Communicating Risk: Assessing Compliance of Tobacco Products to Cigarettes and other Tobacco Products Act (Packaging and Labelling) Amendment Rules 2015 in Delhi, India

Abstract

Background: Tobacco is a public health problem with both health and economic consequences. Pictorial health warning (PHW) under cigarettes and other tobacco products Act, May 2003 (COTPA), offers advantages of being more universally available, low cost, and high exposure. The current study aims to assess compliance of smoking and smokeless tobacco products to Section 7, 8, and 9 of COTPA Amendment Rules 2015. Materials and Methods: This cross-sectional study was conducted in the city of New Delhi during November–December 2017. All nine districts were included in the study and in each district, three public places, a Metro station, a hospital, and a public park, were randomly chosen for tobacco products collection. A standardized protocol was implemented for acquiring tobacco products from these 27 diverse points. Data collected were entered into MS Excel to make digital spreadsheets and were analyzed using SPSS version 21. Results: Among 98 tobacco products, 57 (58%) and 41 (42%) were smoke form and smokeless form, respectively. Foreign Cigarette Brands and Beedi showed the least compliance followed by khaini and Gutkha. PHW was absent on 12 products (8 foreign brands of smoking type and 4 smokeless type). 42.8% (n = 42) of packaging was found to contain promotional inserts, while just 20.4% (n = 20) of the total sample size contained the presence of legislative information. Conclusions: Foreign brands and locally manufactured products (Beedi and Khaini) showed low compliance to new amendments of COTPA. Along with this, the presence of promotional inserts on tobacco packaging might be another issue to be dealt with in the future.

Keywords: Cigarettes and Other Tobacco Products Act, India, pictorial health warning, tobacco

Introduction

Tobacco is a public health problem with both health and economic consequences. Tobacco constitutes 8.8% of global mortality (2000) and total economic cost (smoking) was equivalent in magnitude to 1.8% of the world’s annual gross domestic product in 2012.[1,2] Almost 40% of this cost occurred in developing countries, highlighting the substantial burden these countries suffer.[3] Economic cost attributable to tobacco in India amounted to 22.4 billion US $ (16% direct and 84% indirect cost).[4]

Early efforts toward Tobacco control in India were introduction of Cigarette Act 1975 which embraced “text-only health warning,” enactment of Cigarettes and Other Tobacco Products Act (COTPA) (2003), ratification of the World Health Organization (WHO) framework convention on tobacco control (FCTC) (2004) and National Tobacco Control Programme (2007–2008).[5] The Government of India (GoI) drafted a comprehensive legislation under the guidelines set by FCTC Article 11 for tobacco control - COTPA, May 2003 to control and monitor tobacco trade in India. However, COTPA had its own limitations and weakness in the form of poor compliance and lack of effective implementation.[5–7]

The Ministry of Health and Family Welfare, GoI, generates amendments to scale-up COTPA to international standards based on evidence. One of the key sections under COTPA included regulations for tobacco products packaging which have been used by the tobacco companies as market promotional strategies. Although it may also behave as a strong tool for tobacco regulation when used as pictorial health...
warning (PHW). PHWs improve awareness against tobacco harms among the underprivileged and illiterate sections of the society and are universal, low cost, and offer high exposure. Cigarettes have high social visibility as they are displayed each time the product is used and are often left in public view between uses. Hence, PHW detracts from the glamour and appeal of tobacco products, thus lead to demand reduction and improves memory for the accompanied text with greater information processing. Recent studies show that PHWs were more effective than text-only warnings in terms of attraction, attention, stronger cognitive and emotional reactions, and elicited negative smoking attitude with effectiveness in preventing initiation and promoting the use of cessation services. PHWs are effective in public awareness in countries with multilingual culture and low literacy rates. Recently, the WHO advocated “Plain packaging” which restricts the use of logos, colors, brand images and promotional information other than brand, and product names displayed in a standard color and font style. Australia, France, United Kingdom of Great Britain, and Northern Ireland became the pioneers in implementing Plain Packaging in Tobacco products.

The COTPA amendment rules, 2014 encouraged larger size of the PHW with the intention to reach out people who may be illiterate or may not notice small warnings. The larger PHW came into effect in April, 2015 due to efforts by then Health Minister. Hence, the Government further amended rules for Packaging and Labelling in 2015 which mandated - Health warnings comprising of 85% of the principal display area (PDA) of packaging, including a PHW covering 60%. However, the implementation was delayed till the Supreme Court directive came which made it mandatory to adhere to 85% PHW on all Tobacco products from April 1, 2016. The current study assessed compliance of smoking and smokeless tobacco (SLT) products to Section 7, 8, and 9 of COTPA (Packaging and Labelling) Amendment Rules 2015.

Materials and Methods

This cross-sectional study was conducted in the city of New Delhi during November–December 2017. The city is geographically stratified into nine different districts with a population of approximate 1.68 Crores. It is spread over an area of 1483 Sq km. A stratified random sampling method was chosen. In each of the nine districts, three public places, a Metro station (208 DMRC metro stations), a hospital, and a public park (18,000) were randomly chosen for tobacco products collection. In this study, “public place” was defined according to COTPA 2003 as “places which have public access, whether as of right or not and includes railway waiting rooms, hospital buildings, restaurants, court buildings, public offices, cinema halls, amusement centers, workplaces, shopping malls, libraries, educational institutions, and public conveyances.”

This maintained the diversity in terms of geographic location and covered all the nine districts of the state [Figure 1]. Two trained investigators collected the data from the sites and thus a random sample which was representative of all different/unique brand presentations was collected from tobacco vendors visited across the city. Ethical approval was obtained from Institutional Ethical Review Board before commencing the study.

Sample collection

A standardized protocol was implemented for acquiring tobacco products from these 27 diverse points. One point-of-sale was systematically chosen at each public place: The point-of-sale on the left-hand side of the street. If none were on the left-hand side, data collectors observed a point-of-sale on the right.

From each point of sale, three types of each smoking and SLT products were purchased. After identifying and purchasing three of each that was visible, investigators asked the vendor whether there were any additional packs for sale that were not visible, and if available, these packs were also purchased.

At the time of purchase, data on price and place of acquisition of each pack was recorded. The packs were color coded for easy identifications of districts from which they were obtained.

All panels of each package, front, back, top, bottom, sides, and inside, were assessed and the exact content of tobacco products, location, and size of all health warnings, promotional messages, and legislative and constituent labels were recorded [Figure 2].

The front and back panels were considered as the PDA as per the COTPA and analyzed separately as the front display area is considered the most visible to the user. Packs were also assessed for presence of legislative information like sale restriction to minors, mention of COTPA, Nicotine content, etc.

The size of the warning labels relative to the PDA were calculated using a standard ruler as the area covered by the warning label or labels (warning height × warning width) divided by the PDA [Figure 3].

We defined promotional labels as messages, images, or pictures that directly or indirectly promote the use or consumption of a specific tobacco brand or tobacco usage in general or any matter or statement that is inconsistent with or detracts from the specified health warnings [Figure 4].

To assess compliance, a tool in the form of a checklist was prepared based on the sections of COTPA – The Cigarettes and other Tobacco Products (Packaging and Labelling) Amendment Rules, 2014, and data were recorded through direct observation. Each pack was coded for “features,” which pertain to design elements of the pack, listed in Table 1.
For quality assurance, an independent investigator was asked to review the products and discrepancies were resolved through discussion. This methods helped ensure the quality of data collection throughout the study.

**Statistical analysis**

Compliance of tobacco products with COTPA requirements was dichotomized as not present/present (compliant with 0–1 measure) for each item. Data collected were entered into MS Excel to make digital spreadsheets and were analyzed using SPSS version 21.

**Results**

A total of 27 sites were visited which generated 98 products. Out of 98 products, 57 (58%) and 41 (42%) were smoke form and smokeless form, respectively. Smoke forms included Cigarettes (Indian and Foreign brands) and Beedi (Local brands), whereas smoke-less tobacco included mainly Khaini and Gutkha [Table 2].

Concordance of national legislation with FCTC recommendations and adherence of the packets assessed with national legislation is shown in Table 3. Foreign Cigarette Brands and Beedi showed least compliance followed by Khaini and Gutkha.

Of the 98 products, PHW was absent on 12 products (8 foreign brands of smoking type and 4 smokeless type). Compliance of all Indian smoke forms was acceptable as over 90% of the brands followed the exact specifications of PHWs printed on the packaging, seen in Table 4. There was poor compliance of foreign smoking tobacco forms to Sections 7, 8, and

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**Table 1: Checklist prepared based on guidelines by Framework Convention on Tobacco Control article 11**

| Section 7 | Section 8 | Section 9 |
|-----------|-----------|-----------|
| HW present | HW present on both sides | Language of the textual HW |
| PHW present | PHW covers 85% of principal display area | |
| PHW present below HW | PHW present at the top edge of packaging | |
| PHW present on the largest panel | Picture is not distorted | |
| | Size of PHW is at least 3.5×4.5 cm | |

**Table 2: Descriptive results of checklist according to product type**

| Products | Frequency (%) |
|----------|---------------|
| Indian brands (cigarettes) | 30 (30.6) |
| Foreign brands (cigarettes) | 9 (9.1) |
| Local smoke form (beedli) | 18 (18.4) |
| Local form of SLT (Khaini) | 23 (23.5) |
| Local form of SLT (Gutkha) | 18 (18.4) |
| Total | 98 (100.0) |

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| Total | 98 (100.0) |

SLT: Smokeless tobacco

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Figure 1: State district map showing the sites of data collection
9 of COTPA act, which is evident. Only 11.1% of the foreign brands included the 85% PDA as required under the act.

Nearly all the local smoke form packaging like beedi was found to have a specified PHW, however, only 22.2% (n = 4) of these were found to comply with the 85% PDA specifications.

About 42.8% (n = 42) of packaging was found to contain promotional inserts, while just 20.4% (n = 20) of the total sample size contained the presence of legislative information.

### Discussion

The present study assessed COTPA compliance (Section 7, 8, 9) of tobacco products (SLT and smoke form) in Indian retail market. A total of 98 products were obtained and it was observed that sample had more smoke form products as compared to SLT products.

Foreign brands of cigarette showed least compliance (22.2%, n = 2) to HW on both sides as compared to Indian smoke brands (cigarette [96.6%, n = 29] and Beedi [55.5%, n = 10]). This was in accordance with a study done by Goel et al., in Chandigarh, India, where cigarette (Indian made)
Table 4: Descriptive data for samples \((n=98)\) and compliance to Section 8 of Cigarettes and Other Tobacco Products Act

| Variables | Indian smoke forms \((n=30)\) (%) | Foreign smoke forms \((n=9)\) (%) | Local smoke forms \((n=18)\) (%) | Smokeless forms \((n=98)\) (%) | Total product \((n=98)\) (%) |
|-----------|-----------------------------------|---------------------------------|---------------------------------|-------------------------------|-----------------------------|
| HW present on both sides | 29 (96.6) | 2 (22.2) | 10 (55.5) | 18 (100) | 73 (74.4) |
| PHW covers 85% of principal display area | 28 (93.3) | 1 (11.1) | 4 (22.2) | 16 (88.8) | 58 (59.2) |
| PHW present on top edge | 27 (90.0) | 1 (11.1) | 17 (44.7) | 16 (88.8) | 70 (71.4) |
| Picture size is not distorted | 28 (93.3) | 1 (11.1) | 7 (38.8) | 15 (83.3) | 64 (65.3) |
| Size is at least 3.5×4.5 cm | 28 (93.3) | 1 (11.1) | 6 (33.3) | 8 (44.4) | 59 (60.2) |
| Language as per specification | 29 (96.6) | 6 (66.6) | 18 (100) | 18 (100) | 90 (91.8) |

59.2\% \((n = 58)\) of the products showed compliance to 85\% PHW in the current study. This was in accordance to a study done by Oswal et al. which showed that 60\% of the smoke products showed compliance to 60\% PHW regulation.\[30\] The present finding was in contrast to another study by Goel et al. showed that at least 40\% coverage was shown by 73.1\% of the tobacco products.\[28\] Foreign brands of cigarette were least compliant to PHW coverage followed by Indian cigarette (93.3\%, \(n = 28\)) and Beedi (22.2\%, \(n = 4\)). Although Beedi industry has been aggressively lobbying to exempt Beedi from PHW legislation, it was implemented on all tobacco products in 2009 by Supreme Court of India.\[21\] The current study supports the fact that there is a weak implementation of PHW for Beedi products as compared to Indian Cigarette products.

Although it needs further evaluation to assess how these foreign brands get access into the country, that could address another issue of illicit trade if identified. Illicit trade of foreign tobacco products has doubled since 2004 and India stands at 4\textsuperscript{th} largest illegal cigarette market. Extreme graphic regulation has provided further encouragement to the illegal cigarette trade in India, as illegal cigarettes do not comply with tobacco control regulation of the government. Increase in number of women smokers, attractive packaging, and urge to switch to cheaper illegal cigarettes might explain the growth of foreign brands which escapes the stringent COTPA rules in the country.\[22,29\]

Although Gutkha products were more compliant to Section 8 as compared to Khaini products. Locally manufactured tobacco products (Beedi and Khaini) showed poor compliance which in accordance to the study done by Aruna et al. in Muradnagar, India, in 2009.\[32\]

Picture size was not distorted in 65.3\% \((n = 64)\) of the tobacco products which was in contrast to another study conducted in Chandigarh (92.3\%).\[28\] Promotional inserts were present on 42.8\% of the tobacco products, which was also observed by Osval et al. in Mumbai, India.\[30\] Health warning in same language as on pack was present in 91.8\% \((n = 90)\) which was higher when compared with study by Goel et al. (74.4\%).\[28\]

The current study explored crucial dimension of COTPA compliance in Indian retail market, however, it had its own limitations. The survey was undertaken for a short period of time, which may or may not be representative of time when point of sale violations may be more visible (as in festivals or new product launch). However, the
study overcomes these limitations as the size of sample is significantly robust, and therefore, it presents a fair representation of violations across all the nine districts of New Delhi.

Conclusions

At the end, it may be concluded that foreign brands and locally manufactured products (Beedi and Khaini) showed low compliance to new amendments of COTPA. Along with this, the presence of promotional inserts on tobacco packaging might be another issue to be dealt with in the future. Compliance of PHWs is an important public health measure, and regular enforcement would allow attaining this objective.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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