Portugal

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REGULATORY OVERVIEW

1. Please give a brief overview of the regulatory framework for medicinal products/pharmaceutical products/drugs (as they are called in your jurisdiction), including the key legislation and regulatory authorities.

A medicine is any substance or combination of substances that has healing properties or prevents a disease or its symptoms in human beings or animals, therefore allowing for medical diagnosis or for the restoration, correction or modification of organic functions.

The National Authority on Medicine and Health Products, I.P. (*Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.*) (INFARMED) is the Portuguese regulatory body responsible for medicinal and pharmaceutical products (*see box, The regulatory authority*).

Medicines must have a marketing authorisation granted by the INFARMED to be distributed in Portugal.

Prescription-only medicines are exclusively sold in pharmacies and are submitted to periodic controls, carried out by the INFARMED, to confirm their quality and therapeutic value for the purpose of renewing the authorisation and gaining possible state funding or reimbursement.

Over-the-counter (OTC) medicines can be sold outside pharmacies, under the supervision of pharmacists or pharmaceutical technicians. The stores must be registered by the INFARMED and comply with Decree Law 134/2005, 16 August. Although in general OTC medicines are not subject to state funding or reimbursement, they are subject to the same controls as prescription-only medicines.

Key legislation for medicines includes:

- Medicine Statute: Decree Law 176/2006, 30 August.
- Clinical and Analytical Trials: Law 46/2004, 19 August.
- Manufactured Medicines: Decree Law 95/2004, 22 April.
- Drugs: Decree Law 15/93, 22 January.
- OTC Medicines: Decree Law 134/2005, 16 August.
- Pricing: Decree Law 65/2007, 14 March.
- State Funding: Decree Law 242-B/2006, 29 December.

Key legislation for the National Health Service includes:

- Basis of Health Law: Law 48/90, 24 August.
- National Health Service: Decree Law 11/93, 15 January.
- INFARMED Organic Law: Decree Law 495/99, 18 November.

PRICING AND STATE FUNDING

2. Please give a brief overview of the structure and funding of the national healthcare system.

The national healthcare system is made up of:

- The National Health Service (NHS).
- All other public bodies that carry out healthcare promotion, prevention and treatment activities.
- All private entities and freelance professionals that carry out healthcare promotion, prevention and treatment activities.
- All public and official institutes and services that provide healthcare under the supervision of the Ministry of Health and have their own charter.

The NHS is supervised by the Ministry of Health and administered at regional level by the board of the relevant regional health administration (the regional health administrations are run by boards of directors).

The Ministry of Health and the regional health administrations can contract non-government entities to provide healthcare to NHS beneficiaries, whenever it is deemed advantageous to do so.

3. In what circumstances are the prices of medicinal products regulated?

The public prices of national or imported proprietary medicines (medicinal compounds whose formulae, and often manufacturing procedures, are owned by an individual or corporation under a trade mark or patent) to be placed on the domestic market for the first time, or those having had pharmaceutical formula and dosage alterations, must not exceed certain maximum prices. These prices are determined by the manufacturer (who must then submit the price to the Enterprises Directorate-General for approval) by comparing the proposed price with tax-free reference prices at the

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production or import stages (ex-factory price) in force in certain reference countries (Spain, France, Italy and Greece) for identical or similar medicines. The reference prices are then adjusted according to marketing margins and taxes in force in Portugal.

Discounts can be offered through the whole circuit of the medicine, from manufacturing to sale in pharmacies.

The public prices for generic medicinal products must be at least 30% less than the public prices of the reference medicinal product with the same pharmaceutical formula and dosage, unless the latter costs less than EUR10 (about US$13.66), in which case the price of the generic medicinal product must be, at least, less than 20%.

4. When is the cost of a medicinal product funded or reimbursed by the state? Please briefly outline the procedure and pricing for state funding or reimbursement (for example, is the reimbursement paid to the producer, pharmacist or end-user)?

The state funds the cost of medicinal products sold to the beneficiaries of the NHS. The amount by which the state funds medicinal products is fixed at one of three percentage scales:

- A: 69%.
- B: 37%.
- C: 15%.

There are two funding regimes:

- A general one, for ordinary citizens (using the above percentages).
- A special regime for the citizens most in need, where the above funding percentages are increased.

There are two methods for calculating the funding amount:

- Generally, the funding percentage is applied to the retail price (*Preço de venda ao Público*) (PVP).
- In the case of medicines in homogenous groups that include at least one generic medicine, the appropriate funding percentage is applied to the reference price (that is, the retail price of the most expensive generic medicine of that homogenous group). The state considers, for reimbursement purposes, the reference price (for medicines which have a superior PVP) and the retail price (for medicines where it is inferior to the reference price).

The reimbursement is paid to the pharmacist by the state directly or through the Pharmacies National Association (*Associação Nacional das Farmácias*) (ANF). In this second case, the state gives the reimbursement money to the Association, which then passes it on to member pharmacies. In practical terms, pharmacies receive reimbursements from the Association much sooner than receiving reimbursements directly from the state. Although more complex, this scheme has proved to be more efficient because, as almost all pharmacies belong to the Association, they are reimbursed sooner and the state only has to deal with the Association, instead of having credits with each pharmacy.

MANUFACTURING

5. Please give an overview of the authorisation process to manufacture medicinal products. In particular:

- **To which authority must the application be made?**
- **What conditions must be met to obtain authorisation?**
- **Are there specific restrictions on foreign applicants?**
- **What are the key stages and timing?**
- **What fee must be paid?**
- **How long does authorisation last and what is the renewal procedure?**

Application

The manufacture (in whole or in part), division, packaging and presentation of pharmaceutical products must be authorised by the board of directors of the INFARMED.

Conditions

To manufacture medicinal products, the applicant must have the required technical expertise, facilities and equipment (as set out in Decree Law 176/2006, 30 August).

Restrictions on foreign applicants

There are no restrictions on the manufacturing of pharmaceutical products by foreign-owned laboratories in Portugal. However, the import of drugs from non-EU states is subject to authorisation by the INFARMED.

Key stages and timing

Authorisation is granted on the basis of an application which contains the following details:

- Specifications (therapeutic use, active substances and other technical characteristics).
- Pharmaceutical form (pills, injections or other).
- Manufacturing location.
- The existence of appropriate quality control procedures.

Authorisation to manufacture pharmaceutical products is granted within 90 days of receipt of the application (or 30 days, for authorisation to alter a previous manufacturing permit). If additional information is requested, the deadline is suspended until the requests have been fulfilled. The authorisation may be granted under the condition that the applicant will fulfil all legal requirements within an established period of time.

Fee

Each application costs about EUR500 (about US$683).

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Period of authorisation and renewals

There are no legal provisions relating to the period of the manufacturing permit. If there are no alterations to the pharmaceutical product, the manufacturing authorisations are considered to be granted for an indefinite period.

6. What powers does the regulator have to:

- **Monitor compliance with manufacturing authorisations?**
- **Impose penalties for a breach of a manufacturing authorisation?**

The legal requirements for authorisation to manufacture pharmaceutical products are subject to confirmation and inspection by the INFARMED, which can carry out periodic inspections of distribution and manufacturing facilities to assure compliance with the law. These monitoring powers are fully exercised by the INFARMED.

A breach of the terms of a manufacturing authorisation is an offence punishable by a fine of either:

- Between EUR2,000 (about US$2,731) and EUR3,750 (about US$5,121) if the agent is a singular person.
- Up to EUR45,000 (about US$61,453) if the agent is a company.

A breach occurs whenever the rules of manufacturing procedure set out in Decree Law 176/2006, 30 August are not fulfilled (for example, manufacturing medicines without authorisation).

CLINICAL TRIALS

7. Please give an overview of the regulation of clinical trials. In particular:

- **Which legislation and regulatory authorities regulate clinical trials?**
- **What authorisations are required and how is authorisation obtained?**
- **What consent is required from trial subjects and how must it be obtained?**
- **What other conditions must be met before the trial can start (for example, the requirement for a sponsor and insurance cover)?**
- **What are the procedural requirements for the conduct of the trial (for example, using certain medical practices and reporting requirements)?**

Directive 2001/20/EC on the conduct of clinical trials (Clinical Trials Directive) has been implemented in Portugal through Law 46/2004, 19 August and Decree Law 176/2006, 30 August.

Clinical trials can only:

- Be performed if the INFARMED has given prior authorisation and the Ethics Committee for Clinical Investigation has given a favourable opinion.
- Take place in duly licensed public or private health establishments.
- Be carried out by doctors who are experienced in research.
- Be performed once an interview has taken place between the doctor or a member of the research team and the persons who are participating in the clinic trials, to explain the risks involved (which, in any event, must always be covered by insurance).

The conditions under which all clinical trials are performed must be reported in a protocol (which must be provided to the INFARMED), setting out the trial objectives, conditions and stages. The protocol must also contain the:

- Name and address of the promoter, the researcher in charge of the trial and his collaborators.
- Remuneration due to the researcher, and the contributions made by the promoter in payment of the charges levied by the establishments where the clinical trials are performed.
- Generic denomination and composition of the medicine, and details of the entity that prepared the samples.
- Name of the technical director responsible for the quality of the medicine.
- Type and definition of the clinical trial, adopted techniques and aims.
- Institution and department where the trial is going to be performed and the period within which it should be completed.
- Admissibility criteria for the participants, number of participants and specification of the diagnostics.
- Precautions taken and likely adverse effects.

Consent from those participating in clinical trials must be given freely, expressly and in writing. The written declaration must contain information about the nature, scope, consequences and risks involved in the clinical trial.

The above provisions satisfy all the requirements under the Clinical Trials Directive.

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MARKETING

8. Please give an overview of the authorisation process to market medicinal products. In particular:

- **To which authority must the application be made?**
- **What conditions must be met to obtain authorisation?**
- **What are the key stages and timing?**
- **What fee must be paid?**
- **How long does authorisation last and what is the renewal procedure?**

Application

Companies wishing to place a medicinal product on the Portuguese market must obtain a marketing authorisation from the INFARMED.

Applications can also be submitted to the European Agency for the Evaluation of Medicinal Products (EMEA), under the centralised EU system, for some products. Marketing authorisations obtained from the EMEA under this centralised system are valid in all EU member states.

Conditions

The interested party must submit an application containing the:

- Company name and address of its head offices (or the individual's name and place of residence).
- Body corporate number (National Company Registry) or taxpayer number (not applicable to applicants whose place of residence or head offices are located abroad).
- Proposed name for the medicinal product.
- Pharmaceutical form and composition of all components, in particular, active substances and excipients (an exception is made for raw chemical formulas) as well as the World Health Organisation's recommended international common denomination, if it exists.
- Therapeutic indications.
- Dosage, presentation and how it is to be administered.
- Number of files attached to the application.
- Summary of the medicinal product's characteristics.
- Samples or reproductions of the labels and outer packaging.
- Proposed information leaflet.
- Data concerning the manufacture of the medicinal product and certified proof that manufacturing authorisation has been issued.
- Experts' detailed reports concerning the control methods used by the manufacturer and the results of physical, chemical, biological or microbiological, toxicological, pharmacological and clinical tests.
- Portuguese translations and copies of market placing authorisations issued by other countries for the pharmaceutical product, as well as the decisions and grounds for authorisation denials.
- Information concerning EU member states in which similar requests for market placing authorisation were filed, including the summary of the medicinal product's characteristics and proposed or authorised information leaflets.
- Other information and details required by law.

The INFARMED can require the person responsible for placing a medicinal product on the market to submit samples for control trials, to be performed by a recognised public or private laboratory, of both the:

- Product in its different stages of production.
- Finished product.

Key stages and timing

A decision on whether a medicinal product can be placed on the market must be issued within 210 days of receipt of the application. This deadline can be suspended if the applicant is required to present additional information or clarification, or make alterations to the application.

Fee

Each application for marketing authorisation costs between about EUR250 (about US$341) and about EUR4,240 (about US$5,790), depending on the individual case.

In addition, the holder of a marketing authorisation, or the entity designated by the holder responsible for its marketing, are subject to a marketing surcharge for each prescription or non-prescription drug sold for human or veterinary use. This is 0.4% of the sales volume at the recommended retail price (calculated by applying the maximum marketing margins allowed for subsidised medicinal products) of each product, including those sold to hospitals.

Period of authorisation and renewals

Authorisation is valid for five years and is renewable for five-year periods. The holder must file the application for renewal at least 180 days before the permit expires (the authorisation must not be allowed to expire). The application must describe the pharmacovigilance of the drug and, where necessary, be accompanied by updated documentation that demonstrates the adaptation of the previously authorised drug to scientific and technical advances.

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9. Please briefly outline the abridged procedure for obtaining marketing authorisations for medicinal products. In particular:

- **Which medicinal products can benefit from the abridged procedure (for example, generics)?**
- **What conditions must be met?**
- **What procedure applies and what information can the applicant rely on?**

The authorisation can also be obtained through the mutual recognition procedure, where a licence has already been granted in another EU member state (*see Question 10*).

10. Are foreign marketing authorisations recognised in your jurisdiction? If so, please briefly outline the recognition procedure.

Under the mutual recognition procedure, a licence to place a medicinal product on the Portuguese market can also be obtained through the recognition of a licence already granted by another EU member state and vice-versa. The mutual recognition procedure takes about 90 days.

The applicant must inform the original member state, as well as the Committee of Pharmaceutical Specialities, that the application has been made, attaching the relevant documents. The applicant must also ask the original member state to provide the INFARMED with the elaboration of an evaluation report of the medicine. If this report already exists, it must be sent to the INFARMED. Finally, the INFARMED gives a final opinion on the mutual recognition of the foreign marketing authorisation.

There is a new decentralised procedure consisting of a simultaneous request in various member states. The applicant must choose a reference member state, which prepares and presents to the other member states a report on the application and the respective relevant documents, within 120 days. If the other member states approve it within 90 days, the authorisation for marketing the medicine is granted.

There is also an EC centralised procedure, under which a holder of a marketing authorisation granted by the EC can apply to the INFARMED to register marketing authorisations for a specific medicine in Portugal.

11. What powers does the regulator have to:

- **Monitor compliance with marketing authorisations?**
- **Impose penalties for a breach of a marketing authorisation?**

The INFARMED can carry out periodic inspections of distribution and manufacturing facilities to ensure compliance with the law. These monitoring powers are fully exercised by the INFARMED.

The INFARMED can suspend or revoke the marketing authorisations issued for a medicinal product, if it does not comply with the requirements set out in Decree Law 176/2006, 30 August. These powers are exercised frequently.

The INFARMED's decision to suspend or revoke the marketing authorisation results in the market withdrawal of the medicinal product (totally or limited to certain batches), which must be carried out by the authorisation holder.

In case of a suspension of the marketing authorisation, the authorisation holder is notified to correct the detected errors. The marketing authorisation is revoked if the authorisation holder does not comply.

A breach of the terms of a marketing authorisation, which occurs whenever the rules of marketing procedure set out in Decree Law 176/2006, 30 August are not fulfilled, is punishable by a fine of either:

- Between EUR2,000 (about US$2,731) and EUR3,750 (about US$5,121) if the agent is a singular person.
- Up to EUR45,000 (about US$61,453) if the agent is a company.

12. Are parallel imports of medicinal products into your jurisdiction allowed? If so, please briefly outline what conditions must be met by the parallel importer. Can intellectual property rights be used to oppose parallel imports?

Parallel imports are allowed when authorised by the INFARMED. They are subject to the following conditions:

- The medicine is duly authorised in the member state from which it derives.
- The holder of the national authorisation for the same medicine is notified of the parallel import.
- The holder of the authorisation of the medicine on the member state from which it is imported from is notified of the parallel import.

These holders of authorisations can request that the INFARMED does not authorise the parallel import, based on the following reasons:

- The import medicine is not identical to the reference medicine.
- The import medicine is packed in such a way that it may damage the reputation or identity of the reference medicine, or with another name.
- The import medicine has not been marketed in the import member state by the holder of the authorisation or without its consent.

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13. Please briefly outline the restrictions on marketing practices such as gifts or "incentive schemes" for healthcare establishments or individual medical practitioners.

The holder of the marketing authorisation and the entity responsible for marketing the medicinal product are not allowed to distribute, directly or indirectly, any gifts, offers, pecuniary benefits or benefits in kind to those qualified to prescribe and dispense medicinal products, except when these both:

- Relate to the practice of medicine or pharmacy.
- Are of an insignificant monetary value.

However, they can partially or totally bear the costs of persons qualified to prescribe and dispense medicines attending scientific training or promotional product events, providing these are not dependent on, or in exchange for, the prescribing and dispensing of medicinal products.

14. Please briefly outline the restrictions on marketing medicinal products on the internet, by e-mail and by mail order.

The following factors restrict direct mail and e-commerce sales to consumers:

- The system of state contributions to medicinal product prices is not compatible with electronic transactions.
- Only pharmacies are allowed to sell medicinal products to the public.
- Manufacturers, importers and wholesalers can only sell medicinal products directly to pharmacies or health establishments.
- Advertising laws do not allow the sale of medicinal products by electronic means.

However, direct mail or e-commerce sales are allowed where the medicinal product is not available in the country or where there is no adequate substitute.

In May 2006, the government and the Association signed a protocol. One of the protocol's principles, to be implemented in the near future, will allow pharmacies to sell medicines over the internet.

ADVERTISING

15. Please briefly outline the restrictions on advertising medicinal products. In particular:

- **Which legislation applies and which regulatory authority enforces it?**
- **What types of medicinal product cannot be advertised?**
- **What restrictions apply to advertising that is allowed?**

The advertising of medicinal products is regulated in Decree Law 176/2006, 30 August, compliance with which is enforced by the INFARMED.

The following medicinal products cannot be advertised near the public in general:

- Prescription-only medicinal products, which can only be advertised in specialist magazines or information leaflets aimed exclusively at doctors and other healthcare professionals;
- Medicines containing stupefacients or psychoactive substances;
- Medicines funded by the NHS.

Any form of comparative advertising is prohibited.

The advertising of pharmaceutical products must:

- Encourage correct use of the products, objectively and without exaggeration.
- Be designed in such a way that the message is clearly expressed and indicate that it is a medicinal product.
- Not deviate from the information contained in the authorised summary of the product's characteristics.
- Not be misleading.

Any advertising of medicinal products to the public must not:

- Lead to an inference that medical consultation or surgery is unnecessary, particularly by suggesting a diagnosis or commencing treatment by correspondence.
- Suggest that the effect of the medicinal product is guaranteed to produce results equal to or better than any other treatment or medicine, and presents no adverse reactions.
- Suggest that a person's normal state of health may be improved through use of the product.
- Suggest that the person's normal state of health may be harmed by not using the product, with the sole exception of vaccination campaigns.
- Be aimed mainly or exclusively towards children.
- Refer to recommendations from scientists, healthcare professionals or any other person whose fame may encourage the use of the products.
- Treat the medicine as a nutrition or cosmetic product.
- Suggest that the safety or efficacy of the product is due to its being considered a natural product.
- Encourage inaccurate self-diagnoses, through a detailed description or representation of a medical history.
- Use abusive, frightening or misleading references to demonstrations or guarantee a cure.

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- Use abusive, frightening or misleading visual representations of alterations to the human body caused by disease or lesions, or the action of a medicinal product on the human body or parts of the human body.

PACKAGING AND LABELLING

16. Please briefly outline the regulation of packaging and labelling of medicinal products. In particular:

- **Which legislation applies and which regulatory authority enforces it?**
- **What information must the packaging and/or labelling contain?**
- **What other conditions must be met (for example, information being stated in the language of your jurisdiction)?**

The packaging and labelling of medicinal products are regulated in Decree Law 176/2006, 30 August, compliance with which is enforced by the INFARMED.

The following are all responsible for ensuring that the characteristics of the medicinal product and precautions for its use are clearly printed in Portuguese on the label, without prejudice to simultaneous labelling in other languages:

- The entity responsible for placing the product on the market.
- The manufacturer.
- The importer.

This information must be contained on the outer packaging, the container and the information leaflet.

The outer packaging (or, in its absence, the container) must contain all the information set out in chapter V of Decree Law 176/2006, 30 August in legible indelible lettering. The outer packaging can include signs or symbols explaining some of the required information and other information that is in line with the summary of the product's characteristics and useful for health education. Any kind of advertising is strictly prohibited.

The information leaflet must also follow all the information set out in chapter V of Decree Law 176/2006, 30 August.

Supplying medicinal products or medicinal substances to the public in packaging that does not meet these requirements is prohibited.

TRADITIONAL HERBAL MEDICINES

17. Please briefly outline the regulation of the manufacture and marketing of traditional herbal medicinal products in your jurisdiction.

The manufacture and marketing of traditional herbal medicinal products are subject to a registration procedure with the INFARMED.

Traditional herbal medicinal products are subject to the same rules on advertising, packaging and labelling as other medicines. Further, these products must clearly contain the following information on their packaging:

- The traditional herbal medicinal product is to be used only in the situations described on the packaging and exclusively based on long term use.
- If the symptoms continue, the patient should visit a doctor or a pharmacist.
- The nature of the tradition associated with the product.

Directive 2004/24/EU on traditional herbal medicinal products has been implemented into national law through Decree Law 176/2006, 30 August.

PATENTS

18. What types of medicinal products and related substances and processes can be protected by patents and what types cannot be patent protected? What are the legal criteria to obtain a patent? Which legislation applies?

Patents are regulated in the Industrial Property Code (Chapter I Subchapter I). Generally, to be protected by a patent, an invention must:

- Show an element of novelty (that is, some new characteristic, which is not known in the body of existing knowledge in its technical field).
- Show an inventive step (that is, a degree of inventive activity which could not be deduced by a person with an average knowledge of the technical field).
- Be of industrial use.

A patent can be obtained for any invention (products or processes), in any technological domain, including products and processes that contain or deal with biological substances.

However, chirurgic, therapeutic and diagnostic treatment methods cannot be patented even though the products, substances or compositions used in them can.

19. How is a patent obtained? In particular:

- **To which authority must the application be made?**
- **What fee must be paid?**
- **What are the key stages and timing?**

The authority

A patent application must be made to the National Institute of Industrial Property (NIIP) (*www.inpi.pt*).

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A patent can also be protected in Portugal through a regional office that works for a number of countries, such as the European Patent Office. Under the regional system, an applicant requests protection for the invention in one or more countries, and each country decides whether to offer patent protection within its borders.

In addition, the World Intellectual Property Organisation manages the Patent Cooperation Treaty 1970 (PCT). The PCT provides for the filing of a single international patent application that has the same effect as national applications filed before the respective national offices at the designated countries. An applicant seeking protection can file one application and request protection in as many signatory states as needed.

Fee

The average fees for a patent (including official and the applicant's lawyers' fees, but not technical translations or possible replies to NIIP notifications) are as follows:

- Filing a patent application (including ten claims): EUR666 (about US$910).
- Each additional claim: EUR15 (about US$20).
- Examination fee: EUR287 (about US$392).
- Letters patent document (on grant decision): EUR159 (about US$217).
- Annuity fees: variable fee.

Process and timing

The following procedure and timings apply:

- **Application stage.** If the applicant does not request an urgent publication, the application number and its abstract are published 18 months after the filing of the application.
- **Opposition stage.** Oppositions can be filed within two months from the date of the patent application publication. The applicant must reply within two months from the date of the opposition notification.
- **Examination stage.** If no oppositions are filed, the examination report must be issued within three months from the date of the publication of the application. When there are oppositions, the examination report must be issued within three months from the date of presentation of the applicant's answer to the opposition.
- **Decision.** Any one of the following may occur:
  - the examiner concludes that the patent must not be granted, and the applicant is notified of the examination report and invited to reply to the observations made by the examiner within a two-month period. After this process, if some doubts still exist for the applicant, the examiner must clarify these doubts within one month of the applicant making a request to do so;
  - if the questions raised by the examination report refer only to the object of the protected matter, or to the elimination of claims, drawings and some sentences of the abstract, or the description or modification of the invention title, and the applicant does not voluntarily proceed with these modifications, the examiner can make the according alterations and propose the partial grant of the patent. In all other cases, if the applicant does not comply with the content of the notification, the examiner will refuse the application;
  - the examiner concludes that the patent can be granted and the NIIP publishes the final decision in the Official Bulletin.
- **Final decision stage.** Following the referred eventual replies of the applicant (if it is notified to do so), the NIIP publishes the final decision (either a grant decision, a partial grant decision or a refusal decision).

20. How long does patent protection last? How is a patent renewed or patent protection extended?

Duration of protection

Protection lasts for 20 years from the date of application.

Renewal process

It is not possible to renew the period of protection of a patent.

However, for medicines and pharmaceutical products, it is possible to extend the protection provided by the patent, by a maximum of five years, by requesting a supplementary protection certificate. This is established because the delay between granting the patent and the grant of the medicine's full marketing authorisation reduces the time of effective protection granted to the patent to a time period that is insufficient to pay off the investments made in research.

The application must be presented to the NIIP within six months from the date on which the medicine's full marketing authorisation was granted for the product (if the medicine's full marketing authorisation is issued before the grant of the patent) or within six months from the date of grant of the patent.

The supplementary protection certificate enters into force when the patent has expired.

21. In what circumstances can a patent be revoked?

If the patent owner fails to pay the patent's annuities, the NIIP can declare the cancellation of the registration. Also, the patent owner can renounce its patent rights in a formal signed declaration presented at the NIIP.

In addition, patents can be revoked and declared null and void, by judicial decision, if either:

- The court considers that the object of the application did not meet the criteria for patentability.
- The patent owner disregarded the legal formalities attached to the grant.

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

A patent is infringed when (*Industrial Property Code, Decree Law No. 36/2003 of 5 March*):

- The exclusivity of the patent is not respected, that is, someone:
  - manufactures the artefacts or products that are covered by the patent;
  - uses or applies the means or procedures that are covered by the patent;
  - imports or distributes products obtained in either of the above ways.
- A patent is obtained in bad faith, that is, it does not legitimately belong to the person who obtained it.

In both situations the infringer is liable to imprisonment.

There are three main courses of action against a patent infringement:

- **Warning letter.** A lawyer can send a warning letter to the infringer, threatening him with seizure, compensation claims and imprisonment.
- **Action by the public prosecutor.** A complaint can be made to the government department responsible for the control of economic activities (this is currently the Authority for Economical Activities and Safety of Foodstuffs (*Autoridade Segurança Alimentar e Económica (ASAE)*)) or directly to the public prosecutor. Enforcement agencies can intervene against a violation of a patent's exclusive rights or against patents obtained in bad faith.

Following the presentation of a criminal complaint, the public prosecutor can issue an accusation dispatch and send the file to the Criminal Court. Within the criminal procedures, the owner of the infringed patent can intervene in the proceedings and claim a compensatory indemnity for damages.

- **Civil lawsuit.** A legal action can be filed before the Commercial Court. The court can be asked to:
  - grant an injunction against further infringement of the patent;
  - award the owner a compensatory indemnity for damages.

TRADE MARKS

23. Can a medicinal product brand be registered as a trade mark? What are the legal criteria to obtain a trade mark? Which legislation applies?

It is possible to register a product brand as a trade mark. The registration proceedings are the same as for registering any other trade mark.

There are no specific tests. However, registration is only possible if all of the following basic conditions are fulfilled:

- The product brands must be distinctive, so that consumers can identify them as a particular differentiated product.
- The product brands must not mislead or deceive customers.
- The product brands must not violate public order or morality (this condition is usually considered by the NIIP to include violations of general legislation).

24. How is a trade mark registered? In particular:

- **To which authority must the application be made?**
- **What fee is payable?**
- **What are the key stages and timing?**

The authority

Applications to register a trade mark must be made to the NIIP (including applications for international or community trade marks) (*see Question 21*).

Fee

The average fees concerning trade marks (including official's and the applicant's lawyer's fees) are as follows:

- Application for registration (single class): EUR473 (about US$646).
- Each additional class: EUR301 (about US$411).
- Grant fee for ten years: EUR442 (about US$604).
- Renewals after ten years: EUR346 (about US$472).
- Filing a declaration of intent to use (DIU): EUR130 (about US$178).

Process and timing

A request for the registration of a national trade mark is published in the Official Bulletin two months after it is filed with the NIIP. Following its publication, any third party who wishes to oppose the grant of registration has two months to do so. The NIIP notifies the applicant of the filing of any opposition, and the applicant has a two-month period to reply.

Once the period for the presentation of oppositions has ended, the NIIP analyses the proceedings (this includes a search of previous trade mark registrations). The NIIP then issues a decision (the decision must be issued within 12 months of the date of publication) to either:

- Grant the trade mark's registration.
- Refuse the trade mark's registration where the conditions required to grant the trade mark are not fulfilled and/or the opposition filed is considered to be well-founded.

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25. How long does trade mark protection last? How is a trade mark renewed?

Duration of protection

A registered trade mark is valid for ten years following the date of registration.

Renewal process

A registered trade mark can be renewed indefinitely, providing the renewal fees are paid in time. Renewals are valid for ten-year periods. To obtain the renewal, no proof of use is required.

Payment of the renewal fees must be made during the previous six months of the trade mark's validity. Once this term has expired, it is still possible to renew the trade mark by paying a surcharge within six months of the expiration.

A DIU must be filed at the NIIP every five years from the registration date, except when this coincides with the payment of the renewal fees (every ten years).

Non-payment of the official fees leads to forfeiture of the trade mark's registration.

26. In what circumstances can a trade mark be revoked?

The registration of a trade mark can be revoked by a:

- Declaration of nullity of the trade mark registration by a decision of the Commercial Courts.
- Cancellation of the trade mark registration by a decision of the Commercial Courts.
- Forfeiture of the registration declared by the NIIP.
- Renunciation by the right-holder of the trade mark registration.

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

Infringement of a trade mark occurs if it has been imitated or counterfeited (*Industrial Property Code, Decree Law No. 36/2003 of 5 March*). Counterfeiting and imitation of a trade mark occurs when the following three conditions are met:

- The infringed trade mark was registered before the infringing trade mark.
- Both trade marks refer to similar products or services.
- The trade marks are similar in visual or phonetic aspects and may easily misguide the consumer.

The process of enforcing brand or trade mark infringement and the remedies available are the same as for patent infringement (*see Question 22*).

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

International conventions on patent protection

Portugal is party to the:

- WIPO Paris Convention for the Protection of Industrial Property 1883 (Paris Convention).
- International Convention for the Protection of New Varieties of Plants 1961.
- PCT.
- European Patent Convention 1973.
- WIPO Strasbourg Agreement Concerning the International Patent Classification 1971.
- Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Protection 1977.
- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS).
- WIPO Patent Law Treaty 2000.

International conventions on trade mark protection

Portugal is a member of the:

- Paris Convention.
- WIPO Madrid Agreement Concerning the International Registration of Marks 1891 (Madrid Agreement).
- WIPO Protocol Relating to the Madrid Agreement 1989 (Madrid Protocol).
- Common Regulations under the Madrid Agreement and Madrid Protocol 2004.
- WIPO Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks 1957.
- TRIPS.

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PRODUCT LIABILITY

29. Please give an overview of medicinal product liability law, in particular:

- **Under what laws can liability arise (for example, contract, tort or statute)?**
- **What is the substantive test for liability?**
- **Who is potentially liable for a defective product?**

Legal provisions

Liability for a defective product can arise under:

- Decree-Law 383/89 of 6 November, as amended by Decree-Law 131/2001 of 24 April (*Decree-Law 383/89*).
- Articles 913 to 922 of the Civil Code.
- Law 24/96 of 31 July (*Consumer Protection Law*).

Substantive test

The providers of goods and services to consumers must comply with the requirements of all of the following (*Decree-Law 383/89*):

- Quality.
- Health protection.
- Physical safety.

Goods and services must be fit to satisfy their stated purpose, while bearing in mind the consumer's expectations. It is prohibited to provide goods and services which involve considerable risks in their normal use.

The competent official bodies must seize and remove goods and services that are harmful to the physical health of consumers when used in normal and reasonable conditions (*Article 5, Decree-Law 383/89*).

Liability

There is no specific legislation concerning responsibility for the production and trading of defective pharmaceutical products. However, according to general legislation concerning liability of producers, producers of pharmaceutical products are liable for damage caused by the defective products they have marketed, regardless of fault (*Decree-Law 383/89*). In addition, producers are liable, regardless of fault, if a consumer is provided with a defective product by the seller (*Consumer Protection Law*).

30. What are the limitation periods for bringing product liability claims?

The producer is no longer liable three years after the date when the consumer knew (or should have known) of:

- The damage.
- The defect.
- The producer's identity.

In any event, ten years after the placement of the damaged product in circulation, all rights to hold the producer liable are forfeited.

THE REGULATORY AUTHORITY

National Authority on Medicines and Health Products, IP (*Autoridade Nacional do Medicamento e Produtos de Saúde, IP*) (INFARMED)

T +351 21 798 71 00 (general number)
+351 21 798 71 01/2 (PR)
F +351 21 798 73 16
E *infarmed.publico@infarmed.pt*
W *www.infarmed.pt*

Main areas of responsibility. The INFARMED is responsible for the regulation of medicinal products for human and veterinary use, and health products.

31. What defences are available to product liability claims?

The producer is not liable if it can prove one of the following:

- It did not place the product on the market.
- It can reasonably be concluded that the defect did not exist at the time the product was placed on the market.
- It did not manufacture the product for sale or any other form of commercial distribution.
- The defect in the product was caused by its compliance with mandatory regulations.
- The scientific and technical knowledge at the time the product was placed on the market would not have allowed the detection of the defect.
- In case of a component, the design of the product in which it was integrated, or the instructions given by the product's manufacturer, is responsible for the defect.

32. What remedies are available to the claimant?

Compensation can only be claimed for damages that result in death, personal injury and damage to property (*Article 8, Decree-Law 383/89*).

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33. Are class actions allowed for product liability claims? If so, are they common?

Class actions are permitted, particularly in relation to public health offences and consumer rights' violations, but are very rare. Any citizen, association or foundation that wishes to assert these rights can exercise their entitlement to file class actions, regardless of having a direct interest in the dispute.

The claimants in a class action can represent all the other holders of the rights or interests involved, without a proxy being required.

REFORM

34. Please summarise any proposals for reform and state whether they are likely to come into force and, if so, when.

In May 2006, the government and the Association signed a protocol regarding:

- Liberalisation of pharmacies' property.
- Improvement in access to medicines.
- Maintenance of the quality of pharmaceutical assistance.

The protocol contains a number of principles which will be put into practice in the near future. The most important principles, expected to come into force within the next months, include:

- Any person (pharmaceutical or non-pharmaceutical) will be able to own, directly or indirectly, a pharmacy, but each person will only be authorised to own a limited number of pharmacies.
- In addition to selling medicines, pharmacies will be able to provide pharmaceutical services, such as providing vaccines or give medicines and first aid.
- Pharmacies will be able to sell medicines through the internet.
- Publicity of pharmacies will be authorised.

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