PHARMACY AND MEDICINES REGULATORY AUTHORITY

Quality Medicines for Malawi

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GUIDELINES ON GOOD RELIANCE PRACTICES

8th July 2026

Table of Contents

1. Abbreviations and Acronyms iii
2. Foreword iii
3. Glossary of Terms iv
4. Introduction 1
5. Purpose 2
6. Legal basis 2
7. Scope 2
8. Reliance-based evaluation pathways and key principles for reliance- 2
based evaluation 2
8.1 Abridged review 3
8.2 Verification of the sameness 3
8.3 Recognition 3
8.4 Work-sharing 4
9. Pathway selection and document submission by the applicant 4
9.1 Submission of documentation for reliance procedures 5
9.1.1. General considerations 5
9.1.2. Abridged review 5
9.1.3. Verification of the sameness 5
9.2 Variation of registered medicinal products 6
Appendix I: Applicant's Consent to Share Product Assessment 7
Appendix III: Declaration letter for the sameness 16
10. References 18

1. Abbreviations and Acronyms

API	-	Active Pharmaceutical Ingredient
AMA	-	Africa Medicines Agency
CTD	-	Common Technical Document
EMA	-	European Medicines Agency
ICH	-	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
MAH	-	Marketing Authorisation Holder
Swiss Medic	-	Swiss Agency for Therapeutic Products
SADC-MRH	-	Southern Africa Development Community Medicines Regulatory Harmonisation
RRA	-	Reference Regulatory Authority
PMRA	-	Pharmacy and Medicines Regulatory Authority
WHO	-	World Health Organisation
WLA	-	WHO listed Authorities (WLA)
FPP	-	Finished Pharmaceutical Product

2. Foreword

The Pharmacy and Medicines Regulatory Authority (PMRA) will continue to strengthen its regulatory systems in line with national priorities and global

commitments to enhance access to quality-assured, safe, and effective medical products. Given limited financial and human resources, inadequate expertise in pharmaceutical innovation, and evolving public health needs, regulatory reliance has become essential for optimizing resources, reducing duplication of efforts, and facilitating timely regulatory decision-making. The regulatory reliance does not compromise PMRA's responsibility for ensuring product quality, safety, and efficacy within the local context.

As regulatory reliance continues to enhance regulatory efficiency and global health impact, its formalization becomes more relevant to all stakeholders. Establishing clear guidance and procedures that support international collaboration and mutual reliance on regulatory decisions is crucial for sustaining these collaborative efforts.

In this context, PMRA has developed these Guidelines on Regulatory Reliance for Marketing Authorisation of Human Medicinal Products to leverage regulatory work performed by competent regulatory authorities and optimize regulatory resources, reduce duplication of regulatory effort. This document is intended to guide applicants wishing to submit new applications for marketing authorisation through reliance pathways. The guidelines stipulate the reliance mechanisms, which include standard process work sharing, an abridged review pathway, regional reliance, and unilateral and mutual recognition.

Through these guidelines, the Authority reaffirms its regulatory responsibility while recognizing the value of leveraging assessments and decisions made by trusted and competent regulatory authorities. Irrespective of the requirements as provided for in these guidelines, PMRA has the right to request additional information or define conditions that are not explicitly prescribed in this document that are deemed necessary for establishing the quality, safety, and efficacy of the medicinal products. PMRA retains full sovereign authority and responsibility for all final regulatory decisions taken under reliance pathways.

It is anticipated that this document will accelerate the Authority's decision-making on various regulatory functions and, in turn, ensure access and availability of essential medicines with the required quality standard to protect the public. PMRA remains committed to its mandate and will continue collaborating with national, regional, and international partners to promote regulatory excellence and improve access to essential health products in Malawi.

3. Glossary of Terms

The following terms are defined for the purpose of these guidelines: -

Abridged regulatory pathways

Abridged regulatory pathways are regulatory procedures facilitated by the use of reliance, whereby the regulatory decision is solely or primarily based on the application of reliance. The expectation is that the use of reliance would save resources and shorten timelines compared to standard pathways, while maintaining regulatory oversight standards.

Authority

Refers to the Pharmacy and Medicines Regulatory Authority, or its acronym, PMRA.

Equivalence of regulatory systems

Implicates a strong similarity between two regulatory systems that are mutually established and documented through objective evidence. Equivalence can be established using criteria and approaches such as similarity of the regulatory framework and practices, adherence to the same international standards and guidelines, experience gained in the use of assessments for regulatory decision making, joint activities, and staff exchanges. It is expected that equivalent regulatory systems will result in similar standards and levels of regulatory oversight or "levels of control".

Mutual recognition agreement

According to a definition issued by the Organisation for Economic Co-operation and Development (OECD), a mutual recognition agreement is a principle of international law whereby states party to such agreements recognize and uphold legal decisions taken by competent authorities in another member state. Mutual recognition is a process that allows conformity assessments carried out in one country to be recognized in another country.

Recognition

Recognition differs from other forms of reliance in that recognition involves acceptance of another authority's regulatory decision, whereas reliance involves use of another authority's assessment to inform PMRA's independent decision.

Recognition is the routine acceptance of the regulatory decision of another regulator or trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of country A is sufficient to meet the regulatory requirements of country B. Recognition should be based on evidence of conformity that the regulatory requirements of the reference regulatory authority are sufficient to meet the regulatory requirements of the relying authority. Recognition may be unilateral or mutual and may, in the latter case, be the subject of a mutual recognition agreement.

Reference regulatory authority (RRA)

Refers to a national or regional authority, or a trusted institution such as WHO prequalification (WHO PQ), EMA, USFDA, ZAZIBONA, Africa Medicines Agency, whose regulatory decisions or work products are relied upon by another regulatory authority to inform its own decisions. PMRA shall maintain criteria for the designation and periodic review of recognized Reference Regulatory Authorities (RRAs).

Reliance

The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments and information of others.

Sameness of product

For this document, 'the sameness of the product' means that two products have identical essential characteristics (i.e., the product submitted to the relying authority and the product approved by the reference regulatory authority should be essentially the same). All relevant aspects applicable to medicinal products have to be considered to confirm that the product is the same or sufficiently similar (e.g.,

same qualitative and quantitative composition, same strength, same pharmaceutical form, same intended use, same manufacturing process, same active pharmaceutical ingredient suppliers, the same quality of all excipients, etc.). Additionally, the results of supporting studies of safety, efficacy, and quality, indications, and conditions of use should be the same. The impact of potential justified differences should be assessed by the manufacturer or marketing authorisation holder and the Authority in determining the possibility of using RRA assessments or decisions.

WHO Listed Authority

WHO Listed Authority (WLA) is a regulatory authority or a regional regulatory system that has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking (GBT) and a performance evaluation process.

Work Sharing

This means the process by which NRAs of two or more jurisdictions share the activities or exchange of information to accomplish specific regulatory tasks.

4. Introduction

In recognition of the growing complexity of healthcare innovations, the globalization of pharmaceutical markets, and the need to optimize regulatory resources, the Pharmacy and Medicines Regulatory Authority (PMRA) has developed these guidelines on regulatory reliance for marketing authorisation of medicinal products to provide structured and transparent guidance in implementing reliance mechanisms in regulatory decision-making.

International organisations, including AMA, SADC-MRH, EMA, World Health Organisation (WHO), and National Regulatory Authorities, have endorsed reliance as a best practice for accelerating the availability of health technologies to treat diseases. In recent years, it has become clear that many African NRAs are interested in implementing a risk-based approach. PMRA may apply risk classification criteria when determining eligibility for abridged review or verification pathways, taking into account product complexity, therapeutic risk, public health impact, and regulatory history.

Implementing an effective reliance mechanism can accelerate product approvals by reducing the timeline for the review process and minimizing duplication of work by using available limited resources. This will ultimately leverage regulatory convergence and harmonization, strengthening regional collaboration, and enhancing the availability of good quality, safe and efficacious medicinal products to the public at large.

However, despite its potential benefits, adopting and implementing reliance mechanisms in most NRAs often face significant challenges. These include diversity in regulatory levels and different regulatory requirements, difficulty obtaining unredacted assessment reports, and failure to submit updated product dossiers from recognised regulatory agencies that had approved the product. Furthermore, most traditional reliance processes for abbreviated assessment, which were used internally by the Authority, had no clear guidance for industries on the requirements and procedural aspects of reliance mechanisms.

To overcome these challenges, PMRA has developed this Guideline on Regulatory Reliance for Marketing Authorisation of Human Medicinal Products, which provides a structured approach enabling the applicants to comply with regulatory reliance pathways effectively. The guidelines outline key principles of reliance-based evaluation pathways in which applicants should apply for the marketing

authorisation of medicinal products. Equally, these guidelines prescribe regulatory review pathways of the respective applications, which include abridged review, verification of the sameness, recognition, working sharing, and joint assessment.

This guideline should be read in conjunction with other guidelines, Guidelines for Marketing Authorisation of Medicinal Products, and other product-specific guidelines.

5. Purpose

This guideline is intended to guide the applicants on the requirements and review pathways for marketing authorisation of medicinal products through the reliance approach. The guidance document will also ensure transparency, predictability, and efficiency of regulatory decision-making.

6. Legal basis

These Guidelines are issued pursuant to Section 123 of the Pharmacy and Medicines Regulatory Authority Act No. 9 of 2019 and shall be read in conjunction with the applicable regulations. While PMRA may rely on regulatory decisions and assessment outcomes of recognised reference authorities, it retains its sovereign regulatory authority and responsibility for all decisions relating to the authorisation of medicinal products in Malawi. Accordingly, reliance does not constitute automatic approval or registration of a medicinal product.

Scope

This guideline applies to applications for marketing authorisation of new chemical entities and generic medicines that have been approved or registered by AMA, EMA, WHO, NRAs with WHO-Maturity Level 3 (ML3)/ML4, WLAs, SADC-MRH, and other recognised regional harmonisation initiatives. The guideline also applies to variation applications for registered medicinal products. The Pharmacy and Medicines Regulatory Authority reserves the right to amend the list of recognised reference authorities from time to time, as deemed necessary.

7. Reliance-based evaluation pathways and key principles for reliance-based evaluation

The Authority employs a risk-based approach through reliance pathways in marketing authorisation of human medicinal products to accelerate the approval

process. The reliance-based evaluation pathways are grouped into four major categories as prescribed below. PMRA may apply risk classification criteria when determining eligibility for abridged review or verification pathways, taking into account product complexity, therapeutic risk, public health impact, and regulatory history.

7.1 Abridged review

Abridged review focuses on the medicinal product with adequate evidence that indicates the product underwent vigorous review of the quality, safety, and efficacy and the granted positive outcome by reference regulatory agency (RRA) or other recognised organisations. PMRA will perform a shortened review on the key information/data, including but not limited to manufacturing, specifications, analytical methods, batch analysis, stability, bioequivalence/biowaiver information, regional administrative information, product information, and labelling (module 1) to establish the authenticity and reliability of the submitted data.

7.2 Verification of the sameness

A streamlined review based primarily on verifying, instead of evaluating, information submitted in the application against information already approved by RRA. Note that an unredacted assessment report is required for verification purposes.

The applicant should confirm that the application submitted to PMRA is essentially the same information as that accepted by the Recognized Regulatory Authority, taking into account any specific country requirements, including but not limited to stability zone and labelling requirements.

The applicant should highlight any new information about the product acquired since the application was submitted to the RRA, with the corresponding assessment.

7.3 Recognition

Recognition differs from other reliance mechanisms in that recognition involves acceptance of another authority's regulatory decision, whereas reliance involves use of another authority's assessment to inform PMRA's independent decision.

The Authority may use reliance through recognition of the other regulatory decision to expedite the approval of marketing authorisation of the medicinal products. PMRA may be engaged in unilateral and mutual recognition with recognized regulatory authorities and organisations, inter alia AMA, EMA, WHO/ML4, and WLA. The recognition shall be guided by formal agreements between the Parties.

7.4 Work-sharing

PMRA shall implement work sharing through continental and regional harmonisation initiatives for the assessment of medicinal products. The Authority participates in harmonisation initiatives through AMA, SADC-MRH, WHO, and SwissMedic. These initiatives provide a platform for joint review of medicinal products dossiers and the exchange of information, which ultimately leads to a common decision across the participating NRAs.

8. Pathway selection and document submission by the applicant

During submission for applications, a declaration letter for the sameness indicating the proposed evaluation pathways of the product dossier should be provided. The template for the declaration for the sameness letter is attached as **Appendix III** of this guideline and should be provided in **Module 1**. The proposed pathway should be justified, and the respective sections where the evidence is provided should be indicated. In addition, **Appendix I** and **Appendix II,** and related administrative and general information, should be provided in Module **1.** The technical information should be provided in the respective sections of the CTD document.

The final decision for the determination of the reliance mechanism and evaluation pathway is vested in the Authority. This decision will be based on the completeness, adequacy, and relevance of the submitted reliance documentation.

In instances where reliance documentation is insufficient or missing, the Authority will issue screening queries to provide applicants an opportunity to address the deficiencies. Where such information is not provided or is deemed inadequate, PMRA will proceed with a full independent review of the application.

8.1 Submission of documentation for reliance procedures

8.1.1. General considerations

During review, the Authority reserves the right to request additional documentation or clarification related to the reliance submission at any stage of the evaluation process. If assessment reports from the RRA are not submitted to the Authority within three (3) months of the request date, the application will automatically proceed under the full review pathway. Assessment reports intended for submission may be sent directly to the PMRA through registration@pmra.mw.

The timeframe for review and communication of the final decision should be within the timelines as prescribed in the existing PMRA guidelines. PMRA may also establish pathway-specific review timelines, screening timelines, clock-stop provisions, and query response timelines in applicable procedural guidance documents.

All variations approved by the RRA must be fully incorporated in the submission to the Authority. Applications, including pending (unapproved) variations at the RRA, will not qualify for reliance-based review and shall be subject to full review by the Authority.

8.1.2. Abridged review

Where the abridged review pathway is proposed, the applicant shall be required to submit information as prescribed in the Guidelines on submission of documentation of finished pharmaceutical products approved by EMA and WHO-Listed Authorities (WLA), and relevant PMRA guidelines on marketing authorization.

8.1.3. Verification of the sameness

This is applicable for the verification of the sameness of the human medicinal products approved/registered by SADC-MHRA AMA, EMA, WHO, NRAs, with WHO-Maturity Level 3/ML4, WLAs, and other recognized Regulatory Authorities. The applicant should submit the following: -

a. Full unredacted assessment report from the RRA upon which the marketing authorisation/approval decision was made.

b. Dully filled and signed Applicant's Consent to Share Product Assessment reports attached as **Appendix I**

c. The latest version of the product dossier approved by the Reference Regulatory Authority (RRA) was compiled in CTD format in line with the PMRA's guidelines.

d. A duly filled-in and completed Summary of Quality and Bioequivalence Review Verification of the Sameness Form attached as **Appendix II**.

Note:

a. Where the applicant does not have access to the relevant unredacted assessment report, the Authority shall require a duly completed and signed consent form authorising access to the unredacted assessment report(s) for the respective medicinal product application. In such cases, the applicant shall complete and sign the Applicant's Consent to Share Product Assessment and GMP Inspection Report. For reliance on GMP inspection outcomes, PMRA may verify the GMP inspection report(s) with the reference authority or conduct a desk review, as deemed appropriate.

b. The Authority prefers receiving an unredacted assessment report directly from the applicant and has introduced the consent form only for instances where this is impossible. If the assessment report is not obtainable by the applicant within 60 days from the date of communication with the RRA, the application shall automatically undergo full review, extending the evaluation timeline.

c. The shared assessment reports should be accompanied by submitting the latest version of the product dossier accepted by the Reference Regulatory Authority (RRA) compiled in CTD format in line with PMRA guidelines.

8.2 Variation of registered medicinal products

Applications for variation of medicinal products that have been granted marketing authorisation by PMRA through reliance procedures should provide proof/evidence of approval of the changes from RRA, along with documentation for variation application as prescribed in the PMRA Guidelines on Variations on Registered Medicinal Products.

Appendix I: Applicant's Consent to Share Product Assessment

I, …….…….....…….…….....…… the undersigned on behalf of
……
……who is the Marketing Authorisation Holder/Applicant, do hereby consent that the {*name of the Recognised NRA/Organisation*} shares the assessment reports and subsequent reports generated during additional data/query response and variations submissions with Pharmacy and Medicines Regulatory Authority(PMRA) for the medicinal product(s) listed below.

I further consent that, if relevant, the sharing should also be extended to subsequent variations, as well as information and documentation on any actions taken by reference recognised NRA/Organisation post-marketing authorisation of the medicinal product.

Medicinal Product(s) Details:

S/No.	**Product Brand Name/ Common Name (INN)**	**Product Strength**	**Product Dosage Form and Pack Size**	**Name and address of FPP Manufacturer**	**Registration Number**
1.					
2.					

Name of Authorized Signing Official *("the Applicant/Marketing Authorisation Holder")*

……
Company Name: ……...
Physical address & Postal address: ……..... …… Email: ……...
Telephone……...

Signature …… …….. Date……

Appendix II: Summary of Quality and Bioequivalence Review - Verification of the Sameness Form

The applicant should fill out this template and serve as an assessment report. The summary of information contains critical information accepted by the reference recognized agency/regulatory authority (WHO and NRAs with WHO - Maturity Level 3, 4 & WLAs) to ensure the sameness of data between the accepted product dossier and the new submission.

Note:

a. Do not copy and paste between the columns for RRA and PMRA submission. This must all be completed as per the exact information in the original documents.
b. A duly filled-in and completed copy of the abridged review template in *Microsoft Word format* as part of module 1 should be provided.

1. API INFORMATION SUMMARY

API name(s)	
CEP/ CPQ Number (*if applicable*)	
APIMF number and version (*if applicable*)	
Name and address of API manufacturing site(s)	
GMP status and/or manufacturing license of the API manufacturing site(s), along with the name of the issuing competent regulatory authority from country of origin and where applicable other NRAs/legal existing Organisations	
Polymorphic form (s)	
Sterility, i.e., is the API sterile or nonsterile.	
Quality standard claimed, e.g., BP, Ph. Eur, USP, In-House, etc.	
FPP Manufacturer's API Specifications Number and version	
API manufacturer's API Specification Number and version	

Container Closure System	
Retest period and/or Shelf life	
Storage statement	

2.3. S DRUG SUBSTANCE (or ACTIVE PHARMACEUTICAL INGREDIENT (API))			
Confirm that the information on the API submitted to the Authority is the same concerning that reviewed and approved by WLA concerning the source of the API i.e. API manufacturing site(s) including the bock and/or unit number, the specifications for the API from the FPP manufacturer, the container closure system and the stability.			
Dossier aspects to verify	**Reference** (WHO and NRAs with WHO - Maturity Level 3/WL4 & WLAs)	**Applicant submission**	**PMRA comments**
3.2. S.1.1 Name of the API			
3.2. S.1.3 General properties that may affect the performance of the finished product (for example, polymorphism, solubility in physiological media)			
3.2.S.2.1 Name and address(es) (including specific blocks/units) of the manufacturer(s) of the API(s)/drug substance			
3.2.S.4.1 Control of the API (including the specification reference number, version and date – the copy of the current specification approved by reference recognized regulatory authorities should be included as an attachment to this report)			
3.2.S.4.2 Analytical procedures (including the analytical procedure reference number, version and date – the copy of the analytical procedure may be included as an attachment to this report)			
3.2.S.6 Container closure system			

(Description of container closure system, including specifications and COA)			
3.2. S.7 Stability summary and conclusions (including storage statement and re ‑test period)			

2. COMPARISON OF FINISHED PRODUCT INFORMATION

Confirm that the information on the product/FPP submitted to the Authority is the same concerning that reviewed and approved by WLAs concerning the source of the FPP i.e. FPP manufacturing site(s) including the bock and/or unit number, composition of the FPP, the FPP specifications, the container closure system and the stability.			
Dossier aspects to verify	**Reference (**WHO and NRAs with WHO - Maturity Level 3/4 & WLAs)	**PMRA submission**	**PMRA comments**
3.2. P.1 Description and composition of the FPP (Description of the finished pharmaceutical products as provided in FPP Specification and SmPC)			
3.2. P.3.1 Name(s) and complete address			
(including specific blocks/units) of the manufacturer(s) of the finished pharmaceutical product(s) [FPP(s)] or biological drug products(s) (DP(s)), including the final product release if different from the manufacturer			
3.2.P.3.2. Description: Commercial batch size and batch formula			
3.2.P.3.3. Description of manufacturing process			
3.2. P.5.1 Control of FPP/DP (state the specification reference number, version and date – a copy of the specification should be included as an attachment to the report)			

3.2. P.5.2 Analytical procedures (including the analytical procedure reference number, version and date–a copy of the analytical procedure should be included as an attachment to the report)			
3.2. P.7 Container closure system (including pack sizes, container size or volume specifications and certificate of analysis)			
3.2. P.8 Stability summary and conclusions (including the storage statement and shelf-life			

3. COMPARISON OF THE COMPOSITION OF THE FINISHED PHARMACEUTICAL PRODUCT

a) Reference (WHO and NRAs with WHO - Maturity Level 3/4 & WLAs)

Component and quality standard	**Function**	**Quant. per unit (mg)**	**%**
Total			
PMRA Comments			

Note: where applicable, for example, for layered tablets, the % composition should be computed based on the layer subtotal

b) Applicant submission

Component and quality standard	**Function**	**Quant. per unit (mg)**	**%**
Total			
PMRA Comments			

Note: where applicable, for example, for layered tablets, the % composition should be computed based on the layer subtotal

4. COMPARISON OF COMMERCIAL BATCH SIZE AND BATCH FORMULA

a) **Reference** (WHO and NRAs with WHO - Maturity Level 3/4 & WLAs)

Proposed commercial batch size(s) (e.g. number of dosage units)	
Component and quality standard (and grade, if applicable)	**Quantity per batch (kg/batch)**
Total	
PMRA Comments	

b) PMRA Submission

Proposed commercial batch size(s) (e.g. number of dosage units)	
Component and quality standard (and grade, if applicable)	**Quantity per batch (kg/batch)**
Total	
PMRA Comments	

5. COMPARISON OF SAFETY AND EFFICACY

a) Bioequivalence Information

Bioequivalence/comparative pharmacokinetics

Dossier aspects to verify	**Reference** (WHO and NRAs with WHO - Maturity Level 3/4 & WLAs)	**Applicant submission**	**PMRA comments**
Study Number			
Study title			
Name and address of the clinical facility (or the contract research organisation)			
Name and address of bioanalytical laboratories			
Number of participants			
Test product (name, manufacturer, batch number, manufacturing and expiry date, batch size, location of multipoint dissolution data in physiological media and release media, if different)			
Reference product (name, manufacturer, source, batch number, expiry date)			
Results (geometric ratio and the 90% confidence intervals for the PK parameters)			
Assessor's overall comments on bioequivalence/ comparative pharmacokinetics			

b) BCS-based biowaiver

BCS-based biowaiver Information			
Dossier aspects to verify	**Reference** (WHO and NRAs with WHO - Maturity Level 3/4 & WLAs)	**PMRA submission**	**PMRA comments**

Name and address of the laboratory or contract research organisation(s) where the BCS-based Biowaiver, solubility, and dissolution studies were conducted.			
API in the proposed product about the comparator (confirm that the proposed product contains the same active substance, including salt, ester, ether, or isomer, if applicable)			
Test product (name, manufacturer, batch number, manufacturing and expiry dates, batch size, location of			
multipoint dissolution data in physiological media and release media, if different)			
Reference product (name, manufacturer, source, batch number, expiry date)			
Dissolution method (media, agitation speed, apparatus, volume)			
Assessor's comments on BCS-based biowaiver			
Assessor's overall comments on BCS biowaiver			

c) Additional Strength biowaiver

Additional strength biowaiver information			
Dossier aspects to verify	**Reference** (WHO and NRAs with WHO - Maturity Level 3/4 & WLAs)	**PMRA submission**	**PMRA comments**
Name and address of laboratory or contract research organisation(s) where the biowaiver solubility and dissolution studies were conducted			
Reference strength selected for the BE study			
Biowaiver batch (manufacturer, batch number, manufacturing and expiry dates, batch size, location of multipoint dissolution data in physiological media and release media, if different)			
Biobatch (manufacturer, batch number, manufacturing and expiry dates, batch size)			
Dissolution method (media, agitation speed, apparatus, volume)			
Assessor's overall comments on additional strength biowaiver			

Appendix III: Declaration letter for the sameness

To be completed by the applicant:

Reference Application details {Product name, strength, dosage form}	
Name of recognised regulatory authority	
Approval date/Registration date	
Date(s) of approval of post-registration variation(s), if applicable	

I, {Full name}, {Job title} at {Company's full legal name}, hereby confirm the following for application {Application number, Product name, strength, dosage form} submitted to the Pharmacy and Medicines Regulatory Authority (PMRA) on {Date of application submission} declares that: -

a. The information and documentation provided in support of this submission for marketing authorisation are true and correct;

b. The product submitted for marketing authorisation to PMRA is the same as the product registered/approved with the above-specified recognized regulatory authority/authorities; and

c. The technical information in the dossier submitted to PMRA for marketing authorisation is the same as the latest updated technical information approved by the above-specified recognized regulatory authority/authorities, taking into account all accepted variations.

Any differences in the technical documents related to the quality, safety, efficacy, product information and labelling are discussed, justified and annexed to this declaration letter.

Responsible Person authorised to communicate with the Authority: -

Full name:……

Job title, company:……..

Email address:……..……..…..

Tel. No:……..……

Signature:……...……

Date:……

Place:……

9. References

a. South African Health Products Regulatory Authority. (2024). Guideline for Reliance and Recognition of Regulatory Decisions. Pretoria, South Africa.

b. Tanzania Medicines and Medical Devices Authority. (2025). Guidelines for Regulatory Reliance. Dodoma, Tanzania.

c. World Health Organization. (2021). WHO Expert Committee on Specifications for Pharmaceutical Preparations: Fifty-fifth report (WHO Technical Report Series No. 1033, Annex 10: Good Reliance Practices in the Regulation of Medical Products). Geneva: World Health Organization.

d. World Health Organization. (2023). Good Review Practices: Guidelines for National Regulatory Authorities.

e. Food and Drugs Authority. (2023). FDA reliance guideline on regulatory decision-making (FDA/GEN/GDL-04/02). Food and Drugs Authority, Ghana