MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/05-25-44

PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUG TESTING LABORATORIES.

Date: 29th May, 2025

Target Audience:

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

Alert Summary:

Directorate of Drug Control (DDC) Punjab has informed Drug Regulatory Authority of Pakistan that the samples of below mentioned products have been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Inflamac Injection** Each 3ml contains: Diclofenac sodium…..75mg Reg. No. 036110	25L-001	**M/s. Ipram International,** Plot No. 26, S.S-3, National Industrial Zone, Rawat, Islamabad.	**'Substandard'** on the basis of Visible particulates in injection.
2.	**ZOLREST INFUSION 300mL** Each 300ml vial contains: Linezolid …….600mg Reg. No. 055916	ZL250020	**M/s Bosch Pharmaceuticals (Pvt.) Ltd,** 209, Sector 23, Korangi Industrial Area, Karachi.	**'Substandard'** on the basis of Bacterial Endotoxin Test.
3.	**LAKSOL-NS INFUSION 100mL** Each 100ml contains: Sodium chloride…..0.9g Reg. No. 110827	3021489	**M/s Lakhani Pharma (Pvt) Ltd.,** Sheikh Zayed Road, Rahim Yar Khan, Pakistan.	**'Substandard'** on the basis of Bacterial Endotoxin Test.

4.	**QAD-FEN 90ml Syrup** Each 5ml suspension contains: Ibuprofen….100mg Reg. No. 121509	LS0003	**M/s Qadir Pharmaceuticals,** Fateh Garh Sahuwala Road, Sialkot.	**'Substandard'** with regards to presence of impurity (Ethylene glycol), above the permissible limit.
5.	**BYTEC Tablet** Each film coated tablet contains: Cetirizine dihydrochloride ..……10mg Reg. No. 036183	E089	**M/s. Batala Pharmaceuticals,** 23/B, Small Industrial Estate # 2, Gujranwala.	**'Substandard'** with regards to Impurities test.

Risk Statement:

The use of substandard products can result in therapy failure, increasing the risk of complications, particularly in vulnerable groups such as immunocompromised individuals, as well as pediatric and geriatric population.

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).

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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