



GUIDELINE ON LABELING OF MEDICINES

OCTOBER 15, 2019
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1. INTRODUCTION

Labelling includes any printed, stencilled marked, embossed or impressed text or graphic matter on the immediate container, on the outer pack, and any other printed material supplied together with the medicinal product. These labelling guidelines need to be applied in conjunction with medicines regulations 'Part VIII'.

2. PURPOSE

- To describe and identify the product
- To avoid medication errors
- To contribute towards optimal therapeutic outcome
- To achieve proper handling and storage of the product
- To allow the product to be traced in the event of a concern such as a quality issue

3. SCOPE

The document will serve as a guide to establish minimum requirements for content in labels with reference to specific dosage forms and requirements for product and patient information leaflets according to schedule of the medicine.

4. DEFINITIONS

- Primary label – label upon the immediate container, i.e. container in direct contact with the product
- Secondary label – label on the outer pack immediate to the container holding the product
- Product information leaflet/Package insert (PI) – a leaflet accompanied with the medicinal product containing specific information for the healthcare professional
- Patient information leaflet (PIL) – a leaflet accompanied with the medicinal product containing specific information in lay language, for the patient
- Summary of Product Characteristics (SPC) – a document approved as part of the marketing authorisation of each medicine and aimed at healthcare professionals. It contains more information than the product information leaflet
- Dispensing label – a label giving specific instructions to the patient and attached to the packaging of medicine at the point of dispensing.

5. REQUIREMENTS

Label

The container of every medicine imported, manufactured, processed or packed locally or sold or exposed for sale shall have a label bearing the following information in English language.

- (a) The official or generic name¹ of the medicinal product followed by its pharmaceutical form² and strength³. If applicable, abbreviations for the official pharmacopoeia or formulary⁴ in which specifications of the drug product are described in a monograph shall be included prior to the strength; e.g. Metformin¹ Tablets² B.P.⁴ 500mg³

If appropriate, whether it is intended exclusively for paediatric or adult patients shall be included.

Where the product contains up to three active substances, the international non-proprietary name (INN) or any other commonly used official name such as United States Approved Name (USAN) or British Approved Name (BAN) shall be included. If there are more than one official name for an active substance, the name that has been used most commonly in Sri Lanka (e.g. paracetamol over acetaminophen) shall be preferred.

For products containing more than three active substances, name descriptive of the true nature of the medicinal product shall be used. (E.g. Multivitamin Tablets)

(b) If conformity with a pharmacopoeial monograph is claimed for a product, relevant labeling requirements given in both general and specific monographs shall be adhered to.

(c) The brand/proprietary name (if any)

The brand name should not be already registered for another product. Also, NMRA reserves the right to refuse a brand name which is partially similar to an existing product and could lead to mix up with another medicine, or a brand name deemed inappropriate due to reasons such as exaggeration of its action or of immoral nature.

(d) A statement of the active substance(s) showing quantitative particulars:

(i) The quantity of each active ingredient, identified by its appropriate non-proprietary name, in each dosage unit of the medicinal product expressed in terms of weight, volume, capacity or units of activity; or

(ii) where there is no dosage unit, the quantity of each active ingredient identified by its appropriate non-proprietary name, in the container of the medicinal product expressed in terms of weight, volume, capacity or units of activity or percentage by weight or volume of the total quantity;

For active substances present as salts, they should be clearly indicated.

E.g. each capsule contains Amoxicillin trihydrate equivalent to Amoxicillin 250mg

(e) Pack size: the number of doses, weight, or volume contained in the pack

(f) Excipient(s) known to have undesirable effects and any other ingredients specified by the Authority. Particularly, presence of the following ingredients should be indicated:

(i) Colourant(s) contained in the formulation of any medicinal product

(ii) Sweeteners used as inactive ingredients (quantity in milligram per dosage unit)

(iii) Alcohol content in oral liquids (as a percentage)

(iv) Presence of benzyl alcohol in parenteral preparations.

(v) Preservatives contained in ophthalmic products. (as a percentage)

(vi) Any added microbial preservatives in parenteral preparations. (as a percentage)

(g) The dosage form

(h) The route of administration for injectable products

(i) Storage temperature and, other special storage precautions if any

(j) A special warning that the product must be stored out of reach of children.

(k) Specific instructions if the product needs to be reconstituted, diluted, or prepared by any other means prior to its use

(l) Where applicable, the product is sterile.

(m) Where applicable, the product is free from bacterial endotoxins or that the product is apyrogenic.

(n) For injectable solutions, not to use if visible particles are present.

(o) Any other special warnings and precautions that may be necessary for the particular medicinal product.

(p) The date of manufacture in clear terms (month/year)

(q) The date of expiry in clear terms (month/year)

- (r) The batch or lot number assigned by the manufacturer, and
- (s) The period for which the medicine can be used after opening of the container or after reconstitution of the product, if applicable.
- (t) Specific precautions related to disposal of unused quantities of the product, if applicable.
- (u) The name of the manufacturer and address of the manufacturing site.
 - The name and address of the batch releaser shall be used, if different from the drug product manufacturer.
 - When the product owner is different to the manufacturer, the label shall indicate in the following manner: ‘manufactured by (name and address of actual manufacturer) for (name of product owner)’.
 - In addition, name and address of the packaging site(s) may be included [if different from the manufacturing/release site(s)]

Directives of the National Languages Commission

In keeping with the National Languages Policy requirements, the official or generic name shall be displayed in Sinhala and Tamil languages.

- For medicines dispensed with an intact outer carton (e.g. a liquid bottle, an ointment tube), displaying the name in local languages on the outer carton is sufficient.
- If the product is taken out from the outer carton for dispensing (e.g. blister strips) or if the product has no outer carton, the primary label should indicate the name in local languages.
- The requirement is not compulsory for injections which require professional healthcare staff for administration.

Exemptions for smaller labels

Primary labels on smaller containers such as a blister strip, an ampoule or vial with a volume of 10 ml or less shall contain the following minimum information.

- (a) the generic or common name,
- (b) the brand name (where applicable),
- (c) the strength of the drug,
- (d) lot or Batch number,
- (e) the date of expiry and
- (f) the name or logo of the manufacturer or the product owner.

In addition, route of administration shall be indicated for injections. This may be indicated in abbreviations. The storage instructions shall be indicated on strips.

The information exempted on the primary label should be included on the outer carton and/or the leaflets.

Where practicable, the name and strength of the product should appear over each blister pocket or be oriented centrally across the pack. It is important that the particulars remain available to the user up to the point at which the last dose is removed from the blister pack.

General

Information provided in the labels should be consistent with the information submitted in the application dossier.

If any other foreign language text is included in the label, the applicant must provide an official statement to declare that the foreign text is complete, accurate, contains unbiased information and is consistent with the English text.

All information required to be indicated on the label shall be displayed prominently, legibly and distinctly. Information that is required should be printed on the labels and use of over-stickers is generally not allowed. Over-stickers may be allowed to indicate the name of the medicine in National languages and the price. In such instances, the sticker should not obstruct the view of other required information.

In circumstances where over-stickers cannot be avoided, the applicant should consult the NMRA with appropriate justifications.

Pictures with the exception of company logos are generally not allowed on medicine labels.

The outer carton labels for products with different strengths, dosage forms, or formulations of the same manufacturer should be adequately differentiated (e.g. by using different colour schemes) to minimise confusion and medication errors.

The draft artworks, specimens or mock-ups of outer cartons and primary labels submitted in the dossier should be consistent with the formats, designs and colours of the original labels that would be used on commercial packs to be marketed. Handwritten information on the artworks, specimens, or mockups are not acceptable, with the exception of statements such as “batch number and expiry dates will be printed”.

QR codes or 2D barcodes on the product’s labelling which are intended for logistics control are allowed. However, the inclusion of QR codes or 2D barcodes with links to promotional internet websites or other information sources is not allowed. Generally, indication of website addresses is not allowed.

Product Information Leaflet / Package Insert (PI)

The container of every medicine classified under Schedules II and III of the NMRA regulations shall be accompanied by a printed insert containing information drawn up in accordance the summary of product characteristics.

It shall contain the particulars specified below:

- (a) Generic or official name of the drug product, the dosage form, and the strength.
- (b) Net content of the active substance(s).

When an active substance is present as a salt, this should be clearly indicated.

- (c) Brand or proprietary name, if any.
- (d) Product Description – a description of the relevant physical and chemical characteristics of the drug product and a description of the appearance of the product (colour, markings etc.) should be given.
- (e) For products to be reconstituted before use, the appearance before reconstitution should be stated. If a diluent/ solvent is accompanied with product, a physical description of diluent/solvent should be stated.
- (f) If applicable, information on pH and osmolarity should be provided.
- (g) For tablets designed with a score line, information on the purpose of the score-line should be given, e.g. ‘the score line only serves to facilitate breaking for ease of swallowing and does not divide the tablet into equal half-doses’, or ‘the tablet can be divided into equal halves.’

- (h) Excipients contained in the product, of which the knowledge of presence is important for the safe and effective use of the medicinal product. (e.g. preservatives, colourants, antioxidants etc.)
- (i) Pharmacodynamics/Pharmacokinetics – information to be mentioned in this section include:
- The pharmaco-therapeutic group and if available, the ATC code
 - Mechanism of action of each drug substance
 - Pharmacokinetic properties of each drug substance
 - Clinical trial information relating to clinical efficacy and safety; and
 - Relevant pharmacogenetic information from clinical studies with data showing a difference in benefit or risk to a particular genotype or phenotype.
- (j) Indication and usage – the therapeutic indication(s) of the product.
Information shall include a concise statement of each of the medicine's approved indications, briefly noting any major limitations of use for any or all of its indications. If multiple indications exist, the information be presented in a bulleted format.
- (k) Dosage and administration – the information required include, as appropriate:
- A concise summary of the recommended dosage regimen (e.g., starting dose, dose range, titration regimens, route of administration)
 - Critical differences among population subsets
 - Information on dose adjustments in special populations, e.g. elderly, children, renal insufficiency, hepatic insufficiency and other concomitant diseases and therapies
 - Maximum recommended/tolerated daily dose and the maximum dose for an entire course of therapy;
 - Monitoring requirements: advices relevant for dosage adjustment from monitoring of clinical symptoms and signs and/or laboratory investigations, when appropriate.
 - Other pertinent information, such as relationship to meals and compatibility with other drugs and fluids

Reference to a dosing regimen for an unapproved indication is not acceptable

- (l) Method/Route of Administration – only standard abbreviations should be used. Non-standard or complicated routes of administration should be carefully explained to avoid confusion.
- (m) Contraindications – situations where patients should never or generally not be treated with the medicine.
- (n) Warnings and Precautions – circumstances where caution is required to ensure the safe and efficacious use of the product.
Mention if appropriate, possible effects on the ability to drive vehicles or operate machinery.
- (o) Interactions – forms of interactions with other medicines and other forms of interaction (e.g. with alcohol, food varieties) with clinical significance.
- (p) Use during Pregnancy/Lactation
- (q) Adverse Effects/Undesirable Effects – a description of the adverse reactions under normal use of the medicine and, if necessary, action to be taken by the patient. Provide an indication of severity, clinical importance and frequency, whenever possible.
- (r) Overdose and Treatment – symptoms, signs and recommended treatment of overdose or accidental poisoning.
- (s) Method of preparation – if applicable, the complete method of reconstitution or dilution should be stated. If not accompanied with the product, the names of suitable diluents or solvents to be indicated.
The appearance of the product after reconstitution should be stated. As appropriate, the information on in-use shelf-life after dilution or reconstitution or first opening should be provided in this section or the section “Shelf life”.
- (t) Incompatibilities (for injections only)

- (u) Storage Condition – the storage condition must be consistent with the conclusion of the stability testing and the conditions stated on the product label and/or outer carton.
- (v) Shelf Life – the shelf life must be based on stability data furnished in the dossier and consistent with that stated on the product label and/or outer carton.
The information on in-use shelf-life after dilution or reconstitution or first opening should be provided (if applicable).
- (w) Available pack size(s) - All pack sizes intended to be marketed should be listed. Reference should be made to the primary container closure system (e.g. glass vials, PVC/Aluminium blister, Alu/Alu blister, HDPE bottle, ampoule, etc.).
- (x) Any other components accompanying the product should be indicated (e.g. solvent, syringe, measuring cup, needles, etc.). The primary container closure system of the diluent/solvent provided with the drug product should also be described.
- (y) The name and address of the manufacturer, batch releaser or product owner. The site address should be compatible with the address indicated in the COPP and labels.
- (z) The date on which the leaflet was last revised.

Patient Information Leaflet

Every medicine specified in Schedule I or Group A of Schedule II of the NMRA regulations shall be accompanied by a patient information leaflet. In addition, patient information leaflets shall be required for any other medicine specified by the Authority from time to time.

- The patient information leaflets shall be in English, Sinhala and Tamil languages giving specific information on the safe and effective use of the relevant medicine, and shall accompany in each package or container of medicine.
- It should be presented in a legible format and in simple language readily comprehensible to the consumers.
- Pictorials may be used to demonstrate the correct usage of certain dosage forms such as inhalers, ophthalmic products and suppositories
- The information provided in the patient information leaflet should be scientifically accurate and consistent with the product information leaflet and labels of the relevant medicine.

The patient information leaflet shall contain the following particulars:

- (a) Name of the medicine (generic and brand if applicable), dosage form, strength, net content of active ingredient(s), details of certain excipients such as preservatives and colourants as decided by the Authority, and a description of the appearance of the product
- (b) Any specific age groups for which the medicine is intended to, if applicable
- (c) What is this medicine used for?
- (d) How much and how often should the medicine be taken, and how long the course of treatment will last?
- (e) Any other specific directions about how to use the medicine
- (f) Symptoms of serious or frequent possible adverse effects/undesirable effects and what to do if such effect is experienced
- (g) When this medicine should not be used?
- (h) What other medicines or food should be avoided while taking this medicine
- (i) What should be done, if a dose is missed?
- (j) Any risks to the mother and the fetus or the infant from the use of the medicine during pregnancy or breast-feeding.
- (k) Information for any other special groups of patients, if applicable
- (l) Any other precautions that should be taken while taking this medicine
- (m) Signs and symptoms of overdose and what to do if more than the recommended dose has been taken
- (n) How should the medicine be stored?

- (o) Information on in-use shelf-life after dilution, reconstitution, or first opening, if applicable
- (p) General advices e.g. ‘keep away from children’, as decided by the Authority
- (q) The name and address of the manufacturing site
- (r) The name and address of the marketing authorization holder

If the product is sold without a separate leaflet, the information that is required in the PIL must be stated on the outer carton or the primary label.

Dispensing Labels

When a prescription medicine or an over the counter medicine is dispensed to the patient, a dispensing label giving specific instructions on its usage shall be fixed to the packaging of the medicine.

If the dispensing label is fixed to the original commercial pack, it should not obscure important information on the original label. When a medicine has to be prepared or taken out of the original pack, the dispensing label shall be fixed on an envelope or on a suitable container used for packaging the medicine.

The medium of instructions on the dispensing label shall be Sinhala, Tamil, or English, as for the preference of the patient. The text should be clear and legible.

The following particulars shall be included on the dispensing label.

- (a) Name of the patient
- (b) Name of the medicine (generic and brand)
- (c) The dose, frequency of administration
- (d) Other specific directions for use, if any (e.g. before or after meals)
- (e) Quantity of the medicine dispensed
- (f) The name/address of the pharmacy, hospital or clinic
- (g) Name and signature of the pharmacist, the medical practitioner or the dentist
- (h) Medicines for external application should be labelled: “FOR EXTERNAL USE ONLY”

6. REFERENCES

- Guidance for Industry, Labelling for Human Prescription Drug and Biological Products, USFDA
- Medicines (labelling) regulations, HSA Singapore
- Points to consider for Singapore labelling, HSA Singapore
- FIP guidelines for the labels of prescribed medicines, FIP

7. FEEDBACK

7.1 Staff and customers may provide feedback about this document by emailing info@nmra.gov.lk.