

# Compliance with COTPA (Packaging and Labeling) Rules, 2008 and its amendments in smokeless tobacco products sold across Mangaluru taluk, Karnataka, India

## ABSTRACT

**Introduction:** India introduced the Cigarettes and Other Tobacco Products Act (COTPA) (Packaging and Labeling [P and L]) Rules in 2008. These rules utilize the tobacco package to communicate tobacco-caused harms; it also seeks to restrict the delivery of misleading information about the product on the pack. The enormous burden of tobacco-related oral cancers in India necessitates the compliance with the law regarding presentation of information in powerful and salient ways, intentionally designed to increase the awareness in target individuals.

**Objectives:** The objectives of the study are to assess the compliance to implementation and enforcement of the COTPA (P and L) Rules, 2008 and its amendments in 2014 and 2018.

**Materials and Methods:** Chewing tobacco products were retrieved and evaluated for compliance with the law. The specified pictorial and textual health warnings, area, clarity, rotation, and language were assessed as per the recommendations.

**Results and Conclusion:** Even though chewing tobacco products in India have introduced pictorial and textual health warnings, majority of them do not comply with the law. The products displayed the specified health warnings on a total of 70.6% on average, failing to abide by the government-specified average of 85%. 50% of the products did not follow the rotation of pictorial and textual health warning even after completion of the interregnum period of 12 months (September 2019). To ensure consumers' right to be informed about the health risks from a product, all the details regarding the contents, health warnings and messages, and product care instructions must be mentioned as specified under the law.

**KEY WORDS:** COTPA, India, oral cancer, packaging and labeling, smokeless tobacco

## INTRODUCTION

The Government of India ratified the World Health Organization Framework Convention on Tobacco Control (FCTC) in 2005, the first-ever international public health treaty focusing on the global public health issue of tobacco control. The Cigarettes and Other Tobacco Products Act (COTPA) is the chief law governing tobacco control in India.<sup>[1]</sup> It is intended to protect and improve public health by making provisions of evidence-based strategies to reduce tobacco consumption. The Cigarettes and Other Tobacco Products (Packaging and Labeling Rules [P and L]) came into force in 2008 and enlists the health warnings to be displayed on the packages of tobacco products. This has been followed by amendments in recent years, the latest being in 2018.<sup>[2]</sup>

According to the Canadian Cancer Society International Tobacco Packaging Report released in October 2018, India ranks 5<sup>th</sup> jointly with Hong Kong and Thailand in terms of the largest pictorial warnings, with 85% of both sides of the packets covered.<sup>[3]</sup> Although the majority of the cigarette packages follow the government regulations, the level of enforcement in smokeless (chewing) tobacco products is still poor and therefore needs assessment. Hence, the objective of this study was to assess the compliance to implementation and enforcement of the COTPA (P and L) Rules,

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2008; COTPA (P and L) Amendment Rules, 2014; and COTPA (P and L) Second Amendment Rules, 2018 in smokeless tobacco products.

## MATERIALS AND METHODS

Chewing tobacco products were randomly retrieved from vendors across Mangaluru taluk, Karnataka. The study was done in October and November 2019 as the rotation of health warnings on tobacco products completed the interregnum period of 12 months in September 2019, and this was one of the criteria in the evaluation process. After removing the duplicates, 21 brands of commonly used smokeless tobacco products were obtained. The products were evaluated for compliance with the Cigarettes and Other Tobacco Products (P and L) Rules, 2008 and its amendments in 2014 and 2018.<sup>[2]</sup>

The study design was descriptive, and health warnings were considered compliant if:

- The products display the specified health warnings (Rule 3, subrule 1, clause a of Cigarettes and Other Tobacco Products [P and L] Rules, 2008)
- They covered at least 85% of the principal display area of the tobacco package, of which 60% displayed pictorial health warning, and 25% displayed the textual health warning and was positioned on the top edge of the package (Rule 3, subrule 1, clause b of Cigarettes and Other Tobacco Products [P and L] Amendment Rules, 2014)
- The elements of the specified warnings are not severed, covered, or hidden in any manner when the package is sealed or opened. (Rule 3, subrule 1, clause c of Cigarettes and Other Tobacco Products [P and L] Rules, 2008)
- There were no images, pictures, or messages that directly or indirectly promote the use or consumption of a specific tobacco brand (Rule 3, subrule 1, clause d of Cigarettes and Other Tobacco Products [P and L] Amendment Rules, 2014)
- No products are sold without the specified health warning on the package (Rule 3, subrule 1, clause e of Cigarettes and Other Tobacco Products [P and L] Rules, 2008)
- The textual health warning is inscribed in the language used on the package (Rule 3, subrule 1, clause f of Cigarettes and Other Tobacco Products [P and L] Amendment Rules, 2014)
- There is no false, misleading, or deceptive information that is intended to create an erroneous impression about the characteristics, health effects, or other hazards of the tobacco product (Rule 3, subrule 1, clause g of Cigarettes and Other Tobacco Products [P and L] Rules, 2008)
- The name of the product, name and address of the manufacturer, quantity, date of manufacture are mentioned on the package (Rule 3, subrule 1, clause h of Cigarettes and Other Tobacco Products [P and L] Amendment Rules, 2014)
- There is no design on the package that obscures the health warnings (Rule 4 of Cigarettes and Other Tobacco Products [P and L] Rules, 2008)
- The product follows the rotation of specified health warnings (Rule 5, subrule 2 and 3 of Cigarettes and Other Tobacco Products [P and L] Second Amendment Rules, 2018)
- The product displays the textual health warning “TOBACCO CAUSES CANCER” and “TOBACCO CAUSES PAINFUL DEATH” in white font color on a red background and the words “QUIT TODAY CALL 1800-11-2356” in white font color on a black background with printing resolution of minimum 300 dpi (Schedule, paragraph 1, clause 1 of Cigarettes and Other Tobacco Products [P and L] Second Amendment Rules, 2018) [Figure 1]
- The product displays the specified pictorial health warning (Schedule, paragraph 2 of Cigarettes and Other Tobacco Products [P and L] Second Amendment Rules, 2018) [Figure 1]
- The total size of the specified health warning is not <3.5 cm (width) ×4 cm (height) and is legible, prominent, and conspicuous. (Schedule, paragraph 3 of Cigarettes and Other Tobacco Products [P and L] Amendment Rules, 2014).<sup>[2]</sup>

## RESULTS

Health warnings were displayed on 20 out of 21 brands of chewing tobacco products and were positioned toward the top edge of the package in 19 brands. Only one product was sold without any health warning. In 3 brands, the pictorial and textual health warnings occupied 100% of the length of the display area. In the remaining 18 brands, an average of 50.2% and 20.3% display area was covered by the pictorial and textual health warning, respectively, with a total of 70.6% on average, failing to abide by the government-specified average of 85% [Figure 2a and b].

Elements of the health warnings in all the brands were grossly severed when the package was opened. Two brands displayed the manufacturer's photo on the display area, compromising the display area meant for the health warnings. These are considered as promotional messages which are against the regulations.



**Figure 1:** The new pictorial and textual health warning to be displayed on all tobacco products sold in India from September 2019

The textual health warnings were inscribed in the language used on the package (English and Hindi/English and Kannada) which was displayed on either side of the package. Two brands of smokeless tobacco were available as filter pouches, which claimed to be tobacco filter pouches. Such claims could be false and delivering misleading information to the consumers and it intends to create an erroneous impression regarding the characteristics, health effects, or other hazards of the tobacco product [Figure 2c].

Excluding the one brand which did not display any health warnings, 10 brands did not follow the rotation of pictorial and textual health warning even after completion of the interregnum period of 12 months (September 2019) [Figure 2d]. This could be because of old stock which is still being circulated with the previous pictorial and textual health warning. The remaining 10 displayed the new graphic health warning and the new textual health warning “TOBACCO CAUSES CANCER” and “TOBACCO CAUSES PAINFUL DEATH” in white font color on a red background and the words “QUIT TODAY CALL 1800-11-2356” in white font color on a black background.

Although the size of the textual health warning was legible and prominent, the color, intensity, and clarity of pictorial health warnings were severely tampered with, failing to deliver the intended health warning [Figure 2e]. Two brands also used glitter type of packaging that obscured the clarity of pictorial health warnings [Figure 2c]. The graphic images were also found to be split on the package due to printing errors [Figure 2f]. The name of the product, name, and address of the manufacturer were mentioned in all the brands; however, the date of manufacturing was mentioned only in 11 brands.



**Figure 2:** (a-f) Pictorial and textual health warnings on smokeless tobacco products

The above results clearly depict nonadherence to COTPA rules by the manufacturers which demand strict action by the government.

## DISCUSSION

Complying with the Supreme Court judgment and notification from the FSSAI, Karnataka state in India banned the sale, manufacture, and storage of gutkha and all its variants on May 31, 2013.<sup>[4]</sup> In October 2016, the state government banned the sale of flavored chewing tobacco that was being sold as an alternative to the banned gutkha following a petition filed by the Cancer Patients Aid Association. However, within 6 months, in May 2017, the ban was reversed. As per the Global Adult Tobacco Survey-2 survey India 2016–2017, 29.6% of men, 12.8% of women, and 21.4% of all adults in India use smokeless tobacco.<sup>[5]</sup> 22.2% of men, 10.3% of women, and 16.3% of all adults in Karnataka state in India use smokeless tobacco.<sup>[6]</sup> The average age of initiation of smokeless tobacco among daily users is 18.8 years. 46%–47% of users thought of quitting because of the warning label on these products.<sup>[5]</sup>

Article 11 of the FCTC stresses on using tobacco packages to communicate tobacco-caused harms; it also requires to restrict the delivery of misleading information about the product on the package. It also outlines mechanisms by which parties to the treaty can increase the effectiveness of their tobacco P and L. Key elements include location; size; color; use of pictorials; rotation; language; message content; source attribution; and information on constituents and emissions.<sup>[7]</sup>

There have been very few studies to assess compliance with the law on health warnings on smokeless tobacco products. Mullanpudi *et al.* in a recent study in 2019 noted that compliance with national legislation laws was found to be low and demanded strict measures.<sup>[8]</sup> Smith *et al.* in 2018 reported in a study done in 4 Indian cities that 53% of cigarette packets were compliant with size, placement, and the components of health warnings. However, among smokeless tobacco products, only 1% was compliant with the law.<sup>[9]</sup> Although India has a progressive health warning label law, compliance varies between different tobacco products. A similar study done in Bhubaneswar, India, also found poor compliance with the P and L rules.<sup>[10]</sup> Rahman SM, in a study from Bangladesh, also concluded that compliance was highest for cigarette packets and lowest among smokeless tobacco products.<sup>[11]</sup> This study noted that the products displayed the specified health warnings on a total of 70.6% on average, failing to abide by the government-specified average of 85%. 50% of the products did not follow the rotation of pictorial and textual health warning even after completion of the interregnum period of 12 months in September 2019. Our study also highlights similar results as mentioned above, depicting poor compliance with health warnings.

In a study done by Hammond *et al.* in 2019 on the effectiveness of health warnings across seven countries, it was noted that



pictorial warnings were more effective than textual warnings and graphic warnings were rated more effective than lived experience or symbolic images. This was beneficial in terms of enhancing knowledge of health risks, restricting the appeal among the youth, and motivating users to quit. Pictorial warnings are also capable of deterring young individuals and those with lower education or illiterates from getting into the habit when compared to textual warnings. Graphic images are more likely to be noticed by users and are intended to arouse fear.<sup>[12]</sup> This study clearly indicates toward the poor compliance with the quality of pictorial health warnings. Since a major bulk of Indian consumers of smokeless tobacco is either illiterate or poorly educated, these pictorial health warnings are poorly effective and do not deliver the health messages, as intended. Elements of the health warnings, especially the images, were grossly severed when the package was opened.

Smokeless tobacco was also available as filter pouches, which claimed to be tobacco filter pouches. These products claim to mimic Swedish Snus, associated with relatively low risk of oral cancer, which is attributed to the fact that it contains low levels of tobacco-specific nitrosamines. However, a study by Stepanov *et al.* in 2015 on the Indian variant of filter pouches demonstrated very high levels of nitrosamines.<sup>[13]</sup>

Article 11 of the FCTC suggests that each package of tobacco products and any outside P and L of such products shall contain information on relevant constituents of tobacco products, in addition to the warnings specified.<sup>[7]</sup> However, this criterion is not mentioned in India's COTPA (P and L) Rules and its amendments. Although the majority of the products are manufactured forms of smokeless tobacco and were either flavored or scented, none of these brands mention the ingredients list on the package.

Even though chewing tobacco products in India have introduced pictorial and textual health warnings, the majority of them do not comply with the law. To ensure consumers' right to be informed about the health risks from a product, all the details regarding the contents, health warnings and messages, and product care instructions must be mentioned as specified under the COTPA (P and L) rules 2008 and its amendments. Obligations to provide this information to consumers fall mainly on the manufacturers and failure to do so is a basis of legal liability.<sup>[14]</sup>

Globocan 2018 data reveal that oral cancer is the most common cancer in India among men (16.1% of all cancers).<sup>[15]</sup> The 5-year relative survival for oral cancer patients is approximately 30% in selected regions of India. Findings from case-control studies have suggested that around 80%–90% of oral cancers are directly attributable to tobacco use.<sup>[16]</sup>

## CONCLUSION

The enormous burden of tobacco-related oral cancers in India necessitates the compliance with the law regarding

the presentation of information in powerful and salient ways, intentionally designed to increase the awareness in target individuals. Such studies have to be considered by the government to initiate strict action against the manufacturers who fail to abide by the law.

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## Conflicts of interest

There are no conflicts of interest.

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