MCAZ Medicines Control Authority of Zimbabwe

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CIRCULAR 32 of 2025

Date: 23rd October 2025

To: ALL APPLICANTS, MANUFACTURERS AND PRINCIPALS

Re: **OPERATIONALISATION OF THE ML3 NATIONAL REGULATORY AUTHORITIES (NRAS) RELIANCE MECHANISM**

The Medicines Control Authority of Zimbabwe (MCAZ) is pleased to inform all stakeholders of a significant continental milestone in regulatory cooperation—the operationalisation of the ML3 NRAs Reliance Mechanism. This initiative was launched in collaboration with AUDA-NEPAD and eight other WHO Maturity Level 3 (ML3) National Regulatory Authorities (NRAs) across Africa.

Established through a Memorandum of Understanding (MoU) signed in early 2025, this mechanism provides a robust framework for regulatory reliance, information sharing, and work-sharing among participating NRAs. It aims to enhance regulatory efficiency, avoid duplication of assessments, and accelerate patient access to essential medicines by leveraging the technical expertise and decisions of trusted Authorities.

The formal launch took place during the inaugural Steering Committee Meeting held in Abuja, Nigeria, from 7th to 8th July 2025, where participating authorities established governance structures, elected leadership, and endorsed key operational documents.

Strategic Importance

The ML3 NRAs Reliance Mechanism is a cornerstone initiative that aligns with and strengthens key continental health goals, including the African Medicines Agency (AMA), the African Medicines Regulatory Harmonisation (AMRH) initiative, and the Pharmaceutical Manufacturing Plan for Africa (PMPA). Through this cooperation, the mechanism will:

- Accelerate access to safe, effective, and quality-assured medical products across African markets.
- Support local pharmaceutical manufacturing and strengthen intra-African trade.
- Improve regulatory responsiveness during public health emergencies.
- Enhance confidence in African regulatory systems through transparency and harmonised standards.

Participating National Regulatory Authorities

1. Agence Sénégalaise de Réglementation Pharmaceutique (ARP) – Senegal
2. Egyptian Drug Authority (EDA) – Egypt
3. Food and Drugs Authority (FDA) – Ghana
4. Medicines Control Authority of Zimbabwe (MCAZ) – Zimbabwe
5. National Agency for Food and Drug Administration and Control (NAFDAC) – Nigeria

6. Rwanda Food and Drugs Authority (Rwanda FDA) – Rwanda
7. South African Health Products Regulatory Authority (SAHPRA) – South Africa
8. Tanzania Medicines and Medical Devices Authority (TMDA) – Tanzania

Next Steps for Stakeholders

The participating NRAs are finalising the detailed operational procedures for the Reliance Mechanism. MCAZ will issue subsequent circulars with specific guidance on application processes and eligibility criteria under this new framework. **In the interim, the existing fast-track pathways for products approved by WHO-listed and ML3/4 authorities remain in effect**.

MCAZ's Commitment and Leadership

MCAZ is committed to promoting and implementing reliance frameworks with all WHO ML3/4 and Listed Authorities. As a recognised WHO ML3 regulatory authority and Chair of the Steering Committee for this new mechanism, MCAZ reaffirms its commitment to advancing regulatory excellence and collaboration. We continue to play a pivotal role in promoting access to safe, effective, and quality medicines for all Zimbabweans, while strengthening Africa's public health landscape.

For More Information

To access the MCAZ Reliance Policy, please use the following link: MCAZ Reliance Policy – MCAZ
Alternatively you can use the QR Code below.

Yours faithfully,

MEDICINES CONTROL AUTHORITY OF ZIMBABWE

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R. T. Rukwata (Mr.)
DIRECTOR GENERAL
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