Memorandum of Understanding

Reliance on Regulatory Decisions

Memorandum of Understanding

This Memorandum of Understanding (MoU) is made this ..... day of 2025

BETWEEN the parties listed below:

1. **Tanzania Medicines & Medical Devices Authority, Tanzania (TMDA)**
2. **Food and Drugs Authority, Ghana (FDA)**
3. **The National Agency for Food and Drug Administration and Control, Nigeria (NAFDAC)**
4. **South African Health Products Regulatory Authority, South Africa (SAHPRA)**
5. **Medicines Control Authority of Zimbabwe (MCAZ)**
6. **Agence Sénégalaise de Réglementation Pharmaceutique (ARP)**
7. **Rwanda Food and Drugs Authority (Rwanda FDA)**

Each may be referred to as "the Party" and together as "The Parties".

CONSIDERING that the National Medicines Regulatory Agencies (NRAs) in Tanzania, Ghana, Nigeria, South Africa, Zimbabwe, Senegal and Rwanda have all attained WHO Maturity Level 3 (ML3) status and have a shared commitment to promoting the enhancement of regulated products quality, to ensure the health and safety of their citizens.

TAKING INTO ACCOUNT that Ghana, Nigeria, Tanzania, Zimbabwe, Senegal and Rwanda have each attained ML3 status related to medicines and vaccines (non-producing), while South Africa has attained ML3 status in vaccine (producing).

SEEKING to improve regional cooperation and maximize shared benefits in the field of pharmaceuticals, biological products, and medical devices, and vaccines.

AWARE of the positive contribution that reliance can have in encouraging greater regional harmonization of standards and regulations,

DESIRING to conclude an agreement providing for the reliance of regulatory decisions required for market access to the territory of the Parties,

AFFIRMING the importance of regulatory reliance in sustaining efficient regulatory systems and ensuring the safety, quality, efficacy, and performance of locally registered medical products;

AFTER all parties acknowledged their legal eligibility and capacity to enter into this MoU;

WHEREFORE THE PARTIES AGREED AS FOLLOWS:

Article 1

Background Information on the Parties

1. Tanzania Medicines & Medical Devices Authority (TMDA)

The Tanzania Medicines and Medical Devices Authority (TMDA) is responsible for regulating the safety, quality and effectiveness of medicines, medical devices and diagnostics. TMDA main responsibility is stated in the Health Policy, 2007 and its mandate is stipulated in the Tanzania Food, Drugs and Cosmetics Act (TFDCA) Cap. 219 as amended by the Finance Act of 2019. The Act provides for the efficient and comprehensive regulation and control of the safety and quality of medicines, medical devices and diagnostics in Tanzania. To improve public service delivery, TMDA is managed as an Executive Agency by the Executive Agencies Act, Cap. 245 as amended in 2009. TMDA achieved a stable and well-functioning system for medical products in April 2019, the first to be confirmed to reach WHO ML-3 in Africa.

2. Ghana Food and Drugs Authority (FDA)

The Ghana FDA, established in 1992, is the National Regulatory Body responsible for overseeing the regulation of food, drugs, food supplements, herbal and homoeopathic medicines, veterinary medicines, cosmetics, medical devices, household chemical substances, tobacco and tobacco products, blood and blood products, and the conduct of clinical trials protocols. The Public Health Act, 2012 (Act 851) provides the legal mandate for the establishment of the Ghana FDA. In April 2020, the Ghana FDA attained WHO maturity level 3 status after being assessed with the Global Benchmarking Tool, meeting all indicators that define a maturity level 3 (ML3) agency.

3. The National Agency for Food and Drug Administration and Control (NAFDAC)

The National Agency for Food and Drug Administration and Control (NAFDAC) was established by Decree No. 15 of 1993 as amended by Decree No. 19 of 1999 and now the National Agency for Food and Drug Administration and Control Act Cap N1 Laws of the Federation of Nigeria (LFN) 2004 to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, medical devices, packaged water, chemicals and detergents (collectively known as regulated products). The agency was officially established in October 1992. Its mission is to safeguard public health by ensuring that these products meet the necessary standards. In March 2022, NAFDAC joined the community of NRAs who have attained WHO ML3 status.

4. South African Health Products Regulatory Authority (SAHPRA)

The South African Health Products Regulatory Authority (SAHPRA) is an entity of the National Department of Health and is tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products. This includes clinical trials, complementary medicines, medical devices and in vitro diagnostics. Furthermore, SAHPRA has the added responsibility of overseeing radiation control in South Africa. SAHPRA's mandate is outlined in the Medicines and Related Substances Act (Act No 101 of 1965 as amended) as well as the Hazardous Substances Act (Act No 15 of 1973). In October 2022, WHO confirmed SAHPRA's attainment of ML3 for vaccine regulation. This means that SAHPRA has a stable, well-functioning and integrated regulatory system to ensure the quality, safety, and efficacy of vaccines that it registers. SAHPRA's ML3 status applies only to the regulatory function of vaccine regulation.

5. Medicines Control Authority of Zimbabwe (MCAZ)

The Medicines Control Authority of Zimbabwe (MCAZ) is responsible for regulating and controlling the quality of medicines and medical devices in Zimbabwe. It ensures that these products are safe, effective, and of high quality to protect public health. The Zimbabwe's regulatory system has attained Maturity Level 3 (ML 3) for the regulation of medicines and vaccines (non-producing). This achievement follows a comprehensive assessment and the successful implementation of critical recommendations by the WHO. Zimbabwe now joins the ranks of only six African nations to have reached this significant milestone. These are the United Republic of Tanzania in 2018, Ghana in 2020, the Federal Republic of Nigeria in 2022, the Republic of South Africa in 2022.

6. Agence Sénégalaise de Réglementation Pharmaceutique (ARP)

The Senegalese drug regulatory authority, known as the "*Agence Sénégalaise de Réglementation Pharmaceutique*" (ARP) is the regulatory authority that oversees medicine regulation in Senegal. The ARP is responsible for ensuring the safety, efficacy, and quality of medical products in Senegal. It performs the following regulatory functions: marketing authorization, inspection, licensing, import control, pharmacovigilance, market and quality control, and clinical trials. In December 2024, ARP was the seventh country in Africa to reach Maturity Level 3 (ML3) in WHO's global classification of national regulatory authorities, underscoring their commitment to ensuring safe, effective and high-quality medical products for their populations.

7. Rwanda Food and Drugs Authority (Rwanda FDA)

Rwanda Food and Drugs Authority (FDA) was established by the law N° 003/2018 of 09/02/2018 determining its mission, organization and functioning. The mandate of the Authority is to protect public health through the regulation of human and veterinary medicines, vaccines and other biological products, processed foods, poisons, medicated cosmetics, medical devices, household chemical substances, and tobacco and tobacco products. In December 2024, the Authority attained

WHO ML3 status for the regulation of medicines and vaccines (non-producing). This recognition affirms Rwanda's commitment to maintaining the highest standards in public health protection through robust regulatory oversight and demonstrates Rwanda FDA's capability to effectively regulate and monitor the safety, quality, and efficacy of medicines, vaccines, and medical devices in Rwanda. It assures the public and our partners that Rwanda's pharmaceutical regulatory framework meets international standards.

Article 2

Purpose of the Memorandum

The primary objective of this MoU is to establish a framework for reliance of regulatory decisions, aimed at expediting the regulatory processes among the seven (7) NRAs that are parties to this MoU. It outlines the terms and understanding between the Parties regarding the reliance of regulatory decisions for medicines and vaccines.

To this end, the MoU seeks to streamline the application submission and evaluation processes to ensure timely regulatory decision-making. This will be achieved through information sharing, work-sharing, and reliance (either partially or fully) on assessment reports generated by the Parties to this Agreement. These collaborative pathways are designed to facilitate prompt regulatory reviews and evaluations, accelerating the process without compromising the quality of work conducted on submitted documents. Additionally, the MoU ensures that authorized products or clinical trials meet established and internationally accepted regulatory requirements.

Under this MoU, the concept of reliance implies that work completed by one Party—such as assessment reports, Quality Control laboratory reports, GMP/GCP inspection reports, and similar documents—is shared with the other Parties. Each Party will then utilize this shared work according to its own scientific knowledge and regulatory procedures, considering factors such as differences in conditions of use and patient populations, while still retaining its own regulatory responsibilities.

The Parties acknowledge that reliance can be unilateral, bilateral, mutual, or multilateral. Each Party will leverage the information from shared reports and decisions to make informed regulatory decisions, while maintaining its regulatory responsibilities.

Article 3

Definitions

1. **Definitions:**
    - "Parties" refers to the regulatory authorities mentioned above.

- "Regulatory decisions" include approvals, rejections, and other determinations made about the assessment of medicines and vaccines.
- "Reliance" is the act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information, in reaching its own decision.
- "GMP/GCP" stands for Good Manufacturing Practice/Good Clinical Practice.
- "QC" stands for Quality Control.

Article 4

Roles and Responsibilities of the Parties

4.1 Document Sharing and Feedback:

a. Share relevant reports (e.g., assessment, GMP/GCP inspection, QC laboratory).
b. Ensure the quality and accuracy of shared documents.
c. Provide timely feedback on shared documents.

4.2 Reliance:

a. Recognize and integrate regulatory decisions and assessments from other Parties.
b. Facilitate and support reliance on each other's assessment reports and inspection findings.
c. Share regulatory decisions and assessments.
d. Allow reliance on marketing authorization status and GMP inspection reports for locally manufactured products, especially concerning medical products and vaccines.

4.3 Collaborative Participation:

a. Actively participate in joint assessments, work-sharing, and collaborative regulatory activities.
b. Engage in mutual capacity-building programs as needed, with agreed-upon fees.

4.4 Transparency and Communication:

a. Commit to transparent and timely communication between Parties.
b. Leverage shared regulatory expertise to enhance the local regulatory process.

4.5 Technical Expertise Sharing:

Collaborate by sharing technical expertise in product testing.

4.6 Governance:

Constitute a steering committee comprising the heads of the NRAs involved in providing strategic direction for implementation and expediting solutions to implementation bottlenecks. The Steering Committee will oversee an Operations Team responsible for technical implementation. This structure should be maintained for

approximately two years until fully operational, with feedback mechanisms to make necessary adjustments.

4.7 Monitoring and Evaluation:
Commit to regularly evaluating the MoU's effectiveness, including periodic reviews of collaborative activities and shared outcomes.

4.8 Continuous Improvement:
Encourage continuous improvement by sharing best practices, innovations, and lessons learned from the regulatory processes.

4.9 Resource Sharing:
Consider pooling resources, such as databases, tools, and personnel, to enhance the efficiency of joint regulatory activities.

4.10 Legal Compliance:
Ensure that all collaborative activities comply with the relevant legal and regulatory frameworks of each Party and update the MoU as necessary to reflect changes in legislation.

4.11 Sustainability and Commitment:
Demonstrate a long-term commitment to the collaboration, ensuring the partnership remains sustainable and beneficial for all Parties involved.

Article 5

Duration of the Agreement

This MoU is valid for three (3) years from the date of its signing, and it is automatically renewed for a similar period unless more than three of the Parties notify the others in writing of their desire to terminate it, at least six months before its expiry.

Article 6

Confidentiality of Information

Confidentiality of data and information shall apply to all information disclosed by one of the Parties to the other Party, whether it is communicated in writing, orally, electronically, or in any other form. All information exchanged under this MoU shall be considered confidential and shall not be disclosed to any third party without formal written consent from the disclosing party. Such information shall not be used for any other purposes except for the purpose of this MoU.

Article 7

Implementation and Follow-Up

The Steering Committee shall be responsible for the implementation of and follow-up on the articles of this MoU. It shall also consult periodically and at the request of any Party concerning the implementation of this MoU.

All forms of cooperation within the framework of this MoU shall be implemented in compliance with the domestic legislation and regulations of the respective parties.

Article 8

Amendments

Any Party may request in writing to amend this MoU. Any amendment accepted by the Parties should be in writing and shall be signed and shall form an integral part of this MoU. Such amendments shall enter into force on such date as determined by the Parties.

Any revision or modification should not prejudice the rights and obligations arising from this MoU before or up to the date of such revision or modification.

Article 9

Settlement of Disputes

Any disputes arising from the interpretation or implementation of this MoU shall be resolved amicably through consultations and negotiations among the Parties.

Article 10

Termination Conditions

This MoU may be terminated by any Party upon providing 90 days written notice to the other Parties. The termination of this MoU does not affect the implementation of any cooperative activity that had been agreed upon before expressing such desire and had not yet been completed at the time of its termination.

Signatures:

Each Party's authorized representative shall sign below to signify their acceptance and commitment to this Memorandum of Understanding.

Tanzania Medicines & Medical Devices Authority (TMDA):

DR. ADAM MITANGU FIMBO 5/3/2025

(Name, Signature, Date)

Witness (Name, Signature, Date)

Ghana Food and Drugs Authority (FDA):

DELESE MIMI DARKO 04/02/2025

(Name, Signature, Date)

Witness (Name, Signature, Date)

The National Agency for Food and Drug Administration and Control (NAFDAC):

MOJISOLA ADEYEYE 5/3/25

(Name, Signature, Date)

Witness (Name, Signature, Date)

Medicines Control Authority of Zimbabwe (MCAZ):

Richard T. Ryanoos 4/2/2025

(Name, Signature, Date)

Witness (Name, Signature, Date)

South African Health Products Regulatory Authority (SAHPRA):

Boitumelo Semete-Makokotlela 4/Feb/2025

(Signature, Name, Date)

Witness (Name, Signature, Date)

Agence Sénégalaise de Réglementation Pharmaceutique (ARP):

Dr Alioune Ionou Abou Talib DIOUF

Le Directeur Général

11/04/2025

(Signature, Name, Date)

Witness (Name, Signature, Date)

Rwanda Food and Drugs Authority (Rwanda FDA):

Emile BIENVENU 05/02/2025

(Signature, Name, Date)

Witness (Name, Signature, Date)