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Argentina

Emilio N Vogelius, Hugo J Eppens Millán, Florencia Rosati and Ana Andrés
Estudio Beccar Varela

www.practicallaw.com/7-518-3454

REGULATORY OVERVIEW

1. What is the regulatory framework for the authorisation, pricing and reimbursement of drugs, biologicals and devices (as they are termed in your jurisdiction)?

Legislation

The main medicinal products regulation is National Law 16,463, supplemented by Decree 9763/1964.

Law 16,463 and Decree 9763/1964 regulate all matters related to the import, export, production, manufacturing, refining, marketing and warehousing of all drugs, chemical products, reactive products, pharmaceutical forms, medicine, diagnosis elements and any other product that can be used and applied in human medicine (medicinal products). All persons and entities that carry out any of these activities are subject to this law and decree, which establish the main guidelines, principles and obligations that must be followed. All activities must be carried out under the technical direction of a professional with a university degree in pharmacy or chemistry.

The following regulations are the main rules that apply to medicinal products and related activities:

- **Decree 150/1992.** This establishes the procedure that must be followed to register medicinal products with the Medicines, Food and Medical Technology National Administration (ANMAT) and the requirements that must be met to manufacture, fraction, prescribe, issue, commercialise, import and export medicinal products.
- **Decree 1299/1997.** This regulates all stages of the marketing chain of medicinal products and determines how manufacturers or importers can market their medicinal products.
- **Disposition 2819/2004.** This establishes good manufacturing practices (GMPs) that must be followed by manufacturers, importers and exporters of medicinal products.
- **Disposition 4980/2005.** This sets the rules that apply and the requirements that must be followed in the promotion and advertising of:
  - over-the-counter (OTC) products;
  - medical and dentistry devices;
  - cosmetic products;
  - food;
  - dietary supplements;
  - household cleaning products;
  - in vitro diagnostic products for self-testing.
- **Resolution 627/2007.** This regulates the promotion of prescribed medicines to medical practitioners and establishes the parameters that must be met in such promotion.
- **National Law 25,649.** This establishes that medical practitioners must prescribe all medicines using the generic name of the medicine.

Regulatory authorities

The main national authority is the Ministry of Health. However, in 1992 the Ministry of Health created the independent entity ANMAT within the scope of the Ministry of Health to ensure better control and supervision of medicinal products. ANMAT controls and is in charge of all activities related to medicinal products (*see box, The regulatory authorities*).

Argentina is divided into 23 jurisdictions and, although ANMAT is a national authority, each of these jurisdictions also has a health authority. This means that persons and entities carrying out activities in connection with medicinal products in any of those jurisdictions are subject to the control of both ANMAT and, depending in the specifics of each case, the local health authority where the activity is performed.

Biotechnology and combination products

Biotechnology and combination products are treated similarly to other medicines.

PRICING AND STATE FUNDING

2. What is the structure of the national healthcare system, and how is it funded?

Argentina does not have a centralised healthcare system. However, regulation in the form of laws, decrees, resolutions and dispositions issued at a national, provincial and municipal level govern health matters.

Three sectors exist in the health care system:

- A public health system, which is funded by national, provincial and municipal public funds raised mainly through taxes.
- Social security entities, many related to labour unions, which are funded mainly by contributions made by employers and employees.
- A private health system, which is funded mainly through contributions made by individuals to companies that provide health services. These companies work similarly to health insurance companies (individuals contribute monthly payments and receive medical treatment and medicinal products when needed).

The Ministry of Health is the main national entity governing national healthcare policy. However, in the last two decades a number of services have been transferred to the provincial or municipal government (most of the public hospitals in Buenos Aires have been transferred from the national field to the municipal one, for example). Each province, and the capital city of Buenos Aires, has its own ministry that manages health policy at a local level.

Both the social security entities and the private health companies have entered into specific agreements with the commercial chain to fund the supply of medicinal products. (In general, all stages of the commercial chain are involved in such agreements.)

In addition, the government has issued specific programmes for special need cases, such as the *Programa Remediar* and *Plan Nacer*. The government also supports social security entities and private health companies in cases where the medical treatment and/or the medicinal products are very expensive and/or are not locally available.

3. How are the prices of medicinal products regulated?

The general principle is that the prices of medicinal products are fixed by the laboratory authorised by the regulatory authorities to market them. However, in practice, prices are strictly controlled by the state.

The public authorities are permanently concerned to reduce the impact of the price of medicinal products on the state budget and have introduced various laws to this end, including:

- Law 23,660 establishing the Medical Mandatory Programme, which aims to set a mandatory minimum medical assistance level in all health systems.
- Law 23,661 creating the Health Insurance System.

4. When is the cost of a medicinal product funded by the state or reimbursed to the patient? How is the pharmacist compensated for his dispensing services?

Resolution 500/2004 establishes the guidelines covering the management of special programmes (*Administración de Programas Especiales*). This programme was created to assist where medical treatment is expensive for both the individual requiring medical help and the social security entity to which that individual is associated. The programme subsidises, or reimburses, totally or partially the cost of medical treatments, medical devices and medicinal products. To obtain such aid it is necessary to file a detailed application with a full description of the assistance required and the reasons for such aid. Assistance is not mandatory and grants depend on both the case presented and budgetary considerations.

Social security entities (including the *Instituto Nacional de Servicios Sociales para Jubilados y Pensionados* (PAMI), which covers retired individuals) and private health companies (together, health entities) have supply agreements with all laboratories that participate in the local pharmaceutical industry. These agreements mean that medicinal products (prescribed by an associated medical practitioner) are supplied to individuals covered by the health entities at a discounted rate. The laboratories also have agreements with wholesalers and pharmacies to supply medicinal products under the terms of these supply agreements.

Individuals acquire the product at the discounted price in any pharmacy taking part in the agreement. Discounts differ depending on which product is acquired and the relevant health entity.

Products are sold by laboratories to wholesalers at full price, wholesalers sell the products to pharmacies at full price and end users pay the discounted price. The difference between what is paid by the wholesaler and the pharmacy and the amount received from the end user is compensated through credit notes. An audit of the products sold must be completed before compensation is paid or credit notes are issued to the health entities.

Agreements between health entities and laboratories can be made through a capita system where health entities pay a fixed amount and, if differences result from a major expenditure, these are absorbed by the commercial chain or the health entities pay discounted prices for products dispensed.

Pharmacies are compensated through the difference between the acquisition and sale price or, if specific agreements are made, through a fee for each product dispensed.

MANUFACTURING

5. What is the authorisation process for manufacturing medicinal products?

Application

Only authorised laboratories can manufacture medicinal products in Argentina. This authorisation must be requested from and granted by ANMAT. Entities intending to manufacture medicinal products must be authorised by ANMAT. Before filing an authorisation request, laboratories must have complied with the requirements of Decree 150/1992 (*see below, Conditions* and *Question 1, Legislation*).

Conditions

Laboratories can request to be authorised as either:

- A manufacturing laboratory.
- A marketing laboratory.
- An importer of medicinal products.

Manufacturing laboratory. To obtain authorisation from ANMAT to manufacture medicinal products, companies must ensure that (*Decree 150/1992*):

- Their activities are under the supervision and technical direction of a pharmacist or a chemist.
- Facilities are adequate for the nature of the products to be manufactured.
- All equipment and test elements for the trial, control and preservation of the products are supplied.
- Sanitary and health conditions are maintained.

- Records including manufacturing, control and protocols are maintained.
- Products are only delivered to persons authorised for their use, possession and sale.

The laboratory and the technical director are jointly liable for complying with these requirements. In addition, Disposition 2819/2004 establishes GMPs, with which all manufacturing laboratories must comply when manufacturing medicinal products.

In addition, when requesting authorisation to be a manufacturing laboratory, the entity must file the following documents:

- Power of attorney.
- Evidence of payment of AR$21,420 fee (as at 1 November 2011, US$1 was about AR$4.24).
- Certified copies of the company's bye-laws or partnership contract duly registered before the Public Registry of Commerce.
- Plans of the premises where the manufacturing will take place, indicating all areas.
- Certified copy of the ownership title or the lease agreement of such premises.
- Evidence of registration before the Customs Authority. (This is only necessary if the laboratory is going to import products as well as manufacture.)
- Evidence of registration with the tax authority and tax identification.
- Municipal authorisation certificate of the premises.
- Authorisation granted by provincial health authorities, if applicable.
- Certified copies of invoices for equipment purchased and materials for quality control of the products.
- Certified evidence of the technical director's registration with the Health Ministry.

Marketing laboratory. Marketing laboratories are laboratories that can register medicinal products in their own name but entrust the manufacturing of products to a local manufacturing laboratory. To be authorised as a marketing laboratory, the laboratory must have a:

- Quality control lab.
- Technical director.
- Warehouse for the products it markets.

To obtain marketing laboratory authorisations, laboratories must fulfil the same conditions as manufacturing laboratories (*see above, Manufacturing laboratory*). However, the premises required are considerably smaller with considerably fewer restrictions, as only quality control of products takes place with no manufacturing.

Importer. To obtain authorisation to be an importer of medicinal products, the company must file the same information and documents as required for manufacturing laboratories (*see above, Manufacturing laboratory*). The premises required are considerably smaller than for manufacturing.

The importer must also have a:

- Quality control lab.
- Technical director.
- Warehouse for the products it imports.

Restrictions on foreign applicants

Only entities duly incorporated in Argentina can be authorised as manufacturing laboratories. Only local entities authorised by ANMAT can manufacture, market, import, export and distribute medicinal products.

If a foreign company wants to manufacture, it must either:

- Incorporate a local company, which requests the authorisation.
- Enter into a commercial relationship with a local laboratory.

As only local laboratories can register medicinal products with the ANMAT Medicinal Product Registry for marketing medicinal products, the medicinal product is considered to be registered by the local laboratory by ANMAT and third parties.

Key stages and timing

Manufacturing laboratory. Following an authorisation request, ANMAT evaluates the documents filed and inspects the premises where the manufacturing will take place to confirm that GMPs are complied with. The authorisation procedure can take up to 12 months, depending on the results of the inspection and whether the petitioner must make any amendments or changes to the premises at ANMAT's request.

Following authorisation, the manufacturing laboratory must register the medicinal products they intend to manufacture with ANMAT. In order to manufacture, market, import and export medicinal products, the products must be registered with ANMAT and included in the ANMAT Medicinal Products Registry (*see Question 8, Marketing*).

Marketing laboratory and exporter. The procedure for obtaining an authorisation to be a marketing laboratory or an exporter can take between six to 12 months. Authorisation can be delayed or denied due to public policy that favours industrial investments.

Fee

The relevant current fees for filings with ANMAT (*Disposition 2415/2011*) can be found on the ANMAT website (*www.anmat.gov.ar/webanmat/normativas_medicamentos_cuerpo.asp*).

Period of authorisation and renewals

The authorisation to be a manufacturing laboratory, a marketing laboratory or an importer, once obtained, does not have an expiration term.

6. What powers does the regulator have in relation to manufacturing authorisations?

Monitoring compliance

ANMAT supervises and controls the:

- Health and quality of medicinal products.

- Activities, processes and technologies that are performed in relation to the supply, production, manufacture, refining, import/export, warehousing and marketing of medicinal products.
- Manufacturing premises and premises of marketing laboratories and importers, through technical inspection of the working conditions and quality control systems used. The purpose of those inspections is to:
  - verify that laboratories are in compliance with all GMPs, manufacturing authorisations and marketing authorisations (MAs);
  - direct laboratories to modify production, distribution and marketing procedures that may be of health risk.

Imposing penalties

ANMAT can impose and enforce penalties for breaches of GMPs or manufacturing or MAs. The penalties are detailed in local regulations and laboratories can defend and question imposed penalties.

Law 16,463 regulates penalties, sanctions and fines for breaches of regulations related to medicinal products or related activities.

The penalties include:

- Warning.
- Monetary fines.
- Total or partial, temporary or definitive closure of the premises in which the breach occurred.
- Suspension or barring of the activity performed by the laboratory.
- Seizure of products in breach.
- Cancelation of the authorisation to manufacture or commercialise products.

CLINICAL TRIALS

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities

Clinical trials are regulated by Resolution 1480/2011 issued by the Ministry of Health and Disposition 6677/2010 issued by ANMAT. These two regulations rule all matters related to the authorisation and performance of clinical trials including:

- Procedure for obtaining ANMAT's authorisation to carry out a clinical trial.
- Principal investigator's obligations and responsibilities.
- Sponsor's obligations and responsibilities.
- Composition and task of the ethics committee.
- Inspection procedure.
- Content of informed consent.
- Protocol of the trial.

Authorisations

ANMAT is the regulatory authority in charge of authorisation, supervision, control and inspection of clinical trials.

Before a clinical trial is carried out the sponsor or its representative in Argentina must receive authorisation from ANMAT after filing the following:

- Sponsor details.
- Study details including:
  - full name;
  - phase of the trial;
  - name of the product;
  - protocol;
  - informed consent;
  - monograph of the product;
  - number of planned participants in the country.
- Documents that must be attached to the presentation include:
  - payment of fee;
  - composition of the Independent Board of Data Monitoring, if any;
  - certified copy of the document detailing the tasks delegated by the sponsor to its representative in the country, if applicable;
  - sworn statement of compliance with GMPs;
  - study protocol;
  - draft of informed consent;
  - monograph of the product;
  - request of import of materials or samples of the study;
  - sworn statement by the technical director of the batches of products to be imported;
  - copy of the product's label in Spanish.
- Principal investigator's details.

The trial must also be approved by the ethics committee and filed with the request for trial authorisation. The trial must be approved by the director of the medical institution where it will be carried out and filed with ANMAT.

Consent

Before subjects can participate in clinical trials, their informed consent must be obtained. A subject's informed consent confirms that the subject completely and fully understood the implications of participating in the trial and the decision to participate was freely made. Informed consent must be obtained by the principal investigator or a qualified and authorised sub-investigator. If the subject cannot give informed consent, his legal representative must provide consent (although the subject's consent must also be obtained in these cases if at all possible).

If the subject has an educational, cultural, social or economic vulnerability, an independent witness must be present when obtaining informed consent. If the majority of the study's subjects are vulnerable, the ethics committee may determine that this requirement applies to all cases.

The informed consent form must be approved by ANMAT and the ethics committee. Before obtaining informed consent, the principal investigator must provide clear, true and complete information adequate to the subject's level of comprehension and must allow the subject, or his representative, to ask any questions he may have. All matters and circumstances related to informed consent must be evidenced in the subject's medical history. If new information is presented in relation to the study, or amendments are made to the protocol that may affect the safety of the subject, a new consent relating to this information and/or amendments must be obtained.

Trial pre-conditions

The financing of the trial must be evidenced in a written and signed agreement between the sponsor, principal investigator and medical institution. The sponsor must also have insurance or another form of guarantee to ensure that all risks and potential damages that subjects may suffer as a consequence of their participation in the trial are covered.

Procedural requirements

The procedural requirements include the requirement to obtain approval from the Data Protection Registry (the entity that oversees the wording of informed consent).

MARKETING

Authorisation and abridged procedure

8. What is the authorisation process for marketing medicinal products?

Application

A medicinal product must be registered with the Medicinal Product Registry of ANMAT to be marketed in Argentina. Only local laboratories duly authorised by ANMAT to manufacture, market, and/or import/export medicinal products can register medicinal products (*see Question 5, Manufacturing: Conditions*). Therefore, before a product can be registered, the laboratory must request ANMAT authorisation to be an authorised laboratory.

Authorisation conditions

A laboratory can receive an MA in one of two ways:

- By registering a medicinal product in its own name and obtaining the corresponding MA.
- By acquiring an already registered medicinal product and transferring the MA from one laboratory to the other.

There are two types of registry:

- Registry of medicinal products to be manufactured in Argentina and those to be imported from countries listed in Annex II of the Decree 150/1992 (Australia, Mexico, Brazil, Cuba, Chile, Finland, Hungary, Ireland, China, Luxembourg, Norway and New Zealand) that are similar to others already registered with ANMAT.
- Registry of medicinal products to be manufactured in Argentina, the marketing of which is authorised in at least one of the countries listed in Annex I of Decree 150/1992 (United States, Japan, Sweden, Switzerland, Israel, Canada, Austria, Germany, France, United Kingdom, the Netherlands, Belgium, Denmark, Spain, Italy).

Registering a new medicinal product. To register a new medicinal product and obtain the corresponding MA, the following information must be provided to ANMAT:

- Information on the product including the:
  - product's proposed name;
  - formula;
  - pharmaceutical form in which it will be presented;
  - pharmacological classification (international classification number).
- Technical information of the product including:
  - method of control;
  - period of shelf life;
  - method of manufacturing;
  - bioavailability data of the products.
- Label details.
- Patient information leaflet.
- Certificate of commercialisation of the corresponding country's health authority if the product to be registered is imported from the countries listed in Annex II of Decree 150/1992.

The products must be manufactured in laboratories approved by government entities of the countries listed in Annex I of Decree 150/1992 or by ANMAT, and must comply with ANMAT's manufacturing requirements and quality control. Products to be imported from the countries indicated in Annex II of Decree 150/1992 must be authorised and commercialised in the country of origin when registering with ANMAT.

In addition to the information required for registering a new medicinal product, information of the product's effectiveness and innocuousness must be filed if the medicinal product is to be:

- Manufactured locally and is new in Argentina, with the exception of those medicinal products authorised to be commercialised in any of the countries indicated in Annex I and II of Decree 150/1992.
- Imported from a country listed in Annex II of Decree 150/1992, if the product, although commercialised in any of these countries, did not have a similar product registered with ANMAT.
- Imported and manufactured in a country not included in Annex I or II of Decree 150/1992 and was not authorised for marketing in any of the countries listed in Annex I of Decree 150/1992.

ANMAT evaluates all information filed, requests new information and/or clarifications to the petitioner if necessary and decides whether or not to grant authorisation.

Acquiring an already registered medicinal product. The transfer of MAs must be registered with ANMAT to acknowledge the authorisation's new owner. To transfer MAs parties must file the transfer agreement with ANMAT, together with a form provided by ANMAT completed and signed by both parties. The registration of the MA transfer takes up to 90 days.

Other conditions

There are no further conditions related to what a company must do after market entry to maintain authorisation, other than renew such authorisation every five years. The medicinal product should be distributed through wholesalers duly authorised by the Ministry of Health and made accessible to patients through pharmacies that must also be duly authorised. Medicines can also be provided in hospitals and other public health sites.

Key stages and timing

The time that the registration procedure takes depends on whether the medicinal product to be registered has already been approved for use in any of the countries listed in Annex I of Decree 150/1992, or if a similar product was previously authorised for marketing in Argentina or any of the countries indicated in Annex I of Decree 150/1992. Generally, it takes more than 90 days and could extend to up to more than one year depending on the complexity of the product's technical aspects.

Fee

The current fees for almost all and most relevant filings that can be done with ANMAT (under Disposition 2415/2011) can be found on the ANMAT website (*www.anmat.gov.ar/webanmat/normativas_medicamentos_cuerpo.asp*).

Period of authorisation and renewals

MAs last for five years and for renewals, new applications must be made with ANMAT 30 days before the end of the five-year term.

New applications must include the:

- Product's generic and commercial name.
- Number of the MA.
- Pharmaceutical formulas and concentrations to be renewed.

The following documentation must also be filed:

- Evidence of the marketing of the product.
- Certified copy of the MA.
- Copy of the labels and prospects.

Post-marketing commitments and pharmacovigilance obligations

ANMAT issued a Guide for the Good Practices in Pharmacovigilance following recommendations of the World Health Organisation (WHO) and developed a system to update information on different medicinal products.

Any modification in packaging and/or labelling is subject to approval by ANMAT. ANMAT also receives suggestions to packaging and/or labelling modifications.

9. Which medicinal products can benefit from the abridged procedure for marketing authorisation and what conditions and procedure apply? What information can the applicant rely on?

If a medicinal product is authorised to be marketed in at least one of the countries listed in Annex I of Decree 150/1992, it can be registered with ANMAT for its import and marketing in Argentina. In these cases, registration is automatic although the following must be provided:

- Patient information leaflet.
- The marketing certificate of the corresponding country's health authority if the product to be registered is imported from the countries listed in Annex II of Decree 150/1992.

This procedure takes about four months.

Registration requires evidence of the product's MA in one of the countries listed in Annex I of Decree 150/1992. It is not necessary to file clinical and preclinical trials regarding safety and effectiveness of the product.

Registration granted under this procedure is only for the import and marketing of the particular medicinal product. Registration of similar or bioequivalent medicinal products intended to be manufactured locally must comply with the requirements for local laboratories (*see Question 8*).

10. Are foreign marketing authorisations recognised in your jurisdiction?

Foreign MAs are not directly recognised in Argentina. However, ANMAT takes foreign MAs into consideration, depending on the country that issued such authorisation, for the registration of similar or same products and granting of the corresponding local MA.

11. What powers does the regulator have in relation to marketing authorisations?

Monitoring compliance

ANMAT has full power to control and supervise compliance with MAs and can perform any and all inspections that it considers appropriate to confirm that the MAs are respected and complied with.

Imposing penalties

ANMAT can impose penalties similar to those imposed for breaches of MAs (*see Question 6*).

Parallel imports

12. Are parallel imports of medicinal products into your jurisdiction allowed?

Intellectual property rights cannot be used to oppose parallel imports. Under patent law it is generally accepted that exhaustion of rights has taken place when a product has been placed in the market of a foreign country by the holder of the Argentine patent or with his consent, provided the foreign country where the product has been placed in the market complies with the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS) standards for patent holders' rights.

Restrictions

13. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

Manufacturing laboratories are prohibited from giving incentives or benefits of any kind to medical practitioners (*Resolution 627/2007*).

Exceptions include allowances given by manufacturing laboratories as part of their commercial policy to:

- Members of a marketing chain.
- Distributors.
- Licensed drug manufacturers.
- Drug stores.

Professional advancement scholarships can be given for training courses, participation in conferences, symposiums and scientific assemblies, provided the selection procedure is fair and transparent.

14. What are the restrictions on marketing medicinal products on the internet, by e-mail and by mail order?

It is not permitted to market medicinal products on the internet, by e-mail or by mail order. All medicinal products, including OTC products, must be sold in pharmacies.

ADVERTISING

15. What are the restrictions on advertising medicinal products?

Legislation and regulatory authority

Any form of public announcement of products that require an authorised prescribed delivery and are regulated by ANMAT is prohibited (*Law 16,463*).

Promotion of medicinal products, other than OTC products, can only be addressed to practitioners authorised to prescribe or deliver medicines and must provide the technical and scientific information necessary for the addressees to know the therapeutic properties of the medicine. It must also include material product information, including:

- Generic and trade name of the medicine.
- Quantitative and qualitative composition.
- Pharmaceutical form.
- Indication, counter indications and adverse effects.
- Warnings and cautions.
- Doses.
- Name and address of the titleholder.
- Prescription regime.
- Delivery conditions.

Restrictions

Advertising of OTC products is permitted, subject to control, and penalties can be imposed in the event of infringement by ANMAT.

Advertising of OTC products must not encourage their use and must include a disclaimer recommending a visit to a medical practitioner.

Documentary promotion means any promotion made through publications, such as magazines, bulletins, and books or similar as well as audiovisual media on optical, magnetic or similar means.

Internet advertising

Internet advertising falls within the definition of documentary promotion (*see above, Restrictions*).

PACKAGING AND LABELLING

16. Outline the regulation of the packaging and labelling of medicinal products.

Legislation and regulatory authority

The legislation includes Decree 150/92 and Regulation 3683.

ANMAT is the regulatory authority for packaging and labelling of medicinal products.

Information requirements

ANMAT must approve information on labels and indication slips concerning:

- Indications.
- Dosage.
- Adverse effects.
- Counter indications.

Promotional statements are not permitted.

Labels must include the following information (*Decree 150/92*):

- Name and address of the laboratory.
- Name of the laboratory's technical director.
- Product's brand and generic name printed in the same size and type.
- Formula of the product per unit.
- Content of the package.
- Expiration date.
- Storage information and sale condition (whether it should be prescribed in a special way such as a double recipe).
- Number of the manufacturing batch.
- Serial manufacturing and sale numbers.
- Statement that the product is approved by the Ministry of Health.

The indication slips must reproduce the:

- Information referred to in the labels.
- Pharmacologic and therapeutic effects attributed to the product indicating precise clinical information.
- Warnings.
- Precautions.
- Counter-indications.
- Antagonisms, where applicable.
- Antidotes.
- Adverse effects that usual indicated dosage and maximum and minimum dosages may cause.
- Pharmaceutical forms.
- Presentations.
- All filings submitted to local administrative entities such as ANMAT.

Other conditions

ANMAT enacted Regulation 3683 in May 2011 under which pharmaceutical companies must place a support or storing device with capacity to store a univocal code supervised and audited by ANMAT on the package of each of unit of a medicinal product for sale to the public.

All information must be given in Spanish.

TRADITIONAL MEDICINES

17. Outline the regulation of the manufacture and marketing of alternative or complementary medicinal products.

Law 16,463 regulates all matters related to the local import, manufacturing, deposit and marketing of medicinal products, including alternative or complementary medicines, and herbal products. ANMAT is the regulatory authority and products are regulated as either medicinal, cosmetic or food products depending on the chemical formulation of the product. Generally, if products have a therapeutic effect they are considered to be medicinal products.

ANMAT classifies products and publishes from time to time the National Therapeutic List including frequently used magistral recipes (*recetas magistrales*) that have a medicinal effect and recognised therapeutic action.

PATENTS

18. What are the legal conditions to obtain a patent and which legislation applies? Which products, substances and processes can be protected by patents and what types cannot be patent protected?

Conditions and legislation

Under Argentine legislation, national or foreign natural or legal persons can obtain patents provided they are domiciled or are considered domiciled in Argentina.

The applicable legislation is the Patent Law 24,481 as amended by Law 24,572 and approved by Decree 260/96 (Patent Law).

Scope of protection

For patent protection both the product and the process must be (*section 4, Patent Law*):

- Novel (any invention that is not state of the art).
- Inventive (when the creative process or its results do not detract from the prior art as obvious to a person skilled in the technical field concerned).
- Capable of industrial application.

The following are not considered inventions (*section 6, Patent Law*):

- Discoveries, scientific theories and mathematical methods.
- Literary or artistic works, or any other aesthetic creation, and scientific works.
- Schemes, rules and methods for performing mental acts, playing games or doing business, and computer programs.
- Reporting forms.
- Methods of surgical, therapeutic or diagnostic treatment applicable to the human body or to animals.
- The juxtaposition of known inventions or mixtures of known products, variations in shape, dimensions or materials, except in the case of their combination or merger so that they cannot function separately or when the qualities or main functions of these are modified to obtain an industrial result not obvious to someone skilled in the art.
- All kinds of living matter and substances existing in nature.

The following are not patentable (*section 7, Patent Law*):

- Inventions whose exploitation should be prevented in the territory of Argentina in order to preserve public order or morality, health or life of humans or animals or plant life or to prevent serious damage to the environment.
- The entire biological and genetic material existing in nature or its replica, in the biological processes involved in animal, plant and human reproduction, including genetic processes involving material capable of conducting its own replication in normal and free conditions such as in nature.

19. How is a patent obtained?

Application and guidance

Patent applications must be filed with the Patent Office at the National Institute of Industrial Property (*Instituto Nacional de la Propiedad Industrial*).

The Patent Office's web site (*www.inpi.gov.ar/templates/index.asp*) provides Spanish guidance on the application procedure and fees (*www.inpi.gov.ar/templates/patentes_aranceles.asp*).

Process and timing

The Patent Office's examiner will make a preliminary formal examination to resolve any defects in the application 90 days after the patent application is filed. Once approved, the patent application is published in a Patent and Trade Mark Bulletin within 18 months of the patent filing date. Early publication can be requested on payment of an early publication fee. After publication, the Patent Office's examiner conducts an in-depth examination, following the payment of the in-depth examination fee. If the fee is not paid within three years of the patent filing date, the patent application is considered abandoned.

The process of granting a patent is five years on average, depending on the technical area of the invention. However, in pharmaceutical, chemical and biotechnological inventions, this term can reach eight years or more.

Deposit system

The Patent Office does not operate a deposit system. Patent applications are subject to both formal and in-depth examinations when granted (*see above, Process and timing*).

20. How long does patent protection typically last? Can monopoly rights be extended by other means?

Duration and renewal

The patent has a non-renewable twenty-year term of protection, starting from the patent filing date.

Extending protection

Patent protection cannot be extended.

21. How can a patent be revoked?

Patents can be revoked both for:

- Lack of payment of annual maintenance fees.
- Lack of exploitation of the invention.

The Patent Law provides for compulsory licences if voluntary licences are not granted and where the invention is not exploited. Cancellation due to lack of exploitation is only admitted in cases of abuse of rights by the patent holder, if the granting of compulsory licences has not been enough to prevent abuse.

When a patent is granted to a third party, the patent lapses if is not exploited for a period of two years (for reasons attributable to the patent holder).

Patents can be declared null and void due to either:

- Lack of novelty.
- Lack of inventive step.
- Lack of industrial application.
- Having been granted in contradiction to the Patent Law provisions (*see Question 18, Patents: Scope of protection*).

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

Conditions for infringement

A patent is infringed when someone:

- Produces or makes others produce one or more objects in violation of the patent holder's rights.
- Imports, sells, places on sale or exposes or introduces into Argentina, one or more objects in violation of the patent holder's rights.

Claim and remedies

In addition to criminal prosecution, the patent holder or his licensee can pursue civil remedies to stop the illegal exploitation of the invention from continuing and to obtain compensation for damages suffered.

When filing a patent certificate, the patent holder or his licensee can request, under the guarantees that the court may deem necessary, the following precautionary measures:

- The confiscation of one or more samples of infringing items, or the description of the procedure in question.
- The inventory or seizure of counterfeited items and special machines for the manufacture of goods or performance of the incriminated procedure.

The courts may order precautionary measures in relation to a granted patent in order to:

- Prevent patent infringement from taking place and, in particular, prevent the entry of infringing goods into the channels of commerce, including imported goods immediately after customs clearance.
- Preserve relevant evidence of the alleged infringement.

In either case the following conditions must all be satisfied (before granting any measure the court will require an expert appointed by the court to issue a report on evidence of these conditions within a maximum of 15 days):

- There is a reasonable probability that the patent, if challenged by the defendant, would be declared valid.
- It is summarily evidenced that any delay in granting such measures will cause irreparable harm to the patent holder.
- The damage that can be caused to the patent holder exceeds the damage that the alleged infringer can suffer if the measure is wrongly granted.
- There is a reasonable probability of infringement of the patent.

In exceptional cases such as when there is a demonstrable risk of evidence being destroyed the Courts may grant such measures without the intervention of the other party.

When granting any precautionary measure, the court will order the applicant to provide a guarantee or equivalent assurance to protect the defendant and prevent abuse.

Some jurisdictions (that is, Buenos Aires, Córdoba and others) provide for a mandatory mediation procedure, before a public or private mediator, to take place before trial except in the event of precautionary measures.

Foreign parties can present before Argentinean Courts (under section 348 of the Civil and Commercial Procedure Code). An *arraigo* (bond) may be demanded if the claimant does not have assets in Argentina or is not domiciled in Argentina.

23. Are there non-patent barriers to competition to protect medicinal products?

There are no other barriers to competition other than those under Intellectual Property Laws and regulatory obligations, such as having good standing certificates issued by ANMAT authorising the marketing of products.

TRADE MARKS

24. What are the legal conditions to obtain a trade mark and which legislation applies? What cannot be registered as a trade mark and can a medicinal brand be registered as a trade mark?

Conditions and legislation

National or foreign natural or legal persons can obtain trade marks provided they are domiciled or considered domiciled in Argentina.

The applicable legislation is the Trade Mark Law 22,362 (TML).

Scope of protection

Trade marks can be comprised of one or more words with or without conceptual content, drawings, emblems, monograms, engravings, prints, stamps and images, bands, combinations of colours applied in a particular place or product packaging, packaging, containers, combinations of letters and numbers and the letters and numbers for their special design, advertising phrases, and any other sign with distinctive capacity (*TML*).

Medicinal product brands and their packaging can be registered as trade marks.

The following are not considered trade marks and cannot be registered (*section 2, TML*):

- Names, words and signs that are the necessary or usual designation of the product or service to be distinguished, or that are descriptive of their nature, function, qualities or other characteristics.
- Names, words, signs and slogans that have passed into general use before their application for registration.
- Shape given to products.
- Natural or intrinsic colour of the products or a single colour applied on them.

The following cannot be registered as trade marks (*section 3, TML*):

- Trade marks identical to previously registered or applied for trade marks to distinguish the same products or services.
- Trade marks similar to other already registered or applied for trade marks to distinguish the same products or services.
- National or foreign appellations of origin. An appellation of origin is the name of a country, a region, a particular geographical location or area that gives a product qualities and characteristics that are exclusive to the geographical environment.
- Trade marks that are likely to mislead about the nature, properties, merit, quality, processing techniques, function, source of price or other characteristics of the goods or services to be distinguished.
- Words, drawings and other signs that are contrary to morality and decency.
- Letters, words, names, logos or symbols, that are used or must be used by the federal, provincial, municipal, religious and health organisations.
- Letters, words, names or symbols that are used by foreign nations and international organisations recognised by the Argentine government.
- The name, pseudonym or portrait of a person, without his consent or that of his heirs until the fourth degree.
- Designations of activities, including names and company names, that are descriptive of an activity, to distinguish products. However, acronyms, words and other signs with distinctive capacity forming part of those may be registered to distinguish goods or services.
- Advertising phrases that lack originality.

25. How is a trade mark registered?

Application and guidance

Trade mark applications must be filed with the Trade Mark Office at the National Institute of Industrial Property (*Instituto Nacional de la Propiedad Industrial*).

The Trade Mark Office's web site (*www.inpi.gov.ar/templates/index.asp*) provides Spanish guidance on the application procedure and fees (*www.inpi.gov.ar/templates/marcas_aranceles.asp*).

Process and timing

When a trade mark application is filed, the Trade Mark Office's examiner conducts a preliminary formal examination to amend any formal defects of the application. Once approved, the trade mark application is published in a Patent and Trade Mark Bulletin within about two to five months starting from the trade mark filing date. After publication, and within a 30 days period, third parties can file oppositions to the trade mark application. If oppositions are filed, they block the trade mark application procedure, until either an agreement is reached with the opponent or a lawsuit is filed against the opponent (with a view to finding the opposition baseless). Mediation is mandatory before filing a lawsuit. Once the lawsuit finishes, the Trade Mark Office's examiner conducts an in-depth examination and, if approved, the trade mark if granted.

The process of granting a trade mark takes about 12 to 18 months, provided the trade mark application does not receive third party oppositions or official actions.

26. How long does trade mark protection typically last?

Duration and renewal

The protection term is ten years starting from the date of the grant.

The use of a trade mark to cover a different product or service than the one covered by the trade mark, or even as part of the designation of an activity, is enough to authorise the renewal of the trade mark.

Extending protection

Protection is renewable for equal and successive periods provided the trade mark is used to distinguish a product or service within five years before the expiration date.

27. How can a trade mark be revoked?

At the request of a party, a trade mark can be declared cancelled provided it has not been used in the country within five years before the action filing date, except in force majeure cases.

A trade mark cannot be cancelled if:

- It was not used in a class but the same trade mark was used in the marketing of a product or providing a service in other classes.
- It was used as part of the designation of an activity.

However, trade marks can be declared null and void if registered:

- In violation of the provisions of the TML.
- By someone who, when applying for registration, knew or should have known that the trade mark belonged to a third party.
- For marketing by a person whose regular business is the registration of trade marks for that purpose.

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

Conditions

A trade mark is infringed by those who:

- Counterfeit or fraudulently imitate registered trade marks.
- Use a counterfeited, fraudulently imitated or unauthorised third party trade mark.
- Put up for sale or sell a registered counterfeited, fraudulently imitated or unauthorised third party trade mark.
- Put up for sale, sell or otherwise market products or services with counterfeited or fraudulently imitated trade mark.

Claim and remedies

In addition to criminal prosecution, the trade mark holder can pursue civil remedies to stop the illegal use of the trade mark from continuing and to obtain compensation for damages suffered.

The trade mark holder can request the:

- Seizure and sale of goods and other items with the infringing trade mark.
- Destruction of infringing trade marks and names and all the elements that include them, if they cannot be separated from them.

At the request of a party the court can order the publication of the judgment at the expense of the offender if he is convicted or defeated in a trial.

When filing a trade mark certificate, the trade mark holder can request, under the guarantees that the court may deem necessary, the following precautionary measures:

- Seizure of objects with infringing trade marks.
- Inventory and description.
- Seizure of one of the objects in violation.

Patent and trade mark licensing

29. Does a patent or trade mark licence agreement and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body?

Registration of patent or trade mark licence agreements is not mandatory but is necessary to obtain certain fiscal benefits.

Fiscal benefits involved in registration include that a:

- Natural or legal person residing in the country can deduct the amounts paid to the foreign licensor as expenses.
- Natural or legal person residing abroad benefits from a reduced tax rate on taxable income subject to income tax.

Patent and trade mark conventions

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

Argentina is party to the WIPO Paris Convention for the Protection of Industrial Property 1883 (Paris Convention) and TRIPS.

PRODUCT LIABILITY

31. Outline the scope of medicinal product liability law.

Legal provisions

The manufacture, production and marketing of medicinal products, the practice of medicine, informed consent and good clinical practice are dealt with under specific and different federal laws and other administrative regulations. Product liability is dealt with under general principles of law included in the Argentine Civil Code (CC), particularly in Sections 1,109 to 1,136, and in the Consumer Defence Law 24,240, as amended by Law 26,361 (CDL).

Substantive test

If liability is grounded on contractual or extra-contractual basis, it will be either subjective (founded in tortuous fraud or negligence) or objective (based in product defect or in its own created liability). Making a distinction between fraud and negligence is relevant to determine the consequences the debtor might face.

Causality between the medicinal product and the alleged damages is the main issue to be considered in liability attribution, as well as any circumstantial evidence collected.

Liability

Laboratories, hospitals and clinics, their medical directors, medical practitioners, investigators and sponsors of clinical trials and, in certain cases, drug stores, can be considered jointly and severally liable for damages arising from the provision of medicinal products.

32. How can a product liability claim be brought?

Limitation periods

Products liability claims can be filed directly before the courts. Some jurisdictions (including Buenos Aires, Córdoba and others) require mediation before bringing the case to court. Claimants sometimes report the case to a consumer authority before moving into the courts, usually to reach a quick settlement.

The statute of limitation period is:

- Two years for claims based in extra-contractual liability.
- Ten years for contacts.

However, if claims are based on the CDL, the minimum statute of limitation term is three years (*section 50, CDL*).

Court precedents and recognised authors are almost unanimous in considering that the relationship between laboratories and patients is based in extra-contractual grounds.

The CDL rules are not applicable to professions as the one performed by the medical practitioners (*section 2, CDL*).

Class actions

Class actions can be brought before the courts by any duly incorporated consumer organisation when collective interests are affected or threatened (*section 55, CDL*).

Foreign claimants

Foreign parties can bring claims before the courts. An *arraigo* can be demanded if the claimant does not have assets in Argentina and is not domiciled in Argentina.

33. What defences are available to product liability claims?

In subjective liability cases, the defendant must prove that he has not taken part in any wrongful act or misconduct. In objective liability cases, the victim's own liability or that of a third party not linked to the claimant, must be considered.

THE REGULATORY AUTHORITIES

Ministry of Health

W *www.msal.gov.ar*

Main areas of responsibility. The Ministry of Health's main areas of responsibility include:

- Overseeing the health of the Argentine population.
- Authorisation of, among others, medical institutions, pharmacies and institutions to perform medical studies and analysis.
- Registration of all medical practitioners, pharmacists and other professionals related to medical care.
- Organising and awarding public bids related to medicine products.

Medicines, Food and Medical Technology National Administration (ANMAT)

W *www.anmat.gov.ar*

Main areas of responsibility. ANMAT's main areas of responsibility include:

- Authorisation, control, supervision and inspection of the manufacturing, production, fractioning, packaging, distribution, commercialisation, import and export of medicines, medical technology, food and cosmetic products.
- Registration of medicines, medical technology, food and cosmetic product before their manufacturing, import, distribution and commercialisation.
- Control, supervision, inspection and authorisation of all clinical trials performed in Argentina.
- Authorisation, control, supervision and inspection of manufacturing and commercialisation of household cleaning products.

Parties can only agree to limit their liability on specific contracts between them, not as a general practice. Wilful misconduct cannot be waived. The defendant´s liability can be reduced if it is possible to show that the claimant contributed to the damage. Other situations such as facts caused by third parties (for example, legislative requirements) may reduce the liability of the defendant or, depending on the factual situation, cause other parties to contribute to compensate the claimant. In principle, manufacturers must learn about all effects that the products may cause.

34. What remedies are available to the claimant? Are punitive damages allowed for product liability claims?

Claimants typically ask for complete indemnification before the courts for damages suffered, which can include psycho-physical and moral damages, lost profits, medical fees and other expenses.

During the trial, and in certain circumstances (that is, a favourable first instance Court pronouncement even appealed, or when the alleged right is plausible and there is a serious risk based on the delay to arrive at a final decision), claimants are entitled to request from the Judge a monetary payment or other kind of injunction order against the defendant and its assets.

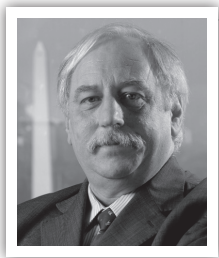
Claimants can ask for punitive damages, although claims are not common as this has been incorporated into legislation (*section 52, CDL*). In those few cases that punitive damages have been awarded, the amounts have not been significant.

REFORM

35. Are there proposals for reform and when are they likely to come into force?

There are no proposals for a general reform of health regulations and the scope of the latest regulations has been limited to specific matters. The general public policy trend is to reduce the economic cost of health treatments (such as allowing bidding for rights to supply vaccines and other products).

CONTRIBUTOR DETAILS



EMILIO N VOGELIUS

Estudio Beccar Varela
T +54 11 4379 6836
F +54 11 4379 6869
E *evogelius@ebv.com.ar*
W *www.ebv.com.ar*

Qualified. Argentina, 1976

Areas of practice. Life sciences; arbitration; mergers and acquisitions; general advice to companies.

Recent transactions

- Daily assistance to several pharmaceutical companies, including acquisition of plants and products, contractual commercial matters, clinical trial agreements, procedures before the Ministry of Health.
- Advisor to the Chamber that joins foreign laboratories in Argentina.

HUGO J EPPENS MILLÁN

Estudio Beccar Varela
T +54 11 4379 6861
F +54 11 4379 6869
E *heppens@ebv.com.ar*
W *www.ebv.com.ar*

Qualified. Argentina, 1995

Areas of practice. General advice to companies; insurance law; litigation; insolvency proceedings; bankruptcies; sports law.

FLORENCIA ROSATI

Estudio Beccar Varela
T +54 11 4379 6862
F +54 11 4379 6869
E *frosati@ebv.com.ar*
W *www.ebv.com.ar*

Qualified. Argentina, 1997

Areas of practice. Patents and trade marks; intellectual property; general advice to companies.

ANA ANDRÉS

Estudio Beccar Varela
T +54 11 4379 4711
F +54 11 4379 6869
E *aandres@ebv.com.ar*
W *www.ebv.com.ar*

Qualified. Argentina, 2005

Areas of practice. Life sciences and general advice to companies.