



ZAMBIA MEDICINES REGULATORY AUTHORITY

PUBLIC NOTICE

CALL FOR SUBMISSION OF APPLICATIONS FOR GRANT OF MARKETING AUTHORISATION FOR MEDICINES AND ALLIED SUBSTANCES (HUMAN AND VETERINARY USE)

The Zambia Medicines Regulatory Authority (ZAMRA) wishes to inform **ALL** manufacturers, importers, distributors, and marketing authorisation holders (MAHs) of medicines and allied substances that Marketing Authorisation is a prerequisite to placement of medical products on the Zambian market.

In accordance with Section 39 of the Medicines and Allied Substances Act No. 3 of 2013, no medicine or allied substance shall be placed on the Zambian market unless it has been granted Marketing Authorisation. This requirement ensures that all medicines and allied substances made available to the public meet the requisite standards of **quality, safety, and efficacy**.

All applications must be submitted in the prescribed format and accompanied by the required documentation and fees as outlined in the ZAMRA Guidelines for Marketing Authorisation. Submissions should include complete dossiers in Common Technical Document (CTD) format. A separate application is required for each product application.

Only products that have been duly granted marketing authorisation may be imported, distributed, advertised, or sold on the Zambian market.

Applications shall be submitted electronically on the ZAMRA Integrated Regulatory Information Management System (IRIMS) accessible on the following link: <https://app.zamra.co.zm:42882/portal/#/public/app-home>.

ZAMRA remains committed to ensuring the availability of safe, effective, and quality-assured medicines and allied substances for the protection of public and animal health in Zambia.

NOTE: The Authority will prioritise the registration of medicines of high public interest for both human and animal use.

For further information, do not hesitate to contact the undersigned via email at pharmacy@zamra.co.zm or call +260 211 432350/ 432351.

Mr. Makomani Siyanga

DIRECTOR-GENERAL

Date: 13th October 2025