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

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

**BFDA/MPD/02/OFL/2026-2027/**952 **31 July 2026**

**Regulatory Notification on the Detection of an Unregistered Medicinal Product Containing Undeclared Diclofenac**

The Bhutan Food and Drug Authority (BFDA) has observed an increasing trend of members of the public purchasing or bringing medicinal products from across the border for personal use or for their family members. Many of these products are marketed for the relief of knee pain, joint pain, arthritis, and other musculoskeletal conditions, but are inadequately labelled, bear foreign-language labels or fail to disclose their active ingredients. Consequently, consumers may unknowingly use medicines without knowing what they contain.

Following the referral of several suspected medicinal products to the BFDA for regulatory assessment, laboratory analysis confirmed that one product marketed with the claim "No Side Effect" contained undeclared Diclofenac Sodium and Diclofenac Potassium, despite no declaration of these pharmaceutical active ingredients on the product. The product consisted of blue and white capsules, white round tablets, and white oblong tablets, with diclofenac detected in the capsules and round tablets.

The detection of undeclared pharmaceutical active ingredients is a matter of significant public health concern. Consumers and healthcare professionals rely on product labels to identify the active ingredients in medicines and determine whether they are appropriate for use. Medicines with unknown or undisclosed ingredients may lead to inappropriate use, duplication of therapy, drug interactions, allergic reactions, and other avoidable health risks.

The BFDA therefore advises the public not to purchase, import, receive, or consume medicinal products that do not clearly identify their active ingredients or that make misleading claims such as "No Side Effect." Members of the public are also reminded that medicines imported for personal use must comply with the provisions of the Medicines Act of the Kingdom of Bhutan 2003 and the Bhutan Medicines Rules and Regulations 2025, including the prescribed limits for personal importation.

The BFDA Public Safety Advisory containing pictorial representations of the affected product is attached herewith for reference. The BFDA urges the public to exercise caution when purchasing or bringing medicines from abroad, particularly products that do not clearly disclose their contents or make exaggerated therapeutic claims. Consumers should not assume that a product is safe or effective simply because it is marketed as "natural," "herbal," or "free from side effects." Knowing what medicine you are taking is essential for its safe and appropriate use.

This notification is issued in the interest of protecting public health. For any clarification, please contact the BFDA at the toll-free number 1555 or via email at mpd@bfda.gov.bt

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