

## **Briefing 4: Adoption of guidelines for implementation of Article 11 (Packaging and labelling of tobacco products)**

**Third session of the Conference of the Parties to the  
WHO Framework Convention on Tobacco Control  
17-22 November 2008, Durban, South Africa**

### **Recommendation**

**The Framework Convention Alliance strongly endorses the draft guidelines for implementation of Article 11 (Packaging and labelling of tobacco products) (Document FCTC/COP/3/7) and recommends that the third session of the Conference of the Parties to the WHO Framework Convention on Tobacco Control adopt the draft guidelines in full and without change.**

### **Background**

Under Article 11 of the WHO Framework Convention on Tobacco Control (FCTC), Parties undertake a number of important commitments with respect to the packaging and labelling of tobacco products. Article 11 gives effect to one of the key guiding principles of the FCTC: 'Every person should be informed of the health consequences, addictive nature and mortal threat posed by tobacco consumption and exposure to tobacco smoke' (Article 4.1). Article 11 requires Parties: to implement, within a period of three years after entry into force of the FCTC for each Party, effective measures to ensure that all tobacco product packaging and labelling carry large, rotating health warnings and do not promote tobacco products by false, misleading or deceptive means; and to require that all tobacco product packaging and labelling contain information on relevant constituents and emissions of tobacco products as defined by national authorities.

Effective regulation of tobacco product packaging and labelling is a proven tobacco control measure. Effective health warnings on packaging increase awareness of the health effects of tobacco use and exposure to tobacco smoke, and decrease consumption of tobacco products.<sup>1</sup> They are highly

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<sup>1</sup> See generally: David Hammond, 'Tobacco Labelling & Packaging Toolkit: A Guide to FCTC Article 11' (January 2008), available at [http://www.igloo.org/community.igloo?r0=community&r0\\_script=/scripts/folder/view.script&r0\\_pathinfo=%2F%7Bf0ce20c6-7a3c-409a-a5c9-15e2b251a129%7D%2Ftobaccolab&r0\\_output=xml](http://www.igloo.org/community.igloo?r0=community&r0_script=/scripts/folder/view.script&r0_pathinfo=%2F%7Bf0ce20c6-7a3c-409a-a5c9-15e2b251a129%7D%2Ftobaccolab&r0_output=xml); World Health Organization, *WHO Report on the Global Tobacco Epidemic, 2008: the MPOWER Package* (2008); Canadian Cancer Society, 'Controlling the Tobacco Epidemic: Selected Evidence in Support of Banning All Tobacco Advertising and Promotion, and Requiring Large, Picture-Based Health Warnings on Tobacco Packages' (Ottawa: Canadian Cancer Society, International Union Against Cancer, 2001), available at <http://gea2000.org/tobacco/docs/advertising/evidence.doc>.

cost-effective, with the role of governments being to enact legal requirements, and the costs of complying with the requirements falling on the tobacco industry. Effective measures are also needed to prevent tobacco manufacturers from using packaging and labelling to communicate misleading and deceptive messages about the harmfulness of products and undermine the effectiveness of health warnings.

The Conference of the Parties (COP) decided at its second session (COP-2) to establish a working group to elaborate draft guidelines on the implementation of Article 11 for presentation to its third session (COP-3). The working group has presented draft guidelines (Document FCTC/COP/3/7).

### **The draft guidelines**

The Framework Convention Alliance (FCA) congratulates the Article 11 working group, and particularly the key facilitator Parties – Australia, Brazil, Canada, Peru and the Philippines – for the excellent work that they have done in elaborating draft guidelines. FCA considers that the draft guidelines should be adopted by COP-3 in full and without change.

The draft guidelines elaborated by the working group offer very useful guidance to Parties in implementing Article 11. They draw on the large body of evidence about the effectiveness of regulation of packaging and labelling of tobacco products and on the experiences – both successes achieved and challenges encountered – of Parties that have implemented packaging and labelling measures. They provide advice and recommendations not only on the substantive content of laws and regulations implementing Article 11, but on processes for developing, introducing, monitoring, evaluating and reviewing these laws and regulations. The guidelines are truly comprehensive, and, if adopted, will greatly assist Parties in effectively implementing Article 11 of the FCTC.

FCA supports the draft guidelines in full, and comments here on some of their particularly important features:

#### *Purpose, principles and use of terms*

The introductory section of the draft guidelines contains an excellent explanation of the importance of effective packaging and labelling measures (para 3):

Globally, many people are not fully aware of, misunderstand or underestimate the risks for morbidity and premature mortality due to tobacco use and exposure to tobacco smoke. Well-designed health warnings and messages on tobacco product packages have been shown to be a cost-effective means to increase public awareness of the health effects of tobacco use and to be effective in reducing tobacco consumption. Effective health warnings and messages and other tobacco product packaging and labelling measures are key

components of a comprehensive, integrated approach to tobacco control.

The section also notes the importance of international cooperation and mutual support as ‘fundamental principles for strengthening the capacity of Parties to implement fully and improve the effectiveness of Article 11 of the Convention’ (para 5).

### *Developing effective packaging and labelling requirements*

This section commences with an excellent overview of the evidence on the effectiveness of health warnings and other messages in communicating health risks and reducing tobacco use (para 7). It notes that:

- the effectiveness of health warnings and messages increases with their prominence;
- larger warnings with pictures are more effective than small, text-only messages, being more likely to be noticed, better communicating health risks, provoking greater emotional responses and increasing the motivation of tobacco users to quit and to decrease consumption;
- large picture warnings are more likely to retain their effectiveness over time and are particularly effective in communicating health effects to low-literacy populations, children and young people;
- the effectiveness of health warnings and messages can be enhanced if: they are located on principal displays areas, and at the top of these areas; are colour, rather than black and white; multiple warnings and messages appear concurrently; and health warnings and messages are periodically revised.

The section then provides very useful, specific advice and recommendations with respect to the content and design of health warnings and messages. Key recommendations include:

- Parties should require that warnings and messages be located on *both* the front and back of packages, recognizing that the front is the most visible for most package types (para 8);
- Parties should aim to cover as much of the principal display areas of packages as possible with health warnings and messages, recognizing ‘the evidence that the effectiveness of health warnings and messages increases with their size’ (para 12);
- Parties should require full-colour pictorial warnings, recognizing that ‘[e]vidence shows that health warnings and messages that contain both pictures and text are far more effective than those that are text only’ and have the ‘added benefit of potentially reaching people with low levels of literacy and those who cannot read the language(s) in which the text of the health warning or message is written’ (paras 14 and 18);
- Parties should specify clear requirements for rotation of health warnings and messages to maintain saliency and enhance impact (paras 19-22);

- Parties should use a range of health warnings and messages to increase the likelihood of impact, informed by evidence that ‘health warnings and messages are likely to be more effective if they elicit unfavourable emotional associations with tobacco use and when the information is personalized to make the health warnings and messages more believable and personally relevant’ (paras 23 and 26); and
- Parties should include messages in addition to warnings about the harmful effects of tobacco use and exposure to tobacco smoke, such as advice on cessation (para 23).

The section concludes with useful advice on implementation of Article 11.2, under which Parties agree to require information on relevant constituents and emissions of tobacco products as defined by national authorities, recommending that Parties require *qualitative* statements about the emissions of tobacco products and not require quantitative or qualitative statements that might imply that one brand is less harmful than another (paras 32-34). Reference is made in this section to the section on preventing packaging that is false, misleading deceptive or likely to create an erroneous impression (paras 43-45), where the reasons for not using tar, nicotine, carbon monoxide or other smoke emission yield numbers are explained.

#### *Process for developing effective packaging and labelling requirements*

This section provides useful advice on ensuring that requirements apply across different types of products, with content of messages tailored as appropriate to different tobacco products, such as cigarettes, cigars, smokeless tobacco, pipe tobacco, bidis and water pipe tobacco (para 36); specifying how requirements apply to different types and shapes of packaging (para 37); considering designing warnings targeted at relevant subgroups (para 38); using appropriate pre-marketing testing, in accordance with available resources and time (paras 39-40); involvement of the public (para 41); and coordination of the introduction of new measures with a broader, sustained public information and education campaign (para 42).

#### *Developing effective packaging and labelling restrictions*

This section provides useful guidance on implementation of the obligation under Article 11.1(a) to ensure that packaging and labelling do not promote a tobacco product by means that are false, misleading, deceptive or likely to create an erroneous impression about its characteristics, health effects, hazards or emissions. The section notes that the terms listed in Article 11.1(a) – ‘low tar’, ‘light’, ‘ultra-light’ and ‘mild’ – should be regarded as ‘indicative but not exhaustive’ and recommends that the terms ‘extra’, ‘ultra’ and ‘similar terms in any language that might mislead consumers’ be prohibited (para 43). The section specifically recommends prohibiting the display of figures for emission yields, such as tar, nicotine and carbon monoxide on packaging and labelling, including when used as part of a brand name or trademark (para 44). This is because, as the section notes, emission yields derived from smoking-machine testing ‘do not provide valid estimates of human exposure’

and the marketing of cigarettes with stated tar and nicotine levels ‘has resulted in the mistaken belief that these cigarettes are less harmful’.

The section also recommends that Parties consider adopting measures to implement ‘plain packaging’: 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 (para 46). It explains that plain packaging requirements ‘may increase the noticeability and effectiveness of health warnings and messages, prevent the package from detracting attention from these and address industry design techniques that may suggest that some products are less harmful than others’.

### *Legal measures*

This section provides useful guidance on ensuring that considerations relating to administration, compliance and enforcement are adequately addressed, including: identifying the authority or authorities responsible for overseeing implementation (para 48); applying measures to all products sold within the jurisdiction, whether domestically manufactured, imported or intended for duty-free sale, with consideration to circumstances in which measures would apply to exported products (para 49); ensuring that the costs of placing health warnings and messages, and information on constituents and emissions, on packaging is borne by the tobacco industry (para 50); ensuring that compliance with health warning and message requirements does not remove or diminish any other legal obligations of the tobacco industry, such as to warn consumers about health hazards (para 51); ensuring clear, detailed specifications are provided in order to limit the opportunity of manufacturers and importers to deviate in implementation and to prevent inconsistencies between products (para 52); providing a ‘source document’ with high-quality visual samples of how health warnings, messages and other information are to appear on packaging (para 53); ensuring that adhesive labels, stickers, cases, covers, sleeves, inserts and onsets do not obscure, obliterate or undermine health warnings and messages (para 54); ensuring that legal responsibility for compliance is placed on manufacturers, importers, wholesalers and retail establishments (para 55); specifying a range of penalties commensurate with the severity of violations (paras 56-57); granting appropriate powers to enforcement authorities (para 58); specifying a single deadline by which manufacturers, importers, wholesalers and retailers must only supply products that comply with the new requirements (which is useful to prevent deliberate ‘stockpiling’ of products bearing old warnings and messages) (para 59); and reviewing measures periodically and updating them as new evidence emerges and specific health warnings and messages wear out (para 60).

### *Enforcement*

This section contains useful advice with respect to ensuring the necessary infrastructure for compliance and enforcement activities and provision of an appropriate budget (para 61); strategies to encourage and monitor compliance

(paras 62-63); responding to non-compliance (para 64); and the making and investigation of complaints (para 65).

#### *Monitoring and evaluating packaging and labelling measures*

This section (paras 66-71) contains useful advice on the monitoring and evaluation of packaging and labelling measures in order to assess their impact on target populations and identify any improvements needed, on monitoring tobacco industry compliance, and on sharing the results of monitoring and evaluation.

#### *International cooperation*

This section begins with a recognition that '[i]nternational cooperation is essential for progress in such an important, constantly changing area' (para 72). It notes that several Articles of the FCTC provide for the exchange of knowledge and experience to promote implementation, with particular focus on the needs of developing country Parties and Parties with economies in transition. It also notes that cooperation for the transfer of technical, scientific and legal expertise and technology, as required by Article 22, would strengthen the implementation of Article 11 – particularly useful examples include the provision of licences quickly, easily and without cost by Parties to allow other Parties to use their pictorial health warnings, and the sharing of legal and other expertise in countering tobacco industry arguments against packaging and labelling measures.