MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/01-25-13

SUBSTANDARD FLAGYL INJECTION BATCH NO. AD482 MANUFACTURED BY M/S. SANOFI AVENTIS PAKISTAN LIMITED, KARACHI.

Date: 28th January, 2025

Target Audience:

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

Alert Summary:

Senior Drug Inspector ICT Islamabad has informed DRAP that samples below product has been reported substandard by Drug Testing Laboratory (DTL) Rawalpindi:

S#	Product Name	Batch No.	Manufactured by	Test Results
1	Flagyl Injection 100ml (Metronidazole 500mg)	AD482	M/s. Sanofi Aventis Pakistan Limited, Plot No. 23, Sector 22, Korangi industrial area, Karachi	Substandard w.r.t. Endotoxin test performed

Risk Statement:

Endotoxin containing intravenous products can lead to a range of consequences, including fever, chills, shock, organ failure, which can even prove fatal. Even small amounts of endotoxin in an injection can cause significant harm, particularly in vulnerable individuals like immunocompromised patients or those with pre-existing medical conditions.

Action initiated:

The regulatory field force of DRAP and Provincial Drug Control departments have been requested to immediately conduct market surveys for detection and removal of these products from the market.

Advice for Healthcare Professionals:

DRAP urges heightened vigilance in affected supply chains and requests reporting of adverse reactions or quality issues to the National Pharmacovigilance Centre (NPC), DRAP via the Adverse Event Reporting Form or online via this link. Further information of reporting problems to DRAP is available on this link.

Advice for Consumers / general public:

Consumers with the affected batches should report to the Drug Regulatory Authority of Pakistan (DRAP) and consult their healthcare provider if they experience any issues related to the drug.

Drug Regulatory Authority of Pakistan
محفوظ، موثر اور معیاری اشیائے علاج

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