# MEDICAL PRODUCT ALERT

**DRAP ALERT NO.** Nº I/S/1-25-11

## RECALL OF ADULTERATED SAFEMED INFUSION BATCH NO. SJU-0824 MANUFACTURED BY M/S AHAD INTERNATIONAL PHARMACEUTICALS LTD, DI KHAN.

**Date: 16th January, 2025**

### Target Audience:

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

### Alert Summary:

The Senior Drug Inspector, District Health Office, Quetta collected the samples of Infusion Safemed and sent them for test and analysis. The Provincial Drug Testing Laboratory, Quetta, has declared following batch of Infusion Safemed, manufactured by M/s. Ahad International Pharmaceuticals Ltd., Sheikhupura, as **Adulterated.** The injection was found to contain foreign matter, which is visible to the naked eye.

| S# | Product Name | Composition | Batch details | Manufactured by |
|---|---|---|---|---|
| 01 | Safemed 500mg Infusion<br><br>Reg. No. 045824 | Metronidazole | Batch No. SJU-0824 | M/s. Ahad International Pharmaceuticals Ltd. 13-Km, Gomal University, Multan Road Dera Ismail Khan. |

### Risk Statement:

An injectable product that contains foreign matter is considered adulterated and may compromise the standard quality of the drug, as it may not be sterile. Sterility is a fundamental quality attribute for all injectable drugs. The presence of adulterated material can lead to serious adverse reactions in patients, including, but not limited to, the following:

(i) Anaphylactic shock, which can be fatal.

(ii) Skin rashes, itching, and difficulty in breathing.

(iii) Suboptimal or no therapeutic effect for the intended medical treatment.

**Action initiated: -**

The field force under administrative control of DRAP and Provincial Drug Control departments have been directed to immediately conduct market surveys for detection of presence and removal of mentioned batch 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 product. 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).

**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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