MEDICINES CONTROL AGENCY

THE GAMBIA

Reliance Policy

November 2023

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1 INTRODUCTION

1.1 BACKGROUND

1.1.1. Strong regulatory systems for medicines and related products remain a critical element of well-functioning health systems. In view of the extent and complexity of regulatory oversight, National (Medicines) Regulatory Authorities (NRAs) like the Medicines Control Agency (MCA) The Gambia must consider enhanced, innovative and more effective forms of collaboration in order to make the best use of the available resources and expertise, avoid duplication and concentrate their regulatory efforts and resources where most needed.

1.1.2. Reliance represents a smarter way of regulating medicines and related products in a modern regulatory world. Reliance brings benefit to the industry, patients and consumers, national governments, as well as the donor community, and international development partners by facilitating and accelerating access to quality medicines and related products.

1.1.3. The Agency's perception of reliance implies that the work done is shared by the recognised ("recognised" meaning stringent, mature, credible and/or capable) NRA as defined and listed by the WHO (see Appendix I), or by regional and international bodies that are acknowledged as reference institutions. This is done through access to e.g. assessment reports, inspection reports, quality control lab reports, certificates, etc., while the Agency uses this work according to its own scientific knowledge and regulatory procedures (such as differences in conditions of use, patient population, etc).

1.1.4. An essential part of reliance is information-sharing, which is seen in the growing number of international initiatives.

1.1.5. MCA accepts that reliance can be unilateral, bilateral (mutual) or multilateral, and it will leverage on the information in the imported reports and/or decisions to arrive at a regulatory decision, but will maintain its own regulatory responsibilities for decision-making.

1.1.6. The Agency shall activate the reliance pathway to facilitate regulatory decisions either on a case-by-case basis or at the explicit request of the applicant.

1.1.7. The instituted alternative pathways are designed to facilitate conducting regulatory reviews and evaluations in a timely manner and at the same time, accelerate the evaluation process without compromising the quality, safety and efficacy of medicines and related products, as well as the design of clinical trials.

1.2 LEGAL BASIS

1.2.1. The usage of reliance by MCA is supported/embedded in Part II, section 4 (e) of the Medicines and Related Products Act, 2014 and Part XIII, section 82 (2) of the Medicines and Related Products Regulations, 2020.

1.3 WHO DEFINITIONS

1.3.1. **Reliance**
The act whereby the NRA in one jurisdiction may take into account and give significant weight to assessments performed by another NRA or trusted institution, or to any other authoritative information in reaching its own decision. The relying authority remains independent, responsible and accountable regarding the decisions taken, even when it relies on the decisions and information of others.

1.3.2. **Recognition**
Acceptance of the regulatory decision of another regulator or trusted institution. Recognition should be based on evidence 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.

1.3.3. **Work-sharing**
A process by which NRAs of two or more jurisdictions share activities to accomplish a specific regulatory task. The opportunities for work-sharing include joint assessment of applications for authorization of clinical trials or marketing authorizations, joint inspections for good practices, joint post marketing surveillance of the quality and safety of medical products, joint development of technical guidelines or regulatory standards and collaboration on information platforms and technology. Work-sharing also entails exchange of information consistent with the provisions of existing agreements and compliant with each agency's or institution's legislative framework for sharing such information with other NRAs.

2 PURPOSE, SCOPE AND OBJECTIVE

2.1. This policy shall promote a more effective and efficient approach to the evaluation and authorisation of applications that has been approved by a recognised NRA or regional and international body while retaining the Agency's regulatory responsibilities and decision making, thereby promoting access to quality-assured medicines and related products. This is achieved in a variety of ways–including information and/or work-sharing and reliance (partly or fully) on regulatory functions including assessment reports, GMP/GCP inspection reports and QC laboratory reports.

2.2. This document applies to the regulatory oversight of medicines and related products addressing all regulatory functions spanning the full life cycle of a medicine or related product.

2.3. The objective of this document is to promote a more effective and efficient approach to regulation, thereby encouraging a more efficient use of time and resources and promote access to quality-assured medicines and related products.

3 POLICY STATEMENT

3.1. The Agency shall consider possible approaches in the context of the needs and characteristics of the national health and regulatory system. The

decision to practice reliance shall take into consideration the existing capacities, regulatory systems' needs, the availability of an authority that the Agency can rely upon with confidence, and how reliance can complement these capacities to drive efficiencies and the optimal use of resources.

4 PRINCIPLES UNDERPINNING RELIANCE

4.1. The Agency shall consider the following reliance principles:

- **Universality**
  Reliance applies to all NRAs, irrespective of their levels of maturity or resources.
- **Sovereignty:**
  Reliance should be a sovereign decision. The Agency should decide if it wants to use reliance, on whom it is going to rely and how.
- **Transparency:**
  Reliance processes should be transparent regarding standards and processes. In addition, the basis/rationale for relying on a specific entity should be disclosed and understood by all parties.
- **Consistency:**
  Reliance on a specific process/evaluation/decision should be established for specific and well-defined category of products/ practices and should as well be predictable. Thus, it is expected that reliance shall be applied consistently for all products/practices in the same predetermined category.
- **Legal basis:**
  Reliance should be coherent with national legal frameworks and supported by clear mandates/regulations that aim at the efficient implementation. Adoption of these legal frameworks should not detract from the efficiencies gained by reliance.
- **Competency:**
  Reliance requires that authorities being relied on should have and maintain competencies and performance in the given area and prove the use of internationally accepted standards. The competencies should be bench-marked by transparent processes that develop trust on the capacities of these reference authorities.
  Conversely, the Agency should build the necessary competencies for critical decision making for proper implementation, having a number of critical tools like information sharing arrangements or information platforms among others.

5 EXAMPLES FOR USE OF RELIANCE

5.1 REGISTRATION AND/OR MARKETING AUTHORISATION

5.1.1. Several pathways are available through NRAs or regional and international bodies that are acknowledged as reference institutions for the purpose of reliance on/use of relevant marketing authorisation decisions, reports or

information in order to enable the use of an abridged reliance pathway.

5.1.2. The WHO Collaborative Registration Procedure (CRP) facilitates the assessment and accelerates the national registration of WHO prequalified medicines and related products approved by a stringent regulatory authority. The CRP operates by providing unredacted assessment, inspection and performance evaluation (in the case of in vitro diagnostics) reports upon request (and with the consent of the manufacturer) to participating NRAs.
The Agency use reliance in its decision making process on registration of products for marketing in The Gambia in the following circumstances:

- If the product has already been evaluated and listed as a WHO Prequalified Product through the WHO PQ collaborative registration procedure between WHO and NRAs;
- If the product has already been evaluated and listed as a product of either the WHO collaborative registration pilot for stringently authorised products, including through the EU-Medicines for all or 'EU-M4all' Procedure (previously known as EU's Article 58 procedure) or the Swissmedic's Marketing Authorization for Global Health products or the International Generic Drug Regulatory Programme (launched July, 2014);
- If the product has been registered and/or granted marketing authorisation for more than 6 months by a recognised and is actually on the market of the reference authority, where applicable; or
- If the product has been evaluated and listed as an output of the West African Medicines Harmonization initiative of the Economic Community of West African States (ECOWAS).

5.2 INSPECTIONS

5.2.1. In the field of inspections, governments and NRAs in different regions and parts of the world have worked on mutual recognition agreements in order to rely on each other's inspection outcomes in the fields of Good Manufacturing and Good Distribution Practices (GMP and GDP) of medicinal products for human or veterinary use, Good Clinical Practices (GCP) and Good Pharmacovigilance Practices (GVP), avoiding the duplication of inspections and making the best use of resources.

GMP Inspections

5.2.2. The Agency shall recognise pharmaceutical inspections by a recognised NRA for facilities manufacturing medicines located in the territory of the issuing authority. In addition, MCA may accept official GMP documents such as GMP inspections and batch certification for the manufacturer issued by a recognised NRA, European Medicines Agency (EMA) or WHO.

5.2.3. The reliance shall apply to pharmaceutical inspections of manufacturing facilities carried out during the marketing of products ("post-approval inspections") and before products are marketed ("pre-approval inspections").

5.2.4. The Agency shall accept an official GMP document issued by a recognised

NRA and rely on the factual findings in such document.

5.2.5. MCA may in specific circumstances opt not to accept an official GMP document issued by a recognised NRA for manufacturing facilities if there is the indication of material inconsistencies or inadequacies in an inspection report, quality defects identified in the post-market surveillance or other specific evidence of serious concern in relation to product quality or consumer safety. The Agency should in such cases notify the relevant NRA of the reasons for not accepting the document and may request clarification from that authority.

5.2.6. In the course of importation of medicines the Agency may request a recognised NRA for a post-approval official GMP document.

Other Inspections

5.2.7. AVAREF has published a guide for the inspection of clinical trials which can support mutual recognition of inspections of clinical trials between countries that apply the same standards and procedures of inspection. Where relevant, MCA may consider an understanding such as a mutual recognition agreement between inspectorates.

5.3 CLINICAL TRIAL AUTHORISATION

5.3.1. Work-sharing for clinical trial assessment is happening in some regions, such as the European Union and via the African Vaccine Regulatory Forum (AVAREF).

5.3.2. The Agency use reliance in its decision making process on clinical trial authorisation in the following circumstances:

- If the investigational product has already been evaluated and listed as a WHO Prequalified Product through the WHO PQ collaborative registration procedure between WHO and NRAs;
- If the investigational product has already been evaluated and listed as a product of either the WHO collaborative registration pilot for stringently authorised products, including through the EU-M4all Procedure or the Swissmedic's Marketing Authorization for Global Health products or the International Generic Drug Regulatory Programme (launched July, 2014);
- If the investigational product has been authorised in a clinical trial or granted marketing authorisation by a recognised NRA (e.g. WHO Listed Authority); or
- If either the trial or the investigational product has been evaluated and judged satisfactory at a joint review meeting facilitated by the World Health Organization under the African Vaccine Regulatory Forum (AVAREF).

5.3.3. AVAREF recommends in the guideline for joint and assisted reviews of clinical trial applications also post-approval collaboration by participating countries such as sharing the results of any significant and serious observations from the safety monitoring or any other activity related to the oversight of the trials in all sites by the NRAs that authorised the trial.

5.3.4. The decision of the Agency may concern the suspension or termination of a clinical trial based on safety concerns or lack of efficacy identified by other NRAs, information from international organisations, literature, or other sources as applicable.

5.4 PHARMACOVIGILANCE

5.4.1. MCA continually ensures the safety of marketed products through its established pharmacovigilance system. To ensure that safety issues are promptly identified and the necessary regulatory actions taken, the Agency considers decisions from NRAs and regional and international bodies on the safety of medicines that impact negatively on the health of patients and consumers.

5.4.2. In the field of pharmacovigilance, the exchange and sharing of data is critical. More than 100 Member States contribute by sharing their safety data to the WHO Global database of individual case safety reports (ICSR) - VigiBase - developed and maintained by the Uppsala Monitoring Center (UMC).

5.4.3. The Agency relies upon this resource (and thereby, on each-others' data) as a single point of pharmacovigilance information to confirm and validate signals of adverse events with medicines that the Agency have observed.

5.4.4. Another mean of information-sharing with respect to pharmacovigilance is the transmission of information by a Rapid Alert between different NRAs relating to the recall of products which have quality defects or which are falsified when urgent action is required to protect public health and animal health.

5.4.5. The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) stipulates for their members that the procedure may be used also for transmission of other information such as cautions-in-use, product withdrawals for safety reasons or for follow-up messages to any of the above listed categories.

5.4.6. The European Medicines Agency (EMA) maintains a Rapid Alert list that includes all EEA Member States, MRA partners, WHO and PIC/S participating authorities.

5.5 LABORATORY SERVICES (QUALITY CONTROL)

5.5.1. MCA relies on or recognises analytical reports from laboratories which are WHO Pre-qualified or recognised by WHO or ISO/IEC 17025:2017 accredited and awarded by an International Laboratory Accreditation Cooperation (ILAC) member.

5.6 ADOPTION OF EXISTING GUIDELINES

5.6.1. Before initiating the development of a new guideline, the Agency shall

clarify whether there are already existing guidelines for the same topic, and if so, their applicability and acceptability to the national regulatory context.

5.6.2. The benefits of this approach include:

- Facilitation of global harmonisation of medicines and related products regulation; and
- Optimal use of resources (financial/personal).

5.6.3. Prior to adopting any guideline, the MCA will undertake an extensive process of internal and external consultations to ensure the guideline is consistent with prevailing requirements in The Gambia.

6 RELIANCE PROCEDURE

6.1 VERIFICATION

6.1.1. Verification is an administrative process to reach a regulatory decision, based on registration or other regulatory functions by a reference institution. The NRA does not undertake any further assessment activity on its own. Verification is applied where conformity with requirements of the reference institution is sufficient to meet the requirements of MCA.

6.1.2. The Agency shall verify that a product intended to be **imported** and distributed in The Gambia has been duly registered or granted marketing authorisation by a recognised NRA and based on that may permit the import and distribution.

6.1.3. In the case of **product registration**, the product should have been registered or granted marketing authorisation for more than 6 months, should be actually on the market of the reference authority, where applicable, and the product characteristics (use, dosage, precautions) for national registration should conform to that agreed in the authorisation by the recognised RA. In addition, there should be an assurance that the product is either identical or similar to that approved by the recognised NRA or the reference RA in terms of quality, safety and efficacy.

6.1.4. For **clinical trial** submissions, the application (protocol, IB, nonclinical reports, previous study reports and other relevant documents) should be identical to that submitted, evaluated and approved by the recognised NRA.

6.2 ABRIDGED/ABBREVIATED REVIEW

6.2.1. Abridged/abbreviated review is the assessment of suitability of use under local conditions and regulatory requirements, while relying partly or fully on prior assessment and inspection outcomes as well as Quality Control (QC) laboratory reports from the reference institution to inform the local decision

6.2.2. The abridged/abbreviated review may pertain to the full submission or parts thereof, depending on the suitability of use under local conditions and regulatory requirements.

6.2.3. The evaluation of a certain part of the application (e.g. relevant to use under local condition) such as product quality data in relation to climatic conditions and distribution infrastructure and a benefit-risk assessment in

relation to use in the local ethnic population, medical practice/culture and patterns of disease and nutrition may be necessary.

6.3 DOCUMENTATION

6.3.1. In addition to the full assessment report from the recognised NRA, the applicant shall be required to submit e.g. a full product development dossier or a full clinical trial application as required by the relevant MCA guidelines towards authorisation of the application, if applicable through the reliance pathway.

6.4 EVALUATION

6.4.1. Evaluation of the imported assessment report(s) shall be executed in accordance with laid down procedures to ensure appropriateness and completeness of the assessment findings and conclusions.

7 REFERENCES

- WHO. Good reliance practices in regulatory decision-making for medical products: high level principles and recommendations, Technical Report Series No. 1033, Annex 10. 2021
- WHO. Evaluating and Publicly Designating Regulatory Authorities as WHO listed Authorities, Policy Document. 21 June 2021
- Pan American Health Organization (PAHO). Regulatory Reliance Principles: Concept Note and Recommendations. 2018
- Food and Drugs Authority (FDA) Ghana. Reliance Policy. 2019
- African Vaccine Regulatory Forum (AVAREF). Guide for the Inspection of Clinical Trials. September 2019
- African Vaccine Regulatory Forum (AVAREF). Guideline for joint and assisted reviews of clinical trial applications. September 2019
- Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). standard Operating Procedure. Procedure for handling rapid alerts and recalls arising from quality defects. 01 July 2017 (accessed 01 November 2023)
- Gambia Medicines and Related Products Act, 2014
- Gambia Medicines and Related Products Regulations, 2020
- MCA Communications Policy, October 2023

8 DOCUMENT HISTORY

Version #	Implementation Date	Reasons for Change:
1	09 December 2020	New Document
2	24 December 2021	New template for policy used; editorial changes; definition of reliance added; reliance on adopting guidelines included; list

Version #	Implementation Date	Reasons for Change:
		of recognised institutions added.
3	15 November 2023	Editorial changes; inclusion of some WHO-definitions, inclusion of reliance in clinical trials and pharmacovigilance activities; update of references.

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APPENDIX I: LIST OF MCA RECOGNISED INSTITUTIONS

The following agencies/institutions/organisations are recognised by MCA:

- European Medicines Agency (EMA)
- the National Medicines Regulatory Authorities (NRA) of 27 Member States of the European Union (EU) and 3 EU associated states of the European Economic Area (EEA) (EU: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden; EEA: Iceland, Liechtenstein, Norway)
- Medicines and Healthcare Products Regulatory Agency (MHRA (UK))
- U.S. Food and Drug Administration (US-FDA)
- Pharmaceuticals and Medical Devices Agency (PMDA (Japan))
- Swissmedic (Switzerland)
- Health Canada
- Therapeutic Goods Administration (TGA (Australia))
- World Health Organization (WHO (Prequalification Programme))
- African Vaccine Regulatory Forum (AVAREF)
- Economic Community of West African States/West African Health Organization (ECOWAS/WAHO)
- Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S)
- NRAs with WHO global benchmarking maturity level of at least 3.