

Spain

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REGULATORY OVERVIEW

- 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.**

The main regulatory framework is set out by:

- Law 29/2006 (26 July 2006) on guarantees and the rational use of medicinal products and medical devices.
- Royal Decrees on particular regulatory issues.

The existing Royal Decrees are being replaced by new ones to conform with and develop Law 29/2006. Medicinal products must be authorised for marketing by one of the following:

- The Agency on Medicinal Products and Medical Devices (*Agencia Española de Medicamentos y Productos Sanitarios*, AEMPS) (see box, *The regulatory authorities*). This is responsible for national marketing authorisations and mutual recognition procedures (see *Questions 8 and 10*).
- The Agency for the Evaluation of Medicinal Products (EMA). This is responsible for the centralised procedure.

At EU level, the centralised procedure is mandatory for:

- Medicinal products developed by recombinant DNA technology and/or controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes, including transformed mammalian cells and/or hybridoma and monoclonal antibody methods.
- Orphan medicinal products.
- Medicinal products which contain a new active ingredient, not as yet authorised in the EU, relating to:
 - AIDS;
 - cancer;
 - a neurodegenerative disease;
 - diabetes; and
 - auto-immune diseases and other immune dysfunctions, and viral diseases.

The pricing of medicinal products within the healthcare system is determined by the General Directorate for Pharmacy and Medical Devices (*Dirección General de Farmacia y Productos Sanitarios*, DGFPS) (see box, *The regulatory authorities*).

PRICING AND STATE FUNDING

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

The Ministry of Health has competence to rule on all healthcare issues, including funding and the inclusion of medicinal products in the National Healthcare System (NHS).

Attached to the Ministry of Health are several organisations with responsibility over specific areas of health and welfare regulation, including:

- AEMPS.
- DGFPS.
- The regional governments of the Autonomous Communities, which implement measures on medicinal products in their territories.

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

The prices of medicinal products are regulated under Article 90 of Law 29/2006.

DGFPS regulates the industrial price of medicinal products sold in Spain and financed by social security funds or state funds allocated to healthcare (that is, included in the NHS (see *Question 4*)), as follows:

- **Laboratory selling price.** This is fixed by the Interministerial Medicinal Products Price Commission, dependent on the Ministry of Health (see *Question 4*). The pricing decision can be for a limited duration (no less than one year).
- **Public retail price.** This is calculated by adding to the laboratory selling price both the annually updated commercial margins (fixed by resolution of the Ministry of Health) for wholesalers and pharmacies, and value added tax (VAT).

Prices of medicinal products not sold in Spain, or financed by social security or state funds, are not regulated.

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)?

Once a medicinal product has been authorised, DGFPS must decide, before it is marketed, whether it should be included in the NHS and therefore publicly funded. When making that decision, DGFPS takes into account criteria of a general and objective nature, which include (*Article 89.1, Law 29/2006*) the:

- Seriousness, duration and after effects of the various pathologies for which the product was approved.
- Requirements of certain groups.
- Product's therapeutic and social use.
- Limits of the public healthcare budget allocated to pharmaceutical benefits.
- Availability of medicinal products or other alternatives that treat the same illnesses.
- Level of innovation of the medicinal product.

Certain groups, subgroups, categories or classes of medicinal products are excluded from public financing, as decided by the government. The level of the laboratory selling price is also determined by objective and verifiable criteria, in particular, the:

- Manufacturing costs (including administrative and marketing costs).
- Research and development costs.
- Profit element.

The resulting price must be corrected by the therapeutic importance of the medicinal product (based on reports on the therapeutic use of the medicinal product developed by AEMPS) and by the proportionality principle, to ensure the price accords with existing alternatives.

The level of reimbursement is capped by a system of reference pricing. Reference prices are the maximum amount the NHS will fund for each medicinal product in a group, taking into account the criteria provided in Article 89.1 of Law 29/2006 (*see above*) as well as the average price of the medicinal product in the EU. For this purpose, a group of medicinal products is the total of the financed medicinal product's presentations that have the same active ingredient and identical administration route (at least one of those must be a generic medicinal product). Paediatric presentations make up independent groups.

The reference price for each group is the arithmetic average of the three medicinal products with the lowest costs in a group, for each route of administration, in terms of the defined daily dose. Generic medicinal products cannot exceed the reference price.

Certain innovations with therapeutic utility can be excluded from the system of reference pricing for up to five years. Additionally, Article 89.5 of Law 29/2006 provides that the government must periodically review the list of the reimbursed medicinal products and medical devices, according to:

- The criteria of rational use.
- Scientific knowledge.
- The appearance of new medicinal products with a higher therapeutic use.
- The appearance of side effects.

Reimbursement is normally paid by the NHS to the pharmacist (through the Official Association of Pharmacists of each region).

MANUFACTURING

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

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

Applications are made to AEMPS in Spanish (although DGFPS can establish that part of the application can be presented in a different language) and co-signed by a technical director. Certain information and documents must be provided with the application (*Article 18, Royal Decree 1564/1992*).

Conditions

The conditions are as follows (*sections II and III, Royal Decree 1564/1992 and section I.2, DGFPS Circular 17/1997*):

- **Personnel requirements.** The manufacturer must have sufficient technically qualified personnel, under the management of a technical director, to guarantee the product's quality and perform the required controls. Manufacturing laboratories must also have an employee responsible for quality control and for the manufacturing process. Although, under very specific circumstances, the technical director can perform the duties of quality control, a separate person must always be responsible for the manufacturing process.
- **Material and technical requirements.** A manufacturing laboratory must have independent manufacturing premises and separate warehouse and quality control departments.

- **Quality requirements.** Laboratory processes must comply with the Good Laboratory Practices (*Royal Decree 822/1993*) and the marketing authorisation conditions (see *Question 8*).

Restrictions on foreign applicants

There are no such restrictions.

Key stages and timing

AEMPS verifies the information provided, and must make a reasoned decision within 90 days of the application. If all requirements are met, AEMPS grants the authorisation, which is then entered in the Unified Registry of Pharmaceutical Laboratories. If they are not, AEMPS informs the applicant that unless all failed requirements are met within three months, the application will be dismissed. There is a right of appeal before AEMPS; if that appeal is unsuccessful, an administrative appeal can be made to the court. During the application, the AEMPS:

- Inspects the premises.
- Informs the applicant of remediable defects, and gives the applicant a period in which to remedy those defects.

The AEMPS can also:

- Request expert advice.
- Require pending information to be provided within ten days (failing which the application is set aside).
- Hear representations from the applicant.

Fee

For current details on fees payable, please see the section *Tasas* within the division *Documentos* of the AEMPS' website (www.agemed.es). For 2008, the fee payable for an authorisation to begin activity as a pharmaceutical laboratory is EUR4,668.69 (about US\$6,673.66).

Period of authorisation and renewals

Authorisations are granted for an indefinite period.

6. What powers does the regulator have to:

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

The health authorities of the Autonomous Communities periodically monitor compliance with manufacturing authorisations. They have powers to inspect, supervise and fine. If a manufacturing authorisation's terms are breached, AEMPS and the health authorities of the Autonomous Communities can impose:

- **Fines.** The level of the fine depends on whether the infringement is classed as minor, serious or very serious.

- **Interim measures.** These are used if there is reasonable suspicion of an imminent and serious risk to health, and can be imposed by both AEMPS and the Autonomous Communities. They include a number of measures, such as:

- putting into quarantine;
- suspending medicinal products from advertising and use;
- provisionally closing establishments, centres and services; and
- suspending the elaboration, prescription, dispensing or supply of medicinal products under research.

CLINICAL TRIALS

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

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

Authorisation

Trials can be submitted to AEMPS for authorisation once a favourable opinion from the relevant Ethics Committee on Clinical Investigation has been received. The Ethics Committees are independent organisations that must be accredited by health authorities of the Autonomous Communities and AEMPS. The approval of the centres where the clinical trial is to be carried out must also be given. The following time-limits apply to the process:

- **Ten days from application.** AEMPS must decide whether the application meets its requirements, and, if it does, inform the applicant that the application is admitted and the application process has begun.
- **60 days from admission of the application.** Authorisation is considered granted if AEMPS does not oppose. An express response is not usually given.
- **15 days from refusal.** If AEMPS refuses to authorise, the applicant has this period to modify its application or make any necessary representations. AEMPS will expressly decide on the revised application.

Other authorisations

The following trials require AEMPS' prior written authorisation, and are subject to special procedural rules:

- Trials that refer to products requiring a qualification as products under clinical investigation (these are pharmaceutical forms of active ingredients that are investigated or used as reference in a clinical trial, including products with a marketing authorisation which are used or combined differently from the authorised form, or are used to treat a non-authorised symptom or gain more information on the authorised use).
- Trials that are undertaken with medicinal products relating to:
 - gene therapy;
 - somatic cell therapy;
 - medicinal products containing genetically modified organisms.

These authorisations have the same time limits as the usual applications, but if there is no response to the application within 60 days, the application is refused.

Consent

A participant in a clinical trial must consent to participation after having understood, by holding an interview with an investigator working for the hospital where the trials are to be carried out, the following (*Article 7.2, Royal Decree 223/2004*):

- The trial's objectives.
- Its risks and inconveniences.
- The conditions under which it will be undertaken.
- The participant's right to withdraw at any time without expressing the real reason for the withdrawal.

The participant's consent must be documented in a specific form.

MARKETING

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

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

Application

An application for marketing authorisation must be made in Spanish to AEMPS, and signed by the applicant and the laboratory's technical director. In some circumstances, an application will need to be made to EMEA.

Conditions

To be granted marketing authorisation, a medicinal product must (*Article 10, Law 29/2006*):

- Achieve the established quality requirements.
- Be safe (that is, in normal conditions of use it does not produce toxic or unwanted effects disproportionate to the benefit obtained).
- Have shown its efficacy for the therapeutic purposes for which it is offered.
- Be correctly identified and accompanied by the required information (accessible and comprehensive for the patient).

Key stages and timing

Royal Decree 1345/2007 (11 October 2007) establishing authorisation, register and dispatching conditions of medicinal products for human use industrially manufactured states that AEMPS must decide whether to grant or refuse the application within 210 days from the application date. The following are the key stages:

- AEMPS receives the application and makes sure it is complete. If not, it gives the applicant ten days to provide the required documentation (for example, the results of pharmacological or toxicological tests or clinical trials). This interrupts the 210-day period when additional information is required to be provided. If this information is not provided, AEMPS informs the applicant and, after three months, the application expires.
- On AEMPS' request, the Committee for the Evaluation of Medicinal Products for Human Use (Committee), an official body of AEMPS, issues a non-binding report during the 210-day period.
- AEMPS makes a final decision on the application within ten days of the Committee's report (if provided).

AEMPS' decision sets out the medicinal product's marketing conditions, including the text, labelling and packaging requirements to comply with the Summary of Product Characteristics (Technical Deed). At the same time, the product is also entered into the Registry of Medicinal Products (Registry).

Fee

The following fees apply:

- Marketing authorisation and entry in the Registry for a prescription-only medicinal product: EUR19,341.30 (about US\$27,647.40).

- Marketing authorisation and entry in the Registry for a generic medicinal product: EUR7,867.52 (about US\$11,246.20).
- Marketing authorisation and inscription in the Registry for an over-the-counter (OTC) medicinal product: EUR7,867.52 (about US\$11,246.20).
- Renewal fees (*see below*): EUR2,185.29 (about US\$3,123.76).
- Declaration fees (*see below*): EUR112.12 (about US\$160.27).

For further details on fees payable, please see the section *Tasas* in the division *Industria* of AEMPS' website (www.agemed.es).

Period of authorisation and renewals

Marketing authorisations are granted for an initial period of five years and can be renewed for an indefinite period, except if, for pharmacovigilance reasons, a defined renewal period is appropriate. Additionally, the marketing authorisation holder must annually declare to AEMPS its intention to market the medicinal product (*Article 21.3, Law 29/2006*). The marketing authorisation expires if its holder does not effectively market the medicinal product within three years or if, once in the market, the medicinal product cannot be found for three years.

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?

An abridged procedure, where the applicant is not required to provide the results of pharmacological or toxicological tests or clinical trials, is available when one of the following applies:

- The application is made with the consent of a marketing authorisation holder of a medicinal product with the same qualitative and quantitative composition and identical pharmaceutical form.
- The active ingredient of the relevant medicinal product has a clearly-established medicinal use of at least ten years in the EU, with known efficacy and an acceptable level of security established by a detailed scientific bibliography.
- The medicinal product is a generic of a reference medicinal product authorised under EU regulations for a minimum period of eight years. The generic medicinal product, however, cannot be marketed in Spain until ten years have elapsed since the initial marketing authorisation was granted (or eleven years if a relevant new indication is subsequently authorised).

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

EU regulations provide for mandatory mutual recognition of marketing authorisations granted by EU member states. If an application is filed for marketing authorisation of a medicinal product that has already been examined by another member state's health authority, AEMPS suspends examination of the application until it receives a report from that health authority. That report is examined by the Standing Committee of the European Commission (Commission), which must issue, within 60 days, a further report to AEMPS. Within the following 30 days, AEMPS must either:

- Grant the authorisation.
- Start a consultation period (if, on public health grounds, the medicinal product cannot be authorised), in which representations of the applicant and the relevant member states are obtained. If AEMPS still refuses to accept the application, a Commission conciliation procedure starts, following which the Commission issues a final decision.

11. What powers does the regulator have to:

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

The powers of AEMPS and the health authorities of the Autonomous Communities in their territories to monitor compliance with and enforce marketing authorisations, are similar to those that can be used if there is a breach of a manufacturing authorisation (*see Question 6*).

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?

Royal Decree 1785/2000 (as modified by Royal Decree 11/2005) governs the regulation of parallel imports of medicinal products in the EU. The following requirements must be met before a member state's medicinal product can be authorised in Spain:

Technical requirements

- The medicinal product must have marketing authorisation in the member state of origin and be entered in AEMPS' Registry of Medicinal Products.
- The labelling and packaging of the medicinal product must meet requirements set out in Royal Decree 1345/2007 (*see Question 16*).

- The conditioning material (that is, the label and the leaflet with the product) must contain information required under Royal Decree 1785/2000 and specify that the medicinal product has been the object of parallel trade.
- Any repackaging must be carried out according to applicable Spanish law and must not affect the medicinal product's original contents.

Qualification requirements

If the parallel importer carries out the conditioning, repackaging or relabelling of the medicinal product in Spain, it needs to be qualified as a manufacturer (*Articles 17 to 27, Royal Decree 1564/1992*). Otherwise, the parallel importer must be qualified as a wholesaler (*Articles 7 to 14, Royal Decree 2259/1994*).

Information requirements

Before the medicinal product is marketed in Spain, the parallel importer must notify the Spanish holder of the marketing authorisation of its intention to market the product in its territory and, on the holder's request, provide a sample of the repackaged product, to verify the product does not damage the trade mark's reputation.

The parallel importer must keep, for at least two years following the expiry date of the imported product, data on every product batch for the health authorities. It must also inform AEMPS when it stops importation activities.

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

It is prohibited to (directly or indirectly) give, offer or promise, to professionals authorised to prescribe or dispatch medicinal products, their relatives or cohabiting people any bonus, pecuniary advantage or benefit in kind, discount or gift. Early payment discounts or discounts on account of sales volumes are allowed to the extent they are not made to the detriment of competitors and are included in the corresponding invoice.

However, hospitality for events of an exclusive professional or scientific character is allowed, provided it is secondary to the main purpose of the event and is not extended to non-health professionals. Gifts, scholarships and sponsorship made to meetings, congresses and similar events involving doctors must exclusively benefit the event's scientific purpose.

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

The sale of prescription-only medicines by post and by telematic procedures is prohibited (*Article 2.5 of Law 29/2006*). Legislation is being developed (but has not yet been adopted) to regulate the sale of OTC products by post and by telematic procedures to ensure they are dispatched from a pharmacy, with a pharmacist's prior personalised assessment. The door-to-door sale of medicinal products and any type of indirect sales to the general public is prohibited.

ADVERTISING

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

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

Advertising of medicinal products for human use is regulated by:

- Law 29/2006.
- Royal Decree 1416/1994.
- DGFP Circular 6/95.

Some of the Autonomous Communities have adopted regional codes that apply in their territories. Restrictions on advertising a medicinal product differ depending on if it is addressed to the general public or to health professionals.

General public

Only medicinal products that have been authorised as public medicinal products (*medicamentos publicitarios*) can be advertised to the general public, subject to a prior administrative authorisation. Authorisation is granted by:

- The Ministry of Health, for advertising campaigns taking place in more than one Autonomous Community's territory.
- The relevant Autonomous Community's health authority, when the advertising campaign takes place solely in its territory.

Public medicinal products are usually OTC products.

Health professionals

An application must be made to the competent health authority of the relevant Autonomous Community where the laboratory is located. The advert must satisfy the requirements set out in:

- Article 76 of Law 29/2006.
- Royal Decree 1416/1994.
- Circular 6/95.
- The applicable regional guidelines.

In addition, pharmaceutical companies associated to *Farmaindustria* (the main Spanish association of pharmaceutical companies) also need to comply with the Code of Conduct for the Promotion of Medicinal Products 2008, which provides fines for breach. This Code also applies to OTC medicinal products for incentives and hospitality (unless there is a collaboration agreement between *Farmaindustria* and *ANFP*, the OTC National Association, where promotion of OTC medicinal products and its control procedures would be specifically addressed for companies which are members of both entities).

PACKAGING AND LABELLING

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

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

The information that labels and leaflets must contain to guarantee proper identification and correct use of medicinal products is set out in:

- Law 29/2006.
- Royal Decree 1345/2007.
- DGFPS Circular 29/1994.
- AEMPS' Circular 2/2000 (as modified by Circular 1/2002).

The text and other features of the packaging and leaflet form part of the marketing authorisation and must be authorised by AEMPS, and must comply with the Summary of Product Characteristics and be written in Spanish (see *Question 8*).

TRADITIONAL HERBAL MEDICINES

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

Herbal medicinal products are regulated as follows (*Article 51, Law 29/2006 and Articles 50 to 54, Royal Decree 1345/2007*):

- Plants, plant mixtures and preparations obtained from plants with therapeutic or preventive use are subject to laws governing magisterial formulae, officinal preparations or pharmaceutical specialties, as the case may be. The applicable law depends on the product type.
- Plants traditionally considered as medicinal plants that are offered without reference to therapeutic, diagnostic or preventive properties, can be freely sold to the public but only at authorised establishments. A list of the permissible traditional plants is established by the Committee on Herbal Medicinal Products (HMPC) of the EMEA (although Royal Decree 1345/2007 establishes transitory periods for those products commercialised under the then in force Order of 3 October 1973).
- Under Article 51.2 of Law 29/2006, the Ministry of Health has published a list of plants whose sale to the public is restricted or prohibited due to their toxicity (*Order SCO/190/2004*).
- Royal Decree 1345/2007 establishes an abridged procedure to register those medicinal plants which fulfil certain requirements.

PATENTS

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

An invention can be protected by a patent if it (*Article 4, Law 11/1986*):

- Is new.
- Involves an inventive step.
- Is capable of an industrial application.

Patents are regulated by:

- Law 11/1986 (modified by Law 10/2002, which brought into force Directive 98/44/EC on the legal protection of biotechnological inventions.
- Royal Decree 2245/1980.

19. How is a patent obtained? In particular:

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

The authority

Patent rights can be obtained by an application to the Agency of Patents and Trade Marks (*Oficina Española de Patentes y Marcas, OEPM*) (www.agemed.es).

Fee

The fees for 2008 are:

- EUR89.89 (about US\$128.49) for the patent application.
- EUR651.48 (about US\$931.26) for the report.

The patent holder must pay annual fees from the third year following the date of registration of the patent (see www.oepm.es).

Process and timing

OEPM carries out a formal examination of the application, but does not examine whether the requirements of novelty or an inventive step have been met. The application is refused if the product is not patentable, or if any formal defect is not remedied by the applicant within two months. After the formal examination of the patent application, the applicant must request a report on the state of the art (report). Following this:

- The application must be published in the Official Journal of Industrial Property (*Boletín Oficial de la Propiedad Industrial*) (Official Journal).

- The report is issued by OEPM, communicated to the applicant, and published in the Official Journal.
- Third parties can file observations on the report, which are notified to the applicant who can submit representations in response.
- OEPM decides, based on the report, third party observations and other representations, whether to grant the patent. If it does, the decision is published in the Official Journal.
- The procedure to obtain registration usually lasts between 30 and 36 months. A rejection can be appealed before the administrative courts.

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

Provided renewal fees are paid and the patent is not revoked, patent rights last 20 years from the date the application is filed.

Patents cannot be extended beyond a term of 20 years, except for medicinal products. Under Regulation (EEC) No. 1768/92 concerning the creation of a supplementary protection certificate for medicinal products, the effective term of patent rights for medicinal products can be extended by a supplementary protection certificate (SPC), for a period of up to five years, equal to the period between the date when the patent application was lodged, and the date when the first marketing authorisation was granted in the EU, minus a period of five years.

21. In what circumstances can a patent be revoked?

Revocation of a patent right can be requested by any person who considers itself damaged by the patent authorisation, and by the government. A patent is revoked when any of the following occur:

- The invention does not meet one of the patentability requirements (see Question 18).
- The invention is not described sufficiently clearly and completely so as to be carried out by an expert.
- The purpose of the patent exceeds the description in the patent application.
- The patent owner was not entitled to apply for a patent.

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

Civil proceedings

Claims must be brought in the mercantile courts, and accompanied by relevant documents and reports by independent technical experts. Mercantile court decisions can automatically be appealed before the provincial courts (*audiencias provinciales*),

which in turn can be appealed to the Supreme Court for certain specific causes only (*tribunal supremo*). The patent holder is entitled to request the following remedies:

- Cessation of the infringing acts.
- Compensation for damage.
- Seizure of the infringing products.
- Attribution of ownership of the infringing products.
- Adoption of any measures that may be required to stop infringement.
- Publication of the court's judgment.

The court can grant an interim injunction if the applicant provides evidence of both of the following (*Article 133, Law 11/1986*):

- If an injunction is not imposed, it may jeopardise the effectiveness of a future decision (*periculum in mora*).
- The applicant has the right to ask for an interim injunction (*fumus boni iuris*).

Criminal proceedings

The patent holder may also be entitled to file a criminal action against the infringer. Criminal offences are committed by a person who, for industrial or commercial purposes, without the consent of the patent holder, and knowing that the patent is registered (*Article 273, Criminal Code, Organic Law 10/1995*):

- Manufactures, imports, possesses, uses, offers or introduces in the market a product protected by a patent.
- Uses, or offers the use of, a patented procedure.
- Possesses, offers or introduces the product into the market, or uses a product obtained directly from the patented procedure.

Punishments include fines, imprisonment and professional disqualification.

TRADE MARKS

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

Product brands can be protected by registration as trade marks, provided:

- The trade mark does not incur the absolute and relative prohibitions contained in Article 5 and 6 et seq of Law 17/2001 (for example, the sign is not distinctive or contrary to law and public order, or is identical to an existing trade mark which identifies an identical product or service).

- The trade mark cannot (*Article 14.2, Law 29/2006 and Article 35, Royal Decree 1345/2007*):
 - mislead as to the therapeutic properties or the nature of the medicinal product;
 - be confused with a Spanish official denomination or an international common denomination;
 - be confused with another medicinal product in the market, or a cosmetic product, or food sold in pharmacies;
 - have been used by a medicinal product that was annulled within the previous five years.

Generic medicinal products are identified by the abbreviation EFG following their denomination. Generics can also be identified with a trade mark when the trade mark complies with the provisions set out above.

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?
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The authority

Trade mark applications must be addressed to either the:

- Autonomous Community where the applicant is domiciled, or has its industrial or commercial establishment.
- OEPM, when the applicant is not domiciled in Spain (see *Question 19*).

Fee

The fee for an application in 2008 is EUR151.35 (about US\$216.35).

Process and timing

The following are the key stages:

- The Autonomous Community or OEPM carries out a formal examination of the application. OEPM then publishes the trade mark application in the Official Journal, unless it considers the trade mark contrary to public policy.
- Third parties who consider they would be damaged by grant of a trade mark can oppose the application; opposition is notified to the applicant who can submit representations in response.
- OEPM decides whether to reject or accept the application; this decision can be appealed before the administrative courts.

The length of the process depends on whether the application is opposed, and usually takes between eight and 20 months.

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

Registration is valid for ten years. A registration can be extended for successive ten-year periods on payment of a renewal fee, currently EUR175.23 (about US\$250.48).

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

A trade mark can be revoked by a court's final judgment where any of the following apply:

- The trade mark owner was not entitled to apply for registration.
- The trade mark infringes the absolute prohibitions contained in Article 5 of Law 17/2001 (see *Question 23*).
- The applicant acted in bad faith.
- The trade mark conflicts with the relative prohibitions (that is, it conflicts with prior rights) contained in Articles 6 to 10 of Law 17/2001.

A claim for nullity of a trade mark must be filed before a mercantile court. Decisions can be appealed to a provincial court. A further right of appeal may be available to the Supreme Court.

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

Civil proceedings

A registered trade mark is infringed when a third party uses, in the course of trade, and without the consent of the trade mark holder:

- Any sign identical to the trade mark for identical products or services for which the trade mark is registered.
- Any sign identical or similar to the trade mark, and identifying identical or similar products or services, which is misleading to the public.
- Any sign identical or similar to the trade mark, which identifies different products or services, when the trade mark is well-known or famous in Spain, and its use may lead to an unfair profit or damage to the trade mark.

A claim must be brought in a mercantile court; decisions delivered by that court can be appealed to a provincial court which can, in turn, be appealed to the Supreme Court. The trade mark owner is entitled to request the following remedies:

- Cessation of the infringing acts.

- Compensation for damages. The trade mark owner has the right to compensation equivalent to 1% of unlawful sales made with no need to provide evidence. If evidence is provided, compensation may be increased.
- Interim remedies to prevent trade mark infringement, in particular, withdrawal from trade of infringing products, packages, advertising material, labelling and other documents.
- Destruction or charitable donation (if possible) of the products unlawfully identified with the trade mark, at the offender's cost.
- Attribution of seized property (where possible).
- Publication of the court's judgment.

Criminal proceedings

A criminal offence is committed by a person who, for industrial or commercial purposes, without the consent of the trade mark holder, and knowing that the trade mark is registered (*Article 274, Criminal Code*):

- Reproduces, imitates, modifies, or uses an identical sign or a sign capable of being confused, to identify the same or similar products or services.
- Intentionally imports those products without the consent of the trade mark holder, irrespective of the lawful or unlawful nature of the product in its country of origin.

Punishments include fines, imprisonment and professional disqualification.

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

Spain is party to the following international conventions:

- WIPO Paris Convention for the Protection of Industrial Property 1883.
- Patent Cooperation Treaty 1970.
- Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure 1977.
- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS).
- WIPO Madrid Agreement Concerning the International Registration of Marks 1891 (Madrid Agreement).
- WIPO Protocol Relating to the Madrid Agreement 1989.
- WIPO Trademark Law Treaty 1994.
- 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.
- WIPO Vienna Agreement Establishing an International Classification of the Figurative Elements of Marks 1973.

THE REGULATORY AUTHORITIES

Agency on Medicinal Products and Medical Devices (*Agencia Española de Medicamentos y Productos Sanitarios, AEMPS*)

T +34 902 510 100
F +34 91 822 5148
E sdaem@agemed.es
W www.agemed.es

Main areas of responsibility. AEMPS is responsible for the following in relation to medicinal products:

- Grant, modification and revocation of manufacturing and marketing authorisations.
- Authorisation of clinical trials.
- Promotion, control and supervision of medicinal products in the market.
- Enforcement of the regulations and entries in the relevant registries.
- The pharmacopeia.
- Guaranteeing the supply of medicinal products.

General Directorate for Pharmacy and Medical Devices (*Dirección General de Farmacia y Productos Sanitarios, DGFPS*)

T +34 91 596 4016
F +34 91 596 4480
E oiac@msc.es
W www.msc.es

Main areas of responsibility. DGFPS is responsible for the following in relation to medicinal products:

- Direction, development and implementation of national pharmaceutical policy.
- Public funding and price setting.
- Establishing special conditions for the prescription and sale of medicinal products in the NHS.

PRODUCT LIABILITY

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

- Under what laws can liability arise (for example, contract, tort or statute)?

- **What is the substantive test for liability?**
- **Who is potentially liable for a defective product?**

Legal provisions

Liability can arise under the following provisions:

- The Civil Code, which applies to contractual or extra-contractual (that is, tortious) liability.
- Royal Decree 1/2007, 16 November 2007, which harmonises product liability rules for defective products.

Substantive test

Manufacturers and/or importers are liable if the claimant proves all of the following:

- The damage.
- The product defect.
- The causal relationship between the defect and the damage.

Liability

The following may be liable:

- The manufacturer and importer are liable for damage caused by a defect in a product which they have manufactured or imported (*Article 135, Royal Decree 1/2007*).
- Other persons involved in the manufacture, import or sale of the defective products (or other operation relating to the marketing of the defective product) can be liable for damage attributable to them (*Articles 1088 et seq (in relation to contractual liability) and Articles 1902 et seq (in relation to non-contractual liability), Civil Code*).

Other persons can be liable for extra-contractual liability under the Civil Code if the injured person can prove, in addition to the damage, an act or omission caused by fault or negligence which is causally related to the damage. With contractual liability, any person involved in the manufacture or sale of the defective product can be held liable if the injured person proves, in addition to the damage, breach of contract by fault, negligence, or a delay in complying with a contractual obligation, which is causally related to the damage.

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

A limitation period of three years runs from the day on which the claimant suffers the damage, provided the identity of the person liable for the damage was known (*Article 143, Royal Decree 1/2007*). The right to bring proceedings ends on the expiry of ten years from the date on which the product which caused the damage was put into circulation (*Article 144, Royal Decree 1/2007*).

For actions brought under the Civil Code, the limitation periods are 15 years for contractual liability and one year for extra-contractual liability (*Articles 1964 (contractual liability) and 1968, section 2 (extra-contractual liability), Civil Code*).

31. What defences are available to product liability claims?

The manufacturer or importer is not liable if it can prove one or more of the following:

- It did not put the product into circulation.
- The defect which caused the damage did not exist at the time when the product was put into circulation.
- The product was not manufactured for sale or any form of distribution with an economic purpose, or it was not manufactured, imported or distributed by the manufacturer or importer in the course of its business.
- The defect is due to the product complying with existing mandatory regulations.
- In the case of a manufacturer or importer of a component, the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product.

Fault on the claimant's part can diminish or extinguish the manufacturer's or importer's liability. If proceedings are brought against other persons under the Civil Code, the claimant must prove that the defendant is liable for the damage through fault, negligence or breach of contract (*see Question 29*).

32. What remedies are available to the claimant?

The following remedies are available, depending on the relevant law:

- An action for damages is available for contractual and extra-contractual liability under the Civil Code and Royal Decree 1/2007.
- An action for damages on the basis of product liability under Royal Decree 1/2007, where the product defect caused death, physical injuries or material damage in other goods used by the claimant for private consumption.

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

Class actions for product liability claims filed by associations of consumers and users are permitted (*Articles 6.1.7 and 6.1.8, Law 1/2000*). However, there is no relevant case law, as class actions for product liability claims are relatively novel and uncommon.

REFORM

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

Law 29/2006 (26 July 2006) on guarantees and rational use of medicinal products and medical devices is the central regulation governing medicinal products. The law still requires development through a large number of Royal Decrees, during 2008 and 2009. Many provisions of Law 29/2006 (such as the sale by post or by telematic means of certain medicinal products) do not appear to be enforceable until such legislation is enacted. This particularly applies to rules on medical devices, which are included in Law 29/2006, but need legislation to be effectively enforced. Such specific legislation is currently being developed, including for medical prescriptions and traceability.

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Jane Clavin, Knowledge Services Manager, A&L Goodbody.

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