

**Zambia Medicines Regulatory Authority****Reliance Guideline for the Grant of Marketing Authorisation for Medicine and
Allied Substances**

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**Abbreviations and Acronyms**

AMA	African Medicines Agency
API	Active Pharmaceutical Ingredient
CTD	Common Technical Document
EAC	East African Community
EFDA	Ethiopian Food and Drug Authority
EMA	European Medicine Agency
EPAR	European Public Assessment Report
EU	European Union
EU CP	European Union Centralised Procedure
EU DCP	European Union Decentralised Procedure
eRIS	electronic Regulatory Information System
EU	European Union
FPP	Finished Pharmaceutical Product
GMP	Good Manufacturing Practice
GRP	Good Regulatory Practices
GRelp	Good Reliance Practices
ICH	International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use)
IGAD	Intergovernmental Authority Development
MHRA	UK Medicines and Health products Regulatory Authority
MHLW/PMDA	Labour and Welfare Labour/Pharmaceutical and Medical Devices Agency
NMRA	National Medicines Regulatory Authority
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PIL	Patient Information Leaflet
RECs	Regional Economic Communities
RRA	Reference Regulatory Authority
SA	South Africa
SADC	Southern African Development
SAHPRA	South African Health Products Regulatory Authority
SwissMedic	Swiss Agency for Therapeutic Products
SmPC	Summary of Product Characteristics
SRA	Stringent Regulatory Authority
TGA	Therapeutic Goods Authority - Australian
UK	United Kingdom
US FDA	United States Food and Drug Administration
US	United States
VICH	International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products
WHO	World Health Organization
WLA	WHO Listed Authority
ZAMRA	Zambia Medicines Regulatory Authority

**Introduction**

The Zambia Medicines Regulatory Authority (ZAMRA) is mandated under the medicines and allied substances Act No 3 of 2013 of the Laws of Zambia to regulate medicines and allied substances to ensure that all medicines and allied substances being made available to the Zambian people consistently meet the set standards of quality, safety and efficacy.

The Authority has been making continuous efforts to enhance the efficiency of regulatory systems in providing quality, safety and efficacy assured medicines to end users. In this regard, the Authority adopts good reliance practices (GRelp) to optimize the use of existing resources and expertise, avoid duplication, and focus their regulatory efforts and resources where they are most required. GRelp are anchored on overall good regulatory practices (GRP), which serve as a framework for developing sound, cost-effective, and efficient regulation of medical products as a crucial element of enhancing health systems.

This 'Guideline on Reliance for Medicine Marketing Authorization has been developed to promote a more efficient approach to the registration and approval process, ultimately improving access to quality-assured, effective, and safe medicines. The reliance is an alternative/non-routine authorization pathway to the standard approval pathways - especially for applications where the safety and efficacy of the product have already been confirmed or when the Clinical Trial has been approved and/or initiated in a well-resourced regulatory authority(s). It reflects the Authority's current thinking on the safety, efficacy, and quality of medicines and is not an exclusive approach. The Authority reserves the right to use its own procedures to establish the safety, efficacy, and quality of medicines.

Purpose

The purpose of the guideline on reliance is to establish a structured and efficient approach to utilizing regulatory decisions, assessments, and information from other National Medicines Regulatory Authorities (NMRAs) or institutions in the registration and marketing authorization process for
Version 1.0



medicines. It also outlines the actions taken and carried out by the Authority while assessing applications filed under this approval pathway, in order to improve the registration and market authorization process, ultimately improving timely access to quality-assured medicines for the public.

Scope

This document covers the activities and procedures followed by the Authority in implementing the principles of good reliance practices in the registration and Grant of marketing authorization of medicines approved or listed by Reference Regulatory Authorities (RRAs) or institutions. It applies to applications for initial marketing authorisation, post-approval amendments, and renewals filed under both routine and non-routine processes.

Glossary

Abridged review. A limited independent assessment of specific parts of the dossier, or submission for suitability of use under local conditions and regulatory requirements, while relying on prior assessment and inspection outcomes from a RRA or trusted institution to inform the local decision. The abridged review is based on assessment reports, and Good Manufacturing practices (GMP) inspection reports from reference authorities, plus specific parts of the Common Technical Document (CTD).

Authority. This refers to Zambia Medicines Regulatory Authority.

Recognition. It is acceptance of the regulatory decision of an NMRA or trusted institution with which the Authority shares a recognition agreement.

Reference Regulatory Authority. Term used to refer to the list of regulatory authorities whose assessment ZAMRA recognizes.

Reliance. An act whereby the ZAMRA takes into account and gives significant weight to assessments performed by a Reference Regulatory Authority, trusted institution, another NMRA or any other authoritative information in reaching its own decision. ZAMRA remains independent, responsible and



accountable for the decisions taken, when it relies on the decisions, assessments and information of others.

Reliance pathways. An alternative non-routine approval pathway used by the authority in its regulatory decisions regarding marketing authorization of a product based on assessment outcomes of Reference Regulatory Authority (ies) or institutions.

Sameness of product. For the purpose of this document, the sameness of product means that two products have identical essential characteristics (i.e., the product being submitted to the relying authority and the product approved by the reference regulatory authority). All relevant aspects applicable to the medicinal products have to be considered in order 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, 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.

Stringent Regulatory Authority (SRA). A regulatory Authority which is a member of the International Conference on Harmonization (ICH) or an ICH observer or is associated with an ICH member through a legally binding mutual recognition agreement. This term is being replaced by WHO Listed Authority (WLA).

Verification Review. A streamlined assessment conducted by the ZAMRA on a product that has been evaluated and approved by a Reference Regulatory Authority or trusted institution when use of the WHO SRA procedure is not possible.

**Principles of good reliance practices**

The principles of the reliance in this guideline are in line with the WHO recommendations to enhance regulatory efficiency, reduce duplication, and improve timely access to safe, quality and efficacious medicines.

1) Sovereignty of decision-making

The decision to practice reliance and how best to do so rests with the Authority. Reliance does not imply dependence or outsourcing its decision-making authority or responsibility. The Authority maintains independence, responsibility and accountability in regulatory decision-making.

2) Transparency

The reliance approach remains transparent regarding standards, processes and approaches adopted in implementing reliance measures. In addition, the rationale for relying on a specific entity shall be disclosed and fully understood by all parties.

3) Legal bases

This reliance guideline is coherent with the national legal frameworks and supported by Marketing Authorization policy document no. Z/POL/003 and Current CTD guidelines. This is the legal basis that gives the authority a clear mandate to adopt and implement activities undertaken by the WHO, ZAMRA recognized reference regulatory authorities, mutual or multi-lateral agreements entered by Zambia or other international organizations relevant to its regulatory works.

4) Consistency

The Authorities' reliance assessment or decision shall be established for specific, well-defined categories of products and processes. The scope of regulatory activities in which reliance may be practiced should be clearly defined, and the practice of reliance should be transparent and predictable.

5) Competency

The necessary competencies for critical decision making to facilitate proper implementation of the reliance guidelines will be made available. The competencies are benchmarked by transparent processes that develop trust in the capacities of recognized regulatory authorities.

Reliance pathways for Marketing Authorization

The authority employs reliance as one of its regulatory decision-making pathways to accelerate the approval of medicines registration. The reliance aims to reduce turnaround times for approval of medicines compared to standard regulatory practices, so as to ensure timely access to safe, effective and quality assured medicines to end users.

This risk-based approach considers various factors, such as the type and source of products assessed, the level of resources and expertise available, the public health needs and priorities of the country and opportunities for reliance. For marketing authorization, the assessment process for applications submitted via reliance pathway may involve verification review, abridged review or recognition. Hence the ZAMRA may either verify the assessment outcome of the reference regulatory authority or trusted institution to recognize their decision or conduct abridged review of the applications to



make its decision after confirmation of the applicability of the assessment outcomes or accept the regulatory decision of an NMRA or trusted institution with which the Authority shares a recognition agreement.

a) Verification review

Verification focusses on verifying the authenticity and completeness of documented evidence submitted by the applicant. It is applicable for products approved by RRAs or institutions. The verifications involve confirmation of sameness of submitted data with the applications submitted to the reference authority or institution. Both the medicine and the dossier submitted to ZAMRA should be the same as the one that has been assessed by the reference regulatory authority or trusted institution with respect to its essential characteristics (e.g. same qualitative and quantitative composition, strength, pharmaceutical form, intended use, manufacturing process, suppliers of active pharmaceutical ingredients, and quality of all excipients and manufactured at the same manufacturing site).

Verification is particularly applicable for products approved under WHO-prequalification programs, those assessed and accepted under AMA and IGAD.

b) Abridged Review

The reference regulatory authority's or trusted institution's assessments may not always account for specific circumstances that can significantly affect the benefit-risk of a medicines in other countries or regions. Hence, this review focuses on assessing specific aspects of the dossier that are relevant to the Zambian context while relying on prior evaluations conducted by trusted authorities or institutions. It involves conducting evaluation of module 1 and specific aspects of the dossier regarding the safety, efficacy and quality data, in view of the information provided in the assessment reports of the reference regulatory authority.

In the case of products approved by the reference regulatory authorities or institutions with which the authority has no mutual recognition agreements, ZAMRA may accept the decision of the RRA or institution based on the partial review of selected sections and/or modules of the application dossier. Such review is applicable for products assessed and accepted by the Regional Economic Communities (RECs) other than AMA and IGAD or agencies evaluating medicines for global health program such as EMA article 58 and through the Swiss medic's Marketing Authorization for Global Health products or the International Generic Drug Regulatory Programme could also be considered under this scheme.

c) Recognition

This is a streamlined registration/approval process based on directly recognizing the outcome of a review from a RRA with which ZAMRA shares a recognition agreement.

Eligibility for granting Marketing Authorization through reliance procedure

- 1) A product that is manufactured by a holder of a valid cGMP certificate and manufacturing license issued by a listed RRA (refer to Annex 1).
- 2) A WHO Prequalified product.



- 3) The product is registered by a Stringent Regulatory Authority (SRA), World Health Organization (WHO) Listed Authorities or has been assessed through regulatory mechanisms such as the EU's Article 58 Procedure or Swiss Medic's Marketing Authorization for Global Health Products or the International Generic Drug Regulatory Programme (launched July 2014).
- 4) An innovator product or new chemical entity that has been registered for more than 12 months in a VICH member state, ICH founding/standing regulatory member state, United States, Japan or Canada.
- 5) The product is registered by an NMRA which is an active participant in the SADC-Zazibona Joint Collaborative Registration Process or East African Community (EAC) collaborative registration.
- 6) The product is registered by an NMRA which has signed a Memorandum of Understanding with the Authority for collaboration in the area of marketing authorization.
- 7) The product is registered by a NMRA which has attained WHO Maturity Level 3 or 4 for medicines and medical devices.
- 8) The product contains an active pharmaceutical ingredient (API) with an established safety profile, ascertained over a long time and does not require bioequivalence studies.
- 9) The product is being imported for emergency use in the public and animal health system and meets any of the requirements as set out under requirements 1) and 8).
- 10) Any other requirement as may be determined by the Authority from time to time.

Requirements for application submission

General conditions

- 1) Applications dossier should be only for products assessed and accepted by the reference regulatory authorities
- 2) The applicant should submit a full CTD dossier and declare the "sameness" of the reference regulatory authority approved medicine with the one applied for grant of marketing authorization.
- 3) If any differences exist between the dossier submitted to ZAMRA and the dossier submitted to a recognized regulatory authority or institution, all such differences should be clearly indicated and justified.
- 4) The submitted product should be prequalified and/or registered and marketed in the market of one of the reference regulatory authority's countries, except for products prequalified by WHO, jointly assessed products and products approved for global health program.
- 5) Submission of the application dossier should be through the electronic Regulatory Information System portal, via appropriate route of application.
- 6) Commitment letter to notify the Authority when there is pending variation, withdrawal from the market or ban by reference regulator or trusted body due to any notice of concern.
- 7) GMP waiver certificate/letter issued by ZAMRA and copy of valid GMP issued by any of the RRA, laboratory testing report (when applicable), and safety report (when applicable).
- 8) Full modules with CTD document as per our Guideline for Registration of Medicines.
- 9) A declaration indicating that any post approval changes were reported and accepted by the reference regulatory authority or trusted institution. This declaration should include the list of variations not yet accepted by reference regulatory authority or trusted institution and section of the dossier affected by the accepted variations.
- 10) A copy of the marketing authorization, or the equivalent thereof, issued by the reference NRA or institution to demonstrate that the product is registered or licensed in accordance with the reference NRA or institution requirements. If applicable, a copy of the latest renewal of the



marketing authorization should also be provided.

- 11) A copy of the currently approved FPP specifications (release and shelf-life), dated and signed or certified by authorized personnel, with the analytical test procedures in appropriate section of the dossier.
- 12) Stability study report conducted as per the conditions prescribed in the Medicine Registration Guideline of the Authority.
- 13) Signed quality information summary

For products accepted by IGAD joint assessment

A letter for the expression of interest including the reference number of the application submitted to IGAD.

Criteria for selection of reference regulatory authority

Regulatory authorities or institutions shall fulfil at least the following criteria to be included in the list of Zambia recognized reference regulatory authorities

- a) NMRA or institution that publishes detailed information on the approved medicines (like public assessment report, labeling information and regulatory action, deferred or rejected product information) on its website or include in the approved or qualified list of medicines throughout the product life cycle as applicable.
- b) Member of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), and an ICH observer, being the European Free Trade Association.
- c) A regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement.
- d) National regulatory authority or institution that has signed memorandum of understanding or legally binding agreement with the Authority.

Application submission and assessment

Application Submission

- a) For all types of reliance-based application submissions, applicants are recommended to submit their application through ZAMRA IRIMS portal.
- b) The applicant should submit the application through the relevant application pathway of ZAMRA IRIMS portal and specify the desired path according to his/her need and upload the required full CTD data and annexed documents (cGMP, CPP, payment receipt, all data required to be filled).
- c) The validation office may be contacted for pre-submission technical support for verifying the required documents and get guidance to the most suitable review and approval pathways.

Application Assessment

- a) Assessment of applications will be conducted in accordance with the relevant marketing authorization guidelines and assessment SOPs.
- b) The assessment timeline shall be in line with the ZAMRA charter on service delivery.

**Evaluation of Post-Approval Changes**

- a) Following the same reliance principles and mechanisms adopted in the new marketing authorization, ZAMRA may also broadly apply those mechanisms in managing post-approval changes that are already approved by reference authorities or institutions.

Evaluation of Renewal

- a) ZAMRA will apply same reliance principles and mechanisms adopted in the new marketing authorization managing renewal application submitted by already approved by reference authorities or institutions.

Withdrawal and cancellation of medicines due to safety and efficacy issues

- a) ZAMRA shall conduct periodic reviews of safety, efficacy and quality of registered medicines. For this purpose, the Authority may rely on and take into consideration information concerning safety, quality and efficacy of any registered medicines, particularly those accepted under its reliance procedure as per this guideline.
- b) Received information will be reviewed based on the available supporting evidence and risk-based approaches will be followed by considering national laws, regulations and guidelines, as well as regional and international guidelines, monographs and standards.

**Annex 1: List of recognized reference NMRA and Collaborative procedure**

The list of ZAMRA's current Reference Regulatory Authorities(RRAs) includes:

- a) WHO listed Authorities (WLA)
- b) WHO Maturity level 3
- c) Health Canada.
- d) Medicines and Health Products Regulatory Agency (MHRA (UK))
- e) Swiss Agency for Therapeutic Products (SwissMedic)
- f) Therapeutic Goods Administration (TGA) -Australia
- g) US Food and Drug Administration (US FDA)
- h) NRAs which have signed MoUs with ZAMRA
- i) World Health Organization (WHO)
- j) ZAZIBONA
- k) AVAREF
- l) European Medicines Agency
- m) African Medicines Agency

**Annex 2: Sameness Declaration for Verification Evaluation Procedure****To be Completed by the Applicant:**

Application for {Proposed product name}	{Name of Recognized Regulatory Authority}
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 for registration of {name of product} submitted to the Zambia Medicines Regulatory Authority (ZAMRA) on {Date of application submission}:

- The information and documentation provided in support of this submission for registration is true and correct.
- The product submitted for registration with ZAMRA is the same as the product registered with the above specified RRA.
- The technical information in the dossier submitted to ZAMRA for registration is the same as the technical information approved by the above specified RRA, taking into account all amendments that the above specified RRA has approved since registration.
- The "same" product is characterized by:
 - a) The same product dossier content;
For WHO PQ vaccines submitted to the WHO in Product Summary File (PSF) format, this content needs to be transferred to CTD format
 - b) The same manufacturing chain, processes and control of materials and finished product, and in the case of vaccines also by the same batch release scheme;
 - c) The same active pharmaceutical ingredient (API) and finished pharmaceutical product (FPP) specifications
 - d) The same essential elements of product information for pharmaceutical products, and in the case of vaccines, by the same product information, packaging presentation and labelling.

Information which need not be the same:

- a) Module 1, region-specific administrative requirements
- b) Minor differences which are not considered essential may include differences in administrative information, brand name, format and level of detail of product information as per regional requirements, labelling of internal and external packaging and language of product information.



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I hereby confirm that if documents have been submitted by [Insert full company legal name here] which were received by the above specified RRA, these documents are completed and unredacted.

Full name of Responsible Pharmacist / Person Authorised to communicate with the Authority:

Company:

Email address:

Telephone Number:

Signature:

Date:

Place:

Annex 3: Verification Review Template



VERIFICATION REVIEW TEMPLATE

THIS DOCUMENT SHOULD BE COMPLETED BY THE APPLICANT TO ENSURE INCLUSION OF ALL NECESSARY INFORMATION

This verified review template will be used for assessment in cases where the applicant's product has been registered with a Recognized Regulatory Authority. The following shall be noted:

- Ensure that this template is submitted as word document and not as PDF.
- If full/unredacted assessment reports cannot be obtained by the applicant from the Recognized Regulatory Authority please use other registration routes.
- **Complete all sections.** The columns for RRA and ZAMRA submission shall be completed with text taken directly from the relevant section in the respective reports, as well as the reference to the location in the dossier.
- **References to the location in the dossier will not be accepted without the actual text accompanying them.**
- Ensure sufficient detail is included in this template to make an accurate comparison between the RRA and ZAMRA submission.
- Do not copy and paste between the columns for RRA and ZAMRA submission. These shall all be completed as per the exact information in the original reports.

1. Administrative data



Non-proprietary Name of the Finished Pharmaceutical Product (FPP)	
Proprietary name of the Finished Pharmaceutical Product (FPP)	
International non-proprietary name(s) of the Active Pharmaceutical Ingredient(s) (API(s)), including form (salt, hydrate, polymorph)	
Strength(s)	
Date of Submission <for official use only>	
Date of Evaluation <for official use only>	
Number of Binders	
Product Registration receipt number <for official use only>	
Application Number <for official use only>	
ATC code	
Dosage form	
Route of administration	
Proposed indication(s)	
Applicant name and address	
Contact information	
Conclusion of the evaluation <for official use only>	

2. Similarity of Data Set: PRODUCT QUALITY

Item to verify	Recognized Regulatory Authority: {Name of RRA} submission	ZAMRA submission	Evaluator comments
Name and complete address of the applicant	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Name(s) and complete address(es) of the manufacturer(s) of the finished pharmaceutical product(s) [FPP(s)], biological drug products(s) (DP(s)), including the final product release if different from the manufacturer.	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	



Item to verify	Recognized Regulatory Authority: {Name of RRA} submission	ZAMRA submission	Evaluator comments
ACTIVE PHARMACEUTICAL INGREDIENT (API) (NAME, MANUFACTURER)			
Name of API	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
General properties that may affect the performance of the finished product (e.g. polymorphism, solubility in physiological media)	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Name and address(es) of the manufacturer(s) of the API(s)	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
DMF/APIMF number	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Control of the API (including, the specification reference number, version and date. The copy of the specification may be included as attachment to the report)	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Container closure system	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Stability summary and conclusions (including storage statement and re-test period)	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
FINISHED PHARMACEUTICAL PRODUCT (FPP)			



Item to verify	Recognized Regulatory Authority: {Name of RRA} submission	ZAMRA submission	Evaluator comments
Description	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Manufacturer (Name, address and responsibility)	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Narrative description of the manufacturing process [No need to compare the whole manufacturing process. can just look at the blank master production document reference number, version and date, together with information on the site.]	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Control of FPP/DP State the specification reference number, version and date, copy of the specification must be attached as attachment to the report.	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Container closure system	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Stability summary and conclusions (incl., the storage statement and shelf life)	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Lot / batch release documents for biologicals	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	



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Item to verify	Recognized Regulatory Authority: {Name of RRA} submission	ZAMRA submission	Evaluator comments
<i>General comments from evaluator</i>			
<i>Comments from second assessor</i>			

**Composition**

RRA: {Name of RRA}

Component and quality standard	Function	Quant. per unit (mg)	%
Total			
<i>General comments from evaluator</i>			
<i>Comments from second assessor</i>			

ZAMRA submission

Component and quality standard	Function	Quant. per unit (mg)	%
Total			
<i>General comments from evaluator</i>			
<i>Comments from second assessor</i>			

Commercial batch size and batch formula

RRA: {Name of RRA}

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	
<i>General comments from evaluator</i>	
<i>Comments from second assessor</i>	

ZAMRA 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	
<i>General comments from evaluator</i>	
<i>Comments from second assessor</i>	

3. Similarity of Data Set – CLINICAL (SAFETY AND EFFICACY) – If applicable

Pharmacokinetic / safety / efficacy related information used for SRA approval. Indicate:		
Type of study	“X” in appropriate box	Comparator product, where applicable
Bioequivalence / Comparative pharmacokinetics,		
Biowaiver based on Biopharmaceutics		



Classification System (BCS) biowaiver		
Additional strength biowaiver		
Clinical data		
Comparative pharmacodynamic and potential immunogenicity		
Other (please specify)		
<i>General comments from evaluator</i>		
<i>Comments from second assessor</i>		

BIOEQUIVALENCE / BIOWAIVERS			
Item to verify	Recognized Regulatory Authority: {Name of RRA} submission	ZAMRA submission	Evaluator comments
Study number	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Study title	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Clinical facility or the Contract Research Organisation (CRO)	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Bioanalytical laboratories	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Company performing pharmacokinetic / statistical analysis	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Overall trial design and plan: Description, study dates, sample size	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	

**BIOEQUIVALENCE / BIOWAIVERS**

Item to verify	Recognized Regulatory Authority: {Name of RRA} submission	ZAMRA submission	Evaluator comments
Test Product: Name, manufacturer, batch number, batch size, location of multi-point dissolution data in physiological media and release media, if different	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Reference product: Name, manufacturer, source, batch number, expiry date	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
Results: Conclusion and review of summary of results (table)	{Extract from relevant report section} Location in report:	{Extract from relevant dossier section} Location in dossier:	
<i>General comments from evaluator</i>			
<i>Comments from second assessor</i>			

4. Labelling

The following minimum information appears on the label:

Particulars to appear on <the outer packaging> <and> <the immediate packaging>	Yes / No	Evaluator comments
1. Name of the product: {(invented) name strength pharmaceutical form} {active substance(s)}		
2. Statement of active substance(s)		
3. List of excipients {only critical/special excipients are listed here}		
4. Pharmaceutical form and contents		
5. Method and route(s) of administration /if no specific information: "read the package leaflet before use."		



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6. Special warning that the medicinal product must be stored out of the sight and reach of children {normally: "keep out of the sight and reach of children."}		
7. Other special warning(s), if necessary		
8. Expiry date		
9. Storage conditions		
10. Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if appropriate		
11. Name and address of the supplier / applicant		
12. Provision for marketing authorization number}		
13. Batch number		
14. Proposed category of distribution		
15. Instructions on use		
<i>General comments from evaluator</i>		
<i>Comments from second assessor</i>		



Additional information as per Zambian requirements

Minimum particulars to appear on blisters or strips	Yes / No	Evaluator comments
1. Name of the product: {(Invented) name strength pharmaceutical form} {Active substance(s)}		
2. Name of the supplier / applicant		
3. Expiry date		
4. Batch number		
General comments from evaluator		
Comments from second assessor		

Additional information as per Zambian requirements

Minimum particulars to appear on small immediate packaging units	Yes / No	Evaluator comments
1. Name of the product: {(Invented) name strength pharmaceutical form} {Active substance(s); Route of administration}		
2. Method of administration		
3. Expiry date		
4. Batch number		
5. Contents by weight, by volume or by unit		
6. Storage condition		
7. Category of distribution		
General comments from evaluator		
Comments from second assessor		

5. APPLICANT COMMITMENTS TO RRA

Applicant to state any commitments to RRA that may require follow up.

Please do not just state a reference to a section of a report. Please insert a summary of text as per the example below:



1. [The Applicant undertook to continue long-term testing of <INN of API> for a period of time sufficient to cover the whole provisional re-test period (period ending month/year)]
2. The Applicant undertook to continue long-term testing of < FPP reference number, trade name (INN of API), strength, pharmaceutical form> for a period of time sufficient to cover the whole provisional shelf-life (period ending month/year)
3. The Applicant committed that three consecutive production batches would be prospectively validated and a validation report in accordance with the details of the validation protocol provided in the dossier--- would be made available as soon as possible for evaluation by assessors or for verification by the inspection team.]

**References**

1. EFDA. (2024). Guidelines on Reliance for Medicine Marketing Authorization. December, 1–18.
2. FDA. (2024). FDA Rwanda Guidelines on Reliance for Regulatory Decision Making. February, 1–14.
3. SAHPRA. (2024). Reliance guideline. May, 1–25.
4. WHO. (2021). Good reliance practices in the regulation of medical products: High level principles and considerations. WHO Technical Report Series 1033, 55(10), 237–267.

Change History

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change
Version 01		Initial Issue