



**FCTC**

WHO FRAMEWORK CONVENTION  
ON TOBACCO CONTROL

## **Guidelines for implementation of Article 11**

Packaging and labelling of tobacco products

Adopted by the Conference of the Parties at its third session (decision FCTC/COP3(10))

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# **Guidelines for implementation of Article 11 of the WHO Framework Convention on Tobacco Control (Packaging and labelling of tobacco products)**

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

### *Purpose*

1. Consistent with other provisions of the WHO Framework Convention on Tobacco Control and the intentions of the Conference of the Parties to the Convention, these guidelines are intended to assist Parties 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 labelling measures. Article 11 stipulates that each Party shall adopt and implement effective packaging and labelling measures within a period of three years after entry into force of the Convention for that Party.

### *Principles*

2. In order to achieve the objectives of the Convention and its protocols and to ensure successful implementation of its provisions, Article 4 of the Convention states that Parties shall be guided, *inter alia*, by the principle that every person should be informed of the health consequences, addictive nature and mortal threat posed by tobacco consumption and exposure to tobacco smoke.

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.

4. Parties should consider the evidence and the experience of others when determining new packaging and labelling measures and aim to implement the most effective measures they can achieve.

5. As provided for in Articles 20 and 22 of the Convention, international collaboration and mutual support are fundamental principles for strengthening the capacity of Parties to implement fully and improve the effectiveness of Article 11 of the Convention.

### *Use of terms*

6. For the purposes of these guidelines:

- “legal measures” means any legal instrument that contains or establishes obligations, requirements or prohibitions, according to the law of the relevant jurisdiction. Examples of such instruments include, but are not limited to acts, laws, regulations and administrative or executive orders;

- “insert” means any communication inside an individual package and/or carton purchased at retail by consumers, such as a miniature leaflet or brochure.
- “onsert” means any communication affixed to the outside of an individual package and/or carton purchased at retail by consumers, such as a miniature brochure beneath the outer cellophane wrapping or glued to the outside of the cigarette package.

## **DEVELOPING EFFECTIVE PACKAGING AND LABELLING REQUIREMENTS**

7. Well-designed health warnings and messages are part of a range of effective measures to communicate health risks and to reduce tobacco use. Evidence demonstrates that the effectiveness of health warnings and messages increases with their prominence. In comparison with small, text-only health warnings, 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 picture 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. Other elements that enhance effectiveness include locating health warnings and messages on principal display areas, and at the top of these principal display areas; the use of colour rather than just black and white; requiring that multiple health warnings and messages appear concurrently; and periodic revision of health warnings and messages.

### ***Design elements***

#### ***Location***

8. Article 11.1(b)(iii) of the Convention specifies that each Party shall adopt and implement effective measures to ensure that health warnings and messages are large, clear, visible and legible. The location and layout of health warnings and messages on a package should ensure maximum visibility. Research indicates that health warnings and messages are more visible at the top rather than the bottom of the front and back of packages. Parties should require that health warnings and messages be positioned:

- on both the front and back (or on all main faces if there are more than two) of each unit packet and package, rather than just one side, to ensure that health warnings and messages are highly visible, recognizing that the frontal display area is the one most visible to the user for most package types;
- on principal display areas and, in particular, at the top of the principal display areas rather than at the bottom to increase visibility; and
- in such a way that normal opening of the package does not permanently damage or conceal the text or image of the health warning.

9. Parties should consider requiring, in addition to the health warnings and messages referred to in paragraph 8, further health warnings and messages on all sides of a package, as well as on package inserts and onserts.

10. Parties should ensure that health warnings and messages are not obstructed by other required packaging and labelling markings or by commercial inserts and onserts. Parties should also ensure, when establishing the size and position of other markings, such as tax stamps and markings as per

the requirements of Article 15 of the Convention, that such markings do not obstruct any part of the health warnings and messages.

11. Parties should consider introducing other innovative measures regarding location, including, but not limited to, requiring health warnings and messages to be printed on the filter overwrap portion of cigarettes and/or on other related materials such as packages of cigarette tubes, filters and papers as well as other instruments, such as those used for water pipe smoking.

#### *Size*

12. Article 11.1(b)(iv) of the Convention specifies that health warnings and messages on tobacco product packaging and labelling should be 50% or more, but no less than 30%, of the principal display areas. Given the evidence that the effectiveness of health warnings and messages increases with their size, Parties should consider using health warnings and messages that cover more than 50% of the principal display areas and aim to cover as much of the principal display areas as possible. The text of health warnings and messages should be in bold print in an easily legible font size and in a specified style and colour(s) that enhance overall visibility and legibility.

13. If a border is required, Parties should consider excluding the space dedicated to framing health warnings and messages from the size of the health warning or message itself when calculating the percentage of display area occupied by them, that is to say the space dedicated to the frame should be added to the total percentage of space occupied by the health warnings and messages and not included within it.

#### *Use of pictorials*

14. Article 11.1(b)(v) of the Convention specifies that health warnings and messages on tobacco product packaging and labelling may be in the form of or include pictures or pictograms. Evidence shows that health warnings and messages that contain both pictures and text are far more effective than those that are text-only. They also 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. Parties should mandate culturally appropriate pictures or pictograms, in full colour, in their packaging and labelling requirements. Parties should consider the use of pictorial health warnings on both principal display areas (or on all main faces if there are more than two) of the tobacco products packaging.

15. Evidence shows that, when compared with text-only health warnings and messages, those with pictures:

- are more likely to be noticed;
- are rated more effective by tobacco users;
- are more likely to remain salient over time;
- better communicate the health risks of tobacco use;
- provoke more thought about the health risks of tobacco use and about cessation;
- increase motivation and intention to quit; and
- are associated with more attempts to quit.

16. Pictorial health warnings and messages may also disrupt the impact of brand imagery on packaging and decrease the overall attractiveness of the package.

17. When creating pictures for use on tobacco product packaging, Parties should obtain, where possible, ownership or full copyright of images, instead of allowing graphic designers or other sources to retain copyright. This provides maximum flexibility to use the images for other tobacco control interventions, including mass media campaigns and on the Internet. It may also enable Parties to grant licences to other jurisdictions to use the images.

### ***Colour***

18. The use of colour, as opposed to black and white, affects the overall noticeability of pictorial elements of health warnings and messages. Therefore, Parties should require full colour (four-colour printing), rather than black and white, for pictorial elements of health warnings and messages. Parties should select contrasting colours for the background of the text in order to enhance noticeability and maximize the legibility of text-based elements of health warnings and messages.

### ***Rotation***

19. Article 11.1(b)(ii) of the Convention specifies that health warnings and messages shall be rotating. Rotation can be implemented by having multiple health warnings and messages appearing concurrently or by setting a date after which the health warning and message content will change. Parties should consider using both types of rotation.

20. The novelty effect of new health warnings and messages is important, as evidence suggests that the impact of health warnings and messages that are repeated tends to decrease over time, whereas changes in health warnings and messages are associated with increased effectiveness. Rotation of health warnings and messages and changes in their layout and design are important to maintain saliency and enhance impact.

21. Parties should specify the number of health warnings and messages that are to appear concurrently. Parties should also require that health warnings and messages in a specified series be printed so that each appears on an equal number of retail packages, not just for each brand family but also for each brand within the brand family for each package size and type.

22. Parties should consider establishing two or more sets of health warnings and messages, specified from the outset, to alternate after a specified period, such as every 12–36 months. During transition periods, when an old set of health warnings and messages is being replaced by a new set, Parties should provide for a phase-in period for rotation between sets of health warnings and messages, during which time both sets may be used concurrently.

### ***Message content***

23. Using a range of health warnings and messages increases the likelihood of impact, as different health warnings and messages resonate with different people. Health warnings and messages should address different issues related to tobacco use, in addition to harmful health effects and the impact of exposure to tobacco smoke, such as:

- advice on cessation;
- the addictive nature of tobacco;

- adverse economic and social outcomes (for example, annual cost of purchasing tobacco products); and
- the impact of tobacco use on significant others (premature illness of one’s father due to smoking, for example, or death of a loved one due to exposure to tobacco smoke).

24. Parties should also consider innovative content for other messages, such as adverse environmental outcomes and tobacco industry practices.

25. It is important to convey health warnings and messages in an effective manner; the tone should be authoritative and informative but non-judgemental. Health warnings and messages should also be presented in simple, clear and concise language that is culturally appropriate. Health warnings and messages can be presented in various formats, such as testimonials and positive and supportive information.

26. Evidence suggests 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. Health warnings and messages that generate negative emotions such as fear can be effective, particularly when combined with information designed to increase motivation and confidence in tobacco users in their ability to quit.

27. The provision of advice on cessation and specific sources for cessation help on tobacco packaging, such as a web site address or a toll-free telephone “quit line” number, can be important in helping tobacco users to change their behaviour. Parties should be aware that an increased demand for cessation-related services might require additional resources.

### ***Language***

28. Article 11.3 of the Convention specifies that each Party shall require that the warnings and other textual information specified in Article 11.1(b) and Article 11.2 appear on each unit packet and package of tobacco products, as well as on any outside packaging and labelling of such products, in the Party’s principal language or languages.

29. In jurisdictions where there is more than one principal language, health warnings and messages can be displayed on each principal display area in more than one language, or, alternatively, a different language can be used for different principal display areas. Where appropriate, different languages or language combinations could also be used in different regions of a jurisdiction.

### ***Source attribution***

30. An attribution statement gives an identified source for the health warnings and messages on tobacco product packaging. There are, however, mixed views about whether they should form part of health warnings and messages. Some jurisdictions have provided a source attribution statement in order to increase the credibility of the health warnings and messages, while others have decided not to include a source attribution out of concern that it might detract from the impact of the warning. Where a source attribution statement is required, it is often located at the end of the health warning, in a smaller font size than the rest of the warning. Ultimately, Party-specific circumstances, such as beliefs and attitudes among target population subgroups, will determine whether the use of source attribution is likely to increase credibility or reduce impact.

31. If required, a source attribution statement should specify a credible expert source, such as the national health authority. The statement should be small enough not to detract from the overall noticeability and impact of the message, while being large enough to be legible.

### ***Information on constituents and emissions***

32. Article 11.2 of the Convention specifies that each unit packet and package of tobacco products, and any outside packaging and labelling of such products, shall, in addition to the warnings specified in Article 11.1(b), contain information on relevant constituents and emissions of tobacco products as defined by national authorities.

33. In implementing this obligation, Parties should require that relevant qualitative statements be displayed on each unit packet or package about the emissions of the tobacco product. Examples of such statements include “smoke from these cigarettes contains benzene, a known cancer-causing substance” and “smoking exposes you to more than 60 cancer-causing chemicals”. Parties should also require that this information be shown on parts of the principal display areas or on an alternative display area (such as the side of packaging) not occupied by health warnings and messages.

34. Parties should not require quantitative or qualitative statements on tobacco product packaging and labelling about tobacco constituents and emissions that might imply that one brand is less harmful than another, such as the tar, nicotine and carbon monoxide figures or statements such as “these cigarettes contain reduced levels of nitrosamines”.

35. The above three paragraphs should be read in conjunction with paragraphs 43–45.

## **PROCESS FOR DEVELOPING EFFECTIVE PACKAGING AND LABELLING REQUIREMENTS**

### ***Product category considerations***

36. Article 11.1(b) of the Convention requires each Party to adopt and implement effective measures to ensure that each unit packet or package of tobacco products and any outside packaging and labelling of such products carry health warnings and messages. There should be no exemptions for small-volume companies or brands or for different types of tobacco products. Parties should consider requiring different health warnings and messages for different tobacco products such as cigarettes, cigars, smokeless tobacco, pipe tobacco, bidis and water pipe tobacco, in order to better focus on the specific health effects related to each product.

### ***Different types of packaging***

37. Parties should have a comprehensive understanding of the many different types of tobacco product packaging found within their jurisdiction, and should indicate how the proposed health warnings and messages will apply to each type and shape of packaging such as tins, boxes, pouches, flip-tops, slide and shell packages, cartons, transparent wrappers, clear packaging or packages containing one product unit.

### ***Targeting population subgroups***

38. Parties should consider designing warnings that target subgroups, such as youth, and adapting the number of health warnings and their rotation accordingly.

### ***Pre-marketing testing***

39. Depending on the available resources and time, Parties should consider pre-marketing testing to assess the effectiveness of the health warnings and messages on the intended target population. Pre-marketing testing can permit identification of unintended effects, such as inadvertently increasing the craving to smoke, and assessment of their cultural appropriateness. Consideration should be given to inviting civil society organizations not affiliated with the tobacco industry to contribute to this process. Ultimately, pre-marketing testing can be less costly than changes to legal measures at a later stage.

40. Parties should note that pre-marketing testing need not be long, complex or expensive. Valuable information can be obtained from simple focus groups of the target population, and Internet-based consultation is a quick and inexpensive alternative. Pre-marketing testing can be undertaken in parallel with the drafting of legal measures to avoid undue delay in implementation.

### ***Public information and involvement***

41. Parties should inform the public of proposals to introduce new health warnings and messages. Public support will assist Parties in introducing the new health warnings and messages. Parties should ensure, however, that public information and involvement do not unduly delay implementation of the Convention.

### ***Supporting communication activity***

42. The introduction of new health warnings and messages is more effective when it is coordinated with a broader, sustained public information and education campaign. Timely information should be provided to the media, as media coverage can increase the educational impact of new health warnings and messages.

## **DEVELOPING EFFECTIVE PACKAGING AND LABELLING RESTRICTIONS**

### ***Preventing packaging and labelling that is misleading or deceptive***

43. Article 11.1(a) of the Convention specifies that Parties shall adopt and implement, in accordance with their national law, effective measures to ensure that tobacco product packaging and labelling do not promote a tobacco product by any means that are false, misleading, deceptive or likely to create an erroneous impression about the product's characteristics, health effects, hazards or emissions, including any term, descriptor, trademark or figurative or other sign that directly or indirectly creates the false impression that a particular tobacco product is less harmful than others. These may include terms such as "low tar", "light", "ultra-light" or "mild", this list being indicative but not exhaustive. In implementing the obligations pursuant to Article 11.1(a), Parties are not limited to prohibiting the terms specified but should also prohibit terms such as "extra", "ultra" and similar terms in any language that might mislead consumers.

44. Parties should prohibit 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. Tar, nicotine and other smoke emission yields derived from smoking-machine testing do not provide valid estimates of human exposure. In addition, there is no conclusive epidemiological or scientific evidence that cigarettes with lower machine-generated smoke yields are less harmful than cigarettes with higher smoke emission yields. The marketing of cigarettes



with stated tar and nicotine yields has resulted in the mistaken belief that those cigarettes are less harmful.

45. Parties should prevent the display of expiry dates on tobacco packaging and labelling where this misleads or deceives consumers into concluding that tobacco products are safe to be consumed at any time.

### ***Plain packaging***

46. 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 detracting attention from them, and address industry package design techniques that may suggest that some products are less harmful than others.

## **LEGAL MEASURES**

### ***Drafting***

47. In drafting legal measures with respect to tobacco product packaging and labelling, Parties should consider issues such as who will be responsible for their administration, the available approaches for ensuring compliance and enforcement, and the level or levels of government involved.

### ***Administration***

48. Parties should identify the authority or authorities responsible for overseeing implementation of tobacco product packaging and labelling measures. Parties should consider ensuring that the relevant authority responsible for tobacco control matters is the same as that which administers the legal measures. In the event that the administration is made the responsibility of another area of government, the relevant health authority should provide input into label specifications.

### ***Scope***

49. Parties should ensure that the packaging and labelling provisions related to Article 11 of the Convention apply equally to all tobacco products sold within the jurisdiction, and that no distinction is made between products that are manufactured domestically or imported or intended for duty-free sale within a Party's jurisdiction. Parties should consider circumstances in which measures would apply to exported products.

### ***Costs***

50. Parties should ensure that the cost of placing health warnings and messages, as well as information on constituents and emissions, on tobacco product packaging is borne by the tobacco industry.

### ***Liability***

51. Consistent with Article 19 of the Convention, Parties should consider including provisions to make it clear that the requirement to carry health warnings and messages or to convey any other information about a tobacco product does not remove or diminish any obligation of the tobacco industry, including, but not limited to, obligations to warn consumers about the health hazards arising from tobacco use and exposure to tobacco smoke.

### ***Specific provisions***

52. Parties should ensure that clear, detailed specifications are provided for in their legal measures in order to limit the opportunity for tobacco manufacturers and importers to deviate in the implementation of health warnings and messages, as well as to prevent inconsistencies among tobacco products. In drafting such measures, Parties should review, inter alia, the following list:

- packaging and products (please refer to paragraph 37);
- language(s) to be used in mandated text of health warnings and messages and in information on constituents and emissions on packaging, including how languages should appear if there is more than one language;
- rotation practice and time frames, including the number of health warnings and messages to appear concurrently as well as specifications of transition periods and deadlines within which the new health warnings and messages must appear;
- distribution practices, in order to obtain equal display of health warnings and messages on retail packages, not just for each brand family but also for each brand within the brand family for each package size and type;
- how text, pictures and pictograms of health warnings and messages should actually appear on packaging (including specification of location, wording, size, colour, font, layout, print quality), including package inserts, onserts and interior messages;
- different health warnings and messages for different types of tobacco product, where appropriate;
- source attribution, if appropriate, including placement, text and font (similar detailed specifications as for the health warnings and messages themselves); and
- prohibition of promotion by means that are false, misleading, deceptive or likely to create an erroneous impression, in accordance with Article 11.1(a) of the Convention.

### ***Source document***

53. Parties should consider providing a “source document”, which contains high-quality visual samples of how all health warnings and messages and other information are to appear on packaging. A source document is particularly useful in the event that the language used in the legal measures is not sufficiently clear.

### ***Adhesive labels and covers***

54. Parties should ensure that adhesive labels, stickers, cases, covers, sleeves, wrapping and tobacco manufacturers’ promotional inserts and onserts do not obscure, obliterate or undermine

health warnings and messages. For example, adhesive labels might be allowed only if they cannot be removed and are used only on metal or wood containers that hold products other than cigarettes.

### ***Legal responsibility for compliance***

55. Parties should specify that tobacco product manufacturers, importers, wholesalers and retail establishments that sell tobacco products bear legal responsibility for compliance with packaging and labelling measures.

### ***Penalties***

56. In order to deter non-compliance with the law, Parties should specify a range of fines or other penalties commensurate with the severity of the violation and whether it is a repeat violation.

57. Parties should consider introducing any other penalty consistent with a Party's legal system and culture that may include the creation and enforcement of offences and the suspension, limitation or cancellation of business and import licences.

### ***Enforcement powers***

58. Parties should consider granting enforcement authorities the power to order violators to recall non-compliant tobacco products, and to recover all expenses stemming from the recall, as well as the power to impose whatever sanctions are deemed appropriate, including seizure and destruction of non-compliant products. Further, Parties should consider making public the names of violators and the nature of their offence.

### ***Supply deadline***

59. In order to ensure the timely introduction of health warnings and messages, legal measures should specify a single deadline by which manufacturers, importers, wholesalers and retailers must only supply tobacco products that comply with the new requirements. The time allocated need only be enough to allow manufacturers and importers to organize the printing of new packages. It has been considered that a period of up to 12 months from the enactment of the legal measures should suffice in most circumstances.

### ***Review***

60. Parties should recognize that the drafting of legal measures for packaging and labelling of tobacco products is not a one-time exercise. Legal measures should be reviewed periodically and updated as new evidence emerges and as specific health warnings and messages wear out. When undertaking periodic reviews or updates, Parties should take into account their experience in using their packaging and labelling measures, the experiences of other jurisdictions, as well as industry practices in this area. Such reviews or updates can help identify weaknesses and loopholes and highlight areas in which the language used in the measures should be clarified.

## **ENFORCEMENT**

### ***Infrastructure and budget***

61. Parties should consider ensuring that the infrastructure necessary for compliance and enforcement activities exists. Parties should also consider providing a budget for such activities.

### ***Strategies***

62. To enhance compliance, Parties should inform stakeholders of the requirements of the law before it comes into force. Different strategies might be required for different stakeholders, such as tobacco manufacturers, importers and retailers.

63. Parties should consider using inspectors or enforcement agents to conduct regular spot checks of tobacco products at manufacturing and importing facilities, as well as at points of sale, to ensure that packaging and labelling comply with the law. It may not be necessary to create a new inspection system if mechanisms are already in place that could be extended to inspect business premises as required. Where applicable, stakeholders should be informed that tobacco products will undergo regular spot checks at points of sale.

### ***Response to non-compliance***

64. Parties should ensure that their enforcement authorities are prepared to respond quickly and decisively to instances of non-compliance. Strong, timely responses to early cases will make it clear that compliance is expected and will facilitate future enforcement. Parties should consider making the results of enforcement action public in order to send a strong message that non-compliance will be investigated and action will be taken.

### ***Complaints***

65. Parties should consider encouraging the public to report violations in order to further promote compliance with the law. It might be helpful to establish an enforcement contact point for reporting alleged cases of non-compliance. Parties should ensure that complaints are investigated and dealt with in a timely and thorough manner.

## **MONITORING AND EVALUATING PACKAGING AND LABELLING MEASURES**

66. Parties should consider monitoring and evaluating their packaging and labelling measures to assess their impact as well as to identify where improvements are needed. Monitoring and evaluation also contribute to the body of evidence that can assist the efforts of other Parties in implementing their packaging and labelling measures.

67. Monitoring of the tobacco industry's compliance should be initiated immediately after legal measures have come into force and should be conducted continuously thereafter.

### ***Impact on populations***

68. It is important to assess the impact of packaging and labelling measures on the target populations. Parties should consider measuring aspects such as noticeability, comprehension, credibility, informativeness, recall and personal relevance of health warnings and messages, health knowledge and perceptions of risks, intentions to change behaviour and actual behavioural changes.

### ***Baseline and follow-up***

69. Parties should consider adopting strategies to evaluate the impact of packaging and labelling measures both before and at regular intervals after they are implemented.

### ***Resources***

70. The extent and complexity of actions to evaluate the impact of tobacco product packaging and labelling measures will vary among Parties, depending on the objectives and the availability of resources and expertise.

### ***Dissemination***

71. Parties should consider publishing, or making available to other Parties and to the public, the results gathered from monitoring of compliance and evaluating impact.

## **INTERNATIONAL COOPERATION**

72. International cooperation is essential for progress in such an important, constantly changing area as tobacco control. Several articles of the Convention provide for exchanges of knowledge and experience to promote progress in implementation, with a particular focus on the needs of developing country Parties and Parties with economies in transition. Cooperation among Parties to promote the transfer of technical, scientific and legal expertise and technology, as required by Article 22, would strengthen the implementation of Article 11 of the Convention globally. One example of such cooperation would be the provision of licences quickly, easily and without cost from Parties to other jurisdictions seeking to use their pictorial health warnings. International cooperation would also help to ensure that consistent and accurate information relating to tobacco products is provided globally.

73. Parties should endeavour to share legal and other expertise in countering tobacco industry arguments against packaging and labelling measures.

74. Parties should consider reviewing the reports of other Parties, pursuant to Article 21 of the Convention, to enhance their knowledge of international experience with respect to packaging and labelling.

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