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

Drug Registration & Regulatory Affairs (DR & 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 (see appendix 1).

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

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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 the 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 the 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 each indication, 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 are cross-referenced here.

4.3 Contraindications

Situations where the drug product must not be given for safety reasons, i.e.

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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, Breast-feeding 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 their comparative 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

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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 the 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 30⁰C” 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).

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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

10. DATE OF REVISION OF THE TEXT

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>

[Additional instructions and examples]

{<example text>}

1. NAME OF THE MEDICINAL PRODUCT

{(Product) name strength pharmaceutical form}

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

[API and strength: e.g.: Each film-coated tablet contains: Lamivudine 150 mg]

Excipients with known effect:

Each tablet (unit dose) contains x mg of <excipient known to have safety concern> (add as many as present in the unit dose). Note that even if the excipient is present in the FPP below the threshold in the EC guideline, the amount of each excipient in the guideline should be specified.

Both names of the azo dyes should be given, due to different practices in different countries, e.g.: FD&C Yellow #5/Tartrazine

{For a full list of excipients, see section 6.1}

3. PHARMACEUTICAL FORM

[Include a description of the visual appearance of the product pharmaceutical form as marketed, including information on pH and osmolarity as required.

Information on appearance of reconstituted parenteral solution should appear under section 6.6.]

[e.g.: White coloured, biconvex capsule-shaped film-coated tablet having a score on one side and “XL 5” debossed on the other side.]

<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.>

<The tablet should not be divided.>

[Product scoring may be recommended or required, or scoring is specified for an innovator or comparator product(s), or when division into fractional doses may be necessary according to recommended posology.]

4. CLINICAL PARTICULARS

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4.1 Therapeutic indications

< {Product name, strength, dosage form} is indicated in <adults> <neonates> <infants> <children> <adolescents> <aged {x to y}> <years> <months>>.>

4.2 Posology and method of administration

Posology

Pediatric population

<The <safety> <and> <efficacy> of {X} in children aged {x to y} <months> <years> {or any other relevant subsets e.g. weight, pubertal age, gender} <has> <have> not <yet> been established.>

<No data are available.> <Currently available data are described in Section <4.8> <5.1> <5.2> but no recommendation on a posology can be made.>

< {Product name, strength, dosage form} should not be used in children aged {x to y} <years> <months> {or any other relevant subsets e.g. weight, pubertal age, gender} because of <safety> <efficacy> concern(s).>

<There is no relevant use of {product name, strength, dosage form} <in the pediatric population> <in children aged {x to y} <years>, <Months> {or any other relevant subsets e.g. weight, pubertal age, gender} <in the indication....>

< {Product name, strength, dosage form} is contraindicated in children aged {x to y} <years> <months> {or any other relevant subsets e.g. weight, pubertal age, gender} <in the indication...> (see Section 4.3).>

Method of administration

4.3 Contraindications

<Hypersensitivity to the active substance(s) or to any of the excipients <or {name of the residue(s)}>.>

4.4 Special warnings and precautions for use

4.5 Interaction with other medicinal products and other forms of interaction

<No interaction studies have been performed.>
<Interaction studies have only been performed in adults.>

4.6 Pregnancy and Lactation

<Pregnancy>

<Lactation>

<Fertility>

<Women of childbearing potential>
<Contraception in males and females>
<Pregnancy>
<Lactation>
<Fertility>

4.7 Effects on ability to drive and use machines

< {Product name, strength, dosage form} has <no <or negligible> influence> <minor influence>, <moderate influence> <major influence> on the ability to drive and use machines.>

<No studies on the effects on the ability to drive and use machines have been performed.>

<Not relevant.>

4.8 Undesirable effects

<Pediatric population>

4.9 Overdose

<No case of overdose has been reported.>

<If overdose occurs the patient should be monitored for evidence of toxicity and standard supportive treatment applied as necessary>

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: {group}, ATC code: {code}

<Mechanism of action>
<Pharmacodynamic effects>
<Clinical efficacy and safety>
<Resistance>
<Paediatric population>

5.2 Pharmacokinetic properties

<Absorption and Bioavailability>
<Distribution>
<Metabolism>
<Elimination>
<Special Population>

5.3 Preclinical safety data

<Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to

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reproduction and development.>

<Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.>

<Adverse reactions not observed in clinical studies, but seen in animals at exposure levels similar to clinical exposure levels and with possible relevance to clinical use were as follows:>

<Mutagenicity and Carcinogenicity>

<Reproductive toxicology>

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

[List all excipients except solvents removed during processing.] [Grades/standards should not be indicated.]

[The ingredients of mixtures (colourants, inks, capsule shells) should be listed. Flavour ingredients do not need to be listed. Only the solids of the printing ink should be included, usually shellac and black iron oxide.]

[Check colourants to ensure they are acceptable for use (EU, Japan, US lists). If a colourant is noted that is discouraged for use, a note should be made in the assessment report.]

6.2 Incompatibilities

<Not applicable.>

<In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.>

<This medicinal product must not be mixed with other medicinal products except those mentioned in Section 6.6.>

<This section is mostly of quality concern for parenteral products.>

6.3 Shelf life

[Information on the finished product shelf life and on the in-use stability after 1st opening and/or Reconstitution/dilution should appear here. Only one overall shelf life for the finished product is to be given even if different components of the product may have a different shelf life (e.g. powder & solvent).]

If different pack types differ in shelf life, this should be clear.

<...> <6 months> <...> <1 year> <18 months> <2 years> <30 months> <3 years> <...>

In-use period: <established period e.g. for hygroscopic product stored in bottles>

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6.4 Special precautions for storage

[General storage conditions of the finished product should appear here, together with a cross-reference to section 6.3 where appropriate:

<For storage conditions of the <reconstituted> <diluted> medicinal product, see Section 6.3.>

[For blisters in cartons where the carton is necessary for light protection, the statement, “Store tablets in the blisters in the provided carton” is necessary.]

6.5 Nature and contents of container

<special equipment for use, administration or implantation>

[All pack sizes must be listed. If applicable, add:]

<Not all pack sizes may be marketed.>

[The container/closure description should include all parts of the primary packaging including desiccant, void filler or adsorbent cotton filler and dosing device(s) if relevant. Dimensions/volume/capacity may be listed. Shape and colour of the bottle and the cap type (including plastic e.g. PP), should be stated.

[E.g. sealed LDPE bag, placed inside a round white HDPE bottle with plain PP screw cap and aluminium tagger (packs of 100 Tablets & 1000 Tablets)]

[For blisters in cartons where the carton is necessary for light protection, the carton is an important aspect of the package description.]

<Not all pack sizes may be marketed.>

6.6 Special precautions for disposal <and other handling>

[Include practical instructions for preparation and handling of the product including disposal of the medicinal product, and waste materials derived from the used medicinal product.]

[Information on appearance of reconstituted parenteral solution should appear here]

<No special requirements.>

<Any unused product or waste material should be disposed of in accordance with local requirements.

7. <APPLICANT/MANUFACTURER>

{Name and address}

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< {Tel} >

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