The Pharma Legal Handbook

Venezuela

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

Venezuela

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

Prepared in association with Hoet Pelaez Castillo & Duque, a leading law firm in Venezuela, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

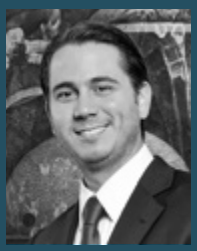
HOET PELAEZ CASTILLO & DUQUE
Av. Eugenio Mendoza, Torre IASA, Piso 3
La Castellana, Caracas 1060
Venezuela
Email: infoip@hpcd.com

PharmaBoardroom is not responsible for any mistakes contained within this publication. For specific advice on any legal issue, please contact a qualified professional.

Copyright: All rights reserved. No part of this publication maybe reproduced in any form or by any means, whether electronic, mechanical or otherwise including photocopying, recording or any information storage or retrieval system without prior written consent of PharmaBoardroom. While every attempt is made to ensure the accuracy of the information contained in this report, neither PharmaBoardroom nor the authors accept any liabilities for errors and omissions. Opinions expressed in this report are not necessarily those of the authors.

*** THIS REPORT WAS ORIGINALLY PUBLISHED IN MAY 2020 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.**

THE AUTHORS

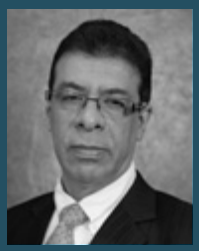


JOAQUÍN NÚÑEZ LANDÁEZ

PARTNER

Joaquín joined HPCD in 2012 and became partner in 2016. He worked for many years in an renowned law firm in the USA, where he gained a valuable international perspective. He started his professional career in 2004 and has worked in other well-known intellectual property firms in Venezuela. Joaquín specializes in patents, trademarks, copyrights, data privacy protection, LifeSciences and Biotechnology and Administrative and Court remedies applied to Intellectual Property.

jnunez@hpcd.com



CARLOS PACHECO

JUNIOR PARTNER

Carlos joined HPCD in 2003 as Patent Manager. He was consultant for the World Intellectual Property Organization in patent-related matters in Argentina, Paraguay, EL Salvador, Honduras and Costa Rica; Director of the Patents Office at the Venezuelan Registry of Industrial Property; Patents Examiner in the areas of Organic Chemistry, Pharmacy, and Petrochemical; and Advisor for the drafting of the Andean Manual of Procedures for Request of Patents.

cpacheco@hpcd.com

HOET PELAEZ CASTILLO & DUQUE

1942 • 2017 75 ANNIVERSARY

Established in 1942

www.hpcd.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?	The Regulatory authority is the National Institute of Hygiene
2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and medical devices?	Organic Law of Health and Resolution NUMBER-0010-9921 of the MINISTRY OF HEALTH AND SOCIAL DEVELOPMENT dated September 1999.
3. What are the steps to obtaining authorization to develop, test, and market a product?	To obtain a Health Registry, the interested party must meet the following requirements: a. Appoint a legal representative, professional in the area of Health. b. Submit an application form designed by the Ministry of People's Power for Health, accompanied by a copy of the following collections: 1. Articles of Incorporation and Bylaws with their modifications, if any; 2. Industry and Commerce Patent of the corresponding applicant; 3. Authenticated power of attorney document granted to the legal person to processing application; 4. Academic title of the processing Health professional. c. Submit a list of products subject to commercial exploitation; d. A report of the inspection of the premises that will serve as storage of the products, executed by the Ministry of Health and Social Development.
4. What are the approximate fees for each authorization?	Approximately 200 to 400 USD, depending on the procedure and the authorization request.
5. For how long are marketing authorizations/registrations valid? How are marketing authorizations/registrations renewed?	The validity of the Registration / authorization varies between 5 and 7 years depending on the application. The renewal must be requested at least 6 months prior to the expiration of the registration / authorization, using the form F-RCDM-007.

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 in both cases, only the required documentation varies.
7. How are combination products (drug + drug, drug + biologic, drug + device, biologic + device, drug + biologic + device) regulated?	There are specific instructions for each of the mentioned combinations.
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?	Once the sanitary registration has been granted to the specialty pharmaceutical, the Representative of the product in the country (holder of the sanitary registry), must notify the National Institute of Hygiene, the beginning of the commercialization, request the collection of samples of the first batch and pay the respective rate. There is a Division of Drug Control, which annually carries out a program of controlling products marketed in Venezuela, in accordance with the criteria established in the respective procedure, for which the respective samples will be collected. This regulatory regime is not comparable with that from the USA or the European.
9. What is the potential range of penalties for noncompliance?	The failure in the notification of the beginning of commercialization or the non-commercialization of the product in the time established in the current regulations, leads to the cancellation of the respective sanitary registration.
10. Is there a national healthcare system? If so, how is it administered and funded?	The Constitution of Venezuela guarantees the right to Health. For this purpose, the State will create, exercise the rectory and manage a National Public Health System, of an intersectoral, decentralized and participatory nature, integrated into the social security system, governed by the principles of gratuity, universality, integrity, equity, social integration and solidarity. The Ministry of the People's Power for Health (MPPS) is the governing body of the health sector in Venezuela, that is responsible for the regulation, formulation, design, evaluation, control and monitoring of health, social development and health policies, programs and plans; the integration of the sources of financing and allocation of resources of the National Public Health System; comprehensive health care to all sectors of the population, especially low-income ones; and the promotion of citizen participation. The financing of the National Public Health System is mandatory for the State, through the integration of fiscal resources and mandatory social security contributions, among others.

Another public provider of Health Service is the Venezuelan Institute of Social Security (IVSS).

11. How does the government (or public) healthcare system function with private sector healthcare?	The government Health system works very poorly compared to the private health system.
12. Are prices of drugs and devices regulated and, if so, how?	There are currently no effective government controls to regulate the prices of medications and medical devices.
13. How are the drugs and devices used by patients paid for? What roles do public and private payers play?	In general, the costs of medications (drugs) and devices must be paid by patients. The role of the government and private entities in the payment of these items is very limited due to the high inflation rates that exist in Venezuela.
14. Who dispenses drugs and devices to patients and how are those dispensers compensated?	Most of the time, medications and devices are distributed to patients by the private sector that pays attention to the patient; When the patient goes to a public organization in the vast majority of cases, it must be the same patient who provides the supplies and / or assumes their cost.
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?	The professional and legal responsibilities of the suppliers of drugs and medical devices in Venezuela are established by: • The National Constitution; • The Organic Health Law; • The Organic Drug Law; • The Medication Law; • The Law of Pharmacy and its Regulation; • Civil and Criminal Codes.