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

# RAPID ALERT

**DRAP ALERT No**: Nº I/S/10-25-91

## CRACKDOWN AGAINST FALSIFIED / SPURIOUS DRUG PRODUCT

**Date: 16th October , 2025**

**Target Audience:**

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

**Problem Statement:**

Drug testing Laboratory from Punjab informed the Drug Regulatory Authority of Pakistan that the sample of below mentioned product has been declared ***'Spurious'*** as its packaging falsely claims that it was manufactured by a licensed pharmaceutical company which has formally disowned the said product. The details of report are as under:

| S# | Product Name | Batch No. | Manufacturer | Remarks |
|---|---|---|---|---|
| 1. | **Tablet Myteka 10 mg**<br><br>Each film coated tablet contains:<br>Montelukast Sodium eq. to Montelukast …. 10 mg | 156428 | *Purported to be manufactured by:*<br><br>M/s HILTON PHARMA (PVT) LTD. PLOT NO. 13-14, SECTOR 15, KORANGI INDUSTRIAL AREA, KARACHI, | Sample is '**Spurious'** as described under Section 3(zb)(i) & (ii) of Drugs Act 1976. |

**Risk Statement:**

Use of *Myteka Tablet 10 mg* ***(Batch No. 156428)***, falsely labeled as manufactured by M/s Hilton Pharma (Pvt.) Ltd.**,** has been declared **spurious and substandard**, as testing revealed **no active ingredient** and the product is **falsified** under Section 3(zb)(i)&(ii) of the Drugs Act, 1976. Such falsified medicine poses a serious risk of treatment failure and adverse outcomes, particularly for asthmatic and allergic patients relying on genuine therapy. Consumers and healthcare professionals are advised to immediately stop using the said batch, verify authenticity, and report any suspected products to DRAP or the concerned Provincial Drug Control authority.

**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.

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

**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

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