Chambers
Global Practice
Guides

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

Pharmaceutical Advertising 2022

Portugal: Law & Practice
Francisca Paulouro and Ana Isabel Lopes
VdA

practiceguides.chambers.com

Trends and Developments

Contributed by:
Francisca Paulouro and Ana Isabel Lopes
VdA see p.6

Advertising, Digitalisation and Patient Empowerment: New Trends for the Pharmaceutical Industry in Portugal

Introduction

The Portuguese legal regime applicable to the advertising of medicinal products has its origins in the European Union legal framework, resulting from the transposition of Directive 2001/83/EC (the "Directive").

While this should lead us, in light of the extremely narrow margin of freedom given to member states in the transposition of the Directive – particularly concerning promotion rules – to a common legal framework, unfortunately that is not the case for Portugal.

The Portuguese legislator, in certain aspects, clearly went beyond what the Directive provides. Among these, and with particular relevance, are the notion of advertising and the extension of the prohibition of pharmaceutical companies from being allowed to grant benefits to healthcare professionals (HCPs) and patients.

These specificities of the Portuguese legal framework significantly impact the activities of pharmaceutical companies in Portugal.

As an example, the disclosure of scientific information, a sensitive topic throughout the EU, faces additional hurdles in Portugal. Similarly, certain initiatives freely carried out by pharmaceutical companies throughout the EU, are often barred from being implemented in Portugal, as is the case with patient support programmes.

The notion of advertising

Under Portuguese law, the underlying purpose of a given initiative developed by pharmaceutical companies is completely immaterial to its qualification as advertising. In other words, if an initiative promotes a given medicine, it will fall within the notion of advertising, even if this is not its intention. Should it be designed to promote a medicine, it is undoubtedly advertising. However, initiatives which are not intended as such, but which directly or indirectly have as an effect an increase in the purchase, dispensation or consumption of a medicinal product, will also fall under the notion of advertising.

The law provides for very few exceptions. In line with the Directive, only the labelling and information leaflet, correspondence required to reply to a specific query, information related to packaging, warnings or adverse reactions, price lists and information related to human health or diseases – provided that these do not make any indirect or direct reference to a medicine – are excluded from the scope of promotion rules.

As a result of this extremely broad definition of advertising, 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 thin line between informing and advertising

This extremely thin line between information and advertising poses several challenges to pharmaceutical companies and is a relevant setback in the dissemination of information and knowledge.

One of the clearest examples of said challenges is the disclosure of information regarding ongoing clinical research or regarding medicines which are still undergoing regulatory approval, even if at the early stages.

While the prohibition of off-label advertising is a common standard within the EU, in Portugal, 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 severely limited.

Given the broad definition of advertising, any communication of this nature can be considered off-label advertising and is therefore prohibited. Consequently, the debate regarding new medicines and ongoing clinical research is very often made behind closed doors and no incentive is given for a more public, comprehensive and transparent discussion on future available treatments within the scientific/medical community. Disclosure of scientific advances is therefore often severely compromised.

A further example of these challenges is related to disclosure of information by pharmaceutical companies to the general public.

Another standard within the EU is the prohibition of advertising of prescription drugs to the public. Disclosing purely objective and educational information on a given prescription drug, such as educational material with precautions and/or instructions for the administration of the medicine, if not within the scope of a Risk Management Plan, entails a very significant risk of being condemned by the Regulatory Agency. The latter is very conservative when it comes to the enforcement of promotion rules, particularly when patients are involved.

In a digital world such as the one we live in, where boundaries have to a great extent lost their meaning, and where information that is prohibited in Portugal is attainable by a simple click, one cannot but question such a state of affairs.

Risks and benefits of a more flexible approach – COVID-19

COVID-19 undoubtedly shook this approach.

Everywhere in the media one could read/hear about the virus, the potential treatments that eventually proved not to be treatments after all, the vaccines, their mechanisms and their side effects. Topics which are usually only discussed within the scientific community were now discussed in public, by the general public, and by "experts" who often had limited knowledge of science. Opinions were formed, some to be rapidly dismissed, others to persist. The lack of trust in the scientific community also increased. Movements challenging scientific and medical evidence were widespread, and "science" finally found a place in the public debate.

The authorities have, to a certain extent, allowed and promoted the debate, both in the disclosure of information which is usually reserved for HCPs, and by allowing the media and pharmaceutical companies to publicly discuss available or experimental vaccines and/or medicines for the prevention and/or treatment of COVID-19, without initiating any action against the pharmaceutical companies. This was, however, an exception, which could easily be justified by a pandemic of unprecedented scope.

Nevertheless, certainly lessons can be learned. It is key to inform, it is key to raise awareness, yet it is also key to prevent and block misinformation. The public, patients, are a vulnerable target.

Finding the right balance is the real challenge – not for pharmaceutical companies, but for the

legislator and regulators. And it is all the more complex in the digitalised, empowered-patient scenario that presently exists.

Patient empowerment

Traditionally, pharmaceutical companies essentially engaged with HCPs and healthcare organisations (HCOs), focusing all their communication strategy on reaching this audience.

The pharmaceutical industry has now evolved in a different direction. Pharmaceutical companies have been slowly, steadily and increasingly concentrating on patients and patient organisations. Focus is now on the patient journey and experience, and patients are now at the very heart of pharmaceutical activity (beyond the pill).

Meanwhile, patients are following the same path. Patients are now more eager to get involved with the scientific/medical community, demanding a seat at the table to discuss the availability of treatments, their efficacy and what type of healthcare they have access to. They no longer solely rely on their physician's advice and want to understand their alternatives, what is most suitable for them. Patients now want to make informed choices.

As a result, patients have also become advocates for certain treatments for diseases. They have now gained a very audible voice and their position is taken into account by the media, the regulator, and the medical community in general.

The legal framework, however, has remained static and has not followed such an evolution. Pharmaceutical companies have therefore been faced with yet another challenge: how to reach patients.

Advertising and even purely objective information, if branded, is not an option. Supporting patients through patient support programmes (as they are commonly known), which can bring significant benefits to patients and which often fill in deficiencies or inefficiencies in the healthcare system, bringing added value for all, is severely restricted in Portugal.

Patient organisations have therefore increasingly gained importance, with pharmaceutical companies seeing these as one effective way to reach out to patients. The result: a strong increase in collaboration between patient organisations and the pharmaceutical industry in the last few years, be it through the sponsorship of events, the provision of services by patient organisations, or by joint collaboration devoted to disease-awareness campaigns.

Suddenly, we are no longer dealing only with patient organisations, and new "players" have joined the mix in the form of patient advocates, patient experts, patients and caregivers.

Once more, however, the legislator and the regulator have remained static, ignoring this new reality – for them, patient advocates, patient experts, patients and caregivers continue to be no more than the public in general.

In the absence of a legal framework, the pharmaceutical industry has resorted to self-regulation and has approved yet another code of ethics specifically addressing the relationship between pharmaceutical companies, patient organisations, patient advocates, patient experts, patients and caregivers.

Digitalisation

Before the COVID-19 pandemic, pharmaceutical companies had already started to invest in their online communication strategy, but the pandemic has certainly accelerated such investment.

Pharmaceutical companies are aiming both at HCPs, with congresses and webinars in virtual

settings, and also at the general public, by setting up social media accounts, recording podcasts and organising online awareness campaigns. Influencers have also played their part, engaging with pharmaceutical companies to promote over-the-counter medicines or to assist in disease-awareness campaigns.

The digital world provides challenges of its own, however.

Patients who are actively seeking more medical and scientific information can now find this in the digital arena, with free and immediate access to cross-border information and advertising on medicines which may or may not be available in Portugal. However, this is without the mediation of an HCP. Without the scrutiny of the medical and scientific community, patients are left to evaluate on their own the accuracy of the information they have access to.

Pharmaceutical companies want and seek to participate in this digital world and believe that this online presence will be both beneficial for their own communication strategy and also for patients, who will have access to more reliable sources of information.

However, the challenge is how to adjust the traditional rules to this new reality. The legal regime applicable to pharmaceutical advertising was made for a different world.

In Portugal, in contrast to what has happened in other countries, the regulator has not issued any guidance on how to handle or tackle this digital world and it interprets and applies the rules in exactly the same manner as in the past.

With a lack of specific guidance from the regulator, pharmaceutical companies have again resorted to self-regulation, and the Pharmaceutical Industry Association issued guidelines on the use of digital channels in June 2021. This set of guidelines aims to align the legal and ethical regime with the digital reality.

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 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. VdA offers robust solutions grounded in consistent standards of excellence, ethics and professionalism. The excellence of VdA's team is recognised by both 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 six jurisdictions in addition to Portugal, with broad sectoral coverage in all Portuguese-speaking African countries – Angola, Cabo Verde, Equatorial Guinea, Mozambique, São Tomé and Príncipe – as well as Timor-Leste.

AUTHORS

Francisca Paulouro joined VdA in 2002, and is of counsel and head of the life sciences practice. 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 operating in Portugal. She is active in promotional and advertising activities; marketing authorisations and renewals; regulatory data protection and marketing exclusivity; pricing, reimbursement and market access in general; manufacture and distribution; compliance programmes; and clinical trials.

Ana Isabel Lopes joined VdA in 2016. She is an 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. Ana Isabel also recently contributed to a pharmaceutical advertising comparative legal guide.

VdA

Rua Dom Luís I, 28
1200-151
Lisbon
Portugal

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