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

RAPID ALERT

DRAP ALERT No: Nº I/S/12-25-127

CRACKDOWN AGAINST FALSIFIED / SPURIOUS/ UNREGISTERED DUPHALAC SYRUP 100 ML

Date: **30th December, 2025**

Target Audience:

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

Problem Statement:

The Drug Testing Laboratory (DTL), Punjab has informed the Drug Regulatory Authority of Pakistan that a sample of the below-mentioned drug product has been declared **spurious** upon analysis.

The contract manufacturer, **M/s Highnoon Laboratories Ltd., 17.5 Km Multan Road, Lahore (DML No. 000155)**, for the genuine registration/marketing authorization holder, **M/s Abbott Laboratories (Pakistan) Ltd., Karachi**, of **Duphalac Syrup**, has confirmed that the impugned batch was **not manufactured by them** and is therefore **spurious**.

The product is purported to be manufactured by **M/s Abbott Laboratories Co., Canada**, and has been declared **"Unregistered (Falsified)"**.

S#	Product Name	Batch No.	Manufacturer	Remarks
1.	**Syrup Duphalac 100ml** Each 100 ml contains: Lactulose ……. 66.7 g	251986	Purported to be manufactured by M/s Abbott Laboratories Co. Canada.	The sample has been declared **"Spurious"** as per Section 3(zb)(i) & (ii) of the Drugs Act 1976.

Risk Statement:

The circulation of a **spurious and unregistered Duphalac Syrup (Lactulose)** poses a **significant risk to public health**, particularly to **pediatric patients, elderly individuals, and patients with chronic constipation or hepatic disorders**, who are the primary users of this product. As the impugned batch was not manufactured by the authorized contract manufacturer and lacks regulatory oversight, there is a heightened risk of **incorrect composition, contamination, reduced or excessive strength, and therapeutic failure**, which may lead to **worsening of disease, electrolyte imbalance, dehydration, or other serious adverse health outcomes**.

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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

محفوظ، موثر اور معیاری اشیائے علاج

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