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# Pharmaceutical Products



# THE OPPORTUNITY

The Mexican pharmaceutical industry offers emerging opportunities for Canadian companies.

- Mexico has the world's tenth largest pharmaceutical industry, with a well-trained labour force.
- Intellectual property legislation has been tightened, creating markets for previously copied drugs as well as generic pharmaceuticals.
- Price controls have been liberalized and there have been substantial price increases, widening the profit margins of Mexican producers.
- Preferential purchasing by the public health system will be phased out under the North American Free Trade Agreement (NAFTA).
- Mexican drug manufacturers will eventually gain access to American and Canadian markets.
- Mexico lacks the research infrastructure needed to develop new drugs.

# THE ROAD TO DEREGULATION

Mexico's pharmaceutical industry is the tenth largest in the world, with a domestic market of some US \$3.5 billion. For many years, the government regulated the industry with the principal goals of displacing imports and making cheap drugs available to the public. Tariffs were high. Intellectual property laws were weak, allowing for widespread copying of foreign-developed drugs. And prices were regulated to keep profit margins thin.

The organization of the Mexican pharmaceutical sector reflects these traditional policies. About sixty multinational pharmaceutical companies set up operations in Mexico to supply the local market, using raw materials imported from affiliated firms in other countries. These companies account for some 90 percent of the private sector market, but none of them claims more than a 6 percent market share. In contrast, a small number of relatively large Mexican-owned companies cater to the public health system. This system is comprised of the Instituto Mexicano del Seguro Social (IMSS), Mexican Institute for Social Security, the Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado (ISSSTE), Institute of Social Security and Services for Public Employees, and a number of private health plans run by large government-owned enterprises such as Petróleos

# SUMMARY REPORT

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Mexicanos (Pemex), the national oil company. Preferential purchasing policies have so far directed this business almost entirely to Mexican firms. A larger number of Mexican companies supply the major producers of dosage forms with pharmochemicals and other inputs.

The public health system covers virtually all of the population. But since the drugs they distribute are mostly generic and are purchased at low prices under large annual contracts, the public sector accounts for 36 percent of the market by volume and only 10 percent by value. The private sector concentrates on more expensive patented drugs with wider profit margins. Import penetration is about 10 percent of the domestic market, including both the private and public sectors.

By restraining profit margins and encouraging copying, this environment discouraged the development of pharmaceutical research facilities. As a result, Mexico does not have an established infrastructure for the development of new drugs.

Trade liberalization and deregulation is beginning to change this picture. In 1992, Mexico enacted new intellectual property regulations, which prohibited the outright copying of drugs. Two years later, the loophole that allowed copying as long as the manufacturing process was unique, was closed. Beginning in 1991, price controls were liberalized and retail prices have risen substantially. The advent of the North American Free Trade Agreement (NAFTA) on 1 January 1994, might have been expected to lead to the further integration of the pharmaceutical industry in Canada, the United States and Mexico. So far it has not, largely because of strict regulation governing the introduction of new drugs.

In the medium term, however, new opportunities are expected to emerge. Under NAFTA, Mexican firms will gradually lose their tariff protection, currently about 14 percent, and also their preferential access to public tenders. This will force them to broaden their product lines and compete more directly with the multinationals. Increased patent protection is likely to lead to a new emphasis on generic drugs as a substitute for patented drugs that are no longer being copied. And the industry is likely to expand its exports of such products to countries in Central and South America which do not have their own pharmaceutical industries.

These developments will create opportunities for Canadian firms to form joint ventures with Mexican counterparts to develop new products, based either on Canadian patents or on generic versions of drugs with expired patents. There will also be increased opportunities for Canadian firms to bid on Mexican government procurements.

# THE MEXICAN PHARMACEUTICAL SECTOR

The Mexican pharmaceutical sector is one of the country's most dynamic industries, contributing about 13 percent of manufacturing gross domestic product (GDP) and about 0.5 percent of total GDP. The industry developed rapidly following the discovery of steroid hormones in the early 1940s. Mexico has an abundant supply of certain plants of the *discorea* family, which are used to produce these hormones, and it soon became the source of almost all the world's steroids, including both raw material and dosage forms.

In the 1960s, government programs designed to encourage import displacement were successful in stimulating the growth of the pharmochemical industry to provide raw materials to pharmaceutical manufacturers. Nonetheless, both the pharmaceutical and pharmochemical sectors continue to rely heavily on imported inputs. According to estimates by the *Instituto Mexicano de Ejecutivos de Finanzas*, two thirds of pharmochemical inputs and 20 percent of packaging materials are imported. Overall, import penetration in the pharmaceutical industry is only 10 percent.

There are more than 300 pharmaceutical enterprises registered with the Cámara Nacional de la Industria Farmacéutica (Canifarma), National Chamber of the Pharmaceutical Industry. They include 88 foreign companies and 135 Mexican companies which manufacture medicines for human consumption. Another 43 companies produce pharmochemicals and the rest are manufacturers of auxiliary health products. Employment is estimated at about 50,000 persons, of which about 15 percent are engaged in pharmochemical production.

Large economies of scale are reflected in a high concentration of production among a few large firms. According to *Canifarma* data, one-third of the enterprises account for 93 percent of sales and 77 percent of employment. The industry is concentrated in the Federal District and the State of Mexico, which together account for 63 percent of pharmaceutical undertakings. Jalisco is another important pharmaceutical production centre.

The bulk of production comes from about 60 multinational firms and a few large Mexican companies. Virtually all of the major international pharmaceutical producers have a presence in Mexico. The multinational production facilities are generally world-class, although there is a lack of research infrastructure. Their products are



## PHARMACEUTICAL PRODUCTION, 1994

millions of Mexican pesos			
For specialties	4,534		
Anti-infectives	2,399		
Bactericides	1,629		
Digestive system	1,273		
Central nervous system	1,005		
Respiratory system	910		
Cardiovascular system	591		
Veterinary	571		
Locomotion system	504		
Dermatological products	384		
Non-therapeutic	263		
Bacteriostatics	209		
Antiparasiticals	176		
Blood and hematopeic organ	is 148		
Genitourinary organs	102		
Salts	75		
Not specified	1,633		
Total	16,406		

Source: Instituto Nacional de Estadística, Geografía e Informática (INEGI), National Institute for Statistics, Geography and Informatics, 1995.

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mainly foreign-developed drugs produced for the domestic market, even though Mexico has developed important export markets elsewhere in Latin America. Some observers believe that the recent improvement in patent protection for pharmaceuticals will lead to more locally developed drugs.

The industry has grown rapidly over the past few years, partly on the strength of deregulated prices. Higher prices more than offset higher materials costs following the peso devaluation beginning in December 1994. In addition, the demand for pharmaceutical products is not very sensitive to price changes and the industry is, therefore, not particularly vulnerable to the state of the overall economy. As a result of these forces, pharmaceutical output rose by an estimated

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### **IMPORTS OF PHARMOCHEMICAL PRODUCTS\***

US dollars

	World		Canada		
	1994	1995	19 <del>9</del> 4	1995	
Artificial mixtures of natural hormones without antibiotics	6,170,399	6,921,566	828,168	1,089,103	
Penicillin or derivatives, or streptomycin or derivatives	7,766	187,448	0	22,600	
Disinfectants for mouth, ears, nose or throat	13,774	8,612	0	0	
Medicines consisting of two or more antibiotics	161,591	43,761	3,058	0	
Other medicines containing antibiotics	3,531,722	3,720,902	0	0	
Injectable solutions containing insulin	620	1,228	0	0	
Medicines containing other antibiotics	7,852	2,712	0	0	
Anesthetics	761	0	0	0	
Preparations containing vincristine sulphate	0	0	0	0	
Other preparations containing alkaloids or derivatives	489,994	197,141	0	C	
Preparations containing sodium lime	1,234	890	0	C	
isotonic solutions, glucose serum	0	49,616	0	C	
Hydrolyzed proteins	749,504	2,125,398	0	t	
Medicines containing vitamins with minerals, in gel capsules	146,225	7,907	0	(	
Antineuritics associated with vitamins B1 and B12, injectable	0	146	0	(	
Preparations of polypeptide inhibitor of kallikrein	0	2,616	0	(	
Colloidal solution containing sodium, potassium and					
calcium chlorides	7,372	2,425	0		
Homeopathic medicines	99,944	137,300	0		
Sorbitol and aluminum, sodium or magnesium hydroxide complex	60,463	26,831	0		
Mixture of adonis, convallaria, oleander and scilla glucide	29,827	45,508	0		
Only of chlostridiumpeptidase	29	0	0		
Iodine-polyvinyl-pirrolidone powdered	818,928	964,004	0		
Other medicines not in					
dosage form	17,357,324	17,112,362	13	76,01	
Total	29,655,329	31,558,373	831,239	1,187,71	

\*Note: not in dosage forms for retail.

Source: Instituto Nacional de Estadística, Geografía e Informática (INEGI), National Institute for Statistics, Geography and Informatics.

### **IMPORTS OF PHARMACEUTICAL PRODUCTS\***

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US dollars

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|                                                                                                | World           |             | Ca                     | Canada    |  |
|------------------------------------------------------------------------------------------------|-----------------|-------------|------------------------|-----------|--|
|                                                                                                | 1994            | 1995        | 1994                   | 1995      |  |
| Zidovuline (azidotimidine)                                                                     | 4,932,252       | 410,497     | 0                      | 373,050   |  |
| Penicillin or derivatives, or streptomycin or derivatives                                      | 3,412,270       | 2,845,444   | 124,533                | 353,264   |  |
| Mixtures of natural hormones without antibiotics                                               | 34,374,711      | 19,790,633  | 78,026                 | 118,672   |  |
| Other antibiotics                                                                              | 22,086,750      | 20,838,063  | 4,578                  | 42,781    |  |
| Other medicines containing vitamins                                                            | 4,766,996       | 6,107,256   | 34,607                 | 3,919     |  |
| njectable solutions containing insulin but not antibiotics                                     | 2,204,058       | 2,339,647   | 0                      | 0         |  |
| Other medicines containing insulin but not antibiotics                                         | 1,454,607       | 54,550      | · 0                    | 0         |  |
| Containing adrenal cortical hormones                                                           | 49,719          | 112,416     | 0                      | 0         |  |
| Anesthetics                                                                                    | 419             | 1,064       | 0                      | 0         |  |
| Preparations containing vincristine sulphate                                                   | 323,648         | 71,486      | 0                      | 0         |  |
| Other preparations containing alkaloids or derivatives                                         | 1,426,050       | 2,611,356   | 12,810                 | 0         |  |
| Aedicines in tablets of multiple core and retarded disintegration                              | 979,317         | 415,095     | 0                      | 0         |  |
| Antineuritics associated with vitamins B1 and B12, injectable                                  | 49,654          | 315,588     | 0                      | 0         |  |
| Preparations containing sodium lime                                                            | 11,801          | 3,405       | 0                      | 0         |  |
| sotonic solutions, glucose serum                                                               | 3,161,764       | 55,217      | 0                      | 0         |  |
| lydrolyzed proteins                                                                            | 17,103          | 45,033      | 0                      | 0         |  |
| Other medications                                                                              | 259,685         | 433,518     | 0                      | 0         |  |
| Colloidal solution containing sodium, potassium and                                            |                 |             |                        |           |  |
| calcium chlorides                                                                              | 1,312,800       | 1,655,337   | 933                    | 0         |  |
| Iomeopathic medicines                                                                          | 259,613         | 227,501     | 20,12 <del>9</del>     | 0         |  |
| orbitol and aluminum, sodium or magnesium                                                      |                 |             |                        |           |  |
| hydroxide complex                                                                              | 822             | 1,155       | 0                      | 0         |  |
| ledicines containing tri-iodomethane, butyl aminobenzoate,<br>mint and eugenol                 | 26,177          | 68,246      | 0                      | 0         |  |
| Iedicines containing sodium fluoride and glycerine                                             | 604             | 710         | 0                      | 0         |  |
| ledicines in spray containing tetracaine chlorhydrate and                                      | 004             | 710         | U                      | U         |  |
| ethyl aminobenzoate                                                                            | 0               | 182         | 0                      | 0         |  |
| thyl chloride                                                                                  | 73,047          | 99,003      | 0                      | 0         |  |
| ledicines containing ethanol, in spray                                                         | 289,884         | 2,470       | 0                      | 0         |  |
| lixtures of adonis, convallaria, oleander and scilla glucide                                   | 0               | 142         | 0                      | 0         |  |
| ledicines in tablets containing azathioprine or chlorambucil or melfalan etc.                  | 335,259         |             | -                      | -         |  |
| ijectable solutions containing atracurium biciliate or acyclovir                               | 1,281,601       | 438,796     | 0                      | 0         |  |
|                                                                                                |                 | 859,506     | 0                      | 0         |  |
| ledicines containing monoclonic antibodies<br>,2,3 propanotriol trinitrate absorbed in lactose | 66,963<br>5 114 | 131,930     | 0                      | 0         |  |
|                                                                                                | 5,114           | 27,661      | 0                      | 0         |  |
| ther medicines consisting of two or more constituents<br>packaged for retail                   | 108,892,514     | 111,543,621 | 1,392,704              | 1,333,621 |  |
| otal                                                                                           | 192,055,202     | 171,506,528 | 1,592,704<br>1,668,320 | 2,225,307 |  |

\*Note: dosage forms for retail.

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Source: Instituto Nacional de Estadística, Geografía e Informática (INEGI), National Institute for Statistics, Geography and Informatics.



13 percent during 1995, in spite of a 7 percent drop in total GDP.

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The industry benefits from relatively low labour costs, even though pharmaceutical workers earn from two to three times the national average wage. The industry invests about 3 percent of sales in training programs, according to one estimate.

# **FOREIGN TRADE**

Mexico is a net importer of pharmaceutical products. The domestic industry exports dosage forms to Central and South America, but this trade is more than offset by imports of pharmochemicals and other inputs. In the medium term, the North American Free Trade Agreement (NAFTA) should create opportunities for the export of Mexican pharmaceuticals to the United States and Canada. But in the short term, sales are limited by investigation and approval procedures by the US Food and Drug Administration and by similar regulations in Canada. Another problem is that Mexican pharmaceutical companies are not set up for American and Canadian distribution.

In 1995, Mexico imported about US \$203 million worth of pharmochemical and pharmaceutical products, which is about 6 percent of the total Mexican market. Imports declined by 9.2 percent in 1995, as a result of the economic crisis spawned by the peso devaluation beginning in December 1994. The US Department of Commerce has predicted that imports from the US will rise by 20 percent in 1996, mainly on the strength of intra-corporate transfers by multinational firms.

The US accounts for about one-quarter of the import market. The other major foreign competitors are Switzerland, Germany and the United Kingdom, which together claim almost half of the import market. Canada's import market share is estimated at 1.7 percent for 1995.

Mexico depends upon imported raw materials and intermediate pharmochemicals for many of the products it produces. Nonetheless, about 85 percent of pharmaceutical imports by value are in dosage forms packaged for retail sale.

# CUSTOMERS

There are two principal market segments in the Mexican pharmaceutical industry. Private sector distributors account for about 90 percent of the value and 64 percent of the volume of pharmaceutical sales, according to estimates by *Grupo Financiero Bancomer*. These distributors concentrate on the products of the multinational drug companies which satisfy 85 percent of private demand.

The public sector accounts for the remaining 10 percent of value and 36 percent of volume. The Instituto Mexicano del Seguro Social (IMSS), Mexican Institute for Social Security, is the largest customer in this group, followed by the Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado (ISSSTE), Institute of Social Security and Services for Public Employees, and pharmacies operated for employees by large public sector employers. This segment is serviced mainly by small-to-medium sized Mexican companies. Sales are generally through public tenders.

Pemex is the largest public sector employer supplying drugs to its employees. It operates 46 pharmacies, as part of its internal health care system. The company conducts an annual tender for all of its pharmaceutical needs. The 1996 contract was awarded to *Grupo Casa Autrey* in a deal worth US \$28 million. *Autrey* is also a major supplier to the *IMSS* and the *ISSSTE*. The size of the public sector market is probably underestimated. Public agencies are often forced to buy products from commercial distributors because of long delays in the public procurement process.

The annual market for pharmaceutical products in Mexico is estimated at more than US \$3.5 billion. This implies per capita consumption of just over US \$35, which is much lower than in developed countries. This is partly because only a small proportion of the population is covered by private health care insurance.

Medicines for human consumption are distributed directly to public and private health institutions and large retail chains by the pharmaceutical companies. But an estimated 90 percent of private sales are handled through distributors. McKesson Corp., the largest pharmaceutical distributor in North America, holds a 23 percent interest in NADRO, which has a 25 percent share of the Mexican pharmaceutical market. Other national distributors are Grupo Casa Autrey, Casa Marsam and Drogueros de México. There are four semi-national and 15 regional distributors. There are 14 major drugstore chains, with about 16,000 branches and about 20,000 drugstores overall. Mexico's largest drugstore chain is Farmacias Benavides, which had 445 stores in 1995.

# THE PUBLIC HEALTH CARE SYSTEM

The Sistema Nacional de Salud, National Health Care System, is divided into separate systems for those who are employed in the formal economy and for those who are not. Mexicans who can afford to pay have the third alternative of using private health care facilities, which tend to offer faster service.

The body responsible for health care policy and regulation throughout





Mexico is the Secretaria de Salud (SS), Secretariat of Health. The SS also delivers medical services to the poorer segments of Mexican society through a system of clinics and hospitals.

The SS has been substantially expanded in recent years and now makes health care services available to virtually every Mexican. Primary care clinics have been established in a growing number of remote towns and villages. The budgets of the nine principal entities in the SS exceed US \$10 billion.

Individuals are eligible for different programs that make up the SS, depending mainly on their employment status, economic status and location.

Roughly half of the population consists of formally employed persons and their families. They are covered by the *población derechohabiente*. This is a premium-based system funded by employer and employee contributions to a variety of health care entities. There are several programs covering different types of employers. A separate system serves the health care needs of Mexicans who are not employed, who are self-employed or who are engaged in the informal economy. It is referred to as the *población abierta*, or open system.

The SS is based on an extensive infrastructure of more than 14,000 medical service centres, of which about 13,000 are primary care facilities. About three-quarters of these facilities fall under the jurisdiction of the open system. General hospitals are a key element of both systems, but two-thirds of specialized hospitals are in the open system. Although several hospitals in the larger cities are comparable to those in Canada, Mexican facilities average only 86 beds.

There is also a parallel private health care system, catering to affluent



Mexicans, which is financed entirely by user fees. This system is supported to some extent by private insurance policies. Data provided by the Asociación Mexicana de Instituciones de Seguros (AMIS), Mexican Association of Insurance Institutions, indicates that less than 3 percent of Mexicans are covered by private health insurance.

The Mexican health care sector is described in greater detail in the market profile on Medical Equipment and Health Care Services, which is part of the Department of Foreign Affairs and International Trade (DFAIT) Export *i* Mexico series and available through the InfoCentre.

# **COMPETITORS**

The competitive situation differs in Mexico's public and private sector markets. Mexican companies dominate the public sector market because of purchasing policies that give preference to local suppliers. Mexicanowned companies win between 80 and 90 percent of all public tenders. Under the provisions of the North American Free Trade Agreement (NAFTA), Mexico may continue to give preference to domestic suppliers until 2001.

The situation is reversed in the private sector, where multinational companies have an estimated 90 percent market share. Because the private market is much more profitable than the public one, multinational firms claim a large percent of industry profits. There are more than 60 multinational firms in the market, leading to a fragmented market with no single company claiming more than a 6 percent market share. Nonetheless, 10 multinational companies control about one-third of the market.

### LEADING MANUFACTURERS OF PHARMACEUTICALS IN MEXICO, 1996

ranked by 1995 sales

| 1  | Glaxo Wellcome      | 21 | Roussel             |
|----|---------------------|----|---------------------|
| 2  | Syntex              | 22 | Merck               |
| 3  | Roche               | 23 | Rhone Poulenc Rorer |
| 4  | Bristol             | 24 | Byk Gulden          |
| 5  | Ciba Geigy          | 25 | Smith Kline Beecham |
| 6  | Wyeth               | 26 | Richardson Vicks    |
| 7  | Janssen             | 27 | Sanofi Winthrop     |
| 8  | Abbott Laboratories | 28 | Sandoz              |
| 9  | Bayer               | 29 | Mead Johnson        |
| 10 | Promeco             | 30 | Columbia            |
| 11 | Merck Sharp & Dohme | 31 | Grossman            |
| 12 | Boheringer Ing.     | 32 | Schering Mexicana   |
| 13 | Senosiain           | 33 | Armstrong           |
| 14 | Sanfer              | 34 | Searle              |
| 15 | Scheramex           | 35 | Whitehall Robins    |
| 16 | Hoechst             | 36 | Cilag               |
| 17 | Upjohn              | 37 | Plough              |
| 18 | Pfizer              | 38 | Lepetit             |
| 19 | Eli Lily            | 39 | Liomont             |
| 20 | Lakeside            | 40 | Rimsa               |

Source: United States Department of Commerce, 1996.

TRENDS AND OPPORTUNITIES

The market for pharmaceuticals, especially over-the-counter products, has grown substantially over the past few years. Vitamins and other health care products are regarded as a defence against unhealthy conditions caused by air pollution and inadequate sanitation. Mexico is also a significant exporter of these products, mostly to Central and South America. Major exports include steroids and antibiotics. The US Department of Commerce has estimated the 1996 market at about US \$4 billion and predicts that the import market will continue to grow at about 6 percent annually.

### NEW INTELLECTUAL PROPERTY PROTECTION

Mexico's capabilities for basic pharmaceutical research are limited. One reason is that, in the interests of low costs for consumers, the government allowed Mexican firms to copy foreigndeveloped drugs for about 50 years. In June 1991, Mexico's Ley de Fomento y Protección de la Propiedad Industrial, Law for the Promotion and Protection of Industrial Property, was extended to include chemicals and pharmaceuticals, among other products. At the same time, the term of patents was extended from 14 to 20 years. This stopped outright copying, but it still allowed Mexican firms to manufacture foreign-developed formulations if they could demonstrate that they used a different process to make them.

In August 1994, the government amended the law to bring it into compliance with the North American Free Trade Agreement (NAFTA). This closed the loophole in the process. Observers believe that this will create incentives for development of new pharmaceutical products in Mexico. Since Mexico does not have an extensive research infrastructure, this may create opportunities for Canadian companies to enter into technological joint ventures with local firms. While few Mexican firms have the resources to develop major new drugs, improved patent protection will create a demand for generic drugs. The continuing access of Mexican firms to the public sector market, at least for the next several years, may sustain demand for such products. The export market in Central and South America will also support this subsector.

The new patent law will also create a public sector market for patented drugs for which there are no generic equivalents. Canadian owners of such patents will find opportunities for direct sales or for licencing agreements.

### **PRODUCTS IN DEMAND**

Bactericides for human use have been in increasing demand, with growth of almost 50 percent during 1995. Production of medicines for the cardiovascular system grew by about 80 percent over the same period. Medicine for the blood and circulatory system grew by more than 50 percent. Drugs for the digestive system have remained stable, while production of antiparasitical, bacteriostatic and dermatological products has fallen.

# REGULATORY ENVIRONMENT

The Mexican pharmaceutical industry is heavily regulated. Pharmaceuticals may not be produced or sold in Mexico without government approval. The government also regulates prices and provides intellectual property protection for pharmaceutical formulas and production processes.

### **HEALTH REGULATIONS**

The Secretaria de Salud (SS), Secretariat of Health, is responsible for approval of pharmaceutical products imported into Mexico. A decree published in the *Diario Oficial*, Mexican National Gazette, on 27 December 1995 identifies the products subject to prior authorization. The list includes about 50 Harmonized System (HS) categories in the 3003 and 3004 groups.

An import permit must be obtained before these products can enter Mexico. Compliance with these regulations is the responsibility of the importer, but the exporter will have to provide much of the documentation. An application for an import permit must be accompanied by a physical, chemical or microbiological analysis, as well as a sanitation certificate and a certificate of free sale. The SS samples and tests pharmaceuticals when they are imported into Mexico for the first time. Products falling under the SS regulations are exempt from Mexico's general labelling regulations for retail products, because the SS regulations include their own labelling requirements.

### LABELLING REGULATIONS

Health care products which are not listed in the 27 December 1995 decree must still be registered with the Secretaría de Salud (SS), Secretariat of Health. An import permit is not required, but the SS must be notified of each shipment. A letter or form of notification must accompany the same set of documents that are required for an import permit. Products in this category must comply with Mexico's general labelling requirements if they are destined for retail sale. The labelling regulations are set out in a decree published in the Diario Oficial on 26 December 1995. These regulations have been in a state of constant revision since 1994, and exporters should verify the requirements with the importer prior to shipment. Spanish-language labels must be affixed to the product before they can enter Mexico.





### PRICE CONTROLS

Traditionally, pharmaceutical prices have been tightly regulated to ensure a supply of low-cost drugs to the Mexican public. These controls were liberalized beginning in 1991, as part of the government's broad reforms designed to expand the role of market forces in the economy.

In 1991, the government implemented the *Programa de Modernización de la Industria Farmacéutica*, Modernization Program of the Pharmaceutical Industry. Part of this program was an initiative to widen profit margins and encourage capital spending on modernization and expansion. During the three years ending in 1994, prices rose 28 percent. Further price increases were allowed in 1995, to bring them into line with the cost of imported inputs, which had risen because of the peso devaluation beginning in December 1994.

### PHARMACEUTICALS AND NAFTA

Pharmaceuticals should be among the products that benefit most from the tariff reductions under the North American Free Trade Agreement (NAFTA). Third countries face tariffs set at Mexico's maximum of 20 percent. Tariffs on Canadian and American pharmaceuticals were 14 percent in 1995 and will be phased out entirely by 1 January 2003.

In spite of the tariff reductions, access to pharmaceutical markets in all three countries is limited by regulations intended to ensure the efficacy and purity of drugs sold to the public. Drugs approved for sale in one country do not automatically receive approval in the other two.

This situation has led to what is reportedly the first instance of a private suit against a government under the provisions of NAFTA. A Mexican drug manufacturer has filed suit against the Government of Canada, claiming that Canada's drug regulations are more restrictive than those of the US or Mexico.

In March 1996, a complaint was filed against Canada under NAFTA by the Mexican company Signa, of Toluca, which produces fine chemicals and pharmaceutical intermediaries. Signa operates a joint venture with the Canadian company ACIC of Brantford, Ontario, also known as Apotex. According to media reports, the joint venture planned to produce a generic version of the pharmaceutical Cipro, for sale in Canada, as well as in other markets. The complaint alleges that Canada has impeded Signa's efforts to enter the Canadian market. Signa is seeking compensation totalling C \$50 million to make up for lost revenues. In a media interview, Signa's lawyer said that this is the first time an investor has brought a case directly against another government under NAFTA.

# MARKET ENTRY STRATEGIES

There are three principal approaches to selling pharmaceutical products in the Mexican market. Canadian companies can sell to the private sector through a distributor, enter into a joint venture with a Mexican drug manufacturer, or bid directly on public tenders for public sector procurement.

Contacts with distributors and potential partners are often accomplished through participation in trade shows. The leading trade show is *Expo Farma/Interphex*. The 1997 event will be held in Mexico City in May 1997.

Pharmaceutical distributors are included in the *Guía de Proveedores y Servicios en el Área de La Salud*, published by *Ediciones PLM*, of Mexico City. Drug manufacturers are listed in the directory of the *Instituto Mexicano de Ejecutivos de Finanzas*. Help is also available from the Canadian Embassy in Mexico City and from the consulates in Monterrey and Guadalajara.

Procurements of pharmaceutical products by the Sistema Nacional de Salud, National Health Care System, are done primarily through public tenders. Mexican companies receive preference. Although these preferences will be eliminated under the North American Free Trade Agreement (NAFTA) by 2001, a joint venture with a Mexican firm is probably the most effective strategy in the medium-term for accessing this market. In spite of the preferences, more than 10 percent of public procurements are already directed to foreign firms. In most cases, this involves specialized products not produced in Mexico. The list of such products has expanded under more rigorous patent regulations introduced in 1994.

The Ley de Adquisiciones Públicas, the Public Procurement Act, governs all purchases within the Sistema Nacional de Salud. The health system and its procurement practices are described in detail in the Market Profile on Medical Equipment and Health Care Services which is part of the Department of Foreign Affairs and International Trade (DFAIT) Export *i* Mexico series and available through the InfoCentre.

### **KEY CONTACTS**

### CANADA

### **Canadian Government**

### Department of Foreign Affairs and International Trade (DFAIT)

DFAIT is the Canadian federal government department most directly responsible for trade development.





The **InfoCentre** should be the first contact point for advice on how to start exporting. It provides information on export-related programs and services, acts as an entry point to DFAIT's trade information network, and can provide copies of specialized export publications and market information to interested companies.

### InfoCentre

Tel.: 1-800-267-8376 or (613) 944-4000 Fax: (613) 996-9709 FaxLink:\* (613) 944-4500 InfoCentre Bulletin Board (IBB): Tel.: 1-800-628-1581 or (613) 944-1581

Internet:

http://www.dfait-maeci.gc.ca

\*FaxLink is a faxback system which provides summaries on a range of Mexican markets. It must be contacted through your fax machine. Dial from your fax phone and follow the voice prompt instructions.

The Trade and Economic Division of the Embassy of Canada in Mexico can provide vital assistance to Canadians venturing into the Mexican market. The trade commissioners are well-informed about the market and will respond in whatever measures possible to support a Canadian firm's presence in Mexico.

### Trade and Economic Division

The Embassy of Canada in Mexico Schiller No. 529 Col. Polanco 11560 México, D.F. México Tel.: (52-5) 724-7900 Fax: (52-5) 724-7982

### **Canadian Consulate**

Edificio Kalos, Piso C-1 Local 108-A Zaragoza y Constitución 64000 Monterrey, Nuevo León México Tel.: (52-8) 344-3200 Fax: (52-8) 344-3048

# Canadian Consulate

Hotel Fiesta Americana Local 30-A Aurelio Aceves No. 225 Col. Vallarta Poniente 44110 Guadalajara, Jalisco México Tel.: (52-3) 616-6215 Fax: (52-3) 615-8665

International Trade Centres have been established across the country as a convenient point of contact to support the exporting efforts of Canadian firms. The centres operate under the guidance of DFAIT and all have resident trade commissioners. They help companies determine whether or not they are ready to export, assist firms with market research and planning, provide access to government programs designed to promote exports, and arrange for assistance from the trade commissioners in Ottawa and trade officers abroad. Contact the International Trade Centre nearest you.

World Information Network for Exports (WIN Exports) is a computerbased information system designed by DFAIT to help Canada's trade development officers abroad match foreign needs to Canadian capabilities. It provides users with information on the capabilities, experience and interests of more than 24,000 Canadian exporters. For general information, call (613) 944-4WIN (4946); to register on WIN Exports, call (613) 996-2057, or fax 1-800-667-3802 or (613) 944-1078.

### Program for Export Market Development (PEMD)

PEMD is DFAIT's primary export promotion program. It supports a variety of activities to help Canadian companies expand into export markets. PEMD shares up to 50 percent of eligible expenses. Program financial assistance is a repayable contribution, not a grant, and must be approved in advance. For general information, call the InfoCentre at 1-800-267-8376. For applications for assistance through this program, call the International Trade Centre nearest you. In Quebec, PEMD is administered by the 13 regional offices of the Federal Office of Regional Development (FORD Q).

### Industry Canada

#### **Health Industries Branch**

Industry Canada 235 Queen Street Tenth Floor, East Tower Ottawa, ON K1A 0H5 Tel.: (613) 954-3077 Fax: (613) 952-4209

### Canadian International Development Agency (CIDA)

CIDA is an important possible source of financing for Canadian ventures in Mexico. A special fund is available through CIDA under the Industrial Cooperation Program (INC). This program provides financial contributions to stimulate Canadian privatesector involvement in developing countries by supporting long-term business relationships such as joint ventures and licensing arrangements. For more information, call (819) 997-7905, or fax (819) 953-5024.

# Export Development Corporation (EDC)

EDC helps Canadian exporters compete in world markets by providing a wide range of financial and risk management services, including export credit insurance, financing to foreign buyers of Canadian goods and services, and guarantees.

EDC has established relationships with leading commercial and public sector institutions in Mexico and Latin America. For information on the full range of EDC services, call (613) 598-2500, or fax (613) 598-6858.





### Revenue Canada

Revenue Canada, Trade Administration Branch provides service in English, French and Spanish. Revenue Canada publications and customs notices are also available by calling or faxing the NAFTA Information Desk: 1-800-661-6121 or (613) 941-0965; fax: (613) 952-0022.

### Business and Professional Associations

# Canadian Pharmaceutical

Association 1785 Alta Vista Drive Ottawa, ON K1G 3Y6 Tel.: (613) 523-7877 Fax: (613) 523-0445

#### **Canadian Council for the Americas**

Executive Offices 360 Bay Street Suite 300 Toronto, ON M5H 2V6 Tel.: (416) 367-4313 Fax: (416) 367-5460

#### Alliance of Manufacturers and Exporters Canada

99 Bank Street Suite 250 Ottawa, ON K1P 6B9 Tel.: (613) 238-8888 Fax: (613) 563-9218

# Alliance of Manufacturers and Exporters Canada

75 International Boulevard Fourth Floor Etobicoke, ON M9W 6L9 Tel.: (416) 798-8000 Fax: (416) 798-8050

### The Canadian Chamber of Commerce

55 Metcalfe Street Suite 1160 Ottawa, ON K1P 6N4 Tel.: (613) 238-4000 Fax: (613) 238-7643

### Forum for International Trade and

**Training Inc.** 155 Queen Street Suite 608 Ottawa, ON K1P 6L1 Tel.: (613) 230-3553 Fax: (613) 230-6808



240 Sparks Street RPO Box 55011 Ottawa, ON K1P 1A1 Tel.: (613) 523-3510

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### **Open Bidding Service**

P.O. Box 22011 Ottawa, ON K1V 0W2 Tel.: 1-800-361-4637 or (613) 737-3374

## **Canadian Standards Association**

178 Rexdale Blvd. Etobicoke, ON M9W 1R3 Tel.: (416) 747-4000 Fax: (416) 747-4149

### **Standards Council of Canada**

45 O'Connor Street Suite 1200 Ottawa, ON K1P 6N7 Tel.: (613) 238-3222 Fax: (613) 995-4564

### Mexican Embassy in Canada

Embassy of Mexico 45 O'Connor Street Suite 1500 Ottawa, ON K1P 1A4 Tel.: (613) 233-8988 Fax: (613) 235-9123

### MEXICO

### **Government Departments**

Secretariat of Health General Directorate for the Control of Health Products Secretaría de Salud (SS) Dirección General de Control de Insumos para la Salud Departamento de Dictamen Técnico Registro y Revisión de Medicamentos Av. Mariano Escobedo No. 373 Col. Chapultepec Morales 11570 México, D.F. México Tel.: (52-5) 254-0962/2525, Fax: (52-5) 250-6962

### Secretariat of Health General Directorate for the Sanitary Control of Goods and Services Secretaría de Salud (SS)

Dirección General de Control Sanitario de Bienes y Servicios Av. Donceles No. 39, Piso 1 Col. Centro 06010 México, D.F. México Tel.: (52-5) 521-3050/9134 Fax: (52-5) 512-9628

### Secretariat of Health General Directorate for Public Health Services of the Federal District

Secretaría de Salud (SS) Dirección General de Servicios de Salud Pública del Distrito Federal Av. José Antonio Torres No. 661, P.B. Col. Asturias 06850 México, D.F. México Tel.: (52-5) 740-0633/2306 Fax: (52-5) 740-6633

### Secretariat of Health

General Directorate for Purchasing Secretaría de Salud (SS) Dirección General de Recursos Materiales y Servicios Generales Paseo de la Reforma No. 506, Piso 22 Col. Juárez 06600 México, D.F. México Tel.: (52-5) 553-1376/8901 Fax: (52-5) 286-9705

### Mexican Institute for Social Security (Medical Center Division) Instituto Mexicano del Seguro Social (IMSS) División de Centros Médicos Av. Durango No. 289, Piso 9 Col. Roma 06700 México, D.F. México Tel.: (52-5) 553-8424, 286-3877 Fax: (52-5) 286-2948





Mexican Institute for Social Security **Division for Consumer Goods** Purchasing Instituto Mexicano del Seguro Social (IMSS) Subjefatura de Adquisiciones de Bienes de Consumo Calzada Vallejo No. 675 Col. Magdalena de las Salinas 07760 México, D.F. México Tel.: (52-5) 587-4422 ext. 1622/1623/1624 Fax: & Tel.: (52-5) 587-4422, ext. 1622

### Institute of Social Security and

Services for Public Employees Instituto de Seguridad y Servicios Sociales para los Trabajadores del Estado (ISSSTE) Av. San Femando No. 547 Edificio B, P.B. Barrio de San Femando 14070 México, D.F. México Tel.: (52-5) 606-8258 Fax: (52-5) 606-7383

### Institute of Social Security and Services for Public Employees Acquisition Division

Instituto de Seguridad y Servicios Sociales para los Trabajadores del Estado (ISSSTE) Subdirección de Adquisición Callejón Vía San Femando No. 12, Piso 4, Barrio de San Fernando 14070 México, D.F. México Tel.: (52-5) 606-7008 Fax: (52-5) 606-5766

Banco de Comercio, S.A. (Bancomer) Av. Universidad No. 1200 Col. Xoco 03339 México, D.F. México Tel.: (52-5) 621-3301/3302, 621-0034 Fax: (52-5) 621-3988 National Institute for Statistics, Geography and Informatics General Directorate of Politics and Informatics Standards Instituto Nacional de Estadística, Geografía e Informática (INEGI) Dirección de Políticas y Normas en Informática Av. Patriotismo No. 711-A, Piso 10 Col. San Juán Mixcoac 03730 México, D.F. México Tel.: (52-5) 598-7617/7490 Fax: (52-5) 598-7738

### National Oil Company

Petróleos Mexicanos Internacional (PMI) Av. Marina Nacional No. 329 Torre Ejecutiva, Piso 20 Col. Huasteca 11311 México, D.F. México Tel.: (52-5) 227-0010 Fax: (52-5) 227-0012

### Mexican Business and Professional Organizations

National Chamber of the Pharmaceutical Industry Cámara Nacional de la Industria Farmacéutica (Canifarma) Av. Cuauhtémoc No. 1481 Col. Santa Cruz Atoyac 03310 México, D.F. México Tel.: (52-5) 688-9616 Fax: (52-5) 688-9714

### **National Retailers Association**

Asociación Nacional de Tiendas de Autoservicios y Departamentales (ANTAD) Av. Homero No. 109, Piso 11 Col. Chapultepec Polanco 11560 México, D.F. Mexico Tel.: (52-5) 254-1714/6620 Fax: (52-5) 202-4495

### Mexican Assocation of Insurance Institutions

Asociación Mexicana de Instituciones de Seguros (AMIS) Av. Madero No. 21 Col. Tlacopac, San Angel 01040 México, D.F. México Tel.: (52-5) 662-0153 Fax: (52-5) 662-8036

### Trade Fairs .

### EXPO FARMA '97

May 13-16, 1997 ExhibiMex Asociación Farmacéutica Mexicana, A.C. Av. Antonio M. Anza y Av. Cuauhtémoc Col. Doctores México, D.F. México Tel.: (52-5) 524-0993 Fax: (52-5) 534-5098

### Mexican Media

Business Mexico (Monthly) Carlos Pozos, Advertising The American Chamber of Commerce of Mexico Lucema No. 78, Col. Juárez 06600 México, D.F. México Tel.: (52-5) 724-3800 Fax: (52-5) 703-2911/3908

### Expansión

(Twice monthly) Sinaloa No. 149, 9th. Floor Col. Roma Sur 06700 México, D.F. México Tel.: (52-5) 207-2066 Fax: (52-5) 511-6351

*El Financiero* Weekly International Edition 2300 S. Broadway Los Angeles, CA 90007 USA Tel.: (213) 747-7547, (1-800) 433-4872 Fax: (213) 747-2489





### **Pharmaceutical Distributors Guide**

El Guía de Proveedores ý Servicios en el Area de Salud Ediciones PLM Organización Ponce S.A. de C.V. Av. San Bernardino No. 17 Col. del Valles 03100 México, D.F. México Tel.: & Fax: : (52-5) 687-1214

### Selected Mexican Distributors

Casa Autrey, S.A. de C.V. Av. Netzahualcoyotle No. 79 Col. Centro 06080 México, D.F. México Tel.: (52-5) 227-4500 Fax: (52-5) 227-4560 CASA Marzam, S.A. de C.V. Av. Municipo Libre No. 198 Col. Portales 03300 México, D.F. México Tel.: (52-5) 605-1967 Fax: (52-5) 625-2701

NADRO, S.A. de C.V. Ave. Londres No. 107, Piso 8 06600, México, D.F. México Tel.: (52-5) 207-2055 Fax: (52-5) 208-5226



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