# ANNOTATED SUMMARY OF PRODUCT (SmPC) CHARACTERISTICS TEMPLATE

[Should the product to which a completed Summary of Product Characteristics (SmPC) refers be prequalified, the completed SmPC(s) will form Part 4 of the WHO Public Assessment Report that will be posted on the website of the WHO Prequalification Team: medicines (PQTm).

During evaluation for prequalification, applicants may present SmPCs for different strengths within one document, but they should indicate clearly, through use of grey-shaded titles, the strength or presentation to which alternative text elements refer. However, a separate SmPC, per strength and per pharmaceutical form, containing all pack-sizes related to the strength and pharmaceutical form concerned, will have to be provided by the applicant.

Standard statements are provided in the template. These should be used whenever they are applicable. Any use — to accommodate product-specific requirements — of alternative or additional statements will be reviewed by WHO on a case-by-case basis.

*Please also consult the prequalification guidance document:* Ensuring Consistency Between Product Information Documents.

<text> signifies text to be selected or deleted as appropriate.

{text} refers to information to be added.]

1. **NAME OF THE MEDICINAL PRODUCT**

{(Invented) name strength pharmaceutical form}

[® ™ symbols should not be included here or anywhere else in the SmPC. “Tablets” or “capsules” should be used, rather than “tablet” or “capsule”.]

1. **QUALITATIVE AND QUANTITATIVE COMPOSITION**

[Name of the active substance(s) in the language of the text.]

*[Qualitative and quantitative composition in terms of the active substances and constituents of the excipient, knowledge of which is essential for proper administration of the medicinal product. The usual common name or chemical description should be used. See also* Guideline on Excipients in the Dossier for Application for Marketing Authorisation of a Medicinal Product of the Committee for Medicinal Products for Human Use*, and the European Medicines Agency’s guidance on excipients labelling.]*

<Excipient(s):>

For a full list of excipients, see Section 6.1.

1. **PHARMACEUTICAL FORM**

[The pharmaceutical form should be stated according to those defined in the Standard Terms database, of the European Directorate for Quality of Medicines and HealthCare, in the singular. Where the Standard Terms database short standard term is used on small immediate packaging materials, the short term should be added in brackets.]

[Include here 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.]

<The score line is only to facilitate breaking for ease of swallowing and not to divide into equal doses.>

<The tablet can be divided into equal halves.>

1. **CLINICAL PARTICULARS**
   1. **Therapeutic indications**

*[Specify, if appropriate* <This medicinal product is for diagnostic use only.> If applicable, results of clinical trials should be included under Section 5.1.]

* 1. **Posology and method of administration**

[In case of restricted medical prescription, start this section by the relevant conditions.

Method of administration: directions for proper use by healthcare professionals or by the patient. Further practical details for the patient can be included in the Patient Information Leaflet, e.g. in the case of inhalers, subcutaneous self-injection.

Instructions for preparation should be placed under Section 6.6 or 12, and cross-referenced here.]

<{(Invented) name} is not recommended for use in children <above> <below> {age Y} due to <a lack of> <insufficient> data on <safety> <and> <or> <efficacy> <(see section <5.1> <5.2>)>.>

<The experience in children is limited.>

<There is no experience in children> <(see section <4.4> <5.2>)>.>

<There is no relevant indication for use of {(Invented) name} in children.>

<{(Invented) name} is contraindicated in children (see section 4.3).>

* 1. **Contraindications**

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

* 1. **Special warnings and precautions for use**
  2. **Interaction with other medicinal products and other forms of interaction**

<No interaction studies have been performed.>

<Interaction studies have been performed only in adults.>

* 1. **Pregnancy and lactation**

[See prequalification guidance: Section Guidance for Part 4 — Summary of Product Characteristics (SmPC) — of a WHO Public Assessment Report (WHOPAR).]

[Results from reproduction toxicology to be included under Section 5.3 and cross-referenced here, if necessary.]

* 1. **Effects on ability to drive and use machines**

<{Invented name} has <<no> or negligible> influence> <minor or moderate influence> <major influence> on the ability to drive and use machines.> *[Describe effects where applicable.]*

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

<Not relevant.>

* 1. **Undesirable effects**

*[*See *prequalification guidance*: Section Guidance for Part 4 — Summary of Product Characteristics (SmPC) — of a WHO Public Assessment Report (WHOPAR).*]*.

Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

* 1. **Overdose**

[Describe the symptoms, emergency procedures, and antidotes (if available) in case of overdose.]

<No case of overdose has been reported.>

1. **PHARMACOLOGICAL PROPERTIES**
   1. **Pharmacodynamic properties**

Pharmacotherapeutic group: {group *[lowest available level]*}, ATC code: {code}

[For products approved under “conditional approval”, include the following statement:]

<This medicinal product has been authorized under a so-called “conditional approval” scheme. This means that further evidence on this medicinal product is awaited. The European Medicines Agency (EMA) will review new information on the product every year and this SmPC will be updated as necessary.>

[For products approved under “exceptional circumstances”, include the following statement:]

<This medicinal product has been authorized under “Exceptional Circumstances”. This means that due to <the rarity of the disease> <for scientific reasons> <for ethical reasons> it has not been possible to obtain complete information on this medicinal product. EMA will review any new information which may become available every year and this SmPC will be updated as necessary.>

* 1. **Pharmacokinetic properties**
  2. **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 reproduction.>

<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:>

1. **PHARMACEUTICAL PARTICULARS**
   1. **List of excipients**

[Each to be listed on a separate line according to the different parts of the product.]

[Name of the excipient(s) in the language of the text.]

* 1. **Incompatibilities**

<Not applicable.> *[If appropriate, e.g. for solid oral pharmaceutical forms.]*

<In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.> *[e.g. for parenterals.]*

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

* 1. **Shelf life**

[Information on the finished product shelf life and on the in-use stability after first 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 and solvent).]

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

* 1. **Special precautions for storage**

*[For storage condition statements see prequalification guidance*: Section Guidance for Part 4 — Summary of Product Characteristics (SmPC) — of a WHO Public Assessment Report (WHOPAR).*]*.

*[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>*]*

* 1. **Nature and contents of container**

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

<Not all pack sizes may be marketed.>

* 1. **Special precautions for disposal**

[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.]

<No special requirements.>

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

1. **APPLICANT/SUPPLIER**

[Country name in the language of the text. Telephone, fax numbers or email addresses may be included (but no websites or emails linking to websites).]

{Name and address}

<{tel}>

<{fax}>

<{email}>

**8. WHO PREQUALIFICATION REFERENCE NUMBER**

<……...>

1. **DATE OF PREQUALIFICATION/RENEWAL OF PREQUALIFICATION**

<{DD/MM/YYYY}> <{DD month YYYY}>

[Item to be completed by the applicant once prequalification has been granted or renewed. The date should not reflect approvals linked to subsequent variations. Both the date of prequalification and, if prequalification has been renewed, the date of the (last) renewal should be stated in the format given in the following example:

Date of prequalfiication: 3 April 1985. Date of last renewal: 3 April 2000.]

1. **DATE OF REVISION OF THE TEXT**

[Item to be completed by the Applicant at time of printing once a change to the SmPC has been approved..]

{MM/YYYY}

**Reference list**

*[This list provides references to relevant WHO guidelines and to relevant literature and databases, in addition to the SmPC(s) of the innovator product(s). The list is compiled by WHO.]*

*[It is recommended that the following reference to PQTm’s website is included:*

<Detailed information on this product is available on the PQTm website. (See:

http://www.who.int/prequal)>*]*