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Life Sciences 2023

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Portugal: Law & Practice

Eduardo Nogueira Pinto,
Hugo Monteiro de Queirós, Eliana Bernardo and Ricardo Rocha
PLMJ

PORTUGAL

Law and Practice

Contributed by:
Eduardo Nogueira Pinto, Hugo Monteiro de Queirós,
Eliana Bernardo and Ricardo Rocha
PLMJ

Contents

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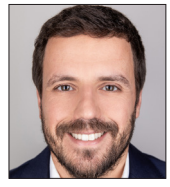
The firm would like to thank Vasco Granate for his contribution to this chapter.

Authors

Eduardo Nogueira Pinto is a partner at PLMJ, where he heads the healthcare, life sciences and pharmaceuticals practice. He has 20 years' experience in advising Portuguese and foreign companies, and has worked on many projects in the areas of healthcare and pharmaceuticals. Eduardo focuses on regulatory matters, licensing, compliance, advertising, prices and reimbursements, contracts and market access. He has a law degree from the Faculty of Law of Universidade Católica Portuguesa.



Hugo Monteiro de Queirós is a partner at PLMJ and head of the intellectual property practice. He has more than 15 years' professional experience, and advises on patents, trade marks, designs, copyright and software licensing. Hugo also has a strong focus on IP litigation, with an emphasis on dealing with arbitration and court cases involving patent disputes and trade mark enforcement. He also drafts opinions and contracts in all areas of intellectual property. Hugo has been an Official Industrial Property Agent since 2012 and a European Trademark and Design Attorney since 2016. He is a frequent speaker at universities and at Portuguese and international congresses and seminars.

Eliana Bernardo is a managing associate at PLMJ, in the healthcare, life sciences and pharmaceuticals practice, and has more than 15 years' experience in legal practice. She acts for Portuguese and multinational companies from various sectors, including industry, the distribution and retail sale of medicines, medical devices, food supplements, and cosmetics and personal hygiene products. Eliana assists her clients with licensing, prior medical assessments, the reimbursement and revision of medicine prices, compliance and controlled substances. She also has experience in administrative litigation.

Ricardo Rocha is a senior associate at PLMJ, in the healthcare, life sciences and pharmaceuticals practice, and has more than seven years' experience. He focuses on providing regulatory advice to Portuguese and international companies in the pharmaceutical industry. He assists his clients with all matters relating to the development and marketing of medicines, medical devices, food supplements and cosmetics. Before joining PLMJ, Ricardo was a lawyer at Glintt – Global Intelligent Technologies.

PLMJ

Av. Fontes Pereira de Melo, 43
1050-119
Lisboa
Portugal

Tel: +351 213 197 300
Fax: +351 213 197 400
Email: plmjlaw@plmj.pt
Web: www.plmj.com/en/

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation for Pharmaceuticals and Medical Devices

The rules on medicines for human use come from Decree-Law 176/2006 of 30 August 2006, while the rules on medical devices come from Decree-Law 145/2009 of 17 June 2009 and Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 (the Medical Devices Regulation – MDR). There are also several sets of regulations implementing the decree-laws in different matters.

The regulatory body that applies and enforces pharmaceutical and medical device regulation is the INFARMED (the National Authority of Medicines and Health Products, IP). INFARMED is part of the State's indirect administration and is endowed with administrative and financial autonomy. It is responsible for carrying out the responsibilities of the Ministry of Health under the supervision and guidance of the Minister of Health.

As a rule, decisions regarding expenditure on medicines and medical devices are taken by the Minister of Health, who may delegate these decisions to INFARMED.

1.2 Challenging Decisions of Regulatory Bodies That Enforce Pharmaceuticals and Medical Devices Regulation

INFARMED's decisions regarding medicines and medical devices may be challenged through administrative and/or judicial channels, within a given period.

Individuals and entities who are affected by these decisions can react against them, mainly on the grounds of breach of the law. These means of reaction are common to decisions that affect other products (eg, food supplements), although there may be specific details.

1.3 Different Categories of Pharmaceuticals and Medical Devices

Certain categories of medicines and medical devices are subject to specific regulation. For example:

- medicines containing psychotropic and narcotic substances are regulated by Decree-Law 15/93 of 22 January 2022, Decree-Regulation 61/94 of 12 October 1994, Law 33/2018 of 18 July 2018 and Decree-Law 8/2019 of 15 of January; and
- medical devices for in vitro diagnosis are regulated by Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 and Decree-Law 189/2000 of 12 August 2000.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials of medicines and clinical studies of medical devices are regulated by different pieces of legislation.

Medicines

Clinical trials on medicines are regulated by Regulation (EU) 536/2014 of the European Parliament and of the Council of 16 April 2014 ("Clinical Trials Regulation") and Law 21/2014 of 16 April 2014 ("Clinical Trials Law").

The entry into force of the Clinical Trials Regulation on 31 January 2022 involved the entry into force of the Clinical Trials Information System (CTIS), through which all clinical trial submission, assessment and supervision processes in

the EU are to be submitted. The Clinical Trials Regulation provides for a three-year transition period, with the following timeline:

- from 31 January 2022 to 31 January 2023, clinical trial sponsors were able to choose to submit their clinical trial applications under the Clinical Trials Directive or through the CTIS;
- from 31 January 2023, new applications for clinical trials in the EU and the European Economic Area must be submitted under the CTIS; and
- by 31 January 2025, all ongoing trials will have to be transferred to the CTIS under the Clinical Trials Regulation.

Medical Devices

The rules regarding clinical studies of medical devices are found in Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and in Decree-Law 145/2009, which establishes the rules regarding the research, manufacturing, marketing, putting into use, monitoring and advertising of medical devices and their accessories. With the entry into force of the MDR, the rules of Decree-Law 145/2009 that contradict the MDR are no longer applicable; only the rules that do not contradict the MDR remain in force. The Portuguese legislation implementing the MDR is undergoing the legislative process and awaiting publication.

In Vitro Medical Devices

The legal rules applicable to in vitro medical devices are established in Decree-Law 189/2000 of 12 August and Decree-Law 145/2009.

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (IVDR) has been applicable since 26 May 2022. In January 2022, the European Parliament and the Council adopted a staggered extension of its transition period, ranging from 26 May 2025 for high-risk in vitro diagnostics to 26 May 2027 for lower risk in vitro diagnostics, and to 26 May 2028 for certain provisions concerning devices manufactured and used in health institutions.

However, in January 2023 the European Commission published a draft amendment to extend transitional periods for the MDR and the IVDR.

The amending act must now go through the EU legislative process, starting with the public consultation.

2.2 Procedure for Securing Authorisation to Undertake a Clinical Trial

Medicines

In the transition period up to 31 January 2023, authorisation to conduct a clinical trial of a medicine was obtained under the rules established in the Clinical Trials Law or through the CTIS, pursuant to the Clinical Trials Regulation.

If the sponsor opts for the Clinical Trials Law arrangements, the application for authorisation to conduct clinical trials must be submitted to INFARMED through the National Clinical Trials Register, together with the relevant documentation.

INFARMED will decide on the application for authorisation within 30 days, and may ask the applicant for additional information once only.

Within the period granted, the sponsor may change the content of the application for authorisation, only once, and the period will be suspended until the change is made. If the sponsor does not change the application as requested, the clinical trial may not be conducted.

INFARMED may decide on the need to obtain express authorisation to conduct trials involving the following medicines:

- those that do not have a marketing authorisation (MA) and that are listed in Annex A to Regulation (EC) 726/2004 of the European Parliament and of the Council of 31 March 2004; and
- those which have special characteristics – ie, whose active substance or substances are biological products of human or animal origin or contain biological components of human or animal origin, or whose production requires such components.

Clinical trials involving the following medicines will require express authorisation from INFARMED:

- those for gene therapy;
- those for somatic cell therapy;
- those containing genetically modified organisms; and
- those for xenogeneic cell therapy.

If the application for authorisation is submitted under the Clinical Trials Regulation, it should be submitted through the CTIS and the sponsor of that application should propose a reporting member state, which will be responsible for the analysis of the application.

Medical Devices

Applications to conduct clinical investigations as defined in the MDR must be submitted by the sponsor to the member state(s) in which the clinical investigation is to be conducted. The application must be submitted through the electronic system referred to in the MDR, accompanied by the documents referred to in Chapter II of Annex XV of the MDR.

2.3 Public Availability of the Conduct of a Clinical Trial

Clinical trials of medicines and clinical studies of medical devices are available on the National Clinical Trials Register website at www.rnec.pt. The results of clinical trials and clinical studies of medical devices are not available in publicly accessible databases.

2.4 Restriction on Using Online Tools to Support Clinical Trials

The methods of recruitment for clinical trials of medicines and clinical studies of medical devices must follow the legally prescribed rules. In addition to physical advertising methods, digital means can be used for this purpose. These means may also be used for monitoring purposes, provided that they do not jeopardise the purpose and safety of the trial.

2.5 Use of Data Resulting From the Clinical Trials

Data from clinical trials of medicines and clinical studies of medical devices may qualify as personal data in the sense of sensitive data. However, if the data is fully anonymised (and not merely pseudonymised), it is no longer personal data so does not fall within the category of sensitive data. Anonymisation implies that the identity of the data subject is unobtainable, in which case the data becomes anonymous.

If the resulting data is still personal data, it might be transferred to third parties or affiliates, provided such transfer complies with the requirements set out in the General Data Protection Regulation (GDPR), notably when it comes to consent and information obligations, security of the processing issues, joint-controllership or sub-processing agreements, and international data transfers. If the resulting data is anonymised data, then those GDPR requirements do not apply.

2.6 Databases Containing Personal or Sensitive Data

The requirements under the GDPR regarding the processing of health data apply with regard to the grounds for the lawfulness of processing, transparency and security measures.

3. Marketing Authorisations for Pharmaceutical or Medical Devices

3.1 Product Classification: Pharmaceutical or Medical Devices

Products are classified through the definition of medicine (function and/or presentation) and the definition of medical device provided in the applicable legal provisions. In the case of borderline products, the purpose intended by the manufacturer of the product in question and the mechanism through which the main desired effect is achieved are taken into consideration.

3.2 Granting a Marketing Authorisation for Biologic Medicinal Products

Medicines developed by means of one of the following biotechnological processes must be subjected to the centralised community procedure:

- recombinant DNA technology;
- controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells; and
- hybridoma and monoclonal antibody methods.

3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices

Medicines

In the case of medicines, the MA is valid for five years; after the first renewal, it is valid indefinitely or, if considered necessary, for a second five-year period. The renewal of the MA is subject to a specific renewal procedure.

An MA may be revoked, suspended or amended whenever there is non-compliance with the applicable legal and regulatory provisions, or with the conditions of the MA in question. This includes when it is concluded that the risk-benefit balance is unfavourable, the medicine is harmful or the manufacturing process does not comply with the applicable good practices.

Medical Devices

No authorisation is required for placing medical devices on the market. The manufacturer must submit the medical device to a conformity assessment and notify the competent authority that the medical device has been made available on the market. INFARMED may withdraw a product from the market or may suspend, restrict or subject to certain conditions the placing on the market and putting into service of a device or group of medical devices under certain conditions – namely, when the use of medical devices could compromise the health and safety of patients or other persons, or for public health reasons.

3.4 Procedure for Obtaining a Marketing Authorisation for Pharmaceutical and Medical Devices

The marketing of a medicine may follow one of these procedures:

- a national procedure, if the medicine is intended to be approved only for placing on the Portuguese market;
- a mutual recognition procedure, in which an authorisation obtained in a member state is used to apply for authorisation in a new member state;
- a decentralised procedure, when the application is submitted in several member states simultaneously and when the medicine does not have an MA in any member state; and
- a centralised procedure, managed by the European Medicines Agency (EMA), leading to an MA that is valid in all member states.

Any change in the terms of an MA must be subject to an application for a variation of the MA, including changes to the summary of product characteristics and any conditions, obligations or restrictions affecting the MA, or changes to the labelling or package leaflet in connection with changes to the summary of product characteristics.

An MA may be transferred to a new holder through the submission of a transfer application by the MA holder.

The placement of a medical device on the market does not require authorisation (see **3.3 Period of Validity for Marketing Authorisation for Pharmaceutical or Medical Devices**).

3.5 Access to Pharmaceutical and Medical Devices Without Marketing Authorisations

Medicines without an MA or without an MA that is valid in Portugal may be made available to patients through the exceptional use authorisation, under which they can be accessed by patients through early access programmes, which have a specific regulation issued by INFARMED.

Regarding medical devices, INFARMED may authorise the placing on the market or putting into service of a medical device for which no conformity assessment procedures have been carried out but the use of which is in the interest of public health or patient safety or health.

Compassionate use also takes place in the context of clinical trials.

3.6 Marketing Authorisations for Pharmaceutical and Medical Devices: Ongoing Obligations

The MA for a medicine may be granted subject to the subsequent conduct of additional studies or compliance with special rules regarding safety and the reporting of all incidents associated with the use of the medicine and the measures to be taken, the conduct of a post-authorisation safety or efficacy study, or the fulfilment of other obligations established by INFARMED.

After the granting of an MA, INFARMED may require its holder to conduct a post-authorisation safety study if there are doubts about the risks of the authorised medicine or if knowledge about the disease or clinical methodology indicates that previous efficacy evaluations may need to be significantly revised.

The holder of an MA is obliged to comply with the obligations provided for by law – namely, to comply with pharmacovigilance obligations and to make this or other data proving that the benefit-risk relationship of the medicine remains favourable available to INFARMED.

Manufacturers of medical devices other than investigational devices must report any field

safety corrective action to INFARMED, as well as any serious incident or any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected to have undesirable side effects that could have a significant impact on the benefit-risk analysis, and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations for Pharmaceutical and Medical Devices

INFARMED publishes information on the status of an MA application and its assessment report on its website. It suppresses any commercially confidential information and allows access to the summary of product characteristics and the package leaflet, as well as information on the medical devices placed on the market.

3.8 Rules Against Illegal Medicines and/or Medical Devices

Decree-Law 26/2018 of 24 April 2018 incorporated the European legislation on falsified medicines into Portuguese law. This legislation establishes the mandatory placement of safety devices on the packaging of certain medicines, which must be checked by all participants in the chain, to allow the detection of falsified or adulterated medicines in the circuit and the individual identification of packaging.

Under the regulatory framework, INFARMED must draw an annual surveillance activity plan and perform appropriate checks on the conformity characteristics and performance of medical devices, including, where appropriate, a review of documentation and physical or laboratory checks based on adequate samples.

3.9 Border Measures to Tackle Counterfeit Pharmaceutical and Medical Devices

INFARMED established a protocol with the Tax and Customs Authority to inspect and intercept counterfeit medicines. The Legal Framework for Tax Infractions and Customs Crimes also provides for the existence of customs offences and crimes associated with the counterfeiting of goods, which may include counterfeit medicines and medical devices.

4. Manufacturing of Pharmaceutical and Medical Devices

4.1 Requirement for Authorisation for Manufacturing Plants of Pharmaceutical and Medical Devices

The manufacture of medicines, experimental medicines and medical devices requires authorisation from INFARMED.

The manufacture of medicines requires the existence of facilities licensed for the purpose, and compliance with good manufacturing practices. The facilities are subject to periodic inspections by INFARMED, which certifies their compliance and issues a certificate of good manufacturing practices, which is valid for three years.

For medical devices, facilities must obtain an industrial activity licence in accordance with the applicable legislation and have an industrial activity code associated with the categories of medical devices produced in conjunction with the respective manufacturing activities performed.

5. Distribution of Pharmaceutical and Medical Devices

5.1 Wholesale of Pharmaceutical and Medical Devices

Authorisation for the wholesale of medicines is issued by INFARMED and covers the activities of supplying, holding, storing or delivering medicines for processing, resale or use in medical services, healthcare facilities and pharmacies, excluding the supply to the public. It specifies the facilities from which distribution is carried out and is subject to the validity of the certificate of good distribution practices, which must be renewed every five years.

The wholesale of medical devices is subject to prior notification to INFARMED and covers the activities of supplying, holding, storing or supplying medical devices for resale or use in medical services, healthcare facilities, pharmacies and other points of sale to the public, excluding supply to the public. The application must be submitted at least 60 days before the start of the distribution activities and must include the full address of the distribution facilities. It does not have an expiration date.

5.2 Different Classifications Applicable to Pharmaceuticals

For dispensing to the public, medicines are classifiedinto prescription-only medicines (MSRMs) and non-prescription medicines (MNSRMs). The former can also be classified as renewable, special or for restricted use in specialised monitored conditions, and the latter as MNSRMs for dispensing only in pharmacies.

6. Importation and Exportation of Pharmaceuticals and Medical Devices

6.1 Governing Law for the Importation and Exportation of Pharmaceutical Devices and Relevant Enforcement Bodies

The import and export of medicines is regulated by Decree-Law 176/2006 of 30 August 2006 and by related legislation on good practice in transportation and distribution. For medical devices, the MDR and Decree-Law 145/2009 are applicable.

INFARMED is the entity responsible for monitoring compliance with these regulations.

6.2 Importer of Record of Pharmaceutical and Medical Devices

Any natural or legal person duly authorised and licensed for that purpose by INFARMED can be an importer of medicines and medical devices.

6.3 Prior Authorisations for the Importation of Pharmaceuticals and Medical Devices

The import and export of medicines and medical devices requires the economic operator to be licensed by INFARMED for that purpose. For personal use, medicines can be transported only for the necessary period, provided that they are accompanied by a medical prescription, when necessary. In the case of emergency situations or donations, INFARMED will assess each case individually.

6.4 Non-tariff Regulations and Restrictions Imposed Upon Importation

The regulations to be considered upon importation of any products into the Portuguese terri-

tory, which is part of the customs territory of the European Union, are as follows:

- Regulation (EU) 952/2013 of the European Parliament and of the Council of 9 October 2013, which approves the Union Customs Code;
- Commission Delegated Regulation (EU) 2015/2446 of 28 July 2015; and
- Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015.

6.5 Trade Blocs and Free Trade Agreements

Portugal is part of the EU and the single European market, and it applies the principle of free movement of goods and services; it also has harmonised regulatory rules for medicines and medical devices.

7. Pharmaceutical and Medical Device Pricing and Reimbursement

7.1 Price Control for Pharmaceuticals and Medical Devices

Price Control for Medicines

Non-reimbursed medicines have free pricing arrangements, but all other medicines have their prices regulated and are subject to maximum price rules or notified price rules. They cannot be sold unless the MA holder obtains a retail price (RP).

The RP of the medicine is composed of:

- the ex-factory price (EFP), which is the maximum price at the stage of production or import and has fixed rules for its determination;
- the wholesalers' and retailers' selling margins, as fixed by ministerial order;
- the tax on the sale of medicines; and
- value-added tax (VAT).

The MSRMs intended to be dispensed and used in National Health Service (NHS) establishments are also subject to maximum price rules, and their final price is composed of the EFP, the sale tax and VAT.

The prices of medicines subject to the maximum price rules are reviewed annually. The pricing rules for medicines are set out in Decree-Law 97/2015 of 1 June 2015 and regulated by several Ministerial Orders (in particular Ministerial Order 195-C/2015 of 30 June 2015 and Ministerial Order 154/2016 of 27 May 2016).

Requests for price authorisation and price revision communications follow their own procedures and are submitted to INFARMED by the MA holder.

Price Control for Medical Devices

As a rule, medical devices financed by the State have fixed maximum prices. Medical devices not financed by the State have free pricing.

The pricing rules for medical devices are set out in Decree-Law 97/2015 of 1 June 2015, and there are Ministerial Orders that define the maximum prices applicable to certain devices or groups of medical devices, which usually include the marketing margins and VAT. In these cases, the RP proposed is indicated by the manufacturer at the time of the request for reimbursement to INFARMED, which follows its own procedure.

7.2 Price Levels of Pharmaceutical or Medical Devices

Price Levels of Medicines

The price of medicines is generally set and reviewed on the basis of the prices in the refer-

ence countries with comparable GDP per capita or lowest price level, defined annually among EU countries.

The Ministerial Order 35/2023 of 26 January has defined Spain, France, Italy and Slovenia as reference countries in 2023.

Price Levels of Medical Devices
The price of medical devices does not depend on the prices applied in other countries.

7.3 Pharmaceuticals and Medical Devices: Reimbursement From Public Funds

Public financing of medicines and medical devices depends on an application to INFARMED by the MA holder or the manufacturer, respectively. This public financing may be full or partial and differs according to various factors, including pathologies or special groups of patients, therapeutic indications, prevalence of certain diseases in the population, etc; see **7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices**.

7.4 Cost-Benefit Analyses for Pharmaceuticals and Medical Devices

Cost-Benefit Analyses for Medicines
State funding of medicines is, as a rule, cumulatively subject to prior technical-scientific demonstration of therapeutic innovation or equivalence for the therapeutic indications claimed, as well as demonstration of the economic advantage of the medicine. These factors are not decisive in fixing the price of medicines, because these prices tend to be fixed taking into account the prices in the reference countries – see **7.1 Price Control for Pharmaceuticals and Medical Devices** and **7.2 Price Levels of Pharmaceuticals or Medical Devices**.

Cost-Benefit Analyses for Medical Devices
A cost-benefit analysis is also carried out in the financing of medical devices by the State, considering the therapeutic innovation demonstrated for the clinical purposes claimed and the demonstration of an economic advantage – see **7.1 Price Control for Pharmaceuticals and Medical Devices**.

7.5 Regulation of Prescriptions and Dispensing by Pharmacies

In order to ensure the sustainability of the NHS, the prescribing of reimbursed medicines is made using the international non-proprietary name and may only include the commercial name of the medicines in the exceptional cases listed in the law. Pharmacies are obliged to inform the patient about the medicine that, in compliance with the prescription, has the lowest price. These rules apply to reimbursed medical devices, with the necessary adaptations.

8. Digital Healthcare

8.1 Rules for Medical Apps

As software, medical apps are considered active medical devices under the MDR, with lifestyle and well-being apps being expressly excluded from the scope of the MDR. The classification criteria are provided by the MDR and supporting documents are published for this purpose by the European Commission.

8.2 Rules for Telemedicine

The rules on telemedicine are laid down in the Code of Ethics of the Portuguese Medical Association, which establishes standards for the safety and quality of the means used.

8.3 Promoting and/or Advertising on an Online Platform

The advertising of medicines and medical devices is highly regulated and there are specific regulations for each of these product categories, which are also applicable to online portals, company webpages and social networks.

8.4 Electronic Prescriptions

Electronic prescribing is the rule and has been in place for several years. Non-electronic prescriptions are exceptions and are only allowed in specific cases.

8.5 Online Sales of Medicines and Medical Devices

Regarding medicines, under certain circumstances, pharmacies and MNSRM outlets can perform home delivery of medicines, and such medicines can be ordered over the internet. Medicines cannot be delivered by post or courier.

It is possible to market medical devices online and deliver by post or courier. Admissibility must be assessed on a case-by-case basis and, in any case, the quality of the medical device must be guaranteed.

8.6 Electronic Health Records

Health-related records are regulated as health data under the GDPR, and health-related information is considered sensitive data under the GDPR. Moreover, Law 58/2019 of 8 August 2019, which ensures the implementation of the GDPR, contains specific obligations regarding professional secrecy. These obligations apply to all member of corporate bodies, employees and service providers of the controller, and to students and researchers in the field of health who have access to such data. The data subject must be notified of any access made to their personal data, and the controller must ensure that a traceability and notification mechanism is in place.

There are no special requirements for cloud platforms. Portugal does not restrict the processing of health data to its territory, so the general rules provided in Chapter V of the GDPR on international data transfers apply. It is permitted to store sensitive patient data on cloud platforms. However, regarding information security, in addition to the general requirements of the GDPR, most public bodies, including public hospitals, are obliged to comply with Council of Ministers Resolution 41/2018. This defines technical guidelines for the Public Administration on the security architecture of networks and information systems regarding personal data.

9. Patents Relating to Pharmaceuticals and Medical Devices

9.1 Laws Applicable to Patents for Pharmaceutical and Medical Devices

The Portuguese Industrial Property Code (IPC) contains the most relevant provisions for patents, including for patent prosecution and enforcement.

Special inhibitory actions relating to pharmaceutical patents and generic medicines are available under Law 62/2011 of 12 December 2011.

The most common issues encountered by pharmaceutical companies in Portugal relate to patent disputes between originator and generic companies under Law 62/2011. Other issues that usually arise relate to the validity of patents and supplementary protection certificates (SPCs).

There are no specific patentability requirements for medicines or medical devices per se. However, according to the IPC, processes for cloning human beings, processes for modifying the germinal genetic identity of the human being and uses of human embryos for industrial or commercial purposes are not patentable.

Methods of surgical or therapeutic treatment are also not patentable, but the products, substances or compositions used in any of these methods may be patented.

9.2 Second and Subsequent Medical Uses

Second and subsequent medical uses of a known substance or composition are regarded as patentable in Portugal, provided that any such use meets the general patentability requirements.

According to the Guidelines of the Portuguese Institute of Industrial Property, the term "use" may include new dosage regimes and new patient groups.

There is no clear guidance from the Portuguese courts as to what specific activities constitute infringement of second and subsequent patents of medicines. However, in a 2015 judgment, the Lisbon Second Instance Court decided that the patent-holder of a second medical use patent can only react against the applicant of an MA for the generic medicine if the active pharmaceutical ingredient is prepared and adopted for the specific therapeutic use that is patented. In the first instance decision of this case, the ad hoc arbitral tribunal considered that one cannot conclude that there has been an infringement of the second use patent if the generic medicine does not have the patented use as a therapeutic indication according to the granted MA.

9.3 Patent Term Extension for Pharmaceuticals

The patent-holder may obtain a patent term extension for medicines by applying for an SPC.

The application for an SPC is regulated in the IPC and is governed by Regulation (EC) 469/2009 of the European Parliament and of the Council of 6 May 2009 ("SPC Regulation"). The SPC application must be filed with the Portuguese Industrial Property Office (INPI) in Portuguese, with a copy of the first MA of the product in Portugal.

If granted, the SPC can extend the protection conferred by the basic patent for the time that has passed between the filing of the patent application and the date of grant of the MA, minus five years.

The validity of the SPC cannot exceed five years from the expiry of the basic patent, except when it concerns medicines for paediatric use, where a further six-month extension is available.

Patent term extensions via an SPC may be challenged by any interested party before the INPI if the date of the first MA indicated by the patent-holder in the SPC application is incorrect. The INPI can also amend the validity period of an SPC of its own motion when it verifies the existence of an error.

An action for the revocation of an SPC can be brought by any interested party before the Portuguese Intellectual Property Court, under the IPC.

9.4 Pharmaceutical or Medical Device Patent Infringement

Similarly to other patents, medicine or medical device patents give the patent-holder the right to prevent any third party from:

- manufacturing, offering, stocking, placing on the market or using a product that is the subject matter of the patent, or importing or possessing it, for any of the purposes previously mentioned;
- using the process that is the subject matter of the patent or, if the third party knows or should have known that the use of the process is prohibited without the consent of the patent-holder, offering to use it; and
- offering, stocking, placing on the market or using, or importing or possessing for those purposes, products obtained directly by the process that is the subject matter of the patent.

Applying for an MA does not qualify as a patent infringement action in Portugal. However, the publication of an MA for a generic medicine by INFARMED enables the patent-holder to file a special inhibitory action under Law 62/2011 for invoking incompatible patent rights. The patent-holder can also request the IP Court (or an arbitral tribunal, if arbitration is agreed between the parties), in such action, to determine precautionary measures to prevent infringement of the patent in question.

The threat of infringement is actionable to inhibit any imminent infringement.

9.5 Defences to Patent Infringement in Relation to Pharmaceuticals and Medical Devices

Specific defences to patent infringement in relation to medicines and medical devices in Portugal include an experimental use exemption and, in particular, the Bolar exemption.

Compulsory licences on patents are provided for in the IPC in general terms, but there are no relevant precedents in Portugal with regard to the granting of compulsory licences. In any case, compulsory licences may be granted in Portugal in the following circumstances:

- lack or insufficient exploitation of the invention;
- dependency between patents;
- public interest;
- under EU and Portuguese Competition law; and
- under Regulation (EC) 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of medicines for export to countries with public health problems.

9.6 Proceedings for Patent Infringement

Patent infringement proceedings may be brought by the patent-holder or by the licensee. The licensee's right to bring an action depends on the specific terms of the corresponding licence agreement and on the record of the licence at the INPI.

Although patent infringement is a crime under Portuguese law, the typical procedure for patent infringement actions is a civil lawsuit at the IP Court. Special inhibitory actions relating to pharmaceutical patents and generic medicines are available under Law 62/2011 and must also be filed at the IP Court or, upon agreement of the parties, before an institutional or ad hoc arbitral tribunal.

Civil remedies include preliminary and permanent injunctions granting the patent-holder the right to prevent any imminent infringement or to prohibit the continuation of the infringement. There is also the possibility of requesting the IP court to order the infringer to pay a periodic penalty for breach of the judgment, and to order

the destruction, recall or definitive removal of the infringing goods from the channels of commerce. Damages claims for infringement are also possible.

Invalidity is available as a defence in civil infringement proceedings on the merits, through the filing of a counterclaim for revocation of the patent or SPC.

9.7 Procedures Available to a Generic Entrant

In theory, under the Civil Procedure Code, pre-launch declaratory actions are possible for generic market entrants, although as far as is known there are no relevant precedents in Portugal in this regard. Nullity actions for the invalidation of patents or SPCs in advance of attempted market entry are also possible.

Law 62/2011 (see **9.1 Laws Applicable to Patents for Pharmaceuticals and Medical Devices**) created a special action applicable to patent litigation involving generic medicines, whereby patent-holders can pursue an early assessment of prospective patent infringement, after publication of the MA applications for generic medicines. This law led to a large number of court cases and also to a large number of settlement agreements between patent-holders and generics.

Although the procedure provided for in Law 62/2011 is triggered by the publication of the MA, this procedure does not stay the grant of the MAs or their effect once granted, which means that no patent linkage effect exists.

10. IP Other Than Patents

10.1 Counterfeit Pharmaceuticals and Medical Devices

Counterfeiting consists of the complete reproduction of a sign that is protected as a trade mark. The IPC provides that trade mark counterfeiting is a criminal offence, punishable with imprisonment for up to three years or a fine of up to 360 days. Civil liability also arises from trade mark counterfeiting.

Custom procedures against counterfeit medicines and medical devices are available under Regulation (EU) 608/2013 of the European Parliament and of the Council of 12 June 2013.

10.2 Restrictions on Trade Marks Used for Pharmaceuticals and Medical Devices

Besides the general requirements and impediments provided for in the IPC with respect to trade mark composition (that apply to all marks), Decree-Law 176/2006 further provides that the name of a medicine may comprise a trade mark, as long as that trade mark is not misleading with regard to the therapeutic properties and nature of the product.

Furthermore, the EU Regulations on medical devices also prohibit the use of misleading trade marks.

Under trade mark law, non-counterfeit genuine medicine or medical device products may suffer import restrictions if there is a prior registered trade mark in Portugal that prevents the use of the mark by the importer (eg, on the basis of likelihood of confusion).

10.3 IP Protection for Trade Dress or Design of Pharmaceuticals and Medical Devices

IP protection for the trade dress or design of medicines and medical devices, or their packaging, is potentially available under design rights, copyright and trade mark rights, provided they meet the legal requirements for that protection.

10.4 Data Exclusivity for Pharmaceuticals and Medical Devices

According to an a contrario interpretation of Decree-Law 176/2006, data exclusivity for medicines (chemical drugs and biologicals) will last for at least eight years from the date of granting of the MA for the reference medicine.

Under the same Decree-Law, marketing exclusivity of the reference medicine lasts ten years from its first MA approval, or 11 years from its first MA approval if the originator obtained a new therapeutic indication within eight years of that date that brings significant clinical benefit.

11. COVID-19 and Life Sciences

11.1 Special Regulation for Commercialisation or Distribution of Medicines and Medical Devices

During the COVID-19 pandemic, INFARMED issued guidelines to simplify the import and export of medicines, particularly regarding the import and export of medicines with controlled substances.

INFARMED also issued transitional guidelines to make the import, manufacture and distribution of medical devices faster and more efficient during the pandemic. In addition, it relaxed a number of rules that made it very time-consuming to obtain the necessary devices.

11.2 Special Measures Relating to Clinical Trials

Within the constraints imposed by the pandemic, INFARMED issued guidelines to mitigate the impact of the pandemic on clinical trials that were in progress or about to start. These measures do not specifically target clinical trials of medicines to treat COVID-19. INFARMED stressed the possibility of remote visits through technological means, ensuring the collection and recording of the information foreseen for the visit.

The EMA also implemented exceptional measures regarding the approval and documentation of medicines to treat COVID-19.

11.3 Emergency Approvals of Pharmaceuticals and Medical Devices

The EMA has created a specific, expedited procedure for the approval of medicines, which is characterised by significantly shorter timeframes for the review and approval process.

11.4 Flexibility in Manufacturing Certification as a Result of COVID-19

Within the context of the COVID-19 pandemic, INFARMED has established special and temporary abbreviated procedures for the certification of medical devices that are essential to answer the needs caused by the pandemic – eg, the certification of medical devices such as surgical masks and ventilators for medical purposes.

11.5 Import/Export Restrictions or Flexibilities as a Result of COVID-19

In the context of the outbreak of the pandemic, INFARMED and other authorities issued guidance on easing import requirements for medical devices needed to contain the spread of the virus.

11.6 Drivers for Digital Health Innovation Due to COVID-19

Telemedicine was already allowed in Portugal before the pandemic. These means were used more frequently during the pandemic period, considering the saturation of the NHS hospitals and health facilities.

11.7 Compulsory Licensing of IP Rights for COVID-19-Related Treatments

There is no intention to issue compulsory licences for COVID-19-related treatments or vaccines.

11.8 Liability Exemptions for COVID-19 Treatments or Vaccines

No liability exemptions have been introduced in existing or new provisions regarding COVID-19 vaccines or treatments.

11.9 Requisition or Conversion of Manufacturing Sites

During the pandemic period, industries were turned over to the production of medical devices. Several textile industries temporarily converted their production to the production of medical devices (mainly surgical masks).

11.10 Changes to the System of Public Procurement of Medicines and Medical Devices

Measures to make public procurement more flexible were adopted to ensure the immediate availability of goods and services urgently needed to respond to the pandemic. In addition, an exceptional system of public procurement, expenditure authorisation and administrative authorisation was created. In this system, the creation of exceptional arrangements for simplified direct adjustment stands out, particularly for the acquisition of medicines and medical devices.

In any case, the (almost) non-existence in 2023 of exceptional measures related to COVID-19 should be highlighted. The exceptional and temporary reimbursement regime for Rapid Antigen Tests (TRAg) for professional use prescribed in the National Health Service, which was one of the last remaining measures in force, ended on 30 September 2022.

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