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MINISTRY OF HEALTH & FAMILY WELFARE GOVERNMENT OF INDIA

REPORT OF TASK FORCE ON Tobacco Control



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The chapter in the current report is likely to be published as series of review articles in the Annals of the National Academy of Medical Sciences (India).

Disclaimer:

The views and opinions expressed in this report are those of the authors and do not necessarily reflect the official policy or position of any organisation.

National Academy of Medical Sciences (INDIA)

Directorate General of Health Services (Dte.GHS) Ministry of Health & Family Welfare, Govt of India

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We also acknowledge, with sincere appreciation, the efforts of all members of the Task Force, particularly the chairs of the thematic chapters:

Dr. Rana J. Singh, Dr. Pankaj Bhardwaj, Dr. Monika Arora, Mr. Ranjit Singh, Dr. Upendra Bhojani, Dr. Sonu Goel, Dr. Shalini Singh, and Ms. Opender Gill, who collaborated with domain experts to bring depth and insight to their respective sections.

A special note of appreciation is due to Dr. Prakash Chandra Gupta, Chairperson, and Dr. Sonu Goel, Secretary of the NAMS Task Force for Tobacco Control, for their visionary leadership and dedicated efforts in steering this initiative.

Finally, we extend our gratitude to all clinicians, academicians, and legal experts whose expertise and commitment have significantly enriched the content and quality of this document.

PREFACE



Dr. Prakash C. GuptaChairperson, NAMS Task Force
on Tobacco Control
Director - Healis Sekhsaria Institute
for Public Health



Prof. Sonu Goel
Secretary, NAMS Task Force on Tobacco Control
Director, Resource Centre for Tobacco Control Professor,
Department of Community Medicine
and School of Public Health
PGIMER, Chandigarh

It is with great pleasure and a sense of profound responsibility that we introduce this document compiled by the National Academy of Medical Sciences (NAMS) Task Force on Tobacco Control. As the Chairperson and Secretary of this esteemed task force, it has been an honour and a privilege to lead a dedicated team of experts in addressing one of our most critical public health challenges. The NAMS Task Force comprises of multiple working groups, namely arranging a series of chapters Tobacco Endgame, Youth Intervention, Tobacco Industry Interference, e-cigarettes, Tobacco Cessation Services, TAPS - Prohibit Brand Sharing/Stretching Regulations, Bidi & Other Indigenous Products, and Smokeless Tobacco Products. Through these concerted efforts of these working groups, the NAMS Task Force aims to enhance tobacco control measures in India. We hope this recommendation document prepared after intensive deliberation the NAMS Task Force serves as a crucial tool in the ongoing battle against tobacco use. Compiling insights of experts coupled with research findings shall provide evidence-based recommendations for advocacy efforts aimed at tobacco control.

Moreover, the contents in the document shall offer policymakers valuable insights into the most effective strategies and interventions for combating tobacco use within the country. By leveraging the information within this document, policymakers can develop and implement more robust tobacco control measures, thereby contributing to the broader public health agenda

and fostering healthier communities. As we navigate the complex tobacco control landscape, we must remain steadfast in our commitment to protecting public health and advancing evidence-based interventions. We extend our sincere gratitude to the NAMS and Task Force members for their unwavering dedication and commitment, as well as to the various Working Groups within it. Together, we are poised to significantly impact creating a healthier, tobacco-free future for all.

LIST OF ABBREVIATIONS

- Al Artificial Intelligence
- AIIMS All India Institute of Medical Sciences
- ANM Auxiliary Nurse Midwife
- ASHA Accredited Social Health Activist
- CDC Centers for Disease Control and Prevention
- CBAC Community Based Assessment Checklist
- COTPA Cigarettes and Other Tobacco Products Act
- CSR Corporate Social Responsibility
- CT-CardiovascularToxicants
- DA Disability-Adjusted Life Year
- DALYs Disability-Adjusted Life Years
- DBT Department of Biotechnology
- DBT/WellcomeTrustIndia Alliance Department of Biotechnology/WellcomeTrustIndia Alliance
- DEITY Department of Electronics and Information Technology
- DHF Digital Health Foundation
- DRI Directorate of Revenue Intelligence
- EVALI E-cigarette or Vaping Product Use-Associated Lung Injury
- ENDS Electronic Nicotine Delivery Systems
- ENNDS Electronic Non-Nicotine Delivery Systems
- ESG Environmental, Social, and Governance
- FCTC Framework Convention on Tobacco Control
- FDA U.S. Food and Drug Administration
- FSSR Food Safety and Standards Regulations
- FTND Fagerström Test for Nicotine Dependence
- FTP Flavoured Tobacco Products
- GATS Global Adult Tobacco Survey
- GATS2 Global Adult Tobacco Survey 2
- GDP Gross Domestic Product
- GSA Generation Saviour Association
- GST Goods and Services Tax
- HCP Healthcare Provider
- HCP Health Care Professional
- HRIDAY Health Related Information Dissemination Amongst Youth ICD-11 International Classification of Diseases, Eleventh Revision ICMR - Indian Council of Medical Research
- ILBS Institute of Liver and Biliary Sciences
- IMA Indian Medical Association
- INR-Indian Rupee
- ITC Indian Tobacco Company
- ITCS Index for Tobacco Control Sustainability
- IVRS Interactive Voice Response System
- JIPMER Jawaharlal Institute of Postgraduate Medical Education & Research

- JUUL A brand of e-cigarette
- MACT Management of Tobacco Control
- MAHE Manipal Academy of Higher Education
- MoH Ministry of Health
- MoHFW Ministry of Health and Family Welfare
- MOIC Ministry of Information and Broadcasting
- NABH National Accreditation Board for Hospitals & Healthcare Providers
- NCD Non-Communicable Diseases
- NCDs Non-Communicable Diseases
- NCTC National Cancer Treatment Center
- NIC National Institute of Health
- NICPR National Institute of Cancer Prevention and Research
- NIMHANS National Institute of Mental Health and Neurosciences
- NOHP National Oral Health Program
- NTEP National Tuberculosis Elimination Program
- NGO Non-Governmental Organization
- NMC National Medical Commission
- NTCP National Tobacco Control Program
- NTQLS National Tobacco Quitline Services
- NTTLs National Tobacco Testing Laboratories PECA Prohibition of Electronic Cigarettes Act PHFI Public Health Foundation of India
- PHW Pictorial Health Warnings
- PPP Public Private Partnership
- RCTC Resource Centre for Tobacco Control
- RCF Rajasthan Cancer Foundation
- RDT Reproductive or Developmental Toxicants
- SEATCA South-East Asia Tobacco Control Alliance
- SEBI Securities and Exchange Board of India
- SIPHER Strategic Institute for Public Health Education & Research
- SLT Smokeless Tobacco
- SNS Social Networking Sites
- SOP Standard Operating Procedure
- TAPS Tobacco Advertising, Promotion, and Sponsorship
- TCC Tobacco Cessation Center
- TCCRC Tobacco Cessation Clinic Resource Center
- THR Tobacco Harm Reduction
- TFYC Tobacco Free Youth Campaign
- ToFEI-Tobacco Free Educational Institutions
- TVL-Tobacco Vendor Licensing
- UPVHA Uttar Pradesh Voluntary Health Association
- USD-United States Dollar
- WHO World Health Organization
- WHO-FCTC World Health Organization Framework Convention on Tobacco Control
- WHO MPOWER-World Health Organization's MPOWER measures
- YLLs Years of Life Lost

OPERATIONAL DEFINITION OF TERMS USED IN THE REPORT

- 1. **Tobacco Control:** The strategic actions, policies, and programs aimed at reducing the health, social, and economic burden of tobacco use through regulatory, educational, and behavioral interventions at national, regional, and local levels.
- 2. **Smokeless Tobacco (SLT):** Any form of tobacco consumed without burning, including chewing, sniffing, or placing tobacco products in the mouth. This category includes products like gutkha, khaini, and paan with tobacco.
- 3. **Tobacco Vendor Licensing (TVL):** A regulatory measure that mandates vendors to acquire licenses to sell tobacco products, with the aim of controlling the availability and sales of tobacco, particularly near educational institutions and other public areas.
- 4. **Endgame Strategy:** A comprehensive approach aimed at permanently reducing tobacco use prevalence to minimal levels, or eliminating the commercial sale of tobacco products within a specific timeframe.
- 5. **Tobacco Advertising, Promotion, and Sponsorship (TAPS):** The marketing and promotional activities undertaken by the tobacco industry to advertise tobacco products, increase sales, and maintain brand presence, including surrogate advertising.
- 6. **Tobacco Industry Interference (TII):** The efforts by tobacco companies to influence policy-making, delay or obstruct regulations, and undermine tobacco control efforts through lobbying, litigation, and partnerships with influential stakeholders.
- 7. **Pictorial Health Warnings (PHW):** Graphic images and text on tobacco product packaging that depict the negative health consequences of tobacco use. PHWs are mandated to cover a significant portion of the packaging surface to deter consumption.
- 8. **Tobacco Cessation Centers (TCC):** Specialized facilities or services established to help individuals quit tobacco use, offering behavioral counseling, pharmacological treatment, and community outreach to reduce tobacco dependence.
- 9. **WHO MPOWER:** A set of six evidence-based tobacco control measures developed by the World Health Organization to assist in the implementation of effective strategies to reduce tobacco use.

MPOWER stands for:

- o Monitoring tobacco use and prevention policies
- o Protecting people from tobacco smoke
- o Offering help to quit tobacco use
- o Warning about the dangers of tobacco
- o Enforcing bans on tobacco advertising, promotion, and sponsorship
- o Raising taxes on tobacco

- 10. **Corporate Social Responsibility (CSR) by Tobacco Industry:** Public relations activities undertaken by the tobacco industry under the guise of corporate responsibility, often used as a strategy to maintain a positive image while promoting their products indirectly.
- 11. **Electronic Nicotine Delivery Systems (ENDS):** Devices such as e-cigarettes and vapes that deliver nicotine to users in vapor form, often marketed as alternatives to traditional tobacco products but carrying health risks of their own.
- 12. **Nicotine Replacement Therapy (NRT):** A treatment designed to help tobacco users quit by providing low doses of nicotine without the harmful effects of smoking, available in forms such as gums, patches, and lozenges.
- 13. **National Tobacco Control Program (NTCP):** The Government of India's initiative under the Ministry of Health and Family Welfare, aimed at creating awareness about the harmful effects of tobacco use, implementing tobacco control laws, and providing support to tobacco users in quitting.
- 14. **Framework Convention on Tobacco Control (FCTC):** The first international public health treaty negotiated under the World Health Organization, aimed at reducing the demand and supply of tobacco products worldwide through comprehensive regulatory measures.

EXECUTIVE SUMMARY

The National Academy of Medical Sciences (NAMS) Task Force for Tobacco Control in India was established to tackle the widespread issue of tobacco use, which significantly impacts the nation's public health. India, as the world's second-largest tobacco consumer, faces substantial challenges in regulating a range of products, including cigarettes, bidis, smokeless tobacco, and emerging products like e-cigarettes. Although the country has enacted laws such as the Cigarettes and Other Tobacco Products Act (COTPA) 2003 and ratified the WHO Framework Convention on Tobacco Control (FCTC), there remain significant gaps in enforcement and implementation.

The NAMS Task Force was created to evaluate the current status of tobacco control in the country, prioritize key areas, and provide evidence-based recommendations to enhance policy effectiveness. The task force has been organized into specialized working groups addressing key priority areas i.e. Tobacco Cessation Services, Tobacco Industry Interference, Youth Interventions, Smokeless Tobacco Products, Bidi & Other Indigenous Products, E-cigarettes, Tobacco Endgame, and Tobacco Advertising and Promotion.

Major Recommendations

1. Tobacco Industry Interference

- I. Formulate a comprehensive national policy aligned with WHO FCTC Article 5.3, involving all government ministries to prevent and manage tobacco-related harms, with clear goals, multi-departmental strategies, and a framework for addressing conflicts of interest.
- II. Implement measures for mandatory reporting and transparency in interactions with the tobacco industry, while rejecting partnerships, prohibiting preferential treatment, and regulating CSR activities.
- III. Establish an independent body to monitor and report tobacco industry interference, including creating an Indian Tobacco Industry Interference Index, to ensure accountability and protect public health policies from industry influence.

2. E-Cigarette

- I. Ensure the strict enforcement of the 2019 ban on e-cigarettes, with significant penalties for violations, including online sales and cross-border marketing.
- II. Campaigns and initiatives to create and improve awareness regarding the harms of ENDS products and laws about their restrictions.
- III. It is recommended to actively engage schools and community organizations in initiatives aimed at increasing awareness of the harmful effects of e-cigarettes.

3. Youth Intervention

- I. Increase the legal age for purchasing tobacco products to 21 years to delay initiation and reduce long-term tobacco use among youth.
- II. Mandate tobacco-free policies in all educational institutions, ensuring enforcement and periodic assessments to maintain compliance.
- III. Introduce age-appropriate to bacco prevention education in school curricula at all levels to raise awareness and empower youth to make informed choices.

4. Tobacco Endaame

- Develop and implement long-term policies aimed at achieving near-zero tobacco use prevalence by 2030, with special focus on phasing out the commercial sale of tobacco products.
- II. Strengthen the enforcement of tobacco control initiatives by introducing measures such as

- vendor licensing and providing alternative employment opportunities for those in the tobacco industry, ensuring a gradual phase-out of tobacco sales.
- III. Foster strategic preparedness to effectively counter tobacco industry interference and influence across all sectors, including the media, through nationwide adoption of Article 5.3 of the Framework Convention on Tobacco Control (FCTC).

5. Bidi & Other Indigenous Products

- It is recommended that the Ministry of Commerce and Industry, in collaboration with the Ministry of Micro, Small, and Medium Enterprises, reconsider the classification of the bidi industry as a cottage industry and reassess the regulatory and tax exemptions currently granted to manufacturers, given the significant health risks posed to both consumers and workers involved in production.
- II. Civil society organizations should be actively involved in raising awareness among bidi workers about the health risks associated with bidi rolling, while also educating them on alternative livelihood opportunities.
- III. Academicians are encouraged to conduct operational and exploratory research across various domains to support the development of effective prevention and cessation strategies, as well as to counter the tobacco industry's misleading narratives.

6. TAPS (Tobacco Advertising, Promotion, and Sponsorship) - Prohibit Brand Sharing/Stretching

- I. The Central Government should enforce a comprehensive ban on point-of-sale tobacco advertising and promotion, including visible product displays, to reduce tobacco use, particularly among youth.
- II. State Governments should implement licensing mechanisms for tobacco vendors, with compliance to tobacco control laws as a condition for granting or renewing licenses.
- III. Civil society organizations should actively monitor and report violations of tobacco advertising and promotion laws to relevant authorities, aiding in the enforcement of COTPA regulations.

7. Tobacco Cessation Services

- I. Establish a national expert group to develop a strategic action plan for tobacco cessation across all healthcare levels, ensuring sustainable financial support and infrastructure.
- II. Integrate tobacco cessation services into existing national health programs and expand community-based cessation initiatives through training of healthcare workers at the primary level.
- III. Encourage collaboration between public and private sectors, including insurance schemes, to ensure comprehensive coverage and reimbursement for tobacco cessation treatments, with quality assurance through accreditation of services.

8. Smokeless Tobacco Products

- I. Fully enforce existing tobacco control laws, including WHO FCTC provisions, COTPA, and Pictorial Health Warnings on smokeless tobacco (SLT) products, with strict penalties for violations.
- II. Implement nationwide campaigns to raise public awareness about the health risks of SLT use, focusing on vulnerable populations, and integrate tobacco cessation services into national health programs.
- III. Introduce mandatory vendor licensing for SLT sales to regulate accessibility, particularly to minors, and implement comprehensive tax reforms to increase SLT taxation in line with WHO recommendations.

INTRODUCTION

Tobacco utilization remains a significant public health concern in India, leading to a substantial burden of disease, disability, and mortality. India stands as the second-largest consumer of tobacco globally, showcasing a wide array of tobacco products utilized nationwide, encompassing items like cigarettes, bidis, smokeless tobacco, and emerging options such as e- cigarettes. The tobacco crisis in India is intricately influenced by cultural, economic, and social elements, rendering it a pivotal realm for public health interventions.

Despite the presence of an all-encompassing tobacco control legislation in India, namely the Cigarettes and Other Tobacco Products Act (COTPA) 2003, and the nation's dedication to international frameworks like the WHO Framework Convention on Tobacco Control (FCTC), notable deficiencies persist in the efficient execution and enforcement of tobacco control strategies. These deficiencies are notably conspicuous in domains like Tobacco Cessation Services, the taxation on Bidi & Other Indigenous Products, management of E-cigarettes, Youth Intervention initiatives, and reinforcement of Tobacco Advertising and Promotion.

Moreover, Tobacco Industry Interference (TII) is a persistent obstacle to effective tobacco control measures in influencing policy formulation and subverting public health endeavours through diverse tactics, including advocacy, legal actions, and corporate social responsibility (CSR). This interference not only obstructs the enforcement of prevailing regulations but also jeopardizes advancements towards realizing a Tobacco Endgame and fostering a Tobacco-Free Generation (TFG).

With the pressing necessity to tackle these shortcomings, the NAMS has instituted a National Task Force on Tobacco Control in India. The task force is designed to evaluate the present status of tobacco control in India, pinpoint areas necessitating immediate attention, and present practical recommendations to fortify tobacco control policies and actions. The focal points encompasses upon Tobacco Cessation Services, Bidi & Other Indigenous Products, E- cigarettes, Youth Interventions, TAPS (Tobacco Advertising and Promotion), addressing Tobacco Industry Interference in managing Smokeless Tobacco Products and advocating for Tobacco Endgame.

BACKGROUND

Tobacco consumption is a prominent factor in preventable mortality on a global scale, with India carrying a disproportionate portion of this burden. According to the National Family Health Survey, in 2021, the number of adult tobacco users in India exceeds 330 million, resulting in over a million deaths annually due to tobacco-related illnesses. The economic repercussions of tobacco usage in India are substantial, with huge healthcare expenses and reduced productivity costing billions of dollars each year.

Despite notable advancements in curtailing tobacco consumption through measures like the enforcement of graphic health warnings on tobacco products, the prohibition of smoking in public areas, and the escalation of tobacco taxes, banning of electronic cigarettes & gutkha certain areas remain inadequately attended to. A significant issue is the prevalent use of smokeless tobacco, especially among rural and socioeconomically disadvantaged groups. The significance of Bidi smoking, a substantial contributor to tobacco usage in India, is frequently disregarded in tobacco management tactics due to its perceived cultural and economic value. The introduction of novel tobacco commodities like e-cigarettes creates an additional hurdle for tobacco regulation in India. These products are frequently advertised as safer substitutes to conventional tobacco items, aiming at the younger population and non-smokers, potentially undoing decades of progress in tobacco control efforts.

Youth involvement stands out as another crucial domain necessitating immediate focus. The tobacco industry persists in targeting young individuals using diverse tactics, including the marketing of flavoured tobacco items, social media promotions, and brand expansion. This is particularly alarming given research demonstrating that a majority of tobacco users initiate consumption during their adolescent years, leading to prolonged dependency and heightened susceptibility to tobacco-linked maladies.

The issue of Tobacco Industry Interference (TII) is widespread, with the industry deploying sophisticated strategies to undermine tobacco control policies and standards. The industry's sway is evident in the delays in executing tobacco control measures, the weakening of current regulations, and the advocacy for policies favourable to the industry.

In reaction to these obstacles, the NAMS Task Force on Tobacco Control endeavours to craft a comprehensive document addressing these crucial deficiencies in tobacco regulation in India. The report will furnish evidence-driven suggestions for reinforcing tobacco control policies and actions, concentrating on the recognized priority sectors. Through bridging these gaps, the task force aims to contribute to the overarching objective of alleviating the burden of tobacco- related ailments and fatalities in India, progressing towards a Tobacco-Free Generation.

TERMS OF REFERENCE (TORS) FOR THE TASK FORCE

The following are the proposed terms of reference for the Task Force on Tobacco Control in India:

1. To access the current status of Tobacco control in the country and identify priority (thematic) areas

Activities to be undertaken:

- Formation of an advisory committee based on their expertise and experience to guide on different aspects of tobacco control
- Conduction of review of literature pertaining to priority (thematic) areas relevant to tobacco control. The relevant technical documents, published papers, reports, and various national and state guidelines will be used as reference materials.
- Understand the challenges and barriers faced in implementing tobacco control measures in India and identify the factors hindering program implementation.
- Facilitate regular meetings with the task force to finalize the priority/thematic areas to be addressed.
- 2. To identify existing gaps in the thematic areas of Tobacco control in India. Activities to be undertaken:
- Formation of working groups in various thematic areas based on their expertise/experience.
- Regular meetings/ focused group discussions of the working groups.
- Undertaking SWOT analysis and identification of critical gaps in various thematic areas.
- Development of Capacity-building programs in various thematic areas and conducting various webinars/workshops for multiple stakeholders.
- 3. To suggest suitable recommendations to various stakeholders for improvements in the area of tobacco control.

Activities to be undertaken:

- Regular meetings with various stakeholders to review the program and develop consensus statements.
- Development of white paper/position paper on key thematic areas.
- Prepare a comprehensive report and submitted to NAMS for advocacy with various stakeholders.

METHODOLOGY

The development of the Task Force report on Tobacco Control in India followed a structured, multiphased approach (Figure 1).

The process began with a planning phase led by the Resource Centre for Tobacco Control (RCTC), Department of Community Medicine and School of Public Health, PGIMER, Chandigarh, under the leadership of Prof (Dr.) Sonu Goel, Director, Resource Centre for Tobacco Control. This phase was driven by the recommendations proposed during the "3rd National Consultation on Dissemination of Good, Replicable, and Innovative Practices of Tobacco Control in India," held in New Delhi on July 18, 2023. The consultation brought together Directors from 14 All India Institutes of Medical Sciences (AlIMS), with 12 directors attending in person and 2 participating remotely. These institutions, autonomous public medical universities under the Ministry of Health and Family Welfare, were also joined by Directors from the Public Health Foundation of India (PHFI), the National Institute of Cancer Prevention and Research (NICPR), The Union--International Union Against Tuberculosis and Lung Disease, the National Institute of Health and Family Welfare (NIHFW), besides Deputy Director General of Health Services -Directorate General of Health Services, Ministry of Health and Family Welfare, Govt of India, and a former Union Health Secretary, Govt of India.



Figure 1: Methodology Flowchart for the Development of the NAMS Task Force Report on Tobacco Control in India

Following the recommendation of the 3rd National Consultation in Delhi, the RCTC team began mapping experts to form the National Task Force, engaging in internal discussions with various senior key stakeholders to nominate the members of the NAMS Task Force for Tobacco Control in India.

Following this, the first official meeting of the NAMS Task Force for Tobacco Control was called for December 14, 2023, from 1:30 PM to 4:00 PM, at the Golden Tulip, Sector 29, Gurugram. During the first official meeting, the Terms of Reference (TOR) included the following:

- I. To assess the current status of Tobacco control in the country and identify priority (thematic) areas.
- I. To identify existing gaps in the thematic areas of Tobacco control in India.
- II. To suggest suitable recommendations to various stakeholders for making improvements in the area of Tobacco control.

During the Task Force meeting, the Chairperson and Secretary of the Task Force were formally appointed. Prof (Dr.) Sonu Goel nominated Dr. Prakash C. Gupta as Chairperson, Dr. Suneela Garg seconded the same. Thereafter, he graciously accepted the role. Then, Dr. P.C. Gupta nominated Prof (Dr.) Sonu Goel as Secretary for the task force, with all members accepting the same, Prof (Dr.) Sonu Goel accepted the role.

The meeting included a comprehensive discussion on the challenges and obstacles encountered in implementing tobacco control measures. Key priorities in tobacco control were identified, and it was agreed that each expert would be responsible for addressing one or two of these priorities, based upon his/her expertise. To facilitate this, working groups in & primary thematic areas, each consisting of 6-7 members, were established, to submit their chapters within the next three months:

The thematic areas and the Chairperson names are as follows:

- 1. Tobacco Cessation Services Dr. Rana J. Singh, Director Tobacco Control, Vital Strategies (South East Asia)
- 2. Bidi & Other Indigenous Products Dr. Pankaj Bhardwaj, Professor & Academic Head, School of Public Health, All India Institute of Medical Sciences, Jodhpur (AIIMS), Jodhpur
- 3. E-cigarettes Dr. Monika Arora, Vice President (Research and Health Promotion), Public Health Foundation of India (PHFI)
- 4. TAPS- Prohibit Brand Sharing/Stretching Mr. Ranjit Singh, Legal Expert, Supreme Court of India
- 5. Tobacco Industry Interference Dr. Upendra Bhojani, Faculty & DBT/Wellcome Trust India Alliance Senior Fellow, Institute of Public Health, Bengaluru
- 6. Tobacco Endgame- Prof (Dr.) Sonu Goel, Professor, Department of Community Medicine and School of Public Health, Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh
- 7. Smokeless Tobacco Products- Prof (Dr.) Shalini Singh, Director & Scientist G, ICMR National Institute of Cancer Prevention and Research, Ministry of Health and Family Welfare, Government of India.
- 8. Youth Intervention- Ms. Opinder Preet Kaur Gill, Director Programs, Generation Saviour Association.

During the meeting, the following key action points were proposed and followed:

- 1. The Secretariat of the Working Groups has been established at PGIMER, Chandigarh. It shall share a draft structure of the chapter with all chairpersons of the working group before 25th December 2023.
- 2. The working group chairperson will share the list of proposed members in their respective groups in a Google Form link before 31st December 2023.
- 3. The working group chairs shall share the concept note of various chapters before 30th January 2024. The comments on the concept note shall be shared by the Secretariat to respective Chairpersons.
- 4. The working group shall submit the chapter by 31st March 2024.
- 5. The chapters submitted by working groups shall be screened by the Secretariat and thereafter reviewed by experts by 15th April 2024.
- 6. The next draft of the chapter (after incorporating the changes suggested by the reviewers) shall be sent to the Secretariat by 30th April 2024.
- 7. The Secretariat thoroughly reviewed the draft chapters and communicated on an individual basis to the working group team for value addition in the chapter. This exercise was completed by 31st May 2024.
- 8. The final document was thereafter submitted to the Secretariat with the intent to be further submitted to NAMS before 31st September 2024.
- 9. A WhatsApp Group for regular communication on working group activities for smooth coordination shall be prepared by the Secretariat, PGIMER, Chandigarh.

Following the first meeting, the second official meeting of the NAMS Task Force for Tobacco Control was conducted on January 25, 2024, from 3:00 PM to 4:15 PM online. It was done to review and streamline the process, as discussed in the last meeting. The working groups and additional experts suggested by members in the meeting (and agreed upon by Chairs) are as follows:

- Tobacco Cessation Services (Chair: Dr. Rana J. Singh):
 Additional Name Suggested include Dr Abhishek Ghosh
- Bidi & Other Indigenous Products (Chair: Dr. Pankaj Bhardwaj)
 Additional Names Suggested include Dr Yogesh Jain, Dr Nirmalya Mukherjee, Dr Radhika Khajuria, Ms Bhavna Mukhopadhyay.
- 3) E-cigarettes and Youth Intervention (Chair: Dr. Monika Arora)
 It was consensually agreed that two distinct groups shall be formed, one focusing exclusively on the themes of e-cigarettes and other on youth intervention, each led by different individuals. Ms. Opender Gill was appointed chair of the Youth Intervention group, which included members such as Mr. Cyril Alexander, Jyoti Choudhary, Susan Samson, Dr. Puneet Chahar, and Aastha Bagga. Meanwhile, Dr. Monika Arora was designated as chair of the E-cigarettes group, with members including Dr. Tina Rawal, Ms. Niharika Rao, Dr. Rakesh Gupta, Dr. Shivam Kapoor, Dr. Mangesh S. Pednekar, Dr. Melina Samar Magsumbol, and Mr. Praveen Sinha.
- 4) TAPS- Prohibit Brand Sharing/Stretching (Chair: Mr. Ranjit Singh)

Additional names suggested include Dr. Radhika Shrivastav, Dr. Pragati Hebbar, Dr. Garima Bhatt, Ms. Rishika Khare, Ms. Vaishaki Malik, and Mr. Cyril Alexander.

5) Tobacco Industry Interference (Chair: Dr. Upendra Bhojani)

Additional names suggested include Dr. Muralidhar M. Kulkarni, Dr. Mira B. Aghi, Mr. Cyril Alexander, Mr. Vivek Awasthi, Dr. Nirmalya Mukherjee, Dr. Aastha Bagga, and Ms. Jhumki/Pradeep Nagar.

6) Tobacco Endgame (Chair: Dr. Sonu Goel)

Additional names suggested include Dr. Pankaj Chaturvedi, Mr. Arun Verma, Dr. Mira B. Aghi, and Mr. Prabhakara.

7) Smokeless Tobacco Products (Chair: Dr. Shalini Singh)

Additional names suggested include Dr. Dhirendra Sinha, Mr. Deepak Mishra, and Dr. Mangesh S. Pednekar/Dr. Namrata Puntambekar.

The chairs obtained concurrence from the additional members and recorded their names in a Google sheet. It was told that all working groups should conduct their first meeting by February 10, 2024, and share the recording and photos with the Secretariat at PGIMER for documentation. Additionally, the structure of the working papers, as decided in the previous meeting, was discussed, with further expert suggestions being sought.

8) Youth Intervention (Chair: Ms. Opender Preet Kaur Gill)

Additional names suggested include Mr. Cyril Alexander, Ms. Jyoti Choudhary, Ms. Susan Samson, Dr. Puneet Chahar, Dr. Tina Rawal, Dr. Aastha Bagga.

7. Task Force Members

Prof (Dr) Sonu Goel
Secretary, NAMS Task Force for Tobacco
Control
Professor, Department of Community
Medicine and School of Public Health
Postgraduate Institute of Medical
Education and Research (PGIMER),
Chandigarh.

Name of the working group and chairs of the working groups

1. Smokeless Tobacco Products

Dr. Shalini Singh Director & Scientist G ICMR – National Institute of Cancer Prevention and Research Ministry of Health and Family Welfare, Government of India.

2. Tobacco Industry Interference

Dr. Upendra Bhojani Faculty & DBT/Wellcome Trust India Alliance Senior Fellow Institute of Public Health Bengaluru.

3. Tobacco Cessation Services

Dr. Rana J. Singh Director-Tobacco Control Vital Strategies (South East Asia)

4. Bidi & Other Indigenous Products

Dr. Pankaj Bhardwaj

Professor & Academic Head School of Public Health

All India Institute of Medical Sciences Jodhpur (AIIMS), Jodhpur.

5. TAPS- Prohibit Brand Sharing/ Stretching

Mr. Ranjit Singh, Legal Expert Supreme Court of India.

6. Tobacco Endgame

Dr. Sonu Goel, Professor, Department of Community Medicine and School of Public Health Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh.

7. E-cigarette

Dr. Monika Arora Vice President (Research and Health Promotion) Public Health Foundation of

India (PHFI)

8. Youth Intervention

Ms. Opinder Gill

Director Programs, Generation Saviour Association (GSA)

Working group experts

Tobacco Cessation Services (Chair: Dr. Rana J. Singh):

Members:

- I. Dr. Puneet Chahar
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CHAPTER-1

Tobacco Industry Interference in India:
Implications on Public Health and Measures
to Protect Effective Tobacco
Control Policies/Programs

Tobacco industry interference in India: implications on public health and measures to protect effective tobacco control policies/programs

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Background

In this section, we describe what is tobacco industry interference and why it is problematic for effective tobacco control and public health in general. We then briefly describe the nature and extent of tobacco industry interference globally and in India. We also highlight some of the major tobacco industry interference tactics observed in India.

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Tobacco industry interference

The World Health Organization (WHO) defines tobacco industry interference as "...a broad array of tactics and strategies used directly or indirectly by the tobacco industry to interfere with, or influence, the setting and implementation of effective tobacco control measures..."(1). Tobacco industry is unique and it is unlike many other industries as (i) tobacco industry produces products that are known to be lethal killing half of their users prematurely, (ii) tobacco industry negatively affects environment (land, air, water) throughout the lifecycles of tobacco products, (iii) for long, tobacco industry kept hidden from public and governments, the knowledge that tobacco and nicotine are harmful to human health, and (iv) there has been a well-documented history of its interference in public policy and programs related to tobacco to delay, dilute or stall tobacco control measures and/or make them in favor of industry interests. Tobacco industry can't be seen as a legitimate stakeholder in tobacco control as there is a fundamental and irreconcilable conflict between the interest of tobacco industry. Tobacco industry primarily produce and profit from sales of lethal tobacco products, whereas public health policies and programs aim to protect people's health from tobacco-related harms (2).

Tobacco industry may be understood narrowly or more broadly. For example, the World Health Organization Framework Convention on Tobacco Control (WHO-FCTC) defines the tobacco industry to be made up of "...tobacco manufacturers, wholesale distributors and importers of tobacco products" (3). The Africa Centre for Tobacco Industry Monitoring and Policy Research defines tobacco industry to be made up of "...large trans-national companies, state-owned entities and domestic growers, manufacturers, importers, wholesalers and retailers of tobacco. It also includes a wide range of supporting consultancies specializing in such areas as marketing, legal services and lobbying" (4). Hence, in the context of tobacco industry interference in public health, the tobacco industry is seen as not just those entities that are directly engaged in production and sale of tobacco products but also any other individual or entity that works towards furthering the interest of the tobacco industry.

Tobacco Industry Interference: A Global Challenge

Tobacco industry interference in effective tobacco control policies and programs is indeed a global challenge. There have been several documented instances of industry interference within global tobacco control efforts. An inquiry by the WHO revealed tobacco industry interference within the process and functions of the WHO (1). WHO-FCTC, the first ever global health treaty initiated by the WHO, in its preamble, recognizes "the need to be alert to any efforts by the tobacco industry to undermine or subvert tobacco control efforts and the need to be informed of activities of the tobacco industry that have a negative impact on tobacco control efforts..."(3). The WHO-FCTC in its Article 5.3, part of the general obligations, states that "In setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law"(3).

The global tobacco industry interference index, which is produced by the Global Centre for Good Governance in Tobacco Control, uses publicly available information to map tobacco industry interference and implementation of the WHO FCTC Article 5.3 in several countries across the globe (5). The index provides a score of up to 100 for each country, wherein greater the score greater the degree of tobacco industry interference and lesser the implementation of the WHO FCTC Article 5.3. The global tobacco industry interference index for the year 2023 included 90 countries covering about

87% of the world's population (5). It revealed that none of the countries were spared from tobacco industry interference. For the 80 countries that had previous reports or index scores available for comparison, the tobacco industry interference worsened in 43 countries. Some improvement indicating progress in protecting their public health policies from tobacco industry interference was seen in 29 countries, while eight of the countries experienced status quo (5).

Tobacco Industry Interference in India

India is no exception when it comes to tobacco industry interference in public health policies and programs. There have been several documented instances of tobacco industry interference resulting in negative impact on effective tobacco control policies/programs or their implementation. For example, delay and dilution in implementation of pictorial health warnings on tobacco products, and delays and/or setbacks in implementation of prohibitions on gutka and/or pan masala containing tobacco (6,7). Trade Representatives of Electronic Nicotine Delivery System (TRENDS) opposed all government-led efforts right from issuing

an advisory to making an ordinance and passing "The Prohibition of Electronic Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement)", 2019 Act (8).

The tobacco industry interference index score for the year 2023 for India was 58 out of 100 indicating a relatively high degree of tobacco industry interference (5). Globally, out of 90 countries that were ranked (in an increasing order of tobacco industry interference) in the year 2023, India stood at 43rd place (5). India has shown some improvements in reducing the tobacco industry interference index scores since the year 2018 when such index was produced for the first time for India. A study analyzing the trend in tobacco industry interference and the level of implementation of WHO-FCTC Article 5.3 from 2018 to 2021 revealed that the overall score of the tobacco industry interference index for India decreased by 15 points from 72 (in 2018) to 57 (in 2021) (8). This improvement in implementing the WHO-FCTC Article 5.3 has largely come from limiting the unnecessary interactions between the tobacco industry and public agencies, avoiding conflicts of interest within public officials for tobacco control, and adopting preventive measures for tobacco industry interference. However, major gaps remain in areas of preventing industry participation and influence in policy development and implementation, regulating the so-called corporate social responsibility (CSR) activities by tobacco industry, preventing state provision of benefits or incentives to tobacco industry, and enhancing transparency (8). Also, one needs to be cautious about interpreting such change as these indices are based only on publicly available information while tobacco industry interference by its very nature may be hidden from public gaze. In fact, the most recent tobacco industry interference index (in 2023) reported a score of 58, one point higher than in the year 2021.

More recently, studies in India have also looked at tobacco industry interference at sub-national (state) level. Kumar et al (9). used an index adopted from the Southeast Asia tobacco control alliance tobacco industry interference index to assess the implementation of the WHO-FCTC Article 5.3 in Karnataka. They put the index score at 46 out of the total score of 95 indicating high degree of tobacco industry interference in the state. They found that the so-called CSR activities by tobacco industry, conflicts of interest among public officials/agencies for tobacco, and unnecessary interactions between public agencies and tobacco industry were the major areas of tobacco industry interference (9,10).

Another study (unpublished) looked at assessing the level of tobacco industry interference in 10

Indian states over a period of nearly 3 decades (1990-2017). It used a tool adopted from the South-East Asia Tobacco Control Alliance (SEATCA) on tobacco industry interference. The index score implied the extent of industry interference, i.e., higher the score was for a state, greater was extent of its interference. A wide variability was seen across the states. Karnataka had the highest number of tobacco industry interference incidents (n=112) with the index score of 441.8, while Nagaland had no such incidents with an index score of zero (11). Of course, we need to keep in mind that the index relied only on publicly available information. They found that the highest number of tobacco industry interference incidents were related to governments providing benefits to tobacco industry, followed by the so-called CSR activities by tobacco industry, followed by unnecessary interactions between governments and tobacco industry, followed by industry participation in policy development (11).

Major Tobacco Industry Interference Tactics

Tobacco industry is known to use several interference tactics that are well documented globally

(1). We highlight some of the major interference tactics used in the Indian context (12). Tobacco industry has been known to exaggerate the economic and livelihood significance of itself. It does this through reports it publishes, through press meets as well as through paid advertisements and lobbying. While it is difficult to arrive at the precise estimates of tobacco dependent livelihoods in India (given the informality in the sector), Nayak NS (13). shows that a careful estimation based on reliable government sources puts tobacco dependent livelihoods in India to be around 7.25 million against an exaggerated claim of about 45.7 million workers by a tobacco industry body. When industry boasts of contributions to the economy, it does not highlight the economic costs of tobacco-related diseases. John et al. (14) estimated that the cost of tobacco-attributable diseases and deaths for the year 2017-18 for people aged 35 years and older to be INR 1773.4 billion amounting to about 1.04% of India's Gross Domestic Product. Also, they reported that the excise revenues generated from tobacco in the previous year accounted for merely 12.2% of the total costs incurred. At household level, the consumption expenditures on tobacco have shown to cut down expenditures on some of the essential items such as child education and food (15).

Litigations by the tobacco industry, especially challenging tobacco control reforms, is another common strategy to delay or stall effective tobacco control measures. Dsouza and Bhojani (7,16), demonstrate how the tobacco industry systematically used litigations to challenge regulations by state governments to prohibit smokeless tobacco products. Litigations not only result in delays and/or dilutions in policies and their implementation, but also leads to intimidation of regulatory authorities and tobacco control advocates. The use of the so-called corporate CSR activities by the tobacco industry is another such tactic. While CSR by businesses is seen as a desirable attribute of responsible business conduct in India and globally, the WHO considers such activities by tobacco industry as nothing but personal relations strategy (17). This is because the core business of the tobacco industry, which is to produce and profit from tobacco products that are lethal, is not in line with the social goals. The CSR activities create a favorable image of tobacco industry among public and policy makers while hiding its hazardous impact on society. It enables companies to use CSR as an instrument to earn societal recognition and license to operate, while erasing the harm accruing from the product it produces. It also enables tobacco industry an ease-of-access to policy influencers or policy makers as it often gets into partnerships with public agencies or provides sponsorship to public events through its CSR. This remains one of the major problematic aspects of tobacco industry

operations in India. In fact, Yadav et al. (18). estimated that the tobacco industry spent/claimed about USD 36.6 million into CSR activities during the COVID 19 pandemic in India.

Besides political donations, tobacco industry is also known to fund research as well as educational programs. It is known to fund non-government organizations (NGOs) working in the social sector (19). Such contributions create a potential for the tobacco industry to shape these programs while raising its public profile. Political donations could become a barrier for those political parties, when they come to power, in taking stringent regulatory actions on tobacco industry. Tobacco industry has been one of major purchasers of electoral bonds, between 2019 and 2024. Tobacco industry is also known to engage in lobbying. Several actors and organized associations within the tobacco sector have often expressed their resistance to effective tobacco control measures through public demonstrations. Tobacco industry is also known to use front groups which "purports to represent one agenda which in reality is meant to solely serve interest/s of tobacco industry whose sponsorship is hidden or rarely mentioned.". (20).

Preventing Industry Interference

In this section, we provide a brief account of how policies to prevent tobacco industry interference evolved in India and the present status. We then describe gaps in existing policies as well as major challenges in effective implementation of these policies in states and at national level.

Evolution of policies to prevent to bacco industry interference in India

In the year 2004, India signed and fully ratified the WHO-FCTC and was the eighth country to do so. India played a leading role in FCTC negotiations to finalize its provisions and was the regional coordinator for the South-East Asian countries. As mentioned earlier, Article 5.3 of the WHO-FCTC, a part of general obligations, relates to protecting public health policies from tobacco industry interference. The WHO FCTC has also evolved guidelines for its implementation. The key recommendations for the parties (member countries signatories to the convention) include: (i) raising awareness on tobacco harms and the industry interference; (ii) limiting interactions with the industry and make them transparent; (iii) rejecting partnerships and non-binding/enforceable agreements with the industry; (iv) avoiding conflicts of interest for government officers; (v) mandating the industry to provide transparent and accurate information; (vi) denormalizing and regulating the so-called CSR activities by the industry; (vii) avoiding preferential treatment to the tobacco industry; and (viii) treating state-owned tobacco industry in the same way as any other tobacco industry (2).

However, neither tobacco control legislation at national level in India (cigarette and other tobacco products act, 2003) include a specific provision, nor there exists a separate national-level policy in line with the Article 5.3 of the WHO-FCTC. There have been voices demanding such a policy in India. A few public interest litigations specifically sought reliefs relating to implementation of the Article 5.3 of the WHO-FCTC. For example, in 2010, Karnataka High Court (W.P.No.27692/2010) directed Tobacco Board of India (a public agency) to withdraw funding and participation from a tobacco industry supported Global Tobacco Networking Forum (21). In the same litigation, the petitioner demanded the national government to form a policy in line with the Article 5.3 of the WHO-FCTC and submitted to the court a draft for such a policy that the respondent undertook to consider while framing such a policy (22). The Ministry of Health and Family Welfare (Government of India) brought in a code of conduct for officials working for the ministry and various institutions governed by the ministry to prevent tobacco

industry interference in the year 2020. In a later litigation in Madras High Court (W.P.

No. 9955 of 2014), a petitioner challenged CSR by tobacco industry and demanded that such funds be collected by the state- and/or central- government from tobacco industry for their specific use in strengthening tobacco control and/or care of those suffering from tobacco related diseases (23). As a result, a notification was issued from the Ministry of Corporate Affairs indicating that the businesses shall comply with the laws of the land including the tobacco control law while doing CSR activities.

In 2015, Punjab became the first Indian state to adopt a policy in line with the Article 5.3 of the WHO-FCTC. Since then, several states and some of the districts within states have adopted a policy in line with the Article 5.3 of the WHO-FCTC (24). In 2021, the Ministry of Health and Family Welfare (Government of India) adopted a code of conduct to prevent tobacco industry interference. This code applies to all the officials working within institutions governed by this ministry, its departments and all the autonomous institutions and offices under its jurisdiction and to any person acting on their behalf (25).

Gaps and Challenges

We now discuss some of the major gaps in policies as well as challenges in preventing tobacco industry interference in India.

Lack of a comprehensive national policy

While India has signed and fully ratified the WHO-FCTC, India is yet to adopt a national policy in line with the Article 5.3 of the Convention. The Ministry of Health & Family Welfare has adopted a code of conduct for public officials working within the ministry as well as within institutions governed by the ministry (25). The drawbacks of this policy are that it does not cover the entire government and its agencies and it does not have clear provisions on how the policy will be administered in case violations occur or are reported under this policy.

Gaps in sub-national level policies

There are still several states and union territories that are yet to adopt a policy in line with WHO FCTC Article 5.3. A study by Bassi at al. (26), that reviewed policies in line with the WHO-FCTC Article 5.3 adopted at state and district levels in India between the year 2015 and 2019 revealed several gaps in these policies. The study revealed that none of these policies had provisions mandating tobacco industry to report information to governments in a transparent and accountable manner. Also, none of these policies prevented preferential treatment to the tobacco industry by states. Many of these policies had no provisions to regulate the so-called CSR activities of the tobacco industry (26). Since 2019, some more states have adopted a policy in line with the WHO FCTC Article 5.3, in varying formats. While these policies imply a positive leadership at sub-national level, there remains a room to enhance these policies for them to have provisions corresponding to all the recommendations contained in the WHO-FCTC Article 5.3 implementation guidelines.

Sub-optimal implementation of existing policies

While 22 states and union territories in India have adopted WHO-FCTC Article 5.3 policy guidelines in some form to prevent tobacco industry interference, these policies are not being fully implemented as already described in the preceding paragraph. Some of these policies are yet to fully develop the implementation mechanisms including clear procedures on how to deal when complaints are received or what kind of penalties are to be imposed on violators. While health department officials

are generally aware of such policies, non- health departments that are equally or often more frequently the targets for tobacco industry interference are not always aware about these policies (26,27).

Lack of systematic monitoring of tobacco industry interference

At present, monitoring of tobacco industry activities including industry interference remains limited to producing a national level tobacco industry interference index on an annual basis using publicly available information. Many NGOs that are active in tobacco control serve as a watchdog and have flagged several incidences of tobacco industry interference. Often, its NGOs who have produced the India Tobacco Industry Interference Indices over the years. However, there is a lack of a robust sustainable system for comprehensive, systematic, ongoing monitoring of tobacco industry activities/interference in India. Given that publicly available information may not be enough to capture industry interference and given the lack of systematic monitoring efforts, it is highly likely that much of the industry interference goes undetected or is recognized only in hindsight. Also, there is no protection offered to whistleblowers under the prevailing policies.

Conflicts of interest within governments for tobacco control

India is among the largest producers and exporters of tobacco leaf in the world. Hence, tobacco, apart from being a health hazard, evokes many different interests including that of revenue and employment generation within governments. So, there remains conflicting interest by various public agencies in tobacco. An exploratory study by Rao et al. (28). In India could locate at least 100 instances of conflicts of interest within a two-year period of the study. They categorized these instances into six categories: (i) public support for tobacco industry by government representatives; (ii) ownership of, or investments in, tobacco companies by government functionaries; (iii) a person holding simultaneous positions in tobacco companies and the government; (iv) partnerships between the tobacco industry and public agencies; (v) conflicting public policies; and (vi) government agencies offering incentives to tobacco industry. The presence of conflicting interest for tobacco within governments makes it complex and creates potential for the tobacco industry to interfere with public policies related to tobacco, which needs to be addressed urgently by governments (28).

The changing face of tobacco industry in India

Due to several factors, tobacco businesses and associated entities have transformed and are transforming in a way that either makes it difficult to identify them as tobacco businesses or makes them a stakeholder in public health. For example, some of the large cigarette companies, globally and in India, have expanded into sectors other than tobacco including pharmaceuticals. They then often argue that they should not be treated as tobacco businesses while they still earn revenues from the tobacco sector. Also, as they expand into sectors like food, agriculture, hospitality or health, they claim/seek a role in formulation of public policies related to health. There is no mandate for businesses operating in the tobacco sector to get registered as such as tobacco business in India.

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RECOMMENDATIONS

5.1 Tobacco industry interference

5.1.1. For government at national level

Recognizing and framing the tobacco-related harms/burden as a broader development issue and hence making it a part of the national vision and policy documents. It implies the need to have a national level all-of-the-government articulation of a strategic document/policy setting the vision for preventing tobacco- and nicotine-related harms with tangible goals and multi- departmental strategies (incorporating both supply- and demand-side measures and including but not limited to those promoting alternative safer livelihoods for workers engaged in tobacco industry) to achieve these goals including a review framework.

The strategic document shall specify how various ministries of the government of India, and the governments across national, state, and local level will work together to align their actions to prevent and manage tobacco-related harms. Such a document will articulate, in a tangible manner, how the prevailing conflicts in tobacco-related mandates of various ministries (esp. health, finance, agriculture, human resources, commerce and industry, cooperative) will be resolved to optimize synergies.

There is a need for a national whole-of-the-government policy in line with the WHO FCTC Article 5.3 guidelines. This could be a separate policy and/or could be inserted in the COTPA through appropriate amendment (possibly under the section 2 of the COTPA).

Such policy at minimum shall include provisions for governments to (1) raise

awareness about the addictive and harmful nature of tobacco products and tobacco industry interference with public policies related to tobacco; (2) establish measures (such as code of conduct or protocols) to limit interactions with tobacco industry to the minimum and when absolutely necessary for regulatory purposes and ensuring transparency of such interactions; (3) eliminate and/or reject partnerships and non-binding or non-enforceable agreements with tobacco industry; (4) avoid conflict of interests within government officials/employees for tobacco control; (5) mandating tobacco industry to provide accurate information in transparent manner; (6) denormalize and regulate so-called CSR and related activities by tobacco industry; (7) prohibited any preferential treatment to tobacco industry; (8) treat government-owned tobacco industry in the same way as any other tobacco industry.

Government shall issue an advisory to all the states and union territories explaining the WHO- FCTC Article 5.3 related commitments and urging for adoption of appropriate policy measures at state level. Here, having a comprehensive national framework/policy cutting across ministries and departments in line with the WHO-FCTC Article 5.3 guidelines, and advising it as a minimum framework to states and union territories will ensure uniformity across states and union territories.

Government shall consider expanding the scope of the WHO-FCTC Article 5.3 related policy to also include elected political leaders, political parties, and civil society.

Government shall consider disallowing retiring senior officers (who have served in decision making capacities) from key business-related sectors (finance, industry, agriculture etc.) to join tobacco industry boards.

It is important to recognize that the tobacco industry is a special case wherein the core business of the industry (i.e., production of the lethal products) is not aligned with the desirable social goals including public health. In such circumstances, the CSR activities by the tobacco industry ends up promoting the societal image of the industry while allowing access of the industry representatives to decision makers creating potential for policy/program interference. Hence, the tobacco industry shall not be allowed to publicize the claims of CSR like other sectors. This will require an amendment to the Companies Act (section 135) barring tobacco industry to engage in mandatory spending on CSR. Instead, the industry may be made liable to pay financial costs or a specific tax towards restoring/addressing health and environmental damages. A committee jointly formed through representatives from the Ministry of Health and Family Welfare and the Ministry of Corporate Affairs may govern the allocation of such funds for effective tobacco control measures.

In a similar logic, considering the negative impact of the tobacco industry on population health, social outcomes and environment, the tobacco industry shall either be excluded from ESG rating exercises treating it as a 'sin' sector or it needs to be compared with other sin/extractive industries. In either case, the tobacco industry shall not be allowed to publicize the ESG activities/ratings. Instead, the tobacco industry shall be mandated to comply with ESG norms and mandated to report in a tobacco sector-specific template as part of the Business Responsibility and Sustainability Reporting that includes its compliance with the prevailing

tobacco control laws.

Tobacco industry, being a special case, shall be mandated to be registered and function as tobacco business, preventing them from also operating into other sectors or emerging into a business conglomerate. Government shall adopt an operational definition of tobacco industry as any individuals and/or entities engaged in tobacco production, import, export, wholesale, or retail business of tobacco but also including a wide range of supporting entities specializing in such areas as marketing, packaging, legal services and lobbying.

Government agencies and business undertakings shall not invest in tobacco industry and divest the existing investments in a time-bound manner.

Tobacco industry shall be put in a negative list excluding it from any investment (domestic or foreign) and industrial incentives including any tax-related incentives/exemptions (inclusive of those given to the bidi industry).

Government shall regulate lobbying and/or personal relation activities by industries (including tobacco industry) making it transparent and providing information in the public domain.

Government (ideally through the ministry of health and family welfare) shall establish and fund robust monitoring and violation reporting mechanisms, ideally an autonomous independent body, to track progress of implementation of the WHO-FCTC Article 5.3. This shall include periodic production of Indian Tobacco Industry Interference Index and establishment of an observatory to monitor tobacco industry interference. Such an observatory shall include representatives from relevant government agencies, academic and civil society organizations. Reporting about the industry interference could be integrated with the prevailing management information system of the national tobacco control program.

Akin to the Article 5.3, Codes of conduct or staff regulations for all branches of governments should include a "whistleblower function" with adequate protection.

Government shall consider establishing a robust tobacco industry interference monitoring system employed in collaboration with civil society and other stakeholders and use existing enforcement mechanisms to meet their obligations under WHO-FCTC Article 5.3.

5.1.2. For governments at state level

Over and above the recommendations made above for the national level governance, the recommendations for governments at state level are following:

Several state governments that are yet to adopt a state-wide whole-of-the-government policy in line with the WHO FCTC Article 5.3 shall adopt the appropriate policy at earliest. Ideally, this could be achieved through amending the COTPA at state level or alternatively adopting a separate policy.

States that have adopted a policy (protocol or code of conduct) in line with the WHO FCTC Article 5.3 require to amend these policies in order to close some of the gaps in these policies in order to address all the recommendations provided in the guidelines for the WHO FCTC Article 5.3 (especially including but not limited to denormalizing and regulating CSR, preventing preferential treatment to tobacco

industry, treating government-owned tobacco industry in the same way as any other tobacco industry, mandating tobacco industry to provide accurate information in transparent manner, code of conduct for public officials, constitution of empowered committee).

States that have adopted a policy in line with the WHO FCTC Article 5.3 need to develop a detailed and operational implementation and enforcement related guidance. Governments shall strictly enforce the policy. Also, these should sever ties with the tobacco industry through a due notification.

Government shall consider expanding the scope of the WHO FCTC Article 5.3 related policy to also include elected political leaders, political parties, and civil society.

Government shall consider disallowing retiring senior officers (who have served in decision making capacities) from key business-related sectors (finance, industry, agriculture etc.) to join tobacco industry boards. Those already working in such positions should be asked to relinquish their positions within a timeline of not more than a year.

Government agencies and business undertakings shall not invest in tobacco industry and divest the existing investments in a time-bound manner, not exceeding three years.

Tobacco industry shall be put in a negative list excluding it from any investment (domestic or foreign) and industrial incentives including any tax-related incentives/exemptions.

Government (ideally through the ministry of health and family welfare) shall establish and fund robust monitoring and violation reporting mechanisms, ideally an autonomous independent body, to track progress of implementation of the WHO FCTC Article 5.3. This shall include periodic production of Indian Tobacco Industry Interference Index and establishment of an observatory to monitor tobacco industry interference. Such an observatory shall include representatives from relevant government agencies, academic and civil society organizations.

Government shall consider prohibiting societies and trusts receiving tobacco industry funding (donations, CSR etc.).

5.1.3. For civil society

(We include here the entities that are not government in nature and that are not forprofit private businesses, and hence including but not limited to community-based organizations, non- government and voluntary organizations, faith-based organizations, academic institutions, research organizations)

Civil society organizations shall not receive tobacco industry funds (donations, CSR etc.) and shall adopt a policy in line with the WHO FCTC Article 5.3.

Civil society organizations shall raise awareness on tobacco industry interference with tobacco related public policy and programs.

Civil society organizations shall invest in building capacity of relevant stakeholders including courses on tobacco control for effectively monitoring and addressing tobacco industry interference.

Civil society organizations shall support the state- and national-level tobacco control authorities in their endeavors to prevent tobacco industry interference including but not limited to monitoring of tobacco industry interference and bringing it to the notice of relevant authorities.

Civil society organizations may play a mediating role sensitizing and bringing together diverse stakeholders for shared understanding and actions for preventing tobacco industry interference.

Civil society organizations shall invest in researching various facets related to tobacco industry interference and promote knowledge dissemination, thus enhancing understanding of the issues related to tobacco industry interference.

5.1.4. For businesses

Businesses operating in the tobacco sector aimed at producing tobacco for human consumption (recreational use) shall consider deliberate, planned, and tangible exit from tobacco business.

Businesses operating in the tobacco sector must comply with the prevailing tobacco control regulations.

Conglomerate businesses that also operate in tobacco sector shall make tobaccosector specific reporting as part of their Business Responsibility and Sustainability Reports to the SEBI

Business conglomerates, which includes tobacco in its product portfolio, should do independent branding for tobacco, thus making it different from other products.

Businesses shall consider divesting from tobacco sector investments including investments in shares/mutual funds and adopt appropriate ethical financing frameworks.

Businesses shall be mandated to raise awareness about the addictive and harmful nature of tobacco products and tobacco industry interference among their employees.

Business conglomerates, which include tobacco in its product portfolio should disclose the percentage of profit from tobacco that is being invested in CSR activities.

Mandatory CSR activities, under the Companies Act, should be banned for potentially harmful industries such as tobacco companies and instead an equivalent amount should be collected as a direct government levy. This funding could then be distributed by the state to be allocated for tobacco control and other public health purposes.

Celebrities across sectors (sports, films etc.) shall refrain from endorsing and advertising tobacco as well as other alleged non-tobacco products (routinely used for surrogate advertising of tobacco products). There shall be strict punitive measures to deter celebrity endorsement of tobacco products.

CHAPTER-2

E-Cigarettes: Landscape, Health Impacts, Regulations

E-Cigarettes: Landscape, Health Impacts, Regulations, and Recommendations

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Background

This chapter presents a comprehensive overview of e-cigarettes, with a particular focus on the urgent need to address the rising use of e-cigarettes among youth in India. It delves into the various factors that influence the accessibility and affordability of these devices, highlighting the challenges that persist despite regulation. The section on the health impacts of e-cigarettes discusses several critical concerns, including nicotine addiction, respiratory and cardiovascular health issues, and mental health implications. The chapter recommendations include building enforcement capacity, forming district- level committees in collaboration with civil society organizations, and enhancing coordination among various government ministries. The recommended measures emphasize the need to address online violations, conduct raids, track illegal smuggling, and promote tobacco cessation programs. It also calls for stricter enforcement of restrictions on marketing that targets youth.

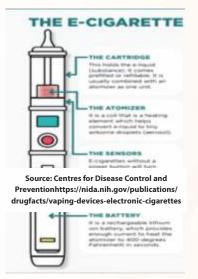
Introduction Definition of e-cigarettes and its products

National Cancer Institute, USA defines e-cigarettes as "a device that has the shape of a cigarette, cigar, or pen and does not contain tobacco. It uses a battery and contains a solution of nicotine, flavourings, and other chemicals, some of which may be harmful." (1). Broadly, ENDS (Electronic Nicotine Delivery System) and Electronic Non-Nicotine Delivery System (ENNDS) are vaping devices that heat a liquid to produce vapor/aerosol that is inhaled by the user. They are known by various other names such as "electronic cigarettes", "vapes", "vape-pens", "Pod Mods" and come in many shapes, sizes, and device types. The basic design of e-cigarettes consists of the following three components: (1) a part that holds a liquid solution (e-liquid or e-juice) typically a mixture of propylene glycol and glycerol with nicotine and flavouring chemicals; (2) a power source, usually a battery; (3) the heating element (atomizer) (2). E-cigarette devices can be designed in several ways. They exist either as a single device or as a multiple-component product (3), They can be disposable, rechargeable and/or refillable.

The evolution of E-cigarettes or vaping, products (4):

Electronic nicotine delivery systems (ENDS), commonly known as Ecigarettes, were invented back in 2003 and formally introduced and brought to market in 2007 (5). Nearly a decade after the invention, 466 brands encompassing nearly eight thousand flavours exist in the markets (6). It was around 2009- 2010, when ENDS began gaining popularity in the Indian markets, youth in particular (7). A premier tobacco company in India launched and marketed its e-cigarette brand in 2014, with a hot marketing strategy: 'pleasure of smoking anytime anywhere' (8). The evolution of e-cigarettes or vaping products has progressed through several generations:

First generation: Introduced around 2007, disposable e-cigarettes, also known as "cigalikes," replicated the appearance and sensation of traditional cigarettes. These first-generation devices were intended for



single use and were neither rechargeable nor refillable. They aimed to closely mimic the smoking experience and served as substitutes for cigarettes, appealing to individuals attempting to quit smoking or seeking alternatives. This type of e-cigarette is activated by a power button that must be held during use or by drawing breath through the device which triggers an electronic airflow sensor in the battery section. This type was first disposable, once the battery was discharged. First-generation e-cigarettes, often resembling combustible tobacco cigarettes, are also referred to as cigalikes or "vape sticks." Some cigalikes are slightly longer or narrower than traditional cigarettes, known as "pen style", devices.

Second generation: During this phase, rechargeable e-cigarettes with prefilled or refillable cartridges became prominent. These cartridges housed e-liquids containing nicotine, flavourings, or other additives and were connected to rechargeable battery pens (9). This phase also introduced variations such as e-hookahs and rechargeable versions. Typically, the cartridge and battery pen were sold separately, often in starter packs. Second-generation e-cigarettes featured a clearomizer—a transparent cartridge containing e-liquid and an atomizer—paired with a slim battery. These devices were often shaped like pens, larger and cylindrical compared to their predecessors, and known as "tank systems" due to their transparent reservoirs capable of holding larger e-liquid volumes.

Third generation: Third-generation devices, often advertised as "vaping" products, represent a significant departure from combustible tobacco cigarettes. They bear little resemblance to cigarettes aesthetically, with many being square or rectangular and featuring customizable and rebuildable atomizers and large-capacity lithium batteries. Additionally, users have been modifying or building their own devices, known as "mods," since the availability of e-cigarettes. These differences in design and engineering impact the size, distribution, and amount of aerosol particles produced. Variability in levels of chemicals and nicotine in the e-liquid/aerosol determines the composition of the aerosol delivered to the user (10). Tanks or mods became popular, offering users customizable options. These devices were rechargeable Source: Centres for Disease Control and



Source:CentresforDiseaseControland Preventionhttps: //nida.nih.gov/publications/drugfacts/ vaping-devices-electronic-

Preventionhttps://nida.nih.gov/ publications/drugfacts/ vaping-devices-electronic- and designed for multiple uses. Sub-ohm tanks, featuring low-resistance coils, were developed to produce larger aerosol clouds and deliver nicotine or other substances more effectively.

Fourth generation: Fourth-generation e-cigarette devices, the latest iteration, are essentially third-generation devices with added temperature control functionality. Users can set a temperature limit, ensuring stable vaporization temperature even with longer and more frequent puffs. This feature helps reduce the risk of dry and burnt hits (11). These devices offer the versatility to vape alternative products such as plant materials and drug-containing waxes. Some models allow for e-liquid to be dripped directly onto the heating coil, enhancing vapor strength and taste. These vaporizers feature customizable options, including different types of heating coils, some specifically for vaporizing solids. Pod mods, like JUUL and Suorin, entered the market with prefilled or refillable pods and adjustable systems. Utilizing nicotine salts for smoother inhalation, these devices are shaped like USBs and contain pods with higher nicotine concentrations, catering to users seeking stronger hits (12).

Vaporizers: An inhalation device used to release the active substances of organic or inorganic materials as an aerosol through the application of non-combusting heat. Vaporizers can be used to aerosolize dry herbs, wax, or oil, releasing their active ingredients for inhalation. They were versatile tools used for various materials, including marijuana, to deliver aerosols without combustion.

Market growth and trends

According to the latest analysis, the global E-Cigarette market is valued at USD 20.61 billion (approx. INR 1,690.02 billion.) in 2023. It is anticipated to experience an annual growth rate of 3.06% (CAGR 2024-2028) on a global scale, generate a revenue of USD 26.0 billion (approx. INR 2,132 billion) in 2024, and projected to reach a market size of USD 46.98 billion (approx. INR 3,852.36 billion) by the end of 2030. The market is largely fragmented, with smaller, non-tobacco companies dominating it.

Most popular brands worldwide are BAT's Vuse, JUUL Labs' JUUL, RELX, Elfbar, blu, Logic, and NJOY. Most popular brands in India are: JUUL, iGet, Elfbar, DYB, IQOS, and Dinner Lady (13).

E-cigarettes and their impact on Health: Nicotine addiction and its consequences

Addiction is compulsive drug use at the cost of health consequences. To bacco users consume to bacco regularly because of nicotine addiction. Only a small percentage of to bacco users quit unassisted. The use of medicines including Bupropion, Varenicline, and nicotine-replacement therapy (NRT) along with counselling doubled the quit rate. A brief euphoria (enhanced alertness and an ability to concentrate with improved recall) due to endorphins is there when nicotine is taken. For most to bacco users, the brain changes due to nicotine exposure result in addiction which on abstinence precipitates withdrawal symptoms. After quitting, withdrawal symptoms in the majority last from one to four weeks, but in a few cases, it may last for months (14).

Respiratory health implications:

The harmful chemicals when using E-Cigarettes include some flavours and nicotine or THC (the chemical in marijuana), causing an inflammatory response. Vitamin E is frequently used as a thickening agent in e-liquids. It is safe when used on the skin or taken orally but is an irritant when inhaled. Also, chemicals like Diacetyl, a food additive, used to deepen e-cigarette flavours damage bronchioles in the lungs. Acrolein, used as a weedicide can also damage lungs.

Popcorn Lung resulting from e-cigarettes is bronchiolitis obliterans which results from damage to the bronchioles. Diacetyl, a food additive (present in e-cigarette) used to simulate butter flavour, causes inflammation and permanent scarring in the bronchioles and makes breathing difficult. Further, individuals who inhale oily substances present in e-liquid, suffer from E-cigarette-related Lipoid Pneumonia leading to inflammation in the lungs. Lungs may collapse with spontaneous Pneumothorax with E-Cigarette use when there's a hole in the lung through which oxygen escapes. E-cigarette use may be associated with an increased risk of bursting of air blisters leading to lung collapse.

E-cigarettes may be tumour promoters and cause lung cancer due to the many chemicals inhaled. Ultrafine particles due to E-Cigarette use deposited deep in the bronchial tree can lead to the development of cancer. Second-hand smoke from e-cigarettes is known to contain ultrafine particles, Nicotine, Diacetyl, and Benzene (15). However, since these products have been in the market for a short time, not many long-term studies are available.

Cardiovascular health implications:

The studies on the effect of smoking e-cigarettes on myocardial infarction in subjects who never smoked conventional cigarettes reported oxidative stress, endothelial dysfunction, platelet activation, and inflammation (16). The available literature shows that the use of e-cigarettes is associated with an increased risk of cardiovascular diseases (17). It has also been observed that smokers are likely to become dual users with e-cigarette use (18). It is also evident that e-cigarettes also lead to an increase in heart rate, arrhythmias, and increased blood pressure and formaldehyde, a toxic chemical that can lead to heart diseases.

The vascular changes due to e-cigarette use include inflammation, oxidative stress, endothelial dysfunction, vascular injury, platelet aggregation, and atherosclerosis (19).

Mental health and other health issues:

Nicotine from tobacco or e-cigarettes leads to other addictions in later life. E-cigarettes are used by

teens mostly who have symptoms of depression, but the use may worsen the symptoms (20). Moreover, it can lead to decreased judgment, and problems in concentrating and nicotine dependence, which is associated with increased anxiety, restlessness, and irritability. The use of ecigarettes leads to mood swings, insomnia, depression, and suicidal tendencies (21). A higher level of alcohol dependence, and loneliness was also reported amongst users (22).

E-cigarette use during pregnancy:

E-cigarette liquids also contain flavours, chemicals, and other additives that are not safe for the foetus given the damage to the developing brain. It can also lead to premature births, low birth weight, and systemic inflammation (23). Exposure to e-cigarette aerosol has been associated with the increased expression of inflammatory cytokines in both in vitro and in vivo studies which causes high levels of serum high-sensitivity C-reactive protein and increased expression of inflammatory cytokines that may lead to cardiovascular disease, respiratory diseases, and several cancers similar to conventional cigarette smoking (24, 25).

E-cigarettes can lead to injuries:

Explosions have happened in defective e-cigarette batteries when being charged, leading to fires and serious burn injuries (26). Additionally, due to Nicotine toxicity, children have been poisoned by swallowing, breathing, or even absorption through skin or eyes (27).

Electronic cigarette uses and perception during COVID-19

It has been observed during COVID-19 that those who use E Cigarettes may be at higher risk for worsening symptoms injury to the lungs and other health effects as mentioned above (28). The Center for Disease Control (CDC) in 2019 started an investigation of increased lung injuries with symptoms of breathlessness, cough, and chest pain and hospitalization during COVID-19, mostly using ecigarettes. By February 2020 about 2800 hospitalizations were recorded and the condition came to be known as EVALI (e-cigarette product use associated with lung injury) (29).

Association of E-Cigarette Use and Metabolic Syndrome:

E-cigarette use or dual use of e-cigarettes and tobacco cigarettes leads to Metabolic Syndrome, which is associated with increased blood sugar levels, high blood pressure, elevated triglycerides, and reduced HDL-cholesterol (good quality cholesterol) (30).

Access and availability

Electronic cigarettes are marketed as innovative, colorful, and portable technological gadgets, while other products are designed to even look like everyday school supplies such as highlighters and USB drives. Technophilia, or a positive orientation towards new technology – especially among youth – has been cited as a factor of young people's attraction and curiosity towards electronic cigarettes. Marketers emphasize that these products may be used in public areas where smoking cigarettes is prohibited. These products are also shown to improve sociability and as a marker of glamourous lifestyles. Another marketing strategy is to offer price promotions to consumers making electronic cigarettes affordable and accessible to young people which may undermine taxation policies.

Findings of the study (2023) reported electronic cigarettes were obtained by young adults primarily through their network, specifically peers (57%) or siblings (17%) and from retail electronic cigarette shops (46%) and tobacconists (32%). The social context of electronic cigarette use occurred at parties (46%), at home (36%), at restaurants and cafes (33%) and even workplaces (30%). Underage users

often borrow or access devices from friends or older siblings who can legally buy the products (31, 32).

Tobacco Enforcement and Reporting Movement (TERM), an online Al-driven tool that monitors marketing instances on social media and digital news platforms, reported electronic cigarettes being sold online to youth by third-party retail shops. Customers order these

Image 1. Customers can purchase electronic cigarettes via private messaging apps like WhatsApp. This is a screenshot of a WhatsApp conversation between a customer and seller. This positive feedback was shared by the seller on his Instagram account.

Image source: vape_india_smoke

products by sending personal messages to a WhatsApp number or through the Facebook messenger application (Image 1). Despite the ban, adolescents and young adults can buy these products from ecommerce platforms, online stores, and through social media applications (33, 34).

A population-based representative household survey of electronic cigarette awareness showed that adolescents (12-14 years of age) in Mumbai (16%) and Kolkata (11%) had higher awareness than their caregivers (35). In 2015, a study on online sales of ENDS revealed that 69% of the 65 ENDS models sold in India were flavoured, and non-compliant with Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 (COTPA, 2003), luring the youth to experiment and ultimately leading to nicotine addiction (36). At that time, due to the absence of any clear regulations, online shopping portals and social media sites were selling and advertising the ENDS in the Indian markets. It became evident that the majority belonged to a younger age group, and were tobacco smokers and online buyers.

E-cigarette and Regulations The Ministry of Health and Family Welfare (MoHFW), on 8th August 2018, issued an advisory to ban the "sale (including online sales), manufacture, distribution, trade, import, export and advertisements of ENDS" (37), followed by an Ordinance in September 2019 (38), and the Prohibition of Electronic

Cigarettes (Production, Manufacture, Import, Export, Transport, Sale, Distribution, Storage and Advertisement) Act, 2019 (No. 42 of 2019), on 2nd December 2019 which eventually came into force on 5th December 2019 (39), also known as PECA (40). It was designed to protect people, especially adolescents and young adults from the health harms of electronic cigarette use. The advertising in traditional mass media (cinema, radio, tv, billboards) and on the internet of electronic cigarettes is also banned.

A multi-centric study conducted immediately after the ban in India found that 35.6% of internet electronic cigarette vendors (IEVs) were not compliant with the Ordinance and the Act (41). A similar study conducted to assess the e-cigarette retailer storefronts availability in India revealed that despite being aware (90%) of the Ordinance, ENDS were sold by 18.6% of the retailers (42).

Despite the ban, regulating e-cigarette use in India remains challenging due to a persistent black market, undermining tobacco control efforts. Comprehensive tobacco control policies, youth and parent education, strict marketing regulations, and enhanced enforcement are crucial. While PECA 2019 is a milestone, further amendments to penalize e-cigarette use are needed to effectively curb its usage nationwide.

Conclusion:

E-cigarettes represent a complex issue with associated significant health risks. E-cigarettes have been marketed as alternatives to traditional tobacco products, their use poses significant health risks including nicotine addiction, respiratory and cardiovascular issues, and adverse effects on mental health and pregnancy. The global market for e-cigarettes continues to expand, raising concerns about their efficacy in smoking cessation and associated harmful health outcomes. Their appeal, particularly to youth, and the potential for long-term health effects presents significant challenges.

To effectively combat these issues, a multi-faceted approach is necessary. Strengthening enforcement mechanisms, enhancing the capacity of relevant agencies, and improving coordination among stakeholders are crucial steps. Comprehensive public health strategies, including education and community engagement, are vital for preventing e-cigarette use, particularly among youth. Youth leadership and public-private partnerships can further bolster these efforts by promoting awareness and advocating for stricter regulations. A collaborative approach involving government agencies, health professionals, educators, and community organizations is essential to ensure the effective implementation of PECA and safeguard public health from the risks associated with e-cigarettes.

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RECOMMENDATIONS

5.2 E-Cigarette

5.2.1. At the Government level:

5.2.1.1 Ministry of Health and Family Welfare (MoHFW)

- a) Need to build the capacity of law enforcers, the Department of Education, Directors/officials of the Directorate of Revenue Intelligence (DRI), and the police department, to enforce the restriction on ENDS products at the central and state level or additional officers may be notified for effective enforcement of provisions under PECA-2019.
- Formation of district-level committees including CSOs to monitor the availability of ENDS products and take action through existing legal mechanisms.
- c) Establish a mechanism for: (i) coordination and collaboration between all the stakeholders (inclusive of all concerned ministries); and (ii) planning quarterly update meetings with Ministry of Electronics and Information Technology, Directors of all Directorate of Revenue Intelligence (DRI) units, Chief Secretaries(State) Director Generals of Police (State), Department of Education (State), and other relevant ministries/departments(Central and State) on strictest enforcement of PECA-2019 including appropriate reporting mechanism for all stakeholders.
- d) Collect information/data on E-Cigarettes/ENDS as part of regular national/sub-national tobacco surveillance to strictly monitor regulations and actions on sale and advertising, promotion of ENDS products on the internet, online stores, and home deliveries aligned to PECA 2019.

- e) Do not allow projects/grants promoting "harm reduction or reduced harm"(1).
- f) Need to enhance the scope of the prevailing policies in line with the WHO FCTC Article 5.3 [state protocols and the MOHFW Code of Conduct to prevent tobacco industry interference] to include the E-Cigarettes/ENDS industry.

5.2.1.2. Ministry of Electronics and Information Technology

a) Identify, remove/block and take strict action against violations regarding the sale, advertisement, and web presence of Ecigarettes/ENDS. All commercial webpages (.com, .biz, and others as notified) be barred by MOIC/ DEITY and generate regular reports of monitoring.

5.2.1.3. Ministry of Home Affairs -

- a) Authorized enforcement agencies should conduct raids on kiosks particularly those near schools, in order to seize the illegal e-cigarettes.
- b) Frame appropriate guidelines elucidating the process for the prompt, complete, and irretrievable disposal of stock of electronic cigarettes seized by authorized officers in coordination with the Central/State Pollution Control Boards.

5.2.1.4. Directorates of Revenue Intelligence (DRIs) -

a) Mechanism to provide regular update to DRIs in every state and UT to investigate the illegal smuggling of banned E-Cigarettes/ENDS and take appropriate measures under PECA-2019

5.2.1.5. Health Care Professionals (HCPs), Media and CSOs-

- a) HCPs should be trained and sensitised to the needs of Indian smokers in order to encourage and implement tobacco cessation.
- b) Encourage reporting of violations of sale or misleading media stories at the State- & local- levels and provide a thrust to policymakers, and enforcement officers to take legal action against violators.

5.2.2. Public-private partnerships for awareness campaigns at Educational Institution and Community Level:

- a) Campaigns and initiatives to create and improve awareness at the school (including integration into the School Health Program), college/university, and community level regarding the harms of ENDS products and laws about their restriction.
- b) Teachers and parents to be engaged in awareness about the adverse impact of nicotine on adolescents' brains and other attributable health effects of ecigarette use.
- c) Mass Sustainable media campaigns to disseminate information on the harms of ENDS products and burst myths associated with them.
- d) TOFEI guidelines to be expanded on awareness on ENDS, develop/update teacher training manual for the school health programmes on ENDS

- e) Stricter enforcement of the prohibition on ENDS products, especially in restaurants, pubs, and bars.
- f) Electronic cigarette companies may also be prohibited from using flavors, designs, or labels that appeal to youth.

5.2.3. Need for school and community engagement:

- a) Engaging adolescents and youth at school and in the community is crucial to combating the rise in e-cigarette use. School-based education programs (including the School Health Program under Ayushman Bharat) provide vital information about the risks while involving parents through workshops help them identify and prevent e-cigarette use.
- b) Collaboration with community organizations, healthcare providers, and local businesses creates a supportive environment, and empowering youth to promote within their peer groups leverages peer influence for positive change and fosters a culture of prevention. By combining these approaches, school, and community engagement initiatives can work synergistically to address the complex challenges posed by youth e-cigarette use.
- c) In India, fostering youth leadership to address the challenges posed by ecigarette usage requires a multifaceted approach. Firstly, empowering youth through peer education initiatives is essential. By training young leaders to educate their peers about the risks associated with e-cigarette use, we can leverage peer influence to promote healthier choices and discourage experimentation with these products.
- d) Equipping young individuals with media literacy skills is crucial in navigating the pervasive influence of e-cigarette marketing. By teaching youth to evaluate advertisements and media messages surrounding e-cigarettes critically, and empowering them to make informed decisions and resist societal pressures to use these products.
- Engaging youth in policy discussions is crucial for effective e-cigarette e) regulation, ensuring that measures reflect their needs and concerns. Ultimately, by investing in youth leadership and engagement, we can create a more inclusive and impactful approach to tackling the e-cigarette epidemic in India. Example: Tobacco-related content on social networking sites: evidence from a youth-led campaign in India (44): A youth-led campaign was conducted to identify and analyse violations of tobacco advertising, promotion, and sponsorship (TAPS) on Social networking sites (SNS). Through capacitybuilding webinars, the youth identified 748 posts violating tobacco advertising laws, with 84.7% promoting smoking products and many endorsed by celebrities. Additionally, the youth identified 148 pages that were selling tobacco products online, mostly on Instagram (62.7%) and Facebook (23.7%)., and 1,412 hashtags (#vape and #smoke being the most prevalent) related to tobacco promotion were identified. These findings highlight the urgent need to amend COTPA, 2003, particularly Section 5, to include all internet-based platforms in the prohibition of tobacco advertising and promotion to protect Indian youth. In 2017-18, adolescents from the HRIDAY youth network monitored violations of Tobacco Control Laws in India and at the point of sale of Electronic Nicotine Delivery Systems (ENDS).

CHAPTER-3

Youth Intervention

The youth of today are the leaders of tomorrow
- Nelson Mandela E-Cigarettes: Landscape, Health Impacts, Regulations, and Recommendations

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Background

This chapter provides a comprehensive summary of the role of youth interventions in tobacco control, highlighting its significance for saving both the current and future generations. The chapter also delineates the problem of tobacco use among youth, new products and trends of tobacco and nicotine products in young generations, tobacco industry interference in youth related interventions, gaps and challenges in youth related interventions and efforts undertaken by various stakeholders to tackle tobacco and nicotine menace among youth.

Introduction:

Healthy youth are the best hope for the future. Their own health today, their health in future as well as the health of their next generation depends on their behaviour and habits of today, as they not only shape their own future but the future of their next generation (1). Youth interventions are not only important but are essential as they can help in preventing youth from falling prey to habits especially substance abuse like tobacco use (2).

Tobacco use stands out as one of the most detrimental behaviours impacting youth health. The prevalence of tobacco use among adolescents in India and worldwide poses a significant public health challenge. Tobacco consumption is linked to a myriad of serious health issues, including respiratory diseases, cancers, cardiovascular conditions, and adverse reproductive outcomes. For young individuals, tobacco use can severely compromise physical fitness, hinder academic performance, and deteriorate overall well-being. The effects are not just immediate but can extend into adulthood, often leading to chronic health conditions and decreased quality of life.

Globally, tobacco consumption is responsible for millions of deaths each year, highlighting its severe impact on public health. The World Health Organization (WHO) reports that tobacco causes over 8 million deaths annually. Of these, 7 million deaths are directly attributable to tobacco use, while an additional 1.2 million deaths are due to exposure to secondhand smoke (3). This staggering statistic underscores the gravity of the tobacco epidemic and its far-reaching consequences.

Looking ahead, the situation is expected to worsen if effective measures are not implemented. By 2030, it is projected that 80% of tobacco-related deaths will occur in low- and middle-income countries, most of them shall be the productive youth population. This shift will not only rob individuals of their productive years but also increase the risk of poverty among dependent family members (4). The future impact of tobacco use is thus deeply concerning, particularly for regions already struggling with health and economic challenges.

In this context, youth interventions become even more critical. Addressing tobacco use among young people through targeted programs and policies can prevent the initiation of smoking and reduce the prevalence of tobacco-related diseases. By investing in effective youth interventions today, we can safeguard the health of future generations and mitigate the long-term public health and economic consequences of tobacco use.

Tobacco Use Among Youth

The initiation of tobacco use typically occurs during adolescence. Globally, in 2019, around 155 million individuals aged 15-24 years were estimated as tobacco smokers (5). Alarmingly, approximately 82.6% of current smokers initiate tobacco use between the ages of 14-25 years. As many as 90% of eventual smokers start tobacco use before the age of 19 years. If tobacco is not taken up in adolescence it rarely is later in life.

In India, the prevalence of current use of tobacco among students aged 13-15 years is eight percent (6). According to the Global Adult Tobacco Survey (GATS -2) India, nearly 14% of youth aged 15-24 years use tobacco in some form. Rural youth, students, female sex, and poor socio-economic strata prefer smokeless whereas urban, male, and lesser educated youth lean towards the smoked form of tobacco (7).

Tobacco use among youth has serious implications. In the long term, tobacco consumption is implicated in about 90% of lung cancer cases, 30% of all cancer deaths, 75% of cases of chronic bronchitis and emphysema, and 25% of cardiovascular disease. But it also has short-term effects, increasing the severity of influenza, reducing the immune response, adversely affecting the foetus of pregnant women, and diminishing respiratory and athletic performance among many (8). New hazards are arising from the increased promotion of and the use of tobacco products by young people of smokeless tobacco, which contributes to disfiguring diseases of the teeth and gums and cancer of the mouth. The sooner a young person begins smoking, the more profound the loss of life expectancy, with studies showing that those who start at 15 years of age could lose up to eight years of life, while those starting at 25 might lose around four years. Hence, it is evident to point out that youth represent a vulnerable population susceptible to the harmful effects of tobacco use.

Three factors are strongly associated with tobacco use by young people: peer pressure; simulation of their tobacco user siblings and parents; and tobacco use during their employment (8). It can also be ascertained from scientific evidence that youth substance abuse can be credited to diverse factors including easy availability of tobacco, socio-demographic characteristics, and low levels of awareness about the health consequences of tobacco use. Preventing initiation, discouraging experimentation, guarding against tobacco industry interference as well as aiding in providing tobacco cessation are essential strategies to protect health and well-being of youth (9).

New Tobacco Products and Trends

Varieties of smoking and smokeless tobacco products are available in India. New tobacco products, such as e-cigarettes and flavoured tobacco, are gaining popularity among the youth, exacerbating the problem of adolescent tobacco use. Ever use of e-cigarettes was reported by three percent of students (3% of boys and 2% of girls) in India (6). E-cigarettes were perceived as relatively harmless compared to regular hookahs and conventional cigarettes (9). These products often contain nicotine, a highly addictive substance, and have been associated with harmful cardiovascular effects. Due to the high palatability and misperceptions regarding reduced ill effects of the constituents of Flavoured Tobacco Products (FTP), these are disproportionately used by the youth and young adults (10). Flavoured tobacco products, including menthol, fruit, and candy flavours, are particularly appealing to young users and contribute to the initiation of tobacco use among adolescents (11).

Moreover, shisha smoking has become increasingly popular, especially among young people who may perceive it as a safer alternative to traditional cigarettes. However, shisha smoking is associated with various adverse health outcomes, including esophageal cancer, decreased pulmonary function, infertility, and infectious diseases (12).

Tobacco Industry Interference and Youth

The tobacco industry targets youth in many ways. The tobacco industry's targeted tactics towards youth include marketing new products such as e-cigarettes, smokeless tobacco, snus, pouches, and using digital platforms to bypass traditional advertising restrictions. The industry uses social media and streaming platforms to market tobacco and nicotine products to youth. They also use attractive packaging and sell products in fruit and candy flavours. The industry uses tax regulation to ensure that its products are affordable and available. The industry uses these products to gain popularity among youth and as a harm reduction strategy. Enforcing stringent age restrictions, strengthening packaging

and labelling on tobacco products, increasing taxes on tobacco products, raising public awareness, adopting youth protection policies, holding the tobacco industry accountable, ban on tobacco advertising, promotion, and sponsorship: developing a uniform excise structure can be some of the very effective measures to address tobacco industry interference on youth.

Why is Youth Intervention necessary?

Addiction among youth, especially among student community, is a growing concern that threatens the foundation of a healthy and productive society. Substance abuse, including drugs, alcohol and tobacco, not only hampers academic performance but also severely affects mental health and future prospects. Tobacco is often referred to as a "gateway drug," meaning its use can lead to the consumption of more harmful substances. Studies have shown that children and youth who use tobacco today are more likely to experiment with and become addicted to other drugs in the future. Therefore, addressing tobacco use is a critical step in preventing broader substance abuse.

To address these challenges, concerted efforts are needed to protect adolescents from targeted marketing strategies by the tobacco industry, exposure to second-hand smoke, and addiction. Strong enforcement of tobacco control policies, coupled with education and awareness programs, is crucial to prevent initiation, discourage experimentation, and support smoking cessation among adolescents. Additionally, efforts to address the social determinants of tobacco use, including poverty and social acceptability, are essential to creating a healthier environment for future generation (13).

Youth intervention is crucial in tobacco control efforts to prevent young people from starting smoking or using other smokeless tobacco products and new emerging products like e-cigarettes and Hookah/shishas. Youth Intervention requires sustained effort, engaging youth who have continuously demonstrated success. Youth interventions have shown a positive impact in terms of reducing tobacco use behaviours as well as in influencing the external policy environment through their sustained efforts (14). Creating tobacco-free environments in schools, parks, and other public spaces not only reduces exposure to second-hand smoke but also helps to denormalize tobacco use among youth. Media campaigns that target youth with anti-tobacco messages can help change social norms around smoking and vaping. For youth who are already using tobacco, providing access to cessation support services tailored to their needs can help them quit. This might include counselling, quit lines, and digital cessation tools. Since e-cigarettes have become increasingly popular among youth, despite comprehensive bans on them; regulating their illegal sale and use is essential.

Efforts on Youth Intervention by key stakeholders:

Governments of India

The Cigarettes and Other Tobacco Products Act, 2003 or COTPA, 2003 was enacted in India in 2003 to prohibit advertisement of, and regulate the trade and commerce in, the production, supply and distribution of cigarettes and other tobacco products in India. The Act has a dedicated section i.e. section 6 (6a and 6b) which prohibits sale of tobacco to minors and sale of tobacco products within 100 yards of educational institutes. However, it may be noted that there is differential implementation of various sections under COTPA with frequent challans under section 4 (Prohibitions of smoking in public places) as compared sec 6 (5.4 lakh vs 0.93 lakh, as per MIS data for FY 2023-24). Further, Sec 5 prohibits any tobacco advertising, promotions and sponsorships (TAPS) which protects the youth from being attracted towards tobacco products. Film rules (2012) further regulated the pictorial

depiction and banned tobacco product placement within the film and provision of anti-tobacco health spots (30s- beginning and middle), anti-tobacco disclaimer (20s- beginning and middle) and anti-tobacco statis health warning message during the display of products. However, the tobacco industry has devised indirect methods/ surrogate advertisements (via celebrities/ influences etc.) to achieve the same. Section 7, COTPA mandates display of pictorial health warnings (85% PDA, front and back) which deglamourizes the tobacco products and prevent uptake/ motivate the tobacco user to make a quit attempt.

Government of India launched the National Tobacco Control Programme (NTCP) in the year 2007-08 during the 11th Five-Year-Plan. School programs along with training of school teachers are one of the main thrust areas of NTCP (15).

Ministry of Health and Family Welfare (MoHFW), Government of India launched the Tobacco Free Educational Institutions (ToFEI) Guidelines for implementation of tobacco control activities at educational institutions (public and private). The guidelines clearly mentions the roles and responsibilities of the state/ district tobacco control cells along with CSOs (16). Recently, the Department of School and Literacy (DoSEL), Ministry of Education launched implementation guidelines on ToFEI and a Demi Official letter was also issued to all states (17).

MoHFW also launched Tobacco Free Youth Campaign (TFYC) on world no tobacco day 2023 with focus on four strategies i.e. Awareness, Enforcement of COTPA, tobacco free villages and lastly ToFEI implementation in all States (18).

India is the first country to regulate the streaming or Over The Top (OTT) media platforms by placing anti-tobacco warning with the extension of Television and film rules (19). OTT platforms hold a big influence is motivating youth for tobacco use. As Indian youth spend about 8 hours and 29 minutes watching online video content every day, it becomes inevitable to control OTT platforms.

Efforts by NGOs:

Non-governmental organizations have played an important role in enhancing tobacco control across India. A few of the many such initiatives taken by NGOs are as under:

Mobilizing Youth for Tobacco-Related Initiatives in India (MYTRI): It was a Group Randomized Trial in India among 10-16-year-old adolescents in schools in Delhi and Chennai. This 2-year multicomponent intervention, based on the social-ecological model, engaged the State Education Department, school authorities, teachers, and peer leaders to conduct tobacco control activities with school students. Innovative engagement included All India Students Parliament on Health, Tobacco Free Schools (TFS) Model Making Competition, drafting TFS policies etc. MYTRI intervention reduced tobacco use in intervention schools by 17% (20). Project ACTIVITY promoted tobacco cessation and tobacco control among adolescents and youth in community settings (21).

Research on assessing tobacco imagery in Bollywood films by an NGO led to the policy action of Tobacco-free film and television rules, which were then monitored by the youth (22), as the Thumbs Up and Thumb Down (TUTD) Campaign (23).

Ride For Tobacco Free Generation: It was a flagship initiative undertaken by Faith Foundation in collaboration with the State Tobacco Control Cell, District Tobacco Control Cells and other stakeholders namely Indian Medical Association (IMA) and Indian Dental Association (IDA) universities, municipal corporations, private colleges, civil societies, Nehru Yuva Kendra Sangathan

(NYKS), the Union and World Health Organisation etc. The cyclathon travelled 525 and 200 kilometres respectively with 15 riders and a team of 70 youth volunteers covering village panchayats, schools, CHC/PHCs, youth mandals, women groups etc, in a span of five days each year. The volunteers rode across the streets performing skits, holding exhibitions, talking to villagers, students, getting term to take a pledge for tobacco free future generation. While this was a very unique initiative, the important learnings out of this experience are that when children and youth are involved first hand in sensitizing for a cause, their commitment to tobacco free lifestyle is ensured for a lifetime. Getting them involved with the various socio-economic strata and govt. facilities and systems instils a sense of responsibility towards their own peers and a tobacco free generation and also the government system. Both the cyclathons reached out to an approximate of 25000 youth and commoners through its various programs.

In 2019, the Government of India introduced the Tobacco Free Educational Institution (ToFEI) guidelines to ensure a healthy environment for youth. However, Rajasthan's Sikar's dense educational hubs have struggled with compliance due to the easy availability of tobacco products and the exposure of minors to tobacco advertisements near schools. Given the limitations of existing laws, the administration decided to implement a Tobacco Vendor Licensing (TVL) policy. This policy, developed with technical support from Shikshit Rojgar Kendra Prabandhak Samiti (SRKPS) a non-profit organisation currently working on advancing comprehensive tobacco control in Rajasthan and District Tobacco Control Cell (DTCC) Sikar, Rajasthan aimed to prohibit the sale of tobacco products in key areas, specifically Nawalgarh Road and Piprali Road. The implementation of the TVL policy resulted in a significant reduction in the availability of tobacco products near educational institutions. It also highlighted the importance of local bodies in enforcing tobacco control measures and the need for inter-departmental coordination.

In the year 2009, Mary Anny Charity Trust (MACT) a non-profit organisation noticed a high prevalence of tobacco use among the children and youth in slum dweller colony. It was found that they lack

knowledge on the harmfulness of tobacco. Recognising that educating for one-time will not bring any behavioural change among the youth, MACT developed an effective handholding program called Children Against Tobacco/ CAT. CAT model was found to be a powerful and sustainable model in "prevention of tobacco use". The children and youth trained as CAT members and leaders become 'good will' ambassadors in the fight against tobacco. Also they work with and support the school management in effective implementation of TOFEI (Tobacco Free Educational Institution) through a tobacco monitor application. Engaging in such leadership roles enhances their cognitive functions and lead to an improvement in academics and also involvement in other social activities.

Since 28 years Generation Saviour Association, a civil society organisation working in public health is conducting painting competition to observe World No Tobacco day wherein around 600-1000 students participate every year and pledge to live a tobacco free life. One to one sensitization meetings, trainings, technical workshops were conducted by GSA to support Tobacco Free Educational Institutes under the leadership of State Tobacco Control Cells of Punjab and Haryana. 28244 schools in Punjab, 10493 schools and 118 colleges in Haryana have been declared Tobacco Free Educational Institutes.

Conrad Challenge is an annual competition for children aged 13-18 years, being organised by Phillip Morris' Foundation for Smoke Free World (FSFW), in which children from various countries participate.

During the competition representatives of FSFW interact closely with the student contestants and offered them help towards career advice or internships. Despite CBSE guidelines prohibiting schools from allowing student participation in tobacco industry sponsored events, many schools participated in it. Generation Saviour Association requested PS, Health (Punjab), Director- Secondary Education (Haryana) and various schools to prohibit student participation in Conrad Challenge. Besides this the organisation requested schools in the region not to send student participation in this competition. As a result, none of the schools from Punjab, Haryana and Chandigarh participated in the Conrad Challenge.

Generation Saviour Association organised Three-day National Consultation on Tobacco Free Generations (TFG) in Chandigarh where Non-Government Organisation representatives from 13 states of India, namely Punjab, Haryana, Chandigarh, Rajasthan, Bihar, Jharkhand, Delhi, Uttar Pradesh, Gujrat, Kerala, Himachal, Karnataka, West Bengal, participated; followed by an Online Consultation Adopting TFG for fighting Public Health Emergencies.

Gaps and Challenges in Youth Intervention for Tobacco Control in India:

- **Weak Enforcement of Regulations:** Despite laws like COTPA 2003, enforcement is inconsistent, especially in rural areas and near educational institutions.
- Increased Accessibility: Easy availability of tobacco products, particularly smokeless forms, makes it harder to prevent youth initiation.
- **Tobacco Industry Interference:** Aggressive marketing, use of digital platforms, and new products (e-cigarettes, flavored tobacco) target young users.
- Lack of Awareness: Many youth remain unaware of the full health risks associated with tobaccouse.
- **Cultural Acceptance:** Social norms around tobacco consumption, especially in certain communities, hinder preventive efforts.
- Ineffective Monitoring: Limited mechanisms to monitor and track tobacco consumption trends among youth.
- Inadequate School-Based Programs: Insufficient integration of tobacco control education within school curriculums.
- Under-resourced Cessation Services: Limited access to youth-focused cessation programs and services.
- Low Community Involvement: Lack of sustained community engagement to reinforce tobaccofree behaviours among adolescents.

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RECOMMENDATIONS

5.3. Youth Intervention

5.3.1. Recommendations for Ministry of Health and Family Welfare

- a) COTPA, 2003 Amendment for Increasing the Age of purchase of tobacco products to 21 years: Increasing the age of tobacco purchase from 18 to 21 years can bring long lasting impact on tobacco control and give impetus tobacco control efforts. It is seen that later in the life a person initiates tobacco usage, higher are the chances of the person giving up tobacco usage, since a habit developed at a young age is difficult to give up.
- b) Uniform Implementation and amendment of Section 6, COTPA 2003- Section 6 under COTPA, 2003 prohibits sale of tobacco products to and by minors and further prohibition of sale within 100 yards of any educational institution. The national level data (MIS dashboard) reflects gap in implementation of Section 6 as compared to Section 4 under COTPA. Therefore, prioritising the implementation of Section 6 at state and district tobacco control cell and strengthening the legislation with amendment at national and state level by Increasing the fines and increasing the age of purchase of tobacco products from 18 to 21 years.
- c) Complete ban on tobacco product depiction and advertisement on social media and OTT-The age-appropriate warning in OTT platforms fails to serve as a deterrent therefore there should be a complete ban on all kinds of tobacco product depiction, advertisement or the like on OTT but also social media apps.
- d) Ban on online sale of tobacco products: Presently there is no specific law on prohibition of sale of tobacco products through digital platforms like online websites and food delivery apps as a result they are easily accessible not only to the adults but children as well. Regulation on probation on online sale or through any other application is a must.
- e) Ease the protocols on implementation of Section 5 and 7: With a handful of litigations for implementation of Section 5 and 7, it becomes evident that there is an ardent need to ease the enforcement protocols of Section 5 and 7 of COTPA, 2003 so that authorised personnel are not reluctant to take action against the violators.
- f) Compulsory Tobacco Vendor Licensing: TVL can also drastically reduce tobacco consumption. Therefore, tobacco vendor licensing should be mandated and no tobacco sale be allowed from an unregistered tobacco vend.
- g) Enforcement guidelines of PECA: To implement PECA 2019, in letter and spirit, enforcement guidelines should be issued from the ministry. Also, violations and

action taken should be included in Monthly Crime Review of Police. Despite the law online sale through social media is very rampart, there is a need to curtail the same.

5.3.2. Recommendations for Ministry of Education

- a) Encouraging and Institutionalising Tobacco-free Jurisdictions: Tobacco-free policies in strategic settings constitute a cost-effective public health approach that encourages the important long-term goal of de-normalizing tobacco use. There is a need to encourage tobacco-free jurisdictions like tobacco free schools. TOFEI guidelines should be made compulsory and not voluntary to be adhered to for all kinds of educational institutes. Also, along with making self-evaluation compulsory there is a need of periodical assessment for maintaining the standard.
- b) Chapter on tobacco control in all levels of learning: Age-appropriate Chapters on ill impact of tobacco should be part of curriculum at all levels of learning be it school students or at graduate, post graduate levels.
- c) Monitoring and mitigating potential TII in the form of any investment or Corporate Social Responsibility (CSR) in educational institutes: Big tobacco companies indulge in brand promotion via competitions/ CSR aid/ plantation drives/ sponsorships for cultural events etc. which is considered as tobacco industry interferences. Ministry of Education and Ministry of youth affairs and sports should have a clear direction to state govt. and department of education highlighting the need for monitoring and mitigating such TII incidents at school level. Further, a dedicated empowered committee at state level should have active participation of representative from department of education.
- d) Tobacco Free Generation Every child has right to be raised in an environment that is free from tobacco use, and they are given opportunities to not choose to use tobacco ever in life, which can only be possible by adopting Tobacco Free Generation proposal which advocates legislation precluding the sale and supply of tobacco to individuals born after a certain year.

5.3.3. Recommendations for State Government

- a) Tailored and Age-specific tobacco cessation services: Tobacco cessation services should also be designed specific to age groups as the messages and practices differ to be impactful, especially between the adolescents and youth vs. adults. Furthermore, dedicated IEC campaigns regarding the available tobacco cessation services shall eliminate the stigma among the youth to use cessation services.
- b) Inclusion of tobacco control in other related health programs-Tobacco and its harmfulness has to be included in every programs organized by government health department.

5.3.4. Recommendations for Civil Society/NGOs

- a) Local NGOs especially working with children are not supposed to engage in CSR activities funded by tobacco industries. Tobacco control clubs/groups has to be formed at school /college levels where they reiterate the harms of tobacco and take steps to prevent their peer from falling into the tobacco trap.
- b) Youth intervention is an important aspect for tobacco control. Youth engagement must be meaningful, innovative, and not tokenistic. Interventions need to be theory-based, multi-component, and implemented over several years in school or community setting. Governments, Non-Government organisations, individual right activists, academicians should collaborate, cooperate and coordinate to save present and future generations from the scourge of tobacco use.

CHAPTER-4

Endgame for tobacco in India

Endgame for tobacco in India

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Background

This chapter describes the meaning of endgame necessity, its components, progress made worldwide, why it is necessary for India, what will be the challenges and how the implementable recommendations can help to achieve the desired goal.

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Introduction

A literary meaning of the word "Endgame" means final stage of anything (some action or process such as war, dispute, contest, etc.) (1). It has several synonyms too such as an end, finale, culmination, etc

(2). Although when used in reference to tobacco control, it has varied understanding. The one that appears to have a highest clarity is following: stopping commercial sale of tobacco products within a given timeline. This simplistic definition when elaborated for technical and legal purposes respectively means "a permanent elimination within a timeline of structural, social and political dynamics that help sustain the tobacco epidemic" (3).

Endgame is necessary since it is unjust for the governments to allow tobacco industry to make more money through their perverse tactics by making more addicts and deaths through a higher sale of tobacco and nicotine products (3-5). It is also a necessity because episodic thrusts of the existing measures have given some results but not to the extent needed, such as tobacco-free campaigns run in the past by the MoHFW, Government of India, and some states like Rajasthan, Uttarakhand, etc (6). Some facts merit a mention in the context of endgame for tobacco (7). Globally, the number of tobacco-related deaths have increased by about 60% between the years 2008 to 2023 respectively, from 5.4 million to over 8 million now! Forty-four countries are not protected by any of the measures under WHO MPOWER. While this package of demand-reduction measures has extended from 44 countries in the year 2008 to 151 countries in the year 2012, the pace has slowed since the year 2018 (8).

Currently, while tobacco control measures are aimed at reducing an overall burden of tobacco, the tobacco companies are acting unethically to promote their products while subverting, contesting and confronting the regulation (9). Their single-minded goal is to keep on increasing their profits through increased sales of their products which is diametrically opposite to the goal of those working for an effective tobacco control (3). In the year 2018, the basic handbook on tobacco product regulation by WHO has discussed about the failure to regulate tobacco for its contents and emissions. It attributed this failure to: (1) Prevailing challenges in regulating tobacco products; (2) Policy interventions that are highly technical in nature; (3) Translational conversion of science into regulation.10 Hence, it becomes necessary to move from attempts of regulating tobacco products to working on endgame measures (4).

Following myths prevail in reference to tobacco use and tobacco industry: (1) Tobacco is a normal consumer product; (2) Tobacco industry is just like any other industry; (3) Tobacco epidemic is primarily due to individuals' choice and behaviour; and (4) Tobacco alone is not the cause of death (1). It is because of these deep-rooted societal norms, a priority has emerged to a change in our focus from people-centric solutions (focusing on behavioural change to stop adolescents initiating tobacco use, and for the current users to quit) to the elimination of the tobacco industry (that it ceases to exist), thus, making our world tobacco-free through an endgame (4).

Following components have been identified for any individual or organization contemplating to work for Tobacco endgame (3):

- 1) The Definition of Endgame that is acceptable to all;
- 2) The Potential Policies such as tobacco/nicotine-free generation, reduction in tobacco retail outlets to a minimum, tobacco-free zones (tobacco-free workplaces, tobacco-free gram panchayats), etc.;
- 3) Normalizing the society for not initiating tobacco use, quitting by the current users and staying

- tobacco-free ubiquitously;
- 4) Legal considerations (from global to local) including FCTC treaty and trade agreements to the national and sub-national laws;
- 5) Targets under SDGs and NCD control: e.g., Reduction in tobacco use by 30% by 2025;
- 6) Environmental issues related to: (a) tobacco cultivation, e.g., exposure to pesticides; and (b) tobacco waste products (TWPs);
- 7) Multi-stakeholder engagements by the government/s inclusive of concerned politicians, policy planners, administrators (the decision makers), public health officials, academicians and researchers, communities, civil societies and the people at large, private health sector and medical/health insurance companies, media, etc.;
- Presently 53 countries working for the endgame either have definite endgame targets (the countries under European Union and Pacific Islands plus another 18 countries) or these are well-positioned for it (7 more countries).
- 23 of these are in LMICs Africa, Latin America, Middle East, and South Asia
- Their cluster description varies from

 (a) Endgame ready (India, Bhutan, Sri
 Lanka & Pakistan), (b) Almost ready,
 (c) More action needed to (d) Early epidemic stage
- These have a commonality, i.e., an Advanced tobacco control policy and a low smoking prevalence
- 8) Strategic planning for a tobacco-free future by permanently eliminating the structural, social and political dynamics "within a given timeline" that sustain tobacco epidemic. It will depend upon context, jurisdiction, policy, attitude and politics locally etc.; and
- 9) Working with media-building narrative, countering tobacco industry rhetoric, rehabilitating tobacco-crop cultivators and workers of tobacco industry, etc.

Many countries have initiated a consideration to reset their goal from accelerating tobacco control to an endgame for tobacco (Figure 1) (11). It requires to holistically combine measures that focus on tobacco products, those who use these, the market (inclusive of demand and supply) and institutions (government, tobacco industry or a third-party, e.g. a public health agency) as a comprehensive package (5, 12, 13). The need is urgent to work strategically for the endgame through the health- and non-health-sectors and with stakeholders at all levels (14). A demonstrable active and wider public support for policy planners to come on board is critical, especially from the current smokers (6).

The recently concluded tenth Conference of Parties (COP 10) at Panama had several overlapping issues such as human rights, environment and endgame (15). It has prioritized the endgame by establishing an expert group to explore forward-looking measures (Article 2.1) that go beyond minimum FCTC measures and report its findings at COP 11 (16).

Why endgame for India?

India has a national program to control tobacco (NTCP- National Tobacco Control Program) (17), a specific act (COTPA- Cigarette and Other Tobacco Products Act of 2003) (18) and portals to quit tobacco (NTQLS- National tobacco quitline services and mCessation) (19-21), besides pictorial health warnings covering 85% of tobacco products' packaging.

	Vear endgame target set	Target year for achieving endgame
Bhetan	2004	2004
Vatican City	2018	2018
New Zedand	2011	2025
irefand	2013	2025
Pacific Islands (Cook Islands, Fig. French- Polymeia, Kichall, Manhall Islands, Microresia, Nasc., New Caledonia, Nove. Palau, Papos New Goltes, Samus, Schomon Islands, Tonga, Turatu, and Varnatio)	2013	2025
Sweden	2016	3035
Finland	2010	2630
Denmark	2016	2630
England	3019	2030
Australia	2021	2030
Wales	2022	2030
France	2023	2030
Scotland	2013	2034
Canada	2018	2035
Bangladedi	2016	2040
NetForfands	2019	3040
EU (Asietria, Belgium, Bulgaria, Croatia, Cyprin, Czesh Rep, Dermark, Estinea, Freland, France, Germany, Genes, Horigary, Ireland, Raly, Latvia, Lithuaria, Usermbusey, Matta, Nechorlands, Poland, Portugal, Bromeria, Mirsakia, Shevenia, Spain, and Swedeni)	2021	2040
Spain	2021	2045
Belgium	2022	2040
Malaysia	2022	2040
come usuations are listed twice as they are include her over mational target.	d in a regional	target and have

Figure 2- Countries and Regions with Endgame timelines



Also, India has surged in WHO MPOWER implementation from year 2008 to year 2018 by 8 positions (49th to 40th position) with relative change in scoring by a score of 7 (from 21 to 28; an increase by 33.33%) on the basis of the scoring done for every indicator under MPOWER; except "M" that had the gradient varying from 0 to 3, the rest ("POWER") had gradient varying from 0-5, accounting for a total score of 34 (4+[5x6]) (22).

Further, beyond the national level initiatives, there are a host of sub-national/state level policy initiatives - often bolder and futuristic - that paves way for endgame like ideas. (e.g., prohibition on certain smokeless tobacco items, government-wide 5.3 policies, vendor licensing, tobacco free generations, etc.

On the contrary, India is a high-burden country with 267 million users (23), 1.35 million deaths annually due to tobaccorelated illnesses (24), economic loss of \sim 1.04% (25) of GDP and humongous adverse impact on environment (26). Except for data on environment, these reports were made 6 to 10 years back while the population of India has increased from 1.29 billion in year 2013 to 1.44 billion in year 2024 (an increase by 0.92% from year 2023) (27) and, thus, presumably with an increase in the actual number of tobacco users and daily deaths due to tobacco-related diseases; the latter increased by over 94% from \sim 1,800 in year 2003 to \sim 3,500 daily in year 2018 (24).

Through India has made some progress which is reflected through reduction in prevalence of tobacco use by 6% in adults over a span of 7 years (2009- 2010 to 2016-17; relative reduction by ~17%) (23), reduction in initiation of tobacco use by 8.4% school-going adolescents between 13- 15 years of age (from GYTS 2003 to GYTS 2019) (28), a varied and generally low compliance is being observed in various sections of COTPA (29). Further, the Index for Tobacco Control Sustainability (ITCS) devised by Vital Strategies and the Union for 27 States/UTs has also reported a grim picture for tobacco control in India (22).

India need not wait to first achieve a substantial reduction in prevalence like many countries that have equated endgame to reducing prevalence to less than 5% by the year 2040 (Figure 2) (11). It simply cannot afford to wait similarly in view of the burden of tobacco, tardy progress in its reduction due to poor enforcement and loss of the lives that will occur in the interim and its overall impact on the national productivity. Also, by accomplishing the goal, it will lead the way for its replication by the neighboring countries in the South- East Asia. Hence, it appears appropriate to propose a timeline of December 2030 for the endgame of tobacco in India.

It becomes relevant at this point of time to discuss how endgame for tobacco, i.e., phasing out tobacco use can achieve a tobacco-free future for India. If India can implement the endgame, the number of deaths caused by tobacco from past use will start decreasing immediately, first rather slowly and then rapidly reaching insignificant levels after a few decades.

Challenges for Endgame

Following points can be considered as India-specific challenges whenever the governments in the Centre and the States and the UTs will be approached to frame a policy and/or enact a law to implement the endgame for tobacco:

- 1. The proposal of the Endgame may get rejected outrightly as coercive, anti-democratic, dictatorial or simply "too radical a concept" that violates the fundamental rights of tobacco industry and all its allies. So, options may be sought within the existing mechanism for tobacco control (NTCP) or as innovations such as tobacco-vendor licensing, tobacco-free gram panchayats, tobacco-free workplaces, tobacco-free generation, etc. as the first step towards the endgame for tobacco. However, their optimal enforcement maybe the "Achilles Heel" for regulation measures to be effective.
- 2. An argument can be that it violates the fundamental rights of tobacco industry and all its allies like right to trade, right to earn livelihood, etc. Nevertheless, these rights get nullified in favor of the fundamental rights related to public health (by protecting people from harms of tobacco).
- 3. Government of India has Tobacco Board (30); and Central Tobacco Research Institute (CTRI) (31) for over half a century. It will be challenging to phase-out both these in view of: (1) their mandate (to grow better quality of tobacco and enhance exports); and (2) mutually beneficial relationship with all concerned ministries such as finance, commerce, agriculture, etc. Further, the Life insurance Corporation of India (LIC of India), a government subsidiary, has investments worth 3,500 crores in a cigarette industry (32). The tobacco endgame will remain a dream only unless these investments in tobacco industry will be withdrawn.
- 4. India as the second largest producer, exporter and consumer of tobacco globally (24, 25, 30), earns a revenue of 53,750 crores (33). But, this total revenue earned amounts to just about 12% of its total spending on managing diseases and deaths due tobacco (1,773.4 billion INR equivalent to 27.5 billion USD) (34).
- 5. The tobacco industry exerts a direct influence on the government as a partner of the largest tobacco industry of India ITC. It also exerts covert influence in form of: (1) funding of the political parties and politicians; and, (2) the support it gets from its front groups, farmers, retailers, informal-sector bidi workers, etc. through their protests and demand for alternative vocations. The governments prefer to avoid any legal confrontation with the industry although the governments have had significant victories in the past on issues such as large pictorial warnings, bans on gutka and

e-cigarettes and similar products.

- 6. Except for the MoHFW, Government of India, and few State Medical and Health Departments, all other ministries have contributed little to inform their departments on the harmful impact of tobacco industry and its allies; and, in acting against these. Hence, their stakes into the interests of the tobacco industry overpowers the concerns these should have on how tobacco adversely affects the health and thus the lives of the people (35). It has led to either missing on stakeholders' engagement or critically delaying the policy decisions.
- 7. Although the tobacco control initiatives and innovations are still civil society dominated, their strength on ground at the best is sketchy, weak and government-dependent; the guidance or thrust given by these do not get supported by the potential beneficiaries- the governments or the local communities.
- 8. The public and private health and insurance sectors have not established any suitable provisions to: (a) promote quitting through their respective workforce and (b) motivate their tobacco-using patients to demand treatment for tobacco (nicotine) dependence.
- Although quitting tobacco formally through existing tobacco cessation services like tobacco cessation clinics, national quitline services and mCessation appears an easy-to-grab solution to reduce tobacco burden, these lack required resources and outreach to be useful in a significant manner.
- 10. There have been repeated attempts by the tobacco industry to nullify PECA 2019 (36). MOHFW will have to find the way to be persistently on guard to not let advocacy of harm reduction ever nullify the gains of PECA 2019.
- 11. The shortcomings to enforce notified sections of COTPA (37), needs to be addressed & appropriate legal options sought which can nullify the muscle power of tobacco industry.
- 12. The potential of threats to the individuals working to counter the motives and/or moves to enhance the profitability of the tobacco industry should also be taken into consideration.
- 13. The mass media has not been utilized optimally and effectively yet to realize the perceived efficacy of the available provisions of tobacco control through government, private sector and civil societies.
- 14. We need to strengthen context-based research/epidemiologic studies to know how people will react or respond on tobacco endgame.

Summary:

Skepticism to the call for an endgame of tobacco should be considered acceptable in view of its efficacy and overall utility. The government will need significant support on a sustainable basis from all its stakeholders to endorse, promote, organize and realize the date-bound tobacco endgame goal and to counter tobacco industry rhetoric, threats and political wrath (39). No one thought before the cigarette century (the 19th century; 1901- 2000) that tobacco products will be sold ubiquitously. Also, no one considered in the preceding century, having smoke-free environments, ban on tobacco advertisements, large pictorial warnings, age restriction for selling tobacco products to minors, etc. But all these impossible scenarios became a reality!

There are challenges to the endgame- to prevail on the moneyed (syn. monied) tobacco industry, its capabilities to influence political will, dilute policies of tobacco control, make governments fearful of its legal coercions and above all a fearful assumption tobacco control activists have: (a) to consider it naïve, untimely and inappropriate; (b) that it will offend the government supportive of the tobacco industry; and (c) that it will unduly antagonize the deceptive tobacco industry further. The endgame for tobacco while urging to stop commercial sale of all tobacco products within a timeline through a phase out, eliminates the uncertainty and constant struggle to control tobacco because it assures a measurable endpoint foreseeable in coming years.

High-burden countries like India should not wait to first lower the prevalence to a low 5% as many in the developed countries think. With the proposed timeline of December 2030, India will lose ~1.5 crore lives prematurely in the interim with its huge adverse impact on the overall development of the country. Undoubtedly, India is capable due to its unique ability to act in times of crisis. Its call for the endgame of tobacco is one such moment where the advantage should not be conceded to the tobacco industry (39).

In conclusion, the global effort towards the tobacco endgame involves a comprehensive and complex journey, combining policy interventions, public health initiatives, and international cooperation. By continuing to innovate and implement stringent tobacco control measures, the vision of a tobacco-free future becomes increasingly attainable, safeguarding public health and ensuring a healthier future for generations to come.

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RECOMMENDATIONS

5.4. Endgame for tobacco

5.4.1. Phase-out:

- (a) Tobacco Board (30), the Central Tobacco Research Institute (CTRI) (2), the cultivation of tobacco, the tobacco industry and all its allies;
- (b) governmental investments into tobacco industry along with support to all their employees in alternative occupations that give these equivalent earnings through a specific "time-bound" rehabilitation plan; and
- the current users which will mean directing: (1) these to register for buying any tobacco product as well to definitely quit through a rigid timeline for all and countrywide; (2) every health facility at all levels of healthcare to establish tobacco cessation services through a systems approach besides improving the services of the NTQLS, mCessation, etc.; and (3) licensing of all the retail outlets in next two years followed by an effective reduction in their number (say by 15% to 20% over next 5-7 years) in a manner that these do not exist after the given timeline.

Tobacco industry defined as including cultivation, manufacturing, trade and retailing, should be classified as a unique industry not eligible for any special facility, incentives, subsidies etc. Imperative to stop all incentives, subsidies etc to the tobacco industry. For example, tobacco crop also gets subsidized irrigation water, fertilisers, pesticides etc. The tobacco industry deducts marketing and advertising expenses as legitimate business expenses from its revenue. All these need to stop for achieving the endgame.

5.4.2. Creation of effective communication channel and contents

Creation of effective communication channel and contents that have relevant data, public opinions, emotional appeals and how the human rights are getting violated; the messages to all the stakeholders should highlight:

- (a) the holistic benefits of a tobacco-free life;
- (b) a win-win situation for the country both economically and environmentally without tobacco industry; and
- (c) gains through the protection of lives.
- Use of all types of regular media (Print, TV and Radio) and the social media (the OTT and other online mediums) to empower their users to understand, talk and demand the endgame for tobacco within the given timeline.
- 5.4.2.2. Suitable empowerment and adequate funding to of the IEC section under National Health Mission and other departments. They should take lead to highlight the value of endgame in leading a tobacco-free life and associate it with benefits to health & their departments related messages.

- 5.4.3. Engagement of the victims of tobacco (both users and their dependents), health professionals (e.g. cardiologists, oncologists, etc.), public health experts, economists, religious leaders, celebrities, community leadership and people at large from all walks of life (regardless of their post, place and social status), etc. as very impactful messengers and influencers whose messages should be well-crafted to have the desired effect.
 - **5.4.3.1.** All the non-users should be suitably engaged, motivated, enriched and empowered to promote the endgame for tobacco by the stated timeline of December 2030.
 - **5.4.3.2.** Optimal utilization of every platform which will bring the decision-makers and people together for highlighting, brainstorming and discussing the endgame for tobacco, and to provide the solutions for its successful implementation in the given timeline.
- 5.4.4. Any suitable moment can be extremely useful although occasions such as festivals, religious and social gatherings, health-related campaigns, election times, etc. may be utilized specifically.
- 5.4.5. The fundamental right to live healthy (Article 21 of the Constitution of India) (3) should be interpreted to accept and lead a tobacco-free life regardless of the arguments over personal liberty. The experts in the subject nationally and internationally who can coordinate and collaborate in support of the issue and to be impactful should be included for their useful and constructive inputs.
- 5.4.6. The governments in the Centre, States and UTs should ensure adequate availability of the resources, both financial and human along with provisions of their sustainability.
- 5.4.7. Multicenter scientific, social, economic and political research should be supported to generate the corroborative evidence on utility of endgame of tobaccolocally as well as nationally.
- 5.4.8. Strategic readiness should be nurtured to effectively tackle the tobacco industry interference and influence at all levels including the media, using adoption of Article 5.3 of FCTC countrywide.

CHAPTER-5

Bidi & Other Indigenous Products

Bidi & Other Indigenous Products

Working Chair and Group members

NAMS Task Force for Tobacco Control Working Group on Bidi and Other Indigenous Products Dr Pankaj Bhardwaj¹, Dr Nitin Kumar Joshi¹, Dr Yogesh Kumar Jain¹, Dr Prashant Kumar Singh², Dr Amit Yadav³, Dr Nirmalya Mukherjee⁴, Dr Om Prakash Bera⁵, Dr Dewesh Kumar⁶, Dr Abhishek Raut⁷, Dr Nilanjana Ghosh⁸

Background

This chapter will go through various dimensions of health, economic and environmental burden posed by bidi industry in the country and highlight the disparities created to bidi users and bidi worker alike, examining the health, environmental, and economic impacts across various states and Union Territories, and exploring the current policies aimed at controlling bidi use. Moreover, the chapter will take the reader through some of the control and regulation strategies, offering recommendations that may be employed to control bidi consumption amongst the Indian population.

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Introduction

Bidi, a traditional form of tobacco product, is prevalent in many parts of South Asia, particularly India, Bangladesh, and Pakistan. Unlike conventional cigarettes, bidis are hand-rolled using tendu or temburni leaves and contain unprocessed tobacco flakes (1). Their affordability and cultural acceptance have contributed to their widespread use, especially among lower socioeconomic groups (2) However, the health hazards associated with bidi consumption are profound and often underappreciated. The health risks of bidi smoking are comparable to, if not greater than, those of conventional cigarette smoking. Availability of wide variety of unregulated bidi products to largely vulnerable socio-economic segment and youth pose an even greater challenge in spread and success of interventions and tobacco control sensitisation activities (3).

Evolution of Bidis in India

Bidis have a long-standing presence in the India subcontinent, deeply rooted in the country's cultural and social fabric. The history of bidis can be traced back to the 17th century when they were first introduced as a cheaper alternative to expensive tobacco products like cigars and cigarettes. The tobacco workers themselves were the first to create them by taking leftover tobacco and rolling it in leaves (4).

The commercial Indian beedi industry saw a rapid growth during the 1930s, driven by an expansion of tobacco cultivation during that time and the national movement to instil support towards Indian industries and Indian products (5). Over time, bidis became popular, especially among the lower-income population, due to their affordability and accessibility yet, the production has evolved from being factory-based to a cottage industry. This shift is also associated with involvement of a home-based women workforce, predominantly employed only in the beedi rolling, and the males continuing to be employed in other aspects of beedi production (5). Moreover, in the 1940s, 1950s, and 1960s, industry gradually shifted from the organized sector to the unorganized sector due to regulations and tax liberalization leading to a decline in factory-based production (6).

The production of bidis involves rolling tobacco flakes in a tendu leaf, a process that requires minimal industrial infrastructure. A single bidi stick is made of 0.2–0.3 grams of dark, sun-dried, and processed tobacco flakes, commonly wrapped in a tendu leaf (Diospyros melanoxylon) or Piliostigma racemosum leaf, and secured at one end with string or adhesive (7). In response to increasing health awareness and regulatory measures, bidi manufacturers began adding filters to their products as an effort to align with more modern cigarette trends and appeal to health-conscious consumers, although their effectiveness is often debated. Another significant evolution of bidi is marked by introduction of flavors. Flavored bidis are designed to enhance the smoking experience by masking the harshness of the tobacco with sweet or aromatic tastes such as cherry, chocolate, mint, and various fruit flavors. This practice has drawn particular concern from health advocates, as flavored tobacco products are often more appealing to younger users, potentially leading to higher rates of smoking initiation. Moreover, the flavours are created by a mix of high concentrations of compounds such as eugenol, anethole, methyleugenol, pulegone, and estragole, several of which have known toxic or carcinogenic properties (8).

Prevalence of Bidi use in India

Bidi is the second most common form of tobacco after smokeless tobacco affecting every single Indian state and Union Territory. The bidi consumption prevalence amongst adults aged 15 years and above ranges from as high as 19.3% in Tripura to 1.5% in Mizoram against the national average of 7.7%.

This marks as many as 72 million active bidi users in the country, as per the GATS-2 India Survey (2016-17) (9). Bidi use is more prevalent among men, with 14% of men smoking bidis compared to just 1.2% of women. Urban-rural disparities are also evident, as rural areas report a higher prevalence (9.3%) compared to urban areas (4.7%). The survey highlights a critical concern: the average age of initiation into bidi smoking is alarmingly low at 10.5 years, underscoring the need for early prevention efforts.

The Global Youth Tobacco Survey (GYTS-4), which focuses on tobacco use among youth aged 13-15 years, reveals that bidi smoking are a cause of significant concern amongst adolescents with 2.1% prevalence of regular use and 4.1% of students having smoked bidis at least once. The prevalence ranged from an extremely high rate of 41.7% in Arunachal Pradesh to 0.1% in Himachal Pradesh. Male students (2.7%) were more likely to smoke bidis than their female counterparts (1.5%), and a greater predilection in rural areas (2.2%) than urban areas (1.7%) reflecting similar gender and regional disparities as seen in adult bidi use.

Health, Economics & Environment Burden

Health Burden due to bidi consumption

Bidi is falsely considered as organic and seldom harmless, amongst its user base. Though bidi stick contains less grams of tobacco in comparison to other tobacco products, the non-porosity of the tendu leaf poses a tendency to self-extinguish leading to higher puff intensity and shorter inter-puff durations, thus delivering more nicotine, carbon monoxide and toxins in the user's body (10). Studies have shown that bidi smokers inhale 1.39 times more carbon monoxide, and 1.42 times more nicotine than cigarette smokers due to the lack of a filter and the nature of the bidi's combustion (11). This leads to a higher incidence of respiratory illnesses, including chronic obstructive pulmonary disease (COPD), bronchitis, and emphysema. Moreover, the risk of developing cardiovascular diseases is significantly elevated among bidi smokers. The unfiltered smoke inhaled from bidis increases the strain on the heart and blood vessels, leading to hypertension, heart attacks, and strokes (1).

Bidis have been strongly linked to various forms of cancer, notably oral, lung, and esophageal cancers. The crude, unrefined tobacco used in bidis contains higher concentrations of carcinogens compared to the processed tobacco in cigarettes. Oral cancer is a major health issue among bidi users, exacerbated by the practice of combining bidi smoking with chewing betel quid, another carcinogenic substance.

Literature reveals a much higher odds of 1.95 (1.59-2.39) for development of wheeze, 1.67 (1.36-2.04) times for development of dyspnoea and 1.63 (1.40-1.89) times for development of chest pain amongst bidi smokers as compared to non-smokers. The FEV1/FVC ratio falls much faster with age for bidi smokers as compared to non-smokers and cigarette smokers and hazard ratios of respiratory (1.55, 95% CI: 1.17-2.06), cardiac events (1.79, 95% CI: 1.23-2.45) and death (1.56, 95% CI: 1.22-1.98) increase manifolds amongst bidi smokers (12). (Duong et al. Lancet Glob Health 2017).

Population attributable fraction may be used as a valid statistical tool to quantify the mortality and morbidity in a population due to a specific risk factor prevalent in the population in question. Based on the population attributable fraction estimates for major diseases occurring due to bidi consumption,

namely, lung cancer, oral cancer, ischemic heart disease, chronic obstructive pulmonary disease and tuberculosis, the quantifiable mortality and morbidity estimates imply over 5.5 lakh deaths, 1.5 crore DALYs, 1.3 crore YLLs and 13.5 lakh YLDs to be annually attributable to diseases occurring due to bidi consumption in the country (13) (Table 1).

Table 1: Disease burden directly attributable to bidi consumption in India

	Death	DALY	YLL	YLD
Oral Cancer	18,143.99	5,32,015.19	5,21,928.55	10,086.63
Lung Cancer	24,923.36	6,35,422.48	6,29,734.26	5,688.22
Ischemic Heart Disease	2,56,143.48	62,78,097.02	61,78,501.45	99,595.57
Tuberculosis	88,526.62	32,78,391.78	29,51,181.27	3,27,210.51
COPD	1,67,845.40	39,66,243.75	30,63,009.33	9,03,234.43
Total	5,55,582.85	1,46,90,170.22	1,33,44,354.86	13,45,815.37

Abbreviations: DALY: Disability Adjusted Life Years, YLL: Premature Life Years Lost, YLD: Years Lived with Disability, COPD: Chronic Obstructive Pulmonary Disease

Across the various subnational regions of the country, the three states with highest disease burden due to bidi consumption were observed to be Uttar Pradesh, Maharashtra and Tamil Nadu. Uttar Pradesh bears a burden of 1.04 lakh annual deaths due to bidi consumption, which accounts for 18.6% of the national estimate, Maharashtra suffers 53.09 thousand deaths (9.5%), while 40.72 thousand deaths (7.3%) occur in Tamil Nadu annually due to diseases occurring attributable to bidi consumption (14) (Table 2).

Table 2: State-wise annual deaths due to bidi consumption

State/UT	Lung Cancer	Oral Cancer	IHD	COPD	ТВ	Total Deaths
Andhra Pradesh	934.66	483.44	13,764.13	6,429.65	2,429.19	24,041.07
Arunachal Pradesh	22.99	10.37	88.21	96.92	82.28	300.77
Assam	645.28	625.10	3,086.66	3,469.53	2,843.37	10,669.94
Bihar	1,256.38	460.38	15,371.37	10,601.67	6,177.36	33,867.15
Chhattisgarh	461.49	387.17	4,281.76	3,064.02	2,817.21	11,011.65
Delhi	456.30	296.97	3,358.12	1,385.53	736.47	6,233.38
Goa	32.01	21.53	426.09	103.24	45.14	628.02
Gujarat	1,310.46	1,607.90	16,203.62	9,070.85	6,262.78	34,455.61
Haryana	490.11	324.29	5,957.81	3,381.82	1,550.52	11,704.55
Himachal Pradesh	189.32	109.06	1,629.67	1,764.02	414.26	4,106.33

J&K and Ladakh 393.68 42.47 2,672.37 2,192.99 450.07 5,751.58 Jharkhand 354.00 273.09 3,920.50 3,025.83 1,747.01 9,320.43 Karnataka 1,443.93 1,293.34 18,367.71 10,267.80 3,289.73 34,662.51 Kerala 1,548.40 870.61 10,901.24 3,666.60 771.23 17,758.07 Madhya Pradesh 1,394.89 1,696.30 13,262.47 11,007.15 5,586.91 32,947.72 Maharashtra 2,407.85 1,951.10 28,534.09 13,357.40 6,835.34 53,085.77 Manipur 117.98 19.46 351.77 223.06 225.52 937.80 Meghalaya 63.89 57.60 183.34 155.03 208.30 668.16 Mizoram 89.05 10.45 46.63 149.96 44.09 340.17 Nagaland 23.87 16.86 171.74 93.46 102.06 408.00 Odisha 758.95 645.30							
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Madhya Pradesh 1,394.89 1,696.30 13,262.47 11,007.15 5,586.91 32,947.72 Maharashtra 2,407.85 1,951.10 28,534.09 13,357.40 6,835.34 53,085.77 Manipur 117.98 19.46 351.77 223.06 225.52 937.80 Meghalaya 63.89 57.60 183.34 155.03 208.30 668.16 Mizoram 89.05 10.45 46.63 149.96 44.09 340.17 Nagaland 23.87 16.86 171.74 93.46 102.06 408.00 Odisha 758.95 645.30 4,000.59 2,435.90 4,177.72 12,018.47 Punjab 668.62 250.04 11,344.43 1,912.40 1,369.28 15,544.78 Rajasthan 1,169.89 681.00 9,706.81 16,584.64 7,305.78 35,448.13 Sikkim 16.20 6.25 77.62 59.01 31.98 191.07 Tamil Nadu 1,631.44 1,248.38 27,45	Karnataka	1,443.93	1,293.34	18,367.71	10,267.80	3,289.73	34,662.51
Maharashtra 2,407.85 1,951.10 28,534.09 13,357.40 6,835.34 53,085.77 Manipur 117.98 19.46 351.77 223.06 225.52 937.80 Meghalaya 63.89 57.60 183.34 155.03 208.30 668.16 Mizoram 89.05 10.45 46.63 149.96 44.09 340.17 Nagaland 23.87 16.86 171.74 93.46 102.06 408.00 Odisha 758.95 645.30 4,000.59 2,435.90 4,177.72 12,018.47 Punjab 668.62 250.04 11,344.43 1,912.40 1,369.28 15,544.78 Rajasthan 1,169.89 681.00 9,706.81 16,584.64 7,305.78 35,448.13 Sikkim 16.20 6.25 77.62 59.01 31.98 191.07 Tamil Nadu 1,631.44 1,248.38 27,452.07 6,179.99 4,206.22 40,718.10 Telangana 574.31 279.38 7,986.72	Kerala	1,548.40	870.61	10,901.24	3,666.60	771.23	17,758.07
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Nagaland 23.87 16.86 171.74 93.46 102.06 408.00 Odisha 758.95 645.30 4,000.59 2,435.90 4,177.72 12,018.47 Punjab 668.62 250.04 11,344.43 1,912.40 1,369.28 15,544.78 Rajasthan 1,169.89 681.00 9,706.81 16,584.64 7,305.78 35,448.13 Sikkim 16.20 6.25 77.62 59.01 31.98 191.07 Tamil Nadu 1,631.44 1,248.38 27,452.07 6,179.99 4,206.22 40,718.10 Telangana 574.31 279.38 7,986.72 3,460.55 1,230.38 13,531.34 Tripura 105.63 51.75 593.60 502.92 130.21 1,384.11 Uttar Pradesh 3,786.70 3,101.13 32,492.79 41,141.91 23,006.60 1,03,529.13 Uttarakhand 343.10 160.36 2,272.24 2,425.29 1,026.57 6,227.56	Meghalaya	63.89	57.60	183.34	155.03	208.30	668.16
Odisha 758.95 645.30 4,000.59 2,435.90 4,177.72 12,018.47 Punjab 668.62 250.04 11,344.43 1,912.40 1,369.28 15,544.78 Rajasthan 1,169.89 681.00 9,706.81 16,584.64 7,305.78 35,448.13 Sikkim 16.20 6.25 77.62 59.01 31.98 191.07 Tamil Nadu 1,631.44 1,248.38 27,452.07 6,179.99 4,206.22 40,718.10 Telangana 574.31 279.38 7,986.72 3,460.55 1,230.38 13,531.34 Tripura 105.63 51.75 593.60 502.92 130.21 1,384.11 Uttar Pradesh 3,786.70 3,101.13 32,492.79 41,141.91 23,006.60 1,03,529.13 Uttarakhand 343.10 160.36 2,272.24 2,425.29 1,026.57 6,227.56	Mizoram	89.05	10.45	46.63	149.96	44.09	340.17
Punjab 668.62 250.04 11,344.43 1,912.40 1,369.28 15,544.78 Rajasthan 1,169.89 681.00 9,706.81 16,584.64 7,305.78 35,448.13 Sikkim 16.20 6.25 77.62 59.01 31.98 191.07 Tamil Nadu 1,631.44 1,248.38 27,452.07 6,179.99 4,206.22 40,718.10 Telangana 574.31 279.38 7,986.72 3,460.55 1,230.38 13,531.34 Tripura 105.63 51.75 593.60 502.92 130.21 1,384.11 Uttar Pradesh 3,786.70 3,101.13 32,492.79 41,141.91 23,006.60 1,03,529.13 Uttarakhand 343.10 160.36 2,272.24 2,425.29 1,026.57 6,227.56	Nagaland	23.87	16.86	171.74	93.46	102.06	408.00
Rajasthan 1,169.89 681.00 9,706.81 16,584.64 7,305.78 35,448.13 Sikkim 16.20 6.25 77.62 59.01 31.98 191.07 Tamil Nadu 1,631.44 1,248.38 27,452.07 6,179.99 4,206.22 40,718.10 Telangana 574.31 279.38 7,986.72 3,460.55 1,230.38 13,531.34 Tripura 105.63 51.75 593.60 502.92 130.21 1,384.11 Uttar Pradesh 3,786.70 3,101.13 32,492.79 41,141.91 23,006.60 1,03,529.13 Uttarakhand 343.10 160.36 2,272.24 2,425.29 1,026.57 6,227.56	Odisha	758.95	645.30	4,000.59	2,435.90	4,177.72	12,018.47
Sikkim 16.20 6.25 77.62 59.01 31.98 191.07 Tamil Nadu 1,631.44 1,248.38 27,452.07 6,179.99 4,206.22 40,718.10 Telangana 574.31 279.38 7,986.72 3,460.55 1,230.38 13,531.34 Tripura 105.63 51.75 593.60 502.92 130.21 1,384.11 Uttar Pradesh 3,786.70 3,101.13 32,492.79 41,141.91 23,006.60 1,03,529.13 Uttarakhand 343.10 160.36 2,272.24 2,425.29 1,026.57 6,227.56	Punjab	668.62	250.04	11,344.43	1,912.40	1,369.28	15,544.78
Tamil Nadu 1,631.44 1,248.38 27,452.07 6,179.99 4,206.22 40,718.10 Telangana 574.31 279.38 7,986.72 3,460.55 1,230.38 13,531.34 Tripura 105.63 51.75 593.60 502.92 130.21 1,384.11 Uttar Pradesh 3,786.70 3,101.13 32,492.79 41,141.91 23,006.60 1,03,529.13 Uttarakhand 343.10 160.36 2,272.24 2,425.29 1,026.57 6,227.56	Rajasthan	1,169.89	681.00	9,706.81	16,584.64	7,305.78	35,448.13
Telangana 574.31 279.38 7,986.72 3,460.55 1,230.38 13,531.34 Tripura 105.63 51.75 593.60 502.92 130.21 1,384.11 Uttar Pradesh 3,786.70 3,101.13 32,492.79 41,141.91 23,006.60 1,03,529.13 Uttarakhand 343.10 160.36 2,272.24 2,425.29 1,026.57 6,227.56	Sikkim	16.20	6.25	77.62	59.01	31.98	191.07
Tripura 105.63 51.75 593.60 502.92 130.21 1,384.11 Uttar Pradesh 3,786.70 3,101.13 32,492.79 41,141.91 23,006.60 1,03,529.13 Uttarakhand 343.10 160.36 2,272.24 2,425.29 1,026.57 6,227.56	Tamil Nadu	1,631.44	1,248.38	27,452.07	6,179.99	4,206.22	40,718.10
Uttar Pradesh 3,786.70 3,101.13 32,492.79 41,141.91 23,006.60 1,03,529.13 Uttarakhand 343.10 160.36 2,272.24 2,425.29 1,026.57 6,227.56	Telangana	574.31	279.38	7,986.72	3,460.55	1,230.38	13,531.34
Uttarakhand 343.10 160.36 2,272.24 2,425.29 1,026.57 6,227.56	Tripura	105.63	51.75	593.60	502.92	130.21	1,384.11
	Uttar Pradesh	3,786.70	3,101.13	32,492.79	41,141.91	23,006.60	1,03,529.13
West Bengal 2,169,76 1,093,22 16,894,56 9,418,90 3,256,83 32,833,26	Uttarakhand	343.10	160.36	2,272.24	2,425.29	1,026.57	6,227.56
10,05 list 5,110,10 5,250,05 52,055,125	West Bengal	2,169.76	1,093.22	16,894.56	9,418.90	3,256.83	32,833.26
Other UTs 62.22 69.69 742.76 217.35 166.21 1,258.22	Other UTs	62.22	69.69	742.76	217.35	166.21	1,258.22

Highest losses in terms of Disability Adjusted Life Years (DALYs) are estimated from the states of Uttar Pradesh (19.5%), Maharashtra (9.2%), Tamil Nadu (7.1%), with annual loss of 28.67 lakh DALYs from Uttar Pradesh, 13.56 lakh DALYs from Maharashtra, 10.47 lakh DALYs from Tamil Nadu (14) (Table 3).

Table 3: State-wise annual DALYs due to bidi consumption

State/UT	Lung Cancer	Oral Cancer	IHD	COPD	ТВ	Total Deaths
Andhra Pradesh	21,546.17	12,413.16	3,20,046.57	1,52,757.35	78,172.38	5,84,935.63
Arunachal Pradesh	618.56	312.57	2,212.33	2,483.97	3,119.07	8,746.48

Assam	17,624.16	19,739.88	82,327.50	86,342.10	1,10,633.18	3,16,666.82
Bihar	30,145.25	13,422.75	3,73,919.56	2,61,451.40	2,20,084.30	8,99,023.26
Chhattisgarh	11,789.68	11,425.05	1,13,642.68	77,557.08	1,01,641.79	3,16,056.28
Delhi	12,057.92	9,196.40	80,520.12	36,199.68	30,374.31	1,68,348.44
Goa	745.20	527.30	8,787.45	2,955.12	1,393.62	14,408.69
Gujarat	35,329.55	50,394.35	4,18,626.44	2,13,479.45	2,30,554.22	9,48,384.00
Haryana	13,184.82	9,300.67	1,55,040.29	81,093.84	56,762.66	3,15,382.28
Himachal Pradesh	4,877.26	3,005.95	38,790.27	36,597.23	13,882.24	97,152.96
J&K and Ladakh	10,576.19	1,190.54	63,715.53	47,973.74	15,696.96	1,39,152.95
Jharkhand	8,149.42	7,533.21	90,649.92	74,869.66	62,661.32	2,43,863.53
Mizoram	2,260.94	310.78	1,089.17	3,419.68	1,598.90	8,679.46
Nagaland	574.82	493.63	3,777.08	2,324.94	3,571.81	10,742.28
Odisha	18,094.51	18,025.86	1,00,460.55	68,677.70) 1,42,525.1	9 3,47,783.81
Punjab	16,403.25	7,623.05	2,83,657.87	54,282.42	2 47,351.82	4,09,318.41
Rajasthan	31,341.11	20,516.29	2,64,346.04	3,55,403.6	55 2,90,724.0	9,62,331.16
Sikkim	400.50	179.83	1,812.94	1,415.99	1,126.83	4,936.09
Tamil Nadu	40,658.18	36,223.61	6,64,379.25	1,68,662.2	28 1,37,063.1	1 10,46,986.44
Telangana	13,608.00	7,540.29	1,94,913.96	86,717.54	42,835.05	3,45,614.85
Tripura	2,704.53	1,528.48	13,837.24	11,586.58	3 4,567.56	34,224.39
Uttar Pradesh	1,01,568.8	93,531.31	8,39,627.12	9,45,122.2	29 8,87,239.1	0 28,67,088.68
Uttarakhand	9,476.70	4,730.14	59,429.40	54,796.30	36,202.11	1,64,634.65
West Bengal	57,129.09	31,171.65	3,83,236.85	2,31,662.2	1,22,698.7	8,25,898.59
Other UTs	1,604.14	1,926.41	17,221.13	6,054.47	5,941.22	32,747.36

Highest mortality burden of in terms of prematurely lost life years (YLLs) are estimated from Uttar Pradesh to be 26.36 lakhs annually (19.8%), 12.17 lakhs from Maharashtra (9.1%), and 9.63 lakhs from Tamil Nadu (7.2%), While, highest morbidity burden in terms of Years Lived with Disability (YLDs) are estimated to be borne by Uttar Pradesh (17.2%), Maharashtra (10.3%) and West Bengal (7.2%), with 2.32 lakh years, 1.39 lakh years, and 96.54 thousand years respectively (14) (Table 4).

Table 4: State-wise annual YLLs due to bidi consumption

State/UT	Lung Cancer	Oral Cancer	IHD	COPD	ТВ	Total Deaths
Andhra Pradesh	21,340.53	12,147.02	3,14,983.24	1,09,513.36	70,058.81	5,28,042.97
Arunachal Pradesh	613.25	306.33	2,148.03	1,738.15	2,749.69	7,555.44
Assam	17,473.37	19,409.33	80,567.21	66,011.78	1,00,745.23	2,84,206.92
Bihar	29,862.73	13,170.66	3,67,605.58	1,98,331.16	1,97,892.37	8,06,862.50
Chhattisgarh	11,686.56	11,229.83	1,11,687.81	59,048.40	94,238.44	2,87,891.04
Delhi	11,951.22	9,012.19	79,060.18	24,601.68	24,939.44	1,49,564.72
Goa	737.91	514.34	8,623.78	1,696.16	1,224.72	12,796.91
Gujarat	35,021.71	49,462.26	4,13,446.44	1,67,075.49	2,10,655.08	8,75,660.98
Haryana	13,070.36	9,123.12	1,52,695.12	60,217.73	51,395.48	2,86,501.82
Himachal Pradesh	4,834.09	2,946.98	38,055.54	29,864.40	12,404.25	88,105.27
J&K and Ladakh	10,486.10	1,165.20	62,756.25	38,535.51	13,925.20	1,26,868.26
Jharkhand	8,070.74	7,391.99	88,418.45	53,667.22	54,894.30	2,12,442.70
Karnataka	35,992.66	35,825.82	4,54,385.45	1,77,320.49	1,09,410.06	8,12,934.47
Kerala	37,245.16	21,716.21	2,17,281.50	57,760.67	19,991.26	3,53,994.80
Madhya Pradesh	35,886.43	49,941.82	3,34,508.56	2,03,149.14	1,93,115.62	8,16,601.57
Maharashtra	57,613.28	56,675.17	6,55,654.53	2,26,077.28	2,21,243.15	12,17,263.41

Manipur		2,997.87	552.90	8,099.16	3,850.78	6,709.70	22,210.41
Meghalaya		1,641.24	1,707.03	4,202.30	2,755.98	6,892.31	17,198.86
Mizoram		2,241.71	304.63	1,030.80	2,624.46	1,423.16	7,624.77
Nagaland		569.54	484.08	3,670.48	1,534.41	3,252.85	9,511.37
Odisha		17,924.93	17,697.83	97,259.85	44,706.58	1,29,690.43	3,07,279.62
Punjab		16,251.55	7,467.04	2,80,266.11	34,815.33	41,731.10	3,80,531.12
Rajasthan		31,070.37	20,137.45	2,59,730.56	3,02,803.15	2,65,003.31	8,78,744.84
Telangana	1	3,479.33	7,372.51	1,91,949.40	60,487.60	36,265.00	3,09,553.84
Tripura	2	,680.73	1,500.09	13,544.35	8,750.67	4,060.66	30,536.50
Uttar Pradesh	1	,00,702.60	91,954.75	8,28,134.03	8,00,598.20	8,14,152.65	26,35,542.24
Uttarakhand	9	,397.46	4,641.85	58,562.08	46,247.78	33,345.59	1,52,194.76
West Bengal	5	6,619.10	30,535.22	3,75,357.09	1,63,274.05	1,03,577.32	7,29,362.77
Other UTs	1	,589.63	1,886.15	16,937.19	3,849.79	5,195.18	29,457.94

Economic Burden due to bidi consumption – Healthcare, revenue and productivity losses

Bidi is well perceived as a low-cost alternative to cigarettes. Despite its detrimental health effects, the industry escapes many regulations and are subjected to far less taxation than other tobacco products. Being treated largely as a "swadesi" cottage industry, only a nominal tax of 28% GST, with Rs 1.02 NCCD and Rs 0.05 Excise per 1000 sticks is levied on manufactured bidi packs (15). The resultant taxation marks the final MRP with only 22% proportion of tax, in stark contrast to other tobacco products at 52% (Cigarettes) and 64% (Smokeless Tobacco). While, the value recommended by the World Health Organization's Framework Convention on Tobacco Control (WHO FCTC) remains at 75%. Furthermore, the manufacturers with a production value of less than 4 million beedis per year are traditionally exempted from taxation, resulting in many small cottage industries (16).

Any attempt to regulate the largely unregulated industry, and imposition of taxes in line with other tobacco products are largely met by two counter narratives of the industry, stating beedis as "less harmful" by citing the "organic" origin of the product, and quoting the large amounts of revenue contributed to the countries exchequer and huge employment opportunities generated. The annual revenue received from the bidi industries amount to INR 4.74 billion annually, however, estimates reveal that for every 1 rupee of tax generated by bidi industry takes away 8 rupees of the revenue in form of healthcare expenditure due to its devastating impact on human health. The following section

breaks the economic burden due to bidi consumption into three major costs: 1) Healthcare economic burden, 2) Revenue foregone, and 3) Potential productivity losses.

Healthcare economic burden

Scientific literature based on estimation of smoking attributable fraction of bidi on all cause mortality in India estimates the annual economic costs incurred in the treatment of diseases attributable to bidi smoking. The total annual healthcare costs thus estimated amount to INR 805.5 billion. This includes direct and indirect mortality costs of INR 527.4 billion and direct medical expenses of INR 168.8 billion (17). This accounts for 0.53% of the entire national GDP that is lost in the management of bidi related diseases.

Revenue foregone

All forms of tobacco products, including cigarettes and smokeless tobacco are subjected to excise tax and compensation cess over and above the prevalent Goods and Service Tax. The only tobacco product which is not imposed with similar taxation is bidi. As a result of this, the where the net effective tax proportion on cigarettes and smokeless tobacco remain at 52% and 64% respectively, bidi are subjected to a nominal tax proportion of 22% in the final MRP. Moreover, due to regulatory exemptions of non- registration upto a turn-over of 40 lakhs or 4 million annually, a large segment (79.4%) of bidi industry remains completely exempted from taxation (18).

Considering the price elasticity of demand as a result of potential price increase due to regulations and taxations, it is estimated the industry evades a tax revenue of INR 8.62 billion at current regulated proportion, if the industry were taxed similar to other smoked tobacco products, namely cigarettes. Moreover, the estimates suggest that the government exchequer may benefit with a surplus of INR 9.6 billion annually, with a marginal increase of 10% product regulation (10% reduction in tax exemption limit of the current 40 lakh turn annual over) and with a standard 100% product regulation (completely stripping of tax exemption limit), as is the case of every other tobacco product, the government would benefit with a surplus of INR 46.33 billion in revenue annually from bidi industry (19).

Potential Productivity Losses

The loss of DALYs associated due to bidi consumption may be equated to sum of years of potential life lost due to premature death as well as the years of productivity life lost due to disability compared to a standardised life expectancy. The DALY values when multiplied with the GDP per capita of the nation could be used a valid indicator to obtain the potential productivity losses to the nation due to a specific risk factor.

Considering the national GDP per capita of India as USD 2,100, the productivity losses as a result of disability and death due to bidi consumption are calculated to be USD 30,440,970,752.26 (USD 30.44 billion). Thus, at the annual national GDP of USD 2,869 billion (2019), the economic losses as result of potential productivity losses (death and disability) due to bidi smoking amount to 1.08% of the total GDP of the country. Considering the average USD to INR exchange rate for 2019 to be INR 70.4 per USD, the economic losses equate to a loss of INR 21,43,04,43,40,959.11 (INR 21.43 lakh crores or INR 2.1 trillion annually) (14).

Table 5: Economic burden attributable to bidi consumption in India

Economic Cost Parameter	Total Cost
Healthcare economic burden	
Direct and Indirect Mortality Costs	INR 527.4 billion
Direct Medical Expenses	INR 168.8 billion
Revenue foregone	
Cigarette equivalent taxes at current regulation	INR 8.62 billion
Cigarette equivalent taxes at 10% increased regulation	INR 9.6 billion
Cigarette equivalent taxes at 100% regulation	INR 46.33 billion
Potential Productivity Losses	INR 2.1 trillion
Total Economic losses	INR 2.85 – 2.89 trillion
Total Revenue from Bidi Industry	INR 4.74 billion

Thus, it may well be argued that the total costs associated with bidi consumption in the country far exceed the revenue and divest a significant proportion of the national GDP. (Table 5).

Environmental Burden due to bidi consumption

Tobacco crop is in itself a labour and resource intensive crop. Cultivating tobacco requires large amount of resource inputs such as water, pesticides, and agro-chemicals. The ecology is immensely harmed right from cultivation, processing, production and further due to disposal of tobacco. (WHO, 2017)

(20). The crop cultivation leads to deforestation, soil depletion, loss of soil nutrients and pollution due to heavy use of agro-chemicals. These agricultural practices release harmful chemicals into the ecosystem, impacting both terrestrial and aquatic life. Despite known harms of the tobacco industry, and it being designated under the category of a "heavy polluter", the bidi industry is permitted to continue as a cottage industry with many units operating within residential areas. These home-based units expose workers and families to serious health hazards and pollute the surrounding waters and soil.

Ambient monitoring of bidi manufacturing factory indoor pollution levels reveal 150-fold increase in inspirable dust levels (1.6mg/m3), and ailments such as rapid pulse rate, low haemoglobin, chronic bronchitis, tuberculosis amongst the bidi workers. Bidi rolling is also associated with higher levels of cotinine, glutathione and thioethers (mutagen) in users and non-user workers who are subjected to environmental exposure to tobacco dust (21).

Though it is heavily argued that bidi butts are biodegradable, nevertheless, they consist of un-smoked remnant tobacco. Carelessly discarded butts leach out toxic chemicals (heavy metals, nitrosamines, polycyclic aromatic hydrocarbons, nicotine), and the runoff from streets drain water bodies, affecting

aquatic species. Carelessly thrown cigarette and bidi butts are common cause of forest and residential fires which further threaten life, property and forest lands (22).

Additionally, the post-harvest processing and curing of tobacco involve burning wood and other fuels, leading to air pollution and increased carbon emissions. Uncontrolled fires are frequently reported in tendu leaf plucking areas, as there is a traditional practice of using fires to cut back the young exposed shoots of tendu plant and to injure its roots so that they may coppice and produce fresh, green, good quality leaves for bidi rolling. A 0.8 correlation coefficient of tendu producing areas and forest fires between years 2011 and 2021 indicated tendu producing areas to have a very high susceptibility to forest fires. Such forest fires are associated with emission of as much as 3.9 mt of CO2 emissions (23).

Another aspect of bidi related environmental burden that largely goes unnoticed is the metric tonnes of waste that is discharged carelessly in the environmental due the consumption of these products by such large number of people. The consumed product waste from bidi cumulatively amounts to nearly 14 thousand tonnes of waste annually, in form of plastic (7.4 thousand tonnes), paper (6.3 thousand tonnes) and non-biodegradable filter (39 thousand tonnes) (24) (Table 6).

Table 6: Estimated potential annual state-specific waste from bidi consumption (in tonnes)

Name of States	Plastic	Paper	Filter	Total	% of National Estimate
Jammu & Kashmir	59.92	51.00	0.32	111.24	0.81
Himachal Pradesh	71.90	61.19	0.38	133.47	0.97
Punjab	137.86	117.33	0.73	255.93	1.86
Chandigarh	6.26	5.33	0.03	11.62	0.08
Uttarakhand	127.00	108.09	0.68	235.76	1.71
Haryana	323.88	275.64	1.72	601.24	4.36
Delhi	126.16	107.37	0.67	234.21	1.70
Rajasthan	605.97	515.72	3.22	1124.91	8.16
Uttar Pradesh	1714.48	1459.13	9.12	3182.74	23.08
Chhattisgarh	82.02	69.80	0.44	152.25	1.10
Madhya Pradesh	514.33	437.73	2.74	954.79	6.92
West Bengal	1084.08	922.62	5.77	2012.47	14.59

Jharkhand	130.47	111.04	0.69	242.20	1.76
Odisha	148.42	126.31	0.79	275.52	2.00
Bihar	316.64	269.48	1.68	587.81	4.26
Sikkim	1.54	1.31	0.01	2.86	0.02
Arunachal Pradesh	16.10	13.70	0.09	29.89	0.22
Nagaland	15.47	13.17	0.08	28.72	0.21
Manipur	9.94	8.46	0.05	18.46	0.13
Mizoram	1.31	1.11	0.01	2.42	0.02
Tripura	58.11	49.46	0.31	107.88	0.78
Meghalaya	37.64	32.03	0.20	69.87	0.51
Assam	208.71	177.63	1.11	387.45	2.81
Gujarat	317.46	270.18	1.69	589.33	4.27
Maharashtra	179.15	152.47	0.95	332.57	2.41
Goa	2.63	2.24	0.01	4.88	0.04
Andhra Pradesh	255.16	217.15	1.36	473.67	3.43
Telangana	142.20	121.02	0.76	263.98	1.91
Karnataka	297.93	253.56	1.58	553.07	4.01
Kerala	106.56	90.69	0.57	197.81	1.43
Tamil Nadu	326.76	278.09	1.74	606.59	4.40

This waste litters the environment with paper, plastics, microplastics, and filters, which without a proper disposal mechanism, end up polluting water, air and land with heavy metals, toxins and residual nicotine. The filters found in few bidi brands are essentially plastic made from cellulose acetate, which only degrade under severe biological conditions but remains non-degraded. When collected on beaches, sewage, streets they choke sewage ducts in the process. The heavy metals, chemicals and toxins from these filters seep into the aquatic ecosystems endangering the marine life and microorganisms. The resulting biological magnification of toxins due to this process are potentially devasting for environment as well as humans (25). Moreover, the plastics and cellophane used in the outer packaging are similarly neglected from proper disposal and end up in landfills.

Cellophane is largely debated as a natural or "organic" product as it is derived from plant extracts. Although it is biodegradable, but releases its own set of toxins during the process, that were incorporated during its processing. When littered mixed with other non-biodegradable materials and poly-propylene based plastic cellophane, the set becomes non-biodegradable and ends up everywhere, including landfills, streets, drains, rivers and other aquatic environments, and remain there for decades together (26). In most areas, the responsibility for cleaning up the waste falls on the government using taxpayer funding. This cumulative environmental impact underscores the need for sustainable practices and regulatory measures in bidi production.

Policies and Regulations for Bidi Control in India

The industry is currently classified as a cottage industry and enjoys great regulatory and tax exemptions. As a result, bidi packs often violate government mandated tobacco control norms, such as outdated pictorial health warning, blurry and poorly visible health warnings, uniform packaging, and disposal rules (27). The conical packing of bidi bundles also facilitate the non-compliance of prescribed health warning representation in its packs.

Bidi sticks are also marketed as flavoured products with pictures of well accepted deities, sport legends and names linked to religious beliefs of the people. Any counter argument to harms against bidi use is met with a rebuttal of bidi being "poor man's pleasure" and is largely ignored during legislative enforcements (28).

Lax regulatory policies not only make the product easily accessible to youth and those wanting to "experiment" but also paves way to initiation to transition to other tobacco products. Such demographics, amplify the burden of cancer, heart diseases, and respiratory ailments, contributing to pronounced health disparities. Given the typical onset of health effects after two or three decades of tobacco use, the nation faces a looming threat from the consequences of high prevalence and early initiation (29).

Thus, bidi control strategies demand a multifaceted approach, targeting various aspects of behavioural change, policy interventions, and health education. Effective interventions for bidi use reduction must address both the supply and demand sides of bidi consumption while considering the socio-economic contexts.

The following section outlines some of the key policies and regulations to reduce bidi use in the country.

Bans and Restrictions: The Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 or the COTPA Act implements strict bans on advertising, promotion, and sponsorship of bidis, thus targeting a reduction in product visibility and appeal, especially to younger demographics. Additionally, comprehensive bans on public smoking and stringent enforcement of such regulations can decrease social acceptance of bidi smoking. However, the enforcement remains partial due to low enforcement prioritization (30).

Packaging and Labeling: Mandating plain packaging and graphic health warnings on bidi packs is crucial for communicating the severe health risks associated with bidi smoking. The Cigarettes and Other Tobacco Products (Packaging and Labelling) Rules, 2008 requires all tobacco products,

including bidis, to display graphic health warnings covering at least 85% of the packaging (31). However, in practice, the implementation of these packaging norms remains inconsistent. For instance, in many rural areas, bidis are often sold loose or in small bundles without any packaging at all, bypassing the regulations entirely.

Taxation and Pricing: The Goods and Service Tax Laws in India place bidi at 28% GST slab with separate taxes of Re 1.02 NCCD and 0.05 excise per 1000 sticks making the tax proportion merely 22% of the final retail price (17) As per the WHO FCTC, taxation and pricing measures are the single most efficient tool to control the demand of all forms of tobacco products including bidi with a recommended taxation of 75% proportion. Higher prices deter use, particularly among price-sensitive populations such as youth and low-income groups. However, it is crucial to ensure that tax increases are substantial enough to make a significant impact and that they are consistently enforced to prevent market evasion.

While primarily focused on health, the taxation of tobacco products, including bidis, also indirectly supports environmental sustainability goals. Higher taxes can deter consumption, and in-turn lower the environmental footprint of tobacco cultivation and waste.

Labour Laws and Welfare Schemes: The Beedi and Cigar Workers (Conditions of Employment) Act, 1966 regulates the working conditions in the bidi manufacturing industry. It covers aspects such as working hours, wages, safety, and health measures, and prohibits child labor in bidi manufacturing (32).

The government has also established welfare schemes for bidi workers, including health care, housing, and education for their children and pension benefits within the Beedi and Cigar Workers Act. These schemes are funded through a welfare fund, which is financed by a cess on the production of bidis (32).

Environmental Policies for Bidi Industry: Although bidis traditionally use natural leaves for wrapping, modern bidi packaging sometimes involves plastic components, such as outer wrappers or small packaging units. Plastic Waste Management Rules, 2016 (Amended 2021), aim to reduce plastic waste, require manufacturers to ensure that any plastic used in packaging is recyclable or biodegradable. The bidi industry must comply with these rules to minimize its environmental impact (33).

Environmental Protection Act, 1986 mandates all industries, including the bidi industry, to comply with environmental standards to prevent pollution. This includes managing waste from bidi production, ensuring that any chemical use in the processing of tobacco, or the manufactured product, does not harm the environment, and adhering to air and water quality standards (34).

Forest Conservation Act, 1980: The bidi industry relies heavily on tendu leaves, which are harvested from forests. The Forest Conservation Act regulates the use of forest land and resources to ensure that bidi production does not lead to deforestation or the degradation of natural habitats (35).

ESG Guidelines: Increasingly, companies in the bidi industry are being evaluated based on ESG criteria. This includes their impact on the environment, their contribution to social well-being (such as fair labour practices), and their governance standards. Compliance with ESG guidelines can influence a company's reputation, access to capital, and regulatory standing (36).

It is clearly evident that bidi being no less harmful than their conventional counterparts, are largely promoted to be "indigenous" by the tobacco industry front groups. In doing so, they provide an easy

access and initiation to the new and vulnerable users. Where cheaper pricing makes them more lucrative to the illiterate and weaker segments of the society, poor warnings deter effective control communications and imparting the motivation to quit. Implementing and enforcing bans on products like gutka, which are already illegal in many regions, can reduce availability and consumption. Cessation support and improving the access to cessation programs for such users, including tailored counselling and nicotine replacement therapies, can support users willing to quitting. There is a need of expanding these programs and making them accessible and affordable, especially in rural areas. Lastly, it is of equal important to offering alternative livelihood opportunities and vocational rehabilitation to those involved in the production and sale of these products to reduce economic dependency on such employments. Agricultural training programs and microfinance initiatives can facilitate this transition.

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RECOMMENDATIONS

5.5. Bidi & Other Indigenous Products

5.5.1. Recommendations to Ministries

- lt is of utmost importance that the Ministry of Commerce and Industry along with the Ministry of Micro, Small and Medium Enterprises reconsider the status of bidi industry as a cottage industry and the regulatory and tax relaxation the manufacturers enjoy, considering the heavy toll on health of its consumers and the people involved in the production. Furthermore, bidi packs violate the norms for pictorial health warnings and being largely fragmented and unregulated, give way to illicit product circulation in the market. Implementation of licensing at every stage of bidi manufacturing and selling by the vendors, regulation of production and marketing of bidi will be the key to elimination of such violations resulting in better implementation of control policies.
- b) The bidi manufacturing companies should be held liable with imposition of financial levies to account for the high cost of waste management and disposal by The Central Pollution Control Board. The existing Plastic Waste Management Rules, ESG guidelines for the industries and environmental sustainability initiatives should expand to tobacco cultivation, bidi manufacturing and tendu patta collection procedures.
- c) The Ministry of Health and Family Welfare must recognise bidi rolling as occupational health hazard due to high and constant nicotine exposure amongst the bidi rollers. The ministry should prioritize health education amongst bidi workers about the health hazards of bidi rolling, smoking and passive smoking through health awareness campaigns, provide of better healthcare services, including screening and treatment for tobacco-related illnesses, through health centers and health camps and encouraging them towards completing their education.
- d) The Ministry of Skill Development and Entrepreneurship should provide support for vocational rehabilitation to help bidi workers transition to alternative livelihoods, with trainings and education programs, subsidies and

- infrastructure for new businesses, and job placement services for better income-generation occupations.
- e) Bidi workers are often underpaid. The Ministry of Labour & Employment needs to adopt, implement and enforce centralised minimum wage laws, pension and health benefits to ensure that workers receive a uniform and fair compensation for their work.
- f) Such a form of exploitation creates a cycle which the workers find extremely difficult to cope from, pushing generations into the same profession and highly frequent incidences of child labour.
- g) Necessary amendments in the Beedi and Cigar Workers (Conditions of Employment) Act, 1966, Child Protection Laws and Labour laws need to be made for a stringent enforcement with clearly defined and harsher penalisation provisions.
- h) Setting up of accessible, convenient, transparent & efficient grievance redressal mechanism for workers to report low or delay payment and other exploitations.
- i) Ministry of Finance should consider an increase the taxes on bidis in line with other tobacco products, to discourage smoking and allocate the additional revenue collection to bidi workers for social welfare programs and alternate livelihood.
- j) Framework for regulation and tracking of bidi tobacco from cultivation to processing and manufacture of bidi, possibly by inclusion of the bidi tobacco as per the SOP for tobacco auctions under the Tobacco Board of India.

5.5.2. Recommendation to Civil Society

- a) Civil society organizations can help raise awareness about the health risks of beedi rolling amongst the workers along with their sensitization regarding alternate livelihoods opportunities. This can include organising awareness campaigns, providing information and engaging with the local rural and tribal communities to promote healthy livelihoods.
- b) Civil Society may contribute to unravelling the illicit networks and trade chain of beedi products and help in evidence generation for policymakers to aid in stricter regulations.
- c) Organisations working for environment protection should evaluate and document the environmental burden of beedi trade, especially the impact tendu leaf collection has on the forest, and inform the policymakers and other stakeholders.
- d) Organisations aiming for social inclusion and human rights must investigate and expose the exploitative incidents and practices in beedi trade that undermine basic concept of equity.

5.5.3. Recommendations to Academia

- a) Academicians can conduct operational and exploratory research in various domains such as beedi taxation, brand analysis, compliance with existing laws, vendor density prevalence and illicit trade, which are largely unexplored in the beedi industry. This will help develop effective prevention and cessation strategies as well as to counter the misleading narratives of tobacco industry.
- b) Agricultural institutions can research the viable crop alternative crops to help beed farmers to switch from their current jobs.
- c) Academia may collaborate with government departments and civil society organizations to advocate for tobacco control policies to include beedi at the local, national, and international levels. This can include working with policymakers to conduct research, develop evidence-based policies, design interventions and providing expert testimony and consultations.

CHAPTER-6

Tobacco Advertisement Promotion & Sponsorship Prohibition of Brand Sharing & Stretching

Tobacco Advertisement Promotion & Sponsorship Prohibition of Brand Sharing & Stretching

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Background

In this chapter, we expect to provide an in-depth understanding of the tactics employed by the tobacco industry to promote tobacco use through advertising, promotion, and sponsorship (TAPS), particularly targeting vulnerable populations such as youth. We will explore the legislative framework in place to regulate TAPS, including key provisions under COTPA and the Framework Convention on Tobacco Control (FCTC), while highlighting the existing gaps and challenges in enforcement. Furthermore, we will offer insights into judicial interventions and propose recommendations to strengthen TAPS regulations for a more comprehensive ban in India.

The tobacco industry either directly or indirectly through false, misleading, deceptive or erroneous impression indulge in tobacco advertising, promotion and sponsorship (TAPS). The objective of the tobacco companies has always been to draw in young, impressionable people to the tobacco industry. "Catch them young" is their moto, and and using tobacco products is associated with maturity, modernity, wealth, elegance, and social class norms (1). The general public's health is greatly harmed by tobacco use and its products, and the unrestrained promotion of these goods will draw in younger people and impressionable minds who are unaware of the serious and harmful effects of using them (2).

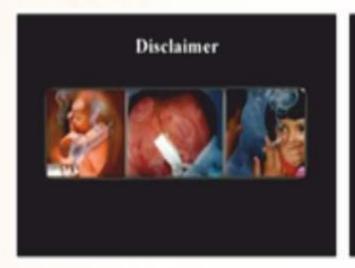
The first law to require the warning that smoking cigarettes is harmful to one's health to be included on all cigarette ads was the Cigarettes (Regulation of Production, Supply and Distribution) Act, passed in 1975. State and municipal governments then passed local tobacco control legislation that included a ban on tobacco product ads.

A complete prohibition on all tobacco products is required under Article 13 of the WHO Framework Convention on Tobacco Control (FCTC), the first public health agreement ratified by the World Health Assembly in May 2004. India must abide by the FCTC's rules and regulations in order to lower tobacco use worldwide, having signed the treaty on February 27, 2005. But a concentrated attempt to finally eradicate all direct and indirect tobacco-related TAPS was only made with the passage of the Cigarettes and Other Tobacco Products Act 2003 (COTPA).

Advertisements that indicate or encourage the use of cigarettes or any other tobacco product are prohibited by Section 5 of the COTPA. Direct and indirect advertising of tobacco products by those involved in their manufacture, distribution, or supply, as well as by those in control of a media outlet, are prohibited under Section 5, Subsection (1). Tobacco product ads are not authorised to be shown in accordance with Section 5, Subsection (2); nevertheless, they are permitted on packages and at points of sale. Promotion of tobacco use and the trademark or brand name of tobacco products in exchange for sponsorship, gifts, prizes, or scholarships are prohibited under Section 5, Subsection (3). The COTPA, which otherwise aims to outlaw tobacco ads completely, has been made weaker by the exception granted to advertisements at "point of sale," "in," and "on" packages of tobacco goods. Further the Government's effort to regulate POS advertisements by prescribing limits on advertisements board (size, display, text, etc), viz, COTPA 2004 Rules, has had no major impact due to gaps in the parent statutes.



India enacted new regulations in October 2012, as announced under Section 5 of the COTPA. These regulations addressed, among other things, the usage and presentation of tobacco goods and brands in both local and international motion pictures and television shows. These regulations stipulate that any movie that shows tobacco products or their usage must, among other things, have a disclaimer, health warnings against tobacco use, and spots. In May 2023, these regulations were expanded to include streaming services, sometimes known as over-the-top (OTT) platforms.



Disclaimer Tobacco use leads to cancer, heart attacks, lung disorders and other deadly diseases. The characters shown in this film or programme do not support the use of any type of tobacco products such as Bidi, Cigarettes, Khaini, Zarda etc. or their promotion in any manner.

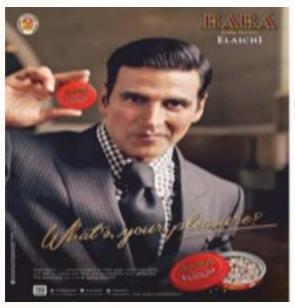


Prevalent practices on TAPS

The most common modes of TAPS are, direct and indirect advertisements at point of sale, brand stretching, through electronic, print and social media and promotion through CSR activities and entertainment media. When a tobacco brand name, emblem, trademark, logo, trade insignia, or any other distinguishing feature—such as unique colour combinations—is connected to a non-tobacco product or service in a way that makes the two products or services likely to be associated, it's known

as "brand stretching." Manufacturers of bidi, for instance, use brand stretching to promote their product. In this method, non-tobacco products such as Kajah Bidi and Kajah Tea are advertised with the brand name, emblem, trademark, logo, or trade insignia, or any other distinguishing feature (such as unique colour combinations) associated with the bidi tobacco brand prominently displayed. In case of SLT products, brand name, trademark, logo etc, associated with SLT products is visible in the advertisement of non-SLT products like: Baba Zarda and Baba Elaichi etc, or, where distinctive feature (including distinctive colour combinations) etc, associated with SLT brand is visible in the advertisement of non- SLT products like Chaini Khaini and Chaini Chaini Mouth Freshner. Further, direct and indirect advertisements of non-tobacco product sold in conjunction or conjointly with tobacco product `chotu`, through registered trademark of tobacco products, example: Vimal Panmasala(sold with SLT product V3), Vimal Elaichi etc. Similar to this, brand sharing happens when a non-tobacco product's trade insignia, trademark, logo, or other distinctive feature (such as unique colour combinations) is connected to a tobacco product or company in a way that makes the tobacco product or company and the non-tobacco product or service likely to be associated.

Brand Streching









Brand Sharing



Point of Sale Advertisements/Tobacco Depiction on Film Posters



This is despite the fact that COTPA 2004 Rules regulates point of sale advertisements, depiction of tobacco products and its use in entertainment media(including ban on display of tobacco use on films posters/teasers) and bans surrogate advertisements through the use of name, brand, colours, layout, presentation etc., associated with tobacco products for marketing, promoting or advertising other goods, services and events(Rule 2(e) 'Indirect Advertisement'). Heavy advertising and promotion of the non-tobacco product is done so that the customers do not forget their tobacco brands, for which advertisements are banned. Further tobacco industry also continue to indirectly promote its products through sponsorships, examples are cricket matches, musical events, award shows, school and college events, events at festivals, waste disposal and cleanliness campaigns etc.

Judicial Intervention on TAPS

The Indian judiciary has played a significant role in promoting tobacco use and trade regulation.

Specifically with respect to TAPS, there are several instances where courts have supported strict implementation of TAPS provisions. In a case against the red & white bravery award campaign, the Hon'ble Court ensured withdrawal of campaign and further directed implementation of COTPA 2003 in its letter and spirit (3). The Honourable Court ordered the State Road Transport Corporation and Municipal Transport Services to take down the gutkha/pan masala advertisements and other offensive items that were posted on the public conveyance (4). Hon'ble Court directed withdrawal of sponsorship to a tobacco industry sponsored event in compliance of Section 5 of COTPA (5). Hon`ble Supreme Court through various orders supported implementation of Films Rules (6). Guidelines prohibiting the online promotion of cigarettes, tobacco products, alcohol, and other intoxicants were formulated as a result of the Honourable Court's directive to the Ministry of Electronics and Information Technology (MEITY) (7). In a case filed for violation of Section 5 and POS Rules of COTPA in Chief Judicial Magistrate Court (CJM) of Mandi (HP), Hon`ble Court sentenced the accused to undergo imprisonment and pay fine (8). The Ministry of Corporate Affairs and the Ministry of Health were instructed by the Hon. High Court to investigate all issues and intergovernmental interactions in order to determine the most effective way to fulfil the tobacco industry's CSR scheme and the model that should be developed for it. On May 16, 2016, the Ministry of Corporate Affairs released a circular outlining that tobacco businesses are not allowed to violate COTPA 2003 requirements while engaging in their CSR initiatives (9). Hon'ble High Court directed inclusion of section 5 of COTPA compliance as a specific condition in the license issued by the Municipal Corporation (10).

In an appeal against the Bombay High Court's orders to halt the implementation of the COTPA Rules regarding the promotion and advertising of tobacco products, the Honourable Supreme Court made the following observations (11):

"The consumption of tobacco and tobacco products has huge adverse impact on the health of the public at large and, particularly, the poor and weaker sections of the society which are the largest consumers of such products and that unrestricted advertisement of these produces will attract younger generation and innocent minds, who are not aware of grave and adverse consequences of consuming such products. We have no doubt that the Central Government and the State Governments across the country are alive to the serious and grave consequences of advertising tobacco and various products manufactured by using tobacco. They know that the consumption of these products will result in rapid increase in the number of cancer patients and huge proportion of the Budget earmarked for health of the common man will have to be used for treating the patients of cancer."

The following instruction was provided by the Honourable Supreme Court when it overturned the Bombay High Court's stay orders:

"We also make it clear that as a sequel to setting aside of the interim order passed by the High Court, the Central Government and the Governments of all the States shall be bound to rigorously implement the provisions of the 2003 Act and the 2004 Rules as amended from time to time"

Challenges to TAPS

While the Indian legislative framework offers a comprehensive mechanism to regulate and ensure the implementation of TAPS ban in India through general and specific subject matter laws, there are still gaps in the regime that needs to be addressed. It has been more than two decades to the enactment of COTPA which forms the primary legislation to ban TAPS, however despite an elaborate section 5, there are certain exemptions that the law provides, such as exemption to point of sale advertisements, no specific provisions addressing promotion through, corporate social responsibility activities, online

sale, product display, new mediums (internet, smart phones etc), flavouring etc. Thus, the existing gaps undermines the law, which otherwise envisions a comprehensive ban on tobacco advertisements. Further the implementation of the ban on TAPS is very weak in India as the enforcement agencies limit their effort in only addressing violation of compoundable offence which is punishable with fine and there is minimal effort to enforce non-compundable offence related to TAPS under section 5 and related Rules of COTPA. There is also rampant brand stretching of tobacco products, where tobacco brand name, emblem, trademark, logo or trade insignia or any other distinctive feature is connected with a non-tobacco product to mark a clear association. TAPS also, faces challenges, from conflicting legislations, for example, the Cable TV Network Regulation that allows advertisements of co-branded products and the Food Safety Act 2006 and its regulations allow advertisements of Pan Masala, which is sold with smokeless tobacco products.

Home delivery of tobacco products though online sale via internet, e-commerce sites, apps etc., is another big deviation from the guidelines for implementation of Article 13 of the WHO FCTC. Further there is no bar on registration of a trademark that is once used for tobacco product to be registered as a non-tobacco product allowing tobacco companies to register similar and identical tobacco and non-tobacco trademarks for their surrogate advertising and promotion through brand stretching and sharing.

Depiction of tobacco imagery continues in films and more now on Over The Top platforms. While COTPA Section 5 regulations applicable to films and television programmes have been extended to OTT platforms as well, its implementation and enforcement remains limited. Unfortunately, the incidence of tobacco imagery in movies, including those rated for minors, is still common on OTT platforms, requiring active and regular monitoring and enforcement.

Thus, there is a need to address the gaps in TAPS provisions of COTPA by replacing existing section 5 of COTPA with a stronger, robust and updated legislation, aligned with Article 13 of FCTC and its guidelines and global best practices, by removing exemptions and including regulation of direct and indirect of advertisements, promotion and sponsorship of tobacco (TAPS) through new mediums, CSR activities, point of sale display etc.. Further there is a need to rigorously implement the existing provisions on direct and indirect advertisements, POS regulations, regulation of tobacco imagery in the entertainment media by filing regular complaints before the courts of Judicial Magistrate.

Annexure-1

- 5 (1) No one is allowed to start, produce, distribute, or broadcast any kind of advertisement or promotion for cigarettes or other tobacco products via any medium, and no one is allowed to encourage the use or consumption of tobacco products in any way.
 - The term "medium" in this context refers to the following: audio, audio-visual, print (including national and international newspapers and magazines, pamphlets, leaflets, flyers, and letters), billboards, hoardings, posters, signs, non-tobacco products, tobacco accessories, buildings or other structures, vehicles, television, radio, films, music, games, live performances, the internet, including over-the-top media services, social media platforms, mobile phones, and other new technologies.
- (2) For any kind of pecuniary benefit direct or indirect, or otherwise, no one should-
- (a) display, cause to be displayed, allow, or authorise the display of any cigarette or tobacco product advertisement on any media.
- (b) supply or offer to supply free samples of a tobacco product, even in exchange for marketing research or taste tests; or

- (c) import, distribute, sell, or offer for sale any candy, food products, toys, or other items that are intended to look like tobacco products or whose packaging is meant to seem like the packaging typically seen on tobacco products; or
- (d) offer any discount to sell any tobacco product; or
- (e) offer any gift item or any discount with the purchase of any tobacco product; or
- (f) provide incentives, participate in loyalty programs, or hold competitions linked to tobacco products or brand names, whether or not such activities necessitate the purchase of tobacco products; or
- (g) advertise on the internet that you will sell or expose to sell any tobacco product, whether in exchange for money or on credit, or by any other means; or
- (h) use a tobacco product's name, brand, mark, or trademark on, in connection with, or for marketing, promoting, or advertising any other good, service, or occasion; or
- (i) when marketing, promoting, or advertising any other good, service, or occasion, use specific hues, designs, or presentations that are connected to specific tobacco products; or
- (j) add anything to cigarettes or other tobacco products that has the potential to change, intensify, improve, or impart flavour; or
- (k) use a name, mark, or brand that is associated with, or in use for any other product, service, or occasion in order to promote tobacco products; or
- (I) Use to bacco products in advertisements for other products and services.
- (3) No person shall—
- (a) supply, accept, arrange, start, or participate in sponsorship related to tobacco products, including cigarettes;
- (b) advertise cigarettes or other tobacco products, or agree to advertise them, whether directly or indirectly, using any trademark, trade name, or brand name;
- (c) Promote tobacco products, such as cigarettes, by donations, other means, or through activities related to corporate social responsibility.

Explanation- For the purposes of this provision, "promote" refers to any commercial message, suggestion, or action that has the intention, result, or likely result of directly or indirectly endorsing to bacco usage or products.

Explanation-for the purpose of this section, "sponsorship" refers to any type of financial support given to a person, event, or activity with the intention, result, or likely result of directly or indirectly endorsing the use of tobacco products.

Explanation-for the purpose of this section, "trade mark" refers to any portion or entirety of a trademark registered under the Trade Marks Act of 1999 for goods that contain or are related to tobacco products, regardless of whether the same or comparable trademarks are also registered for other goods.

- (4) At the entrance to a warehouse or shop that offers cigarettes or other tobacco products for distribution or sale, as well as their packaging, no one is allowed to display, permit, authorise, or cause to display any kind of cigarette or tobacco product, or its packaging.
 - **Explanation.**—For the purpose of this section, "display" refers to the act of making a cigarette, or any other tobacco product, or its packaging, visible to the general public, rather than just when a sale of a particular tobacco product is taking place.
- (5) The person in charge of a warehouse or store that offers cigarettes or other tobacco goods for sale or distribution is responsible for making sure that the items are stored in a closed dispenser or container that is inaccessible to the general public;
 - Under the conditions specified by rules enacted under this Act, a board listing the types of cigarettes and other tobacco products that are for sale may be moved.

References

- 1. Mahesh Bhatt v. Union of India, WP© No. 18761/2005; 147 (2008) DLT 561
- 2. Health for Millions v. Union of India, Writ Petition (Civil) 549 of 2008; (2014) 14 SCC 496.
- 3. Hemant Goswami Vs GPI & Ors., CWP NO. 313/2005, (Punjab & Haryana High Court, Chandigarh)
- 4. Amarsinh Z Choudhari Vs UOI (Special Civil Application No.4848 of 2009) (High Court of Gujarat)'
- 5. Institute of Public Health Vs The State Government of Karnataka & Ors. (W.P. No. 27692/2010)
- 6. Union of India Vs Mahesh Bhatt, (SLP© No. 8429-8431 of 2009)
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- 8. Food Safety Officer Vs Yadav Singh
- 9. S. Cyril Alexander Vs UOI & Ors, (Writ Petition No. 9955/2014)
- 10. Faith Foundation Vs State of Gujarat (W.P NO. 173 of 2017)
- 11. Health for Million vs. Union of India & Ors. (Civil Appeal No. 5912-5913/2013)

RECOMMENDATIONS

5.6. Tobacco Advertising, Promotion, And Sponsorship

5.6.1. Recommendations for Central Government

- a) Ban point of sale advertising and promotion: All kind of advertising and promotion at point of sale including visible display of all tobacco products should be banned. This may be done by removing the proviso under section 5 of COTPA that currently makes exception for point- of-sale advertising. Point of sale advertising prohibitions have been shown to be strongly related with a decrease in juvenile smoking experimentation, according to a research that evaluated data from 130 nations (4). According to a research that examined data from 77 nations, a prohibition on point-of-sale displays decreased the incidence of daily smoking by almost 7% (5). TAPS (Tobacco promotion, Promotion and Sponsorship) is outlawed in at least 42 nations, and 21 of them additionally ban the display of tobacco products. TAPS includes point-of-sale promotion. This is also aligned with the proposed amendments under the draft COTPA Amendment Bill 2020.
- b) Comprehensive TAPS ban law: By adhering to Article 13 of the WHO-FCTC and its guidelines, a comprehensive TAPS ban law should be introduced. It should, among other things, contain specific provisions under Section 5 of COTPA to address promotion through CSR initiatives, online sales, the distribution of free samples, product displays, new media (such as SMS, the internet, mobile apps, smart phones, etc.), sponsorship, and other new media through a Model TAPS Ban Law-Annexure-1.
- c) Amend definition of indirect advertisement under COTPA Rules: Definition of 'indirect advertisement' under the 2004 COTPA Rules, should be amended to include a ban on the use of a trade name or trade mark of tobacco product for marketing, promoting or advertising other goods, services and events.
- d) Activate Section 5 Monitoring Committee: The committee constituted at the

- national level for monitoring violations under Section 5 of the COTPA should be renotified and strengthened for making them active and functional to mitigate all incidences of TAPS within their jurisdiction. 1. The committee members ought to be made aware of the necessity of regularly monitoring TAPS and following up on infractions.
- e) Effective enforcement of COTPA provisions: Concerted and coordinated effort should be made by the Centre with the State/UT`s Governments to rigorously enforce Section 5 of COTPA, in line with the Hon`ble Supreme Court`s direction, ... "the Governments of all the States shall be bound to rigorously implement the provisions of the 2003 Act and the 2004 Rules as amended from time to time" (6).
- f) Maintain consistency across various laws: Central Government should resolve discrepancies in the Cable TV Network Act, Food Safety and Standards Act, Consumer Protection Act, Juvenile Justice Act and COTPA with respect to TAPS laws. This may be achieved by inserting a clause having overriding effect of COTPA on other laws. To permanently mitigate the problem, a clear and consistent policy against TAPS is required, particularly with regard to brand stretching of tobacco products through harmonisation of various laws and regulations.
- g) Health warnings on Areca Nut and Pan Masala products: The Food Safety and Standards (Labelling and Display) Amendment Regulations, 2022, should be rigorously implemented which mandates that all packages of Pan Masala should have a warning "Chewing of Pan Masala is Injurious to Health" covering 50% of the front-of-pack of the label. A similar provision should be implemented for all areca nut products under the Act.
- h) Ban on advertising of Areca Nut and Pan Masala products: Central Government should prohibit all direct and indirect advertisements of Areca Nut and Pan Masala products through all mediums, by making suitable modifications in the Food Safety and Standards Act and Regulations. According to the Act's packaging and labelling requirements 2.4.5 clauses 30 and 31, pan masala and areca nut are considered "injurious to health" items. Thus, a ban on their advertisement shall be in the interest of public health as there is rampant direct and indirect advertisement in print, electronic and outdoor media, of pan masala by undermining the harmful and injurious nature of the product.
- i) No direct or indirect advertising or promotion of brand stretching and brand sharing products: Central Government should apprise all manufacturers and producers who apply for any registrations that registration of a trade name or trade mark shall not entitle its advertisement and promotion in contravention of the comprehensive TAPS laws. Tobacco Products, Pan Masala and Food Products have been registered in different classes of Trade Marks, but having the same word mark/brand name, colour, logo, proprietor, address etc., which has led to surrogate advertisements of tobacco and its ancillary products due to lack of clear guidelines.
- j) Prohibit registration of brand extension and brand sharing products: Central Government should introduce adequate safeguards in the Trademarks Act to prevent brand extension or brand sharing.

- k) Strict Implementation of Rules regulating tobacco depiction in entertainment media: The CBFC, Broadcasting Authority and Inter-Ministerial Committee designated for enforcing the provisions of the Rules regulating depiction of tobacco products and usage in entertainment media (theatres, television, OTT or streaming platforms), should take strict note of all violations and recommend appropriate action including prosecution of violators under Section 5 of COTPA.
- Guidelines for implementation of section 5 and its regulations: The Central Government should establish guidelines for the efficient application of COTPA section 5 and its enabling rules, which include those governing the portrayal of tobacco products and their usage in films, television shows, and over-the-top (OTT) or streaming platforms. In order to better comply with these regulations and safeguard innocent and vulnerable youth from unwarranted exposure to tobacco imagery in films, television shows, and over-the-top (OTT) platforms, the Ministry of Health and Family Welfare should think about offering the necessary directions, including guidelines and orientation, to all stakeholders and competent authorities implementing the provisions of Section 5, including the rules pertaining to film, TV, and OTT.

5.6.2. Recommendations for State Governments

- a) All State Governments should constitute monitoring committees at the state and district levels for acting against violation of Section 5 of the COTPA, within their jurisdiction. The committee members should be sensitized on the need to continuously monitor TAPS and conduct regular follow-up with regard to violations.
- b) The Authorized Officers at the State Level shall file a complaint before the Judicial Magistrate for violation of section 5 of COTPA as it's a non-compoundable offence.
- c) Municipal authorities in the State/UTs should implement the Ministry of Health & Family Welfare (MOHFW), advisory dated 21st September 2017 and the Ministry of Housing and Urban Poverty Alleviation advisory dated Sept. 28, 2018, inter-alia requesting State Governments to develop mechanism for licensing of tobacco vendors. Enforcement of TAPS laws can be improved by making its compliance a condition in the licensing of tobacco vendors. Including condition that suspension or withdrawal of a vendor's license for violations of COTPA is an effective sanction.

5.6.3. Recommendations for Civil Societies

- a) Civil Societies at the National, State and District Level should actively participate in the implementation of Section 5 of COTPA, by reporting violation to the Monitoring Committees.
- b) Civil Societies should disseminate information and generate awareness on the TAPS laws, to improve enforcement.
- c) Civil Societies should file regular complaint on the MoHFW/WHO portal, violation-reporting.in, for contravention of section 5 of COTPA.
- d) Civil Societies should register grievance before the Digital Publisher Content Grievances Council (DPCGC), for contravention of OTT Rules.

CHAPTER-7

Tobacco Cessation Services in India: Strategies, Level of Implementation and Recommendations

Tobacco Cessation Services in India: Strategies, Level of Implementation and Recommendations

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Background

The chapter shall provide insights into the existing strategies for tobacco cessation with level of their implementation and finally recommendations for MoH, State Govt. and other departments for advancing the tobacco cessation services in India.

Introduction

Tobacco is one of the most addictive substances known to humans. Nicotine is the principal psychoactive component in tobacco which triggers the release of neurotransmitters such as dopamine, which is associated with pleasure, reward and relaxation. This dopamine release reinforces the behavior of smoking or tobacco chewing, eventually leading to the development of dependence. Nicotine withdrawal symptoms such as cravings, irritability, and anxiety, further contribute to its addiction making quitting difficult. Furthermore, factors such as social and environmental cues, genetic predisposition, and stress also influence this addiction. (1,2).

Diagnosis of tobacco dependence typically involves assessin the criteria outlined in standardized diagnostic criteria such as the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) or the International Classification of Diseases (ICD-11). These criteria broadly include factors such as unsuccessful attempts to quit or cut down on tobacco use, spending a significant amount of time obtaining or using tobacco, and experiencing withdrawal symptoms while attempting to quit (3).

The severity of tobacco dependence can be assessed using instrument such as the Fagerström Test for Nicotine Dependence (FTND) for cigarette smoking and smokeless tobacco which assesses factors such as the frequency of tobacco use, the urgency of tobacco use upon waking, and the amount of tobacco consumed to measure the severity of dependence. Scores on the FTND help classify individuals into different levels of dependence, ranging from low to high, guiding treatment strategies and interventions (4,5). Additionally, healthcare professionals may consider other factors, such as the frequency and duration of tobacco use, unsuccessful quit attempts, willingness/ desire to quit and the presence of withdrawal symptoms when diagnosing tobacco dependence and assessing its severity to provide a tailored tobacco cessation counselling.

Establishment of Tobacco Cessation Clinics/Services in India was an initiative by the Ministry of Health, and Family Welfare (MoHFW), Government of India and World Health Organization (WHO). Initially, 13 tobacco cessation clinics were established in Anand, Bhopal, Bangalore, Chandigarh, Chennai, Cuttack, Delhi (2), Goa, Jaipur, Lucknow, Mumbai, and Patna in 2002 which were further expanded to 18 centers in 2005. The services offered at these clinics included individual intervention in the form of behavioral counseling and pharmacotherapy. The centers also intended to create awareness among the general public about the harmful effects of tobacco and about the desirability of tobacco cessation through awareness programs, exhibitions training programs on tobacco cessation for various professionals, and educational materials i.e. booklets, pamphlets and manuals etc. aimed at specific groups of the population. The Tobacco Cessation Clinic Resource Center (TCCRC) at National Institute of Mental Health and Neurosciences, (NIMHANS), Bangalore, was the national coordinating center for all the TCCs (6).

Existing Strategies for Tobacco Cessation

- 1. Behavioral strategies for Tobacco cessation [7-11]
 - i. Brief Intervention (5As) for tobacco users willing to Quit
 The 5As (Ask, Advise, Assess, Assist, Arrange) of a brief intervention summarize all the

activities that a healthcare providers (HCPs) can do to help a tobacco user within 3 - 5 minutes, specifically in a primary care setting or busy practice.

- a. The first step is Ask which involves identifying and documenting tobacco use for every patient/ individual. Asking about tobacco use should be done in friendly manner and should be part of the all-medical notes.
- b. Advise all current tobacco users to quit: All HCPs should advise their patients to quit tobacco. Simple advice to quit by the physician has been shown to increase the quit rate (OR 1.3 95% CI 1.1-1.6) compared to placebo or no intervention (8) (Fiore, et al, 2008). The advice should be strong, relevant and personalized. It has been seen that specific advice linked to the patient's clinical condition works best. Also, it has been found that the timing of the "ask" has a significant impact. The key step of Advise starts with a good and inquisitive listening.
- c. Assess for willingness: It is important to understand that addiction is a brain disease, and craving and withdrawal symptoms are part of this illness. You should assess the user in willing to quit at this time.
- d. Assist by Providing Brief Counseling: Making sure that help is available in case of any difficulty increases the person's confidence. Counselling also includes fixing a quit date, making environmental manipulations, tackling withdrawal symptoms and handling relapses.
- e. Assist by Offering Medications: Evidence is accumulating that providing medications improves the outcome even in the person who is not contemplating complete guitting.
- f. Arrange Follow up: It is important to have regular contact with the person. The first contact should be within first week of the quit date, preferably on 3rd day itself (after 48 hours). Studies have shown that spending just about 3 to 5 minutes during these follow-ups increases overall abstinence rates significantly. However, spending more time is associated with better outcomes (9). Preliminary experience of the TCC clinics in India have shown that retention in follow-up increases the chances of quitting (2).

Table 1 demonstrate the effectiveness of various counselling interventions in tobacco cessation with Brief advice and brief counselling being effective for achieving quit outcomes as compared to no treatment.

Type of intervention	Strength	Risk ratio (95% CI)
Smoking cessation counselling	o f evidence	(Placebo or no treatment: 1)
Individual	A	1.39 (1.24-1.57)
Group	В	1.98 (1.60-2.46)
Telephone quit line	В	1.37 (1.26-1.50)
Physician intervention	Α	1.66 (1.42-1.94)
Brief advice to quit		
Brief counseling	Α	1.84 (1.60-2.13)

Relapse Prevention:

Just like any other chronic disease which is prone to remissions and relapses, it is highly likely that persons addicted to tobacco may relapse i.e. returning to the use of tobacco product after a period of abstinence. It is important to educate patients about the likelihood of relapses and how to deal with them positively. Some common types of relapse triggers are emotional (stress, anxiety, happiness etc.), life- pattern (work break, before going to bed, finishing meals etc.), social (going to party, bar, concert, being with friends) and/or withdrawal (craving for taste/smell of cigarettes, need to do something with hands/mouth etc).

Identifying triggers for relapse in advance and discussing alternate ways of dealing with such triggers, particularly urges and craving, developing a healthy lifestyle, learning how to deal effectively with tension or mood changes and engaging the support of family and friends in addition to support provided by the health provider are all important components of relapse prevention counselling. Further, smoke free environment (workplace, public place and household) can reduce the frequency of relapse among smokers.

ii. Enhancing Motivation to quit to those NOT willing to quit (5Rs):

In patients still not willing to quit or reduce tobacco use, 5R intervention is used to tilt the balance towards quitting. This can be achieved by discussing the advantages/disadvantages of using versus stopping tobacco. Developing discrepancy, eliciting motivational statements i.e. why should you quit? expressing empathy, avoiding argumentation and supporting self-efficacy are important strategies.

The 5 R's are (1) Relevance (how quitting is relevant personally), (2) Risks (potential negative consequences of tobacco use that are relevant to tobacco user), (3) Rewards (potential relevant benefits of quitting tobacco use), (4) Roadblocks (identify barriers or impediments to quitting like craving at present), and (5) Repetition (If tobacco user still not ready to quit repeat intervention at a later date). Addressing these in motivational interviewing mode to get their own answers will help many of these to be ready to quit. It may need more than one interaction. Therefore, keeping the door open as and when they can decide to quit is very useful. The aim is to convert the denial into a readiness to quit. Using educational material may be helpful.

Key takeaways for Behavioral Counselling

- Counselling of any nature for tobacco cessation is effective
- Brief intervention even lasting for a few minutes is effective
- Brief advice to quit by a physician increases quit rates
- Proactive telephonic counselling is better than the reactive one
- Tailor-made web-based counselling might be helpful
- In persons not very keen to quit, an extended intervention with motivation enhancement components like 5Rs may be useful
- Combined pharmacotherapy and behavioral support doubles the quit rate

2. Pharmacological Strategies for Tobacco Cessation [12]

Pharmacotherapy plays a crucial role in tobacco cessation, significantly enhancing quit rates when combined with behavioral support. Healthcare providers should tailor treatments to individual needs, balancing efficacy and safety to maximize the chances of successful cessation. following is its brief description:

- I. Nicotine Replacement Therapy (NRT): Nicotine Replacement Therapy (NRT) aims to alleviate withdrawal symptoms. Currently nicotine gums, lozenges, patches and nasal sprays are available; the first two in 2 mg and 4 mg formulations. Combination NRT (e.g., patch plus gum) may be useful for some individuals.
 - NRT provides medicinal nicotine in a lower dose. It helps in minimizing withdrawal symptoms, cravings mostly. The patients should be advised to self-titrate the use of gums/lozenges as necessary. It should be chewed /suck until the satisfaction achieved matches the use of tobacco in the past; and, nothing should be ingested by mouth for next 15 minutes.
 - NRT is generally safe in view of its toxic limit of 40 mg/ 24 hours for an adult. It should be used with caution in patients with uncontrolled hypertension. Its use is contra-indicated in patients with recent myocardial infarction (nicotine is vasoconstrictive), minors, pregnant women and lactating women.
- ii. Bupropion: Bupropion is a non-nicotine medication originally developed as an antidepressant. It has proven effective for smoking cessation due to its impact on neurotransmitters involved in addiction. Bupropion inhibits the reuptake of norepinephrine and dopamine, reducing withdrawal symptoms and the rewarding effects of nicotine. Bupropion is usually taken as 150 mg OD for 3 days followed by 150 mg BD for 7-12 weeks.
 - Bupropion is contraindicated in individuals with history of seizure or hepatic disorders (cirrhosis liver), eating disorders, and those undergoing abrupt discontinuation of alcohol or sedatives. Common side effects include insomnia and dry mouth.
- iii. Varenicline: Varenicline is a partial agonist-antagonist at the α4β2 nicotinic acetylcholine

receptor, which mediates the addictive properties of nicotine. Varenicline binds to nicotinic receptors, providing partial stimulation to reduce withdrawal symptoms while also blocking nicotine from binding, thus decreasing the rewarding effects of smoking. It should be started initially as 0.5 mg once daily for three days, increased to 0.5 mg twice daily for next 4 days and then increased to 1 mg twice daily for 12 weeks. It may be used as a stand-alone therapy or in combination with NRT.

Varenicline has been associated with neuropsychiatric symptoms in some patients, including changes in mood and behavior (suicidal tendencies). gastrointestinal disturbances, particularly nausea.

- iv. Combination Pharmacotherapy: Combining different pharmacotherapies may enhance cessation success rates, e.g. using NRT with bupropion or combining different forms of NRT (patch and gum) has shown superior results compared to monotherapy (9). However, careful monitoring for any side effects is required.
- v. Second-Line Therapies: These include nortriptyline (tricyclic antidepressant) and clonidine (alpha- 2 adrenergic agonist). Both have shown some efficacy in smoking cessation. Further, Cytisine, a partial agonist of nicotinic acetylcholine receptors. Although it has been found to be effective in smoking cessation in a recent systematic review, it is not used in India due to its non-availability (13) (Puljević C 2024).

It should be noted that while 2 mg NRT gum or logenzes are the OTC drugs, the rest need a doctor's advice and prescription.

Tobacco Cessation services in India

1. Population Level strategies (National Tobacco Quitline Services and m-Cessation) [14-17]

i. National Tobacco Quitline Services (NTQLS), started on 30th May 2016 at VPCI, Delhi NTQLS is a sponsored scheme of Ministry of Health and Family Welfare, Government of India. This is a confidential, non-judgmental telephone-based tobacco cessation counselling and referral service for anyone seeking help for himself/herself or another person to quit tobacco. It can be accessed through a toll-free number 1800-11-2356 between 8 AM to 8 PM on all days, except Monday. The main objective is to help tobacco users to quit through counselling, referrals, mailed materials, training to healthcare providers, web-based services. Initially the services were offered in two languages Hindi and English. Now 3 more Centres have been established at Guwahati (Dr. Bhubaneswer Barooah Cancer Institute), Bangalore (National Institute of Mental Health And Neuro Sciences) and Mumbai (Tata Memorial Center) for giving counselling in total 15 different languages.

NTQLS works in reactive and proactive ways. The tobacco users initiate the call and the counselors or quit coaches sitting in the Quit-line office responds to the callers. The quit coaches register the callers, assess them and apply the intervention strategies. Intervention strategies include 5As (Ask, Advise, Assess, Assist and Arrange), or 5Rs (Relevance, Risks, Rewards, Roadblocks, Repetition), depending on the level of nicotine dependence and intention to quit. Overall, the NTQLS population-level strategy seeks to create a comprehensive approach to tobacco control that addresses the social, economic, and environmental factors that influence tobacco use. The Delhi-based NTQLS has

- reported a quit rate of \sim 40% at the end of 1-year. Further it reported that while the cost per quitter was \sim Rs. 1630, the cost per successful quitter was \sim Rs. 5,100 (17).
- ii. m-Cessation (18), is a unique program started in January 2016, to reach out to those willing to quit tobacco use and support them towards successful quitting through text messages sent via mobile phones. The initiative is fully supported by the Government of India. In this strategy, those desirous of quitting give a missed call to a toll-free number (011-22901701). m-Cessation uses two-way messaging between the individual seeking to quit tobacco use and programme specialists providing them dynamic support. The National Tobacco Control Programme (19), and the Union Ministry of Health and Family Welfare, with support from the WHO and the International Telecommunication Union's 'Be He@lthy, Be mobile' initiative have implemented this programme in colaboration.

Till date, the programme has over 2.1 million self-registered users and an average quitting rate of 7 per cent for both smokers and users of smokeless tobacco at six months after enrolment.

(20) (WHO Global Tobacco Epidemic Report, 2019)

2. Community Level tobacco cessation services (Tobacco Cessation Centers and Community Cessation Approaches):

i. Tobacco Cessation Centers: National Tobacco Control Program (NTCP) is currently implemented across all the state and UTs covering more than 740 districts. It aims to create awareness about harmful effects of tobacco consumption" and "help people to quit tobacco". Further, Setting-up and strengthening of cessation facilities including provision of pharmacological treatment facilities at district level is one of the key thrust areas under NTCP. (21).

At national level, National Tobacco Control Cell, MoHFW has released modules/guidelines viz. Tobacco Dependence Treatment guidelines, Training manual for doctors and health worker guide to advance tobacco cessation in India. Recently, on WNTD 2024, Operational Guidelines for establishment of TCCs at Medical Institutions was also released by MoHFW. (22).

At state level, a STCC is required to focus on raising profile of tobacco cessation with dedicated training and capacity building sessions for the NTCP staff and health care providers and further pushing for establishment of TCCs at health care facilities.

At district level, a separate budget head is provisioned (INR 15000) for training on tobacco cessation. A DTCCs should advance the tobacco cessation at district level in following steps:

- Identify an appropriate place in the respective local district-, medical college-, dental college- hospital/s and/or tertiary care center (under NCD programs), deaddiction clinics/TB Units/PHCs/CHCs etc. and
- 2. Train their Medical Officers/ ANMs as well as those working at CHCs/ PHCs, so that these latter health facilities too function as satellite centers (22).
 - Human Resource and financial provisions: A provision should be made for at least one counsellor/ psychologist for each TCC. A TCC is provided a non-recurring grant of INR 2,50,000 under the budget for procuring the equipment such as CO analyzer

and running it under the NTCP. Further, there is separate provision of INR 2,00,000 per year for pharmacological treatment which can be used to buy Nicotine gums, Patches etc based upon state preferences (21).

Currently in India, 600+ TCCs are functional under NTCP at District Hospital and 650+ TCCs have been established other than NTCP i.e. at Dental Hospitals/ Medical Institutions/ sub district hospitals/ rural district hospitals/ NCD clinics/ NOHP clinics etc. and provided counseling to more than 13.5 lakhs tobacco users (23).

ii. Community Cessation Approach (Brief Advice): Community based counselling is an established strategy for preventing initiation of tobacco use and enabling the tobacco users to quit. The primary health workers including ASHA, ANMs/ Multi-Purpose Health Workers (MPWs) and other health workers play an important role (due to vicinity and accessibility to the community) in creating awareness, identifying tobacco users, documentation of tobacco use, increasing coverage of brief advice and referral to the nearest tobacco cessation center if required. The health workers should identify and list the tobacco users in the community and provide brief advice and regular follow up for enabling quitting by the user.

Health workers should also be trained for providing brief advice and further sensitized about the existing tobacco cessation services at national level (NTQLS/ m-cessation), State (state level health helplines and quit lines, if any) and district level (TCCs under NTCP/ Other than NTCP) for efficient referral system. Operational guidelines under NTCP emphasizes on community-based counselling and household follow ups to encourage tobacco users to quit. Various modules released under national health mission (ASHA NCD module, Multi-Purpose Workers (MPW)-on Prevention, Screening & Control of NCD, Health workers guide) have explicitly mentioned about role of health workers in providing brief advice for tobacco cessation (24-26). However, studies have reported that only 1/4th of the ANMs reported that they have been provided prior training for tobacco cessation (27) [Panda R et al. 2015]

3. Integration of Tobacco Cessation Services with other national level programs

Tobacco Cessation has a primary role in achieving Universal Health Coverage (UHC). With respect to NCDs, tobacco smokers have 2-3 folds higher relative risk of coronary heart disease (CHD), 1.5 times for stroke, 1.4 times for chronic obstructive pulmonary disease (COPD) and 12-fold risks for lung cancer. Tobacco contributes to around 40% of mortality from TB which is a cause for great concern. The prevalence of TB is three times higher among ever-smokers as compared to that of never smokers. Tobacco use in any form causes poor oral health outcomes like oral cancer, oral mucosal lesions, periodontal disease, implant failure, salivary gland hypofunction, dental caries among many other oral diseases and conditions (28-34).

Thus, convergence of tobacco cessation services within National Health Programs such as National Programme for Non Communicable Diseases (NP NCD previously NPCDCS), National Mental Health Programme (NMHP), National Programme for Health Care of the Elderly (NPHCE), National Oral Health Programme (NOHP), Drug De-Addiction Programme (DDAP), and National Tuberculosis Elimination Program (NTEP) (Figure 1), will assist in expanding the coverage of cessation services (at least Brief advice) and thus enhancing quit rates significantly. Brief advice if delivered regularly and ubiquitously within a healthcare delivery system, has the potential to reach over 80% of tobacco users in a nation annually and thus excelling to achieve SDG 3.3 by 2030.

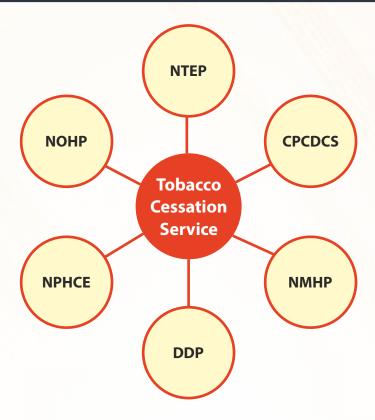


Figure 1: Integration of TCC services with National Health Programs

Integrating national health programs with tobacco cessation services has many challenges including stigma and misconception about tobacco use, various cultural and socioeconomic factors, dearth of awareness about linkage of tobacco use with other morbidities, lack of willingness and coordination among Community Healthcare Workers, deficiency of skilled and trained tobacco cessation experts, constraint on account of time, human resource, suboptimal participation of healthcare professionals, inadequate coordination among various stakeholder, data management, regularity in monitoring and evaluation, fragmented healthcare systems, lack of vertical and lateral integration with other Health programs and Policies, and lack of political leadership and commitment (Figure 2).



Figure 2: Challenges in Integrating National Health Programs with tobacco cessation services

However, there are several opportunities for integration of tobacco cessation services with National Health Programs which are as follows (Figure 3):



Figure 3: Opportunities of integrating tobacco cessation services with National Health Programs

- a. Comorbidity Management: Integration allows for the identification and management of tobacco users and can improve treatment adherence, reduce relapse rates and enhance overall comorbidities control efforts.
- b. Shared infrastructure and Resources: lead to cost savings, increased efficiency and improved access to tobacco cessation services for individuals accessing other healthcare services.
- Training and Capacity Building: Integrating to bacco cessation services with NTEP, NOHP and NCD
 programs provides common opportunities for training and capacity building among healthcare
 providers.
- d. Cross Referral Mechanism: Healthcare providers within NTEP, NOHP or NCD programs can refer individuals who use tobacco to specialized cessation services, while tobacco cessation providers can refer patients with TB, Oral health, or NCDs for appropriate care.
- e. Policy Alignment and Advocacy: Advocating for comprehensive tobacco control policies within the National Health Programs can help strengthen tobacco cessation efforts and promote a supportive environment for tobacco users trying to quit.
- f. Data Sharing and Monitoring: Enables comprehensive evaluation of effectiveness of cessation interventions, as well as tracking progress in reducing tobacco use prevalence among population accessing different healthcare services.
- g. Community Engagement and Awareness: Community- based interventions across various programs can raise awareness about the link between tobacco use and various health conditions, encourage health behaviour change and promote utilization of cessation services.
- 4. Integration of Tobacco Cessation services in Medical/ Dental colleges/ Nursing colleges/ AYUSH/ Private hospital Settings India has a vast network of medical, dental, nursing and public health

institutions. Countrywide, it has 757 medical colleges, 312+ dental colleges, 2,400 plus pharmacy colleges and over 2694 nursing colleges with affiliations to their respective councils (35-37).

Integration of tobacco cessation delivery through these is of paramount importance interest and shall make the cessation services more affordable, accessible and thus increase the coverage to tobacco users being provided counselling & pharmacotherapy. The MoHFW has already released guidelines for establishing TCCs under dental (2018) and medical colleges (2024) countrywide. At the State-level, an administrative lead by the department of medical education shall be vital for these institutes to have optimally trained staff that will provide the quality services on a regular basis.

Besides abiding to the WHO recommendations under MPOWER for its "O (Offer to Quit)" component, (38). TCCs under medical institutes have significant utility in view of: (1) their position as apex healthcare institutes in their respective locales, (2) a relatively high footfall of the patients and their care givers in these institutions, (3) the proven competence and capabilities of the staff working there, (4) the ease with which they accept and adapt to the newer undertakings overcoming the challenges howsoever daunting and, above all, (5) a setup that can sustain such services with meager resources (39).

The Institutions/ hospital administrations will find it easy if these accept to work through the Systems Approach that comprises of: (1) Screening of all patients (above the age of 10 years) attending their hospitals for current or former use of any type of tobacco; (2) Delivery of treatment through counseling and pharmacotherapy; and (3) proactive follow-up of the treated patients for at least six months to assess their quit status and the support many patients need in the interim.

The medical institutions/ public hospitals should participate in data capturing, reporting and management in collaboration with state cell to quantify the coverage and evaluate the performance of the TCCs. This step will be of the prime value to monitor and evaluate the functioning of the TCCs as well overall efficacy of the tobacco-free cessation delivery services through these medical institutes. It will be very useful to make suitable provisions to integrate their results on the MIS dashboard on the NTCP portal (23)

While the preceding paras refer mostly to the institutes run through the Government health sector, now is the time to mandate participation of the private health sector holistically and by all its health facilities countrywide along with a foolproof integration of a useful insurance program, preferably at no- or minimal (affordable)- cost. The private health sector should know that besides its ethical professional conduct to provide treatment of tobacco abuse and nicotine addiction to all the needy attending it in a timely manner, the delivery of tobacco cessation through its varied portals is a useful business model and a win-win scenario of all the stakeholders, the hospitals, HCPs and above all their tobacco using patients and their families. The delivery of this additional preventive service will not only assist their HCPs to optimally treat tobacco addiction as a stand-alone disease but will also contribute significantly towards management of tobacco-related illnesses as comorbidities.

Also, it will be timely to implement solutions that are appropriate and optimal to the prevailing challenges and done as a package deal instead of a piece-meal approach. The foremost will be a prompt utilization of the resources backed-up in a sustained manner for each and every institute

as the variations in their current status of delivering to bacco cessation are vast. Secondly, it will be critical to have an accountability established for those assigned to the cessation delivery- no tobacco using patients should go unattended and provided at least brief advice. Thirdly, a high visibility of the existence of the cessation services and its accessible location in the institutional premises will be very useful (40-41).

Emerging disruptive Tobacco Harm Reduction (THR) approaches (ENDS/HTPs/ synthetic nicotine/Nicotine pouches) for tobacco cessation

Harm reduction generally means a reduction of harm at an individual as well as community level. A product that harms a community cannot be called a harm reduction product. The term harm reduction was initially used to reduce the harm from addictive drugs but now the tobacco or ecigarette industry is using the term to promote e-cigarettes as are supposedly less harmful and may help in cessation. The tobacco/vaping industry wants people to continue to be addicted to nicotine through continuous use of HTPs, ENDS or Nicotine pouches rather than their false notion of 'Harm Reduction' or quitting tobacco use.

The public health community aims for and supports that tobacco cessation does not mean addiction to another addictive substance present in HTPs/ENDS. Since these have Nicotine in chemical form, it is time to talk about 'Harm Elimination' (41-47) The details of the harms caused by ENDS and like products are discussed in another chapter.

Capacity Building for tobacco cessation

As per GATS2, the current tobacco cessation landscape reveals significant gaps -Only 37.4% of smokeless tobacco (SLT) and 54.5% of smokers are asked about their tobacco usage by HCPs. Additionally, merely 31.7% of SLT and 48.8% of smokers receive advice to quit from HCPs (48) A Cochrane Review highlights the critical role of interventions, noting only a 21% success rate in quitting without support. Yet, a significant majority, 71.7% of smokers and 74.9% of SMT users attempt to quit on their own without HCP assistance.

Despite diverse advertisements and promotion strategies highlighting benefits of quitting tobacco and motivation of the users of tobacco to quit, the best opportunity for tobacco users to quit promptly and effectively is when a tobacco-user is reaching out to a health facility at any level of healthcare. The HCPs besides helping to set a social norm for tobacco-free life, should be participating in tobacco cessation delivery due to: (1) Their position to play a prominent role as a messenger, promoter and clinician treating tobacco dependence; (2) The opportunity they have for their every tobacco-using patient to ask, advise and assist in quitting.

In an ideal scenario, every HCP should deliver to bacco cessation to every to bacco using patient at every clinical encounter on every visit to a health facility regardless of the healthcare level-Primary to Tertiary!

At present, the majority of HCPs do not participate in tobacco cessation delivery due to following reasons: (a) their ignorance as the subject is not included under their curriculum; (b) their being the tobacco users currently; (c) limited time to serve for patients reporting under their own specialty; (d) the technology used to register patients (Hospital Information System- HIS) is not utilized for identifying tobacco users; (e) the delivery of tobacco cessation service lacks financial incentive; (f) consideration that counseling is not my job! It should be done by the counselors; (g)

unable to reform and, thus perform as a clinician rather than public health approach; and, lastly, (h) misunderstanding among them about the efficacy of treatment of tobacco use. Further, limited scope of tobacco cessation services in health insurance schemes and low demand of services from patients presents inherent challenges (49-50).

Training HCPs help: (a) Improve quit rates; (b) Protect youth; (c) Reduce prevalence of tobacco-related illnesses: NCDs, TB, mental illnesses, HIV AIDS, etc. (d) Reduce burden of tobacco-related deaths; (e) Prevent economic loss due to premature loss of lives; and (f) Eliminate environmental destruction-Pollution, Fires, etc (51).

But, undoubtedly, capacity building of the HCPs should be prioritized under NTCP and beyond the government sector, for all those working in the private health sector, both in urban and rural geographies. At the outset, it should preferably be done at the state-level as ToTs (Sessions to Train the Trainers) through classroom teaching along with role-plays as these bring a higher and focused participation and learning. Therefore, it should be followed by their interactive empowerment sessions to serve the Master Trainers for training HCPs at the district to primary levels of healthcare. The trainers should stay aware of the need to provide training that is interactive and result-oriented; and, has the desired quality. Monitoring and evaluating trainings', and reporting on their outcomes either dynamically through the NTCP MIS Dashboard or through the state-specific software can be very useful.

Their representative professional bodies or their respective councils at the State- or National-level may be entrusted with the task that every HCPs has been trained in the given timeline. Setting their accountability enabling these to do so effectively will be necessary and useful (50).

MoH released various guidelines for capacity building of HCPs including starting tobacco cessation services (2009), Training Manual for Doctors- NTCP (2011), Tobacco Dependence Treatment Guidelines (2011), Health worker guide (2010) and recently, Tobacco Cessation in dental settings- reference manual for dental professionals (2022) etc. since the launch of NTCP in 2008-09. NIMHANS have used various initiatives for capacity building of health care professionals in tobacco cessation with their on-site and online comprehensive tobacco cessation certificate courses via ECHO platform. (52-53).

Non-Government sector have also contributed in exploring and strenthening the tobacco cessation services in India. Few of the initiatives are mentioned below:

- Technical Support and Capacity Building (Tobacco Intervention Initiative by IDA for capacity building of dentist in tobacco cessation, SIPHER, ICanCaRe capacity building through e learning platform, Toxin Taxation, Rajasthan Cancer Foundation (RCF), SCCoPE Strengthening Cessation Capacity of Primary Care Professionals by PHFI)
- Model of TCC at private hospital (RCF and ICanCaRe Intervention Models, mobile application/ Private Quitline and Virtual clinics) etc.

Setting up of Tobacco Cessation Centre: [54]

A TCC is defined as fixed premises where qualified health professionals/ counsellors provide tobacco (smoke and smokeless form) cessation therapy to help patients in their attempts to quit the habit. The therapy can involve individual or group counselling and may include the dispensing of pharmacological aids if the center is registered and equipped to do so.

The objectives of an effective tobacco cessation center/clinic are to focus on patient care and community-based services. The Patient care services may include behavioural interventions along with pharmacotherapy relapse prevention strategies as well as a integrated referral policies to higher centers. A clear patient protocol must be drawn and necessary follow-ups should be scheduled. The pharmacy in the hospital should have adequate supply of various medications like bupropion and nicotine replacement therapy like nicotine gums, nicotine patches and nicotine lozenges along with other supplementary drugs. The healthcare professionals need to undergo relevant and regular training programs in tobacco cessation, some of which has been enumerated in the chapter

Health Awareness posters and educational materials which are locally relevant and culturally acceptable should be designed and displayed in different mediums like print, audio-video etc. There should be efforts made to use technology tools and social media to propagate information regarding tobacco cessation strategies.

A TCC in a hospital setting may be planned in such a manner that it has a minimum area of 120 to 150 square foot with dedicated space for Health Education in the waiting area as well as space for group counselling too. The location of the TCC may be identified as per availability and accessibility within the hospital premises. There has to be appropriate space for digital displays as well as display of other health education materials. A detailed patient care protocol in tobacco cessation clinic should be laid down along with its scope of services.

The TCC should preferably have clinical diagnostic instruments like stethoscope, BP apparatus, breath analyzers, spirometer along with measuring tape and stadiometer along with cotinine strips for urine analysis, which is optional. The TCC data should be integrated with the electronic hospital information management system and inter-departmental referrals may be made accordingly. There has to be a team approach wherein specialist from various departments like general medicine, psychiatry, oncology and other allied departments like medical social work etc could coordinate with the nodal officer of the tobacco cessation clinic. Further the National Tobacco Quitline- 1800-11-2356 Services should be displayed at various locations of the hospital.

Regular monthly data should be recorded and maintained. Monitoring and evaluation have to be an integral part of the continuous quality improvement of the patient care services in the tobacco cessation clinic. Tobacco Cessation Clinics in Hospitals should work systematically in collaboration with various departments within as well as in the communities from where the patients can be referred and provided counselling and/or pharmacotherapy treatment.

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RECOMMENDATIONS

5.7. Tobacco Cessation

5.7.1. Recommendation for the MoHFW:

- a) Constitutions of a national expert group/advisory group for advancing tobacco cessation in India with half yearly review of existing services.
- b) Drafting of National Strategic Action Plan for advancing tobacco cessation at all levels of healthcare in India in both governmental and private health care sectors along with suitable provisions for adequate and sustained financial support for human resource availability and suitable infrastructure.
- c) Updating and/ or revising the existing guidelines (Health worker guides/ tobacco dependence treatment guidelines, guidelines for doctors etc.) on

- tobacco cessation and dependence for health care workers and professionals (Medical/Dental/Nursing/AYUSH).
- d) Drafting of guidelines with focus on product specific intervention models/ youth and adolescent, women and vulnerable population (elderly, tribals, slums etc.) to ensure equal opportunities to these for availing cessation services.
- e) Dedicated IEC/ mass media Campaigns in all regional languages besides Hindi and English for enhancing awareness about harms of tobacco and availability of tobacco cessation services across various states in India.
- f) Integration of National Tobacco Quit Line Services (NTQLS) with m-cessation to address the unattended calls and exploring use of IVRS/ Chatbot/WhatsApp/ Al along with Public Private Partnership (PPP) models to scale up Quitline services.
- g) Training/ capacity building program specific to tobacco cessation via cascade training approach should be developed by MoHFW and implemented by state and UT governments.
- h) Integration of cessation indicators from all levels (NTQLS/ m-cessation, TCCs, Brief advice at primary level, other program like NTEP, NOHP) into existing Management Information System (MIS platform) under NTCP to dynamically assess the overall coverage of cessation services at all levels of healthcare.
- Involvement of private bodies/ national associations of health professionals (IDA/IMA/ associations of Nurses, Pharmacists etc.) for promotion of cessation services in India.
- j) Ensuring the quality of the delivery of tobacco cessation service through accreditation of all TCCs under Indian Public Health Standards (IPHS) through NABH and other accreditation agencies.
- k) ICMR and other funding agencies should have a specific call to research to promote multi-center high quality evidence/ operational research for tobacco cessation in India with sustainable funding support. Further, opportunities for collaborative research with existing national institutes of eminence working in tobacco control. (Resource Centre for Tobacco Control, PGIMER/ NICPR, National Resource centre for oral health and tobacco cessation/ NIMHANS etc.) should be promoted with further involvement of AlIMS and state medical institutes.
- Insurance Regulatory and Development Authority of India (IRDAI) and PMJAY Ayushman Bharat and other state health insurance schemes should be mandated to reimburse the entire cost of tobacco dependence treatment for all tobacco users registering with any health/Life insurance.
- m) Nicotine replacement therapy should be readily and sufficiently available at TCCs at district hospitals under NTCP till primary health care level.
- n) Continuing with the Over-The-Counter (OTC) access to Nicotine Gum/Lozenges up to 2 mg (as per schedule K of drugs and cosmetic act, 1945) to ease its access and its optimal utilization by the tobacco users who are willing to quit. Further, global literature suggests limited evidence of its abuse/ dual use/ use by teens or non-smokers.

o) Establish an accrediting body to ensure all tobacco treatment courses meet standardized practices.

5.7.2. Recommendations for State Government and relevant departments

- Focus and expansion of brief cessation services/ community cessation services up to the primary health care level with training of ASHAs, ANMs for providing brief advice.
- b) Further, establishing an integrated reporting mechanism into Community Based Assessment Checklist (CBAC) form for brief tobacco cessation services, outcome and referrals to TCCs.
- Leveraging on State health helplines with existing resources to include tobacco cessation services and serve as subsidiaries to the NTQLS for mutual support and efficacy.
- d) The State NHMs should be enabled to integrate tobacco cessation services into all national health programs under its umbrage such as NTEP, NOHP, NP-NCD, RBSK, NMHP, HIV AIDS, etc.
- e) Exploring PPP model to further promote and expand coverage of cessation services at all levels of health care.
- f) All health institutions (Medical/Dental/AYUSH/ Nursing/ private hospitals with OPDs) should establish TCCs with adequate training to the staff for efficient cessation services.
- g) Satellite TCCs should be established as an extension of the existing TCCs at district hospitals/medical colleges/dental colleges/ private hospitals etc.
- h) A TCC should be part of the Inspection proforma under regular inspection/ renewal/establishment/ evaluation under NMC/ DCI/ Other governing/ professional regulatory bodies such as NABH.
- i) Geotagging of the TCCs (Public/ private) in the state should be prioritized for ease of tobacco users to locate the tobacco cessation services available nearby.
- j) Medical/ Dental/ AYUSH/ Nursing colleges should have provision of tobacco cessation skill certification for the students as part of the internship program.
- k) State NTCP cells should establish a mechanism for integrated reporting and monitoring/evaluation of cessation services from all levels and connecting district tobacco control cells (DTCC) to TCCs in the districts.
- Workplace cessation- All workplaces (Govt. or private) should motivate their employees with tobacco use to quit and should have provision to offer aid for tobacco cessation services to existing users in collaboration with private/ govt. tobacco cessation centers.
- m) Further, State Govt. and other institutions/ private offices should have protocol to have a declaration about no tobacco use while hiring employees with any false declaration leading to legal proceedings.
- n) Public sector undertakings (PSUs) and corporate offices declare themselves as smoke- free to protect employees from second-, third- and fourth-hand smoke as well use of any other kind of tobacco and/or nicotine product.

CHAPTER-8

Smokeless Tobacco Products: Indian and Global Perspective

Smokeless Tobacco Products: Indian and Global Perspective

Working Chair and Group members

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Background

This chapter presents the Indian perspective of SLT products; their prevalence; use by demographic and socio-economic status; their types; physical and chemical properties; testing protocols; regulatory landscape; initiatives for SLT control in India; the key challenges and gaps in SLT regulation in the country and some case studies. In order to highlight the concerns surrounding SLT products and offer best practice recommendations for laws governing SLT use, the current chapter reviewed the available published and unpublished data as well as expert opinions.

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Introduction:

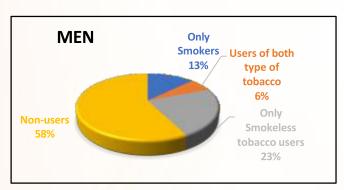
Products containing smokeless to bacco (SLT) are used by over 300 million people worldwide

(1). SLT product use is more common and preferred over smoking in South-East Asian nations like Bangladesh, Nepal, and India. It is estimated that over 650,000 deaths are caused by the consumption of SLT products annually worldwide (2). Over 85% of the DALYs lost due to SLT use is accounted for by the South and Southeast Asian countries, of which India bears 70% of this burden alone (3). The false notion that SLT products are a safer alternative to smoking, poses significant challenges in SLT control in terms of preventing use initiation and persistence of its use (4). The cultural adoption of smokeless tobacco (SLT) in South Asia, despite its non-native origins, has created significant obstacles for tobacco control initiatives, highlighting the complex interplay between imported practices and local traditions. The control of the use of SLT products has not advanced as much as it could because the primary goal of tobacco control worldwide has been to reduce cigarette smoking. (5), within the South-East Asia region.

While smoked tobacco is more common among men, SLT consumption is not limited to men alone; it is also prevalent among vulnerable groups such as children, teenagers, and women including during pregnancy (6). Research suggests that the onset of tobacco use is often linked to early life challenges, including socioeconomic conditions, financial hardships, and health-related issues experienced during childhood (7).

SLT Use in India:

Currently, 28.6% of people in India use tobacco in any way; solely smokeless forms are consumed by 12% of women and 23% of males (Figure 1). Nearly 6% of the men and 1% of women consume smoked as well as the smokeless form of tobacco (8). In India, SLT use attributes to an estimated 368,127 deaths which include 151,051 men and 217,076 women (9).



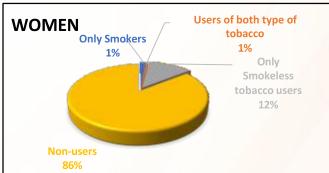


Figure 1: Tobacco use according to gender (Percentage distribution) [GATS 2 India 2016-17]

The state of Himachal Pradesh has the lowest prevalence of adult SLT usage, per data from the most recent Global Adult Tobacco Survey (3.1%), whereas Tripura has the highest overall prevalence (48.5%) (Table 1). The consumption of SLT products by women is also reported to be the highest in Tripura. In Chandigarh, Punjab and Himachal Pradesh less than 1% of women consume SLT products. In absolute terms, Uttar Pradesh accounts for more than one fifth (22%) of total SLT product users in India. Moreover, one-third (33%) of the SLT product users in the country are in Maharashtra and Uttar Pradesh (Table 1).

Table 1: Current smokeless tobacco (SLT) users aged 15 or above in India by States/UTs (Percentage) [GATS 2 India 2016-2017]

State	Current Tobacco Use	Only Smokeles s Tobacco	Both Smoked and Smokeles s	Men (Age 15 or above)	Women (Age 15 or above)	Smokeless Tobacco Use (By Pregnant Women)
Total	28.6	21.4	3.4	29.6	12.8	7.4
Himachal Pradesh	16.1	3.1	1.2	6.1	0.1	0.0
Jammu & Kashmir	23.7	4.3	1.4	6.8	1.5	1.1
Puducherry	11.2	4.7	0.8	4.5	4.9	0.0
Kerala	12.7	5.4	2.0	7.4	3.6	0.0
Chandigarh	13.7	6.1	1.8	10.4	0.8	1.1
Haryana	23.6	6.3	2.4	10.0	2.2	0.0
Goa	9.7	6.5	1.0	9.2	3.6	0.0
Andhra Pradesh	20.0	7.1	1.4	7.6	6.6	0.0
Punjab	13.4	8.0	1.8	15.0	0.3	0.0
Delhi	17.8	8.8	2.3	13.7	3.2	0.0
Sikkim	17.9	9.7	2.7	13.8	5.1	4.6
Telangana	17.8	10.1	0.6	11.3	9.0	0.0
Tamil Nadu	20.0	10.6	1.0	11.9	9.3	0.0
Uttarakhand	26.5	12.4	3.9	21.2	3.4	0.0
Rajasthan	24.7	14.1	2.6	22.0	5.8	0.0
Karnataka	22.8	16.3	2.3	22.2	10.3	0.0
Gujarat	25.1	19.2	1.8	27.6	10.0	7.7
West Bengal	33.5	20.1	3.2	22.8	17.2	5.4
Meghalaya	47.0	20.3	4.9	11.6	29.1	20.7
Bihar	25.9	23.5	2.7	41.9	3.6	3.2
Maharashtra	26.6	24.4	1.6	31.7	16.6	7.8
Madhya Pradesh	34.2	28.1	4.1	38.7	16.8	13.1
Uttar Pradesh	35.5	29.4	7.4	42.6	15.2	13.2
Mizoram	58.7	33.5	9.2	21.3	46.0	43.3
Jharkhand	38.9	35.4	7.7	54.1	15.7	5.9
Chhattisgarh	39.1	36.0	2.4	47.7	24.5	15.9
Nagaland	43.3	39.0	8.9	46.0	31.5	29.1
Arunachal Pradesh	45.5	39.3	16.5	50.1	27.7	38.2
Assam	48.2	41.7	6.8	50.5	32.5	12.4
Odisha	45.6	42.9	4.3	52.1	33.6	33.8
Manipur	55.1	47.7	13.5	50.2	45.2	36.5
Tripura	64.5	48.5	11.7	40.8	56.5	36.6

Almost 19 types of SLT products are used in different states and union territories within India. The most prevalent SLT product is Khaini (mixture of tobacco & lime) in the majority of the states and UTs, while the states of Tripura, Manipur, Meghalaya, Kerala, Karnataka, Puducherry, and Tamil Nadu are the main users of paan, or betel quid along with tobacco. Besides, Gutka (mixture of areca net, tobacco & lime) is mostly prevalent in Gujarat, Rajasthan, and Madhya Pradesh. Paan Masala with tobacco is common in Nagaland and tobacco is orally applied in the form of tuibur and hidakphu (watery tobacco products) in Mizoram, Chhattisgarh, and Odisha (8). (Table 2)

11	Betel quid with tobacco/Paan	Betel leaf or Paan	Consumed in	Used all over India.
• •	beter quia with tobacco/r dan	mixed with	chewed form	osea an over maia.
	7/////	areca nut, catechu,	cheweatom	
	11111111	slaked lime and		
	1111			
		flavours such as		
	7	camphor,		
		menthol,		
		rosewater, sugar,		
		cardamom,		
		aniseed, mint,		
		clove and spices		
12	Khaini	Sun-dried or	Sucked slowly for	Uttar Pradesh, Bihar,
		fermented	10 – 15 minutes by	Jharkhand, Manipur, West
		coarsely cut	placing it between	Bengal, Mizoram,
		tobacco leaves	the cheeks and the	Maharashtra, Sikkim,
		mixed with slaked	gums.	Arunachal Pradesh,
		lime		Assam, Madhya Pradesh,
				Chhattisgarh, Delhi.
13	Chewing tobacco plain / tambakoo	Tobacco leaves,	Chewed or sucked.	Used all over India.
		shredded finely		
		or coarsely.		
14	Guthka/Gutka	Sweeteners	Sucked	Used all over India.
		and	an	
		flavourings	d chewed.	
		combined with		
		finely		
		choppe		
		d tobacco that		
		has been sun-		
		dried and roasted,		
		areca nut, slaked		
		lime, and		
		catechu.		
15	Vizapatta/Zarda	A mixture of	Predominantly	Used all over India
		flavoured tobacco	used in	
		flakes, menthol,	combination with	
		aromatic spices,	betel quid.	
	///	herbs, saffron,	Chewed alone	
		fragrances,	either mixing with	
	/ // // // // // // // // // // // // /	sandalwood	areca nut or lime	
		oil,		
		silver flakes, raw		
		kiwam, and lime		
		(provided		
		separately by		
		the manufacturer).		
		"Zafrani Zarda" is		
		flavoured with		
		saffron.		

16	Sada Patta/Loose leaf/ Tobacco leaf/ Chadha	Loose air cured tobacco leaves	Chewed	India
		used for smoking and chewing.		
17	Gul	A mixture of pyrolyzed powdered tobacco with tendu leaf ash, marketed in small	Used as dentifrice on teeth and gums.	Along with the eight North- Eastern States of India, Uttaranchal, Uttar Pradesh, Bihar, Jharkhand, and Orissa.
		sachets or tin cans as a dentifrice.		
18	Kharra	Mixture of catechu, lime, areca nut, and tobacco with additional ingredients.	Sucked an d chewed.	Maharashtra, India
19	Kiwam / Qiwam	A mixture of thick paste that contains tobacco leaf extracts, additives like musk and spices such as cardamom, saffron, aniseed etc	Chewed; a n optional ingredient for betel quid.	India
20	Mishri	It is roasted and powdered tobacco.	Used predominantly as a dentifrice	Gujrat and its nearby areas of Maharashtra
21	Mawa	It's a blend of slaked lime, tobacco flakes, and thinly sliced areca	Chewed	Gujrat and its nearby areas of Maharashtra
22	Dohra/Dhora	nut. tobacco, slaked lime, areca nut, and additional ingredients like catechu (Kattha), peppermint, and cardamom combined in a moist mixture.	Chewed an d sucked.	Jaunpur, Prayagraj and Pratapgarh district of Uttar Pradesh
23	Gudakhu / Gudhaku	A mixture of paste prepared from fine dust of tob acco leaves, lime, molasses (Sheera), and red soil (Gerumati)	Consumed by Rubbing over the gums and teeth.	West Bengal, Bihar, Orissa, Chhattisgarh, Uttaranchal and Uttar Pradesh.

				- · · · · · · · · · · · · · · · · · · ·
24	Tapkir/Tapkeer/Bajar/Dry snuff	A powder of dry tobacco available in varieties such as unflavoured and flavoured with menthol or perfumes extracted	Nasal or Oral use	Eastern part of India, as well as Goa, Gujarat and Maharashtra
		from		
		natura		
		I flowers and hers.		////////////
25	Creamy snuff	A mixture of finely	Used by rubbing on	Used all over India.
		grounded	the gums and	
		tobacco, glycerine,	teeth.	
	////	clove oil,		
		menthol		
		, spearmint,		
		salts,		
		camphor, other		
		hydrating agents, and water and		
		commercially		
		manufactured as a		
		paste.		
26	Tuibur / tobacco water / hidakphu	lt is	Kept in mouth for 5	North Eastern states of
		tobacco	to 10 minutes or	Mizoram and Manipur, India
		smoke-infused	used as a gargle.	
		water. bottled		
		for both storage		
		and sale.		
27	Kapoori/Mainpuri	A mixture of slaked	Consumed as	Uttar Pradesh, India specially
		lime	Chewed	in the Mainpuri district.
		treate	an	·
		d	d sucked.	
		tobacco leaves,		
		finely cut betel		
		nuts and flavours		
		such as		
		powere		
		d cardamom,		
		cloves, Kweara (extract from the		
		Pandanus		
		odoratissimus		
		fragrant flower),		
		powdered		
		sandalwood		
		and		
		occasionally		
		added Catechu.		

28 Red tooth powder/Lal dantmanjan	A mixture of red	Predominantly	In Indian states – Uttar
/red tooth paste	fine	used as a	Pradesh, Uttaranchal, Bihar,
	tobacc	dentifrice	Mizoram, Orissa, Nagaland,
	o powder, herbs,		Meghalaya, Assam, Arunachal
	and flavours with		Pradesh, Tripura, Goa,
	an additional mix		Manipur, Maharashtra and
	of		Sikkim
	pepper, ginger		
	and camphor		
29 Snus	Tobacco,	Kept in mouth for	New emerging
	moisturizers,	30 minutes	smokeless tobacco
	sodium		product in India
	carbonate, salt,		
	sweeteners		
	, flavouring		

Source: World Health Organization. Available

at:https://extranet.who.int/fctcapps/fctcapps/fctc/kh/slt/news/smokeless-tobacco-slt-products

Harmful effects of SLT:

SLT products contain over 30 carcinogens (Table 3 & 3a) (10), which are responsible for a range of adverse health impacts including oral cancers, cardiovascular diseases and other non-communicable diseases (2,11). Additionally, in accordance with the Federal Food, Drug and Cosmetic Act (12), the

U.S. Food and Drug Administration (FDA) has compiled a list of tobacco products' harmful and potentially harmful constituents (HPHCs), classifying them as cardiovascular toxicants (CT), respiratory toxicants (RT), carcinogens (CA), reproductive or developmental toxicants (RDT), and addictive substances (AD). Nicotine, an alkaloid, responsible for tobacco addiction exists in an unionized form at alkaline pH in the SLT products. The absorption of nicotine is influenced by several factors such as pH, nicotine concentration and moisture content. The SLT goods are made attractive by the addition of tastes and additions like spices. (Table 3b).

The International Agency for Research on Cancer (IARC) launched a program in 1969 with the aim of evaluating the carcinogenic risks that chemicals pose to humans and critically analysing monographs on particular chemicals. Subsequently, the programme broadened its scope of evaluation including carcinogenic substances linked to complex combinations, biological and physical agents and lifestyle elements, along with occupation specific hazards. Globally, the single largest cause of cancer is tobacco consumption. In volume 38 (IARC, 1986) (13) and 83 (IARC, 2004a) (14), sufficient evidence was provided for carcinogenicity of tobacco smoking in humans. Volume 37 (IARC, 1985) (15), evaluated some types of SLT products for evidence of carcinogenicity in humans and in volume 89 (IARC, 2007) (10), all types of SLT products are classified as Group 1 carcinogens. Tobacco-specific nitrosamines NNN and NNK are also classified as Group 1 carcinogens in volume 89 (IARC, 2007) based on the solid evidences in exposed humans. In volume 100E (IARC, 2012), SLT products are classified as Group 1 carcinogens and provided evidence on being the cause of cancers of pancreas, oesophagus and oral cavity (16). Furthermore, the INTERHEART research, which was carried out in 52 countries, projected that in 2010, the use of SLT products resulted in 204,309 deaths and 4.7 million disabilityadjusted life years (DALYs) caused by coronary heart disorders (11). In 2021, the Indian Council of Medical Research (ICMR), India also documented tobacco monograph where all the initiatives to

reduce the tobacco hazard undertaken by Government of India and ICMR till the year 2019 were compiled (17). The tobacco monograph highlighted the different types of SLT products used in the country, their prevalence, carcinogenicity with the aim to provide valuable insights for awareness campaigns and public health policies to curb the tobacco related harms.

Table 3: The list of available chemicals identified in SLT products with their IARC Classification.

Chemical	IARC	Chemical	IARC
Components	Classification	Components	Classification
Arsenic	1	Mercury	3
Acetaldehyde	2B	Morpholine	3
		(Precursor of	
		NMOR)	
Aflatoxin M1	2B	Morpholine	3
		(Precursor of	
		NMOR)	
Anthracene	3	Morpholine	3
		(Precursor of	
		NMOR)	
Acenaphthene	3	NDMA	2A
Acrolein	3	NDEA	2A
Benzo[e]pyrene	3	Nitrite	2A
Benzo[a]pyrene	1	Nitrate	2A
Beryllium	1	NDBA	2B
Benz[a]anthracene	2B	NSAR	2B
Benzo[b]fluoranthene	2B	NEMA	2B
Benzofluoranthenes (j)	2B	NPYR	2B
Benzo[k]fluoranthene	2B	NPIP	2B
Benzo [g, h, i] perylene	3	NMOR	2B
Cadmium	1	NDELA	2B
Chrysene	2B	Naphthalene	2B
Chlordane	2B	NAT	3
Cobalt	2B	NAB	3
Crotonaldehyde	3	NPRO	3

Chromium	3	NHPRO	3
DDT	2A	NGL	3
Dibenz[a,h]anthracene	2A	N-Nitrosoguvacine	3
Dibenzo [a, i] pyrene	2B	NNK	1
Ethyl carbamate	2A	NDMA	2A
Endrin	3	NDEA	2A
Eugenol	3	Nitrite	2A
Fluoranthene	3	Ochratoxin A	2B
Fluorene	3	Pyrene	3
Heptachlor	2B	Phenanthrene	3
Indeno[1,2,3-cd]	2B	Quercetin	3
pyrene			
Lead	2B	Triphenylene	3
MNPN	2B	5MC	2B
Maleic hydrazide	3		

Reference: Group 1: "Carcinogens to humans", there are sufficient evidence of carcinogenicity in humans or experimental animals; Group 2A: "Probably carcinogenic to humans", where there is limited evidence of carcinogenicity in humans and sufficient in experimental animals; Group 2B: "Possibly carcinogenic to humans", there are limited evidence of carcinogenicity in humans and less than sufficient evidence in experimental animals; Group 3: "Unclassifiable as to carcinogenicity in humans", in this case evidence of carcinogenicity is inadequate in humans and animals." [18]

Table 3A: Nicotine, % free nicotine, free nicotine, and protonated nicotine in different Indian SLT products.

S. No.	SLT Category	Sample I. D	Nicotine (mg/g)	% Free Nicotine	Free Nicotine (mg/g)	Protonated Nicotine (mg/g)
1.	Khaini					
		K1	20.704	2.68	0.554	20.150
		K2	23.649	5.32	1.258	22.390
		K3	31.934	0.71	0.228	31.706
		K4	51.135	2.74	1.402	49.733
		K5	18.591	2.29	0.425	18.166
		K6	18.484	2.39	0.442	18.042
		K7	24.444	2.24	0.547	23.896
		K8	16.051	2.80	0.449	15.601
		K9	19.160	3.35	0.643	18.517
		K10	31.524	0.24	0.075	31.449
		K11	17.034	28.95	4.931	12.104

2.	Moist Snu	ıff				
		MS1	7.185	98.99	7.113	0.073
		MS2	7.883	99.33	7.830	0.053
		MS3	2.595	97.60	2.533	0.062
3.	Snus					
		S1	7.962	99.48	7.921	0.042
		S2	9.511	99.41	9.455	0.056
		S3	21.428	99.72	21.369	0.059
		S4	6.184	95.629	8.168	0.0357
4.	Gul					
		G1	10.914	99.08	10.813	0.101
		G2	ND	-	-	-
		G3	11.192	98.99	11.078	0.113
		G4	19.902	99.41	19.786	0.117
5.	Pan masa	ıla				
		PM1	ND	_	_	_
		PM2	ND	-	_	-
		PM3	ND	-	-	-
		PM4	ND	-	ı	-
		PM5	ND	-	ı	
		PM6	ND	-	-	-
		PM7	ND	-	-	-
6.	Zarda					
		Z1	16.361	0.23	0.038	16.323
		Z2	16.356	0.19	0.031	16.325
		Z3	17.470	0.25	0.044	17.427
7.	Qiwam					
		Q1	6.156	0.43	0.026	6.130
		Q2	4.206	0.36	0.015	4.191
		Q3	2.918	0.22	0.006	2.911
8.	Mainpuri	Kapoori		<u>'</u>		
		MK1	2.593	3.74	0.097	2.496
		MK2	0.663	21.98	0.146	0.517

ND: not detected

Table 3 B: Physical and chemical profiles of SLT products available in India

Smokeless tobacco type	Moisture	рН	Nicotine content mg/g	Un-protonated nicotine content mg/g	% Un- protonated nicotine
Kharra	8.49	8.17	7.37	4.31	58.55
Gudhaku	15.48	9.62	5.81	5.67	97.55
Gul	6.39	9.43	27.17	24.85	91.84
Khaini	22.78	9.33	4.67	4.45	95.33
Zarda	11.92	5.28	19.82	0.035	0.18
Pan Mashala	6.59	8.84	0.0	0.0	86.61
Chewing Tobacco	19.55	6.47	17.50	3.12	25.18

Protocols for Testing of SLT Products:

In the year 2005, WHO Tobacco Free Initiative (TFI) established a Global Tobacco Testing Laboratory network based on the recommendations of WHO's Study Group on Tobacco Product Regulation (TobReg) to build and strengthen tobacco product testing and research capacity in accordance with WHO FCTC Articles 9 and 10. The standard operating procedures (SOPs) for testing the contents of tobacco products were developed and validated by the WHO Tobacco Laboratory Network (TobLabNet). The WHO TobLabNet SOPs provide technical guidance and tools to Parties for strengthening regional as well as national regulation of nicotine and tobacco products. The WHO TobLabNet SOP 12, SOP 13 and SOP 14 provides the methaods to determine the pH, nicotine, and moisture content in SLT products respectively.

The Indian government initiated the National Tobacco Control Programme (NTCP) in 2007–2008 to guarantee the successful execution of the WHO Framework Convention on Tobacco Control (WHO FCTC) and the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 (COTPA). In order to test tobacco products, three National Tobacco Testing Laboratories (NTTLs) were established in India: one at the National Institute of Cancer Prevention and Research (ICMR) in Noida, one at the Regional Drug Testing Laboratory (RDTL) in Guwahati, and one at the Central Drug Testing Laboratory (CDTL) in Mumbai. The NTTLs use the standard operating procedures of the WHO or the globally validated modifications for testing SLT products (Table 5).

Standard Operating procedures for testing Smokeless Tobacco Products

SI. No.	SOP	Purpose of SOP	Testing Facility
1	WHO TobLabNet SOP	Standard operating procedure	National Tobacco
	12	for measurement of the nicotine content of smokeless tobacco products	Testing Laboratories; WHO Recognised Laboratories
2	WHO TobLabNet SOP	Standard operating procedure	National Tobacco
	13	for measurement of the	Testing Laboratories;
	13	moisture content in smokeless	WHO Recognised
		tobacco products (it can also be	Laboratories
		used to measure the	
		flavouring and	
		water content).	
3	WHO TobLabNet SOP	Standard operating procedure	National Tobacco
	14	for measurement of smokeless	Testing Laboratories;
	14	tobacco products' pH.	WHO Recognised
			Laboratories

Regulatory Landscape of Smokeless Tobacco Products:

The tobacco product regulation varies globally with few countries have stricter regulations including for overall tobacco cultivation, manufacturing, advertising, import and export bans while other countries have more lenient policies. Few countries have formulated policies focused on standards for SLT products based on the chemical compositions. The standards across the world to regulate the

permissible levels of chemical constituents in the SLT products vary significantly. The quality standards of SLT product Swedish snus have been successfully regulated according to the GothiaTek® standards by the Swedish Food Act (19). The standards for constituents, manufacturing, maximum levels of undesired constituents, guidance levels are regulated along with the consumer information which provides the declaration of the ingredients. These implementations have resulted in lower levels of heavy metals and TSNAs in the Swedish snus. Although, there is no study showing direct correlation between lower levels of TSNAs and less incidence of oral cancer, a smaller number of oral cancer cases were observed with the use of Swedish snus (19). The regulations by the U.S. Food and Drug Administration (FDA) and the Federal Food, Drug, and Cosmetic Act have made reporting of ingredients, harmful and potentially harmful constituents mandatory (20).

India has implemented various policy measures regarding SLT products since the Cigarettes and Other Tobacco Products Act (COTPA) was notified in 2003 and Principal Rules were formulated in 2004 (21).

More information on the policy measures adopted till date to regulate SLT use in India is available in **Table 4.**

Table 4: Regulation of SLT use in India by adopting policies adopted from 2003-2004 onwards

Tobacco Control Laws	Description	Year
Cigarettes and Other Tobacco Products Act (COTPA) 2003 and Principal Rules 2004 (22,23)	This compre hensive Central -level law was intended to regulate consumption and sale of all tobacco products Section 4: Prohibits smoking in all indoor workplaces and public places. Section 5: Prohibits advertisement of cigarette and other tobacco products without a he alth warning at the point of sale. It also prohibits all direct and indirect advertising of the smoking and smokeless forms of tobacco, except at the point of sale with a health warning and restrictions. Section 6a: Prohibits sale of tobacco products to a person below 18 years and on noncompliance the imposed fine is INR 200. Section 6b: Prohibits sell of tobacco products within the radius of 100 yards of educational institutes.	2003

Prevention of Food Adulteration Act, 1954 and Rules 1955, and 1st Amendment Rules, 2004 (24)	The Act and its Rules (repealed in January 2011) mandates the following for the packages containing food products: • List all the ingredients • Identify the Manufacturer, packager or importer • State the weight of the contents • Health warning (that chewing tobacco or paan masala is injurious to health) to be displayed on the packages.	2004
Goa Public Health Amendment Act, 2005 (8)	The Act was implemented in 2005 that prohibits manufacture, sale, storage, distribution or exhibition of all types of tobacco products (Smoking or smokeless or any food article containing tobacco) within 50 meters of certain places/institutions, including healthcare, educational, religious, playgrounds, sports complexes and government buildings.	2005
Prevention of Food Adulteration (PFA) Act, 1954, Rule 44J (2008), 8 th Amendment Rules, 2005 (25)	The rule prohibits any harmful substances in the food products that may be injurious to health, explicitly prohibits the use of tobacco and nicotine in any food products.	2006
Food Safety and Standards Act, 2006, Article 30 (2)(a) (13)	 As per this law "Food" is considered as any substance that is intended for human consumption, whether in a processed, unprocessed or partially processed form. The Food Safety and Standards Authority of India and the State Food Safety Departments regulates the manufacturing, processing, packaging, storage, transport, distribution and sale of food products. The Act grants authority to the Food Safety Commissioner of each state to prohibit, the manufacture, storage, distribution, or sale of any food article for not exceeding one year, in the interest of public health. Pan masala and/or flavoured/scented tobacco are banned using this law in some states. 	2006

COTPA 2003: Pictorial and text warnings on packages Rule (14): On December 1 2007 Sections 7-10 and 20 of COTPA came into force; and implemented from May 31, 2009 (15)	Section 7-10: It requires text and pictorial warnings on packages of smoking and smokeless forms. Section 20: It outlines the penalties specified for manufacturers of tobacco products without the specified warning.	2007
Cable Television Networks (Amendment) Rules, G.S.R. 138 (E), February 27, 2009 (16)	It prohibits direct tobacco advertisement on cable television networks; however, indirect advertisement is allowed with certain conditions.	2009
Plastic Waste Management and Handling Rules, 2011, under the Environment Protection Act, 1986 (17) which was notified on February 7, 2011.	The rules ban the use of plastic sachets for storage, packaging and sell of gutkha, pan masala and tobacco due to concern over pollution. The petition of Rajasthan High Court was upheld by the Supreme Court of India. [26]	2011
notified on August 1,2011. (28)		
Legal Metrology (Packaged Commodities) Rules, 2011. (29)	Effective from April 1, 2011, the Rules mandate product packages to list the ingredients, identification of manufacturers, packager or importers and product weight (above 10g).	2011
Food Safety and Standards (Packaging and Labelling) Regulations, 2011 (30)	These regulations mandate food packages to state the food name, ingredients, additives, flavours, colours, details of manufacturer, packager or importers, weight of the content, packaging date, best -before date for consumption and the following warnings. Paan Masala: "Chewing of paan masala is injurious to health"; Supari: "Chewing of supari is injurious to health" (Note: It excludes Chewing tobacco).	2011
Food Safety and Standards (Food Products Standards and Food Additives) Regulations. (31)	Section 2.11.5: It specifies the permitted ingredients in paan masala, emphasizing on the exclusion of any harmful substance. Section 3.1.3: It specifies the maximum limit of sodium saccharin in paan masala. Section 3.1.11: It prohibits use of monosodium glutamate in paan masala.	2011

GSR 619 (E), COTPA notification. (32)	This notification prohibits tobacco sale to and by minors: "No sale to and by minors."	2011
Juvenile Justice (Care and Protection of Children) Act, 2015. (33)	This Act bars gift or sale of tobacco to minors (Persons under 18 years old), punishable by a fine of up to 1 lakh INR and a rigorous imprisonment up to 7 years.	2016
Goods and Services Tax (GST). (34)	Goods and Services Tax (GST), is the highest tax slab, that is applicable to retail tobacco sales. Under this regime, the National Calamity Contingent Duty (NCCD) and a compensation cess to states are also included, replacing the previous state levies. (35)	2017
Tobacco vendor licensing requirement. (36)	Tobacco vendors may be mandated to register with the municipal authorities for a sales license to sell tobacco products by States. Eligibility will be considered based on the compliance with all requirements, including only tobacco sales and no sale of other goods.	2018
COTPA 2003, Section 11: Tobacco Testing Laboratories	Three National Tobacco Testing Laboratories (NTTLs)- one of each in Noida, Guwahati and Mumbai, were recognized under NTCP on September 5, 2019. ICMR-NICPR, the Noida lab, is the apex centre (37) and has begun to test	2019
	for nicotine and magnesium carbonate in paan masala. (38)	
Spitting ban in Public Places. Under the disaster Management Act, 2005, and a few other laws, i.e., Sections 268 and 269 of the IPC, state laws banning spitting, the Swachh Bharat Abhiyan (Clean India Mission) and some local laws. (39)	States are empowered under this law to prohibit spitting and the sale and use of SLT products in public places during the COVID-19 pandemic, with penalties for violators.	2020
Ministry of Environment, Forest and Climate Change (MoEFCC, 2022), Notification No. G.S.R. 571(E), dated August 12, 2021 effective from July 1, 2022 (40)	The Rules prohibit the manufacturing, import, stocking, sale, distribution and use of certain single-use plastic items, such as polystyrene and expanded polystyrene effective from July 1, 2022. The items are as follows • Plastic sticks with ballons, ear buds with plastic sticks, candy sticks, plastic flags, icecream sticks, polystyrene (thermocol) for decoration.	2021

	• Cups, plates, cutlery such as spoons, forks,	
	knives, trays, straw, packaging or wrapping films around sweet boxes, cigarette packets,	
	invitation cards, stirrers, PVC or plastic banners less than 100 micron.	
COTPA notification no G.S.R. 400 (E). (41)	The Government of India, on May 31, 2023, introduced new regulations under the Cigarettes and Other Tobacco Products Amendment Rules, 2023 to further discouraging the glamorization of tobacco use. These rules mandate to include health warning and disclaimers in any online content featuring tobacco products. Specifically, anti-tobacco health spots lasting at least thirty seconds must be featured at the beginning and midpoint of such content. Additionally, prominent anti-tobacco health warnings must be displayed throughout the presentation of tobacco products. Moreover, a twenty-second audio-visual disclaimer regarding the ill effects of tobacco use must	2023
	 All the patients visiting the medical institute will undergo mandatory tobacco use screening and be referred to TCC for cessation services. With designated staffing, the TCC will operate on a daily basis providing group and individual counselling, maintaining through record-keeping. Protocols will be established for scheduling appointments and conduction telephonic follow ups. Updated organization charts and job descriptions will be maintained by the center, ensuring digital record of data in a standardized format. For information dissemination and reporting, effective communication channels with institutional and state authorities will be established. To complement general awareness efforts, specialty-specific Information, Education and Communication (IEC) materials will be used to sensitize healthcare professionals, patients and caregivers on the harmful impact of tobacco use. 	

Following May 31, 2009, the COTPA 2003 Rules went into effect, and despite persistent tobacco industry interference, pack warnings—which include both text and picture warnings on packages—were implemented per the Supreme Court's directive (31). A scorpion image with the English text "Tobacco Kills" was the first pictorial warning on SLT products, occupying 40 percent of the front surface of the pack (32). Nonetheless, the full implementation was completed by the end of November 2011 and included four graphical representations of head and neck cancer and a new set of images was unveiled in 2013. Furthermore, as of April 1, 2016, an additional 85% of the front and rear of the pack had to be occupied by new images and warnings (33). From April 1, 2012, Madhya Pradesh and other states implemented gutkha ban aligned with the Food Safety and Standard (Prohibition and Restrictions on Sales) Regulations (FSSR) notification released on August 1, 2011. Altogether 33 States and Union Territories (UTs) also banned paan masala containing tobacco and gutkha by December 2013, under this provision (34).

Apart from this, a knowledge hub on SLT was established to create policy related awareness, mass media communication and other activities in alignment with the statement of WHO FCTC (35). In order to raise public knowledge of the dangers associated with tobacco use, the National Tobacco Control Programme (NTCP), which was introduced in 2007, has been facilitating mass media outreach throughout the country. The WHO FCTC Knowledge Hub on Smokeless Tobacco was created at ICMR-

NICPR, Noida, on April 6, 2016, with the aim of generating awareness about the risks associated with SLT use and supporting worldwide efforts to prevent SLT use by providing technical and scientific research-based evidence (36).

Table 5 represents India's effort in implementing articles of WHO Framework Convention on Tobacco Control (FCTC). India has regulated SLT products using existing laws in the country such as Juvenile Justice Act 2015, Goods and Services Tax Act 2017, Environmental Protection Act 1986 etc (37). However, the challenge remains in continuous monitoring, enforcement and evaluation of policy measures intended for effective SLT control within the country.

Table 5: Implementation of WHO FCTC for regulation of SLT products in India

WHO FCTC Articles	Measures taken in India	Comment
Article 6: Taxation and Pricing measures	Yes	Goods and Services Tax (GST), is the highest tax slab, that is applicable to retail tobacco sales (38). Tax is inefficient as it is fixed, and not indexed.
Articles 9 and 10: Regulation of contents and emissions	Yes	The COTPA was created by the Indian government in 2003 and forbids advertising, trade and commerce regulation, manufacturing, supply, and distribution. All

		tobacco products must also undergo testing for tar and nicotine under the statute (39).
Article 11: labelling and packaging measures	Yes	On Smokeless Tobacco products pictorial health warnings (PHW) should comprise of 85% of the principal display area (1)
Article 12: Education, communication, training, and public awareness	Yes	India, the only Party to the WHO FCTC launched A thorough public media campaign agains t smokeless tobacco use. (1)
Article 14: Offering tobacco cessation	Yes	May 27, 2024 saw the release of Operational Guidelines for Establishing Tobacco
		Cessation Centres in Medical Institutes by the Ministry of Health and Family Welfare, Government of India (40).
Article 13: Tobacco advertisement, promotion, and sponsorship	Yes	All forms of direct and indirect forms of tobacco advertisements are banned in India. India is the only nation globally to enforce regulations on Tobacco Free Film and Television Rules, including restrictions on smokeless tobacco products (1).
Article 16: Restrictions on sale to and by minors	Yes	• India has banned the sale of tobacco products, including smokeless tobacco products to individuals under 18 years. India has banned

		the sale of tobacco products within 100- yard radius of any educational institute (1).
Article 18: Environmental impact of tobacco	Yes	India prohibits the use of plastic sachets for smokeless tobacc o product packaging and enforced ban on tobacco use in public places (1).
		Knowledge Hub on Smokeless Tobacco (KH- SLT) in April 2016. The knowledge hub' s objective is to support the Parties to the WHO FCTC Secretariat in gathering and producing
India partially banned the import a		evidence on a range of SLT-related topics and informing the development of SLT control policies (35).

India partially banned the import and sales of some forms of smokeless tobacco products (1).

During Covid-19 pandemic, India imposed ban on spitting in public places following SLT use to prevent the spread of SARS -COV2 transmission and several states of India implemented the ban (37).

Global Good & Resources in SLT

Several countries have been considering taking policy measures beyond the Framework Convention on Tobacco Control (FCTC) to fight against the increased prevalence and emerging smokeless tobacco products worldwide (Table 5).

Table 5: Good Practices in SLT product regulation from across the world:

Country Name	Good Practices in Tobacco Product	References
	Regulation	
USA	According to the Comprehensive	(1)
(Not a Party to WHO FCTC)	Smokeless Tobacco Health Education Act of	
	1986, health warnings must be included on	
	all SLT	
	packages sold in the United States.	
Sri Lanka, Bhutan,	Manufacturing, selling, and importing SLT	(43)
Singapore, and	products are all prohibited.	
others		
Thailand	Sale of import of SLT products prohibited	(44)
Malaysia	Graphical or any other kind of	(45-50)
	representation on the product grading,	
	quality or supremacy is prohibited.	
USA, UK and India	The depiction of ingredients (tar and	(45-50)
	nicotine) on the tobacco packs are mandatory	
EU Countries	In any tobacco products, the ingredients	(51,52)
	used is required to report by the tobacco	
	industry to the EU countries.	
	Health warnings on tobacco and related	
	products.	
Ecuador	The information on the adverse effects of	(50)
	tobacco products including SLT is required	
	to submit by the manufacturers to the	
	authorities and the general public (Organic	
	Law for the	
	Regulation and Control of Tobacco, 2011).	
Bangladesh	License is required to sell SLT products.	(50)

Canada	Additives are prohibited in tobacco products	(45,50)
	Pictorial health warning: covering 75% on	
	the two principal display surfaces.	
Sweden, Georgia,	Pictorial health warning: covering 30% or	(53,54,55)
USA	more of the package area	
Brazil	Pictorial health warning: covering 30% of the front and 100% of the back side of the package.	(55)
Nepal	Pictorial health warning: covering 90% of the principal display areas of SLT product packages	
Georgia	Disclosure of information on all ingredients, toxic compounds and flavours used in tobacco product is mandatory.	(60)
Mexico	All kinds of flavouring and additives are prohibited in tobacco products.	(60)
Armenia	Compliance certificate or a compliance sign with stamp is required for raw tobacco as well as tobacco products available in the domestic market.	(60)
Jordan	The licensing and monitoring of tobacco products is under the Tobacco Unit at the Food and Drug Administration.	(60)
Uruguay	The declaration of nicotine and tar is required to be submitted via an electronic form for all tobacco products.	(60)
Saudi Arabia, Australia, Uruguay, Thailand	Plain packaging for tobacco products including SLT.	(50,51,53)
Canada, Dominican	Mandatory textual health warnings	(45,47,61,62,63,64)
Republic, Sweden,		
Myanmar, USA and		
UK		
Lebanon	Awareness education on t he risks associated with tobacco consumption including SLT is provided to public.	(65)
Canada,	All forms of direct and	(52, 66-74)
Bangladesh,	indirect advertisements are prohibited.	
Myanmar and India		

Pakistan	Advertisement of tobacco products are restricted if not aligned with the Federal committee guidelines (Pakistan Tobacco Ordinance, 1968).	(1)
Bangladesh,	Prohibits sale of tobacco products	(50,55,75,62,76-81)
Argentina, Brazil,	including SLT to minors (below 18 years of age) by law.	
Canada, India,		
Dominican		
Republic,		
Myanmar, Pakistan,		
Nepal, Tobago,		
Trinidad, USA		
Myanmar, India	Tobacco sale is prohibited within 100 yards of any Educational Institute.	(52,82)
Pakistan	Tobacco sale is prohibited within 50 meters of any educational institute	(83)
Bhutan, Sri Lanka and Bhutan	Complete ban on SLT. Whereas, the cultivation, manufacturing, distribution and sale of SLT products are comprehensively prohibited.	(52,75,84-88)
Australia, India, Brazil, Bahrain, Iran, New Zealand,	Some forms of SLT product sale and import are partially prohibited.	(52,75,84-89)
Tanzania, UK and		
Thailand		
Myanmar	Use of SLT products is prohibited in the metropolitan areas.	(52)
Nepal	Use of SLT products is prohibited in the public places and government workplaces.	(75)
USA (Cities such as	SLT products are prohibited at the sport	(90-92)
New York, Chicago,	venues in the baseball parks in the city.	
Boston, San		
Francisco and		
Los Angeles)		

Existing gaps in smokeless to bacco control in India:

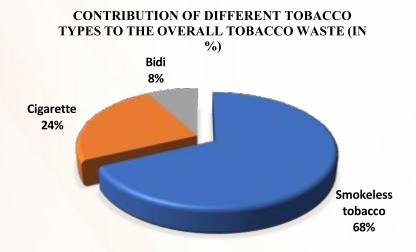
Marketers and direct sellers of tobacco products are prohibited from selling to minors; however, the enforcement of these laws is inadequate.

Gutkha is widely available and used in India despite banned by many states. To reduce the addiction rates and mitigate the detrimental effects on the oral mucosa, the prohibition of gutkha was implemented. By introducing paan masala, a non-tobacco product with ingredients like slaked lime, areca nut, catechu, and additives like flavours under the same brand names, the tobacco industries have devised ways to get around the ban. The tobacco is offered in a separate, complimentary small packet. This enables the consumers to prepare their own gutkha mixtures. Users frequently add more tobacco for high stimulation because of the availability of this two- or twin-packet form, which increases their risk of consuming excessive amounts of nicotine (93). A survey conducted in India also showed that twin-packet use was common and that illegal SLT goods were available in semi-urban and rural locations.

Case Studies on Smokeless Tobacco Products

1. Environmental Impact of SLT Use:

A cross-sectional survey was conducted by the ICMR-National Institute of Cancer Prevention and Research, Noida in collaboration with the All-India Institute of Medical Sciences, Jodhpur from January to April 2022 in 33 districts of 17 states and UTs across India packaging materials of tobacco products including smokeless forms available in the country were studied to assess the environmental burden in terms of paper, plastic, filter, and foil both at the State and National level. Nearly 58 SLT product brands, 70 cigarette and 94 bidi brands were studied. The gross weight and segregated weights of the paper, plastic, filters, and foils used in the samples were measured and the same was correlated with the GATS-2 survey data to compute the final results.



Total annual waste produced by all tobacco products in the country

Cigarettes - 40,846 tonnes

Bidi - 13,770 tonnes

Smokeless Tobacco - 115,715 tonnes

Total - 1,70,331 tonnes

All forms of tobacco products starting from bidis, cigarettes and chewing tobacco contribute to massive solid waste production indicating the need for stronger and urgent policy implementation and monitoring to ensure compliance with tobacco control policies (94,95,96).

2. Plain Packaging for Smokeless Tobacco products:

The advertisement and brand promotion of tobacco products are highly dependent on the product packaging used by the tobacco industry (97). Policy on plain and standard packaging when implemented has been proven to reduce the prevalence of smoking due to reduced attractiveness of the products and the appeal of the products can be reduced (98,99,100). The effect of packaging has been studied on the pre-consumption advertisement at the point of sales and mostly on the smoking form of tobacco (99). A recent study in India, reported 86% of the litter from SLT produced from branded products after consumption (101). Implementation of plain and standard packaging for the SLT products may impact SLT consumption and eradicate the marketing channel.

3. Youth Initiatives to prevent Smokeless Tobacco Use:

Mass media campaigns, comprehensive state wise and community tobacco control programs have provided sufficient evidence of preventing tobacco use initiation and reducing the prevalence of tobacco use among youth. School-based programs result in producing a short-term effect and reducing the tobacco use prevalence among school going youth (102). From Asia, four countries have used different strategies via social and print media to raise public awareness on the adverse health outcomes of SLT use. However, implementation of the mass media campaign against SLT use was reported in only India [8,103] and increase in quit attempts have been reported by the exposed group (47.7%) as compared to the non-exposed group (34.2%) (104).

4. Cessation support for SLT Users:

Various tobacco cessation interventions such as pharmacological, behavioral, or combination of both have been tested to accomplish tobacco cessation. The same has been applied to SLT users as well. SLT cessation assisted by healthcare providers have been reported in from Kenya, Bangladesh and India (105). In the UK, SLT users of South Asian origin demonstrated effectiveness of short-term SLT cessation through nicotine replacement therapy (NRT) along with behavioural intervention (106). A study was carried out in India, Bangladesh and Pakistan to develop cessation strategies for SLT users and the preliminary results provide critical inputs towards effective tobacco control measures in Indian setting (107).

5. Integration of Tobacco Screening and Cessation Counselling in Antenatal Care:

Despite the known risks associated with tobacco use during pregnancy, between 5 and 8% of pregnant women in India use tobacco products. Various forms of SLT products such as Betel quid with tobacco (Paan), Gul, Zarda, Mawa and Gutkha (Annexure I: Table 1) are popular amongst Indian pregnant women as compared to western world where smoked tobacco is more popular (108,109,110). Antenatal check-ups provide the opportunity to assess and support pregnant women for quitting tobacco use. A study to test the integration of tobacco use screening and tobacco cessation services into routine antenatal care within the Indian public health system indicated that behavioural counselling during pregnancy is an effective cessation strategy and a quit rate of nearly 70% was achieved in the study (111). The study can be replicated in the national health programme.

Recommendations:

[I] Enforcement of Existing Guidelines by National and Sub-national level (state governments):

- (I). Effective and full implementation of the WHO-FCTC provisions and the guidelines with focus on SLT control: An overall commitment to implement effectively and fully the provisions of the WHO-FCTC and their guidelines by all arms of the government is an important first to meet the goals of tobacco control including SLT control. This is also a clear recommendation and a target for achieving the 'health for all' goal under the United Nations Sustainable Development Goals.
- (ii). Effective implementation and enforcement of COTPA, FSSA, JJA and other laws and regulations applicable to SLT control: All enforcement officials under various legislation should be well trained to effectively implement the provisions of the tobacco control laws with respect to SLT control.
- (iii). Compliance with the Pictorial Health Warnings on SLT products: Majority of SLT products in the country do not comply with the PHW regulations. Strict directions should be issued by the MoHFW and other competent authorities to all SLT manufacturers to comply with the PHW regulations. All violator companies should be prosecuted by the competent authorities for violation of Section 7 of COTPA.
- (iv). Prohibition of brand stretching or brand sharing of tobacco products: The WHO FCTC Article 13 and COTPA prohibit any kind of direct and indirect advertising, promotion and sponsorship (TAPS) of tobacco products and brands. Brand stretching and brand sharing of tobacco products, surrogate advertisement is inherently TAPS and should be enforced strictly. Registration and manufacturing of any non-tobacco products with the existing tobacco brands and vice-versa should be completely prohibited. Moreover, advertisement of non-tobacco products such as Pan Masala and products containing areca nut and products classified injurious to health by the FSSA should be completely prohibited.
- (v). Impose ban on spitting in public places: COVID-19 gave the opportunity to reduce tobacco use during the pandemic by prohibiting public smoking and spitting. Efforts should be made to make the public aware about implications of public spitting following SLT use and a ban on public spitting should be imposed to curb the health burden of public spitting and meet the goals of public sanitation and hygiene.

[II]. Development of New Guidelines by National and Sub-national level (State governments):

- (I). Advancing research for SLT control: While there is a felt need for national research policy on tobacco control, focus should be given to research dedicated to impact and implications of SLT use in the country. Medical, dental and other health institutions should collaborate and focus on multi-centric, multi-product based research questions that will support effective policy for SLT control in the country and support the vision of a tobacco free generation in India.
- (ii). Eliminating Tobacco Industry Interference: Policy guidelines in line with the WHO FCTC Article 5.3 should be prepared by the Ministry of Health and Family Welfare and adopted and implemented across all departments at the national and state level.
- (iii). Increase minimum legal age of purchase to 21 years with an aim to advance tobacco-free generation: Despite the ban on sale of tobacco products to any person below the age of 18 years under COTPA and Section 77 of the Juvenile Justice Act, tobacco use and exposure to minors is

- abundantly visible in the country. Legislative efforts should be made to protect the minors from tobacco industries commercial interests by increasing the minimum legal age for sale of all tobacco products to 21 years along with implementing tobacco free generation policies that impedes sales and supply of tobacco products to any individual born after a specific year.
- (iv). Standardised Packaging for SLT Products: The packaging of the SLT products along with all other tobacco products should be standardized with the mandate on the pack size, shape, weight, height, packaging material etc. This may be done by the Ministry of Health and Family Welfare along with the rotation of PHW under Section 7 of COTPA.
- (v). Pictorial health warnings on non-tobacco products such as Pan Masala, Meethi Supari etc.: Products that contain areca nut as one of the ingredients should also display pictorial health warnings as most of these products are consumed along with SLT products and especially by minors. It can be done by the FSSAI by issuing an appropriate notification to this effect under FSSA.
- (vi). Prohibition of additives in Smokeless Tobacco Products: Use of additives such as flavours, sweeteners, fragrances to increase the attractiveness or palatability of the SLT products should be prohibited. Guidelines or explanation on the violation of existing regulation on prohibition of any ingredients like tobacco or nicotine in any food items by FSSAI (Food Safety and Standards Authority of India) should be issued with strict compliance monitoring by all state and district level food safety officials.
- (vii). Cessation Services focused on Smokeless Tobacco use: Promotion of cessation services for users of SLT products should be promoted in all national programs through all health and related institutions. Focus should be given on the awareness and benefits of SLT cessation in regional languages through mass media campaigns. Training modules should be developed and all healthcare providers should be periodically trained for effective SLT cessation services. Moreover, there should be integration of tobacco cessation in other disease control programs such as Tuberculosis, Non-communicable disease, Oral Health, Maternal and Child Health etc.
- (viii).Comprehensive approach to SLT taxation: In India, tobacco leaves, the main raw material used for SLT products, are taxed at a rate of 5%, that includes 2.5% Central & 2.5% State Goods and Services Tax. Besides, the final SLT products are also sold in small packs and at a very minimal price. To achieve the 75% tax recommendation by WHO on the retail price of tobacco products, a comprehensive approach to SLT taxation should be adopted under the annual budgets of the country.
- (ix). Vendor Licensing for the sale of tobacco products: Enforcement of the tobacco control measures are at stake due to the absence of compliance monitoring at the point of sale. This can be addressed by introducing tobacco vendor licensing in India. This will also address the easy availability and accessibility, especially to minors. Retail vendor licensing should be adopted and implemented to regulate tobacco sales as per the prescriptions of law in line with the provision of COTPA and WHO-FCTC.
- (x). Regulation of SLT Products: Regulation of SLT products and their contents are not well defined under COTPA. Detailed analysis of the harmful nature of their contents, both at physical and chemical level along with their toxicity and emissions are required. Periodic testing of the SLT products marketed in the country including new SLT products should be carried out by the National Tobacco Testing Laboratories and shared with the MoHFW and state governments for taking effective and appropriate regulatory measures. Such periodic testing of SLT products

- would also help in mapping the regional diversity of SLT products from the samples received through various states.
- (xi). Evidence based mass communication and awareness campaigns on adverse health impacts of SLT use: The MoHFW, under the NTCP, should consider a comprehensive IEC plan focused on SLT control. This should be evidence-based and field-tested and also address the social media audience along with countering the tobacco promotion on such platforms as well.
- (xii). Ban of online sale of SLT products: The MoHFW should consider issuing notification for ban of online sale of tobacco products and their surrogates, such as those delivering grocery products which is in violation of various provisions of COTPA and Juvenile Justice Act and of the FSSA. Online sale is also inherently considered TAPS as per WHO-FCTC Article 13 guidelines.

[III]. Actions for other key stakeholders:

Civil Society:

- (I). Civil society organizations should advocate for stronger measures of tobacco control policies both at state and national levels through grassroots mobilization, lobbying efforts and campaigns.
- (ii). Community-based educational and intervention programs should be conducted regularly to raise public awareness of the harm of SLT use. Special focus should be provided to women of reproductive age, pregnant and lactating women, children and youth.
- (iii). Civil societies may take part in providing support and resources for tobacco cessation services and programs such as helplines, counselling, peer support groups etc. particularly targeting the populations vulnerable using SLT.

Businesses:

- (I). Businesses should adopt initiatives of corporate social responsibility (CSR) prioritizing to support tobacco control efforts and public health. Initiatives such as workplace policies that discourage use of tobacco and promote cessation. Besides, tobacco free institute initiative in the business organizations should focus on all forms of tobacco products including SLT with regular monitoring and sensitization of the employed personnel.
- (ii). Any involvement in the manufacturing, marketing or distribution of the SLT products should be prohibited and avoided.
- (iii). By partnering with the public health organizations, NGOs and government agencies, businesses can initiate communities-based programs and implement them for reducing the consumption of SLT products and improving the outcomes of public health.
- (iv). Business organization should be trained and guided on the WHO FCTC Article 5.3 and any investment from the tobacco industry should be diverted to avoid tobacco industry interference.
- (v). In India most of the SLT products are manufactured in cottage industries or in homes in the unregulated sector. People who are engaged with the cultivation and manufacturing of SLT products should be provided with counselling on health awareness and support for alternative business opportunities in line with the WHO FCTC Article 17 and 18.

Conflict of Interest:

The authors declare that they have no conflicts of interest.

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RECOMMENDATIONS

5.8. Smokeless Tobacco Products

- 5.8.1. Enforcement of Existing Guidelines by National and Sub-national level (state governments):
 - 5.8.1.1. Effective and full implementation of the WHO-FCTC provisions and the guidelines with focus on SLT control: An overall commitment to implement effectively and fully the provisions of the WHO-FCTC and their guidelines by all arms of the government is an important first to meet the goals of tobacco control including SLT control. This is also a clear recommendation and a target for achieving the 'health for all' goal under the United Nations Sustainable Development Goals.
 - 5.8.1.2. Effective implementation and enforcement of COTPA, FSSA, JJA and other laws and regulations applicable to SLT control: All enforcement officials under various legislation should be well trained to effectively implement the provisions of the tobacco control laws with respect to SLT control.
 - 5.8.1.3. Compliance with the Pictorial Health Warnings on SLT products: Majority of SLT products in the country do not comply with the PHW regulations. Strict directions should be issued by the MoHFW and other competent authorities to all SLT manufacturers to comply with the PHW regulations. All violator companies should be prosecuted by the competent authorities for violation of Section 7 of COTPA.
 - 5.8.1.4. Prohibition of brand stretching or brand sharing of tobacco products: The WHO FCTC Article 13 and COTPA prohibit any kind of direct and indirect advertising, promotion and sponsorship (TAPS) of tobacco products and brands. Brand stretching and brand sharing of tobacco products, surrogate advertisement is inherently TAPS and should be enforced strictly. Registration and manufacturing of any non-tobacco products with the existing tobacco brands and vice-versa should be completely prohibited. Moreover, advertisement of non- tobacco products such as Pan Masala and products containing areca nut and products classified injurious to health by the FSSA should be completely prohibited.
 - 5.8.1.5. Impose ban on spitting in public places: COVID-19 gave the opportunity to reduce tobacco use during the pandemic by prohibiting public smoking and spitting. Efforts should be made to make the public aware about implications of public spitting following SLT use and a ban on public spitting should be imposed to curb the health burden of public spitting and meet the goals of public sanitation and hygiene.
- 5.8.2. Development of New Guidelines by National and Sub-national level (State governments):

- 5.8.2.1. Advancing research for SLT control: While there is a felt need for national research policy on tobacco control, focus should be given to research dedicated to impact and implications of SLT use in the country. Medical, dental and other health institutions should collaborate and focus on multi-centric, multi-product based research questions that will support effective policy for SLT control in the country and support the vision of a tobacco free generation in India.
- 5.8.2.2. Eliminating Tobacco Industry Interference: Policy guidelines in line with the WHO FCTC Article 5.3 should be prepared by the Ministry of Health and Family Welfare and adopted and implemented across all departments at the national and state level.
- 5.8.2.3. Increase minimum legal age of purchase to 21 years with an aim to advance tobacco- free generation: Despite the ban on sale of tobacco products to any person below the age of 18 years under COTPA and Section 77 of the Juvenile Justice Act, tobacco use and exposure to minors is abundantly visible in the country. Legislative efforts should be made to protect the minors from tobacco industries commercial interests by increasing the minimum legal age for sale of all tobacco products to 21 years along with implementing tobacco free generation policies that impedes sales and supply of tobacco products to any individual born after a specific year.
- 5.8.2.4. Standardised Packaging for SLT Products: The packaging of the SLT products along with all other tobacco products should be standardized with the mandate on the pack size, shape, weight, height, packaging material etc. This may be done by the Ministry of Health and Family Welfare along with the rotation of PHW under Section 7 of COTPA. 5.8.2.5.Pictorial health warnings on non-tobacco products such as Pan Masala, Meethi Supari etc.: Products that contain areca nut as one of the ingredients should also display pictorial health warnings as most of these products are consumed along with SLT products and especially by minors. It can be done by the FSSAI by issuing an appropriate notification to this effect under FSSA.
- 5.8.2.6. Prohibition of additives in Smokeless Tobacco Products: Use of additives such as flavours, sweeteners, fragrances to increase the attractiveness or palatability of the SLT products should be prohibited. Guidelines or explanation on the violation of existing regulation on prohibition of any ingredients like tobacco or nicotine in any food items by FSSAI (Food Safety and Standards Authority of India) should be issued with strict compliance monitoring by all state and district level food safety officials.
- 5.8.2.7. Cessation Services focused on Smokeless Tobacco use: Promotion of cessation services for users of SLT products should be promoted in all national programs through all health and related institutions. Focus should be given on the awareness and benefits of SLT cessation in regional languages through mass media campaigns. Training modules should be developed and all healthcare providers should be periodically trained for effective SLT cessation services.

Moreover, there should be integration of tobacco cessation in other disease control programs such as Tuberculosis, Non-communicable disease, Oral Health, Maternal and Child Health etc.

- 5.8.2.8. Comprehensive approach to SLT taxation: In India, tobacco leaves, the main raw material used for SLT products, are taxed at a rate of 5%, that includes 2.5% Central & 2.5% State Goods and Services Tax. Besides, the final SLT products are also sold in small packs and at a very minimal price. To achieve the 75% tax recommendation by WHO on the retail price of tobacco products, a comprehensive approach to SLT taxation should be adopted under the annual budgets of the country.
- 5.8.2.9. Vendor Licensing for the sale of tobacco products: Enforcement of the tobacco control measures are at stake due to the absence of compliance monitoring at the point of sale. This can be addressed by introducing tobacco vendor licensing in India. This will also address the easy availability and accessibility, especially to minors. Retail vendor licensing should be adopted and implemented to regulate tobacco sales as per the prescriptions of law in line with the provision of COTPA and WHO-FCTC.
- 5.8.2.10. Regulation of SLT Products: Regulation of SLT products and their contents are not well defined under COTPA. Detailed analysis of the harmful nature of their contents, both at physical and chemical level along with their toxicity and emissions are required. Periodic testing of the SLT products marketed in the country including new SLT products should be carried out by the National Tobacco Testing Laboratories and shared with the MoHFW and state governments for taking effective and appropriate regulatory measures. Such periodic testing of SLT products would also help in mapping the regional diversity of SLT products from the samples received through various states.
- 5.8.2.11. Evidence based mass communication and awareness campaigns on adverse health impacts of SLT use: The MoHFW, under the NTCP, should consider a comprehensive IEC plan focused on SLT control. This should be evidence-based and field-tested and also address the social media audience along with countering the tobacco promotion on such platforms as well.
- 5.8.2.12. Ban of online sale of SLT products: The MoHFW should consider issuing notification for ban of online sale of tobacco products and their surrogates, such as those delivering grocery products which is in violation of various provisions of COTPA and Juvenile Justice Act and of the FSSA. Online sale is also inherently considered TAPS as per WHO-FCTC Article 13 guidelines.

5.8.3. Actions for other key stakeholders:

5.8.3.1. Civil Society:

a) Civil society organizations should advocate for stronger measures of tobacco control policies both at state and national levels through grassroots mobilization, lobbying efforts and campaigns.

- b) Community-based educational and intervention programs should be conducted regularly to raise public awareness of the harm of SLT use. Special focus should be provided to women of reproductive age, pregnant and lactating women, children and youth.
- c) Civil societies may take part in providing support and resources for tobacco cessation services and programs such as helplines, counselling, peer support groups etc. particularly targeting the populations vulnerable using SLT.

5.8.3.2. Businesses:

- a) Businesses should adopt initiatives of corporate social responsibility (CSR) prioritizing to support tobacco control efforts and public health. Initiatives such as workplace policies that discourage use of tobacco and promote cessation. Besides, tobacco free institute initiative in the business organizations should focus on all forms of tobacco products including SLT with regular monitoring and sensitization of the employed personnel.
- b) Any involvement in the manufacturing, marketing or distribution of the SLT products should be prohibited and avoided.
- c) By partnering with the public health organizations, NGOs and government agencies, businesses can initiate communities-based programs and implement them for reducing the consumption of SLT products and improving the outcomes of public health.
- d) Business organization should be trained and guided on the WHO FCTC Article 5.3 and any investment from the tobacco industry should be diverted to avoid tobacco industry interference.
- e) In India most of the SLT products are manufactured in cottage industries or in homes in the unregulated sector. People who are engaged with the cultivation and manufacturing of SLT products should be provided with counselling on health awareness and support for alternative business opportunities in line with the WHO FCTC Article 17 and 18.

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