PRODUCT RECALL ALERT

DRAP ALERT NO. Nº I/S/10-22-25

RECALL OF HUMAN ALBUMIN 20% BIOTEST

(MANUFACTURED BY M/S BIOTEST AG, GmbH)

Date: 06th October 2022.

Target Audience:

- Healthcare Professionals- Physicians, Pharmacists, and Nurses.
- General Public.

Alert Summary:

DRAP has received a rapid alert from the Paul-Ehrlich Institut, Federal Institue of Vaccine and Biomedicines, Ministry of Health, Germany, with respect to the quality defect and voluntary recall of 06 batches of Human Albumin 20%, 100mL manufactured by the Botest AG, GmbH. Out of these six batches, one batch was imported in Pakistan by the authorized registration holder M/s Eastren Trade & Distribution Co, (Pvt) Limited, Karachi. The importer has been directed to immediately recall the stock of defective batch **C236831P02** from the market. Regulatory field force is directed to supervise the recall progress. Detail of Product(s) are as under:

Product Name	**Reg. No.**	**Lot. No.**	**Mfg. date**	**Exp. date**	**Mfg. by**	**Name of Importer**	**Details of defect/ Reason of Recall**
Human Albumin 20% Biotest	008459	C236821P02	17-09-2021	31-08-2024	M/s. Biotest AG, GmbH	M/s. Eastern Trade & Distribution Co., (Pvt) Limited. Karachi	Suspicious results within determination of endotoxins by monocyte activation test and limulus amoebocyte lysate test 10-11 months after certification for marketing. At the time of batch release rabbit pyrogen test was well within specifications.

Action Initiated: -

The company is directed to immediately recall the defected batch of product(s) from the market. All Pharmacists and chemists working at distributions and Pharmacies are required to **immediately return** the stock of above mentioned batch of product to the company. Regulatory field force of all federating units (DRAP, Provincial Health Departments and States) have also increased surveillance in the market to ensure the effective recall of defective product(s).

Advice for Healthcare Professionals: -

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by this substandard batch.

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 Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.

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.