

REPORT

# The Pharmaceutical Industry in Chile:

*Installed capacity, stakeholders  
& investment incentives*

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1.

# THE PHARMACEUTICAL INDUSTRY IN CHILE

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**InvestChile** - Foreign Investment Promotion Agency

  [www.investchile.gob.cl](http://www.investchile.gob.cl)

The pharmaceutical industry in Chile has shown some interesting developments in recent years. The pandemic has fostered greater interest in innovative developments, particularly in vaccines and pharmaceuticals. Evidence of this is the presence of Chinese biopharmaceutical company Sinovac - Biotech Ltd. in the country and Chile's return to domestic vaccine production.

The following data from the "Estudio del Impacto de la Industria Farmacéutica en Chile" (Study of the Pharmaceutical Industry's Impact in Chile) (Harrison & Carrasco, 2020), published by the Federation of Chilean Industry (SOFOFA), offers some interesting contextual information:

- Each year the sector contributes a total of approximately US\$1.8 billion, or 0.82% of total value added, equal to 0.73% of the country's GDP. This contribution has a positive indirect impact on other sectors of the local economy, including the manufacturing industry (17%), wholesale and retail sales (13%), transportation (8%), and other professional, scientific, and technical services (8%).
- In terms of employment, the pharmaceutical industry effectively generates more than 68,000 formal jobs annually (direct, indirect, and induced), accounting for 1.03% of all employment in Chile.
- The industry's productivity -expressed in value added per worker- is ranked second highest in the country, after the transportation and telecommunications sector, and almost one-third higher than the manufacturing industry average.
- The study concludes that the pharmaceutical sector extended average life expectancy in Chile by 0.8 years from 1986 to 2000, and by 1.27 years from 2000 to 2009, accounting for 40% and 73%, respectively, of overall life expectancy increases in the country during those periods.



In 2018, the domestic market accounted for 71.97 million UF (an indicator whose value in pesos is adjusted daily in accordance with the Consumer Price Index, approximately USD 3 billion), distributed among pharmacy chains (34.74 million UF), the public market (21.64 million UF), independent pharmacies (8.51 million UF), and private institutions (7.08 million UF). These figures are taken from the “Informe Final de Estudio de Mercado sobre Medicamentos” (Final Report of the Market Study on Medicines), published by the National Economic Prosecutor’s Office (FNE).

The figures above reflect the importance of the sector, which in Chile has mainly been based on the importation of pharmaceutical products. However, the pandemic has created growth potential in the Chilean market that has attracted foreign companies, which see an opportunity to establish a base for their operations in the country and use it as a springboard for further expansion. A key advantage in this regard is Chile’s extensive network of free trade agreements that favor exports to meet the demand for pharmaceutical products in the region and around the globe.

The section below describes the procedures and timelines set out by the Public Health Institute of Chile (ISP) for authorizing operations involving medicines, clinical trials, and medical devices.

2.

# PUBLIC HEALTH INSTITUTE OF CHILE (ISP)



Since 2016, the Public Health Institute of Chile (ISP) is recognized as a regional reference National Regulatory Authority (NRA) for medicines in the region, along with its counterparts in Argentina, Brazil, Canada, Colombia, Cuba, the United States, and Mexico. The evaluation and approval of NRAs is based on the verification of indicators included in the data collection tool used by the Pan-American Health Organization (PAHO). This instrument was designed according to the recommendations of the World Health Organization (WHO) to strengthen regulatory bodies.

Regional reference NRAs are regulatory authorities categorized in Level 4, the highest level established in the qualification table, which means they are national regulatory authorities that are competent and efficient in the performance of the health regulation functions recommended by PAHO/WHO to guarantee the efficacy, safety, and quality of medicines.<sup>1</sup>

The following entities are crucial to the work of the ISP:

- **ANAMED- Agencia Nacional de Medicamentos (National Drug Agency):**

The ISP, through ANAMED, is responsible for the control of pharmaceutical products that are manufactured locally, exported, or imported for distribution in Chile, verifying their quality, safety, and efficacy. Likewise, it exercises control over manufacturing, storage, distribution, and sale establishments, as well as control of cosmetic products.

- **ANDID Agencia Nacional de Dispositivos Médicos, Innovación y Desarrollo (National Agency for Medical Devices, Innovation, and Development):**

The ISP, through ANDID, is responsible for ensuring the safety and performance of medical devices, including in vitro diagnostic devices used in the country, through activities of control, enforcement, and oversight at all stages of their life cycle. ANDID is also responsible for supporting, promoting, and undertaking in-house applied research on key health issues facing the Chilean people that fall within the ISP's purview, the results of which contribute to scientific knowledge and further public health in Chile.

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<sup>1</sup> See [PanAmerican Health Organization](#)



3.

# AUTHORIZATIONS FOR ESTABLISHMENTS AND MEDICINES

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All pharmaceutical production, conditioning, and quality control laboratories that wish to operate in Chile must undergo a pre-evaluation of their flowcharts and plans before submitting to the evaluation process for authorizing establishments.

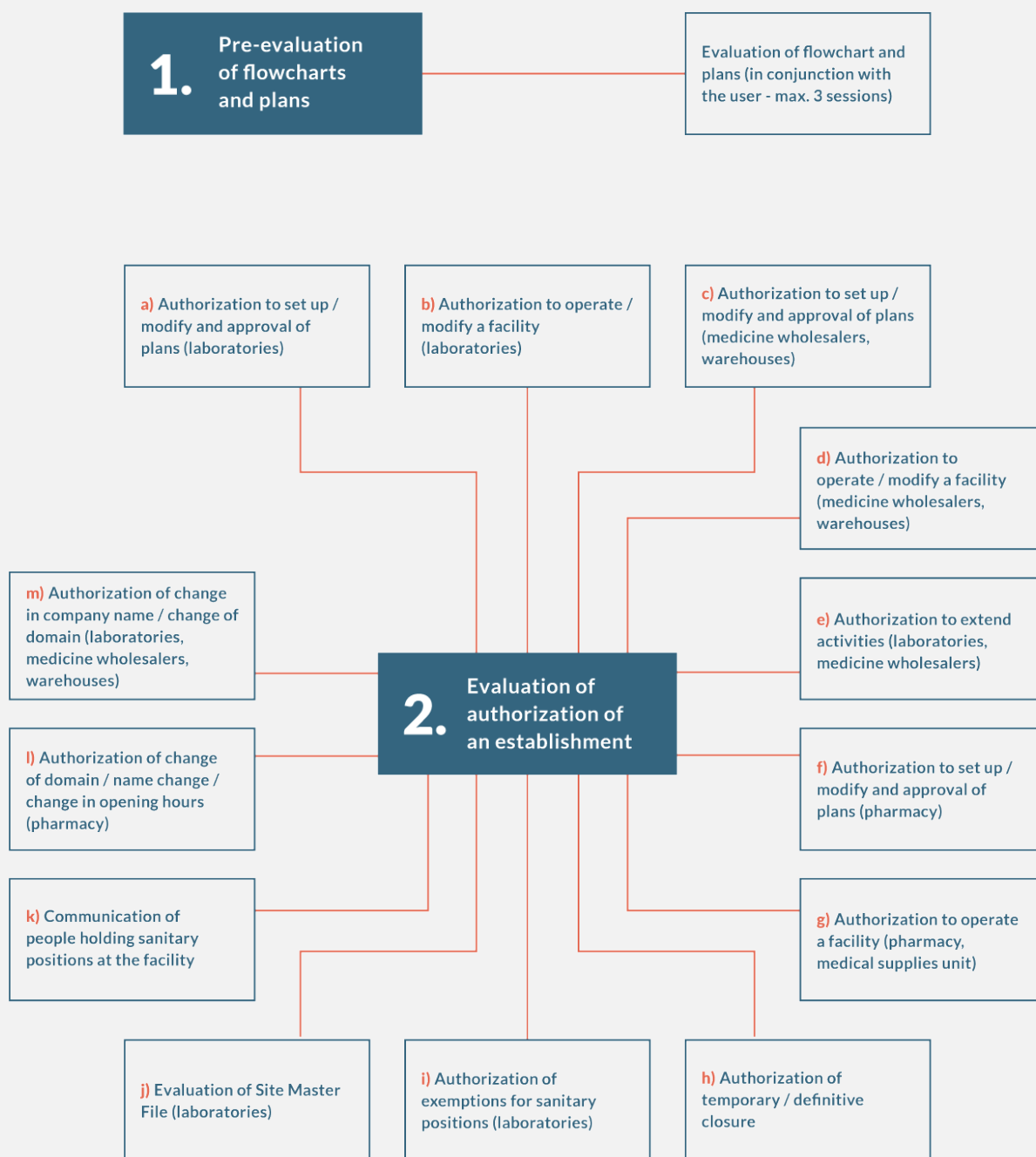


Figure 1: Summary of activities required for authorization of an establishment

Details of the fees<sup>2,3</sup> and technical requirements are published on the ISP's website, [www.ispch.cl](http://www.ispch.cl), for each type of service noted below.

#### AUTHORIZATION OF INSTALLATION AND APPROVAL OF PLANS

Service	Code	Average processing time
Evaluation of flowchart and plans	4122053	100 business days
Pharmaceutical production laboratory	4122024	57 business days
Evaluation of flowchart and plans	4122053	66 business days
Pharmaceutical conditioning laboratory	4122055	72 business days
Evaluation of flowchart and plans	4122053	77 business days
External quality control laboratory	4122001	69 business days
Evaluation of flowchart and plans	4122053	50 business days
Medicine Wholesaler	4160001	35 business days

#### AUTHORIZATION TO OPERATE

Service	Code	Average processing time
Pharmaceutical production laboratory	4122026	70 business days
Pharmaceutical conditioning laboratory	4122056	55 business days
External quality control laboratory	4122003	57 business days
Medicine Wholesaler	4160002	37 business days

<sup>2</sup> <https://www.ispch.cl/productos-y-servicios/prestaciones/> (In Spanish only)

<sup>3</sup> <https://www.ispch.cl/wp-content/uploads/2020/09/Prestaciones-Secci%C3%B3n-Autorizaci%C3%B3n-Establecimientos.pdf> (In Spanish only)



Today in Chile, 27 pharmaceutical production laboratories, 9 pharmaceutical conditioning laboratories,<sup>4</sup> and 47 quality control laboratories are authorized to operate.<sup>5</sup>

All are regularly inspected by the Institute, according to the guidelines set out in Annex 4 of the 37th Report of the WHO on Good Manufacturing Practices (GMP), Annex 1 of the 44th Report of the WHO, and Annex 2 of the 45th Report of the WHO on Good Laboratory Practices (GLP). There are also up-to-date guides for GMP and GLP inspections, which support the work of inspectors and are useful to the regulated entity as well, as they set out the requirements of routine inspections and identify critical aspects of each one. These guides are available on the ISP website (Exempt Resolution 1230 of 2020 and 1660 of 2016).<sup>6</sup>

According to the inspection and monitoring system implemented by ANAMED, each pharmaceutical laboratory authorized is subject to regular inspections at least once every three years, which enables adequate oversight of risks associated with the manufacture and control of medicines.

Chile has an installed capacity to safely store and distribute pharmaceutical products and vaccines through its authorized wholesalers and warehouses. These must strictly comply with the requirements of the Good Storage and Distribution Practices, which are mandatory for these kinds of establishments.

There are also specific requirements for establishments that store and distribute refrigerated and frozen products, to ensure that these sensitive products are stored and transported under proper conditions (Technical Standard 208). These establishments are also inspected under ANAMED's monitoring and oversight programs.

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<sup>4</sup> <https://www.ispch.cl/anamed/establecimientos-farmaceuticos-y-cosmeticos/laboratorios-de-produccion/> (In Spanish only)

<sup>5</sup> <https://www.ispch.cl/anamed/establecimientos-farmaceuticos-y-cosmeticos/laboratorios-farmaceuticos-de-control-de-calidad/> (In Spanish only)

<sup>6</sup> <https://www.ispch.cl/normativa-anamed/>

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There is a robust and strict regulatory framework for the manufacture, control, storage, and distribution of medicines, with clear guidelines for establishments. These regulations are available on the Public Health Institute website:<sup>7</sup>

- Good Manufacturing Practices:

Technical Standard 127 approved under Exempt Decree 159 of 2013 and Technical Standard 173, approved under Exempt Decree 1284 of 2014.

- Good Laboratory Practices:

Technical Standard 139 approved under Exempt Decree 543 of 2012 and Technical Standard 180, approved under Exempt Decree 919 of 2015.

- Good Storage and Distribution Practices:

Technical Standard 147, approved under Exempt Decree 57 of 2013.

- Good Practices for the Storage and Transport of Refrigerated and Frozen Medicines:

Technical Standard 208, approved under Exempt Decree 48 of 2019.

The Institute also authorizes and oversees bioequivalence and biowaiver research centers in Chile, with 43 domestic and international centers currently authorized.<sup>8</sup> Among these, 19 in vivo or in vitro bioequivalence research centers are currently operating in Chile, and 5 offer third-party services; there is also a permeability (R+D) laboratory that serves Chilean and international third parties.

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<sup>7</sup> <https://www.ispch.cl/normativa-anamed/> (In Spanish only)

<sup>8</sup> <https://www.ispch.cl/anamed/bioequivalencia/centro-de-estudios-de-bioequivalencia-bioexencion/> (In Spanish only)

### 3.1. Authorization of Clinical Studies.

The ISP, through the National Drug Agency ANAMED, authorizes or denies authorization for the use of pharmaceutical products in clinical studies and ensures that studies are conducted as per Good Clinical Practice (GCP) and current national legislation and standards, which are consistent with international guidelines, to ensure the protection of participants and the quality of the data obtained from the research. Special provisional authorization for research purposes has a maximum duration of one year, with the possibility of successive yearly renewals.

Noteworthy aspects of conducting clinical studies in Chile:

- There is a clear regulatory framework that sets out criteria for implementing scientific research projects with human subjects. These regulations define the rights and responsibilities of the patients and owners of the study, the standards that must be met, and other aspects.<sup>9,10,11</sup>
- The timeframe for the evaluation and authorization of clinical trials involving pharmaceutical products is 45 days.
- The National Medicines Agency of Chile inspects clinical trials conducted at research centers.
- The Public Health Institute maintains a public record of all scientific research with human subjects involving pharmaceutical and other medical elements.

To conduct a clinical study, the applicant must present the following, among other documents:

- Research project
- Informed consent form
- Insurance policy to a Scientific Ethics Board, accredited by the health authority

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<sup>9</sup> [Supreme Decree No. 3/10 Approving Rules for the National System for the Control of Pharmaceutical Products for Human Use](#) (In Spanish only)

<sup>10</sup> [Decree Law 725/67 of the Sanitary Code](#) (In Spanish only)

<sup>11</sup> <https://www.ispch.cl/anamed/estudios-clinicos/notificacion-easris/> (In Spanish only)

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It should also present other documents detailed in the following link:

<https://bit.ly/3Me2yHI>

- Trial protocol in English and Spanish, including the tentative deadline for carrying out the study.
- Researcher's Manual in English and Spanish.
- Informed consent and assent form (if applicable), approved by an accredited Scientific Ethics Committee.
- Graphic labeling project for the product to research.
- Total amount of pharmaceutical products used in the study, including placebos.
- Favorable report for the execution of the trial, issued by an accredited Scientific Ethics Committee.
- Letter stating that the pharmaceutical product will be imported or manufactured in the country.
- Copy of the sanitary resolutions of the establishments that will participate in the trial.
- Specific requirements for clinical laboratories.
- Certificate of compliance with Good Manufacturing Practices for the establishment that manufactures the pharmaceutical product to be used in the clinical study.

Once the Clinical Scientific Ethics Committee issues a favorable report, these documents must be sent to the ANAMED Department requesting authorization for the pharmaceutical products slated for use in the clinical study. Once the corresponding authorizations have been obtained from the ISP and the director of the research center, the clinical study protocol can be carried out in the country (Figure 2: Flowchart for Clinical Studies).

It should be noted that the ISP, through ANAMED, inspects pharmacological clinical trials to verify compliance with current regulations and with Good Clinical Practices.

While a clinical study is being conducted, reactions, adverse situations, or serious events can arise that affect the health of the participants to varying degrees. The Sponsor (owner of the study) or their representative must report such occurrences to the ISP.<sup>12</sup>

#### CLINICAL STUDIES

Service	Code	Average processing time
Request authorization for the importation, manufacture, or provisional use of a pharmaceutical product for the purpose of clinical studies.	4111035	28 business days
Renew annual authorization for the importation, manufacture, or provisional use of a pharmaceutical product for the purpose of clinical studies.	4111108	15 business days

<sup>12</sup> [Law 20.120 Regarding Scientific Research on Human Beings, their Genome, and the Prohibition of Human Cloning](#) (In Spanish only)

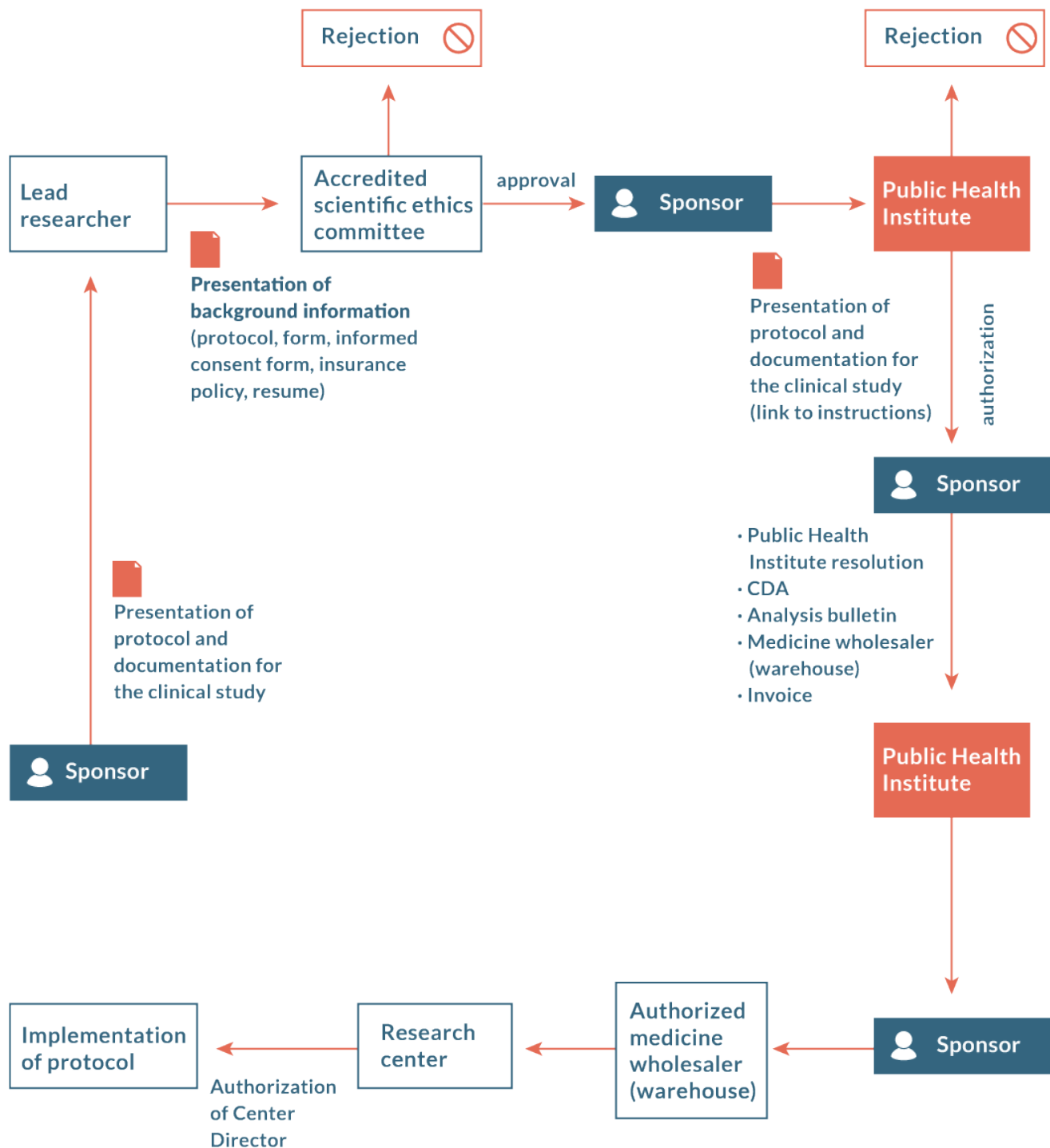


Figure 2: Flowchart of Clinical Studies







### 3.2. Sanitary Registration Authorization.

For the sanitary registration process, all pharmaceutical products imported to or manufactured in Chile for distribution or use of any kind within the national territory must hold a sanitary registration (Article 20 of Supreme Decree 3/10).<sup>13</sup>

The sanitary registration of a pharmaceutical specialty consists of an evaluation process and systematic study of its pharmaceutical, pharmacological, toxicological, and clinical properties to verify its quality, safety, and efficacy. When authorized, the product is recorded on a special consecutively numbered register maintained by the ISP, which enables and authorizes its distribution and use in the country. Different sanitary registration procedures exist:

- Ordinary registration: 6-month maximum for evaluation, from the date the corresponding fee is paid, and once the admissibility evaluations are complete.
- Simplified registration: 5-month maximum for evaluation.
- Abbreviated registration: 4-month maximum for evaluation.
- Fast-track registration: 3-month maximum for evaluation, not applicable to biological products.

Details of the fees<sup>14,15</sup> and technical requirements for medicine registration are published on the ISP website, [www.ispch.cl](http://www.ispch.cl), for each type of service noted below.

<sup>13</sup> Supreme Decree 3/10 Approving Rules for the National System for the Control of Pharmaceutical Products for Human Use (In Spanish only)

<sup>14</sup> <https://www.ispch.cl/productos-y-servicios/prestaciones/> (In Spanish only)

<sup>15</sup> <https://www.ispch.cl/wp-content/uploads/2020/09/Prestaciones-Secci%C3%B3n-Autorizaci%C3%B3n-Establecimientos.pdf> (In Spanish only)

## ADMISSIBILITY AND SANITARY REGISTRATION

Service	Code	Average processing time
Admissibility of the request for ordinary registration of pharmaceutical products.	4112126	10 to 30 business days
Ordinary registration of pharmaceutical products.	4112127	6 to 8 months for non-biological products
Admissibility of the request for simplified registration of pharmaceutical products.	4112124	20 business days
Simplified registration of pharmaceutical products.	4112125	3 to 5 months

It should be noted that the form for submitting information for the sanitary registration process, approved in Resolution 2232 of September 14, 2020,<sup>16</sup> is based on the *Common Technical Document* (CTD), which offers a set of specifications that combine all reference material on quality, safety, and efficacy in a single form that accompanies a request for medicine registration in Chile. This common registration dossier, valid in any of the three ICH regions (Europe, United States and Japan), guarantees the quality, safety and efficacy of the drug and is accepted by most of the regulatory agencies in the world.

Details of the registration requirements and procedure are found in the document: *Procedimiento de registro sanitario de medicamentos en Chile* (Procedure for sanitary registration of medicines in Chile), which is on the ISP website.<sup>17</sup> Annex I sets out the procedure for obtaining sanitary authorization.

<sup>16</sup> [https://www.ispch.cl/wp-content/uploads/2021/03/Procedimiento-de-registro-sanitario-de-medicamentos-en-Chile\\_revisado\\_jefatura\\_03\\_03\\_2021.pdf](https://www.ispch.cl/wp-content/uploads/2021/03/Procedimiento-de-registro-sanitario-de-medicamentos-en-Chile_revisado_jefatura_03_03_2021.pdf)

<sup>17</sup> [https://www.ispch.cl/wp-content/uploads/2021/02/2232-2020\\_Formato\\_presentaci%C3%B3n\\_antecedentes\\_para\\_registro.pdf](https://www.ispch.cl/wp-content/uploads/2021/02/2232-2020_Formato_presentaci%C3%B3n_antecedentes_para_registro.pdf)  
(In Spanish only)

Currently, 12,300 pharmaceutical products are registered with the ISP, which can be consulted at the following link <https://registrosanitario.ispch.gob.cl/>. Also, more than 120,000 cosmetic products are registered in the country.

It is important to note that requests can be processed online through the Public Health Institute's web platform, which is linked to the National Customs Service (SNA) electronic processing system. This system reduces SNA processing times for importers and exporters, as the two agencies share authorizations associated with imports and exports.

For more information on the foreign trade process, visit the following link <https://bit.ly/36uZCW7>.

Details of the fees<sup>18,19</sup> and technical requirements for the foreign trade process are published on the ISP website, [www.ispch.cl](http://www.ispch.cl), for each type of service noted below.

For more information on guides and instructions related to the ANAMED Department, visit the following link <https://bit.ly/3Me373V>.

## FOREIGN TRADE

Service	Code	Average processing time
Certificate of Customs Destination (CDA), Law 18.164	4111027	2 hours
Authorization for the use and disposition of products subject to ISP sanitary control and covered under Law 18.164 (by product)	4111109	24 hours
Notification of export (by product)	4111103	2 hours

<sup>18</sup> <https://www.ispch.cl/productos-y-servicios/prestaciones/> (In Spanish only)

<sup>19</sup> <https://www.ispch.cl/wp-content/uploads/2020/09/Prestaciones-Secci%C3%B3n-Autorizaci%C3%B3n-Establecimientos.pdf> (In Spanish only)



# 4. REGULATIONS AND SANITARY REGISTRATION OF MEDICAL DEVICES



The current general regulations governing medical devices (MD) in Chile are found in Health Ministry Supreme Decree 825/1998.<sup>20</sup>

The current regulatory regime requires ISP sanitary registration for seven kinds of medical devices.

Sanitary registration of a medical device may be requested by the legal manufacturer domiciled in Chile or by an authorized representative or owner. Quality must be accredited.

To market, distribute, or use the following medical devices on national territory, the sanitary authorization granted by the ISP must first be obtained, as required by current regulations:

- Single-use latex surgery gloves (D.S. 342/2004)
- Single-use latex medical exam gloves (D.S. 342/2004)
- Rubber latex condoms (D.S. 342/2004)
- Single-use sterile hypodermic needles (D.S. 1887/2007)
- Single-use sterile hypodermic syringes (D.S. 1887/2007) N°1887/2007)
- Synthetic male condoms (D.S. 93/2018)
- Female condoms (D.S. 93/2018)
- Portable Automatic External Defibrillators (D.E.N 42/2021)

To submit an online application (GICONA), applicants can use the online information processing system, <https://bit.ly/3rNgP5s>.

More information on service codes and their respective fees is available on the ISP website: <https://www.ispch.cl/prestacion/9100003/>.

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<sup>20</sup> <https://www.ispch.cl/normativa-andid/> (In Spanish only)

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## 4.1 Customs Destination Certificate (CDA)

All medical devices imported to Chile must obtain permission from the ISP and the CDA to be transported from the custom's facility to a warehouse.

Information on medical devices not requiring sanitary registration can be found at the following link <https://bit.ly/3LBCxB5>.

For medical devices that require sanitary registration, the application can be made through the GICONA web platform, <https://bit.ly/3rNgP5s>.

## 4.2. Compliance Verification for In Vitro Diagnostic Reagents

Exempt Resolution 4.331 of 2016, of the ISP, published in the Official Gazette on December 2, 2016, establishes compliance verification criteria for in vitro diagnostic reagents used for serological screening by blood services. The resolution requires Chilean blood banks to use ISP-approved screening kits and also empowers the ISP to verify the compliance of all in vitro diagnostic reagents used for serological screening (in serum and plasma specimens) of donors at the country's blood donation services.

Under Resolution 4.331, before selling its products, each company must request compliance verification for in vitro diagnostic reagents for Hepatitis B, Hepatitis C, HIV, HTLV I-II, Syphilis, and Chagas disease screening.

To do so, it must meet the requirements set out in Form ANDID/013 and in the Instruction Sheet for Form ANDID/013. Once the admissibility criteria are met and all information required in the above-mentioned forms is provided, the applicant company must submit the “Request for Admissibility of Compliance Verification for In Vitro Diagnostic Reagents,” Code 9100013. Once the documentation submitted is found to be complete and correct, a Resolution of Admissibility is issued, so the verification of the reagent’s compliance can proceed.

Once this Resolution of Admissibility is in hand, the applicant company must officially submit the “Request for Compliance Verification for an In Vitro Diagnostic Reagent,” attaching the form applicable to the kit that needs to be verified. Each reagent has its own specific form, depending on the diagnostic marker:

- COVID-19 Form, Code 9400001
- Chagas Disease Form, Code 2330023
- HTLV I/II Form, Code 2156027
- Hepatitis C Form, Code 2155032
- Hepatitis B Form, Code 2155031
- HIV Form, Code 2155028
- Syphilis Form, MHA-TP test, Code 2130013
- Syphilis Form, USR test, Code 2130009
- Syphilis Form, RPR test, Code 2130008
- Syphilis Form, VDRL test, Code 2130007

Applicants are advised to read the available Technical Sheet for each test service provided.

Lastly, an ANDID Department professional will notify the applicant company by email of the date when the reagent will be evaluated and will coordinate how the rulings will be conveyed.

### 4.3. Compliance Verification for COVID-19 Tests

According to ISP Exempt Resolution 1.586 of 2021, companies can voluntarily submit the compliance verification of their SARS-CoV-2 virus diagnostic kits.

Compliance verification has two stages:

The Admissibility stage and the Compliance Verification stage.

The forms, instruction sheets, and technical sheets for this process are available at the following links:

- [http://www.ispch.cl/prestaciones?field\\_codigo\\_value=9100013&title=](http://www.ispch.cl/prestaciones?field_codigo_value=9100013&title=)
- [http://www.ispch.cl/prestaciones?field\\_codigo\\_value=9400001&title=](http://www.ispch.cl/prestaciones?field_codigo_value=9400001&title=)

For kits that do not meet the criteria outlined above, the company in question may choose to obtain a Certificate of Review of Information Accompanying a Medical Device, issued by the Public Health Institute (ISP), which will review the information attesting to the quality, safety, and effectiveness of the medical device. More information on this process can be found on the ISP website: <https://www.ispch.cl/prestacion/9100002/>



# 5. CHILEAN TRADE ASSOCIATIONS



### **Chilean Chamber of Pharmaceutical Innovation. CIF**

This chamber was established in 1953 as the *Cámara de la Industria Farmacéutica de Chile* (Chamber of the Pharmaceutical Industry of Chile) to promote best practices and foster the development of the industry in Chile. Since then, it has evolved into the CIF, which currently groups together 23 global pharmaceutical research companies present in Chile.

<https://www.cifchile.cl/>

### **Industrial Association of Pharmaceutical Labs. ASILFA**

The ASILFA board consists of highly qualified professionals in the industry and has become a leader in the field and spokesperson to the Chilean authorities and pharmaceutical trade associations in Chile and internationally.

The association's aim is to provide products of the highest quality, produced in accordance with the most demanding international technological standards.

<https://www.asilfa.cl/index.php>

### **Chilean Medical Device Association. ADIMECH**

Founded in December 2017, the association seeks to make a significant contribution to the wellbeing of the Chilean people by providing safe, high-quality, innovative products that have a positive impact on their quality of life.

<https://adimech.org/>



# 6. BENEFITS OF INVESTING IN CHILE



Chile has the most open economy in the world, with the greatest number of free trade agreements with leading global economies. The country was also an early adopter of new technologies and market demands, which has transformed it not only into a natural regional platform for providing low-tariff access to key markets, but also into an excellent laboratory for testing new products and technologies.

Chile also offers incentives such as:

- **R&D Law.** Managed by CORFO, the Chilean Economic Development Agency, the law provides access to a 35% tax credit on first category tax for the amount invested in R&D, while the remaining 65% invested can be considered a necessary revenue-producing expense, regardless of the company's line of business.
- **VAT exemption on imported capital goods.** This provides a VAT exemption for certain imported capital goods destined for a variety of development, exploration, or extraction projects in Chile, including mining, energy, telecommunications, technology research and development, and medical and scientific projects, provided that they represent an investment of at least USD 5 million.
- **Law of 'extreme zones'.** Applicable to the regions of Arica y Parinacota, Tarapacá, Los Lagos (Palena Province), Aysén and Magallanes. Three benefits are offered under this law: (1) tax credit on first category tax ; (2) labor subsidy and (3) DFL 15 – subsidies for investments in production.
- **Tax treaties.** Chile has signed tax treaties with 33 of the globe's leading economies.
- **30 FTAs.** Chile has signed free trade agreements with 64 economies that represent 88% of global GDP.

# InvestChile

## Foreign Investment Promotion Agency

InvestChile is the public organization that promotes Chile internationally as a destination for foreign direct investment, serving as a bridge between investor's interests and the business opportunities the country offers.

We provide tailor-made and individually-focused assistance, working closely with private organizations, public institutions and ministries to plan and offer attractive sectorial projects to promote investment.

Check out our services  
and **let's make your next  
project happen!**



Hubspot International  
Recognition Success Story 2021



The Best Investment  
Promotion Agency in  
South America 2019,  
2020, 2021'



'The Best Investment  
Promotion Agency 2019'

Government Standard  
of Excellence

WEB AWARDS 2017

Government Standard  
of Excellence



## We Advise / We Connect / We Support

### AT EVERY STAGE:



#### PROSPECTION



#### PRE- INVESTMENT



#### LANDING



#### ESTABLISHED COMPANY

### SPECIALIZED SERVICES:

#### Knowledge & Info

- FDI statistics, business opportunity facts & figures
- Market insights & sectorial highlights
- Legal & tax information
- Detailed reports & studies on installation / sector-specific costs
- Portfolios of public projects & tenders

#### Promotion & Advice

- Meeting agenda/e-meetings with public & private players
- Investor delegations & B2B meetings
- Investment roadshows, conferences & workshops
- Detailed information on installation/sector-specific costs
- Investment incentives & special programs (i.e., R+D+i, visas, tax deductions/credits)

#### Guidance & Access

- Dedicated expert-sector managers speaking several languages
- Sector-specific and legal advice on starting up
- Contact with key players within the business ecosystem & site visits
- Assistance in applying for financial incentives & government programs
- Public-private portfolios & public tenders
- Incorporation into the Regional Support Network for projects outside the Santiago Metropolitan Region

#### Permanent Support

- Ongoing assistance for landing & expansion/re-investment
- Policy advocacy
- #InvestChileE-Consulting with immediate -free of charge- assistance to resolve your concerns
- #DoingBusinessfromhome initiative to do business safely and remotely: Virtual Investor's Toolkit with everything you need to facilitate the landing and expansion of your investment project.
- Management of contacts and difficulties with public sector institutions to speed up your investment (i.e., permits, R&D+i, human capital)
- Media management to highlight your company's contribution to the country
- Special advisory on value-added & sustainable development initiatives
- Contact with public and private partners to foster synergies and cooperation

**Over 700 companies advised each year!**

**Find it all with InvestChile!**

# #InvestChileTools to power up your business.

We are an environmentally friendly agency strengthening our commitment to promoting sustainable development in Chile.

Our promotional material is mainly digital, which helps us to raise awareness of 'Why Chile' is the ideal place to invest so that your project prospers.



## How to Invest in Chile

\*中文

A complete guide to setting up your business operations.  
Steps involved in setting up/Incentives for foreign investment/ Intellectual Property/ Chile's tax structure/Environmental legislation/ Visas and foreign visitors/ Personal data protection legislation/Labor laws and social security.



## Sectoriales e-Books

Projections and opportunities in Food, Energy, Mining, Venture Capital and Global Services in Chile.



## InvestChile Talks

The Power of Dialogue.  
Talks and virtual events with speakers from the public and private sectors on the economic situation and investment opportunities in Chile.



## InvestChile Insights

Reports, studies and guides that address FDI-related topics.



## ChinaDesk

Assistance, tools and contents in Mandarin to facilitate your arrival and expansion in Chile.



## Portfolio InvestChile

This public-private portfolio includes over 120 projects in different industries, such as: Infrastructure, tourism, energy and mining.

## References and Bibliography\*

<sup>1</sup> PanAmerican Health Organization: [https://www3.paho.org/hq/index.php?option=com\\_content&view=article&id=1615:2009-sistema-evaluacion-autoridades-reguladoras-nacionales-medicamentos&Itemid=1179&lang=en](https://www3.paho.org/hq/index.php?option=com_content&view=article&id=1615:2009-sistema-evaluacion-autoridades-reguladoras-nacionales-medicamentos&Itemid=1179&lang=en)

<sup>2</sup> <https://www.ispch.cl/productos-y-servicios/prestaciones/>

<sup>3</sup> <https://www.ispch.cl/wp-content/uploads/2020/09/Prestaciones-Secci%C3%B3n-Autorizaci%C3%B3n-Establecimientos.pdf>

<sup>4</sup> <https://www.ispch.cl/anamed/establecimientos-farmaceuticos-y-cosmeticos/laboratorios-de-produccion/>

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<sup>6</sup> <https://www.ispch.cl/normativa-anamed/>

<sup>7</sup> <https://www.ispch.cl/normativa-anamed/>

<sup>8</sup> <https://www.ispch.cl/anamed/bioequivalencia/centro-de-estudios-de-bioequivalencia-bioexencion/>

<sup>9</sup> Supreme Decree 3/10 Approving Rules for the National System for the Control of Pharmaceutical Products for Human Use, <https://www.bcn.cl/leychile/navegar?idNorma=1026879&idParte=>

<sup>10</sup> Decree Law 725/67 of the Sanitary Code, <https://www.bcn.cl/leychile/navegar?idNorma=5595&idParte=>

<sup>11</sup> <https://www.ispch.cl/anamed/estudios-clinicos/notificacion-easris/>

<sup>12</sup> Law 20.120 Regarding Scientific Research on Human Beings, their Genome, and the Prohibition of Human Cloning, <https://www.bcn.cl/leychile/navegar?idNorma=253478&idParte=>

<sup>13</sup> Supreme Decree 3/10 Approving Rules for the National System for the Control of Pharmaceutical Products for Human Use, <https://www.bcn.cl/leychile/navegar?idNorma=1026879&idParte=>

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\* The list corresponds to additional information and sources cited as footnotes on the respective pages, according to relevance

## References and Bibliography\*

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<sup>16</sup> [https://www.ispch.cl/wp-content/uploads/2021/03/Procedimiento-de-registro-sanitario-de-medicamentos-en-Chile\\_revisado\\_jefatura\\_03\\_03\\_2021.pdf](https://www.ispch.cl/wp-content/uploads/2021/03/Procedimiento-de-registro-sanitario-de-medicamentos-en-Chile_revisado_jefatura_03_03_2021.pdf)

<sup>17</sup> [https://www.ispch.cl/wp-content/uploads/2021/02/2232-2020\\_Formato\\_presentaci%C3%B3n\\_antecedentes\\_para\\_registro.pdf](https://www.ispch.cl/wp-content/uploads/2021/02/2232-2020_Formato_presentaci%C3%B3n_antecedentes_para_registro.pdf)

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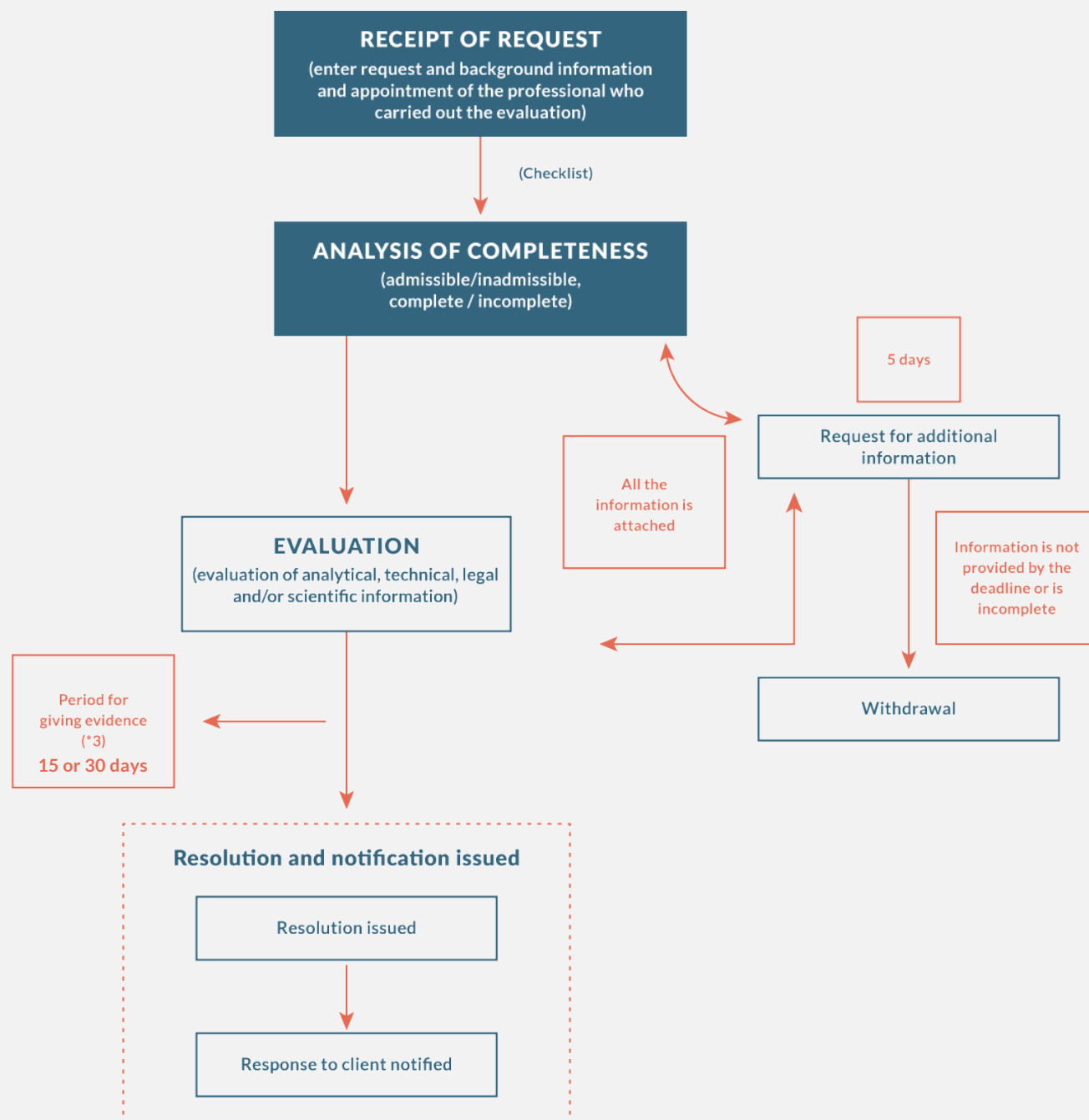
<sup>20</sup> <https://www.ispch.cl/normativa-andid/>

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\* The list corresponds to additional information and sources cited as footnotes on the respective pages, according to relevance

# Appendix

## Sanitary Authorization Procedures





InvestChile Insights - eBook Series

InvestChile<sup>+</sup>  
INVESTMENT EBOOKS Insights

REPORT

# The Pharmaceutical Industry in Chile:

*Installed capacity, stakeholders  
& investment incentives*

1<sup>ST</sup> EDITION: APRIL 2022

InvestChile<sup>+</sup>

