MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/4-25-37

SUBSTANDARD PRODUCTS DECLARED BY DRUG TESTING LABORATORIES.

Date: 22nd April, 2025

Target Audience:

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

Alert Summary:

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

S#	Product Name	Batch No.	Manufacturers	Remarks
1.	**Omsana-AM Tablet** Each film coated tablet contains: Amlodipine (as besylate)….5mg Olmesartan Medoxomil….20mg Reg. No. 058557	155367	**M/s Hilton Pharma (Pvt) Ltd**, Plot No. 13-14, Sector-15, Korangi Industrial Area, Karachi.	**'Substandard'** on the basis of Test for Impurities (Organic impurities).
2.	**BYTEC Tablet** Each film coated tablet contains: Cetirizine dihydrochloride.…10mg Reg. No. 036183	E605	**M/s. Batala Pharmaceuticals,** 23/B, Small Industrial Estate # 2, Gujranwala.	**'Adulterated'** as defined under clause (iv) of sub-section (a) of section 3 of Drugs Act, 1976.
3.	**Myteka Sachet** Each sachet contains: Montelukast sodium eq. to Montelukast…..4mg Reg. No. 039695	155384	**M/s Hilton Pharma (Pvt) Ltd**, Plot No. 13-14, Sector-15, Korangi Industrial Area, Karachi.	**'Substandard'** on the basis of Assay Test & Test for Impurities (Organic impurities).

4.	**Isanex 1g Injection** Each vial contains: Ceftriaxone sodium eq. to ceftriaxone…1g Reg# 024657	IA-703	**M/s Humayun International Pharma (Pvt) Ltd.,** 20-Km, Satiana Road, Faisalabad.	**'Substandard'** on the basis of Sterility test & Bacterial Endotoxin Test.
5.	**Medi-Lox Tablet** Each film coated tablet contains: Ciprofloxacin as HCl….250mg Reg# 056133	425	**M/s Medicon Pharmaceutical Industries (Pvt) Ltd.,** B-1/11, Industrial Estate, Hyatabad, Peshawar.	**'Substandard'** on the basis of Dissolution 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
محفوظ، موثر اور معیاری اشیائے علاج

DRAP, Islamabad
+92 051 9255969
gsms@dra.gov.pk