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

RAPID ALERT

DRAP ALERT No: Nº I/S/03-26-13

SPURIOUS TABLET D-GEST DYDROGESTERONE 10 mg) (BATCH NO. DGH007)

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. 01-10096006005/DTL dated 21-02-2026 has declared Tablet D-Gest (Dydrogesterone 10 mg), labeled as manufactured by M/s Pharma Health Pakistan (Pvt.) Ltd., 17-Km Ferozepur Road, Lahore, as **Spurious** under Section 3(zb)(ii) of the Drugs Act, 1976, as laboratory analysis revealed that Dydrogesterone was not identified by FTIR and assay testing showed 0.0 mg per tablet against the labeled claim of 10 mg (specification limit 90–110%), indicating complete absence of the declared active pharmaceutical ingredient.

S#	Product Name	Batch	Manufacturer	Test Result
1	**Tablet D-Gest** (Dydrogesterone 10 mg)	DGH007	M/s Pharma Health Pakistan (Pvt) Ltd. 17-Km Ferozepur Road Lahore **(DML # 000761)**	Declared Spurious (API absent)

Risk Statement:

Dydrogesterone is indicated for management of progesterone deficiency conditions including threatened miscarriage, menstrual disorders, and luteal phase support. Laboratory findings confirmed complete absence of the active ingredient, resulting in total therapeutic failure. Use of such product may lead to serious clinical consequences including pregnancy loss, hormonal imbalance, and failure of prescribed treatment. The public health risk is assessed as **high**, particularly in pregnant women and hormone-dependent patients.

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.

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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 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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