#  Application Form for Medicine Registration

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| Application Number |  |
| Date of submission of the dossier  |  |
| Name of the 1st Evaluator |  | Signature |
| Name of the 2nd Evaluator |  | Signature |
| Date of 1st evaluation |  |
| Date of 2nd Evaluation |  |
| Number of files received  |  |
| **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  |
| 1.0 Name and address of Applicant |
| **Company name:** **Address:**  **Country:** **Telephone:****E-Mail:** mailto:korlyns@korlynspharm.com |
| *For PPB use only* |
| 1.1 | Type of the Medicinal product licence application |
|  | Type of the medicinal product application New/innovator MA      Generic MA      Conditional Authorization      Emergency Use Authorization      Extension application      Duplicate license     Renewal/Re-registration\*      \* If variation has been made, information supporting the changes should be submitted. See PPB variation guidelines for registered medicinal products.  |
| 1.2 | Trade/Proprietary name (proprietary Product name):  |
| *For PPB use only* |
| 1.3 | **Approved / INN / generic name/Active Pharmaceutical Ingredient (API):** |
| *For PPB use only* |
| 1.4  | **Strength of the Active Pharmaceutical Ingredient (API) per unit dosage of the product and specifications of the API:** |
| *For PPB use only* |
| 1.5  | Dosage form |
| **1.5.1** | **Pharmaceutical Dosage form of the product:** |
| **1.5.2** | **Therapeutic Indication(s):** |
| **1.5.3** | **Route*(s)* of administration (use current list of standard terms – European Pharmacopoeia):**  |
| **1.5.4** | **Maximum Daily Dose (MDD) for the Drug Product:** |
| *For PPB use only* |
| **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:** |
| *For PPB use only* |
| 1.7  | Visual Description of the product |
| *For PPB use only* |

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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):**  |
| **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:**  |
| *For PPB use only* |
| **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:** |
| *For PPB use only* |
| 1.10 | Legal category |
| **1.10.1**  | **Proposed dispensing category/classification:**   |
| **1.10.2**  | **For products subject to medical prescription:**   |
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| 1.11  | Country of origin or country of release:  |
| *For PPB use only* |
| 1.12  | Product Marketing Authorisation in the country of origin. (Attach certificate of pharmaceutical product from competent regulatory authority)  |
| [ ]  **Authorised** Countr**y:** Date of authorisation**:** Proprietary name**:** Authorisation number**:** [ ]  RefusedCountry: **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:  |
| *For PPB use only* |
| 1.12.1 | Registration status from countries with Stringent Regulatory Authorities (SRAs) where applicable |
| *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 PPB Partner States |
| *For PPB use only* |
| 1.12.4 | Certificates of approval of DMF (Drug Master File) by Stringent Regulatory Authority |
| *For PPB use only* |
| 1.12.5 | Manufacturing Licence and Product Licence |
| *For PPB use only* |
| 1.13  | **Pre-registration analysis of the finished pharmaceutical product:** (Attach certificate of analysis from a recognized WHO Prequalified Quality Control Laboratory in Kenya and within the Region) |
| *For PPB use only* |
| 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 active pharmaceutical ingredient**  |
| **ACTIVE INGREDIENT:** **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 | **1.15.2 Good Clinical Practice (GCP) or Good Laboratory Practice (GLP)**  |
|  | **Information on the Reference Product (i.e., for a generic drug product application)** |
|  | Brand Name of the Reference Product: |
|  | Dosage Form(s): |
|  | Strength(s): |
|  | Marketing Authorisation Holder’s Name: |
|  | Country source of Reference Product Used in Bioequivalence Study(ies): |
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| *For PPB use only* |
| 1.16  | **Name and complete address of the Local Technical Representative of Manufacture (for finished pharmaceutical 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:** |
| *For PPB use only* |
| 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 |

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| 1.18 Batch number(s) and Batch Types of the final blood product used in  |
| **Clinical/bioequivalence studies** |  |
| **Stability studies**  |  |  |  |
| **Validation/production scale batches** |  |  |  |
| **Comments: -**  **Batch size (** **)** |
| Composition of clinical, primary stability and validation/production FPP batches ()  |
| Ingredients | **Administration Unit**  | **Bioequivalence**[batch number | **Primary stability**[batch number- **]** | **Production**[batch number**]** |
| Mg/ IU | %\* | Kg | %\* | Kg | %\* | kg | %\* |
| **Active :** |
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| **Excipients:** |
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| Equivalence of the composition or justified differences | The compositions of the stability and validation batches are the same and differences are justified.  |
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| **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.  |
| **1.19.1** | Specification of active ingredient(s) from API manufacturer (Specification number and Version): |
| **1.19.2** | Specification of active ingredient(s) from FPP manufacturer (Specification number and Version): |
| **1.19.3** | Specification of Finished Pharmaceutical Product (Specification number and Version): |
| **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: Company name:       Address:      Country:      Telephone:      Telefax:      E-Mail:       |

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| 1.21 DECLARATION BY AN APPLICANT |
|  | 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.I further confirm that the information referred to in my application dossier is available for verification during GMP inspection.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. I further agree that I am obliged to follow the requirements of Kenya, andLegislations and Regulations which are applicable to medicinal products.Name:Position in the company: Signature:Date: For PPB use only OVERALL QUERIES AND RECOMMENDATIONS FOR THIS MODULEOfficial stamp: ……………………………..*\* Note: If fees have been paid, attach proof of payment*  |

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|  PPB use only |

# Annex IV: Expert Declaration Form

The following is an example of a suitable declaration form:

**Quality /Non-clinical / Clinical** (delete those not appropriate)

I, the undersigned, declare that I have:

1. the suitable technical or professional qualifications to act in this capacity (for more information, refer to the enclosed *curriculum* vitae).
2. fully examined the data provided by the applicant and have provided references to the literature to support statements made that are not supported by the applicant’s original data. This report presents an objective assessment of the nature and extent of the data.
3. provided a report based on my independent assessment of the data provided.
4. based my recommendations, regarding suitability for registration, on the data provided herewith. I have considered the attached data and have recommended as to suitability for registration of the intended dose forms and presentations according to the proposed product information document.

I further declare that this expert report represents my own view.

Further, I declare the following to be the full extent of the professional relationship between myself and the applicant:

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