LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)

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RELIANCE POLICY

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Table of Contents

1 Abbreviations 2

2 Glossary 4

3 Introduction 6

3.1 Legal basis 6

3.2 Background 6

3.3 Objective 7

3.4 Scope 7

4 Principles of good reliance practices 7

4.1 Universality 8

4.2 Sovereignty of decision-making 8

4.3 Transparency 8

4.4 Respect of national and regional legal basis 8

4.5 Consistency 9

4.6 Competence 9

5 Applications of reliance 11

5.1 Emergency Preparedness 11

5.2 Registration and/or marketing authorisation 12

5.3 Inspections 13

5.4 Clinical Trial Authorisation 13

5.5 Pharmacovigilance 14

5.6 Laboratory services (quality control) 15

6 Adoption or use of existing guidelines and regulations 15

7 Reliance Procedure 15

7.1 Verification 15

7.2 Abridged or Abbreviated review process 16

7.3 Documentation 17

7.4 References 17

8 Annexes ..... **Error! Bookmark not defined.**

8.1 Annex 1: LMHRA procedure for application for marketing authorisation vs Reliance pathway ..... **Error! Bookmark not defined.**

8.2 Annex: LMHRA procedure for review of application for clinical trials authorisation.....**Error! Bookmark not defined.**

1.0 Abbreviations

CT	Clinical Trials
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GRP	Good Regulatory Practice
GVP	Good Pharmacovigilance Practice
ILAC	International Laboratory Accreditation Cooperation
IB	Investigator's Brochure
LMHRA	Liberia Medicines & Health Products Regulatory Authority
NRA	National Regulatory Authority
OECD	Organisation for Economic Co-operation and Development
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme
PSUR	Periodic safety update report
RMP	Risk Management Plan
UMC	Uppsala Monitoring Centre
WHO	World Health Organisation

2.0 Glossary

Abridged regulatory pathways	Regulatory procedures facilitated by reliance. Facilitation can be such that reliance is based solely or partially on application of reliance. This usually entails some work being done by the national regulatory authority (NRA) that is practising reliance and supplementing it with reliance.
Equivalence of regulatory systems	A similarity between regulatory systems established via objective means such as adherence to the same international standards e.g. WHO Global Benchmarking Tool.
EU-M4all	EU-Medicines4all
Full reliance	This means that the authority relies on the entire assessments/inspection and quality control reports performed by another regulatory authority.
International standards and guidelines	In the context of this document, the term refers to relevant WHO standards and guidelines and any other relevant internationally recognized standards (e.g. International Organization for Standardization or pharmacopoeia standards) and guidelines (e.g. International Council on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use [ICH] or guidelines of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme [PIC/S]).
Maturity level (ML)	The maturity of regulatory systems is divided into four levels, characterized as follows: · ML1: some elements of regulatory systems exist; · ML2: evolving national regulatory systems that partially perform essential regulatory functions; · ML3: stable, well-functioning and integrated regulatory systems; and · ML4: regulatory systems operating at advanced level of performance and continuous improvement.
Mutual recognition agreement	According to the Organisation for Economic Co-operation and Development (OECD), a mutual recognition agreement is a principle of international law whereby states party to mutual recognition agreements recognize and uphold legal decisions taken by competent authorities in another member state. Mutual recognition is a process, which allows conformity assessments (of

	qualifications, product…), carried out in one country to be recognized in another country.
Partial reliance	Means that the authority relies on certain documents/parts of the assessments performed by another regulatory authority, while for the other part(s) an independent, full assessment of the documentation submitted by the applicant is conducted assessment process.
Recognition	Acceptance of the regulatory decision of another regulatory authority or trusted institution. Recognition is 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. Recognition usually requires formal and binding legal provisions.
Reliance	The act of one regulatory authority considering and giving significant weight to actions performed by another regulatory authority or trusted institution, in reaching its own decision. The relying authority remains independent, responsible and accountable for the decisions taken, even when it exercises reliance.
WHO Listed Authority	A WHO Listed Authority (WLA) is a regulatory authority or a regional regulatory system (RRS) which has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking and performance evaluation process.
Work-sharing	A process by which NRAs of two or more jurisdictions conduct activities cooperatively to accomplish a specific regulatory task. Examples of 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.

3.0 Introduction

3.1 Legal basis

This reliance policy is applied by the LHMRA in accordance with Part IV Section 2 (1) m & n of the LMHRA Act say LMHRA reserves the right to promulgate regulations as necessary to meet its responsibilities under this Act, including regulations providing for administrative hearings necessary for effective enforcement of this Act; develop and disseminate guidelines, procedures, guidance and other materials necessary for effective implementation of the functions of the Authority; This reliance policy is also in accordance with all memoranda of understanding (MOU) signed between LMHRA and other regulatory authorities. Even in the absence of MOU, LMHRA retains the right to rely on any World Health Organization (WHO) listed authority as well as international organizations such as WHO, Uppsala Monitoring Centre (UMC), European Medicines Agency (EMA), The Pharmaceutical Inspection Co-operation Scheme (PIC/S) and other similar international organizations that are fit for purpose.

3.2 Background

In pursuance of its mission to achieve the highest possible standards of quality, safety and efficacy for medicines and health products in Liberia, the Liberia Medicines & Health Products Regulatory Authority (LMHRA) shall employs legal, effective, efficient and transparent regulatory systems using competent and highly motivated human resource backed by adequate technology, to safeguard public health in Liberia.

As a partner in efforts towards improving universal health services at a continental and global level, LMHRA is willing to share and exchange regulatory information with other recognised national regulatory authorities (NRAs) as well as regulatory organisations, as a universal principle. This interdependence of NRAs allows for the most efficient and effective use of available resources and expertise. This principle of reliance permits LMHRA to be influenced by the output of other NRAs whenever possible, while placing a greater focus at national level on value-added regulatory activities that LMHRA is responsible for. The principle of reliance can be applied, but not limited, to vigilance, market surveillance and control, quality control, licensing inspection, clinical trials oversight, and oversight of local and international manufacturing and distribution. The LHMRA may also rely on safety information from scientific bodies such as the Uppsala Monitoring Centre (UMC) and World Health Organisation (WHO).

In LMHRA, reliance facilitates timely access to safe, effective, quality-assured medical products and can support regulatory preparedness and response, particularly during public health emergencies. LHMRA shall activate the reliance pathway in case of public health emergency, to ensure continuity of its regulatory function but also to accelerate access to medical products needed in the context of the emergency e.g. accelerated authorization of pre-qualified vaccines during a pandemic.

3.3 Objective

To facilitate and accelerate regulatory processes and activities with the use of information from approved stringent and well-resourced NRAs while retaining the LMHRA's regulatory responsibilities and decision-making autonomy. The decision to practice reliance shall take into consideration the existing capacities and regulatory systems' needs of the LMHRA. Depending on the availability of an authority and access to their information, LMHRA can rely upon any national or international authority or organisation with confidence and weigh how reliance can complement LMHRAs capacities to drive efficiencies and the optimal use of resources.

The purpose of the reliance policy is to:

- specify regulatory procedures to complement the regulatory framework and the national legislation on reliance and recognition.
- enable collaboration with other authorities.
- enable work-sharing (for example, through regional networks); and
- enable reliance on decisions from other regulatory authorities and laboratories and international organizations (as WHO, PICs, EMA etc).

3.4 Scope

The scope of this Reliance policy shall be applicable to the regulatory oversight of medicinal products for human and veterinary use (including vaccines and medical devices) encompassing all regulatory functions spanning the full life cycle of a medicinal product in Liberia.

4.0 Principles of good reliance practices

A decision to practice reliance by the LMHRA is guided by its existing capacity, regulatory systems' needs and the availability of an authority on which it can rely on with confidence.

4.1 Universality

Reliance is applicable to any NRA, irrespective of its resource capacity or level of maturity. Different NRAs use reliance for different reasons. Some use it to increase or build in-house capacity when there is the requisite expertise but not enough to perform their regulatory work as efficiently as they would like. Others use reliance to gain expertise that they do not have locally. Reliance is relevant for all resource settings.

4.2 Sovereignty of decision-making

The decision to practice reliance and how best to do so rests with LMHRA. In this manner, reliance does not imply dependence or delegation of responsibility. In applying reliance, LMHRA maintains its independence, sovereignty and accountability in regulatory decision-making. LMHRA retains its right to make sovereign choices concerning if it wants to use reliance, on whom it is going to rely and how it will rely.

4.3 Transparency

NRAs should be transparent about the standards, processes and approaches they adopt in implementing reliance measures. The basis and rationale for relying on a specific entity should be disclosed and fully understood by all relevant parties. Transparency measures should be encouraged through the publishing and sharing of regulatory information to facilitate information exchange among NRAs. NRAs that seek to act as reference agencies are encouraged to issue public assessment reports in a common language to document their regulatory decisions. Relying NRAs should use such reports as the primary source of information for assessments.

4.4 Respect of national and regional legal basis

Reliance practices should be coherent with national and regional legal frameworks and policies on medical products, supported by clear mandates and regulations that ensure efficient implementation of reliance as part of government policy on good regulation. Use of reliance does not remove the need for a capable local regulatory authority; on the contrary, it should be used to maintain and build local capacity for regulatory decision-making.

4.5 Consistency

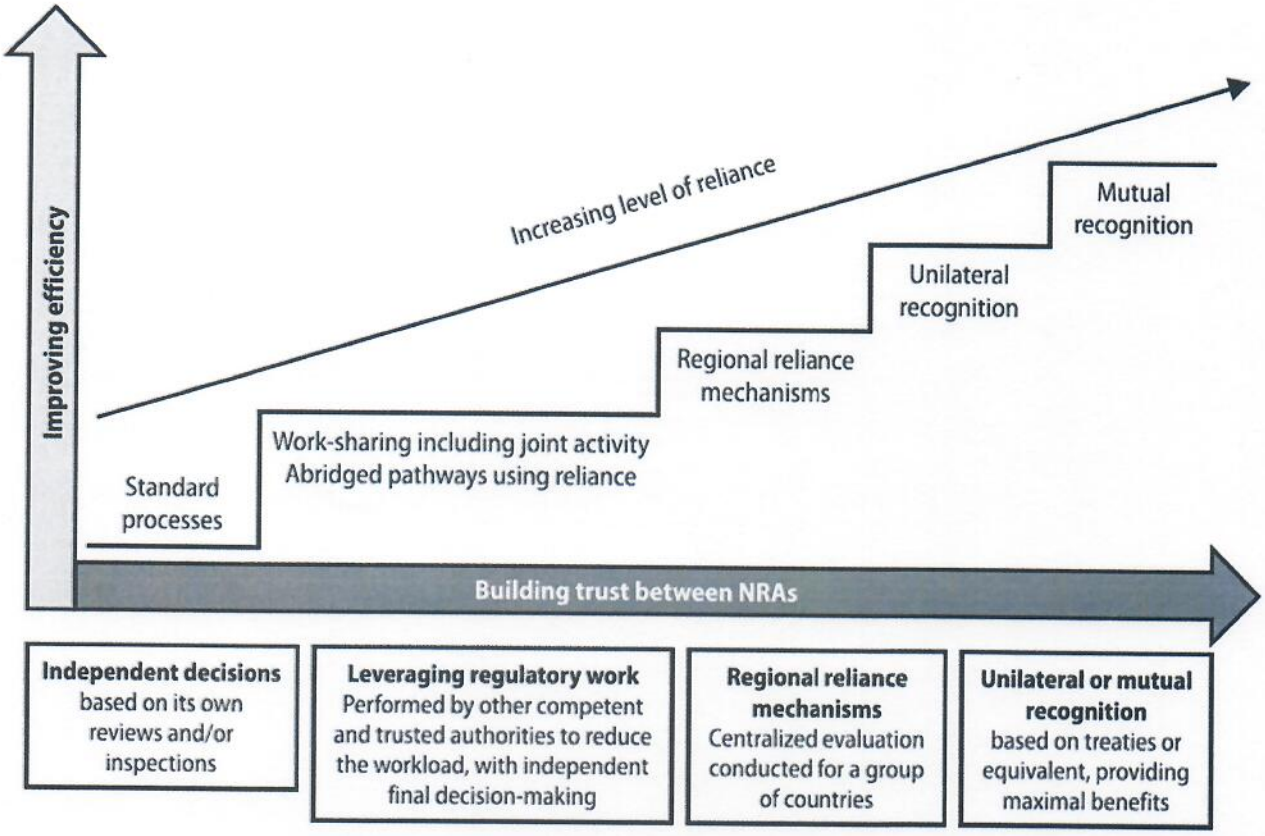
Reliance on an assessment or decision from another authority should be established for specific, well-defined categories of products and processes. The scope of regulatory activities in which reliance may be practised should be clearly defined, and the practise of reliance should be transparent and predictable. Thus, reliance should be expected to be applied consistently for products and processes in the same categories.

4.6 Competence

Implementation of reliance requires that NRAs have the necessary competence for critical decision-making.

Equally, the authorities being relied upon should have and maintain competence and operate within a robust, transparent regulatory system based on international standards and guidelines, as well as GRP, and a well-functioning quality management system. Competence may be benchmarked through transparent processes for developing trust and building confidence in the reference authorities.

According to the WHO Annex 10 Good reliance practices in the regulation of medical products: high level principles and considerations, the main pillars of reliance are: work-sharing, regional reliance, unilateral or mutual recognition (see below Pic 1).



Pic 1. Key concept of reliance (adopted from WHO Annex 10 Good reliance practice guideline).

3. Risk-based approach

LMHRA defines its own strategy for an appropriate risk-based approach to reliance, which includes factors such as the type and source of products evaluated, the level of resources and expertise available in the NRA, the public health needs and priorities of the country and opportunities for reliance. Four different reliance based regulatory pathways and levels of reliance could be envisaged, with increasing degrees of assessment by the relying NRA:

- verification of sameness of the medical product to ensure that it is the same as that assessed by the reference regulatory authority. Sameness should always be verified in any of the reliance approaches listed here.

- confirmation of the applicability of the assessment outcomes of another authority for regulatory decision making in the national context in terms of legal and regulatory settings, benefit–risk assessment, co-morbidities, unmet medical needs, risk management plans and any quality-

related specificities such as climatic zones for product stability, etc. In case of differences, such as in target population, epidemiology and other features of the disease, medicines used concomitantly and other factors that can substantially affect the benefit–risk profile of a medicine, as well as quality parameters, especially in relation to the stability under different climatic conditions, appropriate evidence should be provided by the manufacturer.

- abridged assessment of data on quality, safety and efficacy or performance, considering information in the assessment reports of the reference regulatory authority; and

- joint assessment or work-sharing between two or more regulatory authorities. This may take various forms, including a primary review by one authority followed by a joint assessment session to finalize the report and comments or distribution of the modules (e.g. quality, non-clinical and safety or efficacy) between the authorities.

Regardless of the approach, it is expected that the timelines will be shorter than the standard timelines and resources will be used more effectively when reliance is used. The reduction in timelines will depend on the level of reliance and any additional assessment required locally. Nevertheless, the accelerated timeline established for reliance procedures should be sufficient for the relying authority to properly review the assessment of the reference authority and perform the necessary local assessments, including of local labelling, product sameness and the applicability of the data to the country. The specific timelines for each regulatory function and respective procedures will be agreed and established based on the type (routine or non-routine) and the gravity of situation in case of the public health emergency. The instructions and operating procedures guiding the preparedness measures and managing public health threats by implementing the reliance mechanism, abridged procedures and expedited reviews are developed and could be adapted to the specific cases if necessary.

5.0 Applications of reliance

5.1 Emergency Preparedness

- LMHRA requires that all vaccines be approved for use in Liberia prior to marketing. However, marketing authorization of vaccines may not always be possible during emergency situations and thus LMHRA may need to authorize the use of vaccines via expedited or accelerated pathways. LMHRA may apply reliance by taking into consideration factors such as whether a vaccine has been approved by a recognised regulatory authority or recommended by other

trusted institutions (such as WHO), the phase of a pandemic (if applicable) and the risk to the population based on the potentially limited quality, safety and efficacy data available for a vaccine during an emergency situation.

- The sameness of the product being submitted to LMHRA for emergency use or in emergency situations and the product approved by the recognised regulatory authority will always be considered as part of the evaluation process. LMHRA will consider all relevant aspects of sameness including same qualitative and quantitative composition, same strength, same pharmaceutical form, same intended use, same manufacturing process, same suppliers of active pharmaceutical ingredient and same excipient quality before applying reliance.
- Additionally, the results of supporting studies (from a recognised authority) of vaccine quality, safety and efficacy, indications and conditions of use can also be relied upon. Depending on the level of reliance, the LMHRA may also require further data to confirm the applicability of the assessment outcome in its national context, or may perform an abridged assessment.

5.2 Registration and/or marketing authorisation

- LMHRA applies reliance to facilitate the registration of medicinal products. The Collaborative procedure between the WHO Prequalification Team and NRAs in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines and the Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities have been implemented for this reason.
- The LMHRA applies reliance in its decision making for registration of medicinal products for marketing in Liberia 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 NRA of WHO GBT maturity level 3 or higher and is actually on the market of the reference NRA, where applicable; or
- If the product was evaluated and listed as an output of the West Africa Medicines Regulatory Harmonization Project of the West African Health Organization (WAHO).

5.3 Inspections

- LMHRA recognises pharmaceutical inspections conducted by recognised NRAs for facilities manufacturing, distributing or supplying medicinal or related products located in the territory of the issuing authority. Furthermore, LMHRA may accept official documentation concerning inspections and their outcomes, issued by recognised NRAs for manufacturing companies located outside the territory of the issuing authority.
- This reliance applies to pharmaceutical inspections of manufacturing, distribution or supply facilities carried out during the pre and post marketing phases of products ("post-approval inspections") and before products are marketed ("pre-approval inspections"). LMHRA accepts official GMP, GVP, GLP and GCP certificates and other related documents issued by a recognised NRA and rely on the factual findings in such documents. LMHRA reserves the right however, in specific circumstances not to accept official inspection related documents issued by a recognised NRA. In cases of substantial inconsistencies or inadequacies in an inspection related document, LMHRA in such cases enters discourse with the relevant NRA and requests for clarification from that authority. LMHRA may apply reliance by using work-sharing in the form of taking part in joint inspections and leveraging on the regulatory expertise of other recognised NRAs.

5.4 Clinical Trial Authorisation

- LMHRA recognises clinical trial authorisations by recognised stringent NRAs. 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. LMHRA also relies on safety information from safety reporting in clinical trials that are conducted in countries with recognised 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-M4 all Procedure or the Swissmedic's Marketing Authorization for Global Health products or the International Generic Drug Regulatory Programme.
- If the investigational product has been authorised in a clinical trial or granted marketing authorisation by a recognised NMRA (e.g. WHO Listed Authority).
- The trial o r the investigational product has been evaluated and judged satisfactory in a joint review meeting facilitated by the West African Medicines Harmonization initiative of the Economic Community of West African States (ECOWAS) or World Health Organization under the African Vaccine Regulatory Forum (AVAREF).
- In order to facilitate product development, regulatory decision-making, and access to promising new medical products, LMHRA may consider the regulatory decisions taken by other regulatory authorities for the multi-country trials that are being implemented in Liberia because of post approval monitoring activities, or perform a joint assessment as a form of work-sharing.
- In case of emergency, the Agency applies reliance pathways as non-routine procedure for Clinical Trial Authorization.

Work-sharing for clinical trial assessment is a form of reliance that is happening at a regional level, for example in Africa, via the African Vaccine Regulatory Forum (AVAREF).

5.5 Pharmacovigilance

- LMHRA relies upon the WHO Global database of individual case safety reports (ICSR) - VigiBase - developed and maintained by the Uppsala Monitoring Center (UMC) for safety information used in assessment of signals and other safety issues.
- The unreacted assessment reports of PSURs, DSURs, RMPs, signals, public assessment reports, inspection reports, regulatory decisions such as product recalls and withdrawal of marketing authourisation and other pharmacovigilance related processes from other recognised NRAs may provide valuable insights and may inform the decision-making processes of LMHRA while also reducing the workload for the LMHRA.
- The LMHRA considers decisions concerning safety information from well-resourced and stringent NRAs on the safety of medicinal products. The reliance of LMHRA on safety information of a medicinal product of concern, will be applied if the medicinal product in question has been registered and/or granted marketing authorization by a recognised NRA

for a period not less than 6 months. However, LMHRA reserves the right to also apply reliance even if these conditions are not met.

5.6 Laboratory services (quality control)

On a case-by-case basis, the LMHRA's Quality Control Laboratory (QC Lab) shall rely on or recognize analytical reports from laboratories, which are WHO Pre-qualified or ISO/IEC 17025:2017 accredited and awarded by International Laboratory Accreditation Cooperation (ILAC) members.

6.0 Adoption or use of existing guidelines and regulations

LMHRA relies upon existing PV and CT guidelines and regulations developed by other recognized NRAs and international bodies for purposes of developing or updating LMHRA guidelines and regulations, according to their applicability and acceptability to the Liberian national regulatory context. Guidelines and or regulations from recognized NRAs may also be used by LMHRA to make regulatory assessments or decisions according to their applicability and acceptability to the Liberian national regulatory context.

7.0 Reliance Procedure

LMHRA has procedures in place for conducting regulatory activities such as assessing application for marketing authorisation or CT application (see flow charts in Annex 1 or 2), however, reliance on recognised NRAs may result in the normal procedures being adapted as necessary. The reliance procedure includes but is not limited to:

7.1 Verification

- LMHRA shall verify that a product intended to be imported and distributed in Liberia has been duly registered or granted marketing authorisation by a recognised NRA and based on that may permit the import and distribution of said product. Liberia may or may not undertake any further internal assessment of said product, relying completely or partially on recognised NRAs as necessary or possible.
- In the case of product registration, the product should be registered or granted marketing authorisation for no less than 6 months; should be on the market of a recognized authority, where applicable, and the product characteristics (use, dosage, precautions) for registration in

Liberia should conform to that agreed in the authorisation by the recognised NRA. In addition, there should be an assurance that the product is either identical or like that approved by the recognised NRA in terms of quality, safety and efficacy.

- For clinical trial submissions, LMHRA may approve application for CT if the application (protocol, IB, nonclinical reports, previous study reports and other relevant documents) are identical to that submitted, evaluated and approved by a recognised NRA, without undertaking any further internal assessment of the application.
- In the case of safety concerns such as signals or emerging safety issues arising from post marketing surveillance of registered products, LMHRA shall verify the quality and seriousness of the safety information received.

7.2 Abridged or Abbreviated review process

- LMHRA may apply an abridged or abbreviated review process in fulfilling any of its regulatory activities, by relying partially or fully on prior assessments and or inspection outcomes provided by a recognised NRA, to inform regulatory decisions. LMHRA may apply abridged or abbreviated processes after ascertaining the suitability of use within the context of Liberia and the national regulatory requirements, without following the full standard procedure of the said process. For example, in the case of application for marketing authorisation (see annex 1), LMHRA may omit the evaluation phase and or the product registration committee phase and decide based on the review of a recognised NRA.
- An abridged or abbreviated process may pertain to the full submission of an application package or parts thereof, depending on the suitability of use under local conditions and regulatory requirements. LMHRA may rely on information from other recognised NRAs as is appropriate on a case-by-case basis.
- The evaluation of a certain part of the application (e.g. use of product under local conditions); such as product quality data in relation to climatic conditions and distribution infrastructure; or a benefit-risk assessment in relation to use in the local ethnic population, medical practice/culture and patterns of disease and nutrition; may be deemed necessary by LMHRA. Reliance on information from other recognized NRAs may be applied as is appropriate on a case-by-case basis.

- The review of signals or emerging safety issues concerning marketed products may be abridged or abbreviated, depending on the suitability of use within the context of Liberia and the national regulatory requirements. LMHRA may use the evaluation and decisions made by recognised NRAs to make their own regulatory decisions, without employing standard internal review processes.

7.3 Documentation

- LMHRA, in addition to a full assessment report from a recognised NRA, may require an applicant to submit e.g. a full product development dossier or a full clinical trial application as required by the relevant LMHRA guidelines, through the reliance pathway.
- LMHRA may require submission of further documentation concerning safety issues e.g. periodic safety update report (PSUR) or risk management plans (RMP), as deemed appropriate on a case-by-case basis.

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The *Reliance Policy is Hereby Promulgated and Approved by the Managing Director on this 6th Day of May A. D. 2026.*



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