
CHAMBERS GLOBAL PRACTICE GUIDES

Pharmaceutical Advertising 2024

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

Portugal: Trends & Developments
Francisca Paulouro and Ana Isabel Lopes
VdA



PORTUGAL



Trends and Developments

Contributed by:

Francisca Paulouro and Ana Isabel Lopes
VdA

VdA is a leading international law firm with more than 40 years of history, recognised for its impressive track record and innovative approach in 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. VdA offers robust solutions grounded in consistent standards of excellence, ethics and professionalism. Recognition of the excellence of our work is shared by the team, as well as with clients and stakeholders, and is

acknowledged by 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 industry. Through the VdA Legal Partners network, clients have access to seven (Angola, Cabo Verde, Equatorial Guinea, Mozambique, Portugal, São Tomé and Príncipe) jurisdictions, with a broad sectoral coverage in all Portuguese-speaking African countries, as well as Timor-Leste.

Authors



Francisca Paulouro joined VdA in 2002, and is of counsel and head of the life sciences practice area. Francisca has devoted her career to life sciences and is a national

reference for pharmaceutical companies both in day-to-day assistance and complex matters. She is recognised by peers and clients for her clear, precise and sophisticated advice; her knowledge of the pharmaceutical and medical devices industry; her reliability and responsiveness; and her ability to oversee teams from different disciplines. Francisca regularly assists major multinational pharmaceutical companies and biotech companies operating in Portugal in, amongst others, the following domains: promotional and advertising activities; compliance; distribution; regulatory data protection; and clinical trials.



Ana Isabel Lopes joined VdA in 2016. She is a senior associate in the life sciences practice area, where she actively provides legal assistance to companies in the healthcare sector, namely

pharmaceutical and medical devices companies. She assists these companies in their day-to-day activities, including with the rendering of legal advice on promotional initiatives and compliance matters, clinical trials, contract drafting and negotiation as well as other regulatory matters.

VdA

Rua Dom Luís I, 28
Lisbon
1200-151
Portugal

Tel: +351 21 311 3400
Fax: +351 21 311 3406
Email: vda@vda.pt
Web: www.vda.pt



Portuguese Pharmaceutical Advertising Rules Are Stricter Than the Common EU Standard

The legal regime applicable to the advertising of medicinal products in Portugal stems from EU Directive 2001/83/EC (the “Directive”). Considering the extremely narrow margin of freedom given to EU member states in the transposition of the Directive, particularly where promotion rules are concerned, one would expect this to lead to a common legal framework throughout the EU.

Although such a common legal framework does exist, the truth is that Portuguese lawmakers went beyond what the Directive provides in matters which significantly impact the activity of pharmaceutical companies operating in Portugal. This is so in relation to, at least, two key aspects: the notion of advertising itself and a general prohibition on granting any kind of benefit to patients.

Broad Portuguese definition of advertising

Firstly, contrary to the Directive, Portuguese law does not require that an informative, canvassing or inducing activity be aimed at promoting a medicinal product for it to qualify as advertising for that product; it is sufficient that it has such an effect.

As a result of this extremely broad definition of advertising, the common EU standard on prohibition of off-label advertising goes a step further in Portugal: any disclosure of information directly or indirectly related to a product made by pharmaceutical companies both to the scientific/medical community and to patients may result in the application of advertising rules. The possibility of pharmaceutical companies informing the scientific/medical community of research that is being carried out or of potential new therapies which could have a significant impact on the treatment of patients – even if made in an objective and balanced manner – is therefore severely limited.

Prohibition on the granting of benefits extend to patients as well as HCPs

Secondly, and whereas throughout the EU the rule is that pharmaceutical companies are prevented from providing any kind of benefit to healthcare professionals (HCPs), as set-forth in the Directive, in Portugal, this prohibition has been extended to patients: pharmaceutical companies are also forbidden from granting any kind of benefit to patients, regardless of its nature. And this entails that patient support programmes, often implemented in other member states, are set aside when it comes to Portugal – often negatively impacting patients.

Contributed by: Francisca Paulouro and Ana Isabel Lopes, VdA

These aspects of the Portuguese legal framework significantly affect the activities of pharmaceutical companies operating in Portugal.

As the setting evolves to digital and patients seek an active role in their treatment options, the existing legal framework is proving insufficient to address these new challenges.

Key Trends in Portuguese Pharmaceutical Advertising

Navigating the digital world

In recent years, the digital world has emerged as the primary platform for dialogue and interaction between pharma companies and the healthcare community.

Initially, online initiatives were modest and primarily focused on institutional advertising, introducing companies, their core values, and product portfolios. Websites and platforms primarily served as information deposits, without facilitating further engagement or allowing for further interaction.

Regarding prescription-only medicinal products, caution was partly due to the interpretation of Infarmed (the Portuguese agency responsible for supervising pharmaceutical advertising activities) of the applicable law, which forbade any reference to products on companies' websites. This stance has since been revisited following the Court of Justice of the European Union case law on this matter, but the conditions under which references to prescription-only medicines on websites are allowed remain stringent.

As the online ecosystem has evolved and become more sophisticated, so have the initiatives carried out by pharma companies. Turning to IT and consultancy firms, pharma companies started to develop highly specialised and tar-

geted online resources, such as e-learning platforms, websites for hosting webinars and online events, podcasts, e-commerce platforms and apps designed to aid disease management or to assist HCPs in their medical practice. These tools have proven to be crucial for educating both HCPs and patients.

Beyond the general complexities of advertising medicinal products within a detailed and strict legal framework, the set-up of these online resources has brought its own set of challenges.

The legal regime was utterly unprepared for the digital revolution. While regulation is abundant in what concerns printed materials (eg even determining the font and size of the text to be included) and physical events (eg, even determining limits to hospitality costs and regulating the dates of travel) such rules were enacted when advertising was limited to face-to-face interaction and visits of sales representatives – far from to digital ads, platforms and webinars.

In this regard, Infarmed has not yet provided for any additional guidance on how to adapt the existing rules to the new landscape. The general position is that the regime applies equally to the online and physical worlds, without exceptions, and should be interpreted accordingly.

Unfortunately, no changes are expected on this front. In the absence of guidance from the authorities, self-regulatory guidelines from the Portuguese Pharmaceutical Industry Association, Apifarma, have been filling the gaps for digital advertising. In 2021, Apifarma published its Guide for the Use of Digital Channels, which includes general rules and principles applicable to all online communications and guidelines for specific digital channels. It further identifies permitted activities for each. These sets of rules

Contributed by: Francisca Paulouro and Ana Isabel Lopes, VdA

should be followed by Apifarma member companies, which constitute the majority of the pharma companies operating in Portugal, whenever engaging in digital activities.

Patient engagement

More importantly and consistent with the trend of the last few years, pharma companies are eager to maintain discussions with the general public, including patients and patients' organisations.

Medicinal products, together with other health technologies, have taken over the spotlight and have been extensively debated in public forums. The general public is awakening to topics such as market access, the pricing of medicinal products, reimbursement policies, and the availability of innovative treatments. As a result, the media has also shown a greater interest over the last few years in several different medicinal products, from medicines used for treating diabetes and obesity to new treatment options for cancer, as well as new uses for psychotropics. This interest has been accompanied by increased concerns related to the unavailability of medicinal products, which has also been subject to heavy public scrutiny. Patients' organisations have also turned more active, carrying out several initiatives aiming at increasing public awareness and demanding swifter access to innovative products.

Unfortunately, more information being available does not always equate to more informed patients. The absence of reliable sources is one critical aspect of this trend. Patients are, by default, more vulnerable and exposed. Without the knowledge needed to assess the profile of medicinal products and treatments from a clinical standpoint, they rely on the sources they have access to.

Given their position in the market, pharma companies are expected to contribute to the debate, directly receiving information requests from patients and requests for collaboration from patients' organisations. Patients and patients' organisations are also interested in working together with pharma companies to understand their treatment options and wish to join efforts to demand faster access to new health technologies. There is an increased demand for comprehensive and understandable information on medicinal products, and pharma companies are also eager to play a role in educating the several involved stakeholders.

Regrettably, once again, the regulatory regime has not kept up with this evolution. With the exception of disease awareness campaigns, in the broad sense, interaction between pharma companies and the public faced significant risk of being considered advertising, allowing no room for dialogue between these stakeholders outside of promotion rules. The regime does not recognise pharma companies as a potential vehicle for accurate and valuable information for the general public, and therefore discourages interaction.

While Pharma Companies have been calling for a distinction between informative and promotional information for the past few years, Infarmed has remained silent on the matter. Promotional rules apply if there is a reference, even an indirect one, to a medicinal product.

Apifarma tends to have a more lenient approach on this matter, having approved a specific Code of Conduct for the relations between the pharmaceutical industry and patients' associations, patients' advocates, patient experts, patients and caregivers, in line with the principles approved by European Federation of Pharma-

Contributed by: Francisca Paulouro and Ana Isabel Lopes, VdA

ceutical Industries and Associations (EPFIA), self-regulatory rules cannot supersede the legal regime.

Pharma companies are severely limited in their ability to engage with patients. Maintaining a close link with these stakeholders, providing objective, accurate and balanced information, without crossing into promotional territory, is key. It is a difficult balance to achieve, but there should be room for it.

What Lies Ahead: No Expected Changes for 2024?

While pharma companies operating in Portugal have been vocal about the unsuitability of the legislative framework for pharmaceutical advertising given the changes in the sector and the shift to the digital environment, such concerns have not yet been addressed by the regulator and are not expected to be addressed soon.

The most significant development on this front is the much-anticipated review of the pharmaceutical framework in Europe, published by the European Commission on 26 April 2023 and currently under discussion in the European Parliament.

However, as far as advertising is concerned, the proposal does not represent a major departure from the rules provided for under the Directive. While the true impact can only be assessed following approval of the legislative package, as it stands, the proposal maintains the core rules of the current regime.

It is true that a number of changes are introduced, such as the reference to professionals licensed to administer medicinal products under the definition of HCPs and the prohibition on using any form of advertising that aims to negatively highlight another medicinal product. However, this is already covered by the Portuguese rules and will therefore have only limited impact.

Bearing the above in mind, the regime for pharmaceutical advertising will most likely remain unchanged in 2024, requiring pharma companies to continue to seek a balance between ensuring full compliance with the high standards of the regime while still striving to contribute to debates within the community and to conduct innovative projects and initiatives.

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 Katie.Burrington@chambers.com