Medicine Quality Alert: Class I Medicine Recall of Paragen (Paracetamol 1% w/v) Injection Batch Number K4290027

The Pharmacy and Poisons Board has mandated Pro Med Pharmaceuticals Limited to initiate an urgent recall of Paragen Injection Batch Number K4290027.

From: Pharmacy and Poisons Board Date of Recall Initiation: 24th April 2025

Recall Reference Number: REC/2025/015

Recall Classification: Class I **Recall Level**: Consumer-level

Manufacturer: KamlaAmrut Pharmaceutical LLP, India

Local Technical Representative (LTR): Pro Med Pharmaceuticals Limited

Product name: Paragen Injection

Active Pharmaceutical Ingredient: Paracetamol 1% W/V

Affected counties: All

Affected Batch

| Batch Number | Date of Manufacture | Date of expiry | Pack Size |
|--------------|---------------------|----------------|-----------|
| K4290027 | 03/2024 | 02/2026 | 100ml |

Brief description of the problem

The Pharmacy and Poisons Board has mandated Pro Med Pharmaceuticals Limited to initiate an urgent recall of Paragen Injection Batch Number K4290027 identified in the Kenyan market, which had exhibited a color change to black.

Action for healthcare professionals

Quarantine all remaining stock and stop further distribution, sale, issuing, or use of the above batches immediately. Await contact from Pro Med Pharmaceuticals Limited 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 enquiries about consignments of the impacted batch, please contact Pro Med Pharmaceuticals Limited at: info@promedpharma.co.ke or Telephone at +254 706 002 005.

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 <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 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