



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Single Market Enforcement
Notification of Regulatory Barriers

Message 201

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Notification: 2025/0602/ES

Forwarding of the response of the Member State notifying a draft (Spain) to of Greece.

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2. Spain

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4. 2025/0602/ES - X00M - GOODS AND MISCELLANEOUS PRODUCTS

5.

6. Bilateral Response (BR) to the Detailed Opinion of Greece

Spain thanks the Greek authorities for the submission of their comments on the notified preliminary draft law. In the interest of greater coordination of tobacco control policies within the European Union, and as part of the joint work in the fight against this epidemic, together with the other Member States, the Kingdom of Spain proceeds to provide more information regarding the origin, motivation and scope of the content of the measures proposed at national level.

The current factual situation in Spain.

Currently, the market for tobacco and related products in Spain is expanding rapidly, with a constant evolution of the existing supply and significant access to all types of consumers through aggressive communication and marketing campaigns carried out by the manufacturing companies. Thus, the penetration of these products has been observed in a wide range of businesses, with no connection to the traditional tobacco sector, that make up the market at regional and local level within the sales and services sector to the final consumer. This extensive market penetration leads to widespread accessibility of these products among the population. Thus, according to the data provided by the National Institute of Statistics (INE) Spain has a total of 514,441[1] placing the country at the forefront in terms of available supply within the European Union.

On the other hand, the legislation currently in force in Spain has significant shortcomings, as there has been no comprehensive update adapted to the national situation for more than 15 years, since the adoption of Law 42/2010, of 30 December 2010 and Royal Decree 639/2010, of 14 May 2010. Thus, it should be emphasised that the changes introduced in 2017 through the preliminary draft law currently in the process of being updated were limited to the literal and



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exclusive transposition of European regulations. The same pattern—carrying out a minimal review of the regulations without considering content adapted to the national context—was repeated recently, in 2024, through the transposition of Commission Delegated Directive (EU) 2022/2100 of 29 June 2022.

As can be seen, the considerable time that has elapsed—more than a decade—combined with the current dynamic nature of the market for tobacco and related products, means that national legislation is now significantly out of date and fails to reflect the current situation of the tobacco and related products market in Spain.

During this period, the Department of Health has faced a number of challenges arising from the emergence of new products, which it has sought to address through ineffective regulatory measures.

For example, in the case of heated tobacco, there has been a proliferation of marketing campaigns to promote tobacco consumption, both in the media and on social media, as well as in various hospitality venues and at public events. Due to the inadequate regulation of such products, there has been a conflict in legal interpretations in Spain, as commercial court rulings take a different position from those of the administrative courts, thereby permitting, in most cases, the running of campaigns to promote consumption that reach the general public through various channels.

This situation of lack of adaptation of national regulations has also been observed with regard to the regulation of electronic cigarettes. Consequently, the current regulations are limited to the provisions set out in the 2014 European Directive, which means that communication and marketing campaigns can be carried out in various public spaces.

On the other hand, with regard to products with mixed characteristics, with or without the presence of tobacco or nicotine, the lack of adapted regulation has led to their being placed on the market without evaluation by the health authorities or the appropriate health safeguards, thereby putting the health of the consumer at risk, as well as their information and perception in this regard. This would be the case for nicotine-free electronic cigarettes, nicotine pouches and heated herbal products. The notified draft aims to resolve the problems arising from this situation by establishing a series of health-related requirements and obligations that are necessary for their proper control and oversight.

This situation of widespread access, lack of effective regulation, or in some cases, deregulation, has led to increased consumption and therefore serious harm to public health, requiring urgent action at the national level, especially in the absence of an updated framework at the European level.

The prevalence data on the consumption of tobacco and related products in Spain, available through official health surveys [2,3], are available below.

Among school-age children aged 14 to 18, the age of initiation of consumption, as well as the onset of daily use, has remained stable over the last 30 years, staying between 13–14 and 14.5–15 respectively. The latest figures show that the average age of initiation of daily consumption is 14.7 years. A trend towards a gradual decrease in prevalence over time can be observed. This decline is more pronounced among men than among women, but the prevalence remains higher among men.

As for electronic cigarettes, we see that in recent years the consumption of these products among younger people has increased. The ESTUDES 2025 survey found that 49.5% of secondary school students have tried electronic cigarettes. Of these, most said they had used them with nicotine-free cartridges (60.7%), 14.9% had used them with nicotine, and the remaining 24.4% had used cartridges or liquids of both types. In contrast, in the general population, the Spanish Health Survey indicates that only 1.6% of the population uses e-cigarettes, while 3.36% have used them in the past. It is therefore observed that these novel products have the most significant impact on the younger population, making it necessary to take measures specifically designed to protect this age group.

In response to these alarming figures, particularly amongst children and young people, this Department has taken the initiative and therefore proposed the development of the Comprehensive Plan for the Prevention and Control of Smoking 2024–2027 [4], which was recently approved. The notified draft constitutes the implementation of one of its main measures. It should be noted that the Plan has been agreed upon by different social, governmental, and scientific sectors and, in line with this response, identifies the need to introduce various improvements not yet contemplated in the harmonised regulation of the Union, as a result of significant changes experienced both at epidemiological level and in consumption patterns, as well as in the current configuration of the market for tobacco products and related products in our country.

Justification for the need to update the regulation

The justification for the need to update Law 28/2005, in the context of the fight against tobacco use, is based on the evolution of tobacco products and related products and the need to strengthen measures for the protection of public health, especially among young people.



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The measures introduced in the update to the Spanish regulation comply with the justification criteria laid down by EU legislation, which focus primarily on legality, necessity and proportionality.

The national legislation is aligned with the European directives and does not contradict them; it complements them and in some cases is more restrictive, an issue that is admitted. Its primary objective is the protection of public health and the measures are considered proportionate to the aim pursued, since they seek to restrict the consumption of tobacco and related products, prevent their initiation, especially among young people, and improve information for consumers, particularly regarding novel products without harmonised legislation.

1. Regarding exceeding the harmonized European framework, the imposition of restrictions on the free movement of goods within the single market, and the adoption of less stringent measures than the disproportionate ban on disposable electronic cigarettes

The draft bill includes product categories that are not currently covered by harmonised European Union legislation and therefore does not conflict with Directive 2014/40/EU nor any other EU legislation, as these products are not currently regulated at EU level.

Consequently, Member States have a degree of regulatory discretion to regulate this type of product, which has been exercised in a manner consistent with and comparable to the existing regulatory framework for other related products. In this regard, the inclusion of the new definitions set out in paragraph 2 of the draft—concerning what is considered a related product or nicotine pouches (both of which are absent from Directive 2014/40/EU) as well as heated herbal products, or the definition of a device for the consumption of tobacco or related products—is necessary and draws on criteria already applied to similar products, such as electronic cigarettes, thereby respecting the principle of regulatory consistency.

In any case, the new regulation on the advertising, sale, supply and consumption of tobacco and related products is limited to what is strictly necessary to ensure the protection of public health and is aligned with the requirements already established for products currently harmonised by the European Union.

The proposed regulatory framework is based on the need to ensure a high level of protection of public health, as provided for in Article 168 of the Treaty on the Functioning of the European Union (TFEU). In the absence of European-level harmonisation for this product category, it is up to Member States to adopt appropriate measures in this area, in line with the jurisprudence of the Court of Justice of the European Union.

The provisions established, including requirements on advertising, promotion, sale, and consumption, are based on the precautionary principle and seek to provide consumers with clear, truthful, and consistent information about products that may have health implications, especially among young people and non-smokers. This issue is all the more significant given that industry-led communication campaigns have been observed in Spain that present a biased or misleading view of emerging and related products and their actual implications for health.

The regulations have been designed in a proportionate manner, following a regulatory impact analysis and under consideration of less restrictive alternative measures. The ban on the sale of disposable electronic cigarettes has been introduced to ensure the proper protection of children and young people, who are the primary target audience for these products.

According to the available data [3], among the school population aged 14 to 18, the prevalence of electronic cigarette use increases with age, although there is a slight decline in use among 18-year-olds. The highest proportion was found among 17-year-olds (57.2%). Therefore, we see that in recent years the consumption of these products among younger people has increased. The ESTUDES 2025 survey found that 49.5% of secondary school students have tried electronic cigarettes. Of these, most said they had used them with nicotine-free cartridges (60.7%), 14.9% had used them with nicotine, and the remaining 24.4% had used cartridges or liquids of both types. The prevalence of this substance among girls remains slightly higher than among boys (50.5% and 48.5% respectively). In contrast, in the general population, the Spanish Health Survey indicates that only 1.6% of the population uses e-cigarettes, while 3.36% have used them in the past. It is therefore observed that these novel products have the most significant impact on the younger population, making it necessary to take measures specifically designed to protect this age group.

Similarly, the Health Behaviour in School-aged Children (HBSC) study of 2022 [5] found that 12.1% of adolescents aged 11 to 18 had used electronic cigarettes at least once, with usage increasing with age and reaching 18.8% among those aged 17 to 18 (20.6% among girls and 18.9% among boys).

Tobacco-related products such as cigarettes or have been found to be a gateway to the consumption of other tobacco products. As scientific evidence has shown on numerous occasions, this implies a serious public health problem that



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requires special attention when improving the current regulation of these devices which, camouflaged to appear harmless with attractive colours and shapes, contribute to the normalisation and the initiation of nicotine use among young people, increasing the risk of long-term addiction [6,7].

In addition, electronic cigarettes may contain chemical substances that are hazardous to health, as well as heavy metals from heating elements and batteries. A disease associated with the use of electronic cigarettes, EVALI (E-cigarette or Vaping product use Associated Lung Injury), has also been described, which causes acute lung damage and may be related to multiple causes. All of this supports the fact that regulating tobacco-related products facilitates the monitoring of associated risks.

Specifically with regard to single-use cigarettes, in ACS Central Science [8], a group of researchers reported that, after a few hundred puffs, some disposable vaping devices release higher levels of metals and metalloids than older refillable electronic cigarettes and traditional cigarettes, thereby increasing the risk of health problems for users.

Disposable electronic cigarettes, designed to be used once and then thrown away, contain a mixture of nicotine, flavourings and chemical additives which, when heated, produce potentially harmful compounds. Some studies highlight the presence of heavy metals, formaldehyde and other carcinogenic substances in concentrations higher than those found in refillable electronic cigarettes. This is partly due to the lower manufacturing quality of disposable models and the fact that they are not designed to withstand prolonged use.

It has also been found that users of disposable electronic cigarettes tend to consume more nicotine in a shorter period of time, which increases the risk of addiction and of cardiovascular and respiratory damage. Ease of purchase, low price and lack of information about their risks contribute to their popularity, especially among adolescents.

For its part, the evidence of this increase is based, among other factors, on studies such as those conducted in the United States [9,10], which reveal alarming data on the dual use of tobacco and other products, as well as other national and international studies showing an increase in problems arising from the dual use of tobacco and electronic cigarettes [11,12,13]. Likewise, there has been a considerable increase in the points of sale where these products are marketed, as well as in the promotion and advertising of these products across all possible platforms, such as social media and public events. It is further evidenced by observed consumption patterns, with these products now being consumed in smoke-free places where tobacco-use had previously ceased. These new alternatives circumvent regulations in areas where smoking is prohibited and create a copycat effect that undermines compliance with current regulations.

In response to this negative situation, particularly amongst children and young people, efforts are being made in Spain to control and prevent the use not only of tobacco products, but also – and with a particular focus on this specific demographic – of new products.

Therefore, in April 2024, the Comprehensive Plan for the Prevention and Control of Tobacco 2024-2027 [4] was approved, establishing the strategic lines, objectives and goals to be carried out during the coming years.

Specifically, the notified draft forms part of the implementation of two of its five objectives, namely “Objective 1. Prevent the onset of tobacco and related product use”. Thus, within that objective, the Plan specifically provides for the following:

- Regulate the sale and consumption of tobacco-related products.
- Ban additives imparting aromas in tobacco and related products.

More specifically with regard to the obvious environmental problem posed by single-use electronic cigarettes, the notified draft involves the development of its “Objective 3. Reduce environmental exposure to emissions of tobacco and related products in public and private spaces and reducing the ecological footprint”. Thus, within that objective, the Plan specifically provides for the following:

- Promote measures to reduce the environmental impact of tobacco and related products, in coordination with MITERD.

Member States wishing to analyse and further study the content of the approved Comprehensive Plan can do so through the link published in the corresponding section of the website of the Spanish Ministry of Health [4].

It should be noted that the Plan has been agreed upon by different social, governmental, and scientific sectors and, in line with this response, identifies the need to introduce various improvements not yet contemplated in the harmonised regulation of the Union, as a result of significant changes experienced both at epidemiological level and in consumption patterns, as well as in the current configuration of the market for tobacco products and related products in our country.

As regards the possibility of adopting less restrictive measures, it should be noted that the proposal put forward by Greece – a ban on the sale of disposable electronic cigarettes to minors – is a measure that has already been in place in Spain for years and is now outdated. Spain has thus been implementing measures to protect children and young people for over 20 years, since 2005, having recognised not only the ban on the sale of tobacco products to minors, but also a broad prohibition on any product that imitates or encourages the act of smoking, extending the restriction to sweets,



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such as classic chocolate cigarettes, or any other objects shaped like tobacco products that may be attractive to minors. Thus, through the approval of Law 28/2005 of 26 December 2005 on health measures against smoking and regulating the sale, supply, consumption and advertising of tobacco products [14] and in accordance with Article 3.2, the following was established:

2. It is forbidden to sell or deliver tobacco products or any other product that imitates and encourages smoking to persons under the age of 18. In particular, the sale of sweets, snacks, toys or other objects in the form of tobacco products and that could be attractive to minors is prohibited. The sale of tobacco by individuals under 18 years of age is also prohibited.

The labelling of tobacco products must include an express reference to the ban on their sale to persons under 18 years of age.

This measure was further extended in 2014 by Law 3/2014 of 27 March, amending the consolidated text of the General Law on the Protection of Consumers and Users and other supplementary laws, approved by Royal Legislative Decree 1/2007 of 16 November [15]. This regulation introduced a Twelfth Additional Provision to the regime previously limited to tobacco products, in order to adapt it to developments in the market resulting from the emergence of novel products such as electronic cigarettes and any similar or related products. The text of the Additional Twelfth Provision is as follows: 'Twelfth additional provision. Consumption and sale to minors of nicotine-delivery devices and similar products.

One. The consumption of nicotine-delivery devices and similar products shall be subject to the same provisions laid down for tobacco consumption as set out in Article 6 and those referred to in Article 3(2) and Article 3(3).

Following the adoption of these restrictive measures, and based on the epidemiological data outlined above, the existing shortcomings in Spain are evident, forcing us to adopt more far-reaching and robust measures that go beyond those already implemented, which have proven to be of limited effectiveness or ill-suited to the current market context in Spain, given the proliferation of this product category – disposable electronic cigarettes – which are becoming increasingly popular and accessible among young people due to their low price.

It is also worth noting the prevalence of sweet flavours and aromas in this type of product, a matter of great importance given that, as the World Health Organisation (WHO) points out, “flavours are one of the main reasons that encourage young people to try tobacco and nicotine products”, and these serve to “enhance the appeal of nicotine pouches, heated tobacco products and disposable electronic cigarettes—addictive and harmful products that are thus very actively targeted at young people”. The WHO therefore urges States to follow the example of other countries as part of a public health strategy aimed at curbing the increase in consumption among young people [16].

Several scientific studies, as well as WHO [17], have warned that fruity, sweet or menthol flavours reduce the perception of risk and significantly increase the probability of experimental and habitual consumption among adolescents and young people. Scientific evidence shows that the availability of flavours is one of the most decisive factors in the adoption of these products by new users. Furthermore, an analysis of the data for Spain from the EU-CEG European Portal shows that any discussion of disposable electronic cigarettes is inevitably linked to aromas and flavours, as the available data indicates that 99.5% of those on the Spanish market contain them, with only a negligible proportion featuring tobacco-like flavours.

In this context, the national intervention through this notified preliminary draft law, as well as the ban on flavours introduced by the draft Royal Decree—both measures included in the Comprehensive Plan—are consistent with one another, with the objectives of the Directive, and with the scope for action granted to Member States to protect public health.

In addition, although Article 34 prohibits restrictions on intra-Community trade, Article 36 provides for derogations on grounds of public health. In this case, the proposed measures are justified on the grounds of general interest (health protection), are appropriate and necessary for limiting the risk of nicotine initiation and dependence among vulnerable groups and do not constitute covert discrimination or an arbitrary restriction on trade. They are therefore covered by the EU legal framework.

Therefore, the prohibition of single-use electronic cigarettes is a health measure that has been adopted in light of the potential toxic and addictive effects this substance has on people, with ample scientific evidence to support this [18].

This toxic and addictive potential justifies the adoption of the prohibition for the proper protection of public health, supported by the application of Article 36 TFEU “The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or transit justified on grounds of public policy, public morality and public security, the protection of health and life of humans and animals, the preservation of plants, the protection of national artistic, historical or archaeological heritage or the protection of industrial and commercial property.”



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Finally, and in line with the proper preservation of the environment set out in the aforementioned article of the TFEU, it should be noted that the issue is not limited to human health. Disposable electronic cigarettes generate plastic waste, lithium batteries and electronic components that are not usually recycled properly, increasing environmental pollution. Thus, all electronic cigarettes generate waste through their components (they belong to the category of Waste Electrical and Electronic Equipment (WEEE)), with an even greater impact in the case of single-use electronic cigarettes. The ban on their sale has been introduced with a view to enhancing environmental protection, in line with the existing waste reduction strategy set out in European and national legislation. Thus, in Spain, “Law 7/2022 of 8 April 2022 on waste and contaminated soils for a circular economy” [19] establishes among its objectives the minimisation of the negative effects of waste generation and management on human health and the environment. Likewise, and in line with the principles governing the circular economy, the aim should also be to make efficient use of resources, with a determined strategic commitment from all public administrations, as well as the involvement and commitment of all economic and social stakeholders.

The aforementioned law, as well as this preliminary draft law, are consistent with the objective of transforming the European Union into a “recycling society” and contributing to the fight against climate change, following the adoption in 2008 of Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, and repealing certain Directives. This new directive established the waste hierarchy principle as a key instrument for decoupling the relationship between economic growth and waste production. This principle sets out the order of priority for waste management actions: waste prevention, preparation for reuse, recycling, other forms of recovery (including energy recovery) and, finally, waste disposal.

It is clear that the marketing of single-use electronic cigarettes is incompatible with the principle of the waste hierarchy recognised in European legislation, since it fails to comply with its first two principles, namely the prevention of waste generation and the promotion of reuse.

Finally, it is worth noting the growing awareness of this emerging environmental problem in Spain across various sectors; for instance, in the healthcare sector, the Spanish Society of Family and Community Medicine (semFYC) launched communication campaigns on the issue following the publication of its special report on the matter [20]. Meanwhile, in the hospitality sector, and specifically within the beach bar sub-sector, we have observed the impact of this through complaints from staff regarding litter left behind by customers in a natural environment, with a particular impact on the surroundings [21]. This trend in our country is consistent with that already observed in other countries, such as Australia [22]. Thus, it should be emphasized that Spain, as a leading tourist destination with many kilometres of accessible beaches, has a high level of awareness in this regard; public authorities must therefore pay particular attention to this matter to ensure that these beaches are properly protected and used responsibly. It is worth noting, based on data from Nofumadores.org, that the number of beaches with policies to raise awareness of this issue has grown exponentially in recent years, increasing from a total of 15 beaches in 2014 to 897 in 2025 [23].

2. On the extension of the ban on smoking in public spaces and the scope of the ban to a distance of 15 meters.

Since 2010, following the adoption of the latest comprehensive amendment to the Law that is the subject of this notification, Spain has been a pioneer in protecting citizens’ right to health in public spaces, both indoors and outdoors. A prime example of this is the ban on smoking in playgrounds and children’s play areas, a measure that was subsequently adopted in other countries. Despite initial opposition, the legislation was also positive in that it included a ban on smoking in the hospitality and leisure establishments mentioned by the Greek authorities.

Despite the initial forecasts of job losses and economic downturns made by the hospitality industry’s employers’ association, subsequent experience has shown that such fears were unfounded. Accordingly, the reports on the public health impact assessment of Law 42/2010 following the implementation of the legislation are now available on the Ministry of Health’s website. These reports highlight the significant reduction in exposure to second-hand tobacco smoke (SHTS), which has been particularly marked in hospitality venues (where concentrations of nicotine and PM2.5 fell by more than 90%), as well as the substantial declines in the prevalence of tobacco use. Thus, in 2014, an overall reduction in the prevalence of current smokers (daily and occasional) of two percentage points was observed among the population aged 15 and over (25.4% in 2014 compared to 27% in 2011). Furthermore, the public gave their support; the 2012 Health Barometer already reflected the law’s widespread acceptance. In response to rating their “level of agreement that the Law has been an appropriate measure”, the average was 7.62 (on a scale from 1 “strongly disagree” to 10 “strongly agree”) [24,25].

Furthermore, in this regard, our country has had positive experience of implementing smoke-free outdoor seating areas,



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adopted by several autonomous communities during the COVID-19 pandemic.

With the 2010 amendment, Spain abandoned the previous system – known as the “Spanish model” – which allowed smokers and non-smokers to coexist in public or shared spaces. This model had been promoted, both in Europe and Latin America, by the hospitality and leisure sectors in close collaboration with the tobacco industry. Thus, the Spanish Hospitality Business Confederation has been receiving funding from one of the world’s leading tobacco companies for decades, as can be seen from a consultation of its official website [26,27].

This model, which imposes partial consumption bans and is based on the “accommodation schemes” and “courtesy of choice” or “social acceptability” initiatives promoted by the industry in the late 1990s, has been shown to be ineffective according to the available scientific evidence [28,29,30].

One of the reasons for the ineffectiveness of this model of “coexistence” between smokers and non-smokers lies precisely in the layout of outdoor seating areas in Spain’s hospitality sector, a sector of great importance that is frequently used by the public. Current regulations prohibit smoking in spaces with more than two walls and a roof. The wide variety of terrace types, materials and structural heights in Spain creates a significant problem regarding regulatory compliance, as there is uncertainty—both among the authorities responsible for enforcement and among the public—regarding whether the right to health is protected in the specific space they are using. To address this current issue in our country, the preliminary draft law removes the requirements relating to the presence or absence of partitions and their number, thereby making it easier to comply with the regulations and providing the public with greater clarity regarding the rights they are entitled to when visiting hospitality and catering spaces.

With regard to the ban on smoking within a 15-metre radius, it should be noted that this applies only to certain outdoor spaces that require enhanced protection due to their specific characteristics. Thanks to this new amendment, set out in the Comprehensive Plan mentioned above, Spain is once again leading the way, as it did with the 2010 amendment, by offering special protection for certain locations and their surrounding spaces, such as access points to public administration buildings, healthcare facilities, educational establishments, social centres and playgrounds, amongst others. Once again, the essential aim of protecting children and young people is evident in the rationale the draft bill, as is also the case with the measure prohibiting single-use electronic cigarettes.

It should be noted that this measure, adopted in accordance with our strictly national powers, has been widely called for by members of the public and by relevant associations and organisations during the consultation, public hearing and public information process [31,32].

3. Regarding the introduction of measures prohibiting advertising, promotion and sponsorship for certain products.

It should be made clear to the Greek authorities that this draft aims to provide greater clarity and legal certainty regarding the rules on advertising, promotion and sponsorship for new and emerging products. Thus, with regard to heated tobacco, the situation in Spain is different from that in Greece or in other countries of the European Union, since there are significant legal discrepancies concerning the scope of the legislation currently in force. In this respect, there are two judicial rulings that set out conflicting views on how the devices intended for consumption mentioned by Greece in its opinion should be treated, arguing for their distinct nature. Firstly, there is a ruling from the commercial courts which holds that advertising the electronic device amounts to the promotion of a tobacco product and therefore constitutes an act of unfair competition. Conversely, there is another ruling from the administrative courts which considers that the device is not a tobacco product and is therefore not subject to the bans on advertising, promotion and sponsorship. Please find attached the operative part of the two rulings and their references:

Commercial Court No. 3 of Madrid [33].

RULING

Having upheld the claim brought by ALTADIS, S.A. against the defendant PHILIP MORRIS SPAIN, S.L., I hereby issue the following rulings:

1. I declare that the defendant has committed acts of unfair competition consisting of unlawful advertising of the IQOS device and HEETS tobacco.
2. I order the defendant to cease such acts, specifically the communications campaign relating to those products as it has been conducted to date, and to refrain from repeating them in the future.
3. I order the defendant to publish the operative part of this ruling, at its own expense, in the newspaper ‘Expansión’.
4. The defendant is ordered to pay the costs of the proceedings.



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National High Court. Administrative Chamber [34]

WE HEREBY RULE

That we must UPHOLD, and hereby UPHOLD, the administrative appeal lodged by the legal representatives of PHILIPS MORRIS SPAIN S.L. against the decision issued by the Ministry of Economy and Business on 13 August 2018, as described in the first legal ground of this ruling, which we annul on the grounds that it is contrary to law. The defendant is ordered to pay the costs.

As can be seen, this adverse situation calls for an urgent solution, which this draft law aims to provide, thereby ensuring greater legal certainty and, contrary to Greece's assertions, avoiding any breach of the principle of equal treatment between undertakings subject to the same legal framework, as well as preventing any restrictions on trade resulting from the distortion of free competition arising from the possible commission of acts of unfair competition. It should be borne in mind that a clear, unambiguous and stable regulatory framework is what enables different economic operators to compete with one another in a fair and balanced manner, with the same rules applying to all and without the risk of legal uncertainty as to how national courts or the public administration might interpret the law in one way or another, thereby precluding any possibility of arbitrariness. The adoption of a new regulatory framework, adapted to the current realities of the tobacco products market, through the adoption of this draft bill, is the only way to address the adverse effects on free competition that currently exist.

As for e-cigarettes, this preliminary draft law also aims to address the shortcomings identified since the previous amendment, which was introduced to transpose the European Directive. Consequently, matters such as the advertising, promotion and sponsorship of this category of products in areas such as outdoor advertising, information society services, or events and shows—issues of national scope—are not regulated and therefore require an update of the current legislation. Furthermore, in line with the commitment to the protection of children and young people that runs throughout the notified preliminary draft law, this measure aims to prevent so-called “digital smoke” and address the alarming statistics surrounding it. In this regard, the Spanish Association Against Cancer (AECC) published a study showing that nine out of ten young people have been exposed to the smoke seen on screens, doubling their chances of becoming consumers of tobacco and new forms of nicotine consumption such as electronic cigarettes, hookahs or smokeless heated tobacco products [35]. Thus, as the study indicates, the predisposition to the consumption of electronic cigarettes is double that of tobacco among non-users (rising from 3.2% to 6.3%), and is almost four times higher (11.8%) when we look specifically at the desired use of hookahs among young people who do not currently use them. On the other hand, the study indicates that 82.5% of young people have been exposed in at least one way to “digital tobacco smoke” on platforms or in the media, and 83% have been exposed in at least one way to vaping or hookahs. This means that 91.3% of all young people have been exposed to some form of smoke inhalation via social media or other digital platforms.

The report concludes, in line with the classification of products adopted by the notified draft, that “these findings call for urgent action to expand existing legislation so that it can regulate and protect young people in these spaces where it is not currently effective enough, as well as to treat new forms of smoke and aerosol inhalation in the same way as traditional tobacco, as we are talking about a consumption habit that poses serious risks to public health, and whose promotion, as we have seen, is widespread across digital environments”.

Finally, with regard to the argument concerning the “different objective characteristics” of heated tobacco products recognised in Directive 2014/40/EU, it should be noted that the preliminary draft is consistent with the steps taken under EU legislation. Thus, through the approval of the Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products. This amendment is based on the Commission's report of 15 June 2022 on the establishment of a substantial change in circumstances regarding heated tobacco products, in accordance with Directive 2014/40/EU. That report provided information and statistics on market developments showing that there had been an increase in the sales volume of heated tobacco products of at least 10% in at least five Member States and that the retail sales volume of heated tobacco products exceeded 2.5% of total tobacco product sales at European Union level, thereby demonstrating that a substantial change of circumstances had occurred in relation to heated tobacco products. Thus, both European and national legislation must adapt to developments in the tobacco and related products market, without becoming a rigid and inflexible framework that prevents health authorities from taking action in response



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