National Agency for Food & Drug Administration & Control (NAFDAC)

Registration & Regulatory Affairs (R & R) Directorate

GUIDELINES FOR THE PREPARATION OF SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) FOR DRUG PRODUCTS IN NIGERIA (HUMAN DRUGS)

SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

The NAFDAC Drugs and Related Products Registration Regulations and NAFDAC Drugs and Related Products Labelling Regulations require that drug product registration application include labelling information in accordance with extant provisions prescribed in the respective regulations. Summary of Product Characteristics (SmPC) forms an intrinsic and integral part of product information provided in the registration application and usually presented as part of section 1.3 of module 1 of product dossier in CTD format.

The SmPC sets out the agreed summary of scientific and clinical information about a drug product, and how to use the drug product safely and effectively based on information distilled during the course of regulatory assessment of the drug product application. The SmPC must be updated throughout the life cycle of the product as new data emerge, however changes are only made upon approval by the Regulatory Agency.

The SmPC is the basis of information for healthcare professionals on how to use the drug product safely and effectively. The Package Information Leaflet (PIL) is drawn up in accordance with the SmPC.

This guideline therefore provides advice on the principles of presenting information in the SmPC. Applicants should maintain the integrity of each section of the document by only including information in each section which is relevant to the section heading. Information which may need be addressed in more than one section of the SmPC, the individual statements may cross-refer to other sections of the SmPC where relevant.

PRINCIPLES:

(i) The SmPC should be worded in clear and concise language (see below regarding font size and format)
(ii) All words, statements, and other information required shall be in the English language
(iii) Consistent medical terminology should be used throughout the SmPC
(iv) The SmPC provides information on a particular drug product; therefore, it should not include reference to other drug products (e.g. through statement such as “Like other medicines of the same class …”) except when it is a class warning recommended by a competent authority.
(v) The principles set out in this guideline are applicable to all drug products except that section 4 and 5 of the SmPC for generic products should entirely be adopted from the most current version of SmPC for the corresponding innovator product as approved by a competent Regulatory Authority.
(vi) Electronic form/template is provided with practical outline on how to draw up the SmPC (refer to the agency’s website).

CONTENT:

SmPC for each product should be prepared by providing relevant and specific information under the following headings and subheadings and in the following order as outlined in the approved SmPC template:

1. NAME OF THE DRUG PRODUCT

The brand name (where applicable) and or the generic name should be followed by both the strength and the pharmaceutical/dosage form.

Strength

The strength should be consistent with the quantity stated in the quantitative composition and in the posology. Where the SmPC is presented for more than one strength of the same drug product, the applicable strengths should all be stated in the same format (e.g 25mg, 50mg 100mg) and use of decimal place should be avoided where such can easily be removed (e.g 250µg/microgram, not 0.25mg)

Pharmaceutical/Dosage form

The pharmaceutical/dosage form of a drug product should be described by a single standard term and using the plural form if appropriate (e.g., tablets).

No reference should be made to the route of administration unless this element is part of the standard term or where there is a particular safety reason for its inclusion or where there are identical products, which may be distinguished only by reference to the route of administration (e.g "XXX For Intravenous use" versus "XXXX For Intramuscular use".

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Full details of the qualitative and quantitative composition in terms of the active substance(s) and excipients, knowledge of which are essential for proper administration of the drug product, should be provided in section 2.

Excipients present in the product with specific pharmacological effect of concern as listed in the Annex to the "European Commission's *Guideline on the excipients in the label and package leaflet of medicinal product for human use*" should be stated here under a separate subheading qualitatively, and, quantitatively

The following standard statement should be included at the end of the section, i.e. 'for full list of excipients, see section 6.1'.

If a diluent is part of the medicinal product, information should be included in the relevant sections (usually sections 3, 6.1, 6.5 and 6.6).

Qualitative declaration

The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant.

Quantitative declaration

The quantity of the active substance should be expressed per dosage unit (for metered dose inhalation products, per delivered dose and/or per metered dose), per unit volume, or per unit of weight and should be related to the declaration of strength in section 1.

Salts and hydrates

Where the active substance is present in the form of a salt or hydrate, the quantitative composition should be expressed in terms of the mass (or biological activity in International (or other) units where appropriate) of the active moiety e.g. '60 mg toremifene (ascitrate)' or toremifene citrate equivalent to 60 mg toremifene'

3. PHARMACEUTICAL FORM

The pharmaceutical form should be described by a full standard term using the singular form. The term used in this section should be the same as the term used in section 1.

A visual description of the appearance of the product (colour, markings, etc.) should be given, in a separate paragraph to the standard term, e.g. for tablet "White, circular flat bevelled-edge tablets marked '100' on one side"

In case of tablets designed with a score line, information should be given on whether or not reproducible dividing of the tablets has been shown. e.g. 'the scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses', 'the tablet can be divided into equal halves.
Information on pH and osmolarity should be provided, as appropriate.
In case of products to be reconstituted before use, the appearance before reconstitution should be stated in this section. Appearance of the product after reconstitution should be stated in sections 4.2 and 6.6.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The indication(s) should be stated clearly and concisely and should define the target disease or condition distinguishing between treatment (symptomatic, curative or modifying the evolution or progression of the disease), prevention (primary or secondary) and diagnostic indication. When appropriate it should define the target population especially when restrictions to the patient populations apply.

4.2 Posology/Dosage and method of administration

Posology/Dosage

The dosage should be clearly specified for each method/route of administration and for eachindication, as appropriate.

Special populations

Dosage adjustments or other posology related information in specific patient groups should be stated where necessary, in well-defined sub-sections ordered by importance.

Method of administration

The route of administration and concise relevant instruction for correct administration and use should be given here. Information on instructions for preparation or reconstitution should be placed in section 6.6 'Special precautions for disposal of a used or unused drug product and other handling of the product and cross-referenced here.

4.3 Contraindications

Situations where the drug product must not be given for safety reasons, i.e. contraindications, are the subject of this section. Such circumstances could include a particular clinical diagnosis, concomitant diseases, demographic factors (e.g. gender, age) or predispositions (e.g. metabolic or immunological factors, a particular genotype and prior adverse reactions to the medicine or class of medicines). The situations should be unambiguously, comprehensively and clearly outlined.

4.4 Special warnings and precautions for use

The order of warnings and precautions should in principle be determined by the importance of the safety information provided.

4.5 Interaction with other drug products and other forms of interaction

This section should provide information on the potential for clinically relevant interactions based on the pharmacodynamic properties and *in vivo* pharmacokinetic studies of the medicinal product, with a particular emphasis on the interactions, which result in a recommendation regarding the use of this drug product.

4.6 Fertility, pregnancy and lactation

Efforts should be made to provide the reasons for the recommendations for use in pregnant or lactating women and in women of childbearing potential. This information is important for the healthcare professionals informing the patient.

Efforts should be made to update the recommendations for use during pregnancy and lactation on the basis of increasing human experience in exposed pregnancies which eventually supersede the animal data.

In case of contraindication, this should be included in section 4.3.
Information should be provided on use in Women of childbearing potential / Contraception in males and females, Pregnancy, Breastfeeding and effect on fertility.

4.7 Effects on ability to drive and use machines

On the basis of the pharmacodynamic and pharmacokinetic profile, reported adverse reactions and/or specific studies in a relevant target population addressing the performance related to driving and road safety or using machines, specify whether the medicinal product has a) no or negligible influence b) minor influence, c) moderate influence or d) major influence on these abilities.

4.8 Undesirable effects

This section should include all adverse reactions from clinical trials, post-approval safety studies and spontaneous reporting for which, after thorough assessment, a causal relationship between the medicinal product and the adverse event is at least a reasonable possibility, based for example, on theircomparative incidence in clinical trials, or on findings from epidemiological studies and/or on an evaluation of causality from individual case reports. Adverse events, without at least a suspected causal relationship, should not be listed in the SmPC.

4.9 Overdose

Describe acute symptoms and signs and potential sequelae of different dose levels of the drug product based on all available information including accidental intake, mistakes and suicide attempts by patients. Taking into account all relevant evidence, describe management of overdose in man, e.g. in relation to monitoring or use of specific agonists/antagonists, antidotes or methods to increase elimination of the medicinal product such as dialysis

5. PHARMACOLOGICAL PROPERTIES

Sections 5.1 – 5.3 should normally mention information, which is relevant to the prescriber and to other health-care professionals, taking into account the approved therapeutic indication(s) and the potential adverse drug reactions. Statements should be brief and precise. The sections should be updated regularly when new information becomes available, especially in relation to the pediatric population

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

5.3 Preclinical safety data

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

A list should be given of the excipients, expressed qualitatively only. All excipients, which are present in the product, should be included, even those present in small amounts, such as printing inks.

6.2 Incompatibilities

Information on physical and chemical incompatibilities of the medicinal product with other products with which it is likely to be mixed or co-administered should be stated.

6.3 Shelf life

The shelf life should be given for the drug product as packaged for sale and, if appropriate, after dilution or reconstitution or after first opening.

A clear statement of the shelf life should be given, in an appropriate unit of time, and including in-use shelf life where necessary.

6.4 Special precautions for storage

Use standard statement e.g "Do not Store Above 30^0C" reflecting the long-term stability condition used in establishing shelf-life for the drug product. Ancillary storage should be included where necessary and should be consistent across all the components of the product information e.g PIL and labels.

6.5 Nature and contents of container

Reference should be made to the immediate container; the material of construction of the immediate container should be stated ('glass vials', 'PVC/Aluminium blisters', 'HDPE bottles'); and any other component of the product should be listed.

All pack sizes should be listed. Pack sizes mentioned should include the number of units, number of doses (for e.g. multi-dose vaccines, inhalers, etc.), total weight or volume of the immediate container, as appropriate, and the number of containers present in any outer carton**.**

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Instructions for disposal should be included here, if appropriate for the product.

7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

Name and permanent address or registered place of business of the Certificate of Product Registration Holder. Telephone, fax numbers or e-mail addresses may be included (not websites or emails linking to websites).

8. DRUG PRODUCT MANUFACTURER

Name and factory address or site address of the product manufacturer.

9. NAFDAC REGISTRATION NUMBER(S)

The assigned NAFDAC Registration number should be stated here

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FORMAT /FONT SIZE:

(i) The SmPC should be worded in clear and concise language
(ii) The headings (e.g., "NAME OF THE DRUG PRODUCT") should be set in 8-point Helvetica Bold Italic, left justified.
(iii) The subheadings (e.g., "Therapeutic indications") should be set in 6-point Helvetica Bold, left justified
(iv) The information should be set in 5-point Helvetica Regular, left justified
(v) Text-selectable pdf and MS word Copy of the SmPC for each drug product should be provided.

REFERENCES:

1. Drug and Related Product Labelling Regulations 2021. https://www.nafdac.gov.ng/wp-content/uploads/Files/Resources/Regulations/REGULATIONS_2021/DRUG-AND-RELATED-PRODUCT-LABELLING-REGULATIONS-2021.pdf

2. European Commission's Guideline on Summary of Product Characteristics (SmPC). https://health.ec.europa.eu/system/files/2016-11/smpc_guideline_rev2_en_0.pdf

3. United States' CFR - Code of Federal Regulations Title 21/chapter-I/subchapter-C/part-201. https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-201