WHITE PAPER ON REGULATORY REGIMES FOR NOVEL TOBACCO AND NICOTINE PRODUCTS

Prepared by:

Civitas Consultancies Pvt. Ltd

Knowledge Partner:

Centre for Public Policy Research

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ACRONYMS

COTPA	Cigarettes and Other Tobacco Products Act
E-cigarettes	Electronic Cigarettes
ENDS	Electronic Nicotine Delivery Systems
EU TPD	European Tobacco Products Directive
FCTC	Framework Convention on Tobacco Control
FDA	Food and Drug Administration
GATS	Global Adult Tobacco Survey
glo	Heated Tobacco Product
HnB	Heat not Burn
HTPs	Heated Tobacco Products
ICMR	Indian Council of Medical Research
IQOS	Heated Tobacco Product
MRTP	Modified Risk Tobacco Product
PHE	Public Health England
Ploom-TECH	Heated Tobacco Product
RIVM	National Institute for Public Health and the Environment
SLT	Smokeless Tobacco
TARI	Thought Arbitrage Research Institute
UK	United Kingdom
US	United States
WHO	World Health Organisation

Executive Summary

India has upwards of 200 million users of tobacco and related products, second only to China. Tobacco consumption related illnesses are a gargantuan public health threat that claims close to a million lives each year. On the pretext of tobacco "epidemic", the Indian government imposed a blanket ban on the production, import, export, transport, sale, distribution, storage and advertisement of electronic cigarettes with the passing of the Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.

In 2019, a white paper published by the Indian Council of Medical Research (ICMR) recommended the prohibition of e-cigarettes in India owing to reasons such as increased use by youth, harmful health effects to smokers and non-smokers and potential to convert users to smoking. Based on this, the Prohibition of Electronic Cigarettes Act, 2019 was enacted which prohibits e-cigarettes, where e-cigarettes have been defined to include all forms of "ENDS, Heat not Burn products, e-Hookah and the like devices". This blanket definition is likely to create confusion as Heat not Burn (HNB) products differ from Electronic Nicotine Delivery System (ENDS) (which includes e-cigarettes). HNB products contain or use tobacco and not liquid nicotine (which is the case for ENDS and e-cigarettes), hence they should be governed and regulated as tobacco products. The ICMR had reviewed and analysed only ENDS and e-cigarettes whereas the HNB products were not included in the review and discussions.

Mounting evidence from across the world indicates that the regulatory regimes governing e-cigarettes' usage should not have an all-or-nothing approach for circumventing harm. While being a harmful product in its own right, e-cigarettes are increasingly being recognised as a viable alternative to conventional cigarettes. They deliver the addictive component, that is, nicotine without the harmful elements of tobacco smoke. The paucity of scientific evidence on the long term impact of e-cigarettes, in support and opposition of e-cigarettes, has resulted in diverging policies internationally. Many countries, such as the UK, Canada, Newzealand, widely considered leaders in tobacco control have chosen the path of regulating less risky alternatives like ENDS thereby adding further strength to their tobacco control measures. The regulations of e-cigarettes can be framed in a manner that balances the potential use of e-cigarettes as a new technology to reduce the use of or as an alternative that reduces risk and harm from combustible tobacco products while, at the same time, safeguarding against the possibility of expanding tobacco use among non-using youth and young adults, long-term former smokers, and other vulnerable populations. The current menace of the tobacco problem and the decades long battle against it highlights that awareness, warnings labels and taxation alone cannot fight the battle. The government needs to provide cigarette smokers the option to switch to less harmful products that have been developed through scientific research and promote products that help in the cessation of tobacco use. Hence the government needs to take on a multidimensional and scientific evidence backed stance in adopting harm reduction alternatives for the betterment of its citizens.

Keywords: *e-cigarettes, ENDS, Heated tobacco products, tobacco harm reduction, prohibition, regulation in India*

1. Introduction

Tobacco is universally regarded as one of the major public health hazards and is responsible directly or indirectly, for an estimated eight lakh deaths annually in the country (WHO 2022). Tobacco smoking is one of the world's most serious and preventable public health risks, particularly in low- and middle-income countries. According to the World Health Organisation, the scale of the human and economic tragedy that tobacco imposes is shocking, but it is also preventable. India is the second largest consumer of tobacco in the world and accounts for almost half of all oral cancers and the highest burden of tuberculosis globally. According to the Global Adult Tobacco Survey India, 2016-17 nearly 267 million adults (15 years and above) in India (29 percent of all adults) are users of tobacco. India is home to over 11 percent of the world's cigarette smokers, and also has a significantly larger proportion of the population smoking tobacco in its alternative or local forms (e.g., bidis, hookah, chilam, shisha, water pipes); chewing or masticating smokeless tobacco (SLT) in various forms, e.g., khaini, zarda, gutkha, and paan masala in combination with or without betel (Areca) nut; or a combination of the two (mixed users) (Sharan et al 2020). Nearly 200 million people use oral smokeless tobacco in India and another 100 million smoke tobacco.

India is among the countries with the lowest quit rates[1] for smoking, which is less than 20 percent for men (GATS 2 2017). Tobacco consumption in India is more prevalent among the socially disadvantaged and economically weaker group and they face higher exposure to tobacco harms. It was reported in a review that the population with lower socioeconomic status had more inclination towards tobacco consumption and quit attempts are less likely to be successful in these individuals mainly due to reduced community support for quitting, less motivation to quit, very strong addiction, increased likelihood of not completing pharmaceutical and behavioural intervention for tobacco quitting, psychological problems such as lack of self-efficacy, and tobacco industry marketing (Hiscock et al 2011).

Most of the efforts to counter the tobacco epidemic have been directed at creating awareness about the ill-effects of tobacco and these efforts have yielded almost universal awareness. Over 90 per cent of adults in India, across strata, identify tobacco as being harmful (Global Adult Tobacco Survey India Report 2016-2017). However, widespread awareness has not led to any incremental gains in tobacco cessation or adoption.

Additional gains in overcoming the ill-effects of tobacco are therefore unlikely to come from more awareness campaigns alone. Hence, scientific innovations that lead to new products that are less harmful to public health and serve as a better alternative should be evaluated.

2. Novel Tobacco and Nicotine Products

Novel tobacco and nicotine products are alternative nicotine delivery systems with significantly less harmful emissions than smoke from the combustion of tobacco leaves and could be an option for those who are unable to achieve smoking abstinence using other available means.

There are a wide range of definitions of novel, non-conventional, non-traditional tobacco products. There is a clear distinction that is made within the broad category of novel tobacco and nicotine products by most regulators and health organisations as 1)Electronic Nicotine Delivery Systems (ENDS) and 2) Heated Tobacco Products (HTPs)

A more specific definition of the two categories has been given by the WHO. In a statement from January 2017, WHO described Electronic Nicotine Delivery Systems and Electronic Non-Nicotine Delivery Systems (ENDS/ENNDS) as "battery powered devices that heat a solution (e-liquid) to create an aerosol which frequently contains flavourings, usually dissolved into Propylene Glycol or/and Glycerin. All ENDS (but not ENNDS) contain nicotine. Electronic

[1] Quit rates are a key metric that describes the percentage of users who successfully quit.

cigarettes, the most common prototype, are devices that do not burn or use tobacco leaves, but instead vaporise a solution the user then inhales. The main constituents of the solution, in addition to nicotine when nicotine is present, are propylene glycol, with or without glycerol and flavouring agents. ENDS solutions and emissions contain other chemicals, some of them considered to be toxicants." Electronic Nicotine Delivery Systems (ENDS) comprise a wide range of products - vapes, e-hookahs, electronic cigarettes and e-pipes.

As stated earlier, there is another category of novel tobacco products known as HTPs - that are based on heating of tobacco to release a nicotine containing aerosol. The distinction here is that they use processed tobacco in the form of a cartridge similar to a cigarette but does not involve burning or combustion. The WHO information sheet from May 2018, defines "Heated Tobacco Products are tobacco products that produce aerosols containing nicotine and other chemicals, which are inhaled by users, through the mouth. They contain the highly addictive substance nicotine (contained in tobacco), which makes HTPs addictive. They also contain non-tobacco additives and are often flavoured. HTPs mimic the behaviour of smoking conventional cigarettes, and some make use of specifically designed cigarettes to contain the tobacco for heating."

In the preamble of decision FCTC/COP8(22) dated 6 October 2018, the Parties to the WHO Framework Convention on Tobacco Control recognized that "heated tobacco products are tobacco products, and are therefore subject to the provisions of the WHO FCTC".

The Indian Government in its Act failed to make the distinction between two very distinct classes of products. The Act defines electronic cigarette "as an electronic device that heats a substance, with or without nicotine and flavours, to create an aerosol for inhalation and includes all forms of Electronic Nicotine Delivery Systems, Heat Not Burn Products, e-Hookah and the like devices, by whatever name called and whatever shape, size or form it may have, but does not include any product licensed under the Drugs and Cosmetics Act, 1940[2].

In effect, the Indian Act is at variance with global definitions as it does not differentiate between the two classes of products. This variation implies that while the WHO identified HTPs (or Heat Not Burn products as defined in the Indian law) as tobacco products subject to WHO FCTC which is implemented in India through "The Cigarettes And Other Tobacco Products (Prohibition Of Advertisement And Regulation Of Trade And Commerce, Production, Supply And Distribution) Act, 2003" (COTPA), the 2019 Prohibition of Electronic Cigarette Act clubs them together without any basis.

The hasty decision of the government to ban e-cigarettes, 'heat not burn' products and other like products without delving into the scientific evidence should be relooked.

3. Prohibition of Electronic Cigarettes Act, 2019

On July 10, 2019, the central government informed Parliament that e-cigarettes worth $1,91,781 were imported into India between 2016-17 and 2018-19 (Rawat 2019). These were mostly imported from China, the US, Hong Kong and Germany. The Indian e-cigarette market was categorised as a vaporizer, vape mod, cig-a-like, and T-Vapour based on the product. The rising popularity of vaporizers was due to varied factors such as moderate cost, dense aerosol production, and flexibility with the type of flavours that can be used with this device (P&S Intelligence 2019).

With e-cigarettes gaining popularity in India, the Government of India passed the Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019 ("Act") on December 5, 2019.

[2] For the purposes of this clause, the expression "substance" includes any natural or artificial substance or other matter, whether it is in a solid state or in liquid form or in the form of gas or vapour.

A white paper on e-cigarettes published by the Indian Council of Medical Research (ICMR) recommended its prohibition in India owing to reasons such as increased use by youth, harmful health effects, and its impact on converting users to smoking. The **key concerns** of the Ministry of Health while banning e-cigarettes were around the rising increase of youth uptake, use of flavoured liquids and the absence of long term studies/data to substantiate the claim that e-cigarettes are less harmful and aid in tobacco cessation.

Scientific evidence from across the world suggests that e-cigarettes are less harmful than traditional cigarettes and it has aided smokers in quitting.

As per the Public Health England and the United States National Academies of Sciences, Engineering and Medicine, e-cigarettes are substantially less harmful than traditional cigarettes as they lack the tar and carbon monoxide of traditional cigarettes because combustion, which produces significant toxic substances, does not occur (Public Health England 2016). Therefore, substituting e-cigarettes for traditional cigarettes may reduce the smoker's exposure to numerous toxic substances and carcinogens.

A clinical trial in the United Kingdom found that people who used e-cigarettes to quit smoking were twice as likely to succeed as people who used other nicotine replacement products such as patches or gum (Hajek et al 2019).

The first- time study of its kind in India "Patterns of tobacco and e-cigarette use status in India: a cross-sectional survey of 3000 vapers in eight Indian cities" found that e-cigarettes could potentially be an effective partial or complete substitute for tobacco use for some smokers and smokeless tobacco users in India (Sharan et al 2020). It also argued that frequent e-cigarette use was one of the strongest correlates of being a former smoker. This is in contrast to the argument put forth by the government that youth uptake and first- time smokers are on a rise.

This white paper attempts to look into the details of the Prohibition of Electronic Cigarettes Act, 2019 and cross-country experiences in regulating e-cigarettes, and also suggests regulatory measures that can be adopted in the Indian context.

4. The Challenge Facing Tobacco Regulation: Quit or Die OR harm reduction?

Tobacco use is the leading cause of preventable disease and premature morbidity in the world. The WHO has observed that there are more than 1 billion smokers in the world today; it anticipates that there will be around the same number in the foreseeable future. The situation is particularly acute in Asia, home to nearly 60 percent of the world's smokers. There are more than 100 million people in India who use tobacco regularly. India has the world's most diverse range of tobacco options which varies from 'dangerous' to 'very dangerous' and two in three smokers die of tobacco related illness. Over the last 50 years, all tobacco products were seen as "Deadly in Any Form or Disguise," as a 2006 WHO campaign phrased it.

The WHO's Framework Convention on Tobacco Control, the world's first public health treaty, therefore requires or urges its 150+ Parties (including India) to adopt measures to reduce the demand for tobacco products (e.g., warning labels, public health campaigns, tax increases) and reduce the supply of tobacco products (including encouraging tobacco growers to shift to alternative crops). Although touted as a success, smoking rates have only modestly declined over the Treaty's first 10 years in force - around 2% in total, according to a 2017 study published in The Lancet.

The Treaty also includes the concept of tobacco harm reduction - encouraging tobacco users to switch to less harmful alternatives. The FCTC defines tobacco control as "a range of supply, demand and harm reduction strategies that aim to improve the health of a population by eliminating or reducing their consumption of tobacco products and exposure to tobacco smoke" but very little focus has been given to that, though.

Tobacco harm reduction is based on the principle of reducing harm from cigarettes through devices that reduce the harms associated with smoking by

providing nicotine (cleaner form of nicotine intake) to people who cannot or do not want to quit (by themselves or with currently-approved methods).

Over the last 15 years, technological and scientific innovations have led to the development of a wide variety of tobacco and nicotine products that are significantly safer than cigarettes; over a relatively short period of time, millions of smokers worldwide have switched to these products. These include:

- **Snus**, a Swedish form of smokeless tobacco that is specially cured and has very low levels of carcinogens ordinarily found in oral tobacco, has led Sweden to have the lowest male smoking rate in the world and among the lowest cancer incidence.

- **E-cigarettes**, which use battery power to generate an aerosol from a nicotine containing liquid, have been widely adopted. In the UK, the government encourages smokers who do not quit to switch to e-cigarettes. Public Health England's successive reports since 2018 reviews all the available evidence and concludes (again) that they are 95% less hazardous than cigarettes.

- **Heated tobacco products** or 'heat not burn tobacco products are now sold in nearly 40 countries worldwide. These heat tobacco rather than burning it and generate a nicotine-containing vapour without containing tobacco. A number of government and scientific agencies have reviewed the available evidence and determined heated tobacco products have the potential to be much less hazardous than cigarettes. The February 2018 report by Public Health England noted that "compared with cigarette smoke, heated tobacco products are likely to expose users and bystanders to lower levels of particulate matter and harmful and potentially harmful compounds…" .

Many in the public health community, believe that this wide range of innovative products has the potential to dramatically reduce the premature death and disease caused by tobacco use. A 2014 letter by more than 50 global tobacco policy experts to the head of the World Health Organisation stated:

"*We have known for years that people 'smoke for the nicotine, but die from the smoke': the vast majority of the death and disease attributable to tobacco arises from inhalation of tar particles and toxic gases drawn into the lungs. There are now rapid developments in nicotine-based products that can effectively substitute for cigarettes but with very low risks. These include for example, e-cigarettes and other vapour products, low-nitrosamine smokeless tobacco such as snus, and other low-risk non-combustible nicotine or tobacco products that may become viable alternatives to smoking in the future. Taken together, these tobacco harm reduction products could play a significant role in meeting the 2025 UN non-communicable disease (NCD) objectives by driving down smoking prevalence and cigarette consumption. Indeed, it is hard to imagine major reductions in tobacco-related NCDs without the contribution of tobacco harm reduction. Even though most of us would prefer people to quit smoking and use nicotine altogether, experience suggests that many smokers cannot or choose not to give up nicotine and will continue to smoke if there is no safer alternative available that is acceptable to them. The potential for tobacco harm reduction products to reduce the burden of smoking related disease is very large, and these products could be among the most significant health innovations of the 21st Century - perhaps saving hundreds of millions of lives. The urge to control and suppress them as tobacco products should be resisted and instead regulation that is fit for purpose and designed to realise the potential should be championed by WHO."*

There is broad consensus that these products are less harmful than cigarette smoking. The UK, the US, and New Zealand have explicitly recognized the value of policies encouraging the development, assessment and availability of safer products that could make more harmful tobacco products obsolete.

A report by the World Health Organisation on ENDS and ENNDS states that "If the great majority of tobacco smokers who are unable or unwilling to quit would switch without delay to using an alternative source of nicotine with lower health risks, and eventually stop using it, this would represent a significant contemporary public health achievement." (World Health Organisation 2016).

The future of tobacco is therefore at a crossroads: Will governments encourage and regulate novel

tobacco- and nicotine-containing products that could make smoking obsolete, or will they maintain their current approaches, imagining a tobacco-free future and expecting tobacco growers, tobacco companies and tobacco users to somehow disappear?

5. Framework of Indian Legislation

India ratified the WHO Framework Convention on Tobacco Control (FCTC) in 2004. FCTC is the first ever international public health treaty focusing on the global public health issue of tobacco control. The objective of the convention is to devise means of tobacco control based on current, relevant, scientific, technical and economic considerations.

The primary national tobacco control law is the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 (COTPA). COTPA has granted authority to the Ministry of Health and Family Welfare, which has since passed over 15 notifications that amend, clarify and expand COTPA.

The COTPA prohibits the advertisement of and provides for the regulation of trade and commerce, production, supply and distribution of cigarettes and other tobacco products and connected matters.

Tobacco products have been defined to mean the products specified in the Schedule to COTPA. This Schedule includes products like cigarettes, cigars, cheroots, bidis etc. COTPA also provides power to the central government to add any other tobacco products to the Schedule.

Heated Tobacco Products or Heat not burn contain or use tobacco and hence they should be governed and regulated as tobacco products and regulated under COTPA, 2003.

According to the National Institute for Public Health and the Environment (RIVM) "The [change in cumulative exposure] was estimated to be 10- 25-fold lower when using HTPs instead of cigarettes (Slob et al 2020). Overall, the conclusion seems to be warranted that consuming HTPs instead of cigarettes will be associated with a substantial increase in life expectancy, for the subgroup of smokers who would die from cancer.

With this principle, Heated Tobacco Products or Heat not Burn Products could be classified as tobacco harm reduction products.

Tobacco cigarettes are the most harmful product for nicotine intake. When conventional cigarettes are available in every corner of our country and are being sold with impunity, the government's swift decision to ban harm reduction & related products without understanding and analysing the effect and impact is a matter of grave concern. However, a substantial negative health impact is expected to remain from consuming HTPs as compared to total abstinence from tobacco products.

6. Legislation on novel tobacco and nicotine products: Key countries and their policies

The growing body of scientific evidence, in support and opposition of e-cigarettes, has resulted in diverging policies internationally. Many countries such as the UK, Canada, Newzealand, widely considered leaders in tobacco control have chosen the path of regulating less risky alternatives like ENDS thereby adding further strength to their tobacco control measures. The regulations being followed by Japan, European Union, the US, Canada, New Zealand and in the UK and the US FDA's authorization for the IQOS (heated tobacco product) should provide a basis on which governments (like India) and public health organisations can regulate smoke-free alternatives to differentiate them from cigarettes in order to protect and promote public health. Following are the regulatory pathways adopted in a few regions:

United Kingdom

In the United Kingdom, the use, sale and advertising of e-cigarettes are legal, and e-cigarettes are not covered by laws restricting smoking in public places. In the UK, the government has explicitly embraced electronic smokeless products, and recommends smokers who do not or cannot quit, to consider switching to these reduced harm products. This move has resulted in the UK smoking prevalence falling at

unseen rates and demonstrates the success of policies advocating control over prohibition.

The proportion of current smokers in the UK decreased from 14.1 percent in 2019 to 13.8 percent in Quarter 1 2020 (around 6.7 million). Experimentation with e-cigarettes has steadily increased in recent years in England and Great Britain as a whole. However, regular use remains low, with 1.7 percent of 11 to 18-year-olds in Great Britain reporting at least weekly use in 2018 (it was 0.4 percent among 11-year-olds and 2.6 percent among 18-year-olds). Vaping continues to be associated with smoking. The proportion of young people who have never smoked who use e-cigarette at least weekly remains very low (0.2 percent of 11-18 year olds in 2018). This can be compared with the smoking data from 2016 which is used for measuring progress in reaching the goals of the tobacco control plan for England. These indicated that 7 percent of 15 year olds were regular (at least weekly) smokers in 2016 (8 percent in 2014). This is in contrast to the claim that vaping among children less than 18 years is on a rise.

The Royal College of Physicians, Tobacco Advisory Group, explained in its landmark April 2016 report titled "Nicotine without smoke: tobacco harm reduction" that smokers smoke predominantly for nicotine, that nicotine itself is not especially hazardous, and that if nicotine could be provided in a form that is acceptable and effective as a cigarette substitute, millions of lives could be saved (Royal College of Physicians 2016). This report makes the case for harm reduction strategies to protect smokers.

Public Health England, too has concluded in their report titled "E-Cigarettes: An evidence update" that "E-cigarettes are 95 percent less harmful than normal cigarettes" and "there is a need to publicise the current best estimate that using e-Cigarettes is around 95 percent safer than smoking." (McNeill et al 2015)

The Cochrane Review, recognized as the gold standard for evidence-based medicine, concluded e-cigarettes were more effective in helping smokers quit than traditional nicotine replacement therapies[3]. (McRobbie et al 2014). A study with 886 participants across the UK revealed that the 1-year abstinence rate was 18.0% in the e-cigarette group, as compared with 9.9% in the nicotine-replacement group. It concluded that E-cigarettes were more effective for smoking cessation than nicotine-replacement therapy when both products were accompanied by behavioural support. (Hajek et al 2019)

Public Health England and its findings

In July 2016, Public Health England (PHE), an executive agency of the Department of Health in the UK, issued guidance on the use of electronic cigarettes in public places and workplaces. PHE recommends:

- *Make clear the distinction between vaping and smoking*: Electronic cigarette use does not meet the legal or clinical definitions of smoking and electronic cigarettes are less risky and help drive down smoking rates.

- *Ensure policies are informed by the evidence on health risks to bystanders*: Evidence of harm from secondhand smoke is conclusive and provides the basis for smoke-free legislation (Health Act 2006). However, scientific evidence shows that the risk to health from secondhand vapour is extremely low compared to smoke and insufficient to justify prohibiting cigarettes.

- *Identify and manage risks of uptake by children and young people*: Because adult smokers use e-cigarettes to quit smoking, these products can help reduce young people's exposure to secondhand smoke and smoking role models.

- *Support smokers to stop smoking and stay smoke-free*: Vapers should not be required to use the same space as smokers, as this could undermine their ability to quit and stay smoke-free.

- *Support compliance with smoke-free laws and*

[3] A Cochrane Review is a systematic review of research in health care and health policy that is published in the Cochrane Database of Systematic Reviews. Cochrane Reviews use primary research to generate new knowledge about the effects of an intervention (or interventions) used in clinical, public health or policy settings.

policies: Maintain and support compliance with smoke-free requirements by emphasising a clear distinction between smoking and vaping. Accurately indicate where vaping is prohibited or allowed, and communicate the policy clearly for everyone to hear.

US FDA and its ruling

The US FDA has said that it has taken action on approximately 99% of the nearly 6.7 million ENDS products submitted for premarket authorization, including issuing marketing denial orders for more than 1 million ENDS products.

Modified Risk Tobacco Product (MRTP) for a tobacco product is a legal designation in the United States that poses lower health risks to individual users and the population as a whole when compared to existing products in the market like cigarettes. MRTP came into the picture when the marketing of the tobacco products was misleading the consumers (using words like "light" or "mild") which might give them the impression that the products posed less of a health risk than other tobacco products. Consequently, the Family Smoking Prevention and Tobacco Control Act of 2009, gave the Food and Drug Administration the power to regulate the tobacco industry and made it illegal for tobacco products to be marketed as lower risk products unless the FDA authorised such a designation.

Manufacturers seeking MRTP application, are required to provide the FDA with detailed information including:

- The relative health risks to individuals who would use the product.
- The likelihood that existing users of tobacco products will switch to the product rather than quit altogether or that persons who do not use tobacco products will use the product.
- The risks and benefits to persons from the use of the product compared to approved smoking cessation products.

US FDA authorised the Marketing of a Heat Not Burn product, IQOS from Philip Morris, as a 'Modified Risk Tobacco Product (MRTP)'. The US FDA determined the company demonstrated that because the IQOS Tobacco Heating System heats tobacco and does not burn it, it significantly reduces the production of harmful and potentially harmful chemicals compared to cigarette smoke.

Furthermore, studies showed switching completely from combusted cigarettes to the IQOS Tobacco Heating System significantly reduces the body's exposure to 15 specific harmful and potentially harmful chemicals. The toxicological assessment also found that, compared with cigarette smoke, IQOS aerosols contain considerably lower levels of potential carcinogens and toxic chemicals that can harm the respiratory or reproductive systems. Additionally, the FDA found that the applications supported the required consumer understanding findings.

In March 2022, the FDA authorised several tobacco-flavoured ENDS products from Logic Technology Development LLC (Logic) under the Logic Vapeleaf, Logic Power and Logic Pro brands, including devices. According to FDA "These products were authorised after the agency's review of the product applications concluded, among other things, that the likely benefit for adult smokers who significantly reduce their cigarette use (or who switch completely and experience cigarette use cessation) outweighs the risk to youth, provided that the company follows post-marketing requirements to reduce youth access and youth exposure to their marketing. While today's action permits these specific products to be sold in the U.S., it does not mean these products are safe nor are they 'FDA approved.' All tobacco products are harmful and potentially addictive. Those who do not use tobacco products shouldn't start." Interestingly, in the same notification, the US FDA also issued marketing denial orders to Logic for multiple other ENDS products.

In October 2021, the FDA authorised the first set of electronic nicotine delivery system (ENDS) products ever to be authorised by the FDA through the Premarket Tobacco Product Application (PMTA) pathway. The FDA issued marketing granted orders to R.J. Reynolds (RJR) Vapour Company for its Vuse Solo closed ENDS device and accompanying tobacco-flavoured e-liquid pods. The FDA said that the RJR Vapor Company had submitted data to the FDA that demonstrated that marketing of these

products was appropriate for the protection of public health.

In June 2022, the US FDA issued marketing denial orders (MDOs) to JUUL Labs Inc. for all of their products marketed in the United States including the JUUL device and four types of JUUL pods: Virginia tobacco flavoured pods at nicotine concentrations of 5.0% and 3.0% and menthol flavoured pods at nicotine concentrations of 5.0% and 3.0%. The FDA said that it had determined that the applications lacked sufficient evidence regarding the toxicological profile of the products to demonstrate that marketing of the products would be appropriate for the protection of public health. "In particular, some of the company's study findings raised concerns due to insufficient and conflicting data - including regarding genotoxicity and potentially harmful chemicals leaching from the company's proprietary e-liquid pods - that have not been adequately addressed and precluded the FDA from completing a full toxicological risk assessment of the products named in the company's applications," it said.

The US FDA has, therefore, applied clinical and scientific evidence based yardsticks to decide on novel tobacco products. Instead of a blanket ban on products, it has based its decisions on the toxicological profile of the products in order to arrive at a decision based on the potential impact on public health.

The FDA specifically regulates the manufacture, import, packaging, labelling, advertising, promotion, sale, and distribution of ENDS, including components and parts of ENDS but excluding accessories.

Examples of regulated components and parts of ENDS include:

- E-liquids
- A glass or plastic vial container of e-liquid
- Cartridges
- Atomizers, the part of the ENDS that turns e-liquid into vapour for inhalation
- Cartomizers and clearomizers, which, similar to atomizers also deliver e-liquid in vapour form
- Certain batteries
- Digital display or lights to adjust settings
- Tank systems
- Drip tips or mouthpieces
- Flavourings for ENDS
- Programmable software

According to Mitch Zeller, J.D., director of the FDA's Center for Tobacco Products, product authorization is based on manufacturers demonstrating that the possible benefits to adult smokers outweigh the risk of youth possibly initiating. According to Zeller, "We are making progress in our review of flavoured ENDS, and we will continue to deny marketing of products where the applicant hasn't provided enough evidence to show that the potential benefit to adult smokers outweighs the considerable risk to youth. We are committed to continuing to take the appropriate actions to protect our nation's youth from the dangers of all tobacco products, including e-cigarettes, which remain the most commonly used tobacco product by youth in the United States."

Japan

Japanese laws do not specifically regulate either e-cigarettes or heated tobacco products. Instead, these new product categories fit into general definitions within existing laws.

Nicotine-containing e-cigarettes, for example, are treated simply as nicotine-containing consumer products. Japanese law prohibits the sale of nicotine-containing consumer products (other than tobacco products) unless they are approved by the Japanese Pharmaceutical and Medical Devices Agency. Heated tobacco products, on the other hand, are legal. Although Japanese law does not currently explicitly define heated tobacco products, they are regulated as "other tobacco products for smoking," not as cigarettes.

All tobacco products sold in Japan are required to bear health warning labels on the product packaging. The warning labels required on packages of heated tobacco products are different from those applied to cigarette packages. Although Japanese law does not currently establish specific labelling requirements for heated tobacco products, the law establishes warning requirements for pipe and "other manufactured tobacco products"; those warning labels are currently

applied to heated tobacco products. Those warnings must occupy 30% of the front and back of product packaging and must include one of a series of different textual warnings.

In Japan, overall tobacco consumption is decreasing as cigarettes are quickly replaced by heated tobacco products like IQOS, glo, and Ploom-TECH. Heat not Burn (HnB) products have been successful in reducing cigarette smoking in Japan so far. Reports suggest that HnBs are not causing the "Gateway phenomenon" in the younger generation in Japan.

European Union

The European Tobacco Products Directive (EU TPD)[4] aims to improve the functioning of the internal market for tobacco and related products, while ensuring a high level of health protection for European citizens. The EU TPD establishes separate regulatory requirements for novel, heated tobacco products and for electronic cigarettes which are similar to tobacco regulations.

EU TPD creates a separate regulatory category for novel tobacco products that do not fall within the existing tobacco product categories. Novel tobacco products can be either a product for smoking or smokeless, with the key differentiator being the presence or absence of combustion.

According to the EU Tobacco Products Directive (2014/40/EU), a 'novel tobacco product' is defined as a tobacco product that does not fall into any of the following categories: cigarettes, roll-you-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use ; and was placed on the market after 19 May 2014. Examples of novel tobacco products include: electronic cigarettes and heated tobacco products (HTPs).

Further, the directive defines electronic cigarettes as a product that can be used for consumption of nicotine-containing vapour via a mouthpiece, or any component of that product, including a cartridge, a tank and the device without a cartridge or tank. Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single- use cartridges.

The EU definition of Heated Tobacco Products is a product that produces aerosols containing nicotine and other chemicals, which are inhaled through the mouth and contain highly-addictive nicotine; they mimic the behaviour of conventional cigarette smoking

- **Heated Tobacco Products and EU TPD**

The EU TPD has been transposed into national law in most EU Member States, and as a result, heated tobacco products are regulated as "novel smokeless tobacco products." Importantly, for heated tobacco products, which may consist of a consumable tobacco product and an electronic device designed to heat the tobacco to produce an emission, the electronic device is not subject to regulation under the EU TPD.

Market access: Notification/Authorization: Article 19 of the directives of EU TPD obligates the Member States to establish a system of notification or authorization, with which manufacturers must comply before placing a product on the market. When transposing the EU TPD into national law, most Member States have opted for a notification system, which obligates manufacturers or importers to submit a notification consisting of available scientific studies and other available and relevant information such as risk/benefit analysis of the product.

The EU TPD provides for differentiated health warnings across product categories which more accurately reflect the known risks of the products. Specifically, under the EU TPD:

- Smokeless novel tobacco products must bear smaller (30 percent) text-only health warnings, whereas cigarettes and roll-your-own tobacco must bear larger (65 percent) graphic health.

- The health warning language is more consistent with the known risks of the products concerned.

Ingredients: The EU TPD restricts the use of some

[4] The Tobacco Products Directive (TPD) or European Tobacco Products Directive (EUTPD) is a directive of the European Union which places limits on the sale and merchandising of tobacco and tobacco related products in the EU

ingredients for cigarettes and roll-your-own tobacco products, including those which impart a "characterising flavour," such as menthol. However, other tobacco products, including novel smokeless tobacco products, are exempt from many of the prohibitions on ingredients, including menthol.

Marketing: EU Directives prohibit the cross-border advertising of tobacco products, including television, radio, print and internet advertising; under the EU TPD, those same requirements apply to novel tobacco products. Many Member States have established different requirements for non-combustible tobacco products than for cigarettes and other smoked tobacco products. For example, in Italy, regulators have developed a regulatory scheme that authorises manufacturers to communicate information about less toxic products . The ministerial decree defines the rules and procedures whereby research is submitted by a manufacturer and is evaluated by the government " to recognize the reduction of toxic components and the potential risk reduction of novel tobacco products, compared to combustible tobacco products."

Reporting requirements of ingredients and emissions: Member states must require manufacturers and importers of all tobacco products (including novel smokeless tobacco products) to submit a list of all ingredients (including their quantities) used to manufacture the tobacco products, accompanied by a statement setting forth the reason for the inclusion of such ingredients, as well as toxicological data regarding the ingredients. Manufacturers or importers must also inform the competent authorities of the Member States concerned if the composition of a product is modified in a way that affects the pertinent article of the regulation.

Electronic Cigarettes and EU TPD

According to Article 2 of the EU TPD, an electronic cigarette is defined as: "a product that can be used for consumption of nicotine-containing vapour via a mouthpiece , or any component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single-use cartridges."

Market access: Notification/Authorization: Article 20 requires manufacturers to notify the relevant Member State government before placing an e-cigarette on the market. This requirement does not apply to combustible tobacco such as cigarettes. The notification must include, among other things, the list of ingredients in, and emissions resulting from the use of the product, available toxicological data, and information on the nicotine dose and uptake.

Packaging and labelling: The EU TPD requires e-cigarettes to bear the same size health warnings as smokeless tobacco products, which are smaller (30 percent) than those required for cigarettes and roll-your-own tobacco products (65 percent). Furthermore, the health warning language for e-cigarettes is more consistent with the known risks of the tobacco products concerned.

The Member States must ensure that unit packets of electronic cigarettes and refill containers include a leaflet with specific information regarding instructions, warnings, possible adverse effects, the manufacturers' contact details, addictiveness and toxicity. Unit packs and any outside packaging must list all the products' ingredients and carry one of three health warnings contained in the regulation.

Ingredients: The EU TPD requires that only ingredients of high purity be used to manufacture nicotine-containing liquid. Additionally, except for nicotine, only ingredients that do not pose a risk to human health when heated or unheated shall be used in the nicotine-containing liquid. Finally, some combustible tobacco product ingredient restrictions also apply to e-cigarettes, however, the ban on menthol does not.

Marketing: The EU TPD obligates Member States to ensure that commercial communications with the aim or direct or indirect of promoting electronic cigarettes or its components are prohibited, except for publications intended exclusively for professionals in the trade of electronic cigarettes and for publications in third countries that are not principally intended for the EU market. Commercial communication on the radio, public or private contributions to radio programs and public or private contribution to any event, activity,

or individual person with the aim or direct or indirect effect of promoting electronic cigarettes or its components is also forbidden. The EU TPD further forbids audiovisual commercial communications.

As with heated tobacco products, some EU Member States have established different rules for communicating about e-cigarettes than for cigarettes and other combustible tobacco products.

Analysis

Prohibition leads to unintended consequences like illegal production and sale. Banning popular psychoactive drugs has a very low success rate, as is evident from India's own experience with alcohol.

The experiences of countries like the US, UK, European Union indicates that the adoption of e-cigarette and heat not burn products has aided in the tobacco harm reduction journey. The UK from the beginning has resorted to the regulatory mechanism of e-cigarettes and heated tobacco products. The evidence discussed concludes that the policy adopted aides in tobacco cessation.

In the US it has mandated the manufacturers to get approvals from FDA by proving that the product contributes to the betterment of public health. All the countries that have regulated e-cigarettes and heat not burn products have followed a regulatory pathway similar to that of other tobacco products like cigarettes. The regulations mainly address the concern that the consumption of e-cigarettes is increasing among the younger population by making it illegal to sell the products to populations who are under eighteen years of age and also by restricting the advertisements.

Educating potential consumers, supporting consumers in their journey to quit, and incentivising the industry to help consumers should be strengthened in the country. The regulations can be framed in a manner that balances the potential use of e-cigarettes as new technology to reduce the use of combustible tobacco products against the possibility of expanding tobacco use among non-using youth and young adults, long-term former smokers, and other vulnerable populations.

7. Recommendations on Novel Nicotine and Tobacco Products Legislation in India

Despite stringent laws on smoking and tobacco control, India still has more than 100 million smokers in the world. While tobacco control strategies driven by regulation, taxation, counselling and therapeutic nicotine replacement techniques for smokers are the need of the hour, these strategies can be complemented by allowing well-regulated, scientifically substantiated, less harmful alternatives made available for smokers who are unable to quit by any means.

Reduced harm products, when regulated by law, can help create an impact on the current smoking population. Governments in countries like Japan, Korea, US, many countries in Europe, Canada, New Zealand and in the UK have embraced safer alternatives and made them legally available under strict regulations.

Novel Tobacco products which reduce harm include E-cigarettes/ENDS and heated tobacco products (HTPs) or Heat Not Burn Products. They are alternatives to traditional cigarettes. Scientific studies have proven these products to be less harmful alternatives to cigarettes for nearly 1 billion smokers worldwide. A range of such novel products is legally available for smokers in other countries like the UK, USA, Japan, New Zealand etc.

Legalising e-cigarettes, heated tobacco products and like devices, and regulating them is the need of the hour.

It is recommended that a regulatory pathway should be adopted and regulations of e-cigarettes (which are a part of ENDS-Electronic Nicotine Delivery System) should be different from the regulation of tobacco products as they do not contain tobacco.

The following are the regulations that are recommended to be implemented:

1. The E-Cigarettes Prohibition Act of 2019 should be repealed and replaced by an E-Cigarettes Regulation Act.

2. Heated Tobacco Products or Heat Not Burn Products that use tobacco in any form as part of the product should be regulated under COTPA 2003 rather than under the E-Cigarettes Regulation Act.

3. The E-Cigarettes Regulation Act should regulate manufacture, import, packaging, labelling, advertising, promotion, sale and distribution of ENDS.

4. The Act should set minimum standards on product, material to be used, heating temperatures, safety norms, toxicology standards for both liquid and resultant aerosols, and permissible levels of delivery of nicotine to the consumer.

5. COTPA 2003 should be amended to regulate the manufacture, import, packaging, labelling, advertising, promotion, sale, and distribution of HTPs or Heat Not Burn Products. The amended clauses of COTPA should set minimum standards on products, material to be used, heating temperatures, safety norms, toxicology standards for both constituent tobacco and resultant aerosols, and permissible levels of delivery of nicotine to the consumer.

6. All novel tobacco and nicotine products regulations should contain provisions prohibiting sale to children less than 18 years of age.

7. E-cigarettes and HTPs should be classified differently and subject to different tax structures.

8. There should be a mandatory listing of contents used and warnings regarding the continued use of the product.

9. Detailed procedures need to be established along the lines of the USFDA Modified Risk Tobacco Product applications for authorization of products.

10. There needs to be clear regulations on marketing, labelling and distribution to prevent the novel tobacco nicotine products becoming gateways for recruitment of smokers.

11. The medical fraternity should be encouraged to evaluate the merit of these products and keep a record of their efficacy.

12. A long term study of the health impact of these products on smokers switching to these products needs to be undertaken.

13. National Tobacco Testing Laboratories or new Laboratories should be entrusted with the task of continuous testing of products being introduced in the market for toxicity, safety and other parameters.

14. The two regulations should cover the following elements:

a. Black listing of contents that cannot be included in e-liquids
b. Maximum nicotine delivery
c. Strength of nicotine in e-liquids
d. Standards for nicotine, propylene glycol and other chemicals based on US FDA standards
e. Safety standards including tamper proofing and childproofing, breakage and leakage
f. Disposal of exhausted e-cigarette cartridges or liquid containers
g. Flavours and additives
h. Duty and tax structure that enables e-cigarette access to weaker economic classes that have the lowest quit behaviour.
i. Mandatory reporting of the levels of harmful and potentially harmful constituents (HPHCs) found in the products and smoke. HPHCs are chemicals or chemical compounds in tobacco products or tobacco smoke that cause or could cause harm to smokers or non-smokers.

8. Conclusion

Imposing a ban on e-cigarette or less harmful alternatives takes away the right of smokers from shifting to a better alternative. Hence, they move back to traditional cigarettes, which take a further toll on the health and costs the exchequer a hefty amount. The direct health expenditure on treating tobacco-related diseases alone accounts for 5.3 percent of total health spending in India in a year (WHO). It has been found that treatment of tobacco-related diseases and the loss of productivity caused therein cost the country almost Rs. 13,500 crore annually, which more than offsets all the benefits accruing in the form of revenue and employment generated by the tobacco industry. Banning also leads to the emergence of illicit markets. Illicit products can be more harmful due to the disregard for regulations and safety standards.

The Government of the day should identify better alternatives and encourage innovation that can

eventually lead to the betterment of public health. With initiatives like the National Tobacco Control Programme that aims to help people quit tobacco use and facilitate implementation of strategies for prevention and control of tobacco, adopting to newer products and technologies that are less harmful compared with introducing stricter policies on traditional cigarette consumption and imposing similar restrictions on these harm reduction alternatives is a step in the right direction. It is essential for the government to take on a multidimensional and unprejudiced stance in adopting harm reduction alternatives for the betterment of its citizens.

The existing ban overlooks the extensive literature and mounting evidence from across the world which indicates that the regulatory regimes governing e-cigarettes' usage should not have an all-or-nothing approach for circumventing harm. While being a harmful product in its own right, e-cigarettes are increasingly being recognised as a viable alternative to conventional cigarettes. They deliver the addictive component, that is, nicotine without the harmful elements of tobacco smoke and provide a choice to the smokers to switch to a less harmful alternative. E-cigarettes do not expose the user to many of the constituents of cigarette smoke (eg, tars, oxidant gases, and carbon monoxide) that are responsible for many of the tobacco-attributable diseases.

When the lives of 1.2 million Indians are lost every year only due to the consumption of tobacco, the government should adopt policies to stem the rot of tobacco consumption instead of banning products that serve as a better alternative to traditional cigarettes.

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Annexure

Background Readings on ENDS/HTPs

S. No.	Research / Study/ White Paper/ Policy	Country/ Theme
1	Does the gateway theory justify a ban on nicotine vaping in Australia.pdf	Australia
2	Electronic cigarettes what can we learn from.pdf	Australia
3	McKell-Institute-Vaping-in-Australia.pdf	Australia
4	Mendelsohn.pdf	Australia
5	Mendelsohn_CP_Wodak_A._Vaping._Ten_frequently_asked_questions._Respiratory_MedicineToday_2018_3134-36.pdf	Australia
6	MendelsohnCHallWBorlandR.CouldvapinghelplowersmokingratesinAustralia.DrugAlcoholRev2020.pdf	Australia
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8	WodakAMendelsohnCP.TheAustralianApproachtoTobaccoHarmReductionIsEvenMoreMisguidedThantheUSApproach.AJPH2020.pdf	Australia
9	Feb 2022- Strengthening Europe in the fight against cancer.pdf	Europe
10	Regulation of e-cigarettes in Germany and other EU countries.pdf	Europe
11	The EU ban on the sale of Snus.pdf	Europe
12	Consensus-statement_G02.pdf	India
13	LALIT BHASIN REPRESENTATION ON E- CIGARETTES BILL.pdf	India
14	Patterns_of_tobacco_and_e-cigarette_use_status_in_.pdf	India

15	The-Prohibition-of-Electronic-Cigarettes-production-manufacture-import-export-transport-sale-distribution-storage-and-advertisement-Ordinance-2019.pdf	India
16	Status in Japan on THR.pdf	Japan
17	JAPANESE EXPERIENCE WITH HEAT-NOT-BURN.pdf	Japan
18	Tobacco Harm Reduction and NNTPs_Japan_Nov 2020.pdf	Japan
19	5_Heated Tobacco Products - Government agencies assessments and research.pdf	HTP
20	Heated Tobacco Products_ A Review of Current Knowledge and Initial Assessments.pdf	HTP
21	Selected Third Party Assessment of IQOS July 2020.pdf	HTP
22	Population Impacts of Snus.pdf	Sweden
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24	Epidemiological evidence on snus.pdf	Sweden
25	50 years of increasing snus use in Swedish men.pdf	Sweden
26	5. BMA - E-cigarettes - balancing risks and opportunities - Nov	UK
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28	Public Health England - Full Report - Evidence review of e-cigarettes and heated tobacco products 2018 - Feb 2018.pdf	UK
29	Public Health England - Press Release - E-cigarettes-an-emerging-public health consensus - 15 Sep 2015.pdf	UK
30	Public Health England - Underpinning evidence for the estimate that e-cigarette use is around 95pc safer than smoking.pdf	UK
31	Vaping_in_England_an_evidence_update_February_2019.pdf	UK

32	Vaping_in_England_evidence_update_March_2020.pdf	UK
33	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/962221/Vaping_in_England_evidence_update_February_2021.pdf	UK
34	4_IQOS_FDA Complete Review.pdf	USA
35	2_FDA Press Release_MRTP.PDF	USA
36	https://www.fda.gov/news-events/press-announcements/fda-issues-decisions-additional-e-cigarette-products#:~:text=The%20FDA%20authorized%20these%20tobacco,of%20exposure%20to%20harmful%20and	USA
37	ENDS ENNDS Report by WHO.PDF	WHO
38	FCTC_COP_8_10-EN - Progress report on regulatory and market developments....pdf	WHO
39	WHO HTP Fact sheet 2019.pdf	WHO
Media Articles		
1	Expert panel to explore 'harm reduction' as an alternative public health strategy for governments - Washington Times	
2	England's Vape Trends | Planet of the Vapes	
3	Providing alternatives to cigarettes the far better option (nst.com.my)	
4	China's Opportunity to Have a Significant Impact on Tobacco Harm Reduction - Vaping Post	
5	Six reasons why nicotine is not your enemy, Health News, ET HealthWorld (indiatimes.com)	
6	Do e-cigarettes help quit smoking? Let's see the evidence (indiatimes.com)	
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