MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/05-25-43

RECALL OF XARELTO 15MG TABLET, BATCH NO. BXK4E11, DUE TO A LABELING ERROR ON SECONDARY PACKAGING

Date: 20th May, 2025

Target Audience:

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

Alert Summary:

The firm M/s Bayer Pakistan (Pvt.) Ltd., Karachi has requested for correction of a typographical error identified on the secondary packaging of **Xarelto 15 mg Tablets**, Batch Number BXK4E11. The error pertains to the incorrect indication of product strength on the outer label, which may lead to potential dosing errors. The details of the product are as under:

S#	Product Name	Composition	Batch No.	Marketing Authorization Holder
1.	**Xarelto 15mg Tablet** Reg No. 072549	Each film coated tablet contains: Rivaroxaban…15mg	BXK4E11	**M/s Bayer Pakistan Private Limited.,** Plot No. 23, Sector No.22, Korangi Industrial Area, Karachi.

Risk Statement:

Incorrect labeling can cause a patient to receive the wrong dosage of a medication. This may result in underdosing, where the medication is not effective, or overdosing, which can lead to harmful side effects or toxicity.

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 batch 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 product. 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 the batch of mentioned product. 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 product 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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