RAPID ALERT

DRAP ALERT NO. Nº I/S/2-23-8

URGENT RECALL OF SUSPECTED PRODUCTS

Date: 20th February, 2023

Target Audience:

- Regulatory Field Force
- Pharmacists and Chemists at Distribution, Pharmacies and Medical Stores
- Healthcare Professionals- Physicians, Pharmacists, and Nurses at hospitals and clinics etc.
- General Public

Problem Statement:

Medical Control Agency Gambia has issued a Safety Alert Ref: - MCA/AD/23/MJK(029) dated 13th February,2023 for **KOF Relief Syrup** bearing Batch# L394, manufactured by M/s Davis Pharmaceutical Laboratories, Islamabad-Pakistan due to presence of Ethylene Glycol (EG) at unacceptable levels. DRAP Inspectorate has initiated the investigation based on this information, and decided to recall all suspected products manufactured by the firm using the same source of excipient i.e Glycerin and Propylene Glycol (PG).

The details of suspected contaminated products are as under: -

Sr#	Product Name	Composition	Batch No(s).	Manufactured by
1.	Bromgen Syp 100mL (Reg, **Export Only)**	Bromhexine HCl	L392	M/s Davis Pharmaceutical Laboratories, Islamabad-Pakistan
2.	Kof Relief Syp 100mL **(Reg, Export Only)**	Chlorpheniramine Maleate Ammonium Chloride Sodium Citrate Menthol Green Banana Flavour	L394	
3.	Macofen Syp 100mL **(Reg, Export Only)**	Ibuprofen	L395	
4.	Vomitil Suspension 120mL **(Reg, Export Only)**	Domperidone	L400, L408, L414,	

DRAP, Islamabad **92 51 9107404** **gsms@dra.gov.pk**

Sr#	Product Name	Composition	Batch No(s).	Manufactured by
5.	Asperfin Syp 60mL	Ketotifen	L401	M/s Davis Pharmaceutical Laboratories, Islamabad-Pakistan
6.	Davis Tonic Syrup 250mL, 120ml	Vitamin B12 Vitamin B1 HCl Vitamin B2 Vitamin B6 Vitamin B3 Folic Acid Vitamin B5 Sodium Glycerophosphate Manganese Sulphate Ferric Ammonium Citrate	CS07, CS20, CS21, CS23, CS30, CS31, CS42, CS70, CS71, CS159	
7.	Zinc Syp 60mL	Zinc Sulphate Monohydrate	CS06, CS36, CS37, CS38, CS39, CS45, CS46, CS47, CS48, CS60,CS75, CS76, CS80, CS81, CS83, CS92, CS93	

Action Initiated: -

The manufacturing company has been directed to **immediately recall** the suspected batches of these products from the market. All Pharmacists and chemists working at distributions and Pharmacies should immediately check their stocks and **stop supplying** these batches of products. The remaining stock should be quarantine and return to the supplier / 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 increase vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by these suspected batches of products.

Adverse reactions or quality problems experienced with the use of any of these products 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.

DRAP, Islamabad | 92 51 9107404 | gsms@dra.gov.pk

Advice for Consumers / General public: -

Consumers should **stop** using these products bearing the affected batch number(es) and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to taking or using these drug product, and report the incident to Drug Regulatory Authority of Pakistan / National Pharmacovigilance Centre or provincial pharmacovigilance centers.

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 professionals in case of any doubt.

Drug Regulatory Authority of Pakistan
محفوظ، موثر اور معیاری اشیائے علاج

DRAP, Islamabad | 92 51 9107404 | gsms@dra.gov.pk