

Health
Decree-Law n.º 6/2016
of February 22

Law n.º 109/2015, of August 26, which amended and republished Law n.º 37/2007, of August 14, approved rules for the protection of citizens from involuntary exposure to tobacco smoke, and measures to reduce demand relating to addiction and quitting consumption, transposing to the internal legal system Directive 2014/40/UE, of the European Parliament and its Council, of April 3, 2014, concerning the reconciliation of legislative, regulatory and administrative provisions of the member States with regard to the manufacture, display and sale of tobacco products and related products, as well as Delegated Directive 2014/109/UE, of the Commission, of October 10, 2014, which amends Annex II of Directive 2014/40/UE of the European Parliament and its Council, which establishes the library of illustrated warnings to be used for tobacco products. The aforesaid Directive has delegated to the European Commission the definition of certain technical aspects relating to labeling and the specifications for the configuration, design and format of health warnings, taking into account the different packages, through acts of execution. Accordingly, the Execution Decision (EU) 2015/1735 of the Commission, of September 24, establishes the exact position of the general warning and the informational message on rolling tobacco sold in pouches, pursuant to the terms of n.º 6 of Article 9. of Directive 2014/40/UE, of the European Parliament and its Council, of April 3, 2014, whereas Execution Decision (EU) 2015/1842 of the Commission, of October 9, determines the technical specifications for the configuration, design and format of combined health warnings for tobacco products for smoking, pursuant to the terms of n.º 4 of Article 10. of Directive 2014/40/UE, of the European Parliament and its Council, of April 3, 2014. This provision has been enshrined in Law n.º 109/2015, of August 26, particularly in Articles 11.-A and 11.- B.

Thus:

In accordance with what is set forth in sub-paragraph a) of n.º 6 of Article 11.- A and in n.º 7 of Article 11.- B of Law n.º 37/2007, of August 14, as amended and republished by Law n.º 109/2015, of August 26, and pursuant to the terms of sub-paragraph a) of n.º 1 of Article 198. of the Constitution, the Government decrees as follows:

Article 1. Purpose

This Decree-Law establishes rules on:

- a) The positioning of general warnings and informational messages on rolling tobacco products sold in pouches, transposing to the internal legal system Execution Decision (EU) 2015/1735 of the Commission, of September 24, 2015;
- b) Technical specifications for the design, configuration and format of combined health warnings, taking into account the different kinds of packages for tobacco products for smoking, transposing to the internal legal system Execution Decision (EU) 2015/1842 of the Commission, of October 9, 2015.

Article 2. Position of the general warning and informational message on rectangular pouches

1 — With regard to rolling tobacco contained in rectangular pouches with a flap that covers the opening, the general warning and the informational message must, pursuant to the terms of Nos. 1 and 2 of Annex I to this Decree-Law, of which it comprises an integral part:

- a) Be printed on the two surfaces that are visible when the individual package is completely open;
- b) Be positioned close to the upper edge, and covering 50% of the respective surfaces on which they are printed.

2 — In the cases referred to in the preceding item, the general warning must be printed on the surface of the top.

Article 3. Position of the general warning and informational message on vertical pouches and rectangular pouches with flat backs

1 — With regard to rolling tobacco in vertical pouches, the general warning and informational message must, pursuant to the terms of n.º 3 of Annex I of this Decree-Law:

- a) Be positioned on the surface at the back of the pouch that is visible when the pouch is placed on its bottom, that is, at the base of the package;
- b) Cover 50% of the surfaces on which they are printed, with the surfaces calculated using their dimensions after the edges have been sealed.

2 — In the cases referred to in the foregoing item, the general warning must be printed on the surface above the fold at the base of the package, and the informational message on the surface below the fold.

Article 4. Configuration and format of combined health warnings

1 — Combined health warnings may, pursuant to the terms of Annex II to this Decree-Law, of which it comprises an integral part, adopt an overlapping, or side by side format.

2 — The overlapping format is used when the height of the combined health warning is greater than 70% of its width, pursuant to the terms of n.º 1 of Annex II to this Decree-Law, and:

- a) The photograph must occupy 50% of the surface of the combined health warning within the outer black border, and be placed above the combined health warning;
- b) The written warning and information for quitting smoking must occupy 38% and 12% of the surface of the combined health warning within the outer black border, respectively, with both appearing beneath the photograph.

3 — The side to side format is used when the height of the combined health warning is greater than 20%, but less than 65% of its width, pursuant to the terms of n.º 2 of Annex II to this Decree-Law, and:

- a) The photograph must occupy 50% of the surface of the combined health warning within the outer black border, and be placed to the left of the combined health warning;

b) The written warning and information for quitting smoking must occupy 40% and 10% of the surface of the combined health warning within the outer black border, respectively, with both appearing in the lower right part of the combined health warning.

4 — If the combined health warning is greater than or equal to 65%, but less than or equal to 70% of its width, any of the formats provided for in the foregoing items can be adopted, as long as all of the elements of the combined health warning are totally visible, and are not falsified.

5 — Whenever, due to the shape of an individual package or the outer package, the height of the combined health warning is equal to or less than 20% of its width, the combined health warning must be designed in an extra-wide side to side format, pursuant to the terms of n.º 3 of Annex II to this Decree-Law, and the photograph must occupy 35%, the written warning 50%, and the information for quitting smoking 15% of the surface of the combined health warning within the outer black border.

Article 5. Design of the combined health warning

1 — The combined health warning must be printed in four color CMYK, with all elements in black C0, M0, Y0 and K100, and the elements in hot yellow C0, M10, Y100 and K0, and it must be reproduced at a minimum resolution of 300 dpi when printed in real size.

2 — The written warning must be printed in white on a black background, and the information for quitting smoking in black on a hot yellow background, pursuant to the terms of Annex II to this Decree-Law.

3 — If a side to side format, an inverted overlapping format or an extra wide side to side format is used, a 1-millimeter (mm) black border must be printed between the information for quitting smoking and the photograph in the panel of the information for quitting smoking.

4 — The photograph must be reproduced without the application of effects, color adjustment, touching up or increasing background images, and it must be proportionally adapted, without being extended or reduced, and it cannot be cut off too close to, or too far from, the focal point of the image.

5 — The written warning and the information for quitting smoking must be aligned to the left and vertically centered, be printed in Neue Frutiger Condensed Bold typeface, and be as large as possible, to ensure maximum visibility of the text.

6 — The written warning must be printed in characters of a uniform size, and be reproduced as stated in Annex II of Law n.º 109/2015, of August 26, including with respect to the use of upper case letters, but excluding the identification of sub-paragraphs.

7 — The minimum size of the characters in the written warning must be 6 points (pt), and the minimum size of the characters in the information for quitting smoking 5 pt, while the space between the lines must be 2 pt greater than the size of the characters in the written warning, and 1 to 2 pt greater than the size of the characters in the information for quitting smoking

8 — For tobacco products for smoking that are not cigarettes, rolling tobacco or tobacco for water pipes, the size of the characters or the space between the lines of the written warning and the information for quitting smoking indicated in the foregoing item can be reduced, when this is shown to be unavoidable, and as long as all elements in the combined health warning are completely visible.

Article 6. Special rules for certain individual packages with folding flap

For individual packages with a folding flap, what is set forth in n.º 2 of Article 4. is not applicable, and the combined health warnings must be placed on the front of individual packages with a folding flap, ensuring that none of the three elements of the combined health warning is broken up when the individual package is opened, in accordance with the following terms:

a) When the fold is less than the surface indicated for the photograph in sub-paragraph a) of n.º 2 of Article 4. and compliance with this provision causes the photograph to be separated upon opening:

i) The written warning must be placed above the combined health warning, with the information for quitting smoking and the photograph below it, pursuant to the terms of n.º 4 of Annex II to this Decree-Law;

ii) The photograph must occupy at least 50% of the surface of the combined health warning, the written warning at least 30% and the information for quitting smoking at least 10%, but not more than 12% of the surface of the combined health warning within the outer black border.

b) When the fold is greater than the surface indicated for the photograph in sub-paragraph a) of n.º 2 of Article 4. and compliance with this provision causes the written warning or the information for quitting smoking to be separated upon opening, the photograph:

i) Must be placed above the combined health warning, with the written warning and the information for quitting smoking below, pursuant to the terms of n.º 1 of Annex II to this Decree-Law;

ii) Must occupy at least 50% of the surface of the combined health warning, the written warning at least 30%, and the information for quitting smoking at least 10% but not more than 12% of the surface of the combined health warning within the outer black border.

Article 7. Punitive regimen

Infractions of what is set forth in this Decree-Law constitute offenses punishable pursuant to what is set forth in sub-paragraph e) of n.º 1 of Article 25. of Law n.º 37/2007, of August 14, as amended and republished by Law n.º 109/2015, of August 26, and they are subject to the punitive regime indicated in this law.

Article 8. Transitory Provision

1 — For rolling tobacco in rectangular pouches with a rolling flap, made of polyethylene, polypropylene or a laminated material, the following rules are applicable, up until May 20, 2018, and pursuant to the terms of n.º 4 of Annex I to this Decree-Law:

a) The informational message can be positioned on the surface that becomes visible when the package is partially unrolled;

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- b) The general warning can be positioned on the surface of the bottom that becomes visible when the package is totally open;
- c) The inside of the flap, which becomes visible when the package is totally open, must not be printed on or used in any other way;
- d) The general warning and the informational message must be positioned together with the upper border of the respective surfaces on which they are printed.

2 — Pouches of rolling tobacco manufactured or introduced into free circulation by May 20, 2018, and labelled with the general warning and the informational message pursuant to the terms of the foregoing item can be placed on the market up until May 20, 2019.

Reviewed and approved in the Council of Ministers on January 21, 2016. — *António Luís Santos da Costa* — *Augusto Ernesto Santos Silva* — *Adalberto Campos Fernandes* — *Paulo Alexandre dos Santos Ferreira*.

Promulgated on February 12, 2016.

Publication is hereby ordered.

The President of the Republic, ANÍBAL CAVACO SILVA.

Counter signed on February 17, 2016.

The Prime Minister, *António Luís Santos da Costa*.

ANNEX I

(referred to in Articles 2., 3. and 8.)

1 — Rectangular pouch with flat back (pursuant to the terms of n.º 1 of Article 2.):

[diagrams accompanied by illegible text]

2 — Rectangular pouch with rolling flap (pursuant to the terms of n.º 1 of Article 2.):

[diagrams accompanied by illegible text]

3 — Vertical pouch (pursuant to the terms of n.º 1 of Article 3.):

[diagrams accompanied by illegible text]

4 — Rectangular pouch with rolling flap, made of polyethylene, polypropylene or a laminated material (pursuant to the terms of n.º 1 of Article 7.):

[diagrams accompanied by illegible text]

ANNEX II

(referred to in Articles 4., 5. and 6.)

1 — Overlapping format (pursuant to the terms of n.º 2 of Article 4. and item i) of sub-paragraph b) of Article 6.):

[diagrams]

1. Photograph
2. Written warning
3. Information for quitting smoking

2 — Side by side format (pursuant to the terms of n.º 3 of Article 4.):

[diagrams]

1. Photograph
2. Written warning
3. Information for quitting smoking

3 — Extra wide side by side format (pursuant to the terms of n.º 5 of Article 5.):

[diagrams]

1. Photograph
2. Written warning
3. Information for quitting smoking

4 — Inverted overlapping format (pursuant to the terms of item i) of sub-paragraph a) of Article 6.):

[diagrams]

1. Photograph
2. Written warning
3. Information for quitting smoking
4. Soft folding flap