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Union Minister for Health and Family Welfare  
Ministry of Health and Family Welfare  
Government of India

Shri Shrikar Pardeshi  
Joint Secretary  
Prime Minister's Office  
Government of India

Shri Piyush Goyal  
Union Minister of Commerce & Industry  
Ministry of Commerce & Industry  
Government of India

Shri Ravi Shankar Prasad  
Union Minister of Law & Justice and Electronics  
and Information Technology  
Ministry of Law & Justice and Electronics and  
Information Technology  
Government of India

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August 30, 2019

Dear Dr. Vardhan and Shris Pardeshi, Goyal and Prasad,

We appreciate the opportunity to provide comments regarding the proposal to ban e-cigarettes. It is with this in mind that we write to urge the India government, to consider regulation that allows its citizens continued access to reduced-risk products. In light new scientific and policy evidence<sup>1</sup> that has emerged over the last five years supporting a global harm reduction approach to smoking we can find no credible evidence that suggests that a ban on alternative nicotine delivery systems, including e-cigarettes, will meet its stated objective – to protect and improve public health.

In fact, we believe that these products present an opportunity improve the health of people who use combustible products. Denying smokers access to much safer products and new ways to quit smoking carries obvious dangers that have not yet been recognized – but certainly will as long as cigarettes are given a continued advantage in the marketplace. There are no ethical or scientific reasons why a government would continue to ban products as evidence shows that, beyond any reasonable doubt, these products impose a much lower risk on the consumer than cigarettes – which remain freely available throughout India. There is no justification for denying smokers who cannot or do not want to quit the option to switch to a much lower risk product. In fact, it is a form of regulation that carries with it harmful, unintended consequences – namely, more smoking and harmful tobacco use – that already kills more than 1 million Indian citizens and nearly 10 percent of all deaths annually. We urge the administration to pursue a regulatory approach to tobacco products that will favor products that are much lower in risk than combustible products that encourage smokers to switch.

Public Health England, the National Academies of Science, Engineering and Medicine<sup>2</sup> and the FDA<sup>3</sup> have recognized nicotine products exist on a continuum of risk, with e-cigarettes, Snus and heat-not-burn

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<sup>1</sup> Tobacco Harm Reduction: Evidence Update, by Carrie Wade and Chelsea Boyd, R Street Policy Study August, 2019 <https://www.rstreet.org/2019/08/07/tobacco-harm-reduction-evidence-update/>

<sup>2</sup> “The Public Health Consequences of E-cigarettes,” National Academies of Science, Engineering and Medicine, January 2018. <http://nationalacademies.org/hmd/reports/2018/public-health-consequences-of-e-cigarettes.aspx>. “Across a range of studies and outcomes, e-cigarettes appear to pose less risk to an individual than combustible tobacco cigarettes.”

<sup>3</sup> Scott Gottlieb, M.D., on comprehensive regulatory plan to shift trajectory of tobacco-related disease, death,” Statement from FDA Commissioner,” U.S. Food and Drug Administration, 2018.

technologies at the lower end near traditional nicotine replacement therapies, and combustible cigarettes at the highest end of the risk spectrum. Importantly, in its comprehensive report, Public Health England has stated that e-cigarettes are unlikely to exceed 5 percent of the risk associated with combustible cigarettes<sup>4</sup>. Recognition that these products present a reduced risk is because they don't employ the traditional cigarette combustion process that releases 7,000 chemicals – some of which are highly carcinogenic – the FDA commissioner Scott Gottlieb has made reduced-risk products like e-cigarettes central to the FDA's roadmap<sup>5</sup>.

While it's the addiction to nicotine that keeps people smoking, it's primarily the combustion, which releases thousands of harmful constituents into the body at dangerous levels that kills people. This fact represents both the biggest challenge to curtailing cigarette addiction – and also holds the seeds of an opportunity that's a central construct for our actions. E-cigarettes may present an important opportunity for adult smokers to transition off combustible tobacco products.

It is noteworthy that in the United States, the first heat-not-burn product, IQOS, was granted marketing approval by the FDA April 30, 2019<sup>6</sup>. This marketing approval would not have been possible if this heat-not-burn product did not meet the rigorous standards set forth by the FDA, including being evaluated by the FDA as “appropriate for the protection of public health”<sup>7</sup> taking account the risks and benefits to the population as a whole.

ANDS have quickly become the number one quit tool in many parts of the world, allowing an untold number of smokers to quit cigarettes. Economic modeling has suggested that e-cigarettes are contributing to a more rapid decline in smoking rates than were seen in previous years. In the United States and United Kingdom e-cigarettes have outpaced traditional quit methods (Varenicline, nicotine replacement therapies or counseling)<sup>8</sup> and with a higher degree of success<sup>9</sup>.

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<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm568923.htm> “A key piece of the FDA's approach is demonstrating a greater awareness that nicotine – while highly addictive – is delivered through products that represent a continuum of risk and is most harmful when delivered through smoke particles in combustible cigarettes.”

<sup>4</sup> Tobacco Advisory Group, “Nicotine without smoke: tobacco harm reduction,” Royal College of Physicians, 2016. p. 87. <https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0>.

<sup>5</sup> Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use, “Statement from FDA Commissioner,” U.S. Food and Drug Administration, 2018. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm>

<sup>6</sup> FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway, April 30, 2019. <https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway>

<sup>7</sup> U.S. Department of Health and Human Services Food and Drug Administration Section 910 of the Federal Food, Drug, and Cosmetic Act - Application for Review of Certain Tobacco Products. Sec 910(c)(4). <https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/section-910-federal-food-drug-and-cosmetic-act-application-review-certain-tobacco-products>

<sup>8</sup> “E-cigarettes: a new foundation for evidence-based policy and practice” Health & Wellbeing Directorate, Public Health England, August 2015 [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](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)

<sup>9</sup> S. H. Zhu, *et al.*, E-cigarette use and associated changes in population smoking cessation: evidence from US current population surveys. *BMJ* **358**, j3262 (2017). <https://www.bmj.com/content/358/bmj.j3262>

Snus use in Sweden is considered to be the primary reason that daily smoking prevalence is below 5 percent, making Sweden a “non-smoking” country by many public health bodies. This is in sharp contrast to the smoking prevalence rate in the rest of the EU (26 percent) where Snus is banned. Perhaps most interesting is the decrease in smoking prevalence is highest in males, who have an estimated smoking prevalence of between 2-5 percent as of 2018, a dramatic drop from before snus became a popular cessation tool among smokers<sup>10</sup>. Finally Heat-not-burn technology has contributed to a dramatic decline in cigarette consumption in Japan, where cigarette volumes have fallen by 33 percent in three years, from 43.6 billion sticks in Jan-March 2016 to 29.1 billion sticks in Jan-March 2019.<sup>11</sup> Analysts at Citi Group attribute this disruption of the cigarette market to heated tobacco products.<sup>12</sup>

The importance of this cannot be overstated. Policy that encourages smokers to switch to e-cigarettes if they cannot quit or do not wish to will significantly reduce the enormous burden of disease that combustible cigarettes impose on society.

While concerns about youth uptake of e-cigarettes and that e-cigarettes could encourage smoking later in life are understandable, they are unfounded. A recent study shows that, in the United States e-cigarette use is much higher among young who currently smoke than youth who have never smoked<sup>13</sup>. Furthermore, an update from Public Health England indicates that vaping remains low in adolescent never smokers, approximately 0.2 percent of younger never smokers use e-cigarettes<sup>14</sup>. However, even if the prevalence of e-cigarette use increases among younger never smokers, as long as we continue to see combustible use decline this should be considered a positive step in the health and welfare of our global populace.

When considering regulations aimed at reducing the burden of smoking, we strongly urge the union government to consider the utility of harm reduction and reduced risk products alongside prevention measures. We recommend that these products are subject to policy and regulatory measures that maintain the safety of these products and increase their availability with the goal of displacing combustible cigarettes. This view is widely held among tobacco policy experts. In October 2018, 72 experts wrote the Director General of the WHO calling for a progressive approach to tobacco harm

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<sup>10</sup> No Fire, No Smoke: The Global State of Tobacco Harm Reduction 2018 (2018).

<https://gsthr.org/report/full-report-online-ch02> <https://gsthr.org/countries/s/se>

Estimates for 2016 are reported at 5 percent; preliminary estimates for 2018 are at 2 percent.

<sup>11</sup> “Japanese Domestic Cigarette Sales Results, Monthly reports 2016-19,” Japan Tobacco, June 2019.

<https://www.jt.com/media/news>.

<sup>12</sup> Adam Spielman, “The new world of tobacco,” Citi Group, April 18, 2018, p. 20.

<https://thefly.com/landingPageNews.php?id=2691422&headline=PM;BTI-Citi-upgrades-Philip-Morris-downgrades-BTI-in-new-world-of-Tobacco>.

<sup>13</sup> M. S. Dunbar *et al.*, Disentangling Within- and Between-Person Effects of Shared Risk Factors on E-cigarette and Cigarette Use Trajectories From Late Adolescence to Young Adulthood. *Nicotine Tob Res*, (2018). For further analysis see: <https://www.rstreet.org/2019/02/20/reviewed-work-disentangling-within-and-between-person-effects-of-shared-risk-factors-on-e-cigarette-and-cigarette-use-trajectories-from-late-adolescence-to-young-adulthood/>

<sup>14</sup> McNeill A, Brose LS, Calder R, Bauld L & Robson D. Vaping in England: an evidence update February 2019. A report commissioned by Public Health England. London: Public Health England. (2019) [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/781748/Vaping\\_in\\_England\\_an\\_evidence\\_update\\_February\\_2019.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/781748/Vaping_in_England_an_evidence_update_February_2019.pdf)

reduction to achieve our common aims to reduce the burden of cancer, cardiovascular and respiratory disease in support of the Sustainable Development Goals<sup>15</sup>.

These are established and new technologies that deliver nicotine to the user without combustion of tobacco leaf and inhalation of tobacco smoke. These technologies offer the prospect of significant and rapid public health gains through ‘tobacco harm reduction’. Users who cannot or choose not to quit using nicotine have the option to switch from the highest risk products (primarily cigarettes) to products that are, beyond reasonable doubt, much lower risk than smoking products (e.g. pure nicotine products, low-toxicity smokeless tobacco products, vaping or heated tobacco products). We believe this strategy could make a substantial contribution to the Sustainable Development Goal to reduce premature deaths through non-communicable diseases (SDG Target 3.4).

We encourage Prime Minister Modi’s Administration, including the Ministry of Health to keep these products available and we propose that, rather than an outright ban on these products, a proper regulatory framework that encourages a switch from combustibles to reduced risk products will greatly improve the health of your citizens.

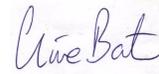
Respectfully submitted,

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<sup>15</sup> Letter from 72 specialists in nicotine science, policy and practice to Director General World Health Organisation, *Innovation in tobacco control: developing the FCTC to embrace tobacco harm reduction*, 1 October 2018  
<https://clivebates.com/documents/WHOCOP8LetterOctober2018.pdf>