



Global Health Supply Chain Program

GHSC-QA Product Quality Alert Notice 2023-01

February 20, 2023

Product Quality Alert Summary

In response to WHO Medical Product Alerts No 1/2023, 6/2022 and 7/2022, GHSC-QA requests increased surveillance and diligence of liquid dosage forms, especially cough syrups that contain the following excipients including propylene glycol, sorbitol, and /or glycerin/glycerol. These types of products, manufactured by Marion Biotech Pvt, Maiden Pharmaceuticals Limited, and other, have been found to contain unacceptable amounts of diethylene glycol and ethylene glycol as contaminants.

Risks

Diethylene glycol and ethylene glycol are toxic to humans when consumed and can prove fatal. Toxic effects can include abdominal pain, vomiting, diarrhea, inability to pass urine, headache, altered mental state, and acute kidney injury which may lead to death. Consumption of diethylene glycol and ethylene glycol may result in serious injury or death, especially in children.

GHSC-QA Risk Mitigation Requirements

Suppliers shall complete a review of liquid dosage forms, that are not WHO Prequalified or approved for marketing (registered) by USAID recognized stringent regulatory authorities and offered for procurement to USAID procurement service agents. The review shall include and evaluation each product formulation and excipients to determine the presence of propylene glycol, polyethylene glycol, sorbitol and/or glycerin/glycerol. A third-party certificate of analysis showing absence of ethylene glycol and diethylene glycol for all lots shall be provided for liquid dosage forms containing propylene glycol, polyethylene glycol, sorbitol and/or glycerin/glycerol, until further notice.

Please direct the respective answers and any questions about this matter to the technical contact listed below:

Organization	Name/Function	E-mail address
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