

FORM 8A

**The Pharmacy and Medicines Regulatory Authority Act, 2019**

(Act No. 9 of 2019, Part IV Section 62)

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| **APPLICATION FOR A MARKETING AUTHORISATION** |
| **Please complete it electronically** | Shaded fields for official use only | Application No. |  |
| Date and Time |  |
| *Information required* | *Information Provided* |  |
| **PART 1****PARTICULARS OF APPLICANT** |
| **A** | **PARTICULARS OF COMPANY** |  |
| 1. | (a) Name of business entity |  |  |
|  | (b) Tax Payer Identification Number (where applicable) |  |  |
| 2. | Type of business entity |  |  |
| 3. | Business premises |  |  |
|  | 1. Plot No:
 |  |  |
|  | 1. Street:
 |  |  |
|  | 1. Telephone No:
 |  |  |
|  | 1. Fax No:
 |  |  |
|  | 1. Mobile No:
 |  |  |
|  | 1. Email address
 |  |  |
|  | 1. Postal address
 |  |  |
|  | 1. Town
 |  |  |
|  | 1. District
 |  |  |
|  | 1. Province
 |  |  |
|  | 1. Country
 |  |  |
| **B** | **CONTACT PERSON**  |  |  |
|  | 1. Name
 |  |  |
|  | 1. Designation
 |  |  |
|  | 1. Physical address
 |  |  |
|  | 1. Postal address
 |  |  |
|  | 1. Phone No.
 |  |  |
|  | 1. Fax No.
 |  |  |
|  | 1. Email address
 |  |  |
| **C** | **LOCAL RESPONSIBLE PERSON (Applicable to foreign based applicants)** |  |
|  | Name |  |  |
|  | Designation |  |  |
|  | Physical address  |  |  |
|  | Postal address |  |  |
|  | Phone No.  |  |  |
|  | Fax No. |  |  |
|  | Email address |  |  |
| **PART II****PARTICULARS OF THE PRODUCT** |
|  | Name of the medicine |  |  |
|  | International non-proprietary names of the active pharmaceutical ingredient, including form (salt, hydrate, polymorph) and strength (in case of a herbal medicine, specify the botanical, English or any other name and the quantities of each ingredient) |  |  |
|  | ATC code |  |  |
|  | Dosage form |  |  |
|  | Route of administration |  |  |
|  | Name and site address of source of the active raw material (in case of herbal medicine) |  |  |
|  | Container, closure and administration system |  |  |
|  | Proposed indication (specify target species in case of veterinary medicine) |  |  |
|  | Package size |  |  |
|  | Shelf life (months) |  |  |
|  | Storage conditions/ instructions |  |  |
|  | Proposed category of distribution |  |  |
|  | Marketing authorisation status in other countries |  |  |
|  | **PART III****PARTICULARS OF MANUFACTURER** |  |
|  | **Name, address and responsibility (e.g. fabrication, packaging, labelling, testing etc.) of each manufacturer, including contractors and each proposed production site or facility involved in manufacturing and testing of the product:** |  |
|  | Name: |  |  |
|  | Physical address (include block(s)/unit(s) if applicable |  |  |
|  | Responsibility: |  |  |
|  | *If more than one site is involved (e.g. manufacturing of dosage form, primary packaging, release etc.), clearly identify the site for each stage.* |  |
|  | *Copies of the latest GMP certificate for manufacturer and packers or a copy of the appropriate manufacturing licence issued by Pharmacy and Medicines Regulatory Authority or any PICs country.*  |  |
|  | *Declaration letter stating that any subsequent inspection did not reveal non-conformance to GMP requirements.* |  |
| **PART IV****COMPOSITION** |
|  | List of all components of the finished pharmaceutical product and their amounts on a per unit, batch and percentage basis including individual components of mixtures prepared in-house (e.g. coatings) and overages, if any |  |
|  | **Ingredients and quality standard (in case of a herbal medicine, specify the botanical, English or any other name** | **Function (reason for inclusion)** | **Strength (Label Claim)** |  |
| **Quantity per unit dosage form (e.g. mg/Tablet)** | **% per unit dosage form** | **Quantity per batch** | **% per batch** |  |
| <complete with appropriate title e.g. core tablet, contents of capsule, powder for injection> |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **Subtotal 1** |  |  |  |  |  |  |
| <complete with appropriate title e.g. film-coating> |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **Subtotal 2** |  |  |  |  |  |  |
| **Total** |  |  |  |  |  |  |
|  **PART V** **PROPOSED SCHEDULE** |  |
|  | Controlled Drug (CD) |  | POM |  | PIM |  | P |  | GSL |  |  |
|  | Applicants are encouraged to indicate which category they are requesting, however, Pharmacy and Medicines Regulatory Authority reserves the right to change and/or apply only those categories provided for in their legislation. |  |
|  |  **PART VI**  **Evidence of Registration**  |  |
|  | State whether the product is registered in originating country (attach evidence of registration in the form of Certificate of Pharmaceutical Product (COPP) from National Medicines Regulatory Authority). |  |
|  | List ICH and/or Observers where the product is approved (attach evidence of registration) |  |
|  | State whether the product has been withdrawn/suspended/revoked in any regulated market |  |
|  | Date of withdraw/suspension /revocation  |  | Reason for withdraw/suspension/revocation |  |  |
| **PART VII****TYPE OF APPLICATION** |
|  | Indicate the type of medicine, the type of data included as proof of efficacy, and the review procedure using a check mark (√) or a cross (X) |  |
| ***Human Medicine:*** | NCE |  | **Data as proof of efficacy:** |  |
| Chemical |  | Multisource |  | Preclinical |  |  |
| Biological |  | Biosimilar |  | Clinical |  |  |
| ***Veterinary Medicine:*** |  |  | Bio-study |  |  |
| Chemical |  |  |  | BCSbiowaiver |  |  |
| Biological |  |  |  | Bibliography |  |  |
| **Herbal:** |  |  |  |  |  |  |
| **Review Procedure proposed by the applicant:** |  |
| Routine |  | WHO CRP/SRA |  | ZAZIBONA |  | Fast Track(Expedited) |  |  |
|  |  |  |  |  |  |  |  |  |
| **DECLARATION AND SIGNATURE:**I declare that all the information I have stated in this application is correct and truthful to the best of my knowledge and belief. I understand that submission of false information shall render the application void and that if approval is granted, the market authorisation may be revoked.**Particulars of the Person signing on behalf of the Applicant**…………………………………………… …………………………………………………………. Name Designation…………………………………………… ………………………………………………………… Signature Date |

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| **FOR OFFICIAL USE ONLY**Date of Submission: …………………………………………………………………………………………....…… Application Number: …………………………………………………………………………………………………Payments Receipt Number: ……………………………………………………………………..…………………Application complete (proceed to evaluation): …………………………………………………………………Application incomplete (refer to applicant for additional information): ………………………………… ……………………………………………………………………………………………………………………………OFFICIALSTAMP |