Smokeless Tobacco Products: Indian and Global Perspective

Working Chair and Group members

Authors:

Dr. Shalini Singh[1], Sanchita Roy Pradhan[1], Dr. Mausumi Bharadwaj[1], Dr. Mohammad Sajid[1], Dr. Namrata Puntambekar[2], Dr. Prashant Kumar Singh[1], Dr. Amit Yadav[3], Deepak Mishra[5], Dr. Dhirendra N. Sinha[5]

[1.]Director, ICMR-National Institute of Cancer Prevention and Research, Noida, India

[2.]Healis Sekhsaria Institute for Public Health, Navi Mumbai, India

[3.]Vital Strategies, New Delhi, India

[4.]Socio Economic and Educational Development Society (SEEDS), New Delhi, India

[5.]School of Preventive Oncology, Patna, India.

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best practice recommendations for laws governing SLT use, the current chapter reviewed the available published and unpublished data as well as expert opinions.

Introduction:

Products containing smokeless tobacco (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).

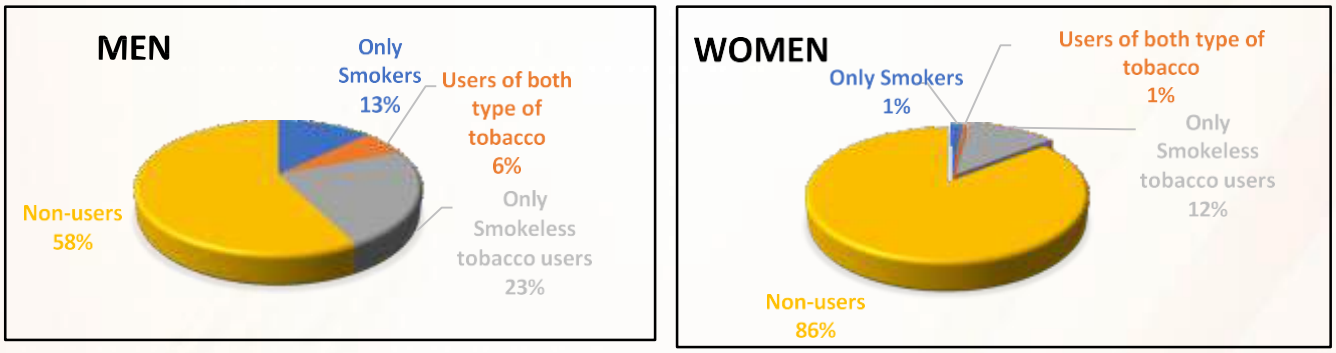


Figure 1: Tobacco use according to gender (Percentage distribution) [GATS 2 India 2016-17]

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 Smokeless Tobacco	Both Smoked and Smokeless	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)

Table 2: Smokeless Tobacco Products Available in India

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

16	Sada Patta/Loose leaf/ Tobacco leaf/ Chadha	Loose air cured tobacco leaves used for smoking and chewing.	Chewed	India
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 and 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; an 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 nut.	Chewed	Gujrat and its nearby areas of Maharashtra
22	Dohra/Dhora	tobacco, slaked lime, areca nut, and additional ingredients like catechu (Kattha), peppermint, and cardamom combined in a moist mixture.	Chewed and sucked.	Jaunpur, Prayagraj and Pratapgarh district of Uttar Pradesh
23	Gudakhu / Gudhaku	A mixture of paste prepared from fine dust of tobacco 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 from natural flowers and hers.	Nasal or Oral use	Eastern part of India, as well as Goa, Gujarat and Maharashtra
25	Creamy snuff	A mixture of finely grounded tobacco, glycerine, clove oil, menthol, spearmint, salts, camphor, other hydrating agents, and water and commercially manufactured as a paste.	Used by rubbingon the gums and teeth.	Used all over India.
26	Tuibur / tobacco water / hidakphu	It is tobacco smoke-infused water. bottled for both storage and sale.	Kept in mouth for 5 to 10 minutes or used as a gargle.	North Eastern states of Mizoram and Manipur, India
27	Kapoori/Mainpuri	A mixture of slaked lime treated tobacco leaves, finely cut betel nuts and flavours such as powered cardamom, cloves, Kweara (extract from the *Pandanus odoratissimus* fragrant flower), powdered sandalwood and occasionally added Catechu.	Consumed as Chewed and sucked.	Uttar Pradesh, India specially in the Mainpuri district.

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

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 un-ionized 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 disability-adjusted 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 Components	IARC Classification	Chemical Components	IARC Classification
Arsenic	1	Mercury	3
Acetaldehyde	2B	Morpholine (Precursor of NMOR)	3
Aflatoxin M1	2B	Morpholine (Precursor of NMOR)	3
Anthracene	3	Morpholine (Precursor of NMOR)	3
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] pyrene	2B	Quercetin	3
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 Snuff					
		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 masala					
		PM1	ND	-	-	-
		PM2	ND	-	-	-
		PM3	ND	-	-	-
		PM4	ND	-	-	-
		PM5	ND	-	-	-
		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					
		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	pH	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

Sl. No.	SOP	Purpose of SOP	Testing Facility
1	WHO TobLabNet SOP 12	Standard operating procedure for measurement of the nicotine content of smokeless tobacco products	National Tobacco Testing Laboratories; WHO Recognised Laboratories
2	WHO TobLabNet SOP 13	Standard operating procedure for measurement of the moisture content in smokeless tobacco products (it can also be used to measure the flavouring and water content).	National Tobacco Testing Laboratories; WHO Recognised Laboratories
3	WHO TobLabNet SOP 14	Standard operating procedure for measurement of smokeless tobacco products' pH.	National Tobacco Testing Laboratories; 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), 8th 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, ice-cream 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 th e 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 against 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 tobacco 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 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 Regulation	References
USA (Not a Party to WHO FCTC)	According to the Comprehensive Smokeless Tobacco Health Education Act of 1986, health warnings must be included on all SLT packages sold in the United States.	(1)
Sri Lanka, Bhutan, Singapore, and others	Manufacturing, selling, and importing SLT products are all prohibited.	(43)
Thailand	Sale of import of SLT products prohibited	(44)
Malaysia	Graphical or any other kind of representation on the product grading, quality or supremacy is prohibited.	(45-50)
USA, UK and India	The depiction of ingredients (tar and nicotine) on the tobacco packs are mandatory	(45-50)
EU Countries	In any tobacco products, the ingredients used is required to report by the tobacco industry to the EU countries. Health warnings on tobacco and related products.	(51,52)
Ecuador	The information on the adverse effects of 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).	(50)
Bangladesh	License is required to sell SLT products.	(50)

Canada	Additives are prohibited in tobacco products Pictorial health warning: covering 75% on the two principal display surfaces.	(45,50)
Sweden, Georgia, USA	Pictorial health warning: covering 30% or more of the package area	(53,54,55)
Brazil	Pictorial health warning: covering 30% of the front a nd 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 Republic, Sweden, Myanmar, USA and UK	Mandatory textual health warnings	(45,47,61,62,63,64)
Lebanon	Awareness education on t he risks associated with tobacco consumption including SLT is provided to public.	(65)
Canada, Bangladesh, Myanmar and India	All forms of direct and indirect advertisements are prohibited.	(52, 66-74)

Pakistan	Advertisement of tobacco products are restricted if not aligned with the Federal committee guidelines (Pakistan Tobacco Ordinance, 1968).	(1)
Bangladesh, Argentina, Brazil, Canada, India, Dominican	Prohibits sale of tobacco products including SLT to minors (below 18 years of age) by law.	(50,55,75 ,62,76-81)
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, Tanzania, UK and Thailand	Some forms of SLT product sale and import are partially prohibited.	(52,75,84-89)
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 New York, Chicago, Boston, San Francisco and Los Angeles)	SLT products are prohibited at the sport venues in the baseball parks in the city.	(90-92)

Existing gaps in smokeless tobacco control in India:

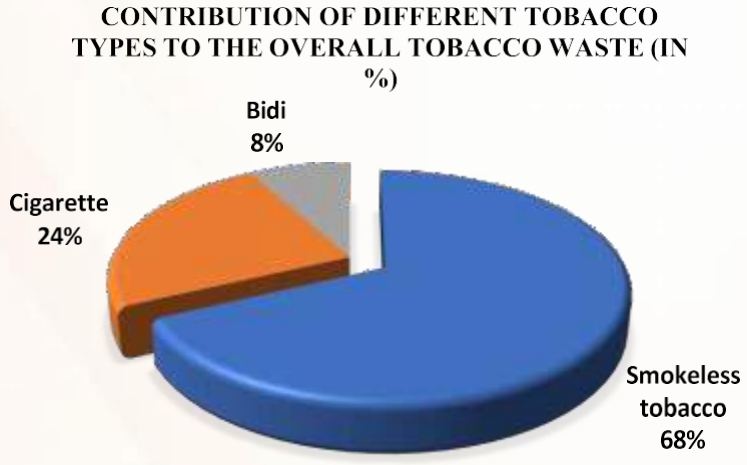
Marketers and direct sellers of tobacco products are prohibited from selling to minors; however, the enforcement of these laws is inadequate.

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 Packagingfor Smokeless Tobaccoproducts:***

   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 toprevent 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 Indiansetting(107).

5. ***Integration of Tobacco Screening and Cessation Counsellingin 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.

References:

1. Chugh A, Arora M, Jain N, Vidyasagaran A, Readshaw A, Sheikh A, Eckhardt J, Siddiqi K, Chopra M, Mishu MP, Kanaan M. The global impact of tobacco control policies on smokeless tobacco use: a systematic review. The Lancet Global Health. 2023 Jun 1;11(6): e953-68.
2. Niaz K, Maqbool F, Khan F, Bahadar H, Hassan FI, Abdollahi M. Smokeless tobacco (paan and gutkha) consumption, prevalence, and contribution to oral cancer. Epidemiology and health. 2017;39.
3. Siddiqi K, Husain S, Vidyasagaran A, Readshaw A, Mishu MP, Sheikh A. Global burden of disease due to smokeless tobacco consumption in adults: an updated analysis of data from 127 countries. BMC medicine. 2020 Dec; 18:1-22.
4. Thakur JS, Paika R. Determinants of smokeless tobacco use in India. Indian Journal of Medical Research. 2018 Jul 1;148(1):41-5.
5. Mehrotra R, Yadav A, Sinha DN, Parascandola M, John RM, Ayo-Yusuf O, Nargis N, Hatsukami DK, Warnakulasuriya S, Straif K, Siddiqi K. Smokeless tobacco control in 180 countries across the globe: call to action for full implementation of WHO FCTC measures. The lancet oncology. 2019 Apr 1;20(4):e208-17.
6. Gupta PC, Ray CS. Smokeless tobacco and health in India and South Asia. Respirology. 2003 Dec;8(4):419-31.
7. Mutti-Packer S, Reid JL, Thrasher JF, et al. The role of negative affect and message credibility in perceived effectiveness of smokeless tobacco health warning labels in Navi Mumbai, India and Dhaka, Bangladesh: a moderated-mediation analysis. Addict Behav 2017; 73: 22–29
8. Global Adult Tobacco Survey Report India 2017. Ministry of Health and Family Welfare. Available at: https://ntcp.mohfw.gov.in/assets/document/surveys-reports- publications/Global-Adult-Tobacco-Survey-Second-Round-India-2016-2017.pdf
9. Sinha DN, Suliankatchi RA, Gupta PC, Thamarangsi T, Agarwal N, Parascandola M, Mehrotra R. Global burden of all-cause and cause-specific mortality due to smokeless tobacco use: systematic review and meta-analysis. Tobacco control. 2018 Jan 1;27(1):35-42.
10. IARC Working Group on the Evaluation of Carcinogenic Risks to Humans, International Agency for Research on Cancer. Smokeless tobacco and some tobacco-specific N- nitrosamines. World Health Organization; 2007
11. Teo KK, Ounpuu S, Hawken S, Pandey MR, Valentin V, Hunt D, Diaz R, Rashed W, Freeman R, Jiang L, Zhang X. Tobacco use and risk of myocardial infarction in 52 countries in the INTERHEART study: a case-control study. The lancet. 2006 Aug 19;368(9536):647-58.
12. Products, C. for T. Established List of HPHCs in Tobacco Products and Tobacco Smoke, U.S. Food and Drug Administration. Available at: https://www.fda.gov/tobacco-products/rules- regulations-and-guidance/harmful-and-potentially-harmful-constituents-tobacco-products- and-tobacco-smoke-established-list
13. IARC Working Group on the Evaluation of Carcinogenic Risk of Chemicals to Humans. Tobacco Smoking. Volume 38. IARC, Lyon, France, 1986.
14. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Tobacco Smoke and Involuntary Smoking. Volume 83. IARC, LYON, FRANCE 2004.
15. IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Humans. Tobacco Habits Other Smoking; Betel-Quid and Areca Nut Chewing; and Some Related Nitrosamines. Volume 37. IARC, LYON, FRANCE 1985.
16. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Personal Habits and Indoor Combustions. Volume 100E. IARC, LYON, FRANCE 1985.
17. Tobacco monograph. Indian Council of Medical Research. 2021. Available at: https://main.icmr.nic.in/sites/default/files/upload_documents/Tobacco_Monograph.pdf
18. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans VOLUME 97 1,3-Butadiene, Ethylene Oxide and Vinyl Halides (Vinyl Fluoride, Vinyl Chloride and Vinyl Bromide). IARC, LYON, FRANCE 2008.
19. Rutqvist LE, Curvall M, Hassler T, Ringberger T, Wahlberg I. Swedish snus and the GothiaTek® standard. Harm reduction journal. 2011 Dec;8:1-9.
20. Products, C. for T. Harmful and Potentially Harmful Constituents (HPHCs), U.S. Food and Drug Administration. Available at: https://www.fda.gov/tobacco-products/products- ingredients -components/harmful-and-potentially-

harmful-constituents- hphcs#:~: text=The% 20Food %2C%20Drug%20and%20Cosmetic,tobacco% 20products%20and %20tobacco%20smoke.

21. Report on tobacco control in India 2022. Available at: https://ntcp.mohfw.gov.in/ assets/document/surveys-reports - publications/ Report%20on%20 Tobacco%20 Control%20in%20India%202022_22%20April%20 2024.pdf Accessed 11 June 2024.
22. Global Progress Report on Implementation of the WHO Framework Convention on Tobacco Control 2023. Available at: https://fctc.who.int/publications/m/item/2023-global- progress-report#:~:text=Overview, FCTC)% 20on%2027%20February%202005.
23. GBD 2019 Chewing Tobacco Collaborators. Spatial, temporal, and demographic patterns in prevalence of chewing tobacco use in 204 countries and territories, 1990– 2019: a systematic analysis from the Global Burden of Disease Study 2019, The Lancet Public Health, Volume 6, Issue 7, 2021, Pages e482-e499, ISSN 2468-2667, https://doi.org/10.1016/S2468-2667(21)00065-7.
24. Global Tobacco Surveillance System Data (GTSSData). Centers for Disease Control and Prevention. Available at: https://nccd.cdc.gov/GTSSDataSurveyResources/ Ancillary/DataReports.aspx?CAID=2
25. Sinha DN, Suliankatchi RA, Gupta PC, Thamarangsi T, Agarwal N, Parascandola M, Mehrotra

    R. Global burden of all-cause and cause-specific mortality due to smokeless tobacco use: systematic review and meta-analysis. Tobacco control. 2018 Jan 1;27(1):35-42.
26. Bhawna G. Burden of smoked and smokeless tobacco consumption in India-results from the global adult tobacco survey India (GATS-India)-2009-2010. Asian Pacific Journal of Cancer Prevention. 2013;14(5):3323-9.
27. Bharati B, Sahu KS, Pati S. Prevalence of smokeless tobacco use in India and its association with various occupations: A LASI study. Frontiers in Public Health. 2023 Feb 27;11:1005103.
28. Rutqvist LE, Curvall M, Hassler T, Ringberger T, Wahlberg I. Swedish snus and the GothiaTek® standard. Harm reduction journal. 2011 Dec;8:1-9.
29. Products, C. for T. Harmful and Potentially Harmful Constituents (HPHCs), U.S. Food and Drug Administration. Available at: https://www.fda.gov/tobacco-products/products- ingredients-components/harmful-and-potentially-harmful-constituents- hphcs#:~:text=The%20Food %2C%20Drug%20and%20Cosmetic, tobacco%20products %20and %20tobacco%20smoke
30. Report on tobacco control in India 2022. Available at: https://ntcp.mohfw.gov.in/ assets/ document/surveys-reports-publications/Report%20on%20Tobacco% 20Control% 20in%20India%202022_22%20April%20 2024.pdf Accessed 11 June 2024.
31. Supreme Court of India. Health for Millions Trust v. Union of India and Others, Writ Petition (Civil) 549 of 2008. Available from: https://www. tobaccocontrollaws.org/litigation/ decisions/ in20090506-health-for-millions-v.-union-o
32. Ministry of Information and Broadcasting (MIB). Cable Television Networks (Amendment) Rules, G.S.R. 138(E), 27 February 2009. LatestLaws.com, 2022. Available from: https://www.latestlaws.com/bareacts/centralacts-rules/media-laws/cable- televisionnetworksregulation- act1995/cable-televisionnetworksamendment-rules-2009, accessed 11 June 2024
33. Government of India. Ministry of Health & Family Welfare. Notification. New Delhi, October 15, 2014.Available at:http://karhfw.gov.in/nrhm/NTCP/ Letter%20for %20Enforcement%20Issued%20to%20 Chief%20Secrtaries% 20f%20All%20State%20 Governments(Annexure-A).pdf
34. Press Information Bureau (PIB), Ministry of Environment, Forest and Climate Change. Tobacco Ban in the Country, 9 December 2013. New Delhi: Government of India; 2013. Available from: https:// pib.gov.in/newsite/ PrintRelease.aspx?relid=101237, accessed 11 June 2024.
35. Ministry of Environment, Forest and Climate Change. Notification No G.S.R. 571 (E), New Delhi; 12 August 2021. The Gazette of India: Extraordinary. Available from: https:// static. pib. gov. in/ Write Read Data/ specificdocs/documents/2021/aug/doc202181311. pdf, accessed 11 June 2024
36. WHO FCTC Knowledge Hub on Smokeless Tobacco. WHO FCTC Secretariat; 2020. Available from: http:// untobaccocontrol.org/kh/smokeless-tobacco/ visionand-mission/, accessed 11 June 2024.
37. Yadav A, Singh PK, Yadav N, Kaushik R, Chandan K, Chandra A, Singh S, Garg S, Gupta PC, Sinha DN, Mehrotra R.

Smokeless tobacco control in India: policy review and lessons for high- burden countries. BMJ global health. 2020 Jul 1;5(7):e002367.

38. John RM, Dauchy E, Goodchild M. Estimated impact of the GST on tobacco products in India. Tob Control. 2019;28(5):506–12. doi: 10.1136/ tobaccocontrol-2018-054479.
39. Kaur J, Jain DC. Tobacco control policies in India: Implementation and challenges. Indian J Public Health 2011; 55 : 220-7.
40. Ministry of Health and Family Welfare, Operational guidelines for establishing tobacco cessation centres in Medical institutes. Available from : https://ntcp.mohfw.gov.in/ assets/document/Guideline- manuals/Operational% 20Guidelines% 20for%20 Establishing%20Tobacco%20Cessatio n%20Centres%20in%20Medical% 20Institutions.pdf. Accessed 10th June 2024.
41. Welding K, Saraf S, Iacobelli M, Smith KC, Puntambekar N, Gupta PC, Cohen JE. Beyond Gutka: Evidence of Illegal Smokeless Tobacco in Rural and Semi-urban Areas in India. Nicotine Tob Res. 2022 Apr 28;24(6):929-932. doi: 10.1093/ntr/ntab251. PMID: 34893893; PMCID: PMC9048865.
42. FightAgainstSmokingCommissionreport:reignitethefightagainst smoking. https://www.fightagainstsmoking.org/ Date: 2021. Date accessed: June 10, 2024
43. Saraf DS, Mehrotra R, Chandan K, Sinha DN, Yadav A. A review of trade practices of smokeless tobacco products in terms of prohibition on sale, manufacturing & importation in Framework Convention on Tobacco Control ratified Parties. Indian J Med Res. 2018 Jul;148(1):90-97. doi: 10.4103/ijmr.IJMR_2027_17. PMID: 30264757; PMCID: PMC6172913.
44. Siddiqi K, Vidyasagaran AL, Readshaw A, Croucher R. A policy perspective on the global use of smokeless tobacco. Current addiction reports. 2017 Dec;4:503-10.
45. Samet JM, Wipfli H. Unfinished business in tobacco control. JAMA 2009; 302: 681– 82.
46. Barraclough S, Gleeson D. Why packaging is commercially vital for tobacco corporations. Asia Pac J Public Health 2017; 29: 132–39.
47. Longman JM, Pritchard C, McNeill A, Csikar J, Croucher RE. Accessibility of chewing tobacco products in England. J Public Health 2010; 32: 372–78.
48. Thejus T, Jayakrishnan T. Pictorial warnings on tobacco products: how delayed and diluted in India? Indian J Med Ethics 2009; 6: 105–06.
49. Khan A, Huque R, Shah SK, et al. Smokeless tobacco control policies in South Asia: a gap analysis and recommendations. Nicotine Tob Res 2014; 16: 890–94.
50. Pan American Health Organization. Manual for developing tobacco control legislation in the region of the Americas. Washington: Pan American Health Organization, 2013.
51. European Commission. Tobacco: product regulation. https://health. ec.europa.eu/tobacco/product-regulation_en (accessed July 26, 2024).
52. WHO. WHO study group on tobacco product regulation: report on the scientific basis of tobacco product regulation: fifth report of a WHO study group. 2015. https://apps.who.int/iris/ handle/10665/161512 (accessed July 26, 2024).
53. Liu ST, Nemeth JM, Klein EG, Ferketich AK, Kwan M-P, Wewers ME. Adolescent and adult perceptions of traditional and novel smokeless tobacco products and packaging in rural Ohio. Tob Control 2014; 1: 3.
54. Near AM, Blackman K, Currie LM, Levy DT. Sweden SimSmoke: the effect of tobacco control policies on smoking and snus prevalence and attributable deaths. Eur J Public Health 2014; 24: 451–58.
55. WHO. WHO Report on the Global Tobacco Epidemic, 2019: offer help to quit tobacco use. 2019. https://www.who.int/publications/i/ item/9789241516204 (accessed July 26, 2024).
56. Mostafa A, Mohammed HT, Hussein RS, et al. Do pictorial health warnings on waterpipe tobacco packs matter? Recall effectiveness among Egyptian waterpipe smokers & non-smokers. PLoS One 2018; 13: e0208590.
57. Mutti-Packer S, Reid JL, Thrasher JF, et al. The role of negative affect and message credibility in perceived effectiveness of smokeless tobacco health warning labels in Navi Mumbai, India and Dhaka, Bangladesh: a moderated-mediation analysis. Addict Behav 2017; 73: 22–29.
58. WHO. WHO study group on tobacco product regulation: report on the scientific basis of tobacco product regulation: fifth report of a WHO study group. 2015. https://apps.who.int/iris/ handle/10665/161512 (accessed July 26, 2024).

59. Naznin E, Wynne O, George J, et al. Smokeless tobacco policy in Bangladesh: a stakeholder study of compatibility with the World Health Organization's Framework Convention on Tobacco Control. Drug Alcohol Rev 2021; 40: 856-63.
60. Global Progress Report on Implementation of the WHO Framework Convention on Tobacco Control 2023. Available at: https://fctc.who.int/publications/m/item/2023-global- progress-report#:~:text=Overview,FCTC) %20on%2027%20February%202005.
61. Rickert WS, Joza PJ, Trivedi AH, Momin RA, Wagstaff WG, Lauterbach JH. Chemical and toxicological characterization of commercial smokeless tobacco products available on the Canadian market. Regul Toxicol Pharmacol 2009; 53: 121-33.
62. Kozlowski LT, Sweanor DT. Young or adult users of multiple tobacco/nicotine products urgently need to be informed of meaningful differences in product risks. Addict Behav 2018; 76: 376-81.
63. Popova L, Ling PM. Nonsmokers' responses to new warning labels on smokeless tobacco and electronic cigarettes: an experimental study. BMC Public Health 2014; 14: 997.
64. Peeters S, Gilmore AB. How online sales and promotion of snus contravenes current European Union legislation. Tob Control 2013; 22: 266-73.
65. Walker MW, Evans SA, Wimpy C, Berger AT, Smith AA. Developing smokeless tobacco prevention messaging for at-risk youth: early lessons from "The Real Cost" smokeless campaign. Health Equity 2018; 2: 167-73.
66. Yadav A, Ling P, Glantz S. Smokeless tobacco industry's brand stretching in India. Tob Control 2020; 29: e147-49.
67. Simpson D. India/Australia: row over oral tobacco cricket ads. Tob Control 2012; 21: 302-03.
68. Sinha DN, Palipudi KM, Oswal K, Gupta PC, Andes LJ, Asma S. Influence of tobacco industry advertisements and promotions on tobacco use in India: findings from the Global Adult Tobacco Survey 2009-2010. Indian J Cancer 2014; 51: S13-18.
69. Bansal-Travers M, Fong GT, Quah ACK, et al. Awareness of pro tobacco advertising and promotion and beliefs about tobacco use: f indings from the Tobacco Control Policy (TCP) India Pilot Survey. J Epidemiol Glob Health 2014; 4: 303-13
70. Singh SK, Schensul JJ, Kashyap GC. The reach of media to smokers and smokeless tobacco users in India: evidence from the global adult tobacco survey (GATS). J Pop Social Stud 2018; 26: 42-52.
71. Sinha DN, Bhartiya D, Kumar A, Singh H, Mehrotra R. Men in Myanmar submerged in tobacco: women following. Nicotine Tob Res 2017; 19: 1397-98.
72. Patel S, Rendell H, Maudgal S, Oswal K. Tobacco industry tactics with advertisements at the point of sale in Mumbai. Indian J Cancer 2013; 50: 245-49.
73. Arora M, Gupta VK, Nazar GP, Stigler MH, Perry CL, Reddy KS. Impact of tobacco advertisements on tobacco use among urban adolescents in India: results from a longitudinal study. Tob Control 2012; 21: 318-24.
74. Govil S, Dhyani A, Mall AS. Compliance assessment of tobacco vendors of Ahmedabad city to India's Tobacco control legislation. Indian J Community Health 2016; 28: 374- 77.
75. Singh PK. Smokeless tobacco use and public health in countries of South-East Asia region. Indian J Cancer 2014; 51: S1-2.
76. Tanski S, Emond J, Stanton C, et al. Youth access to tobacco products in the United States: findings from wave 1 (2013-2014) of the population assessment of tobacco and health study. Nicotine Tob Res 2019; 21: 1695-99.
77. Chin N, Dozier A, Quinones Z, et al. A qualitative study of tobacco use in eight economically disadvantaged Dominican Republic communities. Glob Health Promot 2017; 24: 23-32.
78. Harrell MB, Arora M, Bassi S, Gupta VK, Perry CL, Srinath Reddy K. Reducing tobacco use among low socio-economic status youth in Delhi, India: outcomes from project ACTIVITY, a cluster randomized trial. Health Educ Res 2016; 31: 624-38.
79. Konfino J, Ferrante D, Goldberg L, Caixeta R, Palipudi KM. Tobacco use among youths-Argentina, 2007 and 2012. MMWR Morb Mortal Wkly Rep 2014; 63: 588-90.
80. Htin Aung Myint MN, Yamamoto E, Ko MH, Khaing M, Reyer JA, Hamajima N. Knowledge, attitude, and usage pattern of tobacco among high school students in Nay Pyi Taw, Myanmar. Nagoya J Med Sci 2019; 81: 65-79.

81. Ahmad F, Khan Z, Siddiqi K, et al. Awareness perceptions of and compliance with tobacco control policies among naswar vendors in Khyber Pakhtunkhwa Pakistan. Tob Control 2022; 31: e111–17.

82. Periyasamy S, Krishnappa P, Renuka P. Adherence to components of health promoting schools in schools of Bengaluru, India. Health Promot Int 2019; 34: 1167–78.

83. Tobacco Control Cell Ministry of National Health Services, Regulations and Coordination, Government of Pakistan. Prohibition of smoking and protection of non- smokers health ordinance. 2002. http://tcc.gov.pk/downloads.php (accessed July 26, 2024)

84. Srikrishna SR, Rao M. Where now for tobacco control--the place for harm reduction and product regulation in UK tobacco control policy: a perspective from India. J Public Health 2009; 31: 13–14.

85. Gurung MS, Pelzom D, Dorji T, et al. Current tobacco use and its associated factors among adults in a country with comprehensive ban on tobacco: findings from the nationally representative STEPS survey, Bhutan, 2014. Population Health Metrics 2016; 14: 28.

86. Wei Hiong N, Hefler M. Singapore: ban on emerging tobacco products. Tob Control 2015; 24: 427–28.

87. Beaglehole R, Bonita R, Yach D, Mackay J, Reddy KS. A tobacco-free world: a call to action to phase out the sale of tobacco products by 2040. Lancet 2015; 385: 1011–18.

88. Parliament of the Democratic Socialist Republic of Sri Lanka. National authority on tobacco and alcohol. 2023.

https://www.nata. gov.lk/web/index.php?option=com_content&view=article&id=7&Ite mid=121&lang=en (accessed July 26, 2024).

89. Britton J. Should doctors advocate snus and other nicotine replacements? Yes. BMJ 2008; 336: 358

90. Kephart L, Setodji C, Pane J, et al. Evaluating tobacco retailer experience and compliance with a flavoured tobacco product restriction in Boston, Massachusetts: impact on product availability, advertisement and consumer demand. Tob Control 2019; 29: e71–77.

91. Sisk S. Chicago takes smokeless tobacco out of the park. CDS Rev 2016; 109: 14–16.

92. Michele Issel L, Bayha K, Nelson A. Implementation phase of the Tobacco-Free Parks Ordinance: a policy evaluation using photographic data. Public Health 2019; 167: 1–7.

93. More CB, Rao NR, Hegde R, Brahmbhatt RM, Shrestha A, Kumar G. Oral submucous fibrosis in children and adolescents: Analysis of 36 cases. J Indian Soc Pedod Prev Dent. 2020 Apr- Jun;38(2):190-199. doi: 10.4103/JISPPD.JISPPD_173_20. PMID: 32611867.

94. Jain YK, Bhardwaj P, Joshi NK, Singh PK, Lal P, Kapoor S, Gupta MK, Goel AD, Sharma PP, Singh S. India's environmental burden of tobacco use and its policy implications. The Lancet Regional Health-Southeast Asia. 2024 Jan 1;20.

95. Grilo G, Kaplan B, Cohen JE, et al. Tobacco product litter as a form of postconsumption marketing: an observational study in India Tobacco Control Published Online First: 12 January 2024. doi: 10.1136/tc-2023-058407.

96. Jain YK, Bhardwaj P, Joshi NK, Singh PK, Lal P, Kapoor S, Gupta MK, Goel AD, Sharma PP, Singh S. Estimating the weight of consumed tobacco product waste in various Indian states: a novel method to assess the potential burden of tobacco product waste. Tob Control. 2023 Sep 21:tc-2023-058118. doi: 10.1136/tc-2023-058118. Epub ahead of print. PMID: 37734958.

97. Wakefield M, Morley C, Horan JK, Cummings KM. The cigarette pack as image: new evidence from tobacco industry documents. Tobacco control. 2002 Mar 1;11(suppl 1):i73-80.

98. World Health Organization. Recommending plain tobacco packaging. 2023. Available: https://www.who.int /europe/health-topics/tobacco/recommending-plain-tobacco- packaging#tab=tab_1

99. Hoek J, Gendall P, Eckert C, Louviere J. Dissuasive cigarette sticks: the next step in standardised ('plain') packaging?. Tobacco control. 2016 Nov 1;25(6):699-705.

100. McNeill A, Bauld L, Hammond D, Hartmann-Boyce J. Tobacco packaging design for reducing tobacco use. Cochrane Database of Systematic Reviews. 2017(4).

101. Grilo G, Kaplan B, Cohen JE, Bhattacharya P, Mukherjee N, Welding K, Kennedy RD. Tobacco product litter as a form of postconsumption marketing: an observational study in India. Tobacco control. 2024 Jan 12.

102. Executive Summary—Preventing Tobacco Use Among Youth and Young Adults ... Available at: https://www.hhs.gov/sites/default/files/preventing-youth-tobacco-use-exec- summary.pdf.

103. Mehrotra R, Sinha DN. Global challenges in smokeless tobacco control. Indian Journal of Medical Research. 2018 Jul 1;148(1):1-3.

104. Murukutla N, Yan H, Wang S, Negi NS, Kotov A, Mullin S, Goodchild M. Cost- effectiveness of a smokeless tobacco control mass media campaign in India. Tobacco control. 2018 Sep 1;27(5):547-51.

105. Mehrotra R, Sinha DN, Szilagyi T. Global smokeless tobacco control policies and their implementation. Noida: National Institute of Cancer Prevention and Research. 2017. Available at: http://www.nicpr.res.in/images/Globalsmokeless-NICPR-imp19418-1.pdf

106. Croucher R, Shanbhag S, Dahiya M, Kassim S, Csikar J, Ross L. Smokeless tobacco cessation in South A sian communities: a multi-centre prospective cohort study. Addiction. 2012 Dec; 107:45-52.

107. ASTRA. (2021). SMOKELESSTOBACCO CESSATION IN INDIA [Report]. Available: https://www.astrasouthasia.com/wp-content/uploads/2020/12/Smokeless-Tobacco- Cessation-in-India-Factsheet.pdf

108. Nair S, Schensul JJ, Begum S, Pednekar MS, Oncken C, Bilgi SM, Pasi AR, Donta B. Use of smokeless tobacco by Indian women aged 18–40 years during pregnancy and reproductive years. PLoS One. 2015 Mar 18;10(3):e0119814.

109. Schensul JJ, Begum S, Nair S, Oncken C. Challenges in Indian Women's readiness to quit smokeless tobacco use. Asian Pacific journal of cancer prevention: APJCP. 2018;19(6):1561.

110. Verma P, Pandey P, Thakur A. Prevalence and determinants of tobacco consumption among pregnant women of three Central Indian Districts. Tropical Journal of Obstetrics and Gynaecology. 2017 Nov 3;34(2):99-106.

111. Chaudhary J, Gupta E, Singh PK, Singh S. Tobacco exposure among antenatal women in India: Challenges in tobacco screening & cessation counselling. Indian Journal of Medical Research. 2023 Nov 1;158(5&6):477-82.

References: Annexure I

1. Chandrupatla SG, Tavares M, Natto ZS. Tobacco use and effects of professional advice on smoking cessation among youth in India. Asian Pacific journal of cancer prevention: APJCP. 2017;18(7):1861.

2. Cui H, Zhang ST, Yang HJ, Ji H, Wang XJ. Gene expression profile analysis of tobacco leaf trichomes. BMC plant biology. 2011 Dec;11:1-0.

3. Sharma P, Cheah NP, Kaur J, Sathiya Kumar S, Rao V, Morsed FA, Choo MY, Murthy P. Physical and chemical characterization of smokeless tobacco products in India. Scientific Reports. 2023 Jun 1;13(1):8901.

4. Richter P, Spierto FW. Surveillance of smokeless tobacco nicotine, pH, moisture, and unprotonated nicotine content. Nicotine & Tobacco Research. 2003 Dec 1;5(6):885-9.

5. Nasrin S, Chen G, Watson CJ, Lazarus P. Comparison of tobacco-specific nitrosamine levels in smokeless tobacco products: High levels in products from Bangladesh. PLoS One. 2020 May 26;15(5):e0233111.

6. Stanfill SB, da Silva AL, Lisko JG, Lawler TS, Kuklenyik P, Tyx RE, Peuchen EH, Richter P, Watson CH. Comprehensive chemical characterization of Rapé tobacco products: Nicotine, un- ionized nicotine, tobacco-specific N - nitrosamines, polycyclic aromatic hydrocarbons, and flavor constituents. Food and chemical toxicology. 2015 Aug 1;82:50-8.

7. Al-Mukhaini NM, Ba-Omar TA, Eltayeb EA, Al-Shehi AH. Characterisation of nicotine and cancer-enhancing anions in the common smokeless tobacco Afzal in Oman. Sultan Qaboos University Medical Journal. 2015 Nov;15(4):e469.

8. Halstead MM, Watson CH, Pappas RS. Electron microscopic analysis of surface inorganic substances on oral and combustible tobacco products. Journal of Analytical Toxicology. 2015 Nov 1;39(9):698-701.

9. Verma S, Yadav S, Singh I. Trace metal concentration in different Indian tobacco products and related health implications. Food and Chemical Toxicology. 2010 Aug 1;48(8-9):2291-7.

10. Mehrotra R, Yadav A, Sinha DN, Parascandola M, John RM, Ayo-Yusuf O, Nargis N, Hatsukami DK, Warnakulasuriya S, Straif K, Siddiqi K. Smokeless tobacco control in 180 countries across the globe: call to action for full implementation of WHO FCTC measures. The lancet oncology. 2019 Apr 1;20(4):e208-17.

11. London ED. Patterns of nicotine action in the brain. Tobacco Control. 1994 Jun;3(2):101.

12. Henningfield JE, Heishman SJ. The addictive role of nicotine in tobacco use.

13. Benowitz NL, Porchet H, Sheiner L, Jacob III P. Nicotine absorption and cardiovascular effects with smokeless tobacco use: comparison with cigarettes and nicotine gum. Clinical Pharmacology & Therapeutics. 1988 Jul;44(1):23-8.

14. Oliver AJ, Jensen JA, Vogel RI, Anderson AJ, Hatsukami DK. Flavored and nonflavored smokeless tobacco products:

rate, pattern of use, and effects. Nicotine & Tobacco Research. 2012 Apr 22;15(1):88-92.

15. Kostygina G, Ling PM. Tobacco industry use of flavourings to promote smokeless tobacco products. Tobacco control. 2016 Nov 1;25(Suppl 2):ii40-9.

16. Lisko JG, Stanfill SB, Watson CH. Quantitation of ten flavor compounds in unburned tobacco products. Analytical Methods. 2014;6(13):4698-704.

17. National Tobacco Control Programme. The Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act, 2003 [COTPA 2003]. Ministry of Law and Justice, The Gazette of India Extraordinary, Part II, Section I, 19 May 2003. Available from: https://ntcp.nhp.gov.in/ cigarettes_and_ other_tobacco_products, accessed 11 June 2024

18. National Tobacco Control Programme. Cigarettes and other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Rules, 2004. Ministry of Health and Family Welfare, The Gazette of India, Extraordinary Part II, Section 3, Subsection (I), Notification GSR 137, 25th February 2004. Available from: https://ntcp.nhp.gov.in/cigarettes_and_other_ tobacco_products, accessed 11 June 2024.

19. Food Safety and Standards Authority of India. Repealed Acts/Orders: Prevention of Food Adulteration Act, 1954. Ministry of Health and Family Welfare, Government of India; 2022. Available from: https://fssai.gov.in/cms/repealed- acts-orders.php, accessed 11 June 2024

20. Gupta PC, Arora M, Sinha D, Asma S, Parascondola M, editors. Smokeless Tobacco and Public Health in India. New Delhi: Ministry of Health and Family Welfare, Government of India; 2016. Available from: https://nhm.gov.in/NTCP/Surveys- Reports-Publications/ Smokeless_Tobacco_and_Public_Health_in_India. pdf, accessed 11 June 2024.

21. Kumar N & Aggarwal & Partners, Advocates & Solicitors. Acts, 2016: The Prevention of Food Adulteration Rules 1955; Rule 44J, inserted by the PFA (8th Amendment) Rules, 2005, vide notification No GSR670 dated 17.11.2008. No Date. Available at: http://www.nkumaran daggarwal.com/acts/view-act.\ php?id=427&cat=29&title=The%20Prevention%20 of%20Food%20Adulteration%20Rules,%20 1955#a67, accessed 11 June 2024.

22. Food Safety and Standards Authority of India. Food Safety and Standards Act, 2006: Ministry of Law and Justice (Legislative Department), New Delhi, the 24th August, 2006. Ministry of Health and Family Welfare, Government of India; 2006. Available

from: https:// fssai.gov.in/cms/food-safety-and-standardsact2006.php, accessed 11 June 2024.

23. Ministry of Health and Family Welfare. Notification S.O. 1955 E for coming into force of the provisions of Section 7(1),(2),(3),(4), 8, 9, 10 and 20 of COTPA. Subsection ii. New Delhi, 16th November, 2007.

24. Supreme Court of India. Health for Millions Trust v. Union of India and Others, Writ Petition (Civil) 549 of 2008. Available from: https://www. tobaccocontrollaws.org/litigation/ decisions/ in20090506-health-for-millions-v.-union- o

25. Ministry of Information and Broadcasting (MIB). Cable Television Networks (Amendment) Rules, G.S.R. 138(E), 27 February 2009. LatestLaws.com, 2022. Available from: https://www.latestlaws.com/bareacts/centralacts-rules/media- laws/cable-televisionnet worksregulation- act1995/cable- televisionnetworksamendment-rules-2009, accessed 11 June 2024

26. Press Information Bureau (PIB), Ministry of Environment, Forest and Climate Change. The Plastic Waste (Management and Handling) Rules, 2011 Notified, 07 February 2011. New Delhi: Government of India; 2011. Available from: https://pib.gov.in/ newsite/ PrintRelease.aspx?relid=69649, accessed 11 June 2024.

27. M/s Tamil Nadu Scented and Chewing Tobacco Manufacturer's Association v. Union of India in Writ petition 9606/2007 and 5311/2008, High Court of Tamil Nadu

28. Goverment of India Ministry of Railways circular no 20011/TG.III/600/48, 2011 September 15

29. Food Safety and Standards Authority of India. The Food Safety and Standards (Prohibition and Restrictions on sales) Regulations, 2011. New Delhi: Ministry of Health and Family Welfare, Government of India; 2011-a. Available from: https://fssai.gov. in/cms/food-safety-and-standards-regulations.php, accessed 11 June 2024.

30. Ministry of Consumer Affairs, Food & Public Distribution (MCAFPD), Government of India. The Legal Metrology Act 2009 (Packaged Commodities) Rules, 7 March, 2011. Department of Consumer Affairs. Available from: https://consumeraffairs.nic.in/acts- and-rules/ legal-metrology/the-legal-metrologyact-2009, accessed 11 June 2024.

31. Food Safety and Standards Authority of India. The Food Safety and Standards (Packaging and Labelling) Regulations, 1 August, 2011. New Delhi: Ministry of Health and Family Welfare, Government of India; 2011-b. Available from: https://fssai.gov.in/cms/ foodsafety-and-standards-regulations.php, accessed 11 June 2024.

32. Food Safety and Standards Authority of India. The Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 1 August, 2011. Ministry of Health and Family Welfare, Government of India; 2011-c. Available from: https://fssai.gov. in/cms/food-safety-and-standards-regulations.php, accessed 11 June 2024.

33. National Tobacco Control Programme. Cigarettes and Other Tobacco Products (Prohibition ofAdvertisement, Regulation of Trade and Commerce, Production, Supply and Distribution) Amendment Rules, 2011. Notification on Section-6(a) of the Act, No. GSR 619(E), 11 August, 2011. Ministry of Health and Family Welfare, Government of India. Available from: https://ntcp.nhp.gov.in/cigarettes_and_other_ tobacco_products, accessed 11 June 2024.

34. Ministry of Law and Justice. The Juvenile Justice (Care and Protection of Children) Act, 2015 (Act no. 2 of 2016), The Gazette of India, Extraordinary, Part II, Section 1, 1 January, 2016. New Delhi: Government of India. Available from: http://cara.nic.in/PDF/JJ%20 act%202015.pdf, accessed 11 June 2024.

35. Central Board of Indirect Taxes and Customs – Goods and Services Tax. GST Rates; Goods Rates Booklet, 03-July-2017, p 138. New Delhi: Department of Revenue, Ministry of Finance, Government of India; 2021. Available from: https://cbic- gst.gov.in/ gstgoods- services-rates.html, accessed 11 June 2024.

36. John RM, Dauchy E, Goodchild M. Estimated impact of the GST on tobacco products in India. Tob Control. 2019;28(5):506–12. doi: 10.1136/ tobaccocontrol-2018-054479.

37. Chauhan G. Licensing tobacco vendors in the state of Himachal Pradesh in India - challenges, opportunities and the way forward to implement the new legislation. Tob Induc Dis 2018;16.

38. National Tobacco Control Programme. Tobacco Testing, National Tobacco Testing Laboratory. Ministry of Health and Family Welfare, Government of India; 2019. Available from: https://ntcp.nhp.gov.in/ tobacco_testing, accessed 11 June 2024

39. Centre urged to ban 15 pan masala brands. Times of India; 14 October 2019. Available from: https:// timesofindia. indiatimes. com/ city/ patna/ centre- urged- to- ban- 15 - pan- masala brands/ articleshow/71569709.cms, accessed 11 June 2024.

40. Government of India. Ministry of Home Affairs Order . 15 April 2020 Available from: https://www. mha.gov.in/sites/default/files/MHA%20order%20 dt%2015.04.2020% 2C%20with%20Revised%20 Consolidated%20Guidelines_compressed%20%283%29.pdf

41. Ministry of Environment, Forest and Climate Change. Notification No G.S.R. 571 (E), New Delhi; 12 August 2021. The Gazette of India: Extraordinary. Available from: https:// static. pib. gov. in/ Write Read Data/ specificdocs/documents/2021/aug/doc202181311. pdf, accessed 11 June 2024

42. Ministry of Health and Family Welfare. The Gazette of India: Extraordinary. Available from:

https://ntcp.mohfw.gov.in/assets/document/Cigarettes%20and%20other%20Tobacc o%20Products%20 (Prohibition%20of%20Advertisement%20and%20Regulation%20of %20Trade%20and %20Commerce, %20Production,%20Supply%20and%20Distribution) %20Amendment%20Rules,%202023.pdf, accessed 10 June 2024.

43. Ministry of Health and Family Welfare, Operational guidelines for establishing tobacco cessation centres in Medical institutes. Available from: https:// ntcp. mohfw. gov. in/ assets/ document/ Guideline- manuals/ Operational%20Guidelines %20for%20Establishing %20Tobacco%20Cessatio n%20Centres%20in% 20Medical%20Institutions.pdf. Accessed 10th June 2024.

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.

6. References:

(1). Swasticharan L, Arora M, Sinha P, Ray CS, Munish VG and Shrivastav R, Editors. Report on Tobacco Control in India 2022 (Vol 2). Ministry of Health and Family Welfare, Government of India.

(2). Academike. Article 21: Understanding The Right to Life and Personal Liberty from CaseL a w s - Academike Explainer. Available at https://www.lawctopus.com/academike/ article-21-of-the-constitution-of-india-right- to-life-and-personal-liberty/. Accessed on 16th March 2024.

(4). Mahesh Bhatt v. Union of India, WP(C) No. 18761/2005; 147 (2008) DLT 561

(5). Health for Millions v. Union of India, Writ Petition (Civil) 549 of 2008; (2014) 14 SCC 496.

(6). Union of India Vs Mahesh Bhatt, (SLP(C) No. 8429-8431 of 2009)