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All Stakeholders

RE: RENEWAL OF REGISTRATION FOR THERAPEUTIC HUMAN MEDICINES

Reference is made to the BoMRA letter dated 2 April 2020 on the above subject matter.

The renewal of registration for products authorised more than 5 years ago commenced in April 2020. The renewal process started with antiretroviral products as the Authority is implementing a phased approach to effectively manage the number of applications.

Applicants with products registered on or before 31 March 2015 that have not submitted renewal applications are requested to submit proposed schedules of when they intend to submit renewal applications to the Authority. These proposed schedules should be submitted no later than 1st November 2020.

Submission requirements for renewal applications are as follows:

- Completed hard copy Application Form signed in indelible ink. Please quote the BOT number in the Application form and dossier.
- A full dossier including completed Quality Information Summary (QIS) and Renewal Form.
- Applicable fees
- The guideline and the forms are available on the website: www.bomra.co.bw.

Subject to a successful outcome, the registration of the products will be renewed, and the product details updated on the Medicines Register.

If there are any further questions on this process, please contact: humanmeds.renewal@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