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Editor-in-chief

Callum Campbell

Publisher

Richard Davey

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Portugal

Maria de Lourdes Lopes Dias and Paula Neves Ramalho

Lopes Dias & Associados

Organisation and financing of health care

1 How is health care in your jurisdiction organised?

In Portugal, there are three coexisting systems: the national health system (SNS), special health insurance for certain professions (such as ADSE, which is a special system for government agents or SAMS for bank employees) and private health insurance, which are taken voluntarily by people, and complement the SNS.

The Ministry of Health, which defines the health-care policy and management of the SNS, assures the right to health protection to the entire population through the national system, meaning that all the institutions, health services and hospitals cover the whole Portuguese population; the SNS guarantees that the population has health services throughout Portugal. Other institutions are in charge of particular aspects, such as the Portuguese medicines regulatory entity (Infarmed), the central administration for the health system and regional health administrations that cover the whole of Portugal.

When patients need health care, they go to local health centres or to hospitals in the area of their residence. The SNS assigns a family doctor to each patient to take care of all the patient's problems. The family doctor has the patient's entire clinical history. Where the patient needs other care, the doctor will refer the patient to his or her local hospital. The national system is organised by area and each patient will generally be seen at a health centre or hospital in the area of his or her residence.

2 How is the health-care system financed in the outpatient and inpatient sectors?

The health-care system is financed mostly by the state budget, namely by taxes. It is also financed by direct payments, generally a small fixed fee. When a patient goes to a health centre or a hospital, he or she pays a fee, the *taxa moderadora*, which aims at balancing the use of the SNS. However, taxes represent 95 per cent of the financing of Portuguese health system.

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertisement of medicinal products to the general public and health-care professionals?

Infarmed is the authority responsible for the overseeing the advertising of medicinal products. The National Council of Medicines Advertisement was also created in accordance with article 163 of the Portuguese Medicines Law (Decree-Law No. 176/2006 of 30 August), which implemented in Directive No. 2001/83/CE into Portuguese law. Decree-Law No. 176/2006 was amended by Decree-Law No. 182/2009 of 7 August, but which did not change any of the provisions on marketing and advertisement.

The advertisement of medicinal products is covered by the Portuguese Medicines Law and by Infarmed's Resolution No. 044/CD/2008 of 7 February.

We also have to take into account the Portuguese Advertising Code (Decree-Law No. 330/90 of 23 October, amended by Decree-Law No. 57/2008 of 26 March), which may be also applicable.

4 What are the main rules and principles applying to advertising aimed at health-care professionals?

The advertising aimed at health-care professionals is ruled by article 154 of the Medicines Law and Infarmed's Resolution No. 044/CD/2008 of 7 February.

According to the Medicines Law, medicines to be sold on prescription can only be advertised to health-care professionals in technical publications or other types of information exclusively directed at doctors and other health professionals. In these cases it is permitted to supply free samples of those medicines to doctors under certain circumstances and limits. The Resolution establishes a limit on free samples that can be supplied to doctors annually for each medicine, namely 12 units per year. Further, free samples are only allowed to be supplied within two years of the date of the medicine's commercialisation.

Any advertising must indicate the name of the medicine, the essential information according to the summary product characteristics (SmPCs), whether it is a prescribed medicine, and the reimbursement by the government regarding that medicine. This information is not required where the advertising only aims at calling the attention to the medicine's name.

The advertising material must include the following:

- the name of the medicine;
- the qualitative and quantitative composition of the medicine;
- the pharmaceutical form;
- the therapeutic indications;
- the posology and way of administration; and
- any adverse effects.

There are other elements that the advertising should contain, in case they are relevant to the clinical side:

- any warnings and special precautions of use; and
- any drugs interactions.

Regarding this information, in case of any doubt, pharmaceutical companies can consult Infarmed, which will decide on the matter within 30 days. The inclusion of all the information aforementioned on the advertising is the market authorisation holder's responsibility. MA holders must send the advertising material to Infarmed in a proper form within 10 days of the advertisement's publication.

In this regard Infarmed, the Portuguese Association of Pharmaceutical Industry (APIFARMA) and the Portuguese Press Association signed a protocol and created a commission to work between 1 April and 30 September 2008 in order to settle any issues that could arise from the application of the Resolution regarding the advertising of medicines aimed at health-care professionals. There is also a

protocol between APIFARMA and the Association of Pharmacies (ANF) in order to protect the public interest regarding the advertising of medicines.

It is forbidden to advertise medicines aimed at the public if they are prescription-only medicines or if they contain substances defined as drugs or psychotropic materials.

- 5** What are the main rules and principles applying to advertising aimed at the general public?

Article 153 of the Portuguese Medicines Law rules applies to advertising aimed at the general public. Medicines that do not need prescription and medicines with no reimbursement by the SNS may be freely advertised to the general public. This type of publicity to the general public requires more specific information, such as:

- information regarding the use of the medicine, therapeutic indications and special precautions; or
- the instruction that the patient must carefully read the information contained on the label and in case of doubt or continuation of the symptoms he or she should consult a doctor.

Direct distribution of medicines to the public by the industry is forbidden. It is also forbidden to mention of the name of the medicine in any actions near the general public.

The main difference between the advertising aimed at health-care professionals and the general public concerns prescription medicines. Prescription medicines may only be advertised to health-care professionals. Prescription-only medicines carry extra warnings (for instance, in case of self-medication or a wrong dosage, which can be very dangerous to health), which is why they are not advertised to the general public. Also, medicines reimbursed by the national health system may not be advertised to the public because as the medicine is reimbursed by the government, that reimbursement should not be used to finance marketing campaigns.

- 6** What are the most common infringements committed by manufacturers with regard to the advertisement rules?

In 2008, Infarmed started 10 processes against manufacturers and issued 65 warnings. The 10 processes were related to misleading publicity. The warnings, in 85 per cent of the cases, regarded the non-inclusion of essential information according to the SmPCs.

According to a Lisbon Court decision in Procedure No. 7187/06-5 of 22 May 2007, a pharmaceutical company was ordered to pay a penalty of €14,000, which was reduced on appeal to €7,000. According to this decision, the company promoted an irrational use of the medicine when it advertised the medicine and divulged information besides the information contained in the SmPCs, exaggerating some properties. Indeed, the text of the advertising may not provide more information than the information included in the SmPCs.

- 7** Under what circumstances is the provision of information regarding off-label use to health-care professionals allowed?

According to article 154(2)(b) and article 2(1) of the Resolution on the Advertising of Medicines, any publicity aimed at health-care professionals must contain essential information compatible with the information contained in the SmPCs.

Article 1(2)(a) of the Resolution defines 'Essential information compatible with the summary products characteristics' as the elements of the SmPCs considered mandatory, including, if that is the case, the relevant elements from the clinical viewpoint, which can be written in different terms but cannot diverge from the information stated in the approved SmPCs.

- 8** Which legislation governs the collaboration of the pharmaceutical industry with health-care professionals?

A Code of Ethics applies to several aspects of the activity of the pharmaceutical industry, published by APIFARMA, which entered into force on 1 July 2008. There is also the Ethics Protocol Association of Pharmacists and Physicians.

In Europe, there is a Standing Committee of European Doctors (CPME) and the pharmaceutical industry is represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA).

- 9** What are the main rules and principles applying to the collaboration of the pharmaceutical industry with health-care professionals?

The collaboration between the pharmaceutical industry, represented by APIFARMA, and the Portuguese Doctors' Association started in 1992. There is a protocol between them that establishes their cooperation based on common interests and a programme for innovation and improvement in drug therapy in order to encourage public health in Portugal. Despite strict rules, members of APIFARMA or MA holders may organise or support the distribution of medicines and scientific training, such as conferences or symposia, that contribute to the recognised professional training of doctors.

- 10** What are the most common infringements committed by manufacturers with regard to collaboration with health-care professionals?

There are no relevant infringements of which the general public has been informed.

- 11** What are the main rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations?

There is an association between the pharmaceutical industry and the patient's organisations that was created in 1999, which promotes workshops, annual reports and the supply of very important information. There are several patients' organisations such as the Protective Diabetic Association, the Portuguese Association of Relatives and Friends of Alzheimer's Patients, the Portuguese Society of Multiple Sclerosis Patients, the Portuguese Association of Parkinson's Patients, etc.

There are some important principles and concerns:

- the implementation of channels of dialogue to enable the sharing of information and encourage open discussion;
- the understanding within the pharmaceutical industry of the positions and needs of patients;
- the adoption of common positions on health policy in Portugal in order to reflect the consensus of the patients' associations and APIFARMA;
- presentation of solutions to help solve some of the problems that patients face in Portugal;
- accessibility to new therapies;
- the time of adoption of new medicines and the delay in response regarding the process of decision of reimbursement by the national health system;
- geographical accessibility (opening time and location of pharmacies);
- financial difficulties of some patients' associations; and
- understanding the patients' needs.

- 12** Are manufacturers' infringements of competition law pursued by national authorities?

Yes. The aspects regarding the price of drugs and price agreements between pharmaceutical companies, such as cartel agreements in the proposals by pharmaceutical companies in public tenders, are relevant to the application of competition law to the pharmaceutical

sector. Mergers between pharmaceutical companies should also be taken into account on this regard. There are some judicial processes regarding mergers between pharmaceutical companies that have been decided by the Lisbon Commercial Court.

13 Is follow-on private antitrust litigation against manufacturers possible?

Yes, it is possible. If a private party suffers damages resulting from any anti-competitive conduct, it must present a complaint to the Portuguese Competition Authority, and the Authority will start an investigation process, with that private party being admitted to intervene as a counterparty in such process. The complaining party may also ask for preventive measures where the anti-competitive conduct could cause imminent and serious damage that may be irreparable or difficult to repair should the action not be taken. Counterparties also have the right to be heard in specific aspects of the litigation process. If the process concludes that the anti-competitive conduct occurred, the private party may have grounds to sustain a judicial process demanding indemnity from the common courts.

Compliance – medical device manufacturers

14 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with health-care professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

Decree-Law No. 145/2009 of 17 June of 2009, which transposed into Portuguese law Directive No. 2007/47/CE of European Parliament and Council, applies to the investigation, manufacturing, commercialisation, vigilance and the advertising of medical devices.

The legislation also distinguishes between the advertising aimed at health-care professionals and that aimed at the general public, and this is as rigorously enforced as it is in the pharmaceutical sector.

Article No. 46 of the Decree-Law rules that advertising to the public must contain information regarding the name of the medical device or its commercial name, all essential information for the secure use of the device, including special precautions, as well as the advice to the patient to carefully read the label and instructions for use.

Pharmaceuticals regulation

15 Which legislation sets out the regulatory framework for granting marketing authorisations and placing medicines on the market?

The relevant legislation is the Portuguese Medicines Law (see question 3). This Decree-Law sets out the framework for the acquisition of MAs, namely the process to be followed by Infarmed that will allow the relevant medicine to be commercialised. It also applies to special market authorisations, exceptional market authorisations, parallel imports and other related matters.

16 Which authorities may grant marketing authorisation in your jurisdiction?

The entity in Portugal responsible for enforcing regulatory rules in the pharmaceutical sector and that can grant MAs is Infarmed.

With the publication of Decree-Law No. 176/2006, as amended by Decree-Law No. 182/2009 of 7 August, Infarmed was given more powers, in the sense that the granting of market authorisations rests only on its decision and no longer depends on confirmation by the health minister.

17 What are the relevant procedures?

Companies have to apply for MAs to Infarmed, which will examine the regularity of the process and the validity of the application. Where all the information supplied is correct, the MA will be granted. The

decision is published in Infarmed's website, together with the product's identification and pharmaceutical form.

Infarmed has some specific departments that are entrusted with the enforcement of these regulatory rules such as the national system of pharmacovigilance of drugs for human use, the inspection system, and a drugs evaluation commission. The DGE (General Directorate for Companies) oversees drugs prices.

18 Will licences become invalid if medicinal products are not marketed within a certain time? Are there any exceptions?

According to article 77(3) of the Portuguese Medicines Law, when a MA is granted, the medicine has to be commercialised within three years of the authorisation date, otherwise the MA will expire. There are no exceptions, unless Infarmed considers that there is a reasonable justification for the non-commercialisation of the medicine.

19 Which medicines may be marketed without authorisation?

All medicines for human use must have a MA issued by Infarmed. However, the Medicines Law establishes an authorisation of special utilisation (AUE) and authorisation of exceptional utilisation (AEX). According to article 92 and Infarmed's Decision No. 105/CA/2007 of 1 March, Infarmed can authorise the utilisation of medicines in Portugal even if they do not have a valid MA in Portugal. However, this special authorisation can only be granted in the following circumstances:

- if the medicines are indispensable for the treatment of special pathologies or for specific diagnostics;
- when it is necessary to avoid transmission of some diseases; and
- in exceptional cases for a specific patient.

An exceptional authorisation may also be granted, according to article 93, which means that Infarmed may authorise, based on the interests of public health, the commercialisation of medicines that do not have any valid authorisation in Portugal but do in other countries.

In these cases, pharmaceutical companies can apply to Infarmed for an exceptional authorisation, who will then notify the competent authority of the member state and ask for a copy of the evaluation report of the medicine and a copy of the MA in that country. If such authorisation is granted, this will be notified to the European Commission (the cancellation of any authorisation will also be communicated). Infarmed will define the conditions, deadlines, the documents that must be presented and other relevant aspects to grant this authorisation, namely, the conditions of such import authorisation.

According to article 9(3) of Infarmed's aforementioned decision, companies must apply for this special authorisation once a year, in September, to start selling in the next year. The holder of this exceptional authorisation must respect all the legal obligations that derive from the Medicines Law, including labelling, SmPCs, publicity and pharmacovigilance.

Infarmed will refuse this authorisation only based on insecurity or the quality of the medicine (eg, the transport conditions of the medicine product).

However, where there is a different product approved in Portugal recommended for the same disease, the exceptional authorisation will not be granted by Infarmed because there are no reasons to allow the decision based on public health.

20 What, according to the legislation and case law, constitute medicinal products?

According to article 3 of the Portuguese Medicines Law, a medicinal product is any substance or combination of substances presented for treating or preventing diseases and can be administered or used in humans to establish a medical diagnosis, with pharmacological,

Update and trends

The liberalisation of profits on the sale of medicines between wholesalers and pharmacists with the pharmaceutical industry has been under discussion since May 2009. With this new system of liberalisation, wholesalers and pharmacists will now negotiate directly with the pharmaceutical industry.

Decree-Law No. 65/2007 of 14 March establishes the system of prices for medicine. According to article 17, the profit margins for reimbursed medicines are 6.87 per cent for wholesalers and 18.25 per cent for pharmacists. For medicines that are not reimbursed by the government, the percentage is 8 per cent for wholesalers and 20 per cent for pharmacies. At the present moment, these are the profit percentages that wholesalers and pharmacies obtain with the commercialisation of medicines.

A proposal has been submitted to the government aiming at a provision that will define a percentage to be freely established in negotiations between wholesalers and pharmacists with the pharmaceutical industry.

None of these alterations will affect patients because the government will keep defining the maximum sale price of the medicine, which is the average market price of the reference countries (Spain, France, Italy and Greece). On the other hand, the Portuguese government is of the opinion that this liberalisation will reduce the price of some medicines.

APIFARMA, the Portuguese Association of Generic Medicines, the ANF, the Wholesalers' Association and the opposition to the government do not agree with this system of liberalisation. They argue that this system could affect the supply of medicines when suppliers and sellers cannot reach an agreement regarding the profits. The only association that will gain from this liberalisation will be the ANF, which has almost 25 per cent of the distribution market, besides the fact that 95 per cent of pharmacies in Portugal are its associates. The ANF will be in a dominant position in the market with this new system; this is being contested, although the final price to be paid by the patient will not be affected.

immunological or metabolic action, or to restore, correct or modify physiological functions.

Products are classified according to their composition (any substance or combination of substances presented for treating or preventing diseases), but also their function (that they can be administered or used in humans in order to establish a medical diagnosis).

Pricing and reimbursement of medicinal products

21 To what extent is the market price of a medicinal product governed by law or regulation?

Regarding prices of pharmaceutical products, Decree-Law No. 65/2007 of 14 March establishes the prices of pharmaceutical products for human use. However, this Decree-Law does not apply to the drugs needing medical prescription for exclusive hospital use; this price has to be negotiated with the DGE. Decree-Law No. 176/2006 states in article 103 that it is Infarmed that sets and authorises the price of drugs that are partly reimbursed by the national health system.

Governmental Decree No. 300-A/2007 of 19 March establishes the rules for the formation of new drugs prices, the terms in which the prices will be altered and the annual actualisation of prices. The market price of a medicinal product is proposed to the DGE, which will approve it or not. As mentioned, the DGE is the authority that has competence to define the prices and ensure the fulfilment of the regulatory laws on this matter.

22 In which circumstances will the national health insurance system reimburse the cost of medicines?

Decree-Law No. 118/92 of 25 June, amended by Decree-Law No. 129/2005 of 11 August, describes the circumstances of reimbursement by the national health system of medicinal products. According to this Decree-Law, the decision to reimburse payment for medicines depends on technical and scientific criteria that prove the efficiency and effectiveness of the medicine according to the indications claimed.

The level of reimbursement can be of 95 per cent, 69 per cent, 37 per cent or 15 per cent, depending on the therapeutic indications, the medicinal utilisation, the entity that prescribed the medicine and the administration of the medicine in some patients with specific pathologies; reimbursement may be granted for the following items:

- drugs containing new active substances with an innovative pharmacological action, which will fill a gap in therapy by being more efficient or better tolerated than alternative treatments existing in the market;
- new drugs, with similar qualitative composition to other drugs already marketed and reimbursed, if, in the same pharmaceutical form, they submit a price 5 per cent below the lowest non-reimbursed generic;
- new pharmaceutical forms of products, new dosages of products or newly packaged products already reimbursed with the same qualitative composition, if the need and therapeutic and economic benefits are proven;
- new drugs that do not constitute significant therapeutic innovation and do not have the same qualitative composition of others already reimbursed, if the economic advantages towards products already reimbursed are demonstrated; and
- combinations of medicines that have financial benefits.



María de Lourdes Lopes Dias

mld@ld-lawfirm.com

Av 24 de Julho, no. 60, 2.º Esq
1200-869 Lisbon
Portugal

Tel: +351 21 392 02 90
Fax: +351 21 395 47 66
www.ld-lawfirm.com

Medicine quality and access to information

23 What rules are in place to counter the counterfeiting and illegal distribution of medicines?

In Portugal there are no specific rules to avoid counterfeiting of medicines. According to Portuguese Industrial Property and Criminal Codes, counterfeiting is a crime that can be punished by imprisonment or a penalty equivalent to 360 days of imprisonment.

There is a draft European Commission Directive regarding counterfeiting and illegal distribution of medicines. The importance of including the sale of medicines over the internet in the Directive has been discussed, because the internet is the most important source of counterfeiting and illegal distribution of medicines. Also, the European Federation of Pharmaceutical Industries and Associations (EFPIA) has asked the European Parliament to consider the elaboration of this Directive a priority.

In this draft, the Commission has proposed many alterations to Directive No. 2001/83/CE, such as:

- some obligations for interested parties in the chain of distribution of medicines, besides the wholesalers;
- a legal obligation for the Commission to introduce safety warnings on the medicines packaging;
- to forbid, in principle, the alteration of any safety warnings on the package;
- to reinforce the rules regarding inspection and transparency of the inspection results, and inspection of wholesalers' warehouses.

24 What recent measures have been taken to facilitate the general public's access to information about prescription-only medicines?

The general public may only have access to information regarding prescription-only medicines while in pharmacies. As previously mentioned, such medicines may only be advertised to health-care professionals and not to the general public.

25 Outline major developments to the regime relating to safety monitoring of medicines.

According to article 166 of the Medicines Law, a national system of pharmacovigilance was implemented, which gives responsibility on this matter to Infarmed. Some alerts are also issued by Infarmed in which the general public and health professionals are informed of some adverse reactions to medicines, the removal of medicines from the national market and other useful information regarding medicines in Portugal.

Also, pharmaceutical companies must consider alerting Infarmed to any possible errors in prescribing, dispensing or administering a medicine and especially to any serious adverse reactions that may be caused by changing the formulation of the posology. Infarmed will circulate this alert between doctors, pharmacists and other health-care professionals under the pharmacovigilance system implemented according to national and European guidelines.

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