དཔལ་ལྡན་འབྲུག་གཞུང་། གསོ་བ་ལྟན་ཁག འབྲུག་བཟའ་ཚས་དང་སྨན་རིགས་དབང་འཛིན།
ROYAL GOVERNMENT OF BHUTAN
MINISTRY OF HEALTH
BHUTAN FOOD AND DRUG AUTHORITY

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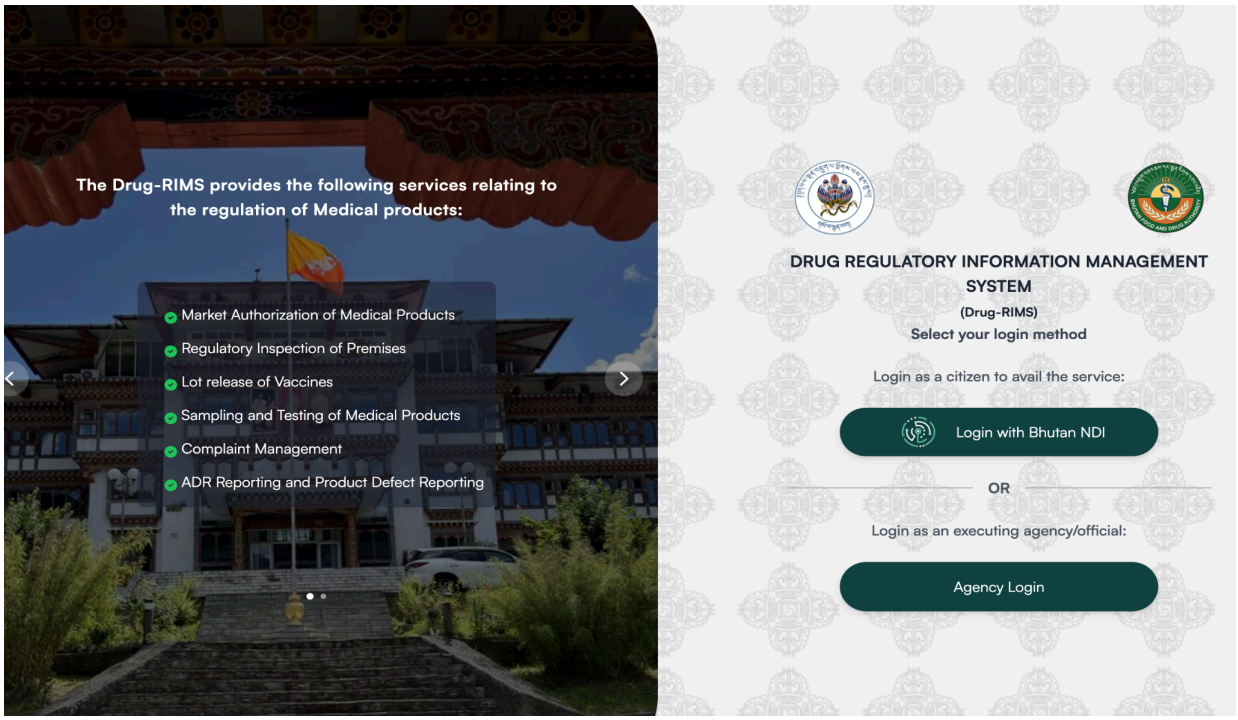
Press Release

Launch of Drug Regulatory Information Management System (Drug-RIMS), and the Procedural Manual for the Operation of Sanitary and Phytosanitary (SPS) National Enquiry Point (NEP)

In its ongoing efforts to enhance regulatory efficiency, accuracy and transparency, the Bhutan Food and Drug Authority (BFDA) is pleased to announce the launch of the Drug Regulatory Information Management System (Drug-RIMS), an online system for whole regulatory functions concerning medical products. The system was inaugurated by the Hon'ble Chairperson of the BFDA Governing Board, His Excellency Lyonpo Tandin Wangchuk, Minister, Ministry of Health on 30 December, 2025. The system will serve as a centralized platform for stakeholders and the general public to access information, avail regulatory services and enable regulators to conduct regulatory operations more effectively connecting the core functions under the medical products regulation.



The new platform will support the following key services and functions:

1. **Market Authorization of Medicinal Products:** All medicinal products will now be evaluated and approved for use in Bhutan through Drug-RIMS. Importers can securely submit product dossiers and receive real-time updates on the status of their applications.
2. **Regulatory Inspections:** Drug-RIMS will host records of inspections conducted in government and private health facilities, including manufacturing units. The system allows for efficient tracking of compliance, identifying both conformities and non-conformities.

3. **Market Control Functions:** The platform will support post-market surveillance, health product advertisement clearance, lot release, sampling and testing registry and export authorizations, strengthening overall market oversight.

4. **Quality Management System:** Drug-RIMS will also document, manage, and verify all regulatory procedures under the BFDA's Medical Product Division, ensuring consistency, reliability and transparency in regulatory operations.

The implementation of Drug-RIMS will be carried out in a phased manner, with a transition timeline of two years to ensure the complete transfer of all regulatory operations onto the platform. The system is expected to improve efficiency for regulators and inspectors while providing faster, more transparent services to clients, importers, and allied healthcare professionals.

Similarly, Hon'ble Lyonpo launched the **Procedural Manual for the Operation of Sanitary and Phytosanitary (SPS) National Enquiry Point (NEP)**. The NEP was established in BFDA with the Cabinet Directive issued in December 2024.

As the country resumed its accession process to the World Trade Organization (WTO), the establishment and operationalization of the NEP marks a key milestone in meeting the requirements of

the WTO Agreement on the Application of Sanitary and Phytosanitary Measures. The NEP serves as a central platform to promote transparency on Bhutan's regulatory measures related to food safety, and animal and plant health, enabling trading partners to better understand and comply with national standards. This fosters trust, facilitates smoother export and import of agricultural and food products, boosting trade volumes, and strengthens Bhutan's position in regional and global markets.

To provide a centralized digital platform for sharing information on Bhutan's sanitary and phytosanitary measures, SPS Portal was also developed and made public. Through the portal, domestic agencies, exporters, importers, and international partners can obtain timely and reliable information on Bhutan's food safety, and animal and plant health standards. This not only facilitates better understanding and compliance with national requirements but also reduces delays and administrative burdens in information exchange.

The Procedural Manual for the Operation of SPS NEP, developed by the BFDA, provides detailed guidance on the structure, coordination, and responsibilities of the NEP. It aligns Bhutan's SPS framework with international best practices and WTO transparency provisions. By streamlining communication and coordination across relevant sectors, the manual enhances regulatory efficiency, scientific integrity, and responsiveness to global SPS developments. Ultimately, it supports Bhutan's efforts to ensure food safety, protect animal and plant health, and promote safe, sustainable trade while reinforcing confidence in Bhutanese agri-food products worldwide.

Bhutan Food and Drug Authority