



དཔལ་ལྷན་འབྲུག་གཞུང་། གསོ་བ་ལྷན་ཁག འབྲུག་བཟང་ཆས་དང་སྐྱེན་རིགས་དབང་འཛིན།

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



BFDA/MPD/02/OFL/2025-2026/ 3338

16 March 2026

### Regulatory Notification on Publication of Revised Guidelines for Market Authorization of Medicinal Products

The Bhutan Food and Drug Authority (BFDA) is pleased to announce the publication of the revised Guidelines for Market Authorization of Medicinal Products, as endorsed during the 41<sup>st</sup> Drug Technical Advisory Committee (DTAC) meeting. These revised guidelines reflect the adoption of current international regulatory best practices, including recommendations from the World Health Organization. The updates aim to strengthen regulatory oversight and enhance assurance of the safety, efficacy, and quality of medicinal products available in the country.

The following guidelines will replace the Guideline for Registration of Medicinal Products 2020:

1. Guideline for Market Authorization of Medicinal Products via standard route 2025 - Book I;
2. Guideline for Market Authorization of Medicinal Products via Abridged Route 2025 - Book II;
3. Guideline for Post Approval Variation of Medicinal product 2025 - Book III; and
4. Guideline for Market Authorization of Traditional Medicines 2025 - Book IV.

To ensure a smooth transition and uninterrupted access to essential medicines, all products currently registered under the **Expedited Route and Company Registration pathways** will be granted a one-time renewal. Upon the expiry of this renewal period, these products must comply with the revised market authorization requirements. Effective immediately, no new applications will be accepted through the aforementioned routes.

Furthermore, the amendments to the validity period of the Market Authorization, as outlined in Regulatory Notification No. **BFDA/MPD/02/OFL/2024-25/336**, shall be effective only after the fulfillment of the new regulatory requirements.

For further clarification, applicants may contact the Medical Product Division, BFDA, via [mpd@bfd.gov.bt](mailto:mpd@bfd.gov.bt) or call us at 1555.

This notification is issued for information, and strict compliance.

Director