

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

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



**LETICIA
AGUIAR**

Leticia Aguiar is part of the team covering Chemical, Pharmaceutical, Biotechnical and Food Industries at FERRERE. She specialized in legal advice on acquisition of companies, product lines and other transactions related to those sectors.

She has broad experience of diverse aspects in the market of chemicals, laboratories, food, phytosanitarian and veterinarian products, as well as the applicable regulatory practice. She has participated in laboratory merger processes, representations, changes in distribution models, and transfers of marketing authorizations. For over a decade Aguiar has advised Sanofi-Aventis Uruguay SA, Glaxo SmithKline Uruguay SA, and Abbott Laboratories Uruguay SA, and has successfully defended their interests vis-à-vis the public administration.

In processes involving sale of business lines she has provided counsel to the diagnostics area of Siemens Healthcare to set up business in Uruguay, obtain authorization from the Ministry of Health, and transfer tenders underway, in order to start up operating activities. In addition, she has advised this company on the expansion of its businesses, which implied the introduction in Uruguay of the Company's industry and energy lines.

She participated, with the Chemical and Pharmaceutical Association of Uruguay, in the compilation of health rules, published in books and CD titled Marco Regulatorio de la Industria Farmacéutica y Afines (Pharmaceutical and Related Industries Regulatory Framework), a frequent research tool for authorities of the industry.

Since 2003 she has been an instructor in Company Law at Universidad ORT (Uruguay).

Leticia is an attorney from Universidad de la República (Uruguay), 2001; she has a Graduate Course in Food Law (2004) and a Master's program in Administrative Law of Economic Regulations also from Universidad de la República.



**STELLA
WENG**

Stella Weng has longstanding experience in IP. She has been advising leading international companies in various fields, such as the pharmaceutical industry, sports, apparel, beverages, fast food and accommodation services for over twenty years on topics ranging from trademark and patent protection to defense of IP rights.

Her practice includes assisting clients with the efficient management of large trademark portfolios, recordal of assignments, mergers and licenses as well as taking care of the administrative defense of patents and trademarks, dealing with oppositions, annulment and revocation actions.

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

Weng is particularly alert to trademark misuse and registration and has staved off numerous attempts at illegal appropriation and unauthorized use of foreign trademarks.

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.



**BRUNO
BERTOLOTTI**

Bruno Bertolotti is a member of the Corporate team handling Chemical, Pharmaceutical and Food industries at FERRERE. He specializes in legal advice on installation and launching of projects and product lines in the country and other transactions related to those sectors.

For seven years he has been advising Siemens, Ecolab, Sanofi-Aventis, Novartis, Bayer, Herbalife, Abbvie, Nestlé, Arcor, GlaxoSmithKline and Abbott, among others. He has participated on corporate acquisitions, separation of Abbott and AbbVie laboratories’ lines of business, contract analysis, representations, changes in distribution models and transfers of sales authorizations.

On a day-to-day basis he participates in representing the area’s clients in their relations with regulatory authorities, achieving successful results in obtaining licenses and operating authorizations from the Ministry of Transportation and Public Works, the Ministry of Health and the Cannabis Regulation and Control Institute.

He has advised different clients on public tenders, including calls for bids by the Ministry of Tourism, the Centralized Procurement Unit, the Cannabis Regulation and Control Institute, the National Electric Company (UTE), the National Waterworks Company (OSE), the National Port Administration.

Bruno is an attorney graduated from Universidad de la República (Uruguay), 2015. He has a diploma in American and International Law, Southwestern Institute for International and Comparative Law of the Academy of American and International Law (Dallas, Texas), 2017. He is currently studying for a Master’s program in Civil Law with specialization in Contracts at Universidad Católica del Uruguay.

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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?

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

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

4. What are the approximate fees for each authorization?

5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?

6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?

7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?

8. How is compliance with regulation monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?

9. What is the potential range of penalties for noncompliance?

10. Is there a national healthcare system? If so, how is it administered and funded?

11. How does the government (or public) healthcare system function with private sector healthcare?

12. Are prices of drugs and devices regulated and, if so, how?

13. How are drugs and devices used by patients paid for? What roles do public and private payers play?

14. Who dispenses drugs and devices to patients and how are those dispensers compensated?

15. What are the professional and legal responsibilities of those who dispense drugs and devices? What role do they play in providing patient care, information, and safety?

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 of Law 9,202 (MSP Organic Law), Law 15,443 (Drugs Law), Decree 521/984, Decree 324/999 and Decree 12/007 (Drugs), Decree 3/008 (Medical Devices) and Decree 38/015 (Biologicals). 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 and Decree 521/984 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/CPD evidencing that the foreign manufacturer is authorized by its country's regulatory authority.

DRUGS

Decree 324/999 states that in order to register a drug, the manufacturer or importer must inform and submit to the MSP, among others:

- (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) labeling 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 biologicals and biosimilars. Besides the information and documentation