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The International Comparative Legal Guide to:

Pharmaceutical Advertising 2015

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A practical cross-border insight into pharmaceutical advertising

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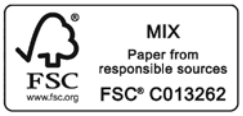

General Chapter:

Country Question and Answer Chapters:

Spain

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1 General – Medicinal Products

1.1 What laws and codes of practice govern the advertising of medicinal products in Spain?

Advertising of medicinal products in Spain is governed by a combination of legislation and codes of practice.

The provisions contained in European Union Directives regarding the advertising of medicinal products have been implemented through Royal Decree 1416/1994. The Ministry of Health issued an Instruction in 1995 (Circular 6/1995) reflecting the position of the authorities regarding the interpretation of Royal Decree 1416/1994 on certain matters. Some Autonomous Regions (regional authorities) which are competent for the implementation of these rules have also issued Guidelines. Some provisions contained in Law 29/2006 on medicinal products and medical devices may also be relevant, especially with regard to sanctions for breach of the rules.

In addition to this set of rules, Farmaindustria, the Spanish Pharmaceutical Industry Association, published the Code of Conduct of the pharmaceutical industry in 2002, which has been amended and updated several times (hereinafter, the "Code of Conduct"). The latest version of the Code of Conduct came into force on 1 January 2014. This Code updates and consolidates in a single text the rules on the interaction of the pharmaceutical industry with healthcare organisations and patient organisations.

ANEFP, the industry association which is responsible for over-the-counter medicines, has also approved its own Code of Conduct on the promotion of OTC medicinal products. Furthermore, the Ministry of Health published a Guide on the advertising of OTC medicinal products in April 2011 (which includes a Code of Conduct on the promotion of medicinal products to the general public), which is expected to be updated in the coming years.

In addition to medicinal product-specific rules, other general legislation may be relevant, such as the 1988 Law on Advertising and the 1991 Law on Unfair Competition (both of them modified by Law 3/2013).

1.2 How is "advertising" defined?

According to Article 1 of the Royal Decree 1416/1994, advertising of medicinal products shall include any form of informative offer, commercial research or inducement designed to promote the prescription, dispensation, sale or consumption of medicinal products. The advertising of medicinal products shall include, in particular:

- Advertising of medicinal products to the general public.
- Advertising of medicinal products to persons qualified to prescribe or dispense them.
- Visits by medical sales representatives or informative agents to persons qualified to prescribe or dispense medicinal products.
- Supply of samples.
- Sponsorship of promotional meetings attended by persons qualified to prescribe or dispense medicinal products.
- Sponsorship of scientific congresses attended by persons qualified to prescribe or dispense medicinal products and, in particular, payment of their travel and accommodation expenses in connection therewith.
- 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 intrinsic value is minimal.

1.3 What arrangements are companies required to have in place to ensure compliance with the various laws and codes of practice on advertising, such as "sign off" of promotional copy requirements?

According to Articles 20 and 21 of the Royal Decree 1416/1994, as well as the Code of Conduct, the marketing authorisation holder shall establish within its undertaking a scientific service in charge of the management of the information related to the medicinal products marketed by the company. The company and the scientific service must fulfil the following obligations:

- Revise and control any promotional materials in order to ensure that the advertising of medicinal products complies with the legal requirements and that the information contained in such materials is in accordance with the marketing authorisation and the SmPC.
- Ensure that the medical sales representatives and any personnel involved in the promotion of medicines or interaction with healthcare professionals or patient organisations 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 of medicinal products.
- Supply the Health Authorities with the information and assistance they require (including a sample of all advertisements performed) and ensure that the decisions of the Health Authorities are immediately and fully complied with.

On the other hand, the Code of Conduct obliges pharmaceutical companies to have a written procedure for internal monitoring of compliance with the Code of Conduct.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities? If so, what aspects should those SOPs cover?

Yes, companies must have written procedures for internal monitoring compliance with the Code of Conduct. Additionally, the Code of Conduct recommends that the different departments (Marketing-Sales, Medical, Regulatory, Legal, Finance-Administrative) participate and get involved in the committees, policies or internal procedures that the company implements in this area.

1.5 Must advertising be approved in advance by a regulatory or industry authority before use? If so, what is the procedure for approval? Even if there is no requirement for prior approval in all cases, can the authorities require this in some circumstances?

Advertising to persons 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 Autonomous Region where the company is located, accepting responsibility for ensuring that only persons entitled to prescribe or dispense medicinal products shall have access to the relevant publication.

On the other hand, the Ministry of Health may, in exceptional circumstances, make advertising of a specific medicinal product to healthcare professionals subject to a prior approval system. Any decision of this nature must be duly justified and shall affect all products having the same composition.

Since July 2013, advertising of over-the-counter (OTC) medicines to the general public no longer require any administrative authorisation.

According to Article 21 of Royal Decree 1416/1994, companies must send an annual index with all its advertising activities to the Health Authority of the Autonomous Region where the company is located.

1.6 If the authorities consider that an advertisement which has been issued is in breach of the law and/or code of practice, do they have powers to stop the further publication of that advertisement? Can they insist on the issue of a corrective statement? Are there any rights of appeal?

Health Authorities may suspend an advertisement if it is contrary to the applicable laws and regulations. Furthermore, if the advertisement constitutes a risk for the health or security of consumers, the Health Authorities may order the publication of the resolution and a corrective statement where the advertisement was published.

The decision by the Health Authorities may be appealed within the term of one month to its administrative superior at the Ministry of Health.

These actions are without prejudice of the fact that some authorities may initiate any of the remedies of cessation and rectification foreseen under the Law on Advertisement and the Law on Unfair Competition.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? To what extent may competitors take direct action through the courts?

Failing to comply with the rules governing the advertising of medicines may 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 it 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 prejudice caused, and the profits obtained from the infringement.

The responsibility for enforcing these rules lies with the Autonomous Regions. These authorities are rather strict in scrutinising materials which companies notify to them. Sometimes their action is limited to a warning and a request to amend the materials or to refrain from their further use. In some cases, however, they enforce the rules by imposing fines.

Under the Code of Conduct, companies have agreed not to file complaints against each other directly before the Courts or the Health Authorities without first raising the issue with the Code of Conduct Commission. The procedure at the Commission may conclude 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 Conduct refers. The competent body to impose these sanctions is the Jury of Advertising, a specialised body within the Association for Self-regulation of Advertising.

Since the Code of Conduct became applicable, several companies have been fined.

Public authorities may also act *ex officio* against companies breaching these rules. In some cases, criminal sanctions may apply.

1.8 What is the relationship between any self-regulatory process and the supervisory and enforcement function of the competent authorities? Can, and, in practice, do, the competent authorities investigate matters drawn to their attention that may constitute a breach of both the law and any relevant code and are already being assessed by any self-regulatory body? Do the authorities take up matters based on an adverse finding of any self-regulatory body?

The Code of Conduct states that laboratories that adhere to the Code shall file their claims against the advertising practices of other companies before the Code of Conduct Deontological Commission before raising the issue with the Health Authorities or the Courts.

This notwithstanding, the Health Authorities may, and in practice do, 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 which is being or has been assessed by the Health Authorities or the Courts.

1.9 In addition to any action based specifically upon the rules relating to advertising, what actions, if any, can be taken on the basis of unfair competition? Who may bring such an action?

According to Law 29/2006, any advertising in breach of the Law of Advertising shall be considered as an unlawful act under the Law on Unfair Competition. Furthermore, the actions that may be taken for breach of the Law on Advertisement and for breach of the Law on Unfair Competition have been unified in order to avoid any conflict between jurisdictions. Such actions are the following (which may be taken individually or on a cumulative basis):

- 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.
- Action of rectification of any deceitful, incorrect or false information contained in the unlawful advertising, including the publication of the court ruling.

All of the above 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.

2 Providing Information Prior to Authorisation of Medicinal Product

2.1 To what extent is it possible to make information available to healthcare professionals about a medicine before that product is authorised? For example, may information on such medicines be discussed, or made available, at scientific meetings? Does it make a difference if the meeting is sponsored by the company responsible for the product? Is the position the same with regard to the provision of off-label information (i.e. information relating to indications and/or other product variants not authorised)?

Any advertising of a medicinal product which has not obtained a marketing authorisation is expressly prohibited in Article 2 of Royal Decree 1416/1994.

Some authorities understand, however, that in some specific cases, making information available to healthcare professionals should not be seen as advertising and should be considered merely a transfer of scientific information. In these cases, the authorities are ready to accept that information on medicines may be given prior to their approval. However, it is sensible to take a rather restrictive approach regarding these activities, because any materials containing promotional statements shall undoubtedly be considered as illegal advertising.

On the other hand, the authorities and the Code of Conduct accept that information on products authorised in countries other than Spain may be given at international congresses or meetings held in Spain attended by numerous professionals from other countries, provided that the materials are written in the language of the country where the product is approved or in English, and that the company giving this information clearly indicates (at least in Spanish) that the medicinal product is not marketed or authorised in Spain.

The same position should apply to the provision of off-label information. In fact, Royal Decree 1015/2009, of 19 June, which regulates the use of medicinal products in special situations, states in article 16 that marketing authorisation holders must neither make any off-label promotion of any medicinal product, nor distribute any type of material which may indirectly stimulate the use of the product in conditions different from those resulting from the SmPC.

2.2 May information on unauthorised medicines and/or off-label information be published? If so, in what circumstances?

Information on unauthorised medicines and/or off-label information may not be published. Only objective and appropriate information of genuine scientific interest which is not promotional may be provided upon prior request.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply?

It is possible to issue press releases to both professional and general audiences, provided that the releases concern a matter of legitimate interest for potential investors, shareholders or future employees for its possible impact on the future economy of the company (for example, significant developments in the process of research, evaluation or authorisation of a medicinal product) and that they are not promotional in tone. Referring to a trade name, for instance, may raise an issue. If a contract exists between the company and the media where a press release is published, the press release shall be deemed to be advertising material and must therefore be subject to the general rules.

2.4 May such information be sent to healthcare professionals by the company? If so, must the healthcare professional request the information?

Any company may respond to specific requests for information, but when doing so, it must not attach any promotional material to its answer. It is safer to channel these matters through the medical affairs department rather than through sales and marketing departments.

2.5 How has the ECJ judgment in the *Ludwigs* case, Case C-143/06, permitting manufacturers of non-approved medicinal products (i.e. products without a marketing authorisation) to make available to pharmacists price lists for such products (for named-patient/compassionate use purposes pursuant to Article 5 of the Directive), without this being treated as illegal advertising, been reflected in the legislation or practical guidance in Spain?

There is no rule under Spanish legislation specifically reflecting the ECJ judgment in the *Ludwigs* case. As set forth above, any advertising of a medicinal product which has not obtained a marketing authorisation is expressly prohibited in Article 2 of Royal Decree 1416/1994. However, the same Royal Decree states that price lists shall not be considered as advertising, provided that such lists do not contain information regarding the medicinal products.

2.6 May information on unauthorised medicines or indications be sent to institutions to enable them to plan ahead in their budgets for products to be authorised in the future?

There are no provisions in Spanish law or in the Code of Conduct regarding these matters. However, in practice this is accepted by the Spanish authorities provided that said information does not contain any promotional elements.

2.7 Is it possible for companies to involve healthcare professionals in market research exercises concerning possible launch materials for medicinal products as yet unauthorised? If so, what limitations apply? Has any guideline been issued on market research of medicinal products?

Involving healthcare professionals in market research and other such exercises is accepted as long as the requirements set forth in questions 2.4 and 5.4 are met.

According to the Code of Conduct, market research studies (including social and opinion research) must meet the following requirements:

(i) The conduct of the study shall not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products. Studies must be approved prior to their conduct by the scientific service or by the compliance officer. The sales network of the pharmaceutical company cannot play any role in the conduct and implementation of the study.

(ii) Have a written protocol in which its objectives, methodology, expected results and its use are clearly established. Proportionality between the universe and the sample must be guaranteed (simple random sample, a margin of error of 5%, 95% confidence and 50% heterogeneity level).

(iii) Written agreements shall be signed with the professionals and/or the entities with which the studies will be carried out, specifying the nature of the services to be provided, the professionals' participation and payment conditions, etc.

(iv) Payments to participating professionals must be based on market criteria and be proportionate to the time devoted, the work done, and the responsibilities assumed, and must be adequately documented. Payments shall be made in cash.

(v) The responses or data obtained must be pooled processed.

(vi) The study results will not be advertised or used in promotional material.

Any exception to the former requirements should have prior approval of the Farmaindustria Code of Conduct Surveillance Unit. In any case, companies must communicate studies to the Farmaindustria Code of Conduct Surveillance Unit prior to their start. This communication is not mandatory in any of the following circumstances:

(i) The sponsoring or financing by the company does not exceed 50%.

(ii) The company does not have access (before, during or after the study) to the identity of healthcare professionals who participate in the study, nor has it participated in their selection, beyond the definition of the type of healthcare professional participating.

(iii) The study does not imply any remuneration for the participants or it implies the remunerated participation of less than 20 healthcare professionals.

The Code of Conduct obliges companies to comply with the transparency obligations referred to in question 7.2 for market research studies when a company knows the identity of the healthcare professional or health organisation that participate in said study.

3 Advertisements to Healthcare Professionals

3.1 What information must appear in advertisements directed to healthcare professionals?

As regards advertisements to healthcare professionals, according to article 10 of Royal Decree 1416/1994, such advertisements must include:

- The name of the medicinal product.
- The name and address of the marketing authorisation holder.
- Qualitative and quantitative composition.
- Essential data of the SmPC.
- 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 reimbursed by the Spanish National Health System.
- The estimated cost of treatment if it is possible to determine it.

Abbreviated advertisements will only be accepted as a reminder for products which have been authorised for more than two years and will consist solely of the name of the product and the International Common Denomination if the medicinal product contains only one active substance, as well as the logo of the medicinal product and the pharmaceutical company. No other statements may be included in an advertisement of this nature, but the authorities do accept pictures of the packaging, notwithstanding the fact that, by inserting such pictures, the advertisement includes particulars such as the pharmaceutical form or the package size.

3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to studies not mentioned in the SmPC?

In general terms, the information that may appear in an advertisement shall be precise, balanced, honest, objective, based on adequate scientific evaluation and sufficiently complete as regards the therapeutic value of the medicinal product.

An advertisement may refer to studies not included in the SmPC, provided that such studies do not contradict the information included in the SmPC. In any case, the Code of Conduct requires that the studies shall be quoted in an exact manner and tables or graphics shall be reproduced literally.

3.3 Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional materials?

The Code of Conduct states that the use of personal communications or quotes from healthcare professionals in promotional materials shall reflect exactly the opinion of the author and shall not be used without his/her express consent.

We recommend a very cautious approach to this practice because authorities are rather strict in scrutinising endorsements by healthcare professionals in order to verify that there is no economic interest behind the declarations quoted in the promotional materials.

3.4 Is it a requirement that there be data from any, or a particular number of, "head to head" clinical trials before comparative claims may be made?

No, this is not a requirement in Spain.

3.5 What rules govern comparative advertisements? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product which had not yet been authorised in Spain?

Comparative advertising is regulated under the General Law on Advertising and the Code of Conduct. Such advertising is legal if: (i) the products or characteristics compared are comparable, essential and relevant; and (ii) the comparison is objective. Comparisons of medicinal products are generally accepted and widely used, subject always to the general tone of the advertisement being balanced and fair.

The competitor's brand name or trademark 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 such trademark. Reference to medicinal products not yet authorised in Spain must comply with the rules set forth in question 2.1.

As regards advertising to the general public, comparison between medicinal products is only allowed for products of the same pharmaceutical company.

3.6 What rules govern the distribution of scientific papers and/or proceedings of congresses to healthcare professionals?

Royal Decree 1416/1994 states that information regarding human health or diseases shall not be considered as advertising provided there is no reference, even indirectly, to medicinal products.

The Code of Conduct further states in this regard that scientific papers published in renowned scientific sources shall not be considered as advertising and can be therefore freely distributed to doctors, provided they do not contain printed, stamped or electronically-linked trademarks or trade names of medicines, advertising slogans or other advertising material, related or not to this information. Such documentation may be accompanied by corporate advertising about the laboratory, but this corporate information shall not have any connection with the scientific information.

3.7 Are "teaser" advertisements permitted that alert a reader to the fact that information on something new will follow (without specifying the nature of what will follow)?

Such advertisements are not referred to in Royal Decree 1416/1994, or in the Code of Conduct. Our opinion is that they would likely be considered illegal.

4 Gifts and Financial Incentives

4.1 Is it possible to provide healthcare professionals with samples of medicinal products? If so, what restrictions apply?

Article 16 of Royal Decree 1416/1994 requires that delivery of free samples shall be made on an exceptional basis and only to persons qualified to prescribe medicinal products.

Under these provisions, free samples may be manufactured and delivered only for medicinal products which:

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

On the other hand, no samples of medicinal products containing psychotropic or narcotic substances may be supplied.

As to the conditions under which delivery of free samples may be carried out, these are as follows:

- only a maximum of 10 samples for each medicinal product each year per qualified person, during a maximum period of two years after the granting of the marketing authorisation, is allowed;
- any supply of samples must be in response to a written request, signed and dated, from the recipient;
- the laboratories supplying samples 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 resale" and its reimbursement sticker shall have been annulled; and
- each sample shall be accompanied by a copy of the SmPC and by updated information on its price, conditions of reimbursement by the National Health System and, if possible, estimated cost of treatment.

4.2 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply?

Offering gifts is only permitted in the context of promoting OTC medicinal products provided that its cost is insignificant (no more than 30 Euros) and is related to the practice of medicine.

The Code of Conduct prohibits offering gifts within the context of promoting prescription-only medicines. However, the Code of Conduct permits offering printed materials used to promote or provide information on medical practice and medicinal products, reprinting supplements from scientific articles, and educational materials provided to healthcare professionals for their own use or for use with patients provided that (i) they are relevant to the practice of medicine or pharmacy, (ii) they benefit patient care, and (iii) their market price does not exceed 60 Euros. The offer to healthcare professionals of gifts which comply with said requirements are excluded from the transparency obligations referred to in question 7.2.

Donations of money to healthcare professionals are not permitted, although the Code allows for minor travelling expenses incurred by healthcare professionals attending scientific events to be paid in cash.

4.3 Is it possible to give gifts or donations of money to healthcare organisations such as hospitals? Is it possible to donate equipment, or to fund the cost of medical or technical services (such as the cost of a nurse, or the cost of laboratory analyses)? If so, what restrictions would apply?

The Code of Conduct allows gifts, donations or the funding of the cost of medical or technical services to institutions, organisations, associations and foundations whose members are healthcare professionals 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: (i) must not be offered as an inducement to prescribe or use any particular product; (ii) must be for the internal use of the institution in general and not for the use of an individual (portable electronic devices are expressly prohibited); and (iii) must be recorded in a document to be kept by the pharmaceutical 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).

The Code of Conduct obliges companies to comply with the transparency obligations referred to in question 7.2 regarding the offer of gifts or donations to healthcare organisations.

4.4 Is it possible to provide medical or educational goods and services to healthcare professionals that could lead to changes in prescribing patterns? For example, would there be any objection to the provision of such goods or services if they could lead either to the expansion of the market for, or an increased market share for, the products of the provider of the goods or services?

The provision of medical or educational goods and services cannot be made in return for a change in prescribing patterns. This notwithstanding, a company would not be liable if the good or service provided to the healthcare professional (subject to the rules regarding gifts, hospitality and advertising being observed) makes the healthcare professional change their prescribing patterns based on scientific and objective grounds.

4.5 Do the rules on advertising and inducements permit the offer of a volume-related discount to institutions purchasing medicinal products? If so, what types of arrangements are permitted?

With regard to pharmacies, only reasonable volume-related discounts and discounts for early payment are acceptable, provided that such discounts: (i) do not induce the purchase of the product in prejudice of its competitors; and (ii) are reflected in the corresponding invoice. Discounts to pharmacies cannot exceed 10% for medicinal products financed by the National Health System. For those products not financed by the National Health System, the reasonability of the discount shall be analysed on a case-by-case basis. With regard to supplies to hospitals, discounts are subject to the public procurement system.

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed?

Generally, this is not possible. However, it is customary to sell equipment for a price which is contingent on the purchase of medicinal products, subject to anti-trust rules which may apply to tying arrangements.

4.7 Is it possible to offer a refund scheme if the product does not work? If so, what conditions would need to be observed? Does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

Offering a refund scheme for medicinal products dispensed at pharmacy offices is considered to be contrary to the Code of Conduct. In our opinion, it may be contemplated in agreements with public hospitals for prescription-only medicines.

4.8 May pharmaceutical companies sponsor continuing medical education? If so, what rules apply?

Pharmaceutical companies may sponsor continuing medical education events. The sponsorship shall be stated in all documents related to the event, as well as in any published derivative work. If applicable, rules regarding hospitality (as set forth below) shall be observed.

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

Hospitality offered to healthcare professionals by pharmaceutical companies at professional and scientific events is acceptable provided that the following conditions are met:

- such hospitality must always be reasonable in level (the cost must not exceed what recipients would normally be prepared to pay for themselves) and remain subordinate to the main scientific objective of the meeting; and
- hospitality must not be extended to persons other than healthcare professionals.

The Code of Conduct has also laid down various practical rules regarding hospitality, such as:

- The need to notify Farmaindustria's Surveillance Unit when a company organises a congress of at least 20 people and includes at least one overnight stay.
- Hospitality may be granted only for the duration of the scientific 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 and the hospitality cannot include the organisation of social, entertaining or cultural events (except for reasonable welcome cocktails, working meals and gala dinners).

- The presence of accompanying persons is not allowed.
- A limit of 60 Euros is established for meals and luncheons per guest.

As a general rule, it is not acceptable to organise events at venues outside the Spanish territory, unless when justified from a logistical point of view because most of the participants come from outside Spain or because the congress or expertise object of the event is located abroad. In such cases, the company shall abide by the rules of the Code of Conduct applicable in the country where the event is located.

There are also some obligations on the recipient, among which is the obligation to state the funds received and the source of financing in the publication of papers and lectures in the congresses and meetings.

5.2 Is it possible to pay for a healthcare professional in connection with attending a scientific meeting? If so, what may be paid for? Is it possible to pay for his expenses (travel, accommodation, enrolment fees)? Is it possible to pay him for his time?

According to the Code of Conduct, it is possible to pay reasonable and strictly necessary travel, accommodation and enrolment costs to healthcare professionals attending a scientific meeting. Payment of such expenses should be made directly to the event organiser, except for minor travelling expenses duly justified. No payment can be made for the time incurred by the healthcare professional to attend the event.

Payment of reasonable fees and reimbursement of out-of-pocket expenses is possible for speakers and moderators, under the conditions set forth in question 5.4.

5.3 To what extent will a pharmaceutical company be held responsible by the regulatory authorities for the contents of, and the hospitality arrangements for, scientific meetings, either meetings directly sponsored or organised by the company or independent meetings in respect of which a pharmaceutical company may provide sponsorship to individual healthcare professionals to attend?

A pharmaceutical company may be held responsible for the contents and hospitality arrangements for a scientific meeting if such event has been organised and/or mainly sponsored by such company.

5.4 Is it possible to pay healthcare professionals to provide expert services (e.g. participating in advisory boards)? If so, what restrictions apply?

It is possible to pay healthcare professionals for expert services (such as 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 healthcare professionals 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, and a proper invoice must be issued by the healthcare professional. Payments in kind can only be accepted exceptionally upon prior authorisation from Farmaindustria's Surveillance Unit.
- If the healthcare professionals hired for a given project are more than 20, this shall be notified to Farmaindustria's Surveillance Unit.
- It is recommended that the agreement shall include a clause by means of which the healthcare professional undertakes to declare that they provide services to the company every time they write or publicly assert any matter related to the company.

Due to the transparency obligations introduced by the Code of Conduct, companies shall have to publish the payments made to healthcare professionals related to said provision of services.

5.5 Is it possible to pay healthcare professionals to take part in post-marketing surveillance studies? What rules govern such studies?

The Code of Conduct states that post-authorisation surveillance studies shall fundamentally have a scientific or formative purpose and shall not be undertaken as a promotional activity.

The design and follow-up of such studies shall be carried out by the medical or clinical trial department, but nothing impedes involving outside healthcare professionals as long as the requirements set forth in question 5.4 are met.

The rules which govern such studies are set forth in the recent Royal Decree 577/2013, which regulates the pharmacovigilance of medicinal products, and the Ministerial Order SAS 3470/2009 on post-marketing surveillance studies.

5.6 Is it possible to pay healthcare professionals to take part in market research involving promotional materials?

The Code of Conduct makes special reference to market research studies, which shall be governed by the Code of Conduct of the European Pharmaceutical Market Research Association. In this regard, the pharmaceutical company sponsoring the market research cannot know the identity of the healthcare professionals taking part in the market research, and the healthcare professionals shall not be able to link the research with a pharmaceutical company or a specific product. The remuneration shall be duly formalised, at market prices and taking into account the time employed. Payments in kind can only be accepted exceptionally upon prior authorisation from Farmaindustria's Surveillance Unit.

6 Advertising to the General Public

6.1 Is it possible to advertise non-prescription medicines to the general public? If so, what restrictions apply?

Non-prescription medicines which are not publicly financed may be advertised to the general public. The general conditions that advertising messages for OTC medicinal products must meet are:

- Messages shall make clear that it is an advertisement and that the product is a medicinal product.
- Any message must conform to the leaflet and the conditions and requirements set forth in the marketing authorisation.
- Messages shall be precise, balanced, honest, objective, and sufficiently complete so as to allow a citizen to judge the therapeutic value of the medicinal product in understandable language.
- Messages must contain at least the complete name of the medicinal product, the name and/or logo of the holder of the marketing authorisation, a therapeutic indication and composition of the product, and the number of authorisation of the advertisement from the Ministry of Health. Furthermore, the message shall include recommendations that the Ministry of Health may determine in order to prevent any risks and to promote their rational use, as well as an invitation to read the instructions of the leaflet and to consult a pharmacist.
- Reminder advertisements (only acceptable for products sufficiently known and which have been promoted for at least two years) will only include the name of the product. A blurred image of the packaging is also acceptable, 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 medicinal product.

Furthermore, Royal Decree 1416/1994 states that the advertising of a medicinal product to the general public shall not contain any material which:

- Gives the impression that a medical consultation or surgical operation is unnecessary.
- Suggests that the effects of taking the medicine are guaranteed, unaccompanied by side effects or 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 the good health of the subject can be enhanced by taking the medicine or could be affected by not taking the medicine.
- Suggests that its use may enhance sports abilities.
- Is directed exclusively or principally at 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, healthcare professionals, or celebrities.
- Mentions that the product has obtained a marketing authorisation in any country or any other authorisation.

Finally, the mentioning of the following therapeutic indications is prohibited:

- Tuberculosis.
- Sexually transmitted diseases.
- Other serious infectious diseases.
- Cancer.
- Chronic insomnia.
- Diabetes and other metabolic illnesses.

6.2 Is it possible to advertise prescription-only medicines to the general public? If so, what restrictions apply?

Advertising prescription-only medicines to the general public is expressly prohibited by Law 29/2006 and Royal Decree 1416/1994.

6.3 If it is not possible to advertise prescription-only medicines to the general public, are disease awareness campaigns permitted encouraging those with a particular medical condition to consult their doctor, but mentioning no medicines? What restrictions apply?

Disease awareness campaigns where no direct or indirect reference to a medicine is made are permitted and do not fall under the rules which apply to advertising of medicinal products.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply?

This is a controversial issue in Spain and it should be analysed on a case-by-case basis. However, if the information about the medicine is relevant from a scientific or economic point of view and the press release does not have a promotional tone, it may be considered as corporate information of the company and therefore, may be published in non-scientific journals.

6.5 What restrictions apply to describing products and research initiatives as background information in corporate brochures/Annual Reports?

Corporate advertising (meaning advertising which relates to the company, provided there are no references, even indirect, to specific medicinal products) shall not be subject to the rules regarding the promotion of medicines.

The description of research initiatives in corporate brochures or other informative documents accessible to the public is accepted as long as such description is objective and reasonable according to the usages of the sector.

6.6 What, if any, rules apply to meetings with, and the funding of, patient organisations?

According to the Code of Conduct, any collaboration between pharmaceutical companies and patient organisations shall be recorded in a written agreement, stating the objective of the collaboration, the activities to be performed by each of the parties, the amount, sources and purposes of the financial support and any other relevant non-financial support.

With regard to meetings with patient support groups, these shall be held at appropriate venues, avoiding those which are extravagant or renowned for their entertaining facilities. The hospitality offered by the pharmaceutical company must always be reasonable and remain subordinate to the main scientific objective of the meeting.

Hospitality shall be limited to travel, accommodation, meals and registration fees (it shall not include the organisation of leisure or entertaining activities). Payment of such expenses should be made through the patient organisation.

It is not acceptable to organise events at venues outside Spain, unless when: (i) most of the participants come from outside Spain; or (ii) a relevant resource or expertise is located abroad (in the second case the location shall be approved by Farmaindustria's Surveillance Unit). In any case, the hospitality standards set forth for healthcare professionals shall not be surpassed.

7 Transparency and Disclosure

7.1 Is there an obligation for companies to disclose details of ongoing and/or completed clinical trials? If so, is this obligation set out in the legislation or in a self-regulatory code of practice? What information should be disclosed, and when and how?

Pharmaceutical companies must publish detailed information in the clinical trials they perform, in accordance with the current legislation and, moreover, with the "Joint Position on Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases 2009 and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature 2010", available at http://clinicaltrials.ifpma.org.

For every applicable reporting period, companies shall have to publish the transfers of value on an aggregate basis made in relation to research and development activities (including information regarding clinical trials).

7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected, what information should be disclosed, from what date and how?

There is no Spanish legislation which obliges companies to publish information regarding the transfers of value provided to healthcare professionals, healthcare organisations or patient organisations.

7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations or patient organisations? If so, what companies are affected, what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

Yes, the Code of Conduct implemented the rules contained in the EFPIA Code on disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organisations and patient organisations. The new obligations are consistently similar to the rules contained in the EFPIA Code. Consequently, from 2015, companies which are members of Farmaindustria will be obliged to document and disclose all transfers of value made during the previous year, such as any direct or indirect payment or grant, either cash or benefits in kind, and regardless of its purpose, made to recipients who are healthcare professionals or a healthcare organisation. Said disclosure must be done through the company's website. The only payments excluded from this obligation are those associated with (i) commercial transactions with distributors and pharmacy offices, including certain transactions with healthcare organisations, (ii) activities related to products or medicines that are not prescription-only medicines, and (iii) activities not detailed in Appendix I of the Code of Conduct, such as the provision of educational materials or of medical utilities, samples, dinners or luncheons. Disclosure is to be made on an individual basis or in the aggregate under terms and conditions similar to those set out in the EFPIA Code.

Companies which enter into collaborations with patient organisations or service agreements with said patient organisations must also comply with transparency obligations.

8 The Internet

8.1 How is Internet advertising regulated? What rules apply? How successfully has this been controlled?

In general terms, the same rules apply as for other forms of advertising. The Code of Conduct recalls that all promotional activities that are performed in the digital environment are subject to identical rules and limitations as those which apply in other traditional channels. In this sense, the Code of Conduct highlights the importance of using valid channels within a context that is basically scientific or professional, and that should be intended exclusively for healthcare professionals authorised to prescribe or dispense medicines. Such healthcare professionals should need to identify themselves in order to have access to this information.

In addition, the Guide on the advertising of OTC medicinal products published in April 2011 by the Ministry of Health states the following specific requirements (in addition to the general requirement regarding advertising to the general public) for the advertising of OTC products on the internet:

- The information regarding medicinal products shall be clearly differentiated from the general information included in the webpage (such as information about illnesses, health advices, etc.).
- The top band of the webpage may include just the trademark of the product if the complete name of the same appears in the main page.
- The date of last actualisation of the webpage shall be stated.

In practice, enforcement remains an issue regarding companies located outside Spain.

On the other hand, Royal Decree 870/2013 regulates the sale of medicines not subject to prescription through the internet. Such internet sales are permitted, provided that the medicinal products are supplied by a pharmacy, with the intervention of a pharmacist, after that pharmacist has provided personalised advice to the purchaser, and in accordance with the rules applicable to the products to be sold. Under this Royal Decree, only approved websites may offer these products, and prior to using the internet as a sales channel, the pharmacy must first communicate its intention to the regional authority. In order to ensure that the internet channel is properly used, the regulation obliges the pharmacist to make an individual assessment of each order to make sure that even these OTC medicinal products are used properly. However, no gifts, discounts or similar offers connected with the promotion or sale to the public of medicinal products can be made, except for legally admitted discounts.

8.2 What, if any, level of website security is required to ensure that members of the general public do not have access to sites intended for healthcare professionals?

The entity responsible for the website must ensure that those parts of the site which contain promotional information about prescription-only medicinal products may only be seen by persons who are legally entitled to prescribe or dispense medicinal products, including a clearly legible warning indicating that the information is intended only for healthcare professionals. Healthcare professionals who access the content must declare their status as a healthcare professional. In practice, this is normally made by requesting the medical licence number of the healthcare professional.

8.3 What rules apply to the content of independent websites that may be accessed by a link from a company-sponsored site? What rules apply to the reverse linking of independent websites to a company's website? Will the company be held responsible for the content of the independent site in either case?

The Code of Conduct establishes that a company shall be liable for the content of websites accessed by a link from its website. Additionally, general rules on liability shall apply.

8.4 What information may a pharmaceutical company place on its website that may be accessed by members of the public?

It has been commonly accepted, following the guidance issued by the Pharmaceutical Committee, that the unmodified and unabridged publication on the internet of information which has been authorised by competent authorities (e.g. 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. Other information which is not considered advertising of medicinal products, such as information about human health or diseases (with no direct or indirect reference to any medicinal product), or corporate information about the company, may also be placed on the open part of a company's website. All of the above is acceptable unless the presentation of this information clearly constitutes a "hidden inducement" to promote the prescription, dispensation, sale or consumption of the medicinal product. The existence/non-existence of a "hidden inducement" must be checked on a case-by-case basis, taking into account the overall presentation of the information.

8.5 Are there specific rules, laws or guidance controlling the use of social media by companies?

The same rules on advertising apply to advertising through social media. It is forbidden to advertise prescription-only medicines on social media. In particular, the Code of Conduct imposes on companies the obligation to adequately train their employees in this regard.

9 Developments in Pharmaceutical Advertising

9.1 What have been the significant developments in relation to the rules relating to pharmaceutical advertising in the last year?

There have not been any significant developments in relation to the rules relating to pharmaceutical advertising in the last year.

9.2 Are any significant developments in the field of pharmaceutical advertising expected in the next year?

The rules on the promotion and advertising of medicinal products may be adapted to the changes introduced in 2013 in Law 14/1986, which removed the need for prior administrative approval for advertising of over-the-counter medicinal products.

9.3 Are there any general practice or enforcement trends that have become apparent in Spain over the last year or so?

No, there are no general practice or enforcement trends that have become apparent in Spain.

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