**FORMAT FOR CTD COVER LETTER**

Ref: ..................................................

Applicant: .........................................

Address: ...........................................

Post code: ......................................... Town ................. Country: ...........................

Date: ................................

Reference: .........................

The Secretary to the Authority,

National Drug Authority, Plot 19 Lumumba Avenue

P.O. Box 23096, Kampala, Uganda

Phone: (+256) 41-7788100

E-mail: ndaug@nda.or.ug

Subject: Submission of Application(s) for Registration of Product Name(s) and strength(s)

Dear Sir,

We are pleased to submit our Application(s) for a registration of finished pharmaceutical product(s) whose details are as follows:

Name of the finished pharmaceutical product(s): ......................................................

Pharmaceutical form(s) and strength(s): ..................................................................

INN/active substance(s): ......................... ATC Code(s): ..........................................

You will find enclosed the submission dossier as specified hereafter:

CD rom; Quality Overall Summary and Bioequivalence Trial Information in word format and body data in pdf format

We confirm that all future submissions for this specific product will be submitted in this same format

We confirm that the electronic submission has been checked with an up-to-date and state-of- the-art virus checker.

The relevant fees have been paid.

Yours sincerely,

Signature: ..............................................................................

Name: ...................................................................................

Title: ......................................................................................

Phone number: .......................................................................

Email address: .........................................................................

**APPLICATION FOR REGISTRATION OF A PHARMACEUTICAL PRODUCT FOR HUMAN USE IN UGANDA**

|  |  |
| --- | --- |
| Application Number | [For NDA use only] |
| Date of submission of the dossier  | [For NDA use only] |
| **MODULE 1: ADMINISTRATIVE INFORMATION** |
| **1.0 PARTICULARS OF THE PRODUCT**  |
| 1.1 | Type of the pharmaceutical product application Innovator: Generic Renewal\* *\** If variation has been made, information supporting the changes should be submitted using the *Guidelines for Variation of Registered Pharmaceutical Products for Human Use.*  |
| 1.2 | Proprietary Name |
| 1.3 | International Non-proprietary Name (INN) of the Active Pharmaceutical Ingredient (API)  |
| 1.4  | Strength of Active Pharmaceutical Ingredient (API) per unit dosage form:  |
| 1.5 | Name and address (physical and postal) of the Applicant . |
| (Company) Name: Address: Country: Telephone: Telefax: E-Mail:  |
| 1.6  | Pharmaceutical Dosage form and route of administration\* \* List of standard terms for dosage forms and routes of administration is available in the *Guidelines on Submission of Documentation for Registration of a Pharmaceutical Products for Human Use* in Uganda |
| 1.6.1 | Dosage form:  |
| 1.6.2 | Route(s) of administration (use current *List of Standard Terms*)  |
| 1.7  | Packing/pack size:  |
| 1.8  | Visual description *(Add as many rows as necessary)* |
| 1.9 | Proposed shelf life (in months):  |
| 1.9.1 | Proposed shelf life (after reconstitution or dilution):  |
| 1.9.2 | Proposed shelf life (after first opening container):  |
| 1.9.3 | Proposed storage conditions:  |
| 1.9.4 | Proposed storage conditions after first opening:  |
| 1.10 | Other sister pharmaceutical products registered or applied for registration  |
| 1.10.1 | Do you hold a certificate (s) of registration for other pharmaceutical product (s) containing the same active substance (s) in the Uganda?If yes state; ▪ Product name (s), strength (s), pharmaceutical form (s):  ▪ Registration number(s):  ▪ Indication(s):  |
| 1.10.2 | Have you applied for registration of pharmaceutical product (s) containing the same active substance (s)? ▪ Product name (s), strength (s), pharmaceutical form (s):  ▪ Indication(s):  |
| 1.11  | Pharmacotherapeutic group and ATC Code |
| 1.11.1 | Pharmacotherapeutic group:  |
| 1.11.2 | ATC Code: (*Please use current ATC code)* |
| 1.11.3 | If no ATC code has been assigned, please indicate if an application for ATC code has been made: [ ]  |
| 1.12 | Distribution category: Controlled Drug [ ]  POM [ ]  Pharmacy Only [ ]  OTC [ ]  General sale [ ] *(Applicants are invited to indicate which categories they are requesting, however, NDA reserves the right to change and/or apply only those categories provided for in their national legislation)* |
| 1.13  | Country of origin:  |
| 1.14  | Product Marketing Authorisation in the country of origin (Attach Certificate of Pharmaceutical Product). If not registered, state reasons |
| [ ]  **Authorised**  Country: Date of authorisation (dd-mm-yyyy): Proprietary name: Authorisation number: [ ]  **Refused**Country: 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: date of suspension/revocation (dd-mm-yyyy): Reason for suspension/revocation: Proprietary name:  |
| 1.15  | List EAC countries and SRAs where the product is approved.  |
| 1.16  | Name(s) and complete physical address(es) of the manufacturer(s) |
| 1.16.1 | Name(s) and physical address(es) of the manufacturing site of the finished pharmaceutical product (FPP), including the final product release if different from the manufacturer**.** Alternative sites should be also declared here**.** *All manufacturing sites involved in the manufacturing process of each step of the finished product, stating the role of each including quality control / in-process testing sites should be listed.*(Add as many rows as necessary) |
| Name: Company name: Address: Country: Telephone: Telefax: E-Mail:  |
| 1.16.2 | Name(s) and physical address(es) of the manufacturer(s) of the active pharmaceutical ingredient(s) (API)*(Add as many rows as necessary)**All manufacturing sites involved in the manufacturing process of each source of active substance, including quality control / in-process testing sites should be listed.*  |
| Name: Company name: Address: Country: Telephone: Telefax: E-Mail:  |
| 1.17  | Name and address (physical and postal) of the Local Technical Representative / agent(Attach acopy of Notarised power of attorney for the local technical representative /agent)*if applicable)*  |
| Name: Company name: Address: Country: Telephone: Telefax: E-Mail:  |
| 1.18 | Name and address (physical and postal) of the person or company responsible for pharmacovigilance  |
| Name: Company name: Address: Country: Telephone: Telefax: E-Mail:  |
| 1.19 | State the reference/monograph standard such as British Pharmacopeia, United States Pharmacopeia, Ph. Eur., In-house monograph e.t.c. used for Finished Pharmaceutical Product.  |
| 1.20 | Qualitative and Quantitative composition of the active substance(s) and excipient(s) *A note should be given as to which quantity the composition refers (e.g. 1 capsule).*  |
|

|  |  |  |  |
| --- | --- | --- | --- |
| Name of active ingredient(s)\* | Quantity /dosage unit | Unit of measure  | Reference/Monograph standard |
| 1. |  |  |  |
| 2. |  |  |  |
| 3. |  |  |  |
| e.t.c  |  |  |  |
| Name Excipient(s) |
| 1. |  |  |  |
| 2. |  |  |  |
| 3 |  |  |  |
| 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 active 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:* - Active substance(s): - Excipient(s):  |

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| 1.21 | 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:  |
| **2.0 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 pharmacovigilance to monitor the safety of the product in the market and provide safety update reports to the National Drug Authority. I further agree that I am obliged to follow the requirements of the National Drug Authority.Legislations and Regulations which are applicable to pharmaceutical products. It is hereby confirmed that fees will be paid/have been paid according to the national/Community rules\*Name: …………………………………………………………………..……………………….Position in the company:………………………………………………………………………Signature: …………………………………………………………………………….…………Date:……………………………………….. Official stamp:……………………………..*\* Note: If fees have been paid, attach proof of payment*  |