Botswana Medicines Regulatory Authority

BOMRA
MEDICINES REGULATORY AUTHORITY

Approved By: _____

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Director - Product Evaluations and Registration

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Contents

Revision status sheet

Page	Changes Made	Issue No.	Process owner (Title)	Initiated By (Name)	Reviewed By (Name)	Date
4	Add BRIMS and CRP, remove CD in abbreviations	5.0	DPER Manager		Theo Mosala	04/08/2025
9-10	Aligned timelines with new service standards	5.0	DPER Manager		Theo Mosala	04/08/2025
4-5	Align with BRIMS portal	5.0	DPER Manager		Theo Mosala	04/08/2025
8-9	Separated human and veterinary timeline: graphic representation	4.0	DPER Manager			20/09/2021
	Guideline name changed to Guideline on submission of applications and BOMRA timelines.	3.0	DPER manager			01/09/2021
8-9	Changes made to timelines in section 6B	3.0	DPER Manager			01/09/2021
5	Editorial changes	2.0	DPER Manager			01/11/2020
5	Addition of 4.1.10 and 4.1.15	2.0	DPER Manager			17/11/2020
7	Addition of section 6.A.1, 6.A.2 and 6.A.3	2.0	DPER Manager			17/11/2020

1 Purpose

The purpose of this guideline is to ensure consistency in the submission of applications by applicants and to communicate applicable timelines.

2 Scope

This guideline is applicable to applications submitted for screening, new applications for registration, responses, restricted part of DMF, variation applications and renewals.

3 Definitions and Abbreviations

3.1 Definitions

None

3.2 Abbreviations

The following abbreviations shall apply;

3.2.1 BOMRA - Botswana Medicines Regulatory Authority

3.2.2 BRIMS – BoMRA Regulatory Information Management System

3.2.3 CRP – Collaborative Registration Procedure

3.2.4 DMF - Drug Master File

3.2.5 PDF - Portable Document Format

4 Method

4.1 Submission on BRIMS

4.1.1 All required documentation shall be submitted via the BRIMS portal. Applicants can access guidance on step-by-step guidance on how to manage accounts and lodge applications on the BRIMS helpdesk at the following link, https://helpdesk.bomra.co.bw/knowledgebase.

4.1.2 Applicants shall submit information per the Guideline on Application for Registration of Complementary Medicines ***BOMRA/ER/CM/P03/G01***, Human Medicines' Registration Quality Guidelines ***BOMRA/ER/MD/P04/G08***, Guideline for Registration of Pharmaceutical VMPs ***BOMRA/ER/VET/P01/G01***, Guideline for Registration of Immunological VMPs ***BOMRA/ER/VET/P02/G02*** and Guideline for Registration of Complementary Veterinary Medicines in Botswana ***BOMRA/ER/VET/P06/G01***.

4.1.3 The information shall be readable and usable on standard Microsoft office and PDF software.

4.1.4 The folders if compressed should be in standard compression formats such as ZIP.

4.1.5 For documents submitted in PDF format, text searchable formats should be used and appropriately indexed. For instance, in submission of responses the PDF format should be bookmarked for the various responses to the queries.

4.1.6 Receipt for payment shall also be uploaded where payments where made outside of BRIMS. .

4.1.7 Product sample is required for applications for registration only after passing screening and variations that affect the label or appearance of the product.

4.1.8 Submitted DMFs shall indicate the application numbers so that they can be linked with the original submission.

4.1.9 Product samples should be sent to the following address:

Botswana Medicines Regulatory Authority

Plot 112, Gaborone International Finance Park

Gaborone, Botswana

4.1.10 Find attached Annexure rEF1 which gives an example of granularity levels required for CTD format.

4.1.11 Find attached Annexure 2 on registration timelines.

4.1.12 If an application is submitted for a product that has multiple strengths, applicants should also submit for registration of the strength for which bioequivalence was demonstrated.

5. Annexure 1: Granularity Levels Required for CTD Format

Module 3	3.2	3.2.S	3.2.S.1	3.2.S.1.1
				3.2.S.1.2
				3.2.S.1.3
			3.2.S.2	3.2.S.2.1
				3.2.S.2.2
				3.2.S.2.3
				3.2.S.2.4
				3.2.S.2.5
				3.2.S.2.6
			3.2.S.3	3.2.S.3.1
				3.2.S.3.2
			3.2.S.4	3.2.S.4.1
				3.2.S.4.2
				3.2.S.4.3
				3.2.S.4.4
				3.2.S.4.5
			3.2.S.5	
			3.2.S.6	
			3.2.S.7	3.2.S.7.1
				3.2.S.7.2
				3.2.S.7.3

Key

Files

Folders

Annexure 2: Registration timelines

6.A Timelines indicated in this document reflect the time that the application is at BOMRA. Applicants will be given a maximum of 3 months to respond to queries.

6.A.1 In cases where deadlines are not met in response to queries sent it will result in the application being rejected/closed.

6.A.2 Once all cycles to respond have been exhausted, any application with outstanding issues will be rejected.

6.A.3 In cases of technical deficiencies that the applicant has not addressed, applications will also be rejected.

If the applicant still wishes to pursue a rejected application, a new application with applicable fee should be submitted. A new reference number will be issued and any decision on the new application will be independent of the previous application. Should the applicant wish to expedite review of the new application, expedited fee is applicable.

Graphical illustration of timelines: Human (Conventional/allopathic)

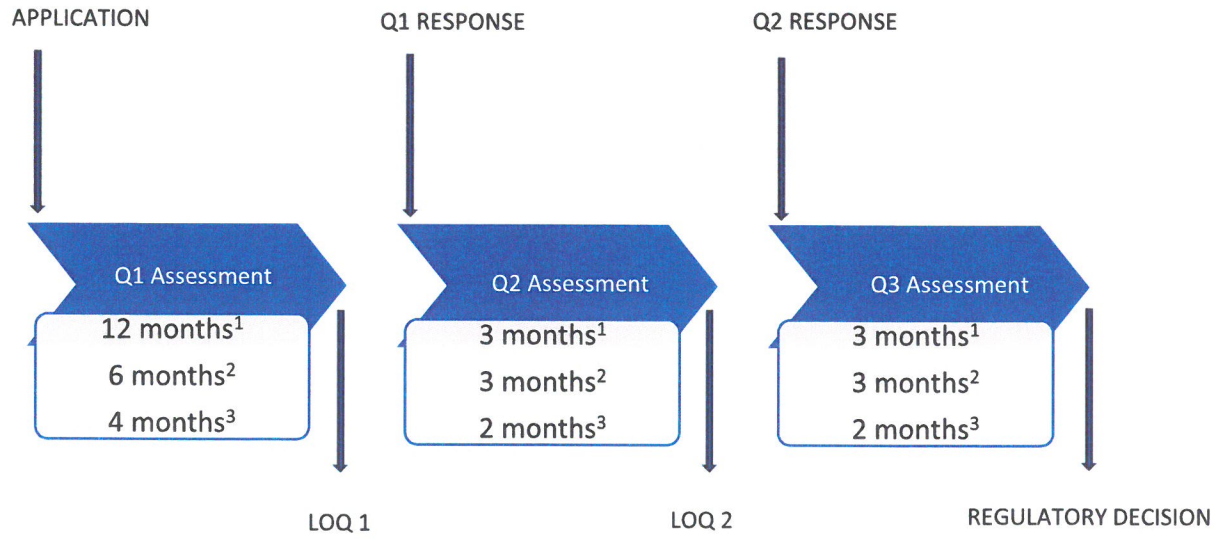

Figure 1: Timelines for Registration of Medicines:(1 – Normal Process Human Medicines , 2 –Normal Process Complementary & Veterinary Medicines , 3 – Expedited Process All medicines)

6.B TIMELINES

6.B1 Conventional/allopathic human medicines

6.B1.1 Screening timelines: 3 months.

6.B1.2 Registration timelines:

6.B1.2.1 Normal process: 18 months.

6.B1.2.2 Expedited / Fast tracked products: 8 months.

6.B1.2.3 Products partly manufactured locally: 12 months.

6.B1.2.4 Products fully manufactured locally: 12 months.

6.B.1.2.5 CRP and/or reliance: 3 months

6.B1.3 Variation timelines:

6.B1.3.1 All Variations: 6 months.

6.B1.4 Renewals timelines

6.B1.4.1 Renewals: 6 months

6.B1.5 Exemptions timelines:

6.B1.5.1 Exemptions: 48 working hours

6.B2 Complementary Medicines

6.B2.1 Screening timelines: 3 months.

6.B2.2 Registration timelines:

6.B2.2.1 Normal process: 12months.

6.B2.2.2 Expedited / Fast tracked products: 8months.

6.B2.2.3 Products partly manufactured locally: 12months.

6.B2.2.4 Products fully manufactured locally: 8 months.

6.B2.2.5 Intermediate Risk products: 4 months.

6.B2.2.6 Low Risk products: 3 months.

6.B2.3 Variation timelines: All Variations: 3 months

6.B2.4 Renewals timelines

6.B2.4.1 Renewals: 6 months

6.B3 Veterinary medicines

6.B3.1 Screening timelines: 3 months.

6.B3.2 Registration timelines:

6.B3.2.1 Normal process: 12months (for all veterinary medicines, regardless of source)

6.B3.2.2 Expedited / Fast tracked products: 8months.

6.B3.2.5 CRP and/or reliance: 3 months

6.B3.3 Variation Timelines: All Variations: 3 months