RECALL ALERT

DRAP ALERT NO. N^{o} I/S/09-24-36

RECALL OF SUBSTANDARD DRUG PRODUCTS FORM MARKET

Date: 24th September, 2024.

Target Audience:

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

Alert Summary:

The Directorate of Drugs Control (DDC) Punjab has detected substandard batches of the following products based on their analysis from Drug Testing Laboratories (DTLs). The Government Analysts have declared the samples of these products as out of specification and are directed to be recalled from the market. The details of the affected products and their batches are as under:

S#	Product Name	Composition	Batch No.	Manufactured by	Test Results
01	**Painsa** 75mg/3ml **Injection** Reg. No. 077269	Diclofenac Sodium	PA415	M/s. Wimits Pharmaceuticals (Pvt.) Ltd., Lahore.	Substandard
02	**Metroin Infusion** 100ml Reg.No 071279	Metronidazole 500mg/100ml	MT24-058, MT24-060 MT24-061, MT24-062 MT24-063	M/s. Saturn Pharmaceuticals (Pvt.) Ltd., Lahore.	Substandard
VETERINARY USE DRUG PRODUCTS					
03	**Oxytocin Injection** Reg.No 019928	Oxytocin 10 I.U/ml	V6-143	M/s. ISIS Pharmaceutical & Chemical Works, Karachi.	Substandard
04	**Selmec Injection** 50ml **Reg.No.** 071087	Ivermectin 20mg/ml	SN-113	M/s. Selmore Pharmaceuticals (Pvt.) Ltd., Lahore.	Substandard
05	**Rasomycin-10 Injection** **Reg.No.** 003791	Oxytetracyclin 100mg/ml	VJ. 1340	M/s. Star Laboratories (Pvt.) Ltd., Lahore.	Adulterated
06	**Rasomycin LA 20% Injection** **Reg.No.** 003791	Oxytetracyclin 200mg/ml	VG. 1626		Adulterated
07	**Rasomycin-5 Injection** **Reg.No** 003791	Oxytetracyclin 50mg/ml	VK. 1467		Adulterated

Risk Statement:

The above mentioned list contains drugs for Human and Veterinary use. Impact of use of Substandard/Adulterated products may lead to sub-optimal therapeutic effect which may lead to therapy failure or other associated problems.

Action initiated: -

The manufacturing companies of these products have been directed to immediately recall the defected batches of products from market. All pharmacists and chemists working at distributions and pharmacies should immediately check their stocks and stop supplying these products. The remaining stocks should be quarantined and return to supplier / company. The regulatory field force of all federating units (DRAP, Provincial Drug Control departments and States) has been directed to increase market surveillance to ensure removal of the defected batches of products from the market.

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 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.

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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