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Pharmaceutical Advertising

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Law and Practice

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Contents

Faus & Moliner was founded in 1997 and focuses on pharmaceutical law, commercial contracts, corporate transactions, corporate governance, compliance, competition law, public procurement, product liability, advertising, litigation and arbitration. Faus & Moliner 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. The firm decided to pursue this specialisation route because its founding partners were convinced that they would be able to create more value for clients if they not only offered solid legal skills, both theoretical and practical, but also a deep knowledge of the social and economic environment of the sector in which their clients operate. Faus & Moliner combines legal skills and specialisation with a practical and business-oriented manner of practising law, allowing it to offer innovative solutions and at the same time to provide adequate responses to the cases which are entrusted to it. Nowadays, the firm is formed of ten lawyers, all of them specialised in the life sciences sector.

Authors

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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, regulatory authorities guidelines and codes of conduct adopted on a voluntary basis by the pharmaceutical industry.

General rules on advertising are incorporated 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 through Royal Decree 1416/1994. In this regard, the Ministry of Health issued an Instruction in 1995 (Circular 6/1995) regarding the interpretation of this Royal Decree. In addition, some Spanish autonomous regions (Spain is divided into 17 autonomous regions), which are competent for the implementation of rules on advertising of medicinal products, 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 published a guide on the advertising of over-the-counter (OTC) medicinal products to the general public. 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 that regulate interactions with healthcare professionals (HCPs), healthcare organisations (HCOs) and patient organisations (POs). Farmaindustria, the Spanish innovative medicinal products industry association, published the first version of its code of conduct on the promotion of prescription-only medicinal products in 2002. It has since been updated several times (the last version of the code was published in September 2016, updating the rules on transfers of value to HCPs, HCOs and POs). The Spanish generic medicinal products industry association (AESEG) and the Spanish over-the-counter medicinal products industry association (ANEFP), 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 its affiliates and third companies under their control complying with the code when they perform promotional activities in Spain and/or they undergo interactions 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 shall include:

- advertising directed at the general public;
- advertising directed at 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
- inducing to prescribe or dispense medicinal products by means of giving, offering or promising any benefit, whether 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 shall not be considered as advertising of medicinal products, and, therefore do not fall under the rules that apply to such advertising:

- the labelling, the Summary of Product Characteristics (SmPC) and the leaflet of the medicinal product;
- correspondence accompanied, where applicable, by any document of a non-promotional nature (for example, scientific articles) that is needed to respond to a specific question about a particular medicinal product, but only if it refers to the question that is the subject of enquiry;
- specific information and relevant documents related to, for example, changes in packaging, adverse reaction warnings in the framework of pharmacovigilance, sales catalogues and price lists, provided that no 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 shall not be considered as advertising of medicinal products:

- information on certain medicinal products that the physician can provide to the patient that, due to the complexity of dosage, route of administration, etc, require providing additional information – only if such information is intended to improve adherence to treatment;
- corporate advertising, meaning advertising that relates to the company, provided there are no references, 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 the trade mark of the medicinal product.

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 Comparative Advertising

Under the Law 3/1991 and the Code of Farmaindustria, comparative advertising directed at 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.

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

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 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. The fact that the owner of the medicinal product sponsors the event where the information is made public is not relevant if the requirements regarding the contents of the information are met.

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. The materials must also clearly indicate (at least in Spanish) that the medicinal product is not marketed or authorised in Spain.

3.2 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. 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.

3.3 Provision of Information to Healthcare Institutions

There are no provisions in Spanish law or in the Code of Farmaindustria regarding this matter. In practice, regulatory authorities and the authorities responsible for enforcing 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.

4. Advertising to the General Public

4.1 Main Restrictions on Advertising to the General Public

Advertising of prescription-only medicinal products and/or public financed medicinal products directed to the general public is prohibited under 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 any of the following therapeutic indications is not allowed:

- tuberculosis;

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

4.2 Information Contained in Advertising to the General Public

Messages shall 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 shall not contain any statement that:

- 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/or
- mentions that the product has obtained a marketing authorisation in any country or any other authorisation.

Reminder advertisements, the purpose of which is merely to remind the target audience about the name of the medicinal product, are acceptable only for products sufficiently known and that have been promoted for at least two years. Reminder advertising 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 types 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 shall 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 shall be held at appropriate venues, avoiding those that 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 subordinate to the main scientific objective of the event. Hospitality shall be limited to the travel, accommodation, meals and registration expenses (it shall not include the organisation of leisure or entertaining activities) and shall 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 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:

- a written agreement is entered into 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 shall be clearly identified;

- the criteria used to choose the expert shall be related to the identified needs; the person in charge of the selection shall have the necessary expertise to evaluate the candidates; the experts hired shall be approved by the internal supervisor of the company;
- the number of experts hired shall not exceed the number reasonably necessary to achieve the identified objectives;
- the company shall keep documental records of the services provided;
- the payment to the PO shall not entail an inducement for the PO to recommend the medicinal products of the company;
- the remuneration paid shall 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 or 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 shall 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 a 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.

4.4 Restrictions on Endorsements by Healthcare Professionals

There are no provisions in Spanish law regarding these matters.

However, the Code of Farmaindustria states that the use of personal quotes from HCPs in promotional materials shall reflect exactly the opinion of the author and shall not be used without his or her specific consent. A very cautious approach to this practice is recommended because Spanish authorities are rather strict in scrutinising these endorsements, in order to verify that there is no economic interest behind the declarations quoted in the promotional materials.

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 at HCPs legally entitled to prescribe or dispense medicinal products shall 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. In any case, studies must be adequately reflected in the promotional material, in a way that its addressee may by him- or herself verify the truthfulness and accuracy of the information.

5.3 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 shall not have any connection with the scientific information.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

Advertising directed at 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 ensuring that only HCPs entitled to prescribe or dispense medicinal products shall have access to the relevant publication. However, the Ministry of Health may, in exceptional circumstances, make advertising of a specific product subject to a 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 at the general public does not need to be approved in advance by a regulatory or industry authority.

This is without prejudice of the fact that any advertising is subject to review 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 and as the Code of Farmaindustria state that the marketing authorisation holder shall 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 also obliged to have a written procedure in order to monitor compliance with the Code. Additionally, the Code of Farmaindustria recommends that the different departments (marketing–sales, medical, regulatory, legal, finance–administrative) participate and are 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

In general terms, advertising activities on the internet are subject to identical requirements as those that are performed through traditional channels.

As regards internet advertising directed at HCPs, valid channels within a context that is basically scientific or professional must be used. Those channels shall be intended exclusively for HCPs authorised to prescribe or dispense medicinal products; those HCPs should need to identify themselves in order to have access to the information. Companies should be aware that they shall be also liable for the content of the websites accessed by a link from their own website(s).

As regards advertising directed at the general public, the Guide on advertising of OTC medicinal products published by the Ministry of Health states the following specific requirements (additional to the general requirements for advertising of OTC medicinal products) for advertising on the internet:

- information regarding the medicinal products shall be clearly differentiated from the general information included in the website, such as information about illnesses, health advices, etc;
- the top side of the webpage may only include the brand name or the trade mark of the product, provided that the complete name of the same appears in the main page; and
- the date of last actualisation of the webpage shall be stated.

Law 34/2002 on Information Society Services and Electronic Commerce, as well as some provisions contained in Royal Decree 870/2013, which regulates the sale of OTC medicinal products through the 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 Spanish regulations, the company must ensure that those parts of its website that contain promotional information about prescription-only medicinal products may only be accessed by HCPs entitled to prescribe or dispense such products.

Under the Code of Farmaindustria, a clearly legible warning must also be included in those parts of the website directed at HCPs only. It will indicate 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.

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), shall normally not be considered as advertising and can therefore be openly published on the internet.

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 that 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**, below. This prohibition shall 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 stationery 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, and pens and notepads 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**.

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 – provided that the prior authorisation from AEMPS is obtained. Authorisation by the AEMPS may be granted only for medicinal products that:

- 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 must be observed:

- 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 shall not be bigger than the smallest presentation of the product authorised in Spain;
- each sample shall be marked "free sample – not for sale" and its reimbursement sticker shall have been annulled; and
- samples shall 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 Transparency**, below.

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 shall be stated in all documents related to the event and 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 shall abide by the rules of the code of conduct applicable in the country where the event is located;
- a limit of EUR60 is established for meals and luncheons per guest;
- hospitality shall 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 to in **10 Transparency**, below.

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

The hospitality offered to HCPs cannot include the organisation or payment 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**, **9.2** and **9.3**. 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 dona-

tions and/or the funding of the cost of medical or technical services to institutions, organisations, associations and foundations whose members are HCPs and/or that 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**, below, 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 appropriateness of the discount shall 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 shall be clearly identified.
- The criteria used to choose the expert shall be related to the identified needs, and the person in charge of the selection shall have the necessary expertise to evaluate the candidates. The experts hired shall 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 shall keep documental records of the services provided.
- The payment to HCP shall not entail an inducement to promote the prescription, dispensation, sale or consumption of medicinal products.
- The remuneration shall 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; 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 shall 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.
- 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 who 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 shall have to 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 HCPs 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 that 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 cases 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 in this situation.

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 shall 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 that 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 SmPC 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 that companies notify to them. 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 resolution 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 shall 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 shall be fixed depending on 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 resolutions 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 the companies adhered to these codes shall file their claims against the advertising practices of other companies before the bodies in charge of enforcing these codes of conduct prior to raising the issue with the regulatory authorities or the courts.

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 shall refrain from assessing any issue that 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. By 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 that will be reviewed and updated have not been published.

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