Dr Tedros Adhanom Ghebreyesus Director General World Health Organisation Avenue Appia 20 1202 Geneva Switzerland

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Dear Dr. Adhanom Ghebreyesus

# Innovation in tobacco control: developing the FCTC to embrace tobacco harm reduction

We write to express our hope that WHO will assume a leadership role in promoting effective and fast-acting policies for regulating tobacco and nicotine. In this letter, we propose that WHO and related stakeholders adopt a more positive approach to new technologies and innovations that have the potential to bring the epidemic of smoking-caused disease to a more rapid conclusion.

In the field of tobacco control and public health, the world has changed significantly since the Framework Convention on Tobacco Control was signed in 2003. It is impossible to ignore or dismiss the rise of Alternative Nicotine Delivery Systems (ANDS). These are established and new technologies that deliver nicotine to the user *without combustion of tobacco leaf and inhalation of tobacco smoke*. These technologies offer the prospect of significant and rapid public health gains through 'tobacco harm reduction'. Users who cannot or choose not to quit using nicotine have the option to switch from the highest risk products (primarily cigarettes) to products that are, beyond reasonable doubt, much lower risk than smoking products (e.g. pure nicotine products, low-toxicity smokeless tobacco products, vaping or heated tobacco products). We believe this strategy could make a substantial contribution to the Sustainable Development Goal to reduce premature deaths through non-communicable diseases (SDG Target 3.4).

The concept of tobacco harm reduction is coded into the definition of 'tobacco control' set out in the FCTC (Article 1.d), and we believe it now needs to be fully expressed in the FCTC and by the Parties in their approach to implementation. To that end, we offer some guiding principles for your consideration for the development of the next phase of global tobacco control, starting from the next Conference of the Parties (COP-8, 1-6 October, Geneva).

- Tobacco harm reduction is integral to tobacco control. Harm reduction is a widely practiced strategy in public health (e.g. HIV, drug use, sexual health) and should become an integral component of tobacco control – helping smokers to quit smoking or diverting them from ever starting, and, in either case greatly reducing their risk.
- From a health perspective, the major distinction between nicotine products is whether they are combustible or non-combustible. It is not whether they are tobacco or non-tobacco products or whether they are established or novel. Given the principal focus of the FCTC is management of health risks, this distinction should be integral to the design and implementation of the FCTC<sup>1</sup>.

We recognise that poor production standards and the inclusion of slaked lime (calcium hydroxide), areca nut and other hazardous ingredients in some traditional tobacco-containing products such as gutka and paan can make these products much more hazardous than other smokeless tobacco products.

- Tobacco harm reduction is supportive and synergistic with the 'MPOWER' policies that underpin the FCTC. By providing more diverse options for users to respond to taxes or other measures, harm reduction can improve the effectiveness of conventional measures and mitigate the unintentional harmful consequences of such policies to continuing users, for example the impact of cigarette taxes on people who would otherwise continue to smoke.
- Stakeholders should give appropriate weight to the benefits and opportunities of tobacco harm reduction. They should not focus exclusively on unknown risks to health, especially when these are minor or improbable risks. A lost opportunity for a public health gain represents a real harm to public health, and should be recognised as such.
- Youth uptake of any tobacco or nicotine product demands a coherent and adaptable strategy focussed on reducing present and future harms to young people. Policies to address youth nicotine use should be based on an understanding of youth risk behaviours, the interactions between use of different products (for example, for some young smokers the potential displacement of smoking by low risk products may be beneficial), and due regard for the overall balance of harms and benefits to both adults and to youth arising from interventions.
- Uncertainty about long-term effects should not be a reason for paralysis. It is true we will not
  have complete information about the impacts of new products until they have been used
  exclusively for several decades and given the complex patterns of use, we may never. But we
  already have sufficient knowledge based on the physical and chemical processes involved, the
  toxicology of emissions, and biomarkers of exposure to be confident these non-combustion
  products will be much less harmful than smoking. We also know with certainty that the
  incumbent product (cigarette) is extremely harmful.
- FCTC and its implementation should embrace "risk-proportionate regulation". This means that the stringency of regulation or taxation applied to product categories should reflect risk to health. For example, there should be high taxes on cigarettes, but low or no taxes on vaping products. It is reasonable to ban all advertising of combustible products, but to place controls on advertising for non-combustible products (to protect never-smoking youth in particular) and so allow enough promotion so that smokers can still learn of alternatives and can be encouraged to switch. This risk-proportionate approach should be adopted throughout the FCTC.
- WHO and Parties to the FCTC should be aware of and careful to avoid the harmful unintended consequences of prohibitions or excessive regulation. If WHO-endorsed policies make noncombustible alternatives to smoking less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibit innovation and development of new and improved products, then these policies can cause harm by perpetuating smoking.
- The FCTC negotiations should become open to more stakeholders. There are many stakeholders, including consumers, the media and public health experts with pro-harm-reduction views, who should be part of the process. We are concerned that the FCTC has been excluding appropriately diverse perspectives and that its deliberations and decisions could be more robust and credible if its proceedings were more open.

We are concerned that WHO and the Convention Secretariat are not embracing these principles and in many cases are doing the opposite. We have seen the more detailed letter to you of 3 September

by Abrams et al regarding prohibition and excessive regulation<sup>2</sup>. We recommend that this letter be read carefully by everyone with an interest in the future of tobacco control.

We believe that it is time for tobacco control to embrace tobacco harm reduction. We hope that WHO and Parties to the FCTC will advance this agenda at the Eighth Conference of the Parties of the FCTC, starting today. We will share this letter with relevant stakeholders.

The authors of this letter confirm no conflicts of interest with respect to the tobacco industry and that no issues arise with respect to Article 5.3 of the FCTC.

Yours sincerely,

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<sup>&</sup>lt;sup>2</sup> Abrams DB, Bates CD, Niaura RS, Sweanor DT. Letter to WHO Director General, 3 September 2018. (link to letter)

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