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

RAPID ALERT

DRAP ALERT No: Nº I/S/11-26-64

Unregistered Advil Cold & Sinus Caplets and Epanutin Capsule

Date:, 26th November, 2026

Target Audience:

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

Problem Statement:

Central Drugs Laboratory (CDL), Karachi has declared the below-mentioned samples of drug products as "**Unregistered**".

Following are the details:

Sr. No.	Name of product	Batch Number	Name of manufacturer	Remarks
1	**Advil Cold & Sinus Caplets** **(**Ibuprofen and Pseudoephedrine)	9G2E	***Purported to be manufactured by:*** Wyeth Pharmaceuticals Company, USA	The drug product has been declared as Unregistered.
2	**Epanutin 100mg Capsule** **(**Phenytoin Sodium)	NL1256	***Purported to be manufactured by:*** Pfizer, Germany	The drug product has been declared as Unregistered.

Risk Statement:

The above-mentioned products are unregistered, for which the quality, safety, and efficacy have not been evaluated. As a result, there is no assurance that the product complies with established regulatory and quality standards for pharmaceutical products.

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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 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 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
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