**Annex 4b QIS-RI-BTP**

**Quality Information Summary (QIS) of the Biotherapeutic Product Approved by a Reference Institution (RI) (QIS-RI-BTP)**

**A1. Biotherapeutic Product (BTP) or corresponding Similar Biotherapeutic Product (SBP) information (as currently approved by RI)**

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| --- |
| A1-1. Product reference number (RI number)  |
|  |
| A1-2. Reference institution |
|  |
| A1-3. Name of the holder of the Marketing Authorization and official address |
|  |
| A1-4. Proprietary name of the drug product (DP) in the RI country/region |
|  |
| A1-5. International Nonproprietary Name (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 (e.g. engineered mouse/humanized/fully human monoclonal antibody, type of IgG), 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 RI at the time of submission of the SBP application)**

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| A2-1. Product reference number (RI number), if applicable. |
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| A2-2. Reference institution |
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| A2-3. Name of the holder of the Marketing Authorization and official address |
|  |
| A2-4. Proprietary name of the drug product (DP) in the RI 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 features (e.g. engineered mouse/humanized/fully human monoclonal antibody, type of IgG), 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 |
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| 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 |
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| A2-14. References/source of information with corresponding URL addresses (e.g. labelling, EU SmPC, EPAR – Scientific Discussion, PMDA Review reports, FDA Chemistry review, scientific literature…) |
|  |

**BTP or corresponding SBP information (as currently approved by the RI) 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) |  |
|  |
|  |
| Excipients with known effects if applicable |

**RBP information (as currently approved by the RI) 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, British Pharmacopoeia, United States Pharmacopeia) 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 RI approval of the SBP. Indicate: (Applicable for a SBP submitted for prequalification) |
| Name of the RBP |  |
| Name of the holder of the Marketing Authorisation 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 RI |
| Contact person and postal address |  |
| (International code) Telephone number |  |
| (International code) Fax number |  |
| Email address |  |

**Change history to QIS-RI and product information**

**Date of preparation of original QIS-RI: ……………………**

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