

# MedTech Mexico Market Overview



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## 1. Introduction

**Locating opportunities in the MedTech sector in Mexico.** It is essential to understand the Irish MedTech offer. Enterprise Ireland<sup>1</sup> has a total of 123 companies listed as MedTech companies, twenty-four of which have a footprint in LATAM with seven operating in Mexico.

The Healthcare sector is comprised of a variety of services to support the healthcare needs of a community.

A universally agreed-upon classification of sectors does not exist. Yet to perform an analysis of Ireland's healthcare offer, we broadly classified them into:

- OEM / Manufacturing Sub-Supply
- Medical devices, equipment, and supplies
- Digital health
- End-to-end solutions for companies, logistics, engineering, and maintenance services
- Research, Pharmaceuticals & Related Segments
- Others

Some companies fall into the definition of more than one sector. For instance, some are OEMs and provide maintenance services.

### 1.1. Original Equipment Manufacturer (OEM) /Manufacturing Sub-supply

**Definition:** Companies whose goods are used as components in another company's products which in turn sell the finished item to users.

**Percentage of companies in the sector:** 29/123 = 23.5%.

**Presence in LATAM and Mexico:** 9 (31%) have a market in LATAM, 3 (10.3%) in Mexico, 1 (3.4%) have its manufacturing facilities in Mexico.

**Overview of products and services:** moulding (including injection moulding and micromoulding with laser), CNC machining, precision engineering.

**Specific areas:** neurovascular, cardiovascular (including catheters), orthopedics, wound care.

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<sup>1</sup> Enterprise Ireland, The Irish Advantage, Medtech Irish Companies, Accessed January 07, 2022 Referenced from: <https://irishadvantage.com/>

## 1.2. Medical devices, equipment, and supplies

**Definition:** Companies that sell finished products to users, including medical devices, medical equipment, and medical supplies.

**Percentage of companies in the sector:**  $25/123 = 20.32\%$ .

**Presence in LATAM and Mexico:** 5 (20%) in LATAM, 1 (4%) is mentioned as a worldwide market but is unspecified, 1 (4%) in Mexico.

**Overview:** Most companies manufacture medical devices (17). Specific areas of interest: cardiovascular and respiratory sensors, ultrasound devices, orthopedics, prosthetics, dermatology devices, devices for lung disease, air filters, catheters, vascular closure devices, microscopes, and HD cameras; as well as devices for urine incontinence and wound care.

The remaining companies provide medical equipment or supplies, including mattresses and supports in order to avoid the development of pressure ulcers, refrigeration systems, personal protection equipment, medical supplies (e.g. gloves), medical emergency products, and labels for hospital use.

## 1.3. Digital health

**Definition:** companies that develop mobile medical apps and software that support clinical decisions, assist healthcare providers in administrative work, or provide tools for patients.

**Percentage of companies in the sector:**  $24/123 = 19.5\%$ .

**Presence in LATAM and Mexico:** 2 (8%) have a market in LATAM, 1 (4%) in Mexico.

**Overview:** Most companies can be grouped into two areas, both of which would be the first two that are previously described. Seven companies provide solutions to manage medical records, schedule appointments and virtual visits, along with other clinical and administrative activities that are necessary to run a hospital and/or clinic. One of them is **specifically** for dental care. Six provide software and apps that monitor patients' outcomes via telemedicine, and they organize care for older adults and patients with chronic diseases. One or two companies represent the other groups by monitoring body response to different diets, improving patients' adherence, avoiding prescription errors, instituting rehabilitation programs, increasing athletes' performance, managing databases through clinical trials and connected medical devices; and implementing hand hygiene strategies.

## 1.4. End-to-end solutions for companies, logistics, software, engineering and maintenance services

**Definition:** Companies that are not providers of raw materials or OEMs, yet they provide automation solutions, engineering and logistic solutions, among others.

**Percentage of companies in the sector:** 25/123 (20.3%), of which two also are OEM.

**Presence in LATAM and Mexico:** 6 in LATAM, 2 in Mexico, yet these two companies in Mexico are also OEM.

**Overview:** Among the services provided by these companies, we can mention cybersecurity, software for project management, manufacturing execution systems, tracking systems, automation, big data analysis, digital transformation, inventory management, design of prototypes and marketing consultancy, quality control, analysis of the performance of manufacturing facilities, calibration, and maintenance services.

## 1.5. Research, Pharmaceuticals & Related Segments

**Definition:** Companies that provide diagnostic molecular tests, biological agents, that are related to the pharmaceutical industry.

**Percentage of companies in the sector:** 17/123 = 13.8%.

**Presence in LATAM and Mexico:** 4 (23.5%) in LATAM, 1 (5.8%) in Mexico .

**Overview:** Five companies manufacture and distribute diagnostic tests for infectious diseases, chronic disease (mainly diabetes), maternal and fetal disease, and autoimmune disease. Five develop biological agents such as gene-editing tools, cells, antibodies, peptides, lectins, and enzymes for clinical diagnosis, research, as well as to the pharmaceutical industry. Two are consultancy firms, one specializes in clinical trials for food supplements, and the other specializes in post-marketing surveillance for pharmaceutical companies and research institutions. The other four manufactured products do not fall into other areas, such as biomarker panels in cancer, microfluidic pumps, and associated biochips for cell-based assays; as well as the design and manufacturing of tissue adhesives and the testing of indoor air quality.

## 1.6. Others

**Definition:** companies that do not fall into any previous descriptions but may somehow support the healthcare sector.

Percentage of companies in the sector:  $5/123 = 4\%$  .

Presence in LATAM and Mexico: 1 in LATAM.

**Overview:** There are four companies whose primary clients are part of the healthcare sector. One is an architecture firm. The second has educational programs, and the third is a supplier of leaflets, while the last provides storage. The remaining company manufactures food supplements and herbal remedies.

Based on what Ireland's previously described health care can offer, the market study will present a general overview of the medical sector in Mexico and, at the same time, a focus on areas where Irish firms have expertise.

A review of the medical sector cluster in Mexico will be presented to analyze potential opportunities for (OEM) manufacturing in order to supply and produce for the domestic market with the objective of selling to the U.S. and Canadian market by bringing opportunities through end-to-end solutions. The medical device market will be explored by providing information regarding the market, competition, distribution channels, government purchases, and registration process for medical devices in Mexico by way of a study of opportunities in the digital health market. Lastly, key organizations and government entities will be listed that are essential players in the Medical sector.

The objective of this study is to understand the medical sector in Mexico and the opportunities that they offer for Irish firms.

## 2. Structure of Health Service System in Mexico

This chapter will provide a general overview of the health service system in Mexico. Socio-demographic data is included in order to have a better understanding of the system.

- Socio-demographic data and health status in Mexico
- Overview of the Mexican Health System
- Social Insurance
- Public Service of the uninsured
- Public Health Infrastructure
- Private Sector
- Non-profit private institutions
- Human resources
- Economic context and Healthcare expenditure (% of GDP) in Mexico
- Mexico in perspective: Comparison with OECD

### 2.1. Socio-demographic data and health status in Mexico

According to the last national census, the population in Mexico in 2020 was slightly over 126 million people, which places Mexico as the 11th most populous country in the world (INEGI, 2020) Currently, annual population growth is 1%. (World Bank, 2020), The fertility rate has steadily decreased since 1990 when it reached 3.4, and 2.1 women/children respectively in 2020. (INEGI, 2020).

Mexico has a young population. The median age in 2020 was 29 years but the population is gradually aging. In 2000, the median age was 22. (INEGI, 2020) The population of Mexico is projected to stop growing in 2050. (CONAPO, 2019) In that year the 65 and over age group is expected to represent 16.8% of the population. This age group currently represents 8.5% of the population of Mexico. (CONAPO, 2019); (INEGI, 2020).

Moreover, life expectancy in Mexico has improved dramatically, from 47.3 years in 1950 to 75.1 in 2019. (CONAPO, 2019) The infant mortality rate has also improved, from 170.8 deaths/1000 infants in 1951 to 12.6 in 2016. (Navarro-Robles, 2019) Data is summarized in Table 1.

*Table 1 Demographic indicators*

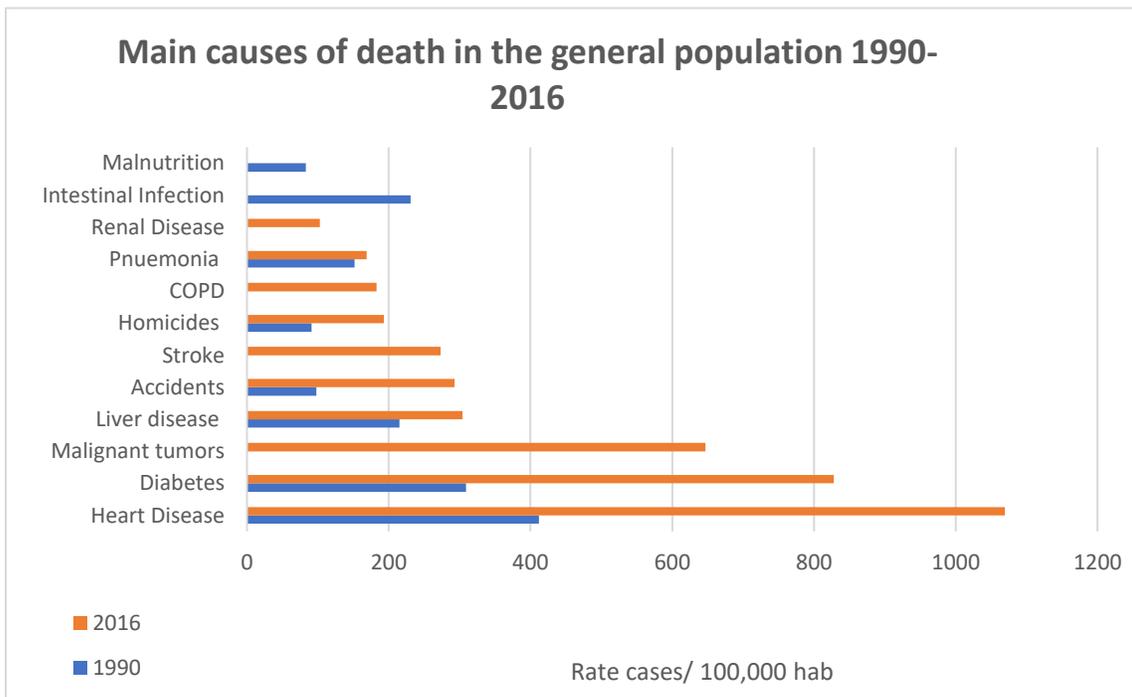
<b>Indicator</b>	<b>Data in 2020 or most currently available</b>
Total Population	126,014,024 people
Fertility rate	2.1 women/children
Life expectancy	75.1 years
Median age of population	29 years
Population from 0 –14 years of age (% of total)	25.2%

Population 65 years and greater (% of total)	8.5%
Infant mortality rate (infant mortality rate under 1/1000 live births)	12.6

Sources: (CONAPO, 2019); (Navarro-Robles, 2019); (INEGI, 2020)

The burden of disease has shifted from communicable to non-communicable diseases. See Figure 1. In 1990, 44% of the total burden of disease was from chronic disease, rising to 78% in 2016. (González Block MA, 2020) Obesity is one of the main risk factors for diabetes and heart disease. Mexico ranks second highest in the world in the overall prevalence of obesity and highest in the world for overweight and obese children.

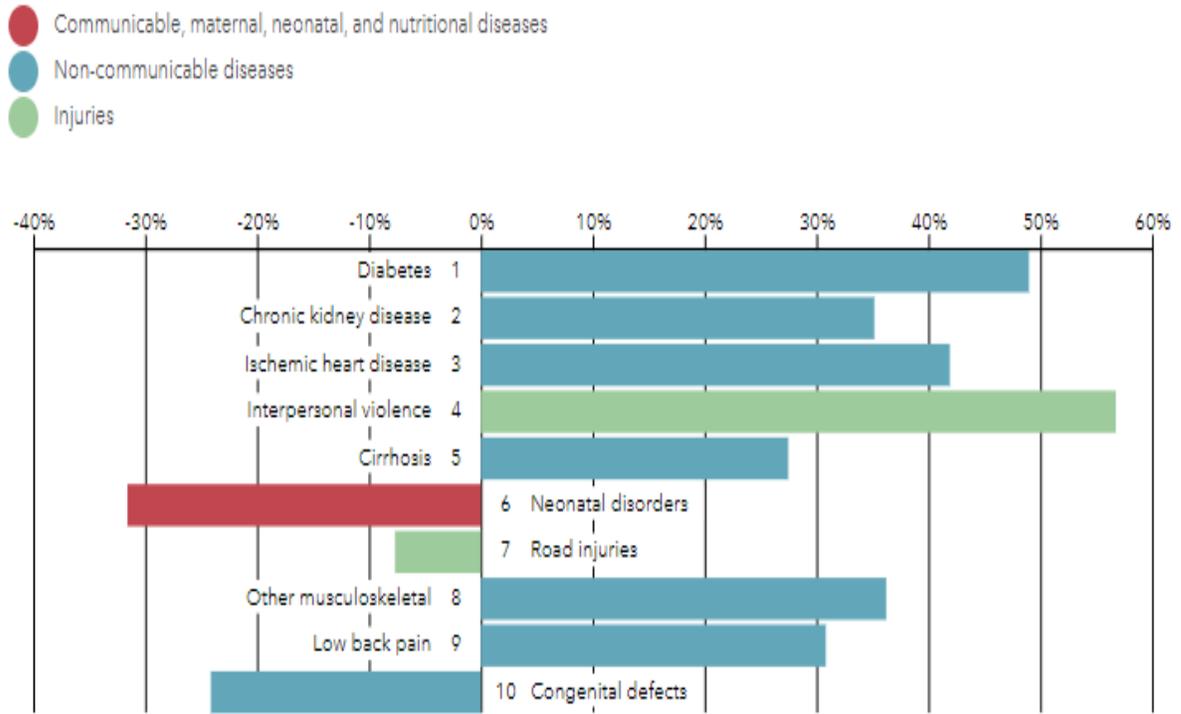
Figure 1 Main causes of death in the general population. 1990-2016



Source: Modified from (Secretaría de Salud & Dirección General de Epidemiología, s.f.). Transición epidemiológica\_2018

In 2020, the 4 four leading causes of mortality were: Heart disease (20.3%), COVID-19 (18.6%), Diabetes (14%), and malignant tumors (8.4%). (INEGI, 2020).

Figure 2 Top causes of DALYs in 2019 and percentual change 2009-2019



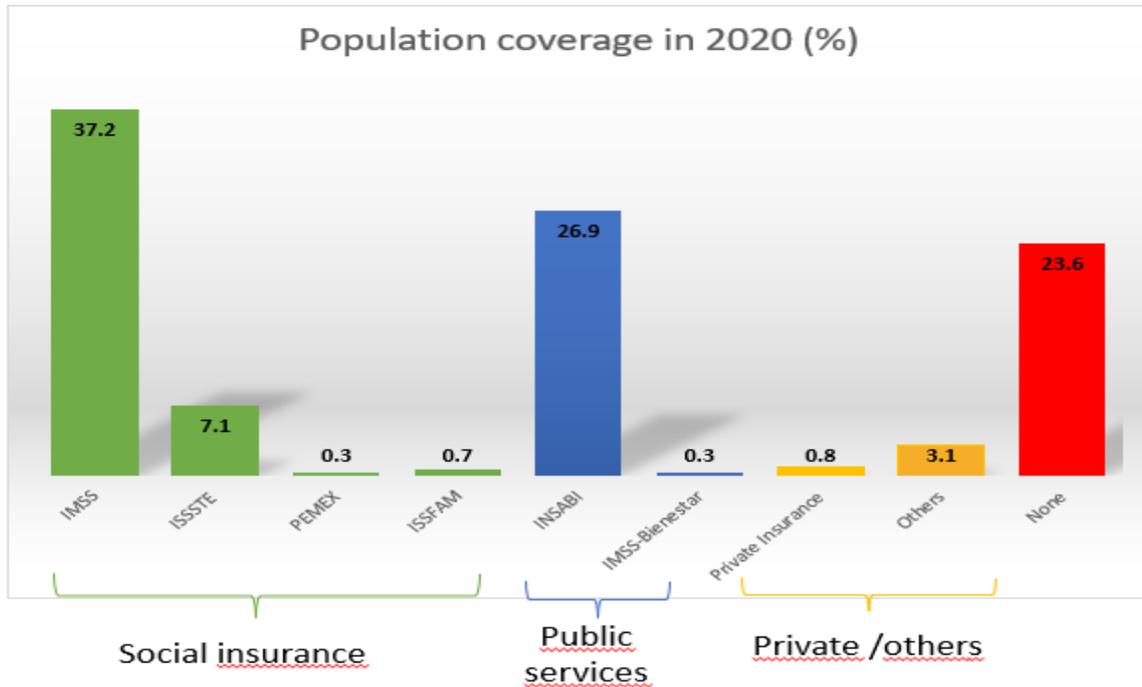
Source: (Health data, 2021)retrieved January

To better assess the overall burden of disease, we should analyze the disability-adjusted life year (DALY), a time-based measure that combines years of life lost due to premature mortality (YLLs) and years of healthy life lost due to disability (YLDs). Figure 2.

### Overview of the Mexican Health System

One of the main characteristics of the Mexican health system is that it is highly segmented. In practice, it is a patchwork of diverse and often overlapping systems. We can recognize three subsystems (social insurance, public service for the uninsured, and private sector) which collectively cover about 76.4% of the Mexican population in 2020. (CONEVAL, 2021) It should also be noted that the populations protected by social insurance or public services are highly mobile because coverage depends on the person’s employment situation. Referred to figure 3.

Figure 3 Population Coverage by subsystem



Source: Adapted from (CONEVAL, 2021)

### 2.1.1. Social Insurance

This subsystem covers formal salaried employees /forces, retired personnel, and their families. There are several institutions that provide social insurance depending on the place of employment of the worker. For example, workers of private companies are enrolled in the Mexican Social Security Institute (IMSS, for its acronym in Spanish) while the Government Workers’ Social Security and Services Institute (ISSSTE, for its acronym in Spanish) provides coverage for employees who hold public office. ISSSTE is divided into a federal branch and a state branch. Each state has its own “ISSSTE”, e.g., ISSTECH is the local ISSSTE of the southern state of Chiapas and ISSEMyM is the local ISSSTE of the State of Mexico and its municipalities. Other institutions in this subsystem are, the Institute of Social Security for the Armed Forces (ISSFAM, for its acronym in Spanish), and the national oil company of Mexico known as PEMEX. ISSFAM is also divided into SEDENA for the military and SEMAR for the marines.

IMSS, ISSSTE, ISSFAM, and PEMEX provide medical insurance, disability insurance, a pension, and in some cases, other benefits such as funeral services. The two main institutions in this subsystem are IMSS and ISSSTE. They cover about 37.2% and 6.1% of the Mexican population respectively. ISSFAM and PEMEX only cover 0.8% (CONEVAL, 2021).

Each institution has its own network of healthcare facilities that cover funding and regulations. They are vertically structured organizations and highly centralized. Covered individuals have access only to the providers and facilities employed by those vertical organizations, and there

is no choice of provider among the organization. Despite the fact that social insurance institutions provide a wide range of services, problems like long wait times, barriers to access specialized care, dubious quality of healthcare in some cases, lack of trust, and the shortage of medicines forces many to seek care outside social insurance institutions which results in out-of-pocket expenses.

### 2.1.2. Public service for the uninsured

Healthcare for the uninsured population is mainly provided by the Health Institute for Well-being (INSABI, for its acronym in Spanish), which is part of the Federal Ministry of Health (MoH). Healthcare in marginalized suburban communities and rural areas is provided mainly by a program known as IMSS-Bienestar.

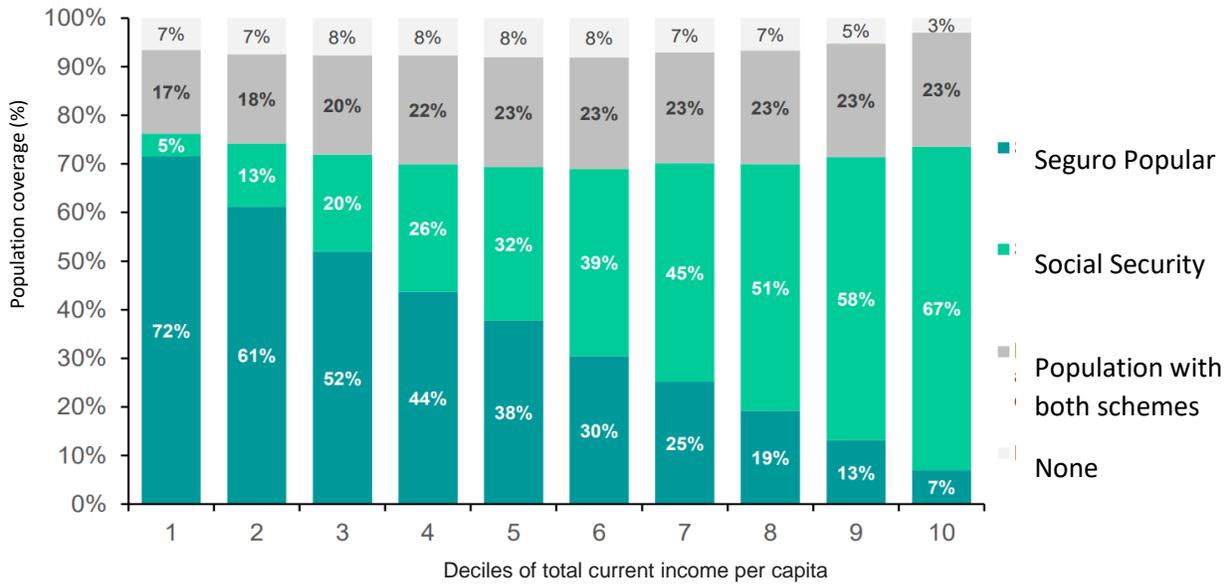
The federal MoH coordinates the National Health System through several undersecretaries and federal commissions. The MoH is also the main health care funder of health services for the uninsured and the main provider of specialized hospital services, which are mostly located in Mexico City. Every state has its local MoH, and through their networks they provide primary and general hospital care. There are six regional High Specialized Hospitals in key cities that provide tertiary care outside of Mexico City.

The “Seguro Popular”, which literally means Popular Insurance, was established in 2003. It was established as a financial protection program for those without social insurance. Enrollment in the “Seguro Popular” was voluntary.

People enrolled in SP paid an annual fee based on their income and in exchange were provided a limited package of health benefits that included 284 medical interventions grouped into 5 categories: preventive health, general and specialized medicine, emergency, general surgery, and obstetrics. It also covered selected high-cost “catastrophic events”, such as breast cancer or liver transplants, but not hemodialysis for terminal kidney disease or kidney transplants. Members of Seguro Popular received healthcare in the state and federal networks of the MoH, as well as through private providers. In 2018, it covered 42.1% of the population. (CONEVAL, 2021).

The poorest segment of the population were the primary users of the Seguro Popular. (CONEVAL, 2018) Notwithstanding, the Seguro Popular was also appealing for some people with social insurance. See Figure 4.

Figure 4 Population with social security and/or Seguro Popular based on deciles of total current income per capita, 2018



Source: (CONEVAL, 2018). Retrieved from: [https://www.coneval.org.mx/Evaluacion/IEPSM/Documents/Seguro\\_Popular\\_Seguro\\_Medico\\_Siglo\\_XXI.pdf](https://www.coneval.org.mx/Evaluacion/IEPSM/Documents/Seguro_Popular_Seguro_Medico_Siglo_XXI.pdf)

Even if coverage was partial, the Seguro Popular managed to decrease the percentage of uninsured people from 49.6% of the total population in 2000 to 17.3% in 2015. Out-of-pocket spending decreased from 53.9% of the total health expenditure in 2000 to 41.3% in 2015. (González Block MA, 2020)et al). Nevertheless, the program raised important criticism due to its partial coverage, low level of satisfaction from beneficiaries, and lack of transparency of allocation of resources especially at the state level, among others. With the administration of López Obrador, the Seguro Popular ended, and in January 2020 the newly created INSABI replaced it.

The aim of INSABI is to provide complete health coverage for the uninsured population at no cost. It also centralizes health services financing by removing it from state health providers. However, state health authorities are still obliged to provide the same service. It also aims to replace all private subcontracting with only public providers.

Despite initial enthusiasm with INSABI, results have not been as good as promised. According to an autonomous public organism that evaluates Public Policies, since INSABI took over health coverage has plummeted, and it covers only 26.9% of the population (CONEVAL, 2021). In addition to a decline in coverage, the MoH has been accused of being unable to guarantee health

services (Méndez, 2021), and medicines (Roldán, 2021). Several reports have surfaced of accusations that patients are still charged fees in certain situations. (Miranda, 2020) (Ortega, 2020). Also, INSABI does not endeavour to provide service to the insured population, thereby affecting people who are not satisfied with the services provided by IMSS or ISSSTE but who are nevertheless, unable to contract private insurance.

“IMSS-Bienestar” has existed since 1973 but has changed its name several times throughout its history. It was previously known as “IMSS-Coplamar”, “IMSS-Prospera” and then “IMSS-Oportunidades”. It is a federal health program that is administered by IMSS to provide basic health care to the rural poor through a separate network of clinics and hospitals. It provides healthcare to 11.6 million people in 19 states.

In March 2022, new changes are on the horizon. The federal government announced that the newly created INSABI will no longer provide healthcare, but limit its functions to burocreatic tasks and purchase of drugs and supplies (Ortega, 2020). Healthcare will now be provided by IMSS-Bienestar. This change in public policy is scheduled to begin in the country’s smallest states: Nayarit, Tlaxcala, and Colima (Coronel, 2021).

### 2.1.3. Public health infrastructure

There are 1,395 public hospitals that represent about 30% of the total number of hospitals in the country. Nevertheless, they are usually larger than private hospitals as they account for more than 70% of the available hospital beds in the country. Most of these hospitals provide service to the non-insured population, as 761 are run by the MoH. Among the hospitals of the MoH there are 12 National Institutes of Health, 6 federal hospitals, and 5 regional highly specialized hospitals. IMSS runs 270 hospitals, ISSSTE 112, IMSS-Bienestar 81, while the remaining hospitals are run by PEMEX, ISSFAM, or universities. (Information System of the Ministry of Health, 2020) Most hospitals are concentrated in urban areas, with only 3.3% located in rural localities.

In regard to out-patient clinics, the public system has more than 28,000 units. (Information System of the Ministry of Health, 2020). Another relevant parameter for evaluation is the availability of health equipment. Table 2 summarizes the equipment available according to official data.

**Table 2 Medical Equipment in public institutions**

Public Institution	<i>Linear accelerator</i>	Mammography unit	Magnetic resonance Unit	Computed Tomography Scan	Angiograms	Radiotherapy Unit
MoH	34	329	45	151	66	35
IMSS-Bienestar	0	5	0	0	0	0
Statal MoH	2	24	7	18	5	3
IMSS	22	250	25	126	29	26
ISSSTE	3	123	10	52	9	4
PEMEX	0	20	1	9	1	0
ISSFAM	7	27	9	27	22	3
Universities	7	4	3	2	6	7
<b>TOTAL</b>	<b>75</b>	<b>782</b>	<b>100</b>	<b>385</b>	<b>138</b>	<b>78</b>

Adapted from: <http://sinaiscap.salud.gob.mx:8080/DGIS/>

The OECD reports that Mexico has a total of 2,910 MRI per 1,000,000 inhabitants (OCDE, 2020). If we consider the Mexican population, we can estimate that the country has close to 365 MRI units. This means, that the public system has 27.3% of the available units, yet it provides care for more than 70% of the population. Also, Distribution among public institutions is not even. For example, ISSSTE covers 7.1 % of the population, while ISSFAM covers 0.7% yet the former only has one more MRI unit.

Overall, the Mexican public health system faces shortages and inconsistencies in health resources. The availability of medical technology is skewed towards the private sector, with many high-cost interventions still scarce within the public sector. The probability of a person incurring out-of-pocket expenses is high even if he/she has social insurance. (Bock, 2020) The number of people that received medical care through the private sector increased from 2018 to 2020, from 21.5 to 27.1 million people respectively (CONEVAL, 2021)

#### 2.1.4. Private sector

The private health subsystem in Mexico is large and continues to grow. Up to 45% of total outpatient consultations and 19.5% of hospital care are provided by private providers (Bock, 2020).

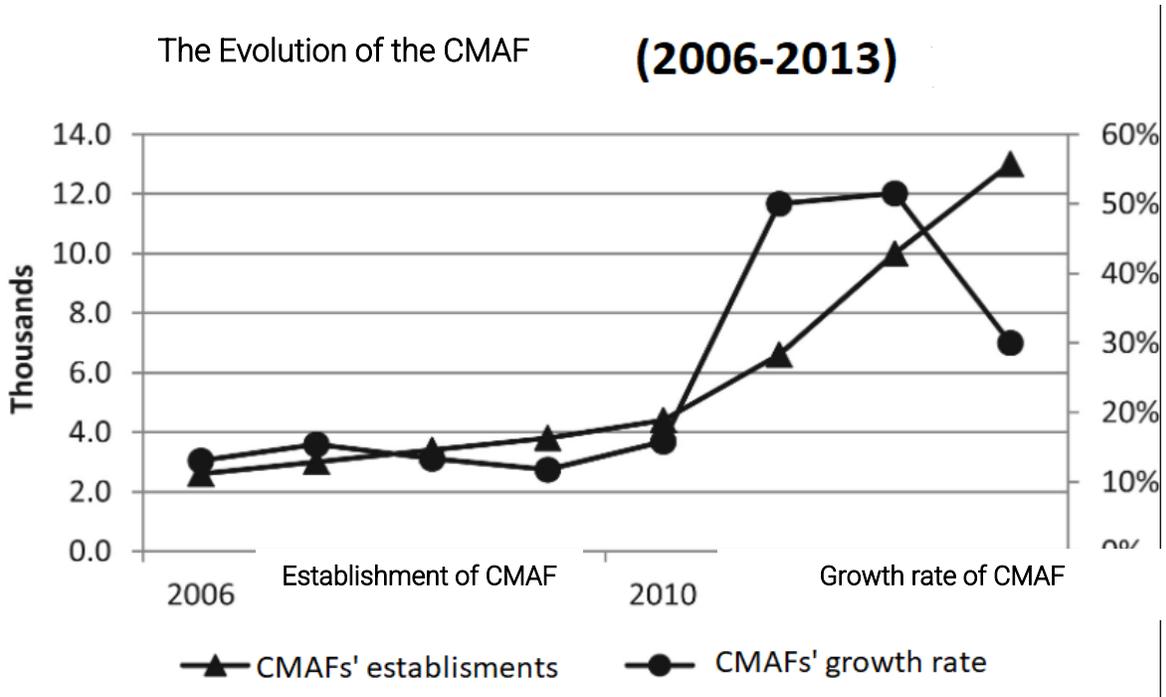
The private sector is constituted mostly of small hospitals and clinics as well as medical offices that are adjacent to private pharmacies (CMAF, for its acronym in Spanish), with a few large national corporations primarily in the hospital and pharmaceutical sectors.

The private sector is also segmented, as it pertains to socioeconomic strata. Households in the socioeconomic strata E to C tend to prefer private care for minor conditions through general physicians (GP). Most of these GPs are pharmacy chain employees and provide their services at low cost in CMAF. This sector of the population also has access to hospital care mainly in small hospitals with less than 20 beds.

They pay mostly out-of-pocket. For the households in the socioeconomic strata C+ to A, outpatients consultations are given either by the CMAF, mainly when the condition is acute and deemed as “non-serious”, or by specialist physicians through self-referral. Most specialist physicians have their offices in large private hospitals and are the main source of referral for hospital admissions. Minor care, such as a one-time specialist consultation is mostly paid out-of-pocket, while expenses from hospital care and surgical interventions are mainly covered by private health insurance.

CMAF is an interesting phenomenon. This concept started in 1997 initially targeting low-income households, and was provided by a single pharmacy chain known for selling generic drugs. Since 2010, CMAFs have experienced major growth, and the model has been adopted by the largest pharmacy chains of the country. (See Figure 5) and it is no longer specific to the low-income population. Interestingly, 65% of CMAFs users are insured by a public institution (Pérez-Cuevas R, 2013),

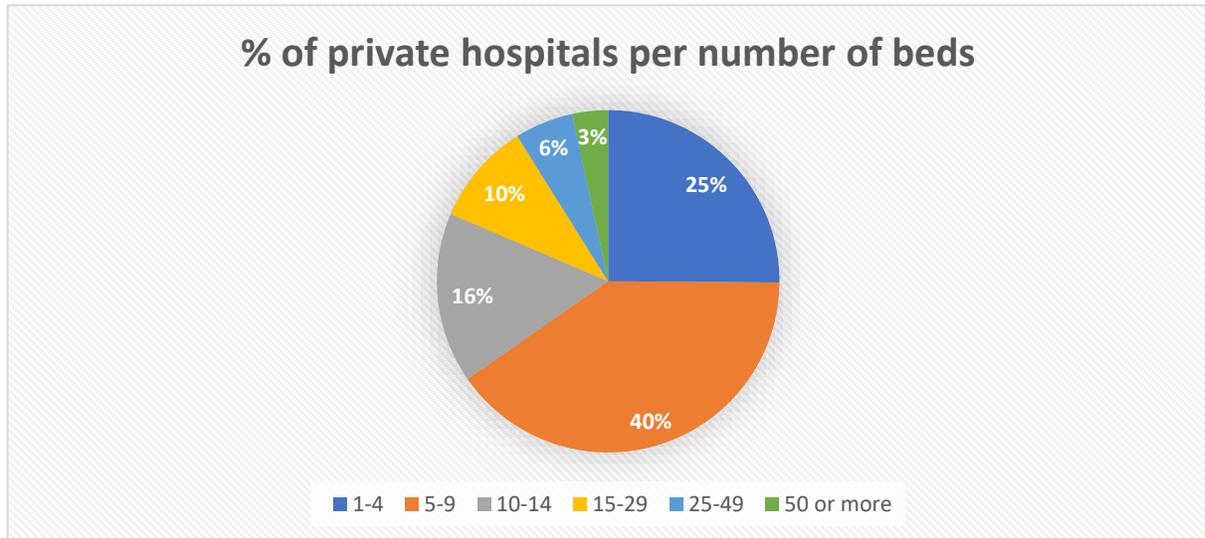
Figure 5 Evolution of CMAF



Source: (García-Díaz, 2017)

CMAFs are deemed as “convenient” because they offer very short waiting times, minimum cost per consultation, or no cost at all, and side-by-side location to private pharmacies. (García-Díaz, 2017) Nevertheless, there seems to be an overprescription by GPs in CMAFs that raises out-of-pocket expenditure and the quality of care provided is poorly measured. (Perez-Cuevas R. DSoubova, 2014).

Figure 6 Number of beds in private hospitals



Source: Adapted from (INEGI, 2020)

[https://www.inegi.org.mx/contenidos/saladeprensa/boletines/2020/EstSociodemo/EstadisticaSalud2019\\_08.pdf](https://www.inegi.org.mx/contenidos/saladeprensa/boletines/2020/EstSociodemo/EstadisticaSalud2019_08.pdf)

According to INEGI, in 2019 there were 2,855 hospitals in Mexico. The majority of the private sector hospitals in Mexico are small institutions, with only 96 (3%) providing 50 beds or more. (See figure 6)

Private hospitals are also highly concentrated, with 52.2% of hospital beds located in six states: Mexico City (14.1%), the State of Mexico (11.5%), Jalisco (9.1%), Guanajuato (6.1%), Nuevo León (6.1%), and Puebla (5.3%).

About 10% of the private hospitals have more than 20 beds and are certified by the General Health Council (CSG, for its acronym in Spanish). These hospitals are regarded as: “the Best in Private Hospital Rankings”. ABC Medical Center, Médica Sur, and hospitals belonging to the Ángeles Group are among the top five hospitals in the country, all of which are located in the Metropolitan Area of Mexico City (Blutitude-FUNSALUD, 2021)The group of MAC Hospitals is interesting because they are the youngest hospital chain in the country and is rapidly growing. The group started in 2008 and they intend to have 20 hospitals across the country by 2025. (Expansion, 2021).

### 2.1.5. Non-profit private institutions

International organizations such as the Red Cross are present in Mexico. The Mexican Red Cross is mainly known for providing emergency services since 1910. They run 31 hospitals and 11 blood banks across the country (Cruz Roja, 2022).

Other non-profit private institutions have surged due to social mobilization. The rehabilitation of patients with disabilities is one of the areas that has cast more attention on Mexican society. Of these, the Teletón Foundation is probably the most well-known. It began operations in Mexico in 1999. It operates 22 Rehabilitation and Childhood Inclusion Teletón Centres (CRITs, for its acronym in Spanish) in the country, offering care to children up to 18 years of age who struggle with neuromusculoskeletal disabilities. They also opened a center specifically for treating autism in 2012 and another for oncologic patients in 2013. According to their website, close to 27,000 children and teenagers are treated every year. ( (Fundación Teletón, 2022).

FUCAM is another well-known non-profit private institution. Since 2005, FUCAM provides specialized breast cancer treatment with a highly specialized unit located in Mexico City, that covers all aspects of diagnostic care and disease staging to reconstructive surgery or palliative care. FUCAM also runs an early detection program with four medical offices in Oaxaca, Chiapas, Morelos, and the State of Mexico, and mobile units across the country. (FUCAM, 2022)

### 2.1.6. Human resources

According to the 2021 National Survey of Occupation and Employment, there are 305,418 working physicians in the country. 67% are GPs and 33% are specialist physicians, with 2.4 physicians/inhabitants. (INEGI, 2020).

The most recent workforce data available of the public system dates from 2019. In that year, the public system had a total of 164,996 physicians, of whom 43.15% were GPs or family doctors, and 56.85% were specialists. The data is summarized in table 3.

**Table 3 Number of Physicians in the public system.**

GPs and family doctor	Pediatrician	Gynecologist and Obstetrician	General Surgeon	Internal Medicine Physician	Trauma and emergency doctor	Physician with other Specialty	Dentist	Total
71,209	11,212	10,823	9,078	6,880	10,587	30,652	12,066	<b>177,062</b>

Adapted from: <http://sinaiscap.salud.gob.mx:8080/DGIS/>

In addition to the 177,062 physicians and dentists, there are 26,066 medical residents in the public system, and there are 286,239 nurses working in the public system. Professional nurses number 181,386, of whom 20% are specialist nurses and 80% are general nurses. The remaining 104,853 are technical personnel with a high school education. ( (Information System of the Ministry of Health, 2020) In 2021 there were 87,363 physicians employed in private hospitals. In private hospitals, 87.29% are specialists, while only 12.7% are GPs. The number of residents is also considerably lower: there are only 1,935 in the private system. (INEGI, n.d.)Data on physicians working outside public institutions or private hospitals, such as small private

offices, is unreliable. Many of the GPs that are employed in the private system work in the CMAFs which are not considered in the report by INEGI. It is estimated that the CMAFs employs over 20,000 physicians. (López-Manning & García-Díaz, 2017).

When these figures are considered, it must be kept in mind that physicians frequently work in more than one public institution, or they combine public and private practice.

#### Regulation

The MoH is organized into three undersecretaries and six federal commissions:

The Undersecretary for Administration and Financing

The Undersecretary for Health Sector Integration and Development

The Undersecretary for Health Prevention and Promotion

The National Commission Against Addictions

The National Commission for National Institutes of Health and Highly Specialized Hospitals (CINSHAE)

The Federal Commission for the Protection Against Sanitary Risk (COFEPRIS)

The Health Institute for Well-being (INSABI)

The National Commission of Bioethics

The National Medical Arbitration Commission

## 2.2. Economic context and Healthcare expenditure (% of GDP) in Mexico

Mexico is the 12th largest economy in the world and the second largest in Latin American based on its gross domestic product (GDP). It is an upper middle-income country with one of the highest per capita incomes in Latin America.

Nevertheless, economic growth has slowed down in the last decades. Average growth was just above 2%, while per capita the average growth was about 1% between 1980 and 2018. The per capita income of the country has been dissimilar to that of higher-income economies. The Per capita GDP in 2018 stood at 34.0% of U.S. per capita GDP, compared to 49.0% in 1980.

A relevant issue affecting the country is inequality. The average GDP per capita is highly unequal among states. The average GDP per capita is higher in northern states. For example, the per capita GDP of Nuevo León is close to the GDP per capita in Poland, while that of the southern state of Chiapas is only slightly above that of Honduras. Social development also varies considerably across states. (World Bank, 2020).

The Human Development Index (HDI) is a summary measure for assessing the development of a country. In 2020, the HDI of Mexico was 0.77) (Human Development Report , 2020) Nevertheless, it has a high variability among states. Mexico City has the highest HDI in the country (0.83), while Chiapas has the lowest ( 0.67). Mexico has the worst income inequality in the OECD. In 2018, the Gini coefficient which measures inequality within populations between 0 and 1, with 1 being the most unequal, stood at 0.45, as opposed to the OECD average of 0.32 (The World Bank, 2018).

Total health expenditure based on the GDP of the country experienced important growth from 2000 to 2003. In 2009, it reached its highest point representing 6.1% of the GDP. In 2019, total health expenditure decreased to 5.4% of the GDP (Figure 7), while the OECD average for the same year was 12.5%. Public spending represents slightly less than 50% of total health expenditures. In 2019, it was 49.3%. As illustrated in figure 8, public spending has shown a declining trend since 2013.

Figure 7 Current Health expenditure (% of GDP)



Retrieved from: <https://datos.bancomundial.org/indicador/SH.XPD.CHEX.GD.ZS?locations=MX>

Figure 8 Domestic general government health expenditure (% of current health expenditure) - Mexico



Retrieved from: <https://datos.bancomundial.org/indicador/SH.XPD.GHED.CH.ZS?locations=MX>

Just under half of public health spending is directed towards outpatient care, and a third funds hospital services. The fragmented institutional framework for health care generates unnecessarily high administration costs, and when considered as the percentage of total health costs it is the highest among OECD countries. The fragmentation also leads to unequal health outcomes. (World Bank, 2020) Diabetes mellitus is one of the diseases with the highest impact on health expenditure. Direct costs of diabetes care were estimated at 1.1% of the GDP in 2013, with diabetes complications representing 87.2% of the total diabetes related-health expenditures (Barraza-Lloréns M, 2015) .

### 2.2.1. Mexico in perspective: Comparison with OECD

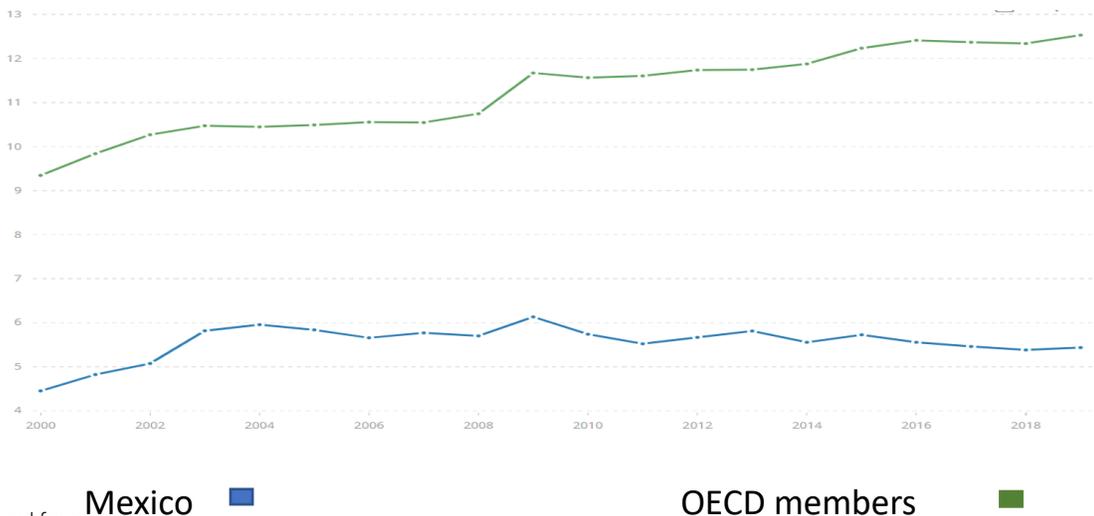
The Organization for Economic Co-operation and Development (OECD) is an organization committed to economic development and to the improvement of public policies. The OECD collects data, analyses, and forecasts economic development that guide public policies. It is one of the most reliable sources of comparable statistical, economic, and social data. Mexico is one of the 37 countries that are members of the OECD, while 5 countries are key partners of the OECD. (OCDE, 2021)) Most members are high-income economies with a very high Human Development Index (HDI).

When we compare Mexico to other OECD members it is evident that the country has several areas of opportunity. Life expectancy in Mexico is five years below the OECD average: 75 vs 81

years. Nevertheless, life expectancy in Mexico has kept growing unlike most of the other OECD members.

Health expenditure in Mexico is among the lowest amongst the OECD members. Figure 9 compares current health expenditure in Mexico with the OECD average. Not only is the OECD average significantly higher, but health expenditure in the country remains mostly static. Basic health coverage in Mexico is among the lowest of the OECD while out-of-pocket expenditure is among the highest.

**Figure 9 Comparison of current health expenditure in Mexico (% of GDP) with OECD members**



Retrieved from: <https://datos.bancomundial.org/indicador/SH.XPD.CHEX.GD.ZS?locations=MX-OE>

Mexico has a shortage of healthcare personnel. It also has a shortage of hospital beds and expensive medical technology. For example, magnetic resonance imaging (MRI) machines per million inhabitants is 2.6 when compared to the OECD average of 15.6. Similar levels exist with respect to gamma cameras and radiation therapy equipment, while access to mammograph equipment is just 42.5% compared to the OECD average.

In terms of risk factors Mexico has lower rates of alcohol and smoking consumption, but the prevalence of overweight and obesity is higher. The latter is one of the main risk factors for diabetes, which is a major health problem in Mexico. Table 4 compares Mexico to the OECD key indicators of healthcare status.

Table 4 Comparison between Mexico and the OECD

INDICATOR	Mexico	OECD AVERAGE
<b>Health Status</b>		
Life expectancy (life expectancy at birth)	75	81
Avoidable Mortality (Deaths per 100,000 in the population)	366	199
<b>Risk factors</b>		
Smoking (% population 15+)	8	17
Alcohol consumption (litres/per capita 15+)	4	9
Overweight/Obesity (% population)	75	56
<b>Health access</b>		
Population coverage (% population covered by government programs)	89	98
Financial protection (% expenditure from public sources )	49	71
<b>Quality of Healthcare</b>		
Effective primary care (Avoidable COPD admission/100,000 people)	65	171
Effective preventive care (% of women 50+ with a mammography screening)	45	62
Effective secondary care (30 day mortality following AMI/100,000 people)	28	7
<b>Resources</b>		
Health expenditure (% GDP)	5.4	12.5
Hospital beds (per 1 000 people)	1	4.4
MRI Machines (per 1 000 000 people)	2.6	15.6
Doctors (per 1 000 people)	2.4	3.6
Nurses (per 1 000 people)	2.9	8.8
COPD: Chronic obstructive pulmonary disease, AMI: Acute myocardial infarction, GDP: Gross domestic product, MRI: Magnetic resonance machine		

Adapted from: Health at a Glance 2021: OECD Indicators. <https://www.oecd.org/health/health-at-a-glance.htm> (González Block MA, 2020), <https://datos.bancomundial.org/indicador/SH.XPD.CHEX.GD.ZS?locations=MX-OE>

## 3. Regulation in Mexico Medical Equipment/Devices

### 3.1. Regulation and control

In the 1990s, the Council of the European Communities established harmonized codes and specifications for technical safety features and inspection procedures for medical devices. (Commission, 1990) The European initiative showed the importance of having technical references, standards, and evaluation of medical devices to allow commercialization and the safety of patients. In this new technological world, there is a need to have obligatory regulations and surveillance to ensure the safety and performance of medical devices.

Governments are responsible for health policies, and as such, they must regulate the correct use of medical devices. Governments establish controls that are supervised by a responsible authority. In 2001, the Official Gazette of the Federation in Mexico published information regarding the creation of an institution to control, regulate, and prevent sanitary risk to the population, known as the Federal Commission for the Protection against Sanitary Risk (COFEPRIS for its acronym in Spanish) (CANIFARMA, 2019) COFEPRIS is responsible for:

1. Regulating control and surveillance in the following areas:
  - a. Health establishments
  - b. Pharmaceuticals, herbal remedies, and medical devices
  - c. Food and food supplements
  - d. Cosmetics and beauty products
  - e. Tobacco
  - f. Fertilizers and pesticides
  - g. Nutrients for plants
  - h. Essential chemical substances, narcotics, and psychotropic drugs
  - i. Biotechnology products
  - j. Importation and exportation of the above products
  - k. Occupational health
2. Preparing and Issuing guidelines in coordination with other authorities in accordance with Official Mexican Standards.
3. Managing the federal health care system in coordination with state governments.
4. Coordinating Health Services to the community.
5. Identifying, analyzing, evaluating, regulating, controlling, and performing the conditions and requirements to prevent and manage sanitary risks.
6. Issuing, extending, or revoking sanitary authorizations and certifications.
7. Applying research strategies, evaluating, and monitoring sanitary risks.
8. Imposing administrative penalties for non-compliance with the dispositions of the law.

9. Participating with other units of the health ministry in actions that prevent and control diseases and epidemiology surveillance.

COFEPRIS has created a transparent process for registering products in Mexico and maintains cooperative liaisons with other countries in order to regulate and unify sanitary standards. Mexico also has equivalency agreements with other countries in which the requirements, tests, procedures, and evaluations are considered equivalent to what the Mexican authorities require. (Federation, dof.gob.mx, 2020).

### 3.2. Use and risk classification for Medical Devices

#### 3.2.1. Use or classification of medical devices

COFEPRIS defines a medical device as any substance, mix of substance, material, instrument or apparatus (this includes the operational software), that is used independently or combined with a procedure for the diagnosis, monitoring, or prevention of diseases in humans; or as auxiliaries in treatment and disability; as well as those used for replacement, correction, restauration or modification of the anatomy or for physiological process. See figure 10.

*Figure 10 Medical Devices y use*



Source: COFEPRIS <https://www.gob.mx/cofepris>

### 3.2.2. Medical Devices Risk Classification

For registration purposes, medical devices are classified according to risk. Table 5 shows the three classifications used in Mexico:

Table 5 Medical Devices Risk Classification

Medical Devices Risk Classification	
CLASS	Description
I	Medical devices of low risk, in general, are devices that are not introduced in the human body.
II	Devices or consumables that are introduced to the human body for a period of fewer than 30 days.
III	Devices or consumables that are introduced to the human body for a period of more than 30 days.

Source: The National Chamber of the Pharmaceutical Industry (CANIFARMA for its acronym in Spanish)  
<https://dispositivosmedicos.org.mx/clasificacion-de-los-dispositivos-medicos/>

For determining risk classification the criteria are based on 23 rules known as "Criteria for Medical Device Classification.", indicating the characteristics of the products in relation to their use, activity, contact, and permanence with the organism as well as the class to which they belong.

To obtain a sanitary registration you need to make sure that the medical device is classified correctly, if the medical device is imported or manufactured in Mexico, and if it is a new registration or an extension.

### 3.3. General Sanitary Registration Process

The Federal Commission for the Protection against Sanitary Risk (COFEPRIS for its acronym in Spanish)<sup>2</sup> is a government institution that provides sanitary authorizations in Mexico. There are four types of sanitary authorizations: licenses, permits, registrations, and sanitary control cards.

Sanitary registrations are granted for four types of products:

- Drugs
- Medical Devices
- Pesticides
- Plant Nutrients

<sup>2</sup> Federal Commission for the Protection against Sanitary Risk <https://www.gob.mx/cofepris/>

### 3.3.1. Sanitary registration process

There are differences that exist depending on the product for the sanitary registration, but at the same time, they are similarities. A review of sanitary registration for medical devices will be carried out for this study.

For a new registration, the first step is to classify by risk the medical device, and the second is to determine whether it is an imported device and if there is an equivalency agreement in place. For medical devices, there are applicable agreements with the Food and Drug Administration (FDA-USA), Health Canada (Canada), the Ministry of Health, Labor and Welfare (MHLW -Japan). There is also a similar agreement if the device is manufactured in Mexico. Based on the foregoing regarding sanitary registration for medical devices, there are eleven types that are designated by letters that range from A to K. Below is an example of the terminology used for the registration of new medical devices:

COFEPRIS –04-001-B COFEPRIS Institution provides sanitary registration  
04 Medical Device  
001 New registration  
B Imported products (foreign manufacturing).

If a foreign company wants to sell its medical device in Mexico, it needs sanitary registration. To present all the documents and start the process, the foreign firm has to designate an authorized person who can do it on their behalf.

The documents you need to present for the registration include a pre-filled application form along with a compiled dossier or registration file. (Kenko, 2021).

On May 31<sup>st</sup>, 2021 the regulations for health supplies were modified, and the documents accompanying the applications must be completed in Spanish or English. Documents issued by authorities of other countries must be apostilled or legalized. If they are written in a language other than Spanish or English they must be accompanied by their corresponding translation by an expert translator. (Federation, dof.gob.mx, 2021).

Some of the documents that must be included in the dossier are the following:

An authorization letter from the manufacturer that allows the commercialization, distribution, and storage of the product.

A Certificate of Free Sale in which the foreign authority states that the product complies with the legal dispositions of the country and that the product will be used with no restrictions.

### Good Manufacturing Practice Certificate

If the product has an equivalent of the same, then the registration for medical devices must be shown to the FDA, Health Canada, or the MHLW of Japan. The Mexican Guidelines for Good Manufacturing Practices Concerning Medical devices is NOM-241-SSA1-2021 .<sup>3</sup>

On June 22, 2021, due to the need to import medications and medical devices that are not produced in Mexico, the Health Supplies Regulation was modified. New equivalents were accepted for registration. Those equivalents include the European Commission and Swissmed (Federation, dof.gob.mx, 2021).

### General information about the product

The documents mostly describe the functionality of the medical devices, their use, and general aspects.

### User's manual

Contains information regarding the operation, maintenance, cleaning, and conditions for preservation, along with warnings, contraindications, and any other relevant device information.

### Label Information

Presentation of the label or project label of the device. The label must adhere to the Mexican Standard NOM-137-SSA1-2008<sup>4</sup>.

### Manufacturing Process Description

A complete description of the manufacturing process, including stages, establishments, and final assembly.

### Laboratory Test

Based on international standards.

### Biocompatibility Test

Verifiable proof that the device does not cause toxicity or is irritating or sensitive to skin.

### Stability Test

Applies to those devices that have an expiration date.

### Clinical Trials

The trial must demonstrate the use of the device, its functionality, and safety when used by individuals.

### Sterilization Information

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<sup>3</sup> NOM-241-SSA1-2021 [https://dof.gob.mx/nota\\_detalle.php?codigo=5638793&fecha=20/12/2021](https://dof.gob.mx/nota_detalle.php?codigo=5638793&fecha=20/12/2021)

<sup>4</sup> NOM-137-SSA1-2008 [http://www.dof.gob.mx/normasOficiales/3570/SALUD13\\_C/SALUD13\\_C.htm](http://www.dof.gob.mx/normasOficiales/3570/SALUD13_C/SALUD13_C.htm)

It must include all sterilization process and a sterilization certificate.

### Packaging Information

Description of primary, secondary, and third packaging materials.

In addition to the above, it is required to present:

- A filled out application form including a receipt of payment
- A signed declaration from a designated health specialist in Mexico in this area who certifies that the documents are valid, truthful, correct, and provided by the manufacturer.
- Operating License

All sanitary registrations are valid for five years and can be renewed for an additional five years. If a renewal is not carried out, then the registration will be canceled.

What is the cost to register a medical device in Mexico?

The cost will vary depending on the risk classification of the medical device. The cost per registration that COFEPRIS charges for each are as follows: (COFEPRIS, 2021).

- Class I: \$13,522.77 Mexican Pesos
- Class II: \$19,833.38 Mexican Pesos
- Class III: \$25,242.50 Mexican Pesos

You also need to take into consideration other costs that are involved in the process, such as a fee for the consultant or company in charge of the registration, a fee for a legal representative, holder of registration, labeling, etc.

It is important to determine if the products can be considered as a group of products, since this may impact the number of sanitary registrations required for the devices. Some of the factors that can affect the group include accessories, kits, additional components, presentations, same use and technology, same materials etc.

COFEPRIS has an area known as the Integral Service Center (CIS for its acronym in Spanish). The CIS<sup>5</sup> provides customer service and offers detailed information in the institution on how to perform a procedure and carry it through until a final resolution is reached.

COFEPRIS has experienced delays in their resolutions, and the situation only worsened due to the COVID-19 pandemia. Their priorities have been focused on approving health supplies in

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<sup>5</sup> <https://www.gob.mx/cofepris/acciones-y-programas/centro-integral-de-servicios?state=published>

order to respond to the demands of the pandemic. The processing time for receiving an answer is between 6 months to 1 year or more.

In May 2021, COFEPRIS implemented a plan called "quickness strategy to control delays" (ECAR for its acronym in Spanish) In order to resolve this situation. The program only includes administrative modifications. (COFEPRIS, 2021) .

If you want to have full control over the sanitary registration, it is recommended that you have an independent holder. This will allow the registration rights to be granted to your distributors, and as such, these rights will be cancelled if they are not being executed. Moreover, registration and renewals can be transferred to another company.

If you decide to use your own distributor to register, the only advantage will be not paying the registration fee, but you will not be able to designate new distributors or have any control over the sanitary registration process.

### 3.3.2. Examples of consulting companies that offer registration services

Below is a list of consulting firms that provide registration services. The companies are listed in alphabetical order. We advise you to search for several options and recommend reviewing the services of the company and their respective background before working with any of them. Any other firm can help you in the process of registering a product in Mexico.

1. Aguilar Murguía Asesores en Servicios Integrales de Salud S.A. de C.V. (AMASIS)  
México City México  
Web Site: <http://www.amasis.com.mx/>
2. ASA Ink Consultora  
Mexico City, México  
Web Site: <https://www.asaink.mx/>
3. Caper Soluciones S de RL de CV (CAPER)  
Mexico City, Mexico  
Web Site: <https://caper.com.mx/>
4. Emergo by UL  
Web Site: <https://www.emergobyul.com/>
5. Inteligencia en Soluciones Regulatorias S.A. de C.V. (UDELA)  
Mexico City, Mexico  
Web site: <https://udelaglobal.com/>
6. Isa Health

Monterrey, N.L, México

Web Page: <http://www.isahealth.com/>

7. Gestoría de Asuntos Regulatorios Regisan

Mexico City, Mexico

Web Site: <https://registro-sanitario-regisan.com/en/>

8. Raf Consulting

Mexico City, Mexico

<https://www.rafconsulting.net/>

9. Veraque S. de R.L. de C.V.

Cuautitlan Izcalli, Estado de México

Web Site: <https://veraqueconsulting.com/>

## 4. Digital Health Applications in Mexico

The chapter will review the evolution of digital health in Mexico and its regulations and internal policies, as well as competition in the market and potential opportunities in the same.

### 4.1. Overview

Technology has grown in recent years, affecting all areas of life, including our health. Digital health refers to the use of information and communications technologies in medicine and other health professions. It is a tool, not a substitute for healthcare. Digital health has a broad scope and includes the use of wearable devices, mobile health, health information technology, telehealth, and telemedicine. (Ronquillo & Meyers A, 2021).

Wearable devices include medical-grade monitoring and diagnostic devices prescribed and analyzed by medical professionals, such as an ECG Holter system. Some medical devices are non-medical-grade and are used for self-monitoring of health or physical activity.

Mobile health refers to providing health services and information via mobile technologies such as mobile phones. It is not always possible to draw a line between wearable devices and mobile health, as these frequently interconnect.

Health information technology refers to the electronic systems health care professionals and patients use to store, share, and analyze health information, such as electronic healthcare records, electronic prescribing, or programs for Medical Practice Management.

Big data initiatives has the potential to revolutionize the healthcare sector. Effectiveness of physicians can be improved if big data is launched successfully. It will work as a guiding tool to help the clinicians in complex decision-making. (Chauchan, 2021).

Telehealth is an umbrella term that includes a broad range of technologies and services to provide patient care and improve the healthcare delivery system, including non-clinical services such as continuing medical education. In contrast, telemedicine refers to remote clinical services, giving a specialized clinical consultation to a patient in a remote location.

Since many of these functions are closely related, the terms described are sometimes used interchangeably, and statistics on the matter are sometimes confusing. Also, the industry is growing at an impressive speed, usually faster than regulations and policies.

### 4.2. Regulation

The regulation of digital health in Mexico is in the initial stage. In 2015 there was an attempt to regulate the sector. A NOM, (in English: Official Mexican Standards), was published, but the project was cancelled in 2018. (Ramirez, 2021).

The Food and Drug Administration, (FDA), regulates and approves medical devices such as software, algorithms, and artificial intelligence. This type of technology was designated as Software as a Medical Device (SaMD) (**Salud Digital, n.d.**).

The International Medical Device Regulators Forum (IMDRF) defines "Software as a Medical Device" (SaMD) as software intended to be used for one or more medical purposes that perform these functions without being part of a hardware medical device. (**International Medical Device Regulators Forum, 2013**).

The Federal Commission for the Protection against Sanitary Risk, (COFEPRIS for its acronym in Spanish), has a working group for the regulation of SaMD. The working group is composed of medical companies and pharmaceuticals, academic institutions, and the School of Biomedical Engineering<sup>6</sup>.

The objective of COFEPRIS is to review and change the Official Mexican Standards (NOM for its acronym in Spanish) involved in the operation, supervision, and surveillance related to SaMD. One of these NOM is the 241 SSA1 2020, which sets good manufacturing practices for medical devices<sup>7</sup>.

Actually, there is no precise and integrated regulation to provide health services through technology. In 2004, the National Center for Health Technology Excellence, (CENETEC for its acronym in Spanish), was created. It is a decentralized unit of the Ministry of Health which specializes in digital health. The functions and responsibilities of CENETEC include the spreading and diffusion of health technology and establishing national technology infrastructure guidelines. CENETEC is also responsible for developing and incorporating telemedicine services, including using and adopting technology to provide health services. (García, 2021).

### 4.3. Wearable devices

Mexico is the 3rd largest market for wearable devices, after the U.S. and Canada (Global Health Intelligence, 2015), though several sources point out that the market in China is much larger than that of Mexico. (Consumo TIC, 2020) These devices are automatic, non-invasive, and are used either to treat chronic diseases, such as diabetes, or to monitor specific variables of the person wearing them. The market includes therapeutic wearable devices, diagnostic devices,

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<sup>6</sup> <https://cib.org.mx/>

<sup>7</sup> NOM-221-SSA1-2021

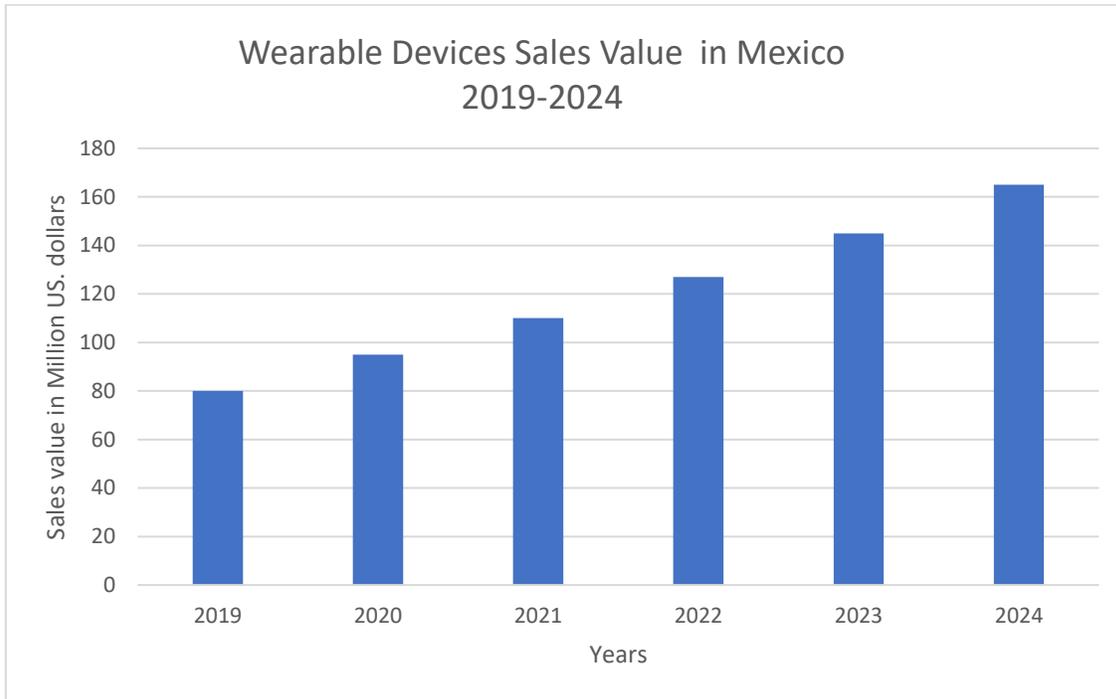
[https://dof.gob.mx/nota\\_detalle.php?codigo=5638793&fecha=20/12/2021#:~:text=Esta%20Norma%20tiene%20por%20objeto,requerimientos%20de%20calidad%2C%20seguridad%20y](https://dof.gob.mx/nota_detalle.php?codigo=5638793&fecha=20/12/2021#:~:text=Esta%20Norma%20tiene%20por%20objeto,requerimientos%20de%20calidad%2C%20seguridad%20y)

vital sign monitoring devices, remote patient monitoring, fitness, and activity monitoring devices.

Among the worldwide major market players are Zephyr Technology Corp., Omron Healthcare, Basis Science, Sotera Wireless, Polar Electro Oy, Philips Healthcare, Covidien Plc, LifeSense Group, and ResMed. (Global Health Intelligence, 2015) Specifically for smartwatches and wearables focused on monitoring fitness activities, firms such as Apple and Samsung control over one-third of the market. Nevertheless, LifeWatch Ag, Fitbit, and Garmin are also major players. (Fernández, 2020).

By the third trimester of 2020, there were 9.4 million users of smartwatches in Mexico, representing an adoption of 9.1% of the Mexican population over 12 years of age (The Competitive Intelligence Unit, 2021). The adoption of this technology is still limited, leaving an exciting growth potential, as shown in Figure 11.

*Figure 11 Wearable devices sales value in Mexico from 2019 to 2024 (Million US dollars)*



Source: Wearables Sales Mexico 2019-2024 Statista <https://www.statista.com/statistics/1109435/wearables-sales-mexico/>

#### 4.4. Mobile Health (mHealth)

During the 2019 pandemic, 22% of all downloaded mobile apps were related to wellness, health care, and fitness. (The Competitive Intelligence Unit, 2021).

The accelerated growth of mhealth in the world can be measured by the estimated number of health apps available. More than 97 thousand can be downloaded, and of those, 70% are related to wellness and fitness. The other 30% are exclusive to health professionals and their patients. Apps that are used for the supervision of chronic patients will continue to increase in the coming years. (NTT Data, n.d.).

Allied Market Research predicts that by 2030 the world market for fitness apps will reach 120 billion dollars, and it is expected that the market will continue to grow 24.3% annually. The use of apps among Mexican users has increased from 73,661 hours in 2020 to 9 million 516 thousand hours in 2021, as per the data from Comscore. (Cortes, 2022).

As in many other countries, such applications in Mexico have been developed based on four main areas: the administrative simplification of public institutions, situations where medical emergencies arise, medical advice and health indicators (including scheduling events and symptoms), and monitoring sports cycles or fitness tracking. (Cruz-Cortes, 2020). Table 6 shows the mobile applications in the public health system in Mexico.

*.Table 6 Mobile applications in the public health system in Mexico.*

APP	FUNCTION
	IMSS app that provides information to the users of procedures, services, location of clinics, and scheduled medical appointments, etc.
	ISSSTE app that links the user to ISSSTE online services regarding the scheduling or cancelling of appointments, etc.
	The ISSSTE app is for recipients and for the general public. It provides help and support in the event of a heart attack.
Covid 19 MX 	This app from the Ministry of Health provides information on what to do in case of a COVID infection. It includes direct access to the

	epidemiology centre as well as health services that are close to your location, etc.
<p><b>Tu Perfil IMSS</b></p> 	This allows IMSS Workers to have access to administrative procedures.
<p><b>Cardio Enlace</b></p> 	This App from the National Cardiology Institute allows patients with heart disease to monitor vitals signs and other parameters, and to share the information with their physician. The App allows monitoring the patient from their home. Released March 2022.

Source: Adapted from (Cruz-Cortes, 2020)

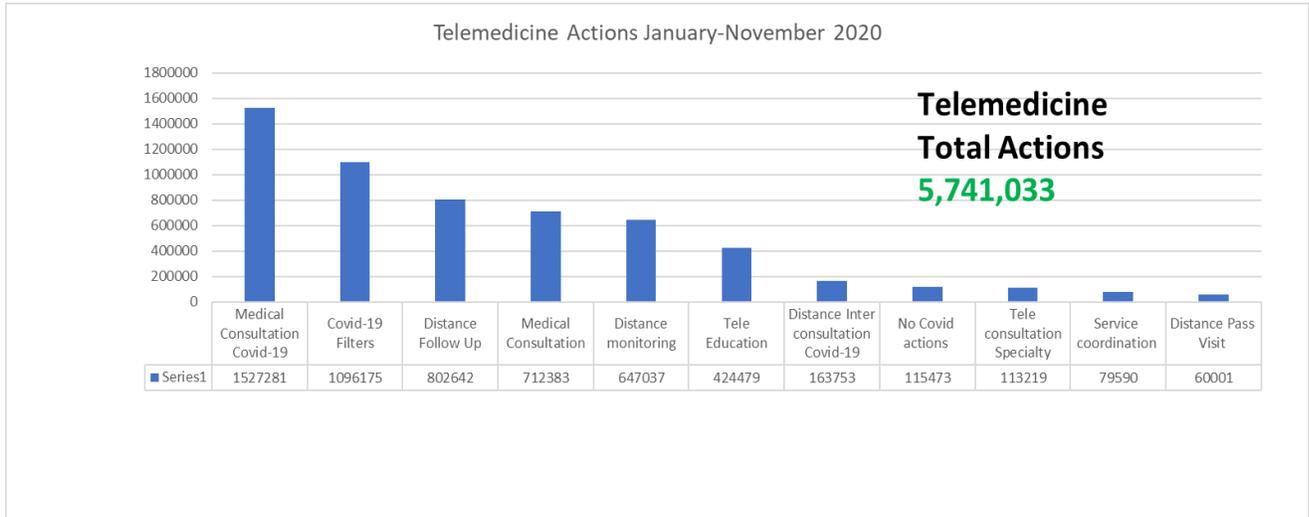
#### 4.5. Telemedicine

The use of IT in the health care system in Mexico started in the 70s with the use of the citizens band radio for communication. In 1990 the Ministry of Health extended its service coverage using radio communication. The first large-scale telemedicine program in Mexico was carried out through a pilot project by ISSSTE in 1995, using a computer system to transmit the signal, which in turn was received by satellite. The program included 18 telemedicine centres, and the program lasted from 1995 to 2007. (Arroyo, 2017).

In 2004 the National Center for Technology Excellence in Health (CENETEC for its acronym in Spanish) was created. It has contributed to the implementation of conduct for telemedicine with respect to its adoption into the national health care system in Mexico. The Covid 19 pandemic has forced the adoption of new technologies in the public sector to provide remote health care services to patients and to monitor patients in the hospital. Many state health agencies have implemented telemedicine projects to provide medical care during the pandemic. By 2019, 23 states had infrastructure and telemedicine programs in place. (Moraz-Perez, 2021).

The Covid-19 pandemic was crucial for the rapid adoption of telemedicine and telehealth in both private and public institutions. According to official data from CENETEC and the Ministry of Health in 2019, close to 127,000 medical consultations were provided across the public healthcare system in the country. Psychiatry and Internal Medicine were the most frequent specialties that used telemedicine. In 2020, telemedicine and other digital health activities had achieved impressive growth. See figure 12.

Figure 12 summarizes digital health activities performed in the public health system during 2020.



Source: TeleSalud and Cenetec 2020 <https://cenetec-difusion.com/observatoriotelesalud/info-prog-tm/>

Telemedicine programs have also been implemented in the private sector. Médica Sur, one of the leading private hospitals in Mexico, has a telemedicine service known as My Digital Hospital. The patient can request an appointment with a general physician or a specialist. The consultation takes place online, and if needed, the professional can order laboratory tests or images.<sup>8</sup> Hospitales Angeles also has a telemedicine program in which the consultation can be with a general physician or specialist. The Telemedicine service of Grupo Angeles is through the Ever Health platform.<sup>9</sup>

Another method of accessing telemedicine is through the use of Apps. They are several apps in the market. Some apps include electronic medical records, appointment scheduling, and the possibility of having online consultations. Examples such as these are: Doctoralia, Eleonor, MedicalManik, etc.

Smart doctor<sup>10</sup> allows physicians to provide virtual consultations by providing informed consent before the interaction and adhering to confidentiality protocols such as HIPPA.

<sup>8</sup> [https://www.medicasur.com.mx/es/ms/Mi\\_Hospital\\_Digital\\_Medica\\_Sur](https://www.medicasur.com.mx/es/ms/Mi_Hospital_Digital_Medica_Sur)

<sup>9</sup> <https://hospitalesangeles.com/telemedicina/>

<sup>10</sup> <https://smartdoctor.la/>

Telemedicina Latam<sup>11</sup> is a general physician or specialist network that provides consultation online. The company offers medical services to patients or private companies by providing health care services to their employees online.

Galena Medical is a general physician or specialist network that provides consultation online. The platform can be use by the patient to search for medical advise; the physician that can become members of the network and private companies. <sup>12</sup>

DoctorYa<sup>13</sup> is an App that you can download to access online medical support by paying a fee through PayPal.

#### 4.6. Non-Medical Software (Health information technology)

The Mexican market has available software applications that can be used in hospitals, clinics, and doctor offices. Public institutions use a variety of commercial and tailor-made software that is adapted to their needs.

The following electronic health records are accredited in Mexico:

Electronic Health Record (EHR) manages patient medical records from various medical health systems.

Electronic Medical Record (EMR) is managed and utilized by members of the same health institution.

Hospital Information Systems (HIS) manages the financial, clinical, and operative aspects of medical institutions. (Competitive Intelligence Unit , 2021).

##### 4.6.1. Electronic Health Record

The Ministry of Health defines an electronic health record as a "detailed set of information in chronological order that compiles all aspects relating to a patient's health and that of his family at a given period of his life; and represents a basis for knowing the health condition, medical acts, and procedures executed by the medical team throughout a medical event." (Ochoa J. A., 2018).

An Electronic Health Records (EHR) must comply with the Official Mexican Standard NOM-024-SSA3-2012. They must be standardized, traceable, secure, and confidential, and must support interoperability.<sup>14</sup>

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<sup>11</sup> <https://www.telemedicina.lat/>

<sup>12</sup> <https://galena.mx/>

<sup>13</sup> <https://doctorya.mx/>

<sup>14</sup> NOM-024-SSA3-2012 <http://www.dgis.salud.gob.mx/descargas/normatividad/normas/DOF-30NOV12-NOM-024-SSA3-2012.pdf>

The Official Mexican Standard NOM-004-SSA3-2012 stipulates what information the patient record must contain. The NOM defines a clinical record as the unique set of patient information and personal data for medical care. The record consists of written, graphic, imaging, electronic, and any other document type. Health care personnel must show all corresponding annotations that are related to their intervention with regard to the medical care of their patients.<sup>15</sup>

To fully understand and correctly apply the NOM-024-SSA3-2012, which regulates the EHR systems in Mexico, consultation of the other three official norms is required. These official norms are: NOM-035-SSA3-2012 for health information; NOM-004-SSA3-2012 for the EMR, and NOM-017-SSA2-1994 for epidemiological surveillance (Competitive Intelligence Unit, 2021).

In addition, NOM-024-SSA3-2012 states that the EHRs must use the fundamental catalogues established in Appendix "A" of the NOM, known as the Matrix of Basic Catalogues. This allows for the interoperability of healthcare data for EHRs to be used in a variety of different systems throughout the country.<sup>16</sup>

Using an electronic health record that fails to comply with NOM-004-SSA3-2012 can incur a fine for the physician up to 1,642,880 Mexican pesos<sup>17</sup>. (Comunicae, 2019).

#### 4.6.2. Use in Public Healthcare Institutions

Even though the public health systems in Mexico are obliged to use Electronic Health Records, the Mexican government does not enforce their use. State health institutions in Mexico, MoH, and National institutes have several EHR systems that are independent from one another, and some have no system whatsoever, and are still using paper records. (Neme, 2019).

A review was carried out of the reported EHR that is used by government institutions. Sixty-five systems were identified at the national level. Forty are reported in state health institutions in Mexico, 15 are at national institutes of health and highly specialized regional hospitals (MoH), 4 are in IMSS, 3 are in ISSSTE and 1 is in PEMEX. SEDENA, The National System for Integral Family Development (DIF for its acronym in Spanish), and SEMAR. (Neme, 2019).

The EHR systems used are from different software suppliers and are custom developed. SIGHO (Information System for Hospital Management) is used in both state health institutions in Mexico and highly specialized regional hospitals. PEMEX, SEDENA, DIF, and SEMAR have their

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<sup>15</sup> NOM-004-SSA3-2012 [http://dof.gob.mx/nota\\_detalle\\_popup.php?codigo=5272787](http://dof.gob.mx/nota_detalle_popup.php?codigo=5272787)

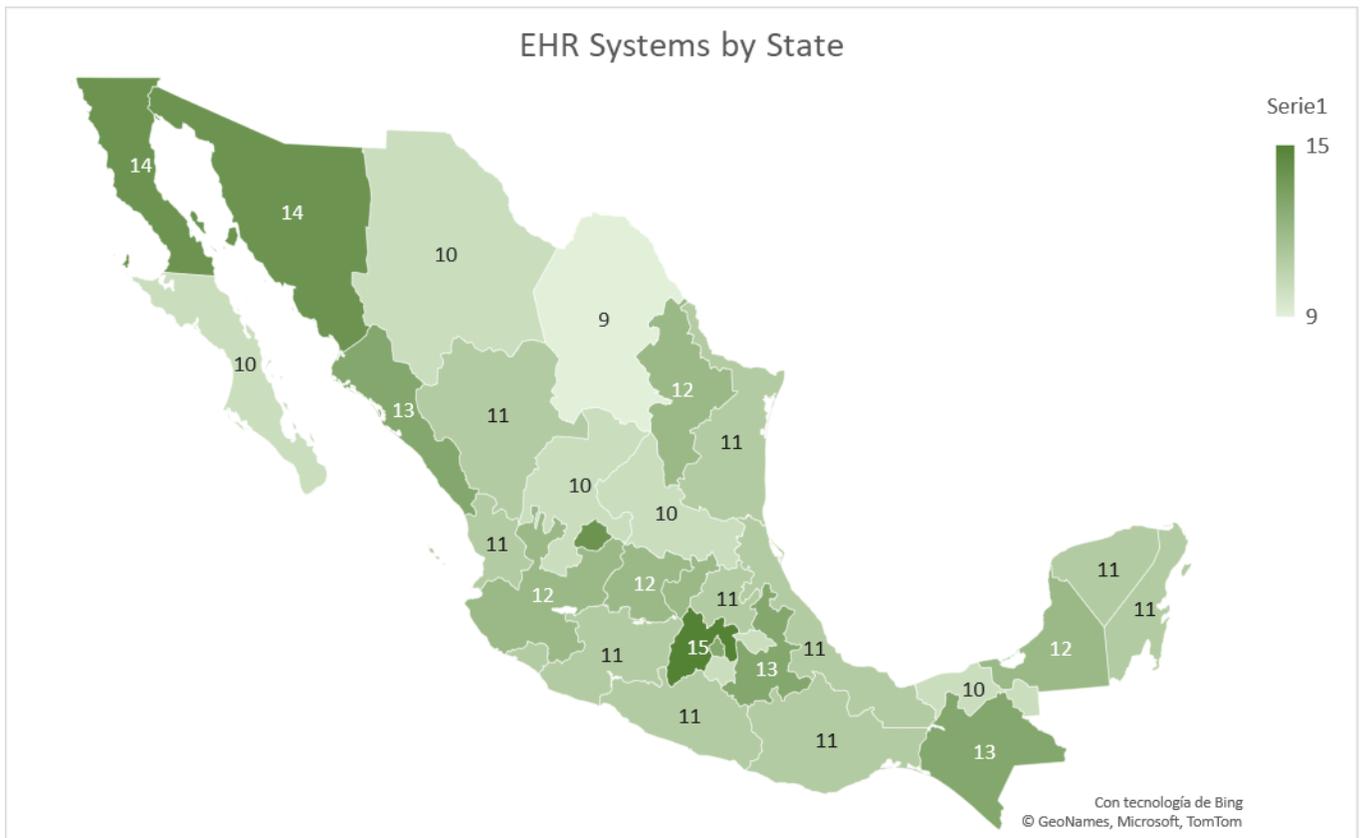
<sup>16</sup> Ministry of Health Catalogues [http://www.dgis.salud.gob.mx/contenidos/intercambio/iis\\_catalogos\\_gobmx.html](http://www.dgis.salud.gob.mx/contenidos/intercambio/iis_catalogos_gobmx.html)

own internal system. (Neme, 2019) . Some of them are custom developed by enterprises such as DSP, which has its own SISHOS branch. [Sistemas Hospitalarios \(SISHOS\) \(dsp.mx\)](http://www.dsp.mx)

Other systems used are Dedalus, Salud total, DXC Technology, TCA Software solutions, MEDSYS, among others.

The figure 13 shows the number of EHR systems used by states, including state and federal health institutions.

*Figure 13 EHR systems used by state*



Source: Neme Sofia, A 20 años de la implementación del expediente clínico electrónico en México, Vol. 5, 2019 Conamed Boletín. Referenced from: [http://www.conamed.gob.mx/gobmx/boletin/pdf/boletin26/Besp26\\_10.pdf](http://www.conamed.gob.mx/gobmx/boletin/pdf/boletin26/Besp26_10.pdf).

Even though the health system in Mexico has tried to have one EHR, there is not one system at the institutional level that is robust, integrated, and able to exchange information with other public health or private institutions. Many of the systems in place are not standardized or certified, and headings are different, which results in a breakdown of information in the public health system of Mexico. (Neme, 2019).

#### 4.6.2.1. Business Case Mexico City Health System

In 2014, the Ministry of Health in Mexico City, (SEDESA for its acronym in Spanish), presented its EHR medical administration and hospital information system (SAMIH for its acronym in Spanish). It was considered a successful experience to manage the electronic records for patients for the 31 hospitals that SAMIH operates. The implementation of SAMIH, was carried out in a record time of two years (Neme, 2019).

The SAMIH platform is classified as one of the best in complying with the HL7 (Health Level Seven)<sup>18</sup> protocol. SAMIH integrates clinical systems, pharmacies, laboratories, imaging, and blood banks. The administration and storage of the database, images, and laboratory studies have two data centres that will enable interoperability between the Mexico City Hospital Medical Units (Everis Spain , 2016).

Since its implementation, four million patients have been registered, of which: 339,645 patients have been monitored, 644,880 clinical notes have been made, and more than 109,720 applications and electronic prescriptions have been documented (Competitive Intelligence Unit , 2021).

SAMIH was a joint development between the Mexican firm Telmex and Everis. (Canales TI, 2016).

#### 4.6.3. The private experience

The technological adoption of hardware is up to date in the health system of Mexico. Private hospitals have invested significantly in equipment for critical applications. Software applications still have a long way to go. There is a need to implement security solutions to manage and protect data, such as clinical records.

Select, an IT Consulting firm, mentioned that business opportunities lie in the digitalization of the private and public sectors. The firm also noted that opportunities in digital transformation exist in data architecture for standardization and governance, managing clinical records, and sharing information among private and public health institutions, suppliers, and for electronic prescriptions. **Fuente especificada no válida..**

The public sector institutions like IMSS and ISSSTE currently work with large system integrators and administrative services organizations. A similar situation is found in large private hospitals. There is an area of opportunity in small and medium-sized private hospitals and clinics. **Fuente especificada no válida..**

Before the Covid-19 pandemic, 98% of the large private hospitals adopted technology and intensely worked on digital transformation. Because of Covid-19, this sector had to increase services and improve its digital infrastructure.

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<sup>18</sup> <https://www.hl7.org/>

During 2020, small and medium-sized private and specialized hospitals almost doubled the use of digital technologies. For medium-size hospitals, this ranges from 30% to 60%, for specialty clinics from 40% to 80%, and for small hospitals from 5 to 10%. **Fuente especificada no válida..**

Some of the solutions used in clinics are listed below.

Ecaresoft is used for hospitals and clinics under the brand name Cirrus. Its headquarters is located in the U.S. The company has sold to medium-sized and large hospitals in 5 countries; [Christus Murguerza](#) (ranked among the ten leading private hospitals), and is an important client of Ecaresoft. <https://www.getcirrus.com/en> .

SC Telecom is a solution provider that covers several sectors, including health. Their health solutions have several EHR, management, hospitalization, and cloud services modules. Some examples of their Mexican clients are: [Hospital Ebor](#), [Hospital Moscati](#), [Centro Médico Peninsular](#) .

<https://www.sctelecom.com.mx/software-hospitalario>

Medsi, a Mexican firm that offers solutions for doctors and clinics, is also a software factory. The company is based in Merida, Yucatán. <https://www.medsicom.mx/emr.html>

Many physicians with private offices and small hospitals and clinics are now using EMR. It saves time, the information is safe, and it can be shared with other health professionals. Solutions that are currently available in the market include a module that can keep track of schedules and appointments.

Here are some examples:

- ✓ Compuexpediente <https://www.compuexpediente.com/>
- ✓ Daktaris <https://daktarisys.com/>
- ✓ Medsisel <https://expedienteclinico.mx/>
- ✓ SalusStandard [http://softwaresalus.com/descripcion\\_software\\_salus.aspx#standard](http://softwaresalus.com/descripcion_software_salus.aspx#standard)
- ✓ Medilink <https://www.softwaremedilink.com/>
- Doctoralia <https://www.doctoralia.com.mx>
- doc.com <https://doc.com>
- Smart doctor <https://smartdoctor.la>
- ✓ Alephoo <https://www.alephoo.com/contacto>
- ✓ Hi Doc <https://www.hidoc.com.mx/expediente>

These software solutions provide several services related to digital health. Doctoralia<sup>19</sup> is a social network where patients can find medical specialists and provide reviews of their services. The solution also provides physicians with an agenda to schedule appointments with the possibility for creating EMR and for providing electronic prescriptions. Others, such as

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<sup>19</sup> <https://www.doctoralia.com.mx>

Compuexpediente and Eleonor, are more oriented toward creating EMR. Hi Doc assists patients in finding a healthcare professional.

There are also available digital solutions to receive laboratory results and radiology images in the Mexican market. An example is a solution called **Labsis**, which is a laboratory information system. It has the tools to manage hospital laboratories and interconnect with hospital information systems using the HL7 Standard protocol. This solution is used in several laboratories and in public and private institutions in Mexico. Their corporate office in the U.S. <https://labsis.com/>

Xsystems is a Mexican company which has more than 15 years of clinical experience, and they provide laboratory tests results.

[Xyhttp://www.xsystems.com.mx/px-lab.html#modulorecepstems](http://www.xsystems.com.mx/px-lab.html#modulorecepstems)

Nubix Cloud is a solution to delivering radiology images in DICOM format. The images can be viewed on PC, and by e-mail, WhatsApp, and SMS. Laboratories and clinics are the clients of the company in Mexico. <https://nubix.cloud/>

#### 4.6.3.1. *Digitalization Challenges in Mexico*

An important factor that affects digitalization is the investment in telecommunications infrastructure that allows users to use technology and reduce the digital bridge. To determine the level of technology access and use, the ICT Development Index monitors and compares developments in information and communication technology (ICT) between countries over a period of time. The ICTT Development Index evaluates the level of development on a scale from 0 to 10, with 0 being no development and 10 being the highest.<sup>20</sup>

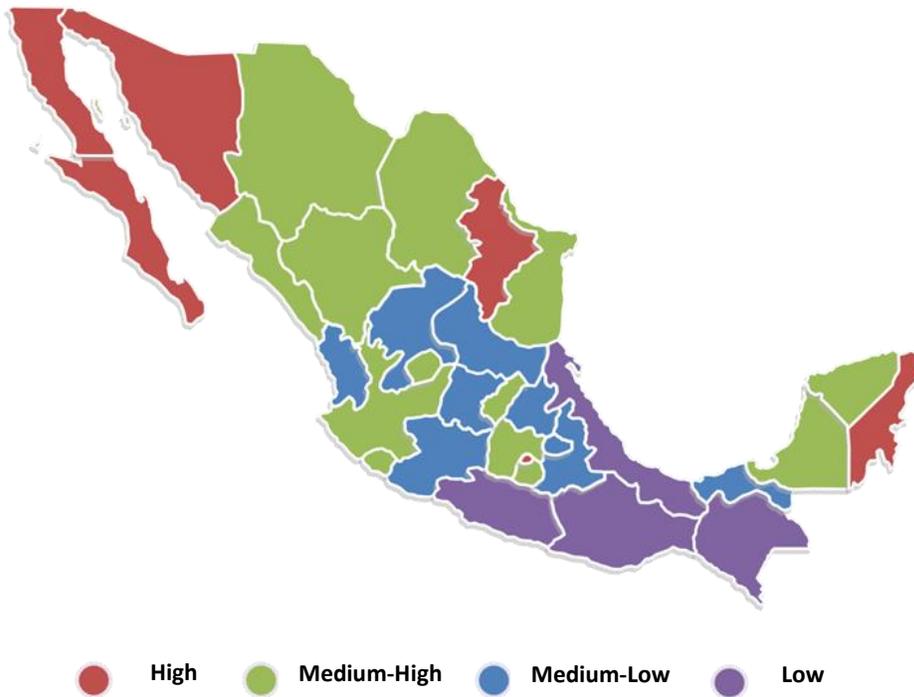
Based on the ICT Index, the Social Intelligence Unit<sup>21</sup> rates the difference in ICT development in Mexico by comparing all states. Mexico City was the state with the highest Development at 6.98, followed by Nuevo León with 6.56, Sonora with 6.53. The states of Chiapas, Guerrero, and Oaxaca have the lowest indexes, with 3.18, 3.63, and 3.90 respectively. (Ochoa M. , 2020 ). See figure 14.

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<sup>20</sup> International Communication Union, <https://www.itu.int/en/about/Pages/default.aspx>

<sup>21</sup>The Social Intelligence Unit <http://www.the-siu.net/wordpress/idx-mx/>

Figure 14 ICT Development Index by State



Source: The Social Intelligence Unit <http://www.the-siu.net/wordpress/idt-mx/>

The population of Mexico City as well as those states with a higher ICT Index have better opportunities to access distance education, mobile communication, and telehealth services than states like Chiapas. In spite of the advantages that telecommunication reform has made in Mexico, 40% of the population does not have Internet access in their homes. (Asociacion Mexicana de Internet, n.d.).

During the Covid-19 pandemic, Internet users had to adapt and adopt technology to carry out their activities remotely. Among Internet users, 45% had to accelerate the adoption of this technology. The lack of Internet service forced users to search for spaces with connectivity. One of the standard solutions was to use the Internet in the home of relatives or friends. (26% of users did so during 2020) (Asociación de Internet de Mexico, 2021).

Despite all efforts to increase technology development, the digital bridge between States does not change. Those states that lag behind experience greater difficulties in reaching the national ICT average. (The Social Intelligence Unit, 2022).

The Competitive Intelligence Unit (CIU) presented a series of recommendations to achieve the implementation and access to telemedicine in Mexico. (Competitive Intelligence Unit, 2021).

- Public health policies that promote and enforce the use of EHR in all health institutions (public and private) along with the adoption of IT devices such as smartphones and wearables to access and feed the system is needed.
- The use of an interoperability system will allow the exchange and interaction of information of the EHR.
- Establishing training courses for medical students and physicians on the use of HER is recommended.
- Promoting the use of smart phones and wearables will provide access to patient information.
- A policy that promotes connectivity by expanding access to EHR, especially in the southern states, will be extremely beneficial.
- Promoting connectivity in public health centres is recommended, since at least 11,000 public health centres lack sufficient connectivity.

## 5. Purchase process for medical products in Mexico

The purpose of the following chapter is to explain how purchases are made in Mexico in the public and private health care systems. It is highly important to remember that the first step to selling in Mexico is to have your products registered in Cofepris.

### 5.1. Government Purchases

In 2018 a new government started in Mexico. Andrés Manuel López Obrador (AMLO) took office in December. During his presidential campaign he promised to reduce corruption in all government areas, including the purchasing of medications, treatment supplies, and medical devices. The president mentioned that the purchases made by the previous administration were provided by 10 suppliers that represented 80% of the acquisitions. AMLO explained how the corruption took place. A public tender was issued for 1,500 drug keys, however companies would only provide 1,000 keys and wait until the sector needed the other 500 immediately, and given the urgency of the situation, the supplier would sell the unit at two or even three times higher than the normal cost. (Forbes, 2019) The new administration has striven to transform the purchasing process in order to make it more efficient and transparent by eliminating such practices.

One such change was the cancellation of the so-called popular insurance (Seguro Popular), which was created to protect the population that was not covered by health insurance. The new administration considered that the program was not providing a good service, was not free of cost, and the patient had to pay a certain amount depending on his/her income. It was also mentioned that there was a shortage of medications in the health units. The Seguro Popular was substituted by the Institute of Health for Welfare (ISABI for its acronym in Spanish). Its goal is to provide and guarantee free health services, medications, and other supplies to people without health coverage.

INSABI is governed by four work principles:

- Supply medicines and equipment to health units in order to provide quality medicines and free health services to the population without social security.
- Provide medical care by having sufficient health care personnel.
- Provided adequate and professional health infrastructure
- Ensure fair treatment and justice in the workplace to their healthcare workers. (Finance, 2020)

In 2019 the Mexican government created the Health Fund for Well-Being (FONSABI), a public trust formed by the terms of the federal law that governs budget and finance and INSABI which acts as a trustor. FONSABI was formed with three goals in mind:

- To provide assistance for diseases that produce catastrophic expenses, including the financing of treatments, medications, and infrastructure.
- To examine infrastructure needs in regions experiencing social marginalization.
- To complement existing resources in order to ensure the supply and distribution of medications and materials to the uninsured population.

In 2019 the new administration started planning the new purchasing process for medications with a focus on improving health care and prices for the general public.

Improving prices will include creating a national compendium of drugs. Institutions will be required to consolidate all purchases that will lead to cost savings, better prices, and higher quality.

An improvement in public health will usher in a standardization of treatments. All public sectors will follow the same protocol and deliver the same drugs. Medical improvement entails planning purchases which are based on the opinion of a medical expert, and not the suppliers. (AMLO ORG , 2021).

In July 2020, the president and the Ministry of Foreign Affairs, the Ministry of Health, and INSABI signed an agreement with the United Nations Office for Project Services (UNOPS ). UNOPS and INSABI will be in charge of the procurement of medicines and materials at a national level for the entire public health system from 2021 to 2024. This will aim to eliminate corrupt practices and to generate savings by creating certainty and transparency in the acquisition process. (Garrod, n.d.) ..

UNOPS will provide experience in the purchasing process and best practices and comply with world standards. UNOPS includes the validation and certification of the companies that will supply medications. Only those companies that pass through the filters of UNOPS will be awarded the contract<sup>22</sup>.

The bidding mechanism of UNOPS includes a national and international market analysis that obtains information from suppliers and a price analysis through the Economist Intelligence Unit<sup>23</sup> to achieve the greatest supply with the best price, along with the highest quality and savings.

Changing the purchasing process caused a shortage of medicines at all levels of the health care system in Mexico. It became severe during the pandemic due to the use of resources that were allocated to control it.

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<sup>22</sup> Proyecto para la compra de medicamentos y material de curación en México Accessed March 10, 2022.

Referenced <https://www.proyectosaludmexico.org/unops-insabi.html>

<sup>23</sup>UNOPS Economist Intelligence Unit <https://observatorio.unops.org/>

For 2021, 2,034 medicine keys were requested from the UNOPS acquisition which included the requirements for the following institutions: (INSABI, 2021)

Ministry of Health (MoH)

Defense Ministry (SEDENA)

Marine Ministry (SEMAR)

INSABI and federal entities

National Health Institutes

Reference Federal Hospitals

Highly Specialized Regional Hospitals

Mexican Institute of Social Security (in Spanish: IMSS)

Social Security System for State Workers

UNOPS awarded a total of 1,038 keys that represented 697 million pieces of medicine 198.2 million pieces of healing material, covering 996 keys that correspond to 710 medicine keys and 286 healing material keys. (INSABI, 2021).

Even though the Mexican government intended to have an efficient and effective purchasing process, the reality is that there has been a shortage of supplies, medicines, and materials in all public health institutions during 2022. For the current year, UNOPS is still behind.

In the second semester of 2022 it was decided that UNOPS would only cover one semester, not the entire year. One of the chief complaints was the shortage of medicines for treating children with cancer. For 2022 UNOPS will only cover 28 cancer treatment keys instead of 155 from 2021. INSABI will be in charge of buying patent medicine and will purchase it directly from the supplier. This reduction arose as a consequence of the previous bidding of UNOPS, in which 48% were not awarded. The government stated that 13% of the keys did not receive an offer, 12% were over the reference price, and 7% came from disqualified suppliers. Another problem encountered was paying the suppliers. Goods are required to be delivered to the state warehouses in order to receive payment, but there was no coordination between UNOPS and state agencies, and therefore payments were delayed. In comparison, only 9% of the offers were not covered in the past administration. (Martin, 2021).

Selling to the government can be complicated, and the rules can easily change. Nevertheless, many international firms with operations in Mexico supplied the Mexican government. A complete list of the companies awarded in the past bidding can be reviewed at the website of UNOPS at: <https://www.proyectosaludmexico.org/licitaciones.html>. The list includes information of companies awarded and the products that they sold. The keys awarded for domestic and international biddings can be reviewed at the same link.

This new process has brought opportunities to new suppliers. During the previous administration, 18 suppliers covered 80% of all government purchases. With this new scheme,

97 suppliers cover 80% of the offers. For international bidding, UNOPS has received the participation of 19 countries from the continents of Asia, Europe, and America. (INSABI, 2021).

Nevertheless, it is essential to have contacts with authorities from the public systems of Mexico in order to receive information on time for the bidding process, present products and technology to the medical staff, and to learn about the needs and requirements of hospitals or institutions.

## 5.2. Private Purchases

As mentioned in chapter one, private hospitals in Mexico are highly concentrated, with 52.2% of hospital beds located in six states: Mexico City (14.1%), the State of Mexico (11.5%), Jalisco (9.1%), Guanajuato (6.1%), Nuevo León (6.1%), and Puebla (5.3%).

The number of private hospitals in Mexico is 2,855, of which 91% are small, less than 24 beds, 158 hospitals are considered medium-sized with 25-49 beds, and 99 hospitals have 50 or more beds. (Coronel, 2021).

In 2020, the magazine [Expansión](#) published, in collaboration with the Mexican Health Foundation and Blutitude Consulting, the first private hospitals ranking. (See table 7). The 2021 ranking included the analysis of 500 private hospitals representing 17.5% of private hospitals and 17,000 beds, which signifies 50% of beds in the private sector. Six of the best ten hospitals are located in the Mexico City metropolitan area, and the other four are in the Monterrey metropolitan area, Nuevo León.

Table 7 Expansion Ranking of the Best 10 Private Hospitals in Mexico

Expansion Ranking of the Best 10 Private Hospitals in Mexico			
Position	Hospital Name	Location	Web Site
1	Centro Médico ABC Campus Observatorio	Mexico City Metropolitan area	<a href="https://centromedicoabc.com/">https://centromedicoabc.com/</a>
2	Médica Sur	Mexico City Metropolitan area	<a href="https://www.medicasur.com.mx/">https://www.medicasur.com.mx/</a>
3	Hospital Ángeles del Pedregal	Mexico City Metropolitan area	<a href="https://hospitalesangeles.com/pedregal/">https://hospitalesangeles.com/pedregal/</a>
4	Christus Muguerza Hospital Alta Especialidad	Monterrey Metropolitan area	<a href="https://www.christusmuguerza.com.mx/hospital-alta-especialidad">https://www.christusmuguerza.com.mx/hospital-alta-especialidad</a>
5	Centro Médico ABC Campus Santa Fé	Mexico City Metropolitan area	<a href="https://centromedicoabc.com/">https://centromedicoabc.com/</a>
6	Hospital Español	Mexico City Metropolitan area	<a href="https://www.hespanol.com/">https://www.hespanol.com/</a>
7	Hospital Ángeles Lomas	Mexico City Metropolitan area	<a href="https://hospitalesangeles.com/lomas/">https://hospitalesangeles.com/lomas/</a>
8	Hospital San José TecSalud	Monterrey Metropolitan area	<a href="https://www.tecsalud.mx/hospitalsanjose">https://www.tecsalud.mx/hospitalsanjose</a>
9	Christus Muguerza Hospital Sur	Monterrey Metropolitan area	<a href="https://www.christusmuguerza.com.mx/hospital-sur">https://www.christusmuguerza.com.mx/hospital-sur</a>
10	Hospital Zambrano Hellion TecSalud	Monterrey Metropolitan area	<a href="https://www.tecsalud.mx/hospitalzambranohellion">https://www.tecsalud.mx/hospitalzambranohellion</a>

Adapted from: <https://expansion.mx/empresas/2021/11/19/estos-son-los-mejores-hospitales-privados-de-mexico-2021>

The National Association of Private Hospitals is an umbrella organization that represents the main private hospitals in Mexico. <sup>24</sup> The private hospitals have their purchasing and logistics departments. The medical suppliers have relations with different hospital areas depending on their products. They give demonstrations and provide samples and tests to show the benefits of their solutions. The area that is interested will request the product from the purchasing department, which will be in charge of acquiring the products and paying the suppliers.

Some hospitals are part of groups that reduce costs in order to consolidate purchases. The main hospital groups in Mexico are:

- Grupo Ángeles, with 32 hospitals located throughout the country <sup>25</sup>
- Star Medica group with 15 hospitals located in different regions of Mexico.<sup>26</sup>

<sup>24</sup> <http://www.anhp.org.mx/>

<sup>25</sup> <https://hospitalesangeles.com/hospitales-angeles>  
<https://www.grupoempresarialangeles.com/sectores/grupo-angeles-servicios-de-salud/>

<sup>26</sup> <https://www.starmedica.com/home/es/info-corporativa>

- The Christus Muguerza group that has a network of 18 hospitals. The group is part of Christus Health that has hospitals in the southern United States, Mexico, Chile, and Colombia.<sup>27</sup>

The Mexican Hospitals Consortium is an organization that comprises 52 private hospitals in 25 states that have an average of 29 beds each. One of the goals of the consortium is to consolidate purchases in order to help small hospitals and to reduce costs.<sup>28</sup>

Medical equipment companies provide different selling options to hospitals and clinics, as well as to doctors, to help them acquire medical devices or equipment.

- Commodatum (gratuitous loan). The equipment is loaned, but there is a contract to buy all the supplies required to use the equipment, such as catheters, contrast media, etc.
- Leasing the right to use the equipment by paying a monthly fee for a certain period. The leasing contract is between the financial institution and the end-user.
- Per event, renting of equipment or services for specific surgeries or procedures.
- Direct sales, suppliers can provide 90 to 180 days of credit based on the hospital or financial situation of the clinic.

Examples of some Mexican leasing firms specializing in medical equipment.

Retrofin SA de CV <https://leasemd.mx/#/home>

Arrendamex <https://arrendamex.com.mx/medico/>

Egen Capital <https://www.engen.com.mx/salud/>

These companies that rent equipment are specialized in various medical areas and offer different solutions related to equipment and supplies.

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<sup>27</sup> <https://www.christushealth.org/about>

<sup>28</sup> <https://cmhac.com/hospitales/>

## 6. Manufacturing in Mexico to sell in the North American Market

Mexico has become a global key player as a manufacturer of Medical Devices and is the eighth producer globally. In addition, it is the largest exporter to the US Market. Mexico has the talent, capabilities, and infrastructure to continue on this path. (Ulloa, Mexico Industry, 2021).

The manufacturing industry began to supply the US market in the 60s, which was the beginning of the "Maquiladora Industry." The benefits of having an operation in Mexico were cost, available personnel, and political and economic stability (Hernández, 2022) . The Maquiladora industry has continued over the years. It has evolved from assembly and garment manufacturing or simple manufacturing processes to having specialized and high-skilled labor that works in the medical, aviation, automotive, and electronics industry. The concept of nearshoring, having a production center close to consumers, has benefited Mexico. Foreign companies have looked at moving their operations to serve the US and Canadian market, which has cost savings advantages along with the benefits of the United States-Mexico-Canada free trade agreement (USMCA).

The medical device industry in Mexico has continued to grow and has become an important part of the manufacturing sector in Mexico. This section presents the main Cluster in Mexico and its benefits for foreign companies on how to target the North American Market.

In 2020, there was an increase in the use of medical devices in Mexico, representing 9.8 billion dollars a 22.5% increase over 2019. In 2019, the medical device industry primarily exported 10.1 billion dollars worth of medical devices. The medical device industry represents 2.41% of the exports of Mexico. (Lara, 2021) While the country imported \$ 4.4 billion dollars in 2017. (AMID & KPMG, 2019).

### 6.1. Medical Clusters in Mexico

The National Institute of Statistics and Geography (INEGI, n.d.) reports that in Mexico there are 2,453 specialized units using medical devices in operation, which are mainly located in Mexico City, the State of Mexico, Baja California, Chihuahua, Jalisco, Sonora and Guanajuato. (INEGI, n.d.).

Using data from INEGI regarding these specialized units using medical devices, the information was filtered using criteria based on the number of employees per unit. Only 8.9% of the medical units in Mexico have more than 50 employees. The location of such units is shown in Table 8.

Table 8 Specialized units using medical devices in Mexico with more than 50 employees

<b>Specialized units using Medical Devices (More than 50 employees)</b>	
<b>Mexican State</b>	<b>No. Units</b>
Aguascalientes	1
Baja California	61
Chihuahua	35
Mexico City	12
Coahuila	7
Guanajuato	1
Hidalgo	1
Jalisco	12
Mexico	14
Morelos	11
Nuevo León	8
Puebla	4
Queretaro	1
San Luis Potosí	2
Sonora	16
Tamaulipas	12
Tlaxcala	4
Veracruz	1
Yucatan	3
<b>Total</b>	<b>206</b>

Source: Modified from INEGI Directorio Estadístico Nacional de Unidades Económicas, March 2022

The numbers presented in the table help us determine the Mexican state that has more specialized medical device manufacturing or specialized clusters, as described below.

The most important cluster of the country is in Baja California. The cluster is responsible for approximately 50% of the total national exports of the sector, and has 79 manufacturing plants. (CANIFARMA, 2020) Most of the companies are affiliated with Baja's Medical Device Cluster [in Spanish: la Asociación Industrial de Productos Médicos de las Californias A.C.]. Only 5% of the companies are of Mexican origin.

The cluster comprises key manufacturers, suppliers, and individuals from academia and relevant government agencies. Some of the items manufactured in Baja California include pacemakers and their batteries, ophthalmic lenses, wheelchairs, catheters, defibrillators, urinary

bags, electric thermometers, and many others. (Tecma-Communication, 2020) These companies are located in Tijuana, Ensenada, Mexicali, and Tecate.

One such company that has a long history of manufacturing in Baja California is Medtronic, whose plants assemble stent-grafts, catheters, and human heart-valve replacements. Welch Allyn manufactures diagnostic devices, patient monitoring systems, vital signs devices, and GE Medical Systems (GEMS). (Tetakawi, 2020) Carl Zeiss Vision Mexico started operations in 1984. Today the company has an annual average production of 45 million ready-made glasses and 8 million personalized prescription eyeglasses. (Sandoval, n.d.).

In Chihuahua, Ciudad Juarez is Bio el Paso – Juarez, a 501(c)(6) Nonprofit (IRS, n.d.) conceived by the Medical Center of the Americas Foundation. The region includes West Texas, Southern New Mexico, and Northern Mexico (Chihuahua). The cluster consists of medical device manufacturers, biotech startups, healthcare providers, academic institutions, and organizations. The region has significant manufacturers from all over the world, with 30 factories in the region producing class I, II, and III medical devices. Some of the companies in the region are CardinalHealth, BD, ASO wound Care, Johnson & Johnson, and there are also several contract manufacturers such as RexMed and Seisa Medical. Manufactured devices include catheters, orthopedic supports, surgical equipment, respiratory and ophthalmic devices, wound care, and electronic and mechanical Infusion pumps in the region.<sup>29</sup>.

Johnson & Johnson opened their first plant in Ciudad Juarez in the '70s. Today the plant has three plants under the names of Ethicon, Biosense Webster, and Codman; the latter of which is one of the largest manufacturing complexes for the firm in the world. Johnson & Johnson manufactures products for laparoscopic surgery, cauterizing devices, and sutures. Their products are exported all over the world. (Gutierrez, 2021).

Most of the manufacturing companies follow the Maquiladora Model, that is, plants that are located in free trade zones and close to the US border.

Tamaulipas, also a border state, has increased the manufacturing of medical devices by having assembly and plastic injections capabilities. The state has 13 companies located in Nuevo Laredo, Matamoros, and Reynosa. The most important company in Tamaulipas is Erika de Reynosa, the manufacturing plant in Mexico for Fresenius Medical Care<sup>30</sup>, the leader in manufacturing devices for chronic renal failure. The Reynosa plant has 20 production lines and 4,000 employees.

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<sup>29</sup> Bio El Paso-Juarez <https://bioelpasojuarez.org/>

<sup>30</sup> <https://fmc-mexico.com/>

Haemotronic<sup>31</sup> is an Italian manufacturer of single-use medical devices for infusion and dialysis, and has a manufacturing plant in Reynosa, with an average production of 5 million infusion sets. (Ulloa, Mexico Industry, 2021).

The Jalisco cluster is known as the Biomedical Engineering Cluster, since most clusters are composed of companies, academia, government institutions, and other organizations. To manage the Cluster a non-profit organization was created with the participation of the Mexican Society of Biomedical Engineering (SOMIB), The School of Biomedical Engineers of the Jalisco State (CIBEJ), and the Technology science and innovation center of Jalisco (CEDITE). The cluster is composed of 48 affiliated Mexican companies. This cluster is a mix of companies from manufacturers of medical devices, digital health solution developers, distributors of medical devices and equipment, and suppliers.

Jabil, one of the world leaders in contract manufacturing, is located in the Technology Park of Guadalajara. The plant started operations in 1997 and is a Tier I electronic service provider. Jabil also has a plant in Chihuahua and Tijuana.

The State of Mexico has been a substantial manufacturing base for many industries and has an important automotive, pharmaceutical, and chemical industry. In the area of medical devices, the state has some important investments. The Mexican firm Medipro Internacional SA De CV, whose commercial name is Atramat, manufactures sutures, needles, and implants, and it has a plant in Mexico as well as another in Turkey. The company exports to 80 countries. <sup>32</sup>

BD (Becton Dickinson) has a plant in Cuatitlan Izcalli, the State of Mexico, and it produces 52% of the production of syringes. BD is building a new plant in Cuamatla, Cuatitlan Izcalli, that will produce caps for injection devices. (Santiago, 2021).

Sonora is a border state with an important industrial hub for aerospace, electronics, automotive, plastic, textile, and medical devices. The company Tetakawi, formerly known as Off-Shore Group, is a shelter services provider that allows foreign companies to easily establish and operate in Mexico. The company has three industrial parks in Sonora that are located in Empalme, Guaymas, and Hermosillo, and has four more in other Mexican states. An example of a company that is part of the shelter is Medtronic, whose plant is in the industrial park of Empalme. The company manufactures arterial implants, suture needles, nickel alloy rings, plastic, and nitinol auxiliary devices for surgery. (Tetakawi, 2021).

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<sup>31</sup> <https://www.haemotronic.it/company/>

<sup>32</sup> Accessed March 09, 2022. Referenced from: <https://www.atramat.com.mx/>

Our final stop will be in Morelos, a state that borders Mexico City, which has various large Mexican-owned companies in the medical sector. For example, Esigar Quirurgica manufactures catheters, clinical thermometers, and cleaning accessories for surgery.<sup>33</sup> Degasa is a leading manufacturer of wound care, disposables, and antiseptics, and exports to the Latin American and North American markets.<sup>34</sup> And lastly, IMP is a company that manufactures blood bags and transfusion kits, urine bags, and foley catheters.<sup>35</sup>

## 6.2. Products manufactured in Mexico

The medical device industry in Mexico manufacturers the following products:

- Pacemakers and their respective batteries
- Ophthalmic lenses
- Monitoring Devices
- Wheelchairs
- Catheters
- Defibrillators
- Urinary bags
- Electric thermometers
- Stent-grafts
- Catheters
- Human heart-valve replacements
- Products for Laparoscopic surgery
- Cauterizing devices
- Sutures
- Devices for chronic renal failure
- Syringes

## 6.3. Location

The majority of the medical device clusters are located in the states that border the US. The map below shows the location of the main medical device areas of the country. (Figure 15)

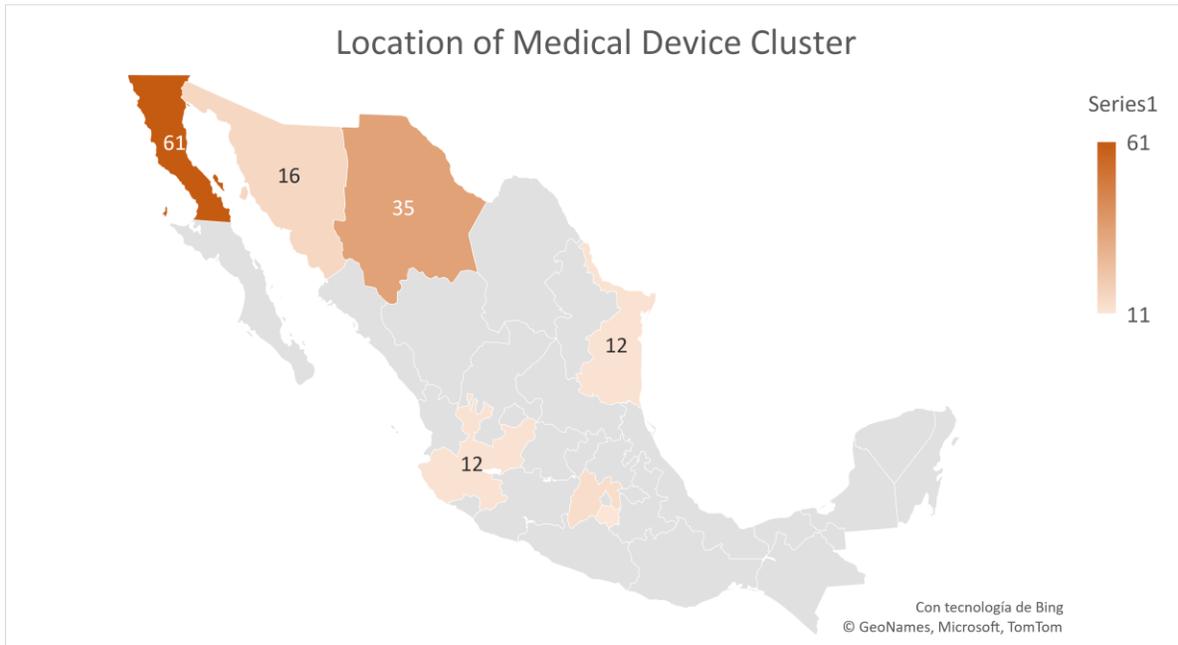
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<sup>33</sup> Accessed March 09, 2022. Referenced from: <https://esigarquirurgica.com/>

<sup>34</sup> Accessed March 09, 2022. Referenced from: <https://www.degasa.com/>

<sup>35</sup> Accessed March 09, 2022. Referenced from: <https://ipm.mx/>

Figure 15 Location of Medical Device Cluster in Mexico.



Source. Source: Modified from INEGI Directorio Estadístico Nacional de Unidades Económicas, March 2022

#### 6.4. Competitive advantages of establishing a plant in Mexico

The maquiladora model is known as the Decree for the Development and Operation of the Maquiladora Export Industry (IMMEX for its acronym in Spanish) and is the prevailing model for manufacturing in Mexico to produce goods destined to the US and to other international markets. The location of the plants is in a free-trade zone close to the US border. The maquiladora program began in 1965. (Loya, n.d.).

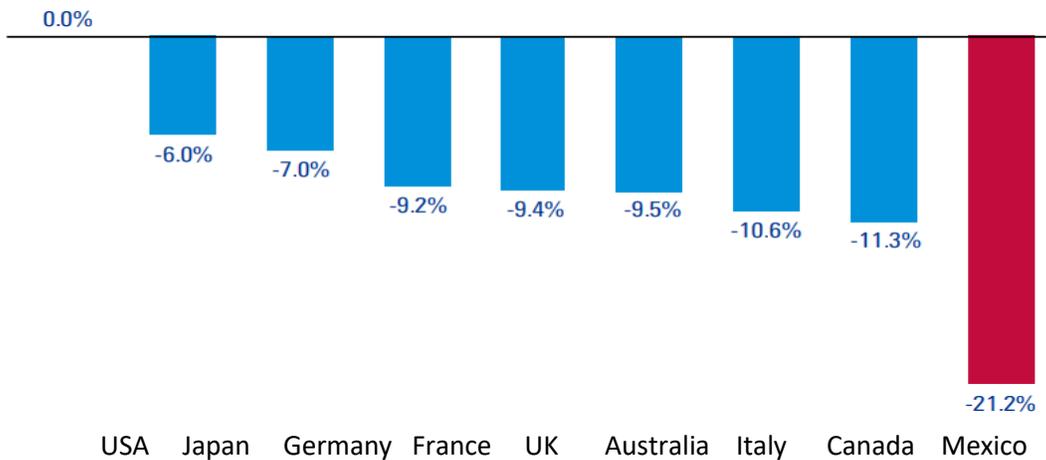
What benefits are offered by the maquiladora model? (Sanchez, n.d.).

1. The importation of raw material, machinery, or any supply required for manufacturing is tax-free and should be used to transform a finished product for export.
2. Fiscal benefits, for example, for temporary imports, the maquiladora does not pay the Value-added tax. (VAT).
3. Savings in labor costs. Mexico offers qualified and reliable labor.
4. Reduction in transportation costs due to the proximity to the US market.
5. Some maquiladoras also include shelter services which provide administrative services, act as employers in Mexico, and are released from permanent establishment status in Mexico.

According to data compiled by the Mexican Association of Innovation Industries of Medical Devices (AMID, for its acronym in Spanish), establishing a manufacturing plant in Mexico

reduces costs up to 21% compared to the USA. See Figure 16. While the cost of manufacturing precision components in Mexico is 9.8% less than the cost of manufacturing in the USA.

*Figure 16 Savings in costs of manufacture of Medical Devices, 2015 by country as a percentage when compared to the USA*



Source: AMID & KPMG, La industria de dispositivos médicos: impulsora del bienestar social en México, 2019.

These advantages attract foreign investment, in 2019 Mexico's foreign direct investment reached US \$ 39.5 Billion.<sup>36</sup>

Overall, the manufacturing clusters previously described are represented by large foreign-owned companies that assemble high technology medical devices from imported materials exporting the final product to the US market. Additionally, Mexico's medical device industry has a parallel model mainly oriented to the domestic market with enormous growth potential.

### 6.5. Domestic Market

This model predominates in Mexico city and the metropolitan area. There are about 100 establishments that manufacture medical devices, most are small and medium-sized enterprises (SMEs), and according to INEGI they directly employ nearly 4 000 people. (Saúl de los Santos, 2021) This number of employees is considerably low compared to the number of jobs created by the industry. In 2018, the medical device industry was responsible for creating 146,945 jobs; 88.24% of these posts were on manual labour. (AMID & KPMG, 2019).

<sup>36</sup> Data Mexico <https://datamexico.org/>

Many of these enterprises are oriented to the fabrication of high-volume medical consumables with simple technology (e.g.: syringes, bandages, sutures, catheters, tubes, IV cannulas), medical furniture, medical equipment (such as pressure relief mattresses, hospital beds, walkers, and basic wheelchairs) or surgical instruments.

Examples of such companies are Atramat, well-known for producing high-quality sutures. Mare a producer of surgical instruments, and several companies that manufacture surgical furniture such as Muebles Médicos Maya, Mobiliario Médico Las Torres, Leader Medical, Fabrimex, Comexa, and Reysa.

Some companies are manufacturers, but they also import and distribute medical equipment and furniture. These local providers also export their products and services, mainly to South and Central America. Mexico is the 4th largest exporter of needles, catheters worldwide. (AMID & KPMG, 2019).

Distribution channels for the domestic market are diverse, including direct importers, representatives, sales agents, retailers, local subsidiary companies of foreign exporters. Sometimes the same company manufactures some medical devices and imports and distributes others.

An attractive model of distribution is described by the company known as Vitalmex. The Mexican company started as an engineering company providing maintenance and consulting services for the medical device industry. In 1999, they started their current business model known as a provider of "articulate healthcare services". They provide disposable and non-disposable medical devices, maintenance, and technical support to hospitals hiring their services.

They mainly focus on surgical specialties, intensive care units, and other hospital services that require high-technology medical devices to function. Their policy is that they provide customized service, do so through more than 250 providers. They also manufacture medical devices in a world-class unit located in Morelos.

They are suppliers of private and public hospitals. In 2013, they acquired the German company "Gimmi", known for specialized instruments and devices for minimal invasion surgeries. Their market is in more than 60 countries. (Navarro, 2020).<sup>37</sup>

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<sup>37</sup> Vitalmex <https://www.vitalmex.com.mx/>

## 7. Conclusions

MedTech in Mexico is a sector that has been growing, and has received FDI from companies interested in using Mexico as a platform to manufacture and supply the U.S. market. Tax advantages and the Free Trade Agreement with the U.S. and Canada have been a key factor for growth.

The Medtech manufacturing sector in Mexico is sophisticated and specialized, and offers high-quality labour. In addition, it is in close proximity to one of the largest markets in the world, the U.S.

The establishment of a manufacturing plant in a medical device cluster in Mexico provides infrastructure, suppliers, logistics, management and the support of government and academic organizations.

The private health sector invests in technology, and Covid-19 has accelerated the digital transformation. The private health sector in Mexico only covers 4% of the population. It is a small market but can be a gateway to the Mexican market.

The Medical sector is highly regulated, so the first challenge that foreign companies face is being able to register their products or solutions in Mexico. In order to sell your products, you must have them registered. This is a requirement.

The pandemic has increased Telemedicine services both at the private and public levels, allowing patients to receive medical consultations online. This tendency will continue to grow, and there will be a need for solutions and services.

In Mexico, the number of specialized doctors has declined. Telemedicine services, electronic health records, and diagnostic tools will allow them to provide more efficient services to a larger number of patients.

Investment in IT infrastructure in Mexico, specifically in large urban areas, allows for a digital transformation in all sectors of the economy, including health. Private hospitals have invested in digital transformation and will require to do so to offer quality services, to control inventories, to manage electronic health records, and to reduce operating costs.

In Mexico, high technology equipment and medical devices use foreign technology that is manufactured in Mexico or imported. Only 5% of Mexican medical manufacturers produce high technology products.

Selling in the health care system in Mexico is a complex process. Foreign companies need to assign a distributor that has both the experience and the connections in the healthcare system, in order to participate successfully in government bids. The other scenario is to establish a Mexican corporation and have an advisory team that specializes in government bids.

One of the best selling tools is to work with medical equipment companies that can provide financing options to hospitals and clinics, as well as with doctors to help them acquire medical devices or equipment.

The Medtech sector offers opportunities, but it is important to do a specific market study on the products or services, and to establish a market entry strategy to succeed in the market.

## 8. Resources

### 8.1. Government Institutions

Mexico's Ministry of Health.

<https://www.gob.mx/salud>

Federal Commission for the Protection against Sanitary Risk. (COFEPRIS)

<https://www.gob.mx/cofepris>

National Center of Excellence Health Technology. (CENETEC)

<https://www.gob.mx/salud/cenetec>

Health Institute for Well-being. (INSABI)

<https://www.gob.mx/insabi>

Mexican Social Security Institute. (IMSS)

<http://www.imss.gob.mx/>

Government Workers' Social Security and Services Institute. (ISSSTE)

<https://www.gob.mx/issste>

Mexican Government Health Data.

<http://sinaiscap.salud.gob.mx:8080/DGIS/>

### 8.2. Private organizations and Industry Chambers

Dispositivos Médicos Canifarma

The Canifarma is the National Chamber of Pharmaceutical Industry. The chamber created a division that deals with medical devices. The division provides information and advice to companies in that sector.

<https://dispositivosmedicos.org.mx/>

Mexican Council of Diagnosis

Group of clinical laboratory companies.

<https://comed.mx/>

Mexican Society of Biomedical Engineering

Association of Biomedical Engineers.

<https://somib.org.mx/>

The National Association of Private Hospitals Umbrella Organization represents the interests of the leading private hospitals in Mexico.  
<http://www.anhp.org.mx/>

Mexican Hospitals Consortium  
Total of 52 medium and small private hospitals in Mexico.  
<https://cmhac.com/>

HealthTech Association Mexico  
The association is formed of IT companies focused on digital health transformation.  
<https://asociacionhealthtech.mx/>

### 8.3. Magazines or Websites

Saludario  
Health news in Mexico.  
<https://www.saludario.com/>

El Hospital  
Web site that provides health news and medtech information.  
<https://www.elhospital.com/>

PLM Supplier Guide  
PLM is a directory of medical suppliers and distributors. PLM offers an APP for Medical devices suppliers for Android and Apple.  
<https://www.guiadeprovedoresplm.com/>

### 8.4. Events

Expo Med  
Exhibition of medical suppliers and distributors. Expo Med is part of Inform Markets.  
August 31<sup>st</sup> to September 2<sup>nd</sup> 2022.  
Centro Banamex Mexico City  
<https://www.expomed.com.mx/en/home.html>

Medica Expo  
Medical device trade show.  
October 25-27, 2022  
WTC Mexico City  
<https://medical-expo.com.mx/>

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Tel. (52-55) 2455-3973