# The Life Sciences Law Review

Fifth Edition

Editor
Richard Kingham

Law Business Research

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# EDITOR'S PREFACE

The fifth edition of *The Life Sciences Law Review* covers a total of 37 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. The chapters are arranged to describe requirements throughout the life cycle of a regulated product, from discovery to clinical trials, the marketing authorisation process and post-approval controls. Certain other legal matters of special interest to manufacturers of medical products – including administrative remedies, pricing and reimbursement, competition law, special liability regimes and commercial transactions – are also covered. Finally, there is a special chapter on international harmonisation, which is of increasing importance in many of the regulatory systems that are described in the national chapters.

Now, more than ever, it is important for leaders in the pharmaceutical and medical device industries and their advisers to be knowledgeable about the laws and regulations in major jurisdictions around the world. In the past year, there have been significant developments in the regulation of drugs and medical devices, especially in the United States, where a new law – the 21st Century Cures Act – was passed at the end of 2016. There are prospects for further developments in the coming year. The new president and the Republican-controlled Congress will consider legislative measures affecting the pharmaceutical and medical device sectors, including proposed repeal of the Affordable Care Act, continuing inquiries into pricing of medical products and reauthorisation of user fee laws that fund a substantial part of the drug and device approval processes. The United Kingdom will initiate formal proceedings to begin the process of withdrawing from the European Union, with potential consequences for the medical products sectors. Other jurisdictions, including China and India, are considering reforms to their regulatory systems for medicinal products.

Each of the chapters has been written by leading experts within the relevant jurisdiction. They are an impressive group, and it is a pleasure to be associated with them in the preparation of this annual publication.

**Richard Kingham**
Covington & Burling LLP
Washington, DC
March 2017

# Chapter 26

# PORTUGAL

*Paulo Pinheiro and Francisca Paulouro*[1]

## I INTRODUCTION

The life sciences sector in Portugal is heavily regulated, with the legal framework applicable both to medicines and medical devices closely following the EU regulatory framework. Nevertheless, in some areas national legislation goes beyond what is provided for in the relevant directives; this being particularly noticeable, for example, in matters related to promotion, wholesale distribution and clinical trials. Pricing and reimbursement are exclusively dealt with at national level, being beyond the scope of EU legislation, with the exception of transparency measures and procedural requirements provided for in the Transparency Directive.[2]

The National Authority of Medicines and Health Products, IP (Infarmed) is the Portuguese national regulatory agency for medicines and medical devices. In addition to its competence for technical health regulation, Infarmed's powers also cover pricing and reimbursement. Price approval of prescription products, including products for hospital use, is also attributed to this agency. Infarmed plays a significant role in the reimbursement of medicines, being the entity responsible for conducting the relevant procedures and proposing decisions to the Minister of Health.

1 Paulo Pinheiro is a partner and Francisca Paulouro is an of counsel at Vieira de Almeida & Associados.

2 Council Directive of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems.

## II THE REGULATORY REGIME

The Medicines Act[3] consolidates in one piece of legislation the regime applicable to, among others, the marketing authorisation, manufacture, import, export, marketing, labelling, promotion and pharmacovigilance of medicines; transposing into Portuguese Law several directives, including Directive 2001/83/EC,[4] as amended (the Directive).

Medical devices, in turn, are governed by Decree-Law 145/2009,[5] which, further to transposing several Directives (including Directive 93/42/EEC,[6] as amended) related to the manufacture, marketing and vigilance of medical devices, establishes the regime applicable to promotion. With regard to promotion, Decree-Law 145/2009 closely follows the regime foreseen for medicines.

### i Classification

The definitions of a medicinal product for human use and of a medical device are identical to those arising from EU legislation, with the distinction between them being made on the basis of the intended use and the mechanism through which this is achieved. As is the case under the Directive, where any doubt arises, the classification as a medicinal product prevails.

### ii Non-clinical studies

Directive 2010/63/EU[7] on the protection of animals used for scientific purposes was transposed into Portuguese Law in August 2013.[8] This regime follows closely the one provided for in the corresponding Directive, thus establishing several requirements applicable to the use of animals for scientific or educational purposes, namely in what concerns the accommodation, care and use of animals in procedures; the origin, breeding, marking and killing of animals; licensing of breeders, suppliers and users; and the procedures for evaluation and authorisation of scientific or educational projects.

In addition, and similarly to what happens at EU level, the testing of finished cosmetic products and cosmetic ingredients on animals is prohibited, with the same applying to the marketing thereof if animal testing was conducted for cosmetic purposes.

### iii Clinical trials

In April 2014, a new legal regime for clinical research was approved,[9] consolidating in one single legal act the provisions applicable to clinical studies, be it interventional or not, and covering medicines, medical devices and cosmetics. The regime set forth therein covers

3 Decree-Law 176/2006 of 30 August 2006, as amended.

4 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use.

5 Decree-Law 145/2009 of 17 June 2009.

6 Council Directive 93/42/EEC of 14 June concerning medical devices.

7 Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010.

8 Decree-Law No. 113/2013 of 7 August 2013.

9 Law No. 21/2104 of 16 April 2014.

that provided for in Directive 2001/20/EC[10] regarding the conduct of clinical trials on medicinal products for human use and the provisions of Directive 2007/47/EC[11] on clinical investigation with medical devices.

All clinical studies are subject to a prior favourable opinion from the competent ethics committee. In addition, clinical trials with medicines depend on authorisation from Infarmed, with the same applying to interventional studies with Class III medical devices, implantable medical devices and long-term invasive devices falling within Classes IIa or IIb. For the remaining classes of medical devices, interventional studies depend only on the favourable opinion from the ethics committee and on notification to Infarmed. The conduct of clinical interventional studies with cosmetics should also be notified in advance to Infarmed, with the sponsor being entitled to initiate the study should Infarmed not issue an unfavourable decision within 30 days from said notification.

Both the sponsor and the investigator are jointly and severally liable, regardless of fault, for material and non-material damage suffered by subjects – liability that must be covered by insurance. Should an interventional study be at stake, there is a legal presumption that damage that affects the health of subjects during the study and for a one-year period following its term (which may be extended by the ethics committee) is caused by the study. This reverses the general rule on burden of proof, subject to which, whosoever alleges damage should demonstrate the causal relationship between the damage and the act (in this case, the study).

### iv Named-patient and compassionate use procedures

Similar to what happens under EU legislation, the general rule is that medicines can only be marketed following the granting of a marketing authorisation. In exceptional circumstances, however, Infarmed may authorise the use of non-approved medicines, such as, when the product is, subject to a clinical assessment, considered indispensable for the treatment of a given pathology and there is no therapeutic alternative among authorised products.

It should be noted that within the context of interventional clinical studies, following the conclusion thereof, the sponsor is under an obligation to supply the investigational medicinal product or the device under clinical investigation for free until its marketing, should the investigator consider that continuation of its use by the former participant is indispensable and that there are no therapeutic alternatives with an equivalent degree of safety and efficacy.

10 Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

11 Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007, amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.

### v Pre-market clearance

The Medicines Act reflects EU rules in this regard and thus medicines can only be placed in the market following the granting of a marketing authorisation – Infarmed being the competent authority for authorising medicines that follow national procedures.

The marketing, in Portugal, of medical devices bearing a CE marking, does not require any authorisation from Infarmed. Nonetheless, Infarmed must be notified of all medical devices marketed by a given entity prior to its commercialisation.

### vi Regulatory incentives

The Medicines Act reflects the regime provided for in the Directive regarding regulatory data protection and market exclusivity. Generic applications cannot be submitted for an eight-year period following the first authorisation in the EU. After this eight-year period has elapsed, the generic cannot be launched in the market for an additional two-year period – a period that may be extended for one supplementary year should the innovator, within the data exclusivity period of eight years, obtain a marketing authorisation for one or more indications of significant clinical benefit.

Patent linkage is not permitted. The Medicines Act expressly provides that marketing authorisations cannot be dismissed on the grounds of the potential existence of industrial property rights of the reference product. A similar rule exists for pricing and reimbursement decisions.

There are no special provisions to encourage the development or market launch of innovative products. On the contrary, special provisions to encourage the sale of generics exist in a variety of areas; for example, generics benefit from a simplified regime regarding pricing and reimbursement, and prescription is mandatorily made by active substance once a generic is launched in the market, the rule being that of generic substitution, save in very limited circumstances expressly provided for by law.

### vii Post-approval controls

Pharmacovigilance rules applicable to medicinal products were modified in 2013 with the transposition into Portuguese Law of Directives 2010/84/EU and 2012/26/EU.[12] In this same year, the provisions of Directive 2011/62/EU[13] as regards the prevention of the entry into the supply chain of falsified medicinal products were also transposed, with the Medicines Act currently closely following the EU legislation on these matters.

The same can be said regarding medical devices, where the vigilance requirements stem from the relevant Directives. In addition, a pharmacovigilance system has been enacted similar to that which applies to medicines.

### viii Manufacturing controls

In line with what is provided for in the Directive, the manufacture of medicinal products is subject to prior authorisation from Infarmed, even if products are intended for export. Such

12 Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 and Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012.

13 Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011.

an authorisation will only be granted if the applicant has adequate premises that comply with the applicable legislation, and with the European Commission Guidelines on Good Manufacturing Practices, and has a qualified person permanently and continuously at its disposal. Said qualified person who is responsible for all manufacturing activities performed, must be a pharmacist registered with the Portuguese Order of Pharmacists. Any change to the manufacturing authorisation requires prior authorisation from Infarmed. In addition, the Medicines Act was amended in 2013, transposing Directive 2011/62/EU and thus requiring that the manufacturers of active substances established in Portugal register their activity with Infarmed.

The manufacture of medical devices, as well as the assembling, packaging, processing, fully refurbishing, labelling or assigning to them a purpose different from that of its original intended use, among others, is subject to prior notification to Infarmed. The engagement in these activities is dependent on the applicant having adequate premises and equipment with capacity to ensure the manufacture, storage and conservation of medical devices and a technician responsible to ensure the quality of the activities performed.

In addition, and in line with what is set forth in EU regulations, manufacturers or their authorised representatives placing medical devices on the Portuguese market should notify Infarmed thereof, with the level of information to be provided in said notification varying depending on the classification or nature of the device concerned.

### ix Advertising and promotion

The regime applicable to the advertising of medicines closely follows the regime provided for in the Directive. The major differences relate to the definition of advertising, to the scope of the prohibition on granting benefits to healthcare professionals and to the prohibition on granting any kind of benefit to patients, matters in respect of which the Medicines Act goes beyond what is established in the Directive.

The definition of advertising is broader than that set forth in the Directive, advertising being considered, under the Medicines Act, as any kind of information, canvassing activity or inducement that has as its object or effect the promotion of the prescription, dispensation, sale, purchase or consumption of medicines. Contrary to what is foreseen in the Directive, Portuguese law does not require that a given conduct be designed to promote a given product to qualify it as advertising. It suffices that the conduct at stake has such an effect.

Secondly, the Medicines Act extends the scope of the prohibition on pharmaceutical companies granting gifts, pecuniary advantages or benefits in kind to healthcare professionals to also include bonuses – a notion that is associated with the granting of discounts in kind, such as free products. The broadening of this prohibition is particularly relevant to the relationship between pharmaceutical companies and pharmacies, being hardly in line with the EU legal framework and with the principle that promotion rules do not apply to measures or trade practices related to prices, margins and discounts – provided for both in the Directive and in the Medicines Act.

Finally, the Medicines Act was amended in 2013 to prohibit pharmaceutical companies from granting any kind of benefit to patients. Resembling what has already happened in relation to healthcare professionals, companies cannot currently grant or promise to grant, directly or indirectly, gifts, prizes, bonuses, pecuniary advantages or benefits in kind to patients.

Although companies are under an obligation to provide Infarmed with a summary description of all advertising materials, no prior-approval requirement exists. In addition, and as from 2013, companies must notify Infarmed in advance of the sponsorship of any congress, symposia or event of an educational or promotional nature.

The regime applicable to advertising and promotion of medical devices is very similar to that applicable to medicines. There is, however, no prohibition on granting gifts to the public, neither are companies required to notify Infarmed of advertising materials or sponsorship of congresses. The advertising of medical devices, the use of which requires the intervention of healthcare professionals, such as implantable medical devices, cannot be promoted to the public.

### x Distributors and wholesalers

Wholesale distribution of medicines is subject to prior authorisation from Infarmed, with the only exception being – similar to what happens under the Directive – for holders of manufacturing authorisations in relation to the products covered by said authorisations.

The granting of such an authorisation is dependent on the applicant having adequate equipment and premises, located in Portugal, to ensure proper conservation and distribution of medicines and a technical director, who must ensure, on an effective and permanent basis, the quality of the activities carried out in the distribution premises. The technical director must be a pharmacist registered with the Portuguese Order of Pharmacists and personally fulfil his or her responsibilities in the wholesale premises. Up until 2013, the technical director had to exercise the functions of the role on an exclusive basis and could not perform said functions for more than one company, even if the wholesale distribution premises were the same. Currently a technical director may cumulate functions within the same wholesale premises, up to a limit of five wholesale distribution authorisations. In 2015, a new regulation on good distribution practices applicable to the wholesale distribution of medicines[14] was approved, closely following Commission Guideline 2013/C 343/01.[15]

In addition, wholesalers are under a legal obligation to have permanently available medicines in sufficient quantity and variety to ensure the appropriate and continued supply of medicinal products with a view to guaranteeing the satisfaction of patients' needs. The minimum quantities of products that wholesalers must keep at all times to comply with this public service obligation were set forth in a regulation issued by Infarmed.

In 2013, to address shortages of medicinal products on the Portuguese market, mainly resulting from parallel exports to other European Union Member States, the Medicines Act was amended, granting Infarmed powers to list the medicines of which it requires notification prior to exportation (within and outside the EU). In 2015, Infarmed published a regulation setting forth the terms applicable to said notification as well as the medicines covered thereby – a list that has been regularly updated – with wholesalers currently being under an obligation to notify in advance all sales made to countries outside Portugal of medicines included therein. In addition, marketing authorisation holders, wholesalers and pharmacies must notify Infarmed, on a monthly basis, of the quantities of certain listed medicinal products that are sold, dispensed, exported or subject to intra-community commerce. The compatibility of this regime with principles of EU law has always been far from clear. In

14 Infarmed's Resolution No. 047/CD/2015 of 19 March 2015.

15 Commission Guideline 2013/C 343 of 5 November 2013.

2016, the European Commission initiated a procedure against Portugal, determining, in its reasoned opinion, that Portugal should suppress unjustified and disproportionate notification obligations because they constitute an obstacle to the free movement of goods within the EU. In order to comply with the terms of the reasoned opinion, Infarmed's regulation has been reviewed and a draft is currently under public consultation. Finally, Infarmed has the power to prevent the exportation of medicines – be it inside or outside the EU – on the grounds of protection of public health or to ensure patient access to a given medicinal product.

Finally, the notion of brokering of medicinal products, provided for in the Medicines Act follows closely that of Directive 2011/62/EU.[16] As in the regime foreseen under this Directive, engagement in the activity of brokering does not require prior authorisation from Infarmed; neither is it dependent on the existence of premises or a permanent address in Portugal. Persons brokering medicines with a permanent address in Portugal must register their activity with Infarmed.

Engagement in the activity of wholesale distribution of medical devices, although not subject to express authorisation from Infarmed, must be notified in advance to said authority, and is only permitted if (as applicable to medicines) the applicant has adequate premises and equipment with capacity to ensure good storage, conservation and distribution of medical devices and a responsible technical director is appointed to the wholesale premises to ensure the quality of the activities performed. In contrast to the regime applicable to medicines, the technical director does not have to be a pharmacist but must have an adequate technical qualification to ensure the quality of the distribution activity, as well as adequate knowledge of the legislation and regulations applicable to medical devices. In contrast to what is applicable to medicines, the wholesale premises do not have to be located in Portugal. Nonetheless, should the premises be located abroad, the applicant must comply with the Portuguese legal provisions applicable to the wholesale distribution of medical devices. In 2016, good distribution practices applicable to the wholesale distribution of medical devices were finally approved[17] after the general legal regime applicable to medical devices was published in 1999. The regime that was recently approved is extremely demanding and, in many aspects, follows the regime currently applicable to the wholesale distribution of medicines.

### xi Classification of products

The criteria laid down in the Medicines Act for classifying a medicine for medical prescription are very similar to those provided for in the Directive.

Such a classification has relevant consequences for the regime applicable to advertising, pricing, reimbursement and point of sale or dispensing. Only non-prescription products may be promoted to the general public, which is the same under the Directive. In addition, while there is no price control for non-prescription drugs (and the rule is that non-prescription products are not subject to reimbursement), prescription products have their maximum sales price approved, regardless of whether they are reimbursed or not. Finally, whereas the dispensing of prescription drugs is restricted to pharmacies – unless subject to restricted medical prescription, in which case they can only be dispensed or administered in hospitals – over-the-counter products (OTCs) may be sold at points of sale duly authorised by Infarmed.

16 Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011.

17 Ministerial Order No. 256/2016 of 28 September 2016.

### xii Imports and exports

In line with the regime set forth in the Directive, and as was described in subsection viii, *supra*, in relation to their manufacture, the importation of medicines is also subject to prior authorisation from Infarmed, and with very similar requirements. The importation of active substances is also subject to registration with Infarmed. The export of medicinal products does not require any authorisation from Infarmed; neither does such an activity require registration with Infarmed.

As to medical devices, there are no additional requirements related to imports and exports other than those applicable to the manufacture, placing in the market and wholesale distribution, analysed above.

### xiii Controlled substances

The manufacture, use, marketing, distribution, importation, exportation and possession of narcotics and psychotropic substances are subject to a specific regime. Narcotics and psychotropic substances are divided into several categories, each category identifying the substances belonging thereto. Infarmed is the entity responsible for authorising engagement in said activities in relation to certain categories of substances. Specific requirements also exist for prescription, dispensing and keeping of records when such substances are included in medicinal products.

Note that further to constituting a misdemeanour punishable with a fine, engagement in any of the above-mentioned activities without the relevant authorisation may be considered as a criminal offence.

### xiv Enforcement

Infarmed is entrusted with the supervision and enforcement of regulatory provisions applicable to medicines and medical devices.

The breach of said provisions is considered a misdemeanour punishable with a fine calculated by reference to the infringer's turnover if not exceeding a predetermined fixed amount – in which case the latter will apply. Together with this penalty, breach of the provisions of the Medicines Act, including advertising, may give rise to additional ancillary sanctions to be applied by Infarmed, such as, a prohibition on exercising the activity, exclusion from participation in public tenders and the suspension of any authorisations and permits – all up to a maximum of two years.

Should the infringement of promotion rules be at stake, both regarding medicines and medical devices, Infarmed may order that the condemnatory decision be published in the media as well as the suspension of advertising of the product concerned for a period of up to two years. Medicinal products may further be delisted as a result of infringement of promotion rules.

## III PRICING AND REIMBURSEMENT

On 1 June 2015, Decree-Law No. 97/2015 was published, creating the System of Assessment of Health Technologies (SiNATS). SiNATS gathers in one single legal diploma the provisions applicable to pricing, reimbursement and prior evaluation procedures.

In short, SiNATS brings about three main changes:

*a* clear reinforcement of the powers of public authorities – the state being granted the capacity to unilaterally and in an almost unlimited manner amend and terminate contractual agreements executed with the pharmaceutical industry;

*b* an unprecedented concentration of powers within Infarmed; and

*c* flexibility on applicable rules, considering that several matters are referred to governmental and Infarmed's regulations, thus facilitating the swift change of provisions.

Several Decrees have been approved since the entry into force of SiNATS, establishing the regime regarding specific matters, such as: (1) the procedure for reimbursement and prior evaluation;[18] and (2) the rules and procedures applicable to the setting and revision of prices of medicines subject to medical prescription and reimbursed OTCs, as well as corresponding marketing margins.[19]

Notwithstanding the importance of SiNATS, the essential features of the previous regimes remain untouched. For example, Portuguese rules on pricing and reimbursement of medicines continue to differ, essentially depending on the classification of the product for dispensing purposes.

Medicines subject to medical prescription yet not restricted medical prescription, and generally sold in street pharmacies, have to undergo a price approval procedure before Infarmed prior to being launched in the market. In this context, a maximum sales price is approved, which, in the case of branded products, is determined by reference to the price applied in three reference countries. Said price is subject to annual revision in accordance with the same criteria. One of the most important innovations brought by SiNATS concerning this regime is that the maximum sales price may now be requested and approved within the reimbursement procedure (previously, the marketing authorisation holder could only request reimbursement following the respective price approval).

Approval of reimbursement is within the competence of the Minister of Health and will only be granted should the therapeutic added value and economic advantage of the product be demonstrated.

Another striking feature of SiNATS lies in the increased importance of the execution of agreements between Infarmed and the marketing authorisation holders, although the execution thereto continues not to be legally mandatory. These agreements typically set forth a maximum sales value for the reimbursed product, which, once exceeded, will determine a payback by the marketing authorisation holder to the National Health Service equivalent to the amount of reimbursement in excess of said limit. Other types of agreements are now expressly provided for under SiNATS, such as risk-sharing arrangements. SiNATS also approved specific rules for the reimbursement of similar biological medicines conditioning the approval thereto to its price not exceeding 80 per cent of the price of the reference biological medicine.

A 'reference price' system exists in the context of reimbursement. Until a generic is launched on the market, the percentage of state reimbursement, ranging from 15 per cent to 90 per cent, save in exceptional circumstances provided for in specific regulations, applies to

18 Decree No. 195-A/2015 of 30 July.

19 Decree No. 195-C/2015 of 30July.

the retail sales price of the product. The placing in the market of a generic, however, gives rise to the creation of a 'homogenous group', composed of branded or innovative medicines and generics with the same active substance, dosage, method of administration and pharmaceutical form, and to the approval of the correspondent reference price – equivalent to the average of the retail sales price of the five lowest-priced products included in the group. Following approval of the reference price, the maximum amount of state reimbursement for products included in the relevant group will be determined by applying the applicable reimbursement percentage to said price.

In parallel, with a view to being sold to National Health Service hospitals, medicines subject to medical prescription have to undergo a prior evaluation procedure, in the context of which the respective maximum sales prices are approved by the Ministry of Health, or Infarmed, should said competence be delegated. Until the approval of SiNATS this regime only existed for medicines subject to restricted medical prescription. Note, however, that if the medicine is already reimbursed, it is exempt from this procedure – unless otherwise decided by the Ministry of Health or Infarmed, should said competence be delegated.

As with reimbursement, the therapeutic added value and economic advantage of the product under evaluation must be demonstrated within this procedure for a favourable decision to be issued. Such a decision further implies the execution of an agreement between Infarmed and the marketing authorisation holder whereby, among other aspects, the maximum sales price to hospitals is established. Just as we have seen in the context of reimbursement, these agreements also usually establish a maximum sales value for the product, which, if exceeded, should be paid back by the marketing authorisation holder.

Regarding medical devices, prior to the approval of SiNATS in 2015, the rule applicable thereto was that the relevant sales price was either free or arose from public procurement procedures, whenever applicable, with the exception of test strips, needles, syringes and lancets destined for persons with diabetes that were subject to a price control and reimbursement regime.

As a result of SiNATS, the medical devices sector may evolve from a reality of commercial freedom, in which only the prices of these products were controlled, to one of high regulation. In fact, SiNATS foresees the possibility of administratively setting the sales price of medical devices and of approving their reimbursement, as well as conditioning these products to a prior evaluation procedure, similar to that which exists for medicines, with a view to being used or purchased by National Health Service hospitals. In practice, this general legal framework has rarely been enforced and the medical devices sector continues to be poorly regulated.

## IV ADMINISTRATIVE AND JUDICIAL REMEDIES

Final decisions from Infarmed in the context of regulatory, pricing and reimbursement matters are subject to judicial review by administrative courts. The decisions are immediately effective, with the initiation of legal action *per se* not suspending the effects thereto. Matters of a technical nature are not reviewed by administrative courts except in cases of manifest error and administrative courts do not issue technical judgments.

In addition, decisions issued by Infarmed within the context of misdemeanour proceedings initiated for breach of regulatory provisions are subject to appeal before the judicial courts.

## V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYERS

The Medicines Act transposed into Portuguese law the provisions of the Directive on the promotion of medicinal products, including interactions with healthcare professionals. The rule is, therefore, that pharmaceutical companies cannot offer or promise to offer, directly or indirectly, gifts, pecuniary advantages or benefits in kind to healthcare professionals, unless they are inexpensive and relevant to the practice of medicine or pharmacy. For several years there was no legal indication as to what should be considered 'inexpensive'. This state of affairs changed in 2013 when a Decree was published that (as had already been similarly foreseen in the Code of Ethics of the Pharmaceutical Industry Association) set €25 as the inexpensive limit. This amount was increased to €60 in late 2014.

In addition, transparency obligations were enacted in 2013, obligating pharmaceuticals companies to notify Infarmed of any payment or offer made, the value of which exceeds €60, to any individual or legal entity, such as healthcare professionals, medical or scientific associations, patient associations and healthcare institutions. An identical obligation falls upon the recipient. This information is publicly available on Infarmed's website.

Within the context of medical devices, the regime is less strict. Although the principle that no offer can be made to healthcare professionals unless of insignificant value and relevant to the healthcare professional's practice also exists, no limit is expressly provided for the notion of 'insignificant'. In addition, no transparency obligations have yet been enacted – although said regime has already been approved by the government and is awaiting promulgation by the President.

In early 2014, a specific conflict-of-interest regime for the health sector was approved. Said regime prevents, among others, members of commissions, working groups, juries and National Health Service consultants whose role involves the market access of products (e.g., involvement in pricing and reimbursement procedures, in pharmacoeconomic assessments, in the approval of therapeutic guidelines and purchase procedures) from performing functions, either regularly or occasionally, for payment by pharmaceutical companies. Breach of these rules constitutes a misdemeanour punishable with a fine. In addition, in the event of such a breach, the opinions issued or decisions adopted by said commissions, working groups, juries and consultants do not produce any legal effects and any decisions adopted by decision-making bodies based on the same are considered null and void.

## VI SPECIAL LIABILITY OR COMPENSATION SYSTEMS

With the exception of damages arising from harm suffered by subjects in clinical studies (the regime described in Section II.iii, *supra*), there is no specific compensation or liability regime applicable to damages arising from harm caused by the use of medicines or medical devices. Product liability claims are therefore subject to the general legal regime concerning liability for defective products.

## VII TRANSACTIONAL AND COMPETITION ISSUES

The Portuguese Competition Law (Law No. 19/2012) prohibits agreements, concerted practices and decisions by associations of undertakings, as well as abuses of a dominant position, capable of preventing, distorting or restricting competition in the Portuguese

market. Competition rules apply to pharmaceutical companies whenever possible, despite such companies being subject to strict regulation in matters such as market access, distribution and pricing.

The Portuguese Competition Authority (PCA) focused on competition issues related to distribution and abuse of dominance, having, in the course of 2016, requested information on a number of cases on refusal to deal with wholesalers and on distribution networks on pharmaceutical products.

Proceedings initiated in 2014 in relation to patent settlement agreements between AstraZeneca and Teva/Ratiopharm have meanwhile been closed, with the PCA finding that the settlement was indeed confined to the resolution of the dispute.

In May 2016, the Portuguese Competition Court confirmed the PCA decision imposing a fine upon a major pharmaceutical company, although reducing the amount to €3 million from €7 million. The case was initiated in 2008 when the PCA fined said company (as well as three other major pharmaceutical companies) for bid rigging in several public tenders for the supply of reagent strips to Portuguese hospitals between 2001 and 2004. This 2016 decision puts an end to a long judicial battle, in the context of which more than 20 interim decisions were awarded.

The Portuguese Competition Court also confirmed the PCA decision imposing a fine on the National Association of Pharmacies (ANF) and three companies of the ANF Group, again reducing the global amount of the fine. The case dates back to 2015, when the PCA fined ANF and three companies of the ANF Group a total of just over €10.3 million for abuse of dominant position in the form of a margin squeeze (reduced by the Portuguese Competition Court to €6.89 million). Having found that the ANF Group maintained activity both in the market for sale of pharmacies' commercial data, and, since 2009, in the market for the provision of pharma market studies based on that data, the PCA concluded that between 2010 and 2013 the prices charged by the ANF Group for pharmacies' commercial data (upstream market) and for pharma market studies based on those data (downstream markets) did not leave an equally efficient competitor active in the downstream market a sufficient margin to cover its costs.

During 2016, the PCA engaged in a nationwide road show dedicated to promoting competition rules awareness and, in particular, the need to fight bid rigging in public procurement. Indeed, announcing its priorities for 2017, the PCA highlighted once again the importance of ensuring effective competition in public procurement procedures. Therefore, investigations launched by the PCA regarding the conditions under which public hospitals are supplied may be expected. The priorities for 2017 also provide that the PCA intends to increase the number of ex-officio cases by 15–20 per cent and that a dedicated online tool and hotline will be implemented in order to receive complaints, which may also result in an increased number of antitrust investigations.

## VIII CURRENT DEVELOPMENTS

As expected, 2016 was a year dedicated to the implementation of SiNATS. While the medical devices sector was, in essence, spared, the medicines sector was heavily impacted, with Infarmed, among others, initiating several reimbursement revaluation procedures in more than one therapeutic area with a view to determining whether reimbursement continued to be justified and enforcing its extremely broad powers within reimbursement contracts executed with pharma companies. Containing public expense with pharmaceuticals was a

priority in 2016 and will certainly drive the year 2017. This is clear in the National Strategy for Medicines and Health Products approved by the government in October 2016 for the period of 2016–2020. The priorities foreseen in that period include the systematic re-evaluation of reimbursed medicines, the issuance of therapeutic recommendations (already present in 2016), the introduction of changes to the price referencing system when generics or biosimilars exist, and the increase of the quota use of generics and biosimilars. The Budget Law for 2017 actually provides that the government should reinforce measures to encourage the use of generics so that the respective quota achieves 40 per cent.

Changes are also expected in the field of promotion of both medicines and medical devices. The government is keen to reinforce measures to ensure that National Health Service hospitals are not influenced by any kind of support received from pharmaceutical companies. Going beyond the Directive, where interaction with healthcare professionals in the context of promotion of medicines is one of the key concerns, the government now focuses on National Health Service hospitals, purchasers of medicines and medical devices, with a view to guaranteeing neutrality and impartiality within the scope of public purchases. Strict measures are expected in this regard. The enactment of transparency obligations within the medical devices sector, similar to those that exist in the medicines sector, are also expected.

## Appendix 1

# ABOUT THE AUTHORS

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Paulo Pinheiro is a partner at Vieira de Almeida & Associados and head of the firm's life sciences and public law practice groups. He has deep knowledge of regulatory matters, both under EU and national law, and has extensive experience in life sciences (pharmaceuticals, biotechnology, medical devices and cosmetics). For the past 20 years, he has been working with the major innovative pharmaceutical companies operating in Portugal as well as the Portuguese Pharmaceutical Industry Association. He is constantly ranked by *Who's Who Legal* as a recommended lawyer for life sciences. His expertise in public law covers a variety of matters, such as, regulation, public procurement, public-private partnerships, litigation and arbitration proceedings, and multiple sectors of activity, including, health, telecoms, energy and natural gas, transport, water and waste. He is a member of the Commission for Access to Administrative Documents, an independent administrative body, operating under the aegis of the Parliament, and responsible, among others, for issuing opinions on matters regarding citizens' right to access administrative information. As an acknowledgement of his standing in public law, he has, for several years, been ranked as a leading individual by *Best Lawyers*, *Chambers Europe* and *The Legal 500*.

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Francisca Paulouro is an of counsel at Vieira de Almeida & Associados, and has worked in the firm's life sciences practice group for more than 10 years. She has significant expertise in regulatory matters related to pharmaceuticals, biotechnology, medical devices and cosmetics, both under EU and national law. She is fully dedicated to life sciences, assisting, on a day-to-day basis, several major innovative pharmaceutical companies operating in Portugal, and the Portuguese Pharmaceutical Industry Association. Her expertise and work with clients cover a wide range of matters, such as pricing and reimbursement, distribution and marketing,

clinical trials, promotion, marketing authorisation and data exclusivity; matters in which she has been involved in several cross-border projects. She is ranked by *Who's Who Legal* as a recommended lawyer for life sciences.

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