FIELD SAFETY ALERT

DRAP ALERT NO. Nº I/S/10-22-29

MARKET SURVEILLANCE REPORT

Date: 28th October 2022

Target Audience:

- Regulatory Field Force
- Healthcare Professionals - Physicians, Pharmacists, and Nurses.
- General Public.

Problem Statement:

DRAP received a complaint regarding the presence of following suspected product in the market. This product is not imported and marketed by the authorized registration holder and neither DRAP has issued import clearance for this product. National Control Laboratory for Biological has also not issued any lot release to this product. The product detail is as under: -

Sr.	Product name	Composition	Batch No.	Manufactured by (as stated on label)
01	**IMMUNORHO 300µg (1.500iu) (PFS; Pre-filled syringe)**	Human anti-D immunoglobulin	M05W25212	M/s. KEDRION BIOPHARMA.

Actions Initiated: -

The Regulatory Field Force has been directed to increase the market surveillance and confiscate this product. All Pharmacists and chemists working at distributions and Pharmacies should **immediately check** the stock and stop supplying this product. The remaining stock should be quarantine immediately, and supplier(s) information should be provided to the Regulatory field force (DRAP, Provincial Health Departments and States) in order to ensure the removal of suspected products.

Advice for Healthcare Professionals: -

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

Adverse reactions or quality problems experienced with the use of this product shall 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 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 / licensed retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professionals in case of any doubt.