The Pharma Legal Handbook

Uruguay

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

PHARMA BOARDROOM

Uruguay

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

Prepared in association with FERRERE, a leading south american law firm, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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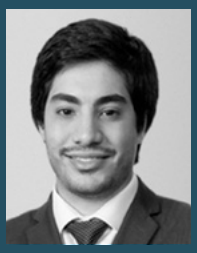
THE AUTHORS



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Agustín Marchesano is a member of the FERRERE Life Sciences team, where he provides advice on regulatory and general corporate aspects.

His practice focuses primarily on obtaining authorizations, permits and registries with different regulatory authorities, such as the Ministry of Health, the Ministry of Livestock, Agriculture and Fishing, the Cannabis Regulatory and Control Institute, and the National Seed Institute. He also participates in advice on arranging representations, transfer of marketing authorizations, drafting and review of contracts, and analysis of regulatory queries.

He collaborates with companies on bid processes for government procurement of drugs, medical inputs and chemical products, providing advice throughout the procedure, responding to opportunities to review files, filing administrative appeals, preparing assignments of rights and filings with the Unified Government Suppliers Registry.

From 2016 to 2017 he worked in the firm's Litigation and Arbitration department, on judicial processes for contract and tort liability, bankruptcy and insolvency proceedings, and judicial recoveries of assets.

He has authored and coauthored publications on contracts, civil liability and issues related to the pharmaceutical industry. He has participated as attendee and speaker at academic seminars, conferences and congresses on civil and commercial law.

Lawyer, Universidad de la República (Uruguay), 2017. Postgraduate in Corporate Consultancy, Universidad de Montevideo, Uruguay, 2020. Master´s Degree in Health Law and Bioethics, Universidad de Castilla-La Mancha, Spain, 2020. Master´s Degree in Private Law, Universidad Nacional de Rosario, Argentina (in progress).

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She is currently involved in assisting a major global pharmaceutical group with its local patents.

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THE AUTHORS

MARTIN FRIDMAN

Martín Fridman heads up the Human Health practice area and is a member of the FERRERE Litigation and Arbitration team. He advises a broad range of companies on complex commercial litigation matters. He is a versatile practitioner, with experience in diverse specialties.

He has experience in litigation related to banks. He currently is in charge of advice to financial institutions such as Discount Bank, BBVA and Exprinter on management of their respective asset portfolio recovery efforts. He is also knowledgeable in bankruptcies and insolvency proceedings.

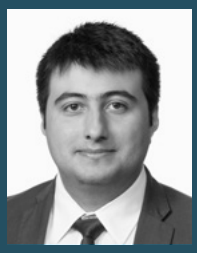
Martín has experience in insurance, and has participated in advice on coverages and recovery litigation for prestigious international insurers such as AIG and MetLife.

He handles advice to health institutions on compliance with regulations, protocols and risk prevention, and medical liability litigation. He has worked with health care clients including Hospital Británico, Asociación Española, Blue Cross & Blue Shield, and SUAT, among others.

He participates in advising companies in diverse sectors of activity on labor litigation, which led to his mention in The Legal 500 Latin América 2014 as a recommended professional in the area of Labor and Employment.

He is the author of various papers related to human health, commercial and insurance law. He has spoken on the same subjects in a variety of academic meetings. He is an instructor of Civil Law at the Law School of Universidad de la República (Uruguay).

In his community service activities Martín participates in advising Fundación Logros, a local foundation engaged in the "School Orchard" project.



MATHIAS ROJAS

Mathías Rojas is a member of FERRERE's Life Science team. He specializes in legal advice to companies involved in the pharmaceutical, food and pharmaceutical products industry on regulatory aspects and data privacy. His practice is based mainly on advising on licensing, permits, obtaining different authorizations for companies, as well as procedures related to the concession of proxies, transfer of registrations, regulatory advice on new structures and regulatory reforms.

He provides legal assistance advising on products' advertising and labeling, as well as in the structuring of strategies for complaints/defense of clients' interests before the regulatory authorities. In addition, he has participated in requests for access to public information, providing counseling to clients throughout the procedure, analysis of regulatory queries and successfully conducting legal actions for access to public information.

He assists, among others, Van Dam S.A. (Arcor), Nestlé del Uruguay S.A., Kraft-Heinz, Abbott Laboratories Uruguay S.A., Murry S.A. (Scienza), Sanofi-Aventis Uruguay S.A., AbbVie S.A., GlaxoSmithKline Uruguay S.A. and Bayer S.A.

He is author and co-author of publications, among them, on actions for relief, especially in relation to medicines and Human Rights issues. He has participated as speaker in academic conferences on civil law and human rights.

At present, he is Professor at Universidad ORT of Business Law, Economic Transactions Law and Legal Framework for International Relations.

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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 authority responsible for applying and enforcing the regulatory framework in relation to drugs, biologicals and medical devices is the Ministry of Public Health (MSP), which is part of the Executive Branch.

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

The regulatory framework for the authorization of drugs, biologicals and medical devices is mainly comprised by Law 9,202 (MSP Organic Law), Law 15,443 (Drugs Law), Decree 521/984, Decree 12/007 (Drugs), Decree 3/008 (Medical Devices), Decree 38/015 (Biologicals) and Decree 18/020 (Regulation for the registration, production, export, import and sale of medicinal products for human use.). These regulations are supplemented by other decrees, resolutions and ordinances published by the MSP.

Price control in the private sector is not regulated.

In Uruguay, there is no reimbursement in the private sector.

Notwithstanding, the National Resources Fund (FNR), an institution created by Decree-Law 14,897 as a non-state public entity, provides financial coverage for some highly specialized medical procedures and high-cost drugs to the users of the National Integrated Healthcare System. Also, the National Reference Center on Congenital Defects and Rare Diseases (CRENACEDER), which is part of the Social Security Institute (BPS), provides drugs for treatment of rare diseases.

3. What are the steps to obtaining authorization to develop, test, and market a product?

Pursuant to Law 15,443, Decree 521/984 and Decree 18/020 manufacturers or importers must obtain an authorization of the MSP in order to test, develop, import and market products (authorizations are granted for product category, e.g., drugs, biologicals, medical devices, homeopathic, etc.).

In order for a company to obtain authorization as a manufacturer or importer, the company must be incorporated in Uruguay, have a responsible technician holding a Uruguayan accredited degree, a warehouse (either own or outsourced) and a manufacturing plant (in the case of manufacturers). Likewise, the company must submit documentation such as facilities authorizations (e.g., Municipality, National Fire Department, Hygienic and Environmental, Potable Water, etc.), operational procedures, list of products to be manufactured/imported, outsourced agreements if any (e.g., technical service for medical devices, product testing, storage). The companies' authorization proceedings may take approximately between four and eight months if no objections are raised and considering it is the company's first request for authorization.

Also, in order to sell products in the Uruguayan market, manufacturers or importers must obtain a marketing authorization -granted by the MSP- for each particular product.

Marketing authorizations: Requirements and timeframes vary among drugs, biologicals and medical devices. Each category of product has its own regulation indicating the requirements (documentation and information) for registering the product and obtaining marketing authorization.

For drugs and biological, qualitative, and quantitative tests must be performed in finished products. In the case of the import of finished products, before registration, the importer must submit to the MSP: (i) a power of attorney granted to the importer by the foreign manufacturer authorizing the importer to distribute the products in Uruguay and; (ii) a GMP/CPP, issued by Regulatory Authorities of member countries of the International Council for Harmonisation (ICH), or National Regulatory Authorities recognised by PAHO/WHO as Regional Reference Authorities, evidencing that the foreign manufacturer is authorized by its country's regulatory authority.

Drugs: Decree 521/984 and Decree 18/020 states that in order to register a drug, the manufacturer or importer must inform and submit to the MSP a protocol that shall be submitted in CTD (Common Technical Document) format, as defined by the ICH guideline M4, including, among other, the following information: (a) name proposed for the drug; (b) qualitative – quantitative formula; (c) monograph of active or inactive raw materials; (d) pharmaceutical form; (e) methodological analytics of the finished product; (f) description of the characteristic of the pharmaceutical form; (g) qualitative analysis of active raw materials in the finished product; (h) quantitative analysis; (i) hygienic control of the non-sterile finished product; (j) sterility control of pyrogenics and safety, as applicable; (k) stability study of active raw material/s; (l) updated pharmacological basis of the foreseen therapeutic effect of active raw material/s. The submission of further documentation might be necessary -for demonstrating interchangeability and bio-comparability- depending on whether raw materials are already present in other registered drugs or drugs pending registration or whether they have been approved or not by FDA or EMA; (m) draft prospectus; (n) labelling design.

The approval timeframe depends on the type of proceedings followed: (i) expedited: 30 days approx.; (ii) standard: 12-18 months approx.

Biologicals and Biosimilars: Decree 38/015 sets forth the requirements to grant the marketing authorization for biologics and biosimilars. Besides the information and documentation for drugs set forth by Decree 324/999, the following must be submitted, among others:

Biologicals: (i) GMP of the active ingredient's manufacturer; (ii) evidence of marketing in other countries, in the case of imported products; (iii) information on active ingredient/s; (iv) information on the