DRUG REGULATORY AUTHORITY OF PAKISTAN
Division of Quality Assurance and Laboratory Testing

RAPID ALERT

DRAP ALERT No: Nº I/S/10-25-85

CRACKDOWN AGAINST UNLICENSED / UNAUTHORIZED MANUFACTURERS

Date: 09th October , 2025

Target Audience:

- Regulatory Field Force of DRAP and Provincial Drug Control departments.
- Healthcare Professionals
- Consumers

Problem Statement:

Drug testing Laboratories from Provinces have informed the Drug Regulatory Authority of Pakistan that the samples of below mentioned products have been declared ***'Spurious'*** as its packaging falsely claims that it was manufactured by a licensed pharmaceutical company whereas it was not. The details of reports are as under:

S#	Product Name	Batch	Manufacturer	Remarks
1.	**Cipotic – D® Sterile Eye Drops** Each ml contains Ciprofloxacin (as HCl) ... 1 mg Dexamethasone ……. 1 mg	F1538	*Purported to be manufactured by* M/s Barrett Hodgson Pakistan (Pvt) Ltd. F/423 SITE Karachi.	Sample declared ***"Spurious"*** with regards to Section 3(zb)(i) & (ii) of the Drugs Act 1976 and *'substandard'* on the basis of pH & sterility test.
2.	**Tablet Danzen DS** Each enteric coated tablet contains: Serratiopeptidase ……..... 10 mg (20,000 serratiopeptidase units)	3945	*Purported to be manufactured by* M/s Helix Pharma (Pvt) Ltd. A/56 SITE Mangopir Karachi.	Sample declared ***"Spurious"*** with regards to Section 3(zb)(i) & (ii) of the Drugs Act 1976.
3.	**Tablet Tebisil 250 mg** Each tablet contains: Terbinafine (as HCl) …. 250 mg	517	*Purported to be manufactured by* M/s Saffron Pharmaceuticals (Pvt) Ltd. 19-Km Sheikhupura Road Faisalabad	Sample declared ***"Spurious"*** with regards to Section 3(zb)(i) & (ii) of the Drugs Act 1976.
4.	**Capsule Cefspan 400 mg** Each Capsule contains: Cefixime …….400 mg	F0580	*Purported to be manufactured by* M/s Barrett Hodgson Pakistan (Pvt) Ltd.F/423 SITE Karachi.	Sample declared ***"Spurious"*** with regards to Section 3(zb)(i) & (ii) of the Drugs Act 1976.

DRAP, Islamabad + 92 051 9255969 gsms@dra.gov.pk

5.	**Tablet Brexin 20 mg** Each tablet contains: Piroxicam B-Cyclodextrine eq. to Piroxicam …….. 20 mg	1206410	*Purported to be manufactured by* CHIESI FARMACEUTICI S.p.A.- 26/A, Via Palermo - PARMA-ITALY	Sample declared *"Spurious"* with regards to Section 3(zb)(i) & (ii) of the Drugs Act 1976.

Risk Statement:

The above mentioned purported drug products are confirmed as **falsified/spurious,** as its packaging falsely claims that it was manufactured by a licensed pharmaceutical company whereas it was not. Laboratory testing has revealed that the product contains **no active pharmaceutical ingredient**, resulting in **complete lack of therapeutic effect**. Such falsification poses a **serious risk to public health**, potentially leading to **treatment failure**, **disease progression**, and even **life-threatening outcomes**, particularly for patients relying on these medications for critical care. The public is strongly advised **not to use these purported drug products** and to report any suspicious or unverified medicines to DRAP immediately.

Action Initiated: -

The Regulatory Field Force of DRAP and Provincial Drug Control Departments has been directed to conduct surveillance activities throughout the supply chain to confiscate the falsified products.

Advice for Healthcare Professionals: -

DRAP requests healthcare professionals to have increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by above mentioned product. Any adverse events or quality problems experienced with the use of these products should be reported to National or Provincial pharmacovigilance centers using Adverse Event Reporting Form or online through this link. Further information on reporting problems to DRAP is available on this link.

Advice for Consumers:

Consumers should not use these products and should contact their physician or healthcare provider(s) if they have experienced any problem related to taking or using the above mentioned 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.

Drug Regulatory Authority of Pakistan

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