DRUG REGULATORY AUTHORITY OF PAKISTAN
DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/01-26-129

DRUG PRODUCTS DECLARED SUBSTANDARD BY CENTRAL DRUG LABORATORY KARACHI.

Date: 14th January, 2026

Target Audience:

- National Regulatory Field Force of DRAP and Provincial Drug Control Departments.
- Healthcare Professionals (Physicians, Pharmacists & Nurses).
- General Public.

Alert Summary:

Central Drug Laboratory (CDL) Karachi informed that the samples of below mentioned drug products have been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**DIFAM Injection 3ml** Diclofenac Sodium (75mg/3ml) **(Reg. # 014651-EX)**	D260005, D260006	M/s Bosch Pharmaceuticals (Pvt) Ltd. (DML # 000707) Plot No. 209 Sector 23 Korangi Industrial Area Karachi.	The samples have been declared **"Sub-Standard"** on the basis of assay test.

Risk Statement:

Use of a sub-standard injectable diclofenac may lead to therapeutic failure or overdose-related toxicity, including inadequate pain and inflammation control, gastrointestinal bleeding, kidney injury, cardiovascular complications, and injection-site reactions. The groups most likely to be affected include patients receiving injections for acute pain, post-operative pain, arthritis, trauma, and emergency care, particularly elderly patients, individuals with kidney, heart or gastric disease, and hospitalized patients, where incorrect dosing may result in serious and potentially life-threatening outcomes.

Action initiated: -

The field force of DRAP and Provincial Drug Control departments have been directed to immediately conduct market surveys for detection of presence and removal of mentioned batches from the market.

Advice for Pharmacies/Medical stores: -

All pharmacists and chemist working at distributions and pharmacies should **immediately check** their stocks and stop supplying mentioned products. The remaining stocks should be quarantined and returned to the supplier/company. Regulatory field force of all federating units (DRAP and Provincial Health Departments) should also increase surveillance in the market to ensure the effective recall of defective products(s).

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Advice for Healthcare Professionals: -

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by batches of mentioned products. Adverse reactions or quality problems experienced with the use of above mentioned product are to be reported to the National Pharmacovigilance Centre (NPC), DRAP using Adverse Event Reporting Form or online through this link. Further information of reporting problems to DRAP is available on this link.

Advice for Consumers/general public: -

Consumers should stop using products bearing the affected batch number(s) and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product, and report the incident to Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.

Drug Regulatory Authority of Pakistan
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