Screening Checklist for Biotherapeutic Products and their corresponding SBPs

Abridged pathway

# Part A – Administrative Information (WHO Guidelines on submission of documentation for the pilot procedure for prequalification of rituximab or trastuzumab approved by stringent regulatory authorities)

**Originator Biotherapeutic Product (BTP) or Similar Biotherapeutic Product (SBP) information**

|  |  |  |
| --- | --- | --- |
| **Dossier screening #** | **Applicant short name** | **Submission date** |
|  |  |  |
| **Screening date** | **Recommendation** |
|  |  |
| **Proprietary name of the drug product (DP) of originator BTP or corresponding SBP in the SRA country/region**  |
|  |
| **Name of the drug substance for the current application for rituximab or trastuzumab originator BTPs or their corresponding SBPs** |
|  |
| **Strength** |
|  |
| **Is the product strength invited (listed in EOI)?** (If not: **STOP SCREENING** and comment – note that some manufacturers may be claiming as a strength a nominal fill amount rather than what is delivered from the presentation. This should not result in outright rejection of the dossier but will require a clarification). The naming of the product strength should be in the form indicated in the EOI. |
|  |
| **Packaging, pack sizes and shelf life** for each different packaging format |
|  |
| **Has the candidate originator BTP or corresponding SBP been registered by SRA(s)?** |
|  |
| **Is the Application correctly applying for the Abridged assessment pathway (i.e. or is there an indication the product was NOT accepted by an SRA or is NOT currently on the SRA market)?**  |
|  |
| **Is evidence provided that the originator BTP or SBP is currently on the market of the SRA region/country?** |
|  |
| **Reference Stringent regulatory authority name** |
|  |
| **When the candidate product is an SBP, is the indication the same as per RBP SmPC?** |
|  |
| **Has a covering letter been submitted, expressing interest in participating in the WHO prequalification procedure and confirming that the information submitted in the product dossier is complete and correct?** |
|  |
| **Proprietary name of the drug product (DP) RBP in the SRA country/region**  |
|  |
| **RBP, name of marketing holder (if applicable)** |
|  |
| **Stringent regulatory authority that approved the RBP (if applicable)**  |
|  |
| **Is all documentation in English and/or it includes officially certified English translations (i.e. product information)?** |
|  |
| **Name of the holder of the Marketing Authorization and official address (must be in English)** |
|  |
| **Full name of applicant and official address** |
|  |
| **Is the applicant for prequalification same as the marketing authorization holder? If not, has supporting documentation defining the responsibilities of the PQ applicant and the MA been submitted? The applicant and MAH must be of the same group of companies. The applicant should be the MAH**  |
|  |
| **Name, title and contact details of the designated contact person** |
|  |

# Part B – Document required by WHO Guidelines on submission of documentation for abridged assessment

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Originator BTP or SBP****Only for SBPs** |  | **Information required****(please comment below, if requirements not fully met)** | **YES** | **NO** |
|  | 1 (a) | Is a statement present confirming that for WHO prequalification, the Drug Product, including but not limited to composition/formulation, strength, manufacturing, specifications, packaging, product information, will, at the time of submission and after prequalification, in all respects be the same as the product registered with the reference SRA? |  |  |
|  | Comment |  |
|  | 1 (b)  | Is a statement present indicating that the product is currently on the market of the reference SRA’s country or region? |  |  |
|  | Comment |  |
|  | 2  | Is a copy provided of the marketing authorization, or the equivalent thereof, issued by the reference SRA to demonstrate that the product is registered or licensed in accordance with the reference SRA’s requirements? If applicable, a copy of the latest renewal of the marketing authorization should also be provided (comment) |  |  |
|  | Comment |  |
|  | 3 | Has a copy been provided of the current WHO-type certificate of a pharmaceutical product issued and fully completed, including answers to each question, by the reference SRA? |  |  |
|  | Comment |  |
|  | 4 | Is the latest SRA-approved product information provided (summary of product characteristics (SmPC), or an equivalent thereof, the patient information leaflet (PIL), or equivalent thereof, and the labelling) of the product? Provide a web link to the SRA-approved product information, preferably on the website of the SRA itself, if available. |  |  |
|  | Comment |  |
|  | 5 (a) | Have the names been provided of all SRA approved DS manufacturers, physical address(es) of manufacturing site(s) (and unit if applicable), including intermediates, contractors and release testing (and function of each site)? |  |  |
|  | Comment |  |
|  | 5 (b) | Have the names been provided of all SRA approved DP manufacturers, physical address(es) of manufacturing site(s) (and unit if applicable), including intermediates, contractors and release testing (and function of each site)? |  |  |
|  | Comment |  |
|  | 6 (a) | Has a tabular listing been provided of the product batches manufactured for the market of the reference SRA’s region or country since approval or during the past five years, whichever is shorter? [*The table should include at least the following information: the batch number (of both the DS and DP), batch size (number of units), date of manufacture, manufacturing site (of both the DS and DP), expiry date and pack type/size*] |  |  |
|  | Comment |  |
|  | 6 (b) | Has a copy been provided of the most recent product quality review, prepared according to the requirements of the reference SRA? |  |  |
|  | Comment |  |
|  | 7 (a) | Is the quality information summary for the product been provided in word format and are all sections completed (except the WHO reference number? [*The QIS-BTP-SRA template, available at http://www.who.int/medicines/regulation/prequalification/QIS-BTP-SRA\_June2018.docx, should be fully completed and submitted with the application. The QIS-SRA provides a condensed summary of key information on the BTP as approved by the reference SRA at the time of application for prequalification*] |  |  |
|  | Comment |  |
|  | 7 (b) | Does the QIS-BTP-SRA template contain any dossier references instead of including the required data in the template (not accepted)? Does the QIS-BTP-SRA template contain any altered section(s) (i.e. deletion – not accepted)? |  |  |
|  | Comment |  |
|  | 8 | Has a public assessment report, such as the Scientific Discussion of the European Public Assessment Report (EPAR), issued by the reference SRA been provided? [*Assessment report(s) issued by the reference SRA that are not publicly available may be requested*.] |  |  |
|  | Comment |  |
|  |  9 (a) | Are details of the pharmacovigilance system provided?**For points 9 (a-c)** [according to the WHO Guidelines on evaluation of SBPs/BTPs or the WHO Guidelines on the quality, safety and efficacy of biotherapeutic protein products prepared by recombinant DNA technology] |  |  |
|  | Comment |  |
|  |  9 (b) | Does the RMP include a description of the risks of the product together with the measures to minimize such risks, taking into consideration patient treatment and current clinical practice in low- and middle-income countries and for supply of the product based on its prequalification status? |  |  |
|  | Comment |  |
|  | 9 (c) | Are post marketing safety reports provided? |  |  |
|  | Comment |  |
|  |  9 (d) | Have the arrangements been described for handling complaints and product recalls used for supply of the product based on its prequalification status, including provisions for informing WHO and the procurement agencies? |  |  |
|  | Comment |  |
|  |  9 (e) | Have restrictions been described for procedures on distribution or recalls, including manufacturer-initiated recalls? |  |  |
|  | Comment |  |
|  | 10 | Has a sample(s) of the product in market packaging(s) with the respective certificate of analysis been provided? [This should be provided with the submission to enable visual inspection thereof. No special transportation is required for the samples for the purpose of this requirement].  |  |  |
|  | Comment |  |
|  | 11 | Has a copy been provided of the currently approved DP specifications (release and shelf-life), dated and signed or certified by authorized personnel, with the analytical test procedures? |  |  |
|  | Comment |  |
|  | 12 (a) | Has evidence been provided that the product will - prior to – and at the time of packing –be kept within the storage temperature limits recommended by the manufacturer? |  |  |
|  | Comment |  |
|  | 12 (b) | Are the shipment and transportation validation studies in line with the principles laid out in the WHO guideline for international packaging and shipping of vaccines? [shipping validation at an ambient temperature of 43°C minimum (for at least 48 hours), as already established in the WHO guideline for international packaging and shipping of vaccines]?**If NO** please respond to question 12c |  |  |
|  | Comment |  |
|  | 12 (c) | **If point 12 (b) answer is NO:** If the applicant followed a different approach, are the differences justified and the equivalence of the approach discussed and supported by data? Data expected for the assessment includes a summary of the packaging procedures for international shipments (including box sizes and types, packing volumes, etc.), and the validation protocols and reports of the shipping boxes used for supply of the product based on its prequalification status? |  |  |
|  | Comment |  |
|  | (i) | Is the RBP declared in the dossier in agreement with that in the SBP Public Assessment Report from the reference SRA? |  |  |
|  | Comment |  |
|  | (ii) | Has the latest SRA-approved product information (summary of product characteristics (SmPC), or an equivalent thereof, the patient information leaflet (PIL), or equivalent thereof, and the labelling) of the RBP, or the web link to the SRA-approved product information of the RBP, preferably on the website of the SRA itself, been provided? |  |  |
|  | Comment |  |

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| --- |
| **Comments on deficiencies****with reference to table above and specific dossier sections** |
| **Additional data requested**(to be communicated to the applicant) |
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