RAPID ALERT

DRAP ALERT NO. Nº I/S/02-20-09

COUNTERFEIT AND UNREGISTERED PARACETOL 500MG TABLETS

(MANUFACTURED BY M/S. RORYAN PHARMACEUTICALS, PESHAWAR)

Date: 6th April, 2023

Target Audience:

- Pharmacists and Chemists at Distribution, Pharmacies and Medical Stores
- Healthcare Professionals- Physicians, Pharmacists, and Nurses at hospital and clinics etc.
- General Public

Problem Statement:

Drug inspector Diamer/Astore took the sample of Paracetol 500mg Tablets (Bach No. 470) and sent to Drug Water and Food Testing Laboratory, GB, for test/analysis purpose which has been declared as counterfeit product.

The product detail is as under: -

Product Name	**Manufactured by**	**Remarks by Laboratory**
Paracetol Tablets (Claimed to contain Paracetamol) **Batch No. 470** Mfg. Date: 11-22 Exp. date: 11-24	Ms. Roryan Pharmaceuticals (Pvt.) Ltd., Peshawar.	The sample is Counterfeit under the Drugs Act 1976 as it resembles with Panadol 500mg Tablets by M/s GSK. **The Product has also been declared Un-Registered By DRAP.*

***** Registration Board in its 312th meeting has cancelled the registration of Paracetol 500mg Tablets of M/s Roryan Pharmaceutical Industries Pvt. Limited Peshawar, bearing Registration No. 059421. Cancellation letter was issued on 09-12-2021 vide No. 3-5/2021-RRR (M-312).

Risk Statement:

Paracetamol is used for mild to moderate pain including headache, migraine, nerve pain, toothache, sore throat, period pains and general aches and pains. It is also used to help reduce fever. Unregistered/falsified product may lead to adverse reactions including but not limited to following:

DRAP, Islamabad **92 51 9107404** **gsms@dra.gov.pk**

- Blood disorders, such as thrombocytopenia and leukopenia.
- Liver and kidney damage.
- Sub therapeutic effect regarding fever, inflammation and pain control.

Action Initiated: -

The manufacturer has been directed to immediately recall the product from the market. The Regulatory Field Force has been directed to increase surveillance throughout the supply chain. 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 supplier of such products should be provided to the Regulatory field force (DRAP, Provincial Health Departments and States) to ensure the removal of this product.

Advice for Healthcare Professionals: -

DRAP requests increased vigilance at hospitals and within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by this product.

Adverse reactions or quality problems experienced with the use of this product shall be reported to the National Pharmacovigilance Centre(NPC), DRAP 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 / General public: -

Consumers should not use this product and shall contact their physician or healthcare provider if they have experienced any problem related to taking or using this drug product, 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 51 9107404 | gsms@dra.gov.pk