

CHILE

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Executive Summary

Protectionism towards the domestic industry characterises the Chilean market, currently the seventh largest market in the Americas region at nearly US\$1.1 billion. The domestic industry specialises in generic and copycat products, supplying 80% of the market by volume and 56% by value. Factors shaping the pharmaceutical industry include new trade agreements such as the US-Chile FTA (January 2004); potential long-term TRIPS-related patent enforcements; further compliance with bioequivalence tests, generic substitution and GMP standards in 2005; increasing retail/wholesale competition; and OTC switches as a measure of market diversification.

The country is also enacting a general reform affecting the healthcare sector. "Equity, participation, solidarity and quality" are the four pillars of the Chilean Healthcare Planning Objectives 2000-2010. As part of the health reform, a five-law bill is currently under approval, and public-private partnerships are being considered as further sources of investment.

Key Data

	Value	Year	World Ranking
Population (millions)	15.4	2002	38
GDP per capita (US\$)	4,870	2004	44
Health expenditure per capita (US\$)	325	2004	37
Health expenditure as % of GDP	6.7	2004	41
Hospital Beds per 1,000 population	2.6	2001	62
Physicians per 1,000 population	1.2	2000	69
Pharmaceutical Expenditure (US\$ millions)	1,095.7	2004	39
Pharmaceutical Expenditure per capita (US\$)	71.1	2004	40

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INTRODUCTION

During the last five years Chile has successfully overcome the economic crisis. Continuous reforms in the country have guaranteed and risen living standards of its 15.4 million population over neighbouring countries, although unemployment remains high at around 10%. GDP is expected to grow by 4% in 2004, although more optimistic sources from the Central Bank of Chile indicate a figure in between 4% and 5.5%. Trade liberalisation and opportunities for investments are also key in Chile's success, fuelled by new trade agreements with the EU (2002-03), the US-Chile FTA (January 2004) and the Korea-Chile FTA (April 2004).

Health status in Chile faces traditional problems of poverty, environmental conditions and infectious diseases (hepatitis, TB, whooping cough and AIDS) associated to developing countries, together with other problems more associated to the developed world, including an ageing population and chronic illnesses (circulatory, neoplasms and respiratory). Inequalities remain, when infant mortality can vary from two per thousand population in urban and rich areas, to over 34 in less controlled areas. Life expectancy in the country is among the highest in the region, at an average of 76 years.

"Equity, participation, solidarity and quality" are the four pillars of the Chilean Healthcare Planning Objectives 2000-2010. This is a major step to strengthen a more preventive and universal primary care system, enforce and expand the programme AUGE to 56 ailments by 2007, improve IT health systems and improve management and auditing needs. The goals for 2010 are to increase health equities, meet the needs of the ageing population, face sociological changes, service an "empowered" population and continue to enhance sanitary surveillance.

The Chilean pharmaceutical market is the seventh largest market in the Americas (0.4%), behind the USA (87.3%), Canada (4.5%), Mexico (3.1%), Brazil (3.1%) Argentina (0.7%) and Colombia (0.4%). In 2004, pharmaceutical spending was around US\$1,095.7 million at consumer prices, equivalent to US\$71.1 per capita.

The market is highly competitive due to the presence of a well-developed domestic industry specialised in generics and copycat products, which supplies nearly 80% of the market by volume and 56% by value. Around 72% of the market is prescription-only medicines (POM), 20% OTC and 8% generic. The number of major pharmaceutical players is around 63, of which 32 are domestic. Leading domestic manufacturers include Recalcine, Saval, Andrómaco, Maver and Bago. International investors include LabChile (acquired by IVAX in mid-2001), GSK, Pfizer, Bayer and Merck.

BACKGROUND

Geographic



...rica and borders Peru, Bolivia and Argentina. Chile has a population density of around 19.8 inhabitants per square kilometer. The majority of inhabitants residing in urban areas. The

Source: CIA World Factbook.

Political

Executive authority in the Republic of Chile rests with the President, who is directly elected every six years. Legislative authority rests with the National Congress, which has two chambers, the Senate and the Chamber of Deputies.

The current President is Ricardo Lagos Escobar, who assumed office in March 2000. Dr Pedro Garcia has been the Minister of Health since October 2002. Municipal elections will take place in October 2004. New confrontation between the main political parties Concertación and Alianza can be expected in the next presidential elections scheduled for December 2005.

The military has always had an extremely strong influence over Chilean politics, although this has receded somewhat following the fall of the dictator, General Pinochet, in 1989. The transition to democratic government since this date has so far gone smoothly. The current situation is stable, and has allowed for rising living standards, but tensions between the democratic and military factions make the political scene potentially volatile.

Economic

Chile is generally perceived to be one of Latin America's better economic performers. Between 1980 and 1997, the annual real growth rate in the country's economy averaged more than 5%, reaching a high of 10.6% in 1995. The impact of the Asian crisis during the late 1990s did, however, result in limited growth of 0.5% in 1998 and an economic decline of 7.9% in 1999, in US\$ value.

During the early months of 2000, the economic situation improved, but by the end of the year, optimism for a strong economic recovery was waning in the face of a stubbornly high unemployment rate of around 10%. Moderate growth of 3.7% but decline of 10.1% in US\$ value was recorded for 2000 and 2001, respectively. Due to the continuing depreciation of the Chilean peso against the dollar, GDP in dollar terms fell from around US\$70.1 billion in 2000 to US\$63.0 billion in 2001. One quarter of the population is considered to be poor.

In September 2002, the Central Bank revised its real growth forecast for 2002 to just 2.1%, with growth for 2003 projected at 3.3% and 2004 at 4%. Slow growth factors cited by the bank include continuing depressed internal demand, the slowdown in the American economy, the financial crisis taking hold in other parts of Latin America and higher oil prices. In 2004, GDP is estimated at US\$75.0 billion, equivalent to GDP per capita of around US\$4,870. This high increase in US\$ value is mainly due to the Chilean peso's appreciation against the dollar.

GDP Growth, 1996–2004

	GDP (US\$ Billion)	GDP Growth (%)
1996	67.9	~
1997	73.0	7.5
1998	73.4	0.5
1999	67.6	-7.9
2000	70.1	3.7
2001	63.0	-10.1
2002	66.0	4.8
2003*	68.3	3.4
2004*	75.0	9.9

Source: Central Bank of Chile. * Espicom's estimates based on GDP growth in Chilean pesos of 3.3% in 2003 and 4.0% in 2004, plus Chilean peso's appreciation against the US\$ of 0.11% in 2003 and an adjusted annual 5.63% (quarterly appreciation of 14.57% as a reference) in 2004.

Trade liberalisation and opportunities for investments are also key in Chile's economic success. Chile has recently entered into bilateral and multi-lateral agreements with Canada, the USA, the EU and some Australasian countries. The US - Chile FTA took effect in January 2004. It eliminates tariffs by 85% and full elimination of tariffs will be complete in 12 years. Other notable agreements include the Korea – Chile FTA signed on the 1st April 2004 and a new agreement with the EU. Consequently, the new public health structure under reform in the country implies economic opportunities for international collaboration. Further information on these trade agreements can be found at www.chileinfo.com and www.chileusafta.com/

POPULATION

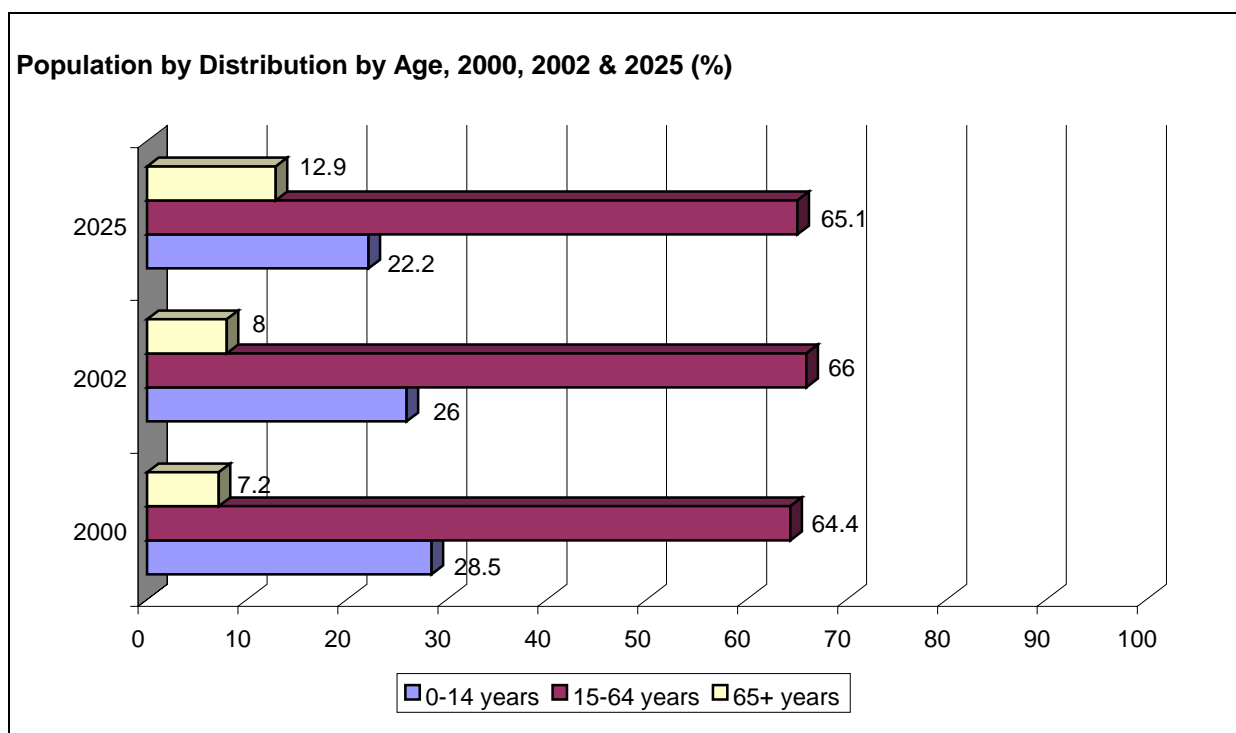
According to the latest census published by the Ministry of Health's Department of Statistics and Health Information (DEIS), taken in April 2002, the population of Chile is 15.1 million. However, other more recent sources from DEIS indicate a figure closer to 15.4 million. At the time of the previous census, conducted in 1992, Chile had a population of 13.3 million, meaning that the number of inhabitants has grown at an average annual rate of 1.2% over the past decade, compared to an increase of 1.6% over the previous decade. Average population density has increased to 19.9 inhabitants per square kilometre, compared with 17.7 at the time of the 1992 census. Population density in 2002 ranged from 0.8 in Aisén del General Carlos Ibáñez del Campo, to 393 in the Santiago Metropolitan Region. Over 85% of the population live in an urban environment, with around 40% residing in Santiago.

Population by Region, April 2002 Census

	Population	Area (Km ²)	Pop. Density
De Tarapacá	426,351	58,698.1	7.3
De Antofagasta	492,846	126,443.9	3.9
De Atacama	252,353	75,573.3	3.3
De Coquimbo	600,363	40,656.3	14.8
De Valparaíso	1,542,492	16,396.1	94.1
Del Libertador General Bernado O'Higgins	773,950	16,341.4	47.4
Del Maule	904,104	30,325.3	29.8
Del Biobío	1,853,678	36,929.3	50.2
De La Araucanía	864,929	31,842.3	27.2
De Los Lagos	1,061,735	67,013.1	15.8
Aisén del General Carlos Ibáñez del Campo	86,697	109,024.9	0.8
De Magallanes y de la Antártica Chilena	151,869	132,033.5	1.2
Región Metropolitana de Santiago	6,038,974	15,348.8	393.4
Total	15,050,341	756,626.3	19.9

Source: INE.

The age structure of the population remains predominantly young, with around 26% of Chileans being under 15 years of age in 2002. The Chilean population is, however, ageing. In 1995, the proportion of the population aged 65 years or over was less than 7.0%. The Institute of National Statistics (INE) estimates that the proportion of over 65s increased to 7.2% in 2000 and will continue to rise to 12.9% by 2025. The under 15 population will gradually decrease to 22.2% of the total over the same period.



Source: 2000 & 2025, INE. 2002, DEIS.

HEALTH STATUS

Basic sanitation in Chile is considered adequate in comparison with other Latin American countries. In urban areas, 95% of the population have access to safe drinking water. This falls to 73.3% in populous rural zones and 8.2% in less populated areas. Around 73% of urban areas are covered by the sewerage system, but 97% of waste water is released without being treated.

The Chilean birth rate has been declining steadily, falling from 23.5 births per thousand population in 1990 to 16.8 in 2001. In 2001, 259,069 births were registered in Chile, a decrease of 16% since 1990. Births still considerably outnumber deaths, however, resulting in a natural increase rate of 11.7 per thousand population in 2001. The crude mortality rate has been stable at between 5.3 and 5.5 deaths per thousand population since 1992.

The decline in the number of infant deaths in Chile in recent years has been striking, due to the implementation of maternal and infant health programmes and the improvement in sanitation, health education and per capita wealth. In 1980, infant mortality in Chile stood at 32 per thousand live births. By 1992, it had improved to 14.3 per thousand live births - the lowest rate in Latin America, after Cuba. In 1997, infant mortality fell to a low of 10.0 deaths per thousand live births, before increasing slightly to 10.3 in 1998 and 10.1 in 1999. Figures for 2000 and 2001 indicate a fall to 8.9 and 8.3, respectively. Maternal mortality, the main cause of which is abortion, stood at 17 deaths per 100,000 live births in 2001. Abortion has been a leading cause of maternal mortality, although in 2001, there were only four deaths directly attributed to abortion, compared to 14 in 1998.

Life expectancy at birth in Chile is among the highest in the region, at around 73 years for males and 79 years for females.

Demographic Indicators, 1995-2001

	1995	1996	1997	1998	1999	2000	2001
Births	279,928	278,729	273,641	270,637	263,867	261,993	259,069
Births/ 1,000 pop.	19.7	19.3	18.7	18.3	17.6	17.2	16.8
Deaths	78,531	79,123	78,472	80,257	81,984	78,814	81,871
Deaths/ 1,000 pop.	5.5	5.5	5.4	5.4	5.5	5.4	5.3
Infant deaths	3,107	3,095	2,732	2,793	2,654	2,336	2,159
IMR/1,000 live births	11.1	11.1	10.0	10.3	10.1	8.9	8.3
Neonatal mortality	1,695	1,743	1,569	1,614	1,547	1,467	1,290
NMR/1,000 live births	6.1	6.3	5.7	6.0	5.9	5.6	5.0
Maternal mortality	86	64	61	55	60	n/a	45
MMR/1,000 live births	0.31	0.23	0.22	0.2	0.23	n/a	0.17
Natural increase	201,397	199,606	195,169	176,848	181,883	183,179	177,198
Rate/1,000 pop.	14.2	13.8	13.3	12.9	12.1	12.0	11.7
<i>Life expectancy:</i>							
Males	72.2*	n/a	n/a	n/a	72.6	73**	n/a
Females	78.3*	n/a	n/a	n/a	78.7	79**	n/a

Source: DEIS. *1995-2000 estimates. **2000-2005 estimates.

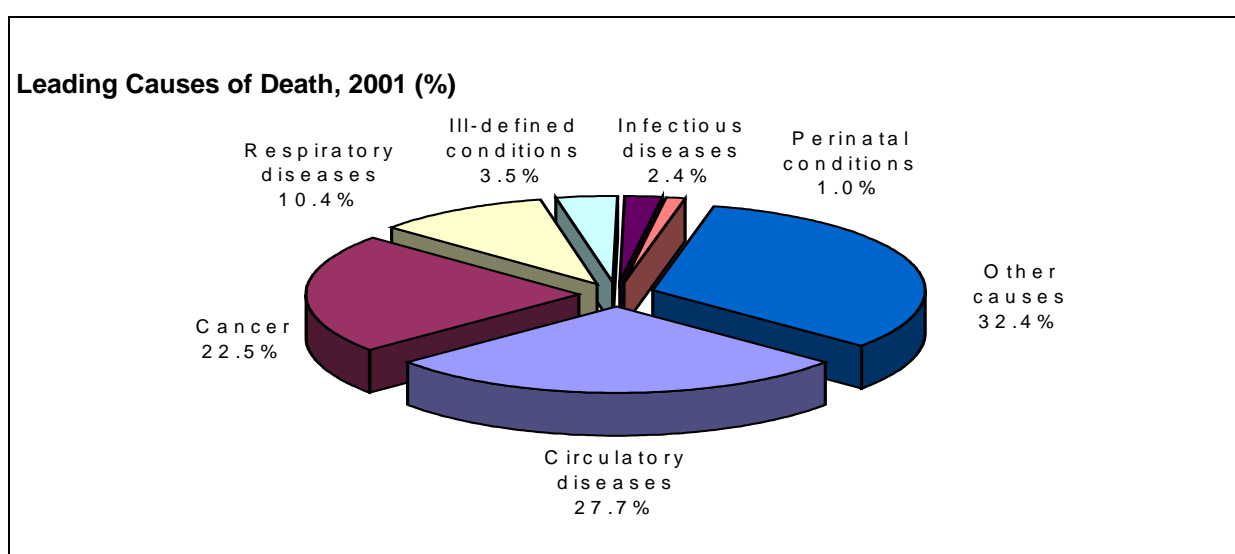
Causes of Death

The leading cause of mortality in Chile is circulatory disease, which accounted for 28% of all registered deaths in 2001. Ischaemic heart disease and cerebrovascular disease accounted for over two thirds of these in total, equivalent to 9.5% (7,812 deaths) and 9.6% (7,845 deaths) of all deaths respectively.

There is, however, evidence of a downward trend in deaths from circulatory diseases. The crude mortality rate for this cause group declined from 163.7 per 100,000 population in 1990 to 147.2 per 100,000 in 2001, an overall decrease of 10.1% over the period.

The second most frequent cause of death in 2001 was cancer, accounting for 22% of the total. The death rate for cancer has been increasing in recent years, from 107.5 per 100,000 population in 1990 to 119.4 per 100,000 in 2001.

Deaths due to respiratory diseases increased dramatically between 1982 and 1990, from 52 to 73 deaths per thousand population, most of which were due to pneumonia which remains the leading cause of respiratory deaths. In 2001, 10% of deaths were attributed to respiratory illnesses, a rate of 55.4 per 100,000 population.



Source: DEIS.

Deaths by Cause, 2001

	Total	Rate/100,000 Pop.
Circulatory diseases	22,666	147.2
Cancer	18,394	119.4
Respiratory diseases	8,531	55.4
External causes	7,623	49.5
Hepatic cirrhosis	3,077	20.0
Diabetes mellitus	2,951	19.2
Ill-defined conditions	2,871	18.6
Transport accidents	2,061	13.4
Infectious & parasitic diseases	1,999	13.0
Suicides	1,625	10.6
Congenital anomalies	908	5.9
Perinatal conditions	855	5.6
HIV-AIDS	552	3.6
Tuberculosis	318	2.1
Maternal deaths	45	*0.17

Source: DEIS. *Rate/100,000 live births.

Causes of Death, 1990-2001

	1990	1995	1996	1997	1998	1999	2001
Circulatory diseases	21,568	21,117	21,471	20,732	22,057	22,730	22,666
Cancer	14,163	16,429	16,747	17,000	17,472	17,886	18,394
Respiratory diseases	9,632	9,883	9,799	9,987	10,222	11,467	8,531
Accidents & poisonings	9,587	8,836	8,410	8,280	8,125	7,652	~
Digestive diseases	4,902	5,758	6,024	5,858	5,788	5,530	~
Signs, symptoms & ill-defined conditions	6,100	4,008	3,544	3,718	3,502	3,712	2,871
Endocrine, nutritional & metabolic disorders	1,871	2,805	3,197	2,567	3,129	3,294	~
Infectious & parasitic diseases	2,475	2,087	2,049	2,465	2,287	2,218	1,999
Genitourinary diseases	1,597	1,690	1,742	1,703	1,820	1,932	~
Perinatal conditions	1,700	1,022	1,036	996	948	932	855
Other causes	4,839	4,896	5,104	5,166	4,907	4,631	26,557
All causes	78,434	78,531	79,123	78,472	80,257	81,984	81,873

Source: DEIS.

Deaths by Cause, 1998-1999

	1998 Total	1999 Total	1999 Male	1999 Female
Intestinal infectious diseases	236	237	97	140
Tuberculosis	357	351	255	96
Septicaemia	679	532	245	287
Other infectious & parasitic diseases	1,015	1,098	756	342
Malignant tumour of the stomach	2,891	3,038	2,014	1,024
Malignant tumour of the colon	697	799	318	481
Malignant tumour of the trachea, bronchus & lung	1,797	1,843	1,243	600
Malignant tumour of the breast	992	983	10	973
Malignant tumour of the neck of the uterus	728	727	-	727
Leukaemia	501	534	282	252
Other malignant tumours	9,866	9,962	5,201	4,761
Diabetes mellitus	2,235	2,381	1,084	1,297
Nutritional deficiencies	575	611	300	311
Anaemias	222	221	106	115
Mental illness	869	488	314	174
Meningitis	130	111	58	53
Chronic rheumatic fever of the heart	260	332	126	206
Hypertensive disease	2,034	2,207	964	1,243
Acute myocardial infarction	5,706	5,855	3,390	2,465
Other ischaemic heart disease	2,255	2,093	1,041	1,052
Cerebrovascular disease	7,559	7,859	3,877	3,982
Atherosclerosis	465	535	204	331
Other circulatory diseases	3,778	3,849	1,912	1,937
Pneumonia	6,121	6,971	3,485	3,486
Influenza	87	135	44	91
Bronchitis, emphysema & asthma	2,270	2,467	1,348	1,119
Gastric ulcer	218	265	165	100
Appendicitis	56	48	27	21
Cirrhosis & other chronic liver diseases	3,611	3,320	2,348	972
Diseases of the skin & subcutaneous tissue	316	578	230	348
Diseases of the musculoskeletal system	338	342	100	242
Nephritis, nephrosis & nephrotic syndrome	94	54	27	27
Hyperplasia of prostate	64	62	62	-
Abortion	14	5	-	5
Other obstetric causes (direct & indirect)	20	21	-	21
Congenital anomalies	1,148	1,060	533	527
Perinatal conditions	948	932	551	381
Signs, symptoms & ill-defined conditions	3,502	3,712	1,746	1,966
Other diseases	7,478	7,714	3,743	3,971
External causes	8,125	7,652	6,218	1,434
Total	80,257	81,984	44,424	37,560

Source: DEIS.

Infant Mortality

The leading causes of infant mortality in Chile are perinatal conditions and congenital anomalies. In 2001, these two conditions accounted for 39.2% and 31.2% of deaths of children under one year of age respectively. A further 9.0% were attributed to respiratory illnesses, mainly pneumonia.

Infant Mortality by Cause, 2001

	Males	Females	Total	As % of Total
Perinatal conditions	489	357	846	39.2
Congenital anomalies	341	332	673	31.2
Signs, symptoms & ill-defined conditions	120	105	225	10.4
Respiratory diseases	114	80	194	9.0
Other infectious & parasitic diseases	29	32	61	2.8
Nervous system diseases	36	25	61	2.8
External causes	12	18	30	1.4
Nutritional deficiencies	12	5	17	0.8
Circulatory diseases	13	4	17	0.8
Intestinal infectious diseases	8	5	13	0.6
Neoplasias	7	4	11	0.5
Other diseases	4	3	7	0.3
Genitourinary diseases	2	2	4	0.2
Total	1,187	972	2,159	100.0

Source: DEIS.

Morbidity

According to the Ministry of Health, the infant vaccination programme in Chile covers around 97.6% of infants for diphtheria, pertussis, tetanus and polio. There have been no reported cases of diphtheria since 1997. In 2001, there were ten reported cases of tetanus and 1,611 cases of whooping cough.

In 2001, 2,603 new cases of tuberculosis were reported, of which 2,230 were respiratory tuberculosis and 373 other tuberculosis. This compares to over 6,000 new cases reported in 1990. A widespread educational campaign, sanitary food control and an epidemiological watch helped Chile to reduce the spread of the cholera epidemic, which started in Peru in 1991. As a result of this campaign, the number of cases was reduced from 147 in 1991 to zero in 1995. There were four reported cases of malaria in 2001 and eight cases in 2000.

The northern region around Antofagasta has the greatest incidence of skin cancer in Chile, with around 3.8 cases per 100,000 population proving fatal, compared with the national average of 1.1. In February 1997, it was reported that Antofagasta health officials attribute the high rate to the arsenic content in the drinking water, rather than to excessive exposure to sunlight. High concentrations of arsenic are found in volcanic rock and thermal water, which is washed into the drinking water sources, where it dissolves and reaches the general population.

Influenza is one of the most prevalent infectious diseases with 172,930 cases reported in 1998. The most prevalent notifiable infectious disease is hepatitis. In 2001, there were 6,157 reported cases of hepatitis, including 271 cases of hepatitis B. Among sexually transmittable diseases, syphilis is the most common, with 3,724 cases reported in 1997, followed by gonorrhoea, with 2,329 cases reported in the same year. Reported HIV-AIDS cases considerably increased to 1,596 in 2001.

Reported Cases of Infectious Diseases, 1993-2001

	1993	1995	1996	1997	1998	2000	2001
Diphtheria	8	3	2	1	0	0	0
Scarlet fever	7,478	5,149	4,075	4,553	n/a	n/a	n/a
Paratyphoid fever	261	281	277	173	*	*	*
Typhoid fever	1,373	1,137	1,118	1,076	1,122	873	728
Tuberculosis	4,598	4,150	4,178	3,880	3,653	n/a	2,603
Hepatitis	6,048	15,446	9,867	10,671	5,958	6,012	6,157
-Hepatitis A	820	2,706	1,554	1,795	n/a	n/a	n/a
-Hepatitis B	137	130	133	149	n/a	210	271
-Other hepatitis	5,091	12,610	8,180	8,727	n/a	n/a	n/a
Meningococcal infection	562	561	532	550	n/a	559	489
Meningitis	380	397	341	316	375	n/a	n/a
Mumps	7,931	2,766	2,374	2,312	2,224	n/a	n/a
Rubella	4,120	2,067	1,143	3,940	4,571	n/a	n/a
Whooping cough	600	361	1,146	1,456	2,482	3,484	1,611
Influenza	148,535	138,186	141,625	158,455	172,930	n/a	n/a
Tetanus	18	11	11	178	15	10	10
Gonorrhoea	4,205	2,886	2,688	2,329	2,362	n/a	n/a
Genital herpes	320	310	325	349	n/a	n/a	n/a
Syphilis	4,958	4,128	3,574	3,724	3,631	n/a	n/a
Other venereal diseases	108	112	146	697	n/a	n/a	n/a
AIDS	246	351	427	552	486	442**	1,596

Source: MINSAL. *Included under typhoid fever. **Preliminary figure, cumulative total (1984-2000) is 4,085.

HEALTH EXPENDITURE

Chile spends around 6.7% of GDP on healthcare. In 2004, total health expenditure is estimated to be in the region of US\$5.0 billion, approximately half from the public sector and half from the private sector and other. Annual per capita health expenditure is recovering at around US\$325.

Public sector health spending mainly comprises central government funding for the health sector (which finances hospital services run by the national health service system (SNSS) and primary care services run by the municipalities), and spending under the public health insurance scheme FONASA. Private health expenditure includes spending undertaken by ISAPRE's private health insurance schemes, private patient co-payments and out-of-pocket expenditure. Other spending comes from health services run for the benefit of members of the armed forces, the police and employees of large corporations.

All employees must contribute 7.0% of their wages towards either a public or private health insurance scheme.

National Health Expenditure, 1995 & 2004 (US\$ Million)

	1995	As % of Total	2004	As % of Total
Public sector	1,582.6	38.7	2,500	50.0
Private sector/ISAPRE	1,035.6	25.3	1,000	20.0
Others	1,475.5	36.0	1,500	30.0
Private co-payments	211.8	5.2	~	~
Work-related injuries & illnesses	178.6	4.4	~	~
Armed forces	405.3	9.9	~	~
Private dental health	136.9	3.3	~	~
Pharmaceutical	474.8	11.6	~	~
Others	68.0	1.7	~	~
Total Expenditure	4,093.7	100.0	5,000	100.0

Source: 1995, WHO's estimates. 2004, Espicom's estimates.

Public Health Expenditure: Fonasa

According to the Ministry of Health, public health expenditure in 2004 is estimated in the region of CH\$1,500,629, which is equivalent to around US\$2.5 billion. This is an increase of 5.9% or CH\$83,283 million on 2003 budget. Of this increase, 50.65% will be allocated to AUGE and the remaining to other areas. More information on expenditure can be found in the subsection *Investment for the Reform*, within the *Healthcare Development* section.

Public Health Spending, 1991-2004

	Spending CH\$ Million	Growth Rate (%)	Spending as % of GDP	Spending by Source of Income (%)			
				State Contribu- tions	Insurance Contribu- tions	Operating Income	User Co- payments
1991	508,602	16.8	2.1	46.9	40.0	5.7	7.4
1992	622,567	22.4	2.3	51.0	35.9	6.2	6.9
1993	731,133	17.4	2.5	54.6	33.1	5.7	6.6
1994	804,620	10.1	2.5	54.9	32.1	6.5	6.5
1995	868,258	7.9	2.4	55.9	31.2	6.4	6.5
1996	945,737	8.9	2.5	55.8	31.0	6.8	6.5
1997	1,020,807	7.9	2.5	55.4	31.0	7.1	6.6
1998	1,095,508	7.3	2.8	54.3	30.4	7.9	7.4
1999	1,156,542	5.6	2.9	54.2	30.8	7.4	7.6
2000	1,255,052	8.5	3.0	54.1	31.4	6.7	7.8
2001	1,373,148	9.4	3.2	54.0	31.9	6.2	8.0
2002	1,386,191	0.9	3.0	51.0	34.4	6.2	8.4
2003*	1,417,346	2.2	3.1**	~	~	~	~
2004*	1,500,629	5.9	3.3**	~	~	~	~

Source: FONASA, 2002. * MINSAL, 2004. ** Espicom's estimates based on data released by MINSAL for the Health Reform.

During the 1990s, public health expenditure grew at a compound annual rate of around 12%, rising from CH\$435,288 million in 1990 to CH\$1,255,052 million in 2000, although growth in the first half of the decade was double that of the second half. Measured in dollars, health expenditure rose from US\$1.3 billion in 1990 to US\$2.3 billion in 2000. In 2002, there was a slight rise of just 0.9 % to CH\$1,386,191 million (circa US\$2.0 billion).

Public health spending as a percentage of total public spending on social services increased from 15.3% in 1990 to 17.6% in 2000, whilst the percentage of the central government budget on social services allocated to health increased from 7.5% to 9.6%. Government financing in 2002 accounted for slightly more than half of public health expenditure, at 51.0%. In the same year, health insurance contributions under the public scheme accounted for 34.4% of spending and patient co-payments 8.4%.

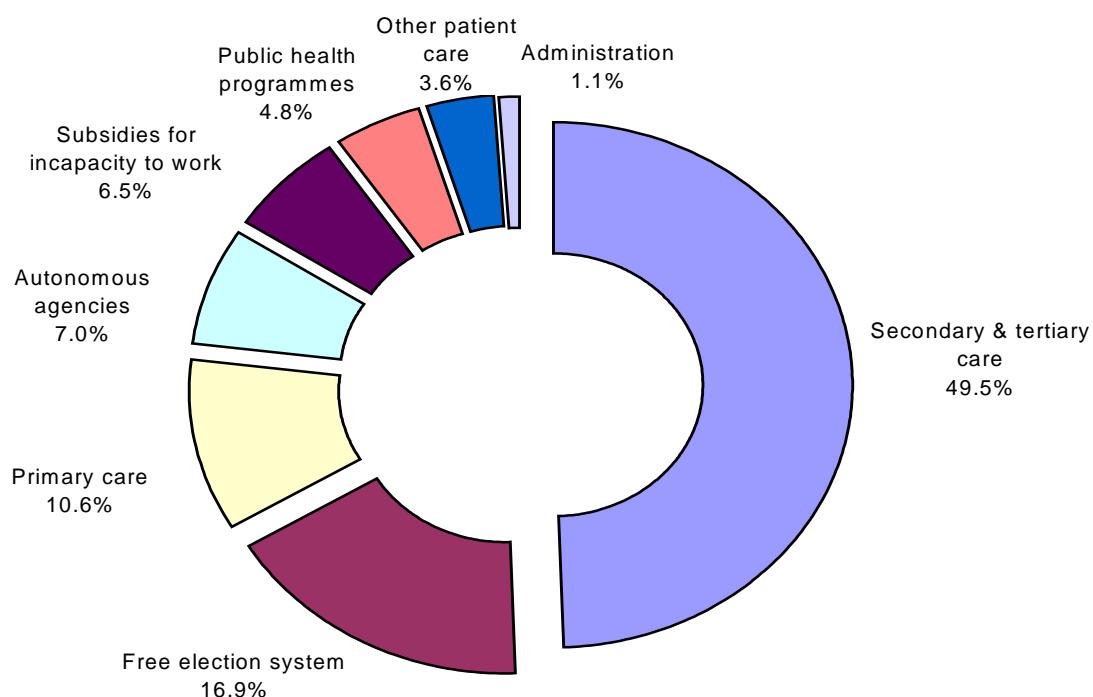
Of the CH\$1,386 billion spent on health services under the public system in 2002, the majority of spending was on the institutional system, which accounted for 60.1% of the total. Spending on secondary and tertiary care accounted for 82.4% of this figure and primary care 17.6%. Primary care services are provided by the municipalities. These are financed by funds transferred from the Ministry of Health, according to the Fapem primary care allocation, which is calculated on a per capita basis.

The Modalidad de Libre Elección (free election system whereby patients can choose their own doctors, or health institutions for a particular health service subject to co-payments) accounted for 16.9% of spending, whilst 4.8% was spent on SNSS public health programmes.

Public Health Spending by Sector, 2002

	CH\$ (Million)	As % of Total	Change 01/02 (%)
<i>Institutional system</i>	834,164	60.2	7.6
Primary care	147,622	10.6	16.7
Secondary & tertiary care	686,542	49.5	5.8
<i>Free election system</i>	234,268	16.9	9.1
Patient care	215,014	15.5	9.9
Net medical assistance	19,254	1.4	0.6
<i>SNSS public health programmes</i>	67,000	4.8	6.8
PNAC (Programa Nacional Alimentación Complementaria)	29,005	2.1	13.0
Other including vaccinations	37,995	2.7	2.5
<i>Other</i>			
Other patient care	49,215	3.6	1.7
Subsidies for incapacity to work	89,569	6.5	9.5
Administration	15,245	1.1	14.4
Autonomous agencies (Superintendencia de Isapres, Subsecretaría de Salud, ISPCH, CENABAST)	96,731	7.0	-45.3
Total	1,386,191	100.0	0.9

Source: FONASA.

Public Health Spending by Type, 2002 (%)

Source: FONASA.

Public Health Sector Budget by Type of Expenditure, 2002

	CH\$ 000	As % of Total
Personnel costs	525,039	37.9
Goods and services (consumption)	214,895	15.5
Goods and services (production)	19,604	1.4
Anticipated spending on patient services	296,084	21.4
Transfers	214,364	15.5
Regional investments	202	<0.1
Capital investment	25,477	1.8
Financial investment	24,036	1.7
Capital transfers	-	-
Operations from previous years	14,273	1.0
Operations from previous years	52,169	3.8
Other outstanding obligations	48	<0.1
Total	1,386,191	100.0

Source: FONASA.

Private Health Expenditure: ISAPRE

According to annual data from 2002, the ISAPRE's system had revenues of CH\$728,529 million, equivalent to US\$1.03 billion. This was a minimal increase compared to CH\$722,456 million in 2001. Operating and administration costs in 2002 accounted for 83.5% and 14.7% of total, with increasing operating results of CH\$12,959 million. Between January and September 2003, there were recorded revenues of CH\$567,641 million. Estimated annual figures for 2003 are in the region of CH\$735,000 million, or US\$1.05 billion.

ISAPRE's Balance Sheet, 2001-2002

	2001		2002		Annual Change
	CH\$ Million	As % of Total	CH\$ Million	As % of Total	
Revenues	722,456	100.0%	728,589	100.0%	0.8%
Operating costs	603,368	83.5%	608,288	83.5%	0.8%
Administration and sales costs	115,165	15.9%	107,343	14.7%	-6.8%
Operating results	3,924	0.5%	12,959	1.8%	230.3%
Non operating results	11,680	1.6%	-151	0.0%	-101.3%
Results	12,909	1.8%	10,373	1.4%	-19.6%

Source: Superintendencia de Isapres.

ISAPRE's Balance Sheet, 2002-2003 (January-September)

	2002*		2003*		Change
	CH\$	As % of Total	CH\$	As % of Total	
<i>Number of Isapres</i>	22**	~	18**	~	-18.2%
<i>Balance sheet (CH\$ Million)</i>					
Revenues	554,243	100.0%	567,641	100.0%	2.4%
Operating costs	461,974	83.4%	469,169	82.7%	1.6%
Administration costs	82,409	14.9%	82,108	14.5%	-0.4%
Operating results	9,859	1.8%	16,364	2.9%	66.0%
Non operating results	3,720	0.7%	-493	-0.1%	-113.2%
Results	11,524	2.1%	12,434	2.2%	7.9%
<i>Revenues by type of payment (CH\$ million)</i>					
Legal payment of 7%	418,426	75.5%	413,225	72.8%	-1.2%
Additional legal payment of 2%	2,827	0.5%	1,636	0.3%	-42.1%
Voluntary additional payment	118,461	21.4%	138,544	24.4%	17.0%
Employers' payment	14,528	2.6%	14,235	2.5%	-2.0%
Total revenues	554,243	100.0%	567,641	100.0%	2.4%
<i>Average monthly indicators (CH\$)</i>					
Total payment per contributor	48,081	~	50,403	~	4.8%
Voluntary additional payment per contributor	10,277	~	12,302	~	19.7%
Operational cost per contributor	17,701	~	18,691	~	5.6%
Social security costs per contributor	14,378	~	15,315	~	6.5%
Subsidies costs per contributor	7,155	~	7,167	~	0.2%
Administration costs per contributor	3,158	~	3,271	~	3.6%

Source: Superintendencia de Isapres. * Period from January to September. ** Number of establishments.

ORGANISATION & ADMINISTRATION

Both the public and private health sectors in Chile are regulated by the Ministry of Health. As well as providing healthcare services, the public and private sectors also participate in health insurance. Both the public and private system offer the full range of health services, although health promotion is the responsibility of the public sector.

In addition to the central administration in Santiago, the Ministry of Health is represented at a regional level by the Regional Ministerial Health Secretary (SEREMI).

Organisations reporting to the Ministry of Health include:

- The National Health Services System (SNSS - Sistema Nacional de Servicios de Salud), which provides health services in the public sector to *Ley 18,469* beneficiaries. This includes all individuals contributing to the National Health Fund and their dependants, being independent workers or pensioners, assisted pensioners and family members covered by subsidies and the poor;
- The National Health Fund (FONASA - Fondo Nacional de Salud), which manages both government funds assigned to the health sector and health insurance funds;
- The Superintendency of Isapres (ISAPRE – Sistema de Salud Previsional), through which the Ministry of Health supervises the private insurance system;
- The Institute of Public Health (ISPCH – Instituto de Salud Pública de Chile), which controls pharmaceutical products and produces vaccines;
- The Central Purchasing Agency (CENABAST - Central de Abastecimiento del Ministerio de Salud); and
- The Environmental Health Service for the Metropolitan Region, which is responsible for conducting preventive health programmes involving environmental aspects.

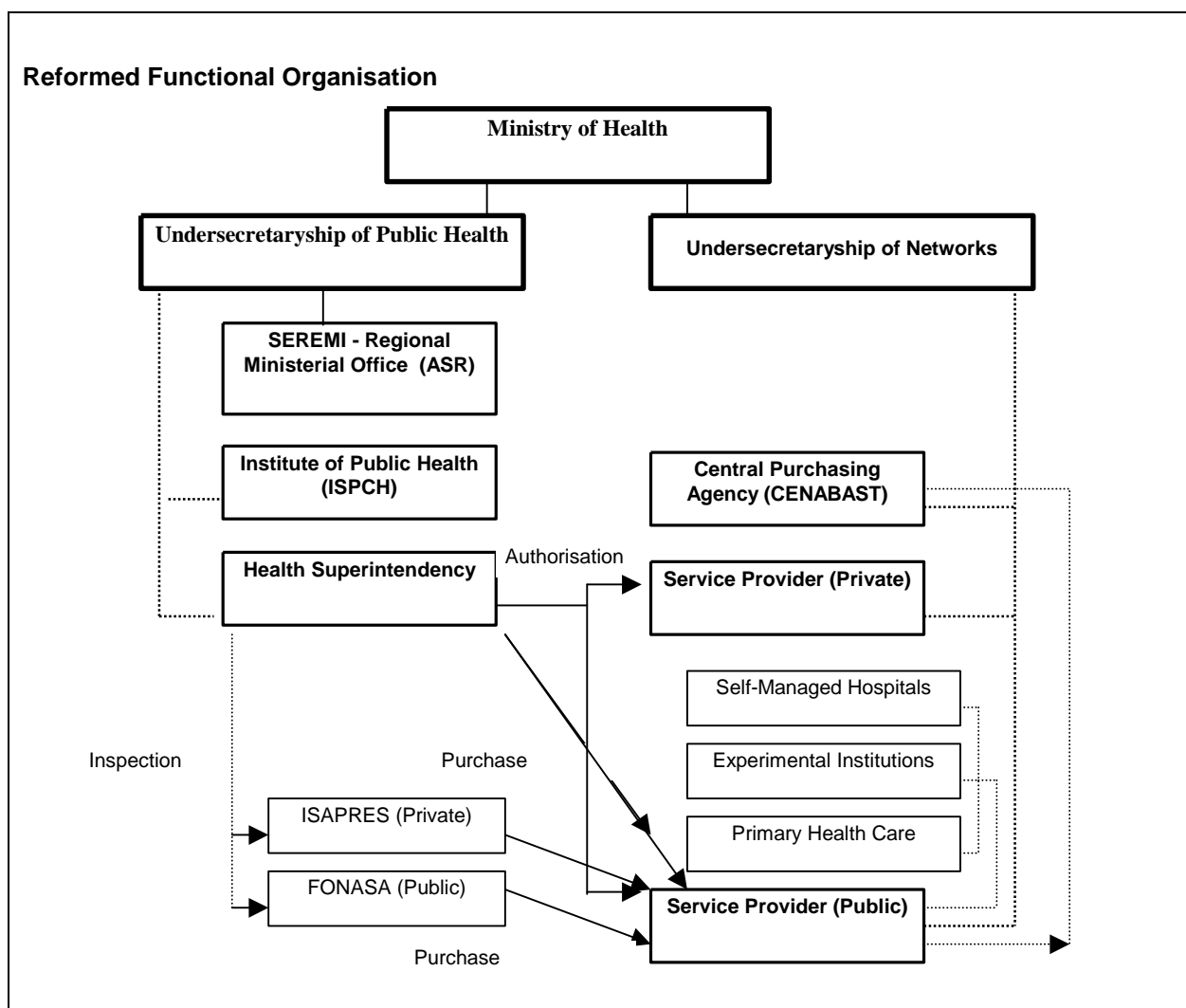
The health system is partially financed through a system of compulsory health insurance contributions. Employees contribute 7.0% of their wages to either a public or private health insurance scheme under a scheme set up in the early 1980s, whereby people who were covered by the compulsory system were given the option of opting out of the NHCSS and channelling their health fund taxes into private pre-paid health plans called Isapres (Instituciones de Salud Previsional).

Isapres also receive additional voluntary contributions from their members. As ISAPRE's coverage grew during the 1980s and early 1990s, the number of people opting out of the state system increased. Between 1982 and 1997, the proportion of the population contributing to the National Health Fund (FONASA) fell from 85.1% to 59.9% (8,753,407 beneficiaries).

However, ISAPRE's membership has declined since 1998, and the proportion of the population relying on the public health system increased to just under 70% in 2001 (10,442,101 beneficiaries) and this figure rises to over 80% in the 65+ age group.

Reformed Functional Organisation

Under the current reforms, the Ministry of Health will operate through two main organisms: the *Undersecretaryship of Public Health* and the *Undersecretaryship of Networks*. The Regional Health Authorities (ASR) will act as the "watchdog" for the MOH. At a decentralised level, there will be four main units: the *Health Superintendency*, responsible for FONASA (public) and ISAPRE (private), the *Health Services*, responsible for primary healthcare, the *Public Health Institute* and the *Central Purchasing Agency (CENABAST)*. For more information, see *Healthcare Development*.



Source: MINSAL, 2004. Note: discontinuous line indicates non-hierarchical relationship and decentralisation.

Sanitary Authority Changes

At Present

- Ministry of Health (MOH) is the head health authority
- The Undersecretary of Health is responsible for managing the National System of Public Health Services
- The Undersecretary of Health also regulates the whole health system
- Health services are in charge of regulation and public provision in their territories
- There is the superintendency of private health Insurance

After the New Law

- MOH continues being the head health authority
- Two undersecretaries are created: the Undersecretary of Public Health, in charge of public provision; and the Undersecretary of Networks, regulating health providers and public health
- Regional secretaries are in charge of regulation and public health services
- Health services are in charge of the provision of individual health services
- Change to the Health Superintendency of insurance and services

Source: MINSAL, 2004.

Health Beneficiaries by Sector

The number of beneficiaries from the public sector in 2002 rose to around 10.3 million, equivalent to 67.5% of the total. The private sector covered 2.8 million beneficiaries, equivalent to 18.5%, whereas the remaining 2.1 million beneficiaries, or 14%, were covered by other bodies.

Health Beneficiaries, 1990-2002

	Public Sector	As % of Total	Private Sector	As % of Total	Other	% of Total	Total
1990	9,729,020	73.7	2,108,308	16.0	1,372,292	10.4	13,209,619
1991	9,414,162	70.1	2,566,144	19.1	1,452,039	10.8	13,432,345
1992	8,788,817	64.3	3,000,063	22.0	1,869,196	13.7	13,658,075
1993	8,537,786	61.5	3,431,543	24.7	1,913,442	13.8	13,882,771
1994	8,644,479	61.3	3,669,874	26.0	1,788,039	12.7	14,102,392
1995	8,637,022	60.3	3,763,649	26.3	1,913,976	13.4	14,314,646
1996	8,672,619	59.7	3,813,384	26.3	2,034,606	14.0	14,520,609
1997	8,753,407	59.5	3,882,572	26.4	2,086,055	14.2	14,722,034
1998	9,137,599	61.2	3,679,835	24.7	2,102,303	14.1	14,919,737
1999	9,403,455	62.2	3,323,373	22.0	2,387,706	15.8	15,114,534
2000	10,157,686	66.4	3,092,195	20.2	2,056,749	13.4	15,306,630
2001*	10,156,364	67.2	2,940,795	19.5	2,017,641	13.3	15,114,800
2002	10,327,218	67.5	2,828,228	18.5	2,149,065	14.0	15,304,511

Source: FONASA from CASEN (1996-1998), ISAPRE (1990-2002) and INE (1992-2002). * Census by April 2002.

SNSS / FONASA

The SNSS comprises mainly 28 health services (Servicios de Salud) across the country. The health services provide three levels of care: primary, secondary and tertiary. The management of public health facilities is decentralised. Since the healthcare reforms were completed in 1988, primary care facilities, including most clinics, health posts and rural health centres, have been run by the 335 municipalities. The public hospital sector is administered by the respective health services. The SNSS currently serves around two thirds of the population, including the poor, assisted pensioners and family members covered by subsidies, who do not contribute directly to any health insurance scheme. Public health system beneficiaries are entitled to free primary care in doctors' offices. Contributions towards hospital care are income dependent as follows:

- A. The poor, beneficiaries of welfare pensions and family members covered by subsidies - free,
- B. Gross monthly income up to CH\$90,500 - free,
- C. Gross monthly income of CH\$90,500-CH\$110,120 - 10%,
- D. Gross monthly income greater than CH\$110,120 - 20%.

Individuals contributing to the National Health Fund (FONASA – Fondo Nacional de Salud) and their dependants also have the freedom to choose their own doctors, institutions or health organisations for a particular health service under the Modalidad de Libre Elección (free election system). The service provider must be authorised by FONASA and beneficiaries are required to make co-payments for services in accordance with Health Services Tariffs under Law 18,369 and FONASA provisions.

This system makes it possible for FONASA contributors to receive medical attention from authorised professionals and private healthcare establishments. These are coded as level one, two or three. Beneficiaries either buy a bond from FONASA which covers them for treatment at one of these levels or pay for a Programa de Atención de Salud (healthcare programme). The 'free election system' also covers certain rooms within public hospitals. If a patient chooses to be hospitalised in one of these, an authorisation (sworn declaration) must be signed at the time of admission.

ISAPRE

ISAPRE's coverage grew from 1.4% of the population in 1982 to 26.5% in 1995. However, since 1998, membership of the ISAPRE's system has declined and by February 2004, the number of beneficiaries has fallen to 2.71 million, a 26.2% decrease compared to December 1998, and equivalent to around 17.6% of the population. Of the 2.71 million beneficiaries, about 94.3%, or 2.56 million, belong to Isapres abiertas, whereas the remaining, about 5.7% or 153,531, to Isapres cerradas. The number of payers to Isapres in 2004 rose to 1.23 million, whereas the remaining were associated beneficiaries related to the payers.

ISAPRE's Beneficiaries, 1995-2004

	Total Beneficiaries	Change (%)
1995	3,763,649	~
1996	3,813,834	1.3
1997	3,882,572	1.8
1998	3,679,835	-5.2
1999	3,323,373	-9.7
2000	3,092,195	-7.0
2001	2,940,795	-4.9
2002	2,828,228	-3.8
2003	2,729,088	-3.5
*2004	2,717,111	-0.4

Source: Superintendencia of Isapres. * By February 2004.

Since the scheme began, both the quality of ISAPRE's healthcare services and consumer satisfaction have improved. However, healthcare costs and, consequently, ISAPRE's subscription fees, have increased faster than wages and it is becoming more difficult for the ISAPRE's sector to provide healthcare to the middle and lower income groups. Lower wage workers have effectively been priced out of the market.

Falling numbers have also been attributed to higher unemployment, with people who lose their jobs transferring to the state FONASA system. It should also be noted that the Isapres are able to select their members and exclude high risk individuals from private insurance. Contributions to Isapres average nine per cent of salary (basic 7% plus additional 2%). Around 80% of ISAPRE's members have additional catastrophic cover for high cost illnesses.

There are basically two types of Isapres: abiertas (open) and cerradas (closed). Open Isapres are profit-driven companies open to all, and consequently have the lion's share of ISAPRE's members. By May 2003 there were 621 open Isapres. Closed Isapres provide or finance health services for employees of specific companies and membership is restricted to employees of those companies. In general, this type of Isapre is not profit driven. By May 2003, there were 76.

ISAPRE's System by Establishments, 2003

	Number of Establishments*	Market Share** (%)
Consalud S.A.	94	24.3
ING Salud (2)	102	21.0
Isapre Banmédica	97	17.6
Colmena Golden Cross	54	12.3
Masvida	73	6.9
Vida Plena (3)	58	6.2
Vida Tres	43	4.8
Promepart	30	4.0
Normédica	57	1.9
Sfera	13	1.0
Alemana Salud (1)	0	0.0
<i>Total Isapres Abiertas</i>	621	100.0
El Teniente	9	30.7
Chuquicamata	5	21.9
Banco del Estado	16	17.9
CTC - Istel	20	11.4
Ferrosalud	14	6.6
San Lorenzo	4	4.9
Río Blanco	4	3.4
Cruz del Norte	4	3.2
<i>Total Isapres Cerradas</i>	76	100.0
Total	697	100.0

Source: Superintendencia de Isapres. *Establishments are listed by May 2003. **Market share for each Isapre in relation to its respective market (abierto or cerrado) by December 2002. (1) Alemana Salud was registered as an Isapre in January 2001. Statistical information is not available though. (2) In August 2002, Cruz Blanca acquired ING Salud. The resulting Isapre is ING Salud SA. (3) In December 2002, Cigma Salud and Vida Plena merged into Vida Plena SA.

The largest open Isapres by February 2004 are Consalud, with 248,093 members and 615,067 beneficiaries in total, accounting for 22.6% of the total, and ING Salud SA, with over 281,531 members and 588,049 beneficiaries in total, 21.6% of the total. The largest closed Isapres are El Teniente (1.7%) and Chuquicamata (1.2%).

Beneficiaries by Isapres, February 2004

	Number of Payers	Number of Dependants	Total	As % of Total (Abiertas vs Cerradas)	As % of Total
Consalud S.A.	248,093	366,974	615,067	24.0	22.6
ING Salud S.A.	281,531	306,518	588,049	22.9	21.6
Isapre Banmédica	223,978	267,160	491,138	19.2	18.1
Colmena Golden Cross	156,386	190,992	347,378	13.6	12.8
Masvida	93,345	101,696	195,041	7.6	7.2
Vida Tres	67,932	70,345	138,277	5.4	5.1
Promepart	58,532	40,240	98,772	3.9	3.6
Normédica	21,764	31,250	53,014	2.1	2.0
Sfera	20,743	16,081	36,824	1.4	1.4
<i>Total Abiertas</i>	<i>1,172,304</i>	<i>1,391,256</i>	<i>2,563,560</i>	<i>100.0</i>	<i>94.3</i>
El Teniente	18,226	28,116	46,342	30.2	1.7
Chuquicamata	10,222	23,675	33,897	22.1	1.2
Banco del Estado	13,073	13,962	27,035	17.6	1.0
CTC - Istel	5,692	9,513	15,205	9.9	0.6
Ferrosalud	6,248	7,896	14,144	9.2	0.5
San Lorenzo	2,028	4,910	6,938	4.5	0.3
Río Blanco	1,604	3,620	5,224	3.4	0.2
Cruz del Norte	1,527	3,239	4,766	3.1	0.2
<i>Total Cerradas</i>	<i>58,620</i>	<i>94,931</i>	<i>153,551</i>	<i>100.0</i>	<i>5.7</i>
Total	1,230,924	1,486,187	2,717,111	~	100

Source: Superintendencia de Isapres.

Other Healthcare Providers

The remainder of the population is covered by other health providers, including the army, police and the university medical system. In 2002, the number of beneficiaries rose to 2.14 million, or 14% of total population. The Chilean armed forces and police force own and operate a small number of hospitals and a number of medical centres. The funding and purchasing functions of these bodies are independent of the Ministry of Health.

There are also non-profit private healthcare providers, including Red Cross establishments, non-government organisations, corporate medical services (for employees) and occupational health insurance funds (mutuales) which run work-related health facilities for almost two million employees.

HOSPITAL SERVICES

Hospital Resources

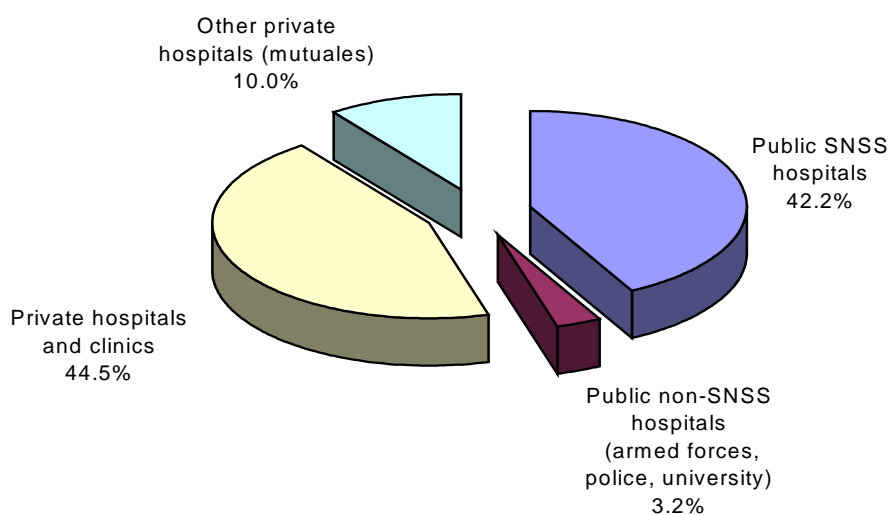
In 2001, there were a total of 438 hospitals and clinics, compared to 405 in 1999. There were 199 public hospitals, of which 185 belonged to the SNSS and 14 belonged to other bodies such as the armed forces, police or university. In the private system there were 239 hospitals and clinics, of which 44 hospitals were managed by "mutuales" of employees. Around 60% of public health expenditure is allocated to SNSS hospitals, which serve the needs of between 70-80% of the total population. On average, SNSS hospitals provide six million specialised consultations, 12 million urgent medical attentions and 1.2 million discharges each year.

Hospitals & Clinics, 2001

	Number of Hospitals	Number of Beds
<i>Public sector</i>		
Public SNSS hospitals	185	30,047
Public non-SNSS hospitals (armed forces, police, university)	14	2,308
<i>Private sector</i>		
Private hospitals and clinics	195*	6,831
Other private hospitals*	44	1,513
Total	438	40,699

Source: MINSAL. *These include hospitals of "mutuales" of employees financed by the Law of work-related accidents and diseases (Ley de Accidentes del Trabajo y Enfermedades Profesionales).

Hospitals and Clinics by Supplier, 2001 (%)



Hospitals & Clinics, 1994-1999

	1994	1995	1996	1997	1998	1999
<i>Public Sector</i>						
SNSS Hospitals	180	178	182	182	182	184
Type 1 (maximum complexity)	20	20	20	20	20	20
Type 2 (medium complexity)	30	30	30	31	32	32
Type 3 (medium complexity)	24	24	23	23	23	23
Type 4 (low complexity)	106	106	105	108	107	107
Contracted Hospitals	n/a	9	10	14	14	15
Non SNSS Hospitals (armed forces, police, university)	n/a	n/a	n/a	n/a	n/a	14
<i>Private Sector</i>						
Other private hospitals	37	37	44	44	44	44
Private hospitals & clinics	167	168	121	121	121	148
Total	384	392	357	361	361	405

Source: MINSAL.

The number of beds in the private sector more than doubled between the introduction of the ISAPRE's system in the 1980s and 1995, counterbalancing the small decline in the number of public beds available. Since then, however, bed numbers have declined gradually in both sectors. The total number of available beds descended to 40,699 in 2001, which is a decrease of 3.5% compared to 42,163 beds in 1999. Of this, around 30,000 were managed by public SNSS hospitals, of which 27,998 were operational. Bed occupancy of operational beds was 71%.

Hospital Beds, 1990-2001

	1990	1992	1993	1994	1995	1996	1997	1998	1999	2001
SNSS	32,515	32,176	32,579	31,804	31,579	31,353	30,956	30,336	30,965	30,047
Other	10,499	10,985	11,063	11,208	11,549	11,419	11,031	11,083	11,198	10,652
Public	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	2,857	2,308
Private	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	8,341	8,344
Total	43,014	43,161	43,642	43,012	43,128	42,772	41,987	41,419	42,163	40,699

Source: MINSAL.

There were around 2.6 beds per thousand population in 2001, compared to 2.8 in 1999. The metropolitan region of Santiago had over 38% of all hospital beds in the country in 1999, followed by Biobío (13.6%) and Valparaíso (11.7%).

Hospital Beds by Region, 1999

	Number	As % of Total	Rate per 000 Population
Región Metropolitana de Santiago	16,080	38.1	2.7
Del Biobío	5,727	13.6	3.0
De Valparaíso	4,941	11.7	3.2
De Los Lagos	2,947	7.0	2.8
De La Araucanía	2,664	6.3	3.1
Del Maule	2,548	6.0	2.8
Del Libertador General Bernado O'Higgins	1,844	4.4	2.4
De Antofagasta	1,587	3.8	3.4
De Coquimbo	1,213	2.9	2.1
De Tarapacá	1,009	2.4	2.6
De Magallanes y de la Antártica Chilena	682	1.6	4.4
De Atacama	624	1.5	2.3
De Aisén del General Carlos Ibáñez del Campo	297	0.7	3.2
Total	42,163	100.0	2.8

Source: MINSAL.

In 1998, 20.2% of public hospital beds were allocated to paediatrics, 19.0% to medical specialties, 16.0% to obstetrics and 12.5% to surgery. While the total number of beds was reduced by some 5.8% between 1990 and 1998, the percentage allocation by specialty remained little changed.

Public Hospitals Beds by Specialty, 1990-1998

	1990	1992	1994	1995	1996	1997	1998	As % of Total
Paediatrics	7,034	6,961	6,739	6,550	6,409	6,257	6,190	20.2
Medicine	6,072	5,942	5,981	5,830	5,730	5,891	5,809	19.0
Obstetrics	5,050	5,106	5,009	4,951	4,951	4,888	4,914	16.0
Surgery	3,605	3,702	3,847	3,846	3,828	3,826	3,836	12.5
Other services	3,646	3,209	3,016	3,152	3,311	3,206	3,295	10.8
Other	2,839	3,083	3,158	3,235	3,231	3,064	3,052	10.0
Psychiatry	3,246	3,135	3,028	2,995	2,828	2,805	2,550	8.3
Traumatology	1,023	1,038	1,026	1,020	1,065	1,021	977	3.2
Total	32,515	32,176	31,804	31,579	31,353	30,958	30,623	100.0

Source: MINSAL.

Hospital Activity

Public hospitals provide over 70% of hospital treatment. According to a survey carried out in November 2000 by the Ministry of Planning, public hospitals were responsible for 75% of hospital stays and 83% of births. Private clinics are responsible for 10%-15% of hospital treatment, rising to 25% of surgery.

Hospital Treatment by Sector and Health Insurance Affiliation, 2000 (%)

	Hospitalisation	Surgery	Normal Childbirth
<i>Establishment</i>			
Public	75.4	64.1	83.0
Private	10.3	25.3	12.6
Other*	14.3	10.7	4.3
<i>Health Insurance</i>			
Public system	77.9	63.9	77.6
ISAPRE	14.3	26.0	14.0
Other*	7.9	10.1	8.4

Source: MIDEPLAN, Encuesta CASEN 2000. *Including armed forces and unclassified data.

There were around 1.56 million discharges from Chilean hospitals in 2001, of which 75.3% were from SNSS hospitals. This is equivalent to 1,180,852 SNSS discharges, although other DEIS sources indicate a figure closer to 1,173,829.

Hospital Discharges, 1995-2001

	1995	1996	1997	1998	1999	2000	2001
SNSS	1,064,224	1,078,478	1,092,995	1,112,348	1,121,351	1,157,165	1,180,852
Rate / 000 pop.	74.9	74.8	74.7	75.0	74.7	76.1	76.7
Total	1,435,036	1,468,675	1,495,480	1,516,600	1,520,989	n/a	1,566,187
Rate / 000 pop.	101.0	101.9	102.3	102.3	101.3	n/a	n/a

Source: DEIS.

In 2001, 21% of hospital discharges were due to pregnancy and birth, including normal delivery. Digestive diseases accounted for 11.6% of hospital discharges during the year, respiratory diseases for 11.5% and genitourinary diseases for 7.4%.

Hospital Discharges by Cause, 2001

	Number	As % of Total
Complications of pregnancy, birth & the puerperium	328,241	21.0
Digestive diseases	181,524	11.6
Respiratory diseases	180,620	11.5
Genitourinary diseases	115,681	7.4
Neoplasms	96,592	6.2
Circulatory diseases	93,735	6.0
Infectious and parasitic diseases	52,503	3.4
Diseases of the musculoskeletal system and connective tissue	45,465	2.9
Perinatal conditions	37,639	2.4
Endocrine, nutritional and metabolic diseases	27,856	1.8
Mental diseases	26,698	1.7
Eye-related diseases	25,136	1.6
Skin and subcutaneous diseases	22,475	1.4
Nervous system diseases	20,032	0.0
Other diseases	332,002	21.2
Total	1,566,187	100.0

Source: DEIS.

In 2002, 27,687 SNSS occupational hospital beds provided 7,191,224 hospital days, an increase of 4.1% over 2001. Bed occupancy rose to over 70%. Discharges by bed amounted to 42. The average length of stay (ALOS) was 6.1 days.

SNSS Hospital Activity, 1997-2002

	1997	1998	1999	2000	2001	2002
Hospital days	6,696,445	6,814,427	6,851,977	6,826,469	6,905,894	7,191,224
Surgical procedures	744,354	742,718	738,738	757,591	767,138	n/a
Births	128,070	124,724	125,799	121,263	119,722	n/a
Dialysis treatments	97,459	103,812	107,702	108,349	103,524	n/a
Diagnostic /therapeutic procedures	587,191	637,518	676,372	717,267	756,307	n/a
Diagnostic tests	33,131,550	35,070,432	36,743,719	39,678,492	41,627,502	n/a

Source: DEIS.

SNSS Hospital Indicators, 1994-2002

	1994	1995	1996	1997	1998	1999	2002
Beds per thousand population	2.3	2.2	2.2	2.1	2.1	2.1	2.6
Bed occupancy (%)	69.9	69.7	69.4	70.2	70.5	n/a	70.6
Discharges per bed	33.6	33.7	34.4	35.3	36.7	36.2	42.4
Average stay (days)	6.9	7.0	7.1	6.8	6.8	n/a	6.1

Source: DEIS.

Medical treatment carried out under the free election system in 2001 included nearly 900,000 bed days, 8.6 million consultations, 9.7 million diagnostic examinations and 5.3 million clinical and therapeutic procedures.

Free Election System Activity by Level, 2001

	Level 1	Level 2	Level 3	Total
Medical consultations	4,214,201	162,505	4,255,237	8,631,943
Diagnostic examinations	1,340,168	1,773,995	6,608,455	9,722,618
Clinical & therapeutic support procedures	1,358,638	310,792	3,622,078	5,291,508
Hospitalisation (bed days)	899,401	-	-	899,401

Source: MINSAL.

In 1999, of the 128,780 surgical procedures undertaken under the free election system, 14.1% were abdominal procedures, 12.8% were ophthalmological procedures, while obstetric surgery and urology & supra-renal surgery accounted for around 10% each.

Free Election System Activity by Type of Treatment, 1998-1999

	1998	1999	Change (%)
<i>Medical consultations</i>	6,627,362	6,851,849	3.4
<i>Diagnostic examinations</i>	7,741,746	8,011,458	3.5
Clinical laboratory	6,178,491	6,422,976	4.0
Diagnostic imaging	1,354,715	1,378,845	1.8
<i>Clinical & therapeutic support procedures</i>	3,705,743	3,839,242	3.6
Nuclear medicine	28,725	29,603	3.1
Physical medicine & rehabilitation	2,319,666	2,414,125	4.1
Psychiatry	146,746	161,207	9.9
Neurology & neurosurgery	41,897	41,015	-2.1
Ophthalmology	516,797	532,634	3.1
ENT	68,596	68,154	-0.6
Cardiology & pneumology	313,552	341,831	9.0
Gastroenterology	71,503	79,559	11.3
Urology	127,138	96,744	-23.9
Orthopaedics & traumatology	30,177	29,524	-2.2
Obstetrics & gynaecology	19,312	19,184	-0.7
<i>Surgical procedures</i>	103,078	128,780	24.9
Neurosurgery	1,810	2,663	47.1
Ophthalmology surgery	12,002	16,430	36.9
ENT surgery	5,694	7,292	28.1
Cardiovascular surgery	3,988	6,261	57.0
Abdominal surgery	12,937	18,094	39.9
Urology & supra-renal surgery	8,663	12,710	46.7
Gynaecological surgery	7,028	9,793	39.3
Obstetric surgery	14,609	12,827	-12.2
Caesarean sections	8,117	9,363	15.4
Traumatology & orthopaedic surgery	7,951	10,895	37.0
<i>Hospitalisation (bed days)</i>	801,085	806,585	0.7

Source: MINSAL.

There was a steady increase in hospital activity in the ISAPRE's sector during the 1990s. Between 1994 and 1999, the number of hospital discharges increased by 153.1% to 424.5 thousand. Data from 2000-2001 show a considerable decrease to 263.4 thousand discharges, but this might be more attributable to ISAPRE's data management. Data has been centralised by the ISAPRE's system from 2000 onwards whereas previous data was the result of compiling individual data from each Isapre. The number of bed days also increased during the 1990s, by 58.7% to 1,457,100 in 1999.

ISAPRE's Activity, 1990-2002

	*Total Treatments (000s)	Growth (%)	Bed Days (000s)	Growth (%)	Hospital Discharges (000s)	Growth (%)
1990	18,640.1	~	703.7	~	n/a	n/a
1991	23,381.5	25.4	n/a	n/a	112.5	~
1992	27,713.4	18.5	n/a	n/a	234.9	108.9
1993	32,395.1	16.9	n/a	n/a	263.8	12.3
1994	34,811.9	7.5	918.1	30.5	277.3	5.1
1995	36,518.4	4.9	n/a	n/a	330.2	19.1
1996	38,962.8	6.7	1,093.3	19.1	366.2	10.9
1997	40,770.6	4.6	1,142.8	4.5	387.1	5.7
1998	42,600.2	4.5	1,198.9	9.7	402.9	4.1
1999	43,515.0	2.1	1,457.1	27.5	424.5	5.4
2000	43,462.5	-0.1	n/a	n/a	349.1	-17.8
2001	42,127.3	-3.1	n/a	n/a	263.4	-24.6
2002	42,299.9	0.4	n/a	n/a	n/a	n/a

Source: Superintendencia de Isapres. * These include medical consultations, diagnostic examinations, clinical support procedures, surgical procedures and other procedures.

Treatments undertaken by ISAPRE increased between 1990 and 1999. However, there was a decrease between 2000 and 2001 – due to ISAPRE's change of data management. Total treatments in 2002 stood at 42.3 million. Of this, medical consultations accounted for around 27% whereas diagnostic examinations for 37%. Comparing 2002 with 2001, treatments decreased in all the categories except in other procedures. Growth in total increased by just 0.4%.

ISAPRE's Activity by Type of Treatment, 2001-2002

	2001	2002	Growth (%)
<i>Medical consultations (000s)</i>	11,482.2	11,450.6	-0.3
<i>Diagnostic examinations (000s)</i>	15,757.5	15,548.6	-1.3
Laboratory examinations (000s)	12,635.7	12,423.6	-1.7
Imaging (000s)	2,635.0	2,643.2	0.3
Anatomic pathology (000s)	486.9	481.7	-1.1
<i>Clinical support procedures (000s)</i>	8,955.8	7,783.1	-13.1
Vaginal births (000s)	19.4	15.9	-18.1
Other procedures (000s)	8,936.4	7,767.1	-13.1
<i>Surgical procedures (000s)</i>	316.0	312.7	-1.1
Caesarean sections (000s)	34.8	31.0	-10.9
Other surgical procedures (000s)	281.2	281.7	0.2
<i>Other procedures (000s)</i>	5,615.8	7,205.0	28.3
Total (000s)	42,127.3	42,299.9	0.4

Source: Superintendencia de Isapres.

In 2001, 17.6% of ISAPRE's hospital discharges were due to pregnancy and birth. Digestive diseases accounted for 12.8% during the year, neoplasms for 11.8%, genitourinary diseases for 10.2% and respiratory diseases for 9.2%. The major causes of ISAPRE's hospital discharges are similar to the findings in the public sector.

ISAPRE's Hospital Discharges by Cause, 2001

	Number (000s)	As % of Total
Complications of pregnancy, birth & the puerperium	46.5	17.6%
Digestive diseases	33.7	12.8%
Neoplasms	31.1	11.8%
Genitourinary diseases	26.8	10.2%
Respiratory diseases	24.3	9.2%
Poisonings and other causes	17.6	6.7%
Diseases of the musculoskeletal system and connective tissue	15.7	6.0%
Circulatory diseases	14.9	5.7%
Other diseases	10.3	3.9%
Eye-related diseases	6.6	2.5%
Nervous system diseases	6.4	2.4%
Infectious and parasitic diseases	6.1	2.3%
Mental diseases	3.7	1.4%
Diseases related to contact with health services	3.7	1.4%
Skin and subcutaneous diseases	3.7	1.4%
Congenital diseases	3.1	1.2%
Perinatal conditions	3.1	1.2%
Endocrine, nutritional and metabolic diseases	3.1	1.2%
Ear-related diseases	1.8	0.7%
Blood-related diseases	1.0	0.4%
Total	263.4	100.0%

Source: Superintendencia de Isapres.

OUTPATIENT CARE

In 1998, there were a total of 3,726 facilities offering outpatient services in Chile, of which 2,366 were run by the public sector. The majority of facilities are rural health posts, providing basic healthcare to rural communities. Around 68% of public sector facilities provided primary care, the majority of these coming under the jurisdiction of the municipalities. In the private sector, ambulatory care is provided at polyclinics and medical centres, with diagnostic services being available at 506 clinical laboratories.

Outpatient Facilities, 1993-1999

	1993	1994	1995	1996	1997	1998	1999
<i>Public sector</i>							
Surgeries/consulting rooms	495	503	497	497	526	526	526
Rural Health Posts	1,061	1,104	1,102	1,102	1,144	1,144	1,144
Rural Medical Stations	733	721	721	720	696	696	703
<i>Private sector</i>							
Polyclinics	387	387	387	387	387	387	n/a
Medical Centres	467	467	467	467	467	467	n/a
Clinical Laboratories	506	506	506	506	506	506	n/a

Public Primary Care Resources, 1998

	Municipal Administration	Health Service Administration	Total
General urban surgeries	228	18	246
General rural surgeries	149	0	149
Hospital consulting rooms	0	117	117
Rural health posts	1,075	31	1,106
Total	1,452	166	1,618

Source: MINSAL.

Over 40 million outpatient consultations are recorded each year. According to a survey carried out by the Ministry of Planning in November 2000, nearly 60% of general medical consultations and 42% of specialist consultations take place in the public sector.

Medical Treatment by Place of Treatment and Health Insurance Affiliation, 2000 (%)

	General Consultation	Specialist Consultation	Emergency Consultation	Dental Treatment	Laboratory Tests	X-rays
<i>Establishment</i>						
Public	58.6	42.1	76.9	32.2	49.4	42.2
Private	36.7	50.3	18.8	57.7	44.0	50.0
Other*	4.7	7.7	4.3	10.2	6.7	7.7
<i>Health Insurance</i>						
Public system	70.8	62.9	78.0	51.3	66.6	62.3
ISAPRE	20.5	27.4	12.9	35.0	22.9	25.7
Other*	8.7	9.7	9.1	13.7	10.5	12.0

Source: MIDEPLAN, Encuesta CASEN 2000. *Including armed forces and unclassified data. Medical Consultations, 1990-1997

Medical Consultations, 1990-1997

	1990	1992	1993	1994	1995	1997
Law 18,469 beneficiaries (000)	25,792.0	26,905.8	25,801.7	27,645.0	27,730.5	30,016.2
ISAPRE's beneficiaries (000)	6,890.9	9,813.9	11,514.8	12,132.3	11,982.6	13,199.7
Total (000)	32,682.9	36,719.6	37,316.6	39,777.3	39,713.0	43,215.9
Consultations per inhabitant	2.5	2.6	2.7	2.8	2.8	3.0

MEDICAL PERSONNEL

Chile has approximately 1.2 doctors per thousand population. In 2000, the Colegio Médico de Chile reported a total of 18,236 doctors, although 1,671 of these were over the age of 70. Around 60% of doctors are based in the Metropolitan region, which has a ratio of 1.8 doctors per thousand population. Around 70% of doctors are men (63% in the under 50 age group).

Doctors by Sex and Age Group, 2000

	Male	Female	Total
Under 25 years	17	15	32
25 - 29	731	429	1,160
30 - 34	1,256	765	2,021
35 - 39	1,640	874	2,514
40 - 44	1,968	1,142	3,110
45 - 49	1,772	1,090	2,862
50 - 54	1,465	454	1,919
55 - 59	1,174	207	1,381
60 - 64	813	138	951
65 - 69	513	102	615
70 - 79	767	127	894
80+	676	101	777
Total	12,792	5,444	18,236

Source: Medical College of Chile.

Doctors by Specialty, 1995-2000

	1995	1996	1997	1998	1999	2000	As % of Total
Internal medicine	2,122	2,245	2,248	2,213	2,211	2,256	12.4
Paediatric	1,563	1,760	1,783	1,757	1,768	1,808	9.9
General practitioners	1,139	1,112	1,037	1,014	1,364	1,348	7.4
General surgery	1,116	1,216	1,229	1,209	1,207	1,233	6.8
Gynaecology and obstetrics	879	1,010	1,031	1,021	1,024	1,146	6.3
Anaesthesia and re-animation	395	473	488	483	484	502	2.8
Psychiatry	420	476	480	471	478	487	2.7
Traumatology and orthopaedics	380	419	435	440	440	443	2.4
Specialty not declared	6,853	4,986	5,492	5,830	5,842	6,061	33.2
Other specialties	2,766	2,960	3,069	3,029	3,035	2,952	16.2
Total	17,633	16,657	17,292	17,467	17,853	18,236	100.0

There were 10,552 doctors working for the SNSS in 1999, an increase of 10.8% over 1995. In addition to doctors, the SNSS also employs a small number of dentists; 1,355 in 1999. The WHO estimated the total number of dentists to be around 0.4 per thousand population in 1996.

Medical Personnel Employed by the SNSS, 1995-1999

	1995	1996	1997	1998	1999	As % of Total
Auxiliary paramedics	21,600	22,328	22,336	22,664	22,913	53.0
Doctors	9,521	7,849	7,888	8,308	10,552	24.4
Graduate nurses	3,131	3,226	3,354	3,479	3,677	8.5
Midwives	2,024	2,072	2,087	2,161	2,187	5.1
Dentists	1,180	1,102	1,111	1,078	1,355	3.1
Medical technicians	1,107	1,118	1,127	1,128	1,177	2.7
Nutritionists	526	534	545	552	551	1.3
Physiotherapists	438	444	452	378	496	1.1
Pharmacists	256	252	257	323	321	0.7
Total	39,783	38,925	39,157	40,071	43,229	100.0

Source: MINSAL.

In 1997, 12,948 were doctors authorised to provide services under the free election system. Other approved medical personnel included 1,979 physiotherapists, 1,438 midwives, 74 pharmacists and eight dental surgeons.

Free Election System Medical Personnel, 1997

	Number	As % of Total
Doctors	12,948	73.3
Physiotherapists	1,979	11.2
Midwives	1,438	8.1
Medical technicians	817	4.6
Psychologists	230	1.3
Graduate nurses	161	0.9
Pharmacists	74	0.4
Dental surgeons	8	0.0
Total	17,655	100.0

Source: FONASA.

HEALTHCARE DEVELOPMENT

With the recent improvements in Chile's health indicators, the health system has entered a transitional phase, facing the traditional problems of poverty and environmental conditions associated with developing nations, together with problems more often associated with the developed world, such as an ageing population and chronic illnesses.

Evening up the existing imbalance of access to good quality healthcare is a priority for the present government in Chile. This imbalance is highlighted by variations in the infant mortality rate of less than 6-7 per thousand live births in some wealthy areas and up to 40 per thousand in poorer districts. The imbalance is also evident from the distribution in spending between the public and private sectors, with the private sector benefiting from superior financial and technological resources.

Improved ambulatory care provision is a priority of the health ministry, in order to prevent unnecessary hospitalisation and alleviate the pressure on hospitals. Diagnostic, therapeutic and some surgical procedures can be undertaken in diagnostic centres on an outpatient basis. Diagnostic centres are linked to a National Health Service hospital centre.

The government is implementing a US\$1.2 billion poverty alleviation programme encompassing health, education, housing and public works. A key feature of the programme will be decentralisation, so that the decision-making process will be closer to the providers and users of services - those people directly affected by policy decisions. One major change will be the decentralisation of buying procedures, through the creation of an electronic exchange, which will allow intermediation within the buying process.

In order to improve the health system through its priorities of poverty alleviation, greater equity, decentralisation and management reform, the Chilean government has received considerable support from the international community. Assistance has been received from individual countries and from multilateral aid agencies.

The Reform: The Chilean Healthcare Planning Objectives, 2000-2010

"Equity, participation, solidarity and quality" are the four pillars of the Chilean Healthcare Planning Objectives 2000-2010. This is a major step to strengthen a more preventive and universal primary care system, enforce and expand the AUGE programme, improve IT health systems and better respond to management and auditing needs. The goals for 2010 are to decrease health inequities, meet the needs of the ageing population, face sociological changes, service an "empowered" population, and continue to enhance sanitary surveillance.

SWOT Analysis of the Chilean Health System

Strengths

- Pro-active government: “a healthier Chile with a health system” (Lagos’ presidency)
- Health education amongst the population
- Strong NHS (it dates from 1952)
- Strong sanitary code
- Wide coverage of the public health system
- Sophisticated private services
- High skilful medical personnel
- General population supporting AUGE

Weaknesses

- Still high level of poverty in some areas
- Imbalance of private vs public and urban vs rural health services
- Mixed role of the government as provider and regulator
- Mixed role of ISAPRE as insurer/provider
- Shared attributions in environmental health
- Insufficient health technology
- Public health workforce worried about job security
- Weak consumer groups

Opportunities

- Poverty alleviation
- Further development of AUGE, primary healthcare and outpatient/ambulatory solutions
- Further decentralisation of health providers and new national and regional health authorities, ie the Health Superintendency
- New healthcare network management: self-managed hospitals
- New human resources management: improvement of health training and education
- Fostering public-private health partnerships
- Modernisation of IT health systems
- Development of patient charts
- Establishments of people’s health rights and duties

Threats

- Weak economy – although recovering
- Still high level of communicable diseases and increasing chronic illnesses
- High financing for the health reform, although this has been partially covered with a general VAT increase
- ISAPRE’s opposition to the functional change
- Opposition from private insurers and public health workforce

Source: *Espicom, 2004.*

Major Structural Implementations, 2000-2010

Implementations

- 1) Separation of health service providers from health authority functions
- 2) Network management
- 3) Self-managed hospitals
- 4) Financial incentives for health workforce and retirement incentive schemes
- 5) Prioritisation of diseases
- 6) Compensation fund to palliate health discriminations
- 7) Improved regulation of Isapres
- 8) Patient charts
- 9) Other financing for the public health service

Source: *MINSAL, 2004.*

Legal changes need to be implemented as part of the health reform. More concretely, there is a five-law bill currently under reform in Chile. Two of these laws, *Health Authority and Management* (Law 19,937) and *Financing Government Expenditure*, have already been passed. *Health Guarantees System (Auge)* is expected for approval in March 2005. The two remaining laws for approval are *Private Health* and *People's Rights and Duties*.

The Five-Law Reform Bill

Financing Government Expenditure	Health Authority and Management	Health Guarantees System (AUGE)	Amend Private Health Law	People's Rights and Duties in Health
<ul style="list-style-type: none"> Passed and in effect from 2003 	<ul style="list-style-type: none"> It modifies Law 2,763 Law 19,937 passed To be in effect in January 2005 	<ul style="list-style-type: none"> To be in effect in March 2005 	<ul style="list-style-type: none"> It modifies Law 18,933 Isapres' Solvency Project in effect General bill to be in effect in July 2004 	<ul style="list-style-type: none"> To be in effect from January 2005

Source: MINSAL, 2004.

Financing Government Expenditure Law

After the new law implementation, public health services will be funded through general taxes, whereas individual health services will be funded through an adjustment of payroll fees and general taxes. In order to subsidise the health reform through general taxes, the law approves a VAT increase from 18% to 19% between October 2003 and December 2006. On the 1st January 2007, VAT will be restored to 18%.

Health Authority and Management Law

Law 19,937 has been passed and will be in effect in January 2005. It modifies previous Decree Law 2,763. New modifications include new national and regional authorities, new healthcare network management, and new human resources management.

New national and regional authorities:

- The Ministry of Health will operate through two main organisms: the *Undersecretaryship of Public Health* and the *Undersecretaryship of Networks*. The Regional Health Authorities (ASR) will act as the "watchdog" for the MOH.
- At a decentralised level, there will be four main units: the Health Superintendency, responsible for FONASA (public) and ISAPRE (private); the Health Services, in charge of primary health care; the Public Health Institute (ISPCH) and the Central Purchasing Agency (CENABAST). See the *Organisation and Administration* section.

New healthcare network management:

- Hospital administration is to be modernised and decentralised, resulting in "network management" developments. It is expected that about 28 healthcare network managers will be responsible for devising strategies to enhance outpatient and preventive medicine, in compliance with the Guarantee System and the Health Goals.
- There are also plans to have 57 self-managed hospitals in the network by March 2005. Critical areas for management will be *training, transfer of appropriate technology, Information and Communications Technology (ICT), flow simulation, increasing ambulatory care and a reform support group*.
- The government is also seeking to expand the role of ambulatory medicine to relieve the pressure on hospitals. The long-term target is to treat 80% of diseases on an outpatient basis, but this will require many more family doctors to be trained.

New human resources management:

- An incentive package for earlier retirement for around 5,000 employees has been agreed – this includes a nine-month salary benefit. Also, instead of promoting the workforce by seniority, it has been decided that promotion should be competitively based on experience and achievements.

Reformed Health Authority and Management Law

New National & Regional Health Authorities	New Healthcare Network Management	New Human Resources Management
<ul style="list-style-type: none"> • MOH – Government and regulatory head body • Creation of the Undersecretariats of Public Health and Health Care Networks • The Regional Health Ministry Secretariats to act as the “watchdog” • Establishment of the Health Superintendency for insurance and service provider administrations 	<ul style="list-style-type: none"> • Healthcare Network is comprised of public and private establishments under agreement • Health service directors act as “network managers”: they coordinate health initiatives, allocate funds, review achievements and reveal budgets • Establishment of two types of public hospitals: low-complexity and self-managed 	<ul style="list-style-type: none"> • Financial incentives based on performance • Careers based more on performance and experience, than seniority • Retirement incentive schemes

Source: MINSAL, 2004.

Health Guarantees System (AUGE) Law

The Lagos administration has drawn up a far-reaching reform programme for the health sector. A key component is a minimum care plan known as the Plan for Universal Access and Guarantees for Health Impact (Acceso Universal con Garantías Explicitas – AUGE). AUGE was conceived in May 2000 with the aim of solving and re-addressing the inequalities between “the poor” and the rest of the society, and improving health resources in terms of effectiveness and efficiency.

Initially, AUGE did not have much support from the health services. Among its main detractors, there were public workers worried about job security and the advent of managed care, and private insurers which did not want to commit to the new programme. It was in the end the general population who really pushed the plan.

AUGE legally enforces public and private insurers to offer a mandatory benefits package for a group of diseases, including guaranteed access, maximum waiting times, quality care and financial protection. The AUGE plan, for instance, fixes maximum waiting times for non-urgent medical attention, including two days for GP consultation, 15 days for routine diagnostic tests (blood, urine, X-ray, ultrasound) and one month for a specialist consultation. The National Advisory Council is responsible for reviewing the package every three years.

Major criteria for determining this package include social values, universal coverage, “integral and incremental” input, health priorities and effectiveness. AUGE guarantees free or low-cost treatment for 56 serious ailments for the entire population irrespective of health insurance status. The minimum care plan will have to be offered by FONASA and ISAPRE to all their beneficiaries at the same rates, although ISAPRE will be able to continue to offer additional cover for other ailments/benefits.

Health Priorities under AUGE**Major Ailments to be Covered by AUGE**

- Accidents that require intensive care
- Acute respiratory infection (under 15 years)
- Alcohol and drug dependency
- All childhood cancers
- Aneurysms
- Annual dental check-ups and treatment (under 15 years and pregnant women)
- Arterial hypertension (over 1.7 million patients)
- Arthrosis
- Benign hyperplasia of prostate
- Bladder cancer
- Breast cancer
- Bronchial asthma
- Cataracts
- Central nervous system tumours and cysts
- Cervical cancer
- Chronic obstructive pulmonary disease
- Chronic renal insufficiency
- Circulatory disorders
- Congenital heart disease
- Cystic fibrosis
- Dental emergencies
- Depression
- Diabetes mellitus type I and II (number of diabetics put at over 635,000)
- Diabetic retinopathy
- Epilepsy
- Scoliosis
- Eye trauma
- Gastric cancer
- Haemophilia
- Hare lip and cleft palate
- Hernia
- HIV/AIDS
- Leukaemia
- Loss of teeth in adults
- Lymphoma
- Major burns
- Medical supervision of childbirth with analgesia if requested
- Mobility aids for the elderly (walking sticks, wheelchairs etc)
- Multiple trauma
- Myocardial infarction
- Neural tube defects
- Pneumonia in the elderly
- Prematurity
- Prostate cancer
- Refractive disorders
- Respiratory disorders in new-born babies
- Retina detachment
- Retinopathy of premature babies
- Rheumatoid arthritis
- Severe psychiatric disorders
- Squint (under nine years old)
- Stroke
- Surgery that requires prosthesis
- Terminal cancers (palliative care)
- Testicular cancer

Source: MINSAL, 2004.

From August 2002 to 2003, AUGE undertook a pilot programme covering over 23,000 patients from the public health sector, affected by five health priorities. Among them, prompt treatment was guaranteed in three priority areas: childhood cancers (radiotherapy or chemotherapy within 30 days of referral), congenital heart disease (specialist consultation within 14 days of referral), and kidney disease (specialist consultation within 30 days of referral, dialysis or kidney transplant for all confirmed cases).

AUGE Pilot Programme, 2002-2003

Health Priority	Number of Cases
Palliative care for terminal cancer	8,505
Cervical uterine cancer	7,562
End-stage renal disease and transplants	4,065
Operable congenital heart disease	1,889
Childhood cancer	1,329
Total	23,350

Source: MINSAL, 2004.

AUGE will be expanded to 12 health priorities which will benefit over 75,000 patients annually in 2004. Treatments will be made available for diabetes type I, acute myocardial infarction (AMI), breast cancer, cataracts, HIV/AIDS, among others. The future phase of implementation will take place between 2005 and 2007.

Expansion of AUGE Pilot Programme, 2004

Health Priorities

- Acute myocardial infarction (AMI)
- Arthrosis (hip replacement)
- Breast cancer
- Cataracts
- Diabetes type I
- HIV/AIDS
- Lymphoma
- Neural tube defects
- Palate fissures
- Schizophrenia
- Scoliosis
- Testicular cancer

Total number of cases (expected) > 75,000

Source: MINSAL, 2004.

In April 2004, the Chilean Senate's Health Commission ratified the proposal to create the Fondo de Compensación Solidario as a further measure to finance AUGE. It is estimated that around 80,000 people will transfer from private to public insurance, although ISAPRE's figures are more in the region of 245,000 people. The package will be mandatory in March 2005, not only for the public sector but also the private one. The coverage of health priorities will finally be extended to a total of 56 health priorities that account for 70% of the "burden of diseases" in Chile.

Private Health Law

Modifying Law 18,933, this bill reforms ISAPRE and will be in effect in July 2004. There is also a separate section, the Isapres' Solvency Bill, which is already in effect. At a general level, the Free Election System (Método de Libre Elección – MLE) has to be offered by ISAPRE. Also, ISAPRE no longer has the power to modify any programmes. In practice, the Superintendency of Health takes control, setting up any agreements with service providers, programming cover and prices, and facilitating other related processes.

Isapres' Solvency Bill

Agreements

- Isapres' net worth must be equal or superior to 0.3 times its total debt.
- Guarantee: equivalent to the debt held with its members and healthcare providers
- Default: special supervisory and inspectorial system for the Health Superintendency: contingency and adjustment plan; rejection of plan, then intervention via a provisional administrator
- Transitory regulation: random distribution of the beneficiaries of a bankrupted Isapre amongst the other institutions operating in the market place
- The sale of the member portfolio is permitted

Source: MINSAL, 2004.

Rights and Duties Law

This bill regulates the rights and processes for a person to receive medical attention. It is important that patients are guaranteed healthcare without discrimination. There is also the right to receive visitors, religious assistance, and any other general information. This bill, to be in effect in January 2005, empowers patients to take advantage of the available health resources.

Investment for the Reform

In the 1990's there was an intensive hospital renovation focused on the purchase of high technology in diagnostics and support, the development of new buildings, and the extension of the primary healthcare network. New buildings of high and moderate complexity were built in Iquique, San Felipe, Santiago, Los Angeles, Temuco, Valdivia, Puerto Montt and Coyhaique.

Investments peaked in 1994 at CH\$64,000 million, equivalent to US\$152.33 million. Since then, investments have decreased from around US\$75-80 million a year to US\$45-50 million. Investment in 2003 accounted for CH\$29,000 million in 2003, equivalent to US\$41.25 million. Currently, there is a deficit for technological update estimated in US\$1,000 million.

Annual maintenance of the installed resources is estimated at US\$59 million for infrastructure and US\$65 million for equipment. Economic annual requirement for further expansion would be in the region of US\$55 million. So far, there has been a budget increase of 5.9% in 2004, what is equivalent to CH\$83,283 million or US\$139.6 million. Of this, 50.65% has been allocated to AUGE and 49.35% to keep the reform ahead.

The total budget for 2004 is CH\$1,500,629 million, or US\$2,515.35 million, compared to CH\$1,417,346 million in 2003. Of 2004 budget, the allocation for primary healthcare is CH\$235,061 million, or US\$394.1 million. This is an increase of 11.5%, equivalent to CH\$24,244 million or US\$40.65 million, compared to CH\$210,817 million in 2003. Budgeted programme agreements 2003-2007 increase to CH\$196,947 million or US\$330.25 million, including 33 projects in ten regions.

Budgeted Programme Agreements, 2003-2007 (CH\$ Millions)

	2003	2004	2005	2006	2007	Total
MINSAL*	20,155	34,881	39,066	28,238	4,946	127,285
GORE**	12,638	16,742	22,758	16,934	590	69,662
Total	32,792	51,623	61,824	45,152	5,536	196,947

Source: MINSAL, 2004. *MINSAL (Ministerio de Salud) – Ministry of Health. **GORE (Gobierno Regional) – Regional Office.

Main Investment Projects, 2003-07

Region	Type of Investment	Investment, CH\$ Million
II Region	<ul style="list-style-type: none"> • Standardisation: Regional Hospital of Antofagasta • Standardisation: Calama Hospital • Construction: healthcare centre, Antofagasta Northern zone 	21,867
III Region	<ul style="list-style-type: none"> • Standardisation: Cipiapo Hospital (first stage) • Reinvestment: Vallenar Hospital (design) 	866
IV Region	<ul style="list-style-type: none"> • Structural repair: Coquimbo Hospital • Standardisation: Coquimbo Hospital Critical Units • Standardisation: Ovalle Hospital • Standardisation: La Serena Hospital 	7,432
V Region	<ul style="list-style-type: none"> • Standardisation: Gustavo Fricke Hospital • Standardisation: Los Andes Hospital • Standardisation: Llay Llay Hospital • Standardisation: Hanga Roa Hospital 	26,086
Metropolitan Region	<ul style="list-style-type: none"> • 20 Primary healthcare centres 	16,480
VI Region	<ul style="list-style-type: none"> • Standardisation: Rancagua Regional Hospital • Standardisation: Santa Cruz Hospital • Standardisation: San Fernando Hospital • Standardisation and reinvestment: primary healthcare centres 	23,315
VII Region	<ul style="list-style-type: none"> • Standardisation: Talca Regional Hospital 	4,264
VIII Region	<ul style="list-style-type: none"> • Standardisation: Guillermo Grant Benavente Hospital • Standardisation: Talcahuano Hospital • Standardisation: Herminda Martin de Chillan Hospital • Standardisation: Curanilahue Hospital • Standardisation: San Carlos Hospital • Standardisation: Cañete Hospital • Standardisation: Lota-Coronel Hospital Complex 	39,668
IX Region	<ul style="list-style-type: none"> • Standardisation: Temuco Regional Hospital • Standardisation: Victoria Hospital • Reinvestment: Puerto Saavedra Hospital • Standardisation: Nueva Imperial Hospital 	40,117
XII Region	<ul style="list-style-type: none"> • Standardisation: Punta Arenas Regional Hospital • Standardisation: Puerto Natales Hospital • Standardisation: Porvenir Hospital 	14,132
10 Regions	33 Projects	194,227

Source: MINSAL, 2004.

Development of Public and Private Health Partnerships

The recent political and economic stability in Chile has fostered new foreign investment in the country and a general interest in public-private partnerships. These have been put in practice in public works, ie construction and operation of motorways and prisons. Chile is now very keen on applying the experience of the British health system in public-private health partnerships.

Private participation (PPA) funding could help to subsidise the current deficit needed for technological update, free public funds for social programmes and could also open opportunities for international collaboration. There are seven projects with an estimated budget of CH\$207,574, or US\$348.0 million, of which around 20%, equivalent to CH\$41,415 million or US\$69.4 million, could be funded by private participation. The main aim is to reinstate self-managed hospitals, at least the 30 largest (400-1,000 beds), via infrastructural and equipment investments.

Potential Areas for PPA Funding

	Human Resources	Equipment	Infrastructure
<i>Support units</i>			
Nutrition			
Surgery			
Transport			
Laundry			
Sterilisation			
Others			
<i>Therapeutic diagnostic units</i>			
Imaging			
Laboratory			
Physical Medicine			
Bloodbank			
Others			
<i>Clinical services</i>			
Medicine			
Surgery			
Psychiatry			
Neurology			
Others			

Source: MINSAL, 2004. Light grey – High eligibility for private participation. Medium grey – Medium eligibility. Dark grey – Low eligibility.

Potential Projects for PPA Funding, CH\$ Million

	Hospital	Estimated Cost	Private Participation
IV Region	Serena-Coquimbo	35,000	7,000
V Region	Gustavo Fricke	15,500	3,000
VII Region	Talca Regional Hospital	29,100	5,820
VIII	GG Benavente - Traumatology	21,839	4,368
Metropolitan Region	Salvador Infante	46,135	9,227
Metropolitan Region	Barros Luco T – EG Cortes	42,000	8,400
Metropolitan Region	Maipu	18,000	3,600
5 Regions	7 Projects	207,574	41,415

Source: MINSAL, 2004.

Training and Education Investment

Public health training areas for implementation include new competencies and specialisations, stronger management capacity, AUGE's implementation, access of public workforce to relevant training, primary healthcare model development, family health trained workforce, and selected teams of specialists. New public health processes also need to be devised, for instance need-detection methods, up to date educational processes including e-learning, and impact indicators.

In order to fund the new training, there is an annual budget for health services allocated through the National Budget Law. About US\$ 5,465,504 have been allocated for training in 2004, an increase of 93.4%, or US\$2,639,947, compared to US\$2,825,557 in 2003. For primary healthcare, Law 19,378 highlights the importance of training in career development, and establishes remuneration on the basis of improvement. There is also an annual budget allocation for primary healthcare through the National Budget Law via each local council.

NHS Training Spending, 2001-2003 (US\$)

	2001	2002	2003
Specialists programme	641,788	646,560	1,103,600
Senior management formation programme	179,545	211,920	49,176
Rural nursing support programme	5,150	28,483	28,802
Specific programmes subtotal	826,483	886,963	1,181,578
Training and further training	1,098,893	1,015,427	1,643,979
Total	1,925,376	1,902,389	2,825,557

Source: MINSAL, 2004.

PHARMACEUTICAL MARKET ENVIRONMENT

Pharmaceutical Regulation

The Institute of Public Health of Chile (ISPCH – Instituto de Salud Pública de Chile) is the body responsible for pharmaceutical regulation. This includes registration, importation, production, storage, distribution, publicity and promotion. The *Organisation & Administration* section of this report shows the functional integration of the ISPCH within the Ministry of Health.

The Ministry of Health's Regulations for the National System for Control of Pharmaceutical Products, Food for Medical Use and Cosmetics, are contained in Decree 1,876, 1996. This updated the 1981 law and incorporated changes and improvements to the sanitary code. However, many regulations established by Decree 1,876 are "ignored" and some have become obsolete when comparing them to other countries.

Major Users of ISPCH's Services, 2002

	Number of Companies
Clinical laboratories	910
Environmental laboratories	95
Occupational health laboratories	16
Bloodbanks	113
Pharmaceutical industry	232
Health services	29
Public and private hospitals	400
Public and private transplant centres	20
Potential kidney receptors	779
Total	2,594

Source: ISPCH 2002.

Among ISPCH's other tasks are sanitary surveillance, public health promotion and public health research. More concretely, the ISPCH is responsible for Good Manufacturing Practices (GMP) processes, product registration and modification, production and control of vaccines, environmental health and occupational health. Inspection of the distribution chain is undertaken at local level by the regional health services.

ISPCH's Strategic Objectives, 2002

1. Programmes for quality control of clinical laboratories, environmental health, occupational health and bloodbanks
2. Regulation of the pharmaceutical industry:
 - GMP and usage regulation
 - Product registration
 - Pre- and post-marketing control programmes
3. Sanitary surveillance
4. Technological transference
5. Transplant programmes
6. Information to users

Source: ISPCH 2002.

The ISPCH has been the object of many criticisms in recent years from both domestic and international manufacturers or importers. Domestic manufacturers have expressed their views through their two main trade organisations: ASILFA (The Industrial Association of Chilean Pharmaceutical Manufacturers) and CANALAB (National Chamber of Manufacturers). International companies, mainly importers and a few manufacturers, are represented by CIF (The Chamber of the Pharmaceutical Industry).

The CIF has criticised domestic manufacturers for their lack of GMP compliance and bioequivalence tests, and how the ISPCH has been tolerant with them since 2001. For both domestic and international manufacturers, the ISPCH has been slow in processing product registrations, especially for original products. There is also the consensus that the ISPCH should be more focused on guaranteeing further product quality and stock control, and use more resources in this area. A final criticism is related to ISPCH's accumulation of legal proceedings, most of them advertising-related. This is considered to be a waste of ISPCH's resources.

In general, the ISPCH is perceived as slow and old and much modernisation is needed. According to the CIF, the new ISPCH should be a body responsible for a professional and nationally rationalised drug control in the country. It should include a department for authorisation, registration and inspection; an analytical chemistry sub-department; and a National Centre for the Information on Medicines and Pharmacovigilance (CENIMEF). Also, the ISPCH should actively cooperate with universities for further research, and should delegate the national production of vaccines.

Postponed GMP-Compliance

July 2001 was the first deadline for companies to meet GMP certification. By 1st May 2002, the second deadline, sources from the Chamber of the Pharmaceutical Industry (CIF) indicated that only eight out of 58 manufacturing plants (28 pharmaceutical, 30 cosmetic), equivalent to 13.3%, had complied with GMP standards.

Other sources indicated that 18 out of 28 pharmaceutical production sites had complied with GMP standards by 2003. ASILFA, for instance, acknowledged that its associated manufacturers were GMP certified, with the exception of their most recent built manufacturing plants. It even went further stating that all the companies in Chile had invested around US\$3-20 million to improve manufacturing standards in the last six years.

Unsurprisingly, CIF has criticised the lack of GMP-compliance affecting local production sites and processes in Chile. Whereas the international companies represented by the CIF comply with GMP, the domestic industry, some of them due to the lack of economic resources, is some steps behind.

A new deadline has been established for 2005, which has exasperated the CIF. For them, this again shows ISPCH's tolerance and protectionism for the domestic industry against international interests. LabChile also states that out of over 1,200 controls needed for GMP certification, the ISPCH only performs around 50.

Lack of Bioequivalence Tests

Lack of bioequivalence tests is another related issue for consideration. The Ministry of Health is planning to trial bioequivalence tests on around 15 products between 2005-09. Around three of these products will be tested per year. If tests are enforced in the long-term, this will be a blow mainly for domestic manufacturers of generic and copy products.

Delay in Product Registrations

Manufacturers usually wait an average of 13 months for the registration of original products (cost CH\$400,000) and 16 months for any modification of original products (cost CH\$100,000). Whereas the registration of original products should take 120 days (four months), registration of similar products should take 90 days (three months).

However, timescales were reduced by the ISPCH to just below ten months as average in 2002. According to the Chamber of the Pharmaceutical Industry (CIF), ISPCH should be more efficient, especially when considering products already approved by the FDA or EMEA.

For the CIF, there is a need for the ISPCH to operate electronic registrations that speed up the process. The process needs to become more professional and less personal. There is also a need for electronically governing the drug control system in the country.

Lack of Product Quality Standards

Faults in product registration result in product quality problems. Between 1997 and 1999, the ISPCH analysed 218 products, of which 30 showed faults (14%). However, the scope of this analysis is very poor when the number of products in the market is 3,950 in 2003. According to the review published in Sept-Oct 2001 by the Journal of the Chilean College of Chemists-Pharmacists (Revista del Colegio de Químico-Farmacéuticos de Chile), pharmaceutical products made up in pharmacies did not meet the minimum quality standards either.

Another point of consideration is the blurred control on active ingredients. Manufacturers can change product quality specifications after obtaining product registrations as they do not inform the ISPCH and the ISPCH does not have the resources to find out. For the CIF, there is also a lack of procedures mainly affecting generic and similar products; whereas registration of original products must be complete, registration of generic and similar products is more simplified.

As the CIF puts it, this is only a reflection of the tolerance and protectionism towards the national industry. The CIF advocates for the ISPCH to be more focused on product quality. However, over 70% of physician-prescriptions are for generic and similar products, which for the domestic industry shows that their products are safe and reliable.

Also, the number of legal proceedings based on quality issues is 50-50 between domestic and international manufacturers, and considering the higher participation by volume of domestic companies, domestics are better off. Domestic manufacturers such as Recalcine go further and claim that imported drugs should be more controlled in terms of quality.

Poor Stock Control

Another problem is poor stock control undertaken by the ISPCH. There are around 3,950 products in 8,000 presentations in Chile. However, the stock controls undertaken by the ISPCH were limited to just 80 products in 2002. This figure is very low and statistically poor. According to the CIF, stock controls should be applied to all products.

According to the ISPCH, stock controls in 2002, although very limited, were applied not only to the retail market but also the institutional market, including the Central Purchasing Agency (CENABAST). In general, poor stock control was due to ISPCH's lack of investments in the necessary equipment, need for a larger technical unit where to operate analyses, and lack of personnel – just nine inspectors. In spite of this, the ISPCH undertook pre-marketing controls, the so-called “control de serie”, on products with problems.

Accumulation of Legal Proceedings

Another major criticism by the industry is ISPCH's accumulation of legal proceedings in 2003, some of them dated from 1998/9. In 2002, there were over 250 pending legal proceedings mainly against around 34 manufacturers but also other establishments, of which 60-70% were advertising-related and the rest of them mainly due to labelling irregularities – very few were related to issues on product quality.

Legal proceedings can be reported to the ISPCH via two main routes: “oficio” which is when health authorities report any irregularity, and “denuncia” which is when manufacturers or competitors denounce each other. For the ISPCH, most of the legal proceedings, mainly based on advertising issues reported by multinationals, was the result of a commercial “war” among manufacturers. There were battles such as Pfizer vs Recalcine on the issue Viagra vs Helpin in 2002, or Volta vs Maver in 2000. In certain way, this “dirty war” compromised ISPCH's resources when issues such as product quality were more relevant.

In 2003, there was a further investigation instigated by legal proceedings against Bestpharma. Bestpharma had apparently imported irregular products and had also been denounced by other competitors for labelling or advertising irregularities (17 legal proceedings). According to many, the ISPCH has ignored these reports based on the fact that Bestpharma was the second supplier of the Central Purchasing Agency (CENABAST), after LabChile. The result, however, was a fine for the value of US\$58,824 for Bestpharma. The rest of the proceedings were speeded up in 2003, with estimated earnings for the ISPCH of CH\$800 million, or US\$1.13 million.

ISPCH's Modernisation

In 2003, the Minister of Health announced that the ISPCH would speed up product registration and GMP compliance processes. To tackle this, the number of ISPCH's personnel will be increased, around CH\$30 million will be injected in the ISPCH and the ISPCH's legal team will be restructured. As part of the Health Reform in the country, the ISPCH is being modernised in 2004, with six main areas to be restructured.

- 1) IT will be applied to product registration, sanitary surveillance, and patient education on the rational use of drugs.
- 2) All the management processes will be optimised.
- 3) It is necessary to gather more information on public health so the ISPCH can fully act as a research body for the Ministry of Health.
- 4) Development of studies on sanitary surveillance.
- 5) Further prevention and control of diseases.
- 6) Continuing support on kidney and bone marrow transplants and on neoplasms for AUGE's programme are needed.

Production of Vaccines

Another issue of consideration in 2003 was the production of vaccines. The ISPCH is under negotiations with universities and private businesses for the production of vaccines after the closure of ISPCH's laboratory. This production site was producing around two million units a year but was closed by mid-July 2002 due to economic reasons and concerns over hygiene and technology. The new project is to create a public-private consortium, independent of the Institute, comprising a laboratory, a university and a technical team from the Institute.

Patent Protection & Intellectual Property Rights

A patent, trademark and industrial design law was implemented in Chile in September 1991 (Law 19,039), under which patent protection is provided for pharmaceuticals. There are, however, deficiencies in the law. Patent protection only lasts for 15 years from the date of filing, five years less than the international standard. There is also a lack of provision for extending patent terms for delays due to regulatory approval processes, and no 'pipeline' protection for pharmaceutical products patented in other countries prior to patent protection being available in Chile. The first patent-protected products began to appear on the Chilean market in 1998.

Since 1999, a new patent law has been debated by Parliament, which is intended to bring Chilean patent law into line with international standards (TRIPS compliant) and which will significantly increase the protection of products developed by research-based pharmaceutical companies. The law, which should have been enforced in January 2000 according to the WTO-imposed deadline, has been fiercely resisted by domestic producers, which have built up substantial manufacturing operations dedicated to producing branded copies of original products. However, the Parliament is expected to approve the new legal text before 21st May 2004 and enforce the new law before the end of the year.

The FTA agreement between the USA and Chile and the related TRIPS compliance will mean the expansion of patented drugs in Chile for a period of 20 years, which could increase drug prices, at least in the long term. In the short to medium term, Chile will not be affected so much. The advantage for Chile is that patents will be considered from the date when they were requested in the country of origin, not from the date when they were marketed in Chile. Currently, there is a large number of international drug blockbusters whose patent is or will be expiring in the next few years. This guarantees that Chile will still be able to produce its copycat products in detriment of international research-based companies.

Other issues remain unclear in the new proposed patent law. Article 51 should be clarified to avoid any misunderstanding as to when compulsory licences can be issued. It is also of concern that the new law does mention parallel imports. The new law does address the needed "linkage" between health authorities and patent offices, but its implementation does not guarantee the full protection of intellectual property rights.

Also to consider, the number of patent applications and registrations in Chile is relatively low and most of them come from foreign companies. In 2003, there were 2,406 patent applications in the country, of which international companies submitted 2,077 or 86.3%. Pfizer, Roche and Novartis were among the five companies that submitted the highest number of applications. By countries, the USA submitted 831 applications, followed Germany (257), Switzerland (193) and the Netherlands (129).

Pharmaceutical Registration

Pharmaceutical products must be registered with the Institute of Public Health in Chile, which is responsible for enforcing the provisions of the sanitary code and regulations, and ensuring quality control. Registered products may be subjected to quality control checks at any stage of manufacture, distribution or marketing. New product registrations are valid for five years, with renewals after that.

The registration procedures for original drugs require longer waiting periods and higher standards of documentary evidence than for subsequent registries of theoretically similar products. In this respect, one criticism of the Ministry of Health's requirements in this respect is that applications for original drugs are usually made by foreign manufacturers. Also, because of the different registration procedures and the lack of 'pipeline' patent protection, locally produced copycat drugs have a strong commercial advantage.

From 1999 to 2002, new product registrations of original products increased from 228 to 257, but still less than one third of the 710 and 791 new product registrations of similar products in the same period. Also, registrations of original products took an average of 319 days in 2002, equivalent to 10.6 months, compared to 267 days in 2001, equivalent to 8.9 months. On the other hand, registrations of similar products took an average of 256 days in 2002, equivalent to 8.5 months.

Product Registrations, 1999-2002

	1999	2000	2001	2002
Original products	228	234	214	257
Similar products	710	746	825	791

Source: ISPCH, 2002.

The delay in product registration, both for original and similar products, was mainly due to the nature of the process – still manual in 2002 and therefore cumulative, although with provisions for computerisation in 2003. Overall, the ISPCH effectively undertook 46% of original product registrations and 38% of similar product registrations in 2002, in spite of ending its "convenio" with the Pharmacology Society (Sociedad de Farmacología), responsible for submitting 90% of the expert information for product registration.

Also, the ISPCH achieved 19% of GMP visits that had planned to 118 laboratories (of these, only 28 were pharmaceutical); 99% of authorisations of "uso" and "disposición", taking an average of three days; 68% of analyses on active ingredients as part of stock control process; and 100% of product controls in the pre-marketing stage.

ISPCH's Activities, 2001-2002

	2001	2002
Original product registrations	214	257
Similar product registrations	825	791
No. of GMP visits	25	22
Authorisations of "uso" and "disposición"	25,087	24,452
Stock control	18,109	11,916
Pre-marketing product control	1,843	1,602

Source: ISPCH 2002.

Applications for import registration must be accompanied by official certification, as recommended by WHO. Registration of pharmaceutical products under a licensing agreement from another country requires authorisation from the manufacturer to produce, import and distribute its products in Chile.

In order to establish the identity, power, purity, stability and other requirements regarding physical, chemical, microbiological and biopharmaceutical quality of active elements and pharmaceutical forms of drugs for which registration is required, ISPCH will follow the related norms contained in the pharmacopoeias and their supplements currently in force in the country.

These include: Chilean Pharmacopoeia, International Pharmacopoeia, European Pharmacopoeia, US Pharmacopoeia and National Formulary, British Pharmacopoeia, French Pharmacopoeia, German Pharmacopoeia, German Homeopathic Pharmacopoeia and Pharmacopoeia Wilmar Schwabe. In addition, the technical reports of WHO's Committee for Biological Standards and the relevant USA Code of Federal Regulations are in use. Anything that is not included in the above is subject to the discretion of the Institute.

The Institute will approve or refuse a registration application within 90 days of receipt, except where additional information is required from other bodies/experts, when the time period is extended by 30 days. The Ministry of Health makes the final decision for refusal of registration.

Once sanitary registration has been approved for the import of a finished product by any legal entity, further applications for registration are not required by other importers, provided the product is sourced from the same laboratory and country of origin. If not, the product must be proven to have the same formulae, quality and stability specifications as the registered product, through the free sale certificate or official certificate issued by the health authority in the manufacturer's country of origin.

Pharmaceutical Labelling

By Decree 1,876 (1996), product labelling is ISPCH's responsibility. Lettering on packaging and instructions for use must be in Spanish. Other languages are, however, allowed in addition for imported products. Contrary to other countries, OTC products, subject to "easier" manipulation (use of similar colours, brand names, labelling), are less label-regulated than POM products.

Pharmaceutical Advertising

Product advertising is regulated by the ISPCH through Decree 1,876 (1996). In 2002, of 250 legal proceedings undertaken by the ISPCH, around 60-70% were advertising related, whereas the remaining were based on labelling irregularities – just a few were considered on the basis of deficiencies on product quality.

Promotion of OTC products is allowed only through the accurate and complete reproduction of labels, information booklets for patients, texts and appendices previously approved under the registration process, or which are specifically required for a product already registered. Previous authorisation from the Institute is not required but the regulations must be adhered to.

Prescription drugs cannot be advertised to the general public. Prescription drugs can be promoted to health professionals authorised to prescribe and dispense, without prior authorisation from the Institute, through announcements intended to inform them of a product's introduction or presence on the market. Promotional material must contain approved text, and include the name and logo (if there is one) of the manufacturing or importing laboratory, or be complete and accurate reproductions of the approved labels/leaflets. The information provided must be truthful, complete and documented, and is subject to verification.

No incentives for healthcare professionals are allowed, as these may lead to irrational prescribing. In 1998, five Chilean pharmaceutical companies were summoned by the ISPCH for awarding certain pharmacies cash rewards for recommending their products, despite the requirement of a prescription. The system was allegedly started by Prater Laboratory with the anaemia drug Infor.

According to article 107 of regulation 1,876, the use in pharmacies of "publicity means which could lead to the supply of a non-indicated drug, such as samples or any other method which promotes consumption and self-medication" is not allowed.

Pharmaceutical Pricing

There is no price control in Chile. However, the Central Purchasing Agency (CENABAST) acts a reference centre for prices. Pharmaceutical prices are among the lowest in the region, due to the presence of a well-developed domestic industry and growing market share for generics. In 1999, the average price of a drug on the Chile market was US\$3.3, compared to a regional average of US\$5.1. Prices vary widely according to product type. Whilst the average price of a generic is just US\$0.6, branded products manufactured by multinationals sell for around US\$6 and copy products manufactured by local companies sell for around US\$4.

Whilst prices in dollar terms have generally fallen in recent years, the marked depreciation of the peso against the dollar, which has made imported active ingredients and finished products much more expensive, has caused local prices to rise. In August 2002, for example, whilst the overall price index only rose by 0.4% during the month, medical product prices rose by an average of 2.5% and some classes of drugs recorded even higher rises, including antihistamines (11.6%), antibiotics (8.1%), antitussives and bronchodilators (5.3%), tranquillisers and antidepressants (4.5%), and antihypertensives (3.2%).

Further price increases are anticipated when the new patent law, which is being debated by Congress, is enforced, mainly as a result of market exclusivity for original products and higher manufacturing costs.

Pharmaceutical Reimbursement

Reimbursement is by no means comprehensive. Only around 15% of the population covered by the public health system are entitled to free drugs or minimum co-payments. Under the Método de Libre Elección (Free Election System), prescription reimbursement is virtually non-existent and there is very little drug reimbursement during hospitalisation.

Under the Institutional Attention System segment of the SNSS, there are four income groups for reimbursement purposes, with A being the lowest. Health services are reimbursed as follows:

- General urban or rural surgeries, or rural first aid posts - pharmaceutical products included in the Arsenal Farmacológico Básico for Rural First Aid Posts and the Arsenal Farmacológico for Health Centres, approved by the Health Ministry, are 100% reimbursed.
- Specialty surgeries - pharmaceutical products included in the Formulario Nacional de Medicamentos (National Drugs Formulary) are 100% reimbursed for patients in income groups A and B, 90% for group C and 80% for group D.
- Inpatients receive reimbursement for pharmaceuticals at 100% for income groups A and B, 60% for group C and 35% for group D.

Drugs obtained under the Atención en la Modalidad Institucional (Institutional Attention System) must be charged according to a valid price list, which is issued twice each month by the Central Purchasing Agency (CENABAST). For drugs that are not listed, charges must be equivalent to the cost of replacement.

Within the ISAPRE's system, levels of reimbursement vary between companies and individual insurance schemes, and not all companies reimburse prescription drugs. In general, Isapres usually cover drugs required during hospitalisation for a defined period of time. Drugs required during ambulatory care are covered in some cases, but this would be subject to an agreement between the Isapre and the pharmaceutical suppliers.

Pharmaceutical Distribution

The pharmacy chains Farmacias Ahumada, Salcobrand and Cruz Verde are the major players in the retail pharmaceutical distribution channel. Together, they own over half of the major 1,400 pharmacy establishments and 92% of total retail pharmacy market. They are represented by the National Association of Pharmacy Chains (ANACAF - Asociación Nacional de Cadenas de Farmacias).

Retail Market Share of Major Pharmacy Chains, 2003

	Market Share (%)	Number of Pharmacies
Farmacias Ahumada	32.0	226
Salcobrand	31.4	236
Cruz Verde	28.6	300
Farmalider	n/a	42
Independent Pharmacies	8.0	600
Total	100	1,404

Source: Espicom's estimates, 2004.

The number of independent pharmacies has drastically decreased, and around 600 are associated to the Union of Chilean Pharmacy Owners (UNFACH - Unión de Dueños de Farmacias de Chile). After the reduction of independent pharmacies and disintegration or control of major distributors (Farmacentral, Socofar and Droguería Uñoa), these three pharmacy chains monopolistically dominate the retail pharmacy channel, directly negotiating and imposing their rules with manufacturers.

Farma Lider, the pharmacy subsidiary of supermarket D&S, leads the drug supermarket sector, mainly participating in the OTC market. Finally, the Central Purchasing Agency (CENABAST) is the centre responsible for purchasing and distributing medical and pharmaceutical products for around 25% of the public institutional market.

Own-labelled production, price competitiveness and product and market diversification shape the pharmacy sector. According to Farmacias Ahumada, Chilean pharmacies are characterised by poor pharmacological culture, high stock piling, unawareness of therapeutic indications and risks, and high technical information difficult to be understood.

Pharmacy Own-Labelled Production

Pharmacy chains are diversifying their product sales. Out of the metropolitan area, about 47% of pharmacy sales are food, perfume and home and personal care (HPC) products. As a consequence, the drug retail pharmacy market has decreased by around 1.8% in sales volume and 2.55% in sales value – the retail sales market at manufacturers' prices was estimated at nearly US\$500 million in 2003.

Since 1998, the three major pharmacy chains have also launched themselves into the production of cosmetics, home and personal care (HPC) products, natural products and drugs. In the drug market, they are competing with manufacturers mainly in the so-called OTC branded generics, which have an average price of US\$3.9 compared to "pure" generics at US\$0.60. Their prices are equal, and lower in some cases, to prices offered by branded manufacturers.

The sales of own-labelled products, including mainly drugs but also cosmetics and HPC, already accounted for over US\$51 million in 2003. Farmarcias Ahumada, through 40 third-party manufacturers, 30 domestic including Prater and ten foreign, has its own drug product lines, after launching its first products under the brand FASA in 1996. Its sales of own-labelled products (drugs and cosmetics) account for 8.5%.

Salcobrand, by external manufacture undertaken by Recalcine and Medipharm, also produces its own drug product lines and cosmetics under the brand FarmaPrecio. Sales of own-labelled products (drugs and cosmetics) account for around 7%. Cruz Verde's production through Mintlab is relatively small compared to both Ahumada and Salcobrand and is focused on HPC and natural products. Its sales of own-labelled product account for 2%.

From Price Competitiveness to Product and Market Diversification

Own-labelled production is not the only way for pharmacy chains to achieve a bigger market. The three major chains were also involved in price competition in 2002, when they drastically reduced their prices by 30%, even below profit levels. Another tactic was to offer discounts of up to 20% on certain days of the week.

As a result, pharmacy chains could only achieve a very small profit margin of 2-3% on a mark-up of around 30% on manufacturers' prices. This might have negatively affected the pharmaceutical distribution channel, as one third of manufactured products were sold to chains and manufacturers were already stretching themselves.

As a counterbalance, the three pharmacy chains opted for opening more outlets in the country. Also, Farmacias Ahumada took advantage of Falabella's investment in the company to launch operations internationally. This way, they could sell more products at a small profit. As a result, there was a saturation of outlets in the most densely populated areas, including Santiago de Chile, Puente Alto, San Bernardo, Maipo and La Florida.

According to UNFACH, there were not price wars as such but agreements between the three major chains to fix prices at their convenience and further destabilise independent pharmacies. In 2003, ASILFA recorded price increases, mainly due to high dollar exchanges and imports of raw materials. Still then, UNFACH adduced this to price fixations by pharmacy chains. Whereas pharmacy chains can absorb price increases, independent pharmacies are negatively affected.

The reality is that there was a high price war between chains in 2002, with very cost-effective products for consumers but associated economic difficulties for chains and manufacturers. However, pharmacy chains changed their price tactics to keep afloat in the market. In 2003, the tendency was to offer promotional deals, as a way to recover profit levels lost in 2002, further position own-labelled products, keep attracting more customers, penetrate new markets as FASA did in Mexico, and diversify as when Salcobrand launched six supermarkets named OK Market.

Retail Pharmacy Chains

Farmacias Ahumada

Farmacias Ahumada (FASA) is the leading pharmacy chain in Chile claiming a 33.6% share of the retail pharmaceutical market in 2003, up from around 30% in 1999. Market share estimated by Espicom in 2004 is 32.0%. FASA achieved consolidated sales of CH\$630.6 billion (US\$897 million) in 2003, of which CH\$240.5 billion (US\$342.2 million) were generated in the Chilean market. Revenues from operations in Chile grew by 1.9% in 2003.

FASA's Sales by Country, 2002-2003

	2002		2003		Growth (%)
	CH\$ Million	US\$ Million	CH\$ Million	US\$ Million	
Chile	235,946	335.3	240,530	342.2	1.9
South America	80,606	114.5	82,930	118.0	2.9
Mexico	~	~	307,092	436.8	~
Total	316,552	449.8	630,552	897.0	99.2

Source: Farmacias Ahumada, 2004.

Pharmaceutical products account for around 65% of turnover. The company produces its own products, which are sold under the FASA brand name. In 2003, the number of pharmaceutical outlets throughout Chile descended to 226 from 234 in 2002. In addition to its operations in Chile, Farmacias Ahumada has operations mainly in Brazil, Mexico and Peru.

FASA acquired 77% of the Brazilian pharmaceutical company Drogamed in the state of Parana in 2000 and the remaining 23% in 2001, as part of its strategy to participate in the pharmacy distribution in the South of Brazil. Its market share in Brazil is just 1%, increasing to 5.4% in the South of Brazil. Fasamed, ex Drogamed, operated 108 outlets in 2003, of which 33 were drugstores.

In August 2002, FASA entered into an agreement to acquire one of Mexico's main pharmacy chains, Farmacias Benavides. Operations in Mexico in 2003 accounted for CH\$307 billion, equivalent to US\$437 million. FASA's market share in Mexico is 2.9% and operations are run through 507 stores. The acquisition has made FASA the largest operation of its kind in Latin America.

In Peru, FASA runs 101 stores, accounting for 10.2% of the Peruvian pharmacy market. Combined operations in Brazil and Peru rose to CH\$83 billion in 2003, equivalent to US\$118 million. This represents an increase of 2.9% over the previous year's operations.

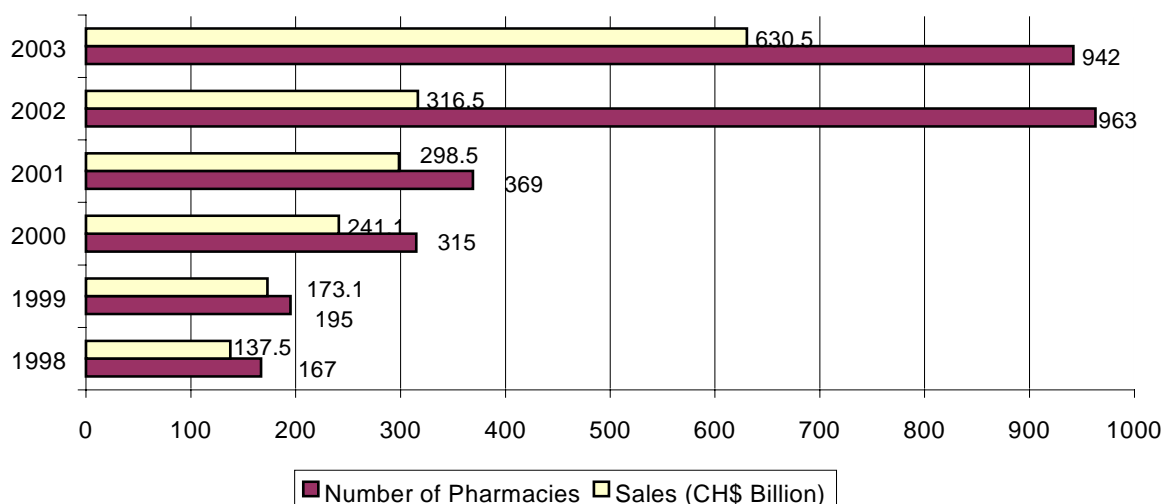
FASA's Market Share and Number of Pharmacies by Country, 2002-2003

	Brazil		Chile		Mexico		Peru	
	2002	2003	2002	2003	2002	2003	2002	2003
Market share (%)	1.0	1.02	33.1	33.6	~	2.9	8.1	10.2
Number of Establishments	115	108	234	226	~	507	91	101
Competitors	Nissei Ultraméd Multifarma		S&B Cruz Verde		Farmacias Guadalajara Farmacias del Ahorro		BTL Incafarma Superfarma	

Source: Farmacias Ahumada, 2004.

FASA has passed from operating 167 outlets in Chile in 1998 to nearly 942 outlets in Brazil, Chile, Mexico and Peru in 2003. By consolidating its Mexican operations in 2003, FASA achieved a massive sales growth of 99.2% in 2003.

FASA's Sales and Number of Pharmacies, 1998-2003



Source: Farmacias Ahumada, 2004.

After the merger of Sodimac and Falabella in 2003, it is expected that FASA will launch new operations in Colombia and Argentina, taking advantage of the retail experience supplied by these two giants – Falabella has a 20% stake in FASA, with option for a further 5%. There are also rumours that the merged company could take over FASA, adding pharmacy retail operations to its broad product portfolio.

Farmacias Salcobrand

Farmacias Salcobrand was formed from a merger of the Salco and Brand pharmacy chains in 2001 and is owned by the Selman, Jaque and Colodro families. The new entity has the most comprehensive coverage in geographical terms with 236 outlets. Salcobrand claimed a 33% share of the retail pharmacy market with an annual turnover in excess of US\$300 million in 2001, of which around 30% was due to sales of personal care and beauty products. Market share estimated by Espicom in 2004 is 31.4%.

The group has two manufacturing entities, one for pharmaceutical and one for cosmetics. Salcobrand recently announced the launch of a new scheme to distribute drugs to independent pharmacies at competitive prices. Previously, this market had been served almost exclusively by Socofar. Salcobrand was planning to open six minimarkets called OKMarket in 2003, entering the supermarket sector.

Cruz Verde

Cruz Verde is owned by the Harding brothers. Geographically, it is the chain with the biggest expansion in Chile. By June 2003, it had 300 outlets, compared to 40 in 1995, and claimed a market share rose to 30.3%. Market share estimated by Espicom in 2004 is 28.6%. The company's acquisition of Conosur pharmacy chain in 2001 helped to its aggressive market penetration in the last years. Prior to the merger with Conosur, Cruz Verde had annual sales of US\$216 million.

Unlike its two major rivals, business operations are focused almost entirely on pharmaceutical products. Cruz Verde also owns the distribution company Socofar, which supplies independent pharmacies. Also, it runs a retail card, the TCV card, among 2 million users, representing 7% of sales. Sales growth for 2003 was estimated at 20%.

Farmalider

D&S, the largest Chilean supermarket launched itself in the pharmacy market in 1999. An aggressive expansion based on low prices and market increase has positioned its pharmacy chain Farmalider in direct competition with the three main pharmacy chains. By 2004, Farmalider had 42 pharmacies, mainly located within D&S supermarkets.

CENABAST

The Central Purchasing Agency (CENABAST) centralises around 25% of public expenditure on pharmaceuticals and medical products. It establishes buying agreements for the public sector every six months for a basket of around 1,400 products. CENABAST's activity is roughly divided 68%-32% between pharmaceuticals and other commodities. Price negotiations, transparent purchasing processes, competence among suppliers and purchasing volume, timescale and standardisation are CENABAST's strengths in order to obtain price reductions.

CENABAST is regulated by Decree Law No. 2,763, 1979. Since October 2002, purchasing processes are managed through the portal Chile-Compra (www.chilecompras.cl). In 2003, Chile-Compra had over 48,000 suppliers, of which 96.8% or 46,481 were microentrepreneurs (MEs) and small and medium scale enterprises (SMEs). Its self-financing is the result of its intermediary role of buying and selling.

Although Chile-Compra's policies are strengthening relationships with domestic MEs and SMEs, their active participation in the portal was at a ratio 6/10 compared to big companies' participation at a ratio of 9/10. By December 2003, about 87% of public purchases were published on Chile-Compra's Web site. As average, there were 6.2 tenders by purchase.

There are around 550 establishments that buy individually, when CENABAST's aim is to act a procurement centre for them, therefore reducing costs. Two reasons explain why public establishments do not purchase 100% of their products in CENABAST; they are not obliged to do so, and cash purchases are obstacles for them. A comparative study undertaken in October 2003 showed that CENABAST could save up to 55% of total public expenditure costs in a sample covering 7% of the total universe of drugs purchased by CENABAST.

According to CENABAST, public institutional expenditure represents 25% of the pharmaceutical market. However, according to ASILFA, the percentage is more in the region of 21% for total institutional market¹ (including CENABAST plus clinics), equivalent to US\$137 million in 2001 at manufacturers' prices, and estimated US\$153.2 in 2004.

In 2003, CENABAST spent US\$34.5 million in centralised pharmaceutical and medical purchases, US\$41.4 million in National Complementary Feeding Programmes (PNAC – Programa Nacional de Alimentación Complementaria) and US\$23.4 in other ministerial programmes. Total expenditure in 2003 rose to US\$99.3 million, equivalent to CH\$69,780 million. Actual total expenditure in Chilean pesos increased by 12.3% between 2001 and 2003. Due to the peso's depreciation against the dollar, the increase in dollar's value in the same period was reduced to 1.5%.

CENABAST's Total Expenditure, 2001-2003

	2001		2002		2003	
	CH\$ Million	US\$ Million	CH\$ Million	US\$ Million	CH\$ Million	US\$ Million
Centralised purchases	20,190	31.8	20,577	29.2	24,256	34.5
PNAC*	28,520	44.9	31,712	45.1	29,102	41.4
Ministerial programmes	13,408	21.1	15,345	21.8	16,422	23.4
Total	62,118	97.8	67,634	96.1	69,780	99.3

Source: CENABAST 2004. * National Complementary Feeding Programme (PNAC – Programa Nacional de Alimentación Complementaria).

In terms of centralised procedures for purchasing pharmaceuticals and medical devices, these continually increased from CH\$19,720 million in 2000 to CH\$24,256 million in 2003. CENABAST's estimates for 2004 rise to CH\$31,280 million, equivalent to US\$52.1 million. Due to the peso's fluctuation against the dollar, figures in dollars show a decrease between 2000 and 2002, following increases in 2003 and 2004.

CENABAST's Centralised Purchases (Pharmaceutical/Medical), 2000-2004

	CH\$ Million	Growth (%)	US\$ Million	Growth (%)
2000	19,720	~	36.6	~
2001	20,190	2.4	31.8	-13.0
2002	20,577	1.9	29.2	-8.0
2003	24,256	17.9	34.5	18.0
2004	31,280	29.0	52.1	51.0

Source: CENABAST, 2004.

In the near future, CENABAST's main goal is to act as a purchase intermediary for 80% of total public expenditure for pharmaceuticals and medical supplies, which is equivalent to around CH\$100,001 million – total public expenditure for these products is estimated at around CH\$125,120 million or US\$208.4 million. Centralisation will also result in further savings for reducing the public health system's debt, estimated at CH\$35,000 million or US\$49.8 million in 2003.

All CENABAST's purchases from 1st January 2002 are published via www.cenabast.cl. This web site can help new suppliers as it provides information on prices, products and quantities. It is also a management tool for hospitals, as CENABAST's web site offers reference prices for purchasing pharmaceuticals and medical products.

¹ Total institutional market is understood as public institutional market (Cenabast and public hospitals/clinics) and private institutional market (private hospitals/clinics).

CENABAST's Pharmaceutical Expenditure

Regarding CENABAST's pharmaceutical purchases, CENABAST reduced its centralised purchases from CH\$15,500 million (US\$28.7 million) in 2000 to CH\$13,500 million (US\$19.2 million) in 2002. Centralised purchases accounted for 29.3% of total pharmaceutical expenditure, and 65.6% of total expenditure. Having said that, pharmaceutical purchases in primary care rose from CH\$2,500 million in 2000 to CH\$3,500 million in 2003.

CENABAST's Expenditure (Pharmaceutical vs Total), 2002

	Pharmaceutical			Total		Pharmaceutical as % of Total
	CH\$ Million	US\$ Million	As %	CH\$ Million	US\$ Million	
Centralised purchases	13,500	19.18	29.3	20,577	29.2	65.6
PNAC	23,000	32.68	50.0	31,712	45.1	72.5
Ministerial programmes	9,500	13.50	20.7	15,345	21.8	61.9
Total	46,000	65.36	100.0	67,634	96.1	68.0

Source: *Emol* (2003) from *Health Commission* (2003).

In 2002, there were 121 major suppliers in pharmaceutical centralised purchases, 41 in the programme PNAC, and 14 in ministerial programmes. More specifically, centralised purchases of 82 products from LabChile accounted for CH\$1,400 millions (US\$2.0 million) and purchases of 87 products from Bestpharma for CH\$1,300 million (US\$1.8 million). Both LabChile and Bestpharma had around 10% of CENABAST's market. Other major manufacturers included Sanderson and Rider.

Trade Fairs

Some conferences from April to December 2004 are listed below.

Conferences, 2004

	Chilean Location	Date
Congreso Chileno de Dermatología y Venereología	Santiago de Chile	01/04/04
V Jornadas Traumatología Clínica Alemana	Santiago de Chile	01/04/04
V Curso Internacional Avances en Pediatría Neonatal	Concepción	14/04/04
Actualización en Otorrinolaringología	Santiago de Chile	16/04/04
Curso Annual American College of Physicians	Santiago de Chile	10/05/04
Simposio Problemas Reumatológicos del Adulto Mayor	Santiago de Chile	28/05/04
Curso Internacional de Endodoncia,	Santiago de Chile	04/07/04
V Curso Internacional de Duelo	Santiago de Chile	22/07/04
XXVI Curso Postgrado: Urgencias Cardiovasculares	Santiago de Chile	22/07/04
XIV Curso de Terapia Antimicrobiana	Santiago de Chile	06/08/04
*XV Congreso Chileno de Cancerología	Valdivia	09/09/04
*Congreso Conjunto de las Sociedades de Nefrología	Termas de Puyehue	10/09/04
59 Congreso Chileno de Neurología, Psiquiatría y Neurocirugía	Iquique	21/10/04
XXVI Congreso Chileno de Medicina Interna	Viña del Mar	26/10/04
XXVII Congreso Chileno de Urología	Pucón	27/10/04
XLI Congreso Chileno de Otorrinolaringología, Medicina y Cirugía de Cabeza y Cuello	Valdivia	10/11/04
Congreso Chileno de Endocrinología y Metabolismo	Concepción	11/11/04
XLIV Congreso Chileno de Pediatría	Rancagua	16/11/04
XXV Congreso Chileno de Reumatología	Termas de Chillán	17/11/04
XXXI Congreso Chileno de Gastroenterología	Viña del Mar	02/12/04

PHARMACEUTICAL MARKET

The Chilean pharmaceutical market is estimated at US\$1,095.7 million in 2004. Both generic and copy products account for 39% of market share by volume, whereas patented prescription-only medicines (POM) and over-the-counter (OTC) products for just 22%. By value, generics decreased their share to 8% though, which leaves a 49% share for copy products and 43% for patented POM and OTC products.

Market Growth Estimates, 2001-2008

	Market (US\$ Million)	Real GDP Growth (%)
2001*	1,030.0	2.8
2002*	964.4	2.1
2003*	997.4	3.3
2004*	1,095.7	4.0
2005**	1,145.0	4.5
2006**	1,202.2	5.0
2007**	1,268.4	5.5
2008**	1,344.5	6.0

Source: Espicom's estimates. *Based on GDP estimates from the Central Bank of Chile and peso's fluctuation against the US\$. ** Based on GDP estimates.

There are 63 major players in the market, 31 foreign and 32 domestic. The major leading companies are LabChile, Recalcine, Saval, Andrómaco, Bayer, Roche, Novartis, Bago and Abbott. Domestic manufacturers have 56% market share by value and, for the time being, are able to counter increasing foreign competitiveness. R&D investments are estimated to rise to US\$45 million in 2005.

Still heavily reliant on imports of raw materials worth US\$62.7 million in 2002, exports to other Latin American countries rose to US\$54.5 million in 2003. Also, new trade agreements with Europe (2002-03), the USA (January 2004) and Korea (April 2004) might result in increasing export opportunities of up to 25% for domestic manufacturers.

But there are also TRIPS-related patent enforcements that are likely to result in increasing long-term pharmaceutical spending. As a consequence, domestic manufacturing will switch from copy products to branded products under licence from multinationals. Currently though, the average drug price remains at around US\$3, well below neighbouring Latin American countries.

The Ministry of Health and the Institute of Public Health are planning to start bioequivalence tests in 15 major drugs from 2005 to 2009. The aim is to encourage generic substitution which it is bad news for foreign manufacturers. Also, many copy and generic products will be affected for their lack of bioequivalence or GMP standards. Overall, the development of the new health reform will boost pharmaceutical expenditure.

Tough competition for both local and international manufacturers also arises from the three major pharmaceutical chains monopolising the retail pharmacy market, those being SalcoBrand, Farmacias Ahumada and Cruz Verde. Their sales of own-labelled drugs rose to US\$51 million in 2003.

The Outlook of the Chilean Pharmaceutical Industry, 2004

Major Factors

- Trade agreements with the USA, Europe and Korea
- Potential long-term TRIPS-related patent enforcements
- Bioequivalence tests, generic substitution and GMP standards in 2005
- Development of the new health reform boosting pharmaceutical expenditure
- Increasing competition from own-labelled products produced by monopolistic pharmacy chains
- OTC switches to increase market share
- Increasing foreign investment

Source: Espicom, 2004.

The Market

Following a decade of steady growth during the 1990s, peaking at mid-90s, the pharmaceutical market stagnated during the economic recession in 1998-99, contracted during 2000-01, again stagnated in 2002-03 and finally is recovering in 2004. The downturn in pharmaceutical spending is primarily due to Chile's slow economic recovery, which has depressed consumer spending. A concerted campaign to curb the excessive use of antibiotics, which increased sharply during the 1990s, has significantly cut consumption of these products.

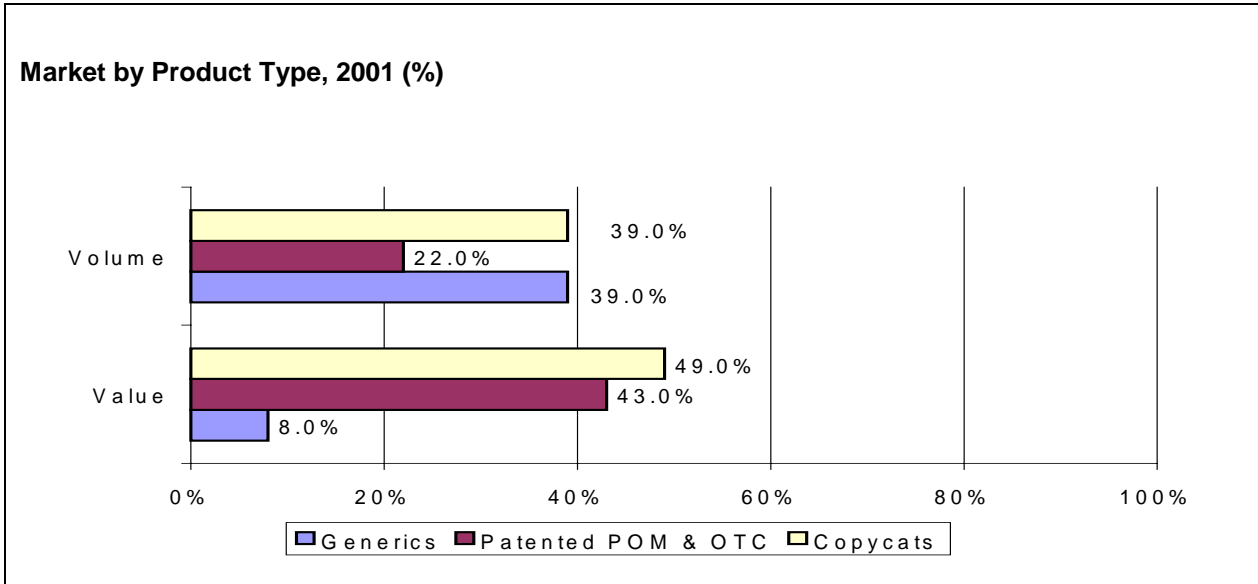
According to the pharmaceutical association ASILFA, which represents domestic manufacturers, the Chilean market for pharmaceuticals was worth US\$650 million at manufacturers' prices in 2001. The retail pharmacy market had sales of US\$513 million in 2001, making up 79% of the market. The institutional market, which comprises sales of manufacturers/importers to CENABAST and clinics, had sales of US\$137 million, accounting for the remaining 21%. In terms of dollar currency, retail pharmacy sales of US\$513 million in 2001 represented a fall of 7.7% over the US\$556 million recorded in 2000.

Pharmaceutical Expenditure, 2001-2004 (US\$ Million)

	Real GDP Growth* (%)	Peso's Appreciation against US\$ (%)	At Consumers' Prices		At Manufacturers' Prices		
			Total (US\$ Million)	Growth (%)	Total (US\$ Million)	Pharmacy (US\$ Million)	Institutional (US\$ Million)
2001	2.8	-17.7	1,030.0	~	650.0***	513.0***	137.0***
2002	2.1	-8.3	964.4	-6.4	618.5	493.8	124.7
2003	3.3	0.1	997.4	3.4	639.6	510.7	129.0
2004	4	5.6**	1,095.7	9.9	702.7	561.0	141.7

Source: Espicom's estimates. *Estimated by the Central Bank of Chile. **Espicom's adjusted annual Chilean peso's appreciation (quarterly appreciation of 14.57% was recorded between January-March 2004). *** Estimated by ASILFA.

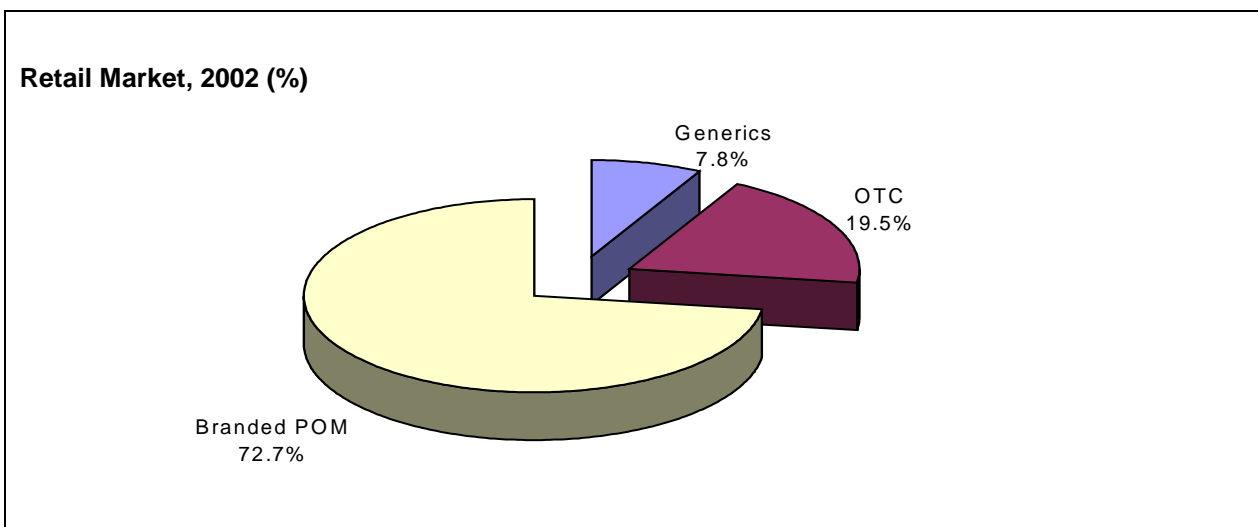
By product sales, the Chilean pharmaceutical market is inundated with copy products, those understood as copies of original drugs (POM or OTC) without patent protection. In 2001, these accounted for 39% of the market in volume and 49% of the market in value. Although generic and copycat products had the same share in volume, generics saw their participation in value considerably reduced to just 8%. Branded products were able to concentrate 43% of the market in value with just 22% of the market in volume.



Prescribed Drugs

According to sources from El Mercurio, the retail ethical market (both branded and generics, either original or copied), amounted to US\$397.4 million in 2002, of which US\$358.0 million were branded or copied POM, whereas estimated US\$38.5 million were generics. Total branded POM market was equivalent to 72% of total retail market, estimated at US\$493.8 million, whereas the OTC market accounted for 20% and generics for 8%.

By 2002, the retail market decreased around US\$62.2 million, from US\$556 million in 2000 to US\$493.8 million in 2002. This decrease mainly affected the branded/copied POM market (excluding generics). The ISPCH liberated 17 pharmacological compounds, what it meant an increase of OTC switches and a decrease in POM products. Also, the economic crisis since 1999 affected the spending power of consumers, resulting in a decrease of POM consumption.

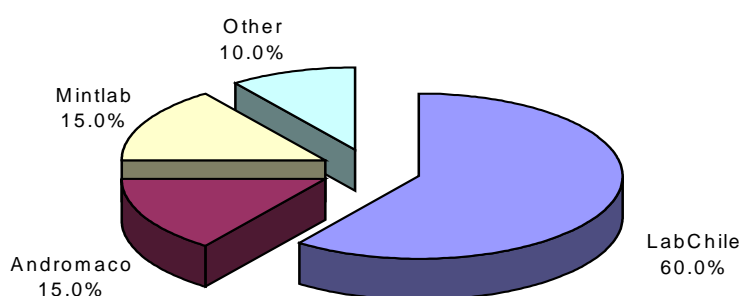


Source: El Mercurio, 2002. Espicom's estimates, 2004.

Generics

Chile is a highly developed generic market and most of the domestic industry is generic-focused. Of the total 160-170 million units sold in Chile, around 39% are generic. Generic sales increased to around US\$38.5 million at manufacturers' prices in 2002. Laboratorio Chile remains as the leader with 60% market share, followed by Andrómaco and Mintlab, both with 15% market shares.

The Generic Market, 2002 (%)



Source: ASILFA.

Generic substitution is not legally enforced in Chile. However, the Ministry of Health and the Institute of Public Health (ISPCH) are reviewing a potential list of 16 products for generic substitution in 2005, subject to the approval of bioequivalence tests. A public review of the subject will take place in October 2004.

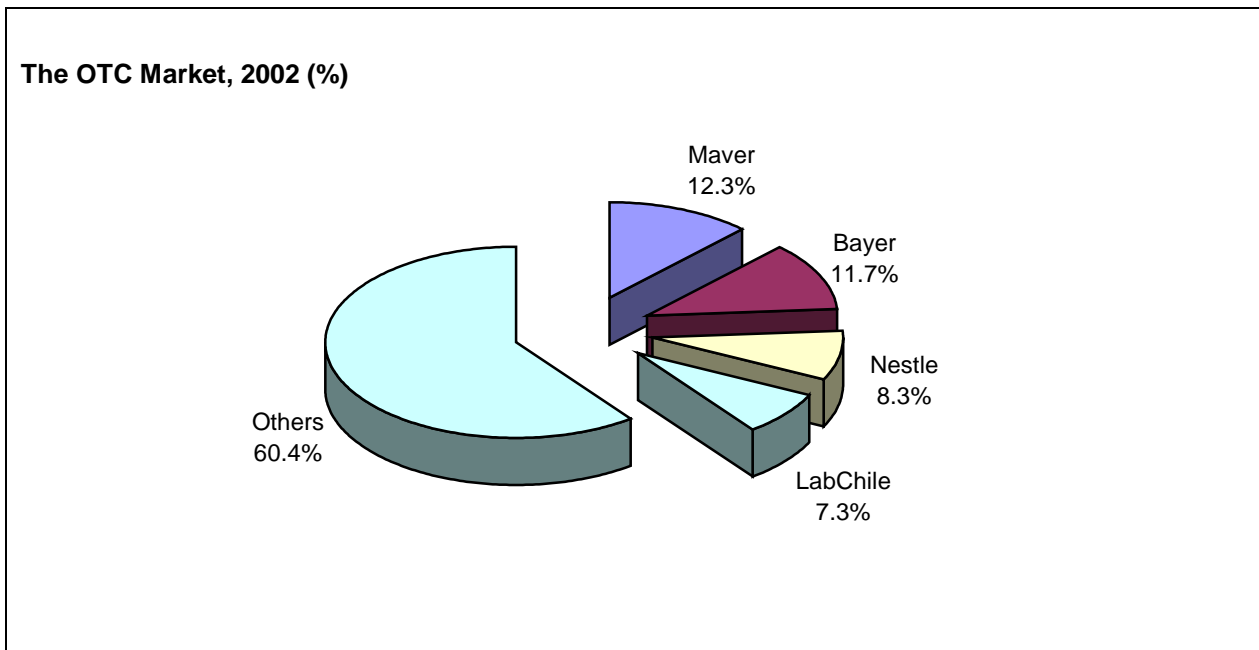
Strong lobbying undertaken by the pharmaceutical industry stopped the implementation of bioequivalence tests in 1999. However, the current health reform needs this implementation ahead in order to decrease AUGÉ's pharmacological cost, estimated at one fifth of total reform budget, CH\$550,000 million.

Bioequivalence tests would cost manufacturers in the region of US\$20-30,000 per product. Overall, there are around 4,000 products sold in the Chilean market what would total an investment of US\$80 million. Also important, laboratories must have GMP certification. Of the 28 drug manufacturing plants in Chile, 18 were GMP approved by 2003, after spending over US\$30 million since 2000.

Both ASILFA and CIF Chile are against generic substitution as they believe it will allow free pharmacy dispensing in detriment of physicians' prescribing -pharmacy chains might dispense at their own choice, favouring generics and their own-label products. There also fears that the cost of applying bioequivalence tests and GMP standards will increase the price of products - the average price per product is around US\$3 in Chile, whereas the average price per generic product decreases to US\$0.60. Also, they claim that physicians should be allowed to prescribe branded products, without interchangeability if stated as such.

OTC Products

According to sources from El Mercurio, the OTC market at manufacturers's prices in 2002 amounted to US\$96.4 million. Roughly, this is equivalent to 20% of the retail pharmacy market. Major OTC producers include Maver (12.3% of the OTC market), Bayer (11.7%), Nestle (8.3%) and LabChile (7.3%).

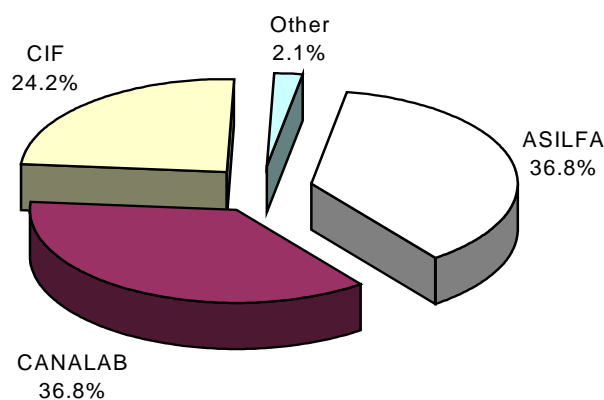


Source: El Mercurio, 2003.

Domestic & Foreign Production

The number of laboratories has dropped from 109 in 1999 (58 domestic and 51 foreign) to around 63 in 2004 (32 domestic and 31 foreign). They are represented by three main trade organisations. The Industrial Association of Chilean Pharmaceutical Manufacturers (ASILFA - Asociación Industrial de Laboratorios Farmacéuticos Chilenos AG) has ten Chilean manufacturers associated that together comprise around 37% of the market. The National Chamber of Manufacturers (CANALAB – Cámara Nacional de Laboratorios) represents other local manufacturers that account for a further 35% of the market. The Chamber of the Pharmaceutical Industry of Chile (CIF Chile – Cámara Industrial Farmaceutica de Chile) mainly represents 21 international companies, most of them importers, that account for 24% of the market. The remaining 2% of the market belongs to other companies that are not associated.

Market Share by Trade Organisations, 2003 (%)



Source: Emol (2004) from Health Commission, 2004.

Major Pharmaceutical Players in Chile, 2004

ASILFA	CIF CHILE*	Other Companies	
Andrómaco (CH)	Abbott (USA)	3M (USA)	Raffo (ARG)
Bago (CH)	Alcon (SWI)	Bestpharma (CH)	Recalcine (CH)
Biosano (CH)	Allergan (USA)	Boston (CH)	Rider (CH)
Labomed (CH)	Aventis (FR)	Chemopharma – Sanitas (CH)	Sanderson (CH)
Maver (CH)	Bayer (SWI)	Dentaid (SP)	Stiefel (USA)
Pharma Investi (AR-CH)	BMS (USA)	Fasa (CH)	Volta (CH)
Sanitas (CH)	Boehringer (GER)	Galderma (SWI)	
Saval (CH)	Eli Lilly (USA)	Garden House (CH)	
Silesia (CH)	GSK (UK)	Grifols (SP)	
Tecnofarma (CH)	Hormoquimica (NET)	Grunenthal (GER)	
	Merck (GER)	LabChile (USA-CH)	
	MSD (USA)	Lab. Drog. Nacional (CH)	
	Novartis (SWI)	Lafi – Recalcine (CH)	
	Pfizer (USA)	Master – Silesia (CH)	
	Roche (SWI)	Mintlab (CH)	
	Sanofi-Synthelabo (FR)	Pasteur (CH)	
	Schering de Chile (GER)	Pentafarma (CH)	
	Schering Plough (USA)	Prater (CH)	
	Wyeth USA	Proquifar (COL)	

Source: Espicom. Note: Argentina (AR), Chile (CH), Colombia (COL), France (FR), Germany (GER), Spain (SP), Switzerland (SWI), United States (USA). *Of 21 companies associated to CIF Chile, there are 19 listed.

The number of products in the market has decreased from 5,500 products in 7,100 presentations in 1999 to around 3,950 products in 8,000 presentations in 2004. Major domestic manufacturers include Recalcine, Saval, Andrémaco and Bago, whereas major foreign companies include Bayer, Roche, Novartis and Abbott. Arama, Heel, Hochstetter and Knop are major homeopathic manufacturers. The market leader, LabChile, was acquired by IVAX in 2001.

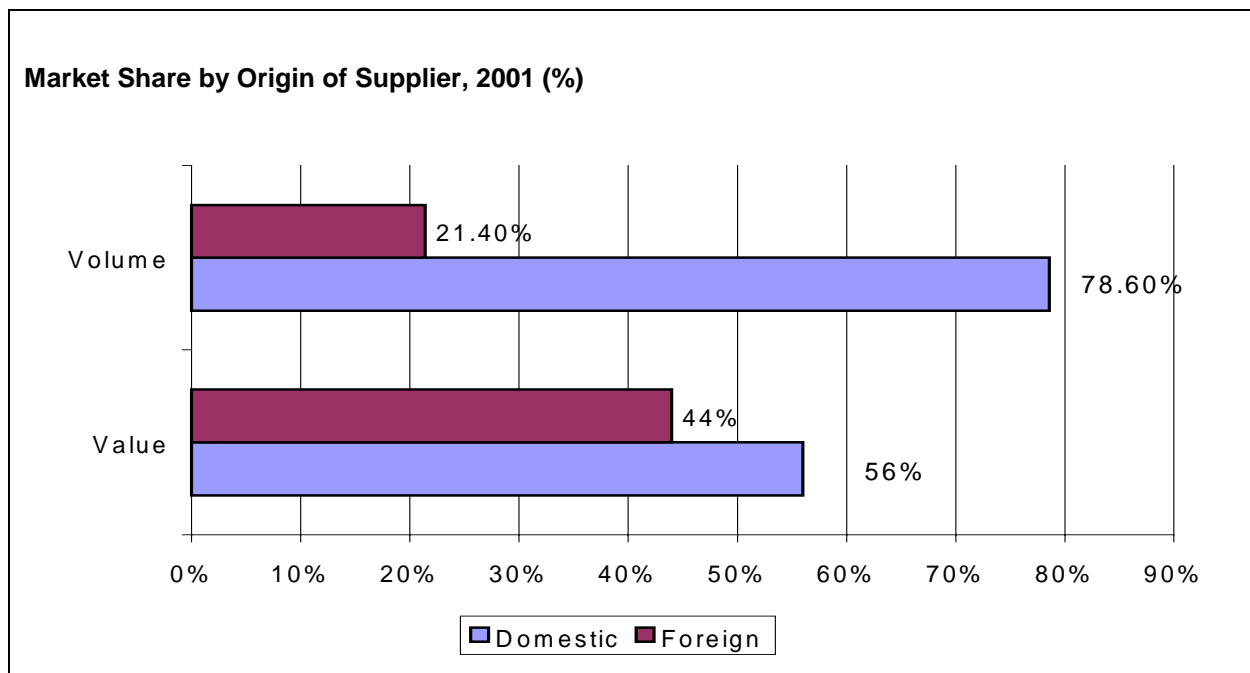
Major Pharmaceutical Players by Market Share in Value, 1998 & 2004

Ranking	1998*		2004**	
	Market Share	Ranking	Market Share	Ranking
LabChile	13.3	LabChile	9.5	
Recalcine	9.4	Recalcine	8.0	
Saval	7.0	Saval	6.6	
Andrómaco	4.5	Andrómaco	5.0	

Source: *ASILFA, 1998. **Individual company estimates, 2004.

Of the major 63 companies operating in Chile, nearly half of them are foreign (17 from Europe, 11 from the USA and three from Latin America). Foreign manufacturers, by selling mainly branded and OTC drugs but also generics, retain just 21.4% of the market in volume but nearly half of the market in value, exactly 44%, as their products are priced at an average of US\$6.

On the contrary, domestic producers do have a high market share in volume, 78.6%, by selling generic and copycat products. However, their participation in value is reduced to 56% as their products are sold at around US\$2, even if they are almost totally reliant on expensive imported active ingredients. Of this share, 35% is from the ten manufacturers associated to ASILFA. Within the public institutional market, the market share by value of national companies rises to 90% compared to 10% of foreign companies.



Source: ASILFA, 2001.

New trade agreements with the EU (2002-03), USA (January 2004) and Korea (April 2004) might negatively affect domestic manufacturers when considering patent enforcements. ASILFA's opinion is that new patent enforcements could be anticompetitive in Chile, resulting in foreign monopolies in production and marketing. There are also fears that this could derive in higher pharmaceutical expenditure per capita, increasing health government expenditure and less drug access by the less well-off.

SWOT Analysis of the Domestic Pharmaceutical Industry in Chile**Strengths**

- Highly developed generic market by volume at 39%
- The market share in value for copy products in 2001 was 49%
- Physician-prescribing of domestic drugs rises to 70%, especially in the public sector
- Domestic exports to Latin America estimated at US\$70 million in 2002

Weaknesses

- Low generic market share in value at 8%
- Monopolistic pharmacy chains which negotiate directly with manufacturers
- Lack of compliance to GMP standards
- Bureaucratic Health Public Institute
- High import costs of raw-materials

Opportunities

- GDP relatively recovering at 4% in 2004 after 1999 recession
- The Chilean peso has depreciated by 60% since 1998, so opportunities for exports, although peso's appreciation in 2004 could diminish exports
- New trade agreements with Europe, USA and Asia so chances for exporting (increase of 25% exports to the USA expected for 2004)
- New health reform with AUGE expansion will boost pharmaceutical expenditure
- Plans from the government to start generic substitution in 2005

Threats

- Increasing patent enforcements
- Bioequivalence tests starting in 2005
- The three major pharmacy chains increasing their production of own-labelled drugs: sales of US\$51 million in 2003

Source: *Espicom, 2004.*

SWOT Analysis of the Foreign Pharmaceutical Industry in Chile**Strengths**

- 43% market share in value for patented POM and OTC products
- High physician-prescribing of POM products in the private sector

Weaknesses

- Highly developed generic and copy market
- Low-level increases in pharmaceutical prices, at an average of US\$3 per product in 2003, although increasing
- Low R&D investment although investment for 2005 is estimated at US\$45 million
- Bureaucratic Health Public Institute (ISPCH) for product registrations
- Monopolistic pharmacy chains which negotiate directly with manufacturers

Opportunities

- GDP recovering at 4% in 2004 after 1999 recession
- Increasing foreign investment
- Increasing patent enforcements by signing TRIPS
- New trade agreements with Europe (2002), USA (Jan 2004) and Korea
- Mergers and acquisitions for cost-effective manufacturing
- Expansion of the drugstore format
- OTC switches
- By 2005 domestic manufacturers need to comply with GMP standards

Threats

- The Chilean peso has been depreciated by 60% since 1998, so consumers need low drug prices. Peso's appreciation in 2004 could increase prices though
- Plans from the government to start generic substitution in 2005
- The three major pharmacy chains increasing their production of own-labelled drugs: sales of US\$51 million in 2003
- Patents are considered in Chile from the date when the patent was requested in the USA, not the date when the product entered the Chilean market

Source: *Espicom, 2004.*

In recent years, a number of multinationals have closed their pharmaceutical plants in Chile, except mainly Bayer and Pfizer. Many multinationals now serve the Chilean market from strategic regional plants in other Latin American countries such as Argentina and Brazil. In the search for economies of scale at regional level, other companies have chosen to form strategic alliances with domestic producers. In 1998, Synthélabo set up a joint venture with Laboratorios Recalcine SA, Synthélabo Rec SA, in which Synthélabo holds a 52.5% interest and Laboratorios Recalcine SA a 47.5% interest.

In a final note for consideration, full implementation of the AUGE plan would considerably boost pharmaceutical consumption by guaranteeing treatment for a wide range of chronic disorders, including diabetes, hypertension, AIDS/HIV, asthma, rheumatoid arthritis and most forms of cancer.

Domestic Producers

Andrómaco

Laboratorios Andrómaco SA has around 400 employees and achieved annual turnover in excess of US\$25 million in 2001. In 2003, sales increased by 3% and revenues by 64%, from CH\$1,532 million in 2002 to CH\$2,518 million in 2003 (US\$3.6 million). Andrómaco ranks fourth in the Chilean pharmaceutical market with a market share of around 5% in 2004. In the generic market alone, its market share is around 15%. Overall, it produces/distributes over 70 million units in a range of 500 products in more than 1,000 presentations.

Laboratorios Andrómaco was originally established in 1942 as a Chilean subsidiary of the Spanish company, Laboratorios Lasa. During the 1970s, the company was bought by a group of Chilean and Spanish investors. Between 1979 and 1982, Andrómaco acquired Laboratorios Lumiere Americanos SACI and Laboratorios Benguerel Ltda, enabling the company to consolidate its position as a leading manufacturer.

In 1989, Andrómaco began to enter other Latin American markets, and now has subsidiaries in Bolivia, Colombia, Ecuador and Peru under the name ABL Pharma International, and a distribution network in Central America and the Caribbean, including Costa Rica, El Salvador, Guatemala, Haiti, Honduras and Panama.

Andrómaco manufactures its own range of ethical pharmaceuticals, generics, OTC and dermocosmetic products. Its manufacturing site is GMP approved, occupies 10,000m² and employs 300 employees. Within ethical pharmaceuticals, it produces products for general and internal medicine, cardiology, dermatology, gynaecology, neuropsychiatry, paediatrics, gastroenterology, ophthalmology and odontology.

Andrómaco also represents several foreign pharmaceutical companies in the Chilean market, including Bioibérica Spain, Chiesi Spain, Ferrer Spain, Fournier France, Fujisawa (Klinge) Germany, Isdin Spain, Lacer Spain, Leo Denmark, Newport Costa Rica, OM Switzerland, Phoenix Argentina, Recordati Italy, Schwabe Germany, Statem Serum Denmark, Vifor Switzerland and Zambon Italy.

Exports in 2002 amounted to nearly US\$3 million. Export destinations included Bolivia, Costa Rica, Ecuador, Haiti, Panama, Peru and Switzerland.

Bago

A subsidiary of the Argentinian-based Bago group, Laboratorio Bago de Chile has been active in Chile since the 1940s. The company currently employs almost 300 people and claims third position in the market for ethical pharmaceuticals by volume.

The company's 2,500m² production plant produces 17 million units per annum, of which 80% is destined for the Chilean market and 20% for export to neighbouring markets, mainly Argentina, Ecuador, Peru and Bolivia. Exports in 2002 amounted to nearly US\$2.5 million. Bago markets around 60 products in Chile, including 45 branded products in 101 presentations and 15 generics in 27 presentations.

Bestpharma

Founded in 1987, Laboratorio Bestpharma SA is a Chilean pharmaceutical importer of GMP-certified products but also a manufacturer mainly responsible for retail product packaging. Originally, Bestpharma aimed at entering the Argentinean and Brazilian markets where profits were bigger than in Chile, but market barriers prevented this.

Consequently, its main focus concentrated on maximising the Chilean market. A strategy based on good quality at competitive prices plus efficient delivery (24 hours in the Metropolitan areas, 48 hours in the other regions) has made Bestpharma the second biggest supplier to CENABAST, after LabChile. After over 15 years in the market, its annual sales reached around US\$15 million in 2003.

Other strategies for market penetration included its focus on the generic gap left by LabChile in products listed in the Ministry of Health's "Petitorio Nacional". Also, it has opted for supplying low consumption medicines that for other manufacturers were not interesting, ie for tuberculosis. Nowadays, Bestpharma is the only manufacturer comparable to LabChile by volume.

Its portfolio includes 400 products for marketing, and 750 products registered in the ISPCH. Since 1997, it has its own manufacturing site. Employees number 100 of whom around 18 are chemical-pharmacists. Major suppliers of imports include countries such as Austria, Brazil, China, Germany, India, Korea and Spain. Exports to India, Paraguay and Peru rose to US\$188,654 in 2002.

Its products are distributed in Chile via its National Centre of Supplies or via direct sales. In the public sector, it sells products to 200 hospitals and 536 health centres. In the private sector, it sells to 130 hospitals or clinics and over 1,100 pharmacies. When Bestpharma entered the retail pharmacy distribution market in 2002, there were many obstacles from other competitors, especially from LabChile, which saw a threat to its retail generic market. It was then when legal proceedings against Bestpharma started to accumulate.

Until September 2002, Bestpharma had had only three legal proceedings, mainly because of concerns on product quality. By mid 2003, about 17 legal proceedings were reported against Bestpharma out of 250 legal proceedings issued by the Institute of Public Health, most of them labelling or advertising-related. There were also reported irregularities in its imported materials (altered composition, or missing information detailing original manufacturer, address, etc). The legal proceedings were closed in April 2003, and Bestpharma was fined US\$58,824.

Biosano

Established in the 1940s, Laboratorio Biosano SA mainly manufactures generic injectables that represent 140 active ingredients, participating in 40% of the national market. By third quarter 2002, total sales reached US\$6 million, of which 70% were domestic and 30% exports.

Domestically, it produces and distributes products for hospitals, private clinics, dialysis centres, etc. Exports in 2002 reached US\$943,674 with export destinations including Colombia, Honduras, Nicaragua, Panama, Paraguay and Peru. Future aims are to reinforce Biosano's presence in Bolivia, Costa Rica, Dominican Republic, Ecuador and El Salvador. Once installed in these markets, the company aims to enter Mexico and Brazil, its final targets in a long-term strategy.

A new US\$10 million production site of 6,000m² was inaugurated in the end of 2002 aiming at increasing international sales by 50% and domestic sales by 25%. Internationally, it will secure its position in Central and South America, and enter the existing and acceding European market. Biosano already represents three European laboratories, including Filaxis, Serral and B&D. As well as producing analgesics, anaesthetics, psycotropics and vitamins, apart of needles, syringes and oncological products, the new site will be producing pre-filled syringes and new dialysis and haemo-derived products.

LabChile

Until its acquisition by the US manufacturer Ivax in mid-2001, Laboratorios Chile SA (LabChile) was the country's leading domestic pharmaceutical manufacturer, claiming 27.5% of the Chilean market in volume terms and 12.8% in value terms in 1999. In the generic market, its market share by value is around 60%. Production of the company's range of human and veterinary pharmaceutical products is undertaken at two production facilities in Santiago, and two in Argentina.

LabChile's Market Share, 1998-1999

	Market Share by Value (%)		Market Share by Volume (%)	
	1998	1999	1998	1999
LabChile	13.3	12.8	27.5	27.5
Branded	9.0	8.6	10.3	11.1
Generic	52.7	49.8	55.3	53.3

Source: LabChile.

Founded in 1896, LabChile has over 900 products on the Chilean market. Over the last few years, the company has been introducing higher priced branded products and OTC products into its human range, in addition to its traditional range of generics, covering over 11 therapeutic areas. The introduction of new branded and OTC products has become a distinctive advantage for the company's leading positioning in the domestic market. In 1999, about 61.1% of LabChile's sales by volume were branded and 38.9% generic, whereas by value, about 89.8% were branded and 10.2% were generic.

After adverse economic conditions in 1998 and 1999, LabChile had revenues of US\$173 million in 2000, of which US\$87 million came from the Chilean market. Sales in Chile increased by 3% in 2001 to US\$90 million. Retail sales account for around 80% of LabChile's domestic market, with the remaining 20% going to private and public institutions, e.g. hospitals and clinics. In 1999, ethical pharmaceuticals accounted for 84% of retail sales, OTC products 11% and veterinary products 5%. At the time of the Ivax acquisition, LabChile claimed a 50% share of the generics market, an 8.5% share of the market for branded products and an 8.5% share of the market for OTC products. Estimated market share in 2004 is 9.5%.

LabChile's Sales, 1991-2000 (US\$ Million)

Fiscal Year	Sales	Growth (%)
Sep-91	26.1	~
Sep-92	44.7	71.3
Sep-93	50.1	12.1
Sep-94	57.3	14.4
Sep-95	64.8	13.1
Sep-96	99.9	54.2
Sep-97	166.2	66.4
Sep-98	184.7	11.1
Sep-99	176.6	-4.4
Sep-00	173.3	-1.9

Source: LabChile.

Pharmatrade, a wholly owned subsidiary that was a holding company until November 1996, became the distributor of LabChile's products to the retail market in December 1996. Since beginning operations, Pharmatrade has incorporated additional customers and begun developing new distribution channels, such as supermarkets for some OTC products. In 1999, Pharmatrade began trading via the company's web site, www.pharmatrade.cl. Also, LabChile participates in a joint venture with Consalud, Farmasalud. Both companies hold 50% of eight pharmacies located in the ISAPRE's medical centre system.

LabChile's principal foreign market is Argentina (40% of revenues in 1999), where the company manufactures over 84 branded in 206 presentations covering 11 therapeutic areas through its 100% owned Armstrong and Syncro subsidiaries. These were acquired between 1994 and 1997, and claim a combined share of around 2.8% of the Argentinean market. Sales in 1999 rose to CH\$37,447 million, equivalent to US\$73.5 million. LabChile also has a 50% share in Farma System in Argentina.

In Peru (5.4% of revenues in 1999), LabChile owns distributor Newpharm, which distributes 182 product presentations from LabChile (POM, generic and OTC) and 590 products from third-party laboratories in that country. LabChile's product sales accounted for 70% of Newpharm's total sales. In 1999, Peruvian sales increased by 50%, to CH\$5,037 million (US\$9.9 million). Around 94% of sales were pharmaceuticals, the remainder being cosmetic products. LabChile claimed around 14.6% of the Peruvian generics market by value, with overall sales equivalent to just over 1% of the pharmaceutical market in 1999.

LabChile currently exports to over a dozen other markets in Latin America, including Brazil and Colombia, where the group set up subsidiaries in 1998 and 1999, LBC Pharmaceuticals Brasil and LBC Pharmaceuticals Colombia, respectively. It also exports to Bolivia, Ecuador, Panama and Paraguay. In 2002, LabChile prepared to enter the Mexican market through Ivax's subsidiary company and planned to invest US\$5 million in plant infrastructure and new technology to increase productivity and lower manufacturing costs. Investment in 2001 was around US\$3 million.

Exports in 2002 were over US\$11.5 million. Destinations included Argentina, Bolivia, Bulgaria, Colombia, Ecuador, El Salvador, Germany, Guatemala, Haiti, Honduras, Italy, Lebanon, Macedonia, Nicaragua, Panama, Paraguay, Peru, Spain and Uruguay. Finally, LabChile initiated its veterinary business in 1997 to mainly cover the salmon cultivation industry in Chile, claimed to be the second largest in the world. The domestic share in 1999 rose to 11%, with 72 veterinary product presentations targeting both livestock and pets. Sales in 1999 reached CH\$1,523 million, equivalent to near US\$3 million.

Labomed

With over 40 years in the market, Instituto Farmacéutico Labomed SA has exclusive licences with Italfarmaco, Sigma-Tau, Yamanouchi, Om-Switzerland and Zambon-Italy. Exports to Bolivia in 2002 reached just US\$27,000.

Maver

Laboratorio Maver SA, founded in 1923, manufactures generic pharmaceuticals, branded products and cosmetics at its 50,000 square feet plant in Santiago. As overall, it produces 48 brands in 255 presentations. In addition, Maver manufactures and distributes products under licence for various overseas companies.

The company was the sixth largest domestic pharmaceutical company in 2000, with a market share of around 2.5% and claims to be the leading manufacturer and supplier of OTC products in Chile. Estimates in 2004 indicate a market share closer to 3.3%. The company's flagship products are Tapsin, the leading analgesic on the Chilean market, and the effervescent salt Disfruta, also a market leader. Other important products include the tranquilliser Armonyl and the sleep inducer Sueñum.

Maver distributes its products directly to pharmacies, hospitals, health centres, etc, and has been exporting to Central and South America since 1989. Maver is now seeking to significantly expand its export business. Exports to Bolivia and Peru in 2002 were nearly US\$651,000. The company recently invested over US\$20 million in a new 11,500m² factory in La Lampa, which complies with GMP standards, and which is said to be one of the most advanced of its type in Latin America.

Mintlab

Founded over a decade ago, Mintlab specialises in the production and supply of generics, claiming a 30% share of the generic market by volume. In 2002, its market share by value rose to 15%.

The company has two pharmaceutical manufacturing plants: a 500m² plant specialising in penicillins with an annual output of six million packaged units, and a 4,000m² plant for other products with an annual output of 48 million packaged units. Mintlab's product range comprises over 200 presentations in most pharmaceutical forms, including tablets, capsules, suppositories, suspensions, ointments, powders, injectables and inhaled forms. The product range is being expanded by around 30 launches a year.

Since 1997, Mintlab has exported to a number of Latin American countries including Bolivia, Cuba, Ecuador, Guatemala, Honduras, Panama, Paraguay, Peru and Uruguay. According to the Chilean Trade Commission (ProChile), exports in 2002 amounted to US\$831,223. Major destination countries were Bolivia, Ecuador, Guatemala, Honduras, Panama and Spain.

Product exports included halogenated derivatives of adrenal cortical hormones, medicaments containing corticosteroid hormones, medicaments containing penicillins or derivatives, mixed or unmixed medications containing other antibiotics, other medicaments, and other medicaments containing vitamins or other products.

Recalcine

Founded 80 years ago, Laboratorios Recalcine is Chile's leading privately-owned pharmaceutical manufacturer with a turnover of US\$63 million, including retail pharmacy sales in Chile of US\$42 million in 2001. The company has over 300 products on the Chilean market and claims a market share approaching 10%. Market share in 2004 is estimated at 8%.

Recalcine has two pharmaceutical manufacturing plants, which manufacture products in a wide range of pharmaceutical forms, including tablets, capsules, syrups, solutions, injectables, suppositories, eye drops, creams, ointments, powders and nasal sprays. Annual output is 26.5 million packaged units, one third of which is exported to other parts of Latin America, including Ecuador, Peru, Venezuela, Bolivia and Paraguay.

Laboratorios Recalcine forms part of Corporación Farmacéutica Recalcine. This Corporation also comprises laboratories Lafi and Pediapharm – specialist in the pediatric market- among others. In addition to manufacturing its own products, Recalcine represents a number of major multinationals including Abbott Laboratories, Boehringer Ingelheim, Eli Lilly, Pfizer, Sanofi-Synthélabo and Solvay Pharmaceuticals.

In 2001, Recalcine announced a major investment plan to triple production output within five years, although the company says execution of this project depends on how the new patent law would be implemented. Recalcine has already invested US\$7 million to get its current manufacturing facilities up to GMP standard.

Sanderson

Laboratorios Sanderson SA is a privately-owned pharmaceutical manufacturer founded in 1942. The number of employees is over 250. Its 150 products are mainly sold to the Chilean public health system via CENABAST and to several Latin American countries. Exports account for around 40% of sales. Estimated sales in 2002 are in the region of US\$14.8 million.

It mainly produces injectables, high volume parenteral solutions (SPGV), low volume parenteral solutions (SPPV), concentrated solutions for hemodialysis, and other solutions for organ preservation and irrigation. It also acts as a representative of hospital supplies in both the public and private sectors (hospitals, health centres, dialysis centres and pharmacies). It exclusively represents the medical device manufacturer, WLGore.

Its GMP-approved 10,000m² manufacturing site was built in 1996 at a cost of US\$7.5 million. This is claimed to be the most modern site for injectables in Chile. It also has a manufacturing site in Peru to meet export demands. Exports in 2002 rose to nearly US\$6 million.

Destinations included Bolivia, Colombia, Costa Rica, Dominican Republic, Ecuador, Germany, Mexico, Nicaragua, Paraguay, Peru, United States and Uruguay. It has also registered products in Brazil, El Salvador, Guatemala and Honduras. Activities are also developed in Cuba, Mexico and Venezuela.

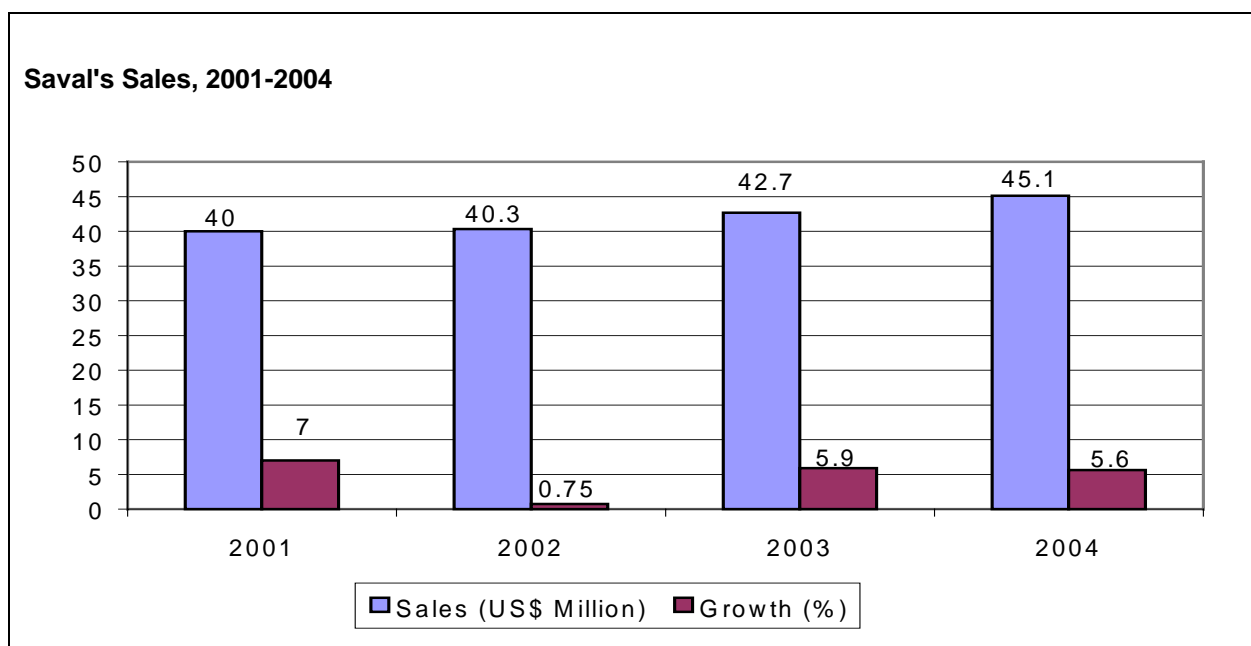
Saval

Laboratorios Saval, based in Santiago and founded in 1939, is Chile's third largest pharmaceutical company with 580 employees, of whom 450 work in Chile. In 2003, projected sales amounted to CH\$30,000 million, equivalent to US\$42.7 million, of which US\$5 million were from exports. Sales growth for 2003 was estimated at 5.9% whereas growth for 2004 is estimated at 5% locally and 10% internationally. Total sales for 2004 are estimated at US\$45.1 million, giving the company a 6%-7% market share, being the third leading pharmaceutical manufacturer in Chile.

Saval's Domestic vs International Sales Growth, 2003-2004

	2003	Growth (%)	2004	Growth (%)
Domestic Sales (US\$ Million)	37.7	~	39.6	5.0
International Sales (US\$ Million)	5	~	5.5	10.0
Total Sales (US\$ Million)	42.7	5.9	45.1	5.6

Source: Saval, 2003. Espicom's estimates, 2004.



Source: Saval and Espicom's estimates. Note: In 2001 and 2002, the Chilean peso further depreciated, therefore the growth between 2001 and 2002 is relatively small in US\$ value.

Laboratorios Saval produces around 80 products in 300 presentations. The company originally produced only ophthalmic products, but has since expanded into other areas including infectology, immunology, oncology, gastroenterology, bronchopulmonology, cardiology, rheumatology and psychiatry. Its manufacturing site is located in the north of Santiago and comprises 18,000m². Around 17% of production is exported. Exports in 2002 rose to nearly US\$5.9 million. Destinations included Argentina, Bolivia, Dominican Republic, Ecuador, El Salvador, Panama, Paraguay, Peru, United States and Uruguay.

During 2001, Saval made investments of around CH\$1.5 billion, equivalent to US\$2.4 million, including CH\$710 million (US\$1.1 million) in technological upgrades and CH\$200 million (US\$314,990) in expanding the workforce by 20%. Expected investments for 2003/4 were in the region of US\$1.7 million, in addition to US\$600,000 in 2003.

Silesia

Founded in 1948, Laboratorios expanded significantly during the 1970s and 1980s and is now Chile's fifth largest domestic pharmaceutical company. The company has annual pharmaceutical sales in Chile of around US\$16 million. In 2001, sales amounted to US\$14 million, with a market share approaching 3%.

In 1996, Laboratorios Silesia entered into a joint venture with Rottapharm Research V.B. Rottapharm Chile SA was the first joint venture in the pharmaceutical field between a Chilean company and a multinational. It also has licences and distributes products for around 30 international companies, mainly from Japan, Europe, USA and one from Mexico.

In 1997, Laboratorios Silesia set up its first international subsidiary with the founding of Silesia Peru. Since then, the company has also built up a strong presence in Bolivia, Ecuador, Paraguay, Peru, Uruguay and Central America - including Guatemala and Dominican Republic. Exports in 2002 were around US\$773,274, including exports to Austria.

Research & Development

R&D activities in Chile are limited. There is no research conducted into new molecules. According to ASILFA, local manufacturers invest US\$120 million each year in pre and post marketing research. In order to raise their profile in the market, a number of foreign companies have begun to undertake preclinical and clinical studies to adapt products to the Chilean market.

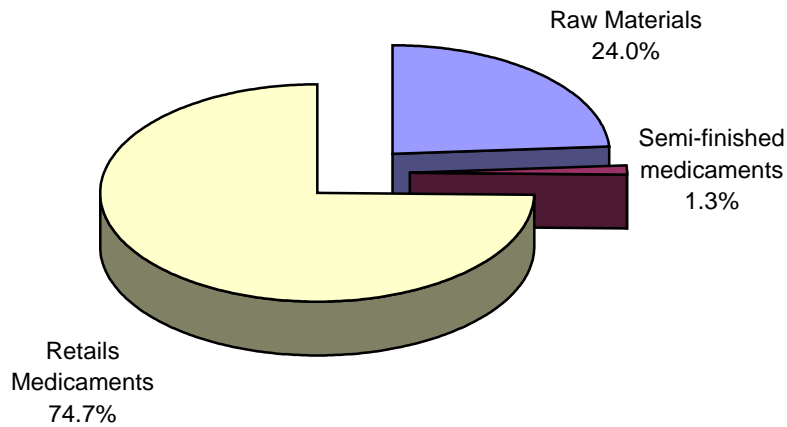
According to El Mercurio, around 5,000 patients (4,700 outpatients and 300 hospitalised) participated in multicentric clinical trials phase III developed by international companies in 2003. These trials are developed following the legal framework of Ruling 57 of the Ministry of Health. One of the criticisms from CIF Chile is that phases I & II are not allowed in the country.

INTERNATIONAL TRADE

Imports

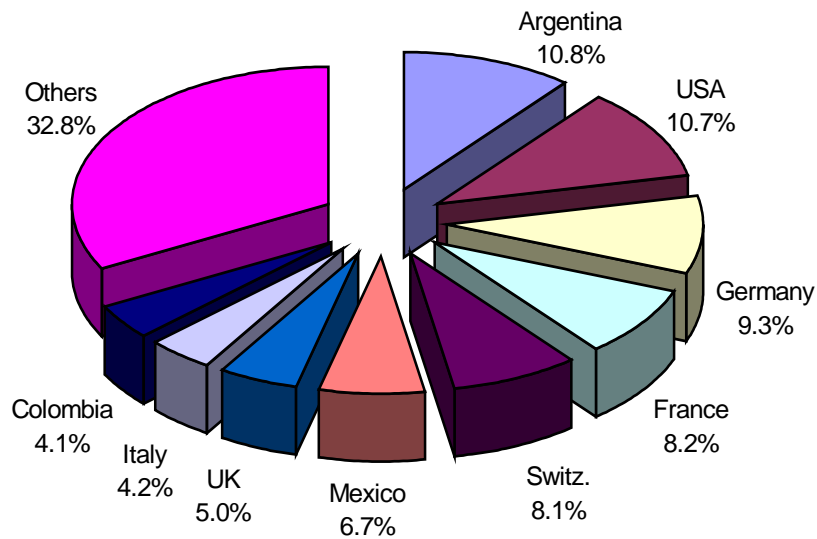
Chile imported pharmaceuticals valued at US\$261.3 million in 2002. This was a reduction of 10.5% compared with the US\$292.1 recorded in 2001. Finished medicaments stood at US\$195.3 million in 2002, equal to just under 75%. Raw materials stood at US\$62.7 million, or 24%. The remainder was semi-finished medicaments, which amount to US\$3-4 million a year.

Imports by Category, 2002 (%)



In 2002, the EU accounted for 41.6% of imports, or US\$108.6 million. There were six principal EU suppliers; Germany, France, UK, Italy, Spain and the Netherlands. Switzerland accounted for a further 8.1%. Outside Europe, the three major suppliers were Argentina (10.8%), USA (10.7%) and Mexico (7.7%).

Leading Suppliers, 2002 (%)



France was the leading supplier of raw materials in 2002, with US\$11.4 million or 18.2% of the total. Almost all of this was vaccines for human use (US\$6.6 million) and provitamins and vitamins (US\$3.9 million). Other leading suppliers included Germany (10.8%), USA (9.2%), Spain (8.4%) and China (7.5%).

Leading Suppliers of Raw Materials, 2002 (US\$000s)

	Raw Materials	% of Total
France	11,388	18.2
Germany	6,774	10.8
USA	5,766	9.2
Spain	5,242	8.4
China	4,715	7.5
Netherlands	4,282	6.8
Denmark	3,308	5.3
Italy	3,090	4.9
Switzerland	2,977	4.8
India	2,818	4.5
<i>Subtotal</i>	<i>50,360</i>	<i>80.4</i>
Total	62,670	100.0

In spite of the economic crisis, Argentina was the leading supplier of finished medicaments in 2002, with shipments valued at nearly US\$26 million, equivalent to 13.3% of the total. However, this is a decrease of 17.7% over 2000 shipments, US\$30.8 million. The second supplier was the US, accounting for nearly US\$22 million or 11.3% of total supplies. The USA increased its position as a supplier by 9.9% compared to figures from 2002 at US\$20.0 million. Other major suppliers were Switzerland (9.2% of total), Germany (8.8%), Mexico (7.9%) and the UK (6.2%).

Leading Suppliers of Finished Medicaments, 2002 (US\$000s)

	Medicaments	% of Total
Argentina	25,990	13.3
USA	21,985	11.3
Switzerland	18,055	9.2
Germany	17,247	8.8
Mexico	15,466	7.9
UK	12,161	6.2
Colombia	10,607	5.4
France	10,040	5.1
Brazil	10,038	5.1
Italy	7,767	4.0
<i>Subtotal</i>	<i>149,356</i>	<i>76.5</i>
Total	195,319	100.0

Imports of Pharmaceuticals, 1998-2002 (US\$000s)

	1998	1999	2000	2001	2002
Sulphonamides	2,079	1,587	1,403	1,345	979
Provitamins & vitamins	16,953	14,999	16,027	18,415	14,016
Pituitary anterior hormones	0	0	0	0	0
Cortisone, hydrocortisone, prednisone and prednisolone	185	181	278	153	236
Halogenated derivatives of adrenal cortical hormones	1,072	262	378	476	388
Other adrenal cortical hormones	0	0	0	0	0
Insulin	0	0	0	0	0
Oestrogens and progestogens	3,159	2,439	3,445	2,837	3,754
Other hormones	621	564	1,065	867	1,254
Glycosides	149	95	201	368	529
Opium alkaloids	917	843	861	992	637
Quinine	0	0	0	0	0
Other cinchona alkaloids	0	0	0	0	84
Caffeine	1,825	2,323	733	1,564	1,855
Ephedrines	416	304	376	388	423
Theophylline & aminophylline	92	116	46	80	43
Rye ergot alkaloids	318	395	263	332	209
Nicotine	0	0	0	0	0
Other vegetable alkaloids	147	54	86	152	91
Penicillins	4,121	3,310	3,000	3,875	3,660
Streptomycins	28	20	38	83	0
Tetracyclines	1,483	619	1,174	970	1,117
Chloramphenicol	348	171	137	136	149
Erythromycin	7,228	5,952	3,074	4,589	3,585
Other antibiotics	5,418	3,750	3,390	3,362	2,809
Glands, organs & other extracts	846	555	494	785	455
Antisera and other blood fractions	3,395	2,889	4,173	5,275	3,690
Vaccines, human use	5,118	7,768	10,636	11,941	11,757
Vaccines, veterinary use	4,934	4,951	7,286	9,727	8,962
Other antisera/vaccines	2,139	1,742	2,044	2,124	1,988
Subtotal raw materials	62,991	55,889	60,608	70,836	62,670
Penicillins, streptomycins	677	619	161	188	64
Other antibiotics	883	1,294	671	1,492	802
Insulin	0	0	0	0	0
Other hormones	271	291	29	25	76
Alkaloids	0	0	0	0	0
Others	2,017	2,083	3,096	3,014	2,405
Subtotal semi-finished medicaments	3,848	4,287	3,957	4,719	3,347
Penicillins, streptomycins	4,089	4,549	4,580	5,953	5,609
Other antibiotics	18,365	17,164	15,249	19,327	15,620
Insulin	1,563	2,254	2,608	2,168	2,673
Other adrenal cortical hormones	3,806	4,733	5,818	11,393	8,036
Other hormones	9,558	12,828	13,058	12,866	13,346
Alkaloids	3,273	2,992	2,663	3,657	3,085
Vitamins or provitamins	8,271	8,002	7,594	11,607	8,941
Other	113,584	132,915	136,734	149,561	138,009
Subtotal retail medicaments	162,509	185,437	188,304	216,532	195,319
Total	229,348	245,613	252,869	292,087	261,336

Leading Suppliers, 2002 (US\$000s)

	Argent.	USA	Germany	France	Switz.	Mexico
Sulphonamides	0	5	104	0	157	0
Provitamins & vitamins	43	76	2,803	3,933	1,595	0
Pituitary anterior hormones	0	0	0	0	0	0
Cortisone, hydrocortisone, prednisone and prednisolone	0	1	0	0	0	0
Halogenated derivatives of adrenal cortical hormones	0	41	66	0	0	0
Other adrenal cortical hormones	0	0	0	0	0	0
Insulin	0	0	0	0	0	0
Oestrogens and progestogens	819	132	0	0	63	10
Other hormones	216	0	0	0	60	0
Glycosides	0	0	66	0	60	0
Opium alkaloids	0	92	2	172	86	0
Quinine	0	0	0	0	0	0
Other cinchona alkaloids	0	0	0	0	0	0
Caffeine	0	0	436	0	0	0
Ephedrines	0	0	120	0	161	0
Theophylline & aminophylline	0	0	0	0	9	0
Rye ergot alkaloids	0	0	0	0	0	0
Nicotine	0	0	0	0	0	0
Other vegetable alkaloids	0	0	35	0	0	0
Penicillins	0	0	0	0	0	2,058
Streptomycins	0	0	0	0	0	0
Tetracyclines	0	0	0	0	0	0
Chloramphenicol	0	0	0	0	0	0
Erythromycin	78	0	0	0	114	0
Other antibiotics	0	284	140	18	32	0
Glands, organs & other extracts	121	118	0	0	0	0
Antisera and other blood fractions	234	616	176	69	420	0
Vaccines, human use	0	1,509	2,612	6,628	220	0
Vaccines, veterinary use	540	2,805	0	203	0	48
Other antisera/vaccines	11	87	214	365	0	0
Subtotal raw materials	2,062	5,766	6,774	11,388	2,977	2,116
Penicillins, streptomycins	0	0	0	0	0	0
Other antibiotics	108	42	18	0	0	0
Insulin	0	0	0	0	0	0
Other hormones	76	0	0	0	0	0
Alkaloids	0	0	0	0	0	0
Others	99	225	203	126	237	0
Subtotal semi-finished medicaments	283	267	221	126	237	0
Penicillins, streptomycins	529	33	75	31	53	159
Other antibiotics	1,203	3,029	1,014	384	909	1,049
Insulin	0	375	115	81	53	146
Other adrenal cortical hormones	2,791	573	84	154	0	116
Other hormones	420	576	2,221	628	315	261
Alkaloids	1,599	20	109	377	89	173
Vitamins or provitamins	2,572	176	306	37	924	405
Other	16,876	17,203	13,323	8,348	15,712	13,157
Subtotal retail medicaments	25,990	21,985	17,247	10,040	18,055	15,466
Total	28,335	28,018	24,242	21,554	21,269	17,582
Percentage of Total	10.8	10.7	9.3	8.2	8.1	6.7

Leading Suppliers by Category, 2002 (US\$000s)

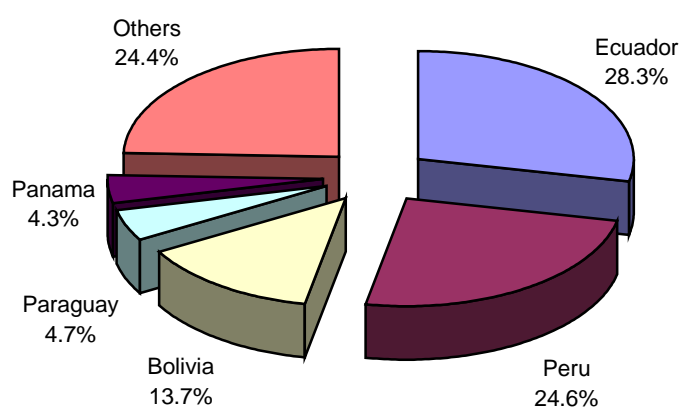
	Imports	Leading Supplier	Shipments	% of Total
Sulphonamides	979	Switzerland	157	16.04
Provitamins & vitamins	14,016	France	3,933	28.1
Pituitary anterior hormones	0	~	~	~
Cortisone, hydrocortisone, prednisone and prednisolone	236	Italy	159	67.4
Halogenated derivatives of adrenal cortical hormones	388	Spain	152	39.2
Other adrenal cortical hormones	0	~	~	~
Insulin	0	~	~	~
Oestrogens and progestogens	3,754	Netherlands	2,634	70.2
Other hormones	1,254	Italy	852	67.9
Glycosides	529	China	292	55.2
Opium alkaloids	637	UK	227	35.6
Quinine	0	~	~	~
Other cinchona alkaloids	84	Belgium	84	100.0
Caffeine	1,855	Spain	1,325	71.4
Ephedrines	423	Switzerland	161	38.1
Theophylline & aminophylline	43	Italy	23	53.5
Rye ergot alkaloids	209	Italy	164	78.5
Nicotine	0	~	~	~
Other vegetable alkaloids	91	Brazil	56	61.5
Penicillins	3,660	Mexico	2,058	56.2
Streptomycins	0	~	~	~
Tetracyclines	1,117	China	992	88.8
Chloramphenicol	149	Spain	86	57.7
Erythromycin	3,585	India	1,641	45.8
Other antibiotics	2,809	China	807	28.7
Glands, organs & other extracts	455	Argentina	121	26.6
Antisera and other blood fractions	3,690	Spain	1,697	46.0
Vaccines, human use	11,757	France	6,628	56.4
Vaccines, veterinary use	8,962	USA	2,805	31.3
Other antisera/vaccines	1,988	Denmark	1,027	51.7
<i>Semi-finished medicaments</i>				
Penicillins, streptomycins	64	Slovenia	64	100.0
Other antibiotics	802	Peru	321	40.0
Insulin	0	~	~	~
Other hormones	76	Argentina	76	100.0
Alkaloids	0	~	~	~
Others	2,405	Spain	619	25.7
<i>Retail medicaments</i>				
Penicillins, streptomycins	5,609	India	839	15.0
Other antibiotics	15,620	USA	3,029	19.4
Insulin	2,673	Denmark	1,809	67.7
Other adrenal cortical hormones	8,036	Argentina	2,791	34.7
Other hormones	13,346	Ireland	2,870	21.5
Alkaloids	3,085	Argentina	1,599	51.8
Vitamins or provitamins	8,941	Colombia	3,242	36.3
Other	138,009	USA	17,203	12.5
Total	261,336	Argentina	28,335	10.8

Exports

Chile has an increasing pharmaceutical export sector but results in 2002 were disappointing after a 20.5% increase in 2001. Predictions for 2002 were in the region of US\$75 million. However, the total exported in 2002 was only US\$44.7 million. This was an increase of 35.0% over 1998 though, where exports stood at US\$33.1 million. About 98.2% of all exports in 2002 were of retail medicaments, 1.3% raw materials and just 0.5% semi-finished medicaments.

The leading destination for Chilean pharmaceutical exports is Ecuador, accounting for US\$12.7 million in 2002. This was equal to 28.3% of the total. This was followed by Peru with US\$11.0 million, equivalent to 24.6%. Other leading destination countries were also Latin American; Bolivia accounted for US\$6.1 million (13.7%), Paraguay for US\$2.0 million (4.7%) and Panama for US\$1.9 million (4.3%).

Leading Destinations, 2002 (%)



CHILE

Recorded pharmaceutical data from the Chilean Trade Commission (ProChile – Dirección de Promoción de Exportaciones, Ministerio de Relaciones Exteriores de Chile) showed that, of around US\$45 million, US\$30 million were accountable to 16 major pharmaceutical exporters. These included LabChile (US\$11.5 million), Sanderson (US\$5.9 million) and Saval (US\$5.9 million). Some exporters were not listed, but the below table can give a rough indication of how exports stood in Chile by pharmaceutical manufacturer.

Exports by Pharmaceutical Companies, 2002

	Exports (US\$)	Destinations
LabChile	11,562,100.0	Argentina, Bolivia, Bulgaria, Colombia, Ecuador, El Salvador, Germany, Guatemala, Haiti, Honduras, Italy, Lebanon, Macedonia, Nicaragua, Panama, Paraguay, Peru, Spain, Uruguay
Sanderson	5,930,910.0	Bolivia, Colombia, Costa Rica, Dominican Republic, Ecuador, Germany, Nicaragua, Paraguay, Peru, United States, Uruguay, Venezuela
Saval	5,892,320.0	Argentina, Bolivia, Dominican Republic, Ecuador, El Salvador, Panama, Paraguay, Peru, United States, Uruguay
Andrómaco	2,970,710.0	Bolivia, Costa Rica, Ecuador, Haiti, Panama, Peru, Switzerland
Bago	2,461,710.0	Argentina, Bolivia, Ecuador, Peru
Biosano	943,674.0	Colombia, Honduras, Nicaragua, Panama, Paraguay, Peru, Venezuela
Mintlab	831,223.0	Bolivia, Ecuador, Guatemala, Honduras, Panama, Spain
Silesia	773,274.0	Austria, Bolivia, Dominican Republic, Ecuador, Guatemala, Paraguay, Peru, Uruguay
Maver	650,738.0	Bolivia, Peru
Prater	306,406.0	Argentina, Colombia, Ecuador, India, Peru, United States
BestPharma	188,654.0	India, Paraguay, Peru
Knop	90,704.7	Peru
Chemopharma	49,473.4	Ecuador, Switzerland
Arama	41,478.0	Uruguay
Medipharm	34,715.4	Peru
Labomed	27,094.0	Bolivia
Rider	24,814.3	Ecuador, Peru
Total	29,809,288.8	~

Source: ProChile, 2004. Note: Data on Recalcine was not available.

In 2003, ProChile recorded pharmaceutical exports to the value of US\$54.5 million, an increase of nearly 22% compared to US\$44.7 million in 2002. LabChile and Bago, accounting for 35.8% of total exports, were the leading pharmaceutical exporters, followed by Saval, Recalcine and Sanderson. The total number of exporters increased to 35.

Exports of Pharmaceuticals, 1998-2002 (US\$000s)

	1998	1999	2000	2001	2002
Sulphonamides	0	0	0	0	0
Provitamins & vitamins	83	0	0	0	58
Pituitary anterior hormones	0	0	0	0	0
Cortisone, hydrocortisone, prednisone and prednisolone	0	0	0	0	0
Halogenated derivatives of adrenal cortical hormones	0	0	0	0	0
Other adrenal cortical hormones	0	0	0	0	0
Insulin	0	0	0	0	0
Oestrogens and progestogens	0	0	0	0	0
Other hormones	0	0	0	0	0
Glycosides	0	0	0	0	0
Opium alkaloids	0	0	0	0	0
Quinine	0	0	0	0	0
Other cinchona alkaloids	0	0	0	0	0
Caffeine	0	0	0	91	0
Ephedrines	0	0	0	0	0
Theophylline & aminophylline	0	0	0	0	0
Rye ergot alkaloids	0	0	0	0	0
Nicotine	0	0	0	0	0
Other vegetable alkaloids	0	0	0	0	0
Penicillins	0	0	0	0	0
Streptomycins	0	0	0	0	0
Tetracyclines	0	0	0	107	0
Chloramphenicol	0	0	0	0	0
Erythromycin	191	109	0	0	0
Other antibiotics	0	0	0	0	0
Glands, organs & other extracts	0	0	0	0	0
Antisera and other blood fractions	383	532	339	511	313
Vaccines, human use	81	89	117	62	25
Vaccines, veterinary use	0	0	0	0	100
Other antisera/vaccines	106	13	27	45	78
Subtotal raw materials	844	743	483	816	574
Penicillins, streptomycins	0	0	0	0	0
Other antibiotics	52	85	68	23	3
Insulin	0	0	0	0	0
Other hormones	0	0	0	0	0
Alkaloids	0	0	0	0	0
Others	248	193	228	500	223
Subtotal semi-finished medicaments	300	278	296	523	226
Penicillins, streptomycins	1,873	1,187	2,106	2,611	2,237
Other antibiotics	4,049	2,745	3,244	3,976	3,999
Insulin	0	0	0	0	0
Other adrenal cortical hormones	1,219	719	664	948	1,519
Other hormones	1,205	2,279	2,095	2,021	3,615
Alkaloids	1,423	1,214	1,334	2,086	2,317
Vitamins or provitamins	1,353	1,145	1,320	1,681	2,198
Other	20,857	18,962	22,861	26,787	28,045
Subtotal retail medicaments	31,979	28,251	33,624	40,110	43,930
Total	33,123	29,272	34,403	41,449	44,730

Leading Destinations, 2002 (US\$000s)

	Ecuador	Peru	Bolivia	Paraguay	Panama
Sulphonamides	0	0	0	0	0
Provitamins & vitamins	0	0	0	0	0
Pituitary anterior hormones	0	0	0	0	0
Cortisone, hydrocortisone, prednisone and prednisolone	0	0	0	0	0
Halogenated derivatives of adrenal cortical hormones	0	0	0	0	0
Other adrenal cortical hormones	0	0	0	0	0
Insulin	0	0	0	0	0
Oestrogens and progestogens	0	0	0	0	0
Other hormones	0	0	0	0	0
Glycosides	0	0	0	0	0
Opium alkaloids	0	0	0	0	0
Quinine	0	0	0	0	0
Other cinchona alkaloids	0	0	0	0	0
Caffeine	0	0	0	0	0
Ephedrines	0	0	0	0	0
Theophylline & aminophylline	0	0	0	0	0
Rye ergot alkaloids	0	0	0	0	0
Nicotine	0	0	0	0	0
Other vegetable alkaloids	0	0	0	0	0
Penicillins	0	0	0	0	0
Streptomycins	0	0	0	0	0
Tetracyclines	0	0	0	0	0
Chloramphenicol	0	0	0	0	0
Erythromycin	0	0	0	0	0
Other antibiotics	0	0	0	0	0
Glands, organs & other extracts	0	0	0	0	0
Antisera and other blood fractions	0	0	0	0	0
Vaccines, human use	0	0	0	25	0
Vaccines, veterinary use	0	0	0	0	0
Other antisera/vaccines	0	0	0	0	0
Subtotal raw materials	0	0	0	25	0
Penicillins, streptomycins	0	0	0	0	0
Other antibiotics	0	0	3	0	0
Insulin	0	0	0	0	0
Other hormones	0	0	0	0	0
Alkaloids	0	67	14	0	0
Others	0	0	0	0	0
Subtotal semi-finished medicaments	0	67	17	0	0
Penicillins, streptomycins	900	690	407	57	0
Other antibiotics	1,617	1,044	499	123	188
Insulin	0	0	0	0	0
Other adrenal cortical hormones	102	305	229	52	32
Other hormones	542	705	301	204	34
Alkaloids	923	501	571	202	78
Vitamins or provitamins	615	687	392	117	174
Other	7,972	7,002	3,707	1,306	1,428
Subtotal retail medicaments	12,671	10,934	6,106	2,061	1,934
Total	12,671	11,001	6,123	2,086	1,934
Percentage of Total	28.3	24.6	13.7	4.7	4.3

Balance of Trade

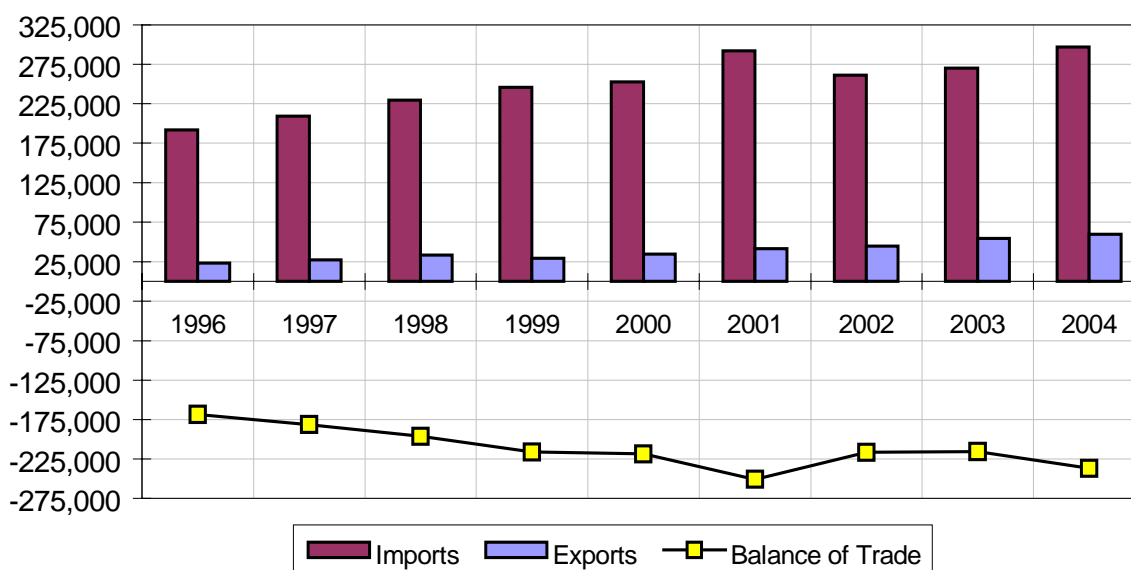
The balance of trade remains negative at US\$216.6 million in 2002. In 2004, Espicom estimates that imports will increase up to US\$296.8 million and exports to US\$50.8 million, with a balance trade of US\$246 million. The new health reform and enhanced consumer spending power accelerated by the economic stability will enhance the pharmaceutical industry. Exports can also be boosted by the new trade agreements.

Balance of Trade, 1996-2004 (US\$)

	Imports	% Change	Exports	% Change
1996	191,891.0	~	23,060.0	~
1997	209,029.0	8.9	27,407.0	18.9
1998	229,348.0	9.7	33,123.0	20.9
1999	245,613.0	7.1	29,272.0	-11.6
2000	252,869.0	3.0	34,403.0	17.5
2001	292,087.0	15.5	41,449.0	20.5
2002	261,336.0	-10.5	44,730.0	7.9
2003	270,230.0*	3.4	54,500.0**	21.8
2004	296,777.4*	9.8	59,854.0*	9.8

Source: United Nations Statistics Division. * Espicom's estimates based on GDP growth in Chilean pesos of 3.3% in 2003 and 4.0% in 2004, plus Chilean's peso's appreciation against the US\$ of 0.11% in 2003 and an adjusted annual 5.63% (quarterly appreciation of 14.57% as a reference) in 2004. **Prochile's estimates.

Balance of Trade, 1996-2004 (US\$000s)



Pharmaceutical Balance of Trade, 1998-2002 (US\$000s)

	1998	1999	2000	2001	2002
Sulphonamides	-2,079	-1,587	-1,403	-1,345	-979
Provitamins & vitamins	-16,870	-14,999	-16,027	-18,415	-13,958
Pituitary anterior hormones	0	0	0	0	0
Cortisone, hydrocortisone, prednisone and prednisolone	-185	-181	-278	-153	-236
Halogenated derivatives of adrenal cortical hormones	-1,072	-262	-378	-476	-388
Other adrenal cortical hormones	0	0	0	0	0
Insulin	0	0	0	0	0
Oestrogens and progestogens	-3,159	-2,439	-3,445	-2,837	-3,754
Other hormones	-621	-564	-1,065	-867	-1,254
Glycosides	-149	-95	-201	-368	-529
Opium alkaloids	-917	-843	-861	-992	-637
Quinine	0	0	0	0	0
Other cinchona alkaloids	0	0	0	0	-84
Caffeine	-1,825	-2,323	-733	-1,473	-1,855
Ephedrines	-416	-304	-376	-388	-423
Theophylline & aminophylline	-92	-116	-46	-80	-43
Rye ergot alkaloids	-318	-395	-263	-332	-209
Nicotine	0	0	0	0	0
Other vegetable alkaloids	-147	-54	-86	-152	-91
Penicillins	-4,121	-3,310	-3,000	-3,875	-3,660
Streptomycins	-28	-20	-38	-83	0
Tetracyclines	-1,483	-619	-1,174	-863	-1,117
Chloramphenicol	-348	-171	-137	-136	-149
Erythromycin	-7,037	-5,843	-3,074	-4,589	-3,585
Other antibiotics	-5,418	-3,750	-3,390	-3,362	-2,809
Glands, organs & other extracts	-846	-555	-494	-785	-455
Antisera and other blood fractions	-3,012	-2,357	-3,834	-4,764	-3,377
Vaccines, human use	-5,037	-7,679	-10,519	-11,879	-11,732
Vaccines, veterinary use	-4,934	-4,951	-7,286	-9,727	-8,862
Other antisera/vaccines	-2,033	-1,729	-2,017	-2,079	-1,910
Subtotal raw materials	-62,147	-55,146	-60,125	-70,020	-62,096
Penicillins, streptomycins	-677	-619	-161	-188	-64
Other antibiotics	-831	-1,209	-603	-1,469	-799
Insulin	0	0	0	0	0
Other hormones	-271	-291	-29	-25	-76
Alkaloids	0	0	0	0	0
Others	-1,769	-1,890	-2,868	-2,514	-2,182
Subtotal semi-finished medicaments	-3,548	-4,009	-3,661	-4,196	-3,121
Penicillins, streptomycins	-2,216	-3,362	-2,474	-3,342	-3,372
Other antibiotics	-14,316	-14,419	-12,005	-15,351	-11,621
Insulin	-1,563	-2,254	-2,608	-2,168	-2,673
Other adrenal cortical hormones	-2,587	-4,014	-5,154	-10,445	-6,517
Other hormones	-8,353	-10,549	-10,963	-10,845	-9,731
Alkaloids	-1,850	-1,778	-1,329	-1,571	-768
Vitamins or provitamins	-6,918	-6,857	-6,274	-9,926	-6,743
Other	-92,727	-113,953	-113,873	-122,774	-109,964
Subtotal retail medicaments	-130,530	-157,186	-154,680	-176,422	-151,389
Total	-196,225	-216,341	-218,466	-250,638	-216,606

DIRECTORY

Government Organisations

Central Purchasing Agency (CENABAST - Central de Abastecimiento del Sistema Nacional del Servicio de Salud), Avda. Manuel A. Matta 644, Santiago, Chile.
Tel: +56 2 556 9061. Fax: +56 2 556 7205.
<http://www.cenabast.cl>

Ministry of Health (MINSAL – Ministerio de Salud), Enrique Mac-Iver 541, Piso 3, Santiago, Chile. Tel: +56 2 639 4001. Fax: +56 2 238 7736. <http://www.minsal.cl>

National Health Fund (FONASA - Fondo Nacional de Salud), Monjitas 665, Santiago, Chile. Tel: +56 2 664 8892. Fax: +56 2 639 9725. <http://www.fonasa.cl>

Public Health Institute (ISPCH - Instituto de Salud Pública de Chile), Avda. Marathon 1000, Santiago, Chile. Tel: +56 2 350 7477. Fax: +56 2 238 4536.
<http://www.ispch.cl>

Statistics and Information Department (DEIS – Departamento de Estadísticas e Información de Salud), Mac Iver 541, Santiago, Chile. Tel: +56 2 630 0662. Fax: +56 2 630 0656.
<http://deis.minsal.cl/index.asp>

Superintendency of Isapres (SISP – Superintendencia de Isapres), Enrique Mac-Iver 225, Santiago, Chile. Tel: +56 2 240 0700. Fax: +56 2 240 0800.
<http://www.sisp.cl>

Other Organisations

Chilean Isapres (ISAPRE – Isapres de Chile), Alcantara 44, Piso 4, Las Condes, Santiago, Chile. Tel: +56 249 7920. Fax: +56 249 70 60. <http://www.isapre.cl>

Industrial Property Department (DPI – Departamento de Propiedad Industrial de Chile), Moneda 970, Piso 10, Santiago, Chile. Tel. For patents: +56 2 688 2823/6981771. Fax: +56 2 688 3484. <http://www.dpi.cl>

National Institute of Statistics (INE – Instituto Nacional de Estadísticas), Av. Presidente Bulnes 418, Santiago, Chile. Tel: +56 2 366 777. Fax: +56 2 671 2169.
<http://www.ine.cl>

Trade Associations

Asociación Industrial de Laboratorios Farmacéuticos Chilenos AG (ASILFA), Avda. Vitacura 2771, Oficina 301, Las Condes, Santiago. Tel: +56 2 213 9446. 9350. Fax: +56 2 213 9445. <http://www.asilfa.cl/>

Cámara de Comercio de Santiago AG, Santa Lucía 302, Santiago. Tel: +56 2 6321232. Fax: +56 2 6333395.

Cámara de la Industria Farmacéutica de Chile AG (CIF), Hernando de Aguirre 1981, Santiago. Tel: +56 2 222 52959. Fax: +56 2 205 2060.

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