# PRODUCT RECALL ALERT

**DRAP ALERT NO.** N$^{o}$ I/S/08-23-32

## RECALL OF PLIVIL INJECTION (BATCH NO. 847)
### (MANUFACTURED BY M/S. PLIVA PAKISTAN, BALUCHISTAN)

**Date:** 6th Sep, 2023

## Target Audience:

- Healthcare Professionals particularly working in the critical care areas of hospitals including Physicians, Pharmacists, and Nurses.
- Procurement Officers at Hospitals and Healthcare Institutions,
- Pharmacists and Chemists at Distribution, Pharmacies and Medical Stores

## Alert Summary:

The Secretary, PQCB Baluchistan has informed DRAP that samples of Plivil Injection (Batch No. 847) manufactured by M/s. Pliva Pakistan (Pvt.) Ltd., B-77, Lasbella Industrial Estate, Baluchistan, has been analyzed by the Government Analyst, Drug Testing Laboratory (DTL), Baluchistan, Quetta and declared as **Adulterated and misbranded** based on analysis.

The detail of the product is as under:

| Product Name | Composition | Manufactured by | Remarks |
|---|---|---|---|
| Plivil 25mg/ml Injection<br>**Batch # 847**<br>Mfg. Date **02-2023**<br>Exp. Date **02-2025** | Pheniramine Maleate 25mg/ml | M/s. Pliva Pakistan (Pvt.) Ltd., B-77 Lasbella Industrial Estate, Baluchistan. | DTL Quetta declared the sample as adulterated and misbranded based on foreign particles in the solution and illegible information on some vials. |

## Risk Statement.

Presence of foreign particles may interact within the injectable solution and may change the chemical consistency of the solution. If injected, they can cause **inflammation, tissue damage, or allergic or immunogenic reactions**. Additionally, unclear labels on the drug products may create difficulty in reading and understanding of drugs, and may lead to medication errors such as taking the wrong medication or the wrong dose

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## Action Initiated: -

The manufacturer has been directed to immediately recall the defective 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. The regulatory field force of all federating units (DRAP and Provincial Health Departments) should 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 these defective lots of products.

Adverse reactions or quality problems experienced with the use of this product may be reported to the National Pharmacovigilance Centre(NPC), DRAP using the 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 the 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 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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