**< Name of the Biotherapeutic product >**

**< National Drug Authority); Date......... >**

**PART A - ADMINISTRATIVE INFORMATION**

| **Sr. No.** | **To be completed By** | 1. **Biotherapeutic Product Information**
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| --- | --- | --- |
|  | Applicant | **Name of the Biotherapeutic Product** | < Invented/Trade name > |
|  | Applicant | **Indications for RBP** | Indications for reference biotherapeutic product in full or summary + English reference |
|  | Applicant  | **MAH**  | Name and address |
|  | Applicant  | **Active ingredient manufacturing facilities and batch release site for the finished product** (if applicable) | < Name(s) and address(es) >< Confidential – Not Released > |
|  | Applicant  | **Name of the active ingredient(s)** |  (INN/ Common name/ Local name/ BQ if applicable) |
|  | Applicant  | **Pharmaco-therapeutic group** | e.g. ATC code |
|  | Applicant  | **Substance category**  | As described in International Nonproprietary Names (INN) for biological and biotechnological substances <https://www.who.int/medicines/services/inn/BioRev2014.pdf> |
|  | Applicant  | **Pharmaceutical form** | Standard Term |
|  | Applicant  | **Quantitative composition** | Strength |
|  | Applicant  | **Route of administration** | Route  |
|  | Applicant | **Packaging/material** | Primary container |
|  | Applicant | **Package size(s)** | Presentations available |
|  | Applicant | **Local legal basis** | Legislative Reference |
|  | Applicant | **Local Biotherapeutic Product guidelines** | Reference to applicable guidelines |
|  | NDA | **Date of authorisation/licensing of Biotherapeutic Product** | Approval date for Biotherapeutic product |

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| **Sr. No.** | **To be completed By** | 1. **Summary of outcomes**
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|  | Applicant | **Quality data** | High level summary of data included in quality evaluation/analysis. |
|  | Applicant | **Pre-clinical data** | High level summary of data included in pre-clinical evaluation. |
|  | Applicant | **Clinical data(Pharmacokinetic, Pharmacokinetic data, safety and Efficacy data)** | Summary of included in clinical evaluation  |
|  | NDA | **Authorised indications for Biotherapeutic Products** | Indications approved following review – in full or if available in English on NDA website: provide summary and link.  |

**PART B - SUBMITTED DATA AND REVIEWER SUMMARY**

| **Sr. No.** | **To be completed by** | **Data required**  |
| --- | --- | --- |
| 3.1. | Applicant | **Quality data. Composition of the Biotherapeutic product(s)**  |
| Provide name of active substance and strength.Provide names (qualitative) of excipients used in formulation. |
| 3.2. | Applicant | **Quality data. State-of-the-art methods** |
| Include high level summary of physicochemical test methods and biological activity studies used for characterisation. |
| 3.3. | NDA | **Quality data assessment outcome** |
| Provide high level summary review of quality data. Specify any implications to the quality, efficacy and safety of the product. |
| 3.4. | Applicant | **Mechanism of action** |
| Describe mechanism of action relevant to indications applied for. |
| 3.5. | Applicant | **Non-clinical data. *In vitro* studies** |
| Specify dose used and length of the study. |
| 3.6. | Applicant | **Non-clinical data. *In vivo* studies** |
| Specify animal model(s), e.g. dose used and length of the study. |
| 3.7. | NDA | **Non-clinical data assessment outcome**  |
| Provide high level summary review of non-clinical data and outcome including the implications to efficacy and safety of the product. |
| 3.8. | NDA | **CLINICAL STUDIES** **-** include relevant study data from the following (not all may be required) which have been included to demonstrate biosimilarity.* Pharmacokinetic, PK
* Pharmacodynamic, PD
* Efficacy
* Safety
* Immunogenicity
 |
| 3.9. | Applicant | **Clinical data. PK studies**  |
| Specify study number(s) and summary of design, population, objective and endpoint, dose used and length of the study. |
| 3.10. | NDA | **Clinical data. PK data assessment outcome** |
| Provide high level summary review of PK data and outcome including how it relates to efficacy or safety of the product. |
| 3.11. | Applicant | **Clinical data. PD studies**  |
| Specify study number(s) and summary of design, population, objective and endpoint, dose used and length of the study. |
| 3.12. | NDA | **Clinical data. PD data assessment outcome** |
| Provide high level summary review of PD data and outcome including implications to the efficacy and safety of the product. |
| 3.13. | Applicant | **Clinical data. Efficacy studies**  |
| Specify study number(s) and summary of design, population, objective and endpoint (e.g. equivalence margins), dose used and length of the study. |
| 3.14. | NDA | **Clinical data. Efficacy data assessment outcome**  |
| Provide high level summary review of clinical efficacy data and outcome (No differences expected, however, justification may be appropriate). |
| 3.15. | Applicant | **Clinical data. Safety/ Immunogenicity studies** (specify population, dose used, length of the study and comparability margins) |
| Specify study number(s) and summary of design, population, objective and endpoint, dose used and length of the study (ies). |
| 3.16. | NDA | **Clinical data. Safety/ Immunogenicity data assessment outcome** |
| Provide high level summary review of clinical safety and immunogenicity data and outcome.Safety. ADRs do not pause any potential risk to the patient or the risks are low.Immunogenicity. Antibody formation in Biotherapeutic product does not pause any potential risk to the patient or the risks are low. |
| 3.17. | Applicant | **Additional information about the quality, safety and efficacy** | As appropriate, if not previously included. |
| 3.18. | Applicant | **Post-authorization measures**  |
| Is a risk management plan available? Which Q/ S/ E studies are included? |
| 3.19. | NDA | **Post-authorization measures assessment outcome.** |
| < The risk management plan (or equivalent) was considered to be acceptable. >< No additional risk management activities are foreseen post-approval.> |
| 3.20. | Applicant | **Availability of additional relevant information in the local language/ link** |
| As required /appropriate |

**PART C - REVIEWER CONCLUSIONS**

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| --- |
| To be completed by NDA |
| **Conclusions on Quality, Safefy, Efficacy and approval** |
| The reviewer should comment and conclude on the following:-<The data provided by the Applicant was in line with the local legislation and guidelines.><The data provided by the Applicant was in line with the local legislation, guidelines and international guidelines.>Quality All major physicochemical characteristics and biological activities of Biotherapeutic product are acceptable.Non-clinicalEnsure that the right animal models were used and there were no major safety issues that are likely to affect humans.Clinical StudiesThe PK / PD / efficacy studies to demonstrate efficacy in patient population provided robust evidence of therapeutic relevance.Safety: The ADRs observed with biotherapeutic are outweighed by the therapeutic benefit.Immunogenicity: Antibody formation in Biotherapeutic product does not pause any potential risk to the patient or the risks are low.Risk Management< The risk management plan (or equivalent) was considered to be acceptable. >< No additional risk management activities are foreseen post-approval.>Overall Conclusion<Satisfactory assurance of quality, safety, efficacy and relevance was demonstrated using appropriate methods><Concerns raised during the review relating to < summarise major issues > were resolved during the procedure.>The biotherapeutic product <trade name > was considered approvable. |