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18<sup>th</sup> February 2020

Attention: All Stakeholders

Dear All,

**RE: NOTICE – COMPLIANCE WITH MEDICINES AND RELATED SUBSTANCES ACT AND REGULATIONS**

1. The above matter bears reference.
2. Please note that the Botswana Medicines Regulatory Authority (BoMRA) is charged with the implementation of the Medicines and Related Substances Act (MRSA), Regulations and Guidelines. The MRSA deals with requirements for the use of both human and veterinary medicines, cosmetics and medical devices.
3. Members of the public, and more particularly persons dealing with importing, exporting, manufacturing, distributing, selling and dispensing of medicines are expected and advised to familiarize themselves with the provisions of the MRSA, its Regulations and Guidelines.
4. No importing, exporting, manufacturing, distributing, selling and dispensing of medicines may be done without obtaining the requisite licenses, authorisations and/ or exemptions from BoMRA. Medical practitioners, dentists, pharmacy technicians and other health personnel should further ensure they have the requisite approvals from the Minister of Health and Wellness, the Director of Health Services and/or the Director of Veterinary Services as the case may be.
5. BoMRA has further identified the widespread occurrence of a number of contraventions of the MRSA, which it would like to bring to your attention, including the following:
  - a. Dispensing of schedule 2 medicines to persons without prescriptions;
  - b. Dispensing of medicines by persons not authorized to dispense;
  - c. Importing, distributing and selling of unregistered medicines;
  - d. Advertising of medicines with false medical claims;
  - e. Selling of registered and unregistered medicines via social media platforms;
  - f. Use of medicines for unintended/illegal purposes. e.g. Bronclear and Misoprostol;
  - g. Absence of Responsible Pharmacists/Authorised persons from pharmaceutical operations during trading hours;




**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 Kgallwane / Ms Shameela Winston / Mr Meshack Baoleki / Dr. Malaki Tshipiyagae / Dr Letlhogile Modisa / Dr Stephen Ghanie



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- h. Inadequate record keeping leading to lack of product traceability into and out of pharmaceutical operations; and
  - i. Failure by Marketing Authorisation holders to monitor product safety and report adverse events observed.
6. All stakeholders affected by this notice are advised to cease practices that lead to contraventions of the MRSA, and to note that BoMRA shall be taking the requisite action to ensure compliance thereto. Failure to adhere to the prescribed laws shall result in sanctions including fines and/or imprisonment, and further, in the case of licensed/approved medical practitioners, dentists, pharmacy technicians and other health personnel, suspension and revocation of licenses/approvals.
7. If any clarity is required on any aspect of the provisions dealing with medicines or should any person wish to report a contravention of the MRSA they are advised to contact BoMRA at [info@bomra.co.bw](mailto:info@bomra.co.bw) or on 373 1720 for assistance. Further information may be obtained from [www.bomra.co.bw](http://www.bomra.co.bw).
8. We look forward to your cooperation in ensuring the medicines used in Botswana remain safe and efficacious and availed through prescribed channels and avenues.

Sincerely Yours,

Dr. Stephen Ghanie  
**Chief Executive Officer**

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