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Rwanda Food and Drugs Authority

RWANDA FDA GUIDANCE ON FORMAT AND CONTENT OF LABELS FOR HUMAN MEDICINAL PRODUCTS

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FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by the Law N° 003/2018 of 09/02/2018. One of the functions of Rwanda FDA is to regulate matters related to quality, safety and efficacy of human medicinal products in order to protect public health by increasing access and availability of essential medicines.

Considering the provisions of the technical Regulations N° CBD/TRG/010 Governing the registration of human medicinal products especially in its articles 6, 7, 8, 9, 12 and 32, and the Guidelines No DHT/GDL/001 on submission of documentation for registration of human medicinal products, the authority has to issue the *Guidance N°: DAR/GDL/010B on Format and Content of Labels for Human Medicinal Products*

Rwanda FDA adopted the Common Technical Document (CTD) Guidelines on Submission of Documentation for registration of human medicinal products. These guidelines have been developed to provide guidance to the applicants and the Authority in managing applications for registration of human medicinal products. These guidelines were developed in reference to the existing Ministry of Health (MOH) guidelines on submission of documentation for registration of Human Pharmaceutical Products which were domesticated based on Compendium of Medicines Evaluation and Registration for Medicines Regulation Harmonization in the East African Community, World Health Organization (WHO) and the International Conference on Harmonization of Technical Requirements for Registration of Medicines for Human Use (ICH) and other available literature.

The Authority acknowledges all the efforts of key stakeholders who participated in the development and validation of these guidelines.

Dr Charles KARANGWA
Acting Director General

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1. TABLE OF THE CONTENT

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2. INTRODUCTION

This guideline is written to assist applicants and Marketing Authorization Holders in drawing up the labelling

and preparing the mock-ups or specimens of the sales presentations[1]

The guidance gives advice on the presentation of the content of the labelling and on the design and layout concepts which will aid the production of quality information.

Labelling covers both outer packaging and inner packaging. Although inner packaging may include a lesser set of particulars, many of the principles outlined in relation to outer packaging will apply equally to the labelling of blister packs or other small package units.

Labelling ensures that the critical information necessary for the safe use of the medicine is legible, easily accessible and that users of medicines are assisted in assimilating this information so that confusion and error are minimized.

3. GENERAL REQUIREMENTS

(a) **The label text**

Particulars in the label shall be easily legible, clearly comprehensible and indelible.

(b) **Conformity with the Summary of Product Characteristics**

The label text should be in conformity with the summary of products characteristics.

(c) **Language**

The labelling must be presented at least in one of the official language used in Rwanda. If more than one language is used, then all of the text must be in each language and the overall readability should not be adversely affected.

The content of all language versions must be identical. It is recommended to group different text elements for each language, where appropriate.

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Rwanda Food and Drugs Authority

[1] A mock-up is a copy of the flat artwork design in full color, presented so that, following cutting and folding where necessary, it provides a rep-lica of both the outer and immediate packaging so that the three dimensional presentation of the labeling text is clear. This mock-up is generally referred to as a paper copy and not necessarily in the material of the sales presentation. A specimen is a sample of the actual printed out outer and immediate packaging materials and package leaflet (i.e. the sales presentation)

(d) **Products with different strengths**

Container labels may look similar across multiple strengths of the same product or across multiple products within a company's product line.

Product labels for medicinal products with multiple pharmaceutical strengths, within a manufacturer's product line, should be designed such that the products are identifiable and can be significantly differentiated from one another. Colour differentiation on product labels should be an effective tool that can differentiate products within a manufacturer's product line.

When applying differentiating colour, the applicant should ensure that the text highlighted by the differentiating colour has adequate colour contrast against the background colour on the container label.

(e) **Label layout and artwork**

Images, pictograms and other graphics may be used to aid comprehension of the information on the labels of non-prescription medicines only and not on the container labels of prescription medicines.

Images, pictograms and other graphics should exclude any element of a promotional nature and should only be used to aid navigation, clarify or highlight certain aspects of the text and should not replace the actual text.

The overall layout should not be misleading or have any inappropriate connotations in a way that no doubt about the meaning of a particular pictogram will be perceived.

4. PARTICULARS TO BE INCLUDED ON THE LABEL

(a) **Outer packaging or, where there is no outer packaging, on the immediate packaging**

The label should include at least the following:

i. Proprietary Name where applicable
ii. International Non-Proprietary name(s) of the Active Pharmaceutical Ingredient(s)
iii. Amount of each Active Pharmaceutical Ingredient present in a dosage unit
iv. List of excipients known to be a safety concern for some patients, e.g. lactose, gluten, metabisulfites, parabens, ethanol, or tartrazine. For parenterals and topical preparations, all excipients should be listed.
v. Pharmaceutical form and contents of the container, e.g. number of dosage units, weight or volume.

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Rwanda Food and Drugs Authority

vi. Method and route(s) of administration and the statement "Read the patient information leaflet before use."
vii. Special warning that the medicinal product must be stored out of the reach and sight of children ("Keep out of the reach and sight of children").
viii. Other special warnings and handling precautions, if necessary (e.g. in case of specific toxicity of the agents)
ix. The word "sterile" if the product is sterile
x. Batch number assigned by the manufacturer
xi. The manufacturing date
xii. The expiry date
xiii. Special storage conditions, if applicable
xiv. Special precautions for disposal of unused medicinal products or waste material derived from such medicinal products, if appropriate
xv. The name and address of the Marketing Authorization Holder
xvi. Physical address of the site responsible for release of the finished product
xvii. Advice on general classification for distribution, e.g., Controlled Medicines, Prescription Only Medicines, Pharmacy Only Medicines, Over-the-Counter and General Sales List
xviii. Instruction on use
xix. The proprietary name, strength and expiry date in braille (Marburg Medium)
xx. The registration number issued by Rwanda FDA

(b) **Guidance for small containers**

For containers of less than or equal to 10 ml capacity that are marketed in an outer pack such as a carton, and the outer pack bears all the required information, the immediate container should contain at least these minimum information (added):

i. Brand Name of the FPP, INN name, strength, pharmaceutical form, active substance(s) and route(s) of administration
ii. Method of administration
iii. Batch number assigned by the manufacturer
iv. Expiry date
v. Manufacturing date if space is enough
vi. Contents by weight, by volume or by unit
vii. The name and address of the manufacturing site — or a logo that unambiguously identifies the company.
viii. Directions for use, and any warnings or precautions that may be necessary

(c) **Guidance for Blisters and strips**

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Rwanda Food and Drugs Authority

Blisters and strips should include, as a minimum, the following information (printed directly):

i. Name, strength and pharmaceutical form of the FPP
ii. Name and physical address of the manufacturing site (the site responsible for release of the finished product)
iii. The batch number assigned by the manufacturer
iv. The expiry date [Note that for co-blistered products, the expiry date is that of the product which expires first.]
v. The manufacturing date, if space is enough
vi. The batch number assigned by the manufacturer.
vii. Directions for use, and any warnings or precautions that may be necessary.

(d) **Additional labelling information required by some Partner States**

Rwanda FDA may with time require certain additional information on labels, e.g.:

i. Price of the medicinal product;
ii. The reimbursement conditions of social security organizations;
iii. Identification and authenticity;
iv. A statement that the product is a property of government

Such information should be accommodated on the label in a box, to appear on one side of the pack.

5. CONTROL OF THE COMFORMITY OF THE LABELING

The labelling of the medicinal product forms part of the authorization and it must, therefore, be approved by Rwanda FDA when the authorization is granted.

Any changes to the labelling, which are not connected with the Summary of Product Characteristics, shall be notified to Rwanda FDA. Therefore, if a Marketing Authorization Holder wishes either to introduce any label text additional to that in the decision or to change any aspect of the labelling they must first notify this change to Rwanda FDA, who shall inform the Marketing Authorization Holder whether the proposed change is accepted or not.

6. CHANGES TO THE LABELLING

Any changes to the labelling, which are not connected with the Summary of Product Characteristics, shall be notified to Rwanda FDA. Therefore, if a Marketing Authorization Holder wishes either to introduce any label text additional to that in the decision or to change any aspect of the labelling he must first notify this change to Rwanda FDA, who shall inform the Marketing Authorization Holder whether the proposed change is accepted or not.

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7. DOCUMENT REVISION HISTORY

Date of Revision	Revision Number	Document Number	Change Made
01/05/2021	Rev_0	DAR/GDL/010B	First Issue

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