



2016 Top Markets Report **Medical Devices** Country Case Study

Mexico

Mexico is a sizeable market for all types of medical devices. Imports of equipment, instruments, disposable and dental products reached \$4.1 billion in 2014. Imports of U.S. products are duty free if they comply with the NAFTA certificate of origin. U.S. products are valued because of their high quality, after sales service and good prices compared to competing products. U.S. companies should take advantage of geographical proximity to start or grow their presence in Mexico.

Overall Rank

11

Market Entry

All medical equipment and devices can be imported duty free with a NAFTA certificate of origin. Imports are subject to a 16 percent VAT tax. All medical and health care products that touch or affect the human body must be registered with the Mexican Secretariat of Health (SSA) prior to sale or use in Mexico. Foreign manufacturers need a legally appointed Mexican distributor/ representative, who will be in charge of obtaining the sanitary registration/ market approval and will be the responsible for the product(s) in Mexico. The Commercial Service in Mexico can provide a detailed list of requirements and advice for processing market approval in that country for U.S. medical devices.

Current Market Trends

Most large public and private hospitals desire modern and very specialized medical devices. Some medium and small private hospitals with limited budgets buy used or refurbished equipment. Public hospitals by law cannot buy used or refurbished products. In order to save resources, recently, many public and private hospitals have been hiring companies that offer “integral surgery services” and provide service “per event,” offering all the

Country Highlights

Capital: Mexico City
Population: 120 million (est. 2013)
GDP (USD): 1.26 trillion (2014)
Currency: Mexican peso (MXN)
Language: Spanish
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necessary products required to perform a surgery. This concept has been expanded to other areas where hospitals can use integral suppliers for different processes, like sterilization. In this way, hospitals avoid making large investments in materials, pharmaceuticals and instruments and also reduce the costs involved in keeping and controlling inventories and maintaining instruments for specialized surgeries.

All public institutions ask suppliers to register with their organization. These institutions may award purchases under \$3,100 directly to a selected provider. Purchases over that amount must be done through public tenders. All private health care facilities select suppliers by requesting price

quotations. Their decisions are based on the best equipment at the best price.

Main Competitors

Most large international corporations offering medical devices have a presence in Mexico. Medium and small foreign suppliers usually sell through legally appointed distributors.

Current Demand

Public health care institutions account for 70 to 80 percent of total medical services provided nationwide while private health care institutions cover approximately 25 to 30 percent of the Mexican population, including 32 million people with private medical and accident insurance. Some patients affiliated with social security also have private medical insurance.

In the public sector, there are 1,169 hospitals, 194 of which are highly specialized medical units. In the private sector of 3,560 hospitals, only about 100 have over 50 beds and offer highly specialized medicine. Most of the hospitals offering specialty health care services are located in medium and large Mexican cities. There are also some medium sized private hospitals that offer specialty services and focus on high income, insured patients.

Imports supply about 80 percent of medical equipment and instruments and about 40 percent of medical disposable and dental products. In 2014, total imports in these four groups of products reached \$4.1 billion. Of these imports, 55 percent, or \$2.3 billion dollars, were of U.S. origin. Main competitors are from Belgium, Brazil, Canada, China, France, Germany, Israel, Italy, Japan, the Netherlands, South Korea and the United Kingdom.

Barriers

Obtaining sanitary registration and market approval of medical devices is often technical and time-consuming, but products that have been approved by the U.S. FDA generally are also approved in Mexico. Due to a shortage in resources, there have been some delays in receiving registration and marketing approvals from COFEPRIS, the Mexican Agency in charge of registering and approving medical devices, in the last two years.

COFEPRIS has worked closely with the industry to deregulate products that do not cause patient risk. On December 22, 2014, COFEPRIS published an agreement containing a list of 2,242 products that are no longer considered medical devices and, therefore, do not require sanitary registration/market approval in Mexico and can be freely imported. This list is to be updated periodically. COFEPRIS is also analyzing other ways to expedite the sanitary registration of FDA-approved medical devices.

To be imported into Mexico, some medical products need to comply with technical standards or NOMs (Norma Oficial Mexicana). Classification is based on the Harmonized System (HS).

There are few Mexican standards for medical devices, but various agencies are preparing more standards to be issued in the near future. Updated information on NOMs and other sanitary processes is available through COFEPRIS (www.cofepris.gob.mx).

Trade Events

AMIC Dental
November • Mexico City, Mexico • amicdental.com.mx

Expomed
June • Mexico City, Mexico • expomed.com.mx

Expo DICLAB
September 2016 • Mexico City, Mexico • expodiclab.com Clinical and scientific laboratory products.

Specialized events are also organized by medical academies and associations and may be excellent opportunities for companies offering high-technology medical devices.

Resources

Public Institutions
www.cofepris.gob.mx
www.salud.gob.mx
imss.gob.mx
www.issste.gob.mx
cenetec.salud.gob.mx

Private Hospitals

grupoempresarialangeles.com

hsj.com.mx

abchospital.com.mx

medicaltravel.com.mx

medicasur.com.mx

Additional Market Research

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COFEPRIS in English

<http://www.cofepris.gob.mx/paginas/idiomas/ingles.aspx>