

Original Research Article

Assessment of compliance of smoke-form and smokeless tobacco product packages with COTPA packaging and labelling amendment rules, 2024

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ABSTRACT

Background: Pictorial health warnings (PHWs) on tobacco packages are a proven tobacco control tool. India mandates that PHWs cover 85% of the principal display area under COTPA, as updated by the December 2024 amendment rules. Evidence on manufacturer-level compliance as assessed at the point of retail sale remains limited. We assessed compliance of smoke-form and smokeless tobacco product packages at retail outlets in Mumbai with the December 2024 COTPA amendment rules and compared compliance between categories.

Methods: A cross-sectional observational study was conducted in Mumbai from September to November 2025. Packages were collected from diverse retail settings by purposive sampling with saturation. A validated structured checklist based on the December 2024 amendment rules was used. Descriptive statistics and Fisher's exact test were applied.

Results: 48 packages (30 smoke-form, 18 smokeless) were assessed. Only 27 (56.3%) displayed PHWs in accordance with December 2024 regulations, 15 (31.3%) carried outdated warnings, and 6 (12.5%) had no PHW. Among packages with current PHWs (n=27), smokeless products showed poorer compliance than smoke-form on warning size (0% versus 95.0%, $p<0.001$), 'not for minors' message (28.6% versus 95.0%, $p=0.001$), and pictorial quality (0% versus 100%, $p<0.001$). Misleading descriptors were more prevalent on smokeless products (57.1% versus 10.0%, $p=0.024$).

Conclusions: Compliance with COTPA packaging and labelling regulations remains inadequate at the retail level, with smokeless tobacco sector showing the greatest deficiencies. Urgent enforcement action, regular retail-level monitoring, and sector-specific regulatory attention are essential to translate packaging mandates into effective tobacco control outcomes.

Keywords: Compliance, COTPA, India, Pictorial health warnings, Smokeless tobacco, Tobacco packaging

INTRODUCTION

Tobacco use remains one of the leading preventable causes of premature death globally. It accounts for more than eight million deaths annually, of which approximately 1.2 million are attributable to second-hand smoke exposure. The majority, nearly 80% of the estimated 1.3 billion tobacco users worldwide, reside in low- and middle-income countries (LMICs), where the health and economic consequences are most severe.¹ The

global economic cost of smoking-attributable diseases has been estimated at US\$ 1.85 trillion annually, equivalent to approximately 1.8% of world GDP.²

India bears a disproportionately large share of this burden, given the widespread use of both smoke and smokeless tobacco products. According to the Global Adult Tobacco Survey (GATS-2) 2016-17, approximately 267 million adults (28.6%) use tobacco in some form. Tobacco causes more than one million deaths annually in

India.¹ The total economic cost attributable to tobacco-related illnesses among adults aged ≥ 35 years was estimated at ₹1.77 lakh crore (US\$ 27.5 billion) in 2017-18, encompassing direct medical expenditure and indirect productivity losses due to morbidity and premature mortality.⁴ These figures highlight the enormous public health and economic imperative for robust tobacco control measures in India.

Pictorial health warnings (PHWs) on tobacco product packages are one of the most cost-effective tobacco control interventions. Evidence demonstrates that graphic warning labels enhance awareness of tobacco-related health risks, reduce the appeal of tobacco products, encourage cessation, and discourage initiation, particularly among younger and less literate populations.⁵⁻⁷ Recognizing this, article 11 of the WHO framework convention on tobacco control (WHO FCTC) recommends that countries implement large, rotating health warnings on all tobacco packages, covering at least 30% of the principal display area and ideally 50% or more.⁸

India has progressively strengthened the regulation of tobacco packaging over five decades.⁹ The regulatory journey began with the smoking hazards advertising bill (1969), followed by the cigarettes act, 1975, which mandated a textual warning on cigarette packs. A major milestone was the enactment of the cigarettes and other tobacco products act (COTPA), 2003, which extended statutory health warning requirements to all tobacco products under sections 7-10. The COTPA (packaging and labelling) rules, 2006, introduced PHWs, implemented nationwide in 2009 and subsequently revised in 2010 and 2011. A landmark strengthening of regulations in 2014 mandated warnings covering 85% of the principal display area (60% pictorial and 25% textual), enforced from April 2016. Further updates in 2018 introduced new warning images and Quitline information, followed by the COTPA (packaging and labelling) amendment rules, 2022, with revised warning images and rotation schedules.¹⁰

Most recently, the Government of India notified the cigarettes and other tobacco products (packaging and labelling) amendment rules, 2024 (Gazette Notification No. G.S.R. 693(E), dated 5 December 2024).¹⁰ This amendment introduced updated pictorial health warning images along with the mandatory textual warning 'tobacco causes painful death' and the cessation message 'quit today- call 1800-11-2356'. Two warning images were specified for rotation, with the first image required from June 2025 and the second image coming into effect 12 months thereafter.

Despite these progressive regulatory advances, evidence on actual compliance of tobacco product packages with the current COTPA amendment rules, 2024, at the point of retail sale, which directly reflects manufacturer-level adherence to packaging obligations, remains limited.

Previous compliance studies in India have revealed persistent deficiencies in PHW size, image quality, and adherence to rotation, however, none have evaluated compliance with the most recent 2024 amendment. Given that the smokeless tobacco sector in India is largely unorganized and has historically shown lower regulatory compliance, a systematic examination across product categories is essential. Assessing compliance at the retail level provides a practical and direct proxy for evaluating manufacturer adherence, since packaging is applied at the point of manufacture.

This study was therefore undertaken to fill this critical evidence gap and to inform ongoing enforcement and policy efforts.

This study assessed compliance of smoke-form and smokeless tobacco packages at retail outlets in Mumbai with the COTPA (packaging and labelling) amendment rules, 2024, and compared PHW size, placement, image quality, language, cessation messaging, and prohibited elements between categories.

METHODS

A cross-sectional observational study was conducted to assess the compliance of tobacco product packages with the COTPA (packaging and labelling) amendment rules, 2024. The study was carried out in Mumbai from September to November 2025. Tobacco product packages were purchased from retail outlets across diverse urban settings, including areas adjoining local railway stations, vegetable markets, construction sites, bars and restaurants, and urban slum settlements, to capture the range of products available to consumers across different socio-economic and commercial environments.

Since tobacco packaging is applied by manufacturers and importers, retail outlets serve as the point of consumer access and provide a direct, practical means of assessing manufacturer-level compliance with statutory packaging obligations. Retail surveillance is a recognized and widely used approach for monitoring tobacco packaging regulations.

Tobacco product packages were collected by purposive sampling with saturation. Purposive sampling was employed to systematically capture diverse product types (smoke-form and smokeless), brands, and pack sizes available across different retail contexts. Collection from each retail outlet continued until no new brands or packaging variants were identified, indicating saturation. Shopkeepers were requested to display all available tobacco products, including those not on open shelves, to maximize capture of available variants.

As no prior data were available on compliance with the December 2024 COTPA amendment rules, a formal sample size calculation was not feasible. The study aimed to include all tobacco packaging variants encountered at

retail outlets during the study period, following the purposive sampling with the saturation principle.

All tobacco product packages (both smoke-form and smokeless forms) available for sale at the selected retail outlets during the study period were included. Packages of the same brand with identical packaging variants were excluded to avoid duplication; only distinct packaging variants were retained for assessment.

A structured checklist was developed based on the provisions of the COTPA (packaging and labelling) rules, 2006, and the COTPA (packaging and labelling) amendment rules, December 2024, drawing on validated tools used in previous compliance studies.^{11,12} The checklist was reviewed by subject experts in tobacco control and public health for content validity. A pilot assessment of ten packages was conducted to refine the instrument and standardize measurement procedures before commencement of the main study.

The finalized checklist assessed the following parameters:

Manufacturer/importer name, address, quantity, and date of manufacture; maximum retail price (MRP); presence, placement, and rotation status of pictorial health warning current December 2024 image versus outdated rotation versus no warning; Coverage of PHW relative to the principal display area (PDA): total $\geq 85\%$, pictorial $\geq 60\%$, textual $\geq 25\%$; correct placement at the top edge, in the same direction as the main text; whether the warning was obscured when the pack was sealed or opened; language appropriateness and dual-language display; clarity and legibility of textual warning; presence of the tobacco cessation Quitline number (1800-11-2356); display of the 'not for minors' message; presence of misleading descriptors (e.g., 'light', 'mild', 'natural', 'herbal'); promotional images or text that could reduce the impact of health warnings; presence of headshots or facial images on the package.

Each package was examined individually for compliance with the current pictorial health warning as specified under the December 2024 amendment. The total surface

area of each package and the dimensions of both pictorial and textual health warnings were measured using a calibrated physical scale to calculate the percentage coverage of the principal display area (PDA). All packages were independently re-examined by the investigator to ensure accuracy and reliability.

Data were entered in Microsoft Excel and analysed using descriptive statistics. Compliance with each parameter was summarized as frequencies and percentages, stratified by tobacco product category (smoke-form and smokeless). Fisher's exact test was applied to compare compliance rates between categories, given the small expected cell frequencies. A p value of <0.05 was considered statistically significant.

RESULTS

Packages collected

A total of 48 tobacco product packages were procured and assessed during the study period (September–November 2025). Of these, 30 (62.5%) were smoke-form tobacco products (including cigarettes and bidis), and 18 (37.5%) were smokeless tobacco products (Table 1).

Table 1: Distribution of tobacco product packages collected (n=48).

Type of tobacco package	Number	Percentage
Smoke-form	30	62.5
Smokeless	18	37.5
Total	48	100.0

Pictorial health warning compliance status

Among all 48 packages assessed, only 27 (56.3%) displayed a PHW conforming to the current December 2024 COTPA amendment (image 1 of the new rotation). Fifteen packages (31.3%) bore a PHW from a previous rotation cycle (outdated warning), and 6 packages (12.5%) had no PHW at all (Table 2).

Table 2: Pictorial health warning (PHW) compliance status by tobacco product category (n=48).

Tobacco product category	PHW as per current regulation (December 2024) (%)	Outdated PHW (previous rotation) (%)	No pictorial health warning (%)
Smoke-form (n=30)	20 (66.7)	6 (20.0)	4 (13.3)
Smokeless (n=18)	7 (38.9)	9 (50.0)	2 (11.1)
Total (n=48)	27 (56.3)	15 (31.3)	6 (12.5)
Fisher's exact p value	P=0.077		

*Assessed among packages with current PHW only (n=27). Fisher's exact test, two-tailed.

Even setting aside quality and size deficiencies, 43.8% of all packages at retail were not displaying the mandated current-cycle PHW, either carrying outdated warnings

(31.3%) or no warning whatsoever (12.5%). Among smoke-form products (n=30), 13.3% had no PHW, and a further 20.0% had outdated warnings, among smokeless

products (n=18), a strikingly higher 50.0% carried outdated warnings, and 11.1% had no warning at all. The difference in overall PHW compliance between smoke-form (66.7%) and smokeless (38.9%) did not reach statistical significance (Fisher's exact $p=0.077$), likely reflecting the limited sample size, the direction and magnitude of this difference are clinically and programmatically meaningful.

Compliance among packages with current PHW (n=27)

Further analysis of the 27 packages bearing the current PHW examined compliance with product information, warning display, size, placement, language, and quality requirements (Tables 3-5).

Table 3: Compliance with general packaging and warning display requirements among packages with current PHW (n=27).

Compliance Parameter	Smoke-form (n=20) Yes (%)	Smokeless (n=7) Yes (%)	Total (n=27) Yes (%)	P value†
Product information				
Manufacturer/importer name present	20 (100)	7 (100)	27 (100)	1.000
Manufacturer address present	20 (100)	7 (100)	27 (100)	1.000
Quantity of product mentioned	20 (100)	5 (71.4)	25 (92.6)	0.064
Date of manufacture present	20 (100)	5 (71.4)	25 (92.6)	0.064
MRP/Unit price visible	20 (100)	7 (100)	27 (100)	1.000
Health warning display				
Pictorial warning on both principal display areas	20 (100)	7 (100)	27 (100)	1.000
Textual warning on both principal display areas	20 (100)	7 (100)	27 (100)	1.000
'Not for minors' message displayed	19 (95.0)	2 (28.6)	21 (77.8)	0.001*

† Fisher's exact test, two-tailed. * $p<0.05$ (statistically significant).

Table 4: Compliance with warning size, placement, and language requirements among packages with current PHW (n=27).

Compliance parameters	Smoke-form (n=20) Yes (%)	Smokeless (n=7) Yes (%)	Total (n=27) Yes (%)	P value†
Placement and size requirements				
Warning placed at top edge, aligned with main text	20 (100)	5 (71.4)	25 (92.6)	0.064
Total warning covers $\geq 85\%$ of principal display area	19 (95.0)	0 (0)	19 (70.4)	$<0.001^*$
Pictorial warning covers $\geq 60\%$ of PDA	19 (95.0)	0 (0)	19 (70.4)	$<0.001^*$
Textual warning covers $\geq 25\%$ of PDA	19 (95.0)	0 (0)	19 (70.4)	$<0.001^*$
Warning NOT obscured when pack sealed/opened	20 (100)	2 (28.6)	22 (81.5)	$<0.001^*$
Language and communication requirements				
Language appropriate for brand/region	20 (100)	2 (28.6)	22 (81.5)	$<0.001^*$
Quitline number (1800-11-2356) present	20 (100)	7 (100)	27 (100)	1.000

† Fisher's exact test, two-tailed. * $p<0.05$ (statistically significant). PDA = Principal Display Area.

Table 5: Warning quality and presence of prohibited elements among packages with current PHW (n=27).

Compliance Parameter	Smoke-form (n=20) Yes (%)	Smokeless (n=7) Yes (%)	Total (n=27) Yes (%)	P value†
Warning quality				
Textual warning clear and legible	20 (100)	7 (100)	27 (100)	1.000
Adequate resolution of pictorial warning	20 (100)	0 (0)	20 (74.1)	$<0.001^*$
Adequate colour contrast of warning	20 (100)	0 (0)	20 (74.1)	$<0.001^*$
Prohibited/deceptive elements				
Misleading descriptors present	2 (10.0)	4 (57.1)	6 (22.2)	0.024*
Promotional images/text reducing warning impact	14 (70.0)	7 (100)	21 (77.8)	0.155
Headshots/face images on package	0 (0)	0 (0)	0 (0)	1.000

† Fisher's exact test, two-tailed. * $p<0.05$ (statistically significant).

Product information

Manufacturer/importer name, address, and MRP were present on all 27 packages (100%). Information on product quantity and date of manufacture was present in 92.6% overall, with notably lower rates in the smokeless category (71.4% each; Fisher's exact $p=0.064$).

Health warning display and 'not for minors' message

PHWs (both pictorial and textual) were displayed on both principal display areas of all 27 packages (100%). However, the statutory 'not for minors' message was present in only 77.8% of packages overall, and was present on 95.0% of smoke-form but only 28.6% of smokeless packs, a statistically significant difference (Fisher's exact $p=0.001$).

Warning size, placement, and language

The most striking disparity was in warning size compliance. All three mandatory size criteria (total $\geq 85\%$ of PDA, pictorial $\geq 60\%$, textual $\geq 25\%$) were met by 95.0% of smoke-form packages but by none of the smokeless packages (0%; Fisher's exact $p<0.001$ for all three). Correct placement at the top edge was observed in 92.6% overall. Warnings were not obscured when sealed or opened in 81.5% overall but in only 28.6% of smokeless packs (versus 100% of smoke-form; $p<0.001$). Language appropriateness was achieved in 81.5% overall (100% smoke-form, 28.6% smokeless; $p<0.001$). The cessation Quitline number (1800-11-2356) was present on all 27 packages (Table 4).

Warning quality and presence of prohibited elements

Textual warnings were clear and legible on all 27 packages. Adequate pictorial warning resolution and colour contrast were observed in all 20 smoke-form packages (100%) but in none of the 7 smokeless packages (0%; Fisher's exact $p<0.001$). Misleading descriptors (such as 'herbal', 'natural', or 'mouth freshener') were present on 22.2% of packages overall, with a significantly higher prevalence among smokeless products (57.1% versus 10.0% in smoke-form; $p=0.024$). Promotional images or text that could potentially diminish the impact of health warnings were observed on 77.8% of all packages, with no statistically significant difference between categories ($p=0.155$). No package displayed headshots or facial images (Table 5).

DISCUSSION

This study provides a timely and systematic assessment of the compliance of tobacco product packages sold at retail outlets in Mumbai with the recently notified COTPA (packaging and labelling) amendment rules, 2024. Three findings stand out as particularly significant from a public health and regulatory perspective.

First, a strikingly high proportion of packages at retail, 43.8% were not displaying the mandated current PHW. One in eight packages (12.5%) had no PHW at all, and nearly one in three (31.3%) displayed outdated, out-of-rotation warnings. The circulation of packages without any PHW, alongside a larger number carrying obsolete warning images, reveals systemic gaps in both manufacturer adherence and supply chain surveillance. Satpathy et al, in a compliance study in Bhubaneswar, similarly found that a substantial proportion of tobacco packages lacked or carried outdated PHWs, with bids showing particularly low compliance.¹¹ The pattern observed in Mumbai reflects these findings, suggesting that the problem of PHW non-compliance is not geographically confined but reflects a broader structural failure in implementation across the country. The presence of out-of-rotation warnings is itself a violation, it represents a manufacturer's practice of continuing to use old stock or old printing templates, effectively evading the rotation mandate that is designed to prevent warning fatigue. From a policy standpoint, time-bound clearance of pre-amendment stock from retail supply chains should be enforced by the Ministry of Health and Family Welfare (MoHFW) and the National Tobacco Control Programme (NTCP) to eliminate the continued circulation of outdated warnings.

Second, the disparity in compliance between smoke-form and smokeless tobacco products is both stark and consistent. Among the subset of packages displaying current PHWs, smokeless tobacco products failed on nearly every measured compliance parameter: warning size (0% versus 95% for smoke-form), pictorial quality (0% versus 100%), language appropriateness (28.6% versus 100%), and the 'not for minors' message (28.6% versus 95%), all statistically significant. Dinakar et al found that while most smokeless tobacco products displayed health warnings in Mangaluru, Karnataka, the average coverage was only 70.6%, well below the mandated 85%, and many did not adhere to rotation or quality standards.¹² The consistently poor performance of the smokeless tobacco sector across geographies and time points likely reflects the largely unorganized nature of this industry, involving numerous small-scale manufacturers with limited regulatory oversight, and insufficient resources or incentives for compliance. This demands prioritized enforcement targeting smokeless tobacco manufacturers, who demonstrate the poorest compliance profile, as a direct policy response.

Third, the high prevalence of promotional elements, present on 77.8% of all assessed packages, is a serious concern. While promotional images are not entirely prohibited under COTPA, those that diminish the salience or impact of PHWs undermine the core purpose. Misleading descriptors such as 'herbal', 'natural', and 'mouth freshener', found on 57.1% of smokeless packs are directly prohibited under COTPA, as they create false perceptions of reduced harm.¹⁰ This is particularly problematic given evidence that pictorial warnings are

more effective when they are prominent and unimpeded by competing visual or textual elements.^{6,7} Active prosecution of misleading descriptors and adoption of plain packaging provisions to limit promotional elements are urgent policy priorities.

Mutti et al demonstrated experimentally that graphic images produced the highest impact on risk perception and motivation to quit among smokeless tobacco users in India and Bangladesh.¹³ However, PHW effectiveness requires correct implementation. The deficiencies identified directly undermine this, particularly in the smokeless tobacco sector, where the health burden is greatest.

CONCLUSION

Out-of-rotation warnings, inadequate coverage, and misleading descriptors suggest deliberate manufacturer non-compliance. Retail outlets serve as the final checkpoint, making regular retail-level surveillance a practical, low-cost enforcement mechanism.

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