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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº II/S/10-25-103

DRUG PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUG TESTING LABORATORIES

Date: 28th October, 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 from Province informed that the sample of below mentioned drug products have been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Injection Remedy** Mecobalamin: 500mcg/ml (Reg. # 040385)	R-2411 & R-2419	M/s Pak Risen Pharmaceuticals Plot No. 3, Block B, Phase I - II, Industrial Estate Hattar. (DML # 000573)	The sample is declared as **"Sub-Standard" on** the basis of Assay Test & **"Adulterated"** on the basis of identifying **Cyanocobalamin** (9.7 mcg/ml).
2.	**Injection Neocobal** Mecobalamin: 0.5 mg/ML (Reg. # 071447)	S-2825	M/s Pulse Pharmaceuticals (Pvt) Ltd. Mozay Badoke Raiwind Road (Sua Asil Road) Lahore. (DML # 000564)	The sample is declared as **"Sub-Standard" on** the basis of Assay Test & **"Adulterated"** on the basis of identifying **Cyanocobalamin** (0.106 mg/ml).

Risk Statement:

Administration of these defective injections may result in therapeutic failure, delayed neurological recovery, or persistence of deficiency symptoms**,** particularly among diabetic, anemic, elderly, and neuropathic patients who rely on Mecobalamin therapy for nerve regeneration and metabolic balance. In severe cases, the presence of unintended forms of Vitamin B12 (Cyanocobalamin) may lead to altered metabolic response or unexpected adverse effects in patients with impaired renal or hepatic function.

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.

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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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