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Ref: MRA 1/8/5 Vol I (53)

22 January 2020

All Stakeholders

RE: Update - Introduction of Paid Regulatory Services

Reference is made to our letter dated 06 January 2020 with the above subject matter.

Following the publication of Medicines and Related Substances Regulations of 2019, which were gazetted on the 27th December 2019, the Botswana Medicines Regulatory Authority (BoMRA) will offer paid regulatory services with effect from 3rd February 2020. Please refer to Schedule 5 (pages C.1168 to C.1177) of the said regulations, for the approved fees for all regulatory services offered at BoMRA.

The following are the steps to be followed by the applicant:

1. Submit request for Service(s) Form.
2. Receive Proforma Invoice from BoMRA.
3. Make payment (non-refundable) as per the received Invoice.
4. Submit an application with proof of payment.
5. Receive acknowledgement from BoMRA.

Owing to the anticipated influx of applications for registration, BoMRA will initially, until further notice, accept five (5) applications per month per institution. Your cooperation in this matter will be highly appreciated.

Veterinary medicines

BoMRA wishes to notify all stakeholders, including the members of the public that the Authority intends to commence receipt of new applications for registration of veterinary medicinal products (VMP) in Q2 (July – Sept) of the 2020/2021 Financial year.

Below is the work plan in preparation for receipt of the new applications for Registration of VMPs.

#	Activity	Proposed date
1	Stakeholder engagement to discuss requirements for submission of applications for registration of VMPs	March 2020
2	Deadline for submission of comments from stakeholders	30 April 2020
3	Incorporation and finalization of requirements for submission of applications for registration of VMPs	May 2020
4	Notification of the opening date for receipt of new applications for registration of VMPs	June 2020
5	Receipt of new applications	Aug 2020

Board Of Directors

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

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

Cosmetics

Registration of cosmetics has not commenced. The Authority is in the process of developing the regulatory framework for cosmetics. Currently there are no regulatory requirements to register, clear, import or distribute cosmetics, however, importation of skin bleaching cosmetic products remain illegal. Furthermore, we will communicate the regulatory procedures in due course.

Medical Devices

Registration of medical devices has not commenced due to the amendments to the Act. In the meantime, BoMRA advises manufacturers of medical devices to refer to the relevant International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC) standards relevant to their products to ensure compliance. We will communicate the consultative process to discuss the regulations and guidelines in due course.

Licensing & Inspections

BoMRA will move away from the purchase order authorisation system to processing of Import/Export permits for human medicines starting from 3rd February 2020 and all applications shall be routed through our email address impex@bomra.co.bw, along with the purchase order. The applicant is required to pay fee for the permit as per new regulations. This follows the issuance of Import and Export permits for Veterinary medicinal products in July 2019.

The public and our valued stakeholders are further advised that all Applications for licensing of New Veterinary premises and license renewals for existing premises are, effective 1st January 2020 issued by BoMRA.

Laboratory

The Authority is currently not offering any laboratory services as the laboratory is being developed.

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

Yours Sincerely,



Dr Stephen Ghanie
Chief Executive Officer

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