The Legal 500 & The In-House Lawyer
Comparative Legal Guide
Portugal: Pharmaceutical Advertising

This country-specific Q&A provides an overview of the legal framework and key issues surrounding pharmaceutical advertising law in the Portugal.

This Q&A is part of the global guide to Pharmaceutical Advertising.

For a full list of jurisdictional Q&As visit **http://www.inhouselawyer.co.uk/index.php/practice-areas/pharmaceutical-advertising**

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1. **What laws are used to regulate advertising on medicines in your jurisdiction?**
    - 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 established the advertising principles and a prohibition upon National Health Service Hospitals to request and receive benefits from the pharmaceutical industry and from other health technologies companies, except if such receipt is previously authorized by the competent authority and does not arm their impartiality and neutrality.

2. **Are there any self-regulatory or other codes of practice which apply to the advertising of medicines? a) If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)? b) What is the legal status of the self-regulatory codes?**

APIFARMA – Portuguese Pharmaceutical Industry Association approved the following codes, which are applicable to Pharmaceutical Companies that are associated members:

- 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 Conduct Governing the Relations Between Pharmaceutical Industry and Patients´ Organisations
- Code of Good Practice for Communication

Such codes are solely binding for the respective associated members.

3. **Is there a statutory or generally accepted definition of "advertising"? a) What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example? b) Does the definition apply equally to all target audiences?**

Advertising of medicines is defined in article 150 (1) of Decree Law 176/2006 of August 30 as any form of information, prospection or incentive which scope or effect is the promotion of medicine´s prescription, dispense, sale, acquisition or consumption in any of the following circumstances:

(a) Before the public in general;

(b) Before wholesale distributors and healthcare professionals;

(c) Through the visit of medical sales representatives to healthcare professionals;

(d) Through the provision of samples or commercial bonus to wholesale distributors and healthcare professionals;

(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 healthcare professionals;

(g) Through the sponsorship of congresses or meetings of scientific nature attended/participated by healthcare professionals, namely through the direct or indirect payment of the respective hosting costs;

(h) Through the reference to the commercial name of a medicine.

Yes.

4. **Are press releases regarding medicines allowed in your jurisdictions, and if so what are the restrictions on these (bearing in mind the target audience)?**

Solley allowed on over the counter medicines if the same are not under State reimbursement. Medicines subject to medical prescription can only be advertised in technical publications or in other information supports destined and exclusively accessible by physicians and by other healthcare professionals.

5. **Are there any processes prescribed (whether by law or Codes of Practice) relating to the approval of advertising of medicines within companies?**

No. The applicable law foresees that Market Holders of medicines are obliged to dispose of a

scientific service responsible for the information related with the medicines and to maintain complete and detailed registers of all the advertising of medicines and to secure that the advertising complies with all the obligations imposed by law.

6. Do companies have to have material approved by regulatory bodies prior to release?

Only in case of vaccination campaigns, which are to be previously approved by local Regulatory Authority. No prior approval of the remaining advertisement, but companies may consult previously the Regulatory Authority on specific campaigns or on specific advertising materials.

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

7. Is comparative advertising for medicines allowed and if so, what restrictions apply?

Comparative advertising of medicines is solely permitted before healthcare professionals, being therefore prohibited before the general public.

Accordingly, with Apifarma´s Code of Ethics the comparative advertising should be sustained in relevant and comparable aspects. It cannot be misleading, defamatory and the comparation of the medicines should be based on the medicine characteristics specifications, instructions of use, technical documentation or credible clinical data.

8. Is it possible to provide information on unauthorised medicines or unauthorised indications? Is it possible to provide information on unauthorised medicines or unauthorised indications during a scientific conference directed at healthcare professionals, or to

send information to healthcare professionals?

No. Advertisement, by any way or form, of unauthorised medicines or indications is forbidden.

9. **Please provide an overview of the rules that apply to advertising to the general public for prescription only medicines and over the counter medicines, an indication of the information that must or must not be included.**

Prescription only medicines and over the counter medicines under reimbursement cannot be advertised before the general public. Advertising of the same is solely permitted before the healthcare professionals.

Over the counter medicines that are not under State reimbursement may be advertised before the general public. Such advertising shall expressly mention that is related with a medicine and shall legibly contain in the respective advertising support, the following:

(a) Name of the medicine, common name if the product contains only on active substance, or respective brand;

(b) Necessary information concerning the rational use of the medicine, including therapeutic information and special precautions;

(c) Notice to the user to carefully read the information contained in the leaflet and labelling of the medicine and warning to consult the physician or pharmacist in case of persistence of symptoms.

Non-reimbursed over the counter medicines advertising before the general public, cannot contain any information that:

(a) Leads to the conclusion consultation or surgical operation is unnecessary, in particular, by offering a diagnosis or by suggesting treatment by mail;

(b) Suggests that the effect of the medicine is assured without adverse reactions or secondary effects, with superior or equivalent results towards other treatment or medicine;

(c) Suggests that the average health condition of a person may be armed if the medicine is not used, except in case of vaccination campaigns approved by the Regulatory Authority;

(d) Is exclusively or mainly destined to children;

(e) Refers recommendations of scientists, healthcare professionals or of other individuals that because of their celebrity, could encourage the consumption of medicinal products;

(f) Treats the medicinal product as food product, cosmetic or of body hygiene or as any other product;

(g) Suggests that the safety or efficacy of the medicine is due to the fact that is a natural product;

(h) May induce to a fake self-diagnosis, by a description or detailed representation of the anamnesis;

(i) Refers in an abusive, daunting or misleading way to statements or healing assurance;

(j) Use in an abusive, daunting and 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.

10. Are there any restrictions on interactions between patients or patient organisations and industry (e.g., consultation, sponsorship)? If so, please describe those briefly.

Regarding the patients, although there is no specific legal provision prohibiting interactions between the industry and the same, the prohibitions and constrains mentioned in previous paragraph 9 concerning the advertising of over the counter medicines and of prescribed medicines are to be considered as restriction for such interactions. In addition, there is a legal prohibition to grant or promise to grant, directly or indirectly, to patients benefits: prizes, gifts, bonus or pecuniary or in-kind benefits by the industry.

In what concerns the interactions with patient organizations, sponsorship and consultation is permitted. Apifarma´s Code of Conduct governing the relations between Pharmaceutical Industry and Patient Organisations, contains several rules on such interactions, namely the following:

(a) The industry is required to conclude a written agreement with any patient organization when granting, directly or indirectly, any sponsorship or any pecuniary or in-kind benefit;

(b) Patient organizations may conclude services agreements with the industry concerning the support and investigation on health matters;

(c) The industry may contact the patient associations to participate in meetings though designated speakers, experts and/or consultants;

(d) The industry may support the hospitality costs of the representatives of patient organizations, which are limited to traveling, meals, lodging and register costs.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example can information about clinical trials, or copies of journal be sent?

The advertising before healthcare professionals 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 the product characteristics;

(c) The classification of the medicine concerning the dispense regime of the same, namely if it is a prescribed medicine, when applicable;

(d) The respective reimbursement regime;

(e) The date of the issuance of the advertising material in question and dates of its last revision;

(f) The information contained in the advertising material must be accurate, updated, verifiable and sufficiently complete to allow the recipient to correctly assess the therapeutic value of the medicine;

(g) 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.

Information on clinical trials and copies of journal may be disclosed to healthcare professionals.

12. May pharmaceutical companies offer gifts to healthcare professionals and are there any monetary limits?

Pharmaceutical companies cannot offer gifts to healthcare professionals nor any pecuniary or in-kind benefit, except if the same are of insignificant pecuniary value (less than 60 Euros) and cumulatively relevant for the medicine or pharmaceutical practice.

13. Are pharmaceutical companies allowed to provide samples to healthcare professionals?

Yes, if cumulatively the following requisites are met:

(a) The number of samples to provide in each year to each healthcare professional cannot be superior to 4 samples, if lowest number is not defined by Marketing Authorization;

(b) The samples are to be requested by the healthcare professional 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 commercialization;

(d) The samples packaging must contain the references «Free Sample» and «Prohibited Sale» or other similar references;

(e) The samples shall be accompanied by the summary of the product characteristics.

The samples can only be provided in the following two years after the start of the commercialization of the medicine.

It is prohibited to provide samples of medicines containing drugs and psychotropic substances.

14. Is sponsorship of scientific meetings or congresses and/or attendance by healthcare professionals to these events? If so, which restrictions apply? Do additional restrictions apply to events taking place abroad?

Sponsorship of scientific meetings or congresses is permitted as well as the attendance by healthcare professionals to such events.

Sponsorship of scientific meetings or congresses are to be communicated until 10 working days before the date of the event to local Regulatory Authority (Infarmed). The documentation concerning each sponsorship and event is to be kept by the company for 5 years.

The sole costs to be paid by pharmaceutical companies to healthcare professionals concerning their attendance to these events are the hosting costs: registration, travel, stay and meals. The stay costs cannot surpass the period comprehended between the day before the event and the day after the ending of the same.

The Apifarma´s Code of Ethics for Promotion Practices of the Pharmaceutical Industry and Interaction with Healthcare Professionals and Institutions, Organisations or Associations Comprising Healthcare Professionals, establishes that the cost of the meals within the national territory cannot exceed 60,00 €, per meal, and 90,00 € 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 be therefore applicable.

These events cannot have any social program or activity that may prejudice or prevent the full

attendance of the healthcare professionals to the professional or scientific sessions of the event. The selection of the location for the events shall obey to adequate professional and logistic criteria, namely in what respects the level of hospitality and financial costs which are to be adequate towards the purpose of the event.

In what concerns events taking place abroad, Apifarma´s Code of Ethics for Promotion Practices of the Pharmaceutical Industry and Interaction with Healthcare Professionals and Institutions, Organisations or Associations Comprising Healthcare Professionals foresees that the events organized by associated members shall take place in Portugal, except if in logistic terms it is more adequate to take place abroad, considering: (i) the countries of origin of the most part of the event attendees and/or (ii) the location of the resources or the relevant knowledge of the scope or theme of the event.

The above referred Code of Ethics also establishes that the international events organized, supported or sponsored by the associated 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.

15. What are the restrictions on the organisation of cultural, sports or other non-scientific events in relation to scientific conferences by pharmaceutical companies?

As referred in the previous paragraph 14, the events cannot have any social program or activity that may prejudice or prevent the full attendance of the healthcare professionals to the professional or scientific sessions of the event.

However, Apifarma´s Code of Ethics for Promotion Practices of the Pharmaceutical Industry and Interaction with Healthcare Professionals and Institutions, Organisations or Associations Comprising Healthcare Professionals, establishes in what refers to the hospitality costs, that such costs are to be restricted to the main purpose of the event, and cannot include entertainment events (for example: leisure, entertainment of sport events/activities).

The above-mentioned Code of Ethics also establishes that cannot be selected locations and/or touristic resorts that are best known for its leisure, entertainment or sports facilities.

16. Is it possible to pay for services provided by healthcare professionals and if so, which restrictions apply?

Yes. Services may be contract and paid to healthcare professionals for their active participation, namely through the presentation of scientific communications in scientific events or training sessions or promotional events of medicines, once, in any case, the payment in question is not dependable or constitutes a compensation for the prescription or dispense of medicines.

In accordance with Apifarma´s Code of Ethics for Promotion Practices of the Pharmaceutical Industry and Interaction with Healthcare Professionals and Institutions, Organisations or Associations Comprising Healthcare Professionals, the payment to healthcare professionals must be reasonable and reflect the market value of the services to be provided by the same.

17. Are pharmaceutical companies permitted to provide grants or donations to healthcare professionals or healthcare institutions? Does it matter if the grant or donation is monetary or in kind?

No, except if such grants or donation in kind are of insignificant monetary value (under 60 €) and is cumulatively relevant for the medicine or pharmaceutical practice.

18. Are pharmaceutical companies required to disclose details of transfers of value to healthcare professionals or healthcare institutions? If so, please indicate whether this is a legal requirement or not, and describe briefly what the companies must report and how. Do these transparency requirements apply to foreign companies and/or companies that do not yet have products on the market?

Yes, and it is a legal requirement.

The transparency rule established in Decree Law 176/2006 of August 30, imposes the report of all pecuniary benefits of 60 € or above, granted to healthcare professionals and healthcare

institutions. Such report is to occur in local Regulatory Authority 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).

The applicable provision of the quoted Decree Law defines benefit as any advantage, value, good or right assessable in cash, regardless the attribution form, as a prize, sponsorship, subsidy, fees, subvention or any other.

19. When if at all with a competent authority have to get involved in authorising advertising? Is advertising on the internet (including social media) for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

In accordance with Decree Law 176/2006 of August 30, the competent authority registers and may assess all the advertising of medicines and may impose corrections to the same. For such purposes, and as determined in advertising ruling issued by the authority, pharmaceutical companies are required to submit to the authority a descriptive memory of all medicine´s advertising supports in a 10-day term counted since the date of the publication of each advertising support or of the first publication of the first advertising material in case of advertising campaigns.

The competent authority shall be involved on vaccination campaigns or promotional campaigns of generics, because the same are to be previously authorised by the authority.

The authority may also identify and issue specific ruling in situations that, considering the respective advertising supporting material or the recipients of the advertisement, may justify the exemption of the inclusion of some mandatary elements of advertisement.

Advertising of over the counter medicines to be disclosed to the general public, in websites and social media is permitted, once it complies with the requirements listed in paragraph 9, above.

As informed by the competent authority in two specific Informative Circulars, websites of pharmaceutical companies may disclose information, accessible by the general public, on the

respective prescription only medicines, under reimbursement or not, in the following conditions:

(a) Exclusively in the respective institutional website and not in social media network or in any other disclosure mean;

(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 authorized.

Advertising of in 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.

Pharmaceutical companies may include access restrictions on the websites and disclose information solely destined to healthcare professionals.

20. Are there any anti-bribery rules apply to communications between pharmaceutical companies and healthcare professionals or healthcare organizations?

There are no such specific rules applying to such communications.

21. What are the rules (whether statutory or self-regulatory) which govern the offering of benefits or inducements to healthcare professionals?

Article 158 of Decree Law 176/2006 of August 30 and article 21 of Apifarma´s Code of Ethics for Promotion Practices of the Pharmaceutical Industry and Interaction with Healthcare Professionals and Institutions, Organisations or Associations Comprising Healthcare Professionals.

22. Which bodies are responsible for enforcing the rules on advertising and the rules on inducement? Please include regulatory authorities, self-regulatory authorities and courts.

Infarmed – *Autoridade Nacional do Medicamento e Produtos de Saúde*, IP, is the supervising and enforcing authority on advertising and inducement infringements to the applicable law. The decisions taken by this authority in administrative offense procedures may be challenged before the Competition, Supervision and Regulation Court, which decision may be challenged before the Court of Appeal.

The infringements to Apifarma´s Codes and respective provisions, namely on advertising and inducement, are committed to Apifarma´s Ethics Council, which mat impose penalties to the associated members.

23. On what basis and before which bodies or courts can companies initiate proceedings against competitors for advertising infringements?

Companies may report advertising infringements to:

(a) the competent authority (Infarmed), which will assess the reported facts and shall decide on initiating or not an administrative procedure against the infringer;
and/or

(b) Apifarma, which Ethics Council shall assess the reported facts and may decide on imposing the penalties foreseen in Apifarma´s By-Laws.

In each of the cases the complainant company shall not be part of any of the procedures initiated by Infarmed or by Apifarma.

24. What are the penalties, sanctions or measures that regulators

or courts can impose for violating medicines advertising rules and rules on inducements to prescribe in your jurisdiction?

Decree Law 176/2006 of August 30 establishes the penalties that may be imposed by Infarmed and by the Courts, in case of violation of the legal provisions contained in this legal diploma, namely the ones referring to advertising inducement to prescribe.

Such infringements may be punishable with a fine between 2000 € and 15% of the business volume of the infringer or 180.000 €, whichever is lower.

The following additional sanctions may also be imposed:

(a) Loss in favour of the State of illicit objects, equipment and devices;

(b) Interdiction, for a maximum period of two years, of the infringer business activity;

(c) Deprivation of the right to participate in public tenders for a maximum period of two years;

(d) Suspension of authorizations, licenses and of other titles attributing rights for a maximum period of two years.

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

(a) The decision on imposing of fines may also determine the publication in the social media of the essential elements of the condemnation;

(b) The suspension of the advertising of the relevant medicine for a maximum period of two years;

(c) A procedure to exclude the relevant medicine from its reimbursement by the State, may also be initiated;

(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.

25. **What is the relationship between procedures before or measures taken by the self-regulatory authority and the procedures before or measures taken by courts/government competent authorities?**

None. The national authority on medicines (Infarmed) is the supervising and enforcement entity for medicines and Apifarma is the association of the pharmaceutical industry, the supervise and enforces the respective codes of ethics and conduct before the associated members.

26. **Are there any recent enforcement trends in relation to pharmaceutical advertising in your jurisdiction? Please report any significant (publicly known) enforcement actions in the past two years.**

Infarmed does not disclose the decisions on advertising or on any other topic concerning eventual infringements to the applicable law and established ruling.