

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> | | | | | | | | | | | | | | | | | | |  |
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| **Subtotal 1** |  | | | | |  | | | |  | | | |  | | |  | |  |
| <complete with appropriate title e.g. film-coating> | | | | | | | | | | | | | | | | | | |  |
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| **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 |  | | | | |  | | | |  | | | | BCS  biowaiver | | |  | |  |
| 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): …………………………………  ……………………………………………………………………………………………………………………………  OFFICIAL  STAMP |