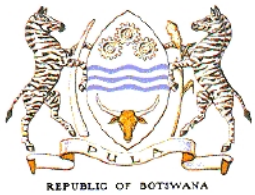
RENEWAL OF REGISTRATION OF REGISTERED MEDICINES AND APPLICATION OF B LISTED MEDICINES

APRIL 2015



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1.0 INTRODUCTION

In accordance with the provisions set out in regulation 3 of the Drugs and Related Substances Regulations 1993 (Registration of Drugs) holders of market authorizations for registered products should submit a renewal application, after five years from the date of registration of the product.

The objective of this quality review submission is to enable the Medicines Regulatory Authority to renew registration of the product based on an evaluation of the data and information submitted by the applicant of a registered product which includes verification of the acceptability of the product meeting current norms and standards, and assessment of consistency of the quality of the registered FPPs, and its manufacturing process(es) over the identified period.

For the B Listed medicines, applicant may use this guideline to apply for registration of these medicines. The Drugs Advisory Board is of the view that the B Listed medicines have been in the market for a long time and hence this guideline would be suitable to get the crucial information about the medicines.

2.0 DOCUMENTS

The applicant should submit the following documents electronically (in PDF format):

- Application Form
- A covering letter containing a clear statement by the responsible person submitting the quality review, indicating that the information submitted is true and correct.
- Completed Quality Overall Summary (QOS)
- Stability Raw Data for API and FPP (B Listed Medicines)
- Summary of key product information (as per Appendix 1)
- Variations to the product (as per Appendix 2)

A hard copy of the Botswana Medicines Regulatory Authority Application Form, referred above as Application Form, should be submitted.

A QOS, completed in WinWord format, should be provided as well. It should reflect the requirements of current registration guidelines and should also take into account technical and scientific progress.

The API and FPP specifications should be provided in tabulated format, comparing the specifications at registration and at the time of the submission of renewal application (as per Appendix 3).

Copies of the current API and FPP specifications, duly signed and dated, should be provided, including the standard test procedures. The specifications should indicate the reference number, version number, effective date and change history if any.

An annual Product Quality Review (see WHO good manufacturing practices for pharmaceutical products: main principles, TRS 961 page 105) should be submitted as supportive documentation.

3.0 SAMPLES

One sample with current labeling and packaging materials should be submitted for assessment purposes. More samples for testing may be required as and when necessary/required.

4.0 PACKAGE INSERT/PATIENT INFORMATION LEAFLET

Original package inserts and patient information leaflets should be submitted.

5.0 CERTFICATES

GMP certificates, CPPs/COPPs and Registration certificates should be submitted

Appendix 1: Summary of key product information

This section compares key information of the FPP at the time of registration or listed and at the time of submission for renewal or registration respectively. Table 1 should be completed by the applicant. Include remarks, as a footnote to Table 1, where deemed necessary to clarify the information provided.

Table 1: Summary of key information

Item	Registered dossier	Current data**
Product number (e.g. BOT00000 or B93000001)		
INN Name, strength and pharmaceutical form		
Applicant(Name, physical address and contact numbers)		
Manufacturing site(s) of FPP, with physical address (including unit and block numbers) and contact numbers (List separately if different steps are performed by different sites e.g. packaging, quality control)		
Batch size(s) of FPP		
Product description (visual appearance)		
Primary and secondary packaging material(s) and pack size(s)		
Storage conditions of FPP		
Shelf-life of FPP		
FPP specification(s) reference number and/or version*		
Manufacturer(s) of API(s), with physical address (including unit and block numbers) and contact numbers(List each API separately)		
Number/version of each APIMF associated with the FPP		
Storage conditions of API		
Retest period of API (s)		
API Specification(s) reference number and/or version (for each API)*		
All commitments and their outcomes		

* According to the latest editions of *The International Pharmacopoeia* (Ph.Int.), the European Pharmacopoeia (PhEur), the British Pharmacopoeia (BP) and/or the United States Pharmacopeia (USP). Where in-house specifications have been approved and there is now a monograph in any of the internationally-recognized pharmacopoeias (Ph.Int, PhEur, BP, USP), the specifications should be updated to comply with the new monograph or demonstrated to be at least equivalent. In case no compendial monograph is in place, the applicant should ensure that the approved in-house specifications are updated, through the Variation process, to reflect the requirements of current registration guidelines and take into account technical and scientific progress (e.g. current ICH guidelines, General chapters of the Ph.Int.). Each new version of documents should allow traceability to the registered dossier and approved variations.

** If there has been no update of the dossier then indicate "N/A" (not applicable).

Appendix 2: Variations to the product

The applicant should submit a review, in tabular format, of any minor and/or major changes (including those pending) to the initially registered product/to the terms of the initially registered dossier. The same should apply to the B listed product. Table 2 should be completed by the applicant.

Table 2: Information on variations to the registered product

	Reference no.	**Date of submission**	**Date of approval /rejection and reference number of the letter**	**Date of implementation**
Major changes				
Description of the change, e.g. change in the primary packaging site of a sterile product				
Minor changes				
Description of the change according to the DRU variation guide				

Appendix 3
Summary of Specifications of API(s) and FPP information
This section compares specifications of the API and FPP at the time of registration and at the time of the submission for renewal. Table 3 should be completed by the applicant.
Include remarks, as a footnote to Table 3, where deemed necessary to clarify the information provided. Generate a table for the FPP and each API separately.

Table 3.Summary specifications of API(s) or FPP information

Name of API or FPP

Parameter	**Specification on Registered dossier**	**Current data****
Identification		
Description		
Assay		
Water content		
Etc.		