དཔལ་ལྡན་འབྲུག་གཞུང་། གསོ་བཅུད་ཁག། འབྲུག་བཟའ་ཚལ་དང་སྨན་རིགས་དབང་འཛིན།

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

BFDA/MPD/02/OFL/2025-2026/ 3336

16 March 2026

Regulatory Notification on Publication of List of Medicinal Products requiring Bioequivalence study data and Biowaiver Data

The Bhutan Food and Drug Authority (BFDA) hereby notifies all Marketing Authorization Holders (MAHs), applicants, manufacturers, importers, and other relevant stakeholders that the Authority has published followings, as endorsed during the 41st Drug Technical Advisory Committee (DTAC) meeting:

1. A list of medicinal products for which submission of **Bioequivalence (BE) study data** is mandatory; and
2. A list of medicinal products that are **exempted** from submission of Bioequivalence study data but are required to submit **Biowaiver data**, such as **Comparative Dissolution Study (CDS) data**.

Bioequivalence (BE) and biowaiver requirements are internationally recognized regulatory tools to ensure that generic medicinal products are therapeutically equivalent to their respective reference (innovator) products. Bioequivalence studies are conducted to demonstrate that the rate and extent of absorption of the active pharmaceutical ingredient (API) from a generic product are comparable to those of the reference product, thereby ensuring comparable safety and efficacy.

Accordingly, applicants are hereby informed that:

1. Medicinal products listed under the Bioequivalence-required category must be supported by acceptable in vivo Bioequivalence study data at the time of submission of the Marketing Authorization application; and
2. Medicinal products listed under the Biowaiver-eligible category are exempted from in vivo Bioequivalence studies but must submit appropriate Comparative Dissolution Study data and other supporting documents in line with applicable regulatory requirements.

All applications for Marketing Authorization submitted to the Authority shall strictly comply with the published lists and applications that do not meet these requirements may be subject to rejection.

The published lists are available on the official website of the Bhutan Food and Drug Authority. Stakeholders are advised to review the lists carefully prior to submission of applications.

For further clarification, applicants may contact the Medical Product Division, BFDA, via mpd@bfda.gov.bt or call us at 1555.

This notification is issued for information and strict compliance.

Director