Medicine Quality Alert: Class II Medicine Recall of Tricohist Expectorant Batch No 0723040

The Pharmacy and Poisons Board has mandated Biodeal Laboratories Ltd, Kenya, to initiate an urgent recall of Tricohist Expectorant Batch No 0723040

From: Pharmacy and Poisons Board

Published: 22nd October 2024

Recall Reference Number: REC/2024/027

Recall Classification: Class II Recall Level: Retail/Facility Level

Manufacturer: Biodeal Laboratories Ltd, Kenya

Product name: Tricohist Expectorant

Active Pharmaceutical Ingredient: Diphenhydramine HCl B.P 5mg Promethazine HCl B.P 2.5mg Ephedrine HCl B.P 7.5mg Ammonium Chloride

B.P 90mg Sodium Citrate B.P 45mg per 5ml

Affected Counties: All

Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
0723040	07/2023	06/2026	60ml

Brief description of the problem

The Pharmacy and Poisons Board conducted quality control testing of Tricohist Expectorant, to check for compliance with registered specifications. The product failed to comply with the specifications of the test parameter on Assay for Diphenhydramine HCL and Promethazine HCl.

Action for healthcare professionals

Quarantine all remaining stock and stop further distribution, sale, issuing, or use of the above batches immediately. Await contact from Biodeal Laboratories 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-level recall.

Further Information

For inquiries about consignments of the impacted batch, please contact Biodeal Laboratories Ltd at: qa@biodealkenya.com or chriskibathi@biodealkenya.com or Tel: +254 720 333 829 or +254 734 333 829.

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:

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

For any further enquiries and feedback on the product recall, kindly contact the post-marketing surveillance unit of The Pharmacy and Poisons Board Kenya via email at pms@ppb.go.ke