MEXICO: MEDICAL DEVICES REGULATION

Federal Commission for the Protection against Sanitary Risk – COFEPRIS

STAKEHOLDER OPEN FORUM

September, 2018.
• The Federal Commission for the Protection against Sanitary Risk (COFEPRIS) is a decentralized entity of the Ministry of Health with technical, administrative and operational autonomy.

• It was conceived by law as a macro sanitary regulator compared to other international sanitary agencies which regulate specific industries individually.
What is COFEPRIS?

COFEPRIS regulates the following industries and business process.

Regulated Sectors

1. Food and Beverages
2. Health Supplies
3. Health Services
4. Cosmetics and beauty products
5. Pesticides, Vegetable nutrients and Toxic substances
6. Emergencies
7. Labor Safety and Health
8. Environmental Risks
These industries represent **9.8%** of Mexican GDP.
COFEPRIS regulates **44 cents out of every Mexican peso** spent by households in Mexico through 3 categories: Food, beverages; health care; and personal care products.

**Household Expenditures per Category**
(as a % of total household expenditures)*

- **Food, beverages and tobacco**: 34.0%
- **Health care products**: 56.2%
- **Personal care products**: 2.5%
- **Others**: 7.3%

* Only current monetary expenditures are considered.

Characteristics of health regulatory policy

- Its main objective is to improve population access to health products
- Rests on four fundamental pillars and the pillars are aligned with the **3 priorities of health** policy established by the Federal Government.

### Government's Health Policy Priorities

1. Effective Access
2. Service Quality
3. Prevention

### Pillars of Health Regulatory Policy

- Ensuring **the safety, quality and efficacy** of all drugs.
- Offering a reliable and predictable scheme.
- Removal of barriers to entry of safe and of high quality products.
- Harmonized with best international practices.
Global Harmonization Initiatives

ICH - harmonisation for better health
PIC/S
World Health Organization
IMDRF
Pan American Health Organization
i-p-r-f.org - International Pharmaceutical Regulators Forum
ICMRA - International Coalition of Medicines Regulatory Authorities
Medical Device Global Industry

Global production in 2015  663 billion USD

1) Johnson & Johnson
2) GE Healthcare
3) Medtronic
4) Baxter International
5) Siemens Healthcare
6) Philips Healthcare
7) Cardinal Health
8) Covidien
9) Abbott Labs
10) Stryker

The 10 largest companies

North America 41%
Europe 19%
Asia Pacific 30%
South and Central America 1%
Medical Device Global Production

Growth estimate 2015-2020

Expected Annual Growth: 6.2%

International Trade

Exports: 219.9 B USD

Imports: 210.9 B USD

Production by Country, 2015

- Estados Unidos: 253 Billion USD
- China: 147 Billion USD
- Alemania: 43 Billion USD
- Suiza: 28 Billion USD
- Japón: 26 Billion USD
- México: 15 Billion USD
- Otros: 15 Billion USD
Top 20 exporting countries of medical devices, 2015 (bd)

Source: ProMexico
Top 20 importing countries of medical devices, 2015 (bd)

- USA: 41,676
- Germany: 17,196
- Netherlands: 13,688
- China: 13,142
- Belgium: 11,102
- Japan: 10,867
- France: 10,039
- United Kingdom: 8,239
- Italy: 5,842
- Canada: 5,404
- Australia: 4,515
- Switzerland: 4,458
- Spain: 4,048
- Mexico: 3,963
- Singapore: 3,306
- Korea: 3,229
- Russia: 2,951
- Brasil: 2,622
- India: 2,566
- Austria: 2,009

Source: ProMexico
Medical Devices in Mexico

- Total Production: 15,220 million USD
- Largest Producer in Latin America
- 8° largest world exporter
- 14° largest world importer
- 156,831 persons employed in 2015
Medical Devices in Mexico

Main investment clusters in Mexico

- **Sonora**: Baxter (EU), Greatbatch (EU), Medtronic (EU), Nellcor Puritan Bennett (Irlanda), Össur (Islandia) y Welch Allyn (EU).

- **Baja California**: Baxter (EU), Greatbatch (EU), Medtronic (EU), Nellcor Puritan Bennett (Irlanda), Össur (Islandia) y Welch Allyn (EU).

- **Chihuahua**: Bard (EU).

- **Jalisco**: Zeyco y PYMPSA (México).

- **Edo. de México**: Braun (Alemania) y Baxter (EU).

- **México City**: Becton Dickinson y Medtronic (EU), Arroba Ingeniería, Internacional Farmacéutica, Lides y Vitalmex (México).

- **Morelos**: Equipos Médicos Vizcarra, Industrias Plásticas Médicas y Laboratorios Le Roy (México).

2,393 establishments

- **Sonora**
  - 3rd World exporter of tubular needles for suture

- **Baja California**
  - 4th World exporter of medical instruments and equipment for dental and veterinary surgery

- **Chihuahua**
  - 4th World exporter of syringes, catheters and similar instruments

- **Jalisco**
  - 4th World exporter of medical furniture for surgery,
Medical Devices in Mexico

Medical device production in Mexico, 2010-2016*
(million USD)

2010: $12,161
2011: $13,443
2012: $14,188
2013: $14,339
2014: $15,220
2015*: $16,148
2016*: $17,133

Growth rate 6.1%

México: Important supplier of the United States
Robust Medical Devices Regulation in Mexico

General Health Act

Health Supplies Bylaw (RIS)

United States of Mexico Pharmacopoeia (FEUM)

Official Resolutions and Norms

*GHTF and IMDRF foundations and principles

17 bis: COFEPRIS competences
194, 262: Terms and Definitions
263-268 bis, 295: Imports
310: Advertising
376: Market Authorization
398-400: Inspections

82: Market Authorization
83: Classification
224-225: Safety measures

MD Supplement: it defines and establishes the specifications and methods of analysis for its verification to guarantee the quality and optimal functioning.

NOM-241-SSA1-2012: GMP.
NOM-137-SSA1-2008: Labelling.
NOM-240-SSA1-2012: Technovigilance.
Regulatory actions in Medical Devices in Mexico

2010
- Equivalence Agreements: FDA (United States) y Health Canada (Canadá).

2011
- Authorized Third parties
- Reclassification of Selected Medical Devices: 96 low risk and 1,669 specified as non Medical Device.

2012
- Equivalence Agreement PMDA (Japan).

2013
- Checklist implemented.
Regulatory actions in Medical Devices in Mexico

2014
- Reclassification update: total of 2,242 specified as non Medical Device.

2015
- Accepting ISO 13485 as equivalent to EIR
- Check List for Equivlaelence and Extensions

2016
- New call for Authorized Third parties
- Update Mexican Pharmacopeis of Medical Devices

2017
- Update NOM 240 Medical Device Post Market Surveillance
- Update NOM 241 Good Manufacturing Practices
## Trade Negotiations

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CONCLUSION

- Mexico is the **largest exporter** of medical devices in Latin America, with a production equivalent to **15 billion dollars**.

- Mexico is ranked approximately **8th world exporter** and within of the **20 largest world importers**.

- The sector generates more than **130 thousand jobs**.

- Mexico has robust regulatory structure

- Mexico is strongly committed to advance in international regulatory harmonization
THANK YOU

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