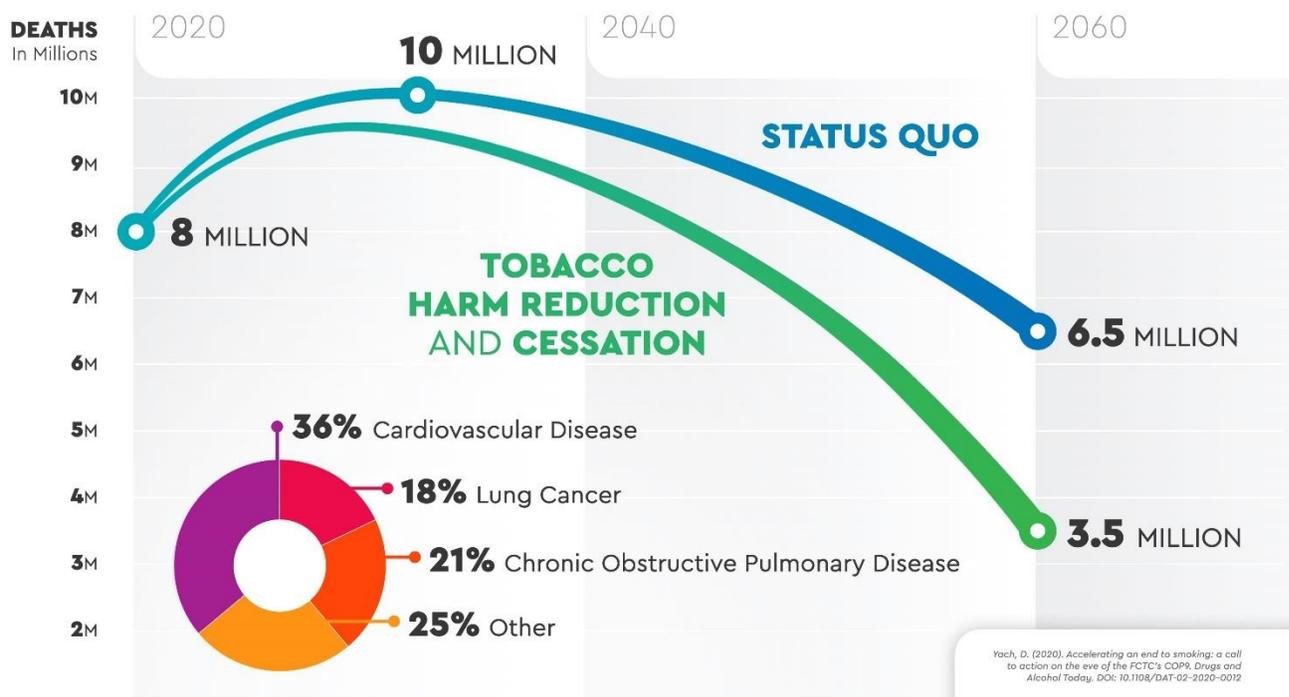


**Perspectives regarding the Report on the Tenth Meeting of the WHO Group on Tobacco Regulation to be considered at the 148th session of the Executive Board of the World Health Organization
Statement by Foundation for a Smoke-Free World**

Recognizing that the tobacco epidemic is a global problem with dire consequences for public health, we are writing to you to express concern regarding the recently published [Report of the Tenth Meeting of the WHO Study Group on Tobacco Regulation](#) (TobReg), published 23rd December 2020. (WHO 2020A) Specifically, we wish to highlight the document’s failure to thoroughly assess novel and emerging tobacco products, despite related requests made to the WHO, via the Convention Secretariat, by the Conference of the Parties at its eighth session in 2018. (WHO 2018). We believe that the recommendations made in the TobReg report will seriously undermine progress needed to end smoking. Specifically, the report fails to address the potential benefits of tobacco harm reduction. These benefits are nontrivial. A recent analysis indicates that wider adoption of this approach could (conservatively) save 3 million deaths annually by 2060. (Yach 2020)

Estimated Trends in Tobacco-Related Deaths 2020–2060



Formalized in 2003, the TobReg study group is intended to “advise WHO about scientifically sound recommendations to Member States addressing the most effective evidence-based means in order to fill regulatory gaps in tobacco control and achieve a coordinated regulatory framework for tobacco products.” (WHO 2020B) Given the group’s mandate, its tenth meeting should have entailed careful deliberation on issues related to the regulation of new and emerging tobacco products—including electronic nicotine delivery systems (ENDS) and heated tobacco products (HTPs). Yet, the report indicates that any discussions on this topic were incomplete and their evidence base wanting.

Unfortunately, we have noted several significant oversights in the report—deficiencies that are troubling given the potential for TobReg to influence regulatory narratives ahead of the Ninth Conference of the Parties (COP9)

to the WHO Framework Convention on Tobacco Control (WHO FCTC). The most critical oversights relate to the following topics:

Harm reduction

The WHO FCTC definition of tobacco control includes the term *harm reduction*, implying a critical role for this approach.(WHO 2005) Yet, TobReg fails to similarly acknowledge the value of this strategy. Indeed, the report neglects to explicitly address the core benefit of harm reduction—namely, to significantly reduce the death and disease caused by combustible cigarettes. Instead, TobReg paints harm reduction products (HRPs) as threats to tobacco control, and nothing more. This depiction misses an opportunity to provide a balanced assessment of HRPs’ potential to reduce smoking rates—an outcome that has been demonstrated in countries such as the UK, Japan, Sweden, and South Korea. (Cummings 2020; Euromonitor 2019; Foulds 2003; ONS 2020) Rather than explore this potential, the report focuses narrowly on demand and supply issues, to the detriment of its broader mandate.

Indeed, TobReg entirely overlooks the fact that we are in the midst of an era of rapid technology transformation. The latest review of patents issued by the US Patent Office shows that the “electrical smoking devices” represent the second fastest growing field for patent issuance between 2016 and 2020—placing the technology just behind computer systems based on biological models and ahead of machine learning.(Decker 2021) The flurry of technological advancement in this sector will lead to healthier, safer products. Given as much, these tools warrant serious consideration by the WHO.

Evidence base

As a highly influential report, TobReg should be accompanied by an impeccable evidence base. In several places, however, adequate references are not provided. According to the report, the TobReg advisory recommendations were developed on the basis of information documented in a series of nine background papers and two horizon scanning papers; yet these papers are not referenced. Additionally, the report cites the *WHO Technical Report Series no. 1029*, which is “in preparation”; and the technical content, scientific review, and methodological strengths and weaknesses of these papers are not mentioned. Without provision and appraisal of the “evidence-base,” the current recommendations fail to achieve transparency and are uninterpretable beyond the closed meetings of TobReg.

This is particularly concerning given that many of the report’s statements are contradicted by other sources, including those used by FDA and Cochrane reviews in their assessments of heated tobacco products and e-cigarettes, respectively. (FDA2016; FDA 2019; Hartmann-Boyce 2020). The study group's report can hardly be characterized as providing “helpful guidance” if the scientific basis of their recommendations is not provided.

Product Differentiation

As new product classes emerge and gain popularity, it is critical that research and regulatory bodies clearly distinguish between these classes, as their risks and benefits can vary greatly. The present report fails to differentiate in this manner, often conflating ENDS, electronic non-nicotine delivery systems (ENNDS), and HTPs. This oversight is particularly evident in the report’s recommendations, which focus primarily on HTPs. Indeed, clear recommendations for e-cigarettes and other products are difficult to glean from the report.

In addition to the oversights outlined above, the report falls short with respect to its recommendations. Lacking access to a full technical report and background papers, our assessment of these recommendations will remain limited to explicit statements made within the summary document EB 148/47. Statements warranting attention include:

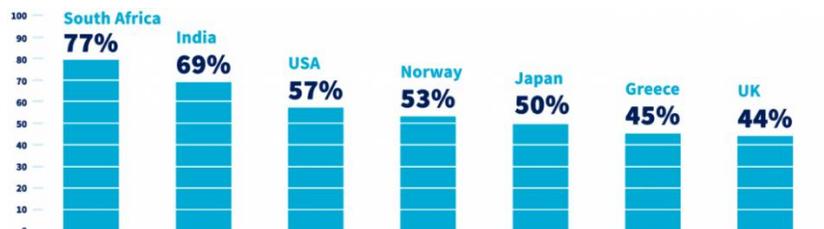
RE 29(a): “maintain focus on evidence-based measures... and seek to avoid being distracted from these actions by the promotion of novel tobacco products.”

This recommendation appears to promote the status quo in tobacco control, despite the fact that existing approaches have yielded little progress toward reducing adult smoking rates. Its vague allusion to novel products (understood to include HRP) also disregards the almost 100 million people who use such products across at least 40 countries. (GSTHR 2020) Indeed, from the above statement it is difficult to ascertain whether this advice applies only to countries where such products are not already used, or if it is a universal recommendation. Regardless, the suggestion to simply ignore novel products misses an opportunity to promote health via innovation in this space.

RE 29(e): “ensure that the public is well informed about the risks associated...[with HRP].”

Just as it is critical to inform the public about the risks of using a given product, so too must health officials endeavor to disseminate information about positive outcomes associated with product use. In the case of HRP, TobReg assesses the negative consequences of adoption, but fails to consider the potential benefits of use among smokers. This oversight represents a gross failure of the public’s right to information about alternative products that can minimize health risk. The report also fails to address public misconceptions that may arise as a product of nongovernmental organizations (NGOs) that systemically subvert science. The promulgation of misleading information by such groups has yielded widespread confusion regarding the relative risk of nicotine, HRP, and combustible cigarettes. For example, a 2019 seven country survey found that between 44.2% and 77.3% of tobacco users believed nicotine is the primary cause of tobacco-related cancer—a dangerously false belief that well-funded NGOs help to spread. (Rajkumar 2020) Here, banning all discussion of HRP is not the solution, as such a strategy withholds critical information that could help people quit combustible cigarettes.

Percentage of respondents who answered YES when asked if tobacco-related cancer is primarily caused by nicotine:



RE 29(f): “rely on independent data and to support continuing independent research...along with critically analysing and interpreting tobacco industry-funded data.”

Rigorous data and critical analyses are, inarguably, vital to effective tobacco control. As such, we endorse the above statements, which are in line with Foundation for a Smoke-free World and UNESCO Open Science views. (UNESCO 2020) However, in addition to these actions, TobReg should consider strategies that enhance public access to research funded by the tobacco industry. Such research is routinely used by leading regulatory bodies like the USFDA. Yet, many scholarly journals ban research on harm reduction and research funded by the tobacco and e-cigarette industry, despite the scientific merit and potential utility of this work. Imagine if WHO applied that logic to industry-funded COVID-19 vaccine research. We would have no vaccines.

On the whole, TobReg’s treatment of HRP marks a departure from emerging consensus regarding the promise of these products. Indeed, rather than proceed from the latest research, these recommendations echo others with similar funding ties (see Table 1). This finding is worrisome, considering the potential impact of the report. The recommendations imply that HRP threaten health, undermine tobacco control policy, and provide no benefits to combustible users. This stance, if absorbed by governments, will reinforce use of combustible products and ultimately subvert efforts to curb deaths caused by smoking.

Table 1. Recommendations about the regulation of e-cigarettes and heated tobacco products

<p><u>WHO – Executive Board</u> <u>23 December 2020</u></p>	<p><u>WHO – Europe</u> <u>25 May 2020</u></p>	<p><u>THE UNION</u> <u>27 May 2020</u></p>
<p>“To maintain focus on evidence-based measures to reduce tobacco ... and seek to avoid being distracted ... by the promotion of novel tobacco products such as heated tobacco products”</p>	<ul style="list-style-type: none"> • Governments should introduce a system for the pre-market assessment of novel tobacco products, including HTPs. • Prevent the initiation of HTP use. 	<p>E-cigarettes and HTP products should be subject to TAPS (Tobacco Advertising, Promotion and Sponsorship) bans and smokefree legislations.</p>
<p>“To use Existing Regulations for tobacco products to regulate heated tobacco products ...including in countries in which these tobacco products are currently not legally available.”</p>	<ul style="list-style-type: none"> • Protect tobacco-control policies and activities from all commercial and other vested interests related to HTPs ...in accordance with Article 5.3 of the WHO FCTC. • HTPs should be taxed similarly to other tobacco products. 	<p>Countries must prioritize evidence-based, proven interventions such as WHO FCTC and MPOWER measures.</p>
<p>“To apply the most restrictive tobacco control regulations to heated tobacco products (including the device).”</p>	<ul style="list-style-type: none"> • Regulate, including restrict, or prohibit, as appropriate, the manufacture, importation, distribution, presentation, sale and use of HTPs. 	<p>The sale of e-cigarettes and HTP should be banned in LMICs.</p>
<p>“To prohibit all manufacturers and associated groups from making claims about reduced harm of heated tobacco products, compared with other products, or portraying heated tobacco products as an appropriate approach for cessation of any tobacco product.”</p>	<ul style="list-style-type: none"> • Prevent health claims being made about HTPs. • Marketing of HTPs should not be permitted unless there is conclusive evidence that compared to conventional cigarettes, the product reduces exposure to harmful and potentially harmful components and reduces health risks. 	<p>Tobacco products should not be manufactured, imported, exported.</p>
<p>“To ban all activities related to the commercial marketing of electronic nicotine delivery systems, electronic non-nicotine delivery systems and heated tobacco products, including in social media and through organizations funded by and associated with the tobacco industry.”</p>	<ul style="list-style-type: none"> • Apply measures regarding advertising, promotion and sponsorship of HTPs in accordance with Article 13 of the WHO FCTC.; 	<p>E-cigarettes and HTPs should also be subject to TAPS (Tobacco Advertising, Promotion, and Sponsorship) bans and smokefree legislations.</p>
<p>WHO is a partner for the Bloomberg Initiative to Reduce Tobacco Use (BI). The FCTC-Secretariat’s observatories to monitor tobacco industry also receive funding through the BI Grants program.</p>	<ul style="list-style-type: none"> • Armando Perugga, a main author, worked for WHO-TFI, which is funded by Bloomberg Initiative to Reduce Tobacco Use 	<p>BI official partner and receives all tobacco control funding from BI.</p>

References

Cummings KM, Nahhas GJ, Sweanor DT. What Is Accounting for the Rapid Decline in Cigarette Sales in Japan?. *International Journal of Environmental Research and Public Health*. 2020;17(10):3570.

Decker S. IBM Leads in Quantum Computing, Ford in Driverless Car Patents. *Bloomberg.com*. 12 Jan 2021. Available at: <https://www.bloomberg.com/news/articles/2021-01-12/ibm-leads-in-quantum-computing-ford-in-driverless-car-patents>. Accessed 14 Jan 2021.

Euromonitor International. Tobacco in South Korea. 2020. Available at: <https://www.euromonitor.com/tobacco-in-south-korea/report>. Retrieved from the Passport Database 13 Jan 2021.

Foulds J, Ramstrom L, Burke M, Fagerström K. Effect of smokeless tobacco (snus) on smoking and public health in Sweden. *Tob Control*. 2003;12(4):349–359

FDA. Scientific Review of Modified Risk Tobacco Product Application (MRTPA) Under Section 911(d) of the FD&C Act -Technical Project Lead. Submitted 8 Nov 2016. Available at: <https://www.fda.gov/media/139796/download>. Accessed 13 Jan 2021.

FDA 2019. Modified Risk Granted Orders — Risk Modification. 11 Oct 2019. Available at: <https://www.fda.gov/media/131922/download>. Accessed 21 Jan 2021.

Foulds J, Ramstrom L, Burke M, Fagerström K. Effect of smokeless tobacco (snus) on smoking and public health in Sweden. *Tob Control*. 2003;12(4):349–359.

GSTHR. The Global State of Tobacco Harm Reduction (2020) (<https://gsthr.org/resources/item/burning-issues-global-state-tobacco-harm-reduction-2020>), accessed 13 Jan 2021.

Hartmann-Boyce J, McRobbie H, Bullen C, Begh R, Stead LF, Hajek P. Electronic cigarettes for smoking cessation. *Cochrane database of systematic reviews*. 2016(9).

ONS. Adult Smoking in the UK: 2019. Release Date: 7 Jul 2020. Available at: <https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/bulletins/adultsmokinghabitsinngreatbritain/2019>. Accessed 13 Jan 2021.

Rajkumar S, Adibah N, Paskow MJ, Erkkila BE. Perceptions of nicotine in current and former users of tobacco and tobacco harm reduction products from seven countries. *Drugs and Alcohol Today*. 2020 Jul 10.

UNESCO. UNESCO Recommendation on Open Science. 2020. Available at: <https://en.unesco.org/science-sustainable-future/open-science/recommendation>. Accessed 13 Jan 2021.

WHO. WHO Framework Convention on Tobacco Control. Updated 2005. Available at: https://www.who.int/tobacco/framework/WHO_FCTC_english.pdf. Accessed 13 Jan 2021.

WHO. Decision: FCTC/COP8(22) Novel and emerging tobacco products. 6 Oct 2018. Available at: [https://www.who.int/fctc/cop/sessions/cop8/FCTC_COP8\(22\).pdf](https://www.who.int/fctc/cop/sessions/cop8/FCTC_COP8(22).pdf). Accessed 13 Jan 2021.

WHO (2020A). Report on meetings of expert committees and study groups. 23 Dec 2020. Available at: https://apps.who.int/gb/ebwha/pdf_files/EB148/B148_47-en.pdf. Accessed 13 Jan 2021/

WHO (2020B). WHO Study Group on Tobacco Product Regulation (TobReg). Available at: https://www.who.int/tobacco/industry/product_regulation/tobreg/background/en/. Accessed 13 Jan 2021.

Yach D. Accelerating an end to smoking: a call to action on the eve of the FCTC's COP9. *Drugs and Alcohol Today*. 2020 May 21.