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

RAPID ALERT

DRAP ALERT No: Nº I/S/12-25-124

CRACKDOWN AGAINST UNLICENSED / UNAUTHORIZED MANUFACTURERS

Date: 30th December , 2025

Target Audience:

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

Problem Statement:

Central Drugs Laboratory, Karachi informed that the following purported products have been declared **"unregistered"** and reportedly manufactured by entities not licensed or authorized by DRAP. The relevant laboratory findings and product details are as under:

S#	Product Name	Batch No.	Manufacturer (unlicensed)	Remarks
1.	**Tablet Taskeen-e-Dard**	091	M/s LEO HEALTH CARE & RESEARCH LABORATORIES KARACHI.	The sample has been declared **"Unregistered / Falsified"** as it contains **Diclofenac Sodium**, an active pharmaceutical ingredient, while the manufacturing facility is not registered with DRAP.
2.	**Tablet Pain Nil**	01	M/S HAKEEM PURANA DAWAKHANA KARACHI	The sample has been declared **"Unregistered / Falsified"** as it contains **Diclofenac Sodium**, an active pharmaceutical ingredient, while the manufacturing facility is not registered with DRAP.

Risk Statement:

The above-mentioned purported products have been confirmed as falsified, as they are manufactured by entities that are neither licensed nor authorized by the Drug Regulatory Authority of Pakistan (DRAP). These products are being illegally manufactured and marketed without regulatory oversight, rendering their quality, safety, and efficacy highly doubtful. The circulation and use of such unregulated products pose a serious risk to public health, including treatment failure, disease progression, and potential life-threatening consequences.

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The public is strongly advised to avoid the use of these unregistered products and report any suspicious or unauthorized medicines to DRAP through its official reporting channels.

The presence of Diclofenac Sodium in unregistered and falsified tablet products manufactured by unlicensed facilities poses a **serious public health risk**, particularly to **low-income patients, elderly individuals, and persons with chronic pain conditions** who may use such products without medical supervision.

As Diclofenac is associated with **gastrointestinal bleeding, renal impairment, and cardiovascular risks**, the absence of regulatory oversight, quality control, and proper labeling significantly increases the likelihood of **overdose, adverse drug reactions, and treatment failure**, thereby endangering public safety.

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

محفوظ، موثر اور معیاری اشیائے علاج

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