RAPID ALERT

DRAP ALERT No: I/S/02-25-25

PRESENCE OF UNREGISTERED TRAMADOL FORMULATIONS IN THE MARKET

Date: 27th February, 2025

Target Audience:

- Regulatory Field Force of DRAP and Provincial Drug Control departments.
- Healthcare Professionals
- Pharmacies and medical stores

Problem Statement:

Federal Government Analyst, CDL, Karachi has notified the Drug Regulatory Authority of Pakistan that samples of the following products, seized by Customs, have been declared '***Unregistered***' (falsified). The labels of these samples claim '***Tramadol hydrochloride***' which has been confirmed by the test reports. Moreover, the labels do not provide any information regarding the manufacturer. The details of the reports are as below:

Sr#	Product name	Batch	Mfg. date	Expiry date	Test Results
1.	Tramaking 225 Tablets	TM-044	03-2023	03-2026	Un-Registered (Falsified)
2.	New Tramadol 225 Tablets	TRD2015	02-2022	02-2027	Un-Registered (Falsified)
3.	TramaKing 250 Capsule	TKC2001	03-2022	03-2027	Un-Registered (Falsified)
4.	New Royal 225mg Tablets	TM-037	04-2023	04-2026	Un-Registered (Falsified)
5.	Tamral-250 Tablets	243	NIL	03-2026	Un-Registered (Falsified)
6.	Tramaking Mega 225 Tablets	TRD2002	05-2022	05-2027	Un-Registered (Falsified)
7.	TramaKing 250 Tablets	TRK2001	03-2022	03-2027	Un-Registered (Falsified)

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Risk Statement:

Falsified products having no identification of manufacturer pose a great risk to the health of patient and can cause adverse drug reactions or may lead to therapy failure that can result in fatal consequences.

Action Initiated: -

The Regulatory Field Force has been directed to conduct surveillance activities to confiscate the abovementioned Un-Registered/falsified products. All Pharmacists, chemists, and other healthcare professionals working at distributions, pharmacies, healthcare facilities, and other aspects of the supply chain system should immediately check the stock, and information related to the suppliers of such products should be provided to the Regulatory field force (DRAP, Provincial Drug Control Departments) to ensure the removal of these product from the circulation.

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
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