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Pharmaceutical Advertising

Spain
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Law and Practice

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1. Regulatory Framework

1.1 Laws and Self-Regulatory Codes

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 on advertising are comprised in General Law 34/1988 on Advertising and Law 3/1991 on Unfair Competition. On the other hand, the provisions contained in EU Directives on advertising of medicinal products have been implemented in Spain through Royal Decree 1416/1994. In this regard, 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, some Spanish autonomous regions which are competent for the implementation of rules on advertising of medicinal products (Spain is divided into 17 autonomous regions) have adopted guidelines reflecting the position of the regional authorities on certain matters (the most important ones are the ones issued in the regions of Madrid and Catalunya). Furthermore, in 2011 the Ministry of Health issued the first version of a Guide on the advertising of over-the-counter medicinal products, including rules of conduct on the promotion of OTC medicinal products to the general public. In 2019, the Spanish Ministry of Health published an updated version of such Guide. Royal Decree-legislative 1/2015 on medicinal products and medical devices is also important as it sets forth the sanctions for breach of the rules on advertising of medicinal products.

In addition to the above-mentioned rules, Spanish trade associations of different sectors of the pharmaceutical industry have adopted codes of conduct which regulate interactions with healthcare professionals (HCPs), healthcare organisations (HCOs), and patient organisations (POs). Farmaindustria, the Spanish innovative medicinal products industry association, published in 2002 the first version of its 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), and has since updated it several times (the last version of this Code was published in October 2016, updating the rules on transfers of value to HCPs, HCOs, and POs). 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

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 Difference Between Information and Advertising

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

- the labelling, the Summary of Product Characteristics, 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:

- 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; and
- texts written and produced by journalists within the scope of 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.

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

This is a controversial issue in Spain and it should be analysed on a case-by-case basis. According to 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 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, it may be considered as corporate information, and, therefore, may be published in non-scientific journals directed to the general public. However, if there is a contractual relationship between the company and the media where a press release is published, the press release will be deemed to be an advertising material and must therefore be subject to the rules regarding this activity.

2.4 Comparative Advertising

Under the 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 competitors' 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 to refer to a competitor either explicitly or implicitly (Ruling of Jury of Advertising of Autocontrol on the case "Sanofi-Aventis vs Italfarmaco – Hepaxane®", dated 8 January 2020).

Comparative advertising directed to the general public is only allowed for products of the same pharmaceutical company.

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 (as described in the following sections) regulatory authorities, as well as the provisions of the Code of Farmaindustria, accept the possibility that companies make information available to HCPs and HCOs prior to the approval of the medicinal products if it is merely a transfer of 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 resulting from 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.

On the other hand, 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 clearly indicate (at least in Spanish) that the medicinal product is not marketed or authorised in Spain.

3.3 Provision of Information to Healthcare Professionals

Any company may respond to specific requests for information from the HCPs, provided the conditions mentioned in **2.2 Difference Between Information and Advertising** are met. Information must be provided reactively and not proactively. However, it is more 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 provisions in Spanish law or in the Code of Farmaindustria regarding the sending of information on unauthorised medicinal products or indications. 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 prepare their budget, provided it does not contain promotional statements.

3.5 Publication of Compassionate Use Programmes

Advertising compassionate use programmes is prohibited under Spanish law. Royal Decree 1416/1994 prohibits any advertisement 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 to make any advertising on the use of the medicinal product.

4. Advertising to the General Public

4.1 Main Restrictions on Advertising 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 Decree-legislative 1/2015, Royal Decree 1416/1994 and the Code of Farmaindustria.

On the contrary, non-prescription medicinal products (OTC medicinal products) which are not publicly financed may be advertised to the general public.

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. Furthermore, advertising of medicinal products to the general public for the 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.

4.2 Information Contained in 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, does 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; and
- 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, is acceptable only for products sufficiently known and which have been promoted for at least two years, 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 kind of 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 these matters.

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, 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 kind of collaborations, and must not be the exclusive sponsor of a PO, nor try to influence in 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 the prior approval by the Farmaindustria's Deontological Surveillance Unit. Hospitality offered by the company must always be reasonable and remain subordinated to the main scientific objective of the event. Hospitality must be limited to the travel, accommodation, meals and registration expenses (it must not include the organisation of leisure or entertaining activities), and must only be made available to accompanying persons if they attend as helpers of patients. Payment of such kind of expenses has to be made through the PO.

It is also possible to pay 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:

- enter 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 cooperating 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 documental records of the services provided;
- the payment to 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 he/she provides services to the company every time he or she writes or publicly asserts any matter related with the company.

Additionally, under the Code of Farmaindustria companies have to 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 its 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 it is possible to determine it.

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, use of 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 on the case "Gilead vs 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 him/herself verify the truthfulness and accuracy of the information.

5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

Advertising the use of one medicinal product in combination with another one 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 on the case "Gilead vs 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 medicinal device.

5.4 Restrictions on Reprints of Journal Articles

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. Reprints may be accompanied by corporate advertising relating to the pharmaceutical company, but such advertising must not have any connection with the scientific information.

5.5 Medical Science Liaisons

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 Difference Between Information and Advertising** 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 advertisements 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 ensur-

ing 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 of Farmaindustria 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. Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

Broadly speaking, advertising activities on the Internet are subject to identical requirements as those which are performed through traditional channels.

As regards advertising directed to HCPs through 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 should need to identify themselves in order 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 Internet, may also apply.

7.2 Advertising of Medicines on Social Media

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 in this regard.

7.3 Restrictions on Access to Websites

According to the Spanish regulations, the 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. On the other hand, 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.

7.4 Provision of Disease Awareness Information to Patients Online

Companies may provide information to patients online on disease awareness, as long as such information does not contain any direct or indirect reference to any medicinal product or active substance.

8. Inducement/Anti-bribery

8.1 General Anti-bribery Rules

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, 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 Decree-legislative 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 **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 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

According to Royal Decree 1416/1994, a gift 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 allowed to give memory cards containing informative or formative material, provided its 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 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. Transparency**.

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 costs 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 services providers. No monetary reimbursement can be made to the HCPs attendees for expenses incurred to suppliers, except in the case of minor travel costs (eg, 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
- samples 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. 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 congress or meetings. According to Royal Decree 1416/1994, hospitality must be reasonable in level (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:

- 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 the 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) is 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; and
- companies must comply with the transparency obligations referred in **10. Transparency**.

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. Transparency** regarding the offer of grants or donations to HCOs.

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

With regard to 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 in prejudice of 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.

With regard to 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:

- it is necessary to enter 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 shall not exceed the number reasonably necessary to achieve the identified objectives;
- the company must keep documental records of the services provided;
- the payment to 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 must 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. Transparency** regarding the payments made to HCPs related to said provision of services.

9.8 Prior Authorisations or Notifications

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:

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

10. Transparency

10.1 Requirement 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 (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 its purpose - whose recipient is a HCP or HCO. The only payments excluded from this obligation are those associated with commercial transactions with distributors, retail pharmacies, as well as 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 has ruled that companies must inform HCP on the disclosure of his or her personal data. However, there is no need that the HCP consents to the disclosure of his or her 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.

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

Transparency requirements described above 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 for the case that 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 in the market is irrelevant for this purpose.

11. Enforcement

11.1 Enforcement Bodies

Except for the 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 Advertising Infringements

Any advertising in breach of the General Law 34/1988 on Advertising will be considered as an unlawful act under the 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: 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 of the right to claim damages, if the advertiser has acted wilfully or negligently and/or 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.

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.

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 contents of the SmPCs, and the conditions under which comparative advertising is fair. Another area on which various rulings have been adopted refer to the limits on hospitality that may be offered to HCPs.

11.3 Penalties for Violating 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.

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, if the breach was intentional, if there was fraud or connivance, if 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.

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 adhered 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. On the other hand, 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

During the last few years, the number of complaints filed by companies under the relevant code in respect of competitors' advertising materials or promotional activities decreased sharply. In contrast, the bodies responsible for ensuring compliance with the Code of Farmaindustria were very active during said period, resulting in an increased number of cases where companies had to adopt corrective measures. In some cases, settlement was accompanied by a voluntary economic contribution made by companies to the fund created by Farmaindustria to promote rational use of medicinal products.

On the other hand, in early 2018, the Spanish regulatory authorities announced their intention to review and update the provisions contained in Royal Decree 1416/1994, currently regulating advertising of medicinal products for human use in Spain. To this end, these authorities launched a public consultation to gather the opinion of the interested parties. Nevertheless, up until today, the key points which will be reviewed and updated have not published.

Faus & Moliner Abogados is a modern boutique law firm, specialised in dealing with legal matters typical of the pharmaceutical industry and other 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 pharma 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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