The Pharma Legal Handbook

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

PHARMA BOARDROOM

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.

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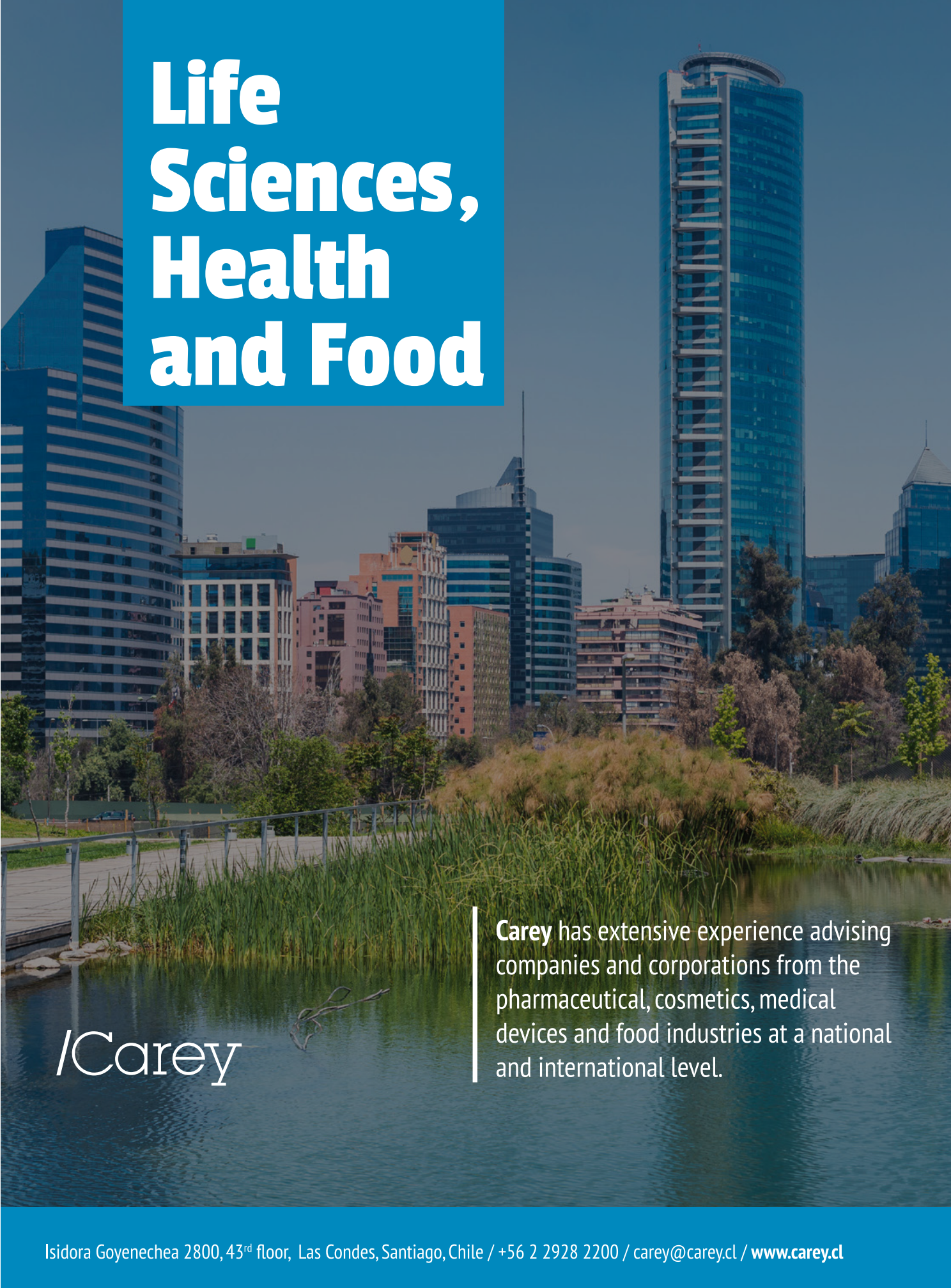
Life Sciences, Health and Food
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Carey has extensive experience advising companies and corporations from the pharmaceutical, cosmetics, medical devices and food industries at a national and international level.
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01

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?

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.

2. What is the regulatory framework for the authorization, pricing, and reimbursement of drugs, biologicals, and 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. We will later provide more information on the provisional use of pharmaceutical products.

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.

Additionally, during 2020, modifications were made to Supreme Decree No. 3/2010 with the purpose of modifying the conditions for the abbreviated registration procedure and incorporating a new accelerated registration process, as will be described.