GETTING THE DEAL THROUGH

Life Sciences

in 24 jurisdictions worldwide

2014

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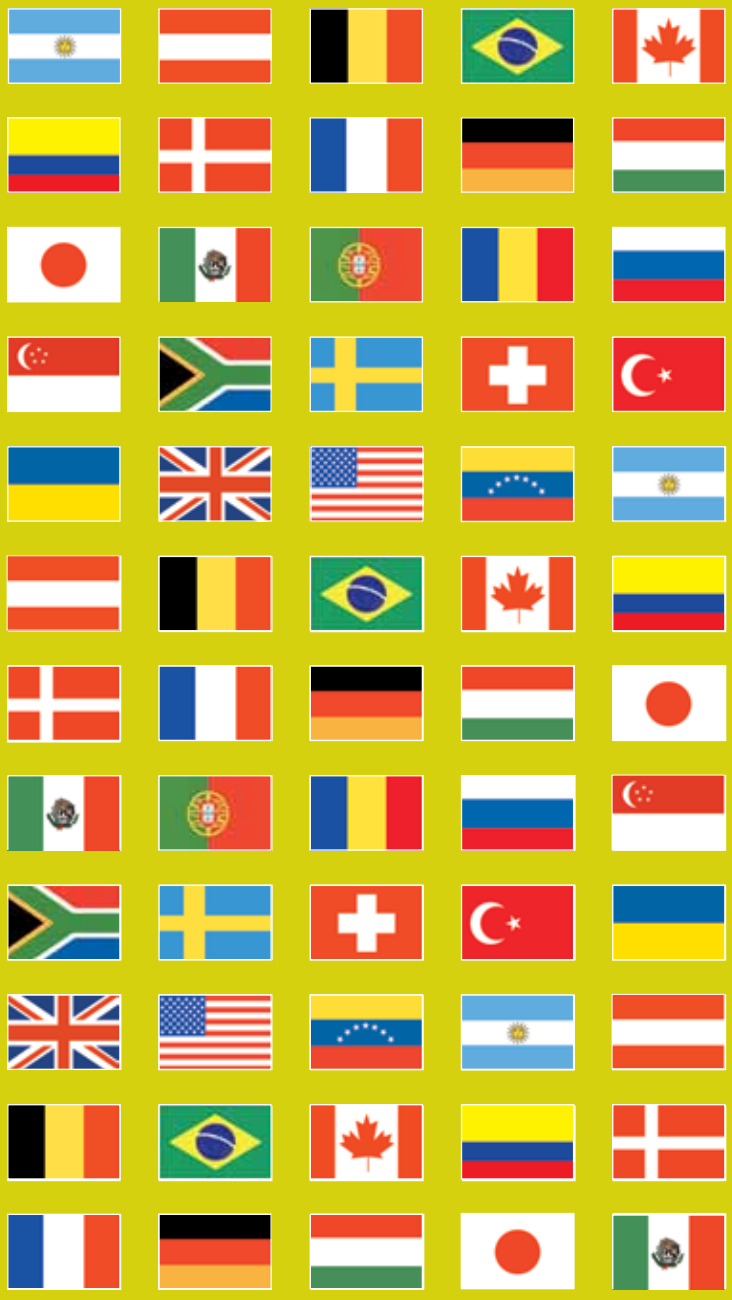

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Portugal

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Organisation and financing of health care

1 How is health care in your jurisdiction organised?

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 adjustment and reform programme, which has been financing the Portuguese National Health-Care System (NHS). To benefit from this programme, Portugal had to implement reform measures in the health-care system and reduce public spending on pharmaceuticals to 1.25 per cent of the GDP by 2012, generate additional savings in hospital operating costs and devise a strategy to eliminate arrears.

In compliance with the reform programme, the government is implementing the measures stated in the Troika Memo, in order to achieve the agreed objectives. Until the end of 2013, Portugal should comply with the terms of the Troika Memo and has been audited nine times. According to the Troika's Seventh Revision Report of June 2013, the current objectives regarding the health sector are to improve its efficiency and effectiveness through a more rational use of the services and expense control, and to generate additional savings in respect to medicinal products in order to reduce global public spending in this area to 1 per cent of the PIB until the end of 2013.

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).

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, rules were approved respecting the 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).

The 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 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 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 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, on January 2012 a new legal framework came into force regarding the Patients Moderating Fees (Decree-Law No 113/2011, 29 November 2011). There are exemptions, for example for pregnant women, children up to 12 years old and 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.

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

By the end of 2013, the Ministry of Health is expected to implement for the first time an annual system for the evaluation of medical careers. The purpose is to evaluate the human resources of the NHS. If further human resources are required, they should be hired through employment agreements instead of services agreements with providers of medical services.

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) (the 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 to the payee and to the receiver with respect to any type of sponsorship, benefit or value in money, good or right which may have a value in money. 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.

In 2013, the Code of Medicinal Products suffered two major changes. Firstly, in February it was amended by Decree-Law No. 20/2013 (14 February 2013), transposing Directive 2010/84/EU (15 December 2010) as regards pharmacovigilance. Subsequently, that Code was also amended in September by Decree-Law No. 128/2013 (5 September 2013), transposing Directive 2009/35/EC (23 April 2009) on the colouring matters which 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. Substantial amendments have been introduced to the Code of Medicinal Products, including those regarding the advertising of medicinal products.

According to these new legal provisions, the 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 granted to any entity or individual, namely associations or any other entity, regardless of its form or nature, representative of a certain patient group or medical companies, associations or corporations scientifically oriented or of 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 service provided by independent workers, are not subject to the duty of notification. Furthermore, the recipients of these benefits, which include not only the mentioned associations or corporations, but also any entity or individual (namely health-care professionals) must notify Infarmed and register that fact at Infarmed's website. These rules only apply to values exceeding €25. Infarmed further clarified that any hospital, service or medical society which organises a certain congress must be identified as beneficiaries 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, bonus or pecuniary benefits or benefits in kind, unless they are insignificant and relevant for medicine or pharmacy 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 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 is not allowed, and neither 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 pharmaceutical 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, bonus or pecuniary benefits or benefits in kind to the 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 advertising rules, namely regarding comparative advertising. In 2012, there was an increase of infringements procedures started by Infarmed. Infarmed's 2012 Activities Plan clearly mentions the need to strengthen Infarmed's knowledge regarding the market, in order to comply with the principles applied to the promotion of the rational use of medicinal products, medical devices and cosmetic and body hygiene products. Infarmed further emphasises the importance of the evaluation of medicinal products advertising, for which the notifications made by marketing authorisation holders through the Medicinal Products Advertising System has 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 an advertisement 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 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 157–162), 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. These rules have suffered substantial changes in 2013 with a view to conferring more transparency to sponsorships and grants, given by the pharmaceutical industry to any public or privately-held entity or any individual, in cases exceeding €25.

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 advertising 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 and must be notified to Infarmed within 30 days. 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. 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, as well as by distributors, arise from misinterpretations 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 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. 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 Portuguese Competition Law (Law 19/2012, 8 May 2012) 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, 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 (17 June 2009) 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. 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. In 2013, this 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), transposing other three EU Directives. 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 (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 (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 a view to 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 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 in Infarmed's website. The marketing authorisation holder may challenge the invalidity within 10 days of the 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 at stake;
- the medicinal product is a vaccine or a medicinal product for in-patients only, which has not been selected in a public tender to supply the Portuguese national health service;
- the medicinal product at stake may be used in case of disaster or pandemic situations;
- if Portugal acts has a 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 of a decision.

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 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. The 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, 29 November 2011), entering 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 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 three member states of the EU, that have a gross domestic product per capita comparable to Portugal or that have a lower price level. The Portuguese government will establish the three reference countries for this purpose on an annual basis. In 2013, those countries were Spain, France and Slovakia. Pricing reviews are made on an annual basis.

The maximum prices for reimbursed medicinal products must be approved by Infarmed. The annual review of prices for sale to outpatients of reimbursed medicinal products is established in Ministerial Order 4/2012 (2 January 2012). The annual prices review of branded products must be requested by the companies each year until 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 the companies 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 product, and may not exceed 50 per cent of the maximum price of the reference 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. After 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 of medicinal products to be purchased by the NHS hospitals, applicable to medicinal products that were not subject to the prior evaluation procedure. The reference member states are the same ones that set the prices of medicinal products to be sold to outpatients (Spain, France and Slovakia for 2014).

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 the first stage, the 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, there is an invitation addressed by each hospital 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, 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 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?

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 subject to medical prescription (or not) is Infarmed.

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, 3 October 2006). 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?

Directive 2011/62/UE (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' has been introduced into national law reproducing the definition established in Directive 2011/62/UE. According with these new rules, manufacturers and distributors must notify Infarmed and the marketing authorisation holder immediately if they become aware of a falsified medicinal products, or if there is 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

Update and trends

It is expected that Directive 2011/24/UE (9 March 2011) on the application of patients' rights in cross-border health care will soon be transposed into Portuguese law. The Health Ministry submitted a draft legislation transposing the mentioned Directive to public consultation. Directive 2011/24/UE 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. This Directive introduces important changes such as 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 national authorities responsible for e-Health, designated by the member states. 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 registry or marketing authorisation under the terms of the Medicinal Products Code and includes the following elements:

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

The pharmacist may refuse to provide medical prescriptions issued in another member state if there are legitimate and justified doubts regarding its authenticity. eHealth has particular concerns that the legislative draft did not determine the responsible national authority.

Apart from this upcoming legislation, the major legislative developments were essentially the 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.

Furthermore, Order 5456-B/2013 of 23 April established new measures regarding the acquisition of medical devices by the services and establishments of the NHS, aiming at cost reductions. According to this Order, the NHS services and establishments may only purchase medical devices, either through a competitive public procurement procedure or not, for less 15 per cent than the 2012 prices for a similar device.

outer packaging of medicinal products, or 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.

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.

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 has been ruled through 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 sale of the cheapest medicinal products, except if the patient opts for another medicinal product with the same INN. 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, the hand written prescription is only allowed in exceptional situations and the word 'exception' must be inserted under the logo of the Ministry of Health.

The Infarmed and the ACSS published a Joint Informative Note (01/INFARMED/ACSS) establishing specific guidelines on this matter, which were addressed to the patients as well as to the 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 of each homogeneous group, chosen among the five medicinal products with lower prices in the market, and must sell the cheapest one to the patient. The cost of the 'fifth lower price' is registered in a database provided daily by Infarmed to the companies of the 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 which 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 with no additional costs when it is not available at the pharmacy.

Moreover, the above-mentioned informative note establishes rules applicable in three different situations

- prescription by INN (or absence of the exceptions) when there is a homogeneous group;
- prescription by INN (or 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 to their doctor or to the pharmacist, and regarding the situations where they have the right to opt for another product. The information is also available at Infarmed's website. Whenever the patient is entitled to opt in, 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 (5 September 2013), mainly regard the safety matters of medicines. 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 in order 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 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, covering the entire population at no cost. This NVP provides a vaccination schedule recommended by the health authorities in Portugal, however the NVP is not confined to the vaccination recommended at national level, for there are still vaccination approaches for special groups such immunocompromised individuals, health professionals at risk, travellers to endemic areas and others, which are also 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), where 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 meet WHO targets.

ADVOGADOS

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