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🌐 Botswana Medicines Regulatory Authority
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Promoting access to safe medicines

Ref: MRA 6/1/2 Vol X (230)

18 December 2023

Marketing Authorization Holder

Dear Sir/ Madam,

Re: RETENTION OF PRODUCTS ON THE BOTSWANA MEDICINES REGISTERS FOR THE 2024/2025 FINANCIAL YEAR

Reference is made to the above subject matter.

The Botswana Medicines Regulatory Authority (BoMRA) herein referred to as the Authority would like to notify all stakeholders that, in terms of Section 24 (4) of the Medicines and Related Substances Act of 2013, “where the Authority registers a medicine, the person who applied for the registration shall submit information to the Authority annually, in the prescribed manner accompanied by a prescribed fee”. This provision aims to maintain the Medicines Registers in an updated state. Thus, all Marketing Authorization Holders (MAHs) are required to pay annual retention fees for all the products they intend to retain on the Medicines Registers for the 2024/2025 financial year.

The MAHs who have product registrations in Botswana, should use the Register(s) available on the BRIMS self-service portal and BoMRA website to extract the list of all their products currently registered with the Authority and indicate the list of products they intend to retain. The sales quote for such products as determined by the MAH shall then be generated. Payment of the annual fees should be done not later than the 31st of March 2024.

Notes

- A. Annual retention fees for this cycle are applicable to products registered from the year 2022 backwards.
- B. Medicines Registers for Veterinary Medicines and Human Medicines are available on the BRIMS self-service portal. The retention process for eligible products will be rolled out from BRIMS self-service portal for these classes of medicine. As such no sales quotes will be generated manually.
- C. Products for which the Authority would not have received the annual retention fees by the 31st of March 2024 shall be suspended from the Register in April 2024. These products will not be able to access the Botswana market, thereafter.
- D. The following fees will be applicable as per Regulations of 2019:



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a. Human Medicines

- | | |
|---|----------|
| i. Imported NCE/Generic | BWP 1000 |
| ii. Fully manufactured locally (NCE) | BWP 1000 |
| iii. Fully Manufactured locally (Generic) | BWP 500 |

b. Complementary medicines BWP 400

c. Veterinary Medicines BWP 915

Request for sales quotes, where applicable, should be sent to **registration@bomra.co.bw**. The proof of payment and the product lists to be retained should be emailed to **medicineregister@bomra.co.bw**. For any annual retention fees related enquiries please contact BoMRA on the same email address.

Yours Sincerely,

Dr. Seima Dijeng

ACTING CHIEF EXECUTIVE OFFICER