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Bhutan Food and Drug Authority

ANNUAL REPORT 2023-24

MEDICAL PRODUCT DIVISION

Our Quality Policy

"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."

Ministry of Health, Royal Government of Bhutan
P.O Box 726, Kawajangsa
Thimphu, Bhutan

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Hear from our Director

Mrs. Gyem Bidha
Director

"Our commitment to quality risk management has been a cornerstone of our regulatory approach. By systematically identifying, assessing, and mitigating risks, we have reinforced our capacity to protect public health."

It is with great pride and a deep sense of responsibility that I present the Annual Report of the Medical Product Division (MPD) for the fiscal year 2023-2024. This report encapsulates the tireless efforts, significant milestones, and the unwavering commitment of our team towards ensuring the health and well-being of the Bhutanese people through stringent regulation and oversight of medical products including blood and blood products and medical devices.

In an ever-evolving landscape of healthcare and consumer safety, the MPD has remained steadfast in its mission to uphold the highest standards of quality, safety, and efficacy/effectiveness for all medical products available in our markets.

Our commitment to quality risk management has been a cornerstone of our regulatory approach. By systematically identifying, assessing, and mitigating risks, we have reinforced our capacity to protect public health. This proactive stance not only aligns with global best practices but also ensures that our regulatory decisions are underpinned by robust scientific evidence and risk-based assessments. The implementation of these principles has led to significant improvements in our regulatory processes, making them more transparent, efficient, and effective.

I extend my heartfelt gratitude to our dedicated staff, stakeholders, and partners whose unwavering support and collaboration have been instrumental in our achievements this year. As we look ahead, we remain resolute in our vision to safeguard public health and enhance the quality of life for all Bhutanese citizens. Together, we will continue to build a resilient and responsive regulatory environment that meets the challenges of today and anticipates the needs of tomorrow.

Tashi Delek!

Organization Framework

Who we are

The erstwhile Drug Regulatory Authority (DRA) is an autonomous government agency established on 14th June, 2004 as per the Medicines Act of the Kingdom of Bhutan 2003 which was passed by the 81st session of the National Assembly of Bhutan. The core mandate of the Authority is to enforce the Medicines Act, which translates to ensuring the quality, safety and efficacy of medicinal products in the country. Over the years, regulatory framework and tools have been developed and enforcement measures strengthened towards regulating the medicinal products in line with the changing dynamics around the world.

Ensuing civil service transportation across different sectors, authorities erstwhile known viz Drug Regulatory Authority (DRA), Bhutan Food and Agriculture Regulatory Authority (BAFRA) and Bhutan Narcotics Control Authority (BNCA) are restructured as a single entity called Bhutan Food and Drug Authority (BFDA). This restructuring exercise depicted the agency's commitment to modernize their structure to advance and achieve the common missions set. Into the bargain, restructuring had also fostered optimal use of limited resources, enhanced service delivery, reduced work duplication and usher in professionalism.

Now, the DRA is known as the Medical Product Division (MPD) under the BFDA. This rebranding aligns with the broader organizational changes and reinforces the division's role in maintaining the standards for medicinal products. The MPD continues to uphold the core mandate of ensuring the quality, safety, and efficacy of medicinal products, reflecting the BFDA's ongoing commitment to regulatory excellence and public health in Bhutan.

The Vision

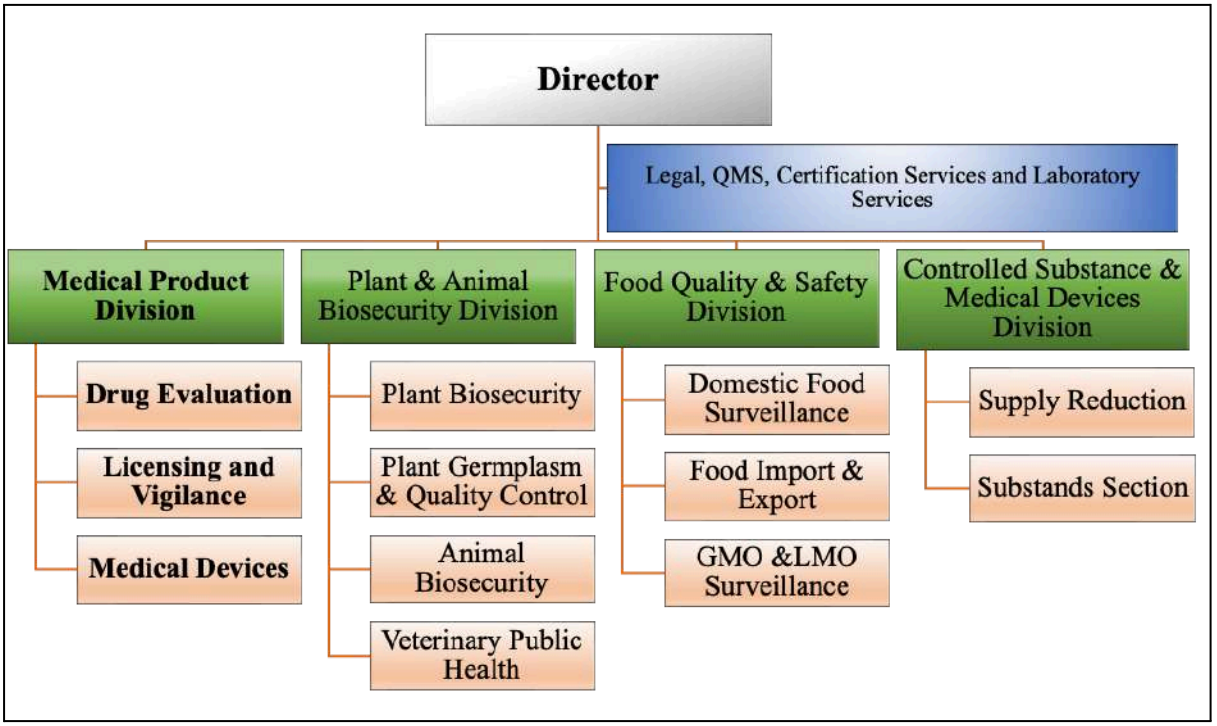
Excellence in protecting and advancing the health and safety of the Nation

The Mission

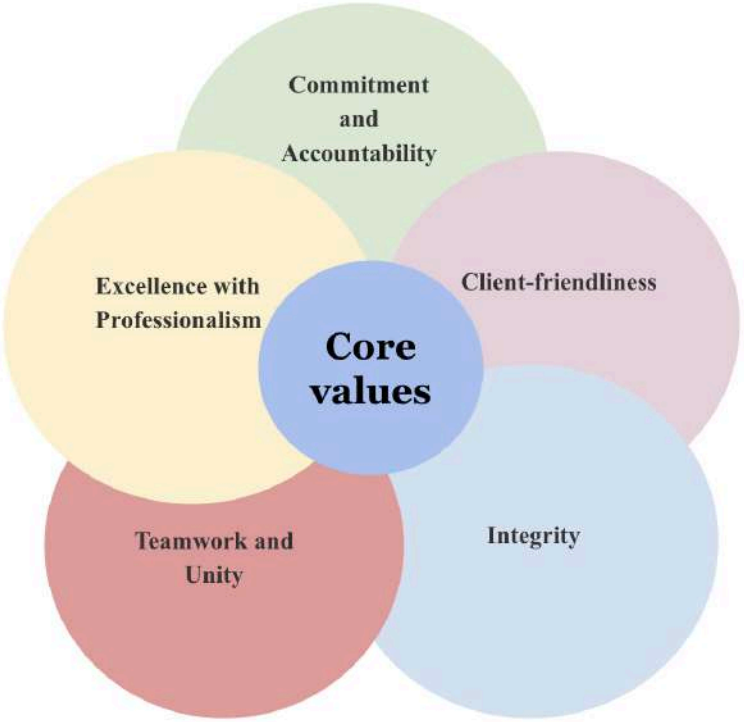
To protect the health of human, animals, plants and environment by ensuring:

1. safety and quality of food and agricultural products;
2. effective plant and animal biosecurity systems;
3. quality, safety and effectiveness of medical products and
4. reduce supply and demand of controlled substances.

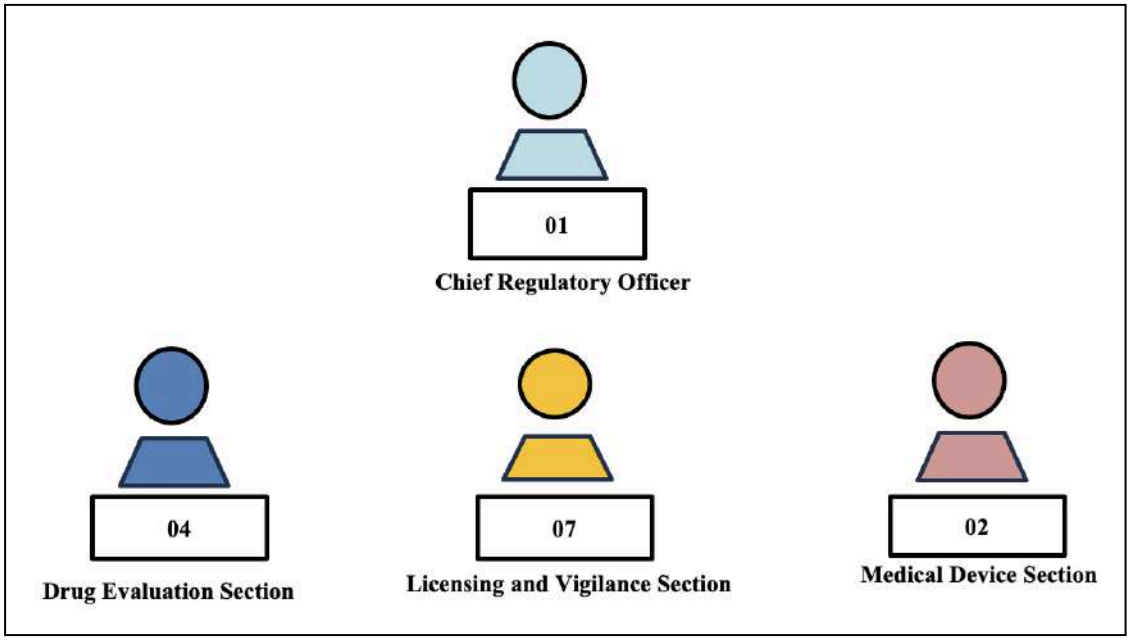
Organogram



Our core values



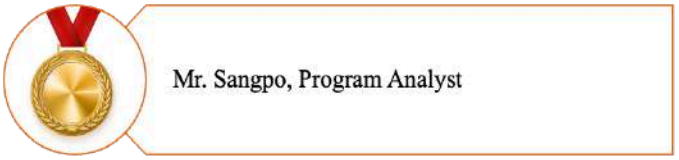
Human Resource

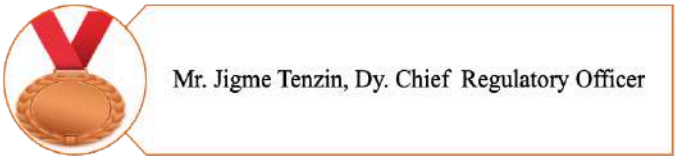


Accolades

In keeping with the Royal Command, the Civil Service Act of Bhutan 2010 (Section 88), and BCSR 2012 (Chapter 09), the RCSC institutionalized the Civil Service Awards. The dedicated awards are as follows:

1. 10-19 years of service (Bronze Medal)
2. 20-29 years of service (Silver Medal)
3. 30+ years of service (Gold Medal)





Services

Registration of Medical Products

As per section 16.2 of the Medicines Act of the Kingdom of Bhutan, 2003, "All medicinal products manufactured, sold and distributed and imported/exported from Bhutan shall be registered under the provisions of the act". Registration of medical products including blood and blood products & Medical Devices is a mechanism to ensure safety, quality and effectiveness of medical products. The applicant has to submit required documents along with an application fee of Nu. 500/-. Each application is subjected to evaluation and the turnaround time for the registration is 60 calendar days from the date of application adopting "Stop Clock principle". The registration certificate fee is Nu.1500/- per product. Any changes after registration of the product should be subjected to the post approval variation process and accordingly approved by the Medical Product Division.

Listing of Health Supplements

Health Supplements are products used to supplement a diet and to maintain, enhance and improve the health function of the human body. An applicant shall apply for listing of health supplements by submitting required documents and a fee of Nu. 500/-. The product will be listed within 60 calendar days upon fulfillment of conditions set in "The Guideline for Regulating Health Supplements" adopting "Stop Clock principle".

Import Authorization for Medical Products

As per section 22 of the Act, import of any medical product in the country shall require an Import Authorization from the authority prior to import. Import Authorization is issued within a turnaround time of 3 working days from the date of application.

Export Authorization for Medical Products

In accordance with section 23 of the Act, export of any medicinal product shall require an Export Authorization from the authority prior to export of the medicines to other countries. Export Authorization is issued within a turnaround time of 7 working days from the date of application.

Registration of Competent Person

In line with section 19.2 of the Act, only Competent Person shall engage in the manufacture, sale, dispensing and distribution of medicinal products. The applicants should appear for a Competent Person (CP) examination and should get registered with the authority. This service can be availed within a turnaround time of 7 working days for both new application and renewal by paying a fee of Nu. 300/- for each along with required documents.

Technical Authorization for Sale & Distribution of Medical Products

In keeping with section 24.1 of the Act, applicants are required to obtain technical authorization for sale and distribution of medicinal products from the authority. This is a prerequisite for obtaining a trade license from the Ministry of Industry, Commerce and Employment (MoICE). This service can be availed within a turnaround time of 10 working days for new applications and 7 working days for renewal of the same by paying a fee of Nu. 900/- along with required documents.

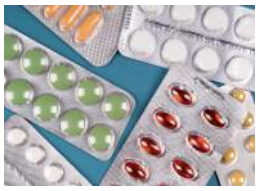
Change in ownership, name of pharmacy, name of Competent Person or location of pharmacy

Wholesale or retail pharmacies who wish to change the ownership of Technical Authorization or the location of the premise or name of Pharmacy or Competent Person should apply to the authority for the change. This service can be availed within a turnaround time of 7 working days by paying a fee of Nu. 300/- along with required documents.

Provisional and Technical Authorization for Manufacture of Medical Products

As per section 21 of the Act, all medical products to be manufactured in the country shall require prior approval from the authority. The applicant should apply for Provisional Authorization for manufacture followed by Technical Authorization for manufacture along with a fee of Nu. 5000/- respectively. The Technical Authorization for Manufacture is a prerequisite for obtaining a license from the Ministry of Industry, Commerce and Employment (MoICE) for manufacturing any medical products.

Disposal of Expired Drugs from Private Pharmacies



As per section 22 (i) of the Waste Prevention and Management Act of Bhutan, 2009, the Drug Regulatory Authority is responsible for ensuring waste prevention and management in pharmaceutical firms and pharmacies. Accordingly, the authority facilitates annual disposal of pharmaceutical waste generated from retail pharmacies. Considering the concentration of retail pharmacies, Thimphu and Phuentsholing are identified as collection centers.

Issuance of GMP, CoPP & FSC

This service is used by Pharmaceutical manufacturers in the country for certification against current Good Manufacturing Practices and issuance of Free Sale Certificates.

Clearance for Advertisement

As per section 27 of the Act and rule 234 of the Bhutan Medicines Rules and Regulation 2019, any advertisement of medicinal products shall require prior approval from the authority. Advertisements may be in any form such as audio, video, pamphlets, brochures, posters, banners, and social media platforms. Any entity or individual advertising medicinal claims of any products without prior approval from the authority is subjected to issuing warnings and imposing fines. The service can be availed within a turnaround time of 5 working days.

Navigate our numbers

1. Market Authorization of Medical Products

Market Authorization	Pharmaceuticals	Medical Devices
Total number of medical products approved	207	11
Total number of medical product renewed	147	6
Total number of medical product subjected to post approval variation	13	0

2. Regulatory Inspections

Good Manufacturing Practice audit conducted	6
Sale and distribution inspections conducted	168
Self Inspections conducted	37

3. Laboratory Testing

	Pharmaceuticals	Medical Devices
Total number of product tested	327	3
Number of product passed	464	0
Number of product failed/doubtful	22	3

4. Market control

	Pharmaceuticals	Medical Devices
Import Authorization issued	520	17

5. Lot release

Total number of lot release performed	34

6. Vigilance

Total number of products recalled	10
Total number of Adverse Drug Reaction analyzed	113
Total Number of Substandard and Falsified medical product reports analyzed	18

7. Licensing Establishment

Total number of new Provisional Authorization for Manufacture issued	4
Total number of new Technical Authorization for Manufacture issued	1
Technical Authorization for Sale and Distribution for medical products issued	22
Total number of Competent Person registered	54

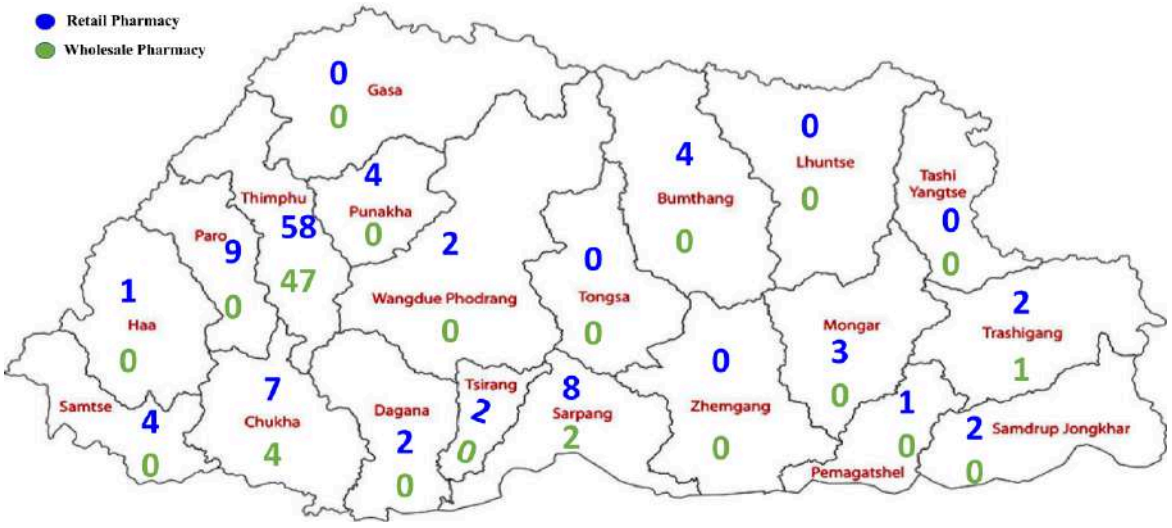
8. Certificates issued

Export Authorization	47
Certificate of Pharmaceutical Products	41
Free Sale Certificate	1
Good Manufacturing Practice Certificate	2

9. Guideline developed/revised

New Guidelines developed	Revised Guidelines
1. Guidelines for cancellation, suspension and withdrawal of medical products 2023; 2. Guideline for approval of premises for sale and distribution of medical products	Guidelines for disposal of medical product waste

10. Distribution of private pharmacies



Explore our milestones

Stakeholder Consultation Meeting

Stakeholder engagement is pivotal for the Bhutan FDA, involving pharmaceutical supply and industry stakeholders in developing and implementing regulatory procedures. This engagement ensures diverse perspectives are considered, enhances regulatory legitimacy and transparency, and improves outcomes. The Medical Product Division held its first stakeholder meeting for the fiscal year 2023-24 from August 22-24, 2024. Focused on the private pharmaceutical sector, participants included wholesalers, retailers, and industry representatives. The agenda covered updates to the regulatory framework, training on regulatory functions, and consultations on division proposals.

The three-day stakeholder consultation meeting in Bhutan focused on updates and training related to civil service transformation and regulatory advancements in pharmaceuticals and medical devices. Highlights included the establishment of the Bhutan Food and Drug Authority (BFDA) to replace the previous Drug Regulatory Authority. The first day featured a crucial training session by the Drug Evaluation Section of the Medical Product Division (MPD), which addressed challenges in dossier compilation for market authorization applications. Stakeholders also adapted to a new electronic dossier submission system, improving efficiency with online portals.

Day two concentrated on medical device regulations, a newer area for many stakeholders. The MPD's Medical Device Section outlined administrative requirements and technical specifications necessary for market authorization. Discussions included safety issues concerning Diethylene Glycol (DEG) and Ethylene Glycol (EG) in pediatric medications, with regulatory responses

On the final day, deliberations focused on challenges confronting private pharmaceutical entities and the BFDA. Stakeholders also highlighted progress made in establishing the Pharmaceutical Association of Bhutan as a recognized civil society organization. The MPD presented proposed protocols aimed at streamlining the registration process for medicines, including measures to introduce application submission windows and prioritize essential medicines. These proposals, designed to foster operational efficiency and mitigate delays, garnered consensus among the majority of stakeholders following constructive dialogue and deliberation throughout the meeting.

The stakeholder meeting served as a crucial platform for constructive dialogue between the BFDA and private pharmaceutical entities. Addressing regulatory updates, training, and proposals to streamline registration processes, the meeting promoted collaboration to improve Bhutan's pharmaceutical regulatory framework. Stakeholder participation and acceptance of proposed procedures underscored a commitment to overcoming challenges and advancing the sector.

DrukMed Sensitization to National, Regional and Cluster hospitals

With the support from the Fleming Fund Project, an initiative was undertaken to enhance healthcare practices through the development of the online mobile application "DrukMed". This application has been designed to offer healthcare professionals an easily accessible and user-friendly tool that serves as an instant reference guide for vital medication-related information. Its functionality extends across various online platforms, with availability on Google Play for Android users and the App Store for iOS users.

Recognizing the critical role that healthcare professionals play in utilizing the "DrukMed" application effectively, the Bhutan Food and Drug Authority with support from Fleming fund Project conducted a two-day sensitization workshop to create awareness to health professionals across National, Referral, and Cluster Hospitals by acquainting them with the mobile application. The primary objective of the sensitization initiative was to ensure that healthcare workers adapt at navigating and utilizing the "DrukMed" application to its fullest potential. 17 health professionals (namely Physicians and Pharmacist/Pharmacist technicians) attended the workshop.

As part of the broader agenda, the sensitization workshop also served as a dynamic platform for fostering insightful discussions on pertinent issues related to Antimicrobial Resistance (AMR), products defect and Adverse Drug Reaction (ADR) reporting.

ISO 9001:2015 Lead Auditor Training

Completing the ISO 9001:2015 Lead Auditor Training was a profound learning experience that enhanced both my technical knowledge and practical auditing skills. The training emphasized the importance of meticulous preparation, effective communication, and ethical conduct. One of the most significant takeaways was the value of continuous improvement, not only within the organizations we audit but also in our approach to auditing itself.

The interactive nature of the training, with its blend of theoretical instruction and role-playing exercises, ensured that we were well-prepared to apply our learning in real-world situations. The role-playing exercises were particularly beneficial, as they provided a safe environment to practice and refine our skills. The trainers' expertise and real-world insights added immense value, bridging the gap between theory and practice.

The ISO 9001:2015 Lead Auditor Training has undoubtedly equipped me with the skills and knowledge necessary to conduct effective QMS audits. It has also instilled in me a deeper appreciation for the principles of quality management and the role of auditors in fostering organizational excellence. This training has prepared me to contribute meaningfully to the continuous improvement efforts of any organization including our own QMS, ensuring compliance with ISO 9001:2015 and driving sustainable quality improvements. As I move forward in my career, I am confident that the competencies I have gained will enable me to lead audits with integrity, precision, and a commitment to excellence.

Certified Excellence: ISO 9001:2015 Quality Standard Achieved!

The erstwhile Drug Regulatory Authority (DRA), now Medical Product Division (MPD) has been implementing some provisions of ISO 9001:2015 since 2016. Embarking on this journey to ISO 9001:2015 certification is a strategic decision that underscores the Medical Product Division (MPD), Bhutan FDA's commitment to quality and continuous improvement. The roadmap to achieving this prestigious certification begins with the fundamental step of implementing a Quality Management System (QMS). This process starts with the meticulous drafting and implementation of Standard Operating Procedures (SOPs), ensuring that all business processes are clearly defined and standardized.

In order to ensure enhanced and comprehensive compliance to the QMS, MPD incorporated its success indicator in the agency work plan and individual work plan and consequently various endeavors were undertaken to align MPD's processes, products and services with the ISO 9001:2015. From initial internal audits to management reviews, every step is designed to align with ISO 9001:2015 standards, culminating in a successful certification audit. This will not only help to meet but exceed quality expectations of the services and ultimately the end products MPD render.

The ISO 9001:2015 certification is a testament to our unwavering commitment to quality and excellence. It reflects our dedication to providing the best products and services to our customers, continuously improving our processes, and fostering a culture of quality within the MPD.

Crash Course for Competent Person

The Crash course for Competent Persons was first initiated in 2013 in response to a request from a group of retired health workers. The Bhutan Medicines Board was apprised of this matter, and during its 11th meeting, it recommended conducting a 120-hour pharmacy crash course for the applicants. This initiative aimed to address the pressing need for Competent Persons in the country, ensuring that there was a sufficient number of qualified individuals to meet the demand in the private pharmacy.

Similarly, in the light of the current situation of non-availability of the pharmacy professionals in the market, the need for Competent Person became critical once again. As a result, a 120-hour crash course for ex-health workers, including Health Assistants (HA), Clinical Officers (CO), and Assistant Clinical Officers (ACO), was reintroduced. This decision was in line with the recommendations from the 11th Bhutan Medicines Board meeting and was implemented following the directives of the Honourable Health Minister.

The Bhutan Food and Drug Authority in collaboration with the Khesar Gyalpo University of Medical Sciences of Bhutan (KGUMSB) conducted a three-week course from 16 October to 6 November. 18 health workers (retired) who were eager to update their skills and contribute to the healthcare system participated in the course. The course mainly focused on Pharmaceutical Jurisprudence, Pharmacy Practice, Pharmaceutics and Pharmacology.

Quality Risk Management Workshop: A First in the Medical Product Division

Quality Risk Management (QRM) is a systematic process for assessing, controlling, communicating, and reviewing risks to the quality of processes, services and products. By identifying potential risks early, the MPD can implement measures to mitigate these risks, thereby preventing issues that could compromise the quality and efficiency of the services, processes and products the MPD offers.

For MPD, the importance of QRM cannot be overstated as the MPD is responsible for protecting public health by ensuring that the medical products meet rigorous safety and quality standards. By incorporating QRM principles, MPD can more effectively oversee the entire lifecycle of medical products. This proactive approach helps in identifying and managing risks that could lead to product recalls, adverse health outcomes, or regulatory non-compliance.

Implementing QRM within MPD also enhances their ability to make informed-based and evidence-based decisions through risk assessments. This approach aligns with regulatory requirements and guidelines, such as those outlined by the International Council for Harmonisation (ICH) in ICH Q9. Moreover, MPD can prioritize the available resources and focus on high-risk areas.

Recognizing and understanding the utmost importance of Quality Risk Management, MPD convened the workshop on QRM from 19th-21st December, 2023 at Phuentsholing. The members are the Director of BFDA, Chief of MPD, Section heads and some officials from MPD. The workshop was groundbreaking for MPD as it not only equipped the participants with essential risk management skills but also reinforced MPD's commitment to maintaining the highest standards of quality and safety in services, processes and products MPD offers.

Training on Materiovigilance for regulators and Health professionals

In 2022, the Medical Product Division under the Bhutan Food and Drug Authority (BFDA) expanded its regulatory scope to include medical devices. Recognizing the nascent stage and complexity of medical device regulation, building capacity in this area especially in post-marketing aspects became imperative. To address this need, the BFDA, in collaboration with the Indian Pharmacopoeia Commission (IPC) and the Central Drug Standard Control Organization, conducted a five-day training on materiovigilance for regulators and health officials in February 2024 in Punakha.

The primary objective of the training was to equip regulators and health officials with the necessary tools and knowledge to ensure the ongoing safety and effectiveness of medical devices in the market. The IPC, serving as the National Coordination Centre (NCC) for the

Materiovigilance Programme of India (MvPI), has a proven track record of delivering high-quality materiovigilance training with experienced trainers.

Materiovigilance is a critical component of post-marketing surveillance, focusing on the monitoring and reporting of adverse events related to medical devices.Through the training, the regulators were able to gain technical insights required to initiate vigilance activities for medical devices. Additionally, the program included health professionals, such as nurses and biomedical engineers, who play a crucial role in ensuring the safe use of medical devices. These health professionals were also sensitized to medical device regulation and materiovigilance practices.

3rd 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 and key stakeholders 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.

The 3rd Management Review Meeting of the Medical Product Division (MPD) was convened at Paro from April 11th-12th, 2024 and it exemplifies the importance and effectiveness of these

reviews. During this meeting, 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. The importance of MRMs lies in their ability to provide a structured approach to continuous improvement as data related to quality objectives, customer feedback, organization climate survey, internal audits, and corrective actions are thoroughly reviewed. This comprehensive analysis helps in understanding the root causes of issues and in implementing effective solutions.

The meeting concluded with a reinforced commitment to continuous improvement and strategic initiatives for the upcoming year. The outcomes of this meeting include the implementation of enhanced risk management strategies, a focus on staff training and development. This proactive approach ensures that the MPD remains at the forefront of regulatory excellence and continues to safeguard public health effectively.

Vigilance workshop

The vigilance of medical products is one of the WHO's nine core functions for the regulatory authorities. It serves as an integral part for post-market surveillance of medical products that are distributed and consumed by the general public. Vigilance activities play a crucial role in identifying safety information about medical products which are not discovered during the clinical trials and drug approval processes. This information assists regulators in gaining better understanding of medical products and enables them to take timely regulatory actions to ensure safety of the patients.

With the financial support from the WHO, the Medical Product Division, under the Bhutan FDA conducted a Vigilance workshop for medical products in two batches targeting all the relevant healthcare professionals. Doctors, Nurses and Pharmacists/Pharmacy Technicians from all the hospitals from 10 bedded to referral hospitals in the country including military hospitals of the Royal Bhutan Army were trained on pharmacovigilance, Materiovigilance system; and related tools for reporting incidents to the BFDA. The first batch of the sensitization workshop took place from April 22nd to 26th, 2024, at Kaila Guest House, Bumthang with 35 participants from the eastern districts. The second batch was held from

May 27th to 31st, 2024, at Hotel River Valley in Punakha with 48 participants from the western districts.

Participants were educated on the importance of vigilance and skills for identifying adverse events associated with medical products. They were also trained on using reporting forms and online reporting systems. Additionally, participants were provided credentials for VigiFlow and the Substandard & Falsified Product Reporting System for reporting incidents related to use of medical products. Hands-on training on using the system was also carried out during the workshop. Further, to promote physical and mental wellbeing, a post workshop football match amongst the participants was also organized. Such activities are anticipated to cultivate cooperation and coordination among the participants by providing opportunities for them to interact and know each other more.

The workshop included participant introductions, a brief mindfulness meditation session, presentations, Q&A sessions, group work, and hands-on activities. The 5-day program concluded with participants committing to actively engage in the vigilance system. They agreed to share the knowledge gained with their colleagues and promote a culture of reporting any suspected adverse events associated with medical products and substandard or falsified products.

Training on Standard Operating Procedure and Quality Management System for Medical Gas Manufacturers

A robust Quality Management System (QMS) is very important to ensure the quality, safety and efficacy of medical products produced, thereby upholding patient safety and regulatory compliance. Implementing a comprehensive QMS enables medical product manufacturing firms to systematically control processes, mitigate risks, and continually enhance product quality, fostering trust among consumers. Documentation, particularly in the form of Standard Operating Procedures (SOPs), plays a critical role in the effective implementation of QMS.

Good Manufacturing Practice audits across the manufacturing firms in the country highlighted deficiencies in QMS knowledge among employees including the Competent Person (especially the medical oxygen gas manufacturers), particularly in the proper development and implementation of SOPs. To bridge the gap and enhance understanding of QMS while ensuring the proper development and implementation of Standard Operating Procedures (SOPs), the Medical Products Division, Bhutan Food and Drug Authority conducted a three-day workshop on Quality Management System sensitization and the development of quality SOPs from 13-15 May 2024 in Gelephu for the employees including the Competent Person of the four medical oxygen gas manufacturers. By enhancing knowledge and skills in QMS and SOP development, the workshop also aimed to significantly improve compliance with QMS and ultimately meet Good Manufacturing Practice requirements.

Pilot Inspection for Medical Devices

In 2022, the Medical Product Division under the Bhutan Food and Drug Authority (BFDA) expanded its regulatory scope to include medical devices. In our aim to commence post marketing surveillance and to assess the feasibility of inspections for medical devices, pilot inspection was planned and conducted in eleven districts. Inspection of medical devices is a critical component of healthcare management, ensuring the safety, functionality, and compliance of devices used in medical settings. The inspection included representatives of regional referral hospitals, district hospitals, and Primary Healthcare Centres. The inspection focused on various stages of the life cycle of medical devices (consumables and equipment) once they were brought to the hospital stores. It covered storerooms, laboratories, and wards, examining storage conditions, documentation and records, equipment calibration, and medical waste management..

The pilot inspection has highlighted several key findings that emphasize the need for standardized guidelines for the storage and distribution of medical products across all government health facilities. The development of both a common inspection checklist and a self-inspection checklist was found essential to streamline the inspection process and maintain high standards for medical devices. Additionally, the calibration of medical equipment and proper disposal of medical waste must be systematically addressed. Given that the regulation of medical devices is still in its nascent stages, there is an urgent need to educate and sensitize health professionals on these regulations and also on quality management systems. By taking these steps, Bhutan can enhance the overall management of medical products, ensuring better healthcare outcomes for its population.

Sensitization workshop for BFDA Regional and Cluster Offices on Regulation of Medical Products, Controlled Substances, and Tobacco

The reorganization of three regulatory agencies into the Bhutan Food and Drug Authority aims to enhance regulatory processes and enforcement by establishing an integrated regulatory framework and realigning agency functions to prioritize strategic objectives. To facilitate this transition, guidelines for field officials on the regulation of Medical Products, Controlled Substances, and Tobacco & Tobacco Products 2024 were developed, providing clear guidance for regulatory officials overseeing food, plant, and animal biosecurity at regional and cluster offices.

In line with this objective, a training program was organized in Bumthang from June 4-6, 2024. This program involved officials from five regional and fifteen cluster offices, ensuring they fully understood and comply with regulatory requirements for medical products, controlled substances, and tobacco. The training included sensitizing field inspectors to the core mandates of the four technical divisions under the BFDA: Medical Product Division, Controlled Substance and Medical Device Division, Food Quality and Safety Division, and Plant and Animal Biosecurity Division. Hands-on sessions and discussions provided practical training on the guidelines.

The training also aimed to promote collaboration and coordination among regulatory officials across headquarters, regional offices, and cluster offices, fostering a unified approach to regulation and enforcement. The concept of work sharing, in line with the recent civil transformation, was significantly highlighted during the training.

Transformation of Drug Regulatory Authority (DRA) to Bhutan Food & Drug Authority (BFDA)

In accordance with the Civil Service Act of Bhutan 2022, the Drug Regulatory Authority (DRA), Bhutan Narcotic Control Authority (BNCA), and Bhutan Agriculture and Food Regulatory Authority (BAFRA) have been merged to form the Bhutan Food and Drug Authority (BFDA). The BFDA is mandated to:

- Ensure the quality and safety of food and feed,
- Ensure the quality, safety, and effectiveness of medical products,

- Regulate narcotic drugs, psychotropic substances (NDPS), precursor chemicals, tobacco, and tobacco products, and
- Protect biodiversity, the environment, and the agricultural system from pests, diseases, invasive species, and genetically modified organisms.

The BFDA operates as a department under the Ministry of Health. A governing board, composed of prominent stakeholders, will provide strategic direction to the BFDA. Additionally, technical advisory committees will be established to offer independent expert advice on the BFDA's mandates, with their composition determined by the specific technical advice required.

The DRA, originally an autonomous body established in 2004 under the Medicine Act of the Kingdom of Bhutan 2003, is now restructured as the Medical Product Division under the BFDA. This reorganization aims to enhance collaboration, eliminate duplication of efforts and reduce wasteful public expenditure, thereby streamlining processes and services.

WHO Global Benchmarking of National Regulatory Authority of Bhutan

The Global Benchmarking Tool (GBT), an initiative by the World Health Organization (WHO), sets a globally recognized standard for evaluating and assessing National Regulatory Authorities (NRAs). Developed in response to World Health Assembly (WHA) Resolution 67.20 on regulatory system strengthening for medical products, the GBT is the first truly "global" standard allowing objective assessments of national regulatory systems. The tool evaluates the overarching regulatory framework and components through a series of sub-indicators across nine core regulatory functions.

The GBT adopts the concept of "Maturity Levels" to enable WHO and regulatory authorities to assess the overall maturity of the regulatory system. This maturity is measured on a scale from 1 (existence of some elements of a regulatory system) to 4 (operating at an advanced level of performance and continuous improvement). The GBT mechanism enables WHO to:

1. Identify strengths and areas for improvement of NRAs
2. Develop Institutional Development Plans (IDPs) to address identified gaps.
3. Prioritize IDP interventions.
4. Monitor progress and interventions.

As of December 2023, 95 WHO member states have been benchmarked using the GBT platform, including both formal benchmarking by WHO and self-benchmarking by the regulatory authorities themselves. Bhutan's erstwhile Drug Regulatory Authority (DRA) first conducted its self-benchmarking in 2021. In March 2022, the DRA was formally pre-benchmarked by WHO via a virtual platform, leading to the development of numerous IDPs aimed at improving the regulatory system in Bhutan and addressing current system gaps.

In 2022, following civil service reform, the DRA of Bhutan merged with two other regulatory agencies—the Bhutan Agriculture and Food Regulatory Authority (BAFRA) and the Bhutan Narcotics Control Authority (BNCA)—to form the Bhutan Food and Drug Authority (BFDA). The establishment of the BFDA presented new opportunities for the former DRA in its quest for formal benchmarking by the WHO. To follow up on the pre-benchmarking exercise conducted in 2022, two WHO experts visited Bhutan in July 2023 to review the progress of IDP implementation. This visit was instrumental in confirming the pre-benchmarking findings and the status of IDP implementation since the civil service reform.

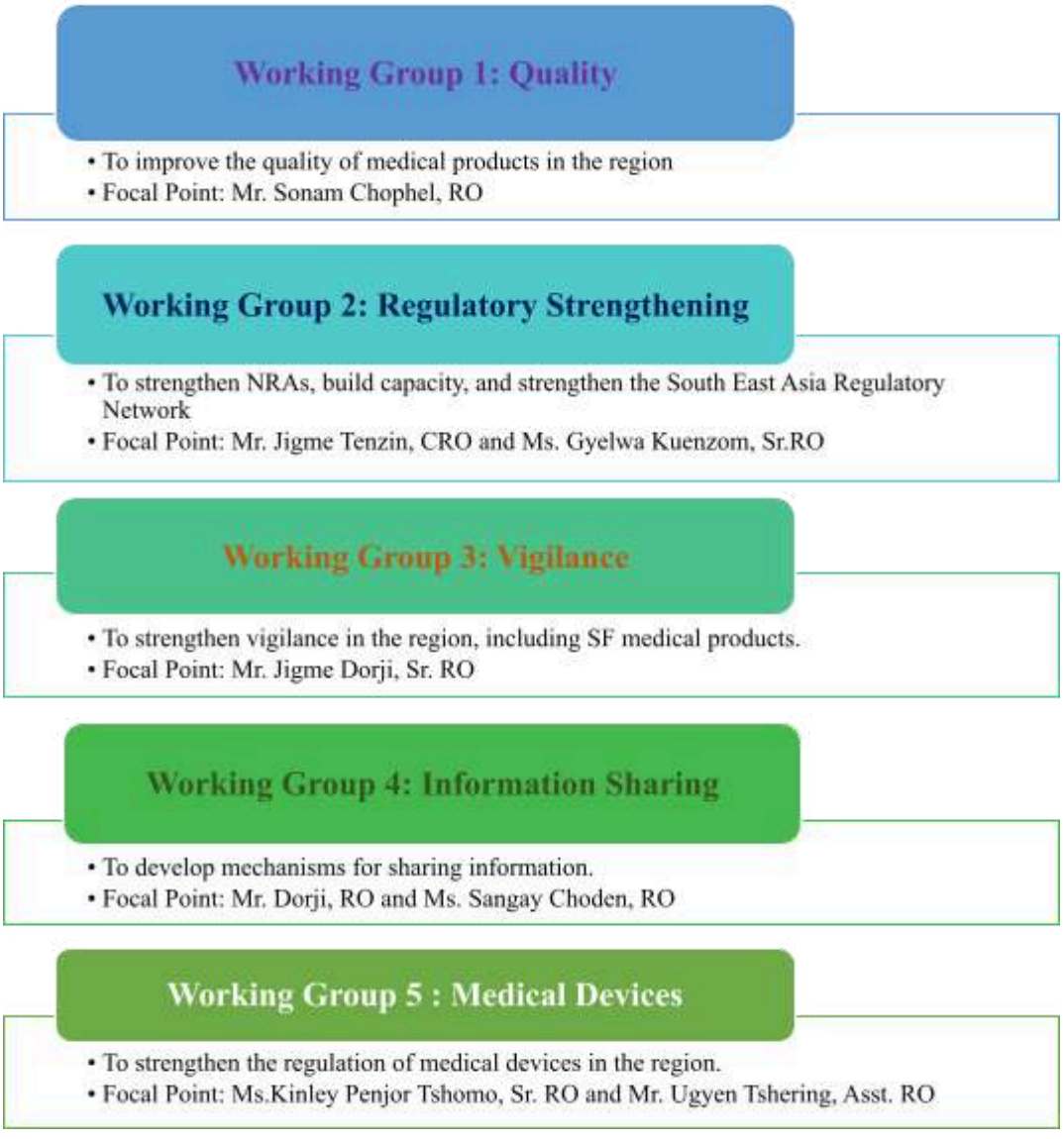
The Medical Product Division under the BFDA now shoulders the responsibility of implementing the IDPs with the objective of reaching Maturity Level 3 within the 13th Five year Plan. Achieving a high maturity level in the GBT assessment offers immense benefits for Bhutan, ensuring that public health is safeguarded with an optimal regulatory framework. Additionally, these maturity levels foster mutual recognition and reliance among regulatory authorities across member states, promoting global objectives of timely access to safe, efficacious, and high-quality medications for all.

International Presence

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 affordable, 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. They also ensure the effective implementation and assessment of approved actions. There are five working groups, each including representation from the Medical Product Division, Bhutan Food and Drug Authority



Medical Product Division in the global platform

July 2023, Indonesia

Meeting of the Assembly of the Members of the SEARN

September 2023, Thailand

Training on medical device regulation

October 2023, Maldives

Consultation on a model for efficient regulation of medicines and vaccines by National Regulatory Authorities with very limited resources

November 2023, Nepal

Regional workshop on the conversion of Emergency Use Authorization to full Marketing Authorization for Pandemic Vaccines

December 2023,Japan

PMDA-ATC Medical Devices Seminar 2023

February 2024, Nepal & Cambodia

1. Development of detailed technical implementation plan for phase II of the fleming fund country grant
2. Meeting of focal points for WHO Global Surveillance and Monitoring System in South-East Asia (SEA) and Western Pacific (WP) regions

March 2024, Thailand

Pricing, reimbursement policy, and benefit package for medicines at HITAP office

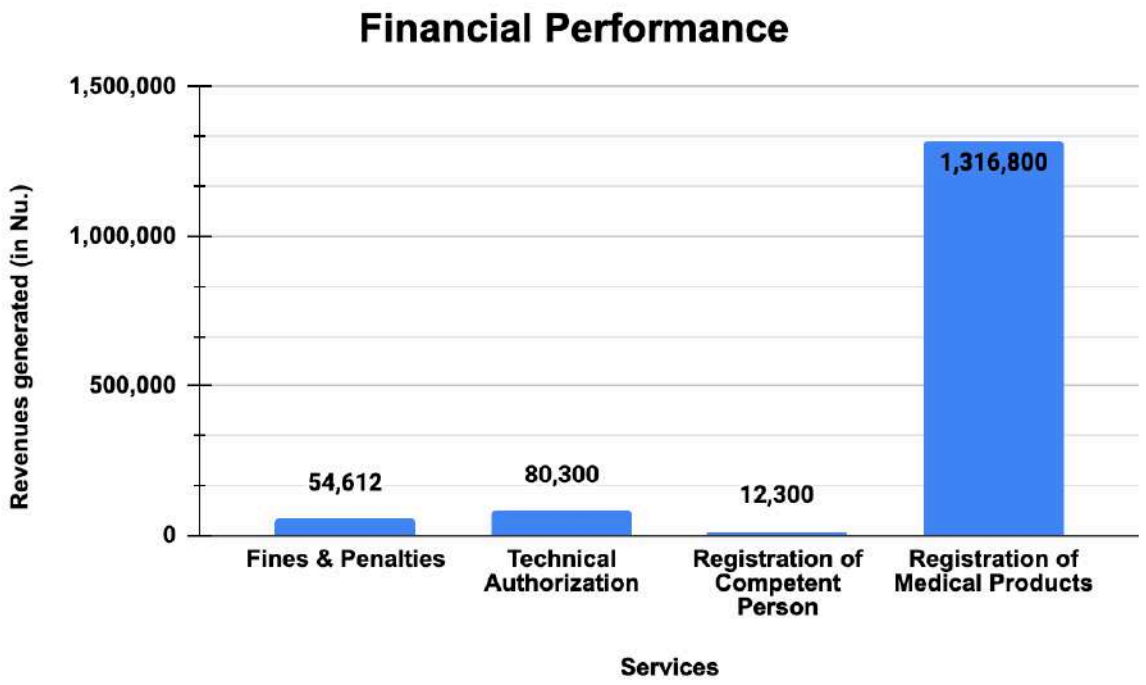
May 2024, Switzerland & Thailand

1. WHO Regulatory Training Course Therapeutic Products (Swissmedic)
2. Regional hybrid workshop on improving access and building capacity on the optimal use of reference standards

June 2024, Thailand & India

1. Workshop on Substandard and Falsified Veterinary Products (SFVP) for Regulators of Veterinary Medicinal Products in Asia and Pacific
2. Regional Workshop on Implementation of GRP for Vaccines Regulation based on emerging novel technologies

Financial Performance



Annexure

Annexure I: Annual Work Plan for 2023-24 FY

a. Licensing and Vigilance Section

SN	Output relevant to Division	KPI (Activities that contribute towards achieving the output)	Sub-activity	Approved budget (in millions)	Target Areas/Deliverables	Responsible official	Timelines (Months of 2023-2024)												Remarks
							7	8	9	10	11	12	1	2	3	4	5	6	
1	Regulatory services provided within the defined TAT	Issuance of GMP Certificate or decide on the fate of issuance of GMP certificate	1. GMP inspection of the firm 2. Verfication of CAPA plan 3. Issuance of GMP certificate	0.05	Issuance of GMP certificate within TAT	Gyelwa Kuenzom	The certificate will be issued within the Turn Around Time (TAT) as an when application for GMP certificate is received												The Budget will be met from GMP Audit
		Issuance of Lot Release Cetificate	1. Verification of summary lot protocol 2. Visual inspection of vaccines 3. Verification of cold chain integrity	N/A	Issuance of Lot Release certificate within TAT (2 working days)	Sonam Jamtsho	The certificate will be issued within the Turn Around Time (TAT) as an when application for Lot Release is received												
		Registration of Competent Person (CP)	1. Revision of CP question bank	NA		Jigme Dorji			x										
			2. Verification of documents received for new registration of CP and renewal 3. Conduct of CP exam and issuance of marksheets 4. Issuance of CP certificate	NA	Issuance of CP certificates	Karma	CP exams to be conducted every 2 months												
		Issuance of Technical Authorization (TA)	1.Verification of documents received for new TA, renewal and change of TA details 2. Conduct of site verification inspection 3. Issuance of TA certificates	NA	Issuance of TA certificates	Karma	The certificate will be issued within the Turn Around Time (TAT) as an when application for TA is received												
		Issuance of Import Authorization (IA) and Export Authorization including CoPP and FSC	1. verification of documents submitted for obtaining IA, EA, CoPP, FSC 2. Issuance of certificats/authorizations	NA	Issuance of Import and Export Authorization	Sarim Tshering	The IA, EA, CoPP and FSC will be issued within the Turn Around Time (TAT) as an when application is received												
		Issuance of PAM and TAM	1.Assessment of PAM and TAM application/renewal applications 2. Conduct of GMP Audit for TAM approval 3. Issue PAM and TAM certificates	0.05	Issuance of PAM and TAM certificates	Gyelwa Kuenzom	The certificate will be issued within the Turn Around Time (TAT) as an when application for PAM and TAM is received.												The budget will be met fonm GMP Audit
2		Inspection of government health facilities and veterinary centers involved in storage, distribution and dispensing of pharmaceutical products including inspection of Blood Centers and Blood Storage Centers	1. Draw annual inspection plan and target.	0.6	Annual inspection plan endorsed	Guru Sarim Tshering			x										
			1. Inspection of human and veterinary health facilities.		Government health facilities inclusive of veterinary facilities as per the plan/target inspected and regulatory CAPA implemented	Guru Sarim Tshering				x				x	x	x	x		
		Inspection of government health facilities and private facilities involved in storage, distribution and dispensing of medical devices	2. Follow-up CAPA and verify its implementati			Guru Sarim Tshering	Follow up for CAPA within 14 days from the inspection date												
		Inspection of private pharmacies both retail and wholesale, and project clinics	1. Draw annual inspection plan and target	0.4	Annual inspection plan endorsed	Guru Sarim Tshering			x										
			1. Inspection of human and veterinary health facilities. 2. Follow-up CAPA and verify its implementation.		Complinace rate of private pharmacies catagorized and standard baseline set for other Pharmacies	Guru Sarim Tshering													
		Benchmarking of Pharmacy	1. Data collected from the pilot study will be analyzed		Data collected from the pilot study of Benchmarking of Pharmacy analyzed	Gyelwa Kuenzom						x	x						

SN	Output relevant to Division	KPI (Activities that contribute towards achieving the output)	Sub-activity	Approved budget (in millions)	Target Areas/Deliverables	Responsible official	Timelines (Months of 2023-2024)												Remarks
							7	8	9	10	11	12	1	2	3	4	5	6	
	Regulatory enforcement and activities conducted with financial prudence		2. Phase I benchmarking for retail phamacy conducted		Retail pharmacies across the country are benchmarked	Gyelwa Kuenzom								x	x	x			
		Pharmaceutical waste disposal	Facilitiate and monitor the Pharmaceutical waste disposal of private pharmay	NA	Pharmaceutical waste from private pharmacies disposed	Guru Sarim Tshering						x	x	x	x	x	x	x	
		Good Manufacturing Practice audit of Pharmaceutical manufacturing firms	1. Draw annual inspection plan and target.	0.3	Annual inspection plan and target endorsed	Gyelwa Kuenzom		x											
			1. GMP audit of medical product manufacturing firm inclusive of medical gas manufacturer. 2. Follow-up CAPA and verify its implementation.		GMP audit conducted for the manufacturers as per the plan/target and regulatory CAPA implemented	Gyelwa Kuenzom			x					x		x			
		Handling and management ADR, AEFI and product defect reports	1. Conduct causality assessment of ADR and AEFI reports 2. Share the reports to UMC for global database 3. Take regulatory actions based on the ADR and AEFI reports, if required.	N/A		Jigme Dorji	x	x	x	x	x	x	x	x	x	x	x	x	
			4.Assessment of suspected defective medical products and communicate with the applicants			Sarim Tshering	x	x	x	x	x	x	x	x	x	x	x	x	
			5. Conduct of recall committee meeting 6. Issue recall notifications 7. Share the information on the recalled products in the GSMS system 8. Dessiminate/take regulatory actions based on the product alert/safety issues received from the WHO			Jigme Dorji	x	x	x	x	x	x	x	x	x	x	x	x	
3	New regulatory mechanism and strategies aligning with the developed Bhutan initiated and transformed	Revision of TAM guidelines	1. Analysis of need to review the Guidelines	N/A	Guideline reviewed with updated procedure and current practices	Gyelwa Kuenzom						x	x						
			2. Review of guidelines											x	x				
			3. Publish the guidelines														x	x	
		Development of modules for crash course for Pharmacy Competent Person.	Module for crash course developed.	N/A	Conduct of Crash Course of pharmacy completed	Gyelwa Kuenzom			x										
			Crash course for interested applicants for Pharmacy Competent Person completed.							x									
		Revision of Pharmacovigilance guideline	1. Analysis of need to review the Guidelines	N/A	Guideline reviewed with updated procedure and current practices	Jigme Dorji			x										
			2. Conduct consultative meetmgs and review the guideline								x	x		x	x				
			3. Publish the guidelines														x		
		Development of guideline for TAS	1. Conduct need analysis	N/A	Guideline reviewed with updated procedure and current practices	Karma			x										
			2. Conduct consultative meetmgs and review the guideline								x	x		x	x				
			3. Publish the guidelines														x		
		Development of guiding document for field inspectors of the BFDA	1. Development of guiding document	N/A	Guideline reviewed with updated procedure and current practices	Guru and Sarim Tshering			x	x	x								
			2. Finalization of guiding document									x							
			3. Sensitization workshop for Field inspectors											x					

SN	Output relevant to Division	KPI (Activities that contribute towards achieving the output)	Sub-activity	Approved budget (in millions)	Target Areas/Deliverables	Responsible official	Timelines (Months of 2023-2024)												Remarks
							7	8	9	10	11	12	1	2	3	4	5	6	
		Revision of inspection Guideline	Review of the draft Inspection Guideline	N/A	Guideline reviewed with updated procedure and current practices	Sarim Tshering				x									
			2. Conduct consultative meetings and review the guideline								x	x							
			3. Publish the guidelines										x						
4	Number of medical products including blood & blood products tested	Testing of medical products in National Drug Testing Laboratory	1. Sampling of medicinal products 2. Sending samples for analysis 3. Recall of substandard products	0.9	Testing of medical products at NDTL	Sonam Jamtsho				50		50		50		50			<40% of budget to be allocated for external testing and >60% in strengthening coordinaiton and capacity with NDTL
		Testing of medical products in external laboratories			Testing of medical products at external laboratories		15				20		20		25		20		
		Testing of medicinal products using GPHF minilab testing kits	1. Draw sampling plan/target for minilab testing 2. Sampling of medicinal products 3. Analysis of samples	0.7	Samples tested as per the sampling plan or target	Guru Sarim Tshering													
	Regulatory services and activities strengthened leveraging ICT.	Optimal utilization of G2C services system with the changes incorporated in the system	1. Integrate the updated certificate formats for CP, IA, TA, and CP marksheets, along with any other modifications necessitated by the establishment of the new agency (BFDA). 2. Perform a comprehensive gap analysis of the existing G2C online services system (G2C) and proposing enahncement and potential additions to the processess associated with CP, IA, and TA 3. Communicate with the GovTech and the developer whenever required	N/A	Optimal utilization of G2C services system	Jigme Dorji			x		x	x	x						

b. Drug Evaluation Section

SN	Output relevant to Division	KPI (Activities that contribute towards achieving the output)	Sub-activity	Approved budget	Target Areas/Deliverables	Responsible official	Timelines (Months of 2023-2024)												APA Target	Remarks	Implementation Status
							7	8	9	10	11	12	1	2	3	4	5	6			
	Proportion of regulatory services delivered as per TAT	Assessment of Product dossiers for Market Authorization of Medicinal Products	1. Dossier Evaluation for Product registration	0.9	Issuance of registration certificate for approved medicinal products	Sonam Chophel Sangay Choden Dorji Thinley Zangpo			x	x	x	x	x	x	x	x	x			The certificate will be issued within the Turn Around Time (TAT) as an when application for Market Authorization is received.	
		Health Supplement Listing	1. Assessment of Health Supplement applications		Issuance of listing certificates for approved Health supplements	Sonam Chophel Sangay Choden Dorji Thinley Zangpo			x	x	x	x	x	x	x	x	x			The certificate will be issued within the Turn Around Time (TAT) as an when application for listing of health supplement is received.	
2	New regulatory mechanism and strategies aligning with the developed Bhutan initiated and transformed	Develop and Implement internal mechanisms for efficient regulatory Operations on routine tasks.	Implement monthly Window period for Dossier submittion	0		Sonam Chophel			x	x	x	x									Completed
			Implement Prioritization of application for Dossier applications			Sonam Chophel			x	x	x	x									Completed
		Develop and publish guideline for Cancellation, Suspension and Withdrawal of Medicinal products.	Develop draft guideline for Cancellation, suspension and withdrawal of medicinal products	0		Sangay Choden	x														Completed
			Conduct consultation meeting with the technical officials on the development of the Guideline			Sangay Choden	x														Completed
			Seek public consultation on the Draft Guideline	0		Sangay Choden		x													Ongoing
			Publish the Guideline once comments from public consultation	0		Sangay Choden					x										Pending
			Develop SOP for cancellation, Suspension and Withdrawal of medicinal products	0		Sangay Choden						x									Completed
		Develope SOP for institution of WHO-CRP and SRA-CRP of Medicinal Products	Develop Zero Draft for the SOP	0		Sangay Choden & Thinley Zangpo				x											Pending
			Share the Draft to the WHO team and compile recommendation			Sangay Choden & Thinley Zangpo				x											Pending
			Finalise the SOP after Technical Consultation with the WHO and Sensitize to the staff			Sangay Choden & Thinley Zangpo					x*										Pending
	Regulatory enforcement and	Revision of Guideline for	Conduct Need analysis for Revision of Guideline	0		Dorji, Sangay Choden		x													
			Develop draft Guideline for Market Authorization of Medicinal Product via Standard Route	0		Sonam Chophel & Thinley Zangpo			x		x			x							Completed
			Develop Draft Guideline for Market Authorization of Medicinal Products via Fast-track Route	0		Sangay Choden & Dorji			x		x										Completed

SN	Output relevant to Division	KPI (Activities that contribute towards achieving the output)	Sub-activity	Approved budget	Target Areas/Deliverables	Responsible official	Timelines (Months of 2023-2024)												APA Target	Remarks	Implementation Status
							7	8	9	10	11	12	1	2	3	4	5	6			
3	Regulatory enforcement and activities conducted with financial prudence.	Revision of Guideline for registration of Medicinal products 2020	Consultation meeting to finalise the Guideline for Market Authorization of Medicinal Product via Standard Route	0		Sonam Chophel & Thinley Zangpo			x		x			x							Completed
			Consultation meeting to finalise the Guideline for Market Authorization of Medicinal Product via Fast-track route	0		Sangay Choden & Dorji			x					x							Completed
			Sensitization of the New Guidelines to the Stakeholders	0		ALL				x											Pending
4	Enhanced collaboration and coordination with the stakeholders.	Conduct Management Review	Plan and conduct management review meeting	0		Dorji								x							
5			Conduct Consultation meeting with Stakeholders in the development of an Integrated Regulatory System	0.5		ALL					x				x						

c. Medical Device Section

Annexure I. Detailed Work Plan, 2023-2024

SN	Output relevant to Division	Activities that contribute towards achieving the output	KPI	Approved budget	Target Areas/Deliverables	Responsible official	Timelines (Months of 2023-2024)												Remarks
							7	8	9	10	11	12	1	2	3	4	5	6	
1	Regulatory services provided within the defined TAT.	Registration of medical devices	100% of dossier applications received are prescreened within TAT	NA	Registration of medical devices within 60 calendar days	Ugyen Tshering						x							
			50% of total fast track Medical Devices dossier received are evaluated and regulatory decisions communicated within TAT considering the stop-clock principle			Ugyen Tshering						x							
			50% of total Full Medical Devices dossier received are evaluated and regulatory decisions communicated within TAT considering the stop-clock principle			Kinley P Tshomo/Ganga Devi Giri						x							
			25% of total fast track Medical Devices dossier received are evaluated and regulatory decisions communicated within TAT considering the stop-clock principle			Kinley P Tshomo/Ganga Devi Giri						x							
		Issuance of import for medical devices	100% of application received for import are processed within TAT	NA	100% of application received for import are processed within TAT	Ugyen Tshering						x							
2	New regulatory mechanism and strategies aligning with the developed bhutan initiated and transformed	Training on Materiovigilance system for medical device conducted	17 BFDA officials and 6 Health professionals successfully trained on materiovigilance	0.7	Training conducted by February 2024	Ganga D Giri								x					RGoB budget
		Post marketing surveillance system for medical device instituted	1. Checklist for inspection of medical devices (Good Dispensing practice and Good Storage Practice) implemented	0.1		Ugyen Tshering							x						
			2. Inspection of 20 government facilities	0.4	Pilot inspection conducted by February									x					
		Obtain ISO 9001:2015 Certification for Medical Product Division(MPD), Bhutan Food and Drug Authority.	Non-conformities raised by Bhutan Standards Bureau resolved and Quality manual revised by November, 2023 to obtain ISO 9001:2015 certificate for MPD by December, 2023.	NA		Ganga D Giri				x									
		Conduct Internal Audit for processes and system of Medical Product Division(MPD) to ensure compliance with the ISO 9001:2015 standard.	1. Internal Audit planned and conducted for MPD in December, 2023.	0.1								x							
			2. CAPA plan developed for the Non-conformities raised by the internal audit team and communicated to audit team and all sections of MPD by January, 2024.	NA									x						
		Develop Guidelines/Standard operating procedures for Adverse Event and Quality Defect, Document Filing System and Reliance for Medical Device registration.	1. Guidelines for Adverse Event and Quality Defect developed by November,2023.	NA						x									
			2. SOP for Procedure for Document Filing System developed by September,2023.	NA					x										
			3. Reliance guideline developed to optimize resources for medical devices registration by December,2023.	NA								x							
		Revision of Pharmaceutical waste disposal guideline	1. Guideline for combination product	NA		Kinley P Tshomo							X						
			1. Guidelines for disposal of pharmaceutical wastes revised with inclusion of medical device waste disposal 2. Procedure on disposal of medical device waste clearly stipulated in the guideline	NA						x									
		Data Analysis of KAP survey and in-person interview for strengthening medical device regulation is conducted	Publication of KAP survey and in-person interview for strengthening medical device regulation.	NA		Kinley P Tshomo								x					
3	Enhanced collaboration and coordination with relevant stakeholders	Training of Market Authorization Holders for medical device	Training of Market Authorization Holders on regulatory requirement for medical devices including dossier compilation	NA		Kinley P Tshomo		x											

Reach Out

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