



MEXICAN PHARMACEUTICAL INDUSTRY

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Overview

In terms of sales, Mexico has become a very profitable market for pharmaceuticals. The Mexican pharmaceutical market is the leading and the most developed in Latin America and the ninth largest worldwide, with sales valued at US\$13.5 billion in 2006.

The private sector holds approximately 80% of the total value of the market, and the public sector 20%, but in terms of distribution, the public health sector traditionally dispenses the largest amount, although of a limited number of products and brands, to the Mexican population.

Mexico is a significant regional producer. International and domestic producers compete in the market and Mexico has become an important exporter of pharmaceuticals towards Europe and the U.S. Approximately 390 companies, domestic and multinational, manufacture pharmaceutical products in Mexico.

The import market represents 13% of total sales, with the largest share of imports coming from the United States, country that holds a 25% share of the total import market.

It is expected that in the coming years, domestic production will lose market participation against imported products, especially those coming from Canada and the U.S., due to a strong demand for hi-tech branded imported medicines.

Some other factors are contributing to fuel the growth of imported products: the North American Free Trade Agreement has eliminated import duties for U.S. pharmaceutical products, the compliance with intellectual property rights, the advances in patent and trademark protection, and the overall improvements in the business and regulatory environments.

The market outlook for legitimate, bioequivalent generics is very strong in Mexico, largely due to new government programs that are focusing on the procurement of generics and the expected liberation of more than five thousand patents in the short term. With the leading international players in off-patent medicines active, the sector is projected to be worth US\$750 million in 2010.

New pharmaceutical regulations were enforced in 2005. By updating Article 376 of the General Health Law in January 2005, product registration is no longer unlimited and now only lasts for a five-year period. At the same time, bioequivalence standards were finally fully implemented.

As a result, Mexico offers a significant untapped growth potential for the bioequivalent generics segment, which now represents only 4% of total pharmacy sales. This segment is expected to register the highest increase in the Mexican pharmaceutical market during the coming years.

Per-capita spending on pharmaceuticals in Mexico is the highest in Latin America (US\$110) and is rising at about 6% per year. Nevertheless, the country is said to be under-spending on healthcare. Against an OECD average for healthcare spending of 8.9% of GDP, Mexico allocated an estimated 6.7% of its national wealth to the sector in 2006. The systemic lack of resources is variously attributed to under-funding of the two dominant state-run premium-based reimbursement schemes, IMSS and ISSSTE, which together account for more than half of annual expenditures on pharmaceuticals. The private insurance sector accounts for only 5-6% of annual health spending. In this context, the retail pharmaceutical market remains dominant, accounting for around 75% of total sales, while out-of-pocket disbursements by consumers account for some 88% of all drug spending.

However, the government is attempting to resolve the historic inadequacies of healthcare provision in Mexico. A new scheme aiming to cover treatment costs, known as Seguro Popular, has been introduced. The program's pharmaceutical purchases were budgeted at about US\$375 million in 2006, but provision is expected to rapidly increase in the near term.

Distribution channels are becoming more competitive. There are 20 regional distributors in the country but only four leading national distributors -Casa Marzam, Casa Saba, NADRO and Proveedora de Medicamentos- dominate the pharmacy sector. Casa Saba and NADRO alone account for 60%.

According to current regulations, in order to export pharmaceutical products to Mexico, the exporting company must register and import those pharmaceutical products through a "host pharmaceutical manufacturer", a local manufacturer holding a sanitary license for such products. This firm acts as "guarantor" with the local authorities vis a vis the foreign company, in particular with regards to manufacturing practices, registration, quality control, etc.

In most cases it is recommended that foreign firms associate with a local pharmaceutical manufacturer to import and distribute their products in the Mexican market, however, a foreign company can appoint any distributor as long as the registration and the import processes are supported by the "host pharmaceutical manufacturer".

SSA Registration Requirements

There are stringent regulations for selling pharmaceutical products in the Mexican market. Their importation is basically covered by the *Ley General de Salud* (General Health Law) together with the *Reglamento de la Ley General de Salud en Materia de Insumos para la Salud* (Regulations of the General Health Law with Respect to Health Related Products) and the *Reglamento de Control Sanitario de Productos y Servicios* (Regulations for the Sanitary Control of Products and Services).

It is important to know the following information when entering the Mexican pharmaceutical market:

- All individual products need to be registered with the *Secretaría de Salud* (SSA) (Secretariat of Health) prior to their distribution in the country.
- In order to do so, the exporting company needs to associate with a local laboratory or pharmaceutical firm with manufacturing facilities in Mexico.
- This manufacturing facility needs to be certified by the *Secretaría de Salud* and by the IMSS. The latter has more stringent regulations than the other and is therefore considered more important.
- This firm acts as “guarantor” with the local authorities vis a vis the foreign company, in particular with regards to manufacturing practices, registration, quality control, etc.
- Only those companies that are manufacturing and selling locally are allowed to import pharmaceutical products. Therefore, a foreign firm needs to either associate with a local laboratory or set up its own manufacturing facility in Mexico.
- In order to be sold through the public health care system, all pharmaceuticals need to be included in the “cuadro básico” of authorized products.
- All public purchases of medicines are undertaken through public tenders. These tenders are published in the *Diario Oficial* or official gazette. Information on tenders can also be obtained at www.compranet.gob.mx.

All matters related to health are regulated by the *Ley General de Salud* (General Health Law). In its article 221 it describes a medication (*medicamento*) as “all substance or mixture of substances, of natural or synthetic origin, having a preventive, therapeutic or rehabilitating effect presented in its pharmaceutical form...”. Medications can be further classified according to Article 226 within the following fractions for their sale:

- I. Medications that can only be purchased with a medical prescription or a special permit from the SSA according to Chapter V (narcotics);
- II. Medications that can only be purchased with a medical prescription that is kept by the pharmacy and that needs to be registered in a special control book in accordance with Chapter VI (psychotropic substances). A maximum of two presentations of the same product can be prescribed and the prescription is only valid for 30 days.
- III. Medications that can only be purchased with a medical prescription and can be supplied up to three times with the same prescription. The prescription has to be stamped each time and the sale needs to be registered each time in a control book. After three times, the prescription is kept by the pharmacy.
- IV. Medications that can only be purchased with a medical prescription and can be re-supplied as many times as the doctor indicates it.
- V. Medications that do not require a prescription but can only be sold in pharmacies.
- VI. Medications that do not require a prescription and can be sold in other establishments than pharmacies.

It is the sole responsibility of the SSA to determine which medications fall into each category.

Chapter XIII deals with imports and exports. According to this, the SSA can identify, confirm, certify and oversee the sanitary quality of all imported products. In order to import medications and their raw materials it is necessary to obtain a sanitary authorization from SSA.

According to the *Reglamento de la Ley General de Salud en Materia de Insumos para la Salud* (Regulations of the General Health Law with Respect to Health Related Products) imports of pharmaceutical specialties for sale in Mexico can only be made:

- After obtaining the product registration as authorized by the SSA;
- By individuals and/ or companies that have the necessary installations to safely handle them and that can guarantee their quality control and pharmaceutical vigilance;
- These establishments need to have a sanitary license.

In order to hold the title of the sanitary registration of a medication, it is necessary to have the sanitary license issued in favor of a manufacturer or laboratory of medications or biologic products for human use (Article 168).

In order to obtain the sanitary license for a product, it is necessary to present (Article 167):

- The technical and scientific documentation that demonstrates:
 - The identity and purity of its components;
 - The stability of the finished product;
 - The therapeutic efficacy and safety in accordance with the corresponding scientific information;
- The information for prescription;
- The label project.

Additionally, in order to obtain the sanitary registration of alopatic medications manufactured abroad (Article 170), it is necessary to include the following documents:

- The free sale certificate issued by the sanitary authorities of the country of origin;
- A certificate that the company has a permit to manufacture medicines and a certificate of good manufacturing practices issued by the corresponding authority of the country of origin;
- The letter of representation, when the manufacturing laboratory abroad is not an affiliate or mother company of the laboratory requesting the registration.

In the case of products that are not listed in the *Farmacopea de los Estados Unidos Mexicanos* (Pharmacopeia of the United Mexican States), the information of pharmacopeias of other countries can be used when their analysis procedures are

undertaken in accordance with specifications and recommendations of specialized organizations or other international sources of scientific information (Article 167).

In the case of medications that have active ingredients that are not registered in Mexico but that are registered and freely sold in their country of origin, the resolution procedure should take 60 days; in the case of new molecules the determination should be provided in 90 days.

In order to register their products for sale in Mexico, foreign companies therefore have to:

1. Find a local manufacturer or laboratory holding a sanitary license and that can act as legal representative for them in Mexico. The U.S. company can not register any products directly in Mexico. The Mexican importer needs to be registered with the Secretariat of Health (*Secretaría de Salud- SSA*).
2. Determine the exact classification under the Harmonized System for its products with a competent Mexican customs broker.
3. Determine in the official gazette (*diario oficial*), which lists the classification and codification of merchandises subject to sanitary regulations by the SSA, what type of requirements are applicable to each product.
4. Through the Mexican partner, obtain the necessary registration from SSA within one of the 6 categories listed above. If an OTC registration is sought, it is necessary to reduce the number of claims and state them with words such as: “helpful in...”, “prevents...” since otherwise each and every claim has to be substantiated with clinical tests.
5. In the case of prescription medications, provide the documentation requested by SSA and/or undertake all the necessary clinical research determined by the SSA with a recognized and approved institution in order to obtain the sanitary license. These clinical studies have an estimated cost of Mex\$50,000 to Mex\$200,000 depending on the protocol and number of patients defined by SSA;
6. Obtain approval for the brand name and register it before SSA.
7. There are two separate requirements according to the classification of the product: A sanitary import notice or a prior to import sanitary permit. Either one of these will have to be processed by the corresponding directorate according to the product classification.
 - The sanitary import notice (*Aviso Sanitario de Importación*) is presented at customs and has no cost. It is prepared annually and covers all shipments made during that year. It basically includes information on the importer and the product. It also lists as annexes a sanitary certificate (*constancia sanitaria*), a free sale certificate (*certificado de libre venta*) or laboratory analysis (*análisis de laboratorio*) but there is no indication as to whether these are mandatory.

- The prior to import sanitary permit (*Permiso Sanitario Previo de Importación*) is more complex. The format for this covers a maximum of two products. If more products need to be registered, an annex to this permit needs to be requested (*Anexo de Solicitud de Permiso Sanitario Previo de Importación*). The cost for this is Mex\$1,105 (roughly US\$116). If there is a restriction of sampling, each sample has a cost of Mex\$815 (US\$86) and laboratory analysis are not included and have to be paid separately if necessary. The cost to import samples or doses for personal consumption is Mex \$144 (US\$15). The requirements to obtain this permit are:
 - i. Notice of operation (*aviso de funcionamiento*) by the Mexican company.
 - ii. Duly filled format requesting the permit.
 - iii. Import classification under the Harmonized System Code.
 - iv. Original form of the sanitary certificate issued by the country of origin. This should include a certification that the lot is fit for human consumption, the physical and chemical composition, microbiological analysis, specific analysis if necessary, geographical origin and effective time period.
 - v. If this sanitary certificate is not available all of the following documents need to be submitted: Free sales certificate, certificate of origin, physical and chemical analysis, microbiological analysis and specific analysis if applicable.
 - vi. Labels in Spanish.

For more information, see www.ssa.gob.mx in the section on procedures (*tramites*). All formats are also available in the site.

Labeling Requirements

Specific labeling requirements established by the *Reglamento de la Ley General de Salud en Materia de Insumos para la Salud* (Regulations of the General Health Law with Respect to Health Related Products) determine that all products need to have a label including the following information:

- Generic name;
- Distinctive name (product name);
- Declaration of active ingredients;
- Identification and address of the manufacturer and distributor if applicable;
- Instructions for conservation;
- Expiration date;
- Lot number;
- Dosage and ways of administration;
- Precautionary information, including on risks during pregnancy;
- Warnings;
- Information or symbol identifying it as a Generic Interchangeable Medication;
- Sanitary registration number.

When the information is provided in another language, it also needs to be written in Spanish in at least the same size, from the country of origin.

The Official Mexican Standard (NOM) that determines labeling requirements on medicines for resale in Mexico is NOM-072-SSA1-1993. According to this NOM, the text contained in the label(s) must first be approved by SSA. A draft label is required when applying for SSA's registration. All of the information described by this NOM must be covered and in Spanish, even if it contains information in other languages. This Mexican Official standard is mandatory for all medicines to be sold in Mexico as well as for medical samples. It does not apply to homeopathic products.

Section 5 of this NOM describes the information that label must contain. The most important elements are:

1. Brand name
2. Generic name
3. Pharmaceutical form
4. Concentration of the active ingredient
5. Formula stating the word "Formula"
6. The formula declaration must state the generic name of the pharmaceuticals used, their amount, and base equivalent.
7. Dosage
8. Ways of administration
9. Conservation and storage data
10. Warnings and precautions
11. Sanitary registration code (this code must be exactly as it appears in the SSA's official registration document followed by the classification under which the product falls (Roman I to VI see Article 226 above)
12. Lot number
13. Expiration date
14. Manufacturer's data (in this section, data for both the U.S. manufacturer and the Mexican distributor must be included)
15. Contents: units, volume, weight, etc.
16. Maximum retail price
17. Secondary containers
 - 17.1. Brand name
 - 17.2. Generic name
 - 17.3. Pharmaceutical form
 - 17.4. Concentration
 - 17.5. Content description
 - 17.6. Formula
18. The rest of the information described in sections 5 and 6 of the standard must be distributed all over the surface.
19. If product comes only in one container, this must include all of the information.
20. Labels for small containers (ampoules, flasks up to 5 ml, sachets, pre-filled syringes, etc.), and collective or additional packaging are further described in the NOM.

21. When there is information in a language other than Spanish, they must correspond in size and font type.
22. In no case will it be permitted to cover the original information with a sticker without SSA's authorization.

Medicines may include a leaflet with instructions when these cannot fit into the labeling area, and are required by the nature of its handling, use, or preparation.

NOM-072 also provides the specific data for medicines distributed by the public sector and the GI (Generico Intercambiable - Exchangeable Generic) line.

Additional Requirements

The basic Mexican import document is the “pedimento de importación”. This document must be accompanied by a commercial invoice in Spanish, a bill of lading, and documents demonstrating guarantee of payment of additional duties for undervalued goods if applicable, and documents demonstrating compliance with Mexican product safety and performance regulations if applicable. The import documentation must be prepared and submitted by a licensed Mexican customs broker.

Products qualifying as North American under NAFTA must use the NAFTA Certificate of Origin in order to receive preferential NAFTA treatment. This may be issued by government agencies, producers, exporters, industrial and commercial chambers or associations that are legally authorized in the U.S. or other countries, and does not have to be validated or formalized.

Mexico has also recently begun requiring certificates of quality before certain products can be sold in Mexico.

All products entering into Mexico must have a free sale certificate. This certificate proves that the imported goods are also sold in the country of origin. A letter from the local chamber of commerce stating that this product is sold in the local market is sufficient proof for this requirement.