All correspondence should be addressed to the Director General

Notice No: ZAMRA/MA/AS/N/2026/01

In reply, please quote .....

ZAMBIA MEDICINES REGULATORY AUTHORITY

Date: 4TH MAY 2026

NOTICE

To: All Local Responsible Persons, Applicants and Marketing Authorisation Holders (MAHs)

SUBJECT: MANDATORY USE OF THE INTEGRATED REGULATORY INFORMATION MANAGEMENT SYSTEM (IRIMS) ONLINE PORTAL FOR ISSUANCE AND RESPONSE TO ADDITIONAL INFORMATION FOR ALLIED SUBSTANCES FOR HUMAN USE

The Zambia Medicines Regulatory Authority (the Authority) wishes to inform all stakeholders and applicants that, effective **1st June 2026**, the process for issuing and responding to additional information requests (**Queries**) following the assessment of applications for Grant of Marketing Authorisation (MA) for **Allied Substances** for human use will be through the **ZAMRA IRIMS Online Portal**.

Issuance of Queries via IRIMS Portal

Following the technical assessment of dossiers submitted for the grant of Marketing Authorisation of Allied Substances, the Authority will no longer issue manual query letters. All requests for additional information, will be generated and issued exclusively through the IRIMS online portal.

Applicants are advised to monitor their registered IRIMS user accounts regularly to ensure timely receipt of these notifications. Further, applicants are advised to look out for email notifications on their respective registered email for messages requiring actions.

Head Office
Plot No: 2350/M
Off Kenneth Kaunda International Airport Road.
P.O. Box 31890, Lusaka, ZAMBIA
Tel: +260 211 432 350 /432 351
E-mail: pharmacy@zamra.co.zm

Report Adverse Reactions to:
Pharmacovigilance Unit, Lusaka
Tel: +260 211 432 356
E-mail: npvu@zamra.co.zm
Website: www.zamra.co.zm

Mandatory Portal Submission of Query Responses

In our continued effort to enhance regulatory efficiency and ensure a robust audit trail, **all responses** to queries must be uploaded and submitted via the IRIMS portal within the stipulated timelines.

No physical (hard copy) responses or **email submissions** will be accepted for applications active on the portal after the effective date.

The system will track timelines for responses; **failure to submit additional information** within the prescribed regulatory period may lead to the **closure or rejection** of the application.

This transition is part of the Authority's commitment to digitising regulatory processes to:

- **Increase Transparency:** Allow applicants to track the real-time status of their queries and assessments.
- **Improve Efficiency:** Reduce the turnaround time for the evaluation and approval of applications for Allied Substances submitted.
- **Ensure Data Integrity:** Maintain a centralised and secure electronic record of all regulatory correspondence.

Support and Technical Assistance

Applicants who encounter challenges with the IRIMS interface are encouraged contact our ICT support team at **irims.support@zamra.co.zm**.

For technical regulatory inquiries, please contact the Marketing Authorisation Department – Allied Substances Unit at **allied@zamra.co.zm**.

ZAMRA remains committed to ensuring that all Allied Substances available on the Zambian market meet the set standards of quality, safety, and effectiveness.

For any clarifications, please do not hesitate to contact the Authority on the following:

Plot No. 2350/M,

Off KK International Airport Road

P. O Box 31890 Lusaka

Tel: +260 211 432 350, +260 211 432 351, +260 211 432 352

Email: **pharmacy@zamra.co.zm**

Makomani Siyanga (Mr)
DIRECTOR- GENERAL