Medicines Quality Alert: Class II recall of Rocephin 1g IV by Roche Kenya Limited

Roche Kenya is conducting a voluntary recall of Rocephin 1g IV, batch B0752B04 due to the detection of pinholes in 10 mL Water for Injections (WFI).

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Recall Reference Number: REC/2022/07 Recall Classification: Class II Recall Level: Retail/Facility Level Manufacturer: F. Hoffmann-La Roche Ltd, Kaiseraugst Local Technical Representative: Roche Kenya Product name: Rocephin 1g IV Active Pharmaceutical Ingredient: Ceftriaxone Affected Batch

Batch number	Expiry date	Pack size
B0752B04	03/2024	1 vial with 1g active ingredient + 1 ampoule with 10 ml solvent

Brief description of the problem

One batch of Rocephin 1g IV had pinholes in 10mL Water for Injection (WFI).

Advice for healthcare professionals

You are advised to immediately quarantine and to stop supplying the impacted batch of the product. Roche Kenya will contact you to arrange for the return of the product.

Advice for patients

No action is required for patients as this product is administered in the healthcare facility setting.

Further Information

For stock enquiries please contact Roche Kenya Limited by email at: <u>joyce.mbithi@roche.com</u> or via telephone: +254 733 455 532

You are advised to promptly report any cases of adverse events and suspected substandard and falsified products to the nearest healthcare facility or through the following channels:

- <u>https://pv.pharmacyboardkenya.org/users/mpublic</u>
- USSD code at *271#
- 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 information please contact the Pharmacy and Poisons Board by email: pms@ppb.go.ke