# APPLICATION FORM FOR REGISTRATION OF BIOTHERAPEUTICS AND SIMILAR BIOTHERAPEUTIC PRODUCTS

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| **Form 1** | | | APPLICATION FOR REGISTRATION OF BIOTHERAPEUTICS AND SIMILAR BIOTHERAPEUTIC PRODUCTS | | |
| **To** | | | THE CEO  PPB OFFICES,  LENANA ROAD,  DRUG REGISTRATION DEPARTMENT,  P.O. BOX 27663-00506,  NAIROBI. | | |
| **Application Number** | | |  | | |
| **Date of submission of the dossier** | | |  | | |
| **Name of the 1st Assessor** | |  | | | Signature |
| **Name of the 2nd Assessor** | |  | | | Signature |
| **Date of 1st Assessment** | |  | | | |
| **Date of 2nd Assessment** | |  | | | |
| **CONCLUSION OF THE ASSESSMENT**  **RECOMMENDED** *(no outstanding issues)*  **QUERY RAISED** *(Indicate the sections where query is raised)*  **REJECTED** *(indicate the module(s) that led to the rejection)*  ***(Please delete which does not apply)*** | | | |  | |
| **TYPE OF APPLICATION – HUMAN PRODUCT** | | | | | |
| **MODULE 1: ADMINISTRATIVE INFORMATION** | | | | | |
| **SECTION 1: PARTICULARS OF THE PRODUCT** | | | | | |
| **1.11 Name and address of Applicant** | | | | | |
| **Company name:**  **Address:**  **Country:**  **Telephone:**  **E-Mail:** | | | | | |
| **1.12 Type of Medicinal Product Application ( Tick where appropriate)** | | | | | |
| New (Innovator) BIOTHERAPEUTIC PRODUCT  **OR**  SIMILAR BIOTHERAPEUTIC PRODUCT**.** | | | | | |
| *For PPB use only* | | | | | |
| **1.2** | **Trade/Proprietary name (prorietary Product name):** | | | | |
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| **1.3** | **Approved / INN / generic name of the drug substance** | | | | |
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| **1.4** | **Strength of drug substance(s) per unit dosage form of the product and specifications of the drug substance(s), including the reference/ monograph standard for each drug substance(s).** | | | | |
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| **1.5** | **Dosage form** | | | | |
| **1.5.1** | **Pharmaceutical Dosage form of the product:** | | | | |
| **1.5.2** | **Specifications of the Finished Pharmaceutical Product:** | | | | |
| **1.5.3** | **Route(s) of administration (use current list of standard terms - European Pharmacopoeia):** | | | | |
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| **1.6** | **Packing/Pack size of the product:** | | | | |
| **1.6.1** | **Pack size:** | | | | |
| **1.6.2** | **Primary packing materials:** | | | | |
| **1.6.3** | **Secondary packing materials:** | | | | |
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| **1.7** | **Visual Description of the product (Add as many rows as necessary)** | | | | |
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| **1.8** | | **1.8 Proposed Shelf life of the product (in months):** | |
| **1.8.1** | | Proposed shelf life (after reconstitution or dilution) (if applicable): | |
| **1.8.2** | | Proposed shelf life (after first opening container): | |
| **1.8.3** | | Proposed storage conditions: | |
| **1.8.4** | | Proposed storage conditions after first opening: | |
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| **1.9** | | **Pharmacotherapeutic group and ATC Code** | |
| **1.9.1** | | **Pharmacotherapeutic group:** | |
| **1.9.2** | | **ATC Code:** | |
| **1.9.3** | | **If no ATC code has been assigned, please indicate if an application for ATC code has been made:** | |
| **1.9.4** | | **Proposed indication(s) for the product:** | |
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| **1.10** | | **Indicate Legal category** | |
| **1.10.1** | | **POM (Prescription only Medicine) unless otherwise, provide justification)** | |
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| **1.11** | | **Country of origin or country of release:** | |
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| **1.12** | | **Product Marketing Authorisation in the country of origin. (Attach certificate of pharmaceutical product from competent regulatory authority) If not registered, state reasons** | |
| **Authorised**  **Country:**  **Date of authorisation:**  **Proprietary name:**  **Authorisation number:**  **Refused**  **Country: Not applicable**  **Date of refusal (dd-mm-yyyy):**  **Reason for Refusal:** | | | **Withdrawn (by applicant after authorisation)**  **Country:**  **Date of withdrawal (dd-mm-yyyy):**  **Proprietary name:**  **Reason for withdrawal:**  **Suspended/revoked (by competent authority)**  **Country: Not applicable**  **date of suspension/revocation (dd-mm-yyyy):**  **Reason for suspension/revocation:** |
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| **1.12.1** | | **Registration status from countries with Stringent Regulatory Authorities (SDRAs) where applicable**  **SDRAs - Documents to be attached:** | |
| ***For PPB use only*** | | | |
| **1.12.2** | | **List of countries in which a similar application has been submitted** | |
| ***For PPB use only*** | | | |
| **1.12.3** | | **Statement on whether an application for the Marketing Authorisation has been previously rejected, withdrawn or repeatedly deferred in the EAC Partner States** | |
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| **1.12.4** | | **Certificates of approval of Drug Substances(s)/ immunogenic s substance(s) Master (DMF) by Stringent Regulatory Authority** | |
| ***For PPB use only*** | | | |
| **1.12.5** | | Manufacturing Licence and Product Licence | |
| ***For PPB use only*** | | | |
| **1.13** | | Certificate of Analysis from a WHO Prequalified Laboratory in Kenya and the lot release certificate issued by the regulatory authority of country of origin  for those samples submitted with the application | |
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| **1.14** | | Name(s) and complete address (es) of the manufacturer(s) | |
| **1.14.1** | | Name and complete address(es)of the manufacturer(s) of the FPP, including the finished pharmaceutical product release if different from the manufacturer. | |
| **Marketing Authorisation Holder:**  **Company name:**  **Address:**  **Country:**  **Telephone:**  **E-Mail:**  **Manufactured By:**  **Company) Name:**  **Address:**  **Country:.**  **Telephone:**  **Telefax :**  **If the manufacturer is different to 1.1 above, explain the relationship** | | | |
| 1.14.2 | | Name(s) and complete address (es) of the manufacturer(s) of the Drug substance | |
| **The active immunogenic substance: (Add as many rows as necessary)**  **Company) Name:**  **Office Address :**  **Country :**  **Telephone :**  **Fax :**  **Contact Person :**  **E-mail :** | | | |
| ***For PPB use only*** | | | |
| **1.15** | | **Compliance to Good Manufacturing Practice (GMP) and Good Clinical Practice** | |
| **1.15.1** | | **Good Manufacturing Practice (GMP) from PPB** | |
| **1.15.2** | | **Good Clinical Practice (GCP) or Good Laboratory Practice (GLP)** | |
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| **1.16 .1** | | **Name and complete address of the Local Technical Representative of Manufacture (for finished pharmcautical Product)**  **Company name:**  **Address:**  **Country:**  **Telephone:**  **E-Mail:**  **If the Local Technical Representative is different to 1.1 above, explain and provide evidence for the relationship:** | |
| **1.16 .2** | | **Name and address (physical and postal) of the person or company responsible for pharmacovigilance**  **Company name:**  **Address:**  **Country:**  **Telephone:**  **E-Mail:** | |
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| **1.17** | | **Product Information** | |
| **1.17.1** | | **Summary of Product Characteristics (SPC):** | |
| **1.17.2** | | **Prescribers/Patient information leaflet:** | |
| **1.17.3** | | **Mock-ups and Photo scan of the product:** | |
| **1.18** | 1.18 Batch number(s) and Batch Types of the final product used in  Clinical studies:  Stability studies:  Validation/production scale batches Validation/production scale batches:  Comments:  Comments: Provide Reasons for comments , e.g batch numbers N/A  Qualitative and Quantitative composition of the drug substance(s) and excipient(s)  A note should be given as to which quantity the composition refers (e.g. 1 Vial ).   |  |  |  |  | | --- | --- | --- | --- | | Name of drug substance(s)\* | Quantity /  dosage unit | Unit of measure | Reference/  monograph standard | | 1. |  |  |  | | 2. |  |  |  | | e.t.c |  |  |  | | Name of excipient(s) | | | | | 1. |  |  |  | | 2. |  |  |  | | e.t.c |  |  |  | | Note: \* Only one name for each substance should be given in the following order of priority: INN\*\*, Pharmacopoeia, common name, scientific name  \*\* The drug substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant.  Details of averages should not be included in the formulation columns but should be stated below:  - Drug substance(s):  - Excipient(s): | | | | | | |
| |  |  | | --- | --- | | 1.19 | State the reference/monograph standard such as British Pharmacopeia, United States Pharmacopeia, Ph. Eur, Japanese Pharmacopeia, In-house monograph  e.t.c. used for Finished Medicinal Product. | | 1.20 | Name and address (physical and postal) of the Contract Research Organisation(s) where the clinical studies of the product were conducted. (If applicable) | | Name: N/A  Company name:  Address:  Country:  Telephone:  Telefax:  E-Mail: | |  |  |  | | --- | --- | | **1.21 DECLARATION BY AN APPLICANT** | | |  | 1. I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge. 2. I further confirm that the information referred to in my application dossier is available for verification during GMP inspection. 3. I also agree that I shall carry out pharmacovigelance to monitor the safety of the product in the market and provide safety update reports to the National Medicines Regulatory Authority. 4. I further agree that I am obliged to follow the requirements of Kenya, and 5. Legislations and Regulations which are applicable to medicinal products.   Name:  Position in the company:  Signature:  Date:  Official stamp:……………………………..  *\* Note: If fees have been paid, attach proof of payment* | | | | |
| PPB use only  **OVERALL QUERIES AND RECOMMENDATIONS FOR THIS MODULE** | | | |