International Comparative Legal Guides

Pharmaceutical Advertising 2026

A practical cross-border resource to inform legal minds

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1 General – Medicinal Products

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

Laws: concerning legal texts, the advertising of medical products is governed by:

- Decree Law 176/2006 of August 30, as amended, which establishes the legal regime applicable to medicines;
- Decree Law 5/2017 of January 6, which establishes the advertising principles and a prohibition on National Health Service ("NHS") hospitals from requesting and receiving benefits from the pharmaceutical industry and from other health technology companies, except if such receipt has been previously authorised by the competent authority (local Regulatory Authority) and does not harm their impartiality and neutrality; and
- Decree Law 330/90 of October 23, as amended, which approves the Advertising Code.

Administrative regulations: through administrative regulations, the local Regulatory Authority, the National Authority of Medicines and Health Products, I.P. ("Infarmed"), and the Secretary of State of Health regulate some specific topics on the advertising of medical products.

Codes: the Portuguese Pharmaceutical Industry Association ("APIFARMA") approved the following codes, which are applicable to pharmaceutical companies that are APIFARMA members:

- the Code of Ethics for Promotion Practices of the Pharmaceutical Industry and Interaction with Healthcare Professionals and Health Organisations ("Code of Ethics");
- the Code of Conduct for the Relations Between the Pharmaceutical Industry and Patients' Associations, Patients Advocates, Patients Experts, Patients and Caregivers ("Code of Conduct");
- the Code of Good Practice for Communication; and
- the Guidelines on the Use of Digital Channels.

1.2 How is "advertising" defined?

The advertising of medicines is defined in article 150 (1) of Decree Law 176/2006 of August 30, as amended, as any form of information, prospection or incentive which is within the scope of, or has the effect of, promoting the prescription, dispensation, sale, acquisition or consumption of medicines in any of the following circumstances:

(a) before the public in general;
(b) before wholesale distributors and healthcare professionals ("HCPs");
(c) through the visit of medical sales representatives to HCPs;
(d) through the provision of samples or commercial bonuses to wholesale distributors and HCPs;
(e) through the granting, offer or promise of pecuniary or in-kind benefits, except when their value is insignificant;
(f) through the sponsorship of promotional meetings attended by HCPs;
(g) through the sponsorship of congresses or meetings of a scientific nature attended/participated in by HCPs, namely through the direct or indirect payment of the respective hosting costs; and
(h) through reference to the commercial name of a medicine.

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

The Market Holders of medicines are obliged to have a scientific service responsible for the information related to the medicines and for maintaining complete and detailed records of all the advertising of medicines, including indications of the target audience, channel and date of first dissemination.

The same scientific service must ensure that the advertising activities comply with all the obligations imposed by law and codes, and that the medical sales representatives have the appropriate professional qualifications.

The scientific service should keep advertising records for a five-year period and should make such records available for consultation or inspection by the local Regulatory Authority. The scientific service is also required to cooperate with such Authority and other competent authorities in all that is deemed necessary within the scope of the authorities' respective legal powers.

1.4 Are there any legal or code requirements for companies to have specific standard operating procedures (SOPs) governing advertising activities or to employ personnel with a specific role? If so, what aspects should those SOPs cover and what are the requirements regarding specific personnel?

Pharmaceutical companies are not legally required to establish standard operating procedures ("SOPs") governing advertising activities. However, they are required to comply with the obligations referred to in the answer to question 1.3 above.

The scientific service referred to in the answer to question 1.3 above should preferably be supervised by a qualified person (a physician or a pharmacist, as established by article 4, no. 2, of APIFARMA's Code of Ethics).

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

Only in cases involving vaccination campaigns or promotional campaigns of generics before the general public, which require prior approval by Infarmed. Otherwise, such campaigns could be classified as prohibited advertising activity.

Notwithstanding, the Market Holders or holders of medicine registers are required to submit to the local Regulatory Authority, for information purposes, within 10 days, one sample of each advertising material concerning each medicine.

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

In accordance with Decree Law 176/2006 of August 30, as amended, the local Regulatory Authority may assess all advertising of medicines, may decide to end any further disclosure or publication, and may also impose sanctions (fines and ancillary penalties) in case of breach of the advertising legal provisions contained in the mentioned legislation.

Corrective measures, temporary or definitive, may be imposed by the Authority if deemed necessary to hinder a breach of the applicable law requirements, whether the advertising activity has already been initiated or not.

The Authority may also identify and issue a specific ruling in situations which, considering the respective supporting advertising material or the recipients of the advertisement, may justify an exemption from the inclusion of some mandatory elements of the advertisement.

The decisions taken by the Authority may, in the general terms for administrative decisions, be challenged.

1.7 What are the penalties for failing to comply with the rules governing the advertising of medicines? Who has responsibility for enforcement and how strictly are the rules enforced? Are there any important examples where action has been taken against pharmaceutical companies? If there have not been such cases, please confirm. To what extent may competitors take direct action through the courts in relation to advertising infringements?

Infarmed (the local Regulatory Authority) is the enforcement authority for the advertising of medicines and may decide on the imposition of fines in case of infringement of the applicable legal provisions established by Decree Law 176/2006 of August 30, as amended.

The fines range from €2,000, at the minimum, to 15% of the business volume of the infringer or €180,000, whichever is lower, at the maximum.

The following accompanying sanctions may also be imposed (depending on the seriousness of the infraction and the level of fault):

(a) loss, in favour of the State, of illicit objects, equipment and devices;
(b) interdiction, for a maximum period of two years, of activity of the infringing company;
(c) deprivation of the right to participate in public tenders for a maximum period of two years; and
(d) suspension of authorisations, licences and other titles attributing rights for a maximum period of two years.

In case of infringement of advertising legal provisions, the specific following accompanying sanctions may also apply:

(a) the decision on imposition of fines may also determine the publication on social media of the essential elements of the condemnation;
(b) the suspension of advertising the relevant medicine for a maximum period of two years;
(c) a procedure to exclude the relevant medicine from the reimbursement regime by the State may be initiated; and
(d) the infringer's medical sales representative may be prevented from visiting NHS hospitals and services, in case of violation of the legal regime by such visits.

In addition, infringements to APIFARMA's codes and respective provisions, namely on advertising and inducement, are dealt with by APIFARMA's Ethics Council, which may impose the following penalties on its members:

(a) a simple warning;
(b) a reprimand; and/or
(c) a penalty up to the amount of five years' worth of membership fees.

Infarmed and APIFARMA do not disclose the decisions on advertising or on any other topic concerning infringements to the applicable law and established rules.

Competitors may take actions before the courts in relation to advertising infringements through civil liability lawsuits if the respective requisites are met in each case.

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

There is no relationship between the self-regulatory process and the one enforced by the competent authority (Infarmed).

Infarmed supervises and enforces compliance with the applicable law and administrative regulations by pharmaceutical companies (manufacturers, marketing authorisation holders) and wholesale distributors, importers and exporters of medicinal products. On the other hand, APIFARMA is the local professional association of the pharmaceutical industry that supervises and enforces its Codes of Ethics and Conduct upon its associated members. The procedures, decisions and penalties are completely separate.

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

Such advertising activities might result in the breach of legal provisions of other legal areas. Acts of unfair competition are, under Portuguese law, punishable as administrative offences. Furthermore, the interested parties may request before the courts preventive actions or compensation for damages through civil liability lawsuits.

1.10 Do the above rules apply to statements by healthcare providers (such as clinics or pharmacies) and members of the public (including influencers), as well as to pharmaceutical companies?

The general rules applicable to the advertising of medicinal products apply to testimonial advertising.

Furthermore, and in accordance with the Advertising Code, testimonial advertising must include personalised, genuine and verifiable testimonials relating to the experience of the person giving the testimonial or of the person they represent; depersonalised testimonials are permitted, provided they are not attributed to a specially qualified person, in particular due to the wearing of uniforms, dress uniforms or clothing characteristic of a particular profession.

2 Providing Information Prior to Authorisation of Medicinal Product

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

Advertising of a medicine before it is authorised or off-label information is not permitted.

However, if the information to be provided is related to human health or human diseases (as may be the case with some scientific information concerning human diseases), and as long as a specific medicine is not referenced, directly or indirectly, such information may be disclosed and it will not be considered "advertising", as foreseen in article 151, no. 1-d) of Decree Law 176/2006 of August 30. In the same sense, APIFARMA's Code of Ethics, specifically article 5, no. 4, foresees the exclusion of the right of pharmaceutical companies to inform the scientific community about the advances in the field of medicinal products and therapeutics from the prohibition of advertising medicines not yet authorised or off-label information, permitting therefore the disclosure of the results of the scientific research they are carrying out for that purpose. Nevertheless, considering the abovementioned article 151, no. 1-d) of Decree Law 176/2006 of August 30, it is recommended not to mention, directly or indirectly, the commercial name of the medicine.

A case-by-case analysis of this topic is strongly recommended.

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

Information on unauthorised medicines and/or off-label information may be published with the constraints mentioned in the answer to question 2.1 above and may only be disclosed and accessed by the scientific community.

2.3 Is it possible for companies to issue press releases about unauthorised medicines and/or off-label information? If so, what limitations apply? If differences apply depending on the target audience (e.g. specialised medical or scientific media vs. mainstream public media), please specify.

No. Please consider the answers to questions 2.1 and 2.2 above.

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

The information mentioned in the answer to question 2.1 above may be sent to HCPs, as they are, for this purpose, part of the scientific community. The constraints mentioned in the answer to question 2.1 are applicable.

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

The ECJ judgment in the *Ludwigs* case had no impact on Portuguese legislation. However, as established by Decree Law 176/2006 of August 30, non-approved medicines may be provided to patients under a specific exceptional use authorisation, to be granted by Infarmed once the established requisites are met. The situation of the *Ludwigs* case is not addressed as one of the established requisites.

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

Taking into consideration the prohibition of advertising unauthorised medicines or indications, as explained above in the answer to question 2.1, providing such information to institutions with the mentioned purpose is not permitted.

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

Yes, it is, in the general terms of the professional services that may be provided by the HCP to pharmaceutical companies (please see the answer to question 5.4 below), since this does not fall within the definition of advertising and it does not constitute a means of inducing prescriptions, which is strictly prohibited.

3 Advertisements to Healthcare Professionals

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

Advertisements before HCPs shall include, in a legible way in the respective advertising material, the following:

(a) the name of the medicine;
(b) the essential information compatible with the summary of product characteristics ("SmPC");
(c) the classification of the medicine concerning the dispensation regime of the same, namely if it is a prescribed medicine, when applicable;
(d) the respective reimbursement regime; and
(e) the date of the issuance of the advertising material in question and the date of its last revision.

3.2 Are there any restrictions on the information that may appear in an advertisement? May an advertisement refer to: (a) studies not mentioned in the SmPC; or (b) studies which have not been published either in peer-reviewed journals or at all ("data on file")?

The information contained in the advertising material must be accurate, up to date, verifiable and sufficiently complete to allow the recipient to correctly assess the therapeutic value of the medicine; and the references and the illustrative material of medical publications or scientific works used in the advertising support shall be correctly reproduced and should mention the respective source.

In this context, an advertisement may refer to studies not mentioned in the SmPC, provided that there is no contradiction between them; however, since information must be verifiable, it does not seem possible to mention studies that have not been published.

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

There are no restrictions to the inclusion of endorsements by HCPs in promotional materials. However, under the Advertising Code, testimonials should be genuine and verifiable (please see the answer to question 1.10 above).

3.4 What rules govern comparative advertisements? Is there a requirement for "head to head" clinical trial data? Is it possible to use another company's brand name as part of that comparison? Would it be possible to refer to a competitor's product or indication which had not yet been authorised in your jurisdiction?

Comparative advertising of medicines can only be disclosed to HCPs and is therefore prohibited from being disclosed to the general public.

Accordingly, with APIFARMA's Code of Ethics, comparative advertising should be based on relevant and comparable aspects. It cannot be misleading or defamatory and the comparison of the medicines should be based on the medicines' characteristic specifications, instructions of use, technical documentation or credible clinical data.

Therefore, using another company's brand name as part of a comparison is not prohibited. However, it does not seem admissible to refer to a competitor's product or indication which has not yet been authorised, taking into consideration the explanations provided in section 2 above.

3.5 What rules apply to environmental "green" claims made in relation to specific products in promotional material?

There are no specific rules on this matter. Green claims must, under the general terms of the Advertising Code, respect the principles of lawfulness, identifiability, truthfulness and respect for consumer rights.

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

There are no specific rules on this matter. However, the information to be disclosed should take into consideration what is highlighted in the answers to the questions in section 2 and question 3.1 above.

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

Considering the mandatory elements for advertisements directed to HCPs detailed in the answer to question 3.1 above, it seems that "teaser" advertisements are not permitted.

However, under the law, it is possible to develop an advertising piece for the sole purpose of bringing attention to the name of the medicine. In this case, those elements are not mandatory.

3.8 Where Product A is authorised for a particular indication to be used in combination with another Product B, which is separately authorised to a different company, and whose SmPC does not refer expressly to use with Product A, so that in terms of the SmPC for Product B, use of Product B for Product A's indication would be off-label, can the holder of the MA for Product A nevertheless rely upon the approved use of Product B with Product A in Product A's SmPC, to promote the combination use? Can the holder of the MA for Product B also promote such combination use based on the approved SmPC for Product A or must the holder of the MA for Product B first vary the SmPC for Product B?

As a general principle, off-label advertising is not permitted. Therefore, it seems the MA holder for Product A may promote the combination use (once the combined use with Product B has been authorised), but the MA holder for Product B cannot promote the combined use (since it would be off-label under its own SmPC), and, therefore, the MA holder for this last product should first vary the respective SmPC.

4 Gifts and Financial Incentives

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

Yes, if cumulatively the following requisites are met:

(a) the number of samples provided in each year to each HCP

cannot be more than four, if the lowest number is not defined by the marketing authorisation;
(b) the samples are to be requested by the HCP by means of written request, duly dated and signed;
(c) the samples cannot have a larger size than the smallest presentation of the medicine under commercialisation;
(d) the samples' packaging must contain the words "Free Sample" and "Prohibited Sale" or other similar words;
(e) the samples shall be accompanied by the SmPC; and
(f) the samples can only be provided in the following two years after the start of the commercialisation of the medicine.

Providing samples of medicines containing drugs and psychotropic substances is prohibited.

4.2 Are there any restrictions on the value of payments or benefits that may be provided to healthcare professionals or healthcare organisations for consultancy services? Is it necessary to obtain advance approval from the authorities for the arrangements?

There are no legal rules fixing the value of payments granted to HCPs or healthcare organisations ("HCOs") for consultancy services.

In accordance with APIFARMA's Code of Ethics, payments must be reasonable and reflect the market value of the services to be provided by the same.

No advance approval from the authorities for the arrangements is required.

4.3 Is it possible to give gifts, donations or grants to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

No, except for grants or donations in kind with insignificant monetary value (under €60) and cumulatively with relevance for the medicine or pharmaceutical practice.

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

It is possible to provide support, both financial and non-financial, to HCOs, with the aim of supporting healthcare services, research activities or continuing medical education. The support should not constitute an incentive nor a compensation to recommend, prescribe, purchase, supply, dispense, sell, administer or use medicines.

However, in accordance with article 9 of Decree Law 5/2007 of January 6, NHS hospitals can neither request nor receive, directly or indirectly, pecuniary or in-kind benefits from pharmaceutical companies, health technology companies or related companies when such actions may harm the impartiality and neutrality of the hospitals. When impartiality and neutrality are not at risk, prior authorisation to receive the benefit should be requested by the NHS hospital's management bodies to Infarmed.

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

The providing of medical or educational goods or services should not constitute an incentive or compensation for recommending, prescribing, purchasing, supplying, dispensing, selling, administering or using medicines.

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

Price discounts are outside the scope of the rules on advertising of medicines and may be granted to such institutions in the context of established commercial relationships.

4.7 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? Are commercial arrangements whereby the purchase of a particular medicine is linked to provision of certain associated benefits (such as apparatus for administration or the provision of training on its use) as part of the purchase price ("package deals") acceptable? If so, what rules apply?

In general, contingencies cannot be imposed on the purchase and supply of medicinal products, as they could be considered an incentive to prescribe, purchase, supply, dispense or use medicines. However, if a certain medicinal product requires specific training on its use or administration, this could be offered/disclosed when it is considered essential in order to fulfil the purpose of such medicinal product.

4.8 Are more complex patient access schemes or managed access agreements, whereby pharmaceutical companies offer special financial terms for supply of medicinal products (e.g. rebates, dose or cost caps, risk share arrangements, outcomes-based schemes), permitted in your country? If so, what rules apply and does it make a difference whether the product is a prescription-only medicine, or an over-the-counter medicine?

Special financial terms for the supply of medicines are usually agreed between pharmaceutical companies and Infarmed under reimbursement agreements of medicines or under previous evaluation agreements to supply NHS hospitals. By these agreements, the medicine's maximum price, annual cap concerning the maximum sales to NHS hospitals, outcomes, risk-sharing mechanisms, etc. are usually agreed upon (article 6 of Decree Law 97/2015 of June 1). Discounts may also be granted to purchasing entities, as mentioned in the answer to question 4.6 above.

4.9 Is it acceptable for one or more pharmaceutical companies to work together with the National Health System in your country, pooling skills, experience and/or resources for the joint development and implementation of specific projects? If so, what rules apply?

This possibility is not specifically addressed by the applicable law. Therefore, the assessment should be made on a case-by-case basis under the general principles governing the advertising of medicines. Namely, it is to be stressed that this kind of initiative can harm the impartiality and neutrality of NHS hospitals or be understood as an incentive to prescribe, purchase, supply, dispense or use medicines (please see the answer to question 4.4 above).

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

Pharmaceutical companies may sponsor continuing medical education by supporting the participation of HCPs in scientific or educational events, whether promoted by pharmaceutical companies or by third parties. The sole costs to be paid concerning their attendance at these events are the hosting costs: registration; travel; stay; and meals.

These events cannot have any social programme or activity that may prejudice or prevent the full attendance of HCPs at the professional or scientific sessions of the events (entertainment events are not permitted). The selection of the location for the events shall comply with adequate professional and logistic criteria, namely with respect to the level of hospitality and financial costs which are to be adequate for the purpose of the events.

The applicable law consists of articles 160 and 161 of Decree Law 176/2006 of August 30.

APIFARMA's Code of Ethics is also applicable.

4.11 What general anti-bribery rules apply to the interactions between pharmaceutical companies and healthcare professionals or healthcare organisations? Please summarise. Is there a specific duty placed on companies to prevent bribery and, if so, what must companies do in order to comply with the duty? What is the relationship between the competent authorities for pharmaceutical advertising and the anti-bribery/anti-corruption supervisory and enforcement functions? Can and, in practice, do the anti-bribery competent authorities investigate matters that may constitute both a breach of the advertising rules and the anti-bribery legislation, in circumstances where these are already being assessed by the pharmaceutical competent authorities or the self-regulatory bodies?

The anti-bribery rules apply to the interactions between pharmaceutical companies, HCPs and HCOs, and are, in general, defined in the Portuguese Criminal Code. If the same facts constitute both a breach of the advertising rules, which may lead to the initiation of an administrative offence procedure, and also of the anti-bribery legislation, therefore possibly constituting a crime, Infarmed, as the local Regulatory Authority, is obliged to report them to the Public Prosecutor's Office.

However, if the same facts also constitute a breach of APIFARMA's Codes of Conduct and Ethics, the respective Ethics Council may investigate and sanction APIFARMA members autonomously (please see the answer to question 1.8 above).

5 Hospitality and Related Payments

5.1 What rules govern the offering of hospitality to healthcare professionals? Does it make a difference if the hospitality offered to those healthcare professionals will take place in another country and, in those circumstances, should the arrangements be approved by the company affiliate in the country where the healthcare professionals reside or the affiliate where the hospitality takes place? Is there a threshold applicable to the costs of hospitality or meals provided to a healthcare professional?

Pharmaceutical companies may offer hospitality in the context of a sponsorship (please see the answer to question 4.10 above). HCPs may participate in cross-border events and the respective hospitality costs and arrangements may be approved either by the affiliate where the HCPs resides or by the affiliate where the event takes place, depending on the entity (affiliate) that acts as the promoter of the event or on the entity that invited the HCP.

The support can only be granted to the HCP who will attend the event concerned, and the costs are to be restricted to the main purpose of the event, and cannot include entertainment events (for example, leisure and sports events/activities).

The costs of the stay cannot surpass the period between the day before the event and the day after the ending of the same and cannot be locations and/or touristic resorts that are best known for their leisure, entertainment or sports facilities. The cost of the meals within the national territory cannot exceed €60 per meal – €90 in international events – except when in the latter case, the legislation or the Code of Ethics in effect in a specific foreign country establishes a higher amount for the meal cost, which will therefore be applicable.

As regards events taking place abroad, APIFARMA's Code of Ethics establishes that international events organised, supported or sponsored by APIFARMA members shall follow the rules established by this Code and those established by the Code of Ethics of the country in which the event takes place.

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

Yes, in the context of the sponsorship of continuing medical education (please see the answer to question 4.10 above) or in the context of active participation, namely through the presentation of scientific communications in scientific events, once it has been established that the payment in question is dependable and does not constitute compensation for incentivising the prescription or dispensation of medicines. However, just attending an event as opposed to participation as a speaker is not considered a professional service and it is therefore not possible to pay healthcare professionals in this regard.

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

A pharmaceutical company can be held responsible for the

breach of relevant legal requirements contained in Chapter IX (Advertising) of Decree Law 176/2006 of August 30, in cases where: there is a relevant act or omission of such company; the company acts as a promoter or sponsor of such meeting; or the company solely acts as the sponsor of the HCP that will attend independent meetings. Namely, articles 158, 160 and 161 of this law are to be complied with by pharmaceutical companies; in case of breach, the Authority may initiate an administrative offence procedure and impose fines and ancillary sanctions, as mentioned in the answer to question 1.7 above.

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

Yes. Pharmaceutical companies can enter into professional services agreements with HCPs to acquire expert services. HCPs can also be paid for acting as an active participant (speaker) in a scientific or training event, once it has been established that such payment is dependable and does not constitute compensation for incentivising the prescription and dispensation of medicines.

In accordance with APIFARMA's Code of Ethics, payments to HCPs must be reasonable and reflect the market value of the services to be provided by the same.

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

Yes, it is, in the general terms of the professional services provided by the HCP to pharmaceutical companies (please see the answer to question 5.4 above).

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

Yes, it is, in the general terms of the professional services provided by the HCP to pharmaceutical companies (please see the answer to question 5.4 above).

6 Advertising to the General Public

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

Non-prescription medicines may be advertised to the general public if they are not under State reimbursement and the advertising respects the following rules:

(a) it does not lead to the conclusion that a consultation or surgical operation is unnecessary, in particular, by offering a diagnosis or by suggesting treatment by mail;
(b) it does not suggest that the effect of the medicine is guaranteed without adverse reactions or secondary effects, with superior or equivalent results in comparison to another treatment or medicine;
(c) it does not suggest that the average health condition of a person may be harmed if the medicine is not used, except in case of vaccination campaigns approved by the local Regulatory Authority;
(d) it is not exclusively or mainly targeted at children;
(e) it does not refer to recommendations of scientists, HCPs or other individuals who could, because of their celebrity status, encourage the consumption of the medicinal products;
(f) it does not treat the medicinal product as a food, cosmetic or body hygiene product or as any other product;
(g) it does not suggest that the safety or efficacy of the medicine is due to the fact that it is a natural product;
(h) it does not induce an incorrect self-diagnosis, by a description or detailed representation of the anamnesis;
(i) it does not refer, in an abusive, daunting or misleading way, to statements or guarantees of recovery; and
(j) it does not use, in an abusive, daunting or misleading way, visual representations of human body changes caused by diseases or lesions, or by the effect of a medicine in a human body or parts of it.

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

It is not possible to advertise prescription-only medicines to the general public.

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

Disease awareness campaigns as described are permitted, once it has been established that the campaign materials and events do not mention, directly or indirectly, a medicine. This kind of initiative is expressly excluded from the scope of the Advertising Chapter of Decree Law 176/2006 of August 30.

6.4 Is it possible to issue press releases concerning prescription-only medicines to non-scientific journals? If so, what conditions apply? Is it possible for the press release to refer to developments in relation to as yet unauthorised medicines or unauthorised indications?

No. Issuing press releases on prescription-only medicines, and on unauthorised medicines and indications, to non-scientific journals is not permitted.

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

The information to be disclosed must be relevant for the purpose of such documents and cannot constitute a means to advertise medicines and to induce prescription, sale, consumption, dispensation or sale of medicines, which is critical for prescription-only medicines, non-approved medicines and off-label use of medicines, as explained above.

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

Pharmaceutical companies may, as a general principle,

interact with patient organisations. APIFARMA's Code of Conduct contains several rules on such interactions, namely the following:

(a) the pharmaceutical industry is required to conclude a written agreement with any patient organisation when granting, directly or indirectly, any sponsorship or any pecuniary or in-kind donation;
(b) the pharmaceutical companies may not ask or require to be the exclusive financing entity of a patient association or of any of its activities or events;
(c) patient organisations may conclude services agreements with the pharmaceutical industry concerning support and investigations/education on health matters;
(d) pharmaceutical companies and patient associations may build partnerships that are based on a legitimate and common interest for the development of specific projects, with activities and time-limited tasks;
(e) the pharmaceutical industry may contact patient associations to participate in meetings/events (of a non-promotional nature); and
(f) the pharmaceutical industry may support the hospitality costs (limited to travelling, meals, lodging and register costs) of the representatives of patient organisations.

6.7 What rules apply to consultancy arrangements with patient organisations or patient organisation representatives?

Any services provided by patient organisations to companies in the pharmaceutical industry must, in accordance with APIFARMA's Code of Conduct, be preceded by a written agreement, which must include the minimum content set out in the Code of Conduct; companies must, in accordance with the Code of Conduct, establish an internal approval process for such agreements.

6.8 May companies provide items to or for the benefit of patients? If so, are there any restrictions in relation to the type of items or the circumstances in which they may be supplied?

Pharmaceutical companies, companies responsible for the promotion of medicines and wholesale distributors cannot give or promise to give, directly or indirectly, to the general public (which includes the patients) prizes, gifts, bonuses or pecuniary or in-kind benefits.

6.9 What are the rules governing company funding of patient support programmes?

In Portugal there are no specific legal provisions on patient support programmes. Therefore, the general rules on the granting of benefits to patients are to be considered when assessing these programmes; namely, article 153 (7) of Decree Law 176/2006 of August 30, which establishes that "*the MA or register holder, the company responsible for the information or promotion of a medicine, or the wholesale distributor cannot give, or promise, directly or indirectly, to the general public, prizes, offers, bonuses or pecuniary or in-kind benefits*". By the same token, article 158 (1) of the same Decree Law prohibits the granting of benefits to the patients of HCPs.

On this topic and in the same vein, Infarmed issued an Informative Circular clarifying that, under the mentioned articles 153 and 158, the funding of domestic support services is qualifiable as a benefit granted to the general public (in which patients are included) and, therefore, is expressly prohibited.

However, in some specific circumstances (namely in relation to the particularities of a specific medicine or of its administration), it is arguable that the provision of some services supports the patient (for instance, for safety reasons) and therefore, in such cases, the funding of a patient support programme may be admissible. A case-by-case analysis is strongly recommended.

7 Transparency and Disclosure

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

The details of ongoing and completed clinical trials are available in the National Registry of Clinical Trials and in the EU Clinical Trials Register, and correspond to the information communicated in the context of the authorisation and monitoring procedures by the competent authorities.

7.2 Is there a requirement in the legislation for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations, patient organisations or members of the public (including journalists)? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how?

Yes. The entities under the scope of Decree Law 176/2006, including pharmaceutical companies, must report benefits of €60 or above, granted to HCPs, HCOs or patient organisations. Such report is to be made through Infarmed's transparency platform during the following 30 working days from the effectiveness of the benefit (payment of the benefit or granting of the same in case of granting of goods or rights assessable in cash).

Benefits are defined in article 159 of Decree Law 176/2006 of August 30, as any advantage, value, good or right assessable in cash, regardless of the respective form, as a prize, sponsorship, subsidy, fee or subvention, or in any other form.

The recipient is notified via email by Infarmed to validate – or not – the reported information. Any recipient that does not validate the reported information should inform Infarmed of the related reasons. If the recipient remains silent on the reported information, it is considered tacitly accepted.

7.3 Is there a requirement in your self-regulatory code for companies to make publicly available information about transfers of value provided by them to healthcare professionals, healthcare organisations, patient organisations or members of the public (including journalists)? If so, what companies are affected (i.e. do these requirements apply to companies that have not yet been granted a marketing authorisation and/or to foreign companies), what information should be disclosed, from what date and how? Are companies obliged to disclose via a central platform?

Yes. APIFARMA's Code of Ethics establishes that Member

Companies should publicly disclose any benefits in kind or pecuniary benefits they directly or indirectly grant to a Healthcare Professional or to an institution, organisation or association comprising healthcare professionals, as provided for by national legislation. Pharmaceutical companies that are associated members of APIFARMA are therefore required to comply with transparency legal rules as established by Decree Law 176/2006 of August 30, and to report the granting of benefits through the Authority's transparency platform.

7.4 What should a company do if an individual healthcare professional who has received transfers of value from that company, refuses to agree to the disclosure of one or more of such transfers?

Pharmaceutical companies do not require the agreement of HCPs to disclose the transfers, as such disclosure is legally mandatory. The HCPs may or may not validate the transfer of value as mentioned in the answer to question 7.2 above.

8 Digital Advertising and Social Media

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

Advertising on the internet shall comply with the rules applicable to advertising in general as established in Chapter IX of Decree Law 176/2006 of August 30, and also with the Advertising Regulation approved by the local Regulatory Authority.

Specifically on internet advertising, the Authority (Infarmed) issued two specific Informative Circulars, following the European Court of Justice judgment of May 5, 2011 (procedure no. C-316/09), establishing that the advertising of medicines subject to medical prescription, under reimbursement or not, may be disclosed to the general public, under the following conditions:

(a) it is exclusively on the respective institutional website and not on social media or through any other means of disclosure support; and
(b) the information to be disclosed, jointly and simultaneously, shall solely contain the faithful reproduction of the packaging of the medicine and the literal and full reproduction of the respective leaflet and/or of the medicine's summary of characteristics, as authorised.

Medicines not subject to medical prescription may be advertised on social media and shall comply with the rules contained in Chapter IX – Advertising – of Decree Law 176/2006 of August 30.

Advertising on websites and using social media to advertise medicines containing substances defined as drugs or psychotropic substances in the international conventions for drugs and psychotropic substances is prohibited.

In addition, APIFARMA recently approved Guidelines on the Use of Digital Channels, systematising the existing rules, approved by APIFARMA's Code of Ethics, international codes and guidelines and national law and regulations.

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

The levels of websites or digital platforms security is not specified, but we deem as applicable that all security measures related to access restrictions should be implemented.

In this regard, APIFARMA's Guidelines on the Use of Digital Channels suggest, as an example, the implementation of a system for registration of the HCP (with its full name and professional body membership number or other elements that allow the effective verification of the HCP's identity), access to the contents through a username (email, professional body membership number, unique code, etc.) and a unique password for each HCP.

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

There are no specific legal rules on this topic but considering that pharmaceutical companies are responsible for the content of the respective websites and respective tools and of the respective digital platforms, providing access to information that might violate the applicable legal framework or professional code rules is to be avoided. APIFARMA's Guidelines specifically foresee that whenever pharmaceutical companies use external links to independent websites in the respective advertising materials to be provided to a healthcare professional, it should be ensured that, in the case that such independent website refers to medicines under prescription, such medicines are not promoted to the general public.

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

Please consider the answer to question 8.1 above.

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

Yes. Please consult the answer to question 8.1 above.

8.6 Are there any restrictions on social media activity by company employees using their personal accounts, including interactions with third parties through "likes", "applauds", etc.?

According to APIFARMA's Guidelines on the Use of Digital Channels, pharmaceutical companies are responsible for the information disclosed by their employees and shall ensure that internal policies and procedures on communication in digital channels are in place, to assure compliance with the medicines advertising legal framework and data protection.

Such responsibility also covers information on the pharmaceutical company or respective medicine marketed that might be eventually disclosed by the employees through personal digital channels of a private nature used by the employees, in particular, if the employees:

(a) received instructions or have been authorised or supported by the pharmaceutical company to do so;
(b) refer to the brand of prescription-only medicine marketed by the pharmaceutical company; or
(c) refer to studies developed by the pharmaceutical company, which can only be disclosed to health professionals.

Pharmaceutical companies must have internal guidelines on how their employees must use digital channels, including

their personal accounts. Pharmaceutical companies should promote adequate training, namely, on how to act in the context of social media (personal accounts), what information of the pharmaceutical company can be disclosed and in what context, given the restrictions imposed on communication with the general public.

8.7 Are there specific rules governing advertising and promotional activity conducted virtually, including online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia?

Online interactions with healthcare professionals, virtual meetings and participation in virtual congresses and symposia are subject to the general rules applicable to conventional meetings as established in the legal framework on advertising activities.

In this regard, APIFARMA's Guidelines on the Use of Digital Channels foresee specific guidance:

(a) **Applicable Codes in case of international events**: (i) the rules of the Code in place in the country of origin of the majority of participants should be followed; (ii) if the organisation body is based in Europe, EFPIA, IPFMA and MedTech Codes are to be complied with; (iii) invitations to HCPs are ruled by the Code in force in the respective country of origin; (iv) HCPs shall consent on the rules applied to virtual congresses or events; and (v) the associated pharmaceutical companies shall expressly indicate in the respective virtual stands (through pop-ups or other means) the differences that may exist in the different countries regarding the promotion of medicinal products, in particular, if the therapeutic indications of the medicinal products are not approved in all relevant countries.

(b) **Target audience**: the different programmed activities should expressly indicate the target audience (HCPs or others, such as Patient Organisation representatives, journalists, etc.), access should be differentiated towards the diversity of attendees and, if there is no restricted access for HCPs, the associated pharmaceutical companies shall consider alternative mechanisms for the promotion of the respective medicines.

(c) **Hospitality**: offering hospitality is not permitted, except if some of the speakers or attendees are gathered at the location specifically designated for the event, in which case a meal may be provided if permitted by the agenda of the event.

(d) **Sponsorships**: the sponsorship amount shall be determined considering the use of digital media, shall be referenced in the sponsorship agreement and shall be solely destined for the event in question.

9 Developments in Pharmaceutical Advertising

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

Over the past year, there have been no significant developments regarding the rules on the advertising of medicines.

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

No developments are expected on this matter.

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

Infarmed and APIFARMA do not disclose decisions on advertising or on any other topic concerning eventual infringements of the applicable law and established rules.

9.4 Do you consider that the applicable legislation, codes and guidance in your country are keeping pace with current ways to publish and access information, particularly in digital format? If not, where do you see the most significant gaps?

Although the law does not specifically regulate these matters (with the general rules applying), APIFARMA has issued clear and detailed guidelines (Guidelines on the Use of Digital Channels, mentioned in the answer to question 1.1 above) regarding the use of digital channels.

Fernanda Matoso joined the firm in 1984 and became a partner in 1988.
Fernanda coordinates the life sciences practice area and the team of lawyers also engaged in this practice, was formerly the coordinator of the public law and urban planning practice area (until May 2017), and was for several years a member of the firm's Board of Directors.
Fernanda has a diverse practice as a lawyer. Currently, her practice is mainly focused on life sciences, especially in dealing with international pharmaceutical companies that market medicines and medical devices in Portugal.
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The firm's reputation amongst both peers and clients stems from the excellence of the legal services provided. The firm's work is characterised by unique technical expertise, combined with a distinctive approach and cutting-edge solutions that often challenge some of the most conventional practices. With a team comprising over 250 lawyers at a client's disposal, Morais Leitão is headquartered in Lisbon with additional offices in Porto, Funchal (Portugal) and Singapore. Due to its network of associations and alliances with local firms and the creation of the Morais Leitão Legal Circle in 2010, the firm can also offer support through offices in Angola, Mozambique, Cape Verde, Timor-Leste and Macau.

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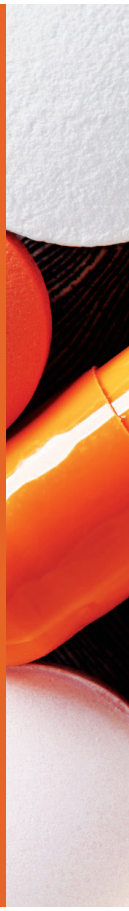
- Developments in Pharmaceutical Advertising



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