RECALL ALERT

DRAP ALERT NO. Nº I/S/06-24-28

RECALL OF SUBSTANDARD DRUG PRODUCTS FROM MARKET

Date: 14th June, 2024.

Target Audience:

- National Regulatory Field Force.
- Healthcare Professionals (Physicians, Pharmacists & Nurses).
- Pharmacists and Chemists at Distribution, Institutional suppliers
- General Public.

Alert Summary:

The Directorate of Drugs Control (DDC) Punjab vide Alert No. 137/2024 and 135/2024 has informed that the following samples of drug products have been declared as Substandard by Drug Testing Laboratories (DTL). Details of test reports are as under:

S#	Product Name	Batch No.	Manufactured by	Test Results
01	Metroin 100ml infusion	MT23-014	M/s. Saturn Pharmaceuticals, Lahore.	Substandard
02	Tozen-D Ophthalmic Suspension	TW019	M/s. Epharm Laboratories, Karachi.	Substandard
03	Ann-Vil 50ml Injection	V-44423	M/s. Venus Pharma, Lahore.	Substandard
04	Arpes Powder for Injection	AR-099	M/s. MTI Medical, Lahore.	Substandard
05	Torax 60ml Syrup	24-24	M/s. Siza International, Lahore.	Unacceptable Ethylene Glycol level identified
06	Zonid 120ml syrup	Z396	M/s. Bloom Pharmaceuticals, Hattar.	
		Z244		
		Z243		
		Z413		
		Z398		
		Z414		
		Z397		

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Action Initiated: -

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 affected batches of mentioned products. Adverse reactions or quality problems experienced with the use of these products 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.\

Distributors and pharmacies are advised to be vigilant and report any suspected batch of the product(s) in the supply chain to the DRAP using the **online form**, or through phone at +92 51 910 73 17, or by Email at gsms@dra.gov.pk.

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
محفوظ، موئثر اور معیاری اشیائے علاج

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