Chile

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
Chile

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

Prepared in association with Carey, the largest law firm in Chile, it should answer any questions linked to Regulation, Pricing, Clinical and Preclinical Trials, Marketing, Manufacturing, Trademarks and Patents.

Carey is Chile’s largest law firm, with more than 270 legal professionals. Carey is a full service firm. The corporate, litigation and regulatory groups include highly-specialized attorneys covering all areas of law.

The firm’s clients list includes some of the world’s largest multinationals, international organizations, and important local companies and institutions. The firm’s lawyers have graduated from the best law schools in Chile and most of its mid and senior level associates have graduate degrees from some of the world’s most prominent universities. Several are also currently university professors.

The firm is an effective bridge between legal systems. Most of its partners and senior associates have worked in North America, Asia, and Europe, as foreign or regular associates with leading international law firms, or as in-house counsel for major corporations or international institutions.

We are the law firm in Chile with the most practice areas ranked as band 1 by Chambers Latin America: Banking and Finance; Capital Markets; Corporate, M&A; Labor; Energy and Natural Resources; Mining; Intellectual Property; Life Sciences; Projects; Tax And Telecommunications.

Contact details:
Isidora Goyenechea 2800, 43rd Floor, Las Condes, Santiago, Chile
+56 2 2928 2200
carey@carey.cl
www.carey.cl

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 may be 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 APRIL 2019 AND THE INFORMATION CONTAINED WITHIN IS SUBJECT TO CHANGE.
* **LAST UPDATE: JUNE 2020**
THE AUTHORS

GUILLERMO CAREY

Ignacio is partner of Carey and co-head of the firm’s Intellectual Property and Information Technology Group. His practice focuses on life sciences, biotechnology and public law, advising companies on intellectual property issues related to the pharmaceutical industry, cosmetics, medical devices, commercialization and advertisement of these products, scientific research, clinical studies, regulation of medical professions, privacy, data protection, public and private procurement and biddings, licenses, distribution and franchises. He also represents clients in administrative processes and in sanitary, administrative and judicial litigation derived from those operations.

He has been recognized in Life Sciences by international publications such as Chambers Latin America and Who’s Who Legal. He is Professor of Pharmaceutical Regulatory Affairs and Civil Law. Also he is member of the Chilean Bar Association.

He is author of several local and foreign publications related to life sciences and regulatory law.

Ignacio graduated from Universidad de Chile.

igillmore@carey.cl
+56 2 2928 2612

IGNACIO GILLMORE

Guillermo is partner of Carey and head of the Life Sciences group. Also, he is co-head of the firm’s Intellectual Property and Information Technology, and Venture Capital and Private Equity Groups. His practice specializes in intellectual property, life sciences, IP litigation, licensing, distribution and franchise agreement, data privacy, technology law, trademarks, patents, electronic commerce, technology transfer and data protection. Guillermo has advised high-impact Chilean technology companies on technology transfer, and the internationalization of these. He has also advised the Chilean Government on various fronts related to IP and transfer of technology.

He has been widely recognized by international publications including Chambers Latin America, The Legal 500 and others. Also, he has been awarded as Lawyer of the Year in Intellectual Property by Best Lawyers and with the Award of Merit by AIPPI.

He is member of the International Trademark Association, the Inter-American Association of Intellectual Property, the Licensing Executives Society Chile and the Chilean Bar Association. Also, he is a former member of Grupo Acción Digital, appointed by the government as part of Chile’s digital agenda plan, former vice-president of the National Council for Domain Names and IP Addresses of Chile, former member of the Board of the Chilean Industrial Property Association, former assistant secretary general of the International Association for the Protection of Intellectual Property and others. Guillermo graduated from Universidad Católica de Chile.

gcareyc@carey.cl
+56 2 2928 2612
THE AUTHORS

COUNSEL

Fernando is counsel of Carey’s Intellectual Property and Information Technology Group. His practices areas are focused on intellectual property, infringement of intellectual property rights litigations, licenses, technology transference franchising, distribution and registration processes and invalidation of trademarks, patents and other industrial rights. He has vast experience on advising companies involved in pharmaceutical market (Life Science), on issues regarding the protection and defense of intellectual property assets, as well as regulatory matters concerning the pharmaceutical industry, cosmetics, medical devices and food products.

He has been recognized in Intellectual Property by several international publications, including Chambers Latin America, Best Lawyers, The Legal 500 and others.

He is director and vice president of Licensing Executives Society Chile, member of the Chilean Intellectual Property Association and member of the Chilean Bar Association. Also, he is former member of the legal division of the Comptroller General of the Republic.

Fernando graduated from Universidad Central and holds a degree in Intellectual Property for countries of Latin America and the Caribbean from the Industrial Property Office of Brazil, a degree in Administrative Management of Industrial Property from the European Patents Office in Hague, Netherlands, he attended to the Academy of American and International Law in Dallas and a degree in Pharmaceutical Regulatory Affairs in Pharmaceutical, Biological and Cosmetic Products from Universidad de Chile among others.

fgarcia@carey.cl
+56 2 2928 2665

REGULATORY AFFAIRS MANAGER

Alejandra is Regulatory Affairs Manager of Carey’s Pharmaceutical and Biotechnology Group. Her work is focused in the preparation, processing and obtaining of sanitary registrations of pharmaceutical, veterinary and cosmetic products. She also has extensive experience in processing authorizations for the use and commercialization of foods, for human or animal use, as well as for medical devices. She also advises companies on intellectual property issues related to the pharmaceutical industry.

She is professor and coordinator of several Industrial Property and Pharmaceutical related courses in Universidad de Chile. Also, she is former Invention Patent’s Registrar and Examiner for the Industrial Department of the Chilean Ministry of Economy.

Alejandra graduated with maximum distinction as Chemical Pharmacist from Universidad de Chile. She holds a degree in Quality Management and Leadership from the same university and she attended an IP Course at the World Industrial Property Organization in Geneva, Switzerland. Also, she has followed up training courses in examinations and searches of patent applications in INAPI, EPO, OEPM andOMPI.

adelrio@carey.cl
+56 2 2928 2766
Life Sciences, Health and Food

Carey has extensive experience advising companies and corporations from the pharmaceutical, cosmetics, medical devices and food industries at a national and international level.
## CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>REGULATORY, PRICING, AND REIMBURSEMENT OVERVIEW</td>
<td>8</td>
</tr>
<tr>
<td>PRECLINICAL AND CLINICAL TRIAL REQUIREMENTS</td>
<td>20</td>
</tr>
<tr>
<td>MARKETING, MANUFACTURING, PACKAGING AND LABELING, ADVERTISING</td>
<td>26</td>
</tr>
<tr>
<td>TRADITIONAL MEDICINES AND OVER-THE-COUNTER PRODUCTS</td>
<td>37</td>
</tr>
<tr>
<td>PRODUCT LIABILITY</td>
<td>41</td>
</tr>
<tr>
<td>PATENTS AND TRADEMARKS</td>
<td>47</td>
</tr>
<tr>
<td>REGULATORY REFORMS</td>
<td>54</td>
</tr>
<tr>
<td>CANNABINOID DRUGS, MEDICINAL CANNABIS AND OPIOID DRUGS</td>
<td>56</td>
</tr>
<tr>
<td>ORPHAN DRUGS AND RARE DISEASES</td>
<td>63</td>
</tr>
<tr>
<td>BIOSIMILARS AND BIOLOGICS</td>
<td>68</td>
</tr>
</tbody>
</table>
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?
In Chile, the regulatory authority responsible for the enforcement of the regulatory framework for pharmaceutical products, including biologicals, and medical devices is the Public Health Institute (ISP), which is a functionally decentralized and autonomous public service overseen by the Ministry of Health (MoH).

In turn, the Ministry of Health is the main health authority in Chile, which, pursuant to the provisions of the Chilean Sanitary Code, is responsible for the issuance of the respective regulations which govern the import, clearance, export, production, manufacturing, fractioning, storage, handling, transport, distribution, sale, pharmacovigilance, traceability, advertising, promotion or information to professionals, medical use or scientific investigation of pharmaceutical products and for the progressive implementation of the provisions for medical devices.

In Chile, the authorization for the commercialization of a pharmaceutical product is governed by the Sanitary Code, the regulations set forth in Supreme Decree No. 3/2010, issued by the MoH, which contains the Regulations for the National Control System of Pharmaceutical Products for Human Use and by ancillary regulations and technical guidelines approved by the MoH and the ISP (e.g. Decree No. 500 of 2012 of the MoH approving Technical Guideline No. 136 establishing the active ingredients included in pharmaceutical products that must demonstrate therapeutic equivalence and its amendments; Decree No. 27 of 2012 of the MoH approving Technical Guideline N° 131 defining the criteria to prove therapeutic equivalence in pharmaceutical products in Chile and its amendments; and Decree No. 945 of 2014 of the MoH approving Technical Guideline No. 170 on sanitary registration for biotechnological products derived from recombinant DNA techniques and its amendments, among several others).

Medical devices are governed by the Sanitary Code and the regulations set forth in Supreme Decree No. 825/1999 which contains the Regulations for Products and Devices of Medical Use. Furthermore, medical devices law and regulations incorporate a progressive implementation through grounded Supreme Decrees issued by the Ministry of Health –prior report issued by the ISP–, indicating the specific medical devices which will need to fulfill the provisions included in the Sanitary Code and Supreme Decree No. 825/99 in order to be manufactured, imported, commercialized and distributed in Chile.
Currently, regulated medical devices to which sanitary restrictions apply include latex surgical gloves for single use, latex medical examination gloves and latex condoms (Decree No. 342/2004 of the MoH), sterile hypodermic needles for single use and sterile hypodermic syringes for single use (Decree No. 1.887/2007 of the MoH) and synthetic masculine condoms and feminine condoms (Decree No. 93/2018 of the MoH).

There is no general regulatory reimbursement process or pricing laws for pharmaceutical products or medical devices.

Nevertheless, the health coverage of pharmaceutical products and medical devices is based on a public and private insurance system and universal coverage programs, being the most relevant the Explicit Health Guarantees (GES plan) and the High Cost Treatment Financial Protection System (Ley Ricarte Soto).

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

#### PHARMACEUTICAL PRODUCTS

Any pharmaceutical product, whether imported or manufactured in the country, requires a sanitary registration (marketing authorization) in order to be distributed or used under any title in Chile (a pharmaceutical product may be exceptionally authorized by the ISP to be used temporarily without prior sanitary registration if an epidemic, emergency or catastrophe occurs, or if required for an urgent medical use or for scientific research or clinical trials).

In general terms, for the sanitary registration of a pharmaceutical product the applicant will be required to comply with general requirements including the submission of administrative information, technical information, pharmaceutical quality information and data on safety and efficacy of the product. Special requirements will also be applicable for fixed dose combination products, pharmaceutical combination products, phytopharmaceutical products; homeopathic products and biologicals.

Safety and efficacy data, including full preclinical and clinical studies for the product will be necessary to be submitted in order to achieve the sanitary registration of a pharmaceutical product under the standard registration procedure (procedimiento ordinario de registro), applicable, in general terms for innovator products. Nonetheless, Chilean regulations, in specific cases, also include the possibility to file for a simplified procedure (procedimiento simplificado de registro), permitting the omission of specific safety and efficacy data, available for generics products, as will be described.

#### 3.A. Standard Procedure (“Procedimiento Ordinario”) for the registration of Pharmaceutical Products (new drugs, biologics)

The standard procedure is the general procedure established under Chilean regulations for the sanitary registration of pharmaceutical products and will be applicable in all cases defined under article 53 of Supreme Decree No-03/2010 which, in general, relates to: