Baker McKenzie.

Promoting Medical Products Globally

Handbook of Pharma and MedTech Compliance

SPAIN

Spain

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Introduction

In Spain, regulations regarding the advertising of medical products for human use are based on the implementation of EU legislation into Spanish law, as well as the EFPIA Code on the promotion of prescription-only medicines to, and interactions with, healthcare professionals[1] (the "EFPIA Code") and the Eucomed Code in the codes of ethics approved by the Spanish industry associations. However, both the Spanish law and the industry code of ethics are more detailed with regard to incentives to healthcare professionals and studies not classified as clinical trials, and that the industry codes of ethics establish additional control mechanisms regarding hospitality, contracts with healthcare professionals and market research studies.

Regulatory Framework

Royal Legislative Decree 1/2015 of 24 July 2015, approving the revised text of the Law 29/2006 of 26 July 2006 on Guarantees and the Rational Use of Medicines and Medical Devices (RLD 1/2015), establishes the general framework to regulate the promotion and advertising of medicinal products and medical devices in Spain.

The basic legislation regulating advertising of medicines for human use is Royal Decree 1416/1994 of 25 June 1994. Through Circular 6/98, the General Directorate of Pharmacy and Medical Devices (the current Medicines and Medical Devices Agency) clarified various points contained in Royal Decree 1416/1994.

Royal Decree 1416/1994 includes a broad definition of the concept of advertising of medicines, which includes all the types of promotion and market research.

[1] Final consolidated version dated 13 August 2013.

The autonomous communities have progressively been acquiring responsibilities in the health field, including certain aspects relating to the advertising and promotion of medicines for human use. Consequently, depending on the area in which the advertising or promotion takes place and/or the location of the corporate headquarters of the pharmaceutical company advertising or promoting its products, not only must Royal Decree 1416/1994 and RDL 1/2015 be taken into account, but also the complementary and interpretative legislation developed in the corresponding autonomous community. By way of example, below is a list of the regulations of the autonomous communities of Catalonia and Madrid, since the majority of pharmaceutical companies and medical journals with the largest circulation are located there.

Catalonia: Guide for Advertising of Medicines for Human Use (Third Edition, October 2009)

Madrid: Law 19/98, of 25 November 1998 of the Autonomous Community of Madrid; Order No. 1085/1998, of 25 May 1998 of the Department of Public Health and Social Services regulates the acknowledgement of public health and/or social interest of acts of a scientific nature; Pharmacy Circular No. 1/2000, of the General Directorate of Public Health of the Autonomous Community of Madrid is regarding applicable general standards contained in certain articles of Royal Decree 1416/1994, of 25 June 1994, on advertising `aimed at persons qualified to prescribe or supply medicines; and Pharmacy Circular 1/2002 of the General Directorate of Public Health deals with promotional visits to physicians and other promotional activities performed in the public healthcare centers of the Autonomous Community of Madrid.

On the other hand, pharmaceutical companies belonging to Farmaindustria are governed by the Spanish Code of Practice for the Pharmaceutical Industry (the "Farmaindustria Code"),[2] based on the EFPIA Code. Farmaindustria has also adopted guides for the

[2] Version June 2014.

development of the Farmaindustria Code of Good Practices and has set up a queries procedure.

The promotion of medical devices is regulated by several royal decrees: Royal Decree 1591/2009 on medical devices; Royal Decree 1662/2000 on in vitro diagnostics medical devices; and Royal Decree 1616/2009 on active implantable medical devices.

Meanwhile, pharmaceutical companies belonging to Spanish Federation of Health Technology Companies (Fenin) are governed by the Code of Good Practices (the "Fenin Code"),[3] which is based on the Eucomed Code. Fenin has adopted an implementation guide for the Fenin Code.

Permitted and Prohibited Practices

Royal Decree 1416/1994 includes advertising activities involving the promotion of medicines by written advertising and by other means.

No medical product may be advertised until it has received the relevant marketing authorization or customer engagement (CE) marking. For medical products eligible for reimbursement, no promotion can start until the reimbursement procedure has ended.

In addition to written advertising, promotion includes technical information on medicines that is transmitted during visits to physicians, the distribution of free samples, the regulation of incentives and the sponsorship of scientific meetings. These activities are examined further below.

Gifts

Spanish legislation regulates the incentives given to persons qualified to prescribe or supply medical products and expressly prohibits giving, offering, or promising to such persons, in the framework of promoting medical products, incentives, bonuses, discounts or gifts,

[3] Version December 2009.

except those of insignificant value and relevant to the practice of medicine or pharmacy.

RLD 1/2015 specifically states that bonuses and discounts shall be considered prohibited incentives. The exceptions to this prohibition are discounts for early payment or volume of sales offered by distributors to pharmacies, subject to the product not being promoted against its competitors. Discounts should be reflected in the relevant invoice.

The legislation does not include a list of the possible incentives or gifts that may be given to healthcare professionals. Therefore, gifts traditionally given for Christmas or for other social events are also subject to the legislation if their purpose is the promotion of medical products.

Giving money is expressly prohibited under all circumstances, regardless of the amount.

The Farmaindustria Code establishes that the above prohibition does not apply to the direct or indirect offering or provision of stationery or items for the practice of medicine or pharmacy that meet the following conditions: (i) the items are not related to a prescription- only medicine; and (ii) the market price does not exceed EUR10. In addition, the Farmaindustria Code establishes that the direct or indirect provision of informational or educational materials to healthcare professionals will be permitted, provided that they meet the following three conditions: (i) the material is inexpensive -- in this regard a material is considered inexpensive when the market price does not exceed EUR60; (ii) the materials are directly relevant to the practice of medicine or pharmacy; and (iii) the materials directly benefit the patient. Finally, items of medical utility aimed directly at the education of the healthcare professional and patient care may be directly or indirectly provided to healthcare professionals if they are inexpensive (i.e., their market price does not exceed EUR60) and do not offset routine business practice of the recipient.

The Fenin Code sets a limit of EUR30 per healthcare professional for the provision of stationery or items for the practice of medicine or pharmacy.

However, this value restriction does not apply to books, publications or other materials regarding professional issues, whether in optical, magnetic, electronic or similar form, as well as to funding of services that contribute to improve the training of healthcare professionals.

The authorities have given no indication as to what constitutes an insignificant value.

In addition, the industry codes establish that donations to health institutions are only permitted if:

- they are carried out in order to collaborate with healthcare, research, teaching/training or social or humanitarian care;
- they are formalized in writing, with the company retaining a copy of the evidencing documents; and
- they do not constitute an incentive for the recommendation, prescription, purchase, supply, sale or administration of medical products.

Any donations that do not meet the above requirements may be considered prohibited incentives.

It is important to remember that gifts that include the advertising of prescription-only medicines are prohibited.

Pharmaceutical companies must include in the annual index of advertising activities to be submitted to the health authorities in the area where their registered office is located (in Catalonia, before the end of the first quarter of the following year, and in Madrid, before 1 March of the following year), all the advertising activities carried out, as well as a list of the incentives given to persons qualified to

prescribe or supply medicines, indicating the amount and group of receivers by specialty.

These requirements are applicable to the promotion of medicines. If it is the general image of the pharmaceutical company that is being promoted (i.e., corporate advertising) without reference to specific medicines, the abovementioned limitations do not apply, provided that there is no direct relation or association between the image of the pharmaceutical company and any specific medicines. However, Circular No. 6/95 issued by the General Directorate of Pharmacy and Medical Devices (now Medicines and Medical Devices Agency) indicates that if pharmaceutical company advertising includes an offer or support that is an incentive, such benefit must have an insignificant value and must be related to the practice of medicine or pharmacy. This requirement goes beyond the provisions of Royal Decree 1416/1994, which treats the promotion and advertising of medicines exclusively and does not apply to the promotion of the general image of the pharmaceutical company.

Sponsorship of Scientific Meetings, Congresses, Courses, Prizes and Grants

Advertising and promotion of medical products by pharmaceutical companies may be carried out within the framework of scientific meetings or congresses. In the framework of international congresses of acknowledged prestige and importance held in Spain and attended in significant numbers by professionals from other countries, it is possible to promote medicines and indications not authorized in Spain but authorized in the countries represented in the congress. In these cases, the fact that the medicine or indication is not authorized in Spain must be clearly stated. Similar provisions regarding medical devices that have not yet obtained the CE marking apply.

The Farmaindustria Code establishes the obligation on the part of pharmaceutical companies to inform the Surveillance Unit of the Pharmaceutical Industry (USD), the body responsible for the active monitoring of compliance with the Farmaindustria Code, of any scientific and promotional meetings and events organized by them

prior to their taking place. This obligation will only be applicable if the three following conditions are met: (i) the event is organized – directly or indirectly - or sponsored exclusively or mainly by the notifying pharmaceutical company; (ii) they include at least one night of accommodation (for attendees or speakers); and (iii) the participants include at least 20 healthcare professionals. Failure to inform the relevant body – when it is compulsory – shall be considered a breach of the Farmaindustria Code, regardless of whether the meeting or event abides by the Farmaindustria Code or not.

It is also mandatory to inform the USD of any events organized by third parties when the pharmaceutical company organizes the attendance of a group of more than 20 healthcare professionals who practice in Spain to a referred third-party event (e.g., scientific societies, professional organizations, etc.) at a national and international level. However, if the USD previously validated the event, notice will not be required. Such sponsorship activities must be included in the annual index of advertising activities to be submitted to the health authorities. Pharmaceutical companies must also keep a record, which must be made available to the competent authorities, of the amounts contributed to scientific meetings as well as a list of the health professionals who were offered hospitality.

The definition of sponsorship includes hospitality offered, directly or indirectly, within the framework of exclusively professional and scientific events, as well as any kind of event (whether it be a congress, conference, symposium, seminar, experts' meetings, researchers' meetings, training sessions or any other similar activity) organized or sponsored by a pharmaceutical company or company under its control, and to all participants in the above, whether they are healthcare professionals or any other persons who, in the practice of their profession, may prescribe, purchase, distribute, dispense or administer medical products, or may have an impact on any of those activities.

Sponsored activities must be exclusively scientific and professional, and may be organized by the pharmaceutical company or by an

external company. The essential element that must be emphasized is that the event that gives rise to hospitality must be of an exclusively scientific and professional nature. In this regard, organizing or collaborating in events that include entertainment or leisure activities is not permitted. The Farmaindustria Code specifies that this prohibition does not include welcome cocktails, business lunches and gala dinners, which are customary in the official programs of scientific conferences and meetings, provided that they are reasonable, moderate and do not include additional elements (cultural, leisure and entertainment, etc.).

The term hospitality includes the actual travel and accommodation expenses and the registration fee paid by the pharmaceutical company. Hospitality must always be moderate and subordinate to the main purpose of the meeting. The receivers of such hospitality should be health professionals only.

The idea of moderation must be understood in the sense that travel and accommodation expenses must be reasonable and not exaggerated, and that they must be limited to the days scheduled period of the scientific meeting. The Farmaindustria Code used by the industry states that the cost of hospitality should not exceed that which the receivers would normally be willing to pay in the same circumstances. A maximum cost of EUR60 (including taxes) per guest applies for any form of hospitality associated with meals. Payment for a meal that costs more than this maximum threshold will be considered a breach of the Code. For events involving meals that take place outside Spain, the maximum threshold established by the national association of the country where the event occurs will apply. With regard to accommodation, four-star hotels are the appropriate standard for all kinds of events. Five-star hotels may be used, provided that all of the following conditions are met: there are more than 200 participating healthcare professionals; it is a business hotel within city limits and it is not ostentatious; it is the venue for the event (or for events organized by third parties, if there is no room availability in the seat of the event); and prior authorization is obtained from the USD for events mainly sponsored or organized by the pharmaceutical

company. However, sponsoring or organizing events that take place in the following types of hotels can never be justified: five-star superior, five-star luxury, five-star major luxury (various types of five-star luxury hotels in Spain), sports resorts, theme parks, wine-hotels and other establishments in similar categories.

In addition, the Farmaindustria Code limits the possibility of organizing or sponsoring events outside Spain, unless it is the case that most of the guest participants are from other countries or that a relevant resource or certain expertise, which is the main purpose of the event, is located in another country (in this case, it must have the prior authorization of the USD). The Fenin Code includes similar provisions.

The concept of being subordinate expresses the fact that there must be a relationship between the main purpose of the meeting and the job performed by the professional who is being offered hospitality. Likewise, hospitality must be limited to the acts directly related to the scientific meeting and must not be extended to leisure activities and entertainment. Acts of hospitality in violation of legal provisions shall be considered advantages in kind, which are expressly forbidden by law. Spanish regulations do not limit to the amount that a pharmaceutical company may contribute to scientific meetings.

The Farmaindustria Code establishes that, where a pharmaceutical company sponsors a meeting, congress, symposium or any other similar activity, the sponsorship will be mentioned in all documentation relating to the event, as well as in any work, speech or document published relating to the event. It also establishes that reasonable fees and expenses, including travel expenses, may be paid to those participating as speakers or moderators.

No monetary compensation may be offered merely to compensate for the time used by healthcare professionals to attend the event.

Moreover, Spanish pharmaceutical companies shall ensure compliance with the abovementioned provisions by their parent

company, subsidiaries and other related companies if the promotional activities are directed at health professionals performing their services in Spain, whether invited to foreign countries or to events in Spain.

Inspection of prizes, grants, contributions and subsidies to congresses, travel grants and similar items is an executive power granted to the autonomous communities by the legislation on pharmaceutical products.

The Autonomous Community of Madrid regulates the issue of certificates acknowledging the health and/or social interest of scientific acts that take place in the Autonomous Community of Madrid. The recipients may mention their certificates in the advertising and documentation regarding the certified activity. In addition, the management of public healthcare centers shall have to authorize the assistance to scientific acts organized or sponsored by pharmaceutical companies.

In the Autonomous Community of Catalonia, a seal of quality for sponsored scientific activities may be requested from the Catalan Council of Continuing Medical Training. The Catalonian Guide on promotion on medicinal products for human use includes the obligation to inform of any sponsoring activities prior to their taking place which, in our view, exceeds the obligations imposed by Royal Decree 1416/1994.

Visits to Physicians

Visits to physicians are one of the preferred types of interactions between pharmaceutical companies and persons qualified to prescribe or supply medicines. Royal Decree 1416/1994 defines "visit to a physician" as "the type of relationship between the pharmaceutical companies and the persons qualified to prescribe or supply medicines for the purpose of informing and advertising medicines, carried out by the medical representative and based on the transmission of technical knowledge required for the objective assessment of its therapeutic utility."

Medical representatives must be duly accredited and adequately trained by the pharmaceutical company they represent.

The Farmaindustria Code requires that a company have a standard procedure to guarantee adequate training regarding the Farmaindustria Code and to ensure that employees are capable of complying with the Farmaindustria Code.

Royal Decree 1416/1994 establishes the documentation and information that medical representatives must provide or have available in each visit relating to the products presented. This includes the summary of product characteristics, information on the different pharmaceutical forms and dosages, the prescription and supply regime, price information, conditions of the National Health System's financing of the medicine and, when possible, the estimated cost of treatment.

In visits to physicians, the medical representatives may use the various legally authorized methods of promotion and advertising, such as providing documentary information or free samples, or offering incentives and invitations to seminars and congresses. In each case, the medical representatives must comply with the legal requirements for each type of promotional activity.

Medical representatives are an important link in the pharmacovigilance system for medicines. The law establishes that they must report any information they receive from the professionals visited regarding the medicines they promote to the pharmaceutical company's scientific service, especially adverse reactions reported to them. The activity of the medical representative is incompatible with the exercise of any professional activity in the cycle of prescription, supply or administering of medicines.

Legal regulations do not require a medical representative to exclusively work for one pharmaceutical company. The pharmaceutical companies for which the medical representative works

for are responsible for the fulfilment of the legal obligations imposed on visits to physicians.

Visits to physicians have traditionally taken place in person, with the physical presence of the medical representative. However, there is nothing to prevent a "visit" to a physician from taking place via video-conference or any other media that does not require the physical presence of the medical representative. In such cases, the requirements of providing or having available the summary of product characteristics and all other information and documentation stipulated by law must be met, just as for in-person visits.

The assumption of health competences by all autonomous communities, including the cost of the provision of health assistance, has caused several of them to regulate, or begin the process of regulating, promotional visits to physicians, with the intention of restricting such visits.

Since a review of the different regulations would exceed the scope of this chapter, we shall limit ourselves to highlighting the prevailing tendencies and the more recent experiences. The points that differ by degrees of restriction are: encouragement of collective visits in place of individual visits; limitations on the places in which the promotional visits may take place; requirements concerning prior schedules of the visits; limitation of the days and hours that may be dedicated to visits; and limitations of the frequency of visits to physicians by any given pharmaceutical company.

Visits to pharmacists have grown in Spain since the growth of over-the- counter (OTC) medicines and the generics market as a result of the direct distribution by pharmaceutical companies. The Farmaindustria Code specifies that the above provisions also apply to promotional visits to pharmacists.

Finally, the Farmaindustria Code establishes that pharmaceutical companies must ensure that: their medical representatives have sufficient scientific knowledge to be able to accurately and

responsibly present information regarding the medicines; they are aware of the obligations set forth in the Farmaindustria Code; and their knowledge is up-to-date on the developments in the field.

Samples

Spanish law considers the distribution of free samples as an exceptional promotional activity and therefore limits the kinds of medicines that can be promoted in this way, the receivers of such promotion and the duration of the promotional activity. Distribution of free samples is limited to persons qualified to prescribe and therefore excludes distribution to persons qualified to supply medicines. The Farmaindustria Code specifies that free samples must be delivered directly to the health professionals qualified to prescribe, or to the persons duly authorized by the above. In addition, autonomous communities tend to regulate the distribution of free samples in public healthcare centers.

Since it is an exceptional activity, distribution of free samples does not extend to all medicines. Those that can be distributed are subject to time and quantity limitations.

Only industrially manufactured medicines that meet the following requirements can be given out as free samples:

- Those whose formulas contain an active medicinal substance or substances which, because of their novelty in the therapeutic field, require prior knowledge on the part of prescribing physicians
- Those which, though not included in the preceding category, present a new pharmaceutical preparation or form, a unit dose or concentration, or a form of administering or are intended for a different manner of administering from those currently used, and represent a therapeutic advantage over them as well
- Those for which, while they contain known pharmacological or therapeutic medicinal substances, new pharmacological

actions have been discovered and which therefore have a new therapeutic indication

Thus, generic medicines may not be promoted through distribution of free samples, as they lack the element of therapeutic novelty.

However, even those medicines that meet the abovementioned requirements may not be given out as free samples if they contain psychotropic or narcotic substances, or if they cause dependence. The Ministry of Public Health and Consumer Affairs may also expressly exclude certain medicines from this manner of promotion.

The owner of the marketing authorization must apply for further authorization to manufacture and distribute free samples from the Medicines and Medical Devices Agency. Such application is not subject to any particular formality.

After this special authorization is obtained, free samples may be distributed - limited only to prescribing physicians - under the following conditions:

- A maximum of 10 samples of each medicine per year and per physician may be given. The health authorities may increase the number of samples per year for those medicines whose special therapeutic interest so warrant.
- Distribution must be for a maximum of two years from the date of authorization.
- Each set of samples distributed must be in response to a written request that is signed and dated by the receiver.
- Pharmaceutical companies that distribute free samples must maintain a system of adequate control. This includes the authorizations, as well as a register of requests and deliveries of free samples handled. Besides this, the annual advertising index must include a list of the free samples distributed.

- Samples must be identical to the smallest presentation of the medicine being marketed.
- Each sample must bear the words "Free Sample: Not for Sale" and have the coupon-seal removed or nullified.
- Each delivery of free samples must be accompanied by a copy of the technical data sheet, together with the latest price information, financing conditions offered by the National Health System, if applicable, and when possible, the estimated cost of treatment.

In general, the distribution of free samples of pharmaceuticals limited to hospital use or diagnostics is not prohibited. Any rules adopted by the relevant hospital should be observed.

In line with the above, the Farmaindustria Code stipulates that when samples are distributed in hospitals, the requirements and procedures of the hospital in question must be respected.

Finally, it must be highlighted that changes made to the EFPIA Code in June 2011 included the provision that healthcare professionals cannot be given more than four samples for each new medicine, and that such medicine has to be requested. This restriction has not been implemented in the Farmaindustria Code as of the publishing date of this book.

No specific regulation applies to the delivery of samples related to medical devices. Therefore, the delivery of samples is subject to the restrictions applicable to gifts, unless they are samples with no commercial value.

Transparency provisions

The Farmaindustria Code has implemented the transparency provisions of the EFPIA Code on disclosure of transfers of value from

pharmaceutical companies to healthcare professionals and healthcare organizations[4]. The main obligations are as follows:

- Document and openly publish all transfers of value using the template of the Code on the laboratory's website. Furthermore, laboratories must provide this information to the Professional Ethics Supervisory Unit (USD) annually.

- Donations, events (sponsorships, registration fees, travel, and accommodation) and the provision of services, as well as transfers of value relating to research and development; this excludes the delivery of materials, the delivery of samples, and hospitality (lunches or dinners), as well as transfers of value resulting from commercial transactions in relation to non-prescription medicines.

- To the extent that is legally possible, laboratories must publish this information individually, except for transfers of value relating to research and development. If such information is published collectively, the following must be identified for each category: (i) the number of recipients involved; and (ii) the overall amount attributable to these transfers of value. A detailed itemization must be provided upon request by the recipient and/or the applicable authorities.

- Laboratories must adopt a specific internal procedure to guarantee compliance with the transparency obligation.

- Annual publication within the first six months following each applicable period (calendar year), together with a document summarizing the methodology used, the information provided, and how it was obtained and classified; the first applicable period is 2015. Therefore, laboratories must have the procedure, the methodology and the data-collection

[4] Dated 15 August 2013.

mechanism in place prior to 1 January 2015, so as to publish the first data in the first six months of 2016.

- The information disclosed shall be required to remain in the public domain for a minimum of three years after the time such information is first disclosed, unless, in each case: (i) a shorter period is required under applicable national law or regulation; or (ii) the recipient's consent relating to a specific disclosure, if required by applicable national law or regulation, has been revoked, and this revocation is legally binding for the company.

Consequences of Breach

The health authorities are responsible for enforcing compliance with the legal provisions applicable to the advertising of medical products, including the promotional activities aimed at healthcare professionals.

Royal Decree 1416/1994 does not establish any definition of infringement or administrative sanctions, but refers to the infringements and sanctions as given in Law 25/1990, on Medicines and Law 14/1986, on General Public Health Act. The reference to Law 25/1990 should now be understood as a reference to RDL 1/2015. The royal decrees relating to medical devices include specific infringements, in line with those of Law 14/1986 and RDL 1/2015.

Infringements are classified into three categories: minor, serious and very serious. The criteria used in determining the class of infringement takes into account health risk, profits to be earned, degree of intentionality, seriousness of the health and social alarm caused, generalization of the infraction and recidivism.

Minor infringements relating to the activities examined above are:

- failure to provide obligatory information in the annual advertising index;

- obstruction of inspections related to medical devices by means of any action or omission that obstructs or delays such inspections;
- failure to comply with the obligation to collaborate with the health authorities in the evaluation or control of the medicines or medical devices;
- the advertising of master formulas or official preparations;
- the display of non-authorized medical devices at trade fairs and scientific meetings without disclosing the fact that they are not yet authorized, and
- failure to meet the requirements laid down by the regulations of the autonomous communities governing visits to physicians.

Fines for minor infractions may be up to EUR30,000.

Serious infractions of the activities described above include:

- obstruction of inspections related to medicines by means of any action or omission that obstructs or delays such inspections;
- the direct or indirect offering of any type of incentive, bonus, unauthorized discount or gift by anyone with direct or indirect interests in the production, manufacture and marketing of medical products to healthcare professionals for the prescription, dispensing or administering of medical products, or to patients or persons with whom they live;
- the prescription, dispensing, and administering cycle by healthcare professionals, provided that they are currently engaged in such responsibilities, acting as medical representatives, representatives, commissioned personnel or information agents of pharmaceutical companies;

- providing or concealing data, declarations or any other information to be mandatorily submitted to the competent health authorities so that such data, declarations or information is not truthful or gives rise to untruthful conclusions, with the aim of obtaining a profit, whether financial or otherwise;
- advertising of medical devices directed to the public, when the advertising of such kind of medical devices is prohibited unless such behavior must be considered a very serious infringement; and
- the commission of three minor infringements within a period of one year.

Fines for serious infringements range from EUR30,001 to EUR90,000.

Very serious infringements will include:

- the promotion, advertising or information directed to the public of non-authorized medicines or when such activities do not comply with the legal requirements;
- the offering of bonuses, gifts, prizes, contests or the like as method for the promotion or sale of medical products to the public;
- the promotion, advertising or disclosure of information to the public of products or preparations, with medicinal purposes, even though the product itself does not explicitly mention such purposes, including medicinal substances and their compounds that are not authorized as medicines;
- failure to fulfil the requirements and conditions set forth by law regarding the advertising and commercial promotion of products, materials, substances, energies or methods that have beneficial effects on health;

- advertising of genetic diagnosis medical devices directed to the public; and
- the commission of three infractions classified as serious within a period of two years.

Fines for very serious infractions range from EUR90,001 to EUR1 million. This amount may be increased by up to five times the value of the products or services involved in the infraction.

The health authorities set penalties taking into account the negligence or intentionality of the violator, fraud or collusion, noncompliance with previous warnings, the company's business volume, the number of persons affected, damages caused, profits earned from committing the infraction, permanence or transience of risks, and recidivism for the commission within a period of one or more years of an infraction of the same nature when so declared by a final ruling.

Likewise, RDL 1/2015 sets forth provisions governing a specific action of cessation that may be taken when the advertising of medicines for human use, medical devices or products with purported health properties violates the Law itself, its implementing provisions or the General Public Health Act, affecting the collective or individual interests of consumers and users.

The Law provides that the following persons are authorized to exercise such action of cessation:

- The Spanish National Institute of Consumption and the relevant bodies or entities of the autonomous communities and local corporations competent in matters concerning the protection of consumers
- Consumer and user associations meeting the requirements set forth by the General Act for the Protection of Consumers and Users, or where applicable, in the autonomous community legislation governing the protection of consumers

The Prosecution Department

Institutions of other member states of the European Union created for the protection of the collective or individual interests of consumers authorized as a result of their inclusion on the list published for such purpose in the Official Journal of the European Communities Individuals having been conferred a lawful right or having a lawful interest The cessation may be sought from the time when such advertising activity commences until its conclusion. Similarly, action may be taken to prohibit any practice when such practice has ceased at the time of such action and there is sufficient indication to fear that the stated practice may be resumed immediately.

In the case of medical devices or products with purported health properties, the exercise of the action of cessation must be preceded by a request for cessation directed to the infringer. The infringer will have 15 days to cease such advertising.

Professional Codes of Conduct

As indicated above, Farmaindustria has a Code of Practice for the Pharmaceutical Industry. The currently applicable Farmaindustria Code was approved in June 2014.

The Farmaindustria Code covers all promotional practices targeted at healthcare professionals authorized to prescribe and supply medicines, as well as associations of patients; it does not cover general promotional activities targeted at the general public.

Possible sanctions for violation of the Farmaindustria Code include monetary penalties ranging from EUR6,000 to EUR360,000, reporting of the infringement to the competent health authority, and expulsion of the offending company from Farmaindustria.

The Farmaindustria Ethics Committee, and the Self-regulation Board of the *Asociación Para la Autorregulación de la Comunicación Comercial* (Association for the Self-Regulation of Commercial Communications - Autocontrol) supervise compliance with the

Farmaindustria Code. Farmaindustria's members have agreed to try to settle their disputes within the Ethics Committee on a confidential basis as a first step. If no agreement is reached, the Ethics Committee will refer the matter to the board. The board's decisions are binding. Since the creation of the board as a decision-making body, it has issued a large number of decisions concerning several aspects of the Farmaindustria Code.

In addition, the Farmaindustria Code includes the internal regulations for the supervisory bodies as well as a Q&A annex.

Pharmaceutical companies manufacturing or distributing medical devices that belong to Fenin have adopted a Code of Good Practices, which entered into force in 2005 and was updated in 2009. In addition, Fenin approved, and updated in December 2009, the regulations of implementation and the implementation guide of its code, and in 2015 a Q&A document. The code is implemented by means of the Fenin's Code of Conduct Commission, which refers cases that are not solved by conciliation to the Jury of Autocontrol. The code provides penalties to be imposed on infringers, which include economic penalties ranging from EUR1,000 to EUR100,000, notice of the infringement to be served on the competent health authority, and deregistration of the infringing company from Fenin.

Civil and Criminal Liability

Civil Liability

As mentioned, infringements regarding medical products are subject to administrative sanctions (please see "Consequences of breach"). In addition to the administrative sanctions, if an infringement of the regulations entails a significant market advantage for the offending pharmaceutical company, any competitor (understood to mean any person acting in the market whose economic interests have been directly damaged or threatened) may legitimately file suit for unfair competition. Based on such suit, the competitor may request, among other actions, the removal of the effects caused by the offending act and compensation for damages caused by the offending act if willful

misconduct or negligence were involved. Compensation may include publication of the sanction. If the suit for unfair competition is filed by workers or other agents in the exercise of their contractual duties and responsibilities, the suits will be filed against their principal.

Suits for unfair competition may be filed up to one year after grounds for filing are known and the party who committed the act of unfair competition is identified and, in any event, up to three years after the commission of the act.

Criminal Liability

Some of the administrative infringements examined may give rise to criminal liability. In this case, the criminal proceedings for the same offense suspend the administrative proceedings.

The Spanish Criminal Code lists crimes and misdemeanors as well as their penalties and criminal liability. The Criminal Code was amended by Organic Law 5/2010, and subsequently by Organic Law 1/2015, to, among others, introduce the criminal liability of legal entities. Therefore, according to the Criminal Code, legal entities will be criminally responsible for: offenses committed, on its behalf and to its direct or indirect benefit, by its legal representatives, or individuals or members of boards who are authorized to make decisions in the name of the legal entity or have control or management faculties (the "Representatives"); and offenses committed in the exercise of its activities, on its behalf and to its direct or indirect benefit, by those subject to the authority of the Representatives, if the offenses have been committed due to the serious failure of the Representatives to comply with their obligations to supervise and control, taking into consideration the relevant circumstances of the specific case.

Notwithstanding the above, according to Organic Law 1/2015, which amended the Criminal Code, legal entities will be exempt from criminal liability if they have adopted, prior to the commission of the crime, an organization and management model that includes supervision and control measures capable of preventing such crimes or materially reducing the risk of such crimes being committed (i.e., if

they have adopted what is traditionally known as a compliance program).

In any case, in order for a compliance program to exempt legal entities from criminal liability, the following must also be complied with, according to Organic Law 1/2015:

- The functioning and compliance of the Compliance Program must have been bestowed to a compliance officer/compliance body with independent powers of initiative and control or which has been legally entrusted with the power to supervise the internal controls of the company. For companies allowed to submit simplified financial statements, these functions may be directly assigned to the board of directors.
- The individual authors must have committed the criminal offense while fraudulently eluding the compliance program.
- There must have been no omission or insufficient exercise of the supervision and control functions by the compliance officer/compliance body.

Furthermore, Organic Law 1/2015 provides guidelines on the requirements that compliance programs must meet in order to exempt companies from criminal liability. Such requirements are similar to those already imposed by jurisdictions like the United States and the United Kingdom:

1. Risk assessment: of the crimes that should be prevented
2. Standards and controls: to mitigate any criminal risks detected
3. Financial management system: to be put in place to prevent the identified crimes
4. Whistleblowing channel: to report to the compliance officer/compliance body any violation of the compliance program

5. Disciplinary system: to sanction the violation of the compliance program

6. Audits: to conduct periodical reviews and adjustment of the compliance program to any new circumstances or needs

With regard to the specific crimes related to promotional or advertising activities, the Spanish Criminal Code includes various types of crimes that should be noted. Regarding the content of the promotion or advertising of medical products, the Criminal Code punishes manufacturers and marketers that, in their offers or advertising of products or services, make false allegations or claim untrue characteristics for them, thereby causing serious, evident damage to consumers.

A public official may not receive gifts in connection with his or her public activity, since this could constitute a bribe. Thus, a public official incurs criminal liability if he or she requests or receives gifts in exchange for executing an unfair act in the exercise of his or her position or for failing to perform or delaying performance. He or she also incurs criminal liability for accepting a gift offered in consideration of his or her function or in exchange for an act that is not legally prohibited. In the same way, any person who corrupts or attempts to corrupt authorities or public officials with gifts, offers, or promises incurs criminal liability. The Spanish Criminal Code does not include a minimum amount above which liability exists. Academics have suggested application of the doctrine of the social adequacy (importance of the gift to influence the conduct of the public official) in order to exclude socially accepted behavior or behavior that is clearly insufficient to influence the public official. However, the Spanish Supreme Court has warned that the existence of a gift is sufficient to incur criminal liability, without the need to quantify the gift. Criminal liability is also incurred if the gift or donation is given to a third party intermediary acting under instructions from the public official or public authority.

Likewise, criminal liability is incurred when any individual influences a public official or public authority who is a healthcare professional by using any situation derived from his or her personal relationship with this, or any other public official or public authority, in order to obtain a resolution that may either directly or indirectly generate economic benefit for such or any other individual.

In the same way, a public official servant who influences another public official in this way incurs criminal liability, as does one who requests gifts or any other remuneration from another to carry out such acts.

Additionally, criminal liability is incurred by any public official or public authority who, acting by virtue of his or her position in any phase of public contracting or in the liquidation of government-issued securities or government assets, makes an arrangement with the interested parties or uses any other artifice to defraud a public institution.

Another of the novelties introduced by Organic Law 5/2010 is the regulation of corruption between private individuals. Criminal liability is incurred by any person who, directly or through a third party, offers or grants any non-justified benefit or any advantage of any other nature to a private healthcare professional in order to obtain a favor from such healthcare professional in breach of his or her duties related to the purchase or sale of goods or the engagement of professional services. Criminal liability is also incurred by any private healthcare professional who, directly or through any third person, receives, requests or accepts any non-justified benefit or any advantage of any other nature in order to favor the person providing such benefit or advantage over third parties, in breach of his or her duties in the purchase or sale of goods or in the engagement of professional services.

Finally, payment of outlays for legally permitted activities, such as pharmacovigilance activities for medicines and travel expenses to scientific seminars and congresses, when such activities do not meet

the obligatory scientific requirements or are for illicit purposes, may involve criminal liability. Thus, on 7 November 2001, the Supreme Court upheld the bribery conviction and two-year prison sentence given to the person in charge of a pharmaceutical company and its medical representative for giving incentives to Social Security physicians so that they would prescribe certain medicines. The court ruled that the money was paid in order to increase sales of the pharmaceutical company's products and thus was to be considered a prohibited incentive, regardless of it being paid in the guise of pharmacovigilance activities for medicines. In addition, the expert opinions had shown that said activities did not meet the normally required scientific standards.

The punishment for private individuals for offers or advertising that include false or untrue allegations is imprisonment for six months to one year, or a *per diem* fine for 12 to 24 months; the punishment for legal entities is a fine for six months to two years.

The punishment for bribery of healthcare professionals who are public officials is imprisonment for three to six years, a *per diem* fine for 12 to 24 months, and disqualification to act as a public official for nine to 12 years, if the act is an unfair act; imprisonment for two to four years, a *per diem* fine for 12 to 24 months, and disqualification to act as a public official for five to nine years, if the act falls within the scope of acts inherent to his position; and imprisonment for six months to one year and suspension as a public official for one to three years, if the gift was offered in consideration of the professional's function.

The penalties for private individuals for bribery of public officials are the same punishment and fines mentioned above. The punishment for private legal entities is a *per diem* fine for two to five years, or from three to five times the value of the gift if higher, if the punishment for individuals is imprisonment for more than five years; a *per diem* fine for one to three years, or from twice to four times the value of the gift if higher, if the punishment for individuals is imprisonment between two and five years; or a *per diem* fine for six months to two years or

from twice to three times the value of the gift if higher, if the punishment for individuals is imprisonment for less than two years.

The punishment for influencing healthcare professionals who are also public officials is imprisonment for six months to two years, a fine from once to twice the price of the income, and disqualification to act as a civil servant for five to nine years. The punishment for private individuals who influence a public official or public authority is imprisonment for six months to two years and a fine of up to twice the amount of profit sought or earned; and for legal entities, a fine from six months to two years.

The punishment for a public authority or civil servant who commits fraud in public tenders or against government assets is imprisonment for one to three years and barring from public office or employment for six to 10 years.

The penalty for individuals for private corruption is imprisonment for six months to four years, disqualification to act as an entrepreneur from one to six years, and a fine of up to three times the value of the gift; and for the legal entity, fines for two to five years.

The penalties that may be imposed upon legal entities are particular to each of the crimes for which legal entities can be held criminally liable. The following are examples of sanctions set forth in the Spanish Criminal Code: fines; winding up of the entity; suspension of the legal entity's activities for a maximum period of five years; closure of the legal entity's premises and establishments for a maximum period of five years; a prohibition on the legal entity to continue engaging in the same activities in the course of which the offense was committed (this may be for a defined period of up to 15 years, or indefinitely); ineligibility of the legal entity to obtain subsidies and other public grants, public sector contracts, and tax/social security rebates and incentives for up to 15 years and; judicial intervention for as long as considered necessary (up to a maximum of five years).

In addition, during the preliminary investigation of a case, the examining magistrate may order the temporary closure of a company's premises or establishments, the suspension of its operations, or any other intervention deemed appropriate, as a precautionary measure.

The Spanish Criminal Code requires that in the application of these penalties – excluding the penalty of a fine – the following factors must be taken into account: the need for the penalty in order to prevent the continuation of the criminal activity or the effects thereof; the economic or social consequences of the penalty, particularly for the employees; and the position within the organization of any individual who failed to exercise due control.

Public Procurement and Fraud

Supply contracts signed with public administrations (generally the result of public tenders) must meet the conditions and requirements established by the applicable legislation, as well as the general and particular administrative specifications and the applicable technical specifications. Consequently, promotional offers for public administration contracts that do not fit into the legally established contract award procedure are inadmissible. For example, bids offering the delivery of products at a reduced price or the delivery of technical equipment, unless included in the administrative specifications of the tender in question excluded from the tender procedure as a consequence of their reduced value, are inadmissible. Specifically, no bids should be presented outside the normal procedures of public tender.

Infringement of administrative regulations may result in the cancellation of the tender, with the consequent termination of the contract and the obligation to indemnify the party not guilty of the cancellation, as well as a temporary prohibition to contract with the public administration. Criminal liability could also be incurred if the public official used the bids received for his or her own profit.

Contracts with Healthcare Professionals and Medical Institutions

There are many types of contracts with healthcare professionals and medical institutions, depending on the purpose and objectives of the contract. As indicated above, contracts for the purpose of encouraging the prescription or dispensing of medical products are prohibited, regardless of the fact that such a contract may have a legally acceptable purpose.

In order to examine the legal requirements that are to be met, we will divide contracts into the following categories: clinical trial contracts; post-authorization contracts; market research studies contracts; and scientific consulting and advisory contracts with healthcare professionals and entities composed of healthcare professionals.

Medicines Clinical Trial Contracts

The requirements for clinical trial contracts are to be found in Royal Decree 1090/2015, which allow Spain to gradually adapt and comply with Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC of 4 April 2001. Clinical trials must have prior authorization from the Medicines and Medical Devices Agency and from the Ethics Committee of the corresponding hospital or healthcare institution where they will be carried out. The Ethics Committee will examine the trial protocol.

The purpose of this type of contract is not the promotion of medical products, but the study of some of the elements necessary for their initial authorization or later modifications of the technical data sheets or CE marking. Due to the scientific rigor with which they are prepared and reviewed and their eminently scientific goals, these trials should have nothing to do with the promotion of medical products. It is prohibited to promote medical products that have not obtained the relevant authorization.

Medicines Post-Authorization Contracts

Studies carried out after authorization is granted are included among the pharmacovigilance activities for medicines. These studies are carried out on authorized medicines and must adhere to the content of the summary of technical characteristics. Their goal is to identify or quantify a specific aspect of the medicine's safety profile. Here, we will refer to observation studies rather than Phase IV clinical trials.

Royal Decree 1344/2007, of 11 October 2007, governing the pharmacovigilance of medicines for human use, defines post-authorization studies as those studies whose purpose is to complete the information obtained during the clinical development of medicines prior to their authorization. The decree likewise prohibits those studies whose aim may be to promote the prescription of medicines, and it establishes that the health authorities, within the scope of their duties, must provide guidelines on the conditions under which such studies must be carried out, in order to favor those with a real scientific interest and to prevent those with purely a promotional purpose. Such guidelines must be implemented through specific regulations laid down by each Autonomous Community with authority to enforce laws on pharmaceutical products.

In order to ensure that homogeneous regulations are established, relevant guidelines have been drafted to serve as guidance and reference points for the implementation of regulations by the different Autonomous Communities in their area. Such guidelines are set forth in Order SAS/ 3470/2009 of 16 December 2009.

In the case of a post-authorization observational prospective follow-up study (post-authorization observational studies in which the patients are selected for their exposure to a certain medicine and are then monitored during a sufficient period of time depending on the event in question after the date when the initial research began), the promoter and the principal researcher must specifically stipulate the procedures that must be followed in the study protocol to ensure that the study does not modify the normal prescription practices of the physician or

practices for the dispensing of the drug (in the case of medicines that do not require a prescription). The medicine must be prescribed through the normal channels. If it is viewed that the medicine must be provided through different procedures, this must be properly justified in the protocol.

The guidelines establish a procedure for registration and control by the Autonomous Communities and the Spanish Medicines and Medical Agency, which is only applicable to prospective follow-up studies. Any post-authorization prospective follow-up studies avoiding such procedures are not deemed to be authorized, and the participation of promoters and health professionals in non-authorized studies is treated as a misdemeanor and is subject to an administrative penalty, without prejudice to any civil, criminal or other liabilities that may arise. Likewise, when the post-authorization observational study is required as a condition in the marketing authorization of the medicinal product, or when it is required by the health authorities to clarify safety issues, or when it forms part of the risk management plan to be carried out by the marketing authorization holder, such study must be authorized by the Spanish Medicinal Products and Medical Devices Agency.

The Farmaindustria Code includes provisions on post-authorization studies, which follow the recommendations given by the Advisory Commission. The Farmaindustria Code includes the obligation to comply with the relevant legislation in the carrying out of such studies. It establishes that the aim of post-authorization studies must be, in substance, scientific or training-related. The Farmaindustria Code also establishes that the medical and research departments shall be responsible for the design and monitoring of post- authorization studies, and sales persons should only be involved in logistic matters.

Investigation with Medical Devices

Investigation with medical devices is regulated by the royal decrees of medical devices. According to these royal decrees, if the investigation involves a medical device without a CE mark or to be used for an indication not included in the relevant conformity assessment

procedure, the prior authorization of the Medicines and Medical Devices Agency must be obtained. In all cases, such investigations require the approval of the Ethics Committee duly certified by the relevant autonomous community.

Market Research Studies

The Farmaindustria Code also governs market research studies. Market research (including social and opinion research) consists of the systematic collection and interpretation of information on individuals or organizations, using statistical and analytical methods and techniques of the social sciences applied to obtain new perceptions or provide elements of support for decision-making.

In these studies, the identities of respondents are not revealed to the user of the information without their specific consent, nor are respondents contacted for sales actions as a direct result of having provided the information.

In addition, to ensure that market research studies do not represent an inducement to prescription or contain incentives prohibited by the Farmaindustria Code, pharmaceutical companies undertake to:

- communicate the existence of the study prior to its start, in accordance with the section related to the Rules of Procedure for the Control Bodies of the Farmaindustria Code;
- ensure that the study does not modify the physicians' prescription habits or the pharmacists' dispensing habits;
- have a written protocol in which the study's objectives, methodology, expected results and its use are clearly established;
- ensure that payment to participating professionals must be based on market criteria and be proportionate to the time devoted, the work done and the responsibilities assumed, and that the payment is adequately documented;

- be approved, prior to execution, by the scientific department of the company or by its compliance officer; and
- be approved, prior to their conduct, by the pharmaceutical company scientific service or by the compliance officer.

Scientific Consulting and Advisory Contracts with Healthcare Professionals and Entities Comprised of Healthcare Professionals

The Farmaindustria Code permits using healthcare professionals as consultants and advisors, whether in groups or individually, for services such as communications at meetings as speaker or moderator, educational activities and expert meetings, even if such participation involves remuneration and/or travel and boarding expenses.

Such arrangements must meet the following requirements:

- They are contracted for the purpose of collaborating with healthcare, research, teaching/training or the organization of professional or scientific events.
- A written contract or agreement is agreed in advance of the commencement of the services, which specifies the nature of the services to be provided.
- A legitimate need for the services is present.
- The criteria for selecting consultants are directly related to the identified need, and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria.
- The number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified need.
- The contracting company maintains records concerning, and makes appropriate use of, the services provided by consultants.

- The hiring of the healthcare professional to provide the relevant service is not an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product.
- Payment 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. Note that payments shall be made in cash; payments in kind are only permitted with prior authorization of the Unit.
- If a healthcare professional attends an event in a consultant or advisory capacity, the relevant provisions regarding hospitality shall apply (Article 11 of the Farmaindustria Code).

When the contracting of this kind of service for a single project or activity involves paid participation of at least 20 healthcare professionals, the pharmaceutical company must notify such contracting to Farmaindustria before the services start. Failure to provide notification regarding these services shall constitute an infringement of this Farmaindustria Code. This is also applicable to the agreement made with healthcare institutions composed of healthcare professionals.

The abovementioned transparency obligations imposed by the Farmaindustria Code must also be complied with.

In their written contracts with consultants, companies are strongly encouraged to include provisions regarding the obligation of the consultant to declare that he or she is a consultant to the company whenever he or she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company. Similarly, companies that employ, on a part-time basis, healthcare professionals that are still practicing their profession are strongly encouraged to ensure that such persons have an obligation to declare

his or her employment arrangement with the company whenever he or she writes or speaks in public about a matter that is the subject of the employment or any other issue relating to that company.

The Fenin Code provides for the contracting of health professionals for providing services such as research, advising, consultation, training, studies and conferences, subject to the following requirements:

- Formalization must be made via a written contract, which specifies the services to be provided and the relevant remuneration.
- Remuneration to healthcare professionals for studies, conferences, data-collection or collection of any other type of information available in a healthcare center must be acknowledged and approved by the center at the relevant levels of responsibility.
- Remuneration must be in line with market value. It will be subject to taxation and/or withholding, as provided by law, and will be paid for the agreed services or products actually provided. Such services or products should contribute advantages to the medical community.
- In the event that hospital resources are used and a remuneration to healthcare professionals exists, the medical center must be a party to the contract.
- The provision of services may not be dependent on any obligation to the use or acquisition of products or services.

Recommendations

Firstly, it is necessary to analyze the promotional practice that the medical product company plans to carry out in order to identify and revise promotional practices that could be totally or partially outside the law.

Additionally, companies should develop an internal code for the company's personnel, both those engaged in promotional activities in the company's headquarters and the medical representatives. The code will classify and list the promotional practices that the pharmaceutical company decides to engage in. The purpose of the code is to provide an internal control document that will allow the company's management to have on record the identification and classification of the promotional activities carried out, as well as to control and avoid possible liability caused by illegal promotion activities. It is advisable that this document identifies those actions that are authorized by the pharmaceutical company, as well as all supporting documentation and the various levels of responsibility and approval involved in carrying them out.

This third edition of "Promoting Medical Products Globally. Handbook of Pharma and MedTech Compliance" is intended to provide an overview of the applicable compliance laws governing the cooperation between the medical industry and physicians in Europe, North America, Latin America and the Asia Pacific region. It highlights the legal framework within which medical device and pharmaceutical companies cooperate with health care professionals. It deals with common sponsoring practices such as invitations, conferences and financial grants for research, personnel and equipment as well as other promotional activities such as the giving of gifts, samples and other items and services which are of interest to health professionals. We trust that the third edition is a useful resource for lawyers, compliance officers, managing directors and managers in marketing and medical departments of the medical industry to assess the legal impact on their promotion and marketing activities involving healthcare professionals or medical institutions.

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