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Does India's Ban on Electronic Cigarettes Improve Public Health Outcomes?

M.V. Rajeev Gowda

Shonali Thangiah[*#]

Abstract

In 2019, India banned Electronic Nicotine Delivery Systems (ENDS) – a broad category that includes electronic cigarettes, vaping devices, and Heat Not Burn (HNB) devices – because of concerns about health impacts, youth vulnerability, and their potential to undermine tobacco control efforts. This is a missed public health opportunity to reduce tobacco consumption, if ENDS actually help reduce and wean users off nicotine dependency in less harmful ways. This paper applies a risk analysis framework to examine whether India's ban on ENDS improves public health outcomes, or whether an alternative approach such as regulation would be more effective. It studies global responses and compares how public health goals are served in the United States of America and the United Kingdom, based on four key parameters of concern – health impacts, normalisation of ENDS usage among non-smokers, appeal among youth, and device safety. This comparison demonstrates that the United Kingdom's regulation-focused approach delivers superior outcomes across all four parameters. Thus, the evidence-based recommendation for India would be to regulate at least HNB devices under the Cigarettes and Other Tobacco Products Act (as they utilise tobacco), as this can help reduce harm and promote innovation in devices that can wean users off nicotine dependence.

Keywords: ENDS (Electronic Nicotine Delivery Systems), smoking cessation, risk analysis, public health

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[*] Prof. M.V. Rajeev Gowda is a Former Member of Parliament and Former Chairperson and Professor, Centre for Public Policy, Indian Institute of Management Bangalore; Visiting Professor, Kautilya School of Public Policy and Indian School of Business. Shonali Thangiah is an independent researcher.

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1. Introduction

In 2019, India enacted the Prohibition of Electronic Cigarettes Act, 2019 which banned a broad category of Electronic Nicotine Delivery Systems (ENDS) including electronic cigarettes, vaping devices, and Heat Not Burn (HNB) products. The government justified the ban on the basis of certain risks, including their potential impact on health, ability to attract youth, and concern that ENDS would undermine tobacco control efforts. This article applies a risk analysis framework to examine whether the ban will improve public health outcomes or whether regulation would be a more effective alternative policy approach.

2. India's E-Cigarettes Ban

2.1 Overview

ENDS were being sold in the Indian market without prior permission from regulatory authorities. Therefore, in August 2018, the Union Ministry of Health and Family Welfare (MoHFW) issued an advisory to state governments to regulate e-cigarettes by stopping approvals for new products and imposing restrictions on sales and advertisements. By March 2019, 12 states acted in compliance with this order (The Wire 2019). The order was challenged in the Delhi High Court, which issued a temporary stay on these restrictions on March 18, 2019.

On February 18, 2019, following reports that ENDS manufacturer Juul Labs was planning to enter the Indian market, the Secretary MoHFW, Preeti Sudan, wrote to the Union Commerce Ministry and the Prime Minister's Office calling for a ban on Juul's entry into India. She argued that "*Novel products such as 'JUUL' are harmful and addictive and could potentially undermine our tobacco control efforts,*" because of their *"...easy availability, disguised appearance and the false notion of being safe*" (Kalra 2019). She added that: "*It is felt that the young generation would be particularly vulnerable to such products and gimmicks.*"

Thereafter, a ban on the broad category of Electronic Cigarettes was introduced through the promulgation of a Presidential Ordinance – The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Ordinance, 2019 – on September 18, 2019 (Press Information Bureau 2019).

The Ordinance targeted both ENDS and HNB devices. ENDS are battery-operated electronic cigarettes that generate dosages of vaporised nicotine or non-nicotine solutions for inhalation. Their ingredients include propylene glycol and vegetable glycerine, and some even contain flavour additives. The United States Food and Drug Administration (FDA) recognises a number of devices under the umbrella of ENDS, including e-cigarettes, vaporizers, vape pens, and hookah pens (U.S FDA 2022).

ENDS are distinct from 'heated tobacco products' (HTPs) or 'heat not burn' devices (HNBs) – HNBs contain tobacco, while ENDS do not. HNBs do not contain nicotine solutions and instead operate by heating a tobacco stick, leaf, or sheet in order to release nicotine. The tobacco is not burned

but is heated just enough to release an aerosol. Thus, HNB devices do not produce any of the ash or smoke associated with combustible cigarettes or beedis.

Figure 1: Comparison of Combustible Cigarettes, ENDS, and HNBs.

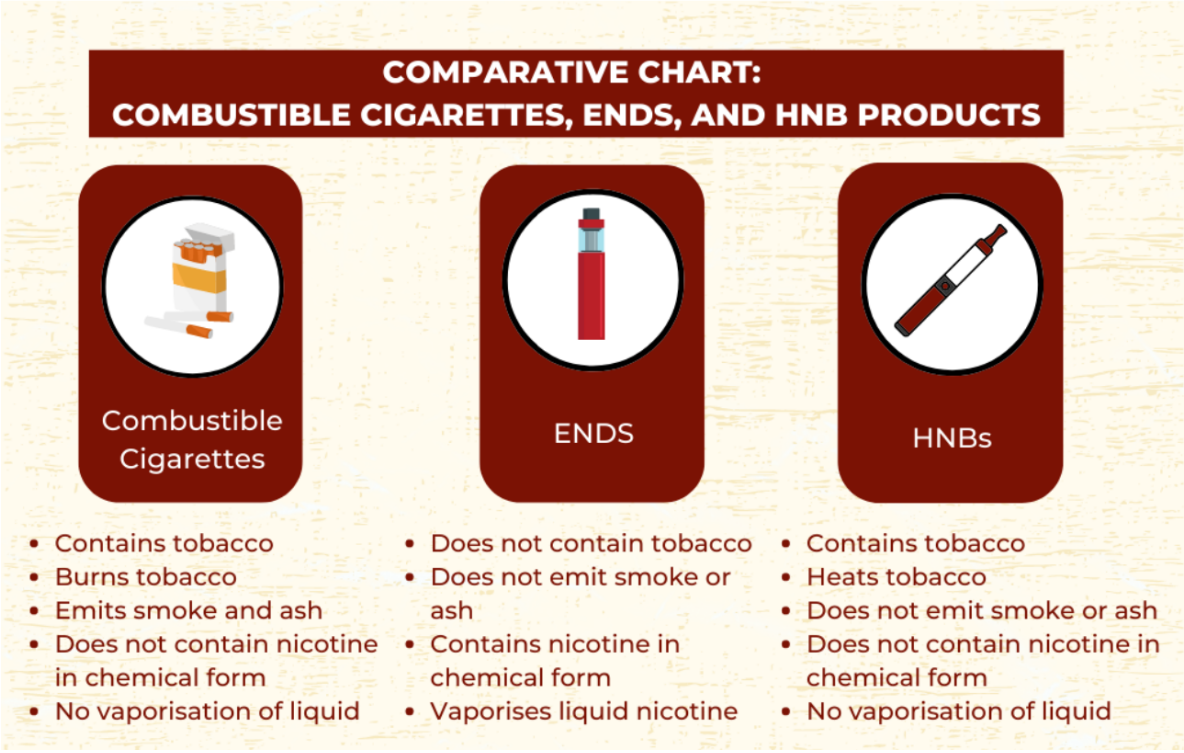


Image Source: Authors

The Prohibition of Electronic Cigarettes Act, 2019, passed on December 2, 2019, replaced the Ordinance. During the parliamentary debates, several Members of Parliament raised concerns about the blanket ban on ENDS devices, emphasising that: (1) The ban would trigger underground markets for ENDS devices; (2) Banning ENDS devices blocks the innovation of products that could be less harmful sources of nicotine, and which could help reduce or end users' dependence on combustible tobacco; (3) HNBs use tobacco; hence they should instead be regulated under the Cigarettes and Other Tobacco Products Act (COTPA)[1]; (4) If potentially less harmful ENDS and HTP products are unavailable, youth will likely experiment with more harmful combustible tobacco.(Lok Sabha 2019a; Lok Sabha 2019b; Rajya Sabha 2019).

Conventionally, draft Bills are expected to be opened for public comments and to be examined in detail by the appropriate Parliamentary Standing Committee. In this case, although the Bill was put forth for public consultations, it was enacted by Parliament without addressing the suggestions received.

The motivation for the ban's urgency can be discerned from the views of the then Secretary, MoHFW, Ms. Preeti Sudan, and the then Union Minister for Health and Family Welfare, Dr. Harshvardhan. In a newspaper opinion article, Sudan wrote that when she served in the Ministry of Youth Affairs and Sports, she once noticed teenagers in her neighbourhood smoking cigarettes.

Thereafter she pushed successfully for criminalising the sale of tobacco to minors through an amendment to the Juvenile Justice Act, 2015 (Sudan 2020). In the Rajya Sabha, Dr. Harshvardhan stated that it was urgent to pass the Bill because of "very, very strong threat from tobacco companies" preparing to launch ENDS products in the Indian market (Rajya Sabha 2019). He argued that ENDS devices needed to be banned pre-emptively before they develop a major user base among children and youth.

An Expert Committee set up by the MoHFW issued a report in May 2019, recommending a blanket ban on ENDS devices (including HNB products), based on a consideration of harmful health effects reported in other countries, their potential to lure youth toward nicotine consumption, and what it considered to be inadequate proof that they serve as smoking-cessation devices (Chakma, Dhaliwal, and Mehrotra 2019). It did not study the range of ENDS and HNB devices, their differential technologies and impacts, or the use of HNBs as an innovative tobacco harm reduction product.

2.2 Implications of the Ban and Its Current Status

Historically, bans on products trigger the emergence of underground markets, and of criminal elements seeking to profit from such illicit commerce. India's experiences with alcohol prohibition demonstrates how bans lead to thriving black markets, such as in Gujarat where liquor worth an average of Rs. 34 lakhs per day was seized across 20 months (Choudhary and Sharma 2021). Bans also result in a significant loss of revenue to the exchequer. Maharashtra is estimated to have lost Rs. 2,570 crores between 2015-2020 owing to a liquor ban in select districts (Ibid). Beyond the economic costs, there are also unintended public health risks. Spurious liquor has killed more people in India than drugs. In 2020, there were 947 accidental deaths due to consumption of illicit/poisonous liquor, against 514 from drug overdoses (National Crime Records Bureau 2021).

Similarly, India's ban on e-cigarettes may not have prevented the consumption of ENDS but only driven these products underground, while simultaneously driving away responsible ENDS and HNB brands (Soni 2020). Since the ban was enacted in 2019, there have been regular reports of seizures of e-cigarettes whose worth amounts to crores (Press Trust of India 2023; The Hindu Bureau 2022; Basheer 2022; Lalitha 2022; Singh 2022; Times of India 2023). The Directorate of Revenue Intelligence conducted two seizures of e-cigarettes worth Rs. 68 crores in just September 2022 alone (Press Information Bureau 2022).

Reports indicate that ENDS devices can be purchased both online and at neighbourhood cigarette shops. Illegitimate businesses (with possibly dangerous, unregulated products) flourish near schools and colleges (Indian Express 2023), including through WhatsApp groups (Matharu 2023), pointing to continued use of ENDS devices. Advertisements for e-cigarettes in India continue to be broadcast on social media through third-party retailers. The Indian market actually provides customers with covert options for buying e-cigarettes through phone numbers and WhatsApp (Murukutla et al. 2022).

The MoHFW is now working with states and law enforcement to enforce the ban in full. A significant hurdle is that the ban falls under the purview of different ministries, due to the sale of e-cigarettes through both online channels and brick-and-mortar stores (Matharu 2023).

The ban's failure to meet its stated objectives has led to several calls for its reversal and replacement with a more scientific regulatory framework for e-cigarettes, based on the principles of harm reduction (Ray 2022; Press Trust of India 2022). Before deciding whether to impose prohibition on certain goods, governments consider several factors, including revenue, tourism, crime, and unintended consequences on public health. This balance of risk and reward has informed India's regulation of both alcohol and tobacco – products that have impacts on health, but which generate income for the government. It is imperative to examine whether regulation may similarly be appropriate in the case of e-cigarettes.

Finally, in the Finance Bill, 2021, the Union government accepted the classification of novel tobacco and nicotine products as laid down by the World Customs Organization Council, thus acknowledging the difference between cigarettes, e-cigarettes and HNB products for taxation purposes (Government of India 2022). However, this distinction has not been applied in the context of the ban on e-cigarettes.

3. Tobacco Risk Management

3.1 Scale of India's Risks from Tobacco

India is the second largest consumer of tobacco globally (World Health Organisation, n.d.). According to the Global Adult Tobacco Survey India, 2016-17 (GATS 2), 266.8 million adult Indians above the age of 15 use tobacco – both smokeless tobacco products such as khaini, gutka, and zarda, and smoked products such as beedis and cigarettes (Tata Institute of Social Sciences and Ministry of Health and Family Welfare 2018).

Tobacco is among the largest threats to public health in India, accounting for as many as 3,500 deaths per day (Ministry of Health and Family Welfare, Government of India, n.d.; Sinha et al. 2014; Jha et al. 2008). In 2018, WHO estimated the number of tobacco-related deaths at 1 million, which accounted for 9.5% of total deaths (Foundation For A Smoke-Free World 2020). Overall, tobacco use in India has decreased life expectancy by 11 years among women, and by 12 years among men (Economic Times 2021).

Official government data estimates that, in 2011, the cost to the economy attributed to deaths and diseases related to tobacco use stood at Rs. 1,04,500 crores (Ministry of Health and Family Welfare, Government of India, n.d.). This rose to Rs. 1,77,341 crore in 2017-18, accounting for 1% of India's GDP (Press Trust of India 2020). More recent data estimate that 5.3% of India's health expenditure is spent on treating tobacco-related diseases, and that both treatment and loss of productivity has cost India Rs. 13,500 crore annually (Jo 2022). In 2023, the burden of tobacco-related health care expenditure was estimated at 1.04% of the GDP (Economic Times 2023).

Smokeless tobacco is largely preferred by specific demographics – users from rural areas, those with lower education and income, and from socially disadvantaged groups (Boyd 2021). The harms from smokeless tobacco are compounded by the availability of unregulated products in the market. In 2017, 43% of smokeless products were illegal (i.e., with out-of-date health warning labels) and 2% were illicit (i.e., no health warning labels or without Indian health warning labels) (Welding et al. 2021).

While more Indians consume smokeless tobacco, combustible cigarettes are more harmful, due to chemicals in the smoke generated by burning tobacco. 4% of Indians smoke combustible cigarettes, with beedis being the most popular product (Tata Institute of Social Sciences and Ministry of Health and Family Welfare 2018). Beedis produce five times more tar compared to manufactured combustible cigarettes (Mohan, Lando, and Panneer 2018, 2).

Beedi production is largely informal as manufacturers often seek to circumvent tax and labour laws, and products from unregistered entities do not carry health label warnings (Boyd 2021). Beedis are popular among users with lower education and income, and from socially disadvantaged groups, while commercial combustible cigarettes are preferred by those with higher levels of education and wealth (ibid). 55% of beedi packs and 25% of manufactured combustible cigarettes were illegal, while 10% of commercial combustible cigarettes were illicit (Welding et al. 2021).

3.2 India's Policy Measures to Reduce Tobacco-Related Risks

Historically, India's regulation of tobacco began with a light touch, providing statutory warnings about the potential harm of tobacco consumption on health. As evidence of greater harm from tobacco consumption came to light, and society took note of the impact of second-hand smoke and consequently discouraged tobacco consumption, the government's approach to regulating tobacco products became more aggressive. It mandated graphic images of health impacts on cigarette packs, imposed bans on smoking in public spaces including on public transportation, and banned advertisements.

The 2003 COTPA was a landmark comprehensive tobacco control law in India which brought together the various facets of regulation under one framework. Another milestone in tobacco regulation is the National Tobacco Control Programme (NTCP) which funded tobacco control initiatives at the state level.

In addition to ratifying Global Tobacco Control treaties, including the WHO's Framework Convention on Tobacco Control (FCTC), India also uses other instruments for tobacco control including economic incentives like high taxes, regulates the content of tobacco products, promotes awareness about the harms of smoking, and has set up free helplines / 'Quitlines' for users looking to quit (Mohan, Lando, and Panneer 2018, 4-5; Sudan 2020). The Union Budget 2023-24 increased the National Calamity Contingent Duty (a surcharge on excise duty) on specified cigarettes by 16% (Press Information Bureau 2023).

The evolution and range of tobacco-control measures demonstrates how the government has adopted a scientific cause-and-effect and evidence-based approach to tobacco regulation, rather than

a blanket ban, as in the case of the prohibition on e-cigarettes. The government has also not adopted differential regulatory interventions for ENDS and HNB products based on scientific evidence.

4. Risk Balancing as a Benchmark to Evaluate Policy

Rather than the 'quit or die' approach typically used in smoking cessation policies, a third option is to enable those who are unable to reduce their consumption of tobacco to access nicotine in less harmful ways (Rodu and Godshall 2006, 2). This is especially significant since India has the second-lowest quit rate among the countries surveyed under GATS 2 (Economic Times 2021). Smokers who made a quit attempt in the past 12 months remained stagnant at 38.5% under GATS 2 (2016-17), compared to 38.4% under GATS 1 (2009-10) (Tata Institute of Social Sciences and Ministry of Health and Family Welfare 2018).

Tobacco harm reduction strategies can help achieve the National Health Policy 2017 target of reducing tobacco use by 30% by 2025 compared to 2009-10. Innovative non-tobacco (ENDS) and non-combustion products (HNBs) can supplement existing tobacco cessation strategies, which are presently largely confined to nicotine replacement therapies (NRT) (Misra 2022). Adopting harm reduction strategies at scale through national policies can also lower costs and increase access to safer alternatives by lower-income groups (Economic Times 2021).

The diverse range of tobacco and nicotine products available in the market today and innovative products in the pipeline present an opportunity to adopt risk-proportionate regulation based on scientific evidence. Treating all such products as equally harmful will only protect existing products, and deny consumers the right to access safer alternatives (Cummings, Ballin, and Sweanor 2020, 11).

A risk balancing framework allows the government to protect non-smokers and discourage tobacco use overall, while simultaneously protecting tobacco consumers by providing access to innovative, lower-risk products. By imposing a ban and refusing to consider the possibility of using e-cigarettes as a tool to reduce tobacco-related harms, the government may also have deprived tobacco consumers of safer alternatives and their right to make informed decisions.

The FDA conceives of a risk continuum in tobacco regulation (Cummings, Ballin, and Sweanor 2020, 9) where different products carry different levels of risks, and public health goals can be met by increasing or reducing access to them appropriately. Reducing levels of nicotine in combustible tobacco products, high product standards for ENDS and HNBs, public awareness campaigns, education for medical practitioners, taxation policies, and incentives for manufacturers to invest in low-risk products are other key aspects of a risk-proportionate tobacco regulation framework (Cummings, Ballin, and Sweanor 2020, 13; Hatsukami and Carrol 2020, 10).

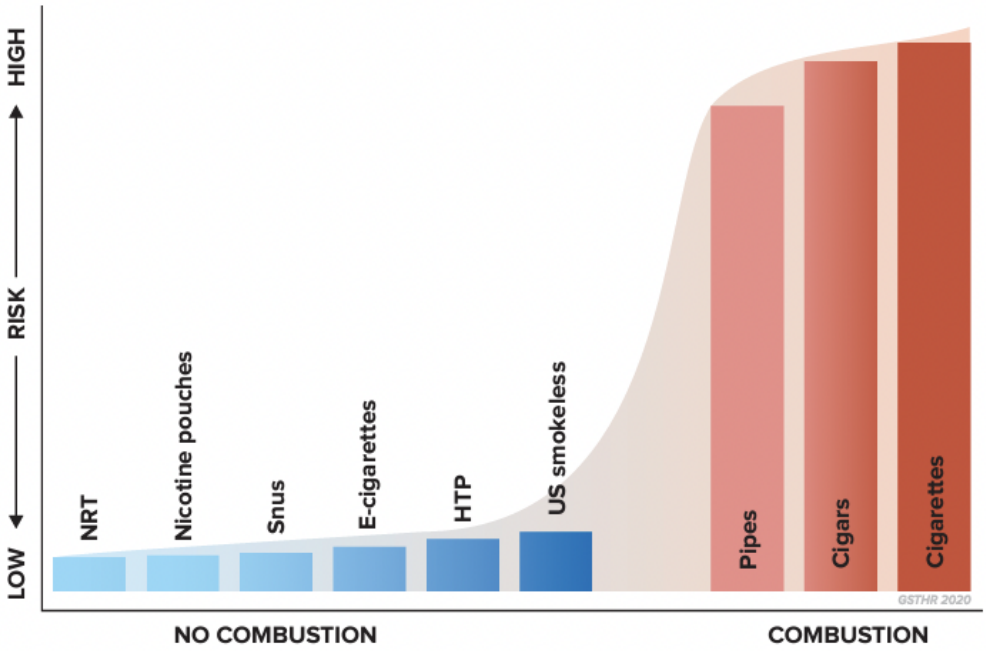
As per the FDA's risk continuum, protecting high-risk tobacco products like combustible cigarettes while prohibiting lower-risk products like ENDS and HNBs is counterproductive; it risks more tobacco-related death and diseases. This would be contrary to the government's fundamental duty to improve public health. Tobacco-related deaths are estimated to rise to 70% by 2030, and

vulnerable communities will be disproportionately impacted due to their higher tobacco usage (Economic Times 2021). Risk-proportionate strategies therefore assume even more importance in the larger fight against tobacco.

4.1 ENDS and HNBs are Lower Risk Products on the Tobacco-Risk Continuum

A WHO report establishes that while there are potential risks associated with toxic chemicals from ENDs and Non-Nicotine Delivery Systems (NNDS), these vary with the device, the e-liquid, and how users operate them (WHO Regional Office for Europe 2020). It further found that the risks from unadulterated ENDS and NNDS under normal conditions are lower compared to combustible tobacco smoke. While the report also flags potential risks associated with heating and inhaling certain flavour additives, such risks can be mitigated by restricting additives and flavourings under a harm reduction framework.

Figure 2: Harm Continuum in Nicotine Products



Source: Global State of Tobacco Harm Reduction 2021

Scientific evidence suggests that the primary cause of smoking-related diseases is not nicotine per se, but instead the harmful chemicals formed while burning tobacco, including tar, carbon monoxide (National Health Service 2022), burnt paper, and other pollutants, all of which can potentially cause long-term damage. Tobacco smoke carries more than 7,000 chemicals, of which at least 250 have been identified as harmful (e.g., carbon monoxide and ammonia); of these 250, at least 69 have been identified as carcinogenic (e.g., arsenic, benzene, formaldehyde) (National Cancer Institute 2017).

The Global State of Tobacco Harm Reduction report (2021) shows how combustible tobacco products pose a far higher risk than non-combustion alternatives like e-cigarettes (ENDS) and HTPs/HNBs. ENDS and HNBs enable users to simulate the behavioural experience of inhaling nicotine aerosol, while avoiding the tar and other hazardous consequences associated with tobacco smoke, and are estimated to be 95% safer (Public Health England 2015). In the short to medium-term, repeated exposure to Propylene Glycol and Glycerol from e-cigarettes is considered to be of low concern, and second-hand exposure to these chemicals have been found unlikely to be a risk to bystanders either (Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment 2020).

Thus, while all tobacco products carry health risks, non-combustible products such as HNBs reduce tobacco-related harms (U.S. FDA 2020). The study of a specific HNB device showed strongly reduced harmful and potentially harmful constituents (HPHC) levels, as well as strongly reduced levels of typical toxicants in the Total Particulate Matter (TPM), as compared to combustible cigarettes (Mallock et al. 2018, 2146).

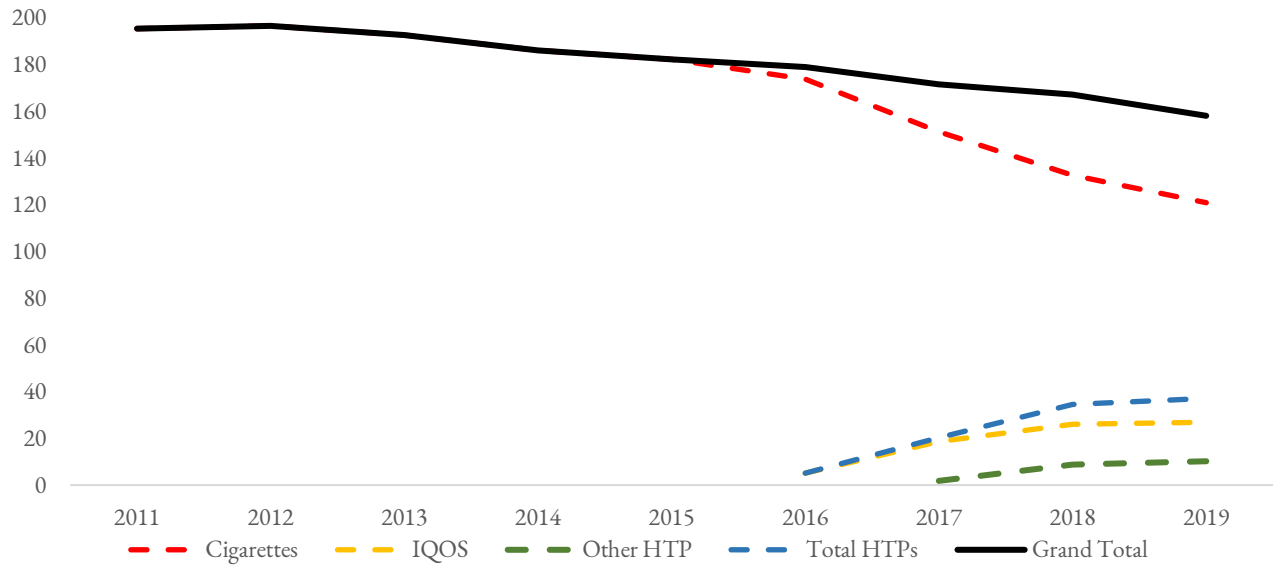
Recognising that non-combustible cigarettes produce lower levels of certain toxins compared to their combustible counterparts, the FDA authorised the marketing of the IQOS Tobacco Heating System, a HNB device (U.S. FDA 2019). The FDA found that the aerosol produced by IQOS had lower levels of toxic chemicals compared to combustible cigarette smoke (ibid).

Another risk observed by the WHO is exposure to certain metals, most likely found in the metallic heating coils and soldered joints used in ENDS devices, including chromium, nickel, and lead. However, the risk of such exposure depends on the product design and engineering, and patterns of use, all of which can be regulated.

The lower exposure to toxicants from ENDs and HNBs implies that switching to these devices may reduce health risks arising from smoking combustible cigarettes, such as impairment of oxygen transport function of the blood, injury of the vascular endothelium, and other harmful impacts at the cellular level (Kvasha et al. 2017). There are also consistent improvements in respiratory symptoms, exercise tolerance, quality of life, and rate of disease exacerbations in patients with Chronic Obstructive Pulmonary Disease (COPD) who switched to HNBs and those who abstained from smoking (Polosa et al. 2021). If HNBs demonstrably help people make the transition away from combustible cigarettes, then banning them closes the door on an important pathway to harm reduction.

A clinical trial in the United Kingdom (UK) also found that e-cigarettes are twice as likely to help people effectively quit smoking compared to other nicotine replacement products, when used along with in-person expert support (National Health Service 2022). While evidence on the use of nicotine vaping products to quit smoking remains mixed (Gravely et al. 2022), HNBs specifically have demonstrably aided the transition away from combustible cigarettes. After the introduction of IQOS in 2014, followed by several other HNBs, there has been a dramatic decline in the sales of conventional cigarettes in Japan (Stoklosa et al. 2020).

Figure 3: Sales of cigarettes, IQOS, and other HTPs (billion sticks) in Japan 2011-2019



Data Source: (Cummings, Nahhas, and Sweanor, 2020). See note for data explanation on data sources and calculation[2]

In India, a survey of 3000 e-cigarette users found that 30% actually quit smoking after using e-cigarettes, and 41% reduced smoking (Sharan et al. 2020). Some users reported quitting and/or reducing smokeless tobacco use (ibid), suggesting that ENDS and HNBs can also help with smokeless tobacco cessation.

Research is needed to assess the long-term health impacts of ENDS and HNBs, including nicotine addiction and lung damage. It took decades to identify harms associated with combustible cigarettes, because cancer and lung-related illnesses take years to manifest (UCLA Health 2020). Experts also remain uncertain about potential lung damage associated with vaping (Shmerling 2022). It is important to acknowledge this knowledge gap and to ensure that regulatory systems are flexible to respond to scientific evidence as it emerges.

5. Global Policy Responses to ENDS

The WHO FCTC defines "tobacco control" to mean a range of supply, demand, and harm reduction strategies, that aim to improve the health of a population by eliminating or reducing their tobacco consumption and exposure to tobacco smoke (World Health Organization 2003). The UN Focal Point on Tobacco or Health (1997) suggested a triadic approach to achieve a substantial reduction in tobacco-related harms for present smokers and future generations – (1) tobacco-use prevention; (2) smoking cessation; and (3) reduction of exposure to tobacco toxins in people who are unable or unwilling to completely abstain from tobacco (Hatsukami et al. 2007).

In 2017, the FDA Commissioner stated "*... we must recognize the potential for innovation to lead to less harmful products, which, under FDA's oversight, could be part of a solution*" (Gottlieb 2017). In the UK, Public Health England (PHE) has underlined that people should be helped to quit

smoking by permitting innovative technologies that "*minimise the risk of harm*" and "*maximise the availability of safer alternatives to smoking*" (Sutherland et al. 2021).

In the European Union, the European Tobacco Products Directive (EUTPD) provides a framework for regulating tobacco and related products, and prioritises public health. It distinguishes Novel Tobacco Products as a separate product category from conventional tobacco products (European Union 2014).

As of February 2021, 73 countries permit the sale of ENDS devices along with restrictions (e.g., United Kingdom, Canada, Malaysia, New Zealand), while 37 banned their sale altogether (e.g., Australia, Singapore, Sri Lanka, Thailand) (Global Center for Good Governance in Tobacco Control 2021). Many countries have adopted harm reduction principles into their tobacco control laws. New Zealand (Government of New Zealand 2020), the Philippines (Republic of the Philippines 2021), Japan (Abramson 2021), Greece (European Union 2014), and Switzerland (Federal Office of Public Health BAG 2023) have all adopted risk-proportionate and differential regulation of ENDS and HNBs.

Norway (Norwegian Directorate of Health 2022) and Uruguay (India Med Today 2021) have both reversed bans on novel tobacco products. The varied experiences of the differing approaches adopted by these countries presents an opportunity to study how India can learn from them to regulate ENDS/HNBs, based on the balance of risk.

6. Comparative Experience of the USA and UK

The nature of evidence that has emerged from different jurisdictions is largely dependent on the model of regulation that has been adopted. In this section, we explore the contrasting approaches and consequent balance of risks within the USA and UK. Based on the evidence available, we attempt to identify lessons that can be applied to the Indian context. The studies referenced below adopt different definitions of e-cigarettes, i.e., they may include both ENDS and HNBs or only ENDS; this distinction will be elaborated wherever possible.

The UK adopted a harm reduction approach, treating ENDS as a safer alternative to combustible cigarettes. Tobacco and e-cigarettes are regulated under the Tobacco and Related Products Regulations, 2016 (TRPR). Vaping devices which do not contain nicotine are regulated under the General Product Safety Regulations, 2005. The TRPR is modelled on the EUTPD and has three main objectives – (1) implementing the EUTPD into UK law, (2) dissuading non-smokers, particularly youth, from developing a smoking habit, and (3) supporting non-smokers in the transition from quitting.

All ENDS devices are required to comply with strict safety standards, as prescribed by the Medicines and Healthcare Products Regulatory Agency (MHRA). This includes limiting the capacity of tanks to 2 ml, limiting the amount of nicotine in e-liquids to 20 mg per ml, and banning ingredients such as specific additives for flavour and colour (Medicines and Healthcare Products

Regulatory Agency 2016). In 2018, the National Institute for Health and Care Excellence also referenced e-cigarettes in its guidelines on interventions designed to stop smoking (Rough 2022, National Institute for Health and Care and Excellence 2021).

The USA, in contrast, adopted an abstinence approach, banning ENDS in some jurisdictions. The FDA, as the nodal regulatory body for tobacco, classified ENDS as regular cigarettes, and required ENDS manufacturers to apply for marketing authorisation within the USA for both new and existing ENDS products. However, such authorisation does not amount to FDA approval or official recognition as being safe.

6.1 Will Regulating ENDS/HNBs Normalise Usage Among Non-Smokers?

A major concern among regulators is that ENDS could become a gateway to smoking of combustible products, particularly among youth. Evidence shows that in both the UK and USA, the usage of ENDS and HNBs among non-smokers has remained low despite the different models of regulation adopted. In particular, there is low knowledge and low usage of HNBs. This suggests that ENDS and HNBs are not a gateway to smoking.

In the USA, data from 2015 (Centers for Disease Control and Prevention, n.d.) and 2020 (Mayer et al. 2020) found that e-cigarettes remain popular among current and former smokers, and the majority of non-smokers who used e-cigarettes were 18-24 years old. A more recent study found that of 5.66 million adults reported to be current e-cigarette users, approximately 23.1% reported themselves as 'never smokers' (ibid).

In the UK, PHE found no evidence on the link between increased e-cigarette use and increased smoking uptake (McNeill et al. 2015). Of the 3.6 million adult population using e-cigarettes between February-March 2021, a majority were ex-smokers and current smokers, with under 200,000 never-smokers (Action on Smoking and Health 2021). Even among UK youth, e-cigarette usage by never-smokers has been largely experimental, with 45.7% of 11-17 year olds citing the reason for their current use as 'Just to give it a try.' (Action on Smoking and Health 2022).

HNB products specifically are not an attraction for never-smokers and former users. These seem to attract one audience – adults who smoke and would otherwise continue to do so. HNB awareness and usage remained low across several jurisdictions, including the USA (Marynak et al. 2018), Japan (Kuwabara et al. 2020), Germany (BZgA-Forschungsbericht 2020), and Switzerland (Jordan et al. 2019).

6.2 Can Restricting Flavours Limit Access and Appeal of e-Cigarettes Among Youth?

The USA experienced a significant increase in the usage of e-cigarettes among high school students between 2011 and 2019 (Owotomo and Walley 2022). A 1000% increase in the usage of disposable e-cigarettes among high school students between 2019 and 2020 caused the FDA to describe the prevalence of youth vaping as an epidemic (Woodcock 2021).

The use of e-cigarettes among youth in the UK is far lower. While there has been an increase in the number of 11–17-year-olds who have tried vaping, the increase is low (Action on Smoking and Health 2022). A 2019 PHE report found that the number of under-18s in the UK who used e-cigarettes weekly or more stood at just 1.7% (McNeill et al. 2019). As of July 2022, as many as 83.8% of UK youth have never tried e-cigarettes, 8.2% are unaware of them, and 10.7% of current youth smokers actually use e-cigarettes to quit smoking (Action on Smoking and Health 2022).

The appeal of e-cigarettes among USA youth could lie in the flavours available, as well as attractive packaging and novel device designs. Flavours range from standards like cinnamon, menthol, and various fruits, to more exotic options like strawberry cheesecake, glazed donuts, cherry cola, etc. The regulatory approaches to catchy flavours and other attractive features in the USA and the UK point to one critical reason why the appeal of ENDS among youth has shown significantly different trends in each jurisdiction.

The USA has not banned flavoured ENDS products as of July 2021. Regulations are limited to a minimum age restriction (21 years) on ENDS products, along with identification requirements, and other FDA guidance on enforcement measures. The FDA has yet to implement its plan for product standards that ban flavours. Between August 2016 and July 2021, the FDA issued more than 11,000 warning letters, and filed more 2,000 civil suits, against retailers who were in violation of its guidance pertaining to ENDS usage among youth. Yet, the number of youth e-cigarette users remains high, at 3.6 million in 2020, and flavoured products are used by more than 8 out of 10 youth e-cigarette users (Centers for Disease Control and Prevention 2020).

In 2015, the UK government made the sale of e-cigarettes to minors illegal, and banned proxy purchase of e-cigarettes by adults for minors. In 2018, the Department of Health and Social Care (2018) stated that regular use of e-cigarettes by youth in the UK is still low, and does not yet merit regulatory intervention.

In the UK, the TRPR prescribes specific regulations to meet its core objective of dissuading young people from smoking. Tobacco products cannot contain ingredients which mask the smell or taste of tobacco, and which are incorporated through additives like fruit, spice, herbs, alcohol, candy, menthol, or vanilla. It prohibits such "characterising flavours" in any component of the tobacco product, as well as additives associated with energy, and which have colouring effects on emissions. Importantly, the TRPR prohibits device features which allow consumers to modify the taste or smell themselves. E-cigarette container packs and refill container packs are also not permitted to reference taste, smell, or other additives except for flavourings or its absence (UK Government 2016).

A 2020 study found preliminary evidence suggesting that the usage of e-cigarettes among the UK's youth may be plateauing, and that products banned in the EU's regulated market are finding purchase in North America where usage persists (Moore et al. 2020). The UK's approach of restricting flavours and packaging may have diminished the appeal of e-cigarettes for youth. In the absence of conclusive data on the potential health impacts of using flavourings in ENDS and HNBs (Rough 2022), it would

be objectively prudent to regulate the use of such additives in anticipation of potential risks to users' health.

6.3 Are ENDS/HNB Devices Safer to Use?

In the USA, there were an estimated 2,000 vape pen explosions and burn injuries between 2015-2017 (Horton 2019). The exact cause of explosions is unknown. They likely stem from faulty batteries and faulty chargers, both of which can be regulated by prescribing industry standards.

In the UK, where the design and engineering of e-cigarette products is regulated by law, exposure to such risks is lower. While available official data does not distinguish e-cigarettes as a cause of fire, data from media reports in the UK suggest that e-cigarettes-related fires are low, with only 43 recorded calls in 2013, and 62 between January-November 2014 (McNeill et al. 2015). The government has issued public guidelines on how to safely charge e-cigarette batteries, and its public awareness drive includes social media campaigns in partnership with industry stakeholders (Department for Business, Energy & Industrial Strategy and Office for Product Safety and Standards 2020).

In 2019-2020, there was an outbreak of "*e-cigarette, or vaping, product use associated lung injury*" (EVALI) in the USA. As of February 18, 2020, there were 2,807 cases or deaths recorded across the country, with 68 confirmed deaths (Centers for Disease Control and Prevention 2020). In the UK, however, vaping has only been implicated in 3 cases registered with the MHRA between May 2016 and February 2021 which involved death, and only 1 of these "appeared" to qualify as EVALI (McNeill et al. 2021).

The Centers for Disease Control's (CDC) investigation of the EVALI outbreak in the USA reveals why the UK did not have a similar experience, and demonstrates how regulation can make e-cigarette usage safer. In the USA, 82% of EVALI patients reported using Tetrahydrocannabinol (THC), the psychoactive compound in cannabis, in their vaping devices (Centers for Disease Control and Prevention 2020). Of those who reported the source of their THC, 78% cited informal sources (ibid). The CDC also linked the outbreak to Vitamin E acetate, an additive in ENDS that contains THC. Vitamin E acetate is prohibited for use in e-cigarettes in the UK (Newton 2020).

With respect to HNBs, any kind of adulteration is restricted by default, as these are specific systems that heat processed tobacco in a controlled manner. Since only tobacco sticks are inserted in the heating device, adulteration is restricted, unlike ENDS that vaporise nicotine-solvents for inhalation.

The UK's record suggests that regulation of ENDS and HNB devices is substantially effective in limiting risks to users. While research is still required to identify exact causes of explosions and implications of inhaling additives, a framework with stringent standards and restrictions is a desirable interim measure of regulation.

8. Lessons for India

8.1 E-cigarette Usage is Minimal in India

The scale of e-cigarettes usage in India is limited to a specific demographic, distinct from those who smoke combustible cigarettes. A study of 3,000 Indian e-cigarette users revealed that users are predominantly male, with the minimum education level of an undergraduate degree, and are 29 years old on average (Sharan et al. 2020). Only 17.5% of surveyed e-cigarette users reported these as the first tobacco products they had tried (ibid). This contradicts the assumption that ENDS and HNBs will serve as a gateway to combustible cigarettes.

Additionally, the number of users is significantly lower than users of combustible cigarettes. GATS data for January 1, 2015 to December 31, 2018, i.e. a year before the ban on e-cigarettes was enacted, revealed that the prevalence of e-cigarette use in India was 0.02% (Pan et al. 2022). This is in stark contrast to the 10.7% of adults who smoke tobacco as per GATS data for 2016-2017 (Tata Institute of Social Sciences and Ministry of Health and Family Welfare 2018). Thus, the scale of potential harm from ENDS and HNBs is dwarfed by the harm from combustible cigarettes.

The limited demographic for e-cigarette users makes sense when considering the cost of devices in India. The online catalogues of five ENDS device retailers revealed the starting price of most devices to be Rs. 1000, and these can reach as much as Rs. 5,000. There are fewer models of disposable vape pens for Rs. 500-1000. However, e-cigarettes may now be gaining popularity among students with lower income levels. A forthcoming study found that such youth are splitting the cost and sharing one device among themselves (Matharu 2023).

In India, 86% of e-cigarette advertisements on social media focused on attractive product features such as novel device designs, flavours, touch screen indicators, and product customizability (Murukutla et al. 2022). The study found that compared to Mexico and Indonesia, India had the highest engagement with social media posts that emphasised such product features. The second most common messaging in India was entertainment (13%), which involved users doing various tricks with ENDS devices. There were zero instances of harm reduction messaging observed. Instagram appears to be the most popular platform for marketing e-cigarettes in India. At least 190 Instagram influencers have been promoting these products (Matharu 2023).

While this study does not represent the full landscape of e-cigarette marketing in India, among other limitations, its findings reveal that restrictions on advertising, device features, and e-liquid flavours can significantly curb the appeal of e-cigarettes. Reversing the ban and regulating ENDS and HNBs is therefore less likely to incentivise non-smokers to take up e-cigarette usage. Regulation of e-cigarettes may at least achieve the more pragmatic public health goal of weaning people off tobacco, thus reducing the toll on public health and the economy.

A majority of smokers in India were concerned about their own dependency on tobacco and wanted to quit. GATS 2 revealed that as many as 55.4% of current smokers in 2016-17 were either

interested in or planning to quit (Tata Institute of Social Sciences and Ministry of Health and Family Welfare 2018). While evidence is inconclusive on whether e-cigarettes or HNBs are effective smoking cessation tools, other jurisdictions which have regulated these devices have demonstrated how they can be used as a safer alternative to combustible tobacco.

Even in the USA, the Surgeon General recently recommended continued scientific investigations of e-cigarettes as an adult smoking cessation aid, in the context of high usage by youth in the country. (U.S. Department of Health And Human Services). In the UK, e-cigarettes have emerged as the most popular smoking cessation aid tool, with 27.2% of people choosing e-cigarettes to help quit smoking, compared to 15.5% who opted for NRT (McNeill et al. 2021).

Studies show that e-cigarettes may be more effective as a smoking cessation tool than NRT, when combined with behavioural support (Hajen et al. 2019), and that there may be higher quit rates associated with nicotine-containing e-cigarettes compared to both NRT as well as non-nicotine e-cigarettes (Hartmann-Boyce et al. 2021).

Unlike nicotine patches, ENDS and HNBS provide similar behavioural cues as smoking cigarettes and inhaling nicotine, specifically the sensory aspects of obtaining a nicotine hit. This makes it easier for users to adopt them as smoking cessation devices. ENDS and HNBs can also be designed to allow users to gradually reduce the quantity of nicotine, and to eventually quit usage altogether.

8.2 Adapting a Risk-Balancing Framework for India

Given the above data, India can learn from the best practices of jurisdictions which have adopted a risk-balancing framework, and draw lessons from those jurisdictions which have already faced the consequences of the abstinence approach. We therefore recommend the following policy measures going forward:

- Allow HNBs initially, and regulate them under relevant provisions of the existing legal framework for tobacco products, i.e., COTPA, since they contain real tobacco. This would initially restrict the availability of e-cigarette-type products to HNBs only (and not ENDS generally) while still paving the way for harm reduction.
- HNB usage can be further regulated by imposing conditions for responsible usage, such as geo-tagging, age-gating, placing caps on consumer purchases, harm reduction messaging, etc.
- Study scientific evidence, international best practices, and commission studies on how HNBs can be used as a harm reduction tool and smoking cessation aid, including statistical models to compare public health outcomes of different interventions (Levy et al. 2021) and decision-theoretic frameworks (Levy et al. 2022). Overall, this would result in more nuanced policy with greater impacts on public health.
- Criminalise the sale of HNBs (and ENDS generally) to minors, either directly or by proxy, and whether in-person or online, and impose stiff penalties for contravention.

- Adopt a stringent regulatory framework for HNB (and ENDS) products, to avoid health risks from unregulated products on the black market. Restrictions and standards on devices, such as on engineering, design, and materials will ensure health and safety standards, and prevent tampering and misuse of devices through illicit additives.
- If and when e-cigarettes are regulatorily permitted, curb their appeal among youth and non-smokers through restrictions on the volume of e-liquid fluids, number of puffs, making the refill of devices cumbersome etc., alongside restrictions on flavourings, additives, packaging, and advertisements.
- Conduct annual surveys of HNB and e-cigarette usage and trends to ensure proactive, flexible, and evidence-based regulatory responses.

9. Conclusion

Based on the evidence from experiences of evolved markets like the UK, USA, EU, and Japan, and the overall balance of risks and benefits, it would be prudent for the Government of India to lift the ban on ENDS and HNBs and to regulate them instead. Prohibition may appear to protect public health, but the risks of unintended consequences run high.

Abstinence-based policies create thriving black markets where product quality is unregulated, leading to greater threats to public health from spurious and dangerous products. Governments also deprive themselves of legitimate tax revenue. Thus, the risks and opportunity costs of bans outweigh the perceived rewards. Regulation has the additional benefit of limiting the government's interference in citizens' private choices.

A risk-balancing regulatory approach recognises that the government can protect public health by continually taking stock of evidence and revising policies to address emerging risks. By banning ENDS and HNB devices, the government has created a system that will not be able to respond readily to the unintended consequences it has set in motion. Undoing this damage from a legislative perspective is both time and resource consuming, while damage to the health of persons using illegal devices may even be irreversible.

Further, the government may have stifled innovation by summarily banning ENDS and HNB devices. Retaining an opening for products that could demonstrably reduce harm would have been a wiser approach, with greater public health benefits. Indeed, given that HNBs are tobacco products which evidence suggests reduce harm (by helping people switch from more harmful cigarettes), it would be appropriate for the government to regulate HNBs separately from ENDS devices.

Thus, the pragmatic way forward for the government is to add HNB products to the Schedule of tobacco products regulated under COTPA. It can then frame product-specific regulations, and impose conditions for their responsible sale, distribution, and usage. The government can work with medical professionals and HNB product manufacturers to utilise these devices to enable smoking

cessation. Such measures would enable users to cease their dependence on nicotine and reduce overall harm from tobacco consumption, thus improving India's overarching public health outcomes.

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NOTES

[1] The Minister's response closed the policy door on innovations in HNB devices which could assist smokers in their cessation efforts. Since the behavioural experience of using HNB devices is closer to the experience of consuming combustible tobacco, they can be useful in weaning smokers off cigarettes. Now, before they can be harnessed for such purposes, a technical distinction between ENDS and HNBs in law will be necessary.

[2] Data sources as mentioned in (Cummings, Nahhas, and Sweanor, 2020): "Conventional cigarette volume comes from the Tobacco Institute of Japan (TIOJ): converted to show the volume of sales in a calendar year in billion sticks. Annual cigarette volume prior to 2016 was obtained from PMI's earnings reports (https://www.pmi.com/investor-relations/reports-filings), which itself is based on the TIOJ data. IQOS sales data comes from Philip Morris International's (PMI's) quarterly earnings reports and were calculated from the reported market share of heatsticks. The other heated tobacco product (HTP) volume is computed as the total market volume less heatstick volume less cigarette volume. We recognize that other HTPs such as Ploom TECH consumables pack consist of five tobacco capsules and one liquid cartridge. Japan Tobacco asserts that one pack of Ploom TECH consumables is equivalent to one pack of 20 combustible cigarette sticks. We used this conversion in the data presented in the table. The total HTP figures shown in the table are determined by adding heatstick volume with other HTP volume."