South African Health Products
Regulatory Authority
Building A
Loftus Park
Arcadia
Pretoria

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GUIDELINE FOR LABELLING OF MEDICINES INTENDED FOR HUMAN USE

This guideline is intended to provide recommendations to applicants wishing to submit applications for the registration of Human Medicines (Categories A and D) containing specified substances. Regarding Category D medicines, the guidance provided herein pertains to general content requirements. Any specific technical guidance indicated in Category D medicine guidelines should be applied. In addition to this guideline, the South African Health Products Regulatory Authority (SAHPRA) reserves the right to request any additional information to establish the safety, quality, and efficacy of a medicine in keeping with the knowledge current at the time of evaluation. SAHPRA is committed to ensuring that all registered medicines meet the required standards of quality, safety, and efficacy. Guidelines and application forms are available via the SAHPRA website.

Document History

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DR BOITUMELO SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER

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Glossary

Abbreviation/ Term	Meaning
eCTD	Electronic Common Technical Document
Mock-up	**Digital** copies of the flat artwork design in full colour, presented so that, following cutting and folding where necessary, it provides a replica of both the outer and immediate packaging, so that the three-dimensional presentation of the label text is clear.
PDF	Portable Document Format
PI	Professional Information
PIL	Patient Information Leaflet
SAHPRA	South African Health Products Regulatory Authority
SmPC	Summary of Product characteristics
Specimen Samples	Samples of the actual printed outer and immediate packaging materials and package leaflet, i.e., the 'sales presentation'.
The Act	Medicines and Related Substances Act, 1965 (Act 101 of 1965, as amended)

1. INTRODUCTION

In terms of Section 35(1)(ix) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965, as amended), hereinafter 'the Act'; the Minister of Health may, in consultation with the South African Health Products Regulatory Authority (SAHPRA), make regulations prescribing the information that must be furnished regarding the use of any medicine or scheduled substance.

The General Regulations made in terms of the Act require that the labelling of medicines intended for human use be made available for each medicine (refer to Regulation 10). As such, the label is required by the Authority to be included in the application for the registration of a medicine (Regulation 16(3)(b)).

The label sets out the agreed position of the medicine as determined as an outcome of the assessment process. As such, the content cannot be changed except with the approval by SAHPRA.

The following guidelines may apply to the label (SAHPRA guidelines unless indicated otherwise):

- Scheduling of Medicines Guideline (SAHPGL-CEM-NS-02)
- Proprietary Names Guideline (SAHPGL-CEM-NS-03)
- Guideline for Professional Information for Human Medicines (Categories A and D) (SAHPGL-CEM-02)
- Complementary Medicines - Health Supplements Safety and Efficacy (7.04_CM_SE_Health_Supplements)
- Guideline For Patient Information Leaflet for Human Medicines (Categories A and D) (SAHPGL-CEM-03)
- General Information Guideline (SAHPGL-HPA-07)

1.1 Purpose

This guideline is intended to provide recommendations to applicants wishing to submit applications for the registration of Human Medicines (Categories A and D) containing specified substances, assist applicants with the correct way of presenting the label for evaluation, and enhance consistency in the content of the label.

1.2 Scope

This guideline applies to the labelling requirements for medicines submitted by applicants for the registration of human medicines (Categories A and D).

2. LEGAL PROVISION

In terms of section 35(1)(ix) of the Act, the Minister of Health may, in consultation with SAHPRA, make

regulations prescribing the information that must be furnished regarding the use of any medicine or scheduled substance. The General Regulations made in terms of the Act require the proposed labelling to be made available for each medicine as per Regulation 16(3)(b) and should comply with the requirements as set out in Regulation 10. Regulation 9 for categories and classification of medicines may be referred to as required. Additional requirements to Regulation 10 have been included in this guideline, which the proposed label should comply with.

3. GENERAL REQUIREMENTS

3.1 Minimum particulars to appear on the proposed label

The following points specify the minimum particulars to appear on the proposed label of the medicine to be submitted for registration (Category A and D):

- The immediate label and label of the other packaging label of the medicine should comply with Regulation 10 of the General Regulations of the Act as applicable.
- Sugar quantity should be stated per unit dose.
- Labels of different pack sizes of the same strength can be presented in one document (eCTD). A separate label for outer and inner packaging should be completed per strength and per dosage form.
- Category and General classification as per regulation 10 (aa) & (bb) should be specified as applicable (refer to Annexure 1 of the General Regulations of the Act for classes of medicines for Category A and D).
- Instructions on the use of the medicine should be specified on the outer packaging label; and
- Other special warning(s), if necessary.

3.2 Mock-up guidance

The following points guide the mock-up to be submitted in the application for registration of a medicine (Category A and D):

- A mock-up of the outer packaging and of the immediate packaging of the medicine must be included with the application for registration in eCTD.
- The mock-ups must be an accurate representation of the intended final packaging.

- The use of different colours to distinguish different strengths is strongly recommended.
- Colours should be chosen to provide a good contrast between the text and the background to ensure maximum legibility and accessibility of the information.

NOTE: The label should be provided to the Authority electronically in both Microsoft Word and Portable Document Format (PDF). SAHPRA reserves the right to request specimens as required.

4. REFERENCES

4.1 World Health Organization, 113 Annotated labelling template.

4.2 SAHPRA Guideline for Professional Information for Human Medicines (Categories A and D).

4.3 Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended.

4.4 General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), as amended.

4.5 Complementary Medicines - Health Supplements Safety and Efficacy (7.04_CM_SE_Health_Supplements).

4.6 Guideline For Patient Information Leaflet for Human Medicines (Categories A And D) (SAHPGL-CEM-03).

4.7 General Information Guideline (SAHPGL-HPA-07)

5. VALIDITY

This guideline is valid for a period of five (5) years from the effective date of revision. It will be reviewed within this timeframe or as and when required.