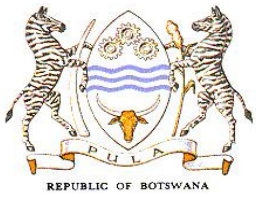
ADDITIONAL REQUIREMENT FOR PRODUCTS REGISTERED IN STRINGENT REGULATORY AUTHORITIES

Second Edition

July 2016



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INTRODUCTION

Registration of medicines is a critical aspect of ensuring public health. The Drugs Advisory Board recognises the competence of Stringent Regulatory Authorities [SRA] (as defined by WHO)[1]. In addition to the SRA as listed by WHO, WHO prequalified medicines and USFDA Tentatively approved products are included in this requirement. This guideline is meant to specifically address applications from SRAs. The applications must comply with all other guidelines and requirements relating to medicines in Botswana. In order to improve access to registered medicines, complete applications will be fast-tracked and evaluated within four (4) months of submission. Therefore, registration in Botswana will be based on registration in the respective SRA.

The Drugs Regulatory Unit (DRU) will accept applications for variations (formulation, shelf life, specifications, additional manufacturing sites - API or FPP etc) provided they have been approved by the SRA. Therefore the applicant should always attach the SRA variation approval in the submission. Failure to attach SRA variation approval will lead to delays or suspension, cancellation etc of products registration.

[1] World Health Organisation (WHO) ***Definition of Stringent Drug Regulatory Authority (SRA):*** means a regulatory authority (in case of the European Union both EMA and national competent authorities are included) which is (a) a member of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ICH (as specified on its website:); or (b) an ICH Observer, being the European Free Trade Association (EFTA) as represented by SwissMedic, Health Canada and World Health Organization (WHO) (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally binding mutual recognition agreement including Australia, Norway, Iceland and Liechtenstein (as may be updated from time to time).

ADDITIONAL REQUIREMENT DOCUMENT

1. The approved summary of product characteristics (SmPC), or an equivalent thereof. Applicants are expected to use the SRA approved SmPC without any changes.

   Any differences in the SmPC / CPP should be highlighted and justified in the initial submission.

2. If the label e.g. colour, artwork which are market specific are different from the product approved by the respective SRA, then a justification for such should be submitted. Variations to the labeling of the FPP should be implemented by the applicant only after the proposed changes have been evaluated and approved by DRU.

3. If the proprietary name of the product is different from the one approved by the SRA, then a justification must be submitted.

4. A signed and dated declaration form (Appendix 1)

APPENDIX 1

DECLARATION BY AN APPLICANT

(PRODUCTS REGISTERED BY STRINGENT REGULATORY AUTHORITIES)

Declaration by an Applicant: I, the undersigned certify that all the information in this form and all accompanying documentation is correct. I further certify that I have examined the following statements and I attest to their accuracy.

The current edition of the WHO GMP guideline on "Good Manufacturing Practice for Pharmaceutical products", and/or equivalent national guideline, is applied in full in all premises involved in the manufacture of this medicine.

1. The formula per dosage form correlates with the master formula and with the batch manufacturing record.
2. The manufacturing procedure is exactly as specified in the master formula and batch manufacturing record.
3. Each batch of all starting materials is either tested or certified (in accompanying certificate of analysis for that batch) against the full specifications in the accompanying documentation and must comply fully with those specifications before it is released for manufacturing purposes.
4. All batches of the active pharmaceutical ingredient (s) (raw materials) are obtained from the source(s) specified in the accompanying documentation.
5. No batch of active pharmaceutical(s) will be used unless a copy of the batch certificate established by the active ingredient manufacturer is available.
6. Each batch of the container/closure system is tested and certified against the full specifications in the accompanying documentation and complies fully with those specifications before it is released for manufacturing purposes.
7. Each batch of the finished product is tested and certified (in an accompanying certificate of analysis for that batch), against the full specifications in the accompanying documentation and complies fully with release specifications before it is released for sale.
8. The person releasing the product is an authorized person as defined by the ICH guideline "Good Manufacturing Practices: Authorized person - the role, functions and training" and /or an equivalent national guideline.
9. The procedures for control of the finished product have been validated. The assay method has been validated for accuracy, precision, specificity and linearity.
10. The holder of the registration is obliged to follow national requirements for handling adverse reaction on its products.
11. The holder of the registration is obliged to follow national requirements for handling batch recalls of its products.
12. Clinical Trials including Bioavailability or Bioequivalence studies were conducted in accordance with Good Clinical Practice.
13. The formula applied for is exactly the same as the formula approved by SRA. The strength, specifications (API, excipients and FPP), etc. are exactly the same as the formula approved by ICHSRA.
14. The information in the dossier submitted to Botswana contains information which is the same as the information in the dossier which is approved in the SRA.
15. Any amendments and variations in the dossier approved by the SRA will be communicated to Botswana within 3 months of approval.
16. The package insert, summary of product characteristics, patient information leaflet submitted in the application are the same as those approved by the SRA.
17. All the documentation referred to in this application is available for inspection.

Name: Position in Company:

Signature: Date:

Qualification: