Medicine Quality Alert: Class II Medicine Recall of Oxytocin Injection BP 10 IU/ML, Batch No. MOEIE-003

The Pharmacy and Poisons Board has mandated Harleys Ltd to urgently recall Oxytocin Injection BP, Batch No. MOEIE-003

From: Pharmacy and Poisons Board
Date of Recall Initiation: 21st March 2025

Recall Reference Number: REC/2025/010
Recall Classification: Class II
Recall Level: Retail/Facility level
Manufacturer: Laborate Pharmaceuticals India Ltd
Local Technical Representative: Harleys Ltd
Product name: Oxytocin
Active Pharmaceutical Ingredient: Oxytocin Injection 10 IU/Ml
Affected counties: All

Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
MOEIE-003	08/2022	07/2025	10 × 1 ml Ampoule

Brief description of the problem
The Pharmacy and Poisons Board collected samples of Oxytocin Injection, Batch number MOEIE-003, during routine surveillance for quality control testing to check compliance with the registered specifications. The test results indicate that the product fails to comply with the specifications for related substances test.

Action for healthcare professionals
Quarantine all remaining stock and stop further distribution, sale, issuing, or use of the above batch immediately. Await contact from Sphinx Pharmaceuticals Ltd to arrange the return.

Action for patients and caregivers
No further action is required by patients as this product is usually administered by healthcare professionals in a hospital setting, and the recall is a Retail/Hospital Pharmacy and Wholesaler/Distributor level recall.

Further Information
For inquiries about consignments of the impacted batch, please contact Harleys Limited at: regulatory@harleysltd.com, info@harleysltd.com or Phone: +254 20 4261000, Mobile: +254 722 202030 | +254 773 106 788 | +254 737 203030.

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
- USSD code at *271#
- Mobile application: mPvERS both Android & iOS
- Email pv@ppb.go.ke or pms@ppb.go.ke
- Telephone No. 0795743049

For any further inquiries 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