EMBASSY OF INDIA
SANTIAGO
CHILE

MEDICAL EQUIPMENT AND SUPPLY

MARKET SURVEY

AUGUST 2017

Commissioned from Ms. Carmen Fuentealba

on behalf of the

सत्यमेव जयते
Economic Diplomacy Division
Ministry of External Affairs

I N D E X

This market survey aims to provide relevant information on the medical equipment and supply market in Chile so that Indian 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 Chilean health system overview

1.1.1 Chile health and demographic indicators

As per 2016 World Health Organization (WHO) statistics[1], 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 forth maternal mortality ratio (22 per 100.000 live births) among American countries.

Additionally, Chile ranked 48th in a study evaluating the Healthcare Access and Quality (HAQ)[2] in 195 countries from 1990 to 2015. The country also ranked top among the countries of Latin America and the Caribbean (LATAM).

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 litters of alcohol per capita per year, which is about 50% more than the world average consumption (6.2 litters). By the other hand, even though the prevalence of tobacco

[1] Source: World Health Statistics 2016: Monitoring health for the SDGs

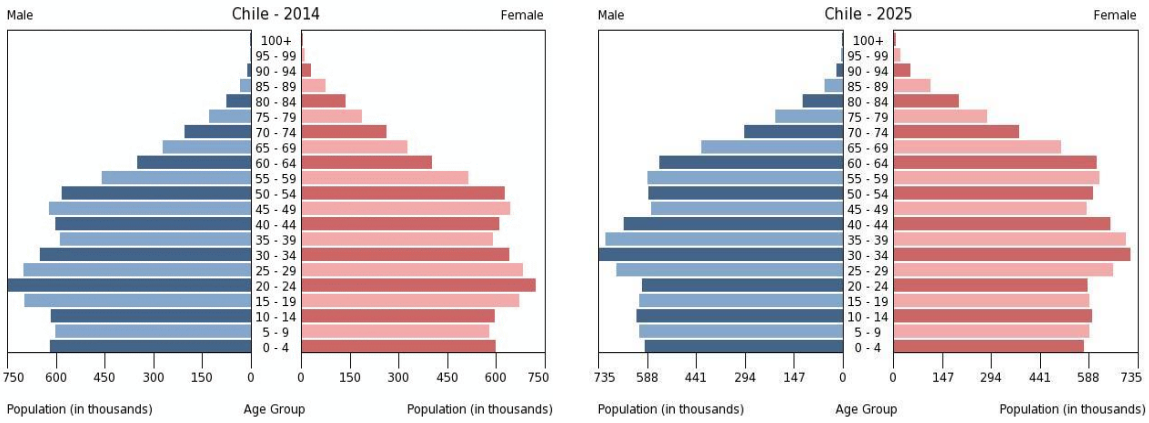
[2] The study has been published in the world's leading independent general medical journal "The Lancet" which focused on 32 pathologies that could have been avoided with timely and effective medical care such as vaccines, routine surgeries or curative treatments.

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 report[3], 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 America[4]. 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 grow of elderly population. Almost 22.3% of total population is in the 0–14 age range, 68.1% in the 15–64 age range, and 9.6% are 65 years or older[5]. 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

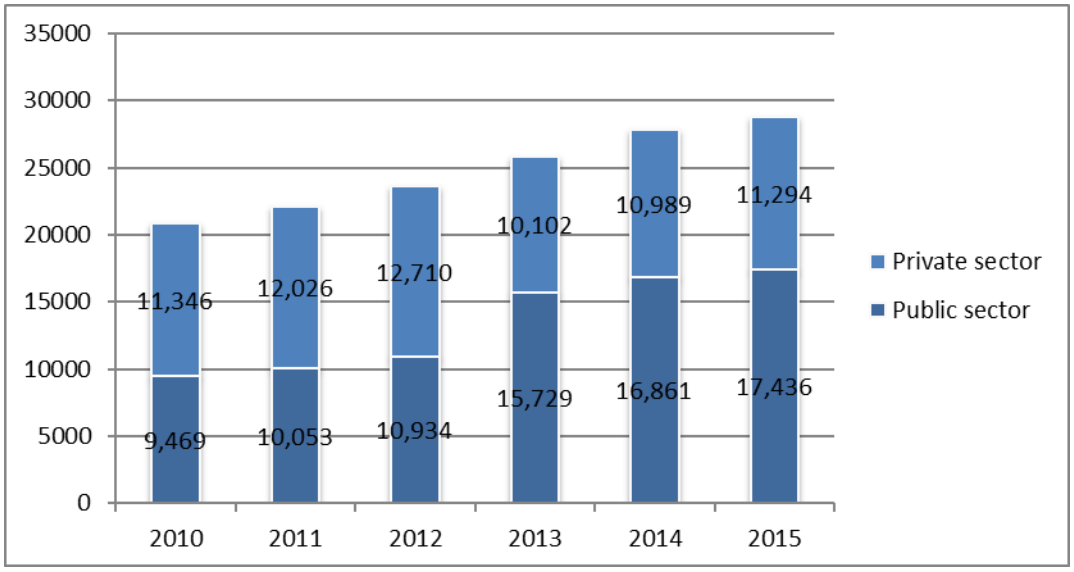
[3] Source "Panorama of Food and Nutrition Security in Latin America and the Caribbean report" - Agriculture Organization of the United Nations (FAO) and the Pan American Health Organization (PAHO).
[4] Source: "Ending Childhood Obesity" - The Commission on Ending Childhood Obesity (ECHO).
[5] Data correspond 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.

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 medical equipment market in Chile in the next years.

1.1.2 Health spending

According to OECD statistics[6], 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. See chart below.

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.

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

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.

1.1.3 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 salaries[7]. It is estimated that 75.2% of beneficiaries belong to the public system, 18.5% to the private one and the remaining 6.3% to other types of health systems.[8]

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 healthcare system, health expenses (such as hospitalization, medical exams and procedures, physician fees, drugs etc.) are fully or partially covered, depending on the Fonasa level in which the beneficiary is classified, according to his income situation. In the private sector, health costs are covered with maximum expense limits per service and/or per year.

Additionally, in 2005, Chilean government implemented GES (Explicit Health Guarantees) system[9]. For a list of 80 diseases, Chileans are granted the right to access to health care (including hospitalisation, medical exams and procedures, drugs, etc.) within a certain period of time and with maximum co-payment. Illnesses representing the highest number

[7]From 2018 on, self-employed workers will be also required to pay a percentage of their income for paying social security contributions.
[8] Source: "Private Health Sector Size". Clinicas de Chile A.G. 2016
[9] For further details on GES system, click on this link: www.supersalud.gob.cl/difusion/665/w3-propertyvalue-1962.html

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.

1.2 Healthcare infrastructure

According to a report prepared by Clinicas de Chile A.G., in 2015 there were 348 hospitals in Chile, with more than a half belonging to the public health system. In total, they represented 37.552 beds. See chart below.

Chilean Hospital infrastructure – 2015

	Number of Hospitals	Number of beds
Public hospitals	187	24.987
Private hospitals	79	6.755
Psychiatric and geriatric clinics	40	1.325
Mutual health hospitals[10]	12	684
Other private hospitals	30	3.801
TOTAL	**348**	**37.552**

Source: Clinicas de Chile A.G.

Almost a third of public hospitals correspond to highly specialized centres. Among private hospitals, around 40% are located in Santiago (the Chilean capital city) and 75% have less than 100 beds.

Regarding primary health centres, in 2015 there were around 2.300 centres belonging to the public system. These centres can include low-complexity community hospitals and urgency services, as well as general, family and rural healthcare centres.

It is worth mentioning that in 2014, the current administration announced the 2014-2018 National Health Investment Plan which considered building or renovating 61 hospitals (representing US$ 4 billion) and 322 primary care centres over the next four years. By 2018, 20 of them were scheduled to begin operating, another 20 would be under construction and the rest would be in process of being tendered. Even if this goal will almost for sure not be achieved during this administration - given the current status of projects- new hospital

[10] Mutual Health Organizations are private non-profit institutions that provide occupational injury insurance, which cover medical services and financial aid in the event of an accident at work.

plans will remain in the pipeline to be constructed in a near future, and therefore, will demand new medical and hospital equipment.

Related to private sector hospitals and clinics, representatives of Clinicas de Chile A.G. forecast a slight decrease in investment in 2017, which has reached between US$ 500 to 600 million per year in the last 5 years. Nevertheless, they state that Chilean economy slowdown has a lower impact in private hospitals, compared to other sectors.

It is noteworthy that current public hospital infrastructure is not enough to cover in due time the demand of public health care system beneficiaries. For this reason, FONASA (the National Health Fund) usually buy services from private hospitals, clinics and healthcare centres through tender processes. In 2016, FONASA bought services to private healthcare providers for around US$ 300 billion, corresponding to 4.3% of its total health expenses. From them, around 70% corresponded to dialysis services.

1.3 Healthcare services

The following chart shows the number of healthcare services provided in 2016 to private system beneficiaries (Isapre) in public and private hospitals and healthcare centres.

Health services provided to private system beneficiaries – 2016[11]

	Public health centers	Private health centers	Total
Medical consultations	364.966	15.034.439	15.399.435
Diagnostic examinations	1.507.314	31.175.525	32.682.839
Medical procedures	487.801	18.591.391	19.079.192
Surgical operations	18.775	415.863	434.638
Other health services	117.265	2.217.566	2.334.831

Source: Superintendencia de Salud

Most of health services to private system beneficiaries are provided by private hospitals and healthcare centres, which generally offer better premises, better technology and shorter waiting times. Besides, most of private health insurance institutions (isapre) have their own

[11] The chart does not include healthcare services provided to public system beneficiaries.

healthcare facilities and/or have agreements with other private ones, offering better coverage to their beneficiaries which translate in a lower co-payment.

Regarding diagnostic examinations, most of them corresponded to laboratory tests (83%), followed by far by imaging tests (15%). In addition, 73% of medical procedures corresponded to physical rehabilitation, followed by clinical psychology (8%) and cardiology and pneumology procedures (5%).

The following chart shows the number of healthcare services per each 1.000 beneficiaries, provided to private system beneficiaries in the last 5 years.

Health services provided to private system beneficiaries per each 1.000 beneficiaries– 2012 to 2016

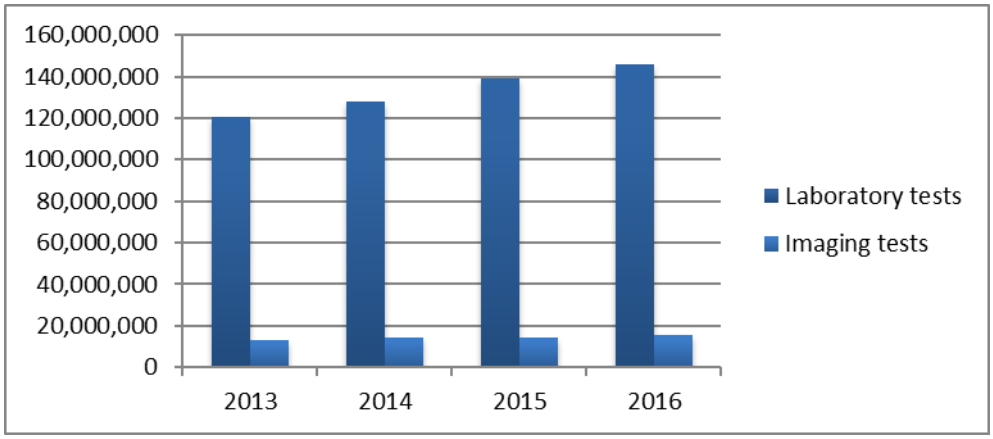
	2012	2013	2014	2015	2016	% 2016 vs. 2012
Medical consultations	4.513	4.586	4.536	4.396	4.489	-0.5%
Diagnostic examinations	8.568	8.868	9.031	9.199	9.527	11.2%
Medical procedures	4.841	5.087	5.296	5.395	5.561	14.9%
Surgical operations	150	137	137	131	127	-15.3%
Other health services	666	716	705	690	681	2.25%

Source: Superintendencia de Salud

It is noteworthy that diagnostic examinations and medical procedures per each 1.000 beneficiaries have consistently grown in the last 5 years. Some market players state that physicians are requesting more and more tests to their patients, in order to avoid diagnostic errors and, therefore, minimize the risk of being accused of malpractice. It is expected that this trend will continue to grow in the future, inasmuch as patients are more aware of their rights and are willing to sue in courts.

The following chart shows total number of diagnostic examination services (laboratory and imaging tests) provided by private and public healthcare service centres in the last 4 years.

Diagnostic examinations – number of services provided



Source: Ministry of Health

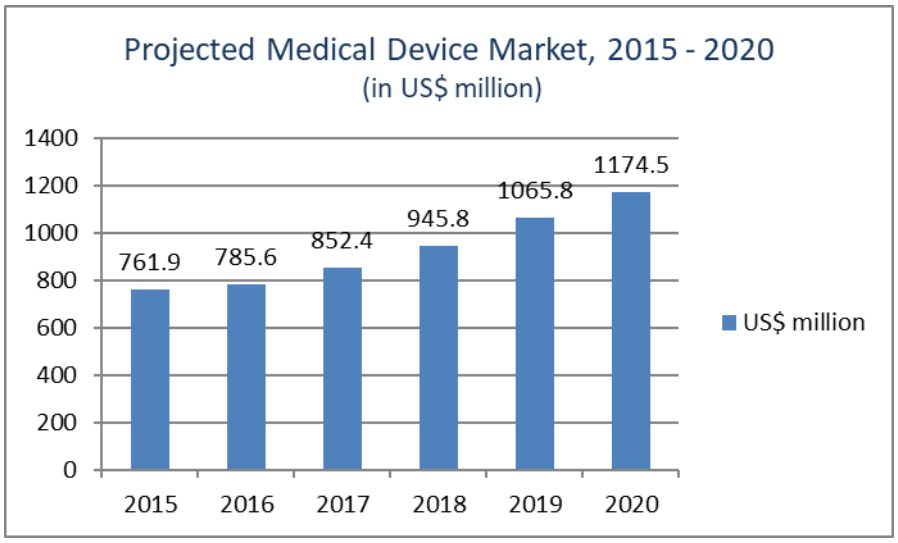
As same as seen in the case of private system beneficiaries, the total number of diagnostic examinations provided by public and private healthcare centres in Chile has increased significantly in the last years (+20.9% in the case of laboratory tests and + 19.5% for imaging tests, within the last 4 years). In 2016, most of laboratory tests (77.7% of total) were conducted by public healthcare centres (hospitals and primary care centres), while most imaging tests (56.5%) were provided by private health centres.

1.4 Medical equipment and supply market

The medical equipment market is small in Chile, but per capita spending is high at a regional level. Current market value reaches about USD 850 million.

For the medical device[12] market, BMI Research forecasts a high single-digit growth in US dollar terms in 2017, rising to double-digits from 2018, driven by public hospital modernisation. The 2017 Chilean health sector budget will focus on improving resources for primary healthcare, which will provide a boost to medical device firms that supply primary healthcare products. See chart below.

[12] Medical devices should be understood as any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s)



Source: BMI research

The above chart shows that the market will record a 2015-2020 CAGR of 9% in US$ terms, which should see the value rise to USD1.2 billion by 2020. This translates into a 2015-2020 grow of 46.6% in the market value per capita, from US$ 42.5 to US$ 62.3.

The market is reliant on imports as production is limited. Chile produces very little medical equipment. Currently, local medical device manufacturing represents less than 10% of the market. Locally-manufactured items tend to be at the lower end of the technology scale, such as bandages and supplies, medical instruments, prosthetics, mechanic-therapy apparatus, basic medical furniture and wheelchairs. There are a few exceptions, including engineering expertise in electromagnetic and magnetic shielding for MRI units.

2. Imports and exports

Import and export statistics contained in this section correspond to the following products, with the respective Harmonized System (HS) code under which they are classified in Chile[13] :

Chapter/code	Description
90.18	Medical Equipment: 90181100 Electro-cardiographs 90181200 Ultrasonic scanning apparatus 90181300 Magnetic resonance imaging apparatus 90181400 Scintigraphic apparatus 90181900 Other 90189010 Defibrillators 90189020 Baby incubators 90189030 Hearth monitors 90189040 Dialysis apparatus 90189050 Anaesthetic instruments and appliances Medical Supplies 90.18.31 Syringes 90.18.32 Needles 90.18.39 Other (catheters, blood bags, etc.)
90.19	Mechanic-therapy appliances; massage apparatus; psychological aptitude-testing apparatus; ozone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus; parts and accessories.
90.22	X-ray, alpha, beta, gamma radiation apparatus; x-ray tubes, x-ray generators, high tension generators, control panels and desks, screens, examination or treatment tables, chairs and other

[13] The HS codes under each type of equipment and supply is classified correspond to the Custom tariff classification defined by the Chilean Customs and in force from January 1, 2017. In some cases, they may not coincide with the codes used in India.

2.1 Imports

During the last 5 years, medical equipment and supply imports have been growing in terms of CIF value at increasing annual rates, with the exception of 2016. In 2016, total imports reached US$ 195.2 million, representing a decrease of 2.5% versus previous year.

Total Medical Equipment and Supply Imports

	2012	2013	2014	2015	2016
CIF Value (in M US$)	177.692.809	179.214.901	181.552.241	200.056.981	195.216.969

Source: Chilean Customs Statistics

Annex 1 (attached to this survey) includes contact data of local medical and hospital equipment importers, some of which are mentioned in this chapter.

2.1.1 Imports by type of product

In 2016, main medical equipment imports correspond to equipment classified under HS chapter 90.18 (46.8%), followed by HS chapter 90.22 (31.9%). See chart below.

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

	2012	2013	2014	2015	2016
90.18					
Medical equipment	65.426.549	77.733.711	82.038.295	90.256.549	91.382.242
Medical supplies	2.788.039	6.148.784	7.024.220	8.247.690	8.847.241
90.19	31.650.598	32.759.922	31.446.424	31.157.679	32.782.302
90.22	77.827.623	62.572.484	61.043.302	70.395.063	62.205.184
TOTAL	**177.692.809**	**179.214.901**	**181.552.241**	**200.056.981**	**195.216.969**

Source: Chilean Customs Statistics

Imports of medical equipment and medical supplies classified under HS chapter 90.18 have increased significantly in the last 5 years (+39.7% and +217.3%, respectively). Imports of medical

equipment classified under HS chapter 90.19 have remain flat during the same period, while Chapter 90.22 equipment imports show significant variations within the last 5 years. [14]

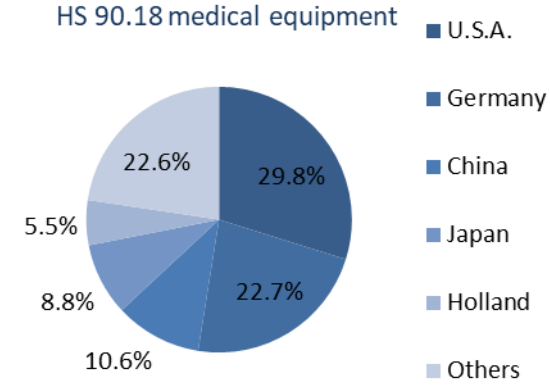
In 2016, 28.3% of medical equipment imported under HS code 90.18 corresponded to other (HS 90.18.19.00), followed by ultrasonic scanning apparatus (22.7%) and magnetic resonance imaging apparatus (20.8%). In the case of medical supplies imported under HS code 90.18, all imports corresponded to needles (HS code 90.18.32.00).

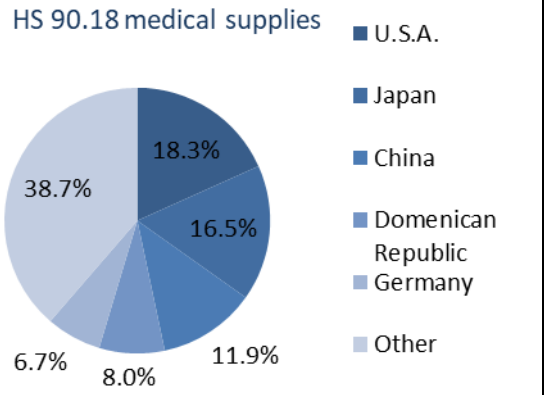
Besides, in 2016 main imports classified under chapter 90.22 corresponded to non-portable X-Ray generators and apparatus (41.1%).

2.1.2 Imports by country

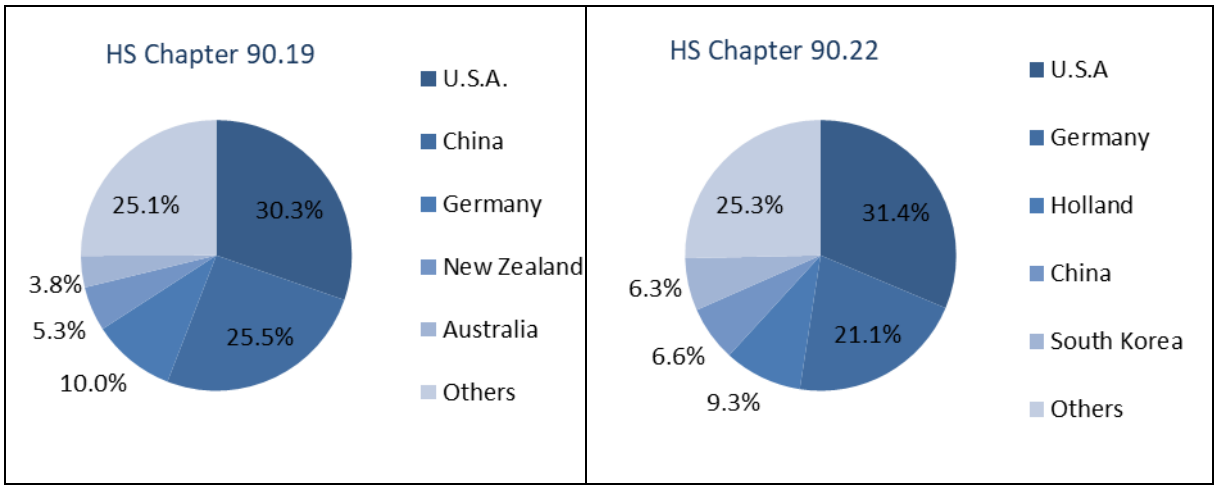
The following chart shows main countries of origins of medical equipment and supply imports, by type of product.

Imports by country of origin – CIF Value 2016





[14] HS chapter 90.22 includes both, equipment and supplies (i.e. tubes) based on X, alpha, beta and gamma radiations. Import value statistics (expressed in US$) may show variations depending on the quantity of radiation equipment imported each years, which have a significantly higher price compared to supplies.



Source: Chilean Customs Statistics

In all cases, almost the same countries of origin of imports are repeated: U.S.A., China, Germany, Japan and Holland. Depending on the type of product, they rank in different positions; nevertheless, U.S.A. is in all cases the main one. Even if – for all types of products – imports from the main 5 countries account for 61.3% to 77.4% of total, it should be noted that imports come from 40 to 55 different countries of origin, depending on the type of product.

Considering the 4 categories of medical equipment and supplies as a whole, main country of origin of imports is U.S.A. (29.9%), followed by Germany (19.9%) and China (11.6%). According to some market players, even if China has importantly improved the quality of the medical equipment they produce, most private Chilean hospitals still prefer equipment from U.S.A. or the European Union and, in particular, manufactured by well-reputed companies, even if they are more expensive.

It is noteworthy that medical equipment and supply imports from India are not significant. In 2016, they represented 0.71 % of total in the case of HS Chapter 90.22 products, and 0.08% and 0.03% in the case of medical equipment and supplies classified under HS 90.18, respectively.

2.1.3 Imports by company

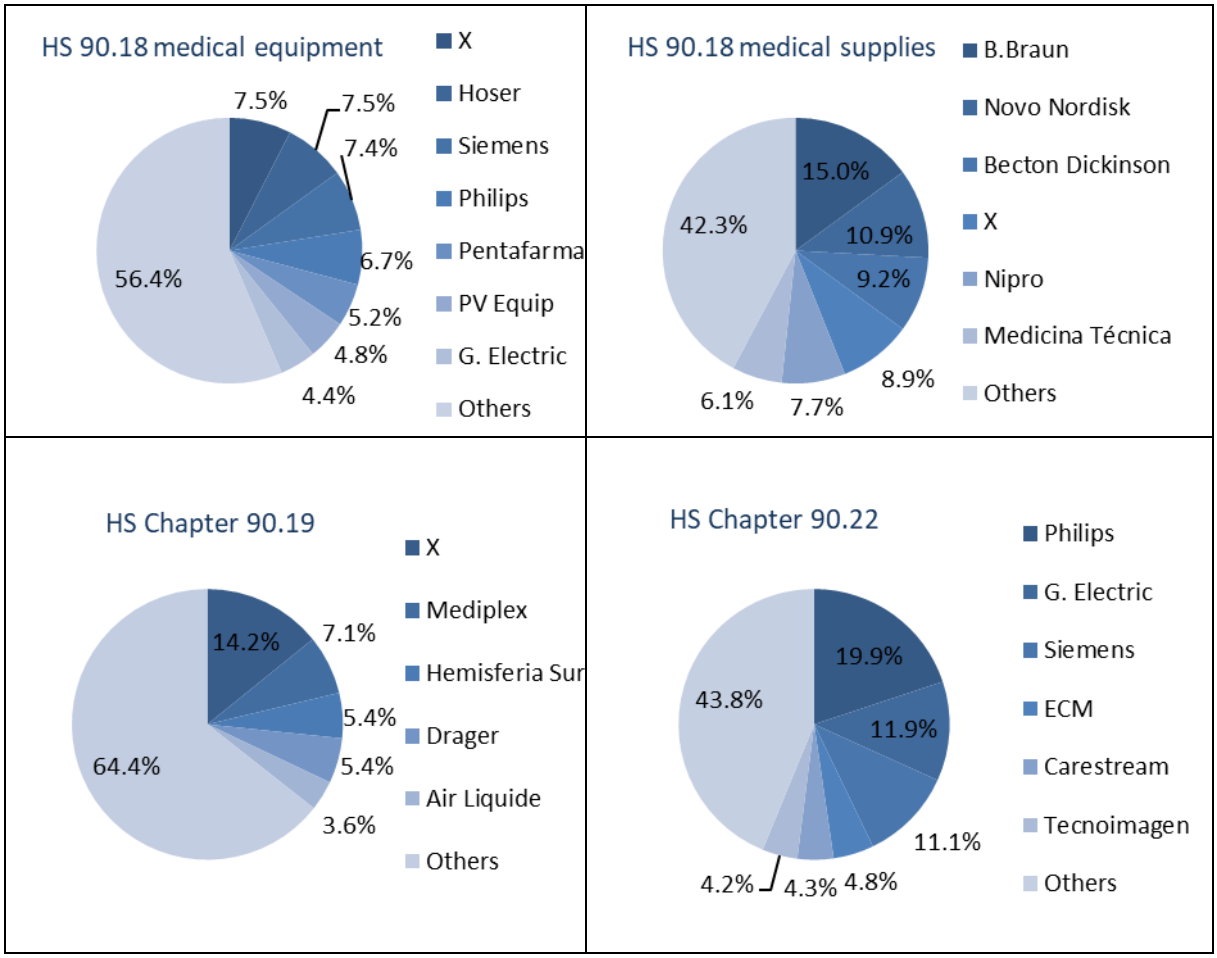
Medical equipment and supply market is quite atomized in terms of the number of companies importing and commercializing in the local market.

Importers are local subsidiaries of well-reputed multinational companies and local companies representing and distributing foreign manufacturers. There are just a few

imports conducted directly by hospitals and clinics. In several categories, market leaders are multinational companies installed in Chile.

The following chart shows main importers of medical equipment and supply imports, by type of product.

Imports by company – CIF Value 2016



Source: Chilean Customs Statistics

2.2 Exports

Given that there are not relevant local medical equipment manufacturers in Chile, there are not significant exports of these products. In the case of medical supplies, there are some minor exports of gloves, in-vitro kits, basic medical furniture and bandages to other countries in the region.

3. Competition Analysis

Companies commercializing medical equipment and supply in the Chilean market could be divided in two categories:

3.1 Multinational companies

Several of the most reputed multinational medical equipment companies have their own subsidiaries in Chile. Among them are Siemens, General Electric, Philips, Drager, etc.

Most of these companies have been operating in the Chilean market for several years and have created a very good reputation among medical equipment decision-takers. They develop an intense and permanent promotional activity among physicians and hospitals executives, i.e. congress sponsoring, scholarship programmes, participation in fairs and exhibitions, etc.

These companies sell directly and/or through other local distributors. These latest are generally also in charge of equipment installation, maintenance and repair.

Prices of these well-known suppliers are generally quite higher than their competitors, i.e. Asian manufacturers. But they often offer better post-sale service, local availability of spare parts and accessories and guarantees, as well as direct financing.

3.2 Representatives

This group is composed by local companies importing and distributing medical equipment and supplies and conducting the whole product supply process. Representatives/distributors buy the products to the foreign manufacturers they represent and are responsible of importing them and conducting custom clearance formalities. They are also in charge of the storage, internal transportation, sales and promotion and customer service. They also take in charge maintenance and repairing services, as well as the training to clients on how to use the equipment. Accordingly, they assume almost all the risk of product operation in Chile.

Given that medical equipment has usually a high price, they are imported at request, once the sale is closed. Depending on the negotiation conditions, the import process is conducted by the representative or by the final client. Most of times, representatives only keep locally in storage minor equipment or some spare parts and components. In some cases, they have a showroom in their premises exhibiting some of the equipment they commercialize.

As well as in the case of multinational company subsidiaries, representatives (especially the largest ones) usually offer direct financing to their clients. This is a very valued factor especially among small clients (small medical centres and doctors cabinets).

In some cases, both multinational company subsidiaries and representatives are willing to significantly reduce the price of equipment (even close to cost) in negotiating with their clients, if the sale is tied to a long-term maintenance contract, for a monthly fee. Also, in many cases, suppliers require the equipment (especially those with advanced technology or highly priced) is installed by them (through a turnkey project) for an additional fee, as a requirement for activating the guaranty.

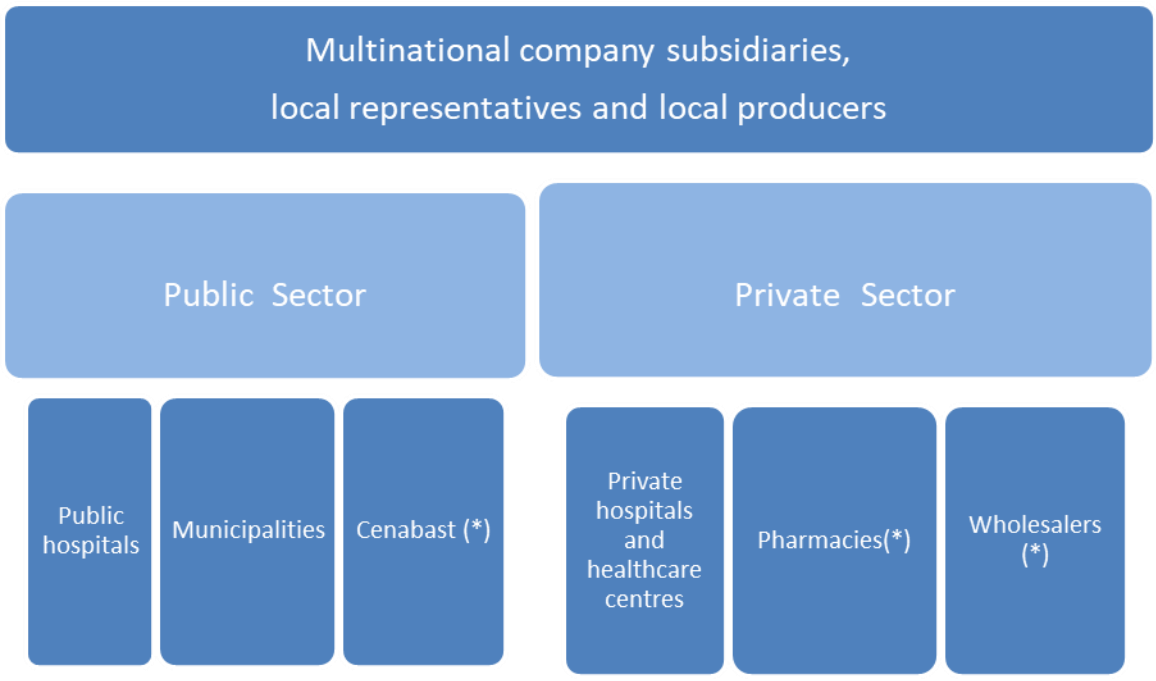
Most Chilean medical equipment representatives and distributors are specialized in only some few medical areas, except of the largest ones which cover a wide range of products. In general terms, they prefer to represent well-known foreign brands (i.e. are already present in several countries) or companies having clear competitive advantages, inasmuch as it makes much easier, cheapest and faster to introduce them into the local market. Low-price but reasonable quality equipment is also very valued by representatives/distributors, as in most of tenders price is the main selection factor.

It is worth mentioning that in most cases representation contracts demand exclusivity, that is to say, local companies cannot represent other competitive brands of the same category. As well, exclusivity is also for foreign companies, which cannot have more than one representative in the country.

ANNEX 1 shows the contact data of some of the main representatives and distributors that import medical equipment and supplies.

4. Distribution channels

The following chart shows main distribution channels for medical equipment and supplies in Chile.



(*) Only for medical supplies. Medical equipment is not distributed through these channels

4.1 Public Sector

The regulatory framework for public procurement in Chile[15] 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: public bidding, framework agreements, private bidding, and direct contracting. Contracting in the first option (the most

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

used in case of medical equipment and supplies) 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 previously agreed with the suppliers. Government agencies get these prices through purchase orders under the conditions specified in the agreements. This modality is used for medical supplies of frequent usage, but not for equipment.

Main public sector medical equipment buyers are Public Hospitals and Municipalities. These institutions also buy medical supplies, as same as Cenabast ("Central Nacional de Abastecimiento"),

4.1.1 Public hospitals

Medical equipment purchase is generally conducted by the Ministry of Health, in both cases: new hospitals construction and reposition. It is estimated that the average lifetime of most medical equipment (such as laboratory and imaging) is 10 to 15 years.

The only exception is the case of hospital concessions[16], which consist in an agreement made between the State and the private sector for the design, financing, construction and/or operation of a hospital or a section of it. In these cases, medical equipment is purchased by the private concessionary.

The process of medical equipment purchase for public hospitals usually requires several approvals from different entities and should follow a pre-established procedure. The purchase does not depend only on the equipment need of a particular hospital, but also on the need of the other hospitals which "compete" for the Ministry of Health budget. The whole process could take from one to several years.

In almost all the cases, medical equipment purchase should be done through the government purchase e-platform ("Mercado Público"). Tender evaluation methodology

[16] It is worth mentioning that current Chilean administration has cancelled hospital concession tenders that were in the pipeline; nevertheless, the hospital concession system is still in force and could be reactivated by future administrations.

usually places price as the main selection factor, but also consider other factors, such as quality and post-sale service.

Public hospitals purchase medical supplies to Cenabast or directly to importers and local producers- through the government purchase e-platform ("Mercado Público") - in case of supplies 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 medical equipment and supplies directly.

4.1.2 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.

Medical equipment purchase for new primary healthcare centres is generally conducted by the Ministry of Health, using the same procedure than for public hospitals. In the case of reposition or additional equipment, the purchase is conducted by municipalities through the government purchase e-platform ("Mercado Público").

As well as in the case public hospitals, municipalities can buy medical supplies for their healthcare centres to Cenabast or directly to laboratories through "Mercado Público" platform.

4.1.3 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 medicaments and medical supplies[17] which are conducted though "Mercado Público" Platform.

[17] 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 and medical supply market. [18] 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 insufficient 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 international public tendering).

4.2 Private sector

Main medical equipment private sector distribution channels are private hospitals, clinics and healthcare centres.

In the case of medical supplies, they can also be distributed through pharmacies and wholesalers.

4.2.1 Private hospitals, clinics and healthcare centres

In 2015, Chile had 161 private hospital and clinics[19], 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 medical equipment and supplies directly to importers and local manufacturers, through private tendering processes. Price is a key evaluation factor, but they also value the opinion of the medical and paramedical staff. The final decision on the equipment to buy also considers factors such as reputed brands, good quality and after-sales reputation.

Many private hospitals receive foreign patients for treatment on a regular basis. They also have agreements with well-reputed international institution, as well as Joint Commission

[18] To review the list of medicaments and medical supplies purchased by Cenabast during current year, click on this link: http://www.cenabast.cl/licitaciones-efectuadas/

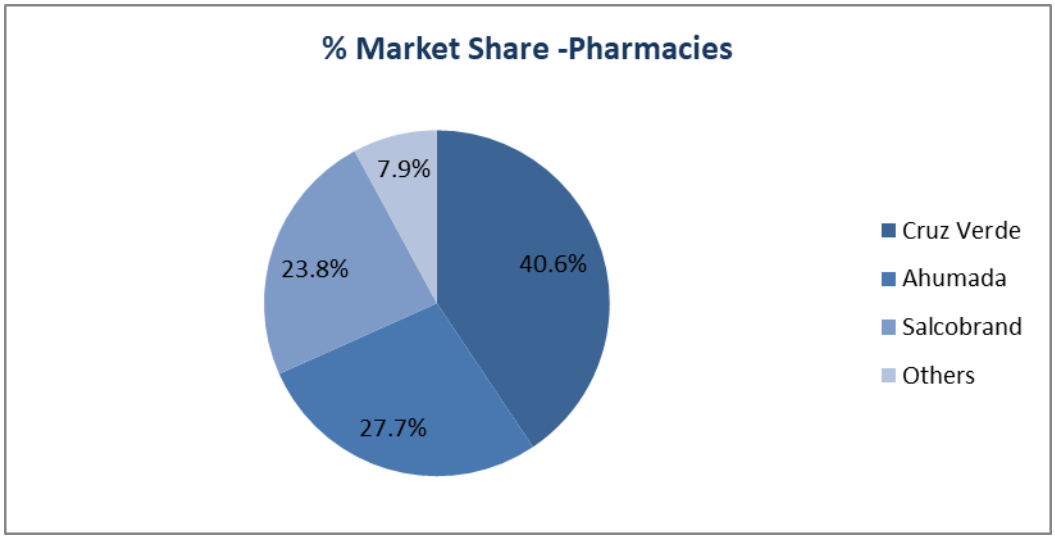
[19] Includes private-owned, armed force, university and occupational-accident mutual hospitals and clinics.

accreditation. Therefore, they need to maintain high standards in terms of infrastructure, equipment and service.

In the case of medical supplies, they sometimes establish long and medium term agreements benefiting of discounts per volume.

4.2.2 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.



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.[20] Most of these products correspond to OTC medicaments, medical supplies and cosmetic and personal care products.

[20] It us worth mentioning that a reform is currently been discussed in Chilean parliament. One of its points is to prohibit pharmacies to have their own laboratories.

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, importers and local manufacturers. Negotiation usually includes discounts per volume, price promotion campaigns and advertising in pharmacies catalogues, among others.

4.2.3 Wholesalers

Distributors gather a large stock of medicaments and medical supplies form 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, importers and local manufacturers.

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.

4.3 Buyer's product requirements

In 2014, the Public Health Institute of Chile (ISP) issued some recommendations to hospitals regarding the purchase of medical devices, according to their risk classification[21]. Even if these recommendations are not mandatory, they are a good approach of the requirements public and private hospitals are currently demanding to medical device suppliers in their tender processes.

Main requirements for medical devices classified in Class III (to which belong most of the products considered in this survey) are the following:

a. Product labelling, if applicable

b. Manual for instructions in Spanish

[21] See the text by clicking on www.ispch.cl/sites/default/files/1_Guia_para_la_Adquisicion_de_Dispositivos_Medicos_en_las_Instituciones_de_Salud.pdf

c. Documentation supporting product certification, such as ISO 13485/2003 or further versions, CE marking, Certificate for Foreign Governments (CFG) issued by the F.D.A., Good Manufacturing Practices (GMP).

d. Certificate validating sterilizing methods, in case of sterile medical devices

e. Electricity safety certificate of compliance according to IEC 60601, in case of electro medical devices.

f. Document accrediting post-sale and technical service.

g. Declaration accrediting and guaranteeing spare part and accessory availability for at least 10 years.

5. Import and commercialization formalities

All medical equipment and supplies imported and commercialized in Chile should meet some formalities. Some of them are the usual to any import, but some are specific for some products, necessary to their 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.

5.1 Certification of Medical Devices

Medical devices in Chile are regulated by article 111 of the Health Code and Supreme Decree (DS) 825/98. This legislation rules the quality control and certification of all products that are manufactured, imported, sold or distributed in the country.

Chilean law classifies medical devices as belonging to one of four groups, according to their associated level of risk. Class 1 relates to the lowest risk and includes bandages, cervical collars and stethoscopes; Class II includes removable dental prostheses and surgical gloves; Class III is comprised of elements such as condoms, dialysis machines and anaesthesia machines; and Class IV, which relates to the highest risk, includes intrauterine devices and heart implants, and valves, among others.

Currently, in Chile only a few products are subject to mandatory control and certification: examination gloves, surgical gloves, condoms, hypodermic needles, syringes for single use, and some IVD reagents. Medical devices not included in this list may currently be sold freely. [22]

Should a certification be obtained, only a registered Chilean Medical Device Manufacturer and Distributor upon the ISP[23] may apply for and hold a license. This representative will also be responsible for post-market surveillance, license modifications, etc. During the application process, all documentation must be submitted in Spanish. The process can be completed in about two months.

Importers of medical devices not subject to mandatory control could get a voluntary certificate called the Background Assessment Certificate (Certificado de evaluación de antecedentes), as well as a voluntary company registration upon the ISP. It is recommended that devices carry these certifications, for commercial purposes (like a "quality label") and in order to anticipate future regulations that may require registration for all devices.

Even if certification is not mandatory for most medical devices, almost all hospitals and clinics require that medical equipment they buy are certified under main international standards, i.e. C.E. marking (European Union) and US Food and Drug Administration (FDA). Buyers also usually ask for quality certifications, such as ISO 13485/2003 (or further versions) and Good Manufacturing Practices (GMP).

In the case of electro-medical equipment, they should also be certified under the Chilean electricity safety standard NCH 2893 (equivalent to international standard IEC 60601).

5.2 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, if applicable
- International Transport Document (Bill of Lading or Air Way Bill)
- Packing List, when necessary

[22] A new law (Medical Drug Act II) is currently been discussed in the Parliament. It will probably extend the list of products subject to mandatory control, optimize the registration process and recognize foreign certifications in the absence of certifying bodies in Chile.

[23] See the list of currently approved medical device distributors and manufacturers by clicking on www.ispch.cl/dispositivos-medicos

- 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.

5.3 Import of medical device products

The import and commercialization of medical devices subject to control (that is, examination gloves, surgical gloves, condoms, hypodermic needles, syringes for single use, and some IVD reagents) 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 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 or the goods to Chile.

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

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 ate 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]

[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/

India and Chile have signed a Partial Scope Trade Agreement (PSA) giving to some pharmaceutical products a tariff preference.. Products benefiting of this preference are the ones classified under the following HS codes:

Chapter/code	Description	Tariff preference
90.18	Medical Equipment:	
	90181100 Electro-cardiographs	80%
	90181200 Ultrasonic scanning apparatus	60%
	90181900 Other	80%
	90189030 Hearth monitors	80%
	Medical Supplies	
	90.18.32 Needles	100%
	90.18.39 Other (catheters, blood bags, etc.)	
	90.18.39.30	80%
	90.18.39.40	100%
	90.18.39.90	100%
90.19	Mechanic-therapy appliances; massage apparatus; psychological aptitude-testing apparatus; ozone therapy, oxygen therapy, aerosol therapy, artificial respiration or other therapeutic respiration apparatus; parts and accessories.	
	90.19.10.00	100%
	90.19.20.20	100%
	90.19.20.90	100%
90.22	X-ray, alpha, beta, gamma radiation apparatus; x-ray tubes, x-ray generators, high tension generators, control panels and desks, screens, examination or treatment tables, chairs and other	
	90.22.14.11	80%
	90.22.14.19	80%
	90.22.30.00	100%
	90.22.90.90	80%

Additionally, medical equipment and supplies are subject to VAT (value added tax), which rate is 19%.

5.5 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 medical equipment and supply producers, and for identifying both the Opportunities open to them and the Threats they face in the Chilean market.

SWOT ANALYSIS

Strengths	**Opportunities**
• Good quality of Indian medical equipment and supplies. • Competitive prices • Wide variety of products. • Existence of experienced Indian producers and exporters. • Duty tax preference (India-Chile Partial Scope Agreement).	• Total market is expected to continue growing in years to come. • Opportunities for low-cost equipment with demonstrable quality. • Existence of several well-reputed potential representatives/distributors • Opportunities in government purchases for new hospital construction • Fast grow of specialty stores and foodservice. • Ayurvedic medicaments and natural products.

Weaknesses	Threats
• Indian medical device industry is still small (2% of global industry) • Indian medical device market has been import-driven (75% of total sales). • Domestic companies concentrates mainly in low-cost devices • Most of Indian medical devices are currently unregulated, meaning no government oversight on its manufacture. New regulation will come into effect in 2018.	• High competition from multinational and largely established companies. • Lack of awareness of Indian medical equipment among decision takers. • Potential changes in regulation that will increase medical device safety control and need of certification.

6.2 Main conclusions

Chilean medical device market is expected to continue growing, reaching USD1.2 billion by 2020 and representing a 2015-2020 grow of 46.6% in the market value per capita, from US$ 42.5 to US$ 62.3. This grow will be mainly driven by the construction of new public hospitals, as well as by the renovation of some of the existing ones. Several new hospitals are still in the pipeline to be constructed in next years and will need to be furnished and equipped.

This translates in a growing demand for equipment, such as autoclaves, surgical tables, non-disposable and disposable surgical instruments, cardiology equipment including pacemakers, monitors (low and medium complexity), central monitors, ventilators, aspiration pumps, , trauma equipment, anaesthesia instruments and appliances and hospital furniture.

Moreover, the growing demand for diagnostic examinations in the public and private healthcare systems will also boost the need of new equipment, such as X-ray, laboratory, ultrasonic and magnetic resonance equipment, as well as of the supplies associated to their usage.

Price is an extremely important factor in medical equipment tenders, especially in the public sector where limited funds cover a large segment of the population. Therefore, there are good opportunities for low-price medical equipment that could guarantee adequate levels of quality and safety, and be able to provide the required international certifications, such as ISO 13485/2003 or further versions, CE marking, Certificate for Foreign Governments (CFG) issued by the F.D.A., Good Manufacturing Practices (GMP), electric safety IEC 60601 certification, etc.

By the other side, state-of-the-art medical technology has good market potential in Chile, especially in the private sector with regular expansion projects. The Chilean private healthcare system is well regarded in the region and maintaining high standards is a permanent goal. The private sector is also price sensitive, but is far more likely to consider recognized brands or last technology equipment that could represent a competitive advantage vis-a-vis their competitors.

Other important trends in the medical equipment market are miniaturization and automation. Customers are now seeking space-saving options for cutting costs. Mobility is also another focus; therefore, portable equipment is highly valued by customers.

To entry into the Chilean market, Indian medical equipment manufacturers are advised to find a local representative or importer, who can be permanently aware of public and private calls for bids, as well as to deal with registration processes (if needed) and import procedures. Moreover, it is very important that the representative can take in charge the training to users and post-sale services, as these activities are requested in almost all tenders. Besides, it is desirable the representative could give direct financing to clients, especially to the small ones.

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.

…….

Embassy Contact Information:
Commercial Section,
Embassy of India,
971 Alcantara,
Santiago, Chile
Tel. 562 22286857
Fax: 562 223217217
E-mail: com.santiago@mea.gov.in; com1.santiago@mea.gov.in