Botswana Medicines Regulatory Authority

Approved By: _____

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Director - Product Evaluations and Registration

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Date of approval (DD/MM/YY)

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Revision status sheet

Page	Changes Made	Issue No.	Process owner's name	Date
5	Editorial changes	2	DPER Manager	01/11/2020
5	Addition of 4.1.10 and 4.1.15	2	DPER Manager	17/11/2020
7	Addition of section 6.A.1, 6.A.2 and 6.A.3	2	DPER Manager	17/11/2020
8-9	Changes made to timelines in section 6B	3	DPER Manager	01/09/2021
	Guideline name change to Guideline on submission of applications and BOMRA timelines.	3	DPER manager	01/09/2021
8-9	Separated human and veterinary timeline: graphic representation	4	DPER Manager	20/09/2021

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 CDs 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 CD - compact disc

3.2.3 DMF - Drug Master File

3.2.4 PDF - Portable Document Format

4 Guidance on CD submission format

4.1.1 The CDs shall be packed in Jewel CD case.

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

4.1.3 One CD is recommended per product but where it is not possible, multiple CDs may be used and individual modules should not be split over multiple CDs (e.g. if possible, Module 1 should be contained on a single CD).

4.1.4 The folders should not be packed into a zip-file, rar-file or any other file format that has been compressed.

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.

a) The use of double-sided discs or email is not acceptable (unless specifically requested).

b) A printed label shall be created and attached for each unit of the CDs with the following information:

1. Indicate whether it is for screening, new submission, response to (new application queries or variation queries), restricted part of DMF, variation or renewal.
2. The applicant's name.
3. The proprietary name(s) of the product.

4. The registration number, in the case of variations and renewals or application number for responses and new application if provided.
5. The Number of CDs per full set- an indication of its place within the set for example, 1/3, 2/3, 3/3.

4.1.6 The authority will retain all the CDs that would have been submitted.

4.1.7 All accompanying application forms (e.g., Initial submissions and variations) shall be submitted as a hard copy signed in indelible ink.

4.1.8 Receipt for payment shall also be submitted.

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

4.1.10 Submissions can be made through hand delivery or couriered directly to the authority. Applicants are also allowed to email variations and responses to rmu@bomra.co.bw, and the same information in CDs to be submitted for filing.

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

4.1.12 Couriered information should be sent to the following address:

Botswana Medicines Regulatory Authority

Plot 112, Gaborone International Finance Park

Gaborone, Botswana

4.1.13 Find attached Annexure 1 which gives an example of granularity levels required for CTD format.

4.1.14 Find attached Annexure 2 on registration timelines.

4.1.15 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				

6. Annexure 2: Registration timelines

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

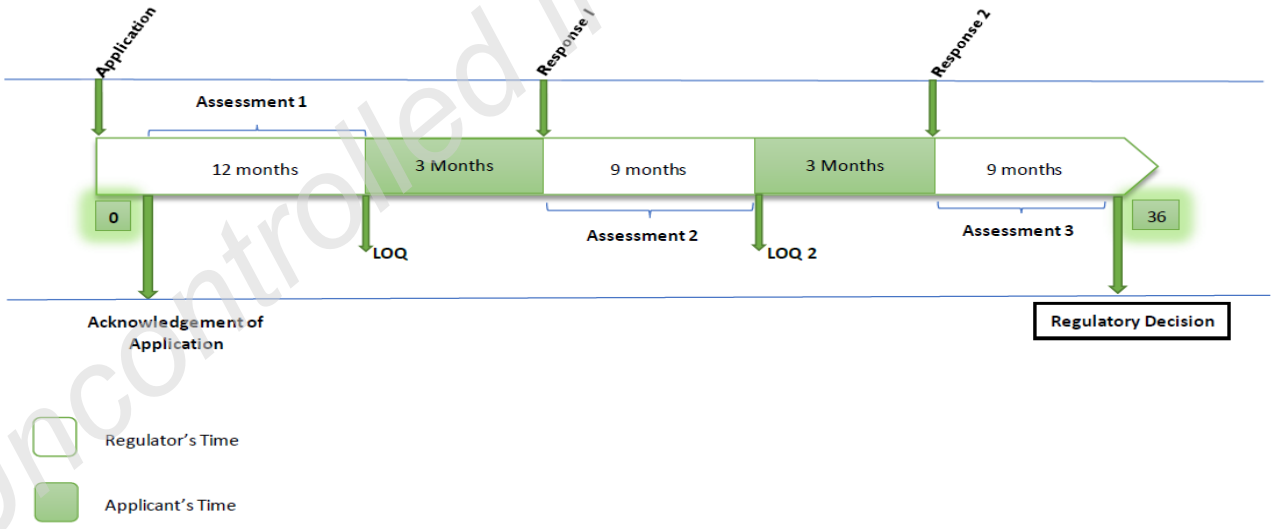
6.A.1 In cases where deadlines are not met in response to queries sent it will result in the application being rejected/closed.

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

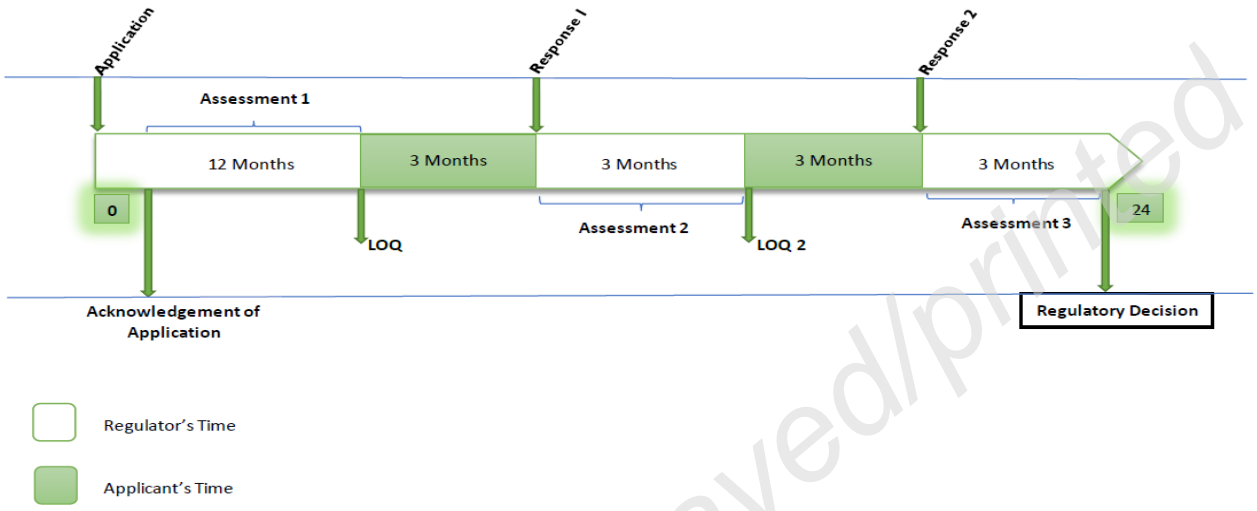
6.A.3 In cases of technical deficiencies that the applicant has not addressed, applications will also be rejected.

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. However, should the applicant wish to expedite review of the new application, expedited fee is applicable.

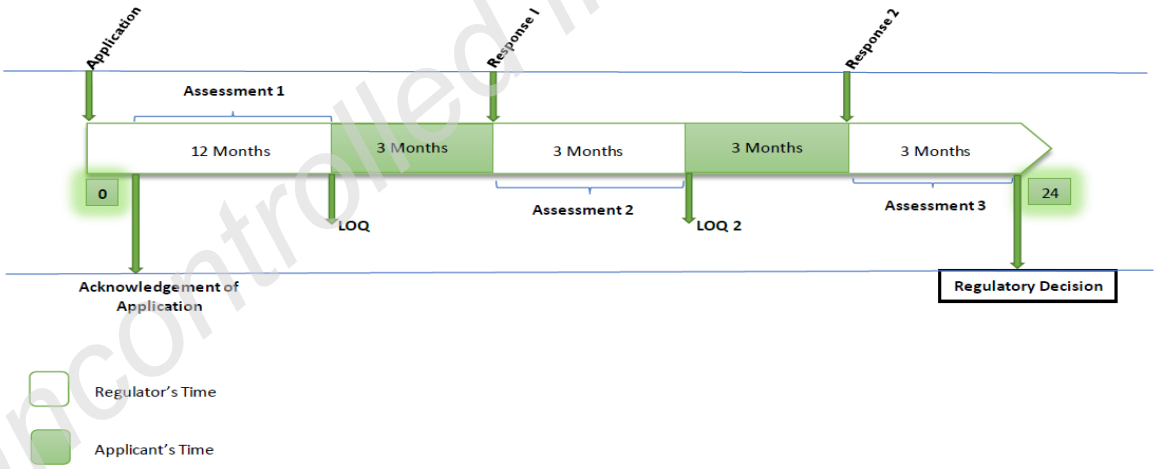
Graphical illustration of timelines: Human (Conventional/allopathic)



Graphical illustration of timelines: Complementary Medicines



Graphical illustration of timelines: Veterinary Medicinal Products



6.B TIMELINES

6.B1 Conventional/allopathic medicines

6.B1.1 Screening timelines: 4 months.

6.B1.2 Registration timelines:

6.B1.2.1 Normal process: 36 months.

6.B1.2.2 Expedited / Fast tracked products: 12 months.

6.B1.2.3 Products partly manufactured locally: 24 months.

6.B1.2.4 Products fully manufactured locally: 18 months.

6.B1.3 Variation timelines:

6.B1.3.1 Notifications: 12 months.

6.B1.3.2 Minor variation: 12 months.

6.B1.3.3 Major variation: 12 months.

6.B2 Complementary Medicines

6.B2.1 Screening timelines: 4 months.

6.B2.2 Registration timelines:

6.B2.2.1 Normal process: 24 months.

6.B2.2.2 Expedited / Fast tracked products: 12 months.

6.B2.2.3 Products partly manufactured locally: 18 months.

6.B2.2.4 Products fully manufactured locally: 12 months.

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

6.B3 Veterinary medicines

6.B3.1 Screening timelines: 4 months.

6.B3.2 Registration timelines:

6.B3.2.1 Normal process: 24 months.

6.B3.2.2 Expedited / Fast tracked products: 12 months.

6.B3.2.3 Products partly manufactured locally: 18 months.

6.B3.2.4 Products fully manufactured locally: 18 months.

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