ZAMBIA MEDICINES REGULATORY AUTHORITY

NOTICE TO ALL MARKETING AUTHORISATION HOLDERS (MAH), LOCAL RESPONSIBLE PERSONS (LRP),AUTHORISED LOCAL DISTRIBUTORS OF MEDICINES AND ALLIED SUBSTANCES AND REGISTERED PREMISES

The Zambia Medicines Regulatory Authority (ZAMRA) was established under the Medicines and Allied Substances Act (No.3) of 2013 to ensure that all medicines and allied substances being made available to the Zambian people meet the required standard of quality, safety and efficacy throughout the chain of manufacture, importation, exportation, distribution, storage and sale.

In 2022 the Authority, in the quest to further improve its efficiency in service delivery to its stakeholders and the general public, implemented an Integrated Registration Information Management System (IRIMS) online platform with regards to various regulatory processes which include among others the submission of applications for marketing authorisation of for Medicines and Allied substances.

As part of Data verification process, the Authority is hereby requesting all MAHs through their respective Local Responsible Persons and Authorised Distributors to provide information on respective registered Medicines and Allied Substances. Please note the information is only for all Products registered by December,2021. The information must comprise the following:

1. Details of the Applicant at first submission
2. Contact Details address (Email address, Telephone/Cellphone number, Physical Address, Country)
3. Product name
4. Application number
5. Marketing Authorization number

6. Date of MA approval
7. Composition (name(s) of active ingredient(s) and respective strength(s))
8. Dosage form
9. Route of Administration
10. Copy of Marketing Authorization document

Furthermore, Registered Premises (Retail and Hospital Pharmacies, Health Shops and Agro-Veterinary Shops and Wholesale establishments) are also required to submit the following information;

1. Details of the Applicant at first submission
2. Contact Details address (Email address, Telephone/Cellphone number, Physical Address, Province and District)
3. Licence Number
4. Date of Approval
5. Copy of Approval documents (Pharmaceutical Licence, Certificate of Registration, Health Shop Permits, Agro-veterinary Shop Permits)

The aforementioned information must be sent through to the Authority through the email verification.info@zamra.co.zm

The information is to be recieved not later than 30th August 2023.

Makomani Siyanga (Mr)
DIRECTOR – GENERAL