

The pharmaceutical sector focuses on researching, developing, producing, and commercializing chemical products or biodrugs used to prevent or treat disease.

Classification of Pharmaceutical Products

Origin	Conventional: of synthetic or chemical origin. Biodrug: active ingredient of biological or biotechnological origin.
Medical Prescription	Controlled: Necessarily prescribed by a physician. Unrestricted: for sale without a medical prescription.
Exploitation Rights	Patent: Includes the molecule used, formulation and production mechanism. Generic: Guarantees the same active ingredient, purity and effects as the patent (product).

Legal Framework

According to the General Health Act, the Ministry of Health is the authority in charge of sanitary regulation, control and promotion through the:

Federal Commission to Protect vs. Sanitary Risks (COFEPRIS; Comisión Federal para la Protección contra Riesgos Sanitarios). <https://www.gob.mx/cofepris>



COFEPRIS is responsible for sanitary regulation, control, and promotion in the terms of the General Health Act (Ley General de Salud) and other applicable legal provisions (<http://transparencia.cofepris.gob.mx/index.php/es/marco-juridico>)

- Agreements (<http://transparencia.cofepris.gob.mx/index.php/es/marco-juridico/acuerdos>)
- Codes (<http://transparencia.cofepris.gob.mx/index.php/es/marco-juridico/codigos>)
- Decreets (<http://transparencia.cofepris.gob.mx/index.php/es/marco-juridico/decretos>)
- Guidelines (<http://transparencia.cofepris.gob.mx/index.php/es/marco-juridico/lineamientos>)
- Legal Order (<http://www.ordenjuridico.gob.mx/>)
- Expenditure Budget of the Federation (<http://transparencia.cofepris.gob.mx/index.php/es/marco-juridico/presupuesto>)
- Recommendations (<http://transparencia.cofepris.gob.mx/index.php/es/marco-juridico/recomendaciones>)

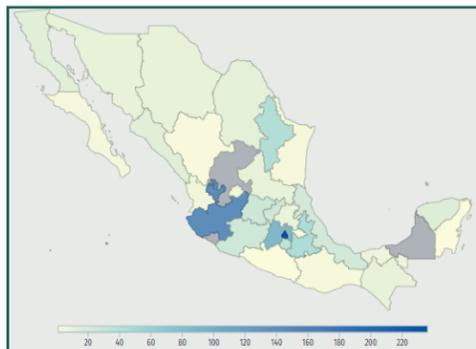
- Notices (<http://transparencia.cofepris.gob.mx/index.php/es/marco-juridico/avisos>)
- Summons (<http://transparencia.cofepris.gob.mx/index.php/es/marco-juridico/convocatorias>)
- Laws (<http://transparencia.cofepris.gob.mx/index.php/es/marco-juridico/leyes>)
- Official Mexican Standards (<http://transparencia.cofepris.gob.mx/index.php/es/marco-juridico/normas-oficiales-mexicanas>)
- Plans (<http://transparencia.cofepris.gob.mx/index.php/es/marco-juridico/planes>)
- Programs (<http://transparencia.cofepris.gob.mx/index.php/es/marco-juridico/programas>)
- Regulations (<http://transparencia.cofepris.gob.mx/index.php/es/marco-juridico/reglamentos>)

The 10 major pharmaceutical companies, according to their international brand value, can be found in Mexico.



Source: Statista
<https://es.statista.com/estadisticas/1027173/valor-de-marca-de-las-principales-farmaceuticas/>

Distribution of Economic Units



837 economic units manufacture pharmaceutical products. Noteworthy are Mexico City (236), Jalisco (141), and the State of Mexico (86).

Total gross output was \$189,260M MX. States with the highest total gross output were Mexico City (\$67,759M MX) and the State of Mexico (\$38,314M MX).

Total revenues were \$191,702M MX in 2019. States with the highest revenues were: Mexico City (\$71,925M MX) and State of Mexico (\$40,119M MX).

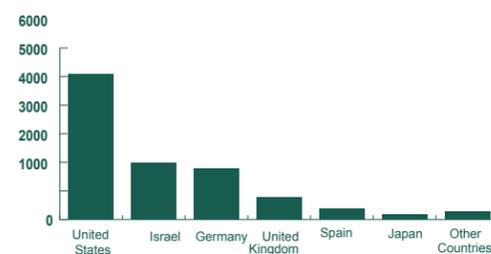
Source: Economic Census.

Main Formalities or Restrictions

Formalities regarding permits, sanitary licenses, notices of operations, and approvals issued by COFEPRIS can be found at:

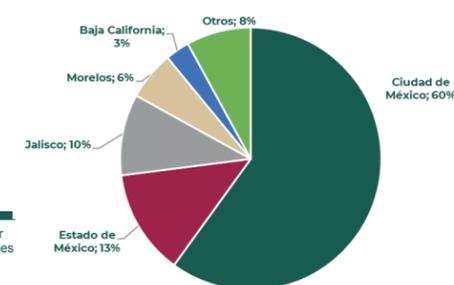
<https://www.gob.mx/cofepris/acciones-y-programas/tipo>

Main countries with foreign direct investment in the pharmaceutical industry in Mexico 1999-2021 (Millions of dollars)



Source: Ministry of Economy

Main recipient states of foreign direct investment in the Mexican pharmaceutical industry 1999-2021



Source: Ministry of Economy

Foreign trade of the companies in the Mexican pharmaceutical sector in 2020 (Millions of dollars (mdd))

Exports: 1,760 millions of dollars
Main destination countries were: United States (43.5%), Panama (6.9%), and Brazil (6%).
Imports: 5,773 millions of dollars
Main countries of origin were: United States (20.2%), Germany (15.8%), and France (8.9%).

Source: UIEG, with BCMM data

National Associations or Chambers

- Cámara Nacional de la Industria Farmacéutica (CANIFARMA) www.canifarma.org.mx
- La Asociación Mexicana de Industrias de Investigación Farmacéutica (AMIIF) www.amiif.org.mx
- Asociación Nacional de Fabricantes de Medicamentos (ANAFAM) www.anafam.org.mx

Organizations of the World

- World Health Organization www.who.int/es
- U.S. Food & Drugs Administration www.fda.gov
- Pharmaceutical Research and Manufacturers of America www.phrma.org
- European Federation of Pharmaceutical Industries and Associations www.efpia.eu
- Pharmaceutical Group of the European Union www.pgeu.eu
- European Pharmaceutical Research Association www.ephmra.org