Medicine Quality Alert: Class II Medicine Recall of Phenysod (Phenytoin Sodium) Injection Batch Number H24119

Zawadi Healthcare Ltd has initiated an urgent voluntary recall of Phenysod (Phenytoin Sodium) Injection Batch Number H24119 Manufactured by Hiral Laboratories Ltd.

From: Pharmacy and Poisons Board Published: 22nd October 2024

Recall Reference Number: REC/2024/028 Recall Classification: Class II Recall Level: Retail/Facility level Local Technical Representative (LTR): Zawadi Healthcare Ltd Manufacturer: Hiral Laboratories Ltd, India Product name: Phenysod Active Pharmaceutical Ingredient: Phenytoin Sodium Injection Affected counties: All

Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
H24119	04/2024	03/2026	5x5ml

Brief description of the problem

The product is being recalled due to a market complaint on formation of a precipitate when mixed with normal saline for infusion.

Action for healthcare professionals

Quarantine all remaining stock and stop further distribution, sale, issuing or use of the above batches immediately. Await contact from Zawadi Healthcare Ltd to arrange the return.

Action for patients and caregivers

No further action is required by patients as this is a Retail/hospital Pharmacy and Wholesaler/Distributor level recall.

Further Information

For inquiries about consignments of the impacted batch, please contact Zawadi Healthcare Ltd at: <u>bhatt@zawadihealthcare.com</u> or <u>sales@zawadihealthcare.com</u> or by Telephone at: +254 733 882 277, +254 788 655 843

You are advised to promptly report any case(s) of adverse events and suspected substandard and falsified products to the nearest healthcare facility or through the following channels:

- <u>https://pv.pharmacyboardkenya.org/users/mpublic</u>
- USSD code at *271#
- Email <u>pv@ppb.go.ke</u> or <u>pms@ppb.go.ke</u>
- Telephone No. 0795743049
- Mobile application: mPvERS both Android and iOS

For any further enquiries and feedback on the product recall, contact the post-marketing surveillance unit at the Pharmacy and Poisons Board via email at <u>pms@ppb.go.ke</u>