དཔལ་ལྡན་འབྲུག་གཞུང་། གསོ་བ་ལྟ་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/2024-2025/** 336 **07 January 2025**

**Regulatory notification on amendments to the validity of Market Authorization of Medical Products**

In line with the resolutions adopted during the first BFDA Governing Board meeting, the Bhutan Food and Drug Authority (BFDA) hereby notifies all relevant stakeholders of an important amendment concerning the validity of Market Authorization for medical products.

To streamline regulatory processes and ensure more efficient access to approved medical products, the BFDA, following endorsement from the Governing Board, has revised the validity period for Market Authorization. The following key amendments will be implemented immediately:

1. **Life-long Validity of Market Authorization**: Market Authorization for medical products shall now remain valid for life, provided all regulatory conditions continue to be met.
2. **Mandatory Periodic Renewal**: While Market Authorization remains valid indefinitely, applicants are required to renew their authorization every three years. The requirements for renewal shall be specified in the updated guidelines for registration of medicinal products.
3. **Timely Submission of Post-Approval Variations**: Applicants are obligated to submit any post-approval variations such as updates to product information or quality data to the BFDA promptly.

These amendments are aimed to enhance regulatory efficiency, reduce administrative delays, and ensure that safe and effective medical products remain continuously available in Bhutan. All stakeholders must fully comply with these revised provisions.

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

9.1.25

**Director**

Director
Bhutan Food and Drug Authority
Thimphu : Bhutan

PABX: +975-2-337074/337075, Fax: +975-2-335803. Director: 02-334271
Website: www.bfda.gov.bt