FOOD AND DRUGS AUTHORITY

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Guideline on Labelling of Drugs

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This guideline replaces 'Guideline for Labelling of Drugs' (FDA/DRI/DER/GL-LOD/2019/12).

No. 17 Indian Ocean Street, Nelson Mandela Avenue, Shiashie • Greater Accra • Ghana
P. O. Box CT 2783, Accra • GPS: GA-237-7316 • (+233) 302 233200 / 235100 • fda@fda.gov.gh

Document Revision History

Date of Revision	Version Number	Changes made and/or reasons for revision
15th March 2019	01	Initial issue
8th January 2024	02	General review of the Guideline in line with the current structure.

Guideline on Labelling of Drugs

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Executive Summary

This guideline is intended to assist applicants in complying with the requirements of labeling for finished pharmaceutical products for submission to the FDA. This guideline prescribes the minimum information required for labeling of finished pharmaceutical products.

1. Introduction

In pursuance of Section 148 of the Public Health Act, 2012 (Act 851) this guideline is hereby made to ensure the proper labelling of all finished pharmaceutical products.

1.1 Legal Basis

This guideline applies to marketing authorization applications for medicinal products submitted in accordance with Section 148 of the Public Health Act 851 of 2012.

1.2 Scope

This guideline focuses on recommendations for the proper labelling of all finished pharmaceutical products.

2. Definitions and Abbreviations

In these Guidelines, unless the context otherwise states

- ✓ **Authority**: the Food and Drugs Authority established under Section 80 of the Public Health Act, 2012.
- ✓ **Brand name:** the proprietary name of the product**.**
- ✓ **Carton:** means a large cardboard container or box in which goods are packed in smaller containers.
- ✓ **Container:** a bottle, jar, box, packet, sachet or other receptacle which contains or is to contain in it, not being a capsule or other article in which the product is or is to be administered or consumed, and where any such receptacle is or is to be contained in another receptacle, includes the former but does not include the latter receptacle.
- ✓ **Container labelling**: all information that appears on any part of a container, including that on any outer packaging such as a carton.
- ✓ **Generic:** INN or common name.
- ✓ **INN:** international non-proprietary name.

- ✓ **Label:** Means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on or attached to a container of any drug.
- ✓ **Product:** a finished pharmaceutical product.
- ✓ **PIL:** Patient information leaflet – information for the user.
- ✓ **SmPC:** summary of product characteristics – information for healthcare professionals.

3. Requirements

1. Labelling shall be informative and accurate
2. Product labels shall be printed. The print shall be in a clear font and legible.
3. The print shall be indelible and not fade when exposed to sunlight.
4. The product name, package or label shall not bear close resemblance to a previously registered product.
5. Despite the proposed name by the applicant, the Authority may reject a name on the grounds that
    a. it constitutes a safety hazard
    b. it is misleading
    c. it is established or based on international non-proprietary names
    d. it stems from a related substance or
    e. for any other sufficient reason determined by the Authority.
6. If the original label is in a language other than English (local or other foreign language), the product information shall be in English or a translation thereof.
7. All products that are not recommended for use in or by children, the statement “not to be taken by children” shall be included.
8. All products shall bear the statement “keep out of the reach and sight of children”.
9. All products meant for external use shall bear the statement “for external use only”.
10. All products meant for veterinary use shall bear the statement ‘for veterinary use only’.
11. All products locally manufactured shall bear FDA registration number.
12. For products manufactured under loan license, the name and address of the actual manufacturer should be on the product label, PIL and SmPC.
13. List of excipients of known safety concern (e.g.; lactose, gluten, metabisulfites, parabens, ethanol, tartrazine) should be stated on the secondary product label. Find information on http://www.ema.europa.eu/docs/en.

14. Please refer to the respective templates at the following sites for patient information leaflet, labels as well as summary of product characteristics (SmPC)
15. Find information on Labelling from : https://fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/TEMPLATE%20LABELLING.pdf
16. Find information on Package Information leaflet from: https://fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/TEMPLATE%20PATIENT%20INFORMATION%20LEAFLET.pdf
17. Find information on Summary of Product Characteristics from: https://fdaghana.gov.gh/images/stories/pdfs/downloads/drugs%20guidelines/TEMPLATE%20SUMMARY%20OF%20PRODUCT%20CHARACTERISTICS.pdf