MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº II/V/08-25-53

VOLUNTARY RECALL OF DRUG PRODUCTS.

Date: 05th August, 2025

Target Audience:

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

Alert Summary:

M/s GlaxoSmithKline Pakistan Ltd., F-268, S.I.T.E., Karachi (DML No. 000233) has informed the Drug Regulatory Authority of Pakistan (DRAP) that the following drug products are being voluntarily recalled due to **defective induction seals**.

S#	Product Name	Manufacturers	Batch No.
1.	Amoxil Forte Suspension 250 mg (Reg. # 006814)	M/s GlaxoSmithKline Pakistan Ltd. F-268 SITE Karachi **(DML # 000233)**	7W9V, 7W9W, 7W9X, 8L5H, 8R3M, 8L5J, 8R4J, 8R4G, 8R3N, 8R4M, 8R4N, 8T5A, 9S5D, 9S5B, 9U6F, 9X3E, 9U6E, 9X3G, 9X3F, AH9Y, AJ2A, AP2M, AP2N, AP2P, AP2T, AS5B, AS5K, AS5F, AT7M, AS5L, C25W, C25X, C37E, C37G, C99F, C58B, CB4N, CB4P, CB4R, CD6T, CD6W, CD6V, DL5L, DL5K, DL5M, EE9R, EE9N, DY5U, EE9T, EG2A, FA8M, FA8N, FB9C, FB9D, FB9E, FB9F, FE9X, FF2A
2.	Amoxil Suspension 125 mg (Reg. # 000508)	M/s GlaxoSmithKline Pakistan Ltd. F-268 SITE Karachi **(DML # 000233)**	8U3B, 8T5G, 8T5L, 8U3A, 8U3G, 8U3H, 8W9S, 8W9T, 925W, 925Y, 926B, 926A, 956M, 956R, 966V, 967C, 967F, 967E, 988F, 988H, 988G, 9B4P, 988K, 9B4M, 9B4S, 9D6K, 9B4T, 9D6M, 9D6P, 9D6T, 9G4N, 9G4P, 9L9N, 9L9M, 9P7R, 9P7S, 9R2V, 9R2U, 9S4Y, 9S5A, AW3A, AW3B, AW3H, AW3D, AY5T, AY5X, AY5V, AY6B, B44T, B44M, B44S, BB2Y, B44V, BB3A, BB3B, BF3B, BF2X, BB3C, BF3C, BF3A, BT9H, BT9G, BT9F, BT9J, BW8R, BW8M, BW8S, BW8T, BX8L, BX8N, BX8P, CG4V, CG4X, CG4W, CG4Y, CJ7B, CJ6W, CJ7C, CJ7D, CP5G, CP5H, CT5X, CT6A, CW3H, CW3G, CY3A, D64P, D64S, CY3K, EP7E, EN4U, EN4T, EP7J, EP7M, EP7P, ET8M, EW3F, F55S, F32W, F55V, F55U, F55T, F97P, F75G, F75J, F75K, F75N, FT2Y, FU7X, FU7Y, FT3A

Risk Statement:

These drug products are being voluntarily recalled by the manufacturer due to a quality defect related to the defective induction seal of bottles, which may potentially compromise product integrity. The undetected defect may pose risk under certain conditions of storage or use. This recall is being carried out as a precautionary measure in consultation with the Drug Regulatory Authority of Pakistan (DRAP) to safeguard public health.

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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