

RAPID ALERT

CRACKDOWN ON ILLEGAL MANUFACTURING AND SEIZURE OF FALSIFIED DRUGS

Date: 29th December 2023

Target Audience:

- Regulatory Field Force.
- Pharmacists and Chemists at Distribution, Pharmacies, and Medical Stores
- Healthcare Professionals- Physicians, Pharmacists, and Nurses at hospitals and clinics etc.
- General Public

Problem Statement:

On December 12, 2023, the regulatory field force in Karachi raided and shut down an illegal drug manufacturing facility. They collected product samples and sent them to the Central Drugs Laboratory (CDL) in Karachi for testing. The Federal Government Analyst at the CDL confirmed that the products seized by FID-III Karachi from the illicit site were "spurious". The test results showed that these products lacked the stated active ingredients. There is a possibility that the fake manufacturers have infiltrated the supply chain with some of their falsified products.

The details of the falsified products are as under:-.

Product Name*	Composition (as per label)	Batch No	Mfg Date	Exp. Date	Manufacturer Name (as per label)	Illustrative Images
AL Coxime 400mg Capsule	Cefixime	110	04-23	03-25	M/s. Alpine Laboratories (Pvt) Ltd., Karachi	
Sinoxime 100mg/5ml Dry Suspension	Cefixime	101813	10-23	09-25	M/s. Alcons Laboratories Pvt Ltd., Karachi	
Flox-G 500mg Tablet	Levofloxacin	760	01-23	12-25		Elox- 50

DRAP, Islamabad

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gsms@dra.gov.pk

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Product Name	Composition (as per label)	Batch No	Mfg Date	Exp. Date	Manufacturer Name (as per label)	Illustrative Images
Flox-G 250mg Tablet	Levofloxacin	761	01-23	12-25	M/s. Alcons Laboratories Pvt Ltd., Karachi	Revelouering
Amcox 125mg/5ml Suspension	Amoxicillin	23217	04-23	03-25	M/s. Alcons Laboratories Pvt Ltd., Karac	Activities of the second secon
Snagxone 1g injection	Ceftriaxone	L23-4	06-23	06-25	M/s Leckman Laboratories Pvt Ltd., Karachi	المعنى Bonner SNAGXONE ini (Cettaxone Sodium) الا gm المعنى كون معند المركزين معند
Leckzolid 600mg Tablets	Linezolid	002	-	09-24	M/s Leckman Laboratories Karachi	LEON LA LEON L
Uniclav 156.25mg/5m I Suspension	Co-amoxiclav	126	09-23	08-25	M/s. Uni-Tiech Pharmaceutical Pvt Ltd., Karachi	156.25mg/dml UNICLAY (Go-amortrian) 90 ml Suspension in Powder to in ORANGE

*The packaging of these products displays fake Drug Manufacturing Licenses (DML) and Drug Registration Numbers (DRN). None of these products are registered and no manufacturers with these names and addresses are licensed by DRAP.

Risk Statement:

The use of falsified products will result in ineffective treatment. This may cause therapy failure which may lead to increased morbidity and also, mortality, in case of untreated infections. Moreover, the safety of these falsified products is also unknown.

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Action Initiated: -

The Regulatory Field Force has been directed to increase the surveillance activities at Health facilities (Hospitals) in addition to markets and confiscate/seize these falsified products without any delay. All Pharmacists and chemists working at distributions and Pharmacies should **immediately check** the stock and halt the distribution/supply of these falsified products. Information related to the supplier of these falsified products should be provided to the Regulatory field force (DRAP, Provincial Health Departments, and States) to ensure the removal of these falsified products.

Advice for Healthcare Professionals: -

DRAP requests increased vigilance at hospitals and within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by these falsified products.

Adverse reactions or quality problems experienced with the use of these products shall be reported to the National Pharmacovigilance Centre(NPC), DRAP using the <u>Adverse Event Reporting Form</u> or online through this <u>link</u>. Further information on reporting problems to DRAP is available on this <u>link</u>.

Advice for Consumers / General public: -

Consumers should not use these falsified products and should contact their physician or healthcare provider if they have experienced any problem related to taking or using any of these falsified products, and should report the incident to the Drug Regulatory Authority of Pakistan / National Pharmacovigilance Centre.

All therapeutic goods must be obtained from licensed pharmacies and other authorized/licensed retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professionals in case of any doubt.

