



དཔལ་ལྷན་འབྲུག་གཞུང་། གསལ་བཟོ་ལག་ འབྲུག་བཟང་ཆས་དང་སློན་རིགས་དབང་འཛིན།

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



BFDA/MPD/02/OFL/2025-2026/ 3487

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**Regulatory Notification on the Recall of Herbal Product COMPOUND HERB INHALER
(HONGTHAI BRAND FORMULA 2)**

The Bhutan Food and Drug Authority (BFDA) has received a safety recall alert from the Thailand Food and Drug Administration (Thai FDA) through the South-East Asia Regulatory Network (SEARN) concerning **COMPOUND HERB INHALER, HONGTHAI BRAND FORMULA 2 (ชย ดมผสมสมุนไพร ตราหงส์ไทย สูตร 2)**, Lot No. 000332, manufactured by Hongs Thai Panich (HONGTHAI COMMERCE), Bangkok, Thailand.

The Thai FDA confirmed the recall of this product following the detection of microbiological contamination, including Clostridium spp., as well as elevated counts of aerobic microorganisms, yeasts, and molds exceeding acceptable limits. The BFDA Public Safety Advisory containing pictorial representations of the affected product is attached herewith for reference.

All importers, distributors, pharmacies, and retail outlets are hereby instructed to immediately cease the sale and distribution of the aforementioned product and to submit all remaining stocks to the BFDA for safe disposal. The general public is likewise advised to discontinue the use of this product if already purchased.

Pursuant to Section 268 of the Bhutan Medicines Rules and Regulations 2019, the product is classified under Schedule A2 (General Sale List Product). As a product under the scope of the regulation, the BFDA is mandated to recall and dispose of defective and substandard medicinal products to protect public health. The BFDA will continue coordinating with the Thai FDA through SEARN to monitor the situation.

This notification is issued for immediate compliance. For any clarification, please contact the BFDA at the toll-free number 1555 or via email at mpd@bfda.gov.bt.

Director

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