UGANDA NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

Development and regulation of the pharmacies and drug shops in Uganda.

Control the importation, exportation and sale of pharmaceuticals.

Provide advice and guidance to the Minister and bodies concerned with drugs on the implementation of the national drug policy and act.

ANNUAL REPORT 2021-2022

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LIST OF ACRONYMS

ADR	Adverse Drug Reaction
AMA	African Medicines Agency
AMR	Antimicrobial Resistance
API	Active Pharmaceutical Ingredient
DP&NM	Department of Pharmaceuticals and Natural Medicines
EAC	East African Community
FY	Financial Year
GDP	Gross Domestic Product
GMP	Good Manufacturing Practices
GoU	Government of Uganda
HCs	Health Centres
HSDP	Health Sector Development Plan
IGAD	Inter Government Agency for Development
KPI	Key Performance Indicators
MAAIF	Ministry of Agriculture Animal Industry and Fisheries
MDAs	Ministries, Departments and Agencies
M&E	Monitoring and Evaluation
MOH	Ministry of Health
NCRI	Natural Chemotherapeutic Research Institute
NDA	National Drug Authority
NDP/A	National Development Plan Act
NDQCL	National Drug Quality Control Lab
NESW	National electronic Single Window
NIRA	National Identification AND Registration Authority
NMP	National Medicines Policy
NPSSP	National Pharmaceutical Sector Strategic Plan
NVDP	National Veterinary Drug Policy
PD	Pharmacy Division
PNFP	Private Not-For-Profit
PSU	Pharmaceutical Society of Uganda
RCOREs	Regional Centres of Regulatory Excellence
SDGs	Sustainable Development Goals
SDT	Service Delivery Timelines
SSFFC	Substandard/Spurious/Falsely labelled/Falsified/Counterfeit
TCMs	Traditional and complementary medicines
UBOS	Uganda Bureau of Standards
UCC	Uganda Communication Commission
UFDA	Uganda Food and Drugs Act
UHC	Universal Health Care
UNCST	Uganda, Uganda National Council for Science and Technology
UNHRO	Uganda National Health Research Organisation
VET	Veterinary
WHO	World Health Organisation
PHP	Public Health Products
PMS	Post Market Surveillance

ABOUT NDA

Mandate of NDA

To ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda, as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs.

The Legal Framework of NDA

The National DRUG Authority was established in 1993 by the National Drug Policy and Authority Statute which in 2000 became the National Drug Policy and Authority (NDP/A) Act 206 of the Laws of Uganda. Within its legislative mandate, National Drug Authority is responsible for;

1. Development and regulation of the pharmacies and drugs in Uganda.
2. Control the importation, exportation and sale of pharmaceuticals.
3. Encourage research and development of herbal medicines.
4. Promote and control local production of essential drugs.
5. Promote rational use of drugs through appropriate professional training.
6. Establish and revise professional guidelines and disseminate information to health professionals and the public.
7. Provide advice and guidance to the Minister and bodies concerned with drugs on the implementation of the national drug policy.
8. Approve the national list of essential drugs and supervise the revisions of the list.
9. Estimate drug needs to ensure that the needs are met.

Vision

A world class drug regulatory Agency.

Mission

To protect and promote human and animal health through the effective regulation of drugs and healthcare products.

Core Values

- We **Care** for the people of Uganda.
- We take **Pride** in what we do.
- We serve with **Integrity**.
- We value **Team spirit**.
- We Embrace **new knowledge and Innovation**.

OUR LOCATIONS

Where we are

The Head office is the NDA Secretariat located at Lumumba Avenue-Rumee Towers and the National Quality Control Laboratory in Mulago. In addition, there are nine regional offices across the country namely; Kampala Extra Region (Akamwesi), Kampala Central Region (Nakawa), West Nile Region (Arua), Northern Region (Lira), Western Region (Hoima), South Eastern Region (Jinja), North Eastern (Soroti), Eastern Region (Tororo) and South Western Region (Mbarara).

We also have presence at port of entries specifically; Entebbe International Airport, Nakawa, Malaba, and Busia. We are collaborating with Uganda Revenue Authority at the other ports to ensure effective control of entry of pharmaceuticals into the country.

Core regulatory Activities

Product Safety

1. Clinical Trials Protocol Review
2. Good Clinical Practice Inspection
3. Pharmacovigilance
4. Control of Drug Promotion
5. Research and drug advert.

Licensing and Inspection

1. GMP inspection
2. Drug Import and Export Control
3. Inspections and Licensing of drug outlets

Product Assessment and Registration

1. Dossier Evaluations
2. Evaluations of Variations
3. Product Registration (review of dossiers)
4. Public action of the National formulary

Laboratory Testing

Testing of medicines and other healthcare product samples from pre-market, port of entry and the market.

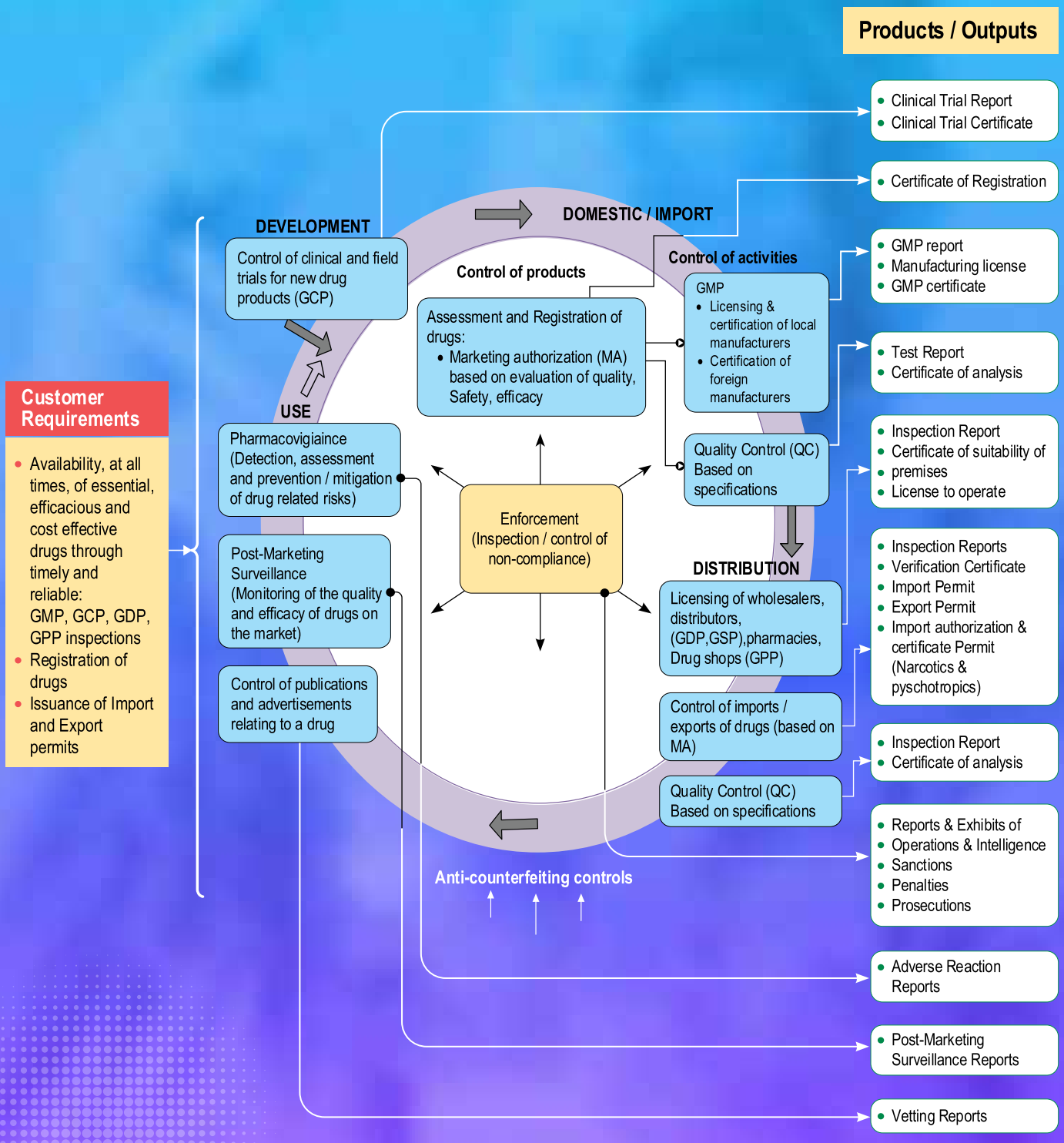
Market Surveillance

Monitoring medicines on the market to ensure that they are safe, efficacious and of good quality throughout their shelf-life.

Scope of Products Regulated

- Human and Veterinary Medicines.
- Surgical Instruments and Appliances.
- Herbal Medicines.
- Health care Products.

Drug Regulatory system process interaction diagram



PROCESS FLOW PER DIRECTORATE

Directorate of Product Safety (DPS)

Directorate of Product Safety ensures that the medicines marketed and used in Uganda meet acceptable levels of safety, quality and efficacy. The directorate team is responsible for pharmacovigilance, safety, regulation of clinical and field trials, exchange of medicines information on and regulation of the promotion of medicines and healthcare products.

The directorate is partitioned into distinct units, each being headed by either a manager or principal officer, who directly supervise their respective regulatory officers; and all the units are under the stewardship of the director. These units are arranged according to the various regulatory function.

Pharmacovigilance Unit

Medical products vigilance, defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medical product-related problems, is extremely important for guaranteeing that safe and effective medical products of high quality are used within the country. The pharmacovigilance unit conducts all activities relating to safety data collection, assessment and communication of safety information on medicines to the concerned stakeholders. Stakeholder engagement and sensitization on pharmacovigilance activities is key to the work done. Vigilance activities are based on a risk management approach.

There are 14 regional pharmacovigilance centres based in national and regional referral hospitals. The coordination of activities countrywide is hinged onto the regional pharmacovigilance centres which are of two types: the regional and national referral hospitals and the NDA regional offices. The NDA regional managers are important in following up the issues of poor quality and lack of efficacy in the private sector as well as receive the adverse drug event reports from public health facilities. The hospital-based centres manage the adverse drug events and medication errors, conduct some preliminary assessment and submit the ADR reports through Vigiflow or manually filled report through the pharmacovigilance centre.

The National Pharmacovigilance Centre in NDA runs a reporting system to monitor the safety of medical products. One important activity within that function is to monitor and assess side effects and other product-related safety issues (e.g., adverse drug reactions (ADRs) for medicines, and adverse events following immunization (AEFI) for vaccines).

The Ugandan National Pharmacovigilance Centre is headed by the Director of Product Safety and is a member of the WHO Programme of International Drug Monitoring. Uganda also participates in the East African Community pharmacovigilance expert working group where it seeks to harmonise vigilance systems and safety requirements in the region. Networking with other international bodies and regulators is important for acquiring, sharing, and exchanging the relevant information on medical products safety. This feeds into evidence-based decisions about drug safety in a timely manner.

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Clinical Trials Unit

In line with section 40 of the National Drug Authority and Policy Act Chapter 206 of the Uganda laws authorizes and regulates drug related clinical and field trials in Uganda to ensure the safety and wellbeing of study participants and also ensure that the data generated from the trials is scientifically valid and reliable. The unit does this through review and approval of clinical trial applications, conduct of clinical trial site inspections for compliance to good clinical practices, development of guidance documents, stakeholder engagement. Clinical Trial Certificates are issued and renewal is granted on an annual basis for the duration of the trial. Variations in clinical trial applications are assessed for approval. Clinical trial protocol deviations, protocol violations, trial termination or suspensions, updates of Investigator Brochures following new safety information are some of the activities handled by the unit. Safety information arising out of the ongoing clinical trials is also assessed by the unit.

Medicines' Information Unit

Control of publication of descriptive matter in relation to drugs is the mandate of NDA under section 33 of the NDPA Act. The medicines information unit champions rational advertisement of medicines by vetting promotional materials to ensure that the information is not misleading and targeted to the right audience. The unit regulates drug labelling and drug promotions in the market for illegal advertisements. Other activities include provision of information to prevent drug and substance abuse, and promote appropriate and safe use of medicines.

Research Unit

The research unit was established to promote knowledge management across NDA by building systems that support research and innovation. This has necessitated building capacity to retain institutional knowledge. This unit coordinate operational research activities within the organization including collaborative and supported research activities with staff.

Directorate of Product Assessment and Registration

The Directorate of Product Assessment and Registration ensures that all medicines registered in Uganda meet national and internationally accepted quality, safety and efficacy standards. The Directorate is mandated to carry out a comprehensive scientific evaluation of marketing-authorization applications so that all pharmaceutical products intended for use in Uganda meet their intended purpose and requirements. The Directorate has a qualified team that handles a range of both human and veterinary locally made and imported drug products. The key activities including; Evaluation of drug registration applications, handling of post-registration amendments to drug applications, archiving information on drug products (new applications, registered and suspended/de-registered) and Preparation and regular update of the National Drug Register.

Directorate of Inspectorate and Enforcement

The Directorate of Inspectorate and Enforcement is responsible for ensuring compliance with the laws and regulations that apply to the manufacture, control and supply of medicines and healthcare products including; human, veterinary, medical devices, natural health products and blood& blood products on the Ugandan market.

Inspectorate and enforcement activities are a crucial foundation of safeguarding the drugs and healthcare products which Ugandans have access to that medicines supplied in Uganda meet consistent high standards of quality, safety and efficacy.

Foreign manufacturing sites are also required to pass an inspection prior to approval of the marketing authorization application. Following approval, a risk-based inspection program maintains on-going surveillance of domestic and foreign manufacturing site compliance with NDA GMP.

GMP Inspectors are responsible for inspecting and authorizing a range of manufacturers of sterile and non-sterile dosage forms, biological products, herbal products and active pharmaceutical ingredients, in addition to analytical laboratories.

The safety and quality of human blood for transfusion, or for further manufacture into blood-derived medicines, is ensured through inspections of relevant collection, processing, testing and storage activities at Blood Establishments and Hospital Blood Banks. These inspections assess compliance with global regulatory requirements, which consider the detailed principles of GMP.

Good Manufacturing practices

GMP Inspectors conduct inspections of pharmaceutical manufacturers to assess compliance with NDA guidance on Good Manufacturing Practice (GMP) and the relevant details contained in marketing authorizations. They ensure

Import Control

Products are allowed entry into Uganda 0nly through gazetted ports of entry. Application for import permit is done online through the NDAMIS portal for licensed premises.

The Import operations, typically focus on issuance of verification certificates following application reviews, Port of entry Inspections and sampling. After the port of entry inspections, a decision of either goods authorization or rejection is issued.

Post Market Surveillance

In addition to getting safe effective and quality products to the market, NDA must ensure that the products currently on the market remain safe and effective.

NDA maintains a system of post marketing surveillance (PMS) and risk assessment programs to identify quality as well as safety and efficacy concerns that did not appear during the drug approval process. The Authority uses this information to update drug labelling, and occasionally to re-evaluate the approval or marketing decision. NDA maintains both reactive and proactive PMS systems including receipt of complaints as well as annual surveys

Our post market surveillance program consists of problem identification, problem assessment, and public-health response.

Regional offices for Inspections & licensing of premises

The nine (9) Regional offices conduct inspections for purposes of support supervision, issuance of certificates of suitability of premises and licensing of retailers and wholesalers.

Inspectors conduct inspections of sites of wholesale premises to assess compliance with Guidelines on Good Distribution Practice (GDP) and the conditions of a wholesale license.

Inspectors will ensure that medicinal products are handled, stored and transported under conditions as prescribed by the marketing authorization or product specification.

Inspections are undertaken for new applicants and renewals, then subsequently on a routine schedule based on a risk assessment of the site.

Enforcement

As part of its regulatory responsibilities, NDA monitors compliance, undertakes enforcement activities and works towards preventing non-compliance.

Enforcement actions include any actions NDA takes to compel or induce compliance in order to mitigate the risk identified by non-compliance with the Act.

Upon completion of an investigation, the NDA may use a range of sanctions, including the issuance of a warning letter or a formal caution. It can suspend, revoke or vary the authorizations held by the manufacturers and distributors of medicines. NDA may pursue criminal proceedings in appropriate circumstances.

Directorate of Corporate Services

The Directorate of Corporate Services contributes towards delivery and development of the NDA entity wide Institutional capacity, which is achieved through provision of human and infrastructure interventions. It comprises of five departments: Human Resource & Administration, Finance Department, ICT department, Quality Management Unit and Business Planning and Development Unit (BPD)

Human Resource and Administration department

The Human Resource and Administration department develops & deploys the requisite human resource capacity to deliver NDA's mandate, as well as manages Staff welfare programs. The Administration unit over-sees deployment of the much-needed functional and administrative infrastructure & Equipment that is central to the provision of a productive office environment for staff.

Finance department

The Finance department is the principle steward for all NDA financial resources and promotes financial sustainability built on existing statutory revenue streams and is the custodian for implementation of internal controls geared towards continued financial compliance.

Information and Communications technology department (ICT)

ICT provides all NDA's strategic ICT infrastructure requirements (Software & Hardware) ensuring that all business processes are efficient and effective as well as leads the automation and integration of supporting processes to enhance institutional efficiency.

Business Planning and Development Department

Business Planning and Development Department (BPD) provides end to end performance tracking and management metrics to ensure delivery and on-time achievement of the NDA strategic plan, annual work plans and budgetary targets. BDP department takes the principle lead in institutional development, investments, statistics, project management, planning, Monitoring and Evaluation as well as risk profiling and management.

Quality Management Unit

Quality Management Unit (QMS) coordinates and directs implementation of NDA quality management systems aimed at improving effectiveness and efficiency to meet customer and regulatory requirements on a continuous basis, and ensure compliance with ISO 9001.

Directorate of Laboratory Services

The National Drug Quality Control Laboratory is a World Health Organization (WHO) prequalified Laboratory with international ISO 17025 accreditation and it is well equipped with robust equipment, qualified personnel and has a well-established and maintained Quality Management System.

The laboratory is mandated to analyse different categories of medicines, medical devices and Public health products, and samples are obtained from pre-market, post shipment and Post Market Surveillance. The directorate has three units including; Medicines Unit, Medical Devices Unit and Quality Management Unit.

Medicines Unit

This is responsible for performing physicochemical analysis of medicines (allopathic and herbal), food fortificants, Acaricides, and public health chemicals. This laboratory is WHO accredited and the scope of accreditation includes; Assay by liquid chromatography, gas chromatography, spectrophotometry, Titration Dissolution, PH, Loss on Drying, Moisture determination by Karl Fisher, Uniformity of Dosage, Identification by FTIR and TLC, Polarimetry. The laboratory is in the final stages of equipping a state-of-the-art microbiology Laboratory process of building capacity for performing Microbiological Analysis.

Medical devices Unit

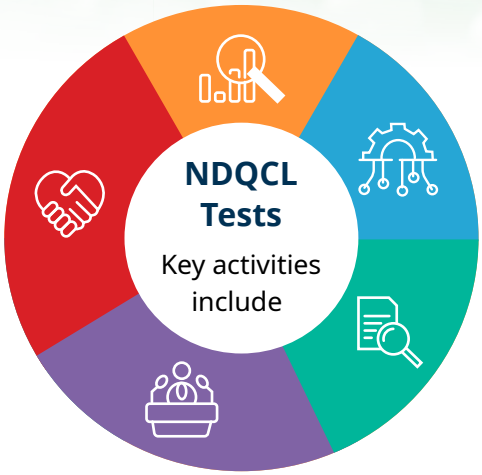
This is accredited to the ISO/IEC 17025:2005; the scope of accreditation incudes; Male latex condoms, Female Condoms, Gloves (Surgical and Examination) and the laboratory also tests syringes and needles, sutures, and is currently building capacity to test catheters, cannulas, RDT kits.

Laboratory Quality Management Unit

Coordinates and directs implementation of NDQCL quality management systems aimed at improving effectiveness and efficiency to meet customer and regulatory requirements on a continuous basis, and ensure compliance with ISO 9001.

NDQCL tests;

All human medicines including herbal medicines, Insecticide treated mosquito nets, Hand sanitizers (Liquids and gels), Veterinary medicines like Acaricides, Medical devices such as male and female condoms, surgical sutures, latex examination gloves, syringes and needles, Rapid Diagnostic Tests, surgical face masks. The Key activities include;



Conducting quality assessment

through laboratory analysis of medicines (human and veterinary), medical devices, surgical instruments and public health products while subsequently reporting accurate and precise results in a timely manner.

Field testing of regulated products

using screening techniques such as NIR spectrometry, Raman spectrometry and TLC techniques.

Conducting investigations

into the quality and safety status of regulated products for purposes of pursing legal or regulatory action.

Providing technical support to local manufacturers

and building their capacity in matters pertaining to quality control of regulated products through onsite and off-site training and laboratory assessments.

Generating scientific evidence and reports

on the quality and safety status of the regulated products in order to inform and facilitate regulatory decision making.

Statement from the Board Chairman

Dear Stakeholders,

I am pleased to present the annual performance report on behalf of the Drug Authority.

This report provides a comprehensive overview of our company's achievements and progress over the past year.

Financial Year Performance:

National Drug Authority (NDA) has continued its strong growth trajectory, achieving record-breaking performance results. Despite the challenging market conditions like COVID 19 in the first half of the financial year, we have achieved development of the 5 year strategic plan 2020 - 2025; construction of the quality control laboratory tower (98% progress) and NDA service delivery improved from 56% - 93% during the reporting period. This commendable performance is a testament to the dedication and hard work of our entire team.

Strategic Initiatives:

Throughout the year, we concentrated our efforts on several strategic initiatives aimed at enhancing our market position and driving sustainable long-term growth. These initiatives included transforming the Information Communication Technology which is intended to transition from NDA management Systems (NDAMIS) to iRIMS specific initiatives, market expansion by adding a regional office in Soroti sub region, product quality control innovation through expanding the product range like biological products, partnerships with Universities, media houses, security forces and cultural institutions. The successful execution of these strategies has already started yielding positive results.

Customer Satisfaction:

At NDA, we firmly believe that customer satisfaction is the cornerstone of our success. We have invested significantly in improving our customer experience by establishing and updating service delivery time lines and customer complaint handling mechanisms. As a result, customer satisfaction levels have reached an all-time high, which has positively impacted our brand reputation and customer retention.

Sustainability and Social Responsibility:

In alignment with our commitment to corporate responsibility, our sustainability efforts have been strengthened over the past years. We have implemented various measures to reduce our carbon footprint, promote responsible sourcing, and support local communities. These efforts include getting rid of the counterfeit drugs from the public. By doing so, we are not only contributing to a sustainable future but also creating shared value for all stakeholders involved.

Looking Ahead:

Despite the ongoing challenges faced by businesses worldwide, we remain optimistic about our future, service excellency and unwavering customer support. With the expected enactment of a new law for NDA, we are confident that our unwavering commitment to delivering value to our customers, employees, and stakeholders will enable us to overcome any obstacles and achieve sustainable success.

Dr. Medard Bitekyerezo
Chairperson National Drug Authority

Statement from the
Secretary to the Authority

Dr. David Nahamya
The Secretary to the Authority

It is with great pleasure that I present to you this year's Annual Performance Report. This document serves as a comprehensive overview of our organization's achievements, highlighting key milestones, challenges overcame, and future prospects.

The pursuit of drug regulatory excellence remains a top priority for us, and this report embodies our commitment to transparency and accountability and highlights valuable insights into our regulatory and non-regulatory services and stability of NDA.

In an ever-evolving local and international drug regulatory business space, understanding our performance is crucial in making informed decisions and charting our future course. The report outlines the strategies implemented to drive growth, manage risks, and ensure sustainability.

At the heart of our success are our dedicated employees, valued clients, Government and supportive stakeholders. We are grateful for their unwavering trust and confidence, which energize us to strive for excellence every day. This report is a testament to their collective efforts and the contributions they have made to our organization's continuity.

Throughout this report, you will find detailed analysis, graphical representations, and key performance indicators, all of which provide a comprehensive and objective assessment of our financial performance. Our aim is to provide you with the necessary tools to evaluate our organization's performance health and make informed decisions about your continued support and partnership.

As we reflect on the challenges and triumphs of the past year among which include; licensing of 17140 drug outlets, increasing Adverse Drug Reaction reporting and evaluations by the public by 211%(2552 to 7938), tested 101.4% of drug samples submitted, recalled 15 products from the market and closed 515 non compliant drug outlets to protect the population, we remain committed to adaptability, innovation, and sustainable growth. We recognize that the global drug regulatory business landscape is dynamic, and we embrace change as an opportunity for progress. These changes include; working towards transitioning of NDA from World Health Organization maturity level 1 to 3 as a minimum by the end of the strategic planning period, adapting regulatory reliance interventions, promoting local pharmaceutical production, increased automation of regulatory services, and adaptive stakeholder engagement .

Lastly, I want to express my appreciation to our stakeholders and partners in drug regulatory business space, for their continued trust and partnership. Your support is vital to our success, and we remain committed to delivering exceptional drug regulatory performance year after year.

I encourage you to delve into this report, scrutinize the numbers, and engage in a dialogue with us. Together, we can chart a pathway towards a prosperous future for Uganda and drug regulatory environment.

David Nahamya
Secretary to The Authority

GOVERNANCE FRAMEWORK OF NDA

Board Members of the Drug Authority

The Authority is composed of 20 members appointed by the Honorable Minister of Health for a three-year term of office in accordance with Section 3 of the Act. The Seventh Authority was appointed on 18th February 2020 ending on 17th February 2023. The following are the current members of the Drug Authority:

Table 1: Members of the Authority 2020-2023

No.	Name	Tittle and Constituency
1	Dr. Medard Bitekyerezo	Chairperson, NDA
2	Maj. Gen. (Dr.) Ambrose K. Musinguzi	Chief of Medical Services, Ministry of Defense
3	Mr. Zackey Kalega	Commissioner Internal Trade, Min. of Trade, Industry & Cooperatives.
4	Dr. Mbabali Muhammad	Representative of Uganda Dental Association
5	Mr. Jamir Mukwaya	Representative of Uganda Herbalists
6	Dr. BD Robert Otto	Head, Department of Pharmacy, Makerere University
7	Dr. Hanifah Naamala Sengendo	Represents the Public
8	Ms. Catherine Adok	Appointed from the public
9	Dr. Bildard Baguma	General Manager, Joint Medical Store, Nsambya
10	Dr. Daniel Kasibule	President, Uganda Veterinary. Association
11	Mr. Kamabare Moses	General Manager, National Medical Stores
12	Dr. Baterana B. Byarugaba	Executive Director, Mulago National Referral Hospital
13	Dr. Morris Seru	Commissioner Health Services, pharmaceuticals and Natural medicine, Ministry of Health.
14	Dr. Grace Nambatya	Executive Director Natural Chemotherapeutics Research Laboratory
15	AIGP. (Dr.). Maj. Tom Magambo Rwabudongo	Director, Criminal Intelligence & Investigations Directorate
16	Dr. Rose Ademun Okurut	Commissioner of Veterinary Services, MAAIF, Entebbe

No.	Name	Tittle and Constituency
17	Dr. Daniel Obua	Representative of Uganda Medical Association
18	Dr. Nelson Musoba	Director, Uganda AIDS Commission
19	Mr. Hussein Oria	Representative of Pharmaceutical Society of Uganda
20	Dr. Henry Mwebesa	Director General Health Services

Members who served on the Drug Authority and where replaced during the period.

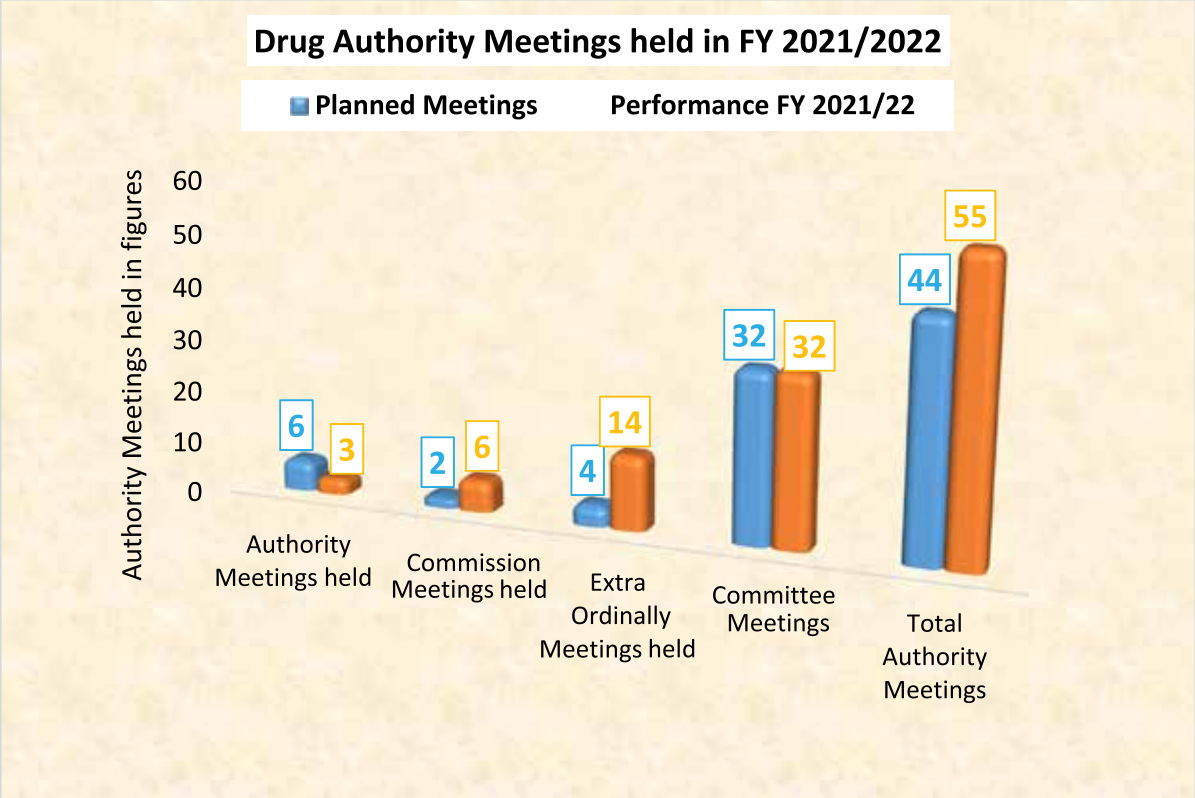
No.	Name	Title and Constituency
1	Mr. Raymond Agaba	Min. of Trade, Industry & Cooperatives.
2	Mrs. Neville Oteba Okuna	Commissioner Health Services, pharmaceuticals and Natural medicine, Ministry of Health.
3	Dr. Sylvia Baluka	President, Uganda Veterinary Association
4	AIGP. Grace Akullo	Director, Criminal Intelligence & Investigations Directorate.
5	Dr. Pakoyo Kamba Fadhiru	Head, Department of Pharmacy, Makerere University.

The following Members were appointed on the NDA Commission:

No.	Name	Title and Constituency
1	Dr. Medard Bitekyerezo	Chairperson, NDA
2	Mr. Kamabare Moses	General Manager, National Medical Stores
3	Ms. Catherine Adok	Appointed from the pubic
4	Dr. Hanifah Naamala Sengendo	Represents the Public
5	Dr. Rose Ademun Okurut	Commissioner of Veterinary Services, MAAIF, Entebbe

Drug Authority Meetings

The Drug Authority exercised its mandate with a total number of 55 meetings conducted against 44 planned as presented in the chart below.



Management Members of
The Drug Authority

National Drug Authority has a total of six (6) Directors heading different directorates and these comprise the Management for the Authority;

Dr. David Nahamya
The Secretary to the Authority

Dr. Mwesigwa Denis
Director Inspectorate and Enforcement

Dr. Hellen Ndagije
Director Product Safety

Dr. Juliet Oketcho
Director Product Assessment and Registration

Madam Annete Ssenkindu
Director of Laboratory Services

Mr. Kayita Rogers
Director of Corporate Services

ENVIRONMENT SAFEGUARD

As we implement our activities, we took care of the environment through monitoring of expired or obsolete products on the market by ensuring that drugs are safely disposed of in an environmentally friendly manner by using accredited service providers for handling, transportation and safe disposal of obsolete pharma and laboratory waste including Green Label Services, P.B Holdings Ltd, Soval International Ltd, Array Services Ltd, ERB Holdings Ltd, Desan Services Ltd and Bin It Services which will minimize risk to the public health and also minimize environmental pollution. This is done because the expired pharmaceuticals and other substandard pharmaceutical products present a serious threat to public health and to the environment. Their elimination from the public and subsequent disposal is embedded in NDAs mandate of ensuring that only safe, efficacious and quality drugs are availed to the entire population of Uganda.

The common methods used at the moment for the safe disposal of pharmaceutical waste are;

- Ultra-high Temperature incineration, inertization & land fill and dilution then flushing into protected soak pit or lagoon.
- However, for specialized items such as hazardous industrial chemicals or laboratory waste, solvents or radioactive waste e.t.c, advice should be sought from relevant authority for this category of waste.

EXECUTIVE SUMMARY

BACKGROUND DESCRIPTION

The National Drug Authority (NDA) was established in 1993 by the National Drug Policy and Authority Statute which in 2000 became the National Drug Policy and Authority (NDP/A) Act, Cap. 206 of the Laws of Uganda (2000 Edition). The Act established a National Drug Policy and National Drug Authority to ensure the availability, at all times, of essential, efficacious, and cost-effective drugs to the entire population of Uganda as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs.

The National Drug Authority (NDA) developed a strategic plan for 2020-2025 for which the Monitoring and Evaluation Plan was developed with intended results at output, Outcome and Impact level to assess its progress toward achieving the goal outlined in the plan. The annual review aimed to put focus on whether the intended results for the year were achieved, document lessons learnt, document challenges that affected performance and recommendations for performance improvement.

The performance at impact and outcome level results are measured using the fifteen (15) Key Performance Indicators as presented in section 7.0 on page 85 of the strategic plan. Whereas the performance results at output level are monitored using the "Activity Based Performance Report on a quarterly, semi-annual and annual basis. The performance reports also capture the required inputs necessary to execute the agreed upon activities in the Programme Implementation Action Plan (PIAPs).

The annual report, therefore, presents the key strategic plan implementation progress results achieved, Major Constraints, Recommendations and Conclusion at National and NDA level.

KEY PERFORMANCE ACHIEVEMENTS FOR FY 2021/2022

Key Performance Highlights for FY 2021/22.

Below are some of the key achievements of the National Drug Authority for the period.

1. Development of the five (5) year NDA strategic plan from FY 2020/2021 – FY 2024/2025.
2. Exercised stewardship over the NDA regulatory functions;
   a) Maintained the National Drug register with a total of 4059 products.
   b) Enhanced the national Pharmacovigilance system as evidenced by the number of ADR reports from 2552 to 7938 ADR reports.
   c) Enhanced scope of pharmaceutical laboratory testing capabilities that included Sterility, Bacterial Endotoxin, Bacterial enumeration, microbial testing, Aflatoxin testing in herbal medicines, screening for adulterant, impurity testing, RDT testing, Sutures, Syringes, Condoms, Mosquito Nets in addition to a range of already existing testing parameters.
3. Completion and operationalization of the Pharmaceutical Microbiology laboratory at the National Drug Quality Control Laboratory at Mulago.
4. Implementation of NDA services to the clients within the agreed service delivery timelines from 56% to 93%.
5. The National Drug Quality Control Laboratory maintained her World Health Organization (WHO) prequalification status following a surveillance inspection conducted by WHO in 2022.
6. National Drug Authority was audited by SGS United Kingdom Ltd in 2022, and maintained ISO 9001:2015 International Standard for Quality Management System certification.
7. National Drug Authority was recognized as a center of excellence for Good Manufacturing Practice by NEPAD (New Partnership for Africa's Development).
8. National Drug Authority was Audited by the ANSI National Accreditation Board (ANAB), based in the United States in 2021, and maintained ISO/IEC 17025 International Standard accreditation.
9. Increased confidence in the NDA laboratory testing services as evidenced by the International bodies like WHO, IGAD, EAC that are utilizing the NDA laboratory.

10 Annually NDA, was awarded two major recognitions as the best health institution in Uganda by the Visionaries of Uganda and Public opinion respectively.

11 The Authority has ensured the recruitment of a balanced professional workforce in the technical regulatory areas and improved the capacity of NDA staff to deliver on the NDA mandate.

12 Strengthened the performance Monitoring and Evaluation system to track the performance of the Strategic Plan on all outcomes and key output indicators, and awarded a contract to a consultancy firm to develop a web-based online management of; Planning, Monitoring and Evaluation, Risk Management and Project Management.

13 Risk management has also been incorporated in the implementation modalities of the plan in a bid to harmonize with the Government of Uganda Risk Management Strategy 2018.

14 Established two (2) new regional offices namely Soroti and Kampala extra to enhance service delivery across the country.

15 Fast tracked emergency response to Public Health such as Covid-19 and Ebola related interventions.

16 Enhanced outreach of Veterinary regulation across the Country as evidenced by the increased multi sectoral collaboration, stakeholder engagement and support supervision visits which has increased visibility of Veterinary services down to the farm level.

17 Enhanced Intelligence led enforcement operations across the Country by curtailing the pilferage of Government drugs, smuggling, trade of counterfeit Pharmaceutical products, and closure of illegal Pharmaceutical outlets.

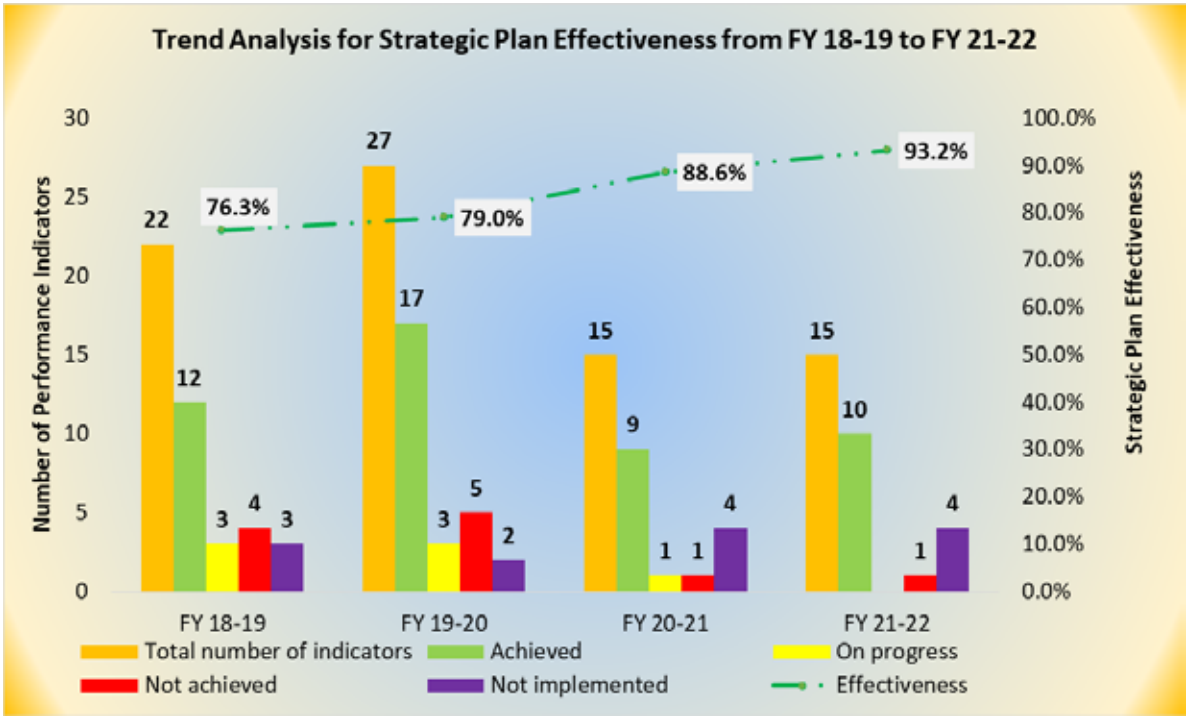
18 NDA has continued to play a pivotal role in the region and the continental level in the various harmonization initiatives by contribution to discussions.

THE NDA PERFORMANCE RESULTS FLOW AT IMPACT AND OUTCOME LEVEL

The NDA Monitoring and Evaluation Plan highlights the results in two categories; the Outcome and Impact results which are measured using a total of 15 Key Performance Indicators that demonstrates the effectiveness or positive/negative planned/unplanned changes that happened after delivery of the Strategic Plan commitments and the Output level indicators which shows the level of implementation and achievement of the Strategic Plan commitments per year.

Implementation Effectiveness of the NDA Strategic Plan including the NDP PIAPs commitments.

To gauge whether NDA is meeting the set objectives thus making short- and long-term changes in the community, National Drug Authority set one (1) Core indicator, which is a high-level indicator that is measuring the higher-level results at goal level. The National Drug Authority also set 14 Key performance Indicators (KPI's) at outcome level to measure the effectiveness of the strategic plan results. NDA also has 56 operational/process indicators for monitoring all the service delivery timelines and all these are subsets of one Key Performance Indicator under objective 1. The output results are presented in the activity performance monitoring reports. Below is the comparative analysis of the effectiveness of the strategic plan results.



As far as meeting the expected strategic plan performance results effectiveness is concerned, NDA improved by 5% from 88.6% to 93% between FY 2020 to FY 2022. The reason for the performance was due to the following;

a) The implementation of the NDA Management Information System (NDAMIS) and its seamless integration with Navision (365 Business Central dynamics) played a pivotal role in facilitating client services.

b) An advancement in the organization's planning and performance management systems was observed, characterized by streamlined reporting and consistent result measurement, resulting in improved efficiency and effectiveness.

c) Tangible strides were made in completion of phase 3 for the laboratory tower on 30th June 2022.

Tabular presentation of the annualized NDA Impact and Outcome Performance Results

Narrative Expected Results	Verifiable Performance Indicators	Targeted Results FY 20/21	Performance FY 20/21	Targeted Results FY 21/22	Performance FY 21/22
Goal: To attain and maintain global best practices in drug regulation by 2025.	Percentage of regulatory functions meeting WHO Maturity Level 3	13%	13%	13%	13%
Outcome one for SO 1: Improved public access and utilization of safe, efficacious and quality drugs and health products	Proportion of improved performance in core service delivery.	65%	82%	70%	81%

Narrative Expected Results	Verifiable Performance Indicators	Targeted Results FY 20/21	Performance FY 20/21	Targeted Results FY 21/22	Performance FY 21/22
Outcome two for SO 1: Improved regulatory systems, processes and procedures that guarantee availability of safe, efficacious and quality drugs and health products.	Proportion of SDT's implemented within the agreed timeline	80%	56%	80%	93%
Outcome for SO 2: Harmonized legislative framework that enables an effective and well-functioning regulatory system for drugs and health products,	Proportion of target stakeholder engaged in advocacy initiatives.	80%	25%	85%	25%
	Proportion of Regulations and Guidelines developed	100%	92%	100%	100%
	Transformation of NDP&A Act into UNFDA	**Expected FY 2024/25**			
Outcome One for SO 3: Increased public awareness, knowledge and practices about safety, efficacy and quality of drugs	Proportion of the stakeholders aware of NDA role.	85%	Not done	90%	Not done
	Proportion of Satisfied customer.	75%	Not done	75%	Not done

Narrative Expected Results	Verifiable Performance Indicators	Targeted Results FY 20/21	Performance FY 20/21	Targeted Results FY 21/22	Performance FY 21/22
Outcome two for SO3: Increased positive perception and visibility of NDA as an effective global standard regulator within the health system.	Proportion of the stakeholders that perceives NDA as playing her role.	59%	Not done	69%	Not done
Outcome one for SO 4: Improved institutional infrastructure to enable effective regulatory service delivery and specialized operations,	% of planned institutional infrastructure implemented.	60%	61%	70%	117%
Outcome two for SO 4: Enhanced digital transformation for regulatory effectiveness,	Proportion of institutional business processes fully automated.	0%	32%	31%	42%
	Percentage of online services accessed throughout the year (Uptime of online services)	99%	100%	99%	100%

Narrative Expected Results	Verifiable Performance Indicators	Targeted Results FY 20/21	Performance FY 20/21	Targeted Results FY 21/22	Performance FY 21/22
Outcome three for SO 4: Increased human resource productivity to deliver the NDA's regulatory mandate.	Proportion of staff who attain 65% of approved performance targets.	95%	100%	100%	100%
Outcome four for SO 4: Improved financial sustainability of NDA	% increase in generated revenue	Plus 5%	8%	Plus 5%	8%
	Working ratio	90%	76%	90%	89%
NDA Annualized Performance Results			**88.6% (9.75/11)**		**93.2% (10.25/11)**

Out of the 15 impact and outcome indicators, eleven (11) were measured with a performance effectiveness of 93.2%. The shortfall of 6.8% was caused by failure to engage the targeted stakeholders for advocacy initiatives. Four indicators were not measured because of the following reasons;

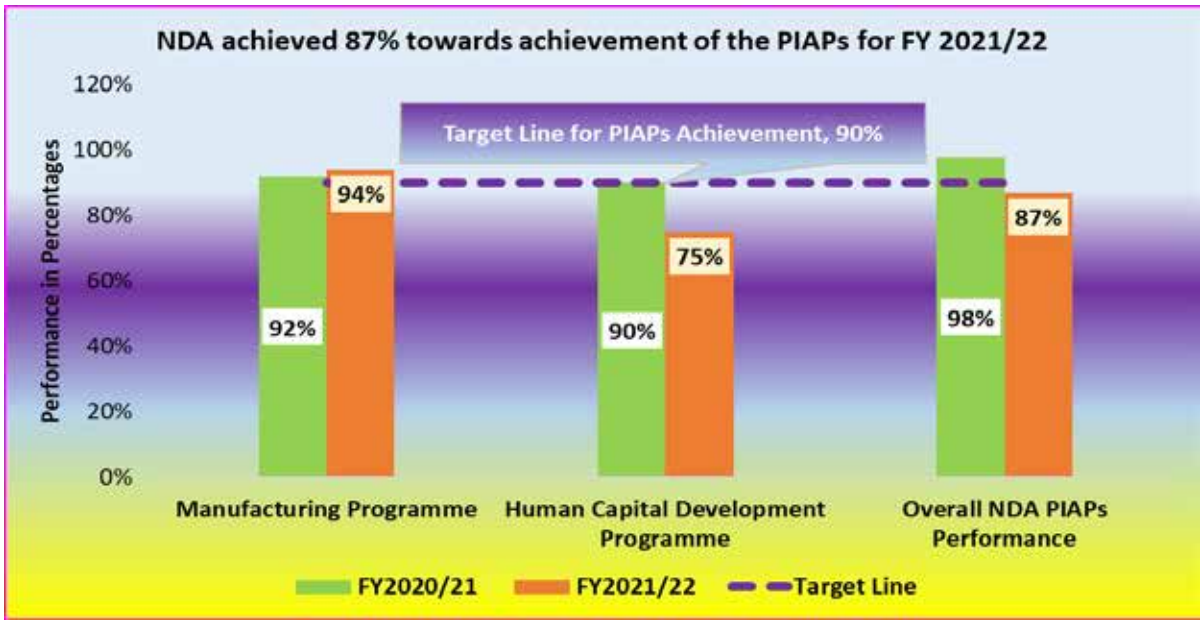
a) NFDA is expected to be in place in the fifth (5th) year.

b) Three (3) indicators on focus area 3 were not implemented because the client satisfaction survey is still ongoing and the final results are expected in the second quarter of FY 2022/2023.

NATIONAL LEVEL PERFORMANCE RESULTS BASED ON NDP III COMMITMENTS

At national level, the NDA strategic plan contributes to NDP III through two program areas which are split into five (5) Program Implementation Action Plans (PIAPs).

The overall achievement of NDA towards the set results of the NDP III PIAPs (Manufacturing and Human Capital Development program) outputs is **87% (11.25 out of 13)** against a set target for the Programme based performance. This performance contributed to the NDP III objective to improve population health, safety and management. The chart below highlights the contribution of NDA to NDP III.



The overall percentage drop of 11% from 98% to 87% was due to the effect of Covid-19 Pandemic that affected a number of activities including licensing, enforcement operations, stakeholder sensitization, collaboration and engagement.

Major Constraints and Recommendations

No.	Challenges	Way Forward
1.	Uganda is not yet at Maturity Level 3 because of the gaps in the existing Law which include weak penalties, existence of policy frameworks in the law, inability to use reliance in regulatory decisions and narrow scope of the law causing conflicting regulatory mandate among MDAs.	Fast tracking of the legal transition of National Drug Authority to eliminate the limitation of attaining maturity level 3 or 4 for better service delivery.

No.	Challenges	Way Forward
2.	Poor quality of Dossiers submitted by the clients.	Continue with capacity building and automation of the registration regulatory processes.
3.	Pilferage of Government drugs.	Collaboration and partnership with MDA's for effective and efficient service delivery especially at local government level.
4.	There is shortage of funds to adequately equip the new laboratory tower.	Lobby for additional funding (USD 21 million) to equip the new laboratory tower.

Conclusion

NDA has made tremendous progress toward the effectiveness of the strategic plan intended results at impact and outcome level with a performance of 93.2% as compared to 80% achievement at output level. In addition, NDA achieved a performance of 87% for the national level NDP III set commitments at the out level. NDA has made significant progress in several areas, particularly in improved service delivery, regulatory systems, institutional infrastructure, and financial sustainability. However, there's a notable challenge in stakeholder engagement, awareness and collaboration on which management has to put in place strides to ensure improvement in this pillar, we also commit to do continuous automation and integration of our management information systems with other health related MDAs, expanded service coverage with customer outreach, Service delivery timelines commitment and transformation of NDA's legal framework and expanding the Mandate of NDA to cover as scope of the pharmaceutical product regulations for improved services like; Medical devices, cosmetics, house hold chemicals among others.

Detailed Approach

The performance matrix of the two programs including their actions, performance, justifications and color bands is presented below;

Manufacturing Program

The NDA strategic plan is aligned to objective 2 of the NDP III Manufacturing Program "Increase value addition for import substitution and enhanced exports" and in particular, the intervention that support existing local manufactures for pharmaceutical products. NDA contributed to the support of the Good Manufacturing Practice (GMP) compliance assessment system for local pharmaceutical manufacturers as well as review and update standards, regulations and guidelines to cater for indigenous Pharma remedies.

The performance against targets is presented in the table below.

<table>
<tr><th>Action</th><th>NDA Performance on PIAPs for FY 2021/22</th><th>Justification</th><th>Dashboard</th></tr>
<tr><td colspan="4">Program: 04 Manufacturing.</td></tr>
<tr><td colspan="4">Sub-program: 041 Industrial and Technological Development.</td></tr>
<tr><td colspan="4">Objective: 0412 Increase value addition for import replacement and enhanced exports.</td></tr>
<tr><td colspan="4">Intervention: 041201 Support existing local manufactures for both medical products and pharmaceuticals.</td></tr>
<tr><td rowspan="2">Review and update standards, regulations and guidelines to cater for indigenous Pharma remedies (incl. Dis-semination, enforcement and M&E).</td><td>A total of two (2) guidelines were reviewed and one (1) regulation was reviewed as highlighted in the table below.
<table>
<tr><th></th><th>Reviewed</th></tr>
<tr><td>Guidelines</td><td>1. Guideline for pre-market submission of domestically manufactured products.
2. Guidelines for regulation of local herbal medicine products in Uganda.</td></tr>
<tr><td>Regulation</td><td>Statutory Instrument 29 for National Drug Policy and Authority (Registration) Regulation.</td></tr>
</table></td><td>Stakeholder consultation for some of the documents developed was affected by Covid-19 restrictions.</td><td rowspan="2"></td></tr>
<tr><td>Licensing status for the Local Manufacturers
<table>
<tr><th>Local Manufacturers</th><th>Inspections done</th><th>Applications approved</th><th>Licensed</th></tr>
<tr><td>Local Human Medicine Manufacturers</td><td>15</td><td>15</td><td>15</td></tr>
<tr><td>Local Veterinary Medicine Manufacturers</td><td>03</td><td>03</td><td>03</td></tr>
<tr><td>Local medical devices Manufacturers</td><td>20</td><td>20</td><td>20</td></tr>
<tr><td>Local Herbal Manufacturers</td><td>04</td><td>04</td><td>04</td></tr>
<tr><td>Total</td><td>42</td><td>42</td><td>42</td></tr>
</table></td><td>Fully Implemented and this promoted accessibility to regulated products in compliant facilities.</td></tr>
</table>

Action	NDA Performance on PIAPs for FY 2021/22	Justification	Dashboard
Provide technical support to local pharmaceutical industries in Good Manufacturing Practices and pre-qualification standards.	Training to local manufacturers A total of four (4) trainings were done. The details are listed below: a) one (1) technical training conducted for local manufacturers to ensure quality submissions for pre-market applications of medicines to be manufactured domestically. b) Two (2) training workshops for local herbal manufacturers to strengthen the systems, processes and procedures for post marketing authorization of drugs and health care products. c) One benchmarking training visit was conducted for herbal manufacturers to understand processes for manufacture of Herbal Oral Solid Dosage form (Capsule; Tablet Manufacturing) at Doctor Choice in Jinja.	The target for GMP Inspections exceeded because of the new local manufacturing facilities established.	
	Good Manufacturing Practice (GMP) Compliance Support Inspections. NDA Conducted a total of 42 Local GMP inspections against a target of 40.	Fully Implemented	
	Pre-Market Testing. Tested a total of 39 batches of human medicine samples out of 45 received and a total of 5 samples of two (2) samples of Metronidazole failed Assay test and three (3) samples of Paracetamol failed Assay test. Tested a total of 43 batches of veterinary samples out of 56 received and all passed the quality tests and allowed for marketing. Out of the 82 samples tested above, seventy-seven (77) samples passed the quality tests and allowed for marketing authorization and five (5) samples including two (2) samples of Metronidazole failed Assay test and three (3) samples of Paracetamol failed Assay tests were recommended for improvements before rolling them on the market.	Partially Implemented and action was taken on the five (5) failures to ensure that the products of local manufacturers pass before being circulated on the market.	
Conduct sensitization and awareness campaigns on locally produced pharma products.	One (1) TV program on domestically manufactured herbal products was held.	Fully Implemented	
	Twelve (12) sensitization and awareness campaigns were conducted for herbal manufacturers to strengthen the systems, processes and procedures for pre and post marketing authorization of drugs and health care products.	Fully Implemented	
NDA Overall Percentage Achievement on Manufacturing Program for FY 2021/22			**94% (7.5 out of 8)**

Human capital development Program:

NDA strategic plan is aligned to objective 4 of the NDP III Human Capital Development (HCD) Program "Improve population health, safety and management". NDA's strategic plan is aligned to interventions that improve the functionality of the health system to deliver quality and affordable preventive, promotive, curative and palliative health care services. NDA implemented regulatory systems, processes, and procedures that guarantee availability of safe, efficacious and quality drugs and health care products used in Uganda to ensure the health of the Ugandan population. The performance against targets is presented in the table below.

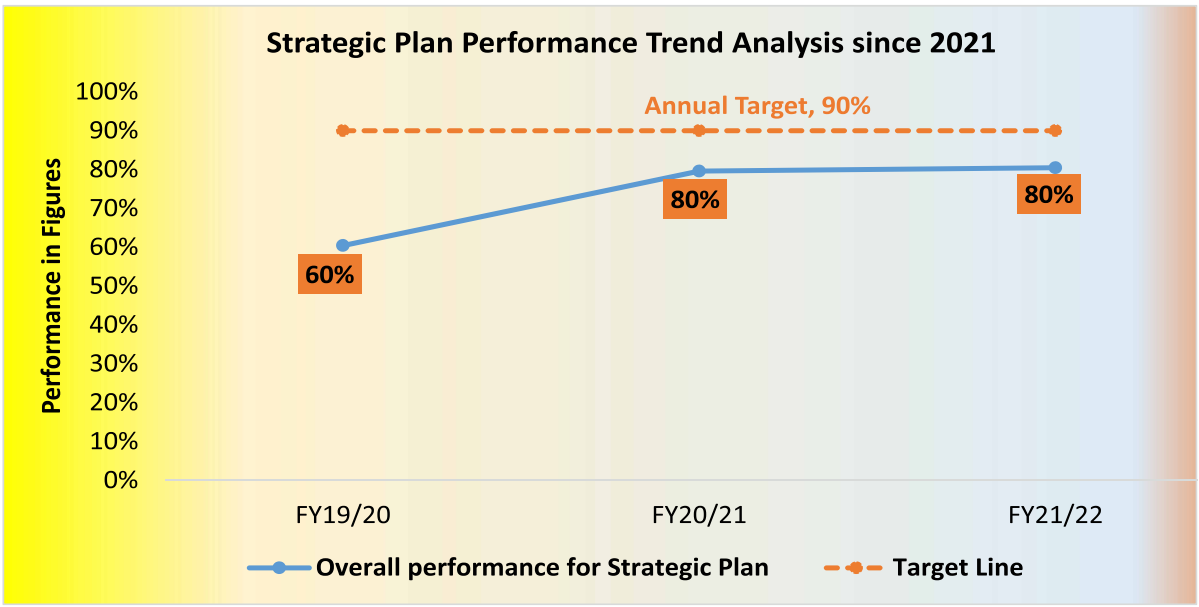
Action	NDA Performance on PIAPs for FY 2021/22	Justification	Dashboard
Program: 12 Human Capital Development.			
Sub-program: 122 Population Health, Safety and Management.			
Objective: 1224 Improve population health, safety and management.			
Intervention: 122417 Strengthen governance, management and effectiveness of the health sector at all levels.			
Construct a Quality Laboratory for National Drug Authority	Commenced the construction of the laboratory tower on 11th October 2019 and by 30th June 2022, the actual overall progress onsite was 98% in comparison with a planned progress of 100% as per the program. **Quality Laboratory for National Drug Authority** will cover laboratory testing of the following areas including; 1. Human medicines 2. Veterinary 3. Herbal 4. Medical devices 5. Cosmetics 6. Food The 2% was due to the following outstanding key areas of the project; a) completion of the curtain walling that has been delayed by PoVc delays for the BMU, b) delayed installation of cleaning cradle/BMU, c) part 3 items for mechanical and electrical aspects for enhancing building efficiency like CAT 6A accessories and UPS, d) connection of UMEME power is pending metering unit, e) performance testing and commissioning of systems and equipment such as generator and lifts, f) building signage, and g) desnagging.	Fully Achieved	

<table>
<tr><th>Action</th><th>NDA Performance on PIAPs for FY 2021/22</th><th>Justification</th><th>Dashboard</th></tr>
<tr><td>Implement the National Drug Authority Strategic Plan</td><td>The Strategic Plan FY 2021-2022 Implementation.
94% (125) of the total of 133 planned core services were implemented during the financial year 2021-2022 and a total of Ugx. 65,378,688,765 (62%) was spent as compared to planned amount of Ugx. 104,686,349,888/= and a total of Ugx. 69,862,961,045 (99.4%) was generated as compared to the projected amount of Ugx. 70,297,342,365/=.</td><td>There was effect by Covid-19 which delayed timely completion of activities especially foreign Good Manufacturing Practice inspections and this also affected the revenue generation.</td><td></td></tr>
<tr><td rowspan="2">Strengthen mecha-nism for regulation and accred-itation of drug outlets within the overall dis-trict health system</td><td>A total of 14,100 (1,318 pharmacies and 12,782 drug shops) were approved and given licenses to operate out of a total of 15,791 (1,582 pharmacies and 14,209 drug shops) licensing applications received as shown in the table below.
<table>
<tr><th>Licensing Summary</th><th>Applications received</th><th>Approved</th><th>Percentage Approval</th></tr>
<tr><td>Pharmacy</td><td>1,582</td><td>1,318</td><td>83.3%</td></tr>
<tr><td>Drug Shops</td><td>14,209</td><td>12,782</td><td>90%</td></tr>
<tr><td>Total</td><td>15,791</td><td>14,100</td><td>89.3%</td></tr>
</table>
Cumulative licensing of pharmacies.
A total of 3,215 pharmacies were approved and given licenses to operate out of a total of 3,785 pharmacies licensing applications received for three years from July 2019 to June 2022.</td><td>Partially achieved because of late submission of renewal applications.</td><td></td></tr>
<tr><td>Good Pharmacy Practice Inspections
NDA Conducted a total of 157 Good Pharmacy Practice (GPP) inspections (62.8%) against the planned 250 GPP inspections. In addition, the Inspections and taking a final regulatory decision for new pharmacy applicants was done in 26 average days against a set target of 40 days.
<table>
<tr><th>Inspections</th><th>Target</th><th>Performance</th><th>% of target achieved</th></tr>
<tr><td>GPP Inspections</td><td>250</td><td>157</td><td>62.8%</td></tr>
</table></td><td>The GPP target was partially achieved because there were challenges with inadequate number of vehicles in some regions coupled with other activities being conducted at the same time.</td><td></td></tr>
<tr><td colspan="3">NDA Overall Percentage Achievement on Human Capital Development Program for FY 2021/22.</td><td>75% (3.75 out of 5)</td></tr>
</table>

Progress on Implementation and Achievement of the Strategic Priorities including the NDP III PIAPs Commitments

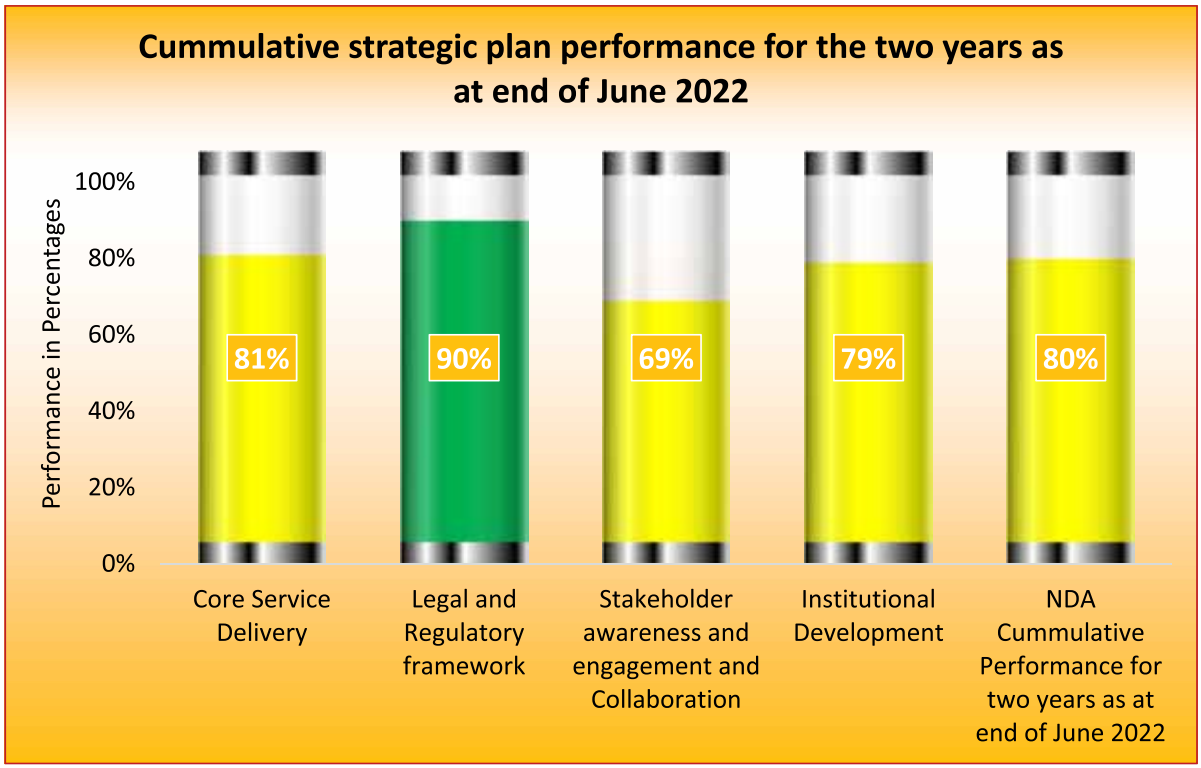
The performance milestones for assessment of monitoring and evaluation of NDA's performance with respect to all the strategies, outcomes, planned activities, indicators and outputs were defined as part of the NDA Strategic Framework that was provided in the Strategic Plan. Data required to populate the indicators as framed was collected through various sources: administrative data, enhanced, when possible, by field data; a survey of experts; public surveys; and document reviews.

Management put in place mechanisms for M&E implementation of the strategic plan. Annually management develops work plan and budget for the implementation action plan. The implementation progress of this strategic plan has been monitored and evaluated and the progress comparative analysis is illustrated in the chart below;



Overall Performance for FY 2021/22. The implementation of the Strategic Plan for the financial year 2021/22 was generally on progress. NDA achieved an average overall performance of 80% progress towards the set targets with; 92% for Legal Regulatory Framework, 81% for Core Service Delivery, 81% for Institutional Development and 69% for Awareness, Engagement and Collaborations as compared to 80% progress for FY 2020/2021. This has increased public access and utilization of safe, effective, quality drugs and health products on the market of Uganda.

Overall Implementation and Achievement of the Strategic Plan including the NDP PIAPs commitments for the two years as at 31st June 2022. The implementation and achievement of the Strategic Plan annual commitments/outputs from 1st July, 2020 to 31st June, 2022 is generally on progress with an average overall performance of 80% towards achievement of set targets with; 90% for Legal Regulatory Framework, 81% for Core Service Delivery, 79% for Institutional Development and 69% for Awareness, Engagement and Collaborations. This has helped in meeting the stakeholder expectations and aspirations, and to enhanced NDA's regulatory service delivery for the medium term. Though more efforts are required to improve on the stakeholder awareness, engagement and collaboration that has remained at the same level as compared to the previous year 2020/2021.



NDA SET COMMITMENTS PERFORMANCE BY FOCUS AREA

Focus Area 1: Core Service Delivery:

Strategic Objective 1:

To improve the Regulatory efficiency and effectiveness that ensures safe, efficacious and quality drugs and health products.

This strategic objective focus on the key actions that NDA undertakes to sustainably improve efficiency and effectiveness of the processes and systems to deliver on its core mandate

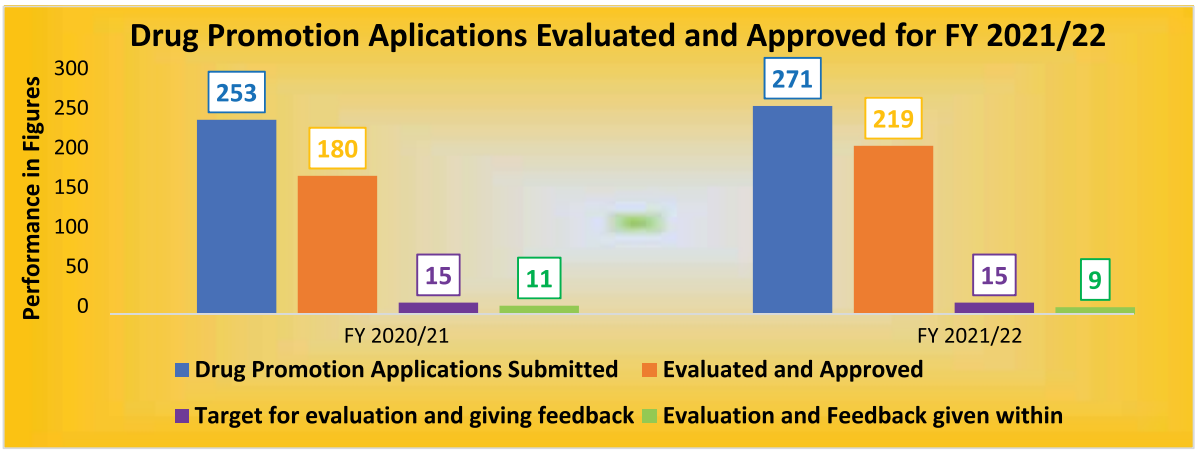
Five key strategies, presented below are proposed to realize the strategic objective;

1.1 Strengthen systems and institute regulatory actions that support local drugs manufacturing.

Control of illegal advertisement of herbal drugs on TVs and Radios.

NDA has engaged Uganda Communication Commission (UCC) to enforce adherence by electronic and print media in order to standardize advertisement of local herbs and minimize unsubstantiated claims. The communication standard by UCC now reads "In cognizance of the special and sensitive nature of drugs and other health care products, all advertisements and promotion thereof shall need prior approval by the National Drug Authority".

NDA evaluated and approved 219 drug promotional materials out of the 271 applications that were submitted for FY 2021/22 as compared to 189 out of the 253 applications for FY 2020/21. The applications were evaluated and feedback given with nine (9) working days against the set target of fifteen (15) working days as compared to eleven (11) working days for FY 2020/21. This has helped to ensure that misleading, biased and inaccurate information on medicines is not disseminated to the public of Uganda.



NDA has continuously engaged herbal medicines manufacturers and promoters on ethical advertising and promotion of medicines. There was gradual appreciation of the need for compliance that indicated an increase in the number of applicants and a reduction in the number of rejected applications.

NDA is cognizant of the public outcry on the misleading advertisements on mainstream media, and necessary steps have been taken to avert this problem. These have included but not limited to;

i) Collaboration with the Uganda Communications Commission (UCC) to work with all media players to curb misleading advertisements and promotions related to drugs on all media stations

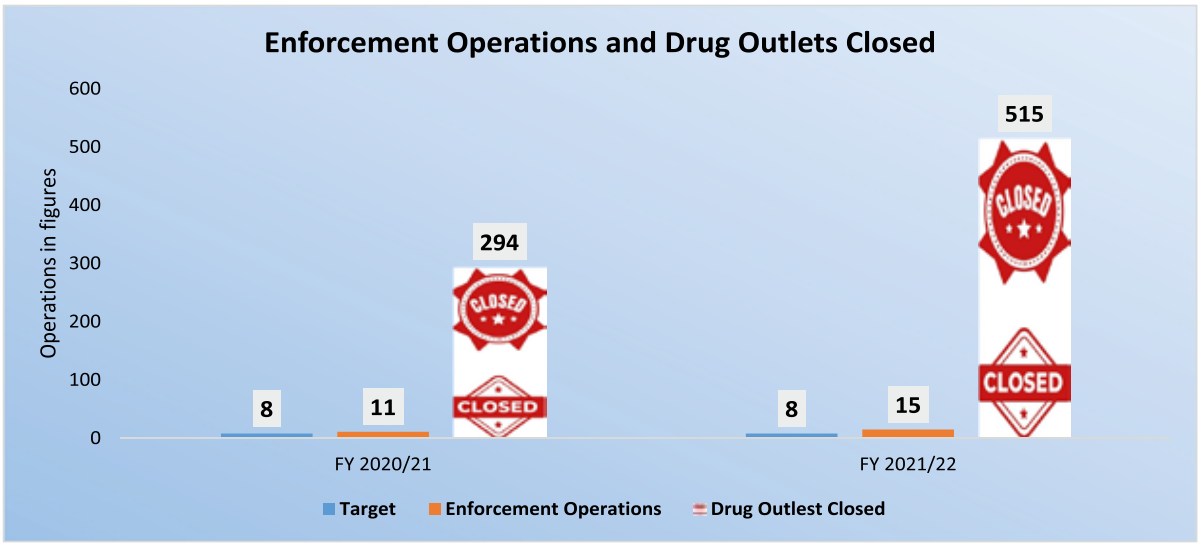
ii) Engagements with media players on their responsibility towards sharing truthful information as indicated in the UCC advertising standards and compliance to NDA requirements.

iii) Engagements with advertisers and promoters of drugs on ethical advertising and promotions

iv) Enforcement of regulatory actions on those who repeatedly advertise or promote drugs without authorization from NDA.

Enforcement of the NDP&A Act and Regulations

NDA conducted enforcement operations throughout the country aimed at apprehending illegal operators and ensuring that licensed persons maintain high quality standards of operations. NDA conducted a total of 15 operations against a set target of 8 operations and 515 drug outlets (50 were pharmacies and 465 drug shops) were closed as illustrated in the chart below.



During this operation, 76 non-compliant cases were filed at Police for FY 2021/22 as compared to 27 for FY 2020/21 of which 61 were submitted to DPP and sanctioned for prosecution for FY 2021/22 as compared to 22 for FY 2020/21. More enforcement regulatory actions were effected on illegal drug outlets as listed in the table below.

Drug Outlet	Impounded		Arrests Made		Court Cases Initiated	
	FY 2020/21	FY 2021/22	FY 2020/21	FY 2021/22	FY 2020/21	FY 2021/22
Pharmacies	06	43	03	44	03	43
Drug shops	1,458	1,855	252	06	14	26

1.2 Strengthen systems and institute actions that support drug regulatory compliance by human and vet practitioners.

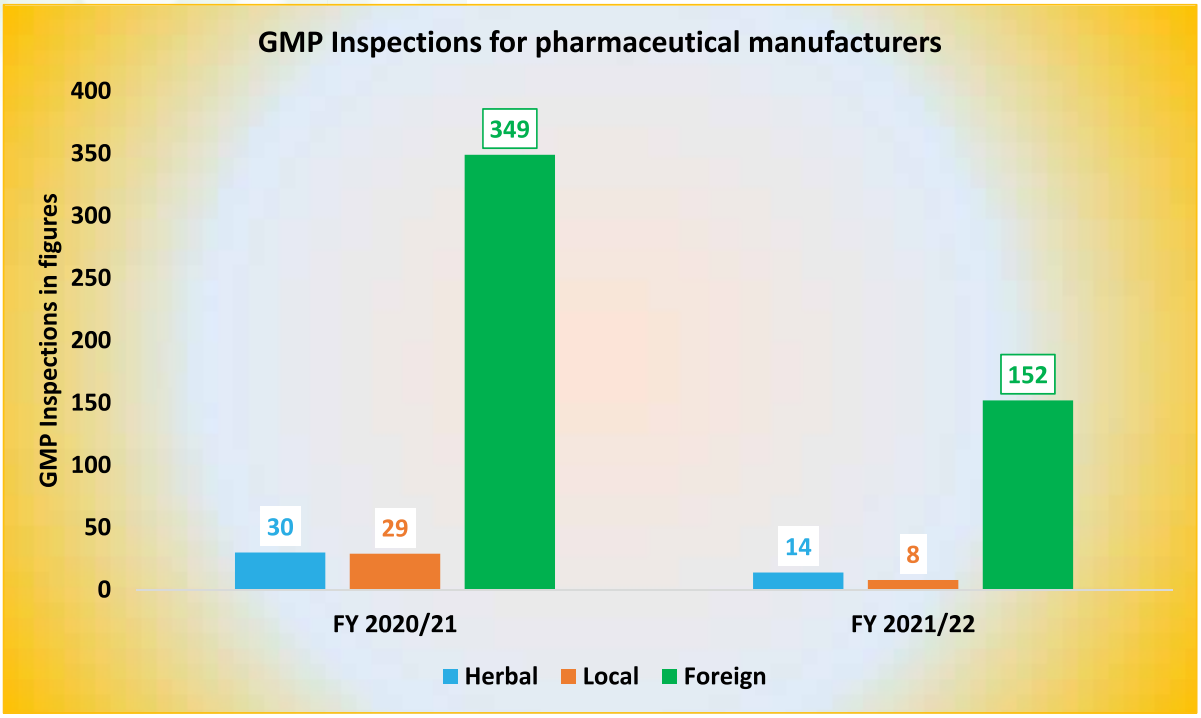
GMP (Good Manufacturing Practice) Inspection

Good Manufacturing practice is conducted every year on both local and foreign pharmaceutical manufacturing facilities to ascertain the quality and compliance aspects in manufacturing of drugs. Part of the quality assessment, involves inspecting the factory where the drug is manufactured to ensure compliance with Good Manufacturing Practices (GMP).

The target for inspections was 170 foreign manufacturers and we inspected a total of 152 (89.4%) as compared to No foreign physical Inspection for GMP for FY 2020/21. However, a total of 349 foreign inspections applications were assessed and issued GMP certificate in line with the board resolution regarding foreign GMP inspection applications. Conducted 31 GMP desk reviews for manufacturing facilities as compared to 110 desk assessments for FY 2020/21.

Planned to inspect 60 local manufacturers and fourteen (14) of them were inspected. There was a reduction in GMP local inspection by 52% as compared 29 inspections for FY 2020/21. This performance was due to majority of local facilities scheduled that turned down inspections due to various reasons which in turn impacted on the number of overall inspections conducted.

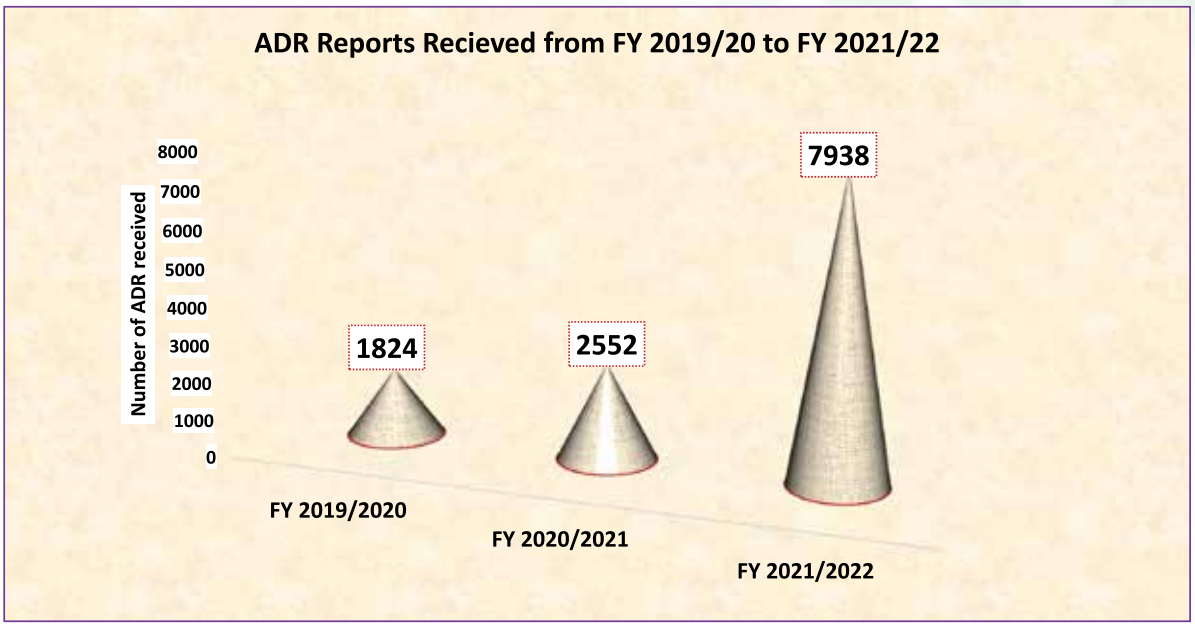
Inspected 28 local herbal manufacturing facilities against a set target of 40 as compared to 30 facilities that were inspected for FY 2020/2021. The target for inspection of local herbal facilities wasn't met because majority of herbal facilities scheduled turned down inspections due to various reasons which in turn impacted on the number of overall inspections conducted and disruption by COVID-19 restrictions with some applicants cancelling inspections. The chart below illustrates the GMP conducted for the two years.



To further support the development of domestic pharmaceutical capacity NDA intends to Conduct routine inspections of all local manufacturers especially high-risk facilities. Follow-up on the GMP road maps for all manufacturers to make improvements in line with their commitments. Support domestic manufacturers in terms of GMP compliance and quality submissions for marketing authorization of products through trainings.

Adverse Drug Reactions Monitoring

There has been a consistent upward trend on Adverse Drug Reactions (ADR) reports which has resulted in several regulatory actions such as recalling some products from the market and issuing safety alerts on some drugs like Hepatitis B Vaccine. The increase of ADR is attributed to the increase in regular feedback, improving more reporting channels, support supervisions, and rollout of market authorization guidelines for Pharmacovigilance which supported detection of treatment failures. A total of 7938 ADR reports were received, evaluated and communicated to the relevant stakeholders as compared to 2552 for FY 2020/21 as shown in the annualized trend below.



From the chart above, NDA recorded a percentage increase of 211% which promoted safety and efficacy of medicines to reduce treatment failures on the market.

In Uganda, the majority of our post market information comes from the ADR reports submitted by clinical teams at health centers across the country. Using the information from your submitted reports, NDA is able to write to manufacturers leading to revision of the Summary of Product Characteristics (SmPCs) and PILs.

Depending on the new safety information emerging from vigilance, updates can be made to the dosage, contraindications, special warnings, precautions for use, undesirable effects and even packaging in order to keep the medicine safe.

Health Care workers are advised to report any Adverse Drug Reaction (ADRs) to the National Pharmacovigilance Center using the Toll-Free line 0800 101 999, the WhatsApp line 0791415555 or email to druginfo@nda.or.ug.

1.3 Strengthen the research capacity for making evidence-based drug regulatory decisions.

Promoting Scientific Research

The Drug Authority has established a scientific research study unit in order to inform the decisions of the Authority. A total of five (5) research studies have been conducted for the FY 2021/22 as listed in the table below:

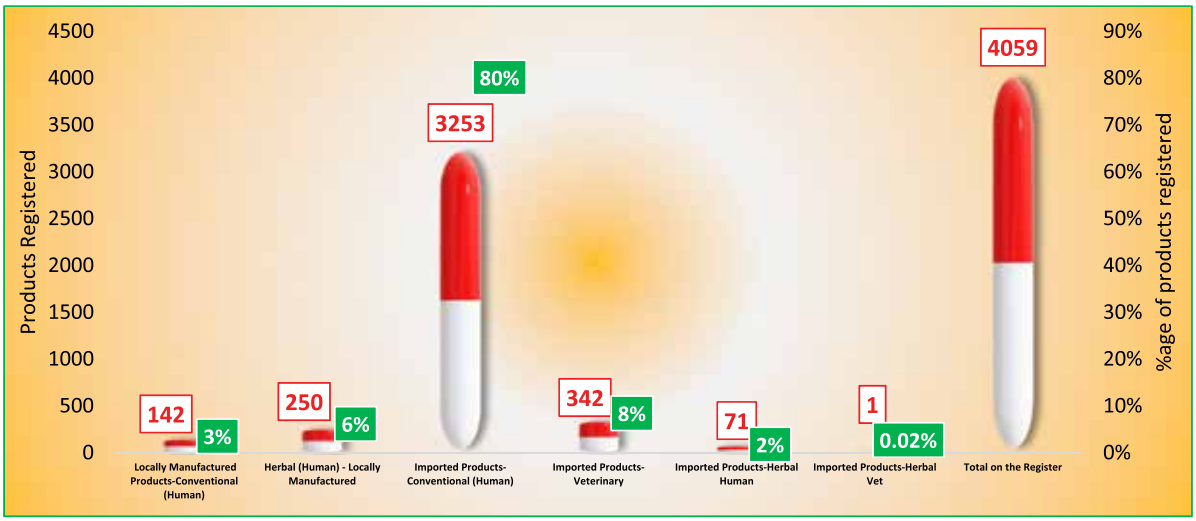
Number	Research Studies conducted in FY 2020/21	Research Studies conducted in FY 2021/22
1.	Evaluate the hyperglycemic effects of DTG among HIV patients on DTG-based HIV treatment.	Study on the impact of the 12 % verification fees on production capacity, cost and availability of the 37 selected medicines.
2.	Reported adverse drug reactions of antiretroviral therapy generic formulations in Uganda.	To evaluate the glycemic effects of Dolutegravir among patients taking DTG based regimens.
3.	The impact of the increase in import verification fees increase on the local production capacity, availability and cost of selected medicines in Uganda.	Skepticism on the quality of generic medicines from countries with non-stringent regulatory authorities.
4.		Survey among health workers on the safety of bupivacaine and ceftriaxone on the market.
5.		Medicine quality, maternal health and the final mile.

From the table above, a total of five (5) studies were conducted for FY 2021/22 as compared to the three (3) studies for the FY 2020/21 thus strengthening the research capacity for making evidence-based drug regulatory decisions.

1.4 Strengthen the systems, processes and procedures for pre-market authorization of drugs and healthcare products.

Product Registration

Currently, the cumulative Pharmaceutical human drugs retained on the drug registered are 4059 products of which a total of 142 are locally manufactured Products for Conventional (Human) medicines contributing to 3% of medicines on the drug register, a total of 250 are locally manufactured products for herbal human contributing to 6%, a total of 3,253 are imported products for Conventional (Human) medicines contributing to 80%, a total of 342 are imported products for Veterinary medicines contributing to 8%, a total of 71 are imported products for herbal human contributing to 2%, one (1) imported product for herbal Veterinary medicines and its contribution is 0.02% on the drug register and the results are presented in the chart illustrated below.



There are incentives given to the local manufacturers by the Government of Uganda including trainings, no fee paid on importation of raw materials, lower fee on registration and variations but the cost of production is still high thus resulting into low locally manufactured essential medicines and this needs the Government to give more incentives to local manufacturers and also reduce on the cost of production.

Development of the National Formulary

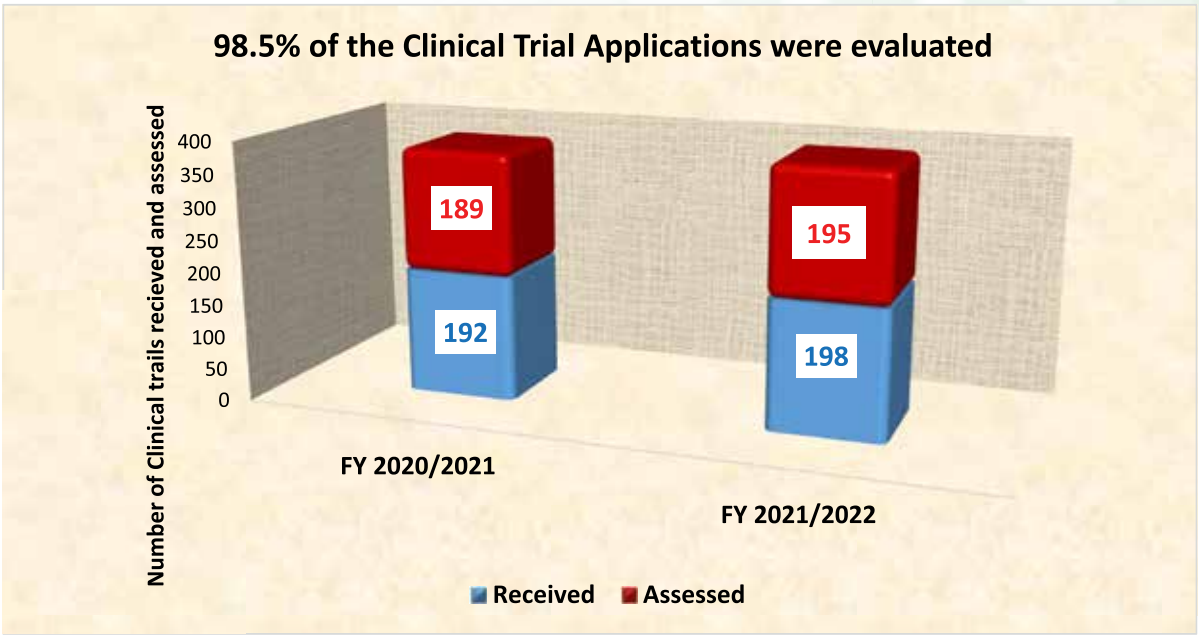
The Sixth Authority approved the first edition of the Uganda National Formulary for human drugs and shared with the Ministry of Health. For the National Formulary - Veterinary drugs, NDA awaits feedback from the Ministry of Agriculture Animal Industry and Fisheries (MAAIF). NDA has been requested by Ministry of Health to update the first edition with the new registered products and come up with the second edition.

Clinical Trial Inspection and Evaluation

The NDA team and core clinical trials team at Baylor College of Medicine's Foundation during a GCP sites to train them on various GCP aspects including investigational Medicinal Product.

Clinical Trials is a field of research that involves testing and evaluating new medicine effects on human health outcomes. Ugandans from different walks of life voluntarily participate in clinical trials with the expectation of potential benefits to the population. The trials may involve drugs that are registered with NDA as well as those that are not registered but have promising outcomes based on the scientific information submitted.

In the period under review, NDA received 198 clinical trial applications of which 195 (98.5%) were assessed as compared to FY 2020/2021 were 98% (189 out of 192) clinical trial applications that were assessed. Out of 38 initial new applications assessed, 36 were assessed with a final decision made within SDTs, out of 88 renewal applications assessed during the financial year, 80 were assessed with a final decision made within SDTs, and out of 69 amendments assessed, 62 applications were assessed with final decision made within SDTs. The Graph below shows the Clinical Trials Trend Analysis from 2020/21 to 2021/22.



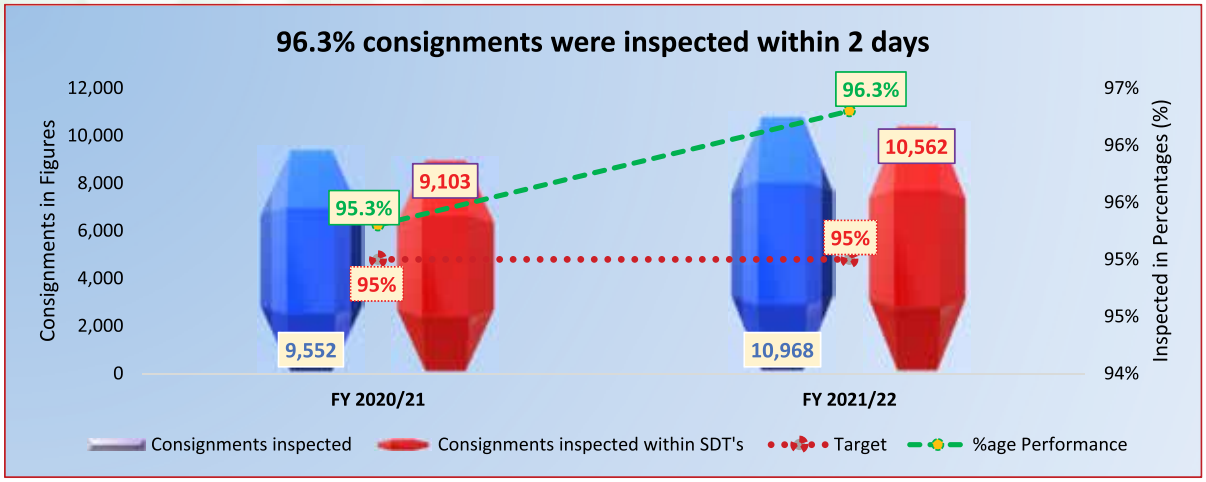
From the chart above, 91.3% (178 out of 195) of the clinical trial applications were evaluated and regulatory action issued within the set Service Delivery Timeline against a set target of 90%.

Good Clinical Practice (GCP) refers to an international set of guidelines that helps make sure that the results of a clinical trial are reliable and that the patients are protected. National Drug Authority (NDA) conducts inspections of clinical trial sites to verify compliance to the conditions of the clinical trial certificate and the principles of GCP. It was also noted that 20 GCP sites were inspected as compared to 21 GCP inspections for FY 2020/2021. This promoted efficacy, safety and quality of drugs on trial.

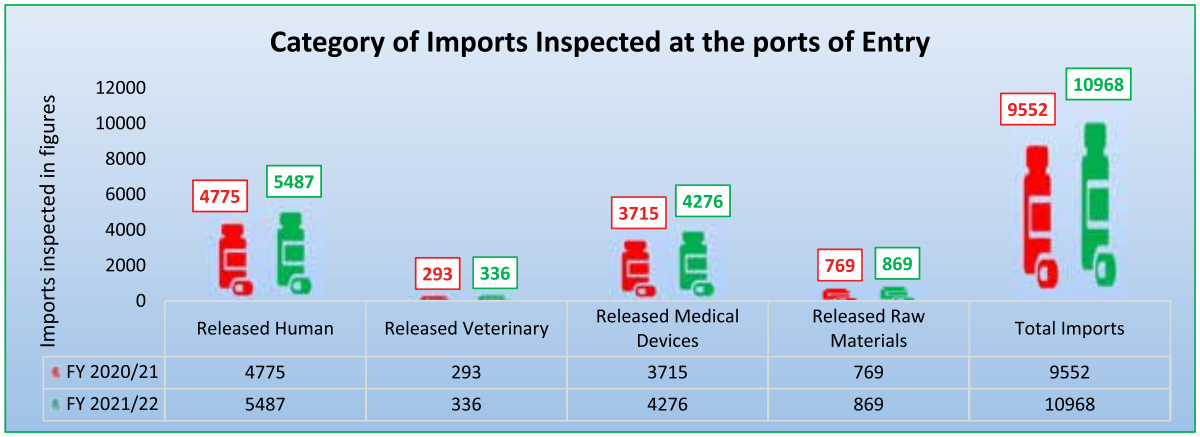
1.5 Strengthen the systems, processes and procedures for post-market authorization of drugs and healthcare products.

Import Verification and Sampling for quality control.

We targeted to have 95% of medicines and devices inspected for conformance and released from the ports of entry within two (2) working days and we managed to release a total of 10,562 (96.34%) out of 10,968 consignments within two (2) days as compared a total of 9,103 (95.3%) out of 9,552 consignments for FY 2020/2021. The graph below shows the comparative analysis for consignments inspected within two (2) days for FY 2020/21 and FY 2021/22.



In addition, the category volume of imports inspected at the ports of entry for the FY 2021/22 and FY 2020/21 are illustrated in the chart below;

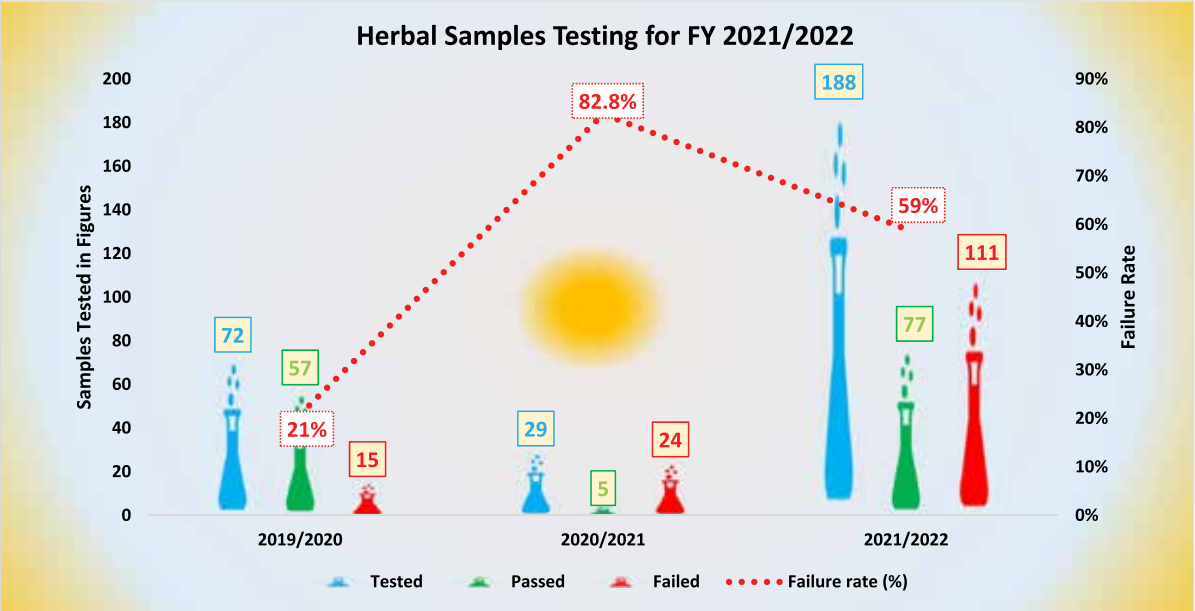


	Released Human	Released Veterinary	Released Medical Devices	Released Raw Materials	Total Imports
FY 2020/21	4775	293	3715	769	9552
FY 2021/22	5487	336	4276	869	10968

From the chart above, NDA registered a fabulous improvement in the volume of imports of 15% as compared to the volume of imports for FY 2020/21 and 251 (2.29%) of the consignments were sampled for quality control testing for FY 2021/22 as compared to 235 (2.46%). This improved quality product on the market. The increase in the number of imports reveals a drop in the number of products locally manufactured and there is a need for the Government of Uganda to reduce on the importation through giving subsidies and supporting the local manufacturing facilities to increase their production capacity.

Laboratory Testing of Herbal Products

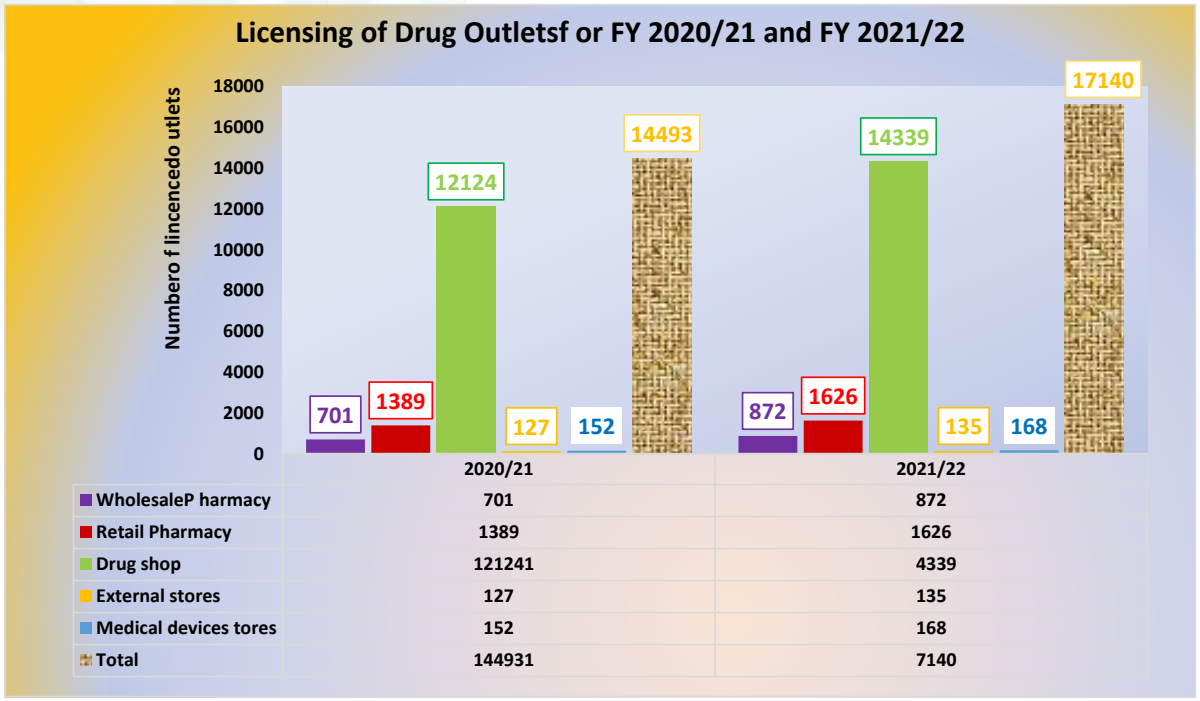
Acquired automated High-Performance Thin Layer Chromatography (HPTLC) equipment used in Herbal product testing. The table below shows the number of herbal products tested and decrease in the failure rate from 82.8% for FY 2020/2021 to 59% for FY 2021/2022.



From the table above, the herbal failure rate has decreased from 82.8% (24 out of 29) for FY 2020/2021 to 59% (111 out of 188) for FY 2021/2022 implying that the quality of herbal products on the market has increased from 17.2% to 41%. The increase in the quality of herbal products is attributed to NDA Drug Authority strengthening the herbal activities at the Secretariat and laboratory, Name and shame of culprits through regulatory actions, and increased vigilance through Post Market Surveillance (PMS), engagement and training of herbal stakeholders. Details of failed samples and the parameters include One hundred and seven (107) samples of herbal/energy drink failed labelling requirements, four (4) samples of herbal medicine had sildenafil in the sample and most of these are manufactured locally.

Licensing of drug outlets

During the reporting period, the licensing cycle has changed from one (1) year to three (3) years license for Pharmacies. The licensing trend is highlighted as shown in the graph below.

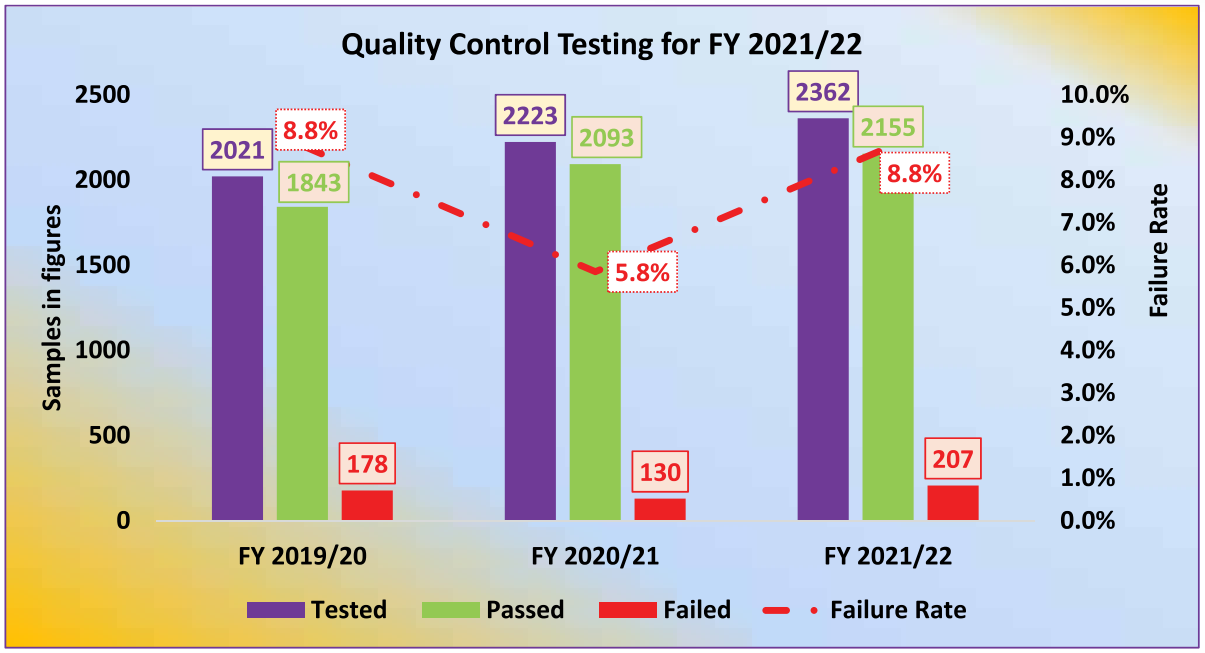


From the chart above, NDA approved 872 against 927 applications received for wholesale pharmacy, approved 1,626 against 1780 applications received for retail pharmacies, approved 135 against 150 application received for external stores, approved 168 against 177 applications for Medical device stores and approved a total of 14,339 against 16,119 applications received for drug shops. In total, NDA approved a total of 17,140 drug outlets of which 2801 were pharmacies and 14,339 were drug shops against a total of 19,153 applications of which 3034 were for pharmacies and 16,119 were drug shops. The fabulous improvement in licensing is attributed to effective support supervision which resulted into increased licensed drug shops and pharmacies which in turn increase the availability of drug at all times to the population of Uganda.

Quality control Testing

Samples tested mainly are drawn from three sources namely; routine post market surveillance, pre- market samples and port of entry. A total of 2,362 (101.4%) batches out of the target of 2,305 batches were tested against 2,330 planned samples. The planned target was achieved because testing depends on the number of samples received from the market and the samples received exceeded the planned.

The chart below presents the trend analysis of samples tested against those received in the FY 2021/22 and previous two years back.



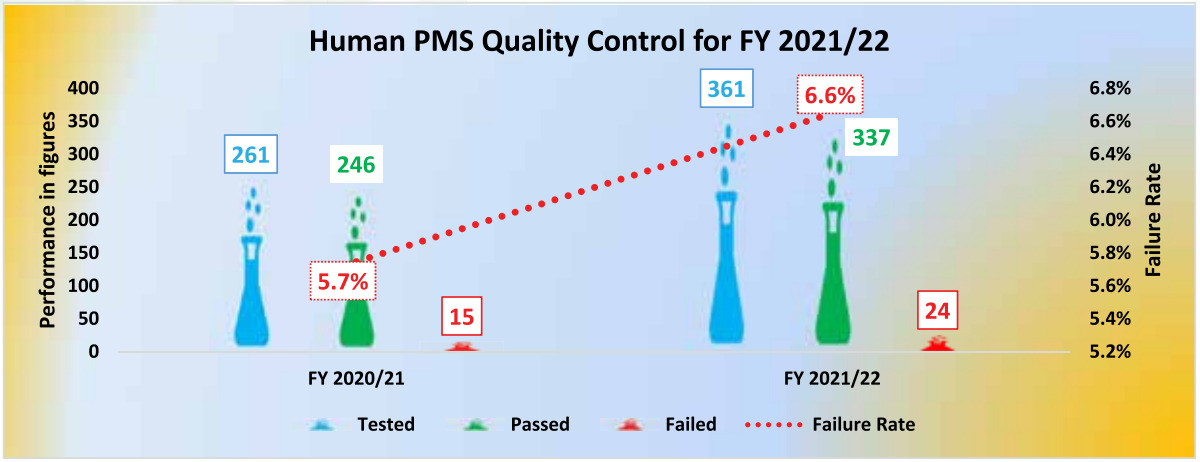
There was a drop in the overall quality of pharmaceutical products from 94.2% for FY 2020/2021 to 91.2% for FY 2021/2022 because of the increased surveillance of suspected substandard and falsified products on the market. Samples were submitted to the lab for confirmation and majority for example Hand Sanitizers, medical gloves and herbal products were found to be substandard.

PMS (Post Market Surveillance)

NDA Tested 845 batches for FY 2021/2022 circulating in the market as compared to compared to 534 batches for FY 2020/2021. There was an increase in the pharmaceutical products quality failure rate up from 88 (16.5%) for FY 2020/2021 to 152 (18%) for FY 2021/2022 and the products that failed were recalled from the market and destroyed. The graph below shows the PMS comparison analysis.

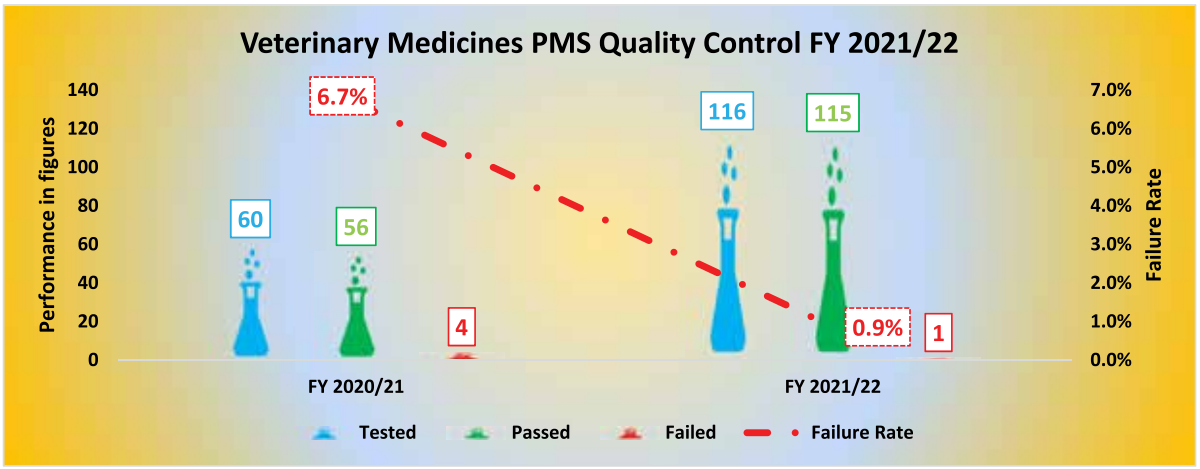
Human Medicines under PMS

NDA Tested 361 batches circulating in the market as compared to 261 batches for FY 2020/2021. There was an increase in the pharmaceutical quality failure rate up from to 15 (5.7%) for FY 2020/2021 to 24 (6.6%) for FY 2021/2022. Out of the overall PMS Quality failure of 18%, Conversional Human medicine samples contributed (15.8%) of PMS sample failure. The graph below shows the Human PMS comparison analysis.



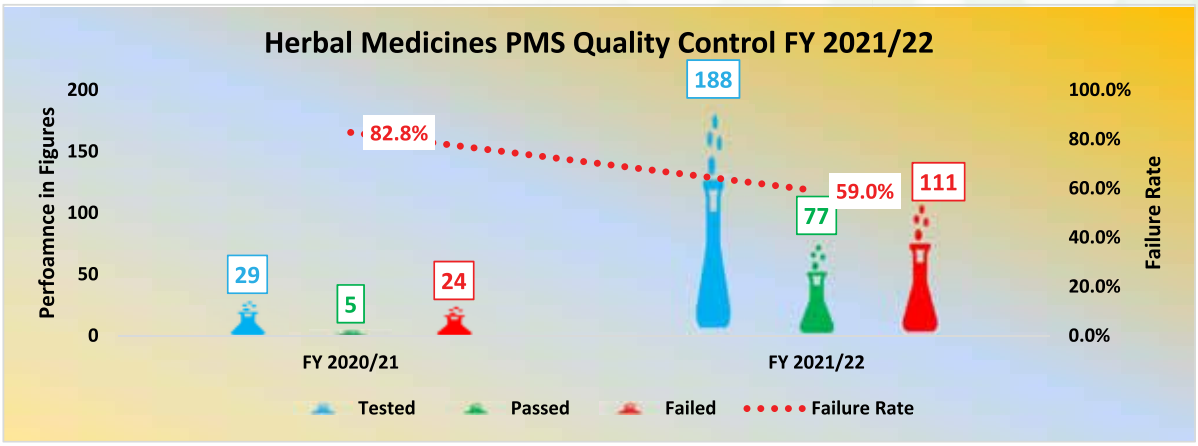
Veterinary Medicines PMS

NDA conducted quality test of 116 veterinary batches circulating on the market as compared to 60 batches for FY 2020/2021. There was a reduction in the pharmaceutical quality failure rate from 4 (6.7%) for FY 2020/2021 to 1 (0.9%) for FY 2021/2022. Out of the overall PMS Quality failure of 18% failure, Veterinary medicine samples contributed 0.7% of PMS sample failure.



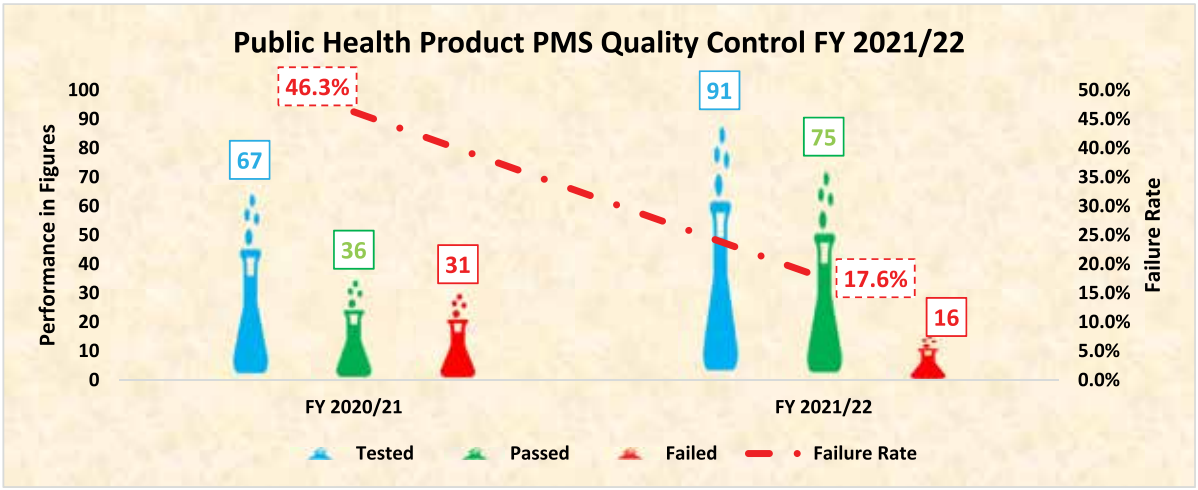
Herbal Medicines under PMS

NDA Tested 188 batches circulating in the market as compared to 29 batches for FY 2020/2021. There was an increase in the pharmaceutical quality failure rate from 24 (82.8%) for FY 2020/2021 to 111 (59%) for FY 2021/2022. Out of the overall PMS Quality failure of 18% failure, herbal medicine samples contributed 73% of PMS sample failure.



Public Health Products under PMS

NDA Tested 67 batches of public health products and all the 67 samples tested were hand sanitizers because of Covid-19 as compared to 91 samples tested for FY 2020/2021. The pharmaceutical quality failure rate reduced from 31 (46.3%) to 16 (23.9%) for FY 2021/22 and they were all hand sanitizers. Out of the overall PMS Quality failure of 18%, Public health product samples contributed (10.5%) of PMS sample failure.



Drug Recalls

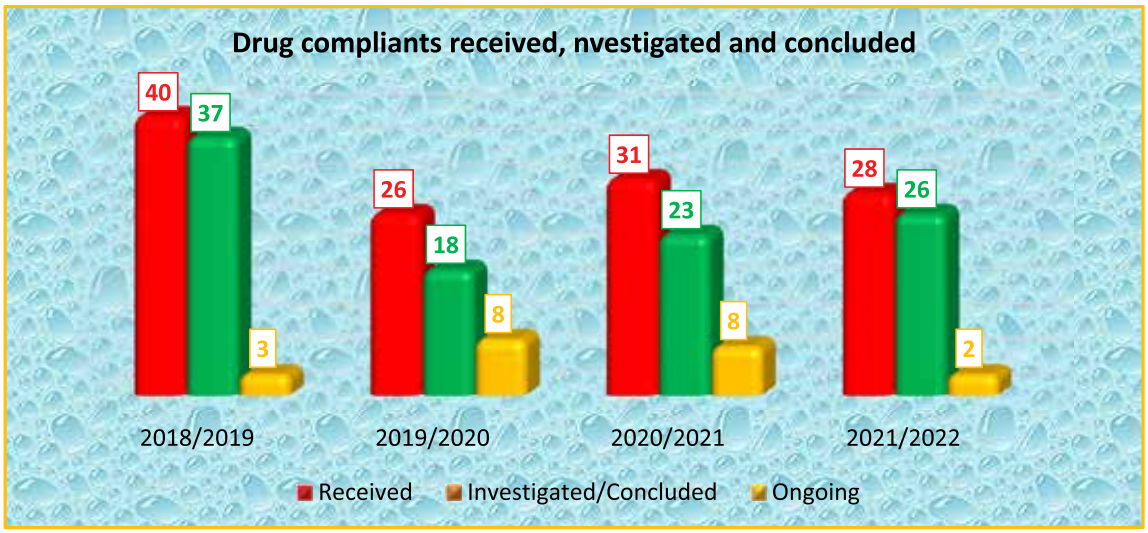
In the period under review, 15 drug recalls were effected compared to 26 recalls in FY 2020/2021. The recalls were due to product defects, quality failure and defects, inefficacy, safety risks. The Local Technical Representatives/Importers/Manufacturers of the recalled drugs submitted root cause investigation reports on the observed non-conformance as well as corrective and preventive action (CAPA) report to avoid recurrence of the failure or defect in the future. The table below shows a list of products that were recalled from the market in the FY 2021/22.

No.	Date Initiated	Brand Name	Batch Number/s	LTR	Manufacturer	Reason/Problem
1	22/07/2021	Dawaprom Syrup	1910286 & 2004051	SUPER MEDIC LTD	DAWA LIMITED	Failed assay tests during stability studies
2	29/07/2021	D-Worm	D22718001	SHURIK LTD	TORQUE PHARMACEU-TICALS LTD	Failure to comply with international pharmacopoeia specification for dissolution tests
3	29/07/2021	Vorm-400	EUGV019002	ROYAL PHARMA 2011 LTD	RAVIAN LIFE SCIENCE PVT LTD	Failure to comply with International Pharmacopoeia specifications for dissolution tests
4	10/09/2021	Hydrogen Peroxide	0017	SMARTCARE LTD	SMARTCARE LTD	The product does not foam
5	17/09/2021	Zenvac (Bupivacaine Hydrochloride 5mg)	LEZ20053	LLOYDS PHARMACY LTD	ZEN PHARMA PVT LTD.	Adverse drug reactions including hallucinations, aggressive behavior, confusion
6	23/09/2021	D-Worm	D22719001	SHURIK LTD	TORQUE PHARMACEU-TICALS LTD - INDIA	Failure to comply with international pharmacopoeia specifications for Dissolution test.
7	12/10/2021	Losar Denk 50, 100 And Colosar Denk 50,100	All	BENLE CONSULT LTD	DENK PHARMA GMBH & CO. KG	Presence of genotoxic impurity character-ized as 4-Chloro Azo-domethyltetrazole
8	30/11/2021	B-Safe	49072021	REDDY'S PHARMA LTD	REDDY'S PHARMA LTD	Failure to comply with specifications for Presence of particulate matter as per Uganda Standard US EAS 789:2013
9	30/11/2021	Vance Hand Sanitizer	01-06-001	VANCE IN-VESTMENTS LTD	VANCE INVESTMENTS LTD	Failure to comply with specification for presence of particulate matter as per Uganda Standard US EAS 789:2013

No.	Date Initiated	Brand Name	Batch Number/s	LTR	Manufacturer	Reason/Problem
10	30/11/2021	Gastro gel Suspension	GT 03.20	MEDIPHARM SALES LTD	MEDIPHARM INDUSTRIES (E.A) LTD	Product caked
11	02/02/2022	Rene Hand Sanitizer	02521	RENE PHARMACY LTD	RENE INDUSTRIES LTD	Results from the laboratory indicate that the batch failed to comply with US EAS 789:2013 specifications for pH tests
12	10/02/2022	Cotrimoxazole 960mg	K59221002	TATA (U) LTD	KOPRAN LIMITED,	Molding of the tablets
13	12/04/2022	Panto Denk	3940	BENLE CONSULT LTD	DENK PHARMA GMBH & CO. KG	OOS incident during ongoing stability study which showed discoloration of tablets caused by oxidation of iron salts due to moisture
14	04/05/2022	Saraya Hand Sanitizer	2107191	SARAYA MANUFAC-TURING (U) LTD	SARAYA MAN-UFACTURING (U) LTD	Failure to comply with the Uganda Standard US EAS 789:2013 specifications for pH tests.
15	24/06/2022	Amitix 125G/L	18023412 & BE 1900550	NILE SERVICES LTD	ALFASAN INT. B.V, CHIMAC SA BELGIUM	Failure to comply with the USP specifications for Assay tests

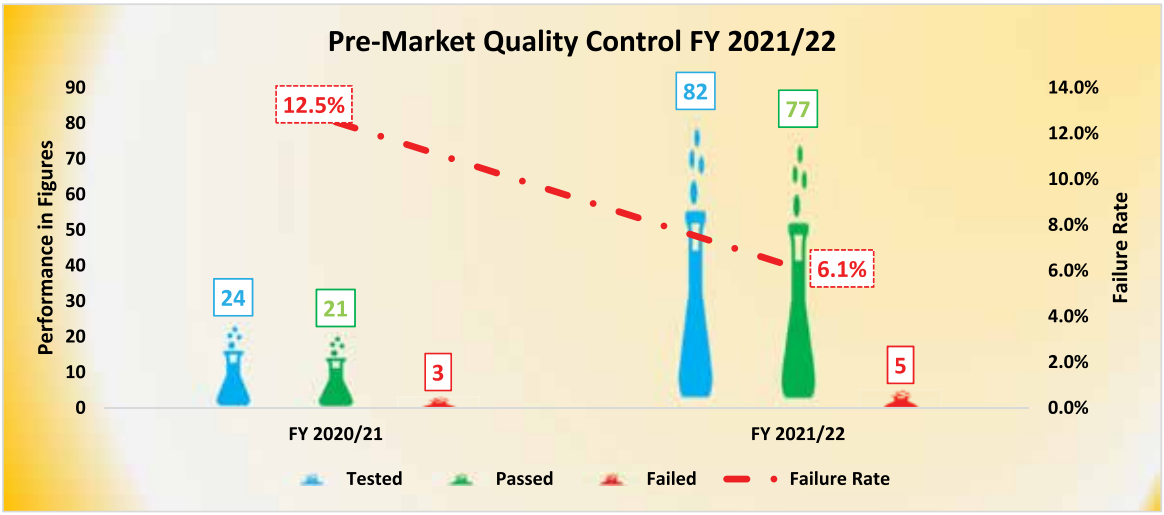
Drug Complaints

A total of 28 drug product-related complaints were received in FY 2021/2022, compared to 31 in the previous financial year. Of the complaints received accounted for 46.3% conventional human products, 17.9% medical devices, 17.9% herbal products and 17.9% veterinary drugs as presented in the chart below.



Pre-Market samples

NDA Tested 82 batches of drugs locally produced before they are allowed on the Ugandan market as compared to 24 samples for FY 2020/2021. The failure rate was 5 (6.1%) FY 2021/22 as compared to 3 (12.5%) for FY 2020/21. The medicines that failed included; two (2) samples of Metronidazole and three (3) samples of Paracetamol both failing Assay test. In FY 2020/2021 three (3) samples of Ciprofloxacin batch 00319, 00119 & 00219 manufactured by Lifeway Pharmaceuticals failed Assay tests.

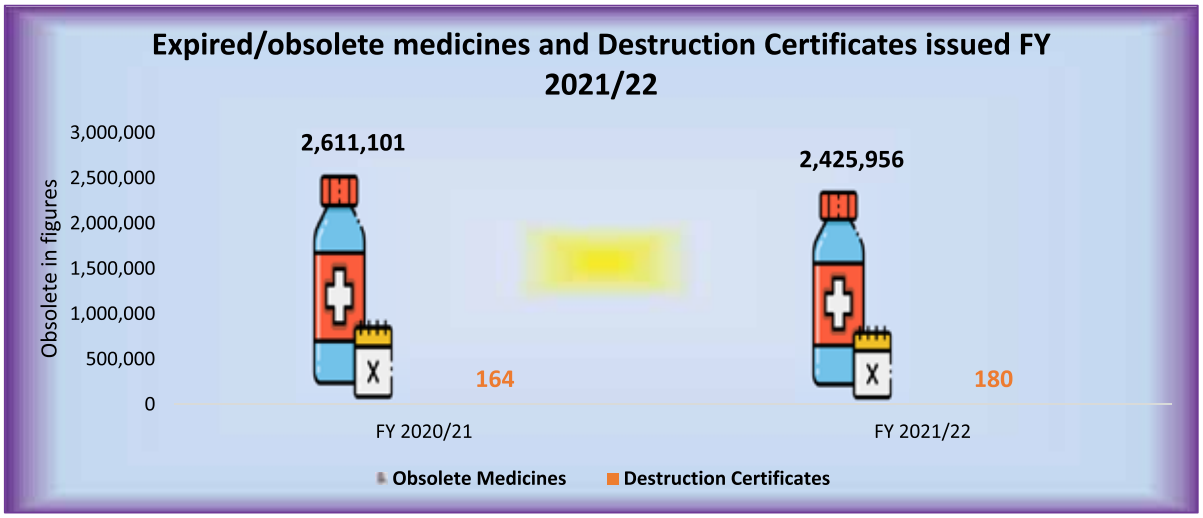


Port of Entry Samples

Medicine samples tested were 1,435 batches of which 50 (3.5%) failed the quality test (10 human medicine, 4 veterinary medicine, 5 condoms and 31 medical gloves) and all the failures were not allowed into the market for circulation. For medical devices, a total of 369 (184.5%) batches were tested out of the targeted 200 batches as compared to 206 batches that were tested for FY 2020/2021.

Drug waste management

NDA under its Corporate Social Responsibility (CRS) obligations, facilitated National Medical Stores to remove and incinerate expired/obsolete medicines and other health products amounting to 2,425,956 kgs for FY 2021/2022 from the public health facilities and PNFPs as compared to 2,611,101 kgs for FY 2020/2021. 180 Destruction certificates were issued as compared to 164 for FY 2020/2021 and this has saved the public from adverse effects of such drugs which would likely be repackaged and sold to the public or abused using other means.



Drug and Substance abuse

NDA has engaged the public especially the youth, created strategic collaborations to enhance provision of the prevention message and issued information education materials to the public.

The National Drug Policy is in tandem with the international regulations on drugs including the conventions on narcotic drugs and psychotropic substances under international control and to fight against drug and substance abuse.

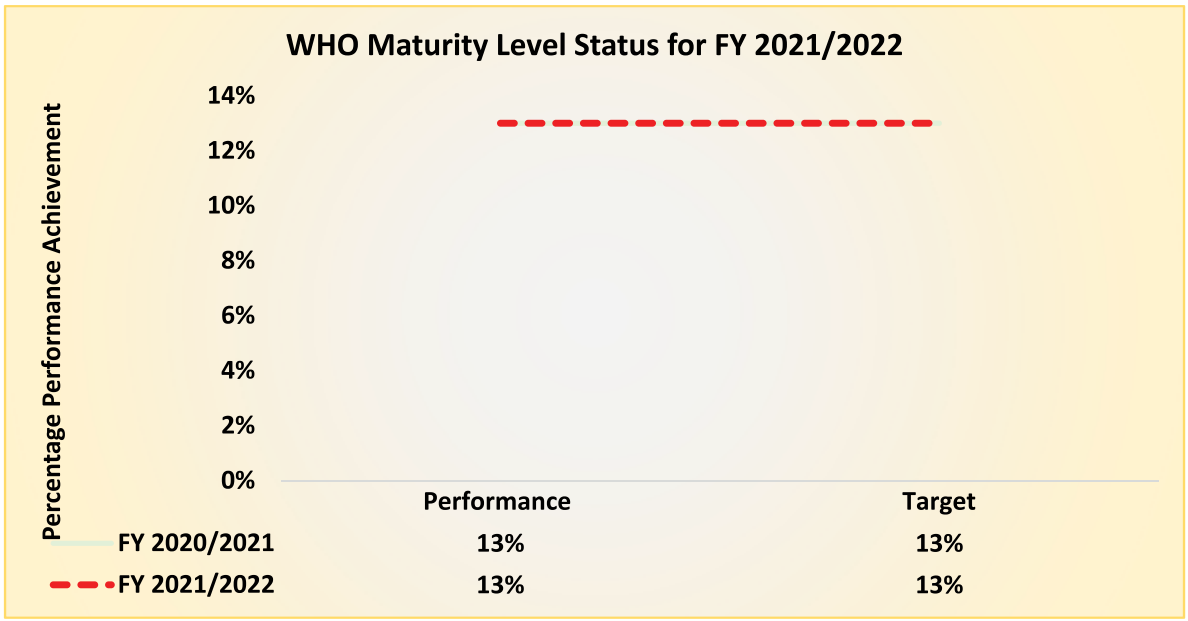
In the 2021/2022 NDA formalized its relationship with the Church of Uganda, through singing a Memorandum of Understanding to support the prevention of drug and substance abuse in the community.

NDA continues to work with the United Nations Office on Drugs and Crime that resulted in 10 radio talks shows against drug and substance abuse in the regions (Central, Northern, and West Nile).

In the period under review, NDA collaborated with Kabale University and the Dioceses of Lango, were 20 secondary schools in the respective regions, compared to 19 in Gulu district in FY 2020/2021. Information on prevention of drug and substance abuse was shared with the students in the different schools and counselling services offered.

Key Performance Indicators for Core Service Delivery

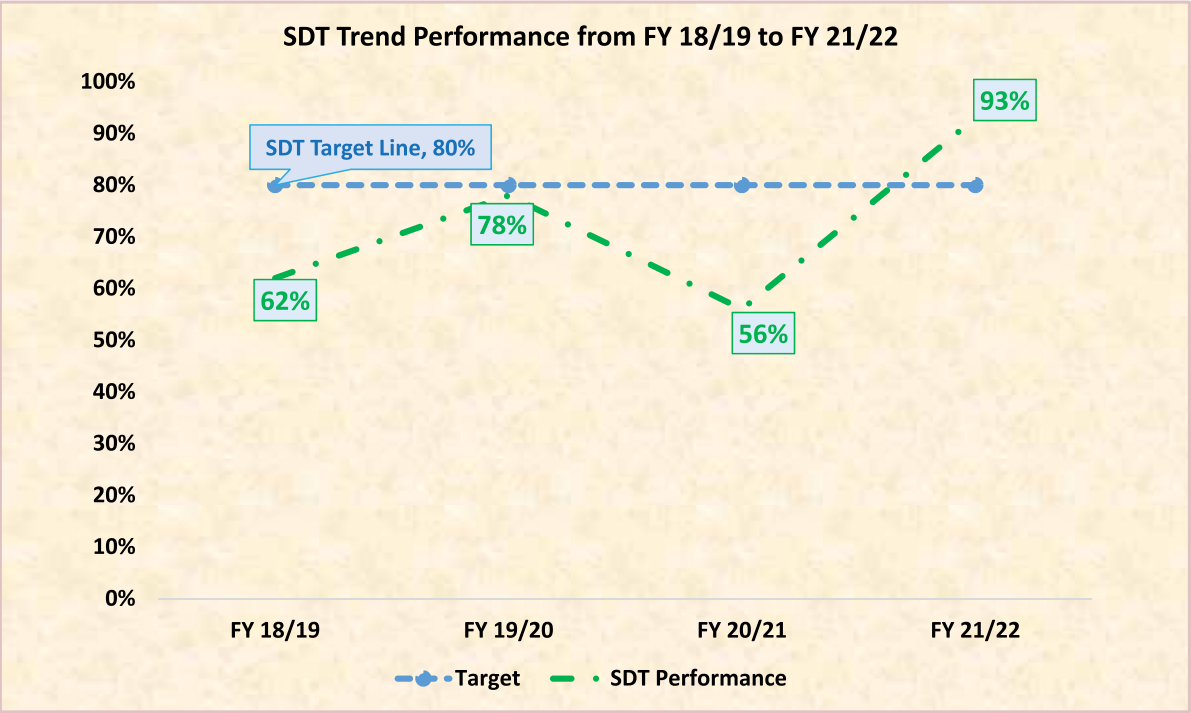
1 Percentage of regulatory functions meeting World Health Organization (WHO) Maturity Level 3.



The chart above shows that out of the eight (8) WHO regulatory function, NDA has one (1) function of the Laboratory that reached and exceed Maturity Level three (3). The seven regulatory functions are at maturity two and one because of the legal aspect of the NDA law.

2 Proportion of SDT's implemented within the agreed timeline.

Currently NDA, has a total of fifty-six (56) Service Delivery Timelines. NDA has registered an improvement in implementation of services to clients within the agreed timelines from 56% for FY 2020/21 to 93% for FY 2021/22. This has improved regulatory systems, processes and procedures that guarantee availability of safe, efficacious and quality drugs and health products. The chart below illustrates the Service Delivery Timelines comparative analysis.



Currently NDA, has a total of fifty-six (56) Service Delivery Timelines. NDA has registered an improvement in implementation of services to their clients within the agreed timelines from 56% for the previous year to 93% for FY 2021-2022. The increase is attributed to the improved efforts in ICT automation of different processes thus using less time in the delivery of services to clients.

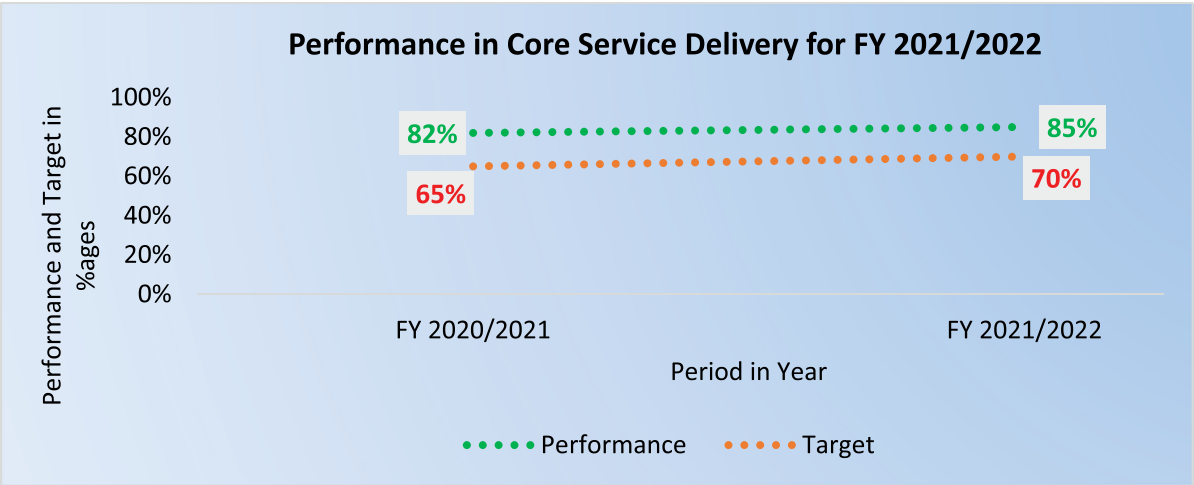
Service Delivery Timelines (SDT) committed for FY 2021/22

No.	Service Delivery	Time lines
1.	Test results from mandatory testing. (Medicine)	48
2.	Test results from mandatory testing after sampling (Medical devices).	30
3.	Test results from client requests after acceptance by the lab (All Products).	45
4.	Test results for pre-market samples (domestic Manufacturers).	60
5.	Test results for Public Health Products (LLINs, Face Masks, Hand Sanitizers and other) samples.	45

No.	Service Delivery	Time lines
6.	Test results for post-market surveillance (medicines)	48
7.	Assessment of application and request for additional information on application for MA (Human Drugs)	396
8.	Assessment of application and request for additional information on application for MA (Veterinary Drugs)	264
9.	Regulatory decision on MA after additional information is received	66
10.	Regulatory decision on MA for domestically manufactured conventional products (Herbal, Conventional)	132
11.	Regulatory decision on minor variation	88
12.	Regulatory decision on Major variation (if the application does not require physical verification)	132
13.	Regulatory decision on Annual or Immediate notification change	80
14.	Publication of the drug register	5
15.	Receipt, screening and acknowledgement of CTA (new, renewals and amendment) Applications	10
16.	Regulatory Decision on a CTA	60
17.	Annual Renewal of ongoing trials	20
18	Amendment of CT Authorizations	20
19.	Regulatory decision on drug promotional materials	15
20.	Publication of advert of approved promotional materials/ advert	4
21.	Feedback on serious ADE reports	20
22.	Feedback on serious AEFIs reports	20
23.	Feedback to applicant of Regulatory decision for licensing of new pharmacy applicants.	35
24.	Feedback to applicant of Regulatory decision for pharmacy renewal.	40
25.	GMP Physical inspection after receipt of application - Foreign	180
26.	GMP Report Feedback to Manufacturer after inspection done within 45 working days	45
27.	CAPA feedback - foreign	20
28.	Feedback after inspection – Domestic	30
29.	CAPA feedback - local facilities	20
30.	Verification of unregistered drugs	10
31.	Verification of registered drugs	3

No.	Service Delivery	Time lines
32.	Clearance of Imports at Ports of Entry	2
33.	Issuance of recall or alert for a substandard or falsified medicine or health care product	14
34.	Acknowledgment of receipt of a product complaint	5
35.	Feedback on a market product complaint	20
36.	Feedback on the effectiveness of recall after receipt of the recall report from the LTR (Local Technical Representative)	10
37.	Feedback of test results from the Lab to the client	5
38.	Acknowledgment of Receipt of Application	10
39.	Regulatory Decision	50

3 Proportion of improved performance in core service delivery



NDA planned to implement a total of one hundred five (105) core activities and by the financial year, a total of 94 core activities were achieved reflection a percentage achievement of 85% as compare to the set target of 70%. There is a tremendous improvement in the performance of the Board as far as achieving the implemented core service from 82% (87 out of 105 implemented) for FY 2020/2021 to 85% (94 out of 110 implemented core activities). This performance is attributed to the Board and Management support given to staff and support from the externa stakeholders.

Focus Area 2: Legal and Regulatory framework

Strategic Objective 2:

To Streamline the legal and regulatory framework for operational effectiveness of NDA.

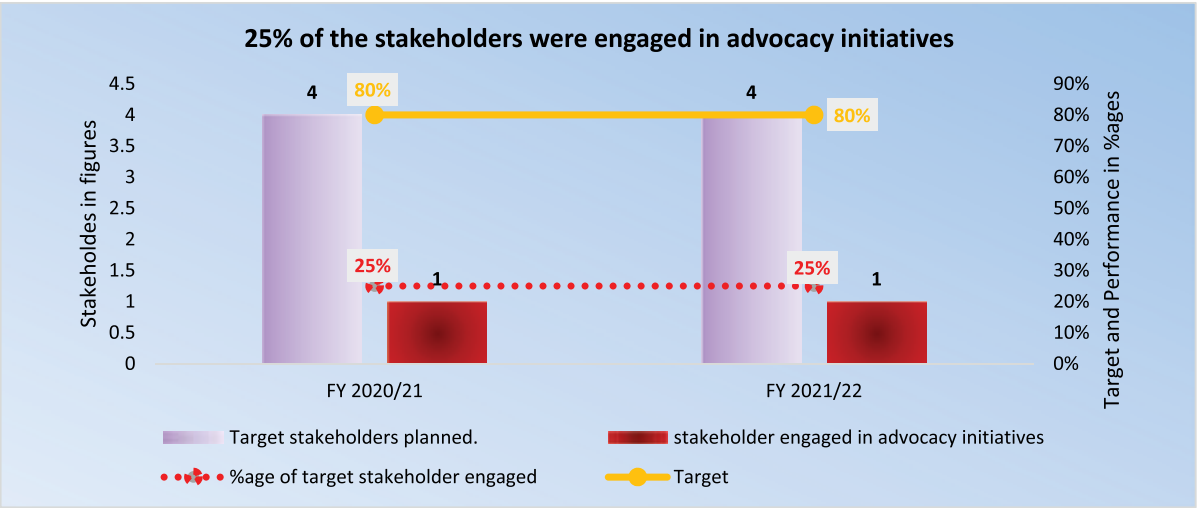
Proper scoping of the regulatory/legal priorities and requisite actions to add value and improve the drugs and health products sub sector regulatory environment will be a key focus of this strategic objective, during the five-year strategic period. The key strategies will be to;

2.1 Advocate for an improved regulatory framework.

Trend performance on KPIs

1 Proportion of target stakeholder engaged in advocacy initiatives

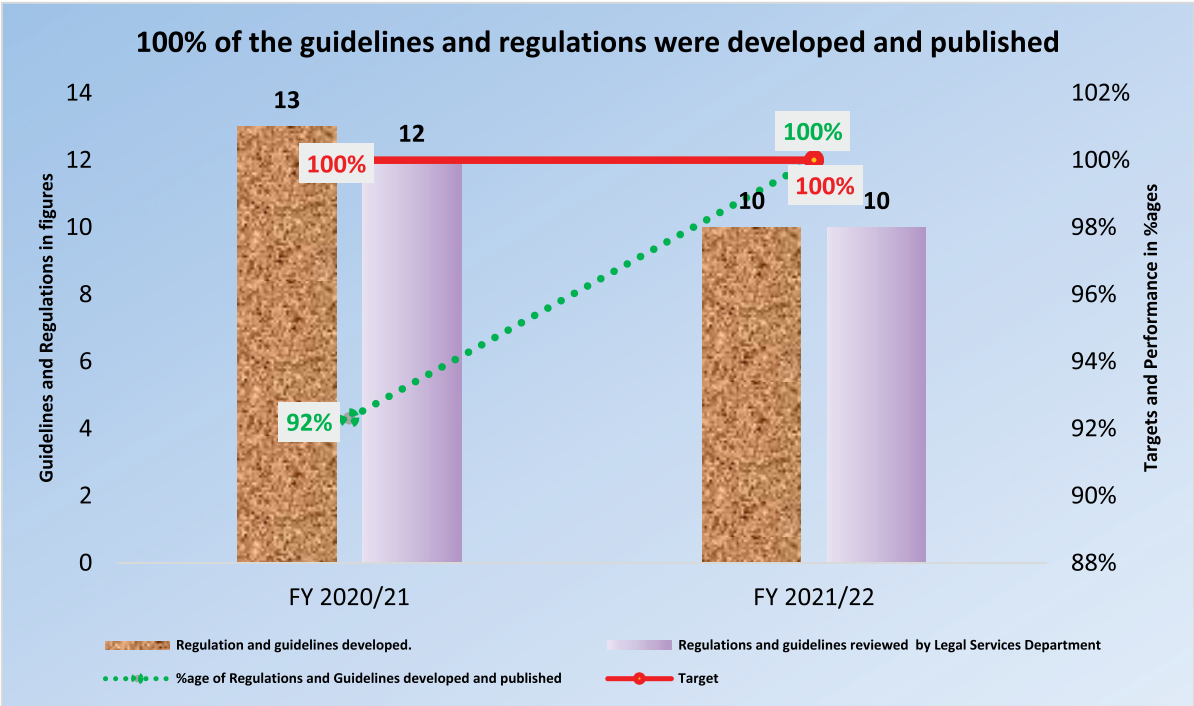
This focus on adequately delivery of regulatory services of the Drug Authority. The performance of 25% (1 advocacy engagement against the 4 planned) were not achieved. The performance for both FY 2021/22 and FY 2020/21 was affected by the law that is not yet progressed in parliament. There is a need for parliament to enact the law for NDA that will enable an effective and well-functioning regulatory system for drugs and health products. The chart below shows the comparative analysis for stakeholder advocacy initiatives for FY 20/21 and FY 21/22.



2.2 Strengthen the regulatory framework

2 Proportion of Regulations Guidelines developed published

NDA has developed regulation guidelines for different processes to be shared with both the internal and external stakeholders. These help the clients to comply to the National Drug Authority medicines and health products standards. In the FY 2021/22, NDA developed and published a total of 10 (100%) guidelines and regulations against 10 that were received as compared to 12 (92%) against 13 received for FY 2020/21. This improvement in performance has resulted into harmonized legislative framework that enables an effective and well-functioning regulatory system for drugs and health products. The chart below illustrates the comparative analysis for FY 21/22 and FY 20/21.



3 Transformation of NDP&A Act into UNFDA.

The Monitoring and Evaluation plan for five (5) years planned to measure this indicator in the last FY because NDA is expected to be transformed in the FY 2024/25.

Focus Area 3: Stakeholder awareness and engagement and Collaboration:

This area of focus shall be harnessed through; Public awareness, collaboration and partnerships with Local government, MDAs, regional and international organizations to create visibility and enhance execution of NDA's mandate.

Strategic Objective 3:

To increase stakeholder awareness, engagement and collaboration to support NDA regulatory functions

Three key strategies, presented below are proposed to realize the strategic objective;

3.1 Strengthen mechanisms for stakeholder awareness and engagement.

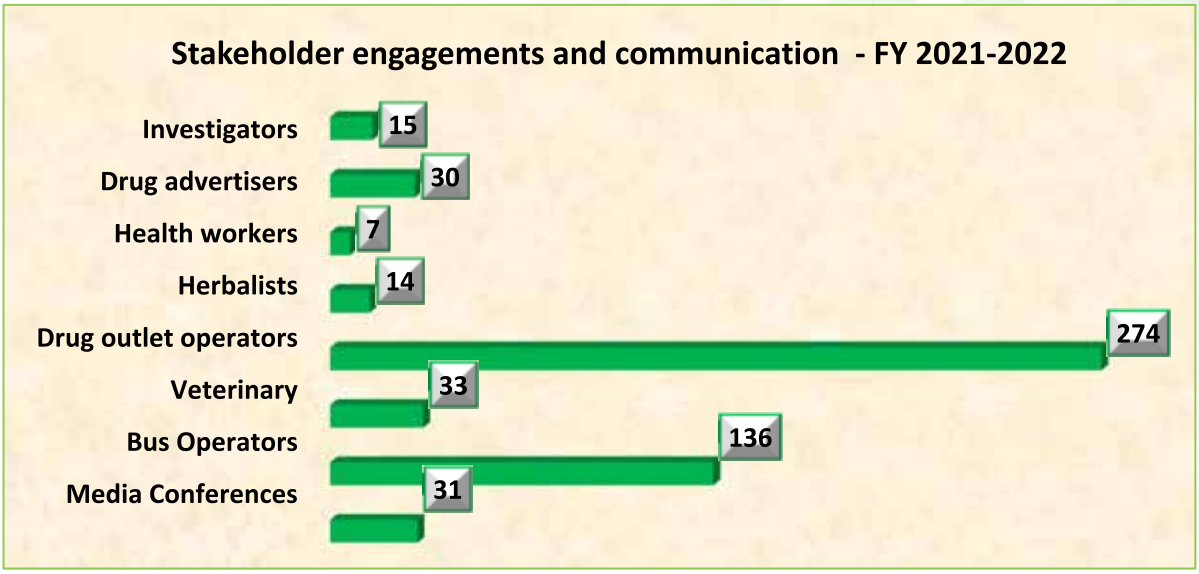
Stakeholder engagements

NDA has also effectively engaged major stakeholders (Parliament, MOH, MAAIF, NMS, Police, Ministry of Finance, Planning and Economic Dev elopment, Ministry of Trade, Industry and Cooperatives, Ministry of Education and Sports, National Planning Authority, National Information Technology Authority - Uganda, PPDA, Ministry of Science, Technology & Innovation, Uganda Investment Authority, URA and Office of the Auditor General) through effective communication, information dissemination and feedback.

3.2 Enhance internal corporate and public relations function

Communication

NDA is cognizant of the need of accurate information flow with stakeholders through defined channels to enhance its image, reputation, trust, transparency and integrity. There were 540 engagements with various stakeholders across the country compared to 523 in FY 2020/2021 as indicated in graph below.



The open and honest engagement with different stakeholders has enabled NDA foster a framework that has minimized challenges in delivering on its mandate.

Areas of engagements centered on NDA's activities like enforcement operations, veterinary drugs, acaricides, drug hawkers, drug promotions/advertising, adverse drug reactions, herbal drugs, and licensing among others.

3.3 Enhance stakeholder collaboration and partnership at national, regional and international level.

NDA has participated actively in EAC Medicines Harmonization activities as illustrated in the table below.

Activities Implemented during the contract period	FY 2020/21	FY 2021/22
EAC MRH joint dossier assessment.	02	04
Expert Working Group meetings held to review GMP inspection reports.	03	02
EAC joint GMP inspections.	08	01
Technical Committee meetings.	10	0

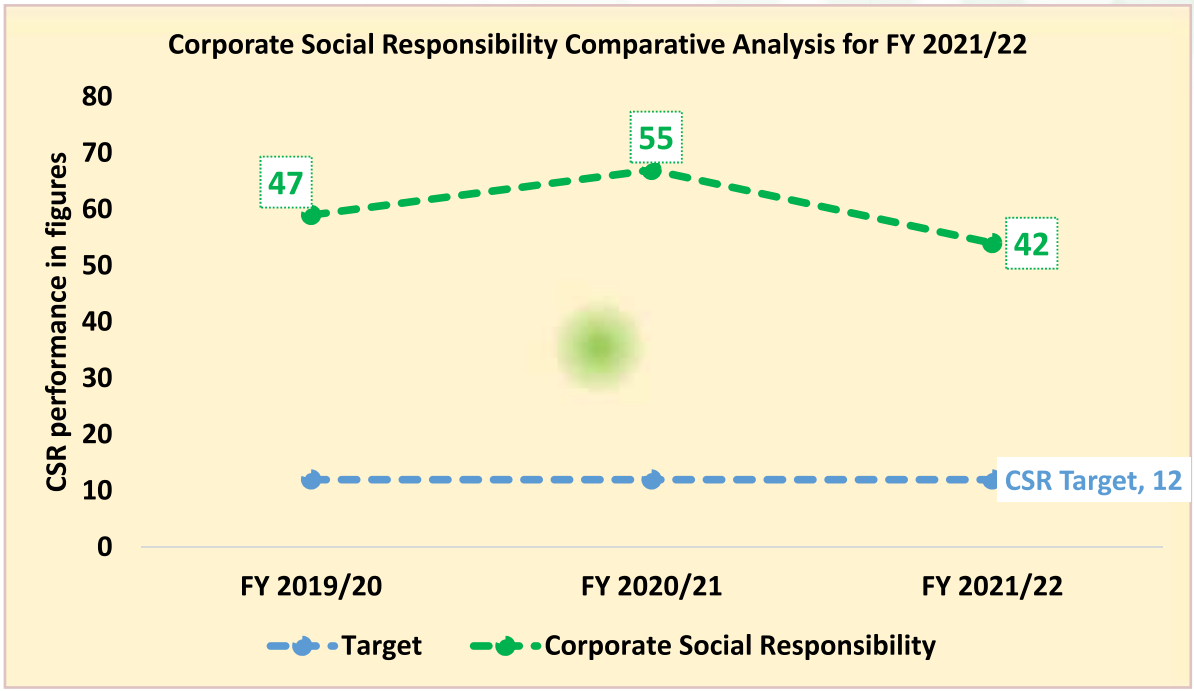
Activities Implemented during the contract period	FY 2020/21	FY 2021/22
Steering Committee meetings.	09	03
Survey on proportion of Substandard and Falsified (SF) medicines.	00	01
Expert Working Group Meetings (Finance, Clinical Trials, Pharmacovigilance, Medical Devices and IVDs).	09	00
EAC Regional Experts to develop a roadmap towards implementation of EAC Technical Cooperation Framework Agreement.	01	00
Meetings held for medicinal products, Africa Medicine Regulators, African Medicines Agency, policy makers, regulators, Industry and other stakeholders.	00	04
Training sessions on access to medicinal products.	02	00

Stakeholder Meetings

The office of Secretary to the Authority attended a total of twenty-five (25) stakeholder meetings against a set target of twelve (12) meetings. The increase in stakeholder meetings increased as compared to twenty (20) meetings for FY 2020/21 because of the need to resolve so many issues at hand.

Corporate Social Responsibility

NDA recognizes the importance of corporate social responsibility and contributed to society's wider goal of sustainable development and transformation alongside its normal business operations. A total of 42 Corporate Social Responsibility projects were financed as compared to 55 against the set target of 12 CSR projects as presented in the chart below.



The performance above the set target is attributed to the engagements and support offered to several communities for the FY 2021/22 which has increased levels of NDA visibility, interactions, potential impressions/reach, and influence.

Trend performance on KPIs

1. Proportion of the stakeholders aware of NDA role.
2. Proportion of Satisfied customer.
3. Proportion stakeholders of the that perceives NDA as playing her role.

The KPI's were all captured in the Client Satisfaction Survey that is ongoing and the final report is expected in January 2023.

Focus Area 4: Institutional Development:

As a regulator, NDA should at all times ensure that it has adequate resources for effective regulation of drugs. It should have in place institutional structures, systems, staffing capacity, governance and management practices that can enhance her planning, coordination and regulatory capacities.

Strategic Objective 4:

To improve NDA institutional capacity to effectively and efficiently implement its functions.

Six key strategies, presented below are proposed to realize the strategic objective;

4.1 Enhance the NDA infrastructure and facilities for her capacity growth. Construction of an ultra-modern Quality Control Laboratory

The actual overall progress on site was 98% in comparison to a planned progress of 100% based on the program with completion of 30th June 2022. There was a delay of 2% experienced in general finishing of the building and final installations of the project. The 2% delay accounts for the following outstanding key areas of the project; Completion of the curtain walling that has been delayed by PoVc delays for the BMU, delayed installation of cleaning cradle/BMU, Part 3 items for mechanical and electrical aspects for enhancing building efficiency like CAT 6A accessories and UPS, Connection of UMEME power was pending metering unit, Performance testing and commissioning of systems and equipment such as generator, lifts, and Building signage.

The list of defects and incomplete work was generated for the last site inspection that was done on 17th October 2022and noted that all the pending defects of the project are to be rectified by 5th November 2022 by the Contractor M/S Seyani Brothers & Co. (U) Ltd and Parbat.

4.2 Strengthen and ensure a sustainable management information system through automation and integration across the organization and other relevant MDAs.

In a bid to improve service delivery, NDA has implemented the National Drug Authority Management Information System (NDAMIS) and the following has been achieved;

No.	Module	Description
1.	Premises Module	The module has been designed to support the entire process of Pharmacy licensing and renewals.
2.	Product Module	That module has been redesigned to support the drug registration and entire drug register
3.	Imports/Exports Module	The module has been modified to ensure that batch numbers and quantities can now be captured and reports being improved progressively.
4	Inspection Module	This module has developed to support inspection of Premises & Imports at the various ports of entry.
5.	GMP Module	The development of Module has been completed and Data cleaning on going (In NDAMIS). This will support all the Good Manufacturing Practices (GMP) inspections and related activities.
6.	Finance Module	The module has been fully developed to manage all payments and invoicing. In addition, integration with the bank & Mobile Money platforms has been achieved.
7.	Clinical trials Module	The module to support the process of clinical trials is still under development.

NDA has committed to working towards achieving 100% automation through improving the existing systems and automation of other business processes.

4.3 Strengthen Corporate Governance practices and Human Resource capacity.

Internal Audit Engagements

Prepared audit engagement plans, programs and notifications for the fourteen (14) audits that were conducted during the year and these include, Financial audit, GMP process audit for Local, GMP process audit for abroad, Legal services department audit, Directorate of Laboratory

services, Procurement department audit, Payroll audit, Public Relations Unit audit, Central region audit, Kampala Extra regional audit, Eastern regional audit, Western regional audit, Spot-check on the business licensing process and general office operations of Eastern region against a set target of fifteen (15) audits. One audit on the construction of Laboratory Tower was not done because the procurement of the Technical person to do the Audit was not done.

Restructuring and staff establishment

The Seventh Authority approved an appropriate organizational structure for NDA and concluded recruitment of new staff. This improved staffing from 282 to 304 employees as of today. The Authority has ensured the recruitment of a balanced professional workforce in the technical regulatory areas by increasing the number of Veterinary Doctors from 6 to 17, recruitment of two (2) biomedical technologists, one (1) Dental Surgeon, twenty-one (21) Chemists, one hundred eleven (111) Pharmacists and one hundred fifty-two (152) other professionals in support functions.

Staff Training and Development

The Authority has invested in training of staff at all levels so as to ensure institutional knowledge enhancement and support succession planning. The institutional budget for staff training and development has increased from One billion six hundred thirty-two million (Ugx. 1.632 billion) to Two billion one hundred seventy-eight million (Ugx. 2.178 billion) representing a percentage improvement of 33% in the FY 2021/22. The Authority has also provided training for its members in key strategic areas of corporate governance, financial and risk management so as to better equip them to better perform their over-sight functions and this has improved the performance of the drug Authority in meeting the set strategic plan commitments for FY 2021/22.

4.4 Enhance the Institutional resource mobilization capacity and sustainability

Resource Mobilization Function

NDA has recruited a Resource Mobilization Coordinator under the office of the Secretary to the Authority to undertake the activities in the Strategic Plan related to resource mobilization and to come up with deliberate initiatives in respect of covering the funding gap of Ugx. 59.785 billion. Our development partners include the following; H.E Ambassador of Denmark to Uganda (Founding Donor for NDA), World Health Organization (WHO) - Country Representative-Uganda, The Head of Global Fund (GF) Geneva, The National Facilitator Global Fund-MOH, Project Coordinator (PC) Global Fund-MOFPED, HE. Ambassador of America to Uganda, HE. The British High Commissioner to Uganda, The Mission Director – USAID, The Director - CDC (Centre for Disease Control), The Director – DFID, H.E Ambassador of Ireland to Uganda, H.E Ambassador of Cuba to Uganda, The Director of KOICA, HE. Ambassador of Germany to Uganda, Country

Director GIZ, HE. Ambassador of Belgium to Uganda, The Country Rep – BMGF, The Country Rep – CHAI, the Country Rep-World bank, The GAVI National Director, The Country Rep- UNICEF, The Country Rep-UNAIDS, The Country Rep-FAO, and the UN Resident Coordinator.

4.5 Strengthen the corporate planning and performance management systems

NDA Planning Function

NDA Planning Unit spear headed the developed a new NDA Strategic Plan and Implementation Action Plan for 2020/21 – 2024/25. The NDA Strategic Plan 2020-2025 has been developed as a drugs and healthcare products regulatory contribution to Vision 2040 with respect to health - of improving life expectancy and reducing infant mortality; NDP III's priority on health - of improving population health. At a regional level, the SP contributes to achieving harmonization with Chapter 21, Article 118 (c) –(f) of the EAC; and to SDG 3 - "Ensure healthy lives and promote well-being for all at all ages." at the global level. The interventions in the plan have also been designed in alignment to the NDP III new programmatic planning and budgeting framework to optimize NDA's contribution to the relevant programs of the national development plan.

Monitoring and Evaluation Function.

NDA set to out to strengthen the M&E function by recruiting a Principal M&E officer and a respective structure of M&E coordinators both at the Head office and in the regions. An M&E plan was developed to guide the institution in developing roles, processes and guideline for conducting the M&E function. In addition, the M&E Plan helps to track the performance of the Strategic Plan on all outcome and Key output indicators and a contract was awarded to the Consultant for installation of an M&E Web –based online system to enhance reporting and feedback on real time.

Risk Management Function

This National Drug Authority (NDA) Strategic Plan has adopted the risk management approach that is consistent with the Government of Uganda Risk Management Strategy 2018 whose main objective is to facilitate the integration of risk management into national development planning, strategy formulation, annual planning and in all systems and processes.

NDA strategic plan 2020-2025 acknowledges the need for risk informed development as a process and not an event. This is because there is a continuous interaction across local, regional and global risks including; Regulatory, Human Capital, Legal, External, Reputation, Technology, financial, strategic among others. The plan has therefore identified, analyzed various potential risks and prescribed possible mitigation, continuous monitoring and management measures during the plan period.

NDA has employed sound enterprise risk management principles, transparent decision-making, and effective communication to prioritize risk. NDA manages nine interrelated categories of risk to effectively regulate and ensure a safe and sound regulatory system that supports drug operators, communities, businesses, and the Ugandan economy.

3.2 Strengthen the Quality Management Systems across the organization

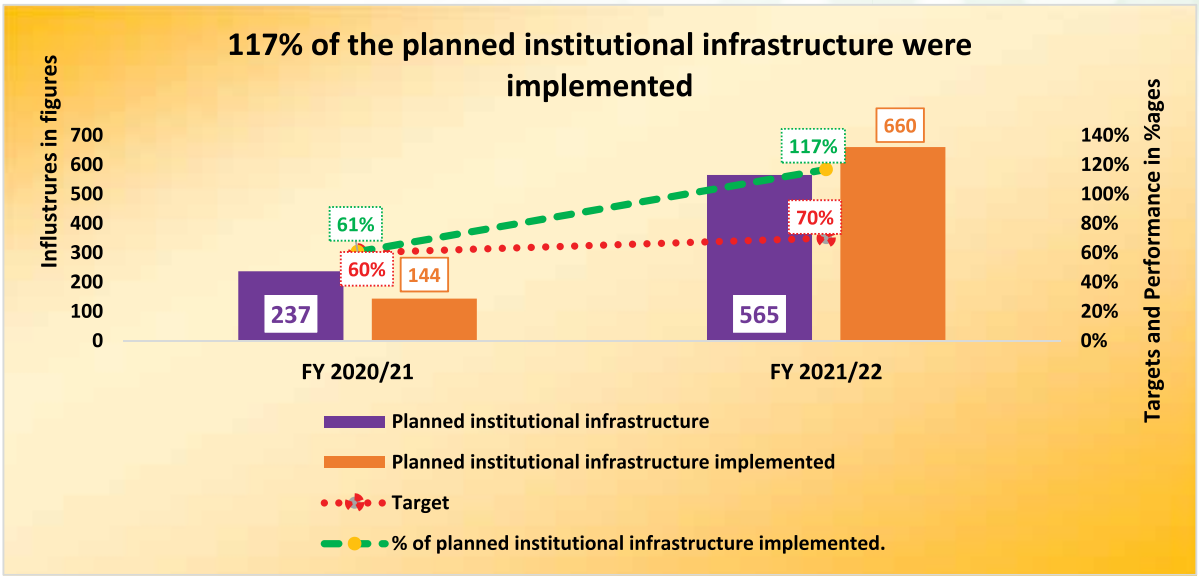
Quality Management System Function

This unit has supported National Drug Authority in Strengthen the Quality Management Systems across the organization. The has ensured that all processes have quality objectives set and standard operating procures in place. The unit has prepared the Authority to ensure that the internal standards are met. NDA was audited by SGS United Kingdom Ltd in 2022, found compliant and was certified to ISO 9001:2015 International Standard for Quality Management System.

Trend performance on KPIs

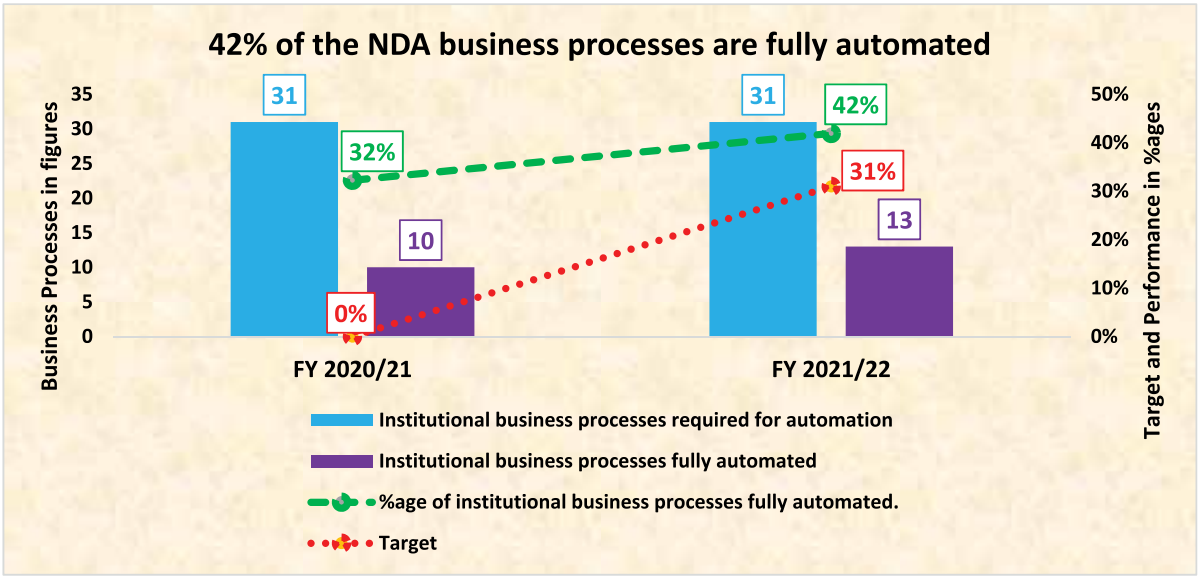
1 %age of planned institutional infrastructure implemented

NDA planned to put in place infrastructures including office furniture, Construction of buildings, Computer items including laptops, projectors, modems, and other equipment's and laboratory equipment's that will enable its staff to perform the strategic plan commitments and meet the set strategic plan objectives for the second year of implementation. A total of 565 institutional infrastructures were planned to be procured of which 660 (117%) were put in place for FY 2021/22 as compared to 144 (61%) out of the planned 237 institutional infrastructures for FY 2020/21. The Authority procured more than requested for in the FY 2021/22 because of the backlog that was carried forward due to the Covid-19 pandemic that disrupted delivery of some equipment's for FY 2020/21. The chart below illustrates the comparative analysis for items procured against those planned for.



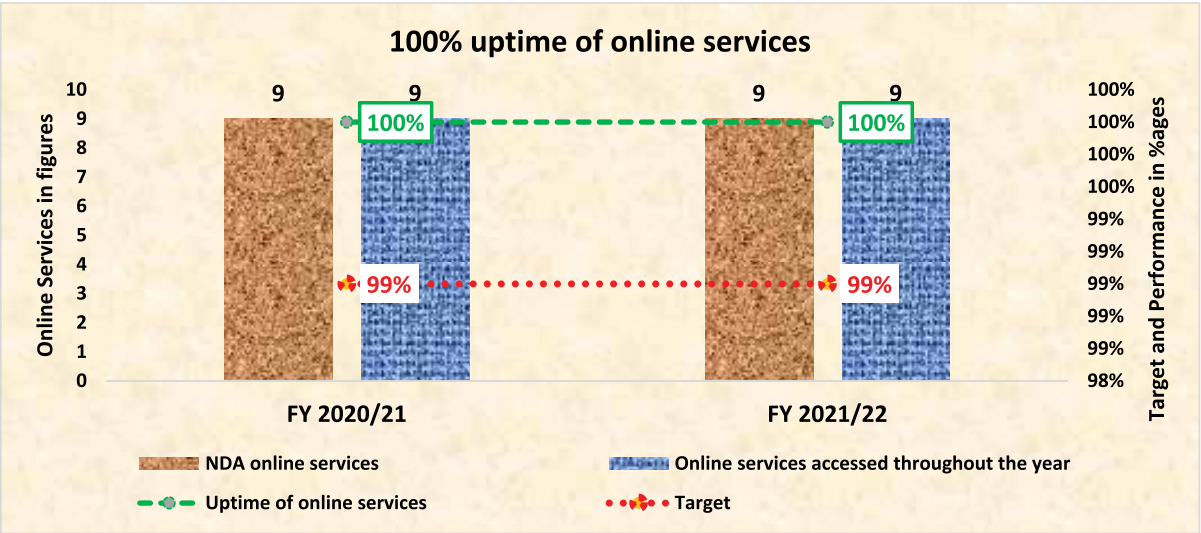
2 Proportion of institutional business processes fully automated.

NDA is planning to automate all the 31 business processes as a way to have improved timely service delivery and enhanced organizational efficiency. In the FY 2021/22, NDA automated more three (3) business processes totaling to 13 (42%) fully automated out of the planned 31 business processes and this is above the set target of 31% for the second year of implementation of the strategic plan. There is an improvement in automation as compared to the FY 2020/21 were only 32% (10 fully automated against 31 planned business processes).



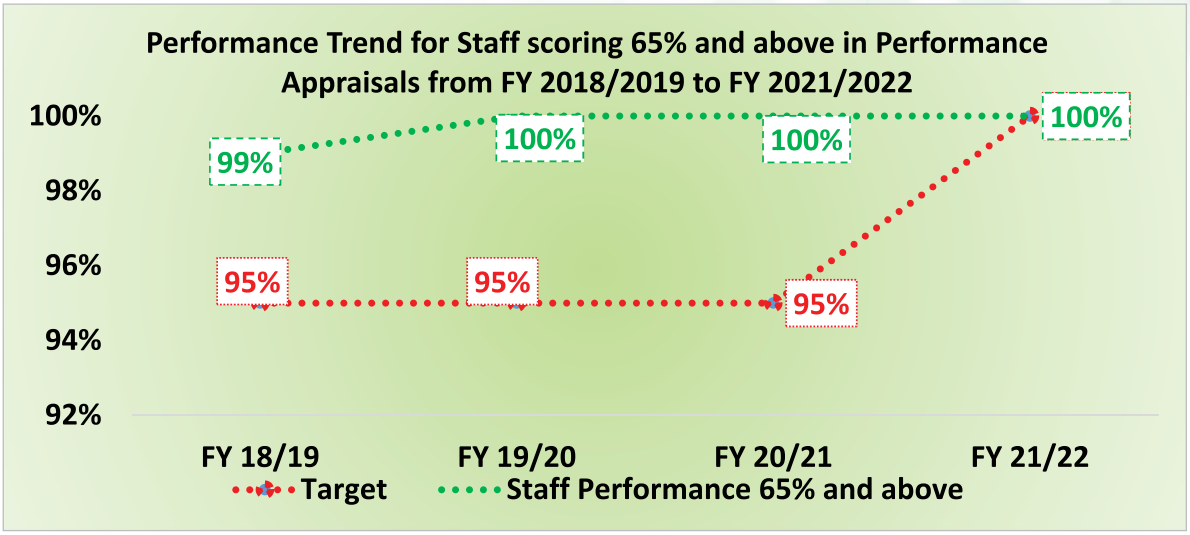
3 Percentage of online services accessed throughout the year (Uptime of online services)

NDA transformed from hard copy review of applications to online services and these services are available and can be accessed for all the working days. A total of nine (9) services including Email services, Drug Promotion (DPROM), the seven (7) NDAMIS modules including Product, Premises, Finance, GMP, IPMS, Import and Export and reporting module. The uptime of the nine (9) services was 100% for the FY 2021/22 and this enhanced digital transformation for regulatory effectiveness. **The graph below illustrates the comparative analysis for the two financial 2021/222 and 2020/21.**



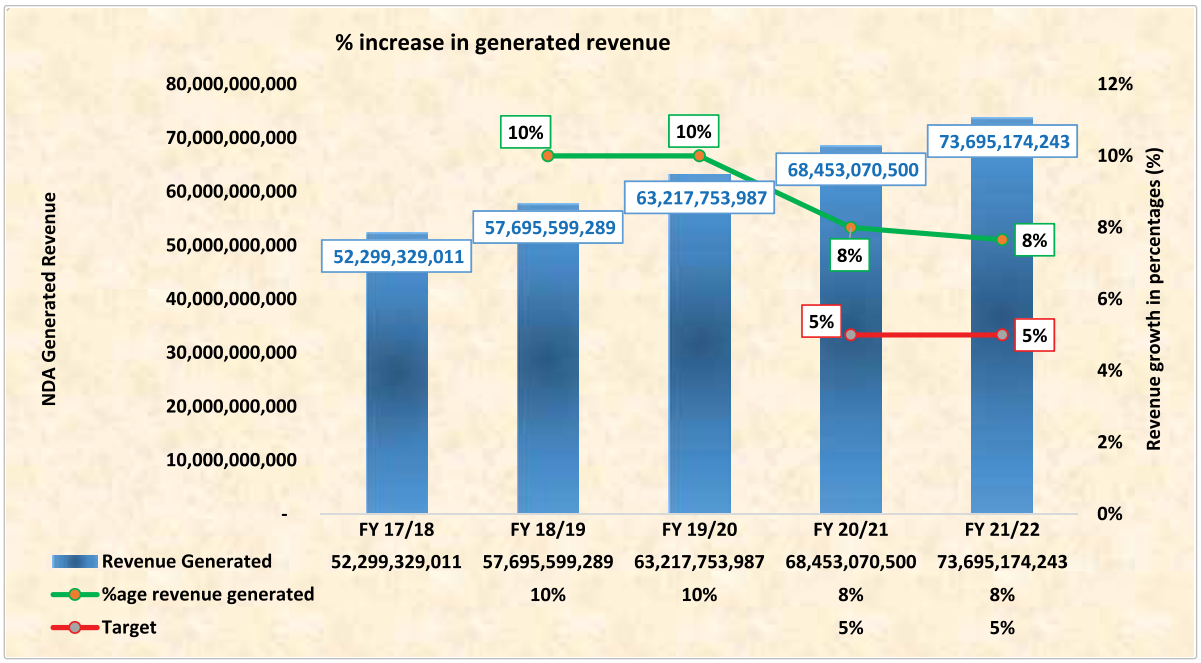
4 Proportion of staff who attain 65% of approved performance targets.

NDA has Increased human resource productivity to deliver the NDA's regulatory mandate as evidenced by the performance of 100% (137 out of 137). All NDA appraised staff have attained 65% and above in their performance targets against the set target of 100%. This performance is attributed to the involvement of Directors, Heads and Unit Managers who supported the teams to ensure that the set targets in the financial year are attained. This therefore, increased human resource productivity to deliver the NDA's regulatory mandate. The performance trend for staff scoring 65% and above in performance appraisals is illustrated in the chart below.



5 % increase generated revenue.

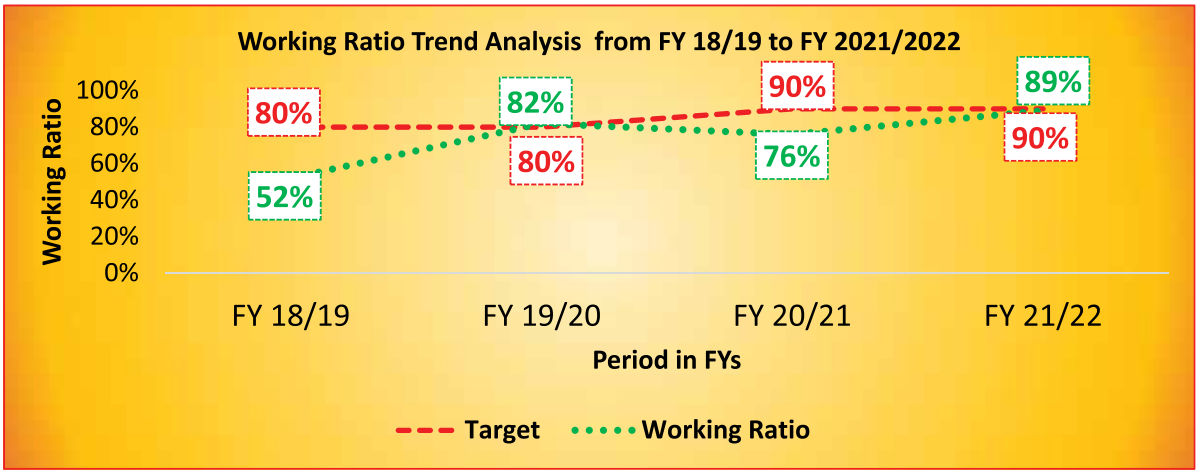
NDA generated a total of Ugx. 73,695,174,243 (105%) out of the projected amount of Ugx. 70,297,342,365. There is an increase in the revenue generated by 8% for FY 2021/2022 as compared to Ugx. 68,453,070,500/= performance for FY 2020/2021 and the increase in revenue generation is attributed to the increased importation that increase the Verification fees during the financial year. The chart below shows the Comparative analysis trend of percentage increase of generated revenue from FY 2018/2019 to FY 2021/2022.



From the chart above, NDA has marked a tremendous increase in the total revenue generated from 10%, 10%, 8% and 8% increase for FY 2017/2018, FY 2018/2019, FY 2020/2021 and FY 2021/2022 respectively. Though there seems to be a drop-in percentage increase in revenue from 10% to 8% for two years due to Covid-19 that affected revenue most especially verification fees (main revenue stream) as most importers could not import because of the economic downturn however, all these are above the set target of 5% for the FY 2020/2021 and FY 2021/2022 thus showing an improved financial sustainability of NDA.

6 Working Ratio

NDA implemented most of the activities for the FY 2021/2022 resulting into an overall FY operational expenditure of Ugx. 65,954,794,173 as compared Ugx. Ugx. 51,959,373,126 for the previous FY 2020/2021. NDA's financial stewardship and sustainability stands at 89% (65,954,794,173 out of a total revenue of Ugx. 73,695,174,243) as compared to 76% (51,959,373,126 expenditures out of a total revenue of 68,453,307,050) for FY 2020/2021. This working ratio means that the Authority spent 89% of the generated annual revenue on planned FY operational activities against a set annual target of 90% and this clearly proves that the Authority has a strong financial stewardship and sustainability. The working ratio trend for four years is illustrated in the chart below.



Lessons Learnt and Actions

No.	Lessons Learnt	Actions to improve Performance
1.	NDA should focus on effectively implementation of the intended results while prioritizing the achievement of the overall goal.	We commit to improve the performance of key contributors to achievement of the goal not withstanding the improvement of legal and regulatory requirements.
2.	Improve on effective engagement of Key stakeholders for effectiveness and efficient service delivery.	We commit to be intentional on the targeted stakeholder engagement results to improve efficiency and effectiveness of service delivery through mechanisms like digitalization, participatory and utilizing the feedback mechanisms for service delivery improvement.
3.	Automation of regulatory services across the country to easy service delivery and accessibility by the clients.	Conducting a technology needs assessment to identify areas that would smoothen service delivery and enhance value creation.
4.	Increase partnership and collaboration in execution of NDA's mandate.	Identify and agree with potential partners, both within the public sector and private industry, who align with NDA's mandate.
5.	Delayed transformation of NDA legal mandate has significantly affected the attainment of the goal which would reflect improved efficiency and effectiveness in drug regulatory services.	Engage government and other key stakeholders to fast track the legal transition of NDA to serve the Ugandan population better.

Challenges and Way Forward

No.	Challenges	Way Forward
1.	Uganda is not yet at Maturity Level 3 because of the Law and it can't ably regulate vaccine manufacturing.	Fast tracking of the legal transition of National Drug Authority to eliminate the limitation of attaining maturity level 3 or 4 for better service delivery.
2.	Poor quality of Dossiers submitted by the clients.	Fast track the enactment of NDA mandate into the new proposed legal mandate to improve service delivery to the Country.
3.	Pilferage of Government drugs.	Collaboration and partnership with MDA's for effective and efficient service delivery especially at local government level.
4.	The National Drug Policy and Authority Act (Cap 206) does not prescribe prohibitive sentences for offenders found to be contravening the Act. This has hampered the prosecution of a number of court cases, which has generally hindered regulatory compliance.	If the enactment of the NFDA bill delays, we propose that Parliament amends the current NDA law to provide stringent punishment for Offenders.
5.	The current legal/regulatory framework under the NDP&A act is inadequate for the regulation of safety, efficacy and quality of cosmetics, medical/ veterinary devices and public health chemicals. NDA is unable to fully make interventions due to inadequate legal framework.	Fast track the approval of the NFDA Bill currently in cabinet to provide for regulation of other products and address the gaps in the current law.
6.	There is shortage of funds to adequately equip the new laboratory tower.	Lobby for additional funding (Uganda Shillings 21 billion) to equip the new laboratory tower.

The Future of NDA

- Transformation of NDA's legal framework and expanding the Mandate of NDA to cover as scope of the pharmaceutical product regulations for improved services like; Medical devices, cosmetics, house hold chemicals among others.
- Continuous international recognition
- Harmonization initiatives
- Expanded service coverage with customer outreach
- Un rivaled local pharmaceutical industrial support
- Super specialized quality control
- Building a community awareness culture on the regulated products and their functionality.
- Automation of the Business processes (a) Clinical trials, b) QMS, c) Product compliant handling, d) Recall handlings, e) Lab (LIMS document control), f) Drug shop licensing, g) Planning and M&E, h) Risk management system, i) Pharmacovigilance, j) Geo-mapping for licensed outlets, k) Procurement system, l) HR, m) Registry, n) Track and trace of pharmaceutical products, o) Enforcement activities, p) Internal audit system, q) Communication channel system, r) Post market surveillance system, s) Procurement plan performance management system, t) LIMS modules, QMS, u) integration of chromatographic systems, and v) Operational Research management system.
- NDA is in the process of integrating its management information systems with other health related MDAs.
- NDA is at concept stage of using Barcodes in tracking and tracing of pharmaceutical products on the Ugandan market.

Our Commitment to our stakeholders

FINANCIAL PERFORMANCE OF NDA

STATEMENT OF COMPREHENSIVE INCOME
FOR THE YEAR ENDED 30TH JUNE, 2022

	Note	2021/2022 ACTUAL Ushs.	2020/2021 ACTUAL Ushs.
Income:			
Internally Generated Funds	15	70,755,647,173	70,540,242,776
Rent from Properties - Net		237,466,851	187,401,702
Sub-total		**70,993,114,024**	**70,727,644,478**
GoU and Donor Funds:			
Funds from WHO[1]		123,748,557	87,802,988
University of Oxford		69,975,040	-
EDTCP Project[2]		-	131,358,774
Deferred Income recognised	7	230,090,406	230,090,407
Sub-total		**423,814,003**	**449,252,169**
Others			
Gains (loss) on Exchange rate	21	3,006,918,511	(2,682,408,006)
Gain on assets disposal			12,050,000
Bank interest	27	281,776,853	176,858,816
Total Income		**74,705,623,391**	**68,683,397,457**
Less:			
EXPENDITURE:			
Administration	16	24,339,085,820	18,479,683,841
Employment	17	41,489,161,736	36,361,494,794
Establishment	18	4,109,404,474	3,490,849,461
Financial charges	19	91,965,849	98,399,122
Sub - total		**70,029,617,879**	**58,430,427,218**
Surplus for the year		**4,676,005,512**	**10,252,970,239**
Loss on assets disposals			(3,298,767)
Surplus for the year carried forward		**4,676,005,512**	**10,249,671,472**

[1] *World Health Organisation*
[2] *European and Developing Countries Clinical Trials Partnership*

NATIONAL DRUG AUTHORITY
STATEMENT OF FINANCIAL POSITION
AS AT 30TH JUNE, 2022

ASSETS:	Note	2021/2022 Ushs.	2020/2021 Ushs.
Non - Current Assets	8	23,342,788,609	21,309,560,948
Capital Work in Progress	23	31,940,778,059	12,911,471,221
Leasehold Investment Property	9	2,700,000,004	2,812,500,003
Total Non-Current assets		**57,983,566,672**	**37,033,532,172**
CURRENT ASSETS:			
Inventory	22	2,905,209,321	2,772,230,543
Accounts receivable	6	47,647,319,618	42,607,112,126
Cash in Hand & Bank	10	45,059,114,709	65,579,942,083
Total Current Assets		**95,611,643,648**	**110,959,284,752**
Total Assets		**153,595,210,320**	**147,992,816,924**
Equity and Liabilities:			
Accumulated Fund			
Capital Fund	7	193,869,911	423,960,318
Revaluation Reserve		22,465,748,188	22,465,748,188
Accumulated Surplus	11	116,674,417,365	**112,413,376,532**
Total Accumulated Fund		**139,334,035,464**	**135,303,085,038**
Liabilities:			
Staff Gratuity Fund	12	31,266,203	3,594,042
Payables and Accruals	14	14,229,908,653	12,686,137,844
Total Liabilities		**14,261,174,856**	**12,689,731,886**
Total Equity and Liabilities		**153,595,210,320**	**147,992,816,924**

The Financial Statements on page 1 to 33 were approved by the Authority on ..... 2022 and signed on its behalf by:

.....
Chairperson

.....
Secretary to the Authority

NATIONAL DRUG AUTHORITY

STATEMENT OF CHANGES IN EQUITY

FOR FINANCIAL YEAR ENDED 30TH JUNE 2022

	Capital Grant Ush.	Revaluation Reserve Ush.	Accumulated Surplus Ush.	Total Ush.
Balance b/f 01/07/2017	**798,549,279**	**13,060,590,938**	**75,965,313,675**	**89,824,453,892**
Capital Grants and Donations				
Deferred Income	**(328,024,570)**			**(328,024,570)**
Prior Year Adjustment				
Revaluation During the Year				
Surplus for the Year			**15,407,182,957**	15,407,182,957
Balance 30 June 2018	**470,524,709**	**13,060,590,938**	**91,372,496,632**	**104,903,612,279**
Balance b/f 01/07/2018	**470,524,254**	**13,060,590,938**	**91,372,496,632**	**104,903,612,279**
Capital Grants and Donations				
Deferred Income	**(328,024,570)**			**(328,024,570)**
Prior Year Adjustment			858,985,160	
Revaluation During the Year		**9,405,157,250**		
Surplus for the Year			**(821,539,920)**	(821,539,920)
Balance 30 June 2019	**142,499,684**	**22,465,748,188**	**91,409,941,872**	**114,018,189,744**
Balance b/f 01/07/2019	**142,498,329**	**22,465,748,188**	**91,409,941,872**	**114,018,188,389**
Capital Grants and Donations	154,463,400			154,463,400
Deferred Income	**(232,253,746)**			**(232,253,746)**
Prior Year Adjustment	589,342,742		(151,204)	**589,191,538**
Revaluation During the Year				
Surplus for the Year			**10,409,319,276**	10,409,319,276
Balance 30 June 2020	**654,050,725**	**22,465,748,188**	**101,819,109,944**	**124,938,908,857**
Balance b/f 01/07/2020	**654,050,725**	**22,465,748,188**	**101,819,109,944**	**124,938,908,857**
Capital Grants and Donations				-
Deferred Income	**(230,090,407)**			**(230,090,407)**
Prior Year Adjustment			53,448	**53,448**
Error Correction Land &Bldg Note 34			344,541,668	**344,541,668**
Revaluation During the Year				
Surplus for the Year			10,249,671,472	**10,249,671,472**
Balance 30 June 2021	**423,960,318**	**22,465,748,188**	**112,413,376,532**	**135,303,085,038**
Balance b/f 01/07/2021	**423,960,318**	**22,465,748,188**	**112,413,376,532**	**135,303,085,038**
Differred- Donations			(55,344,321)	(55,344,321)
Deferred Income-capital grants	**(230,090,407)**			**(230,090,407)**
Prior Year Adjustment			(359,620,358)	**(359,620,358)**
Surplus for the Year			4,676,005,512	**4,676,005,512**
Balance 30 June 2022	**193,869,911**	**22,465,748,188**	**116,674,417,365**	**139,334,035,464**

NATIONAL DRUG AUTHORITY

STATEMENT OF CASHFLOWS

FOR THE YEAR ENDED 30TH JUNE, 2022

	2021/22	2020/21
Cashflow from Operating Activities		
Surplus for the year	4,676,005,512	10,249,671,472
Adjustments:		
Depreciation of other assets other than Investment Property	3,900,293,888	3,344,902,977
Depreciation on Investment Property	112,499,999	112,499,999
Deferred Income	(230,090,407)	(230,090,407)
Loss on disposal of fixed assets	-	3,298,767
Prior Year Adjustment Note 26	(359,620,357)	53,448
Adjusted Cashflow from Operating Activities	**8,099,088,635**	**13,480,336,256**
Working Capital Movements		
(Increase) / Decrease in Accounts Receivable	(5,040,207,492)	(7,214,146,986)
Increase / (Decrease) in Accounts Payable and Accruals	1,543,770,809	1,102,117,497
Increase / (Decrease) in Staff Gratuity Fund	(27,672,161)	-
Net Cash from Operating Activities	**4,574,979,791**	**7,368,306,767**
Investing Activities		
Purchase of Fixed Assets	(5,933,521,549)	(3,094,843,027)
Increase/Decrease in Work In Progress	(19,029,306,838)	(5,478,323,768)
Increase/(Decrease) in Inventory	(132,978,778)	(478,446,254)
Net Cash Flow from Investing Activities	**(25,095,807,165)**	**(9,051,613,049)**
Net Movement in Cash and Cash Equivalents	**(20,520,827,374)**	**(1,683,306,282)**
Cash and Cash Equivalents at the beginning of the year	65,579,942,083	67,263,248,365
Cash and Cash Equivalents at the end of the year	**45,059,114,709**	**65,579,942,083**

NOTES TO THE CASHFLOW STATEMENT

CASH AND CASH EQUIVALENTS

Cash and Cash Equivalents consist of cash and bank balances as follows:

Cash and Bank Balances	45,059,114,709	65,579,942,083
Total	**45,059,114,709**	**65,579,942,083**

National Drug Authority

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