Medicine Quality Alert: Class II Medicine Recall of Phenytoin 100mg Tablets Batch Number 0724016

Biodeal Laboratories Ltd has initiated a voluntary recall of Phenytoin 100mg tablets, Batch Number 0724016

From: Pharmacy and Poisons Board Date of Recall Initiation: 15th July 2025

Recall Reference Number: REC/2025/022

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

Manufacturer: Biodeal Laboratories Ltd, Kenya

Product name: Phenytoin 100mg tablets

Active Pharmaceutical Ingredient: Phenytoin 100mg tablets

Affected counties: All

Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
0724016	07/2024	06/2027	100's

Brief description of the problem

The product is being recalled due to failure to comply with the specifications on appearance, as the product changed color.

Action for healthcare professionals

Stop supplying Phenytoin 100mg tablet (Phenytoin 100mg) BN 0724016 immediately. Quarantine all remaining stock and await contact from Biodeal Laboratories Ltd, Kenya, to arrange the return.

Action for patients and carers

Patients currently prescribed should contact their prescribing healthcare professional. This is because you require a review with your prescribing healthcare professional to discuss alternative treatment options.

Further Information

For inquiries about consignments of the impacted batch, please contact Biodeal Laboratories Ltd, Kenya, at regulatoryaffairs@biodealkenya.com, regulatoryaffairs@biodealkenya.com, or telephone via +254 722 214178

Promptly report any cases 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
- 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, contact the post-marketing surveillance unit at the Pharmacy and Poisons Board via email at pms@ppb.go.ke