

# Drugs and MD approval in Mexico

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DATE : 2013/11/28

# Mexican Government

Ministry of Health in Mexico



COMMISSION FOR THE PROTECTION  
AGAINST SANITARY RISK  
(COFEPRIS)

DRUGS, MEDICAL DEVICES, FOOD, HEALTH SERVICES, CHEMICAL  
SUBSTANCES

# COFEPRIS

## *Scope of Competence*

Sanitary regulation and promotion of the production, commercialization, import export, publicity of, or involuntary exposure to:

### Health-related drugs and technologies

- Drugs
- Medical equipment and devices
- Blood and hemoderivatives
- Organ transplant
- Health services

### Products and Services

- Food
- Beverages
- Tobacco
- Perfumery and beauty products
- Biotechnologicals

### Toxic or dangerous substances

- Pesticides
- Fertilizers
- Chemical precursors
- Essential chemicals

### Health at work

- Work exposure

### Risks derived from environmental factors

- Water
- Air
- Soil

### Basic maintenance

- • Water
- • Markets
- • Residues
- • Trails
- • Sanitary emergencies

## COFEPRIS

### Objectives

- Properly protect the population
- Cooperate to improve the companies' competitiveness in order to insert them in foreign trade flow
- Protect the national productive plant from disloyal competition

# **MISSION STATEMENT OF THE FEDERAL COMMISSION FOR THE PROTECTION AGAINST SANITARY RISK (COFEPRIS)**

“Provide protection to the population from sanitary risk that may cause the use and consumption of goods and services, health inputs, as well as for the exposure to environmental and labor factors, the occurrence of sanitary emergencies and to provide the benefit of health services through the regulation, control and prevention of any sanitary risk”

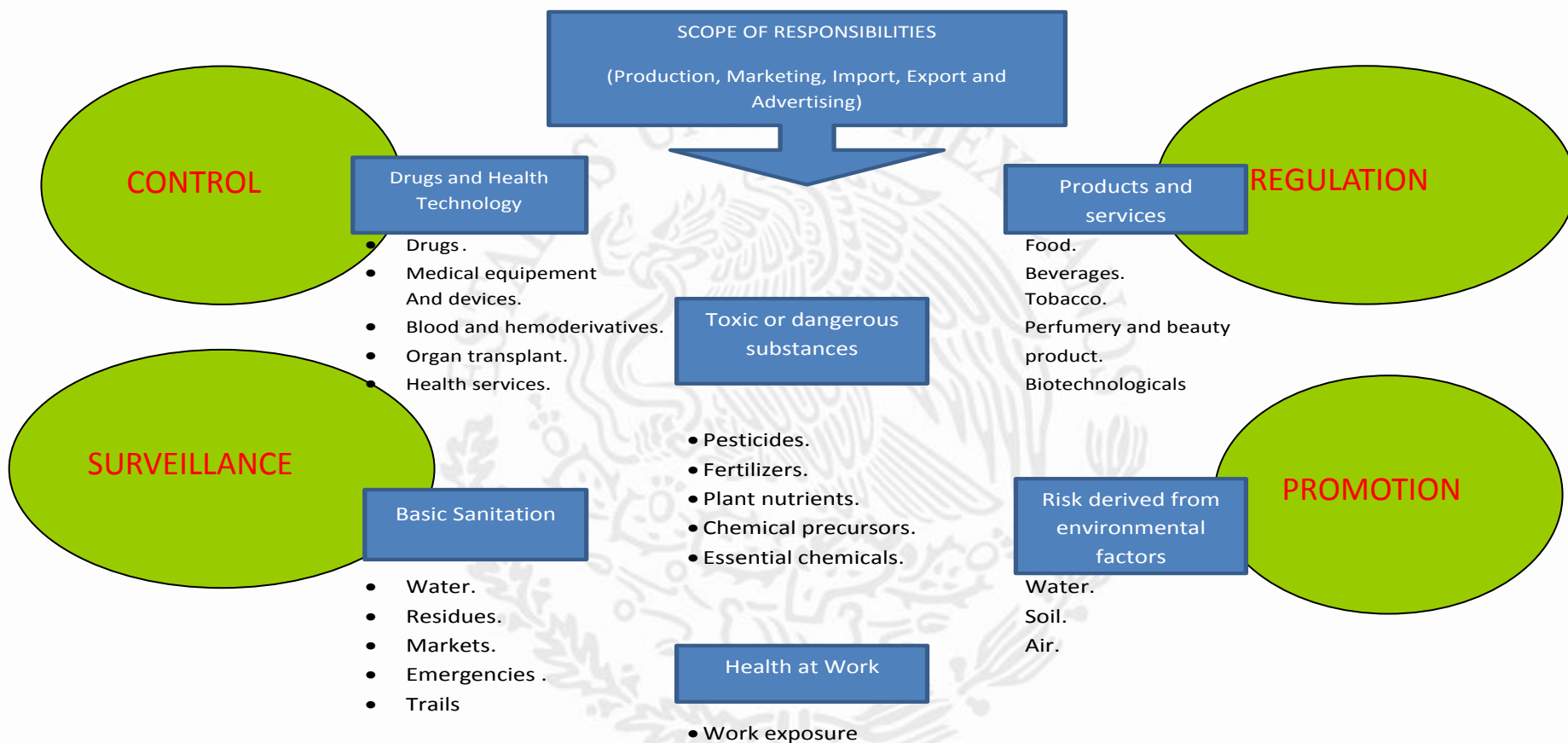
# COFEPRIS

## **Duties, functions and characteristics that by law are attributed to the COFEPRIS**

According to the General Health Law, the Department of Health will exercise sanitary regulation, control and promotion through the Federal Commission for the Protection against Sanitary Risks, for functions regarding (Art. 17 bis):

- Control and supervision of health establishments.
- Prevention and control of environmental factors which have harmful effects on man.
- Basic occupational health and hygiene.
- Sanitary control of products, services and their import and export, and establishments dedicated to processing the products.
- Sanitary control of the process, use, maintenance, import, export, and final disposal of medical equipment, prosthetics, orthosis, functional aids, diagnostic agents, orthodontic goods and services, surgical and health materials, and of the establishments which process these products.
- Sanitary control of the publicity of the activities, products and services.
- Sanitary control of the disposal of organs, tissue and their components, human cells.

# FACULTIES OF COFEPRIS



Provide protection to the population  
from sanitary risk

## SANITARY PROCESSES

### SANITARY CONTROL

Sampling of products, analytical tests, in situ inspection, evaluation of information, evaluation of people.

### SANITARY SURVEILLANCE

Evaluation of conformity against standards, legal actions

### REGULATION

International legal framework, Mexican legal framework (NOM's, Mexican Pharmacopeia)

### PROMOTION

Training, communication, meetings

## APPROVAL FOCUS ON SANITARY RISKS

**RISKS**

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License

**RISKS**

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GMP  
Certification

**RISKS**

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Registration

- Regulation
- Approval
- Surveillance

# COFEPRIS

## Administrative Units:

1. Evidence and Risk Management Commission
2. Sanitary Promotion Commission
3. Sanitary Authorization Commission
4. Sanitary Operation Commission
5. Analytic Control and Expansion of Coverage Commission
6. General Coordination of the Federal Sanitary System
7. Legal and Consultative Coordination Center
8. Administration

Supported by scientific and technical committees conformed by experts from Universities, Research centers, and other Public Government Organizations

## SUPPORT BY THIRD PART AUTHORIZED

### SANITARY CONTROL COFEPRIS

Laboratory  
testing

Units for  
Intercambiability  
studies and  
biosimilarity  
studies

Units for  
GMP visits

Units for pre-  
evaluation of  
drugs and DM  
dossiers

QUALITY SYSTEM  
ISO 17025

NOM 177

QUALITY SYSTEM ISO 17020

## COFEPRIS ARN CERTIFIED

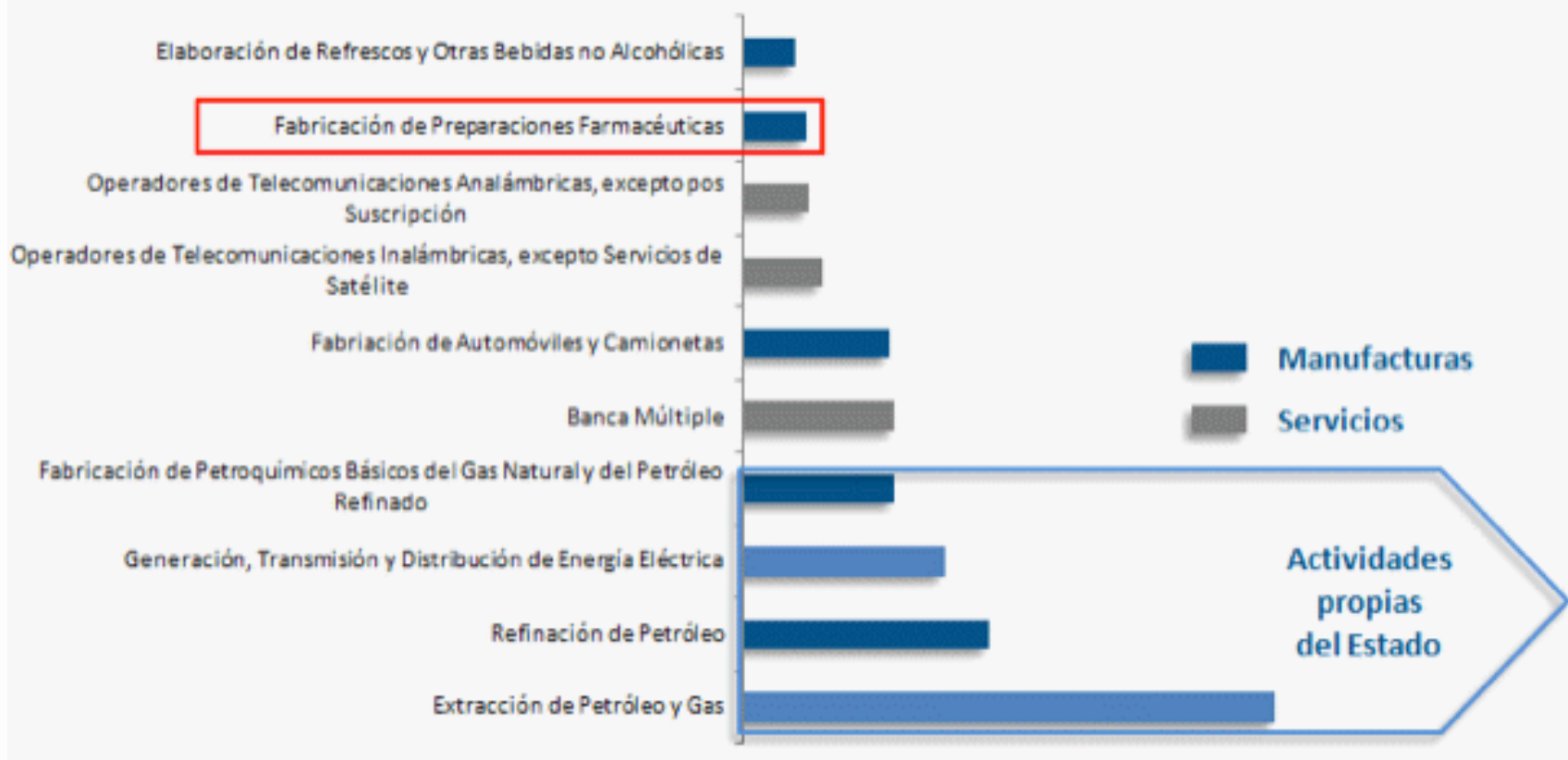
- In 2012 COFEPRIS was approved as a recognized agency for the Americas by the Pan America Health Organization for both vaccines and drugs
- Our reference laboratory was recently approved by OMS for drugs analytical tests
- Currently we are looking for OMS recognition on both vaccines and drugs as a regulatory agency

# FEDERAL SANITARY SYSTEM



# PHARMACEUTICAL ACTIVITY

## Las 10 clases de actividad más importantes según la producción bruta total, 2008



## PHARMACEUTICAL ACTIVITY

224 pharmaceutical plants from 200 different companies (46 are international and the rest are mexican companies)

**TABLA II.2 VENTAS TOTALES DE LA ESPECIALIDAD DE MEDICAMENTOS  
DE USO HUMANO (MILES DE UNIDADES)**

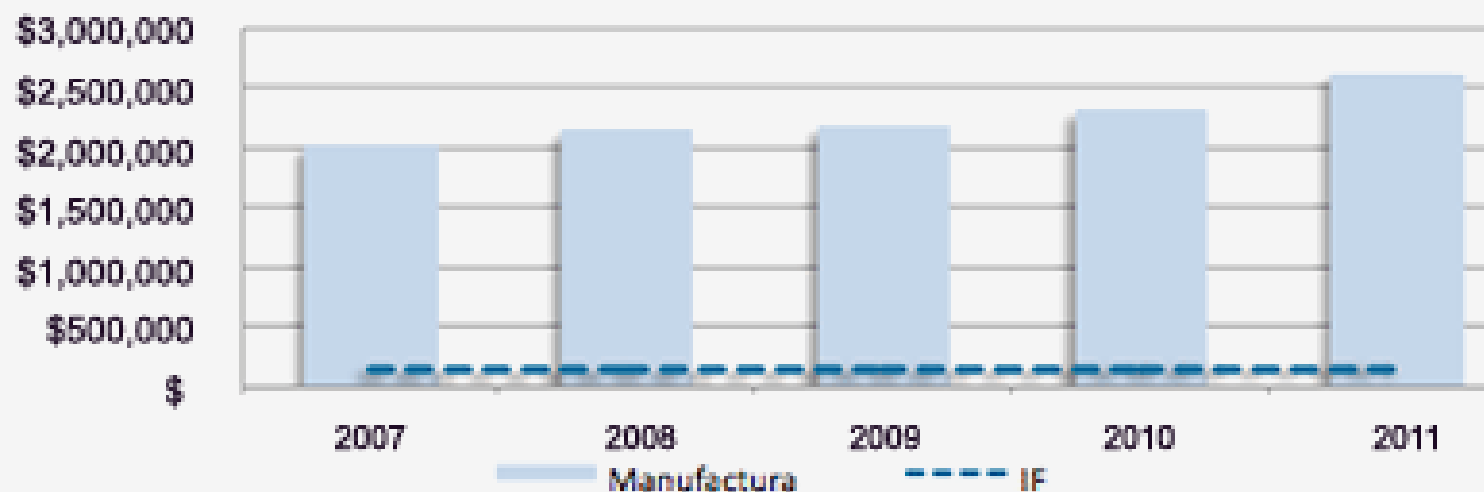
2007	2008	2009	2010
2,258,781	2,192,304	2,402,370	2,526,333
% de la variación	-2.9	9.6	5.2

FUENTE: I Censo de la Industria Farmacéutica en México, CANIFARMA.

Average units sold: 2 500 millions

## PHARMACEUTICAL ACTIVITY

Participación del valor de la industria farmacéutica en el PIB  
Manufacturero (Millones de pesos)



Fuente: I Censo de la Industria Farmacéutica en México, CANIFARMA

21 000 millions of usd dollars

7.2% PIB (manufacture)  
1.2% PIB

## DM ACTIVITY

3 000 millions usd dollars

**TABLA III.3** VENTAS EX FACTORY POR SECTOR DE LA ESPECIALIDAD  
DE DISPOSITIVOS MÉDICOS (MILLONES DE PESOS)

	2007	2008	2009		
Sector público	10,726.02	11,050.74	13,579.95	2009	39.8% 60.2%
Sector Privado	19,072.88	19,670.44	20,497.90	2008	36.0% 64.0%
TOTAL	29,798.90	30,721.18	34,077.85	2007	36.0% 64.0%

■ Sector público ■ Sector privado

FUENTE: I Censo de la Industria Farmacéutica en México,  
CANIFARMA.

**TABLA III.14** INVERSIÓN TOTAL DE LA ESPECIALIDAD  
DE DISPOSITIVOS MÉDICOS (MILLONES DE PESOS)

	2007	2008	2009	2010	2011e	2012e
	1,576.51	2,029.90	2,351.97	3,058.54	2,979.54 <sup>A</sup>	5,551.63 <sup>A</sup>
% de la variación		28.8	15.9	30.0	-2.6 <sup>A</sup>	86.3 <sup>A</sup>

<sup>A</sup> Nota: Los datos de inversión estimados proceden de los montos de crecimiento declarados por las empresas en el cuestionario denominado "Dirección de Finanzas".

FUENTE: I Censo de la Industria Farmacéutica en México, CANIFARMA.

# PHARMACEUTICAL ACTIVITY

## EL SECTOR FARMACÉUTICO EN MÉXICO

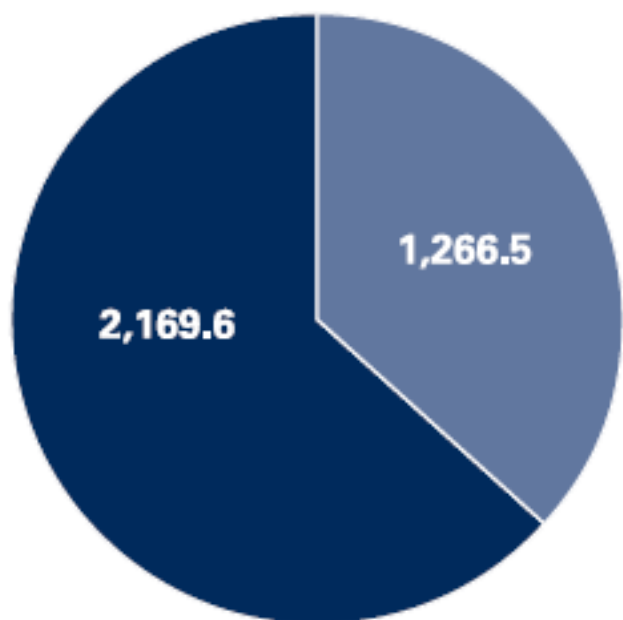
Cuadro 4. Balanza comercial de productos farmacéuticos  
1995-2008 (miles de dólares)

	<i>Exportaciones</i>	<i>Importaciones</i>	<i>Balanza comercial</i>
1995	271 900	324 703	-52 803
1996	403 148	469 124	-65 976
1997	468 656	541 502	-72 846
1998	529 503	679 098	-149 595
1999	606 038	863 232	-257 194
2000	673 005	1 013 001	-339 996
2001	886 711	1 259 226	-372 515
2002	968 550	1 463 707	-495 157
2003	1 033 014	1 778 766	-745 752
2004	1 265 572	2 168 505	-902 933
2005	1 257 250	2 435 047	-1 177 797
2006	1 224 784	3 024 571	-1 799 787
2007	1 311 483	3 388 983	-2 077 500
2008	1 310 739	4 071 420	-2 760 681

Fuente: Elaborado con datos del Banco de México.

# IMPORTATION AND EXPORTATION

**Balanza Comercial 2004/ Trade Balance 2004**  
(Millones de dólares/ Millions of dollars)



- Importaciones
- Exportaciones

*Pharmaceutical products are mainly exported to Germany and the United States of America. As for Latin America, Venezuela is the principal recipient of Mexico's exports, followed by Panama. Finished goods comprise approximately 70 per cent of Mexico's exports; the remainder consists of semi-finished goods and raw materials.*

## DRUGS CLASSIFICATION BY RISK

*Drugs are classified as follows:*

- *Class 1, 2 and 3 are high risk and controlled drugs, such as narcotics*
- *Class 4 drugs are antibiotics, antihypertensive and hypoglycemia drugs*
- *Class 5 and 6 are drugs sold without prescription, usually known as OTC drugs*

# Drugs Approval

- Drugs approval are divided into:
  - New molecules (Chemical synthesis, vaccines, biological or biotechnological)
  - Generics (chemical synthesis)
  - Biosimilars
- As well as in various forms: registration for the first time, and registration extended (each 5 years), modification of the registration

## DRUGS APPROVAL

### CLINICAL TRIALS

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### MANUFACTURING

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GENERIC-INTERCAMBIABILITY  
(Take place in Mexico only)

BIOSIMILARS-BIOSIMILARITY  
(Take place in Mexico or others countries)

Microb and  
physicochemical  
Properties  
GMP's

- Regulation
- Approval
- Surveillance

**Each mode of procedure for sanitary authorization is structured by modules.**

Mode	Module
New molecule	Module I: Administrative and Legal Module II: Quality Information Module III: Preclinical studies Module: IV: Clinical studies
Generic	Module I: Administrative and Legal Module II: Quality Information Module III: Intercambiability studies
Vaccine	Module I: Administrative and Legal Module II: Quality Information Module III: Preclinical studies Module: IV: Clinical studies

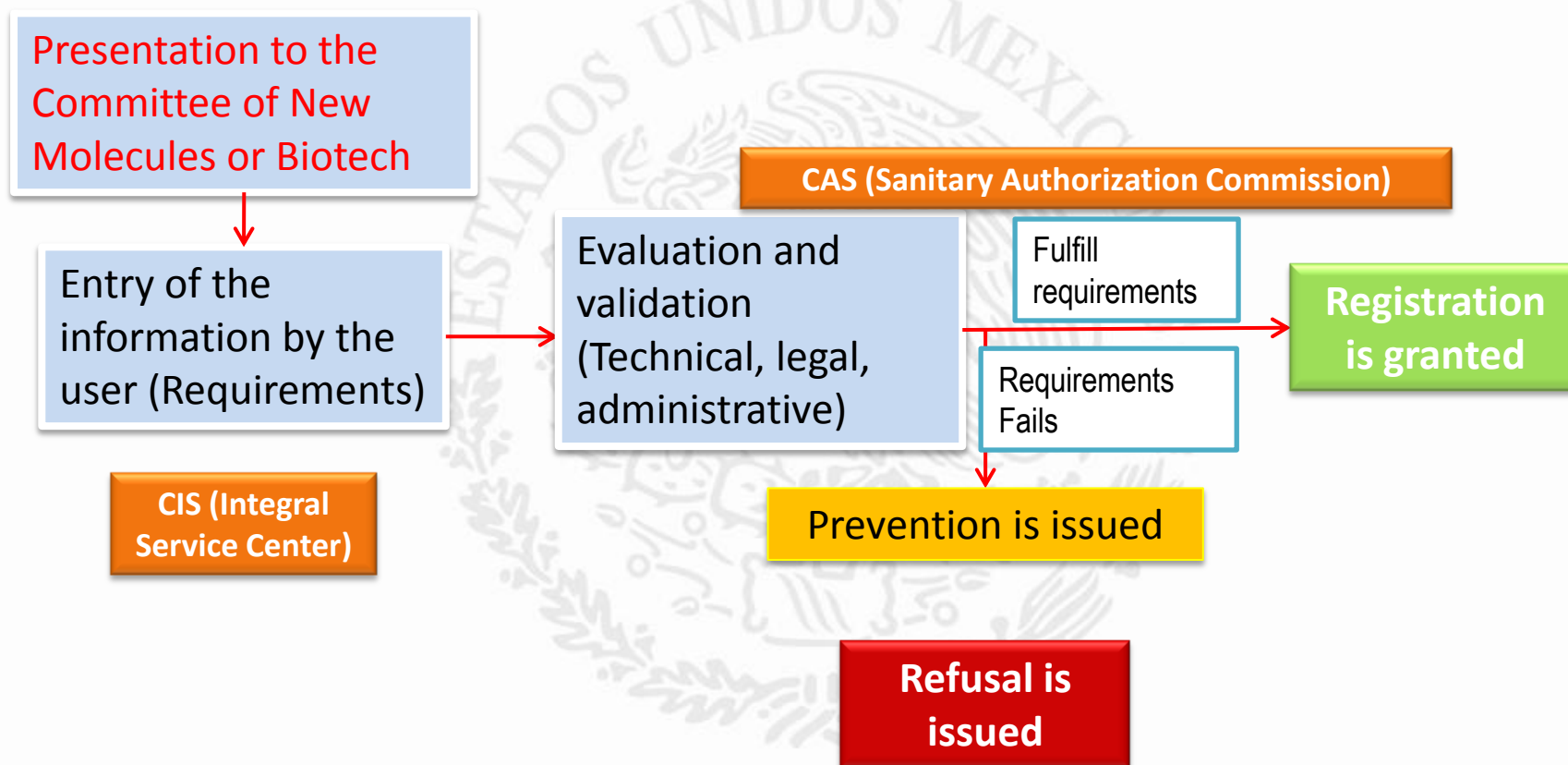
Mode	Module
Biotechnological	Module I: Administrative and Legal Module II: Quality Information Module III: Preclinical studies Module IV: Clinical studies
Biosimilars	Module I: Administrative and Legal Module II: Quality Information Module III: Biosimilarity studies (more characterization less clinical trials)
Orphan	Module I: Administrative and Legal Module II: Quality Information Module III: Preclinical studies Module IV: Clinical studies Module V: Recognition as an orphan drug

## Approval and registration of drugs by equivalence

- COFEPRIS has made equivalence agreements for drug approval, which allow that registered drugs in other countries could be approved expeditiously in Mexico, by Equivalence of the requirements set out in Articles 167 and 170 of the Regulations for Health Supplies.

\*At the moment there is only agreement with FDA of the United States of America, and with the European Commission

# General Approval Process



# MEDICAL DEVICES CLASSIFICATION

Devices known in medical practice, whose safety and efficacy are proven and that generally do not remain in the body.

**Class I**

Devices known in medical practice and that may have variations in the material which they are made or in their concentration and that are gradually introduced into the body. Staying less than 30 days in the body

**Class II**

New devices or recently accepted in medical practice or that are introduced to the body and stay in it for more than thirty days.

**Class III**

# MEDICAL DEVICES

## Registration Form

- General Information of the Institution.
- Type of process.
- Sanitary Registration No..
- No. of application.
- Legal basis.
- Details of the owner's of the sanitary registration.
- Product Features.
- Distinctive name.
- Generic name.

# MEDICAL DEVICES

## Registration Form

- Type of health product.
- Classification.
- Manufacturer information.
- Distributor information.
- Footer.
- Indications for use.
- Description.
- Formula (if any).
- Types of Presentations.

# MEDICAL DEVICES

## Registration Form

- Expiration of the product.
- Base of the advertising.
- Issue and expiration date.
- Signature.
- Observations on the sanitary registration.

## **REGISTRATION OF MEDICAL DEVICES UNDER EQUIVALENCE AGREEMENT**

Given the growing need for technology in medical devices, and in order to facilitate its access to our population, the Equivalence Agreement figure is created, and this help us in the recognition of the requirements, testing, evaluation procedures and other requirements made by other DRAs and that are equivalent to the requirements of the Mexican authority to ensure the quality, safety and efficacy of the Medical Device.

# MEDICAL DEVICES

## Equivalence Agreements

- COFEPRIS in collaboration with the Ministry of Economy, established a system of equivalences that contributes to the availability of high-tech medical products for the Mexican population.
- The Equivalence Agreements of Medical Device with the **FDA and Health Canada** were issued on October 26, 2010.
- The Equivalence Agreement of Medical Device with the Ministry of Health, Labour and Welfare of Japan was issued in January 2012.

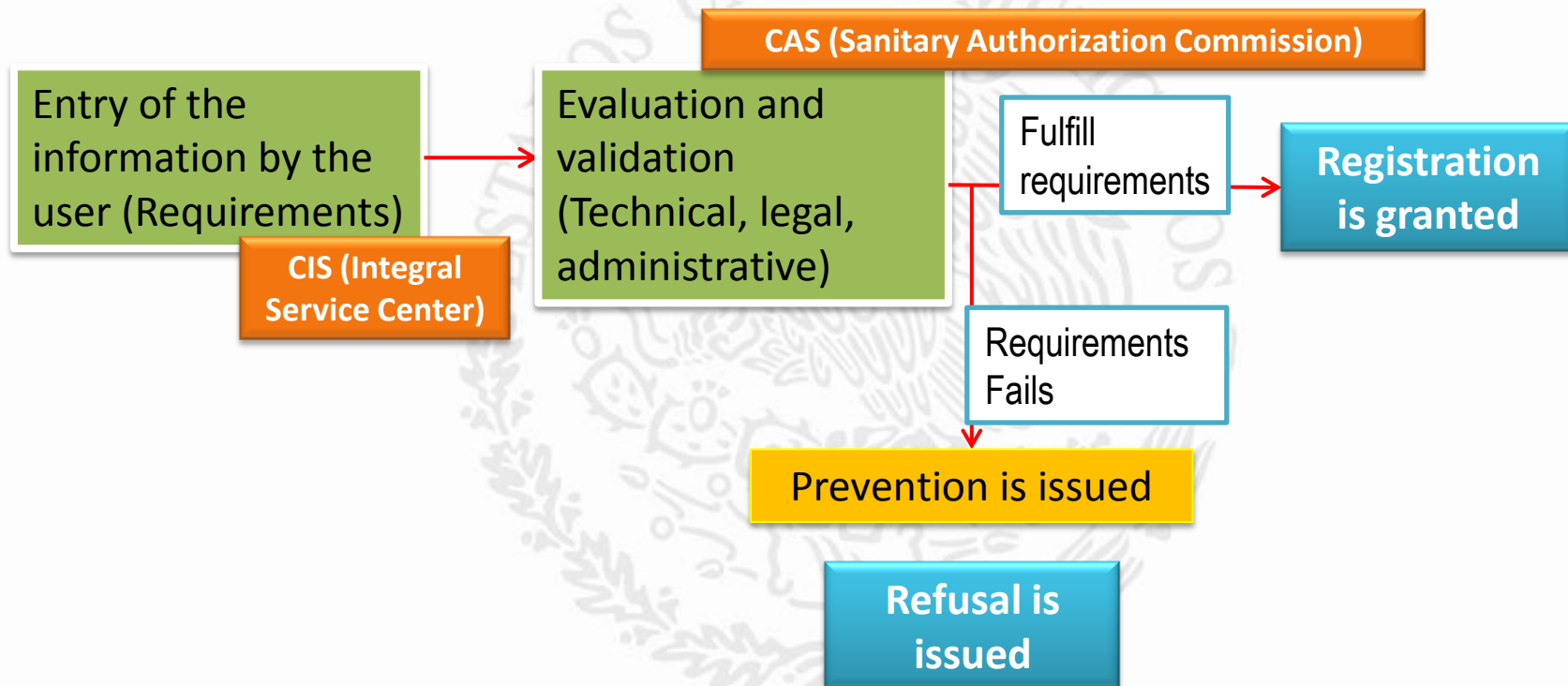
# **MEDICAL DEVICES**

## **Equivalence Agreements**

In order to determine the level of equivalence for the issuance of a Equivalency Agreement, COFEPRIS shall:

- Discuss procedures for technical and scientific evaluation carried out by foreign health authorities to obtain the marketing authorization in their countries.
- Ensure that these procedures guarantee the quality, safety and efficacy of the products.

# Approval of Medical Devices Process



# THANK YOU

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