# DRUG REGULATORY AUTHORITY OF PAKISTAN
## DIVISION OF QUALITY ASSURANCE & LABORATORY TESTING

# MEDICAL PRODUCT ALERT

**DRAP ALERT NO.** Nº I/S/11-25-110

## DRUG PRODUCTS DECLARED SUBSTANDARD BY CENTRAL DRUGS LABORATORY KARACHI.

**Date:** 17th November, 2025

**Target Audience:**

- National Regulatory Field Force of DRAP and Provincial Drug Control Departments.
- Healthcare Professionals (Physicians, Pharmacists & Nurses).
- General Public.

**Alert Summary:**

Central Drugs Laboratory informed that the sample of below mentioned drug product has been declared as '***Substandard***'.

| S# | Product Name | Batch No. | Manufacturers | Remarks |
|---|---|---|---|---|
| 1. | **Dexamex Injection**<br>Each ampoule contains:<br>Dexamethasone sodium Phosphate eq. to Dexamethasone phosphate … 4 mg/ml<br>**(Reg # 015896)** | DX250017 | M/s Bosch Pharmaceuticals (Pvt) Ltd. 221 Bosch House Sector 23 Korangi industrial Area Karachi.<br>(DML # 000358) | The sample has been declared **Substandard** on the basis of the **Sterility test.** |

**Risk Statement:**

Use of a non-sterile injectable product may lead to severe infections, including localized abscesses, sepsis, systemic inflammatory reactions, or life-threatening complications, particularly in hospitalized patients**,** immunocompromised individuals**,** children**,** and the elderly**,** who are more vulnerable to invasive infections. Healthcare professionals, pharmacists, and distributors are strongly advised to immediately stop the use and distribution of the affected batch and take necessary actions for quarantine and recall of the available stock.

**Action initiated: -**

The field force of DRAP and Provincial Drug Control departments have been directed to immediately conduct market surveys for detection of presence and removal of mentioned batches from the market.

**Advice for Pharmacies/Medical stores: -**

All pharmacists and chemist working at distributions and pharmacies should **immediately check** their stocks and stop supplying mentioned products. The remaining stocks should be quarantined and returned to the supplier/company. 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).

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**Advice for Healthcare Professionals: -**

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by batches of mentioned products. Adverse reactions or quality problems experienced with the use of above mentioned product are to 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 products 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 Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.

Drug Regulatory Authority of Pakistan
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