Medicines Control Authority of Zimbabwe

GUIDANCE: DATA REQUIREMENTS FOR APPLICATIONS FOR REGISTRATION OF INHALATION AND NASAL MEDICINES

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GUIDANCE: DATA REQUIREMENTS FOR APPLICATIONS FOR REGISTRATION OF INHALATION AND NASAL MEDICINES

The guidance describes the requirements for applications for registration of inhalation and nasal medicines. In an effort to harmonize MCAZ requirements with those of other National Regulatory Authorities, the organization resolved to adopt the European Medicines Agency (EMA) guidance documents on the quality and clinical requirements for **inhalation and nasal products**. These are available at the EMA website:

Pharmaceutical (Quality Requirements) – CTD Module 3: Guideline on the pharmaceutical quality of inhalation and nasal products

Demonstration of therapeutic equivalence – CTD Module 5: Requirements for clinical documentation for orally inhaled products (OIP) including the requirements for demonstration of therapeutic equivalence between two inhaled products for use in the treatment of asthma and chronic obstructive pulmonary disease (COPD) in adults and for use in the treatment of asthma in children and adolescents

These dosage forms are unique in that the performance of most inhalation and nasal products is not only dependent on the characteristics of the active ingredient and excipients but on the container closure system e.g. the valve and metered system.

The scope of this guidance includes products for administration of the drug substance to the lungs, such as pressurised metered dose inhalers, dry powder inhalers, products for nebulisation, and non-pressurised metered dose inhalers, as well as pressurised metered dose nasal sprays, nasal powders, and nasal liquids. Liquid inhalation anaesthetics and nasal ointments, creams and gels are excluded.

Any changes to the reference documents will also apply to applications for registration submitted to MCAZ. Only aspects specific to inhalation and nasal products are discussed in these reference documents but additional aspects on quality, safety and efficacy as outlined in the MCAZ/WHO/ICH guidelines still apply e.g. procurement of a reference innovator product for interchangeability studies from a stringently regulated market. Deviations from the requirements set out in these guidelines should be justified **scientifically**.

Related information and guidance:

- EMA Scientific guidelines: Clinical efficacy and safety: respiratory system

- Southern African Development Community (SADC) Guidance for the preparation and submission of dossiers in common technical document format http://www.mcaz.co.zw/index.php/downloads/file/63-sadc-guidelines-on-submission-of-applications-in-ctd-format-2015?start=10

- SADC Guideline on Bioavailability / Bioequivalence: http://www.mcaz.co.zw/index.php/downloads/file/65-sadc-guideline-on-ba-be-2015?start=10

- Preparations for Inhalation: aerodynamic assessment of fine particles (Ph. Eur. general chapter 2.9.18)