The Pharma Legal Handbook

Peru

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 · Biosimilars and Biologics

PHARMA BOARDROOM

Peru

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

Prepared in association with Osterling Abogados, one of the most prestigious law firms in Peru, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

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We believe that the key to our success lies in providing optimum quality legal advisory services and timely and effective solutions. We plan to stay on this path, reaffirming our prestige every step of the way, strengthening lifelong ties with our clients, forging new relationships that will benefit from a competitive service.

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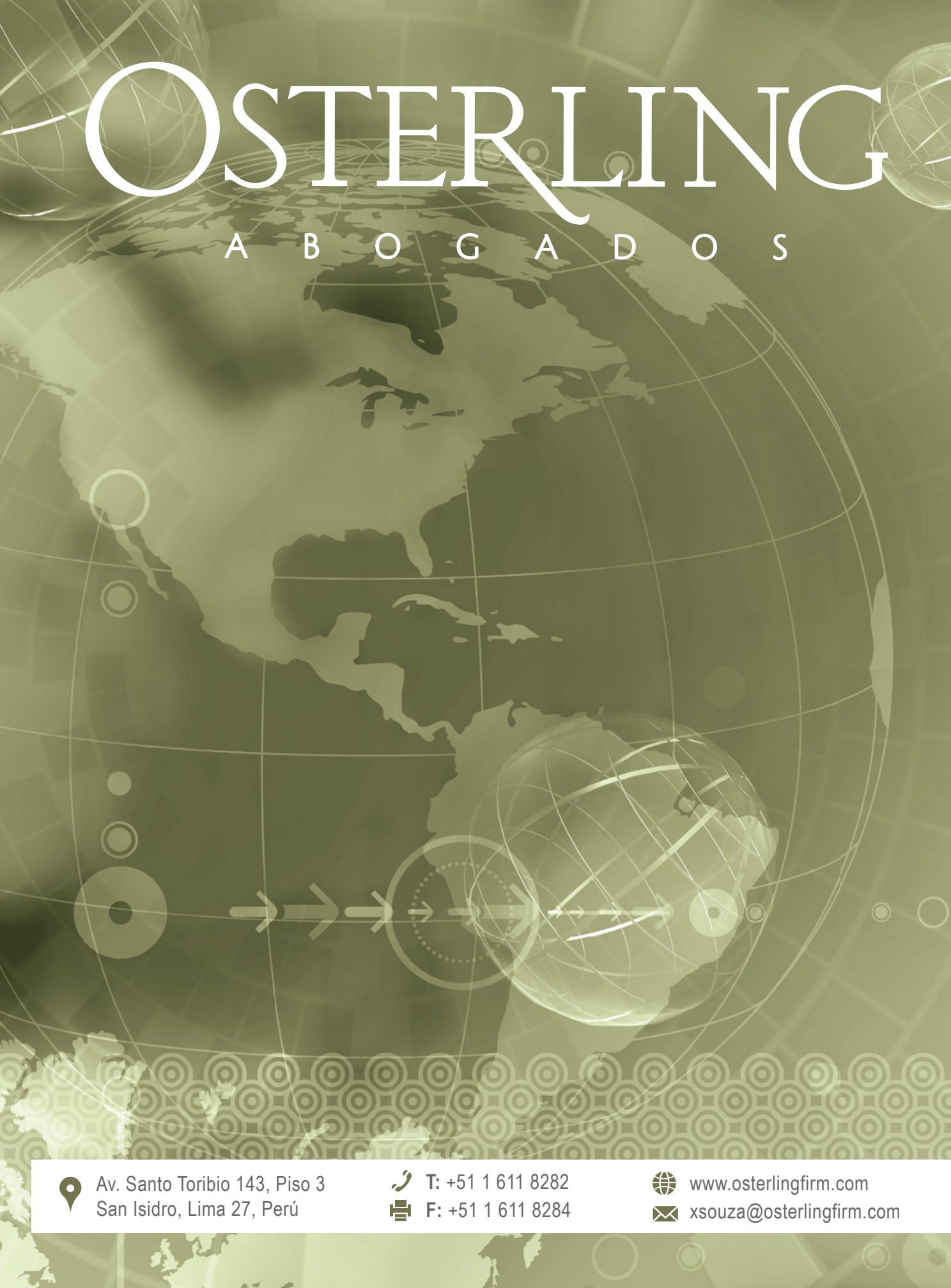
Ximena is also a highly regarded practitioner on trademarks, patents, consumer protection, and unfair competition. Her practice includes advising on advertisement regulations, with a particular focus on comparative and commercial advertising. In terms of contentious areas, she handles complex court and administrative IP litigation.



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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?

Drugs, biological and medical devices are regulated by the Directorate General of Medicines, Supplies and Drugs - (known in Spanish as DIGEMID)

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

The regulatory frameworks for authorization, pricing and reimbursement of drugs, biological and medical devices are the following:

- Law N° 29459, Law on pharmaceutical products, medical devices and sanitary products
- Supreme Decree N°014-2011-SA
- Supreme Decree N° 016-2011-SA

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

For the manufacture of a pharmaceutical product, it is necessary to obtain its Sanitary Registration. It should be noted that obtaining the sanitary registration of a product authorizes its owner for the manufacture, import, storage, distribution, marketing, promotion, dispensation, sale or use thereof, under the conditions established by local regulations.

In that regard, there are two figures that can be presented. On one hand if the owner is a local laboratory, able to directly manufacture the products to later commercialize them or it can order the manufacturing service to a national or foreign laboratory. Regardless, the laboratories must comply with the requirements and sanitary conditions established in local law and have the Certificates of Good Manufacturing Practices, Good Laboratory Practices, Good Distribution Practices, Good Storage Practices, Good Dispensing Practices and Good Practices of Pharmacotherapeutic Follow-up and others approved by DIGEMID. Regarding foreign laboratories, certificates of Good Manufacturing Practices are recognized in high surveillance countries or countries of mutual recognition with Peru.

Considering the aforementioned, the manufacture of a pharmaceutical product, must be carried out by an authorized national laboratory, which must maintain all the conditions by which manufacture of the product was authorized.

In that regard, for the fabrication of pharmaceutical products local laboratories must have certificates of Good Practices, the Sanitary Authorization issued by DIGEMID and the Operating License issued by the local government.

In order to obtain the Sanitary Authorization as a laboratory they must comply with the following requirements:

a) Production areas, storage and pharmaceuticals forms to fabricate;

b) Technical Director;
c) Sketch of the location of the establishment;
d) Sketch of the distribution areas of the laboratory. In the storage area the useful volume of storage must be indicated en cubic meters for each area;
e) Flow diagram of the production processes, by pharmaceutical form, indicating the quality controls for each stage of the process;
f) Zoning license;
g) Sketch of critical support systems;
h) List of critical equipment for production and quality control;

After obtaining the Sanitary Authorization, they must obtain the certificates of Good Practices issued by the DIGEMID.

In case the manufacturing laboratory carries out the quality controls (tests) on the inputs, the intermediate products or devices and the finished product or device, it can do so in accordance with what the Good Laboratory Practices establish.

4. What are the approximate fees for each authorization?

Regarding the commercialization authorization, the fees will depend on the product whose Sanitary Registration is being requested and range from $400 to $1,200.

Regarding the Sanitary Authorization for registration as a laboratory the fee is of around $250

Regarding the Sanitary Authorization for registration as a drugstore the fee is of around $150

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

Sanitary Registrations are valid for 5 years and they can be renewed starting one year before their expiration date. For the renewal the owner of the registration must present all the requirements for registration except for studies supporting the efficacy and safety of the 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?

The authorization process is the same for both type of products. No distinction is made between a local manufacturer and a foreign manufacturer.

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

Products may be commercialized in kits prior to communication to DIGEMID as long as they maintain the conditions by which their Sanitary Registration was granted.

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?

Every batch of products entering the market is subject to a quality control. Furthermore, local health authorities may inspect establishment that store, distribute, commercialize pharmaceutical products and confiscate the products for analysis in any step of the fabrication, storage, distribution or commercialization process.

Confiscations can also be made at bonded warehouses for imported products.

The regulation regime is very strict and as such it could be said that it is comparable to the European and American standards.

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

The range of penalties for noncompliance goes as follows:

- Warning against the owner or legal representative or technical director
- Suspension of the Technical Director
- Fines
- Cancellation of the Certificate for Good Practices
- Suspension of the Sanitary Registration
- Cancellation of the Sanitary Registration
- Temporary suspension of the fabrication or commercialization activities
- Temporal closure of part or all facilities
- Definitive closure of the establishment or its facilities.
- Confiscation of products, devices, materials and/or machinery

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

The national healthcare system is composed of the following bodies:

- Social Health Insurance (EsSalud)
- Health Ministry
- Regional and Local Governments
- Health of the Armed and Police Forces

The healthcare system is financed through the Government.

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

The public and private healthcare systems work separately.

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

The prices of drugs and devices are not regulated in Peruvian regulation. However, there is an obligation to report the prices to DIGEMID's Price Observatory.

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

Regarding medicines and devices used by patients in the national healthcare system, the drugs and devices are subsidized by the Government. Private payers only play a part in the sense that the subsidy is financed by taxes that they pay.