The Pharma Legal Handbook

Argentina

Regulatory, Pricing and Reimbursement Overview · Preclinical and Clinical Trial Requirements · Marketing, Manufacturing, Packaging and Labeling Advertising · Traditional Medicines and OTC Products · Product Liability · Patents and Trademarks · Regulatory Reforms · Cannabinoid Drugs, Medicinal Cannabis and Opioid Drugs · Orphan Drugs and Rare Diseases · Localization · Biosimilars and Biologics

PHARMA BOARDROOM

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**The Pharma Legal Handbook answers essential questions about this environment for pharmaceuticals in Argentina.
It is a must have for any company operating in the country or looking to enter the market.**

Prepared in association with MARVAL O'FARRELL MAIRAL, a leading Argentine law firm, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

*** THIS REPORT WAS ORIGINALLY PUBLISHED IN AUGUST 2018 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**
****LAST UPDATE: FEBRUARY 2020**

MARVAL
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Founded in 1923, Marval, O'Farrell & Mairal is the largest law firm in Argentina. A market leader at both local and Latin American levels, the firm has been providing sophisticated, high quality advice to international and local clients for more than 95 years. The firm comprises over 300 lawyers and has wide experience of international business issues and the complexities of cross-border transactions.

Our unmatched strength allows us to react quickly and to simultaneously handle large, complex and time-consuming transactions without compromising on quality. All our teams are led directly by highly experienced partners and carefully tailored to meet the specific needs of our clients. We have a strong focus on high-end corporate and finance transactions and the largest, most active litigation and arbitration practice in Argentina. Our leading intellectual property department provides a comprehensive service and has unrivalled experience; the firm was originally founded as an intellectual property office. We are also a market leader in a wide range of other key practice areas including life sciences, healthcare, tax, labor and employment, competition/antitrust, energy and natural resources, administrative and public law, insurance and reinsurance, telecommunications and broadcasting as well as real estate and construction.

We are the Argentine member of Lex Mundi, the world's leading association of independent law firms, comprising more than 160 members. We also have an office in New York, providing invaluable support on US transactions.

With a long history of advising multinational companies and international institutions, we have a unique understanding of the Argentine market and how to help our clients achieve their goals. Marval, O'Farrell & Mairal has a 90-year track record of being prepared to respond to any challenge, both in the country and in complex cross-border transactions.

THE AUTHORS

MARTIN BENSADON

Martín Bensadon joined Marval, O'Farrell & Mairal in 1991 and has been a partner of the firm since 1998. He specializes in industrial property and more particularly in patent law, having advised many national and foreign firms in this area.

He graduated as a lawyer from the Universidad de Buenos Aires in 1991 and obtained a Master in Laws at the University of Illinois at Urbana-Champaign in 1996. In the same year he also worked as a foreign associate in the law firm of Wilmer, Cutler & Pickering.

He has participated in seminars on industrial property and has written various articles on subjects related to his area of specialty in national and international publications as well as a book on Argentine Patent Law.

He used to be a postgraduate Professor of Industrial Property at the Universidad Católica Argentina and the Universidad de Palermo while he currently teaches at the Universidad Austral and Universidad de San Andrés. He was a Guest Researcher of the Max Planck Institute for Intellectual Property, Competition and Tax Law and a Visiting Scholar at The George Washington University Law School.

At present he is a member of the Asociación Argentina de Agentes de la Propiedad Industrial, the Asociación Interamericana para la Protección de la Propiedad Industrial, the Association Internationale pour la Protection de la Propriété Industrielle (AIPPI), the Fédération Internationale des Conseils en Propriété Industrielle (FICPI), American Intellectual Property Law Association (AIPLA) and the Colegio de Abogados de la Ciudad de Buenos Aires.

RICARDO A. OSTROWER

Ricardo A. Ostrower joined Marval, O'Farrell & Mairal in 1993 and has been a partner of the firm since 1999.

He is Head of the Litigation and Arbitration department and Co-Head of the Life Sciences department and provides legal advice to leading multinational companies on regulatory strategies and compliance in the pharmaceutical, healthcare, biotech, medical devices, medical-technology devices, dental products, cosmetics, toiletries and perfumes, household cleaning products and food industries.

Ricardo is an experienced litigator, particularly focused on complex civil and commercial litigation as well as in arbitration, including disputes between shareholders, cross-border cases, product liability and corporate law matters. He has also actively participated in class actions, contentious issues related to administrative law matters and in oil & gas and environmental disputes. He has represented several of the largest companies operating in the region in many judicial and arbitral proceedings.

He graduated with honors from the Universidad de Buenos Aires with a degree in Law. He received the Federal Supreme Court Award for being the top graduate in 1992.

He is a founding member of CARAT (Comité Argentino de Arbitraje Nacional y Transnacional) and a member of the AADP (Asociación Argentina de Derecho Procesal).

For several years Ricardo was selected as one of Argentina's leading commercial litigators by different researchers.

Ricardo has written many articles related to his area of specialization. He regularly participates in conferences and seminars in his field of practice.

MARTÍN J. MOSTEIRIN

Martín Mosteirin joined Marval, O'Farrell & Mairal in 2003 and is a partner of the Life Sciences and Health Care Departments

He provides legal advice (both contentious and non-contentious) to leading multinational companies on regulatory strategies and compliance in the pharmaceutical, healthcare, biotech, medical devices, medical-technology devices, dental products, cosmetics, toiletries and perfumes, households cleaning products and food industries, in a broad spectrum of matters from client's day-to-day business to complex cross-border transactions, start-ups, joint ventures, M&As and spin-offs.

Martín graduated from the Universidad de Buenos Aires with a law degree in 2002 and later completed two specializations: The first in Pharmaceutical Regulatory Matters and the second in Corporate Advice in International Trade of Goods, Financial Operations and Payment Methods in Contemporary Commercial Law, both at the same university.

Martín has often participated in topic-specific conferences and seminars in Healthcare & Life Sciences and has written many articles in his practice area. He is an active member of the Life Sciences practice group of the International Bar Association (IBA - Life Sciences), the Health Care and Life Sciences Practice Group of Lex Mundi and the Colegio Público de Abogados de la Capital Federal.


MARVAL
O'FARRELL
MAIRAL
Attorneys at Law
Patent and Trademark Agents
Buenos Aires
Av. Leandro N. Alem 882
C1001AAQ. Buenos Aires. Argentina
T. (+54.11) 4310.0100
www.marval.com
trademarks@marval.com
patents@marval.com

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01 REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW

1. What are the regulatory authorities with jurisdiction over drugs, biologicals, and medical devices in your country?

The National Ministry of Health ("MoH") is the main health authority in Argentina. Nonetheless, in the year 1992, the National Agency of Medicines, Food and Medical Technology (the "ANMAT" after its acronym in Spanish) was created by Decree No. 1,490/1992 (amended and complemented by Decree No. 1,271/2013). The ANMAT is an independent government agency and is granted jurisdiction to control the safety, efficacy, and quality of medicines and to control the activities, process, and technologies performed for the supply, production, manufacturing, fractioning, import and/or export, warehousing, and commercialization of products and materials used for human medicine.

In addition, the ANMAT is the national health authority in charge of registering and/or granting authorization to the persons and companies which are involved in the supply, production, manufacturing, fractioning, importation and/or exportation, warehousing, and commercialization of pharmaceutical products and medical devices, and controlling the execution of such activities. Each province has its own health authority that works jointly with ANMAT, and may issue regulations.

Under the scope of the MoH, the Superintendence of Health Services (the "SSS" after its acronym in Spanish) has monitoring, control, and enforcement capacities over healthcare insurers of the National Health Insurance System and has authority over the national healthcare insurers' providers and the National Institute of Social Security for Retired Persons and Pensioners. At a provincial level, the SSS does not have regulatory authority over the provincial healthcare insurers.

The National Comprehensive Drug Policy Department (the "SEDRONAR" after its acronym in Spanish) is the national agency acting on behalf of the Argentine Executive Branch that controls all operations with certain chemical substances capable of being used in the illicit manufacture of narcotic drugs and psychotropic substances. The activities of production, manufacturing, preparing, repackaging, distribution, commercialization as wholesale or retail, storage, import, export, transport, transship and/or perform any other type of transaction both nationally and internationally of the substances included in lists I and II of Annex I of Decree No.1,095/1996 can only be performed upon the prior authorization and control of the National Registry of Chemical Precursors dependent on SEDRONAR.

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?

Pursuant to Law No. 16,463 (Law on Medicines), the import and commercialization of medicines and medical devices can only be carried out upon the prior authorization and under the control of the ANMAT.

The main national regulations concerning registration of pharmaceutical products (pharmaceutical products and biological drugs) and medical devices include the following:

Pharmaceutical Products

- Law on Medicines (as amended and complemented) governs the activities of production, manufacturing, import, export, fractioning, commercialization, and storage of medicines, chemical products, reactives, pharmaceutical forms, medicines, medical devices, diagnostic devices, and any other product for use or application of medicine on human beings and whoever participates -individuals or corporations- in such activities and can only be performed upon the prior authorization and control of the health authority, in premises duly licensed and managed by a technical director duly appointed with the health authority.
- Executive Decree No. 150/1992 (as amended) applies to the registration, manufacturing, fractioning, prescription, sale, marketing, export and import of medicines. It also provides that as long as the product whose marketing approval is sought has been approved in any of the countries included in Annex I of the Decree, any person may apply for marketing approval without time limitations, submitting minimum information (bioavailability data and a project of label, leaflet and prospect). The list of countries includes, inter alia, Denmark, Japan, the U.S.A., Germany, the U.K., Spain, Italy, and France.
- ANMAT Regulation No. 5,755/1996 (as amended) complements Executive Decree No. 150/1992 and regulates the proceedings to register medicines before the health authority providing different pathways for filing the application form.
- Decree No. 1,299/1997 also regulates the Law on Medicines. This Decree set up the rules for the supply chain of medicines, requiring being prior and duly authorized by the health authority to engage in such activities. Pharmaceutical laboratories must only commercialize their manufactured or imported products (medicines), by themselves or through their distributors, exclusively with pharmacies, drugstores and/or public or private sanitary or healthcare establishments, duly authorized by the corresponding health authority. All medicine products should comply with the legal requirements regarding labeling, packaging, safety requirements, etc., prior to being commercialized.
- The authorization for commercialization approval granted by the health authority with respect to each product should be obtained in order to be allowed to market the product in the country, by correctly passing the "first batch technical inspection" at the facilities of the pharmaceutical company.
- ANMAT Regulation No. 7,075/2011 establishes the requirements and demands for the registration of biological medicines, including the medical specialties of biological origin for human use; industrially manufactured or manufactured with intervention of an industrial proceeding, such as

hemoderivatives; products obtained by means of recombinant DNA; monoclonal antibodies; drugs obtain from biological flows or animal tissues; and other biological products.

- The registration of a biological product with the ANMAT requires the submission of a dossier which must include details of the manufacturer and holder of the certificate of registration of the product, quality information, pre-clinical and clinical information, and a plan for post-marketing surveillance.
- ANMAT Regulation No. 3,397/2012 approved the specific requirements for the authorization of biological drugs and/or monoclonal antibodies obtained from recombinant DNA methods. Those requirements are considered complementary to the ones provided by ANMAT Regulation No. 7,075/2011.
- The registration proceeding for biosimilars is provided by ANMAT Regulation No. 7,729/2011. These drugs are defined as biological drugs whose quali-quantitative composition, therapeutic indication, and proposed administration have backgrounds in other biological drugs registered with the ANMAT or by any foreign health authority (biological reference medicine or comparator), of which there is evidence of effective commercialization and sufficient characterization of its risk-benefit profile.
- Law No. 26,689 (rare diseases) seeks to promote integral healthcare of people with rare diseases (diseases whose prevalence in population is equal to or less than one in 2,000 people in relation to a national epidemiological situation). It also establishes that the social security sector (obras sociales), prepaid medicine companies, and any other healthcare insurance provider must give healthcare coverage to patients with this condition, including at least those benefits determined by the competent authority.
- ANMAT Regulation No. 4,622/2012, as amended and complemented, regulates drugs or medicinal specialties aimed at preventing, diagnosing and treating rare or serious diseases for which there is no secure or effective treatment available (orphan drugs). It sets out the conditions for registering orphan drugs that will be assigned to the category of products authorized under special conditions. The granting of the product registration and the validity term of the marketing authorization certificate will be made by the competent authority on a case-by-case basis taking into account, among other things, the specific characteristics of the involved drug, the complexity of the disease to be treated, and information related to the phases of its development. The labels, leaflets and all information made available for professionals must include the legend "authorized under special conditions" ("autorizado bajo condiciones especiales"), with the same size and highlighting as the brand name and the Argentine Common Denomination or the International Common Denomination.

Medical Devices

- Law on Medicines;
- ANMAT Regulation No. 2,319/2002 as amended and complemented, it sets forth the requirements for a company to be holder of marketing authorization certificates and to commercialize medical devices;