

**L.N. 67 of 2016**

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

**Manufacture, Presentation and Sale of Tobacco and Related  
Products Regulations, 2016**

IN exercise of the powers conferred by article 9(f) of the Tobacco (Smoking Control) Act, the Parliamentary Secretary for Health has made the following regulations:-

**1.** (1) The title of these regulations is the Manufacture, Presentation and Sale of Tobacco and Related Products Regulations, 2016. Citation, scope and commencement.

(2) The scope of these regulations is to implement Directive 2014/40/EU of the European Parliament and of the Council of 3 April 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.

(3) The competent authority responsible for the implementation and enforcement of the obligations provided for in these regulations shall be the Superintendent of Public Health.

(4) These regulations shall come into force on 20th May, 2016.

**2.** For the purposes of these regulations, the following definitions shall apply: Interpretation.

"addictiveness" means the pharmacological potential of a substance to cause addiction, a state which affects an individual's ability to control his or her behaviour, typically by instilling a reward or a relief from withdrawal symptoms, or both;

"additive" means a substance, other than tobacco, that is added to a tobacco product, a unit packet or to any outside packaging;

"age verification system" means a computing system that unambiguously confirms the consumer's age electronically in accordance with national requirements;

"Directive" means Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco

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and related products and repealing Directive 2001/37/EC;

"characterising flavour" means a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the tobacco product;

"chewing tobacco" means a smokeless tobacco product exclusively intended for the purpose of chewing;

"cigar" means a roll of tobacco that can be consumed via a combustion process and is further defined in Article 4(1) of Directive 2011/64/EU;

"cigarette" means a roll of tobacco that can be consumed via a combustion process and is further defined in Article 3(1) of Council Directive 2011/64/EU;

"cigarillo" means a small type of cigar and is further defined in Article 8(1) of Council Directive 2007/74/EC;

"combined health warning" means a health warning consisting of a combination of a text warning and a corresponding photograph or illustration, as provided for in these regulations;

"Commission" means the European Commission;

"consumer" means a natural person who is acting for purposes which are outside his or her trade, business, craft or profession;

"cross-border distance sales" means distance sales to consumers where, at the time the consumer orders the product from a retail outlet, the consumer is located in a Member State other than the Member State or the third country where that retail outlet is established; a retail outlet is deemed to be established in a Member State:

(a) in the case of a natural person: if he or she has his or her place of business in that Member State;

(b) in other cases: if the retail outlet has its statutory seat, central administration or place of business, including a branch, agency or any other establishment, in that Member State;

"electronic cigarette" means a product that can be used for consumption of nicotine-containing vapour via a mouth piece, or any

component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges;

"emissions" means substances that are released when a tobacco or related product is consumed as intended, such as substances found in smoke, or substances released during the process of using smokeless tobacco products;

"flavouring" means an additive that imparts smell and, or taste;

"health warning" means a warning concerning the adverse effects on human health of a product or other undesired consequences of its consumption, including text warnings, combined health warnings, general warnings and information messages, as provided for in these regulations;

"herbal product for smoking" means a product based on plants, herbs or fruits which contains no tobacco and that can be consumed via a combustion process;

"import of tobacco or related products" means the entry into the territory of the European Union, hereinafter referred to as "the Union", of such products unless the products are placed under a customs suspensive procedure or arrangement upon their entry into the Union, as well as their release from a customs suspensive procedure or arrangement;

"importer of tobacco or related products" means the owner of, or a person having the right of disposal over, tobacco or related products that have been brought into the territory of the Union;

"information society services" means any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services;

"ingredient" means tobacco, an additive, as well as any substance or element present in a finished tobacco product or related products, including paper, filter, ink, capsules and adhesives;

"manufacturer" means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under their name or trademark;

"maximum level" or "maximum emission level" means the maximum content or emission, including zero, of a substance in a tobacco product measured in milligrams;

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"nasal tobacco" means a smokeless tobacco product that can be consumed via the nose;

"nicotine" means nicotinic alkaloids;

"novel tobacco product" means a tobacco product which:

(a) does not fall into any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use; and

(b) is placed on the market after 19 May 2014;

"outside packaging" means any packaging in which tobacco or related products are placed on the market and which includes a unit packet or an aggregation of unit packets; transparent wrappers are not regarded as outside packaging;

"pipe tobacco" means tobacco that can be consumed via a combustion process and exclusively intended for use in a pipe;

"placing on the market" means to make products, irrespective of their place of manufacture, available to consumers located in the Union, with or without payment, including by means of distance sale; in the case of cross-border distance sales the product is deemed to be placed on the market in the Member State where the consumer is located;

"pouch" means a unit packet of roll-your own tobacco, either in the form of a rectangular pocket with a flap that covers the opening or in the form of a standing pouch;

"refill container" means a receptacle that contains a nicotine-containing liquid, which can be used to refill an electronic cigarette;

"roll-your-own tobacco" means tobacco which can be used for making cigarettes by consumers or retail outlets;

"retail outlet" means any outlet where tobacco products are placed on the market including by a natural person;

"smokeless tobacco product" means a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use;

"substantial change of circumstances" means an increase of the sales volumes by product category by at least 10% in at least five

Member States based on sales data transmitted in accordance with regulation 5(6) or an increase of the level of prevalence of use in the under twenty-five (25) years of age consumer group by at least five percentage points in at least five Member States for the respective product category based on the Special Eurobarometer 385 Report of May 2012 or equivalent prevalence studies; in any case, a substantial change of circumstances is deemed not to have occurred if the sales volume of the product category at retail level does not exceed 2.5% of total sales of tobacco products at Union level;

"Superintendent" means the Superintendent of Public Health and, to the extent of any delegation or authority given, includes an authorised officer;

"tar" means the raw anhydrous nicotine-free condensate of smoke;

"tobacco" means leaves and other natural processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco;

"tobacco for oral use" means all tobacco products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets;

"tobacco products for smoking" means tobacco products other than a smokeless tobacco product;

"tobacco products" means products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not;

"toxicity" means the degree to which a substance can cause harmful effects in the human organism, including effects occurring over time, usually through repeated or continuous consumption or exposure;

"unit packet" means the smallest individual packaging of a tobacco or related product that is placed on the market;

"waterpipe tobacco" means a tobacco product that can be consumed via a waterpipe. For the purpose of these regulations, waterpipe tobacco is deemed to be a tobacco product for smoking. If a product can be used both via waterpipes and as roll-your-own tobacco, it shall be deemed to be roll-your-own tobacco.

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Maximum emission levels for tar, nicotine, carbon monoxide and other substances.

**3.** The emission levels from cigarettes placed on the market or manufactured in Malta ("maximum emission levels") shall not be greater than:

- (a) 10 mg of tar per cigarette;
- (b) 1 mg of nicotine per cigarette;
- (c) 10 mg of carbon monoxide per cigarette.

Measurement methods.

**4.** (1) The tar, nicotine and carbon monoxide emissions from cigarettes shall be measured on the basis of ISO standard 4387 for tar, ISO standard 10315 for nicotine, and ISO standard 8454 for carbon monoxide.

The accuracy of the tar, nicotine and carbon monoxide measurements shall be determined in accordance with ISO standard 8243.

(2) The measurements referred to in sub-regulation (1) shall be verified by laboratories accredited on the basis of ISO standard 17025 and which are approved by the Superintendent.

These laboratories shall not be owned or controlled directly or indirectly by the tobacco industry.

(3) The Superintendent shall communicate to the Commission a list of approved laboratories, specifying the criteria used for approval and the methods of monitoring applied, and shall update that list whenever any change is made.

(4) The Superintendent shall notify the Commission of any measurement methods used at a national level for emissions from cigarettes other than the emissions referred to in sub-regulation (3) and for emissions from tobacco products other than cigarettes.

(5) The Superintendent shall charge manufacturers and importers of tobacco products, at such times and intervals as the Superintendent may reasonably require, proportionate fees as the Minister may by regulations prescribe, for the verification of the measurements referred to sub-regulation (1).

Reporting of ingredients and emissions.

**5.** (1) Manufacturers and importers are to submit to the Superintendent the following information by brand name and type:

- (a) a list of all ingredients, and quantities thereof, used in the manufacture of the tobacco products, in descending order of the weight of each ingredient included in the tobacco

products;

- (b) the emission levels referred to in regulation 3;
- (c) where available, information on other emissions and their levels.

For products already placed on the market that information shall be provided by 20 November 2016.

Manufacturers and importers shall also inform the Superintendent if the composition of a product is modified in a way that affects the information provided under these regulations.

For a new or modified tobacco product, the information required under these regulations shall be submitted prior to the placing on the market of those products.

(2) The list of ingredients referred to in sub-regulation (1)(a) shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in the tobacco products concerned. That list shall also indicate the status of the ingredients, including whether they have been registered under Regulation (EC) No 1907/2006 of the European Parliament and of the Council as well as their classification under Regulation (EC) No 1272/2008 of the European Parliament and of the Council.

(3) The list referred to in sub-regulation (1)(a) shall also be accompanied by the relevant toxicological data regarding the ingredients in burnt or unburnt form, as appropriate, referring in particular to their effects on the health of consumers and taking into account, *inter alia*, any addictive effects.

Furthermore, for cigarettes and roll-your-own tobacco, a technical document setting out a general description of the additives used and their properties shall be submitted by the manufacturer or importer.

Other than for tar, nicotine and carbon monoxide and for emissions referred to in regulation 4(4), manufacturers and importers shall indicate the methods of measurement of emissions used. Manufacturers and importers of tobacco products into Malta may also be required to provide detailed studies assessing the effects of ingredients on health taking into account, *inter alia*, their addictiveness and toxicity.

(4) The Superintendent shall ensure that the information submitted in accordance with sub-regulation (1) and regulation 6 is

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made publicly available on a website. The Superintendent shall take the need to protect trade secrets duly into account when making that information publicly available and shall require manufacturers and importers to specify, when submitting the information pursuant to sub-regulation (1) and regulation 6, the information which they consider to constitute trade secrets.

(5) The format for the submission and the making available of information referred to in sub-regulations (1) and (6) and regulation 6 shall be in compliance with Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing a format for the submission and making available of information on tobacco products.

(6) Manufacturers and importers shall submit to the Superintendent internal and external studies available to them on market research and preferences of various consumer groups, including young people and current smokers, relating to ingredients and emissions, as well as executive summaries of any market surveys they carry out when launching new products. Manufacturers and importers shall also report to the Superintendent their sales volumes in Malta per brand and type, reported in sticks or kilograms, on a yearly basis starting from 1 January 2015.

(7) All data and information provided to and by the Superintendent under this regulation and under regulation 6 shall be provided in electronic form. The Superintendent shall store all the information electronically and shall ensure that the Commission and other Member States have access to that information for the purpose of applying these regulations. The Superintendent shall ensure that trade secrets and other confidential information are treated in a confidential manner.

(8) The Superintendent may charge manufacturers and importers of tobacco products proportionate fees as the Minister may by regulations prescribe, for receiving, storing, handling, analysing and publishing the information submitted to them pursuant to this regulation.

Priority list of  
additives and  
enhanced  
reporting  
obligations.

**6.** (1) In addition to the reporting obligations laid down in regulation 5, enhanced reporting obligations shall apply to certain additives contained in cigarettes and roll-your-own tobacco that are included in a priority list. The priority list of additives shall be laid down and subsequently updated in accordance with Commission Implementing Acts. This list shall contain additives:

(a) for which initial indications, research, or regulation in other jurisdictions exist suggesting that they have one of the



properties set out in sub-regulation (2)(a) to (d); and

(b) which are amongst the most commonly used additives by weight or number according to the reporting of ingredients pursuant to regulation 5(1) and (3).

(2) Manufacturers and importers of cigarettes and roll-your-own-tobacco containing an additive that is included in the priority list provided for in sub-regulation (1) shall carry out comprehensive studies, which shall examine for each additive whether it:

(a) contributes to the toxicity or addictiveness of the products concerned, and whether this has the effect of increasing the toxicity or addictiveness of any of the products concerned to a significant or measurable degree;

(b) results in a characterising flavour;

(c) facilitates inhalation or nicotine uptake; or

(d) leads to the formation of substances that have carcinogenic, mutagenic and toxic for reproduction (hereinafter "CMR") properties, the quantities thereof, and whether this has the effect of increasing the CMR properties in any of the products concerned to a significant or measurable degree.

(3) Those studies shall take into account the intended use of the products concerned and examine in particular the emissions resulting from the combustion process involving the additive concerned. The studies shall also examine the interaction of that additive with other ingredients contained in the products concerned. Manufacturers or importers using the same additive in their tobacco products may carry out a joint study when using that additive in a comparable product composition.

(4) Manufacturers and importers shall establish a report on the results of these studies. That report shall include an executive summary, and a comprehensive overview compiling the available scientific literature on that additive and summarising internal data on the effects of the additive.

Manufacturers and importers shall submit these reports to the Commission and to the Superintendent if the tobacco product containing this additive is placed on the Maltese market at the latest eighteen (18) months after the additive concerned has been included in the priority list

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pursuant to sub-regulation (1). The Commission and the Superintendent may also request supplementary information from manufacturers or importers regarding the additive concerned. This supplementary information shall form part of the report.

The Commission and the Superintendent may require these reports to be peer reviewed by an independent scientific body, in particular as regards their comprehensiveness, methodology and conclusions. The information received shall assist the Commission and the Superintendent in taking the decisions pursuant to regulation 7.

The Superintendent may charge manufacturers and importers of tobacco products proportionate fees as the Minister may by regulations prescribe, for such peer reviews.

(5) Small and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC shall be exempted from the obligations pursuant to this regulation, if a report on that additive is prepared by another manufacturer or importer.

Regulation of  
ingredients.

7. (1) The placing on the market of tobacco products with a characterising flavour is prohibited.

The use of additives which are essential for the manufacture of tobacco products, for example sugar to replace sugar that is lost during the curing process, provided those additives do not result in a product with a characterising flavour and do not increase to a significant or measurable degree the addictiveness, toxicity or the CMR properties of the tobacco product, shall not be prohibited.

(2) Uniform rules for the procedures for determining whether a tobacco product falls within the scope of sub-regulation (1) shall be laid down by a Commission Implementing Act.

(3) The placing on the market of tobacco products containing the following additives shall be prohibited:

(a) vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks;

(b) caffeine or taurine or other additives and stimulant compounds that are associated with energy and vitality;

(c) additives having colouring properties for emissions;

(d) for tobacco products for smoking, additives that facilitate inhalation or nicotine uptake; and

(e) additives that have CMR properties.

(4) The placing on the market of tobacco products containing flavourings in any of their components such as filters, papers, packages, capsules or any technical features allowing modification of the smell or taste of the tobacco products concerned or their smoke intensity shall be prohibited. Filters, papers and capsules shall not contain tobacco or nicotine.

(5) The Superintendent shall ensure that the provisions and conditions laid down in Regulation (EC) No 1907/2006 are applied to tobacco products as appropriate.

(6) On the basis of scientific evidence, the Superintendent may prohibit the placing on the market of tobacco products containing additives in quantities that increase the toxic or addictive effect or the CMR properties of a tobacco product at the stage of consumption to a significant or measurable degree. The Superintendent shall inform the Commission on such measures taken.

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

(8) The Superintendent may charge manufacturers and importers of tobacco products proportionate fees which the Minister may by regulations prescribe, for assessing whether a tobacco product has a characterising flavour, whether prohibited additives or flavourings are used and whether a tobacco product contains additives in quantities that increase to a significant and measurable degree the toxic or addictive effect or the CMR properties of the tobacco product concerned.

(9) In the case of tobacco products with a characterising flavour whose Union-wide sales volumes represent 3% or more in a particular product category, the provisions of this regulation shall apply from 20 May 2020.

**8.** (1) Each unit packet of a tobacco product and any outside packaging shall carry the health warnings provided for in these regulations in both Maltese and English.

Labelling and  
packaging:  
general  
provisions.

(2) Health warnings shall cover the entire surface of the unit packet or outside packaging that is reserved for them and they shall not be commented on, paraphrased or referred to in any form.

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(3) Health warning on a unit packet and any outside packaging shall be irremovably printed, indelible and fully visible, including not being partially or totally hidden or interrupted by tax stamps, price marks, security features, wrappers, jackets, boxes, or other items, when tobacco products are placed on the market. On unit packets of tobacco products other than cigarettes and roll-your-own tobacco in pouches, the health warnings may be affixed by means of stickers, provided that such stickers are irremovable. The health warnings shall remain intact when opening the unit packet other than packets with a flip-top lid, where the health warnings may be split when opening the packet, but only in a manner that ensures the graphical integrity and visibility of the text, photographs and cessation information.

(4) The health warnings shall in no way hide or interrupt the tax stamps, price marks, tracking and tracing marks, or security features on unit packets.

(5) The dimensions of the health warnings provided for in regulations 9, 10, 11 and 12 shall be calculated in relation to the surface concerned when the packet is closed.

(6) Health warnings shall be surrounded by a black border of a width of 1 mm inside the surface area that is reserved for these warnings, except for health warnings pursuant to regulation 11.

(7) Images of unit packets and any outside packaging targeting consumers in the Union shall comply with the provisions of these regulations.

Labelling and packaging: general warnings and information messages on tobacco products for smoking.

**9.** (1) Each unit packet and any outside packaging of tobacco products for smoking shall carry the general warning: ‘Smoking kills’ and ‘It-tipjip joqtol’.

(2) Each unit packet and any outside packaging of tobacco products for smoking shall carry the following information message: ‘Tobacco smoke contains over 70 substances known to cause cancer’ and ‘Id-duhhan tat-tabakk fih aktar minn 70 sustanza magħrufa li jikkawżaw il-kanċer’.

(3) For cigarette packets and roll-your-own tobacco in cuboid packets the general warning shall appear on the bottom part of one of the lateral surfaces of the unit packets, and the information message shall appear on the bottom part of the other lateral surface. These health warnings shall have a width of not less than 20 mm.

For packets in the form of a shoulder box with a hinged lid that result in the lateral surfaces being split into two when the packet is open, the general warning and the information message shall

appear in their entirety on the larger parts of those split surfaces. The general warning shall also appear on the inside of the top surface that is visible when the packet is open.

The lateral surfaces of this type of packet shall have a height of not less than 16 mm.

For roll-your-own tobacco marketed in pouches, the general warning and the information message shall appear on the surfaces that ensure the full visibility of those health warnings. For roll-your-own tobacco in cylindrical packets the general warning shall appear on the outside surface of the lid and the information message on the inside surface of the lid.

Both the general warning and the information message shall cover 50% of the surfaces on which they are printed.

(4) The general warning and information message referred to in sub-regulations (1) and (2) shall be:

(a) printed in Black Helvetica bold type, Font size 20 on a white background;

(b) at the centre of the surface reserved for them, and on cuboid packets and any outside packaging they shall be parallel to the lateral edge of the unit packet or of the outside packaging.

(5) The precise position of the general warning and the information message on roll-your-own tobacco marketed in pouches, taking into account the different shapes of pouches, shall be in compliance with Commission Implementing Decision (EU) 2015/1735 of 24 September 2015 on the precise position of the general warning and the information message on roll-your-own tobacco marketed in pouches.

**10.** (1) Each unit packet and any outside packaging of tobacco products for smoking shall carry combined health warnings. The combined health warnings shall:

Labelling and packaging:  
combined health warnings for tobacco products for smoking.

(a) contain one graphic chosen from the set of graphical warnings contained in Schedule 1 specified for the production year during which the pack is produced. For the purpose of these regulations:

(i) the set of graphic contained in Part 1 of Schedule 1 is specified for the production year 2016-2017 and every third production year thereafter;

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(ii) the set of graphic contained in Part 2 of Schedule 1 is specified for the production year 2017-2018 and every third production year thereafter;

(iii) the set of graphic contained in Part 3 of Schedule 1 is specified for the production year 2018-2019 and every third production year thereafter;

(iv) "Production year" means a period of twelve (12) months beginning on 20th May and ending on 19th May;

(b) include the following smoking cessation information "Tobacco Stop Line: 80073333; Website: health.gov.mt";

(c) cover 65% of both the external front and back surface of the unit packet and any outside packaging. Cylindrical packets shall display two combined health warnings, equidistant from each other, each covering 65% of their respective half of the curved surface;

(d) show the same graphic on both sides of the unit packets and any outside packaging;

(e) appear at the top edge of a unit packet and any outside packaging, and be positioned in the same direction as any other information appearing on that surface of the packaging. Transitional exemptions apply as follows:

(i) in those cases where the tax stamp or national identification mark used for fiscal purposes is affixed at the top edge of a unit packet made of carton material, the combined health warning that is to appear on the back surface may be positioned directly below the tax stamp or national identification mark;

(ii) where a unit packet is made of soft material, a rectangular area is to be reserved for the tax stamp of a height not exceeding 13 mm between the top edge of the packet and the top end of the combined health warnings.

The exemptions referred to in sub-paragraphs (i) and (ii) shall apply for a period of three years from 20 May 2016. Brand names or logos shall not be positioned above the health warnings;

(f) be reproduced in accordance with the format, layout,

design and proportions specified by the Commission pursuant to sub-regulation (3);

(g) in the case of unit packets of cigarettes, respect the following dimensions:

(i) height: not less than 44 mm;

(ii) width: not less than 52 mm.

(2) The combined health warnings are grouped into three sets as set out in Schedule 1. Each of the 14 graphics in the set of graphical warnings specified for the production year must be displayed to the extent possible in equal numbers on each brand of tobacco products.

(3) The layout, design and shape of the combined health warnings, taking into account the different packet shapes, shall be in compliance with Commission Implementing Decision (EU) 2015/1842 of 9 October 2015 on the technical specifications for the layout, design and shape of the combined health warnings.

**11.** (1) Tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco 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 services referred to in regulation 10(1)(b).

Labelling and packaging: labelling of tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco.

The general warning shall appear on the most visible surface of the unit packet and any outside packaging.

Each text warning listed in Schedule 2 must 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.

For unit packets with a hinged lid, the next most visible surface is the one that becomes visible when the packet is open.

(2) The general warning referred to in sub-regulation (1) shall cover 32% of the relevant surface of the unit packet and any outside packaging.

(3) The text warning referred to in sub-regulation (1) shall

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cover 45% of the relevant surface of the unit packet and any outside packaging.

(4) Where the health warnings referred to in sub-regulation (1) are to appear on a surface exceeding 150 cm<sup>2</sup>, the warnings shall cover an area of 48 cm<sup>2</sup>.

(5) The health warnings referred to in sub-regulation (1) 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.

The health warnings shall be surrounded by a black border of a width of not less than 3 mm and not more than 4 mm. This border shall appear outside the surface reserved for the health warnings.

Labelling and  
packaging:  
product  
presentation.

**12.** (1) The labelling of unit packets and any outside packaging and the tobacco product itself shall not include any element or feature that -

(a) promotes a tobacco product or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions; labels shall not include any information about the nicotine, tar or carbon monoxide content of the tobacco product;

(b) suggests that a particular tobacco product is less harmful than others or aims to reduce the effect of some harmful components of smoke or has vitalising, energetic, healing, rejuvenating, natural, organic properties or has other health or lifestyle benefits;

(c) refers to taste, smell, any flavourings or other additives or the absence thereof;

(d) resembles a food or a cosmetic product;

(e) suggests that a certain tobacco product has improved biodegradability or other environmental advantages.

(2) The unit packets and any outside packaging shall not suggest economic advantages by including printed vouchers, offering discounts, free distribution, two-for-one or other similar offers.

(3) The elements and features that are prohibited pursuant to sub-regulations (1) and (2) may include, but are not limited to, texts, symbols, names, trademarks, figurative or other signs.



**13.** (1) Unit packets of cigarettes shall have a cuboid shape. Unit packets of roll-your-own tobacco shall have a cuboid or cylindrical shape, or the form of a pouch. A unit packet of cigarettes shall include at least 20 (twenty) cigarettes. A unit packet of roll-your-own tobacco shall contain tobacco weighing not less than 30 g.

Labelling and packaging: appearance and content of unit packets.

(2) A unit packet of cigarettes may consist of carton or soft material and shall not have an opening that can be re-closed or re-sealed after it is first opened, other than the flip-top lid and shoulder box with a hinged lid. For packets with a flip-top lid and hinged lid, the lid shall be hinged only at the back of the unit packet.

**14.** (1) The manufacturer and the importer shall ensure that all unit packets of tobacco products are marked with a unique identifier. In order to ensure the integrity of the unique identifier, it shall be irremovably printed or affixed, indelible and not hidden or interrupted in any form, including through tax stamps or price marks, or by the opening of the unit packet. In the case of tobacco products that are manufactured outside of the Union, the obligations laid down in these regulations apply only to those that are destined for, or placed on, the Union market.

Labelling and packaging: traceability.

(2) The unique identifier shall allow the following to be determined:

- (a) the date and place of manufacturing;
- (b) the manufacturing facility;
- (c) the machine used to manufacture the tobacco products;
- (d) the production shift or time of manufacture;
- (e) the product description;
- (f) the intended market of retail sale;
- (g) the intended shipment route;
- (h) where applicable, the importer into the Union;
- (i) the actual shipment route from manufacturing to the first retail outlet, including all warehouses used as well as the shipment date, shipment destination, point of departure and consignee;
- (j) the identity of all purchasers from manufacturing to

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the first retail outlet; and

(k) the invoice, order number and payment records of all purchasers from manufacturing to the first retail outlet.

(3) The information referred to in sub-regulation (2)(a), (b), (c), (d), (e), (f), (g) and, where applicable, (h) shall form part of the unique identifier.

(4) The information mentioned in sub-regulation (2)(i), (j) and (k) shall be electronically accessible by means of a link to the unique identifier.

(5) All economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, must record the entry of all unit packets into their possession, as well as all intermediate movements and the final exit of the unit packets from their possession. This obligation may be complied with by the marking and recording of aggregated packaging such as cartons, mastercases or pallets, provided that the tracking and tracing of all unit packets remains possible.

(6) All natural and legal persons engaged in the supply chain of tobacco products shall maintain complete and accurate records of all relevant transactions.

(7) The manufacturers of tobacco products shall provide all economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, including importers, warehouses and transporting companies, with the equipment that is necessary for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled. That equipment shall be able to read and transmit the recorded data electronically to a data storage facility pursuant to sub-regulation (8).

(8) Manufacturers and importers of tobacco products shall conclude data storage contracts with an independent third party, for the purpose of hosting the data storage facility for all relevant data. The data storage facility shall be physically located on the territory of the Union. The suitability of the third party, in particular its independence and technical capacities, as well as the data storage contract, shall be approved by the Commission.

The third party's activities shall be monitored by an external auditor, who is proposed and paid by the tobacco manufacturer and approved by the Commission. The external auditor shall submit an annual report to the Superintendent and to the

Commission, assessing in particular any irregularities in relation to access.

The Commission, the competent authorities of the Member States, and the external auditor shall have full access to the data storage facilities. In duly justified cases, the Commission or the Member States may grant manufacturers or importers access to the stored data, provided that commercially sensitive information remains adequately protected in conformity with the relevant Union and national law.

(9) Recorded data shall not be modified or deleted by an economic operator involved in the trade of tobacco products.

(10) All personal data shall only be processed in accordance with the rules and safeguards of the Data Protection Act.

Cap. 440.

(11) The technical standards for the establishment and the operation of the tracking and tracing system as provided for in this regulation, including the marking with a unique identifier, the recording, transmitting, processing and storing of data and access to stored data shall be determined in accordance with a Commission Implementing Act.

(12) The technical standards for ensuring that the systems used for the unique identifier and the related functions are fully compatible with each other across the Union shall be determined in accordance with a Commission Implementing Act.

(13) The provisions of this regulation shall apply to cigarettes and roll-your-own tobacco from 20 May 2019 and to tobacco products other than cigarettes and roll-your-own tobacco from 20 May 2024.

**15.** (1) In addition to the unique identifier referred to in regulation 14, all unit packets of tobacco products, which are placed on the market, shall carry a tamper proof security feature, composed of visible and invisible elements. The security feature shall be irremovably printed or affixed, indelible and not hidden or interrupted in any form, including through tax stamps and price marks, or other elements imposed by legislation.

Labelling and packaging:  
security feature.

Tax stamps may be used for the security feature provided that the tax stamps fulfil all of the technical standards and functions required under this regulation.

(2) The technical standards for the security feature and their possible rotation and adaptation to scientific, market and technical

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developments shall be defined by means of Commission Implementing Acts.

(3) Sub-regulation (1) shall apply to cigarettes and roll-your-own tobacco from 20 May 2019 and to tobacco products other than cigarettes and roll-your-own tobacco from 20 May 2024.

Cross-border  
distance sales of  
tobacco  
products.

**16.** (1) Retail outlets engaging in cross-border distance sales of tobacco products may not supply such products to consumers in Member States where such sales have been prohibited.

Retail outlets intending to engage in cross-border distance sales to consumers located in the Union must register with the Superintendent and with the competent authority in the Member State where the actual or potential consumers are located. Retail outlets established outside the Union shall be required to register with the competent authorities in the Member State where the actual or potential consumers are located. All retail outlets intending to engage in cross-border distance sales shall submit the following information to the competent authorities when registering:

- (a) name or corporate name and permanent address of the place of activity from where the tobacco products will 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 website or websites used for that purpose and all relevant information necessary to identify the website.

(2) The Superintendent shall ensure that consumers have access to the list of all retail outlets registered with them. Retail outlets may only start placing tobacco products on the market via cross-border distance sales when they have received confirmation of their registration with the Superintendent.

(3) The retail outlet supplying tobacco products sold via cross-border distance sales shall nominate, to the Superintendent, a natural person to be responsible for verifying, before the tobacco products reach the consumer, that they comply with the national provisions adopted pursuant to these regulations, if such verification is necessary in order to ensure compliance and facilitate enforcement.

(4) Retail outlets engaged 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 Tobacco (Smoking Control) Act. The retail outlet or natural person nominated pursuant to sub-regulation (3) shall provide to the Superintendent a description of the details and functioning of the age verification system. Cap. 315.

(5) Retail outlets shall only process personal data of the consumer in accordance with Directive 95/46/EC and those 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.

**17.** (1) Manufacturers and importers of novel tobacco products shall submit a notification to the Superintendent of any such product they intend to place on the national market. The notification shall be submitted in electronic form six months before the intended placing on the market. It shall be accompanied by a detailed description of the novel tobacco product concerned as well as instructions for its use and information on ingredients and emissions in accordance with regulation 5. The manufacturers and importers submitting a notification of a novel tobacco product shall also provide the Superintendent with: Notification of novel tobacco products.

(a) available scientific studies on toxicity, addictiveness and attractiveness of the novel tobacco product, in particular as regards its ingredients and emissions;

(b) available studies, executive summaries thereof and market research on the preferences of various consumer groups, including young people and current smokers;

(c) other available and relevant information, including a risk/benefit analysis of the product, its expected effects on cessation of tobacco consumption, its expected effects on initiation of tobacco consumption and predicted consumer perception.

(2) Manufacturers and importers of novel tobacco products shall transmit to the Superintendent any new or updated information on the studies, research and other information referred to in sub-regulation (1)(a) to (c). The Superintendent may require manufacturers or importers of novel tobacco products to carry out additional tests or submit additional information. All information

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received pursuant to this regulation shall be made available to the Commission.

(3) Novel tobacco products placed on the market shall respect the requirements of these regulations.

Electronic  
cigarettes.

**18.** (1) Electronic cigarettes and refill containers shall only be placed on the market if they comply with these regulations and with all other relevant national and Union legislation.

This does not apply to electronic cigarettes and refill containers that are subject to an authorisation requirement under Directive 2001/83/EC or to the requirements set out in Directive 93/42/EEC.

(2) (a) Manufacturers and importers of electronic cigarettes and refill containers shall submit a notification to the Superintendent of any such products which they intend to place on the market. The notification shall be submitted in electronic form six months before the intended placing on the market. For electronic cigarettes and refill containers already placed on the market on 20 May 2016, the notification shall be submitted within six months of that date. A new notification shall be submitted for each substantial modification of the product.

(b) The notification shall, depending on whether the product is an electronic cigarette or a refill container, contain the following information:

(i) the name and contact details of the manufacturer, a responsible legal or natural person within the Union, and, if applicable, the importer into the Union;

(ii) a list of all ingredients contained in, and emissions resulting from the use of, the product, by brand name and type, including quantities thereof;

(iii) toxicological data regarding the product's ingredients and emissions, including when heated, referring in particular to their effects on the health of consumers when inhaled and taking into account, *inter alia*, any addictive effect;

(iv) information on the nicotine doses and uptake when consumed under normal or reasonably foreseeable conditions;

(v) a description of the components of the

product; including, where applicable, the opening and refill mechanism of the electronic cigarette or refill containers;

(vi) a description of the production process, including whether it involves series production, and a declaration that the production process ensures conformity with the requirements of this regulation;

(vii) a declaration that the manufacturer and importer bear full responsibility for the quality and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions;

(c) Where the Superintendent considers that the information submitted is incomplete, he shall be entitled to request the completion of the information concerned.

(d) The Superintendent may charge manufacturers and importers of tobacco products proportionate fees which the Minister may by regulations prescribe, for receiving, storing, handling and analysing the information submitted to him.

(3) Electronic cigarettes and refill containers shall only be placed on the market if they comply with the following requirements:

(a) nicotine-containing liquid is only placed on the market in dedicated refill containers not exceeding a volume of 10 ml, in disposable electronic cigarettes or in single use cartridges and that the cartridges or tanks do not exceed a volume of 2 ml;

(b) the nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml;

(c) the nicotine-containing liquid does not contain additives listed in regulation 7(3);

(d) only ingredients of high purity are used in the manufacture of the nicotine-containing liquid. Substances other than the ingredients referred to in sub-regulation (2)(b)(ii) are only present in the nicotine-containing liquid in trace levels, if such traces are technically unavoidable during manufacture;

(e) except for nicotine, only ingredients that do not pose a risk to human health in heated or unheated form are used in the nicotine-containing liquid;

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(f) electronic cigarettes deliver the nicotine doses at consistent levels under normal conditions of use;

(g) electronic cigarettes and refill containers are child- and tamper-proof, are protected against breakage and leakage and have a mechanism that ensures refilling without leakage.

(4) Electronic cigarettes and refill containers shall only be placed on the market if they comply to these further requirements:

(a) unit packets of electronic cigarettes and refill containers include a leaflet with information 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;

(b) unit packets and any outside packaging of electronic cigarettes and refill containers:

(i) include a list of all ingredients contained in the product in descending order of the weight, and an indication of the nicotine content of the product and the delivery per dose, the batch number and a recommendation to keep the product out of reach of children;

(ii) without prejudice to sub-paragraph (i), do not include elements or features referred to in regulation 12, with the exception of regulation 12(1)(a) and (c) concerning information on the nicotine content and on flavourings; and

(iii) carry the following health warning:

‘This product contains nicotine which is a highly addictive substance’ and ‘Dan il-prodott fih



in-nikotina li hija sustanza li tista' faċilment twassal għad-dipendenza'.

(c) health warnings comply with the requirements specified in regulation 9(4).

(5) The following shall also apply to electronic cigarettes:

(a) commercial communications in information society services, in the press and other printed publications, with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers are prohibited, except for publications that are intended exclusively for professionals in the trade of electronic cigarettes or refill containers and for publications which are printed and published in third countries, where those publications are not principally intended for the Union market;

(b) commercial communications on the radio, with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers, are prohibited;

(c) any form of public or private contribution to radio programmes with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers is prohibited;

(d) any form of public or private contribution to any event, activity or individual person with the aim or direct or indirect effect of promoting electronic cigarettes and refill containers and involving or taking place in several Member States or otherwise having cross-border effects is prohibited;

(e) audiovisual commercial communications, to which Directive 2010/13/EU of the European Parliament and of the Council applies, are prohibited for electronic cigarettes and refill containers.

(6) Regulation 16 shall apply to cross-border distance sales of electronic cigarettes and refill containers.

(7) Manufacturers and importers of electronic cigarettes and refill containers shall annually submit to the Superintendent:

(a) comprehensive data on sales volumes, by brand name and type of the product;

(b) information on the preferences of various consumer groups, including young people, non-smokers and the main

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types of current users;

(c) the mode of sale of the products; and

(d) executive summaries of any market surveys carried out in respect of the above, including an English translation thereof.

(8) The information received pursuant to sub-regulation (2) shall be made publicly available on a website, duly taking into account the need to protect trade secrets.

All information received pursuant to this regulation shall be made available, upon request, to the Commission and other Member States, duly ensuring that trade secrets and other confidential information are treated in a confidential manner.

(9) Manufacturers, importers and distributors of electronic cigarettes and refill containers shall establish and maintain a system for collecting information about all of the suspected adverse effects on human health of these products.

Should any of these economic operators consider or have reason to believe that electronic cigarettes or refill containers, which are in their possession and are intended to be placed on the market or are placed on the market, are not safe or are not of good quality or are otherwise not in conformity with these regulations, that economic operator shall immediately take the corrective action necessary to bring the product concerned into conformity with these regulations, to withdraw or to recall it, as appropriate. In such cases, the economic operator shall also be required to immediately inform the Superintendent, giving details, in particular, of the risk to human health and safety and of any corrective action taken, and of the results of such corrective action.

The Superintendent may also request additional information from the economic operators, for example on the safety and quality aspects or any adverse effects of electronic cigarettes or refill containers.

(10) In the case of electronic cigarettes and refill containers that comply with the requirements of this regulation, where the Superintendent ascertains or has reasonable grounds to believe that specific electronic cigarettes or refill containers, or a type of electronic cigarette or refill container, could present a serious risk to human health, he may take appropriate provisional measures. The Superintendent shall immediately inform the Commission and the

competent authorities of other Member States of the measures taken and shall communicate any supporting data.

(11) The notification provided for in sub-regulation (2) shall be in compliance with Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers (notified under document C(2015) 8087).

Technical standards for the refill mechanism shall be laid down and subsequently updated in accordance with Commission Implementing Acts.

**19.** (1) Each unit packet and any outside packaging of herbal products for smoking shall carry the following health warnings: ‘Smoking this product damages your health’ and ‘It-tipjip ta’ dan il-prodott jagħmel ħsara lil saħħtek’.

Herbal products  
for smoking.

(2) The health warning shall be printed on the front and back external surface of the unit packet and on any outside packaging.

(3) The health warning shall comply with the requirements set out in regulation 9(4). It shall cover 32% of the area of the corresponding surface of the unit packet and of any outside packaging.

(4) Unit packets and any outside packaging of herbal products for smoking shall not include any of the elements or features set out in regulation 12(1)(a), (b) and (d) and shall not state that the product is free of additives or flavourings.

**20.** (1) Manufacturers and importers of herbal products for smoking shall submit to the Superintendent a list of all ingredients, and quantities thereof that are used in the manufacture of such products by brand name and type. Manufacturers or importers shall also inform the Superintendent when the composition of a product is modified in a way that affects the information submitted pursuant to this regulation. The information required under this regulation shall be submitted prior to the placing on the market of a new or modified herbal product for smoking.

Reporting of  
ingredients of  
herbal products  
for smoking.

(2) The Superintendent shall make the information submitted in accordance with sub-regulation (1) publicly available on a website, duly protecting trade secrets. Economic operators shall specify exactly which information they consider to constitute a trade secret.

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Importation,  
etc., of  
smokeless  
tobacco banned.

**21.** No person may import, manufacture, prepare, store, keep for sale, sell or supply by way of compensation or otherwise, any smokeless tobacco product.

Transitional  
provisions.

**22.** The following products, which are not in compliance with these regulations, may be placed on the market until 20 May 2017:

(a) tobacco products manufactured or released for free circulation and labelled in accordance with Directive 2001/37/EC before 20 May 2016;

(b) electronic cigarettes or refill containers manufactured or released for free circulation before 20 November 2016;

(c) herbal products for smoking manufactured or released for free circulation before 20 May 2016.

Cooperation and  
enforcement.

**23.** (1) The Superintendent shall ensure that manufacturers and importers of tobacco and related products provide his office and the Commission with complete and correct information requested pursuant to these regulation and within the time limits set out herein. The obligation to provide the requested information shall lie primarily with the manufacturer, if the manufacturer is established in Malta. The obligation to provide the requested information shall lie primarily with the importer, if the manufacturer is established outside Malta and the importer is established inside Malta. The obligation to provide the requested information shall lie jointly with the manufacturer and the importer if both are established outside Malta.

(2) The Superintendent shall ensure that tobacco and related products which do not comply with these regulations, including the implementing and delegated acts provided for in the Directive, are not placed on the market.

Offences and  
penalties.

**24.** Any person who contravenes or fails to comply with any of the provisions of these regulations shall be guilty of an offence and shall, without prejudice to his liability under any other law, be liable, on a first conviction, to a fine (*multa*) of not less than two hundred euro (€200) and not exceeding one thousand euro (€1,000), and where the act or omission constituting the offence subsists for more than a day, the Court shall in addition impose a fine (*multa*) of not less than twenty euro (€20) and not more than one hundred euro (€100) for each day in which such act or omission subsists, and on a second or subsequently conviction, in addition to such fines, and, at the request of the prosecution, to imprisonment for a term not exceeding three months.

**25.** The following regulations -

Revocation.

(a) the Labelling of Tobacco Products Regulations - S.L.315.01;

(b) the Ban on Smokeless Tobacco Regulations - S.L.315.02;

(c) the Tobacco Products (Cigarette Composition) Regulations - S.L.315.05; and

(d) the Use of Colour Photographs or other Illustrations as Health Warnings on Tobacco Products Regulations - S.L.315.08,

are hereby revoked without prejudice to anything done or omitted to be done thereunder.










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**SCHEDULE 1**  
**Graphical health warning library**

(Regulation 10)

**PART 1**

|  |  |  |
|--|--|--|
|  <p>LUNG SURGERY<br/>KIRURĠJA PULMONARI</p> |                      |                       |
| <p>Smoking causes 9 out of 10 lung cancers<br/>It-tipjip jikkawża 9 minn 10 każijiet ta' kanċer fil-pulmun</p>               | <p>Smoking causes mouth and throat cancer<br/>It-tipjip jikkawża kanċer fil-halg u fil-gerżuma</p>     | <p>Smoking damages your lungs<br/>It-tipjip jaghmel hsara fil-pulmuni</p>                                |
| <p>Tobacco Stop Line:<br/>80073333 www.health.gov.mt</p>   | <p>Tobacco Stop Line:<br/>80073333 www.health.gov.mt</p>   | <p>Tobacco Stop Line:<br/>80073333 www.health.gov.mt</p>   |
|    |                     |                      |
| <p>Smoking causes heart attacks<br/>It-tipjip jikkawża l-attakki tal-qalb</p>  | <p>Smoking causes strokes and disability<br/>It-tipjip jikkawża attakki ta' puplesija u diżabilità</p> | <p>Smoking clogs your arteries<br/>It-tipjip isoddlok l-arterji</p>                                      |
| <p>Tobacco Stop Line:<br/>80073333 www.health.gov.mt</p>   | <p>Tobacco Stop Line:<br/>80073333 www.health.gov.mt</p>   | <p>Tobacco Stop Line:<br/>80073333 www.health.gov.mt</p>   |
|   |                    |                     |
| <p>Smoking increases the risk of blindness<br/>It-tipjip iżidlek ir-riskju li taghma</p>                                     | <p>Smoking damages your teeth and gums<br/>It-tipjip iħassarlek snienek u l-hanek</p>                  | <p>Smoking can kill your unborn child<br/>It-tipjip jista' joqtol it-tarbija tieghek qabel it-twelid</p> |
| <p>Tobacco Stop Line:<br/>80073333 www.health.gov.mt</p>   | <p>Tobacco Stop Line:<br/>80073333 www.health.gov.mt</p>   | <p>Tobacco Stop Line:<br/>80073333 www.health.gov.mt</p>   |



**Your smoke harms your children, family and friends**  
**It-tipjip tieghek jagħmel ħsara lil uliedek, familtek u ħbiebek**

Tobacco Stop Line:  
80073333 [www.health.gov.mt](http://www.health.gov.mt)



**Smokers' children are more likely to start smoking**  
**It-tfal ta' min ipejjep għandhom possibiltà akbar li jibdeu ipejpu wkoll**

Tobacco Stop Line:  
80073333 [www.health.gov.mt](http://www.health.gov.mt)



**Quit smoking – stay alive for those close to you**  
**Aqta' t-tipjip issa – ibqa' ħaj għal dawk li thobb**

Tobacco Stop Line:  
80073333 [www.health.gov.mt](http://www.health.gov.mt)



**Smoking reduces fertility**  
**It-tipjip inaqqas il-fertilità**















Tobacco Stop Line:  
80073333 [www.health.gov.mt](http://www.health.gov.mt)



**Smoking increases the risk of impotence**  
**It-tipjip iżid ir-riskju ta' impotenza**

Tobacco Stop Line:  
80073333 [www.health.gov.mt](http://www.health.gov.mt)

PART 2

|  |   |   |
|--|---|---|
|  <p><b>Smoking causes 9 out of 10 lung cancers</b><br/> <b>It-tipjip jikkawża 9 minn 10 każijiet ta' kanċer fil-pulmun</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p>                   |  <p><b>Smoking causes mouth and throat cancer</b><br/> <b>It-tipjip jikkawża kanċer fil-halq u fil-gerżuma</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p>                                      |  <p><b>Smoking damages your lungs</b><br/> <b>It-tipjip jagħmel hsara fil-pulmuni</b></p> <p><small>OPEN WOUND AFTER LUNG SURGERY<br/>         ĠERTA MINTHA WARA KIRURĠJA FIL-PULMUNI</small></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p> |
|  <p><b>Smoking causes heart attacks</b><br/> <b>It-tipjip jikkawża l-attakki tal-qalb</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p>  |  <p><b>Smoking causes strokes and disability</b><br/> <b>It-tipjip jikkawża attakki ta' puplesija u diżabilità</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p>                                  |  <p><b>Smoking clogs your arteries</b><br/> <b>It-tipjip isoddlok l-arterji</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p>   |
|  <p><b>Smoking increases the risk of blindness</b><br/> <b>It-tipjip iżidlek ir-riskju li tagħma</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p>  |  <p><b>Smoking damages your teeth and gums</b><br/> <b>It-tipjip iħassarlek snienek u l-hanek</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p>  |  <p><b>Smoking can kill your unborn child</b><br/> <b>It-tipjip jista' joqtol it-tarbija tiegħek qabel it-twelid</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p>   |
|  <p><b>Your smoke harms your children, family and friends</b><br/> <b>It-tipjip tiegħek jagħmel hsara lil uliedek, familitek u hbiebek</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p> |  <p><b>Smokers' children are more likely to start smoking</b><br/> <b>It-tfal ta' min ipejje għandhom possibiltà akbar li jibdew ipejpu wkoll</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p> |  <p><b>Quit smoking – stay alive for those close to you</b><br/> <b>Aqta' t-tipjip issa – ibqa' haġ għal dawk li thobb</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p>  |
|  <p><b>Smoking reduces fertility</b><br/> <b>It-tipjip inaqqas il-fertilità</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p>  |  <p><b>Smoking increases the risk of impotence</b><br/> <b>It-tipjip iżid ir-riskju ta' impotenza</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p>   |   |



PART 3

|   |   |  |
|---|---|--|
|  <p><b>Smoking causes 9 out of 10 lung cancers</b><br/> <b>It-tipjip jikkawża 9 minn 10 każijiet ta' kanċer fil-pulmun</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p>                  |  <p><b>Smoking causes mouth and throat cancer</b><br/> <b>It-tipjip jikkawża kanċer fil-halq u fil-gerżuma</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p>                                      |  <p><b>Smoking damages your lungs</b><br/> <b>It-tipjip jagħmel hsara fil-pulmuni</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p>   |
|  <p><b>Smoking causes heart attacks</b><br/> <b>It-tipjip jikkawża l-attakki tal-qalb</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p>   |  <p><b>Smoking causes strokes and disability</b><br/> <b>It-tipjip jikkawża attakki ta' puplesija u diżabilità</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p>                                  |  <p><b>Smoking clogs your arteries</b><br/> <b>It-tipjip isoddlok l-arterji</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p>   |
|  <p><b>Smoking increases the risk of blindness</b><br/> <b>It-tipjip iżidlek ir-riskju li taghma</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p>                                       |  <p><b>Smoking damages your teeth and gums</b><br/> <b>It-tipjip iħassarlek snienek u l-hanek</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p>  |  <p><b>Smoking can kill your unborn child</b><br/> <b>It-tipjip jista' joqtol it-tarbija tiegħek qabel it-twelid</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p>         |
|  <p><b>Your smoke harms your children, family and friends</b><br/> <b>It-tipjip tiegħek jagħmel hsara lil uliedek, familtek u hbiebek</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p> |  <p><b>Smokers' children are more likely to start smoking</b><br/> <b>It-tfal ta' min ipejje għandhom possibiltà okbar li jibdew ipejpu wkoll</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p> |  <p><b>Quit smoking – stay alive for those close to you</b><br/> <b>Aqta' t-tipjip issa – ibqa' 'haj għal dawk li thobb</b></p> <p>Tobacco Stop Line: 80073333<br/> <a href="http://www.health.gov.mt">www.health.gov.mt</a></p> |

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The photographs, images and textual illustrations contained in this Schedule have been developed for use on tobacco product packages in accordance with the Commission Delegated Directive 2014/109/EU of 10 October 2014 amending Annex II to Directive 2014/40/EU of the European Parliament and of the Council by establishing the library of picture warnings to be used on tobacco products:

All other uses are subject to the permission of the European Commission.

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## SCHEDULE 2 LIST OF TEXT WARNINGS

(Regulation 11)

- (1) Smoking causes 9 out of 10 lung cancers  
It-tipjip jikkawża 9 minn 10 każijiet ta' kanċer fil-pulmun
- (2) Smoking causes mouth and throat cancer  
It-tipjip jikkawża kanċer fil-ħalq u fil-gerżuma
- (3) Smoking damages your lungs  
It-tipjip jagħmel ħsara fil-pulmuni
- (4) Smoking causes heart attacks  
It-tipjip jikkawża l-attakki tal-qalb
- (5) Smoking causes strokes and disability  
It-tipjip jikkawża attakki ta' puplesija u diżabilità

- (6) Smoking clogs your arteries  
It-tipjip isoddlok l-arterji
- (7) Smoking increases the risk of blindness  
It-tipjip iżidlek ir-riskju li tgħama
- (8) Smoking damages your teeth and gums  
It-tipjip iħassarlek snienek u l-ħanek
- (9) Smoking can kill your unborn child  
It-tipjip jista' joqtol it-tarbija tiegħek qabel it-twelid
- (10) Your smoke harms your children, family and friends  
It-tipjip tiegħek jagħmel ħsara lil uliedek, familtek u ħbiebek
- (11) Smokers' children are more likely to start smoking  
It-tfal ta' min ipejjep għandhom possibiltà akbar li jibdew ipejpu wkoll
- (12) Quit smoking - stay alive for those close to you  
Aqta' t-tipjip issa - ibqa' haj għal dawk li thobb
- (13) Smoking reduces fertility  
It-tipjip inaqqas il-fertilità
- (14) Smoking increases the risk of impotence  
It-tipjip iżid ir-riskju ta' impotenza.
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