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Pharmaceutical Advertising 2023

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SPAIN

Law and Practice

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1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

Advertising of medicinal products in Spain is regulated by a combination of laws, guidelines of the regulatory authorities, and codes of conduct adopted on a voluntary basis by the pharmaceutical industry.

General Rules

General rules on advertising are comprised in General Law 34/1988 on Advertising and Law 3/1991 on Unfair Competition. The provisions related to the advertising of medicinal products contained in EU Directives have been implemented in Spain through Royal Decree 1416/1994. The Ministry of Health issued an Instruction in 1995 (Circular 6/1995, amended by Circular 7/99) regarding the interpretation of such Royal Decree.

In addition, Spanish autonomous regions (Spain is divided into 17 autonomous regions) are competent for the implementation of rules on advertising of medicinal products; in this regard, some autonomous regions have adopted guidelines reflecting the position of the regional authorities on the advertising of medicinal products (the most remarkable guidelines are those issued in the regions of Madrid and Catalunya). Furthermore, the Ministry of Health has issued a guide on the advertising of over-the-counter medicinal products (last updated version published in 2019). Royal Legislative Decree 1/2015, approving the consolidated text of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices, is also noteworthy as it sets forth the sanctions for breach of the rules on advertising of medicinal products.

Codes of Conduct

Spanish trade associations of different sectors of the pharmaceutical industry have adopted codes of conduct regulating interactions with healthcare professionals (HCPs), healthcare organisations (HCOs) and patient organisations (POs). Farmaindustria, the Spanish innovative medicinal products industry association, has issued a code of practice for the pharmaceutical industry (the "Code of Farmaindustria") regulating the advertising of prescription-only medicinal products as well as interactions between pharmaceutical companies and HCPs, HCOs and POs.

The Code of Farmaindustria was updated by a 2021 version, introducing some new aspects regarding areas such as social media and the digital environment, relationships between companies and HCPs, POs and the media. Conversely, AESEG, the Spanish generic medicinal products industry association, and ANEFP, the Spanish over-the-counter medicinal products industry association, among others, have also published their own codes of conduct on the promotion of medicinal products.

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

Self-regulatory codes of conduct apply and have binding effects on companies that are members of the trade association that issued them and on companies that have voluntarily adhered to a code. Companies subject to a self-regulatory code are also responsible for their affiliates and third parties acting on their behalf complying with the code when they perform promotional activities in Spain and/or they interact in any way with HCPs, HCOs and/or POs in Spain.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

According to Royal Decree 1416/1994, advertising of medicinal products includes any form of informative offer, commercial research or inducement designed to promote the prescription, dispensation, sale or consumption of medicinal products.

In particular, advertising of medicinal products includes:

- advertising directed to the general public;
- advertising directed to persons qualified to prescribe or dispense medicinal products;
- visits by medical sales representatives or informative agents of the companies to persons qualified to prescribe or dispense medicinal products;
- supply of samples of medicinal products;
- sponsorship of promotional meetings where persons qualified to prescribe or dispense medicinal products attend;
- sponsorship of scientific meetings attended by persons qualified to prescribe or dispense medicinal products, and, in particular, payment of their travel and accommodation expenses in connection therewith; and
- any inducement to prescribe or dispense medicinal products by granting, offering or promising any benefit, in money or in kind, except when its actual value is minimal.

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

Royal Decree 1416/1994 states that the following informative activities will not be considered as advertising of medicinal products and, therefore, are not subject to the rules that apply to such advertising:

- the labelling and the leaflet of the medicinal product;
- correspondence, together with any document of a non-promotional nature (for example, scientific articles) needed to respond a specific question about a particular medicinal product, provided that such correspondence/documents are true, not misleading and refer only to the question asked;
- information and documents specifically related to changes in packaging, adverse reaction warnings in the framework of pharmacovigilance, sales catalogues and price lists, provided that no other information on the medicinal product is included; and
- information regarding human health or diseases, provided there is no reference, even indirectly (for example, by mentioning its active substance), to the medicinal product.

In addition, the Code of Farmaindustria states that the following informative activities will not be considered as advertising of medicinal products:

- the SmPC;
- information provided by physicians to the patients on certain medicinal products that, due to the complexity of dosage, route of administration, etc, require providing additional information, and only if such information is intended to improve adherence to treatment;
- corporate advertising, meaning advertising which relates to the company, provided there are no references, not even indirect ones, to specific medicinal products;
- texts written and produced by journalists in their professional work, provided that there is

no contractual relationship between the firm responsible for editing or the author of the information and the owner of the medicinal product and/or its trade mark;
- reprints, literal translations of scientific articles and abstracts published in recognised scientific sources or in congresses, provided that they do not include any additional element, such as the name of the medicinal product of the company, regardless of the way in which it is included (link, additional paper, etc), highlights, and trade marks or promotional claims; and
- information on new lines of research mentioning the active ingredient and its properties provided to HCPs or patients, provided that its distribution is a condition mentioned in the authorisation of commercialisation, or that its distribution has been approved by the health competent authorities.

Finally, the description of research initiatives in corporate brochures or other informative documents accessible to the public is also commonly accepted as information by the Spanish authorities, as long as such description is objective and reasonable according to the usages of the sector and non-promotional in tone.

2.3 Restrictions on Press Releases Regarding Medicines

Press releases are a controversial issue in Spain and should be analysed on a case-by-case basis. According to the Code of Farmaindustria, and the rulings of the Jury of Advertising (a specialised body within an association for self-regulation in advertising called Autocontrol; the Jury of Advertising is responsible for hearing cases relating to the breach of provisions of self-regulatory codes, such as the Code of Farmaindustria), if the information on a medicinal product refers to a newsworthy event such as a relevant step in the research and/or authorisation process of such medicinal product, which is relevant for the financial performance of the company, is clearly directed to potential investors, shareholders and/or future employees, and has a non-promotional tone, then it may be considered as corporate information, and, therefore, may be published in non-scientific journals directed to the general public as it is not considered as promotion, but as information.

Determining Whether a Press Release is Advertising

However, if there is a contractual relationship between the company and the media where a press release is published, the press release will most likely be deemed to be an advertising material and would therefore be subject to the rules regarding this activity. On the contrary, Farmaindustria's Deontological Surveillance Unit has stated that it is not correct to interpret the Code of Farmaindustria as meaning that any text written by journalists in their professional work must always and in all cases be considered as advertising merely because there is a contractual relationship with the media, but that additional factors must be assessed.

These other factors to bear in mind to determine whether or not the press release has a promotional nature are mainly the following:

- whether the press release is aimed at promoting the consumption of a product;
- whether the statements contained in the article are made by experts hired by the company;
- whether the tone is laudatory; and
- in the case of various publications, if their content is very similar suggesting that the media did not add further journalistic content, then the chances of it being considered pro-

motional increase substantially (Ruling of Jury of Advertising of Autocontrol in Gilead v VIIV 2DR-JULUCA-DOVATO, dated 25 June 2020).

Guide for Interacting With the Media

The Code of Farmaindustria includes, as Annex III, a guide with a list of recommendations for companies when interacting with the media. When certain conditions are met as explained in this guide, press releases may be considered as having an informative nature (not promotional). For instance, it is recommended that the trade mark of the medicinal product, or its active ingredient, be only prudently and proportionately mentioned – ie, twice maximum and not in the headings.

2.4 Comparative Advertising for Medicines

Under Law 3/1991 and the Code of Farmaindustria, comparative advertising directed to HCPs is allowed provided that:

- the products or characteristics compared are comparable, essential and relevant;
- the comparison is objective, scientifically proven and verifiable from sources immediately accessible to the competitor; and
- the general tone of the advertisement is balanced and fair.

The competitor's brand name or trade mark can be used as part of the comparison, provided that such use is proportionate and is not made with the objective of taking an unlawful advantage of the reputation of the competitor's brand name or trade mark. However, there is no legal or deontological provision requiring an express reference to the trade mark of the medicinal product, as comparative advertising allows for referring to a competitor either explicitly or implicitly (Ruling of Jury of Advertising of Autocontrol in Sanofi-Aventis v Italfarmaco – Hepaxane, dated 8 January 2020).

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

Advertising of medicinal products which have not obtained a marketing authorisation is not allowed. In some specific cases, regulatory authorities, as well as the provisions of the Code of Farmaindustria, accept the possibility of companies making information available to HCPs and HCOs prior to the approval of the medicinal products if it is merely scientific information, instead of an advertising activity. However, it is advisable to take a rather restrictive approach regarding these activities, as any materials containing promotional statements will undoubtedly be considered as advertising.

Additionally, according to Royal Decree 1015/2009, which regulates the use of medicinal products in special situations, marketing authorisation holders must not distribute any type of information which may directly or indirectly stimulate the use of the medicinal product in conditions different from those approved in its SmPC.

3.2 Provision of Information During a Scientific Conference

Objective and non-promotional scientific information on unauthorised medicinal products or unauthorised indications may be provided during congresses or meetings organised by a prestigious scientific society, provided certain conditions are respected.

Conversely, regulatory authorities and the provisions of the Code of Farmaindustria accept that promotional materials on medicinal products authorised in countries other than Spain may be distributed during international congresses or meetings held in Spain, provided that:

- the congress or meeting is attended by numerous professionals from other countries;
- the materials are written in the language of the country where the product is approved or in English; and
- the materials include a clear warning indicating (at least in Spanish) that the medicinal product is not marketed or authorised in Spain.

Although the Code of Farmaindustria does not set a minimum font size for this warning, this is something that must be checked by comparing the letters used in the waring to those used in the rest of the messages. Including this warning as a footnote using a small font size is not enough (Ruling of Jury of Advertising of Autocontrol in Glaxosmithkline v Astrazeneca CD-PS 1/20 Symbicort, dated 7 July 2020).

3.3 Provision of Information to Healthcare Professionals

Any company may respond to specific requests for information from HCPs, provided the conditions mentioned in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information** are met. Information must be provided reactively and not proactively. It is advisable to deal with these matters through the medical affairs department of the company rather than through its sales or marketing departments.

3.4 Provision of Information to Healthcare Institutions

There are no specific provisions in Spanish law or in the Code of Farmaindustria regarding the provision of information on unauthorised medicinal products or indications to HCOs. In practice, regulatory authorities and the provisions of the Code of Farmaindustria accept that objective information on a medicinal product may be provided to HCOs prior to its approval, in order to help prepare their budget, provided it does not contain promotional statements.

3.5 Information About Early Access or Compassionate Use Programmes

Advertising compassionate use programmes is prohibited under Spanish law. Royal Decree 1416/1994 prohibits any advertising of medicinal products which have not yet obtained a marketing authorisation. Also, even when referring to the access of a medicinal product authorised in another country (different than Spain), Royal Decree 1015/2009, regulating the use of medicinal products in special situations, expressly prohibits the holder of the marketing authorisation in the country of origin from any advertising on the use of the medicinal product.

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Advertising of prescription-only medicinal products and/or publicly financed medicinal products directed at the general public is prohibited under Royal Legislative Decree 1/2015, Royal Decree 1416/1994 and the Code of Farmaindustria.

On the contrary, non-prescription medicinal products which are not publicly financed may

be advertised to the general public. Furthermore, advertising of medicinal products to the general public for any of following therapeutic indications is not allowed:

- tuberculosis;
- sexually transmitted diseases;
- other serious infectious diseases;
- cancer;
- chronic insomnia; and
- diabetes and other metabolic illnesses.

According to Royal Decree 1416/1994, any advertising material directed to the general public must clearly indicate that it is an advertisement and that the product advertised is a medicinal product.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Messages must contain at least the complete name of the product, the name and/or logo of the marketing authorisation holder, the therapeutic indication of the product, the composition of the product, an invitation to read the instructions of the leaflet and to consult a pharmacist, and any additional recommendations that the Ministry of Health may determine in order to prevent risks and to promote the rational use of the product.

Additionally, Royal Decree 1416/1994 states that advertising to the general public must not contain any statement which:

- gives the impression that a medical consultation or surgical procedure is unnecessary;
- suggests that the effects of taking the medicinal product are guaranteed, do not have side effects or are better than, or equivalent to, those of another treatment or medicinal product – adjectives such as "perfect", "maximum", "unique", "safe" or "total" are expressly prohibited;
- suggests that a person's health may be improved by taking the medicinal product or that it could be negatively affected by not taking the medicinal product;
- suggests that the use of a medicinal product may enhance sports abilities;
- is directed exclusively or mainly to children;
- suggests that the medicinal product is a foodstuff, cosmetic or other consumer product, or that the safety or efficacy of the medicinal product is due to the fact that it is a natural substance;
- could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or by the action of the medicinal product;
- includes promises of a cure, exaggerated testimonies on the virtues of the product, or recommendations of scientists, HCPs or celebrities; or
- mentions that the product has obtained a marketing authorisation in any country or any other authorisation.

Reminder advertisements, the purpose of which is merely to remind the target audience about the name of the medicinal product, are acceptable only for products sufficiently known and which have been promoted for at least two years, and can only include the name of the medicinal product. According to the guide on advertising of OTC medicinal products published by the Ministry of Health, a blurred image of the packaging is also acceptable in such advertising, provided that the only information clearly visible is the name of the product, the logo of the pharma-

ceutical company, and the identifying colours of the product.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

There are no provisions in Spanish law regarding restrictions on interactions between patients or patient organisations and the pharmaceutical industry.

However, the Code of Farmaindustria states that any collaboration between companies and POs must be formalised in a written agreement, stating:

- the purpose of the collaboration;
- the activities to be performed by each of the parties;
- the financial amount of the collaboration; and
- a description of any relevant indirect support provided by the company and the sources and purposes of the support.

Additionally, companies must have an internal process for the approval of these collaborations, and must not be the exclusive sponsor of a PO or try to influence the content of the publications issued by a PO.

Meetings with patient support groups must be held at appropriate venues, avoiding those which are extravagant or renowned for their entertaining facilities. It is not acceptable to organise events at venues outside Spain, unless most of the participants come from outside Spain, or a relevant resource or expertise is located abroad. However, organising an event outside Spain due to a relevant resource being located at the place where the event is going to be held requires prior approval from Farmaindustria's Deontological Surveillance Unit.

Hospitality offered by the company must comply with the same requirements referred to in **9.1 Gifts to Healthcare Professionals**.

Hospitality must only be made available to accompanying persons if they attend as helpers of patients. Payment of such expenses must be made through the PO. Hospitality cannot include social, entertaining or cultural events, except for reasonable welcome cocktails, working meals and gala dinners.

Scientific Meetings

In the case of virtual meetings, all kinds of hospitality are forbidden.

It is forbidden to offer money to merely compensate for the time spent by patients to attend the meeting.

It is possible to pay a PO for expert services (for example, participating in advisory boards, acting as speaker/moderator at scientific meetings, educational activities, etc), provided that the following requirements are met:

- entering into a written agreement stating the nature of the services and the criteria to calculate the amount of payment;
- the purpose of the services must be co-operating with health assistance and/or research;
- the legitimate need for such services must be clearly identified;
- the criteria used to choose the expert must be related to the identified needs, and the person in charge of the selection must have the necessary expertise to evaluate the candidates – the experts hired must be approved by the internal supervisor of the company;
- the number of experts hired must not exceed the number reasonably necessary to achieve the identified objectives;

- the company must keep documentary records of the services provided;
- the hiring of a PO must not be linked to their participation in a promotional event for a medicinal product;
- the hiring of patients must be carried out through the PO;
- the payment to a PO must not entail an inducement for the PO to recommend the medicinal products of the company;
- the remuneration paid must be at market prices and taking into account the hours of work and the responsibilities undertaken by the expert;
- payments in kind can only be accepted exceptionally upon prior authorisation from Farmaindustria's Deontological Surveillance Unit; and
- it is recommended that the agreement includes a clause by means of which the expert undertakes to declare that they provide services to the company every time they write or publicly assert any matter related to the company.

The Code of Farmaindustria

According to the Code of Farmaindustria, offering money or any kind of gift or services for personal benefit to patients or the representatives of POs is forbidden.

Also, the Code of Farmaindustria contemplates that any material or publication directed to patients must comply with the following requirements:

- it must help patients to get a better understanding of their disease development and improve their life quality – its content, therefore, must be related to patients' health, specific illnesses, hygienic-sanitary measures or healthy habits;
- it must expressly reflect whether they have been sponsored by a company;
- it must clearly and evidently prove that its main objective is to be a support tool for people affected by a certain disease; and
- it must be formative and informative and must visibly include messages that express that they are guidance and informative materials that cannot be interpreted as a substitute for the diagnosis or advice of an HCP.

Additionally, under the Code of Farmaindustria, companies must publish a list of the POs that the company supports, and the POs with which it has entered into a services agreement. Such publication must include a sufficiently detailed description of the support provided by the company to each PO and the amounts annually paid to each PO for their services.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

According to Royal Decree 1416/1994, advertising directed to HCPs legally entitled to prescribe or dispense medicinal products must include:

- the name of the product;
- the name and address of the marketing authorisation holder;
- the qualitative and quantitative composition of the product;
- essential data according to the SmPC, including complete clinical data, indications for use, cautions and relevant contraindications;
- the different dosages and pharmaceutical forms in which the product is available;

- the prescription and dispensation regime applicable to the product;
- the retail price and the conditions under which the product is publicly financed; and
- the estimated cost of treatment, if possible to determine.

Messages must be precise, balanced, honest, objective, based on adequate scientific evaluation, and sufficiently complete as regards the therapeutic value of the product.

Reminder advertisements, acceptable for products sufficiently known which have been promoted for at least two years, can only include the name of the medicinal product and the International Common Denomination if the product contains only one active substance, as well as the logo of the product and the company. No other statements may be included, but the regulatory authorities and the bodies in charge of enforcing the rules of the Code of Farmaindustria do accept including pictures of the packaging.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

Under Spanish rules, using data on file is not allowed for promotional purposes.

However, an advertisement may refer to studies not included in the SmPC of the product, provided that such studies do not contradict the information included in the SmPC (Ruling of Jury of Advertising of Autocontrol in Gilead v ViiV Healthcare New 2DR Era, dated 14 February 2019). In any case, studies must be adequately reflected in the promotional material, in a way that its addressee may by themselves verify the truthfulness and accuracy of the information.

5.3 Advertising of Combination Products

Advertising the use of one medicinal product in combination with another is legally permitted as long as the advertising materials/message are consistent with the SmPC of both products. It is not required for the SmPC to include a specific reference to studies regarding the combined use of medicinal products, as long as such use is compatible with the SmPC (Ruling of Jury of Advertising of Autocontrol in Gilead v ViiV Healthcare New 2DR Era, dated 14 February 2019).

Also, it is legally permitted to advertise medicinal products that include a medical device, provided that the advertisement is consistent with the SmPC of the medicinal product and with the intended purpose of the medical device.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

Companies can provide reprints of journal articles to HCPs. However, under the Code of Farmaindustria, reprints cannot contain printed, stamped or electronically linked trade marks or trade names of medicinal products, advertising slogans, or other advertising materials related (or not) to the information.

5.5 Medical Science Liaisons

Medical science liasons (MSLs) must not proactively discuss scientific information on unauthorised medicines or indications with HCPs. MSLs can provide information to HCPs (provided the conditions mentioned in **2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information** are met) in order to respond to specific questions asked by the HCPs. Information must be provided reactively and not proactively.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

Advertising directed to HCPs qualified to prescribe or dispense medicinal products does not need to be approved in advance by a regulatory or industry authority. However, companies placing an advertisement must send a copy of the advertisement to the health authority of the Spanish autonomous region where the company is located, assuming the responsibility for ensuring that only HCPs entitled to prescribe or dispense medicinal products have access to the relevant publication. The Ministry of Health may, in exceptional circumstances, make the advertising of a specific product subject to prior approval. Any decision of this nature must be duly justified and shall affect all products having the same composition.

Since July 2013, advertising directed to the general public does not need to be approved in advance by the authorities.

This is without prejudice of the fact that any advertising will be subject to control ex-post by the authorities and sanctions may be imposed if it does not comply with the provisions of the law. Additionally, according to Royal Decree 1416/1994, companies must send an annual index summarising all their advertising activities to the health authority of the Spanish autonomous region where the company is located.

6.2 Compliance With Rules on Medicinal Advertising

Royal Decree 1416/1994, as well as the Code of Farmaindustria, state that the marketing authorisation holder must have a scientific service in charge of the management of the information related to the medicinal products marketed by the company.

The scientific service of the company must fulfil the following obligations:

- revise and control any promotional materials in order to ensure that they comply with the legal requirements;
- ensure that the medical sales representatives and any personnel involved in the promotion of medicinal products or in interaction with HCPs, HCOs and/or POs have been adequately trained;
- compile all information regarding the medicinal products marketed, including the maintenance of a registry of the requests for and supply of samples; and
- supply the regulatory authorities with the information and assistance they require, and ensure that the decisions of the regulatory authorities on these matters are immediately and fully complied with.

Under the Code of Farmaindustria, companies are obliged to have a written procedure to monitor compliance with the Code. Additionally, the Code recommends that the different departments (marketing-sales, medical, regulatory, legal, finance-administrative) get involved in the committees, policies or internal procedures that the company implements on these matters.

7. Advertising of Medicinal Products on the Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

Broadly speaking, advertising activities on the internet are subject to requirements identical to

activities performed through traditional channels.

As regards advertising directed to HCPs through the internet, the company must use valid channels within a context that is basically scientific or professional. Those channels must be intended exclusively for HCPs authorised to prescribe or dispense medicinal products, and those HCPs need to identify themselves in order to have access to the information. Pharmaceutical companies can also establish an HCPs status verification system in order for HCPs to have access to the information.

Companies will also be liable for the content of the websites accessed through links from the company's website.

Some provisions of Royal Decree 870/2013, which regulates the sale of OTC medicinal products through the internet, may also apply.

7.2 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

The same rules applicable to other kinds of advertising apply to advertising through social media. In particular, advertising of prescription-only medicinal products on social media which the general public may access is not allowed.

The Code of Farmaindustria imposes on companies the obligation to adequately train its employees on how to behave in the digital environment. In this regard, pharmaceutical companies must have good-practice internal guides directed to their employees and any person acting on their behalf or under their control, or by virtue of an agreement. Companies must also train their employees to prevent them from posting inappropriate content on their personal social networks, such as comments on competitors' products or off-label promotion.

Also, under the Code of Farmaindustria, pharmaceutical companies must clearly and unequivocally inform HCPs and employees attending the meetings organised or sponsored mainly by the company about the prohibition on publishing promotional content related to the meetings on social media. It is advisable to include safeguards in the agreements entered with speakers and attendees.

7.3 Provision of Disease Awareness Information to Patients Online

According to Spanish law, a company must ensure that those parts of its website which contain promotional information about prescription-only medicinal products may only be accessed by HCPs entitled to prescribe or dispense such products. Conversely, it has been commonly accepted, following the guidance issued by the Pharmaceutical Committee, that the unmodified and unabridged publication on the website of information which has been authorised by relevant authorities (for example, the SmPC, the package leaflet, the public assessment reports, price lists) will normally not be considered as advertising and can, therefore, be openly published on the internet.

Under the Code of Farmaindustria, a clearly legible warning must also be included in those parts of the website directed to the HCPs only, indicating that the information is intended exclusively for the HCPs legally entitled to prescribe or dispense medicinal products and, therefore, that specialised training is required for the correct interpretation of the information. Persons who access the content must identify themselves as HCPs entitled to prescribe or dispense medicinal products. Pharmaceutical companies can also

establish an HCP status verification system in order for HCPs to have access to the information.

7.4 Online Scientific Meetings

Any information or material provided online to patients must comply with the requirements referred to in **4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry**.

7.5 Use of Social Media

Spanish law does not include any provision regarding online scientific meetings.

According to the Code of Farmaindustria, scientific online meetings must comply with the same requirements applicable to non-virtual meetings.

In addition, the Code of Farmaindustria provides some specific requirements applicable to online scientific meetings:

- it is forbidden to offer any kind of hospitality in online meetings, and this applies to meetings organised or mainly sponsored by the company, as well as to meetings organised by third parties; and
- notification of online scientific events to the Code of Practice Surveillance Unit is not compulsory.

8. Pharmaceutical Advertising: Inducement/Anti-bribery

8.1 General Anti-bribery Rules Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals

Under the Spanish Criminal Code, companies may be subject to criminal liabilities for bribes offered or given by their employees, directors or other persons under their control to public officials or to private persons.

The penalties that may be imposed on a company for a bribe, which are independent from the penalties that may be imposed on the persons that have committed or participated in the bribe, may be as high as four times the amount of the profit obtained by the company.

However, a company may be exonerated from criminal liability if it demonstrates that prior to the bribe being offered or given, it adopted a compliance system that satisfied the conditions and requirements of the Spanish Criminal Code, and in order to offer or give the bribe the persons involved fraudulently eluded the compliance system and there was no serious breach of the supervision and control duties contemplated in the compliance system.

8.2 Legislative or Self-Regulatory Provisions

According to Royal Legislative Decree 1/2015 and the codes of conduct, it is prohibited for any person with a direct or indirect interest in the production, manufacture and/or placing on the market of medicinal products to directly or indirectly offer to HCPs involved in the cycle of prescription, dispensing and/or administration of medicinal products (or to their relatives or cohabitants) any kind of inducement, bonus, discount, reward or benefit, except for gifts, hospitality and discounts which fulfil the requirements set forth in **4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry**, **9.1 Gifts to Healthcare Professionals**, **9.2 Limitations on Providing Samples to Healthcare Professionals**, **9.3 Sponsorship of Scientific Meetings** and **9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions**. This prohibi-

tion will likewise apply when the offer is made to HCPs prescribing medical devices.

Offering benefits to HCOs and POs is acceptable, provided these benefits are not an inducement to buy, recommend and/or use the products of the company.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

Gifts

According to Royal Decree 1416/1994, gifts to HCPs entitled to prescribe or dispense medicinal products may only be offered when the cost of the gift is insignificant and the gift is relevant for the practice of medicine or pharmacy.

The Code of Farmaindustria offers further guidance and provides that offering gifts to HCPs is only permitted provided that the items have stationary or professional use, are not related to a prescription-only medicinal product and have a market price that does not exceed EUR10. Moreover, such gifts may not be given to HCPs in the context of the promotional and informative visits made by sales representatives of companies, nor in the framework of a congress or meeting organised by a third party, if such visit or event relates to prescription-only medicinal products.

As an exception, it is permitted to give memory cards containing informative or formative material, provided their value does not exceed EUR10. Pens and notepads can be provided in meetings organised by the company, provided that they do not include information regarding prescription-only medicinal products and that their market price does not exceed EUR10.

Educational Materials

Educational materials and items of medical utility can be given as a gift provided that:

- they are relevant to the practice of medicine or pharmacy;
- they benefit patient care;
- they do not alter or modify the routine business practice of the recipient; and
- their market price does not exceed EUR60.

The offer to HCPs of such gifts is excluded from the transparency obligations referred to in **10. Pharmaceutical Companies: Transparency**.

Hospitality

Except in the case of online events, hospitality may also be offered to HCPs at professional or scientific events, provided that it is reasonable and moderate, and strictly limited to necessary logistical means that allow HCPs to attend the event. Hospitality offered may only include payment of real costs of travel, registration and accommodation (hospitality may be only extended to the day after or before the event).

Payments for meals that cost more than EUR60 (taxes included) per person, as well as payments for five-star hotels, five-star grand luxury hotels, sports resort hotels, theme park hotels and/or winery hotels, are prohibited. Payment for cultural, leisure or entertainment activities is also prohibited.

The company must pay these expenses directly to the service providers. No monetary reimbursement can be made to the HCP attendees for expenses incurred to suppliers, except in the case of minor travel costs (taxis, mileage, etc) which are properly justified/evidenced. Hospitality may not be extended to persons other than the HCP attendees.

9.2 Limitations on Providing Samples to Healthcare Professionals

Royal Decree 1416/1994 states that delivery of free samples can only be made on an exceptional basis, and provided that the prior authorisation from the AEMPS is obtained. Authorisation by the AEMPS may be granted only for medicinal products which:

- have a new active substance;
- have a new pharmaceutical form, concentration dosage, or administration route which represents a therapeutic advantage; or
- have new therapeutic indications.

The following requirements/restrictions apply:

- supply of samples must be in response to a written request, signed and dated, from HCPs entitled to prescribe medicinal products;
- only a maximum of ten samples for each medicinal product each year per HCP, during a maximum period of two years after the granting of the marketing authorisation for the medicinal product, is allowed;
- companies must maintain an adequate system of control and accountability;
- samples must not be bigger than the smallest presentation of the product authorised in Spain;
- each sample must be marked "free sample – not for sale" and its reimbursement sticker must have been annulled; and
- a sample must be accompanied by a copy of the SmPC and by updated information on its price, conditions of reimbursement by the Spanish National Health System and, if possible, estimated cost of treatment.

No samples of medicinal products containing psychotropic or narcotic substances may be supplied.

The provision to HCPs of samples is excluded from the transparency obligations for the companies of Farmaindustria referred in **10. Pharmaceutical Companies: Transparency**.

9.3 Sponsorship of Scientific Meetings

According to Spanish regulations, companies may sponsor scientific meetings or congresses, as well as organise informative, professional and/or scientific meetings. Such sponsorship must be stated in all documents related to the event, as well as in any published derivative work.

It is also possible to pay necessary travel, accommodation and enrolment costs to HCPs attending such congresses or meetings. According to Royal Decree 1416/1994, hospitality must be reasonable in level (ie, it must not exceed what recipients would normally be prepared to pay for themselves) and remain subordinate to the main scientific objective of the event. Recipients must indicate the funds received and the source of financing in the publication of papers and lectures in the congresses and meetings. A company may be held responsible for the contents and hospitality arrangements for a meeting or congress if such event has been organised and/or mainly sponsored by such company.

The Code of Farmaindustria provides further guidance, as follows.

- Payments of HCPs travel, accommodation and enrolment costs must be made directly to the provider of these services, except for minor travelling expenses duly justified.
- No payment can be made for the time incurred by the HCP attending the event.
- Hospitality may be granted only for the duration of the event and one additional day.
- Scientific activities must cover at least 60% of an eight-hour working day.

- Tourist locations, sports resorts and the like should be avoided. In addition, it is not acceptable to organise events at venues outside Spain, unless most of the participants come from outside Spain or the congress or expertise object to the event is located abroad (prior approval by Farmaindustria's Deontological Surveillance Unit may be needed). In such cases, the company must abide by the rules of the code of conduct applicable in the country where the event is located.
- A limit of EUR60 (VAT included) must be established for meals and luncheons per guest.
- Hospitality must not be extended in any case to accompanying persons.
- Payment of reasonable fees and reimbursement of out-of-pocket expenses is possible for speakers and moderators.
- Companies must comply with the transparency obligations referred to in **10. Pharmaceutical Companies: Transparency**.

The autonomous regions may place some additional organisational requirements as a consequence of the interaction of the visits made by the sales representatives with the public centres. For example, some regions require the company to submit its visit schedule for subsequent validation.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

The hospitality offered to HCPs cannot include the organisation of social, entertaining or cultural events, except for reasonable welcome cocktails, working meals and gala dinners.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

According to Spanish regulations, grants or donations to individual HCPs are strictly prohibited, except for gifts, samples and hospitality offered to HCPs, provided such gifts, samples and/or hospitality fulfil the requirements set forth in **9.1 Gifts to Healthcare Professionals**, **9.2 Limitations on Providing Samples to Healthcare Professionals** and **9.3 Sponsorship of Scientific Meetings**. Grants or donations to HCOs are acceptable, provided they are not offered as an inducement to buy, recommend and/or use the products of the company.

The Code of Farmaindustria provides specific rules as regards grants or donations to HCOs. The Code allows donations and/or the funding of the cost of medical or technical services to institutions, organisations, associations and foundations whose members are HCPs and/or which provide services of sanitary, social or humanitarian assistance, research or teaching, subject to certain conditions, the most relevant of which are that the gift or donation:

- must not be offered as an inducement to prescribe, recommend or use any particular product;
- must be for the internal use of the institution in general, and not for the use of an individual (portable electronic devices are expressly excluded); and
- must be recorded in a document to be kept by the company.

It is advisable to show these transactions in a written agreement so that the terms under which the funding is awarded are explicit and transparent. Companies must comply with the transparency obligations referred to in **10. Pharmaceutical Companies: Transparency** regarding the offer of grants or donations to HCOs.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

For retail pharmacies, only reasonable volume-related discounts and discounts for early payment are acceptable, provided that such discounts do not induce the purchase of the product with prejudice to its competitors, and are reflected in the corresponding invoice. The reasonability of the discount must be analysed on a case-by-case basis. Companies must also keep a record, which has to be interconnected with the Ministry of Health, of all discounts offered to pharmacies for medicinal products that are financed by the National Health System.

For supplies to hospitals, discounts are subject to the public procurement system.

9.7 Payment for Services Provided by Healthcare Professionals

It is possible to pay HCPs for expert services (for example, participating in advisory boards, acting as speaker or moderator at scientific meetings, educational activities, expert meetings, etc), under the following conditions.

- Entering into a written agreement stating the nature of the services and the criteria to calculate the amount of payment.
- The legitimate need for such services must be clearly identified.
- The criteria used to choose the expert must be related to the identified needs, and the person in charge of the selection must have the necessary expertise to evaluate the candidates. The experts hired must be approved by the scientific service of the company.
- The number of experts hired must not exceed the number reasonably necessary to achieve the identified objectives.
- The company must keep documentary records of the services provided.
- The payment to the HCP must not entail an inducement to promote the prescription, dispensation, sale or consumption of medicinal products.
- The remuneration must be at market prices and taking into account the hours of work or service actually employed and the responsibilities undertaken by the expert. Payments must be explicit and transparent, and a proper invoice must be issued by the HCP. Payments in kind can only be accepted exceptionally upon prior authorisation from Farmaindustria's Deontological Surveillance Unit.
- It is recommended that the agreement include a clause by means of which the HCP undertakes to declare that they provide services to the company every time they write or publicly assert any matter related to the company; and companies must comply with the transparency obligations referred to in **10. Pharmaceutical Companies: Transparency** regarding the payments made to HCPs related to said provision of services.

Annex IV of the Code of Farmaindustria includes a guide for action for companies when contracting services to HCPs and HCOs. Annex IV includes a list with some of the different kinds of services that may exist and the criteria that pharmaceutical companies must comply with.

In addition, this guide establishes a series of questions (23 in total) that companies must be able to answer affirmatively, to ensure that they comply with the provisions of the Code regarding these contracts. These questions are set out in line with IFPMA's "Guidance on Fees for Services".

9.8 Prior Authorisations or Notifications for Activities Between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

According to the Spanish rules, HCPs which provide their services in HCOs depending on the public health system may be obliged to obtain an authorisation of their employer in order to accept the hospitality offered by a company or to provide a service for a company. HCPs are the ones affected by these obligations, and not the companies.

Under the Code of Farmaindustria, the companies must inform Farmaindustria's Deontological Surveillance Unit in the following cases:

- where the company organises the assistance to a congress or event of at least 20 people; and/or
- where the HCPs hired by the company for a given project number more than ten.

In the case of meetings or events that are part of projects that have already been notified by pharmaceutical companies, these do not need to be notified again in accordance with the principle of non-duplication.

Communication will be voluntary in the case of training activities or scientific meetings that are carried out virtually.

10. Pharmaceutical Companies: Transparency

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

The Code of Farmaindustria has implemented the EFPIA rules on disclosure of transfers of value from pharmaceutical companies to HCPs, HCOs and POs. Consequently, since 2015, companies are obliged to document and publish on their website (the first publication was actually made in 2016) all transfers of value made during the previous year – meaning any direct or indirect payment or grant, either cash or benefits in kind, and regardless of their purpose – whose recipient is an HCP or HCO. The only payments excluded from this obligation are:

- those associated with commercial transactions with distributors, retail pharmacies and certain transactions with HCOs;
- activities related to products or medicinal products that are not prescription-only medicinal products; and/or
- activities not detailed in Appendix I of the Code of Farmaindustria, such as the provision of gifts, samples, dinners or luncheons.

Disclosure must be made on an individual basis, except for transfers of value related to R&D. Spanish authorities on personal data protection have ruled that companies must inform an HCP on the disclosure of their personal data. However, there is no requirement that the HCP consents to the disclosure of their personal data.

AESEG has also implemented in its own code the Medicines for Europe rules on disclosure of transfers of value from pharmaceutical companies to HCPs, HCOs and POs.

There are no exceptions regarding the disclosure obligation due to COVID-19 incidences.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

The transparency requirements described in **10.1 Requirement for Pharmaceutical Compa-**

nies to Disclose Details of Transfers of Value apply to transfers of value to HCPs, HCOs and POs performed by companies associated to Farmaindustria/AESEG and/or which have voluntarily adhered to the Codes of Farmaindustria/AESEG. They also apply to transfers of value to Spanish HCPs, HCOs and POs performed by their affiliates, except in the case where such affiliates already publish such transfers of value in accordance with their national code of conduct. The fact that the company does not yet have products on the market is irrelevant for this purpose.

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

Except for those rules resulting from the industry codes of conduct, the responsibility for enforcing the rules on advertising and inducements lies with the health authorities of the Spanish autonomous regions and courts.

The Codes of Farmaindustria, AESEG and ANEFP are enforced by self-regulatory bodies in agreement with Autocontrol, an association for self-regulation in advertising.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Any advertising in breach of General Law 34/1988 on Advertising will be considered as an unlawful act under Law 3/1991 on Unfair Competition. The actions that may be taken before the courts for breach of the Law on Advertising and for breach of the Law on Unfair Competition (which may be taken individually or on a cumulative basis) have been unified in order to avoid any conflict between jurisdictions, as follows:

- action of cessation or prohibition;
- action of declaration of the unlawfulness of the advertising;
- action of removal of the effects produced by the unlawful advertising; and
- action of rectification of any deceitful, incorrect or false information contained in the unlawful advertising, including the publication of the court ruling.

This is without prejudice to the right to claim damages, if the advertiser has acted wilfully or negligently and/or for unlawful enrichment, if applicable.

The referred actions may be brought by any person or company who is affected by the unlawful advertising and, in general, those who have a legitimate interest. These actions may also be brought by consumer associations or other associations when the interests of their members are affected, but they will not have the right to claim damages.

The issues which have been discussed more frequently under these procedures involve the distinction between advertising and information on products, the conformity of advertising materials to the content of the SmPCs, and the conditions under which comparative advertising is fair. Another area on which various rulings have been adopted refers to the limits on hospitality that may be offered to HCPs.

Raising Issues

Under the Codes of Farmaindustria, AESEG and ANEFP, companies have agreed not to file complaints against each other directly before the ordinary courts or the health authorities without

first raising the issue with the bodies in charge of enforcing these codes.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The regulatory authorities are rather strict in scrutinising materials which companies notify to them, and they may suspend an advertisement if they consider it to be in breach of the rules. Furthermore, if the advertisement constitutes a risk for the health or security of consumers, the authorities may order the publication of the ruling and a corrective statement where the advertisement was published.

Failure to Comply

Failing to comply with the rules governing the medicinal products' advertising and/or inducements may also result in administrative sanctions. The general rule is that a breach of the law on this matter may result in a fine being imposed. The amount will depend on various factors including:

- negligence;
- whether the breach was intentional;
- whether there was fraud or connivance;
- whether a failure to comply with previous requests made by the authorities exists;
- the company's turnover;
- the number of persons affected;
- the damage caused; and
- the profits obtained from the infringement.

In some cases, criminal sanctions may apply.

Challenging Decisions

Decisions taken by regulatory bodies may be challenged through an administrative appeal and through judicial review. In some cases, the administrative appeal is compulsory and has to be filed within a month from the date on which the decision was notified. When the administrative appeal is only optional, the interested party may go directly to court within two months from the date on which the decision was notified. During the court case, an injunction may be sought. The chances of obtaining an injunction largely depend on whether the applicant shows that it will suffer irreparable harm in the event that the injunction is not granted.

Under the Codes of Farmaindustria, AESEG and ANEFP, the procedure may conclude with the declaration of the unlawfulness of the advertising, as well as with a fine, the amount of which will be set considering a variety of factors. The damage that a breach of the rules may cause to the image of the industry is one of the criteria to which the Code of Farmaindustria refers. The competent body to impose these measures and sanctions is the Jury of Advertising, a specialised body within Autocontrol. The rulings of the Jury of Advertising are made public through its website.

11.4 Relationship Between Regulatory Authorities and Courts

The Codes of Farmaindustria, AESEG and ANEFP state that, prior to raising the issue before the regulatory authorities or the courts, the companies adhering to these codes must first file their claims against the advertising practices of other companies before the bodies in charge of enforcing these codes of conduct.

Notwithstanding the foregoing, the regulatory authorities may investigate matters on their own initiative, even if they are being assessed by any self-regulatory body, and may also take up matters based on an adverse finding of any self-regulatory body. Conversely, the Jury of Advertising must refrain from assessing any issue which is

being or has been assessed by the regulatory authorities or the courts.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

During the last several years, there have been few cases regarding advertising of medicinal products in Spanish Courts and in Autocontrol. The last two rulings of Autocontrol under the Code of Farmaindustria were issued in 2020 and 2022.

On 30 June 2021, the High Court of Justice of the Basque Country issued a very interesting judgment clarifying, inter alia, that Spanish law does not prohibit the advertising of products which have been granted a marketing authorisation, even when their price and reimbursement decision is still pending from the Ministry of Health. Following this judgment, the Code of Farmaindustria changed its Q&A section (Question 10) by indicating that the advertising of a medicine in these circumstances is not against the Code provided that such advertising includes a warning in this regard and is aimed at HCPs.

One year later, on 17 June 2022, the High Court of Justice of Madrid issued a judgment on terms contrary to those upheld by the High Court of Justice of the Basque Country and ruled that medicinal products cannot be the object of promotion until a decision on their price and reimbursement has been issued, regardless of whether these products have obtained a marketing authorisation.

For more information about this judgment, and the context and conclusions in connection therewith, please refer to the accompanying **Trends & Developments** article.

At the end of July 2022, the Ministry of Health invited all interested parties to make their proposals regarding the preparation of the draft bill amending the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices. The interested parties submitted the proposals, and the new draft law is currently under preparation. For more information about the aspects that will be amended with this new draft law, please see the **Trends & Developments** article.

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

The provisions related to the advertising of veterinary medicines are comprised in Royal Decree 1157/2021, which regulates industrially manufactured veterinary medicines. According to Royal Decree 1157/2021, advertising of prescription-only veterinary medicines is permitted only if addressed to veterinarians and persons authorised to dispense veterinary medicines. Regulations provide for an exception for immunological medicines, which can be advertised to persons in charge of animals.

Advertising of veterinary medicines addressed to the general public must abide by the following requirements:

- comply with the SmPC of the product;
- not include testimonials from HCPs or notorious persons, or expressions that provide assurances of healing; and
- not use claims on the fact that the product has been granted a marketing authorisation.

Also, the following information must be included in the advertising of veterinary medicines (except in the case of advertising for branding purposes) addressed to the general public:

- name of the medicinal product and number of the marketing authorisation;
- identification of the marketing authorisation holder;
- composition of active ingredients;
- indications for use and target species;
- contraindications, precautions and withdrawal periods, if applicable;
- additional indications required in the marketing authorisation; and
- a legend stating “If in doubt, consult your veterinarian”.

Faus Moliner is a modern boutique law firm, specialised in dealing with legal matters typical of the pharmaceutical industry and companies which operate in the life sciences sector. Faus Moliner, which was founded in 1997, focuses on pharmaceutical law, commercial contracts, corporate transactions, corporate governance, compliance, competition law, public procurement, product liability, advertising, litigation and arbitration. The firm advises pharmaceutical and healthcare clients, acts on behalf of large companies and smaller biotech start-ups, and is frequently called upon to advise public authorities on matters such as draft legislation.

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Trends and Developments

Contributed by:
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The latest trends and developments in connection with pharmaceutical advertising in Spain concern the following matters:

- advertising of prescription-only medicinal products to healthcare professionals (HCPs) once they have received a marketing authorisation but before the price and reimbursement decision is issued by the Ministry of Health; and
- foreseeable legislative changes.

This article includes analysis of these matters, providing background information and relevant context when needed.

Advertising of Prescription-Only Medicinal Products to HCPs Before the Price and Reimbursement Decision is Taken by the Ministry of Health (MoH)

Relevant context

In Spain, prescription-only medicinal products cannot be placed on the market immediately once a marketing authorisation (MA) has been granted (either by the European Commission under the centralised procedure or by the Spanish Medicines Agency (AEMPS) under a national procedure, a mutual recognition or a decentralised procedure).

The consolidated text of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices, approved by Royal Legislative Decree 1/2015, states that prior to placing the product on the market, the MA holder or its local representative must offer such product to the MoH so that the MoH may decide whether to reimburse it or not. If in the affirmative, the MoH shall issue a decision (a "P&R Decision") also fixing the maximum price for the units of such product that will be reimbursed. Units that are not reimbursed (ie, private patients or other sales outside the National Health System) may be sold at the price notified to the MoH, provided the MoH does not oppose this on the grounds of protection of public interest.

The possibility of advertising a product after an MA has been issued but before a P&R Decision is adopted has been the subject of controversy in Spain, mainly due to the interpretation given by the Spanish authorities to certain provisions contained in Royal Decree 1416/1994 on promotion of medicinal products for human use.

Article 10.2 of Royal Decree 1416/1994 refers to the minimum information that must be included in any advertising of medicines aimed at HCPs. More precisely, Article 10.2 states that any advertising of medicinal products to HCPs must include information "about the price and reimbursement conditions and, whenever possible, about the estimated cost of the treatment". When referring to this requirement, Article 10.2 states that this information must be provided "if applicable".

Relying on this, some authorities in Spain have understood that advertising may not take place until a P&R Decision has been taken. In some cases, authorities have even stated that advertising cannot take place until the product is effectively placed on the market.

This position was also followed by the Jury of Autocontrol (a specialised body responsible for hearing cases relating to the breach of provisions of self-regulatory codes) when applying the Code of Farmaindustria. Farmaindustria is the Spanish innovative medicinal products industry association, which has issued a code of practice for the pharmaceutical industry regulating the advertising of prescription-only medicinal products as well as interactions between pharmaceutical companies and HCPs, HCOs and POs.

According to numerous rulings of the Jury of Autocontrol, for example in the case Cephalon Pharma, SLU v Prostrakan "Abstral", dated 8 October 2009, the advertising of authorised medicinal products for which a P&R Decision is pending is regarded as a breach of the Code of Farmaindustria.

Relevant trends – June 2021, first judgment in dispute

On 30 June 2021, an important judgment on the aforementioned matter was issued by the High Court of Justice of the Basque Country, in a case filed by Farmaindustria against an order governing visits by medical sales representatives to HCPs in the Basque Country. The appeal was filed because, inter alia, Farmaindustria considered that the order did not allow medical sales representatives to promote, at such visits, authorised medicinal products for which a P&R Decision was pending. The High Court rejected the appeal concluding that neither the order nor any other Spanish applicable law prohibit the advertising of products that have received an MA, even if a P&R Decision is pending.

Interestingly, the Court stated that when interpreting Article 10.2 of Royal Decree 146/1994, relevance must be given to the words "if applicable" contained in such provision, meaning that the information about the price and reimbursement conditions must be given only if such information is available when the advertising is made. The Court also stated that the absence of a P&R Decision cannot be an obstacle for authorised advertising of the medicinal product to HCPs.

Considering this judgment, Farmaindustria modified the Q&A section of its code of practice to include that advertising of authorised medicinal products to HCPs when the P&R Decision is still pending is possible, provided that such advertising includes a warning about such circumstance.

Relevant trends – June 2022, second judgment in dispute

The position maintained by the High Court of Justice of the Basque Country in the judgment of 30 June 2021, which encouraged Farmaindustria to modify its code of practice, was overshadowed by another recent judgment of the High Court of Justice of Madrid dated 17 June 2022.

In this case, the High Court of Justice of Madrid considered that until a P&R Decision has been taken, the requirements for the product to be promoted are not met because Article 10.2 of Royal Decree 1416/1994 imposes the obligation to include, in any advertising of medicinal products, data regarding the price of the product and the conditions of the pharmaceutical provision of the National Health System.

It is interesting to note that the High Court of Justice of Madrid does not state that Royal Decree 1416/1994 or Royal Legislative Decree 1/2015 prohibit promotion before the P&R Decision, but focuses its argument on the minimum content that promotional materials of medicinal products must respect under Article 10.2 of Royal Decree 1416/1994. Thus, in the opinion of the

Court, a medicinal product whose P&R Decision is pending cannot be promoted in compliance with Article 10.2 of Royal Decree 1416/1994.

The High Court of Justice of Madrid, therefore, overlooks the fact that Article 10.2, when referring to the minimum content in terms of price and financing conditions, states that such information must be included "if applicable".

It is also interesting to note how the judgment of the High Court of Justice of Madrid interprets the Basque Country judgment; this allows for a reading of the Madrid High Court judgment in somewhat more favourable terms.

According to the Madrid judgment, the High Court of Justice of the Basque Country examines the characteristics of visits by medical sales representatives, but the Madrid court states that the assimilation of this advertising regime with the documentary advertising of medicinal products should be avoided.

This can be interpreted as meaning that the prohibition on promoting medicinal products before the P&R Decision is taken would only refer to the documentary advertising that is actively made available to the HCP. Under this interpretation, only this documentary advertising would be obliged to include the information set out in Article 10.2 of Royal Decree 1416/1994. This minimum content would not apply to the information that the medical sales representatives can transmit to HCPs, which is what the ruling of the High Court of Justice of the Basque Country refers to.

Foreseeable future

The authors are not aware of the judgment of the High Court of Justice of Madrid being appealed before the Spanish Supreme Court, which is the court competent to revise a ruling issued by a regional High Court.

Consequently, at present two apparently divergent rulings coexist on the possibility for promoting medicinal products before the P&R Decision is issued.

However, the authors are aware that the health authorities of Catalunya have issued public statements and newsletters indicating that promotion before the P&R Decision has been issued is prohibited because such advertising would not comply with Article 10.2 of Royal Decree 1416/1994. These authorities also confirmed that medicinal products holding an MA and with a valid P&R Decision in force cannot be the object of advertising if commercialisation has not been notified to the authorities, since this advertising would be considered misleading.

As discussed further in the following section, Royal Legislative Decree 1/2015 is soon to be amended as a result of the initiative promoted by the MoH. The authors expect that this new version of the legislative decree will provide clarification as to whether a medicinal product whose P&R Decision is pending can be the object of promotion.

Foreseeable Legislative Changes

Amendment of Royal Legislative Decree 1/2015

In July 2022, the MoH opened a public consultation on the first draft of the law that will amend the current Royal Legislative Decree 1/2015. The document published by the MoH shows that the reform being considered will have three principal axes.

- Public financing of medicines – the MoH document refers to adopting new measures

to rationalise pharmaceutical expenditure and promote rational use of public funds. In this regard, it is proposed to modify the reference price system by introducing elements that increase competition and value the contributions that represent an incremental benefit in the use of medicines.
- The experience of the pandemic and the impact of new technologies – the pandemic has created great challenges related to the availability of medicinal products and medical devices. In this sense, the MoH aims to consolidate the non-presential dispensing of medicines for hospital dispensing and telepharmacy in the National Health System.
- Implementation of EU law – the text published by the MoH proposes to make the necessary amendments to incorporate the amendments and definitions of Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro medical devices into Spanish law.

Regarding objectives of the proposed amendment in the specific area of advertising, the MoH document states that the amendment to Royal Legislative Decree 1/2015 aims to clarify the competences of control over advertising activities for medicinal products, as well as to update the advertising regime for medical devices.

The process to approve this new law will be lengthy. After this public consultation period, the Spanish government will prepare a draft of the new law, and it will be put to a public hearing so that contributions can be made. After this, the government will send the draft law to the Spanish Parliament for the legislative amendment to be processed.

Amendment of Royal Decree 1591/2009 and Royal Decree 1616/2009

Regulation 2017/745 (EU) on medical devices is of direct application for member states; however, this regulation leaves certain issues to be further regulated at the national level. Consequently, those aspects of the national regulations that are not compatible with the EU regulation are subject to future amendment. In this context, in 2021 the MoH proposed a new draft on medical devices that would partially repeal Royal Decree 1591/2009 on medical devices and Royal Decree 1616/2009 on active implantable medical devices.

The derogation of these royal decrees is not complete. According to the proposed draft, whose final approval is still pending, the provisions of both decrees relating to promotion, incentives and sponsorship of scientific meetings, as well as the procedures before the notified body, will remain in force but will be subject to future amendment.

New Royal Decree on promotion of medicinal products and medical devices

Finally, according to the 2022 Annual Regulatory Plan (a document that includes the legislative or regulatory initiatives that the various ministerial departments plan to submit each calendar year to the Spanish Council of Ministers for approval), a new Royal Decree on the promotion of medicinal products and medical devices was expected for 2022. However, the MoH did not move forward with this proposal in 2022.

Among the objectives of this new Royal Decree, the Annual Regulatory Plan referred to:

- the need to update the regulatory regime of promotional activities with the technological evolution and predominance of digital media;

- the clarification of the control competences of the autonomous health authorities; and
- the need for a comprehensive regulation of the advertising of medicinal products for human use and medical devices, both to the general public and to health professionals.

At the time of writing this article, the Annual Regulatory Plan for 2023 has just been published and the proposed new Royal Decree on the promotion of medicinal products and medical devices has not been included as an initiative for 2023. The authors cannot exclude that the MoH has decided to abandon this particular initiative, as it may be regarded as being pursued through the amendment of Royal Legislative Decree 1/2015.

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Faus Moliner is a modern boutique law firm, specialised in dealing with legal matters typical of the pharmaceutical industry and companies which operate in the life sciences sector. Faus Moliner, which was founded in 1997, focuses on pharmaceutical law, commercial contracts, corporate transactions, corporate governance, compliance, competition law, public procurement, product liability, advertising, litigation and arbitration. The firm advises pharmaceutical and healthcare clients, acts on behalf of large companies and smaller biotech start-ups, and is frequently called upon to advise public authorities on matters such as draft legislation.

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