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Pharmaceutical Advertising 2025

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Spain: Law & Practice & Trends & Developments

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SPAIN

Law and Practice

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Faus Moliner is a modern boutique law firm that specialises in dealing with the legal matters that are typical within the pharmaceutical industry and companies that operate in the life sciences sector. The firm, 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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1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Concerning the Advertisement and Promotion of Medicines

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

General Rules

General rules on advertising are found 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, the 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 Catalonia). Furthermore, the Ministry of Health has issued a guide on the advertising of over-the-counter (OTC) medicinal products (with the 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, sets forth the sanctions for breach of the rules on advertising of medicinal products.

Codes of Conduct

Spanish trade associations 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 2021 update of the Code of Farmaindustria introduced new provisions addressing areas such as social media and the digital environment, and interactions with HCPs, POs and the media.

Additionally, AESEG, the Spanish generic medicinal products industry association, and ANEFP, the Spanish OTC medicinal products industry association, among others, have also published their own codes of conduct on the promotion of medicinal products.

1.2 Application and Influence of Self-Regulatory Codes on the Advertisement and Promotion of Medicines

Self-regulatory codes of conduct apply and have binding effects on companies that are members of the issuing trade association and those 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 conducting promotional activities and/or interacting in any way with HCPs, HCOs and/or POs in Spain.

Other than that, self-regulatory codes, especially the Code of Farmaindustria, are expressions of the prevailing social environment that forms the context for promotion of medicinal products. Even if these codes are not technically mandatory for non-member companies, it may well happen that authorities refer to their provisions to interpret Spanish regulations. As an example, in December 2023, Catalan authorities signed a collaboration agreement with Farmaindustria, committing to consider its doctrine in regulating medicinal product advertising. Consequently, they issued an informative note on distinguishing between information and promotion of medicinal products, incorporating many interpretations developed by the Control Bodies of the Code of Farmaindustria in recent years.

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 to 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 ingredient), 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 summary of product characteristics (SmPC);
- information provided by HCPs 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 holder 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.

Disease awareness campaigns are not considered promotion as long as they do not make direct or indirect references to any medicinal product. Indirect references may be unavoidable if the company is the sole owner of the approved product for the disease to which the campaigns refer. In such cases, heightened precautions are necessary.

To further distinguish between promotional and informational content, additional elements should be considered. These include whether the communication is active or reactive, the inclusion of comparative claims about different medicinal products, references to medicinal products by their commercial name, and the involvement of the sales, marketing, and market access departments in the campaign's development or execution.

2.3 Restrictions on Press Releases Regarding Medicines

Press releases in Spain are controversial and should be analysed on a case-by-case basis. According to the Code of Farmaindustria and 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 press release covers a newsworthy event related to a medicinal product, such as a milestone in research and/or authorisation process, which impacts the company's financial performance and it is clearly directed to potential investors,

shareholders and/or the future with a non-promotional tone, it may be considered as corporate information. In this case, it can be published in non-scientific journals directed to the general public, as it is considered informational, not promotional.

Determining Whether a Press Release is Advertising

According to the Code of Farmaindustria, if there is a contractual relationship between the company and the media outlet publishing the press release, it is likely to be considered advertising and subject to the relevant rules. However, Farmaindustria's Deontological Surveillance Unit has clarified that this provision should not be interpreted as automatically classifying as any text written by journalists as advertising merely because there is a contractual relationship. Additional factors must be assessed in each case.

These other factors are mainly the following:

- whether the press release aims to promote the consumption of a product;
- whether the statements are made by experts hired by the company;
- whether the tone is laudatory; and
- in cases of multiple publications, if their content is very similar, suggesting minimal journalistic input, the chances of the release being considered promotional 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 in Annex III a guide with recommendations for companies when interacting with the media. If certain conditions outlined in this guide are met, press releases may not be considered promotional. For instance, it is recommended that the trade mark or the active ingredient of the medicinal product be mentioned sparingly – ie, no more than twice 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 overall tone of the advertisement is balanced and fair.

The competitor's brand name or trade mark can be used in a comparison, provided the use is proportionate and does not seek to unfairly capitalise on the competitor's brand reputation. According to the Code of Farmaindustria, if a competitor's brand names are used, the owner of the brand must be clearly and visibly indicated. However, there is no legal or ethical provision requiring an express reference to the trade mark of the medicinal product, as comparative advertising permits both explicit and implicit references to a competitor (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 the Provision of Information Concerning Unauthorised Medicines or Indications

Advertising of medicinal products which have not obtained a Marketing Authorisation (MA) is not allowed. In certain cases, regulatory authorities and the Code of Farmaindustria allow companies to provide scientific information to HCPs and HCOs prior to the approval of the medicinal products, as long as it is not considered promotional. It is advisable to take a rather restrictive approach regarding these activities, due to the risk of them being seen as promotional in nature. For example, active communications to HCPs and HCOs on unauthorised medicines or indications should be avoided. Only reactive interactions would be permitted provided that they do not include promotional claims or commercial offers.

Additionally, according to Royal Decree 1015/2009, which regulates the use of medicinal products in special situations, MA 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.

Regulatory authorities and 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 HCPs from other countries;
- the materials are written in the language of the country where the product is approved or in English (this requires the product being approved somewhere other than Spain); and
- the materials include a clear warning indicating (at least in Spanish) that the medicinal product is not marketed or authorised in Spain.

While the Code of Farmaindustria does not set a minimum font size for this warning, it is important to ensure that the font size of the warning is clearly visible and proportional to the rest of the text in the material. This can be assessed by comparing the letters in the warning with those used in the main body of the text. 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, rather than the 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

Under Spanish law, advertising of compassionate use programmes or other forms of early access is prohibited. Royal Decree 1416/1994 prohibits the advertising of medicinal products which have not yet obtained a MA in Spain. Furthermore, even when referring to the access of a medicinal product authorised in another country, Royal Decree 1015/2009 expressly prohibits the MA holder in the country of origin from advertising 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 to 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 that are not publicly financed may be advertised to the general public. Furthermore, advertising of medicinal products to the general public for any of the 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 MA 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 MA in any country or any other authorisation.

Reminder advertisements, the purpose of which is to remind the target audience about the medicinal product's name, are only acceptable for products that are well-known and have been promoted for at least two years. These advertisements can only include the name of the medicinal product. According to the Ministry of Health's guide on the advertising of OTC medicinal products, 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 pharmaceutical 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.

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 refrain from (i) requesting to be the exclusive collaborator/sponsor of a PO or any of their principal activities or (ii) trying to influence the content of the publications issued by a PO.

The Code of Farmaindustria also provides that the engagement of patients must be arranged through POs.

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.

Gifts and Informative Materials

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.

In addition, the Code of Farmaindustria considers 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's development and improve their quality of life – 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 services agreements. 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 MA 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 with regards to the therapeutic value of the product.

Reminder advertisements, acceptable for well-known products and 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 (for example, a generic reference to the therapeutic area should also be avoided). The regulatory authorities and the enforcement bodies 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).

Furthermore, 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 and instructions for use of the medical device.

5.4 Advertising of Companion Diagnostics

Spanish regulations do not define or establish a specific legal regime for "companion diagnostics". Their advertising is subject to the general rules governing medicinal products and medical devices, depending on the product's legal qualification.

5.5 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.

5.6 Medical Science Liaisons

Medical science liaisons (MSLs) must not proactively discuss scientific information on unauthorised medicines or indications with HCPs as this may be seen as promotion of unauthorised medicinal products. 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 of Advertising Materials

Advertising directed to HCPs qualified to prescribe or dispense medicinal products does require prior approval from a regulatory or industry authority. However, companies must submit a copy of the advertisement to the health authority of the Spanish autonomous region where the company is based and are responsible for ensuring that only such HCPs have access to the 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.

This is without prejudice to 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 report summarising certain advertising activities

to the health authority of the Spanish autonomous region where the company is based.

6.2 Compliance With Rules Concerning Medicinal Product Advertising

Royal Decree 1416/1994 as well as the Code of Farmaindustria state that the MA 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 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, and 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 and Through Digital and Electronic Platforms Including Social Media

7.1 The Advertisement of Medicinal Products on the Internet

Broadly speaking, advertising activities on the internet are subject to requirements identical to activities performed through traditional channels.

Regarding 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 are also responsible for the content of any external websites linked from their own 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 Material Intended for Healthcare Professionals

The same advertising rules apply to social media. In particular, the ban on promoting prescription-only medicinal products to the public is especially relevant. As a result, advertising such products on publicly accessible social media platforms is prohibited.

The Code of Farmaindustria requires companies to adequately train their employees on appropriate conduct in the digital environment. In this regard, pharmaceutical companies must implement internal good-practice guidelines for their employees and any individual acting on their behalf, under their authority, or through an agreement. Additionally, companies must train employees to prevent inappropriate content on their personal social media, such as comments on competitors' products or off-label promotion.

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

7.3 Provision of Disease Awareness Information to the General Public Online

According to Spanish law, companies must ensure that any part of their website containing promotional information about prescription-only medicinal products is accessible only by HCPs entitled to prescribe or dispense such products. Conversely, it has been generally accepted, based on the guidance from the Ministry of Health's Pharmaceutical Committee, that the unmodified and unabridged publication of information authorised by relevant authorities (for example, the SmPC, the package leaflet, the public assessment reports, and price lists) is not considered advertising and may be published openly on the internet.

Under the Code of Farmaindustria, a clearly legible warning must also be displayed on those parts of the website directed exclusively to HCPs. This warning must state that the information is intended solely for the HCPs entitled to prescribe or dispense medicinal products, and that specialised training is required to correctly interpret the information. Additionally, individuals accessing the content must identify themselves as HCPs entitled to prescribe or dispense medicinal products. Companies can also establish an HCP status verification system in order for HCPs to have access to the information.

7.4 Virtual 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**.

Spanish regulations and the Code of Farmaindustria do distinguish between virtual events based on whether they are considered national or international. Regardless, the Code of Farmaindustria specifies that companies cannot offer hospitality (including social events, accommodation, travel and/or personal/subsistence/pocket expenses) for meetings held in a virtual or remote format. Additionally, notification of online scientific events to Farmaindustria's Deontological Surveillance Unit is not compulsory.

7.5 Use of Social Media

Spanish law does not include specific provisions regarding the use of social media for the promotion of medicinal products. The same rules applicable to other kinds of advertising apply to advertising through social media.

According to the Code of Farmaindustria, companies are responsible for the content disclosed through social media, its means of delivery and for channels of communication that they control (directly or indirectly) or finance (exclusively or as

a majority partner). Therefore, companies must implement codes of conduct for their employees and ensure that there are consequences for non-compliance with such codes. They must also implement procedures for monitoring the content to which they provide access, host, temporarily copy or link. These procedures must address the obligation to correct any irregularity quickly. Companies must also possess guidelines and rules of conduct for their employees and third parties acting on their behalf, or under their control establishing standards for responsible conduct in the digital environment, both for when sharing information about, or in the name of, the company as well as when using a medium, means of delivery or channel provided by the company.

8. Pharmaceutical Advertising: Inducement/Anti-Bribery

8.1 Anti-Bribery Legislation Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals

Under the Spanish Criminal Code, companies may be held criminally liable for bribes offered or given by their employees, directors or other individuals under their control to public officials or to private persons.

The penalties that may be imposed on a company for a bribe are separate from those imposed on the individuals that have committed or participated in the bribe. These penalties can be as high as four times the amount of the profit gained by the company.

However, a company may be exempt from criminal liability if it can demonstrate that, before the bribe was offered or given, it implemented a compliance system that met the conditions and requirements outlined in the Spanish Criminal Code. Additionally, the company must prove that the individuals involved fraudulently bypassed the compliance system and there was no serious failure of the supervision and control duties provided by the system.

8.2 Controls on the Provision by Pharmaceutical Companies of Benefits and/or Inducements to Healthcare Professionals

According to Royal Legislative Decree 1/2015 and the codes of conduct, it is prohibited for any individual with a direct or indirect interest in the production, manufacture and/or marketing of medicinal products to directly or indirectly offer any kind of inducement, bonus, discount, reward or benefit to HCPs involved in the prescription, dispensing and/or administration of medicinal products (or to their relatives or cohabitants). However, gifts, hospitality and discounts may be allowed, provided they comply with the specific requirements set forth in **4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry**, **9.1 Gifts to Healthcare Professionals**, **9.2 The Provision of Samples of Medicinal Products to Healthcare Professionals**, **9.3 Sponsorship of Scientific Meetings** and **9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions**. This prohibition 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 cannot 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 materials, 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 EUR70.

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 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 only be extended to the day after or before the event).

Payments for meals that cost more than EUR70 (taxes included) per person, as well as payments for five-star/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. HCP attendees cannot be reimbursed for expenses incurred with suppliers, except in the case of minor travel costs (taxis, mileage, etc) which must be properly documented. Hospitality cannot be extended to individuals other than the HCP attendees.

9.2 The Provision of Samples of Medicinal Products to Healthcare Professionals

According to Royal Decree 1416/1994, the provision of free samples can only be made on an exceptional basis and requires prior authorisation from the AEMPS. The AEMPS may approve

the distribution of samples for medicinal products that:

- have a new active ingredient;
- 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 MA 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 to 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 resulting published materials.

Companies can also pay for the necessary travel, accommodation and enrolment costs to HCPs attending such congresses or meetings. According to Royal Decree 1416/1994, hospitality must be reasonable (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 in control of 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 EUR70 (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 visits made by sales representatives with 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 The Provision of Samples of Medicinal Products 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 with regards to grants or donations to HCOs. The Code allows donations and/or the funding of the cost of medical or technical services to organisations whose members are HCPs and/or which provide services of sanitary, social or humanitarian assistance, research or teaching, subject to certain conditions. These include 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 formalise these transactions in a written agreement for transparency. 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 volume-related discounts and early payment discounts are acceptable, provided that these do not unfairly affect competitors. These discounts must be documented in the corresponding invoice. The reasonability of these discounts 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

HCPs can be paid for providing services (such as participating in advisory boards, acting as speaker or moderator at scientific meetings, engaging in educational activities and expert meetings), provided that:

- a written agreement stating the nature of the services and the payment criteria is entered into with the company;
- the legitimate need for such services is clearly identified;
- selection criteria for experts align with identified needs and are reviewed by a qualified evaluator – the experts hired must be approved by the scientific service of the company;
- the number of experts hired should be strictly limited to what is reasonably necessary to meet the identified objectives;
- the company must keep documentary records of the services;
- payment must not entail an inducement to promote the prescription, dispensation, sale or consumption of medicinal products;
- the remuneration must be based on market rates, considering the actual hours or services provided, as well as the expert's responsibilities (Payments must be clear and transparent, with proper invoicing from the HCP. In-kind payments are only allowed in exceptional cases with prior authorisation from Farmaindustria's Deontological Surveillance Unit.);
- it is recommended that the agreement include a clause requiring the HCP to disclose that they provide services to the company whenever they write about 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 the provision of services.

Annex IV of the Code of Farmaindustria provides guidelines for action for companies when contracting services from HCPs and HCOs. It also includes a non-exhaustive list of the different types of services and the specific criteria that pharmaceutical companies must comply with.

In addition, the guide in Annex IV includes 23 key questions that companies must answer affirmatively to ensure compliance with the Code's provisions regarding contracts with HCPs and HCOs. These questions are set out in line with the International Federation of Pharmaceutical Manufacturers & Associations's Guidance on Fees for Services.

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

HCPs working in public health system-affiliated HCOs may need their employer's authorisation before accepting hospitality or providing services for a company. The responsibility lies with the HCPs to seek permission, not with the companies offering the hospitality or services.

Under the Code of Farmaindustria, 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 HCPs; 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 the 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 European Federation of Pharmaceutical Industries and Associations (EFPIA) rules on disclosure of transfers of value from pharmaceutical companies to HCPs, HCOs and POs. Consequently, since 2015, companies have been obliged to document and publish on their websites (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 – the recipient of which 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, the Spanish generic medicinal products industry association, 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.

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 Companies 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

The responsibility for enforcing advertising and inducement rules, except for the industry codes of conduct, lies with the health authorities of the Spanish autonomous regions and the 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

Advertising violations under General Law 34/1988 on Advertising will be considered as an unlawful act under Law 3/1991 on Unfair Competition. Actions related to breaches of both regulations are unified to avoid jurisdictional conflicts, and may be pursued either individually or cumulatively. These actions are:

- 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.

In addition to exercising these actions, the claimant may seek damages if the advertiser acted intentionally or negligently, as well as in cases of 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 most frequently discussed issues in these legal procedures include differentiating between advertising and information about products particularly in cases concerning the promotion of prescription-only medicinal products to the public and through press releases. Other key points include ensuring advertising aligns with SmPCs and the fairness of comparative advertising. Several rulings have also addressed the acceptable limits of hospitality provided 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 courts or the health authorities without first raising the issue with the bodies in charge of enforcing these codes.

11.3 Sanctions 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 exceptional 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. A preliminary injunction can be sought during a court case. The likelihood of it being granted depends largely on whether the applicant can demonstrate that they will experience irreparable harm if the injunction is not issued.

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 the fine 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 Jury of Advertising, a specialised body within Autocontrol, is responsible for deciding on matters related to the Code of Farmaindustria and imposing measures and sanctions.

11.4 Relationship Between Regulatory Authorities and Courts

The Codes of Farmaindustria, AESEG and ANEFP require member companies or those adhering to the Codes to address their issues about advertising practices internally by filing complaints with the bodies in charge of enforcing these codes of conduct, before turning to regulatory authorities or the courts.

Notwithstanding the foregoing, the regulatory authorities can investigate matters independently, even if they are being reviewed by self-regulatory bodies, and may act on findings from such bodies. Conversely, the Jury of Advertising of Autocontrol must refrain from assessing issues that are under investigation or have been brought to the regulatory authorities or courts.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

In recent years, there have been few legal cases regarding the advertising of medicinal products in Spain, either before Spanish courts or in Autocontrol. The two latest rulings under the Code of Farmaindustria by Autocontrol were issued in May 2023 and April 2024.

Promoting Medicinal Products in Advance of Pricing/Reimbursement Procedures

There is an ongoing debate over whether having undergone a pricing and reimbursement proceeding is necessary to promote a medici-

nal product. On 30 June 2021, the High Court of Justice of the Basque Country ruled that Spanish law does not prohibit advertising a medicinal product while its pricing and reimbursement decision is pending. This led to modifying the Code of Farmaindustria to update its Q&A (Question 10). However, on 17 June 2022, the High Court of Justice of Madrid ruled that promotion is not allowed until the pricing and reimbursement decision is made, as the final price must be included in promotional material. On 15 November 2023, the Spanish Supreme Court admitted an appeal against the Madrid ruling.

As of the date of this publication, there has been no ruling from the Supreme Court on this matter. Authorities in Madrid and Catalonia are strict, arguing that promotion cannot occur until a pricing and reimbursement decision is made.

For more information about this judgment, and the context and conclusions in connection therewith, refer to the Spain Trends and Developments chapter in this guide.

Amending Royal Decree 1416/1994 on Promotion of Medical Products

In April 2023, the Ministry of Health invited all interested parties to make their proposals regarding the preparation of the draft bill amending the Royal Decree on promotion of medicinal products for human use. 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, see the Spain Trends and Developments chapter in this guide.

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

Royal Decree 1157/2021 regulates the advertising of veterinary medicines in Spain. It allows the advertising of prescription-only veterinary medicines only to veterinarians and authorised dispensers. However, there is an exception for immunological medicines, which can also be advertised to persons responsible for animals.

Advertising of veterinary medicines aimed to the general public must comply with the following requirements:

- it must be consistent with the SmPC of the product;
- testimonials from veterinarians or notorious persons, or expressions that provide assurances of healing, are prohibited; and
- claims on the fact that the product has been granted a MA are prohibited.

Moreover, advertising of veterinary medicines aimed to the general public (except in the case of advertising for branding purposes) must include the following information:

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

Trends and Developments

Contributed by:
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Faus Moliner is a modern boutique law firm that specialises in dealing with the legal matters that are typical within the pharmaceutical industry and companies that operate in the life sciences sector. The firm, 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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The Latest in Pharmaceutical Advertising in Spain

Advertising of prescription-only medicinal products to healthcare professionals once they have received a Marketing Authorisation but before the price and reimbursement decision is issued by the Ministry of Health

In Spain, prescription-only medicinal products cannot be placed on the market right away once a Marketing Authorisation (MA) has been granted. 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 Ministry of Health (MoH) so that the MoH may decide whether to reimburse it or not. In the affirmative, the MoH shall issue a decision (ie, a price and reimbursement decision – "P&R Decision").

The possibility of advertising a product after a MA, but before a P&R Decision, has been controversial in Spain, mainly due to the Spanish authorities' interpretation of 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 and sets out 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".

Spanish authorities have traditionally understood that advertising may not take place until a P&R Decision has been taken, because otherwise Article 10.2 of Royal Decree 1416/1994 cannot be complied with considering the information about the price and reimbursement conditions of the product.

However, on 30 June 2021, an important judgment on this 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 prohibits the advertising of products that have received a MA, even if a P&R Decision is pending.

As a result, Farmaindustria modified the Q&A section (Q10) 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.

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. The High Court of Justice of Madrid considered that until the 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.

This ruling does not state that Royal Decree 1416/1994 or the Royal Legislative Decree 1/2015 prohibits promotion before the P&R

Decision but focuses its argumentation on the minimum content that promotional materials of medicinal products must include 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 said Article 10.2 of Royal Decree 1416/1994.

On 15 November 2023, the Spanish Supreme Court admitted an appeal against the judgment of the High Court of Justice of Madrid. The Spanish Supreme Court typically takes six months to two years to decide. If it annuls the ruling, it could pave the way for promoting medicinal products before the P&R Decision. As of the date of this publication, there has been no ruling from the Supreme Court on this matter.

For the time being, authorities in Madrid and Catalonia are strict, arguing that promotion cannot occur until a pricing and reimbursement decision is made.

Upcoming legislative changes

In April 2023, the Ministry of Health invited all interested parties to make their proposals regarding the preparation of the draft bill amending Royal Decree 1416/1994. Among the aspects that the new proposed draft bill is aimed to address are:

- the need to tackle digital advertising;
- the use of social media and audiovisual means;
- the necessity of addressing the distribution of competencies between the state and autonomous communities; and
- the inclusion of obligations for accessibility in advertising for individuals with sensory disabilities.

The interested parties presenting their proposals also suggested that this new draft bill should address aspects such as the possibility to promote medicinal products before the P&R Decision or to provide hospitality to HCPs in the context of events of promotional nature (not only scientific, which is the only aspect contemplated currently), and the possibility for companies to interact with patient organisations and to provide training to HCPs. These two last aspects are only considered within the Code of Farmaindustria, but not within the Royal Decree 1416/1994.

This new Royal Decree is expected to be enacted during 2025.

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