CAPHRA
COALITION OF ASIA PACIFIC
TOBACCO HARM REDUCTION ADVOCATES

May 28, 2024

DR. SAMUEL A. ZACATE
Director General
Food and Drug Administration
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City
Philippines
e-mail address: ntru@fda.gov.ph

Re: **FDA Draft Guidelines for the Authorization of Vaporized Nicotine and Non-Nicotine Products and Novel Tobacco Products with Medicinal or Therapeutic Claims or Reduced Risk Statements Pursuant to Sections 12 (k), 12 (l), and 13 (c) of Republic Act No. 11900**

Dear Director General Zacate,

The Coalition of Asia Pacific Tobacco Harm Reduction Advocates **(CAPHRA**) respectfully submits its comments regarding the FDA Draft Guidelines for the Authorization of Vaporized Nicotine and Non-Nicotine Products (VNNPs) and Novel Tobacco Products (NTPs) with Medicinal or Therapeutic Claims or Reduced Risk Statements as published on your official website.[1]

CAPHRA is an alliance of civil society groups particularly among Tobacco Harm Reduction Advocates and their respective organizations in the Asia Pacific region. We are comprised of adults who formerly smoked and now vape. Our mission is to educate, advocate and represent the right of the at least 15 million adult alternative nicotine consumers in the Asia Pacific region to access and use of products that reduce harm from tobacco use.[2]

As a consumer vaping group, we are dedicated to advocating for the rights and well-being of individuals who use VNNPs and NTPs as less harmful alternatives to traditional smoking. The Philippine Food and Drug Administration (FDA) has proposed a draft regulation that evaluates these products through a pharmaceutical lens. We strongly believe that this approach is inappropriate and counterproductive. This submission strongly cautions that adopting such a regulation will not help consumers switch to less harmful alternatives and may, in fact, hinder harm reduction efforts. We therefore humbly submit the following arguments for consideration of this Honorable Office:

[1] https://www.fda.gov.ph/draft-for-comments/
[2] Tomasz Jerzynski, Stimson, et al., *Estimation of the global number of e-cigarette users in 2020,* Harm Reduction Journal, October 23, 2021, available at https://harmreductionjournal.biomedcentral.com/articles/10.1186/s12954-021-00556-7.

1. Misalignment with Consumer Needs and Realities

The primary purpose of VNNPs and NTPs is to offer smokers a less harmful alternative to traditional cigarettes, facilitating harm reduction rather than serving as medical treatments. Evaluating these products through a pharmaceutical lens imposes stringent requirements that are more suited to medicinal products. This misalignment ignores the practical realities and needs of consumers who seek safer alternatives to smoking. A regulatory framework should acknowledge and address the unique nature and purpose of these products, enabling rather than obstructing their availability and use.

2. Barriers to Access and Innovation

Applying a pharmaceutical framework to VNNPs and NTPs introduces unnecessary regulatory barriers that can stifle innovation and limit consumer access. The stringent requirements associated with pharmaceutical regulations can create significant obstacles for manufacturers, resulting in fewer product choices for consumers. This can discourage smokers from switching to less harmful alternatives, as they may find it harder to access the products that best meet their needs. A more balanced regulatory approach would facilitate market entry and innovation, ensuring that a wide range of safe and effective products is available to consumers.

3. Impact on Public Health Goals

One of the main public health goals is to reduce the prevalence of smoking and the associated health risks. VNNPs and NTPs play a crucial role in achieving this by providing smokers with safer alternatives. However, if these products are subjected to pharmaceutical-grade regulations, their availability and appeal may be significantly reduced. This could result in fewer smokers making the switch, thereby undermining public health objectives. A more appropriate regulatory approach would support harm reduction by ensuring that these products are safe and effective while remaining accessible and appealing to smokers.

4. Consumer Autonomy and Informed Choice

Consumers have the right to make informed choices about their health and well-being. A regulatory framework that imposes pharmaceutical standards on VNNPs and NTPs can limit the availability of information and products, thereby restricting consumer autonomy. Instead, the focus should be on transparent risk communication and providing consumers with accurate information about the relative risks of different products. This empowers consumers to make decisions that best suit their needs and preferences, ultimately supporting harm reduction and public health. By adopting a pragmatic approach to assessing reduced-risk statements, the FDA can empower consumers to make informed decisions based on scientific evidence and expert guidance.

5. Focus on Consumer Education and Transparent Risk Communication

The primary regulatory focus should be on ensuring that consumers have access to accurate, transparent information about the relative risks of VNNPs and NTPs compared to traditional tobacco products. This can be achieved through clear labeling, public education campaigns, and rigorous standards for product safety and quality. By emphasizing informed consumer choice rather than medical treatment, the FDA can better protect public health and support harm reduction efforts. This approach also fosters transparency, trust, and accountability in the regulatory process, ultimately benefiting public health outcomes.

In conclusion, the Philippine FDA's draft regulation on Reduced Risk Statements, if adopted using a pharmaceutical lens, will not help consumers switch to less harmful alternatives. This approach misaligns with the purpose of VNNPs and NTPs, introduces unnecessary barriers to access and innovation, and could hinder public health goals. By instead recognizing the unique nature of these products, embracing harm reduction principles, and prioritizing consumer empowerment, the FDA can promote informed decision-making among smokers and contribute to public health objectives. Embracing a pragmatic regulatory framework will enable the FDA to fulfill its mandate of protecting public health while supporting harm reduction initiatives in the evolving landscape of tobacco consumption. Finally, we therefore respectfully call on FDA to instead adopt Option 1 of the previous Draft Guidelines[3] it issued including the attached Annex A[4] that laid down the more appropriate application process for the authorization of reduced risk statements.

We would like to take this opportunity to thank the Philippine FDA for affording us this opportunity to make written submissions on the draft guidelines. We thank you for your time and we look forward to the favorable actions of this Honorable Office.

Very truly yours,

Nancy E. Loucas, Executive Coordinator
on behalf of the member organisations of CAPHRA

[3] *Available at* https://www.fda.gov.ph/wp-content/uploads/2024/02/Draft-Issuance-on-FDA-Authorization-of-VNNPs-and-NTPs.pdf
[4] *Available at* https://www.fda.gov.ph/wp-content/uploads/2024/02/Appendix-A_RRSA-Application-Process.pdf