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BHUTAN FOOD AND DRUG AUTHORITY

Annual Report 2024-25

MEDICAL PRODUCT DIVISION

Quality Policy of MPD

"We commit to provide consistent regulatory operations with risk based planning and continual improvement in compliance with the recognized standards to meet our consumers' satisfaction and confidence."

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Hear from our Director

"This year saw continued implementation of good reliance practices, advancement in materiovigilance and deeper alignment with international standards and WHO guidance."

Gyem Bidha
Director
Bhutan Food and Drug Authority

It is with great pride and a profound sense of responsibility that I present the Annual Report for the Medical Product Division (MPD) of the Bhutan Food and Drug Authority for the fiscal year 2024–2025. This report reflects not only our key achievements but also our unwavering commitment to ensuring that all medical products in Bhutan are safe, effective, and of the highest quality.
In an increasingly complex healthcare landscape, the role of the regulator has never been more critical.

At the MPD, we have embraced this responsibility by reinforcing our regulatory systems through risk-based approaches, scientific decision-making, and collaborative engagement. This year saw continued implementation of good reliance practices, advancement in materiovigilance, and deeper alignment with international standards and WHO guidance.

We are particularly proud of our strides in expanding regulatory oversight to encompass medical devices, developing post-market surveillance frameworks, and contributing actively to regional and global regulatory dialogues, such as those under the South-East Asia Regulatory Network (SEARN).

None of this would have been possible without the tireless efforts of our dedicated staff, the cooperation of our stakeholders, and the trust placed in us by the public. We remain committed to fostering a culture of quality and transparency, guided by our vision of protecting and advancing the health and safety of the Nation.

As we move forward, we aim not only to respond to today's regulatory needs but to proactively shape systems that are resilient, efficient, and responsive to the evolving landscape of medical products. I invite all our partners and stakeholders to continue this journey with us.

Tashi Delek!

Organization Overview

The **Medical Product Division (MPD)** is one of the core divisions under the Bhutan Food and Drug Authority (BFDA), entrusted with the regulatory oversight of medical products in Bhutan. Established initially as the Drug Regulatory Authority (DRA) in 2004 under the Medicines Act of the Kingdom of Bhutan 2003, it has since evolved into a more integrated and efficient unit following the restructuring of regulatory bodies under BFDA. The division plays a central role in safeguarding public health by regulating medicinal products including medical devices and supplements to ensure their quality, safety and effectiveness.

MPD's responsibilities encompass a wide range of regulatory functions, including product registration, licensing of establishments and professionals, import and export authorization, inspections, market surveillance and post-market vigilance. The division also plays a proactive role in promoting quality assurance systems through the implementation of Good Regulatory Practices (GRP) and risk-based approaches. These efforts ensure transparency, accountability and timely access to essential medicinal products for all Bhutanese citizens.

In line with Bhutan's commitment to global health standards, the MPD actively engages in regional and international regulatory initiatives. The division collaborates with the World Health Organization (WHO), participates in the South-East Asia Regulatory Network (SEARN) and contributes to global forums. These engagements not only enhance Bhutan's regulatory capacity but also enable the MPD to adopt best practices and reliance mechanisms that strengthen its role as a competent, responsive and future-ready regulatory authority.

Vision

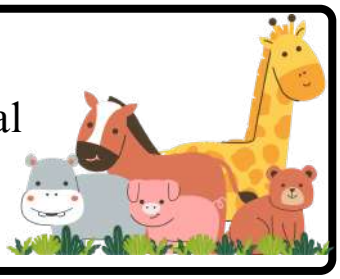
Excellence in protecting and advancing the health and safety of the Nation.

Mission

To protect the health of human, animals, plants and environment by ensuring:

safety and quality of food and agricultural products;

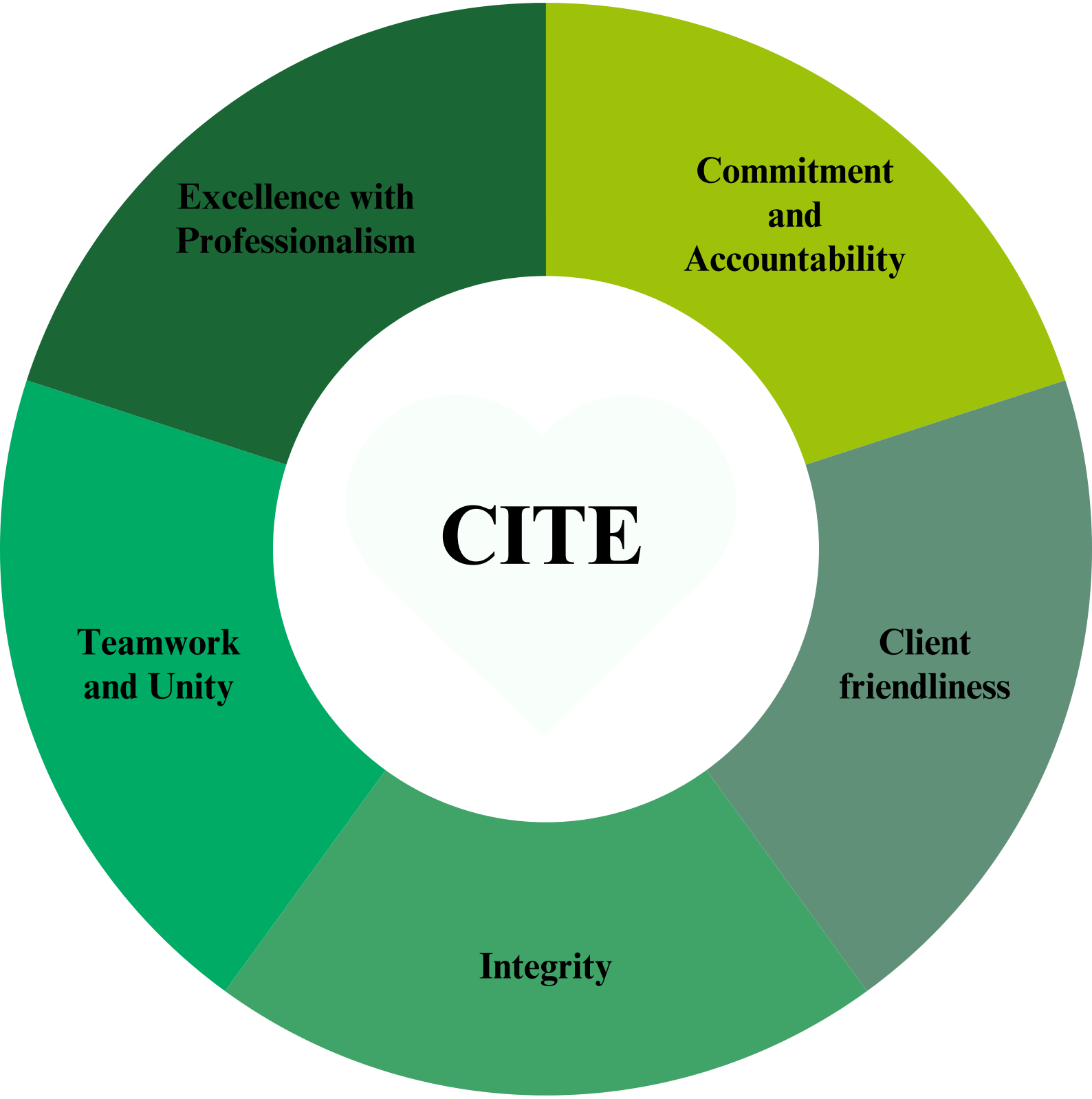
effective plant and animal biosecurity systems;



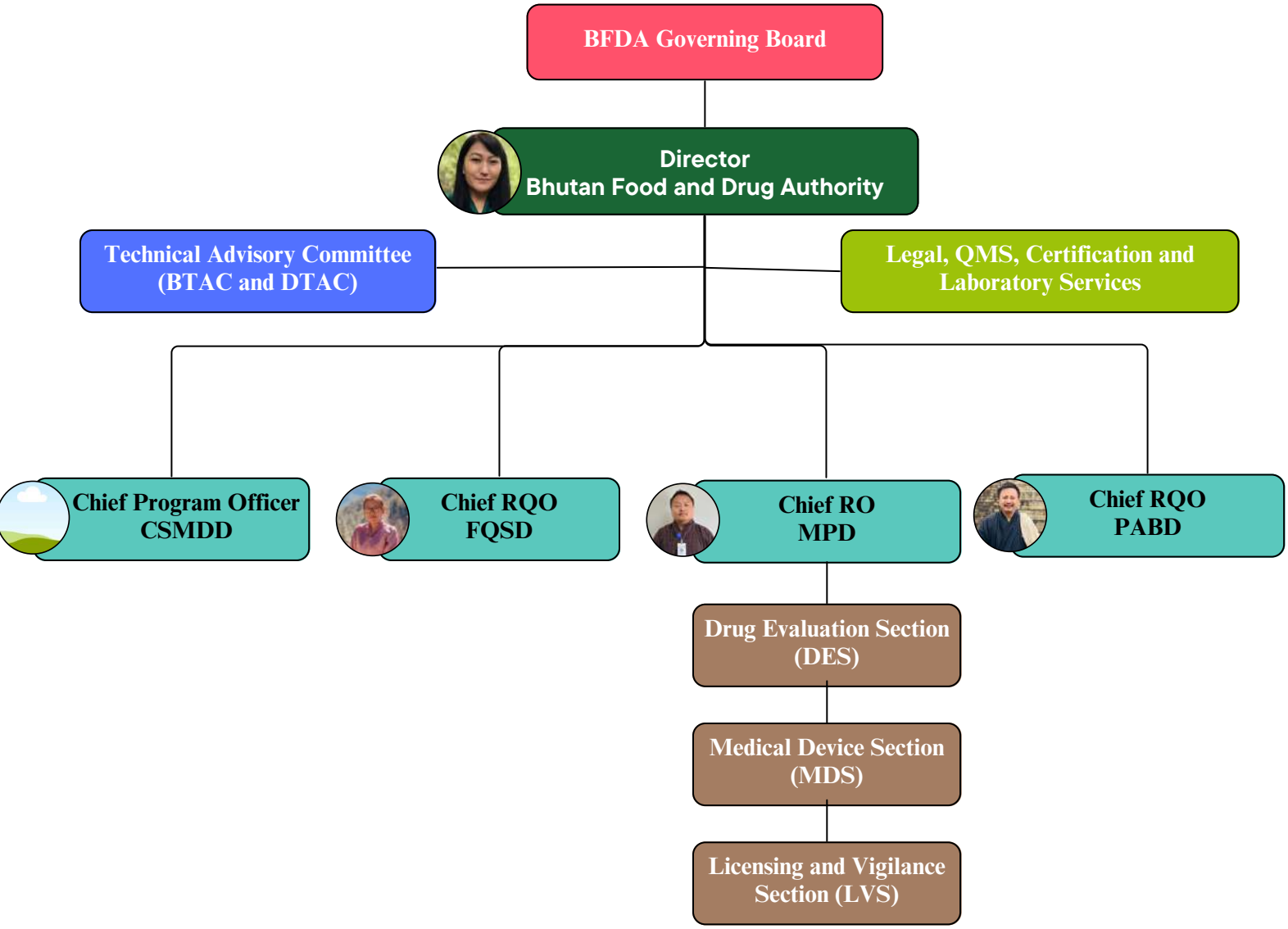
quality, safety and effectiveness of medical products; and

reduce supply and demand of controlled substances.

Core values


Excellence with Professionalism
Commitment and Accountability
CITE
Teamwork and Unity
Client friendliness
Integrity

Organogram


BFDA Governing Board
Director
Bhutan Food and Drug Authority
Technical Advisory Committee
(BTAC and DTAC)
Legal, QMS, Certification and
Laboratory Services
Chief Program Officer
CSMDD
Chief RQO
FQSD
Chief RO
MPD
Chief RQO
PABD
Drug Evaluation Section
(DES)
Medical Device Section
(MDS)
Licensing and Vigilance
Section (LVS)

Human Resource in MPD

Accolades

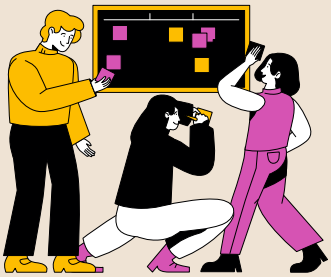
Gold Medal

Ms. Sarim Tshering, Asst. Regulatory Officer

Promotion

Mr. Sonam Chophel, Sr. Regulatory Officer

New Recruits

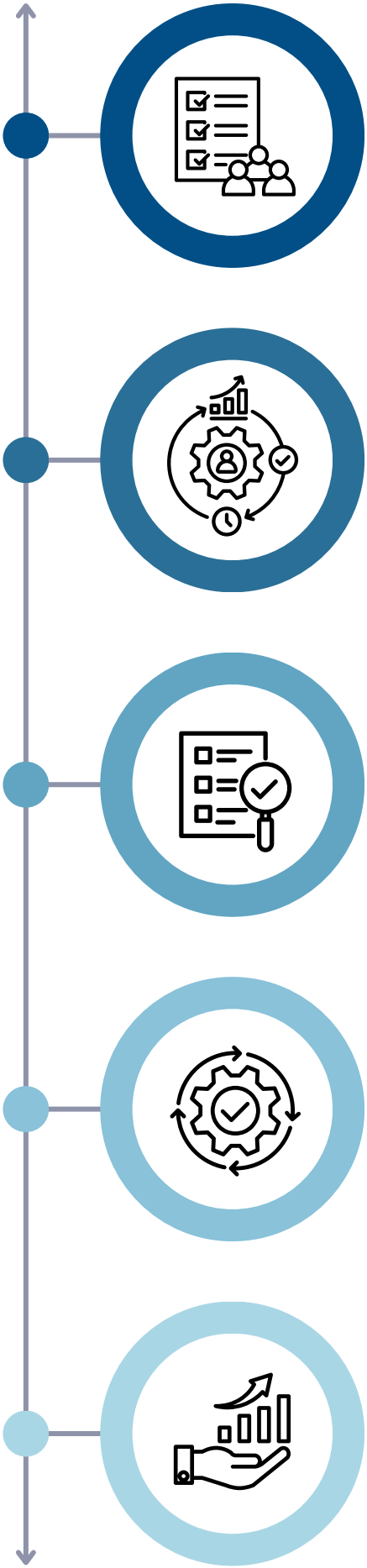


Mr. Tashi Lepcha
Regulatory Officer

Ms. Tenzin Wangmo
Regulatory Officer

Mr. Ugyen Chophel
Regulatory Officer

Services of MPD



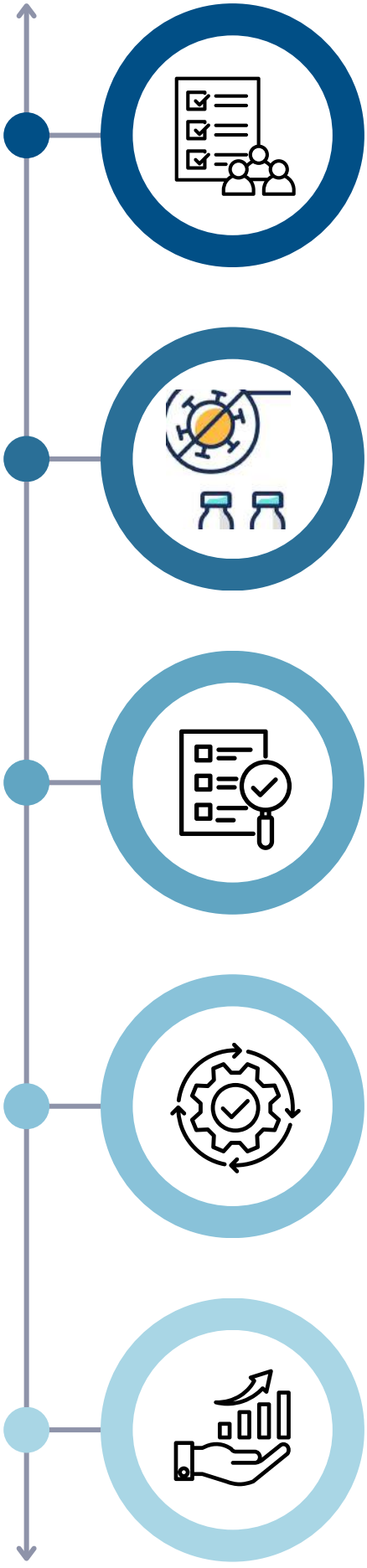
Registration of Competent Person

Technical Authorization for manufacture

Technical Authorization for sale and distribution

Clinical Trial Authorization

Marketing Authorization



Import and export Authorization

Lot Release for vaccines and biologicals

Issuance of cGMP, CoPP and FSC

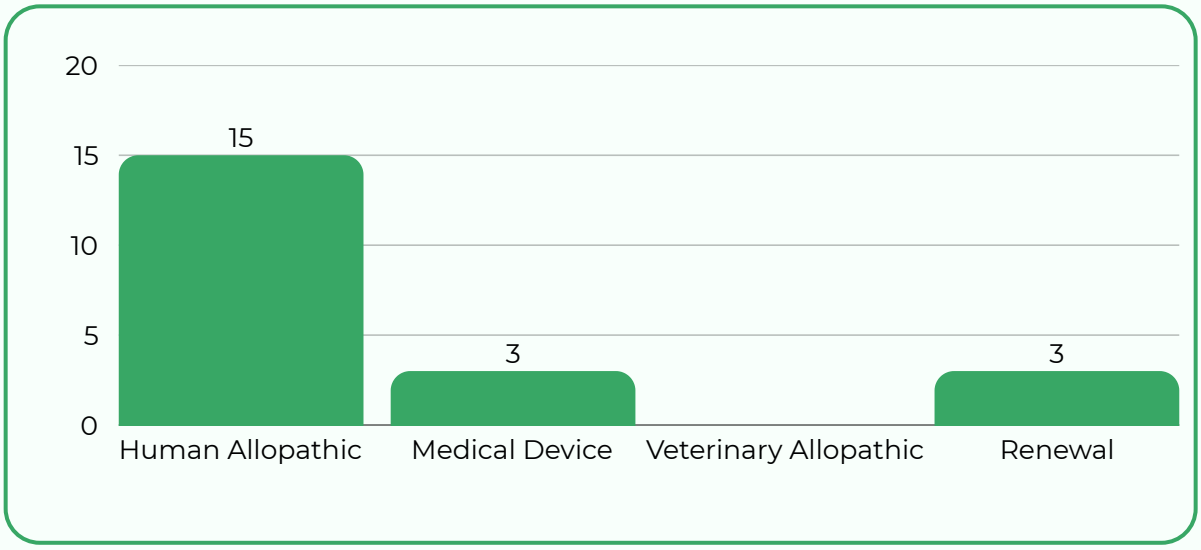
Clearance for advertisement

Disposal of medical wastes

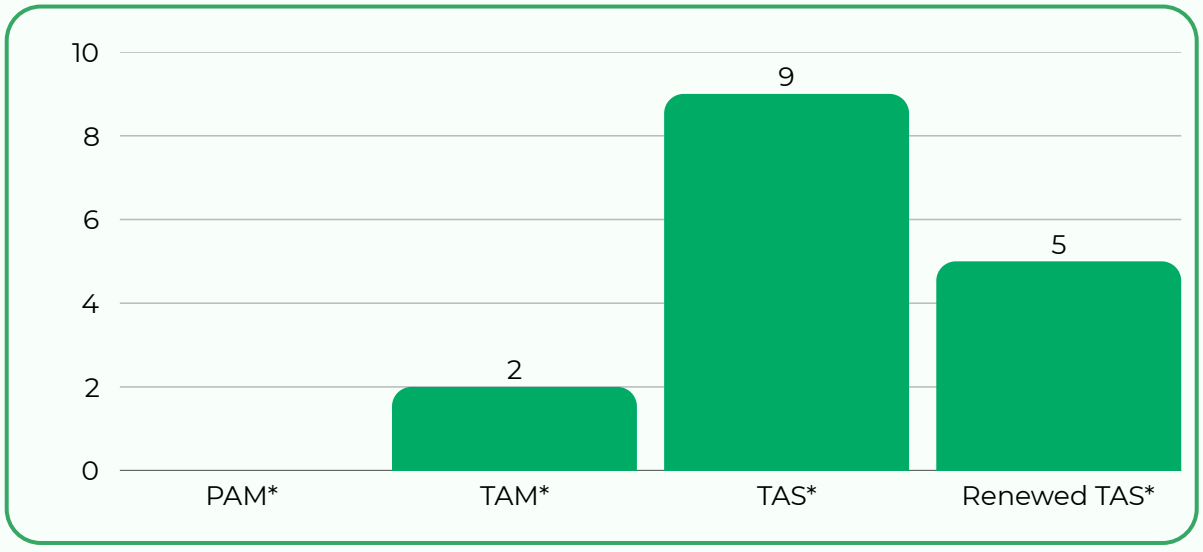
OUR YEAR IN NUMBERS

July 2024-June 2025

Registered Competent Person

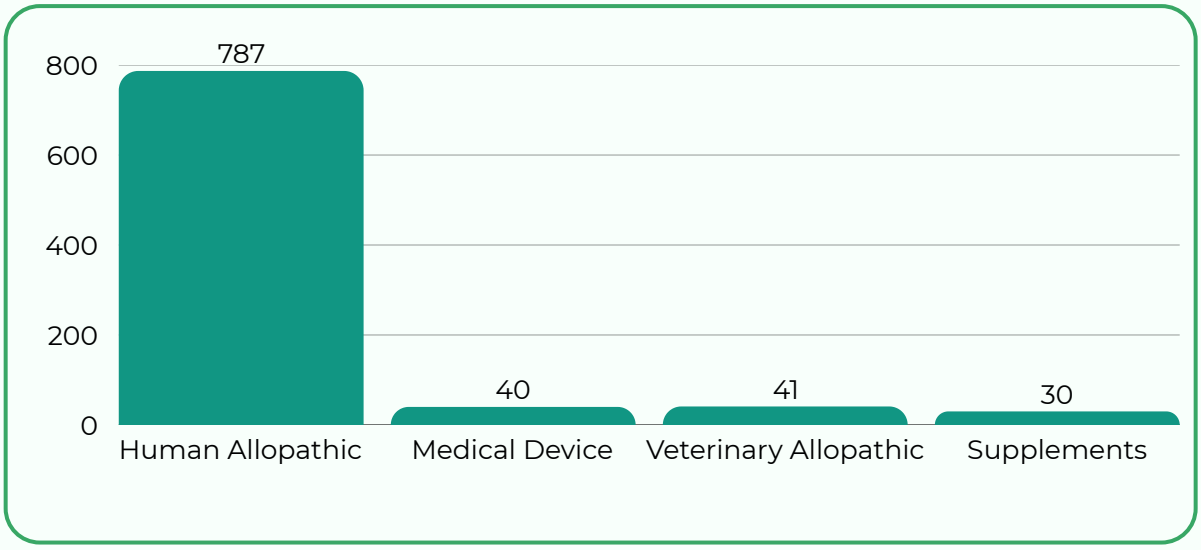


Number of Technical Authorizations issued

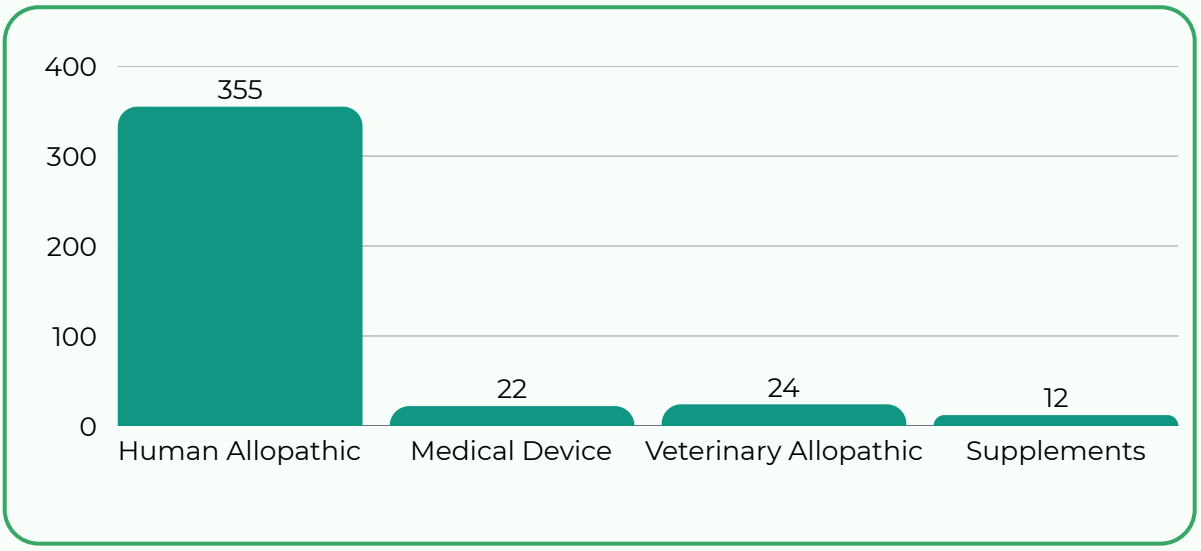


PAM*: *Provisional Authorization for Manufacture*
TAM*: *Technical Authorization for Manufacture*
TAS*: *Technical Authorization for Sale and Distribution*

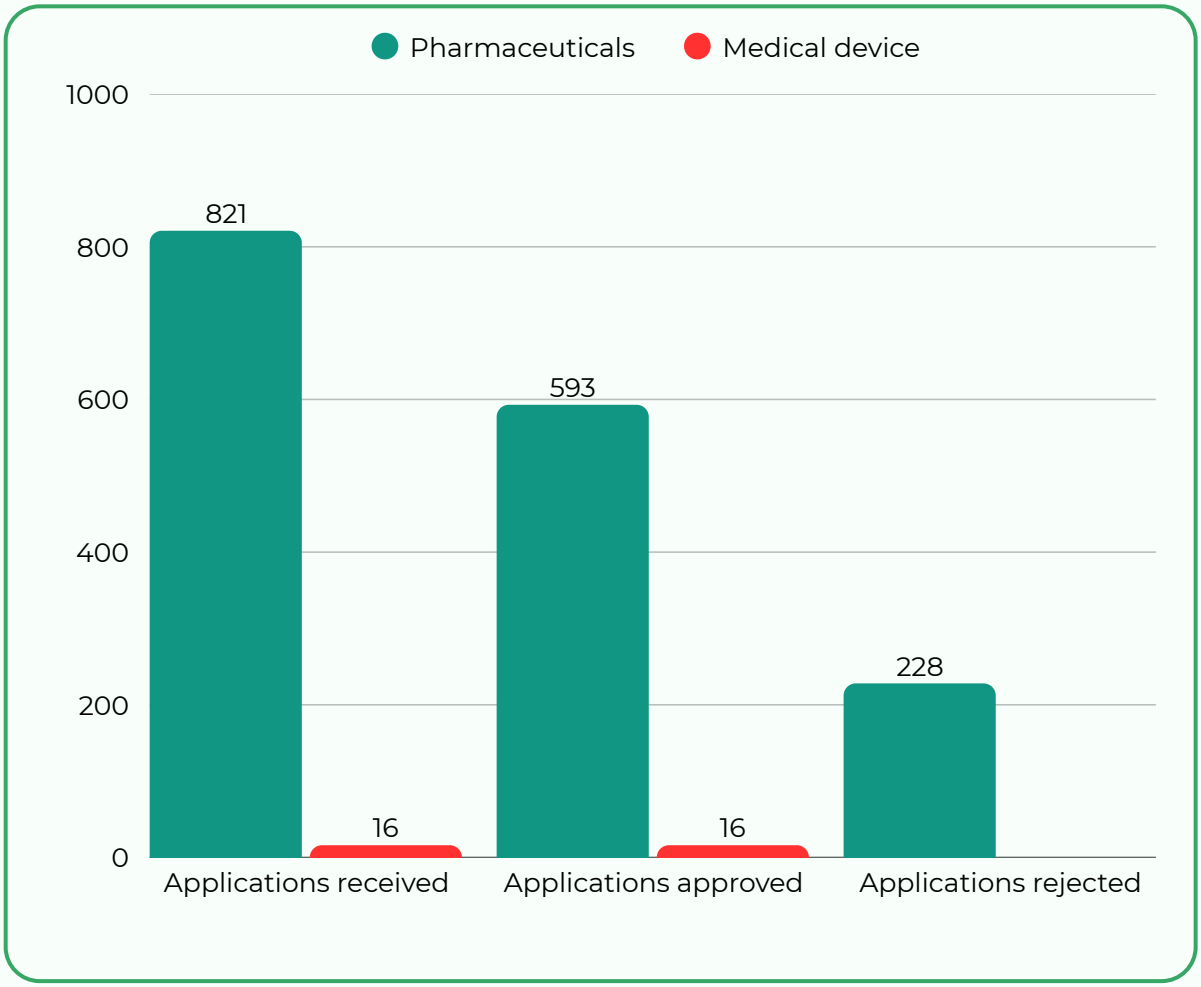
Application received for Marketing Authorization of medicinal products



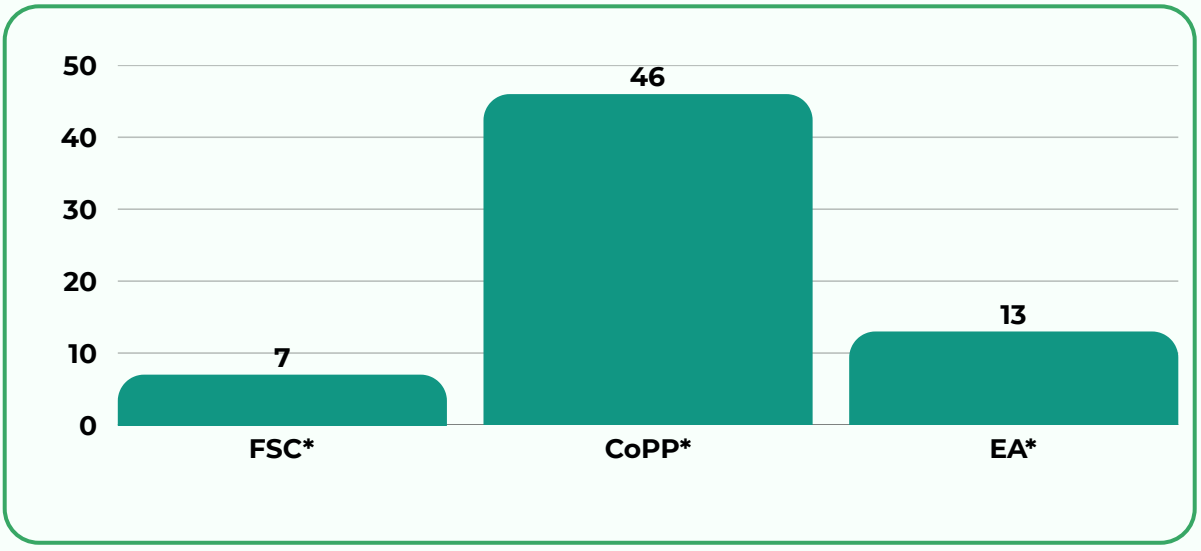
Approved Marketing Authorization of medicinal products



Application for Import Authorization of medicinal products

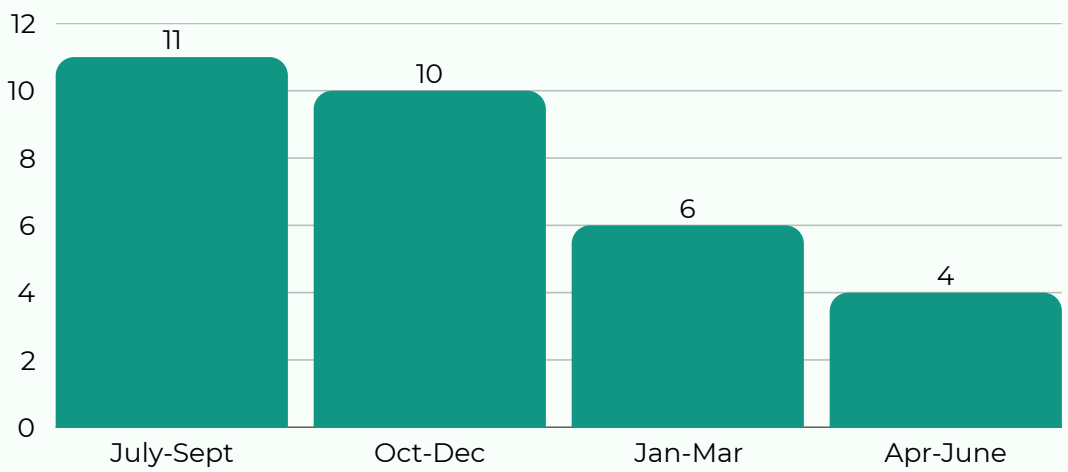


Export certificates issued

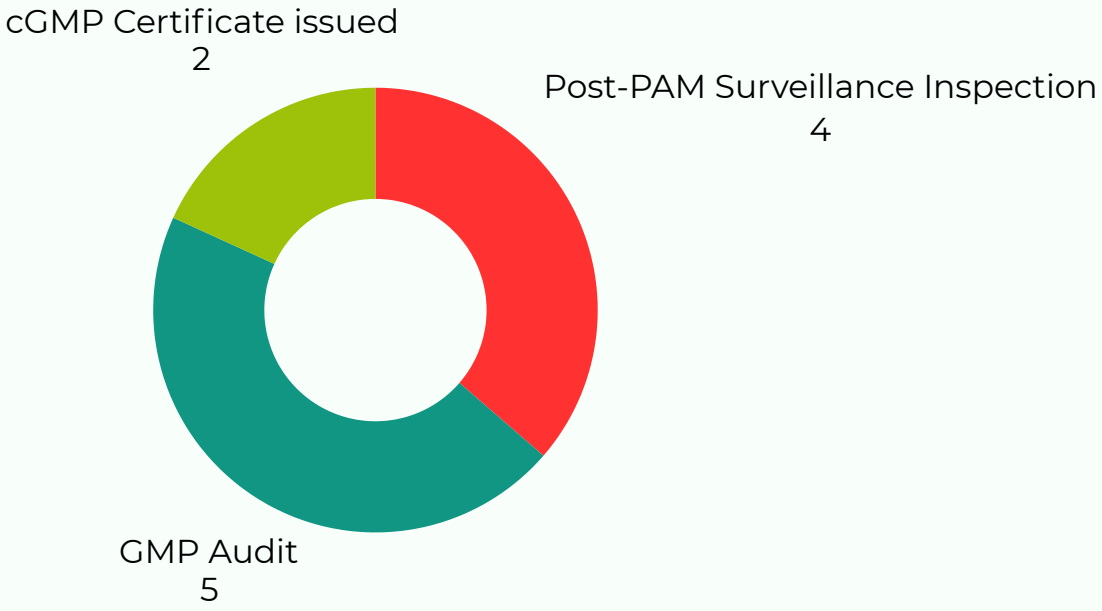


***FSC*:** *Free Sale Certificate*
***CoPP*:** *Certificate of Pharmaceutical Product*
***EA*:** *Export Authorization*

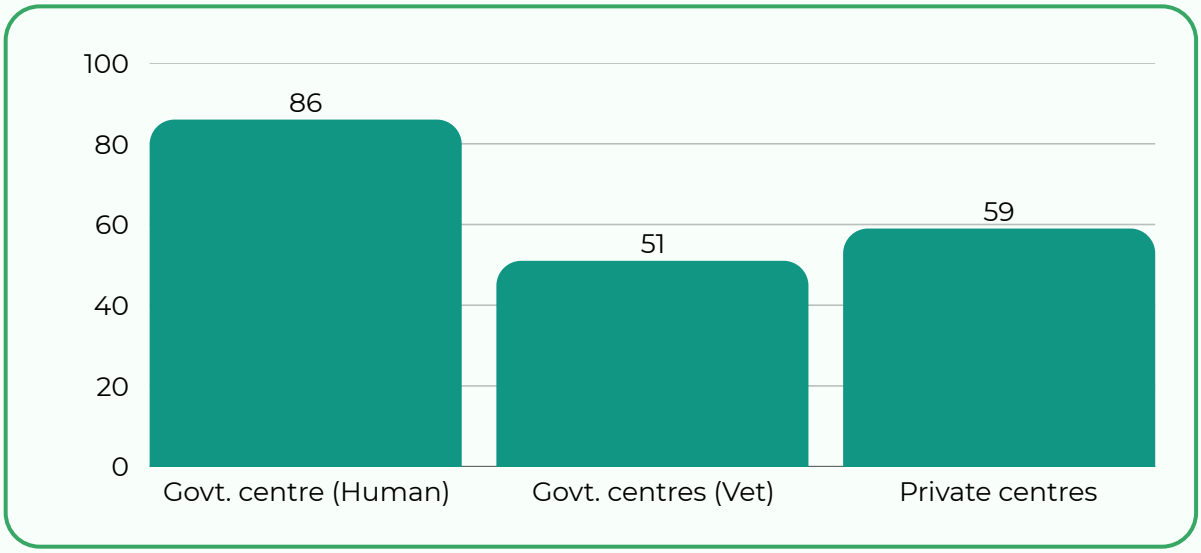
Lot Release conducted for vaccines



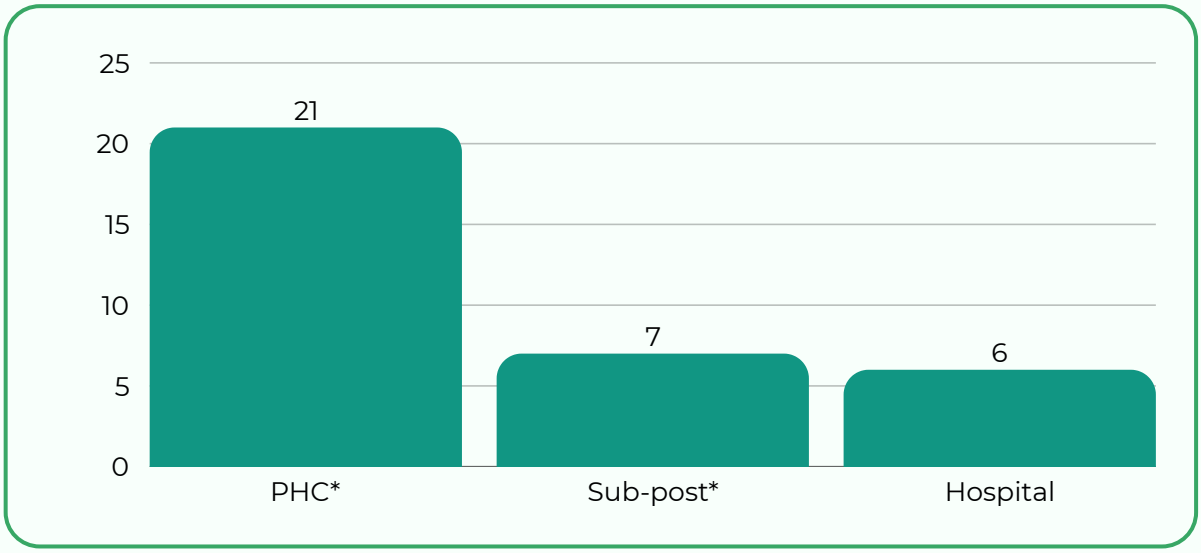
Regulatory Inspection of manufacturing firms



Regulatory Inspection of premises involved in sale and distribution of medicinal products

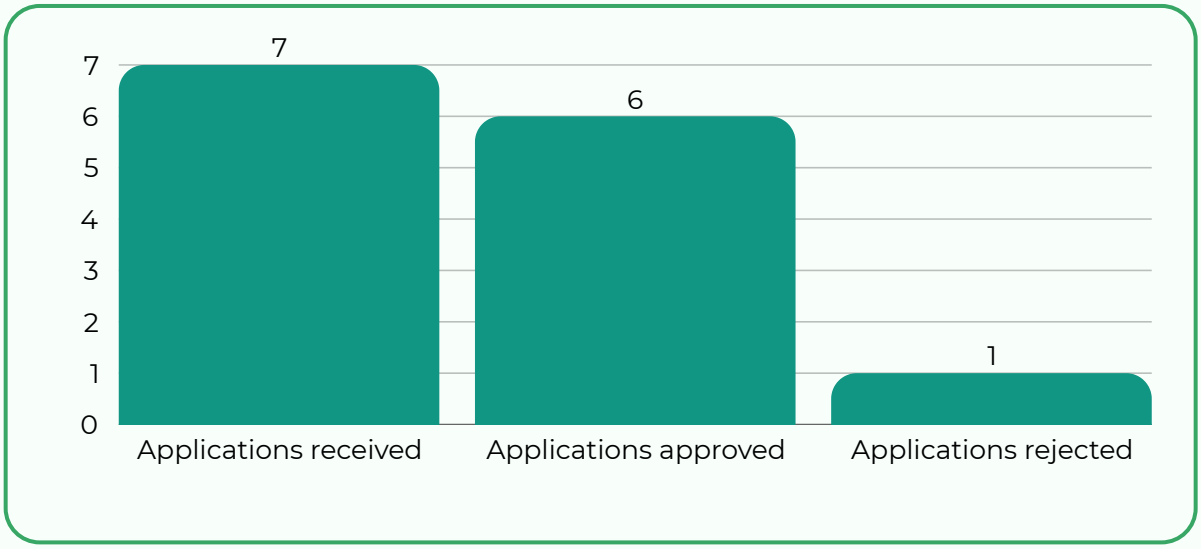


Self Inspection

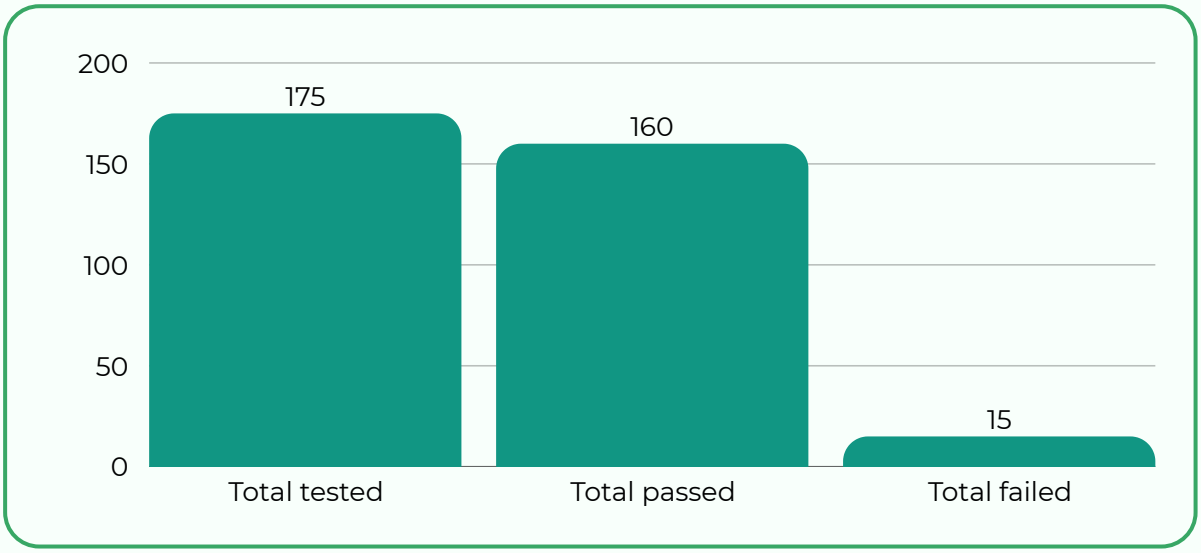


PHC*: *Primary Healthcare Centres*
Sub-post*: *a peripheral health facility established under the Ministry of Health to extend primary healthcare services to remote and hard-to-reach communities.*

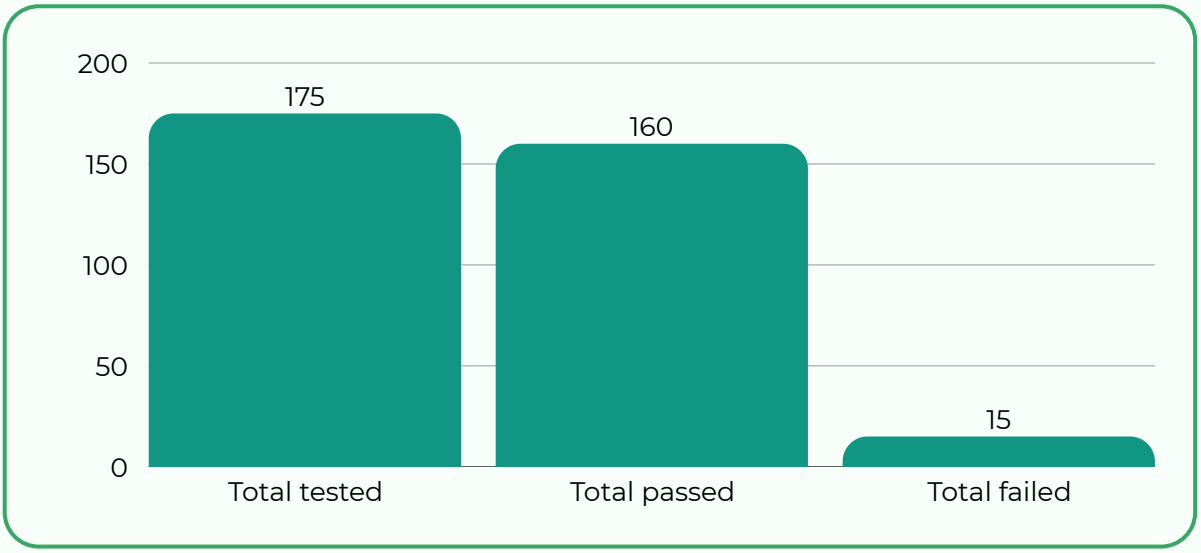
Clearance of advertisement



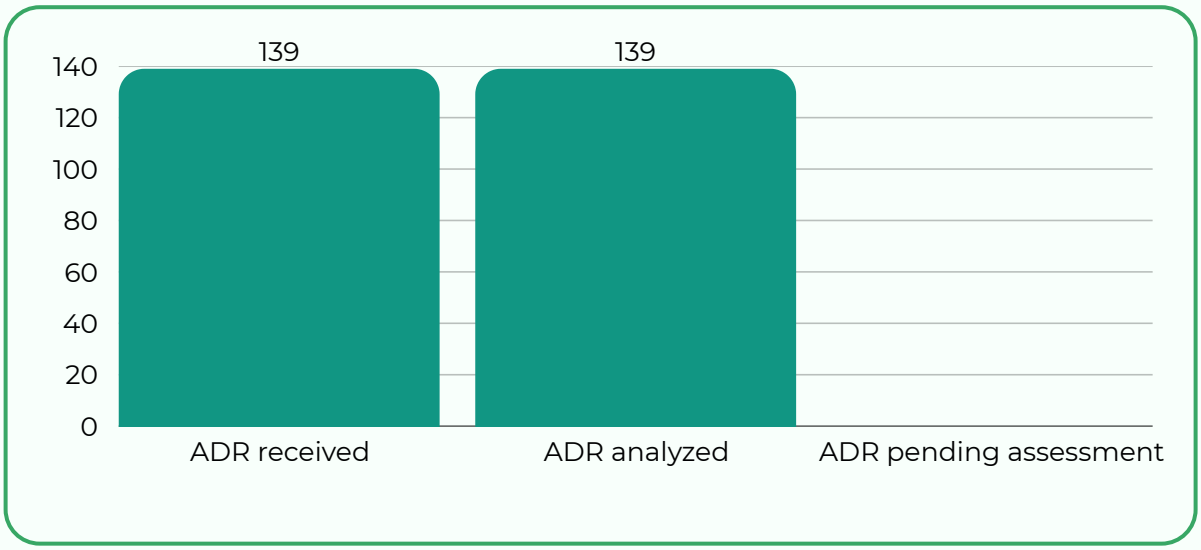
Testing of medicinal products using GPHF mini-lab test kits



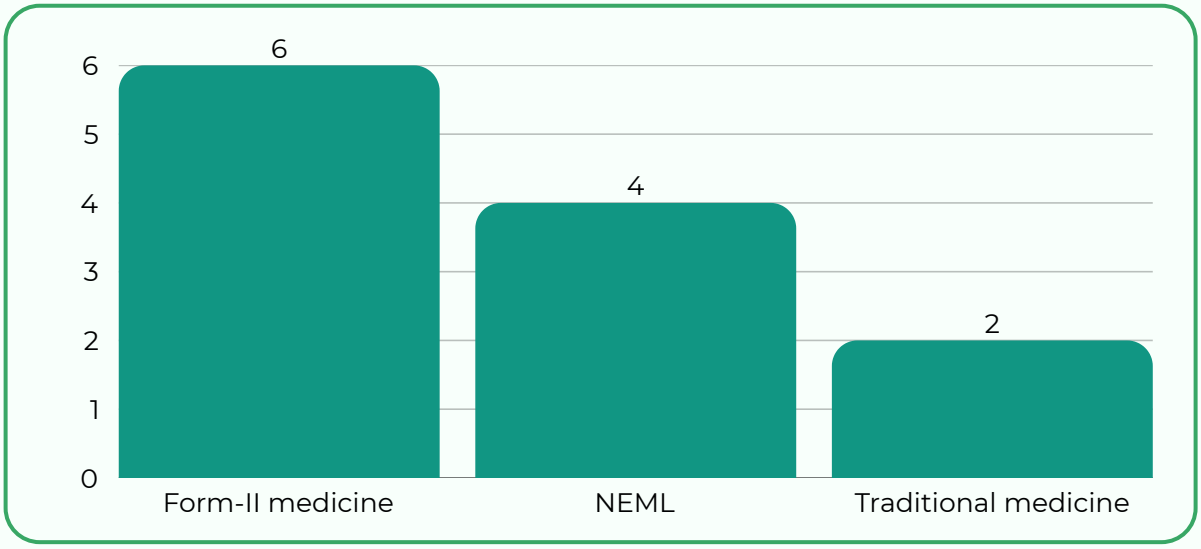
Laboratory testing of medicinal products



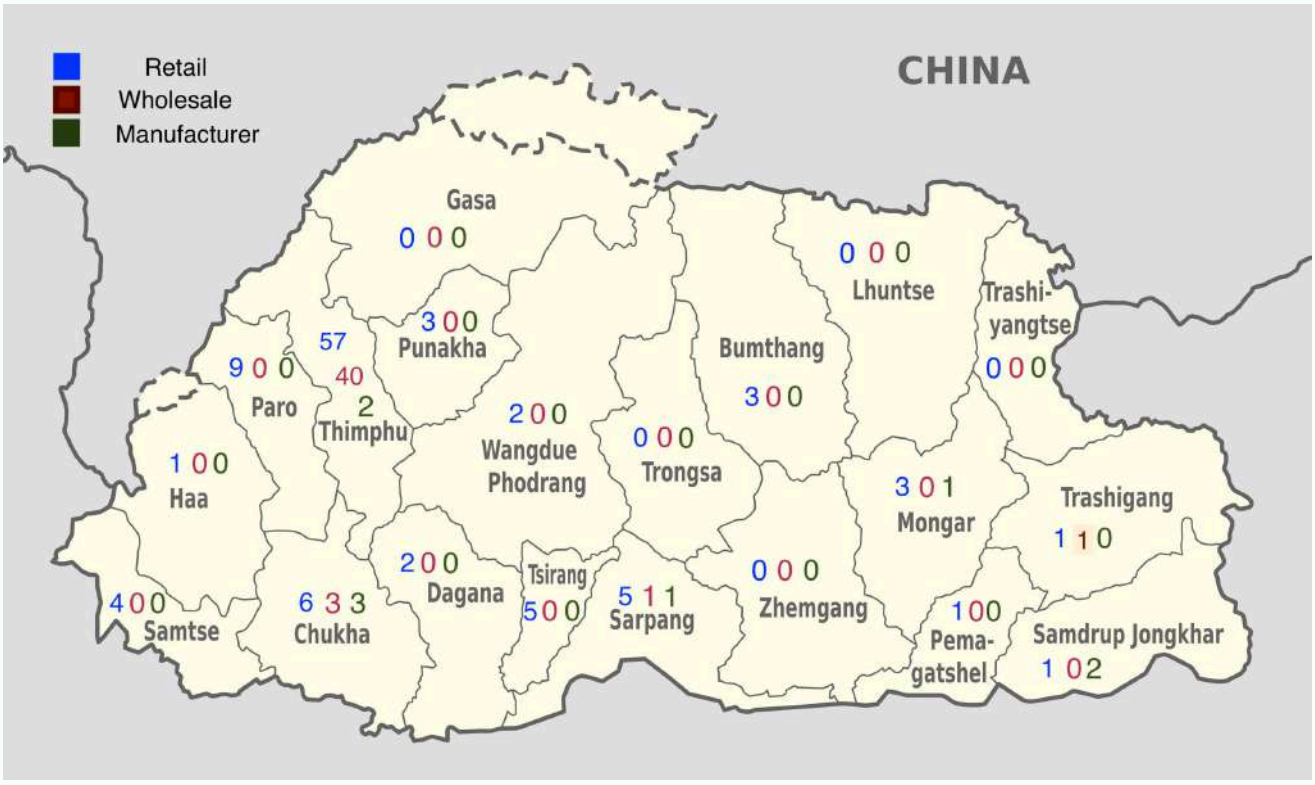
Adverse Drug Reaction (ADR) - Causality assessment



Product Recalls



Distribution of authorized premises



07 NEW GUIDELINES FOR THE REGULATION OF MEDICINAL PRODUCTS

Guideline for Market Authorization of medicinal products via standard route, 2025 - Book I

Guideline for regulatory preparedness on the oversight of emergency use authorized medical products 2025

Guideline for Market Authorization of medicinal products via abridged route, 2025 - Book II

Guideline for Post Approval Variation of Market Authorization of Medicinal products, 2025 - Book III

Guideline for approval of premises for sale and distribution of medical products

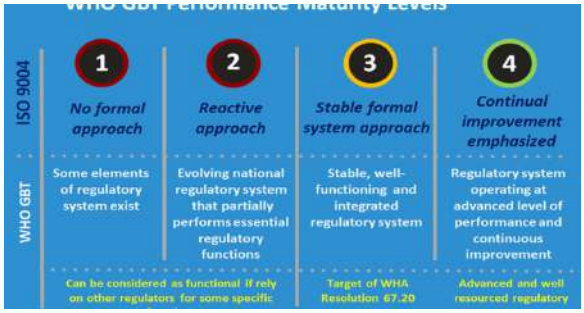
Guideline for Collaborative Registration Procedure (CRP) for pharmaceutical and vaccines 2025

Guidelines for Registration of Combination Products

Advent of Global Benchmarking Tool for Veterinary medicines in Bhutan

Medicines are an integral part of public healthcare and constitute a significant portion of the government's expenditure in Bhutan. Unlike other commodities, pharmaceutical products, whether for human or animal use, must meet the highest standards of quality, safety, and efficacy. A compromise in any of these three parameters can lead to therapeutic failure, worsening of disease, development of resistance, and, in severe cases, death.

To safeguard public health, most countries establish a National Regulatory Authority (NRA), mandated to ensure that only safe and effective medicines are available on the market. Regardless of resource levels, nations large and small, maintain NRAs to regulate the manufacture, import, storage, sale, and distribution of medicines. In the Himalayan kingdom of Bhutan, this responsibility lies with the Bhutan Food and Drug Authority (BFDA).



In recent years, the pharmaceutical supply chain has grown increasingly complex, with raw materials sourced from one country, manufactured into finished products in another, and distributed to yet another. Given that Active Pharmaceutical Ingredients (APIs) and excipients may come from multiple vendors across various countries, it is clear that no NRA can operate effectively in isolation. Regulatory collaboration and harmonization have become essential.

Recognizing this need, the World Health Organization (WHO), following a 2014 World Health Assembly resolution on regulatory system strengthening, introduced the WHO Global Benchmarking Tool (GBT). This tool helps assess and strengthen NRAs globally, enabling them to improve regulatory performance and protect public health more effectively.

Bhutan has greatly benefited from this WHO initiative. Since beginning its WHO-GBT journey in 2019, the BFDA has worked toward becoming a stable, well-functioning, and integrated regulatory agency by 2027. The WHO-GBT process has provided Bhutan with a framework to strengthen its regulatory systems despite limited resources.

However, the WHO-GBT focuses solely on medical products for human use and does not encompass the regulation of veterinary medicines, an area also regulated by the BFDA. As WHO's mandate centers on human health, veterinary regulatory systems, especially in low-resource countries, often lack adequate support or global guidance.

In Bhutan, this challenge is evident, fewer than 30% of essential veterinary medicines are registered with the BFDA, largely due to low annual procurement volumes by the public sector. This regulatory gap has long needed attention.

To address this gap, the Veterinary Medicines Directorate (VMD) of the United Kingdom, in collaboration with the World Organization for Animal Health (WOAH), the Fleming Fund, and the European Union, has recently initiated a pilot self-assessment tool for veterinary medicine regulators. This initiative draws heavily from the WHO-GBT model but is tailored to the unique context of veterinary medicine regulation. It removes functions irrelevant to veterinary medicines and introduces new areas of focus. For instance, while the WHO-GBT defines nine core functions for human medicine regulation, the veterinary version defines eight removing the "Clinical Trials" and "Lot Release" functions and introducing "Batch Testing" instead.

For under-resourced NRAs like the BFDA, this development is significant. It provides structured guidance for veterinary medicines regulation and offers a roadmap for improvement. If successful, this pilot could evolve into a formal Veterinary Global Benchmarking Tool (vGBT) under the WOAH, similar to the WHO-GBT.

While the vGBT remains in its early stages, the BFDA eagerly anticipates its formal adoption into global regulatory frameworks. This would mark a major step forward in ensuring that both human and veterinary medicines are effectively regulated, even in small nations like Bhutan.

By Sonam Chophel

Enhancing Medical Device Safety: First Materiovigilance Workshop for Healthcare Professionals

Vigilance of medical products is a core regulatory function outlined by the World Health Organization (WHO) and a critical element of post-market surveillance. Within this context, materiovigilance the monitoring, reporting and prevention of adverse events associated with medical devices has emerged as a priority area for Bhutan, particularly as the nation continues to expand its regulatory oversight of medical devices. Medical devices were formally brought under regulatory scope in 2022, marking a significant step in Bhutan's commitment to ensuring the safety, quality and effectiveness of these products. However, as the regulation of medical devices is still in its early stages, there remains limited awareness and understanding of materiovigilance among healthcare professionals. Unlike pharmacovigilance, which is more widely recognized, materiovigilance is a relatively new concept in the Bhutanese healthcare system.

To bridge this gap, the Medical Product Division (MPD) undertook a targeted initiative to build national capacity in materiovigilance. A series of training sessions were conducted for healthcare professionals across the country, focusing on the foundational principles of materiovigilance and practical skills for reporting medical device-associated adverse events (MDAEs) and device defects. Facilitated by regulators trained in materiovigilance, these sessions equipped participants with essential knowledge to support the safety monitoring of medical devices. Participants were introduced to newly developed MDAE reporting forms and were encouraged to actively report any adverse events or defects encountered in their daily practice.

A key objective of the training was to promote a culture of reporting and to establish the groundwork for a functional and effective materiovigilance system. This initiative represents an important step towards robust post-market surveillance. Trained healthcare professionals were also encouraged to cascade the knowledge gained to their peers within hospital settings, thereby fostering broader awareness and building institutional capacity. This peer-sharing approach is expected to significantly enhance the national materiovigilance landscape by ensuring that more health workers are capable of identifying and reporting device-related issues. Recognizing the pivotal role of biomedical engineers in ensuring the safety and functionality of medical equipment, the training also emphasized the need for stronger collaboration between healthcare institutions and regulatory authorities. Biomedical engineers responsible for inspecting, maintaining, and troubleshooting medical devices are integral to the early detection of defects and adverse events.

Through this concerted effort, Bhutan has taken a meaningful step toward establishing a comprehensive materiovigilance framework. As the country continues to navigate the evolving landscape of healthcare technology, these foundational activities will ensure that medical devices remain safe and effective for all users.

By Kinley Penjor Tshomo

Surveillance Audit by Bhutan Standard Bureau (BSB)

A Surveillance Audit conducted by the Bhutan Standards Bureau (BSB) is a vital component in maintaining internationally recognized certifications such as ISO 9001 (Quality Management System). These audits are mandatory for retaining certification and demonstrating continuous compliance with the applicable standards.

Following the initial certification audit, which was conducted in October 2024, surveillance audits are carried out once or twice a year during the standard three years certification cycle. Their main purpose is to ensure that the organization's management systems remain effective, current, and aligned with both internal operations and external requirements.

During each audit, the BSB audit team conducts a comprehensive review of the organization's documented management system. They assess how well the system is implemented in practice, verify that any previously identified nonconformities have been addressed, and evaluate the organization's ability to adapt to internal changes (such as staffing or process modifications) and external changes (such as legal, regulatory, or market shifts).

One of the key benefits of a surveillance audit is its ability to identify potential risks or weaknesses early, before they evolve into significant issues. Moreover, as these audits are performed by an impartial external body, they offer a valuable, objective perspective that supports continuous improvement.

Ultimately, BSB's surveillance audits reinforce the organization's credibility and provide assurance to customers, partners, and regulatory bodies that certified processes are consistently maintained not just at the point of initial certification, but throughout the entire certification period.

By Loden Jamtsho

Introduction to Collaborative Registration Procedure

National Regulatory Authorities (NRAs) play a pivotal role in safeguarding public health by ensuring that safe, effective, and quality-assured medical products including medicines, vaccines, and medical devices are available to their populations in a timely manner. One of the primary mechanisms through which NRAs fulfill this mandate is the issuance of marketing authorizations, which confirm that a product meets regulatory standards before it can be distributed and used.

However, for NRAs with limited resources, such as the Bhutan Food and Drug Authority (BFDA), conducting independent, full-scale evaluations of every medical product presents significant challenges. These challenges stem from constrained technical expertise, limited financial and human resources, and the increasing complexity of modern pharmaceuticals particularly biologics, advanced therapies, and products with intricate global supply chains.

To overcome these barriers, reliance-based regulatory approaches have emerged as a practical and efficient solution. These approaches allow NRAs to leverage the evaluations and approvals of reliable reference authorities such as the World Health Organization and other stringent regulatory authorities rather than duplicating assessments.

Among the most effective reliance-based mechanisms is the Collaborative Registration Procedure (CRP), a facilitated regulatory pathway (FRP) that enables NRAs to expedite product approvals by relying on pre-existing assessments from WHO-PQ and other CRP-participating authorities. Under this framework, NRAs gain access to unredacted evaluation reports, inspection findings, and risk-benefit analyses reports, significantly reducing review timelines while maintaining rigorous safety and efficacy standards.

Recognizing the importance of timely access to essential medicines, the BFDA, has actively integrated reliance pathways into its regulatory framework. By participating in initiatives like the CRP, Bhutan ensures that critical medical products such as vaccines for immunization programs, treatments for non-communicable diseases, and novel therapies are registered efficiently without compromising on quality.

By Sangay Choden

Regional hybrid workshop to improve regulation of medical devices and cGBT-Plus for Medical Devices

Access to medical devices, including in vitro diagnostics and assistive technologies, is essential for achieving Universal Health Coverage (UHC), as these products support healthcare from prevention and diagnosis to treatment, rehabilitation and palliation. However, weak regulatory systems can pose significant barriers to accessing safe, effective and quality medical devices. To address this, the World Health Organization (WHO), under the mandate of WHA Resolution 67.20, supports countries in strengthening their regulatory capacity through the promotion of good regulatory practices, international cooperation and reliance mechanisms.

Given the complexity and diversity of medical devices compared to other health products like medicines or vaccines, regulatory oversight of these technologies presents unique challenges. In response, the South-East Asia Regulatory Network (SEARN) 2024–2025 Work Plan prioritizes building the capacity of National Regulatory Authorities (NRAs) for effective medical device regulation. Aligned with this objective, a regional workshop held in February 2025 aimed to enhance participants' understanding of the WHO Regulatory System Strengthening (RSS) programme, the Global Benchmarking Tool Plus Medical Devices (GBT+MD), the Global Model Regulatory Framework for Medical Devices and WHO guidance on post-market and market surveillance.

The GBT+MD is an extension of WHO's broader Global Benchmarking Tool framework, developed specifically to evaluate and strengthen national regulatory systems for medical devices. While it shares foundational regulatory principles with other health products, it is tailored to the unique characteristics of medical devices. The latest version, GBT+MD Revision VI+MD version 2, released in December 2024, defines six regulatory functions under the overarching national regulatory system (RS) framework and includes a glossary and fact sheet to clarify key terms and concepts.

Currently, Bhutan's regulatory focus is largely limited to pre-market control of medical devices, with post-market control, including market surveillance, yet to be established. A key takeaway from the workshop was expert guidance on developing an effective post-market surveillance system suited to Bhutan's context. Additionally, guiding documents that can be adapted to our context were shared. Stakeholder engagement, particularly through consultations with suppliers, was emphasized as a crucial regulatory approach for strengthening post-market surveillance. Another significant insight was the value of the cGBT+Medical Devices tool in assessing Bhutan's current regulatory maturity and identifying areas for development across both pre-market and post-market functions. This tool will be instrumental in informing strategic planning and guiding regulatory improvements. Furthermore, the workshop highlighted the importance of leveraging reliance mechanisms, which are particularly beneficial for small regulatory authorities like Bhutan. Participants gained a deeper understanding of prioritizing reliance pathways, such as the WHO Collaborative Registration Procedure and reliance on Stringent Regulatory Authorities (SRAs). Adopting these mechanisms will not only improve access to quality, safe, and performant medical devices but also bolster Bhutan's regulatory capacity through access to WHO evaluations and global best practices.

By Kinley Penjor Tshomo

Workshop on Implementation of Good Reliance Practices for Vaccines Regulation

"The workshop focused on enhancing regulatory efficiency, fostering collaboration and ensuring timely access to safe, quality and effective vaccines."

A four-day regional workshop organized by WHO-SEARO was held in Pune, India from 25–28 June 2024 to strengthen the capacity of National Regulatory Authorities (NRAs) in implementing Good Reliance Practices (GRP) for regulating vaccines developed with novel technologies. Three regulatory officers from the Medical Products Division, Bhutan Food and Drug Authority participated in the event.

The workshop focused on enhancing regulatory efficiency, fostering collaboration and ensuring timely access to safe, quality and effective vaccines. Activities included expert-led sessions, case studies, site visits and group exercises. Participants explored reliance mechanisms in dossier evaluation, regulatory inspection practices (in particular Good Manufacturing Practices Audit) and regulatory strategy development.

Site visits to the Serum Institute and Gennova Biopharmaceuticals Ltd. allowed hands-on assessments and discussions on the advantages of on-site versus virtual inspections. Sessions led by technical experts from WHO Headquarters, Therapeutic Goods Administration, Australia, Central Drugs Standard Control Organization, India and European Directorate for the Quality of Medicines & HealthCare addressed on frameworks and collaborative approaches such as joint assessments and mutual recognition.

Participants gained practical experience through mock marketing authorization exercises, reinforcing the application of GRP. The workshop highlighted the value of reliance-based strategies and virtual inspections to maximize limited resources while maintaining regulatory standards, contributing to harmonized and efficient vaccine regulation in the region.

By Gyelwa Kuenzom

STAKEHOLDER CONSULTATION MEETING FOR FY 2024-2025

The Medical Product Division of the Bhutan Food and Drug Authority (BFDA) convened its first stakeholder consultation meeting for the financial year 2024–2025 from 03–05 February 2025. The meeting was organized with the overarching objective of strengthening collaboration, enhancing regulatory transparency and improving operational efficiency in the oversight of medical products. Central to this initiative was the goal of fostering an inclusive dialogue between the Authority and key stakeholders including wholesalers, retailers and other relevant actors in the medical product supply chain—to ensure a more responsive and cohesive regulatory environment. A primary focus of the consultation was to facilitate the timely dissemination of regulatory updates, promote mutual understanding of compliance expectations and provide a structured platform for stakeholders to contribute to the regulatory reform process. The meeting served as a critical venue for presenting proposed amendments to existing regulatory frameworks, deliberating on their practical implications and addressing real-world implementation challenges.

Significantly, the discussions highlighted the recurring challenges faced by stakeholders in both the pre-market and post-market phases of medical product regulation. These insights underscored the importance of sustained engagement and collaborative problem-solving to ensure the safety, quality and effectiveness of medical products in Bhutan.

By Sarim Tshering

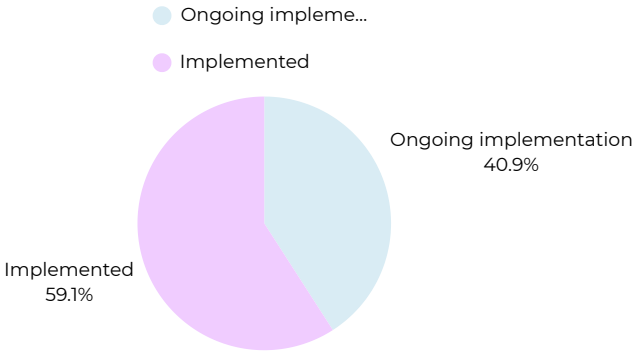
UPDATE - GLOBAL BENCHMARKING JOURNEY OF THE BFDA

It has been five years since the Bhutan Food and Drug Authority (BFDA) embarked on its Global Benchmarking journey, participating in the World Health Organization (WHO)'s assessment for National Regulatory Authorities (NRAs). The WHO Global Benchmarking Tool (GBT) has played a pivotal role in guiding Bhutan's efforts to strengthen its regulatory systems for medical products. Following a pre-benchmarking mission in 2022 by the WHO assessment team, a total of 233 Institutional Development Plans (IDPs) were generated. These IDPs serve as a roadmap for the BFDA to work toward achieving Maturity Level 3, a recognition signifying that the authority functions as a stable, well-integrated, and effective regulatory system. The formal benchmarking assessment is tentatively scheduled for 2027.

Over the past five years, BFDA has made significant strides in implementing the IDPs. Below is a summary of progress based on the nine core functions outlined in the WHO-GBT:

1. **Regulatory system**

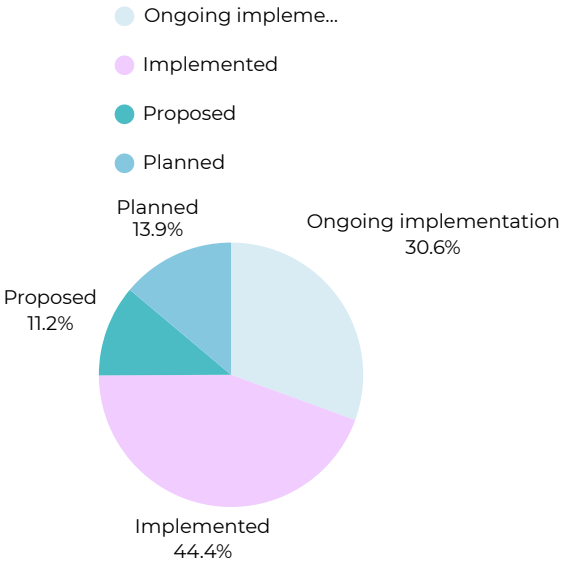
This function refers to the legal and policy framework that enables the NRA to fulfill its regulatory responsibilities. During the pre-benchmarking assessment in 2022, the former Drug Regulatory Authority (DRA) was assigned Maturity Level 1 for this function, with 44 IDPs generated.



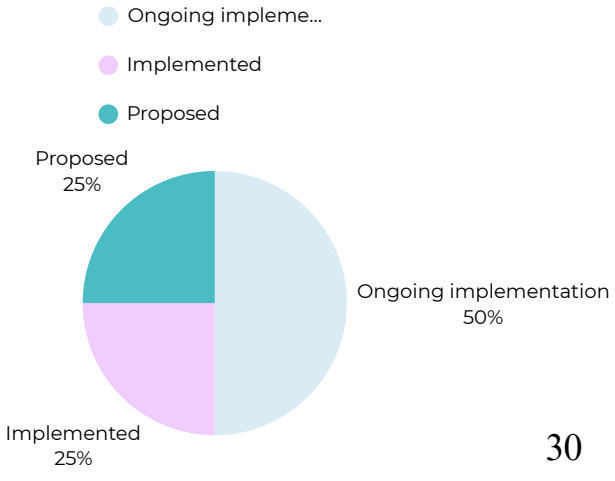
Most of the recommendations were tied to revisions of the Medicines Act of the Kingdom of Bhutan 2003 and the Bhutan Medicines Rules and Regulations 2019. The Medical Products Division (MPD) initiated efforts to revise these legal instruments in line with WHO-GBT recommendations. The revised regulation, titled Bhutan Medicines Rules and Regulation 2025, was presented to the Drug Technical Advisory Committee in May 2025 and is pending endorsement by the BFDA Governing Board later this year. However, the Medicines Act is yet to be amended. To date, approximately 60% of the IDPs under this function have been implemented.

2. Market Authorization and Vigilance

Under the **Market Authorization** function, 36 IDPs were generated, mainly related to the development of technical guidelines and procedures aligned with international standards. Since the pre-benchmarking exercise, five new technical guidelines under Market Authorization have been developed.



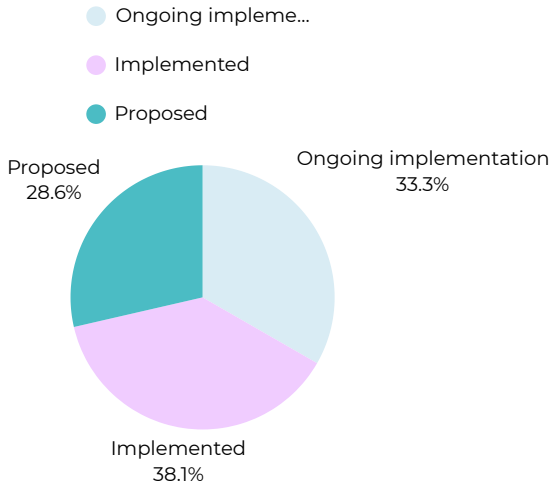
In the **Vigilance** function, 40 IDPs were identified. Key issues included unclear stakeholder roles in pharmacovigilance, particularly among the Vaccine Preventable Diseases Program (VPDP), manufacturers, and suppliers. In response, BFDA has strengthened collaboration with VPDP in Adverse Events Following Immunization (AEFI) reporting and has developed comprehensive Pharmacovigilance Guidelines clarifying stakeholder roles in product recalls, adverse drug reactions, and AEFI.



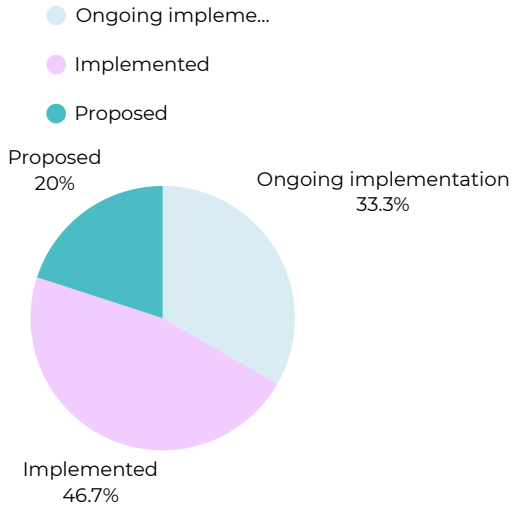
Implementation rates for these functions are strong, with 74% of IDPs under Market Authorization and 73% under Vigilance either implemented or in progress.

3. Regulatory Inspection, Market control and Licensing Establishment

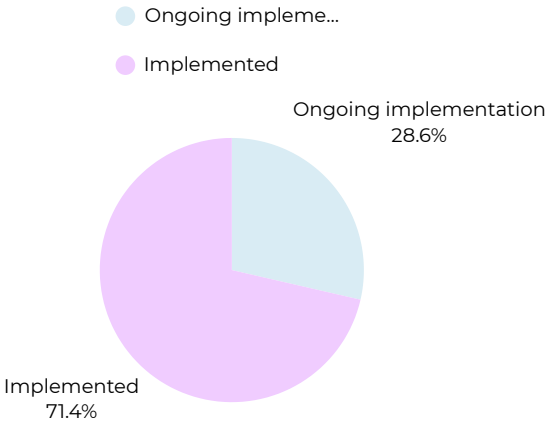
The **Regulatory Inspection** function had 21 IDPs, over 70% of which have been implemented or are in progress. These focused primarily on strengthening GxP inspection capabilities and incorporating comprehensive checklists into inspection SOPs.



Under the **Market Control** function, 15 IDPs were identified, 80% of which have been implemented or are underway. Key recommendations included the adoption of a strategic, risk-based sampling approach and the establishment of a post-market surveillance system. The need for a database to track approved medical product advertisements was also noted.

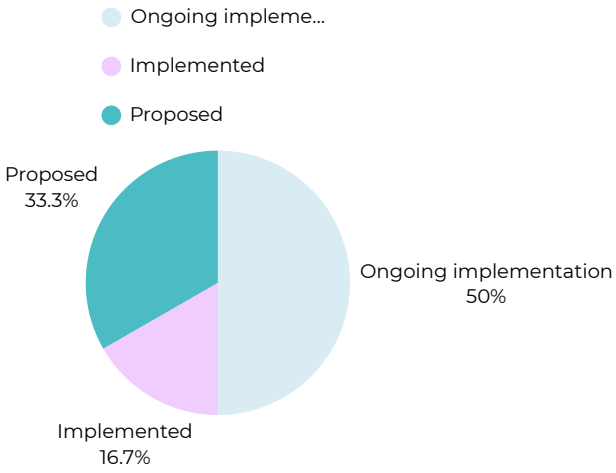


Licensing establishment was one of the few functions where BFDA achieved Maturity Level 2. Only seven IDPs were generated, all of which have been implemented or are nearing completion.

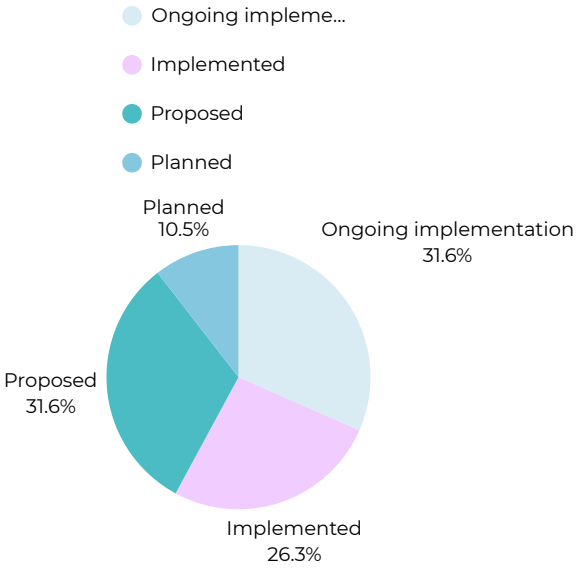


4. Laboratory Testing, Lot Release and Clinical Trial Authorization

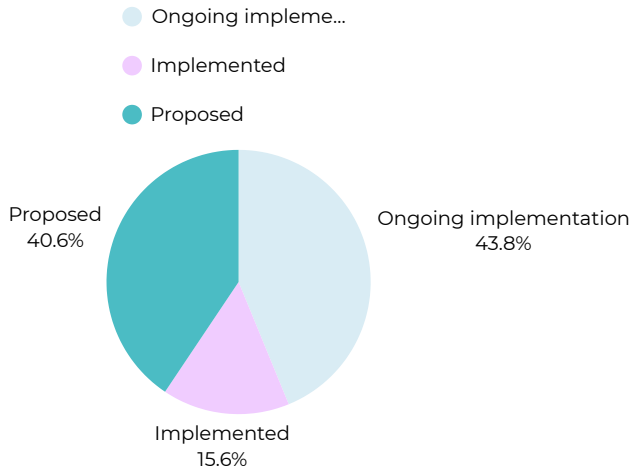
In the Laboratory Testing function, 12 IDPs were generated. Key recommendations included developing criteria for recognizing test results from other NRAs, NCLs, and international bodies; identifying competent laboratories for vaccines and biologicals; and adopting a risk-based testing strategy.



For Lot Release, 19 IDPs were generated. This function emphasized the need for BFDA to establish regulatory frameworks, operational procedures, and training programs for the release of biological products. It also called for legal provisions to exempt lot release in national emergencies and to formally recognize lot release certificates from trusted NRAs.

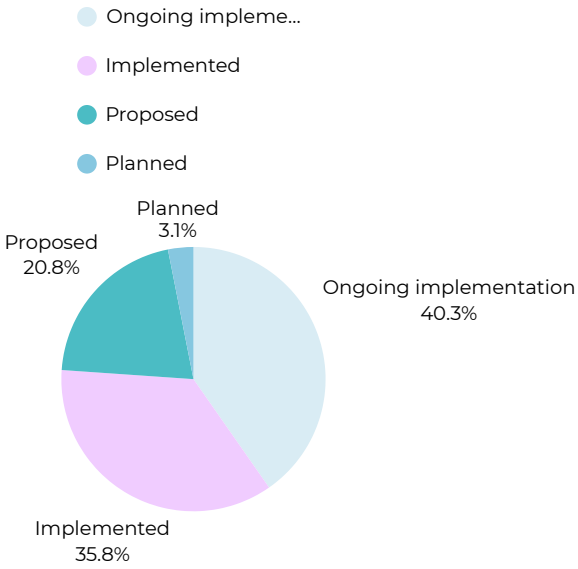


Under Clinical Trial Oversight, 32 IDPs were identified. The primary recommendation was to develop guidelines for trial oversight and conduct training to enhance institutional capacity. Given Bhutan's limited resources and expertise, it was advised that clinical trials be permitted only when aligned with national priorities.



Out of the total 233 Institutional Development Plans (IDPs) generated through the WHO Global Benchmarking Tool (GBT), approximately 75% have been implemented or are currently in progress. Despite this substantial progress, key challenges remain like the amendment of the Medicines Act and the need to strengthen technical capacity in areas such as clinical trial oversight, lot release, and laboratory testing.

While the Bhutan Food and Drug Authority (BFDA) has made significant strides, continued efforts are essential to fully meet the requirements ahead of the formal benchmarking of the Medical Products Division, scheduled under the WHO GBT framework.



By Sonam Chophel

PMDA-ATC & US FDA PEDIATRIC REVIEW SEMINAR

The PMDA-ATC and US FDA jointly conducted a four-day seminar on Pediatric Drug Development from 22 to 25 July 2024 at the PMDA office in Tokyo, Japan. This seminar brought together regulatory and technical experts from PMDA Japan, US FDA and other participating countries to explore the complexities of pediatric drug development. It provided an in-depth understanding of global regulatory frameworks, particularly those of the US FDA, PMDA, and the EU, highlighting differences in mandates and incentives that affect pediatric studies.

The key topics covered during the seminar were on the use of existing knowledge in pediatric development, the concept and application of pediatric extrapolation and ethical considerations in clinical trials involving children. It was emphasized that children's physiological and developmental differences necessitate specialized approaches in drug development. The principle of pediatric extrapolation using adult or reference population data to support pediatric drug approval was explored through ICH guidelines and real-world case studies, helping participants understand how to minimize unnecessary trials in children while ensuring safety and efficacy.

The seminar was a well balanced blend of expert presentations and interactive group work. Sessions on clinical pharmacology provided critical insights into how growth and development impact drug metabolism and dosing in children. Ethical aspects, particularly the need to reduce risk and avoid unnecessary exposure to research in the pediatric population were highlighted. Overall, the program offered participants a comprehensive and practical framework for applying scientific and regulatory principles in pediatric drug development, making it a valuable learning experience for regulators from different National Regulatory Authorities.

By Gyelwa Kuenzom

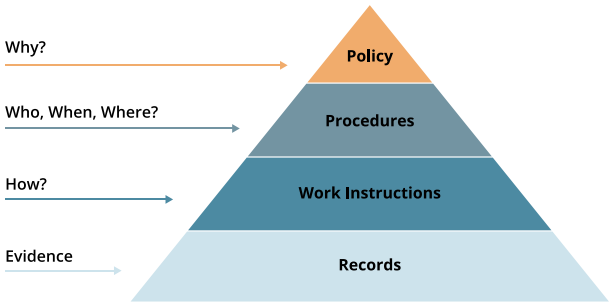
QUALITY MANAGEMENT SYSTEM THROUGH A FRESH LENS

As I joined the Medical Product Division of Bhutan Food and Drug Authority, my perception about the Quality Management system shifted from it being just a regulatory requirement to it being a vital tool for continuous improvement and innovation driven quality management.In the field of medical products , quality would refer to the ability of the product to meet its intended purpose and regulatory requirements and ensure safety, efficacy and reliability.

A well designed QMS will act as an integral framework in ensuring the quality , safety and efficacy (QSE) of medical products.In an area like the Medical Product Division where we deal with medical products directly impacting the public sector , having a robust QMS in place is crucial.

QMS integrates at every phase of the product life cycle starting from clinical trials to Post Marketing surveillance. One of the important models of QMS focuses on prevention and risk mitigation. Quality risk management is to identify, assess, control and review the risk that can impact quality and safety of products thereby enhancing product quality and improving patient safety. One example I learned is the corrective and preventive action (CAPA) which will serve as a useful tool to prevent recurrence of non-conformities in future. QMS aligns with international standards like the WHO guidelines, Good manufacturing practices and ISO guidelines.

Standard Operating Procedures are one of the indispensable parts of QMS. A SOP is a written of step by step procedures that tells us how to carry out a specific task.
A well developed SOP will guide each individual of their roles and responsibilities and will ensure that all the procedures are carried out consistently and in a controlled manner.
Just as the Quality Manager has the most important duty of managing the QMS activities, every team member has equal responsibility of upholding it and QMS ensures that all the staff are trained and confident about their responsibilities especially when there are new members joining the work. Documenting every activity is also an important aspect of QMS. With changing times, cloud based QMS platforms have enhanced transparency and traceability.



If we are to imagine an agency or a workplace without Quality Management System, It will be like stepping into a disorganised world filled with confusion and risks. Without a proper SOP to guide , every individual will start working in a manner that befits themselves leading to lack of accountability. Improper documentation can lead to question of transparency and difficulty of traceability. Audits will turn chaotic and risk will flow in leading to the worst case scenario of impacting product quality and the general public at last.
Building and maintaining a QMS is not just a technical task, its a shared responsibility.
As we move forward, we have to make quality a part of everything we do.

By Tenzin Wangmo

FIELD INSPECTION EXPERIENCE REPORT: ROUTINE AND RISK-BASED REGULATORY INSPECTION UNDER GSDP

In line with the Medicines Act of the Kingdom of Bhutan 2003 and the Bhutan Medicines Rules and Regulation 2019, the Drug Inspectors of the Medical Product Division (MPD), under the Bhutan Food and Drug Authority (BFDA), are mandated to inspect facilities engaged in the storage, sale, and distribution of medical products. These inspections are conducted to ensure compliance with regulatory standards and to uphold the safety, efficacy, and quality of medical products across the country.

As part of the routine regulatory inspection activity under the Good Storage and Distribution Practices (GSDP), I had the opportunity to participate in field inspections led by Mr. Guru as Lead Inspector. For these routine inspections, three teams were deployed, each composed of a lead inspector and a newly recruited regulatory officer. The teams were deployed to three Dzongkhags: Tashiyangtse, Zhemgang, and Lhuentse. Additionally, the teams assigned to Tashiyangtse and Lhuentse collaborated to carry out inspections in Mongar Dzongkhag. Notably, inspections in Mongar were conducted based on a risk-based approach, unlike the routine inspections in other districts.

Prior to deployment, our teams developed a detailed inspection plan, reviewed the working instructions, and signed Conflict of Interest declarations to uphold transparency.

I was part of the team deployed to Lhuentse Dzongkhag.The inspection commenced on 7th April 2025, with travel to Mongar and Lhuentse. The initial days were spent in orientation meetings with relevant stakeholders such as the Dasho Dzongdag, LPO and CMO, followed by the inspection of DVH. From 10th to 28th April, a total of 22 health facilities in Lhuentse were inspected, including the Lhuentse Hospital. We covered both human health facilities (Hospitals and Primary Health Centers) and veterinary establishments, including the Dzongkhag Veterinary Hospital and Renewable Natural Resource and Extension Centers (RNRECs). At each site, inspections began with an opening meeting with the respective health officials. These sessions included sensitization on several key updates:

1. The transition from DRA to MPD and its merger with other divisions under BFDA;
2. The new Bhutan Medicines Rules and Regulation 2025, which aims to standardize enforcement across both private and government premises unlike the 2019 version;
3. The importance of reporting Adverse Drug Reactions (ADRs), adverse events related to medical devices, and transfusion-related reactions; and
4. The renaming of the term “Non-Drugs” to “Medical Devices,” and clarification that these will now be regulated with the same rigor as pharmaceutical products.

During the inspections, we visited every relevant unit within the premises, including medical stores, dispensaries, compounding areas, general wards, MCH units, emergency rooms, and Traditional Medicine Units, essentially any area where medicinal products were stored or used.

Observations made during the inspections were classified into three categories:

❖ Critical Non-Conformities:
1. Dispensing of expired products.
2. Storage conditions exceeding 30±2°C or 70±5% humidity.
3. Lack of segregation for expired drugs and medical devices.
4. Absence of temperature monitoring for cold chain equipment.

❖ Major Non-Conformities :
1. Standard Operating Procedures (SOPs) that were outdated or not periodically reviewed.
2. Medicines stored in direct contact with the floor, lacking appropriate pallets.

❖ Other Observations:
1. Health staff not wearing name tags.
2. Illegible or missing signboards.

"Since this was my first field inspection, the experience was both eye-opening and enriching."

Alongside identifying non-compliances, we provided practical suggestions to the health workers on how to correct and prevent such issues. Our inspections were guided by the "Working Instructions for Government Facilities" checklist, ensuring consistency and completeness across all sites. We also conducted verification of Controlled Drugs (CD), provided guidance on proper CD handling, and emphasized the importance of documentation and appropriate disposal.

At the conclusion of each inspection, we issued an Instant Inspection Report and a Corrective and Preventive Action (CAPA) Form. Facilities were required to submit their CAPA responses with photographic evidence within 14 days. A closing meeting followed, during which we acknowledged the cooperation of the facility staff and encouraged them to seek clarifications or raise concerns.

Conclusion

Since this was my first field inspection, the experience was both eye-opening and enriching. Being part of a real-time inspection team allowed me to apply theoretical knowledge in a practical setting and understand the on-ground challenges health facilities face, especially in remote areas. I learned how to interpret and apply the Working Instructions for various Premises effectively and gained hands-on experience in identifying, categorizing, and documenting non-conformities. Observing how expired medicines and medical devices were being mishandled helped me appreciate the importance of awareness and continuous education among frontline health workers.

I also developed confidence in communicating regulatory expectations, conducting closing meetings, and sensitizing staff about critical topics like BMRR 2025, controlled drug management, and adverse event reporting. Most importantly, I learned that regulatory work is not just about enforcement, it's about supporting improvement, building trust, and contributing to safer healthcare delivery.

By Ugyen Chophel

Digital Transformation

As part of its commitment to improving public service delivery, the Bhutan Food and Drug Authority (BFDA) has undertaken significant digital transformation initiatives aimed at enhancing efficiency, transparency and client convenience.

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

AUTHORIZATION TO IMPORT MEDICAL PRODUCTS IN BHUTAN

Authorization No: BFDA-MPS-LK-2024-2025-0765

The following firm or individual is hereby authorized to import specified medical products to Bhutan for (sale and distribution/ personal use/special purpose/research/health camp) at the premises mentioned hereunder.

Product Details
As per attached list

Name of applicant: M/s. Capital Pharmaceuticals and Medical Supplies
Address of Premise: Jabila Plaza, Building, Changzamtog

This authorization is valid up to 28 November, 2025 (One year from the date of issue/till validity of product registration)

Conditions

1. The applicant shall inform the Authority in writing in the event of any change in the product specifications or other relevant particulars furnished in the original application.
2. The applicant shall import only the medicinal product(s) as per the above list or enclosed list.
3. The importer shall be responsible for timely removal in case of confirmed defective medicinal products from the market.

This authorization is granted vide application no. 135_20254602199 dated 08 May, 2025
of M/s. Capital Pharmaceuticals and Medical Supplies

Date of Print : 03 June, 2025 Medical Product Division

QR Code-based e-Certificates

BFDA has introduced QR code-enabled electronic certificates for services rendered through the Government-to-Citizen (G2C) platform. This eliminates the need for clients to physically visit the BFDA office for certificate collection, streamlining service execution and promoting contactless delivery.

Real-Time Application Updates

Applicants now receive real-time status notifications regarding their submissions, enhancing transparency and reducing the need for follow-ups or in-person inquiries.

Comprehensive Digitization

In addition to G2C services, BFDA is actively working to digitize all remaining services not currently integrated into the G2C system, demonstrating its broader commitment to e-governance.

These efforts reflect the Authority's ongoing commitment to digital governance and its vision of a more efficient, accessible, and citizen-focused regulatory framework.

By Dorji

Revision of Bhutan Medicine Rules and Regulation

The Medical Product Division (MPD) of the Bhutan Food and Drug Authority (BFDA) is governed by the Medicines Act of the Kingdom of Bhutan 2003 and the Bhutan Medicines Rules and Regulation 2019. These frameworks form the basis for regulating medicinal products in the country. However, gaps and deficiencies have been identified in regulations, particularly in areas critical to the WHO Global Benchmarking activities. Updating these provisions is essential to align with the Institutional Development Plan (IDP) and to advance in the maturity level of the National Regulatory Authority (NRA).

It's important to recognize and address the recommendations made by WHO experts regarding the IDPs in order to increase the maturity level of the Medical Product Division under the Bhutan FDA. Notably, the Bhutan Medicines Rules and Regulations, which were last revised in 2019, are set for their next update in December 2024, in line with best practices in Quality Management Systems (QMS).

A key issue in the current regulatory framework is the inconsistency in the enforcement of penalties for government and private facilities. Under BMRR 2019, fines and penalties are applied to Technical Authorization Holders and Competent Persons in case of violations. However, government facilities, which are exempt from the requirement of Technical Authorization and Competent Person, are not subject to these penalties. This discrepancy has been highlighted in a WHO assessment recommending that the same rules be applied to both public and private establishments.

In response to these challenges, a comprehensive revision of the Bhutan Medicines Rules and Regulation has been proposed. This revision was focused on eliminating redundant provisions, streamlining regulatory processes, and fostering clarity, all while aligning Bhutan's regulatory framework with WHO Global Benchmarking standards.

By Dorji

4th Management Review Meeting

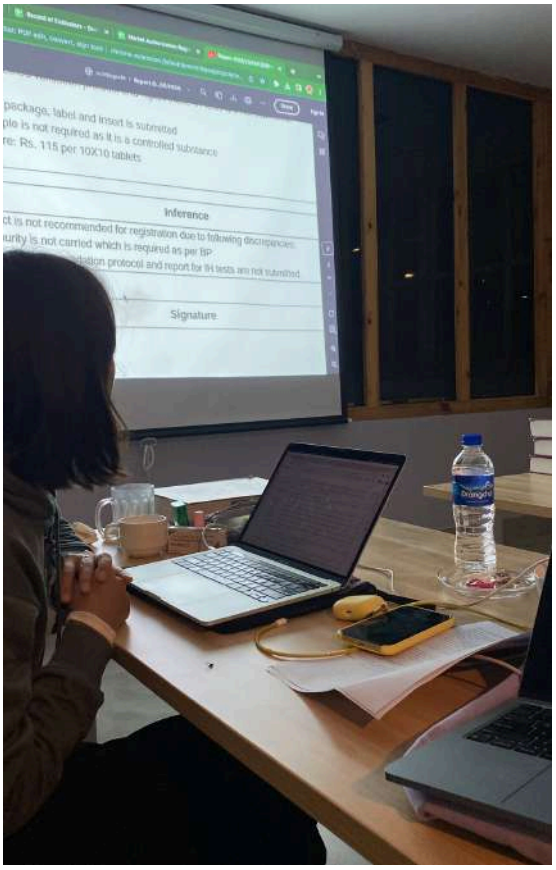
A Management Review Meeting (MRM) is a critical component of an organization's quality management system (QMS), designed to ensure that the system remains effective and aligned with the organization's strategic goals. These meetings involve top management, who review the performance of the QMS, discuss non-conformities and assess opportunities for improvement. By systematically evaluating the QMS, organizations can identify areas for enhancement, ensure compliance with regulatory requirements and align their processes with best practices.

In the 4th Management Review Meeting of the Medical Product Division (MPD), key performance indicators and quality objectives for the past year were analyzed, revealing significant improvements in compliance rates and customer satisfaction. Critical issues, such as growth and advancement of the employees as well as non-conformities in products and services MPD rendered, were addressed with actionable plans.

There was a reinforced commitment to continuous improvement and strategic initiatives for the upcoming year. The proactive approach and risk based approach adopted by the MPD ensures that we remain at the forefront of regulatory excellence and continues to safeguard public health effectively.

By Dorji

REGULATORY DOSSIER EVALUATION REFLECTION

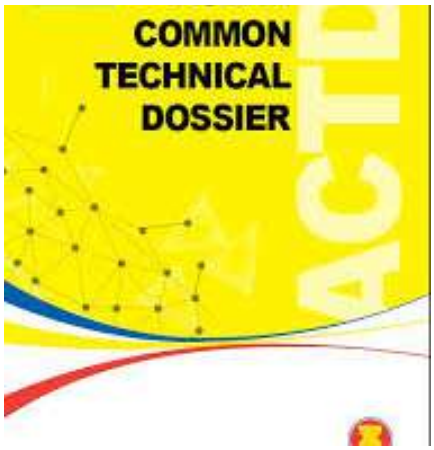


As a newly inducted regulatory officer, my initial experience evaluating a full-route drug registration dossier was both instructive and formative. The process served as a practical immersion into the regulatory framework structured around the ASEAN Common Technical Dossier (ACTD) and WHO-aligned national evaluation requirements.

My responsibilities encompassed both Part I: Administrative and Regulatory Documents and Part II: Quality Documents, as outlined in the national evaluator's checklist. I began with a detailed review of administrative components, verifying that the application form used was the latest version, properly dated, and complete with accurate applicant and product details. The product information was cross-checked for completeness—including the dosage form, strength, composition, therapeutic category, manufacturer, and packaging type—and consistency with the labelling, insert, and packaging materials. Ensuring that the specimen labels matched the product profile and included clear and correct usage instructions was particularly important.

The site master file and manufacturing license were reviewed to confirm the manufacturer's compliance with GMP standards and the validity of the documentation. Additionally, I ensured the Letter of Authorization, Certificate of Pharmaceutical Product (CoPP), and cGMP Certificate were valid, properly formatted, and aligned with the submitted product data. The price structure was also assessed to confirm MRP transparency across the distribution chain.

The most intensive portion of the assessment was Part II: Quality Evaluation, beginning with the drug substance (S). A key learning moment occurred during the evaluation of S.3 (Characterization). Although the dossier included data on the physicochemical properties of the active pharmaceutical ingredient (API), I initially



found this section challenging to assess due to my own limited experience in interpreting structural and analytical characterization data. Understanding how this information supports identity, purity, and quality verification required consultation with senior assessors and reference to pharmacopeial standards and guidelines.

I reviewed the manufacturer's information (S.2), confirmed the certificate of analysis (S.4) for API control parameters, checked the reference standard (S.5) for pharmacopoeial alignment (e.g., USP, BP, IP), and ensured data on container closure systems (S.6) and any stability data or literature (S.7) were appropriately included.

In evaluating the drug product (P), I used a structured checklist to assess key quality aspects, starting with the manufacturing process (P.3), which included reviewing the batch formula, flow diagram, manufacturing steps, in-process controls, and validation protocols to confirm process consistency and reproducibility. The control of excipients (P.4) was verified through Certificates of Analysis, while finished product specifications (P.5) were checked for compliance with relevant pharmacopoeial standards. Stability data (P.8) under long-term (Zone IVB) and accelerated conditions were reviewed for three primary batches, ensuring that testing conditions aligned with regional climatic requirements and that a stability commitment letter was included where needed. For product interchangeability (P.9), I assessed whether a bioequivalence (BE) study was required. Where applicable, BE study results and pharmacokinetic parameters (Cmax, AUC) were reviewed for compliance with regulatory limits. For BCS-based biowaiver candidates, I evaluated API classification, dissolution profiles, and f_2 similarity factors across relevant pH levels.

Despite initial nervousness, the experience fostered professional growth, deepened my regulatory understanding, and highlighted the importance of clarity, integrity, and collaboration in ensuring the quality and safety of medicines.

By Tashi Lepcha

PARTICIPATION IN THE 6TH WHO-NNB GENERAL MEETING

The Bhutan Food and Drug Authority (BFDA) actively participated in the 6th General Meeting of the WHO-National Control Laboratory Network for Biologicals (WHO-NNB), held from 26 to 28 November 2024 in Cairo, Egypt. The event convened 120 participants from 58 WHO Member States, representing national control laboratories (NCLs), regional and international organizations, and vaccine manufacturer associations.

Established in 2016, the WHO-NNB serves as a collaborative platform for national laboratories to strengthen quality control, lot release, and regulatory oversight of WHO-prequalified vaccines and other biological products. The 6th General Meeting focused on:

1. Welcoming new Network members and sharing regulatory practices;
2. Discussing challenges and best practices in vaccine testing and lot release;
3. Enhancing reliance and transparency among member NCLs;
4. Updating on regional and global laboratory strengthening initiatives;
5. Reviewing alternatives to animal testing and risk-based release approaches; and
6. Strengthening post-market surveillance and quality monitoring systems.

Way Forward

1. Strengthened collaboration among NNB members, with enhanced understanding of diverse regulatory environments and applied control strategies;
2. Improved information-sharing through the WHO-NNB SharePoint platform;
3. Commitment to action plans on reliance, transparency, and regulatory harmonization;
4. Renewed focus on continuous capacity building, quality assurance, and reliance mechanisms to support global vaccine access.

World Health Organization

Sixth General Meeting of the WHO-National Control Laboratory Network for Biologicals (WHO-NNB)

26 to 28 November 2024

BFDA's participation in this meeting underscores its ongoing commitment to international regulatory cooperation and its role in ensuring the quality, safety, and efficacy of vaccines distributed in Bhutan. Continued engagement with the WHO-NNB will contribute to the strengthening of Bhutan's national regulatory framework and alignment with global best practices.

By Sonam Jamtsho

REINSTITUTION OF MPD'S REGULATORY GOVERNANCE

The Governing Board of BFDA

The Governing Board of the Bhutan Food and Drug Authority (BFDA) was established as the highest decision-making body to provide strategic direction, oversight and policy guidance to the Authority. Its formation was initiated to ensure transparency, accountability and efficient functioning in the regulation of any articles which falls under the scope of the regulatory purviews. Constituted under the Civil Service Reform Act of Bhutan 2022, the Governing Board of BFDA comprises of the following representations:

1. Chairperson - Hon'ble Lyonpo or Dasho Secretary, Ministry of Health;
2. Member Secretary - Director, Bhutan Food and Drug Authority;
3. Member - Director, Department of Agriculture, Ministry of Agriculture and Livestock;
4. Member - Director, Department of Trade, Ministry of Industry, Commerce and Employment;
5. Member - Secretary General, Bhutan Chamber of Commerce and Industries;
6. Member - Superintendent of Police, Integrated Check Post Management, Royal Bhutan Police; and
7. Member - Department of Health Services, Ministry of Health.

By Kinley Penjor Tshomo

The Drug Technical Advisory Committee (DTAC)

The Drugs Technical Advisory Committee (DTAC) was originally constituted under Section 5.1 of the Medicines Act of the Kingdom of Bhutan 2003, with the primary mandate of advising the then Drug Regulatory Authority (DRA) and its Board on technical matters related to the regulation of medicinal products. Over the years, the DTAC served as a key advisory body, supporting the development and enforcement of regulatory policies and standards to ensure the quality, safety, and efficacy of medicines in Bhutan.

However, with the institutional reform of the public service under the Civil Service Reform Act of Bhutan 2022, which led to the formation of the Bhutan Food and Drug Authority (BFDA) through the merger of the DRA, Bhutan Narcotics Control Authority (BNCA), and Bhutan Agriculture and Food Regulatory Authority (BAFRA), the DTAC became inactive. Its last meeting was held in 2021 during its 40th session, prior to the transition.

In response to the establishment of the BFDA Governing Board and its inaugural meeting in September 2024, the DTAC, along with other essential technical committees, was formally reconstituted as per the Board's resolution. The revitalized DTAC is now mandated to provide technical guidance to the Medical Products Division (MPD) under the BFDA, reinforcing its regulatory oversight in line with global standards.

By Jigme Dorji

International Engagement

Medical Product Division with the South-East Asia Regulatory Network (SEARN)

The SEARN is a volunteer association comprising the National Regulatory Authorities of Bangladesh, Bhutan, the Democratic People's Republic of Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand and Timor-Leste. SEARN aims to ensure timely access to high-quality medical products by enhancing regulatory collaboration, convergence and reliance among South-East Asia's National Regulatory Authorities through improved information sharing, system strengthening, alignment with international standards and collaborative processes.

Different working groups in SEARN were formed to provide specialized technical support and advice within specific regulatory areas in the context of Bhutan. They also ensure the effective implementation and assessment of approved actions. There are six working groups, each including representation from the Medical Product Division, Bhutan Food and Drug Authority.

Working Group 1: Quality

Focal Point: Mr. Sonam Chophel

Working Group 2: Regulatory Strengthening

Focal Point: Mr. Jigme Tenzin and Ms. Gyelwa Kuenzom

Working Group 3: Vigilance

Focal Point: Mr. Jigme Dorji

Working Group 4: Information sharing

Focal Point: Mr. Dorji

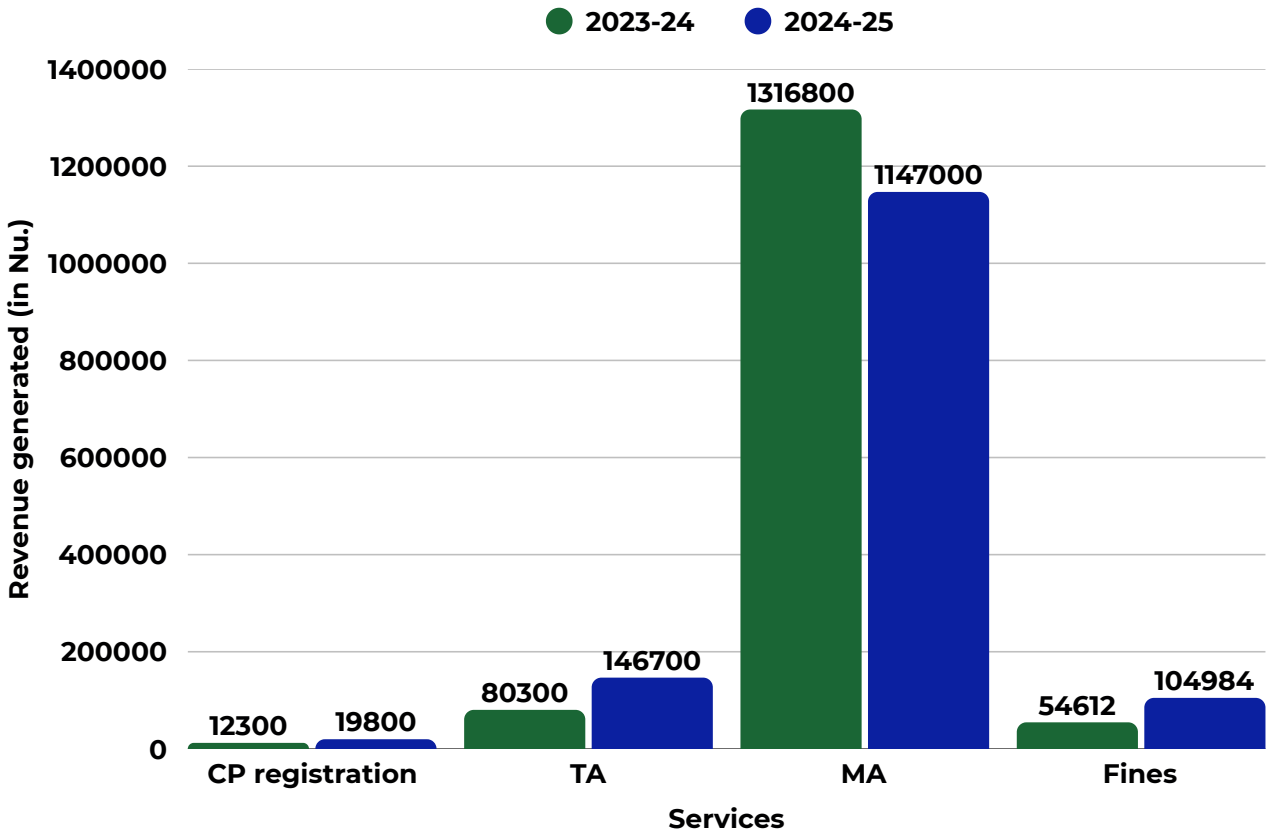
Working Group 5: Medical Devices

Focal Point: Ms. Kinley P Tshomo and Mr. Ugyen Tshering

Working Group 6: Traditional Medicines

Focal Point: Ms. Sangay Choden and Mr. Loden Jamtsho

FINANCIAL PERFORMANCE

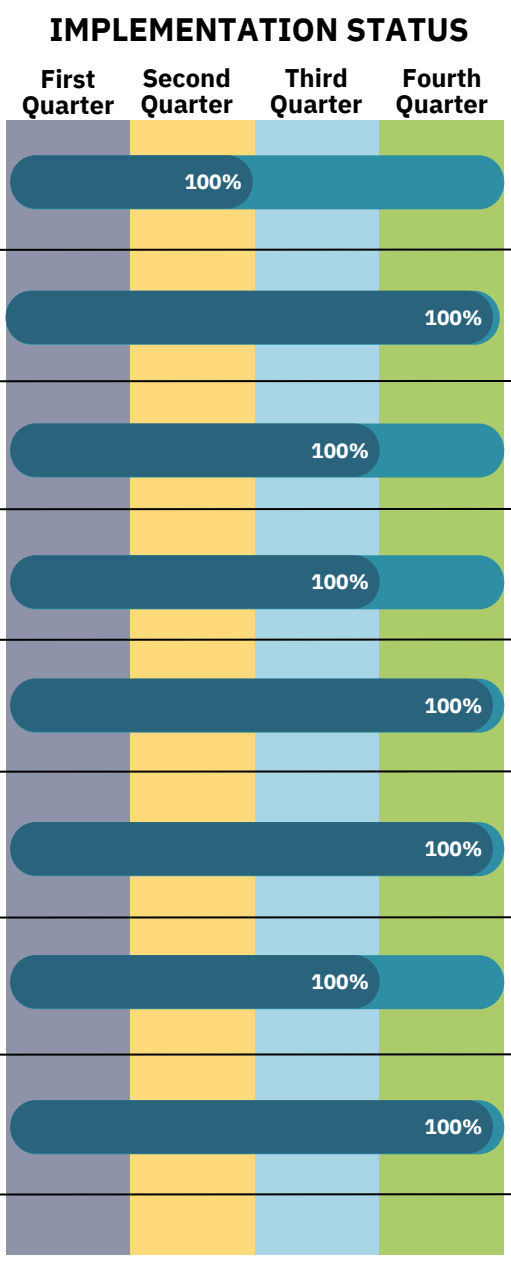


Annexures

ANNUAL WORK PLAN 2024-25

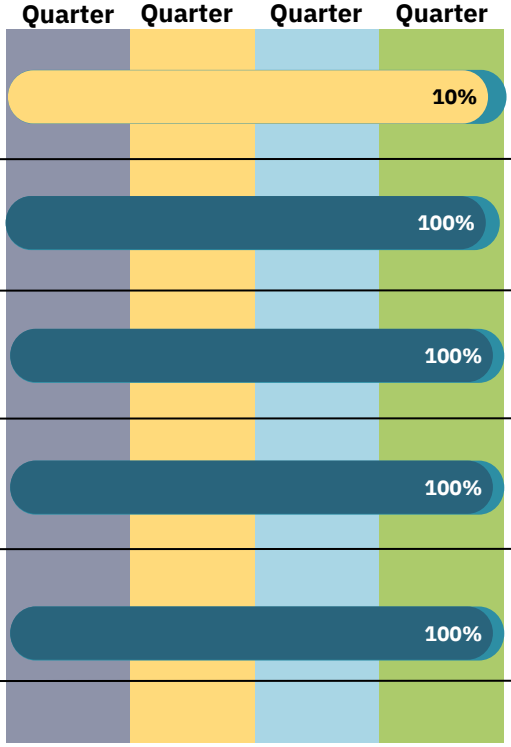
DRUG EVALUATION SECTION

SUB-ACTIVITY	IMPLEMENTATION STATUS
Training of regulators on ISO 9001:2015 to ensure compliance to ISO 9001:2015 standards and sustain the certification	100%
Enhancement of existing services of MPD in the G2C system and/or development of an integrated online system for regulation of medical products	100%
Conduct stakeholder meetings (Market Authorization Holders and law enforcement agencies) - Stakeholder meeting	100%
Subscription of pharmacopoieal standards	100%
Registration of medical products and involvement of external experts during evaluation	100%
Premarket testing of medical products	100%
Revision and/or development of technical guidelines	100%
Revision of Bhutan Medicines Rules and Regulation	100%



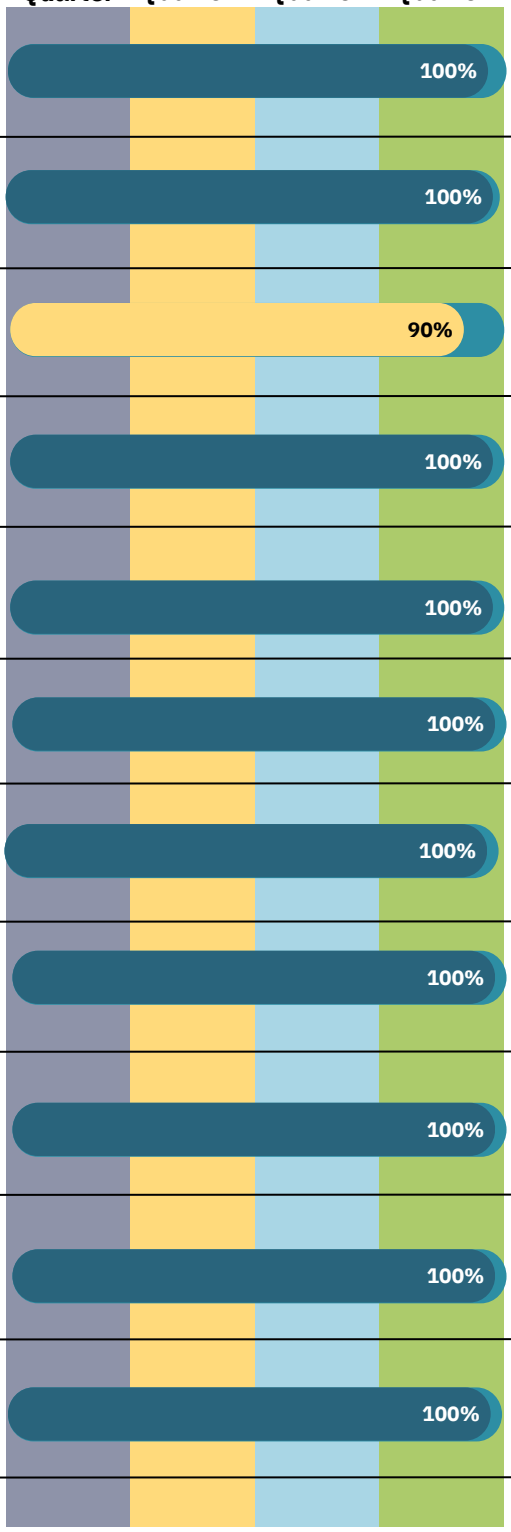
MEDICAL DEVICE SECTION

SUB-ACTIVITY	IMPLEMENTATION STATUS
Revision of Medicines Act of the Kingdom of Bhutan 2003	10%
Develop strategy on Market surveillance for medical devices	100%
Strengthening of materiovigilance system at health settings for Health Professionals	100%
Registration of medical devices	100%
Issuance of import for medical devices	100%



LICENSING AND VIGILANCE SECTION

SUB-ACTIVITY	IMPLEMENTATION STATUS
Procurement of GPHF minilab test kit	100%
Testing of medicines using GPHF minilab test kit	100%
Revision of defective, sampling, inspection and TAM guidelines, and development of GRP guideline	90%
Issuance of Technical Authorizations	100%
Conduct of DTAC meeting	100%
Post market testing of medical products	100%
Registration of Competent Person	100%
Handling and management of ADR, AEFIs & MDAE	100%
Conduct of Lot release for vaccines	100%
Regulatory Inspection of premises involved in sale, distribution and manufacture of medicinal products	100%
Handling and management of Falsified and Substandard medical products	100%



Upcoming Events

JULY

2025

"Institution of Drug-Regulatory Information Management System"

JULY

15-16

"SEARN Assembly at Thimphu"

AUG - DEC

2025

"Sensitization of Bhutan Medicine Rules and Regulation 2025"

JULY - JUNE

2025-26

"Repeal of The Medicine Act of Kingdom of Bhutan 2003"

ACKNOWLEDGEMENT

We extend our sincere gratitude to the **Top Management of the Medical Products Division (MPD)** for their unwavering support, strategic guidance, and steadfast commitment. Their leadership has been instrumental in driving continuous improvement in the implementation of the **Quality Management System (QMS)**, which has played a critical role in sustaining our **ISO 9001:2015 certification.**

We also wish to acknowledge the **officials of MPD** for their meaningful contributions to this Annual Report. Their timely inputs and dedication to upholding the division's mandate have enriched the quality and comprehensiveness of this publication.

A special note of appreciation goes to the **core team** involved in the development of this report. Their invaluable time, collaborative effort and professional dedication have made it possible to present a report that reflects the collective achievements and commitments of the division.

Sonam Jamtsho
ASST. REGULATORY OFFICER

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