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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, entry 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.
- **Prescription-only medicaments (POM):** pharmaceutical products that may be sold only to consumers possessing a valid prescription

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 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 holds a 0.14% share of world sales and accounts for 3% of sales across Latin America. The Chilean drug industry accounts for about 1.2% of national GDP.

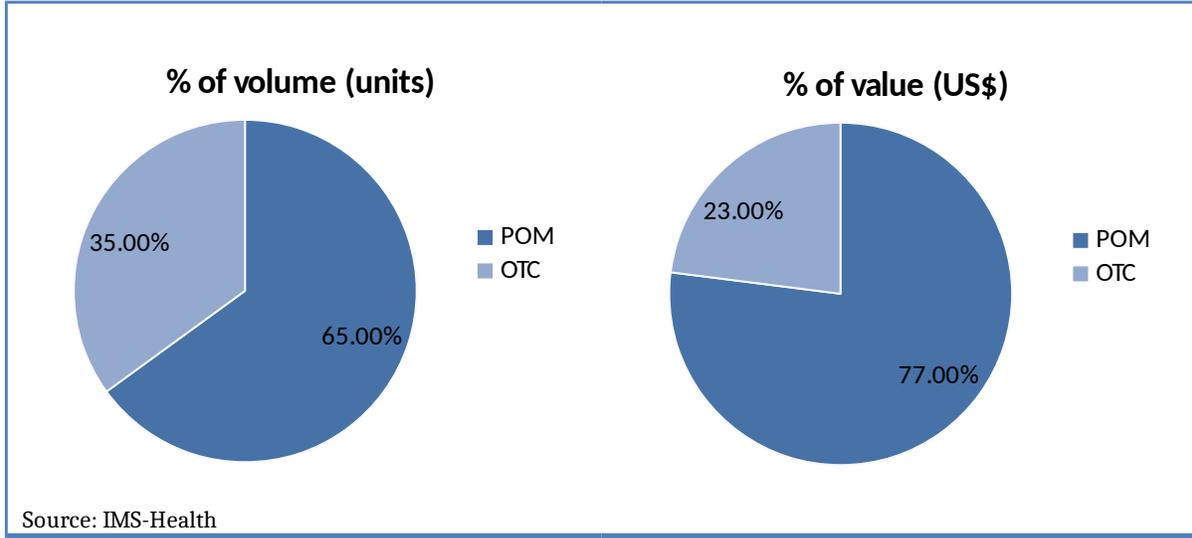
According to IMS Health estimations, Chilean pharmaceutical market sales accounted US\$ 2.400 million in 2015, representing a 12.4% increase compared to previous year. From them, US\$ 1.600 million corresponded to retail sales (mostly to pharmacies), while the rest is mainly institutional sales to private hospitals and clinics and to the public sector.

During the last years, retail market growth has been boosted by the launch of new products and presentations and by price rising, rather than by an increase in volume. Price rising has been mainly due to higher costs, as a consequence of several new regulations and of an increase in currency exchange rates. It is noteworthy that medicament prices are very sensible to exchange rate fluctuations, inasmuch most than a half 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.

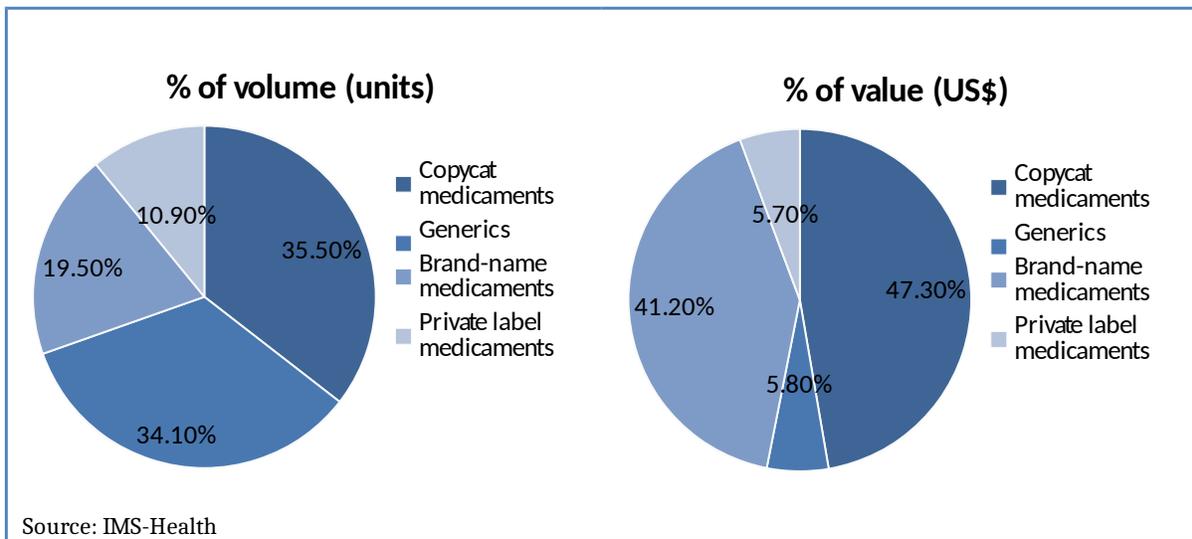
In terms of volume, prescription-only medicaments (POM) represent almost 65% of total retail sales, while in terms of value they correspond to 77% of total. It is worth remembering that prescription-only medicines have usually a higher price than over-the-counter products (OTC). See chart below.

Total Pharmaceutical retail sales - 2015



Among prescription-only medicines (POM), main sales in terms of volume correspond to copycat medicaments (35.5%) and to generics (34.1%). In terms of value, almost 88% of retail sales correspond to copycat medicines (43.3%) and brand-name products (41.2%). See chart below:

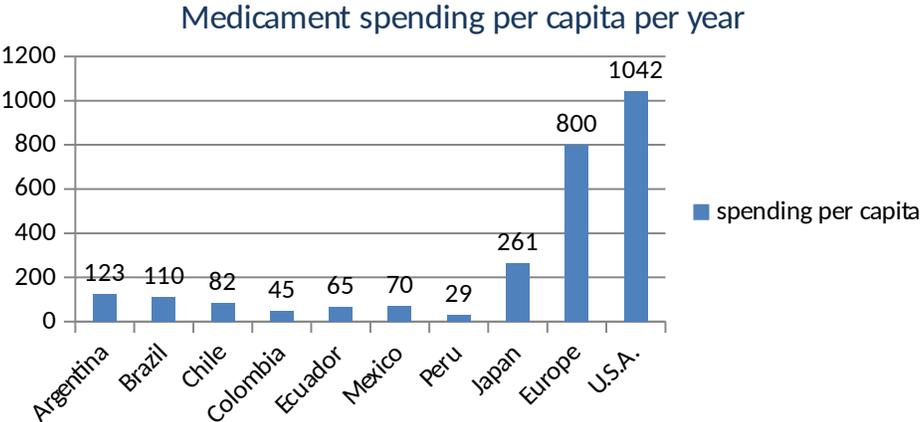
Prescription-only medicines (POM) retail sales - 2015



According to a report prepared by the Ministry of Economy¹, main 20 drug therapeutic classes or categories (from a total of 266) represent almost 50% of total retail sales. Best sold prescription-only medicaments (POM) in Chile are contraceptive hormones (8.3%), non-steroid anti-rheumatic drugs (4.4%), antidepressants (4.4%) and antiepileptic drugs (3.1%). Among over-the-counter products (OTC), bestsellers are skin products (such as emollients and UV protection products) representing 23.3% of sales, followed by non-narcotic pain relievers and antipyretics (9.8%) and flu drugs (5.0%).

As per IMS Health, in 2014 main product segments in terms of retail sales were classic chronic illnesses, woman health and semi chronic illnesses.

As per the same report, medicine spending per capita is relatively low, reaching US\$ 82 per year. Even if it is expected to grow in years to come, Chilean spending per capita is lower than Argentina (US\$ 123) and Brazil (US\$ 110), and quite far from Europe (US\$ 800) and U.S.A. (US\$1.042). See chart below.



Source: IMS Health, World Review, Cartagena 2012.

According to the last National Health Survey², 55% of the total health out-of-pocket expenditure by households corresponds to medicaments. This percentage increases to 67.6% among low-income households. The same survey indicates that this latest group consumes a larger volume of medicaments than high-income households.

1 Source: The medicine market in Chile – 2013. Ministry of Economy

2 The last version of the National Health Survey was issued in 2010. Currently, health authorities are conducting an updated version, which results are expected to be available by the second semester of 2017.

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

As per 2016 World Health Organization (WHO) statistics³, life expectancy in Chile has increased rapidly in last decade, reaching 80.5 years in 2015 (the second highest in the Americas, after Canada), in line with Chilean health spending increase and access improvement to better quality health care. The country also shows the fifth lowest child mortality rate (8.1 per 1.000 live births) and the fourth maternal mortality ratio (22 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 the World Health Organization (WHO), Chile consumes 9.3 liters of alcohol per capita per year, which is about 50% more than the world average consumption (6.2 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 (38%) in the Americas.

Moreover, obesity and overweight are on the rise in Chile and are particularly prevalent among women and children. According to a FAO-PAHO report⁴, Chile has the third highest adult overweight rate in Latin America and the Caribbean, accounting 63% of total population. In relation with childhood obesity and overweight, Chile ranks in the sixth highest position worldwide and in the first in Latin America⁵. Recent 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.

It is worth mentioning that low birth and low mortality rates account for Chile's rapid growth of elderly population. Almost 22.3% of total population is in the 0–14 age range, 68.1% in

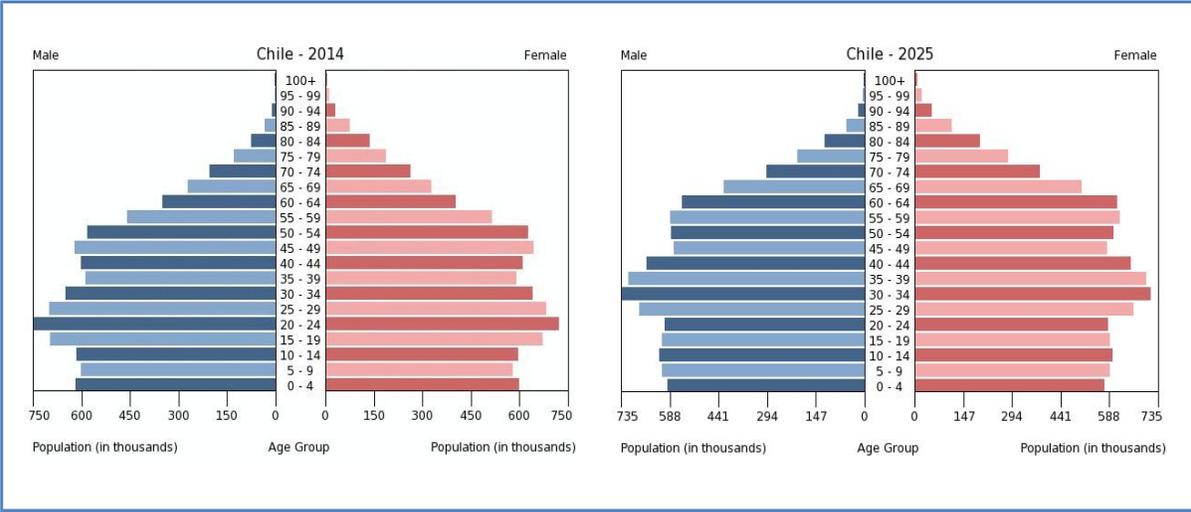
3 Source: World Health Statistics 2016: Monitoring health for the SDGs

4 Source "Panorama of Food and Nutrition Security in Latin America and the Caribbean report" - Agriculture Organization of the United Nations (FAO) and the Pan American Health Organization (PAHO).

5 Source: "Ending Childhood Obesity" - The Commission on Ending Childhood Obesity (ECHO).

the 15–64 age range, and 9.6% are 65 years or older⁶. It is anticipated that the aging population will continue to increase to represent 20.8% of total by 2044.

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.

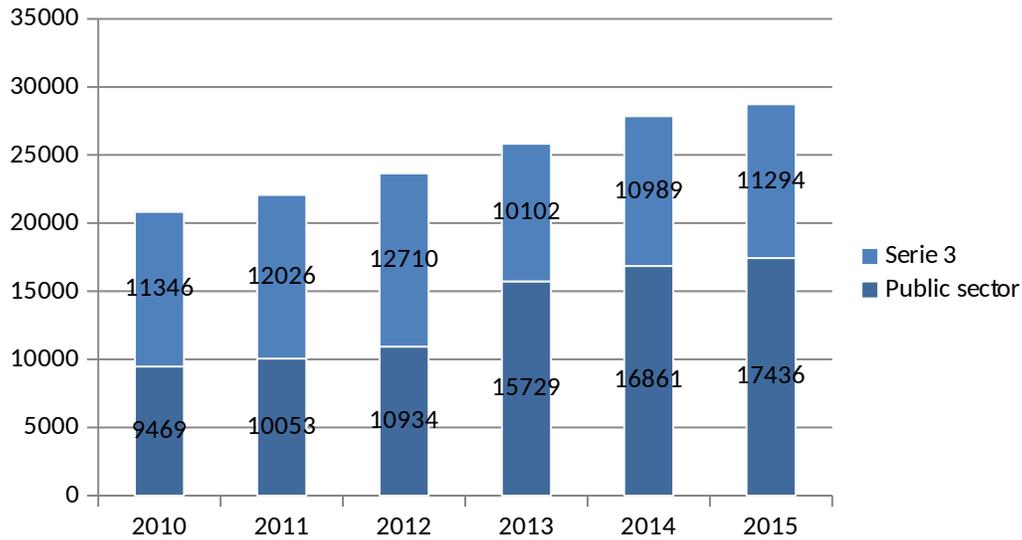
1.3.2 Health spending

According to OECD statistics⁷, health expenditure in Chile reached US\$ 28.730 million in 2015 (at constant prices) and has increased more rapidly than in any other OECD country. This growth was mainly boosted by government spending, which has almost doubled in the last 5 years. To this regard, Chile's healthcare reform and sector investment have expanded the role of the state in the provision of health services and medicaments. See chart below.

⁶ Data correspond to the last Chilean population census (2012). A new simplified census was conducted in April 2017, which results are expected to be available by late 2017.

⁷ Source: OECD (2017), "Health expenditure and financing: Health expenditure indicators", OECD Health Statistics (database).

Health total expenditure - Private and Public (in US\$ million)



Source: OECD statistics

Despite the above, in 2014 per capita Chilean expenditure on health was the fifth lowest among OECD countries and about half the OECD average, that is to say US\$ 1.750 compared with an OECD average of US\$ 3.440 per capita.

By the other hand, the share of GDP allocated to health spending (excluding capital expenditure) was 7.7% in 2015, compared with an OECD average of 8.9%.

Although the share of direct out-of-pocket expenditure by households in total health spending has decreased slightly since 2009, out-of-pocket costs still accounted for one-third of total health spending in Chile in 2013, the 3rd highest share among OECD countries.

1.3.3 Chilean healthcare system.

Chile's health care 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 salaries⁸. It is estimated that 75.2% of beneficiaries

⁸From 2018 on, self-employed workers will be also required to pay a percentage of their income for paying social security contributions.

belong to the public system, 18.5% to the private one and the remaining 6.3% to other types of health systems.⁹

Public health care system (mainly oriented to low-income people) is financed through FONASA (National Health Fund or “Fondo Nacional de Salud”). Those who contribute to FONASA can receive treatment through the public system or can choose a private health care provider and make a co-payment.

The private health care system are handled through 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, and the age and a physician’s assessment of the beneficiary.

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 centers and suffering from arterial hypertension, diabetes mellitus II and high cholesterol.

Additionally, in 2005, Chilean government implemented GES (Explicit Health Guarantees) system¹⁰. For a list of 80 diseases, Chileans 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.

Finally, Law No. 20.850/2015 of the Ministry of Health (best known as “Ley Ricarte Soto”)¹¹ created a financial protection system for diagnostics and treatments of high cost of both public and private health insurance beneficiaries. Financial coverage includes specific pharmaceutical products, foods or medical devices for 14 serious diseases (other will be probably added in the future). Pharmaceutical products included in this system are bought by the public sector through Cenabast (the National Drug Supply Centre).

⁹ Source: “Private Health Sector Size”. Clinicas de Chile A.G. 2016

¹⁰ For further details on GES system, click on this link: www.supersalud.gob.cl/difusion/665/w3-propertyvalue-1962.html

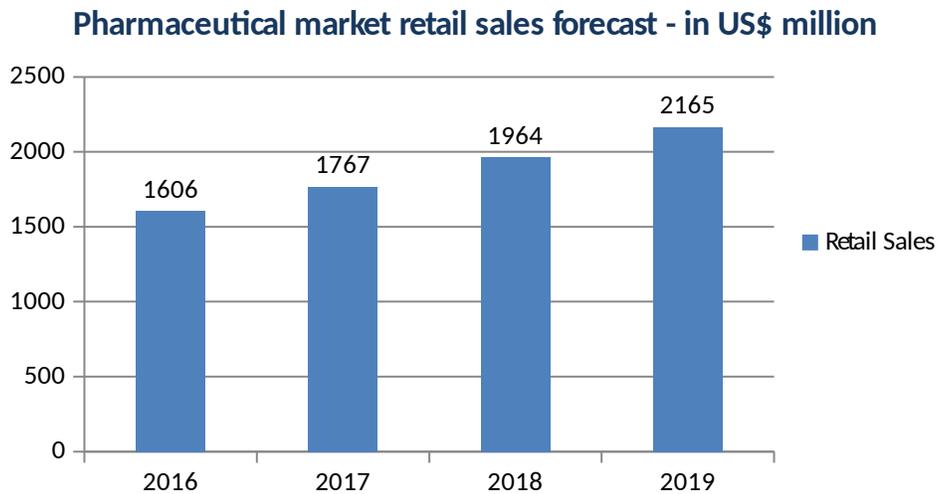
¹¹ For further details on “Ricarte Soto law” and of the specific pharmaceutical products having financial coverage, click on this link: <http://leyricartesoto.fonasa.cl/>

1.4 Pharmaceutical sector prospects

According to BMI Research, Chilean total pharmaceutical market will grow to US\$ 7.800 million in 2026, at an average compound annual growth rate (CAGR) of 7.5%. This growth rate is above the regional median 10-year CAGR for Latin America of 7.2%.

This grow would be the result of different factors, such as high per capita health spending, strong real health spend growth and a relatively large absolute market size, compared to other Latin American countries.

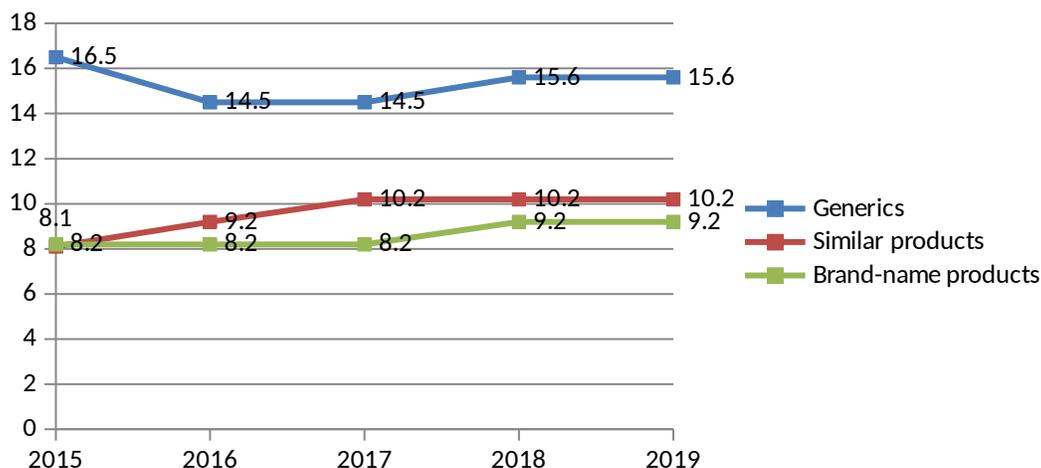
By the other hand, IMS Health estimates that pharmaceutical retail sales will reach US\$ 2.164 million in 2019, growing at an annual rate of 10 to 11%. This rate is far above the increase of the Chilean GDP, which is estimated to grow between 1.5 and 2% in 2017. See chart below:



Source IMS Health

Related to prescription-only medicaments (POM), IMS Health estimates Chilean market will continue to grow during the next 3 years at an average rate of 10%, reaching US\$ 1.660 million in 2019. Main increase will correspond to generics, which will grow at an annual average rate of 15%. It is worth mentioning that from 2014 on, physicians are obliged to include in their prescription not only the brand name of drugs, but also their common names. This makes easier for patients to replace them by generics or copycat products, according to their economic possibilities.

POM retail sales forecast -% of annual grow



Source IMS Health

Finally, estimations for OTC products are that they will continue to grow in the 3 years to come at an average rate of 9%, reaching US\$ 504 million in 2019. This growth will be boosted in part by recent modifications introduced in 2015 to pharmacies' regulation, allowing them to place OTC drugs in their shelves, under some conditions. This modification also allows the expenditure of OTC drugs in other types of stores (i.e. supermarkets, convenience stores), expanding the number and type of channels available for their distribution.

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, with the exception of 2016. In 2016, total imports reached US\$ 1.190 million, representing a decrease of 1.8% versus previous year. Nevertheless, in 2017, imports increased significantly reaching around US\$ 1.330 million.

Annex 1 includes contact data of local pharmaceutical product importers, some of which are mentioned in this chapter.

Total Pharmaceutical products Imports

	2013	2014	2015	2016	2017
CIF Value (in M US\$)	1.163.096	1.182.648	1.212.000	1.190.427	1.329.492

Source: Chilean Customs Statistics

2.1.1 Imports by type of product

Almost 66.7% of imported pharmaceutical products correspond to products classified under the HS chapter 30.4, followed by chapter 30.2 (21.6%).

Total Imports by type of product (in M US\$)

HS Chapter	2012	2013	2014	2015	2016	2017
30.01	5.894	7.437	7.321	4.164	5.519	7.054
30.02	268.223	278.437	255.536	262.568	269.240	286.436
30.03	9.533	12.061	10.175	13.579	10.892	8.892
30.04	647.160	767.415	813.937	828.903	806.312	887.044
30.05	23.864	24.793	27.898	28.111	29.390	31.948
30.06	72.887	72.953	67.781	74.675	69.074	70.458
Total	1.027.561	1.163.096	1.182.648	1.212.000	1.190.427	1.329.492

Source: Chilean Customs Statistics

Most than an half 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:

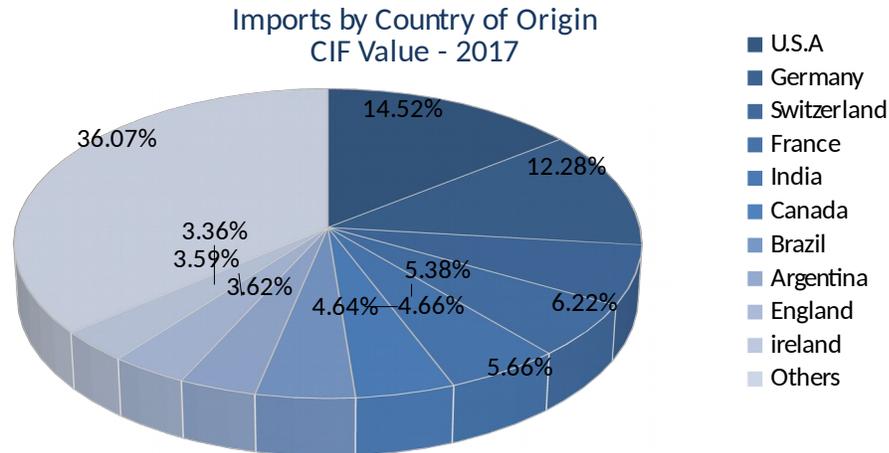
- Products packed in their final presentation for sale.
- Products packed in their primary package (blister, bottle, ampoule, etc.). The local importer repacks (i.e. cardboard boxes) and labels them.
- Product in bulk. The importer conducts locally all the packing and labelling process

Chile primarily imports finished medicines, while medicaments in bulk (corresponding mainly to HS chapter 30.3) account for less than 10% of total imports.

2.1.2 Imports by country

Pharmaceutical product imports are quite atomized in terms of country of origin, coming from 74 different countries.

In 2017, 63.9% of total imports (in terms of CIF value) came from 10 different countries, being the main ones U.S.A. (14.5%) and Germany (12.3%). Both countries have kept their position in the last 5 years as the main countries of origin of pharmaceutical imports.



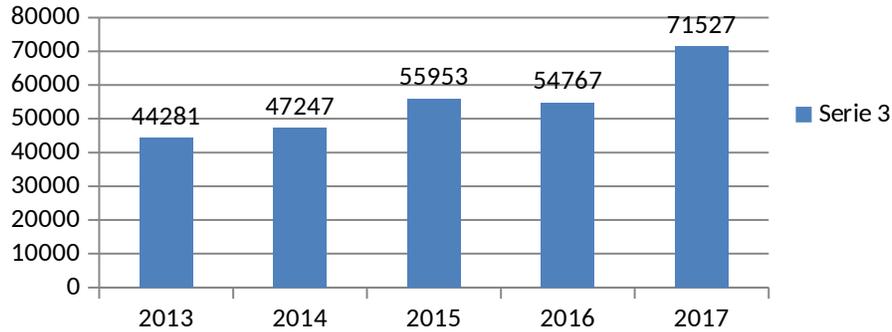
Source: Chilean Customs Statistics

In 2017, imports from India accounted for US\$ 71.5 million, representing a significant growth compared to previous year (+ 30.7%). In 2017 India passed from the 7th to the 5th position in the ranking of Chilean import countries of origin of medicaments. By the other side, Chile ranks in the fifth position of Indian pharma exports to Latin America, after Brazil, Venezuela, Mexico and Colombia.

In the last 5 years, imports from India have rapidly grown year to year, with the exception of 2016 (-2.2%), in line with Chilean pharmaceutical imports lowering behaviour.

In terms of type of product, in 2017 most pharmaceutical imports from India correspond to products belonging to HS chapter 30.4 (91.4%) - which correspond to finished products, reflecting the trend of growing value addition by Indian exporters. Imports classified under HS chapter 30.02 (3.3%) - corresponding mainly to vaccines - rank in second place, showing an increase of two and a half times within the last 5 years. See chart below.

Pharmaceutical Imports from India (in M US\$)

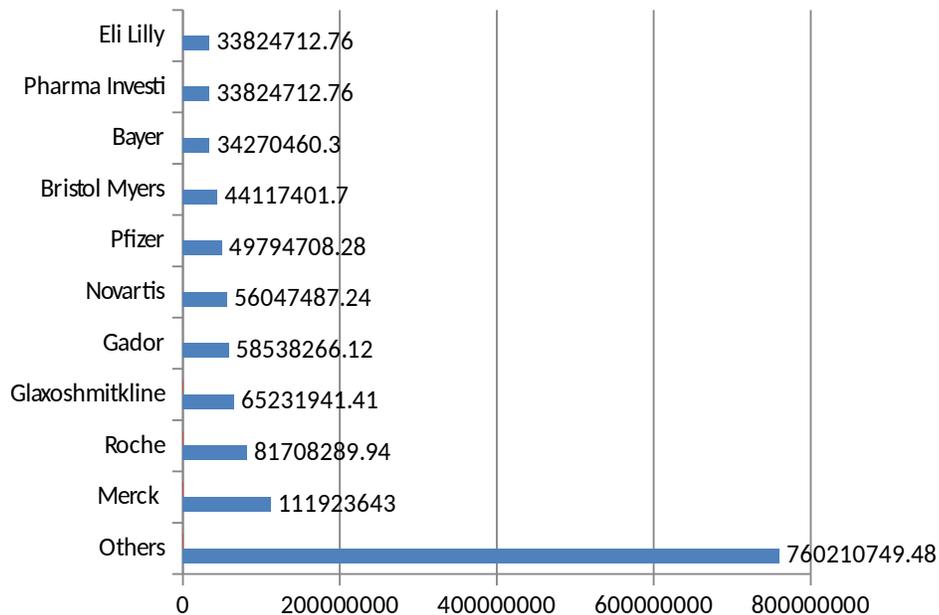


Source: Chilean Customs Statistics

2.1.3 Imports by company

In 2017, almost 725 Chilean companies and natural persons imported pharmaceutical products, showing a quite atomized total market. Ten of these importers gathered around 42.8% of total imports. See chart below.

Pharmaceutical Imports by Company – 2017 (CIF Value)- In M US\$¹²



Source: Chilean Customs Statistics

¹² Merck data includes imports done under Merck S.A. and Merck Sharp and Dohme.

In 2017, a total of 66 companies and natural persons imported pharmaceutical products from India. However, about a half corresponded to 4 companies: Opko Chile, Ascend Laboratories Recalcine and Laboratorio Hospifarma. In all cases, imports corresponded to generics.

It is important to note that some Indian companies such as Dr Reddy's Laboratories, Lupin, Ranbaxy, Torrent, Cellofarm, Glenmark Pharmaceuticals and IPCA Laboratories have local production facilities in Argentina, Brazil and Mexico. As some of these Latin American units also export, it is feasible that some of their products are imported into Chile, but are not registered as Indian products.

2.2 Exports

During the last 5 years, Chilean exports of pharmaceutical products have not been significant, accounting for one-sixth of total imports and representing about 1.1 % of all Chilean medicament manufacturing. See chart below.

Total pharmaceutical products exports

	2012	2013	2014	2015	2016	2017
FOB Value (in M US\$)	157.038	172.288	205.616	198.921	166.273	147.019

Source: Chilean Customs Statistics

In 2017, exports correspond mainly to local laboratories, being the main ones Saval, Recalcine (owned by Abbott) and Laboratorio Chile.

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

3. Competition Analysis

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 several reputed local companies.

Even if Chilean pharmaceutical market operates under a free trade model, there are several provisions companies should meet to be able to commercialize their products (see Chapter 5). It is noteworthy that pharmaceutical market has been in recent years under the 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.

3.1 Companies

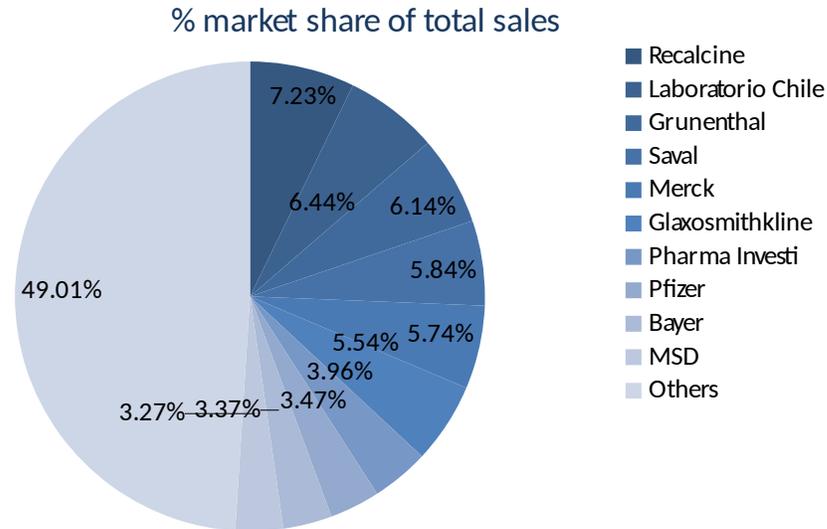
In Chile, there are 25 companies duly registered upon health authorities as production laboratories. These companies can produce, import, pack and fractionate both, pharmaceutical products and raw materials used in this industry.

By the other side, there are 11 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).¹³

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

¹³ Find the updated list of authorized production and conditioning laboratories by clicking on this link: www.ispch.cl/anamed_establecimientos_farmaceuticos/produccion



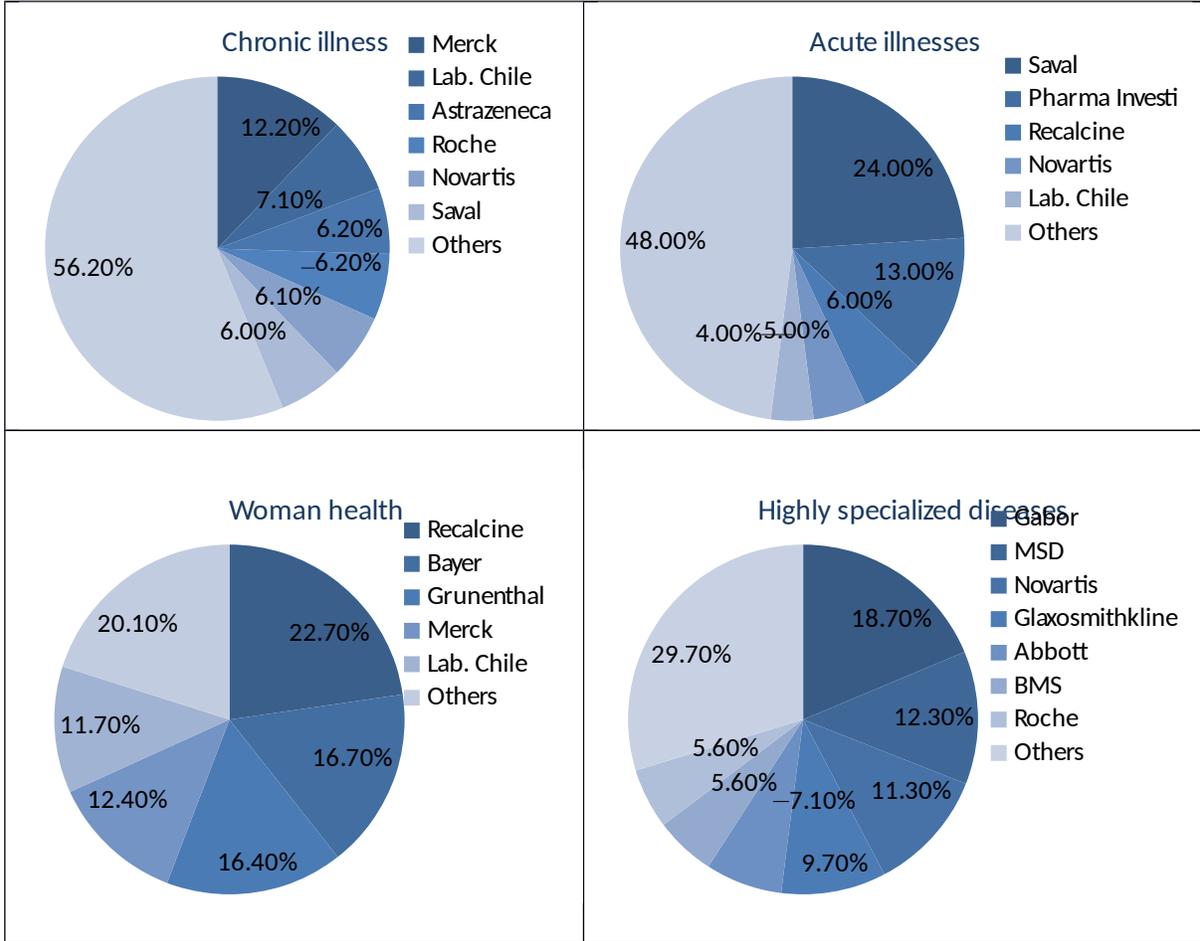
Source: IMS Health

Among these main companies, 3 correspond to 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.

3.2 Products

The following list shows the most sold medicaments in Chile, in terms of volume¹⁴. Most of them are generics, while the rest are copycat medicaments.

Most sold medicaments – Total sales June 2015-May 2016 (in volume)

Comercial Name	Active Ingredient	Sales volume (in units)
Paracetamol 500 mg. tablets	Paracetamol	3.967.794
Ibuprofen 600 mg. tablets	Ibuprofen	3.813.987
Losartan 50 mg. tablets	Losartan	3.466.767
Migranol tablets	Ergotamine + Metamizole	2.827.249
Ketorolac 10 mg. tablets	Ketorolac	2.321.299
Ibuprofen 400 mg. tablets	ibuprofen	2.220.482
Chlorpheniramine Maleate 4 mg. tablets	Chlorpheniramine	2.218.394
Diclofenac retard 100 mg. tablets	Diclofenac	2.070.255
Cefalmin tablets	Chlorphenamine + Ergotamine + Metamizole	2.009.004
Enalapril 10 mg. tablets	Enalapril	1.822.464
Diclofenac 50 mg. tablets	Diclofenac	1.797.163
Kitadol Adults 500 mg. tablets	Paracetamol	1.753.295
Loperamide 2 mg. tablets	Loperamide	1.718.056
Famotidine 40 mg. tablets	Famotidine	1.686.204
Naproxen 550 mg. tablets	Naproxen	1.678.141
Mefenamic acid 500 mg. tablets	Mefenamic acid	1.669.047
Ciprofloxacin 500 mg. tablets	Ciprofloxacin	1.582.149
Loratadine 10 mg. tablets	Loratadine	1.483.845
Ketoprofen 200 mg. tablets	Ketoprofen	1.427.585
Trimebutine 100 mg. tablets	Trimebutine	1.375.188

Source: ISP - IMS Health

3.3 Prices

¹⁴ Source: Information provided by the Public Health Institute “Instituto de Salud Pública” or its acronym ISP) based on a research conducted by IMS Health during the period June 2015 - May 2016.

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, authorities are paying great attention to prices and are evaluating instruments to better inform consumer about price differences among pharmacies and price increases.

From mid-2016 on, pharmacies are obliged to keep in all their stores a price list (digital or in paper). Moreover, medicaments should show their unitary price visibly printed on their secondary package.

It is important to mention that – according to a survey conducted by IQVIA – Chile shows the highest prices of Latin America for the same brand-name medicaments sold by international laboratories. Same conclusion was reached by a survey conducted by IMS Health in 2018. In Chile, the average consumer price of brand-name medicaments is US\$28.5, which is 38% higher than the Latin America average.

As a reference, the following chart shows the average retail prices (19% VAT not included) in 2016 of the 18 most sold medicaments. The chart also shows the price difference (in real terms) compared to previous year.

Most sold medicament prices – 2016 (in US\$)

Comercial Name	Price	% versus 2015
Loratadine 10 mg. x 30 tablets	0.97	+42.3%
Ibuprofen 400 mg. x 20 tablets	0.95	+38.7%
Famotidine 40 mg. x 10 tablets	0.66	+17.5%
Mefenamic acid 500 mg. x 10 tablets	0.88	+16.9%
Paracetamol 500 mg. x 16 tablets	0.71	+16.4%
Ibuprofen 600 mg. x 20 tablets	1.21	+15.9%
Chlorpheniramine Maleate 4 mg. x 20 tablets	0.36	+15.4%
Trimebutine 100 mg. x 20 tablets	1.20	+12.9%
Enalapril 10 mg. x 20 tablets	0.60	+12.5%
Diclofenac retard 100 mg. X 8 tablets	1.36	+9.0%
Cefalmin x 10 tablets	1.72	+2.4%
Loperamide 2 mg. x 6 tablets	0.36	+2.1%
Diclofenac 50 mg. x 10 tablets	0.38	+2.0%
Ciprofloxacin 500 mg. x 6 tablets	1.07	+1.7%
Ketorolac 10 mg. X 10 tablets	1.32	- 1.1%
Losartan 50 mg. x 30 tablets	2.21	- 3.1%
Migranol x 10 tablets	1.48	- 4.4%
Kitadol Adults 500 mg. x 24 tablets	1.55	-13.6%

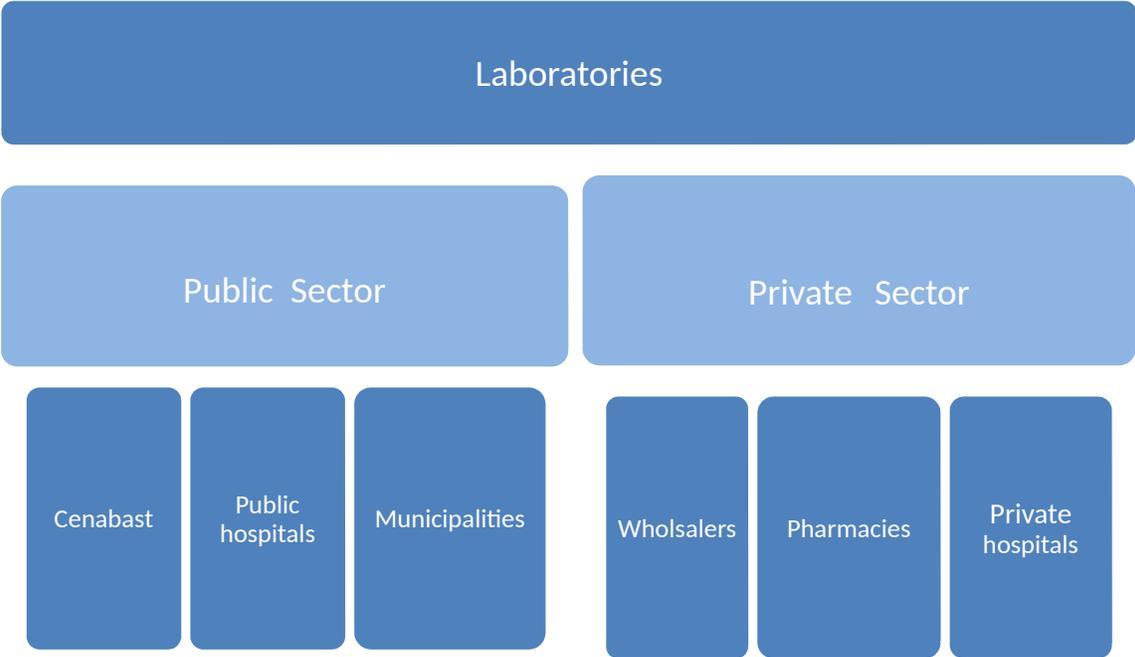
Source: ISP – IMS Health

As seen, most of the most sold medicaments have increased their prices in the last year, mainly due to bioequivalence test costs and to an increase in the currency exchange rate, making imported drugs more expensive.

It is worth mentioning that -recently - Chilean government has created a web page monitoring the prices of medicines prices in pharmacies (www.tufarmacia.gob.cl). This initiative aims to better inform consumers and allow them to compare prices, adding transparency in a highly concentrated pharmacy market.

4. Distribution channels

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



4.1 Public Sector

The regulatory framework for public procurement in Chile¹⁵ 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 the electronic platform “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 must appoint a proxy residing in the country that is empowered to submit the bid and conclude the contract. Once the foreign provider has been awarded the contract, it must open a corporate structure in Chile.

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 (“Central Nacional de Abastecimiento”), 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.

Depending on the demand, Cenabast prepares purchasing processes of a predetermined list of medicaments¹⁶ which are conducted through “Mercado Público” Platform.

¹⁵ Regulatory framework is governed by Law 19,866 of July 2003 and its further modifications.

¹⁶ To review the list of medicaments for 2017, click in this link: www.cenabast.cl/canasta-de-productos-2017/

In 2016, total Cenabast purchases accounted for almost US\$ 645 million, representing almost 26% of total local pharmaceutical market.¹⁷ It is also the largest buyer in the public healthcare sector intermediating 50% of the sector's spending.

It is important to mention that Cenabast can import from other countries, in case of insufficiency or inaccessibility in the domestic supply for public health programs. Even if imports have increased significantly in last years – accounting for US\$ 41 million in 2015 – and are expected to continue growing in the framework of “Ricarte Soto” law, they currently represent less than 10% of total Cenabast purchases. Most of these imports correspond to direct purchases (not through public tendering).

It is worth mentioning that the Institute of Public Health (ISP) can authorize Cenabast to import pharmaceutical products directly without previous registration, in case of inaccessibility to local suppliers. Moreover, a recent resolution the Comptroller General of the Republic in a particular case (AIDS medicines) has opened the gate to consider that high prices of medicines in the local market could constitute an inaccessibility factor. It is expected that in the near future, Cenabast will have much more flexibility to import directly to have access to cheaper prices.

4.1.2 Public hospitals

In 2015, Chile had 348 hospitals; from them, 187 belonged to the public sector, which totaled 24.987 beds (68% of total).¹⁸

The National Health Investment plan 2014-2018 leaded by the Chilean government considers the construction of 20 public hospitals and 322 primary healthcare centres during this period. The investment plan also considers 40 additional hospitals to be built

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

¹⁷ To review the list of medicaments purchased by Cenabast during current year, click on this link: <http://www.cenabast.cl/licitaciones-efectuadas/>

¹⁸ Source: “Private Health Sector Size”. Clinicas de Chile A.G. 2016

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, there are 2.275 primary healthcare centres.

In recent years, 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 90 municipality pharmacies; this is to say, 25% of municipalities have at least one.

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.

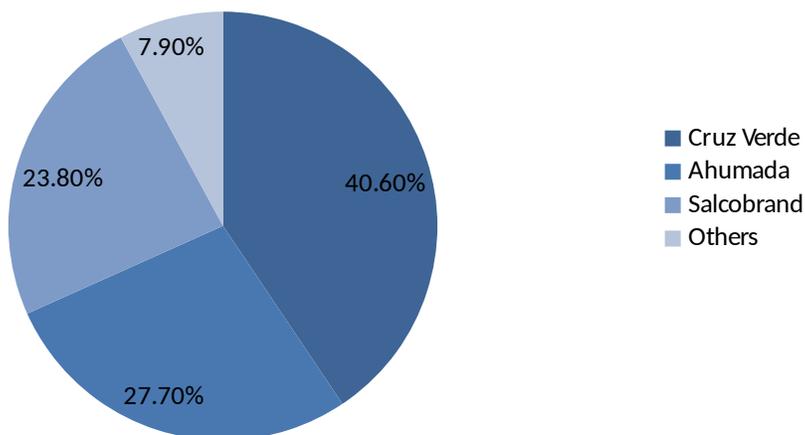
4.2 Private sector

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

The Chilean pharmacy market here is dominated by three pharmaceutical chains: Salcobrand, Ahumada, and Cruz Verde. There are small independent pharmacies too, but their market share is tiny (less than 8%). See chart below.

% Market Share -Pharmacies



Source: Asilfa

Almost 70% of the pharmacies in Chile are foreign owned. Cruz Verde has been bought by Femsa (a Mexican group), while Ahumada belongs to Walgreens Boots Alliance. Salcobrand is still owned by Chilean capitals.

All three chains are vertically integrated; that is to say, have their own laboratories which manufacture and/or import private label products. It is worth mentioning.¹⁹ Most of these products correspond to OTC medicaments, medical supplies and cosmetic and personal care products.

According to the Ministry of Health, in 2015 there were 3.013 pharmacies in Chile, with a half of them located in Santiago, the capital city. From them, about 60% belong to the three main pharmacy chains.

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 recently some online pharmacies have been launched (i.e. Pharol.cl and Farmazon.cl), selling both OTC and POM products. The three main pharmacy chains have also developed the online channel, but only for OTC, beauty and personal care products. Nevertheless, these latest offer the option to buy through a call center.

4.2.2 Distributors

¹⁹ It is worth mentioning that a reform is currently being discussed in Chilean parliament. One of its points is to prohibit pharmacies to have their own laboratories.

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.

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 the main ones are Socofar, Drogueria Ñuñoa, Farma 7 and Schubert.

4.2.2 Private hospitals and clinics

In 2015, Chile had 161 private hospital and clinics²⁰, with a total of 12.565 beds. Some of them are vertically integrated, as they belong to the ISAPRES (“Instituciones de Salud Previsional”), which are in charge of administrating workers health contributions.

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.

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 3/2010²¹ 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 (known as “Instituto de Salud Pública” or its acronym ISP)

5.1 Registration of Pharmaceutical products

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

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

21 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

Health, 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.

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, as well as the payment of the involved fees, could be done in paper or using the Institute’s on line system called GICONA²².

The registration process for a new pharmaceutical product takes on average of 6 to 18 months. Registration fees are around USD 2, 500 and depend on the type of product.

²² Find the complete procedure for submitting sanitary registration applications by clicking on these links:

Ordinary Procedure:

www.ispch.cl/sites/default/files/instructivo_requisitos_solicitud_registro_ordinario_sro_02_12_2014%20%20INCLUYE%20NORMA%20170%20DE%20BIOTECNOL..pdf

Simplified Procedure:

www.ispch.cl/sites/default/files/prestacion/2012/03/instructivo_solicitud_registro_productos_simplificados_11_02_13.pdf

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.

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:

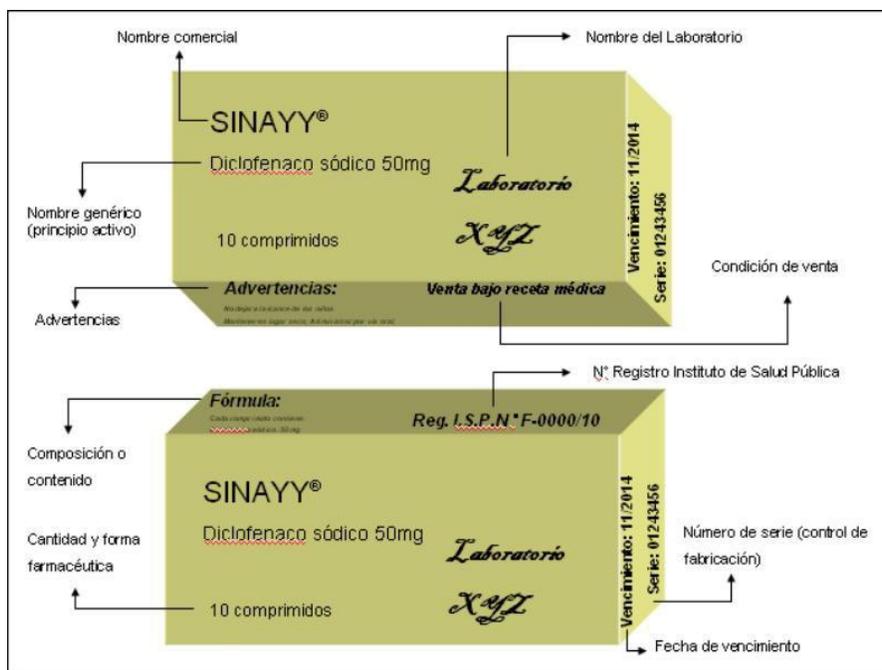
- Should be placed immediately under the name of the product or trade mark.
- Keep the same font and background colour as the name of the product
- Should be printed using a font size not smaller than a half of the font size used for the name of the product, and no smaller than 6 points.
- Should be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

From 2012, generic or similar products containing active ingredients included in a predetermined list²³ 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 1.458 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:



²³ Find the list of active ingredients that should demonstrate their bioequivalence by clicking on this link: <http://www.ispch.cl/sites/default/files/u7/Dto%20Ex%20Minsal%20N%C2%B0500%2C%20aprueba%20norma%20t%C3%A9cnica%20N%C2%B0%20136.pdf>

5.3 Import procedures

In the case of any import, Chilean Customs requires that each customs entry 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 1,000 (FOB) require the participation of a Customs Broker. Minor imports (less than USD 1,000 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 25 Commercial Agreements with 66 countries, which have granted tariff preferences which each country applies to imports.²⁴

India and Chile have signed a Partial Scope Trade Agreement (PSA) giving a tariff preference (ranging from 30 to 100%) to pharmaceutical products classified under some specific HS codes.²⁵ This means that imports of these products pay a duty tax ranging from 0 to 4.2%.

²⁴ 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/

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.

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

25 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

under the PCT, applicants can simultaneously seek protection for a pharmaceutical product in 148 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

<p>Strengths</p> <ul style="list-style-type: none"> • Good quality of Indian pharmaceutical products. • Very 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). 	<p>Opportunities</p> <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 • Fast grow of specialty stores and foodservice. • Ayurvedic medicaments and natural products.
<p>Weaknesses</p> <ul style="list-style-type: none"> • Low experience of India drug exporters in the Chilean market (4.6% of total imports). • Indian bioequivalence certificates are not yet recognized in Chile. 	<p>Threats</p> <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 form 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) 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 being 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.