MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/11-24-46

RECALL OF SUBSTANDARD NEO-PYROLATE INJECTION IV BATCH NO. 105B24 MANUFACTURED BY M/S BROOKES PHARMA (PVT.) LTD, KARACHI.

Date: 28th October, 2024

Target Audience:

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

Alert Summary:

M/s. Brookes Pharma Private Limited, Karachi, has initiated a voluntary recall of voluntary recall of the following product through public notice. The details of the product are as below:

S#	Product Name	Composition	Batch details	Manufactured by
01	Neo-pyrolate Injection IV 1ml × 10's	Glycopyrrolate + Neostigmine Methylsulphate	Batch no. 105B24 Mfg. date: 02-2024 Exp. date: 02-2026	M/s. Brookes Pharma (Pvt.) Ltd, 58-59 sector 15, Korangi Industrial Area, Karachi.

Risk Statement:

The use of substandard injection may pose serious health risks to patients, including reduced efficacy or lack of therapeutic effect and increased risk of adverse drug reactions such as, allergic reactions, anaphylaxis and hypersensitivity reactions.

Action initiated: -

The field force under administrative control of DRAP and Provincial Drug Control departments have been directed to conduct market surveillance for detection of presence and removal of recalled 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 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