Botswana Medicines Regulatory Authority

Approved By: _____ _____

Dr Innocent Ravengai **Date of approval (DD/MM/YY)**

Acting Director - Product Evaluations and Registration

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Revision status sheet

Page	Changes Made	Issue No.	Process owner's name	Date

1 Purpose

The intention of this guideline is to provide recommendations to applicants submitting new registration applications as well as variations. It represents BoMRA's current standing on the safety, efficacy and quality of medicines.

2 Scope

The guideline provides guidance to applicants on how to generate quality, safety and clinical data for conventional human medicines. It should be noted that this guideline is not intended to be an exclusive approach. BoMRA reserves the right to request any additional information to establish the safety, efficacy and quality of a medicine in keeping with current scientific knowledge at the time of evaluation. Applicants can use alternative approaches but these should be scientifically and technically justified. The Authority is committed to ensure that all registered medicines will be of the required safety, efficacy and quality.

3 Definitions and Abbreviations

3.1 Definitions

The following definition shall apply:

3.1.1 The Authority- The Botswana Medicines Regualtory Authority

3.2 Abbreviations

The following abbreviations shall apply:

3.2.1 BCS - Biopharmaceutics Classification System
3.2.2 DPER - Department of Product Evaluation and Registration
3.2.3 EMA - European Medicines Agency
3.2.4 EU - European Union
3.2.5 ICH - International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
3.2.6 IMDRF - International Medical Device Regulators Forum
3.2.7 SADC - Southern African Development Community
3.2.8 US FDA - United States of America Food and Drug Administration
3.2.9 WHO - World Health Organisation
3.3.0 VICH - International Council for Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
3.3.1 TGA – Therapeutic Goods Administration

4 Introduction

The Botswana Medicines Regulatory Authority (BoMRA) has decided to align certain BoMRA medicine policies, procedures and guidelines with those of the ICH, European Medicines Agency (EMA), International Medical Device Regulators Forum (IMDRF and WHO). These policies, procedures and guidelines are in line with the framework of the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). In adopting these documents BoMRA will reflect global best practice in terms of the quality, safety, and efficacy of medical products regulation.

The Authority is hereby is adopting the following ICH, IMDRF, EMA, VICH, TGA, Health Canada and WHO guidelines and endorses the principles contained therein.
NB: Unless mentioned otherwise, where EMA guidelines adopted in Botswana include references to European Union (EU) legislation, the requirements contained in the referenced EU legislation are not applicable to the evaluation of medicines by BoMRA. Botswana legislation will apply wherever relevant and current.

5 Adopted Human Medicines technical guidelines

5.1 List of adopted technical guidelines

The below list of adopted guidelines should be referred to for quality, bioequivalence, safety and efficacy requirements for new registrations, marketing authorization renewals and variations to currently registered products. Current versions are linked below; however, these are subject to updates and the latest published non-draft version should always be referred to. At its discretion the Authority may recognize guidance from the WHO, US FDA and other regulatory authorities with which BoMRA aligns itself. However, applicants are advised to prepare submissions in line with the listed guidelines, read in conjunction with applicable BoMRA guidelines available https://www.bomra.co.bw/index.php/bomra-downloads/guidelines-manuals/category/22-registration

5.1.1 Quality Guidelines

ICH Quality guidelines https://www.ich.org/page/quality-guidelines

5.1.2 Interchangeability (generic products), Bioequivalence studies and Biowaivers

- EMA Guideline on Investigation of Bioequivalence *(also covers additional strength, BCS based biowaivers),* EMA Guideline on Bioanalytical Method Validation (Bioanalytical method validation, presentation of biopharmaceutical and bioanalytical data, and pharmacokinetic and clinical evaluation of modified release dosage forms). https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/clinical-efficacy-safety-clinical-pharmacology-pharmacokinetics
- ICH M9 on biopharmaceutics classification system based biowaivers https://www.ema.europa.eu/en/ich-m9-biopharmaceutics-classification-system-based-biowaivers

- WHO guidances for organizations performing in vivo bioequivalence studies https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/regulatory-standards/trs966-annex9-invivo-bioequivalence-studies.pdf?sfvrsn=510cfeec_2

5.1.3 Safety and Efficacy

- ICH Efficacy Guidelines https://www.ich.org/page/efficacy-guidelines
- ICH Safety Guidelines https://www.ich.org/page/safety-guidelines

5.1.4 Biological products (including biosimilars)

- Active substance and Finished Product https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/biological-guidelines
- Clinical and Safety guidelines https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-guidelines/clinical-efficacy-safety-guidelines
- WHO Similar biotherapeutic products guidelines https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/sbp
- WHO Standards for biotherapeutic products https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/sbp
- EMA Variation guideline https://www.ema.europa.eu/en/human-regulatory/post-authorisation/variations-human-medicines

6 Adopted Veterinary Medicines Quality guidelines

6.1.1 VICH Quality guidelines

- https://www.vichsec.org/en/guidelines/pharmaceuticals/pharma-quality/analytical-validation.html
- https://www.vichsec.org/en/guidelines/pharmaceuticals/pharma-quality/impurities.html
- https://www.vichsec.org/en/guidelines/pharmaceuticals/pharma-quality/pharma-stability.html
- https://www.vichsec.org/en/guidelines/pharmaceuticals/pharma-quality/pharma-specifications.html

6.1.2 VICH Safety guidelines

- https://www.vichsec.org/en/guidelines/pharmaceuticals/pharma-safety/environmental-safety.html
- https://www.vichsec.org/en/guidelines/pharmaceuticals/pharma-safety/metabolism-and-residue-kinetics.html
- https://www.vichsec.org/en/guidelines/pharmaceuticals/pharma-safety/toxicology.html
- https://www.vichsec.org/en/guidelines/pharmaceuticals/pharma-safety/pharma-target-animal-safety.html
- https://www.vichsec.org/en/guidelines/pharmaceuticals/pharma-safety/antimicrobial-safety.html

6.1.3 Efficacy guidelines (VICH and EMA)

- https://www.vichsec.org/en/guidelines/pharmaceuticals/pharma-efficacy/good-clinical-practice.html
- https://www.vichsec.org/en/guidelines/pharmaceuticals/pharma-efficacy/anthelmintics.html
- https://www.vichsec.org/en/guidelines/pharmaceuticals/pharma-efficacy/bioequivalence.html
- Conduct of bioequivalence studies for veterinary medicinal products https://www.ema.europa.eu/en/conduct-bioequivalence-studies-veterinary-medicinal-products

7 Adopted Complementrary Medicines guidelines

7.1 Quality guidelines

- https://www.tga.gov.au/sites/default/files/qwp281900en01.pdf
- https://www.tga.gov.au/sites/default/files/qwp282000en01_0.pdf
- https://www.tga.gov.au/publication/australian-regulatory-guidelines-listed-medicines-and-registered-complementary-medicines
- https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/quality-guide.html

7.2 Safety/indications

https://ods.od.nih.gov/factsheets/list-all/

7.3 Evidence for homeopathic medicines

- https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/evidence-homeopathic-medicines.html#a2

8 Adopted Medical devices guidelines

8.1 Classification

- Principal of Medical Devices Classification https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf

8.2 In Vitro Diagnostics IVDs

- Principal of In Vitro Diagnostic (IVD) Medical Devices Classification https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-wng64.pdf

8.3 Safety and Performance

- Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-181031-grrp-essential-principles-n47.pdf