RAPID ALERT

DRAP ALERT No: I/S/11-24-

CRACKDOWN AGAINST FALSIFIED PRODUCTS

Date: November, 2024.

Target Audience:

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

Alert Summary:

Directorate of Drugs Control (DDC) Punjab and Secretary PQCB Quetta have informed DRAP that samples of various products have been identified as spurious (falsified). Details of test reports are as under:

S#	Product Name	Batch No.	Manufacturer stated on label	Test Results
1	Injection Titan-1000 (CeIftriaxone as Ceftriaxone Sodium 1000 mg/vial) Reg# 021743	22044	Purported to be manufactured by Macter International Limited (as per label claim) F-216, S.I.T.E Karachi-	"Spurious" and “Substandard” with regards to Assay and Sterility test,
2	Film Coated Tablet Dyrone (Dydrogesterone 10mg) Reg# 198069	DR-121	Purported to be manufactured by Solvay (as per label claim), Plot # 32, Sector,2 Highway Petaro Road Jamshoro Sindh	Spurious
3	Film Coated Tablet Solverone 10 mg (Dydrogesterone10 mg) Reg# 068898	SVN-001	Purported to be manufactured by Solvay (Fictitious firm), Plot # 32, Sector,2 Highway Petaro Road Jamshoro Sindh	Spurious
4	Film Coated Tablet Dydowen (Dydrogesterone) 10mg Reg# 101507	736	Purported to be manufactured by Weather Folds Pharmaceuticals, Hattar, Pakistan. Manufactured For: Wenovo Pharmaceuticals Taxila	Spurious
5	Film CoatedTablet DYDRO-FEM Dydrogesterone 10 mg Reg# 555199	DFD10/008 DFD10/009	Purported to be manufactured by Torrent Pharmaceutical, (as per label claim) G-19, Hawkesbay Road SITE, Karachi.	Spurious

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6	Powder For Oral Suspension M.CEF 30 mL Cefixime as Trihydrate 100 mg/5mL Reg# 0432189	D00018	Purported to be manufactured by Dalton Laboratories PVT LTD. (as per label claim) Plot # G-149, Phase L-II Super Highway Road, S.I.T.E. LI Karachi	Spurious
7	Iodex Ointment Reg# 000394	HIAAC	Purported to be manufactured by GSK Pakistan Karachi	Counterfeit (Falsified)

Action initiated:

The field force under administrative control 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 and Healthcare Professionals:

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). 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

محفوظ، موئثر اور معیاری اشیائے علاج