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Mr. Dondo Mogajane
Director General
National Treasury
40 Church Square
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South Africa

Re: Taxation of electronic nicotine and non-nicotine delivery systems (vaping)

January 25, 2022

Dear Director General Mogajane:

We appreciate the opportunity to submit comments regarding the taxation of electronic nicotine and non-nicotine delivery systems (vaping). When considering the taxation and regulation of electronic nicotine delivery systems, weighing the potential public health benefits as well as the potential public health threats is prudent. Combustible tobacco products result in more preventable deaths globally than any other cause, and continually exploring strategies for decreasing tobacco-related morbidity and mortality is vital. Electronic nicotine delivery systems provide such an opportunity.

For people who use combustible tobacco products and cannot or do not want to stop, electronic nicotine delivery systems present a public health opportunity to limit health harms and improve lives.

With this in mind, we urge the National Treasury to consider pragmatic regulations that allow South African citizens broad access to reduced-risk products. Taking a harm reduction approach to tobacco control is supported by scientific and policy evidence and will advance the objective of protecting and improving public health.

Electronic nicotine delivery systems are a harm reduction tool

While no tobacco product is without risk, agencies such as The Royal College of Physicians; Public Health England; the National Academies of Science, Engineering and Medicine; and the Food and Drug Administration (FDA) have acknowledged that nicotine products represent a continuum of risk.¹ On this

¹ Tobacco Advisory Group, *Nicotine without smoke: Tobacco harm reduction*, Royal College of Physicians, April 28, 2016, p. 87. <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0>; "E-cigarettes: a new foundation for evidence-based policy and practice" Health & Wellbeing Directorate, Public Health England, August 2015.

continuum, e-cigarettes and heated tobacco products represent a lower risk, similar to traditional nicotine replacement therapies, and combustible cigarettes present the highest risk to health. By eliminating the combustion process, electronic nicotine delivery systems produce lower quantities of most potentially harmful substances than combustible cigarettes.² It is important to recognize that nicotine, although addictive, is not the component of combustible cigarettes that causes most of the health harms associated with smoking.³ Although nicotine may not be entirely benign, in isolation from combustion, its health effects are relatively insignificant, especially for current smokers.

In the United States, the FDA has recognized that electronic nicotine delivery systems can play a role in the tobacco control landscape. On April 30, 2019, the FDA granted IQOS, a heated tobacco product, marketing authorization through its Premarket Tobacco Product Authorization (PMTA) pathway.⁴ Then, on July 7, 2020, the FDA granted IQOS Modified-Risk Tobacco Product (MRTP) authorization, signifying that it represents a reduced level of exposure to harmful chemicals found in combustible cigarette smoke.⁵ To receive these authorizations, IQOS had to meet rigorous standards established by the PMTA and MRTP pathways, including being deemed “appropriate for the protection of public health.” The “appropriate for the protection of public health” determination is made with respect to the risks and benefits the product presents to the populations as a whole, including users and nonusers of the tobacco product.⁶ Specifically, the FDA had to consider “the increased or decreased likelihood that existing users of tobacco products will stop using such products” and “the increased or decreased likelihood that those who do not use tobacco products will start using such products.”⁷ Since the marketing authorization of IQOS, the FDA has also granted a PMTA to a second electronic nicotine delivery system, Vuse Solo.⁸

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/454517/Ecigarettes_a_firm_foundation_for_evidence_based_policy_and_practice.pdf; “Public Health Consequences of E-cigarettes,” The National Academies of Science, Engineering and Medicine, 2018.

<http://nationalacademies.org/hmd/reports/2018/public-health-consequences-of-e-cigarettes.aspx>; U.S. Food and Drug Administration, “FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease,” U.S. Department of Health and Human Services, July 27, 2017.

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm>.

² David J. K. Balfour, et al. “Balancing Consideration of the Risks and Benefits of E-Cigarettes,” *American Journal of Public Health* (September 2021) pp. 1661-1672. <https://doi.org/10.2105/AJPH.2021.306416>.

³ U.S. Food and Drug Administration, “Nicotine Is Why Tobacco Products Are Addictive,” U.S. Department of Health and Human Services, Aug. 19, 2021. <https://www.fda.gov/tobacco-products/health-effects-tobacco-use/nicotine-why-tobacco-products-are-addictive>.

⁴ U.S. Food and Drug Administration, “FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway,” U.S. Department of Health and Human Services, April 30, 2019. <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway>.

⁵ U.S. Food and Drug Administration, “FDA Authorizes Marketing of IQOS Tobacco Heating System with ‘Reduced Exposure’ Information,” U.S. Department of Health and Human Services, July 7, 2020. <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-iqos-tobacco-heating-system-reduced-exposure-information>.

⁶ U.S. Food and Drug Administration, “Section 910 of the Federal Food, Drug, and Cosmetic Act - Application for Review of Certain Tobacco Products,” U.S. Department of Health and Human Services, last accessed Jan. 24, 2021. <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/section-910-federal-food-drug-and-cosmetic-act-application-review-certain-tobacco-products>.

⁷ Ibid.

⁸ U.S. Food and Drug Administration, “FDA Permits Marketing of E-Cigarette Products, Marking First Authorization of Its Kind by the Agency,” U.S. Department of Health and Human Services, Oct. 12, 2021. <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-e-cigarette-products-marking-first-authorization-its-kind-agency>.

While there are pharmaceutical products available to help people quit smoking, they have relatively low success rates.⁹ A Cochrane Review of the evidence supporting electronic nicotine delivery systems for smoking cessation found, with moderate certainty, that electronic cigarettes with nicotine increase quit rates compared to nicotine replacement therapy.¹⁰ Additionally, public health modeling suggests that electronic nicotine delivery system uptake has led to more rapid declines in smoking rates than in the years prior to their introduction.¹¹ In the United States and United Kingdom, use of e-cigarettes as a quitting aid has outpaced use of traditional quit methods (varenicline, nicotine replacement therapies and counseling) and demonstrates a higher degree of success.¹² Furthermore, a randomized trial of smokers showed that those who used e-cigarettes as a cessation device achieved sustained abstinence at roughly twice the rate of smokers who used nicotine replacement therapy.¹³

In Japan, heated tobacco products have contributed to a dramatic decline in cigarette purchases.¹⁴ In three years, cigarette sales have decreased by 31 percent, from 109.2 billion sticks in 2016 to 75.5 billion sticks in 2019.¹⁵ Analysts at Citi Group attribute this disruption of the cigarette market to heated tobacco products.¹⁶

When properly regulated and integrated into a comprehensive tobacco control strategy, electronic nicotine delivery systems can contribute to dramatic decreases in smoking rates.

Adopt risk-proportionate regulation of electronic nicotine delivery systems

When considering the regulation of electronic nicotine delivery systems, keeping their harm reduction benefits in mind is paramount. One way to do this is to adopt risk-proportionate regulations. For tobacco products, this entails subjecting the most harmful products, combustible cigarettes, to the most arduous

⁹ Gary Green, "Nicotine Replacement Therapy for Smoking Cessation," *American Family Physician*, 92:1 (2015) pp. 24A-B. <https://www.aafp.org/afp/2015/0701/od1.html>.

¹⁰ Jamie Hartmann-Boyce et al., "Electronic cigarettes for smoking cessation," Cochrane Library, Sept. 14, 2021. <https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010216.pub6/full>.

¹¹ David T. Levy et al., "Examining the relationship of vaping to smoking initiation among US youth and young adults: a reality check," *Tobacco Control* (2018). <https://www.ncbi.nlm.nih.gov/pubmed/30459182>.

¹² "E-cigarettes: a new foundation for evidence-based policy and practice," Public Health England (2015). https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/454517/E-cigarettes_a_firm_foundation_for_evidence_based_policy_and_practice.pdf; Shu-Hong Zhu et al., "E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys," *The BMJ* 358, j3262 (July 26, 2017). <https://www.bmj.com/content/358/bmj.j3262>.

¹³ Peter Hajek et al., "A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy," *The New England Journal of Medicine* 380 (2019), pp. 629-37. <https://www.nejm.org/doi/full/10.1056/nejmoa1808779>.

¹⁴ K. Michael Cummings, et al. "What Is Accounting for the Rapid Decline in Cigarette Sales in Japan?" *International Journal of Environmental Research and Public Health*. May 20, 2020; 17(10):3570. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7277739>.

¹⁵ "Japanese Domestic Cigarette Sales Results for December 2016 (Preliminary Report)," Japan Tobacco Inc., Jan. 20, 2017. https://www.jt.com/media/news/2017/pdf/20170120_02.pdf; "Japanese Domestic Cigarette Sales Results for December 2019 (Preliminary Report)," Japan Tobacco Inc., Jan. 22, 2020. https://www.jt.com/media/news/2020/pdf/20200122_E01.pdf.

¹⁶ "Citi upgrades Philip Morris, downgrades BTI in 'new world' of Tobacco," *The Fly*, Feb. 28, 2018.

and restrictive regulations and taking a more permissive approach with lower-risk products. Taking this approach aims to encourage people to transition from higher-risk products to lower-risk products. In the case of taxation, risk-proportionate regulation would tax electronic nicotine delivery systems at a lower level than combustible cigarettes.

Traditional tobacco control measures and harm reduction strategies need not be at odds. Considering ways to incorporate risk-proportionate regulation into a larger tobacco control plan is one way to ensure the safety of the public, allow adult smokers access to reduced-risk products and discourage uptake by adolescents. Risk-proportionate regulation supports the goal of displacing combustible cigarettes and incentivizes people to move away from more harmful products.

Furthermore, predictions show that proper regulation of tobacco products, including regulation of electronic nicotine delivery systems, can lead to decreased cigarette and e-cigarette use and increased quality-adjusted life years over time.¹⁷ A modeling study that applied various forms of regulatory approaches, including public health campaigns, taxation and electronic nicotine delivery system availability, demonstrated that a combination of these approaches would decrease cigarette and e-cigarette consumption by approximately 5 to 10 percent by 2060.¹⁸

Adopting a more progressive approach to tobacco control, one that incorporates tobacco harm reduction, is advised by many tobacco policy experts. In October 2018, 72 experts wrote the director general of the World Health Organization calling for the adoption of a progressive approach to tobacco harm reduction to support the Sustainable Development Goals.¹⁹

Protecting Public Health

Applying risk-proportionate regulation incentivizes new technologies and safer products to evolve in the marketplace, which has the potential to improve the health and welfare of those who cannot or do not want to quit combustible cigarettes. It is estimated that if only 10 percent of current smokers substituted e-cigarettes over the next 10 years, it would save up to 6 million lives by 2100.²⁰

Regulating electronic nicotine delivery systems identically to combustible cigarettes discourages current smokers from switching to less harmful products, perpetuating the health harms caused by combustible cigarettes. However, when risk-proportionate regulations and policies that reflect the reduced harm of electronic nicotine delivery systems are promulgated, governments can significantly decrease the burden of disease that combustible cigarettes impose on society.

One thing is certain: improving and protecting public health is paramount. Recognizing the potential electronic nicotine delivery systems offer for mitigating the risks associated with combustible cigarette use is vital to expanding the tobacco control landscape. We encourage you to consider policies that

¹⁷ Thi Thanh Tra Doan et al., "Evaluating smoking control policies in the e-cigarette era: a modelling study," *Tobacco Control* 29:5 (Sept. 4, 2019). <https://tobaccocontrol.bmj.com/content/tobaccocontrol/29/5/522.full.pdf>.

¹⁸ Ibid.

¹⁹ "Letter from seventy-two specialists in nicotine science, policy and practice," Oct. 1, 2018. <https://clivebates.com/documents/WHOCOP8LetterOctober2018.pdf>.

²⁰ David T. Levy et al., "Potential deaths averted in USA by replacing cigarettes with e-cigarettes," *Tobacco Control* 27:1 (2017), pp. 18-25. <https://tobaccocontrol.bmj.com/content/27/1/18>.

reflect the reduced risk of electronic nicotine delivery systems compared to combustible cigarettes in pursuit of the healthiest possible population.

Respectfully submitted,

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