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Republic of Moldova GOVERNMENT

DECISION No. 613 dated 8/1/2017

approving the Health Regulations on health warnings and labeling of tobacco products, tobacco intended for cigarette rolling and related products

Published on 8/4/2017 in the Official Gazette no. 277-288 Art. No.: 712 Effective Date: 1/1/2018

AMENDED

EMO301 dated 8/18/17, OG 301-315/8/18/17 p. 249

In accordance with art. 15 para. (7) of Law No. 278-XVI dated December 14, 2007 on tobacco control (republished in the Official Gazette of the Republic of Moldova, 2015, No. 258-261, Art. 489), as subsequently amended, the Government DECIDES:

- 1. Approves:
- 1) The Health Regulations on health warnings and labeling of tobacco products, tobacco intended for cigarette rolling and related products, in accordance with Appendix 1;
- 2) Electronic library for combined health warnings, in accordance with Appendix 2.
- 2. The Ministry of Health, Labor and Social Protection controls the enforcement of this Decision.
- 3. Inventories of tobacco products and related products manufactured until the effective date of this Decision shall be marketed before June 30, 2018.
- 4. This Decision becomes effective on January 1, 2018.

PRIME MINISTER

Pavel FILIP

Countersigns: Deputy Prime Minister, Minister of Foreign Affairs and European Integration
Minister of Health, Labor
and Social Protection
Minister of Justice

Andrei Galbur

Stela Grigoras Vladimir Cebotari

Nr. 613. Chisinau, August 1, 2017.

Appendix 1 to Government Decision No. 613 of August 1, 2017

HEALTH REGULATIONS

regarding health warnings and labeling of tobacco products, tobacco intended for cigarette rolling and related products

I. General

1. Health regulations regarding health warnings and labeling of tobacco products, tobacco intended for cigarette rolling and related products (hereinafter referred to as *Regulations*) establish the requirements regarding the contents and presentation of health warnings, other information that must appear on the unit packet and on the outer packaging of tobacco products, tobacco intended for cigarette rolling and related products.

These Health Regulations transpose Chapter II of Directive 2014/40/EU of the European Parliament and of the Council dated April 3, 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (Text with EEA relevance), published in the Official Journal of the European Union L 127 of April 29, 2014.

- 2. Health warnings shall be printed on each unit packet and on any outer packaging of tobacco products, tobacco intended for cigarette rolling and related products, domestic or imported. The texts shall be printed in the official language.
- 3. Health warnings must cover the entire surface that is reserved for them and they must not be commented on, paraphrased or accompanied by other texts or illustrations.
- 4. Health warnings shall be printed in a manner that ensures clarity, visibility and their graphical integrity. Health warnings shall be printed in a manner that ensures they cannot be detached, erased or hidden, covered or interrupted by other inscriptions or illustrations including price tags, tracing marks, location and ownership status tracking/monitoring marks for products in transit, and remain intact when the unit packet is open. Health warnings shall be printed with indelible ink, in lower case, except for the first letter of the first word.
- 5. It is prohibited to print health warnings on excise stamps.
- 6. The use of packaging, bags, wrappers, boxes or any other object, or affixing the excise stamps in a manner that hides, totally or partially, or interrupts health warnings or any component part thereof by manufacturers and retail sellers of tobacco products is prohibited.
- 7. The dimensions of the health warnings shall be calculated in relation to the surface on which they are applied on when the packet is closed.
- 8. The placing on the market of tobacco products, tobacco intended for cigarette rolling and related products is prohibited, in the absence of health warnings, other information that must appear on the unit packet and on the outer packaging of tobacco products, tobacco intended for cigarette rolling and

related products in accordance with the provisions of these Regulations.

- 9. The provisions of these Regulations extend to all economic agents whose type of activity is the production, import and retail sale of tobacco products, tobacco intended for cigarette rolling and related products, regardless of the legal form of organization and the type of property.
- 10. It is established that the public institution responsible for informing tobacco users about the available programs to support individuals who want to quit smoking is the public health institution "Republican Narcology Dispensary". The telephone number 080010001 of the smoking cessation hotline of the designated institution shall be printed on each unit packet of cigarettes, packaging unit for tobacco products, tobacco intended for cigarette rolling and related products. Information concerning the programs available to support people wishing to quit smoking is published on the web page of the Public Medical-Health Institution "Republican Narcology Dispensary".

II. Requirements concerning the contents and presentation of general health warnings when labeling tobacco products for smoking and tobacco intended for cigarette rolling

- 11. Each unit packet and any outer packaging of a domestic or imported tobacco product placed on the market shall carry health warnings. The text is printed in the official language.
- 12. Health warnings must cover the entire surface that is reserved for them and they must not be commented on, paraphrased or accompanied by other texts or illustrations.
- 13. The health warnings shall be framed by a black border of a width of 1 mm that is inside the surface reserved for warnings.
- 14. The health warnings include the general warning "Smoking kills. Quit now!" and the information message "Tobacco smoke contains more than 70 cancer-causing substances."
- 15. The text "Smoking kills. Quit now!" shall be printed on the bottom of one of the lateral sides of the unit packet and outer packaging and covers 30% of the surfaces on which it is printed. The information message "Tobacco smoke contains more than 70 cancer-causing substances." shall be printed on the bottom of the other lateral side of the unit packet and outer packaging and covers 30% of the surfaces on which it is printed.
- 16. In the case of tobacco intended for cigarette rolling, the text "Smoking kills. Quit now!" and the information message "Tobacco smoke contains more than 70 cancer-causing substances" are printed on the surface which becomes visible when the package is opened.
- 17. The text "Smoking kills. Quit now!", as well as the information message "Tobacco smoke contains more than 70 cancer-causing substances" are printed in black bold Helvetica font, on a white background, the letters occupying the greatest possible surface of the surface reserved for the text and for the information message, respectively.

III. Requirements for the contents and presentation of combined health warnings when labeling tobacco products for smoking and tobacco intended for cigarette rolling

- 18. The combined health warning is composed of a warning text mentioned under art. 16 of Law no. 278-XVI of December 14, 2007 on tobacco control (republished in the Official Gazette, 2015, No. 258-261, Art. 489), as subsequently amended, and a corresponding color image, according to Appendix 2.
- 19. The combined health warning shall be printed on both the outer area of the front face and the outer area of the rear face of each unit packet and each outer packaging.
- 20. The combined health warning has the same content on both the front and back of each unit

packet, as well as on any type of outer packaging.

- 21. The combined health warning covers 65% of the front outside surface area and 65% of the back outside surface area of the unit packet or any outer packaging on which they are printed.
- 22. The combined health warning is placed on the top part of the front and the bottom part of the rear face of the unit packet or any outer packaging, positioned in the same direction as other information appearing on the packaging.
- 23. The combined health warning shall be framed by a black border of a width of 1 mm that is inside the surface reserved for warnings.
- 24. Text warnings are as follows:
- 1) Smoking causes 9 out of 10 lung cancers;
- 2) Smoking causes mouth and throat cancer;
- 3) Smoking harms your lungs;
- 4) Smoking causes heart attacks;
- 5) Smoking causes strokes and disability;
- 6) Smoking clogs your arteries;
- 7) Smoking increases the risk of blindness;
- 8) Smoking harms your teeth and gums;
- 9) Smoking can kill your unborn child;
- 10) Your smoke harms your children, family and friends;
- 11) Smokers' children are more likely to start smoking;
- 12) Ouit smoking stay alive for those you love;
- 13) Smoking reduces fertility;
- 14) Smoking increases the risk of impotence

The text warnings shall be printed in black bold Helvetica font on a white background.

- 25. The color image, as part of the combined health warning, must correspond to the text warning specified in Appendix 2.
- 26. The phone number, e-mail address and/or the official webpage of the public institution informing consumers about available programs to support individuals wanting to quit smoking shall be printed on the bottom of the color image. This information shall be printed in bold white Helvetica font and can cover up to 30% of the surface of the color image.

[Section 26 amended by EMO301 dated 8/18/17, OG301-315/8/18/17 p. 249]

- 27. If the height of the combined health warning is greater than 70% of its width, the combined health warning shall be placed vertically, the warning text being placed at the top of the combined health warning, and the color image, including the information referred to under section 18, at the bottom of the combined health warning.
- 28. If the height of the combined health warning is greater than 20%, but smaller than 65% of its width, the combined health warning shall be placed in a side-by-side format, the warning text being placed on the left of the combined health warning, and the color image, including the information referred to under section 18, on the right of the combined health warning. In this case the warning text occupies 50% and the color image occupies 50% of the surface of the combined health warning.
- 29. If the height of the combined health warning is greater than or equal to 65%, but less than or equal to 70% of its width, the combined health warning shall be placed either vertically or in a side-by-side format, provided that all elements of the combined health warning remain fully visible and not deformed.
- 30. The combined health warning must be printed in accordance with the colors of the respective

models displayed in the Electronic library for health warnings.

31. The combined health warnings must be divided into in two sets of seven, which are rotated annually, and appear on an equal number of unit packets of smoking tobacco and tobacco products for cigarette rolling for each brand placed on the market during one year by a single economic operator.

IV. Presentation of tobacco products and tobacco intended for cigarette rolling

- 32. The labeling and presentation of unit packets, outer packaging and tobacco products shall not include elements or characteristics which:
- a) promote the tobacco product using false, misleading means, or that could create erroneous impressions about its characteristics, health effects, risks and emissions, or draw analogies to the anatomical names for human body parts;
- b) suggest that a particular tobacco product is less harmful than others, including using classifications, such as "light", "medium", "ultra", "extra" and others like these, or that a tobacco product has revitalizing, energizing, healing, rejuvenating, natural, organic, or other beneficial effects on health or lifestyle;
- c) refer to smell, taste, presence of flavorings or lack thereof or any other additives;
- d) create associations with food products, cosmetics or toys.
- 33. The elements and prohibited features mentioned in section 32 include, but are not limited to, texts, symbols, names, trademarks, figures of speech or other expressions, misleading colors, inserts or other additional materials, such as adhesive labels, onserts, scratch-offs, and sleeves, or make reference to the shape of the tobacco product.
- 34. It shall be is prohibited to specify the quantity of harmful substances on the outside or inside of unit packets or directly on the tobacco products, including as part of the trademark.
- 35. It shall be prohibited to present food products, toys or other products in the shape of a unit packet or in a shape that creates an association with tobacco products.
- 36. The manufacture of unit packet shall not use special technologies, and the unit packets shall not contain elements that could modify the appearance of the unit packet or that could distract the consumer. These include but are not limited to:
- a) heat-activated inks and/or inks that become fluorescent under certain lights;
- b) inks or designs that become gradually visible in time;
- c) stick-ons that can be removed or scratched off to reveal images or texts;
- d) raised stick-ons, except for the trademark

V. Requirements for the contents and presentation of combined health warnings when labeling tobacco products for smoking other than cigarettes, tobacco intended for cigarette rolling and waterpipe tobacco

- 37. On the sides of each unit packet and on any outer packaging of tobacco products for smoking, other than cigarettes, tobacco intended for cigarette rolling and waterpipe tobacco, the general warning "Smoking kills. Quit now!" and one of the text warnings under section 24 shall be printed.
- 38. The general warning shall be printed on the most visible surface of the unit packet and any outer packaging and shall cover no less than 30% of the relevant surface of the unit packet and outer packaging.
- 39. The general warning is accompanied by the phone number, e-mail address and/or the official webpage of the public institution informing consumers about available programs to support individuals who want to quit smoking.
- 40. The text warning shall be printed on the next most visible surface of the unit packet and any

outer packaging and shall cover no less than 40% of the relevant surface of the unit packet and outer packaging.

- 41. The general warning and the text warnings shall be:
- a) printed in black bold Helvetica font on a white background, the letters occupying the greatest possible surface of the surface area reserved for the text;
- b) centered on the allocated surface, and, on unit packets and outer packaging that have lateral sides, be placed parallel with the lateral edge of the unit packets and outer packaging;
- c) framed by a black border of a width of not less than 3 mm and not more than 4 mm that is outside the surface reserved for warnings
- 42. Textual warnings change every year. Each of these warnings must appear on an equal number of unit packets with such products of each brand.

VI. Requirements regarding health warnings and related product labeling

43. Each unit packet and any outer packaging of related products (nicotine-containing products, including electronic cigarettes and refill containers, which are not subject to regulation in the pharmaceutical and drug field) must contain the following health warning:

"This product contains nicotine. Nicotine is highly addictive."

- 44. The health warning provided under section 43 must:
- a) be printed on the two largest surfaces of the unit packet and any outer packaging;
- b) cover no less than 30% of the outside area of the corresponding surface of the unit packet and any outer packaging.
- 45. Each unit packet and any outside packaging of herbal products for smoking carries the following health warning: "Smoking of this product damages your health", which should be:
- a) centered on the allocated surface of the two larger surfaces of the unit packet and on any outer packaging, and, on unit packets and outer packaging that have lateral sides, be placed parallel with the lateral edge of the unit packet and outer packaging;
- b) cover 30% of the outer area of the corresponding surface of the unit packet and of any outer packaging;
- c) printed with bold black Helvetica font, on a white background, the letters occupying the greatest possible surface of the surface area reserved for the text;
- d) framed by a black border of a width of not less than 3 mm and not more than 4 mm that is outside the surface reserved for warnings.
- 46. The unit packets and any outside packaging of the herbal products for smoking do not include any of the elements or characteristics set forth under art. 19 para. (1) of Law no. 278-XVI of December 14, 2007 on tobacco control.

VII. Traceability of tobacco products, tobacco intended for cigarette rolling and related products

- 47. All unit packets of tobacco products shall be marked according to the method and place established by the manufacturer, indicating the serial number of the lot or its equivalent, thus ensuring the possibility of identifying the place and date of manufacture.
- 48. The marking includes the mention "To be sold in the territory …" specifying the name of the country where the tobacco products are to be sold. For tobacco products sold in the Republic of Moldova the unit packet shall bear the mention "To be sold in the territory of the Republic of Moldova." shall be applied on the unit packet.
- 49. The information stated under sections 47 and 48 must be accessible to consumers and control

bodies in order to identify tobacco products and monitor their movement.

50. It is prohibited to sell tobacco products and related products without supporting documents, issued by producers or importers, to prove the provenance and to ensure the traceability of tobacco products and related products.

VIII. Electronic library for health warnings

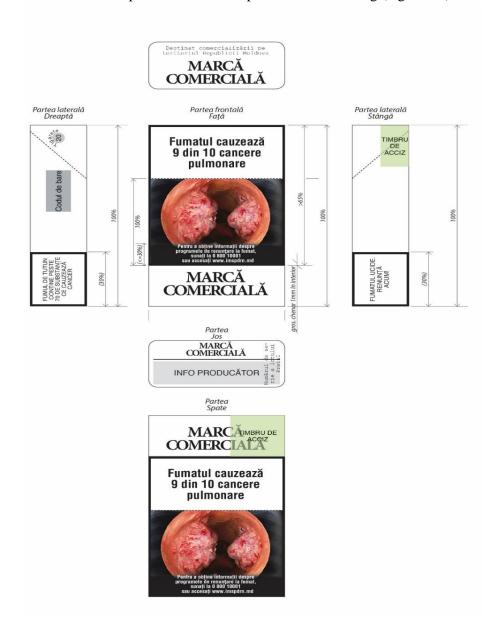
- 51. The Ministry of Health, Labor and Social Protection maintains, by posting on the ministry's website, an Electronic library for combined health warnings listed in Appendix 2.
- 52. The National Public Health Center coordinates and supervises the application of the combined health warnings approved on each unit packet and on any outer packaging of tobacco products, tobacco intended for cigarette rolling and related domestic or imported products before being placed on the market and on those placed on the market.

Appendix 2

Appendix 2 to Government Decision No. 613 of August 1, 2017

Electronic library for combined health warnings

Templates of contents and presentation of health warnings on the unit packets of tobacco products for smoking (cigarettes)



Smoking causes 9 out of 10 lung cancers Pentru a obține informații despre programele de renunțare la fumat, sunați la 0 800 10001 sau accesați www.imspdrn.md Smoking causes mouth and throat cancers Pentru a obține informații despre programele de renunțare la fumat, sunați la 0 800 10001 sau accesați www.imspdrn.md Smoking harms your lungs Pentru a obține informații despre programele de renunțare la fumat, sunați la 0 800 10001 sau accesați www.imspdrn.md Smoking causes heart attacks Pentru a obține informații despre programele de renunțare la fumat, sunați la 0 800 10001 sau accesați www.imspdrn.md Smoking causes strokes and disability Pentru a obține informații despre programele de renunțare la fumat, sunați la 0 800 10001 sau accesați www.imspdrn.md Smoking clogs your arteries Pentru a obține informații despre programele de renunțare la fumat, sunați la 0 800 10001 sau accesați www.imspdrn.md Smoking increases the risk of blindness Pentru a obține informații despre programele de renunțare la fumat, sunați la 0 800 10001 sau accesați www.imspdrn.md Smoking harms your teeth and gums Pentru a obține informații despre programele de renunțare la fumat, sunați la 0 800 10001 sau accesați www.imspdrn.md

Smoking can kill your unborn child Pentru a obține informații despre programele de renunțare la fumat, sunați la 0 800 10001 Your smoke harms your children, family and friends Pentru a obține informații despre programele de renunțare la fumat, sunați la 0 800 10001 sau accesați www.imspdrn.md Smokers' children of are more likely to start smoking Pentru a obține informații despre programele de renunțare la fumat, sunați la 0 800 10001 sau accesați www.imspdrn.md Quit smoking - stay alive for those you love Pentru a obține informații despre programele de renunțare la fumat, sunați la 0 800 10001 sau accesați www.imspdrn.md Smoking reduces fertility

Pentru a obţine informaţii despre programele de renuntare la fumat, sunaţi la 0 800 10001 sau accesaţi www.imspdrn.md

Smoking increases the risk of impotence

Pentru a obţine informaţii despre programele de renunţare la fumat, sunaţi la 0 800 10001 sau accesaţi www.imspdrn.md