# RWANDA STANDARD

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# Labelling and marking of pharmaceutical products — Specification

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In order to match with technological development and to keep continuous progress in industries, standards are subject to periodic review. Users shall ascertain that they are in possession of the latest edition





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# Foreword

Rwanda Standards are prepared by Technical Committees and approved by Rwanda Standards Board (RSB) Board of Directors in accordance with the procedures of RSB, in compliance with Annex 3 of the WTO/TBT agreement on the preparation, adoption and application of standards.

The main task of technical committees is to prepare national standards. Final Draft Rwanda Standards adopted by Technical committees are ratified by members of RSB Board of Directors for publication and gazettment as Rwanda Standards.

DRS 91 was prepared by Technical Committee RSB/TC 15, *Pharmaceutical Products.*

In the preparation of this standard, reference was made to the following standard (s):

TZS 773: Labelling and marking of pharmaceutical products — Specification

The assistance derived from the above source is hereby acknowledged with thanks.

This second edition cancels and replaces the first edition (RS 91: 2015), of which has been technically revised.

## Committee membership

The following organizations were represented on the Technical Committee on *Pharmaceutical products* (RSB/TC 015) in the preparation of this standard.

Rwanda Food and Drug Authority (RFDA)

Rwanda Social security Board (RSSB)

KIPHARMA

Rwanda Inspectorate and Competition and Consumer protection Authority (RICA)

Rwanda Forensic Laboratory (RFL)

University of Rwanda – College of Sciences and Technology (UR-CST)

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# Labelling and marking of pharmaceutical products — Specification

## 1 Scope

This Draft Rwanda Standard specifies requirements of a label for pharmaceutical products. It also gives special labelling and marking requirements for some preparations such as biological, sterile products and aerosols.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/TS 16791:2014, *Aerosol drug delivery device design verification — Requirements and test methods*

RS ISO 780*, Packaging — Pictorial marking for handling of goods*

ISO/TS 16791:2014*, Health informatics — Requirements for international machine-readable coding of medicinal product package identifiers*

## 3 Terms and definitions

For the purposes of this standard, the following terms and definitions apply.

**3.1**

**label**

legal display of written, printed or graphic matter upon the immediate container or the outside container or wrapper of a medicine package

**3.2**

**labeling**

all labels and other written, printed or graphic matter upon an immediate container of preparation or upon, or in any package or wrapper in which it is enclosed except any outer shipping container

**3.3**

**pharmaceutical product**

any medicine, substance or other article manufactured or prepared in any way and intended for use by man as a medicine or as a remedy used for the purpose of medical, dental or veterinary treatment

**3.4**

**package**

package holds, restrains or encloses an article/articles or commodity/commodities to be stored or transported, and is defined as in any of the following definitions:

a) one unit of a product uniformly processed, wrapped or scaled in a stream or container;

b) a quantity of items boxed or wrapped for storage or transportation; and

c) a container in which a product is packed;

**3.5**

**package system**

two groups of components, the immediate container and the protective package

**3.5.1**

**immediate container (primary package)**

container, which includes the closure and any device such as a dropper, which is in direct contact with the product during storage and transportation; it should perform the functions of preservation and protection of the content for required shelf and use life, identification of contents, quantity, quality, manufacturer, facilitates dispensing and use

**3.5.2**

**protective package**

package component which encompasses items which are not intended to be in contact with the product e.g. cartons labels, wrapping, cushioning etc; it should safeguard the contents from deterioration damage or loss between the time the package is closed and the ultimate time the user opens the package

**3.6**

**marking**

numbers, nomenclature, or symbols affixed to items or containers for identification, handling, shipment and storage.

**3.7**

**pictorial markings**

graphic symbols used for conveying the consignor's intentions regarding the handling instructions – this overcomes differences in languages or illiteracy which instructions in language of country of origin of little value



 

## 4 Symbols (and abbreviated terms)

For the purpose of this standard, symbols and pictorial marking given in ISO 780 shall be used and the following abbreviations shall apply.

a) µcg for microgram (s);

b) mg for milligram (s);

c) g for gram; and

d) mL for millilitre (s).

## 5 Requirements of a label

**5.1** A label shall be legible, neat and well balanced. The style of the label shall be appropriate to the preparation, and the size of the label shall match the container.

**5.2** The label shall remain permanently attached to the containers under all storage conditions and an area of the container shall be left uncovered to allow inspection of the contents. If the final container is not suitable for labeling (e.g.: capillary tube), it shall be in a labelled package.

**5.3** The label for internal medicines shall be in black or blue print and those for external use, shall be in red print or against a red background.

## 6 Labelling

### 6.1 General requirements

**6.1.1** The name of the medicine. The name shall be as defined according to the international pharmacopeia.

#### 6.1.2 List of ingredients and expients

A list of active ingredients showing the amount of each present. The unit shall be in percentage or metric units. 1 mg in a capsule, tablet, or other unit dosage form shall be labelled to express the quantity of each therapeutically active ingredient contained in each such a unit. Oral liquid may, alternatively, be labelled in terms of mililitres or drop portions. Distribution category – the words “Prescription Only Medicine”, “General Sales Medicine”, “DDA – Narcotic”, “Pharmacy Only” shall be indicated.

**6.1.3** A statement of the dosage form, strength and net contents.

**6.1.4** A batch number assigned by the manufacturer.

This is capable of yielding the complete manufacturing history of the specific package, including all manufacturing, filling, sterilizing and labelling operations.

**6.1.5** The date of manufacture and the expiry date, (dd/mm/yyyy).

**6.1.6** The name and physical address of manufacturer.

**6.1.7** Any special storage conditions or handling shall be specified as required by law 12/99.

**6.1.8** Indication and directions for use and any warnings that may be necessary:

a) shall be on the label for medicine sold or dispensed directly to the consumer; and

b) each package insert either as a separate entity or as an integral part of the package on which are printed in readable letters under the headings and in the format specified in annex A.

**6.1.9** Directions for use shall be given in Kinyarwanda, English and/or French languages, in addition to any other language (s).

**6.1.10** A statement "**KEEP OUT OF REACH OF CHILDREN**'' in capital letters.

**6.1.11** The label shall contain at least one of the official languages (Kinyarwanda, English or French)

## 6.2 Specific requirements for information presentation

**6.2.1** The name of medicine and strength shall be prominent. If proprietary name is used, letter of generic name should be at least half as large as letters for the proprietary name.

**6.2.2** The strength shall be in percentage metric system and expressed in the smallest whole number. Mass in micrograms should be through to 999 milligrams through 999 then grams. The abbreviations used shall be as given in 4.2.

**6.2.3** "For external use only'', for all liquids, semi-solids and solid preparations for external use.

**6.2.4** "Not to be taken", for the following:

c) liquid preparations that are not administered by mouth;

d) liquid preparations that might worry the patient because the product appears to be used internally, e.g. nasal drops, enemas, eye and ear drops;

e) unit – dose forms not intended for oral use e.g. suppositories, pessaries, inhalation capsules; and

f) solution tablets used to prepare disinfectants and antiseptic solutions.

**6.2.5** "Shake the bottle before use'', for liquid preparations which are disperse systems.

**6.2.6** For biological preparations:



 

**6.2.6.1** The recommended human dose and route of administration;

**6.2.6.2** The nature and amount of any preservative or added substance present in the product or any other inactive substances;

**6.2.6.3** The statement "**WARNING**: discard if the container is damaged or contents show presence of particles or signs of deterioration"; and

**6.2.6.4** For sterile surgical dressings the statement "**WARNING**" Sterile only if wrapper or seals unbroken, discard any unused pieces".

**6.2.7** For aerosols, the statement "**WARNING**": this container is pressurized, keep away from heat including the sun. Do not puncture or incinerate even when empty".

**6.2.8** Any information or pictorial device including proprietary name or registered trade mark (logo) may be displayed on the label provided that it is not in conflict with the requirements nor would mislead or deceive the consumer in any way whatsoever in respect of the medicine.

# Annex A
(normative)

## Format for writing/printing package inserts

Writing/printing shall be as follows:

g) name (both proprietary & international non-proprietary names and dosage form of the product

h) identification (description of the product & package)

i) content and quantity of active ingredient in a dosage unit or suitable mass or volume or unit of the product

j) pharmacology

k) therapeutic class

l) indications

m) side effects and adverse reactions (and interactions)

n) precautions and warning

o) Dosage regimen and directions for use

p) symptoms and treatment of overdose

q) presentation (Packing and pack size)

r) storage instructions and shelf life

s) name and address of registrant

t) name and address of manufacturer and country of origin

u) date of publication of the insert



 

# Bibliography

[1] ISO/IEC Directives, Part 2, *Rules for the structure and drafting of International Standards*, 2016

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