RAPID ALERT

DRAP ALERT No: I/S/04-25-38

PRESENCE OF FALSIFIED INJECTION RHOPHYLAC 300MCG, HUMAN ANTI-D IMMUNOGLOBULIN PURPORTEDLY MANUFACTURED BY M/S. CSL BEHRING AG, SWITZERLAND.

Date: 30th April, 2025

Target Audience:

- Regulatory Field Force of DRAP and Provincial Drug Control departments.
- Healthcare Professionals
- Pharmacies and medical stores

Problem Statement:

Directorate of Drugs Control Punjab (DDCP), vide Alert No. 169/2025, has notified DRAP regarding the presence of falsified Rhophylac 300mcg in the market across Pakistan. Details of the identified product are as under:

Product Details	Batch No.	Purported Manufacturer	Remarks
Injection Rhophylac 300, Human Anti-D Immunoglobulin	P100669751	**M/s CSL Behring Switzerland**, Wankdorfstrasse 10, CH-3000 Bern 22, Switzerland.	**'Spurious'** as per Drugs Act 1976, section 3(z-b) (ii) and **'Substandard'** on the basis of sterility test.

Risk Statement:

The Anti-D immunoglobulin is a commercial biological antibody derived from human plasma that targets red blood cells (RBCs) positive for the Rh (D) antigen (also referred to as the D antigen). It is used to treat immune thrombocytopenic purpura (ITP) in patients with Rh-positive blood. Falsified Injectable products may cause severe and lethal adverse effects as the safety and quality attributes of the products are unknown.

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Action Initiated: -

The Regulatory Field Force has been directed to increase surveillance throughout the supply chain to confiscate the falsified product. All Pharmacists, chemists, and other healthcare professionals working at distributions, pharmacies, healthcare facilities, and other aspects of the supply chain system should immediately check the stock, and information related to the supplier of such product should be provided to the Regulatory field force (DRAP, Provincial Health Departments and States) to ensure the removal of this product.

Advice for Healthcare Professionals: -

DRAP requests healthcare professionals to have increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by batches of above mentioned product. Any adverse events or quality problems experienced with the use of these products should be reported to National or Provincial pharmacovigilance centers using Adverse Event Reporting Form or online through this link. Further information on reporting problems to DRAP is available on this link.

Advice for Consumers:

Consumers should not use this product and should contact their physician or healthcare provider(s) if they have experienced any problem related to taking or using the product and should report the incident to the Drug Regulatory Authority of Pakistan / National Pharmacovigilance Centre.

All therapeutic goods must be obtained from licensed pharmacies and other authorized/licensed retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professionals in case of any doubt.

Drug Regulatory Authority of Pakistan
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