Medicine quality alert: Class II Medicine Recall of Rapiclav 312.5 DT (Amoxicillin & Potassium Clavulanate)

The Pharmacy and Poisons Board has mandated Sai Pharmaceuticals Limited, Kenya, to initiate an urgent recall of Rapiclav 312.5 DT (Amoxicillin & Potassium Clavulanate) batches; JTQ012001, JTQ012002, JTQ012003, JTQ012004, JTQ012005, JTQ012006, JTQ012007, JTQ012008, JTQ012009, JTQ012010, JTQ012011, JTQ012012, JTQ012013, JTQ012014, JTQ012015, JTQ012016, JTQ012017, JTQ012018, JTQ012019, JTQ012020

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Recall Reference Number: REC/2023/14
Recall Classification: Class II
Recall Level: Retail/Facility level
Local Technical Representative: Sai Pharmaceuticals Limited, Kenya.
Manufacturer: Ipca Laboratories Ltd, India
Product name: Rapiclav 312.5 Dispersible Tablets
Active Pharmaceutical Ingredient: Amoxicillin & Potassium Clavulanate
Affected Counties: All

Affected Batches

	Batch Number	Date of Manufacture	Date of expiry	Pack Size
1.	JTQ012001	01/03/2024	29/02/2024	100's
2.	JTQ012002	01/03/2024	29/02/2024	100's
3.	JTQ012003	01/03/2024	29/02/2024	100's
4.	JTQ012004	01/03/2024	29/02/2024	100's
5.	JTQ012005	01/03/2024	29/02/2024	100's
6.	JTQ012006	01/03/2024	29/02/2024	100's
7.	JTQ012007	01/03/2024	29/02/2024	100's
8.	JTQ012008	01/03/2024	29/02/2024	100's
9.	JTQ012009	01/03/2024	29/02/2024	100's
10.	JTQ012010	01/03/2024	29/02/2024	100's
11.	JTQ012011	01/03/2024	29/02/2024	100's
12.	JTQ012012	01/03/2024	29/02/2024	100's
13.	JTQ012013	01/03/2024	29/02/2024	100's
14.	JTQ012014	01/03/2024	29/02/2024	100's
15.	JTQ012015	01/03/2024	29/02/2024	100's
16.	JTQ012016	01/03/2024	29/02/2024	100's
17.	JTQ012017	01/03/2024	29/02/2024	100's
18.	JTQ012018	01/03/2024	29/02/2024	100's
19.	JTQ012019	01/03/2024	29/02/2024	100's

20.	JTQ012020	01/03/2024	29/02/2024	100's

Brief description of the problem
The Pharmacy and Poisons Board (PPB) has received several market complaints on quality issues for Rapiclav 312.5 DT tablets (Amoxicillin & Potassium Clavulanate) manufactured by Ipca Laboratories Ltd, India. The reported complaints primarily pertain to a change in the color of the tablets. In response to these complaints, the PPB conducted a thorough investigation, which revealed that the product did not comply with the market authorization requirements. Consequently, the PPB has instituted a mandated recall of the above-listed twenty batches of Rapiclav 312.5 DT tablets from the Kenyan market.

Action for healthcare professionals
Stop supplying the above batches immediately. Quarantine all remaining stock and await contact from Sai Pharmaceutical Limited, Kenya, who will arrange for the collection of the product.

Action for patients and caregivers
Patients currently prescribed Rapiclav 312.5 DT (Amoxicillin & Potassium Clavulanate) batches; JTQ012001, JTQ012002, JTQ012003, JTQ012004, JTQ012005, JTQ012006, JTQ012007, JTQ012008, JTQ012009, JTQ012010, JTQ012011, JTQ012012, JTQ012013, JTQ012014, JTQ012015, JTQ012016, JTQ012017, JTQ012018, JTQ012019, JTQ012020 should be contacted by 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 batches, please contact Sai Pharmaceuticals Limited at: info@saipharm.com or sales@saipharm.com. or via telephone: tel:+254-20-4454301/2/3, tel:+254-733-741-911, tel:+254-721-243-322

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 pv@ppb.go.ke or pms@ppb.go.ke
- Telephone No. 0795743049
- Mobile application: mPvERS both Android and iOS

For any further information please contact the post-marketing surveillance unit at the Pharmacy and Poisons Board by email: pms@ppb.go.ke