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

RAPID ALERT

DRAP ALERT No: Nº I/S/11-26-60

SPURIOUS/FALSIFIED RHOPHYLAC 300 INJECITON

Date:, 18th November, 2026

Target Audience:

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

Problem Statement:

Marketing Authorization Holder (MAH) of Rhophylac 300 Injection i.e. M/S Hakimsons (Impex) (pvt.) Ltd., Karachi, has informed that the below-mentioned batches of Rhophylac 300 injection available in the market are not associated with their company and do not belong to their authorized product distribution channels and hence are Spurious as per Section 3(z)(b)(ii) of the Drugs Act, 1976. Following are the details:

Sr. No.	Name of product	Batch Number	Name of manufacturer	Remarks
1	Rhophylac 300 Injection Solution for Injection is pre-filled syringe	P100808587 P100933951 P100830101	***Purported to be manufactured by:*** M/S CSL Behring AG, Switzerland	The MAH has confirmed that the packs having the batch numbers as mentioned in the table, are Spurious/Falsified.

Risk Statement:

The use of above-mentioned Spurious/Falsified drug product i.e. Rhophylac 300 Injeciton may pose serious safety and quality concerns for Public Health as administration of a Spurious/Falsified drug product may fail to provide intended response in the body and could expose recipients to unknown safety risks.

Action Initiated: -

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

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