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

RAPID ALERT

DRAP ALERT No: Nº I/S/11-26-53

Spurious/Falsified Hexaxim Vaccine (Batch # X3H421VA)

Date:, 12th November, 2026

Target Audience:

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

Problem Statement:

M/s Hoechst Pakistan Limited Karachi has informed that the below-mentioned product in vial presentation is not registered nor imported into Pakistan for distribution. The product is registered as Pre-filled Syringe. The availability and use of the below-mentioned Spurious/Falsified presentation i.e. Vial may pose serious health consequences to the patients including therapeutic failure and serious unwanted effects.

Following are the details of the Spurious therapeutic product.

Sr. No.	Name of product	Batch Number	Name of manufacturer	Remarks
1	Hexaxim Vaccine Suspension for injection (vial presentation)	X3H421VA	***Purported to be manufactured by:*** M/s Sanofi.	Since M/s Hoechst Pakistan Limited, Karachi has disowned the product in vial presentation therefore, the use of the Spurious/Falsified drug product may pose serious health consequences to the patients.

Risk Statement:

The use of the above-mentioned Spurious/Falsified drug product may pose serious safety and quality concerns for public health including therapeutic failure, adverse health consequences, or exposure to unknown safety risks.

DRAP, Islamabad | + 92 051 9255969 | gsms@dra.gov.pk

Action Initiated:

The Regulatory Field Force of Provincial Drug Control Departments has been asked to conduct surveillance activities throughout the supply chain to confiscate the above-mentioned drug 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 the above-mentioned product 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
محفوظ، موثر اور معیاری اشیائے علاج

DRAP, Islamabad
+ 92 051 9255969
gsms@dra.gov.pk