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

RAPID ALERT

DRAP ALERT No: Nº I/S/10-25-83

CRACKDOWN AGAINST UNREGISTERED / FALSIFIED DRUG PRODUCTS

Date: 08th October , 2025

Target Audience:

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

Problem Statement:

Central Drugs Laboratory Karachi declared the following drug product as **unregistered / falsified.**

S#	Product Name	Batch No.	Purported Manufacturer	Remarks
1.	**Tablet Levitra 20mg** Each film coated tablet contains: Vardenafil (as HCl trihydrate) …… 20mg	BXNZ2488	Purported to be manufactured by M/s Bayer Pharma AG Germany	The sample has been declared **'Unregistered / falsified'** .

Risk Statement:

Since the product is not registered with DRAP, its quality, safety, and efficacy have not been evaluated or approved**.** The batch may contain incorrect or variable amounts of the active ingredient, unknown impurities, or be manufactured under non-compliant manufacturing conditions. Patients using this product may experience therapeutic failure, unpredictable adverse reactions, or serious health consequences due to lack of assured quality and authenticity. Misrepresentation of association with a well-known multinational company further increases the risk of false confidence, delayed appropriate treatment, and medication errors.

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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