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All Stakeholders

## **OPERATIONAL UPDATE AND SERVICES DURING THE LOCKDOWN**

Following the reintroduction of a lockdown for the greater Gaborone zone on the 30<sup>th</sup> July 2020 by His Excellency the President. The Botswana Medicines Regulatory Authority would like to share the following business continuity measures during the lockdown period.

These measures are aimed at minimising the potential disruptions of services during the lockdown period.

#### I. Lockdown Business Hours

While our business operating hours remain unchanged during the lockdown customers are strongly advised to use our online virtual platforms to access our services as 75 percent of the workforce is currently working remotely.

## 2. Suspension of all Meetings and Workshops

We regret to announce the immediate suspension of all stakeholder engagements, these extend to all scheduled meetings, seminars, and workshops. We would like to assure stakeholders that we will be monitoring the developments and the advice by the National COVID 19 Taskforce, and reschedule to a suitable, later date.

#### 3. Registration Services

All core activities related to the registration of medicines are not affected by the lockdown. These include the screening of applications, variations and exemptions, complementary medicines, cosmetics, and medical devices.

Payments for these services can still be made via EFT and direct deposits and proof of payment (POP) must be sent via email to <a href="mailto:kmosala@bomra.co.bw">kmosala@bomra.co.bw</a> or <a href="mailto:records@bomra.co.bw">records@bomra.co.bw</a> highlighting in the subject the application type, name of the product and registration number, where applicable.

The CDs should be submitted once normal operations resume and the following shall apply: Service request forms and proforma invoices will be processed electronically as before. Submissions of samples for registration is on hold until further notice.

**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 Kgattwane / Ms Shameela Winston / Mr Meshack Baoleki / Dr. Malaki Tshipiyagae / Dr Lellhogile Modisa / Dr Stephen Ghanle

Letters will be sent electronically however we urge all applicants to acknowledge receipt of the communication. Hard copies may be collected once we resume normal operations.

## 4. Complementary Medicines and Cosmetics

Service Requests Forms for Complementary Medicines and Cosmetics should be sent via email to <a href="mailto:compmeds.services@BOMRA.co.bw">compmeds.services@BOMRA.co.bw</a>.

All inquiries are to be sent to <a href="mailto:rchihaka@bomra.co.bw">rchihaka@bomra.co.bw</a>; <a href="mailto:sdipula@bomra.co.bw">sdipula@bomra.co.bw</a> and <a href="mailto:kkeakile@bomra.co.bw">kkeakile@bomra.co.bw</a>

# **Exemptions**

All applications and inquiries related to exemptions should be sent to exemptions@bomra.co.bw

#### Medical devices

All applications and inquiries related to medical devices should be sent to medicaldevices.services@bomra.co.bw

### 5. Legal and Enforcement

The Enforcement Department continues to operate and receive reports of infringements of the Medicines and Related Substances Act.

Members who are aware of, or suspect a breach of the Medicines and Related Substances Act may contact BoMRA on +267 74988042, +267 73439790, +267 74988051 or email <a href="mailto:info@bomra.co.bw">info@bomra.co.bw</a>

#### 6. Inspection & Licensing

Application for both license renewals and pre-licensing of new premises continue to be received during the lockdown period.

Scanned copies of applications along with proof of payment (POP) should be sent via email to <a href="mailto:inspections@bomra.co.bw">inspections@bomra.co.bw</a>

Customers are advised that hard copies may only be submitted post lockdown period. Licenses for compliant facilities continue to be issued and will be scanned and emailed to applicant's addresses provided, while the original copy of the license can be collected from the office following the period of Greater Gaborone lockdown. Licensing enquiries can be made to <a href="mailto:inspections@bomra.co.bw">inspections@bomra.co.bw</a> or telephone +2673731727, +26773026216.

Application for Import/Export permit should be submitted via email <a href="mailto:impex@bomra.co.bw">impex@bomra.co.bw</a>
Original application documents accompanied by proof of payment must be submitted at a later date post lockdown. All permits will be emailed back to the applicants.

Further Import/Export inquiries may be communicated through mobile no (+267) 73181144.

#### **Board Of Directors**

## 7. Pharmacovigilance and Clinical Trials

The department continues to receive applications for Advertisement & Promotional materials approvals and for clinical trials approval. Payments for these services can still be made via EFT and direct deposits and proof of payment (POP) must be sent via email to <a href="mailto:kmosala@bomra.co.bw">kmosala@bomra.co.bw</a> or <a href="mailto:records@bomra.co.bw">records@bomra.co.bw</a> highlighting in the subject the application type.

Documents for review may be submitted by e-mail (ekelentse@bomra.co.bw / lkoitsiwe@bomra.co.bw) or by data transfer through shared drives.

Healthcare professionals are encouraged to continue to report ADRs by e-mail (reportadr@bomra.co.bw),

by e-reporting through BoMRA website ( $\underline{\text{https://www.bomra.co.bw}}$ ) or smartphone based Med Safety App.

BoMRA is committed to providing quality regulatory services through active engagement and effective communication even during the lockdown period.

You are encouraged to visit our online platforms, website, (www.bomra.co.bw) and social media platforms for regular updates and feedback.

Sincerely Yours,

Dr. Stephen Ghanie

**CHIEF EXECUTIVE OFFICER** 

