DRUG REGULATORY AUTHORITY OF PAKISTAN
Division of Quality Assurance and Laboratory Testing

RAPID ALERT

DRAP ALERT No: Nº I/S/03-26-10

SPURIOUS INJECTION RHOPHYLAC 300 µg (BATCH NO. P100707423)

Date: 11th March, 2026

Target Audience:

- Regulatory Field Force of DRAP and Provincial Drug Control departments.
- Healthcare Professionals
- Consumers

Problem Statement:

Drug Testing Laboratory (DTL), Punjab vide Test Report No. 01-105012931/DTL dated 06-02-2026 has declared the following sample as **Spurious** under Section 3(zb)(ii) of the Drugs Act, 1976. The product is purported to be manufactured by M/s CSL Behring AG, Switzerland and imported/distributed by M/s Hakimsons (Impex) (Pvt.) Ltd., Karachi; however, verification from the stated importer confirms that the recovered batch does not belong to them and was not legally imported.

The sample also failed Sterility Test (Membrane Filtration Method) and was additionally categorized as Substandard on sterility grounds and Misbranded with respect to labeling.

S#	Product Name	Batch No.	Manufacturer (as per label)	Test Result
1	**Injection Rhophylac 300 µg** (Human Anti-D (Rh) Immunoglobulin) Prefilled Syringe 2 ml (1500 IU / 300 µg)	P100707423	***Purported to be manufactured by:*** M/s CSL Behring AG, Switzerland Imported/Distributed by: M/s Hakimsons (Impex) (Pvt.) Ltd., Karachi	Declared **Spurious**, Misbranded & Substandard (Sterility Failure)

Risk Statement:

The product is a Human Anti-D (Rh) Immunoglobulin injection indicated for prevention of Rh isoimmunization in Rh-negative individuals. Laboratory testing revealed microbial growth in sterility testing, indicating contamination and rendering the product unsafe for parenteral administration. Additionally, the batch has been confirmed as falsified and not legally imported by the authorized distributor. Administration of this contaminated and spurious biological product may lead to serious bloodstream infections, therapeutic failure in prevention of Rh sensitization, and life-threatening complications. The public health risk is assessed as high, particularly for pregnant women and immunocompromised patients.

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Action Initiated: -

The Regulatory Field Force of DRAP and Provincial Drug Control Departments has been directed to conduct surveillance activities throughout the supply chain to confiscate the falsified products.

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 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 these products and should contact their physician or healthcare provider(s) if they have experienced any problem related to taking or using the above mentioned products 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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