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Contributing editor
Alexander Ehlers

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GETTING THE DEAL THROUGH

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Alexander Ehlers

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Organisation and financing of health care

1 How is health care in your jurisdiction organised?

The manner in which health care in Portugal is organised has been subject to many changes in the past few years. Organic changes have taken place regarding which state entities are responsible for centralising purchases for state hospitals. Public tenders to select suppliers for the Portuguese National Health System (NHS) have been launched through electronic platforms, and there have also been some changes regarding the entity that organises such public tenders. These changes have created some difficulties for pharmaceutical industry players that sell to NHS hospitals. Furthermore, public expenditure cuts have affected the prices of medicinal products that are reimbursed by the NHS, and have driven the government to propose the creation of a further tax applicable to pharmaceutical industry sales.

In October 2014, the government presented its proposed 2015 State Budget to the Parliament, which contemplates the creation of a new tax (designated as 'a special charge on the pharmaceutical industry').

According to the proposed 2015 State Budget, and with the aim of ensuring the sustainability of the NHS, the government is authorised to create a charge on the pharmaceutical industry in terms of its expenditure on medicinal products that will apply to entities that are carrying out the first sale of a medicinal product for human use in the Portuguese territory, both where such entities are holders of marketing authorisations or registrations, or are their representatives, intermediaries, wholesale distributors or suppliers holding exceptional use authorisations or other exceptional authorisations for use of medicinal products. The new charge shall be applicable to the amount of the monthly sales of the following medicinal products:

- medicinal products that are reimbursed by the NHS;
- medicinal products that are subject to a restricted medical prescription;
- medicinal products that are sold through exceptional or special use authorisations (eg, named patient authorisations);
- medicinal products that are medicinal gases, or human blood or plasma-derived products;
- packaged medicinal products aimed for use in hospitals; and
- orphan medicinal products.

The sales amount to be considered regarding medicinal products that are reimbursed by the NHS will correspond to the portion of the sale price to the public that is reimbursed by the NHS after deducting VAT and another charge on the marketing of medicinal products (called a 'tax on the sale of commercialised medicines').

A transitory legal framework will apply until the rates of these charges are definitively established. These are still under discussion, and until the 2015 State Budget is voted on and approved, these measures will not be enforceable, and will depend on further regulations to be approved by the government.

Organisation of health care

The Portuguese Constitution establishes the right of all Portuguese citizens to benefit from public health care, which is provided through a health-care system that should cover the whole population and that should be universal. Citizens of other member states of the EU may be entitled to public health care in accordance with the applicable EU rules. Foreign citizens that are resident in Portugal may also benefit from public health-care provision in the case of a reciprocal agreement with the foreign national's state.

The main principles and rules governing public health care and the structure of the health-care system are established in the 1990 Health Law (Law 48/90, 24 August 1990).

Hospitals, health-care centres for outpatients and other entities included in the NHS comprise the health-care providers in Portugal. The NHS depends on and is financed by the state and the public budget. Private entities and professionals may also render health-care services to NHS patients pursuant to agreements with the entities representing the Health Ministry.

All of the services and institutions of the NHS fall under the supervision of the Ministry of Health, which is ultimately responsible for the health-care sector and defining the government's national health-care policy.

Successive governments have continued to organise and reorganise the NHS through the years, mainly since 2002, specifically regarding the nature and functioning of the hospitals integrated in the NHS and the creation and extinction of public bodies and entities.

In 2002, rules were approved respecting health public-private partnerships (Decree Law 185/2002, 20 August 2002) and the rules clarifying the legal framework applicable to each type of hospital integrated in the NHS (Law 27/2002, 8 November 2002).

Hospitals may have different legal forms. Some remain public hospitals, but the majority are now public corporate entities, which are regulated by public law rules but have a certain degree of autonomy with regards to their management. The quality of health-care services and equipment, generally speaking, is not at stake. The main discussion point regarding the NHS has been the excessive cost for the public budget.

Presently, Portugal is divided into five health regions with health-care centres serving the outpatients of each region, and approximately 52 public hospitals.

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

The financing of the health-care system is governed by the Constitution, which states that the right to benefit from public health care is ensured through a universal health-care system, taking into account the social and economic conditions of all citizens and usually with no costs to patients.

The NHS is financed by the state budget. Fees can be charged to certain outpatients, but they only represent a small part of the cost of the service. In compliance with the reform programme, in January 2012 a new legal framework came into force regarding patients moderating fees (Decree-Law No 113/2011, 29 November 2011). There are exemptions, for example for pregnant women, children up to 12 years of age, patients with an incapacity level equal to or higher than 60 per cent and patients in a situation of financial insufficiency. Patients with an average monthly income lower than €628.83 are exempt from patient moderating fees.

The NHS's debt to private suppliers should be repaid by the end of 2013, including its debt of €1.2 billion owed to the pharmaceutical industry for the supply of medicinal products to state hospitals.

The Ministry of Health implemented an annual system for the evaluation of medical careers for the first time at the end of 2013. The purpose is to evaluate the NHS's human resources. If further human resources are required, they should be hired through employment agreements instead of services agreements with providers of medical services. All results are currently published on the website of ERS, the Portuguese Health Regulation

Authority, where they may be obtained according to rating indicators. Only approximately 60 per cent of Portugal's hospitals are currently enrolled on the evaluation system and, because the 2013 the statistical sample was not significant, the available data can only be analysed at the end of 2014. However, a comparative analysis will be possible by the end of 2014, because a larger percentage of hospitals will be enrolled on the system by this time.

Compliance – pharmaceutical manufacturers

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

The rules regarding advertising of medicinal products are contained in the Code of Medicinal Products approved by Decree-Law 176/2006 (30 August 2006) (Code of Medicinal Products), which was amended by Decree-Law 128/2013 (5 September 2013), imposing further notification obligations to Infarmed (the Portuguese National Agency) both on the payee and on the receiver with respect to any type of sponsorship, benefit or value in money, goods or right that may have a monetary value. The Code also transposes EC Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use (as amended) into national law. The Advertising Code approved by Decree-Law 330/90 of 23 October governs advertising in general, including all the aspects regarding the advertising of medicinal products not specifically set out in the Code of Medicinal Products. Regarding medical devices, Decree-Law 145/2009 of June 17 should also be considered, since it established the respective legal framework.

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

The Code of Medicinal Products establishes that all advertising to health-care professionals must include the following:

- the name of the medicinal product;
- essential information compatible with the summary of the product characteristics (SPC);
- the supply classification of the medicinal product (namely, if the supply depends on medical prescription); and
- if the medicinal product's cost is reimbursed by the state.

Adverts to health professionals that consist of a mere reminder should be composed only of the name of the medicinal product.

Prescription-only medicines may only be advertised to health-care professionals. Furthermore, only products that have a valid marketing authorisation or registration in Portugal may be advertised within the Portuguese territory.

Infarmed is responsible for the manufacturing and marketing authorisation of medicinal products. All activities regarding the life cycle of medicinal products are subject to its regulation and supervision, including the advertising of medicinal products. Advertising to health-care professionals is subject to the rules contained in Infarmed Regulation 44/CD/2008, which states those cases where, taking into account the advertising medium, a reduced version of the essential information compatible with the SPC may be included.

In 2013, the Code of Medicinal Products was subject to two major changes. In February 2013, it was amended by Decree-Law No. 20/2013 (14 February 2013), transposing Directive 2010/84/EU (15 December 2010) as regards pharmacovigilance. Subsequently, the Code was further amended in September 2013 by Decree-Law No. 128/2013 (5 September 2013), transposing Directive 2009/35/EC (23 April 2009) on the colouring substances that may be added to medicinal products, as well as Directive 2011/62/EU (8 June 2011) as regards the prevention of the entry into the legal supply chain of falsified medicinal products and Directive 2012/26/EU (25 October 2012) as regards pharmacovigilance. Other substantial amendments introduced into the Code include those regarding the advertising of medicinal products.

According to the above-mentioned new legal provisions, entities covered by the Code of Medicinal Products must notify Infarmed within 30 days of any offer, sponsorship, grant, or any other amount, good or right assessable in cash terms, granted to any entity (regardless of its form or nature), individual, association, or representative of a certain patient group or medical company, association or corporation that is scientifically oriented or conducting clinical studies.

The payment and receipt of salaries or regular and periodic payments, in cash or in kind due to an employment contract or fees paid for services provided by independent workers, are not subject to the duty of notification. Furthermore, the recipients of these benefits, which include not only the previously mentioned associations or corporations but also any entity or individual (namely health-care professionals), must notify Infarmed and register such benefit on Infarmed's website. Since 7 October 2014, these rules only apply to transfers of a value exceeding €60 (previous to 7 October 2014, these rules applied to transfers of a value exceeding €25).Infarmed further clarified that any hospital, service or medical society that organises a certain congress must be identified as the beneficiary of the event, and not the health-care professionals individually considered. The main rule in this respect is aimed at preventing any type of prescription incentives; therefore, the holders of the marketing authorisation or of the registration of medicinal products, as well as companies responsible for the promotion of medicinal products and wholesale distributors, are not allowed to directly or indirectly give or promise to health-care professionals or their patients prizes, offers, bonuses or pecuniary benefits or benefits in kind unless they are insignificant and relevant for medical or pharmaceutical practice.

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

Only medicinal products with a valid marketing authorisation or registration in Portugal and that are classified as not subject to medical prescription can be advertised to the general public.

Furthermore, such medicinal products must not contain psychotropic or narcotic substances or benefit from state subsidy.

Pursuant to the Code of Medicinal Products, vaccination campaigns or campaigns promoting generic medicines carried out by the industry and approved by Infarmed may be advertised to the general public.

The use of comparative messages in advertisements to the general public is not allowed; nor is the direct supply of medicinal products to the general public.

Advertisements to the general public must contain the following information:

- the name of the medicine and INN or brand name;
- the essential information for the rational use of the product, including therapeutic and special precautions; and
- a warning to the patient to peruse the information in the outer packaging and in the package leaflet, and to contact a doctor or a pharmacist if symptoms persist.

Decree-Law No. 20/2013 (14 February 2013) also amended the provisions regarding advertising of medicinal products to the general public. According to this modification, the prohibition to directly or indirectly give or promise prizes, offers, bonuses or pecuniary benefits or benefits in kind to health professionals is also applicable to the general public.

6 What are the most common infringements committed by manufacturers with regard to the advertising rules?

The most common infringements committed by manufacturers regarding advertisement rules arise from the misinterpretation of the advertising rules regarding comparative advertising. Since 2012, an increasing number of infringement procedures have been started by Infarmed. In its 2012 Activities Plan, Infarmed clearly states that it must increase its knowledge of the market in order to ensure the compliance of market players with the principles applicable to the promotion of the rational use of medicinal products, medical devices and cosmetic and body hygiene products. The Plan further emphasised the importance of the evaluation of medicinal products advertising, for which the notifications made by marketing authorisation holders through the Medicinal Products Advertising System play an important role.

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

The inclusion of information regarding off-label use in advertisements is not permitted, as advertisements to health professionals must contain essential information compatible with the SPC. It is not forbidden, however, to provide information regarding off-label use at a scientific event organised for health-care professionals pursuant to the Code of Medicinal Products. Furthermore, it is not forbidden to provide information regarding off-label use of a product in answer to a specific question addressed by a health professional to the company holding the marketing authorisation of such product in Portugal.

8 Which legislation governs the collaboration of the pharmaceutical industry with health-care professionals? Do different rules apply regarding physicians in the outpatient and in-patient sectors?

The Code of Medicinal Products governs the collaboration of the pharmaceutical industry with health-care professionals (articles 157 to 162) and regulates:

- the activities of medical sales representatives;
- offers and grants;
- consulting services;
- advertising at and transparency of scientific, training or promotional events for health professionals;
- hospitality costs; and
- free samples.

These rules were subject to substantial changes in 2013 with a view to ensuring greater transparency regarding sponsorships and grants in amounts exceeding €60 (since 7 October 2014) given by the pharmaceutical industry to any public or privately-held entity or to any individual.

The Code of Ethics regarding the promotional practices of the pharmaceutical industry in collaboration with health-care professionals approved by the Portuguese Association of the Pharmaceutical Industry (Apifarma) regulates these matters in detail. The same rules apply to physicians in both the outpatient and in-patient sectors.

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

Holders of marketing authorisations for medicinal products must create and maintain a scientific service responsible for maintaining information about and advertising regarding all medicinal products.

Medical sales representatives must have adequate training and scientific knowledge to provide accurate and complete information regarding medicinal products.

Providing or promising gifts, pecuniary advantages or benefits in kind to health professionals is forbidden, unless they are inexpensive and relevant to the practice of medicine or pharmacy activities. In accordance with Apifarma's Code of Ethics, an object will be considered inexpensive if its value does not exceed €60.

The sponsorship of events, seminars, congresses or any scientific or promotional event or action, either directly or indirectly, by a manufacturer, holder of a marketing authorisation or distributor of medicinal products, must be mentioned in the documentation related to such events and must be notified to Infarmed within 30 days of the event. Training or informative events and sales promotions may only be addressed to health professionals. There are also hospitality rules that limit the number of days events can run and the selection of the location of events.

Free samples are allowed within certain limits – 12 samples per product, per year to each health professional – and health professionals must request the samples in writing. Each sample shall be no larger than the smallest presentation and accompanied by a copy of the SPC.

Apifarma's Code of Ethics covers all the matters relating to the promotional practices of the pharmaceutical industry in collaboration with health-care professionals, clarifying certain rules by providing further details and guidelines to companies regarding the practices that are allowed.

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

The most common infringements committed by manufacturers and distributors arise from misinterpretation of the rules applicable to promotional events and to advertising in publications addressed only to health-care professionals. These infringements are considered as violating the very broad and undefined rules stating that advertising 'shall encourage the rational use of the medicinal product by presenting it objectively and without exaggerating its properties'.

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

The main principles applying to the collaboration of the pharmaceutical industry with patient organisations are found in Apifarma's Code of Ethics. The Code establishes guidelines that state that pharmaceutical companies that intend to render financial support directly or indirectly to patients' associations must enter into an agreement signed by both parties, following a template attached to the Code. Each company must establish an internal procedure regarding the approval of these agreements.

The use by a pharmaceutical company of a logo or other material protected by copyright belonging to a patients' association must be duly authorised. Furthermore, companies should not influence the contents of associations' materials, although they are allowed to suggest material or scientific corrections. A patients' association may not be sponsored exclusively by one company.

According to the Code, companies may organise or sponsor events for patients' associations as long as any hospitality costs are kept within adequate and reasonable limits.

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

The Portuguese Competition Authority pursues infringements of competition law by manufacturers.

The Portuguese Competition Law (Law 19/2012, 8 May 2012) applies to anti-competitive practices or agreements and mergers that occur in the national territory or that have effects within the national territory.

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

Yes; private antitrust litigation against manufacturers in the case of an infringement of the competition rules that causes damage to third parties is possible.

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?

Medical devices are regulated by Decree-Law 145/2009 (17 June 2009), which establishes the rules regarding investigation, manufacturing, commercialisation, functioning, supervision and advertising of medical devices and respective accessories, and transposes Directive 2007/47/EC into national law. The rules applicable to the advertising of medical devices are identical to the rules applicable to medicinal products.

Advertising to the general public of medical devices that require the intervention and prescription of a health-care professional, namely implantable devices, is not allowed. Apormed, the Portuguese association of companies manufacturing and marketing medical devices, has issued a Good Commercial Practice Code with guidelines regarding the relations between companies and health-care professionals. Supervision of the compliance of companies with these rules might not be as rigorous as it is in the pharmaceutical sector.

Pharmaceuticals regulation

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

The Code of the Medicinal Products provides the legislative framework for granting marketing authorisations and manufacturing authorisations, and for the import, export, marketing, labelling, provision of information, advertising, pharmacovigilance and use of medicinal products for humans. This extensive Code transposes six European Union directives into Portuguese law and regulates the entire life cycle of medicinal products in Portugal. In 2013, the Code was substantially amended by Decree-Law No. 20/2013 (14 February 2013), which transposed into Portuguese law three EU directives, and Decree-Law No. 128/2013 (5 September 2013), which transposed a further three EU directives. Two areas are regulated under separate legal frameworks: clinical trials (which are ruled by Law 21/2014, 16/04; in addition, from 28 May 2016 onwards, Regulation (EU) 536/2014 of the European Parliament and of the Council of 16 April 2014 will be directly applicable in all EU countries, including Portugal); and medicine pricing and reimbursement (which are ruled by Decree-Law 48-A/2010 of 13/05).

16 Which authorities may grant marketing authorisation in your jurisdiction?

The sole entity with powers to grant marketing authorisations in Portugal is Infarmed, which is a public institute under the direct administration of the state. Although Infarmed has administrative and financial autonomy, it follows the aims of the Health Minister and acts under the Minister's supervision.

17 What are the relevant procedures?

The procedures that must be followed to obtain a marketing authorisation in any member state of the European Union are regulated by:

- Regulation 726/2004 (31 March 2004) regarding the centralised procedure that must be filed at the European Medicines Agency (EMA) for certain types of medicinal products; and
- EC Directive 2001/83/EC (6 November 2001) regarding the national procedure, the mutual recognition procedure and the decentralised procedure.

The centralised procedure at EMA is mandatory for certain medicinal products, such as those developed by means of a biotechnological process, advanced therapy medicinal products, new active substances for which the therapeutic indication is the treatment of very serious diseases (eg, HIV, neurodegenerative disorders, diabetes, autoimmune diseases and other immune dysfunctions and viral diseases) and orphan medicinal products.

The centralised procedure may also be followed, on a non-mandatory basis, for active substances that constitute a significant therapeutic, scientific or technical innovation, or that are in the interests of patients' health.

The three relevant procedures that may be filed at Infarmed to obtain a marketing authorisation are as follows:

- the national procedure to obtain a national marketing authorisation;
- the mutual recognition procedure with a view to obtaining recognition in Portugal of a marketing authorisation granted in another member state, or vice versa; and
- the decentralised procedure, in which case the applicant files the procedure simultaneously with several agencies of several member states, one of which will act as the reference member state with the responsibility to prepare the assessment report on the medicinal product.

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

A marketing authorisation will elapse and cease to be valid if the medicinal product has not been effectively marketed on the Portuguese market for a continuous period of three consecutive years. The holder of the marketing authorisation must notify Infarmed of the date of the commencement of the effective marketing of the medicinal product. If the medicinal product is not marketed during the legal period, the marketing authorisation will become invalid, and such fact shall be published on Infarmed's website. The marketing authorisation holder may challenge the invalidity within 10 days of its publication on Infarmed's website. The invalidity may not be declared by Infarmed, even if the medicinal product has not been sold, in any of the following circumstances:

- the medicinal product was not on the market as result of a legal imposition or a judicial decision imputable to Infarmed;
- there is no therapeutic alternative or alternative manufacturers for the medicinal product in question;
- the medicinal product is a vaccine or a medicinal product for in-patients only that has not been selected in a public tender to supply the NHS;
- the medicinal product at stake may be used in cases of disaster or in pandemic situations;
- if Portugal acts as the reference member state for that specific medicinal product and the validity of the marketing authorisation is therefore necessary to ensure the continuity of the supply in the other member state involved;
- the medicinal product at stake will be exported to a third country; or
- the request to obtain state reimbursement is pending a decision.

19 Which medicines may be marketed without authorisation?

In principle, medicinal products marketed in Portugal must all have a marketing authorisation. However, there are exceptional cases where Infarmed may grant a special-use authorisation or exceptional authorisation (see question 20).

Homoeopathic medicinal products may be marketed without an authorisation. These products are subject to a simplified registration process if they do not have specific therapeutic indications placed on the label or on any product information. Furthermore, to qualify for the simplified registration procedure, such products must have a certain pharmaceutical form (oral or external) that does not represent any risk to people.

20 Are any kinds of named patient programmes in place? If so, what are the requirements for pre-launch access?

Named patient programmes are specifically regulated by the Code of Medicinal Products. In exceptional cases, Infarmed may grant a special-use authorisation or exceptional authorisation to medicinal products that are not authorised by the common procedures.

Special-use authorisations may be granted in certain cases listed in the law, such as in cases where there are medical justifications because the medicinal product is absolutely essential for certain pathologies; the medicinal product is required to combat the spread of harmful agents; or the products are purchased by hospital pharmacies for named patients. Exceptional authorisations are granted strictly for public health reasons.

Pricing and reimbursement of medicinal products

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

The market prices of medicinal products are regulated by law. The legal framework applicable to the pricing of reimbursed medicinal products, whether subject to medical prescription or not, was approved in 2011 by Decree-Law 112/2011, 29 November 2011, which entered into force on 1 January 2012 (amended by Decree-Law 152/2012, 12 July 2012). The prices of medicinal products not subject to medical prescription and not reimbursed by the NHS may be freely fixed by intermediary agents in the sales circuit.

The prices of medicinal products subject to medical prescription and products reimbursed by the NHS must comply with very strict rules regarding the calculation of the maximum price for sale to the public (outpatients). These rules are based on an international reference system, pursuant to which the prices must not exceed the average wholesale price for the same product in three member states of the EU that have a gross domestic product per capita comparable to Portugal's or that have a lower price level. The government will establish the three reference countries for this purpose on an annual basis; in 2013, the reference countries were Spain, France and Slovakia. Pricing reviews are carried out on an annual basis.

The maximum prices for reimbursed medicinal products must be approved by Infarmed. The annual review of prices for the sale of reimbursed medicinal products to outpatients is established in Ministerial Order 4/2012 (2 January 2012). The annual prices review of branded products must be requested by companies each year before 15 December, and the new prices will be applicable from 1 January of the next year. The review of the prices of generic products must be requested by companies each year by 15 January, and the new prices will apply from 1 February of the following year. The annual price review of branded products is based on the average prices in the reference countries on the first day of the month prior to the prices review. The prices of generics must be reviewed based on the price of the reference medicinal product, and may not exceed 50 per cent of the maximum price of the reference medicinal product.

Prices of medicinal products that are subject to restricted medical prescription for hospital use must pass an evaluation test based on Infarmed's technical, scientific and economic criteria to obtain evidence on the respective added therapeutic value and economic benefit.

Following a favourable evaluation, Infarmed will approve the maximum price for sale to NHS hospitals. Decree-Law 34/2013 (27 February 2013) further established an international pricing scheme for medicinal products to be purchased by NHS hospitals that is applicable to medicinal products that are not subject to the prior evaluation procedure. The reference member states for such purpose are the same countries set the prices of medicinal products to be sold to outpatients (eg, Spain, France and Slovakia).

22 Must pharmaceutical manufacturers negotiate the prices of their products with the public health-care providers?

There are two stages involved in negotiations with public health-care providers. In the first stage, suppliers of the NHS are selected through centralised public tenders, where the manufacturers or holders of the

marketing authorisation bid with the maximum price applicable to all NHS hospital and services, pursuant to the rules of the Code of Public Contracts (approved by the Decree-Law 18/2008, 29 January 2008, last amended by Decree-Law 149/2012, 12 July 2012). The NHS enters into public supply agreements with the selected suppliers.

In a second stage, regulated by the same Code, each hospital addresses an invitation to suppliers to propose better conditions and win the hospital's contracts, which may involve a negotiation phase.

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

The NHS reimburses the cost of certain medicinal products, provided that the following cumulative requirements are met (pursuant to Decree-Law 48-A/2010,13 May 2010): there is technical and scientific evidence of the added value in therapeutic terms or of the therapeutic equivalence for the therapeutic indications of the products; and there is evidence of the economic benefit. Furthermore, reimbursement by the NHS may also depend on the product filling a therapeutic gap in the market, having new active ingredients, or having a similar composition to other marketed and reimbursed medicinal products but having a price 5 per cent lower when compared with the branded equivalent. Reimbursement will also arise in several other cases, basically following the added therapeutic value or economical added value criteria, or both.

Reimbursement follows a regressive scale of 100 per cent in certain cases for medicinal products subject to restricted medical use (in-patients) or in the case of certain serious pathologies (in-patients and outpatients), and can range from 90 per cent to 15 per cent in other cases (outpatients). Medicines for compassionate use must be provided for free by the manufacturer to the subject of clinical trials even after the trial is completed, if the physician considers that it is essential and that there are no therapeutic alternatives.

24 If applicable, what is the competent body for decisions regarding the pricing and reimbursability of medicinal products?

According to the legal framework for pricing established in Decree-Law 112/2011 (29 November 2011), the competent body for decisions regarding the pricing and reimbursability of medicinal products, whether subject to medical prescription or not, is Infarmed.

Infarmed is competent to authorise the maximum prices for sale to NHS hospitals of medicinal products for restricted hospital use (Decree-Law 195/2006, 3 October 2006). The aforementioned legal provisions have been subject to several amendments.

25 Are manufacturers or distributors of medicinal products statutorily obliged to give a discount?

Discounts (reducing the maximum fixed prices) are allowed throughout the entire medicinal product circuit (ie, by manufacturers, distributors and retailers), but they are not mandatory. The law sets the maximum marketing margins, calculated as a percentage of the price to the public, that are granted to wholesalers and retailers, but these margins are commercial and do not have the nature of a discount.

Medicine quality and access to information

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

Directive 2011/62/EU (8 June 2011), which introduced changes as regards the prevention of the entry into the legal supply chain of falsified medicinal products, was transposed into national law by Decree-Law 128/2013. The definition of 'falsified medicinal product' and of 'brokering of medicinal product' was introduced into national law by reproducing the definition established in Directive 2011/62/EU. According to these new rules, manufacturers and distributors must notify Infarmed and the marketing authorisation holder immediately if they become aware of falsified medicinal products, or if they have any suspicion in that respect. In addition, distributors must verify that the medicinal products received are not falsified by checking the safety features on the outer packaging. The outer packaging of medicinal products (where there is no outer packaging, the immediate packaging), must include safety features enabling distributors and persons authorised or entitled to supply medicinal products to the public to verify the authenticity of the medicinal product and identify individual packs, as well as a device allowing verification of whether the outer packaging has been tampered with. Infarmed is the responsible entity to receive notifications regarding falsified medicinal products.

Under the Criminal Code, medicine and food counterfeiting activities are classified as crimes punishable by up to five years' imprisonment. However, the application of this legal provision requires that evidence of a threat to life or a serious physical threat to individual health be produced. These requirements have been an obstacle to pharmaceutical companies seeking to combat counterfeiting.

The Industrial Property Code also states that counterfeiting activities involving any product protected by proprietary rights are sanctioned with a fine or up to three years' imprisonment.

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

Publicly reimbursed electronic prescriptions for medicinal products and diagnostic means have been mandatory for physicians in the public and private sector since August 2011. The prescription of medicinal products by INN has been subject to new rules over the years. In 2012, further rules were passed restricting the prescription and dispensing of medicinal products (Law 11/2012, 8 March 2012, and Ministerial Order 137-A/2012). These rules impose the mandatory sale of the cheapest medicinal products available, except in cases where the patient opts for another medicinal product with the same INN. The medical prescription must be written in the following form: INN, pharmaceutical form, dosage, presentation and posology. A prescription including a brand name is only allowed with in the following circumstances: the medicinal product does not have any reimbursable generic alternatives, and the original branded medicinal product and licence are unique; and in admissible exceptional cases, such as when the physician provides a valid technical justification for the use of the prescribed medicinal product in certain situations. Such prescription (which must be hand written) is only allowed in exceptional situations, and the word 'exception' must be inserted under the logo of the Ministry of Health.

Infarmed and the ACSS published a Joint Informative Note (01/INFARMED/ACSS) establishing specific guidelines on this matter, which were addressed to patients as well as to prescribers and pharmacies. Pharmacists shall inform patients of the cheapest medicinal products on the market that comply with the medical prescription, and must maintain a stock of at least three medicinal products of each homogeneous group (chosen from the five medicinal products with lower prices on the market), and must sell the cheapest one to the patient. The cost of the 'fifth lower price' is registered in a database provided by Infarmed to companies in the sector on a daily basis.

When dispensing, pharmacists must inform patients about cheaper medicinal products, reimbursed by the NHS, that are available in the pharmacy if they comply with the medical prescription. Patients must be informed of their right to choose a medicinal product that is in compliance with a medical prescription, and of their right to have the cheapest medicinal product on the market made available to them. When such medicinal product is not currently available at the pharmacy, it must be made available within 12 hours and at no additional cost.

Moreover, the above-mentioned Joint Informative Note establishes rules that are applicable in three different situations:

- prescription by INN (or absence of exceptions) when a homogeneous group is involved;
- prescription by INN (or absence of exceptions) when no homogeneous group is involved; and
- prescription by brand when the treatment exceeds 28 days.

Patients may request information regarding the price of prescription-only medicinal products, and regarding the situations under which they have the right to opt for another product, from their doctor or a pharmacist. This information is also available on Infarmed's website. Whenever a patient is entitled to opt for another product, the sentence 'right to opt' must be written on the back of the prescription.

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

Recent amendments to the Medicinal Products Code, established by Decree-Law No 20/2013 (14 February 2013) and Decree-Law No. 128/2013

Update and trends

Directive 2011/24/EU (9 March 2011) on the application of patients' rights in cross-border health care was transposed into Portuguese law in August 2014 when the parliament approved Law 52/2014 (25 August 2014). This Law established the general rule that cross-border health care rendered in the member state of treatment (within legal limitations) is reimbursed to the insured person by the member state of affiliation, following a request application to be filled at the ACSS, IP, a public institute under the Health Ministry. This Law entered into force on 1 September 2014, and requires further regulation that must be approved by the government in order to be fully applicable in Portugal.

Directive 2011/24/EU establishes rules for facilitating safe and high-quality cross-border health care, and promotes cooperation on health care between member states, establishing the right to reimbursement of the costs associated with those health-care services even if no prior authorisation is obtained. It also introduces important changes, including the possibility of recognition of prescriptions issued in another member state, as well as the promotion of cooperation and exchange of information among member states working within a voluntary network connecting those national authorities designated by member states to be responsible for e-Health. The legislative draft states specifically that medical prescriptions issued in another member state are recognised in Portugal if the medicinal product at stake has a valid registration or marketing authorisation under the terms of the Medicinal Products Code and if they include the following elements:

- patient's identification and date of birth;
- issuing date;
- identification of the prescribing health-care professional;
- identification of the prescribed medicine;
- the medicine's pharmaceutical form;
- the quantity of medicine;
- the dosage; and
- the posology.

Pharmacists may refuse to honour medical prescriptions issued in another member state if they have legitimate and justified doubts regarding their authenticity.

One particular concern about the legislative draft is that it does not determine the national authority that will be responsible for e-Health.

Apart from this legislation, the other recent major legislative developments have been two major amendments to the Medicinal Products Code (Decree-Law No. 20/2013 and Decree-Law No. 128/2013) providing new provisions regarding both pharmacovigilance and the prevention of falsified medicinal products.

Finally, Order 5456-B/2013 of 23 April established new measures regarding the acquisition of medical devices by NHS services and establishments, aiming at cost reductions. According to the Order, NHS services and establishments may only purchase medical devices, through a competitive public procurement procedure or otherwise, for 15 per cent less than the prices paid in 2012 for similar devices.

In October 2014, the proposed 2015 State Budget was presented. It contemplates the imposition of a new tax on the pharmaceutical industry. If such proposal is approved, the measures mentioned in question 1 will introduce several changes that will affect the pharmaceutical industry in Portugal.

(5 September 2013), mainly concern medicine safety matters. Directive 2010/84 (15 December), which amends Directive 2001/83/EU as regards pharmacovigilance, was transposed into national law in 2013. This reformulated the Portuguese National Pharmacovigilance System, and included new requirements to prevent, detect and assess adverse reactions to medicinal products placed on the EU market, as the full safety profile of medicinal products can only be known after they have been placed on the market. Directive 2012/26/EU (25 October 2012) also amended Directive 2001/83/EU as regards pharmacovigilance, and further strengthens the European rules respecting the safety and monitoring of medicinal products, and was transposed into national law in 2013.

All developments regarding the safety monitoring and, specifically, the pharmacovigilance of medicinal products that are placed on the Portuguese market, including those that are sent by EMA, are published on a daily basis on the Infarmed website.

Vaccination

29 Outline your jurisdiction's vaccination regime for humans.

Portugal has had a National Vaccination Programme (NVP) in force since 1965 that covers the entire population at no cost. The NVP provides a vaccination schedule recommended by the health authorities in Portugal. However, it is not confined to the vaccinations recommended at national level; in addition, there are vaccination programmes for special groups, such immunocompromised individuals, health professionals at risk, travellers to endemic areas and others, which also form part of the provisions and guidelines of the National Health General Directorate. Each person has a personal health booklet, implemented by Decree-Law 46621/65 (27 October), in which the vaccines are registered. The NVP currently in force was approved by Order 17067/2011 of 21 December 2011. According to WHO data and statistics from October 2013, Portugal rates of vaccination meet WHO targets.

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