

MEDICAL DEVICES SECTOR

In 2018, Mexican government declared the pharmaceutical and medical devices industry a “Strategic Industry to Mexico’s social and economic development and the health of the nation”. The production of the medical device industry was USD\$12,700 million and the consumption was USD\$11,521 million in 2016.

According to ProMéxico¹, Mexico is the third-largest producer and exporter of medical devices in Latin America and the eighth worldwide. There are just over 150 companies producing medical devices in Mexico and 641 exporting companies were recorded in 2016.

Mexico exported USD\$9.04 billion and imported USD\$4.83 in 2016. The main exports were medical, surgical, dental or veterinary instruments and devices, orthopedic articles, mechano-therapy appliances, surgical furniture and apparatus base on the use of X-rays.

The medical devices sector is dynamic, fast-growing and technologically intensive. In this sector, efforts have been made to deregulate the market and the requirements to register inputs that do not pose a health risk, promote the industry by introducing new rules, accompany investment projects and create mechanisms for the transfer of know-how.

According to José Alarcón, PwC Mexico Dean Partner & Strategic Advisor for PwC Health &Pharma LS, in case of the production and distribution of medical devices for domestic market. Alarcón says: “The sector is looking to innovate by providing integrated solutions rather than selling devices in isolation. Over a five-years period (2017-2023), Latin America is expected to be the fastest-growing region in the world, 4,7% and for its part, within this region, Mexico will grow 6,5% - base on Allied Market Research Data.”

In Mexico, the medical devices industry is undergoing exponential development. According to ProMéxico, every year in Mexico the industry manufactures devices worth USD\$12 billion, three-quarters of which are exported. Mexico’s main trade partner in the sector is the US, with 92,8% of its exports going to this country.

The AMID (Mexican Association of Innovative Medical Devices Industry) brings together 32 manufacturing companies – as a whole employing 80 000 people – which work together with the authorities to promote more efficient and transparent regulatory and acquisition processes and contribute to the safety, quality and effectiveness of medical technologies for health services.

Mexico has long manufactured simple devices such as syringes and needles – which hold third and fourth place respectively on the global level and increasingly produces more technologically complex items.

There are six medical device clusters in Mexico and 2 478 economic units were recorded in 2017. The most important clusters in the country are situated in Baja California and Chihuahua. Productos Médicos de las Californias in Baja California represents approximately 50% of the total national exports of the sector and 75 enterprises in total, with 65% of them established in Tijuana. BioMed Ciudad Juárez with more than 20 enterprises and a binational association Mexico-US. The other part of the production is in the states of Estado de México, Jalisco and the Bajío region and to a lesser extent Morelos and Puebla. Until now the medical devices

¹ ProMéxico was the federal government agency responsible for coordinating strategies aimed at strengthening Mexico’s participation in the international economy, supporting the process of exporting and the internationalization of Mexican firms.



sector in Mexico has focused mainly on manufacturing and there thus remain great opportunities for consumption and innovation in accordance with Juan Carlos Jiménez Rincón, president of the AMID.

Foreign Direct Investment into the sector reached an accumulated amount of USD\$2,124 million for the period 2005-2016. The main investor countries were USA, Netherlands, Germany and Italy. In 2016, total flows of FDI into Mexico reached USD\$211 million.

Mexico offers lower operation and labor costs for every level of specialization, as well as lower manufacturing costs for medical equipment, electronic devices and precision components, in comparison to countries that are representative of the industry.

REGISTRATION PROCESS

The process of launching a new medical product that requires registration in Mexico is a tedious, expensive and above all, time-consuming process.

The most difficult stage is to obtain a document called *Registro Sanitario*, which entitles its holder to distribute the product in Mexico and is issued by the Federal Commission for the Protection Against Sanitary Risks (COFEPRIS).

“Registro Sanitario” step by step:

1. Getting familiar with the list of COFEPRIS requirements. They depend on what security class the device has been qualified for. Listed documents are the absolute minimum that must be presented, in addition, the office has the right to request other documents if it deemed necessary (see: *Prevención*).
2. Collecting required documentation, translating it entirely into Spanish (simple translation). At this part of the process, there may be a problem to obtain the documentation required by COFEPRIS from the manufacturer (manufacturer does not have documentation or does not meet the requirements office). The process of collecting and translating documents is a tedious process that requires knowledge and technical knowledge of the language.
3. Getting the so-called *Legal documents*, eg. Free Sales Certificates, ISO or CE Certificates, Proxies. Legal documents must be accompanied by an apostille, certified by a notary in Mexico and translated by a Mexican certified translator.
4. Making a payment for processing the application and issuing the Register.
5. Submission of an application for issuing the Device Register with a complete set of documents in COFEPRIS. From this moment, one should be patient and await the response of the office. The status of the application can be monitored on the office’s website, but there is no chance of any acceleration of the process. Theoretically, the answer should be given within 3 months, but sometimes it takes years to get the answer.
A good solution may be to search help of a company supporting the product registration process, the so-called *Terceros Autorizados*. For payment, they may complete the whole process of Registro Sanitario or its part.
6. COFEPRIS’ response to the application:
 - Positive answer, that is, the office issues the *Registro Sanitario* document;
 - *Prevención* – the office requires submission of supporting documentation and indicates the date by which the required documents should be submitted.



Summing up, the introduction of a medical product to the Mexican market is difficult but not an impossible process.

SECTOR-RELATED CHAMBERS AND ASSOCIATIONS

- **National Chamber of the Transformation Industry (CANACINTRA)** is an autonomous and public organization that facilitates the development of the national industry through interaction with the federal, state and municipal governments, as well as with legislators, to make proposals in favor of companies.
<http://www.canacintra.org.mx/>
- **National Chamber of the Pharmaceutical Industry (CANIFARMA)** operates under the supervision of the Ministry of Economy and the Mexican Business Information System (SIEM) and represents health care companies through policies, programs, instruments, and promotion.
<http://www.canifarma.org.mx/>
- **Mexican Association of Innovation and Medical Device Industry (AMID)** is a group of global medical device leaders committed to the growth of the sector in Mexico.
<http://amid.org.mx/>
- **National Council of the Export Manufacturing Maquila Industry (Index)** represents the Export Manufacturing and Maquila Industry. The leading export companies of medical devices in Mexico belong to the council.
<http://www.index.org.mx/>
- **Productos Médicos de las Californias in Baja California.** Group of key representatives of the sector, suppliers, universities and government agencies. It has almost 90 companies within it.
<https://www.industriamedica.org/>
- **Cluster BioMed Ciudad Juarez.** It has more than 30 enterprises. Binational association Mexico-US. Specialized production of medical devices, infrastructural, and competitiveness.
<http://clusterbiomedjr.com/>

TRADE FAIRS

- **ExpoMED** is the largest International Business Forum in Mexico aimed at health professionals and each year presents the most complete offer of medical equipment, medicines, cutting-edge technologies, products and services for prevention, care and recovery of the health.
Date: June 5-7th, 2019
Address: Centro de Exposiciones y Convenciones – World Trade Center, Montecito 38, Nápoles, 03810, Mexico City.
<https://expomed.com.mx/>

For more information about the Medical Devices Sector, contact Trade Office in Mexico City:

Julio César Acevedo Guzmán
Business Expert 1
julio.acevedo@paih.gov.pl
Tel. +52 55 5211 5076