
ALTERNATE AGENDA FOR THE FRAMEWORK CONVENTION ON TOBACCO CONTROL (FCTC) CONFERENCE OF PARTIES-10 (COP 10)

Prepared By



Civitas Consultancies Pvt Ltd

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Contents

LIST OF ABBREVIATIONS.....	05
LIST OF FIGURES.....	06
1.INTRODUCTION.....	07
1.1 INDIA'S EPIDEMIOLOGICAL TRANSITION.....	08
1.2 SCALE OF INDIA'S RISKS FROM TOBACCO.....	10
2.INDIA'S POLICY MEASURES TO REDUCE TOBACCO-RELATED RISKS.....	12
2.1 REGULATORY AMBIGUITY SURROUNDING PRODUCT DISTINCTIONS.....	13
2.2 THE MISSING STRATEGY OF TOBACCO HARM REDUCTION	14
2.3 ASSESSMENT OF RISK IN ENDS AND HTP: EXAMINING THE EVIDENCE.....	15
3. IMPLICATIONS OF THE BAN AND ITS CURRENT STATUS.....	19
4. TOBACCO RISK MANAGEMENT.....	21
4.1 RISK BALANCING AS A BENCHMARK TO EVALUATE POLICY.....	21
5. LESSONS FOR INDIA.....	23
6. ADAPTING A RISK-BALANCING FRAMEWORK FOR INDIA.....	24
7. CONCLUSION.....	27

List of Abbreviations

CRD	Chronic Respiratory Disease
CVD	Cardiovascular Disease
COTPA	Cigarettes and Other Tobacco Products Act
DALY	Disability-adjusted years
E-cigarettes	Electronic Cigarettes
ENDS	Electronic Nicotine Delivery Systems
EU TPD	European Tobacco Products Directive
FCTC	Framework Convention on Tobacco Control
FDA	Food and Drug Administration
GATS	Global Adult Tobacco Survey
HnB	Heat not Burn
HTPs	Heated Tobacco Products
SLT	Smokeless Tobacco
UK	United Kingdom
US	United States
WHO	World Health Organisation

List of Figures

**Figure 1.1: Top 10 Risk Factors for Morbidity and Mortality (DALYs)
(2007 vs. 2017)**

**Figure 1.2: Cardio-vascular disease: Most Common Cause of
Tobacco-attributable Mortality**

**Figure 1.3: Age in Years vs Percentage of CVD Deaths caused by
Tobacco**

Figure 2.1: Harm Continuum in Nicotine Products

**Figure 2.2: Sales of Cigarettes, IQOS, and other HTPs in Japan 2011-
2019**

Chapter 1

Introduction

As the Conference of the Parties (COP 10) to the World Health Organization Framework Convention on Tobacco Control (FCTC) approaches its next meeting, it is crucial to review India's progress on tobacco control and shed light on strategy and supporting evidence for tobacco harm reduction. The COP is the governing body of the FCTC and is composed of representatives from the countries that are parties to the treaty. It meets biennially to review the implementation of the FCTC, discuss emerging issues related to tobacco control, and make decisions on implementation of the treaty. These meetings provide a platform for sharing best practices, adopting new guidelines, and addressing challenges in tobacco control.

This Report is submitted in line with Section 7, Article 4 of the WHO Framework Convention on Tobacco Control, highlighting the crucial role of civil society participation in achieving the Convention's goals and recognizing the established practice of encouraging inputs to enhance the evidence base. It offers alternative insights and perspectives on the status of FCTC implementation in India thus contributing to the ongoing discourse surrounding tobacco harm reduction in India by emphasising the importance of a comprehensive approach that aligns with international human rights principles.

The history of tobacco in India is long and intricate, deeply entwined in its culture and economics. India has been a significant producer and consumer of tobacco for centuries but its widespread use, particularly in the form of smoking beedi and chewing, has raised significant concerns for public health. India is home to one of the world's largest populations of tobacco users, with approximately one in every three adults using some form of tobacco (GATS, 2017).

The health implications of tobacco use are staggering; smoking and chewing tobacco are linked to serious diseases like cancer, cardiovascular diseases, and respiratory illnesses. More than 1 million adults die each year in India due to tobacco use accounting for 9.5% of overall deaths. As per Centre for Disease Control and Prevention, 7.2 percent of women who gave birth smoked cigarettes during pregnancy. Mothers who smoke or are exposed to secondhand smoke during pregnancy face higher risks of preterm delivery, low birth weight in their babies, and an increased likelihood of Sudden Infant Death Syndrome (SIDS). Babies exposed to maternal smoking or secondhand smoke also have weaker lungs, elevating their susceptibility to various health issues.

Recognizing these challenges, the Indian government has taken measures to curb tobacco consumption, including graphic warnings on packaging, ban on advertising, and imposing high taxes on tobacco products. Yet, the battle against tobacco continues.

1.1 India's Epidemiological Transition

India is currently in the midst of an epidemiological transition, marked by a notable shift in the patterns of disease burden. According to the Global Burden of Disease (GBD) Study of 2016, India has experienced a significant increase in non-communicable diseases (NCDs).

and injuries compared to communicable, maternal, neonatal, and nutritional diseases (CMNNDs). In 1990, at the national level, the top five causes of disease burden were primarily CMNNDs, including diarrheal diseases, lower respiratory infections, neonatal preterm birth, tuberculosis (TB), and measles. However, by 2016, three out of the top five causes of disease burden were attributed to NCDs, such as cardiovascular disease [CVD], chronic respiratory disease, and cerebrovascular disease (like stroke). Some of the primary contributors to the burden of disease and disability-adjusted life years (DALYs) in India were found to be child and maternal malnutrition, air pollution, high systolic blood pressure, and tobacco use see **Figure 1.1**.

Figure 1.1: Top 10 Risk Factors for Morbidity and Mortality (DALYs) (2007 vs. 2017)



DALY, disability-adjusted life year; LDL, low-density lipoprotein; WaSH, Sanitation and hygiene behaviors.
 Source: The Institute for Health Metrics and Evaluation.²⁴

Source: Foundation for a Smoke-Free World, July 2020, India Country Report

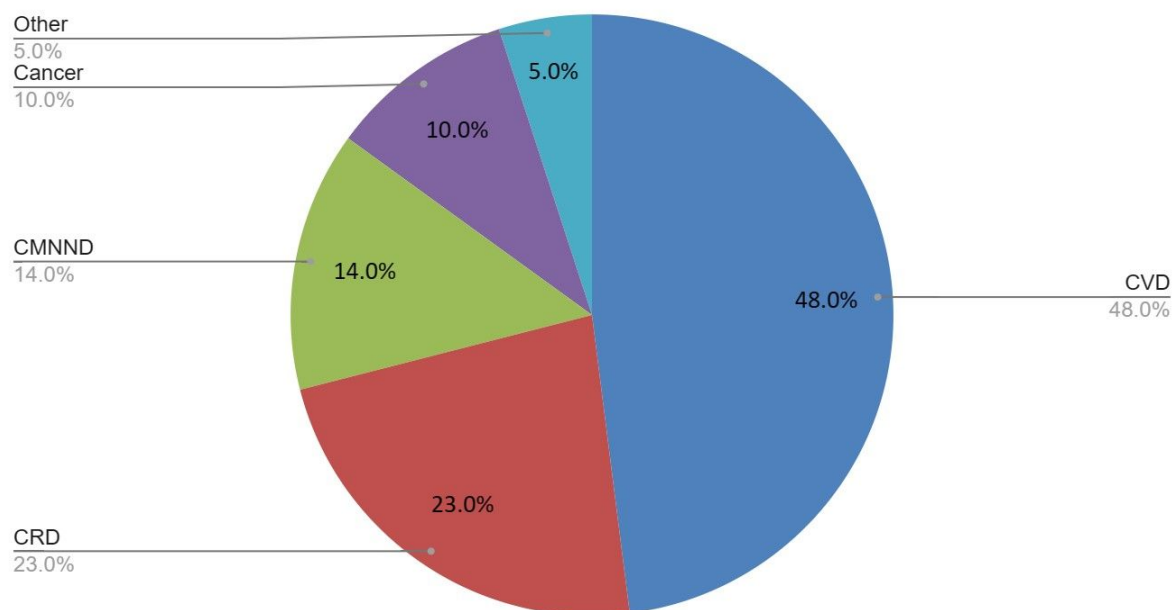
The use of tobacco in India results in over one million deaths annually, comprising 9.5% of all deaths in the country. Globally, eight million people die each year due to tobacco use or exposure to second-hand smoke. The World Health Organization (WHO) estimates that almost half of India's tobacco-related deaths are linked to cardiovascular diseases, with 16% of all cardiovascular disease deaths attributed to tobacco. Notably, individuals aged 30 to 44 years are at a higher risk of tobacco-related cardiovascular diseases.

India shoulders a staggering burden when it comes to oral cancer, accounting for a third of global cases and making oral cancer the sixth most prevalent cancer worldwide.

Tobacco is estimated to be the primary cause of 40% of all cancers in India. Research has proved that chewing of betel nut quid, smoking, use of smokeless tobacco products etc. increase the incidence of cancer.

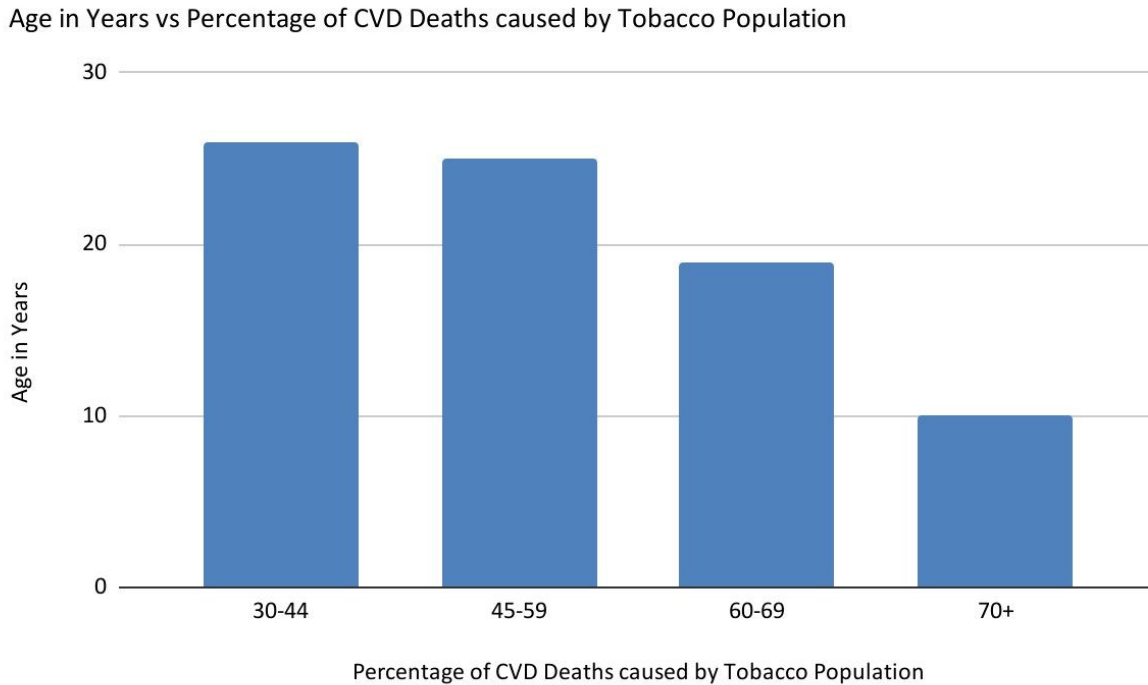
Nicotine, an addictive chemical found in tobacco, is the primary driver for smoking or chewing tobacco. However, while nicotine itself is not carcinogenic, tobacco products contain numerous other carcinogens and toxicants. These substances enter the user's body and contribute to various health issues, ultimately leading to morbidity and mortality.

Figure 1.2: Cardiovascular Diseases: Most Common Cause of Tobacco-attributable Mortality



Source: World Health Organization

Figure 1.3: Age in Years vs Percentage of CVD Deaths caused by Tobacco



Source: World Health Organization

1.2 Scale of India’s Risks from Tobacco

India ranks second globally in tobacco consumption (World Health Organization, n.d.). A survey conducted in 2016-17, known as GATS 2, revealed that 266.8 million Indian adults aged 15 and above use tobacco, encompassing both smokeless products like khaini, gutka, and zarda, as well as smoked options such as beedis and cigarettes (Tata Institute of Social Sciences and Ministry of Health and Family Welfare, 2018). Overall, tobacco use in India has reduced women’s life expectancy by 11 years and men’s by 12 years (Economic Times, 2021).

Official government data highlights the economic toll of tobacco-related deaths and illnesses.

In 2011, the cost to the economy of tobacco use-related issues amounted to INR 1,04,500 crores, which escalated to INR 1,77,341 crores in 2017-18, equivalent to 1% of India’s GDP (Press Trust of India, 2020). Recent figures suggest that 5.3% of India’s healthcare expenditure is allocated to treating tobacco-related diseases, resulting in an annual cost of INR13,500 crores, and in 2023, tobacco-related healthcare expenditure accounted for 1.04% of the GDP (Jo, 2022; Economic Times, 2023).

Smokeless tobacco poses additional challenges due to the prevalence of unregulated products. In 2017, 43% of smokeless tobacco products were illegal (lacking up-to-date health warning labels), and 2% were illicit (absence of health warning labels or non-compliance with Indian health warning labels) (Welding et al., 2021).

Combustible cigarettes are more harmful due to the toxins released when tobacco is burned. Approximately 4% of Indians smoke combustible cigarettes, with beedis being the most popular choice (GATS, 2017). Beedis produce five times more tar compared to manufactured combustible cigarettes (Mohan, Lando, and Panneer, 2018). The largely informal nature of beedi production, driven by efforts to evade taxes and labour laws, results in products from unregistered entities lacking health label warnings (Boyd, 2021). Notably, 55% of beedi packs and 25% of manufactured combustible cigarettes were illegal, while 10% of commercial combustible cigarettes were illicit (Welding et al., 2021).

India also faces a challenge with low quit rates for smoking, particularly among men, where it's less than 20 percent (GATS 2, 2017). Tobacco use is more common among socially disadvantaged and economically weaker groups, which exposes them to higher risks associated with tobacco. Research indicates that individuals with lower socioeconomic status are more inclined towards tobacco consumption, are more exposed to its adverse effects and tend to have less success in quitting. Several factors contribute to this, including reduced community support for quitting, lower motivation to quit, strong addiction, difficulties in completing pharmaceutical and behavioural interventions, psychological issues like low self-efficacy, and influence of tobacco industry marketing (Hiscock et al., 2011).

Efforts to combat the tobacco epidemic in India have primarily focused on raising awareness about the health risks of tobacco, and these efforts have been largely successful in achieving widespread awareness.

Over 90 percent of adults in India, spanning different social strata, acknowledge the harmful nature of tobacco (GAT 2, 2017). However, in spite of high level of awareness, there is limited progress in reducing tobacco use or increasing cessation rates.

The persistence of high tobacco use rates, especially among disadvantaged populations, suggests that addressing tobacco addiction in India requires a more comprehensive approach that goes beyond awareness campaigns. Strategies are required to counter these unique challenges such as improved access to cessation support, addressing psychological barriers, and countering the influence of the tobacco industry to achieve meaningful reduction in tobacco use.

Chapter 2

India's Policy Measures to Reduce Tobacco-Related Risks

India's historical approach to tobacco regulation initially involved minimal intervention, primarily consisting of statutory warnings regarding potential health risks associated with tobacco consumption. However, as mounting evidence illuminated the severe health implications of tobacco use and societal awareness grew regarding the adverse effects of second-hand smoke, the government adopted a more assertive stance in regulating tobacco products. The Comprehensive Tobacco Control Act of 2003 (COTPA) marked a significant milestone by consolidating various regulatory aspects within a unified framework. An additional landmark in the realm of tobacco regulation is the National Tobacco Control Programme (NTCP), which provided funding for state-level initiatives aimed at controlling tobacco usage.

In 2004, the Government of India ratified the WHO Framework Convention on Tobacco Control (WHO FCTC), the first ever international public health treaty focusing on the global issue of tobacco control. The FCTC recognizes that there are three pillars to tobacco control: demand reduction, supply reduction, and harm reduction.

So far, the FCTC's focus has been exclusively on supply and demand. This is evident through initiatives like "MPOWER," a comprehensive policy package designed to counteract the tobacco epidemic.

"MPOWER" sets forth a set of regulatory recommendations that serve as benchmarks for assessing the progress of FCTC Parties in their tobacco control endeavours. These are economic incentives through substantial taxation, content regulation of tobacco products, public awareness campaigns highlighting the hazards of smoking, and the establishment of toll-free helplines, or 'Quitlines,' to assist individuals seeking cessation support (Mohan, Lando, and Panneer 2018, 4-5; Sudan 2020). But the results of tobacco control have been modest.

In 2019, the finance minister of India announced a ban on e-cigarettes, following which manufacturing, import, export, transport, sale, distribution, storage and advertising related to e-cigarettes is prohibited. The evolving framework of tobacco control measures highlights the government's commitment to a systematic, evidence-based approach founded on scientific causality and effectiveness. However, the blanket ban enforced on electronic cigarettes (e-cigarettes) diverges from this nuanced approach. The imposition of a complete ban on e-cigarettes can be attributed to the uncertainty surrounding the classification of these products. The establishment of an effective regulatory framework will only be possible once clear distinctions are drawn.

2.1 Regulatory Ambiguity surrounding Product Distinctions

The government's regulatory approach to different aspects of tobacco and nicotine products exhibits some shortcomings. This is primarily due to a failure to fully understand the distinctions between various products in the market thus leading to the sweeping ban on e-cigarettes.

There is a wide range of definitions of novel, non-conventional, non-traditional tobacco products. There is a clear distinction that is made within the broad category of novel tobacco and nicotine products by most regulators and health organisations

- Electronic Nicotine Delivery Systems (ENDS) and
- Heated Tobacco Products (HTPs)

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

Electronic cigarettes, the most common prototype, are devices that do not burn or use tobacco leaves, but instead vaporise a solution the user then inhales. The main constituents of the solution, in addition to nicotine when nicotine is present, are propylene glycol, with or without glycerol and flavouring agents. ENDS solutions and emissions contain other chemicals, some of them considered to be toxicants."

Electronic Nicotine Delivery Systems (ENDS) comprise a wide range of products — vapes, e-hookahs, electronic cigarettes and e-pipes.

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

The Prohibition of Electronic Cigarettes Act of 2019 instituted a comprehensive ban on e-cigarettes, encompassing all forms of ENDS, HTP, e-hookahs, and similar devices. Although often grouped together as a single product class, these items constitute a diverse array with potentially significant disparities in toxicant production and nicotine delivery mechanisms.

In the preamble of decision FCTC/COP8(22) dated 6 October 2018, the Parties to the WHO FCTC recognized that "heated tobacco products are tobacco products and are therefore subject to the provisions of the WHO FCTC". However, the Indian Government in its Act failed to make the distinction between these two very distinct classes of products.

The Act defines electronic cigarette" as an electronic device that heats a substance, with or without nicotine and flavours, to create an aerosol for inhalation and includes all forms of Electronic Nicotine Delivery Systems, Heat Not Burn Products, e-Hookah.”

In the Finance Bill of 2021, the Union government acknowledged the classification of novel tobacco and nicotine products as laid down by the World Customs Organization Council. The acknowledgement differentiated between traditional cigarettes, e-cigarettes and HTP for taxation purposes (Government of India 2022). However, this distinction has not been applied in the context of the ban on e-cigarettes.

In effect, the Indian Act is at variance with global definitions as it does not differentiate between the two classes of products. This deviation from global definitions implies that while the WHO recognizes HTPs as tobacco products under FCTC, India groups them together without any basis. This decision of the government to ban e-cigarettes, HTP and other like products without delving into the product characteristics needs re-examining.

2.2 The Missing Strategy of Tobacco Harm Reduction

To effectively reduce the prevailing morbidity and mortality associated with tobacco usage within the population, the optimal approach is to abstain from using tobacco in any form. For individuals already dependent on nicotine, who engage in smoking or use smokeless tobacco to satisfy their cravings, it is imperative to provide them with counselling, information, and support to facilitate tobacco cessation, utilising available resources such as nicotine replacement therapy, including nicotine patches, gums, and inhalers, as endorsed by the WHO.

However, global patterns of tobacco dependence and cessation reveal that a significant portion of the population has struggled to achieve complete or even partial tobacco cessation despite the availability of such aids. A study by Hoffmann et al (2019) concluded that FCTC implementation as reflected by adoption of MPOWER demand-and-supply measures has had little if any effect on smoking prevalence. While India has diligently pursued the reduction of both tobacco demand and supply as a primary approach to tobacco control, this strategy has omitted a viable alternative, namely, tobacco harm reduction (THR). Tobacco harm reduction is an approach aimed at reducing the health risks associated with tobacco use, particularly smoking. The primary goal is to help individuals who are unable or unwilling to quit using tobacco altogether to switch to less harmful alternatives. This approach recognizes that while quitting smoking is the best way to improve health, some people may find it difficult to quit and may benefit from alternative strategies.

In Europe, Sweden stands out as a pioneering nation in embracing tobacco control, enhanced by the incorporation of harm reduction strategies. Despite having nicotine use prevalence similar to the EU average, Sweden distinguishes itself by predominantly utilising safer, non-combustible alternatives. As a result, the prevalence of smoking in Sweden is remarkably low at 5.6%, which is nearly five times less than the EU average of 23% (Milton et al, 2023). This substantial reduction in smoking rates has led to Sweden having the lowest incidence of tobacco-related diseases and mortality rates within the EU.

Studies have also demonstrated that smokers who switch to e-cigarettes or heated tobacco

products are more likely to successfully quit smoking altogether. A case in point is Japan, a country with a historical high prevalence of smoking, has experienced a notable shift in recent years towards HTPs. In 2018, a survey commissioned by the Japanese government indicated that the number of individuals using HTP had doubled since 2015, coinciding with a decline in traditional smoking rates. Notably, one study has proposed that the accelerated decrease in cigarette sales in Japan since 2016 is closely linked to the introduction and increasing popularity of HTPs in the market.

One key factor contributing to the effectiveness of HTPs as smoking cessation tools is their capacity to deliver nicotine in a manner that effectively satisfies the user's cravings. This characteristic makes HTPs a viable option for adult smokers who are currently trying to quit.

Nicotine addiction is a formidable obstacle that can hinder many smokers in their attempts to quit. E-cigarettes and HTPs offer a less harmful source of nicotine compared to traditional cigarettes. This reduced harm factor makes it more manageable for individuals who smoke to transition from conventional smoking. This approach has demonstrated its effectiveness as a strategy for assisting smokers in their journey towards cessation.

To reinforce ongoing tobacco control efforts, it is essential to critically consider additional avenues for tobacco harm reduction to complement existing efforts of controlling tobacco usage.

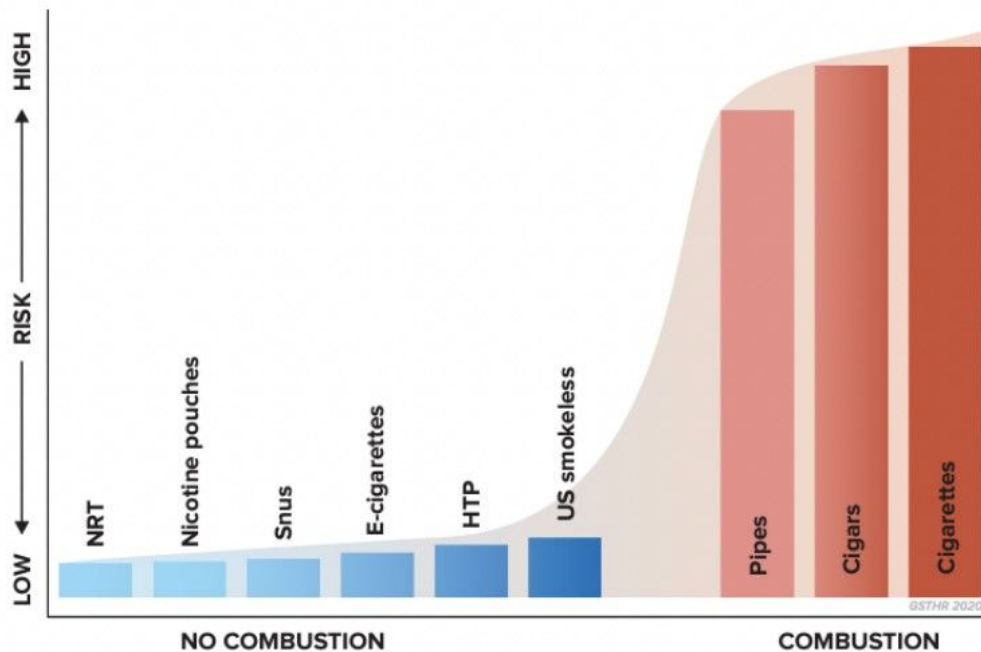
2.3 Assessment of Risk in ENDS and HTP: Examining the Evidence

A WHO report establishes that while there are potential risks associated with toxic chemicals from ENDS and Non-Nicotine Delivery Systems (NNDS), these vary with the device, the e-liquid, and how users operate them (WHO Regional Office for Europe 2020). The report also notes that the risks from unadulterated ENDS and NNDS under normal conditions are lower when compared to the harmful effects of combustible tobacco smoke. Additionally, concerns regarding certain flavour additives can be addressed through restrictions and regulations on flavouring agents within harm reduction framework.

Scientific evidence indicates that the primary cause of smoking-related diseases is not nicotine itself but the harmful chemicals generated during the combustion of tobacco, including tar, carbon monoxide (National Health Service 2022), burnt paper, and other pollutants. Tobacco smoke contains over 7,000 chemicals, with at least 250 identified as harmful, and of those, at least 69 are known to be carcinogenic (e.g., arsenic, benzene, formaldehyde) (National Cancer Institute 2017). Independent and manufacturer-funded studies show that some toxicants found in HTP aerosol are not found in conventional cigarette smoke. In at least one well-selling brand, four chemicals that are possibly cancer-causing and 15 potentially damaging to the genetic structure were found (WHO, 2021). The evidence indicates that HTPs are probably not harmless and that though smokers switching completely from combustible cigarettes to HTPs may reduce their exposure to some harmful and potentially harmful constituents (HPHCs), they do not reduce their exposure to all of them (WHO, 2021).

Figure 2.1: Harm Continuum in Nicotine Products

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Source: Global State of Tobacco Harm Reduction 2021

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The Global State of Tobacco Harm Reduction Report (2021) underscores that combustible tobacco products pose significantly higher risks compared to non-combustion alternatives like e-cigarettes (ENDS) and HTP devices. ENDS and HTP provide users with the experience of inhaling nicotine aerosol while avoiding the harmful consequences of tobacco smoke, and they are estimated to be approximately 95% safer (Public Health England 2015).

Short to medium-term exposure to Propylene Glycol and Glycerol from e-cigarettes is considered of low concern, and second-hand exposure to these chemicals is unlikely to pose risks to bystanders (Committee on Toxicity of Chemicals in Food, Consumer Products, and the Environment 2020). A specific HNB device study demonstrated significantly reduced levels of HPHC as well as typical toxicants in Total Particulate Matter (TPM) compared to combustible cigarettes (Mallock et al. 2018, 2146).

Recognising the reduced toxin levels produced by Heat-Not-Burn Products (HTPs) in comparison to traditional combustible alternatives, the U.S. Food and Drug Administration (FDA), a federal agency dedicated to safeguarding public health, granted marketing authorization for the IQOS Tobacco Heating System, an HTP device (U.S. FDA 2019). Their evaluation revealed that the aerosol generated by IQOS contained significantly fewer toxic chemicals when contrasted with the smoke produced by combustible cigarettes.

A potential risk highlighted by the WHO relates to exposure to certain metals, commonly found in the metallic heating coils and soldered joints of ENDS devices, including chromium, nickel, and lead. However, the extent of this risk depends on product design, engineering, and usage patterns, all of which can be regulated.

The reduced exposure to toxicants from ENDS and HTPs implies that transitioning to these devices may decrease health risks associated with smoking combustible cigarettes, such as impairments in blood oxygen transport function, vascular endothelial injury, and other cellular-level harms (Kvasha et al. 2017).

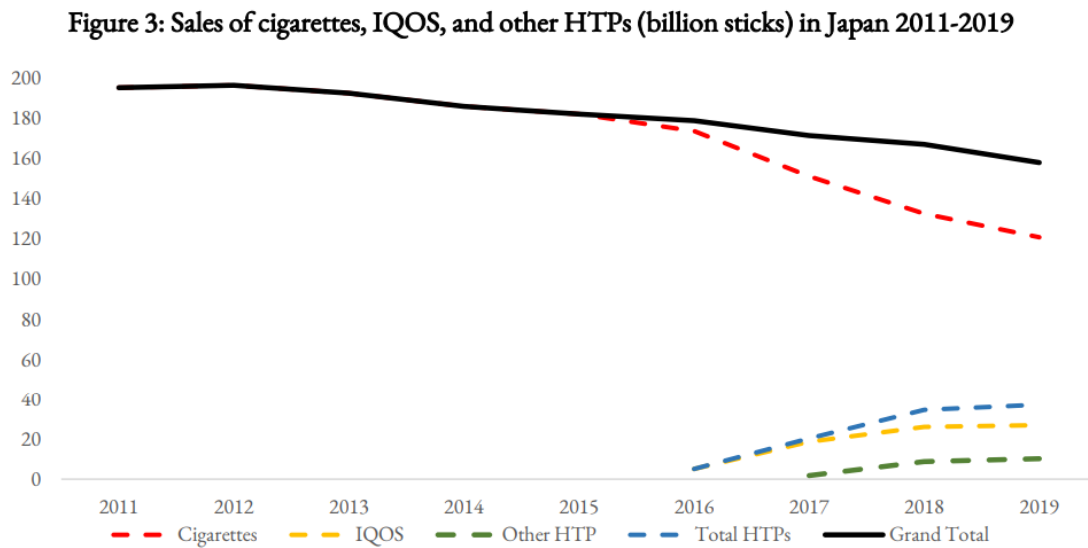
There are also consistent improvements in respiratory symptoms, exercise tolerance, quality of life, and rates of disease exacerbations in patients with Chronic Obstructive Pulmonary Disease who switch to HTPs or abstain from smoking (Polosa et al. 2021). If HTPs demonstrably assist people in shifting away from combustible cigarettes, banning them may close a vital pathway to harm reduction.

A clinical trial in the United Kingdom (UK) found that e-cigarettes are twice as likely to help individuals quit smoking effectively when used alongside in-person expert support compared to other nicotine replacement products (National Health Service 2022). Although evidence regarding the use of nicotine vaping products for smoking cessation remains mixed (Gravelly et al. 2022), HTPs have proven effective in aiding the transition away from combustible cigarettes. After the introduction of IQOS in 2014, followed by several other HTPs, there was a substantial decline in conventional cigarette sales in Japan (Stoklosa et al. 2020).

Similarly, in India, a survey of 3,000 e-cigarette users showed that 30% quit smoking when they switched to e-cigarettes, and 41% reduced their smoking habit (Sharan et al., 2020). Some users even quit or cut down on smokeless tobacco use, indicating that ENDS and HNBs could aid in smokeless tobacco cessation.

However, long-term health effects, such as nicotine addiction and lung damage, still require thorough research. Identifying the harms of combustible cigarettes took decades due to the delayed onset of diseases like cancer and lung issues (UCLA Health, 2020). There still remains uncertainty about potential lung damage from vaping (Shmerling, 2022).

Figure 2.2: Sales of Cigarettes, IQOS, and other HTPs in Japan 2011-2019



Data Source: (Cummings, Nahhas, and Sweanor, 2020). See note for data explanation on data sources and calculation²

Source: Cummings, Nahlas and Sweanor, 2020

Chapter 3

Implications of the Ban and Its Current Status

Historically, the prohibition of various products has consistently led to proliferation of underground markets and the involvement of criminal entities seeking to profit from illicit trade. India's experience with alcohol prohibition serves as a prime example, particularly in Gujarat, where authorities seized liquor worth an average of Rs. 34 lakhs per day over a 20-month period (Choudhary and Sharma 2021). Such bans also result in a substantial loss of revenue for the government, as demonstrated by Maharashtra's estimated loss of Rs. 2,570 crores between 2015 and 2020 due to a liquor ban in specific districts. Furthermore, beyond the economic repercussions, these bans pose unintended public health risks. In India, counterfeit liquor has claimed more lives than drug overdoses, with 947 accidental deaths attributed to the consumption of illicit or poisonous liquor in 2020, compared to 514 from drug overdoses (National Crime Records Bureau 2021).

Similarly, India's prohibition of e-cigarettes may not have deterred their consumption but instead pushed these products into the underground market while also driving away responsible e-cigarette and HTP brands (Soni 2020). Since the ban was enacted in 2019, there have been numerous reports of e-cigarette seizures, amounting to substantial sums (Press Trust of India 2023; The Hindu Bureau 2022; Basheer 2022; Lalitha 2022; Singh 2022; Times of India 2023).

In September 2022 alone, the Directorate of Revenue Intelligence conducted two seizures of e-cigarettes worth Rs. 68 crores (Press Information Bureau 2022). Reports indicate that ENDS devices can be purchased both online and at local cigarette shops. Illicit businesses, potentially offering dangerous and unregulated products, thrive near educational institutions, including through WhatsApp groups (Indian Express 2023), indicating continued use of e-cigarettes. Moreover, advertisements for e-cigarettes continue to circulate on social media through third-party retailers. In fact, the Indian market provides customers with clandestine options for acquiring e-cigarettes via phone numbers and WhatsApp (Murukutla et al. 2022).

The Ministry of Health and Family Welfare (MoHFW) is currently collaborating with state governments and law enforcement agencies to enforce the ban more rigorously. However, a significant challenge lies in the fact that the ban falls under the jurisdiction of different ministries due to the sale of e-cigarettes through both online platforms and physical stores (Matharu 2023). The failure of the ban to achieve its intended objectives has prompted numerous calls for its reconsideration and replacement with a more scientifically grounded regulatory framework for e-cigarettes, founded on harm reduction principles (Ray 2022; Press Trust of India 2022).

Before deciding whether to implement prohibitions on specific goods, governments weigh various factors like revenue, tourism, crime rates, and unintended consequences on public health. This delicate balance between risk and reward has influenced India's regulation of products like alcohol and tobacco—items that impact health but also generate revenue for the government. It is crucial to evaluate whether a similar regulatory approach may be more appropriate in the case of e-cigarettes.

Chapter 4

Tobacco Risk Management

4.1 Risk Balancing as a Benchmark to Evaluate Policy

A less emphasised but viable alternative to cessation policies is facilitating access to nicotine in less harmful ways for those who struggle to reduce their tobacco consumption. This becomes particularly pertinent given that India reports the second-lowest quit rate among countries surveyed under GATS 2 (Economic Times 2021). Smokers attempting to quit remained at a standstill at 38.5% as reported in GATS 2 (2016-17), compared to 38.4% in GATS 1 (2009-10). The adoption of tobacco harm reduction strategies can play a pivotal role in achieving the National Health Policy 2017 target of reducing tobacco use by 30% by 2025 compared to 2009-10. These innovative products can complement existing tobacco cessation strategies, which currently primarily revolve around nicotine replacement therapies (NRT) (Misra 2022). Scaling up harm reduction strategies through national policies can also reduce costs and enhance access to safer alternatives (Economic Times 2021). Given the diverse range of tobacco and nicotine products available today, along with innovative products in development, there is an opportunity to establish risk-proportionate regulations rooted in scientific evidence. Treating all such products as equally harmful would merely safeguard existing products, potentially depriving consumers of safer choices (Cummings, Ballin, and Sweanor 2020, 11).

A risk-balancing framework empowers the government to protect non-smokers and discourage tobacco use overall while simultaneously safeguarding tobacco consumers by providing access to innovative, lower-risk products.

By imposing a ban and refusing to consider the potential use of e-cigarettes as a tool to reduce tobacco-related harm, the government may have deprived tobacco consumers of safer options and their right to informed decision-making. The FDA, for instance, envisions a risk continuum in tobacco regulation (Cummings, Ballin, and Sweanor 2020, 9) where different products carry varying levels of risks, and public health objectives can be achieved by regulating access accordingly.

Reducing nicotine levels in combustible tobacco products, establishing stringent standards for ENDS and HTP, conducting public awareness campaigns, educating medical practitioners, implementing fair taxation policies, and incentivizing manufacturers to invest in low-risk products are all key components of a risk-proportionate tobacco regulation framework (Cummings, Ballin, and Sweanor 2020, 13; Hatsukami and Carrol 2020, 10).

According to the FDA's risk continuum, protecting high-risk tobacco products like combustible cigarettes while prohibiting lower-risk options like ENDS and HTP is counterproductive and increases the risk of more tobacco-related deaths and diseases. This would run contrary to the government's fundamental duty to enhance public health. Estimates indicate that tobacco-related deaths could rise to 70% by 2030, with vulnerable communities bearing a disproportionate burden due to their higher tobacco use (Economic Times 2021). Consequently, risk-proportionate strategies assume even greater importance in the broader battle against tobacco.

Chapter 5

Lessons for India

The number of e-cigarette users prior to the ban was significantly lower compared to traditional cigarette smokers. Data from the Global Adult Tobacco Survey (GATS) for the period of January 1, 2015, to December 31, 2018, revealed that e-cigarette prevalence in India was a mere 0.02% (Pan et al. 2022), while the rate of adult tobacco smoking stood at 10.7% for 2016-2017. Therefore, the potential harm associated with ENDS and HTPs pales in comparison to combustible cigarettes. A study involving 3,000 Indian e-cigarette users found that only 17.5% of these users reported e-cigarettes as their first tobacco product, challenging the assumption that ENDS and HTP act as gateways to combustible cigarettes (Sharan et al, 2020). However, this finding does leave room for consideration that non-smokers might still be inclined to take up e-cigarettes as their initial tobacco product.

Regulating these products may achieve a more practical public health goal of helping people transition away from tobacco, while at the same time ensuring that these products are made available only to individuals who are unable or unwilling to quit smoking cigarettes.

A significant majority of smokers in India express concern about their tobacco dependency and a desire to quit. GATS 2 indicated that 55.4% of current smokers in 2016-17 were either interested in or planning to quit.

While the evidence regarding the effectiveness of e-cigarettes or HTP as smoking cessation tools remains inconclusive, other regions with regulatory frameworks for these devices have shown their potential as safer alternatives to combustible tobacco.

In the United States, for example, the Surgeon General recommended further scientific investigations into e-cigarettes as adult smoking cessation aids, even in the context of high youth usage (U.S. Department of Health and Human Services). In the UK, e-cigarettes have emerged as the most popular smoking cessation tool, with 27.2% of individuals opting for e-cigarettes to quit smoking, compared to 15.5% choosing Nicotine Replacement Therapy (NRT) (McNeill et al. 2021).

Research suggests that when combined with behavioural support, e-cigarettes may be more effective than NRT for smoking cessation (Hajen et al. 2019), with higher quit rates associated with nicotine-containing e-cigarettes compared to both NRT and non-nicotine e-cigarettes (Hartmann-Boyce et al. 2021).

Unlike nicotine patches, ENDS and HTPs offer a more similar behavioural experience to smoking, including the sensory aspects of nicotine intake. This makes them more user-friendly as smoking cessation tools, allowing users to gradually reduce nicotine intake and to eventually quit altogether.

Chapter 6

Adapting a Risk-Balancing Framework for India

Implementing a balanced risk framework for HTPs and ENDS is a prudent approach. Such a framework allows governments to strike a careful equilibrium between addressing potential health risks associated with HTPs/ENDS and recognizing their potential as harm reduction tools. Taking this in account, the following policy measures are recommended,

- **Regulation Based on Product Characteristics:** Develop risk proportionate regulations based on the characteristics and contents of novel tobacco products. Consider setting upper limits for constituents like nicotine and humectants when determining regulations.
- **Establish a sound regulatory framework** for HTP and ENDS to mitigate health risks associated with unregulated products in the black market. Implement standards and restrictions on device engineering, design, and materials to ensure safety and prevent device tampering and misuse through illicit additives.
- **Initial Introduction of HTPs with Regulation:** Permit the use of HTP while subjecting them to relevant provisions within the existing legal framework for tobacco products, such as COTPA, considering that HTP contain actual tobacco.
- **Responsible Product Usage Conditions:** Regulate product usage responsibly by imposing conditions such as geo-tagging, age verification, purchase limits.
- **Protection of Minors:** Restrict the sale of HTPs and ENDS to minors, whether directly or indirectly, in both physical and online markets. Implement robust penalties for violations to deter non-compliance.
- **Conditional Introduction of E-cigarettes:** If e-cigarettes are permitted by regulation, mitigate their appeal among youth and non-smokers through restrictions on e-liquid volume, puff limits, complicated device refilling processes, as well as limitations on flavourings, additives, packaging, and advertising.
- **Regular Surveys and Evidence-Based Regulation:** Conduct annual surveys to monitor HNB and e-cigarette usage and trends. Utilise the collected data to facilitate proactive, flexible, and evidence-based regulatory responses that align with evolving market dynamics and public health priorities. Additionally, a continuous study of scientific evidence, international best practices, and research on how HNBs and ENDS can effectively serve as harm reduction tools and smoking cessation aids, including statistical models and decision-theoretic frameworks. This will enable more informed policy decisions with greater public health impact.

Chapter 7

Conclusion

While prohibition may seem like a measure to safeguard public health, it carries substantial risks of unintended consequences. Policies built on abstinence tend to create thriving black markets where product quality remains unregulated, posing greater threats to public health due to the proliferation of counterfeit and hazardous goods. Additionally, governments miss out on legitimate tax revenue opportunities. Consequently, the potential drawbacks and opportunity costs associated with bans often outweigh the perceived benefits. Furthermore, regulation offers the added advantage of limiting government interference in individuals' private choices.

As COP 10 convenes from November 20-25, it is imperative that all attending Member States prioritize and take action to promote risk-proportionate regulations for THR products. A risk-balanced regulatory approach acknowledges that the government can protect public health by continuously evaluating evidence and adapting policies to address emerging risks. The ban on ENDS and HNB devices, has established a rigid system ill-prepared to respond promptly to the unintended consequences it has triggered. Reversing this damage from a legislative perspective is not only time and resource-intensive but may also result in irreversible health harm to those using illegal devices.

Given that HTPs are tobacco products with evidence suggesting harm reduction potential, particularly in facilitating the switch from more harmful cigarettes, it would be appropriate for the member states to establish separate risk proportionate regulations for HTPs.

Lastly, promote evidence-based, inclusive policymaking within the WHO Framework Convention on Tobacco Control, and consistently research scientific evidence and best practices concerning novel products. This approach will facilitate informed policy decisions that yield significant public health advantages by promoting harm reduction and smoking cessation.

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