

3 June 2020

DR. ROLANDO ENRIQUE D. DOMINGO, M.D.
Director General
Food and Drug Administration
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City
Philippines

Via email: ntru@fda.gov.ph

Re: FDA Draft General Guidelines for the Regulation of Vapor Products and Heated Tobacco Products

Dear Dr. Domingo, M.D.:

The International Network of Nicotine Consumer Organizations (“INNCO”) submits the following comments to the Food and Drug Administration (FDA) in connection with FDA Draft General Guidelines for the Regulation of Vapor Products and Heated Tobacco Products (“Draft Guidelines”). Specifically, INNCO believes that if implemented, the Draft Guidelines will effectively deprive millions of smokers access to tobacco harm reduction (“THR”) products that would allow them to dramatically lower their health risks. Not only would the Draft Guidelines serve as a de facto ban on low risk vapor and heated tobacco products (collectively sometimes herein referred to as “THR products”), it would actually protect the existing market in high-risk combustible tobacco products.

INNCO, a global non-profit with more than 30 member consumer groups, makes this submission in support of the millions of Filipinos who will continue to smoke (or who will be forced back to smoking) if these Draft Guidelines are implemented. INNCO is a consumer organisation, representing the interests of consumers, not industry. INNCO unites the voices of consumer groups across six continents in our call for rights-based, risk-relative and balanced THR policies as a legitimate human right. In connection with tobacco use, harm

reduction in its most basic form embraces a range of policies, regulations and actions that reduce health risks by providing safer replacements for high-risk products and/or by encouraging less risky behaviour.

I. Vapor Products and Heated Tobacco Products are Low-Risk Alternatives to Smoking.

At the onset, we note that there is no doubt that smoking is an incredibly harmful behavior, resulting in a whole host of serious health issues. Likewise, there is no doubt that vapor products and heated tobacco products, while not completely safe, are in fact markedly less harmful as compared with smoking. As first noted by the Royal College of Physicians in 2016, vapor products are “unlikely to exceed 5% of the harm from smoking tobacco,” and therefore, “in the interests of public health it is important to promote the use of e-cigarettes, NRT and other non-tobacco nicotine products as widely as possible as a substitute for smoking.”¹ This position has been continuously reaffirmed, most recently in Public Health England’s 2020 update on vaping, where it found that “vaping regulated nicotine products has a small fraction of the risks of smoking” and that “smokers should be encouraged to try regulated nicotine vaping products along with smoking cessation medications and behavioural support.”²

The acceptance of the low-risk nature of THR products is growing. In fact, the World Health Organization (“WHO”) Regional Office for Europe recently issued a report noting there is conclusive evidence that “completely substituting EN&NNDS for combustible tobacco cigarettes reduces users’ exposure to numerous toxicants and carcinogens present in

¹ Royal College of Physicians, “Nicotine without smoke: Tobacco Harm Reduction,” 28 April 2016, <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction>.

² McNeill, A., Brose, L.S., Calder, R., Bauld, L., and Robson, D. (2020). Vaping in England: an evidence update including mental health and pregnancy, March 2020: a report commissioned by Public Health England. London: Public Health England. <https://www.gov.uk/government/publications/vaping-in-england-evidence-update-march-2020/vaping-in-england-2020-evidence-update-summary>

combustible tobacco cigarettes.”³ This echoes the findings of the National Academies of Sciences, Engineering and Medicine.⁴ Moreover, in connection with heated tobacco products, the United States Food and Drug Administration (“U.S. FDA”) granted a premarket tobacco product application (“PMTA”) submitted by IQOS (a heated tobacco product), and in doing so found that marketing IQOS is “appropriate for the protection of the public health because, among several key considerations, the products produce fewer or lower levels of some toxins than combustible cigarettes.”⁵

II. Harm Reduction is Good Public Policy.

Harm Reduction is not a novel concept. In fact, “harm reduction strategies” are specifically included within the definition of “tobacco control” in Article 1 of the WHO Framework Convention on Tobacco Control (“FCTC”).⁶ A growing number of countries have chosen to reduce smoking in their borders by adopting pragmatic harm reduction strategies that allow adult smokers to make informed choices to dramatically reduce their risks. We note that leading countries have regulated THR products rather than ban them, and, as a consequence, smoking rates in those countries continue to decline.⁷

Calls for countries to ban THR products as part of a tobacco control strategy are misguided, and will actually serve to increase smoking rates. Not only will lack of access to

³ Regional Office for Europe of the World Health Organization, “Electronic Nicotine and Non-Nicotine Delivery Systems: A Brief,” 2020, <http://www.euro.who.int/en/health-topics/disease-prevention/tobacco/publications/2020/electronic-nicotine-and-non-nicotine-delivery-systems-a-brief-2020>

⁴ The National Academies of Science, Engineering, Medicine, “Public Health Consequences of E-Cigarettes.” Washington, D.C. The National Academies Press 2018, <https://pubmed.ncbi.nlm.nih.gov/29894118/>

⁵ “FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway,” Food and Drug Administration News Release, April 30, 2019, <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway>.

⁶ World Health Organization, “WHO Framework Convention on Tobacco Control,” 2003, https://www.who.int/tobacco/framework/WHO_FCTC_english.pdf.

⁷ Examples of countries regulating rather than banning THR products include the United Kingdom, Canada, the United States of America, New Zealand, and various countries in the European Union.

vapor products and heated tobacco products drive many current THR product users back to smoking (or to a completely unregulated black market), it will remove an effective way for the more than 16 million Filipinos smokers to potentially eliminate their smoking habit and improve their health.

III. Vapor Products and Heated Tobacco Products Help Smokers Eliminate their Smoking Habit.

There is substantial and persuasive evidence that THR products are effective in helping people eliminate their smoking habit.⁸ Even the WHO Regional Office for Europe notes that there is evidence showing that “some smokers may successfully quit tobacco by using some type of ENDS frequently or intensively.”⁹ In a recent study involving 886 participants, researchers concluded that vapor products “were **more effective for smoking cessation than nicotine-replacement therapy**, when both products were accompanied by behavioral support.” (emphasis supplied)¹⁰

Given that these products do work to help many people completely replace their smoking habit and improve their health, they should be embraced as a humane and pragmatic solution to help reduce the smoking rate in the Philippines.

⁸ See, for example, Sara Kalkhoran, MD, MAS, Yuchiao Chang, PhD, Nancy A Rigotti, MD, Electronic Cigarette Use and Cigarette Abstinence Over 2 Years Among U.S. Smokers in the Population Assessment of Tobacco and Health Study, *Nicotine & Tobacco Research*, Volume 22, Issue 5, May 2020, Pages 728–733, <https://doi.org/10.1093/ntr/ntz114>.

⁹ Regional Office for Europe of the World Health Organization, “Electronic Nicotine and Non-Nicotine Delivery Systems: A Brief,” 2020, <http://www.euro.who.int/en/health-topics/disease-prevention/tobacco/publications/2020/electronic-nicotine-and-non-nicotine-delivery-systems-a-brief-2020>

¹⁰ Peter Hajek, Ph.D., Anna Phillips-Waller, B.Sc., Dunja Przulj, Ph.D., et al., “A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy,” *N Engl J Med* 2019; 380:629-637, DOI: 10.1056/NEJMoa1808779 14 February 2019.

IV. The Draft Guidelines are a de facto Ban on Vapor Products and Heated Tobacco Products.

Given that THR products are increasingly being recognized as a strategy to eliminate a person’s smoking habit, a pharmaceutical pathway at first blush may sound like a reasoned middle ground. However, the effect of the Draft Guidelines is a de facto ban on low-risk vapor products and heated tobacco products. Products take years – and astronomical sums of money – to successfully navigate the pharmaceutical gauntlet designed to ensure that drugs are safe and effective. In addition to completely pricing small and moderate sized businesses from the market, the pharmaceutical pathway eliminates the very quality and characteristics of THR products that make them such successful alternatives to smoking – diversity.

Product diversity is the single-most important factor in making vapor products a successful alternative to smoking. A variety of devices, flavors, and nicotine strengths allows a smoker to find a product that is satisfying enough to make the switch from smoking to a far less harmful alternative. Even assuming that a vapor product would be eventually approved as a pharmaceutical product (which is a generous assumption given that these products are not “safe” in the absolute sense of the word – only far, far less harmful), the resulting pharmaceutical vapor product will likely be no more effective than the current NRT offerings. Simply stated, trying to force vapor products into a pharmaceutical category will inevitably destroy the very thing that makes it such a successful alternative to smoking.

V. Reasonable Regulation Must Embrace Harm Reduction.

There is a middle ground between unfettered access and complete prohibition, namely, enacting reasonable, proportionate regulation that is risk-relative and balanced.

- A. Ensure products are not sold to minors** as an important first step in preventing youth uptake of nicotine-containing products.
- B. Provide for accurate communication regarding relative risks** to allow adult consumers to make informed choices to eliminate or reduce their risk from smoking. Communications, whether from governmental agencies or contained on product labeling, should accurately and honestly state that while

vapor products and/or heated tobacco products are not risk-free, they are substantially lower risk than smoking.

- C. **Provide reasonable product standards that are attainable and ensure quality and safety.** We note that flavours are a key reason why vapor products are such an effective alternative to smoking. The importance of flavours is recognized not only by the WHO Regional Office of Europe, but is supported by a growing body of research.¹¹

VI. **Conclusion**

There are currently more than 16 million people who smoke in the Philippines. Vapor products and heated tobacco products provide a valuable tool to help reduce the smoking rate. Regulation of such products must be reasonable and proportionate, and relegating these products to a pharmaceutical-only model will result in a de facto ban on low-risk THR products that could help millions make the switch away from smoking and improve their health. People who smoke need more options, not fewer. Denying access to low-risk products or making them more difficult to access than cigarettes, indisputably the most dangerous tobacco product on the market in the Philippines, works against fundamental tenets of public health.

For the foregoing reasons, INNCO respectfully requests that the FDA not implement the Draft Guidelines in its current form, and instead pursue a policy that is in step with countries that are moving towards harm reduction as an ethical and effective means of reducing smoking rates.

Respectfully submitted,

¹¹ See, for example, Farsalinos K, Romagna G, Tsiapras D, et al. Impact of flavour variability on electronic cigarette use experience: an internet survey. *Int J Environ Res Public Health*. 2013;10:7272–82. See also Russell, C., McKeganey, N., Dickson, T. et al. Changing patterns of first e-cigarette flavor used and current flavors used by 20,836 adult frequent e-cigarette users in the USA. *Harm Reduct J* 15, 33 (2018). <https://doi.org/10.1186/s12954-018-0238-6>



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A handwritten signature in black ink, appearing to read "Kim Dabelstein Petersen".

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