PRACTICAL LAW COMPANY

Life sciences in Portugal: overview

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A Q&A guide to life sciences law in Portugal.

The Q&A gives a high level overview of key issues including pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, patents, trade marks, and product liability.

To compare answers across multiple jurisdictions, visit the *Life Sciences Country Q&A tool*.

This Q&A is part of the PLC multi-jurisdictional guide to life sciences. For a full list of jurisdictional Q&As visit *www.practicallaw.com/lifesciences-mjg*.

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Regulatory overview

1. What is the regulatory framework for the authorisation, pricing and reimbursement of drugs, biologicals and devices (as they are termed in your jurisdiction)?

Legislation

The regulatory framework for the authorisation, pricing and reimbursement of drugs, biological and medical devices in Portugal is based on the application at a national level of EU legislation, including:

- Directive 2001/83, on the Community Code relating to medicinal products for human use (Code for Human Medicines Directive).
- Regulation 726/2004, laying down procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (EMA Regulation).
- Directive 93/42/EEC concerning medical devices (Medical Devices Directive).

The relevant legal framework at the national level is contained in the following legislation:

- Statute of the National Health Service (*Decree-Law 11/93, 15 January 1993*).
- Clinical Trials Act (Law 46/2004, 19 August 2004).
- Industrial Property Act (Decree-Law 36/2006, 5 March 2006).
- Human Medicines Act (Decree-Law 176/2006, 30 August 2006) (Medicines Act).
- Medical Devices Act (Decree-Law 145/2009, 17 June 2009).
- Price of Medicines Act (Decree-Law 112/2011, 29 October 2011).
- Price of Restrictive Use Medicines (*Decree-Law 195/2006, 13 October 2006*).

- Funding and Reimbursement of Medicines (*Decree-Law 48-A/2010, 13 May 2010*).

Regulatory authority

The national medicine regulatory authority (INFARMED) is the authority responsible for the monitoring, supervision and enforcement of the provisions of the Medicines Act and the Medical Devices Act. Members of the respective Board of Directors are appointed for a three year period by the Government.

Biotechnology and combination products

Medicinal products developed using one of the following biotechnological processes is subject to centralised approval by the European Medicines Agency under its centralised procedure:

- Recombinant DNA technology.
- Controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells.
- Hybridoma and monoclonal antibody methods.

In respect of combination products where a medical device is designed to administer a medicinal product:

- The placing on the market of the medical device is generally governed by the Medical Devices Act.
- The placing on the market of the medicinal product is governed by the Medicines Act.

If the medical device is placed on the market in such a way that the device and the medicinal product form a single integral unit which is intended exclusively for use in the given combination and which is not reusable, that single-unit product is governed by the Medicines Act.

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Pricing and state funding

2. What is the structure of the national healthcare system, and how is it funded?

The public national healthcare system, (*Serviço Nacional de Saúde*) (NHS), comprises all the public services and units which provide healthcare services, including:

- Groups of health centres.
- Hospitals, irrespective of their legal designation.

- Local health units.

The Statute of the NHS is contained in Decree-Law 11/93, 15 January 1993. The Ministry of Health is responsible for planning, funding, directing, supervising, evaluating and auditing NHS activities.

The NHS is funded through the state annual budget and by moderating fees paid by users.

The NHS also includes a centralised procurement system for hospitals addressed to the purchase of medical products, through the Central Purchasing Authority (*Serviços Partilhados do Ministério da Saúde*) (*SPMS*) (see *www.spms.pt*).

The NHS also has arrangements with private providers for the delivery of diagnostic and therapeutic services (including dialysis and rehabilitation).

3. How are the prices of medicinal products regulated?

The price of medicines which are not over-the-counter (OTC) medicines eligible for reimbursement is regulated by the government through INFARMED in association with the Directorate-General for Economic Activities (*Decree-Law 112/2011, 29 October 2011*). There are different pricing methods:

- The price of both prescription and over-the-counter medicines eligible for reimbursement by the NHS is determined on the basis of the average price of the same medicine in specific reference countries (currently Spain, France and Slovakia) (*Order 91/2013, 28 February 2013*). The reference countries are subject to a yearly review by the Minister of Health.

- Medicines subject to strict medical prescription, when bought by hospitals, are usually subject to a price agreement between the marketing authorisation holders and INFARMED. The price agreement also governs the supply conditions which apply to NHS hospitals (*Decree-Law 195/2006, 13 October 2006*).

- The price of a generic medicine must be 50% of the sale price of the reference medicine of the same dosage and pharmaceutical form (*Decree-Law 112/2011, 29 November 2011*).

- Medicines which are the subject of parallel trade must, in principle, have a sale price 5% below the equivalent medicine for sale in Portugal.

The price of over-the-counter medicines which are not subject to reimbursement by the NHS is not regulated by the public authorities.

4. When is the cost of a medicinal product funded by the state or reimbursed to the patient? How is the pharmacist compensated for his dispensing services?

The cost of a medicinal product can be funded by the state on the basis of either (*Decree-Law 48-A/2010*):

- Its technical-scientific and added therapeutic value.
- Evidence provided in relation to its economic advantage.

The scientific and economic assessment for funding by the NHS is carried out by INFARMED. Medicines which receive upfront reimbursement of the pharmacy sale price by the NHS generally fall within one of four rating bands:

- Band A: 90%.
- Band B: 69%.
- Band C: 37%.
- Band D: 15%.

Decree-Law 48-A/2010 also establishes that special funding and reimbursement regimes apply to:

- Pensioners (by increasing the percentage of reimbursement they receive for medicines in any of the four bands).
- Patients with specific pathologies or included in special groups (by NHS upfront funding of 100% of the medicine sale price).

A pharmacist in a dispensing pharmacy is remunerated through a maximum legal margin based on the approved medicine authorised wholesale price (MAWP). The pharmacist's price margin varies according to the MAWP price, as follows (*Decree-Law 112/2011*):

- Up to EUR5: 27.9 % over the MAWP.
- EUR5.01 to EUR7: 25.7% (plus EUR0.11).
- EUR7.01 to EUR10: 24.4% (plus EUR0.2).
- EUR10.01 to EUR20: 21.9% (plus EUR0.45).
- EUR20.01 to EUR50: 18.4% (plus EUR1.15).
- Over EUR50: a fixed pharmacy margin of EUR10.35.

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Manufacturing

5. What is the authorisation process for manufacturing medicinal products?

The national manufacturing authorisation process closely follows EU law (*Medicines Act*).

Application

The application must be submitted to INFARMED.

Conditions

The application can be made by a natural or legal person and must contain the following information:

- The specification and pharmaceutical form of the medicine.
- Details of where the manufacture of the medicine will be carried out.
- Evidence of compliance with the applicable technical requirements in relation to:
    - technical directors;
    - premises;
    - equipment; and
    - monitoring;
- Identity of the technical director.

Restrictions on foreign applicants

There are no specific restrictions on foreign applicants. The manufacturing facilities must, however, be located in Portugal.

Key stages and timing

The application for authorisation must be decided within a maximum period of 90 days from the date the request is submitted.

Fee

INFARMED applies a standard fee of EUR588.23 for each medicine manufacturing request (*Order 377/2005, 4 April 2005*). INFARMED's fees are published online at *www.infarmed.pt/portal/page/portal/INFARMED/TAXAS*.

Period of authorisation and renewals

The manufacturing authorisation remains valid until INFARMED cancels it or the holder of the licence withdraws it.

6. What powers does the regulator have in relation to manufacturing authorisations?

Monitoring compliance

A manufacturer's facilities are subject to ad hoc inspections by INFARMED. INFARMED can also request access to reports regarding each manufactured medicine lot.

Imposing penalties

In cases of non-compliance with the applicable manufacturing obligations, INFARMED can suspend or revoke the manufacturing licence (for example, if the manufactured medicine does not meet its declared qualities or quantities).

Where non-compliance can be attributed to the manufacturer's technical director, INFARMED can also suspend the technical director from his functions, or refer him to his professional association.

Without prejudice to potential criminal liability, breach of the relevant obligations is a misdemeanour under the Medicines Act, punishable with a fine for each infringement of up to:

- EUR44,891.81 in the case of manufacturing obligations.
- EUR35,000 in the case of the technical director.

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Clinical trials

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities

Clinical trials are regulated by INFARMED. The Clinical Trials Act (*Law 46/2004, 19 August 2004*) enacts at a national level, Directive 2001/20/EC on the conduct of clinical trials.

Authorisations

Each clinical trial is subject to prior authorisation by INFARMED. Generally, decisions are made within 60 days of application. Additional requests for information suspend the applicable deadline until the requested information is provided by the sponsor.

Clinical trials must also receive a favourable opinion from the Ethics Committee for Clinical Research (*Comissão de Ética para a Investigação Clínica*).

Consent

Clinical trial participants must provide written informed consent (*see below, Trial pre-conditions*).

Trial pre-conditions

The conditions which must be met before the trial can begin include:

- A satisfactory evaluation of the anticipated benefits and risks.
- The existence of a protocol.
- Complete details of the clinical trial sponsor, investigator or principal investigator or investigator-co-ordinator.
- Details of the qualifications of all the team members involved in the clinical trial.
- The existence of an investigator's brochure.
- Details of the clinical trial centre(s) and validation of the adequacy of the facilities.
- The provisions for indemnity or compensation in the event of injury or death attributable to the clinical trial.
- The existence of an insurance or indemnity to cover the liability of the investigator and sponsor.
- Details of the amounts and, where appropriate, the arrangements for rewarding or compensating investigators and trial subjects and the relevant aspects of any agreement between the sponsor and the site.

In respect of trial participants, certain minimum conditions must be met:

- A prior interview with the investigator or team member, in which the participant must be informed of the:
    - clinical trial objectives;
    - risks and inconveniences;
    - associated conditions of performance;
    - the participant's right to withdraw from the clinical trial at any time.

- The protection of data privacy rights.
- Written informed consent, referring to the nature, scope, consequences and risks of the clinical trial.
- Details of the associated medical care to be provided during the clinical trial.
- Designation of a contact person to disclose detailed information to participants.

Procedural requirements

A clinical trial must be conducted in accordance with:

- Good clinical practice.
- The approved protocol.
- IINFARMED's clinical trial authorisation.
- The decision of the Ethics Committee for Clinical Research.

Amendments to the protocol can be made provided they:

- Are minor.
- Do not affect the safety of participants.
- Do not alter the scientific evidence on which the conduct of the trial is based.

During the course of the trial, the investigator must report any adverse events to the sponsor, except those identified in the investigator's brochure or in the protocol as not requiring immediate (within a 24-hour period) notification. The sponsor must keep detailed records of all adverse events.
Serious unexpected adverse events that have caused or may cause the death of a participant must be registered and notified to:

- INFARMED.
- All the competent public authorities of all the participating EU member states involved in the trial.
- The Ethics Committee for Clinical Research.

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Marketing

Authorisation and abridged procedure

8. What is the authorisation process for marketing medicinal products?

Application

The application for authorisation to market a medicinal product in Portugal must be submitted to INFARMED. The Medicines Act follows EU law (*Code for Human Medicines Directive*).

A medicinal product must hold a marketing authorisation obtained through one of the following:

- The national procedure.
- The EU member states (including Portugal) procedure. This includes the:
    - decentralised procedure;
    - mutual recognition procedure.
- The centralised procedure of the European Medicines Agency. This is usually used for medicinal products for human use containing a new active substance for which the therapeutic indication is the treatment of any of the following diseases (*EMA Regulation*):
    - acquired immune deficiency syndrome;
    - cancer;
    - neurodegenerative disorder;
    - diabetes;
    - auto-immune diseases and other immune dysfunctions; and
    - viral diseases.

Authorisation conditions

An application for a marketing authorisation must include:

- The name or corporate name and permanent address of the applicant and, where applicable, of the manufacturer.
- The name of the medicinal product.
- Detailed qualitative and quantitative particulars of the constituents of the medicinal product in standard scientific terminology.
- A description of the medicinal product's manufacturing method.

- The medicinal product's
    - therapeutic indications;
    - contra-indications;
    - adverse reactions;
    - posology;
    - pharmaceutical form;
    - method and route of administration; and
    - expected shelf life.
- If applicable, reasons for any precautionary and safety measures to be taken for the storage of the medicinal product, its administration to patients and for the disposal of waste products, together with an indication of any potential risks presented by the medicinal product for the environment.
- A description of the control methods used by the manufacturer.
- The results of physico-chemical, biological or microbiological tests, toxicological and pharmacological tests and clinical trials.
- A summary of the product's characteristics.
- One or more specimens or mock-ups of the product's outer packaging, immediate packaging and package leaflet.

Other conditions

INFARMED can attach supplementary obligations to the marketing authorisation, for example, the execution of post-authorisation safety studies. In addition, a failure to effectively commercialise the medicine for a period of three consecutive years, regardless of the reasons, generally leads to forfeiture of the authorisation. Loss of the marketing authorisation is published on INFARMED's website.

Key stages and timing

INFARMED must make a final decision on a complete marketing authorisation application within a period of 210 days, without prejudice to potential time suspensions (for example, requests for information from the applicant due to detected deficiencies in the submitted file).

Fee

The applicable marketing authorisation base fees include for requests (*Order 377/2005, 4 April 2005*):

- Under the national procedure (per dosage and pharmaceutical form): EUR2915.55.
- From a member state with Portugal as the reference member state (per dosage and pharmaceutical form): EUR7672.50.
- For the parallel import of a medicine (per dosage and pharmaceutical form): EUR1,759.56.

INFARMED's applicable fees are published online at *www.infarmed.pt/portal/page/portal/INFARMED/TAXAS*.

Period of authorisation and renewals

The marketing authorisation is initially granted and valid for a period of five years. After the first renewal, following a formal request by the market authorisation holder, the subsequent authorisation is valid for an indefinite period. In exceptional cases, the renewal of the marketing authorisation may be subject to a limited five-year period.

Post-marketing commitments and pharmacovigilance obligations

The market authorisation holder must have a qualified person responsible for:

- Pharmacovigilance.
- Maintaining a pharmacovigilance master file.
- Operating a risk management system.

INFARMED, in collaboration with the European Medicines Agency and other member states, must have a list of medicinal products that are subject to additional monitoring under the EMA Regulation (which sets out European Community procedures for the authorisation and supervision of medicinal products for human use). The list contains the names and active substances of both:

- Medicinal products authorised in the EU that contain a new active substance which, on 1 January 2011, was not contained in any medicinal product authorised in the EU.
- Any biological medicinal product not covered in the bullet point above that was authorised after 1 January 2011.

The medicinal products listed must include:

- A summary of product characteristics.
- The following statement on the package leaflet: "This medicinal product is subject to additional monitoring", preceded by a black symbol.

9. Which medicinal products can benefit from the abridged procedure for marketing authorisation and what conditions and procedure apply? What information can the applicant rely on?

The abridged procedure is set out in the Medicines Act. If the market authorisation applicant can provide evidence that the medicine's active substance has an established clinical use in the EU for a period of ten years with acceptable safety and recognised efficacy, the applicant is not required to provide pre-clinical and clinical trials data. It is sufficient if the applicant provides an adequate scientific bibliography.

INFARMED has 210 days to make a decision on the applicant's request. Requests for more information by INFARMED suspend this period.

10. Are foreign marketing authorisations recognised in your jurisdiction?

Marketing authorisation granted under the central community procedure by the European Medicines Agency is recognised in Portugal.

Marketing authorisations granted by the equivalent authorities of other EU member states are also, generally, recognised in Portugal. INFARMED usually makes its decision on marketing authorisation within 30 days of access to the assessment report of the equivalent regulatory authority of the other EU member state.

If INFARMED considers that there is a potential serious risk for public health, it can adopt an unfavourable opinion on the request for approval of the marketing authorisation. In the absence of any subsequent agreement between the relevant EU national agencies, an arbitration procedure can be initiated before the European Committee for Medicinal Products for Human Use (CMPH).

In the mutual recognition and decentralised procedures, the CHMP arbitrates in cases where there is a disagreement between member states concerning the marketing authorisation of a particular medicine. The CMPH is composed by one member appointed by each EU member state.

11. What powers does the regulator have in relation to marketing authorisations?

Monitoring compliance

INFARMED has the following powers to monitor compliance with marketing authorisations. It can:

- Execute inspections at the premises of manufacturers, wholesalers, pharmacies and entities responsible for laboratorial controls or a specific medicinal product's manufacturing stages, as well as any other facilities used for such purposes.
- Execute unannounced inspections of the manufacturers of active substances used in the production of medicines, as well as at the premises of holders of marketing authorisations, when there are grounds to suspect non-compliance with good manufacturing practices.
- Verify the facilities, records, documents and pharmacovigilance system of the marketing authorisation holder.
- Collect samples to carry out tests in a laboratory.

Imposing penalties

INFARMED can:

- Suspend, forfeit or alter the content of a marketing authorisation.
- Impose fines of up to EUR44,891.81 for each infringement, subject to judicial review.

Criminal liability may also apply.

Parallel imports

12. Are parallel imports of medicinal products into your jurisdiction allowed?

Parallel imports of medicinal products are allowed into Portugal, provided the following conditions are met:

- The medicine in the member state of origin must have a valid marketing authorisation.
- The medicine must have the same:
    - quantitative and qualitative composition in terms of active substances;
    - pharmaceutical form; and
    - therapeutic indications (different excipients can be used or different quantities of the same excipients if they have no therapeutic impact).
- The authorisation does not pose a risk to public health.

An applicant only needs to declare, not demonstrate, that differences in any inactive excipient do not affect the medicine's therapeutic value or endanger public health, if the medicine has a common origin, namely:

- The medicine is manufactured in another EU member state.
- By a company:
    - contractually linked to the marketing authorisation holder in Portugal; or
    - in the same corporate group.

Generally, the holder of intellectual property rights in a medicinal product which has been placed on the market in the European Economic Area (EEA) is not legally able to impede further marketing of that product in another EEA country.

Restrictions

13. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

There are certain restrictions on advertising medicinal products (*see Question 15*). In addition, marketing authorisation holders or companies responsible for the promotion of medicines and distributors cannot offer or promise to offer, directly or indirectly, to health professionals any of the following (unless the offer relates to an object relevant to the practice of medicine and is of insignificant economic value) (*Medicines Act*):

- Gifts.
- Bonuses.
- Pecuniary benefits.

Both the sponsoring of scientific promotions addressed to health professionals and consultancy agreements engaging health professionals are allowed, provided payments are not conditional on the prescription or dispensing of medicines.

Anti-bribery legislation also applies to the life sciences sector, notably when dealing with public officials and state institutions.

The following provisions may apply:

- Receiving improper payment (*Article 372, Criminal Code*).
- Passive corruption *(Article 373, Criminal Code*).
- Active corruption (*Article 374, Criminal Code*).

Penalties can include imprisonment and criminal fines for representatives of the company, public officials and other third parties for committing certain offences.
Portuguese anti-bribery provisions can apply to offences occurring outside Portugal but exceptions may apply.

14. What are the restrictions on marketing medicinal products on the internet, by e-mail and by mail order?

The home delivery of medicinal products is allowed by (*Order 1427/2007, 2 December 2007*):

- Pharmacies in relation to prescription medicines.
- Pharmacies and over-the-counter (OTC) retailers (*parafarmácias*) in respect of OTC medicines.

Home delivery must be provided in the geographic municipality where the pharmacy or OTC retailer is located and in the surrounding geographic municipalities.
Orders can be delivered at a patient's residence or workplace by any of the following methods:

- Telephone.
- Fax.
- Online pharmacy.
- OTC retailer website.
- E-mail.

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Advertising

15. What are the restrictions on advertising medicinal products?

Legislation and regulatory authority

The advertising of medicinal products is governed by the Medicines Act. INFARMED is responsible for the supervision and enforcement of the provisions on advertising to healthcare professionals and the general public.
INFARMED will open an inquiry where non-compliance is suspected, either on its own initiative or based on a complaint. This can lead to penalties which include fines and loss of licences, authorisations or permits. Decisions are subject to judicial review.

Restrictions

Certain medicines cannot be promoted or advertised to the general public, only to healthcare professionals (for example, doctors, pharmacists and nurses). They must be advertised in scientific publications or other forms of communication with restricted use by health professionals. These medicines include:

- Prescription medicines.
- Medicinal products which contain psychotropic or narcotic substances.
- Medicines subject to reimbursement by the NHS.

Over-the-counter (OTC) medicines can be marketed to the general public.
The advertising of any of the above categories of medicinal products must:

- Comply with the particulars listed in the summary of product characteristics.
- Encourage the rational use of the medicinal product by presenting it objectively, without exaggerating its properties.
- Not be misleading.

All advertising to the general public of an OTC medicine must:

- Clearly indicate that it is an advertisement.
- Clearly identify the product as a medicinal product.
- Include the following minimum information:
    - the name of the medicinal product, as well as its common name if the medicinal product contains only one active substance;
    - the information necessary for correct use of the medicinal product;
    - a legible invitation to read the instructions on the package leaflet or the outer packaging (as the case may be) carefully.

The advertising of a medicinal product to the general public must not contain any material which:

- Gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail.
- Suggests that the effects of taking the medicine are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product.

- Suggests that the health of the subject can be enhanced by taking the medicine.
- Suggests that the health of the subject could be affected by not taking the medicine.
- Is directed exclusively or principally at children.
- Refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products.
- Suggests that the medicinal product is a foodstuff, cosmetic or other consumer product.
- Suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural.
- Could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis.
- Refers, in improper, alarming or misleading terms, to claims of recovery.
- Uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts of it.

Advertising to persons qualified to prescribe or supply medicinal products must include the following:

- Essential information compatible with the summary of product characteristics. The supply classification of the medicinal product.
- The conditions for reimbursement by the NHS.

Measures or commercial practices related to margins, prices and discounts are not subject to the advertising rules of the Medicines Act.

The Portuguese Association of the Pharmaceutical Industry (*Associação Portuguesa da Indústria Farmacêutica*) (Apifarma) has produced a Code of conduct for promotional practices by the pharmaceutical industry with healthcare professionals. The Code reflects the rules and principles of:

- The Medicines Act.
- The European Federation of Pharmaceutical Industries Code on the Promotion of prescription-only medicines to and interactions with healthcare professionals.

Internet advertising

Advertising on the internet is subject to the same rules (*see above, Restrictions*).

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Packaging and labelling

16. Outline the regulation of the packaging and labelling of medicinal products.

Legislation and regulatory authority

The Medicines Act governs the packaging and labelling of medicinal products. INFARMED is responsible for the supervision and enforcement of the provisions applicable to the packaging and labelling of medicinal products.

Information requirements

The following information must appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging:

- The name of the medicinal product followed by its strength and pharmaceutical form, and, when applicable, whether it is intended for babies, children or adults.
- Where the product contains up to three active substances, the international non-proprietary name must be included, or, if one does not exist, the common name.
- A statement of the active substances expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using their common names when available.
- The contents by weight, volume or number of doses of the product.
- A list of those excipients known to have a recognised action or effect. If the product is injectable or a topical or eye preparation, all excipients must be stated.
- The method of administration and, if necessary, the route of administration.
- A space must be left for the prescribed dose to be indicated by the healthcare professional.
- A special warning that the medicinal product "must be stored out of the reach and sight of children" (*manter fora do alcance e da vista das crianças*).
- The expiry date in clear terms (month/year).
- Special storage precautions, if any.

- The name and address of the marketing authorisation holder and, where applicable, the name of the representative appointed by the holder to represent him.
- The number of the authorisation for placing the medicinal product on the market.
- The manufacturer's batch number.
- The sale price, through printing, label or stamp.
- When applicable "free sample" (*amostra gratuita*) or "sale to the public not authorised" (*proibida a venda ao público*).
- Safety features enabling wholesale distributors and persons authorised or entitled to supply medicinal products to the public to verify the authenticity of the medicinal product, and identify individual packs.

Other conditions

The packaging and labelling information referred to above must be:

- In Portuguese.
- Indelible.
- Easily readable and comprehensible.

Tests should be made by the marketing authorisation applicant in relation to the packaging and leaflet on target users, and the results taken into account. The labelling and the package leaflet can also be provided in other languages in addition to Portuguese.

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Traditional medicines

17. Outline the regulation of the manufacture and marketing of alternative or complementary medicinal products.

The Medicines Act rules applicable to the manufacture and marketing or alternative and complementary medicinal products follows EU law closely (*Code for Human Medicines Directive*).

Homeopathic medicinal products are monitored by INFARMED and the national pharmacovigilance system.

Homeopathic medicinal products which satisfy the following conditions can be subject to a simplified registration procedure:

- They are administered orally or externally.

- No specific therapeutic indication appears on the labelling of the medicinal product or in any related information.
- There is a sufficient degree of dilution to guarantee the safety of the medicinal product.

Traditional herbal medicinal products are also subject to a simplified registration procedure with INFARMED in the following circumstances:

- They have indications exclusively appropriate to traditional herbal medicinal products intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment.
- They are exclusively for administration in accordance with a specified strength and posology.
- They are an oral, external and/or inhalation preparation.
- The period of traditional use has elapsed (30 years of continuous use, with at least 15 years of use in an EU member state).
- The data on the traditional use of the medicinal product are sufficient. In particular, the product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience.

The advertising, labelling and packaging requirements of the Medicines Act also apply (*see Question 15 and 16*).

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Patents

18. What are the legal conditions to obtain a patent and which legislation applies? Which products, substances and processes can be protected by patents and what types cannot be patent protected?

Conditions and legislation

Patents are governed by the Industrial Property Act (*Decree-Law 36/2006, 5 March 2006*).

A patent is granted to an invention, in all fields of technology, provided it is:

- New: it does not form part of the state of the art.
- Involves an inventive step: if, having regard to the state of the art, it is not obvious to a person skilled in the art.

- Susceptible to industrial application: it can be made or used in any kind of industry or in agriculture.

Scope of protection

Patents can include:

- Products, substances or compositions used in surgical or therapeutic methods for treating the human body.
- Diagnostic methods used on the human body.

Patents cannot include:

- Discoveries, scientific theories and mathematical methods.
- Materials or substances already existing in nature and nuclear materials.
- Aesthetic creations.
- Schemes, rules or methods for intellectual acts, playing a game or doing business and computer programs.
- Presentations of information.
- Processes for cloning human beings.
- Processes for modifying the germinal genetic identity of human beings.
- The use of human embryos for industrial or commercial purposes.

New processes for obtaining known products, substances or compositions can also be patented.
If a patent concerns a process, the rights conferred by it will cover the products obtained directly by the patented process.

19. How is a patent obtained?

Application and guidance

Patent applications can be made in the following ways:

- Application for a national patent to the National Industrial Property Institute (*Instituto Nacional da Propriedade Industrial*) (INPI). Detailed information and guidance on the application procedure and applicable fees is available on its website at *www.marcasepatentes.pt*.
- Application for a European patent to the European Patent Office (*www.epo.org*).

- Application for an international patent filed under the Patent Cooperation Treaty before the INPI, the European Patent Office or elsewhere.

Process and timing

Provisional patent application. To ensure the priority of a patent, it is possible to file a provisional application and postpone the submission of all the required elements of a full application for a maximum of 12 months.

Regular patent application. Once a regular application has been submitted a preliminary examination follows. Once all the formal requirements are satisfied, the intention to grant a patent is published in the national *Industrial Property Bulletin* within 18 months from the date of receipt of the application (exceptions can be made where an applicant requires an urgent publication).

Patent application opposition. Proceedings can be initiated within two months from the date the application is published by INPI.

The final patent decision is notified by INPI to the applicant and published in the *Industrial Property Bulletin*.

20. How long does patent protection typically last? Can monopoly rights be extended by other means?

Duration and renewal

A patent protection typically lasts for 20 years and is not subject to extensions, though exceptions can apply.

Extending protection

Applications for supplementary protection certificates for medicinal products can be submitted to INPI, to extend protection by up to five years. The application must include:

- A copy of the first marketing authorisation for Portugal identifying the product.
- The number and date of the authorisation.
- A summary of product characteristics.

In addition, a request for an extension of a supplementary protection certificate can be submitted in the case of medicinal products for paediatric use.

Supplementary protection certificates and extensions are provided by INPI in accordance with:

- Regulation 1901/2006 on medicinal products for paediatric use.

- Regulation 469/2009 concerning the supplementary protection certificate for medicinal products.

21. How can a patent be revoked?

A patent can be revoked by a court and in specific cases by the INPI, following a request by the Public Prosecutor's office or by any person, including the patentee, on any of the following grounds:

- The object of the patent cannot be protected.
- If, when granted, procedures or formalities essential to the grant of the right were omitted.
- If public rules were breached.
- If the right does not belong to patent holder.
- A failure to pay fees.
- Renunciation by the patent holder.

If the patent is not exploited within four years of the date of the patent application or three years of the grant date, whichever is later, a third party can apply to the INPI to grant a compulsory licence relating to the patent.

22. How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

Conditions for infringement

A patent holder has the right to prevent others from manufacturing, offering, storing, commercialising or using a patented product or importing or possessing it for any of these purposes without his consent.

A patent holder can oppose all acts constituting a violation of his patent, including the:

- Manufacture of products that are covered by the patent.
- Use or application of means or processes that are the object of the patent.
- Import or distribution of products obtained by any of the above.

Claim and remedies

A civil action against the infringer can claim relief such as:

- An injunction.
- An order to deliver the infringing medicinal products.

- Payment of damages.

In addition, the unauthorised use of a patent is a criminal offence, subject to imprisonment for up to three years or a criminal fine.

23. Are there non-patent barriers to competition to protect medicinal products?

The Medicines Act provides exclusivity periods for medicinal products according to the "8+2+1" rule in the Code for Human Medicines Directive:

- For eight years after the grant of marketing authorisation for a medicinal product, the originator company's pre-clinical and clinical data cannot be used in a generic marketing authorisation application.
- The generic medicine can only be marketed after ten years have elapsed from the initial grant of marketing authorisation to the originator company.
- One additional year of marketing exclusivity is available if a new therapeutic indication is registered, within eight years of the grant of the reference product's marketing authorisation, which is considered of significant clinical benefit compared to existing therapies.

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Trade marks

24. What are the legal conditions to obtain a trade mark and which legislation applies? What cannot be registered as a trade mark and can a medicinal brand be registered as a trade mark?

Conditions and legislation

Trade marks are governed by the Industrial Property Act.

Provided a trade mark adequately distinguishes the products and services of one company from those of others, it can include:

- A sign or set of signs that can be represented graphically, such as the:
  - names of persons;
  - drawings;
  - letters;
  - numbers; or

    - sounds.
- The form of the product or its packaging.

A trade mark can also consist of an advertising phrase for the products or services, provided it is distinct, regardless of protection conferred by copyright.
A trade mark application must contain the following information:

- Details of the applicant's business, tax number (if resident in Portugal) and e-mail address (if any).
- The products the trade mark is designed for:
    - grouped in accordance with the categories in the international product and service classification;
    - defined in precise terms; and
    - preferably using the alphabetical terms in the international product and service classification.
- Expressly indicate that the trade mark is an association or certification trade mark, if the applicant wants to register a collective trade mark.
- The registration number of any award featured or referred to in the trade mark.
- The colours in which the trade mark is used, if these are claimed as a distinctive element.
- The country of first application for registration of the trade mark, and the date and number of the application, if the applicant wishes to claim a right of priority.
- If applicable, the date from which the applicant has been using the trade mark.

Scope of protection

A medicinal name can be registered as a trade mark with the INPI.
The following cannot be registered as trade marks:

- Trade marks that are devoid of any distinctive character.
- Signs that exclusively consist of the form:
    - imposed by the nature of the product itself;
    - of the product necessary for obtaining a technical result; or
    - that confers a substantial value on the product.

- Signs that are exclusively made up of indications that may serve in commerce to designate the type, quality, quantity, purpose, value, geographic origin, period or means of production of the product or the service, or other characteristics of it.
- Trade marks that exclusively consist of signs or indications that have become common use in modern-day language or in the habitual and constant habits of commerce.
- Colours, unless they are combined with each other or with graphics, wording or other particular and distinctive elements.

25. How is a trade mark registered?

Application and guidance

A trade mark application is submitted to the INPI. Detailed guidance on the applicable procedure and fees can be accessed at *www.marcasepatentes.pt*.

The standard fees are, for both an initial trade mark application and renewals:

- In one class: EUR120 for online submission and EUR240 for paper submission.
- For each additional class: EUR30.42 for online submission and EUR60.84 for paper submission.

Process and timing

Once the application is filed, there is an initial examination in accordance with the rules governing the composition of trade marks. The application is published online in the national *Industrial Property Bulletin*.

There follows an opposition period. Any opposition proceedings must be initiated within 2 months from the date the application is published by INPI.

If no grounds for refusal are found, the trade mark registration is granted and the approval decision is published.

26. How long does trade mark protection typically last?

A trade mark registration lasts ten years, beginning on the date of grant. It can be indefinitely renewed for subsequent ten-year periods.

27. How can a trade mark be revoked?

A trade mark can be revoked on the following grounds:

- The trade mark was not the object of serious use for a period of five consecutive years.
- The grounds for registration were not fulfilled.

- The trade mark may mislead the public, particularly as to the quality, nature or origin of the goods or services.

28. How is a trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

Conditions

A registered trade mark is infringed by another trade mark in the following circumstances (*Industrial Property Act*):

- The registered trade mark has priority.
- Both trade marks are designed for identical or similar products or services.
- The trade marks are so similar in graphic, figurative, phonetic or any other terms that the consumer can easily be misled or confused, or that it comprises a risk of association with the already registered trade mark, so that the consumer can only distinguish between them after attentive scrutiny or comparison.

The following actions constitute a criminal infringement of a trade mark:

- Counterfeiting, totally or partially, or reproducing by any other means a registered trade mark.
- Imitating a registered trade mark either as a whole or using characteristic parts of it.
- Using counterfeit or imitated trade marks.
- Using, counterfeiting or imitating well-known trade marks for which registration has already been applied for in Portugal.
- Using trade marks (even for products or services that are not identical or similar) that are an interpretation of or are identical or similar to previously existing trade marks for which registration has been applied for, which enjoy a prestigious reputation in Portugal or the EU (if they are Community trade marks) when such use seeks to derive unjust benefit from the distinctive or prestigious character of the prior trade marks or may be prejudicial to them.
- Using, in products, services, or an establishment or company, a registered trade mark belonging to another person.

Claim and remedies

The civil and criminal penalties are the same as for infringement of a patent (*see Question 22, Claim and remedies*).

Patent and trade mark licensing

29. Does a patent or trade mark licence agreement and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body?

There are no requirements for either a patent or trade market licence agreement or payment of royalties to be approved or accepted by a government or regulatory body. However, licences must be drawn up in writing and if the grant of sub-licences is not provided for in the licence, these can only be granted with the written authorisation of the right holder (*Industrial Property Code*).

Patent and trade mark conventions

30. Is your jurisdiction party to international conventions on patent and trade mark protection?

Portugal is a party to most international intellectual property treaties, including the:

- WIPO Paris Convention for the Protection of Industrial Property 1883.
- WIPO Madrid Agreement Concerning the International Registration of Marks 1891.
- WIPO Madrid Agreement for the Repression of False or Deceptive Indications on Source of Goods 1891.
- WIPO Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks 1957.
- Convention Establishing the World Intellectual Property Organisation 1967.
- WIPO Strasbourg Agreement Concerning the International Patent Classification 1971.
- Patent Cooperation Treaty 1970.
- Trademark Law Treaty 1994.
- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) 1994.
- Protocol Relating to the Madrid Agreement 1989.
- WIPO Patent Law Treaty 2000.
- Singapore Treaty on the Law of Trademarks 2006.

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Product liability

31. Outline the scope of medicinal product liability law.

Legal provisions

Medicinal product liability can arise under criminal law, contract and tort law.
Portugal has a specific legal regime for product liability set out in Decree-Law 383/89 of 6 November 1989, as amended (Product Liability Act) based on Directive 85/374/EEC on liability for defective products (Product Liability Directive).

Substantive test

The injured person must prove (*Product Liability Act*):

- Damage.
- The defect.
- A causal relationship between defect and damage.

The Civil Code also recognises tort liability based on:

- The infringement of legal provisions (*Article 483*).
- Joint and several liability (*Articles 490 and 497*).
- Indemnity limitation in cases of negligence (*Article 494*).
- A general limitation period of three years (*Article 498*).

According to the Civil Code, liability depends on the fulfilment of five cumulative requirements:

- Conduct (act or omission) controllable by human resolution.
- The unlawfulness of the conduct.
- Imputation of the conduct to a natural or legal person.
- The existence of damages.
- A causal link between the conduct and the damage.

A damage claim can also be brought under contractual liability, where there is a contract between the wrongdoer and the natural or legal person suffering the damage.

Liability

The producer is liable for damage, independently of fault, caused by a defect in his product. The producer is defined as one of the following (*Product Liability Act*):

- Manufacturer of a finished product.
- Producer of any raw material.
- Manufacturer of a component part.
- Any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer.

In addition, without prejudice to the liability of the producer, any person who imports into the EU a product for sale or any form of distribution in the course of his business is also considered to be a producer and is responsible as a producer. If the producer cannot be identified, each supplier of the product is treated as its producer unless he informs the injured person, within a reasonable time, of the identity of the producer or of the person who supplied him with the product.

32. How can a product liability claim be brought?

Limitation periods

The limitation periods for bringing a product liability claim are (*Product Liability Act*):

- Three years from the day on which the claimant became aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer.
- Ten years from the date on which the producer put into circulation the actual product which caused the damage, unless the injured person has since started proceedings against the producer.

Class actions

Law 83/95 of 31 August 1995 establishes the legal framework applicable to a representative action. The aim of this type of action is to represent collective or diffuse interests either for prevention (injunction) or for redress (claims for damages). A representative action for a product liability claim in the Portuguese courts can be brought by (*Law 83/95, 31 August 1995*):

- A natural person.
- An association or foundation (in cases which are directly connected with their scope).

Companies cannot use the representative action procedure.

The Portuguese procedure is an opt-out system. The claimant automatically represents all the holders of similar rights or interests at stake who do not opt out following, among others, a public notice of submission of the representative action before the court. The claimant can seek redress for damages suffered but compensation cannot be individually identified and will be determined globally. Representative actions in the context of product liability claims are rare in Portugal.

33. What defences are available to product liability claims?

Standard defences in a product liability claim include that:

- The defendant did not put the product into circulation.
- The defect which caused the damage did not exist at the time the product was put into circulation and came into being afterwards.
- The product was either not:
    - manufactured by the defendant for sale or any form of distribution for economic purpose; or
    - manufactured or distributed by the defendant in the course of his business.
- The defect is due to compliance of the product with mandatory regulations issued by the public authorities.
- The state of scientific and technical knowledge at the time the defendant put the product into circulation was not such as to enable the defect to be discovered.
- In the case of a manufacturer of a component, the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product.

34. What remedies are available to the claimant? Are punitive damages allowed for product liability claims?

The claimant (or his estate) can claim damages for:

- Death.
- Personal injury.
- Damage to, or the destruction of, property (other than the defective product itself), provided the property:
    - is of a type ordinarily intended for private use or consumption; and
    - was mainly used by the injured person for his own private use or consumption.

Punitive damages are not available in Portugal for product liability claims.

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Reform

35. Are there proposals for reform and when are they likely to come into force?

Since 2011 Portugal has been under an EU/IMF Financial Assistance Programme (FAP) which involves a set of initiatives including structural legal measures relating to public finances, financial stability and competitiveness. In relation to the health sector, the FAP for 2013 involves:

- Reduction of debt due to suppliers of the NHS, including pharmaceutical companies (in 2013, pharmaceutical expenditure must be limited to 1% of GDP).
- Increasing the number of patients per family doctor from 1,500 to 1,900.
- Additional centralised public tenders for active substances and medical devices.
- Compulsory e-prescription and international non-proprietary name (INN) prescription.
- Changes in pharmacies' margins in the international reference price system and in the pricing of generics.
- The removal of administrative and legal hurdles to enhance the use of generics.
- Prescription guidelines and regular monitoring of prescription behaviour.

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Regulator details

National medicine regulatory authority (INFARMED) (*Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.*)

W *www.infarmed.pt*

Main areas of responsibility. INFARMED is the government's agency which monitors, assesses and regulates all activities relating to human medicines and health products.

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Patent protection and data and marketing exclusivity

Jurisdiction	Which authority issues patents? Is guidance available on its website?	Can the typical patent term of 20 years be extended?	Are there data and marketing exclusivity protection periods for medicinal products?
Portugal	The Institute of Industrial Property (INPI) (*www.marcasepatentes.pt*) and the European Patent Office (*www.eop.org*). Both websites provide extensive guidance.	No, but supplementary protection certificates are available to extend protection by up to five years, according to EU legislation.	Yes, in accordance with the EU 8+2+1 rule, as follows: • 8 years of pre-clinical and clinical trials data exclusivity for the originator company. • 2 additional years of marketing exclusivity for the originator company. • 1 additional year for new therapeutic indications (conditions apply).

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Online resources

Portuguese Mint and Official Printing Office (*Imprensa Nacional Casa da Moeda*)

W *www.dre.pt*

Description. Official website of the Portuguese Mint and Official Printing Office (*Imprensa Nacional Casa da Moeda*), where the official language version of the legislation referred to in this article can be accessed online (Portuguese version).

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Publications. *European Lawyer; International European Law Tax Review; International Law Office; Portuguese Bar Association; Portuguese Bank Association; The Private Competition Enforcement Review.*

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