MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/06-25-50

PRODUCTS DECLARED SUBSTANDARD BY PROVINCIAL DRUG TESTING LABORATORIES.

Date: 23rd June, 2025

Target Audience:

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

Alert Summary:

The Directorate of Drug Control (DDC) Punjab has informed the Drug Regulatory Authority of Pakistan that the samples of below mentioned products have been declared as '***Substandard***'.

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Medistil Injection** Sterile Water for Injection……5ml Reg. No. 064758	25L608	**M/s. Medisave Pharmaceuticals,** 578-579, Sundar Industrial Estate, Lahore.	**'Substandard'** on the basis of Bacterial Endotoxin Test.
2.	**Kanadex-N Cream** Each gram contains: Dexamethasone-21 phosphate as disodium salt…….1mg Neomycin as sulphate…3500 i.u. Reg. No. 012475	F7-27	**M/s ISIS Pharmaceuticals & Chemical Works,** 25/1-3, Sector 12-C, North Karachi Industrial Area, Karachi.	**'Substandard'** on the basis of Assay of Dexamethasone phosphate.
3.	**Bytec Tablet 10mg** Each Film coated tablet contains: Cetirzine dihydrochloride…..10mg Reg. No. 036183	E090	**M/s Batala Pharmaceuticals.,** 23/B Small Industrial Estate #2, Gujranwala.	**'Substandard'** with regards to impurities test.

4.	**Sterile Water for Injection 5ml** Sterile Water for Injection….5ml Reg. No. 071329	25WF01	**M/s Friends Pharma (Pvt) Ltd.,** 31-Km, Ferozpur Road, Lahore.	**'Substandard'** with regards to visible particulates in injection.
5.	**Cetfin 10mg Tablet** Each film coated tablet contains: Cetirizine dihydrochloride ……10mg Reg. No. 091843	CT67	**M/s. Effort Pharmaceuticals (Pvt.) Ltd,** 28-Km, Ferozpur Road, Lahore.	**'Substandard'** on the basis of Test for impurities (Organic impurities).
6.	**Kanabax Cream 15g** Each gram contains: Dexamethasone….1mg Neomycin Sulphate….3.5mg Reg. No. 070880	KNX-270	**M/s. Baxter Pharmaceuticals,** A-1/A, Phase 1, S.I.T.E., Super Highway, Karachi.	**'Misbranded'** with regards to Labeling as per Section 3(s)(iv), '**Adulterated**' with regards to Section 3(a)(iv) of Drugs Act, 1976, and '**Substandard'** on the basis of Assay of Neomycin and Dexamethasone Phosphate.
7.	**Surgitex Latex Surgical Gloves (powdered)** Surgitex Latex Surgical Gloves Size 7.0 Powdered Sterile Reg. No. MDIR-0001236	20241001	**Manufactured by:** Suzhou Colour-way New Material Co., Ltd, 20 Anmin Road, Huangdai Town, Xiangcheng District 215152, Suzhou, China. **Marketed by:** M/s Al-Hamd Enterprises FL-11/1/1, Block-6, Gulshan-e Iqbal, Karachi.	**'Substandard'** with regards to Sterility Test.

Risk Statement:

The use of substandard products can result in therapy failure, increasing the risk of complications, particularly in vulnerable groups such as immunocompromised individuals, as well as pediatric and geriatric population.

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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