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GROUPING CRITERIA FOR HEALTH REGISTRATION AND RENEWAL OF MEDICAL EQUIPMENT, ORTHOSES, FUNCTIONAL AIDS, DIAGNOSTIC AGENTS, DENTAL PRODUCTS, SURGICAL AND HEALING MATERIALS AND HYGIENE PRODUCTS.

1. OBJECTIVE

- 1.1** Have a guide that allows the standardization of applicable criteria for those products belonging to the categories of medical equipment, prosthetics, orthoses, functional aids, diagnostic agents, dental products, surgical and healing materials and hygiene products; identifying those products that according to their characteristics of use, function, physical or pharmaceutical form, and manufacturing process can be grouped into one or more products in a single medical registration.
- 1.2** The criteria are presented as rules indicating the characteristics of the products and including descriptive and enunciative examples that assist the registrant as much as the sanitary authority to classify the products in an adequate manner, which will permit them to define the corresponding requisites for the registration.
- 1.3** Each individual product should follow the established guidelines in order to obtain the medical device health registration.

2. DIAGNOSTIC AGENTS

A Health Registration may include one or more products or components in accordance with the following guidelines:

2.1 Reagent Package or Kit:

- 2.1.1** It may include: Reagents, Controls, Calibrators and Buffers or Solutions, provided that all of these are intended for the same determination or identification of a single analyte or parameter, under the same method of analysis (clinical chemistry, colorimetry, immunofluorescence, spectrophotometry, etc).
- 2.1.2** In those cases where the storage temperature is not the same for all components it is necessary to present corresponding stability studies and to indicate this condition clearly in the label design.
- 2.1.3** When the products are commercialized inside of the same secondary or tertiary packaging, the period of expiration assigned in the registration will be that of the component having the shortest shelf life.
- 2.1.4** Each one of the components of the reagent kit or package should comply with the applicable NOMs (063, 077 and 078)



2.2 Rapid Tests:

All products that are utilized in the measurements of components of medical interest in tissue samples, fluids, excretions or secretions of the human body, which give a quick result that should be verified by confirmatory laboratory and/or clinical tests.

Included among these are pregnancy and ovulation tests, glucose tests, etc. Rapid tests are grouped in a single registration by physical form of support, such as strip, cassette, pen, etc. In the case of the determination of therapeutic drugs or drug abuse present in body fluids, these can be included in a single registration regardless of the number of determinations by drug type in question, provided that they share the same physical form of support.

2.2.1 In the case of glucometers and other self-diagnostic equipment:

2.2.1.1 Reagent strips together with the control and calibrator can be registered together as Diagnostic Agents under the same registration, provided that they are intended to be used with the same instrument.

2.2.1.1.1 In the case that storage temperature is not the same for all components it is necessary to present corresponding stability studies and to indicate the refrigerating or storage condition clearly on the label design.

2.2.1.2 Cotton with alcohol requires separate registration as a Healing Material.

2.2.1.3 Lancets require separate registration as Medical Instruments.

2.2.1.4 The glucometer along with other self-diagnostic equipment require separate registration as Medical Equipment.

2.2.1.5 In the case that a sales presentation is required that contains various components together with an instrument or instruments for a particular overall use, it is necessary to present the Health Registration for each product or component integrated into the system or kit in order to obtain its registration.

2.3 Culture Media

Culture media is understood to mean the nutritive material that can recover, multiply and isolate the microorganisms so that susceptibility tests can be applied. Culture media will be grouped in a single registration when they have the same composition or formula and physical aspect.

2.4 Control Materials

Control Materials are understood as the preparations used to evaluate the accuracy and precision of substances employed in the measurement of various components in fluids, secretions, excretions or body tissues. They are used in internal programs or external quality control in the laboratory. The control materials are also called verifiers.

In the case of products that are used as external controls, they will be grouped into the following categories:

- Hematology
- Hormonal
- Immunology



- Parasitology
- Clinical Chemistry
- Neonatal Screening
- Virology
- Microbiology
- Medications, Therapeutic Drugs or Drug Abuse

3. MEDICAL INSTRUMENTS

One or more products can be included in a Health Registration in accordance with the following guidelines:

- 3.1** Medical instruments can be grouped in the same registration if they are used for a specific indication of use or surgical procedure such as: arthroscopy, laparoscopy, laryngoscopy, among others.
- 3.2** The instrument that is required specifically for the placement of prosthesis can be registered as a system or a kit, providing that they have the same indication or intended use.
- 3.3** The same registration can include one type of instrument providing that its different presentations or models are made of the same material and have the same indication or intended use, such as: scissors, osteotomes, tips, clips, spacers, curettes, surgical saws, hooks, needle holders, hammers, spatulas, trays, forceps, knives, dilators, dissectors, elevators, among others.

4. HYGIENE PRODUCTS

Hygiene products may be included in a single Health Registration in accordance with the following guidelines:

- 4.1** Products whose formula differs solely in the following components: colorant, flavor or perfume, may be grouped in a registration, in which case 2 or more difference formulations may be included in a single registration (presentations), providing that their general physiochemical characteristics are conserved, which could include, among others: pH, density, viscosity, stability, etc.
- 4.3A** registration may authorize as many presentations as requested by the user providing that they are the same product and only change in size and weight but not in formulation or indication of use.

5 SURGICAL AND HEALING MATERIALS, PROSTHESES, ORTHOSES AND FUNCTIONAL AIDS

Surgical and healing materials that are additional or non-antiseptic or germicidal and are intended for surgical practice or for the treatment of continuity solutions, skin lesions or its annexes such as prostheses, orthoses and functional aids, and are intended to substitute or complement an organ or tissue of the human body, may include one or more products in a single Health Registration in accordance with the following guidelines:



- 5.1 The same type of product with its different presentations or models may be included providing that they are of the same material, formulation or composition and intended use, such as catheters, probes, surgical sutures, disinfecting solutions, among others.
- 5.2 Those products that have the same indication, intended use, or model may be registered as a system, for example: coronary stent systems, systems for blood fractionation, hip prostheses, spinal systems, knee systems, among others.

6 MEDICAL EQUIPMENT

In the case of medical equipment such as machines, accessories or instruments intended specifically for medical or surgical use or for processes of exploration, diagnosis, treatment and rehabilitation of patients such as those intended to conduct biomedical research, one or more products may be included in the Health Registration in accordance with the following guidelines:

- 6.1 Accessories and components that form a part of the medical equipment and that are necessary for carrying out its function may be included with the medical equipment, for example: electrocardiographs with electrodes, ultrasound devices, transducers, among others.
- 6.2 A single registration of specific medical equipment may include different models, presentations or sizes providing that they have the same technology, indication and intended use.

7 GENERAL CRITERIA

- 7.1 The following should be considered for grouping by family: one or more products may be included in a single registration in the following cases:
 - 7.1.1 If the products are fabricated by the same manufacturer or its subsidiary, or by a contract manufacturer authorized by the manufacturer or owner of the product.
 - 7.1.2 If the generic product has the same commercial or distinctive trade name, same indication or intended use.
 - 7.1.3 Presentations intended for distribution in different commercial chains can be included in the same registration providing they retain the same distinctive name.