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

MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/09-25-82

MEDICAL DEVICE DECLARED SUBSTANDARD BY CENTRAL DRUGS LABORATORY KARACHI.

Date: 30th September, 2025

Target Audience:

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

Alert Summary:

Central Drugs Laboratory (CDL) Karachi, has declared the sample of below mentioned Medical Device as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Orange Auto disable Syringes 5ml** (MDMR # 000078)	S5102402	M/s Silver Surgical Complex (Pvt) Ltd, C-40, S.I.T.E II, Super Highway Industrial Area Scheem 33, Karachi. (ELM # 0007)	Sample has been declared of '**substandard'** quality on the basis of results for Auto disable feature.

Risk Statement:

This defect poses a **high risk of reuse of syringes**, which may result in **cross-contamination and transmission of bloodborne infections such as HIV, hepatitis B, and hepatitis C**. Because the defect is not visually detectable before use, healthcare professionals and patients remain unaware of the risk. Given the widespread use of such syringes in **general healthcare settings, including immunization programs and vulnerable populations**, the risk is categorized as **HIGH**, and **immediate market withdrawal and user alert are necessary** to protect public health.

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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