Portugal

Eduardo Nogueira Pinto, AM Pereira Sáragga Leal Oliveira
Martins Júdice & Associados RL

www.practicallaw.com/5-205-5371

REGULATORY OVERVIEW

1. Please give a broad overview of the structure and funding of the national healthcare system.

The national healthcare system is comprised 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.

2. Please briefly describe the regulatory environment for medicinal products/pharmaceutical products/drugs, by whatever name known (referred to below as medicinal products).

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 Pharmacy and Medicinal Products Institute (*Instituto Nacional da Farmácia e do Medicamento*) (INFARMED) is the Portugese 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 (*see Question 9*).

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, in stores run by 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 and 20 February.
- Pricing: Decree 29/90, 13 January, Decree 218-A/92, 20 March and Decree 713/2000, 5 September.
- State Funding: Decree Law 118/92, 25 June.

Key legislation for the National Healthcare 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.

MANUFACTURE AND CLINICAL TRIALS

3. Is authorisation required to manufacture medicinal products? If so, please give an overview of the authorisation process, in particular:

- **To whom should the application be made?**
- **What criteria need to be satisfied to obtain authorisation?**
- **Are there any specific restrictions on foreign applicants?**
- **What are the key stages and timing of the process?**
- **What fee is payable?**
- **Is authorisation given for a fixed period? If so, for how long 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.
- **Criteria.** To manufacture medicinal products, the applicant must have the required technical expertise, facilities and equipment (as set out in Decree-law No. 176/2006, 30 August).
- **Restrictions on foreign ownership.** 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 authorisation is not granted within the relevant time period, the application is deemed to have been denied.

  If additional information is requested, the deadline is suspended until the requests have been fulfilled.
- **Fee.** Each application costs EUR500 (about US$642).
- **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.

4. What powers does the regulator have to monitor compliance with manufacturing authorisations? Does it exercise those powers?

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.

5. In the event of a breach of the terms of a manufacturing authorisation, what are the regulator's powers of enforcement?

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

- Between EUR2,000 (about US$2,566) and EUR3,750 (about US$4,812) if the agent is a singular person.
- Up to EUR45,000 (about US$57,742) 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).

6. Are clinical trials regulated? If so, please give an overview of the necessary consents, authorisations and procedural requirements.

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.

Directive 2001/20/EC on the conduct of clinical trials has been implemented in Portugal and the above provisions satisfy all the requirements under this directive.

PRICING AND STATE FUNDING

7. Are the prices of medicinal products regulated?

The public prices (PP) of national or imported proprietary medicines (a medicinal compound whose formula, and often manufacturing procedure, 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 production or import stages (ex-factory price) in force in certain reference countries (Spain, France and Italy) for identical or similar medicines. The reference prices are then adjusted according to marketing margins and taxes in force in Portugal.

The ex-factory price in Portugal cannot exceed either:

- The lowest ex-factory price in force in the reference countries for identical or similar proprietary medicines.
- The lowest ex-factory price in force, plus one-third of the average of the two lowest ex-factory prices in force in two of the reference countries (whenever the difference between this average and the lowest ex-factory price exceeds 30% of the lowest ex-factory price).

If there is no identical or similar proprietary medicine in a reference country, the ex-factory price must not exceed the highest PP of any similar medicine existing in Portugal. If there is an identical or similar proprietary medicine in the country of origin, the ex-factory price in Portugal must not exceed the ex-factory price in force in that country.

8. In what circumstances will the cost of a medicinal product be funded or reimbursed by the state? How is pricing determined in these circumstances?

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 four percentage scales:

- A: 100%.
- B: 70%.
- C: 40%.
- D: 20%.

There are two funding regimes:

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

There are two methods for calculating the funding amount:

- Generally, the funding percentage (*see above*) 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 (*see above*) 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).
- For a transition period, generic medicines benefit from a 10% increase over the applicable reimbursement percentage.

The reimbursement is paid to the pharmacist by the state directly or through the Pharmacies National Association (*Associação Nacional das Farmácias*) (Association). In this second case, the state gives the reimbursement money to the Association, which then passes it on to member pharmacies. In practice, 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.

MARKETING

9. Is authorisation required to market prescription-only medicinal products? If so, please give an overview of the authorisation process, in particular:

- **To whom should the application be made?**
- **What conditions must be satisfied by the applicant?**
- **What are the key stages and timing of the process?**
- **Is there an abridged procedure?**
- **What fee is payable?**
- **Is authorisation given for a fixed period? If so, for how long 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 Ministry of Health, following consultations with the INFARMED. (In practical terms, the INFARMED determines the decision of the Ministry of Health, which follows the INFARMED's recommendations.)

  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. If a decision is not issued within that time period, the marketing authorisation is deemed to have been denied. This deadline can be suspended if the applicant is required to present additional information or clarification, or make alterations to the application.

- **Abridged procedure.** 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 13*).

- **Fee.** Each application for marketing authorisation costs between EUR250 (about US$321) and EUR4,240 (about US$5,441), 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.

10. Are the marketing authorisation requirements for over-the-counter (OTC) medicinal products the same as those outlined above? If not, please briefly outline how the requirements differ.

OTC products can be medicinal products that do not require prescription, or other products (for example, cosmetics) sold in pharmacies. Non-prescription, OTC medicinal products must meet the same marketing authorisation requirements as prescription-only medicinal products.

11. What powers does the regulator have to monitor compliance with marketing authorisations? Does it exercise those powers?

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.

12. In the event of a breach of the terms of a marketing authorisation, what are the regulator's powers of enforcement?

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.

13. Is there a procedure for mutual recognition of foreign marketing authorisations? If so, please briefly outline the 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.

14. Are there any 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.

15. How are parallel imports regulated?

Parallel imports are now regulated by Decree Law 176/2006, 30 August. 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 INFARMED authorises the import.

16. Is it possible to market medicinal products online, by e-mail and/or 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 priciples, to be implemented in the near future, will allow pharmacies to sell medicines over the internet (*see Question 28*).

ADVERTISING

17. Are there any restrictions on advertising medicinal products (both prescription-only and OTC)? If so, please briefly outline what these are.

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.

Prescription-only medicinal products can only be advertised in specialist magazines or information leaflets aimed exclusively at doctors and other healthcare professionals.

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.
- 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.

Any form of comparative advertising and any public advertising of medicines containing stupefacients or psychoactive substances is prohibited.

PACKAGING AND LABELLING

18. Please give a broad overview of the regulatory framework governing the packaging and labelling of medicinal products.

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 certain details 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 supply of medicinal products or medicinal substances to the public in packaging that does not meet these requirements is prohibited.

TRADITIONAL HERBAL MEDICINES

19. Is the manufacture and marketing of traditional herbal medicinal products regulated in your jurisdiction? If so, please give an overview of the regime.

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.

INTELLECTUAL PROPERTY

20. What are the criteria for patentability?

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.

21. What is the procedure for obtaining patent protection, in particular:

- **To whom should the application be made?**
- **What are the key stages of the process and timing?**
- **What fee is payable?**
- **For how long is protection given?**
- **What is the renewal process?**
- **In what circumstances can a patent be revoked?**
- **Is your jurisdiction a party to any international conventions on patent protection?**

- **Application.** National patent applications in Portugal must be filed at the National Institute of Industrial Property (NIIP).

  Contact details. Campo das Cebolas
  1149 - 035 Lisbon
  Portugal
  T +21 881 81 00
  F +21 886 98 59
  E*atm@inpi.pt*
  W*www.inpi.pt*

A patent can also be protected in Portugal through a regional office that works for a number of countries, like 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.

- **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.** Either:
    - 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 voluntary 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).

- **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$855);
  - each additional claim: EUR15 (about US$19);
  - examination fee: EUR287 (about US$368);
  - letters patent document (on grant decision): EUR159 (about US$204);
  - annuity fees: variable fee.
- **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.
- **Revocation.** 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.
- **International conventions.** 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.

22. When is a patent infringed? What is the process for enforcing patent infringement 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 belong to the patent;
  - uses or applies the means or procedures that belong to the patent;
  - imports or distributes products obtained by 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 can be sentenced to prison.

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.

23. Can product brands be protected by registration as a trade mark? If so, what is the test for obtaining trade mark protection?

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. What is the procedure for obtaining registration of a trade mark, in particular:

- **To whom should the application be made?**
- **What are the key stages of the process and timing?**
- **What fee is payable?**
- **For how long is protection given?**
- **What is the renewal process?**
- **In what circumstances can a trade mark be revoked?**
- **Is your jurisdiction a party to any international conventions on trade mark protection?**

- **Application.** Applications for registration of a trade mark must be made to the NIIP (including applications for international or community trade marks) (*see Question 21*).
- **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.
- **Fees.** 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$607);
  - each additional class: EUR301 (about US$386);
  - grant fee for ten years: EUR442 (about US$567);
  - renewals after ten years: EUR346 (about US$444);
  - filing a declaration of intent to use (DIU): EUR130 (about US$167).
- **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 will lead to forfeiture of the trade mark's registration.
- **Revocation.** 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.
- **International conventions.** 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.

25. When is a registered trade mark infringed? What is the process for enforcing brand or trade mark infringement 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*).

PRODUCT LIABILITY

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

- **Under what laws can liability arise (for example, contract, tort or statute)?**
- **Who is potentially liable for a defective product?**
- **What is the substantive test for liability?**
- **What is/are the limitation period(s) for product liability claims?**
- **What defences are available?**
- **What remedies are available to the claimant?**

- **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).
- **Who is liable?** 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*).
- **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*).
- **Limitation period.** 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.
- **Defences.** The producer is not liable if it can prove one of the following:
  - it did not place the product on the market;

THE REGULATORY AUTHORITY

National Pharmacy and Medicinal Products Institute (*Instituto Nacional da Farmácia e do Medicamento*) (INFARMED)

Contact details. Parque da Saúde Avenida do Brasil 53
1700 Lisbon
Portugal
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*

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

- 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.

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

27. Are class actions permitted for product liability claims? If so, how common are they?

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.

FUTURE DEVELOPMENTS

28. Please summarise any impending developments in the regulation of medicinal products, patent and trade mark law, and product liability.

In May 2006, the Portuguese 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 in practice in the near future. The most important principles 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 render pharmaceutical services, like provide vaccines or give medicines and first aid.
- Pharmacies will be able to offer discounts.
- Pharmacies will be able to sell medicines through the internet.
- Publicity of pharmacies will be authorised.

The sale of lower cost medicine will be compulsory.

Contact:

Abel Mesquita
atm@plmj.pt
Tel. +351 21 319 74 81
Fax. +351 21 319 74 69

"Best Portuguese Tax Firm"
Tax Review Awards

"Portuguese Law Firm of the Year"
IFLR Awards 2006
Who's Who Legal Awards 2006

Lisboa (Head Office)

Edifício Eurolex
Av. da Liberdade, 224
1250-148 Lisboa

Tel. +351 21 319 73 00
Fax. +351 21 319 74 00

Local Offices:
Porto
Algarve

OUR LAWYERS SHARE A COMMITMENT TO UNDERSTAND THE SPECIFIC NEEDS OF EACH CLIENT

Independent comprehensive assistance in all fields of law and an in-depth knowledge of the business and economic environment from a domestic and international perspective are our trademarks since 1968.

Professional quality generated by a demanding work environment and the academic and professional enhancement of our lawyers have always been PLMJ's fundamental values, resulting in consistent international recognition both for PLMJ and its lawyers.

All our lawyers share a commitment to understand the specific requirements and needs of each client as an essential pre-requisite for the most efficient advice.

PLMJ

A.M.PEREIRA, SÁRAGGA LEAL, OLIVEIRA MARTINS, JÚDICE E ASSOCIADOS
SOCIEDADE DE ADVOGADOS, RL

International Offices: Brazil, Angola and Macao (in joint venture with local

E-mail: plmjlaw@plmj.pt - Website: www.plmj.com