**CENTRAL AMERICA RTCA 11.01.02:04**

**TECHNICAL**

**REGULATION**

**PHARMACEUTICAL PRODUCTS. LABELLING OF PHARMACEUTICALS FOR HUMAN USE.**

**CORRESPONDENCE**: This regulation does not necessarily correspond with any international standard.

ICS 11.120 RTCA 11.01.02:04

Central American Technical Regulation, edited by:

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* National Council for Science and Technology, CONACYT (El Salvador)
* Ministry of Economy, Trade and Industry, MEIC (Costa Rica)
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**REPORT**

The respective Technical Standardisation Committees across the Standardisation Bodies of Central America are the bodies in charge to conduct the study or the adoption of standards. They are composed of representatives of Private Enterprise, Government, Consumer Protection Agencies and Academic University.

This document was approved as Central American Technical Regulation RTCA 11.01.02: 04 Pharmaceuticals, Labelling of Pharmaceuticals for Human Use, by subgroups of measures of standardisation and medicines and related products, of the Customs Union. The formalisation of this Technical Regulation involves ratification.

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1. **Objective**

The purpose of this technical regulation is to establish minimum requirements that the labelling of pharmaceutical products for human use must meet, both for products of the territory of Central America and abroad.

1. **Scope**

This technical regulation applies to the labelling of all pharmaceutical products for human use, regardless of their mode of sale, shipment or delivery.

1. **Rules to consult**

RTCA 01:01:11:02 International System of Units (SI)

1. **Definitions and terminology**
   1. **Manufacturer or packager**: company that performs the necessary operations so that a bulk product becomes a finished product.
   2. **Concentration**: the content of active substance by mass (weight) and volume in units of the International System of Units (SI) or in International Units (IU), depending on the dosage form.
   3. **Name of the medicinal product**: the name can be an international name or a brand name. When a brand name is used it must not be confused with the International Nonproprietary name.
      1. **Brand**: record that distinguishes a certain drug, property or exclusive use of a production laboratory.
      2. **International Nonproprietary name**: the name recommended by the World Health Organisation for active ingredients. Also referred to as generic name.
   4. **Dosage**: total amount of drug administered at one time.
      1. **Therapeutic dose**: the amount of a drug to be administered to a patient in a given time interval, to produce the desired therapeutic effect.
      2. **Single dose**: amount of drug that is prescribed for a single administration in contrast to the dose used in multiple administrations.
   5. **Person in charge**: the natural or legal person who is legally responsible for the product with the corresponding authorities.
   6. **Container or package**
      1. **Primary container or primary packaging**: container or package within which the drug is directly placed in the finished dosage form.
      2. **Secondary container or secondary packaging**: container into which the primary packaging containing the drug in its pharmaceutical form is placed for distribution and marketing.
   7. **Narcotic**: substance which has high potential for dependency and abuse and has been classified as such by the Single Convention on Narcotic Drugs of the United Nations.
   8. **Tagging or labelling**: the term tagged or labelled refers to any registration or legend that identifies the product, that is printed, stuck or imprinted on the cover of the primary container or packaging, on the container or package itself or to be attached to the secondary container or packaging.
   9. **Excipient or vehicle**: substance free of pharmacological action to the concentration used that determines or modifies the consistency, shape, volume and/or physicochemical and biopharmaceutical properties of the pharmaceutical preparations. The same excipient may have one or more functions.
   10. **Expiration date**: date placed on the primary and secondary packaging material of a product to indicate the date until which the product is expected to meet quality specifications. This date is established for each lot/batch.
   11. **Pharmaceutical form**: the physical form that is given to a drug, which enables the active ingredient to exercise its action in the place, time and manner indicated.
   12. **Insert leaflet or instructions**: the technical and scientific information that is attached to the finished product, which must contain at least the information necessary for the safe and effective use of the medicinal product it contains.
   13. **Batch**: a certain amount of product, which has been prepared under uniform conditions of production and which is identified with the same code or key production known as the batch number.
   14. **Batch number**: is any combination of letters, numbers or symbols used for the identification of a batch.
   15. **Methods of sales**: different variations by means of which pharmaceutical products can be marketed. These variants are the following:
2. Drugs sold on a physician’s order or prescription drugs;
3. Retained or special prescription drugs when applicable;
4. Over the counter drugs
   * 1. **Drugs sold on a physician’s order or prescription drugs**: It is the pharmaceutical product authorised to be marketed under the protection of a prescription.
     2. **Retained or special prescription drugs**: It is the pharmaceutical product authorised to be marketed under the protection of a special retained prescription or not as applicable.
     3. **Over the counter drugs**: It is the pharmaceutical product authorised to be marketed without a prescription.
   1. **Brand Name**: name that unlike the International Non-proprietary name distinguishes a particular pharmaceutical product, the exclusive property of a production laboratory and protected by law for a period of time.
   2. **Generic Name**: name used to distinguish an active ingredient which is not protected by a trademark. It is commonly used by different manufacturers and recognised by the competent authority to name pharmaceutical products containing the same active ingredient. The generic name generally corresponds to the International Nonproprietary Name.
   3. **Active ingredient**: Any substance or chemical composition having preventive, palliative or curative properties on human diseases.

Any substance or chemical composition that can be administered to humans in order to establish a clinical diagnosis or to restore, correct or modify organic functions.

* 1. **Finished product**: that which is in the container or final packaging, labelled and ready to be distributed and marketed.
  2. **Prescription or doctor’s prescription**: order signed by the legally authorised professionals, so that one or more pharmaceuticals specified therein can be dispensed.
  3. **Psychotropic**: medication that has an effect on the mental functions. Specifically it refers to any drug used for the treatment of disorders or mental illness.
  4. **Route of administration**: route by which the drug is placed in contact with the human recipient so you can exercise local action or systemic action.

1. **General conditions for labelling**

The labelling or marking shall not disappear under normal handling, be easily readable at a glance and be written in Spanish language. However, it may be written simultaneously in other languages but the information must be essentially the same.

The labels may be of paper or any other material that may be attached to the package or packages or a permanent impression on the package or packages; provided that this printing process does not alter the integrity of the container or package on which the printing is performed.

The printing of labels that stick to the container or package may be in the back of them, provided that they are clearly visible and legible through the container or package with its contents.

For purposes of labelling the cradles, trays, bubbles and other accessories are not considered packaging or secondary packaging.

The concentration of vitamins, enzymes, antibiotics and other products that are declared in units shall be expressed in International Units (IU) or units of the International System (SI).

If the product is to be marketed without the container or secondary packaging, the labelling of the container or primary packaging must meet all requirements for the container or secondary packaging.

1. **Labelling of drugs according to their pharmaceutical form**
   1. **Tablets (pills and tablets), capsules, troches, suppositories, pessaries, transdermal patches and similar forms (any route of administration)**
      1. **Labelling of containers/primary packaging**

The minimum information that must be on the labelling of the container or primary packaging of the product is as follows:

1. Name of the medicinal product;
2. Full name of the active ingredients in its common name and its concentration in the form of single-dose (formulations with up to two active ingredients). It is accepted to omit from the blister[[1]](#footnote-1) the active ingredients of drugs like multivitamins, provided it is included in the secondary packaging;
3. Name of the company responsible or laboratory responsible or a logo that identifies the laboratory;
4. Batch number;
5. Expiration date;
6. Content in units (only if in bottles);
7. Dosage form (when there is no container or secondary packaging);
8. Route of administration (when there is no container or secondary packaging) for suppositories, pessaries, vaginal tablets even if there is a container or secondary packaging;
9. Health registration number (when there is no container or secondary packaging).
   * 1. **Labelling of containers/secondary packaging**

The minimum information that must be carried on the labelling of the container or the secondary packaging is as follows:

1. Name of the medicinal product;
2. Batch number;
3. Expiration date;
4. Contents, in units;
5. Dosage form;
6. Route of administration, including special indication on the form of administration when applicable;
7. Product composition per unit dose, indicating the full names of the active ingredients with their concentration;
8. For paediatric use or equivalent phrase (for paediatric use-only products);
9. Keep out of reach of children or similar phrase;
10. Form of sale;
11. Health register number;
12. Name of the manufacturing laboratory and country of origin;
13. Name of the company responsible and country (if different from the manufacturer);
14. Name of the conditioner laboratory or packer (if different to the manufacturer or the person responsible) and country;
15. Storage conditions;
16. Precautions, exceptions and warnings, if they are not included in the insert
    1. **Solutions, syrups, elixirs, suspensions, emulsions, lotions, powders for preparation of suspensions or solutions, injectable into ampoules, prefilled syringes, vial or large volume intravenous injections, aerosols and other similar forms (any route of administration)**
       1. **Labelling of containers/primary packaging**

The minimum information that must be on the labelling of the container or primary packaging of the product is as follows:

1. Name of the medicinal product;
2. Full name of the active ingredients in its common name and its concentration. It is accepted to omit formulations with more than two active ingredients as long as it is by lack of space, as long as it is provided in the secondary packaging
3. Name of the company responsible or laboratory responsible or a logo that identifies the laboratory and country;
4. Batch number;
5. Expiration date;
6. Contents in volume, dose or mass units;
7. Pharmaceutical form except injections when they have individual secondary packaging;
8. Route of administration (abbreviations are accepted only for intravenous injections);
9. Composition of the product per unit of dose indicating the active ingredients with its concentration (when there is no container or secondary packaging);
10. Storage conditions (when there is no container or individual secondary packaging);
11. Method of sales (when there is no container or secondary packaging);
12. Shake well before using (for emulsions and suspensions only);
13. Manner of preparing or reference to read the instructions when applicable (when there is no package / individual secondary packaging);
14. Shelf life after opening or preparation when applicable;
15. Safety warning about explosion hazard, not to expose to heat, not to puncture or incinerate and to avoid eye contact (only for aerosols with flammable propellants);
16. Security warning when applicable (except when justified for reasons of space, it cannot be placed on the primary packaging);
17. Health registration number (when there is no container or individual secondary packaging);
18. In particular cases, the labelling of products in container or packaging of low volume (up to 5 mL), must contain at least the information of paragraphs a, c, d, e, f, h and l; information not recorded must be included in the secondary packaging. In addition, the primary packaging must include the information in paragraph b, unless the product has two or more active ingredients and there is a container or individual secondary packaging; and in case of cold chain products it is essential to include the information in paragraph j except when there is a container or single secondary packaging.
    * 1. **Labelling of containers/secondary packaging**

The minimum information that must be on the labelling of the container or secondary packaging of the product is as follows:

1. Name of the medicinal product;
2. Name(s) of the active ingredient(s) and their concentration;
3. Batch number;
4. Expiration date;
5. Contents in volume, dose or mass units;
6. Pharmaceutical form;
7. Route of administration (abbreviations are accepted only for intravenous injections);
8. Composition of the product per unit of dose indicating the active ingredients with its concentration;
9. Storage conditions;
10. Method of sales;
11. Shake well before using (for emulsions and suspensions only);
12. Manner of preparing or reference to read the instructions when applicable;
13. Shelf life after opening or prepared when applicable;
14. Safety warning about explosion hazard, not to expose to heat, not to puncture or incinerate and to avoid eye contact (only for aerosols with flammable propellants);
15. Security warning when applicable;
16. For paediatric use or equivalent phrase (for paediatric use-only products);
17. Keep out of reach of children or similar phrase (except when the product is for use in the hospital);
18. Health registration number;
19. Name of the manufacturing laboratory and country of origin;
20. Name of the company and country responsible (if different from the manufacturer);
21. Name of the conditioner laboratory or packer and country (if different to the manufacturer or the person responsible);
22. Precautions, exceptions and warnings (if not included in the insert);
23. In the case of vaccines it should also include the nature and amount of adjuvants, preservatives, antibiotics and other aggregate substances that can cause adverse reactions.
    1. **Unguents, ointments, creams, gels, jellies, pastes and other similar forms (for any route of administration)**
       1. **Labelling of containers/primary packaging**

The minimum information that must be on the labelling of the container or primary packaging of the product is as follows:

1. Name of the medicinal product;
2. Name(s) of the active ingredient(s) and their concentration;
3. Name of the company responsible or laboratory responsible or a logo that identifies the laboratory and country;
4. Batch number;
5. Expiration date;
6. Contents in volume or mass units;
7. Pharmaceutical form;
8. Route of administration;
9. Composition of product per unit of measure, indicating the active ingredients with their concentration;
10. Storage conditions (when there is no container or individual secondary packaging);
11. Method of sales (when there is no container or secondary packaging);
12. Health registration number (when there is no container or individual secondary packaging).
    * 1. **Labelling of containers/secondary packaging**

The minimum information that must be on the labelling of the container or secondary packaging of the product is as follows:

1. Name of the medicinal product;
2. Name(s) of the active ingredient(s) and their concentration;
3. Batch number;
4. Expiration date;
5. Contents in volume or mass units;
6. Pharmaceutical form;
7. Route of administration;
8. Composition of product per unit of measure, indicating the active ingredients with their concentration;
9. For paediatric use or equivalent phrase (for paediatric use-only products);
10. Keep out of reach of children or similar phrase;
11. Storage conditions;
12. Method of sales;
13. Health registration number;
14. Name of the manufacturing laboratory and country of origin;
15. Name of the company responsible and country (if different from the manufacturer);
16. Name of the conditioner laboratory or packer and country (if different to the manufacturer or the person responsible);
17. Safety precautions and warnings when applicable.
18. **Special captions**

The secondary container or packaging, or primary container or packaging when the product has no secondary container or packaging, of medicines containing the active ingredients or excipients described in the list of Annex 1 shall bear the inscriptions (or similar phrases) indicating the actions cited therein.

They must also carry captions or phrases similar to those contained in Pharmacological Standards of Central America and Dominican Republic (NFCARD) in its latest version.

1. **Over-the-counter products**

In addition to as indicated in chapters 6 and 7, over-the-counter products must indicate on the labels of the container / primary packaging if they do not have a secondary container / packaging or on the secondary container / packaging if they do not have an insert, the indications, precautions, exceptions, and dosage.

1. **Officinal products (master formulas)**

The minimum information that must be on the officinal products (master formulas) is as follows:

1. Name of the medicinal product;
2. Name and address of the pharmacy and name of the pharmacist responsible;
3. Composition of product per unit of measure, indicating the active ingredients with concentration and including in the text of excipients the c.s. carrier or c.s.o equivalent abbreviations;
4. Route of administration;
5. Dosage and method of administration, for example: Put 2 tablespoons in half glass of water.
6. **Psychotropic or narcotic drugs**

In addition to as indicated in Chapters 6 and 7, for medicines containing narcotics or psychotropics, the phrase: “Caution, can create dependency” or a similar phrase shall be printed on the secondary container or packaging, or in the primary packaging if there isn’t a secondary container or packaging.

1. **Insert, instructions or package insert**

In the case of products in which it is essential to include indications, warnings, exceptions, reactions, dosage, etc., these can be printed on the primary or secondary container /packaging, in the insert, instructions or package insert.

1. **Reference**

For the preparation of this technical regulation the following documents were considered:

1. Protocol to “II workshop on harmonization of criteria for registration of drugs for Central America and Panama”, Guatemala, September 17-19, 1998.
2. European Union Directive 92/27 / EEC of 31 March 1992 on the labelling and package leaflet of medicinal products for human use.
3. Department of regulation and control of pharmaceutical and related products. Ministry of Public Health and Social Welfare of Guatemala. Special captions of mandatory printing on packaging of medicines. Guatemala, 1998.
4. **Monitoring and inspection**

The monitoring and verification of this technical regulation corresponds to the Regulatory Authorities of Health Drug Registration and other competent authorities of each Member State.

**ANNEX 1**

**Special captions**

1. **Tartrazine (oral use)**. Do not administer to people allergic to tartrazine.
2. **Benzyl alcohol (parenteral use)**. It contains benzyl alcohol; do not give to children under six (6) months.
3. **Tetracyclines**. Do not administer to children under eight (8) years, or during pregnancy or breastfeeding.
4. **Acetylsalicylic acid**. Do not administer to children under twelve (12) years with chickenpox or flu.
5. **Acetaminophen (paracetamol)**. Do not administer more than five (5) times the recommended daily dose, or for more than five (5) consecutive days to children, nor more than ten (10) consecutive days to adults. If pain or fever for more than three (3) consecutive days persists, consult a doctor.
6. **Aspartame (oral use)**. It contains phenylalanine; caution to patients with phenylketonuria.
7. **Opio, loperamide or diphenoxylate (indicated in diarrhoea)**. Contraindicated for children under two (2) years. Caution in pregnancy and lactation.

**-— END OF THE TECHNICAL REGULATIONS--**

1. A blister is a unit container for several small manufactured goods consisting of a support board or cardboard on which is glued a sheet of clear plastic pockets in which the various items are housed. [↑](#footnote-ref-1)