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Portugal Pharmaceutical Advertising

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This country-specific Q&A provides an overview of pharmaceutical advertising laws and regulations applicable in Portugal.

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Portugal: Pharmaceutical Advertising

1. What laws are used to regulate advertising on medicines in your jurisdiction?

In Portugal, advertising of medicines is mainly governed by Decree Law no. 176/2006, of 30 August, as amended ('Medicines Code'), which sets-forth, amongst others, the applicable rules to the marketing authorisation, manufacture, import, export, marketing, labelling, promotion and pharmacovigilance of medicines. It also transposes several EU directives into Portuguese law, including Directive 2001/83/EC, in its latest version ('Directive').

Decree-Law no. 330/90, of 23 October, as amended ('Advertising Code'), also plays a significant role. The Decree-Law establishes general rules applicable to advertising activity, applicable on a subsidiary basis to the advertising of medicines.

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?

Yes. The Portuguese Pharmaceutical Industry Association, Apifarma, enacted the Code of Ethics for Promotion Practices of the Pharmaceutical Industry and Interaction with Healthcare Professionals and Health Organisations ('Apifarma Code of Ethics'), aligned with the Code of Efpia – the European Federation of Pharmaceutical Industries and Associations.

a. If there are any such codes, to whom do they apply (companies, or healthcare professionals, for example)?

The Apifarma Code of Ethics is binding only to pharmaceutical companies that are members of Apifarma.

b. What is the legal status of the self-regulatory codes?

Non-compliance with the Apifarma Code of Ethics is considered a disciplinary infraction, which may trigger an infringement procedure before Apifarma's bodies.

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?

Yes, there is a legal definition of advertising, provided for in Article 150 of the Medicines Code. Such definition considers as advertising any kind of information, canvassing activity or inducement which has as its object or effect the promotion of the prescription, dispensation, sale, purchase or consumption of medicines.

a. What does the definition cover? – does it include patient information leaflets, for example, catalogues, disease awareness campaigns or correspondence, for example?

The definition of advertising is quite broad, going beyond what is provided for under the Directive and covering all activities that have a promotional effect, even if not designed to promote a product. Notwithstanding, the following activities are considered advertising:

- Visits of medical sales representatives to healthcare professionals ('HCPs');
- Granting of samples to HCPs;
- Granting, offering or promising to grant benefits (in money or in kind), except when of insignificant value;
- Sponsorship of promotional meetings addressed to HCPs;
- Sponsorship of congresses, or scientific events addressed to HCPs, including, via the payment of hospitality costs, either directly or indirectly; or
- Reference to a medicine's commercial name.

In line with the Directive, the following information and activities are expressly excluded from promotion rules:

- Labelling and the information leaflets;
- Correspondence required to respond to specific queries on a medicine, accompanied by documents, provided that it does not contain any promotional element;

- Information or documents related to packaging changes and to warnings on adverse reactions;
- Sales catalogues and price lists, provided that they only contain reference to the name of the medicine, composition, dosage, pharmaceutical form, presentation and price and are only disclosed before HCPs, wholesale distributors, pharmacies, authorized points of sales for over-the-counter medicines ("OTCs") and entities authorized to directly purchase medicines under the applicable law.
- Disease awareness campaigns, including only information that relates to human health or diseases, – i.e. no reference is made to a medicine, be it directly or indirectly.

b. Does the definition apply equally to all target audiences?

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)?

Press releases are allowed if they comply with promotion rules (see reply 9. under). Considering that they target the general public, they are only permitted for non-reimbursed OTCs. Press releases related to reimbursed OTCs or prescription-only medicines are generally not allowed.

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

Yes. The Medicines Code sets-forth that pharmaceutical companies should have a scientific department responsible for all information made available on their medicines, which must ensure that all advertising is compliant with the law.

The Apifarma Code of Ethics goes further, requiring such scientific department to include a physician or a pharmacist who approves all promotional and informative materials prior to disclosure, ensuring they comply with all applicable laws, regulations and ethical rules, amongst other requirements.

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

No. However, pharmaceutical companies must notify the Portuguese Agency, Infarmed, with a copy of all promotional materials within 10 days following publication or disclosure thereto. The Portuguese Agency may also request to assess materials prior to their release and take all measures to prevent illegal advertising.

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

Yes, but only to HCPs, not the general public.

Comparative advertising must comply with (i) the rules on advertising before HCPs provided for in the Medicines Code and (ii) rules on comparative advertising provided for in the Advertising Code.

Amongst others, the comparison must not be misleading and should rely on objective and scientifically proven information to compare essential, relevant and representative characteristics of the medicines.

The Apifarma Code of Ethics further provides that comparisons between medicines must not be defamatory and should be based on objective, relevant and comparable aspects, namely by reference to (i) the elements included in the SmPC, (ii) credible scientific data and (iii) objective features of the medicines, such as its price.

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. Advertising of unauthorised medicines or indications is strictly forbidden, even if presented during a scientific conference directed at HCPs or proactively sent to specific HCPs.

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, and include the information that must or must not be included.

Prescription-only medicines and reimbursed OTCs cannot be advertised before the general public, only before HCPs.

Non-reimbursed OTCs can be advertised before the general public, provided several legal requirements are met.

Firstly, the general principles applicable to the advertising of medicines under the Medicines Code apply: (i) it should not be misleading, (ii) must contain elements consistent with the information provided for in the approved SmPC and (iii) promote the rational use of medicines, doing so in an objective manner and not exaggerating its properties.

The promotional material must be unequivocally identified as such and include:

- The name and brand of the medicine, as well as the international non-proprietary name (if the medicine contains only one active substance);
- Information on how to correctly use the medicine, including therapeutic indications and special cautions;
- Recommendation to carefully read the information leaflet and label, and advice to consult the physician or pharmacist in case of doubt or persistence of the symptoms.

On the other hand, advertising before the general public cannot contain elements that:

- Give the impression that a medical appointment or a surgery is unnecessary, particularly by offering a diagnosis or by advocating treatment by mail;
- Suggest that the effects of taking the medicine are guaranteed, without adverse reactions or secondary effects, with superior or equivalent results to other treatments or medicines;
- Suggest that the person's health can be improved by taking the medicine;
- Suggest that the person's health can deteriorate if the medicine is not taken, except when the advertisement concerns vaccination campaigns approved by the Portuguese Agency, Infarmed;
- Are directed exclusively or primarily at

children;

- Refer to recommendations of scientists, HCPs or any other person who, because of their celebrity, could encourage the consumption of medicines;
- Treat the medicine as a foodstuff, cosmetic or body hygiene product, or as any other consumer product;
- Suggest that the safety or efficacy of the medicine is due to it being a natural product;
- Lead or may lead to erroneous self-diagnosis through by describing, or making a detailed representation of the anamnesis procedure;
- Refer to claims of recovery in an abusive, scary or misleading way;
- Use visual representations of changes in the human body caused by disease or injury, or by the effect of a medicine on the human body or a body part, in an abusive, scary or misleading way.

Finally, and for member companies of Apifarma, additional rules should be complied with, including (i) ensuring that advertising is adjusted to the general public and (ii) not presenting the product as "safe" or as not presenting risks.

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

Yes. The Medicines Code does not set-forth any specific regime applicable to the interaction between pharmaceutical companies and patients or patients organisations, but general rules on promotion before the general public apply with the necessary adaptations:

- Pharmaceutical companies cannot grant or promise to grant, directly or indirectly, gifts, prizes, bonuses, pecuniary advantages or benefits in kind to patients;
- Events organised by pharmaceutical companies may be addressed to patient organisations, provided that no promotion of prescription-only or reimbursed medicines is made;
- Any transfers of value ("ToV") granted by pharmaceutical companies to patients and/or patient organisations should be disclosed under transparency rules.

For member companies of Apifarma, due regard should also be given to the Code of Conduct for the Relations

Between the Pharmaceutical Industry and Patients' Associations, Patients Advocates, Patients Experts, Patients and Caregivers approved by Apifarma – the Pharmaceutical Industry Association ('Apifarma Code on Interaction with Patient Organisations').

Once more, this Code follows closely the regime provided for in the Efpia Code but goes beyond the rules provided therein. The regime is quite detailed, including rules for sponsorships, grants, rendering of services and other interactions with patients, patient experts and advocates, patients' organisations and other relevant stakeholders.

11. Which information must advertising directed at healthcare professionals contain, and which information is prohibited? For example, can companies provide information about clinical trials, or reprints of scientific journal articles?

Advertising before HCPs should include, legibly, on the materials:

- The medicine's name and classification for dispensing purposes;
- The essential information compatible with the SmPC, including the (i) name, (ii) qualitative and quantitative composition, (iii) pharmaceutical form, (iv) therapeutic indications, (v) posology and method of administration, (vi) contraindications and adverse reactions. Warnings and special cautions for use and interactions with other medicines, if relevant, must also be included.
- The reimbursement regime;
- The date in which it was firstly issued and of its last revision.

These elements may only be dismissed when advertising consists only of a reference to the medicine's name – the so-called name reminders. Subject to the Advertising Regulation, approved by the Portuguese Agency, Infarmed, name reminders can only contain the identification of the medicine (either by its brand, its international non-proprietary name or by both) and of the marketing authorisation holder (e.g. name and address).

Additionally, general principles applicable to the promotion of medicines should be complied with when advertising before HCP, i.e. (i) it should not be misleading, (ii) must contain elements consistent with the information provided for in the approved SmPC and (iii) promote the rational use of medicines, doing so in an objective manner and not exaggerating its properties.

Finally, all information provided to HCPs must be accurate, up-to-date, verifiable and sufficiently complete to enable them to form their own opinion of the therapeutic value of the medicinal product concerned. Scientific quotations and other illustrative matters must be faithfully reproduced and the sources indicated.

Information on clinical trials and reprints of scientific journal articles may be sent to HCPs. Caution should be taken however so as to guarantee that such does not entail off-label promotion, as the promotion of non-authorised medicines or indications is forbidden.

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

Yes, but under very strict limitations.

Under the Medicines Code, pharmaceutical companies cannot offer or promise to offer, directly or indirectly, gifts, bonuses, benefits in money or kind to HCPs, except if of insignificant value – i.e. equal to or lower than € 60 (sixty euro) – and relevant to the HCP's practice (medicine or pharmacy).

Members of Apifarma should comply with additional rules, making a distinction between:

- Promotional gifts, only allowed in the context of promotion of OTCs, which, amongst other requirements, must be lower in value than € 25.00 (twenty-five euro).
- Items of medical utility, which, amongst other requirements, should be equal to or lower in value than € 60.00 (sixty euro).

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

Yes, except for medicines containing narcotics and psychotropic substances.

Free samples can be provided on an exceptional basis, under the following conditions:

- Samples per physician do not exceed the maximum yearly amount (currently twelve samples under the Portuguese Agency Advertising Regulation and four samples under the Apifarma Code of Ethics);
- Samples are provided following a dated and written request, signed by the physician;
- Samples are provided under the smallest

presentation on the market;

- The packaging is marked as "free sample" and "not for sale", or similar wording.
- Samples should be accompanied by the respective SmPC.

Samples may only be provided on the first two years after the beginning of the medicine's effective marketing.

14. Are pharmaceutical companies permitted to sponsor 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?

Yes, sponsorship of meetings or congresses and/or attendance by HCPs to these events is permitted, but in strict conditions in what concerns hospitality costs and event location.

In what concerns hospitality costs, pharmaceutical companies are only allowed to bear enrolment, transportation and accommodation costs. Hospitality can only be paid to the attending HCP and not exceed the period between the day before and the day after the event is held (and should indeed strictly correspond to the event's duration).

The event location should be adequate from a professional and logistic perspective and should have an appropriate financial cost. The venue should be fit to purpose – for example, events should not be held in resorts or venues that are otherwise known for their leisure, entertainment or sports facilities neither should it include social activities that could harm or prevent full participation in the scientific and professional sessions.

The Apifarma Code of Ethics sets-forth additional requirements, such as that of hospitality costs not exceeding what the HCPs would be willing to bear themselves and not being offered to compensate the time spent by the HCP in attending the event.

In what concerns events taking place abroad, the Medicines Code does not provide for any specific rules.

However, the Apifarma Code of Ethics provides that these may only be organised or sponsored if the event is held on the country of origin of most of the attendees, or the event is held at the place where the resources to address the event's topic are located. Apifarma member companies must further comply with the rules of conduct in force at the country where the event takes place. In

case of conflict, the most stringent rules prevail. As for hospitality costs, the Code sets-forth that the costs of meals should not exceed € 90 (ninety euros) unless the respective Code of Ethics or local legislation sets-out a different cap, in which case said cap should apply, even if higher.

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

Organising cultural, sports or other non-scientific events, regardless of their nature, is forbidden.

The Apifarma Code of Ethics explicitly sets out that no entertainment events are permitted.

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

Yes. HCPs can be paid for acting as active participant (speaker) in scientific or training events or any other kind of service. Payment cannot be made in return for prescription and/or dispensing of medicines and the *honoraria* should be reasonable and reflect the market value of the services at stake.

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. Pharmaceutical companies may not provide grants or donations to HCPs – be it in money or in kind. In fact, and in what the interaction with HCPs is concerned, the rule is that no benefits can be granted save if insignificant in value and relevant to the practice of medicine or pharmacy (see reply to 12. above).

As for healthcare institutions, limitations apply to National Health Service healthcare institutions ('NHS Hospitals'), under Decree-Law no. 5/2017, of 6 January. The regime sets-forth that NHS Hospitals cannot canvass or receive, directly or indirectly, benefits in money or kind that may affect their neutrality and impartiality from pharmaceutical companies. They may only receive such benefits if they do not compromise their neutrality and impartiality and are authorised by the

Ministry of Health, who delegated this competence on the Portuguese Agency, Infarmed.

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. Pharmaceutical companies are required to notify the Portuguese Agency, Infarmed of any ToV (be it in kind or in money, in excess of € 60) made not only to HCPs and healthcare institutions, but also, and amongst others, medical or scientific associations/organisations and patient associations. The pharmaceutical company shall disclose, amongst others, the amount of the benefit granted and the identity of the recipient, which will then be published on the Portuguese Agency's website.

19. Are there any restrictions (whether by law or Codes of Practice) on advertising for medicines on social media directed to healthcare professionals or directed to the general public?

Yes. In relation to advertising on social media to HCPs, no specific rules have been enacted. As such, the regime provided for under the Medicines Code applies, with the necessary adaptations – no information that is to be made exclusively available to HCPs should be presented in social media, as it will be available to the general public.

As for advertising directed to the general public, in addition to the general regime rules of the Medicines Code, the Portuguese Agency has recently approved a Regulation with good practices of advertising in digital channels ("Digital Channels Regulation"), including on social media. Said Regulation is only applicable to the promotion of OTCs before the general public.

Specifically for social media, and in addition to general rules, it requires that the advertising message includes a warning for users to carefully read the information on the medicine's packaging and information leaflet. Such warning should be included in the main page with a zoom-in option, making available the link for the information leaflet of the product.

Finally, Apifarma enacted a set of guidelines devoted to the use of digital channels by member companies – Apifarma's Guidelines on the use of Digital Channels ('Apifarma's Guidelines') which also cover advertising on social media (see reply to 20. below).

20. Is advertising on the internet for medicinal products regulated, and if so, how? Should companies include access restrictions on websites containing advertising or other information intended for healthcare professionals?

No, there are no specific rules for advertising on the internet, except for the Digital Channels Regulation issued by the Portuguese Agency – applicable only to advertising of OTCs before the general public (see reply to 19. above).

As for advertising or other information intended for the general public, it should comply with the rules of the Medicines Code and the Portuguese Agency Digital Channels Regulation. Under the Regulation, all advertising on the internet to be clear, truthful and complete so as to allow the recipient to verify the characteristics of the medicine, not to be misleading nor to create any confusion. The advertising message must also be in line with the SmPC and the information leaflet of the medicine.

Additional requirements imposed by the Digital Channels Regulation vary depending on the nature of the digital channel at stake, including, amongst others, digital channels, social media, mobile applications and search engines.

In what concerns advertising or other information intended for HCPs, the rules provided for in the Medicines Code apply, with the necessary adaptations. To ensure that prescription medicines and reimbursed medicines OTCs are advertised exclusively before HCPs, access restrictions on websites containing advertising or other information intended for HCPs should be implemented.

Finally, from an ethical standpoint, the Apifarma Code of Ethics determines that all advertising made on the internet or in other digital channels should be based in technical / scientific / professional principles and comply with the applicable law and the promotion rules included therein. Pharmaceutical companies are required to adopt measures that ensure that the advertising of prescription-only medicines is available only to HCPs.

The Apifarma's Guidelines also sets-forth rules for the

different digital channels. Amongst other requirements, pharmaceutical companies are responsible for all information and materials, promotional or not, disclosed through any digital channel owned by the pharmaceutical company, sponsored or owned by a third party if the latter publishes information regarding the pharmaceutical company, its products or therapeutic areas, on its behalf. Pharmaceutical companies are also responsible for the information shared by their personnel and should provide for internal policies and procedures which assure their compliance with the applicable advertising and data protection rules.

21. Are there any anti-bribery rules that apply to communications between pharmaceutical companies and healthcare professionals or healthcare organisations?

There are no specific anti-bribery rules apply to communications between pharmaceutical companies and HCPs or healthcare organisations.

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

See reply to 12. and 17. above. No benefits can be granted by pharmaceutical companies to HCPs, except if insignificant in value and relevant to the practice of medicine or pharmacy. Benefits, even if permitted, cannot be provided as an incentive nor as in return for recommending, prescribing, purchasing, supplying, selling, administering, or using medicines.

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

The Portuguese Agency, Infarmed, is the regulatory authority responsible for the supervision and enforcement of the advertising rules set-forth in the Medicines Code. Infarmed is hence responsible for initiating administrative offence procedures for the infringement of advertising, conducting these and issuing a final decision, including on potential fines and ancillary sanctions. Such decisions can be challenged before the courts.

In turn, infringements to the Apifarma Code of Ethics are

analysed by Apifarma's bodies, namely by Apifarma's Ethics Council, under a disciplinary process that can result in penalties. Decisions taken by the Apifarma's Ethics Council can be appealed to Apifarma's General Assembly.

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

Pharmaceutical companies may only initiate proceedings in exceptional circumstances. As a rule, they may only file complaints before competent authorities, based on infringement of promotion rules provided for in the Medicines Code. Since the Portuguese Agency, Infarmed is the competent authority to investigate advertising infringements, complaints should be directed at Infarmed.

Pharmaceutical companies may resort to industry self-regulation and file a complaint before Apifarma for breach of the advertisement rules provided on the Apifarma Code of Ethics.

25. 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?

Infringement of promotion rules provided for in the Medicines Code is considered an administrative offence punishable with a fine which may range between € 2,000 and 15% of the infringer's turnover or € 180,000, whichever is lower.

Ancillary sanctions may also apply, be it of a general nature or specific to the infringement of advertising rules, including:

- Publication of the essential elements of the conviction on a newspaper or similar at the expenses of the company;
- Suspension of advertising of the medicine for a maximum period of two years;
- Exclusion of the medicine from State reimbursement, if applicable;
- Should the violation of the regime applicable to the visits of medical sales representatives to NHS Hospitals be at stake, the medical sales representative concerned and/or the marketing authorisation Holder may be

prevented from performing said visits.

For infringement of the Apifarma Code of Ethics, the Apifarma Ethics Council may also apply sanctions, such as:

- A simple warning, or a reprimand;
- A fine (up to the amount corresponding to five years of the contribution due to Apifarma);
- In serious cases, propose to Apifarma's General Assembly the membership suspension or expulsion.

26. 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?

There is no relationship. Procedures before or measures taken by the Portuguese Agency, Infarmed, and the courts are completely independent from procedures or measures taken by Apifarma.

27. 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.

Enforcement actions taken by the Portuguese Agency and by Apifarma are not made public.

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