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Drug Regulatory Authority

Annual Report

ANNUAL REPORT 2021-22

Drug Regulatory Authority,
Royal Government of Bhutan
P.O Box 1556
Thimphu, Bhut

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Foreword

The Drug Regulatory Authority plays an important role in ensuring the quality, safety and efficacy of medicinal products in the country. As the nation transitions to phase two of the COVID-19 pandemic response supported by the evidence of efficacy of the vaccine, the DRA continues to be involved in approval and monitoring of COVID-19 vaccines and other associated medicinal products.

Medicinal products are a fundamental building block of the healthcare system and as we are dependent on import of medicines and medical products, instituting an effective and efficient vigilance system is even more important. The authority strives to establish an effective regulatory system in spite of all the challenges related to quality of medicines.

It is our pleasure to present the annual report 2021-22. We hope that this report will be useful in creating awareness on the mandates and core functions of the DRA and also update the stakeholders on the achievements and challenges of the Authority.

Tashi Delek!

(Wangdi Gyeltshen)
Drug Controller

Acknowledgement

We would like to express our appreciation and gratitude to all that were party to our journey thus far in varying ways. We would also like to express gratitude to those who contributed in developing this report and the editorial members for their efforts in shaping this report.

VISION

The most dynamic, reliable and client-centric model regulatory organization.

MISSION

Promoting availability of quality, safe and efficacious medicinal products for consumers.

About Drug Regulatory Authority (DRA)

The Drug Regulatory Authority (DRA) by ensuring medicinal products available in the country meet applicable standards of safety, quality and efficacy plays a role in protecting and improving public health. The authority regulates human allopathic medicines, vaccines, veterinary medicines, blood and blood products, traditional medicines and health supplements. Stakeholders range from manufacturers, importers, private pharmacies, project clinics and government agencies (Ministry of Health and Ministry of Agriculture and Forests). The authority is governed by the Medicines Board and receives technical advice from two Technical Advisory Committees on Drug and Blood.

Product registration and post marketing surveillance including testing of medical products and inspection of sale, storage and manufacturing premises form the core mandate of the authority. Our primary objective is to increase patient's access to quality-assured medicinal products.

Legislations, policies and strategies with operational documents are in place that enable the authority to perform its functions. However, we regularly review and update our regulatory frameworks and regulations to ensure that they are forward looking and fit for purpose. During the year, we have reviewed the medicines regulations to regulate medical devices, developed inspection and drug testing strategies. To cope with the unprecedented and rapidly changing landscape arising from a global pandemic, we had to remain nimble and adaptive to ensure timely access to diagnostic tests, medicines and vaccines, while ensuring safety, quality and efficacy. The authority granted Emergency Use Authorization (EUA) for deployment of five COVID-19 vaccines and conducted nation-wide surveillance during the 1st and 2nd round of the vaccination campaign and booster dose to ensure compliance to conditions of the EUA including the integrity of the cold chain and monitoring of Adverse Events Following Immunization (AEFI) and also enable midcourse correction.

The authority is comprised of 36 staff and is housed in the rented available office spaces spread over three nearby buildings. Majority of the staff are technical officials and are the foundation to the authority's success. We have developed a list of professional critical skills and complementary competencies to help DRA professionals equip themselves with the skills required of a future-ready workforce. To help staff reach their full potential, we are constantly encouraging our staff to take up courses to upgrade and reskill. It has also been acknowledged that the upkeep of the skills requisite of the specific position is an individual responsibility. We took advantage of the opportunities presented by the pandemic in the form of e-learning courses provided by the development partners and other Stringent Regulatory Authorities. As part of the overall civil service, we are committed to nurturing value driven individuals who feel a strong sense of belonging, and who take pride in the work that we do.

Regulatory compliance is more of data management game and we have been taking advantage of the ICT revolution through digitizing of authority's data and also fostering collaboration with partners for greater synergy to enable us to serve the public better. Most of the regulatory functions are routine processes and we are reviewing the current processes to see how they can be simplified and streamlined using automation. That way, we would be able to relieve our staff from repetitive tasks, and move them towards higher value work and continually improve our work processes by leveraging new technologies to enhance efficiency.

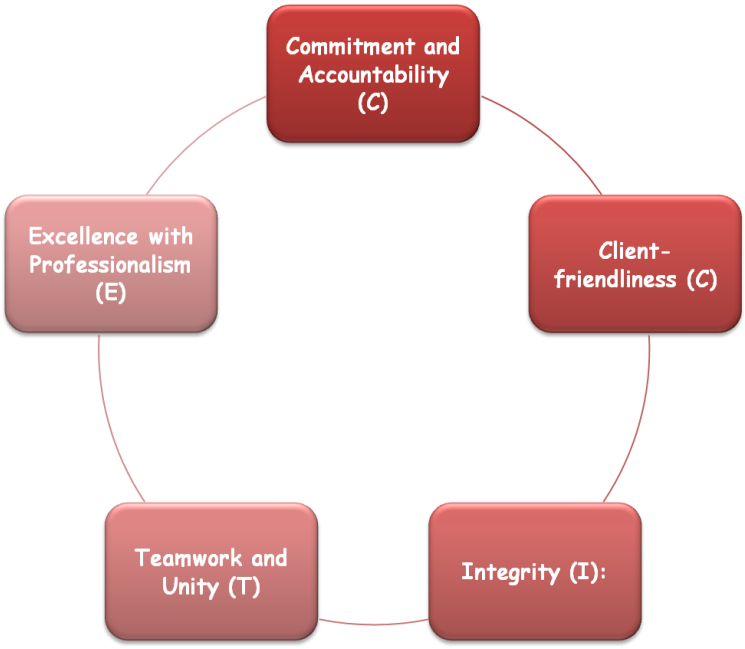
In the connected world, it is imperative than ever for us to build and strengthen our international networks. Indeed, strong partnerships are critical to expanding our capabilities, staying up-to-date with the latest developments in health sciences and promoting harmonization. While the basic tenets and functions of medicines regulation are common, the resources and capabilities of regulatory authorities can vary widely. In this regard, smaller regulators like us have to strengthen global partnership, collaborate with World Health Organization (WHO) and continue to work closely with our South East Asian Regulatory Network (SEARN) counterparts to share knowledge and best practices and promote harmonization and convergence of regulatory practices.

To strengthen management, work standards and ethics, we have adopted the ISO 9001:2015 Quality Management System (QMS) and plans are in place to get certified; to gauge the maturity level and also ascertain the functionality as the National Regulatory Authority (NRA) we have subjected ourselves to the WHO Global Benchmarking that has rendered us improvement and strengthening action plan going forward.

Core Mandates

1. •Authorize the manufacture, import, export, sale, distribution and storage of the medicinal products including blood and blood products
2. •Register medicinal products which are manufactured within as well as imported into the country
3. •List health supplements
4. •Monitor the competency and skills of personnel involved in the manufacture, import, storage and sale of the medicinal products
5. • Inspect premises involved in manufacture, sale, distribution and storage of medicinal products including blood and blood products
6. •Maintain up-to-date information in the form of Bhutan National Formulary and Drug Safety information
7. •Monitor the trends and cases of adverse effects resulting from medicinal products
8. •Inform the public on the use and harmful effects of medicinal products
9. •Promote policies for improved access to cost-effective quality medicinal products
10. •Conduct research on pertinent issues related to medicinal products
11. •Deliver the regulatory services to the public in a cost effective and efficient manner

Our Core Values



Commitment and Accountability (C): We are committed to our job and accountable for our own actions.

Client-friendliness (C): We provide services to our clients efficiently and consider the feedback received from our clients positively.

Integrity (I): We are always open and honest at work and maintain integrity.

Teamwork and Unity (T): We value everyone's role in the organization and believe in the strength of our unity.

Excellence with Professionalism (E): We do things in a systematic manner and strive for excellence.

DRA Services

Registration of Medicinal 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 medicinal products is a mechanism to ensure medicines' safety, quality and efficacy. The applicant has to submit required documents along with an application fee of Nu. 500/-. Each application is subjected to evaluation by the Product Registration Committee and the turnaround time for the registration is 60 calendar days from the date of application. 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 DRA.

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 with the DRA by submitting required documents and a fee of Nu. 500/-. The product will be listed within 30 working days upon fulfillment of conditions set in 'The Guideline for Regulating Health Supplements.

Import Authorization for Medicinal Products

As per section 22 of the Act, import of any medicinal product in the country shall require an Import Authorization from the DRA prior to import. Import Authorization is issued within a turnaround time of 7 working days from the date of application.

Export Authorization for Medicinal Products

In accordance with section 23 of the Act, export of any medicinal product shall require an Export Authorization from the DRA prior to export of the medicines to other countries. Export Authorization is issued within a turnaround time of 2 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 DRA. 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 Medicinal 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 DRA. This is a prerequisite for obtaining a trade license from the Ministry of Economic Affairs. 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 DRA 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 Medicinal Products

As per section 21 of the Act, all medicinal products to be manufactured in the country shall require prior approval from the DRA. 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 Economic Affairs for manufacturing any medicinal 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, DRA facilitates annual disposal of pharmaceutical waste generated from retail pharmacies. Considering the concentration of retail pharmacies, Thimphu and Phuentsholing are identified as collection centers.

Good Manufacturing Practice Certification & Free Sale Certificate

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

Registration of TTI Test Kits

Registration of TTI test kits is a mechanism to ensure TTI test kit safety, quality and performance. The applicant has to submit required documents along with an application fee of

Nu.500/-. The turnaround time for the registration is 60 calendar days from the date of application. The registration certificate fee is Nu.1500/- per product.

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 DRA. 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 DRA is subjected to issuing warnings and imposing fines. The service can be availed within a turnaround time of 5 working days.

Human Resource

Sl. No.	Division	Strength
1	Registration Division	10
2	Post Marketing Control Division	11
3	Planning and Policy Services	03
4	Administration & Finance Section	12
	Total	**36**

New Appointments

In the year 2021(July) and 2022 (January), new Regulatory Officers - Ms Sangay Choden, Pharmacist, Mr. Dorji, Pharmacist and Mr. Thinley Zangpo, Pharmacist, joined the Registration Division and Post Marketing Control Division after successfully getting through the Royal Civil Service Examination.

Thai Volunteer

In the month of May 2022, the DRA welcomed Mr. Nattawat Sirawattanachai, Thai Volunteer (under the scheme "Friends From Thailand"). He will be working with DRA for a year and will be helping to enhance the DRA e-services and information system.

Royal Civil Service Award

Two employees-, Ms. Karma and Ms. Choejay Zangmo received the Royal Civil Service Award (Gold and silver). Mr. Tashi Dhendrup, Regulatory Officer also received a congratulatory certificate for his outstanding performance in FY 2020-21.

HR Challenges

As per the World Health Organization, DRA has nine core functions -national regulatory system; registration and marketing authorization, vigilance, market surveillance and control, licensing establishments, regulatory inspection, laboratory testing, clinical trials oversight and lot release of vaccines. Given limited resources, training to specialize employees in above areas has proven to be an arduous task.

Stories and updates of the year

1. WHO Pre-benchmarking of DRA

The World Health Organization (WHO) has been supporting countries in strengthening their regulatory systems, and promoting equitable access to quality, safe, efficacious, and affordable medical products and health products. Various World Health Assembly resolutions encompass aspects of the need to promote the aforementioned WHO role. National Regulatory Authorities are an essential part of the health system and contribute to better public health outcomes. On the contrary, inefficient regulatory systems themselves can be a barrier to access safe, effective and quality medical products.

The Regulatory System Strengthening (RSS) programme was established a few decades ago in the WHO. The RSS programme is based on a five-step capacity building strategy starting with development of tools used for assessment and benchmarking of the regulatory system in the Member States, followed by the actual benchmarking (assessment) of the National Regulatory Authority (NRA) to identify strengths as well as areas for improvement, the development of an Institutional Development Plan to build on strengths and address areas for improvement. Afterwards, the WHO provides technical support in the implementation of the IDP followed by continued monitoring of progress and outcome/impact.

DRA requested technical assistance from the WHO to support pre-benchmarking in March 2022. The WHO Regulatory System Strengthening Team, together with the WHO Regional Office for South East Asia and WHO Country Office in Bhutan conducted the pre-benchmarking exercise from 7-11 March 2022.

2. Regulatory flexibilities during Covid-19 pandemic in Bhutan

The Drug Regulatory Authority has played significant roles in ensuring timely access to medical products including Covid-19 vaccines during the pandemic. Critical shortages of oxygen were reported in many countries including neighboring India. Responding to the increased demand for oxygen supplies, licensing of new oxygen manufacturing facilities was expedited, and the requirement of key personnel from undergoing competency review by DRA was exempted. An interim guideline adopted for the regulation of surgical face masks and surgical respirators allowed community pharmacies to import and sell surgical face masks and surgical respirators. Imported face masks were approved based on a documentary review.

Bhutan experienced four national COVID-19 lockdowns ranging from 21-42 days. The DRA appointed service delivery focal persons who worked during the lockdowns to deliver essential regulatory services such as import authorizations, vaccine lot release, and product registration. A

team of officials traveled across 17 districts to monitor adverse events following immunizations in 220 and 214 vaccination sites during the first and second vaccination campaigns respectively. Community pharmacies were permitted to operate in respective zones during the lockdowns to facilitate home delivery of basic essential medicines in coordination with the Ministry of Health. The product samples required to be submitted for the registration of medical products were exempted to ease the regulatory burden.

An emergency use authorization (EUA) is a regulatory mechanism adopted by national regulatory authorities to approve the use of unapproved medical products (or unapproved uses of approved medical products) to manage declared public health emergencies for which there are no adequate, approved, and available alternatives 9. In Bhutan, EUA for COVID-19 vaccines and COVID-19 antigen self-test kits were granted by the DRA. Acknowledging the unprecedented speed at which the COVID-19 vaccines were being developed and the complexity involved in performing a complete, independent assessment of the safety, efficacy and quality of such vaccines, a recognition and reliance mechanism was adopted to leverage the assessment conducted by stringent National Regulatory Authorities or Pharmaceutical Inspection Committee/Schemes member countries. The guideline for EUA was formulated to ensure rapid access to COVID-19 vaccines.

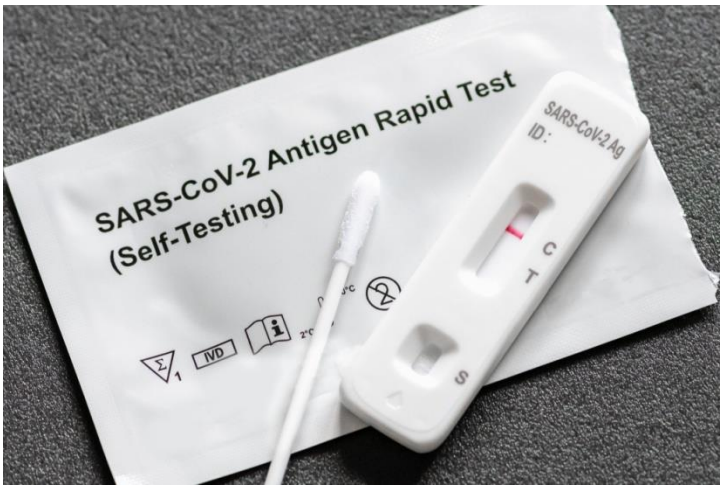
Approval processes for EUA were significantly expedited by reducing turnaround time from 60 days to 7 days by a dedicated team of regulatory officials who reviewed the applications for EUA vis-à-vis the national regulatory requirements. The first EUA for the COVID-19 vaccine was granted on 17 March 2021. Since then, all six COVID-19 vaccines and 4 antigen self-test kits used in the country were issued EUA. Similarly, lot release certificates for COVID-19 vaccines were issued on the date of arrival of the consignment to complement the government's effort for the rapid delivery of COVID-19 vaccines.

Going forward in the post-pandemic era, regularizing EUA to routine marketing approvals needs to be carefully monitored and implemented. Continuing with regulatory processes adopted

during the pandemic could disrupt the whole regulatory system, creating an avenue for substandard products to enter the market. There must be a clear validity for how long the regulatory exemptions applied during the pandemic will continue. The reactive regulatory approach adopted and implemented during the pandemic may have to continue or be replaced post-pandemic. Hence, proper evaluation and risk-benefit rationality must guide such decision makings.

3. Covid-19 Self-Test Kit: What should we know?

A self-test kit is a medical device labeled for use in any environment outside a professional healthcare facility and intended for use by healthcare professionals and lay persons. This includes but is not limited to outdoor environments, office environments, schools, vehicles, emergency shelters, and independent living retirement homes. They detect current infection and are sometimes also called "home tests," "at-home tests," or "over-the-counter (OTC) tests." They give results in a few minutes and are different from laboratory-based tests that may take days to return your result.



COVID-19 Rapid Test Kits are classified as Class D Medical Devices according to Rule 1 of Global Harmonization Task Force Invitro Diagnostic Devices(IVD) Risk classification principles, which states that any IVD medical devices intended for the following purposes are classified as Class D:

- *Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, blood derivatives, cells, tissues or organs in order to assess their suitability for transfusion or transplantation, or*

- *Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening, often incurable, disease with a high risk of propagation*

Self-testing with COVID-19 antigen tests was first authorized by the US Food and Drug Administration in November 2020 to allow symptomatic people and those that had COVID-19 contacts to test themselves. By 2021 antigen tests and self testing was firmly entrenched in most developed countries. In April 2022, the Ministry of Health granted policy clearance for use of the Self-test kit in Bhutan after conducting an assessment on its use and the Drug Regulatory Authority(DRA) started regulating Covid-19 self-test kits thereafter.

The self test kits used for detecting SARS-CoV-2 infection authorized by DRA through emergency use authorization primarily use antigen detection, and the test has advantages and limitations in terms of sensitivity and specificity, cost, results reporting, and results turnaround time. In clinical studies, these tests provide accurate positive results in symptomatic individuals, although negative results are less accurate. There are also accuracy concerns for positive results in asymptomatic individuals. These factors have implications for their clinical interpretation and use.As compared to molecular or PCR testing, at-home COVID-19 test kits may not be the same in terms of accuracy.

The chances of getting a false positive or negative is much higher with at-home rapid antigen tests than in a PCR test.The self- test kit detects the protein part only, and not the entire virus RNA for interpreting the result. Whereas, molecular testing helps detect the RNA or the genetic component of the virus, which is likely to present the most accurate results. However, antigen tests produce results faster than molecular tests do; point-of-care tests yield results in as little as 15 to 30 minutes. In addition, antigen tests are less expensive compared to RT-PCR tests and don’t require specialized laboratory technique. Antigen testing also offers quick screening and detection of COVID-19 among high-risk groups and in high-congregate environments.

The increased demand for COVID-19 testing has led to the rapid development of testing methods and the parallel growth in knowledge, including limitations and advantages of each method. COVID-19 testing has become a pivotal component of public health strategies for curbing the spread of the disease.

4. ISO 13485 Lead Auditor Training

In the quest to enhance competency in the field of medical devices, four officials from the Drug Regulatory Authority availed the virtual training on the Lead auditor ISO 13485:2016 for five days, conducted by the Academy Division of the TUV SUD South Asia Pvt. Ltd, India. The ISO 13485:2016 is an international standard that establishes the requirements for a quality management system specific to the medical devices where an organization needs to demonstrate its ability to provide medical devices and related services to consistently meet customer and applicable regulatory requirements.

During the course of training, the participants were educated on the key principles and practices of effective quality management system audits against ISO 13485, in accordance with ISO 19011 "Guidelines for auditing management systems."The participants were taken through the entire audit process, from planning and initiating the audit through to conducting audit follow-up, to ensure a successful audit in conformity with ISO 13485.

The course provided a comprehensive hands-on training to ensure that the participants thoroughly understand the role of an auditor and acquire the expertise required to perform an effective audit.The training also included case studies, role-plays, exercises, workshops, and group discussions making the training course participative and interactive. At the end of the 5 days training course, the participants were evaluated through a closed book written examination and continuous assessment. Participants who scored 70% and above in both the continuous assessment and written examination were issued a CQI IRCA (Charted Quality Institute - International Register of Certificated Auditors) registered certificate of successful completion of the course, which is renowned in certification and carries worldwide acceptance.

The training has equipped the participants with the required knowledge and skills for effective quality management system audits which would immensely benefit the regulatory agencies in regulating the medical devices and ensuring safe, quality and performance medical devices.

5. National Outbreak Investigation and Surveillance Team for Covid-19

The first case of Covid-19 was detected on March 5, 2020 and subsequently the Ministry of Health (MoH) instituted immediate emergency response. Different teams such as Technical Advisory Group (TAG), National Outbreak Investigation and Surveillance Team (NOIST) and Quarantine Team were formed with officials from different agencies. Officials from the Drug Regulatory Authority were also deployed to MoH to render full support in combating the National Emergency.

Three of the DRA officials became team members of NOIST. The team of about 17 members were divided into two teams and worked alternatively (weekly basis) between their respective

offices and as surveillance members. The team mainly looked after management of quarantine (isolation of positive cases, quarantining of primary contacts, incoming and domestic travelers) and scheduling testing of quarantined individuals (positive cases, primary contacts, incoming travelers and domestic travelers). They also served as a focal point of contact between the MoH and District Covid-19 Task Force.

Enhanced surveillance in each Dzongkhag which began at the later stage was also managed by the NOIST which focused on scheduled testing of frontline workers and randomized testing at institutions and agencies. With the gradual availability of more data on Covid-19, quarantining and testing protocols were timely reversed. The most challenging moments were during the outbreaks and national lockdowns requiring immediate response such as isolation of the positive cases, contact tracing, quarantining and testing of the primary contacts to prevent the spread of the virus. These immediate responses were crucial to know the spread of the virus and accordingly strategize opening of the lookdowns.

The two years of rollercoaster journey as a member of NOIST served as a great learning experience and opportunity. The members were updated on the worldwide information about covid-19 and helped to improve their active listening, communication, problem solving, analytical thinking and critical thinking skills. Most importantly being a member helped to realize the importance of teamwork and understand how each individual in their little ways can play a vital role in combating the pandemic.

6. Online services for DRA

As one of the service providing agencies, digitization of services of the Drug Regulatory Authority (DRA) was found to be ever more significant. The primary objectives of online services is to strengthen delivery of public services, reduce turnaround time (TAT), enhance accessibility and accountability. It also helps promote transparency and provide convenience to the service users.

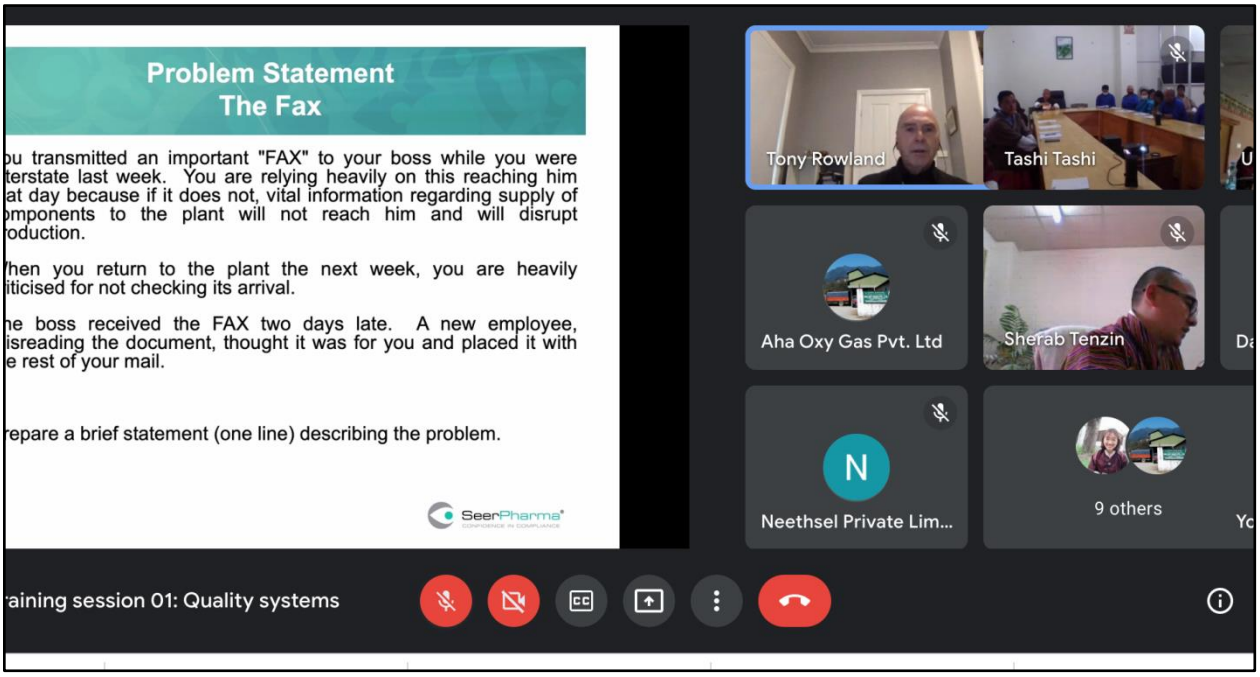
Through the G2C initiative, services of the DRA like import of medicinal products, registration of Competent Person, Technical Authorizations, changes in technical authorization details and renewal of Competent Person and Technical Authorizations have been made online. The G2C services for the DRA have been upgraded and prioritized and currently the upgraded system is under the testing phase.

For government services that need to rely on one another, integration of these existing systems help enable real-time data sharing and reduce the administrative burden on the service users. In our context, any applicant that wishes to establish a firm for sale or distribution and manufacture of medicinal products has to obtain an authorization from the DRA which is a prerequisite for the

trade license. In such cases, integration of the services at DRA and Department of Trade (DoT) would help avoid data duplication and administrative burden on the service users ultimately resulting in an effective and efficient service delivery. An initiative from the DoT has led to the development of Integrated Business Licensing System (IBLS). This integrated system would immensely benefit both the agency and its clients in achieving an efficient service delivery. The system is expected to be functional and live from July 2022.

Registration of medicinal products is another vital function of the DRA whose services are being digitized. Applicants representing drug manufacturers submit product dossiers that are assessed by regulators for compliance with international standards of safety, quality and efficacy. The result of these assessments determine whether their product gets registered or not. A few years ago product dossiers were submitted in hard copies that were often bulky and inconvenient during submissions. Gradually, the DRA encouraged the submission of electronic copies of the product dossiers and in 2022, e-dossiers were made the mandatory format. Submissions of dossiers were also made much more convenient by using Google services like google forms where applicants can submit their dossiers without having to visit the DRA office. The DRA plans to further upgrade the online service of product registration by standardizing the e-dossier format with that of international standards such as the eCTD or NeeS format and also implement an official web portal for e-dossier submissions.

7. Virtual GMP training: Collaboration with Australian Volunteer Program



The Drug Regulatory Authority (DRA) conducted training on Good Manufacturing Practices (GMP) for medical products in collaboration with the Australian Volunteer Program and the scope of activity also included reinforcing the existing system of GMP inspection instituted at the Drug Regulatory Authority. The training was conducted by an Australian Volunteer, Mr. Tony Rowland, the Co-founder, former Director and Senior GxP Consultant with SeerPharma Pty Ltd.

The training and technical assistance initiated from 15 June to 22 September 2021 and during the course of training, various domestic pharmaceutical manufacturers i.e. Azista Bhutan Healthcare Limited, Menjong Sorig Pharmaceutical Corporation Limited, Neethsel Private Limited, Biological Production Unit, National Center for Animal Health, Quality Gases Private Limited, Aha-oxy Gases Private Limited and, Medical and Industrial Gases Industry; and regulators of the Drug Regulatory Authority were entailed. The training included the following modules:

1. Quality Systems and Integration of Quality System Elements
2. Auditing practices

3. Risk Management Principles
4. Supplier Management
5. Process Validation
6. Introduction to Validation
7. Process Validation
8. Cleaning Validation
9. Test Method Validation
10. Periodic Quality Review (PQR) & Basic Stats for PQR
11. Statistical Process Control
12. Equipment Qualification
13. Data Integrity
14. Release for Supply
15. Behavioral GMP

In addition to the foregoing training, the volunteer also assessed the GMP inspection procedures being implemented by DRA by reviewing the standard operating procedures and Guidance document for Technical Authorization to Manufacture Medical Products. Furthermore, albeit, via virtual mode, the GMP inspectors were also provided with a hands-on session of conducting GMP inspection.

Moreover, technical assistance was also provided to Biological Production Unit to enhance the manufacturing practices of vaccines and particularly qualification of critical equipment such as hot air oven, autoclave, freeze dryer. The volunteer was also instrumental in initiating institutional linkage between DRA and Therapeutic Goods Administration, Australia. To substantiate, Tony Rowland extended his expertise to deliberate on the pertinent issues that are anchored to the Good Manufacturing Practices trend in Bhutan and also documents such as Guidance document on Technical Authorization for Manufacture and Regulatory Certifications, Guidelines for Good Manufacturing Practices of Medical Gasses, draft guidelines for registration of medical devices were also reviewed. To this end, DRA is awfully indebted to Tony Rowland and the Australian Volunteer program.

8. GMP inspection at Lingzhi

Menjong Sorig Pharmaceuticals Corporation Limited (MSPCL) is the only pharmaceutical company in the country that manufactures traditional medicine and in addition to importation from India, they source their materials from various pockets of the country including Lingzhi.
With the objective of monitoring the practices that are being employed to collect and harvest indigenous materials and to assess its compliance to Good Collection Practices Guidelines, a GMP inspection was conducted at the Lingzhi Drying Unit of MSPCL. The inspection was conducted in accordance with the on-site GMP inspection of MSPCL.

From the visit, it was observed that the farmers are trained on the procedures relating to collection and harvesting of indigenous herbs and the raw materials are brought to the drying unit in crude form. Then post receipt, the materials are washed, chopped, dried, packaged, labeled and dispatched to MSPCL, Thimphu. Some materials are sun-dried while some are dried under shade and greenhouses, and the facility is also equipped with two tray dryers to expedite the drying processes.

While most of the processes involved in collection, harvesting and pre-processing of crude raw materials were found in compliance with the stipulated guidelines, some minor non-conformities were also raised during the inspection and the authority was appraised that corrective actions relating to changes in infrastructure to minimize the risk of contamination is already initiated.

9. Sensitization of the stakeholders

Stakeholder participation or engagement effectively carried out can mitigate risks and conflicts including dissatisfaction, misalignment, disengagement and resistance to change with the stakeholder groups. Therefore, it is pertinent to engage our stakeholders periodically to inform them on regulatory updates, new procedures and to seek feedback and suggestions on the regulatory approaches adopted by the Authority.

Recently, a sensitization workshop, i.e the 6th stakeholder workshop, was conducted by the Drug Regulatory Authority from 13-15th June, 2022 to create a platform where the stakeholders involved in the regulatory cycle shared their challenges and issues faced by them on a usual basis and mitigations for such problems were also discussed by taking in opinions from the relevant stakeholders.

The workshop involved a total of 89 participants. The stakeholders include the pharmacy wholesalers and retailers, custom office, procurement agency and postal services. The pertinent issues from the private sector were with regards to shortage of Competent person in the market, non availability of certain registered medicines and the import and sale of non registered medicines. The floor was open for plenary discussion for each issue pointed out, its mitigation was discussed among the stakeholders and accordingly the recommendations were drawn.

10. Regulatory Updates

Guidelines developed:

1. Guidelines for lot release of vaccines
2. Guidelines for import, sale, distribution and use of COVID 19 self test kit
3. Guidelines for registration of medical devices
4. Guidelines for clinical trial authorization
5. Guidelines for issuance of import authorisation

No. of Medicinal Products Registered	2997
No. of essential medicines Registered	329
No. of Competent Persons Registered	175
No. of Retail Pharmacies	65
No. of Wholesale Pharmaceutical Firms	28
No. of Manufacturers in the country	7

No. of Private Pharmacies Inspected	41 facilities
No. of government health centers inspected	102 facilities
No. of veterinary centers inspected	51 facilities
No. of facilities with 100% compliant score	100% score by 75 facilities

No. of Medical Products Tested	448
No. of Vaccines Release conducted	16
No. of medical products recalled	6
No. of ADR received	336

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.’