Medical Device Quality Alert: Class II Medical Device Recall of Sigmaflex Latex Examination Gloves (Powdered) Batch No. 20231012 Manufactured by A1 Globe Sdn. Bhd., Malaysia.

The Pharmacy and Poisons Board has mandated Bakpharm Ltd to initiate an urgent recall of Sigmaflex Latex Examination Gloves (Powdered) Batch No. 20231012 Manufactured By A1 Globe Sdn. Bhd., Malaysia.

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

Recall Reference Number: REC/2024/029
Recall Classification: Class II
Recall Level: Retail/Facility Level
Manufacturer: A1 Globe Sdn. Bhd., Malaysia
Local Technical Representative: Bakpharm Ltd
Product name: Sigmaflex Latex Examination Gloves
Active Pharmaceutical Ingredient: Latex Examination Gloves (Powdered)
Affected counties: All

Affected Batch

Batch Number	Date of Manufacture	Date of expiry	Pack Size
20231012	10/2023	09/2028	100s

Brief description of the problem
The Pharmacy and Poisons Board (the board) received a market complaint on Sigmaflex Latex Examination Gloves (Powdered) Batch No. 20231012 Manufactured by A1 Globe Sdn. Bhd., Malaysia. Subsequently, the Board performed an analysis (Water Tightness test) of the complaint samples, and an out-of-specification (OOS) result was obtained.

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

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

Further Information
For enquiries about consignments of the impacted batch, please contact Bakpharm Ltd at: preet@bakpharm.com Tel: +254 20 8042880/5/6/7, +254 722 777400

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 enquiries and feedback on the product recall, kindly contact the post-marketing surveillance unit of The Pharmacy and Poisons Board Kenya “the Board” via email at pms@ppb.go.ke and Recall Feedback Form