Portugal

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ORGANISATION AND FINANCING OF HEALTHCARE

Organisation

1 | How is healthcare in your jurisdiction organised?

The manner in which healthcare in Portugal is organised has been subject to several 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. Private healthcare providers have increased their role in providing healthcare services to the population collaborating with the NHS. Furthermore, public expenditure cuts have affected the prices of medicinal products that are reimbursed by the NHS, and drove the government to propose the creation since 2015 of an additional tax applicable to pharmaceutical industry sales. The new Health Law was finally approved in July 2019 and published in the Portuguese Official Gazette on 4 September 2019 (Law No. 95/2019 of 4 September 2019), with two main modifications: the first regarding the recognition of the status the informal caregiver, which is now recognised in law (Law No. 100/2019 of 6 September 2019), and may apply for a subsidy. The second main change of the new Health Law is that the agreements between the NHS and private healthcare providers are envisaged as an exception, and only allowed whenever the NHS lacks capacity to provide the necessary healthcare in time. The extraordinary charge on the pharmaceutical industry (designated as 'a special charge on the pharmaceutical industry') was created by the 2015 State Budget, approved by Law No. 82-B/2014 of 31 December 2014, which entered into force on 1 January 2015 and is expected to be maintained in the State Budget for 2020. This aims to ensure the sustainability of the NHS in terms of its expenditure on medicinal products, which applies to entities carrying out the first sale of medicinal products for human use in Portuguese jurisdiction, 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, remained in force during 2019 and is expected likewise for 2020. The extraordinary charge may range from:

- 2.5 per cent for reimbursed medicinal products included in homogeneous groups or not included in homogeneous groups for which a marketing authorisation has been granted for at least 15 years and with a price less than €10 covering medicinal gases and derivatives from human blood or human plasma, and orphan medicinal products;
- 10.4 per cent for reimbursed medicinal products not covered by the 2.5 per cent rate; and
- 14.3 per cent for medicinal products subject to a restricted medical prescription, as well as those that have an exceptional use authorisation or exceptional authorisation or are intended for hospital consumption.

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 value-added tax and another charges on the marketing of medicinal products (called a 'tax on the sale of commercialised medicines').

This regime provides a payment exemption of the extraordinary charge by all entities that, individually and unreservedly, adhere to the agreement between the Portuguese state, represented by the Finance and Health Ministries and the Portuguese Pharmaceutical Industry Association (Apifarma), which sets the goals for the maximum amounts of public expenditure with medicinal products and charges according to the sales volume of the pharmaceutical industry companies in order to attain such goals. The entities that adhere to the agreement shall declare it to Infarmed (the Portuguese National Agency for Medicines), and are exempted from the extraordinary charge payment. However, they will be subject to another charge under specific terms of the agreement. The extraordinary charge shall be paid through a declaration with an official template (which was approved by Ministerial Order Np. 77-A/2015 of 16 March 2015) and the non-compliance of this obligation results in a compulsory charge collection by the tax authorities.

Organisation of healthcare

The Portuguese Constitution (article 64), consolidated further by the new Health Law (Law No. 95/2019 of 4 September 2019), establish the right of all Portuguese citizens to benefit from public healthcare, which is provided through the NHS healthcare system, that should cover the whole population, be universal for all citizens, be general, ensuring that all types of healthcare are required to promote the health, and free at point of use, taking into account the economic and social conditions of citizens. Citizens of other EU member states may be entitled to public healthcare in accordance with the applicable EU rules. Foreign citizens that are resident in Portugal may also benefit from public healthcare provision in the case of a reciprocal agreement with the foreign national's home state. The main principles and rules governing public healthcare and the structure of the healthcare system are established in the new Health Law (Law No. 95/2019 of 4 September 2019). Hospitals, healthcare centres for outpatients and other entities included in the NHS comprise the healthcare providers in Portugal.

The NHS depends on, and is financed by, the state and public budget. Private entities and professionals may also render healthcare services to NHS patients pursuant to agreements with the entities representing the Health Ministry. All NHS services and institutions fall under the supervision of the Ministry of Health, which is ultimately

responsible for the healthcare sector and defining the government's national healthcare policy.

Successive governments have continued to organise and reorganise the NHS in past years, mainly since 2002, and specifically regarding the nature and functioning of the hospitals integrated in the NHS and the creation and cessation of public bodies and entities, in particular, in defining and putting into place the relation with private healthcare providers.

In 2019, the rules respecting health-related public-private partnerships (Decree-Law No. 185/2002 of 20 August 2002) was revoked and it is expected that new rules to be approved will narrow the types of structural collaboration of the NHS with private healthcare providers.

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

At present, Portugal is divided into five health regions with healthcare centres serving the outpatients of each region, and approximately 225 hospitals, of which 110 are public hospitals, 111 are private hospitals and four are public-private partnerships.

Financing

2 | How is the healthcare system financed in the outpatient and inpatient sectors?

The financing of the healthcare system is governed by the Portuguese Constitution, which states that the right to benefit from public healthcare is ensured through a universal healthcare system, taking into account the social and economic conditions of all citizens, which tends to be cost-free for patients.

The NHS is financed by the state budget. Fees can be charged to certain outpatients, based on a co-payment scheme, but they only represent a small part of the cost of the service. In compliance with the reform programme, since January 2012, patients' moderating fees (Decree-Law No. 113/2011 of 29 November 2011) apply to those that may benefit of the NHS. Since the Portuguese NHS is free at the point of use, there is an extensive list of exemptions of the payment of the patients' moderating fees, which is increased on a yearly basis. There are exemptions, for example, for pregnant women, children, patients with an incapacity level equal to or higher than 60 per cent and patients with insufficient funds. Furthermore, in accordance with a new legal extension approved by Decree-Law No. 131/2017 of 10 October 2017, the following are also exempt from the payment of moderating fees:

- consultations and supplementary diagnostic tests carried out in the course of screening for HIV/AIDS, hepatitis, pulmonary tuberculosis and sexually transmitted diseases;
- early diagnosis and neonatal diagnosis programmes and pre-exposure prophylaxis for HIV, promoted under the prevention programmes of the Directorate-General for Health; and
- consultations, including complementary acts, prescribed in the course of the provision of palliative care.

Patients with an average monthly income lower than €653,64 are exempt from patient moderating fees.

The NHS's debt to pharmaceutical companies amounted to €947 million in September 2019, with an average payment period of 335 days in 2019.

At the end of 2013, the Ministry of Health implemented for the evaluation of medical care. 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 the Portuguese Health Regulation Authority (ERS), where they may be obtained according to rating indicators. Results are available for the first semester of 2019 of hospitals evaluated under the National Health Assessment System (SINAS) according to various parameters – namely, clinical excellence, patient security, facilities' adequacy and comfort and patient satisfaction.

Basic structures

3 | What are the basic structures of the provision of care to patients in statutory and private care?

The basic differences between patients' statutory and private care is that the statutory structures are nationwide, with regional hospitals and day centres covering Portuguese jurisdiction, and all pathologies and treatments. Private care is centred around the largest metropolitan areas and may not cover every pathology and may not have a co-payment system.

HEALTHCARE SERVICES

Authorisation

4 | What steps are necessary to authorise the provision of health services, and what law governs this?

The ERS is the entity supervising the activity and functioning of healthcare service providers, which includes overseeing the licences for those establishments pursuant to the law (Decree-Law No. 126/2014 of 22 August 2014).

For every type of establishment, there are specific technical requirements applicable to each type of healthcare unit. Privately owned healthcare units that comply with such requirements need to obtain a licence to operate the healthcare unit.

The licence is issued in one of the following procedures:

- the simplified procedure through mere prior notification; or
- the common procedure.

The simplified procedure through a mere communication starts with the electronic login at the licensing platform available on the ERS website, where the applicant must file a liability statement regarding the fulfillment of all legal requirements. This type of licensing will apply to:

- dentists' clinics;
- doctors' clinics;
- nursing centres;
- rehabilitation and physical medicinal units; and
- radiology units.

The common procedure is applicable to all healthcare units that are not covered by the simplified procedure and must obtain a licence to be issued by the common procedure, which requires a compliance inspection to be made by the ERS, where the legal and technical requirements will be verified.

Structure

5 | Which types of legal entities can offer healthcare services?

Publicly owned and privately owned entities, as well as entities belonging to the social economy (charities).

Requirements for foreign health services providers

6 What further steps are necessary for foreign companies to offer health services?

Foreign companies should set up an entity in Portugal in order to offer health services. There are no restrictions regarding the country of origin.

ADVERTISING

Legislation

7 Which legislation governs advertising of medicinal products to healthcare professionals?

The rules regarding advertising medicinal products are contained in the Code of Medicinal Products approved by Decree-Law No. 176/2006 of 30 August 2006 (the Code of Medicinal Products), which was amended by Decree-Law No. 128/2013 of 5 September 2013, imposing further notification obligations to Infarmed 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 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 No. 330/90 of 23 October 1990 governs advertising in general, including all aspects regarding the advertising of medicinal products not specifically set out in the Code of Medicinal Products. Regarding medical devices, Decree-Law No. 145/2009 of 17 June 2009 should also be considered, since it established the respective legal framework.

In 2015, Decree-Law No. 238/2015 of 14 October 2015 was published in order to regulate health advertising practices, by interventions of a public or private nature. The Decree-Law covers advertising that aims to promote all acts carried out in order to protect or maintain health or to prevent and treat diseases, including the offer of diagnosis, as well as any other treatments or therapies and non-conventional therapies.

This Decree-Law forbids any health advertising practices that:

- may mislead the patient regarding the characteristics of a certain act or service;
- may induce the patient into the acquisition of an act or service;
- contain false demonstrations and guarantees of cure or absence of side effects;
- may be misleading regarding the nature, attributes and rights of the intervention favouring the advertising act being undertaken;
- induce the patient into taking a decision regarding a transaction that he or she otherwise would not have taken involving an activity likely to create confusion between acts or services, brands and commercial names of a direct or indirect competitor or to create a conviction of quality through the misuse of a brand or distinguishing marks or by claiming attributes not associated with such brands or marks;
- describe the act or service as 'free', 'free of charge' or 'with a discount' or 'with a promotion' if the patient has to pay a higher amount than the expected amount to respond to such an advertising act; or
- propose the acquisition of acts or services at a certain price, with the intention of promoting a different act or service, and afterwards refuse to offer the patient the act or service initially advertised.

Furthermore, the Decree-Law also prohibits any health advertising practices that limit or may limit significantly the freedom of choice or the behaviour of a patient concerning a certain act or service, may induce unnecessary or harmful consumption or any practices carried out through contests, draws or similar activities that promote health acts or services through the offering of prizes or other kinds of award.

Any breach of the provisions established by this Decree-Law is sanctioned with a fine of €250 up to €3,740.98 for natural persons and €1,000 up to €44,891.81 for legal persons. The Decree-Law entered into force on 1 November 2015.

Most recently, with Decree-Law No. 5/2017 of 6 January 2017, which entered into force on 5 February 2017, major modifications were adopted in Portugal regarding the interactions between industry and healthcare professionals and entities with activities related to healthcare. Decree-Law No. 5/2017 reinforces and recognises a number of general principles that must be respected as regards promotion and advertising of medicines and medical devices. It establishes legal provisions changing the reporting obligations applicable to medicinal products, and establishes for the first time that reporting obligations also apply to companies on the medical devices circuit. Furthermore, these new rules forbid promotional events at Portuguese NHS hospitals and establishments, as well as any event sponsored by the medical devices industry and distributors. The events that may take place within the Portuguese NHS need to be authorised on a case-by-case basis by the Ministry of Health.

Main principles

8 What are the main rules and principles applying to advertising of medicinal products aimed at healthcare professionals?

The Code of Medicinal Products establishes that all advertising to healthcare 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.

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

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

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 healthcare 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.

The transparency rules in the Code of Medicinal Products establish that entities covered by the Code must submit a report at the Infarmed transparency platform 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, owing 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 healthcare professionals), must notify Infarmed and register such a benefit on Infarmed's website. Since 7 October 2014, these rules only apply to transfers of a value exceeding €60 (prior 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 healthcare 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 healthcare 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.

Advertising of medical devices

9 Is the advertising of medical devices to healthcare professionals regulated as rigorously as advertising in the pharmaceuticals sector? What are the main differences?

Medical devices are regulated by Decree-Law No. 145/2009 of 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 requiring the intervention and prescription of a healthcare professional, namely implantable devices, is not allowed. Apormed, the Portuguese association of companies manufacturing and marketing medical devices, has issued its Good Commercial Practice Code with guidelines regarding the relations between companies and healthcare professionals.

Supervision of the compliance of companies with these rules might not be as rigorous as it is in the pharmaceutical sector. However, in Infarmed's Plan of Activities for 2017–2019, an objective is included to reinforce the supervision of both the marketing of medicinal products and the marketing of medical devices. The focus of the Plan of Activities is on improving risk assessment and developing surveillance and warning systems.

DATA PROTECTION, PRIVACY AND DIGITISATION IN HEALTHCARE

Digitisation

10 What are the legal developments regarding digitisation in the healthcare sector and industrial networks or sales channels?

The most recent developments regarding digitisation in the sales channel arise from the amendments introduced by Decree-Law No. 113/2019 of August 19 to the Medicinal Products Act, pursuant to which the holders of the marketing authorisations must have digital records of all requests for supplies received aimed at enabling the control of the supply of the national market.

Furthermore, the most relevant recent development in what regards data privacy was the entering into force of the new Portuguese data privacy law (Law No. 58/2019 of 8 August 2019), that repealed the former data privacy law and executed Regulation (EU) 679/2016 on General Data Protection Regulation (GDPR).

Provision of digital health services

11 Which law regulates the provision of digital health services, and to what extent can such services be provided?

Healthcare services rendered by the Portuguese NHS through digital means have been regulated since 2013 (Dispatch 3571/2013). Healthcare services to be provided by privately owned entities have to be licensed by the ERS, as does any other unit providing healthcare services.

Authorities

12 Which authorities are responsible for compliance with data protection and privacy, and what is the applicable legislation? Have the authorities issued specific guidance or rules for data protection and privacy in the healthcare sector?

The authority responsible for compliance with data protection and privacy is the Comissão Nacional de Protecção de Dados (CNPD). The CNPD has issued guidance with regard to the following:

- personal data in clinical trials (Resolution 1704/2015);
- pharmacovigilance (Resolution 219/2009);
- personal data of deceased persons (Resolution 72/2006); and
- access of third parties to an individual's health data (Resolution 51/2001).

Requirements

13 What basic requirements are placed on healthcare providers when it comes to data protection and privacy? Is there a regular need for qualified personnel?

Healthcare providers must comply with the principles and rules established in Regulation (EU) 679/2016 – namely, the data subjects must receive information regarding personal data processing and provide their unambiguous consent except in certain justified situations listed in the GDPR. As a rule, only healthcare professionals indicated by the data subject may have access to individual health data (Law No. 12/2005 of 26 January 2005, the Law of Gene and Health Data). All collaborators of the healthcare provider that have access to health data must comply with legal confidentiality duties as established in the new data protection law. Healthcare providers, as entities that have to process personal data in order to pursue their core-business, must, according to the interpretation of the GDPR (article 37 1, (b) and (c)) appoint a data protection officer.

Common infringements

14 What are the most common data protection and privacy infringements committed by healthcare providers?

The most common potential infringements are to provide insufficient information to data subjects, failing to obtain consent when necessary and providing unnecessary access to third parties.

COLLABORATION

Legislation

15 Which legislation governs the collaboration of the pharmaceutical industry with healthcare professionals? Do different rules apply regarding physicians in the outpatient and inpatient sectors?

The legislation that applies to the collaboration of the pharmaceutical industry with healthcare professionals is the Code of Medicinal Products (articles 157 to 162), which 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 and in 2017 with a view to ensuring greater transparency regarding sponsorships and grants of amounts exceeding €60 (since 7 October 2014) given by the pharmaceutical industry to any public or privately held entity or to any individual.

In addition to the transparency requirements established in the Medical Devices Statute, Decree-Law No. 5/2017 goes further and recognises and established in law the working of a number of principles that govern all promotional activities regarding medical devices, such as the principles of integrity, respect, moderation, transparency and collaboration.

Furthermore, Decree-Law No. 5/2017 forbids institutions and establishments of the NHS and bodies of the Health Ministry from soliciting directly or indirectly and receiving any benefits, whether pecuniary or in kind, from suppliers of goods and services, including medical products medical devised and other health technologies equipment and services in the area of information technology or suchlike. This prohibition is considered to affect or is capable of acting the exemption and impartiality of the said institutions, in which case the authorisation by the Health Ministry is required. In all cases, sponsorship of pharma or medical devices events by the companies in the Portuguese NHS is not permitted.

The Code of Ethics regarding the promotional practices of the pharmaceutical industry in collaboration with healthcare professionals approved by Apifarma regulates these matters in detail. The same rules apply to physicians in both the outpatient and inpatient sectors.
Furthermore, Apogen, the association of generic medicinal products, also approved its Code of Ethics that entered into force in January 2017, establishing rules for the interaction of any associate with patient organisations and healthcare professionals, such as the promotion of events, visits by healthcare professionals of associate premises, advertising and donations. Apormed, the association of medical devices companies, also approved its Code of Ethics in 2018, establishing rules promoting:

- the independence of physicians' decisions from the role and interactions of medicinal devices companies; and
- transparency and principles of development of medicinal technologies and of safe use of those technologies.

Collaboration with healthcare professionals

16 | What are the main rules and principles applying to the collaboration of the pharmaceutical industry with healthcare 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. 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 healthcare 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 – four samples per product, per year to each healthcare professional – and healthcare professionals must request the samples in writing. Each sample shall be no larger than the smallest product and accompanied by a copy of the Supplementary Protection Certificate.

Apifarma's Code of Ethics covers all the matters relating to the promotional practices of the pharmaceutical industry in collaboration with healthcare professionals, clarifying certain rules by providing further details and guidelines to companies regarding the practices that are allowed. Apogen's Code of Ethics also covers some rules regarding admissible practices in interactions with healthcare professionals and patient associations. In addition, Apormed approved its Code of Ethics in 2018, establishing similar rules applicable to their associates.

Collaboration with patient organisations

17 | 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.

Apogen's Code of Ethics also establishes rules and principles applying to the collaboration of the pharmaceutical industry with patient organisations – namely, obligations of transparency, a prohibition promoting medicinal products within those organisations and the obligation of having all agreements entered into with these organisations in writing.

Common infringements

18 | What are the most common infringements committed by pharmaceutical manufacturers regarding collaboration with healthcare 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 healthcare 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'.

Collaboration on medical devices

19 Is the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as collaboration in the pharmaceuticals sector? What are the main differences?

See www.lexology.com/gtdt

COMPETITION LAW

Authority enforcement

20 Are infringements of competition law by healthcare providers pursued by national authorities?

The Portuguese Competition Authority pursues infringements of the Portuguese Competition Law (Law No. 19/2012 of 8 May 2012), which applies to anticompetitive practices or agreements and mergers that occur in Portuguese jurisdiction or that have effects within the nation's territory. The Autoridade de Segurança Alimentar e Económica (ASAE) pursues infringements applicable to individual practices that restrict commerce as established in the respective legal framework (Decree-Law No. 166/2013 of 27 December).

Private enforcement

21 Is follow-on private antitrust litigation against healthcare providers possible?

Yes. The Portuguese legal framework foresees the private enforcement of antitrust law and the healthcare sector is not excluded in any way. The specific rules of this regime are contained in Law No. 23/2018, which transposes the Private Enforcement Directive (Directive 2014/104/EU), and sets out the procedural rules ensuring that anyone who has suffered harm caused by an infringement of EU and national competition law by an undertaking or association of undertakings can effectively exercise the right to claim full compensation. These rules apply to follow-on and standalone actions alike.

Anti-corruption and transparency

22 What are the main anti-corruption and transparency rules applicable to healthcare providers?

All healthcare providers are subject to the general anti-corruption rules applicable within Portuguese jurisdiction established in the Portuguese Penal Code (Decree-Law No. 48/1995 of 15 March 1995). Hospitals belonging to the NHS are not allowed to promote or receive directly or indirectly any benefits in cash or in kind from the companies supplying products or services in the medicinal products market or in the medical devices market or IT, or other connected activities that may affect the exemption or impartiality.

PRICING AND REIMBURSEMENT

Price regulation

23 To what extent is the market price of a medicinal product or medical device 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, is ruled by Decree-Law No. 97/2015 of 1 June 2015, which created the National System for the Evaluation of Health Technologies (SiNATS) integrating all private and public entities within the health sector. The health technologies covered by this Decree-Law include medicinal products, medical devices, or medical or surgical procedures, as well as prevention, diagnosis and diseases treatment measures used in healthcare. SiNATS aims to shift the pattern of use and acquisition of health technologies, including medicinal products and medical devices, contributing to the achievement of health gains and its harmonisation with other European systems aimed at achieving the same goal. This system will allow health technologies to be the subject of evaluation and reevaluation within an integrated context and with preferential recourse for the establishment of objectives through contracts with authorised marketing authorisation holders. 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. The government is responsible for establishing the three reference countries for this purpose on an annual basis. In 2019, the reference countries were France, Italy, Slovenia and Spain. Pricing reviews are carried out on an annual or extraordinary 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 195-C/2015 (30 June 2015). 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 generic product prices must be requested by companies every 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.

Negotiations between manufacturers and providers

24 Must pharmaceutical and medical device manufacturers negotiate the prices of their products with public healthcare providers?

Negotiations with public healthcare providers takes place in two stages. In the first stage, NHS suppliers 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 Decree-Law No. 18/2008 of 29 January 2008, as amended). 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.

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Reimbursement

25 | 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 No. 97/2015 of 1 June 2015):

- 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 that is 5 per cent lower when compared with the branded equivalent.

Reimbursement will also arise in several other cases, essentially following the added therapeutic value or economic 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 (inpatients) or in the case of certain serious pathologies (inpatients 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.

Price adjudication

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

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Discount

27 | Are manufacturers or distributors of medicinal products statutorily obliged to give a discount to health insurance schemes or third parties?

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, which are granted to wholesalers and retailers, but these margins are commercial and do not have the nature of a discount.

UPDATE AND TRENDS

Key developments of the past year

28 | Is there any legislation expected in the near future that will have a major impact on the current legal environment for medicines or medical devices?

No relevant legislation is expected in the near future that will impact the current legal environment.