

**L.N. 229 of 2023**

**TOBACCO (SMOKING CONTROL) ACT  
(CAP. 315)**

**Manufacture, Presentation and Sale of Tobacco and Related  
Products (Amendment) Regulations, 2023**

IN EXERCISE of the powers conferred by article 9 of the Tobacco (Smoking Control) Act, the Minister responsible for public health has made the following regulations:-

1. (1) The title of these regulations is the Manufacture, Presentation and Sale of Tobacco and Related Products (Amendment) Regulations, 2023 and these regulations shall be read and construed as one with the Manufacture, Presentation and Sale of Tobacco and Related Products Regulations, hereinafter referred to as "the principal regulations".

Citation,  
commencement  
and scope.

S.L. 315.10.

(2) These regulations shall come into force on the 23rd October 2023.

(3) The scope of these regulations is to transpose Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products and to carry out other necessary amendments.

2. In sub-regulation (2) of regulation 1 of the principal regulations immediately after the words "and repealing Directive 2001/37/EC", there shall be added the words ", as may be amended, from time to time".

Amends  
regulation 1 of  
the principal  
regulations.

3. Sub-regulation (7) of regulation 7 of the principal regulations shall be substituted by the following new sub-regulation:

Amends  
regulation 7 of  
the principal  
regulations.

"(7) Tobacco products other than cigarettes, roll-your-own tobacco and heated tobacco products shall be exempted from the prohibitions laid down in sub-regulations (1) and (4):

Provided that for the purposes of this sub-regulation "heated tobacco product" shall mean a novel tobacco product that is heated to produce an emission containing nicotine and other chemicals, which is then inhaled by users and that, depending on its characteristics, is a smokeless tobacco product or a tobacco product for smoking:

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Provided further that the provision of this sub-regulation shall in no way prejudice or reduce the applicability of the ban stipulated in regulation 21."

Amends  
regulation 9 of  
the principal  
regulations.

**4.** Paragraph (a) of sub-regulation (4) of regulation 9 of the principal regulations shall be substituted by the following new paragraph:

"(a) printed on a white background in Black Helvetica bold type, in a font size which ensures that the text occupies the greatest possible proportion of the surface area reserved for it;"

Amends  
regulation 11 of  
the principal  
regulations.

**5.** Regulation 11 of the principal regulations shall be amended as follows:

(a) the marginal note thereof shall be substituted by the following new marginal note:

"Labelling of tobacco products for smoking other than cigarettes, roll-your-own tobacco, waterpipe tobacco and heated tobacco products.";

(b) the first paragraph of sub-regulation (1) thereof shall be substituted by the following new sub-regulation:

"11. (1) (a) Tobacco products for smoking other than cigarettes, roll-your-own tobacco, waterpipe tobacco and heated tobacco products are exempt from the obligations to carry the information message laid down in regulation 9(2) and the combined health warnings laid down in regulation 10. In addition to the general warning provided for in regulation 9(1), each unit packet and any outside packaging of such products shall carry one of the text warnings listed in Schedule 2. The general warning specified in regulation 9(1) shall include a reference to the cessation from smoking services referred to in regulation 10(1)(b);

(b) the general warning shall appear on the most visible surface of the unit packet and any outside packaging;

(c) each text warning listed in Schedule 2 shall be displayed to the extent possible in equal numbers on each brand of these products. The text warnings shall appear on the next most visible surface of the unit packet and any outside packaging;

(d) for unit packets with a hinged lid, the next most visible surface is the one that becomes visible when the packet is open;

(e) for the purposes of this sub-regulation "heated tobacco product" means a novel tobacco product that is heated to produce an emission containing nicotine and other chemical substances, which is then inhaled by users and that, depending on its characteristics, is a smokeless tobacco product or a tobacco product for smoking:

Provided that the provision of this sub-regulation shall in no way prejudice or reduce the applicability of the ban stipulated in regulation 21."

6. Regulation 16 of the principal regulations shall be substituted by the following new regulation:

Susbstitutes  
regulation 16 of  
the principal  
regulations.

"16. (1) Cross-border distance sales of tobacco products to consumers located in Malta shall be prohibited.

(2) Retail outlets located in Malta engaging in cross-border distance sales of tobacco products shall not supply such products to consumers in Member States where such sales have been prohibited. Retail outlets located in Malta intending to engage in cross-border distance sales to consumers located in the Union shall register with the Superintendent and with the competent authorities in the Member State where the actual or potential consumers are located. All retail outlets located in Malta intending to engage in cross-border distance sales shall submit the following information to the Superintendent when registering:

(a) name or corporate name and permanent address of the place of activity from where the tobacco products shall be supplied;

(b) the starting date of the activity of offering tobacco products for cross-border distance sales to consumers by means of information society services;

(c) the address of the websites used for that purpose and all relevant information necessary to identify the website.

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(3) The Superintendent shall make publicly available the list of all retail outlets located in Malta and engaging in cross-border distance sales that are registered in accordance with this regulation. Retail outlets may only start engaging in cross-border distance sales when they have received confirmation of their registration with the Superintendent.

(4) Retail outlets located in Malta supplying tobacco products sold by cross-border distance sales shall nominate to the Superintendent, a natural person who shall be responsible for verifying, before the tobacco products reach the consumer, that they comply with the national provisions of the Member State where the consumer is located at the time that the consumer orders the product.

(5) Retail outlets located in Malta engaging in cross-border distance sales shall operate an age verification system, which verifies, at the time of sale, that the purchasing consumer complies with minimum age requirements provided for under the national provisions of the Member State where the consumer is located at the time that the consumer orders the product. The retail outlet or natural person nominated pursuant to sub-regulation (4) shall provide to the Superintendent a description of the details of the age verification system and how it functions.

(6) Retail outlets located in Malta shall only process personal data of the consumer in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 and that data shall not be disclosed to the manufacturer of tobacco products or companies forming part of the same group of companies or to other third parties. Personal data shall not be used or transferred for purposes other than the actual purchase. This also applies if the retail outlet forms part of a manufacturer of tobacco products."

Amends  
regulation 18 of  
the principal  
regulations.

7. Regulation 18 of the principal regulations shall be amended as follows:

(a) sub-regulation (4) thereof shall be amended as follows:

(i) paragraph (a) thereof shall be substituted by the following new paragraph:

"(a) unit packets of electronic cigarettes and refill containers shall include a leaflet with information in the Maltese or in the English language on:

(i) instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers;

(ii) contra-indications;

(iii) warnings for specific risk groups;

(iv) possible adverse effects;

(v) addictiveness and toxicity; and

(vi) contact details of the manufacturer or importer and a legal or natural contact person within the Union:

Provided that the leaflet containing the information stipulated in this paragraph may be substituted by a label affixed to the packaging or a leaflet contained within the packaging, which includes a Quick Response (QR) code containing an electronic link with information stipulated in this paragraph in either the Maltese or the English language."

(ii) paragraph (c) thereof shall be substituted by the following new paragraph:

"(c) the health warning shall comply with the requirements specified in regulation 9(4). The text of the health warnings shall be parallel to the main text on the surface reserved for these warnings. In addition, it shall:

(i) appear on the two largest surfaces of the unit packet and any outside packaging;

(ii) cover 32% of the surfaces of the unit packet and any outside packaging."

(b) in sub-regulation 6 thereof, immediately after the words "cigarettes and refill containers." there shall be added the

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words "For the purpose of this sub-regulation, the terms "electronic cigarettes" and "refill containers" shall refer to both nicotine and non-nicotine containing electronic cigarettes and refill containers.";

(c) in paragraph (d) of the sub-regulation (7) thereof the words "an English translation thereof." shall be substituted by the words "an English translation thereof:" and immediately thereafter there shall be added the following new proviso:

"Provided that the Superintendent shall monitor the market developments concerning electronic cigarettes and refill containers, including any evidence that their use is a gateway to nicotine addiction and ultimately traditional tobacco consumption among young people and non-smokers.".

Amends  
regulation 19 of  
the principal  
regulations.

**8.** Immediately after sub-regulation (4) of regulation 19 of the principal regulations, there shall be added the following new sub-regulation:

"(5) Regulation 16 shall also apply to cross-border distance sales of herbal products for smoking.".

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