

Re-evaluating the Ban on Alternatives to Conventional Smoking Tobacco Products

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Table of Contents

List of Abbreviations	1
Executive Summary	3
1. Tobacco Consumption – The World vs India	12
1.1 <i>Non-Communicable Disease Targets</i>	<i>12</i>
1.2 <i>The Global Tobacco Epidemic</i>	<i>12</i>
1.3 <i>Tobacco Users in India</i>	<i>16</i>
1.3.1 <i>The Global Adult Tobacco Survey (GATS), 2016-17, India</i>	<i>16</i>
1.3.2 <i>The National Noncommunicable Disease Monitoring survey (NNMS), 2017-18</i>	<i>18</i>
1.3.3 <i>The Global Youth Tobacco Survey (GYTS), 2019, India</i>	<i>19</i>
1.4 <i>Government Policies Aimed at Tobacco Cessation</i>	<i>19</i>
1.5 <i>Impact of High Tax on Smoking Cessation</i>	<i>21</i>
1.6 <i>Objective of the Study</i>	<i>22</i>
2. Technological Innovations in the Tobacco Industry	24
2.1 <i>Introduction</i>	<i>24</i>
2.2 <i>Differences between ENDS and Non-Combustible Cigarettes</i>	<i>25</i>
3. Regulations on Alternatives to Conventional Smoking Tobacco Products Across the World.....	28
3.1 <i>The Approach to Regulation</i>	<i>28</i>
3.3 <i>A Snapshot of E-Cigarette and HNB Classifications and Regulations Globally</i>	<i>31</i>
3.4 <i>Nuances of E-Cigarette and HNB Products Regulations</i>	<i>33</i>
3.4.1 <i>Manufacturer and Importer Disclosure Requirements.....</i>	<i>33</i>
3.4.2 <i>Product Requirements</i>	<i>33</i>
3.4.3 <i>Regulating the Use of Flavours</i>	<i>34</i>
3.4.4 <i>Regulating Nicotine Content</i>	<i>34</i>
3.4.5 <i>Other Aspects for Regulations.....</i>	<i>35</i>
3.5 <i>An Alternative Approach to Regulation</i>	<i>35</i>
4. Re-examining India’s Ban of E-Cigarettes and HNB Products	37
4.1 <i>The Indian Government’s Rational for the Ban</i>	<i>37</i>
4.2 <i>Rational for Revisiting the Ban</i>	<i>38</i>

4.2.1 Addressing the Addictive Nature of Nicotine	38
4.2.2 Addressing Safety Concerns Over Flavours in Combination with Nicotine .38	
4.2.3 Addressing the Risk of Use of Other Psychoactive Substances through These Products	39
4.2.4 Addressing the Risk of Initiating Non-Smokers into Nicotine or Psychoactive Substances	40
4.2.5 Addressing the Risks to Adolescents and Youth.....	40
4.2.6 Addressing Scant Scientific Research Available on E-Cigarettes as a Tobacco Cessation Aid	41
4.2.7 Addressing the Risks to Hindering SDG Goals and WHO NCD Goals	42
5. Next Steps for India	43
Annexure I.....	45
Annexure II	46
Annexure III.....	48
Annexure IV.....	49

List of Tables

Table 1.1: Estimated and Projected Tobacco Usage	14
Table 1.2: Tobacco Users by Region	15
Table 3.1: Overview of Approaches to the Regulation of E-Cigarettes and HNB Products (97 Countries).....	29
Table 3.2: Snapshot of E-cigarettes and HNB (Heat-Not-Burn) products among G20 countries	30
Table 3.3: Snapshot of How Countries Classify E-Cigarettes and What they Regulate	31
Table 3.4: Snapshot of How Countries Classify HNB Products and What they Regulate	31

List of Figure

Figure 1.1: Tobacco Usage Amongst People Aged 15 and Above	13
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List of Abbreviations

ADB	Asian Development Bank
BAU	Business-As-Usual
BIS	Bureau of Indian Standards
COPD	Chronic Obstructive Pulmonary Disease
CCs	Conventional Cigarettes
COTP	Cigarettes and Other Tobacco Products
COTPA	Cigarettes and Other Tobacco Products Act
CDP	Crop Diversification Programme
EC	Electronic Cigarettes
EU	European Union
ENDS	Electronic Nicotine Delivery Devices
FSSA	Food Safety and Standards Regulations
FCTC	Framework Convention on Tobacco Control
FD&C	Food, Drug, and Cosmetic
GAP	Global Action Plan
GATS	Global Adult Tobacco Survey
GYTS	Global Youth Tobacco Survey
GST	Goods & Service Tax
GDP	Gross Domestic Product
HNB	Heat Not Burn
HPHCs	Harmful and Potentially Harmful Constituents
HTPs	Heated Tobacco Products
ICMR	Indian Council of Medical Research
INR	Indian Rupee
mCCs	Menthol Cigarettes
ml	Millilitres
MoH&FW	Ministry of Health & Family Welfare
MRTP	Modified Risk Tobacco Product
mTHS	Menthol Tobacco Heating System
NCCD	National Calamity Contingent Duty
NHS	National Health Service
NNMS	National Noncommunicable Disease Monitoring survey
NTCP	National Tobacco Control Programme
NRT	Nicotine Replacement Therapy
NCDs	Non-Communicable Diseases
OTT	Over-The-Top
PHE	Public Health England
PIB	Press Information Bureau

PMCID	PubMed Central Identifier
PMID	PubMed Identifier
PMTA	Premarket Tobacco Application
RCT	Randomised Controlled Trial
RKVY	Rashtriya KrishiVikasYojna
RTA	Rebuildable Tank Atomiser
RACGP	Royal Australian College of General Practitioners
SDG	Sustainable Development Goal
SA	Smoking Abstinence
ToFEI	Tobacco Free Educational Institutions
TPSAC	Tobacco Product Scientific Advisory Committee
TVPA	Tobacco and Vaping Products Act
UK	United Kingdom
US FDA	United States Food and Drug Administration
USA	United States of America
USFDA	United States Food and Drug Administration
USD	United States Dollar
WHO	World Health Organisation
WNTD	World No Tobacco Day

Executive Summary

Executive Summary

Tobacco Consumption – The World vs India

The World Health Organisation (WHO), through its Global Action Plan (GAP), has set a target of reducing premature mortality from non-communicable diseases (NCDs) by 25 per cent by 2025 in relation to 2010 figures, and a further reduction by one third by 2030. Of the several risks associated with NCDs, it is tobacco related deaths, including those related to second hand smoking that results in the most deaths annually, over eight million of the total of 41 million deaths a year. It has become an important agenda for WHO and every country to monitor the risks associated with NCDs, their causes, and ways to mitigate these risks.

Global trends in tobacco consumption suggest that in 2000 almost 33 per cent of the global population (49 per cent males and 16 per cent females) were tobacco consumers. This has expected to reduce to 20 per cent (34 per cent males and 6.6 per cent females) by 2025. Based on estimates computed by WHO the targets for females will be met by 2025, while that for males may take a few more years.

India's data on tobacco consumption for both adults and youth is drawn from the Global Adult Tobacco Survey (GATS), 2016-17 and the Global Youth Tobacco Survey (GYTS), 2014. The most notable achievement for India has been a reduction in the prevalence of smoking from 34.6 per cent to 28.6 per cent. These results were attributed to some strict tobacco control measures that were enacted by the government during this period.

The GATS-1 survey was held in 2009-10. One of the biggest findings on the GATS-1 survey was the extent of use of smokeless tobacco and its prevalence across the country. This inspired the ban on gutka. The GATS-2 survey was conducted seven years after the first. The survey put total number of tobacco users at 28.6 per cent with a split of 21.3 per cent in urban centres and 32.5 per cent in rural India. It also suggested that the total percentage of people who had stopped smoking (former daily user and formed occasional user) was around 3 per cent only.

The total percentage of people using smoked tobacco, in India, is 10.7 per cent, a little shy of 100 million. Cigarette and bidi seem to be the most preferred form on smoked products at 8.2 per cent and 14 per cent respectively.

GATS-2 was the first survey to collect some data on the knowledge and usage of e-cigarettes. The survey recorded that only 3.03 per cent were aware of e-cigarettes of

which a negligible 0.66 per cent were users among those aware a negligible 0.02 per cent of total adults. In terms of age, while the younger population, not surprisingly were more aware of e-cigarettes, 3.95 per cent of those between 15 and 24 years and 3.39 per cent of those between 25-44 years, the corresponding usage of those who were aware was still negligible at 0.54 per cent and 0.71 per cent for the respective age groups. The usage was also more of an urban phenomenon, particularly amongst the more educated.

Objective of the Study

India banned e-cigarettes and HNB products in 2019. The decision to do so was based on a paper released by the Indian Council of Medical Research (ICMR) in May 2019. Since this paper and the subsequent ban enacted by the Indian government, there have been many developments in both technologies of these products and how they have been regulated by many countries.

The ban on e-cigarettes, HNB products, ENDS, and vaping devices (all collectively referred to as e-cigarettes in India) was placed with the objective to not make it accessible to young adults and because it was assumed that it may in fact increase the prevalence of smokers in the country. However, newer studies have been released that indicate that alternative to conventional smoking tobacco products can play a significant role in tobacco cessation.

The objective of this paper is to examine the rationale for the ban and also examine more recent and evolving literature to see if India needs to re-evaluate the ban on alternative to conventional smoking tobacco products, especially since countries have today acknowledged the importance of these products in smoking cessation. The study relies on secondary data and literature and attempts to bring to fore more recent literatures and regulations that have found such products to help in harm reduction.

Technological Innovations in the Tobacco Industry

Over the years, the tobacco industry has technologically evolved. Smoking tobacco can be categorised into two types - conventional smoking tobacco products and the alternatives to conventional smoking tobacco products. The alternatives to conventional smoking tobacco products can be further classified, of which, two main categories are the Electronic Nicotine Delivery Devices (ENDS) and non-combustible cigarettes.

Electronic Nicotine Delivery Devices (ENDS), also known as vapes or e-Cigarette, are battery-operated devices designed to simulate the experience of smoking. These devices heat a liquid, typically, containing nicotine propylene glycol, vegetable glycerine, and flavourings, into an aerosol or vapour that is inhaled by the user. E-cigarettes typically consist of a battery, heating element, liquid cartridge, and mouthpiece. This process is based on the principles of aerosol science and thermodynamics. The devices may vary in size, shape, and features. The design of e-cigarettes aims to optimise aerosol production and nicotine delivery.

The United States Food and Drug Administration (US FDA) allows for the sale of two types of non-combustible cigarette. The first kind consists of a heating source and tobacco where, the tobacco may be wrapped in paper, which makes it a type of cigarette. This product uses a carbon tip wrapped in glass fibres. The user lights the carbon tip, which heats the dried tobacco inside to a temperature that does not cause the product to create ash or burn down in size. Since the tobacco is heated to a lower temperature than a combusted cigarette to create an aerosol that the user inhales. The second kind is a model that has been authorised in April 2019 that consists of an electronic heating device and sticks made from dried tobacco wrapped in paper. The user places the stick into the electronic heating device, which pierces the stick with a glass-covered ceramic blade that heats the tobacco, creating an aerosol. In USA, heat-not-burn (HNB) products are also classified under non-combustible cigarettes.

The Difference Between ENDS and Non-Combustible Cigarettes

The fundamental difference between ENDS and non-combustible cigarettes is the primary element to be consumed. While all the products utilise a heating mechanism, ENDS primarily rely on a nicotine-based solution (liquid) that is vaporised and inhaled by the user. On the other hand, non-combustible cigarettes involve the heating of real tobacco, which is then inhaled as a tobacco aerosol. This distinction in the key ingredient sets them apart in terms of their composition and experience for the user.

The National Health Service (NHS) of United Kingdom (UK) too has advocated the use of e-Cigarette as an aid to quit smoking while managing nicotine craving for existing smokers. This said, NHS has recommended that e-Cigarettes should not be recommended to non-smokers and cannot be sold to people under 18 years old.

Lüdicke et al (2017) reported a reduction in the levels of harmful and potentially harmful constituents in the aerosol produced by heated tobacco products compared to mainstream cigarette smoke. Additionally, the study noted that the amount of

tobacco used in heated tobacco products was typically lower than in combustible cigarettes.

Even the US FDA is of the opinion that although there is no completely safe tobacco product but non-combusted cigarettes may help reduce the risk of tobacco-related harms for adult smokers who have switched completely from combusted cigarettes.

For the purpose of this study, we would consider two different types of alternatives to conventional smoking tobacco products which will be referred to as e-cigarettes (ENDS) and non-combustible cigarettes, referred to as HNB products in this paper.

Regulations on Alternatives to Conventional Smoking Tobacco Products Across the World

E-Cigarettes and HNBs can be regulated based on how these products are classified. Different countries have taken different approaches to the regulation of e-cigarettes. These range from regulating them as tobacco products, or as medicinal products, to complete prohibition. As many as 75 countries have created a new classification for e-cigarettes and have created separate regulations for them. Of these, there are 24 countries that have classified e-cigarettes as consumer products and regulate them as such. Many countries, as many as 62 (with some overlaps with other categories), regulate e-cigarettes similar to tobacco products. These could be either certain aspects of regulation of e-cigarettes such as its sale and distribution, or it could be that these products as classified as tobacco products and regulated the same way other tobacco products are regulated. With regard to G20 countries' approach to regulations, the majority of the countries have chosen to regulate these products rather than ban them, with the exception of India, Saudi Arabia, Argentina and Brazil.

Nuances of E-Cigarette and HNB Products Regulations

Certain countries that have included more nuanced regulations, recognising some distinction between e-cigarettes and traditional tobacco products.

- *Manufacturer and Importer Disclosure Requirements* - In most countries where e-cigarettes are regulated at par with tobacco, similar disclosures are required to be made about the products. Manufacturers are required to annually file details with respect to contents of their products, their emissions, share any data that suggests addictive behaviour, sales data and so on. In many of these countries, manufacturers are also required to place before the regulating authority as early as six months prior to it being realised in the market for approvals.

- *Product Requirements* - These are nuanced regulations particularly applicable to e-cigarettes. These rules and regulations pertain to criteria of the device. For instance, in Canada there are regulations that mandate child locks for the devices. In Armenia, apart from placing similar requirements of providing child resistant devices, there is also a requirement for refill containers to exceed 10 millilitres (ml) and that the unit of cartridge cannot exceed 2ml. Different countries have detailed regulations along these lines on the devices themselves. Broadly these regulations are consistent across jurisdictions. This indicates a broad consensus atleast across these countries on what kind of device is considered permissible.
- *Regulating the Use of Flavours* - Added flavours to the tobacco has been viewed as a way to enhance its marketability particularly among young adults. Countries such as China and Finland have banned the use of any flavour with tobacco. The Canadian Tobacco and Vaping Products Act (TVPA) empowers the Government to allow or ban flavours, issueing a ban of flavours that are considered to be enticing to young people.
- *Regulating Nicotine Content* - While some alternatives to smoked tobacco products can be regulated under existing laws, new products that have emerged have also managed to bypass the use of tobacco and use only nicotine. Most countries are yet to create a nicotine policy. Hence concentration of nicotine delivery has been left unregulated in many markets. However, many countries that have examined e-cigarettes in detail and have understood the need for separate legislation outside of just the existing tobacco policy, and have imposed limits on nicotine concentration, typically 20 mg/ml. Some countries have higher limits, but common practice seems to be 20 mg/ml.
- *Other Aspects for Regulations* - Regulations and rules pertaining to advertisement, trade and commerce, production, supply and distribution (such as age restriction, geographic location for sales etc.) of alternatives to conventional smoking tobacco products must be in line with existing tobacco regulations.

An Alternative Approach to Regulation

The US has an alternative approach to regulating tobacco products for harm reduction. A Modified Risk Tobacco Product (MRTP) is a tobacco product that has been modified to reduce the harm it causes to the user. MRTPs are regulated by the USFDA, and they must meet certain requirements to be marketed as an MRTP product. An MRTP application must demonstrate that the product will or is expected to benefit the health of the population as a whole. If the FDA approves the product, it will be allowed to be marketed as a Modified Risk Tobacco Product. MRTPs can have

a positive impact by providing smokers with a safer alternative to conventional smoking tobacco products. India could consider such a regulatory approach rather than banning alternatives to conventional smoking tobacco products. This approach can be extended to all kinds of tobacco products.

The Indian Government's Rational for the Ban

In 2019 the Indian government, through the promulgation of the Prohibition of Electronic Cigarettes (production, manufacture, import, export, transport, sale, distributions, storage and advertisement) Ordinance (and then subsequently through an Act), 2019, imposed a ban on all e-cigarettes. The government lists three expected outcomes of the ban – ensuring that these products never take off in the Indian market, especially among the youth, help advance tobacco control efforts of the government for better public health, and contribute to the overall reduction in tobacco consumption and its associated health burden. They further state that the ban has been implemented on the basis of a white paper developed by the Indian Council of Medical Research (ICMR) that had also recommended a complete ban on e-cigarettes.

Rational for Revisiting the Ban

Since the ban was implemented, the market for e-cigarettes and HNB products globally have changed. Products have evolved, many countries have chosen to regulate products rather than ban them, new research has been placed on record, and some studies even suggest that e-cigarettes and HNB products do in fact contribute to smoking cessation. Notwithstanding these developments, the concerns raised by the government are justified, but must also be contextualised in light of new developments and data. For this purpose, each concern of the seven concerns raised by the government (detailed in the PIB release) must be re-examined based on more recent developments, regulatory frameworks across the globe, and data.

- i. *Addressing the Addictive Nature of Nicotine* - A sound nicotine policy and regulations around limiting nicotine delivery are common in other countries. As discussed before, the commonly accepted levels of disbursement or nicotine is 20 mg/ml. India can choose to go with this commonly accepted norm, or can set up a technical scientific committee that can examine these numbers and adapt them to Indian consumption patterns. A sound nicotine-based policy and regulation can easily mitigate this risk.
- ii. *Addressing Safety Concerns Over Flavours in Combination with Nicotine* - Many countries that have put in place a regulatory framework for e-cigarettes and HNB products have dealt with this risk in two broad ways. The government

can issue directives for specific bans on either select or all kinds of flavours through the nodal ministry, in the case of India, the Ministry of Health and Family Welfare.

- iii. *Addressing the Risk of Use of Other Psychoactive Substances through These Products* - Regulations around the manufacturing of the devices are prevalent in many jurisdictions. These include mandates on single use and non-refillable vials, tamper proof sealing, child proof sealing, and so on. In the context of e-cigarettes and HNB products, open tanks and closed tanks refer to two different types of systems used for delivering e-liquid or tobacco. An open tank system allows users to manually refill the tank with e-liquid or insert a pre-filled cartridge. On the other hand, a closed tank system consists of pre-filled cartridges or pods that are not designed to be manually refilled. A technical committee can set the standards for such products in terms of their manufacturing design to help mitigate any of the aforementioned concerns of the government. There are global benchmarks available that can be examined by India. If India does reconsider the ban, then it must be only for closed tank and not for open tanks. This way, the risk of other use can be mitigated.
- iv. *Addressing the Risk of Initiating Non-Smokers into Nicotine or Psychoactive Substances* - There are typically two types of products that are available globally. The first is a use and throw single use device (which are typically the ones that have entered the Indian market illegally) or disposable devices and the other is non-disposable products. The average cost of non-disposable device, when it was allowed to be sold in India, cost around INR 5,000. This is only the cost of the device and does not include the cost of the sticks or e-liquids. If flavours are banned or restricted, then a non-smoker is less likely to spend INR 5,000 for their initiation into smoking tobacco (or any other psychoactive substances), when they could access conventional tobacco products at significantly cheaper rates. The true threat is from disposable devices, which have been flooding the Indian market. These products are priced attractively and cost usually the same as conventional smoking tobacco products. The threat of initiation into using these products can be mitigated by bans on disposable devices and on the sale of any kind of flavoured tobacco. If the market for disposable device is dealt with successfully, then the cost of the non-disposable device itself would act as a natural deterrent to any initiation of non-smoker.
- v. *Addressing the Risks to Adolescents and Youth* - The cost of these products, along with any ban on flavours, acts as a strong deterrent to adolescents and youth accessing these products. However, the influx of many illegal use-and-throw products do pose a considerable risk, since these are typically priced at rates that are similar or lower to conventional cigarettes. Hence, any sale of use and

throw products should continue to be banned in order to ensure that these products are not available at “pocket friendly” prices.

- vi. *Addressing Scant Scientific Research Available on E-Cigarettes as a Tobacco Cessation Aid* - The ICMR paper (May 2019) relied mostly on literature from that period, during which time, studies documenting medium-term and long-term use of alternative non-combustible devices were few. However, five years hence, more literature is now available. Even the USFDA which at the time of the ICMR study had grave concerns over the products, have since augmented their position, primarily due to the emergence of new Randomised Controlled Trial (RCT) studies and evolution of technology. Today, there is new literature that has emerged which also must be considered. Hartman-Boyce et al (2021) conducted a review of multiple studies in the area, including RCTs, covering over 12,804 participants. The study was able to conclude that there was moderate-certainty evidence, to suggest that those using any form of e-cigarettes or HNB products were more likely to quit smoking compared to traditional nicotine replacement therapies that are used. The study also suggests that even usual use of these products leads to benefits in comparison to usage of traditional nicotine and tobacco products.
- vii. *Addressing the Risks to Hindering SDG Goals and WHO NCD Goals* - Based on the GATS-2 results and the GYTS-4 results, India is already on the path to meet the SDG goals that has been committed to. Having said that, India is different from the rest of the world in that, the consumption of smokeless tobacco and the risks posed by these products are still prevalent. It seems ill conceived to think that the risks of e-cigarettes, which as per the GATS-2 survey is used by a negligible amount of people would pose a greater risk to India’s SDG goals, than the presence of conventional smoked products and smokeless tobacco. The larger risk to meeting these targets would be from rural India and from certain sections of urban India that continue to use conventional tobacco products and smokeless tobacco.

Next Steps for India

India has been strongly advocating for a tobacco free India and over the years has put in place various policies that have been focussed on better public health and tobacco harm reduction. However, with 100 million smokers, India cannot become completely smoke free overnight. As a first step, India should also focus on providing more responsible alternatives for those citizens who already consume traditional tobacco. The following recommendations are suggested for consideration.

- India must conduct her own studies to this end in order to understand both medical and behavioural changes and impact of the use of alternatives to smoked tobacco products.
- India must simultaneously examine emerging literature and international experience so that the ban on alternatives to conventional smoking tobacco can be re-evaluated.
- India must also set up a scientific committee that can look at the device and its technology, and also set standards for manufacturing of these products.
 - Part of the terms of reference for this committee must be to understand the different types of products that are available, such as e-cigarettes versus HNB products versus single use products, or open tank versus closed tank technology, to name a few.
 - This scientific committee must also have product manufacturers as members. This way the committee will be able to seek details of existing products and their technical specifications present in other countries from the industry members.
- The Government may also consider delegating the development of standards and their regulations to the Bureau of Indian Standards (BIS).
- Another policy framing committee must also be set up that includes industry members and other stakeholders such the academia, health experts, doctors, and civil society that can study emerging literature on alternatives to conventional smoking products and their implications for India.
 - This committee can also examine the merits of the MRTP approach for India and how it can be integrated with COTPA.
- India must consider creating a regulatory framework for nicotine, e-cigarettes, and HNB products.
 - Part of such a regulatory framework must mandate age verification for sale of these products, similar to current requirements under tobacco regulations.
 - The framework should also mandate sale and distribution of such products through only licensed retail shops.
 - The policy framework should consider bans on certain kind of flavours (or all kinds of flavours) and how to enforce bans on use and throw products.

In conclusion, India must reconsider the ban imposed in light of fresh literature, and base any decision on studies that are conducted in India of Indian citizens. Furthermore, it is suggested that their products be regulated like any other tobacco products, which seems to be the most common approach to regulation internationally.

Chapter 1

Tobacco Consumption - The World vs India

1. Tobacco Consumption – The World vs India

1.1 Non-Communicable Disease Targets

The World Health Organisation (WHO), through its Global Action Plan (GAP), has set a target of reducing premature mortality from non-communicable diseases (NCDs) by 25 per cent by 2025 in relation to 2010 figures, and a further reduction by one third by 2030.¹ The social economic benefits of reducing NCD related deaths and diseases is closely tied to Sustainable Development Goals (SDGs). It is also closely associated with poverty since medical costs associated with treatments of NCDs can push people into poverty and those already in poverty further into a vicious circle.

Of the several risks associated with NCDs, those of modifiable behavioural risks have taken centre stage. These risks relate mostly lifestyle disease, which includes tobacco use, alcohol use, physical inactivity, unhealthy eating habits, to name a few. Of these different kinds of lifestyle led disease and death, around eight lakh deaths are on account of physical inactivity, while abuse of alcohol results in nearly three million deaths annually. However, it is tobacco related deaths, including those related to second hand smoking that results in the most deaths annually, over eight million² of the total of 41 million deaths a year.

It has become an important agenda for WHO and every country to monitor the risks associated with NCDs, their causes, and ways to mitigate these risks through behaviour modifications, constant monitoring, education, and providing economically viable alternatives for citizens.

1.2 The Global Tobacco Epidemic

Every one in six deaths due to NCDs are attributed to tobacco use. In order to meet the targets, set by WHO, tobacco control has been identified as a crucial necessity.³ SDG number 3.1 specifies, “strengthen the implementation of the WHO Framework

¹ WHO Fact Sheets – Noncommunicable diseases, 2023, accessed on <https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases#:~:text=Key%20facts,%2D%20and%20middle%2Dincome%20countries>. Accessed 12/02/2024, 15.30 IST

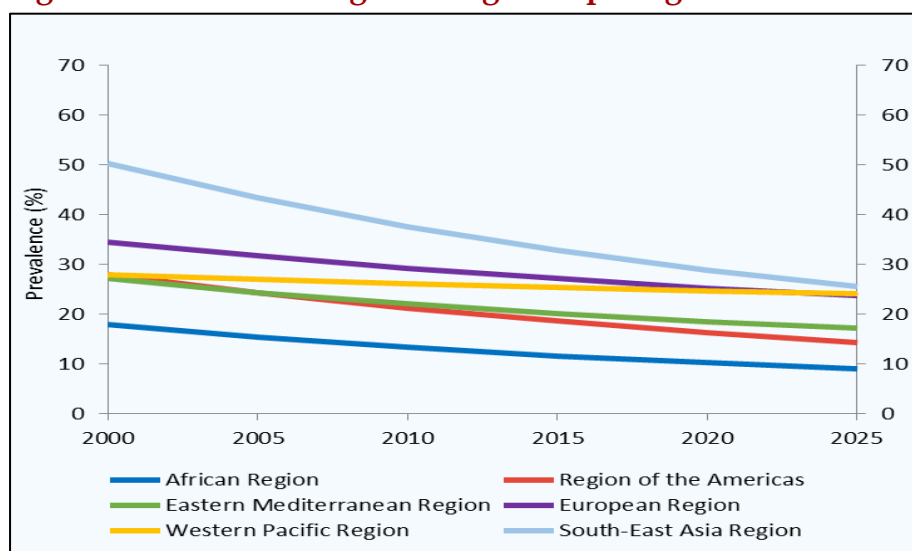
² WHO Fact Sheets – Noncommunicable diseases, 2023 (Global Burden of Disease Study 2019), accessed on <https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases#:~:text=Key%20facts,%2D%20and%20middle%2Dincome%20countries>, Accessed 12/02/2024, 15.30 IST

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223261/>, Accessed 12/02/2024, 15.30 IST

Convention on Tobacco Control (FCTC)” and suggests monitoring age-standardised consumption of tobacco of those fifteen year and above as a parameter of measure.⁴ Global trends in tobacco consumption suggest that in 2000 almost 33 per cent of the global population (49 per cent males and 16 per cent females) were tobacco consumers. This has expected to reduce to 20 per cent (34 per cent males and 6.6 per cent females) by 2025. As of 2020, this currently stands at 22 per cent (37 per cent males and 8 per cent females). In terms of the targets laid out by Global Action Plan (WHO GAP), the total tobacco user population percentage should reduce to 19 per cent, 30 per cent for males and 7.8 per cent for females. Based on estimates computed by WHO the targets for females will be met by 2025, while that for males may take a few more years beyond 2025 to make up for the projected shortfall of 5 per cent.⁵

Even in terms of region wise achievement of targets, South and East Asia along with African region and the Americas are well on their way to meet the 2030 targets by 2025 (Table 1.1). In terms of regions, tobacco usage is highest in the South and East Asia region followed by the Americas. The lowest prevalence is in the African region (Figure 1.1). Even though in terms of percentages, many regions of the world are doing well to meet their targets, in terms if absolute numbers, mostly due to growing populations, the number of tobacco users is actually expected to be higher in 2025 than 2000 for a few regions (Table 1.2).⁶

Figure 1.1: Tobacco Usage Amongst People Aged 15 and Above



Source: WHO Report on Global Tobacco Epidemic, 2021

⁴ WHO Report on The Global Tobacco Epidemic, 2021

<https://iris.who.int/bitstream/handle/10665/344222/9789240032842-eng.pdf?sequence=1> , Accessed 12/02/2024, 15.30 IST

⁵ <https://iris.who.int/bitstream/handle/10665/348537/9789240039322-eng.pdf?sequence=1> (pg 20, WHO global report on trends in prevalence of tobacco use 2000–2025, 4th Edition), Accessed 12/02/2024, 15.30 IST

⁶ <https://iris.who.int/bitstream/handle/10665/348537/9789240039322-eng.pdf?sequence=1> , Accessed 12/02/2024, 15.30 IST

Table 1.1: Estimated and Projected Tobacco Usage

WHO region	Estimated prevalence (%)					Projected prevalence (%)	30% reduction target (%)	Gap ^a	Expected relative reduction under BAU ^b
	2000	2005	2010	2015	2020				
Both sexes									
Global	32.7	29.5	26.7	24.4	22.3	20.4	18.7	-1.7	23.6
African	17.9	15.4	13.4	11.7	10.3	9.1	9.3	0.2	31.7
Americas	28.0	24.4	21.3	18.6	16.3	14.3	14.9	0.6	32.7
South-East Asia	50.4	43.4	37.6	32.9	29.0	25.7	26.3	0.6	31.7
European	34.6	31.7	29.3	27.2	25.3	23.7	20.5	-3.2	18.9
Eastern Mediterranean	27.2	24.4	22.1	20.2	18.6	17.3	15.5	-1.8	21.7
Western Pacific	27.9	27.0	26.1	25.3	24.6	24.1	18.2	-5.9	7.5
Males									
Global	49.3	45.7	42.3	39.5	36.7	34.3	29.6	-4.6	19.0
African	28.7	25.2	22.3	19.9	17.8	16.0	15.6	-0.4	28.2
Americas	35.5	31.1	27.4	24.1	21.3	18.9	19.2	0.3	31.2
South-East Asia	68.2	61.5	55.8	51.1	46.6	42.7	39.1	-3.7	23.4
European	46.5	42.4	38.9	35.8	32.9	30.4	27.2	-3.2	21.7
Eastern Mediterranean	44.1	40.7	37.7	35.3	33.0	31.1	26.4	-4.7	17.4
Western Pacific	50.8	49.8	48.4	47.5	46.4	45.7	33.9	-11.8	5.6
Females									
Global	16.2	13.4	11.1	9.3	7.8	6.6	7.8	1.2	40.8
African	7.1	5.6	4.4	3.5	2.8	2.2	3.1	0.9	49.7
Americas	20.6	17.6	15.2	13.2	11.3	9.8	10.7	0.8	35.5
South-East Asia	32.5	25.2	19.3	14.7	11.3	8.6	13.5	4.9	55.5
European	22.6	21.0	19.7	18.6	17.7	17.0	13.8	-3.3	13.5
Eastern Mediterranean	10.2	8.1	6.4	5.2	4.2	3.4	4.5	1.1	46.8
Western Pacific	5.0	4.3	3.7	3.2	2.8	2.5	2.6	0.1	32.9

^a The target gap is calculated as 2025 target – 2025 projected prevalence. The values are affected by rounding.

^b Business-As-Usual (BAU) means countries continuing to implement policies at the same rate they have in the past.

Source: WHO Report on Global Tobacco Epidemic, 2021

Table 1.2: Tobacco Users by Region

WHO region	Estimated number of tobacco users (millions)					Projected (millions)
	2000	2005	2010	2015	2020	2025
Both sexes						
Global ^a	1367	1358	1341	1323	1298	1270
African	59	58	58	59	61	62
Americas	165	156	148	138	128	118
South-East Asia	479	467	454	444	432	418
European	230	218	205	192	180	168
Eastern Mediterranean	73	78	83	88	92	96
Western Pacific	360	381	393	402	406	408
Males						
Global ^a	1032	1051	1061	1069	1067	1062
African	47	48	49	51	53	55
Americas	103	98	93	88	82	76
South-East Asia	339	343	347	350	351	350
European	153	144	135	126	117	108
Eastern Mediterranean	61	66	72	78	82	87
Western Pacific	329	352	365	376	382	386
Females						
Global ^a	335	307	280	254	231	208
African	11	10	9	9	8	7
Americas	62	58	54	50	46	41
South-East Asia	141	124	108	93	81	69
European	77	74	70	67	63	60
Eastern Mediterranean	13	12	11	10	9	9
Western Pacific	31	29	28	26	24	22

^a Sum of regional totals. Differences are due to rounding.

Source: WHO Report on Global Tobacco Epidemic-2021

The world still has a long way to go in terms of meeting the target for reduced tobacco usage set out by WHO GAP. In most countries, mitigation measures have been targeted more at smoking tobacco than non-smoking tobacco. There were a close to billion smokers in the world in 2015, in contrast to nearly 350 million smokeless tobacco users. Of these, 350 million smokeless tobacco users, nearly 90 per cent are present in 11 countries, with India having 237 million smokeless tobacco users.⁷

⁷ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9308447/> , Accessed 12/02/2024, 15.35 IST

1.3 Tobacco Users in India

India's data on tobacco consumption for both adults and youth is drawn from the Global Adult Tobacco Survey (GATS), 2016-17 and the Global Youth Tobacco Survey (GYTS), 2014. The other survey that provides some broad numbers for tobacco usage is the National Noncommunicable Disease Monitoring Survey (NNMS), 2017-18.

1.3.1 The Global Adult Tobacco Survey (GATS), 2016-17, India

India became a signatory to WHO's FCTC Framework in 2004. As part of this framework, a survey was conducted to monitor tobacco use and other tobacco control measures. The first GATS study, or GATS-1 was undertaken in 2009-10 and the second round, or GATS-2, was undertaken in 2016-17.

The most notable achievement for India has been a reduction in the prevalence of smoking from 34.6 per cent to 28.6 per cent. Similarly, the number of households that allowed for smoking also reduced significantly from 60.4 per cent to 48.8 per cent. These results were attributed to some strict tobacco control measures that were enacted by the government during this period, such as, anti-tobacco consumption messaging in the media, the complete ban on manufacturing and sale of gutka, a hike in taxes on tobacco products, and the increase of health warning on tobacco packages increasing to 85 per cent of the package.

These are all credible achievements in light of the fact that India has the second largest number of tobacco consumers in the world, second only to China. India is also one of the largest tobacco manufacturers in India, even though the government has been doing their best to implement crop diversification in areas that predominantly grow tobacco. Furthermore, the economic costs⁸ arising due to tobacco use in 2017-18 for people above the age of 35 is around USD 27.5 billion.⁹ For the world, it is nearly USD 1.4 trillion spent on healthcare costs, resulting in 1.8 per cent of world gross domestic product (GDP) in loss of productivity.¹⁰

India presents a unique challenge because India has one of the largest smokeless tobacco consumptions. This is despite the ban on gutka and a crackdown on any kind

⁸ *The economic costs of tobacco use typically include direct medical cost including the cost of treating tobacco-related diseases, such as cancer, heart disease, and stroke and cost spent of smoking cessation. It also includes the cost of lost productivity due to premature death and disability due to tobacco use. To understand the economic costs of tobacco better refer to https://www.who.int/docs/default-source/searo/india/tobacco/economic-burden-of-tobacco-related-diseases-in-india-executive-summary.pdf?sforsn=ac0db06_2, Accessed 12/02/2024, 15.35 IST*

⁹ <https://www.who.int/india/health-topics/tobacco>, Accessed 12/02/2024, 15.35 IST

¹⁰ GATS-2 Survey

of advertisement or promotion. The extent of impact of smokeless tobacco is corroborated by the fact that the incidence of oral cancer, almost half of the total global numbers, is higher than that of lung cancer in India. Even though there is a ban in place, anecdotal evidence suggests that the consumption of smokeless tobacco product such as gutkha is still prevalent in India.

The GATS-1 survey was held in 2009-10 and based on those results, policy prescriptions were prescribed in terms of tobacco control. One of the biggest findings on the GATS-1 survey was the extent of use of smokeless tobacco and its prevalence across the country. This inspired the ban on gutkha and while even the tax incidence was hiked marginally on smokeless tobacco prices, it did not have a significant impact on prices.

The GATS-2 survey was conducted seven years after the first and had the opportunity to measure some of the tobacco control measures that the government had introduced in the past. The survey put total number of tobacco users at 28.6 per cent with a split of 21.3 per cent in urban centres and 32.5 per cent in rural India. It also suggested that the total percentage of people who had stopped smoking (former daily user and former occasional user) was around 3 per cent only.

In urban India, the survey recorded 5.9 per cent as only smoker as opposed to 7.9 per cent in rural India. Similarly, the users of smokeless tobacco were higher in rural India at 20.6 per cent versus 12.9 per cent in urban India. In both areas, those using both forms of tobacco were relatively small at 2.3 per cent and 4 per cent in urban and rural India. This is particularly interesting since it suggests that prevalence of smoking, especially smokeless tobacco, is more pronounced in rural India.

Unlike international experience, the highest smoking incidence was recorded for those above 65 years, indicating a lack of any cessation intention during that period. This is further validated by the fact that the next highest age group is between 45 and 64 years. Even more interestingly, for the age group of 15-24, the percentage using smokeless tobacco (at 9.1 per cent) is significantly higher than those smoking tobacco (1.6 per cent).

The total percentage of people using smoked tobacco products in India is 10.7 per cent, a little shy of 100 million. Cigarette and bidi seem to be the most preferred form on smoked products at 8.2 per cent and 14 per cent respectively. The difference is due to the increased prevalence of smoking bidis in rural India at 9.3 per cent. In contrast, the percentage of people using smokeless tobacco is 21.4 per cent, which in terms of sheer numbers is around 200 million, almost twice the number of users of smoked tobacco

products in terms of number. Rural India prefers smokeless tobacco and of these, it is khaini consumption that stands highest in rural India at 13.5 per cent in contrast to 6.8 per cent in urban India. Despite the ban on gutka, there were still a total of 11.2 per cent and 2.8 per cent users of gutka consumption, for urban and rural India combined.

GATS-2 was the first survey to collect some data on the knowledge and usage of e-cigarettes. The survey recorded that only 3.03 per cent were aware of e-cigarettes of which a negligible 0.66 per cent were users among those aware a negligible 0.02 per cent of total adults. In terms of age, while the younger population, not surprisingly were more aware of e-cigarettes, 3.95 per cent of those between 15 and 24 years and 3.39 per cent of those between 25-44 years, the corresponding usage of those who were aware was still negligible at 0.54 per cent and 0.71 per cent for the respective age groups. The usage was also more of an urban phenomenon, particularly amongst the more educated.

In light of the data on e-cigarettes, especially when compared to the numbers of users of smoked and smokeless tobacco, the policy initiative to ban on e-cigarettes, vaping products, and heat not burn (HNB) product, seems premature based on the data provided by the survey.

1.3.2 The National Noncommunicable Disease Monitoring survey (NNMS), 2017-18

The NNMS survey is conducted to monitor the parameters identified to track India's commitment to the WHO NCD Framework targets. The survey has been conducted one year after the GATS-2 survey. One of the parameters that this survey tracks in tobacco usage by adults and young adults.

As per the NNMS survey, the total number of tobacco users, both smoked and smokeless, was 32.8 per cent. Those using smoked tobacco was 9.7 per cent, of which, bidi smokers were highest at 7.4 per cent, while cigarette smokers were only 2.5 per cent. In terms of smokeless tobacco, the total percentage of the used was 21 per cent and only a mere 2.7 per cent used both smoked and smokeless.

More specifically with regard to young adults of the age group between 15 and 17 years, the total percentage of tobacco users was 7 per cent. The mean age for tobacco consumption initiation is 14.2 years, 15.1 years in urban India and 13.9 years in rural India. These figures also include those you have experimented with tobacco usage. With regard to daily use of tobacco of young adults, only 0.3 per cent were daily tobacco smokers, while 2.9 per cent used smokeless tobacco daily.

This survey suggests that tobacco usage instances are low among young adults, and of those using, the instances of usage of smokeless tobacco is higher than that of smoked tobacco.

1.3.3 The Global Youth Tobacco Survey (GYTS), 2019, India

The GYTS is similar to GATS, but the former concentrates on ages 13 to 15 years to monitor tobacco usage. There have so far been four rounds of the survey, with the latest round conducted in 2019. The earlier rounds were conducted in 2003, 2006, and 2009.

The surveys indicate a clear reduction in the number of tobacco users, from 16.9 per cent in 2003 to 8.5 per cent in 2019.¹¹ Between 2006 and 2009 there was an increase in percentage of tobacco users (from 13.7 per cent to 14.6 per cent), and across other parameters. The total number of tobacco smokers¹² in 2019 was 7.3 per cent (5896 respondents) and those using smokeless tobacco was 4.1 per cent (3311 respondents). Cigarette smokers equalled 2.6 per cent (2100 respondents) while the percentage smoking bidis was 2.1 per cent (1699 respondents).

The survey also states that the total percentage of youth who have ever smoked cigarettes or bidis is 8.7 per cent (7027 respondents). This figure is likely to be arguably higher if the total numbers for smoking tobacco as defined in the survey is considered. In contrast, the total percentage of youth who have ever used e-cigarette is only 2.8 per cent (2261 respondents). Irrespective of whether cigarette use, bidi use, or use of smokeless tobacco, the major source of procurement have been through stores and paan shops, despite well over 50 per cent admitting to being denied purchase due to being underage.

1.4 Government Policies Aimed at Tobacco Cessation

India became a Party to the WHO Framework Convention on Tobacco Control (FCTC) on February 27, 2005. “The WHO FCTC is an evidence-based treaty that reaffirms the right of all people to the highest standard of health. The WHO FCTC represents a paradigm shift in developing a regulatory strategy to address addictive substances; in contrast to previous drug control treaties, the WHO FCTC asserts the importance of demand reduction strategies as well as supply issues. The WHO FCTC was developed in response to the globalization of the tobacco epidemic. The spread of the tobacco epidemic is facilitated through a variety of complex factors with cross-border effects, including trade liberalization and direct foreign investment. Other factors such as

¹¹ The total number of students participating in the survey was 97302, of which, 80772 students aged 13-15 years were considered for reporting.

¹² The total number of tobacco users include all form of smoking tobacco such as cigarette, bidi, hookah, cigars, cheroots, cigarillos, water pipe, chillum, chutta, and dhumti

global marketing, transnational tobacco advertising, promotion and sponsorship, and the international movement of contraband and counterfeit cigarettes have also contributed to the explosive increase in tobacco use.”¹³

On signing the WHO FCTC, the Government of India started tightening regulations to rein in the usage of tobacco in the country and introduced several measures to reduce the prevalence of tobacco use.

On the World No Tobacco Day (WNTD) on 31st May 2022, the MoH&FW released the pocket book on Standard Treatment Guidelines for Substance Use Disorders and Behavioural Addictions and Mobile app “Addiction-Rx” for assisting physicians to provide quality care in substance use disorders, under Drug De-Addiction Programme. Further, on the same occasion in 2023, the Government of India has extended the COTP (Cigarettes and Other Tobacco Products) film rules to OTT platforms in India to display anti- tobacco health spots, anti- tobacco health warning as a prominent static message and audio-visual disclaimer on the ill-effect of tobacco use as prescribed in the rules from 1st September 2023. The new rules issue by the nodal ministry can be found in Annexure I.

Some of the other major steps initiated by the Government of India in this direction are discussed below. A detail version of these steps is presented in Annexure II of this document.

- Legislation and Regulations- The government has enacted and enforced stringent laws and regulations to control the production, sale, and consumption of tobacco products. The Cigarettes and Other Tobacco Products Act (COTPA), 2003 is a comprehensive legislation that regulates the advertising, promotion, and sponsorship of tobacco products.
- Health Warnings - The government has mandated graphic health warnings on cigarette and other tobacco product packaging to inform consumers about the health risks associated with tobacco use.
- Tobacco Control Programs - National Tobacco Control Program (NTCP) has been initiated in 2007-08 to raise awareness about the harmful effects of tobacco and to promote tobacco control activities.
- Ban on Public Smoking - Public smoking has been banned in many states and Union Territories to protect non-smokers from exposure to second hand smoke.
- Anti-Tobacco Campaigns - Various awareness campaigns, both at the national and state levels, have been launched to educate the public about the health hazards of tobacco use.

¹³ <https://iris.who.int/bitstream/handle/10665/42811/9241591013.pdf?sequence=1> , Accessed 12/02/2024, 15.35 IST

- Educational Initiatives - Integration of anti-tobacco education in school curriculum to educate children about the dangers of tobacco use.
- Cessation Support - Efforts to provide support and services for tobacco cessation, including helplines and counselling services.
- International Collaboration - Collaboration with international organisations and adherence to global anti-tobacco initiatives, such as the WHO Framework Convention on Tobacco Control (FCTC).
- Higher Taxes and Prices - The government has periodically increased taxes on tobacco products to make them less affordable and discourage consumption.

1.5 Impact of High Tax on Smoking Cessation

Higher taxes on tobacco and tobacco products have led to lowering of usage of such products among consumers (ADB, 2012 (Jha and Chalpouka 1999)).¹⁴ The World Health Organization (WHO) has time and again emphasised that levying of high taxes on smoking tobacco and tobacco products to make it expensive for users has been one of the major instruments to deter smokers globally.¹⁵ This eventually led WHO to recommend capping of all smoking tobacco products at a minimum 75 percent. As per the 9th WHO report on the global tobacco epidemic 2023, of the 182 parties to the WHO Framework Convention on Tobacco Control (WHO FCTC), “...12 percent of the population living in 41 countries were protected by tax rates at 75 percent or more of the price of the most popular brand of cigarettes.”¹⁶ In the Indian context, it has been observed that a 50 percent rise in taxes on cigarettes in India resulted in a total of 9.6 million consumers to quit smoking and/or starting to smoke apart from generating an excess revenue of USD 2.2 billion (ADB, 2012). This is a substantial reduction in smoking in a country like India and has been corroborated by the WHO. Wu et al. (2020) too observed that an increase in taxes on cigarette can deter smoking and cause significant economic benefit to the economy and is a “pro poor” choice of policy for India.¹⁷

In India, cigarettes are taxed at 52.7 per cent, bidis are taxed at 22 per cent and chewing tobacco are taxed at 63.8 per cent. During the Union Budget 2023-24, the Finance Minister of India, Ms Nirmala Sitharaman, announced further 16 per cent increase in

¹⁴ <https://www.adb.org/sites/default/files/publication/30046/tobacco-taxes-health-matters.pdf>, Accessed 12/02/2024, 15.35 IST

¹⁵ <https://www.who.int/europe/activities/promoting-taxation-on-tobacco-products>, Accessed 12/02/2024, 15.35 IST

¹⁶ <https://www.who.int/news-room/fact-sheets/detail/tobacco#:~:text=Only%2041%20countries%2C%20with%2012,the%20retail%20price%20is%20tax.&text=The%20illicit%20trade%20in%20tobacco,security%20concerns%20around%20the%20world.>, Accessed 12/02/2024, 15.35 IST

¹⁷ Wu DC, Sheel V, Gupta P, Essue BM, Luong L, Jha P. Impact of cigarette tax increase on health and financing outcomes in four Indian states. *Gates Open Res.* 2020 May 11; 4:49. doi: 10.12688/gatesopenres.13127.1. PMID: 33089072; PMCID: PMC7548764.

National Calamity Contingent Duty (NCCD) on cigarettes. It must be noted that the cigarettes, chewing tobacco, gutkha, etc. attract GST, Compensation Cess, Basic Excise Duty and NCCD, while Beedis attract GST, Basic Excise Duty and NCCD. The details of these tax components can be found in Annexure III.

This said, with increased taxes and inflated price, there are high chances of spurious and counterfeit products entering markets in India. Patterns of such counterfeiting and spurious circulation of goods are observed quite frequently in case of valuable commodities such as gold and high-end designer products and leisure products such as liqueur and smokes. Moreover, unexpected bans and abrupt imposition of high taxes will lead to flow of grey market goods, which will also hit the exchequer. In fact, spread of spurious and cheap counterfeit products are going to negatively impact the lower income segment more due to unavailability of alternative means.

To counter such a quagmire, the Government need to look for innovations and development in the industry, which can complement the Government's efforts to reduce the use of tobacco by consumers and at the same time develop "harm reduction strategies" suggested by the WHO FCTC.

1.6 Objective of the Study

India banned e-cigarettes and HNB products in 2019. The decision to do so was based on a paper released by the Indian Council of Medical Research (ICMR)¹⁸ in May 2019. The ICMR paper particularly looked at only ENDS and did not distinguish between the different kinds of alternative to conventional smoking tobacco products. Since this paper and the subsequent ban enacted by the Indian government, there have been many developments in both technologies of these products and how they have been regulated by many countries.

A quick online search shows that there exist major differences in opinions amongst health experts and academia across the globe on the potential role of alternative to conventional smoking tobacco products on harm reduction, compared to conventional tobacco products. Emerging literature from several countries seem to suggest that in order to move towards a tobacco free world it is important to provide tobacco users less harmful alternatives that can help them to move away from conventional tobacco products. The National Health Service (NHS) of United Kingdom (UK) states that alternative to conventional smoking tobacco products are in fact a great aid to smoking cessation.¹⁹

¹⁸ Indian Council of Medical Research, "White Paper on Electronic Nicotine Delivery System." May 2019, Indian J Med Res, Epub ahead of print, pp 1-10 DOI: 10.4103/ijmr.IJMR_957_19 E

¹⁹ <https://www.nhs.uk/better-health/quit-smoking/vaping-to-quit-smoking/vaping-myths-and-the-facts/>, Accessed 12/02/2024, 15.40 IST

Without doubt, each country's experience and problems with tobacco consumption are unique, and it is no different for India. The ban on e-cigarettes, HNB products, ENDS, and vaping devices (all collectively referred to as e-cigarettes in India) was placed with the objective to not make it accessible to young adults and because it was assumed that it may in fact increase the prevalence of smokers in the country. However, newer studies have been released that indicate that alternative to conventional smoking tobacco products can play a significant role in tobacco cessation.

The GATS-2 survey undertaken in 2016-17, had already estimated the total number of smoked tobacco users to be just a little shy of a 100 million users (see Section 1.3.1). The total number of smoked tobacco users have likely to have increased in absolute numbers (because of growth in population), despite the ban. Furthermore, the ban has not been able to completely prevent the illegal smuggling of disposable e-cigarettes that are finding their way to Indian markets from China. There have been several instances of seizures that have taken place.

The objective of this paper is to examine the rationale for the ban and also examine more recent and evolving literature to see if India needs to re-evaluate the ban on alternative to conventional smoking tobacco products, especially since countries have today acknowledged the importance of these products in smoking cessation. The study relies on secondary data and literature and attempts to bring to fore more recent literatures and regulations that have found such products to help in harm reduction.

Regulation around smokeless tobacco falls under the purview of state governments and will require a more detailed study, state wise. This study therefore only looks at the ban on e-cigarettes²⁰, and emerging literature and regulations on these types of products, regulations for which fall under the purview of the central government.

²⁰ "electronic cigarette" means 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. (THE PROHIBITION OF ELECTRONIC CIGARETTES (PRODUCTION, MANUFACTURE, IMPORT, EXPORT, TRANSPORT, SALE, DISTRIBUTION, STORAGE AND ADVERTISEMENT) ACT, 2019)

Chapter 2

Technological Innovations in the Tobacco Industry

2. Technological Innovations in the Tobacco Industry

2.1 Introduction

Over the years, the tobacco industry has technologically evolved. It has developed products that can minimise the delivery of tar in the tobacco, nicotine absorbing patches, and oral nicotine pouches. WHO (2018) published the Tobacco Product Regulation: Basic Handbook which noted that, “Many new or modified products fall within the continuum of traditional combusted (cigarette, cigar, bidis) or non-combusted (moist snuff, snus, toombak) tobaccos that have been used for decades and whose health risks are well documented...”²¹ Although it is yet to be tested in India, globally, many such products have been tested by independent researchers and intergovernmental agencies and are often authorised by medical authorities for cessation of smoking tobacco in developed economies.

Smoking tobacco can be categorised into two types - conventional smoking tobacco products and the alternatives to conventional smoking tobacco products. The alternatives to conventional smoking tobacco products can be further classified, of which, two main categories are the Electronic Nicotine Delivery Devices (ENDS) and non-combustible cigarettes.

These alternative to conventional smoking tobacco products, bereft of standard nomenclatures, are often casually clubbed under the same category of e-cigarette and are more often considered one and the same product by most government agencies in India and abroad. A glaring example of such casual use of the term electronic cigarette is evident in Section 3(d) of the Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage And Advertisement) Act 2019, where electronic cigarette has been defined as, “...an electronic device that heats a substance, with or without nicotine and flavours, to create an aerosol for inhalation and include 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.”²²

On the contrary, ENDS and non-combustible cigarettes differ in their scientific and technological aspects.

²¹ <https://iris.who.int/bitstream/handle/10665/274262/9789241514484-eng.pdf?ua=1>, Accessed 12/02/2024, 15.40 IST

²² [https://ntcp.mohfw.gov.in/assets/document/The-Prohibition-of-Electronic-Cigarettes-Production-Manufacture-Import-Export-Transport-Sale-Distribution-Storage-and-Advertisement\)-Act-2019.pdf](https://ntcp.mohfw.gov.in/assets/document/The-Prohibition-of-Electronic-Cigarettes-Production-Manufacture-Import-Export-Transport-Sale-Distribution-Storage-and-Advertisement)-Act-2019.pdf), Accessed 12/02/2024, 15.40 IST

2.2 Differences between ENDS and Non-Combustible Cigarettes

Electronic Nicotine Delivery Devices (ENDS), also known as vapes or e-cigarette, are battery-operated devices designed to simulate the experience of smoking. These devices heat a liquid, typically, containing nicotine propylene glycol, vegetable glycerine, and flavourings, into an aerosol or vapour that is inhaled by the user. E-cigarettes typically consist of a battery, heating element, liquid cartridge, and mouthpiece. This process is based on the principles of aerosol science and thermodynamics. The devices may vary in size, shape, and features. The design of e-cigarettes aims to optimise aerosol production and nicotine delivery.²³

The United States Food and Drug Administration (US FDA) allows for the sale of two types of non-combustible cigarette. The first kind consists of a heating source and tobacco where, the tobacco may be wrapped in paper, which makes it a type of cigarette. This product uses a carbon tip wrapped in glass fibres. The user lights the carbon tip, which heats the dried tobacco inside to a temperature that does not cause the product to create ash or burn down in size. Since the tobacco is heated to a lower temperature than a combusted cigarette to create an aerosol that the user inhales.²⁴ The second kind is a model that has been authorised in April 2019 that consists of an electronic heating device and sticks made from dried tobacco wrapped in paper. The user places the stick into the electronic heating device, which pierces the stick with a glass-covered ceramic blade that heats the tobacco, creating an aerosol.²⁵ In USA, heat-not-burn (HNB) products are also classified under non-combustible cigarettes.

The fundamental difference between ENDS and non-combustible cigarettes is the primary element to be consumed. While all the products utilise a heating mechanism, ENDS primarily rely on a nicotine-based solution (liquid) that is vaporised and inhaled by the user. On the other hand, non-combustible cigarettes involve the heating of real tobacco, which is then inhaled as a tobacco aerosol. This distinction in the key ingredient sets them apart in terms of their composition and experience for the user.

Britton et al. (Aug 2014) concluded that, “While there are many who are concerned that e-cigarettes provide a means by which existing smokers might continue their nicotine use, and new users may become hooked into a lifetime dependence on nicotine, this argument is countered by the fact that, at present, this same process occurs with tobacco, and kills. Smokers smoke for nicotine but are killed by smoke, and despite uncertainty over the potential hazard to health from the nicotine vapour

²³ <https://www.fda.gov/tobacco-products/products-ingredients-components/how-are-non-combusted-cigarettes-sometimes-called-heat-not-burn-products-different-e-cigarettes-and> , Accessed 12/02/2024, 15.40 IST

²⁴ *Ibid*

²⁵ *Ibid*

produced by e-cigarettes, any such hazard is evidently minimal in relation to that arising from inhaling tobacco smoke. Therefore, ethical considerations of perpetuating nicotine addiction need to be balanced against those of denying addicts access to an effective yet much less hazardous alternative. They also apply, but have neither been expressed nor emerged as a problem with conventional NRT. As for young people becoming addicted to nicotine – in the UK in 2012, over 40% of people aged 25 years or under have been, and nearly one in four are still, regular smokers. Any moral risk of uptake of e-cigarette use needs to be contextualised in relation to the likely alternative, which is that significant numbers of users would otherwise take up smoking. While not without risk, long-term use of nicotine from e-cigarettes is likely to have even less impact on health and life expectancy than that of low-nitrosamine smokeless tobacco...”²⁶

A study commissioned by the Public Health England (PHE) and undertaken by McNeill et al. (2015) concurred with Prof. Britton’s 2014 review for PHE reasserting that, “While vaping may not be 100% safe, most of the chemicals causing smoking-related disease are absent and the chemicals which are present pose limited danger. It has been previously estimated that EC are around 95% safer than smoking. This appears to remain a reasonable estimate.”²⁷ The National Health Service (NHS) of United Kingdom (UK) too has advocated the use of e-Cigarette as an aid to quit smoking while managing nicotine craving for existing smokers. This said, NHS has recommended that e-Cigarettes should not be recommended to non-smokers and cannot be sold to people under 18 years old.²⁸

Lüdicke et al (2017) reported a reduction in the levels of harmful and potentially harmful constituents in the aerosol produced by heated tobacco products compared to mainstream cigarette smoke.²⁹ Additionally, the study noted that the amount of tobacco used in heated tobacco products was typically lower than in combustible cigarettes. Haziza et al (2020) on assessment of selected harmful and potentially harmful constituents (HPHCs) in smokers switching to menthol Tobacco Heating System (mTHS) 2.2 compared with smokers continuing smoking menthol cigarettes

²⁶ Britton J, Bogdanovica I, Ashcroft R, McNeill A. *Electronic cigarettes, smoking and population health*. *Clin Med (Lond)*. 2014 Aug;14(4):334-7. doi: 10.7861/clinmedicine.14-4-334. PMID: 25099828; PMCID: PMC4952820. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4952820/>, Accessed 30/01/2024 13.20 IST

²⁷ <https://www.gov.uk/government/news/e-cigarettes-around-95-less-harmful-than-tobacco-estimates-landmark-review>, Accessed 12/02/2024, 15.40 IST

²⁸ <https://www.nhs.uk/live-well/quit-smoking/using-e-cigarettes-to-stop-smoking/>, Accessed 12/02/2024, 15.40 IST

²⁹ Lüdicke, F., Picavet, P., Baker, G., Haziza, C., Poux, V., Lama, N., & Weitkunat, R., (2018), “Effects of switching to the tobacco heating system 2.2 menthol, smoking abstinence, or continued cigarette smoking on biomarkers of exposure: a randomized, controlled, open-label, multicenter study in sequential confinement and ambulatory settings (Part 2). *Regulatory Toxicology and Pharmacology*, 92, 532-545. doi:10.1016/j.yrtph.2017.10.021, Accessed 30/01/2024 13.20 IST

(mCCs) and smoking abstinence (SA) found that switching from mCCs to mTHS significantly reduced the exposure to HPHCs to levels approaching those observed in subjects who abstained from smoking for the duration of the study.³⁰ Even the US FDA is of the opinion that although there is no completely safe tobacco product but non-combusted cigarettes may help reduce the risk of tobacco-related harms for adult smokers who have switched completely from combusted cigarettes.³¹ These apart, certain other studies have also shown that smokers who have completely switched to e-cigarettes or HNB products are more likely to quit smoking altogether.³²

For the purpose of this study, we would consider two different types of alternatives to conventional smoking tobacco products which will be referred to as e-cigarettes (ENDS) and non-combustible cigarettes, referred to as HNB products in this paper.

³⁰ Haziza C, de La Bourdonnaye G, Donelli A, Poux V, Skiada D, Weitkunat R, Baker G, Picavet P, Lüdicke F. Reduction in Exposure to Selected Harmful and Potentially Harmful Constituents Approaching Those Observed Upon Smoking Abstinence in Smokers Switching to the Menthol Tobacco Heating System 2.2 for 3 Months (Part 1). *Nicotine Tob Res.* 2020 Apr 17;22(4):539-548. doi: 10.1093/ntr/ntz013. PMID: 30722062; PMCID: PMC7164581.

³¹ <https://www.fda.gov/tobacco-products/products-ingredients-components/how-are-non-combusted-cigarettes-sometimes-called-heat-not-burn-products-different-e-cigarettes-and>

³² <https://www.ox.ac.uk/news/2022-11-17-latest-cochrane-review-finds-high-certainty-evidence-nicotine-e-cigarettes-are-more#:~:text=New%20evidence%20published%20today%20in,such%20as%20patches%20and%20gums.> , Accessed 30/01/2024 13.20 IST

Chapter 3

Regulations on Alternatives to Conventional Smoking Tobacco Products Across the World

3. Regulations on Alternatives to Conventional Smoking Tobacco Products Across the World

3.1 The Approach to Regulation

E-Cigarettes and HNBs can be regulated based on how these products are classified. Different countries have taken different approaches to the regulation of e-cigarettes (Table 3.1).³³ These range from regulating them as tobacco products, or as medicinal products, to complete prohibition.

As many as 75 countries have created a new classification for e-cigarettes and have created separate regulations for them. These countries include Sri Lanka, Philippines, Argentina, Nepal, New Zealand, Canada, France, Denmark, Germany, Israel, Kuwait, Poland, Saudi Arabia, Sweden, Switzerland, Turkey to name a few.

Of these, there are 24 countries that have classified e-cigarettes as consumer products and regulate them as such. Some of these countries are Canada, England, France, Germany, Switzerland, United States of America (USA).

Many countries, as many as 62 (with some overlaps with other categories), regulate e-cigarettes similar to tobacco products. These could be either certain aspects of regulation of e-cigarettes such as its sale and distribution, or it could be that these products as classified as tobacco products and regulated the same way other tobacco products are regulated.

A more nuanced approach adopted by some of the countries, Australia particularly, is to treat these products as medical products or as medicines. These countries believe that e-cigarettes aid in smoking cessation and can be used in helping people make more responsible tobacco consumption choices.³⁴ Finally, there are those countries that have banned these products completely, such as India.

³³ In almost all literatures discussed, the collective term e-cigarettes also include HNB products. While in reality, there is a difference between HNB products and e-cigarettes, in terms of regulation, only a few have made the effort to create the rightful distinction.

³⁴ <https://www.globaltobaccocontrol.org/en/policy-scan/e-cigarettes/product-classifications> , Accessed 02/02/2024 16.45 IST

Table 3.1: Overview of Approaches to the Regulation of E-Cigarettes and HNB Products (97 Countries)

Approach	Number	Countries	Logic	Mechanisms	Advantages	Disadvantages
Consumer Products	15 countries	Australia*, Canada, France, Germany, Greece, Hungary, Iceland, Indonesia, Ireland, Moldova, South Korea, Switzerland, United Kingdom, United States, Venezuela	<ul style="list-style-type: none"> Reduce harm from product defects or misuse 	<ul style="list-style-type: none"> Mandate quality control standards for e-cigarettes Require packaging standards, such as nicotine concentration indicators and tamper-proof containers 	<ul style="list-style-type: none"> Promotes consumer protection Enables despread accessibility to a less harmful alternative for current smokers 	<ul style="list-style-type: none"> May unintentionally depict e-cigarettes as safe or healthy Increases accessibility for youth Does not stop youth possession of e-cigarettes obtained by adults
Unique Products	68 countries	Argentina, Austria, Azerbaijan, Bahrain, Barbados, Belgium, Brazil, Bulgaria, Cambodia, Canada, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Ecuador, El Salvador, Estonia, Fiji, Finland, France, The Gambia, Georgia, Germany, Greece, Ireland, Israel, Italy, Jamaica, Jordan, Kuwait, Lao People's Democratic Republic, Latvia, Lebanon, Lithuania, Luxembourg, Malta, Moldova, Nepal, The Netherlands, Norway, Oman, Panama, Paraguay, Poland, Portugal, Qatar, Romania, Saudi Arabia, Serbia, Slovakia, Slovenia, Spain, Sri Lanka, Suriname, Sweden, Switzerland, Syria, Tajikistan, Thailand, Timor-Leste, Turkey, Turkmenistan, Uganda, Ukraine, United Arab Emirates, United Kingdom, Uruguay	<ul style="list-style-type: none"> Allows for the creation of legislation that pertains specifically to e-cigarettes 	<ul style="list-style-type: none"> New regulatory mechanisms specifically created for e-cigarettes, depending on a jurisdiction's priorities 	<ul style="list-style-type: none"> Acknowledges that existing regulatory frameworks may not be suitable for e-cigarettes Enables policymakers to tailor e-cigarette legislation to unique needs 	<ul style="list-style-type: none"> Lengthy process to develop and implement new legislation and regulation Does not stop youth possession of e-cigarettes obtained by adults
Tobacco Products	54 countries	Argentina, Austria, Azerbaijan, Bahrain, Brazil, Brunei Darussalam, Bulgaria, Colombia, Costa Rica, Croatia, Ecuador, Estonia, Finland, Georgia, Germany, Greece, Honduras, Indonesia, Iran, Italy, Latvia, Lithuania, Maldives, Malta, Mauritius, Mexico, Moldova, Nepal, The Netherlands, New Zealand, Nicaragua, Norway, Palau, Panama, Paraguay, Poland, Romania, Senegal, Seychelles, Singapore, Slovakia, Slovenia, South Korea, Spain, Sweden, Tajikistan, Thailand, Togo, Turkey, Turkmenistan, United Kingdom, United States, Venezuela, Vietnam	<ul style="list-style-type: none"> Treat e-cigarettes the same as the most comparable existing product 	<ul style="list-style-type: none"> Ban sale of e-cigarettes to youth Restrict marketing and promotion activities Restrict sale and use to designated locations Require warning labels 	<ul style="list-style-type: none"> Fits into already well-established tobacco regulations Discourages e-cigarette initiation and use among youth 	<ul style="list-style-type: none"> May be considered overly restrictive, since e-cigarettes likely do not pose equal health risk as tobacco products Does not stop youth possession of e-cigarettes obtained by adults
Medicinal Products	20 countries	Austria, Belgium, Canada, Chile, Denmark, Estonia, Finland, France, Iceland, Ireland, Jamaica, Japan, Norway, Philippines, South Africa, Sweden, Thailand, United Kingdom, United States, Venezuela	<ul style="list-style-type: none"> Block legal access to e-cigarettes except for smoking cessation therapy 	<ul style="list-style-type: none"> Restrict e-cigarettes to patients with a medical prescription Restrict sales to pharmacies Ban unsubstantiated health claims Enforce medicinal product standards 	<ul style="list-style-type: none"> Discourages e-cigarette initiation among non-smokers Ensures accurate product labelling E-cigarettes may be covered under health insurance plans 	<ul style="list-style-type: none"> Requiring a medical prescription creates a barrier to access e-cigarettes for smoking cessation E-cigarettes from illegal sources may be more harmful than quality-assured products
Component Ban	36 countries	Australia*, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Iceland, Ireland, Israel, Italy, Jamaica, Japan, Latvia, Lithuania, Luxembourg, Malta, Moldova, The Netherlands, Poland, Portugal, Romania, Saudi Arabia, Slovakia, Slovenia, Spain, Sweden, Switzerland, United Kingdom	<ul style="list-style-type: none"> Prevent the worst risks of e-cigarettes like addiction and youth use 	<ul style="list-style-type: none"> Ban e-liquids that contain nicotine Restrict nicotine concentrations in e-liquids Ban e-liquid flavours that may appeal to youth 	<ul style="list-style-type: none"> Nicotine restrictions can reduce the addictiveness of e-cigarettes Flavour restrictions can deter non-smokers and youth from e-cigarette initiation 	<ul style="list-style-type: none"> May discourage smokers from switching to e-cigarettes Banned e-liquid flavours from illegal sources may be more harmful than quality-assured products Does not stop youth possession of e-cigarettes obtained by adults
Poisons or Hazardous Substances	4 countries	Australia*, Belgium, Malaysia, Brunei Darussalam	<ul style="list-style-type: none"> Prevent overdose or accidental use of a harmful substance 	<ul style="list-style-type: none"> Ban e-cigarettes that contain nicotine Restrict nicotine concentrations in e-liquids Require warning labels 	<ul style="list-style-type: none"> Discourages e-cigarette initiation and use May prevent nicotine overdose 	<ul style="list-style-type: none"> May encourage continued use of cigarettes Banned nicotine e-liquids from illegal sources may be more harmful than quality-assured products Does not address non-nicotine e-liquids Does not stop youth possession of e-cigarettes obtained by adults
Prohibition	30 countries	Argentina, Brazil, Brunei Darussalam, Cambodia, Colombia, Egypt, The Gambia, India, Iran, Kuwait, Lao People's Democratic Republic, Lebanon, Mauritius, Mexico, Nepal, Nicaragua, Oman, Panama, Qatar, Seychelles, Singapore, Sri Lanka, Suriname, Syria, Thailand, Timor-Leste, Turkey, Turkmenistan, Uganda, Uruguay	<ul style="list-style-type: none"> Block all legal access to e-cigarettes to prevent harm from them and gateway to more harm 	<ul style="list-style-type: none"> Ban the possession of e-cigarettes Ban the manufacture, export, import and sale of e-cigarettes 	<ul style="list-style-type: none"> Discourages e-cigarette initiation and use by limiting supply to illegal sources Clear public messaging about e-cigarette harms 	<ul style="list-style-type: none"> Blocks access to e-cigarettes for smoking cessation E-cigarettes from illegal sources may be more harmful than quality-assured products Inconsistent with drug control trends

Source: Compiled by Authors from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6760844/#:~:text=According%20to%20evidence%20presented%20on,products%2C%2057%20as%20tobacco%20products%2C> and <https://www.globaltobaccocontrol.org/en/policy-scan/heated-tobacco>, both accessed 02/02/2024 16.45 IST

With regard to G20 countries' approach to regulations, the majority of the countries have chosen to regulate these products rather than ban them, with the exception of India, Saudi Arabia, Argentina and Brazil. Australian and Japan have opted to ban e-cigarettes containing nicotine liquids, but have not banned HNB products.

Table 3.2: Snapshot of E-cigarettes and HNB (Heat-Not-Burn) products among G20 countries

S No.	Country	Regulation
1	Argentina	Import, distribution, sale and advertisement of e-cigarettes are banned.
2	Australia	Selling and buying nicotine- containing e- cigarettes is illegal, but HNB products are not banned.
3	Brazil	The sale, import, and advertising of e-cigarettes and HNB products are prohibited.
4	Canada	The sale and promotion of e-cigarettes and HNB products are strictly regulated, but not banned.
5	China	E-cigarettes are widely available, but HNB products have restrictions and may require approvals.
6	France	E-cigarettes and HNB products are allowed and regulated.
7	Germany	E-cigarettes and HNB products are allowed and regulated.
8	India	The sale, manufacture, and distribution of e-cigarettes and HNB products are banned.
9	Indonesia	E-cigarettes and HNB products are allowed and regulated.
10	Italy	E-cigarettes and HNB products are allowed and regulated.
11	Japan	The sale of nicotine-containing e-cigarettes is prohibited, but HNB products are allowed.
12	Mexico	E-cigarettes and HNB products are allowed and regulated.
13	Russia	E-cigarettes and HNB products are allowed and regulated.
14	Saudi Arabia	The sale, import, and production of e-cigarettes and HNB products are banned.
15	South Africa	E-cigarettes and HNB products are allowed and regulated.
16	South Korea	The sale and advertising of e-cigarettes and HNB products are prohibited.
17	Turkey	E-cigarettes and HNB products are allowed and regulated.
18	United Kingdom	E-cigarettes and HNB products are allowed and regulated.
19	United States	E-cigarette regulations vary by state, and some cities have banned flavoured e-cigarettes and HNB products.
20	European Union (EU)	E-cigarettes and HNB products are regulated, but the regulations differ among member states.

Source: Compiled by authors

3.3 A Snapshot of E-Cigarette and HNB Classifications and Regulations Globally

Table 3.3: Snapshot of How Countries Classify E-Cigarettes and What they Regulate

Of 98	Countries Examined
70	Classify e-cigarettes as vaping products
57	Classify e-cigarettes as tobacco products
24	Classify e-cigarettes as medicinal products
18	Classify e-cigarettes as consumer products
4	Regulate e-cigarettes as poison or hazardous substance
36	Have minimal age of purchase/sale for devices
29	Ban all form and type of e-cigarettes
45	Regulate sales or require marketing authorisation
67	Prohibit or regulate e-cigarette marketing
38	Require health warnings on e-cigarette packaging
32	Regulate the amount of nicotine in e-liquids
32	Do not allow for the use of harmful ingredients other than nicotine
31	Regulate the quality of e-liquids contents
49	Prohibit or restrict use of e-cigarettes in public places
13	Tax e-cigarettes

Source: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6760844/#:~:text=According%20to%20evidence%20presented%20on,products%2C%2057%20as%20tobacco%20products%2C> , Accessed 02/02/2024 16.45 IST

Table 3.4: Snapshot of How Countries Classify HNB Products and What they Regulate

S No.	Parameters	No. of Countries	Type of Regulation	Examples of Countries
1	Product Classification	20	Regulate HNB products as tobacco or tobacco products	China, Israel, Malaysia, Republic of Korea, Turkey, United States
2		10	Regulate HNB products as their own category	Cambodia, Egypt, Germany, Iran, Ukraine
3		9	Regulate HNB products as novel tobacco products	Azerbaijan, Italy, Luxembourg, Norway, Spain, Sweden
4		4	Regulate HNB products as imitation tobacco products	Mexico, Mauritius, Seychelles, Singapore
5	Minimum age	35	Minimum age of purchase/sale/use provisions	
6		2	The minimum age of purchase is under 18 years (16 or 17)	South Africa, Timor-Leste
7		25	The minimum age of purchase is 18 years	Albania, Canada, China, Colombia, Georgia, Israel, Malaysia, New Zealand, Pakistan, Poland, Slovenia, Turkey, Uruguay
8		1	The minimum age of purchase is 19 years	Jordan
9		7	The minimum age of purchase is 21 years	Guam, Kuwait, Mongolia, Niue, Palau, Philippines, United States

S No.	Parameters	No. of Countries	Type of Regulation	Examples of Countries
10	Sale	30	Regulate the sale of heated tobacco products	
11		29	Permit the sale of HNB products regulate their sale, such as with a marketing authorization requirement, cross-border sale restrictions/regulations, restrictions in venues where they can be sold, or other related restrictions	Albania, Brunei Darussalam, Canada, China, Colombia, Ireland, Malaysia, Netherlands, New Zealand, Republic of Korea, Turkey, United States, Uruguay
12		15	Sale of all types of HNB products are banned	Argentina, Australia, Brazil, Cambodia, India, Iran, Mauritius, Singapore, Thailand
13		3	Import of HNB products are banned	Argentina, Singapore, Turkey
14	Marketing	43	Prohibit or regulate advertising, promotion, or sponsorship of heated tobacco products	Albania, Argentina, Brazil, China, Colombia, Germany, India, Israel, Malaysia, New Zealand, Pakistan, Spain, United States
15	Packaging	19	Packaging regulations for heated tobacco products	
16		43	Require health warnings on heated tobacco product packaging	
17	Product regulation	5	Countries regulate the type of heated tobacco products that can be sold, such as restricting the use of certain ingredients or flavours, or restricting concentrations of nicotine in heated tobacco products	
18	Reporting/Notification	34	Pre-marketing notification or have established other reporting requirements	
19		24	Require manufacturers/retailers to notify the competent authority prior to introducing HNB products to the market	Belgium, Denmark, England, France, Italy, Maldives, New Zealand, Poland, Spain, Sweden, United States
20		18	Regulations that require manufacturers/importer to provide reports with detailed information on HNB products being sold within their market	Canada, Colombia, England, France, Greece, Israel, Netherlands
21	Clean air	63	Prohibit or restrict heated tobacco use in public places	
22	Tax	29	Tax HNB products	Azerbaijan, Belgium, Canada, China, France, Germany, Indonesia, Israel, Italy, Japan
23		6	Apply an HNB tax in relation to how they tax other tobacco products	Estonia, Germany, Israel, Italy, Japan, Montenegro
24		9	Apply a specific excise tax based on weight	Canada, Czech Republic, Ireland, Poland, Portugal, Uzbekistan, Wales
25		5	Apply a specific excise tax based on units	Azerbaijan, Georgia, Lithuania, Philippines, Ukraine
26		7	Apply an ad valorem tax	Costa Rica, Ecuador, Georgia, Maldives, Poland, Portugal, Wales

Source: Compiled by authors from <https://www.globaltobaccocontrol.org/en/policy-scan/heated-tobacco> Accessed 02/02/2024 16.45 IST

3.4 Nuances of E-Cigarette and HNB Products Regulations

Where e-cigarettes are treated like tobacco products, all traditional regulations that apply to tobacco products apply also to e-cigarettes. Some of these common regulations include those that pertain to marketing and advertisement, selling to underage persons, and places of sale even. Display warnings are also similar to those of tobacco warnings in terms of content and display percentage on packaging material. In some countries these have been amended slightly, such as changing the word tobacco to nicotine, wherever applicable. However, there are certain countries that have included more nuanced regulations, recognising some distinction between e-cigarettes and traditional tobacco products.

3.4.1 Manufacturer and Importer Disclosure Requirements

In most countries where e-cigarettes are regulated at par with tobacco, similar disclosures are required to be made about the products. In countries such as England, Finland, and even China, manufacturers are required to annually file details with respect to contents of their products, their emissions, share any data that suggests addictive behaviour, sales data and so on. In many of these countries, manufacturers are also required to place before the regulating authority as early as six months prior to it being realised in the market for approvals. In Canada, for instance, it is legally required for manufacturers to submit details of their vaping products and their emissions to the Ministry of Health. There is also a requirement to ensure that this information is available on public domain for public information. This is a good initiative for increased transparency and in the interest of providing consumers with all required information for them to make an informed choice. These requirements are contained in Canada's The Vaping Products Reporting Regulations.

3.4.2 Product Requirements

These are nuanced regulations particularly applicable to e-cigarettes. These rules and regulations pertain to criteria of the device. For instance, in Canada there are regulations that mandate child locks for the devices. In Armenia, apart from placing similar requirements of providing child resistant devices, there is also a requirement for refill containers to exceed 10 millilitres (ml) and that the unit of cartridge cannot exceed 2ml.

In China the National Standards for E-Cigarettes do not allow for people to refill their own containers. The Danish regulations go into even more detail in terms of how many drops of refill liquid can be emitted per minute.

Different countries have detailed regulations along these lines on the devices themselves. Broadly these regulations are consistent across jurisdictions. This indicates a broad consensus atleast across these countries on what kind of device is considered permissible.

3.4.3 Regulating the Use of Flavours

Added flavours to the tobacco has been viewed as a way to enhance its marketability particularly among young adults. Hence countries have taken a measured approach to regulating added flavours to e-cigarettes. Countries such as China and Finland have banned the use of any flavour with tobacco.

On the other hand, some countries such as New Zealand allows for limited flavours such as menthol and mint, which are already available in normal smoked products with general retailers. However, specialised retailers are allowed to sell flavoured tobacco.

Canada and Iceland have a more nuanced take on regulating use of favours. While the Canadian Tobacco and Vaping Products Act (TVPA) empowers the Government to allow or ban flavours, so far, no such specific direction has emerged. The only directive that has been issued is the ban of flavours that are considered to be enticing to young people, flavours that mimic confectionaries, soft drinks or energy drinks, or desserts. Iceland has a similar kind of provision, but goes a step further in banning the manufacturing and sale of any kind of device that can be used along with e-cigarettes to change or enhance the flavour of tobacco.

3.4.4 Regulating Nicotine Content

While some alternatives to conventional smoked tobacco products can be regulated under existing laws, new products that have emerged have also managed to bypass the use of tobacco and use only nicotine.

Most countries, even those with detailed tobacco policy, have not yet felt the need or are yet to conceive the need for a nicotine policy. Hence concentration of nicotine delivery has been left unregulated in many markets.

However, many countries that have examined e-cigarettes in detail and have understood the need for separate legislation outside of just the existing tobacco policy, have also imposed limits on nicotine concentration, typically 20 mg/ml. Some countries have higher limits, but common practice seems to be 20 mg/ml.

3.4.5 Other Aspects for Regulations

Regulations and rules pertaining to advertisement, trade and commerce, production, supply and distribution (such as age restriction, geographic location for sales etc.) of alternatives to conventional smoking tobacco products must be in line with the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 [COTPA, 2003]. In addition, sale of alternatives to conventional smoking tobacco products must be restricted to only authorised stores/outlets. Strict penalty must be imposed on sale of such products by unauthorised vendors.

3.5 An Alternative Approach to Regulation

The US has an alternative approach to regulating tobacco products for harm reduction. A Modified Risk Tobacco Product (MRTP) is a tobacco product that has been modified to reduce the harm it causes to the user. MRTPs are regulated by the USFDA, and they must meet certain requirements to be marketed as an MRTP product.³⁵ An order permitting the sale of an MRTP refers to a single specific product, not an entire class of tobacco products (e.g., all smokeless products). An MRTP application must demonstrate that the product will or is expected to benefit the health of the population as a whole.

To apply for an MRTP, the manufacturer must submit a premarket tobacco application (PMTA) to the FDA. The PMTA must include information about the product's ingredients, its health effects, and its marketing claims, particularly for harm reduction. A manufacturer of MRTP can make either or all of the following claims.³⁶

“Disease claim

The tobacco product presents a lower risk of tobacco related disease or is less harmful than one or more other tobacco products.

Exposure claim

The tobacco product or its smoke contain a reduced level of a substance or present a reduced exposure to a substance.

³⁵ <https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-tobacco-products> , Accessed 02/02/2024 16.45 IST

³⁶ <https://www.fightcancer.org/sites/default/files/FDA%20Regulation%20of%20Tobacco%20Products%20Modified%20Risk%20FINAL%2012.11.20.pdf> , Accessed 02/02/2024 16.45 IST

Exposure claim

The tobacco product or its smoke doesn't contain or is free of a substance."

The application is then evaluated based on the scientific information and data submitted by the manufacturer in their application. The application is reviewed by the Tobacco Product Scientific Advisory Committee (TPSAC) for its recommendations and is also open for public comments. The FDA will then decide whether to approve the product. During this entire process, the USFDA or TPSAC can ask the manufacturer for any additional data or information.

If the FDA approves the product, it will be allowed to be marketed as a Modified Risk Tobacco Product. MRTPs can have a positive impact by providing smokers with a safer alternative to conventional smoking tobacco products.

India could consider such a regulatory approach rather than banning alternatives to conventional smoking tobacco products. This approach can be extended to all kinds of tobacco products. This approach will also be in line with India's objective of moving towards a tobacco free country, but in a systematic manner that focuses on slowly and steadily augmenting consumer behaviour.

Chapter 4

Re-examining India's Ban of E-Cigarettes and HNB Products

4. Re-examining India's Ban of E-Cigarettes and HNB Products

4.1 The Indian Government's Rational for the Ban

In 2019 the Indian government, through the promulgation of the Prohibition of Electronic Cigarettes (production, manufacture, import, export, transport, sale, distributions, storage and advertisement) Ordinance (and then subsequently through an Act), 2019, imposed a ban on all e-cigarettes. The Press Information Bureau (PIB) release (number 1585437)³⁷ states that because these products, "...come with attractive appearances and multiple flavours and their use has increased exponentially and has acquired epidemic proportions in developed countries, especially among youth and children...³⁸," the release argues that there is good reason to ban e-cigarettes.

The government lists three expected outcomes of the ban – ensuring that these products never take off in the Indian market, especially among the youth, help advance tobacco control efforts of the government for better public health, and contribute to the overall reduction in tobacco consumption and its associated health burden.

The press release further states that the ban has been implemented on the basis of a white paper developed by the Indian Council of Medical Research (ICMR) that had also recommended a complete ban on e-cigarettes. It further states that India's ban is justified because the WHO has also urged the same of its member countries since they believed that e-cigarettes do not lead to smoking cessation and that in fact, they could hinder established NRT solutions that are already present.

In summary, the release concludes, "Considering the highly addictive nature of nicotine; safety concern of flavours in combination with nicotine; risk of use of other psychoactive substances through these devices; initiation of nicotine or psychoactive substances by non-smokers, especially adolescents and youth; dual use of e-cigarettes and conventional cigarettes; scant scientific evidence for use of e-cigarettes as effective tobacco cessation aids; threat to country's tobacco control efforts; hindrance in achieving the targets envisaged under Sustainable Development Goals, National Monitoring Framework for Prevention and Control of Non-communicable Diseases and National Health Policy, 2017; and in overall interest of public health as envisaged under Article 47 of the Constitution of India, the decision has been taken to

³⁷ [https://pib.gov.in/PressReleaseDetail.aspx?PRID=1585437#:~:text=In%20a%20major%20health%20and,and%20advertisement\)%20Ordinance%2C%202019.](https://pib.gov.in/PressReleaseDetail.aspx?PRID=1585437#:~:text=In%20a%20major%20health%20and,and%20advertisement)%20Ordinance%2C%202019.) (Refer to Annexure IV for full Press Release). , Accessed 06/02/2024 11.00 IST

³⁸ *Ibid*

prohibit/ban e-cigarettes including all forms of Electronic Nicotine Delivery Systems (ENDS), Heat Not Burn Products, e-Hookah and the like devices.”³⁹

4.2 Rational for Revisiting the Ban

Since the ban was implemented, the market for e-cigarettes and HNB products globally have changed. Products have evolved, many countries have chosen to regulate products rather than ban them, new research has been placed on record, and some studies even suggest that e-cigarettes and HNB products do in fact contribute to smoking cessation. Notwithstanding these developments, the concerns raised by the government are justified, but must also be contextualised in light of new developments and data. For this purpose, each of the seven concerns raised by the government (detailed in the PIB release) must be re-examined based on more recent developments, regulatory frameworks across the globe, and data.

4.2.1 Addressing the Addictive Nature of Nicotine

Nicotine per say is a natural substance and exists naturally in peppers, tomatoes and potatoes.⁴⁰ This is not to say that its consumption in excess cannot cause addiction. However, a sound nicotine policy and regulations around limiting nicotine delivery are common in other countries. As discussed before, the commonly accepted levels of disbursal or nicotine is 20 mg/ml.

India can choose to go with this commonly accepted norm, or can set up a technical scientific committee that can examine these numbers and adapt them to Indian consumption patterns. A sound nicotine-based policy and regulation can easily mitigate this risk.

4.2.2 Addressing Safety Concerns Over Flavours in Combination with Nicotine

Many countries that have put in place a regulatory framework for e-cigarettes and HNB products have dealt with this risk in two broad ways. The first and the easiest is to ban all kinds of flavouring and only allow for the flavour of tobacco. Another method that can be used is to ban the use of enticing flavours, such as, soft drinks, desserts, confectionaries, to name a few of those mentioned before.

The important aspect to note is that these nuanced flavour bans exist and the government can issue directives for specific bans on either select or all kinds of

³⁹ *Ibid*

⁴⁰ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4864980/>, Accessed 06/02/2024 11.00 IST

flavours through the nodal ministry, in the case of India, the Ministry of Health and Family Welfare.

India can also go a step further, and like Iceland and Canada (see Section 3.5.3), ensure that there is a ban on any kind of enabling device that could alter the taste or flavour of natural tobacco.

4.2.3 Addressing the Risk of Use of Other Psychoactive Substances through These Products

Regulations around the manufacturing of the devices are prevalent in many jurisdictions. These include mandates on single use and non-refillable vials, tamper proof sealing, child proof sealing, and so on. In the context of e-cigarettes and HNB products, open tanks and closed tanks refer to two different types of systems used for delivering e-liquid or tobacco.

An open tank system, also known as a "rebuildable tank atomiser" (RTA), allows users to manually refill the tank with e-liquid or insert a pre-filled cartridge. This type of tank typically has a larger capacity and offers more customisation options, such as choosing different flavours and nicotine strengths. Open tanks require some level of user maintenance, including cleaning and replacing coils.

On the other hand, a closed tank system, also referred to as a "closed pod system" or "cartridge-based system," consists of pre-filled cartridges or pods that are not designed to be manually refilled. These systems are generally more user-friendly, as one can simply replace the empty cartridge with a new one when needed. Closed tanks usually have a limited flavour range due to their pre-filled nature.

Both open and closed tanks have their advantages and disadvantages. Open tanks provide more flexibility and cost-effectiveness in the long run since users have the option to refill them with their preferred e-liquid. Closed tanks, on the other hand, offer convenience and simplicity, as there is no need for maintenance or handling e-liquids.

A regulatory framework can be conceived in which a technical committee can set the standards for such products in terms of their manufacturing design to help mitigate any of the aforementioned concerns of the government. Most countries have adopted such practices where technical committees have set standards for manufacturers on the size of the device and the maximum capacity that it can contain. There are global benchmarks available that can be examined by India. If India does reconsider the ban, then it must be only for closed tank and not for open tanks. This way, the risk of other use can be mitigated.

4.2.4 Addressing the Risk of Initiating Non-Smokers into Nicotine or Psychoactive Substances

There are typically two types of products that are available globally. The first is a use and throw single use device (which are typically the ones that have entered the Indian market illegally) or disposable devices and the other is non-disposable products.

The average cost of non-disposable device, when it was allowed to be sold in India, cost around INR 5,000. This is only the cost of the device and does not include the cost of the sticks or e-liquids. If flavours are banned or restricted, then a non-smoker is less likely to spend INR 5,000 for their initiation into smoking tobacco (or any other psychoactive substances), when they could access conventional tobacco products at significantly cheaper rates.

The true threat is from disposable devices, which have been flooding the Indian market. These products are priced attractively and cost usually the same as conventional smoking tobacco products. Furthermore, these also have flavourings that could potentially make them more attractive.

The risk of non-smokers using these products is higher in the case of disposable devices than in the case of non-disposable devices. There is little logic to this rational of the government treating both these products in the same manner. The threat of initiation into using these products can be mitigated by bans on disposable devices and on the sale of any kind of flavoured tobacco. If the market for disposable device is dealt with successfully, then the cost of the non-disposable device itself would act as a natural deterrent to any initiation of non-smoker.

4.2.5 Addressing the Risks to Adolescents and Youth

The GYTS-4 data carried out in 2019 already suggests that adolescents below the age of 15, while may have more knowledge of e-cigarettes, has not resulted in conversion into using these products. As explained before, the cost of these products, along with any ban on flavours, acts as a strong deterrent to adolescents and youth accessing these products. Furthermore, the GYTS-4 data suggests that conventional cigarettes in urban India and smokeless tobacco and bidis in rural India are still the most common form consumption of age groups under 15 and continue to present a larger risk to adolescent and adult health.

However, the influx of many illegal use-and-throw products do pose a considerable risk, since these are typically priced at rates that are similar or lower to conventional

cigarettes. Hence, any sale of use and throw products should continue to be banned in order to ensure that these products are not available at “pocket friendly” prices.

4.2.6 Addressing Scant Scientific Research Available on E-Cigarettes as a Tobacco Cessation Aid

The ICMR paper (May 2019) relied mostly on literature from that period, during which time, studies documenting medium-term and long-term use of alternative non-combustible devices were few. However, five years hence, more literature is now available. Even the USFDA which at the time of the ICMR study had grave concerns over the products, have since augmented their position, primarily due to the emergence of new Randomised Controlled Trial (RCT) studies and evolution of technology. For instance, the ICMR paper predominantly talks only of ENDS, which are a way of delivering nicotine directly in a controlled manner. The paper makes no distinction between ENDS and HNB products. The ban that India promulgated also clubbed different products under the same head, even though technologically they are different.

Today, there is new literature that has emerged which also must be considered. Several studies, while still inconclusive on long term impact of use of alternative non-combustible products, have found evidence to suggest that the use of such products can aid smoking cessation. Hartman-Boyce et al (2021)⁴¹ conducted a review of multiple studies in the area, including RCTs, covering over 12,804 participants. The study was able to conclude that there was moderate-certainty evidence, to suggest that those using any form of e-cigarettes or HNB products were more likely to quit smoking compared to traditional nicotine replacement therapies that are used. The study also suggests that even usual use of these products leads to benefits in comparison to usage of traditional nicotine and tobacco products.

An interesting study undertaken by Levy et al (2023)⁴², looked at the impact of all kinds of vaping products on public health through an indirect estimation tool rather due to commonly acknowledged data limitations. This study used age and sex specific data for Canadian population, tobacco control policies and general smoking prevalence. The study inferred that the smoking prevalence in Canada, particularly for young adults, in fact declined far more rapidly once the regulations around ENDS

⁴¹ Hartmann-Boyce J, McRobbie H, Butler AR, Lindson N, Bullen C, Begh R, Theodoulou A, Notley C, Rigotti NA, Turner T, Fanshawe TR, Hajek P. “Electronic cigarettes for smoking cessation,” *Cochrane Database of Systematic Reviews* 2021, Issue 4. Art. No.: CD010216.

⁴² David T. Levy · Christopher J. Cadham · Zhe Yuan · Yameng Li · Shannon Gravely · K. Michael Cummings, 2023, “Comparison of smoking prevalence in Canada before and after nicotine vaping product access using the SimSmoke model,” *Canadian Journal of Public Health*, <https://doi.org/10.17269/s41997-023-00792-3>

were relaxed, particularly when it was made available much like other consumer products.

Similarly, the National Health Service (NHS) in United Kingdom (UK) has been also recommended the use of smoke free vaping devices and HNB products as a tool to smoking cessation.⁴³

4.2.7 Addressing the Risks to Hindering SDG Goals and WHO NCD Goals

Based on the GATS-2 results and the GYTS-4 results, India is already on the path to meet the SDG goals that has been committed to. Having said that, India is different from the rest of the world in that, the consumption of smokeless tobacco and the risks posed by these products are still prevalent. While warning messages and taxes may have helped reduce tobacco consumption of smoked tobacco, it is yet to be seen whether they have had any real impact on those consuming smokeless tobacco. It seems ill conceived to think that the risks of e-cigarettes, which as per the GATS-2 survey is used by a negligible amount of people would pose a greater risk to India's SDG goals, than the presence of conventional smoked products and smokeless tobacco. Since there is a clear correlation between education levels, possibly income levels, and the use of e-cigarette, the ban of these products can only impact consumption in urban centres, and that too of a specific socioeconomic category of people. The larger risk to meeting these targets would be from rural India and from certain sections of urban India that continue to use conventional tobacco products and smokeless tobacco.

⁴³ <https://www.nhs.uk/live-well/quit-smoking/using-e-cigarettes-to-stop-smoking/>, Accessed 06/02/2024 11.00 IST

Chapter 5

Next Steps for India

5. Next Steps for India

India has been strongly advocating for a tobacco free India and over the years has put in place various policies that have been focussed on better public health and tobacco harm reduction. The impact of these policies reflected in the GATS 2016-17 and GYTS 2019.

However, with 100 million smokers, India cannot become completely smoke free overnight.⁴⁴ It will take time and continuous effort and policy intervention, and during the course of this journey, India also has a responsibility towards those citizens who are addicted to nicotine and are currently consuming the same through combustible tobacco products. As a first step, India should also focus on providing more responsible alternatives for those citizens who already consume traditional tobacco. The following recommendations are suggested for consideration.

Even though, the medium term and long-term impact of alternatives to conventional smoking tobacco products on smoking cessation and harm reduction is under consideration, new emerging literatures suggest that such products can have a positive role to play in smoking cessation and tobacco harm reduction. It is imperative for India to conduct her own studies to this end in order to understand both medical and behavioural changes and impact of the use of these products. Such studies must be based on indigenous trials and surveys involving users from different cultural, social, and economic backgrounds. These studies can be undertaken by Indian premiere science and health research institutions such as the Indian Council of Medical Research (ICMR), National Center for Disease Informatics and Research (NCDIR), National Institute for Research in Tuberculosis (NIRT), Institute of Cytology and Preventive Oncology (ICPO), and National Institute of Medical Statistics (NIMS) among others. In the meanwhile, India must examine emerging literature and international experience so that the ban on alternatives to conventional smoking tobacco can be re-evaluated.

India must also set up a scientific committee that can look at the device and its technology, and also set standards for manufacturing of these products. Part of the terms of reference for this committee must be to understand the different types of products that are available, such as e-cigarettes versus HNB products versus single use products, or open tank versus closed tank technology, to name a few. This scientific committee must also have product manufacturers as members. This way the

⁴⁴ <https://ntcp.mohfw.gov.in/assets/document/surveys-reports-publications/GATS-2-FactSheet.pdf>, Accessed 12/02/2024 13.25 IST

committee will be able to seek details of existing products and their technical specifications present in other countries from the industry members.

Once approved, the Government may also consider delegating the development of standards and their regulations to the Bureau of Indian Standards (BIS). Products that do not meet these standards will not be provided permission for sale and distribution, and any product that is already in the market, but has failed repeated inspection, must be withheld from any future distribution and sale in the market.

Another policy framing committee must also be set up that includes industry members and other stakeholders such the academia, health experts, doctors, and civil society that can study emerging literature on alternatives to conventional smoking products and their implications for India. This committee can also examine the merits of the MRTP approach for India and how it can be integrated with COTPA.

In parallel and based on the recommendations from the scientific committee, India must consider creating a regulatory framework for nicotine, e-cigarettes, and HNB products. Part of such a regulatory framework must mandate age verification for sale of these products, similar to current requirements under tobacco regulations. The framework should also mandate sale and distribution of such products through only licensed retail shops. Furthermore, the policy framework should consider bans on certain kind of flavours (or all kinds of flavours) and how to enforce bans on use and throw products.

In conclusion, India must reconsider the ban imposed in light of fresh literature, and base any decision on studies that are conducted in India of Indian citizens. Furthermore, it is suggested that their products be regulated like any other tobacco products, which seems to be the most common approach to regulation internationally.

Annexures

Annexure I

The new rules added by the Ministry of Health and Family Welfare to the existing COTP for OTT platforms are as follows.⁴⁵

- Health spots, messages, and disclaimers: Publishers of online curated content that display tobacco products or their use will be required to comply with specific guidelines. These include the display of anti-tobacco health spots, lasting a minimum of thirty seconds each at the beginning and middle of the program. Furthermore, publishers must exhibit anti-tobacco health warnings as a prominent static message at the bottom of the screen during the display of tobacco products or their use. Additionally, an audio-visual disclaimer on the ill-effects of tobacco use, lasting a minimum of twenty seconds each, must be shown at the beginning and middle of the program.
- Access to content: The health spots, messages, and disclaimers will be made available to the publisher of the online curated content on the website "mohfw.gov.in" or "ntcp.mohfw.gov.in."
- Legibility and language: The anti-tobacco health warning message displayed as a static message must be legible and readable, with black font on a white background, and must include the warnings "Tobacco causes cancer" or "Tobacco kills." Furthermore, the health warning message, health spot, and audio-visual disclaimer should be in the same language as used in the online curated content.
- Limitations on display: The display of tobacco products or their use in online curated content is prohibited from including the brands of cigarettes or other tobacco products or any form of tobacco product placement. Additionally, the display of tobacco products or their use in promotional materials is strictly prohibited.

⁴⁵ <https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1969704#:~:text=Under%20these%20rules%2C%20now%20all,use%20as%20prescribed%20in%20the> , Accessed 12/02/2024 13.25 IST

Annexure II

Reduction of Tobacco Usage in India (Published by PIB, Release ID 1658278)⁴⁶

- The Ministry of Health & Family Welfare (MoH&FW) has enacted a comprehensive legislation, namely the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 (also known as COTPA 2003) to discourage the consumption of tobacco products in order to protect the masses from the health hazards attributable to tobacco use. The provisions under COTPA, 2003 and the Rules made thereunder mandates prohibition of smoking in public places; ban on sale of tobacco products to and by minors and within 100 yards of educational institutions; prohibition on direct and indirect advertising of tobacco products and mandatory display of specified health warnings.
- In 2007-08, the MoH&FW launched the National Tobacco Control Programme (NTCP) with the aim to
 - Create awareness about the harmful effects of tobacco consumption,
 - Reduce the production and supply of tobacco products,
 - Ensure effective implementation of the provisions under COTPA, 2003
 - Help people quit tobacco use, and
 - Facilitate implementation of strategies for prevention and control of tobacco advocated by WHO Framework Convention of Tobacco Control.
- The stakeholders are being made aware on a regular basis about the adverse effects of tobacco usage on health through various anti-tobacco campaigns vide different mode of communication.
- The Government of India has notified rules to regulate films and TV programmes depicting scenes of tobacco usage to spread awareness. Such films and TV programmes are statutorily required to run anti-tobacco health spots, disclaimers and static health warnings.
- Specified health warnings on tobacco products is enhanced with effect from 1st April, 2016 to 85 per cent of the principal display area of tobacco product packs. Quitline number (a telephone number to help quit smoking) has been included

⁴⁶ <https://pib.gov.in/PressReleseDetailm.aspx?PRID=1658278> , Accessed 12/02/2024 13.25 IST

in new specified health warnings with Quitline number which came into effect on 1st September, 2018.

- The MoH&FW has started National Tobacco Quitline to provide tobacco cessation services to the community and has launched a pan-India “mCessation” initiative to reach out to tobacco users who are willing to quit tobacco use and to support them towards successful quitting through text-messaging via mobile phones. Tobacco cessation centres have also been set up in dental colleges and institutions across the country.
- Revised guidelines for Tobacco Free Educational Institutions (ToFEI) to implement Section-6 of COTPA, 2003 has been disseminated/implemented.
- The Government of India prohibited electronic cigarettes (e-cigarettes) and like devices vide the Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019.
- The Food Safety and Standards Regulations (FSSAI) issued in 2011 under the Food Safety & Standards Act, 2006 lay down that tobacco and nicotine cannot be used as ingredients in Food Products.
- All tobacco products are covered under the highest slab i.e., 28 per cent under Goods & Service Tax (GST) with an additional compensation cess, excluding bidis.
- In order to encourage tobacco workers to shift to alternative vocations, the Ministry of Labour & Employment, Government of India in collaboration with the Ministry of Skill Development & Entrepreneurship, Government of India, has initiated ‘Skill Development’ programme for bidi rollers, to facilitate them to shift to alternative vocations.
- The Department of Agriculture and Cooperation & Farmers Welfare under the Ministry of Agriculture and Farmers Welfare, has extended Crop Diversification Programme (CDP), an on-going sub-scheme of Rashtriya KrishiVikasYojna (RKVY) to 10 tobacco growing states with effect from 2015-16 to encourage tobacco growing farmers to shift to alternate crops/cropping systems.

Annexure III

Break up of taxation on tobacco products in India.⁴⁷

- Goods and Services Tax (GST): Tobacco products such as beedis, cigarettes, chewing tobacco, gutkha, etc. attract GST at the highest rate of 28 per cent.
- Compensation Cess: Compensation cess is leviable on specified tobacco products such as chewing tobacco, gutkha, etc., other than with declared retail sale price, cigarettes, among others, at varying ad valorem rate ranging from 5 per cent to 290 per cent and/or specific rate, on products like cigars, cigarettes, etc. ranging from INR 2076 per thousand to INR 4170 per thousand. Further, the Compensation Cess rate levied on specified commodities like gutkha, chewing tobacco, smoking mixtures for pipes and cigarettes, etc., with declared retail sale price, has been linked to retail sale price and is leviable at a rate ranging from 8 per cent to 69 per cent of retail sale price.
- Basic Excise Duty: Basic Excise Duty is leviable on specified tobacco products such as beedis, cigarettes, chewing tobacco, gutkha, etc. at varying ad valorem rate ranging from 0.5 per cent to 1 per cent or specific rate ranging from 5 paisa per thousand to INR 10 per thousand.
- National Calamity Contingent Duty (NCCD): National Calamity Contingent Duty (NCCD) is leviable on specified tobacco products such as beedis, cigarettes, chewing tobacco, gutkha, etc. at varying ad valorem rate ranging from 25 per cent to 60 per cent or specific rate ranging from INR 1 per thousand to INR 850 per thousand.

⁴⁷ http://www.indiaenvironmentportal.org.in/files/file/monsoon_session_2023/Lok%20Sabha-Tax%20on%20Tobacco%20Products-07%20Aug.pdf, Accessed 12/02/2024 13.25 IST

Annexure IV

Cabinet approves Promulgation of the Prohibition of Electronic Cigarettes Ordinance

Posted On: 18 SEP 2019 4:21PM by PIB Delhi


In a major health and wellness initiative for the country, the Union Cabinet chaired by the Prime Minister Shri Narendra Modi has approved the Promulgation of the Prohibition of Electronic Cigarettes (production, manufacture, import, export, transport, sale, distribution, storage and advertisement) Ordinance, 2019.

Electronic-cigarettes are battery-operated devices that produce aerosol by heating a solution containing nicotine, which is the addictive substance in combustible cigarettes. These include all forms of Electronic Nicotine Delivery Systems, Heat Not Burn Products, e-Hookah and the like devices. These novel products come with attractive appearances and multiple flavours and their use has increased exponentially and has acquired epidemic proportions in developed countries, especially among youth and children.

Implementation:

Upon promulgation of the Ordinance, any production, manufacturing, import, export, transport, sale (including online sale), distribution or advertisement (including online advertisement) of e-cigarettes shall be a cognizable offence punishable with an imprisonment of up to one year or fine up to Rs. 1 lakh or both for the first offence; and imprisonment of up to three years and fine up to Rs. 5 lakhs for a subsequent offence. Storage of electronic-cigarettes shall also be punishable with an imprisonment up to 6 months or fine up to Rs 50,000 or both.

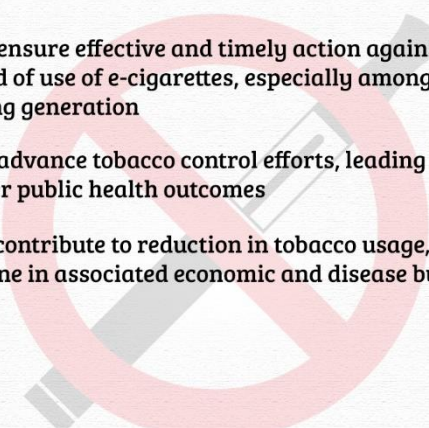
The owners of existing stocks of e-cigarettes on the date of commencement of the Ordinance will have to suo moto declare and deposit these stocks with the nearest police station. The Sub-Inspector of Police has been designated as the Authorized Officer to take action under the Ordinance. The Central or State Governments may also designate any other equivalent officer(s) as Authorized Officer for enforcement of the provisions of the Ordinance.



CABINET DECISION

PROHIBITION OF ELECTRONIC CIGARETTES ORDINANCE

- Will ensure effective and timely action against the trend of use of e-cigarettes, especially among the young generation
- Will advance tobacco control efforts, leading to better public health outcomes
- Will contribute to reduction in tobacco usage, and decline in associated economic and disease burden



MAJOR IMPACT:

The decision to prohibit e-cigarettes will help protect population, especially the youth and children, from the risk of addiction through E-cigarettes. Enforcement of the Ordinance will complement government's efforts for tobacco control and will help in reduction of tobacco use and reduction in associated economic and disease burden.

BACKGROUND:

The current decision has come on the back of an advisory issued by the Government in 2018 to all States to consider banning e-cigarettes. 16 States and 1 UT have already banned e cigarettes in their jurisdictions. Notably, the Indian Council of Medical Research (ICMR), in a recent white paper on the subject, also recommended a complete ban on e-cigarettes based on currently available scientific evidence. The WHO has also urged member countries to take appropriate steps including prohibiting these products. These products are usually marketed as being safer alternatives for conventional cigarettes but such notions of safety are false. On the other hand, available literature suggests that these products may act as gateway products to induce non-smokers, especially youth and adolescents, to nicotine-use, leading to addiction and subsequent use of conventional tobacco products. E-cigarettes are usually promoted by the industry as smoking cessation aids but their efficacy and safety as a quitting aid has not yet been established.

Unlike the tried and tested nicotine and non-nicotine pharmacotherapies that are known to help people quit tobacco use, the WHO does not endorse e-cigarettes as cessation aids. The possibility of tobacco industry interference in tobacco cessation efforts through misinformation about the potential benefits of these products, which are presented as alternatives but in most cases are complementary to the use of conventional tobacco products, also is a present and real possibility. Apart from nicotine, e-cigarettes may also be used for delivery of other psychoactive substances. Scientifically proven nicotine replacement therapies, without the risks associated with e-cigarettes, exist in the form of gums, lozenges and patches for those willing to quit

tobacco use. Widespread use and unchecked proliferation of e-cigarettes and the like devices would seriously undermine and derail Government's efforts to reduce the prevalence of tobacco use.

Considering the highly addictive nature of nicotine; safety concern of flavours in combination with nicotine; risk of use of other psychoactive substances through these devices; initiation of nicotine or psychoactive substances by non-smokers, especially adolescents and youth; dual use of e-cigarettes and conventional cigarettes; scant scientific evidence for use of e-cigarettes as effective tobacco cessation aids; threat to country's tobacco control efforts; hindrance in achieving the targets envisaged under Sustainable Development Goals, National Monitoring Framework for Prevention and Control of Non-communicable Diseases and National Health Policy, 2017; and in overall interest of public health as envisaged under Article 47 of the Constitution of India, the decision has been taken to prohibit/ban e-cigarettes including all forms of Electronic Nicotine Delivery Systems [ENDS), Heat Not Burn Products, e-Hookah and the like devices.

VRRK/PK/SH

(Release ID: 1585437)



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