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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/09-25-75

PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUG TESTING LABORATORIES

Date: 19th September, 2025

Target Audience:

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

Alert Summary:

Drug Testing Laboratory Faisalabad has informed the Drug Regulatory Authority of Pakistan that the samples of below mentioned drug product has been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	Wisdom powder for injection (Ceftriaxone 500mg)	WSM-027	Trigon Pharmaceuticals (Pvt.) Ltd., Thokar-Raiwind road, Lahore.	Substandard on the basis of failure of sterility test.

Risk Statement:

Use of the affected batches of Ceftriaxone Injection may pose a significant risk to patient safety. As this product is administered parenterally, compromised quality (such as sterility failure) can result in serious adverse health consequences. Potential risks include treatment failure, severe infection, sepsis, or life-threatening hypersensitivity reactions. Vulnerable populations, including neonates, children, and immunocompromised patients, are at particular risk of harm. Therefore, continued distribution or use of the defective product may lead to serious, sometimes fatal, health 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).

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.

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