Chambers AND PARTNERS

CHAMBERS GLOBAL PRACTICE GUIDES

Pharmaceutical Advertising 2025

Definitive global law guides offering comparative analysis from top-ranked lawyers

Portugal: Law & Practice

Fernanda Matoso and Alessandro Azevedo
Morais Leitão, Galvão Teles, Soares da Silva & Associados

PORTUGAL

Law and Practice

Contributed by:
Fernanda Matoso and Alessandro Azevedo
Morais Leitão, Galvão Teles, Soares da Silva & Associados

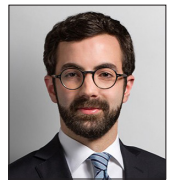
Contents

Contributed by: Fernanda Matoso and Alessandro Azevedo,
Morais Leitão, Galvão Teles, Soares da Silva & Associados

Morais Leitão, Galvão Teles, Soares da Silva & Associados (Morais Leitão) is a leading law and consultancy firm, recognised for excellence, innovation, and the breadth of its practice areas, with an international presence through the Morais Leitão Legal Circle network in Portugal, Singapore, Angola, Mozambique, Cape Verde and Timor-Leste. The firm is recognised by peers and clients alike for providing legal services characterised not only by impeccable technical rigour but also by creativity – often with innovative approaches that challenge conventional methods. Morais Leitão has teams specialising in various economic sectors, offering national and international clients a service of proximity and integrity that guarantees the best defence of their interests.

Authors

Fernanda Matoso is a partner at Morais Leitão, Galvão Teles, Soares da Silva & Associados and co-ordinates the firm's life sciences practice. She is particularly focused on international pharma companies that market medicines and medical devices in Portugal, health technology companies, and the medical cannabis industry and licensing. Fernanda has extensive knowledge of - and expertise in - the regulatory framework for pharmaceutical industry activity and the respective products (medicines, medical devices, cosmetics, food supplements, and other health products), wholesale distribution activity, healthcare institutions, and associated topics such as licensing, marketing authorisation, price regulation, state reimbursement/funding mechanisms, promotional/advertising activities, patient protection, data protection, compliance, and the marketing of health products.



Alessandro Azevedo joined Morais Leitão, Galvão Teles, Soares da Silva & Associados in February 2019 and is a member of the firm's administrative and public law team. Alessandro focuses his practice on several areas of administrative law - namely, public contracts and urbanism for public and private entities in procedural matters and litigation. Alessandro is also experienced in life sciences regulatory practice, particularly in the pharmaceutical industry and its products (medication, medical devices, cosmetics, and dietary supplements) and in controlled substances. On the academic circuit, he is a research collaborator at the Lisbon Public Law Research Centre.

Morais Leitão, Galvão Teles, Soares da Silva & Associados

Rua Castilho 165
1070-050
Lisbon
Portugal

Tel: +351 21 381 74 00
Fax: +351 21 381 74 99
Email: fmatoso@mlgts.pt
Web: www.mlgts.pt

1. Pharmaceutical Advertising: Regulatory Framework

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

The following legislative acts regulate the advertisement and promotion of medicines in Portugal.

- Decree Law 176/2006 of 30 August, as amended, which establishes the legal regime applicable to medicines;
- Decree Law 5/2017 of 6 January, which establishes advertising principles and a prohibition on National Health Service (NHS) hospitals from requesting and receiving benefits from the pharmaceutical industry and from other health technology companies, except if such request or 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 23 October, as amended, which approves the Advertising Code.

In addition, some specific matters are regulated by administrative regulations issued by the regulatory authority, the National Authority of Medicines and Health Products (*Autoridade Nacional do Medicamento e Produtos de Saúde*, or "Infarmed"), and by the Secretary of State of Health.

Self-Regulatory Codes

The Portuguese Pharmaceutical Industry Association (*Associação Portuguesa da Indústria Farmacêutica*, or APIFARMA) approved the following self-regulatory codes:

- the Code of Ethics for Promotion Practices of the Pharmaceutical Industry and Interaction With Healthcare Professionals and Health Organisations (the "Code of Ethics");
- the Code of Conduct for the Relations Between the Pharmaceutical Industry and Patient Associations, Patients' Advocates, Patients' Experts, Patients and Caregivers (the "Code of Conduct"); and
- the Code of Good Practice for Communication.

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

The self-regulatory codes identified in **1.1 Laws and Self-Regulatory Codes Concerning the Advertisement and Promotion of Medicines** are ethical standards. They are binding upon 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 30 August, as amended, as any form of information, prospecting or incentive that 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 their value is insignificant;
- through the sponsorship of promotional meetings attended by HCPs;
- through the sponsorship of congresses or meetings of a scientific nature attended/participated in by HCPs - namely, through the direct or indirect payment of the respective hosting costs; and
- through reference to the commercial name of a medicine.

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

Portuguese laws 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 falls within the criteria established in Article 150(1) of Decree Law 176/2006 of 30 August.

However, Article 151(1-d) of Decree Law 176/2006 of 30 August provides that information relating to human health or human diseases - provided it does not refer to or mention, even indirectly, a medicine - is not subject to advertising regulations, which is deemed to mean that this information does not qualify as advertising. Therefore, disease awareness campaigns and other patient-facing information do not qualify as advertising, as long as they comply with the aforementioned Article 151(1-d).

In addition, APIFARMA's Code of Ethics - specifically, Article 5(4) - excludes from the prohibition on advertising medicines not yet authorised (or off-label information) the right of pharma companies to inform the scientific community about advances in the field of medicinal products and therapeutics, thereby permitting the disclosure of the results of 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 Portuguese law, regulations or self-regulatory codes. Therefore, press releases issued by pharmaceutical companies should comply with the general rules applicable to advertising activity – namely, those concerning the respective content and the audience.

2.4 Comparative Advertising for Medicines

Comparative advertising of medicines can only be addressed to HCPs and is 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 may not be deceitful or defamatory and the comparison of medicines should be based on the medicines' characteristics and specifications, instructions for use, technical documentation or credible clinical data, or objective features such as the price of the medicinal products.

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 (off-label advertising) is not permitted. However, as explained in **2.1 Definition of Advertising**, the dissemination of information on advances in scientific research in the field of medicinal products and therapeutics is permitted – given that 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 on advertising unauthorised medicines or indications (see **3.1 Restrictions on Provision of Information on Unauthorised Medicines or Indications**), the provision of information concerning unauthorised medicines or indications to healthcare institutions for the purpose of preparing budgets, etc, is not permitted.

3.5 Information About Early Access or Compassionate Use Programmes

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

4. Advertising Pharmaceuticals to the General Public

4.1 Main Restrictions on Advertising Pharmaceuticals to the General Public

It is forbidden to advertise the following to the general public:

- prescription-only medicines;
- medicines containing substances defined as drugs or psychotropic substances (at international conventions for drugs and psychotropic substances); and
- medicines under reimbursement by the State.

Advertising of other medicines to the public must be unequivocally identified as such, expressly indicating the specific medicine. Comparative advertising of medicines to the general public is prohibited.

As regards what information is mandatory and what is prohibited in advertising to the general public, see **4.2 Information Contained in Pharmaceutical Advertising to the General Public**.

4.2 Information Contained in Pharmaceutical Advertising to the General Public

Pharmaceutical advertising directed at the general public must contain, at a minimum, the following information:

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

Advertising aimed at the general public may not contain any element that:

- leads to the conclusion that a medical consultation or surgery 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 or guaranteed to have 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 the case of vaccination campaigns approved by the local regulatory authority;
- is exclusively or mainly targeted at children;
- refers to recommendations from scientists and HCPs or to recommendations from 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 it being a natural product;
- induces an incorrect self-diagnosis through a description or detailed representation of a person's medical history;
- refers - in an abusive, frightening or misleading way - to statements or guarantees of recovery; and
- uses - in an abusive, intimidating or misleading way – visual representations of human body changes caused by diseases or lesions

or by the effect of a medicine on a human body or parts of it.

4.3 Restrictions on Interactions Between Patients or Patient Organisations and Industry

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

The limits and constraints are generally established to prevent interactions with patient associations where such interactions qualify as a form of information, prospecting or incentive that is within the scope of, or has the effect of, promoting the prescription, dispensation, sale, acquisition or consumption of medicines under the terms set out in Article 150(1) of Decree Law 176/2006 of 30 August.

In this regard, it should be highlighted that APIFARMA's Code of Conduct prohibits the promotion of prescription-only medicines before a patient association, but provides that such medicines may be promoted to HCPs who assist or co-operate with patient associations. In the same sense, events in which patient association representatives participate that are promoted by the industry may not be of a promotional nature. Furthermore, partnerships, services supply and financial support granted by the industry must be under a written contract. Companies in the industry may not be the sole financing entity of any of the activities and events promoted by a patient association.

5. Advertising to Healthcare Professionals

5.1 Restrictions on Information Contained in Advertising Directed at Healthcare Professionals

Advertising aimed at HCPs must 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;
- the classification of the medicine with regard to 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, up to date, verifiable and sufficiently complete to allow the recipient to correctly assess the therapeutic value of the medicine. References to and the illustrative material of medical publications or scientific works used in advertising support must be correctly reproduced and should mention the respective source.

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

Advertising material 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
- no contradiction is found between the summary of product characteristics and the

information provided in the data on file and in the clinical studies.

5.3 Advertising of Combination Products

Given that combined advertising 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 permitted.

5.4 Advertising of Companion Diagnostics

See **5.3 Advertising of Combination Products**.

5.5 Restrictions on Reprints of Journal Articles for Healthcare Professionals

In Portuguese law and regulations, there are no specific rules regarding the reprinting of journal articles. However, assuming that the reprints are of scientific journal articles, it is believed that such reprints may be provided if they refer to human health and diseases or to scientific information relevant to the practice of medicine.

In accordance with APIFARMA's Code of Ethics, promotional materials published in any printed or digital means of communication should not resemble independent editorial articles and should be clearly identified as being of an advertising nature (Article 5(11)).

5.6 Medical Science Liaisons

The activity of medical science liaisons (MSLs) is not specifically regulated by Portuguese law or regulations. However, regarding MSLs, pharma companies should comply with the general rules applicable to advertising activities as already described.

6. Vetting Requirements and Internal Verification Compliance

6.1 Requirements for Prior Notification/ Authorisation of Advertising Materials

The marketing authorisation holders are required to submit one sample of each advertising material relating to each medicine no longer than ten days after the respective distribution starting dates.

In the context of the sponsorship of congresses, symposiums or any actions or events of a scientific nature or intended to directly or indirectly promote medicines, the sponsor company must communicate the sponsorship to Infarmed at least ten business days before the event.

Vaccination campaigns or campaigns promoting generic medicines aimed at the general public must be approved beforehand by Infarmed. If not, such campaigns could be classified as prohibited advertising activity.

6.2 Compliance With Rules Concerning Medicinal Product Advertising

Pharma companies are not legally required to establish standard operating procedures governing advertising activities. However, they are required to have an internal scientific service responsible for information related to medicines and for maintaining complete and detailed records of all advertising of medicines, with indications of the target audience, medium, and date of first dissemination. The same internal scientific service must ensure that:

- the advertising activities comply with all the obligations imposed by the law and codes; and
- 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 co-operate with this authority and other competent authorities in all that is deemed necessary within the scope of the authorities' respective legal powers. The scientific service should be supervised by a qualified person (a physician or a pharmacist, as established by Article 4(2) of APIFARMA's Code of Ethics).

7. Advertising of Medicinal Products on the Internet and Through Digital and Electronic Platforms Including Social Media

7.1 The Advertisement of Medicinal Products on the Internet

Decree Law 176/2006 of 30 August expressly addresses advertising on the internet. However, this should obviously follow the general rules applicable to advertising activities as already described.

In addition, a local regulatory authority issued two informative circulars establishing specific rules on advertising through the internet and other digital channels. Accordingly, pharma companies may publish publicly accessible information in the following ways:

- exclusively on the respective institutional website and not on social media or on any other disclosure platform; and
- solely containing – jointly and simultaneously – a 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 at international conventions for drugs and psychotropic substances is forbidden.

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

Restrictions on access to web pages containing material intended for HCPs are not specified by the law or regulations. However, companies should take all the necessary measures to ensure that the general public has no access to advertising intended for HCPs and must ensure that the information disclosed complies with the general rules applicable to advertising medicines (to HCPs and to the general public) as already described.

7.3 Provision of Disease Awareness Information to the General Public Online

As disease awareness information is beyond 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, the absence of any direct or indirect reference to a medicine.

7.4 Virtual Scientific Meetings

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

As regards the international or national nature of online scientific meetings, despite the 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 regulations on advertising and with the principles of conventional scientific meetings.

7.5 Use of Social Media

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

8. Pharmaceutical Advertising: Inducement/Anti-Bribery

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

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

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

According to Portuguese law, as a general rule (Article 158(1) of Decree Law 176/2006 of 30 August), the marketing authorisation holder, the company responsible for the information or promotion of a medicine, and the wholesale distributor are prohibited from – directly or indirectly – giving or promising HCPs 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 to medical or pharmaceutical practice (exceptions are defined in **9. Gifts, Hospitality, Congresses and Related Payments**). The same prohibition falls on HCPs, who are prevented from receiving such benefits under Article 158(2) of the aforementioned Decree Law.

In accordance with Article 9 of Decree Law 5/2017 of 6 January, public hospitals and services and bodies of the Ministry of Health may not request – or directly or indirectly receive - any pecuniary or in-kind benefit from pharma companies or health technology companies that either impairs or might impair their impartiality, except if the specific authorisation of the local regulatory authority has been previously granted.

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 Controls on the Provision by Pharmaceutical Companies of Benefits and/or Inducements to Healthcare Professionals**, pharma companies may sponsor the participation of HCPs in scientific or educational events promoted by pharmaceutical companies or by third parties. Such sponsorship is limited to the registration and hosting costs (ie, travel, lodging and meals).

According to APIFARMA's Code of Ethics, support for such costs may only be granted to the HCP(s) who will attend the event concerned. The costs must be restricted to the main purpose

of the event and cannot include entertainment events.

The length of stay covered may not exceed a period of one day either side of the event. Additionally, the event may not be held in a location or tourist resort that is best known for its leisure, entertainment or sports facilities.

The cost of the meals within national territory may not exceed EUR60 per meal. The costs of meals at international events may not exceed EUR90 per meal, except when 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, pharma companies may only give pecuniary or in-kind grants or donations to HCPs if such grants or donations are cumulatively of insignificant economic value (under EUR60) and relevant to medical or pharmaceutical practice.

In accordance with APIFARMA's Code of Ethics, within the scope of the promotion of OTC medicinal products, promotional gifts may be given to HCPs provided said gifts consist of benefits in kind – the value of which does not exceed EUR25 – that are cumulatively relevant to their professional activity and/or involve a benefit for the patient (Article 15(2)).

9.2 The Provision of Samples of Medicinal Products to Healthcare Professionals

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

- the number of samples provided each year to each HCP may not be more than four, if the lowest number is not defined by the marketing authorisation;
- the samples must be requested by the HCP in a written document, duly dated and signed;
- the samples may not be larger than the smallest presentation of the medicine under commercialisation;
- the samples' packaging must contain the references "free sample" and "prohibited sale" or other similar words;
- the samples must be accompanied by a summary of product characteristics;
- the samples may only be provided within the two years following the start of the commercialisation of the medicine; and
- the provision of samples of medicines containing drugs or psychotropic substances is prohibited.

9.3 Sponsorship of Scientific Meetings

Pharma companies may sponsor scientific meetings or congresses organised by third parties. However, even if these take place abroad, the local regulatory authority must be informed of all granted sponsorships at least ten business days before the event.

As established by Decree Law 176/2006, the sponsorship of congresses, symposiums or any actions or events of a scientific nature that directly or indirectly promote medicines must be mentioned in the promotional documentation of such events, in the documentation to be provided to the attendees, and in the documents and reports that might be published after the events. APIFARMA's Code of Ethics contains similar provisions in this regard.

The Code of Ethics establishes that the sponsored events should take place in premises suitable for the main purpose of the event or action. Places and/or complexes that are known

for their leisure, entertainment, sport or luxury/extravagant facilities should not be chosen.

Pharma companies may also support HCPs' attendance of such events. However, this support is 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) is expressly prohibited.

9.5 Grants or Donations to Healthcare Professionals or Healthcare Institutions

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

As regards healthcare institutions, it is possible to provide support - both monetary and 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 6 January, NHS hospitals may not request or receive - directly or indirectly – pecuniary or in-kind benefits from pharmaceutical companies, health technology companies or related companies where 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 requested by the NHS hospital's management bodies from the local regulatory authority (Infarmed).

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

Price discounts or rebates are expressly considered as beyond the scope of the rules on advertising of medicines. However, Article 153(6) of Decree Law 176/2006 expressly prohibits pharma companies from advertising discounts to the general public on medicines subject to medical prescription, medicines containing substances defined as drugs or psychotropic substances, and medicines under reimbursement by the State. Pharma companies may offer discounts to healthcare institutions in the context of an established commercial relationship, but not to HCPs, as the companies are prevented from executing sales to the same.

9.7 Payment for Services Provided by Healthcare Professionals

Pharma companies may enter into professional services agreements with HCPs in order to acquire expert services. HCPs may also be paid for acting as an active participant (speaker, moderator, etc) in a scientific or training event. However, the payments may not constitute financial compensation for the prescription of medicines.

In accordance with APIFARMA's Code of Ethics, the payment of HCPs must be reasonable and must 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, symposiums or any actions or events of a scientific nature or intended to – directly or indirectly – promote medicines must be communicated by the spon-

sor company to Infarmed at least ten business days before the event.

10. Pharmaceutical Companies: Transparency

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

The entities under the scope of Decree Law 176/2006 – among them pharma companies – must report to the local regulatory authority all benefits of EUR60 or more granted to HCPs, healthcare organisations, patient organisations, NHS workers, and bodies or services of the Ministry of Health or of the NHS.

Such report is to be filed via a specific transparency platform within 30 working days following the effectiveness of the benefit (payment of the benefit or granting of the benefit in the 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 will be asked via email by the local regulatory authority to validate – or not – receipt of the benefit. In the case of non-validation, the authority is to be informed of the reason. If the recipient remains silent, the benefit is considered tacitly accepted.

Benefits are defined in Article 159 of Decree Law 176/2006 of 30 August as any advantage, value, good or right assessable in cash, regardless of whether in the form of a prize, sponsorship, subsidy, fee or subvention or in any other form.

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

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

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. Such companies are prevented from promoting medicines within the Portuguese market and therefore may not grant benefits to the individuals or entities mentioned in the preceding paragraph.

11. Pharmaceutical Advertising: Enforcement

11.1 Pharmaceutical Advertising: Enforcement Bodies

The competent public authority for enforcing the rules on advertising is Infarmed. The self-regulatory body is APIFARMA.

The competent court to decide on any issue related to the rules on advertising will depend on the specific claim under decision. As a general rule, the acts issued by Infarmed should be challenged before the administrative courts; however, the administrative sanctions issued by Infarmed should be challenged before the

Competition, Regulation and Supervision Court (according to the available jurisprudence). For civil liability lawsuits, if applicable, the civil courts are competent (see **11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements**).

11.2 Initiating Proceedings for Pharmaceutical Advertising Infringements

Proceedings may be initiated before any of the bodies identified in **11.1 Pharmaceutical Advertising: Enforcement Bodies**, depending on the specific violation and whether the respective requirements are met in each case, as follows.

- Infarmed is the authority responsible for punishing infringements of the law and public regulations.
- APIFARMA's Ethics Council may impose penalties on respective members for infringements of respective codes.
- Competitors may take action in relation to advertising infringements through civil liability lawsuits.

The same conduct may qualify as an infringement of the law and public regulations and of APIFARMA's Code of Ethics provisions – in which case, proceedings may be conducted in parallel, making the respective decisions independent of each other.

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

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

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

- confiscation 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 specific to the case of infringement of advertising legal provisions may also apply, as follows.

- The decision on the imposing of fines may also determine the publication on social media of the essential elements of the condemnation.
- Advertising of the relevant medicine may be suspended 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.
- The infringer's medical sales representative may be prevented from visiting public hospitals and services, in the case of violation of the legal regime for 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.

As the association of the pharmaceutical industry, APIFARMA has a supervisory function and

enforces its codes upon its members. The procedures, decisions and penalties have an ethical nature and are completely independent of the ones taken by public entities (such as Infarmed or the courts).

11.5 Recent Enforcement Trends in Relation to Pharmaceutical Advertising

Infarmed and APIFARMA do not disclose their 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.

12. Veterinary Medicines

12.1 Advertising Veterinary Medicines

Advertising of veterinary medicines is regulated by Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products (the "Regulation"). Advertising of veterinary medicinal products is defined in Article 4(40) of the Regulation as the making of a representation in any form in connection with veterinary medicinal products to promote the supply, distribution, sale, prescription or use of veterinary medicinal products, and comprising also the supply of samples and sponsorships.

The following rules apply:

- only veterinary medicinal products that are authorised or registered may be advertised, unless otherwise decided by the competent national authority;
- the advertising of a veterinary medicinal product will aim at promoting the supply, sale, prescription, distribution or use of the veterinary medicinal product;
- the advertising may not be formulated in such a way as to suggest that the veterinary medicinal product could be a feed or a biocide;
- the advertising must comply with the summary of the product characteristics of the advertised veterinary medicinal product;
- the advertising must not include information in any form which could be misleading or lead to incorrect use of the veterinary medicinal product;
- the advertising must encourage the responsible use of the veterinary medicinal product, by presenting it objectively and without exaggerating its properties;
- the suspension of a marketing authorisation will preclude any advertising during the suspension period of the veterinary medicinal product;
- veterinary medicinal products may not be distributed for promotional purposes, except for small quantities of samples;
- the samples must be appropriately labelled as "samples" and are to be provided directly to veterinarians or other persons allowed to supply such veterinary medicinal products during sponsored events, or by sales representatives during their visits; and
- anti-microbial veterinary medicinal products may not be distributed for promotional purposes as samples or in any other presentation.

The advertising of veterinary medicinal products that are subject to veterinary prescription will only be allowed when addressed exclusively to the following persons:

- veterinarians; and
- persons permitted to supply veterinary medicinal products in accordance with national law.

The advertising of inactivated immunological veterinary medicinal products that are manufactured from pathogens and antigens obtained from an animal or animals in an epidemiological unit and used for the treatment of that animal or those animals in the same epidemiological unit or for the treatment of an animal or animals in a unit having a confirmed epidemiological link is prohibited.

Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages, or benefit in kind may be provided, offered or promised to such persons unless they are cumulatively inexpensive and relevant to the practice of the prescription or supply of medicinal products. On the other hand, persons qualified to prescribe or supply medicinal products may not solicit or accept any prohibited inducement. This prohibition does not prevent the possibility of offering hospitality – directly or indirectly - at events with exclusively professional and scientific purposes, as long as this hospitality is strictly limited to the main objectives of the event.

Although the advertising rules pointed out here address similar topics to those established for human medicinal products – for instance, in establishing prohibitions and constraints on the advertising of veterinary medicines (promotional actions, provision of samples, granting of benefits, and advertising of veterinary products – the legal framework on human medicinal products is much stricter and more detailed.

The General Directorate for Food and Veterinary Medicine is the enforcement authority for the advertising of veterinary medicines.

CHAMBERS GLOBAL PRACTICE GUIDES

Chambers Global Practice Guides bring you up-to-date, expert legal commentary on the main practice areas from around the globe. Focusing on the practical legal issues affecting businesses, the guides enable readers to compare legislation and procedure and read trend forecasts from legal experts from across key jurisdictions.

To find out more information about how we select contributors, email Rob.Thomson@chambers.com