

EXECUTIVE DECREE N° 37778-S

THE PRESIDENT OF THE REPUBLIC

AND THE MINISTER OF HEALTH

In the exercise of the attributions conferred upon them by Articles 50, 140 sub-paragraphs 3) and 18) and 146 of the Political Constitution; 25, 27 paragraph one, 28 paragraph two, sub-paragraph b) of Law No. 6227 of May 2, 1978, “General Law of Public Administration”; 1, 2, 4, 7, 258, of Law No. 5395 of October 30, 1973, “General Law of Health”; 1, 2 and 6 of Law No. 5412 del November 8, 1973, “Organic Law of the Ministry of Health; Law 8655 of July 17, 2008 “Law of Approval of the Framework Convention of the World Health Organization (WHO) for the Control of Tobacco”; 9, 10 and 11 of Law N° 9028 March 22, 2012, “General Law for the Control of Tobacco and its Harmful Effects on Health.”

WHEREAS:

1.- The health of the public is a fundamental human right, as well as a public good protected by the State.

2.- It falls within the competency of the Ministry of Health to define its policies, regulations, plans and the coordination of all public and private health-related activities.

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3.- Article 9 sub-paragraph a) of Law N° 9028, the “General Law for the Control of Tobacco and its Harmful Effects on Health” grants competency to the Ministry of Health to define and approve health messages and health warnings.

4. The presence of harmful substances and carcinogenic agents in emissions caused by the burning of cigarettes and tobacco derivatives - which, in a slow but effective way, causes people's health to deteriorate – has been demonstrated through innumerable scientific studies.

5.- The illnesses and deaths caused by the consumption of tobacco derivative products have reached epidemic proportions in many countries, and will only increase if effective measures to inhibit consumption are not put into practice.

6.- The consumption of tobacco is directly related to illnesses such as chronic bronchitis, pulmonary emphysema, airway hyper-responsiveness, gastrointestinal problems, cardio and cerebral vascular disorders, and various types of cancer of the lung, mouth, kidney and bladder, among others. It also has a negative impact on fetal development, which can lead to premature birth and perinatal death.

7. - the World Health Organisation (WHO - 2012) has established that tobacco is the direct or indirect cause of almost 6 million deaths a year, approximately a third of which occur in developing countries, where, according to estimates, 8 million deaths will occur due to this addiction in the next 20 to 30 years, if effective measures to reduce tobacco consumption and exposure to second-hand smoke are not put into practice.

8. - The harm to health caused by the consumption of tobacco products and derivatives is considered one of the main public health problems at the global level, taking into account not only active smokers, but also the equally deleterious consequences for passive smokers, who are all the people voluntarily or involuntarily exposed to the effects of tobacco.

9. - The consumption of tobacco products and derivatives causes the illness and death of many people of productive age, which increases the costs of medical care and social welfare. Passive

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smokers also comprise a high percentage of those who are afflicted by the effects of this addiction.

10.- There are studies on an international level that prove that the use of terms such as "low tar," "ultralight," "light" and "mild," give the impression that a product is less harmful, causing a greater increase in cigarette consumption.

11.- It has been demonstrated that the incorporation of health messages in labeling tobacco products is an effective means for raising public awareness, and they also have the purpose of informing and educating consumers and the general public about the dangers that tobacco consumption and exposure to tobacco smoke pose for health.

12.- One of the objectives of the General Law for the Control of Tobacco and its Harmful Effects on Health is to disseminate the awareness of the risks that can be attributed to the consumption of products made from tobacco.

13- It has been demonstrated that the incorporation of health messages on packaging for tobacco products is a cost-effective way of raising public awareness concerning the harmful effects of tobacco and tobacco derivatives.

14.- Health messages constitute a way of informing and educating consumers and the general public about the harmful effects that tobacco consumption and exposure to tobacco smoke have on people's health.

15- Health messages provide information that supports strategies to discourage people from starting to consume tobacco and derivatives, above all, young people and adolescents.

16.- In light of all of the considerations set forth, it has become necessary and timely to issue this regulation to regulate the labeling of tobacco products.

THEREFORE, they do hereby

DECREE

this

**REGULATION FOR THE LABELING OF TOBACCO PRODUCTS
AND TOBACCO DERIVATIVES**

Article 1.-Purpose. The purpose of this regulation is to establish regulations on the labeling of primary packaging and secondary packaging of all tobacco products and derivatives.

- a) To inform the entire population and warn consumers about the harmful health consequences, the addictive nature and mortal threat of tobacco consumption and exposure to second-hand tobacco smoke, as well as the benefits of quitting tobacco consumption;
- b) To discourage tobacco consumption and promote quitting tobacco at the moment of its purchase and consumption;
- c) To ensure that packaging and labeling do not contain information or terms that cause confusion for consumers or encourage the public to consume tobacco, or that impair or weaken the message of the health warnings.

Article 2.- Scope of application. This regulation is applicable to all tobacco products and derivatives sold in the country.

Article 3.-Definitions and terminology:

a) Campaign: For the purposes of this regulation, a campaign is understood to refer to each one of the annual periods when the tobacco industry must incorporate messages and health warnings, in accordance with what is established in Article 9 of Law N° 9028.

b) Principal faces or main surfaces: This is the front and rear part or exposed surface of primary and secondary packaging of all tobacco products and derivatives.

c) Side face: The left or right side of primary and secondary packaging of all tobacco products and tobacco derivatives.

d) Net content: This is the weight or number of units of tobacco products and derivatives contained in each package.

e) Distributor: Natural or juridical person, national or foreign, an entity of fact or of law, private or public, which acting in its own name or that of a third party, on its own or another's account, habitually engages in distributing or commercializing tobacco products and tobacco derivatives on a wholesale or retail basis.

f) Packaging: This consists of the following:

i. Primary package or pack: Any receptacle that has direct contact with the tobacco product, for the purpose of protecting it against deterioration, contamination or adulteration, and to facilitate its handling.

ii. Secondary package or carton: Any receptacle that contains two or more primary packages for the purpose of protecting them and facilitating their commercialization until they reach the end consumer. The secondary package is usually used to gather several primary packages in a single purchasing unit.

g) Labeling: This refers to labeling containing all the inscriptions, captions, brands and provisions that are to be printed on any primary or secondary pack containing cigarettes or any tobacco derivative products.

h) Manufacturer: Any natural or juridical person engaged in the manufacture of tobacco products and tobacco derivatives.

i) Importer: Any natural or juridical person in whose name tobacco products and derivatives are imported.

j) Tobacco industry: Any natural or juridical person engaged in the manufacture, wholesale distribution or importation of tobacco products and derivatives.

k) Law N° 9028: “General Law for the Control of Tobacco and its Harmful Effects on Health.”

l) Health message: Warnings addressed to consumers and the public concerning the risks and damage to health caused by the consumption of tobacco products and derivatives, and by exposure to the smoke of tobacco products. They may consist of pictograms, images, captions and similar items.

m) Tobacco products and derivatives: These are products prepared totally or in part using tobacco leaf as a raw material, and intended to be smoked, sucked, chewed or used as snuff, including electronic cigarettes.

n) Tobacco: A plant of the species *Nicotiana Tabacum* which can cause addiction if its leaves are consumed, either in natural form or when it has been industrially processed.

o) Vendors of tobacco products: Natural or juridical persons engaging in any commercial activity for the purpose of wholesale or retail sale of tobacco products, tobacco derivatives and products related with their consumption.

CHAPTER I

GENERAL PROVISIONS

Article 4. – Health warnings describing the harmful effects of tobacco products and derivatives pursuant to the guidelines established in these regulations must appear printed in a permanent form on the principal faces or main surfaces of all primary or secondary packages of tobacco products and derivatives.

Article 5. It is prohibited to include on the labeling of tobacco products and derivatives, phrases, images or any other kind of message that promotes them in a misleading, false or deceitful

fashion. It is also prohibited to use terms such as: “low in tar,” “Light,” “Ultralight,” “Mild,” “extra” and “ultra,” as well as any other term that may lead the public to suppose that one tobacco product is less harmful than another in terms of its content, risks or emissions.

Article 6. - Manufacturers, importers and distributors of tobacco products and derivatives must adapt packs of tobacco products in any presentation intended for end consumers to the provisions established in this Regulation. Sale and distribution will not be permitted of any tobacco products or derivatives that are not in compliance with the provisions established herein.

Article 7. – For tobacco products and derivatives contained in packages or presentations with drawings or forms that make it difficult to adapt them to the standards established herein, the Ministry of Health shall define designs of health warnings in keeping with what is set forth in this Regulation and Law N° 9028.

CHAPTER II

LABELING SPECIFICATIONS

Article 8.- The Ministry of Health shall establish the designs to be used for each one of the campaigns, including the characteristics of the typeface, size, background color of the image or pictogram, through ministerial resolution, which is to be published in the *Diario Oficial La Gaceta* [Official Bulletin, The Gazette]. One year is allowed for all tobacco products and derivatives to comply with what is established in this Regulation. New campaigns are to be announced by the Ministry of Health to manufacturers, importers and distributors of tobacco products and derivatives, with 12 months advance notice prior to the requirement for the new designs to take effect. A period of 2 months that cannot be extended is established for the transition from one campaign to the next to take place, the only interval during which the former designs and new designs established by the Ministry of Health can be used at the same time. All of this is in keeping with the provisions contained in Article 9 of Law N° 9028.

Article 9.- Labeling for primary packaging: All primary packaging of tobacco products and derivatives that are sold in the national territory must comply with the following provisions:

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a) Every primary package of tobacco products and derivatives must allocate fifty percent (50%) of the lower part of its exposed main surfaces or principal faces to print the health warnings established by the Ministry of Health, permanently and in color. Each package of tobacco products and derivatives is to use a different design on each one of its principal faces.

b) The Ministry of Health shall establish via ministerial guidelines the designs to be used in each one of the campaigns, which shall be published in the *Diario Oficial La Gaceta*.

c) Each primary package of tobacco products must include on its lower part a different health message on each one of the principal faces, which are to be rotated annually. During each annual period of rotation, the health warnings established by the Ministry of Health shall circulate in the market. For such purpose, they shall comply with the following provisions:

i. They are to be distributed proportionally, homogeneously and simultaneously with the volume of primary packaging.

ii. Health messages are to be printed in colors that are similar to the colors required, as clearly as possible.

iii. Health messages may not be obstructed by other kind of information on the packaging.

iv. They must be placed in such a way that the normal opening of the pack does not damage or conceal permanently the text or the image of the health warning.

d) The captions: “Exclusively for sale in Costa Rica,” and “Sale to minors prohibited,” must be included in a space that does not impinge upon the space intended specifically for the health warnings. The type face must be Arial Bold N° 12, in such a way that it contrasts with the background color of the image or pictogram so that the text is clearly visible and legible.

e) The health warnings must appear on 100% of one of the lateral faces of the primary packaging, printed legibly, in Arial Bold N° 12, closed upper case typeface, in such a way that the messages stand out against the colors of the pack, to make them readable. Furthermore, this qualitative information on the contents of tobacco products and their emissions must be rotated,

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pursuant to Article 9 of Law 9028, which must contain captions such as: ('By smoking you expose yourself to more than 60 chemical substances that cause cancer.')

f) On the primary package of tobacco products, the following must be identified in print:

i. The product brand.

ii. The net content of product units, country of origin or provenance, and lot number.

iii. Any information that the tobacco industry, distributor or importer may consider necessary, without disrespecting the health warnings that the Ministry of Health has previously approved.

g) Where imported tobacco products are concerned, the information contained in the labeling must appear in the Spanish language, and must comply with the aforementioned requirements printed on the package.

h) Tobacco products and derivatives contained in packs or presentations with designs or shapes that make it difficult to adopt the standards established herein, may submit designs adapted to their particularities in order for the Ministry of Health to undertake their analysis and approval.

Article 10. - Labeling for secondary packaging: Every secondary package containing tobacco products sold in the national territory, must comply with the following provisions:

a) Secondary packaging may be of cellophane or colorless material that do not obstruct the visibility and legibility of the health messages on the units they contain, or other information established for primary packaging.

b) In cases where secondary packaging blocks the visibility of primary packaging or packs of tobacco products, the secondary packaging must meet the same requirements established for primary labeling.

CHAPTER III
THE MINISTERIAL DEPARTMENT RESPONSIBLE FOR DEFINING AND
APPROVING HEALTH MESSAGES.

Article 11.- The Ministry of Health, pursuant to Article 9 of Law N° 9028, shall determine via resolution the Organizational Unit responsible for defining and approving the health messages and warnings that must be printed on primary and secondary packaging of tobacco products and tobacco derivatives.

CHAPTER IV
OVERSIGHT AND ENFORCEMENT

Article 12.- The Ministry of Economy, Industry and Commerce, together with the Ministry of Health, must enforce what is set forth in this Regulation, in accordance with its respective legal competencies. The foregoing is in accordance with sub-paragraph c) of Article 36 of the Regulation of the General Law for the Control of Tobacco and its Harmful Effects on Health, Executive Decree 37185-S-MEIC-MTSS-MP-H-SP, published in *La Gaceta* N° 124 on June 27, 2012.

Article 13.- Failure to comply with the provisions established in this Regulation shall result in application of the sanctions established in Law N° 9028.

Transitory Provision: The tobacco industry shall have a period of twelve months counting from the notification and provision of the respective designs by the Ministry of Health to implement the new health messages and warnings.

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Article 14.- This Regulation is to take effect as of its publication in the *Diario Oficial La Gaceta*.

Issued in the Office of the Presidency of the Republic, San José, on the ninth day of July , two thousand and thirteen.

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