LET_LSE/PMS/0012/08/23

All correspondence should be addressed to the Director General

In reply, please quote .....

ZAMBIA MEDICINES REGULATORY AUTHORITY

PUBLIC NOTICE

Date: 31st August 2023

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

PRODUCT RECALL:
AMOXICLAV-DENK 1000/125 POWDER FOR ORAL SUSPENSION DENK PHARMA GMBH & CO. KG, GERMANY

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 regulate and control the manufacture, importation, storage, distribution, supply, sale and use of medicines and allied substances for human and animal health protection.

ZAMRA wishes to alert healthcare professionals, the pharmaceutical industry and the general public that it is in receipt of a Rapid Alert Notification of a Quality Defect relating to AmoxiClav-Denk (Amoxicillin/Clavulanic acid) 1000/125mg Powder for Oral Suspension manufactured by Denk Pharma GmbH & Co. KG, Germany.

The notification states that Denk Pharma GmbH & Co. KG, Germany is recalling several batches of AmoxiClav-Denk (Amoxicillin/Clavulanic acid) 1000/125mg Powder for Oral Suspension due to out of specification results in ongoing stability studies and associated investigations. It has been noted that the product is exhibiting changes in appearance and deviation of the clavulanic acid content.

This product is registered in Zambia with marketing authorisation number 130/075 and the category of distribution is Prescription Only Medicine. Further, ZAMRA wishes to state that AmoxiClav-Denk (Amoxicillin/Clavulanic acid) 1000/125mg Powder for Oral Suspension **Batch No. 27298** and **Expiry Date 06/2025** was supplied on the Zambian market.

Therefore, ZAMRA has instructed local importers of this product to immediately recall the product from circulation. In the event that you are in possession of the above-mentioned product, please return it to your healthcare provider or supplier who should in turn notify ZAMRA.

If you suffer any adverse drug reaction/event having used this product, you are advised to seek immediate medical advice and report the incident to the National Pharmacovigilance Unit at Zambia Medicines Regulatory Authority by phone: +260

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P.O. Box 31890, Lusaka, ZAMBIA
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Report Adverse Reactions to:
Pharmacovigilance Unit, Lusaka
Tel: +260 211 432 356
E-mail:npvu@zamra.co.zm
Website: www.zamra.co.zm

211 432 356/+260 //956 521 094 or email address at: npvu@zamra.co.zm or pharmacy@zamra.co.zm.

Should the public need further clarification, please do not hesitate to contact the Secretariat.

Makomani Siyanga (Mr.)
DIRECTOR-GENERAL