

PROMOTION OF PHARMACEUTICALS AND MEDICAL DEVICES
Authors: Att. Jordi Faus & Att. Anna Gerboles
GENERAL
1. What laws and codes of practice govern the promotion and advertising of pharmaceuticals and medical devices in your jurisdiction? Please also include any relevant industry and self-regulatory codes.
<p>Advertising of medicinal products and medical devices in Spain is regulated by a complex framework comprising laws, regulatory authorities' guidelines, and self-regulatory codes of conduct adopted on a voluntary basis by the pharmaceutical industry.</p> <p>The General Law 34/1988 on Advertising and Law 3/1991 on Unfair Competition establish the general rules governing advertising. The regulations concerning advertising of medicinal products outlined in EU Directives have been transposed through Royal Decree 1416/1994, on promotion of medicinal products for human use. Further guidance on the interpretation of this Royal Decree was provided by the Ministry of Health (MOH) through an Instruction issued in 1995 (Circular 6/1995, later amended by Circular 7/99).</p> <p>In addition, the promotion of medical devices is governed by Royal Decree 1591/2009, on medical devices.</p> <p>Royal Legislative Decree 1/2015, approving the consolidated text of the Law on Guarantees and Rational Use of Medicinal Products and Medical Devices, sets out the sanctions for breach of the rules on advertising of medicinal products.</p> <p>Spain is divided into 17 regions which are competent for implementing rules on advertising medicinal products. Some Spanish autonomous regions have developed their own guidelines (notably, guidelines issued in the regions of Madrid and Catalunya). Furthermore, the MOH has issued a guide on the advertising of over-the-counter (OTC) medicinal products.</p> <p>Spanish trade associations within the pharmaceutical industry have adopted codes of conduct governing the promotion of medicinal products and health technologies, as well as and interactions with healthcare professionals (HCPs), healthcare organisations (HCOs) and patient organisations (POs). Farmaindustria, the Spanish innovative medicinal products industry association, has issued a Code of Farmaindustria, regulating the advertising of prescription-only medicinal products and interactions with HCPs, HCOs and POs.</p> <p>Similarly, AESEG, the Spanish generic medicinal products industry association; ANEFP, the Spanish OTC medicinal products industry association, or FENIN, the Spanish health technologies industry association, have also published their own codes of conduct</p>
2. How is 'advertising' defined? If relevant in your jurisdiction, what is the difference between promotion and advertisement of pharmaceuticals? Of medical devices?
<p>Advertising means all forms of communication carried out by a natural or legal person, whether public or private, in the course of commercial, industrial, artisanal, or professional activities, aimed at directly or indirectly promoting the contracting of goods, services, rights, and obligations.</p> <p>Specifically, Royal Decree 1416/1994 defines advertising of medicinal products as any form of informative offer, commercial research or inducement designed to promote the prescription, dispensation, sale or consumption of medicinal products; particularly, including the following:</p> <ul style="list-style-type: none">• advertising directed at the general public;• advertising directed at persons qualified to prescribe or dispense medicinal products;• visits by medical sales representatives or informative agents of the companies to persons qualified to prescribe or dispense medicinal products;• supply of samples of medicinal products;• sponsorship of promotional meetings where persons qualified to prescribe or dispense medicinal products attend;• sponsorship of scientific meetings attended by persons qualified to prescribe or dispense medicinal products, and in particular, payment of their travel and accommodation expenses in connection therewith; and• any inducement to prescribe or dispense medicinal products by granting, offering or promising any benefit, in money or in kind, except when its actual value is minimal.

<p>Spanish regulations regarding the promotion of medical devices do not establish a specific list of promotional activities. Nevertheless, the aforementioned definition and list of activities or materials can also be regarded as applicable to the promotion of medical devices.</p>
<p>3. Which are the regulatory and supervisory authorities that regulate and enforce the promotion and advertisement of pharmaceuticals and medical devices? What is the relationship, if any, between any self-regulatory process and the supervisory and enforcement function of the competent authorities?</p>
<p>The main regulatory authority in Spain is the Spanish Medicines Agency (AEMPS) competent for drafting technical aspects of medicinal products, medical devices, cosmetics and personal care products, as well as monitoring in the Spanish market.</p> <p>In addition, Spanish regions are competent for the implementation of rules on the advertising of medicinal products. Alternative self-regulatory systems are applicable for those companies adhere to such systems.</p> <p>The Codes of Farmaindustria, AESEG, ANEFP and FENIN state that, prior to raising the issue before the regulatory authorities or the courts, companies adhering to these codes must first file their claims against the advertising practices of other companies before the enforcement bodies of these codes of conduct.</p> <p>Notwithstanding the foregoing, the regulatory authorities may investigate matters on their 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. Conversely, the Jury of Advertising (a specialised body within an association for self-regulation in advertising called <i>Autocontrol</i>) which is responsible for hearing cases relating to the breach of provisions of self-regulatory codes must refrain from assessing any issue which is being or has been assessed by the regulatory authorities or the courts.</p>
<p>4. Are there other product types that fall under the same regulations on promotion (and advertisement) as pharmaceuticals, such as food supplements, special nutritional products? If so, are there any special considerations for the promotion (and advertisement) of such other product types?</p>
<p>Borderline products are not governed by the rules on promotion of medicinal products and medical devices. These products are governed by Royal Decree 1907/1996 on advertising and commercial promotion of products, activities, or services with alleged health purposes, which sets out a list of prohibited activities in connection with the promotion of these products. The most relevant prohibitions are that they cannot be presented as having any property for the prevention or treatment of any type of disease or having weight loss properties. Additionally, they cannot be endorsed using references to HCP or HCO.</p>
<p>CONSUMER MARKETING</p>
<p>5. Is it possible to promote (or advertise) all forms of pharmaceuticals and medical devices (eg, prescription only or professional use products) directly to the public? Are there restrictions on public promotion (advertisements) in your country and, if so, which ones?</p>
<p>Advertising of prescription-only medicinal products and/or publicly financed medicinal products directed at the general public is banned under Royal Legislative Decree 1/2015, Royal Decree 1416/1994 and the Code of Farmaindustria.</p> <p>However, non-prescription medicinal products which are not publicly financed and do not contain psychoactive ingredients may be advertised to the general public. Nevertheless, it is important to note that the following therapeutic indications cannot be promoted: tuberculosis, sexually transmitted diseases, other serious infectious diseases, cancer, chronic insomnia, diabetes, and other metabolic disorders. Also, the promotional material must clearly indicate that it is an advertisement and that the product advertised is a medicinal product.</p> <p>Messages must contain at least the complete name of the product, the name and/or logo of the marketing authorisation holder, its therapeutic indication, its composition, an invitation to read the instructions of the leaflet and to consult a pharmacist, and any additional recommendations by the MOH.</p> <p>Additionally, any promotional material directed at the public must not contain any statement which:</p> <ul style="list-style-type: none">• gives the impression that a medical consultation or surgical procedure is unnecessary;

- suggests that the effects of taking the medicinal product are guaranteed, do not have side effects or are better than, or equivalent to, those of another treatment or medicinal product – adjectives such as 'perfect', 'maximum', 'unique', 'safe' or 'total' are specifically prohibited;
- suggests that a person's health may be improved by taking the medicinal product or that it could be negatively affected by not taking the medicinal product;
- suggests that the use of a medicinal product may enhance sporting abilities;
- is directed exclusively or mainly to children;
- suggests that the medicinal product is a foodstuff, cosmetic or other consumer product, or that the safety or efficacy of the medicinal product is due to the fact that it is a natural substance;
- could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or by the action of the medicinal product;
- includes promises of a cure, exaggerated testimonies on the virtues of the product, or recommendations of scientists, HCPs or celebrities; or
- mentions that the product has obtained a marketing authorisation in any country or any other authorisation.

For medical devices, Royal Decree 1591/2009 sets out the general ban on promoting the following medical devices to the general public for:

- those intended to be used or applied exclusively by HCP;
- those financed by the Spanish National Health System;
- active implantable medical devices;
- self-diagnostic medical devices, with the exception of those intended for pregnancy diagnosis, fertility, and HIV detection; and
- medical devices for genetic diagnosis.

In terms of the requirements for the promotion of medical devices aimed at the general public, prior clearance is required from the competent authorities of the Spanish region where the promoting company is based. Additionally, all advertising materials must include the type of medical device being promoted, contraindications, possible side effects of the device, and a disclaimer confirming compliance with applicable regulations.

6. Is promotion (and advertising) of pharmaceuticals and medical devices through the internet and social media regulated in your jurisdiction? If so, what are the rules and related restrictions?

Broadly speaking, advertising activities on the internet are subject to the same requirements as those carried out through traditional channels.

As regards advertising addressed to HCPs through the internet, companies must use valid channels within a scientific or professional context, which must be exclusively addressed to HCPs, and require HCPs to identify themselves in order to have access to the information displayed. Additionally, pharmaceutical companies can also establish an HCPs status verification system for accessing the information. Companies will also be liable for the content of the websites accessed through links from the company's website.

7. Must promotions (and/or advertisements) receive prior approvals from regulators before use and if so, what is the procedure (please provide a high-level description)?

Advertising of medicinal products does not require prior approval by regulators. However, regarding promotions addressed to HCPs, companies must send a copy of the advertisement to the health authority of the Spanish region where the company is located. Companies are responsible for ensuring that only HCPs have access to the relevant advertisement. In exceptional cases, the MOH may require prior approval for advertising a specific product. Any such decision must be justified and affect all products with the same composition.

This is without prejudice to the fact that all advertising is subject to *ex-post* control by the authorities, and sanctions may be imposed in case of breach of the law. Additionally, according to Royal Decree 1416/1994, companies are required to submit an annual summary index of all their advertising materials to the health authority of the Spanish region in which they are based.

Promotion of medical devices addressed to the general public requires prior authorisation from the regional authority where the company is based.
8. May information on unauthorised pharmaceuticals and/or off-label information be promoted (advertised)? If so, in what circumstances and under which modalities?
<p>Advertising of unauthorised medicinal products and/or off-label information is not allowed according to Royal Decree 1015/2009 on access to medicines in special situations.</p> <p>Regulatory authorities and the Code of Farmindustria sometimes allow companies to share scientific or newsworthy information with HCPs and HCOs before product approval, provided it is not promotional. It is advisable to take a rather restrictive approach regarding these activities, due to the risk of being perceived as having promotional intent (eg, active communications to HCPs and HCOs on unauthorised medicines/indications informing about a forthcoming launch should be avoided). Only reactive interactions would be permitted, provided that they do not include promotional claims or commercial offers.</p> <p>Promotional materials on medicinal products authorised in countries other than Spain may be distributed during international congresses or meetings held in Spain, provided that:</p> <ul style="list-style-type: none">• the congress or meeting is attended by numerous professionals from other countries;• the materials are written in the language of the country where the product is approved or in English; and• the materials include a clear warning indicating (at least in Spanish) that the medicinal product or the indication object of promotion is not marketed or authorised in Spain. <p>Regarding promotion of medical devices, a CE marking is a prerequisite for commercialisation and for distribution of advertising materials. The draft bill on promotion of medical devices has included the specific ban on promoting medical devices for indications different from those validated by the Notified Body or the ones included in the instructions for use. However, this prohibition is yet not enforceable. A similar ban is contained in the AEMPS' Circular Letter 7/2004, regulating clinical investigations with medical devices. However, this prohibition is not contained in a regulation with the status of Law as in the case of off-label promotion of medicinal products.</p>
9. What rules govern comparative advertisements? Is it possible to use another company's information (including brand name) as part of that comparison? If so, which information and under which conditions? Would it be possible to refer to a competitor's product or indication which has not yet been authorised in your jurisdiction?
<p>Law 3/1991 allows comparative advertisement of medicinal products provided that:</p> <ul style="list-style-type: none">• the products or its characteristics are comparable, essential and relevant (often observed in comparisons between medicinal products and medical devices with same or coincident indications);• the comparison is objective, scientifically proven and verifiable from sources immediately accessible to the competitor; and• the general tone of the advertisement is balanced and fair. <p>Under the Code of Farmindustria, 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 competitor's reputation. If competitor brand names are used, there should be a clear and visible indication on the owner. However, there is no legal or deontological provision requiring an specific reference to the trademark of the medicinal product, as comparative advertising allows for referring to a competitor either explicitly or implicitly.</p> <p>In terms of mentioning a competitor's product or indication that has not yet received approval, Spanish regulations and precedents do not provide specific guidance. Given the potential risk of promoting an unapproved medicinal product or indication, it is prudent to adopt a cautious approach, limiting such references to scientific and informational contexts.</p>
DEALING WITH HEALTHCARE PROFESSIONALS AND HEALTHCARE INSTITUTIONS

10. How are healthcare professionals defined in your jurisdiction? Is there any regulation that restricts promotional (advertisement) communications directed to healthcare professionals? If so, what are those restrictions?
<p>There is no legal definition of healthcare professionals in Spain. The Code of Farmaindustria does consider a HCP any member of the medical, dental, pharmaceutical, nursing or podiatric profession, any other person legally considered as such, or any other person who, in exercising their profession, may perform or participate directly or indirectly in the prescription, purchase, supply, dispensation or administration of medicinal products for human use.</p> <p>According to Royal Decree 1416/1994 any promotional material addressed to HCPs must contain:</p> <ul style="list-style-type: none">• the name of the product;• the name and address of the marketing authorisation holder;• the qualitative and quantitative composition of the product;• essential data according to the SmPC, including complete clinical data, indications for use, cautions and relevant contraindications;• the different dosages and pharmaceutical forms in which the product is available;• the prescription and dispensation regime applicable to the product;• the retail price and the conditions under which the product is publicly financed; and• the estimated cost of treatment, if possible to determine. <p>Messages must be precise, balanced, honest, objective, based on adequate scientific evaluation, and sufficiently complete as regards the therapeutic value of the product.</p>
11. Are there specific rules governing promotional (and advertising) activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?
<p>In general, the regulations governing promotional activities conducted virtually, including interactions with HCP, are the same as those for in-person promotional activities.</p> <p>The Code of Farmaindustria and the FENIN Code state that no type of hospitality should be offered (social events, accommodation, travel and/or personal/subsistence/out of pocket expenses) at virtual meetings.</p>
12. Are there any restrictions to the inclusion of endorsements by healthcare professionals in promotional (advertising) materials? If so, which ones and how may such endorsements take place?
<p>Promotion of medicinal products and medical devices aimed at the general public cannot be endorsed using references to HCP, or HCO. A restrictive interpretation has been applied by the Jury of Autocontrol and has extended the ban to images of hospitals or doctors and interviews with them as a prohibited form of endorsement.</p> <p>The Catalan Guide on the promotion of medicinal products also provides for the bar to include testimonials or endorsements in informative materials addressed to patients, since this could be regarded as promotion.</p>
13. Is it possible to provide healthcare professionals with samples of medicinal products? Or medical devices? If so, what restrictions apply? Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.
<p>According to Royal Decree 1416/1994, provision of free samples of medicinal products to HCPs can only be made on an exceptional basis with prior authorisation from the AEMPS whenever the medicinal product has a new active substance; pharmaceutical form, concentration dosage, or administration route which represents a therapeutic advantage; or therapeutic indications.</p> <p>The following restrictions apply:</p> <ul style="list-style-type: none">• supply of samples must be in response to a written request, signed and dated, from HCPs entitled to prescribe medicinal products;• only a maximum of ten samples for each medicinal product each year per HCP, during a maximum period of two years after the marketing authorisation is granted;• samples must not be bigger than the smallest presentation of the product authorised in Spain;

- each sample must be marked 'free sample – not for sale' and its reimbursement sticker must have been annulled; and
- a sample must be accompanied by a copy of the SmPC and by updated information on its price, conditions of reimbursement by the Spanish National Health System and, if possible, estimated cost of treatment.

When it comes to providing samples of medical devices, regulations do not offer specific guidance. The FENIN Code allows for the provision of samples for consumable medical devices, excluding medical equipment or technologies. Nonetheless, it does not establish any limits on the number of samples or a timeframe for their lawful provision.

Gifts may only be offered to HCPs when the cost of the gift is insignificant, and the gift is relevant to the practice of medicine or pharmacy.

The Code of Farmaindustria provides further guidance, allowing gifts to HCPs only if they have stationary or professional use; are not related to a prescription-only medicinal product and have a market price that does not exceed €10. Moreover, such gifts cannot be given in the context of promotional and informative visits made by sales representatives of companies, nor in the framework of a congress or meeting organised by a third party if such a visit or event relates to prescription-only medicinal products.

The FENIN Code provides for a similar exception, as only training materials and/or products directly related to the practice of the HCP, or that directly benefit the care or attention of patients are permitted, provided that the market price does not exceed €12.

14. What rules govern the offering of hospitality to healthcare professionals?

Hospitality to HCPs is only governed by self-regulatory codes.

Under the Code of Farmaindustria, hospitality may be offered to HCPs at professional or scientific meetings, provided that it is reasonable and moderate, and strictly limited to necessary logistical means that allow HCPs to attend the meeting. Hospitality offered may only include payment of real costs of travel, registration and accommodation. Hospitality may only be extended to the day after or before the event. Payments for meals that cost more than €70 (taxes included) per person, as well as payments for five-star hotels, five-star grand luxury hotels, sports resort hotels, theme park hotels and/or winery hotels, are banned under the Code. Payment for cultural, leisure or entertainment activities is also prohibited. No monetary reimbursement can be made to the HCPs as a form of hospitality.

Similar provisions are outlined in the FENIN Code regarding hospitality, with the threshold for meals set at €80.

15. Are donations made by permit/authorisation holders to healthcare institutions or organisations considered a promotional (advertising) tool? Is there a special regulation on donations?

Donations to HCOs are acceptable if they are not offered as an inducement to buy, recommend and/or use the products of the company.

The Code of Farmaindustria allows donations and/or the funding of the cost of medical or technical services to institutions, organisations, associations and foundations whose members are HCPs and/or which provide services of sanitary, social or humanitarian assistance, research or teaching. The following conditions must be met:

- it must not be offered as an inducement to prescribe, recommend or use any particular product;
- it must be for the internal use of the institution in general, and not for the use of an individual (portable electronic devices are expressly excluded); and
- it must be recorded in a document to be kept by the company.

Under the FENIN Code, donations may be made to charitable entities such as NGOs (charitable donations) or, otherwise, must be granted in a form of an educational or research grant. Companies shall establish independent processes, separate from sales and commercial functions and with robust decision-making mechanisms with clear, consistent, and transparent criteria, for the review and approval of grant applications.

<p>Both the Code of Farmaindustria and the FENIN Code set out the need for donations to be properly documented by the company, ensuring that the terms governing the funding are clearly stated and transparent.</p>
<p>16. Can pharmaceutical laboratories or medical device manufacturers or their licensees support scientific or educational meetings? If so, is there any difference between these two sectors from the perspective of rules on the promotion of products?</p>
<p>Pharmaceutical and medical device companies may sponsor or organise scientific meetings or congresses. Such sponsorship must be stated in all documents relating to the event, as well as in any published derivative work.</p> <p>There are no significant discrepancies between the two sectors, except the FENIN Code offers more detailed requirements for sponsoring scientific or educational meetings. For instance, the FENIN Code mandates the disclosure of the amount allocated for management expenses (with a set limit of ten per cent of the total amount), the necessity to refund any surplus funds remaining after the event concludes, and the obligation to predetermine the recipient profile for educational grants (this being applicable to an educational event with HCPs participating as trainees).</p>
<p>17. Please provide an overview of the rules around the industry and patient organisations' relationships, including funding.</p>
<p>Spanish law does not regulate restrictions on interactions between patients or POs and the pharmaceutical industry.</p> <p>The Code of Farmaindustria states that any collaboration between companies and POs must be formalised in a written agreement, stating:</p> <ul style="list-style-type: none"> • the purpose of the collaboration; • the activities to be performed by each of the parties; • the financial amount of the collaboration; and • a description of any relevant indirect support provided by the company and the sources and purposes of the support. <p>Additionally, companies must have an internal process for the approval of these collaborations and must refrain from requesting to be exclusive collaborator/sponsor of a PO or any of their principal activities or try to influence the content of the publications issued by a PO.</p> <p>The Code of Farmaindustria also provides that engagement of patients must be arranged through POs.</p> <p>Hospitality must comply with the same requirements as hospitality given to HCPs. Hospitality must only be made available to accompanying persons if they attend as helpers of patients. Payment of such expenses must be made through the PO.</p>
<p>18. Is it possible to delegate promotional (advertising) activities to a third party through a service agreement? If so, under which conditions? Is co-promotion regulated in your jurisdiction and if so, how?</p>
<p>Regulations do not address this matter; therefore, delegating promotional activities to third-party service providers is allowed.</p>
<p>19. Is it mandatory in your country to report transfers of value made by permit/authorisation holders to healthcare professionals?</p>
<p>No. However, the Code of Farmaindustria has implemented the EFPIA rules on disclosure of transfers of value from pharmaceutical companies to HCPs, HCOs and POs. Consequently, since 2015, companies adhered or associated to the Code are required to document and publish on their website all transfers of value (ie, any direct or indirect payment or grant, either cash or benefits in kind, and regardless of their purpose) made during the previous year.</p> <p>The same requirements are applicable to those members of FENIN, which has implemented the principles Code of Ethical Business Practices of MedTech Europe; and AESEG, which has also implemented in its own code the Medicines for Europe rules on disclosure of transfers of value from pharmaceutical companies to HCPs, HCOs and Pos.</p>
<p>ENFORCEMENT</p>

20. What penalties and other sanctions are associated with violations related to product promotion (advertisement)? Do supervisory authorities actively impose penalties and other sanctions? Are these penalties and other sanctions announced publicly?

Breach of the rules governing medicinal products and medical devices advertising and/or inducements may result in administrative sanctions, generally the imposition of a fine, the amount of which will depend on various factors (eg wilful or negligent breach; existence of fraud; failure to comply with previous authorities' requests; the company's turnover; the number of persons affected; etc.)

Administrative sanctions are mainly set out in Royal Legislative Decree 1/2015 and are divided in minor, serious and very serious infringements. These infringements are sanctioned with fines ranging from €6,000 to €30,000 for minor infringements, €30,001 to €90,000 for serious infringements, and €90,001 to €600,000 for very serious infringements. Breaches related to the promotion of medicinal products are considered very serious infringements, while breaches related to the promotion of medical devices are considered serious infringements.

Additionally, self-regulatory codes have established their own procedures and sanctions to address breaches of their respective codes.

Only sanctions resulting from very serious infringements are publicly disclosed in the Spanish *Official Gazette*.

21. Who is responsible for enforcement, and how strictly are the rules enforced? To what extent may competitors take direct action through the courts in relation to promotion (advertising) infringements?

Spanish regions and courts are responsible for enforcement. Further, the rules resulting from the Codes of Farmaindustria, AESEG and ANEFP are enforced by self-regulatory bodies in agreement with Autocontrol. Both, regulatory authorities and self-regulatory associations are generally very strict in enforcing sanctions.

In relation to the extent to which competitors can take direct action against third-party infringements, affiliated companies to the industry codes must resort to the established procedure in these Codes (see the response to Question 3). On the other hand, non-affiliated companies' competitors may directly pursue legal action through the courts or regulatory authorities.

FUTURE DEVELOPMENTS

22. Are any significant developments in the field of pharmaceutical or medical device promotion (advertising) expected in the next year or so? Are there any general practice or enforcement trends that have become apparent in your jurisdiction over the last year or so?

There is an ongoing debate regarding whether undergoing pricing and reimbursement proceedings is necessary before promoting a medicinal product. As of the drafting of this survey, no final court ruling has been issued. However, Catalonia and Madrid have taken a strong stance, advocating for the requirement of pricing and reimbursement resolution for lawfully promoting a medicinal product.

In contrast, Farmaindustria has stated that, according to Spanish regulations, only marketing authorisation, and not pricing and reimbursement resolution, is a prerequisite for promoting a medicinal product.

The matter has been brought before Spain's Supreme Court, which, in November 2023, admitted for a final ruling the appeal filed by a company against a sanction issued by the Madrid authorities.

Furthermore, the MOH has recently initiated the public consultation period for the draft Royal Decree on medical device advertising. This proposal addresses several significant aspects, including simplifying the process of obtaining prior clearance for the promotion of medical devices aimed at the public, while also introducing a responsible declaration requirement for advertising specific medical devices. Additionally, the proposal bans hospitality within the context of promotional meetings, limiting it to professional-scientific events, explicitly prohibits off-label promotion, and provides detailed guidance on the minimum and prohibited content in advertising directed at the public.

Finally, in April 2023, the MOH invited all interested parties to submit proposals regarding the preparation of the draft bill amending the Royal Decree on promotion of medicinal products for human use. The new draft law is currently under preparation.