All correspondence should be addressed to the Director General

In reply, please quote LET_LSE_PMS_0008/09/24

ZAMBIA MEDICINES REGULATORY AUTHORITY

PUBLIC NOTICE

Date: 9th September, 2024

To: Distributors, Wholesalers, Retailers, Healthcare Professionals, General Public

MEDICAL PRODUCT ALERTS:

FOR IMMEDIATE RELEASE – The Zambia Medicines Regulatory Authority (ZAMRA) is a statutory body established under an Act of Parliament, the Medicines and Allied Substances Act No. 3 of 2013 of the Laws of Zambia. The main mandate of ZAMRA is to assure the quality, safety and efficacy of medicines and allied substances for human and animal health protection.

The Authority wishes to notify all healthcare professionals, health facilities, pharmaceutical outlets and members of the public as part of its post-market surveillance activities, it has initiated **RECALL** of three (3) medicines stated below.

Reasons for the recall are that the stated batches of Koflex-500 and Dioclox-250 Capsules contain lower amounts of Active Pharmaceutical Ingredient (API) than the declared quantity. The Amoject Injection is being recalled for failure to distribute evenly when shaken, contrary to the product specifications.

Product details:

SN	Product Name	Batch No.	Manufacturer	Expiry Date	Reason for Recall	Category
1	Koflex-500 (Cefalexin) Capsules BP	GLC22007	Kopran Limited, India	May-2025	Low content of API	Human
2	Dioclox-250 (Cloxacillin) Capsules	00718	Keko Pharmaceuticals Industries (1997) Limited, Tanzania	Sep-2024	Low content of API	Human
3	Amoject (Amoxicillin) Injection 15%	F220123	Hebei New Century Pharmaceuticals Co. Limited, China	01/2025	Failure to mix	Veterinary

RISK

All the three (3) medicines are antimicrobials used to treat infections in humans and animals, respectively. Using a medicine with low content of API may lead to incorrect

dosing and may affect the desired treatment outcome and contribute to emergence of antimicrobial resistance.

If you are in possession of these specific batches of these products, please return them to your healthcare provider who should replace it with another batch or brand. Pharmaceutical outlets and health facilities in possession of the affected products should quarantine the products and return them to their supplier(s), for collection and disposal by the respective importers.

Report incidents of Adverse Drug Reactions and Product Quality Problems to the National Pharmacovigilance Unit at Zambia Medicines Regulatory Authority by phone: +260 211 432 356/+260 956 521 094 or email address at: npvu@zamra.co.zm or pharmacy@zamra.co.zm.

Should you need further clarification, please do not hesitate to contact our Secretariat.

Makomani Siyanga (Mr)
DIRECTOR-GENERAL