REGULATION OF HEALTH SUPPLIES

LAST REFORM PUBLISHED IN THE OFFICIAL JOURNAL OF THE FEDERATION: MAY 31, 2021.

Regulation published in the Official Gazette of the Federation, Wednesday, February 4, 1998.

On the margin a seal with the National Coat of Arms, which says: United Mexican States.- Presidency of the Republic.

Ernesto Zedillo Ponce de Leon, President of the United States
Mexicans, in exercise of the power conferred upon me by section I of article 89 of the Political Constitution of the United Mexican States and based on the provisions of articles 39 of the Organic Law of the Federal Public Administration and 60, 194, 194 bis, 197, 198, 200, 200 bis, 204, 210, 221 to 268, 286 bis, 288 to 295, 301 bis, 368 to 379 and 422 of the
General Health Law, I have seen fit to issue the following

REGULATION OF HEALTH SUPPLIES

FIRST TITLE

General provisions

Unique Chapter

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

ARTICLE 2. For the purposes of this Regulation, the following terms shall be understood:

I. Conditioning, the necessary operations that a bulk product must go through to reach its presentation as a finished product;

II. Bioavailability, the proportion of drug that is absorbed into the general circulation after administration of a drug and the time required to do so;

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS SECTION, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(ADDED, DOF OCTOBER 19, 2011)
II Bis. Analytical Certificate, the document that supports the results obtained in a study to determine the composition or nature of a sample, issued by the manufacturer of the product, in accordance with the provisions of the Law, this Regulation and other applicable provisions;

III. Sanitary Condition, the specifications or sanitary requirements that each of the Inputs, Establishments, activities and services must meet and that are established in the corresponding regulations;

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS SECTION, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(ADDED, DOF OCTOBER 19, 2011)
III Bis. International Nonproprietary Name, the name that identifies a pharmaceutical substance or active pharmaceutical ingredient by means of a unique name that is recognized worldwide and is in the public domain;

IV. Distinctive name, the name that the laboratory or manufacturer assigns as a trademark to its pharmaceutical specialties in order to distinguish it from other similar ones, subject to prior approval by the health authority and registration with the competent authorities;

V. Generic name, the name of the medicine, determined through a pre-established method, which identifies the drug or active substance internationally recognized and accepted by the health authority;

VI. Primary Packaging, the elements of the packaging system that are in direct contact with the Input;

VII. Secondary Packaging, to the components that form part of the packaging in which the Input is marketed and are not in direct contact with it;

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS SECTION, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(ADDED, DOF OCTOBER 19, 2011)
VII Bis 1. Clinical studies, tests carried out on humans to demonstrate the quality, safety and efficacy of medicines;

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS SECTION, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(ADDED, DOF OCTOBER 19, 2011)
VII Bis 2. Biocomparability studies, tests, trials and analyses that are essential to demonstrate that a biocomparable biotechnological medicine has the same quality, safety and efficacy characteristics as a reference biotechnological medicine;

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS SECTION, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(ADDED, DOF OCTOBER 19, 2011)
VII Bis 3. Preclinical studies, in vitro or animal studies to demonstrate the quality, safety and efficacy of the product and whose results can be extrapolated to humans;

VIII. Label, tag, mark, brand or graphic image that has been written, printed, stenciled, marked, embossed or intaglioed, engraved, adhered or sealed on any material capable of containing the Input, including the packaging itself;

IX. Pharmacopoeia of the United Mexican States, the document issued by the Secretariat that records the general methods of analysis and the requirements regarding the identity, purity and quality of drugs, additives, medicines and biological products;

X. Homeopathic Pharmacopoeia of the United Mexican States, the document established by Law and issued by the Secretariat, which includes the names, procedures, methods and specifications for the identification, preparation or analysis of homeopathic substances and products;

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS SECTION, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE THAT MODIFIES THE REGULATIONS.

(ADDED, DOF OCTOBER 19, 2011)
X Bis. Technical information, on the tests, analyses, preclinical and clinical studies necessary, where appropriate, to demonstrate the quality, safety and www.ordenjuridico.gob.mx

effectiveness required by the Secretariat to obtain health registration;

XI. Inputs, to the health supplies referred to in article 194 bis of the Law;

XII. Law, to the General Health Law;

XIII. Batch, the specific quantity of any raw material or input, which has been produced in a production cycle, under equivalent operating conditions and during a given period;

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS SECTION, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(ADDED, DOF OCTOBER 19, 2011)
XIII Bis 1. Biocomparable biotechnological medicine, a non-innovative biotechnological medicine that proves to be biocomparable in terms of safety, quality and efficacy to the reference biotechnological medicine through the tests established by the Law, this Regulation and other applicable provisions;

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS SECTION, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(ADDED, DOF OCTOBER 19, 2011)
XIII Bis 2. Innovative biotechnological medicine, the biotechnological medicine that obtains health registration in Mexico, as recognized by the Secretariat;

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS SECTION, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(ADDED, DOF OCTOBER 19, 2011)
XIII Bis 3. Reference biotechnological medicine, the innovative biotechnological medicine that is used as a reference for the registration of biocomparable biotechnological medicines and that is recognized as such by the Secretariat. When the innovative biotechnological medicine is not registered in Mexico, a biocomparable biotechnological medicine previously registered with the Secretariat may be recognized as such;

(REFORMED, DOF JANUARY 2, 2008)

XIV. Generic Medicine, a pharmaceutical specialty with the same drug or active substance and pharmaceutical form, with the same concentration or potency, that uses the same route of administration and that, through the required regulatory tests, has proven that its pharmacopoeial specifications, dissolution profiles or its bioavailability or other parameters, as the case may be, are equivalent to those of the reference medicine;

(ADDED, DOF JANUARY 2, 2008)
XIV Bis. Reference drug, a drug indicated by the Secretariat as such, which is registered by said department, which is commercially available and is selected in accordance with the criteria established in the Standards;

XV. New Molecule: a substance of natural or synthetic origin that is the active ingredient of a medicine, not previously used in the country, whose efficacy, safety and therapeutic purposes have not been fully documented in the scientific literature;

(ADDED, DOF JANUARY 2, 2008)
For the purposes of the New Molecules Committee, those molecules that fall within the following categories will be classified as new:

a. Any drug or medicine that is not registered worldwide and is intended to be registered in Mexico (new molecular entity).

b. Any drug or medicine that, although it exists in other countries, with limited clinical experience or controversial information, is not registered in Mexico and is intended to be registered in our country.

c. Any medicine that attempts to create a combination of two or more drugs that does not exist on the national market.

d. Any drug or medicine existing on the market that is intended to be marketed with another therapeutic indication.

XVI. Standards, to the official Mexican standards;

XVII. Secretariat, to the Secretariat of Health, and

XVIII. Authorized Third Party, the person authorized by the Secretariat to issue opinions regarding compliance with established requirements

by the Secretariat itself or in the corresponding Regulations or to carry out studies, for the purposes of health procedures or authorizations.

ARTICLE 3. The inputs, establishments, activities and services regulated in this Regulation refer to those for human use and consumption, except when expressly referring to others.

ARTICLE 4. The Secretariat, within the framework of the National Health System, will carry out health control and promotion programs and campaigns, inviting the community, producers, health professionals and service providers to participate in their implementation.

ARTICLE 5. The popular action referred to in Article 60 of the Law may be exercised by any person, for which he/she must:

I. Report the facts to the health authority, in writing or verbally;

II. Indicate the fact, act or omission that in your opinion represents a risk or causes harm to the health of the population, and

III. Provide data that allows the identification and location of the cause of the health risk or damage and, where appropriate, the persons involved.

When the complaint is made verbally, the health authority will record it in writing, based on the statements of the complainant, who must sign it, in order to proceed with the respective procedure. In no case will anonymous complaints be processed.

The health authority will inform the complainant of the action taken regarding the complaint.

ARTICLE 6. The application and interpretation of these Regulations is the responsibility of the Secretariat, as well as of the governments of the federal entities within their respective areas of competence, in accordance with the coordination agreements that may be signed.

SECOND TITLE

Inputs

Chapter I

Common provisions

First Section

Characteristics and sanitary conditions

ARTICLE 7. Acts related to the Inputs process are considered to be those that have the following purposes:

I. Medical: Those performed for diagnostic, preventive, therapeutic or rehabilitation purposes;

II. Scientists: Those assigned to research;

III. Industrial: Those intended for the production of inputs or their raw materials, and

IV. Health policy: Those determined by the Secretariat or the General Health Council for reasons of therapeutic efficacy and collective benefit.

ARTICLE 8. The Secretariat shall establish the characteristics that a product must meet to be considered a medicine or other input in the Pharmacopoeia of the United Mexican States or in the corresponding Standards.

Likewise, the quality specifications for additives, drugs and medicines and the procedures for evaluating them shall be those indicated in the current edition, at the time of evaluation, of the Pharmacopoeia of the United Mexican States and its supplements. When the information does not appear in this edition, reference may be made to pharmacopoeias of other countries whose analysis procedures are carried out in accordance with specifications of specialized organizations or other internationally recognized scientific bibliography.

ARTICLE 9. The Standards issued by the Secretariat, in accordance with the nature of the Input, will establish the microbiological, toxicological or health risk specifications, as well as the sanitary production techniques to ensure said specifications and the corresponding sampling, testing and analysis methods.

ARTICLE 10. Drug manufacturers must analyze, identify, store, handle and control the drugs and additives they use, in order to ensure that they comply with the sanitary conditions of identity, purity, safety, quality, stability, sterility and, where applicable, apyrogenicity, and that they are not altered, adulterated or contaminated.

ARTICLE 11. Batches of Inputs must be identified in accordance with the provisions of the corresponding Standards and in relation to the date of manufacture of said products.

ARTICLE 12. No remnants from other batches shall be used in the production of new batches of medicines.

ARTICLE 13. The water used in the preparation, manufacturing, mixing or packaging of the Inputs must be drinkable, except for those cases in which it is established in this Regulation, in the Pharmacopoeia of the United Mexican States or in the corresponding Standard that it must be purified, distilled or have other characteristics.

ARTICLE 14. The materials, equipment, utensils, raw materials and containers used in the manufacture of the Supplies referred to in this Regulation must be harmless and resistant to corrosion and not contain toxic substances, with the exceptions indicated in the corresponding Standards.

ARTICLE 15. Establishments intended for the manufacture of inputs shall carry out analytical control of these. Such control must include:

I. The specifications and techniques for analyzing each of the components used in the process, including sampling of the batch and finished product;

II. Methods for verifying identity, purity, sterility and non-pyrogenicity, when required;

III. Validation of the techniques used;

IV. Storage of retention samples in sufficient quantity for two complete analyses of each batch processed, one year after the expiration date of the same, and

V. The other characteristics and requirements indicated in the corresponding Standard.

Documentary evidence must be kept for one year after the product's expiration date, in accordance with the corresponding Standard.

ARTICLE 16. The specifications, analytical techniques and all documents used in the manufacturing and marketing process of the Inputs must be in Spanish.

ARTICLE 17. The following shall be observed in the transportation of Supplies:

I. Under no circumstances may vehicles be used for the transport of pesticides, plant nutrients, toxic and hazardous substances or cleaning products with corrosive action;

II. When public transport is used, the Supplies will be packaged and packed in such a way that they meet the environmental conditions necessary to preserve their properties;

III. Refrigeration chambers must have graphic temperature control and their doors must remain open for the minimum amount of time necessary to remove or introduce a medication;

IV. Biological products will be kept at the pharmacopoeial refrigeration temperature or as established on the product label;

V. The means of transport must meet the established safety requirements and conditions and its operators must be trained to apply emergency measures in the event of eventualities and accidents. To this end, the Secretariat will coordinate with the Secretariat of Communications and Transport and other competent authorities, and

VI. The means of transport used for the transport and distribution of raw materials or finished products shall be constructed of corrosion-resistant, smooth, impermeable, non-toxic materials that can be easily cleaned.

All vehicles must always be kept clean and in good condition. The equipment installed in them will ensure the preservation of the products and prevent the entry and proliferation of pests or their contamination.

Section Two

Packaging and labeling

ARTICLE 18. The physical, chemical and toxicity characteristics of each type of packaging material and of the substances used to coat the inside of drug containers shall be determined by the corresponding Standard.

ARTICLE 19. Containers that have contained medicines may not be used again.

ARTICLE 20. The packaging system and containers of the Inputs must avoid leaks that may cause harm to health or chemically or microbiologically contaminate the Input.

ARTICLE 21. Medicine containers must have closure systems that make it evident to the user that they have not been opened prior to purchase and that prevent accidental handling by children, as established in the Pharmacopoeia of the United Mexican States or in the corresponding Standard.

ARTICLE 22. Only substances or products authorized by the Secretariat will be used as propellants in containers for aerosol supplies.

ARTICLE 23. The Distinctive Name of Inputs, in addition to complying with the provisions of Article 225 of the Law, when used shall be subject to the following:

I. The Distinctive Name of two or more Inputs, when orthographically or phonetically similar, must be differentiated by at least three letters of each word;

II. The same Distinctive Name of another medicine with a current, revoked or registration in process of registration must not be used, and

III. The same Distinctive Name may only be used when dealing with different pharmaceutical forms or different doses with the same active ingredient and registered by the same laboratory.

ARTICLE 24. Labels must contain at least the following health information and meet the characteristics and requirements established by the corresponding Standard:

I. The Generic Name;

(REFORMED, DOF JANUARY 2, 2008)
II. The distinctive name; in the case of Generic Medicines, its inclusion will be optional;

III. The declaration of active ingredients;

IV. The identification and address of the manufacturer and, where applicable, the distributor;

V. Instructions for its conservation;

VI. The expiration date;

VII. The batch number;

VIII. Dosage and route of administration;

IX. Precautionary legends, including its risk of use during pregnancy;

X. Warning legends;

XI. (REPEALED, DOF JANUARY 2, 2008)

XII. The specifications of the living organism used to prepare the medicine and the name of the disease for which it is intended, in accordance with accepted international nomenclature, when it concerns medicines of biological origin with immunological action.

When the information is expressed in other languages, from the country of origin it must also appear in Spanish, at least, with the same size and typographic proportionality, in accordance with the corresponding Standard.

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS ARTICLE, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(ADDED, DOF OCTOBER 19, 2011)
ARTICLE 24-bis. In addition to the provisions of the previous article, labels on biotechnological medicines must include the following information:

I. Name or company name or designation of the manufacturer and country of origin of the biopharmaceutical;

II. The location of primary packaging of the biotechnological drug, and

III. If applicable, name or business name or designation of the importer.

Innovative biotechnological medicines must include the initials MB on their labels. Biocomparable biotechnological medicines must include the initials MBB on their labels. In both cases, they must include the International Common Name on their labels, regardless of the distinctive name.

ARTICLE 25. When labels contain the Generic and Distinctive Names of the medicines, they must be printed in a proportion such that the size of one is at least a third of the other, measured in points of the same font or, failing that, in Helvetica font.

(REFORMED, DOF MAY 31, 2021)
ARTICLE 26. The labeling of medicines intended exclusively for public health and social security institutions shall be subject to the following provisions:

I. In the primary or secondary packaging intended for the public sector, it must be differentiated from that intended for the private sector;

II. Contain the health information established in articles 24 and, where applicable, 24 Bis of this Regulation, as well as the requirements determined in the corresponding Standard;

III. Include the legend “prohibited for sale” or “property of the Sector” Health”, and

IV. Contain the code of the National Compendium of Health Supplies on the secondary packaging; in the case of medicines that do not contain secondary packaging, it must be stated on the primary packaging.

ARTICLE 27. The labeling of products whose processing is carried out in the national territory and which are intended exclusively for export purposes shall not be subject to the provisions of this Regulation.

Section Three

Prescription

ARTICLE 28. The medical prescription is the document that contains, among other elements, the prescription of one or more medications and may be issued by:

I. Doctors;

II. Homeopaths;

III. Dental surgeons;

IV. Veterinarians, in their area of expertise;

V. Social service interns, from any of the above careers, and

VI. Nurses and midwives.

The professionals referred to in this article must have a professional license issued by the competent educational authorities. Interns, nurses and midwives may prescribe in accordance with the specifications determined by the Secretariat.

ARTICLE 29. The medical prescription must contain the full name and address and the professional license number of the prescriber, as well as bear the date and the handwritten signature of the issuer.

ARTICLE 30. When prescribing, the issuer of the prescription will indicate the dose, presentation, route of administration, frequency and duration.
of the treatment.

ARTICLE 31. The issuer of the prescription shall prescribe the medications in accordance with the following:

(REFORMED, DOF JANUARY 2, 2008)

I. When dealing with Generic Medicines, you must write down the Generic Name and, if you wish, you may indicate the distinctive name of your preference;

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS SECTION, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(ADDED, DOF OCTOBER 19, 2011)
I Bis. In the case of biotechnological medicines, the International Common Name must be noted, and optionally, the distinctive name;

(REFORMED, DOF JANUARY 2, 2008)
II. In other cases, it may express the distinctive name or the generic and distinctive names together;

When the Distinctive Name of the medicine is stated in the prescription, its sale or supply must conform precisely to this name and may only be substituted when expressly authorized by the person prescribing it.

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS PARAGRAPH, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(ADDED, DOF OCTOBER 19, 2011)
The sale and supply of biotechnological medicines must comply with the prescription.

ARTICLE 32. Prescription in public institutions shall be subject to the provisions of each institution, and in all cases only the generic names of the medicines included in the Basic List of Supplies for the first level or in the Catalogue of Supplies for the second and third levels shall be used. As an exception, and with the corresponding authorization, other medicines may be prescribed.

Section Four

Sale or supply

ARTICLE 33. Medicines that bear on their labels or packaging the legend indicating that a medical prescription is required for their sale or supply may only be sold with this condition.

ARTICLE 34. Medicines presented as medical samples, original gifts, and those intended for the exclusive use of public health and social security institutions may not be sold to the public.

ARTICLE 35. Medicines that require a special prescription or a medical prescription for their acquisition may not be sold in the free access mode.

Section Five

Investigation and suspension of activities

ARTICLE 36. The suspension of production or marketing of Inputs must be communicated to the competent health authority within a period of no more than thirty business days from the date on which it was carried out, in writing indicating the causes that gave rise to it.

The resumption of production or marketing must also be communicated in writing to the Secretariat within ten days of this occurring.

The Secretariat reserves the right to take action, based on social interest, when the production or marketing of Inputs is suspended.

ARTICLE 37. When the Secretariat has evidence that an Input lacks safety, efficacy, purity or stability, it will apply the security measures provided for in the Law and, if applicable, revoke its registration, notifying the holder of the registration so that he may state what is appropriate to his rights. When the latter satisfies the safety and efficacy requirements determined by the Secretariat, he may request the suspension of the security measures, provided that the registration has not been revoked.

ARTICLE 38. Adverse reactions to medicines or other inputs that occur during their marketing or use, those reported by health professionals, those published in the scientific literature and those reported by international health organizations, must be immediately brought to the attention of the Secretariat by the holder of the registration, by the distributors or marketers of the inputs.

ARTICLE 39. Research into medicines, including those that are or contain narcotics and psychotropic drugs, shall be subject to the provisions of Title Five of the Law and the Regulations of the General Health Law on Health Research.

Section Six

Destruction of supplies

ARTICLE 40. The destruction of supplies that are or contain narcotics or psychotropic substances must be reported to the Secretariat and carried out in the presence of a health inspector, who will verify that they are destroyed.

In the event that verification is not carried out within ten days following the date of submission of the application, the applicant may carry out the destruction in the presence of a Third Party Authorized by the Secretariat for this purpose.

ARTICLE 41. Inputs that are or contain antineoplastics, hormones, beta-lactams, cephalosphorins, immunosuppressants, blood derivatives, viral biologicals and microbial biologicals, before their final disposal must be inactivated, except if they are incinerated, in such a way that they do not cause a risk to health. Hazardous waste must be treated in accordance with the corresponding Standard.

ARTICLE 42. The destruction or deactivation of the Supplies will be carried out in accordance with the corresponding Standard and, in all cases, the costs incurred will be assumed by the Establishment that has them in possession.

Chapter II

Biological products and blood derivatives

(REFORMED, DOF JANUARY 13, 2011)
ARTICLE 43. For the distribution or sale of biological products and blood derivatives of national or foreign manufacture, each batch must be previously authorized based on the analytical results issued by the Secretariat or by an Authorized Third Party, in accordance with the applicable legal provisions, with www.ordenjuridico.gob.mx

except for products derived from bacterial lysates and microbial preparations for non-immunological oral use.

To obtain the authorization mentioned in the previous paragraph, the applicant must formulate his/her request using the form issued for such purpose by the Secretariat and published in the Official Gazette of the Federation, which will have ten days to resolve the request, once the laboratory results have been received.

The Federal Commission for the Protection against Sanitary Risks may authorize the distribution or sale of the products referred to in this article in a simplified manner, based on the guidelines issued for this purpose by the Secretariat, in terms of the applicable legal provisions, which must consider aspects that allow minimizing the risk to health, and which must be published in the Official Gazette of the Federation.

Chapter III

Narcotics and psychotropics

ARTICLE 44. The obtaining, processing, manufacturing, preparation, mixing, packaging, handling, storage, marketing, export, medical prescription, supply, possession, processing, packaging, transportation, employment, use, consumption and, in general, any act related to narcotics and psychotropic substances, with the exception of those that lack therapeutic value and are currently used in industry, may only be carried out for medical and scientific purposes, with prior authorization from the Secretariat.

ARTICLE 45. The safekeeping and custody of raw materials or medicines that are or contain narcotics or psychotropics is the responsibility of the person who possesses them, who must have official documents proving their legitimate possession, which must be kept for a period of three years.

ARTICLE 46. Public and private establishments intended for the processing, import, export or use of narcotics or psychotropic substances for human use shall have control books authorized by the Secretariat and a security system for their safekeeping and custody.

For the purposes of this Regulation, control books are understood to be the compilation of graphic records obtained by any authorized system, provided that they contain the data necessary for the control of narcotic drugs and psychotropic substances.

ARTICLE 47. The manufacture of batches of raw materials or narcotic or psychotropic medicines, intended to obtain sanitary registration, for marketing or for scientific purposes, will be recorded in the control book authorized by the Secretariat and signed by the person in charge of the requesting laboratory or institution, which will include, as appropriate, the following data:

I. The name of the raw material;

II. The batch number;

III. The origin;

IV. The amount to be used and balance;

V. The use and purpose that will be given to it, and

VI. Summary of the process.

The Secretariat may verify, through a visit order, the operations and data declared, which will be recorded in the corresponding control book, with the exception of what is indicated in section VI of this article.

ARTICLE 48. The manufacture of raw materials or medicines for veterinary use that contain narcotics or psychotropic substances shall be subject to control determined in coordination by the Secretariat and other agencies of the Federal Executive.

ARTICLE 49. Producers who regularly require raw materials or medicines that are or contain narcotics and psychotropics shall notify the Secretariat, by means of a notice, during the months of January to May, of a forecast of the quantities they will demand during the following year.

ARTICLE 50. Only the professionals listed below may prescribe medicines that can only be purchased with a special prescription or with a medical prescription that must be retained by the pharmacy that supplies it or with a medical prescription that can be filled up to three times. www.ordenjuridico.gob.mx

They mention, provided that they have a professional certificate issued by the competent educational authorities:

I. Doctors;

II. Homeopaths;

III. Dental surgeons, for dental cases, and

IV. Veterinarians, when prescribing them for use in animals.

ARTICLE 51. Professionals interested in obtaining the bar code for special prescription drugs shall submit an application in the format authorized for this purpose by the Secretariat, accompanied by the following documentation:

I. Certified copy of the professional license, which accredits them as professionals in any of the branches referred to in the previous article;

II. Copy of official identification, and

III. Written in original and two copies, on letterhead and signed by the director of the institution, in the case of hospital institutions, in which the designation of the professionals responsible for the prescription is specified.

The Secretariat or the state health authorities will register the requesting professional and assign him/her a certain number of codes in a bar code, within a period of five days for the first request and one day for subsequent requests. In the latter case, only the request will be submitted.

ARTICLE 52. Professionals authorized in accordance with the previous article shall prescribe medications in special prescription pads, in original and copy, which shall contain the following information:

I. The folio number and the code expressed in barcode with the doctor's identification;

II. The name, address, professional ID number, specialty, if applicable, and handwritten signature of the physician;

III. The number of days of prescription of the treatment, presentation and dosage of the medication;

IV. The date of prescription, and

V. The name, address and diagnosis of the patient.

The authorized physician will order the printing of special prescriptions, at the time and with the specifications indicated by the Secretariat.

ARTICLE 53. The loss or theft of special prescription pads for prescribing narcotics must be immediately reported to the Secretariat, accompanied by a copy of the report drawn up before the Federal Public Prosecutor's Office.

ARTICLE 54. Possession of medicines containing narcotics or psychotropic substances shall be accredited, when required by the corresponding authorities, with a copy of the special prescription containing the bar code and the handwritten signature of the professional who issues it or with the corresponding invoice.

ARTICLE 55. Foreigners who enter the country and require medicines containing narcotics or psychotropic substances for their treatment must prove their possession by presenting to the corresponding customs office the medical prescription or permit issued by the competent authority of the country from which they come.

ARTICLE 56. Vessels or aircraft with Mexican registration intended for national or international transport may transport medicines containing narcotics or psychotropic substances for the provision of first aid or for urgent cases during the trip, in the quantity indicated by the Secretariat.

The handling and supply of medications used during the trip will be the responsibility of the captains of the vessels or aircraft.

ARTICLE 57. Medicines that are or contain narcotics or psychotropic substances may not be presented in the form of a medical sample or original gift.

ARTICLE 58. Factories or laboratories that process or warehouses that sell the medicines referred to in article 44 of www.ordenjuridico.gob.mx

these Regulations, may only be sold to establishments that have a health license that accredits them, as the case may be, as hospital units, warehouses for the storage and distribution of medicines and biological products or blood derivatives for human use, drugstores, pharmacies or apothecaries authorized to supply narcotics and psychotropic drugs to the public.

ARTICLE 59. The import, export and marketing of raw materials and medicines that are or contain narcotics and psychotropic substances may not, under any circumstances, be sent by mail.

ARTICLE 60. The owners or those responsible for establishments that intervene in the processing, import and export of medicines that are or contain narcotics or psychotropic substances must immediately notify the Secretariat in writing of activities that involve extraordinary volume, significant disappearance or any circumstance in which there are reasonable grounds to consider that there may be diversion of said substances.

Chapter IV

Vitamin Medications

ARTICLE 61. A Vitamin Medication is considered to be a product that in its composition contains only vitamins or minerals as mono or polypharmaceuticals, alone or in association, indicated to prevent or treat conditions due to deficiencies of the same, and which is presented in pharmaceutical form.

The corresponding Standards will determine the recommended daily intake, maximum doses of vitamins and minerals and other specifications.

ARTICLE 62. Vitamin Medicines must have health registration and their sale will not require a medical prescription when none of their components exceed the following daily doses:

Vitamins	Dose
Vitamin A/Retinol	2400 µg
Folic Acid	2000 µg

Beta Carotene	150 mg
Biotin	1000 µg
Vit B1/Thiamine	150 mg
Vit B2/Riboflavin	170 mg
Vit B3/Niacin	500 mg
Vit B5/Ac. Pantothenic	550 mg
Vit B6/Pyridoxine	250 mg
Vit B12/ Cyanocabalamin	1000 µg
Vit C/Ascorbic Acid	2000 mg
Vit D	50 µg
Vit E/d- a-Tocopherol	1000 mg
Vit K	65 µg

Minerals	Dose
Calcium	2000 mg
Copper	10 mg
Chrome	500 µg
Fluorine	5.0 mg
Phosphorus	2000 mg
Iron	75 mg
Magnesium	1000 mg
Manganese	10 mg

Molybdenum	350 µg
Selenium	200 µg
Iodine	500 µg
Zinc	50 mg

Vitamin or mineral medications with doses higher than those indicated in this article, as well as those administered parenterally, regardless of their concentration, will require a medical prescription for their sale, which may be filled as many times as indicated by the prescribing physician.

Chapter V

Homeopathic medicines

ARTICLE 63. Stability tests for homeopathic medicines shall be assessed by physical appearance parameters and microbiological tests, when the products are in pharmaceutical form such as ointments or salves, ear solutions, ophthalmic solutions and others authorized by the Secretariat. They shall be presented on the manufacturer's letterhead and signed by the health officer of the Establishment.

ARTICLE 64. The formulation of a homeopathic medicine may not include procaine, ephedrine, yohimbine, chaparral, germanium, animal or human hormones or other substances that have hormonal or antihormonal activity.

The use of narcotic or psychotropic substances in these medicines will only be permitted when they are diluted and dynamized.

ARTICLE 65. Homeopathic medicines may be sold in establishments that are not pharmacies.

Chapter VI

Herbal medicines

ARTICLE 66. Herbal medicines, in addition to containing plant material, may contain excipients and additives in their formulation.

ARTICLE 67. Herbal medicines are not considered to be those that are associated with isolated and chemically defined active ingredients, nor those proposed as injectables.

ARTICLE 68. The formulation of an herbal medicine may not include narcotic or psychotropic substances of synthetic origin, nor mixtures with allopathic medicines, procaine, ephedrine, yohimbine, chaparral, germanium, animal or human hormones or other substances that contain hormonal or antihormonal activity or any other that represents a risk to health.

ARTICLE 69. When due to the size of the Primary Packaging it is not possible to include the information indicated for the Label, only the following will be entered:

I. The Distinctive Name;

II. The pharmaceutical form;

III. Dosage and route of administration;

IV. Contraindications, if any;

V. The conservation legend, if applicable;

VI. The Lot number;

VII. The expiration date, and

VIII. The alphanumeric key of the record.

ARTICLE 70. When due to the size of the Secondary Packaging it is not possible to include the information indicated for the Label, only the following will be entered:

I. The formula that expresses the botanical name(s) in Latin by genus and species, and excipient or vehicle, as the case may be;

II. The Distinctive Name;

III. The pharmaceutical form;

IV. The therapeutic indication;

V. Dosage, route of administration and instructions for use;

VI. Adverse reactions;

VII. Precautions and contraindications, where applicable;

VIII. Use during pregnancy and lactation;

IX. Pediatric use;

X. The expiration date, if applicable, and

XI. The alphanumeric key of the record.

ARTICLE 71. The sale and supply of herbal medicines that are not narcotics or psychotropic substances may be carried out in establishments that are not pharmacies.

(ITS NAME HAS BEEN REFORMED, DOF2 OF JANUARY 2007)
Chapter VII

Generic Drugs

ARTICLE 72. For the purposes of the provisions of article 376 bis, section I of the Law, medicines intended for the generic market will only be pharmaceutical specialties that, in terms of these Regulations, are interchangeable.

(REFORMED, DOF JANUARY 2, 2008)
ARTICLE 73. The General Health Council and the Secretariat, through publication in the Official Gazette of the Federation, will determine the interchangeability tests, which must be applied in accordance with the corresponding regulations.

ARTICLE 74. (REPEALED, DOF JANUARY 2, 2008)

ARTICLE 75. (REPEALED, DOF JANUARY 2, 2008)

ARTICLE 76. (REPEALED, DOF JANUARY 2, 2008)

ARTICLE 77. (REPEALED, DOF JANUARY 2, 2008)

ARTICLE 78. (REPEALED, DOF JANUARY 2, 2008)

ARTICLE 79. (REPEALED, DOF JANUARY 2, 2008)

ARTICLE 80. (REPEALED, DOF JANUARY 2, 2008)

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS CHAPTER, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(ITS NAME HAS BEEN REFORMED, DOF OCTOBER 19, 2011)
Chapter VIII

Biotechnology Medicines

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS ARTICLE, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(REFORMED, DOF OCTOBER 19, 2011)
ARTICLE 81. For the purposes of this Regulation, a biopharmaceutical is considered to be any substance that has been produced by molecular biotechnology, that has pharmacological activity, that is identified by its physical, chemical and biological properties and that meets the conditions to be used as the active ingredient of a biotechnological medicine.

Likewise, a biotechnological medicine is understood to be any substance that has been produced by molecular biotechnology, that has a therapeutic, preventive or rehabilitative effect, that is presented in pharmaceutical form, that is identified as such by its pharmacological activity and physical, chemical and biological properties.

Biopharmaceuticals and biotechnological medicines may be:

I. Recombinant proteins: Proteins produced by any prokaryotic or eukaryotic biological entity to which a deoxyribonucleic acid sequence that encodes them is introduced by genetic engineering techniques;

II. Monoclonal antibodies: Intact immunoglobulins produced by hybridomas, immunoconjugates, immunoglobulin fragments and recombinant proteins derived from immunoglobulins;

III. Synthetic peptides: Peptides consisting of less than forty amino acids produced by molecular biotechnology techniques;

IV. Synthetic or plasmid nucleic acids: Nucleic acids obtained from natural plasmids or modified by genetic engineering techniques, and

V. Others that, where appropriate, are determined by agreement by the Secretariat, in accordance with technical and scientific advances.

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS ARTICLE, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(ADDED, DOF OCTOBER 19, 2011)
ARTICLE 81-bis. Pharmacovigilance of biotechnological medicinal products must be carried out in accordance with the corresponding standard. Such pharmacovigilance must allow a clear identification of the biotechnological medicinal product, referring specifically to its manufacturer, the International Common Name, the distinctive name and the batch number.

Furthermore, this pharmacovigilance should facilitate the identification of biotechnological therapies administered at all stages of treatment.

Chapter IX

Other Inputs

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

Establishments in which the processing of the inputs 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

in a coordinated manner with the National Commission for Nuclear Safety and Safeguards.

ARTICLE 83. The Secretariat shall classify for registration purposes the Inputs indicated in the previous article, according to the risk involved in their use, as follows:

CLASS I. Those inputs known in medical practice and whose safety and effectiveness are proven and, generally, are not introduced into the body;

CLASS II. Those inputs known in medical practice and which 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, and

CLASS III. Those inputs that are new or recently accepted in medical practice, or that are introduced into the body and remain there for more than thirty days.

ARTICLE 84. New models of Health Supplies referred to in this Chapter, from the same production line and manufacturer, if they have technological advances, will require new registration with the Secretariat.

ARTICLE 85. When, according to their nature, it is required to verify the stability of the Inputs referred to in the previous article, the corresponding Standard for these products must be complied with.

ARTICLE 86. Ethyl alcohol at a concentration of 96º GL requires registration with the Secretariat as a healing material and compliance with the provisions of the corresponding Standard.

ARTICLE 87. The catalogues of the Supplies referred to in this Chapter, as well as the promotional information contained in the magazines
medical publications or printed materials addressed to health professionals are medical dissemination media and the company responsible for the aforementioned publications must give the corresponding notice to the Secretariat.

THIRD TITLE

Herbal Remedies

Unique Chapter

ARTICLE 88. A Herbal Remedy is considered to be a preparation of medicinal plants, or their parts, individual or combined, and their derivatives, presented in pharmaceutical form, to which, by popular or traditional knowledge, relief for some participating or isolated symptoms of a disease is attributed.

Herbal Remedies will not contain in their formulation narcotic or psychotropic substances or any other type of allopathic drug or other substances that generate hormonal, antihormonal activity or any other substance in concentrations that represent a risk to health.

ARTICLE 89. Plants used as raw materials to produce Herbal Remedies must be subjected to treatments to eliminate the microbial flora that accompanies them, in accordance with the Standards issued in this regard or with the corresponding international specifications.

ARTICLE 90. The manufacture of Herbal Remedies must be carried out under conditions that prevent microbiological contamination of their ingredients.

ARTICLE 91. In order to carry out the production of Herbal Remedies of national manufacture, an application must be submitted to the Secretariat, for which the following will be required:

I. Have the activity of a factory or laboratory of Herbal Remedies for human use, which has an internal or external control laboratory and notice of operation;

II. Notification by product, specifying each of the ingredients in its composition or formula;

III. The certificate of microbiological analysis and absence of toxic residues;

IV. The description of the process, which must comply with good manufacturing practices;

V. Have a health officer;

VI. Information on the identity of the components;

VII. The scientific and popular name of the plant or plants used;

VIII. The formula;

IX. The indications and time for its use, and

X. Label projects.

ARTICLE 92. Upon approving the documentation referred to in the previous article, the Secretariat shall assign an alphanumeric control code within a maximum period of twenty days, which must be displayed on the product packaging. If no decision is made within the specified period, the application shall be deemed to be admissible.

ARTICLE 93. To distribute Herbal Remedies, a notice of operation must be issued, which must correspond to the warehouse or distribution business, and a health officer must be present.

ARTICLE 94. To obtain the alphanumeric code for Herbal Remedies of foreign manufacture, in addition to complying with the requirements indicated in article 91, the following documentation must be submitted:

I. The free sale certificate issued by the health authority of the country of origin and a letter of representation from the manufacturer. If the product is manufactured by the parent company or subsidiary of the requesting laboratory in Mexico, a letter of representation will not be required;

II. The copy of the certificate of analysis issued by the company that manufactures the Herbal Remedy, with the letterhead of its corporate name and endorsed by the responsible chemists of the foreign and national company;

III. The certificate of good manufacturing practices, and

IV. The Spanish Label and Back Label projects, in their case.

ARTICLE 95. When the Secretariat becomes aware that a plant or mixture of plants shows signs of toxic or cumulative effects, or any other risk to health, it may prohibit the www.ordenjuridico.gob.mx

import, production, storage, distribution and sale of the Herbal Remedy that contains them.

ARTICLE 96. The sale and supply to the public of Herbal Remedies shall be freely accessible.

ARTICLE 97. Information on Herbal Remedies for advertising and marketing purposes must be aimed at specifying the symptomatic effect and must be the same as that contained on the Label. Under no circumstances may they be advertised as curative.

ARTICLE 98. The provisions relating to Labels, Packaging and Transportation of Inputs referred to in Chapter I of the previous Title shall apply, as appropriate, to Herbal Remedies.

FOURTH TITLE

Establishments

Chapter I

Common provisions

ARTICLE 99. Establishments are considered to be the premises and their facilities, dependencies and annexes, in which the process of the Inputs, activities and services referred to in this Regulation are developed.

ARTICLE 100. For their operation, Establishments must comply with the provisions of this Regulation and those established in the corresponding Standards.

ARTICLE 101. Establishments must be provided with potable water, in sufficient quantity and pressure to satisfy the needs of the persons who are in them, and must have excrement disposal services connected to the drainage network, without prejudice to the fulfillment of other obligations that, where appropriate, may be imposed by other competent departments. For sanitary purposes, non-potable water intakes must be identified by means of a sign that states: non-potable water, do not drink it.

When the Establishment has air conditioning systems in which they come into contact with water, the water must be potable.

ARTICLE 102. Establishments, in accordance with the provisions of the corresponding Standards, must meet the following requirements:

I. The construction elements exposed to the exterior will be resistant to the environment and harmful fauna;

II. Warehouses must ensure the proper conservation and handling of the Supplies, in order to avoid their contamination, alteration or adulteration;

III. Drinking water tanks shall be lined with harmless impermeable material, with smooth interior surfaces, provided with covers and with appropriate protection systems to prevent contamination or alteration of the water;

IV. Office areas, laboratories, dining room, restrooms, reception, production, distribution or any other area required by the process must be separated;

V. Be provided with sufficient lighting, whether natural or artificial, appropriate to the nature of the work, as well as adequate ventilation for the continuous renewal of air and to avoid excessive heat, condensation of steam and dust, and

VI. Wall, floor and ceiling finishes within manufacturing, operation and storage areas shall meet texture, cleanability and impermeability requirements.

ARTICLE 103. Owners of Establishments must comply with the criteria of good hygiene practices regarding the prevention and control of harmful fauna.

ARTICLE 104. The owners of the Establishments will take care of the conservation, cleanliness, good condition and maintenance of the same, as well as the equipment and utensils, which will be appropriate to the activity carried out or services provided in accordance with the corresponding Standard.

ARTICLE 105. To protect the health and safety of workers involved in the process of the Inputs, as well as in the www.ordenjuridico.gob.mx

activities and services referred to in these Regulations, the clothing used for this purpose must comply with the requirements established in these Regulations and in the corresponding Standards.

ARTICLE 106. When the process of the Inputs requires systems for the control of temperature and relative humidity, these must have instruments or devices to record and control the corresponding parameters.

ARTICLE 107. In Establishments dedicated to the processing of Inputs, there may not be additives, raw materials or substances when their use in the manufacture of the Inputs is not justified.

ARTICLE 108. When the holder of a health license or the one who operates under an operating notice intends to deregister the Establishment, he/she must notify the Secretariat at least thirty days before the date on which it ceases to operate, except in the case of unforeseeable circumstances or force majeure.

When narcotics and psychotropic substances are in stock, they must be made available to the Secretariat along with the corresponding control books referred to in the Law, within the same period, duly updated.

Chapter II

Establishments for the processing of inputs

ARTICLE 109. Establishments intended for the processing of medicines must have the areas, facilities, services, equipment and standard operating procedures established in the corresponding Standards.

Warehouses for packaging medicines, biological products and herbal remedies must comply with the requirements established for packaging areas and operations in the Standards corresponding to good manufacturing practices, in order to avoid risks of cross-contamination between products.

ARTICLE 110. Standard operating procedures shall contain the following information:

I. The objective;

II. The scope;

III. Responsibility;

IV. The development of the process, and

V. Bibliographic references.

ARTICLE 111. The procedures referred to in the previous article shall be signed by the persons who prepare and review them and shall be authorized by the health officer; they must also contain a sequential number that reflects the updates that are made, the date of issue or update and the date of application and comply with what is established by the corresponding Standard.

ARTICLE 112. Establishments that process penicillins, medications that are or contain hormones and antineoplastics and microbial immunosuppressants or immunostimulants, with the exception of microbial lysates, must have production systems in their facilities that guarantee that there is no cross-contamination.

Penicillins, cephalosporins, viral or bacterial biologicals and blood derivatives must have specific and independent areas for each of them, so that there is no cross contamination with other manufacturing areas.

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS ARTICLE, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(REFORMED, DOF OCTOBER 19, 2011)
ARTICLE 113. Establishments that manufacture biopharmaceuticals and biotechnological medicines will require facilities according to the processes they carry out and, where appropriate, have separate areas for animal or plant cell strains or lines; in addition to complying with the applicable legal provisions, including the health license indicated in article 198 of the Law. In the case of foreign manufacture, they must have certification of compliance with good manufacturing practices.

In order for the manufacturer of biopharmaceuticals and biotechnological medicines to release a batch, it will be required to comply with the applicable provisions that correspond to guarantee that the product is of quality.

ARTICLE 114. Drugstores, pharmacies and apothecaries must comply with the following requirements:

I. The areas designated for medicines referred to in Sections I, II, III and IV of Article 226 of the Law must be physically separated from other supplies by counters, display cases or shelves. Those in Sections I, II and III must have areas and systems for their safekeeping and custody;

II. Pharmacies located within self-service stores must be installed in specific areas and with the independence determined by the corresponding Standard, and away from the areas of alcoholic beverages, perishable foods and any substance that puts the integrity, purity and conservation of medicines at risk. Medicines in sections I, II, III and IV of article 226 of the Law must be physically separated from the Supplies classified as freely accessible, by counters, display cases or shelves. Those in sections I, II and III must have areas and systems for their storage and custody, and

III. Others established in the corresponding Standard.

They must also submit every six months a notice of the planned purchase and sale of medicines containing narcotics and comply with the provisions of Article 45 of this Regulation.

ARTICLE 115. Magistral formulas that are not psychotropic or narcotic and whose preparation is carried out in drugstores must be registered in a numbered notebook or in electronic automated systems, noting the following data:

I. The date, indicating day, month and year;

II. The name of the preparation;

III. The name of the prescribing physician;

IV. The professional ID number;

V. The prescription number that the drugstore will assign consecutively;

VI. The formula and pharmaceutical form, and

VII. The indications, if applicable.

ARTICLE 116. Establishments that sell or supply medicines may only fill medical prescriptions that comply with the prescription requirements established in these Regulations.

ARTICLE 117. The staff of a drugstore, apothecary or pharmacy, when filling a special medical prescription that must be retained, will record, as the case may be, in the authorized control book, without prejudice to using automated systems for this purpose, the following data:

I. The folio number of the special medical prescription and the date it was issued;

II. The name of the prescribed medication, quantity, dosage and balance;

III. The name, address and professional license number of the prescribing physician, and

IV. The date of the medication discharge.

ARTICLE 118. Drugstores, pharmacies and apothecaries may sell vaccines, blood derivatives and toxoids provided that they have the necessary area and equipment for their storage.

ARTICLE 119. Owners or those responsible for establishments intended for the processing of inputs must immediately notify the Secretariat of any health irregularity they detect therein, of the potential risk to health that it entails, and collaborate in the necessary security measures.

ARTICLE 120. Establishments shall have a single health license regardless of the number of processes or product lines manufactured therein. A new health license shall be required in the case of new Establishments with different addresses. When they diversify their production lines to include medicines with different health requirements, they must update the health license due to the expansion of a new production line.

Chapter III

Health officials

ARTICLE 121. The health officials of factories or laboratories producing medicines and biological products for human use and of factories or laboratories producing raw materials for the production of medicines or biological products for human use shall have the following obligations:

I. Supervise that the manufacturing process of the Inputs complies with the requirements established in the corresponding Standard;

II. Authorize in writing the standard operating procedures;

III. Establish and supervise the implementation of procedures that allow the release of raw materials, drugs in process and finished products;

IV. Authorize in writing the procedures related to the processing of drugs and medications that are or contain narcotics or psychotropics, and

V. Be present during verification visits carried out by the Secretariat or designate, in writing, who will represent them during such visits, in case of absence.

ARTICLE 122. The health officers of chemical, biological, pharmaceutical or toxicology control laboratories, for the study and experimentation of medicines and raw materials or auxiliaries of health regulation, shall have the following obligations:

I. Monitor compliance with good laboratory practices for quality control of the Inputs and their compliance with the requirements established in the corresponding Standard, and

II. Comply with the provisions of sections II, IV and V of the previous article.

ARTICLE 123. Health officials must ensure compliance with good storage practices for supplies, in accordance with the provisions of the corresponding Standard.

ARTICLE 124. The health officials of drugstores shall have the following obligations:

I. Verify that the medicines have a health registration, batch number and expiration date;

II. Preserve the inputs under the conditions indicated on the label;

III. Check, at least once a day, the operation and temperature of the refrigerator for the proper conservation of medications that require it and keep a daily record in a foliated notebook or automatic control system;

IV. Ensure that the equipment is calibrated and the material is clean;

V. Identify and store the substances used in master formulas;

VI. Prepare the master formulas and verify that they are recorded in the book for the control of prescriptions authorized by the Secretariat;

VII. Verify that the entries and exits of these drugs and psychotropic substances are recorded in the control book, in accordance with the provisions of article 117 of this Regulation, endorsing them with his/her autograph signature;

VIII. Supervise that the preparation process of the Inputs complies with the requirements established in the corresponding Standard;

IX. Authorize in writing the standard operating procedures;

X. Establish and supervise the implementation of procedures that allow the release of raw materials, processed medicines and finished products;

XI. Authorize in writing the procedures related to the processing of drugs and medications that are or contain narcotics or psychotropic substances;

XII. Be present during verification visits carried out by the Secretariat, and

XIII. Analyze the medical prescription and, if deemed necessary, request any clarifications from the person who issued it.

ARTICLE 125. The health officers of pharmacies and drugstores must comply with the provisions of Sections I, II, III, IV, XII and XIII of the previous article. When they sell medicines that are or contain narcotics or psychotropics, they must also observe the provisions of Section VII of Article 124 of this Regulation.

(ADDED, DOF MAY 26, 2011)
ARTICLE 125-bis. The health officials of establishments used as Mixing Centers for the preparation of nutritional and medicinal parenteral mixtures must comply with the provisions of Sections I, II, III, IV, VIII, IX, XII and XIII of Article 124 of this Regulation, as well as with the provisions of the corresponding Standard. When narcotics or psychotropic substances are used in the preparation of nutritional and medicinal parenteral mixtures, they must also comply with the provisions of Section VII of Article 124 of this Regulation.

ARTICLE 126. When health officials cease to provide their services, they or the license holders or the owners of the Establishments must inform the Secretariat, in the form issued for such purpose, within ten days after the date of termination, and within thirty days after that date, the owners or holders will notify the appointment of the new official.

ARTICLE 127. Establishments shall independently determine the hours of the health officials, but in no case shall their responsibility be modified, even in the case of infractions committed outside the usual hours of the official or verification visits carried out when the official is not present.

Health officials and the license holders or owners of Establishments shall be responsible for ensuring that at all times, during the Establishment's operating hours, there are persons available who can inform the health authority about the Establishment's operation, in the event of a verification visit.

ARTICLE 128. In the event of temporary absence of more than thirty calendar days of the health officer, he and the license holder or owner of the Establishment must notify the Secretariat of the name of the person who will represent the former, who must www.ordenjuridico.gob.mx

meet the requirements established by the Law and these Regulations for health officials. The health official will continue to be responsible for the Establishment's compliance with health regulations during his/her absence.

Chapter IV

Establishments for Herbal Remedies

ARTICLE 129. Establishments dedicated to the manufacturing, distribution and marketing of Herbal Remedies shall be subject to sanitary control and surveillance.

ARTICLE 130. In the case of Establishments that sell Herbal Remedies, the person responsible may be the owner of the Establishment, in accordance with the terms set forth in Article 261 of the Law.

(ADDED WITH THE ARTICLES THAT COMPOSE IT, DOF MAY 26, 2011)

Chapter V

Establishments intended for Mixing Centers for the preparation of nutritional and medicinal parenteral mixtures

(ADDED, DOF MAY 26, 2011)
ARTICLE 130-bis 1. A Mixing Center is considered to be an establishment for the preparation of nutritional and medicinal parenteral mixtures authorized by the Secretariat, in accordance with the requirements established in the Law, these Regulations and other applicable legal provisions.

(ADDED, DOF MAY 26, 2011)
ARTICLE 130-bis 2. The preparation of nutritional and medicinal parenteral mixtures shall only be carried out with a medical prescription.

(ADDED, DOF MAY 26, 2011)
ARTICLE 130-bis 3. Mixing Centers must have basic bibliography for consultation so that the responsible professional can establish the stability and compatibility conditions of the mixtures.

The basic bibliography for consultation referred to in the previous paragraph must indicate, among other aspects, the technical information of the product, as well as that determined by the corresponding Standard.

For the purposes of this article, compatibility conditions shall be understood as those that determine the possibility that a substance can be mixed with another and its quality, safety and efficacy characteristics persist.

Likewise, stability conditions are understood to be those that determine the time during which the quality, safety and efficacy characteristics of the mixture persist.

(ADDED, DOF MAY 26, 2011)
ARTICLE 130-bis 4. Mixing Centers that use cytotoxics to prepare parenteral mixtures must have facilities that comply with the specifications established in the corresponding Standard.

FIFTH TITLE

Import and export

Chapter I

Import

(REFORMED FIRST PARAGRAPH, DOF JANUARY 2, 2008)
ARTICLE 131. In order to import medicines for commercial purposes, the product must first be registered with the Ministry. If the importer is not the holder of the registration, the holder's consent must be obtained.

Those persons who have the appropriate facilities for their safe handling and who guarantee quality control and pharmacovigilance, in accordance with the requirements established in the corresponding Standard, may import registered inputs for commercialization.

(REFORMED, DOF JANUARY 2, 2008)

The establishments referred to in this article must have a health license or health notice, as appropriate, in accordance with articles 258 and 373 of the Law.

Only medicines with an expiration date greater than twelve months from the date of entry into the country may be imported, except for medicines that by their nature have reduced stability and are so authorized by the Secretariat.

Importers must notify the Secretariat of the arrival of the medicines within five days after customs clearance.

ARTICLE 132. The Secretariat may grant permission for the importation of raw materials or finished products that do not have a health registration, only in the following cases:

I. When any contingency arises;

II. When required by health policy;

III. For scientific research, record keeping or personal use purposes, or

IV. For laboratory tests.

ARTICLE 133. In the case of raw materials or finished products of foreign origin that are or contain narcotics or psychotropic substances, their entry into the country will only be permitted through authorized customs offices.

ARTICLE 134. To receive raw materials or medicines from customs that are or contain narcotics or psychotropics, the following must be complied with:

A. The importing establishment shall inform the Secretariat in writing, within a period of no more than three days, of its entry into the country, stating:

I. The number and date of the import permit;

II. The name, quantity, batch number and expiration date of the Input;

III. The origin;

IV. The transport company, guide number, and

V. The invoice number;

B. The importer must submit the following documentation to the health authority attached to the corresponding customs office:

I. Carbon copy with autograph signature of the import permit;

II. Original and copy of the invoice certified by the Mexican consul in the country of origin;

III. Copy of the manufacturer's certificate of analysis;

IV. Copy of the air, land or sea waybill, and

V. Customs request.

Once these requirements have been met, the Secretariat will immediately bind the entire Input.

ARTICLE 135. For the taking of samples of narcotics or psychotropic substances and the release of the Input, the Establishment must request, using the corresponding form, the presence of a health inspector who will proceed to remove the strips. The Secretariat will have fourteen days to carry out the verification visit and resolve the request.

ARTICLE 136. In order to remove the bands from the raw material or finished product of narcotics or psychotropic substances, the health inspector must verify the batch number, expiration date, quantity and name of the material released based on satisfactory analytical results and record the number and date of the import permit in the record and in the control book. These actions must be carried out in the presence of the owner or the health officer of the Establishment.

ARTICLE 137. When the authorized customs office has an area designated for the reception of narcotics and psychotropic substances, which meets the characteristics and requirements indicated by the Secretariat and other competent authorities, it will not be necessary to present the report established in article 134, and the sampling and verification of data referred to in articles 135 and 136 will be carried out.

of this Regulation, in the area indicated in this paragraph, with the exception of analytical results.

To authorize the use or marketing of the Supplies referred to in the previous paragraph, the owner or health officer of the Establishment must present the certificate of the corresponding analysis carried out by the laboratory itself or by an Authorized Third Party.

ARTICLE 138. For the importation of biological products and blood derivatives of foreign manufacture, authorization from the Secretariat must be obtained and, where appropriate, a written request must be made for the product to be wrapped.

For the removal of bands, packaging and taking of samples, the Establishment must request the presence of a health inspector from the Secretariat. All these acts must be recorded in the verification report in the presence of the health officer of the Establishment. The distribution or sale of the products referred to in this article may be carried out once the provisions of articles 43 and 201 of this Regulation have been complied with.

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS ARTICLE, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(ADDED, DOF OCTOBER 19, 2011)
ARTICLE 138-bis. For the release of imported biotechnological medicines, it will be necessary to have the analytical certificate from the manufacturer and the importer must have the analytical results in accordance with the requirements set forth in the Pharmacopoeia of the United Mexican States and its supplements, or when the pertinent information does not exist therein, with the requirements set forth in the Pharmacopoeias of other countries. The corresponding analyses may be carried out in its quality control laboratory or by any laboratory that has a Certificate of Good Manufacturing Practices issued by the Secretariat. If the analyses are carried out abroad, the maintenance of the closing and temperature control system must be accredited.

ARTICLE 139. The Secretariat will require that the analytical certificates of the Imported Supplies be endorsed by the health officer, or its equivalent, of the manufacturing laboratory and the health officer of the laboratory requesting the registration.

ARTICLE 140. The importation of Herbal Remedies with a health permit for their commercialization will only be permitted to Establishments that have a notice of operation.

ARTICLE 141. Establishments that import used equipment must have a control book or electronic automated systems and must use one page for each medical equipment to record the following data:

I. The name of the imported device;

II. The brand;

III. The import health authorization number;

IV. The date of entry;

V. Tests of its correct operation;

VI. The name of the purchaser;

VII. The invoice number;

VIII. The date of sale, and

IX. The guarantee of effectiveness.

ARTICLE 142. Imported inputs that are in transit in the country do not require registration in Mexico and may not be marketed within the national territory under any circumstances.

ARTICLE 143. The importer must report, at the request of the Secretariat, the destination given to the products or raw materials being imported.

ARTICLE 144. The Secretariat may, at any time, verify the identity and health condition of imported products and raw materials, and may apply the security measures provided for in the Law and these Regulations.

ARTICLE 145. Products or raw materials that require a prior sanitary import permit and are introduced into the country without this permit shall be considered illegally imported. The Secretariat

will apply the corresponding security measures and sanctions and will inform the competent authorities of this fact.

ARTICLE 146. Without prejudice to the provisions of other regulations, importers must retain prior health authorizations for the importation of the Inputs covered by this Regulation for at least three years and, in the case of radiation sources for medical use, for their entire useful life and must exhibit them to the health authority when requested.

ARTICLE 147. Imports of supplies by foreign diplomatic personnel accredited in the country through their embassies shall be governed by international reciprocity, without prejudice to the powers of the Secretariat to identify the supplies to be imported. In the event that they imply a health risk, due to presenting sanitary anomalies that endanger the health of the population, the Secretariat shall adopt the security measures provided for in the Law and in this Regulation.

ARTICLE 148. The importation of inputs whose use or consumption has been prohibited for health reasons in their country of origin or by recommendation of specialized international organizations will not be authorized.

ARTICLE 149. In the event of a national or international health alert, the Secretariat shall take the necessary measures to prevent the import, distribution or marketing of products, raw materials and other ingredients used in their production and which may cause harm to health. These measures shall be published in the Official Gazette of the Federation.

Chapter II

Export

ARTICLE 150. To obtain the certificate for the export of inputs, an application must be submitted in the official format, to which the original letter of acceptance from the final importer on letterhead must be attached. The Secretariat will have five days to resolve the application.

In the case of allopathic medicines and the raw materials and additives involved in their preparation and which are not nor contain narcotics or psychotropics, the Secretariat will have to resolve the

request ten days. If this is not done within this period, the request will be deemed to be admissible.

ARTICLE 151. Once a permit for the export of narcotics and psychotropic substances has been granted, the interested party shall notify the Secretariat of the date on which the export is intended to take place, so that a health inspector may be appointed to draw up a report stating:

I. That the Input corresponds to the authorized one, corroborating numbers and dates of the export and import permits, name of the product, batch number, expiration date and quantity;

II. The name of the transport company, and

III. That the Input was bundled, sealed and sealed.

The above data must be recorded in the control book authorized by the Secretariat, in the presence of the health officer of the Establishment.

ARTICLE 152. When the importing country rejects, for sanitary reasons, an export of inputs or finished product, the exporter and, where appropriate, the manufacturer shall inform the Secretariat of this fact within a period of no more than five days, providing the following data:

I. Identification;

II. The quantity;

III. The presentation;

IV. The lot and batch number;

V. The expiration date;

VI. The date of export;

VII. The name of the manufacturer or exporter;

VIII. The cause of rejection, and

IX. Certification of analysis and analytical method used.

In the event that the exporter decides to re-enter the country's inputs or finished products, he/she must request an import permit.

The health authority will determine the final destination of the inputs and products referred to in this article at the time the exporter presents the opinion on the tests requested by said authority, which must be carried out by authorized laboratories.

In cases where destruction is required, the corresponding costs will be borne by the exporter.

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS ARTICLE, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(ADDED, DOF OCTOBER 9, 2012)
ARTICLE 152-bis. The procedures for importing and exporting health supplies referred to in this Regulation may be submitted electronically.

Applicants who choose to use electronic means for the procedures referred to in the previous paragraph must submit the same information and documentation required by the corresponding procedure in accordance with this Regulation and other applicable legal provisions. Said information and documentation must be submitted by said electronic means.

Procedures carried out by electronic means will be processed and resolved by the same means, so that notifications made to the applicant regarding requirements, actions, resolutions, exhibition, conservation or presentation of authorizations or documentation that must be submitted to the competent authority and, in general, any administrative act derived from said procedures, will be verified electronically, in accordance with the applicable legal provisions.

TITLE SIX

Authorizations and notices

Chapter I

Common provisions

ARTICLE 153 Health authorizations shall be requested on the official forms provided for this purpose by the competent authority, which shall be accompanied by the documents indicated in this Regulation.

(ADDED, DOF JANUARY 2, 2008, REFORMED, DOF MAY 31, 2021)

Documents accompanying applications must be written in Spanish or English.

(ADDED, DOF JANUARY 2, 2008, REFORMED, DOF MAY 31, 2021)

Documents issued by authorities from other countries must be apostilled or legalized; if they are written in a language other than Spanish or English, they must be accompanied by a corresponding translation by an expert translator who has a professional license to practice said profession.

ARTICLE 154. When these Regulations do not specify an express period for deciding on a request, the Secretariat shall have forty days to do so.

In all cases, the deadlines will be counted from the day after receipt of the duly completed health authorization application.

ARTICLE 155. The time limits shall be suspended when the Secretariat expressly and in writing requests the applicant to provide documents, clarifications or missing information, and shall be resumed on the day after the individual provides said information, documents or makes the relevant clarifications. If they are not provided within the period granted for this purpose, the application shall be deemed not to have been submitted.

ARTICLE 156. The Secretariat may request, in writing, additional or missing information from the individual within a period equal to one third of the period granted to resolve the request, when it is of an administrative nature and two thirds, when it is of a technical nature.

If the periods indicated in the previous paragraph elapse without any request for information, the Secretariat may not deny authorization due to lack of information. In the event that the requests

consider active ingredients or therapeutic indications not known in the United Mexican States, the authority may request additional technical information at any time.

ARTICLE 157. Health authorizations granted under the terms of this Regulation may be reviewed by the Secretariat or the states at any time, in accordance with the provisions of the Law and this Regulation.

When the Secretariat determines from the review that the owner does not comply with any provision established in the Law or in this Regulation, it will notify the interested party so that he may, within a period of no more than fifteen days, counted from the date of notification, state what is convenient to his right. After said period has elapsed, whether or not there is a statement from the interested party, the Secretariat will determine what is appropriate.

ARTICLE 158. In the activities, Establishments, Supplies and services subject to this Regulation, the health control card referred to in Article 377 of the Law will not be required.

ARTICLE 159. To obtain authorization for the control books for narcotics and psychotropic substances, it is necessary to submit an application in the official format, to which legal-sized foliated notebooks with binding that prevents the separation of the pages will be attached, with well-defined separations by product, in order to keep control and balance of raw materials and medications, as the case may be, in accordance with the following:

I. Medicines that can only be purchased with a prescription or special permit;

II. Medicines that require a medical prescription for their acquisition, which must be retained at the pharmacy that supplies it;

III. Medicines that can only be purchased with a prescription that can be filled up to three times, and

IV. Raw materials considered narcotics or psychotropic substances.

The Secretariat will respond within one day.

ARTICLE 160. The maximum validity of import and export authorizations will be one hundred and eighty days, which may be extended for an equal period, provided that the conditions under which they were granted do not change.

ARTICLE 161. Documents from a foreign country that are presented for the purpose of importing or registering the Inputs referred to in this Regulation must meet the following requirements:

I. Copies of invoices for used or rebuilt medical equipment will be certified and clearly state that the equipment is used;

II. Certificates of analysis of products containing blood derivatives will be endorsed by the regulatory entity of the country of origin, and

III. Letters of representation shall be authenticated by the legal procedure existing in the country of origin. These letters must be submitted in Spanish or another language, with their respective translation carried out by an expert translator.

(ADDED, DOF AUGUST 17, 2010)
ARTICLE 161-bis. The Secretariat may issue general provisions aimed at recognizing that the requirements, tests, evaluation procedures and other requirements requested by foreign health authorities to allow the sale, distribution and use of inputs referred to in this Regulation in their respective countries are equivalent to those required by the Law, this Regulation and other applicable provisions to guarantee the quality, safety and efficacy that said inputs must satisfy in order to obtain their health registration in the country.

Chapter II

Licenses

ARTICLE 162. To obtain the health license, the application must be submitted in the official format, which will specify the health requirements for the operation of the type of Establishment for which the license is requested, to which will be attached, exclusively, a copy of the Federal Taxpayers Registry issued by the Ministry of Finance and Credit www.ordenjuridico.gob.mx

Public. The Secretariat will have sixty days to decide on the license application. If it does not do so within this period, the application will be deemed admissible.

When the applicant submits certification of compliance with the operating requirements issued by a Third Party Authorized by the Secretariat, the latter will have a period of ten days to resolve the license application. If this is not done within this period, the application will be deemed admissible.

ARTICLE 163. In order to grant the health license, the health authority may carry out verification visits to verify that the Establishments comply with the requirements set forth in the Law, this Regulation and the corresponding Standards, as well as with what is stated in their application.

ARTICLE 164. The licenses of Establishments that use radiation sources for medical use, as well as those responsible for the operation and functioning of said radiation sources, shall be subject, where applicable, to the provisions of the Regulations of the General Health Law on Sanitary Control of Environmental Health, without prejudice to the powers of other agencies.

Chapter III

Records

ARTICLE 165. The Secretariat, when granting the sanitary registration to the Inputs, will identify them by assigning them an alphanumeric code and the initials SSA, which the holder of the registration will express on the labeling of the products, as established by the corresponding Standard.

(REFORMED, DOF JANUARY 2, 2008)
ARTICLE 166. Applications for sanitary registration of allopathic medicines will be resolved by the Secretariat, in accordance with the following:

I. When it comes to medicines that include active ingredients and with therapeutic indications already registered in the United Mexican States, the resolution must be issued within a maximum period of one hundred and eighty calendar days;

II. When it comes to medicines whose active ingredients are not registered in the United Mexican States, but are found at www.ordenjuridico.gob.mx

registered and freely sold in their country of origin, the resolution must be issued within a maximum period of two hundred and forty calendar days, and

III. In the case of medicines with new molecules, prior to the application for sanitary registration, a technical meeting will be held between the applicant and the Committee on New Molecules of the Federal Commission for the Protection against Sanitary Risks. Once the application for sanitary registration is submitted, the resolution must be issued within a maximum period of 180 calendar days.

The New Molecules Committee will be composed of the Commissioner for Health Authorization, the Executive Director of Product and Establishment Authorization, the Director of the National Pharmacovigilance Center, and representatives of academic associations.

When the last day of the period is a non-working day, it will be understood to be extended until the next working day.

If the applicant presents a favorable technical report issued by an Institution recognized as an Authorized Third Party by the Secretariat, the deadlines will be reduced by half.

ARTICLE 167. To obtain the sanitary registration of an allopathic medicine, the following must be submitted exclusively:

I. Technical and scientific information demonstrating:

a. The identity and purity of its components in accordance with the provisions of the Pharmacopoeia of the United Mexican States and its supplements;

b. The stability of the finished product in accordance with the corresponding Standards;

c. Therapeutic efficacy and safety according to the corresponding scientific information;

II. The information for prescribing, in its broad and reduced versions, and (sic)

III. The label project;

(ADDED, DOF SEPTEMBER 19, 2003)

IV. The provisions of Article 167-bis of this Regulation;

(ADDED, DOF JANUARY 2, 2008)
V. For Generic Medicines, instead of what is indicated in section c of section I, the report of the interchangeability tests in accordance with the corresponding Standards and other applicable provisions, and

(ADDED, DOF JANUARY 2, 2008)
VI. Identification of the origin and certificate of good manufacturing practices of the drug issued by the Secretariat or by the competent authority of the country of origin.

(REFORMED, DOF MARCH 14, 2014)
In the event that the applicant submits the certificate from the competent authority of the country of origin, and it comes from countries with which the Secretariat has not signed recognition agreements on good manufacturing practices, the Secretariat will verify compliance with good manufacturing practices and the production process of the medicine, as well as the certification of its active ingredients, in accordance with the corresponding Standards. If this is the case, the Secretariat will set, within a period of no more than twenty business days, the date on which the Secretariat or its authorized third parties will verify compliance with good manufacturing practices and the production process of the medicine, as well as the certification of its active ingredients in the terms provided for in the Law and other applicable provisions. If this verification is not carried out on the scheduled date for reasons attributable to the Secretariat, it will be rescheduled as a priority.

The certification of good manufacturing practices will be valid for thirty months.

Pursuant to Article 391 bis of the Law, the Secretariat may issue certificates based on information, verification of facts or technical recommendations provided by authorized third parties.

(ADDED, DOF MARCH 14, 2014)
In order to grant the health registration referred to in this article, the Secretariat will verify compliance with good manufacturing practices and the production process of the medicine, as well as the certification of its active ingredients, in accordance with the corresponding Standards.

When the pertinent information does not exist in the Pharmacopoeia of the United Mexican States and its supplements, information from pharmacopoeias of other countries whose analysis procedures are carried out in accordance with specifications and recommendations of specialized organizations or other sources of international scientific information may be used.

(ADDED, DOF SEPTEMBER 19, 2003)
ARTICLE 167-bis. The applicant for registration of an allopathic medicine must attach to the application the documentation proving that he is the owner of the patent for the substance or active ingredient or that he has the corresponding license, both registered with the Mexican Institute of Industrial Property.

Alternatively, and in accordance with the list of products established in article 47 bis of the Regulations of the Industrial Property Law, the applicant may declare, under penalty of perjury, that he or she complies with the applicable provisions on patents with respect to the substance or active ingredient that is the subject of the application. In this case, the Secretariat will immediately request the technical cooperation of the Mexican Institute of Industrial Property so that, within the scope of its competence, it may determine within ten days at the latest

business days after receipt of the request, if current patent rights are invaded. In the event that the Mexican Institute of Industrial Property concludes that there are current patents on the substance or active ingredient of which the applicant is not the owner or licensee, it will inform the Secretariat so that it may advise the applicant.

The applicant must provide proof that he/she is the owner of the patent or that he/she has the corresponding license, within the period determined by the Secretariat, which may not be less than five business days from the date the notification has taken effect. In the event that the applicant does not remedy the omission, the Secretariat will reject the application and inform the applicant of the reasons for this determination so that, where appropriate, he/she may resolve the matter before the competent authority. The lack of response from the Mexican Institute of Industrial Property within the specified period will be understood in favor of the applicant.

Without prejudice to the provisions of the two preceding paragraphs, registration of a generic drug for a drug whose substance or active ingredient is protected by a patent may be requested for the purposes of carrying out the corresponding studies, tests and experimental production, within the three years prior to the expiration of the patent. In this case, the health registration will only be granted at the end of the patent's validity.

The information referred to in Articles 167 and 167 bis of this Regulation that is confidential or reserved in accordance with the provisions of international treaties to which Mexico is a party and other applicable legal provisions shall be protected against any disclosure to other parties.

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS ARTICLE, SEE FIRST TRANSITIONAL ARTICLE OF THE DECREE AMENDING THE LAW.

(RENOVATED, DOF AUGUST 5, 2008)
ARTICLE 168. To be the holder of the sanitary registration of a medicine, it is required to have a sanitary license for a factory or laboratory for medicines or biological products for human use. In the case of foreign manufacturers, it is required to have a license, certificate or document that proves that the company has the permission to

manufacture medicines, issued by the competent authority of the country of origin.

ARTICLE 169. To be the holder of the health registration for vaccines and blood derivatives, in addition to complying with all applicable provisions for allopathic medicines, the corresponding Standards for biological products and blood derivatives must be observed.

(REFORMED FIRST PARAGRAPH, DOF JANUARY 2, 2008)
ARTICLE 170. To obtain the sanitary registration of foreign-manufactured allopathic medicines, in addition to complying with the provisions of article 167, sections I to V, of this Regulation, the following documents must be attached to the application:

(REFORMED, DOF JANUARY 2, 2008)
I. The certificate of free sale or equivalent issued by the corresponding authority of the country of origin;

(ADDED, DOF OCTOBER 9, 2012)
In the case of medicines containing new molecular entities that have not been marketed in any other country due to not having the corresponding health registration and that are intended to be registered in Mexico, the certificate referred to in the previous paragraph may be replaced by the report of clinical studies that have the participation of the Mexican population and that demonstrate the safety, quality and efficacy of the product, as well as the document that describes the activities and interventions designated to characterize and prevent the potential risks previously identified, related to the

medications, including measuring the effectiveness of such interventions.

(REFORMED, DOF JANUARY 2, 2008)
II. Certificate of good manufacturing practices for the drug and the medicine, issued by the Secretariat or by the competent authority of the country of origin.

(REFORMED, DOF MARCH 14, 2014)
In the event that the applicant submits the certificate from the competent authority of the country of origin, and it comes from countries with which the Secretariat has not signed recognition agreements on good manufacturing practices, the Secretariat will verify compliance with good manufacturing practices and the production process of the medicine, as well as the certification of its active ingredients, in accordance with the corresponding Standards. If this is the case, the Secretariat will set, within a period of no more than twenty business days, the date on which the Secretariat or its authorized third parties will verify compliance with good manufacturing practices and the production process of the medicine, as well as the certification of its active ingredients in the terms provided for in the Law and other applicable provisions. If this verification is not carried out on the scheduled date for reasons attributable to the Secretariat, it will be rescheduled as a priority.

Certification of good manufacturing practices will be carried out at the request of the party and will be valid for thirty months.

Pursuant to the provisions of Article 391 bis of the Law, the Secretariat may issue certificates based on the information, verification of facts or technical recommendations provided by authorized third parties, and

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS SECTION, SEE FIRST TRANSITIONAL ARTICLE OF THE DECREE THAT MODIFIES THE LAW.

(RENOVATED, DOF AUGUST 5, 2008)
III. The document that accredits a legal representative with domicile in the United Mexican States.

(ADDED, DOF MARCH 14, 2014)
In order to grant the health registration referred to in this article, the Secretariat will verify compliance with good manufacturing practices and the production process of the medicine, as well as the

certification of its active ingredients, in accordance with the corresponding Standards.

ARTICLE 171. Formulas for specialized enteral feeding require health registration; for this purpose, an application must be submitted in the corresponding format, to which the following documents must be attached:

I. Product description;

II. Qualitative-quantitative formula;

III. Draft label with precautionary legends and handling, conservation and storage conditions;

IV. The instructions for use, if applicable;

V. Stability testing;

VI. The certificate of analysis of raw materials and finished product, their control methods and bibliographic references;

VII. Finished product specifications;

VIII. The free sale certificate issued by the health authority or competent body of the country of origin, if the product is imported, and

IX. The product representation letter, if applicable.

The Secretariat will have sixty days to resolve the request.

If the applicant presents a favorable opinion issued by an Authorized Third Party to the Secretariat, the latter will authorize the registration within fifteen days.

ARTICLE 172. Vitamin medicines will require health registration; for this purpose, an application must be submitted in the corresponding format, to which the following documents must be attached:

I. The monograph of the finished product with qualitative and quantitative control methods of all components;

II. Handling, conservation and storage conditions;

III. Description of Primary and Secondary Packaging and non-toxicity tests;

IV. Label projects with cautionary legends;

V. The instructions for use, if applicable;

VI. Stability tests, in accordance with the Standard;

VII. The certificate of analysis of raw materials and finished products, containing the physicochemical and microbiological specifications, and

VIII. The free sale certificate or equivalent, if the product is imported, issued by the health authority or competent body of the country of origin and a letter of representation from the supplier.

The Secretariat will have forty-five days to resolve the request.

If the applicant presents a favorable opinion issued by an Authorized Third Party to the Secretariat, the latter will authorize the registration within fifteen days.

ARTICLE 173. To obtain registration of homeopathic medicines manufactured in the country, an application must be submitted in the official form, to which the following documentation must be attached:

I. Technical and scientific information demonstrating:

a. The identity and purity of its components in accordance with the provisions of the Homeopathic Pharmacopoeia of the United Mexican States and its supplements or, failing that, the homeopathic pharmacopoeias of other countries or international sources of scientific information, and

b. The stability of the finished product in accordance with the corresponding Standard.

II. Therapeutic indications;

III. Label projects;

IV. The pathogenesis of active ingredients;

V. Instructions for its use, if applicable;

VI. The description of the manufacturing process of the medicine to be registered, and

VII. The text of the extended and reduced version of the prescribing information in the case of medicines referred to in sections I to IV of article 226 of the Law.

The Secretariat will have forty-five days to decide on the request. If it fails to do so within this period, the request will be deemed admissible.

If the applicant presents a favorable opinion issued by an Authorized Third Party to the Secretariat, the latter will authorize the registration within a maximum period of fifteen days.

(ADDED, DOF MARCH 14, 2014)
In order to grant the health registration referred to in this article, the Secretariat will verify compliance with good manufacturing practices and the production process of the medicine, as well as the certification of its active ingredients, in accordance with the corresponding Standards.

ARTICLE 174. To obtain registration of herbal medicines manufactured in the country, it is required to submit an application in the official form, to which the following must be attached:

I. Technical and scientific information demonstrating:

a. The identity and purity of its components in accordance with the provisions of special pharmacopoeias or, failing that, international sources of scientific information;

b. The stability of the finished product, and

c. Taxonomic identification.

II. Therapeutic indications;

III. Label projects;

IV. The instructions for its use, and

V. The description of the manufacturing process of the medicine to be registered.

The Secretariat will have forty-five days to resolve the request.

If the applicant presents a favorable opinion issued by an Authorized Third Party to the Secretariat, the latter will grant the registration within a period of fifteen days.

(ADDED, DOF MARCH 14, 2014)
In order to grant the health registration referred to in this article, the Secretariat will verify compliance with good manufacturing practices and the production process of the medicine, as well as the certification of its active ingredients, in accordance with the corresponding Standards.

ARTICLE 175. To obtain sanitary registration for homeopathic and herbal medicines manufactured abroad, in addition to the requirements indicated in articles 173 and 174 of this Regulation, the following documentation must be submitted:

I. The free sale certificate issued by the competent authority of the country of origin;

II. The certificate of analysis issued by the manufacturer of the medicine, on letterhead and endorsed by the health officials of the foreign and national companies, and

III. The manufacturer's letter of representation, only when the laboratory that manufactures it abroad is not a subsidiary or parent company of the laboratory requesting registration.

The Secretariat will resolve the requests within the time limits indicated in articles 173 and 174 of these Regulations, as the case may be.

(ADDED, DOF MARCH 14, 2014)
In order to grant the health registration referred to in this article, the Secretariat will verify compliance with good manufacturing practices and the production process of the medicine, as well as the certification of its active ingredients, in accordance with the corresponding Standards, through the license, certificate or document issued by the competent authority of the country of origin for such purposes.

ARTICLE 176. Any change from national to foreign manufacturing of a medicine will require a change to the registration conditions and must comply with the specifications in the previous article.

To authorize the change from foreign to national manufacturing of any registered medicine, the application must be submitted in the official format and the provisions of articles 167, 173 and 174 of this Regulation must be complied with, depending on the medicine in question.

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS ARTICLE, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(REFORMED, DOF OCTOBER 19, 2011)
ARTICLE 177. To obtain the sanitary registration of innovative biotechnological medicines, it is necessary to submit an application in the official format, which for this purpose is published in the Official Gazette of the Federation, to which the following documentary information will be attached:

I. The biopharmaceutical monograph, composition and formula;

II. The origin and history of the master cell bank, the gene, the construction of the vector-host expression system for the protein of interest and the relevant characterization of the genotype and phenotype;

III. Summary of the biopharmaceutical manufacturing process: strain or cell line, fermentation, separation and purification, as well as the flow diagram corresponding to said process;

IV. Analytical methods: physical, chemical and biological for raw materials and biopharmaceuticals, as well as the validation report of their results, carried out by the manufacturer, for cases in which they are not pharmacopoeial methods;

V. The report of the validation of the manufacturing process, carried out by the manufacturer;

VI. The drug monograph that includes the International Common Name, pharmaceutical form, qualitative and quantitative specifications;

VII. The manufacturing, formulation, filling and packaging processes, as well as their process controls;

VIII. The draft labels and corresponding instructions, as well as the specifications for primary and secondary packaging, in accordance with the Law, this Regulation and other applicable provisions;

IX. Intensive pharmacovigilance program, in accordance with the applicable provisions, and

X. The preclinical and clinical studies that the Secretariat indicates as necessary to demonstrate the safety, efficacy and quality of the product, in accordance with the provisions of the Law, this Regulation and other applicable legal provisions, including the reporting of adverse events and immunogenicity, characterizing the immune response and the evaluation of the correlation between neutralizing antibodies and the pharmacokinetics and pharmacodynamics of the product.

All innovative biotechnological medicines must be submitted for evaluation by the Committee on New Molecules and must be studied by the Subcommittee for the Evaluation of Biotechnological Products prior to submitting the application for health registration, to determine whether the clinical trials are effective in demonstrating their safety, quality and efficacy.

In the case of innovative biotechnological medicines manufactured abroad, in addition to the above documents, those established in sections I, II and III of article 170 of this Regulation must be attached.

The Secretariat shall resolve applications for registration of innovative biotechnological medicines within a period of one hundred and eighty calendar days, counted from the day following the date on which the corresponding application for registration is submitted. The Secretariat may request missing information, on one occasion only, during the first one hundred and twenty calendar days of the aforementioned period, with the interested party having a maximum of one hundred working days to respond, counted from the day following the date on which he or she has been notified of the respective warning.

If the Secretariat does not issue the respective resolution within the specified period, the registration application will be deemed to have been resolved in a negative sense.

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS ARTICLE, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(ADDED, DOF OCTOBER 19, 2011)

ARTICLE 177-bis 1. Clinical studies of innovative biotechnological medicines must be carried out in Mexico:

I. When the medicine is manufactured in the national territory, and

II. When the manufacturing and the aforementioned studies have been carried out abroad and the Secretariat so determines, based on the opinion of the Committee on New Molecules, following consultation with the Subcommittee for the Evaluation of Biotechnological Products.

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS ARTICLE, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(ADDED, DOF OCTOBER 19, 2011, (REFORMED, DOF MAY 31, 2021)

ARTICLE 177 Bis 2. To obtain the sanitary registration of biocomparable biotechnological medicines, it is necessary to submit an application in the official format, which is published for this purpose in the Official Gazette of the Federation, to which will be attached the documentation contained in sections I to IX of article 177 and the preclinical and clinical studies such as biocomparability studies, immunogenicity studies and adverse event reports, and others that the Secretariat determines, following the opinion of the New Molecules Committee.

Once a biocomparable biotechnological drug has demonstrated its biocomparability, it will be authorized for the indications approved by the reference biotechnological drug, provided that the biocomparable biotechnological drug is presented in the same pharmaceutical form and dose as the reference biotechnological drug and that said indications share the same mechanism of action or that the biocomparable biotechnological drug has the same pharmacodynamic effect, either according to what has been published by the reference drug, or, where appropriate, according to clinical experience and available scientific evidence. The foregoing without prejudice to the provisions of international treaties to which Mexico is a party.

Without prejudice to the provisions of the preceding paragraphs, registration of a biocomparable medicine may be requested in respect of a

biotechnological drug protected by a patent, in order to carry out the corresponding studies, tests and experimental production, within the eight years prior to the expiration of the patent. In this case, the sanitary registration will only be granted at the end of the patent validity.

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS ARTICLE, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(ADDED, DOF OCTOBER 19, 2011)
ARTICLE 177-bis 3. The scope of the clinical tests for biocomparability must be supported by the characterization tests of the biopharmaceutical and the biocomparable biotechnological medicine, and the more characterized the product is and the better its physical-chemical comparability is demonstrated, the less clinical evidence will be required.

The posology, dose and route of administration of the biocomparable biotechnological medicinal product must be the same as those of the reference biotechnological medicinal product.

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS ARTICLE, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(ADDED, DOF OCTOBER 19, 2011)
ARTICLE 177-bis 4. Preclinical and clinical studies, in which the applicant for registration of biocomparable biotechnological medicines to support their application, they must use the corresponding reference biotechnological medicine to carry out the comparative and physical-chemical studies. For this purpose, they must submit the following documentary information:

(REFORMED, DOF MAY 31, 2021)
I. In vitro studies. These will not be required when the Secretariat so determines, based on the opinion of the Committee on New Molecules.

(REFORMED, DOF MAY 31, 2021)
II. Reports of preclinical studies in animals, including information comparing the reference biotechnological drug and the biocomparable biotechnological drug. These preclinical studies must be carried out in animal species relevant to the

study model and must include, in accordance with the opinion issued for this purpose by the Committee on New Molecules, the following data:

a. Comparative report of the pharmacodynamic effect and activity relevant to clinical application;

b. Comparative toxicology report in at least one repeat dose toxicity study, including toxicokinetic measurements;

c. The reported duration of the studies must be technically justified to allow the detection of relevant differences in toxicity and immune responses between the biocomparable biotechnological medicinal product and the reference biotechnological medicinal product;

d. If the results of the above-mentioned studies are not sufficient, relevant observations should be included in the same repeated dose toxicology study, including local tolerability, and

e. Reports of other toxicological studies such as pharmacological safety, reproductive toxicology, mutagenesis and carcinogenesis will only be required for the evaluation of biocomparable biotechnological drugs, if the results of the repeated dose studies so require;

(REFORMED, DOF MAY 31, 2021)
III. A report of comparative pharmacokinetic studies when so determined by the Secretariat, taking into account the opinion of the Committee on New Molecules, to demonstrate pharmacokinetic biocomparability between the biocomparable biotechnological drug and the reference biotechnological drug in relation to key parameters;

IV. Pharmacodynamic study reports with the following characteristics:

a. Pharmacodynamic markers should be selected according to their relevance to demonstrate therapeutic efficacy of the product;

b. The pharmacodynamic effect of the biocomparable biotechnological medicinal product and the reference biotechnological medicinal product should be compared in a population where possible differences can be observed, and

c. The design and duration of the studies must be justified.

Combined pharmacokinetic and pharmacodynamic studies may provide useful information on the relationship between exposure and effect, and

V. Comparative efficacy and safety clinical studies for
demonstrate clinical similarity between the biocomparable biotechnological medicinal product and the reference biotechnological medicinal product. These studies must have the following characteristics:

a. The clinical biocomparability parameters and margins must have been justified and specified prior to the performance of said studies and must be clearly indicated in the report of the comparative efficacy and safety studies submitted for evaluation;

b. Comply with the applicable regulations on good clinical research practices that ensure the scientific validity of the study, and

c. For those drugs where the immune response could affect the endogenous protein or its biological function, antibody testing should be performed in clinical safety trials, taking into account the role that hypersensitivity, infusion reactions, autogenicity and loss of efficacy could have.

(REFORMED, DOF MAY 31, 2021)
For the purposes of the preceding sections, the specific requirements for the approval of each biocomparable biotechnological drug will be determined by the Secretariat considering the opinion of the New Molecules Committee.

In the case of biocomparability studies in relation to a reference biotechnological drug, the same must be used throughout the development of the biocomparable biotechnological drug, to compare the quality and the preclinical and clinical studies.

(REFORMED, DOF MAY 31, 2021)

When there is no pertinent information in the Pharmacopoeia of the United Mexican States and its supplements, nor in national guides or monographs, the Secretariat may evaluate the biocomparability tests using information from international guides.

(REFORMED, DOF MAY 31, 2021)
Clinical studies of biocomparable biotechnological drugs may be carried out in Mexico.

(ADDED, DOF MAY 31, 2021, MOVING THE SUBSEQUENT PARAGRAPHS.)

When the applicant for registration of the biocomparable biotechnological drug bases his/her application on the clinical studies of origin, he/she must present clinical studies carried out in Mexico when requesting the corresponding extension.

In the case of biocomparable biotechnological medicines manufactured abroad, in addition to the above documents, those established in sections I, II and III of article 170 of this Regulation must be attached.

The Secretariat shall resolve applications for registration of biocomparable biotechnological medicines within a period of one hundred and eighty calendar days, counted from the day following the date on which the corresponding application for registration is submitted. The Secretariat may request missing information, on a single occasion, within the first one hundred and twenty calendar days of the aforementioned period, with the interested party having a maximum of one hundred business days, counted from the day following the date on which he/she has been notified of the respective warning, for its resolution.

If the Secretariat does not issue the respective resolution within the specified period, the registration application will be deemed to have been resolved in a negative sense.

N. DE E. IN RELATION TO THE ENTRY INTO FORCE OF THIS ARTICLE, SEE FIRST TRANSITIONAL PROVISION OF THE DECREE MODIFYING THE REGULATIONS.

(ADDED, DOF OCTOBER 19, 2011, REFORMED, DOF MAY 31, 2021)

ARTICLE 177 Bis 5. An innovative biotechnological medicine or a biocomparable biotechnological medicine may be approved for

Its use in other clinical indications, provided that there is scientific justification approved by clinical studies, determined by the Secretariat taking into account the opinion of the Committee on New Molecules.

ARTICLE 178. Each batch of manufactured biomedicine before being released must comply with the provisions of the Pharmacopoeia of the United Mexican States regarding quality, purity, identity and potency. When the corresponding information does not exist, information from pharmacopoeias of other countries whose analysis procedures are carried out in accordance with specifications and recommendations of specialized organizations or other sources of international scientific information may be used.

ARTICLE 179. To obtain the health registration of the Inputs referred to in Chapter IX, Title Two of this Regulation, 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 accordance with the terms of the corresponding Standard;

III. The instructions, if applicable, for its use or operation manual in Spanish;

IV. The description of the manufacturing process carried out to obtain the product;

V. The description of the structure, materials, parts and functions, when it comes to medical equipment;

VI. Consistency of good manufacturing practices;

VII. Laboratory tests to verify the specifications of the Input;

VIII. Bibliographic references, and

IX. Any others established by the Secretariat in the corresponding Regulations.

The Secretariat will resolve applications for registration of Class I Inputs within thirty days. Failure to do so within this period will mean that the application is deemed admissible.

For inputs of classes II and III, the Secretariat will have a period of thirty-five and sixty days, respectively, to resolve the request.

In the event that the applicant presents a favorable opinion issued by an Authorized Third Party to the Secretariat, indicating that the Input meets the conditions of safety and efficacy, the Secretariat will authorize the registration within a period of no more than fifteen days.

ARTICLE 180. For the sanitary registration of the Inputs referred to in Chapter IX, Title Two of this Regulation, which are of foreign manufacture, in addition to complying with the requirements indicated in the previous article, an application must be submitted in the official format, to which the following documentation must be attached:

I. The free sale certificate 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 requesting registration in Mexico;

III. The certificate of good manufacturing practices 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 responsible chemists of the foreign company.

The Secretariat will resolve the requests within the time limits indicated in article 179 of this Regulation.

ARTICLE 181. To be the holder of the health registration for the Inputs referred to in Chapter IX, Title Two of this Regulation, it is required to have a notice of operation of a factory or production laboratory, storage or distribution warehouse or conditioning facility established in the national territory.

ARTICLE 182. The registration of the Supplies referred to in the previous article may be used by other distributors, with prior authorization www.ordenjuridico.gob.mx

from the manufacturer and the Secretariat with the manufacturer's representation letter and the corresponding Label project.

ARTICLE 183. Persons other than the holders of the registration may only manufacture the registered products with the authorization of the holder, provided that they manufacture them under the same conditions under which they were authorized for sale, and the following requirements are met:

I. That the Establishment where the product is produced has a health license or operating notice, in accordance with the provisions of this Regulation;

II. That the holder of the health registration has at all times and without any restrictions, the possibility of supervising the conditions of production of the product and establishing, where appropriate, the improvements or adjustments that he deems necessary so that it is produced under the same conditions in which it was authorized, and

III. That the address of the manufacturing establishment and the name and address of the registration holder are identified on the product label, when the external manufacturing process is carried out continuously for more than three hundred and sixty days.

ARTICLE 184. Any modification intended to be made to the conditions under which the Inputs referred to in Chapter IX of Title Two of this Regulation were registered must be previously authorized by the Secretariat, for which purpose the technical, scientific and legal information, where applicable, justifying said modification shall be submitted. When changes are made to drugs or the pharmaceutical form or formulation, a new registration shall be requested, except when it is a reformulation indicated or agreed upon by the Secretariat.

In the event of a change of distributor, the label or back label projects must also be attached, 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 in the Basic Table or in the Supplies Catalogue must be attached and, in the case of radiation sources, a copy of the corresponding license.

(REFORMED, DOF MAY 31, 2021)
ARTICLE 185. They must request, in accordance with the provisions of the corresponding Standard, authorization for modifications to the conditions of www.ordenjuridico.gob.mx

registration of any medicine, by means of an application in the official format accompanied by the draft Label and, where applicable, the draft texts of the extended and reduced versions of the prescribing information, as well as:

(REFORMED, DOF MAY 31, 2021)
I. Stability tests in accordance with the corresponding Standard.
(REPEALED, DOF MAY 31, 2021)
II. Repealed.
(REPEALED, DOF MAY 31, 2021)
III. Repealed.
(REFORMED, DOF MAY 31, 2021)
IV. The control method and specifications of drugs and additives and finished product, for changes in the manufacturing process, primary packaging or additives and excipients, and

V. The provisions of Article 176 of this Regulation for changes

in domestic to foreign or foreign to domestic manufacturing.

(REFORMED, DOF MAY 31, 2021)
ARTICLE 186. The Secretariat shall resolve requests for modifications to the health registration conditions of any medicine within a period of forty-five business days for technical modifications and twenty business days for administrative modifications.

If the Secretariat does not resolve within the aforementioned period, the application will be deemed admissible.

When more than one type of modification to the health registry is requested, the response period will be equal to the longest of those applicable.

In the case of any request for modification to the registration conditions of homeopathic medicines, if the Secretariat does not resolve within the corresponding deadlines, the request will be deemed admissible.

ARTICLE 187. When it concerns exclusively modifications to the texts of the information to be prescribed, in its extended and reduced versions, the Secretariat will have twenty days to resolve the request. If it does not do so within this period, the request will be deemed admissible.

The applicant shall submit the draft text, as well as the bibliographic information supporting the proposed modification.

ARTICLE 188. The Secretariat shall resolve requests for modifications to the registration conditions of the Inputs referred to in Chapter IX of Title Two of this Regulation within a period of twenty-two days. www.ordenjuridico.gob.mx

If the Secretariat does not resolve within this period, the application will be deemed admissible.

(ADDED, DOF MAY 17, 2012)
If the applicant submits a request for modification to the registration conditions with a favorable opinion issued by a Third Party Authorized by the Secretariat, the Secretariat will resolve it within a period of fifteen days.

(REFORMED, DOF MAY 31, 2021)
ARTICLE 189. The letter authorizing the modification to the conditions of health registration shall include a legend indicating the period that the Secretariat grants to the holder of the health registration to exhaust the existence of packaging materials and finished product.

The period set by the Secretariat may not exceed two hundred and forty business days.

(REFORMED, DOF MAY 31, 2021)
ARTICLE 190. The transfer of rights to a health registration of the Supplies covered by this Regulation must be communicated in writing to the Secretariat by the new holder, within a period of no more than thirty working days from the date on which it was made. The documents in which the transfer is recorded and the Label projects in duplicate in which the new holder is stated must be attached to this communication.

(ADDED, DOF JANUARY 2, 2008, REFORMED, DOF MAY 31, 2021)

ARTICLE 190 Bis 1. To obtain the first extension of the sanitary registration of medicines, the following must be submitted with the application:

I. Proof of payment of fees, in terms of the Federal Fees Law;

II. Number or simple copy of the health registration for which the extension is requested;

(REFORMED, DOF MAY 31, 2021)
III. In cases of major modifications that impact the pharmacokinetics of the drug, the technical report issued by the Interchangeability Units must be submitted.

(REPEALED, DOF MAY 31, 2021)
IV. Repealed.

V. Pharmacovigilance report of the medicine, in accordance with the applicable regulations, and

(REPEALED, DOF MAY 31, 2021)
VI. Repealed.

(REPEALED, DOF MAY 31, 2021)
Second paragraph Repealed.

(REPEALED, DOF MAY 31, 2021)
Third paragraph Repealed.

In order to grant the extension of the health registration referred to in this article, the Secretariat will verify compliance with good manufacturing practices of the medicine declared in the registration letter, in accordance with the corresponding Standards.

(ADDED, DOF MAY 31, 2021)
Applications for extension of the Sanitary Registration will not be an additional procedure to review the authorized conditions. The Secretariat will only consider the modifications to the Sanitary Registration to evaluate that the changes made by the manufacturer do not impact the quality, efficacy and safety of the medicine.

(ADDED, DOF JANUARY 2, 2008, (REFORMED, DOF MAY 31, 2021)

ARTICLE 190 Bis 2. To obtain the first extension of the sanitary registration of foreign-manufactured medicines, in addition to what is indicated in article 190 Bis 1, sections I, II, and V of this Regulation, the following must be attached to the respective application:

YO. The document that accredits a legal representative with domicile in the United Mexican States;

In the case of allopathic medicines, a certificate of good manufacturing practices for the medicine, issued by a national regulatory agency recognized by the Secretariat, and

III. In the case of herbal, homeopathic and vitamin medicines, where applicable, a certificate of good manufacturing practices for the medicine, issued by the Secretariat or by the competent authority of the country of origin.

In the event that the applicant presents the certificate of good manufacturing practices of the medicine issued by a national regulatory agency that is not recognized by the Secretariat, the latter will verify compliance with the good manufacturing practices of the medicine, in accordance with the corresponding Standards.

(ADDED, DOF JANUARY 2, 2007, REFORMED, DOF MAY 31, 2021)

ARTICLE 190 Bis 3. To obtain the first extension of the health registration of medical equipment, prostheses, orthoses, functional aids, diagnostic agents, dental supplies, surgical and healing materials, hygienic products, and other medical devices, which are manufactured in the country, the following must be submitted in the following order and with the application exclusively:

I. Proof of payment of fees, in terms of the Federal Fees Law;

II. Number or simple copy of the health registration for which the extension is requested and its modifications;

(REPEALED, DOF MAY 31, 2021)
III. Repealed.

IV. Technovigilance report by product, in terms of applicable regulations;

(REPEALED, DOF MAY 31, 2021)
V. Repealed.

(REPEALED, DOF MAY 31, 2021)
VI. Repealed.

(REPEALED, DOF MAY 31, 2021)
Last paragraph repealed.

(ADDED, DOF JANUARY 2, 2008, REFORMED, DOF MAY 31, 2021)

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

I. The document that accredits a legal representative with domicile in the United Mexican States, and

(REFORMED, DOF MAY 31, 2021)
II. Certificate of good manufacturing practices for the product, issued by a national regulatory agency recognized by the Secretariat, and

For Class I, II and Class III products, the current ISO 13485 certificate or the CE mark certificate issued by an authorized certification body will be accepted as equivalent to the Good Manufacturing Practices certificate.

(REPEALED, DOF MAY 31, 2021)
Third paragraph repealed.

(REPEALED, DOF MAY 31, 2021)
Fourth paragraph repealed.

(ADDED, DOF MAY 31, 2021)
Applications for extension of Sanitary Registration will not be an additional procedure to review the authorized conditions. The Secretariat will only consider the modifications to the Sanitary Registration to evaluate that the changes made by the manufacturer do not impact the quality, efficacy and safety of the input.

(ADDED, DOF JANUARY 2, 2008)
ARTICLE 190-bis 5. Upon notification of the resolution corresponding to the request for extension, the holder of the registration must deliver to the notifier the original of the health authorization and, where applicable, any modifications to it.

If you do not have the original registration, you must present a copy of the report filed with the Public Prosecutor's Office regarding the loss or theft.

(REFORMED, DOF MAY 31, 2021)
ARTICLE 190 Bis 6. Applications for extensions provided for in Articles 190 Bis 1, 190 Bis 2, 190 Bis 3 and 190 Bis 4 must be submitted one hundred and fifty calendar days before the date on which the validity of the corresponding registration expires.

The Secretariat will resolve requests for extension 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 a non-working day, it will be understood to be extended until the next working day. In the event that the

If the Secretariat does not issue the respective resolution within the time limits specified in this article, the request will be deemed admissible.

(ADDED, DOF MAY 31, 2021)
ARTICLE 190 Bis 7. The holders of the Health Registries provided for in articles 190 Bis 1, 190 Bis 2, 190 Bis 3 and 190 Bis 4 of this Regulation, in order to obtain their second and subsequent extension, must submit to the Secretariat, every five years and no later than one hundred and fifty calendar days before the date on which the validity ends, the corresponding application, using the forms that said Secretariat issues for such purpose.

The certificate issued by the Secretariat, as an acknowledgement of receipt of the submitted application, will have the effects of extending the Health Registry, which must retain the same alphanumeric code assigned in accordance with the provisions of article 165 of this Regulation.

If applications are not submitted within the period established for this purpose, the Health Registration will lose its validity and a new registration must be requested in accordance with the provisions of this Regulation.

ARTICLE 191. The review of the sanitary registration of the Inputs is appropriate when:

I. Technical or scientific research or clinical experience indicates that the drug has adverse reactions or toxic effects, immediate or delayed, in relation to the expected benefits;

II. When technical or scientific advances in the matter, duly documented, determine a negative benefit-risk ratio;

III. When there is documented evidence of therapeutic inefficiency of the medication, and

IV. When international organizations so recommend.

ARTICLE 192. Before proceeding to the revocation of the health registration referred to in articles 380 and 381 of the Law, the Secretariat may review, evaluate and request the reformulation of the medication in question.

Chapter IV

Permissions

ARTICLE 193. The Secretariat shall grant permission for the importation of registered medicines or their raw materials, which require it, upon submission of the application in the official form.

ARTICLE 194. In matters of import, the Secretariat may issue the following health permits:

I. Definitive import, authorizing the entry into the country of inputs of foreign origin, to remain in the national territory for an unlimited time;

II. Temporary import, which authorizes the entry of inputs into the country to remain there for a limited time and for a specific purpose, provided that they return abroad within a period of no more than one year;

III. Importation in transit, which authorizes the entry of inputs into the country, for their transfer from one national customs office to another, for their exit abroad, within a period of no more than thirty days, and

IV. Temporary sale or distribution, which authorizes the sale or distribution exclusively of medicines for strategic purposes.

ARTICLE 195. To obtain an import permit for raw materials or medicines that are or contain narcotics or psychotropic substances, the importer must submit an application in the official form.

The Secretariat will decide on the permit within a maximum period of fourteen days.

The validity of the permits will be one hundred and eighty days, which may be extended for ninety days.

ARTICLE 196. To obtain an import permit for medicines that are not registered with the Secretariat, intended for research, laboratory tests, manufacturing, for special treatments for low-incidence diseases with social repercussions or for personal use or are donated, the importer

You must submit an application in the official format, to which you must attach, as appropriate, the following documentation:

I. For research and laboratory tests: copy of the approval letter of the protocol authorized by the Secretariat;

II. For maquila: copy of the corresponding authorization issued by the Secretariat of Commerce and Industrial Development;

III. For special treatments: copy of the professional license and identification of the treating physician;

IV. For personal use: medical prescription, including professional ID number. In the case of narcotics, special prescription with the bar code, and

V. For donations: the donation letter and letter of acceptance of the donation and commitment not to market it.

The Secretariat will have ten days to decide on the request. If it fails to do so within this period, the request will be deemed admissible, with the exception of narcotics or psychotropic substances.

ARTICLE 197. To obtain a permit for the local acquisition of raw materials or medicines that are or contain narcotics or psychotropic substances, intended for the production of medicines, for medical purposes or for scientific research, an application must be submitted in the official form. The Secretariat will decide on the permit within a maximum period of fourteen days. The permit will be valid for one hundred and eighty days.

ARTICLE 198. For the importation of Herbal Remedies, the application must be submitted in the corresponding format and indicate the alphanumeric code referred to in article 94 of this Regulation.

ARTICLE 199. For the importation of the Inputs referred to in Chapter IX, Title Two of this Regulation, except those included in the following article, a copy of the health registration of the product to be imported must be attached to the customs request.

Importers of such inputs must notify the Secretariat in the official form of their arrival, within five days after customs clearance, attaching a copy of the import request and the registry of imported products that was attached.

ARTICLE 200. For the issuance of a prior import permit for heart valves, internal orthoses, pacemakers, prostheses, diagnostic reagents with radioactive isotopes, used supplies, as well as the supplies referred to in Chapter IX, Title Two of this Regulation without registration or in the experimental phase for manufacturing, personal use, for doctors, for research or donations, the importer shall submit an application in the official format, to which he shall attach, as applicable, the following documents:

I. For maquila: copy of the corresponding authorization issued by the Secretariat of Commerce and Industrial Development;

II. For personal use: copy of the medical prescription;

III. For doctors: copy of the professional license;

IV. For research: copy of the approval letter of the authorized protocol, and

V. For donations: donation letter and donation acceptance letter.

The Secretariat will have ten days to decide on the request. If it fails to do so within this period, the request will be deemed admissible.

ARTICLE 201. For the importation of Supplies containing blood derivatives, a certificate of analysis endorsed by the regulatory entity of the country of origin must be presented. This certificate must expressly state that the donors of the blood from which the components used to manufacture the batch were obtained tested negative in the tests to detect antibodies against the Human Immunodeficiency Virus and Hepatitis C, as well as to detect Hepatitis B antigens and others established in the corresponding Standards.

ARTICLE 202. In matters of export, the Secretariat may issue the following health permits:

I. Definitive export, which authorizes the exit of inputs from the country for an unlimited time, and

II. Temporary export, which authorizes the exit from the country of inputs for a specific purpose, provided that they return to the national territory within a period of no more than one year.

ARTICLE 203. To obtain an export permit for raw materials or medicines that are or contain narcotics or psychotropic substances, an application must be submitted in the official form, to which a copy of the import permit issued by the health authority of the recipient country must be attached. The Secretariat will have fourteen days to decide on the application.

ARTICLE 204. To obtain permission to change from national to foreign manufacturing of the Inputs included in Chapter IX, Title Two of this Regulation, an application must be submitted in the official form, to which a certificate issued by the health authority of the corresponding country must be attached. Said application must include the mention that the company is licensed, complies with good manufacturing practices and has a letter of representation from the manufacturer.

If the product is manufactured by the parent company or subsidiary of the factory or laboratory holding the registration requesting authorization in Mexico, a letter of representation will not be required.

ARTICLE 205. To obtain the change from foreign to national manufacturing, an application must be submitted in the official form, to which the following must be attached:

I. The analytical certificate of the finished product, control method and its bibliographic references, and

II. Label projects that comply with the provisions of the corresponding Standard for these products, in Spanish.

Chapter V

Notices

ARTICLE 206. Advertising directed at health professionals of the Supplies referred to in this Regulation must be carried out by means of a notice submitted to the Secretariat, fifteen days before its dissemination or distribution, in the official format to which the advertising project will be attached.

ARTICLE 207. The notice referred to in the previous article must be made under oath to tell the truth that the advertising project meets the requirements established in the Law, the corresponding regulations, the corresponding Standards and the Code of Ethics on the matter.

Chapter VI

Health certificates

ARTICLE 208. For the issuance of certificates in support of exports, it will be sufficient to present an opinion issued by a Third Party Authorized for this purpose by the Secretariat, which establishes the conformity of the processes, products, methods, facilities, services or activities with the specifications established in the health regulations.

In the event that the individual presents an opinion issued by an Authorized Third Party, the deadline for issuing the official certificate will be three days. Otherwise, the deadline for issuing said certificate will be fifteen days, including the verification visit.

ARTICLE 209. To grant the certificate of free sale of the Inputs, it is required to submit an application in the official format to which will be attached, if applicable, a copy of the last production order and the unit formula endorsed by the health officer of the establishment. The Secretariat will have a period of five days to issue the certificate, unless it is requested in a format with special characteristics, in which case an additional five days will be available.

TITLE SEVEN

Authorized Third Parties

Unique Chapter

ARTICLE 210. The Secretariat shall periodically publish calls for the authorization of third parties referred to in Article 391 bis of the Law, which may be natural persons or legal entities.

The Secretariat will also form technical committees made up of experts in specific fields, representatives of chambers and associations and, where appropriate, of the accreditation entity, whose purpose will be to technically examine requests for the granting of authorizations from third parties.

ARTICLE 211. To operate as an Authorized Third Party, it will be necessary to comply with the following:

I. Submit an application stating the legal capacity of the applicant;

II. Demonstrate that the applicant has the technical, material, human and financial capacity, as well as the facilities, equipment and technology to carry out the tests, studies, verifications and other activities necessary to issue the opinions;

III. Have standardized operating procedures that guarantee quality in the performance of their functions;

IV. Not be subject to direct influence by any manufacturer, trader or commercial legal entity of the processes and products to be evaluated, and

V. Present your proposals for activities to be reviewed, as well as describe the services you intend to provide and the procedures to be used.

ARTICLE 212. Once the application for authorization of third parties has been submitted, the Secretariat will proceed to carry out verification visits and, together with the evaluation committee referred to in article 210 of this Regulation, will carry out the evaluations that are necessary to determine whether the requirements referred to in the previous article are met.

If the opinion issued by the Secretariat is not favorable, the applicant will be granted a period of up to one hundred and eighty calendar days to correct the anomalies detected. This period may be extended for an equal period, for one single occasion, when the applicant justifies the need for it.

If the applicant does not correct the anomalies detected within the period granted, the procedure will be considered abandoned and the application will be deemed not to have been submitted.

ARTICLE 213. Authorized Third Parties must:

I. Comply with the regulations applicable to the acts or events in which they participate;

II. Provide their services under non-discriminatory conditions and observe other provisions on economic competition;

III. Avoid the existence of conflicts of interest that may affect their actions and excuse themselves when they exist;

IV. Immediately inform the Secretariat of any irregularities in its relationship with clients, the performance of its functions or non-compliance identified in the processes it evaluates;

V. Provide the Secretariat with reports on the technical opinions and recommendations it issues;

VI. Periodically inform the Secretariat about the services it provides;

VII. Assist the Secretariat in cases of emergency, and

VIII. Allow verification of its activities and provide the Secretariat with free access to its facilities, as well as provide any information requested.

ARTICLE 214. The results of the tests carried out by Authorized Third Parties shall be recorded in a report that shall be signed, under their responsibility, by the person authorized to do so. These reports shall be valid before the Secretariat in accordance with the functions that have been authorized to the third party.

ARTICLE 215. The Secretariat may, at any time, carry out verification visits to verify that the conditions under which the corresponding authorization was granted are met by the Authorized Third Parties.

ARTICLE 216. In the event that the conditions referred to in the previous article do not exist, or the applicable legal provisions are not complied with, the Secretariat shall advise the interested party to correct the anomalies found and shall grant him a period of up to one hundred and eighty days to correct them. When this implies a risk to health, it may temporarily suspend the affected activities.

Failure to comply with the corrections indicated by the Secretariat will result in suspension of the authorization granted, and the Secretariat will grant a new period of ninety days to correct the irregularities. If the Secretariat's instructions are not complied with within this last period, the authorization will be revoked.

ARTICLE 217. The Secretariat will periodically publish in the Official Gazette of the Federation the list of Authorized Third Parties, as well as suspensions and revocations.

TITLE EIGHT

Verification, security measures and sanctions

Chapter I

Verification

ARTICLE 218. Verification visits shall be carried out in accordance with the procedure established by law and shall have the following objectives:

I. Obtain information on health conditions:

a. Of the Establishment;

b. Of the equipment, machinery, utensils and instruments with which the process is carried out;

c. Of the products, raw materials, additives and packaging and container materials used in their production;

d. Health surveillance programs for occupationally exposed personnel;

e. Of the operation of the process;

f. Of the forms of disposal of waste and debris, and

g. Transportation of supplies, when required.

II. Identify health deficiencies and anomalies;

III. Take samples, if necessary;

IV. Apply or release security measures;

V. Carry out health-related guidance, instruction and education activities, and

VI. Any others indicated by the Secretariat, in accordance with the provisions of the Law.

ARTICLE 219. It is the responsibility of the health authority to verify that the Establishments are conditioned for the use for which they are intended or intended, in accordance with the characteristics of the process of the products, taking into account what is established in this Regulation and the corresponding Standards.

ARTICLE 220. The assignment of the Establishment or the place to carry out the verification visit will be determined by any of the following mechanisms:

I. By random selection;

II. Due to contingency or health alert;

III. By programs determined by the health authority, in which case it will be expressly indicated in the corresponding visit order;

IV. By complaint from third parties, in accordance with the terms of Article 5 of this Regulation;

V. At the request of the owner, and

VI. As a follow-up to an administrative procedure initiated by the health authority.

ARTICLE 221. The verification visit order, among other requirements, must include the telephone number of the health authority that issues it so that the owner, manager or person responsible for the Establishment or the place can make inquiries, complaints or reports and, where appropriate, confirm the origin of the verification act.

ARTICLE 222. The verification report must record the circumstances of the diligence referred to in article 401 of the Law and must contain at least the following:

I. The legal accreditation of the verifier to perform the function;

II. The description of the sanitary conditions of the Establishment or the place, equipment, personnel, raw materials, process, procedures and supplies;

III. Completion of the report, based on a specific verification guide for each industrial, commercial or service sector;

IV. The record of any observed health anomalies or deficiencies;

V. Sampling, where appropriate, and

VI. The manifestation of what is the right of the owner, person in charge, manager or occupant of the Establishment or place.

ARTICLE 223. When anomalies are detected during verification visits to Establishments, the Secretariat will grant a period of up to one hundred and eighty calendar days to correct them, provided that they do not imply a risk or damage to health and do not affect the safety and quality of the Supplies.

After the period referred to in the previous paragraph has elapsed, a visit will be made to verify compliance with the corrective actions; in the event that these have not been complied with, the Secretariat will grant a non-extendable period of ninety calendar days to correct them.

After the periods referred to in the preceding paragraphs have elapsed, a visit will be made to verify compliance with the corrective actions; in the event that these have not been complied with, the Secretariat will apply the security measures established in the Law.

Chapter II

Safety measures

ARTICLE 224. If the sanitary conditions of the Establishment, raw materials, process or procedure represent a risk www.ordenjuridico.gob.mx

important for health, the verifiers must take immediate security measures, with the approval or consent of the health authority on which they depend. In this case, it may be granted by telephone and identified by a code.

The security measure imposed must be ratified, modified or revoked within a period not exceeding five days from the appearance of the interested party.

ARTICLE 225. The competent health authorities may order the application of the security measures referred to in article 404 of the Law, when the identity, purity, conservation, concentration or manufacture of the Inputs is affected in the areas, facilities, equipment or manufacturing process; as well as due to non-compliance with good manufacturing practices and, in general, when the provisions of the Law and this Regulation are violated, which imply a serious risk to health.

Chapter III

Sanctions

ARTICLE 226. The health authority shall sanction anyone who violates the provisions of this Regulation, without prejudice to the penalties that may apply when they constitute a crime.

ARTICLE 227. Violation of the provisions contained in articles 107, 184 and 190 of this Regulation shall be punishable by a fine of up to five hundred days of the general minimum wage in force in the economic zone in question.

ARTICLE 228. Violation of the provisions contained in Articles 10, 16, 101, 102, 103, 104, 105, 106, 121, 122, 123, 124, 125, 127, 181 and 206 of this Regulation shall be punished with a fine of between five hundred and one thousand days of the general minimum wage in force in the economic zone in question.

ARTICLE 229. Violation of the provisions contained in Articles 13, 15, 62, 68, 86, 88, 89, 90, 93, 111, 112, 114, 117, 135, 141 and 172 of this Regulation shall be punished with a fine of between one thousand and three thousand days of the general minimum wage in force in the economic zone in question.

ARTICLE 230. The following shall be punished with a fine of three thousand to six thousand days of the general minimum wage in force in the economic zone in question: www.ordenjuridico.gob.mx

violation of the provisions contained in Articles 17, 30, 32, 33, 36, 53, 79, 116, 118, 126, 148, 152, 168, 169 and 174 of this Regulation.

ARTICLE 231. Violation of the provisions contained in Articles 19, 20, 21, 22, 24, 31 last paragraph, 35, 40, 44, 45, 46, 50, 57, 59, 77, 78, 134 and 165 of this Regulation shall be punished with a fine of six thousand to ten thousand days of the general minimum wage in force in the economic zone in question.

ARTICLE 232. Violations not provided for in this Chapter shall be punished with a fine of up to ten thousand days of the general minimum wage in force in the economic zone in question.

TRANSIENTS

FIRST. This Regulation shall enter into force fifteen days after its publication in the Official Journal of the Federation, except for the provisions indicated below, which shall enter into force within the periods indicated, counted from the entry into force of this instrument:

I. After eighteen months, articles 31, section I and 116, and

II. After twenty-four months, Chapters I, II and IV of Title Four shall apply only to persons who import and export vitamin, homeopathic and herbal medicines, as well as herbal remedies. In the meantime, said persons must have a distribution warehouse with a notice of operation.

SECOND. Articles 2, Sections III, paragraph r) and V; 46; 149 Sections I, paragraphs c) and d) and III; 151; 156; 157; 158; 167, Sections IV, V, VI and X; 181, 182 and 183, and Title Twenty-one, relating to Medical Supplies, Narcotics and Psychotropic Substances, of the Regulations of the General Health Law on Sanitary Control of Activities, Establishments, Products and Services, published in the Official Gazette of the Federation on January 18, 1988, are hereby repealed.

THIRD. The administrative provisions in force shall continue to apply until such time as other provisions are issued to replace them, except where they conflict with this Regulation.

FOURTH. In the administrative acts and procedures that are related to the subject matter of this Regulation, which have been initiated or www.ordenjuridico.gob.mx

initiated before this Regulation enters into force, the interested party may choose to continue it in accordance with the procedure in force at the time of its initiation or by the application of this Regulation.

FIFTH. The publication in the Official Journal of the Federation, through which the General Health Council and the Secretariat will determine the tests that must be applied to consider medicines as interchangeable, will be carried out, after hearing the opinion of the industry, within forty-five days of the entry into force of this Regulation.

This publication shall establish the period within which the Secretariat will have to notify the General Health Council and the interested party of its opinion regarding the application referred to in Article 77 of this Regulation.

SIXTH. The forms referred to in these Regulations must be published in the Official Journal of the Federation within six months of this instrument coming into force.

Given at the Residence of the Federal Executive Power, in the City of
Mexico City, Federal District, on the third day of the month of February, nineteen hundred and ninety-eight.- Ernesto Zedillo Ponce de León.- Signature.-
The Secretary of Health, Juan Ramón de la Fuente.- Signature.

N. DE. E. THE TRANSITIONAL ARTICLES OF THE REFORM DECREES TO THIS REGULATION ARE TRANSCRIBED BELOW.

DOF SEPTEMBER 19, 2003.

First. This Decree shall enter into force on the day following its publication in the Official Gazette of the Federation.

Second. The Mexican Institute of Industrial Property shall issue, within sixty calendar days, the provisions relating to the integration, operation and updating of the list referred to in Article 47-bis of the Regulations of the Industrial Property Law that is added pursuant to this Decree, as well as the applicable consultation forms. For this purpose, the Institute shall take into consideration the opinion of the National Chamber of the Pharmaceutical Industry.

DOF JANUARY 2, 2008.

FIRST. This Decree shall enter into force thirty days after its publication in the Official Gazette of the Federation.

SECOND. Applications for health registration that are in process when this Decree comes into force will be processed until their conclusion in accordance with the provisions in force at the time of their submission.

THIRD. To request for the first time the extension of health registrations for medicines and other health supplies, which have been granted for an indefinite period, the provisions of this Regulation and the following must be complied with:

I. The application must be submitted no later than February 24, 2010.

II. In applications for extensions submitted during 2007 and 2008, authorization for modifications to the conditions of the respective health registration may be required in the same procedure. To this end, applicants must comply with the corresponding technical and administrative requirements and it will be sufficient to attach proof of payment of fees for the application for extension of the corresponding health registration.

III. For the extension of the sanitary registration of generic medicines, in all cases the report of the interchangeability tests must be accompanied: a copy of the tests carried out to obtain the GI registration, or the new tests in case of changes that may modify the pharmacokinetics of the medicine, whether in the production equipment, in the quality of the components, in the acceptance criteria or in the production process.

IV. For the extension of the sanitary registration of medical equipment, prostheses, orthoses, functional aids, diagnostic agents, dental supplies, surgical material, healing material, hygienic products and other devices for medical use, the certificate of analysis issued by the company that produces the product must be accompanied, with the letterhead of its corporate name and signed by the responsible chemists, even when there are no changes or any modification of the process in the

plant, in the production process, in the quality of the components or in the acceptance criteria.

V. Until the Secretariat issues a resolution on the application for registration extension, the authorization will remain in force.

VI. Until the corresponding Mexican Official Standards are published in the Official Gazette of the Federation, the Secretariat will use international standards or guidelines as a reference.

FOURTH. The Secretariat shall publish in the Official Gazette of the Federation the procedure for carrying out the sanitary verification visits provided for in this Regulation, within thirty business days following the publication of this Decree.

FIFTH. The Secretariat shall publish in the Official Gazette of the Federation the forms for applications for extension of health registrations for health supplies, within thirty business days following the publication of this Decree.

SIXTH. The corresponding labels may contain the legend or symbol as Interchangeable Generic Drug until February 24, 2010.

SEVENTH. Until February 24, 2010, the General Health Council will continue to prepare and publish periodically in the Official Journal of the Federation a catalogue containing the list of Generic Medicines, which it will keep up to date.

For this purpose, the individual will request the General Health Council to include it in the catalogue by presenting only a copy of the registration that accredits his product as Generic.

The inclusion of a Generic Drug in said catalogue is for informational purposes only and does not constitute a requirement for its marketing.

EIGHTH. The New Molecules Committee of the Federal Commission for Protection against Sanitary Risks shall be established no later than thirty days after the publication of this Decree, and shall approve and publish its Internal Regulations in the Official Journal of the Federation no later than ninety days after having been established.

FIRST.- This Decree shall enter into force as follows:

(a) The day following its publication in respect of its observance in respect of antiretroviral medicinal products;

b) Within six months of its publication, in the case of vitamins, vaccines, serums, blood derivatives, antitoxins, hormones of biological origin, homeopathic medicines and herbal medicines;

c) Within twelve months of its publication, for biotechnological and biological medicines not specified in the previous paragraph;

d) Within eighteen months after its publication, for medicines containing narcotic or psychotropic drugs and freely accessible medicines in accordance with the provisions of sections I, II, III, V and VI of article 226 of the General Health Law, and

e) Within twenty-four months after its publication, for other medicines under the terms of section IV of article 226 of the General Health Law.

SECOND.- Applications for health registration that are in process when this Decree comes into force will be handled in accordance with the provisions in force at the time of their submission.

THIRD.- Any expenditures required to comply with the provisions of this Decree shall be charged to the budgetary availability of the Ministry of Health.

DOF AUGUST 17, 2010.

SOLE.- This Decree shall enter into force on the day following its publication in the Official Gazette of the Federation.

DOF JANUARY 13, 2011.

FIRST. This Decree shall enter into force on the day following its publication in the Official Gazette of the Federation.

SECOND. The simplified authorization procedure referred to in the third paragraph of article 43 of the Regulation will be applicable once the guidelines referred to in said paragraph are issued.

THIRD. Matters in process at the time of entry into force of this Decree shall be dealt with until their conclusion, in accordance with the provisions in force at the time of its commencement.

DOF MAY 26, 2011.

SOLE. This Decree shall enter into force on the day following its publication in the Official Gazette of the Federation.

DOF OCTOBER 19, 2011.

First.- This Decree enters into force one hundred and eighty calendar days after its publication in the Official Gazette of the Federation.

Second.- The Ministry of Health, in accordance with the provisions of the Federal Law on Metrology and Standardization, must adapt and update the Mexican Official Standards corresponding to the provisions of this Decree.

Third.- Those registration application procedures whose resolution is pending at the time of the entry into force of this Decree will be resolved in accordance with the regulations in force at the time of their submission.

DOF MAY 17, 2012.

Sole.- This Decree shall enter into force on the day following its publication in the Official Gazette of the Federation.

DOF OCTOBER 9, 2012.

FIRST.- This Decree will enter into force thirty business days after the date of its publication in the Official Gazette of the Federation, except for the addition of the second paragraph to section I of www.ordenjuridico.gob.mx

Article 170 of the Health Supplies Regulation, which will enter into force on the day following the publication of this Decree.

SECOND.- The provisions of this Decree shall not apply to procedures that have been submitted prior to its entry into force.

DOF MARCH 14, 2014.

Sole.- This Decree shall enter into force on the day following its publication in the Official Gazette of the Federation.

DOF MAY 31, 2021

(Editor's note. TRANSITIONAL ARTICLES OF THE “DECREE BY WHICH VARIOUS PROVISIONS OF THE REGULATIONS FOR HEALTH SUPPLIES ARE REFORMED, ADDED AND REPEALED”.)

FIRST.- This Decree will enter into force on the day following its publication in the Official Gazette of the Federation.

SECOND.- The Ministry of Health will have one hundred and eighty business days from the date of entry into force of this Decree to make the necessary regulatory adjustments for optimal compliance with its content, including the publication in the Official Gazette of the Federation of the format referred to in the first paragraph of article 190 Bis 7.

THIRD.- From the entry into force of this Decree, the public sector will have one hundred and eighty calendar days to implement the necessary measures for the acquisition of medicines that meet the requirements established in this reform to article 26 of the Health Supplies Regulation.

FOURTH.- From the date this Decree comes into force, manufacturers or establishments whose medicines do not comply with the provisions of article 26 of the Health Supplies Regulations will have one hundred and twenty calendar days to exhaust the existence of packaging materials and finished products of those.

FIFTH.- Applications for extension of Health Registration that are in process upon entry into force of this Decree, as well as those that must be submitted during the period until publication of the format referred to in the first paragraph of article 190 Bis 7, will be attended to until their conclusion in accordance with the provisions in force at the time of their submission.

SIXTH.- Holders of health registrations who have a first extension may request a second or subsequent extension, once the format referred to in the first paragraph of article 190 Bis 7 of this Decree has been published, until the aforementioned publication is made, they must comply with the requirements and formats in force at the time of submitting the corresponding extension request.