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

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Press release

Safety information on cough syrups containing high level of Diethylene Glycol (DEG) and Ethylene Glycol (EG) in India

The Bhutan Food and Drug Authority (BFDA) has received safety information from the South-East Asian Regulatory Network (SEARN) concerning the following contaminated cough syrup products in India:

Sl. No	Name of the Product	Manufacturer	Contain of EG & DEG
1.	Syrup COLDRIF Batch no.: SR-13	Sresan Pharmaceutical manufacturer, (Mathura), Kancheepuram, India	46.28% w/v
2.	Respifresh TR Batch no.: R01GL2523	Rednex Pharmaceuticals Pvt Ltd. Kerala, Dist. Ahmedabad, India	1.342%w/v
3.	Relife Syrup Batch no.: LSL25160	Shape Pharma Pvt Ltd., Shekhpur, Gujarat, India	0.616% w/v

Following reports of a cluster of cases, including multiple child fatalities, in India, a total of 19 medicinal samples reportedly consumed by the affected children were subjected to laboratory testing. The analysis revealed that the aforementioned cough syrup contained high levels of Diethylene Glycol (DEG) and Ethylene Glycol (EG).

EG and DEG are commonly used as industrial solvents in products such as antifreeze, paints, and cosmetics that can be fatal even in small amounts, especially for children. According to Pharmacopoeial specifications, the permissible concentration of EG and DEG in oral liquid preparations must not exceed 0.1% w/v.

The BFDA informs the general public that the three contaminated cough syrups are not available in the Bhutanese market, since they are neither approved for use nor authorized for importation into the country. However, the public is strongly advised to refrain from purchasing or using these cough syrups from across the border.

The public is urged to report any suspicious or unauthorized medicines to the nearest BFDA office or contact 1555, 337074/75, or mpd@bfda.gov.bt.

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PABX: +975-2-327031 for Food Quality Safety Division and Plant & Animal Biosecurity Division, 337074/337075 for Medical Product Division and 335371/336577 for Controlled Substance & Medical Device Division

The following regulatory mechanism are in place to ensure the safety of medicinal products in the country:

1. All medicinal products imported, sold and distributed in Bhutan are evaluated and approved by the BFDA. The BFDA ensures all oral liquid formulations are tested for presence of EG and DEG prior to their approval for use in the country. A regulatory notification outlining this requirement was issued to all relevant stakeholders on 25 June 2024(https://bfda.gov.bt/wp-content/uploads/2025/10/Regulatory-Notification-for-Oral-Liquid-Preparations.pdf). To verify if any oral liquid formulations are authorized for use in the country, you may visit the BFDA's website or may navigate with the link provided: https://ris.bfda.gov.bt/Outsider/Medicines/home/home.php

2. The import of any oral liquid formulations into the country are mandated to be accompanied by a test report demonstrating a compliance with safety standards of not more than 0.1% w/v of EG and DEG.

3. Oral liquid formulations, particularly pediatric preparations, are classified as high-risk products and are subjected to increased surveillance by prioritizing laboratory testing to verify the contamination of EG and DEG. In March 2025, the BFDA, in collaboration with the National Medical Product Testing Laboratory, Royal Center for Disease Control, conducted a comprehensive laboratory testing to assess the presence of EG and DEG in oral liquid formulations available in both government health facilities and private pharmacies in the country. All samples complied with the specified regulatory requirements, indicating the absence of EG and DEG contamination.

Gyem Bidha
(Director)

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