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 foreign-developed 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 *Secretaría 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.