The Pharma Legal Handbook

Bolivia

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

PHARMA BOARDROOM

Bolivia

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

Prepared in association with Indacochea & Asociados (IA), a leading Bolivian 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 DECEMBER 2018 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**

IA INDACOCHEA & ASOCIADOS
ABOGADOS / SOCIEDAD CIVIL

Indacochea & Asociados, Abogados (IA), is a law firm founded in 1991. It has 27 years of experience providing legal advice in a comprehensive and global manner, achieving recognition as a Corporate Law Firm.

With a staff of 19 lawyers and legal assistant all of them trained in the best universities in the country, most of them post-graduate studies in the United States, Europe, Argentina and Peru, among others.

Thanks to this is that IA provides legal advice to clients in all areas of corporate-commercial law. The popularity achieved since its foundation, has established itself as a benchmark in the national corporate law. Clear proof of this is that IA has been part of the review and complementation of laws and legal provisions of contemporary Bolivian Commercial Law.

Also, thanks to the modern view of law and understanding of business, Indacochea & Assoaciates has worked - in different areas - with major multinational companies that have been and are investing in Bolivia; and with the most representative and largest Bolivian companies at present.

THE AUTHORS

ANDERE INDACOCHEA

PARTNER

Since her beginnings in Indacochea & Asociados, Andere Indacochea´s practices has focused in corporate and labor law.

The responsibility and confidentiality in handling clients' matters has made her a reference in labor aspects such as handling conflicts internally and before labor authorities, hirings, severance payments, personnel restructuring, and counseling companies in all aspects regarding health funds, retirements, etc. In the corporate area she counsels clients in contracts, corporate aspects, due diligences, etc.

Andere also counsels companies in complying with current regulations issued by the State Agency for Medicines and Health Technologies (Agencia Estatal de Medicamentos y Tecnología en Salud –Agemed) in respect to licenses, authorizations and procedures in order to manufacture, storage, distribution, import and export of medicines and health technologies.

LANGUAGES
- Spanish
- English

andere@indacochea.com

HEIDY SANDOVAL

ASSOCIATE

Heidy Sandoval joins Indacochea & Asociados´ Commercial Department providing outstanding legal counsel in matters related to the analysis and verification of commercial documents that any companies must count on and which are subject to registration.
Thanks to her analytical capacity and professional skills she ensures that companies comply - within the established deadlines - with all the documentation required by the Government Agency of Business Control (AEMP).

She also advises clients on issues related to the State Agency for Medical Products and Health Technology (Agencia Estatal de Medicamentos y Tecnología en Salud –Agemed), counseling clients in complying with legal requirements and procedures in order to register products before authorities.

LANGUAGES
- Spanish

hsandoval@indacochea.com

CONTENTS

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?	In Bolivia the authority that regulates all matters is the State Agency for Medical Products and Health Technology (Agencia Estatal de Medicamentos y Tecnología en Salud -AGEMED- y el Ministerio de Salud dependent of the Health Ministry).
2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?	There is no specific norm that regulates price fixing for medicines or medical products. All other aspects are regulated by Law No. 1737 (Medicine Law), Supreme Decree No. 25235, and other ministerial resolutions that regulate all aspects concerning the sanitary registrations, authorizations, imports, etc.
3. What are the steps to obtaining authorization to develop, test, and market a product?	Companies must comply with all documents required by the health authorities. Once these documents are filed, the Pharmacological Commission will review documents and information provided, about the product. If the product complies with evaluation, qualification, efficiency and security standards, the Pharmacological Commission continues the authorization process, where labeling, sampling and quality control must be met in order to obtain the heath registration number (registro sanitario).
4. What are the approximate fees for each authorization?	In order to obtain authorization for an imported pharmaceutical (medicine, drug, or other) the costs are around US$ 300. If the pharmaceutical is locally manufactured, costs are around US$140. For an imported generic product, costs can be around US$ 230 while a locally manufactured one is around US$ 115.
5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?	Authorizations (registros sanitarios) once issued are valid for a five-year period. Under Bolivian law, renovations must follow the same procedure as if the company wants to register a new product.
6. How does the authorization process differ between brand-name products and generic products? Are there differences for local manufacturers versus foreign-owned manufacturers?	Yes, there are certain differences between them. For example the generic products in order to be able to distribute and commercialize in the country, must be included in a list that is issued by the authority and can proceed to obtaining the authorization directly. All other products must previously be authorized by the Department of Quality Management, Efficiency and Safety and then be able to solicit the products´ authorization.

	The main difference between local and foreign manufactures are the requirements that they need to present before the authority and the costs that need to be incurred by each of them.
7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?	Under Bolivian law, these products don't have a special kind of regulation. Therefore, they are regulated like any other product.
8. How is compliance with regulations monitored and evaluated? Is the regulatory regime comparable with the U.S. Food and Drug Administration or the European Medicines Agency expectations and requirements?	AGEMED is in charge of making sure all regulations are complied with. They do so by asking companies to provide information, documentation and might even inspect warehouses and administrative offices.
9. What is the potential range of penalties for noncompliance?	Penalties can include economic sanctions, confiscation of products, to even cancelling licenses in order to import and/or commercialize products in the country.
10. Is there a national healthcare system? If so, how is it administered and funded?	Yes, Bolivia has a National System of Health which is composed of entities, institutions and organizations both public and private that provide health services, which are regulated by the Health Ministry. In the public sector, the Health Ministry is in charge of regulating and conducting all national policies and strategies. By doing so, all employees can access health care and treatments. In the private sector it is composed of insurance companies, prepaid health companies and nongovernmental organizations. In way of traditional medicine which is widely used in the country, on March 8th, 2006 a special sub-ministry was created in order to facilitate indigenous populations, afro communities amongst other communities. The public sector is finances by the government while the employees sector is financed by both the employees and employers. The private sector is financed by them.
11. How does the government (or public) healthcare system function with private sector healthcare?	The sectors work independently. There might be cases where they work together in public tenders where public institutions buy private medications.

12. Are prices of drugs and devices regulated and, if so, how?	No, prices are not regulated.
13. How are the drugs and devices used by patients paid for? What roles do public and private payers play?	All drugs and devices used by patients must be paid by each patient. Nonetheless, under Bolivian labor law, employees should be affiliated in a public health fund and receive medical services. In this case, there are some medicines and devices that are included in these services. Employers must make monthly contributions in order to cover costs.
14. Who dispenses drugs and devices to patients and how are those dispensers compensated?	The distribution must be made by a qualified pharmacist. Because they are hired as an employee, they receive a monthly salary.
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?	A professional in charge of medication dispensation or distribution must hold the highest ethical principles since a patient's health and life is in game. Therefore, they have civil and even penal responsibilities against them.