International
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Legal Guides

Pharmaceutical Advertising 2020

A practical cross-border insight into pharmaceutical advertising

17th Edition

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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 technologies companies, except if such receipt is 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 Institutions, Organisations or Associations Comprising Healthcare Professionals ("Code of Ethics");
- the Code of Conduct Governing the Relations Between Pharmaceutical Industry and Patients' Organisations ("Code of Conduct"); and
- the Code of Good Practice for Communication.

1.2 How is "advertising" defined?

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) though the granting, offer or promise of pecuniary or in-kind benefits, except when its value is insignificant;
(f) through the sponsorship of promotional meetings attended by HCPs;
(g) through the sponsorship of congresses or meetings of scientific nature attended/participated by HCPs, namely through the direct or indirect payment of the respective hosting costs; and
(h) through the 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 with 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 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 question 1.3 above.

The scientific service referred to in question 1.3 above should preferably be supervised by a qualified person (a physician or a pharmacist, as established by article 3 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 are to be previously approved 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 the advertising of medicines and may also decide to stop further publication and to impose sanctions in case of breach of the advertising legal provisions contained in this law.

The Authority may also impose corrective measures, temporary or definitive, if they are needed 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 the exemption of 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 imposing 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 also 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 of 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 to its members:

(a) simple warning;
(b) reprimand;
(c) 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 all pharmaceutical companies. On the other hand, APIFARMA is the association of the pharmaceutical industry and supervises and enforces its Codes of Ethics and Conduct upon its 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.

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 it could happen 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 4, no. 3, 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 above-mentioned article 151, no. 1-d) of Decree Law 176/2006 of August 30, it is recommended not to mention the commercial name of the medicine.

A case-by-case analysis is strongly recommended.

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

The information on unauthorised medicines and/or off-label information may be published with the constraints mentioned in question 2.1 above and may solely be disclosed and accessible 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 question 2.1 above may be sent to HCPs, as they are, for this purpose, part of the scientific community. The constraints mentioned in 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 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 forbidden.

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 studies not mentioned in the SmPC?

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.

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.

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

There is no such requirement. Regarding comparative claims, please consider the answer to question 3.5 below.

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

Comparative advertising of medicines can only be viewed by HCPs and are therefore prohibited from being viewed by the general public.

Accordingly, with APIFARMA's Code of Ethics, comparative advertising should be based on relevant and comparable aspects. It cannot be misleading, defamatory and the comparation of the medicines should be based on the medicines' characteristics 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.

3.6 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 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 (since the combination 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 Is it possible to give gifts or donations of money to healthcare professionals? If so, what restrictions apply? If monetary limits apply, please specify.

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

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

It is possible to provide support, both financial or non-financial, to healthcare organisations ("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 cannot request nor receive, directly or indirectly, pecuniary or in-kind benefits from pharmaceutical companies, health technology companies or from related companies when such actions may harm the impartiality and neutrality of the hospitals. When impartiality and neutrality are not at risk, a previous authorisation to receive the benefit should be previously requested by the NHS hospital's management bodies to Infarmed.

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

The providing of medical or educational goods or services should not constitute an incentive nor a compensation to recommend, prescribe, purchase, supply, dispense, sell, administer or use medicines.

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

The price discounts are out of scope of the rules on advertising of medicines. However, and according to Infarmed, the pharmaceutical companies can offer discounts to pharmacies in the context of its commercial relations.

4.6 Is it possible to offer to provide, or to pay for, additional medical or technical services or equipment where this is contingent on the purchase of medicinal products? If so, what conditions would need to be observed? 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, no contingencies are to 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 on its use or administration specific training or any apparatus for its administration the same could be offered/disclosed once the same are considered essential to meet the purposes of such medicinal product. There are no specific rules on this topic.

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

It is not possible to offer a refund scheme as described (a refund scheme is possible under specific circumstances; please see the answer to question 4.8 below).

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?

Special financial terms for the supply of medicines are usually agreed between pharmaceutical companies and Infarmed under reimbursement agreements of medicines and 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 with regard to the supply of medicines.

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 in 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 question 4.3 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, both promoted by pharmaceutical companies or by third parties. The sole costs to be paid concerning their attendance to 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 to the professional or scientific sessions of the events (entertainment events are not permitted). The selection of the location for the events shall obey adequate professional and logistic criteria, namely with respect to the level of hospitality and financial costs which are to be adequate towards the purpose of the events.

Applicable law: 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. 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 promoter of the event or on the entity that invited the HCP.

The support only can 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 stay costs cannot surpass the period comprehended 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, and €90 in international events, except when in this last 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.

In what concerns 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 the ones established by the Code of Ethics of the country in which the event shall take 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 an 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, attending such an event is not considered a professional service and it is therefore not possible to pay him for his time.

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 if 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.

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. The pharmaceutical companies can enter into professional services agreements with HCPs in order 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, the payment to HCP 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 previous question 5.4).

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 respect the following rules:

(a) the advertising 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) the advertising 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) the advertising 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) the advertising is not exclusively or mainly targeted at children;
(e) the advertising does not refer to recommendations of scientists, HCPs or of other individuals who could, because of their celebrity status, encourage the consumption of the medicinal products;
(f) the advertising does not treat the medicinal product as a food, cosmetic or body hygiene product or as any other product;
(g) the advertising does not suggest that the safety or efficacy of the medicine is due to the fact that it is a natural product;
(h) the advertising does not induce an incorrect self-diagnosis, by a description or detailed representation of the anamnesis;
(i) the advertising does not refer, in an abusive, daunting or misleading way, to statements or guarantees of recovery; and
(j) the advertising 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 is 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?

Issuing press releases on prescription-only medicines and of 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) patient organisations may conclude services agreements with the pharmaceutical industry concerning support and investigations on health matters;
(c) the pharmaceutical industry may contact patient associations to participate in meetings though designated speakers, experts and/or consultants; and
(d) the pharmaceutical industry may support the hospitality costs (limited to traveling, meals, lodging and register costs) of the representatives of patient organisations.

6.7 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.

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 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 or patient organisations? 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 Market Holders or respective local representative must report benefits of €60 or above, granted to HCPs, HCOs or patient organisations. Such report is to occur in Infarmed's transparency platform in the following 30 working days from the effectiveness of the benefit (payment of the benefit or

granting of the benefit 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, subvention or any other form.

The recipient is notified via email by Infarmed to validate – or not – the reported information. The recipient that does not validate the reported information should inform Infarmed on 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 or patient organisations? 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. Under the APIFARMA's Code of Conduct, there are specific requirements to make publicly available the granting of donations and sponsorships to patient organisations.

The information to be disclosed by APIFARMA members corresponds to: (i) the nature of the provided support; (ii) the monetary value of the provided support; and (iii) the benefits received, as far as significant non-financial supports to which no monetary value can be ascribed are concerned.

This information should be made available on the institutional website of the company or under request, until March 31 each year.

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 need the agreement of the HCP to disclose the transfers and the reporting of such is mandatory. The reporting of the transfer (by the pharmaceutical company) and the validation of the report (by the HCP) are legal duties for both parties, although under Decree Law 176/2006 of August 30, solely pharmaceutical companies may be sanctioned for not reporting such transfer, not HCPs.

8 The Internet

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

Advertising on the internet follows the rules applicable to the advertising activities established in Chapter IX of Decree Law 176/2006 of August 30 and are described, in general, in the sections above. Such advertising should comply with professional, technical and scientific principles.

In this regard, Infarmed issued two specific Informative Circulars establishing specific rules on advertising through the internet and other digital channels. Accordingly, pharmaceutical companies may publish information, accessible by the general public, in the following ways:

(a) exclusively on the respective institutional website and not on social media or on any other 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 medicine leaflet and/or of the summary of the medicine characteristics, as authorised.

Advertising on websites and social media of medicines containing substances defined as drugs or psychotropic substances in the international conventions for drugs and psychotropic substances is forbidden.

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

The levels of website security are not specified, but we deem as applicable that all security measures related to access restrictions should be implemented.

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

There are no specific rules on these matters, but considering that pharmaceutical companies are responsible for the content of the respective websites and respective tools, contributing to access to information that might violate the applicable legal or code rules is to be avoided.

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?

As referred to in question 8.1 above, pharmaceutical companies cannot use social media to disclose information or advertise medicines. Decree Law 176/2006 of August 30 does not address this topic.

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?

In the last year there were no developments on the rules relating to pharmaceutical advertising.

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

There are no expected developments on this matter. However, it is important to note that Infarmed's Strategic Plan for 2020–2022 is still at a preparatory stage.

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 the decisions on advertising or on any other topic concerning eventual infringements to the applicable law and established rules.

Fernanda Matoso joined the firm in 1984 and became a partner in 1988.
She coordinates the Life Sciences practice area and the team of lawyers also engaged in this practice. She was the former coordinator of the Public Law 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 dealing with international pharmaceutical companies that market medicines and medical devices in Portugal and other health products, as well with wholesale distributors. Since 2018, when the use of medical cannabis was approved, Fernanda has been working with investors and companies in this market, namely on licensing procedures for cultivation, manufacture and distribution of medical cannabis products and respective placement in the market as well as other related matters.
Fernanda's sustained knowledge of the national health market, healthcare system and dealing with the local Regulatory Authority is highly recognised. As a practitioner, she has deep expertise of the regulatory framework of pharmaceutical industry activity and the respective products (medicines, medical devices, cosmetics, food supplements and other health products), of wholesale distribution activity, of the healthcare institutions, and associated topics, such as licensing, marketing authorisations, prices regulation, State reimbursement/funding mechanisms, promotion/advertising activities, commercial policies, patients protection, compliance, health products marketing and distribution, clinical trials, commercial contracts, public tenders for the supplies to the National Health Service, and associated litigation and arbitration.

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Alessandro Azevedo started his practice as a lawyer at Servulo Correia & Associados and joined Morais Leitão in February 2019. Currently, his practice is focused on both Life Sciences and Public Law.
As a Life Sciences lawyer, Alessandro is well trained in dealing with regulatory topics that are critical for the activity of pharmaceutical companies and wholesale distributors, and health products such as medicines, medical devices, cosmetics, food supplements. He is well trained in dealing with advertising, promotion and transparency, compliance, licensing of activities and with several other relevant matters of the pharmaceutical industry. His expertise with regard to medical cannabis regulation and licensing of the respective activities such as cultivation, manufacture and placement of medical cannabis in the Portuguese market must also be highlighted.
He also focuses his practice on several areas of administrative law and public procurement, namely on tenders launched for the supplies to be executed to the National Health Service and associated litigation.
On the academic circuit, Alessandro also cooperates with the Administrative Law Investigation Center of the Lisbon University Law School, as assistant investigator.

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Morais Leitão, Galvão Teles, Soares da Silva & Associados (Morais Leitão) is one of Portugal's leading, full-service law firms, with more than 80 years of experience. The firm is internationally recognised for high levels of service and cutting-edge solutions. Specialised legal services in the main areas of law and in different sectors of the economy are a benchmark of the firm, leading to its involvement in the most important operations in Portugal, as well as in high-value cross-border transactions and disputes. With a team of more than 200 lawyers, Morais Leitão has its head office in Lisbon and offices in Porto and Funchal (Madeira Island). To support clients' international strategies, Morais Leitão developed a network of associations with local firms in Angola, Mozambique, Macau and Hong Kong – Morais Leitão Legal Circle – which offers integrated multi-jurisdictional teams.

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