



Zambia Medicines Regulatory Authority

GUIDELINES ON RELIANCE AND RECOGNITION FOR REGULATORY DECISION-MAKING

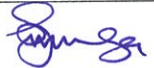
	Name	Designation	Signature	Date
Prepared by	Mr. Matthews Mwale	Director Licensing, Surveillance Enforcement		29/09/26
Reviewer	Mr. Makomani Siyanga	Director General		29/09/2026
Approver	Hon. Prof. Roma Chilengi, MP	Minster of Health		06.10.26



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i. Abbreviations and Acronyms

AMA	African Medicines Agency
API	Active Pharmaceutical Ingredient
CAPA	Corrective Action(s) and Preventive Action(s)
CRO	Contract Research Organisations
CTD	Common Technical Document
EFDA	Ethiopian Food and Drug Authority
FPP	Finished Pharmaceutical Product
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
GRP	Good Regulatory Practices
GReIP	Good Reliance Practices
ICH	International Conference on Harmonisation (of Technical Requirements for Registration of Pharmaceuticals for Human Use)
ILAC	International Laboratory Accreditation Cooperation.
ISO/IEC	International Organisation for Standardisation and the International Electrotechnical Commission
MA	Marketing Authorisation
NRA	National Regulatory Authority
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
QA	Quality Assurance
QC	Quality Control
RRA	Reference Regulatory Authority
SADC	Southern African Development Community
WHO	World Health Organization
WHO PQ	World Health Organization Prequalification
WLA	WHO Listed Authority
ZAMRA	Zambia Medicines Regulatory Authority
ZAZIBONA	SADC Collaborative Medicines Registration Initiative



1. Introduction

The Zambia Medicines Regulatory Authority (“the Authority”) is mandated under the Medicines and Allied Substances Act, Chapter 299 of the Laws of Zambia (“the Act”) to regulate the manufacture, importation, exportation, sale, storage, distribution, use and disposal of medicines and allied substances. The Authority also has the responsibility of ensuring that medicines and allied substances available to the Zambian people conform to the required standards of safety, quality, efficacy and performance, where applicable throughout the supply chain.

The Authority, in the course of efficiently performing its mandate, leverages on the principle of reliance and recognition. The principle of reliance and recognition allows a regulatory authority to take into account regulatory decisions made by other recognised national or international regulatory authorities. Reliance and recognition, introduces flexible administrative enforcement mechanisms, reduces unnecessary regulatory burdens, and aligns Zambia’s regulatory system with international best practices, including the African Union Model Law on Medical Products Regulation and World Health Organization (WHO) Good Regulatory Practices. It further allows the Authority to make the best use of resources, build expertise and capacity, increase the quality of regulatory decisions, reduce duplication of effort and, ultimately, promote timely access to safe, quality, efficacy and performance, where applicable of medicines and allied substances.

These guidelines are issued by the Authority pursuant to section 68 of the Act and are intended to cover reliance and recognition activities in the field of regulatory oversight of medicines and allied substances, addressing all regulatory functions of the Authority spanning the full life cycle of medicines and allied substances.

On one hand, reliance may take many forms and reflect varying degrees of application in recognising or taking account of assessments, decisions or any other authoritative information available from other national medicines regulatory authorities or institutions. On the other hand, recognition may be seen as a special and more complete form of reliance whereby one regulatory authority relies on the decisions of another regulatory authority, system or institution, obviating the need for additional regulatory assessment in reaching its own decision. Recognition usually requires formal and enabling legal provisions.



2. Purpose

The purpose of these guidelines is to establish a structured and efficient approach to utilising regulatory assessments performed or decisions made by a recognised national medicines regulatory authority or institution. These guidelines also outline the requirements and procedures for implementation of reliance and recognition, thereby mitigating the risk of delays in regulatory decisions and improving the turnaround time for service delivery without compromising standards of safety, quality, efficacy and performance, where applicable of medicines and allied substances. The authority remains independent, responsible and accountable for the decisions taken, even when it relies on the assessment performed and decision made by other national medicines regulatory authorities or institutions.

3. Scope

These guidelines cover reliance and recognition activities regarding:

- i. an application for marketing authorisation where the applicant shows that the medicine or allied substance subject of that application is –
 - a) registered in another jurisdiction; and
 - b) compliant with the regulatory requirements of the Act;
- ii. an application for a clinical trial certificate where the applicant shows that the clinical trial or investigational medicine or allied substance subject of that application is -
 - a) registered in another jurisdiction; and
 - b) compliant with the requirements of the Act;
- iii. a medicine or allied substance recalled in another jurisdiction by a recognised national medicines regulatory authority or institution;
- iv. good manufacturing practice inspections conducted in another jurisdiction by a recognised national medicines regulatory authority or institution; or
- v. relevant information received relating to safety of medicines or allied substances, requiring the Authority to make a decision or take an action to protect the public from any safety concern.



4. Definition

In these guidelines, the following terms unless the context states otherwise mean:

“abridged review” means 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 to inform the local decision. The abridged review is based on assessment reports, Good Manufacturing practices (GMP) inspection reports from reference authorities and specific parts of the Common Technical Document (CTD).

“investigational medicine or allied substance” means a medicine or allied substance being tested or used as a reference in a clinical trial, including a medicine or allied substance –

(a) with a marketing authorisation when used, formulated or packaged in a manner different from the specifications in the marketing authorisation;

(b) when used for an indication not specified in authorisation; or the marketing when used accordance with the specifications in the marketing authorisation to obtain further information on the safety, efficacy, performance or use of the medicine or allied substance; or

(c) when used accordance with the specifications in the marketing authorisation to obtain further information on the safety, efficacy, performance or use of the medicine or allied substance

“performance of a medical device” means its ability to achieve the intended purpose specified by the manufacturer, consistently and safely, as demonstrated through verification, validation, and risk management processes.

“quality-assured medicine or allied substance” means a medicine or allied substance that has been assessed and demonstrated, through appropriate regulatory evaluation and ongoing controls, to consistently meet established standards of safety, quality, efficacy and performance, where applicable throughout its lifecycle.

“recognition” means acceptance of decisions made by another national medicines regulatory authority or institution based on evidence that the regulatory requirements of that regulatory authority are sufficient to meet the regulatory requirements of the relying



authority and may be subject of a recognition agreement, and “recognised” shall be construed accordingly;

“Reference Regulatory Authority” means a national medicines regulatory authority or institution that is recognised by the Authority as per criteria provided in these guidelines.

“reliance” means an act where the Authority recognises assessments performed or decisions made by another national medicines regulatory authority or recognised institution, in reaching the Authority’s own decision

“reliance approaches” means an assessment pathway based on reliance.

“WHO Listed Authority (WLA)” means a regulatory Authority which is a member of the International Conference on Harmonisation (ICH) or an ICH observer or is associated with an ICH member through a legally binding mutual recognition agreement. This was previously known as Stringent Regulatory Authority (SRA). The scope of listing should be based on medicines and the following regulatory functions; Marketing Authorisation (MA), Vigilance (VL), Market surveillance and control (MC), Licensing establishments (LI), Regulatory inspection (RI), Clinical trial oversight (CT), Laboratory access and testing (LT) and Regulatory Authority lot release (LR).

5. Principles of good reliance practices

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

i. Sovereignty of decision-making

Reliance is a sovereign decision, therefore, the Authority shall decide when and how to use reliance and recognition when making regulatory decisions. The Authority retains its independence, responsibility and accountability for the decisions taken by way of reliance and recognition.

ii. Transparency

The Authority shall be transparent about the standards, processes and approaches it adopts in implementing reliance measures. Further, the basis and rationale for relying on other recognised national medicines regulatory authorities or institutions, shall be disclosed to persons regulated under the Act.



iii. Compliance with domestic legal requirements

The Authority shall ensure that reliance practices are coherent with national legal frameworks and policies on regulation of medicines and allied substances. Use of reliance does not substitute the performance of the functions of the Authority under the Act.

iv. Consistency

The practice of reliance by the Authority shall be transparent and predictable. The preceding entails that the Authority shall apply reliance consistently for similar circumstances.

v. Competency

Implementation of reliance by the Authority shall be performed by staff with the necessary competence for critical decision-making.

6. Areas of Reliance and Recognition for Regulatory Decision-Making

The concept of reliance and recognition plays an important role in various aspects of decision making taken by the Authority. The following are the regulatory function areas in which reliance and recognition are applied:

6.1 Marketing authorisation of medicines and allied substances

The Authority employs reliance as one of its regulatory decision-making pathways to accelerate the assessment of applications for marketing authorisation of medicines and allied substances. Reliance is a risk-based approach that 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 authorisation, the assessment process for applications based on reliance may involve verification review, abridged review or recognition.

i. 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. The verifications involve confirmation of sameness of the product approved by the RRA.



ii. Abridged Review

The RRA's assessments may not always account for specific circumstances that can significantly affect the benefit-risk of a medicine or allied substance in Zambia. Therefore, this review focuses on assessing specific aspects of a medicine or allied substance and its information that are relevant to the Zambian context while relying on prior evaluations conducted by the RRA. It involves conducting evaluation of administrative information of the dossier and specific aspects of a medicine or allied substance regarding the safety, quality, efficacy and performance data, where applicable, in view of the information provided in the assessment reports of the RRA.

iii. Recognition

This is a streamlined approval process based on directly recognising the outcome of a review from a RRA with which the Authority shares a recognition agreement.

6.1.1 Product Sameness

Product sameness applies to all reliance pathways listed above. Product sameness refers to two products having identical essential characteristics. The essential characteristics that are required to be the same or sufficiently similar include but are not limited to: same product information, qualitative and quantitative composition, strength, pharmaceutical form, intended use, manufacturing process, suppliers of active pharmaceutical ingredients, quality of all excipients and manufactured at the same manufacturing site. Additionally, the results of supporting studies of safety, efficacy, and quality, indications, and conditions of use should be the same.

Product sameness is an important aspect of reliance that ensures that the same product that was assessed and approved by the RRA is the same one being applied for to the relying authority. Therefore, a medicine or allied substance and its information submitted to the Authority should be the same as the one that has been assessed and approved by the RRA.

6.1.2 Product eligibility for application for marketing authorisation through reliance procedure

The Authority may apply reliance procedures for granting marketing authorisation for a medicine or allied substance under the following circumstances:



- i. a medicine or allied substance is registered or listed by at least one RRA;
- ii. an innovator medicine or new chemical entity and allied substance that has been registered by a WLA;
- iii. a medicine or allied substance is covered by the scope of an existing Memorandum of Understanding between the Authority and another NRA;
- iv. a medicine or allied substance is being imported in response to a declared public health emergency or animal disease emergency; and
- v. any other requirement as may be determined by the Authority from time to time.

6.1.3 Criteria for selection of National Medicines Regulatory Authorities and Institutions

National medicines regulatory authorities and institutions shall fulfil at least the following criteria for recognition by Zambia:

- i. WHO;
- ii. included as a WLA and listed for medicines and allied substances for the following functions; Marketing Authorisation (MA), Vigilance (VL), Market surveillance and control (MC), Licensing establishments (LI), Regulatory inspection (RI), Clinical trial oversight (CT), Laboratory access and testing (LT) and Regulatory Authority lot release (LR);
- iii. WHO ML 3 or 4 for medicines and allied substances;
- iv. African Regional Medicines Regulatory Harmonisation Initiatives and Regulatory bodies;
- v. member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), and an ICH observer, being the European Free Trade Association;
- vi. a national medicines regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement;
- vii. national medicines regulatory authority or institution that has signed memorandum of understanding or legally binding agreement with the Authority; or
- viii. Internationally recognised conformity assessment body for relevant ISO standards



(allied substances).

6.1.4 Requirements for expression of interest for reliance

6.1.4.1 An expression of interest for reliance procedure in the grant of marketing authorisation of a medicine or allied substance should meet the following requirements:

- i. the application is for a medicine or allied substance assessed and approved by at least one RRA;
- ii. has a full CTD dossier in the case of a human medicine, dossier in the case of an allied substance or veterinary medicine and a **Sameness Declaration for Verification Evaluation Form in Annex 2** submitted to the Authority;
- iii. differences that exist between the dossier submitted to the Authority and the dossier submitted to an RRA are clearly indicated and justified in the application for grant of marketing authorisation;
- iv. any post-approval commitment documents have been submitted together with the most recent report from the RRA (e.g. Annual Product Quality Report, Periodic Safety Update Report, etc);
- v. the application for grant of marketing authorisation has been submitted electronically through the Integrated Regulatory Information Management System (IRIMS) portal or as advised by the Authority;
- vi. there is a signed commitment letter to notify the Authority of a pending variation, product recall, out of specification or withdrawal from the market or ban by reference regulator due to any notice of concern;
- vii. the medicine or allied substance subject of an application for grant of marketing authorisation was manufactured in compliance with the principles of GMP;
- viii. a declaration indicating that any post approval amendments to marketing authorisation was reported and accepted by a RRA. The declaration must include the list of amendments not yet accepted by the RRA and section of the dossier affected by the accepted amendments;
- ix. has a copy of the marketing authorisation, or the equivalent thereof, issued by the RRA to demonstrate that the medicine or allied substance is registered or licensed or approved in accordance with the RRA requirements. If applicable, evidence or

a copy of the latest renewal of the marketing authorisation should also be provided;

- x. has a stability study report conducted as per the conditions prescribed in the ZAMRA Stability Guidelines; and
- xi. has an updated quality information summary.

6.1.4.2 The Authority may request for additional information in relation to the expression of interest.

6.1.4.3 Applicants may contact the Validation Unit of the Authority for pre-submission technical support and guidance.

6.1.4.4 The assessment of an application for grant of marketing authorisation under the reliance procedure shall be within the timelines specified by the Authority in the Charter on Service Delivery.

6.1.5 Application and Evaluation of Amendments to marketing authorisation

6.1.5.1 In the case of an application for amendment of marketing authorisation, the application must comply with the applicable Amendment Guidelines issued by the Authority.

6.1.5.2 The applicant shall submit the application for amendment of marketing authorisation through the IRIMS portal or as advised by the Authority.

6.1.5.3 The submitted application including any prior assessments and approvals by the RRA shall be used to facilitate the amendment review.

6.1.6 Cancellation of marketing authorisation granted under reliance procedure

6.1.6.1 The Authority shall conduct periodic reviews of the safety, quality, efficacy and performance where applicable, of registered medicines and allied substances.

6.1.6.2 Based on the outcome of the periodic reviews, the Authority may take regulatory action in accordance with the regulations for marketing authorisation issued pursuant to the Act.



6.2 GMP Inspection

6.2.1 The Authority may apply reliance and recognition approaches in its regulatory decision-making relating to GMP inspection of manufacturing sites and related sites. Further, the Authority may apply reliance for determining GMP compliance for pre or post market authorisation.

6.2.2 In determining whether a reliance or recognition is appropriate, the Authority shall apply a risk-based approach. The following reliance approaches may be implemented by the Authority:

i. Joint activity

This is a form of work-sharing whereby a regulatory task is conducted by the Authority in collaboration with other regulatory authorities in order to share assessments, benefit from each other's expertise and discuss any shortcomings of the data being evaluated.

The Authority may participate in a joint inspection with RRA_(s) for sites of common interest resulting in joint inspection reports and official outcome letters that shall serve as the basis for GMP compliance decisions.

ii. Desk Assessment

This is an evaluation of a manufacturing site performed remotely by the Authority using document review only and no live interaction with the site. Document review may lead to issuance of a site compliance rating or determination that an on-site inspection is required.

The key activities for a desk assessment include:

- a) remote review of documents;
- b) request for additional information from the manufacturing site as may be required by the Authority;
- c) issuance of an assessment report; and
- d) communication of the outcome of the assessment to the manufacturing site.

iii. Remote Inspection

This is an evaluation of a site performed remotely by the Authority, relying on technology to facilitate live interactions during the entire assessment period. Remote inspections include video meetings, document sharing, video streaming from the manufacturing site, or other live streaming interactive technology to determine compliance with GMP principles. Circumstances under which remote inspections may be undertaken include:

- a) travel constraints and restrictions;



- b) security concerns in the host country;
- c) facility to be inspected has a good GMP compliance history; or
- d) declared public health emergency or animal disease emergency.

iv. Hybrid Inspection

This is an evaluation or assessment of a manufacturing site performed by the Authority using a combination of on-site and remote inspection. A Hybrid inspection would constitute of:

- a) a team of the same inspectors conducting both on-site and remote assessment of the site at diverse intervals; or
- b) a combination of inspectors on-site and inspectors connecting remotely at the same time using virtual technology.

If an inspection consists of an assessment of relevant documentation away from a manufacturing site with a limited on-site inspection of manufacturing operations, facilities and equipment, the on-site inspection and the assessment away from site shall be considered together as parts of the same inspection. Therefore, a single inspection report and inspection outcome shall be produced by the Authority.

v. Recognition

Under the recognition approach, the Authority retains the discretion to accept or reject the outcomes of inspections and associated regulatory decisions based on its own independent assessment. Recognition may take the following forms:

a) Unilateral Recognition

This is a form of recognition where the Authority accepts a GMP compliance decision of a RRA without conducting its own inspection or detailed assessment of the inspection report. Further, a statement of consent shall be required for the Authority to access additional inspection information under this approach.

b) Mutual Recognition

This approach to reliance is based on Mutual Recognition Agreements (MRAs) or treaties, under which the Authority and another RRA accept each other's GMP inspection outcomes and compliance decisions. Under such MRAs or treaties, the Authority may not repeat inspections that fall within the scope of the agreement, as



the GMP oversight systems are considered equivalent.

Risk-based considerations shall apply to the above listed reliance approaches. Risk based consideration may be given to the type and complexity of medicines or allied substances manufactured at the site, the strength and maturity of the regulatory system of the RRA and the compliance history of the manufacturing facility.

6.2.3 Criteria for selection of a Reference Regulatory Authority (RRA)

6.2.3.1 A national medicines regulatory authority or institution shall fulfil at least one of the following criteria to be included in the list of RRAs recognised by the Authority:

- i. WHO Listed Authorities (WLA) listed for medicines, vaccines or applicable allied substances for all Global Benchmarking Tool functions;
- ii. WHO ML 3 or 4 NRAs for the applicable scope products as determined by WHO benchmarking;
- iii. African Medicines Agency (AMA);
- iv. A member of PIC/s;
- v. Southern Africa Development Community (SADC) collaborative medicines registration initiative (ZAZIBONA);
- vi. Member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), and an ICH observer, being the European Free Trade Association;
- vii. A regulatory authority associated with an ICH member through a mutual recognition agreement.
- viii. National Regulatory Authority or institution that has signed a memorandum of understanding with the Authority.
- ix. Internationally recognised conformity assessment body for relevant ISO standards (allied substances);

The Authority shall publish and maintain a list of recognised RRAs.



6.2.3.2 Eligibility criteria for consideration under the GMP inspection reliance approach.

6.2.3.3 A manufacturing site may qualify for consideration under the reliance approach if it meets the following criteria:

- i. the medicine or allied substance has been granted marketing authorisation or submitted to the Authority for grant of marketing authorisation;
- ii. the medicine or allied substance was manufactured from a site inspected and approved by a RRA and the said medicine or allied substance was included in the scope of the GMP inspection and approval;
- iii. the medicine or allied substance does not have significant or repetitive quality and safety concerns;
- iv. the site has a valid manufacturing license issued by the relevant national competent authority;
- v. the site has a demonstrated good GMP compliance history with the Authority or a RRA; and
- vi. the inspection to be relied on has covered the same site, block, production line, dosage form, and pack size, as applicable.

6.2.3.4 The Authority reserves the right to require an onsite inspection at any stage if reliance is considered insufficient.



6.2.4 Review of eligibility criteria

6.2.4.1 For the purpose of maintaining quality standards in the implementation of reliance for GMP inspections, the Authority shall periodically review the eligibility criteria and, where necessary, redefine Reference Regulatory Authorities (RRAs).

6.2.4.2 This review shall take into account changes in the regulatory status, performance, recognition and credibility of the authorities whose inspection reports are relied upon. Consideration shall be given to developments such as WHO Listed Authority (WLA) status, PIC/S membership, participation in recognised regional regulatory initiatives, and any publicly available information relating to the effectiveness of the RRA oversight.

6.2.4.3 Where a RRA no longer meets the criteria considered adequate for reliance, the Authority may remove the RRA from the list of recognized RRA's for the purposes of GMP inspection reliance or amend the applicable reliance approach based on the RRA's status.

6.2.5 Requirements for expression of interest for GMP inspection reliance

6.2.5.1 A request for GMP inspection may be submitted together with an expression of interest for reliance.

6.2.5.2 An expression of interest must be accompanied by a letter of consent authorising the Authority to access regulatory information from the applicable RRA.

6.2.5.3 The Authority may request additional information in relation to the expression of interest.

6.2.5.4 Despite clauses 2.4.1, 2.4.2 and 2.4.3 above, the Authority may on its own motion and based on the available documentation and information of a manufacturing site apply the reliance approach for a GMP inspection without an expression of interest.

6.2.6 Outcome of reliance

6.2.6.1 When the Authority applies a reliance approach to GMP inspections, the Authority may:

- i. accept the RRA's GMP inspection documents or approvals as evidence of GMP compliance; or
- ii. reject the RRA's GMP inspection documents or approvals giving reasons for the rejection and recommend an onsite inspection of the manufacturing site by the Authority.

6.3 Vigilance

The Authority may recognise or rely on vigilance-related decisions, reports or information from RRAs when making national vigilance decisions. The Authority shall continue to ensure the safety of medicines and allied substances through its established vigilance system. To ensure that safety issues are promptly identified and the necessary interventions implemented, the Authority may consider decisions from RRAs on the safety of medicines and/or allied substances that negatively impact on the health of patients. The following approach may be applied:

6.3.1 Abridged Assessment

The Authority may review published approved Risk Management Plan and Periodic Safety Update Reports assessment by RRAs and make decisions based on such assessments. The Authority may, upon receiving proof of scientific information related to safety of medicines or allied substances, recognise and take any corrective action to protect the public from any eminent safety concerns that may likely arise.

6.3.2 Applying Reliance on the national level

Although the Authority relies on the assessment of RRAs of the vigilance documents, and takes into consideration the information published concerning safety and efficacy issues by those authorities, the Authority may require specific amendments or additional requirements to the recommended actions and implementation plan of risk minimization measure for it to be suitable and effective on the national level. The Authority may request for amendments or additional requirements :



- i. when specific risks may be anticipated in (Zambian population/Zambian Market or Healthcare system) that may not exist in the region of the RRA;
- ii. when the suggested risk minimization activity implementation in Zambia is not applicable in the same method as in the RRA or may not be suitable to Zambian culture;
- iii. when different RRAs have different opinions/assessment regarding a specific signal or risk; or
- iv. in case local data provides additional evidence that may change the reliance on the RRA assessment.

6.4 Clinical Trials

The Authority may rely or recognise relevant clinical trials, decisions on investigational medicines or allied substances, assessment reports and information from RRAs, including those that have MoUs with the Authority to take appropriate regulatory decisions in clinical trial oversight for public health protection.

To facilitate product development, regulatory decision-making, and access to promising new medicines or allied substances, the Authority may consider the regulatory decisions taken by RRAs for the multi-center trials that are being implemented in Zambia because of post- approval monitoring activities.

In case of emergency, the Authority applies reliance approaches as non-routine procedure for Clinical Trial authorisation.

6.5 Quality Control (QC) Testing

6.5.1 The Authority may rely on laboratory testing results from recognised national medicines regulatory authorities or institutions.

6.5.2 National medicines regulatory authorities and institutions shall fulfil at least the following criteria for recognition by Zambia:

- a) WHO listed; or
- b) ISO/IEC 17025:2017 accredited and awarded by an International Laboratory Accreditation Cooperation (ILAC) member.



6.6 Market surveillance and control

The Authority may apply reliance and recognition approaches in its regulatory decision-making relating to market surveillance and control from RRAs where such decisions are relevant and applicable.

Furthermore, the Authority may rely on market surveillance and control decisions arising from the World Health Organization Global Surveillance and Monitoring System (WHO/GSMS), including actions related to substandard and falsified medical products. In addition, the Authority may rely on market surveillance and control decisions taken by regulatory authorities within the Southern African Development Community (SADC) and by regulatory authorities with which the Authority has signed Memoranda of Understanding (MoUs), provided that the information shared is adequate to support risk-based regulatory decision-making such as recalls.

7 References

- i. WHO Good reliance practices in the regulation of medical products: high level principles and considerations. WHO Expert Committee on Specifications for Pharmaceutical Preparations Fifty-fifth report. Geneva, World Health Organization, 2021 (WHO Technical Report Series, No. 1033), Annex 10
- ii. WHO Guidance on good practices for desk assessment of compliance with GMP, GLP and GCP for medical products regulatory decisions. WHO Expert Committee on Specifications for Pharmaceutical Preparations Fifty-second Report Geneva, World Health Organization, 2018 (WHO Technical Report Series, No. 1010)
- iii. Rwanda FDA (2022). Guidelines on Reliance for Regulatory Decision-Making, Doc. No: ODG/RAHC/GDL/001
- ii. EFDA. (2024). Guidelines on Reliance for Medicine Marketing Authorization. December, 1–18.
- iii. FDA. (2024). FDA Rwanda Guidelines on Reliance for Regulatory Decision Making. February, 1–14.
- iv. SAHPRA. (2024). Reliance guideline. May, 1–25.
- v. TMDA (2025) Guidelines for Reliance on Good Manufacturing Practices Inspection, Doc. No. TMDA/DMC/MCIE/G/014 REV.#. 01
- vi. Ethiopian FDA (2024) Guideline on Reliance for cGMP Inspection, Document No. EFDA/GDL/052 Effective: 16/07/2024 Version No: 001



8 Annexures

Annex 1: List of Recognised Reference Authorities and Collaborative Procedures

The list of ZAMRA's current RRAs includes:

- African Medicines Agency
- European Medicines Agency
- NRA's that have attained Maturity level 3 (Refer to WHO website for updated list)
- NRA's that have attained Maturity level 4 (Refer to WHO website for updated list)
- NRA's with which ZAMRA has MoUs
- Regulatory authorities that participate in the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/s)
- WHO listed Authorities (Refer to WHO website for updated list)

The list of ZAMRA's current recognised Collaborative Procedures includes:

- East African Community (EAC) collaborative procedure
- Intergovernmental Authority Development (IGAD) collaborative procedure
- World Health Organisation (WHO) collaborative registration procedure
- ZAZIBONA collaborative procedure

Annex 2: Sameness Declaration for Verification Evaluation Procedure

To be Completed by the Applicant:

Application for {Proposed product name}	{Name of Recognised Regulatory Authority}
Registration date	
Applicant's name	
Date(s) of approval of post-registration variation(s), if applicable	

I, {Full name}, Local Responsible Person at {Applicant's 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 variations that the above specified RRA has approved since registration.
- The "same" product is characterized by:
 - a) The same product dossier content;

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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.

I hereby confirm that the documents that have been submitted are complete and not redacted.

Full name of the Responsible Person:

Company:

Email address:

Telephone Number:

Signature:

Date:

Place: