

# Compliance to Gutka ban and other provisions of COTPA in Mumbai

## Original Article

Pimple S, Gunjal S, Mishra GA, Pednekar MS<sup>1</sup>, Majmudar P, Shastri SS

Department of Preventive Oncology, Tata Memorial Centre, <sup>1</sup>Healis Sekhsaria Institute of Public Health, Navi Mumbai, Maharashtra, India

Correspondence to: Dr. Sharmila Pimple, E-mail: [pimplesharmila@gmail.com](mailto:pimplesharmila@gmail.com)

### Abstract

**BACKGROUND:** Cigarettes and other tobacco products act 2003 (COTPA) is the principal law governing tobacco control in India. Government of Maharashtra in one of its landmark decisions also banned manufacturing, sale and distribution of *gutka* and *pan masala* since July 2012. The desired impact and level of enforcement of the COTPA legislation and the *gutka* and *pan masala* ban in Maharashtra State, however, needs assessment. Among the many provisions within COTPA, the present study seeks to assess compliance to implementation and enforcement of Section 5 and 6 of COTPA including compliance to *gutka* and *pan masala* ban in Mumbai, India. **METHODOLOGY:** Six educational institutes (EI) within the Mumbai metropolitan region were selected in a two stage random sampling process. Area around each EI was manually mapped and all the tobacco products selling outlets within the 100 yards distance were listed by trained Field Social Investigators and were observed to determine compliance for Section 5 and Section 6 of the COTPA legislation and for *gutka* and *pan masala* ban. The vendors/shop owners manning these outlets were also interviewed for their personal sociodemographic details, self-tobacco use, awareness and perception about ill-effects of tobacco and existing tobacco control legislation in the country. **RESULTS:** A total of 222 tobacco retail outlets were listed within 100 yards of the EI in violation to the provisions of Section 6 of COTPA, of which 72 (32.4%) were selling tobacco products on mobile structures. About 53.2% of the tobacco vendors were also users of some form of tobacco. Whereas, nearly 217 (97.7%) vendors were aware about the *gutka* and *pan masala* ban in the State, only 48.2% were aware about the existence of COTPA legislation. None of the EI had a display board prohibiting the sale of tobacco products within a radius of 100 yards of their EI. Only 56.3% tobacco outlets had complied with the mandatory warning display boards indicating tobacco products will not be sold to people below 18 years of age. With regards to point of sale advertisement only 25.2% compliance was noted for display of health warning boards at the point of sale. Nearly 48.6% tobacco outlets exhibited >2 display boards and another 43.2% exhibited hoardings with brand pack photo, brand name in violation to the provision under Section 5. Violation by visible stacking and open display of tobacco products for sale was observed at 51.3% of tobacco outlets. While 41% of tobacco outlets were found displaying *gutka* and *pan masala* packets in violation to the ban. **CONCLUSIONS:** Enacting of the law without robust measures for enforcement has led to widespread noncompliance to the provisions within the tobacco control legislation in the metropolitan city of Mumbai. Strong and sustainable measures need to be incorporated both by civic administration and public health departments for its forceful implementation.

**Key Words:** Cigarettes and other tobacco products act, compliance, *gutka* and *pan masala* ban, tobacco legislation

### Introduction

Increasing use of tobacco in developing countries is contributing immensely towards the rising burden of tobacco-related illnesses and premature deaths in these regions. Alarming increase in the use of tobacco among children, adults and other vulnerable sections of societies represents a great concern to public health local and the national level.

Tobacco is becoming one of the single biggest causes of death worldwide. India is especially impacted by tobacco epidemic with its geographically diverse and heterogeneous smokeless and smoking forms of tobacco use. There are almost 275 million tobacco users in India. Among the adults age group of 15 years and above, over one third (35%) of the population use tobacco products, with 48% of males and 20% of females using some form of tobacco.<sup>[1]</sup> The largest impact of tobacco related disease burden is increasingly affecting the low-middle-income countries like India where each year tobacco use kills about one million Indians and where it remains a serious public health challenge not only resulting in substantial disability, disease and death, but also increasing the social and economic costs of health care in limited health resource settings.<sup>[2]</sup> The Millennium Development Goals too, though does not include an explicit target for reducing

tobacco use, explains how reducing tobacco consumption could contribute and improve the goals related to health outcomes, poverty and hunger in the low-middle income settings.

Effective comprehensive tobacco control laws that can impact reduced consumption are needed. Tobacco legislation in India dates back to 1975 when the Cigarettes (Regulation of Production, Supply, and Distribution) Act, was enacted, which made it mandatory to display a statutory health warning on all packages and advertisements of cigarettes. The Cigarettes Act, 1975, failed to accomplish much because it was not comprehensive in its coverage and was feeble in its provisions.<sup>[3]</sup> This was followed by a new legislation, the cigarettes and other tobacco products act (prohibition of advertisement and regulation of trade and commerce, production, supply, and distribution) 2003 (COTPA), which is the principal law governing tobacco control in India, being more comprehensive covering all tobacco products, including cigarettes for the control of tobacco.<sup>[4]</sup> The above law, is intended to protect and improve public health, by making provisions of evidence-based strategies under the law to reduce tobacco consumption.<sup>[3]</sup> The Act was passed before India became signatory to the World Health Organization (WHO) Framework Convention on Tobacco Control on February 5, 2004.

Again in one its major steps towards antitobacco movement in the state, the Government of Maharashtra banned manufacturing, sale and distribution of *gutka* and *pan masala*, by getting both these items classified as food to come under the purview of the Food Safety and Standards Act 2006 (FSSA). The ban came into force in July 2012 and was successfully upheld by the Bombay High Court for a further extension of one-year till July 2014 in Maharashtra.<sup>[5]</sup>

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However, the desired impact and level of enforcement of the COTPA legislation and the *gutka* and *pan masala* ban in Maharashtra State needs assessment. Among the many provisions with in COTPA our study looked into the compliance to implementation and enforcement of Section 5 and Section 6 of the COTPA legislation with respect to point of sale advertisement of tobacco, prohibition of sale of tobacco products to and by minors and prohibition of tobacco products selling outlets within 100 yards of the selected educational institutes (EI), including compliance to the *gutka* and *pan masala* ban in Mumbai.

## Methodology

This community based cross-sectional study was designed to assess compliance to the provisions made for tobacco control under COTPA specifically with respect to Section 5 for point of sale advertisement of tobacco, and under Section 6 for prohibition of sale of tobacco products to and by minors and prohibition of tobacco products selling outlets within 100 yards of the EI. The study also assessed the knowledge, perceptions and practices towards tobacco use, awareness about harmful effects of tobacco consumption and knowledge about the COTPA legislation and provisions with-in the same among the tobacco vendors outside these EI.

## Design

In order to achieve the above objectives, EI within the Mumbai metropolitan region were selected in a two stage random sampling process to conduct the study. Mumbai city is divided into 29 administrative wards. Six administrative wards were randomly selected and EI imparting secondary and higher secondary education within each of these randomly selected wards was enumerated obtaining the list of these institutes from the Education department of Mumbai Municipal Corporation. One EI each from each of these six administrative wards was selected by random sampling to be representative of the population and region. This being an exploratory study power estimates were not calculated.

The mandatory research study approvals were obtained from the institutional scientific and ethics committees, respectively. Paramedical staff comprising of Medical Social Workers were recruited and trained for in-depth understanding of tobacco-related health problem, the specifications and provisions for tobacco control in the tobacco legislation, conducting the community surveys, identifying tobacco selling outlets, tobacco vendor mapping, administering Informed consent and undertaking vendor interviews with pretested structured questionnaires.

Area around each selected EI was then manually mapped to cover 100 yards distance measured radially starting from the outer limit of the boundary wall of the EI, to identify and enlist all the outlets selling tobacco and/or tobacco products in the vicinity of the EI. All the tobacco products selling outlets with in this 100 yards distance were mapped for their exact location with distance from EI and then enlisted for the study purpose.

This study applied manual mapping of tobacco outlets combining the current location maps obtained from the Indian Journal of Cancer | Dec 2014 | Volume 51 | Supplement 1

municipal authorities along with the physical investigation by trained Field Social Investigators conducted on two separate occasions to measure the spatial density of tobacco selling outlets to obtain accurate number and exact geographic location within the radius of 100 yards of the randomly select EI [Figure 1].

The study field investigators made two rounds of observation on two random days with in the 100 meters radius to locate the tobacco vendors, noting and listing along with marking exact locations on the manually drawn vendor location maps, and the highest number noted was listed for study purpose. The vendors/shop owners manning these outlets were enumerated and after taking informed consent for participating in the study were interviewed by the project staff for their personal sociodemographic details, self-tobacco use, awareness and perception about ill-effects of tobacco and existing tobacco control law in the country. The project interviewers at the time of vendor interviews also observed the tobacco outlets/establishments and recorded details pertaining to the compliance to Section 5 and 6 of the COTPA and violations under *gutka* and *pan masala* ban as addressed in the objectives. The confidentiality and privacy of the participant's responses were maintained as per the norms prevalent at the institute.

Data collected was entered and analyzed using SPSS version 18. Both descriptive and inferential statistics were generated for describing sociodemographic variables associated with the tobacco vendors, tobacco selling outlets and assessing awareness about ill-effects of tobacco and tobacco legislation in the country among the tobacco vendors.

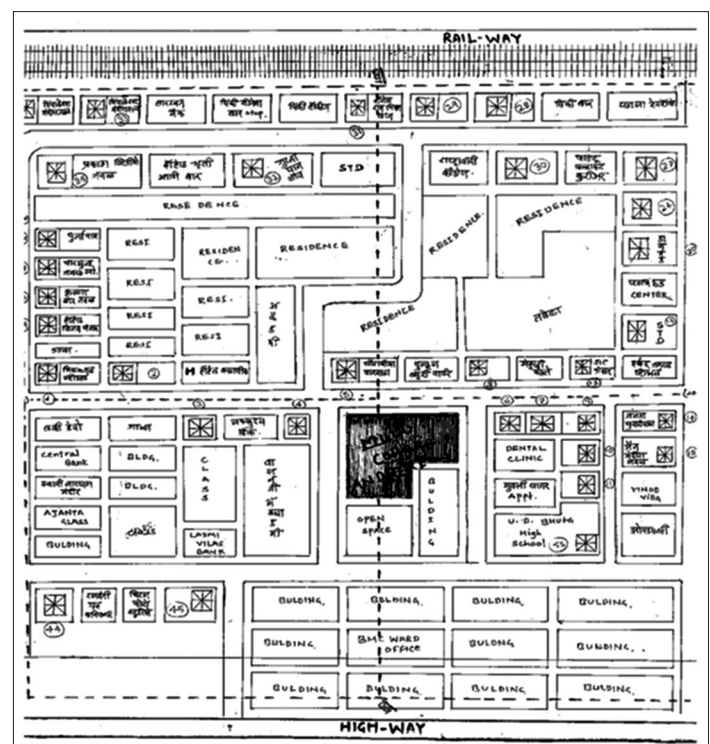


Figure 1: Manual mapping of 100 yards around the EI with listing and numbering of the tobacco outlets

## Results

### Tobacco selling outlets

The study team mapped and listed 222 tobacco outlets within the 100 yards distance of the sampled EI. Among the tobacco outlets 75.2% were exclusively selling various smokeless and smoked tobacco products, other 24.8% were operating as general stores. Nearly 83.8% of the tobacco selling outlets were existing for >10 years against 16.2%, which were operating for <10 years. With regards to structure of tobacco outlets, around 32.4% of tobacco selling outlets were with temporary or mobile makeshift structures (products on display and sale on hand drawn carts, on bicycles etc.,) against 67.6% with permanent structure [Table 1].

### Profile of tobacco vendors

Of the total 222 tobacco vendors selling tobacco products outside the EI, 96.4% were males whereas 3.6% outlets were operated by females. About 28.4% were below 30 years of age, 51.8% were between 30 and 50 years and rest 19.8% were above 50 years, but none was minor. Only 19.8% were illiterate where as 30% had higher secondary and above educational qualification. On enquiry about self-tobacco consumption, 53.2% were consuming some form of tobacco and among these tobacco users, 77% were smokeless tobacco users and only 16% were smokers [Table 2].

Assessment for knowledge about ill-effects of tobacco and awareness about tobacco laws and provisions within the legislation showed that 90% of tobacco vendors were aware about tobacco use being harmful effects to health. Among the 200 vendors who aware about the harms to health, 187 (84.2%) vendors narrated cancers as one of the diseases caused by tobacco consumption, followed by Cardiovascular (18.5%) and respiratory diseases (18.1%).

With regards to knowledge about tobacco legislation, only 107 (48.2%) were aware about the existence of COTPA legislation, whereas 217 (97.7%) vendors were aware about the *gutka* and *pan masala* ban in the State. When asked about the specific provisions with in the COTPA pertaining to Section 5 and 6, 82.9% were aware that no tobacco product can be sold to any person under the age of 18 years, 70.3% were also aware about tobacco products cannot be sold by children below 18 years of age. About 76.6% tobacco vendors were knowledgeable about the provision with in COTPA that they cannot sell cigarette or tobacco products around 100 yards around any EI. About the requirement of health warning boards at the point of sale 49% of vendors admitted to being aware about the same. On enquiry 42.8% vendors said law enforcing authorities visited their shop at least once for inspection.

### Compliance/violations to Section 6: Cigarettes and other tobacco products act

The study team manually mapped 100 yards area around EI and listed 222 tobacco selling outlets around the sampled EI in violation to the provisions of Section 6 of COTPA. All the 222 tobacco selling outlets were observed for compliance to other provisions with in Section 5 and 6 of

**Table 1: Baseline characteristics of tobacco vendors and tobacco selling outlet**

	n=222	Percentage
Tobacco vendors		
Age groups		
Below 30 years	63	28.4
30-50 years	115	51.8
>50 years	44	19.8
Sex		
Male	214	96.4
Female	8	03.6
Education categories		
Illiterate	44	19.8
Primary (1-4)/secondary (5-10)	127	57.2
Higher secondary and above (12)	51	30.0
Self-tobacco product consumption (current)		
Yes	118	53.2
No	104	46.8
Forms of tobacco use by vendor (n=118)		
Smoking forms	19	16.1
Smokless forms	91	77.1
Mixed form	8	6.8
Total	118	
Tobacco outlets		
Type of tobacco outlet		
Exclusive tobacco products vendor	167	75.2
General store	55	24.8
Duration of existence of tobacco outlets		
<10 years	36	16.2
10-30 years	121	54.5
>30 years	65	29.3
Structure of tobacco outlets		
Permanant	150	67.6
Mobile	72	32.4

the COTPA legislation and for *gutka* and *pan masala* ban. The tobacco vendor density for each EI has been listed in Table 3. None of the EI had a display board outside their respective institutions declaring the sale of tobacco products is prohibited in an area within a radius of 100 yards of their EI. Only 125 tobacco outlets (56.3%) had complied with the mandatory display boards with warning indicating tobacco products will not be sold to people below 18 years of age. None of the tobacco outlets had any person who was below 18 years of age selling tobacco products [Table 3].

### Compliance and violations to Section 5: Cigarettes and other tobacco products act; point of sale advertisements

Tobacco outlets were also observed for compliance to Section 5 of COTPA with regards to point of sale advertisement. Only 25.2% compliance was noted for presence of health warning (Tobacco causes cancer or Tobacco kills) on the top edge of the display boards at the point of sale. Display of exterior hoardings advertising tobacco products measured more than the permissible limits of measurement for display (60 cm × 45 cm) at 51.8% of the outlets. Nearly 48.6% tobacco outlets exhibited >2 display boards and another 43.2% exhibited hoardings with brand pack photo,



**Table 2: Awareness about ill effects of tobacco and tobacco legislation in the country**

Characteristics (n=222)	Frequency	Percentage
Knowledge about tobacco use in any form being harmful to health		
Yes	200	90.1
Do not know	22	9.9
Knowledge about tobacco use as risk factor for any diseases		
Cancer	189	85.1
Cardiovascular disorders	41	18.5
Respiratory diseases	40	18.1
Awareness about COTPA 2003		
Yes	107	48.2
No	115	51.8
Awareness about <i>gutka</i> and <i>pan masala</i> ban in the state		
Yes	217	97.7
No	05	02.3
Knowledge about the major provisions with respect to Section 5 and 6 of COTPA		
Cannot sell cigarettes or tobacco products to people below 18 years of age?		
Yes	184	82.9
No	38	17.1
Cannot sell cigarette or tobacco products around 100 yards area of an EI?		
Yes	170	76.6
No	52	23.4
Tobacco products cannot be sold by Children below 18 years of age		
Yes	156	70.3
No	66	29.7
Presence of health warning boards at point of sale		
Yes	109	49.0
No	113	51.0

COTPA=Cigarettes and other tobacco products act; EI=Educational institutes

brand name and other promotional message in violation to the provision under Section 5. Violation by visible stacking and open display of tobacco products for sale was observed at 51.3% of tobacco outlets [Table 3].

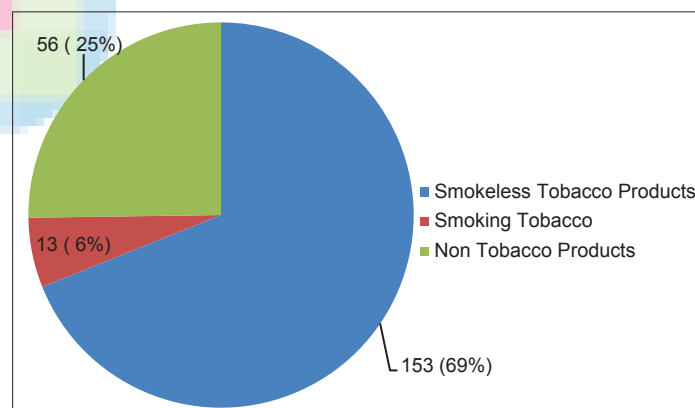
### Compliance/violations to *gutka* and *pan masala* ban

Violations under the recent *gutka* and *pan masala* ban were also noted during the study survey with 91 (41%) tobacco outlets displaying and therefore selling *gutka* and *pan masala* packets for sale. Apart from these 91 outlets noted for violation another 29 tobacco selling outlets though were not found to display *gutka* and *pan masala* products, as a surrogate marker were observed by study investigators for evidence in the form of empty *gutka* and *pan masala* sachets in front of these outlets probably indicating sale of these prohibited products without displaying the same.

On account of the *gutka* and *pan masala* in the state, tobacco vendors were asked for the substitutes demanded by the customers for the same Figure 2. The study noted 153 (69%) asked for other smokeless tobacco products, 13 (6%) turned to smoking forms of tobacco and only 56 (25%) shifted to non-tobacco products.

### Discussion

India's commitment to tobacco control in the country dates back to the Cigarettes Act in 1975. However, the implementation of COTPA and the recent *gutka* and *pan masala* ban in the state needed assessment since its enforcement across country remains variable and has been highly ineffective in most parts of the country.



**Figure 2: Substitutes demanded for *gutka* and *pan masala* by customers (n = 222)**

Our study examined the extent of compliance for specific provisions within Section 5 and 6 of the COTPA regulation and the recent *gutka* and *pan masala* ban around randomly selected EI in Mumbai. The present study enumerated around 222 tobacco vendors within 100 yards of selected EI, in violation of the provisions of Section 6 in COTPA. The study data reflects on the complete lack of regulation and enforcement of the provisions within the law not only in terms of evacuating and displacing the old existing tobacco outlets, but also the inability on the part of the competent authorities to prohibit the establishment of newer outlets within the restricted zones.

Besides the fixed permanent outlets selling tobacco products, one striking finding by our study was the finding

**Table 3: Observed compliance of tobacco selling outlets to the Section 5 and 6 of the COTPA legislation and gutka pan masala ban (total tobacco outlets n=222)**

Compliance/violations to Section 6: COTPA	Frequency	Percentage
Violations of law with presence of tobacco selling outlets with-in 100 yards of six EI	222	100.0
EI 1	45	20.27
EI 2	29	13.06
EI 3	34	15.32
EI 4	41	18.47
EI 5	40	18.02
EI 6	33	14.86
Compliance to presence of appropriate signage outside EI, prohibiting sale of tobacco products with in 100 yards of EI (n=6)	Nil	00.00
Compliance to the signage requirement for presence of display board 60 cm×30 cm on tobacco shop displaying the warning prohibiting sale of tobacco products to persons below 18 years	125	56.3
Compliance/violations to Section 5: COTPA point of sale advertisements		
Compliance to presence of health warning (tobacco causes cancer, or tobacco kills) on the top edge of the display boards at the point of sale	56	25.2
Violation by exhibiting exterior hoardings advertising tobacco products measuring more than the prescribed dimensions (60 cm × 45 cm)	115	51.8
Violation by exhibiting more than two boards at one point of sale	108	48.6
Violation by exhibiting hoardings with brand pack photo, brand name and other promotional message	96	43.2
Violation by open display of tobacco products at tobacco outlets	114	51.3
Compliance/violations to gutka and pan masala ban		
Violation by display of gutka and pan masala packets for sale in tobacco outlets	91	41.0
Violation by selling gutka and pan masala products (surrogate marker observation of empty gutka and pan masala packets found around tobacco outlets)	29	13.10
Visit by law enforcing authorities to the shop	95	42.8

EI=Educational institutes; COTPA=Cigarettes and other tobacco products act

of around 32% mobile tobacco selling outlets with tobacco products mounted on bicycles and hand driven carts in the restricted periphery of the EI. The existence of such mobile outlets by the day certainly raises additional concerns and challenges, which the law implementing authorities need to comprehend since these mobile tobacco selling outlets easily tend to escape from the law enforces by managing to hide from being noticed or quickly escape during patrolling. Such mobile structures calls for stricter enforcement by concerned authorities. The Department of Health in the State Government is the nodal agency to implement this provision. Governments have notified various authorities including Municipal Corporation, Police and the Food and Drug Administration etc., who can be responsible to act under this section. The above findings only highlight the lack of any such authority taking any pertinent measures to prevent the mushrooming of both the permanent as well as movable tobacco outlets with in the restricted zone.

The assessment of tobacco vendors themselves shows high prevalence (53.2%) of tobacco consumption with majority consuming smokeless tobacco products. High level of awareness about the harmful effects of tobacco and tobacco as a risk factor for cancers and heart diseases was also noted among these tobacco vendors, knowledge of which was attributed to exposure to health warnings and advertisement on harmful effects of tobacco on radio and television channels by government agencies.

Most of tobacco vendors (97.7%) knew about the passing of gutka and pan masala ban in the State. With respect to the tobacco legislation (COTPA), though only 48% knew about the existence of the national legislation on tobacco,

>70% of tobacco vendors were aware about the major provisions with in Section 5 and 6 of the COTPA. This shows that information and communication about the major provisions with in COTPA through appropriate government channels coupled with strict enforcement can bring about the desired change. Empowering the civil society including school authorities to report violation is equally important for a sustained campaign to enforce the law.

#### Compliance to Section 5 and 6 of cigarettes and other tobacco products act

Over all our study findings demonstrated poor compliance to both Section 5 and 6 of COTPA. With regards to compliance to Section 6 of COTPA, none of the selected EI in our study had displayed appropriate signage outside, prohibiting sale of tobacco products within 100 yards. In a similar observational study undertaken to assess the status of enforcement of Sections 6 of COTPA in two different jurisdictions (in Delhi and Tamil Nadu) only 24% in Delhi and 10% in Tamil Nadu displayed such a board at a noticeable place outside the institution reports the study. This brings into focus the lack of much needed inter sectoral coordination to involve the education department, one of the major stake holders in enforcing the provisions of the law.<sup>[6]</sup>

Though our study did not find any person below the age of 18 years selling tobacco products, nearly 25% of the tobacco sellers admitted to selling tobacco to minor children, which could be an underestimate and is alarming in the back drop of the rising prevalence of tobacco consumption among 13–15 years age group in various Indian States with Global Youth Tobacco Survey (GYTS)

linking study (2006–2009) highlighting that the sale of tobacco and tobacco products to minors does not show any decline over three years (GYTS linking paper). In a similar observational study cum survey for compliance to COTPA in the state of Odisha, India between May and December, 2011, 36.6% of the respondents had “very often” seen tobacco products being sold to a minor.<sup>[7]</sup> Study from Delhi and Tamil Nadu states reported 16% and 4% of tobacco vendors respectively were observed selling tobacco to minors.<sup>[6]</sup>

Though our study reported 56% compliance for display of warning boards against sale of tobacco products to minors, these boards either did not comply to the size specifications or often not easily visible. Among the observational studies in Delhi and Tamil Nadu, only 32% in Delhi and only 1% of the shops in Tamil Nadu prominently displayed the specified warning boards (6).

Point of sale advertisement of cigarettes or any other tobacco product displayed at the entrance or inside a warehouse or a shop where they are offered for sale is permitted as per the Indian legislation, but the hoardings larger than prescribed (60 cm × 45 cm) at the point of sale, and >2 boards at one point of sale constitutes violation as per the recent 2006 notification.

However, there remains a lot of ambiguity on the number of boards, the exact size and area of placement of the health warnings on these boards giving enough scope for tobacco industry players to exploit the same for their benefit. Observation of point of sale boards over various shops in various cities in India between 2005 and 2006 reports blatant violation of point of sale advertisements after the implementation of the Act. Tobacco advertisement boards satisfying the point of sale requirement were almost nonexistent in the cities.<sup>[8]</sup>

#### Compliance/violations to gutka and pan masala ban

The Maharashtra state government banned *gutka* and *pan masala* across the state from July 20, 2012. And the ban was extended for another 12 months till July 2014. The states earlier attempts to ban *gutka* in 2002 and then in 2008, had met with technical and legal hurdles. These hurdles were overcome after both flavored tobacco products fell within the definition of “food” under the FSSA, and the Commissioner of Food and Drugs Administration had the power to ban them. Our study results point toward 41% violations with display of *gutka* and *pan masala* packets for sale in the tobacco outlets again and as pointed earlier the study looked for surrogate evidence of *gutka* and *pan masala* use with 13% tobacco outlets seen with empty sachets of these products around these shops, which could be an underestimate of the illegal sale of these banned products in circulation.

In an attempt to understand the substitutes demanded by the consumers for these banned products, nearly 69% demanded other smokeless tobacco products and another 6% shifted to smoking tobacco. The above findings are alarming and bring to the fore the enormous addiction potential of these products with 75% of them maintaining

the habit with other tobacco substitutes. Whereas the 25% shift towards non-tobacco products points towards the potential of strong enforcement to wean away tobacco users from tobacco products and also the high sustainable impact of good ground level implementation of legislation in protecting public health, the environment, the anticipated reductions in tobacco use, and tobacco related disease morbidity and mortality.

With respect to COTPA regulation another study conducted in Assam reported lack of complete information and awareness of the Act, public opposition, cultural acceptance of tobacco use, lack of political support, and less priority for tobacco control as perceived barriers for implementation of COTPA in the state.<sup>[9]</sup>

Given the addiction potential of the *gutka* and *pan masala* and over all other tobacco products it not only calls for stringent enforcement and heavy penalty for violators but also calls for adequate state level measures to create sustainable health awareness campaigns to prevent initiation and use of tobacco and making tobacco cessation facilities more accessible to the communities.

#### Conclusion

Though antitobacco activism, national policies and political will to an extent is helping bring in antitobacco legislation in the larger interest of public health, accountability and ownership for robust and sustainable enforcement measures for implementing tobacco legislation are needed to plug the loopholes in the implementation and enforcement mechanisms. Poor implementation results in failure to achieve the projected health benefits of tobacco control for the population. Furthermore, multiple law enforcement agencies do not necessarily ensure proper enforcement. Inspection and enforcement with designated roles and responsibilities and dedicated manpower with appropriate penalty entrusted with single agency is needed for sustainable long term impact. Active measures that influence population behavior and empowers civil society also needs consideration to denormalize tobacco use in the general population.

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