

EMBASSY OF INDIA
SANTIAGO

CHILE
PHARMACEUTICAL MARKET SURVEY
(Updated March 2024)

Commissioned from Ms. Carmen Gloria Fuentealba
on behalf of the



सत्यमेव जयते

Economic Diplomacy Division
Ministry of External Affairs

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This market survey aims to provide relevant information on the pharmaceutical market in Chile so that Indian medicament exporters may get a deep understanding of it and may also develop and execute a successful market entry into Chile.

The survey includes quantitative information such as market size and import and export statistics, among other data. It also contains qualitative information about companies, products, health policies, regulation and registration product requirements, etc.

1. Market Overview

1.1 Pharmaceutical products classification

Supreme Decree 3/2010, Section 7 defines pharmaceutical products as “any substance, natural or synthetic, or a blend of both, intended for human beings for the healing, attenuation, treatment, prevention or diagnosis of diseases and their symptoms, to modify physiological systems or states of mind for the benefit of the person it is administered to”.

For the purpose of this survey, pharmaceutical products will be classified under the following criteria:

- **Over- the-counter products (OTC):** medicaments sold directly to a consumer without a prescription from a healthcare professional. In Chile, there are currently 1.251 OTC products authorized by the public health agency (ISP)
- **Prescription-only medicaments (POM):** pharmaceutical products that may be sold only to consumers possessing a valid prescription. At present, there are 8.005 POM products registered upon the public health agency (ISP)

Prescription only medicaments (POM) will be classified under:

- **Brand-name medicaments:** pharmaceutical products commercialized by the laboratory which is the owner of the corresponding patent.
- **Copycat medicaments:** pharmaceutical products sold by a laboratory different from the drug's original developer, after the patent protections have expired. These products are commercialized under a different brand from the original.

- **Generic medicaments or “generics”:** drugs sold under their chemical name or active pharmaceutical ingredient. This category also includes bioequivalent products, corresponding to medicaments which therapeutic effect has been clinically proven and certified by a competent agency.
- **Private label medicaments (or private label):** drugs sold under pharmacies’ brands. It includes compounded medicaments manufactured at pharmacies’ laboratories massively or upon a prescription.

1.2 Pharmaceutical Market Size

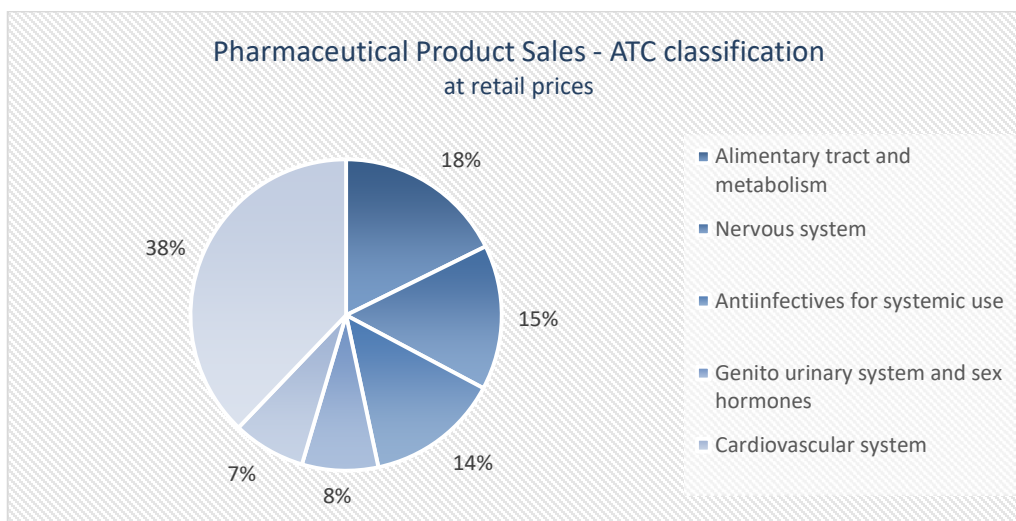
Chile’s pharmaceutical industry moves around US\$1.8 billion, equivalent to 0.73% of national GDP.

According to a survey published by the Federation of Chilean Industry (SOFOFA)¹, the sector indirectly contributes to other sectors of the national economy, such as manufacturing industry (17%), wholesale and retail sales (13%), transportation (8%), and other professional, scientific, and technical services (8%). The industry also contributes in terms of employment, generating more than 68,000 formal jobs (direct, indirect and induced) per year, representing 1.03% of total employment in Chile.

In terms of total sales of pharmaceutical products on the domestic market (at retail prices), the industry accounted for USD 3.226 million in 2022, -13% versus previous year. Among total sales and under ATC classification², most sold pharmaceutical products corresponded to drugs for Alimentary Tract and Metabolism (USD 571.3 million), Nervous System (USD 486.4 million) and Anti-infectives for Systemic Use (USD 447.7 million). See chart below.

¹ “Impact of the Pharmaceutical Industry in Chile survey” (Harrison & Carrasco, 2020),

² The Anatomical Therapeutic Chemical (ATC) classification system divides the active substances into different groups according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties.



Source: OECD Statistics

During the last years, retail market has been boosted by the launch of new products and presentations and by price rising. Price rising has been mainly due to higher costs, as a consequence of several new regulations and of an increase in currency exchange rates. But sold volumes have decreased from 2020, mainly due to the pandemic and the slowdown of the Chilean economy. It is noteworthy that medicament prices are very sensible to exchange rate fluctuations, inasmuch most of them are imported, as well as most of chemical ingredients used for local production.

Despite the above, generic drugs have shown a different behaviour in the last years. Its market growth has been due mainly to volume and, to a lesser degree, to price.

Finally, it is noteworthy that medicament sales show a marked seasonality, doubling in terms of volume during fall and winter seasons (March to September).

1.3 Chilean health overview

1.3.1 Chile health and demographic indicators

According to the Organisation for Economic Co-operation and Development (OECD) ³, life expectancy in Chile was 80.3 years in 2023, the highest of Latin America.

³ Source: Health at a Glance OECD report - 2023

The country also shows the fourth lowest child mortality rate (7.4 per 1.000 live births) and the lowest maternal mortality ratio (13 per 100.000 live births) among American countries.

Despite the above, Chile shows several of the risk factors of the four main non-communicable diseases, that is to say diabetes, cardiovascular diseases, cancer and chronic respiratory diseases. According to a survey conducted in Latin America and the Caribbean, Chile⁴ consumes 8 liters of alcohol per capita per year, about 33% more than the average regional consumption (6 liters). By the other hand, even though the prevalence of tobacco smoking is declining – as a consequence of tax increases and anti-smoking campaigns – Chile continues to be the second highest (25% of daily smokers) of the region.

Contemporary lifestyles marked by unhealthy habits have led to a surge in chronic diseases among the Chilean population. According to the International Diabetes Federation, about 1.75 million adults (or 10.8% of total population) are living with diabetes in Chile and the figures would continue to grow in the next years. Moreover, Chile passed from having the lowest diabetes prevalence in Latin America in 2000, to lead this ranking in 2021. Also, the prevalence of hypertension is 27.6% in people 15 years and older, and approximately 75% in older adults aged 65 years and above.

Moreover, obesity and overweight are on the rise in Chile and are particularly prevalent among men and children. Chile shows the highest adult overweight rate in Latin America and the Caribbean, accounting 46% of total population. Moreover, about 26.4% of the population is obese, +7 points over the average and the fifth highest of OECD countries. Government initiatives (i.e. labelling and advertising control of unhealthy food products and healthy lifestyle promotion campaigns) aim to reverse this situation, but results are barely noticeable yet.

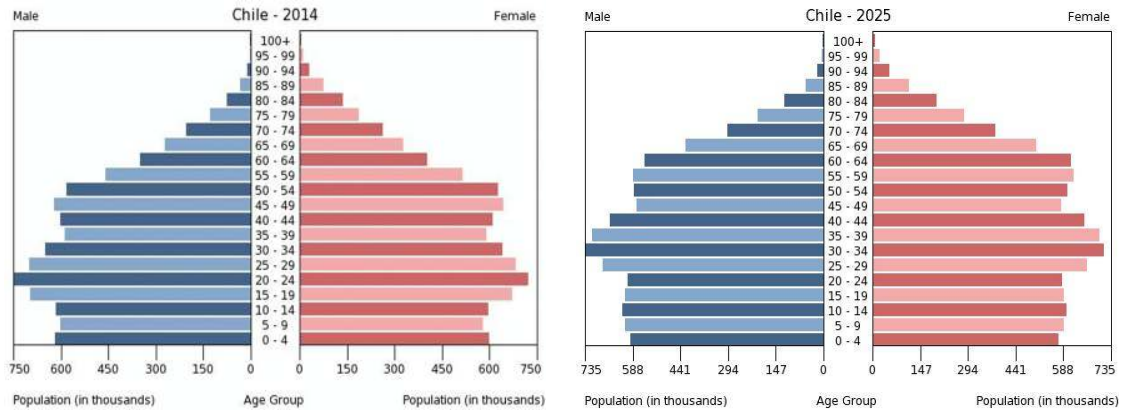
The COVID-19 pandemic has further deteriorated the population's health status, bringing delays in diagnoses and treatments and the increase of waiting lists in the public health system.

It is worth mentioning that low birth and low mortality rates account for Chile's rapid growth of elderly population. Almost 20.1% of total population is in the 0–14 age range, 68.6% in the 15–64 age range, and 11.3% are 65 years or older⁵. It is anticipated that the aging population will continue to increase to represent 20.8% of total by 2044.

⁴ Source: Health Overview: Latin America and the Caribbean 2020 – OCDE and World Bank

⁵ Data correspond to the last Chilean population census (2017). A new census will be conducted in 2024, which results are expected to be available by early 2025.

Chile demographic pyramid – 2014 vs estimate 2025



Source: Indexmundi

All the above factors, together with the increase in the health public expenditure and the fostering of health protection policies, are expected to impact the demand of healthcare services and to boost the pharmaceutical market in Chile in the next years.

1.3.2 Health spending

According to OECD statistics⁶, in 2022 Chile spent USD 2.699 per capita on health, far from the OECD average of USD 4.986 (USD PPP). This is equal to 9.0% of GDP, compared to 9.2% on average in the OECD and the fifth lowest among OECD.

About 62.2% corresponded to government/compulsory financing spending and compulsory health insurance (ISAPRE and FONASA).

Although the share of direct out-of-pocket expenditure by households in total health spending has decreased in the latest years, they accounted for 30.3% of total health spending in Chile in 2022, far from OECD average of 18.6%. From this 30.3%, it is estimated that approximately 40% correspond to medicaments bought in pharmacy retail.

⁶ Source: OECD 2022 Health Statistics (database).

1.3.3 Chilean healthcare system.

Chile's healthcare system incorporates both public and private medical services. Employees are required to participate in either health care system, with a mandatory payment of a percentage of their salaries⁷. It is estimated that 77% of beneficiaries belong to the public system, 17% to the private one and the remaining 6% to other types of health systems.⁸

Public healthcare system is financed through FONASA (National Health Fund or "Fondo Nacional de Salud"). Those who contribute to FONASA can receive treatment through the public healthcare network or can choose a private health care provider and make a co-payment.

The private healthcare system is handled through the ISAPRES ("Instituciones de Salud Previsional"), private institutions that collect and administer the mandatory health contribution from their affiliates. The benefits offered vary depending on the premium paid, the age of the beneficiary and his pre-existent diseases.

Over the last years, the profits of ISAPRES have declined due to increasing healthcare costs and to several lawsuits brought against ISAPRES preventing them from increasing the cost of health plans.

At this time, the continuity of the ISAPRES is uncertain. From one side, the Chilean Supreme Court recently ruled that ISAPRES must retroactively repay to insured beneficiaries approximately USD1.4 billion in premiums. In addition, the Parliament is currently discussing a modification of the Chilean Healthcare law that could result in a universal public healthcare system, letting ISAPRES out of the healthcare system.

In the public health care system, some of the medicaments (previously prescribed by a physician) are given free of cost at hospitals and primary care services, but subject to availability. In the private sector, drugs coverage (full or partial) is, in most cases, limited only to medicaments administrated during hospitalization.

In 2014, Chilean government created a program called "Fondo de Farmacia", that provides some specific drugs – free of cost – to patients attended in public healthcare centres and suffering from arterial hypertension, diabetes mellitus II and high cholesterol.

⁷From 2018 on, self-employed workers are also required to pay a percentage of their income for paying social security contributions.

⁸ Source: "Fonasa Annual Report 2022"

Additionally, in 2005, Chilean government implemented the GES Programme (Explicit Health Guarantees)⁹. For a list of 87 diseases, Chileans – belonging to the public or the private healthcare system - are granted the right to access to health care (including drugs) within a certain period of time and with maximum co-payment. Illnesses representing the highest number of patients under this system are arterial hypertension, depression, diabetes, and hypothyroidism. It is expected that new diseases will be added to GES list in years to come.

The Law No. 20.850/2015 of the Ministry of Health (best known as “Ley Ricarte Soto”)¹⁰ created a financial protection system for high-cost diagnostics and treatments for public and private health insurance beneficiaries. Financial coverage includes specific pharmaceutical products, foods or medical devices for 28 serious diseases (other will be probably added in the future). Pharmaceutical products included in this system are bought by the public sector through CENABAST (see 4.1.1).

1.4 Pharmaceutical sector prospects

According to Statista, the pharmaceuticals market in Chile would generate a revenue of US\$ 2.446 M in 2024. Oncology drugs is expected to be the largest segment, with an estimated market volume of US\$ 471.9 M.

The industry is expected to achieve a steady annual growth rate of 6.24% from 2024 to 2028, resulting in a market volume of US\$ 3,116 M by 2028.

In the long term, it is projected a significant rise in total Consumer health (OTC) and Pharma sales, reaching an estimated value of US\$ 5.320 M by the year 2035.¹¹ This growth will be driven mainly by the aging population (see 1.3.1) and the management of chronic diseases (as diabetes and hypertension).

⁹ For further details on GES programme, click on this link <https://www.supersalud.gob.cl/difusion/665/w3-propertyvalue-1962.html>

¹⁰ For further details on “Ricarte Soto law” and of the specific pharmaceutical products having financial coverage, click on this link: <http://leyricartesoto.fonasa.cl/>

¹¹ Source: Chameleon Pharma Consulting Group.

2. Imports and exports

Import and export statistics contained in this section correspond to pharmaceutical products classified under the following Harmonized System (HS) code chapters:

Chapter	Description
30.01	Glands and other organs (extracts, secretions thereof) for organo-therapeutic uses, dried, powdered or not; heparin and its salts; other human or animal substances for therapeutic or prophylactic uses.
30.02	Human blood; animal blood for therapeutic, prophylactic or diagnostic uses; antisera, other blood fractions, immunological products, modified or obtained by biotechnological processes; vaccines, toxins, cultures of micro-organisms (excluding yeasts) etc.
30.03	Medicaments; (not goods of heading no. 3002, 3005 or 3006) of two or more constituents mixed together for therapeutic or prophylactic use not in measured doses or in forms or packing for retail.
30.04	Medicaments; (not goods of heading no. 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic use, put up in measured doses (incl. those in the form of transdermal admin. systems) or packed for retail sale.
30.05	Wadding, gauze, bandages (dressings, adhesive plasters and poultices), impregnated or coated with pharmaceutical substances or in forms or packing for retail sale, for medical, surgical or veterinary use.
30.06	Pharmaceutical goods

2.1 Imports

During the last 5 years, pharmaceutical product imports have been growing in terms of CIF value, accounting for USD 2.246 million in 2023, +36.8% in a period of five years.

The significant increase observed from 2021 corresponds mainly to COVID vaccines imported in the framework of a massive government vaccines campaign. In 2021, vaccines imports accounted for almost 21% of total pharmaceutical imports.

Annex 1 includes contact data of local pharmaceutical product importers and distributors, as well as institutions and associations that are relevant for the pharmaceutical market.

Total Pharmaceutical products Imports

	2019	2020	2021	2022	2023
CIF Value (in M US\$)	1.642.185	1.734.852	2.467.053	2.337.145	2.246.774

Source: Chilean Customs Statistics

2.1.1 Imports by type of product

In 2023, almost 63.7% of imported pharmaceutical products corresponded to products classified under the HS chapter 30.4, followed by chapter 30.2 (28.2%).

Total Imports by type of product (in M USD)

HS Chapter	2019	2020	2021	2022	2023
30.01	11.593	20.180	12.300	20.603	16.550
30.02	437.360	476.634	969.682	814.936	634.043
30.03	9.739	8.149	9.661	12.443	11.308
30.04	1.071.993	1.110.595	1.306.206	1.116.221	1.431.678
30.05	38.923	41.842	57.818	59.560	48.469
30.06	81.245	77.452	111.386	113.382	104.726
Total	1.642.185	1.734.852	2.467.053	2.337.145	2.246.774

Source: Chilean Customs Statistics

Most of the drugs commercialized in Chile are imported, as same as a high percentage of raw materials (i.e. chemical products) used in local production.

Pharmaceutical products are imported at different stages of production, such as:

- Products packed in their final presentation for sale.
- Products packed in their primary package (blister, bottle, ampoule, etc.). The local importer repacks (i.e. cardboard boxes) and labels them.

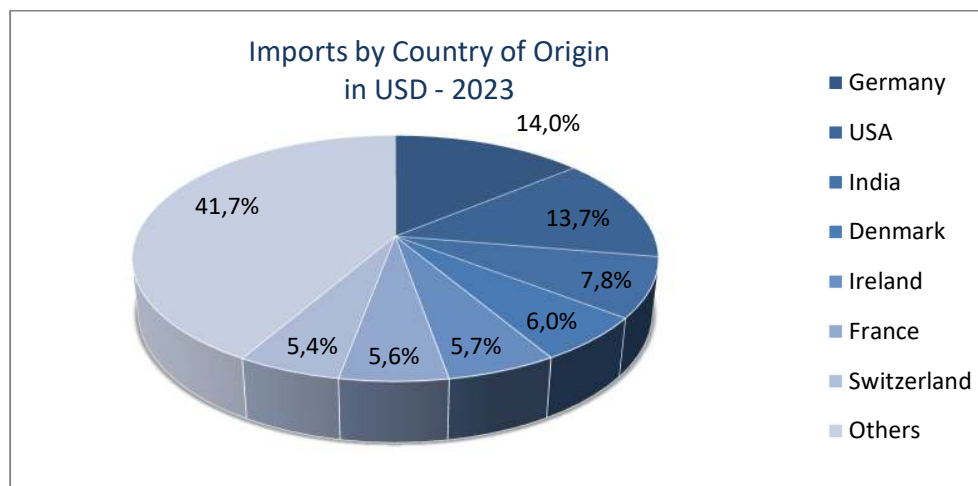
- Product in bulk. The importer conducts locally all the packing and labelling process

Almost all Chilean imports corresponds to the first two stages.

2.1.2 Imports by country

Pharmaceutical product imports are quite atomized in terms of country of origin, coming from 82 different countries in 2023.

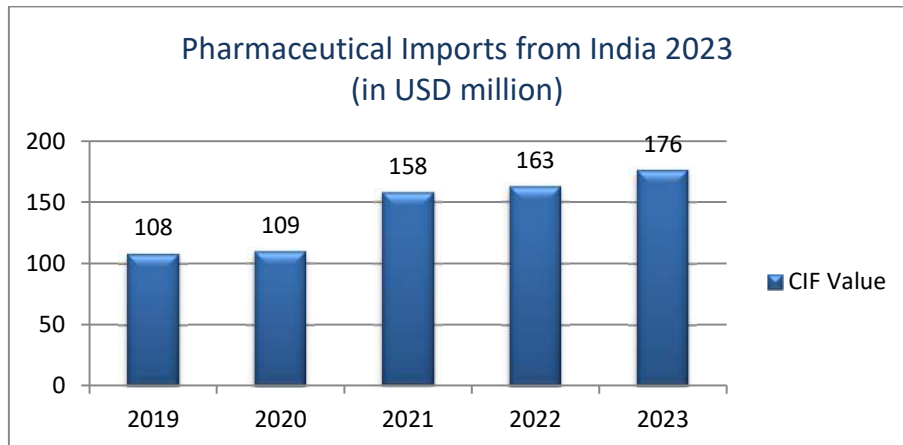
In 2023, 58.3% of total imports came from 7 different countries, being the main ones Germany (14.0%), USA (13.7%) and India (7.8%).



Source: COMTRADE - UN

In 2023, imports from India accounted for about US\$ 176 million, representing a significant growth (+ 62.9%) compared to 5 years ago. Within the same period, India has ranked in the 3th and 4th position in the ranking of Chilean import countries of origin of medicaments. By the other side, Chile ranks in the 28th position of India pharma exports to the world and in the 2nd position of India pharma exports to Latin America, after Brazil.

In terms of type of product, in 2023 most pharmaceutical imports from India correspond to products belonging to HS chapter 30.4 (90.3%) - which correspond to finished products, reflecting the trend of growing value addition by Indian exporters. Imports classified under HS chapter 30.02 (3.1%) - corresponding mainly to vaccines - ranked in second position.

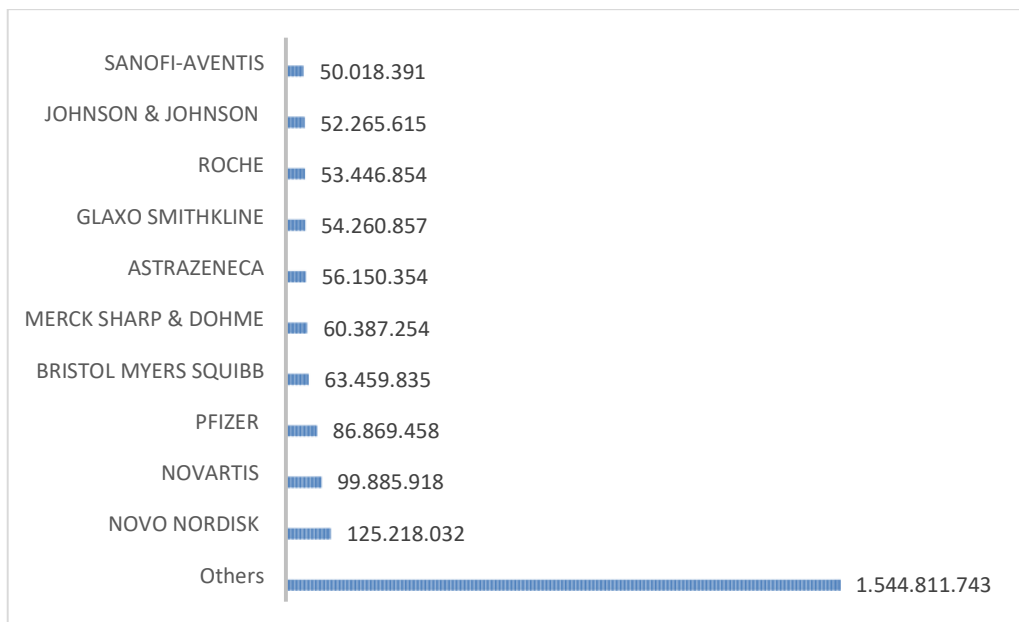


Source: Chilean Customs Statistics

2.1.3 Imports by company

In 2023, almost 556 Chilean companies and natural persons imported pharmaceutical products, showing a quite atomized total market. Ten of these importers gathered around 31.2% of total imports. See chart below.

Pharmaceutical Imports by Company – 2023 (CIF Value)- In M USD



Source: Chilean Customs Statistics

In 2023, a total of 154 companies and natural persons imported pharmaceutical products from India. About 42.5% corresponded to 3 companies: Ascend Laboratories (subsidiary of Alkem Laboratories), Opko Chile and Libra Chile.

It is important to note that some Indian companies - such as Dr Reddy's Laboratories (with commercial offices in Chile), Lupin Laboratories, Sun Pharma and Glenmark Pharmaceuticals - have local production facilities in other countries. As some of these units also export, it is possible that some of their products are imported into Chile, but would not be registered as Indian products.

2.2 Exports

During the last 5 years, Chilean exports of pharmaceutical products have not been significant, accounting for only 6.5% of total imports in 2023. See chart below.

Total pharmaceutical products exports

	2019	2020	2021	2022	2023
FOB Value (in M US\$)	174.756	161.260	171.758	212.067	203.645

Source: Chilean Customs Statistics

In 2023, almost 55% of exports correspond Saval, Synthon and Bago Laboratories.

Almost all Chilean pharmaceutical exports were to Latin American countries. Main ones were Equator, Paraguay, Bolivia and Peru. Most exported products corresponded to medicaments classified under HS chapter 30.04

3. Competition Analysis and Market Characteristics

This section will analyse the main companies that compete in the Chilean pharmaceutical market. A number of the leading pharmaceutical companies are currently commercializing their products in Chile competing with some reputed local companies.

Even if Chilean pharmaceutical market operates under a free trade model, there are several provisions that companies should meet to be able to commercialize their products (see Chapter 5).

It is noteworthy that pharmaceutical market has been in under the permanent scrutiny of the Chilean National Economic Prosecutor's Office due to several cases of price collusion of laboratories and pharmacies, some of them materialized in lawsuits resulting in sanctions and fines.

Besides, this section also analyses some characteristics of the Chilean pharmaceutical market, in terms of products, prices, consumer behaviour and promotion.

3.1 Companies

In Chile, there are 27 companies duly registered upon health authorities as production laboratories. These companies can produce, import, pack and fractionate pharmaceutical products and raw materials used in this industry.

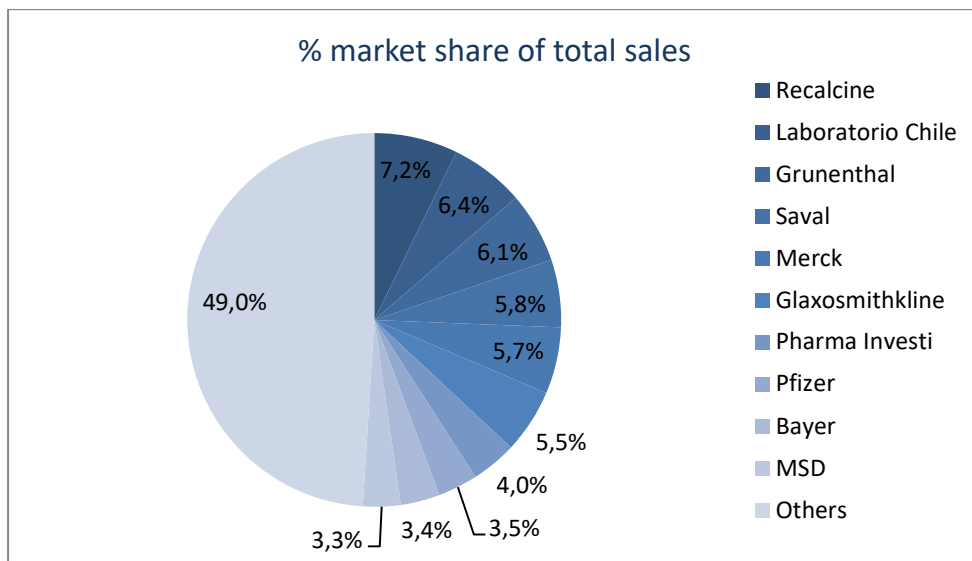
By the other side, there are 9 companies registered as conditioning laboratories, being authorized to conduct processes which do not alter the product primary package. Some of these companies do not commercialize directly their products to final consumers, but provide services to importer laboratories, i.e. labelling and secondary package process (cardboard boxes).

Companies that only import products and do not conduct any production, packing, storage or distribution process are not obliged to be registered upon health authorities.

In total, there are about 75 local and international pharmaceutical companies operating in Chile, dedicated to medicine production and/or import.

3.1.1 Retail sales – main actors

The following chart shows main laboratories and their market share considering total retail sales.



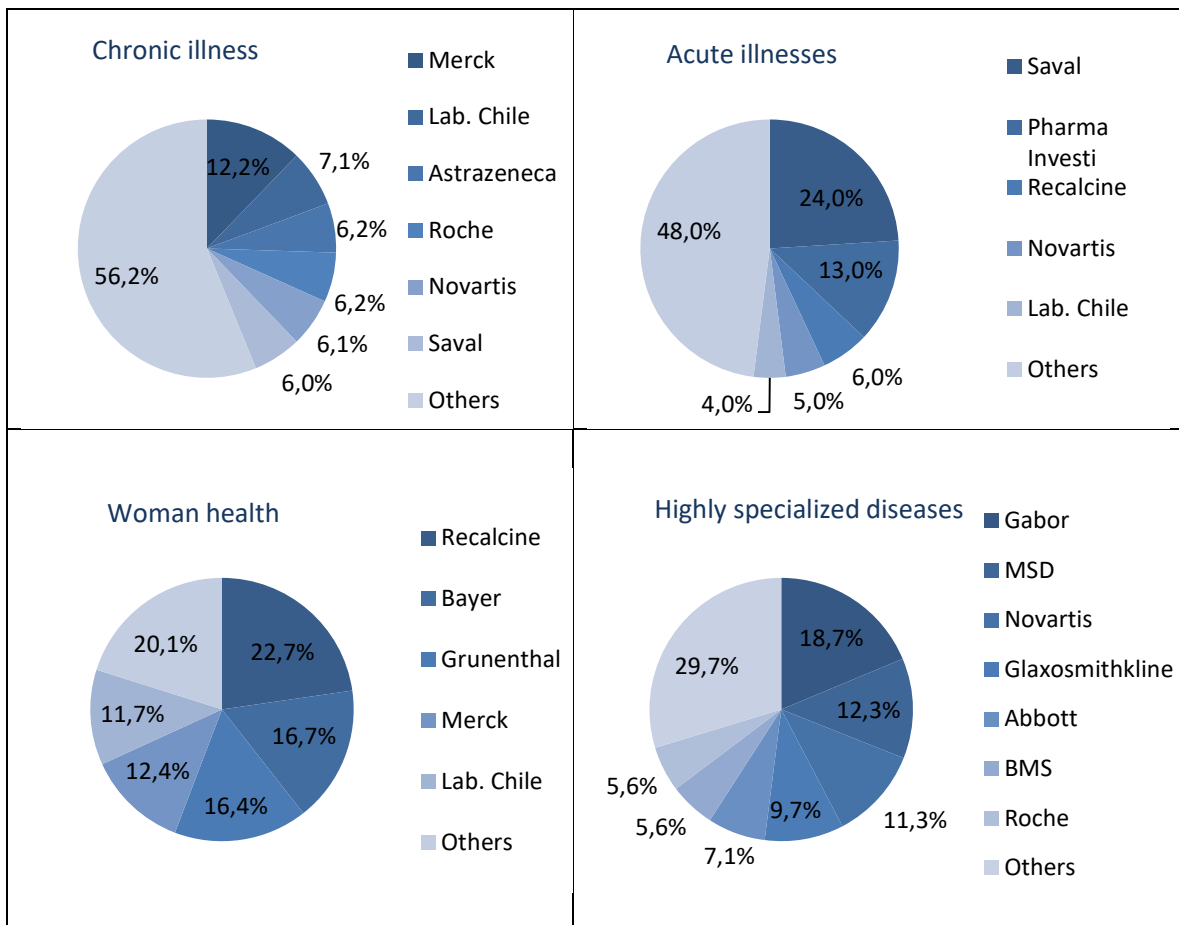
Source: IMS Health

Among these main companies, 3 are local manufacturing laboratories (Recalcine, Laboratorio Chile and Saval), even if the 2 first have been bought by international pharmaceutical companies (Abbott and Teva, respectively).

National laboratories mainly commercialize copycat and generic products, while most multinational companies compete on the domestic market through innovative branded products (some of which are protected by patents).

Even if there are a large number of companies competing, in several therapeutic categories there are only a few competitors, moreover in the case of specific treatments. The following chart shows the companies participating in some of the main therapeutic categories: Chronic Illnesses (cardiovascular, diabetes, respiratory, ophthalmology, etc.), Acute Illnesses (antibacterial, pain relievers, anti-inflammatory, etc.), Woman Health (hormones, contraceptives) and Highly Specialized Diseases (HIV, oncology, immunosuppressive, etc.).

% Market share per therapeutic category



Source: IMS Health

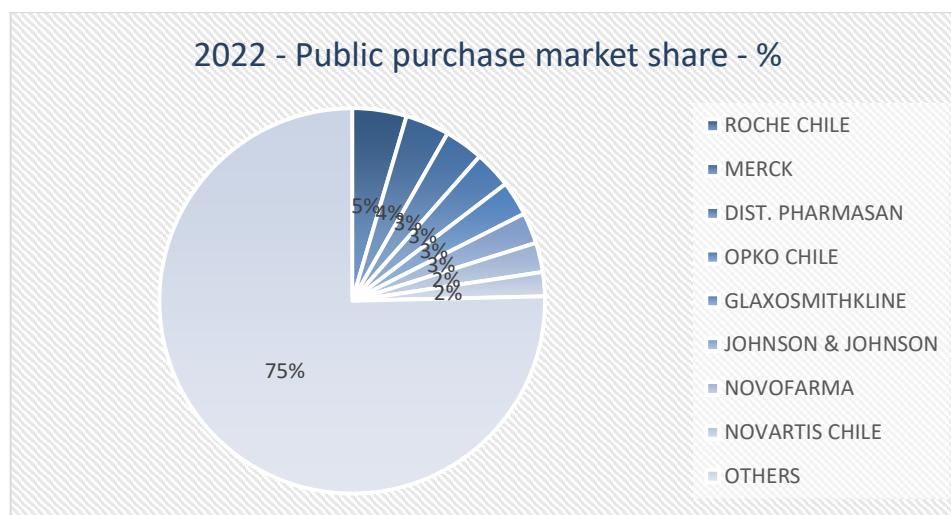
It is worth mentioning that, in line with the Chilean consumer trend toward a healthy and natural lifestyle, there are some laboratories dedicated to produce drugs and food supplies with natural ingredients, such as herbs, plants and seeds. This is a fast-growing market that also includes specialized pharmacies and specialty stores.

3.1.2 Public purchases - main actors

CENABAST manages most of the medicament purchasing processes for public sector, that is, for public hospitals and healthcare centres and ministry programmes. The agency also supplies private and municipal pharmacies (see 4.1.1).

In total, CENABAST represents about 30% of the pharmaceutical product sales in Chile. In 2022, CENABAST purchases were quite atomized. The agency bought to 261 suppliers a total

of 1.768 different products. The following chart shows main CENABAST suppliers, in terms of purchase share.



Source: CENABAST 2022 annual report

3.2 Products

The following list shows the most sold medicaments in Chile, in terms of volume¹². Most of them are generics, while the rest are copycat medicaments.

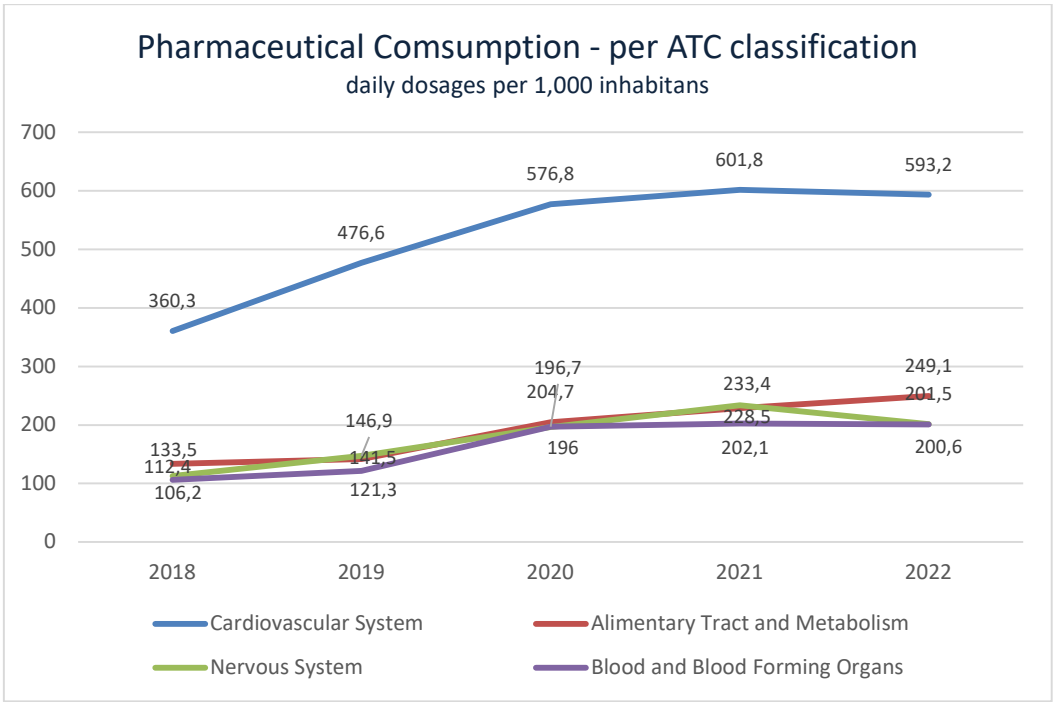
Most sold medicaments – Total sales – 2021 (in volume)

Comercial Name	Active Ingredient	Sales volume (in units)
Paracetamol 500 mg. tablets	Paracetamol	6.359.427
Losartan 50 mg. tablets	Losartan	4.733.831
Ibuprofen 600 mg. tablets	Ibuprofen	4.709.576
Ketorolac 10 mg. tablets	Ketorolac	4.313.806
Anti migraine tablets	Caffeine +Ergotamine + Metamizole	4.003.226
Zopiclone 7.5 mg.	Zopiclone	2.890.661
Mefenamic acid 500 mg. tablets	Mefenamic acid	2.847.559
Naproxen 550 mg. tablets	Naproxen	2.710.259
Ketoprofen 200 mg. tablets	Ketoprofen	2.710.139
Chlorpheniramine Maleate 4 mg. tablets	Chlorpheniramine maleate	2.489.255

Source: ANAMED - ISP

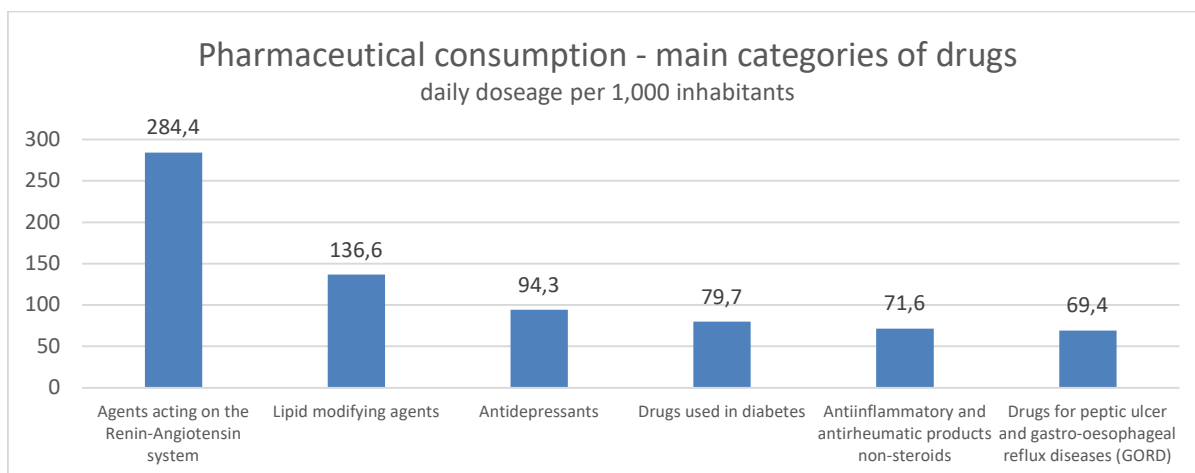
¹² Source: Information provided by ANAMED (National Agency of Medicaments).

According to OCDE statistics, main consumed pharmaceutical products in Chile per organ or system on which they act (ATC classification) are for Cardiovascular System, Alimentary Tract and Metabolism, Nervous System and Blood and Blood Forming Organs. All of them (in terms of daily dosages per 1,000 inhabitants) have increased considerably within the last years. See the following chart.



Source: OCDE Health statistics

The following chart shows main categories of drugs consumed in Chile in 2022 (in terms of daily dosage per 1,000 inhabitants):



Source: OCDE Health statistics

3.3 Prices

Prices and margins are not regulated by authorities at any stage of the distribution chain. However, due to price collusion cases detected among laboratories and pharmacies, there authorities have established certain are some rules to follow.

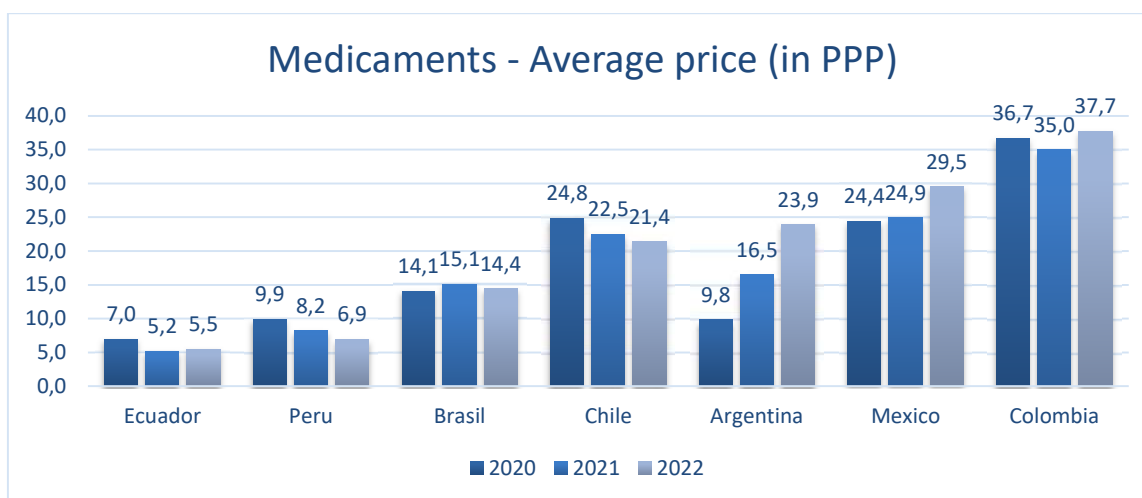
Pharmaceutical product suppliers (manufacturers, importers, distributors, pharmacies and others) are compelled by law to disclose the prices of the products they sell, as well as their discount policy per volume range, temporary price offers, payment terms, guaranties, etc. Price discrimination toward small retailers or pharmacies vis-a-vis pharmacy chains is explicitly forbidden by law.

The above price information should be permanently updated and preferably published in the supplier's web site, if available.

Suppliers are obliged to separately include any additional cost in their sale invoices, such as special exhibitions, promotions, etc.

It is important to mention that – according to a survey conducted by ANACAB/Ipsos¹³– Chile ranks fourth in Latin America in terms of highest prices in medicaments (after Colombia, Mexico and Argentina). In parallel, Chile showed a decrease in the average medicament price within the period 2020-2022.

¹³ Survey conducted in 7 Latin-American countries 2020-2022, including 87 medicaments.



Source: ANACAB/Ipsos

This price reduction in latest years is consistent with the increase in competition in the retail pharmacy segment, due to the entry into the market of several new independent pharmacies and the entry into force of the “CENABAST law” (see 4.1.1).

3.4 Consumer Behaviour

In Chile¹⁴, 57.5% of the population consume at least one active pharmaceutical ingredient. This percentage is higher in the case of women (68.2%) and +65 years old (89.4%). The prevalence of polypharmacy (+ 5 active ingredients) is 12.8%.

Most of the population (86%) state that the medicament they are taking has been prescribed by a physician (generalist or specialist). And 65.2% obtained the medication in a public hospital or health centre, while 30.4% bought it in a pharmacy.

Only 20% of consumers compare different alternatives¹⁵ when buying a POM or OTC medicament. In the case of OTC drugs, the main reason for not comparing is that they are used to/buy always a specific brand (43%).

Related to POM medicines, main reason for not comparing is that the brand was recommended by their physician (56%). And even after comparing, 96% of consumers

¹⁴ National Health Survey 2017

¹⁵ Source: Medicament Market Survey 2020. Fiscalía Nacional Económica FNE

finally decided to buy the brand recommended by their doctor, showing the strong influence of the medical prescription.

Nevertheless, consumers are open to switch to another POM brand under certain conditions. 73% of consumers declare they would do it if a national health institution certifies the replacement medicament has the same effect. And 48% would buy another brand if the pharmacy chemist or seller recommend one with the same effect and at a lower cost.

Finally, there is a growing trend among consumers to prefer products made of natural ingredients to protect their health, promote their wellness or even to cure diseases. According to the Latin American Alliance for Responsible Nutrition (ALANUR), 48% of Chileans are active consumers of nutritional supplements, being vitamins (55%) and Minerals (23%) the main ones.

3.5 Advertising and Promotion

In Chile, only OTC medicines are authorised to conduct advertising and promotion activities to final consumers. These activities should be previously authorised by the Institute of National Health (ISP) and should be in line with what is stated in the product's sanitary register.

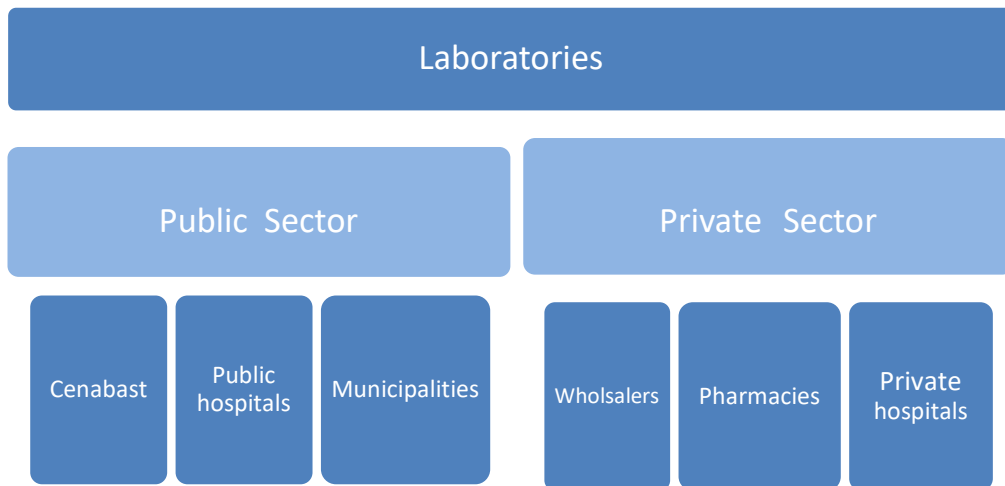
Advertising should communicate only the information contained in the patient leaflet, totally or partially.

The donation of medicines for advertising purposes is forbidden, with the exception of samples to physicians. At this respect, any product information for health professionals should be given exclusively to those authorised to prescribe medicines and to pharmacy chemists.

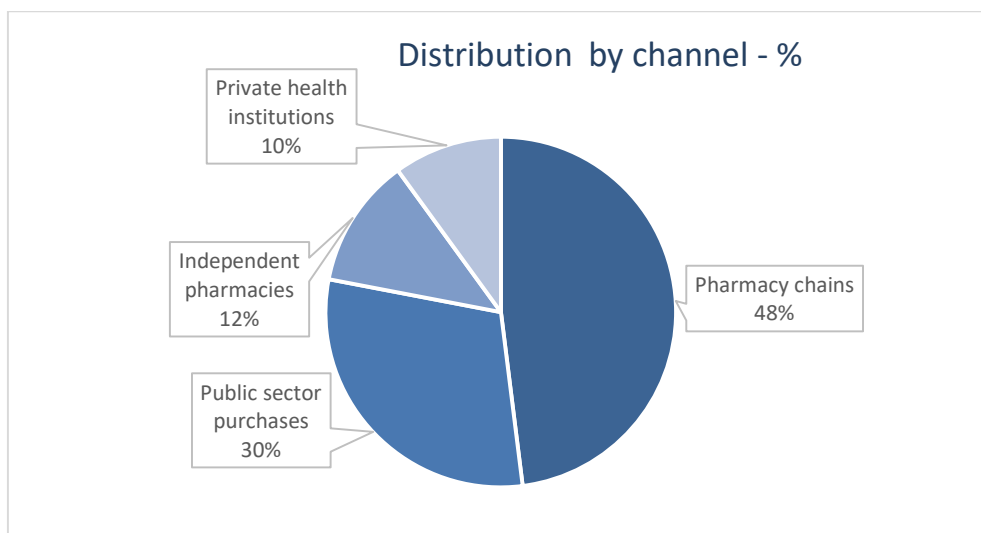
Incentives (understood as payment, gifts, services or economic benefit) intended to induce the usage, prescription, sale or administration of pharmaceutical products to any person are forbidden. Nevertheless, many laboratories – especially the bigger ones – still conduct strong drug marketing toward physicians, such as invitations to congresses (in Chile and abroad), visits of laboratory representatives and sample and promotional material delivery, among others.

4. Distribution channels

The following chart shows main distribution channels for medicaments in Chile.



Even if in latest years the independent pharmacy segment has grown significantly, the distribution of pharmaceutical products - in terms of total purchases - is still quite concentrated in the pharmacy chains (48%), followed by the purchases conducted by the public sector (30%) for public hospitals, health centres and health programmes. See chart below.



Source: FNE (Fiscalía Nacional Económica)

4.1 Public Sector

The regulatory framework for public procurement in Chile¹⁶ applies to public procurement of goods and services from all public entities at the levels of Central Government, Regional and Provincial Governments, Municipalities, Armed Forces, and General Comptroller.

The legislation establishes four procurement instruments: framework agreements, public bidding, private bidding, and direct contracting. Contracting in the first two options (the most used in case of medicaments) is done via an electronic platform called “Mercado Público” (www.mercadopublico.cl).

In the case of public bidding, the call may also be published in other means of calling for competition at international, national or regional level. Foreign bidders are allowed to submit offers but it is highly recommended to appoint a representative in the country, to take care of the importing procedures, storage and distribution.

In framework agreements, the prices of goods and services are agreed with the suppliers. Government agencies get these prices through purchase orders under the conditions specified in the agreements.

Main public sector medicaments buyers are CENABAST, Public Hospitals and Municipalities.

4.1.1 CENABAST

CENABAST (www.cenabast.cl) is a public agency belonging to the Ministry of Health, in charge of the procurement and distribution of medicaments, medical supplies and goods. CENABAST clients are public hospitals and primary healthcare centres as well as the Ministry of Health for their complementary feeding and health programs.

In addition, and in the framework of the called “CENABAST law”, the agency is allowed to supply products (limited to a predetermined list of medicaments) to private and municipal pharmacies. These latest can then benefit of the better prices obtained by CENABAST’s large volumes of purchases.

Depending on the demand, CENABAST prepares purchasing processes of a predetermined list of medicaments¹⁷ which are conducted through “Mercado Público” platform.

¹⁶ Regulatory framework is governed by Law 19,8666 of July 2003 and its further modifications.

¹⁷ To review the list of medicaments, click in this link <https://www.cenabast.cl/listado-de-productos-farmaceuticos-codificados/>

In 2022, total CENABAST purchases accounted for almost US\$ 1.085 million, placing it as the largest Chilean public buyer in the “Mercado Público” platform.

It is important to mention that CENABAST also imports products, in case of insufficiency or inaccessibility in the domestic supply for public health programs. Most of the import operations are in the framework of the product intermediation conducted by the Pan American Health Organization (PAHO). Nevertheless, from 2020, India has been a key supplier of vaccines and anaesthetics.

4.1.2 Public hospitals

In 2022, Chile had 324 hospitals and a total of 37.871 beds. From them, 199 belonged to the public sector.¹⁸

Public hospitals purchase medicaments to CENABAST or directly to laboratories - through the government purchase e-platform (“Mercado Público”) - in case of medicaments CENABAST have not available (i.e. not included in its predetermined medicament list or out of stock). As a general rule, public hospitals do not import medicaments directly.

4.1.3 Municipalities

In Chile, most of primary healthcare centres are run by municipalities. These centres can include low-complexity community hospitals and urgency services, as well as general, family and rural healthcare centres. In total, municipalities operate 2.463 ambulatory health centres.

Some municipalities – motivated by the high cost of medicaments in Chile - created non-profit pharmacies (known as people’s pharmacies) to sell drugs at low cost to their commune residents. These stores usually offer 20% to 80% discount compared to retail. Currently, there are 212 municipality pharmacies distributed in 170 communes.

As well as in the case public hospitals, municipalities can buy medicaments for their healthcare centres and municipality pharmacies to CENABAST or directly to laboratories through “Mercado Público” platform.

¹⁸ Source: Clínicas de Chile A.G. 2022

4.2 Private sector

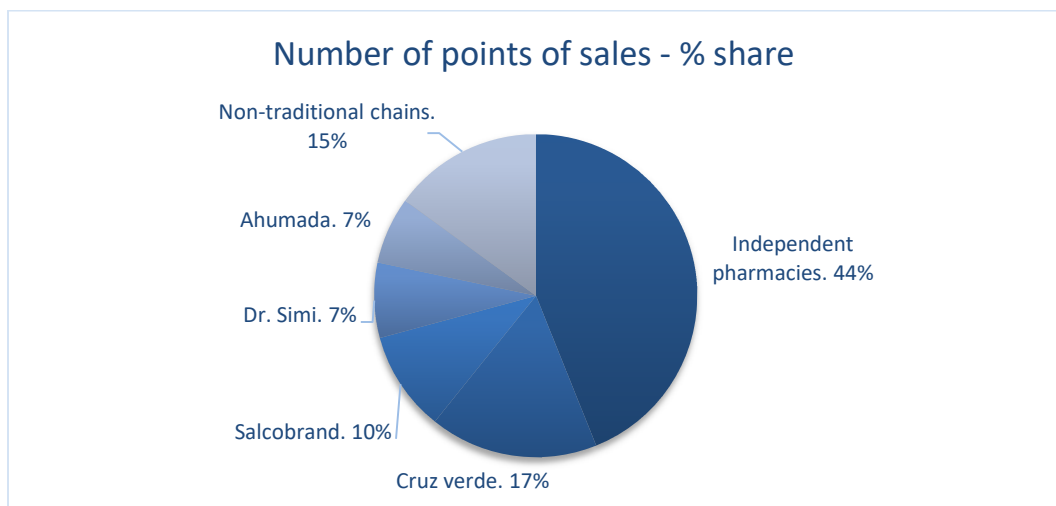
Private sector distribution channels mainly include the retail, composed by pharmacies (chains and independent) and pharmaceutical distributors. Together, they represent almost 67% of the market. They also include institutional sales to private hospitals and clinics.

4.2.1 Pharmacies

In terms of total sales, the Chilean pharmacy market here is dominated by 4 pharmaceutical chains: Salcobrand, Ahumada, Cruz Verde and Dr. Simi.

The first 3 ones are vertically integrated; that is to say, have their own laboratories which manufacture and/or import private label products. Most of these products correspond to OTC medicaments, medical supplies and cosmetic and personal care products. Some of them also prepare compounded formulas upon medical prescription.

In terms of points of sales, independent pharmacies are more numerous. In 2023, there were 4.437 pharmacy points of sales in Chile. About 1.940 (43.7%) corresponded to independent pharmacies, while 1.814 (40.9%) were points of sales belonging to the main 4 pharmacy chains: Cruz Verde, Salcobrand, Dr. Simi and Ahumada. The remaining 663 outlets corresponded to non-traditional chains (i.e. Knopp, Ecofarmacias, Redfarma, etc.). See chart below.



Source: ISP

It is worth mentioning that independent pharmacies have significantly increase their presence in the latest years, passing from 1.276 outlets in 2019 to the current 1.940 (+52%). They have found a market niche in locations where main pharmacy chains have closed their less-profitable outlets and have become more competitive by procuring from CENABAST (see 4.1.1)

Pharmaceutical chains have a strong negotiation power vis-à-vis laboratories. Negotiation usually includes discounts per volume, price promotion campaigns and advertising in pharmacies catalogues, among others.

It is worth mentioning that in 2020, the Ministry of Health issued a Supreme Decree ruling the e-commerce of pharmaceutical products, opening the gate to new competitors in the field of medicine distribution. Pharmacies should be previously approved by the ISP to operate online and are subject to some obligations.¹⁹ Currently, there are several pharmacies selling online, some of them independent and others as part of the main pharmacy chains.

4.2.2 Distributors

Distributors gather a large stock of medicaments and medical supplies from different laboratories and distribute them mainly among small independent pharmacies.

They usually participate as bidders in public tenders through “Mercado Público” Platform. Their advantage in this case is that they can offer product options from different laboratories, as well as to take care of the storage and distribution.

According to IMS Health, distributors represent about 21% in terms of volume and almost 10% in terms of value of total pharmaceutical retail sales. Some of them are Socofar, Pharmasan, Farma 7 and Schubert.

4.2.3 Private hospitals and clinics

In 2022, Chile accounted for 125 private hospital and clinics²⁰²¹, with a total of 11.456 beds. Some of them are vertically integrated, as they belong to the ISAPRES (“Instituciones de Salud Previsional”).

Private hospitals and clinics usually purchase drugs and medical supply purchases directly to laboratories located in Chile, establishing in some cases, long and medium-term agreements, benefiting of discounts per volume.

¹⁹ For more details about obligations related to pharmaceutical e-commerce, as well as the list of online pharmacies already approved, click on this link: www.ispch.gob.cl/anamed/comercio-electronico-de-medicamentos/

²⁰ Source: Clinicas de Chile A.G. 2022

²¹ Includes private-owned, armed force, university and occupational-accident mutual hospitals and clinics.

5. Import and commercialization formalities

All pharmaceutical products imported and commercialized in Chile should meet some formalities. Some of them are the usual to any import, but there are some specific to medicaments, necessary to its entry and further commercialization.

Although most of these formalities are conducted by the importer, it is advisable that the exporter be aware of the documentation and product requirements necessary to fulfil the Chilean regulation.

The Supreme Decree 3/2010²² rules the importation, exportation, production, manufacturing, fractioning, commercialization or storage of pharmaceutical products and every other product used in and applied to human medicine and natural and legal persons involved in said activities.

Said activities may be carried out only, with the previous authorization and under the control of the Institute of Public Health (ISP).

5.1 Registration of Pharmaceutical products

5.1.1 General procedure

Pharmaceutical products should be subject to the previous authorization of the national health authority. They must be registered with a special registry in the Institute of Public Health (ISP), namely, the Sanitary Registry of Pharmaceutical Products (“Registro Sanitario de Productos Farmacéuticos”).

This sanitary registration is independent of the patent registration of a drug and/or other aspects inherent to a pharmaceutical product (presentation, formulas, production processes, etc.). Patent information concerning a new drug is neither requested nor verified when sanitary registration is granted. See Section 6.5.

It should be noted that approvals granted by international agencies (i.e. FDA or EMEA) are favorable background for the registration process but they do not eliminate or bypass it.

²² Find the complete text of the Supreme Decree 3/2010 by clicking on the following link:
http://www.ispch.cl/sites/default/files/decreto_3_0.pdf

The applications for registration of pharmaceutical products with the Sanitary Registry, which has the nature of an affidavit, should be filled according to an established procedure. In general terms, they should include general data, technical information, pharmaceutical quality information and safety and efficacy information.

There is a simplified registration procedure in the following cases:

- Products containing the same active ingredients, in the same quantity and using the same route of administration than already registered products (not benefiting of exclusivity period)
- Products, which active ingredients are sufficiently known and which efficacy, safety of usage and adverse reactions are described in the scientific literature.
- Products that are pharmaceutically equivalent to another already registered, which active ingredients are part of a list of ingredients having specific norms to follow to demonstrate their therapeutic equivalence (bioequivalence).
- Products manufactured in Chile for the sole purpose to be exported.

The registration process and the information and document submission to the Institute of Public Health (ISP), as well as the payment of the involved fees, is done online using the Institute's on line system called GICONA²³.

5.1.2 Bioequivalent products

According to current Chilean regulations, to be considered as therapeutically bioequivalent compared to a reference medicine, a drug must:

- Have a sanitary registration in force.
- Comply with Good Manufacturing Practices (GMP) and quality management.
- Submit a pharmacokinetic study of comparative bioavailability, proving to have the same efficacy and safety than the reference product.

Studies intended to demonstrate therapeutic equivalence should be submitted to the Institute of National Health (ISP) and follow a pre-established procedure²⁴. They could be

²³ Find the procedure for submitting sanitary registration applications by clicking on these links:

Ordinary Procedure: www.ispch.cl/wp-content/uploads/prestaciones/15296/4112126.pdf

Simplified Procedure: www.ispch.cl/wp-content/uploads/prestaciones/15578/4112125.pdf

²⁴ For more information about the procedures, click on this link: www.ispch.gob.cl/anamed/bioequivalencia/

conducted in Chile (by laboratories previously appointed by the ISP) or abroad. In the case of India, there are currently 9 bioequivalence centers duly approved by the ISP²⁵.

Depending on the type of product, requested bioequivalence studies could be “in vivo” or “in vitro”.

It is important to keep in mind that ISP’s bioequivalence procedures have been modified several times within the last years, in many cases to adapt them to the current practices of the FDA and the EMA, as well to the guidelines issued by the World Health Organization (WHO). Therefore, it is advisable that companies always check the regulation in force upon the Institute of Public Health (ISP), before starting a bioequivalence demonstration process.

5.2 Labelling requirements

Medicaments should have a primary and secondary packaging and contain a patient information leaflet.

According to Supreme Decree 3/2010, Section 5, subparagraphs 23 and 24:

- Primary packaging is the layer of packaging used to contain the pharmaceutical product under its definitive form and which comes in direct contact with the product.
- Secondary packaging is the layer of packaging that, apart from being tamper-proof, should allow containing, protecting and preserving the primary packaging.

Products can be exempted from the requirement of the secondary packaging and/or the patient information leaflet, when the primary packaging by itself can guarantee the quality of the product and is able to include the information the secondary packaging and the patient information leaflet should contain.

The labelling information should be printed on the packaging external side or stuck to it. It should not be in contact with its content. The text font should be Arial (or other rectilinear one), which size should be not smaller than 6 points.

²⁵ Check here the list of Chilean and foreign bioequivalence centres appointed by the ISP:
www.ispch.gob.cl/anamed/bioequivalencia/centro-de-estudios-de-bioequivalencia-bioexencion/

The labelling should not contain advertising or promotion claims. In some cases, labelling can include captions or words in other languages in addition to Spanish, but they should not alter the text approved by the Institute during the sanitary registration process.

In case a medicament contains only one active ingredient and has a trade mark, the generic name should be included in the labelling meeting the following requisites:

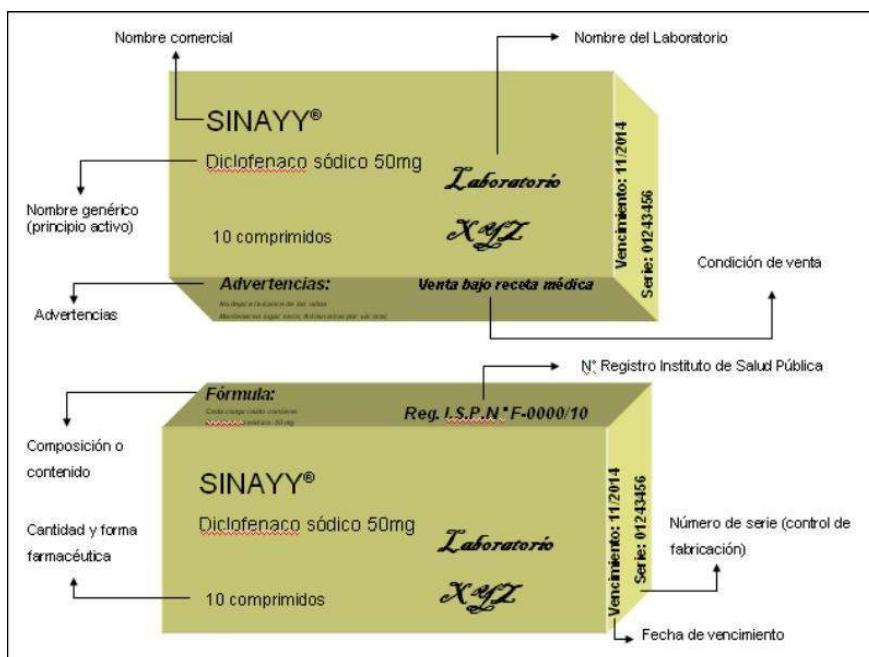
- Should be placed immediately under the name of the product or trade mark.
- Keep the same font and background colour as the name of the product
- Should be printed using a font size not smaller than a half of the font size used for the name of the product, and no smaller than 6 points.
- Should be printed in capitals.
-

5.2.1 Secondary packaging

According to Supreme Decree 3/2010, Section 74, secondary packaging labelling should be in Spanish, written in easily visible characters and including at least the following information:

- Name of the product
- Dosage form (i.e. pill, tablet, capsule, syrup, etc.).
- Unitary dose in mg. or % (in case of products containing only one active ingredient).
- Non-conventional pharmaceutical release form, if it is the case (i.e. extended release caps)
- Number of units
- Name and quantity of each active ingredient and name of the excipients
Example: *“Cada comprimido recubierto contiene: Atorvastatina (como atorvastatina cálcica) 20 mg. Excipientes: Celulosa microcristalina, magnesio estearato, croscarmelosa, hipromelosa, dióxido de titanio”.*
- Name and address of the manufacturer, secondary packaging laboratory, importer or/and distributor, accordingly.
- Route of administration
- Sale condition (over the counter, only on prescription, under filed prescription or under an official prescription).
- Expiration date.
- Sanitary register number, written as “Reg. I.S.P. xxx”
- Batch identification number, written as “serie xxx” or “lote xxx”
- Storage conditions
- The caption “Mayor información en www.ispch.cl”.

See example below:



5.2.2 Primary packaging

The primary packaging labelling should include at least the following information, written in Spanish and in visible characters:

- Name of the product
- Dosage form (i.e. pill, tablet, capsule, syrup, etc.).
- Unitary dose in mg. or % (in case of products containing only one active ingredient).
- Route of administration
- Expiration date.
- Sanitary register number, written as “Reg. I.S.P. xxx”
- Batch identification number, written as “serie xxx” or “lote xxx”

5.2.3 Patient Information leaflet

Prescription-only medicaments (POM) should include a leaflet at least the following information:

Therapeutic indication authorized by the registration resolution.

- Warnings of usage, for example under certain patient conditions (i.e. pregnancy, breastfeeding, allergies, etc.) or activities (i.e. driving, using tools or machinery, etc.)
- Contraindications (i.e. patients with some diseases or medical conditions)
- Interactions (i.e. with other drugs or food/beverages)

- Side effects
- Any other information requested by the Institute of Public Health during the product sanitary registration process

5.2.4 Bioequivalent product labelling

Generic or similar products containing active ingredients included in a predetermined list²⁶ should demonstrate, backed by respective studies and following a strict procedure, that they are equivalent for patients in terms of quality, efficacy and safety.

So far, there are 3.440 products already approved as bioequivalent by the Institute of Public Health.

Bioequivalent products should include a specific logo and a text in their secondary packages.

The logo should be printed in at least 4 of the 6 main sides of the packaging underside, covering at least 20% of their surface. See example below:



²⁶ Find the list of active ingredients that should demonstrate their bioequivalence by clicking on this link: www.ispch.gob.cl/anamed/bioequivalencia/farmacos-y-cronograma-de-exigencia-para-la-demostracion-de-bioequivalencia/

5.3 Import procedures

In the case of any import, an Import Declaration (“declaración de ingreso” or its acronym DIN) should be submitted to the Chilean Customs, using an online system. It should be supported by the following documents:

- Commercial Invoice
- Certificate of Origin
- International Transport Document (Bill of Lading or Air Way Bill)
- Packing List, when necessary
- Value declaration
- Other Documents (i.e. safety certificates)

All imports of a total value exceeding USD 2,000 (FOB) require the participation of a Customs Broker. Minor imports (less than USD 2,000 FOB) can be cleared directly by importers, following a simplified procedure.

Prior import licenses are not requested by authorities. This is valid for any type of goods.

5.4 Duty fees and taxes

The tax treatment applicable to imports into Chile includes the payment of customs duties, Value Added Tax (VAT) and other taxes (if applicable), all calculated on CIF value and determined under GATT valuation standards. Tea imports are subject only to duty taxes and VAT:

The ad-valorem customs duty rate is 6%. However, goods originating in any of the countries or regions having signed a Commercial Agreement with Chile and evidencing such condition by means of a Certificate of Origin can be benefited with a reduction or exemption of import duties.

Chile has signed 33 Commercial Agreements covering 65 economies, which have granted tariff preferences which each country applies to imports.²⁷

India and Chile signed a Partial Scope Trade Agreement (PSA) in 2007 and a further deepening in 2017. It gives tariff preferences (ranging from 20 to 100%) to pharmaceutical

²⁷ Find the list of countries and the complete texts of Commercial Agreements signed by Chile, by clicking on this link: www.direcon.gob.cl/acuerdos-comerciales/

products classified under some specific HS codes.²⁸ This means that imports of these products pay a duty tax ranging from 0 to 4.8%.

At present, both nations are discussing a new deepening of the trade agreement, including more tariff preferences, trade regulatory aspects and rules of origin.

Additionally, medicaments are subject to VAT (value added tax), which rate is 19%.

5.5 Import of pharmaceutical products

Laboratories, drug wholesalers, drugstores, public health entities and, in general any natural person or legal entity are authorized to import pharmaceutical products previously registered with the Institute of Public Health.

Pharmaceutical ingredients can be imported only by drugstores and manufacturing laboratories. Semi-finished products can be imported only by laboratories (devoted to manufacturing, repacking and/or fractioning).

The import and commercialization of pharmaceutical products is subject to two authorizations granted by the Institute of Public Health:

- Custom Destination Certificate (“Certificado de Destinación Aduanera”), authorizing to move the products from Customs area to the establishment (meeting the requirements established by the law) where they will be stored. This authorization is requested for Customs clearance.
- Resolution for Usage and Disposition (“Resolución de Uso y Disposición), which authorizes the usage and distribution of the imported pharmaceutical products.

Both authorizations can be requested at the same time and using the same form through the GICONA on-line system. This can be done before the arrival of the goods to Chile.

Products cannot be used, commercialized or processed in any way until the Resolution for Usage and Disposition is granted.

²⁸ Find the list of pharmaceutical products benefiting of tariff preferences by clicking on www.direcon.gob.cl/wp-content/uploads/2011/03/Anexo-Chile-SA-2017.docx.pdf

5.6 Pharmaceutical product patents

Law 19.039/1991 and its further amendments rule de patentability of pharmaceutical drugs. The amendments brought Chile's intellectual property legal framework in line with TRIPS (WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights).

In addition, Chile joined the Patent Cooperation Treaty (PCT) system in 2009, which facilitates the international filing of patents. By filing one international patent application under the PCT, applicants can simultaneously seek protection for a pharmaceutical product in 193 countries throughout the world.

To be patentable, a pharmaceutical drug must meet three requirements:

- Novelty: A drug will be new if it does not form part of the state of the art.
- Inventive step: A drug involves an inventive step if it is not obvious to a person skilled in the art.
- Industrial application: The new drug must be capable of industrial application.

The law offers patent protection for both pharmaceutical products and processes, providing from 2005 a statutory patent life of 20 years (not extendable) from the application date.

The National Institute of Industrial Property (known as "Instituto Nacional de Propiedad Intelectual" or its acronym INAPI) is the Chilean agency for registering patents, utility models, industrial designs, industrial drawings and layout/designs (topographies) of integrated circuits.

5.7 Trademark protection

Even if it is not mandatory, it is strongly recommended that foreign companies register their trademarks if they aim to use them in Chile. They will permit to uniquely identify a company and its products to its customers and to distinguish them from those of its competitors

It is also advisable that, before using a trademark or logo, companies should check if such signs are already registered in identical terms or in similar terms (from a visual or phonetic point of view).

Trademark protection lasts 10 years and its registration can be renewed indefinitely (for periods of 10 years at a time). According to Chilean law, trademarks cannot be revoked for non-use reasons. The owner of a trademark could authorize a third party to use it under a license contract.

The National Institute of Industrial Property INAPI (www.inapi.cl) is the Chilean agency for registering trademarks, copyrights and appellations of origin. The registration procedure can be done in person or via internet, for a fee. According to Chilean law, it is not necessary to hire a lawyer or trademark agent to file a trademark application. Nevertheless, it is highly recommended in the case of companies having foreign residence, which should appoint a local representative.

6. Market opportunities and conclusions

6.1 SWOT analysis

The following SWOT Analysis is intended to be a useful technique for understanding the Strengths and Weaknesses of India pharmaceutical producers, and for identifying both the Opportunities open to them and the Threats they face in the Chilean market.

SWOT ANALYSIS

Strengths <ul style="list-style-type: none">• Good quality of Indian pharmaceutical products.• Competitive prices• Wide variety of products.• Existence of experienced Indian producers and exporters.• General good image of Indian products.• Duty tax preference (India-Chile Partial Scope Agreement).	Opportunities <ul style="list-style-type: none">• Total market is expected to continue growing in years to come.• Opportunities for generics with demonstrable bioequivalence.• Opportunities for generics for which bioequivalence is not required.• Increase in government purchases for social programmes (i.e. vaccines, Ley Ricarte Soto).• Opportunities to sell directly to CENABAST• Ayurvedic medicaments and natural products.
Weaknesses <ul style="list-style-type: none">• Relatively low experience of India drug exporters in the Chilean market (7.8% of total imports).• Indian exports to Chile are currently limited to a few types of medicaments.	Threats <ul style="list-style-type: none">• Limited number of potential importers/distributors.• Strict sanitary and health requirements, according to Chilean regulation.• High competition from international laboratories.• Very concentrated market.

6.2 Main conclusions

Chilean pharmaceutical market is expected to continue growing, mainly driven by generics. Chilean consumer preference toward less expensive medicaments will increase, in line with the economic slowdown observed in recent years. The Chilean population ageing will also contribute to increase the demand for generics, given that elderly persons have usually a lower disposable income and higher medicament consumption.

Therefore, there are good opportunities for generic products. In the case of medicaments containing the active ingredients included in Chilean bioequivalence regulation, Indian producers should be in position of providing all the necessary technical information and laboratory analysis. It is even possible that importers require Indian manufacturers to partially share the cost of conducting the bioequivalence certification process.

In the case of generics which are not required to demonstrate their bioequivalence, restrictions are fewer. Nevertheless, importers will require good manufacturing practices, as well as quality ingredients and packaging in order to get the product registration and the sale authorization from the Institute of Public Health.

There are also good opportunities in the framework of government purchases, as the public health spending is expected to continue growing within next years. Pharmaceutical products used in national health programs (i.e. vaccines) continue to have good potential. Moreover, it is expected that CENABAST – the public agency in charge of medicament procurement for public hospitals – will increase its direct imports as a way to avoid paying the high prices of local suppliers (national and multinational laboratories).

Despite the above, it is strongly advisable to have a local representative or sales agent, who can be permanently aware of public calls for bids, as well as to deal with registration processes and import procedures.

Setting up manufacturing bases in Chile – alone or in association with Chilean investors – can also facilitate targeting not only the Chilean market but also other markets, taking advantage of the free trade agreements Chile has currently in place.

As some of the main laboratories operating in Chile produce locally (i.e. Saval, Laboratorio Chile and Recalcine), there are also opportunities for Indian exporters to sell pharmaceutical ingredients. India has been selling erythromycin to Chile but can expand to other types of raw materials.

Finally, the fast growing Chilean consumer trend toward a healthy and natural lifestyle will boost the demand for natural products, such as food supplies, herbal preparations and

vitamins. In this framework, the Indian System of Medicines, known as Ayurveda, has good prospect in Chile. Even it is not yet widely known by Chilean population, Ayurveda is gaining popularity mainly because of its low side effects and affordable prices.