**EVALUATIONS AND REGISTRATION DIVISION**

APPLICATION FORM FOR RENEWAL OF PRODUCT REGISTRATIONS

**SECTION 1: APPLICANT DETAILS**

|  |  |
| --- | --- |
| Company Name |  |
| Address | Business |  |
| Postal |  |
| Telephone |  |
| Email Address |  |
| Local Representative1 agent details *i.e. name, address and contact details* (*if applicable and different from applicant*) |  |

*1Please note that the contact listed as the local representative will be the primary contact for communication for this specific application.*

**SECTION 2: PRODUCT INFORMATION**

|  |
| --- |
| **PRODUCT DETAILS** |
| Approved name |  |
| Proprietary name (trade name) |  |
| The form in which the medicine is presented, and the colour thereof |  |
| Strength of the medicine |  |
| Shelf life and storage conditions |  |
| Product registration number |  |
| Country of origin |  |
| Approved indications |  |
| Active pharmaceutical ingredient manufacturer/s |  |
| Finished pharmaceutical product manufacturer/s |  |

**3.0 DOCUMENTATION CHECK LIST**

The following documents have been submitted together with this application form:

|  |
| --- |
| **Note: All documents must be provided for this application to be valid** |
| Supporting documentation*All supporting documentation as stipulated in the Guideline for Renewal of Product Registration have been submitted.*  | Yes No |
| Current MC8 form  |  Yes No |
| Renewal of product registration fees*Applicable fees as per the fee schedule have been paid* |  Yes No |

**4.0 DECLARATION (***Please check all declarations that apply).*

I declare that:

No update of Module 3 quality data has been made at renewal.

Attestation notifying the Authority that no further variations to information provided in the initial application, other than those already submitted to MCAZ as applications for variations, has been included in the submission.

The information contained herein and in supporting documents is correct and true.

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_