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

RAPID ALERT

DRAP ALERT No: Nº I/S/01-26-136

SPURIOUS (TABLET EFASTON 10mg) – Batch # 51062

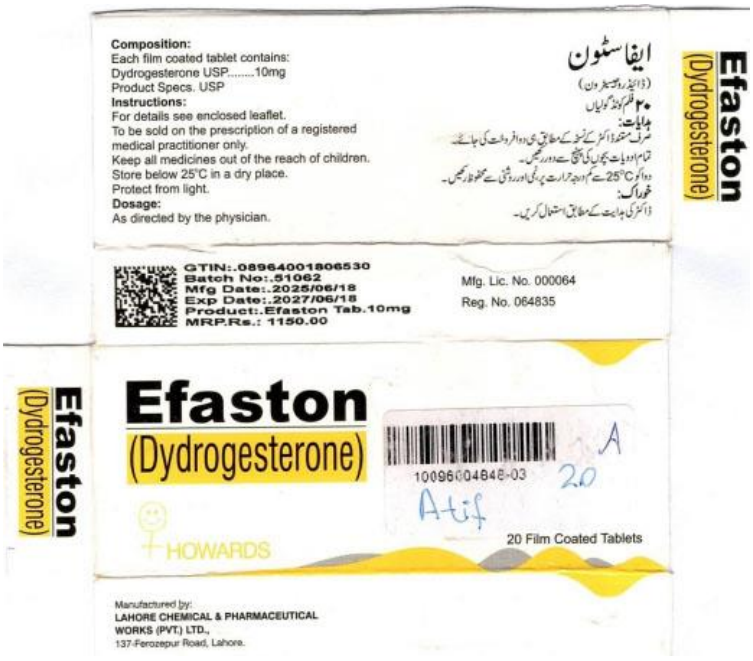
Date: 23rd January, 2026

Target Audience:

- Regulatory Field Force of DRAP and Provincial Drug Control departments.
- Healthcare Professionals (Gynecologists, Obstetricians, Pharmacists, Drug Distributors, Hospitals, Clinics,)
- Consumers (General Public)

Problem Statement:

The Drug Regulatory Authority of Pakistan has been informed through an official test/analysis report issued by the Drug Testing Laboratory, Government of the Punjab, that a sample of **Efaston® (Dydrogesterone) 10 mg film-coated tablets (Reg. # 064835)**, Batch No. **51062**, manufactured by **Lahore Chemical & Pharmaceutical Works (Pvt.) Ltd., Lahore (DML # 000064)**, has been declared **SPURIOUS** under Section 3(zb)(i) of the Drugs Act, 1976. Laboratory analysis confirmed that the declared active ingredient **Dydrogesterone was not identified**, and assay results showed **0.0 mg per tablet**, despite a labeled strength of 10 mg.



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Risk Statement:

Efaston® (Dydrogesterone) is commonly prescribed for gynecological and obstetric indications. Use of a spurious product containing **no active ingredient** may result in **therapeutic failure**, leading to serious clinical consequences, including unmanaged hormonal conditions, pregnancy-related complications, and risk to maternal health.

Action Initiated: -

- The product has been declared **SPURIOUS** under the Drugs Act, 1976.
- Provincial Drug Control Authorities and DRAP Field Forces have been directed to **initiate immediate enforcement action**, including market surveillance, seizure, and recall of the affected batch.
- Further regulatory action is being taken in accordance with applicable laws.

Advice for Healthcare Professionals: -

Healthcare professionals are advised to **immediately stop prescribing, dispensing, or using Efaston® (Dydrogesterone) 10 mg, Batch No. 51062**. All available stock should be verified to ensure procurement from authorized sources only, and any suspected presence of the affected batch in the supply chain must be promptly reported to DRAP or the concerned Provincial Drug Control Authorities. In addition, patients who may have received the said product should be appropriately identified, monitored, and managed clinically in accordance with standard medical practice.

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 are advised **not to use Efaston® (Dydrogesterone) 10 mg tablets of Batch No. 51062**. If this product is currently being used, patients should **immediately consult their healthcare provider** for appropriate medical advice and further management. Medicines should only be purchased from **licensed pharmacies**, and any suspected or doubtful products should be promptly reported to the concerned drug inspectors or to DRAP.

Drug Regulatory Authority of Pakistan

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