Quality Information Summary (QIS) of the Biotherapeutic Product Approved by Stringent Regulatory Authority (SRA)

(QIS-BTP-SRA)

**FOREWORD**

Reference is made to the WHO:

“WHO Pilot Procedure for Prequalification of Biotherapeutic Products: human insulin” and the “WHO Guidelines on submission of documentation for the pilot procedure for prequalification of human insulin approved by stringent regulatory authorities – abridged assessment pathway”

The QIS-BTP-SRA template should be completed so that it provides a condensed summary of key information of the biotherapeutic product (BTP) for h-insulin or its corresponding similar biotherapeutic product (SBP) that is approved by a stringent regulatory authority. It should be submitted in Word format together with the application for prequalification according to the requirements of the above guideline.

Information about the BTP Drug Product (DP) as well as the BTP Drug Substance (DS) is requested.

Section A1 of the template is applicable to all BTP and corresponding SBP applications. It contains information that may be published on the WHO prequalification website. Section A2 is to be completed only for SBP applications. It relates to the reference biotherapeutic product (RBP) used as the comparator for the similarity studies with the SBP. Only publicly available information about the RBP is to be provided in section A2. The references of the corresponding source of information are to be provided under section A2-14.

Section B of the template encompasses information which is either publicly available (e.g., qualitative composition of the excipients) or not publicly available (e.g., DP specification, quantitative composition of the excipients). Section B will not be disclosed to public. Sections B1 and B3 and B5 are applicable to both BTP and SBP applications, whereas sections B2 and B4 are only applicable to SBP applications.

The QIS-BTP-SRA should be revised (using track change mode) and resubmitted in Word format:

* whenever any administrative changes are necessary (e.g. change of contact person), or
* whenever any variations to the drug product that affect the QIS-BTP-SRA have been approved by the SRA, together with the regulatory letter of approval of the variation(s).

**When completing the QIS-BTP-SRA template, this covering *Foreword* should be deleted.**

**A1. Biotherapeutic Product (BTP) or corresponding Similar Biotherapeutic Product (SBP) information (as currently approved by SRA) that may be published on the WHO prequalification website**

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| --- |
| A1-1. Product reference number (WHO number) |
|  |
| A1-2. Stringent regulatory authority |
|  |
| A1-3. Name of the holder of the Marketing Authorization and official address |
|  |
| A1-4. Proprietary name of the drug product (DP) in the SRA country/region |
|  |
| A1-5. INN of drug substance (DS) |
|  |
| A1-6. Dosage form and strength |
|  |
| A1-7. Description of the DP (as in Product Information, e.g. powder for concentrate for solution for infusion; concentrate for solution for infusion, white powder, clear, colourless liquid, excipients) |
|  |
| A1-8. Description of the DS. Brief description of the molecular features, brief description of the manufacturing process (producing cell line, purification methods, presence of viral inactivation steps, etc.) |
|  |
| A1-9. Primary and secondary packaging material(s) and pack size(s) (all pack types) |
|  |
| A1-10. Storage conditions (as in Product Information) and any special precautions for storage (including storage conditions after reconstitution/first opening, where applicable) |
|  |
| A1-11. Shelf-life of the DP (including in-use period and conditions, where applicable) |
|  |
| A1-12. Names of all approved manufacturers of DP, physical address(es) of manufacturing site(s) (and unit if applicable), including intermediates, primary packaging site and release testing (indicate function of each site) |
|  |
| A1-13. Names of all approved DS manufacturers, physical address(es) of manufacturing site(s) (and unit if applicable), including intermediates, contractors and release testing (indicate function of each site) |
|  |

**A2. Reference Biotherapeutic product (RBP) information (as approved by the SRA at the time of submission of the SBP application) that may be published on the WHO prequalification website**

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| A2-1. Product reference number (WHO number), if applicable. |
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| A2-2. Stringent regulatory authority |
|  |
| A2-3. Name of the holder of the Marketing Authorization and official address |
|  |
| A2-4. Proprietary name of the drug product (DP) in the SRA country/region |
|  |
| A2-5. INN of DS |
|  |
| A2-6. Dosage form and strength |
|  |
| A2-7. Description of the DP (as in Product Information, e.g. powder for concentrate for solution for infusion; concentrate for solution for infusion, white powder, clear, colourless liquid, excipients) |
|  |
| A2-8. Description of the DS. Brief description of the molecular, brief description of the manufacturing process (producing cell line, purification methods, presence of viral inactivation steps, etc.) |
|  |
| A2-9. Primary and secondary packaging material(s) and pack size(s) (all pack types) ) if available |
|  |
| A2-10. Storage conditions (as in Product Information) and any special precautions for storage (including storage conditions after reconstitution/first opening, where applicable) |
|  |
| A2-11. Shelf-life of the DP (including in-use period and conditions, where applicable) |
|  |
| A2-12. Names of all approved manufacturers of DP, physical address(es) of manufacturing site(s) (and unit if applicable), including intermediates, primary packaging site and release testing (indicate function of each site) if available |
|  |
| A2-13. Names of all approved DS manufacturers, physical address(es) of manufacturing site(s) (and unit if applicable), including intermediates, contractors and release testing (indicate function of each site) if available |
|  |
| A2-14. References/source of information with corresponding URL addresses (e.g. labeling, EU SmPC, EPAR – Scientific Discussion, PMDA Review reports, FDA Chemistry review, scientific literature…) |
|  |

**BTP or corresponding SBP information (as currently approved by the SRA) that will not be made publicly available**

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| **B1. Composition (formulation) information** | | | | | | |
| Component and quality standard | Function | Unit composition | | | Batch composition (largest approved size) | |
| Quantity per unit or per ml | %  (if applicable) | | Theoretical quantity / batch | %  (if applicable) |
| <complete with appropriate title, e.g., active ingredients, excipients> | | | | | | |
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| Batch size in number of units/L, where applicable | | | |  | | |
| Additionally approved batch sizes — in number of units or L, where applicable (add as many rows as necessary) | | | |  | | |
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| Excipients with known effects if applicable | | | | | | |

**RBP information (as currently approved by the SRA) that will not be made publicly available**

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| --- | --- | --- | --- |
| **B2. Composition (formulation) information (Applicable for a SBP submitted for prequalification)** | | | |
| Name of the RBP | | | |
| Component and quality standard | Function | Unit composition | |
| Quantity per unit or per ml | % (if applicable) |
| <complete with appropriate title, e.g., active ingredients, excipients> | | | |
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| Excipients with known effects if applicable | | | |

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| B3. BTP drug product specifications | | | |
| Standard (e.g. International Pharmacopoeia, European Pharmacopoeia, United States Pharmacopeia, British Pharmacopoeia) if available | | |  |
| Specification reference number and version / effective date | | |  |
| Test | Acceptance criteria  (release) | Acceptance criteria  (shelf-life) | Analytical procedure  (type/source/version) |
| Visual appearance |  |  |  |
| Identity |  |  |  |
| Potency |  |  |  |
| Impurities |  |  |  |
| Endotoxin |  |  |  |
| Sterility |  |  |  |
| etc. |  |  |  |
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| B4. Pharmacokinetic / safety / efficacy related information used for SRA approval of the SBP. Indicate: (Applicable for a SBP submitted for prequalification) | | | |
| Name of the RBP | |  | |
| Name of the holder of the Marketing Authorization of the RBP | |  | |
| **Type of study** | | | “X” in appropriate box |
| Comparability exercise/ similarity exercise (head-to-head comparability studies with the SBP in order to show similarity in terms of | quality | |  |
| safety/non-clinical | |  |
| efficacy/clinical | |  |
| Other (specify) (e.g., pharmaco-toxicological assessment, design of the use of pharmacodynamic markers, pharmacovigilance studies potentially performed, extrapolation of safety and efficacy) | - | |  |
| - | |  |
| - | |  |
| Notes / clarifications |  | | |

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| B5. Contact information for communication with WHO | |
| Contact person and postal address |  |
| (International code) Telephone number |  |
| (International code) Fax number |  |
| Email address |  |

**Key documentation linked to the present submission**

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| --- | --- | --- | --- |
| Document name | Document version | File name | Revision/variation description |
| SRA approved DS/DP manufacturers |  |  |  |
| Product Quality Review |  |  |  |
| Prequalification-specific addendum to the RMP |  |  |  |
| Currently approved DP specifications |  |  |  |
| Etc. |  |  |  |
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**Change history to QIS-BTP-SRA and product information**

**Date of preparation of original QIS-BTP-SRA: ……………………**

|  |  |
| --- | --- |
| Date of revision  (reported variation\*) | Revision/variation description |
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\* Variations approved by the SRA after prequalification of the Drug product and affecting only the QIS-BTP-SRA and/or Product Information should be reported in the change history.