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

RAPID ALERT

DRAP ALERT No: Nº I/S/10-25-92

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:

Novartis Pharma (Pakistan) Ltd., Karachi informed DRAP that falsified **Femara®** 2.5 mg Film Coated Tablet bearing **Batch # TELX5** has been identified in the Pakistani market. The reported batch number is not imported, manufactured, or supplied by **Novartis Pharma (Pakistan) Ltd.**, i.e. the genuine registration holder in Pakistan. The packaging falsely uses the Novartis name and branding, but it does not come from the authorized supply chain.

Risk Statement:

In the case of ***Femara® 2.5 mg Film Coated Tablet (Batch No. TELX5)***, such falsification may lead to **ineffective treatment of hormone-dependent breast cancer**, resulting in **disease progression or relapse**. This poses a serious risk to **female cancer patients, particularly post-menopausal women**, who depend on this medicine for long-term therapy. This alert applies **only to Batch No. TELX5** and does not affect other genuine batches of ***Femara®*** available in the market from the authorized registration holder.

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