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## Botswana Medicines Regulatory Authority




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and Registration**


\_\_\_\_\_

**Date of approval (DD/MM/YY)**

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### Revision status sheet

Page	Changes Made	Issue No.	Process owner's name	Date
4	Added NIH, TGA and VICH to the list of abbreviation	1.0	Manager	18/08/2023
4	Corrected the spelling of Regulatory in 3.1.1	1.0	Manager	18/08/2023
5	Added another sentence in section 5.1.1	1.0	Manager	18/08/2023

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## 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 thinking 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 human and veterinary 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 Authority-** The Botswana Medicines Regulatory Authority

### 3.2 Abbreviations

<b>BCS</b>	Biopharmaceutics Classification System
<b>DPER</b>	Department of Product Evaluation and Registration
<b>EMA</b>	European Medicines Agency
<b>EU</b>	European Union
<b>ICH</b>	International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
<b>IMDRF</b>	International Medical Device Regulators Forum
<b>NIH</b>	National Institutes of Health
<b>SADC</b>	Southern African Development Community
<b>TGA</b>	Therapeutic Goods Administration
<b>US FDA</b>	United States of America Food and Drug Administration
<b>VICH</b>	Veterinary International Conference on Harmonization
<b>WHO</b>	World Health Organisation

## 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

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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 adopting the following ICH, IMDRF, EMA, VICH, TGA, NIH, 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/bomra-downloads/#132-314-wpfd-registration-1657002557>


#### 5.1.1 Quality Guidelines

- ICH Quality guidelines <https://www.ich.org/page/quality-guidelines>
- Draft Guideline on Product Information and Labelling ([https://zazibona.com/wp-content/uploads/2022/11/DRAFT-SADC-GUIDELINE-ON-PRODUCT-INFORMATION-LABELLING\\_version-6\\_-12-Feb-2020.pdf](https://zazibona.com/wp-content/uploads/2022/11/DRAFT-SADC-GUIDELINE-ON-PRODUCT-INFORMATION-LABELLING_version-6_-12-Feb-2020.pdf))

#### 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](https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/regulatory-standards/trs966-annex9-invivo-bioequivalence-studies.pdf?sfvrsn=510cfeec_2)

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### 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 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>

### 6.2 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>

### 6.3 Efficacy guidelines (VICH and EMA)

- <https://www.vichsec.org/en/guidelines/pharmaceuticals/pharma-efficacy/good-clinical-practice.html>

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- <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 Complementary 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/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>