MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

APPLICATION FOR REGISTRATION OF A MEDICINE[1]
Module 1: Administrative Information
Application Form

This application form will 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 of a medicinal product for human use submitted to the South African Regulatory Authority.

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

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

Name:	
Business address:	
Postal address:	
Telephone no:	
Fax no:	
E-mail address:	
Site/Applicant Master File Number:	

[1] Read together with the definition in Act 101 of 1965 as amended

Pharmacist responsible/authorised to communicate with SA Regulatory Authority	
Name:	
Business address:	
Telephone no:	
Fax no:	
E-mail address:	
☐ ***(Attach a letter of authorisation signed by the person responsible for the overall management and control of the business – Annex 1.2.2.2)***	

b) Particulars of the medicine

Product	
[2]*Category:*	
Proprietary name:	
Pharmacological classification:	
Dosage form:	
[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[4]	
Manufacturer(s)*:*	
Physical address of site(s):	
Site Master File reference number(s):	
Date of submission	
Licence number:	
Date of issue:	

[2] In the case of a complementary medicine, also state the relevant discipline.

[3] 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.

[4] If more than one site is involved, clearly identify the site for *each* stage.

***Primary Packer(s)**:*	
Physical address of site(s):	
Site Master File reference number(s):	
Date of submission	
Licence number:	
Date of issue:	
Secondary Packer(s):	
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)**:*	
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)**:*	
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 attached in Annex 1.2.2.1*

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

..... *.....*
Name in block letters *Date of registration*

..... *.....*
Designation *Date of current amendment*

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*		~~*Pre*~~*Non-clinical*	
Biological		*Multisource*		*Clinical*	
Veterinary Medicine:		*Biosimilar*		*Biostudy*	
Pharmaceutical		*Line Extension*		*Other*	
Biological		*Call-up*			
Review Procedure:					
Routine		*AMRP*		*Expedited (Fast Track)*	

Complementary Medicine

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

Review Procedure:			
Routine		*Expedited (Fast Track)*	

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 and Analytical		*Pharmaceutical & Analytical*	
Clinical		*Clinical*	
Proprietary Name		*Proprietary Name*	
Scheduling		*Scheduling*	
Inspectorate		*Inspectorate*	

e) Qualified person for Pharmacovigilance

Name:	
Business address:	
24 Hour Telephone no:	
Fax no:	
E-mail address:	
(Attach CV – Annex 1.2.2.5)	

f) Amendment history

Date of letter of amendment application	*Summarised details of amendment (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	