BoMRA
MEDICINES REGULATORY AUTHORITY

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All Stakeholders

RE: REGISTRATION OF B-LISTED PRODUCTS

Reference is made to the letter dated 10 February 2020 on the above subject matter.

The Botswana Medicines Regulatory Authority (BoMRA) commenced registration of B-listed products (products denoted with "B" in the Human Medicines Register / Blue book) therefore manufacturers are required to submit applications. To allow for a phased transition, variation applications for B-listed applications will only be allowed for changes that affect the following information in the Register / Blue Book:

- Brand name of the product
- Company / Manufacturer name change
- Transfer of Marketing authorization – manufacturing site remaining the same.

Note that applications should be submitted for all B-listed products, even when the variation above has been submitted. Submission requirements are as follows:

- Screening fee following Paid Regulatory Services process.
- After passing screening, application fee following Paid Regulatory Services process.
- Completed hard copy Application Form signed in indelible ink. Please quote the B-number in the Application form and dossier.
- A full dossier including completed Quality Information Summary (QIS).

Subject to a successful outcome, the products will be issued a registration (BOT) number and moved to the BOT-list.

Applicants that have not submitted applications for registration of their B-listed products are requested to submit proposed submission schedules to humanmeds.newapp@bomra.co.bw. These proposed schedules should be submitted no later than 12th February 2021.

If there are any further questions on this process, please contact mmoreri@bomra.co.bw

Yours Sincerely,

N. C. Modutlwa

Dr. Nkaelang Modutlwa
For/ Chief Executive Officer