



GUIDELINE ON THE SUBMISSION OF INFORMATION FOR MODULE 1 OF THE DOSSIER

EFFECTIVE DATE: 08/04/2026

Medicines Control Authority of Zimbabwe

106 Baines Avenue

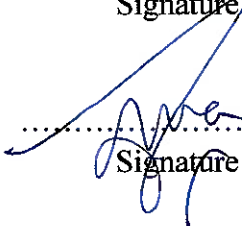
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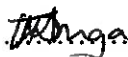
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ABBREVIATIONS AND ACRONYMS

API	Active Pharmaceutical Ingredient
APIMF	Active Pharmaceutical Ingredient Master File
BCS	Biopharmaceutics Classification System
BP	British Pharmacopoeia
CEP	European Certificate of Suitability
CTD	Common Technical Document
DRA	Drug Regulatory Authority
EU	European Union
FDA	United States Food and Drug Administration
FDC	Fixed Dose Combination
FPP	Finished Pharmaceutical Product
ICH	International Conference on Harmonisation
IUPAC	International Union of Pure and Applied Chemistry
INN	International Non-proprietary Name
GMP	Good Manufacturing Practice
Int.Ph.	International Pharmacopoeia
JP	Japanese Pharmacopoeia
MAH	Marketing authorization holder
MASCA	Medicines and Allied Substances Control (General) Regulations
MCAZ	Medicines Control Authority of Zimbabwe
SADC	Southern African Development Community
SI 150	Statutory Instruments 150 of 1991
SmPC	Summary of Product Characteristics
SRA	Stringent Regulatory Authority
PDs	Product Dossiers
Ph. Eur	European Pharmacopoeia
PI	Package Insert
PIL	Patient Information Leaflet
PQIT	Product Quality Information Template
QA	Quality Assurance
QIS	Quality Information Summary
MCAZ-QOS	MCAZ Quality Overall Summary
USP	United States Pharmacopoeia
USD	United States Dollars
WHO	World Health Organisation
WHO TRS	WHO Technical Report Series

1.0 APPLICATION

N/A

2.0 PURPOSE

Objectives

This guideline is intended to:

1. Provide clear guidance on the content, structure, and placement of regional information in Module 1 of the CTD.
2. Outline the general administrative and documentation requirements specific to MCAZ.
3. Assist applicants in the proper compilation and organisation of product dossiers.
4. Promote consistency and standardisation in the format and presentation of submissions.
5. Facilitate efficient screening, validation, and scientific assessment of applications.
6. Reduce deficiencies, queries, and delays during the evaluation process.
7. Enhance transparency, predictability, and consistency in regulatory decision-making.
8. Support the timely development and submission of high-quality dossiers.
9. Improve the overall efficiency of the registration process.
10. Ensure the timely availability of safe, effective, and quality-assured medicinal products.

3.0 BACKGROUND / INTRODUCTION

This guideline provides recommendations for applicants preparing a Common Technical Document (CTD) for the registration of pharmaceutical products with the Medicines Control Authority of Zimbabwe (MCAZ). It is intended to assist applicants in compiling dossiers that meet the regulatory requirements for evaluation of the quality, safety, and efficacy of medicinal products.

This document specifically outlines the format, structure, and presentation of Module 1 of the CTD, which contains region-specific administrative and product information required by MCAZ. This module should contain documents specific to Zimbabwe; for example, application forms, screening forms, fees, package inserts and the proposed label for use in Zimbabwe, and other administrative data necessary to support an application for registration.

Adherence to this guideline will facilitate the efficient review and assessment of product dossiers by ensuring consistency, completeness, and clarity in submissions. Applicants are encouraged to carefully follow the recommendations provided herein to

minimise deficiencies, avoid delays in the evaluation process, and ensure compliance with MCAZ regulatory expectations.

4.0 DEFINITIONS

- 4.1 **Active pharmaceutical ingredient (API):** Any substance or combination of substances used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have a direct effect in restoring, correcting or modifying physiological functions in human beings.
- 4.2 **Applicant:** Means the person or entity by, or on whose behalf, an application for registration is made.
- 4.3 **Established multisource (generic) product:** A multisource product that has been marketed by the applicant or manufacturer associated with the dossier for at least five years and for which at least 10 production batches were produced over the previous year, or, if less than 10 batches were produced in the previous year, not less than 25 batches were produced in the previous three years.
- 4.4 **Finished pharmaceutical product (FPP):** A finished dosage form of a pharmaceutical product which has undergone all stages of manufacture, including packaging in its final container and labelling.
- 4.5 **Innovator pharmaceutical product:** Generally the pharmaceutical product that was first authorised for marketing (normally as a patented product) on the basis of documentation of efficacy, safety and quality.
- 4.6 **Manufacturer** A company that carries out operations such as production, packaging, repackaging, labelling and re-labelling of pharmaceuticals.
- 4.7 **Multisource (generic) pharmaceutical products**
Pharmaceutically equivalent or pharmaceutically alternative products that may or may not be therapeutically equivalent. Multisource pharmaceutical products that are therapeutically equivalent are interchangeable (WHO Technical Report Series, No. 937, Annex 7, 2006).
- 4.8 **Officially recognized pharmacopoeia (or compendium)** Those pharmacopoeias recognized by the MCAZ (i.e. The International Pharmacopoeia (Ph.Int.), the European Pharmacopoeia (Ph.Eur.), the British Pharmacopoeia (BP) and the United States Pharmacopoeia (USP)).
- 4.9 **Principal:** The principal is the product owner or marketing authorization holder (MAH). This is the company that owns the product, is responsible for its quality, safety, and efficacy, and authorizes other parties (e.g., manufacturers or agents) to act on its behalf.

5.0 GUIDELINES

5.1 Granularity of Module 1

Module 1	1.0		
	1.1		
	1.2	1.2.1	
		1.2.2	
		1.2.3	
		1.2.4	
		1.2.5	
		1.2.6	
		1.2.7	
		1.2.8	
	1.3	1.3.1	
		1.3.2	
		1.3.3	
	1.4	1.4.1	
		1.4.2	
	1.5	1.5.1	
	1.6		

Documents rolled up to this level are not considered appropriate

One document may be submitted at this level

5.2 PART B: MODULE 1

Module 1 should contain all administrative documents (e.g. application forms and certifications), labelling, general correspondence and annexes as needed. Documents should be submitted in English and be organised in the order listed below.

Module 1.0 Cover Letter

Documentation		
1.	1.0	Cover Letter

Applicants are required to include a cover letter with all applications. A signed and dated copy of the cover letter should be placed at the beginning of Module 1. The cover letter should clearly state the name and full contact details of the local representative, including the physical address, telephone number, and email address, in line with the requirements of MCAZ Circular 21 of 2024. In addition, the cover letter should provide a brief summary of the application, including the product name, dosage form, strength, and type of application, to facilitate efficient screening and processing by MCAZ.

Module 1.1 Comprehensive table of contents

Documentation		
1.	1.1	Comprehensive table of contents

Module 1 should include a comprehensive table of contents for the entire application. The comprehensive table of contents should include a complete list of all documents provided in the application by module.

In the table of contents, the location of each document should be identified by referring to the volume numbers that contain the relevant documents and any tab identifiers.

Page numbers only should not be used in the table of contents to refer to documents, rather; tab identifiers as described above should be used. Page numbers in addition to the tab identifier should be used to facilitate location within documents where relevant.

Module 1.2 Application Information

Documentation		
1.	1.2.1	Completed, signed and dated MC8 application form

2.	1.2.2	Declaration by the applicant
3.	1.2.3	A screening checklist (see Annex II) indicating that all the sections of the application have been completed and the pages thereof.
4.	1.2.4	Proof of Payment of the appropriate fees
5.	1.2.5	Manufacturing and marketing authorisation(s)/international registration status and/or the WHO certificate of pharmaceutical product (CPP)
6.	1.2.6	Copy of certificate(s) of suitability of the European Pharmacopoeia (CEP) which is valid (including any annexes)

1.2.1 Completed, signed and dated MC8 application form

A completed, signed and dated MC8 form should be submitted for each FPP. For clarity, the following considerations apply in determining whether the FPP requires one or separate applications.

1. Tablets/Capsules/Suppositories/Lozenges:

- i. Different pack-sizes of the same strength and formulation will require one application
- ii. Different strengths and/or formulations will require separate applications.

2. Syrups/Elixirs/Liquids/Solutions (non parenterals)/Creams/ointments:

- i. Different container sizes of the same strength and formulation will require one application
- ii. Same container size of different strengths and/or formulations will require separate applications.

3. Ampoules, Vials and Large Volume Parenterals

- i. Ampoules containing identical solutions of the same strength but of different volumes will require separate applications;
- ii. Ampoules containing solutions of different strengths will require separate applications;
- iii. Ampoules and/or single dose vials containing dry powder, crystals etc., of different mass will require separate applications;
- iv. Dry powders or crystals etc. of the same respective mass, packaged in ampoules and single dose vials will require separate applications;
- v. Ampoules, single dose vials, as well as disposable syringes and cartridges containing identical solutions of the same strength and same volume of liquid will require one application;
- vi. Dental cartridges containing fluids of different volumes will require one application;

- vii. Ampoules containing "water for injection", but of different volumes will require one application;
- viii. Special ampoules of dry powder and "water for injections" contained in the same unit, but intended for mixing at the time of injection, will require one application;
- ix. Ampoules containing identical solutions of different volumes used only as a diluent in the reconstitution of a preparation for parenteral use will require separate applications;
- x. Multi-dose vials of the same strength and formulation in different volumes will require separate applications;
- xi. Multi-dose vials and a single dose ampoule of the same formulation will require separate applications;
- xii. Multi-dose vials containing dry powder of different masses and the same formulation, and having the same concentration when reconstituted will require one application;
- xiii. A container of diluent to be used with any preparation in (iii), (iv) or (xii) will require one application provided that the diluent is also fully described in the dossier together with the product;
- xiv. An ampoule of diluent to be used with any biological preparation will require one application;
- xv. Infusion solutions of the same or different volumes and of the same formulation, which are packed in containers of exactly the same type of material, will require one application;
- xvi. Infusion solutions of the same or different volumes and of the same formulation, which are packed in containers made of different types of materials, will require separate applications;
- xvii. A preparation, packed in plastic containers and intended also to be marketed in glass containers containing the same volume and the same formulation, will require one application provided the following data are submitted: -
 - Characteristics of the rubber stopper;
 - Specifications for the glass;
 - A comprehensive manufacturing process with particular reference to the washing and sterilization cycles and apparatus used;
 - Data on particulate matter (contamination);
 - Stability data with reference to the effect of the pH of the solution.
- xviii. Products with the same strength and formulation but with different colours and/or flavours will require separate applications;
- xix. Applications containing the same active ingredient(s), and where additional indications are sought, where such new indications render the product in a different category of distribution (scheduling status), or different pharmacological classification or have any other restrictions imposed other than the original application, will require separate registration.

4. Different applicants/proprietary names for the same formula;

- i. Same formula applied under different proprietary names will require separate applications.
- ii. Same formula from different applicants will require separate applications.

Guidance on completing the MC8 form

Guidance for Completing the MC8 Application Form for Registration of a Medicine

General Instructions

1. **Form Completion:** Submit a fully completed copy of the MC8 form.
2. **Completeness:** Incomplete or illegible forms will result in processing delays or rejection.
3. **Supporting Documentation:** Attach all required appendices and supplementary documents as outlined in the relevant sections.
4. **Authentication:** The form must be signed by an authorized representative and dated to validate the application.

Section-by-Section Technical Instructions

Particulars of Applicant

1. **Legal Name:** The full registered name of the applicant (company or individual) as per national registration.
Example: “MCAZ Pharmaceuticals (Pvt) Ltd.”
2. **Business Address:** The physical location where the applicant conducts business operations.
3. **Postal Address:** If different from the business address, provide a valid mailing address.
4. **Telephone Number:** Include international dialling code and area code.
Example: “+263 24 2751234”

Particulars of the Medicine

1. **Approved Name (INN):** The International Nonproprietary Name (INN) or generic name of the active pharmaceutical ingredient (API), excluding dosage form or strength.
Example: “Amoxicillin”
2. **Proprietary (Trade) Name:** The brand name under which the product will be marketed.
Example: “MCAZtab”
3. **Patent Information:** Provide the patent title, registration number, name of the patent holder, and indicate whether the patent is still in force.

4. **Dosage Form and Colour:** Specify the pharmaceutical form (e.g., tablet, capsule, suspension) and its physical appearance.
Example: “Oblong shaped off white plain tablets”
5. **Manufacturer and Principal Details:** Full legal names and addresses of the manufacturer and marketing authorization holder.
6. **Country of Origin:** The country where the final product is manufactured and released.
7. **Strength:** The quantity of active ingredient per dosage unit.
Example: “250 mg per capsule”
8. **Pharmacological Classification:** Refer to the Fifth Schedule of the Medicines and Allied Substances Control (General) Regulations for the correct classification.
9. **Local Manufacture/Repacking:** If any part of the manufacturing, repackaging, or relabeling is conducted in Zimbabwe, provide full details.
10. **Manufacture Completion Address:** The site where the final manufacturing step (e.g., packaging, labeling) is completed.
11. **Certificate Storage:** Indicate the secure location where the original registration certificate will be stored.
12. **Application Fees:** State the amount paid and attach proof of payment.

Appendices

Appendix I: Product Composition

Provide a comprehensive breakdown of the formulation:

1. **Active and Inactive Ingredients:**
 - *Example:*
 - *Active:* “Amoxicillin trihydrate equivalent to 250 mg amoxicillin”
 - *Inactive:* “Magnesium stearate, Microcrystalline cellulose”
2. **Chemical Names and Structural Formulas:** Include IUPAC names and chemical structures for all active ingredients.
3. **Specifications:** Reference recognized pharmacopoeias (e.g., BP, USP, EP).
4. **Quantitative Composition:** State the exact quantity of each ingredient per dosage unit.
5. **Justification for Excipients:** Explain the functional role of each excipient (e.g., binder, disintegrant, preservative).
6. **Raw Materials Not in Final Product:** Provide specifications for solvents or reagents used during manufacture but not present in the final product.
7. **Packaging Materials:** Include specifications for all primary packaging components (e.g., blister foil, bottle, cap).

Appendix II: Manufacturing and Controls

1. **Manufacturing Process:** Provide a flow diagram and narrative summary of the manufacturing process.

2. **Analytical Controls:**
 - i. *Raw Materials*: Identity, purity, and quality testing.
 - ii. *In-Process Controls*: Granulation moisture content, tablet hardness, etc.
 - iii. *Finished Product*: Assay, dissolution, microbial limits.
3. **Stability Data:**
 - i. Minimum of three production-scale batches.
 - ii. Include real-time and accelerated stability data.
 - iii. Justify proposed shelf-life and storage conditions.
4. **Batch Documentation:** Submit a complete batch manufacturing record for at least one representative batch.

Appendix III: Registration Status

1. **Country of Origin:** Indicate whether the product is registered in its country of manufacture. Attach a Certificate of Pharmaceutical Product (CoPP) if applicable.
2. **Other Markets:** List countries where the product is registered or under review. Include copies of certificates or letters of approval.
3. **Rejections or Withdrawals:** Provide full disclosure and explanation of any regulatory rejections, deferrals, or cancellations.
4. **Advertising Intentions:** If the product will be advertised, attach draft promotional materials.
5. **Distribution Category:** Specify the intended category (e.g., Prescription Only, Pharmacy Only) and refer to MASCA guidelines for classification.

Appendix IV: Safety and Efficacy Data

1. **Toxicology:** Summarize acute, sub-chronic, and chronic toxicity studies.
2. **Therapeutic Effects:** Provide clinical trial summaries demonstrating efficacy.
3. **Pharmacology:**
 - *Preclinical*: Animal studies, mechanism of action.
 - *Clinical*: Human pharmacodynamic and pharmacokinetic data.
4. **Side Effects and Contraindications:** As stated in the package insert.
5. **Pharmacokinetics and Bioavailability:** Include absorption, distribution, metabolism, and excretion (ADME) data.
6. **Veterinary Products:** State residue depletion studies and withdrawal periods for food-producing animals.
- 7.

Appendix V: Supporting Documentation

Attach the following:

1. A copy of the package insert (patient information leaflet).
2. A copy of primary and secondary packaging labels or drafts.
3. Promotional materials (if applicable).
4. Indicate whether product samples have been submitted (by hand or registered post).

Please note

- The form must be signed and dated by an authorized signatory.
- The applicant must declare that all information provided is accurate and complete to the best of their knowledge.

1.2.2 Declaration by the applicant

A declaration should be made by the applicant or a responsible person nominated by the applicant and who has the requisite skills and necessary qualifications. It is stressed that only a person who can attest to the accuracy of the contents in the application should sign on behalf of the applicant. False / misleading declarations will lead to prosecution. Failure to make the declaration will lead to rejection of the application.

1.2.3 Screening Checklist

A screening checklist in Annex 2 should be completed by the applicant. The Authority will assess the application for completeness upon submission before it is accepted for evaluation by MCAZ. Incomplete applications will be rejected and the applicant requested to submit a complete application. The Authority may charge a re-submission fee for products that fail screening.

1.2.4 Proof of payment of appropriate fees

A copy of the invoice or proof of payment of registration fees should be attached to the application for registration. Applicants should consult the current fee schedule for the correct and appropriate fee. Note that registration fees can be split into three main tiers, depending on the site of manufacture of the FPP. Fees for products wholly manufactured outside Zimbabwe attract a different fee from products wholly or partly (e.g. re-labelled and re-packaged) manufactured in Zimbabwe. All fees are payable according to the gazetted fee schedule unless the full application fee is received, the application will not be accepted. Please note that direct transfers usually attract a commission charged by the banks leading to a shortfall in fees. Provision should, therefore, be made to cover such shortfalls.

Applicants are further advised to specify very clearly in their instructions to the bank that such direct deposits are for application for registration of a medicine to avoid unnecessary delays. Note that the application fee covers the cost of evaluating the initial submission. Major amendments to the original submission will require submission of a new application together with the applicable fees. The application fee excludes the GMP inspection fees, for which a separate charge is applicable. Fees once received are not refundable, including those for rejected applications or voluntary withdrawals by the applicant.

1.2.5 Manufacturing and marketing authorisation(s)/international registration status

List the countries in which:

- i. the FPP (or set of FPPs) has been granted a marketing authorisation;

- ii. the FPP (or one or more of the set of FPPs) has been withdrawn from the market; and
- iii. an application for the marketing of the FPP (or one or more of the set of FPPs) has been rejected, deferred or withdrawn

The details of registration in the country of origin are required. Reasons for non-registration should be stated if the medicine is not registered in the country of origin. Registration status in the country of manufacture should be indicated including any withdrawal, cancellations, suspension / revocations. The reasons for these should also be indicated.

1.2.6 Copy of certificate(s) of suitability of the European Pharmacopoeia (CEP)

Insert a copy of certificate(s) of suitability of the *European Pharmacopoeia* (CEP) including annexures.

1.2.7 Proof of compliance with current Good Manufacturing Practices (cGMP)

Applicants shall submit valid and current evidence of GMP compliance for:

- i. API manufacturer(s)
- ii. FPP manufacturer(s)
- iii. Any contract manufacturing, packaging, or testing sites

1.2.8 Biowaiver requests in relation to conducting a comparative bioavailability study

Applicants seeking a waiver of in vivo comparative bioavailability (bioequivalence) studies shall submit a scientifically justified biowaiver request in accordance with applicable MCAZ guidelines. The justification must clearly state the basis for the biowaiver (e.g., Biopharmaceutics Classification System (BCS)-based biowaiver or additional strength biowaiver) and be supported by appropriate data, including solubility, permeability, and comparative dissolution profiles demonstrating similarity between the test and reference products.

Module 1.3 Labelling and packaging

Documentation	
1.3.1	Summary of product characteristics (SmPC)
1.3.2	Labelling (primary and secondary packaging
1.3.3	Patient Information Leaflet/Package insert

Applicants should include PDF copies of the actual colour labels completed according to MASCA requirements, together with MS Word copies of the SmPC in line with the reference product's and Patient Information Leaflet (package insert), in line with the applicable MCAZ guidelines on product information.

Module 1.4 Regional Summaries

Documentation	
1.4.1	Bioequivalence trial information form (BTIF)
1.4.2	Quality Information Summary (QIS)
1.11.7	Quality Overall Summary (QOS)

Proof of procurement of the biostudy reference product (may include cross-reference to Module 5.3.1)

1.4.1 Bioequivalence trial information form (BTIF)

A completed BTIF should be submitted in word format on the MCAZ template.

1.4.2 Quality Information Summary QIS

Insert a copy of Quality Information Summary QIS. The QIS should be submitted with all additional information and amendment or variations. The QIS template should be completed to provide a condensed summary of the key quality information for the application and constitutes part of the submission package. The QIS provides an accurate record of technical data in the dossier at the time of registration. The QIS is a condensed version of the QOS and represents the final agreed upon key API and FPP information from the dossier assessment (inter alia identification of the manufacturer(s)/site addresses, API/FPP specifications, stability conclusions and relevant commitments).

The QIS template is structured according to the numbering and section headings of the ICH M4Q (CTD-Q) guideline to permit the rapid assembly of the QIS by copying requisite information from the corresponding portions of the QOS filed with the dossier. It is acknowledged that the numbering of the sections in the QIS may not be entirely sequential. Those sections not considered necessary to be included in the QIS have been removed (e.g. 2.3.S.5 Reference standards or materials) and the remaining sections have retained their numbering to be consistent with the original product dossier. The QIS will serve as an official reference document in the course of GMP inspections, variation assessments and product renewals.

Module 1.5 Electronic review documents

A completed QOS should be submitted in word format. Applicable electronic documentation should also be submitted.

Module 1.6 Samples

Applicants shall submit two (2) units of the finished pharmaceutical product (FPP) as samples, accompanied by the corresponding certificates of analysis (CoAs). These samples are required to enable visual inspection of the pharmaceutical product, including the dosage form, packaging components, and labelling, and to allow comparison with the information provided in the Summary of Product Characteristics (SmPC), labelling, and package insert (PIL).

Samples bearing labelling from another market or draft labelling may be accepted, provided that the FPP is identical to the product proposed for registration. Final labelling and product information (SmPC and PIL) will be assessed as part of the dossier. Applicants are expected to submit samples in the final proposed commercial container closure system. Where necessary, MCAZ may request additional samples for the purpose of pre-registration quality control testing. In such cases, applicants shall also provide relevant analytical reference standards, together with their certificates of analysis, to facilitate timely laboratory evaluation. This requirement is essential as the MCAZ laboratory may not routinely maintain reference standards for all medicines. Applicants will be required to pay the applicable cost recovery fee for sample analysis. It should be noted that not all applications will require laboratory analysis, and such requests will be made on a risk-based basis.

6.0 KEY RELEVANT DOCUMENTS

6.1 Attachment 1: MC8 Application for Registration of a Medicine Form
(https://portal.mcaz.co.zw/?sdm_process_download=1&download_id=1036)

6.2 Attachment 2: Screening Checklist
(https://portal.mcaz.co.zw/?sdm_process_download=1&download_id=4094)

7.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change
N/A	N/A	None- New Document