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Smokeless tobacco control in India: policy review and lessons for high-burden countries

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ABSTRACT

We examined the magnitude of smokeless tobacco (SLT) use in India and identified policy gaps to ascertain the priorities for SLT control in India and other high SLT burden countries in the Southeast Asia region. We reviewed and analysed the legal and policy framework to identify policy gaps, options and priority areas to address the SLT burden in India and lessons thereof. In India, 21.4% adults, including 29.6% of men, 12.8% of women, use SLT while more than 0.35 million Indians die every year due to SLT use. SLT use remains a huge public health concern for other countries in the region as well. Priority areas for SLT control should include: constant monitoring, increasing taxes and price of SLT products, strengthening and strict enforcement of existing laws, integration of SLT cessation with all health and development programmes, banning of advertisement and promotion of SLT, increasing age of access to tobacco up to 21 years, introducing licensing for the sale of SLT, standardising of SLT packaging and preventing SLT industry interference in the implementation of SLT control policies besides a committed multistakeholder approach for effective policy formulation and enforcement. SLT control in India and the other high SLT burden countries, especially in the Southeast Asia region, should focus on strengthening and implementing the above policy priorities.

Summary box

- Smokeless tobacco (SLT) contributes to global burden of disease, disability and death, with the highest burden on India and the Southeast Asia region.
- India has taken tobacco control steps both at national and subnational levels which has resulted in significant reduction in tobacco use between 2009-2010 and 2016-2017 but with wide regional variations.
- There is wide gap in existing SLT control policies and their enforcement due to lack of research, training, capacity and adequate resources.
- Several tobacco control policies applicable to smoking products hitherto did not apply to SLT products.
- High SLT burden countries including India, especially its 13 high SLT burden states, should adopt and implement comprehensive tobacco control policies in line with WHO Framework Convention for Tobacco Control (FCTC) and beyond to curb SLT use.
- Greater policy focus and multistakeholder commitment for SLT control research, training, capacity and resources will help high SLT burden countries meet their WHO FCTC obligations.

INTRODUCTION

Nearly 356 million people use smokeless tobacco (SLT) in 140 countries while 82% of this burden lies in the Southeast Asia.[1] Moreover, 29 of these countries have high SLT burden with 10% or more prevalence of SLT use at the population level or either among males or females.[2] Unfortunately, more than 0.65 million people die every year due to SLT use.[3] Most of the SLT products are produced in the traditional markets in the unorganised sector and remain away from regulations, and therefore greatly vary in their composition and health risks.[4 5] Most of these products contain extremely high levels of nicotine resulting in chronic dependence.[6] Research over the period has definitively established that SLT use is responsible for several forms of cancers,[7] is associated with cardiovascular deaths[8] and poor birth outcomes.[9]

Although 181 countries and the European Union have ratified the WHO Framework Convention for Tobacco Control (FCTC), the global focus has remained mainly on curbing cigarette consumption and with little progress on SLT prevention and control.[2] SLT use is more common and replacing smoking as the most popular choice among tobacco users in Bangladesh, India and Nepal.[10] There is an increase in SLT use, and the share of SLT use in overall tobacco use across the three countries has increased.[10] With majority of its tobacco burden as SLT use, several countries from the region have taken some efforts to

curb SLT use including a complete prohibition on manufacture, sale and import of SLT in Bhutan.[11] However, a comprehensive response from all stakeholders is much needed to deal with the problem.[12]

India leads the global efforts in prevention and control of SLT and has implemented several laws, even beyond the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 (COTPA), to curb its use.[2] Although there is clear progress in SLT control in India that can be replicated in the region and other high SLT burden countries, enforcement and continuous monitoring and evaluation of several of these policy measures remains a challenge.[13]

Recently, several academicians, civil society organisations and statutory bodies from Southeast Asia including India have joined a new initiative called Addressing Smokeless Tobacco and Building Research Capacity in South Asia (ASTRA).[14] On behalf of ASTRA India, a policy review and analysis was conducted to identify the existing policies on SLT regulations and the challenges, opportunities and priorities to improve its control in the country and highlight the lessons for the other high SLT burden countries in the region. A comprehensive review of the existing literature to identify the prevailing policies and the gaps therein to control SLT use was undertaken. This included a review of legal documents notified by the government to highlight the SLT-specific policies, laws, regulations and their level of enforcement in the country. The best practices of other countries were also reviewed for comparison and lessons on best practices. Key stakeholders and experts were interviewed during the National SLT Consultation cum Workshop organised in July 2018 to identify policy options and action areas to address SLT burden in India (online supplementary table S1).

PREVALENCE OF SLT USE AND ASSOCIATED DISEASE BURDEN IN INDIA

Nearly 199.4 million adults (21.4% overall, 29.6% men and 12.8% women) in India consume SLT regularly, that is, either daily or occasionally.[15] The use of SLT is more than twice that of smoking (10.7%). The number of male SLT users (141.2 million) is more than twice that of female SLT users (58.2 million). Similarly, the number of SLT users in rural areas (150.3 million; 24.6%) is about three times that in urban areas (49.0 million; 15.2%). The two most commonly used SLT products among adults in India are *khaini*—mixture of tobacco and lime used by 11.2% adults (17.9% men and 4.2% women), and *gutkha*—mixture of tobacco, lime and areca nut used by 6.8% adults (10.8% men and 2.7% women).[15] In addition, about 6% adults (7.1% men and 4.5% women) use SLT with betel quid while another 2.8% adults (4.5% men and 1.1% women) use it with pan masala.[15] Both betel quid and pan masala contain areca nut as an ingredient, thus more adults use SLT with areca nut, which is a class 1 carcinogen, than any other form in India.

The overall disease burden attributable to SLT was based on the risk of mouth (RR 5.12; 95% CI 3.27 to 8.02), pharyngeal (RR 2.60; 95% CI 1.76 to 3.85) and oesophageal (RR 2.57; 95% CI 2.2 to 3.0) cancers.[16] The all-cause mortality attributable to SLT use in India was estimated to be 368 127 people, with nearly three-fifths of these deaths occurring among women (217 076 among women and 151 051 among men).[17]

POLICY IMPLEMENTATION AND GAPS

Table 1 lists the various laws in India that are applicable to the regulation of SLT in the country and the gaps therein.

Although all tobacco products are taxed at the highest bracket of existing goods and services tax in the country, the tax law does not provide for tax paid stamp on any tobacco product.[18] Sale to and by minors is banned under tobacco control and child protection laws,[19] however its legal enforcement remains a challenge. There is a ban on the sale of tobacco products within 100 yards of an educational institution, but this provision is also violated in spite of several High Court orders directing the strict implementation of the provision.[12] One of the key measures recommended under Article 16 of the WHO FCTC to prevent minors access to tobacco, that is, the ban on the sale of tobacco products in loose or in small units, is not implemented, as more than 70% of the tobacco products are sold loose in the country.[15] Unlike the ban on smoking in public places, SLT use was not banned; however, some of the local jurisdictions in the country dealt with this by prohibiting spitting in public places. Several countries have also banned spitting in public places.[20] In wake of the COVID-19 pandemic the Ministry of Health and Family Welfare, Government of India, issued advisory to ban sale, use and spitting in public places.[21] Pictorial health warnings are implemented on all tobacco products including SLT products, while several countries have already adopted plain packaging of tobacco products (table 2). Although direct and indirect advertising is banned under the law, its widespread violation can be seen in the country.[22–24]

Other laws applied on SLT control include the ban on the use of tobacco and nicotine as an ingredient in any food item by the Food Safety and Standards Authority of India (FSSAI).[25] This led to the ban on the sale of gutkha, a scheduled tobacco product and other flavoured SLT products in the country.[12] Regulations under the Cinematograph Act[26] and the Cable Television Networks Act[27] prohibit any kind of glamourisation and promotion of tobacco products including SLT products in movies and television; however, its violations are seen frequently.[28] Several of the SLT product packs do not follow the packaging and labelling requirements under the Legal Metrology Act which mandates name, place and address of the manufacturer to be given on the pack along with

Table 1 Laws applicable for the regulation of SLT in India

Tobacco control policies	Name of the law	Applied on SLT	Gaps/remarks
Mandate to label nicotine and tar contents on the pack	COTPA Section 7(5)	No	Provision yet to be notified.
Mandate to have excise stamp affixed on the pack	Goods and Services Tax Act (GST), 2017	No	No provision so far.
Prohibition on quantity, that is, loose sale or in a small unit	COTPA	No	No provision so far.
Ban on use in public places	Section 10(2)(1) of the National Disaster Management Act, 2005, Section 133 of the Criminal Procedure Code (CrPC), 1973 and Sections 268 and 269 of the Indian Penal Code (IPC), 1860	Yes	With the COVID-19 pandemic several states and local authorities have banned sale and use of SLT in public places.
Pictorial health warning labels on packs	COTPA Section 7(1)	Yes	Enforced since 2009, rotational since 2011.
Restriction on direct advertisement of tobacco	COTPA Section 5	Yes	Complete ban on all media except the internet since 2004.
Restriction on indirect advertisement of tobacco	COTPA Section 5	Yes	Lack of enforcement. Copious violations everywhere.
Prohibition on sale of tobacco to and by minors	COTPA Section 6 and Section 77 of the Juvenile Justice Act, 2015	Yes	Lack of enforcement. Copious violations everywhere.
Ban on sale and distribution of tobacco within 100 yards of educational institutions	COTPA Section 6	Yes	Lack of enforcement. Copious violations everywhere.
Ban on use of tobacco and nicotine as an ingredient in any food item	Rule 2.3.4 of the Food Safety and Standards (Prohibition and Restrictions on Sales) Regulation, 2011	Yes	Sale of twin and separate packs of pan masala and chewing tobacco continues.
Ban on advertisement and glamourisation of tobacco products in films and TV	Guidelines 2(vi)(a) under Section 5B(2) of the Cinematograph Act, 1952 and COTPA Section 5	Yes	Weak enforcement of the law by the Central Board of Film Certification.
Ban on advertisements that promote directly or indirectly production, sale or consumption of cigarettes, tobacco products, and so on	Rule 7(2)(viii)(A) of the Cable Television Networks (Amendment) Rules, 2000	Yes	Indirect advertisements continue in the name of mouth fresheners and other same company, same name, same colour products.
The requirement of weight, measurement, packaging and labelling	Section 3 and Section 18 of the Legal Metrology Act, 2009	Yes	Several tobacco products do not comply with this law.
Ban on use of plastic to pack tobacco products	Rules 2(2) and 4(f) and (i) of the Plastic Waste Management Rules, 2016 under Sections 6, 8 and 25 of the Environment (Protection) Act, 1986	Yes	Violation of the rules continues.
Ban on the use of tobacco in toothpastes/tooth powders	Section 33-DDE of the Drug and Cosmetics Act, 1940	Yes	Violation continues with sale of *gul* and *creamy snuff*.
Licence for manufacturing of tobacco	38(1) of the First Schedule of The Industrial Development Act, 1950 under Sections 2 and 3(i)	No	Licence is issued only for the manufacturing of cigarettes.
Tobacco taxation	Annual Finance Acts and now GST	Yes	Taxes remain short of the WHO recommendations of a minimum 75% tax share of the retail price of tobacco.
Ban on spitting and littering in public places	Section 133 of the CrPC, Sections 268 and 269 of IPC, state laws on spitting ban, other local laws and the Swachh Bharat Abhiyan (Clean India Mission)	Yes	Implementation of these laws remains a challenge. With the influx of COVID-19 pandemic several states and local authorities have revived and strengthened compliance.

COTPA, Cigarettes and Other Tobacco Products Act; SLT, smokeless tobacco.

Table 2 Global best practices in SLT control

Countries	Tobacco control policies	WHO FCTC Article
Australia, Bhutan, Singapore and Sri Lanka	Ban on manufacture sale and import of SLT products[60]	Beyond WHO FCTC
Australia, France, the UK, Norway, Ireland, New Zealand, Hungary, Thailand, Uruguay, Slovenia and Singapore	Plain packaging of tobacco products[2]	Article 11
Nepal, Myanmar, Papua New Guinea, UAE and India	Ban on use and spitting of SLT products in public places[61]	Article 8
Guam, Honduras, Kuwait, Samoa, Singapore, Sri Lanka, Uganda	The minimum legal age of tobacco sale is 21 years[48]	Article 16 and beyond
Malaysia, South Africa, Algeria and Sweden	Nicotine replacement therapy in essential medicine list[2]	Article 14

FCTC, Framework Convention for Tobacco Control; SLT, smokeless tobacco.

the maximum retail price of the product.[29] The latest plastic waste management rule under the Environment Protection Act prohibits the use of plastic to pack any tobacco products, but several manufacturers continue to pack SLT products in plastic pouches.[30] Although the Drug and Cosmetics Act prohibits the use of tobacco as an ingredient in toothpaste or tooth powders, such products continue to be sold in the country.[31] Above all, manufacturing of cigarettes in the country is licensed under the Industrial Development Act, while to start manufacturing an SLT product there is no requirement of a licence.[32]

BARRIERS AND OPPORTUNITIES

The high rate and myriad ways of SLT use in India and the region act as the biggest barrier in SLT control.[4] In addition, its production and sale primarily from the unorganised sector such as cottage industry and household level further multiply the tax and regulatory burden for the governments.[33] This burden is highest in the 13 high prevalence states in India which constitute more than 90% of the country's SLT use (online supplementary table S2). Interference by the SLT industry in development and implementation of effective SLT control, especially by lobbying, tax evasion tactics and litigation against promising policies, has prevented desired effect of such control policies.[12 34] Besides the sociocultural barriers related to SLT use, for example, social acceptability resulting in early initiation, there are other structural barriers, for example, lack of resources, training and capacity for enforcement of SLT control laws and policy initiatives including cessation support; understanding of the market and supply chain of myriad varieties of SLT products, their content and emissions[5]; aggressive surrogate and indirect advertisements by the industry[24]; access and exposure to minors; online sale and promotion and lack of economically viable alternatives for those engaged in growing, producing and retailing of SLT products in the country.[2]

However, the recent surveillance data show an encouraging trend with more than 17% relative decline in SLT use from the prevalence in 2010–2017 in the country.[15] Improvement in the enforcement of the COTPA provisions and implementation of the National Tobacco Control Programme (NTCP) in all districts along with one cessation centre in each district and all dental colleges has been initiated by the government of India.[35] These efforts offer real opportunities to accelerate the reduction in SLT use across the country including the 13 high SLT burden states. With support from the Ministry of Health and Family Welfare, other government and non-government organisations, the National Tobacco Testing Laboratories and the Global Knowledge Hub on Smokeless Tobacco are providing product testing facility, research, training, capacity building and policy support for further strengthening of the SLT control programme and its enforcement in the country.[36] Support from the laboratories and the knowledge hub is also available to other countries in the region and other high SLT burden countries globally.[37]

LESSONS FOR STRENGTHENING SLT CONTROL

The study identifies the following key policy priorities for action by various stakeholders in India and other high SLT burden countries in the region.

Standardised packaging of SLT products: Starting with Australia in 2012, several Parties to the WHO FCTC have now implemented standardised packaging of tobacco products along with plain packaging (table 2). Contrary to the prescription of Article 16 of the WHO FCTC, the SLT products are generally sold in very small packs at a very low price resulting in high access to minors and a negligible impact of tobacco taxation policy. Besides, it also makes the pictorial health warnings less visible and rather ineffective. Considering India, Nepal, Sri Lanka and Timor-Leste have large and stronger pictorial health warnings and Thailand has already adopted plain packaging, the next logical step for the governments in the region should be to standardise the packaging of all tobacco products including SLT products.[38] Standardisation should also mandate other specifications of the pack

including size and weight, that is, no SLT products to be sold in less than 50 g standard packs. The increased price of bigger packs will help in keeping the SLT products out of the minors' reach and make the health warnings more visible, legible and effective.[2] Plain packaging is a necessary step towards denormalising tobacco use.[39] Standardised packaging, including plain packaging, motivates tobacco users to quit, and it limits initiation especially among minors. Standardisation of the products will limit the tobacco industry's capacity to glamourise the packs or create attractive packaging and buying options with small and single unit cheap packs which will make tax measures more effective.

Prohibit brand stretching or brand sharing of tobacco products: Majority of SLT products are consumed along with areca nut products and the SLT industry is engaged in manufacturing and sale of several gateway products with areca nut as its key ingredient, for example, *pan masala, meethi supari* (sweetened areca nut), mouth fresheners using the same brand, colour and design that of its established SLT brands.[24] These brand stretching and brand extension products are then aggressively advertised by the industry as the surrogate for their SLT products to retain brand recall among their customers and recruit new customers through brand loyalty.[40] Brand stretching is prohibited under Section 5 of COTPA and Article 13 of the WHO FCTC and, therefore, registration of any tobacco brand for non-tobacco products should be prohibited by the trademark authorities requiring prohibition on manufacture and sale of a non-tobacco product having any similarity or imitation with any existing tobacco brand.[41] Considering that areca nut is also a class 1 carcinogen its use along with SLT products or as a gateway or surrogate product should be restricted by the tobacco control and food safety department.[42]

No additives, scents, sweeteners or flavourings should be used as an ingredient in tobacco or nicotine products: As per the FSSAI regulation, tobacco and nicotine cannot be used as an ingredient in any food items in India.[25] However, this provision of the law is followed more in violation[43] as most of the SLT products are sold after processing and mixing additives, scents, sweeteners or flavourings that make the tobacco products palatable and pleasant for consumption, especially for young and minors. Although, FSSAI and the Supreme Court of India have expressly directed all states to implement the provisions in letter and spirit its compliance in all states is yet to be achieved.[12] The FSSAI should issue guidelines or notify explanations under the regulation to prevent the use of any such additives, scents, sweeteners or flavourings in tobacco or nicotine products in the country. Other governments in the region should adopt the FSSAI regulations of 2011 to prevent adulteration of food through tobacco and nicotine.[25]

Protection of minors and increasing legal age for sale of tobacco products: Going a step forward from the prohibition on sale to and by minors under COTPA, the Juvenile Justice Act prevents all person from giving or causing to give tobacco to minors. The violation of this provision has exemplary punishment under Section 77 of the Act.[19] Moreover, available literature suggests that addiction to tobacco use is least if the age of experimentation is delayed beyond 25 years. Tobacco industry's internal communications suggest that only a negligible percentage of tobacco users continue tobacco use if they initiate it after 24 years of age.[44] To effectively address this problem and to prevent the present and future generation, the legal age for sale of SLT products should be fixed beyond 21 years as already prescribed for sale of alcohol under the state excise policy in several states in India. Seven countries, including Sri Lanka, already provide 21 years as the minimum legal age for sale of tobacco products (table 2).[45 46]

Strengthening tobacco cessation services: Cessation as a primary means of reducing demand for tobacco products should be promoted across all health programmes of the government with key focus on creating awareness on benefits of cessation through mass media campaigns in local languages. Effective course modules, primarily counselling, should be developed and included under all health and development programmes. The national quitlines under the NTCP should be promoted at the district and local level along with the details of m-Cessation.[47] The cessation counselling facilities should be integrated with the community health centres and all healthcare workers should be trained for basic cessation services including counselling. Nicotine replacement therapy, where necessary, should be made available as part of essential medicine as already done in four countries (table 2).[20 48] Further, community-based research should be promoted to understand the barriers, challenges and opportunities so that appropriate behavioural intervention strategies can be developed and integrated with the community health clinics to promote SLT cessation.

A comprehensive approach to SLT taxation: Unlike cigarettes, there is a lack of comprehensive studies on the economics of SLT products.[18] It is also evident that SLT tobacco products are sold in small packs at very lower prices. Further, tobacco leaves which are used for chewing are taxed differently as compared with other SLT products, for example, in India tobacco leaves are taxed at the rate of 5% (2.5% Central Goods and Services Tax and 2.5% State Goods and Services Tax). For the SLT taxation policy to be effective, all SLT products including tobacco leaves should be taxed at the highest level of taxation in the country, with additional taxes if required to constitute 75% of the retail price as recommended by WHO.[49] In addition to a higher rate of taxation, all SLT products should also have a fixed higher floor price and larger pack size for the taxation policy to achieve the desired objective.[50] SLT taxation as a policy imperative remains under-researched and needs further attention for effective outcomes.[18]

Retail licensing for the sale of tobacco products: In the absence of retail licensing, there is mushrooming of tobacco vendors making it difficult to contain minors'

access and enforcing other tobacco control measures. Retail licensing will limit the number of tobacco vendors and help in ensuring compliance with the tobacco control laws and regulations.[51 52] Within such a licensing condition, food, stationary, toys and other vendors which cater to minors should be precluded from selling tobacco products. Retail licensing will also help in compliance with the Parties obligation under the WHO FCTC Protocol to Eliminate Illicit Trade in Tobacco Products, including the tracking and tracing requirements.[51] State of *Himachal Pradesh* in India has already implemented this along with the prohibition on the loose sale of cigarettes and bidis, while other states like *Punjab* and local jurisdictions like *Patna* Municipal Corporation are also introducing retail vendor licensing for the sale of tobacco products.[53–55]

Tobacco farming and livelihood: Loss of livelihood, especially for farmers and worker, has always remained an area of concern for the governments while implementing tobacco control measures.[56] More synergy between Ministry of Health and Ministry of Agriculture should be initiated to enhance research on alternative crops for tobacco growers. As an alternative to growing or working in SLT industry, governments can rehabilitate such farmers and workers to relevant alternative livelihood options,[57] for example, in India through Skill India Initiative under the National Skill Development Mission. The Ministry of Rural Development should be encouraged to prioritise tobacco farming alternatives and skill building along with tobacco cessation efforts at *Panchayat* (village council) level.

Regulation of product content and emissions: Unlike cigarettes the content and emissions of SLT products are not well established, thus requiring a detailed chemical analysis of the constituents, toxicity and emissions of *SLT* products sold in the region.[58] The notified National Tobacco Testing Laboratories in India can play a decisive role in this field for the region.[59]

CONCLUSION

Unlike the public movement against smoking, especially in public places, the hazards of SLT use have received little attention from the public, researchers and policymakers alike in a region where SLT use is more prevalent than smoking. Although countries in the region have taken steps to curb SLT use, they are yet to meet the WHO recommended standards on various Articles of the WHO FCTC including SLT taxation and ban on SLT advertising. There is a need for advancing and strengthening SLT cessation, where other countries in the region could learn the lessons from India and adopt and integrate the national quitline and mCessation strategies in the existing tobacco control and other health programmes. Product licensing is another key actionable area for the governments as initiated in some of the states and local jurisdictions in India. Strengthening of the SLT control programmes in the region would further require multistakeholder research, training, enforcement and policy action that is supported by adequate human and financial resources. There is a need for implementing innovative and evidence-based strategies including a ban on promotion and sale of SLT products via the internet while preventing the introduction of any new variety of SLT or other novel or imitation products in the market.

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