The Life Sciences Law Review

Fifth Edition

Editor
Richard Kingham

Law Business Research

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EDITOR'S PREFACE

The fifth edition of *The Life Sciences Law Review* covers a total of 37 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. The chapters are arranged to describe requirements throughout the life cycle of a regulated product, from discovery to clinical trials, the marketing authorisation process and post-approval controls. Certain other legal matters of special interest to manufacturers of medical products – including administrative remedies, pricing and reimbursement, competition law, special liability regimes and commercial transactions – are also covered. Finally, there is a special chapter on international harmonisation, which is of increasing importance in many of the regulatory systems that are described in the national chapters.

Now, more than ever, it is important for leaders in the pharmaceutical and medical device industries and their advisers to be knowledgeable about the laws and regulations in major jurisdictions around the world. In the past year, there have been significant developments in the regulation of drugs and medical devices, especially in the United States, where a new law – the 21st Century Cures Act – was passed at the end of 2016. There are prospects for further developments in the coming year. The new president and the Republican-controlled Congress will consider legislative measures affecting the pharmaceutical and medical device sectors, including proposed repeal of the Affordable Care Act, continuing inquiries into pricing of medical products and reauthorisation of user fee laws that fund a substantial part of the drug and device approval processes. The United Kingdom will initiate formal proceedings to begin the process of withdrawing from the European Union, with potential consequences for the medical products sectors. Other jurisdictions, including China and India, are considering reforms to their regulatory systems for medicinal products.

Each of the chapters has been written by leading experts within the relevant jurisdiction. They are an impressive group, and it is a pleasure to be associated with them in the preparation of this annual publication.

Richard Kingham
Covington & Burling LLP
Washington, DC
March 2017

Chapter 2

ARGENTINA

Emilio N Vogelius[1]

I INTRODUCTION

The pharmaceutical industry continues to be a highly regulated sector with a very important presence in Argentina. It has had its ups and downs, especially regarding the presence of multinational subsidiaries developing their business in the country. Not many changes have occurred regarding the issuance of regulations during the past year, in which Carlos A Chiale, an experienced figure in managing the National Administration of Drugs, Food and Medical Devices (ANMAT), resumed his role as head at the end of 2015.

The main issue facing the industry is related to the patentability of pharmaceutical products. This has been a critical issue and a source of never-ending discussions related to the extension of the novelty requirement that a product, or a procedure, should have in order to determine if a specific application is subject to the benefit of the granting of a patent.

The protection of the research, and the consequent patentability of the products, has, however, created broad divisions between the different laboratories that operate in the country. These are:

a laboratories that have products based on previous research, mainly subsidiaries of foreign laboratories;

b local capital laboratories that work through licences negotiated with research laboratories;

c laboratories that sell branded generic products that are not patented in the country; and

d laboratories that sell generic products.

The differences between these laboratories are apparent at an intellectual property level. The primary means of commercialisation of pharmaceutical products is the same in all cases and follows the channel: laboratory–wholesaler–pharmacy. Product distribution is carried out

1 Emilio N Vogelius is a partner at Estudio Beccar Varela.

through specialised companies that usually act on behalf of the different laboratories that constitute their clientele. Another means of commercialisation is through participation in specific bids issued by the public administration or by different hospitals. In these bids the laboratories participate directly and do not follow the usual commercialisation channel. Social security entities are highly involved in calculating discounts to its affiliates working through the regular commercialisation channel mentioned above. Nevertheless, in some cases, bids are called by either public or private social security entities, but these are specific to certain products, such as orphan drugs or vaccines.

Generic products – excluding branded generic products – have very little market relevance.

Along with providing a broad description of the pharmaceutical market, it should be added that the regulation of the commercialisation of pharmaceutical products, medical devices and dietary supplements is controlled and regulated by the Ministry of Health, through its main agency, ANMAT. It is worth mentioning that ANMAT has published on its website a *vade mecum* of all products registered before it, indicating not only the active principles, but also the commercial names and their prices.

II THE REGULATORY REGIME

The principal piece of legislation is Law No. 16, 463, the Law of Medicines, issued by Congress, which has been in force since 1964. Law No. 16, 463 is further complemented by decrees issued by the Executive Power. These decrees are further subject to more specific regulation by means of resolutions issued by ministries, mainly the Ministry of Health. Finally, ANMAT also establishes multiple specific regulations.

ANMAT, consisting of a decentralised controlling entity on matters related to pharmaceutical products, food and medical devices, was created in 1992, through the enactment of Decree No. 1490/92. ANMAT is dependent upon the Ministry of Health, usually through the intervention of the Secretary of Health.

The faculties granted to ANMAT in connection with the pharmaceutical industry not only relate to the approval of laboratories, storehouses and products, but also enable it to act as the controlling public office with respect to the industrialisation and commercialisation of pharmaceutical products.

As a general principle, importers, exporters, manufacturers and distributors of pharmaceutical products must be qualified by ANMAT in order to develop their activities within the pharmaceutical industry. Said authorisation, once granted, is valid throughout the country. Nevertheless, provincial laboratories (authorised to act only at a provincial level) may also be qualified.

ANMAT also plays an important role in the approval and control of clinical trials that take place in the country.

Law No. 16,463 establishes that in order to be authorised, laboratories must manufacture their own products. Considering the economic and political environments, certain laboratories have been authorised to import and commercialise pharmaceutical products without the obligation to manufacture them. There are rules by which ANMAT authorises the referral to third-party laboratories for specific stages of the product manufacturing. Despite these exceptions and other specific situations that exceed the general scope of this chapter, laboratories are required to have their own quality control lab, a storehouse and a technical director. In recent times, ANMAT has discouraged the qualification of companies

only acting as sole importers and sellers of pharmaceutical products. Licensing to authorised laboratories is the most common way to enter the market when the laboratory is not registered in Argentina.

i Classification

The regulatory regime is broad and covers regulations that apply to the commercialisation of all products of its incumbency.

The principal regulations that deal with pharmaceutical products are: Decree No. 150/92 and Resolution No. 233/1996, which establish requirements to register pharmaceutical products and also to qualify as a laboratory (manufacturer, importer, distributor, etc.); Decree No. 1299/97, which regulates the commercialisation of products; Regulation No. 2819/2004, which establishes the good manufacturing practice (GMP) to be followed; and Resolution No. 627/2007, which regulates the promotion of ethical products.

Regulation No. 4890/2005 establishes regulations that deal with free sale pharmaceutical products (over-the-counter (OTC)), medical devices including those that apply to dentistry, cosmetic products, food, dietary supplements, household cleaning products and *in vitro* and self-testing diagnostic products.

Regulations Nos. 3397, 7075 and 7729 have been issued by ANMAT establishing specific requirements for approving biological products.

Owing to the industry's development, ANMAT has issued certain specific regulations that apply to clinical trials, traceability of products and other matters. Additionally, it should be mentioned that some specific laws that deal with the pharmaceutical industry have been enacted, such as Law No. 26,529 that relates to the patient's rights and Law No. 26,689 that relates to orphan diseases.

Biological products listed in Regulation No. 7075 include hemoderivatives, products obtained with recombinant DNA techniques, monoclonal antibodies and biological medicines produced from animal tissues.

In order to register biological products, strict requirements must be met, including providing detailed information regarding the active principle and the manufacturing process of the active principle. Requirements vary in the case of monoclonal antibodies.

As aforementioned, in order for pharmaceutical products, other than biological products, to be authorised, they must be registered with ANMAT. For such registration, the following information must be provided:

a product information;
b technical information;
c label information; and
d leaflet information for patients. In cases where the product to be registered is imported from the countries listed in a specific annex to Decree No. 150/92 (these are countries that have highly developed methods of health control), the certificate of commercialisation of the health authority of the corresponding country shall also be provided. Marketing authorisations are granted for a five-year term and can be renewed as many times as required by the holder.

ii Non-clinical studies

No specific legislation refers to the welfare of animals in clinical trials carried out in Argentina. However, there are several references to how these kinds of trials should take place in Regulation No. 6677/2010 issued by ANMAT and related to the performance of

such trials. Several articles written on this topic relate to bioethical concerns about clinical trials and, moreover, it has been stated that, if possible, this kind of trial should be replaced according to the circumstances of the matter under investigation.[2]

iii Clinical trials

Requirements to perform clinical trials are regulated by Resolution No. 1480/2011 issued by the Ministry of Health complemented by Regulation No. 6677/2010 issued by ANMAT – the regulatory authority in charge of authorisation and control of any clinical trials to be performed.

ANMAT must grant prior authorisation for any clinical trial. The sponsor, which has to be a locally domiciled company or its representative in Argentina, must request authorisation from ANMAT. Information about the sponsor is required, not only for legal purposes, but also for financial purposes to substantiate that it will be able to afford eventual damages. In addition, a guarantee may be required.

Information related to the clinical trial is also required, such as: the name of the study; the phases of the trial; the product involved; the number of subject participants; consent forms that are required from subjects participating in the trial; information about the principal investigator; and information about the site.

The informed consent of the participating subject is required and its wording should prove that the subject clearly understood the implications of participating in the trial. It is the principal investigator's duty to obtain and keep the consent forms. Certain requirements apply to subjects that are vulnerable owing to educational disadvantage. The informed consent form must be approved by ANMAT, the Ethics Committee appointed in connection with the trial and the Data Protection Registry.

iv Named-patient and compassionate use procedures

Regarding orphan drugs, closely related to the named-patient situation, ANMAT issued Resolution No. 840/1995 regarding compassionate use of drugs. This resolution regulates the mechanism for the import of products that are not commercialised in the country and in the instance that a patient requires a specific treatment duly prescribed by his or her physician.[3] The import of such drugs has to be requested in each case by the patient or a civil association.

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2 See 'Animal welfare and the use of laboratory animals in scientific research' by Ana M Jar in *Argentina Journal of Microbiology*, volume 46, No. 2, Buenos Aires, June 2014, also available online at www.scielo.org.ar/pdf/ram/v46n2/v46n2a01.pdf.

3 Drugs for compassionate use must be for clinical situations, such as:

a diseases that compromise the life of the patient;

b diseases that evolve towards disability;

c diseases that cause a permanent disability;

d diseases that deteriorate the quality of life; and

e for eventual therapeutical situations, such as:

- for treating patients who have illnesses for which there are no specific treatments in Argentina;
- for those who are intolerant to every available treatment;
- for those who would not correctly respond to the available treatment;
- for those whose bodies are incompatible with the available drugs; or

Patients must file a declaration by the manufacturer of the drug, the prescription of such drug by the physician and the informed consent of the patient to be treated with such drug.[4] The total amount of drugs to be imported shall be for a treatment that does not exceed 60 days. If the treatment is longer, a new and different request shall be made in each case.

According to Resolutions Nos. 942 and 426 of 2001, the import of these drugs is exempted from the payment of custom taxes and fees.

ANMAT specifically clarifies that its only intervention in this process is to issue a document that will provide the Customs Authority with evidence that the Board of Health endorses the request of the patient. The Board of Health also clarifies that it does not have competence with respect to aspects such as the authorisation for the acquisition of drugs by social security entities, or the provision of the drugs or the acts that need to be carried out to acquire the drug abroad.

Resolution No. 2324/97, also from ANMAT, specifically authorises non-profit Civil Associations that are legal entities to import drugs for compassionate use to sell to their members on a cost-price basis, and establishes that, in order to carry out that import, they must request authorisation from ANMAT (as described in Section II.iii, *supra*). It is important to underline that in many cases, non-profit civil associations have made these requests.

• for those who have been treated with that medicine in a foreign country and might suffer detrimental effects from changing to an authorised drug in Argentina, or when a drug has been discontinued in Argentina and a risk-benefit relationship exists that is reasonable.

4 This resolution makes a distinction that considers whether the drugs that will be imported have been previously authorised for commercialisation in other countries. Regarding drugs that have not been previously authorised for commercialisation, the requirements that have to be complied with in order to import them are: (1) even when the patient has a deadly disease, there must be scientific evidence to conclude that the drug might be effective and that there are not unreasonable risks for the patient; (2) the drug must be, at the time of the request, under investigation in at least one controlled clinical trial (unless all clinical trials have been concluded and the sponsor is actively seeking the approval of the drug); (3) the drug must complete phase II of investigation; (4) at least one clinical study must have been published in a prestigious publication; (5) the preclinical phase must be completed; and (6) the request must be accompanied with the manufacturer's declaration, a medical report indicating the patient information and justification for the use of the drug signed by the physician, and a patient's informed consent in writing, signed by him or her, which explains the reasons why the patient will use that drug. In cases where the patient is a minor or incapacitated the consent must be signed by the responsible person in charge.

With respect to the drugs that have been previously authorised for commercialisation by the health authority of a foreign country, the requirements that have to be complied with in order to import them are: (1) the request must be accompanied with the manufacturer's declaration, a medical report indicating the patient information and justification for the use of the drug signed by the physician, and a patient's informed consent, in writing, signed by him or her and explaining the reasons why the patient will use that drug. In cases where the patient is a minor or incapacitated, the consent must be signed by the responsible person in charge; and (2) the request must be accompanied with preclinical investigation works, the clinical trials for the indication proposed and a certificate that authorises the use of the drug in that country.

Law No. 26,689 has recently been enacted. This law could be defined more as a list of intentions and 'to dos' rather than a specific regulation on the matter. In practice these cases assume the presence of the patient before ANMAT and compliance with specific steps to obtain the import of the necessary drugs that is usually granted. Specific organisations such as associations of patients or foundations usually help to support the psychological state of the patient and family during the procedure.

v Pre-market clearance

No pharmaceutical product, or medical device, can be commercialised without having the approval of the Board of Health, with the exception of products included in clinical trials duly authorised.

The approval of pharmaceutical products by ANMAT should be required by a laboratory duly qualified as such before the Argentine authorities. Laboratories that are not qualified are not allowed to register pharmaceutical products. Nevertheless, it is possible for such laboratories to appoint a local laboratory (either a local subsidiary of a foreign laboratory or a national laboratory) as its representative in order to obtain the marketing authorisation issued by ANMAT in the name of the local laboratory acting on behalf of the foreign laboratory that is not qualified in the country.

General aspects of the procedures have been described in Section II.i, *supra*, however, it is important to highlight that products registered in highly sanitary developed countries can be locally registered through a fast-track procedure that implies local recognition of the foreign marketing authorisation. Once a product is registered, similar products may be registered through a fast-track procedure to be carried out before ANMAT.

vi Regulatory incentives

There are no regulatory incentives that would grant an extension of the patent term in cases in which a specific product has been subject to a patent application.

Nevertheless, a law that deals with confidentiality issues was enacted on 18 December 1966 (Law No. 24,766). This law establishes that during the process to authorise a new product, the confidentiality of the file related to such process should not be made public (Article 4, Law No. 24,766). Nevertheless, the same law establishes that if a patent has been granted for such product, it is possible to perform trials with it, but commercialisation should be kept on stand-by until the patent expires (Article 8, Law No. 24,766).

In contrast, Law No. 25,649 enacted on 18 September 2002, favours the use of generic drugs and obliges doctors to prescribe pharmaceutical products using the name of the active principle of products. The Law, however, does not prohibit the use of the trademark in the packaging of the product, nor does it prohibit prescribing use of the commercial name. The concrete application of the Law has not been clearly effective to date.

vii Post-approval controls

Post-approval controls are managed by ANMAT, principally by means of reports made by parties on infringements to current regulations. Nevertheless, it should be mentioned that ANMAT is authorised to carry out inspections and review products already authorised for its commercialisation. Technical directors, being jointly and severally liable with the laboratory for any damage that a product may cause, are also keen to review batches of products during the manufacture process and once finalised.

Additionally, it is important to note that laboratories usually carry out pharmacovigilance of their products and that agreements specifically related to such issues are commonly executed between laboratories that license their products to third parties.

In connection to this aspect of the business, the Ministry of Health issued Resolution No. 435 in April 2011, concerning traceability of pharmaceutical products that follow a specific product from its manufacture or importing stage, to the time it is exhibited for sale.

In connection to the control of products currently in the market, although not specifically pharmaceutical products, it should be noted that ANMAT prohibited the use of cloflucarban, fluorosalan, hexylresorcinol, triclosan and other antibacterial substances to be used in personal hygiene products (Regulation No. 13832/2016).

viii Manufacturing control

Regulation No. 2819/2004, issued by ANMAT, and including GMP, is the main rule that regulates the manufacture of pharmaceutical products. Such regulation was drafted in line with the Recommendations on Good Manufacturing Practices and Control issued in 2003, by the World Health Assembly and reports of the Pharmaceutical Inspection Corporation Scheme (PE 009–1) and International Conference on Harmonisation – Guide of GMP (Q7A).

For the purpose of verifying the compliance of GMP, ANMAT is empowered to supervise the manufacturing laboratory as well as the sites in which commercial companies and importers develop their business. ANMAT may carry out technical inspections that cover the functioning conditions and quality control used in such places. Additionally, it should be mentioned that the manufacturing sites should also be approved by the municipality in which they are located and that specific approvals on certain aspects, such as disposal of residues and other environmental issues, also apply. Some of these approvals are incorporated at a municipal level.

ix Advertising and promotion

Section 19 of Law No. 16,463 prohibits any form of public announcement of products that require an authorised prescribed delivery. The Supreme Court of Justice has supported this rule in several judgments by stating that the mere release of prescription medicines to the public without professional control may endanger public health.

The Ministry of Health Resolution No. 627/2007 regulates permissible practices for the promotion of pharmaceutical products requiring a medical prescription. Importantly, the resolution forbids pharmaceutical companies from, directly or indirectly, granting, offering or promising healthcare professionals (HCPs) any kind of incentive, such as bonuses or financial perks.

The promotion of medicinal products can only be addressed to practitioners authorised to prescribe or deliver medicines. Such promotion should provide the information, both technical and scientific, to allow practitioners to learn about therapeutic properties of the product. Promotion should be accompanied by informational material supporting the specification data of the approved product. Information should include the generic name and trade name of the pharmaceutical product and its quantitative and qualitative composition, form, counter-indications, adverse effects, warnings, doses, etc.

Only the holder of a marketing authorisation may promote a product. While the holder of a marketing authorisation may entrust promotion to a third party, it maintains

responsibility for all promotional communications and materials. The holder of the marketing authorisation must ensure that its agents or visiting practitioners receive the necessary guidance and comply with the requirements of Resolution No. 627.

The aforementioned regime for promotion does not apply to OTC products or medical devices. Subject to control, advertising of OTC products is permitted. The advertising of OTC products should act as an incentive to use the products. The inclusion of a disclaimer recommending a consultation with a physician is mandatory.

x Distributors and wholesalers

The work of distributors and wholesalers is also under the supervision of ANMAT. Two clear distinctive functions are differentiated: one is the physical storage and distribution of the products and the other relates to the collection of purchase orders and invoicing of the products. Storage facilities are subject to the approval and control of ANMAT.

The latter are companies that represent several laboratories and, acting on their behalf, invoice the products to be sold to wholesalers or pharmacies. Such companies later render accounts and are compensated through a commission.

xi Classification of products

The classification of products is outlined in Section II.i, *supra*. All products (both ethical and OTC) are considered to be pharmaceutical products and should be sold only in pharmacies.

Until approximately five years ago, it was possible to find OTC products sold outside pharmacies (e.g., kiosks); however, settled jurisprudence has established that said products should only be sold in pharmacies and kept behind the counter.

Products for hospital use are usually sold through bids and can be delivered without following the usual commercialisation chain directly to hospitals, both private and public, and without needing to comply with all packaging and labelling requirements that need to be followed for the sale of such products through pharmacies.

In cases in which products are delivered as free samples, the products must include the generic name and brand name in accordance with Article 6 of Law No. 25.649, which requires both names to be of the same size and have the emphasis. Samples should also state: 'Free sample – sale forbidden'.

xii Imports and exports

Import of pharmaceutical products is only authorised after following the regular procedures before the Customs Authorities, plus a prior authorisation granted by ANMAT. Said procedures usually include a visit and clearance of the plant in which the product to be imported is manufactured. The only entity authorised to import a pharmaceutical product is the laboratory that holds the marketing authority granted by ANMAT. The import is subject to clearance before going to marketing by means of a control held by the technical director of the laboratory intervening in the import of the product. The import of products to be used in clinical trials, which are not authorised for marketing, is subject to prior authorisation by the health authorities.

The export of products is authorised in cases in which the marketing authorisation, or a specific document, states that the product is available to be exported.

The donation of pharmaceutical products and medical devices from abroad is also subject to the control of ANMAT, as well as the Custom House, and is subject to specific regulations. For example, products to be donated should be individually described and are subject to control; simply providing a general description of the products is not adequate.

xiii Controlled substances

Psychotropics are subject to a strict, specific regulation that is continuously updated, with strict control carried out by ANMAT. Manufacture, import and use of psychotropics in products is subject to specific procedures and requirements, such as keeping an inventory, which helps to control which psychotropics and precursor chemicals are used in the manufacture of legitimate products.

In addition to measures strictly related to the pharmaceutical industry, a specific public entity – the Planning Secretariat for the Prevention of Drug Addiction and the Fight against Drug Trafficking – has been created to control and take action against the illegal use of such products. Laboratories are also obliged to register before the entity and to comply with its regulations.

xiv Enforcement

ANMAT is authorised to carry out inspections on working plants and to raise any kind of observations it may deem appropriate. In these cases, ANMAT issues a deed that includes all objections and then serves notice to the company to file its defence. After reviewing any evidence that might have been provided, ANMAT issues a resolution. Eventual penalties are a call for attention, fines, closure of the facility and the suspension or even annulment of the authorisation to function.

Depending on the case, the imposition of penalties can also include a penalty for the technical director of the laboratory.

The decision issued by ANMAT is subject to appeal before the federal courts.

III PRICING AND REIMBURSEMENT

The general principle is that each laboratory may set the prices for the sale of its products. Nevertheless, the last government (which was in power until 10 December 2015) exercised strict price controls despite the fact that no law existed that officially regulated prices, even going so far as to initiate administrative actions against companies that it considered were overpricing their products. Other actions that implied an indirect action were related to continuous inspections from the health or tax authorities that did not impede work but created a tense environment that occasionally lasted for weeks, thus affecting normal activities. These inspections are mentioned as an example. The recently elected government takes a more liberal approach on the matter.

It is relevant to offer an explanation regarding the supply of pharmaceutical products to people affiliated to social security entities (affiliates), in particular those that are associated with the public entity that deals with social security protection for retirees: the National Institute of Social Services for Retirees and Pensioners.

Since 1997, there has been an agreement in place between all the laboratories that integrate the pharmaceutical industry and social security entities, some public, some controlled by unions and some private (also known as medical insurance companies). The agreements are usually executed by the three major industry chambers (the Argentine Chamber of

Medical Specialities, the Industrial Chamber of Argentine Pharmaceutical Laboratories and the Business Chamber of Argentine Pharmaceutical Laboratories) acting as representatives of their member laboratories.

In addition to the referred agreement, the above-mentioned chambers entered into other agreements with wholesalers and pharmacies to ensure the provision of products to affiliates throughout the country at the same price and with the same discounts.

Fifteen years ago, the chambers also created a local company in which no chamber has a majority equity control (the auditing company), the purpose of which is to manage and audit the agreements entered. The creation of this company was authorised by the local antitrust agency.

Regarding the agreements, their purpose is not to supply products to social security entities, but rather to benefit the affiliates of the different entities with discounts on products prescribed by their doctors. Some entities have closed lists of doctors, or products or pharmacies, but in general the lists are very broad. Discounts vary according to the products involved.

These discounts are made in each pharmacy on products sold from its own stock and, once audited, later compensated by the social security entity. This means that at the time the products are sold by each laboratory through the regular chain of commercialisation, it is impossible for them to know if the final destination of the products will be an affiliate to any social security entity or not.

No industry chamber negotiates prices of products on behalf of any laboratory. Prices are fixed by the laboratory and are published in *Kairos* and *Manual Farmacéutico*, two specialised magazines. Discounts are calculated based on the published price (i.e., the price of the product for any person not belonging to any social security entity).

The real parties to the agreements are each laboratory and the social security entity. The chambers represent the laboratories for practical reasons. Laboratories must each ratify the agreement. If a laboratory does not want to enter into such an agreement it may refuse to do so.

The following example illustrates how the system works. A product is prescribed by a qualified doctor to an affiliate. The affiliate goes to the pharmacy he or she usually goes to and acquires the product. The pharmacist will sell the product to the affiliate with discounts and inform the sale to the social security entity for its approval. Assuming the prescription is approved, the entity will reimburse the pharmacy through the auditing company, which will check the amount received and pay the amount of the discount afforded by the social security entity to the laboratories, which will then issue credit notes in favour of the wholesaler and, further, from the wholesaler to the pharmacy to compensate the full amount invoiced and paid by the pharmacy and the wholesaler at the time the product was sold by the laboratory. This is a summarised explanation. Much of the system is currently technologically managed (e.g., affiliates have carnets, pharmacies use online systems) and, usually, reimbursements by social security entities are made every two weeks covering various sales, so in practice the system is a bit more complicated; however, the general principles work as explained.

Some products are not subject to discounts.

Wholesalers and pharmacies are also joined in chambers that are very active in the protection of their associates (the Argentine Pharmaceutical Confederation, the Argentine Federation of Pharmacy Chambers, the Association of Mutual and Union Pharmacies of the Republic of Argentina, the Association of Distributors of Medical Specialities and others).

IV ADMINISTRATIVE AND JUDICIAL REMEDIES

The administrative remedies are the responsibility of ANMAT and are described in Section II.xiv, *supra*. Similar procedures apply in the case of faulty products or infringements to the commercialisation regulations, and so on.

Additionally, Sections 200 and onwards of the Criminal Code penalise, with imprisonment and fines, any person who modifies or falsifies medicinal products compromising public health.

V FINANCIAL RELATIONSHIPS WITH PRESCRIBERS AND PAYERS

Most of the financial aspects of the pharmaceutical industry and its relations with prescribers and patients, including those affiliated to social security entities and medical insurance companies, are described in Section II.iv, vi and ix and Section III, *supra*.

In addition to what has been stated, there are special regimes in which public aid for the acquisition of certain products has been established by law, such as in the case of AIDS patients. Other programmes in place are the 'Programa Remediar' and 'Plan Nacer'.

Medical attention is publicly supported through municipal, provincial or national hospitals. Medical assistance in public hospitals is free of charge. Private medical insurance companies have special agreements with private hospitals.

Resolution No. 500/2004 manages specific programmes to help patients afford medical treatments that are very expensive. The programme consists of total or partial subsidies or reimbursement for medical treatments, medical devices and medicinal products. It is not mandatory for the Public Health Administration to grant the aid.

The Ministry of Health Resolution No. 627/2007 regulates permissible practices for the promotion of pharmaceutical products requiring a medical prescription. This resolution forbids pharmaceutical companies from, directly or indirectly, granting, offering or promising HCPs any kind of incentive, such as bonuses or financial perks.

Doctors and other HCPs are also regulated by Law No. 17,132, which prohibits them from obtaining benefits from pharmaceutical companies.

VI SPECIAL LIABILITY AND COMPENSATION ISSUES

Product liability is based on general principles included in the Argentine Civil Code and in the Consumer Protection Law No. 24,240 (CDL), as amended by Law No. 26,361. In general, in cases that are related to claims concerning whether certain trials or products should be covered by the social security organisations to which the claimant subscribes, both public and private, the courts tend to favour the consumer (in this case, the patient). To this extent, the patient is considered to be a consumer, which means that the CDL is also applicable. Nevertheless, all cases are different and should be analysed individually.[5]

The general practice according to the Civil Code obliges the affected party to prove that the product caused the damage suffered. If such statement is supported with evidence, a specific indemnification is fixed by the courts according to the circumstances of the case (e.g., age, disability, expenses incurred, moral damage).

5 Case included in AR/JUR/33790/2016

The CDL incorporates a certain type of 'class action' and allows consumer organisations to initiate actions, when collective interests are affected or threatened. Section 52 *bis* of the CDL allows a request for punitive damages – a clear contrast to the Civil Law.

The enactment of the CDL is quite recent and there are no cases, as of yet, that demonstrate how this law is applied.

There are no special compensation issues in place.

VII TRANSACTIONAL AND COMPETITION ISSUES

i Competition law

The competition regulations in place have been applied by public entities to control prices on pharmaceutical products. Legal actions have been initiated but, to date, no decisions have been issued.

The government has tried to reduce the cost of medical products, principally by enacting Law No. 25,649 on 18 September 2002, which favours the use of generic drugs, obliges doctors to prescribe pharmaceutical products using the generic and non-proprietary name of the product and also requires the inclusion of the generic name in the packaging of the product.

ii Transactional issues

There are no special transactions (other than those available in all countries) that are worth mentioning in this chapter. The pharmaceutical industry has, in general, adapted the commercialisation of products to the method described in Section III, *supra*, which maintains a level of commercial competition with similar products.

Commercial discounts are common practice, as well as distribution agreements or co-marketing agreements that allow the promotion of products by laboratory representatives who are not the owners of the product being promoted.

VIII CURRENT DEVELOPMENTS

Owing to the fact that a newly elected government took office in December 2015, this chapter cannot provide a reasoned deduction of the public policy of the current authorities. Argentina is evolving from an administration that imposed very restrictive rules on commerce in general, and to pharmaceutical commerce in particular, to a completely different administration.

The previous administration enacted regulations that made it difficult or impeded the possibility of patenting pharmaceutical products in Argentina. The pharmaceutical research industry reacted by filing administrative and judicial actions that have not been resolved.

However, the past administration attempted, by informal means, to keep strict control over the pricing of pharmaceutical products. The change in administration is relatively recent but, to date, similar attempts have not been noted. On the contrary, it appears that through the different social security organisations, the purpose of the current administration is to enter into agreements with the pharmaceutical industry, though it should be mentioned that, because of economic reasons, the incidence of local costs, including taxes and labour costs stresses the negotiations between the parties.

Owing to the measures taken by the current administration, foreign trade has returned to normal, which allows for the import of products and active principles, as was the case in the past.

Although changes have been very recent, it appears that the trend is to return to a more liberal market, without abrogating the control that the life sciences market is usually subject to.

Appendix 1

ABOUT THE AUTHORS

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Estudio Beccar Varela

Emilio is a senior corporate law partner of Estudio Beccar Varela. He started his professional career as a clerk to a national commercial court and later moved to the private practice of Estudio Beccar Varela. He is fluent in Spanish and English.

He is currently head of the firm's arbitration team and the life sciences team, and is the partner that initiated such practices within the firm.

The principal focus of his practice within the life sciences team is legal assistance to pharmaceutical companies. He is also the legal adviser for the Argentine Chamber of Medical Specialities, the chamber that includes most local subsidiaries of research laboratories.

He lead the drafting of the 'Argentina' chapter of Practical Law's Life Sciences multi-jurisdictional guide 2012.

Mr Vogelius has participated in several meetings and congresses as a lecturer and has published several works, including co-authoring *World Intellectual Property Rights and Remedies*, published by Oceana Publications Inc (2001), and the chapter on Argentina in *International Arbitration in Latin America*, published by Kluwer Law International (2003).

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