This application form should be included in the South African Common Technical Document – Module 1 Administrative Information.

The application form is to be used for an application for registration, variation or renewal of a medicinal product for Human or Veterinary usesubmitted to the South African Health Products Regulatory Authority.

A separate application form for each strength and pharmaceutical dosage form is required. However, different strengths may be submitted in one dossier.

|  |
| --- |
| Application number |

***a) Particulars of the Applicant/Prospective holder of the certificate of registration (PHCR)***

|  |  |  |
| --- | --- | --- |
| *Name:* | |  |
| *Business address:* | |  |
|  |
|  |
| *Postal address:* | |  |
|  |
|  |
| *Telephone no:* | |  |
| *E-mail address:* | |  |
| *Site/Applicant Master File Number:* | |  |
| ***Pharmacist responsible/authorised to communicate with SAHPRA*** | | |
| *Name:* |  | |
| *Business address:* |  | |
|  |  | |
|  |  | |
| *Telephone no:* |  | |
| *E-mail address:* |  | |
| ***(Include a letter of authorisation signed by the person responsible for the overall management and control of the business – Section 1.2.2.2)*** | | |

***b) Particulars of the medicine***

|  |  |
| --- | --- |
| ***Product*** | |
| *[[1]](#footnote-2)Category:* |  |
| *Proprietary name:* |  |
| *Pharmacological classification:* |  |
| *Dosage form:* |  |
| [[2]](#footnote-3)*Approved name(s):* |  |
| *Strength(s) per dosage unit:* |  |
| *Descriptive name of Biological medicine:* |  |
| *Route of administration:* |  |
| *Country of origin (country in which the original development was carried out):* |  |

|  |  |
| --- | --- |
| ***Manufacturing, packaging, testing sites[[3]](#footnote-4)*** | |
| ***Manufacturer(s)****:* | |
| *Name:* |  |
| *Physical address of site(s):* |  |
|  |
|  |
| *Site Master File reference number(s):* |  |
| *Date of submission* |  |
| *Licence number:* |  |
| *Date of issue:* |  |
| ***Primary Packer(s)****:* | |
| *Name:* |  |
| *Physical address of site(s):* |  |
|  |
|  |
| *Site Master File reference number(s):* |  |
| *Date of submission* |  |
| *Licence number:* |  |
| *Date of issue:* |  |
| ***Secondary Packer(s):*** | |
| *Name:* |  |
| *Physical address of site(s):* |  |
|  |
|  |
| *Site Master File reference number(s):* |  |
| *Date of submission:* |  |
| *Licence number:* |  |
| *Date of issue:* |  |

|  |  |
| --- | --- |
| ***Finished product release control (FPRC)(s)****:* | |
| *Name:* |  |
| *Physical address of site(s):* |  |
|  |
|  |
| *Site Master File reference number(s):* |  |
| *Date of submission:* |  |
| *Licence number:* |  |
| *Date of issue:* |  |
| ***Finished product release responsibility (FPRR)(s)****:* | |
| *Name:* |  |
| *Physical address of site(s):* |  |
|  |
|  |
| *Site Master File reference number(s):* |  |
| *Date of submission* |  |
| *Licence number:* |  |
| *Date of issue:* |  |

*It is hereby confirmed that copies of the latest GMP certificate for manufacturer(s) and packer(s) and/or a copy of the appropriate manufacturing licence(s) have been included in section 1.7.3*

***c) Declaration and signature***

*The undersigned hereby declares that all the information herein, and in the Annexes and Modules hereto, are correct and true and are relevant to this particular medicine, and that all existing data which are relevant to the quality, safety and efficacy of the product have been supplied in the dossier, as appropriate.*

*It is hereby confirmed that fees have been paid according to current legislation, and proof is included in section 1.2.2.1*

*.....................................................………….* *............................…………..*

*Signature of Pharmacist [Section a) above]* *Date of initial application*

*................................................................. ............................…………..*

*Name in block letters Date of registration*

*……………………………………....*

*Date of last renewal*

*................................................................. …………...……..................*

*Designation Date of current variation/*

*renewal application*

***d) Type of application***

***NEW APPLICATION***

Indicate the type of medicine, the submission type and data included as proof of efficacy, and the review procedure using a check mark () or a cross (X): *(include only the relevant table for either orthodox or complementary medicine)*

***Orthodox medicine***

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ***Human Medicine:*** | | | | ***Submission type:*** | | | | ***Data as proof of efficacy:*** | | | |
| *Pharmaceutical* | | |  | *NCE* | | |  | *Non-clinical* | | |  |
| *Biological* | | |  | *Multisource* | | |  | *Clinical* | | |  |
| ***Veterinary Medicine:*** | | | | *Biosimilar* | | |  | *Biostudy* | | |  |
| *Pharmaceutical* | | |  | *Line Extension* | | |  | *Other* | | |  |
| *Biological* | | |  | *Call-up* | | |  |  | | |  |
| *Master* |  | *Duplicate* | | |  | *Clone* | | |  | *Replica* |  |

***Complementary Medicine***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| ***Complementary Human Medicine:*** | | | ***Data as proof of efficacy:*** | | | |
| *First application* |  | | *Low risk claim* |  | *Literature* |  |
| *Line Extension* |  | | *Clinical* |  |
|  |  | | *Non-clinical* |  |
| ***Complementary Veterinary Medicine:*** | | | *High risk claim* |  | *Literature* |  |
| *First application* | |  | *Clinical* |  |
| *Line Extension* | |  | *Non-clinical* |  |
|  | | | *Biostudy* |  |
| *Biowaiver/dissolution* |  |

|  |  |
| --- | --- |
| *For multiple / duplicate applications of the same medicinal product* | |
| *Proposed Proprietary Name(s) of the other product(s):* |  |
|  |  |
|  |  |
| *Date of application(s) (yyyy-mm-dd):* |  |

***AMENDMENT/VARIATION***

Indicate the type of amendment/variation using a check mark () or a cross (X): *(applies to orthodox and complementary medicines)*

|  |  |  |  |
| --- | --- | --- | --- |
| ***Post-registration:*** | | ***Response to pre-registration recommendation:*** | |
| *Pharmaceutical* |  | *Pharmaceutical* |  |
| *Clinical* |  | *Clinical* |  |
| *Biological* |  | *Biological* |  |
| *Proprietary Name* |  | *Proprietary Name* |  |
| *Scheduling* |  | *Scheduling* |  |
| *Inspectorate* |  | *Inspectorate* |  |

***RENEWAL APPLICATION***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Human Medicine:*** | | ***Submission type:*** | | ***Description*** | |
| *Pharmaceutical* |  | *NCE* |  | *Master* |  |
| *Biological* |  | *Multisource* |  | *Duplicate* |  |
| ***Veterinary Medicine:*** | | *Biosimilar* |  | *Clone* |  |
| *Pharmaceutical* |  | *Line Extension* |  | *Replica* |  |
| *Biological* |  |  |  |  |  |

***e) Qualified person for Pharmacovigilance***

|  |  |
| --- | --- |
| *Name:* |  |
| *Business address:* |  |
|  |
|  |
| *24 Hour Telephone no:* |  |
| *E-mail address:* |  |
| ***(Include CV – Section 1.2.2.5)*** | |

***f)***  ***Variation and renewals history***

| *Date of letter of variation or renewal application* | *Summarised details of variation (include Type and Category)* | *Date of  Regulatory Authority response* |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

**UPDATE HISTORY**

|  |  |  |
| --- | --- | --- |
| **Date** | **Reason for update** | **Version & publication** |
| Feb 2009 | First publication released for comment | Version 1, Feb 2009 |
| Nov 2009 | Finalised version released for implementation | Version 2, Nov 2009 |
| March 2011 | Amendment of Sections b) re GMP certificates; c) re date of current amendment | Version 3, March 2011 |
|  | Amendment of introductory section to allow for submission of different strengths in one dossier, and deletion of veterinary medicine. |
| 1 June 2011 | Implementation |
| April 2014 | Amendment of sections b) and d) to include Complementary Medicines | Version 4, April 2014 |
| With immediate effect | Implementation |
| June 2014 | Amendment of section d) | Version 5, Aug 2014 |
| With immediate effect | Implementation |
| May 2019 | Change from MCC to SAHPRA  Removal of Review Procedure and options in section d) | Version 6, May 2019 |
| 18 June 2019 | Implementation |
| March 2023 | Change to new SAHPRA template.  Addition of Renewal Application information | Version 7, May 2023 |
| 01 July 2023 | Implementation |  |

1. In the case of a complementary medicine, also state the relevant discipline. [↑](#footnote-ref-2)
2. Only one name per API in the product should be given: The International Non-proprietary Name (INN) accompanied by its salt or hydrate form (if relevant), or chemical description of the API(s), or as defined in the guideline for Complementary Medicines. [↑](#footnote-ref-3)
3. If more than one site is involved, clearly identify the site for *each* stage. [↑](#footnote-ref-4)