RAPID ALERT

DRAP ALERT NO. Nº I/S/01-24-02

SEIZURE OF CONTAMINATED PROPYLENE GLYCOL (BATCH #C815N3OR41) ALLEGEDLY PRODUCED BY DOW CHEMICAL THAILAND

Date: **11th January 2024**

Target Audience:

- Regulatory Field Force.
- Therapeutic Goods industry
- Manufactures of Oral liquid preparations
- Healthcare professionals

Problem Statement:

The regulatory field force has identified a batch of Propylene Glycol (PG) that was used as a solvent in the manufacturing of oral liquid preparations. The batch was labelled as manufactured by Dow Chemical, Thailand. However, on analysis of a sample by the Central Drug Laboratory in Karachi, an unacceptable level of Ethylene Glycol was found.
The details of the affected batch are as under:-.

Product	Batch No	Mfg Date	Exp. Date	Manufacturer (as per label)	Remarks
Propylene Glycol (Raw Material)	C815N3OR41	03-23	03-25	Dow Chemicals, Thailand	The sample is declared substandard for unacceptable levels of Ethylene Glycol (EG).

Risk Statement:

Ethylene Glycol (EG) contaminated Propylene Glycol (PG) when used in oral liquid preparations, can lead to serious health risks due to EG's toxicity. When ingested, EG is metabolized into toxic metabolites that can affect the central nervous system, and heart, and can cause kidney damage, which can be fatal.

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Action Initiated: -

The Regulatory Field Force has taken possession of a contaminated batch of Propylene Glycol and is investigating the entire supply chain of this batch. The therapeutic goods manufacturer has been instructed to recall any finished products that were manufactured using the same lot of propylene glycol. The Regulatory Field Force has also been instructed to seize all oral preparations that were made using the same batch of propylene glycol if found in the market. DRAP has directed the therapeutic industry to hold finished products manufactured from any other lot of propylene glycol of Dow Chemical Thailand and ensure testing of finished products for EG/DEG contamination before releasing them into the supply chain.

Advice for Therapeutic Goods Manufacturers: -

Manufacturers of therapeutic goods are required to follow these instructions:

1. **Recall Products:** If any batch was manufactured using the same lot (C815N3OR41) of propylene glycol that has been identified as contaminated, all finished products from local and export markets should be recalled.
2. **Hold Other Batches:** All finished products manufactured from any other lot of propylene glycol of Dow Chemical Thailand should be held. These products should be tested for EG/DEG contamination before releasing them into the supply chain.
3. **Screen Raw Materials:** Before using them in the manufacturing of oral liquid preparations, all raw materials should be screened for contamination with EG and DEG.
4. **Analyze Finished Products:** Before their release into the market, all finished products should be analyzed for EG/DEG contamination.
5. **Compliance:** Ensure compliance with all directives issued by DRAP to safeguard public health from contaminated products.
6. **Follow Guidelines:** Adhere to the pharmacopoeia monograph and WHO guidelines for testing EG/DEG in oral liquid preparations during the analysis of both raw materials and finished products.

Our utmost priority is public safety. DRAP is committed to supporting the industry in maintaining rigorous quality control and testing procedures to prevent any potential harm caused by contaminated products.

Advice for Healthcare Professionals: -

DRAP requests healthcare professionals to stay updated with advisories and recalls. Patients should be educated about the risks and symptoms of EG toxicity. Close monitoring of patients using the affected products is crucial, and any adverse events should be reported to National or Provincial pharmacovigilance centres.

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Adverse reactions or quality problems experienced with the use 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 on reporting problems to DRAP is available on this link.

Advice for Consumers / General public: -

Consumers should stay informed about the latest advisories and recalls from DRAP. If they have experienced any problem or unusual symptoms after using oral liquid preparations, seek medical attention immediately and report the incident to the Drug Regulatory Authority of Pakistan / National Pharmacovigilance Centre.

All therapeutic goods must be obtained from 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.

Drug Regulatory Authority of Pakistan
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