UNPACKING PUBLIC HEALTH

POLICY BRIEF

The Way Forward in Health Warnings and Tobacco Packaging Law in India
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Tobacco control laws regulate packing and labeling to achieve two main objectives: First, to inform the users about the health consequences of tobacco and the threat posed by it; Secondly, to counter the tobacco industry’s efforts to advertise tobacco through attractive packaging and branding.
SUMMARY OF RECOMMENDATIONS

There is a worldwide acceptance that in the interest of public health, tobacco control laws should mandate strong and enhanced health warnings. Health warning policies and law are now moving towards plain packaging and India also needs to move in this direction. In this regard, the following recommendations are made:

a) Current legislation on tobacco pack warning, namely The Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act 2003, (‘COTPA’) and the 2014 Rules which mandate 85% health warnings on tobacco packs should be effectively implemented in order to achieve public health goals. The Government must ensure that there is strict compliance with all the provisions of the 2014 Rules including those mandating rotation of pictorial health warnings to ensure that these warnings remain effective.

b) There is a need to move towards introducing plain packaging regulations. The developments and learnings from around the world support such a policy move and the judgment of the Allahabad High Court in the Love Care Foundation case also recommends plain packaging. Legislative focus should also shift towards building momentum towards introducing rules on plain packaging.

c) Plain packaging should be part of a comprehensive package of tobacco control measures, which to be effective should include updated and expanded health warnings, restriction of advertising of tobacco products, investments in anti-smoking social marketing campaigns, increase in tobacco excise and excise-equivalent customs duty on tobacco and tobacco-related products and stronger penalties for tobacco offences.

d) The introduction and implementation of strong health warnings or plain packaging will only be effective if there is a ban on the sale of loose cigarettes in the country. Most tobacco users, especially children, purchase loose cigarettes without the tobacco packs as they are cheaper. Therefore, health warnings are not communicated to major population of tobacco users. It is important to prohibit the sale of loose cigarettes to ensure that health warnings are effective.
There are an estimated

274.9

million
tobacco users in India
according to the Global
Adult Tobacco Survey (GATS)
2009-2010 and this number
is growing rapidly.
ONE

Introduction

Tobacco is the primary cause of preventable death in India.¹ The high prevalence of tobacco consumption remains one of the major challenges to public health. Each year more than 900,000 people die as a result of tobacco use in India, which translates to 2500 deaths everyday. Findings from the Global Adult Tobacco Survey (GATS) 2009-2010 reveal that the estimated number of tobacco users in India is 274.9 million and this number is growing rapidly.

The Global Youth Tobacco Survey-2009, reveals that nearly 15% of youth in India use tobacco. Despite the serious health hazards, there is inadequate knowledge about the negative consequences of smoking or tobacco use among its users.

The tobacco industry continues to market tobacco as an attractive and sophisticated commodity, particularly to young adolescents. Packaging and labeling are important parts of these branding exercises, with tobacco companies investing heavily into the concept, design and attractive colour schemes of tobacco products.² Tobacco control laws, therefore, regulate packing and labeling to achieve two main objectives: First, to inform the users about the health consequences of tobacco and the threat posed by it; secondly, to counter the tobacco industry’s efforts to advertise tobacco through attractive packaging and branding.

This Brief first traces the development of the law on tobacco health warnings in India under the Cigarettes and Other Tobacco Products (Prohibition of Advertisement and Regulation of Trade and Commerce, Production, Supply and Distribution) Act 2003 ("COTPA") and its Rules and the Framework Convention on Tobacco Control (FCTC). This Brief also describes the litigation surrounding the Rules. Finally, the Brief gives recommendations on the way forward by looking at comparative examples on health warnings and the future of tobacco packaging law, which should move towards plain packaging. This will ensure effective health warnings and curtail the use of tobacco packets as advertising tools by the industry.

REFERENCES


Larger warnings with pictures are more likely to be noticed, better communicate health risks, provoke a greater emotional response and increase the motivation of tobacco users to quit and to decrease their tobacco consumption.
The Law on Health Warnings in India

Health warnings were first introduced in India only on cigarette packets under the Cigarettes (Regulations of Production, Supply and Distribution) Act, 1975. This Act prohibited trade, commerce or distribution of cigarettes unless every pack had the warning “Cigarette Smoking is Injurious to Health” on at least one of the largest panels.

This Act was very limited in its application: First, it excluded bidi and chewing tobacco from its purview, thereby leaving out most tobacco users in India from its ambit. Secondly, the Act prescribed a weak textual warning without highlighting the fatal effects of tobacco and its link to cancer and other life threatening diseases. While this law prescribed that the warning be legible and prominent, it did not regulate and standardize the size, colour and language of the lettering to ensure their legibility and prominence. Thirdly, the Act did not mandate any pictorial warnings.

The COTPA prohibited advertisement of tobacco and provided for the regulation of its production, supply and distribution and included the requirement of display of health warnings on tobacco products.

COTPA was enacted during negotiations of an international treaty at the World Health Organization, in order to show commitment to this new treaty.

The main provisions relating to health warnings and packaging are outlined in Sections 7, 8, 9 and 10 of COTPA and require the following:

1) COTPA prohibits trading in tobacco products that do not carry the prescribed health warnings.
2) The specified warnings should appear on not less than one of the largest panels of the package in which cigarettes or any other tobacco products have been packed for distribution, sale or supply.
3) Specified warnings should be legible and prominent,
4) Should be conspicuous as to size and colour.
5) Lettering and graphic material to be distinct from
the background or package labels.

6) Provides for Rules to specify the manner in which a specified warning shall be printed, painted or inscribed on tobacco packages

7) Every package shall be so packed as to ensure that the specified warning is visible to the consumer before it is opened.

8) No package of cigarettes or any other tobacco products shall contain any matter or statement, which is inconsistent with, or detracts from, the specified warning.

9) If warnings are not in compliance with the Act, it would amount to an offence

10) Section 20 contains the punishment for contravention of the provisions on packaging and labelling.

In this manner, COTPA lays down the framework for health warnings to be placed on tobacco packaging and these warnings have been continuously detailed in the various Rules framed under it.

**TWO / 2**

**Article 11 of The Framework Convention on Tobacco Control**

Immediately after the COTPA was enacted, India signed and ratified the WHO Framework Convention on Tobacco Control, 2003, (“FCTC”) an evidence-based treaty on tobacco control. Article 11 of the FCTC obligates parties to adopt and implement effective packaging and labeling measures within three years of its entry into force in the country.

**Article 11 is fairly detailed and requires the following measures to be taken with respect to health warnings:**

1) Tobacco product packaging and labelling should not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions, including any term, descriptor, trademark, figurative or any other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than other tobacco products. These may include terms such as “low tar”, “light”, “ultra-light”, or “mild”.

2) Packaging and labelling of tobacco products should carry health warnings describing the harmful effects of tobacco use, and may include other appropriate messages as approved by the competent national authority

3) Health warnings shall be rotated

4) Health warnings shall be large, clear, visible and legible

5) Health warnings should be 50% or more of the principal display areas but shall be no less than 30%

**TWO / 3**

**Guidelines to Article 11**

The WHO also framed Guidelines for implementation of Article 11 of the FCTC. These Guidelines are intended to assist governments in meeting their obligations under Article 11 of the Convention, and to propose measures that Parties can use to increase the effectiveness of their packaging and labeling measures.

The Guidelines recommend the following:

1) Larger warnings with pictures are more likely to be noticed, better communicate health risks, provoke a greater emotional response and increase the motivation of tobacco users to quit and to decrease their tobacco consumption. Larger pictorial warnings are also more likely to retain their effectiveness over time and are particularly effective in communicating health effects to low-literacy populations, children and young people.

2) Use of colour affects the overall noticeability of pictorial elements of health warnings and messages.

3) Rotation of health warnings and messages and changes in layout and design to maintain saliency and enhance impact.

4) Parties should establish two or more sets of health warnings and messages, specified from the outset, to alternate after a specified period of every 12–36 months.

5) Health warnings and messages are likely to be
more effective if they elicit unfavourable emotional associations with tobacco use
6) No exemptions for small-volume companies or brands or for different types of tobacco products.
7) Parties should consider adopting measures to restrict or prohibit the use of logos, colours, brand images or promotional information on packaging other than brand names and product names displayed in a standard colour and font style (plain packaging). This may increase the noticeability and effectiveness of health warnings and messages, prevent the package from deterring attention from them, and address industry package design techniques that may suggest that some products are less harmful than others.
8) Evaluate the impact of packaging and labeling measures both before and at regular intervals after they are implemented.

TWO / 4
Tobacco Packaging Rules under COTPA

Although the COTPA was enacted in 2003, Rules on specified health warnings were not introduced. Thereafter, in 2004, a public interest petition was filed before the Himachal Pradesh High Court seeking the introduction of rules for strong and legible health warnings on tobacco packs. In this petition, the central government kept seeking time to frame Rules and finally when more than two years had passed, the High Court by its order dated 7.6.2006, noted the “total non-cooperative attitude” of the government in complying with the Court’s direction to introduce strong rules on health warnings and questioned if, by its repeated delays the government was “trying to protect the business or commercial interests of some people at the cost of public interest?” The High Court issued a show cause notice of contempt to the Secretary of the Health Ministry and in response to this contempt notice, in July 2006, the Health Ministry introduced the Cigarettes and Other Tobacco Products (Packaging and Labeling) Rules, 2006 (“2006 Rules”). These Rules prescribed health warnings to cover 50% of the tobacco packs and mandated the skull and bone graphic labels.

The tobacco industry immediately lobbied against these Rules to ensure that they were not brought into force. Due to its lobbying efforts, the implementation of the 2006 Rules was delayed thrice and finally they came into force only in 2008. The Government sought further extensions before the Himachal Pradesh High Court in bringing the 2006 Rules into force, and finally notified that the Rules “will not be given effect till 17 March 2008.”

By this time, the Government completely substituted the 2006 Rules with the Cigarettes and Other Tobacco Products (Packaging and Labeling) Rules, 2008 (“2008 Rules”) which had severely diluted provisions by weakening pictorial warnings and reducing coverage area of warnings from 50% of the pack to 40% and reducing the requirement of health warning coverage to only the front panel of the pack instead of both sides. Therefore, the tobacco industry succeeded in pressurizing the government to dilute the standards of the warning even before the first set of Rules were brought into force.

A similar story of delaying tactics took place once again as the 2008 Rules were not brought into force. Health for Millions, an NGO, filed a petition before the Supreme Court calling for stronger pictorial warning and quick implementation of the Rules. In this petition the Government undertook the enforcement of the 2008 Rules to take effect by 31st May 2009.

In 2010, the Health Ministry amended the 2008 Rules again to introduce new pictorial warnings displaying oral cancer. In 2011 and 2012, the Rules were amended yet again, prescribing four picture options that tobacco companies could choose from. This allowed the industry to choose the milder pictorial warning, thereby weakening the pictorial warnings. These were drastic deviations from the FCTC standards, which made pack warnings less effective.
The 2014 Rules

The above dilution was only remedied in 2014 when The Cigarettes and Other Tobacco Products (Packaging and Labeling) Amendment Rules, 2014 ("2014 Rules") were introduced, amending the 2008 Rules. These Rules mandate that 85% of the principal display area is to be covered with health warnings on the two largest sides of the package. Therefore, the 2014 Rules sought to bring back stronger regulation on health warnings. The Health Ministry constituted an Expert Committee to review pictorial warnings and recommend new pre-tested pictorial warnings and mandated their rotation. The Rules prescribed two images each for smoking forms of tobacco and smokeless tobacco with the warnings stating Smoking causes Cancer.

In compliance with the FCTC, the new Rules mandate rotation of the pictorial warnings every twenty-four months, with each of the two images appearing for twelve months consecutively. The retailers/distributors/importers are granted a grace period of two months to transition between the images, failing which they are prohibited from selling or distributing tobacco products. Therefore the 2014 Rules brought in the much-needed stringent regulations in the interest of public health. The introduction and implementation of the 2014 Rules was equally complicated. The 2014 Rules were introduced and notified to come into force from 1st April 2015. Immediately thereafter, a Parliamentary Sub-Committee on Subordinate Legislation was constituted to reexamine the 2014 Rules and submit its report. The Committee submitted a hurried interim report, noting its receipt of "serious apprehensions expressed... on the livelihood of millions of workers / farmers engaged in the bidi trade". The Report also referred to a letter from one of its members, Shyama Charan Gupta, an MP with well-known ties with the bidi industry where he claimed lack of medical evidence to establish that bidi causes cancer and that its "harmful effects are nil as compared to cigarettes and chewing tobacco". The Sub-Committee recommended that the 2014 Rules be kept in abeyance till the Committee has finally examined the subject.

Despite the fact that the recommendations of the Sub-Committee are not binding, the Health Ministry issued a Corrigendum on 26.3.2015, just four days before the Rules were due to come into force, delaying the implementation of the 2014 Rules indefinitely.

When the 2014 Rules were thus delayed, a public interest petition was filed before the Rajasthan High Court, challenging the Corrigendum. The Rajasthan High Court, by its order dated 3.7.2015, stayed the Corrigendum and as a result, the Rules were to come into force immediately. Even after this order, the government did not take any positive steps and only after a contempt petition was filed, did the Government issue a new Notification, notifying that the 2014 Rules would come into force from 1st April 2016. Thus the implementation of the Rules was delayed by an entire year.

The 2014 Rules follow international best practices on tobacco labeling and largely follows the mandate laid down under the FCTC under Article 11 and also the Guidelines to Article 11. The salient features of the 2014 Rules are as follows:

1) Specified health warning shall cover at least 85% of the principal display area of the package of which 60% shall cover pictorial health warning and 25% shall cover textual health warning, on the top edge of the package, in the same direction as the information on the principal display area.

2) Size of the specified health warning on each panel of the tobacco package shall not be less than 3.5 cm (width) × 4 cm (height), to ensure that the warning is legible, prominent and conspicuous. The size of all components of the specified health warning shall be increased proportionally with the package size to ensure that the specified health warning covers eighty-five per cent (85%) of the
principal display area of the package of which sixty per cent (60%) shall cover pictorial health warning and twenty-five per cent (25%) shall cover textual health warning.

3) Rotation of specified health warnings:
   a) The specified health warnings shall be rotated every 24 months
   b) During the rotation period, there shall be two images of specified health warnings for both smoking and smokeless tobacco products and each of the images of the specified health warning shall appear consecutively on the package with an interregnum period of twelve months.
   c) At the end of the twelve months period, the first image (image 1) of specified health warning shall be replaced with the second image (image 2) of specified health warning, which shall appear for the next twelve months.

While these developments were on-going, the tobacco industry has challenged the constitutional validity of the 2014 Rules in around 43 different petitions that were filed all over the country. The Supreme Court transferred all petitions to Karnataka and a Division Bench of the Karnataka High Court was specially constituted to hear and decide on its constitutional validity and these petitions are pending. An initial stay order was vacated and the 2014 Rules have been implemented since 2016.

REFERENCES

2 Section 3, Cigarettes (Regulations of Production, Supply and Distribution) Act, 1975.


5 World Health Organisation, ‘Guidelines for implementation of Article 11 of the WHO Framework Convention on Tobacco Control (Packaging and labelling of tobacco products)’.

7 Id.

9 Notification No. GSR 402(E) dated 5-7-2006


13 Ministry of Health and Family Welfare, Corrigendum No. GSR 42(E) dated 24-01-2007 (extending the date for coming into force to 1 June 2007); Ministry of Health and Family Welfare, Corrigendum No. GSR 408(E) dated 31-05-2007 (substituting 1 June 2007 to 1 October 2007); Ministry of Health and Family Welfare, Department of Health and Family Welfare, Notification No. GSR 781(E) dated 19-12-2007 (announcing that the Rules will not be given effect to till 17 March 2008).


23 See COTPA Amendment Rules 2010.


28 Id. Order dated 3-7-2015.

30 See Id at Para 15.

31 Ministry of Health and Family Welfare, Corrigendum No. FSR 228(E) dated 26-3-2015. The Corrigendum stated that the Rules “shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint”.

35 Rahul Joshi v. Union of India, WP No. 8680/2015.

38 Id, Order dated 4-5-2016.
Nepal tops the list in terms of health warning size, requiring coverage of at least 90% of the front and back of the package.
THREE

The Future of Tobacco Packaging Law

India is not alone in mandating 85% health warnings on tobacco packaging. Countries all over the world are moving towards increasing health warning sizes, mandating rotation of these warnings and increasingly adopting plain packaging standards.

THREE / 1
Comparative Developments on Health Warnings

As of 2017, 44 countries have laws requiring health warnings to cover more than 65% of the tobacco packages on the front and back. Nepal tops the list in terms of health warning size, requiring coverage of at least 90% of the front and back of the package. Thailand has regulations requiring 85% coverage on the two largest panels. In a constitutional challenge to these Regulations, the Supreme Administrative Court of Thailand upheld the regulations and held that they "are not outside the intended scope of the law on control of tobacco products. The requirements were issued to protect the people and our youth." In Sri Lanka, health warnings cover 80% of the tobacco package and the Sri Lankan Constitutional Court, while upholding these health warnings relied on a judgment of the Indian Supreme Court in *Vincent v. Union of India* where it held that, "Maintenance and improvement of public health have to rank high as these are indispensable to the very physical existence of the community and on the betterment of these depends the building of the society which the Constitution makers envisaged. Attending to public health, in our opinion, therefore, is of high priority – perhaps the one at the top."

In the United States, new legislation on graphic health warnings was upheld by the Court of appeals by relying on Article 11 of the FCTC and the court held, "The government has provided ample evidence supporting the size requirement for the new labels, (see, e.g., World Health Organization, *WHO Framework Convention on Tobacco Control*, art. 11.1(b) (2003)), and Plaintiffs have not shown..."
that the remaining portions of their packaging are insufficient for them to place their brand names, logos or other information. Instead, Plaintiffs primary argument is that the use of such significant labels might dissuade certain smokers from buying their product by making it appear unhealthy or otherwise unattractive. But this is, in some ways, the purpose of the labels—to provide truthful information regarding the health consequences of the product in order to decrease the use of tobacco by young people and dependence on tobacco."^{36}

Therefore, health warnings regulations similar to the 2014 Rules have been introduced in many other jurisdictions and been upheld by the constitutional courts of all the countries where they have been challenged in the protection of public health.

THREE / 2

Plain Packaging

Moving beyond mere increase of the size of health warnings on tobacco packs, the way forward worldwide has been towards plain packaging. Plain packaging, also called “standard packaging” or “generic packaging”, strips the tobacco packs of their branding and design, by prohibiting brand logos, colours and other design features. While the brand name is allowed to appear, the size, shape, colour of the lettering and design of the package are standardized and made plain.

Plain packaging achieves two main objects: First, it emphasizes the pictorial warnings, thereby making them more effective; Secondly, it prevents the advertising and promotion of tobacco through attractive packaging and branding.

Australia was the first country in the world to adopt plain packaging in 2012 through the Tobacco Plain Packaging Act 2011. This legislation mandates updated and expanded health warnings which cover at least 75 % of the front of most tobacco packaging, 90 % of the back of cigarette packaging and 75 % of the back of most other tobacco product packaging. The law also prescribes the entire design and features of the tobacco package, including its colour, dimensions, the size, type and content of the warning, the size and colour of the brand name etc.

Tobacco companies challenged this law before the High Court of Australia, mainly contending that it amounts to an acquisition of the intellectual property (trademark) of the company without just terms as contemplated under the law.\textsuperscript{37} The High Court dismissed the challenge and held that the law, "....reflects a serious judgment that the public purposes to be advanced and the public benefits to be derived from the regulatory scheme outweigh those public purposes and public benefits which underpin the statutory intellectual property rights and the common law rights enjoyed by the plaintiffs. The scheme does that without effecting an acquisition."\textsuperscript{38}

Similarly, in 2015, the United Kingdom introduced plain packaging through The Standardised Packaging of Tobacco Products Regulations 2015. This legislation was also challenged by the tobacco industry.\textsuperscript{39} The High Court of Justice relied on the post-implementation review conducted by the Australian Government, that showed evidence of effectiveness of plain packaging and held that the regulations were proportional, by observing: ".....the restrictions imposed pursue a legitimate public health based interest; a conclusion not challenged by the Claimants."\textsuperscript{40}

Since then, France, Hungary and fourteen other countries are in the process of introducing laws on
Thus, the international support for plain packaging is building momentum. Although, India has just introduced the 2014 Rules mandating 85% health warnings, the government should prepare to bring in standardized packaging in order to increase the effectiveness of pictorial warnings. A move in this direction was made by the Allahabad High Court where in a public interest petition on tobacco packaging, it recommended the introduction of plain packaging and held, "We are of the view that the introduction of standard packaging will remove the final way for tobacco companies to permit their deadly product in an implied manner and cigarettes packets, after implementation of the plain packaging will no longer be a mobile advertisement for the tobacco industry. Tobacco plain packaging measures would be a long-term investment to safeguard the health of the Indian youth. Plain packaging aims to reduce the attractiveness of tobacco products. The noticeability and effectiveness of mandatory health warnings and plain packaging will reduce the ability of attractive packaging to mislead consumer about the harms of smoking." With these observations, the Court directed the government to consider and implement the scheme at the earliest.

In 2012, Lok Sabha MP, Baijayant Jay Panda, also introduced a Private Member’s Bill seeking amendment to COTPA 2003 incorporating plain packaging of tobacco products. Thus, there is increasing momentum and support towards introducing plain packaging in India.

## REFERENCES

30 JT International (Thailand) v. Minister of Public Health, Supreme Administrative Court, Order No. 269/2557, page 58.
32 Id at Para 155.
33 Id at Para 166.
34 AIR 1987 SC 1
35 Decision of the Supreme Court of Sri Lanka in The Matter of Article 122 (1) (b) of the Constitution, S.C. (SD) No.2 of 2015
36 Discount Tobacco City & Lottery, Inc. v. United States 674 F.3d 509 (6th Cir. 2012)
38 Ibid
39 British American Tobacco (UK) Ltd. V. Secretary of State for Health (2016) EWHC 1169 (Admin).
40 Id at Para 38.
42 Love Care Foundation v. Union of India, W.P. 1078 (M/B) of 2013
FOUR

Recommendations

There is a worldwide acceptance that in the interest of public health, tobacco control laws should mandate strong and enhanced health warnings. The public health interest in expanded health warnings clearly overrides the commercial interest and the rights of the tobacco industry. India also needs to reiterate this priority and in this regard, the following recommendations are made:

a) Current legislation on tobacco pack warning, being the COTPA and the 2014 Rules which mandate 85% health warnings on tobacco packs should be effectively implemented in order to achieve public health goals. The Government must ensure that there is strict compliance with all the provisions of the Rules including those mandating rotation of pictorial health warnings to ensure that these warnings remain effective and do not lose their impact.

b) There is a need to move towards introducing plain packaging regulations. The developments and learnings from around the world support such a policy move and the judgment of the Allahabad High Court in Love Care Foundation also recommends plain packaging. Legislative focus should also shift towards building momentum towards introducing rules on plain packaging.

c) Plain packaging should be part of a comprehensive package of tobacco control measures, which to be effective should include updated and expanded health warnings, restriction of advertising of tobacco products, investments in anti-smoking social marketing campaigns, increase in tobacco excise and excise-equivalent customs duty on tobacco and tobacco-related products and stronger penalties for tobacco offences.

d) The introduction and implementation of strong health warnings will only be effective if there is a ban on the sale of loose cigarettes in the country.

Most tobacco users, especially children, purchase loose cigarettes without the tobacco packs as they are cheaper. Therefore, health warnings are not communicated to major population of tobacco users. It is important to prohibit the sale of loose cigarettes to ensure that health warnings are effective.
CLPR extensively engages with public health policy advocacy and strategic litigation on tobacco control. Aligned with constitutional provisions embodying the right to health, CLPR has developed policy initiatives for effective implementation of tobacco control legislation in India. CLPR also works on law and policy initiatives in the fields of constitutional law including the right to education, gender, disability rights and public health.