

I. GENERAL PROVISIONS
THE OFFICE OF THE STATE

13277 *Royal Decree-Law 17/2017, of November 17, amending Law 28/2005, of December 26, on health measures against smoking and which regulates the sale, supply, consumption, and advertising of tobacco products, to transpose Directive 2014/40/EU of the European Parliament and of the European Council, of April 3, 2014.*

Article 43 of the Spanish Constitution establishes the right to health protection and entrusts the public authorities with the protection of public health and the adoption of the necessary preventive measures.

Law 14/1986, of April 25, General Health Law, establishes that the Public Administrations shall direct their actions primarily towards the promotion of health and the prevention of diseases, avoiding activities and products that, directly or indirectly, may have negative consequences for health.

In line with both mandates, Law 28/2005, of December 26, 2005, on health measures against smoking and which regulates the sale, supply, consumption, and advertising of tobacco products, was passed.

At the European Union level, with the adoption of Directive 2014/40/EU of the European Parliament and of the European Council dated 3 April 2014 on the harmonization of the laws, regulations, and administrative provisions of the Member States concerning the manufacture, packaging, and sale of tobacco and related products, and which repeals Directive 2001/37/EC, it was intended to facilitate the proper functioning of the internal market for tobacco and related products, based on a high level of protection of human health, as well as to comply with the obligations under the World Health Organization Framework Convention on Tobacco Control.

The aforementioned Directive 2014/40/EU of the European Parliament and of the European Council, of April 3, 2014, has been for the most part transposed into the Spanish legal system through Royal Decree 579/2017, of June 9, which regulates certain aspects relating to the manufacture, packaging, and marketing of tobacco products and related products. However, the complete transposition of this directive requires amendments to Law 28/2005, of December 26.

First, Article 2 of Law 28/2005, of December 26, 2005, includes certain definitions established in Directive 2014/40/EU of the European Parliament and of the European Council, of April 3, 2014, which were not included in that law, and modifies others to bring them into line with the terms of the aforementioned directive.

As for the regulation of tobacco products, Article 3 of Law 28/2005, of 26 December, explicitly establishes in Article 3 the prohibition of the marketing of tobacco for oral use already provided for in Royal Decree 579/2017, of 9 June. Likewise, additional provision four is amended to clarify the special regime of the Autonomous Community of the Canary Islands,

whose content refers to the provisions of its Statute of Autonomy and to the exclusive powers of the State, but without ignoring the growing regulations derived from European Union Law on tobacco and which must be reconciled with the regime of distribution of powers in force in our legal system.

With regard to nicotine-releasing devices and refill containers, the cross-border distance sale of these products is prohibited in the additional provision twelve, and their advertising, promotion, and sponsorship regime regulated in the additional provision thirteen is amended in order to adapt it to the limitations established in Directive 2014/40/EU of the European Parliament and of the European Council of April 3, 2014.

The regime of violations arising from non-compliance with the new limitations and prohibitions introduced in Law 28/2005, of December 26, 2005, and with the requirements established by regulation regarding the communication and registration demanded from manufacturers, importers and, if applicable, distributors of tobacco products, nicotine-releasing devices, refill packs and herbal smoking products, as well as regarding the manufacture, presentation, and marketing of these products, are amended.

Finally, in accordance with the provisions of Directive 2014/40/EU of the European Parliament and of the European Council of April 3, 2014, Law 13/1998 of May 4, 1998, on Tobacco Market Regulation and Taxation Regulations, is amended in order to prohibit cross-border distance sales of tobacco products to consumers.

As regards the legal instrument through which the limitations and prohibitions established in Directive 2014/40/EU of the European Parliament and of the European Council of April 3, 2014, which require their regulation by a legal norm with the formal status of law, are incorporated into our legal system, Article 86 of the Spanish Constitution establishes that, in case of extraordinary and urgent need, the Government may issue provisional legislative provisions that shall have the status of decree-laws. In the matter at hand, the enabling factors for the approval of the legislative amendment in question are not only the temporal element, made evident by the accumulated delay in the transposition of the aforementioned Directive, whose deadline expired on May 20, 2016, but also the causal element, given the opening of a proceeding for failure to transpose the Directive against the Kingdom of Spain initiated by the European Commission in September 2016, which could lead to the imminent imposition by the Court of Justice of the European Union of a lump sum or penalty payment for failure to communicate national transposition measures after the Kingdom of Spain failed to comply with the Commission's reasoned opinion. To these two factors must be added the material element, reflected in the imperative need to ensure at all times the highest possible level of protection of public health, which in this case requires consistent application throughout the European Union of the harmonizing measures for the regulation of tobacco products and nicotine-releasing devices and refill packs.

By virtue thereof, exercising the authorization granted in Article 86 of the Constitution, at the proposal of the Minister of Health, Social Services and Equality and after deliberation of the Council of Ministers at its meeting held on November 17, 2017,

I PROVIDE:

Sole Article. Amendment of Law 28/2005, of 26 December, on health measures against smoking and regulating the sale, supply, consumption, and advertising of tobacco products.

Law 28/2005, of December 26, 2005, on health measures against smoking and regulating the sale, supply, consumption, and advertising of tobacco products, is amended as follows:

Unofficial Translation

One. Paragraphs a) and f) are amended and new paragraphs g) to j) are added to section 1 of article 2, with the following wording:

«(a) Tobacco products: products that can be consumed and are made up, in whole or in part, of tobacco, whether genetically modified or not. »

«f) Nicotine delivery device: a product, or any of its components, including a cartridge, a reservoir, and the device without a cartridge or reservoir, that can be used for the consumption of nicotine-containing vapor through a mouthpiece. Devices capable of nicotine delivery may be disposable or refillable by means of a refill container and reservoir, or refillable with single-use cartridges. »

«g) Tobacco for oral use: all products intended for oral use, with the exception of products for inhalation or chewing, consisting totally or partially of tobacco in the form of powder, fine particles, or any combination of these forms, in particular those presented in dosage sachets or porous sachets.

h) Refill container: a receptacle of liquid containing nicotine, which can be used to refill a nicotine-releasing device.

i) marketing: making products, irrespective of their place of manufacture, available to consumers, whether or not the products are sold for payment, including by means of distance selling. In the case of cross-border distance sales, the product must be marketed in the Member State where the consumer is located.

j) Cross-border distance selling: distance selling to consumers when, at the time the product is ordered, the consumer is in a Member State other than the Member State or third country in which the retail establishment is established. A retail establishment shall be deemed to be established in a Member State:

1. In the case of a natural person, if his place of business is located in that Member State.

2. In other cases, if it has its registered office, central administration, or place of business, including a branch, agency, or any other kind of establishment, in that Member State. »

Two. A second paragraph is added to paragraph 4 of Article 3, with the following wording:

«The marketing of tobacco for oral use is also prohibited. »

Three. New paragraphs s) to x) are added to section 3 of article 19, with the following wording:

«s) The commercialization of tobacco for oral use.

t) Failure to comply with the regulatory requirements regarding the communication of information by manufacturers and importers of tobacco products, nicotine-releasing devices and refill packs, and herbal smoking products.

u) Failure to comply with regulatory requirements regarding the registration of manufacturers, importers, and distributors of nicotine-releasing devices and refill containers and herbal smoking products.

v) Failure by manufacturers and importers of herbal smoking products to comply with regulatory requirements regarding presentation and marketing.

w) Failure to comply with regulatory requirements regarding the manufacture, presentation, marketing, quality, and safety of tobacco products and nicotine-releasing devices and refill containers.

Unofficial Translation

x) Cross-border distance selling of nicotine-releasing devices and refill containers. »

Four. A second paragraph is added to Article 19, paragraph 4, with the following wording:

«Likewise, the advertising, promotion, and sponsorship of nicotine-releasing devices and refill containers that are not permitted shall constitute a very serious breach. »

Five. The additional provision four is amended to read as follows:

«Additional provision four. Special regime of the Autonomous Community of the Canary Islands.

The provisions of this law are understood without limiting the specificities of the Economic and Fiscal Regime of the Canary Islands with respect to the commercial freedom of tobacco products in establishments located in the Canary Islands, without this exception implying any limitation in the application of the other prescriptions contained in this law, in particular, the provisions of letters a), b), c), d), e) and f) of Article 5 and, in any case, those aimed at the protection of minors.

Notwithstanding the foregoing, it is the responsibility of the Autonomous Community of the Canary Islands, in accordance with its Statute of Autonomy, to adopt the measures that allow the economic development and the organization of the general economic activity in the tobacco sector, without prejudice to the provisions of the regulations of European Union Law that may be applicable and the competencies that correspond to the State.

The Autonomous Community of the Canary Islands shall maintain the powers of surveillance, control, and inspection of tobacco manufacturers and merchants in the islands. »

Six. A new paragraph five is added to the additional provision twelve, with the following wording:

«Five. The cross-border distance sale of nicotine-releasing devices and refill containers is prohibited. »

Seven. The additional provision thirteenth is amended to read as follows:

«Additional provision thirteen. *Limitations on advertising, promotion, and sponsorship of nicotine-releasing devices and refill containers.*

In relation to nicotine-releasing devices and refill containers, the following are prohibited:

- (a) commercial communications in information society services, in the press, and in other printed publications, which have the purpose or the direct or indirect effect of promoting them, with the exception of publications intended exclusively for professionals in the trade of those products and publications which are printed and published in third countries, insofar as such publications are not principally intended for the European Union market.
- (b) commercial communications which have as their aim or direct or indirect effect the promotion thereof on the radio.
- (c) Any form of public or private contribution to radio programs that has the aim or direct or indirect effect of promoting them.

Unofficial Translation

d) Any form of public or private contribution to any act, activity, or individual which has as its object or direct or indirect effect the promotion thereof and which involves various Member States, or takes place in various Member States, or otherwise has cross-border effects.

e) Audio-visual commercial communications, as defined in Article 2.24 of Law 7/2010, of March 31, 2010, General Law on Audio-visual Communication. »

Sole repealing provision. *Repeal of provisions.*

Any provisions of equal or lower rank that oppose, contradict, or are incompatible with the provisions of this Royal Decree-Law are hereby repealed.

Final provision one. *Amendment of Law 13/1998, of May 4, 1998, on Tobacco Market Regulation and Taxation Regulations.*

Section nine of Article 4 of Law 13/1998, of May 4, 1998, on Tobacco Market Regulation and Taxation Regulations, will read as follows:

Nine. The sale and supply of tobacco products by any means other than direct personal sale or through vending machines that meet the conditions stipulated in article 4 of Law 28/2005, of 26 December, on health measures against smoking and regulating the sale, supply, consumption, and advertising of tobacco products, shall be prohibited.

Final provision two. *Incorporation of European Union law.*

By means of this Royal Decree-Law, Directive 2014/40/EU of the European Parliament and of the European Council of 3 April 2014 on the harmonization of the laws, regulations, and administrative provisions of the Member States concerning the manufacture, presentation, and sale of tobacco and related products and which repeals Directive 2001/37/EC is partially transposed into Spanish law.

Final provision three. *Entry into force.*

This Royal Decree-Law shall enter into force on the day following its publication in the Official Gazette of the State.

Given in Madrid, on November 17, 2017.

FELIPE R.

The President of the Government,
MARIANO RAJOY BREY