

---

CHAMBERS GLOBAL PRACTICE GUIDES

---

# Pharmaceutical Advertising 2023

---

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

## **Portugal: Trends & Developments**

Francisca Paulouro and Ana Isabel Lopes  
VdA

## Trends and Developments

### Contributed by:

Francisca Paulouro and Ana Isabel Lopes

VdA see p.7

### Introduction

While the previous few years were focused on how to deal with the COVID-19 pandemic, 2022 finally brought some sense of normality.

Gone, hopefully, are the days of prohibition or of severely restricted visits of sales representatives to healthcare professionals (HCPs) imposed by governmental measures. Events are steadily shifting from digital platforms to classic venues – although digital platforms have certainly come to stay, with hybrid events now making up part of day-to-day life, enabling an increasing proximity and availability which until very recently was not even realisable.

The industry is once more focused on new initiatives and projects, with more innovative ways of promoting products, creating value-added initiatives where healthcare is crucial, and engaging with both HCPs and patients with one key goal: delivering for patients.

Patients have assumed a new and more pronounced role and, now more than ever, are the purpose and the driver for change, in a push for access and affordable medicines. While traditional means of advertising are still present, the truth is that communication has gone digital. This was already the case before the pandemic, and is even more so following it. In the aftermath of COVID-19, pharmaceutical and medical device companies have understood that embracing the digital transformation is not optional – it is the only way forward.

As always, the world changes faster than legislation, and with it come new challenges. In the pharmaceutical sector, the key challenge is navigating a legal framework construed for a non-digital world. In the medical devices sector, in addition to this challenge, companies are faced with a non-harmonised regime at the European Union (EU) level where promotion is concerned.

### Medicinal Products

The Portuguese legal regime applicable to the advertising of medicinal products stems from Directive 2001/83/EC (the “Directive”). Considering the extremely narrow margin of freedom given to member states in the transposition of the Directive, particularly concerning promotion rules, this might be expected to lead to a common legal framework; unfortunately, this is not the case for Portugal.

The Portuguese legislature has gone beyond what the Directive provides in specific matters, including with the notion of advertising and the prohibition on granting any kind of benefit to patients (similarly with the EU prohibition for HCPs). These aspects 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.

Contributed by: Francisca Paulouro and Ana Isabel Lopes, VdA

Contrary to the Directive, the Portuguese regime does not require that the information, canvassing or inducing activity be “designed” to promote medicinal products, it being sufficient that it has such an effect. This constitutes a significant departure from the wording of the Directive, and a considerable challenge for pharmaceutical companies operating in Portugal, rendering the distinction between “informing” and “promoting” almost artificial, with very little room for the former.

Under Portuguese law, the underlying purpose of a given initiative developed by a pharmaceutical company 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 – if these do not make any direct or indirect 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.

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 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.

In fact, any communication of this nature can be considered off-label advertising, and 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 the disclosure of information by pharmaceutical companies to the public. Another standard within the EU is the prohibition on 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 Portuguese regulatory agency.

Given patients' potential vulnerability and absence of knowledge that could enable them to "filter" information, the Portuguese regulatory agency has always been particularly cautious with patient protection, and described as somewhat conservative in its approach to promotion before the public, be it direct or indirect (as could be the case in disease awareness campaigns not strictly raising disease awareness).

However, the latest case law of the Court of Justice of the European Union (CJEU), rendered on 22 December 2022 in Case C-530/20 "Euroap-tieka", may bring this into question and potentially suggest that such a position is to be followed across Europe.

Following a request for a preliminary ruling from the Latvian Constitutional Court, the CJEU was called to decide on a set of questions focusing on a national provision which forbade the inclusion of any information encouraging the purchase of a medicinal product on the basis of its price, special sale or bundle in the advertising of a given medicinal product before the general public. The questions put forward to the CJEU entailed, in essence, addressing two topics:

- the concept of advertising; and
- the boundaries of complete harmonisation in the field of advertising brought about by the Directive.

In its judgment, the CJEU clarified that activities that do not relate merely to dissemination to the public solely of information about medicinal products, but are activities which encourage the purchase of medicinal products, should be considered advertising even if not referring to

a specific medicinal product but to unspecified medicinal products.

It is true that the court was called to analyse a very specific measure which arguably, by its very nature, is promotional. The question remains on how far the agencies of member states will apply the principles arising from such judgment, particularly as regards the following:

- the aim of safeguarding public health would be greatly compromised if an activity seeking to promote the prescription, supply, sale or consumption of medicinal products without making reference to a specific medicinal product did not fall within the concept of advertising; and
- patients do not necessarily have the specific and objective knowledge to enable them to evaluate the therapeutic value of prescription medicinal products, and therefore advertising may exercise a particularly strong influence on the evaluation and choice made by patients, both as regards the quality of the medicinal product and the amount to purchase.

While this discussion is not new, it has again gained relevance given the shift in patient behaviour. Patients are taking their place at the table and are eager to receive more and more information, and are now able to find such information very quickly through digital channels, social media and the internet. Patients are not only interested in knowing their treatment options but are also increasingly interested in knowing and publicly discussing topics such as the safety profile of medicinal products, their reimbursement statuses and even their approval processes.

Contributed by: Francisca Paulouro and Ana Isabel Lopes, VdA

Although this trend appeared prior to the COVID-19 pandemic, the health crisis undeniably emphasised it. Information on medicinal products and health technology was available everywhere, with no filters, and was directly provided to patients.

Understanding that the market has changed, pharmaceutical companies are trying to keep up the pace: even when engaging with HCPs, the focus is on patients and on reinforcing their presence on the internet and digital channels.

Naturally, as patients' interest in these topics grows, so does the need to protect patients. As the latest judgment by the CJEU has shown, the tendency is to increase control over the information shared with patients. While the Portuguese regulatory agency has not been very active in the past year concerning pharmaceutical advertising, there is no doubt it will continue to closely watch companies' activities and behaviour. The question is whether supervising the activities of the pharmaceutical industry will be sufficient for ensuring the protection of patients, especially considering that today patients can easily access information from all kinds of sources.

For now, pharmaceutical companies are left with a dilemma regarding how to comply with the rules while still engaging with patients and answering their demands for more transparent information, including from the pharmaceutical industry, without putting at risk the need to safeguard public health.

## Medical Devices

Contrary to medicinal products, the rules on advertising of medical devices were not addressed at the EU level, either under the former regimes scattered through different directives, or under the Medical Device Regulation

and the In Vitro Medical Device Regulation (hereinafter the MDR and IVMDR, respectively).

The MDR and the IVMDR very timidly address this issue, stating solely that advertising cannot contain elements that may mislead the user or patient concerning the device's intended purpose, safety and performance. Such a principle would always arise from the general rules applicable within the EU both for consumers and for HCPs.

In the absence of harmonisation at the EU level, there are naturally different regimes throughout member states affecting cross-border activities.

While some member states have left the rules on advertising of medical devices subject to the general rules on advertising, others such as Portugal have approved a specific legal regime. This regime closely follows that provided for medicinal products:

- the notion of advertising is similar to that provided for medicinal products, covering any type of information, canvassing activity or incentive which is aimed at or that has as an effect the promotion of use, prescription, discharge, sale, purchase or consumption of medical devices;
- advertising of medical devices should be consistent with the instructions of use of medical devices and promote their safe use, doing so objectively and without exaggerating their properties;
- advertising of medical devices which were not subject to a conformity assessment and were not notified to the Portuguese regulatory agency is forbidden;
- advertising before the general public of medical devices whose use requires the mediation or decision of an HCP (including implantable

Contributed by: Francisca Paulouro and Ana Isabel Lopes, VdA

devices) is forbidden – the law does not provide for an exhaustive list of devices covered by this prohibition, although the Portuguese regulatory agency has recognised that devices that only require the mediation or decision of an HCP at a first stage and can be used by the patient after that without any further intervention of the HCP may be advertised; and

- in general, medical device companies are forbidden from providing any benefits to HCPs.

Such a regime was approved prior to the entry into force of the MDR and IVMDR, yet continues to apply.

Although a major departure from the existing rules is not expected, local legislation to be enacted to complement the regime provided for in the MDR and IVMDR would be a good opportunity to introduce tailor-made rules on the advertising of medical devices – as different from pharmaceuticals and covering an enormous range of realities – and to clarify exactly what can or cannot be advertised before the public.

In the absence of EU harmonisation, self-regulation arising from Medtech Europe and “transposed” by local industry associations plays a significant role and helps to create common standards.

While the rules provided for in self-regulation are quite detailed regarding the interaction between medical device companies, HCPs and health-care organisations, there is still a significant gap concerning the interaction with patients and patients’ associations. Aside from some specific guidance provided by Medtech Europe and the general principle that all advertising activity should prioritise patients, most rules do not address such types of interactions.

This is increasingly more relevant given that the market for medical devices has grown exponentially in the past few years. Medical technology is adding to this pace and new medical devices are available each day. These devices are not only intended for professional use, but also for laypersons. Medical devices made available through app stores or through online platforms are now common – proof that medical device software for patients is at its peak.

The industry has changed, and will continue to do so in a digital era where patients change with it and are at the centre of what is to come. As the medical devices legal framework is significantly altered, it will certainly be important to seize the opportunity to provide for a more adequate legal regime, which should be sufficiently flexible for catering to all types of devices, while still ensuring a high level of protection for patients.

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. 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. It offers robust solutions grounded in consistent standards of excellence, ethics and professionalism. Recognition of the excellence of its work is shared by the team, as well as by clients and stakeholders, and is ac-

knowledged 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 jurisdictions (Angola, Cabo Verde, Equatorial Guinea, Mozambique, Portugal, Sao Tome and Principe), 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. Francisca has devoted her career to life sciences and is a national reference for

pharmaceutical companies both in day-to-day assistance and in 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 with promotional and advertising activities; marketing authorisations and renewals; regulatory data protection and marketing exclusivity; pricing, reimbursement and market access; manufacture and distribution; 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 to

pharmaceutical and medical device 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, and other regulatory matters.

Contributed by: Francisca Paulouro and Ana Isabel Lopes, **VdA**

## VdA

Rua Dom Luís I, 28  
1200-151  
Lisbon  
Portugal

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





---

## 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](mailto:Katie.Burrington@chambers.com)