



## ZAMBIA MEDICINES REGULATORY AUTHORITY

### **NOTICE TO ALL FOREIGN-BASED APPLICANTS AND HOLDERS OF MARKETING AUTHORISATION ON THE OBLIGATION TO APPOINT A LOCAL RESPONSIBLE PERSON**

This notice serves as a reminder to our esteemed **foreign-based** applicants and holders of marketing authorisation of their obligation to appoint a Local Responsible Person in accordance with the provisions of Regulation 17 of Statutory Instrument No. 79 of 2019.

It is a legal requirement that a foreign-based applicant or holder of marketing authorisation designates a person resident in Zambia to act as their Local Responsible Person who shall be responsible for the:

- a) submission of an application, document and product sample on behalf of a foreign-based applicant or holder of marketing authorisation;
- b) receipt of a decision of the Authority relating to an application on behalf of a foreign-based applicant or holder of marketing authorisation; and
- c) implementation of the pharmacovigilance plan on behalf of a foreign-based holder of marketing authorisation.

Failure to appoint a Local Responsible Person may result in regulatory action, including suspension or revocation of marketing authorisation or rejection of an application.

All foreign-based applicants for marketing authorisation are, therefore reminded to state the full name, designation and contact details of the Local Responsible Person in their application.

Furthermore, all foreign-based holders of marketing authorisation are required to submit to the Authority information of their Local Responsible Person, stating their full name, qualifications, contact details, and designated responsibilities by **31<sup>st</sup> December, 2025** through the emails: [pharmacy@zamra.co.zm](mailto:pharmacy@zamra.co.zm) and [addinfoma@zamra.co.zm](mailto:addinfoma@zamra.co.zm).

For further clarification, please do not hesitate to contact the undersigned.

**Director-General**

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**19<sup>th</sup> September, 2025**