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Drug Regulatory Authority

ANNUAL REPORT
2019 - 2020

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Drug Regulatory Authority
Royal Government of Bhutan

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Drug Regulatory Authority
Royal Government of Bhutan
Thimphu, Bhutan; Post Box No. 1556

FOREWORD

The Drug Regulatory Authority plays a very important role in ensuring the quality, safety and efficacy of medicinal products in the country. Medicines and medical technologies are a fundamental building block of the healthcare system. Therefore, ensuring the quality of such products is of utmost importance for successful healthcare outcomes.

As we are highly dependent on import of medicines and medical products, it is even more important for us to have effective and efficient quality monitoring and vigilance systems. Although developing countries around the globe face various challenges related to poor quality of medicines, Bhutan has a functional medicines regulation system which has continuously evolved over the years. Currently, the Authority is also in the process of strengthening regulatory system for medical devices and health supplements.

It is my pleasure to introduce our first Annual Report. I'm hopeful that this report will not only create awareness on the maindates and core functions of DRA but also update the stakeholders on the achievements, challenges and future plans of the Authority.

Tashi Delek!

(Kinga Jamphel)
DRUG CONTROLLER

Acknowledgement

The Drug Regulatory Authority is grateful to the Hon'ble Chairperson and members of the Bhutan Medicines Board for their continuous leadership and strategic directives. The Authority also acknowledges the support and contributions of the members of the Drugs Technical Advisory Committee, Blood Technical Advisory Committee and other committees. We also thank all our stakeholders and clients for their valuable feedback and suggestions.

Finally, we thank all those who contributed in developing this report. In particular, we thank the Editorial Committee members for their efforts in shaping this report.

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DRUG REGULATORY AUTHORITY

VISION

THE MOST DYNAMIC, RELIABLE AND CLIENT-CENTRIC MODEL REGULATORY ORGANIZATION.

MISSION

PROMOTING AVAILABILITY OF QUALITY, SAFE, AND EFFICACIOUS MEDICINAL PRODUCTS FOR CONSUMERS.

Background

The Drug Regulatory Authority (DRA) is an autonomous government agency established on 14th June, 2004 as per the Medicines Act 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. There are well-established mechanisms and platforms to collaborate with various partners including national and international stakeholders, government agencies, professionals and private entities.

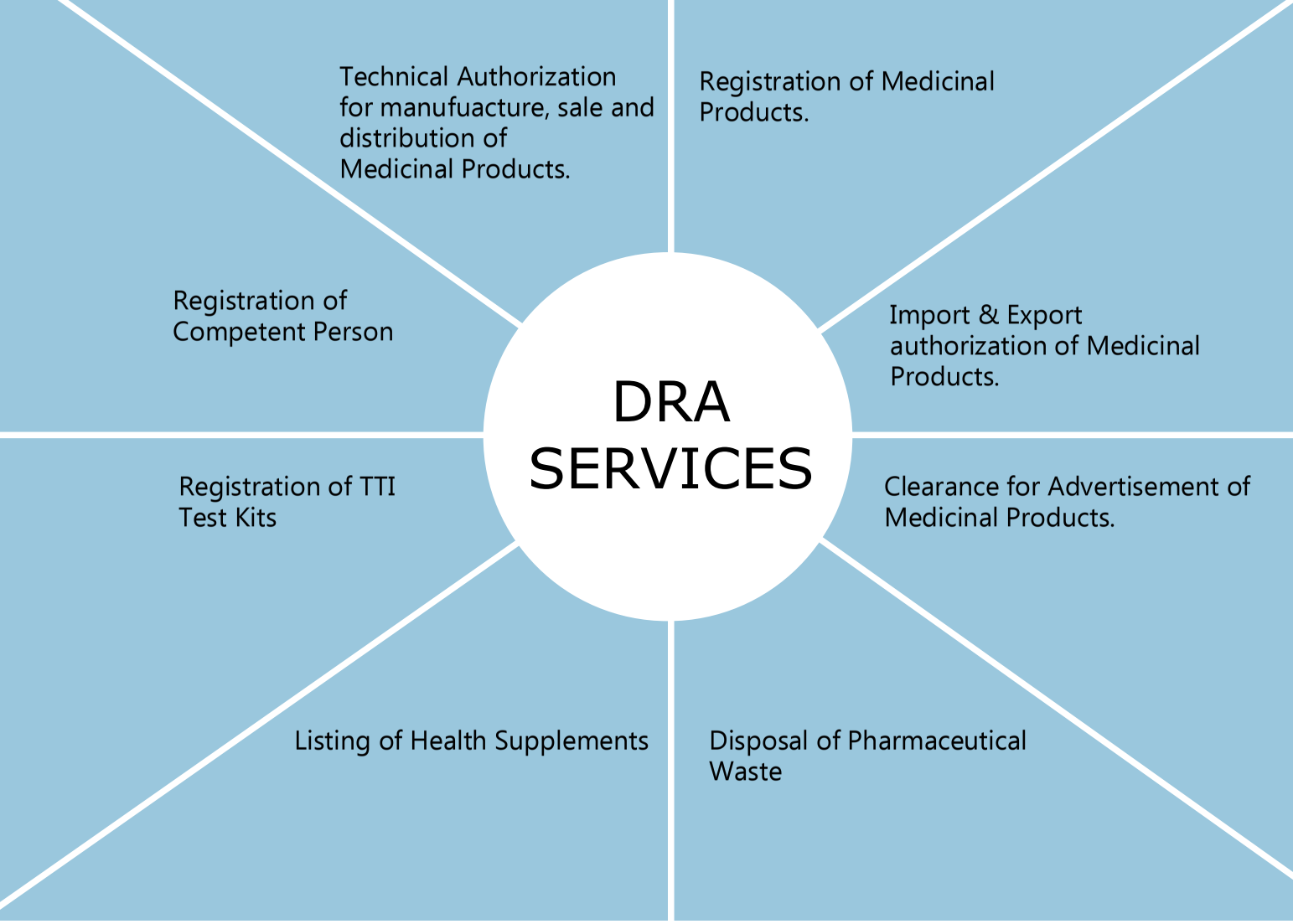
The Bhutan Medicines Board comprised of members from relevant agencies is the highest decision making body for regulatory matters pertaining to medicinal products. The Authority reports to the Bhutan Medicines Board. The Drugs Technical Advisory Committee (DTAC) and the Blood Technical Advisory Committee (BTAC) provide technical support to the Board and the Authority. There are also other sub-committees such as Food-Drug committee, National Pharmacovigilance Committee, Registration Committee and Recall Committee to provide technical advice on various subject matters.

The Authority has three Divisions - Registration Division, Inspection Division and Post Marketing Control Division supported by the Administration and Finance Section.

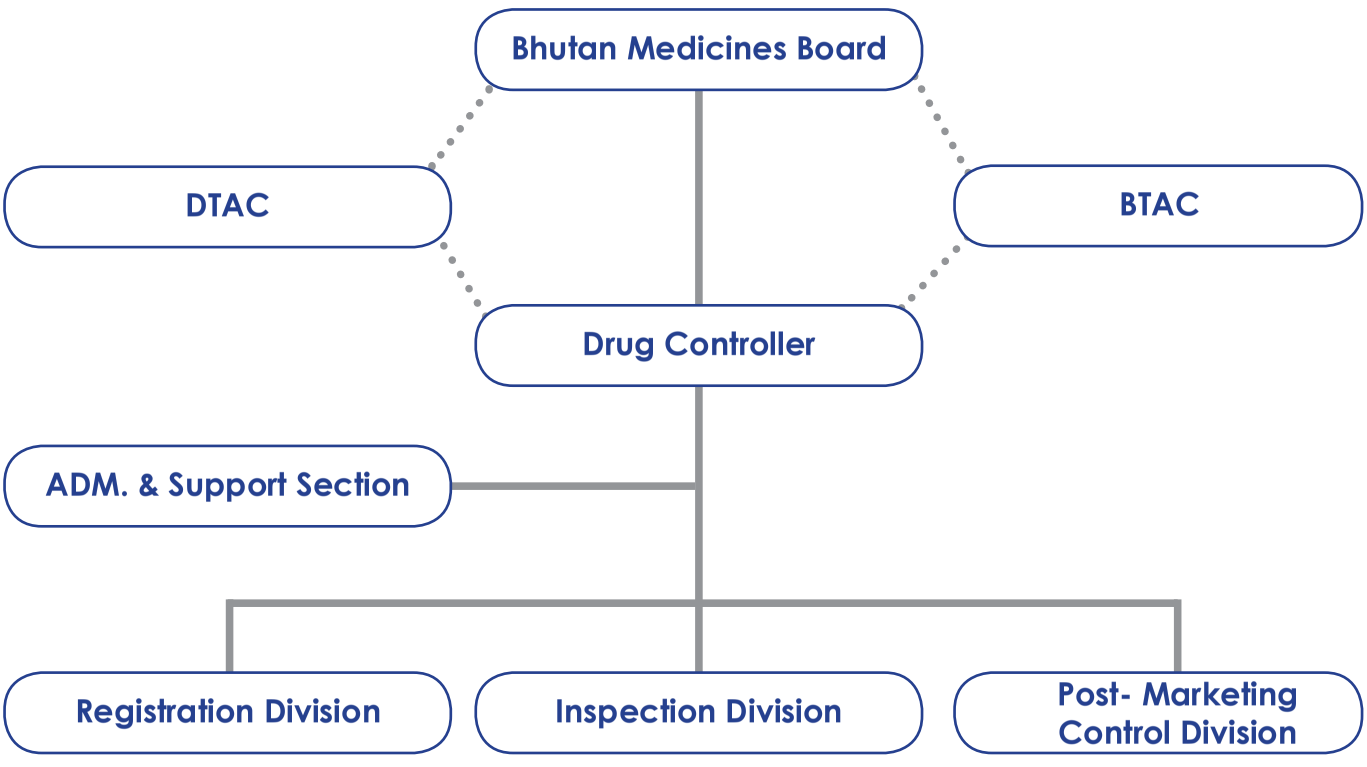
This report aims to provide updates to the stakeholders on the achievements, challenges and future plans of the organization.

Core Mandates

- Authorizing manufacture, import, sale, distribution and storagte of the medicinal products inculding blood and blood products.
- Registration of medicinal products which are manufactured within as well as imported into the country.
- Monitoring the competency and skills of personnel involved in the import, storage, manufacture and sale of the medicinal products.
- Monitoring the competency and skills of personnel involved in the import, storage, manufacture and sale of the medicinal products.
- Inspection/monitoring of premises for manufacture, sale, distribution and storage of medicinal products including blood and blood products.
- Providing up-to-date information in the form of Bhutan National Formulary and Drug Safety information
- Monitoring the trends and cases of adverse resulting from medicinal products.
- Informing the public on the use and harmful effects of medicinal products.
- Promoting policies for improved access to cost-effective quality medicinal products.
- Conducting research on pretinent issues related to medicinal products.
- Delivering regulatory services to the public in a cost effective and efficient manner.

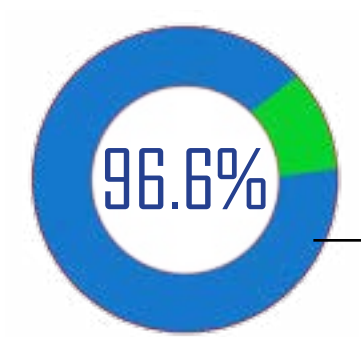

Technical Authorization for manufuacture, sale and distribution of Medicinal Products.
Registration of Medicinal Products.
Registration of Competent Person
DRA SERVICES
Import & Export authorization of Medicinal Products.
Registration of TTI Test Kits
Clearance for Advertisement of Medicinal Products.
Listing of Health Supplements
Disposal of Pharmaceutical Waste

ORGANOGRAM


Bhutan Medicines Board
DTAC
BTAC
Drug Controller
ADM. & Support Section
Registration Division
Inspection Division
Post- Marketing Control Division

Human Resource


Employees of DRA-2019



Total Budget
13.168 M

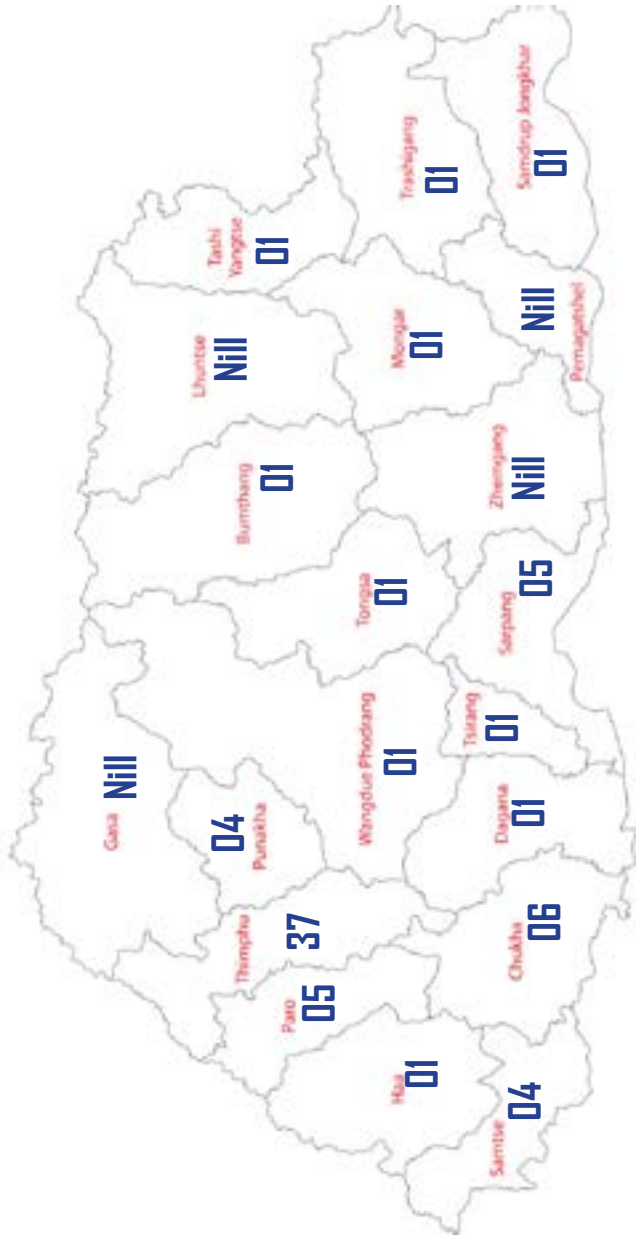
Total Expenditure
12.73 M

Data as of 30th May 2020

Act, Regulations and Guidelines

1. The Medicines Act of the Kingdom of Bhutan 2003.
2. Bhutan Medicine Rules & Regulations 2019.
3. Blood & Blood Products Regulation of Bhutan 2016.
4. Guideline for Management and Handling of Defective Medicinal Products, 2019.
5. Guideline for Sampling Pharmaceuticals & Related Materials 2019.
6. Medical Device Strategy 2018.
7. Guidance document on Technical Authorization for Manufacture and Regulatory Certifications 2018.
8. Inspection Guideline 2018.
9. Guideline for Registration of Transfusion Transmissible Infections (TTI) Test Kits 2018.
10. Guideline for Regulating Health Supplements, 1st Edition 2018.
11. Guideline for Registration of Human Vaccines, 1st Edition 2018.
12. Pharmacovigilance Guide for Adverse Drug Reaction Monitoring and Causality Assessment 2017.
13. Guideline on Pharmacovigilance for Veterinary Centre 2017.
14. Guideline for Registration of API 2015.
15. Guideline for Registration of Biotechnology Products for Human Use 2014.
16. Guideline for Disposal of Pharmaceutical Waste 2014.
17. Guideline for Registration of Biotechnology Products for Veterinary Use 2014.
18. Guideline on Pharmacovigilance for Traditional Medicines 2014.
19. Guideline for filling the ADR forms 2014.
20. Guideline for Application for Registration of Medicinal Products 2013

Distriution of Private Retail Pharmacies



REGULATORY STATISTICS

71 Retail Pharmacies	**29** Wholesale Pharmacies	**2096** Products Registered	**04** Local Manufacturers
143 Competent Persons Registered	**142** Private Pharmacies inspected	**127** Hospitals Inspected	**54** Veterinary Centers Inspected
05 Local Manufacturers Inspected	**07** Overseas Manufacturers Inspected	**02** Blood Centers Inspected	**13** Blood Storage Centers Inspected
67 Hand Sanitizers Tested	**13** Medicines Recalled	**80** Adverse Drug Reactions Received	**234** Medicines Tested

Data as of 30th May 2020

Highlights

2019

Celebration of DRA Foundation Day

June 14 ☑

Coinciding with the World Blood Donor Day, the Drug Regulatory Authority celebrated its first ever Foundation Day on 14th June 2019. The event was graced by the Health Minister, HE Lyonpo Dechen Wangmo as the Chief Guest. Other guests included senior government officials from various agencies such as the WHO, KGUMSB, MoH, MoAF, BoB, MSPCL and representatives of private business entities. On this occasion, Quality Manual, Technical Guidance Document on Manufacturing of Medicinal Products and Newsletter. In addition, advocacy materials were also launched promoting public awareness on antimicrobial resistance, health supplements and blood safety.

Bhutan Medicines Board (BMB) Meeting

August 22 ☑

The nineteenth Bhutan Medicines Board meeting was convened on 22 August 2019 at Hotel Terma Linka, Thimphu. Besides approving the Bhutan Medicines Rules and Regulations 2019, the Board also discussed a wide variety of issues ranging from the need of incinerators for disposal of pharmaceutical waste and regulation of health supplements to strengthening the capacity of the National Drug Testing Laboratory.

Signing of Annual Performance Agreement (APA)

October 07 ☑

The Annual Performance Agreement for fiscal year 2019-20 was signed with the Prime Minister His Excellency Dr. Lotay Tshering on 7th October 2019. Under this performance agreement, the Authority aims at further enhancing the regulatory services by digitalization of regulatory systems and certification for Quality Management System (ISO 9001:2015).

Medsafetyweek

November 25 - 29 ☑

The Authority joined the international community in observing the medicines safety week (25-29 November) organized by the Uppsala Monitoring Center, Sweden, to create awareness for safe use of medicines. TV, Radio, social media platforms were used to create awareness on risk associated with antimicrobial resistance, adverse drug reactions, self-medication and polypharmacy. An animation video on medicine safety was released on the occasion.

Meeting of Drugs Technical Advisory Committee (DTAC)

Dec. 30 - 31 ☑

The 37th DTAC meeting held from 30-31st December 2019. The committee discussed on issues related to import and sale of medicines; technical authorization for veterinary vaccine production; capacity development for laboratory testing and strategies to minimize wastage of medicinal products. The committee endorsed Veterinary Pharmacovigilance Guideline or animal feed supplement guideline.

2020

Meeting of Blood Technical Advisory Committee (BTAC)

January 07 ☑

The 7th BTAC meeting was held on 7th January 2020. The committee reviewed national strategic plan on safe blood and discussed the inspection findings of blood centers and blood storage centers. Furthermore, the committee deliberated on the need of expertise for calibration of biomedical equipment and importance of collaborating with nurses for reporting adverse transfusion reactions.

Capacity Building for Regulation of Health Supplements

January 27-31 ☑

To strengthen the regulatory capacity, a four-days training was conducted from 27-31 January 2020 on regulation of health supplements in collaboration with experts from the Food and Drug Administration, Thailand. The training was attended by officials from the JDWNRH, Bhutan Standards Bureau, Bhutan Agriculture & Food Regulatory Authority, Menjong Sorig Pharmaceuticals Corporation Limited, private stakeholders and DRA.

Annual Stakeholder Meeting

February 27-28 ☑

The annual stakeholder meeting was held from 27-28th February 2020. 75 participants consisting mostly of medicine wholesalers and pharmacy retailers attended the meeting.

The participants were briefed on the global status and situation of COVID-19 and updated on the revised Regulation and Guideline for Registration of Medicinal Products.

Issues related to registration, import and procurement of medicines as well as inspection findings were discussed. The meeting also discussed the importance of the Pharmaceutical Association of Bhutan.

Capacity Building for Regulation of Vaccines

February 11-14 ☑

A training workshop was organized in Paro from 11-14 February 2020 to build capacity in review of Common Technical Dossier and Lot Release. Officials from Department of Livestock and the Drug Regulatory Authority attended the workshop. The training workshop was facilitated by resource persons from Thai Food and Drug Administration and National Institute of Biologics, Noida, India.

Regulatory Updates

Recall of Ranitidine	Following the reports in international media on contamination of some ranitidine products with traces of N-Nitrosodimethylamine (NDMA), the Authority issued a Notification on 4 October 2019, recalling two batches of Ranitidine and suspending the use of other brands. Suspension was later lifted as no contamination was detected.
Revision of Guideline for Registration of Medicinal Products 2013.	The Guideline for Registration of Medicinal Products 2013 has been revised. The revised guideline will be ready for implementation from the coming fiscal year.
GMP Inspection	Nine manufacturing companies in India including health supplement manufacturer and medical device manufacturer were inspected for good manufacturing practices. Following the inspection, necessary regulatory actions were taken considering their compliance to GMP standards.
Regulation of Medical Devices	As per the Medical Device Control Strategy 2018, the Authority has initiated testing of medical devices such as TTI Test Kits, syringes, surgical gloves and condoms.
Monitoring of Blood and Blood Products	A total of 25 centers including 3 Blood Centers and 22 Blood Storage centers were inspected. The compliance rate was above 80.36%.
Regulation of Clinical Trial	All clinical trials involving use of medicinal products will require prior approval from the Authority as per the revised Regulation 2019.
Quality Management System	The Authority initiated implementation of the QMS as per ISO 9001:2015. in 2015. With support from the Bhutan Standards Bureau, stage I of the audit has been conducted.
Testing of Hand Sanitizers	The Authority tested 67 different brands of hand sanitizers for alcohol content and antimicrobial activity. The results are available on the Authority's website www.dra.gov.bt
Emergency Use Authorization	The Authority granted emergency use authorization of Hydroxychloroquine and Azithromycin for management of COVID-19.

International Participation

Bhutan joins the WHO Collaborative Registration Procedure (CRP)

In December 2019, the Authority was accepted to participate in the WHO collaborative registration procedure. This will ensure that we have access to technical reports of the WHO prequalification team and will be able to leverage their assessment reports to accelerate the registration of vaccines and other medical products in the country.

Bhutan joins the WHO-National Control Laboratory Network for Biologicals (WHO-NNB)

In July, 2019 the Authority became a member of the WHO-National Control Laboratory Network for Biologicals (WHO-NNB). This operational network is a platform for collaboration and technical exchange on quality control and quality assurance of vaccines or other biological medicinal products. WHO-NNB's main objectives are to share quality and technical information related to prequalified products; facilitate access to and availability of prequalified vaccines (or other biological medicinal products) through reliance on the batch release of the respective, responsible Network members by recipient countries, thereby reducing redundant testing; promote development of harmonized common standards; and share best practices.

South East Asia Regulatory Network (SEARN)

The Authority became a member of the South East Asia Regulatory Network (SEARN) in 2017. Since then, we have been actively participating in the network meetings. In 2019, Bhutan was appointed as a member of the Steering Committee of the network. This network of South East Asian Regulators is a platform for information sharing on regulatory policies, guidelines, standards etc. between regulatory authorities in the region while also facilitating regulatory support and capacity building.

WHO-International Drug Monitoring Program

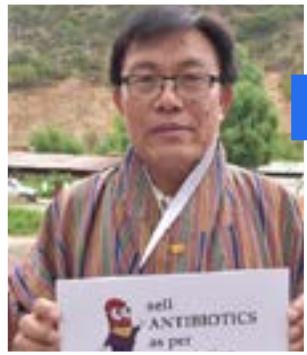
Since our first acceptance in the WHO-International Drug Monitoring Program in 2014, we have been an active member of the drug safety program by taking part in various activities of Pharmacovigilance. Under this program, reports of Adverse Drug Reactions received from the health centers are shared around the country are shared to the Uppsala Monitoring Center and in turn we get access to a global database of medicines safety information in the form of ViGibase and ViGILyse.

Boosting Medicines Safety Communication

In order to boost communication and increase the outreach of medicines safety information, posters and pamphlets were printed on various topics such as Antimicrobial Resistance, Pharmacovigilance and Defective Medicines. Information flyers were also designed and printed for key services such as registration of medicines and competent persons, technical authorization, advertisement clearance, pharmaceutical wastes etc. Relevant health professionals and competent persons can download these materials from DRA's website and printed copies can be obtained from the Post Marketing Control Division, DRA.

Implementing Quality Management System

Following the recommendations of the WHO-GAVI assessment team in 2014, the Authority started implementation of Quality Management System (QMS) based on ISO 9001:2015 since 2015 with financial support from the World Health Organization. The Authority is targeting for QMS certification in the 12th Five Year Plan. To this end, Quality Manual and Standard Operating Procedures are in place and numerous in-house trainings are routinely being conducted. Periodic internal audits are also carried out to monitor the implementation and corrective & preventive actions are taken to rectify the gaps. The findings of internal audits are deliberated in the management review meeting. In 2019, Bhutan Standards Bureau completed the stage-I audit of DRA QMS certification. Stage-II audit is currently pending due to COVID-19 pandemic.



Challenges

The field of health and medicine is progressing rapidly with advancement in science and technology resulting in introduction of new products and treatment methods. This demands the regulators to be abreast with the details of the latest information for market approval and safety monitoring. Following are some of the challenges faced by Authority:

Infrastructure

The Authority currently functions from a rented apartment. Availability of a permanent office space would enhance the security and efficiency of service delivery.

Human Resource

Although the Authority is staffed with adequate number of human resources, given the complexity and technical nature of the products, there is need for more expertise and experience in specific fields.

Registration of Medicinal Products

Due to small market size, importers are not keen to register the products thus posing challenges in implementation of the Regulation.

Domestic Production

Although few firms are in the pipeline, there is no manufacturer of pharmaceutical formulations in the country hampering accessibility.

Legislative Framework

With increased mandates and international developments over the years, the current Act needs to be reviewed to cover areas such as medical devices and diagnostics, cosmetics, health supplements and clinical trials.

Looking Forward

The Authority rejoices in the successful implementation of most of the planned activities despite challenges posed by the COVID-19 pandemic.

In the past year, the Authority used various strategies to mitigate the emerging challenges. In the same manner, we will continue promoting regulatory compliance through better communication and coordination with the stakeholders. The Authority will adopt risk-based strategies to make best use of the limited resources without compromising the quality of medicinal products.

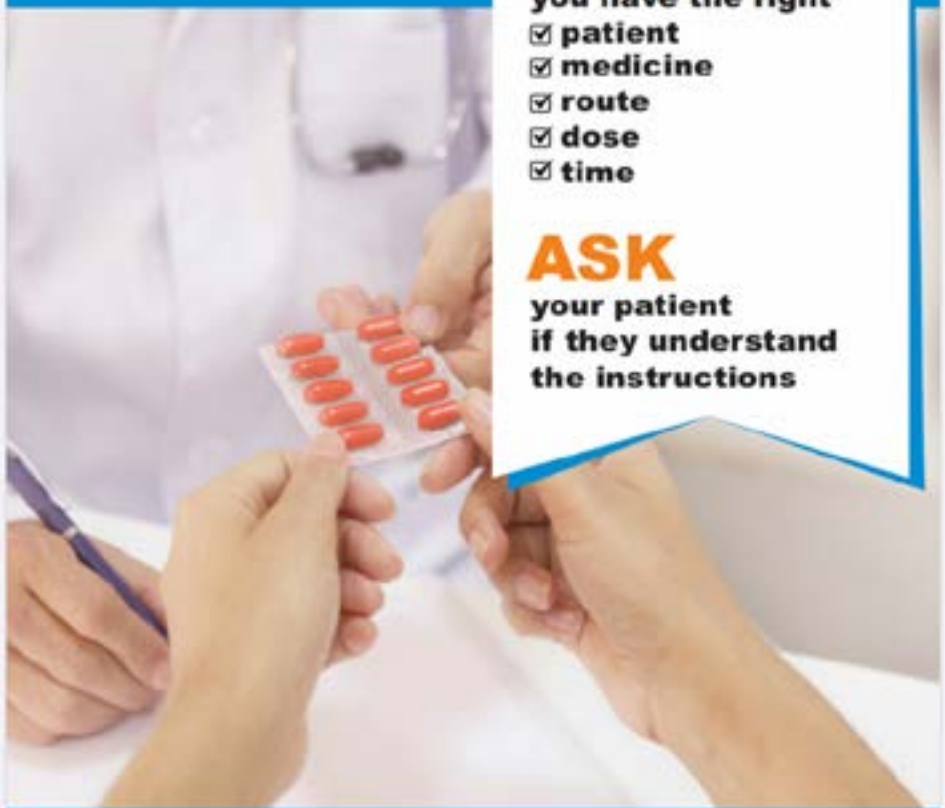
Looking down the line, we envision a Regulatory Authority that is ISO certified and equipped with better legislative tools and skilled human resource to ensure the accessibility, availability and affordability of quality medicinal products for the Bhutanese.

Towards this direction, the Authority will refine the internal working systems in line with ISO 9001:2015 quality management system; process for amendment or repeal of the Act; continue capacity building of the human resource; pursue for a permanent infrastructure; collaborate with international partners and promote local pharma industry.

Upcoming Events

June	14	DRA Foundation Day
September	25	World Pharmacy Day
November	02-06	MedSafety Week
November	18-24	AMR week
March	08 - 14	Patient Safety Week

BEFORE YOU GIVE MEDICINES



KNOW
your medicine

CHECK
you have the right
- ☑ patient
- ☑ medicine
- ☑ route
- ☑ dose
- ☑ time

ASK
your patient
if they understand
the instructions

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Thimphu, Bhutan Phone:+975-2-337074/337075
Website: www.dra.gov.bt

BEFORE YOU TAKE MEDICINES

KNOW
your medicine

CHECK
that you are using
the right medicine
the right way

ASK
your healthcare
professional
if you're unsure

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Avoid wasting medicines
Each year government spends millions to provide free medicines.
It is our responsibility to ensure that medicines are used judiciously.
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Promoting availability of quality, safe and efficacious medicinal products for consumers.

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