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08 January 2025

Notification on Harmonization of Nomenclature premises involved in sale and distribution of Medical Device

In accordance with Section 24.1 of the Medicines Act of the Kingdom of Bhutan 2003 and Section 65 of the Bhutan Medicines Rules and Regulations 2019, the Medical Product Division, Bhutan Food and Drug Authority (BFDA) is responsible for issuing Technical Authorization (TA) for the sale and distribution of medicinal products.

To ensure uniformity, clarity and efficiency in the regulation of premises involved in the sale and distribution of medicinal products, the Authority has mandated a standardized nomenclature system for both retail and wholesale entities. With the recent expansion of the mandate to regulate medical devices, there is also a need to harmonize the naming of premises for medical devices. This will enhance regulatory clarity and eliminate any confusion among stakeholders regarding the scope of authorized activities and products.

Henceforth, the Authority mandates the following naming structure for premises dealing with medical devices (for wholesalers):

- **Any name** chosen by the applicant, followed by the mandatory suffix: **'Medical Supplies'**.

All new applicants for Technical Authorizations must adhere to this naming requirement when submitting their applications, while existing premises with valid TAs must adopt this naming structure during their TA renewal. This standardized nomenclature will facilitate the clear identification of premises, streamline monitoring and surveillance activities, and improve accessibility for stakeholders.

For any queries or further clarifications, please contact the office at +975-2-337074/337075 or mpd@bfda.gov.bt

This notification is issued for immediate compliance.

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