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SMPC STANDARD EVALUATION GUIDELINE IRD-KLVZ-10

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Standard Evaluation Procedure for the Summary of Product Characteristics:

Objective: The objective of this procedure is to ensure the standard evaluation of Summaries of Product Characteristics and to enable SmPCs prepared differently to be presented to healthcare personnel in a standardized manner. These procedures are dynamic and may be modified according to prevailing conditions.

Evaluation Criteria: 1. Evaluation in Terms of Format: SmPCs shall be prepared under the headings set out in the guideline published on 19.1.2007.

The SmPC shall be written as described below.

After "SUMMARY OF PRODUCT CHARACTERISTICS" is written in bold, centered at the top of the first page, in 12-point Times New Roman font;

Product name: The trade name shall be in capital letters, and the strength and form in lower-case letters. In the sections of the SmPC where the product name appears, only the trade name shall be stated in capital letters, without specifying the strength and form. All main headings: shall be written in bold and capital letters. a) Sub-headings under the main heading shall be written in bold, with the first letter capitalized and the remaining letters in lower case. b) The font of headings that may appear under sub-headings shall be determined on the basis of the format set out in the evaluation section in terms of content. A 12-point Times New Roman font shall be used throughout the text.

For imported/licensed manufactured medicinal products, if the medicinal product is authorized in the country from which it is imported, the original SmPC shall be submitted during the evaluation; for generic products, the original approved SmPC of the original molecule shall be submitted. If the original SmPC is not in English, it shall be translated into Turkish and submitted to the Ministry.

It must be borne in mind that the SmPC is an important tool for conveying information to healthcare personnel.

II. Evaluation in Terms of Content: SmPCs shall be reviewed in accordance with the guideline published on 19.1.2007. Through this review, it shall be ensured that the headings specified in the SmPC guideline and listed below, and in particular the information intended to be emphasized, are complete in accordance with the information contained in the SmPC guideline:

1-NAME OF THE MEDICINAL PRODUCT The trade name shall be in capital letters, and the strength and form in lower-case letters. **2-QUALITATIVE AND QUANTITATIVE COMPOSITION** Active substance: shall be stated qualitatively and quantitatively Excipient(s): If the medicinal product in question contains only excipients listed in the guideline concerning excipients, the qualitative and quantitative information on those substances shall be provided in this section; if the excipients are not substances included in the guideline, it is sufficient to state only: "See section 6.1 for excipients."

Qualitative and quantitative information on active substances and on excipients that are necessary and important for the correct administration of the medicinal product shall be stated in full. Detailed information on these excipients shall be provided in section 4.3 or 4.4 of the SmPC

guideline. For this section, reference should be made to the "Excipients in the Packaging and Patient Information Leaflet of Human Medicinal Products" guideline.

Where the solvent forms part of the medicinal product, information shall be provided in the relevant sections (usually sections 3, 6.1, 6.5 and 6.6 of the guideline).

3. PHARMACEUTICAL FORM The first line shall state the pharmaceutical form. The second line shall provide a visual description of its appearance (pH, osmolarity, colour, score mark, etc.). For tablets designed with a score line, information shall be provided as to whether the tablets can or cannot be divided in a reproducible manner (Example: The score line is intended solely to facilitate breaking of the tablet for swallowing, not to divide it into equal doses; the tablet can be divided into equal halves). For products requiring reconstitution prior to use, the appearance before reconstitution shall be described in this section. The appearance of the product after reconstitution shall be described in section 4.2.

4. CLINICAL PARTICULARS 4.1. Therapeutic indications

4.2. Posology and method of administration Posology/frequency and duration of administration: These may be presented under a single heading or, depending on the characteristics of the medicinal product, as separate headings of "Posology" and "Frequency and duration of administration".

Method of administration:

Additional information on special populations: The sub-headings under this heading — renal/hepatic impairment, paediatric population, geriatric population — must be included, and where use is not applicable, the necessary explanation must be provided. Renal/Hepatic impairment: These headings may be presented together or under separate headings. Paediatric population: Geriatric population: . Other (if applicable).

shall be presented in the order given above. The information to be provided under the headings and sub-headings listed above shall be written in normal text colour, even if it appears within a heading. In writing these sections, care shall be taken to use the wording given in the guidelines.

4.3. Contraindications

Contraindications relating to the active substance and excipients (see the "Excipients in the Packaging and Patient Information Leaflet of Human Medicinal Products" guideline) shall be presented in list form, one below the other, in a manner that the reader can quickly understand.

4.4. Special warnings and precautions for use All information to be provided under this section, including headings, shall be written in normal text colour. The information provided in the Contraindications section shall not be repeated here.

In this section, the "special warnings" and "precautions" specifically related to the use of the medicinal product in question shall be explained in separate paragraphs, one below the other, for each different situation. Narration in a single paragraph shall be avoided. Each warning and precaution shall be explained in a separate paragraph in a manner comprehensible to healthcare personnel.

If necessary, particularly important safety-related information may be presented in bold text within a box.

4.5. Interactions with other medicinal products and other forms of interaction All information to be provided under this section, including headings, must be in normal font colour. If no interaction studies have been performed, this must also be clearly stated.

Additional information on special populations All information to be provided under this section, including headings, must be in normal font colour. If no interaction studies have been performed, this must also be clearly stated.

Paediatric population: All information to be provided under this section, including headings, must be in normal font colour. If no interaction studies have been performed, this must also be clearly stated.

4.6. Pregnancy and lactation General advice The pregnancy category must be specified. (Example: A, B, C...).

Women of childbearing potential/Contraception (see SPC Annex-1) This paragraph should then be continued with the standard sentences provided in SPC Annex-1.

Pregnancy

Lactation For the breastfeeding period, the standard sentences provided in Annex-3 of the guideline (SmPC Guideline) must be used.

Fertility All headings in this section must be included, and where not applicable, the necessary explanation must be provided.

4.7. Effects on ability to drive and use machines The effect of the medicinal product on the ability to drive and use machines must be stated, and the paragraph must be concluded with a concluding sentence (Example: Patients should be warned not to drive cars, etc.). However, if the product has no effect on the ability to drive and use machines, this must also be stated in this section.

4.8. Undesirable effects For some products, where a brief explanation has been given before the percentages, the standard statement below must appear immediately beneath that explanation, in normal font (not italic and not bold). Very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$), not known (cannot be estimated from the available data).

Undesirable effects must be presented according to the MedDRA system, and a standard narrative and presentation of information must be ensured. The warnings relating to the systems listed under the undesirable effects must be written in bold, while terms such as common and uncommon must be written in normal font, according to the percentages, with punctuation. Example: Nervous system disorders Common:

Note: in some cases, the term "disorder" may be used instead of "disease". Undesirable effects may be presented in table form, provided that they are given according to the MedDRA system. Important warnings related to undesirable effects must be written in bold at the beginning of this section and enclosed in a box.

Additional information on special populations: If there is additional information on special populations, it must be provided in accordance with the ordering set out in section 4.2 of the guideline. If there is none, this heading and its sub-headings are not required. Example: Paediatric population: If there is additional information on paediatric populations, it must be provided in accordance with the ordering set out in section 4.2 of the guideline. If there is none, this heading and its sub-headings are not required.

4.9. Overdose and treatment Here, information on clinical symptoms associated with overdose and (where available) on their treatment (if any) must be provided.

5. PHARMACOLOGICAL PROPERTIES 5.1. Pharmacodynamic properties Pharmacotherapeutic group

The section must begin with the ATC code. This section must be written scientifically, in the order specified in the guideline and in a manner comprehensible to healthcare professionals. In these descriptions, the mechanism of action, efficacy and safety of the medicinal product must be explained by referring to preclinical and clinical studies (without referencing). Figures and graphs may be used in the descriptions. All presentations and graphs are required to be in Turkish.

5.2. Pharmacokinetic properties General properties

If a brief explanation has been provided under the heading "General properties" before proceeding to the sub-headings absorption, distribution, biotransformation, elimination, linearity/non-linearity status, this is acceptable. Subsequently, the sub-headings absorption, distribution, biotransformation, elimination, linearity/non-linearity status must be presented in plain, underlined form with punctuation marks. Characteristics in patients If there is information to be provided under this section, this heading and the information shall be included. The sub-headings to be included under this section must be presented in plain colour, underlined, with punctuation marks. If there is no information to be provided under this section, this section, including the heading, shall not be included. Pharmacokinetic/pharmacodynamic relationships (if available)

5.3. Preclinical safety data The preclinical safety of the medicinal product must be described using the standard sentences provided in the guideline.

6. PHARMACEUTICAL PROPERTIES

6.1. List of excipients All excipients must be listed qualitatively in a single list, without sub-headings (example: all substances constituting the coating, the explicit formulae of colouring agents, including solvent content, etc.).

6.2. Incompatibilities 6.3. Shelf life (must be stated in months) 6.4. Special precautions for storage This section must not contain a general warning sentence regarding children.

6.5. Nature and contents of container 6.6. Special precautions for disposal and other handling of unused human medicinal products Where applicable, the following statement must be added: "Unused products or waste materials shall be disposed of in accordance with the 'Regulation on the Control of Medical Wastes' and the 'Regulations on the Control of Packaging and Packaging Waste'." Where instructions are necessary to assist healthcare professionals regarding the administration of the product, this information must also be provided at the end of this section. If there are other special precautions, they must be stated in this section, taking the guideline into consideration.

7. MARKETING AUTHORISATION HOLDER 8. MARKETING AUTHORISATION NUMBER(S) 9. DATE OF FIRST MARKETING AUTHORISATION/RENEWAL OF MARKETING AUTHORISATION Date of first marketing authorisation: Date of renewal of marketing authorisation: 10. DATE OF REVISION OF THE SmPC 11. DOSIMETRY (IF APPLICABLE) 12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

OTHER INFORMATION AND DOCUMENTS TO BE SUBMITTED UPON SUBMISSION OF THE SmPC TO THE MINISTRY Photocopies of the sections of the scientific sources utilised in the preparation of the SmPC shall be submitted to the Ministry in a file format.

OTHER SOURCES TO BE PREPARED BY THE MINISTRY The sources to be used for ensuring terminological consistency in Turkish translation will be announced by the Ministry in due course.

Entry into force : This Guideline enters into force upon approval by the President of the Agency. Execution : The President of the Agency shall execute the provisions of this Guideline.

REVISION HISTORY Revision No Revision Date Justification and Explanations 01 18.11.2022 An update to the format of the Guideline has been carried out.

Annex 1 This annex is under review for updating. However, the situations described below remain valid. If the pregnancy category of the medicinal product is X, the following statements should be used. 1. {Generic name} causes/is suspected of causing serious birth defects when administered during pregnancy. {Trade name} is contraindicated during pregnancy (see section 4.3 only if there is an absolute contraindication). and if necessary Women of childbearing potential must use effective contraception during treatment (and for up to x weeks after treatment).

If the pregnancy category of the medicinal product is D, the following statements should be used.

2. {Generic name} has harmful pharmacological effects on pregnancy and/or the fetus/newborn. {Trade name} should not be used during pregnancy unless necessary (the conditions for this should be specified).

If the pregnancy category of the medicinal product is C, the following statements should be used.

3. There are no adequate data on the use of {Generic name} in pregnant women. Studies in animals have shown reproductive toxicity (see section 5.3). The potential risk to humans is unknown. or Animal studies are inadequate with regard to effects on pregnancy /and-or/ embryonal/fetal development /and-or/ parturition /and-or/ postnatal development (see section 5.3). The potential risk to humans is unknown. {Trade name} should not be used during pregnancy unless necessary (the conditions for this should be specified).

If the pregnancy category of the medicinal product is B, the following statements should be used. 4. For {Generic name}, there are no clinical data on exposure during pregnancy. Animal studies do not show direct or indirect harmful effects with respect to pregnancy / embryonal / fetal development / parturition or postnatal development (see section 5.3).

Caution should be exercised when administered to pregnant women. 5. Data from a limited number (.....) of exposure cases during pregnancy do not show adverse effects of {Generic name} on pregnancy or on the health of the fetus/newborn infant. No significant epidemiological data have been obtained to date. Studies in animals have shown reproductive toxicity (see section 5.3). The potential risk to humans is unknown. or Animal studies are inadequate with regard to effects on pregnancy /and-or/ embryonal/fetal development /and-or/ parturition /and-or/ postnatal development (see section 5.3). The potential risk to humans is unknown. Caution should be exercised when administered to pregnant women. 6. Data from a limited number (.....) of exposure cases during pregnancy do not show adverse effects of {Generic name} on pregnancy or on the health of the fetus/newborn infant. No significant epidemiological data have been obtained to date. Animal studies do not show direct or indirect harmful effects with respect to pregnancy / embryonal / fetal development / parturition or postnatal development (see section 5.3). Caution should be exercised when administered to pregnant women. 7. Data from a large number (.....) of exposure cases during pregnancy do not show adverse effects of {Generic name} on pregnancy or on the health of the fetus/newborn infant. No significant epidemiological data have been obtained to date. Caution should be exercised when administered to pregnant women.

If the pregnancy category of the medicinal product is A, the following statements should be used.

8. Well-conducted epidemiological studies do not show adverse effects of {Generic name} on pregnancy or on the health of the fetus/newborn infant. {Trade name} may be used during pregnancy.

After the pregnancy categories of the medicinal product have been stated, the following statements should additionally be included, where applicable.

9. In the case of an interaction with oral contraceptives, information should additionally be provided in section 4.5. {Generic name} interacts with oral contraceptives. Therefore, an alternative, effective and reliable method of contraception should be used during treatment (and for up to x weeks after treatment). or Concomitant use of {Generic name} causes an interaction with oral contraceptives. Therefore, an alternative, effective and reliable method of contraception should be used during treatment (and for up to x weeks after treatment).

10. In the case of male-mediated effects in the pregnancy information, information should additionally be provided in section 4.4. Both sexually active men and women should use effective contraceptive methods during treatment (and for up to x weeks after treatment).