666/2026-DDQA(VII)

Government of Pakistan

Ministry of National Health Services, Regulations & Coordination

Drugs Regulatory Authority of Pakistan

Prime Minister's National Health Complex

Park Road, Chak Shahzad, Islamabad

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Islamabad, the 20th November 2026.

ADVISORY

SUBJECT: ADVISORY TO THERAPEUTIC GOODS MANUFACTURERS: CONTINUED COMPLIANCE FOR THE PREVENTION OF DEG/EG CONTAMINATION IN ORAL LIQUID PREPARATIONS

In continuation of the Drug Regulatory Authority of Pakistan (DRAP) Advisory No. 13-30/2024-DD(QA-VIII) dated 16-04-2025 and Advisory No. 6-2/2025(DDQAVII) dated 14-10-2025, concerning the mitigation of Diethylene Glycol (DEG) and Ethylene Glycol (EG) contamination in Therapeutic Goods. With the onset of the winter season, demand for and production of cough syrups and other oral liquid preparations is expected to rise. It is therefore vital to re-emphasize the critical need for quality assurance measures to safeguard public health and ensure compliance with Good Manufacturing Practices (GMP).

2. In addition to the above-mentioned instructions and the applicable regulatory requirements concerning the quality and purity of Glycerine, Sorbitol and Propylene Glycol, all Therapeutic Goods manufacturers are hereby reminded and directed to continue to ensure strict compliance with the following directions:

i. Procurement of these critical raw materials shall only be from qualified vendors/manufacturers. The vendor qualification process shall be in accordance with the current Good Manufacturing Practices (cGMP) guidelines and applicable rules.

ii. Manufacturers shall ensure pre-use testing of Glycerine, Sorbitol and Propylene Glycol for the presence of DEG/EG impurities in all procured batches, prior to their use in the manufacturing processes. Manufacturers that do not possess in-house testing capabilities shall utilize the services of the Central Drug Laboratory (CDL).

iii. The results of all mandatory purity testing (through in-house facility or CDL Karachi) and the Certificate of Analysis (CoA) obtained from the manufacturer must be thoroughly verified and documented as part of the Batch Manufacturing Record (BMR) to ensure traceability, patient safety and consistent quality of the final product.

iv. Finished oral liquid preparations containing the above excipients shall be released only after the batch records confirm that the above testing and verification have been completed.

v. Manufacturers shall maintain complete records of raw material procurement, supplier details, testing results and batch utilization, and make them available for inspection.

4. All relevant manufacturers are advised to ensure strict compliance with the above directives to ensure product quality and patient safety. Non-compliance with these directives shall attract stringent regulatory action in accordance with the Drugs Act, 1976 / DRAP Act 2012 and rules framed thereunder.

20-11-2026.

(ISHTAIQ SHAFIQ)
Deputy Director (I&E)
Drug Regulatory Authority of Pakistan, Islamabad.

Copy for necessary action:

1. Additional Director, DRAP, Lahore, Karachi, Islamabad, Peshawar and Office in-charge DRAP Quetta, with request to ensure the compliance through Deputy Director (import & export) / area FID.
2. Central Drug Testing Laboratory (CDL) Karachi with the request to process the testing/analysis of these samples on priority.
3. Director MIS, DRAP with the request to upload on the official website of DRAP.

Copy for information and compliance:

1. The Chairman, Pakistan Pharmaceutical Manufacturing Association (PPMA).
2. The Executive Director, Pharma Bureau Pakistan.
3. The Chairman, Pakistan Chemists & Druggists Association.
4. The Chairman, Pakistan Tibbi Pharmaceutical Manufacturers Association (PTPMA), Near Chowk Noranian, Opposite Jamia Masjid Ghausia, New Shalimar, Multan Road, Lahore.
5. The Chairman, Homeopathic Pharmaceutical & Chemist Association Pakistan, 29-A, Anum Road, Industrial Estate (Glaxo Town), 20 Km, Ferozpur Road, Lahore.
6. The Chairman, Pakistan Alternative Medicine Manufacturers Association, Suite No. 503, 5th Floor, Al-Amin Tower, NIPA Chowrangi, Block 10, Gulshan e Iqbal, Karachi.