PRODUCT RECALL ALERT

DRAP ALERT NO. Nº I/S/20-23-23

RECALL OF CAPEX 500 mg TABLET (BATCH # B204006)

(MANUFACTURED BY M/s. ROTEX PHARMA ISLAMABAD)

Date: 16th February 2023

Target Audience:

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

Alert Summary:

A video is circulating on social media regarding presence of a fly/insect in a liquid injection ampoule visible with naked eye, apparently seems to be having **adulterated** quality. The matter is still under investigation, however as a precautionary measure, to prevent any public health hazard, the alleged drug is being recalled from market. Details of the product are given as under:

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Product Name	**Composition**	**Manufactured by**	**Remarks**
Capex 500 mg (Capecitabine) Tablet **Batch No. B204006**	Each tablet contains Capecitabine …. ….500mg	M/s. Rotex Pharma Islamabad	Adulterated drug due to presence of hair punched within the tablet.

Risk Statement:

Drug Product contains hair punched within tablet is of adulterated quality which may compromise the quality of drugs.

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Action Initiated: -

The manufacturer has been directed to **immediately recall** the defected batch of product from the market. All pharmacists and chemists working at distributions and pharmacies should **immediately check** their stocks and stop supplying this batch of product. The remaining stock should be quarantined and returned to the supplier/company. Regulatory field force of all federating units (DRAP and Provincial Health Departments) has also increase surveillance in the market to ensure the effective recall of defective products(s).

Advice for Healthcare Professionals: -

DRAP requests to enhance **vigilance** within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by this defected batch of product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the National Pharmacovigilance Centre(NPC), DRAP using Adverse Event Reporting Form or online through this link. Further information of reporting problems to DRAP is available on this link

Advice for Consumers / General public: -

Consumers should stop using this product bearing the affected batch number(s) and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product, and report the incident to National Pharmacovigilance Centre of Drug Regulatory Authority of Pakistan, through MedSafety Mobile Application, or online at Med Vigilance E Reporting System.

All therapeutic goods must be obtained from the licensed pharmacies, and other authorized retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professional in case of any doubt.

Drug Regulatory Authority of Pakistan
محفوظ، موثر اور معیاری اشیائے علاج

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