INNCO
International Network of Nicotine Consumer Organisations

To: Members of the World Health Organization Executive Board

From: International Network of Nicotine Consumer Organisations (INNCO)

Re: World Health Organization Executive Meeting 18-26 January 2021
Provisional Agenda item 22 EB148/47 regarding the Report of the Tenth Meeting of the WHO Study Group on Tobacco Product Regulation, virtual meeting, 28 September - 2 October 2020

Date: 19 January 2021

We respectfully wish to bring to your attention our comments regarding the WHO Study Group on Tobacco Product Regulation ("Study Group") and its recommendations contained in the above-referenced report ("Study Group's Report"). The International Network of Nicotine Consumer Organisations ("INNCO") is the only global organisation of independent national and regional organisations representing consumers who use Electronic Nicotine Device Systems ("ENDS," but more commonly referred to as "e-cigarettes," "electronic cigarettes," or "vapor products" by the people who use them) and other lower-risk nicotine products such as heated tobacco products ("HTPs"), snus and nicotine pouches. We believe our combined expertise, including extensive knowledge at a hands-on and consumer-behavioural level and also at a scientific level, will inform the Executive Board's discussion and deliberation on the Study Group's recommendations.

These recommendations affect the lives of tens of millions of current ENDS and HTP users, as well as lives of the hundreds of millions of people who currently smoke or use other high-risk forms of tobacco who may be denied effective access to lower-risk products as a result of the Study Group's Report. Therefore, it is imperative that consumers have a voice in these deliberations that so intimately and profoundly impact our ability to improve and safeguard our health.

In addition to a respectful request to have our voice heard and considered, we note that the lack of transparency associated with the Study Group's Report is concerning, not only in foreclosing the opportunity for meaningful discussion of these important issues, but also in serving to undermine

public confidence and trust in the recommendations and the processes used to make those recommendations. Specifically, we highlight the fact that the Study Group Report notes that they reviewed nine background papers and two horizon scanning papers, but none of those papers is disclosed. Similarly, the Study Group Report states their recommendations were assisted by discussions with "invited subject-matter experts," but the names of those experts are not disclosed. Moreover, we are uncertain as to even the composition of the Study Group itself given that the relevant World Health Organization ("WHO") website has not been updated since September 2017.[1] We are likewise concerned that the findings of the Study Group's Report are being publicly shared without sharing the underlying report.

Lack of transparency relating to information crucial in assessing global regulatory policy diminishes trust by the general population, current users and the academic community, which can have consequences far beyond simply the tobacco product regulation arena. In fact, the WHO itself has taken pains to stress the importance of transparency:

> *To build trust, communicators must be transparent about how WHO analyses data and how it makes recommendations and policies. Messages also need to acknowledge uncertainty and quickly address any misconceptions or errors. Communicators must rapidly and publicly report the participants, processes and conclusions of:*
>
> - *guideline development meetings*
> - *International Humanitarian Relief (IHR) emergency committee meetings*
> - *working groups.*
>
> *Transparency of all communications is essential to ensure the credibility and trust of WHO information, advice and guidance.*[2]

Lack of inclusion of consumer stakeholders and lack of transparency in the entire process of making recommendations regarding tobacco product regulation (in particular, regulation of lower-risk tobacco products that consumers are using to reduce their risk and improve their health) has led to an incredible amount of distrust among the very people that WHO ostensibly seeks to help.

[1] https://www.who.int/tobacco/industry/product_regulation/tobreg/members/en/.
[2] "Tactics to apply to make your communications credible and trusted, " WHO website https://www.who.int/about/communications/credible-and-trusted/being-transparent (accessed 18 January 2021).

With this in mind, we offer the following general comments on the Study Group's recommendation, noting that the lack of transparency and lack of disclosures detailed above make it difficult for us to offer more specific comments.

Comments on WHO Study Group Report

27. *"The tenth meeting of the Study Group discussed nine background papers" . . . [and] two horizon scanning papers . . . ."*

If the above papers are intended to "inform policy at a global level", their content should be publicly accessible and open to scrutiny. Likewise, given that there are hundreds, if not thousands, of potentially relevant papers, transparency requires, at a minimum, not only disclosure of the papers, but also disclosure of the process used to select those papers.

28. "*The WHO Secretariat for the Study Group, in consultation with members of the Study Group, invited subject-matter experts . . . . "*

As noted previously, the subject-matter experts have not been disclosed. Transparency demands that not only the names of the experts be disclosed, but also that the process used to select those experts be provided.

Main Recommendations

29. (a) *To maintain focus on evidence-based measures to reduce tobacco use as outlined in the WHO Framework Convention on Tobacco Control and seek to avoid being distracted from these actions by the promotion of novel tobacco products such as heated tobacco products;*

Rather than focusing solely on the goal to reduce or eradicate tobacco use, WHO should also adopt the policy of reducing the harm created by combustible tobacco and toxic forms of oral tobacco products. The former goal wades into morality and individual autonomy and is

difficult to implement in the short term, while the latter is a more pragmatic and achievable objective which produces immediate health benefits.

We are concerned that the Study Group has failed to consider the potential promise that tobacco harm reduction strategies can provide in a world where the most dangerous forms of tobacco (combustible and toxic forms of oral products) are still legal and accessible. Labeling tobacco harm reduction as a "distraction" works a grave disservice to the hundreds of millions of nicotine users worldwide and denies the basic observation that tobacco harm reduction policies are not a distraction and do not supplant traditional tobacco control measures, but, rather, are highly effective strategies to reduce tobacco-related deaths and disease that can be employed as a complement to traditional tools.

29.

(b) to use existing regulations for tobacco products to regulate heated tobacco products (including the device) and consider broadening the scope of the existing regulations, where regulatory loopholes may be exploited by the tobacco industry, including in countries in which these tobacco products are currently not legally available;

(c) to apply the most restrictive tobacco control regulations to heated tobacco products (including the device), as appropriate within national laws, taking into account the need for a high level of protection for human health;

(d) 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 and ban their use in public spaces unless robust independent evidence emerges to support a change in policy;

(e) to ensure that the public is well informed about the risks associated with use of heated tobacco product, including the risks of dual use with conventional cigarettes and other smoked tobacco products, and also their use during pregnancy; to correct false perceptions,

counter misinformation and clarify that reduced exposure does not necessarily mean reduced harm;

Regulations must be proportionate to the relative health risk they pose to the user, and such determinations must be based on current, robust scientific evidence. While it is acknowledged that the majority of evidence on HTPs has been produced by their developers and manufacturers and thus should rightfully be carefully scrutinized, the products themselves are highly technical, and there is currently insufficient experience in the academic field to produce evidence that emulates the standard and quality of their data to date. While we fully recognise (and on some level share) WHO's concern regarding potentially competing/conflicting interests, it should also be acknowledged that similar dichotomies exist in other areas such as the pharmaceutical field. The data IS the science, regardless of its source. Any attribution of toxicity, possible health risks or perceived threats by emerging safer alternatives should and must be considered relative to the deadly harm caused by tobacco cigarettes and toxic forms of oral tobacco. No data should be suppressed solely on the basis that it conflicts with a moral imperative.

Refusing to provide the public with accurate communication of relative health risk disempowers consumers from making informed choices. The right of an individual to make informed choices to reduce their health risk is an established human right. Denying the ability of consumers to make informed choices to reduce their health risks not only damages traditional tobacco control efforts, but also reduces WHO's transparency and credibility. The above holds equally true for lower risk products manufactured by both the independent industry and the tobacco industry.

(f) to rely on independent data and to support continuing independent research on the public health impact of heated tobacco products, along with critically analysing and interpreting tobacco industry-funded data, including but not limited to research data pertaining to emissions and toxicity of heated tobacco products and associated exposures and effects in users and non-users;

Continuing independent research on the public health impact of HTPs is important; however, the stark reality is that institutional (non-industry) funding to evaluate HTPs (and ENDS, for that matter) is virtually non-existent, unless its sole intention is to find evidence of harm, however tenuous. Indeed, some countries such as India have simply prohibited any institutional research on the subject. A wider focus and funding pool needs to be dedicated to evaluating relative risks of ENDS and HTPs versus conventional smoking given that the outcomes affect the health and well being of over one billion people.

(h) 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 organisations funded by and associated with the tobacco industry;

We respectfully suggest the term "commercial marketing" be comprehensively defined. We assume it does not prohibit opinions, personal testimonies or informed comments on current research or about product classes being posted on social media, websites or released for publication in the media. These could not be construed within any current legal definition as constituting 'commercial marketing'. To our knowledge there has been no attempt to engage in the commercial marketing of the products described above by any organisations other than independent manufacturers/retailers or the tobacco industry (the later being subject to individual national and state regulations). A ban on communicating information about the existence or the constant development of ENDS and HTPs will negatively impact millions. WHO should instead consider developing guidelines on, for example, how to accurately convey such information with limitations on where and how it can be displayed. Keeping consumers completely in the dark about less harmful alternatives perpetuates smoking and denies individuals the opportunity to make informed choices that affect their health and well being.

(i) to prohibit electronic nicotine delivery systems and electronic non-nicotine delivery systems over which the user can control device features and liquid ingredients (that is, open systems);

(j) to prohibit the sale of electronic nicotine delivery systems that have a higher abuse liability than conventional cigarettes, for example by restricting the emission rate or/flux of nicotine;

We consider the following points integral in enabling a balanced and critical evaluation of the above proposals of the Study Group.

The tobacco industry was very late in acknowledging the potential of reduced risk nicotine products, likely due in no small part to the recognition that vaping was proving a direct threat to the traditional cigarettes they sell. Moreover, the tobacco industry has purposely refrained from offering consumers any control or flexibility over their products. There are simple reasons for this:

1. Restricting the design of consumables to operate only in conjunction with their own branded products ensures continuity of sales. (Similar comparisons exist in printing machines, pod-based coffee machines, and various other consumer products.)
2. Ensuring their proprietary sealed e-liquid pod/cartridge replacements contain very small amounts of e-liquid and are sold at a premium unit price ensures higher profits.
3. Offering a product which is extremely simple to operate (by almost any age group) ensures ease of mass production, reduced retail space (especially relevant to general convenience stores, gas stations, etc.) and consumer loyalty.

Refillable and flexible “open systems” products, which allow individuals to use a wide variety of e-liquid strengths and flavors (and which in many cases also allow the user to further customize the experience by, for example, adjusting air flow and varying temperature) tend to be used almost exclusively by adults. The recommendation to prohibit these adult-oriented products in favour of sealed systems marketed by the tobacco industry is inexplicable, and we are aware of no serious science which would support such a perverse result. Not only would such a move destroy the global multibillion dollar independent industry, it would be a gift to the tobacco industry, solidifying their hold on the global nicotine market.

Moreover, banning open systems will almost certainly encourage the establishment of a black market in illicit products and fake goods, as well as a surge of unregulated e-liquid which is not subject to regulatory standards and government testing. Black markets pose unnecessary risks to consumers and deprive governments of legitimate revenue.

It should also be noted that despite claims by manufacturers, there is relatively little difference among the various closed-system products, particularly among those produced by the tobacco companies. The open-system products allow consumers to try different levels of nicotine, different flavors and different devices in order to find a combination that allows them to dramatically reduce or completely replace their smoking habit. Effectively destroying product diversity by eliminating open-system products will reduce the number of people who are able to use ENDS to successfully quit smoking.

We also note that open system products are particularly valuable for those who wish to step down their nicotine use by gradually and incrementally reducing the concentration of nicotine in their device. This is difficult (and in some cases impossible) to accomplish with closed systems.

On the basis of the foregoing, we strongly urge that these recommendations be rejected.

(k) to prohibit the addition of pharmacologically active substances (in jurisdictions where they are legal) other than nicotine in electronic nicotine delivery systems, such as cannabis and tetrahydrocannabinol to electronic nicotine delivery systems and electronic non-nicotine delivery systems.

INNCO advocates for tobacco harm reduction products, and products which contain non-nicotine pharmacologically active substances are not within the statutory aims of our organisation. We do note, however, that in jurisdictions where non-nicotine pharmacologically active substances are permitted, consumers of those products must be given access to harm reduction tools (such as electronic non-nicotine delivery systems) to reduce the prevalence of the more harmful practice of smoking these substances.

CONCLUSION

The lack of disclosures and transparency regarding the evidence relied upon by the Study Group in making their recommendations has made it difficult for us to comment in depth. The lack of transparency is particularly troubling given that these recommendations will serve as the basis for many countries to effectively ban or dramatically reduce adult access to a wide variety of safer nicotine products. We note with some dismay that for many of these countries (particularly those who have an ownership or profit interest in tobacco companies), safer nicotine products pose a fairly direct threat to their economic stability.

While reducing cigarette consumption (and the disease and premature death caused by smoking) are of critical importance, there must be a recognition of the continuum of risk associated with various nicotine-containing products. It does not serve the interests of public health to treat the lower risk products in the same fashion as the most dangerous products. In addition to our concerns discussed in this comment about, for example, eliminating open-system products and destroying market diversity, we are also very concerned that at the upcoming Framework Convention on Tobacco Control Conference of the Parties there may be a prioritisation on increasing taxation of ENDS, HTPs, snus, and nicotine pouches under the mistaken premise that all nicotine-containing products must be taxed similarly. In fact, the converse is true, and the likely effect of treating the lower risk products the same as high-risk combustibles is more smoking, more premature death, and more disease, not less.

In other areas relating to drug dependency, WHO has embraced harm reduction as a valid human right and evidence-based strategy which has proven success in saving lives. We encourage WHO to likewise embrace harm reduction as a strategy that complements and augments traditional tobacco control measures. Given the changing landscape created by new disruptive safer nicotine products, goals and strategies must be reevaluated and new harm reduction tools employed to help reduce the use of the most dangerous products.

The escalating WHO strategy to prohibit and reduce adult access to lower risk nicotine products while maintaining legal worldwide access in billions of outlets to deadly smoking products runs counter to achieving the global health objectives of increasing population

health and life expectancy and decreasing the terrible burden of smoking-related death and disease.

On behalf of consumers worldwide, we respectfully urge you to consider our comments, which we believe will provide valuable insight in your deliberations. To those members who have taken the time to read the contents of this email, we offer our sincere gratitude and thank you in advance for your serious consideration of the issues raised by consumer stakeholders.