

# 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. If biotechnology products are treated differently, please specify the differences.**

Decree-Law 176/2006 of 30 August, as amended (Medicines Code), which transposed Directive 2001/83/EC on the Community code relating to medicinal products for human use (Community Code), provides the regulatory framework regarding the manufacture, import, export, marketing, labelling, packaging, advertising, pharmacovigilance and use of medicinal products for human use (and their supervision and inspection) in Portugal.

INFARMED, an agency overseen by the Ministry of Health, is the regulatory authority responsible for the monitoring, supervision and regulation of the medicines sector, with the overall objective of protecting public health.

Along with the Medicines Code, the key legislation includes:

- **Clinical trials:** Law 46/2004 of 19 August 2004 (Law 46/2004).
- **Pricing:** Decree-Law 65/2007 of 14 March 2007, as amended (DL 65/2007).
- **Reimbursements and state funding:** Decree-Law 48-A/2010 of 13 May 2010, as amended (DL 48-A/2010).
- **Medicines for hospital use:** Decree-Law 195/2006 of 3 October 2006, as amended (DL 195/2006).

## PRICING AND STATE FUNDING

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

The Portuguese national healthcare system comprises:

- The National Healthcare Service (NHS) which includes all public entities and services that provide healthcare and have their own budget. Under Decree-Law 11/93 of 15 January 1993, the NHS works under the control or supervision of the Ministry of Health and is organised into regional health administrations (ARS).

- All other public bodies that carry out healthcare promotion, prevention and treatment activities.
- All private entities and freelance professionals that agree with the NHS, through conventions, to supply healthcare services.

The NHS is funded by the State Budget through payments for acts and activities actually performed, in accordance with a price list which includes a classification of these health-related acts, activities and services. Moreover, the NHS's services and establishments can receive certain legally specified types of income, to add to their own budgets.

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

The public sales prices of prescription-only medicines and reimbursed over-the-counter (OTC) medicines must not exceed the maximum sales price approved by the Directorate-General for Economic Activities (DGAE), in accordance with the criteria set out in DL 65/2007. This decree does not apply to either:

- Medicines subject to restricted prescription (for example, medicines for hospital use), whose price is approved by INFARMED under DL 195/2006.
- Non-reimbursed OTC, which are freely priced.

The sales prices are determined, and annually reviewed, by comparison with the prices charged for similar medicines in four reference countries (Spain, France, Italy and Greece). The sales price of a medicine also includes wholesaler and pharmacy marketing margins (presently 8% and 20% respectively), VAT and marketing fees. Discounts on these prices are permitted throughout the products' entire supply chain.

Recently, Ministerial Order 1041-A/2010 of 7 October 2010 imposed a 6% deduction on the maximum sales prices, applicable throughout the supply chain.

The following applies to the pricing of generic medicinal products:

- When no homogenous cluster exists, the sales price of the first generic must be at least 35% lower than the sales price of the respective reference medicinal product with the same pharmaceutical form and dosage, unless the price of the latter is less than EUR10 in all presentations (in which case it must be 20% lower) (as at 1 November 2010, US\$1 was about EURO.7).

- The sales price of generics when a homogenous cluster exists must be less than, or equal to, the reference price of that cluster. The reference price corresponds to the average of the five lowest sales prices charged on the market for the medicines belonging to that cluster. A homogenous cluster consists of medicines with the same qualitative and quantitative composition in active substances, pharmaceutical form, dosage and route of administration, including at least one generic medicine placed on the market.

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**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)?**

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As a general rule, medicines are reimbursed by the state when the following two criteria are met:

- There is technical and scientific evidence of the medicine's therapeutic added value, or its therapeutic equivalence, in respect of the claimed therapeutic indications.
- There is evidence of the medicine's economic advantage.

The reimbursement also depends on fulfilling one of the following criteria (among others) specified in DL 48-A/2010, that the medicines are:

- Medicines containing new active substances with an innovative pharmacological mechanism that bridges a therapeutic gap, by having improved efficacy and/or tolerance than existing alternative treatments.
- New medicines with the same qualitative and quantitative composition as others already marketed and reimbursed if, with the same pharmaceutical form, their prices are 5% lower than the lowest price of non-generic reimbursed medicinal products.
- New pharmaceutical forms, new dosages or new presentations of reimbursed medicines with the same qualitative composition if they present therapeutic and economic advantages.
- New medicines that neither constitute significant therapeutic innovation, nor present the same qualitative composition as others already reimbursed, if they evidence:
  - economic advantages when compared to other reimbursed medicines used for the same therapeutic purposes; and
  - that they possess identical mechanism of action (in that the specific biochemical interaction through which they produce their pharmacological effects is the same) proved by documentation submitted.
- A combination of medicines in whose composition there are active substances already reimbursed, if:
  - they present therapeutic advantages; and
  - their price is not higher than the sum of the prices of the same medicines when administered separately in identical dosage.

The reimbursement of generics is subject to the following criteria:

- The first generic will be reimbursed on the basis of its economic advantage evidenced in the price differential with the reference medicine (see *Question 3*).
- Following approval of the homogenous cluster, the price of the generic must be 5% lower than the lowest sales price of the generic holding at least 5% of the market share.
- As from the fifth generic, the price of the generic must be 5% lower than that of the generic applying for reimbursement immediately before its own application for reimbursement.

A company can apply to INFARMED to have a product listed for reimbursement. The final decision is awarded by the Ministry of Health usually within 75 or 90 days, depending on whether the procedure relates to generics or non-generics, but these are merely indicative deadlines.

The ultimate beneficiaries of reimbursement are the patients, who benefit from state funding in accordance with how the medicines are categorised. The amount of funding received depends on the therapeutic group of the medicine, for example:

- Category A = 90%.
- Category B = 69%.
- Category C = 37%.
- Category D = 15%.

The above shows the percentage of the price refunded by the state.

## MANUFACTURING

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**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?**

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### Application

Under the Medicines Code, the manufacture of medicinal products is subject to INFARMED's authorisation. Authorisation is required for both total and partial manufacture, and for the various processes of dividing up, packaging and presentation. Authorisation is not required where these processes are carried out solely for retail supply by either:

- Pharmacists in dispensing pharmacies.
- Persons legally authorised to carry out those processes.

Authorisation is also not required for the reconstitution of experimental medicines that are exclusively used in hospitals, in health centres or in clinics by pharmacists or other legally authorised persons.

#### Conditions

The manufacturing authorisation must be requested by the manufacturer (whether an individual or a company). The applicant must have licensed facilities and appropriate equipment. The application must include an:

- Indication of the medicines and pharmaceutical forms which are to be manufactured or imported, and the place of manufacture and control.
- Indication of the technical director.

#### Restrictions on foreign applicants

There are no restrictions for foreign applicants who own laboratories in Portugal to apply for a manufacturing authorisation, provided they comply with all the necessary requirements.

#### Key stages and timing

Under the Medicines Code, INFARMED makes a decision within 90 days of the filing of the valid application. INFARMED can request additional information or clarification, where necessary. The authorisation only applies to the location(s) and medicine(s) indicated in the application.

#### Fee

Each application currently costs around EUR590.

#### Period of authorisation and renewals

The law does not impose any time limit on the manufacturing authorisation. Therefore, provided there are no changes concerning the products manufactured or the premises, the authorisation remains effective for an indefinite period of time.

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#### 6. What powers does the regulator have to:

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

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INFARMED can conduct all necessary inspections to ensure compliance with the terms and conditions of the authorisation. If the manufacturer breaches any of those terms and conditions, INFARMED can suspend or withdraw the manufacturing authorisation.

Where there is a breach of the applicable rules, INFARMED can initiate a “misdemeanour procedure” against the manufacturer. A breach of the terms of the manufacturing authorisation is subject to a fine of between about EUR2,000 and EUR44,900.

## CLINICAL TRIALS

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#### 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)?

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The law governing clinical trials is outlined in Law 46/2004, which implements Directive 2001/20/EC on the conduct of clinical trials (Clinical Trials Directive).

The sponsor of the clinical trial, or its legal representative, must be established in an EU member state.

A clinical trial must have the prior approval of INFARMED and a favourable opinion from the National Ethics Committee for Clinical Research (CEIC). All phases of clinical investigation, including bioavailability and bioequivalence studies, must be designed, implemented and reported in accordance with good clinical practices.

An approval request is decided by INFARMED within 60 days (INFARMED can extend this period by 30 days for certain medicines, if required). This request must contain, among other things:

- The protocol.
- The investigator’s brochure.
- The complete identification of the sponsor, the investigator, or the main or co-ordinating investigator.
- The identification and qualifications of all staff members involved.
- For multicentre trials involving the trial centres in other EU member states, or non-EU jurisdictions, the identification of the regulatory authorities and, if applicable, the ethics committee’s opinion, translated into Portuguese.
- Information on the:
  - compensation provided for damages (property and personal damages attributable to the trial);
  - insurance covering the liability of the investigator and sponsor;

- remuneration of the investigator and trial subjects;
- other relevant details of any financial contract between the sponsor and the trial centre.

The clinical trial can only take place if the trial subjects give their free and informed consent in writing. The written declaration provided to trial subjects must contain information about the nature, scope, consequences and risks involved in the clinical trial.

For trial subjects who are minors or adults incapable of giving their informed legal consent, that consent must be given by their legal representatives. Trials that use trial subjects incapable of giving their own legal consent must:

- Be essential to validate data obtained either in trials with persons able to give their informed consent, or by other research methods, and relate directly to a life-threatening or debilitating clinical condition from which the trial subject incapable of giving legal consent suffers.
- Be designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and its developmental stage, and both the risk threshold and the degree of distress permitted in the trial must be specifically defined and constantly monitored.
- Not involve any incentives or financial inducements, except compensation.
- Show grounds for expecting that administering the medicinal product to be tested will produce a benefit to the patient that either outweighs the risks involved, or produces no risk at all.

Any trial subject or their legal representative can, at any time, expressly or tacitly revoke the consent given.

Before consent is obtained from the trial subjects, the following conditions must be met:

- A prior assessment by the applicable ethics committee must conclude that the trial's benefits outweigh the risks involved.
- A contract must be executed between the sponsor and the trial centre that deals with the terms, conditions and economic aspects of the clinical trial. It should include the direct costs (for example, the investigator's remuneration) and the indirect costs (for example, reimbursement of expenses incurred by the trial subjects) of the trial, payment periods and other conditions set by the parties.
- Insurance must be taken out: the sponsor must organise insurance to cover civil liability.

During the trial, the following reporting requirements must be complied with:

- The investigator must report to the sponsor all serious adverse events, except for those foreseen in the protocol and in the investigator's brochure.
- In the event of a trial subject's death, the investigator must inform the sponsor and the ethics committee.

- When there are suspected, unexpected and serious adverse reactions that may cause the death of the subject, these must be notified by the sponsor to:
  - INFARMED;
  - the regulatory authorities of the other EU member states (where involved in the trial);
  - the ethics committee.

## MARKETING

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### 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?
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#### Application

The application for a national, decentralised or mutually recognised marketing authorisation (MA) must be made to INFARMED.

For a centralised MA, the application must first be submitted to the European Medicines Agency (EMA). Once an MA is granted by the EMA, the MA holder must request a registry number from INFARMED before placing the medicine on the Portuguese market.

#### Conditions

To obtain an MA, the applicant must provide INFARMED with the following documentation (among other things):

- Name, or corporate name, and permanent address (in the EU) of both the applicant and the manufacturer.
- Taxpayer number.
- Proposed name for the medicinal product.
- Proposed patient information leaflet (PIL).
- Expert's detailed reports concerning the manufacturer and the results of physical, chemical, biological or microbiological, toxicological, pharmacological and clinical tests conducted on the medicinal product.
- Therapeutic indications, contra-indications and adverse reactions.
- Dosage, pharmaceutical form, method and route of administration and expected shelf life.

INFARMED can require that the applicant submit samples for control trials of both the product in its different stages of production, and the finished product. Control trials are performed by a recognised public or private laboratory.



### Key stages and timing

INFARMED makes a decision on the application for an MA within 210 days following the receipt of the valid application. This period can be extended if the application is incomplete.

### Fee

The fee varies depending on the type of MA, under Ministerial Order 377/2005 of 4 April 2005. The minimum fee is about EUR1,760.

### Period of authorisation and renewals

The MA is valid for five years. After the five-year period, the MA can be renewed. In principle, it can therefore remain valid for an indefinite period of time.

The MA holder must submit a renewal request to INFARMED at least 180 days before its expiry. The renewal application must:

- Describe the pharmacovigilance of the medicine.
- Be accompanied by updated documentation that demonstrates the adaptation of the previously authorised medicine to scientific and technical developments.
- Include information about the medicine's:
  - quality;
  - safety;
  - efficacy;
  - labelling;
  - PIL;
  - summary of product characteristics (SPC).

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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?

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The principal characteristic of the abridged procedure is that clinical trials are not required. However, this abridged procedure can only be used where either:

- The medicinal product is a generic of a medicinal product authorised (for at least eight years) in an EU member state.
- The medicinal product has a well established medicinal use in the EU for at least ten years, with recognised efficacy and an acceptable level of safety, evidenced by a detailed scientific bibliography.

Where a medicinal product is intended for a different therapeutic use, or has a different administration form or dosage, than that of the original medicine, the abridged procedure cannot be used.

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

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Portugal has implemented the mutual recognition procedure for MAs granted in other EU member states. Under the Medicines Code, the applicant must indicate the reference member state (RMS) and supply the following:

- An evaluation report from the RMS.
- Documentation required to consider the application.
- Any other relevant documentation required to elaborate on the evaluation report.

Once received, INFARMED must approve the evaluation report and the draft SPC, label and leaflet prepared by the RMS within 90 days of receipt, and notify the RMS of its decision. If INFARMED considers that approval of the MA could present a risk to public health, it informs the applicant, the RMS, any other member states involved, and the EMA of its unfavourable opinion. If member states cannot reach agreement on the approval within the time limit, they submit the matter to the Committee for Proprietary Medicinal Products.

The decentralised procedure can also be used, where simultaneous requests are submitted to several EU member states. This procedure is very similar to the mutual recognition procedure, and should be used for products that have not yet received authorisation in an EU member state.

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### 11. What powers does the regulator have to:

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

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INFARMED can carry out inspections to ensure that the legal requirements governing the MA are complied with.

Under Article 179 of the Medicines Code, INFARMED can suspend, revoke or withdraw an MA, or impose changes to its terms, if the medicinal product:

- Proves to be harmful under normal conditions of use.
- Lacks therapeutic efficacy.
- Does not have the qualitative and quantitative composition as declared in the MA application.
- Has a negative risk-benefit balance under normal conditions of use.

An MA can also be suspended, revoked, withdrawn or varied if:

- The documentation supporting the application is incorrect, or has not been amended (where necessary).
- The required controls have not been carried out.

INFARMED can also recall a medicine or prohibit its dispensing, where it does not comply with the applicable legal and regulatory requirements, or with the terms of the MA.

The suspension and revocation of an MA always requires the withdrawal of the product from the market.

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**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?**

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Parallel imports of medicinal products are allowed, provided an authorisation is granted by INFARMED. Authorisation is granted if:

- The medicinal product is duly authorised in the member state where it originates.
- The medicinal product is marketed in compliance with the conditions laid down in the Medicines Code and other applicable legislation.
- The medicinal product has the same qualitative and quantitative composition in active substances, the same pharmaceutical form and the same therapeutic indications with regard to the relevant reference medicinal product (different excipients or different quantities can be used if they do not have therapeutic implications).
- It does not represent a risk to the public health.

After examining the application, INFARMED can either approve it, or reject it and return it to the applicant, together with the grounds for refusal. If INFARMED does not return the application within ten days, the applicant notifies the MA holder of the reference medicine in Portugal, so that it may give its position on the application to INFARMED within ten days of the notification. The duly reasoned decision to approve or reject the application is notified to the applicant and is effective following the publication on INFARMED's website. If no notification of an approval or rejection decision (or notification of that information from foreign authorities is pending) is given within 45 days of the application submission, INFARMED returns to the applicant double the fee paid.

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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.**

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The rules governing promotions are established in the Medicines Code as well as in the Code of Ethics for promotion practices of the pharmaceutical industry and interaction with health professionals (APIFARMA Code). Under the rules, the MA holder, the company responsible for the information regarding, or promotion of, a medicinal product, or the wholesale distributor cannot offer, or promise to offer, directly or indirectly, cash benefits, gifts or benefits in kind to healthcare professionals, except when these benefits have a low cash value (EUR25) and are relevant to the practice of medicine or pharmacy, and/or involve a benefit for the patient.

Gifts for healthcare professionals' personal benefit can never be given.

However, the above rules do not apply to healthcare establishments or institutions.

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

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Under Decree-Law 307/2007 of 31 August 2007, the sale of medicinal products to the public can only be carried out by:

- Pharmacies, either at their facilities, by home delivery or through the internet.
- Authorised OTC dispensaries, either at their facilities, by home delivery or on their website.

The sale of medicinal products on the internet is regulated by Ministerial Order 1427/2007 of 2 November 2007 (MO 1427/2007), which provides that:

- The home delivery of prescription-only medicines can only be carried out by the professionals that are entitled to dispense them in pharmacies.
- The home delivery of OTC can only be carried out by the professionals that are entitled to dispense them in pharmacies or authorised OTC dispensaries.

MO 1427/2007 further establishes that medicines can only be ordered online through a pharmacy's website or by e-mail. It also stipulates a geographic limitation, only permitting home delivery within the municipality (or bordering municipalities) where the pharmacy has its brick-and-mortar facilities.

MO 1427/2007 also sets out the rules regarding the websites through which medicinal products can be sold by pharmacies or authorised OTC dispensaries. In accordance therewith, pharmacies and authorised OTC dispensaries selling medicinal products over the internet must have an individual website specifying:

- The location of the pharmacy, or the authorised OTC dispensary.
- Certain information specified in MO 1427/2007, including the price of the services.
- The means of payment accepted.
- The geographic area of delivery.

The website must be registered with INFARMED before it can sell medicinal products.

## ADVERTISING

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**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?
  - If advertising over the internet is treated differently, please identify the differences.
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The advertising of medicinal products is regulated by the following legislation:

- Medicines Code.

- Advertising Code (Decree-Law 330/90 of 23 October 1990, as amended).
- APIFARMA Code.
- INFARMED Regulation on Advertising of Medicinal Products, approved by Deliberation 044/CD/2008 of 7 February 2008 (INFARMED Regulation).

INFARMED has powers to control the advertising of medicinal products and to investigate any matters that could potentially constitute an infringement of the applicable rules.

Any advertising of medicinal products must:

- Promote the rational use of the product.
- Be objective and free of ambiguous language.
- Be based on an updated evaluation of all available scientific proof and compliant with the provisions of the SPC.
- Be compliant with the MA.
- Not be misleading.

Prescription-only medicines, reimbursed medicines and medicines containing narcotics or psychotropic substances cannot be advertised to the general public. These medicines can only be advertised to healthcare professionals and must include the following:

- Name of the product.
- Essential information compatible with the SPC.
- The supply classification.
- The reimbursement regime.

The advertising of OTC medicines must include the following:

- Name of the medicine.
- Information required for the rational use of the product, including therapeutic indications and special precautions.
- Invitation to the consumer to carefully read the information on the outer packaging and on the PIL.

Conversely, the advertising and promotion of OTC must not:

- Imply that medical consultation or surgery is unnecessary, or suggest a diagnosis or advocating treatment by correspondence.
- Suggest that the medicine's effect is guaranteed, without adverse reactions or secondary effects, producing better or equal results than any other treatment or medicine.
- Suggest that the person's normal state of health can be improved through the use of the product.
- Suggest that the person's normal state of health can be prejudiced by not using the product (there is an exception for vaccination campaigns).
- Be aimed exclusively or principally towards children.
- Refer to recommendations from scientists, healthcare professionals or any other person whose fame may encourage the use of products.

- Treat the medicine as a food, cosmetic or hygienic product or any other consumer product.
- Suggest that the safety or efficacy of the medicine is due to the fact it is considered a natural product.
- Induce to an inaccurate self-diagnosis by including a detailed description or representation of a medical history.
- Refer to evidence, or a guarantee, of a cure in an abusive, alarming or misleading way.
- Use abusive, alarming or misleading visual representations of human body changes caused by diseases or lesions, or of the action of a medicinal product in the human body, or in parts of the human body.

In addition to the above requirements, the APIFARMA Code establishes that internet advertising of medicinal products must only be addressed to healthcare professionals and must be based on technical, scientific and professional principles. Pharmaceutical companies should adopt measures to ensure that this advertising is accessed only by healthcare professionals.

## PACKAGING AND LABELLING

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### 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 is regulated by the Medicines Code. INFARMED is the authority responsible for the supervision and control of packaging and labelling.

The packaging and labelling of medicinal products must contain, among other things, the following information:

- Name of the medicinal product, followed by the international non-proprietary name (INN) where the medicine does not have a fixed combination of more than three active substances.
- Dosage and pharmaceutical form.
- Where applicable, the reference that it is intended for infants, children or adults.
- Quantitative and qualitative composition of active substances per unit of administration, volume or weight (using their common names).
- Presentation and content by weight, volume or number of units.
- Method and, if necessary, the route of administration.
- Supply classification.

- Indications on the use of OTC.
- Suitable pictogram warning highlighting the effects of the consumption of the medicine on the ability to drive or operate machinery, where applicable.
- Expiry date.
- Special precautions relating to storage, if appropriate.
- Sales price printed, labelled or stamped, except where the product is reimbursed.
- Name and address of the MA holder and, if appropriate, name of the local representative.
- MA registration number.
- Batch number.
- “MG”, in the case of generic medicines (*Medicamentos Genéricos*).

Each label must only be for one medicine and cannot include any kind of advertising (though signs or images are allowed if they explain any of the information listed above).

The label must be in Portuguese, and should be tested to ensure that it is easily legible, clearly comprehensible and indelible.

The manufacturer and the MA holder are responsible for any breach of the Medicines Code concerning the packaging and labelling.

## TRADITIONAL HERBAL MEDICINES

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

Specific rules applicable to herbal medicinal products are established in the Medicines Code. The same rules apply to the manufacture of these products as for other medicinal products.

Herbal medicinal products that fulfil all of the following conditions are subject to a specific registration procedure to register with INFARMED:

- They have indications exclusively suitable for herbal medicinal products which, by virtue of their composition and purpose, and are intended and designed for use, or for diagnostic, prescription or treatment monitoring purposes, without a doctor’s supervision.
- They are exclusively for administration in accordance with a specified strength and dosage.
- They are an oral, external or inhalation preparation.
- They have benefitted from prolonged therapeutic use in accordance with experts’ advice.
- They are demonstrably not harmful when used as specified, in accordance with current scientific evidence.
- The pharmacological effects or efficacy of the medicinal product are plausible on the basis of long-standing use and experience, in accordance with current scientific evidence.

The regulation of labelling, PIL and advertising (which must contain the indication that the product is to be used according to the specified indications, and that it is exclusively based upon long-standing use) of herbal medicinal products is similar to that for medicinal products. However, an indication that the patient must consult a doctor or other healthcare professional, namely a pharmacist, if the symptoms persist during the period of use, or if adverse reactions occur that are not mentioned in the PIL, must be included on the packaging.

## PATENTS

### 18. What types of medicinal products and related substances and processes can be protected by patents and what types cannot be patent protected? If process patents only are available for these products and substances, please give details including whether the situation is likely to change. What are the legal criteria to obtain a patent? Which legislation applies?

Patents are governed by the Industrial Property Code, approved by Decree-Law 36/2006 of 5 March 2006 (IPC), as amended, and also by international instruments (see *Question 30*).

Patents are granted for inventions satisfying the following requirements:

- Novelty: the subject matter is not comprised in the state of the art.
- Inventive step: the subject matter is not obvious to a person skilled in the art, considering the state of the art.
- Industrial applicability, being useful in any kind of industry, including agriculture.

Products or processes in every technical field are patentable, as well as new processes for known products, substances or compositions, except for:

- Discoveries, scientific theories and mathematical methods.
- Materials or existing substances.
- Aesthetic creations.
- Projects, rules, and methods for performing mental activities (such as games).
- Displays of information.
- Inventions that are considered to be against the law or contrary to public order, public health or morality.
- The human body, or parts of the human body.
- Plant or animal varieties, or essentially biological processes for the production of plants or animals.
- Methods for treatment of the human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body (with the exception of products, in particular substances or compositions, for use in any of these methods).





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## 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?
- Does the patent office operate a deposit system or are applications subject to some form of scrutiny before acceptance?

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### The authority

Patent applications are filed:

- For a national patent, before the National Institute of Industrial Property (INPI).
- For a European patent, before the INPI or the European Patent Office (EPO).
- For international patents, under the Patent Cooperation Treaty 1970 (PCT) before the INPI, EPO or the World Intellectual Property Organisation (WIPO).

### Fee

Administrative fees are due to INPI for the application, publication and examination, and total EUR200, or EUR100 if the application is submitted online. Yearly fees, range from a minimum of EUR50 (in the fifth year) to a maximum of EUR600 (in the 20th year). Other costs, for example those related to legal advice and the fees charged by industrial property agents, depend on the technical field concerned.

### Process and timing

The key stages and timing concerning the grant of a patent are as follows:

- **Application (deposit system).** For the purposes of ensuring priority, the applicant can submit a “provisional application” and postpone the filing of some of the documents required for the full application (which may not be available at the application date) for a period of 12 months. Where this postponement is not required, an application is submitted and a preliminary examination follows. Once all the formal requirements are satisfied, the intention to grant a patent is published in the *Industrial Property Bulletin* within 18 months from the date of receipt of the application (exceptions can be made where an applicant requires an urgent publication).
- **Opposition.** Oppositions can be filed within two months from the date of publication of the intention to grant the patent; the applicant can respond to oppositions within two months from notification of the opposition.
- **Examination.** The examination report must be completed within one month from either:
  - the end of the two-month time limit if no opposition is filed; or
  - the filing of last procedural document within opposition proceedings.

The examination will either lead to a decision to grant or refuse the patent. The applicant is notified of the examination report, and can reply to the observations made by the examiner within two months. If objections have been raised, the applicant can clarify any doubts within one month, and a decision is then taken on whether to grant the patent.

- **Decision phase.** Further to the examination stage, the INPI takes a decision of grant, partially grant or refuse the patent application. This decision is subject to appeal to the courts with jurisdiction on industrial property matters.
- **Publication.** The final decision, and the patent specification (where it is granted), are published in the *Industrial Property Bulletin*.

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## 20. How long does patent protection last? How is a patent renewed or patent protection extended? If the patent itself cannot be extended, can the organisation's monopoly rights be extended by other means, such as supplementary protection certificates or (regulatory) data exclusivity periods?

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Patent protection lasts for 20 years as of the application date.

As a rule, a patent cannot be renewed and its protection cannot be extended. However, under Regulation (EC) 469/2009 concerning the supplementary protection certificate for medicinal products, where the subject matter of a patent is a medicinal product, a process to obtain it or an application of it, the patent holder can request a Supplementary Protection Certificate (SPC). This is issued by the INPI, and extends the 20-year period for an additional (maximum) period of five years. The patent holder must file an application within six months of either:

- The date the first MA for the product was issued.
- The date on which the patent was granted (where the MA is granted before the patent).

SPCs protecting medicines for paediatric use can be extended for an additional six-month period, provided that the product(s) are under an investigation plan under Regulation (EC) 1901/2006 on medicinal products for paediatric use.

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## 21. In what circumstances can a patent be revoked?

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A patent can be revoked in invalidity proceedings initiated by a third party on the following grounds:

- The patentability criteria are not satisfied (*see Question 18*).
- The subject matter is not patentable (*see Question 18*).
- The patent title does not correspond to the subject matter.
- The subject matter, as described, cannot be executed by a person skilled in the art.
- Formalities were disregarded in the granting procedure.
- It infringes the principles of public order.

In addition, a patent holder's title can:

- Be expropriated on the grounds of public interest.
- Lapse for non-payment of the annual fees.

The grant of a patent imposes a duty to exploit the invention within a maximum of four years after the patent application, or three years after the patent is granted (the longer time period is applied). Where there is a lack of exploitation within this deadline, the patent can be compulsorily licensed, albeit not revoked.

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

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The following constitute infringement of a patent:

- Manufacturing, without licence, the goods or products covered by the patent.
- Employing, without licence, the means and processes, or using new applications of the means and processes forming the subject of the patent.
- Importing, selling, offering for sale, putting into circulation, or concealing, in bad faith, products obtained in any of these ways.

These are criminal offences, punishable with a maximum of three years' imprisonment or a fine of EUR180,000.

The following judicial remedies are available to the patent owner:

- Preliminary injunction.
- Infringement proceedings before the Court of Commerce, seeking:
  - a declaration of the infringement;
  - an order to cease the infringing activity;
  - an award of damages.

The patent owner must demonstrate damages, which can include actual damage and loss of profit. Punitive damages are not allowed in Portugal.

- Criminal proceedings, seeking the conviction of the infringer and the award of damages.
- Administrative proceedings, requesting the annulment of acts issued by a public authority, the object of which results in patent infringement (for example, marketing authorisations granted to infringing products).

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## TRADE MARKS

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### 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?

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Medicinal product brands can be protected through the registration of trade marks, which are governed by the IPC. Certain restrictions on trade marks are contained in the Medicines Code

(for example, the prohibition on using colours or drawings that can create difficulties for patients and professionals in identifying products).

As a general rule, any sign, or combination of signs (for example, words, graphic representations and/or combinations of both), combinations of colours, combinations of the shape of a product, and so on, can be registered as a trade mark provided it has a distinctive character, allowing consumers to distinguish different products from different companies. Generic designations or signs simply reproducing the characteristics of the product cannot be trade marked. Neither can the names and symbols of public authorities or international organisations (as specified in law) be trade marked.

In this context any potential conflicting third party rights should also be taken into account, as they can be considered grounds of refusal of the trade mark application or trigger civil and criminal liability of the trade mark applicant, in case of use of the brand at stake.

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### 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

An application for a national trade mark is made to the INPI. The INPI is also the competent authority to consider an application for registration of a Community trade mark under Regulation (EC) 207/2009 on the Community trade mark (Community Trade Mark Regulation). The INPI also considers applications from entities with Portuguese nationality, domicile or establishment for international trade marks registered under the WIPO Madrid Agreement Concerning the International Registration of Marks 1891 (Madrid Agreement) or the WIPO Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks 1989 (Madrid Protocol).

#### Fee

Fees are due for the application, publication and examination. Fees total EUR100 if the application is submitted online, or EUR200 if not. These fees are for one registration class: each extra class costs EUR30 if submitted online, or EUR60 if not. Fees due for maintaining trade mark rights are the same as those due for application, publication and examination.

#### Process and timing

The key stages and timing concerning the grant of a trade mark are as follows:

- **Application (deposit system).** The applicant submits its application to the INPI, who publishes the application in the *Industrial Property Bulletin*.
- **Opposition.** Oppositions can be filed within two months from the publication of the trade mark application, and the applicant can reply within two months from notification of the opposition.

- **Examination.** The examination verifies whether the grounds for refusal are relevant to the trade mark application, or if any oppositions are justified.
- **Decision.** If grounds for refusal apply, the registration is provisionally refused. The applicant must reply to the observations made in the examination report within one month of notification of the provisional refusal. A decision to grant the trade mark, partially grant or refuse it is then made. This decision is subject to appeal to the courts with jurisdiction on industrial property matters.
- **Publication.** The INPI's decision is published in the *Industrial Property Bulletin*.

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

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Trade mark protection lasts for ten years from its registration, and it can be indefinitely renewed for ten-year periods.

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

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A trade mark can be revoked in invalidity proceedings initiated by a third party on the following grounds:

- The registration criteria are not satisfied (*see Question 23*).
- The existence of conflicting prior third-party rights.
- The formalities were disregarded in the granting procedure.
- It infringes the principles of public order.

A trade mark holder's title can lapse if the trade mark is not used for more than five years.

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

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Trade mark infringement occurs in cases of:

- Counterfeiting.
- Imitation.
- Illegal usage.

These are criminal offences, punishable with a maximum of three years' imprisonment or a fine of up to EUR180,000.

The following judicial remedies are available to the trade mark owner:

- Preliminary injunction.
- Infringement proceedings before the Court of Commerce, seeking:
  - a declaration of the infringement;
  - an order to cease the infringing activity;
  - an award of damages.

The trade mark holder must demonstrate damages, which can include actual damage and loss of profit. Punitive damages are not allowed in Portugal.

- Criminal proceedings, seeking the conviction of the infringer and the award of damages.

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#### 28. Is there a requirement for a patent or trade mark licence agreement to be approved by any government or regulatory body? If so, please provide details including anticipated timelines and cost.

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No approval is required for a patent or a trade mark licence agreement.

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#### 29. Is there a requirement for remittance of royalties payable under a patent or trade mark licence agreement to a foreign licensor to be approved by any government or regulatory body? If so, please provide details including anticipated timelines and cost.

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There is no requirement for the remittance of royalties payable under a patent or trade mark licence agreement to a foreign licensor to be approved by any government or regulatory body.

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

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The following international conventions apply to patent protection:

- WIPO Paris Convention for the Protection of Industrial Property 1883 (Paris Convention).
- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS).
- Patent Cooperation Treaty 1970 (PCT).
- Convention Establishing the World Intellectual Property Organisation 1967 (WIPO).
- European Patent Convention 1973 (EPC).
- WIPO Strasbourg Agreement Concerning the International Patent Classification 1971.
- International Convention for the Protection of New Varieties of Plants 1961 (UPOV).
- Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure 1977.

The following international conventions apply to trade mark protection:

- Madrid Protocol.
- WIPO Madrid Agreement for the Repression of False or Deceptive Indications on Source of Goods 1891.
- WIPO Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks 1957.



## PRODUCT LIABILITY

31. 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 1989, as amended (Decree-Law 383/89), which transposes Directive 85/374/EEC on liability for defective products (old Product Liability Directive).
- Articles 913 to 922 of the Portuguese Civil Code, approved by Decree-Law 47 344 of 25 November 1966.
- Law 24/96 of 31 July 1996 (Consumer Protection Law).
- Decree-Law 67/2003 of 8 April 2003, as amended, which transposes Directive 99/44/EC on the sale of consumer goods (Sale of Consumer Goods Directive).

### Substantive test

A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:

- The presentation of the product.
- The use to which it could reasonably be expected to be put.
- The time when the product was put into circulation.

A product is not considered defective for the sole reason that a better product is subsequently put into circulation.

### Liability

There is no specific legislation concerning liability for the manufacture and marketing of defective medicinal products. Under the general legislation regarding producer liability, producers of medicines are liable for damages caused by defective products they have put into circulation, regardless of fault.

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

A limitation period of three years applies to proceedings for the recovery of damages. The limitation period begins to run from the day the claimant became aware, or should reasonably have become aware, of:

- The damage.
- The defect.
- The identity of the producer.

Claims cannot be brought ten years after the date the producer put the defective product into circulation (unless, of course,

## THE REGULATORY AUTHORITIES

**INFARMED** (*Autoridade Nacional do Medicamento e Produtos de Saúde, IP*)

T +351 21 798 71 00  
F +351 21 798 73 16  
E [infarmed@infarmed.pt](mailto:infarmed@infarmed.pt)  
W [www.infarmed.pt](http://www.infarmed.pt)

**Main areas of responsibility.** Under the control of the Ministry of Health, INFARMED is the authority to evaluate, authorise, regulate and control human medicinal products, medical devices and cosmetics.

INFARMED's principal goal is to ensure the quality, safety and efficacy of medicines and the quality, safety and performance of health products to minimise health risks and ensure adequate standards of public health and consumer protection.

**National Industrial Property Office (INPI)** (*Instituto Nacional da Propriedade Industrial*)

T +351 21 881 81 00/808 200 689  
F +351 21 886 98 59  
E [atm@inpi.pt](mailto:atm@inpi.pt)  
W [www.marcasepatentes.pt](http://www.marcasepatentes.pt)

**Main areas of responsibility.** INPI is responsible for the protection and registration of industrial property in Portugal, in accordance with national and international legislation applicable to industrial property rights.

INPI endorses the use of the Industrial Property System in order to foster innovation and competitiveness, promote fair competition and fight against counterfeiting.

the injured person has in the meantime instituted proceedings against the producer).

33. What defences are available to product liability claims?

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

- That it did not put the product into circulation.
- That, having regard to the circumstances, it can reasonably be concluded that the defect which caused the damage did not exist at the time the product was put into circulation.
- That the product was neither:
  - manufactured for sale or any form of distribution for economic purposes; or
  - manufactured or distributed in the course of its business.
- That the defect is due to compliance with mandatory regulations issued by the public authorities.
- That the state of scientific and technical knowledge at the time when the product was put into circulation was not sufficient to enable the existence of the defect to be discovered.

- In the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted, or to the instructions given by the manufacturer of the product.

Liability can be reduced or disallowed if the damage is caused both by a defect in the product and by the fault of the injured person.

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#### 34. What remedies are available to the claimant?

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The claimant can claim compensation for damages caused by:

- Death.
- Personal injuries.
- Damage to, or destruction of, any item of property (other than the defective product itself).

Damage or destruction to property can only be claimed where the property is ordinarily intended for private use or consumption, and was used by the injured person principally for his own private use or consumption.

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

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Although class actions are allowed for product liability claims, principally concerning public health and consumer rights' violations, they are very rare. Any citizen, association or

foundation can exercise their right to file a class action in these cases, regardless of whether they have a direct interest in the dispute. Local public authorities can also file class actions to defend the rights or interests of residents in their respective constituency.

Claimants in a class action can represent all the other holders of the rights or interests involved: a proxy is not required.

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#### 36. Are punitive damages allowed for product liability claims? If so, are they common? What comment can you make about likely quantum?

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Punitive damages are only allowed where they are provided for in a penalty clause (contractual in nature) or they arise from a court decision (for example, in the form of a daily fine for non-compliance with a judgment).

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### REFORM

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

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As from March 2011, medicinal products will only be reimbursed if they have been prescribed by electronic means, through a certain software platform specified for such purpose by the state.

Prescription by INN is expected to become mandatory during 2011.

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### CONTRIBUTOR DETAILS



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**Qualified.** Admitted to the Portuguese Bar Association, as specialist lawyer in administrative law

**Areas of practice.** Public; health; administrative.

#### Recent transactions

- Involved in transactions and projects in the following sectors: health, telecoms, energy and natural gas, transport, water and waste.
- Actively working in regulation and public procurement matters involving these sectors, and establishing public-private partnerships.

**Qualified.** Admitted to the Portuguese Bar Association

**Areas of practice.** Health; public; privacy and protection of personal data.

#### Recent transactions

- Involved in transactions and projects principally focused on regulatory, corporate and data privacy issues in the health sector (including the pharmaceutical industry).
- Actively working in regulation and public procurement matters involving life sciences.