



Medicines Control Authority of Zimbabwe

MCAZ/EVR/GL-29

GUIDELINE ON THE REQUIREMENTS FOR DEMONSTRATING
THERAPEUTIC EQUIVALENCE FOR ORALLY INHALED PRODUCTS
(OIPs) FOR ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY
DISEASE (COPD)

EFFECTIVE DATE: 08/04/2026

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Date



1.0 APPLICATION

This guideline applies to all pharmaceutical manufacturers, applicants and regulatory assessors involved in demonstrating therapeutic equivalence for orally inhaled products for Asthma and Chronic Obstructive Pulmonary Disease (COPD).

2.0 PURPOSE

The purpose of this document is to formalize MCAZ's adoption and implementation of the European Medicines Agency (EMA) Guideline on the Requirements for Demonstrating Therapeutic Equivalence for Orally Inhaled Products (OIPs) for Asthma and Chronic Obstructive Pulmonary Disease (COPD). It informs applicants and assessors of the standards to be applied during product registration and post-approval changes (variations).

3.0 ADOPTION STATEMENT

MCAZ formally adopts the EMA Guideline on the Requirements for Demonstrating Therapeutic Equivalence for Orally Inhaled Products (OIPs) for Asthma and Chronic Obstructive Pulmonary Disease (COPD).

The source guideline is accessible at:

https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-requirements-demonstrating-therapeutic-equivalence-between-orally-inhaled-products-oip-asthma-chronic-obstructive-pulmonary-disease-copd-revision-2_en.pdf

4.0 RATIONALE FOR ADOPTION

To ensure that the MCAZ standards are aligned with international standards and state-of-the-art scientific practices. Adopting international standards such as WHO or ICH reduces duplication of studies, promotes information exchange among the regulators, including reliance, more efficient assessment, aligns the region with global standards, and ultimately increases the availability of medicines to the public. The intended benefits of adopting the EMA Guideline on the Requirements for Demonstrating Therapeutic Equivalence for OIPs for Asthma and COPD are in line with the MCAZ agenda.

5.0 SCOPE

This guideline applies to orally inhaled products intended for the treatment of asthma and COPD. It covers requirements for demonstrating therapeutic equivalence, including invitro

studies, pharmacokinetic studies, and clinical studies, if required. It includes guidance for both new registrations and post-approval changes. It represents the MCAZ's current thinking on Demonstrating Therapeutic Equivalence for OIPs for asthma and COPD.

6.0 VALIDITY

This document is effective from the date of adoption and shall be reviewed as required, but not later than three (3) years from the effective date. In case of revision or updates to the source guideline, the latest version automatically applies, unless a specific transition period is specified by MCAZ.

7.0 ANNOTATIONS/NOTES

None

8.0 DISCLAIMER

All guidelines adopted/adapted by MCAZ from international organizations such as WHO, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) must be read in conjunction with the current, applicable MCAZ guidelines.

MCAZ reserves the right to request additional information in keeping with the knowledge current at the time of evaluation. It is not intended as an exclusive approach as alternative approaches may be used but should be scientifically and technically justified.

9.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change and Amendments
N/A	N/A	None-New Documents