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All Stakeholders

### **RE: REGISTRATION OF B-LISTED PRODUCTS**

Reference is made to the above subject matter.

BoMRA has commenced registration services therefore manufacturers are required to submit applications for registration of B-listed products (products denoted with "B" in the Human Medicines Register / Blue book). To allow for a phased transition while we process these applications, variation applications for B-listed applications will only be allowed for changes that affect the information in the Register / Blue Book, that is:

- Brand name of the product
- Company / Manufacturer name – change in name/address or transfer.

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

- Application fee for screening following Paid Regulatory Services process.
- After passing screening, application fee for B-listed products 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.

If there are any further questions on this process, please contact [mmoreri@bomra.co.bw](mailto:mmoreri@bomra.co.bw)

Yours Sincerely,

Dr. Nkaelang Modutlwa  
**For/ Chief Executive Officer**

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