དཔལ་ལྡན་འབྲུག་གཞུང་། གསོ་བ་ལྷན་ཐག འབྲུག་བཟའ་ཚས་དང་སྨན་རིགས་དབང་འཛིན།

ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
BHUTAN FOOD AND DRUG AUTHORITY

BFDA/MPD-DES/18–03/MC/2023-2024/ 5312 **25 June 2024**

Notification on mandatory submission of testing report for ethylene glycol and diethylene glycol in oral liquid preparations.

In response to recent global incidents of contamination in pharmaceutical oral liquid preparations with ethylene glycol (EG) and diethylene glycol (DEG), resulting in significant loss of life, particularly among children, the Bhutan Food and Drug Authority (BFDA) issues this notification to all Market Authorization Holders, Importers, Manufacturers and all relevant stakeholders.

EG and DEG are widely used as industrial solvents in antifreeze, paints, and cosmetics, but they are highly toxic and potentially fatal if ingested above the safety limits. The World Health Organization (WHO) has issued several rapid product alerts highlighting the contamination of liquid oral medications with these compounds, underscoring the critical need for stringent regulatory measures to safeguard public health.

To protect public health, the BFDA mandates that all pharmaceutical oral liquid preparations be accompanied by certified test reports verifying that EG and DEG levels are within acceptable limits. These test reports must be submitted at the time of dossier submission for product registration. Furthermore, during importation, batch samples must be provided for testing to ensure the absence of EG and DEG beyond permitted limits.

We strongly urge all stakeholders to prioritize the implementation of these requirements to ensure the safety of our medical products and to maintain public trust. This notification is issued for your immediate compliance

Director


BHUTAN FOOD AND DRUG AUTHORITY