



ZAMBIA MEDICINES REGULATORY AUTHORITY

PUBLIC NOTICE

COMMENCEMENT OF IMPLEMENTATION OF THE MEMORANDUM OF UNDERSTANDING (MoU) BETWEEN ZAMRA AND THE EGYPTIAN DRUG AUTHORITY (EDA)

The Zambia Medicines Regulatory Authority (ZAMRA) wishes to officially inform all Marketing Authorisation Holders, pharmaceutical manufacturers, importers, and other stakeholders that the implementation of the Memorandum of Understanding (MoU) between ZAMRA and the Egyptian Drug Authority (EDA) has now commenced.

This collaboration establishes a regulatory reliance mechanism to facilitate the timely availability of quality-assured, safe, and effective medicines on the Zambian market.

KEY FEATURES OF THE RELIANCE FRAMEWORK

ZAMRA will recognise marketing authorisations issued by EDA for medicines manufactured in Egypt and approved for the Egyptian market.

The review and approval process will follow the Recognition Framework for EDA-Approved Products developed jointly by ZAMRA and EDA.

Applications will be processed within 30 working days of submission, provided all requirements are met.

REQUIREMENTS FOR APPLICANTS

Applicants seeking marketing authorisation under this reliance pathway must submit the following:

- 1) Signed Cover Letter and completed ZAMRA application form
- 2) Quality Information Summary (QIS) endorsed and signed by EDA
- 3) CTD Dossier as approved by EDA
- 4) Labelling information in English (cartons, blisters, inserts, and patient leaflets)
- 5) A valid cGMP Certificate issued by EDA
- 6) Proof of payment of the prescribed ZAMRA application fees (as per the SI No. 38 of 2016)
- 7) Electronic submissions should be sent to: ma.reliance@zamra.co.zm (CC: foreign.affairs@edaegypt.gov.eg | export@edaegypt.gov.eg)

BENEFITS TO STAKEHOLDERS

- Reduced review timelines for eligible products
- Cost-effective and faster market entry for quality-assured medicines
- Strengthened regional regulatory collaboration in line with WHO Good Reliance Practices

EFFECTIVE DATE

The reliance pathway is effective immediately. All stakeholders are encouraged to submit eligible applications in line with these requirements.

For further information, contact the undersigned by email: pharmacy@zamra.co.zm | or phone number +260 211 432 350

issued by:

Makomani Siyanga (Mr.)

DIRECTOR-GENERAL

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Date: 22nd July 2025