DRAFT TANZANIA STANDARD

Labeling and marking of pharmaceutical products - Specification

DRAFT TZS P3

TANZANIA BUREAU OF STANDARDS

DRAFT TANZANIA STANDARD **TBS/CDC 16 (4982) P3**

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0 Forewords

This Draft Tanzania Standard is being developed by Pharmaceuticals Technical Committee under supervision of the Chemical Division Standards Committee and this is in accordance with the procedures of the Bureau.

The main task of the technical committee is to prepare National Standards. Draft National Standards are prepared in accordance with the procedures of the Bureau.

This second edition after being finalized will cancel and replace the first edition (TZS 773:2006) which is being revised.

In preparation of this Draft Tanzania Standard referencing was made from
British Pharmacopoeia 2015 Edition
United States Pharmacopoeia 2015 Edition
Pharmaceutical Handbook 10th Ed. Edited by R.G Todd 1975.
Quality Control in Pharmaceutical Industry, volume 1 1972, Edited by Murray S. Cooper
Dispensing for Pharmaceutical Students, 12th Ed, By Cooper Gunn's 1987.
Guidelines on format and content of labels for medicinal products 1st Edition 2015 By TFDA.

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1 Scope

This Tanzania Standard specifies general mandatory and optional requirements of a label for pharmaceutical products. It also gives requirements for secondary packaging or where there is no secondary packaging, primary packaging, small containers, blisters and strips.

2 Normative references

The following referenced documents are indispensable for the application 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.

TZS 857:2005-ISO 780:1997, Packaging – Pictorial marking for handling of goods

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3 Definitions

For the purpose of this Tanzania Standard the definitions given below shall 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

designates 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 medical, dental or veterinary use

3.4 Patient information leaflet

document containing specific information about medical conditions, doses, side effects that is packed with medicines to give the user information about the product

3.5 Package insert

document provided along with a prescription or over-the-counter medication to provide additional information about that product

3.6 Primary package (Immediate container)

enclosure and any device, 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

3.7 Secondary package (Outer package)

enclosure 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.

3.8 Marking

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

pictorial markings – graphic symbols used for conveying the consignor's intentions regarding the handling instructions.

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4.GENERAL REQUIREMENTS

4.1 The label text

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

4.2 Conformity with the Summary of Product Characteristics

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

4.3 Language

The labeling shall be presented in Kiswahili and/or English.

4.4 Particulars to be included on the label

4.4.1 Secondary packaging or, where there is no secondary packaging, on the primary packaging

The label should include at least the following:

a) Trade name (Proprietary Name) where applicable
b) International Non-Proprietary name(s) of the Active Pharmaceutical Ingredient(s)
c) Amount of each Active Pharmaceutical Ingredient present in a dosage unit
d) List of excipients known to be a safety concern for some patients.
e) Pharmaceutical dosage form and contents (in volume, weight or numbers) of the product, e.g. number of dosage units, weight or volume.
f) Method and route(s) of administration
g) For primary packaging read the patient information leaflet before use.
h) 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”).
i) Other special warnings and handling precautions, if necessary (e.g. in case of specific toxicity of the agents)
j) The word “sterile” if the product is sterile
k) Batch number assigned by the manufacturer
l) The manufacturing date
m) The expiry date
n) Special storage conditions, if applicable
o) Special precautions for disposal of unused medicinal products or waste material derived from such medicinal products, if appropriate
p) The name and address of the Marketing Authorized Holder
q) Physical address of the site responsible for release of the finished product
r) Advice on general classification for distribution, e.g., Controlled Medicines, Prescription Only Medicines, Pharmacy Only Medicines, Over-the-Counter and General Sales List
s) Instruction on use
t) The proprietary name, strength and expiry date in braille
u) The registration number of the product.

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4.4.2 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): -

a) Trade Name of the Final Pharmaceutical Product(IPP), International Non-Proprietary name(INN), strength, pharmaceutical form, active substance(s)
b) Method of administration and route(s) of administration
c) Batch number assigned by the manufacturer
d) Expiry date
e) Manufacturing date if space is enough
f) Contents by weight, by volume or by unit
g) The name and address of the manufacturing site— or a logo that unambiguously identifies the company.
h) Instructions for use, and any warnings or precautions that may be necessary

4.4.3 Guidance for Blisters and strips

Blisters and strips should include, as a minimum, the following information (printed directly on the blister or strip):-

a) Name, strength and pharmaceutical form of the FPP.
b) Name and physical address of the manufacturing site (the site responsible for release of the finished product)
c) The batch number assigned by the manufacturer
d) The expiry date [Note that for co-blistered products, the expiry date is that of the product which expires first.]
e) The manufacturing date, if space is enough
f) The batch number assigned by the manufacturer
g) Instructions for use, and any warnings or precautions that may be necessary.

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5 Symbols and abbreviations

5.1 For the purpose of this Tanzania Standard, symbols and pictorial markings given in TZS 857 (see clause 2) shall be used.

5.2 For the purpose of this Tanzania Standard, the following abbreviations shall be used:

a) Mcg or µg for microgram(s)
b) mg for milligram(s)
c) g for gram, and
d) ml for millitre (s)
e) FPP for Final Pharmaceutical Product
f) INN for International Non-Proprietary Name

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