COFEPRIS - GOOD REGULATORY PRACTICES IMPLEMENTATION STATUS

SALUD
SECRETARÍA DE SALUD

COFEPRIS
COMISIÓN FEDERAL PARA LA PROTECCIÓN CONTRA RIESGOS SANITARIOS

Good Regulatory Practices

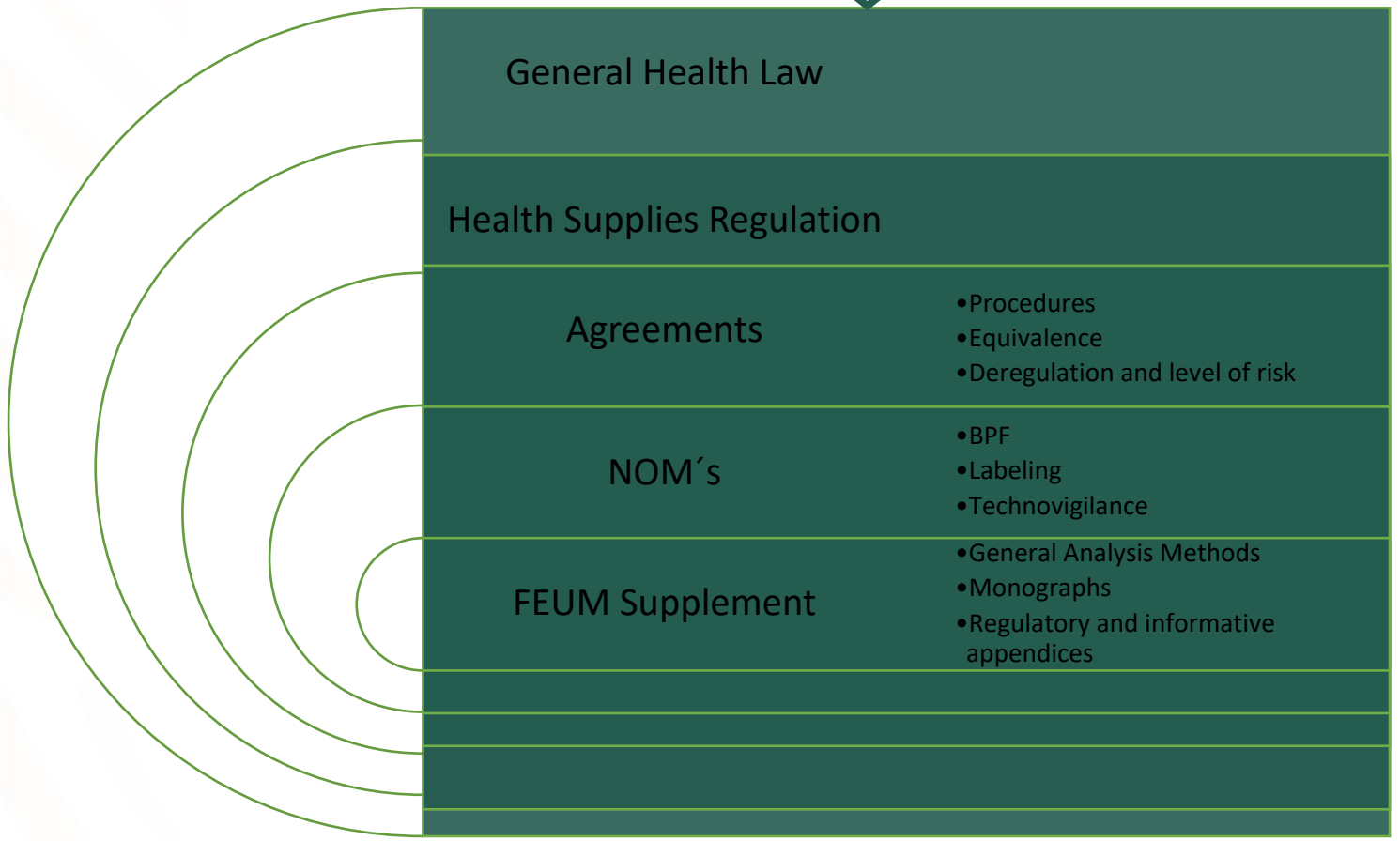
- They contribute to facilitating trade and investment, as well as improving the business environment through transparency provisions that reassure producers, importers and investors about regulations
- Promote transparency and accountability when drafting and implementing regulations.
- Support the development of compatible regulatory approaches between the Parties
- Reduce or eliminate onerous, duplicative or divergent regulatory requirements.

How are MDs regulated in Mexico?

International Treaties
(They regulate with direct impact on some matters)

Other Laws and Regulations LFPA, RLGSMI, RCOFEPRIS

CPEUM
(Right to health)



LGS

- Article 194 Bis.- **medical equipment, prostheses, orthoses, functional aids, diagnostic agents, dental supplies, surgical material, healing and hygienic** products are considered health supplies, **the latter in the terms of section VI of article 262 of this law**

- Article 262 specifies in a general way which products correspond to each classification

- Article 204 establishes that DMs for sale or supply must have sanitary authorization.

- Article 210, 263, 264 ,265 General characteristics of labelling

Classification as health supplies

Type of products

Require authorization

Labeling Overview

RIS*

Labeling (particularities)
- Articles 1, 20, 22, 23,24

Classification based on the risk involved in its use (Class I, II and III)
- Article 83

Sanitary Registration and its modifications
- 165, 179,180, 181, 185

Suspension of activities, adverse reactions
- Articles 36, 37

Establishments (General)
- Articles 99 to 108.

Renewals
- Articles 190a 3 , 190a 4

Surveillance (verification, security measures and sanctions)
- 218 to 232

Notice Operation and Sanitary Registration
Article 82

Import and Export
- Articles 131, 139, 141, 143,144,145, 150, 152-bis, 199

Advertising
- 206

*Art. 1 Regulate the sanitary control of supplies

Agreements

Equivalence agreements (2010,2012)

- Agreements recognizing as equivalent the requirements established in Articles 179 and 180 of the Regulations on Health Supplies and the technical evaluation procedures carried out by COFEPRIS for the granting of sanitary registration of health supplies, to the requirements established by the Food and Drug Administration of the United States of America, by Health Canada of Canada, and by the Ministry of Health, Labor and Welfare of Japan to enable the commercialization of medical devices in its territory.

Deregulation agreements (2011 and 2014)

- Agreement that discloses the list of health supplies considered as low risk for the purposes of obtaining the sanitary registration, and of those products that by their nature, their own characteristics and use are not considered as health supplies and therefore do not require sanitary registration.

NOM´S

GMP

NOM-241-SSA1-2012, Good Manufacturing Practices for Medical Device Manufacturing Establishments

- It establishes the requirements that the processes must meet, from the design of the installation, development, obtaining, preparation, mixing, production, assembly, handling, packaging, conditioning, stability, analysis, control, storage and distribution of medical devices marketed in the country, and aims to ensure that they consistently meet the requirements of quality and functionality to be used by the final consumer or patient.

Labeling

NOM-137-SSA1-2008, Labeling of medical devices.

- It establishes the minimum requirements, which serve to communicate the information to users, which must contain the labeling of medical devices that are marketed or intended for users in the national territory.

Technovigilance

NOM-240-SSA1-2012, Installation and operation of technovigilance

- The purpose of technovigilance is to ensure that the medical devices that are available on the market work in the manner indicated according to the intention of use of the manufacturer (indicated in the corresponding health authorization issued by the Secretariat of Health)

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General Analysis Methods

Monographs

Regulatory and informative appendices

Regulatory needs

Technological advances, new alternatives for diagnosis and treatments

International Treaties

The International Medical Device Regulators Forum (IMDRF)

Homologation of the evaluation tools available through PAHO and WHO

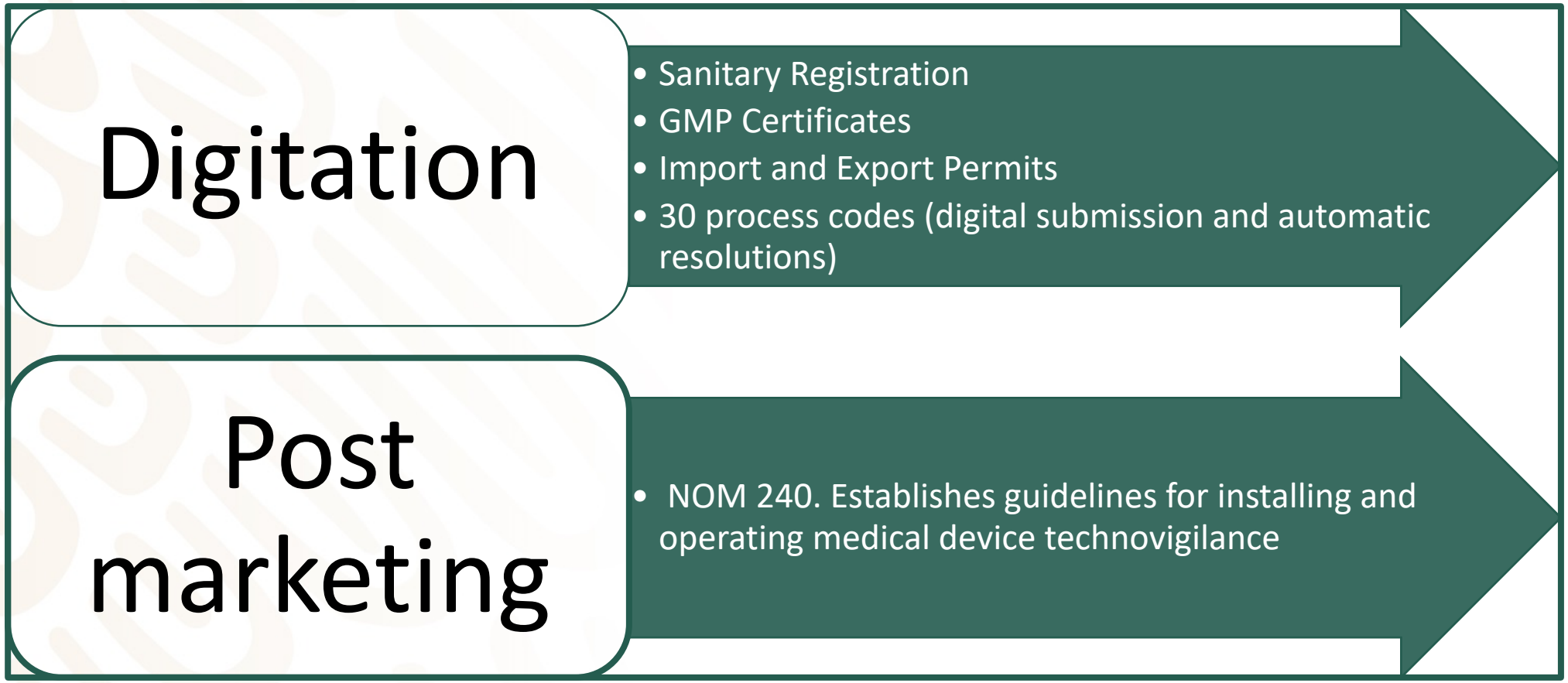
Regulatory improvements

Updating the GMPs NOM

(ISO 13485)

- **Implement the Quality Management System**
- **Quality Risk Management**
- **Design and Development**
- **Manufacturing system**
- **Outsourced activities**
- **Good warehousing and distribution practices**

Regulatory improvements



THANK YOU

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