BoMRA
MEDICINES REGULATORY AUTHORITY

Plot 112 International Finance Park, Gaborone
Private Bag 2 Gaborone Station, Botswana
info@bomra.co.bw

(+267) 373 1720
(+267) 373 1727
(+267) 318 6254

Ref: MRA 1/8/5 Vol II (24) **05 August 2020**

Attention: All Stakeholders,

Dear All,

RE: NOTICE – TRANSITION TO A NEW REGULATORY FRAMEWORK FOR MEDICINES IN BOTSWANA

The above matter bears reference.

Please note that the Medicines and Related Substances Regulations ("Regulations") commenced on the 27th December 2019.

With their advent, the Regulations ushered in new regulatory requirements for the regulation of medicines including new fees and forms. The Botswana Medicines Regulatory Authority ("BoMRA") further developed Guidelines for implementation with the Regulations.

Given the changing regulatory regime, BoMRA has determined transition periods and areas of interest to be noted by the affected stakeholders as follows:

Registration of a Medicine by a Company
In accordance with the MRSA, an applicant for registration of medicines should be a company registered, licensed, or operating in Botswana.

Applicants and market authorization holders shall be given up to *1st April 2021* to ensure that they are companies registered, licensed, or operating in Botswana.

Renewals – Section 24(4) of MRSA
BoMRA shall be implementing a phased approach towards renewal of medicines registrations. BoMRA commenced with renewals of antiretrovirals on the 1st April 2020. The following strategy shall be adopted for renewals by BoMRA:

2020/21 – antiretroviral products
2021/22 – antiretrovirals + antituberculosis products
2022/23 – antiretrovirals + antituberculosis + antimalarial products

BoMRA shall notify applicants when other renewals shall commence.

Medicines requiring renewal shall continue to be valid notwithstanding non - renewal in the interim.

Use of New Guidelines – Complementary Medicines

BoMRA commenced with receiving and processing of applications for complementary medicines on 3rd February 2020.

Prior to the commencement of the new MRS Regulations, applications for complementary medicines were in accordance with the format prescribed in the outgoing guidelines and forms, that had been in use since 2013.

BoMRA shall continue to receive and process complementary medicine applications in line with the outgoing guidelines and forms, up to *3rd February 2021*.

BoMRA shall also be receiving applications in accordance with the new Application for Registration of Complementary Medicines in Botswana Guideline (BOMRA/ER/CM/P03/G01) and forms and, despite the transition permitted, encourages applicants to use the new guidelines and form as they represent best practice for complementary medicines.

All companies/traders of complementary medicines that are not registered are requested to apply for registration of their products as it is not permissible to market unregistered products.

Inspections and Licensing

Inspections and Licensing of all Veterinary medicinal outlets will follow new guidelines as published on the BoMRA website effective July 2020.

urrent Good Manufacturing Practices (cGMP) inspections of international pharmaceutical manufacturers will commence with the relaxing of covid-19 restrictions on external travel. BoMRA has commenced local cGMP Inspections as per WHO guidelines published on the Authority's website (TRS 986 – Annex II).

Licenses for local manufacturers of both human and veterinary medicines will be issued by BoMRA effective 1st August 2020. Revised requirements for applications for manufacturing licenses will be availed on the BoMRA website before this effective date

Manufacturing licenses for medical devices and cosmetics will continue to be issued by the Ministry of Investment, Trade and Industry, Department of Industrial Affairs until a time to be announced. This is meant to minimize business disruptions and ensure seamless handover of the licensing function for all manufacturers of products regulated under the Medicines and Related substances Act. BoMRA will however carry out inspections from time to time to verify compliance with products manufacturing requirements and guidelines.

Please note that the license from BoMRA is based on fitness of facility to operate as a pharmaceutical operation. The licensees will still need to contact Ministry of Trade for trading licenses.

Import and Export Permits
Import and export permits will continue to be issued for human pharmaceuticals, complementary medicines and veterinary medicinal products. This is applicable to both registered products as well as products exempted from registration.

Entities issued with BoMRA exemption letters for medical devices and cosmetics do not require an import permit to bring products into the country during the state of national emergency. Any changes in this position will be timeously communicated to allow for necessary business adjustments.

An announcement on issuance of import and export permits for all other products will be made in due course.

Fees
BoMRA levies fees for the provision of its services, which fees are set out in Schedule 5 of the MRS Regulations.

Please note that Screening for human medicines has been erroneously reflected as P1 1600. The correct fees for Screening are **P1160**, being the amount that shall be levied for Screening by BoMRA.

Forms
Please note the following corrections in the forms of the MRS Regulations, as gazetted in the Government Gazette Extraordinary (Vol LVII, No 102):

a. Form 22 labelled *"Application for Registration of Complementary Medicines"* should read *"Exemption from Registration of Complementary medicine"* and is to be used when applying for exemptions for complementary medicines. The form runs from C1161 to C.1163, **not** C1164.

b. At page C.1164, *"Approval for Registration of a Complementary Medicine"* is a separate form and does not constitute part of the *"Exemption from Registration of Complementary Medicine"* Form. Approvals for registration for complementary medicines shall be as per *"Approval for Registration of a Complementary Medicine."*

The Authority has not commenced issuing Registration Certificates in Form 3 of the MRS Regulations. Registration letters are currently being issued as evidence of registration until a date to be communicated. The letters issued before this date shall remain valid notwithstanding non – renewal of marketing authorization.

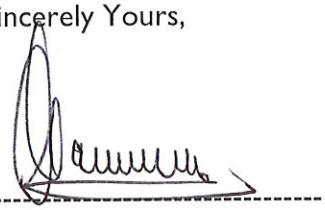
Retention fees
BoMRA shall not be collecting annual retention fees prescribed under the MRSA 24 (4) until 1st April 2021.

Conclusion
Despite the granting of transitions, BoMRA encourages applicants and market authorization holders to align with the new requirements as soon as practicable to avoid future compliance issues.

You are advised that the above does not in any way, reduce or limit BoMRA' s rights to request any information and/or impose any other condition/requirement or take any other action as it may deem necessary to ensure the safety, quality and efficacy of medicines.

If any further clarity is required on any aspect of the provisions dealing with medicines please contact BoMRA at info@bomra.co.bw or on 3731720 for assistance. Further information may be obtained from www.bomra.co.bw.

Sincerely Yours,



Dr. Stephen Ghanie
Chief Executive Officer