MEDICINES CONTROL AGENCY

THE GAMBIA

Reliance Policy

December 2021

TABLE OF CONTENTS

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 (NMRAs) 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. The World Health Organization (WHO) defines reliance as 'the act whereby the NMRA in one jurisdiction may take into account and give significant weight to assessments performed by another NMRA 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'.

1.1.3. 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.

1.1.4. The Agency's perception of reliance implies that the work done is shared by the recognised ("recognised" meaning stringent, mature, credible and/or capable) NMRA 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).

1.1.5. 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.

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 NMRA 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:

- **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 NMRAs 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 NMRAs.
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 NMRAs;
- 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 GMP INSPECTIONS

5.2.1. The Agency shall recognise pharmaceutical inspections by a recognised NMRA for facilities manufacturing medicines or related products located in the territory of the issuing authority. In addition, MCA may accept official GMP documents issued by a recognised NMRA for manufacturing facilities located outside the territory of the issuing authority.

5.2.2. 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").

5.2.3. The Agency shall accept an official GMP document issued by a recognised NMRA and rely on the factual findings in such document.

5.2.4. MCA may in specific circumstances opt not to accept an official GMP document issued by a recognised NMRA 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 NMRA of the reasons for not accepting the document and may request clarification from that authority.

5.2.5. In the course of importation of medicines and related products the Agency may request a recognised NMRA for a post-approval official GMP document.

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 NMRAs;
- 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 NMRA (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).

5.4 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 NMRAs 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.

5.5 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 NMRA 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 NMRA 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 NMRA 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 NMRA.

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 NMRA, 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: high level principles and recommendations, Draft for Comments, June 2020
- WHO, Policy Evaluating and Publicly Designating Regulatory Authorities as WHO listed Authorities, Draft for Comments**,** December 2019
- Pan American Health Organization (PAHO), Regulatory Reliance Principles: Concept Note and Recommendations, 2018
- Food and Drugs Authority (FDA) Ghana, Reliance Policy, 2019

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 of recognised institutions added.

Signature: ..... Date: .....
Executive Director

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 (NMRA) 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)
- NMRAs with WHO global benchmarking maturity level of at least 3