

Title: Regulatory compliance of health warnings on tobacco packs in Karnataka, India

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ABSTRACT

Introduction: In September 2014, the Government of India introduced legislation requiring all tobacco packaging to display a health warning covering 85% (60% pictorial, 25% text) of the principal display area of the pack, of at least 4 cm in height and 3.5 cm width, with legible text in a white font on a black background and in English and / or the same Indian language as the language used on the pack. We evaluated compliance with this legislation in the Udupi district of Karnataka, India.

Methods: We procured one example of every tobacco pack of cigarettes, beedis, chewing tobacco and snuff sold by a convenience sample of retailers in one urban and two rural areas in each of the five administrative blocks of the Udupi district between June to August 2018. For each pack we measured the size of the health warning, calculated the proportion of the pack covered, and assessed the legibility.

Results: A total of 365 packs were collected from retailers, with 357 of these branded and eight, all packs of snuff, unbranded. Warnings on 320 (87.3%) packs did not reach the legally required proportional magnitude, warnings on 140 (38.4%) packs were not legible, and warnings on 117 packs (32.1%) did not meet the language requirement. Only 45 packs (12.3%) were fully compliant.

Conclusions: Compliance with warning legislation in this district of India is low, highlighting the need for more effective enforcement.

Implications: Warnings on tobacco packaging are an important and inexpensive means of communicating the harms associated with tobacco use. However, relatively few studies have explored regulatory compliance with warnings. We collected all unique tobacco packs from 66 retailers in a district in Karnataka in India and assessed whether each met the legislative requirements in terms of warning size and proportion of the pack covered, legibility, and the language used. Of the 365 packs collected, only one in eight was compliant with the

legislative requirements. This study highlights the importance of assessing warning compliance and the need for enforcement in India.

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Introduction

Tobacco is used by over one quarter of adults in India, with 7% using combustible tobacco (cigarettes and beedis), 18% smokeless tobacco, and 3% more than one form of tobacco.¹ One in three persons in rural areas and one in five persons in urban areas use any form of tobacco¹, making effective tobacco control policies a priority for public health. Health warnings on tobacco packs represent one of the most cost-effective ways to communicate the hazards of tobacco use to consumers, and the Framework Convention on Tobacco Control recommends that these warnings include a picture and text which together occupy at least 50% of the main surface areas of packs.² Current evidence suggests that larger warnings help increase salience, recall and perceptions of risk and health knowledge, and are rated as having a greater impact.³

The Government of India implemented the Cigarettes and other Tobacco Products Act (COTPA) in 2003,⁴ and in 2006 stipulated that tobacco packs should carry pictorial health warnings occupying 50% of both sides of the pack, though tobacco company litigation reduced the size of the warning to 40% and delayed the implementation of this stipulation until 2009.⁵ In 2014, a new amendment to COTPA required pictorial health warnings to cover at least 85% of both sides of packs,⁶ although in 2015 the Government postponed the introduction of these warnings to hold further discussions with stakeholders, and it was not until April 1st 2016 that they appeared on packs.

The COTPA law includes three Sections of the act relevant to health warnings: Sections 7, 8 and 9. Section 7 requires a health warning to be displayed on 85% of the front and back of packs. Section 8 provides details related to legibility of the health warning, stipulating that the warning must be clear, at least 4 cm in height and 3.5 cm in width, with the word 'WARNING' in white on a red background and the warning messages "Smoking causes throat cancer" or "Tobacco causes mouth Cancer" in white on a black background.

Section 9 requires the language of the health warning to be in English and / or the same Indian language as the language used on the pack. If the language used on the pack is foreign then the warning has to be in English, unless the language used is partly foreign and partly one of the Indian languages, in which case the warning would need to be in English and one of the official Indian languages.⁴

A Study of compliance with the COTPA health warning requirements has indicated that while factory-made cigarette packs have tended to be compliant, this is often not the case for packs of beedis or smokeless tobacco.⁷ In this study we evaluated compliance of tobacco packs collected in the Udupi district of Karnataka with the provisions in COTPA specific to health warnings. Udupi recently self-declared as highly COTPA compliant.⁸

Methods

We collected tobacco packaging from retailers within three areas (one urban, two rural) of each block of Udupi district of Karnataka. The Udupi district is administratively divided into five blocks (sub-districts), with approximately 0.10 to 0.15 million people in each block and of whom around two-thirds live in rural areas.⁹ We selected a convenience sample of three areas (one urban ward and two villages) per block, giving a total of 15 areas. All retailers selling tobacco products in these 15 areas were included in the study. Data collection was from June to August 2018.

We travelled to every shop selling tobacco in that area and obtained one distinct tobacco pack of every brand sold at the shop. In total, we visited 66 shops across the five blocks. An empty pack of each tobacco brand was procured from each shop where possible. The sale of loose cigarettes is very common in India,¹⁰ with these sold from cigarette packs until the pack is empty. While retailers discard empty packs, at least when they realise that they are empty, it is common for retailers to have empty packs available. If an empty pack was not available a new pack was purchased. We adapted the Tobacco Pack Surveillance

System (TPackSS)¹¹ codebook guidelines for measurement of health warnings on tobacco packs to evaluate their compliance with Sections 7, 8 and 9 of the 2014 COTPA, the detailed requirements of which are as follows:⁶ The measures of compliance were all assessed as yes/no.

Section 7: Warnings must be present on both sides of packs. Pictorial warnings must occupy 60% of the principal display areas, including the area of the pack visible under normal conditions of sale and use, and text warnings a minimum of 25% of this principal display areas. Compliance with Section 7 was therefore confirmed if both the pictorial and text warnings individually meet the requisite minimums of 60% and 25% respectively. This was assessed on cuboid packs using a ruler, and on cylindrical and conical packs using a flexible measuring tape, both of which were calibrated using Vernier callipers.

Section 8: Compliance with Section 8 was confirmed if the pictorial and text warning together should comprise a minimum stipulated height and width of 4 and 3.5 cms respectively, and should be represented clearly on the pack. A clear, conspicuous and legible warning is one that is at least 4 cm long and 3.5 cm wide, assessed using a calibrated ruler for cuboid packs and calibrated flexible measuring tape for cylindrical and conical packs. Clarity was based on visual inspection, i.e. the subjective ability to distinguish the warnings from the background. The text “**WARNING**” should be included in white text on a red background. Combustible tobacco products are also required to carry the text “Smoking causes throat cancer”, and smokeless tobacco products the text “Tobacco causes mouth cancer”, in white text on a black background.

Section 9: Compliance with Section 9 was confirmed when only permitted local Indian or English language is used. The text warning should be in the same language as the language used on the pack. If the language used on the tobacco pack is in the local language, the warning needs to be in the local language. Where the brand is in English, the warning must

be in English. If the brand is mentioned in more than one language the warning must be in each language. If the language used on the pack is foreign, then the warning has to be in English.

Compliance with each of these Sections was evaluated separately and overall compliance said to have been achieved if the health warning fulfilled the criteria required for compliance to all the individual 7, 8 and 9 Sections. Compliance was assessed by two researchers, with any discrepancy resolved after discussion with a third researcher. The study was approved by the Ethics committees at Manipal Academy of Higher Education (Ref no. MAHE/EC/008/2018) and the University of Nottingham (Ref no. 164-1812).

Analysis

Data were entered and analysed using SPSS version 15.0. Descriptive analyses were run for type of tobacco product, with compliance to COTPA Sections 7, 8 and 9 evaluated by frequencies and percentages.

Results

We visited 66 shops across the five blocks, with 40 (60.7%) in rural and 26 (39.3%) in urban areas. We were able to collect 365 packs that included 52 distinct brands. Of the 52 brands identified, seven are owned by local companies, 31 national companies, and 14 multinational companies. The number of brands sold in each shop ranged from one to 20, with an average of five per shop. The language of the packs we obtained were in either English and / or one of the Indian languages. Of the 365 packs, 178 (49%) packs were for combustible tobacco (125 (34%) cigarettes and 53 (15%) beedis) and 187 (51%) for smokeless tobacco (142 (39%) chewing tobacco and 45 (12%) snuff). Among the packs collected, 12 (23%) brands of

combustible tobacco and 18 (34%) brands of smokeless tobacco were repeated. We collected 123 (34%) packs from urban and 242 (66%) from rural areas.

Compliance with Section 7 (Size of the pictorial and text warning)

Almost all (>95%) cigarette, beedi and smokeless tobacco packs, and over 75% of snuff packs, displayed pictorial and text warnings (Table 1). However, compliance with minimum size requirements as a proportion of the principal display areas of both the pictorial and text warning was typically low, ranging from 8% for chewing tobacco to 68% for cigarettes. Overall compliance with Section 7 of COTPA was low (12.3%). Compliance was 0% for local companies, 6.7% for national companies, and 93.3% for multinational companies.

Compliance with Section 8 (Legibility and conspicuousness of warning)

Most packs of cigarettes (97%) and chewing tobacco (97%) had text warnings with the background colour specified by Section 8 of COTPA, see Table 1. Minimum warning dimension regulations were met on 97% of cigarette packs, 72% of beedi packs, 59% of chewing tobacco products, and 20% of snuff packs. Compliance was 19.6% for local companies, 27.6% for national companies, and 52.8% for multinational companies.

Compliance with Section 9 (Language of text warning)

Most cigarette packs (98%) were compliant with Section 9 of COTPA, but compliance of beedis (28%) and snuff packs (27%) was low, typically because the language of the warning was not the same as the language of the product name. Compliance was 21.4% for local companies, 30.2% for national companies, and 48.4% for multinational companies.

Compliance with Sections 7, 8, 9

No snuff or chewing tobacco products, and only 6% of beedi and 34% of cigarette packs were compliant with Sections 7, 8 and 9 (Table 1). We obtained eight unbranded snuff and five smokeless tobacco packs with no warnings; see Figure 1 for examples of non-compliant warnings. Thus, overall compliance was 0% for local companies, 6.7% for national companies, and 93.3% for multinational companies.

Discussion

We found very low compliance with the proportional size, legibility and language requirements for health warnings on tobacco products sold in the Udupi district of India, particularly for products other than cigarettes. We found that for packs of snuff, a tobacco product which has not been included in past research on warning compliance, more than 75% of snuff products had pictorial and text health warnings while none had the required pictorial size and only 11% the required text warning size.

Consistent with past research in India,¹² we found high levels of non-compliance with respect to warnings on smokeless tobacco and beedis. Previous literature has shown mixed compliance^{7,13-16} with regards to COTPA Sections 4 (ban on smoking in public places), 5 (ban on tobacco advertising, promotion and sponsorship), 6a (ban on sale of tobacco to minors) and 6b (ban on sale within 100 yards of any educational institution), ranging from 0%¹³ to 90%¹⁶. What these findings collectively demonstrate is a varying overall compliance with the legislation. There is an urgent need to improve warning compliance in India, particularly for beedis and chewing tobacco (products that are widely used), and especially in rural areas, where most of India's population resides.¹

The difficulty in achieving compliance with anti-tobacco legislation in India,⁹ and indeed in many other low and middle income countries,¹⁷⁻¹⁸ highlights the need for sustained efforts from various departments along with stringent enforcement of law.¹⁹ As retailers are

not permitted to sell tobacco products with warnings which are not compliant with COTPA, and the penalty increases if they are caught doing so more than once,⁴ then surveillance of retailers and reporting of infringements should reduce non-compliance.¹³ The current penalty of 5000 INR²⁰ (approximately £58, 62 Euros or \$70) levied on manufacturers for a first offence of COTPA 7,8,9 is clearly not a deterrent from manufacturing non-compliant packs. This study shows that compliance with warning requirements in India is low, particularly among tobacco products other than cigarettes.

Our study was limited to convenience sampling in a single district in one state of India, and may therefore not be representative of the rest of India, but the low compliance we observed in a district of high COTPA compliance points to inadequacies in the enforcement of the law.

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Declaration of Interests

None declared.

References

1. Global Adult Tobacco Survey (Second Round). India 2016-2017 report. [http://download.tiss.edu/Global Adult Tobacco Survey2 India 2016-17 June2018.pdf](http://download.tiss.edu/Global_Adult_Tobacco_Survey2_India_2016-17_June2018.pdf)
Accessed December 25, 2019.
2. World Health Organization. Guidelines for implementation of Article 11 of the WHO Framework Convention on Tobacco Control. [www.who.int/fctc/treaty_instruments/adopted/Guidelines Article 11 English.pdf?ua=1](http://www.who.int/fctc/treaty_instruments/adopted/Guidelines_Article_11_English.pdf?ua=1)
Accessed April 22, 2019.
3. Hammond D. Health warning messages on tobacco products: a review. *Tob Control* 2011;20:327-37.
4. The Gazette of India. Ministry of Law and Justice. <https://www.tobaccocontrollaws.org/files/live/India/India%20-%20COTPA%20-%20national.pdf> Accessed April 19, 2018.
5. Arora M, Yadav A. Pictorial health warnings on tobacco products in India: Sociopolitical and legal developments. *Natl Med J India* 2010;23:357-59.
6. Ministry of Health and Family Welfare. The Gazette of India. <https://www.tobaccocontrollaws.org/files/live/India/India%20-%20COTPA%20-%20national.pdf> Accessed May 20, 2019.
7. Goel S, Sardana M, Jain N, Bakshi D. Descriptive evaluation of cigarettes and other tobacco products act in a North Indian city. *Indian J Pub Health* 2016;60:273-9.
8. The Times of India. Udupi self declares as highest COTPA compliant district. <https://timesofindia.indiatimes.com/city/bengaluru/udupi-self-declares-as-highest-cotpa-compliant-district/articleshow/62025838.cms> Accessed April 10, 2019.

9. Census of India. Directorate of Census Operations. Karnataka. [https://censusindia.gov.in/2011census/dchb/2915 PART B DCHB UDUPI.pdf](https://censusindia.gov.in/2011census/dchb/2915_PART_B_DCHB_UDUPI.pdf) Accessed June 26, 2019.
10. Eshwari K, Kulkarni MM, Bhagawath R, Mullapudi S, Selvarajan T, Kamath VG. Ban on Sale of Loose Cigarettes: Awareness, Perceptions and Practices among Vendors and Smokers in Karnataka, India. *Indian J Comm Health*. 2020;32(2):394-398.
11. TPackSS : Tobacco Pack Surveillance System India Health Warning Label Compliance Codebook. <https://globaltobaccocontrol.org/tpackss/sites/default/files/India%20Health%20Warning%20Label%20Compliance%20Codebook%202013.pdf> Accessed December 4, 2018.
12. Smith K, Welding K, Saraf S, Washington C, Iacobelli M, Cohen J. Tobacco packaging in India: assessing compliance with Health Warning Label (HWL) laws and marketing appeals for cigarettes, bidis and smokeless products. www.jhsph.edu/research/centers-and-institutes/institute-for-global-tobacco-control/resources/posters-and-presentations/2018/Smith_WCTOH2018_poster.pdf Accessed December 20, 2019.
13. Govil S, Dhyani A, Mall AS. Compliance assessment of tobacco vendors of Ahmedabad city to India's Tobacco control legislation. *Indian J Comm Health* 2016;28:374-7.
14. Kummar JK, Jain K, Verma N, Sinha A, Bhawnani D, Prasad M. *Int J Community Med Pub Health* 2018;5:1327-34.
15. Habbu SG, Krishnappa P. Assessment of implementation of COTPA-2003 in Bengaluru city, India: A cross-sectional study. *J Indian Assoc Pub Health Dent* 2015;13:444-8.
16. Jain ML, Chauhan M, Singh R. Compliance assessment of Cigarette and Other Tobacco Products Act in public places of Alwar district of Rajasthan. *Indian J Pub Health* 2016;60:107-11.

17. Cohen JE, Brown J, Washington C, Welding K, Ferguson J, Smith KC. Do cigarette health warning labels comply with requirements: A 14-country study. *Prev Med* 2016;93:128–34.
18. Iacobelli M, Welding K, Washington C, Smith K, Cohen J. Is health warning label compliance a country or manufacturer issue: a 9-country multi-year study. *Tob Induc Dis* 2018;16(1):597.
19. Sharma N, Chavan BS. Compliance to tobacco-free guidelines (Cigarettes and Other Tobacco Products Act) in medical institute of North India. *Indian J Soc Psychiatry* 2018;34:213-6.
20. Tobacco Free Generation. Types of violation according to the sections of COTPA, 2003 act and penalties. <https://tobaccofree.org.in/node/3876> Accessed August 19, 2019.

Table 1: Compliance with warning regulations by product type

	Smoking tobacco*			Smokeless tobacco**			Total
	Cigarettes (n=125)	Beedis (n=53)	Cigarettes and Beedis (n=178)	Chewing tobacco (n=142)	Snuff (n=45)	Chewing and Snuff (n=187)	Total (n=365)
Section 7 of COTPA							
Packs with pictorial warning	121 (96%)	52 (98%)	173 (97%)	139 (97%)	34 (75%)	173 (92%)	346 (94%)
Pictorial warning on both sides	121 (100%)	41 (77.4%)	164 (92%)	137 (96%)	7 (17%)	146 (78%)	310 (84%)
Pictorial warning (60%)	85 (68%)	3 (5%)	88 (49%)	12 (8%)	0 (0%)	12 (6%)	100 (27%)
Packs with text warning	125 (100%)	53 (100%)	178 (100%)	139 (97%)	35 (77%)	174 (93%)	352 (96%)
Text warning on both sides	123 (100%)	41 (77%)	164 (92%)	137 (96%)	8 (20%)	147 (79%)	311 (85%)
Text warning (25%)	58 (46%)	3 (5%)	61 (34%)	2 (1%)	5 (11%)	7 (3%)	68 (18%)
Section 7 compliance #	42 (33%)	3 (5%)	45 (25%)	0 (0%)	0 (0%)	0 (0%)	45 (12%)
Section 8 of COTPA							
Legibility of warning	121 (96%)	38 (71%)	159 (89%)	84 (59%)	9 (20%)	93 (49%)	252 (69%)
White text warning on black/red background	121 (96%)	18 (34%)	139 (78%)	137 (96%)	4 (8%)	141 (75%)	280 (76%)
Pictorial warning clear	121 (96%)	12 (22%)	133 (74%)	38 (26%)	17 (37%)	55 (29%)	188 (51%)
Text warning clear	125 (100%)	53 (100%)	178 (100%)	139 (97%)	32 (71%)	171 (91%)	349 (95%)
Section 8 compliance ##	121 (96%)	18 (34%)	139 (78%)	83 (58%)	3 (6%)	86 (46%)	225 (61%)
Section 9 of COTPA							
Section 9 compliance ###	122 (97%)	15 (28%)	137 (77%)	99 (69%)	12 (26%)	111 (59%)	248 (67%)
Sections 7, 8, 9 of COTPA							
Compliance with sections 7, 8 & 9	42 (33%)	3 (5%)	45 (25%)	0 (0%)	0 (0%)	0 (0%)	45 (12%)

* Smoking form of tobacco: Cigarettes & Beedis; ** Smokeless form: Chewing tobacco & Snuff

Section 7 compliance: Packs with Pictorial and text warnings on both the sides occupying 60% & 25% of pack size.

Section 8 compliance: Legibility (Specified Health warning of minimum 4 cm height/3.5 cm wide), text warning on contrasting background, text warning clear.

Section 9 compliance: language of the health warning be the same as that of the tobacco pack label.

Figure 1

Figure 1: Examples of non-compliant warnings on pack



A) BEEDI PACK
UNCLEAR WARNING

B) RAW TOBACCO PACK
NO WARNING

C) SNUFF PACK
OLD WARNING

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