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Public Health Policy and the Tobacco Industry

Smoking out the Elephant in the Room

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This combination photo made from file images provided by the U.S. Food and Drug Administration shows cigarette warning labels from the FDA. India's attempts to implement a law that mandates larger health warnings on tobacco products are thwarted by vested interests. File photo: AP

*A law making it mandatory for health warnings to cover 85 per cent of the total display area on packages of tobacco products was put on hold in March, five days before it was to take effect. In this article, Aparna Ravi calls for the implementation of internationally accepted guidelines to protect public health policies from being influenced by the vested interests of the tobacco industry by taking proactive measures to address conflicts of interest.***Aparna Ravi**

On March 26, 2015, the Union Ministry of Health and Family Welfare issued a notification amending the Cigarettes and Other Tobacco Products (Packaging and Labelling) Amendment Rules, 2014 (the "Packaging Rules") that were due to come into force five days later. The operative portion of the amendment was a single sentence – "They [the rules] shall come into force on such date as the Central Government may, by notification in the Official Gazette, appoint".¹ With this, the new Packaging Rules, which required health warnings to cover 85 per cent of the total display area and were due to come into effect on April 1, 2015, were placed indefinitely in abeyance. This article

analyses the principles behind tobacco packaging and labelling regulations, outlines the events that resulted in the unusual practice of holding up the effective date of a legislation that had already been passed, and calls for the implementation of internationally accepted guidelines to protect public health policies from being influenced by the vested interests of the tobacco industry.

Tobacco's Killer Effect: Indian Evidence

The risks and dangers of tobacco use are well established and well documented. According to the World Health Organization (WHO), tobacco kills nearly six million people a year globally. Conservative estimates of the number of tobacco-related deaths in India each year is one million and the Tobacco Control Policy Evaluation Project India has projected that smoking will lead to 1.5 million deaths in 2020. ² A study by the Ministry of Health and Family Welfare estimated the total economic costs of tobacco-related diseases in 2011 in India for persons in the 35 years–69 years age group to be Rs. 1,040,500 crores (US \$ 22.4 billion). ³ This amount was 12 per cent more than the total spending on health expenditures by the central and State governments combined in 2011-12. ⁴ Health Warning Regulations and the WHO Guidelines

Faced with a problem of such enormous magnitude, the appeal of health warnings on tobacco products lies in the simplicity of the approach and their ability to reach the targeted audience. First, health warnings are a simple and cost effective way of communicating the detrimental health effects of tobacco use at a particularly opportune moment – just at the time one feels the urge to smoke (or chew in the case of smokeless tobacco products). Second, the warnings limit the space available for tobacco companies to advertise their image and brand name, thereby reducing the appeal of tobacco products. Yet, while many countries have required some form of health warning on cigarette packages for several years, the use of health warnings has become more refined in the last decade based on empirical evidence.

Research has found that the types of warnings do matter and some work better than others. A study in the European Union (EU) found, for example, that pictorial warnings had the effect of increasing a smoker's motivation to quit. ⁵ There is now ample evidence to demonstrate that graphic health warnings together with concise textual messages are very effective in increasing awareness on the risks and dangers associated with tobacco use, particularly among the youth and among illiterate or semi-literate populations.

It is against this backdrop that Article 11 of the WHO Framework Convention on Tobacco Control (FCTC) ⁶ requires state parties to adopt effective packaging and labelling rules. The guidelines ⁷ for implementation of Article 11 further spell out the recommended packaging and labelling measures that states must adopt as part of an integrated approach towards communicating the dangers of tobacco use. These include recommendations on the design, location and content of the warnings to get the maximum desired effect. The guidelines also point out that warnings comprised of a combination of pictorial and textual messages are likely to have a greater impact than those with only textual messages.

Over time and particularly following the ratification of the FCTC, different countries have tried to enhance the effectiveness of their warnings through various means - by increasing the percentage area of the packaging that the warning should cover, using a combination of pictorial and textual warnings and by requiring pictures to be rotated so that their effect doesn't wear off with time. Some countries, most notably Australia and more recently Ireland and the U.K., have introduced the concept of plain packaging by requiring standardised forms of tobacco packages and prohibiting the use of all brand imagery, logos and trademarks on packages.

In India, the health warnings on tobacco products have gone through several iterations. Shortly after ratifying the FCTC, India drafted a policy on tobacco labelling and, after testing out various health warnings, implemented a new set of warnings in 2009. These new warnings included pictures of a scorpion on smokeless forms of tobacco and an X-ray of a diseased lung on smoking forms of tobacco with the message that smoking causes cancer.

Research, however, revealed that these warnings were not particularly effective as the images had little bearing to the textual message and the pictures of diseased lungs were not easily understood by many people. 8

The packaging rules were again amended, first in 2011 and subsequently in 2012, to introduce changes to the warning messages and images on smoking and smokeless tobacco products. The 2012 amendment 9 also required the new warnings to cover at least 40 per cent of the principal display area of the tobacco package and required that the images be rotated every two years to ensure the sustained impact of the message. The latest amendments to the packaging rules passed on October 27, 2014, were designed to further improve the effectiveness of the health warnings.

The new Packaging Rules 10 also brought India's packaging and labelling fully in line with FCTC requirements, which require that warnings cover at least 50 per cent of the principal display area. Before these rules were passed, the Ministry of Health and Family Welfare constituted an Expert Committee to study the issue. The Expert Committee recommended that the size of the warnings be increased to cover 85 per cent of the front and back of cigarette packages.

The new images and textual warnings that were to appear were agreed upon based on field-testing of the new warnings against dummy packs based on various measures, including their noticeability, impact of information, credibility and clarity. In addition, the new warnings were issued to comply with the requirement that health warnings need to be rotated every two years. These were the factors that resulted in the new Packaging Rules being passed in October last year with the intention of them coming into force on April 1, 2015, exactly two years from the date of implementation of the previous health warnings on April 1, 2013.

The Tobacco Lobby's Long Reach

April 1, 2015 arrived and rather than seeing cigarette packages with the new health warnings, the Union Government announced that the new Packaging Rules were to be kept in abeyance pending further study by a Committee on Subordinate Legislation. In a shocking letter to the Health Ministry, the Committee stated that a medical board should study the health effects of tobacco use on Indians before going ahead with increasing the size of the warnings! What caused the government to take this unusual step of requiring consultation on a law that had already been passed? While it is hard to glean all the details of the working behind the scenes, we do know certain facts. We know that the Ministry of Health and Family Welfare received tens of thousands of representation letters from the tobacco industry and their fronting groups, including tobacco vendors, bidi manufacturers and tobacco farmers, protesting against the implementation of the new rules. Many groups and individuals also filed numerous petitions in courts challenging their constitutionality. One of the members of the Committee, Shyama Charan Gupta, who attracted much ridicule in the media for his claim that there was no evidence that tobacco products caused cancer, is the owner of a major bidi company, which has been in business for three-four decades 11, 12, thereby reflecting a blatant conflict of interest.

All of these factors point to the deep undercurrents of the tobacco industry at work and at its strategic best in terms of advocacy. Packaging regulations have always been challenged vociferously by the tobacco industry as the packaging represents all that these companies have left in their arsenal. At a time when most forms of advertising by tobacco companies are prohibited, the packaging is their last and only chance to project their image and brand. On the very day that the Australian government passed the plain packaging legislation, for example, Philip Morris challenged the new law in court. 13 (The Australian High Court rejected the industry's challenge to the legislation.) In 2011, five tobacco companies launched a legal challenge to enhanced graphic warning requirements on tobacco products introduced by the U.S. Food and Drug Administration on grounds that it violated their First Amendment right to free speech. 14 Tobacco packaging regulations have also been the subject of legal challenges in countries as diverse as Canada, Uruguay, Thailand and Belgium.

Countering Conflict of Interest through Implementation of FCTC Guidelines

How do we ensure that the tobacco industry's voice does not dominate policy debates on tobacco control legislation where public health concerns should be paramount? While India has done little to isolate the tobacco industry from policy making in the area of tobacco control or to check for possible conflicts of interest, the guidelines to the FCTC suggest various measures that, if implemented in letter and spirit, could be steps in the right direction.

Article 5.3 of the FCTC provides that "parties in setting and implementing their public health policies with respect to tobacco control, shall act to protect these policies from commercial and vested interests of the tobacco industry". While this might sound more like a broad policy statement, the guidelines to Article 5.3 articulate specific recommendations and measures that states can take to achieve this goal. These guidelines are based on the principles of isolation and transparency – to isolate the tobacco industry from having any role in policy making with regard to tobacco control, and to ensure transparency of all interactions between the government and the tobacco industry as well as full disclosure of any interests that the government or government officials may have in the tobacco industry and vice versa.

Resource: Guidelines for implementation of Article 5.3 of the WHO Framework Convention on Tobacco Control on the protection of public health policies with respect to tobacco control from commercial and other vested interests of the tobacco industry. [PDF 105KB]

The specific recommendations in the guidelines include limiting interactions with the tobacco industry to what is strictly necessary for regulatory purposes and establishing policies to keep a check on pecuniary or other interests that public officials and government employees may have in the tobacco industry. The guidelines also recommend de-normalising any philanthropic initiatives of the tobacco industry, including corporate social responsibility (CSR) activities that serve as an advertisement for the company, and rejecting any voluntary codes or partnerships proposed by the industry.

Ending the Janus-faced Policy

As we know all too well, India is far from implementing any of these recommended measures. On the one hand, the Cigarettes and Other Tobacco Products Act, 2003 (COTPA) is a helpful piece of legislation that addresses demand reduction measures for tobacco use. The COTPA bans smoking in public places, introduces packaging and labelling requirements for tobacco products, regulates advertising of tobacco products and bans the sale of tobacco products to minors. On the other hand, the Tobacco Board continues to exist and its mandate of "promoting the development of the tobacco industry" has remained unchanged since its establishment in 1975.

The very existence of the Tobacco Board runs against the core objectives of the FCTC and COTPA of reducing tobacco use in the interests of public health. The government has also done little to address conflicts of interest for public officials. It is telling that the government took no concrete steps even in the face of a blatant conflict of interest such as when a "bidi baron" was part of a committee considering the new Packaging Rules.

It is high time that the government addressed the elephant in the room – the tobacco industry's interference with public health policies – by taking proactive measures to address conflicts of interest and implement Article 5.3 of the FCTC. If not, the implementation of COTPA as well as the initiation of new policy initiatives and subordinate legislation aimed at tackling tobacco use all stand the risk of being derailed.

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- 12.^ Gupta, a Member of Parliament representing the ruling Bharatiya Janata Party, is the owner of the Shyam Group, of which the bidi company, Shyam Bidi Works, is one of the core ventures.
- 13.^ JT International v Commonwealth of Australia [2012] HCA 43.
- 14.^ R.J. Reynolds Tobacco Co. v. Food & Drug Admin., NO. 11-5332.

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