Training on Good Regulatory Practices and their Implementation in the Medical Device Sector

Mexico

Session III

The process of developing Technical Regulations applicable to Medical Devices and In Vitro Diagnostic Reagents and ensuring compliance with international obligations – Part I

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Regulation of Health Supplies

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I. Objective

Mutual collaboration between COFEPRIS and the interested sector, for the exchange of ideas and reach a common end.

Legal Framework

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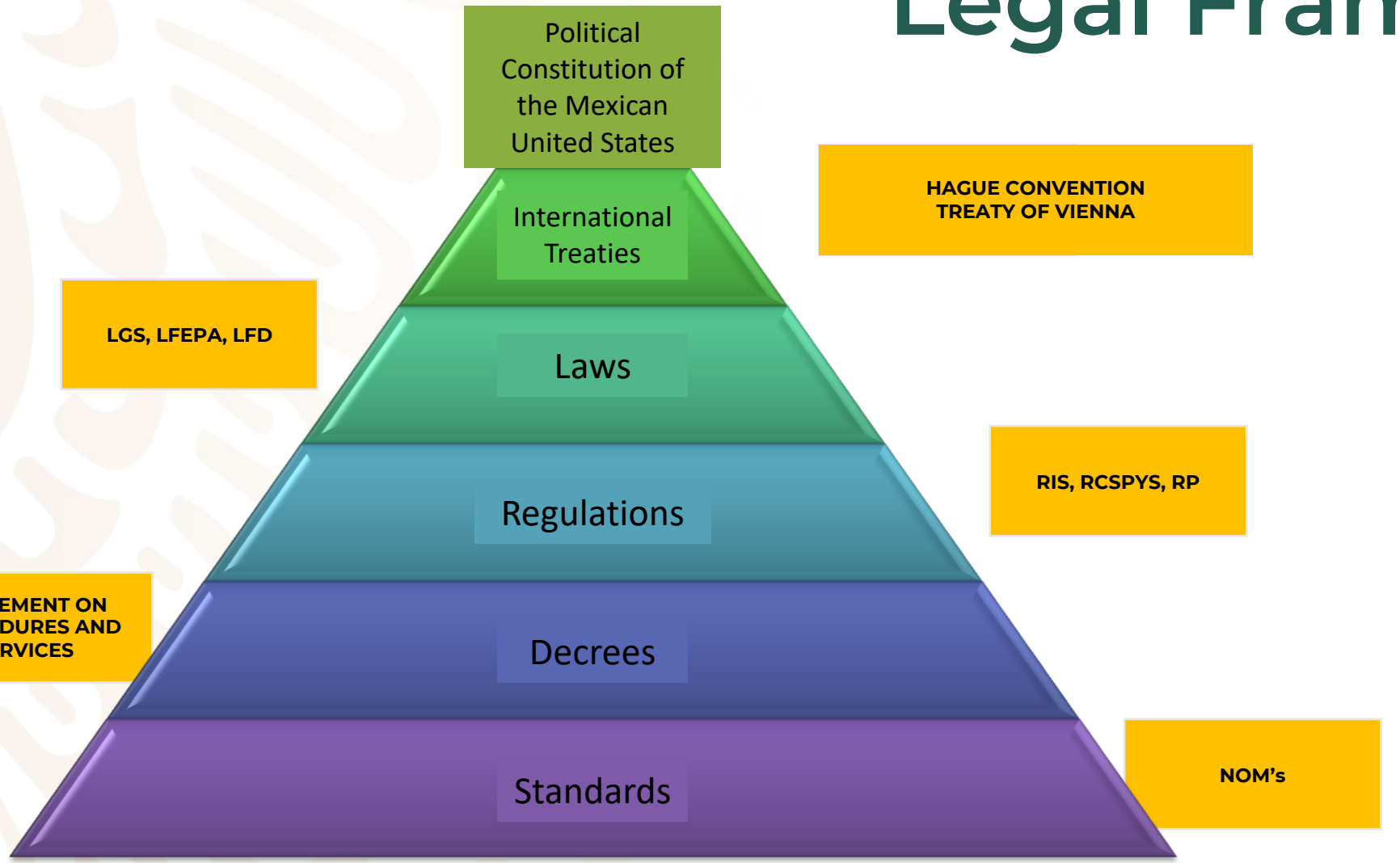
Legal Framework



Medical Devices

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Definition of Medical Devices

To the substance, mixture of substances, material, apparatus or instrument (including the computer program necessary for its proper use or application), used alone or in combination in the diagnosis, monitoring or prevention of diseases in humans or auxiliaries in the treatment of the same and of the disability, as well as those employed in the replacement, correction, restoration or modification of human anatomy or physiological processes. Medical devices include products in the following categories: medical equipment, prostheses, orthoses, functional aids, diagnostic agents, dental supplies, surgical materials, healing materials and hygienic products.

Numeral 3.31 Official Mexican STANDARD NOM-241-SSA1-2012.

Categories


Categories
Medical team: appliances, accessories and instruments for specific use intended for medical, surgical or procedural care of exploration, diagnosis, treatment and rehabilitation of patients, as well as those for activities of biomedical research.
Supplies for dental use: All substances or materials used for dental health care.
Prostheses, orthoses and functional aids: Those devices intended to replace or complement a function, a organ, or a tissue of the human body.
Surgical and healing materials: The devices or materials that add or not of antiseptics or germicides are used in practice surgical or in the treatment of continuity, skin lesions or its annexes.
Diagnostic agents: All Supplies including antigens, calibrating, verifying or controlling antibodies, reagents, reagent equipment, culture media and contrast and any other similar that can be used as an auxiliary to other procedures clinical or paraclinical.
Hygienic products: The materials and substances to be used apply to the surface of the skin or cavities corporal and that have pharmacological or preventive action.

Applicable Articles

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Applicable Articles

ARTICLE 1. The purpose of this regulation is to regulate the sanitary control of supplies and herbal remedies, as well as that of the Establishments, activities and services related to them.

ARTICLE 82. Medical equipment, prostheses, orthoses, functional aids, diagnostic agents, dental supplies, surgical material, healing, hygienic products and other devices for medical use, **require for their production, sale and distribution of sanitary registration.**

The Establishments in which the process of the Supplies mentioned in the previous paragraph is carried out must present a notice of operation, with the exception of those dedicated to the processing of radiation sources for medical use, which require a license issued in coordination with the National Commission for Nuclear Safety and Safeguards.

Applicable Articles

ARTICLE 83 BIS

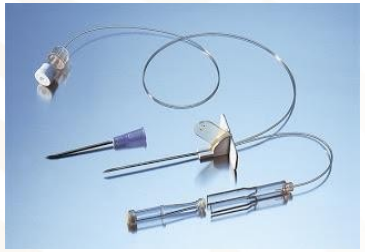
The Secretariat shall classify for registration purposes, according to the risk involved in its use, as follows:

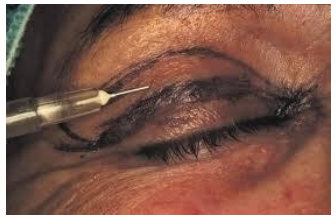
Class I

It defines those medical devices known in medical practice whose safety and efficacy are proven and which generally ***do not remain in the body.***

Class II

Those medical devices known in medical practice and that may have variations in the material with which they are made or in their concentration and, generally, ***are introduced into the body remaining less than thirty days.***





Class III

Those medical devices new or recently accepted in medical practice, or that ***are introduced into the body and remain in it for more than thirty days.***

Applicable Articles

ARTICLE 153. Health authorisations shall be requested in the official formats provided for that purpose by the competent authority, which shall be accompanied by the documents referred to in this Regulation.

ARTICLE 157. The sanitary authorizations granted in the terms of these Regulations **may be reviewed by the Secretariat or the states at any time**, complying with the requirements of the Law and these Regulations.

When the Review is carried out, and the Secretariat determines that the holder does not comply with any provision established in the Law or in these Regulations, it will notify the interested party so that, within a period not exceeding fifteen days, counted from the date of the notification, declares what is convenient to its right. Once this period has elapsed, whether or not there is a statement from the interested party, the Secretariat will determine what is appropriate.

Applicable Articles

ARTICLE 179. To **obtain the sanitary registration** of the Supplies referred to in Chapter IX, of Title Two of these Regulations, it is required to submit an application in the official format, to which the following documentary information will be attached:

I. Scientific and technical information to demonstrate that the Input meets the characteristics of safety and efficacy;
II. The draft Label in Spanish, in the terms of the corresponding Standard;
III. The instructions, if applicable, for use or operation manual in Spanish;
IV. The description of the manufacturing process that is carried out to obtain the product;
V. The description of the structure, materials, parts and functions, in the case of medical equipment;
VI. Good manufacturing practices certificate;
VII. Laboratory tests to verify specifications;
VIII. Bibliographic references, and
IX. The others established by the Secretariat in the corresponding Rules.

The Secretariat shall resolve requests for registration of **Class I Supplies within thirty days**. If not done so within this period, the request will be deemed approved.
For the Supplies of **classes II and III, the Secretariat will have a thirty-five and sixty days period**, respectively, to resolve the request.

Applicable Articles

ARTICLE 180. For **the sanitary registration** of the Supplies referred to in Chapter IX, of title Two of these Regulations, which are of **foreign manufacture**, in addition to complying with the requirements indicated in the previous article, an application will be submitted in the official format, to which the following documentation will be attached:

I. The certificate of free sale or equivalent, issued by the health authority of the country of origin;
II. The manufacturer's letter of representation, if the product is not manufactured by the parent company or factory or laboratory that requests registration in Mexico;
III. The certificate of good manufacturing practice issued by the health authority of the country of origin, and
IV. The original certificate of analysis issued by the company that produces the product, with the letterhead of its corporate name and signed by the chemist responsible for the foreign company.

The Secretariat shall resolve requests within the time limits set out in Article 179 of these Regulation.

Applicable Articles

ARTICLE 181. To be the holder of the sanitary registration of the Supplies referred to in Chapter IX, of title Two of these Regulations, **it is required to have a notice of operation of factory or production laboratory, warehouse of deposit or distribution or conditioning established in the national territory.**

ARTICLE 184. Any modification that is intended to be made to the conditions in which the Supplies referred to in Chapter IX of Title Two of these Regulation were registered, must be previously authorized by the Secretariat, for which the technical, scientific and legal information, where appropriate, that justifies said modification will be presented.

When changes are made to drugs or to pharmaceutical form or formulation, a new registration will be requested, except in the case of a reformulation indicated or agreed upon by the Secretariat.

In the case of change of distributor, the label or back label projects will also be accompanied, when required, in duplicate in Spanish. In the case of Supplies with exclusive presentation for public health or social security institutions, a copy of the corresponding code will be attached in the *Cuadro Básico* or in the Catalog of Supplies and, in the case of radiation sources, a copy of the corresponding license.

Applicable Articles

ARTICLE 188. The Secretariat shall resolve requests for modifications to the conditions of registration of the Supplies referred to in Chapter IX of Title Two of these Regulations within a period of twenty-two days. In the event that the Secretariat does not resolve within that period, the request shall be deemed approved.

ARTICLE 189. The document in which the modification to the conditions of registration is authorized, will contain a legend in which it is indicated that the Secretariat grants the holder of the registration a period of one hundred and twenty days to deplet the inventories of packaging materials and finished product.

ARTICLE 190 Bis 3. To obtain the first **renewal of the sanitary registration** of medical equipment, prostheses, orthoses, functional aids, diagnostic agents, supplies for dental use, surgical material, healing, hygienic products, and other devices for medical use, which are of national manufacture, the following must be submitted in the following order and with the application exclusively the following:

Applicable Articles

ARTICLE 190 Bis 4. To obtain the **first renewal of the sanitary registration** of medical equipment, prostheses, orthoses, functional aids, diagnostic agents, supplies for dental use, surgical material, healing, hygienic products and other devices for medical use, which are of **foreign manufacture**, in addition to what is required in article 190 Bis 3, fractions I, II, and IV, the following must be presented exclusively:

ARTICLE 190 Bis 6. Requests for renewal provided for in Articles 190 Bis 1, 190 Bis 2, 190 Bis 3 and 190 Bis 4 shall be submitted one hundred and fifty calendar days before the date on which the validity of the corresponding registration ends.

The Secretariat will resolve requests for the renewal of Supplies within a maximum period of one hundred and twenty calendar days following the submission of the request. When the last day of the period is non-business, it will be understood to be extended until the next working day. In the event that the Secretariat does not issue the respective resolution within the periods indicated in this article, the request shall be deemed approved.

Health care is everyone's responsibility

Acknowledgements: Lilia Yunel Flores Tapia

THANK YOU!

Jonathan René Flores López

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