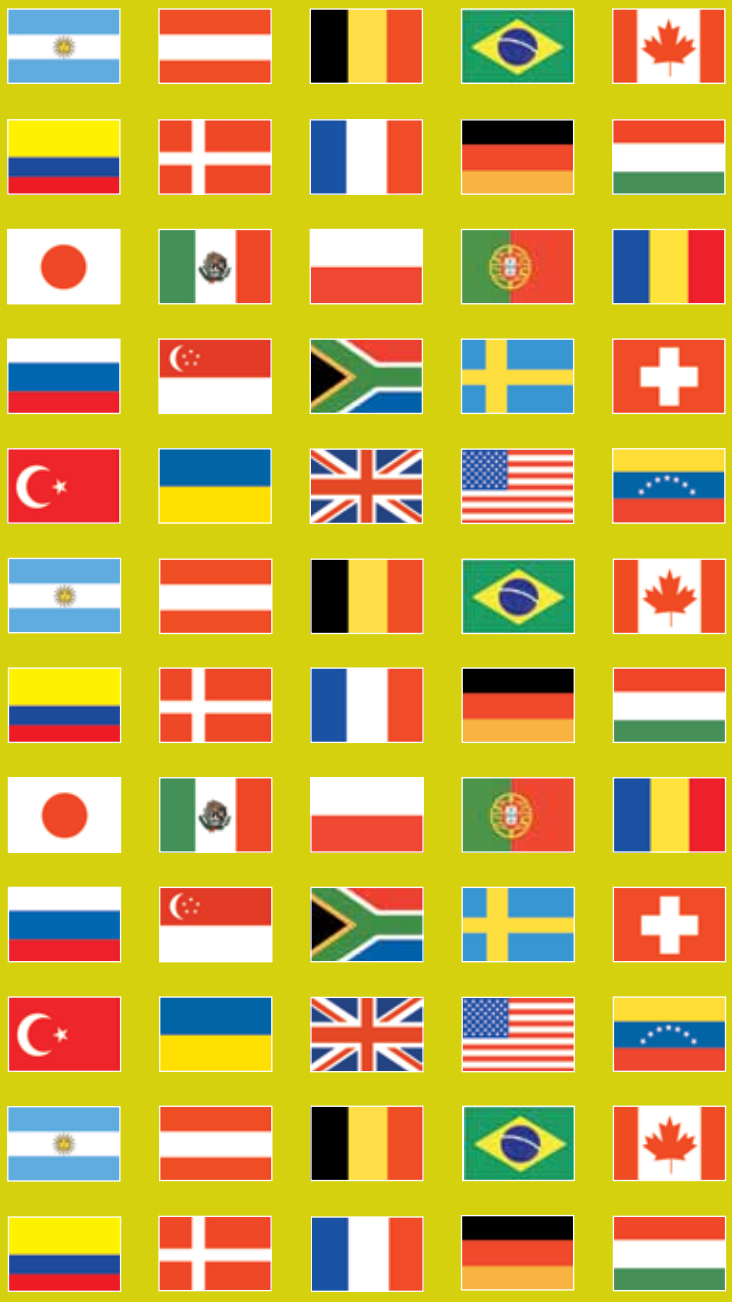
GETTING THE DEAL THROUGH

Life Sciences

in 25 jurisdictions worldwide

Contributing editor: Alexander Ehlers

2013



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Portugal

César Sá Esteves and Ana Menéres

SRS Advogados

Organisation and financing of health care

1 How is health care in your jurisdiction organised?

Portugal's reform programme

On 17 May 2011, the Portuguese Government entered into a Memorandum of Understanding with the European Commission, the European Central Bank and the International Monetary Fund (designated as the Troika Memo) for a three-year Extended Arrangement in support of Portugal's financial adjustment and reform programme, which has been financing the Portuguese National Health-Care System (NHS). To benefit from this financing programme, Portugal must implement reform measures in the health-care system and reduce public spending on pharmaceuticals to 1.25 per cent of GDP by 2012 and to 1 per cent of GDP in 2013 (in line with the EU average), and generate additional savings in hospital operating costs and devise a strategy to eliminate arrears.

In compliance with the reform programme, the Portuguese government is implementing the measures stated in the Troika Memo to achieve the agreed objectives. The first measure respects the review of the NHS moderating fees and the review of the exemption categories (patients that will not pay for health-care services) – this measure was implemented in January 2012. The second measure concerns the pricing and reimbursement of pharmaceuticals, so that the first generic introduced in the market has a maximum price of 50 per cent of the branded product. This measure was approved in 2011 and implemented in 2012. The countries for the reference pricing system were changed to the three EU countries with the lowest price levels or countries with comparable GDP per capita levels. The third measure deals with the prescription of pharmaceuticals, imposing electronic prescriptions for publicly reimbursed medicines and diagnostic means, for public and private sector physicians. Furthermore, the NHS established clear rules for the prescription of medicinal products and the realisation of complementary diagnostic exams based on international prescription guidelines.

Also in compliance with the Troika Memo, changes have been implemented changing the calculation of the profit margins of the pharmacies into a regressive mark-up (which had a negative impact in the business of the pharmacies as the prices of reimbursed medicinal products were simultaneously reduced). This includes the hospitals market implementing a centralised procurement system for the purchase of goods by the NHS to increase competition between suppliers (a centralised procurement system has been in place for some years). The government is also expected to reinforce primary care services to reduce unnecessary visits to specialists and emergency rooms. Finally, concerning NHS hospitals, a strategy and a binding timetable to pay all debts to suppliers was established. Simultaneously standardised accounting and control procedures applicable to all health sector entities were established.

Up to October 2012, in accordance with information that has been disclosed to the public, the NHS costs for medicinal products sold to out-patients in pharmacies has decreased 10.3 per cent, and NHS expenses with medicinal products provided to in-patients has decreased 0.7 per cent.

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 European Union 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 of August 24).

The health-care providers in Portugal are the hospitals, health-care centres for outpatients and other entities included in the NHS. The NHS depends on and is financed by the Portuguese 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 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, defining the government's national health-care policy.

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

The hospitals may have different legal forms. Some remain public hospitals, but the majority are now public corporate entities, which are public entities regulated by public law rules, but with 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 points regarding the NHS have 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 the 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 regarding patients' moderating fees came into force (Decree-Law No. 113/2011 of 29 November). There are exemptions, namely for pregnant women, children up to 12 years of age and patients with an incapacity level that is equal or higher than 60 per cent, as well as patients in need of financial assistance, among other categories. Patients with an average monthly income lower than €628.83 are exempt from patients' moderating fees.

Until the end of 2012, the NHS's €2 billion debt to private suppliers should be repaid, including the debt owed to the pharmaceutical industry for the supply of medicinal products to state hospitals.

Furthermore, in 2013 the Ministry of Health will implement an annual evaluation of medical careers for the first time. The purpose is to evaluate the human resources of the NHS so that, if further staff are required, they should be hired through employment agreements instead of through service agreements with medical service providers.

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 of 30 August (the Code of Medicinal Products), which came into force on 31 August 2006, and consolidates several pieces of legislation. This 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 (the Advertising Code) governs advertising in general, including the advertising of medicinal products in all aspects not specifically set out by the Code of Medicinal Products.

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 its cost is reimbursed by the state.

The advertisement to health professionals can consist in a mere reminder in which case it should be composed only of the name of the medicinal product.

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

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

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 that are classified as not subject to medical prescription can be advertised to the general public.

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

Pursuant to the Code of the 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 the advertisement to the general public and the direct supply of medicinal products to the general public is also forbidden.

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 pharmaceutical if symptoms persist.

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 advertising rules, namely regarding comparative advertising. According to Infarmed's Activities Report regarding the first quarter of 2012, four infringement procedures were started regarding the violation of advertising rules against the holders of marketing authorisations.

Infarmed participated in an international operation involving 100 countries (Pangea V) coordinated by Interpol and the World Customs Organization against counterfeiting medicinal products (in Portugal 34,000 packets were seized with an estimated value of €100,000). Seventy-nine individuals were arrested worldwide, and approximately 4 million counterfeit products were apprehended with an estimated value of €10.5 million. The products in question are mainly drugs for cancer treatment, antibiotics and drugs for erectile dysfunction and slimming. Infarmed has implemented several initiatives with the aim of alerting the general public to the dangers of buying medicinal products online and outside specialised and authorised places.

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 an advertisement is not permitted, as advertisements to health professionals must contain the essential information compatible with the SPC. It is not forbidden, however, to provide information regarding off-label use in 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 in answer to a specific question addressed by a health professional to the company holding the marketing authorisation in Portugal.

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

The Code of Medicinal Products governs the collaboration of the pharmaceutical industry with health-care professionals (articles 157 to 162), regulating the activities of medical sales representatives, offers and grants, consulting services, advertising and transparency

in scientific, training or promotional events for health professionals, hospitality costs and free samples.

The Code of Ethics regarding the promotional practices of the pharmaceutical industry in collaboration with the health-care professionals approved by the Portuguese Association of the Pharmaceutical Industry (Apifarma) regulates these matters in detail. There are no different rules for physicians in the in-patient and outpatient sectors.

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

The holders of marketing authorisations of medicinal products, must create and maintain a scientific service responsible for the information and advertisement regarding all medicinal products.

The medical sales representatives must have adequate training and scientific knowledge in order to provide accurate and complete information regarding the medicinal products.

It is forbidden to provide or promise gifts, pecuniary advantages or benefits in kind to health professionals, unless they are inexpensive and relevant to the practice of medicine or pharmacy. In accordance with Apifarma's Code of Ethics, an object may be considered inexpensive if it does not exceed €25.

The sponsorship of events, seminars, congresses or any scientific or promotional event or action, 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. Training or informative events or sales promotion may only be addressed to health professionals. There are hospitality rules limiting the number of days of the events and the selection of the location of the event.

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

The Apifarma Code of Ethics regarding the promotional practices of the pharmaceutical industry in collaboration with the health-care professionals cover all these matters clarifying certain rules by providing further details and guidelines to the companies regarding the allowed practices.

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 arise from misinterpretations of the rules applicable to promotional events and medical sales representatives' visits.

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. This Code establishes guidelines stating 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 that is attached to this Code of Ethics. 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 the patients' associations must be duly authorised. Furthermore, the companies should not influence the contents of the associations' materials, although they are allowed to proceed to material or scientific corrections. A patients' association may not be sponsored exclusively by one company.

Companies, according to this Code, may organise or sponsor events for patients' associations within adequate and reasonable limits as to hospitality costs.

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

Manufacturers' infringements of competition law are pursued by the Portuguese Competition Authority.

The new Competition Law (Law 19/2012 of 8 May that revoked the former Competition Law of 2003) applies to anti-competitive practices or agreements and mergers occurring in national territory or having effects within the national territory.

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

Yes, the private antitrust litigation against manufacturers in case of infringement of the competition rules causing 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 of 17 June which establishes the rules regarding investigation, manufacturing, commercialisation, functioning, supervision and advertising of medical devices and respective accessories, transposing into national law Directive 2007/47/EC. The rules applicable to the advertising of medical devices are identical to the rules applicable to medicinal products. Apormed, the Portuguese Association of the companies manufacturing and marketing medical devices, approved its Good Commercial Practice Code with guidelines regarding the relations between the companies and the health-care professionals. The supervision of the compliance with these rules might not be as rigorous as 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 authorisation, manufacturing authorisations and the import, export, marketing, labelling, information, advertising, pharmacovigilance and use of medicinal products for human use. This extensive Code transposes into Portuguese law six Directives of the European Union and regulates the entire life cycle of medicinal products in Portugal. There are two areas that are regulated in separate legal frameworks: clinical trials, and pricing and reimbursements.

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 Portuguese state. Although Infarmed has administrative and financial autonomy, it follows the aims of the health minister and depends 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 of 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 of 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 (HIV, neurodegenerative disorder, diabetes, auto-immune diseases and other immune dysfunctions and viral diseases) or orphan medicinal products.

The centralised procedure may also be followed, not on a 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:

- the national procedure to obtain a national marketing authorisation;
- the mutual recognition procedure with the view of obtaining the 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 in several agencies of several member states, one of which will act as a 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?

Yes, 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 years. The holder of the marketing authorisation must notify Infarmed of the date of the commencement of the effective marketing of the medicinal product.

19 Which medicines may be marketed without authorisation?

In principle medicinal products marketed in Portugal must all have a marketing authorisation. There are exceptional cases where Infarmed may grant special use authorisation or exceptional authorisation as mentioned under question 20.

Homoeopathic medicinal products may be marketed without an authorisation. These products are subject to a simplified registration if the products do not have specific therapeutic indications placed on the label or on any product information. Furthermore, to qualify for simplified registration these products must have a certain pharmaceutical form (oral or external), thereby not representing risks to the patients.

20 Are any kinds of named patient (or similar expanded access) 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 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 where:

- there are medical justifications where 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. A new legal framework applicable to the pricing of reimbursed medicinal products either subject or not to medical prescription was approved in 2011 (Decree-Law 112/2011 of 29 November) and entered into force on 1 January 2012 (amended by Decree-Law 152/2012 of 12 July).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 the 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 Spain, Italy and Slovenia and are subject to annual price reviews.

The maximum prices for reimbursed medicinal products must be approved by Infarmed. Previously, prices were approved by a General Directorate of the Economy Ministry (DGAE). The annual review of prices for sale to outpatients of reimbursed medicinal products is established in Ministerial Order 4/2012 of 2 January. The annual price review of branded products must be requested by the companies each year before 15 December and the new prices will be applicable as from 1 January 2013. The review of the prices of generic products must be requested by the companies until 15 January, the new prices will apply from 1 February of the next 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 price review. The prices of generics must be reviewed based on the review of the price of the reference product, and may not exceed 50 per cent of the maximum price of the referenced medicinal product.

The prices of the 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 in order to obtain evidence on the respective added therapeutic value and economic benefit. In case of a favourable evaluation, Infarmed will approve the maximum price for sale to the hospitals of the NHS.

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

Regarding the relation with public-care providers, two stages must be distinguished. In a first stage the suppliers of the NHS are selected through centralised public tenders, where the manufacturers or holders of the marketing authorisation bid with their 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 of 29 January). The NHS enters into public supply agreements with the selected suppliers.

In a second stage, regulated by the same Code, there is an invitation addressed by each hospital to suppliers to propose better

Update and trends

The Portuguese Government continues to implement new measures in line with the commitment laid down in the memorandum of understanding entered into with the European Commission, the European Central Bank and the International Monetary Fund.

The legislative proposal regarding the prescription of medicinal products by INN was approved through Law No 11/2012 of 8 March, establishing new rules for the prescription and dispensing of medicinal products. The medicinal products prescriptions must necessarily include the international non-proprietary name of the active principle, pharmaceutical form, dosage, presentation and instructions to use the medicinal products. In addition, Ministerial Order 137-A/2012 of 11 May was also approved, establishing the legal framework for prescription and dispensing of medicinal products, ruling the conditions of dispensing the cheapest medicinal product, as well as the duties to inform the patients of their option rights, all in compliance with Law 11/2012.

Parliament approved Law 8/2012 of 21 February, laying down the rules applicable to the liabilities undertaken by public entities and the payments in delay, applicable to all public entities of the National Health Care System (NHS). The Law implements new rules of budget planning, namely the reduction of the average deadlines of payment by the NHS from 240 to 90 days (within the necessary adaptation period).

Concerning the regulation of the health sector, a new Intellectual Property Court, as well as a Competition, Regulation and Supervision Court were established through Decree-Law 67/2012 of 20 March 2012. The first is competent to decide upon matters related to Intellectual Property rights, including trademarks and patent litigation, and the latter is competent to deal with matters subject to appeal, review and execution of decisions, orders and all other measures in an administrative offence case, which can be challenged by the Health Regulatory Entity, but not Infarmed.

Finally, regarding the pharmacies sector, the legal framework of retail pharmacies was amended through Decree-Law 171/2012 of 1 August 2012, clarifying the tenders for establishment of new pharmacies and Decree-Law 352/2012 of 30 October was also approved, which regulates the licensing procedure and the attribution of permits for new pharmacies.

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 of 13 May):

- 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, the NHS reimbursement may also depend on the product filling a therapeutic gap in the market, the product having new active ingredients or the product 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 also arise in several other cases, basically following the added therapeutic value or economical added value criteria, or both.

The reimbursement follows a regressive scale of 100 per cent in certain cases for medicinal products subject to medical restricted use (in-patients) or in case of certain serious pathologies (in-patients and outpatients) and it 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 there are no therapeutic alternatives.

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

The competent body for decisions regarding the pricing and reimbursability of medicinal products subject to medical prescription is the Infarmed, according to the legal framework for pricing established in Decree-Law 112/2011 of 29 November.

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

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

Discounts (reducing the maximum fixed prices) are allowed in the whole medicinal product circuit, by the manufacturer, 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?

The counterfeiting and illegal distribution of medicinal products in Portugal is not specifically provided for; general legal provisions penalise these illicit activities. The Criminal Code foresees that counterfeiting activities of medicines and food are classified as a crime 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 the pharmaceutical companies seeking to combat counterfeiting.

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

Most recently, the European Directive 2011/62/EU of 8 June 2011 (amending Directive 2011/83/EC) introduced changes as regards the prevention of the entry into the legal supply chain of falsified medicinal products. This Directive has not yet been transposed into national law (due in January 2013).

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 has been mandatory for physicians in the public and private sector since August 2011. The prescription of medicinal products by INN (International Non-proprietary Name) has been introduced in recent years. In 2012, further rules have been passed restricting the prescription and dispensing of medicinal products (Law 11/2012 of 8 March and Ministerial Order 137-A/2012). These new rules have been imposed on the sale of the cheapest medicinal product. The medical prescription must be written in the form: INN, pharmaceutical form, dosage, presentation and posology. A prescription including the brand name is only allowed with

respect to medicinal products which do not have reimbursed generics or for which the original branded medicinal product and licences are unique and in the admissible exceptions, including the respective technical justification of the physician within the prescribed medicinal product in certain situations; a handwritten prescription 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 addressed to the patients, as well as to prescribers and pharmacies. The pharmacists shall inform the 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 for each homogeneous group, chosen among the five medicinal products with the lowest price in the market, and must sell the cheapest one to the patient. The cost of the 'fifth-lowest price' drug is registered in a daily updated database provided by the Infarmed for the companies in this sector.

When dispensing, the pharmacist must inform the patient of the cheaper medicinal product, reimbursed by the NHS, available in the pharmacy that complies with the medical prescription. The patient must be informed of the right to opt for the medicinal product that is in compliance with the medical prescription and of the right to the cheapest medicinal product in the market, which must be available within 12 hours, at no additional cost, if it is not available at the pharmacy.

Moreover, the above-mentioned Informative Note establishes rules applicable in three different situations

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

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

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

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.

The new European legal framework regarding pharmacovigilance consists of Directive 2010/84/EU of 15 December 2010 and Regulation (EU) N.1235/2010 of 15 December, which apply to medicinal products placed on the Portuguese market. The national legislation has still not seen any developments in this respect. Pharmacovigilance is regulated in the Code of the Medicinal Products, which regulates the National System of Pharmacovigilance, transposing the rules in EC Directive 2001/83/EC. In 2011, Infarmed received 2,100 notifications of adverse reactions with medicinal products and 230 notifications regarding incidents with medical devices.

ADVOGADOS

FOCUS MATTERS.

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