THE LIFE SCIENCES LAW REVIEW

EIGHTH EDITION

Editor
Richard Kingham

THE LAWREVIEWS

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PREFACE

The eighth edition of *The Life Sciences Law Review* covers a total of 33 jurisdictions, providing an overview of legal requirements of interest to pharmaceutical, biotechnology and medical device companies. The chapters are arranged so as 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.

The past year has seen a number of significant developments. Shortly after the publication date for this edition, the European Union will begin enforcing significant changes in the regulatory regime for medical devices. The United States is considering measures to improve the transparency of pricing for prescription drugs. The United Kingdom is addressing changes to drug regulatory systems that must accompany the country's withdrawal from the EU, and drug and device manufacturers are actively planning for the effects of Brexit on their supply chains. The governments in India and China continue to consider changes in their regulatory systems for drugs and medical devices.

It is vitally important that lawyers who advise companies in the life sciences sector and the business executives whom they serve have a working knowledge of the regulations and policies that govern drugs, biologics and medical devices. It is equally important to keep up to date with developments in the regulatory systems, which govern access to the market, pricing and reimbursement, advertising and promotion, and numerous other matters that are essential to success. It is our hope that this annual publication will be helpful in this respect.

All of the chapters have 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 publication.

Richard Kingham
Covington & Burling LLP
Washington, DC
February 2020

Chapter 2

ARGENTINA

Emilio N Vogelius[1]

I INTRODUCTION

The pharmaceutical industry continues to be a highly regulated sector that has a very important presence in Argentina. Its financial results are highly affected by the influence of agreements entered into with social security organisations – mainly the social security organisation that covers retired people – and private health insurance companies. These organisations agree on coverage that favours its affiliates with regard to prices from laboratories, wholesalers and pharmacies. Despite the fact that these kinds of agreements continue to be in place, at least until March 2020, there have been changes in the financial politics these organisations have, owing to the fact that they are now calling for bids and joint purchases of certain products – mainly those related to oncologic and special treatment prognosis, which are usually the most expensive products.

An important change in the commercialisation of pharmaceutical products in the social organisation, that covers retired and challenged people (it includes the higher percentage of sales in the market), is the fact that this organisation decided to terminate agreements with the whole industry, switching to agreements company by company, in an additional effort to reduce the impact of the price of products. We cannot assure that this effort has been successful.

With the exception of regulation related to the acquisition of products not registered in the country, not many changes have occurred during 2019 regarding the issuance of regulations. Carlos A Chiale continued as head of the National Administration of Drugs, Food and Medical Devices (ANMAT). However, due to the recent change in the authorities it is impossible for us to know whether he will continue as head of the ANMAT. It is probable he will be replaced.

At the time of writing, a new Minister of Health has recently been appointed – Ginés González García, who previously acted as Minister during the 2002–2007 period.

The patentability of pharmaceuticals continues to be the main issue affecting the industry and is a source of never-ending discussions related to the extension of the novelty requirement that a product or procedure should have to determine its eligibility for a patent. The 2012 joint resolutions of the Ministry of Industry 118/2012, the Ministry of Health 546/2012 and the Patent Office 107/2012 add requirements to obtain the patentability of pharmaceutical products. Said regulation is still being challenged through the lawsuit triggered by several companies, which has been ongoing since August 2013. This major

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

lawsuit has not even reached the stage in which evidence has been produced, given the fact that it was always a window to carry on negotiations related to patentability being allowed to state that the mentioned joint resolution was never consented to.

The protection of research and consequent patentability of product has, however, created broad divisions between the different types of 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 course of laboratory–wholesaler–pharmacy. Product distribution is carried out 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.

As well as 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 ANMAT. ANMAT has published on its website a vade mecum of all products registered with it, indicating not only their active principles, but also commercial names and 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 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. There has been a recent change of the administrative authorities in the country but it all indicates that this scenario will be the one in force.

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 to develop their activities within the pharmaceutical industry. This 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 scientific, 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 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 laboratory that should be in accordance with the products commercialised by the laboratory, a storehouse and a technical director. Licensing to authorised laboratories is a common way to enter the market when the laboratory is not registered in Argentina. Another way is related to import through exceptional channels as named patients programmes, although this way implies a use of such imports for a different purpose from the one the regulation was issued for.

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

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 qualify as a laboratory (including manufacturer, importer and distributor laboratories); Decree No. 1299/97, which regulates the commercialisation of products; Disposition 3602/2018, No. 3287/2018 and others, which establish the good manufacturing practice (GMP) to be followed classifying all different product alternatives; 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.

As mentioned above, for pharmaceutical 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 Biological products

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

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

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.

The approval of biological products was, during the past year, a matter subject to claims made by laboratories – mainly those that develop innovative products. The fact that triggered such claims was that the regulations issued to approve biological products included the obligation for the authorities (mainly ANMAT) to issue specific guidelines to be complied with to obtain the approval of such products.

These guidelines were listed during the last quarter of 2018. They appeared on ANMAT's website on 12 October, but were not published with any detail as to when they would have to come into force. In addition, these guidelines have not been identified with any regulation number.

The guidelines refer to biological products establishing the need to file a guide, the requirements to register biological products related to the plants, a location of the plants, a report of the clinical aspects, etc. They also refer to vaccines, radiopharmaceutical products, medicines for advanced therapies, blood banks and related products.

Unfortunately such guidelines are only listed and not described. It is not clear if the purpose of complying with them is for internal purposes only, if they would contribute to a final report or how the information compiled would be kept.

iii 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

clinical 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]

iv 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. Additionally, ANMAT has created the National Registry in Health Investigations. Last year Regulation 4009/17 issued by ANMAT established the requirements needed to perform Phase 1 trials.

A clinical trial is an area that has shown a constant increase in activity in the past few years. Investments in research and development in the private sector and pharmaceutical industry reached 22 per cent of the total investments of this sector, according to the most recent information.

ANMAT must grant prior authorisation for any clinical trial. The sponsor, which must be a locally domiciled company or a foreign company's 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 any eventual damages. In addition, a guarantee may be required.

Information related to the clinical trial is also required, such as:

a the name of the study;
b the phases of the trial;
c the product involved;
d the number of subject participants;
e consent forms that are required from subjects participating in the trial;
f information about the principal investigator; and
g information about the site.

The informed consent of the participating subject is required and the wording of the form 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 who 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.

v Named-patient and compassionate use procedures

Regarding orphan drugs, closely related to the named-patient situation, ANMAT issued Resolution No. 4616/2019 to rule over 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. The import of such drugs has to be requested in each case by the patient or its

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.

legal representative. 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. The total amount of drugs to be imported shall be for a treatment that does not exceed 90 days. For long treatments the authorisation is granted for up to 90 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.

Resolution No. 4616/2019 establishes that the import of these products is allowed from high standard pharmaceutical developed countries listed in Annex I of Decree 150/1992, when requested by public authorities to attend a sanitary crisis and medicines are not in the country at a certain moment or are not accessible to patients for justified reasons.

Law No. 26,689 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, which 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.

vi 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 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; 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.

vii 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 that process should not be

made public.[3] Nevertheless, the same law establishes that if a patent has been granted for a product, it is possible to perform trials with it, but commercialisation should be kept on standby until the patent expires.[4]

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. Law No. 25,649, however, does not prohibit use of the trademark in the packaging of the product, nor does it prohibit prescribing the use of the commercial name. The concrete application of the Law has not been clearly effective to date.

viii Post-approval controls

Post-approval controls are managed by ANMAT, principally by means of reports made by parties on infringements to current regulations. Nevertheless, ANMAT is authorised to carry out inspections and to review products already authorised for 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 manufacturing process and once finalised.

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

In connection with 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 with the control of products currently on the market, although not specifically pharmaceutical products, ANMAT prohibited the use of cloflucarban, fluorosalan, hexylresorcinol, triclosan and other antibacterial substances to be used in personal hygiene products.[5]

ix Manufacturing control

Regulation No. 3602/2018, issued by ANMAT and including GMP, is the main rule that regulates the manufacture of pharmaceutical products. This 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, the manufacturing sites should also be approved by the municipality in which they are located and 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.

3 Article 4, Law No. 24,766.

4 Article 8, Law No. 24,766.

5 Regulation No. 13832/2016.

x 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. The promotion should provide sufficient 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 and doses. The only possibility of mentioning non-approved medicinal products is in the frame of specific congresses addressed to medical practitioners, and even in this case products should be identified by their active principle denomination, not being allowed to use the commercial brand.

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. 627/2007.

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.

xi 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. These companies later render accounts and are compensated through a commission.

xii Classification of products

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

Some years ago, it was possible to find OTC products sold outside pharmacies (e.g., kiosks); however, settled jurisprudence has established that OTC 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 these 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 be given the same emphasis. Samples should also state: 'Free sample – sale forbidden'.

xiii Imports and exports

Imports of pharmaceutical products are only authorised after following the regular procedures before the customs authorities, and a prior authorisation granted by ANMAT. These 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 customs authorities, 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.

xiv 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.

xv Enforcement

ANMAT is authorised to carry out inspections on working plants and 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. A new government has recently been put in place. We cannot anticipate what measures it could issue regarding pricing of products, nor what kind of agreements it may require public health insurance companies to enter into regarding the supply of products to its affiliates. Nevertheless, there is a good chance that price vigilance, either direct or indirect through agreements or different measures, could be put in place. Again, at the time of writing the Ministry of Health has requested the reduction of pharmaceutical products prices by approximately 8 per cent, grounding the request in what was called a health emergency.

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). This agreement was terminated in 2019. The agreement was 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 late 2019 it was the intention of the major social security organisation to enter into agreements with each laboratory, either through bids or contracts.

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

Around the year 2000, 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 and sold by pharmacies that adhered to the agreement mentioned. 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. An important purpose of these agreements is to ensure the provision of products throughout the whole country at the same price, without prejudice to the chain of commercialisation or to the affiliates.

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 specialist 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 his or her usual pharmacy and acquires the product. The pharmacist will sell the product to the affiliate with discounts and inform the social security entity of the sale to obtain 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 managed technologically (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. Similar procedures apply in the case of faulty products and infringements of the commercialisation regulations.

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

There continues to be a slow increase in judicial summary actions being brought to courts by patients with the aim of getting their social security organisation, their medical insurance company or the state to allow or afford the provision of products. This is mainly related to cases in which expensive pharmaceutical treatments apply, despite whether or not said product can be imported or locally acquired. It should be noted that sometimes it is the conduct of the social security organisation or medical insurance that triggers the response of a claimant through courts, especially in cases in which a change of treatment (usually for a cheaper one) is suggested or tried to be put into force by the financer.

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 with social security entities and medical insurance companies, are described in Section II, subsections iv, vi and ix, and Section III.

In addition, 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 Health Programme, the Haemophilia National Programme and the Newborn Programme.

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 and Commercial 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.[6]

The general practice according to the civil law obliges the affected party to prove that the product caused the damage suffered. If the party's 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).

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 CDL was enacted in September 1993. The first cases have related to newly produced pharmaceutical products and it is not yet possible to define a trend regarding application of the CDL to such products.

There are no special compensation issues in place.

6 Case included in AR/JUR/33790/2016.

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 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, 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

We do not know what Argentina's politics will look like in the future regarding public health. Owing to the new government's characteristics it appears there will be a higher involvement in the industry. To date, no restrictive rules on commerce in general, other than the one mentioned above consistent with a reduction of the price of products, and to pharmaceutical commerce in particular have been announced.

Regulations enacted by previous administrations that made difficult or impeded the possibility of patenting pharmaceutical products in Argentina are still in place and we expect they will remain in effect. The pharmaceutical research industry reacted by filing an administrative and judicial action that has not been resolved.

Clinical trials have increased and continue to grow in the country.

Discussions on the regulatory area are centred on the regulations needed to qualify biological products in the country.

Appendix 1

ABOUT THE AUTHORS

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Estudio Beccar Varela

Emilio N Vogelius 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 who initiated these 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 led the drafting of several publications, including the Argentina chapter of Practical Law's *Life Sciences* multi-jurisdictional guide in 2012 and several annual editions of *The Life Sciences Law Review*.

Mr Vogelius has participated in several meetings and congresses as a lecturer, including the 2017 Healthcare Compliance Certification Program organised by Seton Hall Law School, Newark, New Jersey, 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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