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I. GENERAL PROVISIONS

MINISTRY OF HEALTH AND SOCIAL POLICY

8388 *Royal Decree 639/2010 of 14 May 2010 amending Royal Decree 1079/2002 of 18 October 2002 regulating the maximum nicotine, tar and carbon monoxide yields of cigarettes and the warnings regarding health and other information to appear on unit packets of tobacco products, together with certain measures concerning the ingredients and the descriptions of tobacco products.*

The labelling of tobacco products is regulated by Royal Decree 1079/2002 of 18 October 2002 regulating the maximum nicotine, tar and carbon monoxide yields of cigarettes and the warnings regarding health and other information to appear on unit packets of tobacco products, together with certain measures concerning the ingredients and the descriptions of tobacco products.

This Royal Decree incorporates into the Spanish legal order Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products. Article 5.3 stipulates that Member States can decide whether health warnings in the form of colour photographs or other illustrations are required on tobacco packages of some or all types of tobacco products, except for tobacco products for oral use and other smokeless tobacco products, as long as they are in accordance with the rules adopted by the Commission.

Commission Decision 2003/641/EC of 5 September 2003 on the use of colour photographs or other illustrations as health warnings on tobacco packages was adopted at the initial stage, followed by Commission Decision C(2005) 1452 of 26 May 2005 on the library of selected source documents. These documents contain colour photographs or other illustrations for each additional warning listed in annex 1 to Directive 2001/37/EC of the European Parliament and of the Council, subsequently modified by Decision C (2006) 1502 of 12 April 2006.

Furthermore, article 11.1 of the WHO Framework Convention on Tobacco Control, ratified by Spain on 30 December 2004, stipulates that health warnings in the form of pictures or pictograms can be an effective means of discouraging smoking.

The object of this Royal Decree is to develop certain points regarding the labelling of tobacco products referred to in Act 28/2005 of 28 December 2005 on health measures to control tobacco use and regulate the sale, supply, consumption and advertising of tobacco products, and also to amend the labelling of tobacco products by incorporating pictures or pictograms. Other countries have proved through experience and research that this is an effective means of discouraging smoking and informing citizens about the health risks related to smoking.

In drafting this Royal Decree, reports have been submitted by the Autonomous Communities and businesses, trade unions, scientific bodies and social organizations have been invited to attend consultations.

This Royal Decree is a basic norm within the meaning of article 149.1.16.^a of the Spanish Constitution and issued in pursuance of articles 24, 25.3, and 40.5 and 6 of the General Health Act 14/1986 of 25 April 1986.

Pursuant to which, at the request of the Minister of Health and Social Policy and in accordance with the State Council and previous deliberations of the Cabinet at its meeting on 14 May 2010,

I DECREE:

Sole article. *Amendment of Royal Decree 1079/2002 of 18 October 2002 regulating the maximum nicotine, tar and carbon monoxide yields of cigarettes and the warnings regarding health and other information to appear on unit packets of tobacco products, together with certain measures concerning the ingredients and the descriptions of tobacco products.*

The following amendment should be made to the Royal Decree 1079/2002 of 18 October 2002:

One. Article 5 to be amended as follows:

«Article 5. *Labelling.*

«1. The tar, nicotine, and carbon monoxide yields of cigarettes marketed in Spain, measured in accordance with Article 4 shall be printed on one side of the cigarette packet in Spanish, the official State language, so that at least 10% of the corresponding surface is covered.

2. Each unit packet of tobacco products, except for tobacco for oral use and other smokeless tobacco products must carry the following warnings:

a) general warnings:

1. 'Smoking kills,' or
2. 'Smoking seriously harms you and others around you.'

The general warnings indicated above shall be rotated in such a way to guarantee their regular appearance on an equal number of unit packets, with an annual tolerance of more or less 5%. The warning shall be printed on the most visible surface of the unit packet, and on any outside packaging, with the exception of additional transparent wrappers, used in the retail sale of the product; and

b) an additional warning taken from the list set out in Annex II that consists of pictures or pictograms and text (combined warnings).

The additional warnings referred to above shall be rotated in such a way to guarantee their regular appearance on an equal number of unit packets, with an annual tolerance of more or less 5%.

This warning shall be printed on the other most visible surface of the unit packet, and on any outside packaging, with the exception of additional transparent wrappers used in the retail sale of the product, respecting the format, source document proportions (electronic file containing the additional warnings provided by the Ministry of Health and Social Policy and available on its web site), and the graphic integrity of the image, text and colours, in line with the printing specifications in Annex III.

These warnings shall cover the entire area reserved for the additional health warning, parallel to the top edge of the packet and in the same direction as the remaining information on the unit packet.

They shall be surrounded by a black border not less than 3 mm and not more than 4 mm in width which in no way interferes with any textual or visual element of the additional warning. The space taken up by the black border shall not be counted as part of the surface that the health warning must occupy.

3. Tobacco products for oral use and smokeless tobacco products shall carry the following warning:

'This tobacco product can damage your health and is addictive.'

This warning shall be printed on the most visible surface of the unit packet, and on any outside packaging, with the exception of additional transparent wrappers, used in the retail sale of the product.

4. The general warning required pursuant to paragraph 2(a) and the warning for smokeless and oral tobacco products referred to in paragraph 3 will cover not less than 30% of the external area of the corresponding surface of the unit packet of tobacco on which it is printed. The additional warning required pursuant to paragraph 2(b) shall cover not less than 40% of the external area of the corresponding surface of the unit packet of tobacco on which it is printed. However, in the case of unit packets intended for products other than cigarettes, the most visible surface of which exceeds 75 cm², the warnings referred to in paragraph 2(a) and 2(b) shall cover an area of at least 22.5 cm² on each surface. The text of general and specific warnings and indications related to the tar, nicotine and carbon monoxide yields required under this Article shall be printed:

- a) in black Helvetica bold type on a white background. The font size must occupy the greatest possible proportion of the area set aside for the text required.
- b) in lower-case type, except for the first letter of the message
- c) centred in the area in which the text is required to be printed, parallel to the top edge of the packet
- d) for products other than those referred to in paragraph 3, surrounded by a black border not less than 3 mm and not more than 4 mm in width which in no way interferes with the text of the warning or information given.

The area set aside for the black border shall not be counted as part of the area that the health warnings about tar, nicotine, and carbon monoxide yields should occupy.

e) In Spanish, the official national language.

6. The following message shall precede the warnings referred to in paragraphs 2 and 3: "Health authority warning". This warning shall appear outside the box referred to in paragraph 2(b) and 5(d). It shall be at least an additional 4 mm in height on unit packets of cigarettes, and shall retain the same proportion on other tobacco product packages. It will be located contiguously with and immediately above the health warnings and shall be the same length as the area designated for the health warnings. The text shall have the same characteristics as those specified in paragraphs 5(a), (b), (c) and (e).

Additionally, the following caption shall be included: "SALE PROHIBITED TO MINORS UNDER 18". This caption shall be placed on one side of the unit packet of cigarettes, so that at least 13% of the corresponding surface is covered. The text shall be printed in upper-case type on two lines and shall have the same characteristics as those specified in paragraphs 5(a), (c) and (e). On all unit packages of other tobacco products, this caption shall be contiguous with and immediately above one of the messages "Health authority warning". It shall occupy an additional area at least 4 mm in height, have the same length as that of the area set aside for the caption, and comply with all the requirements and characteristics specified in paragraphs 5(a), (b) and (e).

7. The nicotine, tar and carbon monoxide yields, health warnings and other requirements in this article must be printed by the original manufacturer or by a third party authorized by the manufacturer. They shall be irremovably printed, indelible and shall in no way be hidden, obscured or interrupted by other written or pictorial matter or by the opening of the packet. They should not be printed on tax stamps. In the case of tobacco products other than cigarettes, the texts may be affixed by means of stickers, provided that such stickers are irremovable.

The unit packets, as well as all exterior packaging used for retail sale shall not have any type of label, sticker, case, sleeve, wrapping or other element that obscures, obliterates or undermines the health warnings and messages referred to in this article.

8. To ensure product identification and traceability, the tobacco product shall be marked in any appropriate manner, by batch numbering or equivalent, on the unit packet enabling the place and time of manufacture to be determined.

9. The sale or shipment of cigarettes without packaging is prohibited.

Two. Article 8, paragraph 2(c), to be amended as follows::

«2. The omission or incorrect display of general and additional warnings and messages about tar, nicotine and carbon monoxide yields, or the reference to the health authority or the prohibition of sales to minors under 18, on unit packets of tobacco products as specified in article 5, or the retailing of tobacco products with any type of cover, bag, flap, box, or other element that totally or partially conceals, masks or covers the warnings, captions and yield messages specified in article 5, are considered to be cases covered by article 35.C.1.^aof the General Health Act. »

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Translated from Spanish (Unofficial Translation)

Three. The current Annex of the list of additional health warnings shall become Annex I, with the same title and content.

Four. Two new Annexes shall be incorporated, numbered II and III, which will include the information contained in parts A and B, respectively, of the Annex to this Royal Decree.

Sole transitional provision. *Marketing extension.*

Upon the entry into force of this Royal Decree and for twelve months thereafter in the case of packets of cigarettes, or twenty-four months in the case of other tobacco products, products not in compliance with the provisions of this Royal Decree may continue to be marketed, and shall be adjusted to the provisions of Royal Decree 1079/2002 of 18 October 2002 and Act 28/2005 of 26 December 2005 on health measures to control tobacco use and regulate the sale, supply, consumption and advertising of tobacco products.

First final provision. *Jurisdiction.*

This Royal Decree, which is a basic norm, is issued in pursuance of article 149.1.16.^a of the Constitution that attributes jurisdiction over the basic principles and general coordination of health matters to the State.

Second final provision. *Entry into force.*

The present Royal Decree shall enter into force the day after its publication in the Official Journal of the State.

Done at Barcelona, 14 May 2010.

JUAN CARLOS R.

The Minister of Health and Social Policy
TRINIDAD JIMÉNEZ GARCÍA-HERRERA

ANNEX

Part A

Annex II

Additional warnings

In order to facilitate the printing of these warnings on tobacco product packaging, the Ministry of Health and Social Policy will provide them in electronic format. They will also be available on the Department's web page.



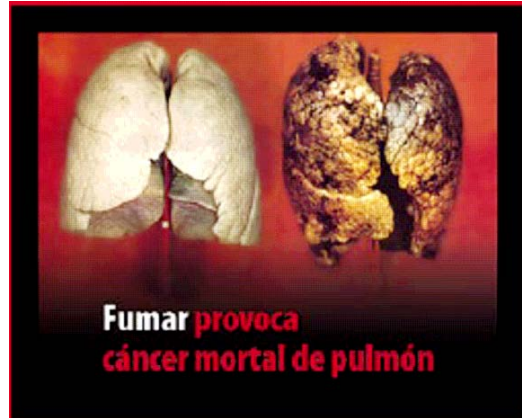
1.

Smokers die young.



2.

Smoking clogs the arteries and causes heart attacks and strokes.



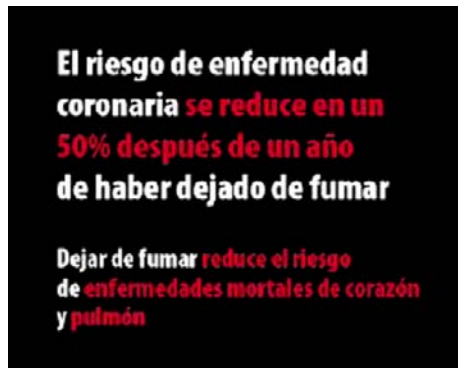
3.

Smoking causes fatal lung cancer.



4.

Smoking is highly addictive, don't start.



5.

The risk of developing heart disease is reduced by 50% one year after you stop smoking.
Stopping smoking reduces the risk of fatal heart and lung diseases.



6.

Smoking can cause a slow and painful death.



7.

Smoking causes ageing of the skin.



8.

Smoking can damage sperm and decreases fertility.



9.

Smoking may reduce the blood flow and cause impotence.



10.

Smoking can damage sperm and decreases fertility.



11.

Smoking when pregnant harms your baby.



12.

Protect children: don't make them breathe your smoke.



13.

You can do it, we can help you. Your doctor or pharmacist can help you stop smoking.



14.

0803 00 00 00 Choose freedom, we'll help you. Get help to stop smoking.

In this last warning the telephone number needs to be changed because in Spain smokers can dial several numbers to get help. The web site of the Ministry of Health and Social Policy is www.msps.es.

PART B

Annex III

Technical specifications for printing of additional warnings

1. General technical specifications:

- a) The warnings must be reproduced without changes to their proportions or colours.
- b) The warnings are conceived as a whole image and must not be amended.
- c) The warnings must be printed in four-colour/-CMYK-/ screen 133 lines per inch.

2. Technical specifications for printing the additional warnings on certain unit packets of tobacco products to prevent image distortion: When the size of the package so requires, the warnings can be modified according to the following rules:

- a) The graphical editing of the textual elements shall be done by varying font size and line breaks to ensure high readability.
- b) For warnings where the illustration is a text, the graphical editing shall be done by varying font size and line breaks. The relative surfaces occupied by text as an illustration and the corresponding text of the additional warning must be respected.
- c) For warnings where a photograph or other illustration is an image, the graphical editing shall be done by proportionate scaling of the photograph or other illustration and varying of the relative surfaces occupied by the photograph or other illustration and the corresponding text of the warning.
- d) When the proportion between the height and the width of the warning is lower than 0.8, the corresponding text of the additional warning, if placed under the photograph or other illustration, may be moved to the right of the photograph or other illustration.
- e) When the proportion between the height and the width of the warning exceeds 1.2, the corresponding text of the additional warning, if placed to the side of the photograph or other illustration, may be moved under the photograph or other illustration.