PUBLIC NOTICE

CALL FOR SUBMISSION OF APPLICATIONS FOR REGISTRATION OF BV21 LISTED VETERINARY MEDICINAL PRODUCTS (VMPS)

The Botswana Medicines Regulatory Authority (BoMRA), referred to herein as the Authority, would like to notify all its valued stakeholders that in accordance with the Medicines and Related Substances Act (MRSA) of 2013, it established a Veterinary Medicines Register comprising the interim BV List (of quasi Market Authorization (MA) / listed VMPs) and the BOV List (of full MA / registered VMPs). In the BoMRA letters sent to the stakeholders, communicating its intention to establish the BV List, it was indicated that inclusion of the products in the BV List was not based on the successful evaluation of the safety, quality, and efficacy of the products and that the stakeholders were, within the next 5 year MA validity period, required to submit an application, in a prescribed manner and accompanied by a prescribed fee, for full registration of the products. The Authority, in its subsequent stakeholder engagements, have communicated the need for all stakeholder whose products have been included on the BV List to consider submission of their dossiers before or at the end of the third year to allow BoMRA adequate time to validate completeness and conduct scientific evaluation of the quality, safety and efficacy of the BV Listed VMPs and issue full MA before or by the end of the first 5 year quasi-MA validity period.

Please note that, all listed VMPs whose listing numbers begin with BV21 are now in their third year of marketing in Botswana based on the quasi-MA granted as per the BV List. All stakeholders who own the said VMPs are expected to compile the dossiers for these products and submit them to the Authority.

The process for application for registration or full MA of VMPs is a 2-step process which is managed through the BoMRA Regulatory Information Management System (BRIMS) as follows:

Product Screening Request: Applicants should submit their dossiers for validation of completeness from their own account on the BRIMS self-service portal.

Product Evaluation & Registration: Upon receipt of confirmation of Completeness of the dossier (BoMRA screening pass/approval letter), applicants will initiate the new application for registration from their own account on the BRIMS self-service portal.

NOTES:

The Authority is no longer considering any further listing of VMPs, and for all products not appearing on the current BV List or BOV List, an application for registration should be submitted to the Authority prior to its marketing in Botswana, unless an exemption authorisation is granted in line with the Veterinary Exemptions Process on the BRIMS.

This call for submission of applications is intended for products appearing on the BV list whose listing number starts with BV21.

Failure to submit applications as requested in para 3 above shall result in the products being suspended and removed from the Veterinary Medicines register.

NO variation applications, other than for MA transfer, change in the name of product, name of Applicant and name of Manufacturer which does not involve change of formulation and manufacturing site, are allowed for listed VMPs.

The said applications shall be accompanied by applicable application fees.

If there are any further questions on the information communicated above, please do not hesitate to contact the Authority on **info@bomra.co.bw** or registration.**vetmeds@bomra.co.bw**

Plot 112, International Finance Park, Gaborone
Private Bag 2, Gaborone Station, Botswana
+267 373 1727/20
Toll Free : 0800 600 216
info@bomra.co.bw
Botswana Medicines Regulatory Authority
www.bomra.co.bw