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Pharmaceutical Advertising

Portugal

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1. Pharmaceutical Advertising: Regulatory Framework

1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines

Legislative Acts

- Decree Law 176/2006 of August 30th, as amended, which establishes the legal regime applicable to medicines;
- Decree Law 5/2017 of January 6th, 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 23rd, as amended, which approves the Advertising Code.

Administrative Regulations

In addition, some specific matters are regulated by administrative regulations issued by the Regulatory Authority, the National Authority of Medicines and Health Products, I.P ("Infarmed"), and the Secretary of State of Health.

Self-regulatory Codes

The Portuguese Pharmaceutical Industry Association (APIFARMA) approved the following self-regulatory codes:

- 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 for the Relations Between the Pharmaceutical Industry and Patients Associations, Patients Advocates, Patient Experts, Patients and Caregivers; and
- Code of Good Practice for Communication.

1.2 Application and Legal Value of Regulatory Codes to Advertising on Medicines

The self-regulatory codes identified in **1.1 Laws and Self-Regulatory Codes Regulating Advertising on Medicines** are ethical standards and they are binding for the APIFARMA's associated members.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

Advertising of medicines is defined in Article 150 (1) of Decree Law 176/2006 of August 30th, 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:

- before the public in general;
- before wholesale distributors and healthcare professionals (HCPs);
- through the visit of medical sales representatives to HCPs;
- through the provision of samples or commercial bonuses to wholesale distributors and HCPs;
- through the granting, offer or promise of pecuniary or in-kind benefits, except when its value is insignificant;
- through the sponsorship of promotional meetings attended by HCPs;
- 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
- through the reference to the commercial name of a medicine.

2.2 Information or Advertising: Disease Awareness Campaigns and Other Patient-Facing Information

Portuguese law and regulations do not make a clear distinction between advertising and information. Therefore, the definition of information, for this purpose, must be understood as included in the definition of advertising, once the disclosed information corresponds to the criteria established in Article 150 (1) of Decree Law 176/2006 of August 30th.

However, Article 151, No 1-d) of Decree Law 176/2006 of August 30th foresees that information relating to human health or human diseases, provided that they do not refer, even indirectly, to a medicine, are not subject to the advertising regulation, which deemed to mean that this information is not qualifiable as advertisement. Therefore, disease awareness campaigns and other patient-facing information as long as they comply with the quoted Article 151, No 1-d), are not qualifiable as advertisement.

In addition, APIFARMA's Code of Ethics, specifically Article 4, No 3, foresees the exclusion from the prohibition of advertising medicines not yet authorised or off-label information the right of pharmaceutical companies to inform the scientific community about the advances in the field of medicinal products and therapeutics, permitting therefore the disclosure of the results of the scientific research they are carrying out for that purpose. Therefore, it deems that data on the advances of scientific research in the field of medicinal products and therapeutics should also be qualified as information, instead of advertising.

Case-by-case analysis is strongly recommended.

2.3 Restrictions on Press Releases Regarding Medicines

Press releases are not specifically addressed by the Portuguese law, regulations or self-regulatory codes. Therefore, the press releases issued by pharmaceutical companies should comply with the general rules applicable to the advertising activity, namely concerning the respective content and the audience.

2.4 Comparative Advertising for Medicines

Comparative advertising of medicines can only be addressed to HCPs and are therefore prohibited from being disclosed to the general public. In accordance with APIFARMA's Code of Ethics, comparative advertising should be based on relevant and comparable aspects. It cannot be misleading, defamatory and the comparison of medicines should be based on the medicines' characteristics specifications, instructions of use, technical documentation or credible clinical data.

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications

The advertisement of unauthorised medicines or unauthorised indications (off-label advertising) is not permitted. However, as explained in **2.1 Definition of Advertising**, the dissemination of information on advances of scientific research in the field of medicinal products and therapeutics is permitted, since the constraints mentioned are met. Such information may solely be disclosed to and accessible by the scientific community.

3.2 Provision of Information During a Scientific Conference

The information mentioned in **2.1 Definition of Advertising** may be disclosed to HCPs, in any context, as they are, for this purpose, part of the scientific community.

3.3 Provision of Information to Healthcare Professionals

See **3.2 Provision of Information During a Scientific Conference**.

3.4 Provision of Information to Healthcare Institutions

Taking into consideration the prohibition of advertising unauthorised medicines or indications, see **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, providing such information to healthcare institutions for thge purpose of preparing budgets, etc, is not permitted.

3.5 Publication of Compassionate Use Programmes

Taking into consideration the prohibition of advertising unauthorised medicines or indications and the limits mentioned in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, to publish such information is not permitted. Compassionate use is solely permitted in the scope of clinical trials.

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Only non-prescription medicines not under State reimbursement may be advertised to the general public. Advertisement to the general public of prescription-on;y medicines and medicines containing substances defined as drugs or psychotropic substances in the international conventions for drugs and psychotropic substances is forbidden.

Advertising of medicines to the public must be unequivocally identified as such, expressly indicating the specific medicine.

Comparative advertising of medicines before the general public is prohibited.

On the mandatory and prohibited information disclosed in the advertising to the general public please consider the answer to **4.2 Information Contained in Pharmaceutical Advertising to the General Public**.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Advertising of medicines before the general public must contain, as a minimum, the following information:

- name of the medicine, as well as the common name, if the medicine contains only one active substance, or the brand;
- information essential to the rational use of the medicine, including therapeutic indications and special precautions; and
- advice to the user to carefully read the information contained in the packaging and in the leaflet and, in case of doubt or persistence of symptoms, to consult a physician or a pharmacist.

Additionally, it is not permitted to include any element that:

- leads to the conclusion that a consultation or surgical operation is unnecessary in particular by offering a diagnosis or by suggesting treatment by mail;
- suggests 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;
- suggests 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 local Regulatory Authority;
- is exclusively or mainly targeted at children;
- refers to recommendations of scientists, HCPs or of other individuals who could, because of their celebrity status, encourage the consumption of the medicinal products;
- treats the medicinal product as a food, cosmetic or body hygiene product or as any other product;
- suggests that the safety or efficacy of the medicine derives from being a natural product;
- induces an incorrect self-diagnosis, by a description or detailed representation of the anamnesis;
- refers, in an abusive, daunting or misleading way, to statements or guarantees of recovery; and
- uses, 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.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Pharmaceutical companies may, as a general principle, interact with patient organisations. However, such interactions must occur within the limits and constrains established by Decree Law 176/2006 of August 30th and of Apifarma's Code of Conduct, which established several rules on such interactions.

The limits and constrains are generally established to prevent interactions with Patient Associations qualifying as a 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 the terms established by Article 150 (1) of Decree Law 176/2006 of August 30th.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

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

- the name of the medicine;
- the essential information compatible with the summary of product characteristics (SmPC);
- the classification of the medicine concerning the dispensation regime of the same, namely if it is a prescribed medicine, when applicable;
- the respective reimbursement regime; and
- the date of the issuance of the advertising

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. 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.

5.2 Reference to Data Not Included in the Summary of Product Characteristics

Advertisements may refer to data or studies not mentioned in the summary of product characteristics, provided that the information complies with that mentioned in **5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals**, and, therefore, once no contradiction is found between the summary of product characteristics and the information provided on the data on file and on the clinical studies.

5.3 Advertising of Combination Products Not Included in the Summary of Product Characteristics

Since combined aadvertising would be qualified as off-label advertising, which is prohibited as explained in **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**, any reference to a combination of products or companion diagnostics not included in the summary of product characteristics is not admissible.

5.4 Restrictions on Reprints of Journal Articles for Healthcare Professionals

In Portuguese law or regulations there are no specific rules regarding the reprinting of journal articles. However, and assuming that the reprints are of scientific journal articles, it is believed that such reprints may be provided if referring to

human health and diseases or to scientific information relevant to the practice of medicine.

5.5 Medical Science Liaisons

The activity of Medical Science Liaisons (MSLs) is not specifically regulated by Portuguese law or regulations. However, regardign MSLs, pharmaceutical companies should comply with the general rules applicable to the advertising activities already described.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation

The market holders, or holders of medicine registers, are required to submit one sample of each advertising material concerning each medicine within ten days of respective distribution starting dates.

In the context of the sponsorship of congresses, symposia or any actions or events with scientific nature or aimed to directly or indirectly promote medicines, the sponsor company must communicate the sponsorship to Infarmed ten business days before the event.

Vaccination campaigns or promotional campaigns of generic medicines before the general public are to be approved beforehand by Infarmed. If not, such campaigns could be classified as prohibited advertising activity.

6.2 Compliance with Rules on Medicinal Advertising

Pharmaceutical companies are not legally required to establish standard operating procedures (SOPs) governing advertising activities. However, they are required have a scientific service responsible for the information related to 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. The scientific service should preferably be supervised by a qualified person (a physician or a pharmacist, as established by Article 3 of APIFARMA's Code of Ethics).

7. Advertising of Medicinal Products on the Internet

7.1 Regulation of Advertising of Medicinal Products on the Internet

Decree Law 176/2006 of August 30th expressly addresses advertising on the internet. However, it should obviously follow the general rules applicable to the advertising activities better described perviously.

In addition, local a regulatory authority issued two 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:

- exclusively on the respective institutional website and not on social media or on any other disclosure support; and
- 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.

7.2 Advertising of Medicines on Social Media

Pharmaceutical companies cannot use social media to advertise medicines (see **7.1 Regulation of Advertising of Medicinal Products on the Internet**).

7.3 Restrictions on Access to Websites Containing Advertising Intended for Healthcare Professionals

Access restrictions are not specified by law or regulations, however, companies should take all actions needed to ensure access to the information occurs in compliance with the general rules applicable to advertising medicines (before the healthcare professionals and before the general public) described in the previous sections.

7.4 Provision of Disease Awareness Information to Patients Online

Since disease awareness information is out of the scope of the advertising activities regulation (see **2.1 Definition of Advertising**), companies may provide disease awareness information to

patients online as long as the general rules are met (namely in what concerns to the absence of any direct or indirect reference to a medicine).

7.5 Online Scientific Meetings

Online scientific meetings are not specifically regulated in the Portuguese law or regulations, therefore, they are subject to the general rules applicable to the conventional scientific meetings and to the rules applicable to the advertising activities in general.

Concerning the international or national nature of online scientific meetings, despite a lack of legislation, they are held in accordance with local practice and local regulatory authority understanding. If the promoter/organiser of such meetings is a national entity, the same should comply with the applicable local law and regulation on advertisement and on conventional scientific meetings principles.

8. Pharmaceutical Advertising: Inducement/Anti-bribery

8.1 General Anti-bribery Rules Applicable to Interactions between Pharmaceutical Companies and Healthcare Professionals

The anti-bribery rules applicable to the interactions between pharmaceutical companies, healthcare professionals and healthcare organisations are, in general, the rules defined in the Portuguese Criminal Code and specific legislation on anti-bribery, which are applicable to both sectors: public and private.

8.2 Legislative or Self-Regulatory Provisions

According to the Portuguese law, as a general rule (Article 158 (1) of Decree Law 176/2006 of August 30), the marketing authorisation holder, the company responsible for the information or promotion of a medicine, or the wholesale distributor are prohibited from giving or promising, directly or indirectly, to health professionals, or their patients, prizes, offers, bonuses or pecuniary or in-kind benefits, except if the same are cumulatively of insignificant economic value (under EUR60) and relevant for the medical or pharmaceutical practice (exceptions are pointed out in **9. Gifts, Hospitality, Congress and Related Payments**). The same prohibition falls upon HCPs, which are prevented from receiving such benefits under the quoted Article 158 (2).

In accordance with Article 9 of Decree Law 5/2017 of January 6th, Public Hospitals and Services and Bodies of the Ministry of Health cannot request nor receive directly or indirectly, any pecuniary or in-kind benefit from pharmaceutical companies or health technology companies that impair or may impair its impartiality, except if previously granted with a specific authorisation of local Regulatory Authority.

Any form of inducement to prescribe medicines is forbidden.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

Following on from **8.2 Legislative or Self-Regulatory Provisions**, pharmaceutical companies may sponsor the participation of healthcare professionals in scientific or educational events, promoted by pharmaceutical companies or by third parties. Such sponsorship is limited to the registration and hosting costs: travel, lodging and meals.

According to the APIFARMA's Code of Ethics, the support for such costs can only be granted to the HCP(s) who will attend the concerned event and the costs are to be restricted to the main purpose of the event and cannot include entertainment events.

The stay costs cannot surpass the period one day either side of the event, 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 EUR60 per meal (EUR90 at 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 addition to this, pharmaceutical companies only may give pecuniary or in-kind grants or donations to HCPs if the same are cumulatively of insignificant economic value (under EUR60) and relevant for the medical or pharmaceutical practice.

9.2 Limitations on Providing Samples to Healthcare Professionals

The provision of samples is, under the Portuguese law, subject to the following conditions:

- the number of samples provided, each year, to each HCP cannot be more than four, if the lowest number is not defined by the marketing authorisation;
- the samples are to be requested by the HCP in writing, duly dated and signed;
- the samples cannot be larger than the smallest presentation of the medicine under commercialisation;
- the samples' packaging must contain the words "Free Sample" and "Prohibited Sale" or other similar words;

- the samples must be accompanied by the summary of product characteristics; and
- the samples can only be provided in the two years following the start of the commercialisation of the medicine; providing samples of medicines containing drugs and psychotropic substances is prohibited.

9.3 Sponsorship of Scientific Meetings

Pharmaceutical companies may sponsor scientific meetings or congresses organised by third parties, even if the same take place abroad. The local Regulatory Authority must be informed of all granted sponsorships in the 10 days before the event.

According to the APIFARMA's Code of Ethics, a sponsorship must be preceded by a written request from the organising entity, dated and signed, addressed to the pharmaceutical company, specifying the scope and the purpose of the same. A sponsorship of any event must be clearly announced prior to and during the event and must be disclosed in all event documentation, as well as in any information material that may result from the event.

According to the same Code of Ethics, the sponsored events should take place in premises suitable for the main purpose of the event or action, and places and/or developments that are known for their facilities for leisure, entertainment or sport should not be chosen.

Pharmaceutical companies may also support HCPs attendance costs to such events, limited to the registration and hosting costs, see **9.1 Gifts to Healthcare Professionals**.

9.4 Sponsorship of Cultural, Sports or Other Non-scientific Events

The sponsorship or organisation of cultural, sports or other non-scientific events (even if in relation to scientific conferences) are expressly prohibited.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Besides those referred in **9.1 Gifts to Healthcare Professionals**, no other grants or donations are permitted.

Regarding healthcare institutions, it is possible to provide support, both monetary or non-monetary, with the aim of supporting healthcare services, research activities or continuing medical education.

However, in accordance with Article 9 of Decree Law 5/2007 of January 6th, 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.

9.6 Restrictions on Rebates or Discounts to Healthcare Professionals or Healthcare Institutions

Price discounts or rebates are expressly considered as out of scope of the rules on advertising of medicines. However, pharmaceutical companies can offer discounts to healthcare institutions in the context of the established commercial relationship, but not to healthcare professionals, as the companies are prevented to execute sales to the same.

9.7 Payment for Services Provided by Healthcare Professionals

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, moderator, etc) in a scientific or training event.

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

9.8 Prior Authorisations or Notifications for Activities between Pharmaceutical Companies, Healthcare Professionals and Healthcare Organisations

Sponsorships of congresses, symposia or any actions or events with scientific nature or aimed to, direct or indirectly promote medicines must be communicated by the sponsor company to Infarmed ten business days before the event.

10. Pharmaceutical Companies: Transparency

10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value

The market holders or respective local representative must report to local Regulatory Authority all benefits of EUR60 or above, granted to healthcare professionals, healthcare organisations, patient organisations, workers of the National Health Service and bodies or services of the Ministry of Health or of the National Health Service.

Such report is to occur in a specific transparency platform in the following 30 working days counted 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 information to be reported is the following: name and data of the beneficiary, nature of the benefit and amount granted.

Beneficiaries shall be notified via email by the local regulatory authority to validate – or not – the receipt of the benefit, case in which the reasoning for the non-validation is to be informed to the Authority. If the recipient remains silent on the reported information, the benefit is considered tacitly accepted.

Benefits are defined in Article 159 of Decree Law 176/2006 of August 30th, 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.

No additional regulations were issued by local regulatory Authorities regarding COVID-19. As such, reports are to be executed within the established legal deadline.

10.2 Foreign Companies and Companies That Do Not Yet Have Products on the Market

Transparency requirements apply to all market holders or to respective local representatives granting benefits to the individual and entities identified in **10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value**. Hence, if the market holder is a foreign entity, the report on the granting of benefits to Portuguese HCPs or to entities mentioned in **10.1 Requirement for Pharmaceutical Companies to Disclose Details of Transfers of Value** is to be executed.

Companies that do not have any products placed on the market and are not operating under a wholesale distribution licence or register do not fall under the legal provisions on transparency.

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

The public competent authority for enforcing the rules on advertising is Infarmed – *Autoridade Nacional do Medicamento e Produtos de Saúde* (National Authority of Medicines and Health Products) I.P.

The self-regulatory body is the Portuguese Pharmaceutical Industry Association (*Associação Portuguesa da Indústria Farmacêutica* or APIFARMA).

The competent court to decide on any issued related to the rules on advertising depends on the specific claim under decision: as a general rule, the acts issued by Infarmed should be challenged before the administrative courts; however, if it is at stake a sanction decision, it should be challenged before the Competition, Regulation and Supervision Court (according to the available jurisprudence). For the civil liability lawsuits, if applicable, civil courts are competent (see **11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements**).

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

The companies may initiate procedures against competitors before any of the bodies identified in **11.1 Pharmaceutical Advertising: Enforcement Bodies**, depending on the specific violation at stake:

- APIFARMA's Ethics Council may impose to the respective members penalties for infringements to respective codes;
- Infarmed is the authority responsible to punish the infringement of law and public regulations; and
- 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.

The same conduct my be qualifiable as an infringement of the codes and to the law and public regulations. In those cases, procedures before APIFARMA and procedures before Infarmed may be conducted in parallel. The procedures, decisions and penalties are completely separate.

11.3 Penalties for Violating Pharmaceutical Advertising Rules and Rules on Inducements to Prescribe

The fines range from EUR2,000, at the minimum, to 15% of the business volume of the infringer or EUR180,000, whichever is lower, at the maximum.

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

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

Accompanying sanctions specifics for the case of infringement of advertising legal provisions may also applied:

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

11.4 Relationship between Regulatory Authorities and Courts

There is no relationship between the procedures before or measures taken by the self-regulatory entity and the measures taken by the courts.

APIFARMA is the association of the pharmaceutical industry and supervises and enforces its codes upon its members. The procedures, decisions and penalties have deontological nature and are completely independent of the ones taken by public entities (such as Infarmed or courts).

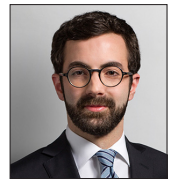
11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

Infarmed and APIFARMA do not disclose the decisions on advertising or on any other topic concerning infringements of the applicable law and established rules. Therefore, there are no identifiable trends in relation to pharmaceutical advertising.

Morais Leitão, Galvão Teles, Soares da Silva & Associados is a leading full-service law firm in Portugal, with a solid background of decades of experience. The firm's reputation amongst both peers and clients stems from the excellence of the legal services provided. The firm's work is characterised by a unique technical expertise, combined with a distinctive approach and cutting-edge solutions that often challenge some of the most conventional practices. With a team comprising over 250 lawyers at a client's disposal, Morais Leitão is headquartered in Lisbon with additional offices in Porto and Funchal. Due to its network of associations and alliances with local firms and the creation of the Morais Leitão Legal Circle in 2010, the firm can also offer support through offices in Angola (ALC Advogados) and Mozambique (HRA Advogados).

Authors

Fernanda Matoso is a partner at the firm and co-ordinates the life sciences practice. Her practice is mainly focused on life sciences, focusing on international pharmaceutical companies that market medicines and medical devices in Portugal. Fernanda has extensive knowledge and expertise in the regulatory framework of the pharmaceutical industry activity and 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, data protection, compliance and health products marketing and distribution.



Alessandro Azevedo joined Morais Leitão in February 2019. He is a member of the firm's administrative and public law team. He focuses his practice on several areas of administrative law, namely public contracts and urbanism, for both public and private entities in procedural matters and litigation. Alessandro is also experienced in administrative law regulations, particularly in the pharmaceutical industry and its products (medication, medical devices, cosmetics and dietary supplements) and in controlled substances. On the academic circuit, he's an assistant investigator at the Administrative Law Investigation Center of the Lisbon University Law School.

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