No. F. 13-30/2024-DD(QA-VIII)
GOVERNMENT OF PAKISTAN
DRUG REGULATORY AUTHORITY OF PAKISTAN
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Islamabad, the 16th April, 2025.

Subject: **ADVISORY TO THERAPEUTIC GOODS MANUFACTURERS: MEASURES TO PREVENT DEG/EG CONTAMINATION IN ORAL LIQUID PREPARATIONS**

Reference is made to the subject cited letter vide No. F. 03-20/2024-QC (335-RB) dated 31-05-2024 and previously communicated directions to therapeutic goods manufacturers regarding Glycerin, Sorbitol and Propylene Glycol.

2. The Drug Regulatory Authority of Pakistan (DRAP) is issuing this advisory due to global concern regarding oral liquid preparations contaminated with Diethylene Glycol (DEG) and Ethylene Glycol (EG), which has caused severe health issues, especially in children, as highlighted by the World Health Organization (WHO). DRAP has proactively addressed this by issuing advisories and guidelines to pharmaceutical manufacturers regarding the safety of Glycerin, Sorbitol, and Propylene Glycol. These previous directives included testing for DEG/EG, using pharmaceutical-grade solvents from qualified vendors, performing identity tests, requiring Certificates of Analysis, reporting analysis results, and risk-based sampling. DRAP has also enhanced surveillance, issued advisories, and extended surveillance to raw materials in coordination with Provincial Drug Control Administrations.

3. Given these concerns, DRAP has taken serious note of the online sale of excipients like Glycerin, Sorbitol, and Propylene Glycol via unverified platforms, including social media and e-commerce sites, posing risks to traceability, authenticity, and potential adulteration. To mitigate these risks, DRAP has inspected manufacturers and vendors, ordered sampling, shared WHO guidelines with health departments and testing labs, investigated supply chains, taken regulatory actions (seizures, FIRs, suspensions, recalls, etc.), collaborated with WHO, and extended DEG/EG testing facilities at Federal and Provincial Drug Testing Laboratories.

4. To address procurement risks, manufacturers are directed not to purchase excipients from unverified sources, including online platforms, and all therapeutic goods manufacturers must perform vendor qualification for excipients and APIs per the DRAP Act 2012, the Drugs Act 1976 and section 3.5.2 read with 6.2.2. of Schedule B-II of the Drugs, LR&A Rules, 1976. Manufacturers must procure these materials from qualified vendors and authorized distributors, adhering to DRAP guidelines that include audits, documentation review, and risk assessment. They must also continue impurity testing of Glycerin, Sorbitol, and Propylene Glycol on each batch, in-house or through CDL, Karachi or Provincial Drug Testing laboratories having said facilities, and conduct risk assessments of their excipient supply chains.

5. DRAP clarifies that adulterated or substandard raw material or finished product samples due to DEG/EG impurities will render the manufacturer liable to regulatory action under Drug Act, 1976, the DRAP Act, 2012 and rules framed there under these Acts. DRAP reiterates its commitment to public health and safety. Manufacturers must prioritize these concerns by adhering to these guidelines and ensuring the quality and authenticity of materials used in therapeutic goods production. DRAP urges enhanced vigilance in procurement and quality control to prevent contaminated materials from entering the supply chain.

(Hafiz Sanaullah Babar)
Additional Director (QA&LT)

Distribution:

i) Additional Director, DRAP, Lahore, Karachi, Islamabad, Peshawar and Office in-charge DRAP Quetta.
ii) Chief Drugs Controller/Inspector, Punjab, Sindh, Khyber Pakhtunkhwa, Balochistan, AJ&K, GB & ICT.
iii) The Director, Drug Testing Laboratory, Lahore, Rawalpindi, Bahawalpur, Multan, Karachi, Peshawar, Quetta, AJ&K and GB.
iv) Pakistan Tibbi Pharmaceutical Manufacturers Association (PTPMA), Near Chowk Noranian, Opposite Jamia Masjid Ghausia, New Shalimar, Multan Road, Lahore.
v) Homeopathic Pharmaceutical & Chemist Association Pakistan,29-A, Anum Road, Industrial Estate (Glaxo Town), 20 Km, Ferozpur Road, Lahore.
vi) Pakistan Alternative Medicine Manufacturers Association, Suite No. 503, 5th Floor, Al-Amin Tower, NIPA Chowrangi, Block 10, Gulshan e Iqbal, Karachi
vii) The Pakistan Pharmaceutical Manufacturing Association (PPMA).
viii) The Pharma Bureau Pakistan.
ix) Pakistan Chemists & Druggists Association.
x) File No. F. 03-41/2023-QC
xi) Master Folder.

Additional Director (QA&LT)