn from the Union market prior to expiry of the periods of market and data protection laid down in Articles 80 and 81 of [revised Directive 2001/83/EC], those periods shall not prevent the validation, authorisation and placing on the market of a medicinal product using the priority antimicrobial as a reference medicinal product in accordance with Chapter II, Section 2 of [revised Directive 2001/83].

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[34] Regulation (EC) No 469/2009 of the European Parliament and of the Council, (OJ L 152, 16.6.2009, p. 1).

***Proposal* for a regulation**
Article 43

Text proposed by the Commission

Article 43

Duration of application of Chapter III

This Chapter shall apply ***until [Note to OP: insert the date of 15 years after the date of entry into force of this Regulation]*** or until the date when the Commission has granted a total of 10 vouchers in accordance with this Chapter, whichever date is the earliest.

Amendment

Article 43
Duration of application of Chapter III

This Chapter shall apply ***immediately after entry into force of this Regulation for 15 years*** or until the date when the Commission has granted a total of 10 vouchers in accordance with this Chapter, whichever date is the earliest.

Five years after entry into force of this Regulation, the Commission shall submit an evaluation report to the European Parliament and to the Council containing a scientific assessment measuring the progress in regards to antimicrobial research and development and the effectiveness of the incentives and rewards in this chapter.

Proposal for a regulation
Recital 77

Text proposed by the Commission	*Amendment*
(77) The development of antimicrobial resistance is a growing concern and the pipeline of effective antimicrobials is obstructed due to a market failure; it is therefore necessary to consider new measures to promote the development of priority antimicrobials that are effective against antimicrobial resistance and to support undertakings, often SMEs, which choose to invest in this area.	(77) The development of antimicrobial resistance is a growing concern and the pipeline of effective antimicrobials is obstructed due to a market failure ***whereby antimicrobial research and development (R&D) is hampered by market failures due to the low commercial value of the antimicrobial medicinal product market.***; It is therefore necessary to ***maintain the efficacy of existing antimicrobials for as long as possible and to*** consider ***a number of*** new measures to promote the development of priority antimicrobials that are effective against antimicrobial resistance and to support undertakings, often SMEs, ***and not-for-profit entities*** which choose to invest in this area. ***It is equally necessary to support research and development of novel antimicrobials through the different phases of antimicrobial development, notably through market entry rewards and milestone reward payments. Additionally, it is considered that the establishment of subscription models which delink the volume of antimicrobial sales to the reward received, notably through voluntary joint procurement, can help overcome these market failures. These measures should facilitate the development alternative treatments such as bacteriophages, that are effective against multi-drug resistant bacteria and can be used as alternative or together with antibiotics. However, addressing AMR will not be solved by R&D alone. To ensure prudent use of existing antibiotics, the Authority should also support the development and procurement of rapid diagnostic tools to ensure appropriate prescriptions.***

Proposal for a regulation
Recital 77a new

Text proposed by the Commission	*Amendment*
(	**(77a)** ***Reluctance to invest in the development of antimicrobials exist in part because the development of antimicrobials is costly and many developers, often SMEs, cannot afford to proceed to the next stage development. Additionally, when an antimicrobial is***

	developed, the market is naturally limited by virtue of the need to prudently use antimicrobials. Therefore, it is necessary to consider further Union level action to support the development of antimicrobials and address existing market failures. It is therefore considered appropriate to develop a milestone payment reward scheme, complemented by a subscription model voluntary joint procurement scheme to ensure a market for developers that delinks volumes sold to payment received

Proposal for a regulation
Recital 77b new

Text proposed by the Commission	*Amendment*
	(77b) Milestone payments are an early-stage financial reward upon achieving certain R&D objectives prior to market approval (e.g. successful completion of phase I). While these mechanisms would serve primarily to provide access to existing antimicrobials, they could also support new antimicrobials in the development phase. Subscription model consists of a series of financial payments to an antibiotic developer for successfully achieving regulatory approval for an antibiotic that meets specific pre-defined criteria. A subscription model scheme through voluntary joint procurement agreements should alleviate concerns for developers buy ensuring there is a market for the antimicrobial when developed.

Proposal for a regulation
Recital 78

Text proposed by the Commission	*Amendment*
(78) To be considered a 'priority antimicrobial', a medicinal product should represent a real advancement against antimicrobial resistance and should therefore bring forward non-clinical and clinical data that underpin a significant clinical benefit with respect to antimicrobial resistance. When assessing the conditions for antibiotics, the Agency shall take into account the prioritisation of pathogens as regards the risk of antimicrobial resistance provided for in the	(78) To be considered a 'priority antimicrobial', a medicinal product should represent a real advancement against antimicrobial resistance and should therefore bring forward non-clinical and clinical data that underpin a significant clinical benefit with respect to antimicrobial resistance. When assessing the conditions for antibiotics, the Agency shall take into account the prioritisation of pathogens as regards the risk of antimicrobial resistance provided for in the

‘WHO priority pathogens list for R&D of new antibiotics’, specifically those listed as priority 1 (critical) or priority 2 (high) or in case there is an equivalent list of priority pathogens adopted at Union level, the Agency should take such Union list into account as a priority.

‘WHO priority pathogens list for R&D of new antibiotics’, specifically those listed as priority 1 (critical) or priority 2 (high) or in case there is an equivalent list of priority pathogens adopted at Union level, the Agency should take such Union list into account as a priority.

Proposal for a regulation
Recital 78 a (new)

Text proposed by the Commission	***Amendment***
	(78a) In addition to the growing threat of antimicrobial resistance, there are other market failures present in the pharmaceutical sector for which further action at Union level is required to meet the public health needs of Union citizens. In particular, there is misalignment between the R&D priorities and the public health needs of Union citizens. The market failures in the Union have, in certain instances, resulted in no available treatments for rare diseases, unequal access to medicinal products, and have led to shortages. This Regulation should therefore address those market failures through a modulated approach to market exclusivities and increased transparency on R&D expenditure to better deliver on the objectives of affordability, accessibility and availability of medicinal products in the Union.

Proposal for a regulation
Recital 79

Text proposed by the Commission	*Amendment*
(79) The creation of a voucher rewarding the development of priority antimicrobials through an additional year of regulatory data protection has the capacity to provide the needed financial support to developers of priority antimicrobials. However, in order to ensure that the financial reward which is ultimately borne by health systems is mostly absorbed by the developer of the priority antimicrobial and not the buyer of the voucher, the number of available vouchers on the market should be kept to a minimum. It is therefore necessary to establish strict conditions of granting, transfer and use of the	79) ***As an alternative, for developers who have not availed of market entry rewards and milestone payment schemes*** the creation of a voucher rewarding the development of priority antimicrobials through an additional ***period*** of regulatory data protection has the capacity to provide the needed financial support to developers of priority antimicrobials. However, in order to ensure that the financial reward which is ultimately borne by health systems is mostly absorbed by the developer of the priority antimicrobial and not the buyer of the voucher, the number of available vouchers on the market should be kept to a minimum. It is

voucher and to further give the possibility to the Commission to revoke the voucher under certain circumstances.

therefore necessary to establish strict conditions of granting, transfer and use of the voucher and to further give the possibility to the Commission to revoke the voucher under certain circumstances. ***Additionally, the monetary value paid for the transfer of the voucher should be directed to the Authority, which should distribute in yearly instalments the amount to the marketing authorisation holder, in order to ensure manufacturing capacity and supply of the priority antimicrobial for which the voucher was created.***

Proposal for a regulation
Recital 80

Text proposed by the Commission	*Amendment*
(80) A transferable data exclusivity voucher should only be available to those antimicrobial products that bring a significant clinical benefit with respect to antimicrobial resistance, and which have the characteristics described in this Regulation. It is also necessary to ensure that an undertaking which receives this incentive is in turn capable to supply the medicinal product to patients across the Union in sufficient quantities and to provide information on all funding received for research related to its development in order to provide a full account of the direct financial support given to the medicinal product.	(80) A transferable data exclusivity voucher should only be available to those antimicrobial products that bring a significant clinical benefit with respect to antimicrobial resistance, and which have the characteristics described in this Regulation. It is also necessary to ensure that an undertaking which receives this incentive is in turn capable to supply the medicinal product to patients across the Union in sufficient quantities and to provide information on all funding received for research related to its development in order to provide a full account of the direct financial ***and indirect*** support given to the medicinal product ***in accordance with Article 57 of [Revised Directive]***.

Proposal for a regulation
Recital 81

Text proposed by the Commission	*Amendment*
(81) To ensure a high level of transparency and complete information on the economic effect of the transferable data exclusivity voucher, notably as regards the risk of overcompensation of investment, a developer of a priority antimicrobial is required to provide information on all direct financial support received for research related to the development of the priority antimicrobial. The declaration should include direct financial support received from any source worldwide.	(81) To ensure a high level of transparency and complete information on the economic effect of the transferable data exclusivity voucher, notably as regards the risk of overcompensation of investment, a developer of a priority antimicrobial is required to provide information on all direct financial support received for research related to the development of the priority antimicrobial. The declaration should include direct financial support received from any source worldwide ***and any indirect financial support in accordance with Article 57 of [Revised***

Directive]

Proposal for a regulation
Recital 82

Text proposed by the Commission	*Amendment*
(82) A transfer of a voucher for a priority antimicrobial may be conducted by sale. The value of the transaction which may be monetary or otherwise agreed between the buyer and the seller, shall be made public so as to inform regulators and the public. The identity of the holder of a voucher that has been granted and not yet used should be publicly known at all times so as to ensure a maximum level of transparency and trust.	(82) A transfer of a voucher for a priority antimicrobial may be conducted by sale ***and may only be transferred once***. The value of the transaction which may be monetary or otherwise agreed between the buyer and the seller, shall be made public so as to inform regulators and the public. The identity of the holder of a voucher that has been granted and not yet used should be publicly known at all times so as to ensure a maximum level of transparency and trust.

Proposal for a regulation
Recital 83

Text proposed by the Commission	*Amendment*
(83) The provisions related to transferable data exclusivity vouchers shall be applicable for a specified period from the entry into force of this Regulation or until a maximum number of vouchers are granted by the Commission in order to limit the total cost of the measure to Member State health systems. The limited application of the measure will also provide the possibility to assess the effect of the measure in addressing the market failure in the development of new antimicrobials addressing antimicrobial resistance and assess the cost on national health systems. Such assessment will provide the necessary knowledge to decide whether to extend the application of the measure.	(83) The provisions related to transferable data exclusivity vouchers shall be applicable for a specified period from the entry into force of this Regulation or until a maximum number of vouchers are granted by the Commission in order to limit the total cost of the measure to Member State health systems. The limited application of the measure will also provide the possibility to assess the effect of the measure in addressing the market failure in the development of new antimicrobials addressing antimicrobial resistance and assess the cost on national health systems. Such assessment will provide the necessary knowledge to decide whether to extend the application of the measure. ***Additionally, by five years after the entry into force of this Regulation, the Commission should provide an evaluation report on the effectiveness of both the milestone payment reward schemes as well as the transferable exclusivity vouchers in the development of priority antimicrobials.***

Proposal for a regulation
Recital 84

Text proposed by the Commission	*Amendment*
(84) The period of application of the provisions on transferable exclusivity vouchers for priority antimicrobials and the total number of vouchers may be extended by the Parliament	(84) The period of application of the provisions on transferable exclusivity vouchers for priority antimicrobials and the total number of vouchers may be extended by the Parliament

and the Council upon proposal by the Commission on the basis of the experience acquired.	and the Council upon proposal by the Commission on the basis of the experience acquired.

COMPROMISE AMENDMENT 53 - CHAPTER XII - GENERAL PROVISIONS (PENALTIES)

(ARTICLE 171, ARTICLE 172)

replacing AMs 193; 194; 1872-1890

supported by
EPP, S&D, RE, Greens, Left

Proposal for a regulation
Article 171 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.	1. ***By … [12 months after the date of entry into force of this Regulation],*** Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify it, without delay, of any subsequent amendment affecting them.

Proposal for a regulation
Article 172 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission may impose financial penalties in the form of fines or periodic penalty payments on the marketing authorisations holder granted under this Regulation if they fail to comply with any of the obligations laid down in Annex II in connection with the marketing authorisations.	1. The Commission may impose financial penalties in the form of fines or periodic penalty payments on the marketing authorisations holder granted under this Regulation if they fail to comply with any of the obligations laid down in Annex II in connection with the marketing authorisations.

Proposal for a regulation
Article 172 – paragraph 5

Text proposed by the Commission	*Amendment*
For the purposes of paragraph 1, the	For the purposes of paragraph 1, the

Commission shall take into account:	Commission shall take into account:
(a)any infringement procedure initiated by a Member State against the same marketing authorisation holder on the basis of the same legal grounds and the same facts;	(a)any infringement procedure initiated by a Member State against the same marketing authorisation holder on the basis of the same legal grounds and the same facts;
(b)any sanctions, including penalties, already imposed on the same marketing authorisation holder on the basis of the same legal grounds and the same facts.	(b)any sanctions, including penalties, already imposed on the same marketing authorisation holder on the basis of the same legal grounds and the same facts.
	(c) the nature, gravity and duration of the infringement and of its consequences, taking into account the nature, scope as well as the number of persons affected and the level of damage suffered by them;
	(e) the size and market share of the entity committing the infringement;
	(f) the intentional or negligent character of the infringement;
	(g) any action taken by the infringing party to mitigate the damage of the infringement;
	(h) the degree of responsibility of the infringing party taking into account technical and organisational measures implemented to prevent the infringement;
	(h) the degree of cooperation with the competent authorities, in order to remedy the infringement and mitigate the possible adverse effects of the infringement;
	(i) the manner in which the infringement became known to the competent authorities, in particular whether, and if so to what extent, the infringing party notified the infringement;
	(j) the risk to public health, including in the case of falsification of medicinal products.

Proposal for a regulation
Article 172 – paragraph 6 – subparagraph 1

Text proposed by the Commission	*Amendment*
Where the Commission finds that the marketing authorisation holder has failed, intentionally or negligently, to comply with its obligations, as referred to in paragraph 1, it	Where the Commission finds that the marketing authorisation holder has failed, intentionally or negligently, to comply with its obligations, as referred to in paragraph 1, it

may adopt a decision imposing a fine not exceeding 5 % of the marketing authorisation holder's Union turnover in the business year preceding the date of that decision.	may adopt a decision imposing a fine not exceeding 5 % of the marketing authorisation holder's Union turnover in the business year preceding the date of that decision.

Proposal for a regulation
Article 172 – paragraph 10

Text proposed by the Commission	*Amendment*
The Commission is empowered to adopt delegated acts in accordance with Article 175 in order to supplement this Regulation by laying down:	The Commission is empowered to adopt delegated acts in accordance with Article 175 in order to supplement this Regulation by laying down:
(a)procedures to be applied by the Commission when imposing fines or periodic penalty payments, including rules on the initiation of the procedure, measures of inquiry, rights of the defence, access to file, legal representation and confidentiality;	(a) procedures to be applied by the Commission when imposing fines or periodic penalty payments, including rules on the initiation of the procedure, measures of inquiry, rights of the defence, access to file, legal representation and confidentiality;
(b)further detailed rules on the imposition by the Commission of financial penalties on legal entities other than the marketing authorisation holder;	(b) further detailed rules on the imposition by the Commission of financial penalties on legal entities other than the marketing authorisation holder;
(c)rules on duration of procedure and limitation periods;	(c) rules on duration of procedure and limitation periods;
(d) elements to be taken into account by the Commission when setting the level of and imposing fines and periodic penalty payments, as well as the conditions and methods for their collection.	(d) elements to be taken into account by the Commission when setting the level of and imposing fines and periodic penalty payments, as well as the conditions and methods for their collection.

COMPROMISE AMENDMENT 54 - CHAPTER XV - FINAL PROVISIONS
(ARTICLE 179 ; ARTICLE 180 (EXCEPT PARA 13); ARTICLE 181)
replacing AMs 1906-1907

supported by
EPP, S&D, RE, Greens, ECR, Left

Article 179 - No amendments

Article 180 - Commission text as compromise, except paragraph 13 (covered by CA 48)

Article 181 - Commission text as compromise proposal & the addition below

Proposal for a regulation
Article 181 – paragraph 3 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	The provisions in Chapter III shall apply from the entry into force of this Regulation.

COMPROMISE AMENDMENT 55 ANNEXES (AND ARTICLE 134A)
replacing AMs 166; 1719; 196-201, 1908-1927

supported by
EPP, S&D, RE, Greens, Left

Annex I - COM proposal as compromise (consistent with directive)

Proposal for a regulation
Annex II – point 16

Text proposed by the Commission	*Amendment*
(16) the obligation to conduct post-marketing studies, including post-authorisation safety studies ***and*** post-authorisation efficacy studies, and to submit them for review, as provided for in Article 20;	(16) the obligation to conduct post-marketing studies, including post-authorisation safety studies**,** post-authorisation efficacy ***studies and post-authorisation environmental risk assessment*** studies, and to submit them for review, as provided for in Article 20;

Proposal for a regulation
Annex II – point 25 a (new)

Text proposed by the Commission	*Amendment*
	(25a) the obligations related to the availability and supply of medicinal products as laid down Chapter X of this Regulation;

Proposal for a regulation
Annex II – point 25 b (new)

Text proposed by the Commission	*Amendment*
	(25 b) the obligations to report on financial support and research and development costs as laid down in Article 57 of [revised Directive 2001/83/EC]

Annex III - No AMs

Proposal for a regulation
Annex IV – Part III – paragraph 1 – point 2 – point e

Text proposed by the Commission	*Amendment*

(e) Reason for shortage;	(e) Reason for shortage ***detailing where applicable information on***:
	(i) raw material disruption
	(ii) API disruption
	(iii) excipient disruption
;;	***(iv) production problem***
	(v) quality problem
	(vi) production capacity
	(vii) logistics problem
	(viii) distribution problem
	(ix) inventory and storage practices
	(x) increase in demand
	(xi) commercial reasons
	(xii) any other reasons

Proposal for a regulation
Annex IV – Part V – paragraph 1 – point 2 – point d a (new)

Text proposed by the Commission	*Amendment*
	(d a) methodology for establishing the demand forecast.

Proposal for a regulation
Annex IV – Part V a (new)

Text proposed by the Commission	*Amendment*
	Part Va
	For the purposes of reporting in accordance with Article 118(1) and for the early detection of supply shortages, wholesalers shall provide the following information in a timely manner:
	1. Product availability information:
	Product availabilities shall be reported per warehouse and shall be indexed as yes/no.
	2. Service level information:
	Service level information which captures the level of fulfilment of wholesale orders by marketing authorisation holders and suppliers shall be reported. Such information involves comparing the quantity ordered with the quantity actually received at the product

level. The resulting difference describes the service level.

COMPROMISE AMENDMENT 56 - CHAPTER XIV (HERA) - AMENDMENTS

replacing AMs 333; 336; 340, 342 (Recitals on HERA); 1697; 1891-1902

supported by
EPP, S&D, RE, Greens, Left

Proposal for a regulation
Article 175 a (new)
Regulation (EC) 851/2004
Articles 11 a (new), 11 b (new), 13, 16, 17 a (new), 17 b (new), 19

Text proposed by the Commission	*Amendment*
	Article 175a
	Amendments to Regulation (EC) No 851/2004
	Regulation (EC) No 851/2004 is amended as follows:
	(1) the following Article 11a is inserted:
	Article 11a
	European Health Emergency Preparedness and Response Authority
	1. The Health Emergency Preparedness and Response Authority (hereafter 'HERA' or 'the Authority') is hereby established as a separate structure under the legal personality of the European Centre for Disease Prevention and Control (ECDC).
	2. The Authority shall be responsible for creating, coordinating and implementing of the long-term European portfolio of biomedical research and development agenda for medical countermeasures against current and emerging public health threats as well as the, production, procurement, stockpiling and distribution capacity of medical countermeasures and other priority medical products in the EU.
	3. The Authority is represented by the Executive Director of the European Centre for Disease Prevention and Control.
	(2) the following Article 11b is inserted:
	Article 11b
	Objectives and tasks of the Authority

1. The Authority shall provide the Member States and the institutions of the Union with strategic direction, resources to develop a robust biomedical R&D capacity to address major public health issues

The Authority shall carry out the following tasks:

(a) setting out a long-term European portfolio or research and development projects in line with public health priorities set by the Commission in consultation with the World Health Organisation;

(b) setting and supporting biomedical R&D projects addressing at least the following areas:

(i) the development of priority antimicrobials as defined in Article 40a [Pharma Regulation];

(ii) the development of medical countermeasures and related technologies;

(c) setting up and management of collaboration with third-party research centres at national and European level, non-for profit entities, academia and industry;

(d) proving strategic advice to the Commission on the allocation of relevant EU grants and other financial sources to ensure appropriate resource allocation for biomedical R&D;

(e) detecting biological and other health threats soon after they emerge, evaluating their impacts and identify potential countermeasures;

(f) assessing and addressing vulnerabilities in global supply chains and strategic dependencies related to availability of medical countermeasures and medicines in the Union, in coordination with the Medicine Shortages Steering Group and Medical Device Shortages Steering Group, established under Regulation (EU) 2022/123;

(g) addressing market challenges by identifying and ensuring the availability of production sites for priority products in the EU;

(h) facilitating joint procurement and distribution of medical products in Member States;

(i) monitoring compliance with funding and procurement agreements;

(j) establishing a mechanism of consultation and cooperation, in line with the one health approach, internally within the European Cenre of Disease Prevention and Control and with other EU bodies and agencies, in particular the European Medicines Agency, European Food Safety Authority and European Environment Agency;

(k) contributing to reinforcing the global health emergency preparedness and response architecture.

3. The Commission is empowered to adopt delegated acts under Article 25 to expand the priority research agenda set in paragraph 1 point (b), in order to address other areas of unmet medical need.

(3) in Article 13 the following point (ba) is added:

(ba) HERA Board;

(5) In Article 16, the following point (da) is inserted:

(da) ensuring the provision of appropriate scientific, technical and administrative support for the HERA Board;

(6) the following Article 17a is inserted:

Article 17a

HERA Board

1. The HERA Board shall be composed of one representative from each Member State, two representatives of the Commission and two representatives of the European Parliament, all with voting rights. All HERA Board members shall be appointed for a two-year term, renewable once.

2. In addition, two public health experts shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission. The list drawn up by the Commission shall be forwarded to the European Parliament, together with the relevant background documents. As quickly as possible, and at the latest within three months of notification, the European Parliament may submit its views for consideration to the Council, which shall then appoint these representatives to the

HERA Board.

3. HERA Board shall be co-chaired by the Director and an elected representative of a Member State. 3. The members of the HERA Board shall be appointed in such a way as to guarantee the highest levels of specialist qualifications, a broad spectrum of relevant expertise, absence of direct or indirect conflict of interest.

4. The term of office for members and their alternates shall be four years. That term may be extendable once consecutively.

5. A representative of the Health Security Committee and a representative of the European Medicines Agency shall attend the meetings of the HERA Board, as permanent observer. Other relevant EU bodies and agencies may be invited to attend as observers, where relevant.

6. The Co-Chairs of the HERA Board may invite relevant stakeholders to attend the HERA Board meetings as observers. Observers shall declare their interest ahead of each meeting.

7. The HERA Board shall adopt its rules of procedure, including regarding election of a Co-Chair and voting procedures.

8. List of members and alternates, rules of procedure, agendas and minutes shall be made available on the Authority's website.

(7) the following Article 17b is inserted:

Article 17b

Tasks of the HERA Board

The HERA Board shall:

(a) Adopt the multiannual strategic planning for the Health Emergency Preparedness and Response Authority;

(b) Adopt strategic decisions concerning HERA on research and innovation and industrial strategy in the area of antimicrobials and medical countermeasures;

(c) Adopting a long-term European portfolio or research and development projects in line with public health priorities set by the Commission in consultation with the World Health Organisation;

(d) Ensure scientific and technical

management of HERA;

(e) Assess the performance of the tasks entrusted to HERA;

(f) Contribute to the coherence of Union's crisis preparedness and response management;

(g) Contribute to the coordinated action by the Commission and the Member States for the implementation of the cross-border health threats regulation;

(h) Contribute to the implementation of the EU's Global Health Strategy, in particular in relations of addressing current and emerging health threats;

(i) Adopt of opinions and guidance, including on specific response measures for the Member States for the prevention and control of serious cross-border threats to health, including antimicrobial resistance;

(j) Adopt proposals for the annual budget of HERA and the monitoring of its implementation.

(9) Article 19 is replaced by the following:

'Article 19

Transparency and Conflict of Interest

1. Members of the Management Board, Members of the HERA Board, members of the scientific panels, members of the Advisory Committee, Executive Director and staff shall undertake to act in the public interest and in an independent manner. They shall not have any direct or indirect financial or other interests in the pharmaceutical or other medical industry which could affect their impartiality. These persons shall make an annual declaration of their financial interests and update them annually and whenever necessary. The declaration shall be made available upon request.

2. The Centre's and Authority's code of conducts shall provide for the implementation of this Article.

3. The Centre and the Authority shall make available the rules of procedure, agendas, minutes and members of the structures referred to in paragraph 1 and their declarations of interest on their website.

4. Stakeholders invited to meetings at the

Centre and the Authority shall declare their interest ahead of the meeting'.

Proposal for a regulation
Recital 78 a (new)

Text proposed by the Commission	*Amendment*
	(78 a) To effectively address major ongoing and upcoming public health challenges, including in particular antimicrobial resistance, while also building on existing resources, the Health Emergency Preparedness and Response Authority (HERA) should be established as a separate structure under the legal personality of the European Centre for Disease Prevention and Control (ECDC). The Authority should be responsible for creating, coordinating and implementing the long-term European portfolio of biomedical research and development agenda for medical countermeasures against current and emerging public health threats, as well as providing tools to ensure EU-wide access to these products, including those to support production, procurement, stockpiling and distribution capacity of medical countermeasures and other priority medical products in the EU. The Authority will play a crucial role in addressing health threats globally. The Authority should primarily focus on the fight against most urgent health threats, including antimicrobial resistance and medicine shortages. However, in the future with increasing capacity, the Authority should expand the scope of its agenda, specifically to tackle other areas of unmet medical need such as rare and neglected diseases. The Authority should have adequate resources to fulfil its mandate.

COMPROMISE AMENDMENT 57 - RECITALS
replacing amendments 1-10; 13;14; 21-26; 28; 29; 202-325; 337-339; 341; 343-348; 381-441; 456-461; 465-515 (all AMs related to Recitals except those concerning AMR; HERA and Sandbox); ITRE 1-16; 20-26; ITRE 31, ITRE 33-39

supported by
EPP, S&D, RE, Greens, Left

Proposal for a regulation
Recital -1 (new)

Text proposed by the Commission	*Amendment*
	(-1) Ensuring that patients receive the medicines they need, when they need them, regardless of where they live in the Union, is a central objective of the European Health Union. Ensuring the competitiveness of the European pharmaceutical industry, whilst providing better availability of medicines and more equal and timely access for patients, is a key deliverable of the proposed EU pharmaceutical reform.

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1 a) This Regulation should contribute to the implementation of the One Health Approach, stressing the well-established interconnectedness between human, animal, and ecosystem health and the need to include those three dimensions when addressing public health threats. Environmental stress and degradation, including biodiversity loss, contribute to the transmission of diseases between, and diseases burdens of, humans and animals. In addition, pollution from active pharmaceutical ingredients negatively affects the quality of waters and ecosystems, proliferates antimicrobial resistance, posing risks to public health globally.

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) The Pharmaceutical Strategy for Europe marks a turning point with the addition	(2) The Pharmaceutical Strategy for Europe marks a turning point with the addition

of further key objectives and by ***creating*** a modern framework that makes innovative and established medicinal products available to patients and healthcare systems at affordable prices**,** while ensuring security of supply and addressing environmental concerns.	of further key objectives and by ***aiming to create an attractive environment for research, development and production of medicines in the Union, along with*** a modern framework that makes innovative and established medicinal products available to patients and healthcare systems at affordable prices, while ***strengthening the fight against shortages of medicinal products and*** ensuring security of supply and addressing environmental concerns.
	[1 a] OJ C 385, 22.9.2021, p. 83.

Proposal for a regulation
Recital 2 b (new)

Text proposed by the Commission	*Amendment*
	(2 b) To supplement the measures to address shortages of medicines, the Commission's communication published on 24 October 2023 aims to address critical shortages of medicines and strengthen security of supply in the Union , by among other things, introducing the launch of a European voluntary solidarity mechanism for medicines allowing Member States to redistribute their available stock in the event of shortages[1 aa].
	[1 aa] Commission communication 'Addressing medicine shortages in the EU' (COM (2023) 672)

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(3) Addressing unequal patient access of medicinal products has become a key priority of the Pharmaceutical Strategy for Europe as has been highlighted by the Council and the European Parliament. Member States have called for revised mechanisms and incentives for development of medicinal products tailored to the level of unmet medical need, while ensuring patient access and availability of medicinal products in all Member States.	(3) Addressing unequal patient access of medicinal products has become a key priority of the Pharmaceutical Strategy for Europe as has been highlighted by the Council and the European Parliament. Member States ***and the Parliament*** have called for revised mechanisms and incentives for development of medicinal products tailored to the level of unmet medical need, while ensuring ***transparency of process,*** patient access and availability ***as well as affordability*** of

medicinal products in all Member States.

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) Previous amendments to the Union pharmaceutical legislation have addressed access to medicinal products by providing for accelerated assessment for marketing authorisation applications or by allowing conditional marketing authorisation for medicinal products for unmet medical need. While these measures accelerated the authorisation of innovative and promising therapies, these medicinal products do not always reach the patient and patients in the Union still have different levels of access to medicines.	(4) Previous amendments to the Union pharmaceutical legislation have addressed access to medicinal products by providing for accelerated assessment for marketing authorisation applications or by allowing conditional marketing authorisation for medicinal products for unmet medical need. While these measures accelerated the authorisation of innovative and promising therapies ***in some areas, and there still exist many unaddressed public health priorities***, these medicinal products do not always reach the patient and patients in the Union still have different levels of access to medicines.

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(5) The COVID-19 pandemic ***has spotlighted*** critical issues which require a reform of the Union pharmaceuticals framework to strengthen its resilience and to ensure that it serves the people under all circumstances.	(5) The COVID-19 pandemic ***further underlined*** critical issues***,*** which require a reform of the Union pharmaceuticals framework to strengthen its resilience, ***while improving availability of medicinal products*** and to ensure that it ***corresponds to public health needs and*** serves the people under all circumstances.
	(5a) The COVID-19 pandemic also highlighted disparities in terms of, capacity of health systems,national immunisation infrastructures, shortagesand preparation. In addition to the measures in this Regulation, Member States should strengthen their national immunisation programmes, ensuring a proper protection of their population against infectious diseases and strengthening pandemic preparedness and response.

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*

(6) ***For the sake of clarity,*** it is necessary to replace Regulation (EC) No 726/2004 of the European Parliament and of the Council[38] with a new Regulation.

(6) It is ***therefore*** necessary to replace Regulation (EC) No 726/2004 of the European Parliament and of the Council[38] with a new Regulation.

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[38] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

[38] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

Proposal for a regulation
Recital 9

Text proposed by the Commission | *Amendment*

(9) As to the scope of this Regulation, the authorisation of antimicrobials is, ***in principle***, in the interest of patients' health at Union level and therefore it should be made possible to authorise them at Union level.

(9) As to the scope of this Regulation, the authorisation of antimicrobials is, in the interest of patients' health at Union level and therefore it should be made possible to authorise them at Union level.

Proposal for a regulation
Recital 12

Text proposed by the Commission | *Amendment*

(12) The structure and operation of the various bodies making up the Agency should be designed in such a way as to take into account the need to constantly renew scientific expertise, the need for cooperation between Union and national bodies, the need for adequate involvement of civil society, and the future enlargement of the Union. The various bodies of the Agency should establish and develop appropriate contacts with the parties concerned, in particular with representatives of patients and healthcare professionals.

(12) The structure and operation of the various bodies making up the Agency should be designed in such a way as to take into account the need to constantly renew scientific expertise, the need for cooperation between Union and national bodies, the need for adequate involvement of civil society, and the future enlargement of the Union. The various bodies of the Agency should establish and develop appropriate contacts with the parties concerned, in particular with representatives of patients***, consumers*** and healthcare professionals.

Proposal for a regulation
Recital 13

Text proposed by the Commission | *Amendment*

(13) The chief task of the Agency should be to provide Union institutions and Member States with the best possible scientific opinions to enable them to exercise the powers of authorisation and supervision of medicinal

(13) The chief task of the Agency should be to provide Union institutions and Member States with the best possible scientific opinions to enable them to exercise the powers of authorisation and supervision of medicinal

products conferred on them by Union legal acts in the field of medicinal products. Marketing authorisation should be granted by the Commission only after a single scientific evaluation procedure addressing the quality, safety and efficacy of high-technology medicinal products has been conducted by the Agency, applying the highest possible standards.

products conferred on them by Union legal acts in the field of medicinal products. Marketing authorisation should be granted by the Commission only after a single scientific evaluation procedure addressing the quality, safety**,** efficacy of high-technology medicinal products has been conducted by the Agency, applying the highest possible standards ***and the completion of an environmental risk assessment.***

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) The Agency's budget should be composed of fees and charges paid by the private sector and contributions from the Union budget to implement Union policies and contributions paid from third countries.	(15) The Agency's budget should be ***transparent*** composed of fees and charges paid by the private sector and contributions from the Union budget to implement Union policies and contributions paid from third countries. ***Although the majority of its funding comes from fees, the Agency is a public authority. It is of utmost importance to safeguard its integrity and independence in order to maintain public trust in the Union regulatory framework***

Proposal for a regulation
Recital 18 a (new)

Text proposed by the Commission	*Amendment*
	(18 a) The Agency should set transparent criteria for the appointment of patients and healthcare professionals representatives to the Committee for Medicinal Products for Human Use and the Pharmacovigilance Risk Assessment Committee in order to ensure a well-balanced representation of medical specialties and diseases amongst appointed members and alternates, as well as to ensure robust rules on the prevention of conflicts of interests. Declaration of direct or indirect financial or other interests in the pharmaceutical or other medical industry which could affect the impartiality of appointed stakeholders should be an integral part of the selection process and subsequently should be made publicly available.

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) Scientific advice for future applicants seeking a marketing authorisation should be provided more generally and in greater depth. Similarly, structures allowing the development of advice for companies, in particular small and medium-sized enterprises ('SMEs'), should be put in place.	(19) Scientific advice for future applicants seeking a marketing authorisation should be provided more generally and in greater depth ***and should be adapted to the specificities of the medicinal product concerned.*** Similarly, structures allowing the development of advice for companies, in particular small and medium-sized enterprises ('SMEs') ***and not-for-profit entities***, should be put in place. ***The Agency should also promote open and public exchanges about latest scientific developments and updates of scientific guidelines.***

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) Promising medicinal products that have the potential to significantly address patients' unmet medical needs should benefit from early and enhanced scientific support. Such support will ultimately help patients benefit from new therapies as early as possible.	(20) Promising medicinal products and certain combinations products of medicinal products and medical devices, as well as medicinal products in exclusive use with medical devices that have the potential to significantly address patients' unmet medical needs should benefit from early and enhanced scientific support***, including through supporting patient-relevant in vitro and in silico technologies which are key to the development of these products***. Such support will ultimately help patients benefit from new therapies as early as possible.

Proposal for a regulation
Recital 20 a (new)

Text proposed by the Commission	*Amendment*
	(20 a) Next to unmet medical needs already recognised in the pediatric, antimicrobial, oncological, rare, and neurodegenerative diseases, attention should also be given to unmet medical in the mental health sphere and treatments therein.

Proposal for a regulation
Recital 21 a (new)

Text proposed by the Commission	*Amendment*
	(21 a) Based on the Ombudsman's decision in the strategic inquiry on how the European Medicines Agency engages with medicine developers in the period leading up to applications for authorisations to market new medicines in the EU[1a], the Agency should enhance transparency of scientific advice. In addition, staff and experts from national competent authorities providing scientific advice should to the extent possible not be involved in a subsequent evaluation of marketing authorisation application for the same products. However, in duly justified cases, such as where the indication of medicinal product concerns a rare disease, that expert should be able to be the same, provided that this is duly documented.
	[1a] European Ombudsman's Decision in strategic inquiry OI/7/2017/KR on how the European Medicines Agency engages with medicine developers in the period leading up to applications for authorizations to market new medicines in the EU, July 2019.

Proposal for a regulation
Recital 25

Text proposed by the Commission	*Amendment*
(25) In certain cases, shortcomings in Member States' system of supervision and related enforcement activities could risk to substantially hinder the achievement of the objectives of this Regulation and those of revised Directive 2001/83/EC which could even lead to the emergence of risks to public health. To address these challenges, harmonised inspection standards should be ensured through the establishment of a joint audit programme within the Agency. This joint audit programme will also further harmonise the interpretation of good manufacturing and distribution practices on the basis of Union legislative requirements. Moreover, it will support further mutual recognition of inspection outcomes between Member States and with strategic partners. Within the joint audit programme, the competent authorities are subject to regular audits conducted by other	(25) In certain cases, shortcomings in Member States' system of supervision and related enforcement activities could risk to substantially hinder the achievement of the objectives of this Regulation and those of revised Directive 2001/83/EC which could even lead to the emergence of risks to public health ***or to environment***. To address these challenges, harmonised inspection standards should be ensured through the establishment of a joint audit programme within the Agency. This joint audit programme will also further harmonise the interpretation of good manufacturing and distribution practices on the basis of Union legislative requirements. Moreover, it will support further mutual recognition of inspection outcomes between Member States and with strategic partners. Within the joint audit programme, the competent authorities are subject to regular

Member States to maintain an equivalent and harmonised quality system and to ensure an appropriate implementation of relevant good manufacturing and distribution practices into national laws and equivalence with other EEA inspectorates.	audits conducted by other Member States to maintain an equivalent and harmonised quality system and to ensure an appropriate implementation of relevant good manufacturing and distribution practices into national laws and equivalence with other EEA inspectorates.

Proposal for a regulation
Recital 26 a (new)

Text proposed by the Commission	*Amendment*
	(26 a) Pharmaceutical research plays a decisive role in the continuing improvement in public health and in ensuring the Union's competitiveness. Medicinal products, in particular those that are the result of long, costly research will not continue to be developed in the Union unless they are covered by favourable rules that provide for sufficient protection to encourage such research. However, it is difficult to establish a direct link between such favourable rules and Union competitiveness because while such rules make Union markets more attractive, medicines' geographical origin and authorised medicines from third countries are equally eligible to receive all Union incentives, just as Union-based innovative companies can equally benefit from incentives in third countries.

Proposal for a regulation
Recital 29

Text proposed by the Commission	*Amendment*
(29) Legal entities that are not engaged in an economic activity such as universities, public bodies, research centres or not-for-profit organisations, represent an important source of innovation and should also benefit from this support scheme. Whereas it should be possible to take account of the particular situation of these entities on an individual basis, such support can best be achieved by means of a dedicated support scheme, including administrative support and through the reduction, deferral and waiver of fees.	(29) Legal entities that are not engaged in an economic activity such as universities, public bodies, research centres or not-for-profit organisations, represent an important source of ***research in unmet medical needs, research in different subpopulations, repurposing, optimisation and*** of innovation and should also benefit from this support scheme. Whereas it should be possible to take account of the particular situation of these entities on an individual basis, such support can best be achieved by means of a dedicated support scheme, including administrative support and through the reduction, deferral and waiver of

fees.

Proposal for a regulation
Recital 30

Text proposed by the Commission	*Amendment*
(30) The Agency should be empowered to give scientific recommendations on whether a product under development, which could potentially fall under the mandatory scope of the centralised procedure, meets the scientific criteria to be a medicinal product. Such an advisory mechanism would address, as early as possible, questions related to borderline cases with other areas such as substances of human origin, cosmetics or medical devices, which may arise as science develops. To ensure that recommendations given by the Agency take into account the views of equivalent advisory mechanisms in other legal frameworks, the Agency should consult the relevant advisory or regulatory bodies.	(30) The Agency should be empowered to give scientific recommendations on whether a product under development, which could potentially fall under the mandatory scope of the centralised procedure, meets the scientific criteria to be a medicinal product. Such an advisory mechanism would address, as early as possible, questions related to borderline cases with other areas such as ***in particular*** substances of human origin, cosmetics or medical devices, which may arise as science develops. To ensure that recommendations given by the Agency take into account the views of equivalent advisory mechanisms in other legal frameworks, the Agency should consult the relevant advisory or regulatory bodies. ***Where there is a doubt about the regulatory status of a particular product under development, which could potentially fall under the mandatory scope of the centralised procedure, meets the scientific criteria to be a medicinal product, the Agency and the relevant advisory bodies responsible for other regulatory frameworks, namely medical devices and substances of human origin should engage in consultations. In such cases, the compendium referred to in Regulation (EU) No [reference to be added after adoption cf. COM(2022)338 final] should be consulted, where relevant. If after consulting the compendium, there remains doubt about the regulatory status the relevant bodies should further consult to determine the regulatory status. The Commission should facilitate the cooperation between the Agency and advisory bodies established by other Union legislation. The opinions and the recommendations of the Agency and the relevant advisory bodies on the regulatory status of the product should be made publicly available after the consultations have taken place.***

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*

(31) To increase transparency of scientific assessments and all other activities, a European medicines web-portal should be created and maintained by the Agency.	(31) To increase transparency of scientific assessments and all other activities, a ***user-friendly*** European medicines web-portal should be created and maintained by the Agency. ***The portal should provide information for all centrally authorised medicinal products, inter alia on safety, efficacy, environmental risk, patient populations, and where relevant information on antimicrobial resistance, shortages, pending obligations for marketing authorisation holders. Sufficient budget should be allocated to the Agency to ensure appropriate implementation of its transparency obligations and commitments.***

Proposal for a regulation
Recital 31(a)

Text proposed by the Commission	*Amendment*
...	***The Union Register of Medicinal products lists all medicinal products for human and veterinary use as well as orphan medicinal products that have received a marketing authorisation by the Commission through the centralised procedure. The information provided in the Register can be used to search for pertinent information on the medicinal product in question, including he active substance, the international non-proprietary name, the anatomical therapeutic chemical (ATC) the indications of the product, information on the authorisation and any post authorisation requirements as well as applicable regulatory protection periods.***

Proposal for a regulation
Recital 33

Text proposed by the Commission	*Amendment*
(33) To optimise the functioning and efficiency of the regulatory system, the structure of the Agency's scientific committees is simplified and reduced to two main Committees for medicinal products for human use, the Committee for Medicinal Products for Human Use (CHMP) and Pharmacovigilance	(33) To optimise the functioning and efficiency of the regulatory system, the structure of the Agency's scientific committees is simplified and reduced to two main Committees for medicinal products for human use, the Committee for Medicinal Products for Human Use (CHMP) and Pharmacovigilance

Risk Assessment Committee (PRAC)**.**	Risk Assessment Committee (PRAC).

Proposal for a regulation
Recital 33a (new)

Text proposed by the Commission	*Amendment*
	(33a) To ensure the adequate expertise and evaluation of the environmental risk assessments of pharmaceutical substances, the Agency should establish a new ad-hoc Environmental Risk Assessment working party. This working party should be involved in the process where necessary depending on the application. The working party will have the scientific knowledge to characterise and assess the risks and their mitigation measures related to themanufacture,, use and disposal of medicinal products The working party should contribute towards the implementation of the One Health Approach and closing the gap between pharmaceutical and environmental assessment.

Proposal for a regulation
Recital 34

Text proposed by the Commission	*Amendment*
(34) The simplification of procedures should not have an impact on standards or the quality of scientific evaluation of the medicinal products to guarantee the quality, safety and efficacy of medicinal products. It should also allow for the reduction of the scientific evaluation period from 210 days to 180 days.	(34) The simplification of procedures should not have an impact on standards or the quality of scientific evaluation of the medicinal products to guarantee the quality, safety and efficacy of medicinal products. It should also allow for the reduction of the scientific evaluation period from 210 days to 180 days.

Proposal for a regulation
Recital 35

Text proposed by the Commission	*Amendment*
(35) The Agency's scientific committees should be ***able to delegate some of*** their evaluation duties ***to*** working parties which should be open to experts from the scientific world and appointed for this purpose, whilst retaining complete responsibility for the scientific opinions issued by them.	(35) The Agency's scientific committees should be ***supported, for*** their evaluation duties ***by*** working parties which should be open to experts from the scientific world and appointed for this purpose whilst retaining complete responsibility for the scientific opinions issued by them.

Proposal for a regulation
Recital 36

(36) The expertise of the Committee for	(36) The expertise of the Committee for

Advanced Therapies (CAT), the Committee for Orphan Medicinal Products (COMP), the Paediatric Committee (PDCO) and Committee for Herbal Medicinal Products (HMPC) is retained through working groups, working parties and a pool of experts who are organised based on different domains and who are giving input to the CHMP and PRAC. The CHMP and PRAC consists of experts from all Member States while working parties consist in majority of experts appointed by the Member States, based on their expertise, and of external experts. The model of rapporteurs remains unchanged. Representation of patients and health care professionals, with expertise in all areas, including rare and paediatric diseases, is increased at the CHMP and PRAC, in addition to the dedicated working groups representing patients and health care professionals.

Advanced Therapies (CAT), the Committee for Orphan Medicinal Products (COMP), the Paediatric Committee (PDCO) and Committee for Herbal Medicinal Products (HMPC) is retained through working groups, working parties, ***ad-hoc working groups***, and a pool of experts who are organised based on different domains and who are giving input to the CHMP and PRAC. ***Their evaluation will continue to encompass all the necessary expertise for each product as part of the rapporteur teams, with the possibility for CHMP and PRAC to call upon additional scientific experts to provide specific input and advice on specific aspects raised during the evaluation. In addition, patients and healthcare professionals will be part of the pool of experts and will also be brought into EMA's work according to their expertise in a certain disease area.*** The CHMP and PRAC consists of experts from all Member States while working parties ***and expert groups*** consist in majority of experts appointed by the Member States, based on their expertise, and of external experts. The model of rapporteurs remains unchanged. Representation of patients***, their caregivers*** and health care professionals, with expertise in all areas, including rare and paediatric diseases, is increased at the CHMP and PRAC, in addition to the dedicated working groups representing patients and health care professionals. ***Information regarding the composition and work of the committees and working groups should be publically available.***

Proposal for a regulation
Recital 37

Text proposed by the Commission	*Amendment*
(37) Scientific committees like the CAT have been instrumental to ensure expertise and capacity building in an emerging technological field. However, after more than 15 years, advanced therapy medicinal products are now more common. The full integration of their assessment in the work of the CHMP will facilitate the assessment of medicinal products within the same therapeutic class, independent of the technology on which they are based. It will also ensure that all biological medicinal products are assessed by the same committee.	(37) Scientific committees like the CAT have been instrumental to ensure expertise and capacity building in an emerging technological field. However, after more than 15 years, advanced therapy medicinal products are now more common. The full integration of their assessment in the work of the CHMP will facilitate the assessment of medicinal products within the same therapeutic class, independent of the technology on which they are based. It will also ensure that all biological medicinal products are assessed by the same committee.

Proposal for a regulation
Recital 39

Text proposed by the Commission	*Amendment*
(39) To allow for a more informative decision making and for exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency regarding medicinal products for human use, in particular to scientific guidelines on unmet medical needs and the design of clinical trials, or other studies and the generation of evidence along the life cycle of medicinal product, the Agency should be able to have recourse to a consultation process of authorities or bodies active along the life cycle of medicinal products. These authorities could be, as appropriate, representatives from Heads of Medicines Agencies, the Clinical Trial Coordination and Advisory Group, the SoHO Coordination Board, the Coordination Group on Health Technology Assessment, Medical Devices Coordination Group, medical devices national competent authorities, national competent authorities for pricing and reimbursement of medicines, national insurance funds or healthcare payers. The Agency should also be able to extend the consultation mechanism to consumers, patients, healthcare professionals, industry, associations representing payers, or other stakeholders, as relevant.	(39) To allow for a more informative decision making and for exchange of information and pooling of knowledge on general issues of scientific or technical nature related to the tasks of the Agency regarding medicinal products for human use, in particular to scientific guidelines on unmet medical needs and the design of clinical trials, or other studies and the generation of evidence along the life cycle of medicinal product, the Agency should be able to have recourse to a consultation process of authorities or bodies active along the life cycle of medicinal products. ***Additionally, to improve regulatory certainty and cross-sectoral cooperation the Commission should on an annual basis, or more frequently where deemed necessary, organise joint meetings with the advisory bodies established in other Union legislation to assess emerging trends and questions on regulatory status of products and find agreement on common regulatory status principles***. These authorities could be, as appropriate, representatives from Heads of Medicines Agencies, the Clinical Trial Coordination and Advisory Group, the SoHO Coordination Board, the Coordination Group on Health Technology Assessment, Medical Devices Coordination Group, medical devices national competent authorities, national competent authorities for pricing and reimbursement of medicines, national insurance funds or healthcare payers. The Agency should also be able to extend the consultation mechanism to consumers, patients ***and their caregivers***, healthcare professionals***, academia***, industry, associations representing payers, or other stakeholders, as relevant.

Proposal for a regulation
Recital 40

Text proposed by the Commission	*Amendment*
(40) Member States should ensure adequate funding of competent authorities to carry out their tasks under this Regulation and under [revised Directive 2001/83/EC]. In addition, in	(40) Member States should ensure adequate funding of competent authorities to carry out their tasks under this Regulation and under [revised Directive 2001/83/EC]. In addition, in

line with the Joint Statement of the European Parliament, the Council of the EU and the European Commission on decentralised agencies[48] , Member States should ensure adequate resources are assigned by the competent authorities of the Member States for the purpose of their contributions to the work of the Agency, taking into account the cost-based remuneration they receive from the Agency.

line with the Joint Statement of the European Parliament, the Council of the EU and the European Commission on decentralised agencies[48] , Member States should ensure adequate resources are assigned by the competent authorities of the Member States for the purpose of their contributions to the work of the Agency, taking into account the cost-based remuneration they receive from the Agency.

Proposal for a regulation
Recital 43

Text proposed by the Commission	*Amendment*
(43) In the interest of public health, marketing authorisation decisions under the centralised procedure should be taken on the basis of the objective scientific criteria of quality, safety and efficacy of the medicinal product concerned, to the exclusion of economic and other considerations. However, Member States should be able, exceptionally, to prohibit the use in their territory of medicinal products for human use.	(43) In the interest of public health, marketing authorisation decisions under the centralised procedure should be taken on the basis of the objective scientific criteria of quality, safety and efficacy of the medicinal product concerned, to the exclusion of economic and other considerations. However, Member States should be able, exceptionally, to prohibit the use in their territory of medicinal products for human use. ***Member States should provide justification for such prohibition of use to the Commission and the Agency.***

Proposal for a regulation
Recital 43 a (new)

Text proposed by the Commission	*Amendment*
	(43 a) The Union is required, pursuant to Article 208 of the Treaty on the Functioning of the European Union, to take account of development objectives in policies that are likely to have an impact on low- and middle-income countries. Union Pharmaceutical legislation has a role to play in the realisation of global public health objectives by promoting the development of efficacious, safe, accessible, and affordable innovations for antimicrobial resistance, poverty-related, emerging and re-emerging health threats, and neglected diseases, and other conditions of global public health interest. The Commission should continue to encourage research, development and innovation in areas of major global health interest, in line with its international commitments.

Proposal for a regulation
Recital 44

Text proposed by the Commission	*Amendment*
(44) The quality, safety and efficacy criteria of [revised Directive 2001/83/EC] should apply to medicinal products authorised by the Union under the centralised procedure. The benefit-risk balance of all medicinal products will be assessed when they are placed on the market, and at any other time the competent authority deems appropriate.	(44) The quality, safety and efficacy criteria of [revised Directive 2001/83/EC] should apply to medicinal products authorised by the Union under the centralised procedure. The benefit-risk balance of all medicinal products will be assessed when they are placed on the market, and at any other time the competent authority deems appropriate.

Proposal for a regulation
Recital 45

Text proposed by the Commission	*Amendment*
(45) Marketing authorisation applications, like any other application submitted to the Agency, should follow the digital by default principle and hence be sent to the Agency in electronic form. Applications should be assessed based on the file submitted by the applicant in accordance with the different legal basis provided by [revised Directive 2001/83/EC]. At the same time, the Agency and the relevant committees may take into account any information that is in its possession. Applicants shall be requested to generally submit raw data, in particular with regard to the clinical trials performed by the applicant in order to ensure a full assessment of the quality, safety and efficacy of the medicinal product.	(45) Marketing authorisation applications, like any other application submitted to the Agency, should follow the digital by default principle and hence be sent to the Agency in electronic form. Applications should be assessed based on the file submitted by the applicant in accordance with the different legal basis provided by [revised Directive 2001/83/EC]. At the same time, the Agency and the relevant committees may take into account any information that is in its possession. Applicants shall be requested to generally submit raw data, in particular with regard to the clinical trials performed by the applicant in order to ensure a full assessment of the quality, safety and efficacy of the medicinal product.

Proposal for a regulation
Recital 45 a (new)

Text proposed by the Commission	*Amendment*
	(45 a) The Agency should pay particular attention to the composition of clinical trials to ensure gender based equity and comprehensive clinical data.

Proposal for a regulation
Recital 46

Text proposed by the Commission	*Amendment*
(46) Directive 2010/63/EU of the European Parliament and of the Council on the protection	(46) Directive 2010/63/EU of the European Parliament and of the Council on the protection

of animals used for scientific purposes[49] lays down provisions on the protection of animals used for scientific purposes based on the principles of replacement, reduction and refinement. Any study involving the use of live animals, which provides essential information on the quality, safety and efficacy of a medicinal product, should take into account those principles of replacement, reduction and refinement, where they concern the care and use of live animals for scientific purposes, and should be optimised in order to provide the most satisfactory results whilst using the minimum number of animals. The procedures of such testing should be designed to avoid causing pain, suffering, distress or lasting harm to animals and should follow the available Agency and the International Committee for Harmonisation (ICH) guidelines. In particular, the marketing authorisation applicant and the marketing authorisation holder should take into account the principles laid down in Directive 2010/63/EU, including, where possible, use of new approach methodologies in place of animal testing. These can include but are not limited to: in vitro models, such as microphysiological systems including organ-on-chips, (2D and 3D) cell culture models, organoids and human stem cells-based models; in silico tools or read-across models.

[49] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

of animals used for scientific purposes[49] lays down provisions on the protection of animals used for scientific purposes based on the principles of replacement, reduction and refinement. Any study involving the use of live animals, which provides essential information on the quality, safety and efficacy of a medicinal product, should take into account those principles of replacement, reduction and refinement, where they concern the care and use of live animals for scientific purposes, and should be optimised in order to provide the most satisfactory results whilst using the minimum number of animals. The procedures of such testing should be ***only used as necessary*** and ***be*** designed to avoid causing pain, suffering, distress or lasting harm to animals and should follow the available Agency and the International Committee for Harmonisation (ICH) guidelines. In particular, the marketing authorisation applicant and the marketing authorisation holder should take into account the principles laid down in Directive 2010/63/EU, ***giving priority to*** new approach methodologies ***(NAMs)*** in place of animal testing. These can include but are not limited to: in vitro models, such as microphysiological systems including organ-on-chips, (2D and 3D) cell culture models, organoids and human stem cells-based models; in silico *tools****. in chemico technologies and any combination thereof*** *or read-across****, aquatic egg*** *models* ***as well as invertebrate species****.* ***Ultimately, efforts should be made to fully replace procedures on live animals for scientific purposes****.* ***The Agency should in its annual report highlight key observations and best practices in the replacement, reduction and refinement of animal testing submitted by applicants.***

[49] Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).

Proposal for a regulation
Recital 47

Text proposed by the Commission	*Amendment*
(47) Procedures should be in place to facilitate joint animal testing, wherever possible, in order to avoid unnecessary	(47) Procedures should be in place to facilitate joint animal testing, wherever possible, in order to avoid unnecessary testing

duplication of testing using live animals covered by Directive 2010/63/EU. Marketing authorisation applicants and marketing authorisation holders should make all efforts to reuse animal study results and make the results obtained from animal studies publicly available. For abridged applications marketing authorisation applicants should refer to the relevant studies conducted for the reference medicinal product.

using live animals covered by Directive 2010/63/EU. Marketing authorisation applicants and marketing authorisation holders should make all efforts to reuse animal study results and make the results obtained from animal studies publicly available. For abridged applications marketing authorisation applicants should refer to the relevant studies conducted for the reference medicinal product.

Proposal for a regulation
Recital 48

Text proposed by the Commission	*Amendment*
(48) The summary of product characteristics and the package leaflet should reflect the assessment of the Agency and be part of its scientific opinion. The opinion may recommend certain conditions that should be part of the marketing authorisation, for example on the safe and efficacious use of the medicinal product or on post-authorisation obligations that have to be complied with by the marketing authorisation holder. Those conditions may include the requirement to conduct post-authorisation safety or efficacy studies or other studies that are considered necessary to optimise the treatment, for example where the proposed dose scheme by the applicant, whilst acceptable and justifying a positive benefit-risk balance, could be further optimised post-authorisation. Where the applicant disagrees with parts of the opinion, the applicant may request its re-examination.	(48) The summary of product characteristics and the package leaflet should reflect the assessment of the Agency and be part of its scientific opinion. The opinion may recommend certain conditions that should be part of the marketing authorisation, for example on the safe and efficacious use of the medicinal product or on post-authorisation obligations that have to be complied with by the marketing authorisation holder. Those conditions may include the requirement to conduct post-authorisation safety or efficacy studies or other studies that are considered necessary to optimise the treatment, for example where the proposed dose scheme by the applicant, whilst acceptable and justifying a positive benefit-risk balance, could be further optimised post-authorisation. Where the applicant disagrees with parts of the opinion, the applicant may request its re-examination.

Proposal for a regulation
Recital 49

Text proposed by the Commission	*Amendment*
(49) Due to the need to reduce overall approval times for medicinal products, the time between the opinion of the Committee for Medicinal Products for Human Use (CHMP) and the final decision on the application for a marketing authorisation should in principle be no longer than 46 days.	(49) Due to the need to reduce overall approval times for medicinal products, the time between the opinion of the Committee for Medicinal Products for Human Use (CHMP) and the final decision on the application for a marketing authorisation should in principle be no longer than 46 days.

Proposal for a regulation
Recital 51

Text proposed by the Commission	*Amendment*
(51) As a general rule a marketing authorisation should be granted for an unlimited time; however, one renewal may be decided only on justified grounds related to the safety of the medicinal product.	(51) As a general rule a marketing authorisation should be granted for an unlimited time; however, one renewal may be decided only on justified grounds related to the safety of the medicinal product.

Proposal for a regulation
Recital 51 a (new)

Text proposed by the Commission	*Amendment*
	(51 a) As a matter of good practice, marketing authorisation should be granted based on comparative clinical trials on patients who are representative of the population to be treated with the product. In addition, patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) should be an integral part of clinical data submitted with the marketing authorisation application in order to assess the quality of care and the impact of the treatments on patients.

Proposal for a regulation
Recital 53

Text proposed by the Commission	*Amendment*
(53) Environmental risks may arise from medicinal products containing or consisting of genetically modified organisms. It is thus necessary to subject such medicinal products to an environmental risk-assessment procedure similar to the procedure under Directive 2001/18/EC of the European Parliament and of the Council[51] , to be conducted in parallel with the evaluation, under a single Union procedure, of the quality, safety and efficacy of the medicinal product concerned. The environmental risk-assessment should be conducted in accordance with the requirements set out in this Regulation and in [revised Directive 2001/83/EC] which are based on the principles set out in Directive 2001/18/EC but taking into account the specificities of medicinal products.	(53) Environmental risks may arise from medicinal products containing or consisting of genetically modified organisms. It is thus necessary to subject such medicinal products to an environmental risk-assessment procedure similar to the procedure under Directive 2001/18/EC of the European Parliament and of the Council[51] , to be conducted in parallel with the evaluation, under a single Union procedure, of the quality, safety and efficacy of the medicinal product concerned. The environmental risk-assessment should be conducted in accordance with the requirements set out in this Regulation and in [revised Directive 2001/83/EC] which are based on the principles set out in Directive 2001/18/EC but taking into account the specificities of medicinal products.

Proposal for a regulation

Recital 53 a (new)

Text proposed by the Commission	*Amendment*
	(53 a) Several care pathways should be explored to make therapies available in all Member States, including by advancing provisions for access to cross border care such as Directive 2011/24/EU and Regulation (EC) No 883/2004. This is particularly important for the advanced therapy medicinal products (ATMPs), as their unique characteristics result in significant infrastructural complexities and system barriers, which can substantially limit their continuously supply.

Proposal for a regulation
Recital 54

Text proposed by the Commission	*Amendment*
(54) [revised Directive 2001/83/EC] permits Member States to temporarily allow the use and supply of unauthorised medicinal products for public health reasons or individual patient needs and that includes medicinal products to be authorised under this Regulation. It is also necessary, that Member States are allowed under this Regulation to make a medicinal product available for compassionate use prior to its marketing authorisation. In those exceptional and urgent situations, where there is a lack of a suitable authorised medicinal product, the need to protect public health or the health of individual patients must prevail over other considerations, in particular the need to obtain a marketing authorisation and consequently, to have available complete information about the risks posed by the medicinal product, including any risks to the environment from medicinal products containing or consisting of genetically modified organisms (GMOs). To avoid delays in making these products available or uncertainties as regards their status in certain Member States, it is appropriate, in those exceptional and urgent situations, that for a medicinal product containing or consisting of GMOs, an environmental risk assessment or consent in accordance with Directive 2001/18/EC or Directive 2009/41/EC of the	(54) [revised Directive 2001/83/EC] permits Member States to temporarily allow the use and supply of unauthorised medicinal products for public health reasons or individual patient needs and that includes medicinal products to be authorised under this Regulation. It is also necessary, that Member States are allowed under this Regulation to make a medicinal product available for compassionate use prior to its marketing authorisation. In those exceptional and urgent situations, where there is a lack of a suitable authorised medicinal product, the need to protect public health or the health of individual patients must prevail over other considerations, in particular the need to obtain a marketing authorisation and consequently, to have available complete information about the risks posed by the medicinal product, including any risks to the environment from medicinal products containing or consisting of genetically modified organisms (GMOs). To avoid delays in making these products available or uncertainties as regards their status in certain Member States, it is appropriate, in those exceptional and urgent situations, that for a medicinal product containing or consisting of GMOs, an environmental risk assessment or consent in accordance with Directive 2001/18/EC or Directive 2009/41/EC of the

European Parliament and of the Council[52] should not be a prerequisite. Nevertheless, in these cases, Member States should implement appropriate measures to minimise foreseeable negative environmental impacts resulting from the intended or unintended release of the medicinal products containing or consisting of GMOs into the environment.

European Parliament and of the Council[52] should not be a prerequisite. Nevertheless, in these cases, Member States should implement appropriate measures ***in line with the precautionary principle*** to minimise foreseeable negative environmental impacts resulting from the intended or unintended release of the medicinal products containing or consisting of GMOs into the environment ***and agree on an appropriate timeline for the delivery of the environmental risk data***.

Proposal for a regulation
Recital 57 a (new)

Text proposed by the Commission	*Amendment*
	(57 a) Given the underserved needs in the area of mental health, the revision should contribute to the increased access to treatments, and the development of novel treatments, for patients who need them most.

Proposal for a regulation
Recital 57 b (new)

Text proposed by the Commission	*Amendment*
	(57 b) The Commission should support the use of early access pilot programs to treat patients with complex comorbidities, including physical and mental health conditions who are often excluded from clinical trials. Allowing this would support evidence gathering on the safety and efficacy of these treatments o. These programs should provide treatment experience for healthcare providers and generating valuable real-world data to inform future authorisations of these treatments.

Proposal for a regulation
Recital 58

Text proposed by the Commission	*Amendment*
(58) There is the possibility under certain circumstances for marketing authorisations to be granted, subject to specific obligations or conditions, on a conditional basis or under exceptional circumstances. The legislation	(58) There is the possibility under certain ***duly justified*** circumstances for marketing authorisations to be granted, subject to specific obligations or conditions, on a conditional basis or under exceptional circumstances. The

should allow under similar circumstances for medicinal products with a standard marketing authorisation for new indications to be authorised on a conditional basis or under exceptional circumstances. The medicinal products authorised on a conditional basis or under exceptional circumstances should in principle satisfy the requirements for a standard marketing authorisation with the exception of the specific derogations or conditions outlined in the relevant conditional or exceptional marketing authorisation and shall be subject to specific review of the fulfilment of the imposed specific conditions or obligations. It is also understood that the grounds for refusal of a marketing authorisation shall apply mutatis mutandis for such cases.

legislation should allow under similar circumstances for medicinal products with a standard marketing authorisation for new indications to be authorised on a conditional basis or under exceptional circumstances. The medicinal products authorised on a conditional basis or under exceptional circumstances should in principle satisfy the requirements for a standard marketing authorisation with the exception of the specific derogations or conditions outlined in the relevant conditional or exceptional marketing authorisation and shall be subject to specific review of the fulfilment of the imposed specific conditions or obligations. It is also understood that the grounds for refusal of a marketing authorisation shall apply mutatis mutandis for such cases.

Proposal for a regulation
Recital 60

Text proposed by the Commission	*Amendment*
(60) Regulatory decision-making on the development, authorisation and supervision of medicinal products may be supported by access and analysis of health data, including real world data, where appropriate, i.e. health data generated outside of clinical studies. The Agency should be able to use such data, including via the Data Analysis and Real World Interrogation Network (DARWIN) and the European Health Data Space interoperable infrastructure. Through these capabilities the Agency may take advantage of all the potential of supercomputing, artificial intelligence and big data science to fulfil its mandate, without compromising privacy rights. Where necessary the Agency may cooperate with the competent authorities of the Member States towards this objective.	(60) Regulatory decision-making on the development, authorisation and supervision of medicinal products may be supported by access and analysis of health data, including real world data, where appropriate, i.e. health data generated outside of clinical studies***, and/or data generated via in silico methods, such as computational modelling and simulation, digital molecular representation and mechanistic modelling, digital twin and artificial intelligence (AI)***.. The Agency should be able to use such data, including via the Data Analysis and Real World Interrogation Network (DARWIN) and the European Health Data Space interoperable infrastructure. Through these capabilities the Agency may take advantage of all the potential of supercomputing, artificial intelligence and big data science***, including results of studies conducted via insilico methods,*** to fulfil its mandate, without compromising privacy rights. ***The Agency should put in place sufficient, effective and specific technical and organisational measures to safeguard the fundamental rights and interests of data subjects in line with Regulation (EU) 2016/679 and Regulation (EU) 2018/1725.*** Where necessary the Agency may cooperate with the competent authorities of the Member

States towards this objective.

Proposal for a regulation
Recital 65

Text proposed by the Commission	*Amendment*
(65) In the preparation of scientific advice and in duly justified cases, the Agency should ***also be able to*** consult authorities established in other relevant Union legal acts or other public bodies established in the Union, as applicable. These may include experts in clinical trials, medical devices, substances of human origin or any other as required for the provision of the scientific advice in question.	(65) In the preparation of scientific advice and in duly justified cases, the Agency should ***promote an open discussion about latest scientific developments and the update of scientific guidelines and*** consult authorities established in other relevant Union legal acts or other public bodies established in the Union, as applicable. These may include experts in clinical trials, medical devices, substances of human origin or any other as required for the provision of the scientific advice in question. ***In addition to providing scientific advice, the Agency should ensure that scientific guidelines are updated and promote public discussion on scientific developments.***

Proposal for a regulation
Recital 66

Text proposed by the Commission	*Amendment*
(66) Through the Priority Medicines (PRIME) scheme, the Agency has gained experience of the provision of early scientific and regulatory support to developers of certain medicinal products that, based on preliminary evidence, are likely to address an unmet medical need and are considered promising at an early stage of development. It is appropriate to recognise this early support mechanism, including for priority antimicrobials and repurposed medicinal products when they fulfil the criteria for the scheme, and allow the Agency, in consultation with the Member States and the Commission, to establish selection criteria for promising medicinal products.	(66) Through the Priority Medicines (PRIME) scheme, the Agency has gained experience of the provision of early scientific and regulatory support to developers of certain medicinal products that, based on preliminary evidence, are likely to address an unmet medical need and are considered promising at an early stage of development, it is appropriate to recognise this early support mechanism, including for priority antimicrobials and repurposed medicinal products when they fulfil the criteria for the scheme, and allow the Agency, in consultation with the Member States and the Commission, to establish selection criteria for promising medicinal products.

Proposal for a regulation
Recital 67

Text proposed by the Commission	*Amendment*
(67) The Agency, in consultation with the Member States and the Commission, should set the scientific selection criteria for medicinal products that receive pre-authorisation support with priority to be given to the most promising developments in therapies. In the case of	(67) The Agency, in consultation with the Member States and the Commission, should set the scientific selection criteria for medicinal products that receive pre-authorisation support with priority to be given to ***public health need and*** the most promising developments in

medicinal products for unmet medical needs, based on the scientific selection criteria set by the Agency, any interested developer can submit preliminary evidence to demonstrate that the medicinal product has the potential to provide a major therapeutic advancement with respect to the identified unmet medical need.

therapies. In the case of medicinal products for unmet medical needs, based on the scientific selection criteria set by the Agency, any interested developer can submit preliminary evidence to demonstrate that the medicinal product has the potential to provide a major therapeutic advancement with respect to the identified unmet medical need.

Proposal for a regulation
Recital 68

Text proposed by the Commission

(68) Before a medicinal product for human use is authorised for placing on the market of one or more Member States, it generally has to undergo extensive studies to ensure that it is safe, of high quality and effective for use in the target population. However, in the case of certain categories of medicinal products for human use, in order to meet unmet medical needs of patients and in the interest of public health, it may be necessary to grant marketing authorisation on the basis of less complete data than is normally the case. Such marketing authorisation should be granted subject to specific obligations. The categories of medicinal products for human use concerned should be the medicinal products, including orphan medicinal products, that aim at the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases, or that are intended to be used in emergency situations in response to public health threats.

Amendment

(68) Before a medicinal product for human use is authorised for placing on the market of one or more Member States, it generally has to undergo extensive studies to ensure that it is safe, of high quality and effective for use in the target population. However, in the case of certain categories of medicinal products for human use, in order to meet unmet medical needs of patients and in the interest of public health, it may be necessary to grant marketing authorisation on the basis of less complete data than is normally the case. Such marketing authorisation should be granted subject to specific obligations. The categories of medicinal products for human use concerned should be the medicinal products, including orphan medicinal products, that aim at the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases, or that are intended to be used in emergency situations in response to public health threats.

Proposal for a regulation
Recital 68 a (new)

Text proposed by the Commission

Amendment

(68 a) There is still a lack of sufficiently detailed and comparable data at Union level to determine the trends and identify possible risk factors that could lead to the development of further measures to limit the risk from antimicrobial resistance and to monitor the effect of measures already introduced. Therefore it is important to collect data on the sales and use of antimicrobials, and data on antimicrobial resistant organisms found in animals, humans and food. To ensure that the information collected can be used effectively,

appropriate rules should be laid down concerning the collection and the exchange of data. The Member States should be responsible for collecting data on the use of antimicrobials under the coordination of the Agency.

Proposal for a regulation
Recital 70

Text proposed by the Commission	*Amendment*
(70) In the event of a risk to public health, the marketing authorisation holder or the competent authorities should be able to make urgent safety or efficacy restrictions on their own initiative to ensure a swift adaption of the marketing authorisation to maintain the safe and efficacious use of the medicinal product by healthcare professionals and patients. If a review is launched on the same safety or efficacy concern addressed by urgent restrictions initiated by a competent authority, any written observations by the marketing authorisation holder should be considered in that review to avoid duplication of assessment.	(70) In the event of a risk to public health, the marketing authorisation holder or the competent authorities should be able to make urgent safety or efficacy restrictions on their own initiative to ensure a swift adaption of the marketing authorisation to maintain the safe and efficacious use of the medicinal product by healthcare professionals and patients. If a review is launched on the same safety or efficacy concern addressed by urgent restrictions initiated by a competent authority, any written observations by the marketing authorisation holder should be considered in that review to avoid duplication of assessment.

Proposal for a regulation
Recital 73

Text proposed by the Commission	*Amendment*
(73) To optimise the use of resources for both applicants for marketing authorisations and competent authorities assessing such applications, a single assessment of an active substance master file should be introduced. The outcome of the assessment should be issued through a certificate. To avoid duplication of assessment, the use of an active substance master file certificate should be mandatory for subsequent applications or marketing authorisations for medicinal products for human use containing that active substance from an active substance master file certification holder. The Commission should be empowered to establish the procedure for the single assessment of an active substance master file. To further optimise the use of resources, the Commission should be empowered to extend the certification scheme to additional quality master files, e.g. in case of novel excipients, adjuvants, radiopharmaceutical precursors and active	(73) To optimise the use of resources for both applicants for marketing authorisations and competent authorities assessing such applications, a single assessment of an active substance master file should be introduced. The outcome of the assessment should be issued through a certificate. To avoid duplication of assessment, the use of an active substance master file certificate should be mandatory for subsequent applications or marketing authorisations for medicinal products for human use containing that active substance from an active substance master file certification holder. The Commission should be empowered to establish the procedure for the single assessment of an active substance master file. To further optimise the use of resources, the Commission should be empowered to extend the certification scheme to additional quality master files, e.g. in case of novel excipients, adjuvants, radiopharmaceutical precursors and active

substance intermediates, when the intermediate is a chemical active substance by itself or used in conjugation with a biological substance.

substance intermediates, when the intermediate is a chemical active substance by itself or used in conjugation with a biological substance.

Proposal for a regulation
Recital 74

Text proposed by the Commission

(74) To avoid unnecessary administrative and financial burdens for applicants, marketing authorisation holders and competent authorities, certain streamlining measures should be introduced. Electronic application for marketing authorisation and for variations to the terms of the marketing authorisation should be introduced. For generic and biosimilar medicinal products, except in specific cases, risk management plans do not need to be developed and submitted to the competent authorities.

Amendment

(74) To avoid unnecessary administrative and financial burdens for applicants, marketing authorisation holders and competent authorities, certain streamlining measures should be introduced. Electronic application for marketing authorisation and for variations to the terms of the marketing authorisation should be introduced. For generic and biosimilar medicinal products, except in specific cases, risk management plans do not need to be developed and submitted to the competent authorities.

Proposal for a regulation
Recital 76

Text proposed by the Commission

(76) It is considered appropriate to also have the possibility for the Commission to grant temporary emergency marketing authorisations to address public health emergencies. Temporary emergency marketing authorisations may be granted provided that, having regard to the circumstances of the public health emergency, the benefit of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent to the fact that additional comprehensive quality, non-clinical, clinical data may still be required. A temporary emergency marketing authorisation should be valid only during the public health emergency. The Commission should be given the possibility to vary, suspend or revoke such marketing authorisations in order to protect public health or when the marketing authorisation holder has not complied with the conditions and obligations set out in the temporary emergency marketing authorisation.

Amendment

(76) It is considered appropriate to also have the possibility for the Commission to grant temporary emergency marketing authorisations**,** to address public health emergencies. Temporary emergency marketing authorisations may be granted provided that, having regard to the circumstances of the public health emergency, the benefit of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent to the fact that additional comprehensive quality, non-clinical, clinical data may still be required. A temporary emergency marketing authorisation should be valid only during the public health emergency. The Commission should be given the possibility to vary, suspend or revoke such marketing authorisations in order to protect public health or when the marketing authorisation holder has not complied with the conditions and obligations set out in the temporary emergency marketing authorisation ***or when a standard or conditional marketing authorisation has been granted for the relevant indication***.

Proposal for a regulation
Recital 76 a (new)

Text proposed by the Commission	*Amendment*
	(76a) It is appropriate to have in place transparency measures and standards regarding the Agency's regulatory activities in relation to medicinal products, in particular those that receive a temporary emergency marketing authorisation. Those measures should include the timely publication of all relevant information on approved medicinal products and medical devices and of clinical data, including clinical trial protocols. The public information regarding clinical trials and marketing authorisation decisions should be in accordance with Regulation (EU) 2022/123 of the European Parliament and of the Council[1a].
_____	_____
	[1a] Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1).

Proposal for a regulation
Recital 78 c (new)

Text proposed by the Commission	*Amendment*
	(***78c) Joint procurement, whether within a country or across countries, can improve access, affordability, and security of supply of medicines. Member States interested in joint procurement of medicines should be able to request the Commission to facilitate joint procurement of centrally authorised medicinal products at the EU level conducted pursuant to [Joint procurement Directive/2014/24].***

Proposal for a regulation
Recital 78 d (new)

Text proposed by the Commission	*Amendment*
	(78 d) To seriously tackle major ongoing public health challenges, the antimicrobial resistance in particular, while also building on existing resources, the Health Emergency

	Preparedness and Response Authority (HERA) should be established as a separate structure under the legal personality of the European Centre for Disease Prevention and Control (ECDC) to boost EU's capability to address health emergencies. The Authority should be responsible for creating, coordinating and implementing the long-term European portfolio of biomedical research and development agenda for medical countermeasures against current and emerging public health threats, as well as providing tools to ensure EU-wide access to these products, including those to support production, procurement, stockpiling and distribution capacity of medical countermeasures and other priority medical products in the EU. The Authority will play a crucial role in addressing health threats globally. The Authority should primarily focus on the fight against antimicrobial resistance and the development of new antimicrobials and medical countermeasures linked to public health emergencies. However, in the future with increasing capacity, the Authority should expand the scope of its agenda, specifically to tackle other areas of unmet medical need such as rare and neglected diseases. The Authority should have adequate resources to fulfil its mandate.

Proposal for a regulation
Recital 86

Text proposed by the Commission	*Amendment*
(86) Medicinal products for rare diseases and for children should be subject to the same provisions as any other medicinal product concerning their quality, safety and efficacy, for example for what concerns the marketing authorisation procedures, the pharmacovigilance and quality requirements. However, specific requirements also apply to them. Such requirements, which are currently defined in separate legislations, should be integrated in this Regulation in order to ensure clarity and coherency of all the measures applicable to these medicinal products.	(86) Medicinal products for rare diseases and for children should be subject to the same provisions as any other medicinal product concerning their quality, safety**,** and efficacy ***and environmental risk***, for example for what concerns the marketing authorisation procedures, the pharmacovigilance and quality requirements. However, specific requirements also apply to them. Such requirements, which are currently defined in separate legislations, should be integrated in this Regulation in order to ensure clarity and coherency of all the measures applicable to these medicinal products.

Proposal for a regulation
Recital 87

Text proposed by the Commission	*Amendment*
Some orphan conditions occur so infrequently that the cost of developing and bringing to the market a medicinal product to diagnose, prevent or treat the condition cannot be recovered by the expected sales of the medicinal product. However, patients suffering from rare conditions should be entitled to the same quality of treatment as other patients; it is therefore necessary to stimulate the research, development and placing on the market of appropriate medications by the pharmaceutical industry.	Some orphan conditions occur so infrequently that the cost of developing and bringing to the market a medicinal product to diagnose, prevent or treat the condition cannot be recovered by the expected sales of the medicinal product. However, patients suffering from rare conditions should be entitled to the same quality of treatment as other patients; it is therefore necessary to stimulate the research, development and placing on the market of appropriate medications by the pharmaceutical industry.

Proposal for a regulation
Recital 88

Text proposed by the Commission	*Amendment*
(88) Regulation (EC) No 141/2000 of the European Parliament and of the Council[55] has proved to be successful in boosting developments of orphan medicinal products in the Union; therefore an action at Union level remains preferable to uncoordinated measures by the Member States which may result in distortions of competition and barriers to intra-Union trade.	(88) Regulation (EC) No 141/2000 of the European Parliament and of the Council[55] has proved to be successful in boosting developments of orphan medicinal products in the Union ***even though more progress needs to be done, as 95% of rare diseases are still without authorised treatment and the treatments available for the 5% are not necessarily transformative or curative***[1a] ; therefore an action at Union level remains preferable to uncoordinated measures by the Member States which may result in distortions of competition and barriers to intra-Union trade. ***The Union should build on its success driving and ensuring a similar degree of innovation under this Regulation.***

Proposal for a regulation
Recital 90

Text proposed by the Commission	*Amendment*
(90) Objective criteria for the orphan designation based on the prevalence of the life-threatening or chronically debilitating condition for which diagnosis, prevention or treatment is sought and the existence of no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the Union should be maintained; a prevalence of not more than five affected persons per 10 000 is generally regarded as the appropriate threshold. The orphan designation criterion on the basis of return on investment has been abolished, since	(90) Objective criteria for the orphan designation based on the prevalence of the life-threatening or chronically debilitating condition for which diagnosis, prevention or treatment is sought and the existence of no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorised in the Union should be maintained; a prevalence of not more than five affected persons per 10 000 is generally regarded as the appropriate threshold. The orphan designation criterion on the basis of return on investment has been abolished, since it has never been used. ***Nevertheless, products***

it has never been used.	***may still lose the orphan status in cases where the population criterion is no longer met.***

Proposal for a regulation
Recital 91

Text proposed by the Commission	*Amendment*
(91) The criterion for orphan designation based on prevalence of a disease may, however, not be appropriate to identify rare diseases in all cases. For example, for conditions which have a short duration and high mortality, measuring the number of people that acquired the disease during a specific time period would better reflect if it is rare within the meaning of this Regulation than measuring the number of people who are 'affected by it' in a specific moment of time. With the aim to better identify only those diseases which are rare, the Commission should be empowered to set up specific designation criteria for certain conditions if the one provided for are not appropriate due to scientific reasons and on the basis of a recommendation of the Agency.	(91) The criterion for orphan designation based on prevalence of a disease may, however, not be appropriate to identify rare diseases in all cases. For example, for conditions which have a short duration and high mortality, measuring the number of people that acquired the disease during a specific time period would better reflect if it is rare within the meaning of this Regulation than measuring the number of people who are 'affected by it' in a specific moment of time. With the aim to better identify only those diseases which are rare, the Commission should be empowered to set up specific designation criteria for certain conditions if the one provided for are not appropriate due to scientific reasons and on the basis of a recommendation of the Agency.

Proposal for a regulation
Recital 92

Text proposed by the Commission	*Amendment*
(92) With the aim to better identify only those diseases which are rare, the Commission should be empowered to supplement the designation criteria by a delegated act if they are not appropriate for certain conditions due to scientific reasons and on the recommendation of the Agency. In addition, the designation criteria require implementing measures to be adopted by the Commission.	***deleted***

Proposal for a regulation
Recital 92 b (new)

Text proposed by the Commission	*Amendment*
	(92 b) What qualifies as a significant benefit in a patient population can change over time, therefore, while ensuring predictability the Agency should also take into account any scientific developments and guidance when assessing the products meeting the significant

benefit criteria.

Proposal for a regulation
Recital 93

Text proposed by the Commission	*Amendment*
(93) If a satisfactory method of diagnosis, prevention or treatment of the condition in question has already been authorised in the Union, the orphan medicinal product will have to be of significant benefit to those affected by that condition. In this context, a medicinal product authorised in one Member State is generally deemed as being authorised in the Union. It is not necessary for it to have Union authorisation or to be authorised in all Member States to be considered as a satisfactory method. In addition, commonly used methods of diagnosis, prevention or treatment that are not subject to a marketing authorisation may be considered satisfactory if there is scientific evidence of their efficacy and safety. In certain cases, medicinal products prepared for an individual patient in a pharmacy according to a medical prescription, or according to the prescriptions of a pharmacopoeia and intended to be supplied directly to patients served by the pharmacy, ***may*** be considered as satisfactory treatment if they are well known and safe and this is a general practice for the relevant patient population in the Union.	(93) If a satisfactory method of diagnosis, prevention or treatment of the condition in question has already been authorised in the Union, the orphan medicinal product will have to be of significant benefit to those affected by that condition. In this context, a medicinal product authorised in one Member State is generally deemed as being authorised in the Union. It is not necessary for it to have Union authorisation or to be authorised in all Member States to be considered as a satisfactory method. In addition, commonly used methods of diagnosis, prevention or treatment that are not subject to a marketing authorisation may be considered satisfactory if there is scientific evidence of their efficacy and safety. In certain cases, medicinal products prepared for an individual patient in a pharmacy according to a medical prescription, or according to the prescriptions of a pharmacopoeia and intended to be supplied directly to patients served by the pharmacy, ***should also*** be considered as satisfactory treatment if they are well known and safe and this is a general practice for the relevant patient population in the Union.

Proposal for a regulation
Recital 94

Text proposed by the Commission	*Amendment*
(94) The competence to designate a medicinal product as an orphan medicinal product, in the form of a decision, is accorded to the Agency. This is expected to facilitate and expedite the designation procedure, while ensuring high level of scientific expertise.	(94) The competence to designate a medicinal product as an orphan medicinal product, in the form of a decision, is accorded to the Agency. This is expected to facilitate and expedite the designation procedure, while ensuring high level of scientific expertise.

Proposal for a regulation
Recital 95

Text proposed by the Commission	*Amendment*
(95) In order to incite faster authorisation of	(95) In order to incite faster authorisation of

designated orphan medicinal products, the validity of orphan designation has been set at seven years, with the possibility of extension by the Agency under certain specified conditions; the orphan designation may be withdrawn at the request of the orphan medicine sponsor.	designated orphan medicinal products, the validity of orphan designation has been set at seven years, with the possibility of extension by the Agency under certain specified conditions; the orphan designation may be withdrawn at the request of the orphan medicine sponsor, ***who may provide a reasoned justification for the withdrawal request. The Agency should make the reasoned justification for the withdrawal request, when provided by the sponsor, publicly available.***

Proposal for a regulation
Recital 99

Text proposed by the Commission	*Amendment*
(99) A vast percentage of rare diseases remains without treatment with research and development clustered in the areas where profit is better assured. Therefore, there is a need to target those areas where research is mostly needed and where investments are most risky.	(99) A vast percentage of rare diseases remains without treatment with research and development clustered in the areas where profit is better assured. Therefore, there is a need to target those areas where research is mostly needed and where investments are most risky.

Proposal for a regulation
Recital 100

Text proposed by the Commission	*Amendment*
(100) Orphan medicinal products addressing a high unmet medical need prevent, diagnose or treat conditions where either no other method of prevention, diagnosis or treatment exists or, if such method already exists, they would bring exceptional therapeutic advancement. In both cases, the criterion of meaningful reduction in disease morbidity or mortality for the relevant patient population should ensure that only most effective medicinal products are covered. The Agency should draw up scientific guidelines on the category of 'orphan medicinal products addressing a high unmet medical need'.	(100) Orphan medicinal products addressing a high unmet medical need prevent, diagnose or treat conditions where either no other method of prevention, diagnosis or treatment exists or, if such method already exists, they would bring exceptional therapeutic advancement. In both cases, the criterion of meaningful reduction in disease morbidity or mortality for the relevant patient population should ensure that only most effective medicinal products are covered. The Agency should draw up scientific guidelines on the category of 'orphan medicinal products addressing a high unmet medical need'.

Proposal for a regulation
Recital 102

Text proposed by the Commission	*Amendment*
(102) In order to incentivise research and	(102) In order to incentivise research and

development of orphan medicinal products addressing high unmet needs, to ensure market predictability and to ensure a fair distribution of incentives, a modulation of market exclusivity has been introduced; orphan medicinal products addressing high unmet medical needs benefit from the longest market exclusivity, while market exclusivity for well-established use orphan medicinal products, requiring less investment, is the shortest. In order to ensure increased predictability for developers, the possibility to review the eligibility criteria for market exclusivity after six years after the marketing authorisation has been abolished.

development of orphan medicinal products addressing high unmet needs, to ensure market predictability and to ensure a fair distribution of incentives, a modulation of market exclusivity has been introduced; orphan medicinal products addressing high unmet medical needs benefit from the longest market exclusivity, while market exclusivity for well-established use orphan medicinal products, requiring less investment, is the shortest. In order to ensure increased predictability for developers, the possibility to review the eligibility criteria for market exclusivity after six years after the marketing authorisation has been abolished.

Proposal for a regulation
Recital 103

Text proposed by the Commission	*Amendment*
(103) In order to encourage faster and wider access also to orphan medicinal products, an additional period of one year of market exclusivity is granted to orphan medicinal products for a Union market launch, with the exception of well-established use medicinal products.	(103) ***deleted***

Proposal for a regulation
Recital 104

Text proposed by the Commission	*Amendment*
(104) To reward research into and development of new therapeutic indications, an additional period of one year of market exclusivity is provided for a new therapeutic indication (with a maximum of two indications).	(104) ***To maximise the potential benefit of clinical research, continued exploration of new indications should be encouraged.*** To reward research into and development of new therapeutic indications, an additional period of one year of market exclusivity is provided for a new therapeutic indication (with a maximum of two indications).

Proposal for a regulation
Recital 105

Text proposed by the Commission	*Amendment*
(105) This Regulation includes several provisions aimed to avoid not-justified benefits being derived from the market exclusivity and to improve accessibility of medicinal products by ensuring faster entry of generics and biosimilars, and similar medicinal products on	(105) This Regulation includes several provisions aimed to avoid not-justified benefits being derived from the market exclusivity and to improve accessibility of medicinal products by ensuring faster entry of generics and biosimilars, and similar medicinal products on

the market. It also clarifies the concurrence of market exclusivity with data protection and defines situations when a similar medicinal product may be granted a marketing authorisation, despite the ongoing market exclusivity.	the market. It also clarifies the concurrence of market exclusivity with data protection and defines situations when a similar medicinal product may be granted a marketing authorisation, despite the ongoing market exclusivity.

Proposal for a regulation
Recital 105a

Text proposed by the Commission	*Amendment*
	(105a) The Agency should refuse the validation for an application for a marketing authorisation referring to data of a reference medicinal product only on the basis of the grounds set out in this Regulation and Directive (Pharma Directive - insert correct reference). The same should apply to any decision to grant, vary, suspend, restrict or revoke the marketing authorisation. The Agency cannot base their decision on any other grounds. In particular, those decisions cannot be based on the patent or SPC status of the reference medicinal product.

Proposal for a regulation
Recital 105 b (new)

Text proposed by the Commission	*Amendment*
	(105 b) One of the overarching goals of this Regulation is to help meeting the medical needs of patients with rare diseases, to improve the affordability of orphan medicinal products and the patient access to orphan medicinal products across the Union, and to encourage innovation in areas of need. While other Union programmes and policies also contribute to these goals, people living with a rare disease continue to face common challenges that are many and multifactorial, including delayed diagnoses, lack of available transformative treatments, and difficulties to access treatments where they live, reflecting the fragmentation of the market across the Member States. The European added value to addressing the needs of people living with a rare disease being exceptionally high due to the rarity of patients, experts, data, and resources, it is appropriate for the Commission to develop, to complement this Regulation, a dedicated framework for rare diseases to bridge relevant legislation, policies

	and programmes, and support national strategies with a view to better meet the unmet needs of people living with rare diseases and their carers. This framework should be needs driven and goals based, and developped in consultation with the Member States and patient organisations as well as, where relevant, other interested parties.

Proposal for a regulation
Recital 106

Text proposed by the Commission	*Amendment*
(106) Before a medicinal product for human use is placed on the market in one or more Member States, it has to have undergone extensive studies, including non-clinical tests and clinical trials, to ensure that it is safe, of high quality and effective for use in the target population. It is important that such studies are undertaken also on the paediatric population in order to ensure that medicinal products are appropriately authorised for use in the paediatric population, and to improve the information available on the use of medicinal products in the various paediatric population. It is also important that medicinal products are presented in dosages and formulations adequate for the use in children.	(106) Before a medicinal product for human use is placed on the market in one or more Member States, it has to have undergone extensive studies, including non-clinical tests and clinical trials, to ensure that it is safe, of high quality and effective for use in the target population. It is important that such studies are undertaken also on the paediatric population in order to ensure that medicinal products are appropriately authorised for use in the paediatric population, and to improve the information available on the use of medicinal products in the various paediatric population. It is also important that medicinal products are presented in dosages and formulations adequate for the use in children.

Proposal for a regulation
Recital 110

Text proposed by the Commission	*Amendment*
(110) In order to not endanger the health of children and avoid to expose them to unnecessary clinical trials, the obligation to agree and conduct paediatric studies in children should be waived when the medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population, the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for children or the disease for which the medicinal product is intended occurs only in adult populations. Nevertheless, in the last case, if on the basis of existing scientific evidence, the medicinal product due to its molecular mechanism of action is expected to be effective against a different disease in children, the obligation should be maintained.	(110) In order to not endanger the health of children and avoid to expose them to unnecessary clinical trials, the obligation to agree and conduct paediatric studies in children should be waived when the medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population, the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for children or the disease for which the medicinal product is intended occurs only in adult populations. Nevertheless, in the last case, if on the basis of existing scientific evidence, the medicinal product due to its molecular mechanism of action is expected to be effective against a different disease in children, the obligation should be maintained.

Proposal for a regulation
Recital 112

Text proposed by the Commission	*Amendment*
(112) With a view to ensuring that research is conducted only when safe and ethical and that the requirement for study data in the paediatric population does not block or delay the authorisation of medicinal products for other populations, the Agency may defer the initiation or completion of some or all of the measures contained in a paediatric investigation plan for a limited period of time. Such deferral should be extended only in duly justified cases.	(112) With a view to ensuring that research is conducted only when safe and ethical and that the requirement for study data in the paediatric population does not block or delay the authorisation of medicinal products for other populations, the Agency may defer, ***based on scientific, ethical and technical grounds or considerations related to public health***, the initiation or completion of some or all of the measures contained in a paediatric investigation plan for a limited period of time. Such deferral should be extended only in duly justified cases.

Proposal for a regulation
Recital 123

Text proposed by the Commission	*Amendment*
(123) The summary of the results of all the paediatric clinical trials included in the European clinical trial database created by Regulation (EU) No 536/2014 should be made publicly available within 6 months after the end of the clinical trials unless this is not possible for justified scientific reasons.	(123) The summary of the results of all the paediatric clinical trials included in the European clinical trial database created by Regulation (EU) No 536/2014 should be made publicly available within 6 months after the end of the clinical trials unless this is not possible for justified scientific reasons.

Proposal for a regulation
Recital 126

Text proposed by the Commission	*Amendment*
(126) It is necessary to take measures for the supervision of medicinal products authorised by the Union, and in particular for the intensive supervision of undesirable effects of these medicinal products within the framework of Union pharmacovigilance activities, so as to ensure the rapid withdrawal from the market of any medicinal product presenting a negative benefit-risk balance under normal conditions of use.	(126) It is necessary to take measures for the supervision of medicinal products authorised by the Union, and in particular for the intensive supervision of undesirable effects of these medicinal products***, and the collection of real-world data*** within the framework of Union pharmacovigilance activities, so as to ensure the rapid withdrawal from the market of any medicinal product presenting a negative benefit-risk balance under normal conditions of use.

Proposal for a regulation
Recital 129

Text proposed by the Commission	*Amendment*
(129) Scientific and technological progresses in data analytics and data infrastructure are essential for the development, authorisation and supervision of medicinal products. The digital transformation has affected regulatory decision-making, making it more data-driven and multiplying the possibilities to access evidence, across the life cycle of a medicinal product. This Regulation recognises the Agency's experience and capacity to access and analyse data submitted independently from the marketing authorisation applicant or marketing authorisation holder. On this basis, the Agency should take initiative to update the summary of product characteristics in case new efficacy or safety data has an impact on the benefit-risk balance of a medicinal product.	(129) Scientific and technological progresses in data analytics and data infrastructure are essential for the development, authorisation and supervision of medicinal products. The digital transformation has affected regulatory decision-making, making it more data-driven and multiplying the possibilities to access evidence ***and real-world data***, across the life cycle of a medicinal product. This Regulation recognises the Agency's experience and capacity to access and analyse data submitted independently from the marketing authorisation applicant or marketing authorisation holder. On this basis, the Agency should take initiative to update the summary of product characteristics in case new efficacy or safety data has an impact on the benefit-risk balance of a medicinal product. ***In such cases, the Agency, after consulting with the marketing authorisation applicant or marketing authorisation holder, before undertaking any such update.***

Proposal for a regulation
Recital 132

Text proposed by the Commission	*Amendment*
(132) The Union and Member States have developed a scientific evidence-based process that allows competent authorities to determine the relative effectiveness of new or existing medicinal products. This process focuses specifically on the added value of a medicinal product in comparison with other new or existing health technologies. However, this evaluation should not be conducted in the context of the marketing authorisation, for which it is agreed that the fundamental criteria should be retained. It is useful in this respect to allow for the possibility of gathering information on the methods used by the Member States to determine the therapeutic benefit obtained by each new medicinal product.	(132) The Union and Member States have developed a scientific evidence-based process that allows competent authorities to determine the relative effectiveness of new or existing medicinal products. This process focuses specifically on the added value of a medicinal product in comparison with other new or existing health technologies. However, this evaluation should not be conducted in the context of the marketing authorisation, for which it is agreed that the fundamental criteria should be retained. It is useful in this respect to allow for the possibility of gathering information on the methods used by the Member States to determine the therapeutic benefit obtained by each new medicinal product.

Proposal for a regulation
Recital 134

Text proposed by the Commission	*Amendment*
(134) In the area of medicinal products, a high level of protection of inter alia citizens,	(134) In the area of medicinal products, a high level of protection of inter alia citizens,

consumers, health, as well as legal certainty, a level playing field and fair competition always need to be ensured and existing levels of protection need to be respected.	consumers, health, ***the environment***, as well as legal certainty, a level playing field and fair competition always need to be ensured and existing levels of protection need to be respected. ***Whenever possible, priority should be given to the use of non-animal approaches.***

Proposal for a regulation
Recital 135 a (new)

Text proposed by the Commission	*Amendment*
	(135 a) The EU market for medicines remains fragmented, despite the EU having a single market and being the second largest market for pharmaceuticals in the world. The organisation of healthcare systems is a national competence of Member States: this allows decisions closer to the patient, but also brings divergences in both pricing and patient access. Better and closer coordination between national authorities opens the door to a more efficient and effective supply of medicines throughout the EU.

Or. en

Proposal for a regulation
Recital 135 b (new)

Text proposed by the Commission	*Amendment*
	(135 b) More often, Member States experienced critical shortages of certain antimicrobials, endangering the health of patients and risking the development of antimicrobial resistance. These critical shortages were the result of changing infection patterns, which strongly increased demand. On the supply side, the long lead times needed to boost production made it difficult to respond quickly. This experience underlined the need for a dedicated effort from all actors to address the issue of critical shortages.

Proposal for a regulation
Recital 136

Text proposed by the Commission	*Amendment*
(136) Shortages of medicinal products represent a growing threat to public health, with potential serious risks to the health of patients in the Union and impacts on the right of patients to access appropriate medical treatment. The root causes of shortages are multifactorial, with challenges identified along the entire pharmaceutical value chain, from quality and manufacturing problems. In particular, shortages of medicinal products can result from supply chain disruptions and vulnerabilities affecting the supply of key ingredients and components. Therefore, all marketing authorisation holders should have shortage prevention plans in place, to prevent shortages. The Agency should provide guidance to marketing authorisation holders on approaches to streamline the implementation of those plans.	(136) Shortages of medicinal products represent a growing threat to public health, with potential serious risks to the health of patients in the Union and impacts on the right of patients to access appropriate medical treatment, ***including longer delays or interruptions in care or therapy, longer periods of hospitalisation, increased risks of exposure to falsified medicinal products, medication errors, adverse effects resulting from the substitution of unavailable medicinal products with alternative ones, significant psychological distress for patients and increased costs for healthcare systems***. ***Member States should collect data on the impact of shortages of medicinal products on patients and consumers, and share relevant information through the MSSG, in order to inform approaches to management of shortages of medicinal products.*** The root causes of shortages are multifactorial, with challenges identified along the entire pharmaceutical value chain, from quality and manufacturing problems. In particular, shortages of medicinal products can result from supply chain disruptions and vulnerabilities affecting the supply of key ingredients and components. Therefore, all marketing authorisation holders should have shortage prevention plans in place to prevent shortages**.** The Agency should provide guidance to marketing authorisation holders on approaches to streamline the implementation of those plans**.**

Proposal for a regulation
Recital 137

Text proposed by the Commission	*Amendment*
(137) To achieve a better security of supply for medicinal products in the internal market and to contribute thereby to a high level of public health protection, it is appropriate to approximate the rules on monitoring and reporting of actual or potential shortages of medicinal products, including the procedures and the respective roles and obligations of concerned entities in this Regulation. It is important to ensure continued supply of medicinal products, which is often taken for granted across Europe. This is especially true for the most critical medicinal products which	(137) To achieve a better security of supply for medicinal products in the internal market and to contribute thereby to a high level of public health protection, it is appropriate to approximate the rules on monitoring and reporting of actual or potential shortages of medicinal products, including the procedures and the respective roles and obligations of concerned entities in this Regulation***, while allowing Member States to adopt or maintain legislation ensuring a higher degree of protection against medicine shortages***. It is important to ensure continued supply of

are essential to ensure the continuity of care, the provision of quality healthcare and guarantee a high level of public health protection in Europe.

medicinal products, which is often taken for granted across Europe. This is especially true for the most critical medicinal products which are essential to ensure the continuity of care, the provision of quality healthcare and guarantee a high level of public health protection in Europe. ***To combat certain shortages, medicinal products prepared for individual patients in a pharmacy according to a medical prescription "magistral formula", or according to the pharmacopoeia and intended to be supplied directly to patients served by the pharmacy "officinal formula", may be used.***

Proposal for a regulation
Recital 138

Text proposed by the Commission	*Amendment*
(138) The national competent authorities should be empowered to monitor shortages of medicinal products that are authorised through both national and centralised procedures, based on notifications of marketing authorisation holders**.** The Agency should be empowered to monitor shortages of medicinal products that are authorised through the centralised procedure, also based on notifications of marketing authorisation holders. When critical shortages are identified, both national competent authorities and the Agency should work in a coordinated manner to manage those critical shortages, whether the medicinal product concerned by the critical shortage is covered by a centralised marketing authorisation or a national marketing authorisation. Marketing authorisation holders and other relevant entities must provide the relevant information to inform the monitoring. Wholesale distributors and other persons or legal entities, including patient organisations or health care professionals, may also report a shortage of a given medicinal product marketed in the Member State concerned to the competent authority. The Executive Steering Group on Shortages and Safety of Medicinal Products ('the Medicines Shortages Steering Group' (MSSG)) already established within the Agency pursuant to Regulation (EU) 2022/123 of the European Parliament and of the Council[56] , should adopt a list of critical shortages of medicinal products and ensure monitoring of those shortages by the Agency. The MSSG should also adopt a list of critical	(138) The national competent authorities should be empowered to monitor shortages of medicinal products that are authorised through both national and centralised procedures, based on notifications of marketing authorisation holders**.** The Agency should be empowered to monitor shortages of medicinal products that are authorised through the centralised procedure, also based on notifications of marketing authorisation holders. ***Information on such shortages should be made available on the webpage referred to in Article 104.***When critical shortages are identified, both national competent authorities and the Agency should work in a coordinated manner to ***communicate the necessary information to patients, consumers and healthcare professionals, including on estimated duration and available alternatives, and*** manage those critical shortages, whether the medicinal product concerned by the critical shortage is covered by a centralised marketing authorisation or a national marketing authorisation. Marketing authorisation holders and other relevant entities, ***importers, manufacturers and suppliers,*** must provide the relevant information to inform the monitoring. Wholesale distributors and other persons or legal entities, including patient organisations or health care professionals ***and consumers and other persons or legal entities that are authorised or entitled to supply medicinal products to the public*** , may also report a shortage of a given medicinal product marketed in the Member State concerned to the

medicinal products authorised in accordance with [revised Directive 2001/83/EC] or this Regulation to ensure monitoring of the supply of those products. The MSSG may provide recommendations on measures to be taken by marketing authorisation holders, the Member States, the Commission and other entities to resolve any critical shortage or to ensure the security of supply of those critical medicinal products to the market. Implementing acts can be adopted by the Commission to ensure that appropriate measures, including the establishment or maintenance of contingency stocks, are taken by marketing authorisation holders, wholesale distributors or other relevant entities.	competent authority. The Executive Steering Group on Shortages and Safety of Medicinal Products ('the Medicines Shortages Steering Group' (MSSG)) already established within the Agency pursuant to Regulation (EU) 2022/123 of the European Parliament and of the Council[56] , should adopt a list of critical shortages of medicinal products and ensure monitoring of those shortages by the Agency. The MSSG should also adopt a list of critical medicinal products authorised in accordance with [revised Directive 2001/83/EC] or this Regulation to ensure monitoring of the supply of those products. The MSSG may provide recommendations on measures to be taken by marketing authorisation holders, the Member States, the Commission and other entities to resolve any critical shortage or to ensure the security of supply of those critical medicinal products to the market. ***Where appropriate, these security of supply measures should also comprise the use of regulatory flexibilities such as on packaging and labelling requirements. However, this flexibility should not undermine high quality and safety standards***. Implementing acts can be adopted by the Commission to ensure that appropriate measures, including the establishment or maintenance of contingency stocks, are taken by marketing authorisation holders, wholesale distributors or other relevant entities.

Proposal for a regulation
Recital 138a (new)

Text proposed by the Commission	*Amendment*
	(138a)
	Wholesalers are usually a key supply link between marketing authorisation holders and the users of medicines, and in those cases, in order to estimate demand, the quantity requested in wholesale orders should be considered.

Proposal for a regulation
Recital 138 b (new)

Text proposed by the Commission	*Amendment*
	(138 b) To avoid that measures foreseen or taken by a Member State to prevent or mitigate a shortage at national level when responding to the legitimate needs of its citizen increase the risk of shortages in another Member State.

Proposal for a regulation
Recital 139 a (new)

Text proposed by the Commission	*Amendment*
	(139a) Public procurement procedures can be an effective tool for tackling shortages of medicinal products. At Member State level, invitations to tender based solely on price and where there is only one bidder increase the risk of shortages of medicinal products and reducing the number of suppliers on the market. At Union level, joint procurement should be recognised as a tool to tackle critical shortages, in particular during a health crisis, as demonstrated by the Covid-19 pandemic.

Proposal for a regulation
Recital 140

Text proposed by the Commission	*Amendment*
(140) It is recognised that improved access to information contributes to public awareness, gives the public the opportunity to express its observations and enables authorities to take due account of those observations. The general public should therefore have access to information in the Union Register of medicinal products, the Eudravigilance database and the manufacturing and wholesale distribution database, after the deletion of any commercially confidential information by the competent authority. Regulation (EC) No 1049/2001 of the European Parliament and of the Council[57]gives the fullest possible effect to the right of public access to documents and lays down the general principles and limits on such access. The Agency should therefore give the widest possible access to the documents while carefully balancing the right for information with existing data protection requirements. Certain public and private interests, such as personal data and	(140) It is recognised that improved access to information contributes to public awareness ***and increases public trust***, gives the public the opportunity to express its observations and enables authorities to take due account of those observations. The general public should therefore have access to information in the Union Register of medicinal products, the Eudravigilance database and the manufacturing and wholesale distribution database, after the deletion of any commercially confidential information by the competent authority ***unless there is an overriding public interest to disclosure, in accordance with Regulation (EC) No 1049/2001.*** Regulation (EC) No 1049/2001 of the European Parliament and of the Council gives the fullest possible effect to the right of public access to documents and lays down the general principles and limits on such access. The Agency should therefore give the widest possible access to the documents while carefully balancing the right for

commercially confidential information, should be protected by way of exception in accordance with Regulation (EC) No 1049/2001.

information with existing data protection requirements. Certain public and private interests, such as personal data and commercially confidential information, should be protected by way of exception in accordance with Regulation (EC) No 1049/2001.

Proposal for a regulation
Recital 141

Text proposed by the Commission	*Amendment*
(141) To ensure the enforcement of certain obligations relating to the marketing authorisation for medicinal products for human use granted in accordance with this Regulation, the Commission should be able to impose financial penalties. When assessing the responsibility for failures to comply with those obligations and imposing such penalties, it is important that means exist to address the fact that marketing authorisation holders could be part of a wider economic entity. Otherwise, there is a clear and identifiable risk that the responsibility for a failure to comply with those obligations could be evaded, which might have an impact on the ability to impose effective, proportional and dissuasive penalties. The penalties imposed should be effective, proportionate and dissuasive, having regard to the circumstances of the specific case. For the purposes of ensuring legal certainty in the conduct of the infringement procedure, it is necessary to set maximum amounts for penalties. Those maximum amounts should not be linked to the turnover of a particular medicinal product but the economic entity involved.	(141) To ensure the enforcement of certain obligations relating to the marketing authorisation for medicinal products for human use granted in accordance with this Regulation, the Commission should be able to impose financial penalties. When assessing the responsibility for failures to comply with those obligations and imposing such penalties, it is important that means exist to address the fact that marketing authorisation holders could be part of a wider economic entity. Otherwise, there is a clear and identifiable risk that the responsibility for a failure to comply with those obligations could be evaded, which might have an impact on the ability to impose effective, proportional and dissuasive penalties. The penalties imposed should be effective, proportionate and dissuasive, having regard to the circumstances of the specific case. For the purposes of ensuring legal certainty in the conduct of the infringement procedure, it is necessary to set maximum amounts for penalties. Those maximum amounts should not be linked to the turnover of a particular medicinal product but the economic entity involved.

Proposal for a regulation
Recital 143

Text proposed by the Commission	*Amendment*
(143) To ensure uniform conditions for the implementation of this Regulation in relation to marketing authorisations for medicinal products for human use, implementing powers should be conferred on the Commission. The implementing powers related to the granting of centralised marketing authorisations and for suspending, revoking or withdrawing those authorisations**,** for granting vouchers, establishing and modifying regulatory sandboxes and decisions on the regulatory	(143) To ensure uniform conditions for the implementation of this Regulation in relation to marketing authorisations for medicinal products for human use, implementing powers should be conferred on the Commission. The implementing powers related to the granting of centralised marketing authorisations and for suspending, revoking or withdrawing those authorisations for granting vouchers, establishing and modifying regulatory sandboxes and decisions on the regulatory

status of medicinal products should be exercised in accordance with Regulation (EU) 182/2011**.**	status of medicinal products should be exercised in accordance with Regulation (EU) 182/2011

Proposal for a regulation
Recital 145

Text proposed by the Commission	*Amendment*
(145) Experience shows that, in clinical trials with investigational medicinal products containing or consisting of GMOs, the procedure to achieve compliance with the requirements of Directives 2001/18/EC and 2009/41/EC as regards the environmental risk assessment and consent by the competent authority of a Member State is complex and can take a significant amount of time.	(145) Experience shows that, in clinical trials with investigational medicinal products containing or consisting of GMOs the procedure to achieve compliance with the requirements of Directives 2001/18/EC and 2009/41/EC as regards the environmental risk assessment and consent by the competent authority of a Member State is complex and can take a significant amount of time.

Proposal for a regulation
Recital 149

Text proposed by the Commission	*Amendment*
(149) It is therefore appropriate to envisage a centralised assessment of the ERA involving experts from the national competent authorities.	(149) It is therefore appropriate to envisage a centralised assessment of the ERA involving experts from the national competent authorities ***and the ad-hoc Environmental Risk Assessment working party***.

Proposal for a regulation
Recital 154

Text proposed by the Commission	*Amendment*
(154) This Regulation is based on the double legal basis of Article 114 and Article 168(4), point (c), TFEU. It aims at achieving an internal market as regards medicinal products for human use, taking as a base a high level of protection of health. At the same time, this Regulation sets high standards of quality and safety for medicinal products in order to meet common safety concerns as regards these products. Both objectives are being pursued simultaneously. These two objectives are inseparably linked and one is not secondary to another. Regarding Article 114 TFEU, this Regulation establishes a European Medicines Agency and provides specific provision with regard to the central authorisation of medicinal products, therefore ensuring the functioning of the internal market and the free movement of medicinal products. Regarding Article 168(4), point (c), TFEU, this Regulation sets high	(154) This Regulation is based on the double legal basis of Article 114 and Article 168(4), point (c), TFEU. It aims at achieving an internal market as regards medicinal products for human use, taking as a base a high level of protection of health. At the same time, this Regulation sets high standards of quality and safety for medicinal products in order to meet common safety concerns as regards these products. Both objectives are being pursued simultaneously. These two objectives are inseparably linked and one is not secondary to another. Regarding Article 114 TFEU, this Regulation establishes a European Medicines Agency and provides specific provision with regard to the central authorisation of medicinal products, therefore ensuring the functioning of the internal market and the free movement of medicinal products. Regarding Article 168(4), point (c), TFEU, this Regulation sets high

standards of quality and safety for medicinal products.

standards of quality and safety for medicinal products.

Proposal for a regulation
Recital 155

Text proposed by the Commission	*Amendment*
(155) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, the rights of the child, respect for private and family life, the protection of personal data and the freedom of art and science.	(155) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union and notably human dignity, the integrity of the person, the rights of the child, respect for private and family life, the protection of personal data and the freedom of art and science. ***Similarly, this Regulation aims to ensure high level of protection of the environment in accordance with article 192, paragraph 1, of the TFEU.***

Proposal for a regulation
Recital 156

Text proposed by the Commission	*Amendment*
(156) The objective of this Regulation is to ensure the authorisation of high quality medicinal products, including for paediatric patients and patients suffering from rare diseases throughout the Union. Where this objective cannot be sufficiently achieved by the Member States but can rather, by reason of its scale, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.	(156) The objective of this Regulation is to ensure the authorisation of high quality medicinal products, including for paediatric patients and patients suffering from rare diseases throughout the Union. Where this objective cannot be sufficiently achieved by the Member States, but can rather, by reason of its scale, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

COMPROMISE AMENDMENT 58 - CHAPTER VI - ORPHAN MEDICINAL PRODUCTS (ARTICLES 63 TO 70 AND 73A AND 73B NEW) replacing AMs 110-117; 1051-1153; 1280-1283, ITRE 63-65

supported by
EPP, S&D, RE, Greens, ECR, Left

ARTICLE 63

Proposal for a regulation

Article 63 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the condition affects not more than five in 10 000 persons in the Union when the application for an orphan designation is submitted;	(a) the condition affects not more than five in 10 000 persons in the Union when the application for an orphan designation is submitted;

Proposal for a regulation

Article 63 – paragraph 2

Text proposed by the Commission	*Amendment*
2. By way of derogation from paragraph 1, point (a), and on the basis of a recommendation from the Agency, when the requirements specified in paragraph 1, point (a), are not appropriate due to the specific characteristics of certain conditions or any other scientific reasons, the Commission is empowered to adopt delegated acts in accordance with Article 175 in order to supplement paragraph 1, point (a), by setting specific criteria for certain conditions.	***deleted***

Proposal for a regulation

Article 63 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission shall adopt the necessary provisions for implementing this Article by means of implementing acts in accordance with the procedure laid down in	3. The Commission shall adopt the necessary provisions for implementing this Article by means of implementing acts in accordance with the procedure laid down in

Article 173(2) in order to further specify the requirements referred to in paragraph 1.	Article 173(2) in order to further specify the requirements referred to in paragraph 1.

ARTICLE 64

Proposal for a regulation

Article 64 – paragraph 2 – subparagraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) justification that the criteria laid down in Article 63(1) ***or in the relevant delegated acts adopted in accordance with Article 63(2)*** are fulfilled and a description of the stage of development, including the expected therapeutic indication.	(d) justification that the criteria laid down in Article 63(1) are fulfilled and a description of the stage of development, including the expected therapeutic indication.

Proposal for a regulation

Article 64 – paragraph 4 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Agency shall adopt a decision granting or refusing the orphan designation based on the criteria referred to in Article 63(1) ***or in the relevant delegated acts adopted in accordance with Article 63(2)*** within 90 days of the receipt of a valid application. The application is considered valid if it includes all the particulars and documentation referred to in paragraph 2.	The Agency shall adopt a decision granting or refusing the orphan designation based on the criteria referred to in Article 63(1) within 90 days of the receipt of a valid application. The application is considered valid if it includes all the particulars and documentation referred to in paragraph 2.

ARTICLE 65

Proposal for a regulation

Article 65 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(c a) reason(s) for the transferring of the orphan designation

ARTICLE 66

Proposal for a regulation

Article 66 – paragraph 5

Text proposed by the Commission	*Amendment*
5. At any time, an orphan designation may be withdrawn at the request of the orphan medicine sponsor.	5. At any time, an orphan designation may be withdrawn at the request of the orphan medicine sponsor. ***The orphan medicine sponsor may provide a reasoned justification for the withdrawal request, which shall be made publicly available.***

ARTICLE 67

Proposal for a regulation

Article 67 – paragraph 3 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) where applicable, any request made in accordance with Article 66(2) and any decisions taken in that respect.

ARTICLE 68

Proposal for a regulation

Article 68 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The orphan medicine sponsor ***may***, prior to the submission of an application for marketing authorisation, request advice from the Agency on the following:	1. The orphan medicine sponsor ***shall***, prior to the submission of an application for marketing authorisation, request advice from the Agency on the following:

Proposal for a regulation

Article 68 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) the conduct of the various tests and trials necessary to demonstrate the quality, safety ***and*** efficacy of the medicinal product, as	(a) the conduct of the various tests and trials necessary to demonstrate the quality, safety**,** efficacy ***and environmental impact*** of

referred to Article 138(1), second subparagraph, point (p);	the medicinal product, as referred to Article 138(1), second subparagraph, point (p);

Proposal for a regulation

Article 68 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Medicinal products designated as orphan medicinal products under the provisions of this Regulation shall be eligible for incentives made available by the Union and by the Member States to support research into, and the development and availability of, orphan medicinal products and in particular aid for research for small- and medium-sized undertakings provided for in framework programmes for research and technological development.	2. Medicinal products designated as orphan medicinal products under the provisions of this Regulation shall be eligible for incentives made available by the Union and by the Member States to support research into, and the development and availability of, orphan medicinal products and in particular aid for research for small- and medium-sized undertakings ***and entities not engaged in economic activity*** provided for in framework programmes for research and technological development.

ARTICLE 69

Proposal for a regulation

Article 69 – paragraph 2 – subparagraph 1

Text proposed by the Commission	*Amendment*
In addition, the applicant shall demonstrate that the medicinal product has been granted an orphan designation and that the criteria set out in Article 63(1) ***or in the relevant delegated acts adopted in accordance with Article 63(2)*** are fulfilled for the therapeutic indication sought.	In addition, the applicant shall demonstrate that the medicinal product has been granted an orphan designation and that the criteria set out in Article 63(1) are fulfilled for the therapeutic indication sought.

Proposal for a regulation

Article 69 – paragraph 3 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Committee for Medicinal Products for Human Use shall assess whether the medicinal product fulfils the requirements set out in	The Committee for Medicinal Products for Human Use shall assess whether the medicinal product fulfils the requirements set out in

Article 63(1) ***or in the relevant delegated acts adopted in accordance with Article 63(2)***. In the situation referred in paragraph 2, subparagraph 2, that Committee shall also assess whether the medicinal product addresses a high unmet medical need as specified in Article 70(1).	Article 63(1). In the situation referred in paragraph 2, subparagraph 2, that Committee shall also assess whether the medicinal product addresses a high unmet medical need as specified in Article 70(1).

Proposal for a regulation

Article 69 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The orphan marketing authorisation shall cover only those therapeutic indications, which fulfil the requirements set out in Article 63(1) ***or in the relevant delegated acts adopted in accordance with Article 63(2)*** at the time when the orphan marketing authorisation is granted.	4. The orphan marketing authorisation shall cover only those therapeutic indications, which fulfil the requirements set out in Article 63(1) at the time when the orphan marketing authorisation is granted.

Proposal for a regulation

Article 69 – paragraph 6

Text proposed by the Commission	*Amendment*
6. An applicant may submit an application for a separate marketing authorisation for other indications which do not fulfil the requirements set out in Article 63(1) ***or in the relevant delegated acts adopted in accordance with Article 63(2)***.	6. An applicant may submit an application for a separate marketing authorisation for other indications which do not fulfil the requirements set out in Article 63(1).

Proposal for a regulation

Proposal for a regulation
Article 70 paragraphs 1 and 2

Article 70	Article 70
Orphan medicinal products addressing a high unmet medical need	Orphan medicinal products addressing a high unmet medical need
1. An orphan medicinal product shall be considered as addressing a high unmet medical need where it fulfils the following	1. An orphan medicinal product shall be considered as addressing a high unmet medical need where it fulfils the following

requirements:	requirements:
(a) there is no medicinal product authorised in the Union for such condition ***or where, despite medicinal products being authorised for such condition in the Union, the applicant demonstrates that the orphan medicinal product, in addition to having a significant benefit, will bring exceptional therapeutic advancement;***	(a) there is no medicinal product authorised in the Union for such condition; or
(b) the use of the orphan medicinal product results in a meaningful reduction in disease morbidity or mortality for the relevant patient population.	***(b) where a medicinal product is authorised for such condition, addition to having a significant benefit, it will bring exceptional therapeutic advancement and the use of the orphan medicinal product*** results in a meaningful reduction in disease morbidity or mortality for the relevant patient population.
2. A medicinal product for which an application has been submitted in accordance with Article 13 of [revised Directive 2001/83/EC] shall not be considered as addressing a high unmet medical need.	2. A medicinal product for which an application has been submitted in accordance with Article 13 of [revised Directive 2001/83/EC] shall not be considered as addressing a high unmet medical need.

Or. en

Proposal for a regulation

Article 70 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Where the Agency adopts scientific guidelines for the application of this Article, it shall consult the Commission ***and*** the authorities or bodies referred to in Article 162.	3. Where the Agency adopts scientific guidelines for the application of this Article, it shall consult the Commission***,*** the authorities or bodies ***and other relevant stakeholders*** referred to in Article 162.

ARTICLE 73: NO AMS

Proposal for a regulation

Article 73a new

Text proposed by the Commission	*Amendment*
	Article73a

	Joint procurement of centrally authorised medicinal products
	1. Upon request from the Member States, the Commission shall facilitate joint procurement of centrally authorised medicinal products at the EU level on Member States' behalf.
	2. The Commission is empowered to adopt delegated acts (to be aligned) in accordance with Article 175 to supplement this Regulation by further defining the conditions and procedures for joint procurements of centrally authorised medicinal products.

Proposal for a regulation

Article 73b new

Text proposed by the Commission	*Amendment*
	Article 73b
	European Framework for Rare Diseases
	By (OP: 24 months after the date of entry into force of this Regulation), the Commission shall, following a consultation with the Member States, patient organisations and other relevant stakeholders, propose a needs driven and goals based European Framework for Rare Diseases with a view to better frame and coordinate Union policies and programmes, and support Member States in the elaboration of national strategies to better meet the unmet needs of people living with rare diseases, and their carers.