THE LIFE SCIENCES LAW REVIEW

SIXTH EDITION

Editor
Richard Kingham

THE LAWREVIEWS

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CONTENTS

PREFACE vii
Richard Kingham

Chapter 1 INTERNATIONAL HARMONISATION 1
Richard Kingham

Chapter 2 LATIN AMERICA OVERVIEW 6
Felipe Coronel

Chapter 3 ARGENTINA 16
Emilio N Vogelius

Chapter 4 AUSTRALIA 29
Anthony Muratore, Stephen Rohl and Matthew Whitaker

Chapter 5 AUSTRIA 43
Karina Hellbert

Chapter 6 BELGIUM 57
Peter Bogaert and Charlotte Ryckman

Chapter 7 BRAZIL 72
Alexandre Einsfeld, Joaquim Queiroz and Ivan Cunha

Chapter 8 CHINA 83
Andrew Shaoyu Chen and John Balzano

Chapter 9 CZECH REPUBLIC 117
Vojtěch Chloupek and Roman Norek

Chapter 10 DENMARK 129
Martin Dræbye Gantzhorn and Lise Aagaard

Chapter 11 EUROPEAN UNION 139
Grant Castle and Robin Blaney

Chapter 12 FINLAND 162
Hanna Paloheimo and Hilma-Karoliina Markkanen

Chapter 13 FRANCE 173
Sophie Pelé

Chapter 14 GERMANY 185
Ulrich Grau and Stefan Stadelhoff

Chapter 15 INDIA 198
Pravin Anand and Archana Shanker

Chapter 16 IRELAND 208
Colin Kavanagh and Ciara Farrell

Chapter 17 ISRAEL 225
Dovev Apel

Chapter 18 ITALY 243
Marco Blei, Luca Gambini, Enzo Marasà and Elisa Stefanini

Chapter 19 JAPAN 259
Takeshi S Komatani

Chapter 20 KOREA 281
Jung Min Jo

Chapter 21 LITHUANIA 294
Rūta Pumputienė and Ieva Balėnė

Chapter 22 NEW ZEALAND 310
Robert Andrew Bycroft and Tina Liu

Chapter 23 NORWAY 325
Kirti Mahajan Thomassen and Rune Nordengen

Chapter 24 PERU 336
María del Carmen Alvarado Bayo and Ricardo De Vettor Pinillos

Chapter 25 POLAND 345
Ewa Skrzydło-Tefelska and Jacek Myszko

Chapter 26 PORTUGAL 357
Paulo Pinheiro and Francisca Paulouro

Chapter 27 RUSSIA 371
Evgeny Alexandrov and Ilya Goryachev

Chapter 28 SINGAPORE 384
Melanie Ho and Jacqueline Chua

Chapter 29 SPAIN 401
Raquel Ballesteros

Chapter 30 SWEDEN 412
Camilla Appelgren and Odd Swarting

Chapter 31 TAIWAN 426
Katherine Juang, Jill Niu and Daisy Wang

Chapter 32 THAILAND 440
Peerapan Tungsuwan and Praween Chantanakomes

Chapter 33 UNITED ARAB EMIRATES 451
Melissa Murray and Saladin Aljurf

Chapter 34 UNITED KINGDOM 460
Grant Castle and Sarah Cowlishaw

Chapter 35 UNITED STATES 475
Richard Kingham and Krista Hessler Carver

Chapter 36 VENEZUELA 511
Luis Lopez-Durán and Rosa Virginia Superlano

Appendix 1 ABOUT THE AUTHORS 519
Appendix 2 CONTRIBUTING LAW FIRMS' CONTACT DETAILS 543

PREFACE

The sixth edition of *The Life Sciences Law Review* covers a total of 34 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. The chapters are arranged so as 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.

It is vitally important that lawyers who advise companies in the life sciences sector, and the business executives whom they serve, have a working knowledge of the regulations and policies that govern drugs, biologics and medical devices. It is equally important to keep current with developments in the regulatory systems, which govern access to the market, pricing and reimbursement, advertising and promotion and numerous other matters that are essential to success. It is our hope that this annual publication will be helpful in this respect.

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 2018

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 the provision in the relevant directives; this is particularly noticeable, for example, in matters related to promotion, wholesale distribution and clinical trials. Pricing and reimbursement are exclusively dealt with at national level, as they are beyond the scope of EU legislation, with the exception of transparency measures and procedural requirements set out in the Transparency Directive.[2]

The National Authority of Medicines and Health Products, IP (Infarmed), is the 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.

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 (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

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

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.

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, as amended by Decree-Law No. 5/2017 of 6 January 2017.

6 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

foreseen for medicines. In early 2017, Decree-Law No. 5/2017[7] introduced general principles applicable to the promotion of medicines and medical devices, and further implemented specific rules for scientific, educational and promotional events that take place in National Health Service entities.

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[8] on the protection of animals used for scientific purposes was transposed into Portuguese law in August 2013.[9] This regime follows closely the one set out in Directive 2010/63/EU, 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,[10] consolidating in one single legal act the provisions applicable to clinical studies, whether interventional or not, and covering medicines, medical devices and cosmetics. The regime covers the provisions of Directive 2001/20/EC[11] regarding the conduct of clinical trials on medicinal products for human use and the provisions of Directive 2007/47/EC[12] 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

7 Decree-Law No. 5/2017 of 6 January 2017.

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

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

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

11 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.

12 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.

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 of the 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.

Within the context of interventional clinical studies, following the conclusion of a study, the sponsor is under an obligation to supply the investigational medicinal product or 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.

v Pre-market clearance

The Medicines Act reflects EU rules in this regard and thus medicines can only be placed on 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 mark 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 established in the Directive regarding regulatory data protection and market exclusivity. Generic applications cannot be submitted for a period of eight years following the first authorisation in the European Union. After this eight-year period has elapsed, the generic cannot be launched on the market for an additional two years. This period 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 other hand, 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 Directive 2010/84/EU and Directive 2012/26/EU.[13] In this same year, the provisions of Directive 2011/62/EU[14] 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 implemented that is similar to the system applicable to medicines.

viii Manufacturing controls

In line with the Directive, the manufacture of medicinal products is subject to prior authorisation by Infarmed, even if products are intended for export. 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. The 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 by 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, providing in the notification the required level of information depending on the classification or nature of the device concerned.

13 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.

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

ix Advertising and promotion

The regime applicable to the advertising of medicines closely follows the regime set out 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 out 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 conduct to have been designed to promote a given product for it to qualify as advertising. It suffices that the conduct at issue has such an effect.

Second, 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, pharmaceutical companies are prevented from granting any kind of benefit to patients. Similarly to what has already happened in relation to healthcare professionals, companies cannot 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, companies must notify Infarmed in advance of the sponsorship of any congress, symposium 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 or benefits to the public. 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.

Similarly to what happens in the medicines sector, medical device companies are now required to notify Infarmed in advance of the sponsorship of any congress, symposium or event of an educational or promotional nature.

x Distributors and wholesalers

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

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, effectively and permanently, 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. Until 2013, the technical director had

to exercise the functions of this role exclusively and could not perform those 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[15] was approved, closely following Commission Guideline 2013/C 343/01.[16]

In addition, wholesalers are under a legal obligation to have medicines permanently available 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 EU 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 European Union). In 2015, Infarmed published a regulation setting out the terms applicable to the notification and to the medicines covered – 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 on this list. In addition, marketing authorisation holders, wholesalers and pharmacies must notify Infarmed, once a month, 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 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 European Union. To comply with the terms of the reasoned opinion, Infarmed revised its rules in 2017.[17] Although the regime of prior notification was maintained, clear and transparent criteria for the inclusion of medicines on the list in question, and for the list's revision, were implemented. Finally, Infarmed has the power to prevent the exportation of medicines – be it inside or outside the European Union – on the grounds of protection of public health or to ensure patient access to a given medicinal product.

The regime governing the brokering of medicinal products under the Medicines Act follows closely that of Directive 2011/62/EU,[18] thus 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 that authority, and is only permitted if (as is 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,

15 Infarmed Resolution No. 047/CD/2015 of 19 March 2015.

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

17 Infarmed Resolution No. 524/2017 of 14 June 2017.

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

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[19] 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 set out in the Directive.

Such a classification has related 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 sale prices 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.

xii Imports and exports

In line with the regime under the Directive, and as described in Section II.viii, 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 regards medical devices, there are no additional requirements related to imports and exports other than those applicable to the manufacture, placing on 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 of which identifyies the substances belonging thereto. Infarmed is the entity responsible for authorising engagement in these activities in relation to certain categories of substances. Specific requirements also exist for prescribing, dispensing and keeping records when such substances are included in medicinal products.

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

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 a criminal offence.

xiv Enforcement

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

A breach of these 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. As well as this penalty, a 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 a single piece of legislation the provisions applicable to pricing, reimbursement and prior evaluation procedures, and introduced 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 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,[20] 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.[21]

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

20 Decree No. 195-A/2015 of 30 July 2015 as amended.

21 Decree No. 195-C/2015 of 30 July 2015 as amended.

Medicines subject to medical prescription but not a restricted medical prescription, and generally sold in street pharmacies, have to undergo a price approval procedure before Infarmed prior to being launched on the market. In this context, a maximum sale price is approved, which, in the case of branded products, is determined by reference to the price applied in three reference countries. This price is subject to annual revision in accordance with the same criteria. One of the most important innovations introduced by SiNATS concerning this regime is that the maximum sale price may now be requested and approved within the reimbursement procedure (previously, the marketing authorisation holder could only request reimbursement following the relevant 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 sale 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 the 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 the retail sale price of the product. The placing on 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 corresponding reference price – equivalent to the average of the retail sale 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 the price.

Similarly, before they can be sold to National Health Service hospitals, medicines subject to medical prescription have to undergo an evaluation procedure, in the context of which the applicable maximum sale prices are approved by the Ministry of Health, or Infarmed, should this 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 subject to reimbursement, it is exempt from this procedure – unless otherwise decided by the Ministry of Health, or Infarmed, should this 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. That decision further implies the execution of an agreement between Infarmed and the marketing authorisation holder whereby, among other aspects, the maximum sale price to hospitals is established. Just as we have seen in the context of reimbursement, these agreements also usually establish a maximum sale 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 being in a state 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 sale prices 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.

In September 2017, significant changes were made to SiNATS.[22] Homogeneous groups were created for similar biological medicinal products and a maximum price was enacted for the sale of these products to National Health Service hospitals.

Infarmed's powers regarding reimbursement have been strengthened. Not only can it modify the terms of reimbursement, but it can also now promote, on its own initiative and at any time, the evaluation or re-evaluation of reimbursement when public health reasons require it.

The rule that medicines covered by the prior evaluation procedure can only be purchased by National Health Service hospitals on an exceptional basis (namely when the patient suffers from a life-threatening disease or risks severe complications and there is no therapeutic alternative), following a specific request from the hospital concerned and prior authorisation from Infarmed, was reiterated and reinforced. This matter was further developed in a regulation approved by Infarmed regarding early access programmes;[23] subject to this regulation, prior to obtaining a favourable decision within the context of a prior evaluation procedure, medicines should be supplied to National Health Service hospitals free of charge. Supply free of charge is subject to a maximum period, determined by reference to the legal deadline for the procedure.

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 a breach of regulatory provisions are subject to appeal before the judicial courts.

22 Decree-Law No. 115/2017 of 7 September 2017.

23 Infarmed Resolution No. 80/CD/2017 of 24 October 2017.

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 for the first time a decree was published that set the inexpensive limit – as had been foreseen in the Pharmaceutical Industry Association Code of Ethics. Since then, this amount has been increased and is currently set at €60.[24]

In addition, transparency obligations were enacted in 2013, requiring pharmaceutical companies to notify Infarmed of any payment or offer in excess of €60 made to any individual or legal entity, such as healthcare professionals, medical or scientific associations, patient associations and healthcare institutions. The recipient is also required to validate this notification and the absence of a validation, or a rejection, will be taken to indicate that the notification is correct. This information is publicly available on Infarmed's website.

Similar rules exist in the context of medical devices. The principle that no offer can be made to healthcare professionals unless of insignificant value and relevant to the healthcare professional's practice dates back to 2009 and, as from 2017, is subject to the exact same limit as that provided in relation to the promotion of medicinal products: €60.[25] Also in 2017, the transparency obligations that apply in the medicines sector were implemented for medical devices. Currently, pharmaceutical companies and medical device companies are subject to the exact same transparency rules.

In early 2014, a specific conflict-of-interest regime for the health sector was approved. The regime prevents, among other things, 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. A 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 the 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.

In addition, as from 2017,[26] National Health Service establishments and services are prohibited from receiving direct or indirect financial benefits or benefits in kind from pharmaceutical and medical device companies, unless it can be demonstrated that receiving the benefits does not compromise the establishment or service's exemption or impartiality, and unless prior authorisation from the Ministry of Health is obtained. Furthermore, educational or scientific events with promotional purposes or sponsored by pharmaceutical or medical device companies cannot take place in National Health Service establishments and services.

24 Order No. 1542/2017 of 31 January 2017.

25 Id.

26 Decree-Law No. 5/2017 of 6 January 2017.

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), 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[27] 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.

On June 2017, the Lisbon Court of Appeal confirmed the decision by the Portuguese Competition Authority (PCA) fining the National Association of Pharmacies (ANF) and three undertakings of the same group for an abuse of dominant position in the form of a margin squeeze in the market for the sale of studies based on pharmacies' commercial data; however, the Court of Appeal reduced the amounts of the fines significantly.

The case dates from 2015, when the PCA concluded an investigation into the market for the sale of pharmacies' commercial data, a market in whic the ANF group is dominant. The PCA decided that, between 2010 and 2013, the prices charged by the ANF group for the sale of pharmacies' commercial data (the upstream market), when compared to the prices charged by the same group for the sale of market studies based on those data (the downstream market), did not allow an equally efficient competitor active in the downstream market to achieve an adequate margin to cover its production costs. The PCA found that this behaviour had affected not only ANF's competitors, which were unable to enter or compete in the downstream market, but also consumers purchasing such studies, namely pharmaceutical laboratories.

When the decision was first challenged, the Competition, Regulation and Supervision Court (TCRS) upheld the PCA decision but reduced the fines to a total of €6.89 million on the understanding that only the turnover related to the markets in which the abuse of dominance took place should be considered for the purpose of calculating fines. On 14 June 2017, the Lisbon Court of Appeal rendered a final judgment in this case, confirming the existence of an abuse, but dismissing the finding that the holding company (Farminveste SGPS) was also liable for the infringement. Since that company had the highest turnover, the fine initially imposed by the PCA was substantially reduced, to a mere €815,000 (a reduction of 92 per cent of the fine imposed by the PCA).

In September 2017, the TCRS confirmed a PCA decision to close an investigation into pharmaceutical companies that had unilaterally decided to refuse to supply a new wholesaler. The TCRS decision established that:

a a distinction could be established between the relevant market for the medicine and the relevant market for the wholesale distribution of the medicine;

27 Law No. 19/2012 of 8 May 2012.

b if a company holds a dominant position, a refusal to deal may be justified by objective reasons related to legitimate commercial interests of the supplier;
c a refusal to supply a (potentially) new counterparty to ensure the stability of the existing distribution network may be treated differently from a termination of an existing commercial relationship;
d a refusal to deal may also be considered a discrimination; and
e the effects of the refusal to deal on consumer welfare may be disregarded as long as the wholesale distribution market remains competitive.

During 2017 the PCA saw its investigation toolbox upgraded with direct and permanent access to the national public procurement databases (as of 1 January 2018) and with a dedicated user-friendly online complaint portal. The PCA also continued to engage in a nationwide awareness campaign on the need to fight bid rigging, with a focus on awarding authorities. As a result, an increased number of investigations launched by the PCA, namely regarding the conditions under which public hospitals are supplied, may be expected soon.

VIII CURRENT DEVELOPMENTS

One of the most significant developments in 2017 was the approval of Decree-Law No. 5/2017, which not only established a mechanism of prior approval by the Ministry of Health regarding any benefit, regardless of its nature, granted by pharmaceutical and medical device companies to National Health Service entities, but also limited the scope of events that could take place in National Health Service establishments and services and that could be sponsored by these companies. Going beyond the Directive, in which interaction with healthcare professionals in the context of promotion of medicines is one of the key concerns, the Portuguese government now focuses on National Health Service hospitals, purchasers of medicines and medical devices with a view to guaranteeing neutrality and impartiality in public purchases.

Containing public expenditure on pharmaceuticals continues to drive public policy. The National Strategy for Medicines and Health Products, approved by the government in October 2016 for the period 2016–2020, is consistent with this purpose. The priorities foreseen for this period include the systematic re-evaluation of reimbursed medicines, the issuance of therapeutic recommendations, the introduction of changes to the price-referencing system when generics or biosimilars exist, and an increase of the quota of generics and biosimilars. The Budget Law for 2018 provides that the government should take measures to encourage the use of generics so that the corresponding share grows to at least 53 per cent in terms of volume of units (a significant increase from the 40 per cent in expense value, as the Budget Law for 2017 determined).

Setting this goal has also brought about related changes in the context of public procurement. The Shared Services of the Ministry of Health (SPMS), which is responsible for the centralised acquisition of goods and services for National Health Service establishments and services, can now purchase generics or biosimilars as soon as they enter the market. This is the result of an Order of the Ministry of Health, published at the end of 2017,[28] which determines that when reimbursement or prior evaluation decisions on generics or biosimilars are published National Health Service hospitals are automatically exempted from the

28 Decree No. 9879/2017 of 15 November 2017.

obligation to purchase medicines pursuant to the centralised framework agreements in force. The Order applies to anti-retroviral, oncological and anti-infective medicines. This essentially means that generics and biosimilars with these therapeutic indications will immediately be able to enter the hospital market and originators will no longer be indirectly protected by the centralised framework agreements in force.

The new Public Procurement Code, which came into force on 1 January 2018, also gave rise to important developments in this context. The amended Code establishes that contracting authorities that are bound to purchase products via centralised framework agreements are exempted from this obligation if they demonstrate that, for a certain acquisition of goods, upholding the agreement would entail a payment 10 per cent higher than the price the contracting authority can obtain outside the centralised framework agreement for a product with the same features and qualities. This allows hospitals to purchase medicines outside the applicable centralised framework agreements even for therapeutic indications that are not covered by the above-mentioned Order.

Appendix 1

ABOUT THE AUTHORS

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Paulo Pinheiro is a partner at VdA 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 consistently 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 several sectors of activity, including health, telecoms, energy and natural gas, transport, water and waste.

As an acknowledgement of his standing in public law, he has been ranked as a leading individual for several years by *Best Lawyers*, *Chambers Europe*, *Who's Who Legal* and *The Legal 500*.

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