

Italy

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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.

The National Healthcare Service (NHS) is made up of several institutional bodies, at national and territorial level, which mutually co-ordinate their activities within their specific areas of competence. At national level the most important institutions are the:

- Ministry of Health (MoH) (*see box, The regulatory authorities*) that directs and leads the policies of healthcare-related issues in Italy.
- Italian Agency of Pharmaceutical Products (AIFA) (*see box, The regulatory authorities*) that has several important powers in different fields, including granting marketing and manufacturing authorisations, and negotiating the prices of medicinal products that are reimbursed by the NHS.

The territorial level comprises the Regions, the self-governing Provinces of Trento and Bolzano, local health units and hospitals, and university institutions.

Regions have, among other things, the following powers:

- Approving the local healthcare plan (in conformity with the national healthcare plan).
- Granting the distribution authorisations.

The main regulation regulating pharmaceutical matters is Legislative Decree 24 April 2006 No. 219, implementing Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive) and Directive 2003/94/EC on good manufacturing practice for medicinal products (GMP Directive).

Other important provisions include Legislative Decree 24 June 2003 No 211, implementing Directive 2001/20/EC on the conduct of clinical trials (Clinical Trials Directive), Legislative Decree 6 September 2005 No 206 (Consumer Code) and Law Decree No 269 of 30 September 2003 (confirmed by subsequent Law No 326 of 24 November 2003) concerning the price and reimbursement system.

PRICING AND STATE FUNDING

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

The NHS is mainly centrally funded by the government through the national income tax system. Citizens do not otherwise contribute to public health expenditure, apart for the following exceptions:

- The Regions can impose a fee (ticket) on any reimbursable healthcare services in general and on Class A products in particular (*see Question 3*).
- Fees for any non-reimbursable healthcare services.

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

The pricing and reimbursement of medicinal products was drastically reformed in 2003 by Law Decree No 269 of 30 September 2003 (confirmed by subsequent Law No 326 of 24 November 2003).

Medicinal products have been divided into two classes:

- Class A includes essential products and those intended for chronic diseases. These are fully reimbursed by the NHS.
- Class C includes other products, which do not have the characteristics of class A. These are not reimbursed.

There is also a sub-class H. These drugs are only reimbursed if administered in a hospital.

The price of products belonging to class C can be freely determined by the marketing authorisation holder. The class C products are fully charged to the patients/buyers. The price of medicinal products belonging to class C can be raised only during January of odd-numbered years by the marketing authorisation holder (*Article 1, Law Decree 87/2005*).

The price of class A products is set through negotiation between the AIFA and the marketing authorisation holder. The negotiation with AIFA is not required for marketing, but is a condition for reimbursement by the NHS. The negotiation process is based on Resolution of Economic Planning Interministerial Committee of 1 February 2001.

The negotiation process may be initiated after the grant of marketing authorisation if the authorisation is national or by mutual recognition. After the final Committee for Proprietary Medicinal Products (CPMP) opinion if the marketing authorisation is centralised and is organised in three steps:

- Presentation of the dossier.
- Discussion.
- Closing of the contract.

In the discussion, the authorisation holder should support its proposals:

- If the drug is innovative, by a documentation showing a favourable relation cost-efficacy.
- If the drug does not have a significant superiority in relation to other drugs already available, other elements of interest for NHS (that is, lower price, lower therapy cost, and so on).
- In any event, forecast of market share, impact on NHS cost, and so on.

The relevant regulation establishes a term of 90 days for the negotiation, but this term is not mandatory. The agreement is for two years. On expiration of the term, each party can request a renegotiation. Renegotiation can be opened during the term in case of change of indications or posology influencing the utilisation level of the drug.

As of May 2007, the negotiation process is web-based. The documents for the negotiation can be submitted by pharmaceutical companies electronically. AIFA's website sets out the updated list of any reimbursable products, their retail price and any information on its reimbursement.

Hospitals purchase the products directly from marketing authorisation holders or manufacturers with a discount of not less than 50% on the public price.

Due to budget constraint in the last few years, the government repeatedly decreased the price of generics (for example see Law Decree No. 78, 31 May 2010).

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

The cost of class A medicinal products are reimbursed by the NHS. The reimbursement is in a direct form (the patient gets the product free of charge and the NHS pays the pharmacies).

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

Medicinal products manufactured in Italy must be produced on a manufacturing site covered by a manufacturer's authorisation. The authorisation is required even for partial production activity such as encapsulation and packaging.

Conditions

A manufacturing authorisation is granted if the applicant complies with all the requirements established in Articles 50 and ff of Legislative Decree 219/06. In particular, among other things, the applicant must:

- Provide products specifications and their pharmaceutical form to be manufactured.
- Describe the place of production and applicable quality controls.
- Have plants, equipments and structures adequate to produce, control and store the products.
- For each plant, employ at least one qualified person, with the academic background and skills legally required to supervise the production process.

Restrictions on foreign applicants

There are no specific restrictions on foreign applicants, provided compliance with domestic rules is assured.

Key stages and timing

AIFA usually arranges a site inspection before issuing a manufacturer's licence. If the information on the application is accurate and complies with the statutory requirements, AIFA must grant the authorisation within 90 days from receipt of the application. If it is not satisfied with the documents provided, AIFA can request further information on the production facility. AIFA can also prescribe conditions to make the premises or the equipment suitable for production and set a period within which these conditions must be satisfied. If authorisation is refused, the applicant must be given reasons.

Fee

Details of the fees are set out on the AIFA website (*see http://pol.aifa.gov.it/docs/tariffarioTabellareING_v114.pdf*). The manufacturing authorisation fee is about EUR12,580 for each plant (Ministerial Decree 24 May 2004). Since 2009 the payment can be submitted electronically. As at 1 November 2010, US\$1 was about EURO.7.

Period of authorisation and renewals

Authorisation for production is granted for an indefinite period of time.



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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AIFA has powers, at any time and without advance notice, to:

- Inspect factories and premises where medicines are manufactured and packaged.
- Collect and analyse samples of medicinal products.
- View copies of documents relevant to the inspection.

AIFA can revoke, vary or suspend an authorisation when a statutory condition of the authorisation is no longer complied with. AIFA notifies the authorisation holder of its proposed action and its reasons. The authorisation holder can challenge AIFA's decision within 15 days.

Where public safety is at risk, authorisation can suspend a licence with immediate effect. Suspension or revocation orders are served on the authorisation holder and published in the *Official Gazette*. Revocation decisions can be appealed to the Regional Administrative Tribunal.

Producers can be fined between EUR10,000 to EUR100,000 and their legal representative can be sentenced to imprisonment (from six months to one year) if a plant operates without:

- Valid and ongoing authorisation.
- Adequate equipment.
- A qualified person.

In case of non-compliance with any of AIFA's decisions, a fine from EUR10,000 to EUR50,000 can apply, unless the breach constitutes a crime.

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)?
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Directive 2001/20/EC on the conduct of clinical trials was implemented by Legislative Decree No. 211/2003, which came into force on 1 January 2004.

Other important provisions are contained in Legislative Decree 200/2007, implementing Directive 2005/28/EC on good clinical practice as regards investigational medicinal products for human use (GCP Directive).

Further, in relation to data privacy issues, on 24 July 2008, the Italian Authority on Data Privacy (*Garante della Privacy*) issued Guidelines for Data Processing within the Framework of Clinical Drug Trials.

The clinical trial must be approved by the competent authority (*Article 1, Legislative Decree of 24 June 2003*). The competent authority is:

- Usually the general manager or the legal representative of the public entities where the clinical trial is intended to take place (that is, the general manager of the *Azienda Unità Sanitaria Locale* (ASL) which is a local NHS unit).
- The MoH, when the study covers biological substances or genetics modified organism or is conducted in relation to products for which a marketing authorisation has not yet been granted.
- The Superior Institute of Health (*Istituto Superiore di Sanità*) (ISS) in case of new drugs as per the list under Article 3, Presidential Decree No. 439 of 21 September 2001.

The competent authority has 60 days to decide on the request for authorisation.

The sponsor can start the trial only after having obtained the approval of the Ethics Committee and provided the competent authority has not raised any motivated objection (*Article 9, Decree 211/03*).

Clinical trial subjects must give their informed consent. The consent must be in writing, signed and dated. For the consent to be valid, the clinical trials subject must be informed of, among others, the:

- Nature, objectives, risks and conditions of the trials.
- Right to not take part in the trial or to withdraw consent at any time without any consequences on the medical treatment.
- Rights concerning his personal data.

This information must be provided during an interview between the doctor or a member of the research team and the clinical trial subject.

Other conditions that must be met before the trial can start are the:

- Assessment of a reasonable likelihood that the targeted population stands to benefit from the results of the research.
- Existence of insurance coverage for any civil liability of the investigator and sponsor.

Clinical trials are conducted in compliance with the protocol (which can be amended during the trial with the consent of the ethics committee), good clinical practices and GMPs.

During the trial, the promoter must be immediately notified of any adverse effects and any information concerning suspect, serious and unexpected adverse reactions which caused the death of trial subjects or threatened their lives. Notice on adverse reactions is also given to the Ministry of Health.

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?
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Application

No medicinal product can be put on the market without an:

- AIFA authorisation (*autorizzazione all'immissione in commercio*) (AIC), which may be national, by mutual recognition or by decentralised procedures.
- EU authorisation granted in accordance with Regulation 726/2004.

Conditions

AIFA requires that the:

- Application and attached documentation (registration file) demonstrate the product meets the relevant criteria and safety, quality, performance and effectiveness for the product to be marketed in Italy.
- Applicant has the services of a qualified person responsible for pharmacovigilance.

The applicant must be established in the EU and the application must include, among other information:

- Identification of the person responsible for placing the product on the market and, if different, the manufacturer's name. In co-production, the co-producers must specify the addresses of their facilities and the stages of production and controls undertaken by each of them.
- Name of the medicinal product.
- Composition (qualitative and quantitative) of all the drug's ingredients expressed in usual terminology.
- Therapeutic indications, contra-indications and side effects.
- Posology, pharmaceutical form, method and route of administration, and expected shelf life.
- Results of clinical trials.

An abridged procedure applies for generics (see Question 9).

Key stages and timing

Marketing authorisation must be granted or denied within 210 days from the filing of the application. If an authorisation procedure for the same medicinal product is pending in another member state, the AIFA does not examine the application and the process is regulated by the mutual recognition provisions. The applicant is notified of this. If the applicant challenges the denial, AIFA renders its decision within the following 90 days.

Fee

The standard fee is EUR55,680 for each single concentration relating to the product in dosage form, payable to the Ministry of Health.

The abridged procedure fee is half the standard fee (*Ministerial Decree 24 May 2004*).

Period of authorisation and renewals

National and mutual recognition authorisations last five years from the date of publication of a ministerial notice in the *Official Gazette*, and are renewable indefinitely for five-year periods.

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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A marketing authorisation applicant does not need to provide the results of pre-clinical tests and clinical trials (required by Article 8), if he can demonstrate that the medicinal product is a generic of a reference medicinal product, which has been on the market in Italy or in the EU for at least eight years (*Article 10, Legislative Decree 219/06*). No generic version of an authorised medicinal product may then be put on the market until ten years from the authorisation of the reference product.

If the reference product has not been authorised in Italy but in another EU member state, the applicant must indicate that member state.

Legislative Decree 219/06 includes a definition of generic medicinal product (that is, equivalent medicinal product, according to Law Decree No. 87/2005) which mirrors the GCP Directive's definition.

A generic medicinal product is defined in Article 10(5) of Legislative Decree 219/06 as a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance are considered to be the same active substance, unless they differ significantly in properties in relation to safety and/or efficacy.



Further, a full dossier is not required if the applicant can demonstrate that the active substances of the medicinal product have been in well-established medicinal use in the EU for at least ten years, with recognised efficacy and an acceptable level of safety. The test and trial results are replaced by appropriate scientific literature.

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

Mutual recognition and decentralised procedures are regulated by Article 41(ff), Legislative Decree 219/06. They apply when the applicant submits the application for recognition of a marketing authorisation in one or more EU member states.

- **Mutual recognition procedure.** When the product has already been authorised in a member state, before submitting the application for recognition of a marketing authorisation, the authorisation holder informs the member state which granted the authorisation at first and on which the application is based (Reference Member State). The competent authority of the Reference Member State prepares an assessment of evaluation of the medicinal within 90 days of the receipt of the request and forwards the assessment of report to the member state or member states concerned by the application.
- **Decentralised procedure.** When the medicinal product has not received a marketing authorisation at the time of application, the applicant requests a member state to act as Reference Member State and to prepare a draft assessment report, a draft summary of product characteristics and a draft of the labelling and package leaflet. The Reference Member State prepares these draft documents within 120 days after receipt of a valid application and sends them to the concerned member states and to the applicant.

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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The AIFA has broad powers, including the power to:

- Check and grant any modification of a marketing authorisation.
- Inspect and ensure that the manufacturing and marketing of the product comply with all applicable rules.
- Suspend AICs, to gather information and decide on revocation or if the irregularities can be amended in a suitable period of time.
- Revoke AICs, if the product is harmful or has a negative risk/benefits ratio under its normal conditions of use or if the discipline concerning the granting or the updating of AICs is violated.

The commercialisation of medicinal products without an authorisation or after the authorisation has been revoked or

suspended constitutes a crime, which can be punished by imprisonment for up to one year and a fine of EUR2,000 to EUR10,000.

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

Parallel imports are allowed and must comply with the following conditions (*Ministerial Decree of 28 September 1997*):

- An import marketing authorisation from the AIFA is required.
- The importer must show that the product fulfils certain criteria and provide documentation in Italian, proving the product has no difference in therapeutic effect from a product authorised in Italy, or that the differences do not affect quality, safety and effectiveness. If satisfied with the application, the AIFA issues the authorisation within 45 days. A fee applies.
- A sample of the imported product must be made available to the AIFA.
- If the product is re-packed, notice must be given to the AIFA.

The courts follow the decisions of the European Court of Justice as far as intellectual property rights can be used to oppose parallel imports.

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

The following regulations on marketing and advertising practices apply (*Title VII of Decree No. 219/2006*):

- Any gift or promotional aid (financial or not) to practitioners or pharmacists is prohibited, unless it is inexpensive and relevant to the practice of medicine or pharmacy.
- Advertising material that is not specifically related to a product can only be given in conformity to the guidelines issued by the Ministry of Health (*Ministerial Decree 14 April 2008*).
- Free samples of medicinal products, limited to a fixed quantity per practitioner, can only be given to practitioners who can prescribe them. The sample must be delivered by representatives and only at the written request of the practitioner.

Specific provisions refer to the duties and restrictions of pharmaceutical companies organising or sponsoring meetings and conventions.

The same restrictions are set out in the Ethics Code of the Association of the Pharmaceutical Companies (*Farmindustria*).

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

Retail distribution is generally limited to pharmacies. However, since 2006, under Law Decree 223/2006, large-scale retail trade can sell over-the-counter (OTC) products and self-medicated products (provided the presence of a pharmacist is assured).

The sale of medicinal products online, by e-mail or mail order is not allowed. However, e-promotion to practitioners is allowed under certain conditions (see *Question 15*).

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?
- If advertising over the internet is treated differently, please identify the differences.

The definition of advertising includes any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products (*Article 113, Legislative Decree No. 219/2006*).

Only OTC medicinal products can be advertised to the public. In February 2010, the MoH issued guidelines on advertising health products (including only OTC medicinal products) through media.

Advertising must be authorised by the MoH, which must consider the opinion of a committee of experts, except when advertising is:

- Manifestly prohibited.
- To be published in the press or broadcast by radio, and has been approved by a competent body recognised by the MoH.
- Part of an already approved message.

The authorisation is deemed granted if no refusal is issued within 45 days of filing a request with the MoH.

Promotion of prescription products to the public is prohibited. Prescription products can only be promoted to general practitioners and pharmacists in specific circumstances.

The following regulations also apply:

- Representatives must have specific qualifications. The average number of calls made to practitioners and pharmacists must be notified to the AIFA annually.
- Pharmaceutical companies must have a person responsible for the scientific service, who is different from the person responsible for pharmacovigilance.

E-promotion to practitioners is subject to the same rules. Promotional material for practitioners must be previously approved by the MoH. The website section reserved for practitioners must be protected by a personal password and have a system identifying the visitor as a doctor.

Infringement is punishable by an administrative fine.

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)?

Labelling must contain all elements required by Article 73(ff) of Decree 219/2006.

The labelling and leaflet must be in Italian. Packaging must bear, among other elements, the name of the product and special warnings (if needed) in Braille. In addition to the name of the marketing authorisation holder, the outer package can also bear the name of the authorised distributor, provided authorisation is obtained from the MoH.

Reimbursable products must have a special bar code stamp identifying the product. This is bought from the governmental stationery office. When the product is dispensed, the stamp is detached by the pharmacist and affixed to a special medical prescription form for reimbursed products, for control purposes.

TRADITIONAL HERBAL MEDICINES

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

Traditional herbal medicines are subject to the same regulations applicable to medicinal products for human use, but with a simplified registration procedure.

Labels and leaflets of traditional herbal medicines must clearly indicate their nature and typical use, and invite the consumer to consult with a specialist in case of symptoms or adverse effects.

Advertising must visibly qualify the product as “medicine of traditional herbal origin to be used for specific indications based on a long term use”.



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?

Patent protection of pharmaceuticals in Italy dates from 1978, when a judgment of the Constitutional Court repealed the article of the former patent law prohibiting patentability. Product patents and process patents are now in place.

Biotechnologies can also be patented but specific provisions apply (see Article 81(ff) Legislative Decree 30/2005, as amended by Legislative Decree 131/2010. Specific provisions exclude the possibility of patenting any technical proceedings which use human embryonal cell).

Any invention with lawful implementation can be patented if the following requirements are met:

- Novelty (in relation to state of the art).
- An inventive step.
- Capability of industrial application.

Patents are mainly regulated by the Industrial Property Code.

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?

Only domestic and not European rules are considered below.

The authority

Applications are made to the Italian Patent and Trade Marks Office (IPTO) (*Ufficio Italiano Brevetti e Marchi*) (see www.uibm.gov.it). No previous validity examinations are made by the IPTO.

Fee

Details of the fees are set out on the UIBM website (see http://www.uibm.gov.it/index.php?option=com_content&view=article&id=2004522&menuMainType=menuServizi&idmenu=11691&lang=it).

Process and timing

A patent is effective from the date the application is published. An application is published either:

- 18 months from the date the application is filed.
- 90 days from the date the application is filed, if the inventor expressly requests immediate publication.

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?

Patents last for 20 years from the date of filing of the complete application. No renewal or extension is allowed.

For pharmaceutical products, a complementary protection certificate (CPC) can extend the patent protection period by up to 18 years, equal to the period between the filing date of the complete patent application and the date of granting the first AIC. To harmonise the CCP with EU Supplementary Protection Certificates (SPCs), which last a maximum of five years, since 1 January 2004, the term of CCPs has been reduced by six months for every year of their original duration.

21. In what circumstances can a patent be revoked?

A patent cannot be revoked but can be challenged before the courts if it is void or has lapsed.

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

Patent rights consist of the exclusive right to put an invention into practice and draw profit from it in Italy under the conditions in the Industrial Property Code.

A patent is infringed if, without the consent by the owner:

- The patented product is produced, used, marketed, sold or imported.
- The patented process is used or exploited to use, market, sell or import products.

A patent holder can bring an action for infringement against those who infringe its exclusive rights. There are specialised sections for IP-related matters in a limited number of courts (first and second level). These sections deal with national and community trade marks, inventions and new plant varieties, utility models, pictures and models, author rights and unfair competition when this interferes with protecting industrial and intellectual property (*Law No. 273 of 12 December 2002, as implemented by Legislative Decree No. 168/2003*). The action can include preliminary relief such as injunctions, seizing and statements to form evidence of the violation.

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?

Medicinal product brands can be registered as a trade mark, according to general trade mark regulations. To obtain registration, a trade mark must be:

- Distinctive for the goods or services to which the application for registration relates.
- Not deceptive or contrary to law or morality.
- Not similar or identical to any earlier trade marks for the same or similar goods or services.

The Industrial Property Code applies.

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 marks applications are submitted to the IPTO.

Fee

For first deposits, the fees are EUR101 for one class and EUR34 for each additional class.

Process and timing

A standard application form is used. The application can only be lodged by an entity with ownership rights under trade mark law or international trade mark agreements. The application must contain a sample of the mark, and should indicate the type of product or service it will distinguish according to the international classification of products and services.

Any interested party can submit to the IPTO its observations on a trade mark within two months of the date of publication of the application or the registration or the first day of the month following the publication on the *WIPO Gazette*.

Within three months from the same dates, a trade mark's legitimate owner and/or exclusive licensees can challenge the trade mark's registration.

If the application is accepted, the IPTO releases the trade mark, effective from the date of its valid and complete application.

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

Trade mark registrations last for ten years from the date of the application, and can be renewed for further ten-year periods.

Renewal applications are submitted to the IPTO by the trade mark's owner within 12 months before the expiry of the existing trade mark. Late submission is allowed until six months after the expiry of the trade mark, subject to an extra application fee.

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

A trade mark registration cannot be revoked, but can be challenged before the courts if the registration is void or has lapsed. This can happen in the following circumstances:

- Non-use of the mark for a continuous period of five years.
 - The mark has become a common term in the trade.
 - The use of the mark has led to the possibility of the public being misled.
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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?

Trade mark infringement occurs if there is third-party use without the consent of the trade mark owner of an identical sign, or there is the possibility of confusion on the product's origin.

A trade mark holder with exclusive rights can bring an action for infringement against those who infringe its exclusive rights. The action is under the jurisdiction of the specialised sections for IP-related matters of ordinary courts and may include preliminary relief such as injunction and statements to form evidence of the violation.

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.

There is no requirement for a patent or trade mark licence agreement to be approved by any government or regulatory body. However, the licence agreement must not be deceptive to consumers (*Article 23, Industrial Property Code*).

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.

No approval is required.

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

Italy is party to the following international conventions on IP protection.

- Protocol Relating to the Madrid Agreement 1989.
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- WIPO Madrid Agreement for the Repression of False or Deceptive Indications of Source of Goods 1891 (Madrid Agreement).
- WIPO Strasbourg Convention on the Unification of Certain Points of Substantive Law on Patents for Inventions 1963.
- Munich Convention on the Grant of European Patents 1973.
- Patent Cooperation Treaty 1970.
- WIPO Paris Convention for the Protection of Industrial Property 1883.
- Strasbourg Agreement Concerning the International Patent Classification 1971.
- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS).

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

Product liability of a producer of medicinal products is regulated by:

- Legislative Decree No. 206/2005 (Consumer Code). Protection under the Consumer Code can be only be used by “consumers”.
- The general provisions of the Civil Code on extra-contractual liability.

Substantive test

The Consumer Code establishes the principle of no-fault liability of the producer in cases of damage caused by a defective product. In particular the injured person must prove the:

- Damage.
- Defect (based on the Consumer Code’s definition).
- Causal relationship between defect and damage.

Therefore, the injured person does not need to prove the producer’s fault.

Under tort liability, the claimant must prove the:

- Defect.
- Damage suffered.
- Existence of a causal relationship between defect and damage.
- Negligence or fault on the part of the defendant.

THE REGULATORY AUTHORITIES

Ministry of Health (Department of pharmaceutical products and medical devices) (MoH)

Main areas of responsibility. The MoH guarantees fairness in the general implementation and protection of the right to health in Italy, and carries out political and administrative guidance activities in healthcare.

Superior Council of Health (*Consiglio Superiore di Sanità*)

Main areas of responsibility. The Superior Council acts as the technical-scientific consulting body of the MoH.

Superior Institute of Health (*Istituto Superiore di Sanità*)

Main areas of responsibility. The Superior Institute carries out research, clinical trial, inspection, advice, documentation and education activities in healthcare.

Agenzia Italiana del Farmaco (AIFA)

Main areas of responsibility. AIFA main areas of responsibility include: registration and pharmacovigilance; surveillance on pharma-production; information, clinical trials and R&D; prices, reimbursement and markets; European Assessment Procedures and relationships with EMEA and other EU agencies.

If the activity carried out by the producer is considered dangerous, the burden of proof of negligence or fault is shifted because it is for the producer to demonstrate he adopted all possible measures to avoid the damage.

Liability

Under the Consumer Code, producers are liable for the defect of the product. A producer is any manufacturer or its agent, or any importer within the EU or any other natural or legal person presenting himself as the manufacturer by identifying the goods or services with his own name, trade mark or other sign having a distinctive character.

Where the producer of a product cannot be identified, each supplier who distributed the product in the course of a commercial activity is treated as a producer unless it informs the injured person, within three months from the request, of the identity and domicile of the producer or of the person who supplied the product. The same provision can be applied to a product imported in the EU territory whenever the importer cannot be identified, even if the producer is known.

Under tort law, any person who by wilful or negligent conduct causes unfair detriment to another must compensate the victim for any resulting damage suffered. Therefore, any entity can be sued for damages caused by defective or faulty products without a direct contractual relationship. When an entity is considered to have carried out dangerous activities, it is liable for damages unless it proves it adopted all possible measures to avoid damage. Many court decisions have applied the last criteria in relation to the marketing and distribution of pharmaceutical products and contaminated blood derivatives.

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

Limitation periods for product liability claims depend on the liability basis invoked by the claimant. In particular:

- Under the Consumer Code, consumers can file an action against the producer within three years from the time when they have (or should have reasonably have) become aware of the damage, the defect of the product and the identity of the producer. In any case, the action is time-barred after ten years from the time when the manufacturer (or the importer in the EU) placed the product on the market.
- Under tort law, the damaged person can bring an action within five years, running from the time when he could exercise his rights. However, the time limit can be extended if the tort is considered a criminal offence.

33. What defences are available to product liability claims?

The defendant can challenge product liability by proving one of the following circumstances of exemption provided for by the Consumer Code:

- The producer did not put the product into circulation.
- The defect causing the damage came into being after the product was put into circulation by the producer.
- The product was not manufactured for profit-making sale or distribution or the product was neither manufactured nor distributed in the course of the business of the producer.
- The defect is due to compliance of the product with mandatory regulations or with binding measures.
- The state of scientific and technical knowledge at the time when the product was put into circulation was not such to enable to consider the product as defective.
- In the case of a manufacturer of a component or a raw material, that the defect is attributable to the design of the (final) product in which they have been incorporated or to compliance with the instructions given by the producer.

However, under the Consumer Code, a producer may be held liable for damages only if the product is considered defective in relation to its intended use.

No damages can be awarded if the victim could have avoided the injury by acting with ordinary diligence and duty of care.

Compliance with existing rules is not sufficient to exclude tort or contractual liability if the agent is found to have acted with negligence, imprudence or lack of skill (these concepts as defined by case law). If the activity carried out by the producer is considered dangerous, the producer is free from liability when he can demonstrate that he adopted all possible measures to avoid the damage.

34. What remedies are available to the claimant?

Remedies available to the claimant include monetary compensation and injunctive relief.

The Consumer Code provides that damage which can be compensated under it is limited to damage resulting from death or personal injury.

If the claimant is suing under tort law, recoverable damages includes material damages and non-material damages (such as the moral damages and the biological damages which consist of an injury against constitutional rights).

If the claimant is suing under contract law, recoverable damages resulting from breach of contract include actual damage and lost profit.

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

Individual rights granted to consumers by the Consumer Code, when homogeneous, can be protected through class actions (*Article 2, Law No. 244 of 24 December 2007 as substituted by Article 49, Law No. 99 of 23 July 2009*).

Any component of the class, also represented by associations or by a committee of which an individual is party to, can act for the declaration of responsibility or for the compensation of damages or restitutions. By joining a class action, the consumer waives his right to any individual compensative or restitutory action based on the same title.

Class actions are not common.

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

Punitive damages are not contemplated, or allowed to be compensated.

REFORM

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

There are currently no proposals for reform.



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Recent transactions

- Member of supervisory bodies of chemical and pharmaceutical companies, under Legislative Decree 231/01.
- Drafting distribution agreements and supply agreements concerning pharmaceutical products and medical devices.
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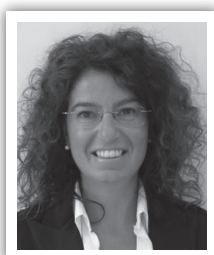
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- Assisting pharmaceutical multinationals in successful legal actions against parallel importers for the protection of their intellectual property rights.
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- Assisting a company in negotiations concerning the purchase of a branch of business for the manufacture of medical devices. Drafting the relevant agreement.