Over 70 experts call on WHO to embrace technology innovation in the fight against diseases caused by smoking

Dear WHO FCTC, do not block the exits for people trying to quit smoking using vaping, smokeless, heated tobacco or novel products. Remember, the enemies of innovation can do more harm than good.

Every two years, the Parties to the WHO Framework Convention on Tobacco Control meet to discuss how to advance the treaty. The 8th meeting of the Conference of the Parties (COP-8) is being held this week, 1-6 October, 2018 in Geneva.

I was one of those agitating for the FCTC back in 1999-2003. Generally, the FCTC doesn't do what normal international treaties do – address some transboundary issue like climate change, international trade or intellectual property. It tries to establish norms for regulation of tobacco commerce *within* countries – a kind of solidarity mechanism for national anti-tobacco policy. The problem is that this idea all goes sour when the WHO, Convention Secretariat and/or Parties agree, in

solidarity, to normalise truly terrible policies – for example, to encourage prohibition of e-cigarettes, to treat all smokeless tobacco as though it is the same and just as risky as smoking, or to regulate heated tobacco products as though they are cigarettes. All really harmful ideas that protect the cigarette trade, perpetuate smoking and cause more disease and death.

Letter to WHO

So, determined to resist this drift into globally harmful policy promotion, a group of 72 of us have put together a letter to register our concern and to suggest there is a better way: to embrace tobacco harm reduction… here it is. The PDF here: Innovation in tobacco control: developing the FCTC to embrace tobacco harm reduction

The text of the letter is below:

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

1 October 2018

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[1].*
- *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 non-combustible 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[2]. 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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Erickson; Jean-François Etter, PhD; Konstantinos Farsalinos, MD, MPH; Prof. Antoine Flahault, MD, PhD ; Jonathan Foulds, PhD; Thomas J. Glynn, PhD; Peter Hajek, PhD; Wayne Hall, PhD; Natasha A. Herrera; Martin J Jarvis, DSc OBE; Martin Juneau , MPs, MD, FRCPC; Dr.Aparajeet Kar, MD; Leon Kosmider, PhD, PharmD; Lynn T. Kozlowski, PhD; Hiroya Kumamaru, MD, PhD; Christopher E. Lalonde, PhD; Murray Laugesen QSO; Jacques Le Houezec, PhD; William Lowenstein, MD; Karl E Lund, PhD; Bernhard-Michael Mayer, PhD; Olivia Maynard, PhD; Andy McEwen, PhD; Ann McNeill PhD; Klim McPherson, PhD, FMedSci, Hon FRCP; Colin Mendelsohn; Robin Mermelstein, PhD; Faares Mili, MD; Thomas J. Miller; Marcus Munafò, PhD; Raymond Niaura, PhD; Caitlin Notley, PhD; David Nutt, DM, FRCP, FRCPsych, FMedSci, DLaws; Konstantinos Poulas, PhD; Philippe Presles, MD; Lars M. Ramström, PhD; Vaughan Rees, PhD; Steven A. Schroeder, MD; John R. Seffrin , PhD; Lion Shahab, PhD; Rajesh N. Sharan, Ph. D.; Michael Siegel, MD, MPH; Roberto A Sussman, PhD; David Sweanor, JD; Professor Umberto Tirelli MD ; Natalie Walker, PhD; Kenneth Warner, PhD; Alex Wodak; Naohito Yamaguchi, MD; Ben Youdan;

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[1] 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.

[2] Abrams DB, Bates CD, Niaura RS, Sweanor DT. Letter to WHO Director General, 3 September 2018. (link to letter)

Earlier letter to WHO

This letter follows and refers to an earlier (3 September, 2018) and more detailed letter from four of us: WHO should reject prohibition and embrace 'tobacco harm reduction' and risk-proportionate regulation of tobacco and nicotine products (PDF) + blog

For the full picture, please read both letters.

Is WHO / FCTC really a prohibitionist over-zealous regulator?

WHO and the FCTC rarely actually say that prohibition is their preferred policy, but they usually act as if it is, always refer to it as one of the legitimate policy options, and often imply it is a baseline policy. Here, we review some previous statements. But first, a view from the top from 2105 suggests that prohibition is the preferred policy:

> *Margaret Chan, the WHO's director-general, expressed concern and urged caution. "E-cigarettes will prompt young people to take up smoking. I recommend that national governments ban, or at least regulate, them," she said. (China Daily, 13 October 2015)*

2014 COP-6

In a Decision of COP-6 (2014) FCTC/COP6(9), the FCTC declares that prohibition is a normal policy option on a par with regulating there products. Of course, a prohibition would leave the market to cigarettes and illicit trade.

> *3. INVITES Parties to consider prohibiting or regulating ENDS/ENNDS, including as tobacco products, medicinal products, consumer products, or other categories, as appropriate, taking into account a high level of protection for human health;*

2016 COP-7

The WHO paper on ENDS for COP-7 (2016) FCTC/COP/7/11, stresses prohibition as the default starting point (eg. see para 29).

> *29. Objective: prevent the initiation of ENDS/ENNDS by non-smokers and youth with special attention to vulnerable groups. Although the debate about whether the use of ENDS/ENNDS is a gateway to smoking is unresolved, preventing this eventuality requires making the initiation and persistence of smoking as difficult as possible. Parties that have not banned the importation, sale, and distribution of ENDS/ENNDS may consider the following options (emphasis added)*

The science base and policy proposals of the WHO COP-7 paper was subject to a blistering critique by the UK Centre for Alcohol and Tobacco Studies.

The Decision of COP-7 (2014) FCTC/COP7(9) also stressed prohibition:

> *3. INVITES Parties to consider applying regulatory measures such as those referred to in document FCTC/COP/7/11 to prohibit or restrict the manufacture, importation, distribution, presentation, sale and use of ENDS/ENNDS, as appropriate to their national laws and public health objectives;*

2018 COP-8

The FCTC Secretariat paper on ENDS for COP-8 FCTC/COP/8/10 is highly negative and strongly prohibitionist. See para 24-26 for an example of unqualified hostility to vaping products, with no recognition whatsoever of the benefits. It goes to the trouble of setting out which parties have prohibited ENDS in a table, but does not tabulate other policy options.

> *25. Data gathered by WHO for the WHO Report on the Global Tobacco Epidemic 2017 using legislation in place by December 2016 illustrate that ENDS were banned in 30 of the 195 WHO Member States globally (about 15%). In the remaining Member States where ENDS were not banned, only about 65 had regulations.*

So the FCTC Secretariat raises only problems (these have no basis in reality) never the opportunities, and it is clearly getting impatient with member states not doing enough:

> *27. Despite ongoing discussions in the COP over the last 10 years with regard to potential approaches to regulate ENDS, there are still a large number of the Parties that are not yet regulating these products, with potential consequences with regard to increasing uptake by young people, the impact on existing tobacco control measures, misleading health claims and deceptive marketing strategies, and ultimately the lack of proper information to consumers.*

So what to do? In terms of policies, it refers back the the two pro-prohibition decisions mentioned above…

28. It seems necessary and timely that Parties develop regulations covering the various policy domains contained in decisions FCTC/COP6(9) and FCTC/COP7(9) by using proper regulatory mechanisms adjusted for the legal framework of every Party