Botswana Medicines Regulatory Authority

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Date of Approval (DD/MM//YY)

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Revision status sheet

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1 Purpose

1.1 The purpose of this guideline is to ensure consistency in the submission of applications by applicants through the Zazibona Collaborative Procedure (CRP) and to communicate applicable timelines.

2 Scope

2.1 This guideline is applicable to new applications for registration submitted under the Zazibona Collaborative Procedure

3.1 Definitions

The following definitions shall apply;

3.1.1 ZAZIBONA - a collaborative medicines registration initiative in Southern Africa focusing on dossier assessments and good manufacturing practice (cGMP) inspections. The initiative was formally endorsed by the SADC Ministers of Health in 2014 and became part of the SADC medicines registration harmonization (MRH) project in 2015.

3.2 Abbreviations

The following abbreviations shall apply;

3.2.1 **CRP-** Collaborative Registration Procedure
3.2.2 **NRA -** National Regulatory Authority
3.2.3 **SADC -** Southern African Development Community
3.2.4 **cGMP -** Current Good Manufacturing Practice
3.2.5 **MRH -** Medicines Regulatory Harmonization

4 Guidance on Submission

4.1 Process to follow:

i. Choose Zazibona pathway during submission of the application on BRIMS customer portal.

4.2 Documents to be submitted:

i. Completed applicable statutory forms.
ii. A cover letter with expression of interest to follow Zazibona CRP.
iii. A positive recommendation letter from Zazibona.

iv. Full updated dossier in line with recommended BoMRA registration quality guidelines (ref: ***BOMRA/ER/MD/P04/G08***), submission guidelines (ref: ***BOMRA/ER/MD/P04/G01***) and any applicable guidelines (dossier should be the same as what has been submitted to Zazibona),
v. A signed declaration letter indicating that the submitted dossier is the same as what was submitted, reviewed and recommended for approval by Zazibona.
vi. All received lists of queries from Zazibona and their responses.
vii. A letter confirming that the applicant has authorized Zazibona to share assessment reports with BoMRA.
viii. Finished product sample packaged in the proposed final container closure material and labelled in line with SADC Guideline on Product Information.

5 Turnaround Times

i. The dossier will be screened for completeness, a verification exercise done to confirm submission of reports followed by assessment of module1.
ii. The outcome of the assessment will be communicated within 90 days from receipt of the application.

NB- For products already recommended for approval through the previous Zazibona process, their assessment will still be abridged in recognition of the approvals. For such products, applicant must indicate in the cover letter that the product was assessed through the previous Zazibona process and was given a positive recommendation. Additionally, applicants should append proof of approval of the product by SADC NRA.

6 References

6.1 Guideline on Submission of Applications and BOMRA timelines - ***BOMRA/ER/MD/P04/G01***

6.2 Registration Quality Guidelines - ***BOMRA/ER/MD/P04/G08***