NAMIBIA MEDICINES REGULATORY COUNCIL

MINISTRY OF HEALTH AND SOCIAL SERVICES

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

This application form will be included in the Namibia 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 or veterinary use submitted to the Namibia Medicines Regulatory Council.

Usually a separate application form for each strength and pharmaceutical dosage form is required.

APPLICATION NUMBER

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

Name:	
Business address:	
Postal address:	

[1] Read together with the definition in Act 13 of 2003 as amended

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

Pharmacist responsible/authorised to communicate with NA 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	
Category:	
Proprietary name:	
Pharmacological classification:	
Dosage form:	
[2]*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]	
Manufacturer(s)*:*	
Physical address of site(s):	

[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)

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

Site Master File reference number(s):	
Date of submission	
Licence number:	
Date of issue:	

***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) or a copy of the appropriate manufacturing licence(s) have been included in section 1.7.3 (delete items not applicable).*

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]

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

....
Designation *Date of current amendment (Post-registration only)*

d) Type of application

NEW 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:***	
Pharmaceutical		*Multisource*		*Pre-clinical*	
Biological		*Biosimilar*		*Clinical*	
Veterinary Medicine:		*Line Extension*		*Biostudy*	
Pharmaceutical		*Call-up*		*Other*	
Biological					
Review Procedure:					
Routine		*AMRP*		*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):

Inspectorate		*Response to pre-registration recommendation:*	
Pharmaceutical and Analytical		*Pharmaceutical & Analytical*	
Clinical		*Clinical*	
Proprietary Name		*Proprietary Name*	

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 *(Post-registration only)*

Date of letter of amendment application	*Summarised details of amendment (include Type and Category)*	*Date of Regulatory Authority response*