Life Sciences

Contributing editor
Alexander Ehlers

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GETTING THE DEAL THROUGH

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Contributing editor

Alexander Ehlers

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Preface

Life Sciences 2018

Ninth edition

Getting the Deal Through is delighted to publish the ninth edition of *Life Sciences*, which is available in print, as an e-book and online at www.gettingthedealthrough.com.

Getting the Deal Through provides international expert analysis in key areas of law, practice and regulation for corporate counsel, cross-border legal practitioners, and company directors and officers.

Throughout this edition, and following the unique **Getting the Deal Through** format, the same key questions are answered by leading practitioners in each of the jurisdictions featured. Our coverage this year includes new chapters on Brazil and the Netherlands.

Getting the Deal Through titles are published annually in print. Please ensure you are referring to the latest edition or to the online version at www.gettingthedealthrough.com.

Every effort has been made to cover all matters of concern to readers. However, specific legal advice should always be sought from experienced local advisers.

Getting the Deal Through gratefully acknowledges the efforts of all the contributors to this volume, who were chosen for their recognised expertise. We also extend special thanks to the contributing editor, Alexander Ehlers of Ehlers, Ehlers & Partner Rechtsanwaltsgelleschaft mbB, for his continued assistance with this volume.

GETTING THE DEAL THROUGH

London
November 2017

Portugal

César Sá Esteves and Ana Menéres
SRS Advogados

Organisation and financing of healthcare

1 How is healthcare in your jurisdiction organised?

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

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 82-B/2014 of 31 December, which entered into force on 1 January 2015 with the aim of ensuring the sustainability of the NHS, in terms of its expenditure on medicinal products, which applies to entities that are carrying out the first sale of a medicinal product for human use in the Portuguese territory, both where such entities are holders of marketing authorisations or registrations, or are their representatives, intermediaries, wholesale distributors or suppliers holding exceptional use authorisations or other exceptional authorisations for use of medicinal products, remained in force for 2016 and now again for 2018. The extraordinary charge is applicable to the amount of the quarterly sales of the following medicinal products:

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

The amount of the extraordinary charge varies between:

- 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 at least for 15 years and with a price inferior to €10; 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 VAT and another charge on the marketing of medicinal products (called a 'tax on the sale of commercialised medicines').

This regime provides an exemption of payment 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 maximum amounts of public expenditure with medicinal products and of charge according to the sales volume of the pharmaceutical industry companies in order to attain such goals. The entities that adhere to the mentioned agreement shall declare it to Infarmed (the Portuguese National Agency for Medicines), and are exempted from the payment of the extraordinary charge; however, they will nevertheless be subject to another charge under specific terms of the mentioned agreement.

The extraordinary charge shall be paid through a declaration with an official template (which was approved by Ministerial Order 77-A/2015 of 16 March) and the non-compliance of this obligation results in the compulsory collection of the charge by the tax authorities.

Organisation of healthcare

The Portuguese Constitution establishes the right of all Portuguese citizens to benefit from public healthcare, which is provided through a healthcare 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 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 state.

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

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 the 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 of the services and institutions of the NHS 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 through the years, mainly since 2002, specifically regarding the nature and functioning of the hospitals integrated in the NHS and the creation and extinction of public bodies and entities.

In 2002, rules were approved respecting health-related 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) were amended by Decree 18/2017 of 10 February 2017.

Hospitals may have different legal forms. Some remain public hospitals, but the majority are now public corporate entities, which are regulated by public law rules but have a certain degree of autonomy with regards to their management. The quality of healthcare 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 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.

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

The financing of the healthcare system is governed by the 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, in January 2012, a new legal framework came into force regarding patients' moderating fees (Decree-Law 113/2011, 29 November 2011). There are exemptions, for example, for pregnant women, children up to 12 years of age, patients with an incapacity level equal to or higher than 60 per cent and patients in a situation of financial insufficiency. Furthermore, in accordance with a new legal extension approved by Decree-Law 131/2017 of 10 October 2017, the following are also exempt from the payment of moderating fees: consultations and supplementary diagnosic 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 also pre-exposure prophylaxis for HIV, promoted under the prevention programmes of the Directorate-General for Health, consultations as well as complementary acts prescribed in the course of the provision of palliative care. Patients with an average monthly income lower than €628.83 are exempt from patient moderating fees. In April 2015, the exemption was expanded to cover minors.

The NHS's debt to pharmaceutical companies amounted to €739 million in May 2017, with an average payment period of 351 days in 2017.

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, where they may be obtained according to rating indicators. In 2017, 160 hospitals were evaluated under SINAS according to various parameters, namely clinical excellence, patient security, facilities adequacy and comfort, focus on the patient and patient satisfaction. Seventy-nine per cent of hospitals were evaluated and 89 per cent obtained the first level, which means that they all met quality standards.

Compliance – pharmaceutical manufacturers

3 Which legislation governs advertising of medicinal products to the general public and healthcare professionals?

The rules regarding advertising of medicinal products are contained in the Code of Medicinal Products approved by Decree-Law 176/2006 (30 August 2006) (Code of Medicinal Products), which was amended by Decree-Law 128/2013 (5 September 2013), imposing further notification obligations to Infarmed 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 330/90 of 23 October governs advertising in general, including all the aspects regarding the advertising of medicinal products not specifically set out in the Code of Medicinal Products. Regarding medical devices, Decree-Law 145/2009 of 17 June 2009 should also be considered, since it established the respective legal framework.

In 2015, Decree-Law 238/2015 of 14 October 2015 was published in order to regulate health advertising practices, by interventions of 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 inexistence of side effects;
- may be misleading regarding the nature, attributes and rights of the intervention in favour of which the advertising act is being carried out;
- induce the patient into taking a decision regarding a transaction that he or she otherwise would not have taken and that involve 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 discount' or 'with promotion' if the patient has to pay a higher amount than the expected amount to respond to such advertising act; or
- propose the acquisition of acts or services at a certain price, with the intention to promote 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 kind of awards. 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 5/2017 of 6 January 2017, which entered into force on 5 February 2017, major modifications were adopted in Portugal regarding the interactions between the industry and healthcare professionals and entities with activities related to healthcare. Decree-Law 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.

4 What are the main rules and principles applying to advertising 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.

Adverts 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 territory.

Infarmed is responsible for the manufacturing and marketing authorisation of medicinal products. All activities regarding the life cycle of medicinal products are subject to its regulation and supervision, including the advertising of medicinal products. Advertising to 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.

In 2013, the Code of Medicinal Products was subject to two major changes. In February 2013, it was amended by Decree-Law No. 20/2013 (14 February 2013), transposing Directive 2010/84/EU (15 December 2010) as regards pharmacovigilance. Subsequently, the Code was further amended in September 2013 by Decree-Law No. 128/2013 (5 September 2013), transposing Directive 2009/35/EC (23 April 2009) on the colouring substances that may be added to medicinal products, as well as Directive 2011/62/EU (8 June 2011) as regards the prevention of the entry into the legal supply chain of falsified medicinal products and Directive 2012/26/EU (25 October 2012) as regards pharmacovigilance. Other substantial amendments introduced into the Code include those regarding the advertising of medicinal products. Recently, Decree-Law 5/2017 extended the transparency legal framework to medical device companies, as mentioned above.

According to the above-mentioned new legal provisions, entities covered by the Code of Medicinal Products 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 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.

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

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

The use of comparative messages in advertisements to the general public is not allowed and 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 international non-proprietary name or brand name;
- the essential information for the rational use of the product, including therapeutic and special precautions; and
- a warning to the patient to peruse the information in the outer packaging and in the package leaflet, and to contact a doctor or a pharmacist if symptoms persist.

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

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

The most common infringements committed by manufacturers regarding advertisement rules arise from the misinterpretation of the advertising rules regarding comparative advertising. Since 2012, an increasing number of infringement procedures have been started by Infarmed. Until the second quarter of 2016, Infarmed evaluated 999 advertising materials, of which 650 concerned medicinal products and 349 concerned health products. During 2016, Infarmed maintained the monitoring of advertising materials submitted through the Medicinal Products Advertising System and improved the management platform for reporting, which improved the transparency of its functioning. Furthermore, Infarmed continues to ensure the compliance of market players with the principles applicable to the promotion of the rational use of medicinal products, medical devices and cosmetic and body hygiene products.

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

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

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

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 in 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 5/2017 goes further and recognises and established in the 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 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.

9 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 presentation and accompanied by a copy of the SPC.

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

10 What are the most common infringements committed by manufacturers with regard to collaboration with 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'.

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

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

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

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

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

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

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

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

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

14 What are the main mandatory anti-corruption and transparency rules applicable to pharmaceutical manufacturers?

The main mandatory anti-corruption rules applicable to pharmaceutical manufacturers, as in general to all entities, are the rules on bribery and active corruption set forth in articles 363 and 374 of the Portuguese Penal Code approved by Decree-Law 48/95 of 15 March 2016, as amended. Any person who commits bribery; those that convince, or try to convince an individual, through an offer or a promise of a material or otherwise benefit by issuing a false statement, a report or provide information that is not provided, being such criminal offense sanctioned with up to two years of imprisonment or 240 days of fine. Committing active corruption on those who directly or indirectly grant or promise to a civil servant, or to a third party with the knowledge of the civil servant, a material benefit or otherwise, to carry out an act or omission against the duties of the civil servant, which is a criminal offence sanctioned with one to five years of imprisonment. The civil servant may be sanctioned for active corruption.

Compliance – medical device manufacturers

15 Is the advertising of medical devices and the collaboration of manufacturers of medical devices with healthcare professionals and patient organisations regulated as rigorously as advertising and collaboration in the pharmaceuticals sector?

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

Advertising to the general public of medical devices that require the intervention and prescription of a healthcare professional, namely implantable devices, is not allowed. Apormed, the Portuguese association of companies manufacturing and marketing medical devices, has issued a Good Commercial Practice Code with guidelines regarding the relations between companies and 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 2015, the reinforcement of the monitoring of medical devices advertising is set as a priority.

Pharmaceuticals regulation

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

The Code of the Medicinal Products provides the legislative framework for granting marketing authorisations and manufacturing authorisations, and for the import, export, marketing, labelling, provision of information, advertising, pharmacovigilance and use of medicinal products for humans. This extensive Code transposes six European Union directives into Portuguese law and regulates the entire life cycle of medicinal products in Portugal. In 2013, the Code was substantially amended by Decree-Law No. 20/2013 (14 February 2013), which transposed into Portuguese law three EU directives, and Decree-Law No. 128/2013 (5 September 2013), which transposed a further three EU directives. Two areas are regulated under separate legal frameworks: clinical trials (which are ruled by Law 21/2014, 16/04 – in addition, from 28 May 2016 onwards, Regulation (EU) 536/2014 of the European Parliament and of the Council of 16 April 2014 will be directly applicable in all EU countries, including Portugal); and medicine pricing and reimbursement (which are ruled by Decree-Law 48-A/2010 of 13/05 and most recently Decree-Law 97/2015 of 01/06).

17 Which authorities may grant marketing authorisation in your jurisdiction?

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

18 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, transposed into Portuguese national law by the Code of Medicinal Products.

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

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

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

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

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

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

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

20 Which medicines may be marketed without authorisation?

In principle, medicinal products marketed in Portugal must all have a marketing authorisation. However, there are exceptional cases where Infarmed may grant a special-use authorisation or exceptional authorisation (see question 21).

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

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

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

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

Exceptional authorisations are granted strictly for public health reasons.

On 6 August 2015, Deliberation 1546/2015 of the Health Ministry and Infarmed was published, approving the new regulation regarding the procedures for granting exceptional use authorisations and the marketing authorisation for those medicinal products for which there is a pending application for a medicinal product authorised in another member state for which there is no authorisation or registration in Portugal.

Pricing and reimbursement of medicinal products

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

The market prices of medicinal products are regulated by law. The legal framework applicable to the pricing of reimbursed medicinal products, whether subject to medical prescription or not, is ruled by Decree-Law 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 the new 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 has as its aim a shift of 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 re-evaluation 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 2017, the reference countries were Spain, France and Italy. 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 the prices of generic products must be

requested by companies each year by 15 January, and the new prices will apply from 1 February of the following year. The annual price review of branded products is based on the average prices in the reference countries on the first day of the month prior to the prices review. The prices of generics must be reviewed based on the price of the reference medicinal product, and may not exceed 50 per cent of the maximum price of the reference medicinal product.

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

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

23 Must pharmaceutical manufacturers negotiate the prices of their products with the public healthcare providers?

There are two stages involved in negotiations with public healthcare providers. In the first stage, suppliers of the NHS are selected through centralised public tenders, where the manufacturers or holders of the marketing authorisation bid with the maximum price applicable to all NHS hospital and services, pursuant to the rules of the Code of Public Contracts (approved by Decree-Law 18/2008 of 29 January 2008, last amended by Decree-Law 214-G/2015 of 2 October), which is presently undergoing a legislative review by the government. 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.

The latest revision of the Code of Public Contracts enters into force on 1 January 2018.

24 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 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.

25 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 97/2015, the competent body for decisions regarding the pricing and reimbursability of medicinal products, whether subject to medical prescription or not, is Infarmed.

Infarmed is competent to authorise the maximum prices for sale to NHS hospitals of medicinal products for restricted hospital use (Decree-Law 97/2015 and Ministerial Order 195-C/2015).

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

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

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

Directive 2011/62/EU (8 June 2011), which introduced changes as regards the prevention of the entry into the legal supply chain of falsified medicinal products, was transposed into national law by Decree-Law 128/2013. The definition of 'falsified medicinal product' and of 'brokering of medicinal product' was introduced into national law by reproducing the definition established in Directive 2011/62/EU. According to these new rules, manufacturers and distributors must notify Infarmed and the marketing authorisation holder immediately if they become aware of falsified medicinal products, or if they have any suspicion in that respect. In addition, distributors must verify that the medicinal products received are not falsified by checking the safety features on the outer packaging. The outer packaging of medicinal products (where there is no outer packaging, the immediate packaging), must include safety features enabling distributors and persons authorised or entitled to supply medicinal products to the public to verify the authenticity of the medicinal product and identify individual packs, as well as a device allowing verification of whether the outer packaging has been tampered with. Infarmed is the responsible entity to receive notifications regarding falsified medicinal products. Most recently, Infarmed published Deliberation 47/CD/2015 of 19 March, approving the regulation regarding good distribution practices for medicinal products for human use, in accordance with article 59(10) of the Code of Medicinal Products. The good distribution practices now approved replace those established by Ministerial Order 348/98 of 15 June. The new regulation provides a special chapter concerning falsified medicinal products. This regulation entered into force on 1 July 2015.

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

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

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

Publicly reimbursed electronic prescriptions for medicinal products and diagnostic means have been mandatory for physicians in the public and private sectors since August 2011. The prescription of medicinal products by international non-proprietary name (INN) has been subject to new rules over the years. In 2012, further rules were passed restricting the prescription and dispensing of medicinal products, namely Law 11/2012 of 8 March 2012). Recently, Ministerial Order 224/2015 of 27 July was published, and has as an objective to introduce electronic prescription with the dematerialisation of the medical prescription. The mentioned rules impose the mandatory sale of the cheapest medicinal products available, except in cases where the patient opts for another medicinal product with the same INN. The medical prescription must be written in the following form: INN, pharmaceutical form, dosage, presentation and posology. A prescription including a brand name is only allowed in the following circumstances: the medicinal product does not have any reimbursable generic alternatives, and the original branded medicinal product and licence are unique; and in admissible exceptional cases, such as when the physician provides a valid technical justification for the use of the prescribed medicinal product in certain situations. Such prescription

(which must be hand written) is only allowed in exceptional situations, and the word 'exception' must be inserted under the logo of the Ministry of Health.

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

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

Moreover, the above-mentioned joint informative note establishes rules that are applicable in three different situations:

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

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

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

Recent amendments to the Medicinal Products Code, established by Decree-Law 20/2013 (14 February 2013) and Decree-Law 128/2013 (5 September 2013), mainly concern medicine safety matters. Directive 2010/84 (15 December), which amends Directive 2001/83/EU as regards pharmacovigilance, was transposed into national law in 2013. This reformulated the Portuguese National Pharmacovigilance System, and included new requirements to prevent, detect and assess adverse reactions to medicinal products placed on the EU market, as the full safety profile of medicinal products can only be known after they have been placed on the market. Directive 2012/26/EU (25 October 2012) also amended Directive 2001/83/EU as regards pharmacovigilance, and further strengthens the European rules respecting the safety and monitoring of medicinal products, and was transposed into national law in 2013.

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

Vaccination

30 Outline your jurisdiction's vaccination regime for humans.

Portugal has had a National Vaccination Programme (NVP) in force since 1965 that covers the entire population at no cost. The NVP provides a vaccination schedule recommended by the health authorities in Portugal. However, it is not confined to the vaccinations recommended at national level; in addition, there are vaccination programmes for special groups, such as immuno-compromised individuals, health professionals at risk, travellers to endemic areas and others, which also form part of the provisions and guidelines of the National Health General Directorate. Each person has a personal health booklet, implemented by Decree-Law 46621/65 (27 October), in which the vaccines are registered. The NVP currently in force was approved by Order 016/2016 of 31 July.

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Private M&A
Product Liability
Product Recall
Project Finance
Public-Private Partnerships
Public Procurement
Real Estate
Real Estate M&A
Renewable Energy
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