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MCA Technical Working Group

Guideline for Labelling of Medicines for Human Use

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This guideline replaces parts of the 'MCA Guideline for Repackaging and Labelling of Medicines, version 3 - 10 July 2020' and should be read in conjunction with the MCA *Guideline for Registration of Medicines* and MCA *Guideline for Registration of Herbal Medicinal Products, where applicable.*

Version #	**Effective Date**	**Reasons for Change:**
1	13 Dec 2017	New document
2	15 April 2020	Editorial changes, reference to the Regulations and labelling for registration included, conditions for license for repackaging for medicines added.
3	10 July 2020	Licensing for repackaging included
4	25 June 2025	Format changed to the current template; editorial changes; title changed; repackaging and relabelling moved to a separate guideline; requirements for SmPC and PIL specified and templates provided.

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Keywords	labelling, medicines, label, summary of product characteristics, SmPC, patient information leaflet, PIL, package insert

Guideline for Labelling of Medicines for Human Use

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Acknowledgements

We duly thank the World Health Organization (WHO) and the European Commission for publishing their guidelines and notices to applicants that contributed in several aspects relevantly to the development of this guideline.

1 Introduction (background)

1.1. The main purpose of **package labelling** of medicines is for the unambiguous identification of the medicine and the conditions for their safe distribution, storage and use by healthcare professionals, patients, caregivers and consumers. Inappropriate labelling can lead to product mix-up and loss of product identity.

1.2. The main purpose of the **Patient Information Leaflet** (PIL) is to inform patients about their medication regarding its administration, precautions and potential adverse effects.

1.3. The main purpose of the **Summary of Product Characteristics** (SmPC) is to provide detailed information to healthcare professionals on medication to ensure safe and effective use.

1.4. This document provides guidance on the labelling of packages of medicines and on the format and content of the PIL and the SmPC.

2 Legal basis

2.1. The regulation of medicines in The Gambia is governed by the provisions and requirements of the Medicines and Related Products Act, 2014, by which the Medicines Control Agency (MCA) was established as the regulatory body for medicines and related products.

2.2. Part II, Section 4 (b) of the Act requires that the Agency regulates the manufacture, labelling, marking and identification of medicines.

2.3. The Medicines and Related Products Regulations, 2020 details in Part VIII, Section 62 – 65 the labelling and information requirements.

3 Scope

3.1. This guideline applies to all prescription, non-prescription and over-the-counter medicines as well as herbal medicinal products and medicines of biological origin like vaccines as defined in the Medicines and Related Products Act and the Medicines and Related Products Regulations.

3.2. It applies to companies or other legal entities applying for the marketing authorisation (registration) of a medicine for marketing in The Gambia, Marketing Authorisation Holders (MAHs), local representatives of MAHs and importers of medicines.

4 Labelling of Medicine Packages

4.1 General Requirements

4.1.1. The primary and, where applicable secondary container of every medicine shall bear a written label. Statements required to appear on the label should be clear, prominent, indelible and legible to the consumer under normal conditions of purchase and use.

4.1.2. The information on the label should not be described or presented in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its use in any respect either pictorially or in words.

4.1.3. The presentation of the product shall not have any resemblance in spelling, pronunciation and layout of invented name or packaging to another product from a different manufacturer or MAH.

4.1.4. All changes to an aspect of the labelling after authorisation of the medicine in The Gambia shall be submitted to the MCA for authorisation as a variation. Refer to the MCA *Guideline for Variations*.

4.2 Format of the labelling

4.2.1. The information on the package has to be of the permanent type in a tamper proof way i.e. any attempt to remove the label will create permanent damage to the packaging. All information present on labels must be printed, using indelible ink. The stamping with ink is not allowed. If coloured text or background is used, the greatest possible contrast must be aimed for.

4.2.2. Labels must be large enough to contain the required information in a large enough font for adequate legibility and occupy a prominent place on the package. The font is of great significance to legibility:

- Simple fonts are suitable;
- Narrow (condensed) or wide fonts should be avoided;
- Clear areas around the text improve legibility;
- The various text items should not therefore be located too close together;
- Fonts less than 7 points should be avoided; justification should be provided if smaller fonts are used.

4.2.3. The name of the medicine should appear on at least two non-opposing faces of the pack to aid accurate identification of the medicine.

4.2.4. All information on labels must be in English. Where the medicine is not labelled in English, a complete translation of the relevant information as determined and approved by the Agency, should be fixed to the secondary packaging of the product. If this is not possible, the English translation should be inserted in the package with prior approval from the Agency.

4.3 Content on the labels

4.3.1. The information on the package shall include:

- the generic name (non-propriety name) and where applicable the proprietary name (invented name, brand name, trade name) of the medicine;
- dosage form (pharmaceutical form) and strength (if not included in the name);
- the approved name of each active ingredient (active substance) and the quantity contained in a dosage unit, or per suitable mass or volume or unit;
- in the case of medicines produced using genetic engineering, the active substance and the name of the genetically modified micro-organism or cell line used in its manufacture;
- in the case of herbal medicinal products, the identification of the active ingredient(s) given by the Latin botanical name in addition to the common name;
- excipients that have a recognised action or effect as determined by the Agency and all excipients, if the medicine is injectable or a topical or eye preparation;
- the presentation and pack size expressed in the appropriate unit or volume;
- instructions for use prior to intake of the medicine where applicable;
- the method, and if necessary, route of administration by means of suitable words or abbreviations;
- the batch (or lot) number of the medicine;
- the manufacture and expiry date in a clear and visible font size;
- the name and address of the manufacturer and marketing authorisation holder (if different from the manufacturer);

- instructions for the storage with specific reference to the applicable storage temperature and other precautions required for the preservation of the medicine;
- special or cautionary warnings as applicable;
- nutritional information in case of nutritional supplements;
- the registration number of the medicine allocated by the Agency (where applicable);
- any specified warnings to be provided on the label as a condition of registration determined by the Agency.

4.3.2. The Agency may in respect of an interchangeable multisource medicine, determine additional information to be provided by the applicant. The Agency may authorise the inclusion of any special information on the label of a medicine that is not required by this guideline to be included.

4.4 Blister packs

4.4.1. If the primary container is a blister pack the **minimum information to be** displayed **are as follows**:

- The generic name and where applicable the proprietary name of the medicine;
- dosage form and strength (if not included in the name);
- name of the marketing authorisation holder;
- manufacture and expiry date; and
- batch or lot number.

4.4.2. The name and strength of the medicine should appear over each blister or be oriented centrally across the pack. The particulars should remain available to the user up to the point at which the last dose is removed from the blister pack.

4.4.3. The required information listed above in section 4.3 should appear on the secondary container.

4.5 Small containers

4.5.1. Where the labelling requirements cannot be legibly applied to a small primary container (nominal value of 10 ml or less), the following minimum information should appear:

- generic name and where applicable the proprietary name of the medicine;
- strength (if not included in the name);
- route and method of administration, if necessary;
- expiry date;
- batch (or lot) number; and
- contents by weight and volume of unit.

4.5.2. The required information listed above in section 4.3 should appear on the secondary container.

5 Patient Information Leaflet (PIL)

5.1. The inclusion of a Patient Information leaflet (PIL), also called package insert or package leaflet, in the packaging of all medicines is obligatory unless all information required is directly conveyed on the labelling. The Information in the PIL is based on Summary of Characteristics information (see below).

5.2. The PIL shall be written and designed to be clear and understandable, enabling the users to act appropriately, when necessary, with the help of healthcare professionals, and be written in English. Where the PIL is not written in English, the original PIL should be translated by certified translator and shall be submitted to MCA for prior approval. The format and content of the PIL required by MCA is contained in the template (**Annex 1**, Patient Information Leaflet template) and shall conform to the Regulations.

5.3. The PIL may include symbols or pictograms designed to clarify certain information which is useful to the patient, but must exclude any element of a promotional nature.

5.4. All changes to an aspect of the PIL after authorisation of the medicine shall be submitted to the MCA for authorisation as a variation. Refer to the MCA *Guideline for Variations*, where applicable.

6 Summary of Product Characteristics (SmPC)

6.1. The provision of the Summary of Product Characteristics (SmPC) or an equivalent professional information is a legal document approved as part of the marketing authorisation of each medicine.

6.2. Separate SmPCs are required for each pharmaceutical form and strength, unless the dosage regimen is based on the use of several strengths or pharmaceutical forms.

6.3. The SmPC should be worded in clear and concise language. Consistent medical terminology should be used throughout the SmPC like e.g. the Medical Dictionary for Regulatory Activities (MedDRA) terminology, in particular for sections 4.3, 4.4 and 4.8.

6.4. Each section of the SmPC should first deal with those issues that apply to the core population for whom the medicine is indicated followed - when necessary – by specific information for any relevant special population (e.g. children or elderly).

6.5. The SmPC provides information on a particular medicine and should therefore not include reference to other medicines except when it is a class warning recommended by a regulatory authority.

6.6. The format and content of the SmPC required by MCA is contained in the template (**Annex 2**, Summary of Product Characteristics template) and shall conform to the Regulations. MCA accepts other formats of professional information, if the content complies with this guideline and the Regulations.

Definitions

Container is the material employed in the packaging of a medicine; containers include primary and secondary containers and transportation containers

Package is a box, packet or any other article in which one or more primary containers of medicines is or are to be enclosed in one or more other boxes, packets or articles

Primary Container / Primary Packaging / Immediate Container is a packaging component that is in direct contact with the dosage form

Proprietary Name / Brand Name / Trade Name / Invented Name is the name of the medicine that belongs to the patent holder under which a medicine is marketed

Secondary Container / Secondary Packaging is a packaging component that is not and will not be in direct contact with the dosage form

References

- Medicines and Related Products Act, 2014
- Medicines and Related Products Regulations, 2020
- MCA Guideline for Marketing Authorisation (Registration) of Medicines (MCA-GL-102).
- MCA Guideline for Variations (MCA-GL-114)
- European Commission. Notice to Applicants: Guideline on the Packaging Information of Medicinal Products for Human Use Authorised by the Union. April 2021
- European Commission. Notice to Applicants: A Guideline on Summary of Product Characteristics. September 2009
- WHO good manufacturing practices for pharmaceutical products: main principles, Annex 2, WHO Technical Report Series No. 986, 2014

Annex

Annex 1: Patient Information Leaflet template (MCA-T-101/01)

Annex 2: Summary of Product Characteristics template (MCA-T-101/02)