

I. GENERAL PROVISIONS

HEAD OF STATE

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

The Spanish Constitution recognizes, on article 43, the right to health protection and entrusts public authorities to watch over public health and to adopt the necessary preventive measures.

Law 14/1986, of 25 April, on General Health, establishes that public Administrations will first and foremost guide their actions towards the promotion of health and the prevention of diseases, avoiding activities and products which, directly or indirectly, may have negative health consequences.

In accordance with both mandates, Law 28/2005, of 26 December, of health measures against tobacco addiction and regulating sales, supplies, consumption and advertising of tobacco products was approved.

Within the European Union, the approval of Directive 2014/40/EU of the European Parliament and of the Council, of 3 April 2014, on the approximation of 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, has aimed to ease the smooth functioning of the internal market of tobacco and related products, on the basis of a high level of protection of human health, as well as to comply with obligations assumed under the Framework Convention on Tobacco Control of the World Health Organization.

The abovementioned Directive 2014/40/EU of the European Parliament and of the Council, of 3 April 2014, has been largely incorporated into the Spanish legal order through Royal Decree 579/2017, of 9 June, regulating certain aspects related to the manufacturing, presentation and placing on the market of tobacco and related products. Nonetheless, this directive's full transposition requires amendments to Law 28/2005, of 26 December.

First of all, article 2 of Law 28/2005, of 26 December, integrates certain definitions established on Directive 2014/40/EU of the European Parliament and of the Council, of 3 April 2014, which were not included on this law, and others are amended to adjust them to the directive's terms.

With regards to the regulation of tobacco products, article 3 of Law 28/2005, of 26 December, expressly establishes the prohibition to placing tobacco for oral use on the market, which had already been contemplated on Royal Decree 579/2017, of 9 June. Furthermore, the fourth additional provision is amended to clarify the special regime of the Autonomous Community of the Canary Islands, which contents refer to the provisions of its Statute of Autonomy and to the State's exclusive jurisdictions, without overlooking the growing regulations derived from the European Union Law on tobacco, and which must be reconciled with the regime of division of competences in force in our legal system.

In relation to nicotine release devices and recharging packages, the twelfth additional provision prohibits these products' cross-border distance selling, and modifies their advertising, promotion and sponsorship system, regulated on the thirteenth additional provision, with the purpose of adapting it to limitations established on Directive 2014/40/EU of the European Parliament and of the Council, of 3 April 2014.

The system of infringements is amended, in relation to breaches derived from the lack of compliance with new limitations and prohibitions introduced on Law 28/2005, of 26 December, as well as with requirements established by regulations on communication and registration required from manufacturers, importers and, where applicable, distributors of tobacco products, nicotine release devices, recharging packages and herbal products for smoking, as well as in relation to the manufacturing, presentation and placing of these products on the market.

Lastly, in agreement with Directive 2014/40/EU of the European Parliament and of the Council, of 3 April 2014, Law 13/1998, of 4 May, regulating the tobacco market and tax legislation, is amended in order to prohibit cross-border distance sales of tobacco products to consumers.

With regards to the normative instrument that incorporates into our legal system the limitations and prohibitions established on Directive 2014/40/EU of the European Parliament and of the Council, of 3 April 2014, which require their regulation on a binding rule, article 86 of the Spanish Constitution establishes that, in case of extraordinary and urgent need, the Government shall enact tentative legislative provisions under the shape of decrees-laws. In the present case, among the factors that enable the approval of the legislative amendment at hand, there is not only a time element, evidenced by the accumulated delay in the transposition of the abovementioned directive, which deadline ended on May 20, 2016, but also a causal element, due to the opening of an infringement proceeding against the Kingdom of Spain, initiated by the European Commission on September 2016, and which could lead to the imminent imposition by the Court of Justice of the European Union of the payment of a lump sum or of a penalty for lack of communication of national transposition measures, since the Kingdom of Spain has not abided by the Commission's reasoned opinion. In addition to these two factors, there is also a material element, reflected in the imperative need to ensure the highest level possible of public health protection at all times, which in this case forces a coherent application throughout the European Union of harmonizing measures of the regulation of tobacco products and nicotine release devices and recharging packages.

By virtue of the above, in exercise of the authorization granted on article 86 of the Constitution, as proposed by the Ministry of Health, Social Services and Equality and prior deliberation by the Council of Ministers on meeting of November 17, 2017,

I STIPULATE:

Sole article. *Amendment of Law 28/2005, of 26 December, of health measures against tobacco addiction and regulating sales, supplies, consumption and advertising of tobacco products.*

Law 28/2005, of 26 December, of health measures against tobacco addiction and regulating sales, supplies, consumption and advertising of tobacco products, is amended on the following terms:

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

«a) Tobacco products: products that can be consumed and made up, fully or partially, of tobacco, genetically modified or not.»

«f) Nicotine release device: a product, or any of its components, including any component of that product, including a cartridge, a tank and the device without cartridge or tank, that can be used for consumption of nicotine-containing vapour via a mouth piece. Nicotine release devices can be disposable or refillable by means of a recharging package and a tank, or rechargeable with single-use cartridges.»

«g) Tobacco for oral use: all tobacco products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco in powder, in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets.

h) Recharging package: a receptacle that contains a nicotine-containing liquid, which can be used to refill a nicotine release device.

i) Placing on the market: making products, irrespective of their place of manufacture, available to consumers, 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.

j) Cross-border distance sales: distance sales to consumers where, at the time when the product is ordered, 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:

1. In the case of a natural person, if he or she has his or her place of business in that Member State.

2. 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, on that Member State.»

Two. A second paragraph is added on section 4 of article 3, with the following wording:

«Placing on the market tobacco for oral use is additionally prohibited.»

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

«s) Placing on the market tobacco for oral use.

t) Not complying with regulatory requirements related to the reporting of information by manufacturers and importers of tobacco products, nicotine release devices and recharging packages, and of herbal products for smoking.

u) Not complying with regulatory requirements related to the registration by manufacturers, importers and distributors of nicotine release devices and recharging packages, and of herbal products for smoking.

v) Not complying with regulatory requirements related to the presentation and placing on the market by manufacturers and importers of herbal products for smoking.

w) The lack of compliance with regulatory requirements related to the manufacturing, presentation, placing on the market, quality and security of tobacco products, and nicotine release devices and recharging packages.

x) The cross-border distance selling of nicotine release devices and recharging packages.»

Four. A second paragraph is added on section 4 of article 19, with the following wording:

«Furthermore, the advertising, promotion and sponsorship of nicotine release devices and recharging packages that are not allowed constitute a very serious infringement.»

Five. The fourth additional provision is amended, with the following wording:

«Fourth additional provision. *Special regime of the Autonomous Community of the Canary Islands.*

This Law is without prejudice of the peculiarities of the Economic and Fiscal Regime of the Canary Islands in relation to the free trade of tobacco products on establishments located in the Canary Islands, where this exception does not imply any limitation to the application of other requirements contained on this law, particularly in relation to letters a), b), c), d), e) and f) of article 5 and, in any case, those aimed to the protection of minors.

Nonetheless, the Autonomous Community of the Canary Islands, in agreement with its Statute of Autonomy, shall adopt measures to allow the economic development and arrangement of the general economic activity in the tobacco sector, regardless of the applicable regulation of the European Union Law and of competences corresponding to the State.

The Autonomous Community of the Canary Islands will maintain surveillance, control and inspection competences on tobacco manufacturers and dealers in the Islands.»

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

«Five. The cross-border distance selling of nicotine release devices and recharging packages is prohibited.»

Seven. The thirteenth additional provision is amended, which wording is the following:

«Thirteenth additional provision. *Limitations to advertising, promotion and sponsorship of nicotine release devices and recharging packages.*

In relation to nicotine release devices and recharging packages, the following is prohibited:

a) Commercial communications in Information Society services, in the press and other printed publications, which aim or direct or indirect effect was to promote them, except for publications that are intended exclusively for professionals in the trade of products and for publications which are printed and published on third countries, where those publications are not principally intended for the Union's market.

b) Commercial communications, which aim or direct or indirect effect was their promotion on the radio.

c) Any form of public or private contribution to radio programmes which aim or direct or indirect effect was their promotion.

d) Any form of public or private contribution to any event, activity or individual person which aim or direct or indirect effect was their promotion, and involved or took place in several Member States or otherwise having cross-border effects.

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

Sole repealing provision. *Repeal of regulations.*

All regulations of equal or lower rank, insofar as they oppose to, contradict or result incompatible with this Royal Decree-Law, are hereby repealed.

First final provision. *Amendment of Law 13/1998, of 4 May, regulating the tobacco market and tax legislation.*

Section nine of article 4 of Law 13/1998, of 4 May, regulating the tobacco market and tax legislation, will be worded as follows:

«Nine. The sale and supply of tobacco products by means other than direct personal sale or vending machines that meet conditions indicated on article 4 of Law 28/2005, of 26 December, of health measures against tobacco addiction and regulating sales, supplies, consumption and advertising of tobacco products, is prohibited.»

Second final provision. *Incorporation of the European Union Law.*

Through this Royal Decree-Law, Directive 2014/40/EU of the European Parliament and of the Council, of 3 April 2014, on the approximation of 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, is partially incorporated to the Spanish Law.

Third final provision. *Entry into force.*

This Royal Decree shall go into effect on the day following its publication in the «Official State Bulletin».

In Madrid, on 17 November 2017.

FELIPE R.

The President of Government,
MARIANO RAJOY BREY