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Portugal: Law and Practice & Trends and Developments

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VdA

PORTUGAL

Law and Practice

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Contents

VdA is a leading international law firm with more than 50 years of history, recognised for its impressive track record and innovative approach in corporate legal services. The excellence of its highly specialised legal services, covering several industries and practice areas, enables VdA to overcome the increasingly complex challenges faced by its clients. Recognition of the excellence of its work is shared across the entire team, as well as by clients and stakeholders, and is acknowledged by leading professional associations, legal publications and academic entities. VdA has been consistently recognised for its outstanding and innovative services, having received the most prestigious international accolades and awards of the legal industry. Through the VdA Legal Partners network, clients have access to eight jurisdictions (Angola, Brazil, Cabo Verde, Mozambique, Portugal, Sao Tome & Principe, Spain and Timor-Leste), with a broad sectoral coverage in all Portuguese-speaking countries.

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1. Regulatory Framework

1.1 Laws and Self-Regulatory Codes Concerning the Advertisement and Promotion of Medicines

Advertisement of medicines in Portugal is mainly regulated by Decree-Law No 176/2006, of August 30th (the "Medicines Code"), which transposes EU Directive 2001/83/EC (the "Directive"). The Portuguese Advertising Code, approved by Decree-Law No 330/90, of October 23rd, sets forth general rules for advertising activities and is also applicable on a subsidiary basis.

This legal framework is complemented by regulations issued by the Portuguese agency Infarmed:

- the Regulation on specific aspects of medicines' advertising (the "Medicines Advertising Regulation"); and
- the Regulation on the Good Advertising Practices regarding Over-the-Counter Medicines through Digital Channels (the "Regulation on Digital Channels").

The Portuguese Pharmaceutical Industry Association (Apifarma) approved two codes of practice that establish ethical rules for the advertisement of medicines and for the interaction with both healthcare professionals (HCPs) and patients and patients' organisations (POs):

- the Code of Ethics for Promotional Practices of the Pharmaceutical Industry and Interaction with Healthcare Professionals and Health Organisations (the "Apifarma Code of Ethics"); and
- the Code of Conduct for the Relations Between the Pharmaceutical Industry and Patients' Associations, Patients Advocates, Patients Experts, Patients and Caregivers (the "Apifarma Code of Conduct").

Additionally, Apifarma enacted guidance regarding the use of digital channels (the "Apifarma Guide on the Use of Digital Channels"), which provides further clarity on rules for the interaction with HCPs and the general public online, including with regard to online events.

1.2 Application and Influence of Self-Regulatory Codes on the Advertisement and Promotion of Medicines

The Apifarma Code of Ethics and the Apifarma Code of Conduct are binding only for pharma companies that are members of Apifarma. Member companies are also responsible for ensuring that their affiliates and any third parties acting on their behalf comply with these rules. In practice, most innovative pharma companies operating in Portugal – even if not members of Apifarma – adhere to the standards set out in these Codes.

1.3 Regulatory Updates

There have been no recent updates in Portugal regarding the regulation of pharmaceutical advertising and promotion, and no such updates are expected in the near future.

2. Scope of Advertising and General Principles

2.1 Definition of Advertising

The notion of advertising in Portugal is extremely 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. Advertising is defined as 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.

The Medicines Code further provides for a non-exhaustive list of activities which are considered advertising, including (among others):

- reference to a brand name;
- visits of sales representatives to HCPs;
- granting of samples to HCPs;
- granting of benefits; and
- sponsorship of promotional meetings, congresses or scientific events addressed to HCPs.

Consistent with the Directive, only the following information and activities are expressly excluded from the advertising regime:

- labelling and information leaflets;
- correspondence needed to answer a specific question about a particular medicinal product (and possibly 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, authorised points of sales for over-the-counter medicines (OTCs) and entities authorised to directly purchase medicines; and
- information relating to human health or diseases, provided there is no reference – even indirect – to a medicinal product.

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

The law does not distinguish between information-sharing and advertising. In fact, the disclosure of information by pharma companies may fall within the scope of the definition of advertising, should it have as its object or effect the promotion of the prescription, dispensation, purchase or consumption of medicines. This renders it very difficult for pharma companies to share information outside the scope of advertising rules.

Nevertheless, disease awareness campaigns fall outside the scope of advertising provided they contain only information related to human health or diseases and no reference to a medicine is made, be it directly or indirectly.

2.3 Restrictions on Press Releases Regarding Medicines

There are no specific legal provisions on press releases. As such, they are permitted if they are compliant with advertising rules, which differ depending on the target audience. This is always a controversial matter that requires a case-by-case analysis.

2.4 Comparative Advertising for Medicines

Comparative advertising is admissible when targeted at HCPs. It should nevertheless comply with the rules provided for in the Advertising Code and the Apifarma Code of Ethics, which, among others, determine that comparative advertising should not be misleading and should rely on objective and scientifically proven information to compare the essential, relevant and representative characteristics of medicines (such as their price).

3. Advertising of Unauthorised Medicines or Unauthorised Indications

3.1 Restrictions on the Provision of Information Concerning Unauthorised Medicines or Indications

The advertising of unauthorised medicines or unauthorised indications is not permitted. Since the disclosure of information may be considered advertising, the possibility of proactively providing information concerning unauthorised products or unauthorised indications is highly restricted – both before HCPs and the general public.

3.2 Provision of Information During a Scientific Conference

Information on unauthorised medicines or unauthorised indications may not be provided during scientific conferences directed at HCPs. The legal regime does not provide for any exception in this regard.

The Apifarma Code of Ethics, however, allows pharma companies to disclose information to the scientific community on the results of scientific research conducted by the companies.

3.3 Provision of Information to Healthcare Professionals

Pharma companies may send information concerning unauthorised medicines or unauthorised indications if said information is needed to reply to a specific query put forward by an HCP, and provided that such reply does not contain any promotional element. This information should therefore be provided reactively.

3.4 Provision of Information to Healthcare Institutions

There are no specific rules on the disclosure of information concerning unauthorised medicines or unauthorised indications to healthcare institutions – the general prohibition on off-label promotion therefore applies. Nevertheless, the disclosure of objective information in the context of commercial negotiations between healthcare institutions and pharma companies may be admissible provided it does not contain any promotional element and is strictly limited to the intended purpose.

3.5 Information About Early Access or Compassionate Use Programmes

The advertising of early access or compassionate use programmes is not permitted given the general prohibition on off-label promotion.

4. Advertising to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

Advertising of prescription-only medicines and reimbursed OTCs before the general public is forbidden. As such, only non-reimbursed OTCs can be advertised.

Advertisement before the public must comply with the following general principles:

- it should not be misleading;
- it should be consistent with the information provided in the summary of the product's characteristics (SmPC); and
- it should promote the rational use of the medicine, in an objective manner and without exaggerating its properties.

The Apifarma Code of Ethics sets forth additional rules which should also be complied with by its members, including the need to ensure that advertising is adjusted to the recipient and that the medicine is not presented as "safe" or as not having risks.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Advertising directed at the general public must be unequivocally identified as such and expressly 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 use the medicine correctly, including reference to therapeutic indications and special precautions; and
- recommendation to carefully read the information leaflet and label, and advice to consult the physician or pharmacist in the case of doubt or continuity of symptoms.

In addition, in line with the Directive, it cannot contain any elements that:

- give the impression that a medical appointment or a surgery is unnecessary, particularly by offering a diagnosis or by suggesting 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 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 by describing or making a detailed representation of the anamnesis procedure;
- refer to claims of recovery in an abusive, alarming or misleading way; or
- 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, alarming or misleading way.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

Pharma companies may interact with patients and POs, provided said interaction complies with the advertising rules set forth in the Medicines Code. There is no specific regime for patients or POs; therefore, general rules on promotion before the general public apply, including the prohibition on advertising prescription-only medicines before the general public.

Interaction with patients and POs is further regulated by the Apifarma Code of Conduct, applicable only to Apifarma's member companies. The Apifarma Code of Conduct includes rules for sponsorships, grants, provision of services and other interactions with patients, patient experts and advocates, POs and other relevant stakeholders.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Advertising directed at HCPs should contain the following.

- The medicine's name and classification for dispensing purposes.
- The essential information compatible with the SmPC, including the name, qualitative and quantitative composition, pharmaceutical form, therapeutic indications, posology and method of administration, contraindications and adverse reactions. Warnings and special precautions for use and interactions with other medicines, if relevant, must also be included.
- The reimbursement regime (there is no obligation to disclose the price of the product).
- The date on which the material was first issued and of its last revision.

Name reminders are permitted, provided these only identify the medicine (either by brand, international non-proprietary name or both) and the marketing authorisation holder (name and address).

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. Additionally, general principles applicable to the advertising of medicines should be complied with when advertising before HCPs – ie, advertising:

- should not be misleading;
- should contain elements consistent with the information provided for in the approved SmPC; and
- should promote the rational use of medicines, doing so in an objective manner and not exaggerating its properties.

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

Data not included in the SmPC of a medicine – such as data on file and data generated from other clinical trials – can be used in advertising, provided that such data does not contradict the information made available in the SmPC of the product. However, pharma companies must ensure that claims made are supported by consistent evidence, and that all sources used are correctly indicated.

5.3 Advertising of Combination Products

Advertising the use of a medicine in combination with another is permitted provided the materials are consistent with the information contained in both SmPCs. General advertising rules apply in this regard.

5.4 Advertising of Companion Diagnostics

There are no specific rules for companion diagnostics products. The rules applicable to the advertising of medicines and of the relevant medical device should therefore be complied with.

5.5 Restrictions on Reprints of Journal Articles for Healthcare Professionals

Reprints of journal articles concerning medicines can be shared with HCPs. There are no specific restrictions, but pharma companies must ensure that the

source is correctly indicated and that the content does not include off-label advertising.

5.6 Medical Science Liaisons

The notion of medical science liaisons (MSLs) is not expressly provided for in the law. Accordingly, MSLs are bound by the restrictions set forth in the Medicines Code regarding the disclosure of scientific information. MSLs should not proactively discuss scientific information or proactively provide information on unauthorised medicines or indications.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation of Advertising Materials

Advertising materials do not require prior authorisation from Infarmed. Nevertheless, pharma companies are required to notify Infarmed of all advertising materials, submitting a copy within ten days of first release or disclosure. Infarmed also has the authority to request access to the materials prior to disclosure and to take measures to prevent their dissemination.

6.2 Compliance With Rules Concerning Medicinal Product Advertising

Compliance with the rules concerning medicines advertising should be ensured by the scientific service of the pharma company, which is responsible for all information made available regarding medicines and for guaranteeing that all advertising released by the company or on its behalf complies with advertising rules. This scientific service is entrusted with several obligations, including the maintenance of complete and detailed records of all advertising conducted by the company.

The Apifarma Code of Ethics additionally requires the scientific service to include a physician or pharmacist responsible for the approval of all advertising and information materials prior to release. These professionals must attest that the materials were reviewed in their latest version and comply with both legal and ethical requirements, among other responsibilities. Furthermore, pharma companies are obliged to appoint a senior worker to supervise compliance with the law and ethical requirements.

Standard operating procedures are not required, though in practice they are commonly used by pharma companies to ensure compliance with advertising rules.

7. Advertising of Medicinal Products on the Internet

7.1 The Advertisement of Medicinal Products on the Internet

Advertising of medicines on the internet is not specifically addressed under the Medicines Code, and general rules apply. As such, as a rule, prescription-only medicines may not be advertised online, unless advertising takes place in a closed environment accessible only to HCPs.

Advertisement of OTCs on the internet should comply with the rules provided for in the Regulation on Digital Channels, which sets forth rules for advertising on different online channels, including social media. This Regulation complements the rules of the Medicines Code, establishing specific information requirements and how should they be displayed on online channels.

Apifarma also enacted the Apifarma Guide on the Use of Digital Channels, which includes a set of principles and rules to be followed by member companies when conducting online activities. It provides guidance on how to interact with HCPs and the general public online, including with regard to online events.

7.2 Restrictions on Access to Websites Containing Material Intended for Healthcare Professionals

Pharma companies are required to restrict access to webpages or any other online platforms containing advertising or any information intended for HCPs, ensuring that the general public does not have access to such platforms.

7.3 Provision of Disease Awareness Information to the General Public Online

Pharma companies are allowed to provide disease awareness information and/or materials to the general public online. Such information must, nevertheless, comply with the rules provided in the Medicines Code and contain exclusively information that relates to human health or diseases – ie, no reference should be made, either directly or indirectly, to a medicine.

7.4 Virtual Scientific Meetings

Virtual scientific meetings are not specifically regulated in the Medicines Code and must therefore comply with the general rules applicable to events. Pharma companies are allowed to sponsor virtual scientific meetings and congresses, as well as virtual attendance of HCPs.

Under the Apifarma Code of Ethics, pharma companies are not allowed to provide any kind of hospitality (eg, meals) for virtual scientific meetings or congresses. Furthermore, the Apifarma Guide for the Use of Digital Channels sets forth detailed rules on virtual events, including the need to limit access to the intended audience, which should be clearly communicated in all activities linked to the event. This Guide further contains rules for determining whether a virtual event should be considered "international". In this regard, virtual events should follow the ethical rules applicable in the country of origin of the majority of the attendees. Invitations to HCPs should follow the legal and ethical rules applicable in the country of origin of each HCP.

7.5 Use of Social Media

Advertising on social media must comply with general advertising rules. As a result, only non-reimbursed OTCs may be advertised on social media.

Under the Regulation on Digital Channels, pharma companies are required to ensure that online advertising is clear, truthful and sufficiently detailed, and allows recipients to verify the characteristics of the medicine. Furthermore, it must be consistent with both the information leaflet and the SmPC. Social media advertising must include disclaimers advising recipients to carefully read the information leaflet and labelling information as well as a link to the information leaflet.

Pharma companies are responsible for all online advertising disclosed both by themselves and by third parties on their behalf. Specifically, the Apifarma Guide for the Use of Digital Channels requires companies to put in place internal procedures and policies governing communication via online channels, including employees' use of such channels through their private accounts, and to provide related training. Pharma companies may be held liable for any infringements committed by their employees.

8. Inducement/Anti-Bribery

8.1 Anti-Bribery Legislation Applicable to Interactions Between Pharmaceutical Companies and Healthcare Professionals

Interactions between pharma companies and HCPs and healthcare organisations (HCOs) fall into general anti-bribery and anti-corruption legislation, including general provisions on corruption and related offences as set forth under the Portuguese Criminal Code.

8.2 Controls on the Provision by Pharmaceutical Companies of Benefits and/or Inducements to Healthcare Professionals

The provision of benefits or any kind of inducement to HCPs is heavily restricted.

Pharma companies cannot directly or indirectly grant or promise to grant gifts, bonuses or benefits in money or kind to HCPs, except if of insignificant value – ie, equal to or lower than EUR60 – and relevant for the practice of medicine or pharmacy. The Apifarma Code of Ethics provides for additional rules for the granting of promotional gifts, allowed only in the context of OTCs' advertising, and items of medical utility, which should not include any promotional element.

Benefits, even if permitted, cannot be provided as an incentive nor as in return for recommending, prescribing, purchasing, supplying, selling, administering or using medicines.

As for HCOs, National Health Service healthcare institutions ("NHS hospitals") cannot directly or indirectly canvass or receive benefits in cash or in kind that may affect their neutrality and impartiality from pharma companies. They may only receive such benefits if they do not compromise their neutrality and impartiality and prior authorisation from Infarmed has been obtained.

9. Gifts, Hospitality, Congresses and Related Payments

9.1 Gifts to Healthcare Professionals

Pharma companies are generally prevented from offering gifts to HCPs, with the only exception being benefits equal to or lower than EUR60 and that are relevant for the practice of medicine or pharmacy.

The Apifarma Code of Ethics sets forth additional requirements, distinguishing between promotional gifts and items of medical utility.

The granting of promotional gifts to HCPs is permitted. The notion of promotional gifts comprises benefits in kind whose value does not exceed EUR25 and that are relevant for the HCPs' practice and/or involve a benefit to the patient. In parallel, pharma companies may also grant HCPs items of medical utility – ie, benefits in kind destined for the provision of healthcare services to patients, not related to medicines advertising, and that are relevant to the HCPs' practice and may contribute to assisting patients with the administration of medicines and/or in managing diseases. The value of items of medical utility should be equal to or lower than EUR60.

Payment of hospitality costs is excluded from the rules above and may be granted in the context of the HCPs' attendance at scientific or promotional events.

9.2 The Provision of Samples of Medicinal Products to Healthcare Professionals

Pharma companies are allowed to provide free samples of medicines that do not contain narcotics and psychotropic substances to physicians, provided that the following requirements are met:

- the supplying of samples must be made in response to a written request dated and signed by the physician;
- samples must be provided under the smallest presentation on the market and marked as "free sample" and "not for sale", or similar wording; and
- samples must be accompanied by a copy of the SmPC.

Samples may only be provided in the first two years after the beginning of marketing of the medicinal product.

In addition, annual limits of samples per physician are set: four samples per physician under both the Medicines Code and the Apifarma Code of Ethics.

9.3 Sponsorship of Scientific Meetings

Pharma companies may sponsor scientific meetings or congresses and/or attendance by HCPs at these events, provided that rules on the payment of hospitality costs are complied with and that the event location is adequate from a professional and logistical standpoint. Sponsorship of events should be clearly disclosed in all documentation related to the event. In this regard, the Apifarma Code of Ethics requires events to take place in appropriate venues (excluding any specific locations recognised primarily for leisure activities) and the event programme to be related to the attendees' practice or relevant to justify the HCPs' attendance, as well as to not include any leisure activities.

Payment of hospitality costs are subject to strict conditions. Under the Medicines Code, pharma companies are only allowed to bear appropriate costs, strictly limited to the main purpose of the event – namely related to the registration, transport and accommodation costs for the attending HCP and exclusively between the day before and after the end of the event. Costs may only be paid for the attending HCPs.

The Apifarma Code of Ethics imposes additional requirements. Under the Code, and among other conditions, the costs of any meals provided to HCPs should not exceed EUR60.

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

The hospitality granted to HCPs should not include the organisation of non-scientific events. Pharma companies may therefore not organise or sponsor cultural, sports or any other leisure activities in connection with scientific conferences.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

Pharma companies may not provide grants or donations to HCPs. The granting of any kind of benefit to HCPs is prohibited, with the exception of the granting of gifts and the payment of hospitality costs (see **8.2 Controls on the Provision by Pharmaceutical Companies of Benefits and/or Inducements to Healthcare Professionals**). Grants or donations to HCOs are admissible, be it in cash or in kind, provided that they are not offered as an inducement to buy, recommend and/or use the products of the pharma company.

The Apifarma Code of Ethics provides for additional rules in this regard, allowing the granting of support to HCOs should it be aimed at events, supporting continuous training or within the scope of the provision of healthcare services and clinical research. In all cases, the provision of grants or donations should be subject to a written agreement between the pharma company and the HCO, among other requirements.

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

Pharma companies may offer rebates or discounts on their medicines to HCOs in the context of their business negotiations. Advertising rules provided for in the Medicines Code do not apply to commercial measures or practices related to margins, prices and discounts.

Notwithstanding, advertising before the public of price discounts on medicines that may not be advertised before the public – such as prescription-only or reimbursed medicines – is expressly forbidden.

9.7 Payment for Services Provided by Healthcare Professionals

Pharma companies may pay HCPs for services rendered, including for acting as active participants (speakers) in scientific or training events or other services. Payment cannot be made in return for prescription and/or dispensing of medicines.

Under the Apifarma Code of Ethics, pharma companies are required to enter into a written agreement with the HCP prior to the provision of the services, and the HCP's selection should be made considering objective criteria related to their knowledge and experience. Honoraria should be reasonable and reflect the market value of the services at stake. Additional requirements apply.

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

Pharma companies are required to report the sponsorship of events to Infarmed ten days in advance. In addition, detailed records of the sponsorship and of the event should be kept for five years.

There is no general requirement to request employer consent; however, depending on the specific labour relationship of the HCPs at stake, they may be obliged to notify or to obtain prior authorisation from the employer in order to render services or attend events sponsored by pharma companies.

10. Pharmaceutical Companies: Transparency

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

Pharma companies are required to report to Infarmed any benefit equal to or higher than EUR60 granted to HCPs and HCOs, medical or scientific associations/organisations and patient associations, among others. Reporting should be made at a public platform managed by Infarmed within 30 days of the granting of the transfer of value, identifying the recipient and the value of the benefit granted, among other details.

Payment of wages or remuneration paid to HCPs in return for work performed in cases where the HCP is economically dependent on the pharma company are excluded from this legal obligation.

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

The legal obligation to report the granting of benefits to Infarmed applies to any entity covered by the Medicines Code, including marketing authorisation holders and local representatives. As such, foreign companies and companies that have not yet begun the marketing of products will be covered by this reporting obligation.

11. Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

Infarmed, is the regulatory authority responsible for enforcing rules on pharmaceutical advertising, including rules on inducement. Infarmed is therefore competent for initiating administrative offence procedures based on the infringement of advertising rules. Decisions taken by Infarmed may be challenged before the competent courts.

The Apifarma Ethics Council is responsible for enforcing rules provided under the Apifarma Code of Ethics, being able to impose sanctions on its member companies in the case of non-compliance.

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Pharma companies can act against competitors for advertising infringements either by lodging a complaint with Infarmed (based on the infringement of legal provisions) and/or before Apifarma (based on the infringement of the rules provided for under the Apifarma Code of Conduct and the Apifarma Code of Ethics), provided the infringer is a member of the association. Pharma companies are only able to initiate proceedings directly in exceptional circumstances, resorting to civil courts, if requirements for civil liability are met.

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

Infringement of pharmaceutical advertising rules, including rules on inducements, provided for in the Medicines Code are considered administrative offences punishable with a fine, which may range between EUR2,000 and 15% of the infringer's turnover or EUR180,000, whichever is lower.

Additionally, ancillary sanctions may be imposed on the infringer, which can include the publication of the conviction in a newspaper or similar at the expenses of infringer and the suspension of advertising activities for up to two years, among others.

As for infringement of the Apifarma Code of Ethics and the Apifarma Code of Conduct, the Apifarma Ethics Council may also apply penalties, such as a simple warning, a reprimand or a fine (up to the amount corresponding to five years of the contribution due to Apifarma). In serious cases, the Council may propose membership suspension or expulsion to Apifarma's General Assembly.

11.4 Relationship Between Regulatory Authorities and Courts

Procedures before or measures taken by Infarmed, and procedures or measures before the courts, are completely independent. The same applies to procedures before or measures taken by Apifarma, as a self-regulatory authority.

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

There are no recent enforcement trends in relation to pharmaceutical advertising in Portugal, as the decisions taken by Infarmed and Apifarma are not made public.

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

The rules applicable to the advertisement of veterinary medicines are provided for in Regulation (EU) 2019/6 of the European Parliament and of the Council (the "Veterinary Medicinal Products Regulation"; VMR),

which replaced Decree-Law No 148/2008, of July 29th, as amended (the "Veterinary Medicines Code").

The VMR sets forth general rules for advertising of veterinary medicines, including rules on the advertising of prescription-only veterinary medicines. Complementary legislation to the VMR is still to be enacted.

The regulatory authority responsible for enforcing veterinary advertising rules is the *Direção Geral de Alimentação e Veterinária* – DGAV.

Trends and Developments

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VdA is a leading international law firm with more than 50 years of history, known for its impressive track record and innovative approach. VdA's highly specialised legal services covering several industries and practice areas enable the firm to overcome the increasingly complex challenges faced by clients. VdA offers dependable solutions, anchored by excellence, integrity and professionalism. The high standard of work is recognised by clients and stakeholders alike, and is acknowledged by professional associations, legal publications and universities. The firm's exceptional output has set it apart in the Portuguese legal market, and proved worthy of the most prestigious international accolades and awards. Through the VdA Legal Partners network, clients have access to legal services in Portuguese-speaking African countries (Angola, Cabo Verde, Equatorial Guinea, Mozambique, Portugal, Sao Tome and Principe), as well as in Timor-Leste.

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Advertising Medicinal Products in Portugal

Pharma industry communications with clients and stakeholders have transformed at a remarkable pace, driven by large-scale adoption of digital tools and other innovative technologies. Portuguese regulation, however, has remained stable for the last two decades. The regime, provided in the Portuguese Medicines Code, stems from EU Directive 2001/83/EC (the "Directive"), with some particularities, including:

- the broad notion of advertising and promotion – in Portugal, any activity that directly or indirectly leads to increase of sales, prescription or consumption is deemed promotional, which means that a message can be qualified as promotion irrespective of its intent; and
- the prohibition on granting benefits or advantages, not only to healthcare professionals (HCPs) but also to the general public.

Such differences significantly impact the way pharma companies advertise their products in Portugal, since there is less margin to qualify an activity as strictly scientific or non-promotional, and since benefits to patients can be at risk of infringing the law, even if they are altruistic and pursue positive health outcomes.

Rules on Online Advertising

As physicians and patients turned to digital media, pharma companies had to adjust and reinforce their digital presence. This shift has brought unique challenges to Portugal.

Considering the broad definition of advertising discussed earlier (ie, every message concerning medicines can be promotional, irrespective of intent), the fluid, decentralised and borderless nature of online communication is an evident source of risk.

The Medicines Code and ancillary regulation (such as the Medicines Advertising Regulation, approved by the Portuguese government agency Infarmed) were not prepared to address the digital revolution. Rules were detailed for traditional channels such as posters, banners, stands and publications in scientific papers, but were silent on social media, webinars, digital platforms or mass emailing. Interpreting the rules in accordance with their spirit, while estimating the regulator's own interpretation and disposition to enforce, can be as strenuous as it is stimulating.

Apifarma Guidelines for Online Medicine Promotion

In the absence of guidance from Infarmed, pharma companies resorted to self-regulation. In 2021, the Portuguese Pharmaceutical Industry Association (*Associação Portuguesa da Indústria Farmacêutica* Apifarma) enacted a set of rules and principles to govern pharma companies in their digital activities.

The Digital Channels Use Guide (the "Guide") established rules and guidelines applicable to online advertising and to member companies when promoting over-the-counter (OTC) and prescription-only medicinal products.

The Guide mirrored the European Federation of Pharmaceutical Industry Associations (EFPIA) Code of Practice (the "EFPIA Code") on digital channels. Some of the principles it included were also contemplated in the later-approved Joint Note for Guidance on social media and digital channels issued by EFPIA and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).

Rather than attempting a profound change of current rules, the Guide set out to provide companies with reliable advice on how to comply online with a law designed for analogical communication. While tremendously useful, it did not innovate or patch up the regime. Furthermore, because it is only binding for Apifarma's member companies, it still did not provide a common standard for all pharma companies operating in Portugal.

New Regulation Concerning Online Advertising of OTC Medicines

In 2024, Infarmed enacted the Regulation on Good Advertising Practices for Over-the-Counter Medicines Through Digital Channels (the "Regulation"). Acknowledging the increasing importance of online advertising, the Regulation sought to ensure that OTC advertising on digital channels and the internet complies with the Medicines Code, particularly with the principles of public health protection and rational use of medicinal products.

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Besides general rules applicable to all online advertising of OTCs, the Regulation imposes requirements specific to each medium, such as digital channels, social media, mobile apps and search engines.

While the Regulation was a great opportunity to revisit the regime and adjust it to a new technological landscape, the outcome was underwhelming. Even though it did set a common set of rules, it is still limited to the advertisement of OTCs before the general public. Infarmed further clarifies that any advertising activity exclusively aimed at HCPs must take place in a restricted access environment and is therefore excluded from these recommendations. As such, modern communications with HCPs and other institutional stakeholders remain unaddressed.

Although there are now several mandatory disclaimers to be added for the promotion of OTCs, concerns and doubts mostly emerge from communication with the general public in respect of prescription-only medicinal products. Pharma companies are still deprived of any guidance on how to ensure compliance with promotional rules when communicating online with the public with no promotional intent.

Increasing Use of Real-World Evidence in Advertising

Real-world data includes healthcare information generated outside clinical research and gathered during routine clinical practice. Such data may include health records, patient registries and even information drawn from social media.

Real-world evidence, in turn, is the information generated through *analysis* of real-world data - allowing companies to assemble information on the use, potential benefits and risks of a medicinal product in the field. The use of real-world evidence is not new. However, progress in digital technologies (including AI) has allowed significant advances.

Marketing potential of real-world evidence

Over the past few years, pharma companies and regulators have become acquainted with the immense potential of real-world evidence in the different stages of the marketing of a product - from the discovery of new medicinal products to pharmacovigilance.

Real-world evidence allows companies to cater for cost-efficiency while researching, developing, approving and effectively marketing their products. Specifically, in terms of market access, real-world evidence allows pharma companies to offer strong confirmation of the value of the medicinal product, improve the patient target, and establish more effective commercial activities. Thanks to the increasing availability and diversity of real-world data, real-world evidence has gained momentum and is now a decisive investigation and business tool.

Advertising is no exception. By enabling pharma companies to better understand the performance of their products, real-world evidence has also allowed pharma companies to develop new advertising techniques.

Real-world evidence can be used:

- as evidence to back up the performance of medicinal products in regular clinical practice;
- as a powerful tool to engage HCPs, given that information gathered from clinical practice may enable them to make more informed decisions, and may enable pharma companies to better understand how HCPs decide and impact outcomes;
- as a way of (re)targeting patients, therefore broadening the scope of the population who can benefit from a given medicinal product;
- to increase credibility, as it provides a global overview of the products, building trust in products that perform well; and
- in the shift towards patient-centred care, highlighting case studies and tailoring messages to different recipients based on real-world data.

Real-world evidence has therefore been widely used in pharmaceutical advertising, mainly to support claims made regarding products, both online and offline. However, using real-world evidence effectively does involve some legal challenges.

Regulatory considerations when using real-world evidence

From a Portuguese law standpoint, pharma companies are not prevented from using real-world evidence to substantiate advertisement claims. However, rules

provided in the Medicines Code would still have to be complied with, which means that companies must be particularly cautious when disclosing information - specifically, if related to prescription-only medicinal products. Companies must further ensure that the information provided by real-world evidence does not contradict – or go beyond – the information made available on the label of the product (ie, in the summary of product characteristics (SmPC)). This issue arises when real-world evidence generates data for off-label indications or for different populations. Pharma companies must also ensure that the data is reliable and robust, as it must be sufficient to substantiate the relevant claim.

Finally, when generating real-world evidence, pharma companies must also consider the possibility of having to comply with the Portuguese Clinical Research Law. Contrary to EU rules on this matter, the Portuguese Clinical Research Law covers all systematic studies aimed at verifying the distribution or effect of health factors, states or outcomes of health processes or interventions conducted in humans or from individual health data, through biological, behavioural, social or organisational aspects. Considering these challenges, real-word evidence will certainly remain top of the agenda for pharma companies advertising medicinal products.

Outlook for 2026

Although changes to the Portuguese legal framework for medicinal products are expected soon, they will probably be focused on pricing, reimbursement and market access conditions, to further develop and regulate the new EU Health Technology Assessment Regulation. No significant changes are hence expected in medicine advertising in the short run. Pharma companies remain required to navigate a specific, strict and complex environment when operating in Portugal.

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