THE PHARMACEUTICAL INTELLECTUAL PROPERTY AND COMPETITION LAW REVIEW

THIRD EDITION

Editor
Daniel A Kracov

THE LAWREVIEWS

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PREFACE

The pharmaceutical business is truly one of the most global industries, with many companies operating in dozens of countries, with differing legal regimes and healthcare systems. In certain respects, the rules governing industry activities have largely become harmonised, such as in drug manufacturing and the conduct of clinical trials; however, in other areas the legal frameworks differ, and those nuances can require significant efforts to both optimise strategies and comply with requirements in local jurisdictions.

In the areas of focus of this book – pharmaceutical intellectual property, including patent linkage and exclusivities, and related competition concerns –it can be critically important to tailor approaches to the local legal environment despite general concepts that may be shared across jurisdictions.

Maximising the value of intellectual property can make the difference in deciding whether to pursue the development of an important new treatment, and in determining its sustained success in the marketplace. Similarly, a failure to carefully manage risks in dealings with competitors, such as generic and biosimilar companies, can result in huge civil and criminal liabilities. This is an area of significant enforcement activity around the world, with large fines being imposed and transactions thwarted if applicable legal constraints are not heeded. Moreover, the links between intellectual property, such as exclusivities, and drug pricing and affordability have been a constant source of political scrutiny, as well as patient and physician concern.

The ongoing global response to the covid-19 pandemic has re-emphasised the importance of rapid drug and biologic product development to public health around the world, and the critical need to maintain incentives to enable such innovations; however, the stakes in demonstrating the need to maintain such protections for innovation have grown even higher as the pandemic has spurred an intense focus on intellectual property and pricing issues associated with vaccines and other needed treatments.

Our objective in framing this updated volume is to give practitioners in the field a one-volume introduction to these critical issues in an array of jurisdictions. I would like to thank the authors for their renewed contributions to this edition of *The Pharmaceutical Intellectual Property and Competition Law Review*. They have produced what we believe is a very useful tool for managing global risks in this area.

Daniel A Kracov
Arnold & Porter
Washington, DC
July 2022

Chapter 7

PORTUGAL

Tânia Luísa Faria and Joana Mota[1]

I OVERVIEW

The health sector, in which the pharmaceutical industry is included, is a prominent, fast-evolving sector in Portugal, which has experienced a remarkable evolution over the past couple of decades.[2]

Portugal has a strong reputation for having a sound, trustworthy and competent workforce in the life sciences sector. Employees in this sector are trained by universities that are up to date with scientific developments and market tendencies, and the government is strategically committed to strengthening the country's scientific resources. Collaboration projects between multinational pharmaceutical corporations, Portuguese biotech firms and reputed universities have produced some of the most advanced research and therapies developed for worldwide application.

According to the latest available data, in 2020 Portuguese investment in research and development (R&D) amounted to an expenditure of €3.236 million, representing 1.62 per cent of the GDP.[3]

Established in 2008, the Health Cluster Portugal (the Health Cluster) includes R&D pharmaceutical companies, hospitals, universities and government bodies. It is a platform located in Porto, which aims to turn Portugal into a competitive player in the research, invention, development, manufacture and commercialisation of products and services of high added value related to health that can compete in a framework of excellence in the international market. It currently has approximately 170 members, embracing the entire spectrum of life sciences in the country.

In 2018, pharmaceutical and biotechnology products accounted for €1.291 billion in exports. This sector represented an annual turnover of around €27 billion, and investment in health reached €462 million in 2017, representing 10.5 per cent of total business investment in R&D in Portugal.

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1 Tânia Luísa Faria is a counsel and Joana Mota is a managing associate at Uría Menéndez – Proença de Carvalho. The authors would like to acknowledge the contribution of their colleagues Margot Lopes Martins and Ricardo Pintão (junior associates) in the preparation of this chapter

2 Arquivo.pt: https://arquivo.pt/wayback/20190424172947/http://www.portugalin.gov.pt/pharmaceutics/ (last accessed: 25 July 2022).

3 Direção Geral de Estatísticas da Educação e Ciência, 'Inquérito ao Potencial Científico e Tecnológico Nacional 2020: Principais Indicadores de I&D Nacionais'.

Public and private healthcare providers are trying to integrate the services that they offer with a view to attracting more medical tourism to Portugal. The Health Cluster and relevant government bodies are working with these players with an aim to establish a consolidated Portuguese presence in this area.

One public policy priority has been to enhance human resources training and qualifications, together with the placement of the workforce in healthcare institutions and measures to attract foreign talent to Portugal. Between 2011 and 2021, the share of human resources in science and technology in the working population in Portugal increased from 26.9 per cent to 44.1 per cent.[4]

In recent years, the most significant events in the life sciences domain in Portugal have been the official opening of the Champalimaud Centre for the Unknown in October 2010 and the placement of the first medicine protected by a Portuguese patent in US pharmacies.

The Champalimaud Centre was made possible by the €500 million donation by the Portuguese entrepreneur António Champalimaud. It is a medical research centre that put Lisbon at the forefront of advances against cancer and the development of neuroscience.

The company BIAL[5] developed the first medicine patented and researched in Portugal to be placed in US pharmacies in April 2014 by Sunovion Pharmaceuticals Inc, a licensee of BIAL. The trade name in the United States for the innovative anti-epileptic drug, Aptiom, was approved by the US Food and Drug Administration in November 2013.

In 2014, BIAL developed a new medicine for Parkinson's disease, Ongentys (opicapone), reinforcing the sustainability and success of its R&D projects. The medicine was granted marketing authorisation (MA) by the European Medicines Agency (EMEA) in July 2016, and its commercialisation in China was announced in 2018.

In 2020, there were 2,922 pharmacies and 191 mobile pharmaceutical units in Portugal, 30 for every 100,000 habitants,[6] and the Portuguese pharmaceutical market was valued at €4.260 billion, with the outpatient market representing 67.3 per cent and the hospital market the remaining 32.7 per cent.[7]

Portugal represents about 2 per cent of the EU pharmaceutical market. In 2019, prescription medicines represented 91 per cent of the total market, whereas non-prescription medicines had a market share of 9 per cent of the pharmacy sector in 2019.

Generic drugs in Portugal achieved a market share of 47.35 per cent in 2016.[8] In 2020, there were 16,534 generic drugs with MAs[9] granted by the Portuguese Regulatory Medicines Agency (Infarmed).

Pharmaceutical products and raw materials imports amounted to nearly €3.047 billion in 2020, while exports amounted to €1.180 million.[10] There were approximately[11] 464 pharmaceutical companies in the country in 2020.

4 Eurostat, 'Human resources in science and technology (HRST)', online data code TSC00025.

5 BIAL, established in 1924, is one of the most important Portuguese pharmaceutical companies, and its investment in research and development has resulted in the first Portuguese patent being commercialised in the US market.

6 Statistics Portugal, 'Health Statistics - 2020' (issue year: 2020).

7 Portuguese Pharmaceutical Industry Association (Apifarma), 'The Pharmaceutical Industry in Figures 2020'.

8 Infarmed, 'Quota de mercado de genéricos'.

9 Infarmed, 'Medicine and Healthcare Products Statistics 2020'.

10 Apifarma, The Pharmaceutical Industry in Figures 2020.

11 Of which 116 were pharmaceutical companies affiliated with Apifarma. See footnotes 7 and 9.

To rapidly increase the level of exports of pharmaceutical products, a public–private partnership between 14 national pharmaceutical groups and companies, AICEP Portugal Global (Business Development Agency), the Portuguese Pharmaceutical Industry Association (Apifarma) and Infarmed set up the Strategic Project for the Export and Internationalisation of the Portuguese Pharmaceutical Industry (PharmaPortugal).[12]

The main body for the enforcement of competition rules in Portugal is the Portuguese Competition Authority (AdC), which ensures respect for the rules that promote and defend competition and holds sanctioning, supervisory and regulatory powers. The AdC has an extensive practice in matters concerning the pharmaceutical industry, within merger control and restrictive practice proceedings.

II LEGISLATIVE AND REGULATORY FRAMEWORK

Decree-Law 176/2006, of 30 August 2006 (the Medicines Act), was approved amid an extensive in-depth review of the Portuguese pharmaceutical legislation carried out in 2006, which implemented several EU directives and reviewed the national legislation in force. The main purpose of the Medicines Act is to regulate the manufacture, quality control, safety, efficacy, entry on the market and advertisement of medicinal products for human use.

The rules governing the regulation of prescription drug pricing were subject to significant changes in 2015 and are now set out in Decree-Law 97/2015 of 1 June 2015, as amended by Decree-Law 115/2017 of 7 September 2017 (Decree-Law 97/2015). The establishment of the sales price for consumers (PVP) of the pharmaceutical products in question depends on the pricing framework used in the 'reference countries' for pricing purposes (according to Ruling 280/2021 of 3 December 2021).[13] The PVP must be determined by calculating the maximum price at the level of production or importation in Portugal (the sale price to wholesalers), which cannot exceed the limits imposed by Article 6 of Ruling 195-C/2015 of 30 June 2015.

Decree-Law 97/2015 also sets out the rules governing the reimbursement of prescription pharmaceutical products. In this regard, Infarmed is the competent authority that analyses any applications filed by the MA holder for the reimbursement of a prescription pharmaceutical product by the National Health System. Infarmed then presents the reimbursement proposal to the Ministry of Health for the latter's final decision, which depends on the verification of two cumulative requirements: a technical-scientific demonstration of the therapeutic innovation or its therapeutic equivalence for the claimed therapeutic indication; and a demonstration of its economic advantage.

In addition to the two requirements described above, reimbursement is also subject to, among other things, one of the following:

a an innovative pharmaceutical product that will overcome any given therapeutic shortcoming, defined by greater efficiency, effectiveness or safety by reference to the existing alternative treatments;

12 As at the time of writing, 12 companies are registered with PharmaPortugal: Atral, Azevedos, BASI, Sidefarma, Bial, Bluepharma, Edol, Iberfar, Recipharm, Grupo Medinfar, Tecnifar and Grupo Tecnimede. See Apifarma, 'Empresas PharmaPortugal'.

13 Spain, France, Italy and Slovenia are referred to as the 'reference countries' for 2022.

b a new pharmaceutical form, a new dosage or a significantly different package size of a pharmaceutical product already reimbursed, with an identical qualitative composition to the extent that the existence of a therapeutic need and an economic advantage are demonstrated or acknowledged; and

c new pharmaceutical products that are not a significant therapeutic innovation, if they present economic advantages in relation to medicinal products already reimbursed, used with the same therapeutic objectives and possessing proven identical action mechanisms.

The main Portuguese legal framework for patents is found in Articles 50 to 125 of the Industrial Property Code, as approved by Decree-Law 110/2018 of 10 December 2018, as amended (CPI). Pursuant to Article 100 of the CPI, patents are valid for 20 years from the date of filing, which may be extended by means of supplementary protection certificates.

The most relevant competition law framework is Law 19/2012 of 8 May 2012, as amended[14] (the Competition Act), which is applicable to all economic activities, whether permanent or occasional, carried out in every sector, without exception. Significant modifications to the Competition Act are expected to result from the transposition of the ECN+ Directive,[15] a process that has been headed by the AdC, having already submitted the final draft transposition proposal to the Portuguese government and which is currently under discussion in Parliament. Based on the final draft transposition proposal, it is clear that the AdC also took advantage of this opportunity to propose some adjustments to the existing Portuguese competition law framework, thus exceeding the scope of the ECN+ Directive.

In 2018, the Portuguese private enforcement regime was established by Law No. 23/2018,[16] following the Private Enforcement Directive.[17] This Law marks the adoption of the first specific set of rules in force in Portugal concerning actions for damages resulting from a breach of competition rules.

There are no specific statutes, regulations or guidelines directly regulating the interaction between pharmaceutical intellectual property and competition issues in Portugal, or acquisitions and infringements within the pharmaceutical sector; however, there are inevitably points that cross over between the two concepts, and pharmaceutical intellectual property-related actions may fall under the general competition law prohibitions.

Under Portuguese legislation, and in accordance with European law, holders of intellectual property rights (IPRs) are not exempt from the competition law rules; therefore, the AdC is competent when, in the context of the use of IPRs, an undertaking infringes any prohibition of practices restricting competition, under Articles 9 and 11 of the Competition Act (respectively corresponding to Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU)). The AdC is also competent to assess merger transactions that meet the notification thresholds, including when they involve assets related to IPRs.

14 The Competition Act was last revised in 2012 and further amended in 2021 by Decree-Law 108/2021.

15 Directive (EU) 2019/1 of the European Parliament and of the Council of 11 December 2018 to empower the competition authorities of the Member States to be more effective enforcers and to ensure the proper functioning of the internal market, OJ L 11, 14.1.2019, pp. 3–33.

16 Law No. 23/2018 of 5 June 2018.

17 Directive 2014/104/EU of the European Parliament and of the Council of 26 November 2014 on certain rules governing actions for damages under national law for infringements of the competition law provisions of the Member States and of the European Union, OJ L 349, 5.12.2014, pp. 1–19.

III NEW DRUGS AND BIOLOGICS – APPROVAL, INCENTIVES AND RIGHTS

i Drugs

As Portugal is an EU Member State, the approval of drugs for placement on the national market is governed by the rules and procedures of the European regulatory system applicable to this area. It, therefore, comprises four possible procedures: the centralised procedure, the mutual recognition procedure, the decentralised procedure and the national procedure. The drug approval process in Portugal is governed by the Medicines Act.

Under the national procedure, to obtain an MA for a specific medicine, an applicant must provide the following information, in accordance with Article 15 of the Medicines Act:

a name or corporate name, permanent address of the applicant and (where applicable) the manufacturer's name;

b VAT number, unless the applicant has its registered office or establishment in another EU Member State; and

c number of dossiers that form the application.

The application must be submitted together with the following information, in Portuguese or English, or both:

a a pharmaceutical form, and qualitative and quantitative particulars of all the constituents of the medicinal product, including but not limited to the active substances and excipients, in their usual terms, and, if applicable, the reference to its international non-proprietary name, or in the absence of this, its chemical name;

b the therapeutic indications, contra-indications and adverse reactions;

c the dosage, method and way of administration;

d reasons to adopt any preventive or security measures to store the drug, its administration or the disposal of its waste, together with an indication of potential environmental risks resulting from the drug;

e one or more copies of the summary of the product characteristics (SPC),[18] a sample of the outer packaging and of the container and, if applicable, the results of the evaluations carried out in cooperation with the target groups of patients;

f a copy of the manufacturing licence valid in Portugal, or when the drug is not manufactured in Portugal, a certificate of the manufacturing licence granted to the respective manufacturer;

g information regarding the manufacturing of the medicinal product, including a description of the manufacturing method;

h a description of the control methods undertaken by the manufacturer;

i a written declaration from the medicine manufacturer, supported by audit reports, attesting that the manufacturer of the active substance of the medicine has complied

18 Which, under Article 18 of the Medicines Act must include the following information: (1) name of the medicinal product; (2) qualitative and quantitative composition; (3) pharmaceutical form; (4) clinical data (therapeutic indications, dosage and way of administration, side effects, warnings and special precautions, pregnancy, effects on drivers, adverse reactions and overdoses); (5) pharmacological properties (pharmacodynamic properties, pharmacokinetic properties and preclinical safety data); (6) pharmaceutical data (a list of excipients, incompatibility, shelf life, special storage precautions, type of outer packaging, instructions for using and handling); (7) marketing authorisation (MA) holder; (8) MA number; (9) first authorisation and renewal date; and (10) latest update.

with the principles and guidelines of good manufacturing practices. The statement should include the date of the last audit report and indicate that the result of the audit report confirms that the manufacturing process follows those principles and guidelines;

j the results of the pharmaceutical tests and preclinical and clinical trials;[19]

k a detailed description of the pharmacovigilance system, together with evidence of the existence of a person responsible for it and of the means required to notify any adverse reaction detected and, if applicable, of the risk management system to be used by the applicant;

l an environmental risk valuation report, including, if applicable, an indication of the measures proposed to limit such risk;

m a statement evidencing that the clinical trials carried out outside the European Community have complied with the ethical requirements set out under the clinical trials legislation;

n a copy of MAs issued in other EU countries, as well as any decision rejecting the granting of the authorisation, the grounds for rejection and a summary of the information in relation to safety, including, when applicable, information related to the periodic safety and adverse reactions;

o a copy of the MAs issued by the authorities responsible in other countries, as well as any decision refusing to grant the authorisation, if any, and the grounds for such refusal;

p a list of Member States in which an application for an MA has been submitted, with copies of the SPC and the package leaflets proposed or authorised therein;

q if applicable, a copy of the qualification of the drug as an orphan drug, with a copy of the opinion of the EMEA;

r a document evidencing the payment of the fees due; and

s other elements detailed in Annex I to the Medicines Act.

In addition to the standard procedures, there are three abridged or expedited applications: the abridged application for generic drugs, the authorisation for special use (ASU) and the early-access programme.

The ASU, as established under Article 92 of the Medicines Act and Infarmed's Regulation 1546/2015 of 6 August 2015, as amended by Regulation 1079/2021 of 21 October, allows Infarmed to authorise the use of medicines for which no MA has been granted if:

a those medicines are considered indispensable (by means of a clinical report) for the treatment and diagnosis of certain pathologies;

b they are necessary to prevent an actual or potential spread of pathogenic agents, toxins, chemical agents or nuclear radiation likely to have harmful effects; or

c they are acquired by a pharmacy and to be used by a particular patient (only in exceptional cases).

Both hospitals and existing MA holders can apply for an ASU. If the applicant is a hospital, the following criteria must be met: there is no other medicine in Portugal that presents an identical qualitative and quantitative composition of active substances and pharmaceutical form, with a valid MA or, if it exists, it is not currently being commercialised; and the

19 Under this requirement, Infarmed may request the entity responsible for the placement of the drug to submit samples of it to a third-party laboratory.

medicine must be considered as essential for the prevention, diagnosis or treatment of certain pathologies, with no proven therapeutic alternative in existence. It is also necessary to demonstrate that the medicine has a well-known clinical benefit or presents preliminary evidence of a clinical benefit.

If the applicant is an existing MA holder, the application must be justified through it being in the interest of patients and the necessity of guaranteeing access to a certain drug in a situation of market disruption, and where there is no proven therapeutic alternative.

The ASU is exceptional and temporary; therefore:

a in the case of medicinal products with a well-known clinical benefit, the ASU expires on the last day of the year for which it was granted;

b in the case of medicinal products with preliminary evidence of clinical benefit, the authorisation is valid at the end of the treatment for which it was requested, with a maximum limit of one year; and

c the ASU expires when the medicines have been distributed to the patients who meet the described exceptional requirements.

In addition, it is also possible for an ASU to be granted to a hospital under an early-access programme, under the conditions established in Infarmed's Resolution 80/CD/2017.

Under Articles 27 and 28 of the Medicines Act, if an MA is granted, it is valid for a period of five years, but is renewable for an indefinite period following its first renewal. In addition, Article 19 of the Medicines Act provides exclusivity periods for medicinal products as follows:

a after the granting of the MA for a medicinal product, the originator company's preclinical and clinical data cannot be used in a generic marketing authorisation application for eight years;

b the generic medicine can only be marketed after 10 years have elapsed from the initial granting of the MA to the originator company; and

c one additional year of marketing exclusivity is available if a new therapeutic purpose is registered, within eight years of the granting of the reference product's MA, which is considered to be of significant clinical benefit compared to existing therapies.

ii Generic and follow-on pharmaceuticals

Under Article 3(1) of the Medicines Act, generic drugs are defined as those with the same qualitative and quantitative composition in active substances, under the same pharmaceutical form, and for which respective bioequivalence with the reference drug has been demonstrated, based on appropriate bioavailability studies.

As such, the procedure for their approval follows the same steps as those described in Section III.i, with some differences established in Paragraphs 3 and 5 of Article 19 of the Medicines Act:

a it is not necessary to present reports on preclinical tests and clinical trials, except when:

- it is not demonstrated that the medicine meets the bioavailability requirements defined in Infarmed's directives or in the Community area;
- the bioequivalence may not be demonstrated by means of bioavailability studies; or
- the medicine has, in relation to the reference medicine, differences in the active substances or its therapeutic indications, in its dosage, its pharmaceutical form or method of administration; and

b the marketing of generic drugs must respect the data and market exclusivity granted to the MA holder of a reference drug, which means that those drugs can only be marketed 10 years after the initial authorisation is granted to the reference medicine at a national or EU level or 11 years after the initial authorisation is granted to the reference medicine, if within the initial eight years the MA holder of the reference medicine has obtained an authorisation to one or more new therapeutic indications, which, upon a scientific evaluation prior to its authorisation, are considered to bring a significant clinical benefit in relation to the existing therapeutics.

A significant modification introduced by the Medicines Act and Law 62/2011 of 12 December 2011 (Law 62/2011) is that the issuing of a generic drug MA is not considered as an infringement of the rights granted by patents or supplementary protection certificates.

iii Biologics and biosimilars

Portuguese law does not define 'interchangeability' or 'substitutability'. The Medicines Act defines an 'essentially similar medicine'[20] as a medicine that has the same qualitative and quantitative composition of active substance or substances, has the same dosage form and is bioequivalent to a reference product. Generic medicines are considered to be essentially similar medicines.

According to the Medicines Act, medicines that are identified as generics on a list of medicines published on the Infarmed website are considered interchangeable and may be substituted for prescribed medicines at the pharmacist's discretion, unless a medicine is prescribed by a product (trade) name and substitution is prohibited.

In addition to this, Portuguese law does not establish any specificity for the approval process of biologic drugs. Further, and in relation to biosimilar medicines, if they do not fall within the definition of generic drugs, owing to, in particular, differences relating to raw materials or differences in manufacturing processes of the biological medicinal product and the reference biological medicinal product, they may not benefit from the simplified procedure of generic drugs. As a consequence, under Article 19(6) of the Medicines Act, the approval of an MA by Infarmed of such a biosimilar drug requires the presentation of appropriate preclinical tests or clinical trials.

Infarmed issued specific guidance on biosimilar substitution in February 2018.[21]

IV PATENT LINKAGE

Law 62/2011 established, among other important changes to the Medicines Act, a compulsory arbitration regime for disputes emerging from industrial property rights whenever reference drugs and generic drugs are at issue. This new regime intended to avoid the excessive use of patent litigation in the administrative courts in Portugal, as had been the case in recent years, where the validity of the administrative acts that might violate industrial property rights was disputed.[22]

20 Article 3, No. 1, Paragraph ss of the Medicines Act.

21 Infarmed, 'Utilização de medicamentos biossimilares e mudança de medicamento biológico de referência para um biossimilar', Guideline No. 5 of February 2018.

22 The enactment of this law was a result of a legislative package negotiated with the 'troika' of the European Commission, the International Monetary Fund and the European Central Bank in the context of Portugal's

With the enforcement of this law, arbitration was mandatory to resolve disputes emerging from industrial property rights related to reference drugs and generic drugs, regardless of whether the dispute related to process, product or utility patents, or whether supplementary protection certificates were at issue.

This law was amended by Decree-Law 110/2018 of 10 December 2018. It now establishes that the disputes emerging from industrial property rights concerning reference and generic drugs, including precautionary proceedings, are subject to voluntary (rather than compulsory) arbitration (institutionalised or not institutionalised) if all parties agree. Proceedings must be initiated within 30 days of the publication of an MA request for a generic drug on Infarmed's website. Any party intending to invoke its industrial property rights (which is usually the owner of the reference drug) may do so at the institutionalised arbitral court or make a request to submit the case to non-institutionalised arbitration.

After notification from the arbitral tribunal, the applicant for the MA must present a defence within 30 days. Failure to do so means that the applicant cannot commence the industrial or commercial exploitation of the drug (which is usually the generic drug) as long as the industrial property rights invoked by the owner of the reference drug remain in force.

In the arbitration proceedings, it is possible to invoke and recognise the invalidity of a patent with an *inter partes* effect. Moreover, in the arbitration proceedings, the documentary evidence must be filed together with the pleadings. The hearing for the production of evidence, which must be presented orally, must take place within 60 days of the filing of the defence.

From the decision rendered by the arbitral tribunal, it is possible to file an appeal with the Court of Appeal; however, this pending appeal does not stay the arbitral proceedings, which means that it does not suspend the decision of the arbitral tribunal.

Resolving disputes through arbitration helps to reach a decision more rapidly, thereby shortening the period of legal uncertainty over the generic drug. The concern regarding efficiency leads to the imposition of tight deadlines and preclusions: failure to respond to the initial pleading will forbid the defendant from marketing the generic medicine until expiry of the industrial property right occurs.

V COMPETITION ENFORCERS

The main body for the enforcement of competition rules in Portugal is the AdC, which is an independent administrative body in charge of the public enforcement of competition law in Portugal, without exceptions in all sectors of the economy in Portugal.

In this context, the AdC is competent to investigate and sanction anticompetitive practices – such as anticompetitive agreements and concerted practices (Article 9 of the Competition Act) and abuse of a dominant position (Article 11 of the Competition Act) – and to assess merger transactions when they meet the notification thresholds. The AdC has significant experience in the pharmaceutical sector, comprising the full spectrum of AdC enforcement.

Judicial appeals against the decisions and proceedings carried out by the AdC fall under the jurisdiction of the Portuguese Competition, Regulation and Supervision Court (the Competition Court) and the Lisbon Court of Appeals.

bailout in 2011 and the execution of a memorandum of understanding (MoU) to avoid defaulting on its debts. One of the main measures set out in the MoU to reform the health system was to increase the prescription and use of generic drugs.

In cases of mere acts of unfair competition matters involving IPRs or patent infringement or conflicts, the AdC and the Competition Court have no jurisdiction, as these come under the jurisdiction of the Intellectual Property Court.

VI MERGER CONTROL

The AdC is competent to assess merger transactions that meet the relevant notification thresholds. In this context, the AdC has noteworthy experience in merger cases in the pharmaceutical and healthcare sectors. The most recent examples include the acquisitions of: Advanz Pharma;[23] Udifar II;[24] the Laboratório de São Lázaro by the Unilabs group;[25] the Raxone business by the Italian company Chiesi Farmaceutici;[26] the MedicalMedia II assets by Stemlab, SA;[27] Logifarma – Logística Farmacêutica SA by Alliance Healthcare and Iberfar;[28] the Priadel assets by Essential Pharma limited;[29] Udifar II by Plural - Cooperativa Farmacêutica CRL;[30] and Cresbard Invest by ArchiMed.[31]

In the context of pharmaceutical intellectual property, the acquisition of IPRs occurs frequently. Under Portuguese competition law, the mere acquisition of IPRs may constitute a merger, provided that it leads to a lasting 'change of control in the whole or parts of one or more undertakings' and that the assets constitute an activity resulting in a presence in a market to which a turnover arises.[32]

A recent example is the *Raxone* case, whereby Chiesi Farmaceutici acquired the rights of representation, distribution and development of the Raxone business, that being the only drug approved on the market for the symptomatic treatment of Leber hereditary optic neuropathy.

Additionally, there is the case of the acquisition of sole control over the assets necessary for the production and marketing of the orphan medicine Cystagon in every country, excluding the United States, Australia and Japan.[33] Cystagon's assets include the assets necessary for the production and marketing of the Cystagon orphan drug, including IPRs, such as trademarks; relevant marketing authorisations and business files related to customers and suppliers; and the rights and know-how necessary for the manufacture of Cystagon.

In this case, the AdC authorised the transaction and considered that it did not present any anticompetitive practices based on three main grounds:

a the operation consisted of the mere vertical integration of the Cystagon assets with its current exclusive distributor, Orphan Europe (having no impact on the structure of the offer of this medicine in Portugal);

b Cystagon was no longer protected by patent rights, which could prevent similar products from entering into the Portuguese market; and

23 Portuguese Competition Authority (AdC), 23 March 2021, Ccent. 15/2021, *Aida Bidco/Advanz Pharma*.

24 AdC, 10 March 2020, Ccent. 4/2020, *Plural/Udifar II*.

25 AdC, 5 March 2020, Case No. Ccent. 2019/52, *Laboratório Hilário de Lima/Laboratório São Lázaro*.

26 AdC, 12 July 2019, Case No. Ccent. 2019/31, *Chiesi/Ativos Raxone*.

27 AdC, 10 July 2019, Case No. Ccent. 2019/28, *Stemlab/Bebécord*Bebé4D*.

28 AdC, 8 November 2018, Case No. Ccent. 2018/38, *AH*IBERFAR/Logifarma*.

29 AdC, 30 August 2018, Case No. Ccent. 2018/33, *Essential Pharma/Ativos Priadel*.

30 AdC, 10 March 2020, Case No. Ccent.2020/4, *Plural / Udifar II*.

31 AdC 26 October 2021, Case No. Ccent No. 46/2021, *ArchiMed / Cresbard Invest*.

32 Article 36, Law No. 19/2012, 8 May 2012.

33 AdC, 27 February 2018, Case No. Ccent. 8/2018, *Recordati/Ativos Cystagon*.

c there was one medicine that could represent a potential competitor to Cystagon in Portugal: Procysbi – despite not being marketed in Portugal, Procysbi held an MA at the European level since 2013 and therefore could potentially enter into the Portuguese market.

In the case of the acquisition of Astellas Pharma's dermatological business by LEO Pharma, the target assets included trademarks, domain names, patents, MAs, cosmetic quality records, safety data, technology and marketing know-how and rights resulting from manufacturing contracts, supply and distribution contracts, in-licensing and out-licensing contracts. Each one of those assets was related to four prescription medicines – Protopic, Pimafucort, Locoid and Zineryt – and a cosmetic product, Locobase Repair.[34]

In another case, the AdC assessed the acquisition of the assets related to the medicine Vesanoid, made up of trademarks, registrations, inventories and agreements relating to the production and marketing of Vesanoid in Portugal.[35] Vesanoid, as an orphan drug with no generic version available, and the only existing treatment for acute promyelocytic leukaemia, had a market share of 100 per cent in Portugal; however, the AdC approved the transaction, considering it to involve a mere transfer of market share without any impact on the competitive structure of the relevant market.

VII ANTICOMPETITIVE BEHAVIOUR

Portuguese law, both in the area of IPRs and competition, is largely based on European law.

The AdC is competent when, within the context of IPRs, an undertaking infringes the prohibition of bilateral or unilateral restrictive practices, respectively established in Articles 9 and 11 of the Competition Act, which mirror Articles 101 and 102 of the TFEU; therefore, under Portuguese law, anticompetitive restraints related to intellectual property in the pharmaceutical sector may fall under either the prohibition of agreements and concerted practices (Article 9) or the prohibition of abuse of dominant position (Article 11).

Anticompetitive practices in breach of Articles 9 and 11 are sanctioned with fines up to a maximum of 10 per cent of the offending undertaking's turnover in the year preceding the decision.[36] The Competition Act also provides for ancillary penalties, which include a prohibition of up to two years on the right to take part in public tenders, as well as the publication of the infringement decision in the Portuguese Official Gazette and in national, regional or local newspapers.

Additionally, members of the board of directors of the infringing undertakings, as well as any individuals responsible for the management or supervision, may be sanctioned with fines that cannot exceed 10 per cent of the individual's annual income deriving from the exercise of their functions in the undertaking concerned. Undertakings may also be subject to the payment of damages, as provided by the private enforcement rules.[37]

Under its supervisory function, the AdC may issue guidance addressed to specific undertakings or sectors. For example, in the pharmaceutical sector, in May 2020 it issued guidance regarding a proposal of the National Association of Pharmacies (ANF) on

34 AdC, 10 March 2016, Case No. Ccent. 6/2016, *LEO Pharma/Negócio de Dermatologia da Astellas Pharma*.

35 AdC, 20 December, Case No. Ccent. 55/2012, *Cheplapharm/Ativos Vesanoid Portugal*.

36 Article 69 of Law 19/2012 of 8 May 2012.

37 Law 23/2018 of 5 June 2018.

the maximum margin to apply in the sale of personal protective equipment against the covid-19 pandemic – which would later be subject to legislative intervention – recalling, in general terms, that the limitation of the freedom of its members through the imposition of commercial (and other) conditions constitutes an infringement of the competition rules, punishable under the Competition Act.[38]

In September 2018, the AdC and the Infarmed signed a memorandum of understanding agreeing on a regular exchange of information on the supervision and monitoring of the sale and consumption of medical products for human use, medical devices and cosmetics, aiming at timely detecting market failures and competitive distortions. The idea of both authorities is to closely monitor the evolution of prices, patent periods, the introduction of generic medicines, the development of biosimilars and shortages of medicines in the market to be able to assess the extent to which anomalous situations may be related to the existence of anticompetitive practices.

In this context, the AdC sanctioned Natus Medical Incorporated (Natus) for alleged restriction of competition in the distribution of essential medical devices in the Portuguese market; thus, Natus was fined €100,000, further to a settlement with the AdC whereby it acknowledged that it engaged in vertical conduct that would have prevented its distributors from selling to customers located outside the geographical areas allocated to them and following unsolicited orders, and further defined the portfolio of products that could be resold by the distributors to specific customers from 2018 until December 2020.[39]

Under this framework, agreements made between undertakings that aim to prevent the access of substitutes to the market, such as pay-for-delay, are prohibited (Article 9 of the Competition Act).

In 2014, in the *AstraZeneca* case, the AdC assessed for the first time a potential pay-for-delay infringement.[40] At issue was an agreement that was concluded between Teva and its subsidiary Ratiopharm with the company AstraZeneca, through which Teva and Ratiopharm agreed to withdraw the product Rosuvastatin Ratiopharm, distributed by Ratiopharm, from the Portuguese market.

In Portugal, AstraZeneca commercialises the medicines Crestor and Visacor, which are composed of the active substance rosuvastatin. Crestor was protected by a patent until 2012 and by a supplementary protection certificate until 2017 (valid at that time); however, Rosuvastatin Ratiopharm, a competing product, entered the market without any verification of the IPRs at stake. In this context, AstraZeneca filed patent infringement proceedings, and the parties settled the conflict through an agreement that covered the withdrawal of Rosuvastatin Ratiopharm from the Portuguese market.

In the same case, the AdC pointed out that intellectual property dispute settlement agreements may be found to be anticompetitive under Article 9 of the Competition Act. To this end, it has clarified that agreements between companies to settle patent litigation are, like any other agreement between undertakings, subject to scrutiny of the competition rules. This means that although companies have the right to settle their patent disputes, they must

38 AdC, 'Competition policy priorities for 2021'.

39 AdC, 27 April 2021, Case No. PRC/2020/3, *Natus Medical Incorporated*.

40 AdC, 29 March 2016, Case No. PRC/2014/04, *AstraZeneca, Teva and Ratiopharm*.

do so while respecting the competition rules; the fact that these agreements are based on a patent dispute and a consequent arbitration decision does not exempt them from complying with the competition rules.[41]

The first time the AdC took interest in what concerns restrictive practices in the pharmaceutical sector was in 2005. The AdC fined five pharmaceutical companies (Abbott, Bayer, Johnson & Johnson, Menarini and Roche) in the first sanctioned cartel case in Portugal.

The case involved the alleged concertation of these five pharmaceutical companies in several public tenders for the supply of reagent strips of various Portuguese hospitals, and a total fine of around €19 million was imposed on these companies. Some of the sanctioned undertakings appealed the AdC's decisions and, because of procedural irregularities, the Commercial Court of Lisbon (competent for competition cases before the Competition Court was established) partially annulled the AdC's decisions and required the AdC to repeat some procedural acts.

Subsequently, in 2008, the AdC restated its first assessment of the case, confirming that the involved undertakings concerted on numerous occasions, from 2001 to 2004, to fix the prices to be submitted in bids for reagent strips in hospital tenders, aiming to raise their prices; thus, having corrected the procedural errors, the AdC again imposed an overall fine of €13.5 million on the appellant companies, which was, at the time, a record fine.[42]

In 2015, in the *ANF* case, ANF, the largest association of pharmacies operating in Portugal, and three other undertakings of the same group[43] had allegedly abused their dominant position through margin squeezing in the market of commercial data of pharmacies, and in the markets of pharma market studies based on this data.[44] In short, ANF made access to IMS Health Lda pharmacy data difficult.

IMS Health Lda provides market studies in the health sector and is an undertaking competing with HMR (a company created within the ANF Group to operate in the market for the production and sale of market research based on commercial pharmacy data). The AdC considered that the ANF Group's practice was abusive and had led to upstream and downstream markets foreclosure. It imposed an overall fine of €10.3 million.

The Competition Court upheld the AdC's decision while reducing the amount of the fine to €6.89 million because of the nature and size of the affected market.[45] ANF appealed this decision, and in June 2017 the fine was reduced for a second time by the Lisbon Court of Appeal on the grounds that the requirements to establish Farminveste's parental liability were not met, resulting in the revocation of the fine of €6.08 million specifically imposed on Farminveste.[46]

Earlier, in 2012, the AdC found that Roche Farmacêutica Química Lda had abused its dominant position (in relation to certain medicines) in the context of tender proposals in hospitals by providing mixed bundles and loyalty discounts in its medicine tender proposals. The AdC imposed a fine of €900,000.[47]

41 ibid.

42 AdC, 11 January 2005, Cases No. PRC/2003/6 and No. 2005/4, *Reagent Strips* cartel.

43 Farminveste SGPS, Farminveste – Investimentos, Participações e Gestão SA and HMR – Health Market Research, Lda.

44 AdC, 22 December 2015, Case No. PRC/2009/13, *Associação Nacional das Farmácias*.

45 Competition Court, 20 October 2016, Case No. 36/16.QYUSTR, *Associação Nacional das Farmácias*.

46 Lisbon Court of Appeal, 14 June 2017, Case No. 36/16.QYUSTR.L1, *Associação Nacional das Farmácias*

47 AdC, 12 April 2012, Case No. PRC/2008/10, *Roche Farmacêutica Química Lda*.

In 2021, the AdC sanctioned AOC Health GmbH with a fine of €35,000 for gun jumping, characterised by the failure to notify, under the merger control regime, the acquisition of Stemlab. Stemlab is the company that controls the Crioestaminal and BebéCord brands.[48]

VIII OUTLOOK AND CONCLUSIONS

Portuguese law does not provide specific provisions regarding the relationship between pharmaceutical intellectual property and competition law, and relies on general competition prohibitions to assess the validity of intellectual property-related practices. The regulation of the crossover between both areas is largely similar in substance to the applicable EU rules because the main legal developments affecting pharmaceutical intellectual property and competition law have occurred at the European level; many issues are yet to be addressed at the national level.

One of the first alleged cartels sanctioned by the AdC involved the supply of pharmaceutical products to Portuguese hospitals. There were also investigations concerning abuse of a dominant position in the pharmaceutical sector, which evidences the relevance of the monitoring activity of the AdC in this sector.

The AdC's decision practice demonstrates a certain concern towards mitigating the eventual anticompetitive effect of practices, including those related to IPRs, in the pharmaceutical sector, which allows for some expected developments at the national level in this area.

Additionally, further to the health and financial crisis arising from the covid-19 pandemic, specific attention is being paid to the pharmaceutical sector. In the context of the pandemic, the AdC has spent time evaluating options to strengthen competition regimes, with a special focus on innovation. It drew attention to the importance of promoting innovation towards a better and more sustainable economic recovery.

Making protection and incentives for innovation one of its priorities for 2021, and again in 2022, the AdC considers that the removal of structural and legislative barriers that impede innovation, efficiency and growth contribute to greater competitiveness between companies.[49] This increasing attention over innovation concerns is leading to more sophisticated, substantive assessments in merger control proceedings, especially for more importance to be given to the merger's impact in terms of reducing choice and harming innovation.

Further developments can undoubtedly be expected in the near future, and undertakings must remain vigilant for new rules and, especially, new enforcement approaches.

48 AdC, 6 October 2021, Case No. DCC-PCC/2021/2, *AOC Health GmbH*.

49 See footnote 38 and AdC, 'Competition policy priorities in 2022'.

Appendix 1

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