






 Plot 112 International Finance Park, Gaborone
 Private Bag 2 Gaborone Station, Botswana
 info@bomra.co.bw

 (+267) 373 1720
 (+267) 373 1727
 (+267) 318 6254

Ref: MRA 1/8/5 Vol I (81)

08 May 2020

All Stakeholders

RE: APPLICATIONS FOR REGISTRATION OF MEDICINES & VARIATIONS

Reference is made to the above subject matter and our letter, ref: MRA 1/8/5 Vol I (53) dated 22 January 2020.

BoMRA commenced receipt of new applications for registration of medicines in February 2020 and owing to anticipated influx of applications, submissions were limited to 5 applications per institution per month. Please be informed that the number of submissions per company are now unlimited with immediate effect. You are advised to familiarize with the submission procedures that are on our website: www.bomra.co.bw.

Regarding variation applications, please be advised that changes to product labelling due to safety updates or submission of Public Safety Update Reports should be submitted **separately** from variation applications as these are processed by the Post Marketing Surveillance & Control of Clinical Trials Department. No fee is applicable to safety updates or updates of product labelling due to safety updates.

If there are any further questions, please contact info@bomra.co.bw.

Yours Sincerely,

Dr. Nkaelang Modutlwa
For/ Chief Executive Officer

Board Of Directors

Mr Duncan Thela (**Chairperson**) / Dr Mbatshi Mazwiduma / Dr Tiroyaone Mampane / Dr Gaseitsewe Sento / Dr Gontle Moleele / Mr Kagiso Balopi

Ms. Botho Kebabonye Bayendi / Dr Joyce Kgatlwane / Ms Shameela Winston / Mr Meshack Baoleki / Dr. Malaki Tshipiyagae / Dr Letlhogile Modisa / Dr Stephen Ghanie