

## Letter from one hundred specialists in nicotine science, policy, and practice

Heads of Delegation  
Parties to the Framework Convention on Tobacco Control  
Ninth Conference of the Parties, 8-13 November 2021

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Dear sir or madam

### **The urgent need to reduce deaths from smoked tobacco: parties should challenge WHO to modernise its approach to tobacco policy**

We are independent experts in tobacco and nicotine science and policy. We write to urge Parties to the FCTC to encourage WHO to support and promote the inclusion of tobacco harm reduction into the Framework Convention on Tobacco Control.

Over the last decade, innovation in the tobacco and nicotine marketplace has meant there are now many nicotine products available that do not involve combustion of tobacco leaf and inhalation of smoke. These smoke-free products include vaping products, novel oral nicotine pouches, heated tobacco products, and low-nitrosamine smokeless tobacco, such as snus. Cigarettes and other smoked tobacco products are responsible for the vast majority of the deaths caused by tobacco use globally. Smoke-free nicotine products offer a promising route to reducing the harms arising from smoking. There is compelling evidence that smoke-free products are much less harmful than cigarettes and that they can displace smoking for individuals and at the population level.

We recognise there is uncertainty as to the benefits and risks associated with the evolving marketplace of non-combustible tobacco products over the longer term, and we recognise there is a continuum of risk in these products. We are also duly cautious about the involvement of the tobacco industry. However, we must also consider the substantial body of evidence we do have and not allow excessive caution or residual uncertainties to deny smokers promising options to switch away from the combustible products that we know with certainty are lethal.

Regrettably, WHO has been dismissive of the potential to transform the tobacco market from high-risk to low-risk products.<sup>1</sup> WHO is rejecting a public health strategy that could avoid millions of smoking-related deaths. We invite you to consider the following seven points and then our six recommendations.

#### **1. Tobacco harm reduction presents significant public health opportunities**

Fifteen past presidents of the leading professional academic society in the field, the Society for Research on Nicotine and Tobacco (SRNT), have written a scientific essay arguing for a rebalancing in tobacco policy to exploit opportunities from reduced-risk products. The authors, some of the most credible experts globally, address many misconceptions regarding risks to health, gateway effects, youth use, and addiction.<sup>2</sup> The paper concludes:

While evidence suggests that vaping is currently increasing smoking cessation, the impact could be much larger if the public health community paid serious attention to vaping's potential to help adult smokers, smokers received accurate information about the relative risks of vaping and smoking, and policies were designed with the potential effects on smokers in mind. That is not happening.

It is not happening in WHO. That must change, if necessary, through the leadership of the Parties if WHO remains unwilling or unable to perform this role.

#### **2. E-cigarettes are a driver of smoking cessation**

Since COP8, evidence has continued to accumulate supporting the role that e-cigarettes play in reducing smoking. In particular, the Cochrane Review, which provides a world-renowned synthesis of clinical trial evidence, concludes in September 2021:<sup>3</sup>

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Nicotine e-cigarettes probably do help people to stop smoking for at least six months. They probably work better than nicotine replacement therapy and nicotine-free e-cigarettes. They may work better than no support, or behavioural support alone, and they may not be associated with serious unwanted effects.

The trial evidence is supported by observational studies, population trends, market data and user testimony.<sup>4</sup> Taken as a whole, the evidence makes a compelling case that smoke-free alternatives to cigarettes displace smoking. The Tobacco Treatment Network of the SRNT recently argued:<sup>5</sup>

Strategies used for combustible product cessation may be adapted for novel products, and treatment recommendations for tobacco use disorder should be made within the context of a harm reduction framework wherein alternative product use may be the desired outcome.

### 3. Tobacco harm reduction can contribute to the Sustainable Development Goals

SDG target 3.4 aims to cut premature deaths from four key non-communicable diseases (NCDs) by one-third by 2030 compared to 2015.<sup>6</sup> Most of the world's nations are far behind the progress necessary to meet the goal.<sup>7</sup> The only way for tobacco control to make a substantial difference over this period is rapid *smoking cessation*.<sup>8</sup> The fastest acting tobacco control measures would mix the driving force of MPOWER measures with the offer of a more straightforward behavioural response for most smokers: switching from smoking to smoke-free products. Such an approach secures a major reduction in disease risk without the additional struggle of quitting nicotine use. Modelling the impact of smoke-free products on tobacco-related morbidity and mortality shows very substantial public health benefits.<sup>9</sup>

### 4. Major regulatory assessments and experience support heated tobacco products

Though heated tobacco products create greater exposures to toxicants than ENDS, pouches or smokeless tobacco, these products may be a more acceptable reduced-risk alternative to smoking for some smokers. The US Food and Drug Administration conducted an extensive evaluation of over two million pages of evidence for a heated tobacco product made by a major tobacco company. The FDA concluded the product is "*appropriate for the protection of public health*" and disclosing to the public that it created significantly lower human exposures to toxicants is "*appropriate for the promotion of public health*".<sup>10</sup> It is also clear that dramatic declines in smoking in Japan followed the introduction of heated tobacco products in 2015.<sup>11</sup> Market data shows an unprecedented decline of over 40 per cent in the volume of cigarettes and cigarillos sold in Japan between 2015 to 2020.<sup>12</sup> Yet, these significant findings are not acknowledged by WHO in its recent paper for COP9 on novel and emerging tobacco products. Disregarding the clear public health potential, WHO asserted:<sup>13</sup>

Regulators should not allow themselves to be distracted by tobacco and related industry tactics or the aggressive promotion of these products.

Further, the Convention secretariat has argued, incorrectly, that heated tobacco product aerosol should be classified as "tobacco smoke".<sup>14</sup> Such an approach underplays the risks of combustion products and inappropriately blurs the critical distinction between smoked and smoke-free products. FCTC parties should not be distracted from the significant public health potential of reduced-risk products simply because tobacco companies make them. Harm reduction approaches inevitably involve products made by commercial entities making consumer nicotine products in competition with cigarettes. The challenge for regulators is to align industry incentives with public health imperatives to reduce harm, an approach known as risk-proportionate regulation.

### 5. Policymakers must recognise unintended consequences of policy proposals

WHO continues to advocate for prohibitions of low-risk alternatives to smoking and applaud those countries that ban these products. For example, Dr Harsh Vardhan, India's Health and Family Welfare Minister, was awarded the WHO Director-General's Special Recognition Award, with the following citation:<sup>15</sup>

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Dr Harsh Vardhan received the award for spearheading the Government of India's legislation to ban e-cigarettes and heated tobacco products in 2019.

However, policymakers must consider the likely or plausible real-world effect of such bans. What effect will it have on India's 100 million smokers who are now denied safer alternatives? Would it mean young people take up smoking instead of ENDS use? Would it create significant illicit trade? Would it mainly serve the interests of India's partially state-owned cigarette industry? More generally, the Royal College of Physicians (London) set out the challenge of unintended consequences in its 2016 report:<sup>16</sup>

However, if [a risk-averse, precautionary] approach also makes e-cigarettes less easily accessible, less palatable or acceptable, more expensive, less consumer friendly or pharmacologically less effective, or inhibits innovation and development of new and improved products, then it causes harm by perpetuating smoking. Getting this balance right is difficult.

In papers for the Conference of the Parties, the WHO routinely advocates for outright prohibitions of smoke-free alternatives to cigarettes or regulation and taxation of smoke-free products equivalent to cigarettes. Neither is appropriate for public health. The danger of this approach is that it forms a *de facto* regulatory protection of the cigarette trade and will, to quote the Royal College, *cause harm by perpetuating smoking*. Evidence is emerging that ENDS use displaces smoking<sup>17 18 19</sup> and that measures to control ENDS use can trigger increases in smoking. For example, evidence suggests e-liquid flavour bans,<sup>20</sup> raising taxes on vaping products,<sup>21 22</sup> e-cigarette advertising bans,<sup>23</sup> and access restrictions<sup>24</sup> may increase cigarette smoking. Excessive regulation of smoke-free alternatives will also unfairly favour the larger companies that make these products, namely the tobacco companies. This is not a call for an unregulated market but for carefully designed risk-proportionate regulation that is mindful of the risks of harmful unintended consequences.

### 6. Place adolescent ENDS use in proper context.

Policymakers are rightly concerned about increases in youth ENDS use, notably in the United States. However, a deeper analysis of the US evidence, segmenting data by frequency of use and prior tobacco use, is revealing and reassuring. It shows that: (1) most adolescent vaping is infrequent, (2) that frequent use and nicotine dependence among tobacco-naïve users is rare, and (3) most frequent use is concentrated in those who have previously used tobacco.<sup>25 26</sup> Despite the rise in adolescent e-cigarette use, there has not been an increase in nicotine dependence.<sup>27</sup> The United States has seen an abnormally rapid decline in teenage smoking coinciding with the uptake of vaping.<sup>28 29</sup> Some young people use ENDS to quit cigarette smoking or as an alternative to cigarettes. As a result, vaping is displacing cigarette smoking among young people and established smokers.<sup>17 18</sup> Though there are positive associations between adolescent ENDS use and subsequent smoking, these are unlikely to indicate a 'gateway effect'. They are more likely to arise from common risk factors – risk-taking characteristics of the individual or their circumstances that incline them to both smoking and ENDS use.<sup>30 31 32 33</sup>

### 7. There is public health support for harm reduction in tobacco control

Harm reduction is practised in many areas of public health (illicit drugs, sexual health, HIV), and the Framework Convention on Tobacco Control (Article 1d) also acknowledges harm reduction as a component of tobacco control. For hundreds of millions of people who struggle to quit smoking or want to continue to use nicotine, these products represent a significant additional pathway to escape from the deadliest ways to use nicotine. *Smoking* accounts for 98 per cent of the global burden of tobacco-related mortality.<sup>34 35</sup> Much of WHO's rhetoric frames tobacco harm reduction as an industry strategy to undermine tobacco control. But this ignores substantial expert support for tobacco harm reduction in public health and tobacco control<sup>36</sup> and the experience of millions of smokers who have successfully switched and are better off physically, socially, and economically.<sup>37</sup>

### Our recommendations

We recommend that Parties to the FCTC take a more questioning and assertive approach to WHO's advocacy on smoke-free alternative to smoking and undertake the following:

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- Make tobacco harm reduction a component of the global strategy to meet the Sustainable Development Goals for health, notably SDG 3.4 on non-communicable diseases.
- Insist that any WHO policy analysis makes a proper assessment of benefits to smokers or would-be smokers, including adolescents, as well as risks to users and non-users of these products.
- Require any policy proposals, particularly prohibitions, to reflect the risks of unintended consequences, including potential increases in smoking and other adverse responses.
- Properly apply Article 5.3 of the FCTC to address genuine tobacco industry malpractice, but not to create a counterproductive barrier to reduced-risk products that have public health benefits or to prevent critical assessment of industry data strictly on its scientific merits.
- Make the FCTC negotiations more open to stakeholders with harm-reduction perspectives, including consumers, public health experts, and some businesses with significant specialised knowledge not held within the traditional tobacco control community.
- Initiate an independent review of WHO and the FCTC approach to tobacco policy in the context of the SDGs. Such a review could address the interpretation and use of science, the quality of policy advice, stakeholder engagement, and accountability and governance. The Independent Panel for Pandemic Preparedness and Response (IPPPR), initiated to evaluate the response to the COVID-19 pandemic, offers such a model.<sup>38</sup>

We believe that it is time for global tobacco policy to draw on the full potential of tobacco harm reduction. We hope the public health science, policy, and practitioner communities will converge on a common purpose to meet the SDGs and to reduce the global burden of tobacco-related disease and premature mortality as quickly and deeply as possible.

We will share this letter with relevant stakeholders.

The signatories to this letter report no conflicts of interest with respect to the tobacco industry and no issues arising under Article 5.3 of the Framework Convention on Tobacco Control.

Yours sincerely

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