UGANDA

NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

ANNUAL REPORT

FY2022-2023

KEY PERFORMANCE ACHIEVEMENTS FOR FY 2022/23

THE NDA PERFORMANCE ACHIEVEMENTS AT EFFECTIVENESS, EFFICIENCY, AND PROCESS LEVEL

NATIONAL-LEVEL PERFORMANCE RESULTS BASED ON NDP III COMMITMENTS


NATIONAL DRUG AUTHORITY

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1.0 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
IRIMS	Integrated Regulatory Information Management System
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
RCORE	Regional Centres of Regulatory Excellence
SDT	Service Delivery Timelines
SO	Strategic Objective
SSFFC	Substandard/Spurious/Falsely labelled/Falsified/Counterfeit
SDGs	Sustainable Development Goals
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, 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

STATEMENT FROM THE BOARD CHAIRMAN

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 (100% 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.

One key initiative that we are actively working towards is the legal transition of NDA by expanding the regulated products scope to include human medicines, cosmetics, household chemicals, invitro diagnostics and public health products, which will further strengthen our regulatory framework and enable us to better serve the public.

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 improved, 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 for example getting rid of the counterfeit drugs from the public gender sensitive recruitment. 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

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 overcome, and prospects.

I am writing to you today as the Secretary to the Authority of the National Drug Authority (NDA) to provide an update on our ongoing efforts to ensure the availability of safe, efficacious, and quality drugs and healthcare products for all.

Our organization is steadfast in its commitment to achieving global best practices in drug regulation by 2025. To this end, we have set ambitious goals and strategic objectives aimed at improving various aspects of our regulatory framework and operations.

I am pleased to report that our recent performance results demonstrate significant progress towards our goals. Despite facing challenges such as low response rates in certain areas of stakeholder engagement, we have achieved a performance effectiveness of 95% across impact and outcome indicators representing 11 out of 15 impact and outcome indicators.

However, we recognize that there is still work to be done to address these challenges and further improve our performance. We are taking proactive measures to revise the customer survey methodologies and strengthen stakeholder engagement strategies to ensure that we continue to meet the needs and expectations of the public.

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.

As Secretary to the Authority, I am fully committed to leading our organization toward achieving our strategic objectives and upholding the highest standards of governance, accountability, and service delivery. We are dedicated to serving the best interests of the public and ensuring that NDA remains a trusted regulatory authority globally.

I want to take this opportunity to express my sincere gratitude to you, the members of the public, for your continued support and trust in the National Drug Authority. Together, we will continue to work tirelessly to safeguard public health and contribute to the well-being of the entire population.

Thank you for your attention, and please do not hesitate to reach out to us with any questions, concerns, or feedback.

Dr. David Nahamya
The Secretary to the Authority

Management Members of the Uganda National Drug Authority

National Drug Authority has a total of eight (8) Directors heading different directorates and these comprise the Management of the Authority;

DR. MWESIGWA DENIS
DIRECTOR OF INSPECTORATE AND ENFORCEMENT, DIE

> **"The directorate provided information and guidance to healthcare professionals, manufacturers, and the public on safe medicine practices and regulatory requirements through targeted meetings, Television and radio talk shows"**

The Directorate of Inspectorate is the enforcement arm of the Authority charged with ensuring compliance with the National Drug Policy and Authority Act and thereby ensuring the availability, at all times, of essential, efficacious, and cost-effective drugs to the entire population of Uganda, as a means of providing satisfactory health care and safeguarding the appropriate use of drugs. The regulatory performance included the licensing of manufacturers, distributors, and suppliers of drugs, control of imports and exports, post-marketing surveillance, disposal of pharmaceutical waste, promotion of compliance through stakeholder engagements and enforcement as follows:

Licensing and Approval:
Inspection and licensing of manufacturers, wholesalers, and distributors to ensure they meet regulatory standards. This included licensing of domestic manufacturers, pharmacies, and drug shops and inspection of foreign manufacturers for compliance with Good Manufacturing Practices (GMP). A total of 24 (109.1%) of the 22 targeted domestic manufacturers were licensed with 155 (64.6%) of the targeted 240 foreign manufacturers inspected for GMP compliance and all the 102 targeted pre-market batches sampled for analysis. All the 2568 targeted pharmacies, 214 targeted medical device outlets and 16751 drug shops were inspected and licensed.

Compliance monitoring:

Monitoring and enforcing compliance with laws and regulations governing the manufacturing, distribution, and sale of drugs. This included ensuring that distributors complied with Good Distribution Practices (GDP), compliance monitoring of licensed outlets, and support supervision to domestic herbal manufacturers and public & private not-for-profit health units. The directorate benefitted from the implementation of the three-year licensing cycle culminating in 783 (108.8%) of the 720 planned GDP inspections, 4049 (106.7%) of the 3795 pharmacy compliance monitoring visits, and 22,638 (102.8%) of the targeted 22,014 drug shop compliance visits. It also conducted 401 (133.7%) of the 300 public & private not-for-profit inspections and 31 (62%) of the 50 domestic herbal manufacturers.

Import and export control:

Through import verification and inspection of consignments at the ports of entry. Up to 14066 (93.4%) of the 15060 applications for import/export verification were completed with 9177 (88.0%) of the 10425 consignments received at the port of entry cleared within two working days.

Post-marketing surveillance:

Overseeing the entire supply chain of drugs, from production to distribution, to ensure that only approved and properly labelled products reach consumers including detecting and preventing the distribution of counterfeit, substandard, or adulterated medicines that could pose risks to public health. A total of 2316 batches were sampled for quality monitoring against a target of 2700 samples and all the 36 (100%) targeted surveillance operations were conducted. The difficulty in getting all the targeted samples is due to the challenges in predicting the actual number of batches that will be imported for sampling at the ports of entry. Additionally, the directorate supervised the disposal of 3,395,384.21 kg of pharmaceutical waste signifying an 18% increase from the 2,867,427kg of pharmaceutical waste disposed of in the 2021/22 period.

Stakeholder engagements:

Providing information and guidance to healthcare professionals, manufacturers, and the public on safe medicine practices and regulatory requirements through targeted meetings and radio/TV talk shows. Radio/television talk shows accounted for 108 (120% of the targeted 90) while engagement meetings contributed 221 (176.8%) of the targeted 125 meetings.

Enforcement and Sanctions:

Taking corrective action against entities that violate regulations. A total of 19 (237.5%) enforcement operations were conducted against a target of 8 planned operations.

These objectives were vital to ensuring that the medicines available in the market are safe, effective, and of high quality, thereby protecting public health.

Moving forward, the directorate is looking to implement risk-based approaches to ensure the availability of safe, efficacious, and quality drugs to the entire population of Uganda as a means of providing satisfactory health care and safeguarding the appropriate use of drugs.

DR. HELEN BYOMIRE NDAGIJE
DIRECTOR PRODUCT SAFETY, DPS

> "We are grateful for the support of our stakeholders and the community as we continue to advance the frontiers of drug safety in Uganda and beyond"

The Directorate of Product Safety (DPS) at the National Drug Authority (NDA) is proud to share the remarkable achievements made in the fiscal year 2022-23, reflecting our unwavering commitment to safeguarding public health through rigorous drug regulation and pharmacovigilance.

Pharmacovigilance System Enhancements: We have significantly bolstered our national pharmacovigilance system, recording an impressive 5,067 Adverse Drug Reactions (ADRs), more than double the anticipated figure of 2,200. This milestone underscores our enhanced vigilance and proactive approach to drug safety and informed decision-making.

Herbal Drug Regulation: In collaboration with the Uganda Communication Commission (UCC), we have fortified the regulation of herbal drugs, culminating in the standardization of advertisement guidelines. Our diligent evaluation of drug promotional materials yielded a high approval rate, with 204 out of 237 applications successfully processed.

Public Awareness Initiatives: Our concerted efforts to raise public awareness of drug and substance abuse have been impactful, thanks to extensive media campaigns, educational programs in schools, and partnerships with faith-based organizations.

Research and Development: The establishment of a dedicated scientific research study unit has been a game-changer, enabling us to conduct five pivotal research studies that inform our evidence-based regulatory decisions.

Clinical Trial Oversight: The efficiency of our clinical trial inspections and evaluations has been exemplary, with 93.7% of applications assessed and 85.9% evaluated within the prescribed timelines. These efforts ensure that clinical trials meet the highest standards of safety and efficacy.

As we reflect on these accomplishments, we remain steadfast in our mission to enhance drug regulation and pharmacovigilance, elevate public health and safety, and foster a culture of informed awareness and research excellence.

DR. AMOREEN NALUYIMA
DIRECTOR OF LABORATORY SERVICES, DLS

> "Our performance is not merely reflected in statistical outcomes; it embodies our resolute dedication to upholding the highest standards in pharmaceutical quality control. We are committed to ensuring that every product reaching the Ugandan consumers is safe, effective, and good quality"

As the Directorate of Laboratory Services, we led a rigorous and comprehensive evaluation of pharmaceutical products, with the primary objective of ensuring consumer safety and product quality. This fiscal year, we successfully integrated the Laboratory Information Management System (LIMS), a strategic advancement designed to enhance laboratory efficiency and data management. Our team conducted quality control testing on 1,915 out of 2,418 samples received, achieving a 79% testing rate. Throughout this process, we maintained our ISO 17025:2017 accreditation and upheld our World Health Organization prequalification, reinforcing our commitment to the highest International standards.

Our efforts have led to measurable improvements in product quality, evidenced by an increase from 91.2% to 93.0% in the overall quality of pharmaceutical products for FY 2022/23. This advancement is directly attributed to enhanced surveillance systems and prompt interventions against substandard and falsified products. Notably, we expanded our testing capabilities and product range, culminating in the commissioning of the Pharmaceutical Microbiology Laboratory.

This expansion included critical items such as hand sanitizers, imported herbal products, face masks, syringes, and needles, reflecting our commitment to addressing emerging public health needs.

Significantly, we enforced stringent regulatory actions on all products identified as substandard or falsified. Items failing to meet required standards, particularly within the herbal product category, were promptly recalled and removed from the market, safeguarding public health.

Our post-market surveillance (PMS) initiatives demonstrated substantial progress during the fiscal year. We analyzed 758 samples, resulting in an increase in PMS pharmaceutical product quality from 82% to 86.7%. Despite challenges associated with human, veterinary, herbal, and public health product samples, our vigilance and dedication to excellence remained unwavering.

In FY 2022/23, our persistent efforts led to a notable decrease in pharmaceutical quality failure rates across various product categories. Our adherence to stringent testing protocols and decisive regulatory actions underscored our unwavering commitment to public health and safety.

DR.JULIET AWORI OKECHO
DIRECTOR OF PRODUCT ASSESSMENT AND REGISTRATION, DPAR

> **"The Directorate has collaborated with WHO, the EAC Medicines Harmonization program, IGAD, and NEPAD-AUDA in the registration of vital medicines and providing technical guidance to the pharmaceutical industry to ensure the availability of quality products on the market."**

The product assessment and registration landscape has witnessed significant strides. Currently, the cumulative pharmaceutical human and veterinary drugs retained on the drug register make up 5,574 products of which 182 are locally manufactured conventional medicines. There has been an increase in locally manufactured herbal human products from 250 in FY 2021/22 to 300 in FY 22-23. This achievement demonstrates the directorate's commitment to fostering a robust regulatory environment through strategic initiatives such as extensive sensitization campaigns, comprehensive training sessions, and herbalist manufacturing learning visits. This has led to a significant growth of local expertise and investment of resources in herbal medicine production.

Furthermore, DPAR has been very instrumental in providing technical assistance to domestic manufacturers by training them to improve the quality of their dossier submissions for marketing authorization. DPAR has also developed tools to support the development and registration of domestically manufactured medical devices.

The Directorate has collaborated with WHO, the EAC Medicines Harmonization program, IGAD, and NEPAD-AUD in the registration of vital medicines and providing technical guidance to the pharmaceutical industry to ensure the availability of quality products on the market.

These milestones highlight the directorate's dedication to ensuring the availability of quality, safe, and effective drugs and healthcare products.

DR. JEANNE BUKEKA MUHINDO
DIRECTOR OF VETERINARY SERVICES, DVS

"Veterinary drug regulation has taken tremendous strides over time thanks to the visionary leadership of the Authority, Management, able staff, and our valued stakeholders. In 2022-2023, outstanding results in enhancing the safety and efficacy of veterinary medicines were registered."

Our team registered great achievements in stakeholder engagement, conducting 177 sub-county-level sensitization meetings in 22 districts, reaching a total of 3,216 stakeholders and 523 animal health workers. The activity objectives were; to increase awareness on the need for drug regulation highlighting the different roles of the stakeholders.

Together with the stakeholders, regulatory gaps and other confounding factors that are likely to affect the safety, efficacy, and quality of drugs were identified and solutions were recommended. We are grateful for the technical support of the Ministry of Agriculture Animal Industry and Fisheries through the zonal inspectors, the District local governments through the offices of the Chief Administrative Officers (CAOs), chairperson fives, Resident District Commissioners (RDCs), the District Veterinary Officers (DVOs), extension and sub-county administrators that made this activity successful. These outreaches also involved the conduct of radio and TV talk shows targeting the farmers and the entire public on appropriate and rational drug use. As a result, improved awareness, and understanding of veterinary drug regulation and increased reporting of Adverse Drug Events (ADEs) by the stakeholders have been noted, fostering collaboration in monitoring compliance and addressing emerging drug-related animal and human health challenges at the community level.

In the area of compliance monitoring and support supervision, the team ensured support to 83 districts reaching a total of 621 veterinary drug outlets. These visits focused on appropriate drug handling, storage, and management of veterinary drugs. This also included monitoring the public as well as the private cold chain for veterinary vaccines, to address concerns of field efficacy of vaccines. A total of 191 private and 45

public cold chain facilities were supported. As a result of this, the Government through the Ministry of Agriculture Animal Industry and Fisheries committed to strengthening the public cold chain at the district level by procuring pharmaceutical refrigerators for all districts, a great step in ensuring effective animal disease control. Some district administrations have also committed to supporting the veterinary vaccine cold chain by procuring pharmaceutical refrigerators. However, the challenge of maintaining the cost of electricity to have the fridges run the full board and the lack of power backups remains big. There is observed improvement in the management and handling of the veterinary drug outlets including compliance with having the Uganda Veterinary Board licensed practitioners taking charge and sitting in the drug outlets to attend to the farmer's needs.

On a global scene, we continue to participate in the World Organization for Animal Health programs as guided, by the East African Community, Food and Agriculture Organization, and World Health Organization, Codex, and other partners. These collaborations have enhanced our ability to perform our mandate and live our vision as a world-class drug regulatory agency.

Management has been committed to strengthening pre and post-marketing surveillance. There is consistent implementation of risk-based sampling that has enabled conduct of more thorough and frequent tests on high-risk categories of veterinary drugs and ensure the market is wiped out of substandard and falsified veterinary products. The Authority and Management have committed to conduct intelligence and enforcement on suspected cases of counterfeiting and falsifying of veterinary drugs where the focus has been on the cattle corridor including the Eastern region where drugs were being sold in shifts and open markets where arrests were made, suspects produced in court, judgments and sentencing obtained in favor of NDA for all the cases.

The Conduct of clinical/ Field trials function has been strengthened where all the received applications were evaluated and feedback given to the principal on time. All field trail inspections were also done on time. We continue to support the awareness of the sponsors and the principal investigators on compliance with the regulatory requirements to ensure that the drugs tested are safe and exhibit efficacy.

We count on everyone to sustain and improve these achievements for effective regulation of veterinary medicines and make the NDA the regulator that it should be. We remain committed to protecting animal and public health, promoting sustainable development, and addressing emerging health challenges through our ongoing efforts in veterinary medicine regulation.

MR. KAYITA ROGERS

DIRECTOR OF CORPORATE SERVICES, DCS

> **"The Directorate of Corporate Services has exhibited outstanding leadership and strategic foresight in spearheading pivotal initiatives aimed at bolstering organizational efficiency, service delivery, and regulatory adherence."**

In the realm of infrastructure development, the Directorate provided a principal oversight over the construction of a state-of-the-art NDA Laboratory Tower, ensured not only its timely completion but also strict adherence to rigorous quality standards. This leadership extended to overseeing consultancy services, encompassing meticulous design reviews and project management, thus highlighting a steadfast commitment to excellence in infrastructure enhancement.

Under Information Technology function

Under ICT, a significant investment has been undertaken to procure and roll out an Integrated Regulatory Information Management System(IRIMS). This transformative endeavor is aimed at fully automating the core regulatory processes of Inspection, licensing, product assessment & registration, clinical trials and support functions for finance management. Upon completion, IRIMS shall yield numerous tangible benefits, enhancing operational effectiveness and strengthening regulatory compliance, as well as giving more visibility and, accountability of core regulatory processes to our stakeholders.

Business Planning and Development

Have been characterized by meticulous orchestration. They played a central role in developing organizational work plans aligned with strategic objectives, while also overseeing the revision of fees to ensure long-term financial sustainability. This dedication to sound fiscal management practices has been evidenced by the prudent utilization of financial resources and the attainment of operational efficiency targets.

In the realm of risk management and governance, the Directorate has been instrumental in implementing an Enterprise-wide Risk Management framework, emphasizing proactive risk identification and mitigation across all core business activities. This approach has fostered robust governance structures and transparent reporting mechanisms, thereby nurturing accountability and bolstering stakeholder confidence.

Additionally, establishing a comprehensive monitoring and evaluation framework highlights the Director's commitment to transparency and continuous improvement. This has facilitated informed decision-making and enhanced stakeholder engagement by assessing performance against strategic objectives and disseminating performance reports and dashboards.

Finance and Accounts

The authority maintained a sound financial system that ensure a sound financial stewardship through revenue management system and prudent spending in a wake of limited resources.

Overall, the Director of Corporate Services has played a pivotal role in driving organizational excellence, fiscal leadership, and stakeholder value creation at NDA, leaving an indelible mark on the institution's trajectory.

MR. JOHN BOSCO TUHAIRWE
DIRECTOR OF HUMAN RESOURCES AND ADMINISTRATION, DHRA

> **"During the year, NDA retained staffing levels and witnessed performance improvement due to the various capacity building programs implemented at Masters and PHD levels, scientific regulatory visits and training."**

In terms of restructuring and staff establishment, the Eighth Authority observed a notable 2.3% increase in staffing, growing from 304 to 311 employees by June 30, 2023. This expansion wasn't merely numerical but strategically focused on augmenting the professional workforce in technical regulatory areas as well as addressing the expanded regional coverage of NDA. Additional recruitment efforts targeted roles such as veterinary doctors, biomedical technologists, chemists, pharmacists, and other professionals. This deliberate approach has fortified our capacity, resulting in enhanced service delivery and improved health outcomes.

Recognizing the importance of gender diversity, NDA has proactively addressed employment gender status. Presently, 37% of the workforce comprises females, with ongoing initiatives promoting women's education, skills training, and work-life balance. These endeavors not only uphold our organizational values but also bolster organizational effectiveness through a more inclusive work environment.

Investments in staff training and development have been substantial this financial year. We've significantly intensified efforts to enrich institutional knowledge and facilitate succession planning. The budget allocated for staff training and development has witnessed a noteworthy increase, underscoring our commitment to continuous improvement. By delivering targeted training in critical areas such as corporate governance and financial management, we've empowered team members to excel in their roles, aligning with our strategic objectives.

Our collective efforts have yielded remarkable enhancements in human resource productivity. Through effective leadership and unwavering support, we've achieved a commendable 100% performance rate across all appraisal categories. Staff members consistently surpass performance targets, reflecting their dedication and our commitment to fostering a culture of excellence. This heightened productivity enables us to fulfill NDA's regulatory mandate with efficiency and precision.

In summary, Directorate of Human Resource and Administration has been characterized by tangible achievements in restructuring, gender diversity, staff development, and productivity enhancement. We are steadfast in our commitment to driving further progress, ensuring our workforce thrives, adapts, and excels in serving NDA's mission.

MR. JOSEPH MUTASAAGA
HEAD BUSINESS PLANNING AND DEVELOPMENT, HBPD

> "There is observed improvement in planning, Risk Management, Monitoring and Evaluation, Statistics and Project Performance programs. The future is brighter in inculcating the culture of effectiveness, efficiency and quality of results"

The planning structure: This composed of the Drug Authority, the office of the Secretary to the Authority and seven Directorates that determine the development and implementation of the strategic plan coordinated by business planning and development function.

The current National Drug Authority (NDA) strategic plan is aligned with the National Development Plan (NDP III) 2020-2025 and National health priorities. The strategic planning structure that guides NDA operations is comprised of a clear goal, vision and mission statement, strategic objectives, and strategies to deliver value to our clients.

Annually the strategy is implemented through the work plan, budget. The performance monitoring and evaluation is conducted quarterly, annually, mid term and end of term basis to ensure the safety, quality and efficacy value propositions for the regulated products.

The performance outlook of the current strategic plan: The NDA strategic plan has already undergone the midterm performance evaluation that resulted in the overall weighted performance achievement rating of 73%. This was considered fairly satisfactory according to the NDA's established rating scale. This level of considered assessment progress towards the achievement of the NDA impact and strategic outcomes. At output-level, performance improved significantly, from 58% to 78% for the period from July 2020 to December 2022 as compared to the previous period July 2016 to December 2019 against a planned target of 90%.

This years' (FY 2022/2023) overall performance achievement at impact and outcome level (**effectiveness level**) was 95% against 93.2% for FY 2021/2022. The implementation achievement (**efficiency level**) of the planned activities was 98% against 91% for the respective financial years.

The factors behind this performance improvement was partly attributed to the automation of some of the regulatory process like imports, licensing, pharmacovigilance reporting, and financial processes among others. There were increased staffing levels, and improved organization planning and performance management systems through streamlined reporting and consistent measurement of results, customer outreaches, and stakeholder engagements.

New Planning Cycle: The new planning cycle that is focused on NDPIV will be underway for the period July 2025 to June 2030. The areas to lookout for in the new strategic plan may include adjustments to align the new strategic plan to ensure sustainability of NDA. We expected enactment of the National Drugs and Health products Bill into law.

Appreciation: Appreciation goes to The Drug Authority, the Secretary to the Authority and all members of staff with recognition of the planning team that have worked tirelessly to ensure that we put together these results and most importantly creating value for the clients that we serve.

2.0 ABOUT NDA

Safe Drugs Save Lives

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;

2.1. 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.

2.2. Function of NDA

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.

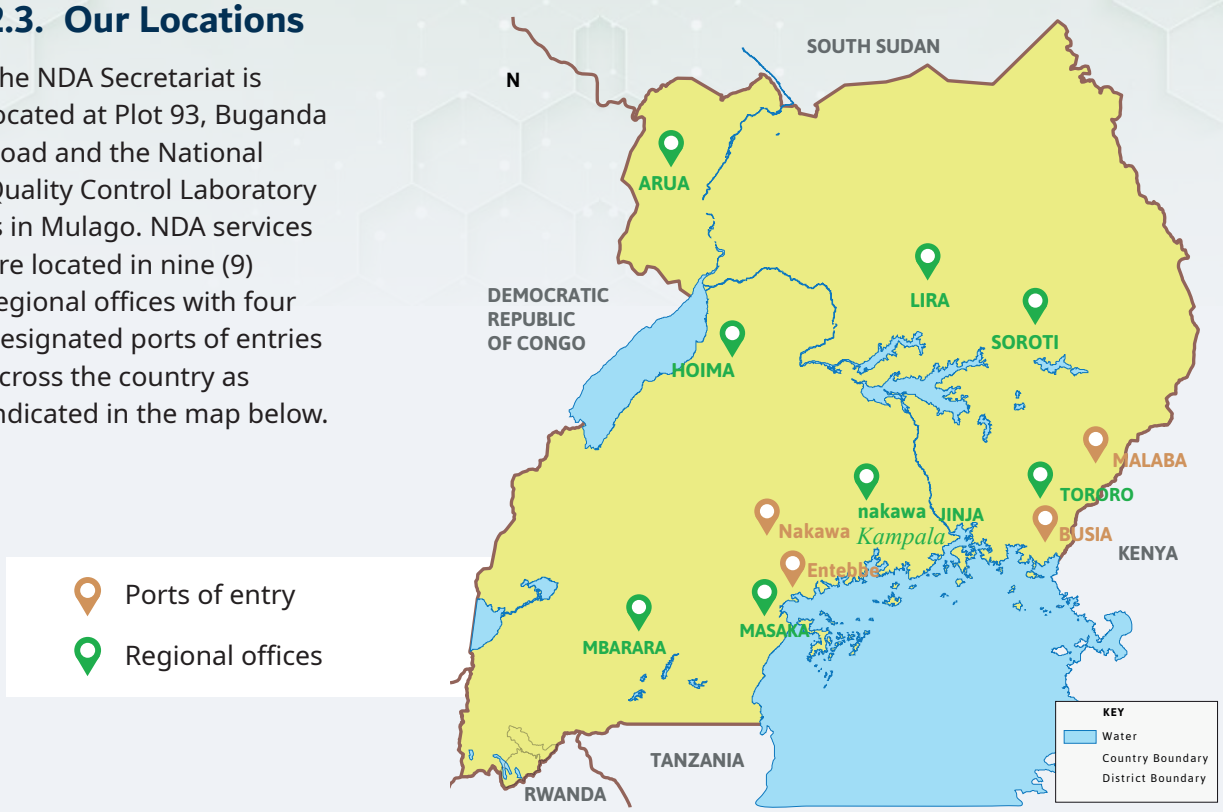
Core Values

- 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.

The above mandate and functions are delivered through the NDA five year strategic plan that is aligned to the Government of Uganda National Development Plan which is integrated with the Sustainable Development Goals and the African Agenda 2063.

2.3. Our Locations

The NDA Secretariat is located at Plot 93, Buganda Road and the National Quality Control Laboratory is in Mulago. NDA services are located in nine (9) regional offices with four designated ports of entries across the country as indicated in the map below.



2.4. Core Regulatory Activities

Core regulatory Activities

Product Safety

1. Clinical Trials Protocol Review
2. Good Clinical Practice Inspection
3. Pharmacovigilance
4. Control of Drug Promotion

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. Publication of the National formulary

Laboratory Testing

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

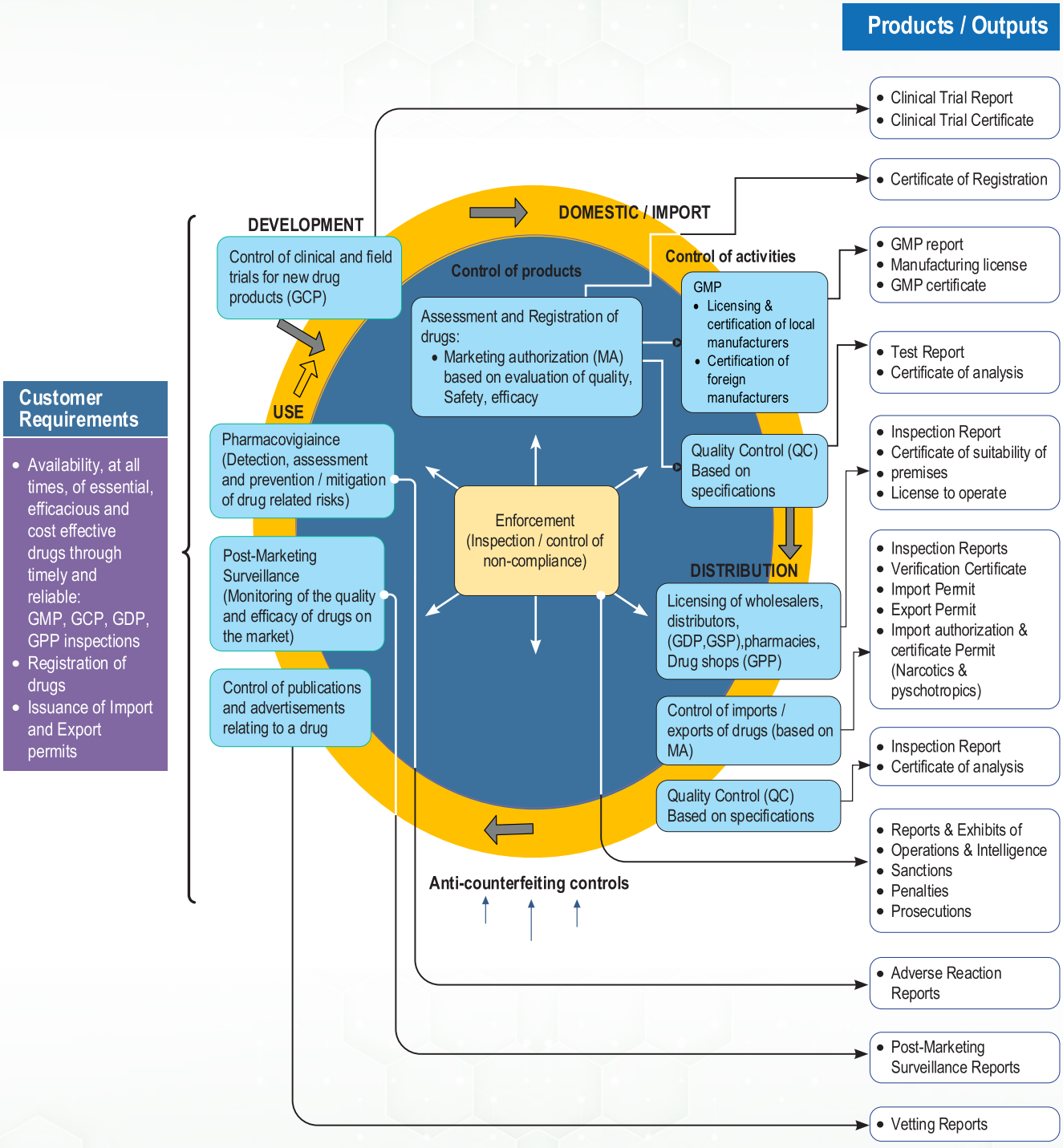
Market Surveillance

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.

3.0 DRUG REGULATORY SYSTEM PROCESS



4.0 EXECUTIVE SUMMARY

The National Drug Authority (NDA) developed a five-year strategic plan aligned to the National Development Plan III against which the performance matrix were designed. The performance results are presented at different levels which include impact, outcome and output at a higher level while the lower level results at activity and input are presented through the implementation efficiency.

Impact and output results attained was 95%, output results were 81% whereas the activity level implementation was 92% .

The annual report, therefore, presents the key performance highlights, major constraints, recommendations and conclusion.

5.0 FINAL KEY PERFORMANCE ACHIEVEMENTS FY 22-23

5.1. Performance Highlights for FY 2022/23.

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

National Regulatory System

Completed the Post Construction, project closure of the laboratory tower building and closed the Defects Liability Period by 30th June 2023.

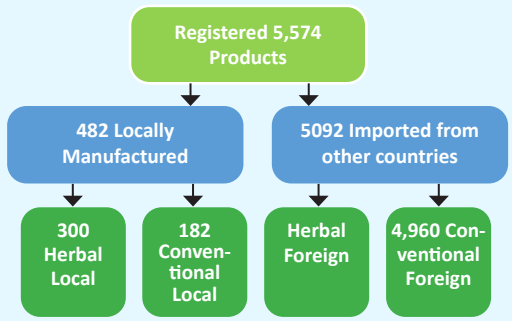
Implemented the NDA services to the clients within the agreed service delivery timelines by **84%** against the set target of **82%**.

NDA has maintained its ISO 9001:2015.

- NDA achieved **95%** at the outcome and impact level, **82%** at the output level, and implemented **92%** of the planned activities.
- NDA expanded its regional scope to Soroti by 1st October 2022.
- Conducted **57** Drug Authority meetings.
- Conducted **46** Management meetings.
- NDA supported **51** Corporate Social. Responsibility projects.
- Conducted **538** stakeholder engagements

Market Authorization

NDA registered **5,574** products on the drug register of which



A total of **2,750** evaluations conducted of which **1,237** were dossiers and **1,513** additional information.

A total of **1,812** variations were evaluated including **313** major, **393** minor, **465** notifications and **641** additional information evaluated.

Premise Licensing

Licensed a total of **14,704** Drug Outlets including;

- **917** Wholesale Pharmacy Licensed
- **1,524** Retail Pharmacy Licensed
- **11,961** Drug Shops Licensed
- **92** External Stores Licensed
- **210** Medical Device Stores Licensed

Licensed a total of **35** Local Manufacturers including;

One **(1)** Local Therapeutic Foods
Seven **(7)** Local Medical Device Manufacturers
One **(1)** Local Medical Gases
Four **(4)** Local Herbal Manufacturers
Sixteen **(16)** Local Pharmaceuticals
Six **(6)** Local Repackaging

Pharmacovigilance

5067 Individual Case Safety Reports (ICSR) were received of which **2,562** were Adverse Events Following Immunization (AEFIs) and **2505** were Adverse Drug Reactions (ADR).

2,562 AEFI reports were evaluated.

2,505 ADR reports were evaluated.

23 AEFI investigations carried out.

05 ADR investigations carried out.

Regulatory Inspection

- Conducted a total of **401** Good Pharmacy Practice (GPP) inspections.
- Conducted total of **26,687** support supervision compliance visits of which **20,768** were human drug shops, **3,922** human pharmacy, **1,870** veterinary drug shops, and **127** were veterinary pharmacy.
- Conducted a total of **179** Good Manufacturing Practice including **24** local and **155** foreign of which **121** were onsite and **34** were desk reviews done.

Clinical Trials

A total of **177** Clinical Trial Applications were evaluated and approved including;

- **25** new CTAs evaluated
- **89** Renewals evaluated
- **63** Amendments evaluated
- A total of **12** Good Clinical Practice (GCP) inspections were conducted.

Market Surveillance and Control

- A total of **1,344** Post Market Surveillance samples were picked for testing.
- **972** Mandatory samples were picked for testing.
- **102** pre-market samples were picked for testing.
- **25** product recalls were handled.
- **18** enforcement operations were conducted
- **845** illegal drug outlets including 96 Pharmacies and **749** drug shops were closed.
- **72** cases were submitted to Director of Public Prosecution (DPP) and sanctioned for prosecution.

Laboratory Testing

- **758** PMS samples were tested for quality control.
- **1,093** Mandatory samples were tested
- **64** pre-market samples were tested
- **490** human samples were tested
- **207** veterinary samples were tested
- **41** herbal samples were tested
- **1,177** medical devices samples were tested
- **94.6%** of Laboratory equipment's fully functional.

One (1) workshop conducted to train the local manufacturers on Analytical method development and Validation.

Veterinary Regulatory Oversight

- **12** veterinary trial sites inspected for two products including Vector acaricide and the NARO anti-tick vaccine trials.
- **22** farm visits conducted based on complaints followed up.
- **45** market surveillance audits conducted focusing on public facilities to withdraw obsolete vaccines.
- **112** compliance monitoring and support supervision visits in drug outlets.

6.0 DIRECTORATE PERFORMANCE ACHIEVEMENTS FOR FY 2022/23

6.1. Directorate of Product Safety (DPS)

The 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, and regulation of the promotion of medicines and healthcare products.

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

6.1.1. 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 Inspectors of drugs are important in following up on 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 Vigi flow 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.

6.1.2. 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 well-being 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, and stakeholder engagements. 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, and 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.

6.1.3. Medicines' Information Unit

Control of the 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 the provision of information to prevent drug and substance abuse and promote appropriate and safe use of medicines.

6.1.4. 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 coordinates operational research activities within the organization including collaborative and supported research activities with staff.

6.2. Directorate of Product Assessment and Registration (DPAR).

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 market-authorization applications so that all pharmaceutical products intended for use in Uganda meet their intended purpose and requirements. DPAR has a qualified team that handles a range of both human and veterinary locally made and imported drug products. The key activities include; 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), preparation, and regular updates of the National Drug Register.

6.3. Directorate of Inspectorate and Enforcement (DIE)

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 for safeguarding the drugs and healthcare products that Ugandans have access to.

6.3.1. Good Manufacturing Practices (GMP)

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 that medicines supplied in Uganda meet consistently high standards of quality, safety, and efficacy.

Foreign manufacturing sites are also required to pass an inspection before approval of the marketing authorization application. Following approval, a risk-based inspection program maintains ongoing 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.

6.3.2. Import Control

Products are allowed entry into Uganda only 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, Ports of entry Inspections, and sampling. After the ports of entry inspections, a decision of either goods authorization or rejection is issued.

6.3.3. Post Market Surveillance

In addition to getting safe effective and quality products on 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 involves problem identification, assessment, and public health response.

6.3.4. Regional offices for Inspections & licensing of premises

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

Inspectors conduct inspections of sites of wholesale premises to assess compliance with the 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.

6.3.5. 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 to mitigate the risk identified by non-compliance with the Act.

Upon completion of an investigation, 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.

6.4. Directorate of Corporate Services (DCS)

The Directorate of Corporate Services contributes towards the delivery and development of the entity-wide Institutional capacity, which is achieved through the provision of Institutional development and sustainability e.g infrastructure investment, performance management, planning, financial sustainability, automation of the business processes, business process optimisation. It comprises three (3) departments: the Finance Department, the Information and Communication Technology (ICT) Department, and the Business Planning and Development Department (BPD).

6.4.1. Finance Department

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

6.4.2. 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 and leading to the automation and integration of supporting processes to enhance institutional efficiency.

6.4.3. Business Planning and Development Department

The 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. BPD department takes the principle lead in institutional development, investments, statistics, project management, planning, Monitoring, and Evaluation as well as risk profiling and management.

6.5. Secretary to the Authority (SA)

The National Drug Authority is headed by the **Secretary to the Authority** and has various directorates to coordinate and meet the overall drug and health products regulatory objectives of the institution. These directorates currently include; the Directorate of Product Assessment and Registration, Laboratory Services, Product Safety, Inspectorate and Enforcement Services, and Corporate Services, Directorate of Veterinary Products, and Directorate of Human Resources and Administration.

The directorate has eight (8) Departments and Units including; the Secretary to the Authority's Office, Quality Management Department, Internal Audit Department, Legal Services Department, International Affairs Unit, Public Relations Unit, Procurement and Disposal Department, and Resource Mobilization Unit.

6.5.1. Quality Management Department

The Quality Management Department (QMS) coordinates and directs the 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.

6.5.2. Public Relations Unit

The Public Relations Unit is key in continuously building and maintaining the National Drug Authority's reputation and image through the formulation and undertaking of short- and long-term Public relations and Communication strategies.

6.5.3. Procurement and Disposal Department

The Procurement and Disposal Department's mandate is to ensure timely procurement and

disposal of quality goods, services and works following the PPDA Act, Regulations, relevant guidelines, and consolidated procurement and disposal plan.

6.5.4. Legal Services Department

The Legal Services Department plays a crucial role in reducing non-compliance with the NDP&A Act, the regulations thereunder, and other laws of Uganda, prosecuting or defending all cases successfully, and increasing our engagements with the judiciary to have them better understand the mandate of NDA and its importance in public health.

6.5.5. Internal Audit Department

The Internal Audit department is significant in assuring that NDA's governance and internal control processes are operating effectively through Audit assurances, and Advisory services.

6.5.6. Resource Mobilization Unit

The Resource Mobilization Unit is a key player in enhancing the NDA's Institutional resource mobilization capacity and sustainability by strengthening the mechanisms for resource mobilization and sustainability to ensure that the funding gaps are bridged and all the priority strategic interventions in the NDA strategic plan are implemented.

6.5.7. International Affairs Unit

The International Affairs Unit is essential in participating actively in EAC and other harmonization initiatives and Harnessing the synergies available through national, regional, and international partnerships and collaborations.

6.6. Directorate of Veterinary Services (DVS)

National Drug Authority controls the manufacture, importation, distribution, and use of both human and veterinary drugs in the country. The three main concerns of veterinary drug regulation are quality, safety, and efficacy (effectiveness).

Veterinary drugs include acaricides which are the most important of animal drugs in terms of volumes and capital investment. Acaricides in Uganda are registered by NDA following well-laid procedures that conform to international standards and following recommendations from the Ministry of Agriculture, Animal Industry and Fisheries (MAAIF), based on pre-registration field trials on efficacy. These trials have always been coordinated by the Ministry of Agriculture and carried out by the National Livestock Resources Research Institute (NaLIRRI). This ensures that the NDA registers acaricides that are tested and confirmed effective in the Ugandan environment. In addition, to the field trials, NDA constantly monitors compliance to quality standards by random sampling and testing of acaricides on the market using standard testing procedures at the NDA's National Drug Quality Control laboratory.

National Drug Authority also has a system of collecting information and giving feedback on the performance of veterinary drugs on the market and in use.

6.7. Directorate of Human Resource and Administration (DHRA)

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

6.8. Directorate of Laboratory Services (DLS)

The National Drug Quality Control Laboratory is a World Health Organization (WHO) prequalified Laboratory with international ISO 17025 accreditation.

The laboratory is mandated to analyze different categories of medicines, medical devices, and Public health products. The samples are obtained from pre-market, post-shipment, and Post Market Surveillance.

While doing its work, it conducts the following activities;

- Conducting quality assessment
- Field testing
- Generating scientific evidence
- Providing technical support
- Conducting investigations

The Directorate has three units including; the Medicines Unit, Medical Devices Unit, and Quality Management Unit.

6.8.1. 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, and Polarimetry. The laboratory is in the final stages of equipping a state-of-the-art microbiology Laboratory process to build capacity for performing Microbiological Analysis.

6.8.2. Medical Devices Unit

This is accredited to the ISO/IEC 17025:2005; the scope of accreditation includes; 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, and RDT kits.

6.8.3. Laboratory Quality Management Unit

The Unit coordinates and directs the implementation of NDQCL quality management systems aimed at improving effectiveness and efficiency to meet customer and regulatory requirements continuously and ensure compliance with ISO 9001.

7.0 ENVIRONMENTAL, SOCIAL AND GOVERNANCE (ESG)

This section presents NDA's commitment to sustainability, and creating value to our clients and stakeholders alike.

7.1. Governance Framework of NDA

7.1.1. 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 as per Section 3 of the Act. The Eighth (8th) Authority was appointed on 22nd February 2023 for the three-year contract that will expire on 21st February 2026.

The Drug Authority and its committee provide oversight on behalf of the honorable Minister of Health as illustrated below.

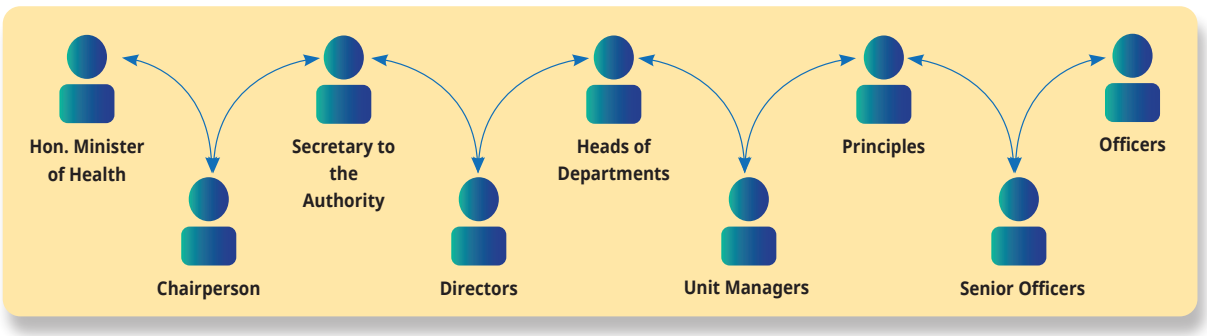


Table 1: Members of the Authority that were appointed for three years from 22nd February 2023

No.	Name	Title and Constituency
1	Dr. Medard Bitekyerezo	Chairperson National Drug Authority
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

No.	Name	Title and Constituency
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. Rosemary Byanyima	Executive Director, Mulago National Referral Hospital
13	Dr. Morris Seru	Commissioner Health Services, pharmaceuticals and Natural medicine, Ministry of Health.
14	Dr. Grace Nambatya Kyeyune	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
17	Dr. Ekwaro Obuku Anthony	Representative of the Uganda Medical Association
18	Dr. Nelson Musoba	Director, Uganda AIDS Commission
19	Dr. Jonans Tusiimire	Representative of the Pharmaceutical Society of Uganda
20	Dr. Henry Mwebesa G.	Director General Health Services

Note:

It is important to note that all the Authority members were retained apart from the two replaced, as highlighted in the table below.

Table 2: Members who served on the Drug Authority were replaced during the current period

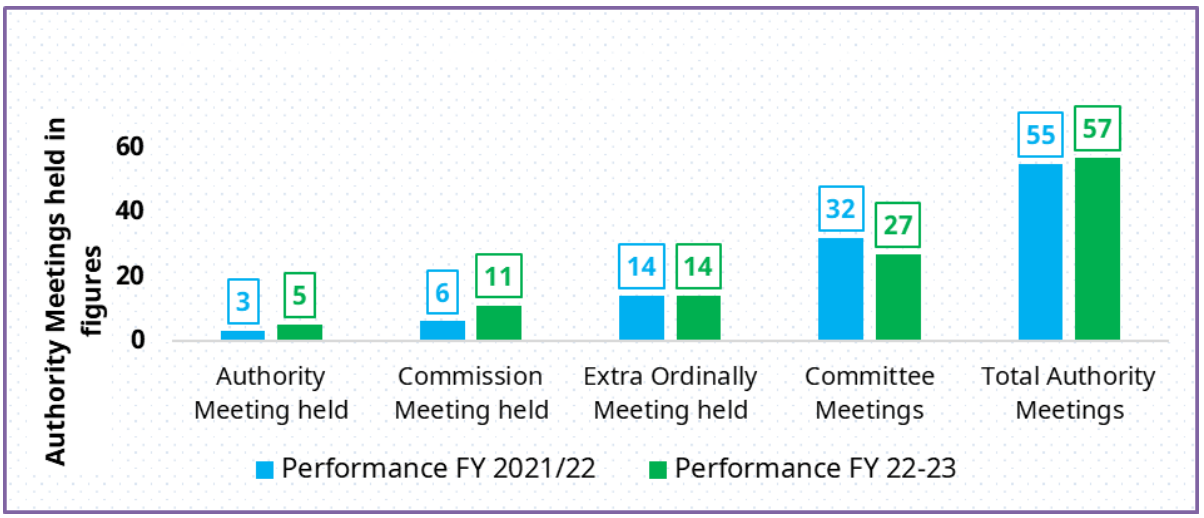
No.	Name	Title and Constituency:
1	Dr. Ekwaro Obuku Anthony replaced Dr. Daniel Obua	Representative of the Uganda Medical Association
2	Dr. Jonans Tusiime replaced Mr. Hussein Oria	Representative of the Pharmaceutical Society of Uganda

Table 3: The following Members were appointed to the NDA Commission

No.	Name	Title and Constituency
1	Dr. Medard Bitekyerezo	Chairperson National Drug Authority
2	Mr. Kamabare Moses	General Manager, National Medical Stores
3	Ms. Catherine Adok	Appointed from the public
4	Dr. Hanifah Naamala Sengendo	Represents the Public

7.1.2. The Drug Authority Meetings

The Drug Authority exercised its mandate with a total number of 57 meetings conducted against 43 planned, as compared to 55 meetings held against the 44 planned for FY 21-22 as presented in the chart below.



The chart above shows a performance improvement of 4% which is attributed to several issues that needed to be discussed by the Drug Authority. The Drug Authority meetings are fundamental in maintaining a robust regulatory system that protects public health while fostering innovation in the Pharmaceutical industry thus resulting in an overall improvement in the effectiveness of the strategic plan by 2% and a 1% increment in the implementation and achievement of the NDP III PIAP's for the reporting period.

7.2. Environmental Safeguard

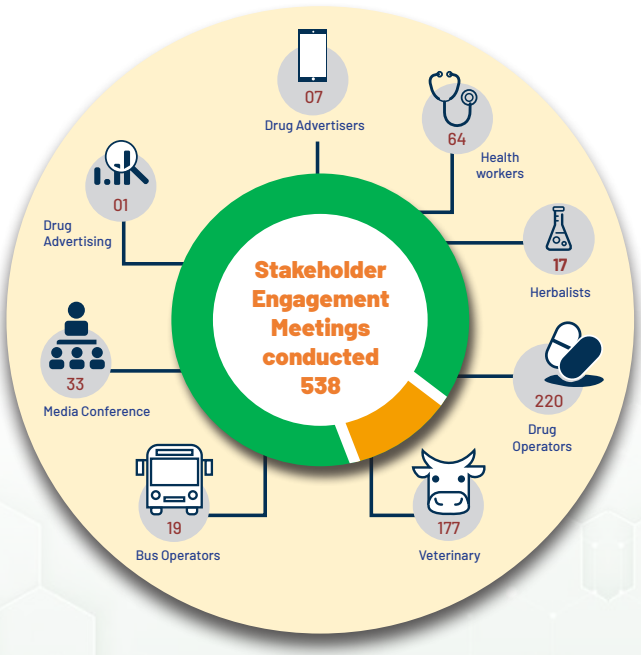
As we implement our activities, we took care of the environment by monitoring expired or obsolete pharmaceutical products and laboratory waste on the market ensuring that drugs are safely disposed off in an environmentally friendly manner using accredited service providers for handling, transportation that include Green Label Services, P.B Holdings Ltd, Soval International Ltd, Array Services Ltd, ERB Holdings Ltd, Desan Services Ltd, and Bin Services which minimized the risks to the public health and also minimized the environmental pollution. This is done because expired pharmaceuticals and other substandard pharmaceutical products present a serious threat to public health and the environment. Their elimination from the public and subsequent disposal is embedded in the NDA 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 & landfill, and dilution then flushing into a protected soak pit or lagoon.
- However, for specialized items such as hazardous industrial chemicals or laboratory waste, solvents or radioactive waste, etc., advice is sought from relevant authorities for this category of waste.

7.3. Social

In regards to human society, the interaction of the individual and the group, or the welfare of human beings as members of society NDA has partnerships, collaborations, and supported health, individuals, and Educating individuals as listed below;



1. NDA HAS PARTNERED WITH AND SUPPORTED TWELVE (12) HEALTH-RELATED ACTIVITIES INCLUDING;

a) Donated 135 clinical mattresses to HCIVs in Busoga kingdom.

b) Funded Uganda Surgeon Associations to conduct surgical camps in the northern regions of Acholi and Lango.

c) Partnered with Kabarole Hospital and Tororo region to hold a surgical camp for children aged 0-12 years.

d) Partnered with Josiah Medical Centre to provide general treatment to the people in Nakaseke district, where NDA supplied them with all medicines.

e) Partnered with PACE Centers Uganda to conduct awareness campaigns about drug shops and substance abuse in western Uganda.

f) Partnered with the Omugo office to offer medical services to the mothers in Bunyoro kingdom.

g) The strategic partnership between NDA and Kabaka Foundation proved to be a game-changer in the crisis of blood scarcity across the country. The prompt mobilization of blood donors resulted in a significant boost to the blood supply, saving countless lives and facilitated the Kabaka's birthday run.

h) NDA provided funds to support the blood bank's quarterly mobilization of blood donors.

i) Partnered with the Uganda Manufacturers Association (UMA) to conduct a medical camp in the Eastern part of the country.

j) NDA provided funds for a medical camp at Bugiri Hospital, located in the southeastern part of the country.

k) Partnered with African Youth Leadership Development and Health Initiatives (AYLDH) in the creation of awareness campaigns among youth and teenage mothers especially on drug substance abuse.

2. NDA SUPPORTED A TOTAL OF THIRTEEN (13) INDIVIDUALS WITH DIFFERENT CONDITIONS AS LISTED BELOW;

a) One (1) diabetic survivor of diabetic conditions.

b) Three (3) kidney transplant patients.

c) Four (4) different cancer conditions.

d) Three (3) accident patients.

e) Provided support to one patient who was deaf and one patient who was mute.

f) One (1) breast cancer patient.

g) One (1) serious adverse drug reaction patient as a result of the COVID-19 vaccine.

3. IN THE FIELD OF EDUCATION, NDA SUPPORTED FIVE (5) INDIVIDUALS AT DIFFERENT LEVELS AS LISTED BELOW;

a) Supported two girls who were struggling at university. Both have since graduated: one is now a teacher and the other a Logistics Management Officer.

b) Supported one (1) A-level girl student and one (1) O-level girl student, who have both now progressed to university.

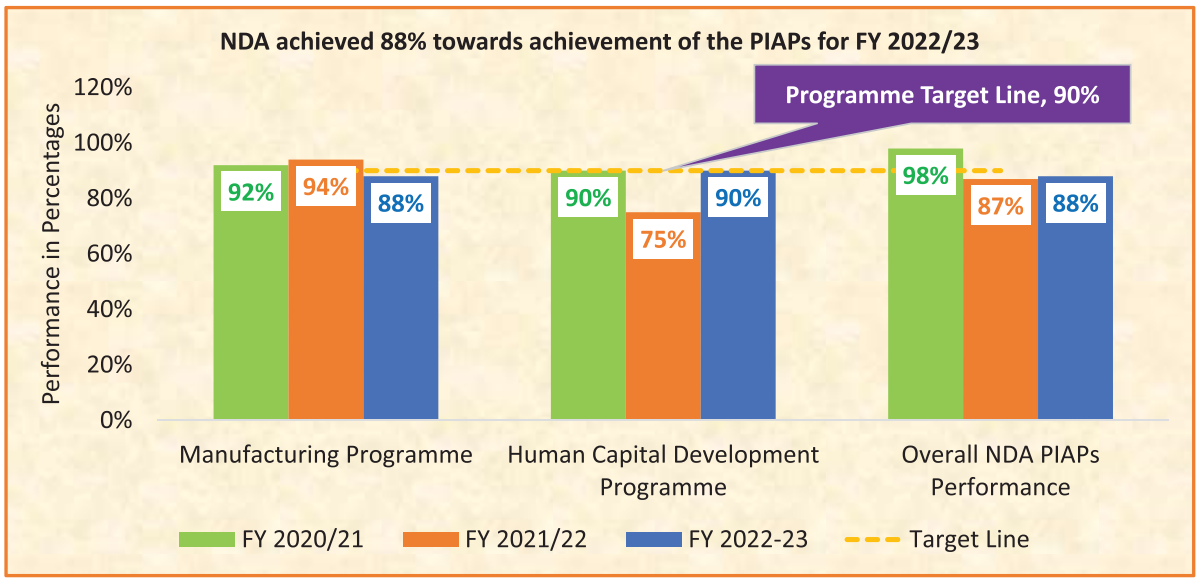
c) Last year, NDA provided support for a single-mother student who sat for the UCE examination.

d) Partnered with Mbarara University of Science & Technology (MUST) to establish a unit for treating pediatric cancer.

8.0 NATIONAL-LEVEL PERFORMANCE RESULTS BASED ON NDP III COMMITMENTS

At the 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 88% (13.25 out of 15)** against a set target of 90%. 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 improvement of 1% from 87% to 88% was due to the effect of tangible strides that were made in the stakeholder awareness, collaboration, engagement, and efforts by the seventh (7th) and eighth (8th) Drug Authority.

9.0 CASCADE OF NDA PERFORMANCE RESULTS

The NDA Monitoring and Evaluation Plan defines the measurement of results at three levels:

1. Outcome and Impact: - These demonstrate the effectiveness of the strategic plan.

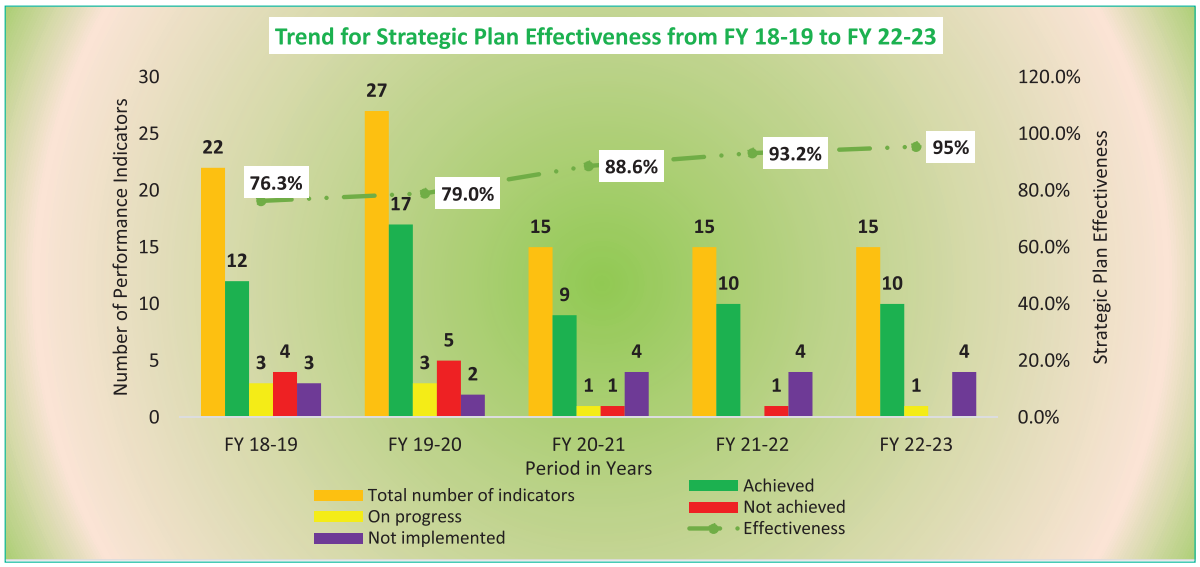
2. Outputs: - These indicate the efficiency of the strategic plan.

3. Process: - This reflects the achievement of service delivery timelines.

The performance results at each level are presented below.

9.1. THE NDA PERFORMANCE RESULTS AT THE IMPACT AND OUTCOME LEVEL.

To gauge whether the NDA is meeting the set objectives thus making short- and long-term improvements in the community, the National Drug Authority set one (1) Core Performance Indicator (CPI), which is a high-level indicator that measures the higher-level results at the goal level. The National Drug Authority also set 14 Key Performance Indicators (KPIs) at the 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. 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 1.8% from 93.2% to 95% between FY 2021 and FY 2023. The improvement is attributed to the following;

a) 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.

b) Tangible strides that were made in stakeholder awareness, collaboration, and engagement reflected by a percentage improvement of 14%.

9.2. Tabular presentation of the annualized NDA Performance Results at goal and outcome levels

Narrative Expected Results	Verifiable Performance Indicators	Targeted Results FY 21/22	Performance FY 21/22	Targeted Results FY 22/23	Performance FY 22/23
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 Strategic Objective 1: Improved public access and utilization of safe, efficacious, and quality drugs and healthcare products	Proportion of improved performance in core service delivery.	70%	81%	75%	78%
Outcome two for Strategic Objective 1: Improved regulatory systems, processes, and procedures that guarantee the availability of safe, efficacious, and quality drugs and healthcare products.	Proportion of SDT's implemented within the agreed timeline	80%	93%	82%	84%
Outcome for Strategic Objective 2: Harmonized legislative framework that enables an effective and well-functioning regulatory system for drugs and healthcare products,	Proportion of target stakeholders engaged in advocacy initiatives.	85%	25%	85%	200%
	Proportion of Regulations and Guidelines developed	100%	100%	100%	100%
	Transformation of NDP&A Act into UNFDA	Planned for FY 2024-2025	**N/A**	**N/A**	**N/A**

Narrative Expected Results	Verifiable Performance Indicators	Targeted Results FY 21/22	Performance FY 21/22	Targeted Results FY 22/23	Performance FY 22/23
Outcome One for Strategic Objective 3: Increased public awareness, knowledge and practices about safety, efficacy and quality of drugs	Proportion of the stakeholders aware of NDA role.	90%	Not Measured	93%	Not Measured
	Proportion of Satisfied customer.	75%	Not Measured	80%	Not Measured
Outcome two for Strategic Objective 3: Increased positive perception and visibility of NDA as an effective global standard regulator within the healthcare system.	Proportion of the stakeholders that perceives NDA as playing her role.	69%	Not Measured	79%	Not Measured
Outcome one for Strategic Objective 4: Improved institutional infrastructure to enable effective regulatory service delivery and specialized operations,	% of planned institutional infrastructure implemented.	70%	117%	79%	100%
Outcome two for Strategic Objective 4: Enhanced digital transformation for regulatory effectiveness,	Proportion of institutional business processes fully automated.	31%	42%	63%	63%
	Percentage of online services accessed throughout the year (Uptime of online services)	99%	100%	99%	100%
Outcome three for Strategic Objective 4: Increased human resource productivity to deliver the NDA's regulatory mandate.	Proportion of staff who attain 65% of approved performance targets.	100%	100%	100%	100%

Narrative Expected Results	Verifiable Performance Indicators	Targeted Results FY 21/22	Performance FY 21/22	Targeted Results FY 22/23	Performance FY 22/23
Outcome four for Strategic Objective 4: Improved financial sustainability of NDA	% increase in generated revenue	Plus 5%	8%	5%	12%
	Working ratio	90%	89%	90%	91%
NDA Annualized Performance Results			**93.2% (10.25/11)**		**95% (10.5/11)**

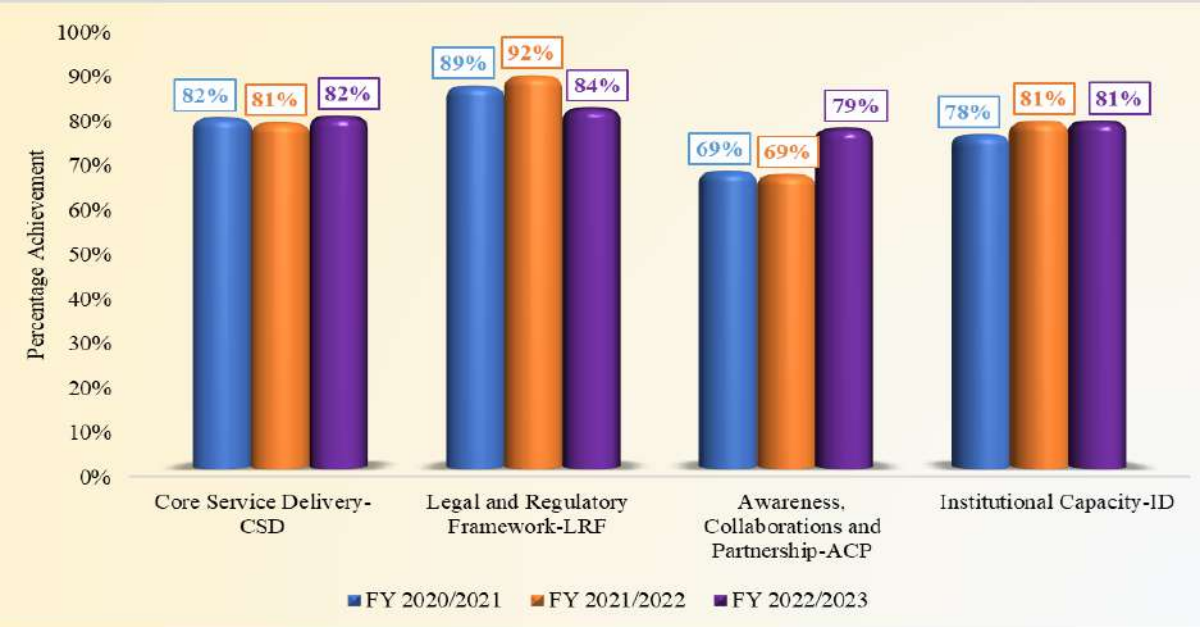
Out of the 15 impact and outcome indicators, eleven (11) were measured with a performance effectiveness of 95%. The effect was noticed in the expected saving of 10%. The Four performance indicators were not measured because of the following reasons;

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

b) Three (3) indicators for focus area 3 (Stakeholder Engagement and Collaboration) highlighted in purple in the table above were not reported on because the response rate of 67% wasn't a good representation of the planned survey sample size.

10.0 THE NDA PERFORMANCE RESULTS AT THE OUTPUT LEVEL

10.1. Trend Analysis of Focus Areas Percentage Achievements against the total commitments from 2020 to 2023

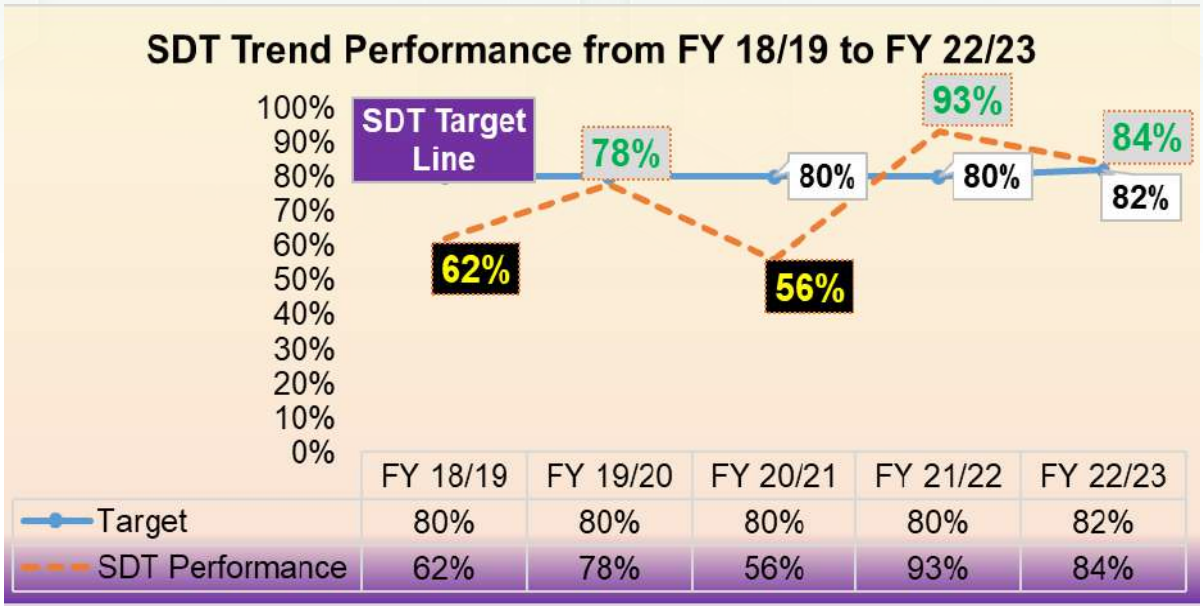


As illustrated above, Core Service Delivery, Legal and Regulatory Framework, and Institutional Development were on progress but Awareness, Engagement, and Collaboration were under-performing but with a percentage improvement of 14%.

10.2. NDA Process Level Results

Currently, NDA has fifty-six (56) Service Delivery Timelines. NDA has registered a percentage drop of 10% in the implementation of services to their clients within the agreed timelines from 93% for the previous year to 84% for FY 2022-2023. However, it's above the set strategic plan timeline target of 82%. The achievement above the set target has improved regulatory systems, processes, and procedures that guarantee the availability of safe, efficacious, and quality drugs and health products.

The chart below illustrates the Service Delivery Timelines comparative analysis.



The drop-in performance presented in the chart above was due to the following reasons highlighted below;

1. Manual and late testing of samples for release due to challenges in LIMS handling data analysis affected the implementation of the service within the agreed timelines.
2. The samples reporting through LIMS were met with system errors that delayed release. Also, the analysis involved an out-of-scope investigation which delayed the release.
3. Applications for facilities in Bangladesh that were not inspected due to delayed Visa approvals for the same country.

THE FUTURE OF NDA

01 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, and household chemicals among others.

02 Continuous international recognition

03 Harmonization initiatives

04 Expanded service coverage with customer outreach

05 Unrivaled local pharmaceutical industrial support

06 Super specialized quality control

07 Building a community awareness culture on the regulated products and their functionality.

08 Automation of more Business processes

08 Automation of more Business processes

a) **Clinical trials,**
b) **QMS**
c) **Product compliant handling**
d) **Recall handling,**
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.**

09 Expanding NDA Infrastructure by building regional offices and NDA Administration block

10 Harnessing artificial intelligence in registration space e.g. online trade, digital prescription, drone delivery of drugs, track and trace etc.

OUR COMMITMENT TO OUR STAKEHOLDERS

Maintaining a proper management system:

We commit to establish and uphold a framework of processes, procedures, policies, and practices designed to effectively oversee and coordinate the operations of an organization. This will encompass various aspects of management, including strategic planning, organizational structure, decision-making processes, communication channels, resource allocation, performance monitoring, and risk management.

A stable and predictable governance structure:

We commit to have a framework of rules, processes, and an institution that guides decision-making, allocation of resources, and the exercise of authority within an organization or a system. This structure will be designed to provide stability, consistency, and reliability in the management and direction of affairs over time.

Infrastructure development and improvement structure:

We commit to have an organized framework and processes involved in planning, implementing, and maintaining physical infrastructure assets within our organization. This will encompass various aspects, including transportation, energy, water supply, communication networks, healthcare facilities, educational institutions, and other essential public services.

Continuous automation and integration:

We commit to have an ongoing process of streamlining and enhancing workflows, systems, and processes within NDA through the systematic adoption of automated technologies and the seamless integration of various software applications and platforms. This approach aims to improve efficiency, reduce manual intervention, enhance data accuracy, and facilitate collaboration across different functional areas.

Continuous staff capacity improvement:

We commit to have an ongoing process of actively involving and communicating with individuals, groups, or entities that have an interest or stake in the activities, decisions, or outcomes of an organization or project. This engagement strategy aims to build trust, foster collaboration, gather input, and address concerns to ensure that stakeholder needs and expectations are considered and integrated into decision-making processes effectively.

Service Delivery timelines commitment:

We make a promise to our stakeholders to provide services within specified timeframes as agreed upon with you our clients because it is a crucial aspect of customer service and satisfaction, as it sets expectations regarding when the customer can expect to receive the desired goods or services.

Continuous staff capacity improvement:

We commit to enhance the knowledge, skills, abilities, and performance of employees within an organization. This concept will emphasize the importance of providing employees with opportunities for growth and development throughout their careers. It will involve various strategies, including training programs, skill-building workshops, mentorship initiatives, performance feedback, and career advancement opportunities. By investing in continuous staff capacity improvement, organizations aim to cultivate a highly skilled and motivated workforce capable of adapting to evolving business needs and achieving both individual and organizational goals.

Multi-sectoral collaboration and partnership:

We commit to involve the cooperation and coordination of various sectors, organizations, agencies, or stakeholders from different fields to address complex challenges, achieve common goals, and promote holistic solutions. This collaborative approach recognizes that many societal issues transcend the capabilities of any single sector or organization and require the combined expertise, resources, and perspectives of multiple stakeholders working together.

Relevant and Adaptive Legal Regime

We promise to conduct thorough examination, analysis, and review of existing laws, regulations, and legal frameworks to ensure their relevance, effectiveness, and adaptability to changing circumstances, societal needs, and emerging challenges. This process is essential for maintaining a dynamic and responsive legal system that can effectively address evolving issues and protect the rights and interests of individuals, businesses, and society as a whole.

CONSTRAINTS AND ACTIONS TO BE TAKEN

01 **LOW STAKEHOLDER ENGAGEMENT RATES**

We commit to engaging with stakeholders at various levels to increase awareness, address concerns, and foster collaborative partnerships.

02 **INADEQUATE RESPONSE RATES FOR CERTAIN KEY PERFORMANCE INDICATORS IN FOCUS AREA 3 FOR STAKEHOLDER AWARENESS, PERCEPTION, AND SATISFACTION.**

We commit to Collaborating with experts to redesign survey methodologies, ensuring higher response rates and more reliable data collection.

03 **DELAYED TRANSFORMATION OF THE 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.

11.0 CONCLUSION

The National Drug Authority (NDA) has made significant strides in its implementation efforts. It has reached a weighted average performance achievement of 88% in fulfilling national-level commitments, achieved a 95% effectiveness rate in terms of impact and outcomes, and recorded an efficiency rate of 81% at the output level. Additionally, the NDA obtained an 84% achievement level in process-related metrics and successfully implemented 92% of the planned activities during the reporting period.

NDA demonstrates a strong commitment to improving regulatory effectiveness and ensuring 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. Its contribution to national-level NDP III commitments shows its impact on population health and safety.

Looking ahead, NDA is committed to addressing challenges and implementing corrective measures. It aims to strengthen regulatory frameworks and enhance public well-being through continuous recognition, active participation in harmonization initiatives, and automation of business processes, expanding service coverage with more customer outreach. Overall, the NDA remains steadfast in safeguarding public health and ensuring the availability of quality, safe, and efficacious healthcare products to the entire population.

12.0 DETAILED REPORT

12.1. Introduction

This section provides a detailed overview of performance results at the National and Institutional levels. The National level results are presented in alignment with the NDA's NDP PIAPs for various programs, and at the Institutional level, they are presented using the Focus Area approach, highlighting effectiveness at the outcome and impact level, as well as efficiency in activity implementation. The report gives the major performance achievements of NDA's strategic plan and the national level results as highlighted in the report below.

12.2. Manufacturing Program Performance Status:

The NDA strategic plan is aligned with objective 2 of the NDP III Manufacturing Program "Increase value addition for import substitution and enhanced exports" and in particular, the intervention that supports existing local manufacturers of pharmaceutical products. NDA contributed to the support of the Good Manufacturing Practice (GMP) compliance assessment system for local pharmaceutical manufacturers as well as reviewed and updated 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 Manufacturing Programme Performance for FY 2022-2023</th><th>Justification</th><th>Rating</th></tr>
<tr><td colspan="4">Programme: 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 manufacturers for both medical products and pharmaceuticals</td></tr>
<tr><td>Review and update standards, regulations, and guidelines to cater for indigenous Pharma remedies (incl. Dissemination, enforcement, and M&E).</td><td>One (1) regulation on "Statutory Instrument 29 for National Drug Policy and Authority (Registration)" was reviewed
Licensing status for the Local Manufacturers for FY 2022-23.
<table>
<tr><th>Local Manufacturers</th><th>Licensed</th></tr>
<tr><td>Local Therapeutic Foods</td><td>1</td></tr>
<tr><td>Local Medical Device Manufacturers</td><td>7</td></tr>
<tr><td>Local Medical Gases</td><td>1</td></tr>
<tr><td>Local Herbal Manufacturers</td><td>4</td></tr>
<tr><td>Local Pharmaceuticals</td><td>16</td></tr>
<tr><td>Local Repackaging</td><td>6</td></tr>
<tr><td>Total</td><td>35</td></tr>
</table></td><td>Fully Achieved</td><td></td></tr>
</table>

Action	NDA Manufacturing Programme Performance for FY 2022-2023	Justification	Rating
Programme: 04 Manufacturing.			
Sub-program: 041 Industrial and Technological Development.			
Objective: 0412 Increase value addition for import replacement and enhanced exports			
Intervention: 041201 Support existing local manufacturers for both medical products and pharmaceuticals			
Provide technical support to local pharmaceutical industries in Good Manufacturing Practices and prequalification standards.	**Stakeholder engagement meetings with the local manufacturers.** A total of four (4) stakeholder meetings were held with local medicine and medical device manufacturers. The details are listed below: a) One stakeholder engagement was held to discuss guidelines on the introduction of locally manufactured products. b) One held with medical device manufacturers and suppliers to discuss the registration and inspection of facilities manufacturing surgical instruments and appliances. c) One stakeholder meeting to discuss analytical method life cycle management. d) One stakeholder meeting with manufacturers to discuss data integrity requirements specifically for the quality control laboratory.	Fully Achieved	
	GMP Training to local manufacturers. A total of three (3) GMP trainings were conducted for all local manufacturers. These included; Pre-market and Post-market requirements including biowaiver requirements, data integrity requirements, and analytical method life cycle management.	Fully Achieved	
	Good Manufacturing Practice (GMP) Compliance Support Inspections. NDA Conducted a total of 42 Local GMP inspections against a target of 40. In addition, 24 GMP inspections were conducted against a set target of 22 foreign, and 97% (22 out of 24) of local manufacturers inspected were approved for licensing.	The target for GMP In-spections was exceeded because of the new local manufactur-ing facilities established.	

<table>
<tr><th>Action</th><th>NDA Manufacturing Programme Performance for FY 2022-2023</th><th>Justification</th><th>Rating</th></tr>
<tr><td colspan="4">Programme: 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 manufacturers for both medical products and pharmaceuticals</td></tr>
<tr><td></td><td>Conduct inspections for herbal manufacturers
A total of 31 herbal facilities were inspected against 50 inspections planned.
The target was not achieved due to several applicants turning down inspections for personal reasons also several herbal manufacturers are interested in notification of their products and once this is done, they turn down inspections.</td><td>Not achieved due to the reason presented under the performance column</td><td></td></tr>
<tr><td></td><td>Pre-Market Testing of Samples.
<table>
<tr><th>Category</th><th>Received</th><th>Tested</th><th>Passed</th></tr>
<tr><td>Human</td><td>93</td><td>53</td><td>51</td></tr>
<tr><td>Veterinary</td><td>9</td><td>11</td><td>11</td></tr>
<tr><td>Total</td><td>102</td><td>64</td><td>62</td></tr>
</table>
From the table above, NDA tested a total of 53 human medicine samples out of 93 received and a total of two (2) samples of Chlorphenamine failed the Assay & Dissolution test and were not allowed into the market.

Tested a total of eleven (11) veterinary samples out of nine (9) received and all passed the quality tests and were all allowed for marketing. The extra samples tested were backlogs from the previous financial year.

Out of the 64 samples tested above, sixty-two (62) samples passed the quality tests and allowed for marketing authorization and two (2) samples of Chlorphenamine failed the Assay & Dissolution test and were recommended for improvements before rolling them on the market.</td><td>Action was taken on the two (2) failures to ensure that the products of local manufacturers pass before being circulated on the market.</td><td></td></tr>
</table>

Action	NDA Manufacturing Programme Performance for FY 2022-2023	Justification	Rating
Programme: 04 Manufacturing.			
Sub-program: 041 Industrial and Technological Development.			
Objective: 0412 Increase value addition for import replacement and enhanced exports			
Intervention: 041201 Support existing local manufacturers for both medical products and pharmaceuticals			
	All new local manufacturers inspected. A total of 69 pre-market assessments have been conducted during the reporting period	Fully Achieved	
Conduct sensitization and awareness campaigns on locally produced pharma products.	**Sensitization Training of local manufacturers in quality control** A total of two (2) sensitization trainings were conducted in quality control; specifically, in analytical method life cycle management and data integrity requirements.	Fully Achieved	
	Training of Locally Herbal Manufacturers Three (3) herbal manufacturers training were conducted including training of herbalists undertaking the occupational herbalist course under NCRI MOH accredited by the directorate of industrial training, training of herbal manufacturers with Notified products, and training of Herbal manufacturers with products under notification and herbalists identified during enforcement and post-marketing surveillance after lab analysis.	Fully Achieved	
	Sensitization and Awareness of herbal manufacturers. 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 healthcare products.	Fully Achieved	
NDA Overall Percentage Achievement on Manufacturing Program for FY 2022-23			**88% (8.8/10)**

12.3. Human Capital Development Program Performance Status:

NDA strategic plan is aligned with objective 4 of the NDP III Human Capital Development (HCD) Program "Improve population health, safety and management". NDA's strategic plan is aligned with 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 the 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 Human Capital Development Programme Performance for FY 2022-2023	Justification	Color Bands and Score
Programme: 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 the National Drug Authority	NDA commenced the construction of the laboratory tower on 11th October 2019 and by 30th June 2023, the actual overall progress onsite was 100% building completion pending issuance of occupancy permit and minor remedies. The Quality Laboratory for the National Drug Authority will cover laboratory testing of the following areas including; a) Human Medicines, Veterinary, Herbal, Medical Devices, and Cosmetics.	Fully Achieved	
Implement the National Drug Authority Strategic Plan	**The Strategic Plan FY 2022-2023 Implementation.** 82% (164.75 out of the total of 201 planned NDA key outputs were achieved during the financial year 2022-2023 and a total of Ugx. **84,228,768,463** (66%) was spent as compared to the planned amount of Ugx. **128,388,665,314**/=	Partially Achieved	

<table>
<tr><th>Action</th><th>NDA Human Capital Development Programme Performance for FY 2022-2023</th><th>Justification</th><th>Color Bands and Score</th></tr>
<tr><td colspan="4">Programme: 12 Human Capital Development</td></tr>
<tr><td colspan="4">Sub-program: 122 Population Health, Safety and Management</td></tr>
<tr><td colspan="4">Objective: 1224 Improve population health, safety, and management</td></tr>
<tr><td colspan="4">Intervention: 122417 Strengthen governance, management, and effectiveness of the health sector at all levels.</td></tr>
<tr><td></td><td>A total of Ugx. 82,744,331,822 (105%) was generated as compared to the projected amount of Ugx. 79,049,743,376/=</td><td>The increase in revenue generation is attributed to the Pharmaceutical business which picked up more than expected in the post-COVID period.</td><td></td></tr>
<tr><td>Strengthen mechanism for regulation and accreditation of drug outlets within the overall district health system</td><td>14,704 (2,743 pharmacies and 11,961 drug shops) were approved and given licenses to operate out of 14,743 (2,782 pharmacies and 11,961 drug shops) licensing applications received as shown in the table below.
<table>
<tr><th>Licensing Summary</th><th>Applications received</th><th>Licenses Approved</th><th>Percentage Approval</th></tr>
<tr><td>Pharmacy</td><td>2,782</td><td>2,743</td><td>98.6%</td></tr>
<tr><td>Drug Shops</td><td>11,961</td><td>11,961</td><td>100%</td></tr>
<tr><td>Total</td><td>14,743</td><td>14,704</td><td>99.7%</td></tr>
</table>
From the table above, 1,741 applications were received for renewal and 1,729 were approved as of 30th June 2023 of which 876 (50.67%) of the approved renewals were licensed within 35 working days. A total of 1041 new applications were received for licensing and 1014 were approved as of 30th June 2023 of which 845 (83.33%) of the approved new applicants were licensed within 35 working days.</td><td>Fully Achieved.</td><td></td></tr>
</table>

<table>
<tr><th>Action</th><th>NDA Human Capital Development Programme Performance for FY 2022-2023</th><th>Justification</th><th>Color Bands and Score</th></tr>
<tr><td colspan="4">Programme: 12 Human Capital Development</td></tr>
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<tr><td colspan="4">Objective: 1224 Improve population health, safety, and management</td></tr>
<tr><td colspan="4">Intervention: 122417 Strengthen governance, management, and effectiveness of the health sector at all levels.</td></tr>
<tr><td></td><td>Good Pharmacy Practice Inspections. NDA Conducted a total of 401 Good Pharmacy Practice (GPP) inspections (133.7%) against the planned 300 GPP inspections.
Target Performance for FY 2022/2023 % of target achieved
<table>
<tr><th></th><th>Target</th><th>Performance for FY 2022/2023</th><th>% of target achieved</th></tr>
<tr><td>GPP Inspections</td><td>300</td><td>401</td><td>133.7%</td></tr>
</table></td><td>The GPP target was fully achieved because the funds allocated were adequate to inspect more than facilities and there were more health facilities to visit hence the overperformance.</td><td></td></tr>
<tr><td colspan="3">NDA Overall Percentage Achievement on Human Capital Development Program for FY 22-23.</td><td>90% (4.5/5)</td></tr>
</table>

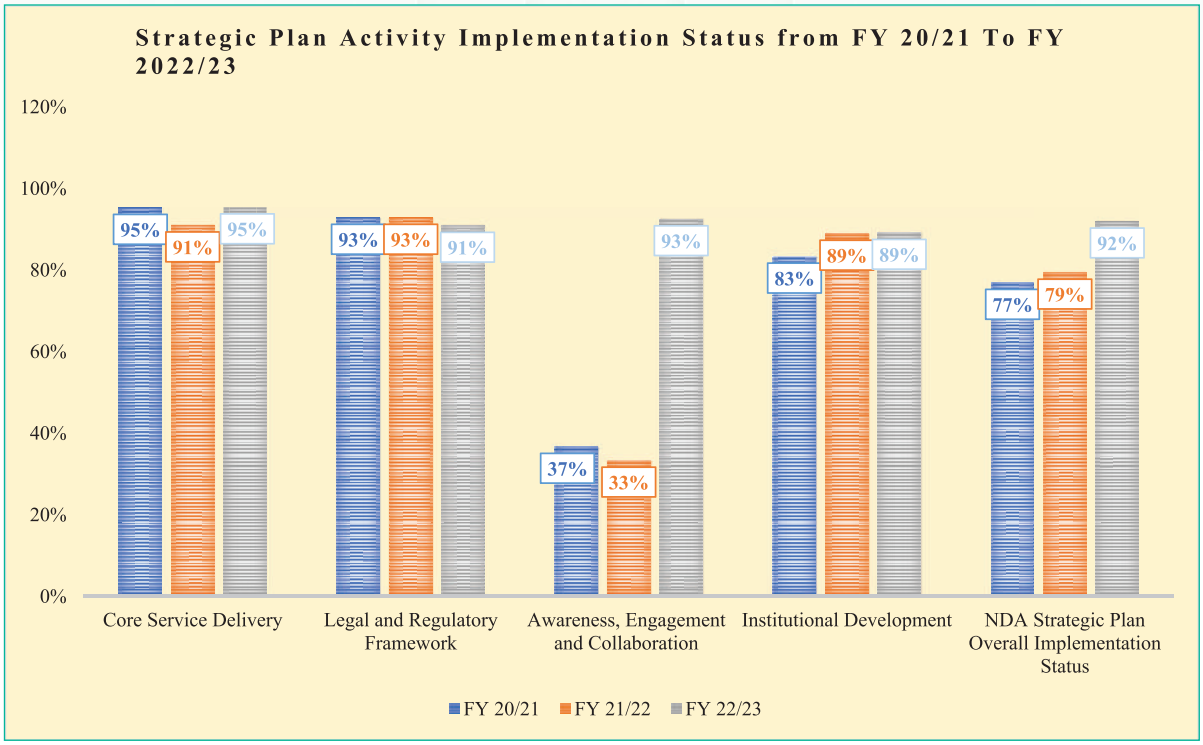
12.4. The Strategic Plan Implementation and Progress on Achievement of the Strategic Focus Area Outputs

The performance milestones for assessment monitoring and evaluation of NDA's performance concerning 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, field data; a survey of experts; and document reviews.

Management put in place mechanisms for M&E implementation of the strategic plan. Annually management develops a work plan and budget for the implementation action plan.

12.5. Strategic Plan Activity Implementation Status for FY 2022/23.

The graph below illustrates the current implementation status of the Strategic Plan activities as documented in the Strategic Plan Implementation Action Plan for FY 2022/23.

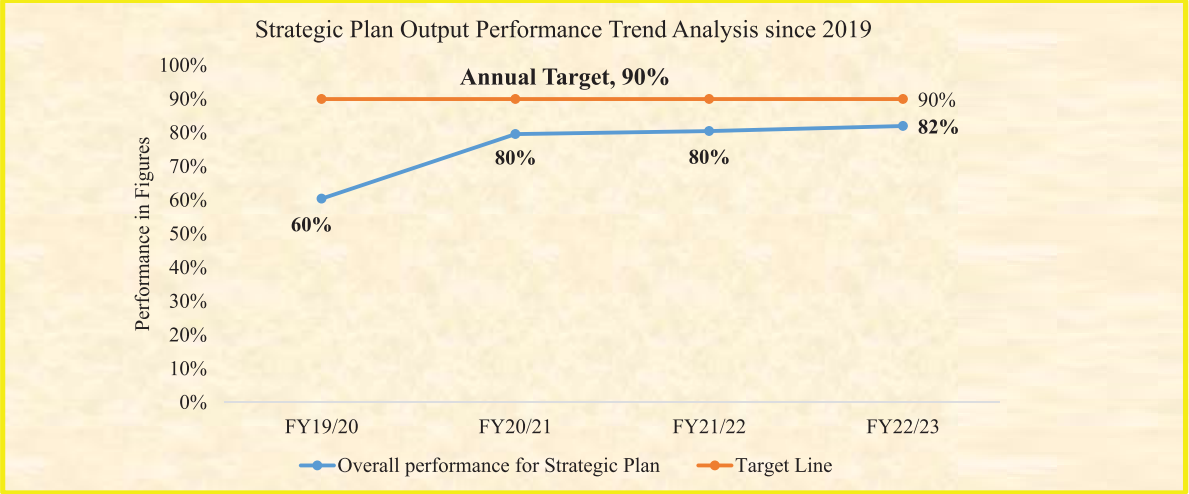


The chart above shows a tremendous improvement of 16% in the implementation of activities as compared to 3% for the previous financial year. This is attributed to the support offered by the Drug Authority, the NDA Management Team, the process owners, and the implementers that ensured planned activities were implemented.

12.6. Overall Output Performance Achievement of the Strategic Plan for FY 2022/23

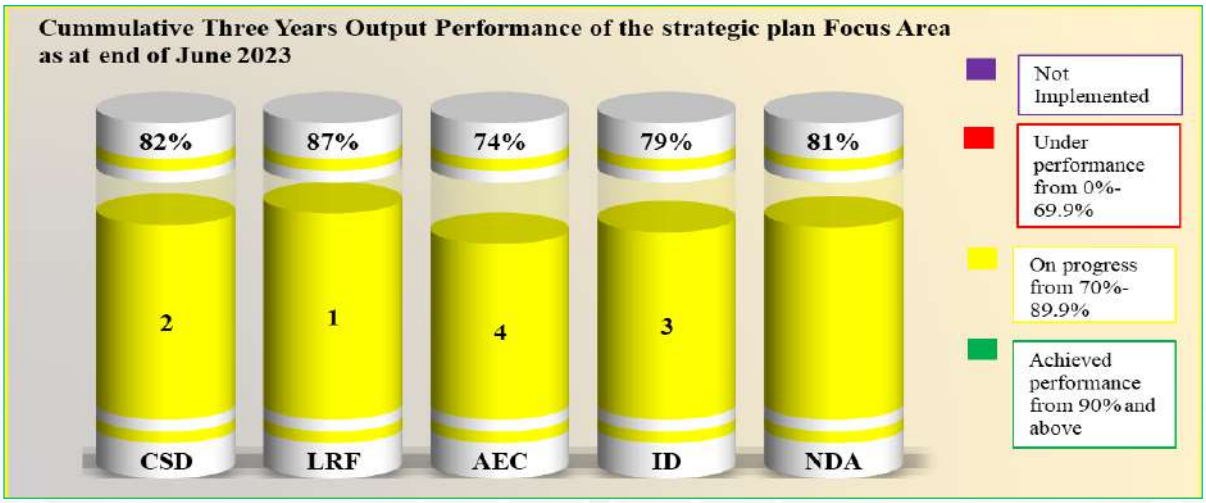
The Strategic Plan output achievement for the financial year 2022/23 improved by 2% compared to the previous performance FY 2021/22. NDA achieved an average overall performance of 82% progress towards the set output targets of 90% with; 84% for Legal Regulatory Framework, 82% for Core Service Delivery, 81% for Institutional Development, and 79% for Awareness, Engagement, and Collaborations as compared to overall performance progress of 80% progress for FY 2021/2022. This has increased public access and utilization of safe, effective, quality drugs and healthcare products on the Ugandan market.

The Output Achievement of the strategic plan reporting period has been monitored and evaluated and the progress comparative analysis is illustrated in the chart below;



12.7. Three Years Overall Achievement of the Strategic Plan Focus Area Outputs including the NDP PIAPs commitments for the three years as of 30th June 2023

The achievement of the Strategic Plan Focus Area annual commitments/outputs from 1st July 2020 to 31st June 2023 is generally in progress with an average overall performance (NDA) of 81% towards the achievement of set targets with; 87% for Legal Regulatory Framework (LRF), 82% for Core Service Delivery (CSD), 79% for Institutional Development (ID) and 74% for Awareness, Engagement and Collaborations (AEC). This has helped in meeting the stakeholder expectations and enhanced NDA's regulatory service delivery for the medium term. Though more efforts are required to improve stakeholder awareness, engagement, and collaboration that is still lagging as compared to the other three (3) Focus areas as illustrated in the chart below.



13.0 NDA SET COMMITMENTS PERFORMANCE BY FOCUS AREA

13.1. 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 focuses on the key actions that the NDA undertakes to sustainably improve the 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;

Strategic Intervention 1.1: Strengthen systems and institute regulatory actions that support local drug manufacturing.

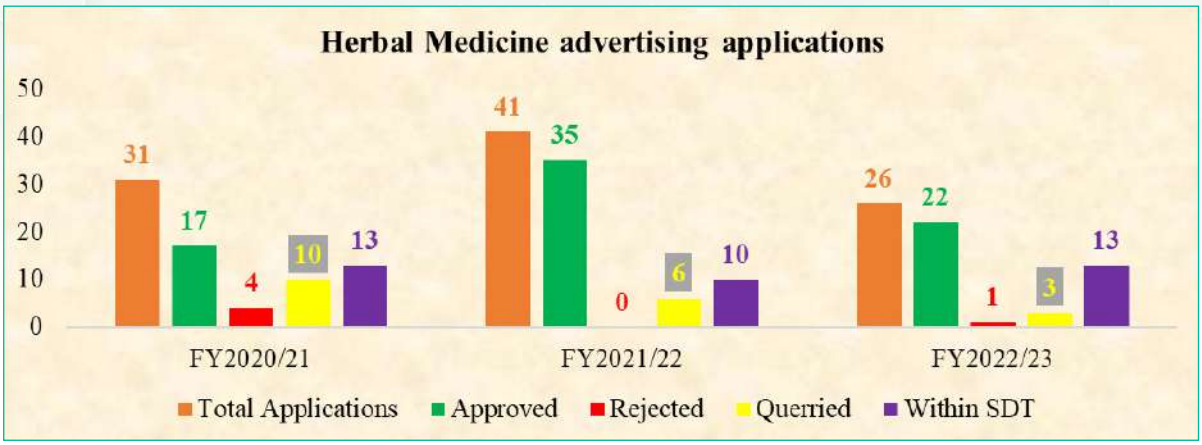
13.1.1. Control of illegal advertisement of herbal drugs on TVs and Radios

NDA has engaged the Uganda Communication Commission (UCC) to enforce adherence by electronic and print media 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 204 drug promotional materials out of the 237 applications that were received for FY 2022-23 as compared to 219 out of the 271 applications for FY 2021/22. The applications were evaluated and feedback was given within six (6) working days against the set target of fifteen (15) working days as compared to nine (9) working days for FY 2021/22. This has helped to ensure that misleading, biased, and inaccurate information on medicines is not disseminated to the public in Uganda thus promoting consumer welfare, public health, and regulatory compliance in the advertising of local herbs and healthcare products in Uganda. The chart below shows the trend analysis of drug promotions submitted, evaluated, and approved by NDA.

13.1.2. Herbal Medicines Drug Promotion Applications

NDA has continuously engaged herbal medicines manufacturers and promoters on ethical advertising and promotion of medicines. There was a gradual appreciation of the need for compliance that indicated an increase in the number of applicants approved within SDT and a reduction in the number of queried applications as illustrated in the chart below.



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

i) Continued focused enforcement activities

ii) Maintaining and enhancing collaborations with other government regulatory institutions e.g. UCC, UNBS, Local government, media, etc.

13.1.3. Drug and Substance abuse

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

NDA creates awareness through the media of which one (1) TV talk show and six (6) radio talk shows were conducted. In regards to engagement with stakeholders on good practices of publication and advertising, NDA conducted two (2) engagements with media broadcasters in Eastern Uganda and herbal Medicine Hawkers in Kiboga and Kyankwanzi and One (1) engagement with media houses in western Uganda.

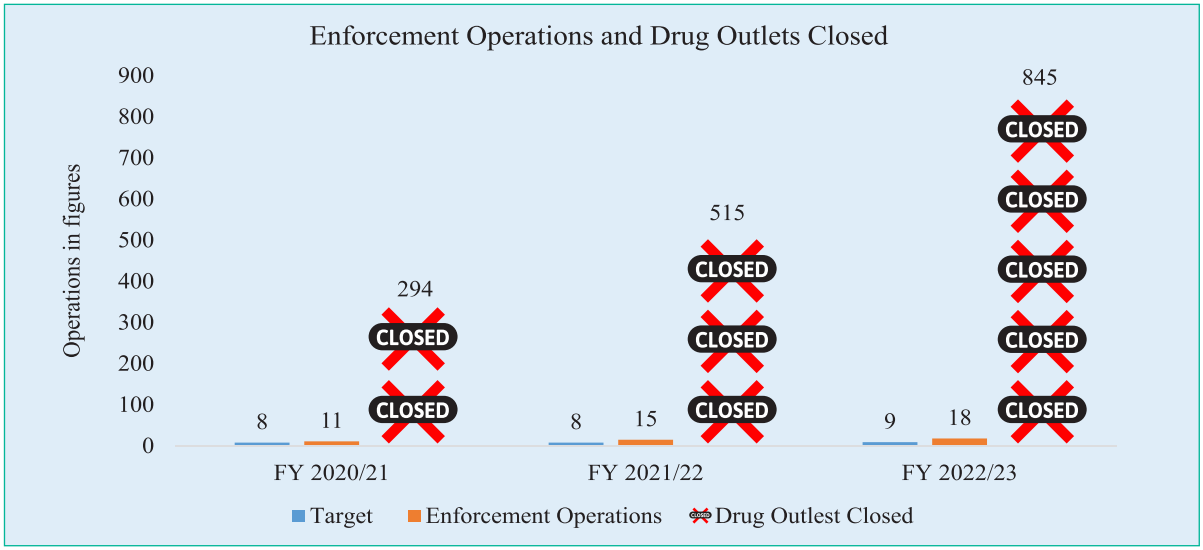
In the period under review, NDA conducted sensitization in schools on the prevention of drug and substance abuse, where 23 schools in the regions were engaged as compared to 20 in the FY 2021/22. With regard to Drug and Substance Abuse preventive activities with faith-based institutions and other institutions, four (4) teachers were trained in Kabale, Lira, and Gulu, and one (1) sensitization activity was conducted in collaboration with The Nabagereka Development Foundation. On rational medicine use and ethical advertising, NDA conducted four (4) engagements in three (3) Universities, engaged secondary school students through debates, and engaged with VHTs from the Kampala region in collaboration with PSU.

About collaborative activities with other regulatory bodies, NDA conducted two (2) meetings with UCC, and UVA with its members and two (2) meetings with MOH.

In terms of **Monitoring, investigations, and enforcement** of drug-related publications and advertisements for compliance, NDA held one (1) electronic monitoring, Physical monitoring and enforcement Joint enforcement (NDA, UCC, UNBS), and Online monitoring and enforcement undertaken.

13.1.4. Enforcement of the NDP& 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 18 operations against the planned 9 operations during the year as compared to 15 operations against a set target of 8 operations for FY 2021-22. Closed 845 drug outlets (96 pharmacies and 749 drug shops) as compared to 515 drug outlets (50 were pharmacies and 465 drug shops) for FY 2021-22 as illustrated in the chart below.



During this operation, 128 non-compliant cases were filed by Police as compared to 76 cases for FY 2021/22 of which 72 were submitted to DPP and sanctioned for prosecution as compared to 61 for FY 2021/22. This improved the availability of safe, efficacious, and quality drugs on the market in Uganda. More enforcement regulatory actions were effected on illegal drug outlets as listed in the table below.

Drug Outlets	Impounded		Arrests Made		Court Cases Initiated	
	FY 2021/22	FY 2021/23	FY 2021/22	FY 2021/23	FY 2021/22	FY 2022/23
Pharmacies	43	91	44	133	43	88
Drug shops	1,855	749	06	74	26	74
Total	**1898**	**840**	**50**	**207**	**69**	**162**

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

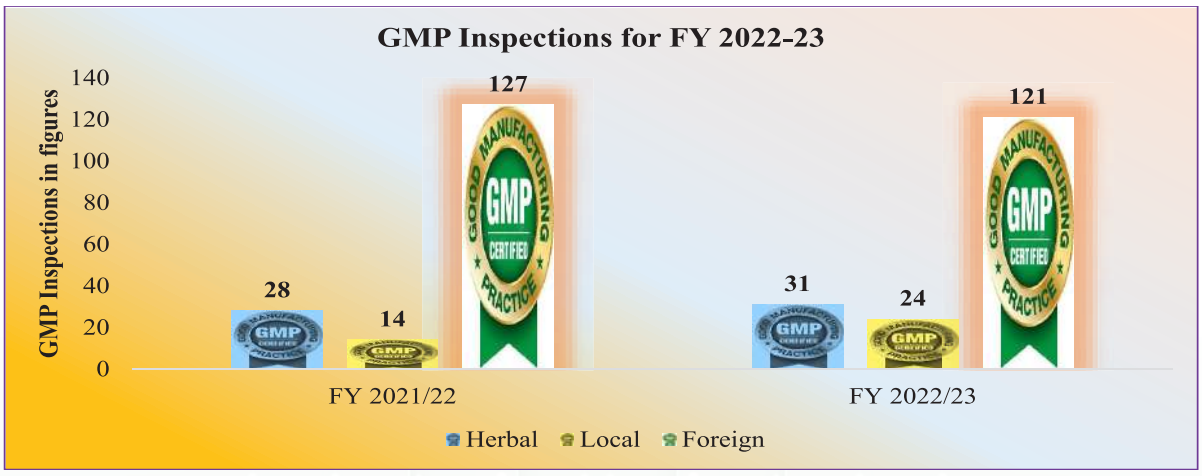
13.1.5. GMP (Good Manufacturing Practice) Inspection.

Good Manufacturing Practice is conducted every year on both local and foreign pharmaceutical manufacturing facilities to ascertain the quality and compliance aspects in the 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 150 foreign manufacturers and we inspected a total of 121 (80.7%) in FY 22/23 as compared to 127 foreign physical inspections for GMP against 170 for FY 2021-22. Conducted 34 GMP desk reviews for manufacturing facilities as compared to 31 desk assessments for FY 2021/22.

Planned to inspect 22 local manufacturers and twenty-four (24) of them were inspected during the year as compared to 14 inspected against 40 planned inspections for FY 2021/22. There was an increase in GMP local inspection by 71% as compared to 14 inspections for FY 2021/22. This performance was due to the majority of local facilities that complied with the inspection schedules which in turn raised the number of overall inspections conducted.

Inspected 31 local herbal manufacturing facilities against a set target of 50 during the year as compared to 28 facilities against 40 that were inspected for FY 2021/22. The target for inspection of local herbal facilities wasn't met because the majority of herbal facilities turned down inspections for personal reasons secondly, several herbal manufacturers were interested in notification of their products and once this was done, they turned down inspections. The chart below illustrates the GMP conducted for the two years.



To further support the development of domestic pharmaceutical capacity NDA intends to;

1. Conduct routine inspections of all local manufacturers, especially high-risk facilities.
2. Follow up on the GMP road maps for all manufacturers to ensure they are making improvements in line with their commitments.

3. Work with IT and developers to ensure IRIMS GMP module is rolled out and operational.
4. Support domestic manufacturers in terms of GMP compliance and quality submissions for marketing authorization of products through training.
5. Improve inspector's performance monitoring and implement a dashboard for each inspection team.
6. Provide opportunities for specialized training/attachments in key areas, such as biologicals, APIs, nuclear medicines, and medical devices.
7. Intensify the inspection of foreign herbal manufacturing facilities.
8. Develop guidelines, and inspection tools, and conduct training for the inspection of CROs and medical devices.
9. Increase the number of API sites inspected.
10. Increase unannounced inspections for domestic manufacturers.
11. Continue support towards improving compliance for herbal manufacturers.

13.1.6. 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. A total of 5067 ADR reports against the expected 2200 reports were received, evaluated, and communicated to the relevant stakeholders as. The expected number of ADRs was surpassed due to pharmacovigilance sensitization meetings that raised awareness among healthcare workers and enhanced ADR reporting as presented in picture 1 below. The reason for this performance is due to an increase in regular feedback, an improvement of more reporting channels, support supervision, and the rollout of market authorization guidelines for Pharmacovigilance which supported the detection of treatment failures. This led to improved safety, improved pharmacovigilance practices, informed decision-making, trust in regulatory oversight, and keen public awareness about healthcare safety. The ADR analysis is shown in the annualized trend below.

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

Picture below depicts the pharmacovigilance sensitization meeting to raise awareness among healthcare workers to enhance ADR reporting.

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

13.1.7. Promoting Scientific Research

The Drug Authority has established a scientific research study unit to inform the decisions of the Authority. A total of five (5) research studies have been conducted for the FY 2022/23 as listed in the table below:

No.	Research Studies conducted in FY 2021/22	Research Studies conducted in FY 2022/23
1.	Study on the impact of the 12 % verification fees on production capacity, cost, and availability of the 37 selected medicines.	Factors Affecting Good Distribution Practices Compliance in Wholesale Distributors in Uganda.
2.	To evaluate the glycemic effects of Dolutegravir among patients taking DTG-based regimens.	Non-prescription access to antibiotics and associated factors in licensed drug shops in Uganda.
3.	Skepticism on the quality of generic medicines from countries with non-stringent regulatory authorities.	The burden of medication errors and the barriers and facilitators to medication error reporting in Uganda. A cross-sectional mixed method study.
4.	Survey among health workers on the safety of bupivacaine and ceftriaxone on the market.	Anti-Microbial Resistance (AMR) Annual Consumption Data.
5.	Medicine quality, maternal health, and the final mile.	Evaluating the Glycemic Effects of Dolutegravir (DTG) Among Patients Receiving Dolutegravir Based Regimens at Mild May Uganda ART sites: A Prospective Cohort Study.

From the table above, a total of five (5) studies were conducted for FY 2022/23 as compared to the five (5) studies for FY 2021/22 thus strengthening the research capacity for making evidence-based drug regulatory decisions.

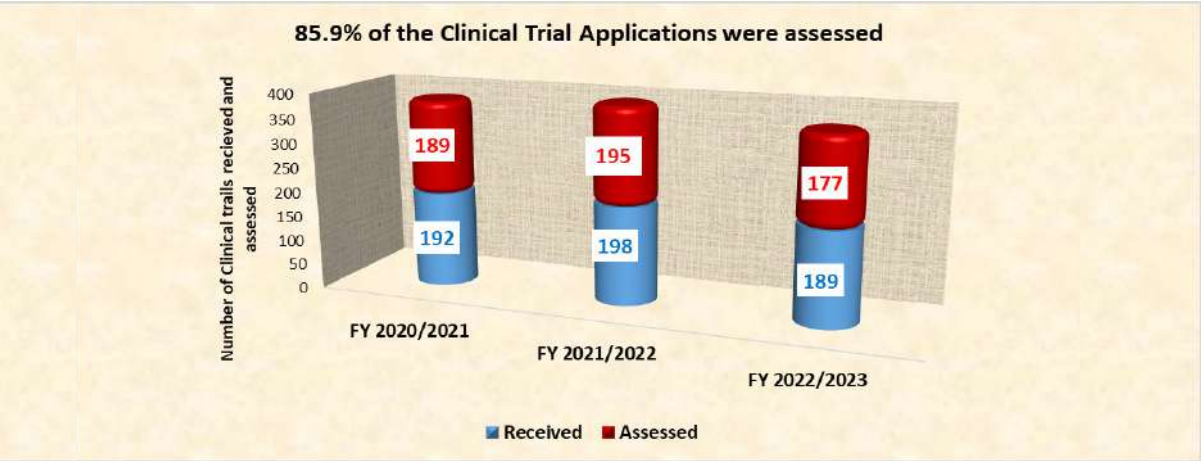
In regards to the application of research recommendations, NDA research findings have been a crucial part in increasing awareness and sensitization among NDA stakeholders in both the public and private sectors and we have done this through; holding dissemination meetings with health workers, academia, and herbalists.

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

13.1.8. Clinical Trial Inspection and Evaluation

Clinical Trials are 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 189 clinical trial applications of which 177 (93.7%) were assessed as compared to FY 2021/22 were 98.5% (195 out of 198) clinical trial applications were assessed. Out of 25 initial new applications assessed, 22 were assessed with a final decision made within SDTs, out of 89 renewal applications assessed during the financial year, 75 were assessed with a final decision made within SDTs, and out of 63 amendments assessed, 55 applications were assessed with the final decision made within SDTs. The Graph below shows the Clinical Trials Trend Analysis from FY 2020/21 to FY 2022/23.



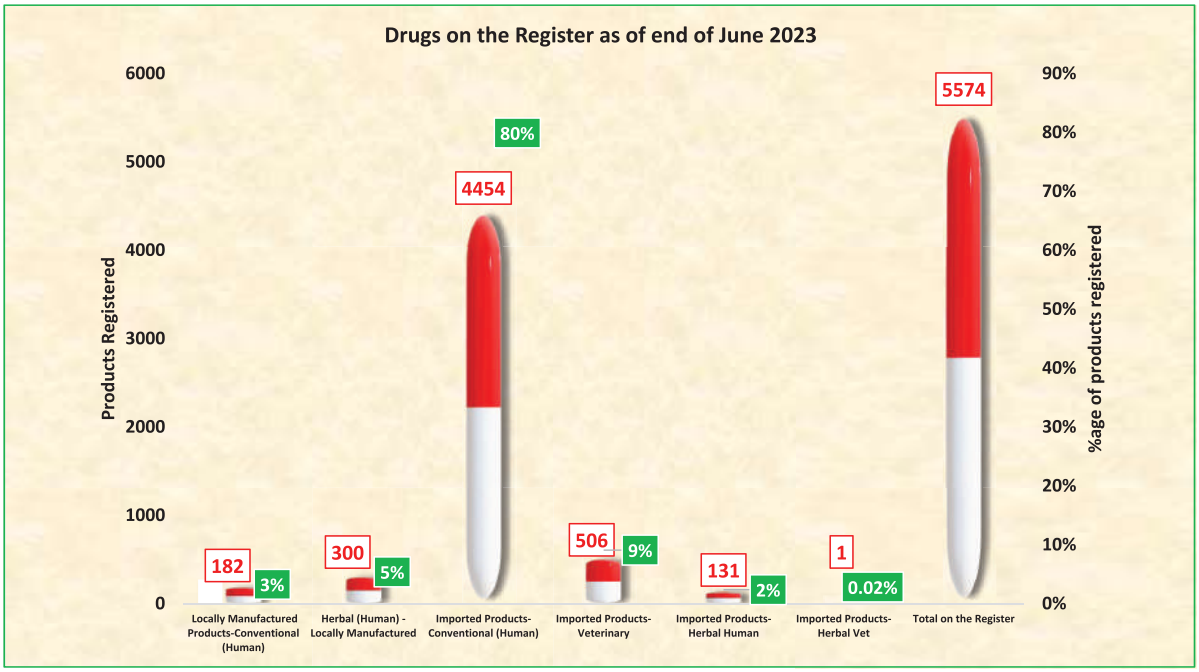
From the chart above, 85.9% (152 out of 177) of the clinical trial applications were evaluated and regulatory action was issued within the set Service Delivery Timeline against a set target of 90%. The performance where regulatory action was issued within the set service delivery timeline shows that the regulatory process is operating efficiently. In addition, it proves that the NDA ensures that the approved treatments meet safety and efficacy standards, thus safeguarding public health.

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 with the conditions of the clinical trial certificate and the principles of GCP. It was also noted that 12 GCP sites were inspected as compared to 20 GCP inspections for FY 2021/22. This promoted efficacy, safety, and quality of drugs on trial.

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

13.1.9. Product Registration

Currently, the cumulative Pharmaceutical human and veterinary drugs retained on the drug register are 5,574 products of which a total of 182 are locally manufactured Products for Conventional (Human) medicines contribute to 3% of medicines on the drug register, a total of 300 are locally manufactured products for herbal human contributing to 5%, a total of 4,454 are imported products for Conventional (Human) medicines contributing to 80%, a total of 506 are imported products for Veterinary medicines contributing to 9%, a total of 131 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.



According to the chart provided, the local herbal manufacturing industry has shown a significant improvement of 20% (from 250 for FY 2021/22 to 300 for FY 22-23). This progress can be attributed to the regional sensitization campaigns that were carried out to encourage herbalists to submit their products for evaluation and registration. Additionally, training sessions were held to educate herbalists on how to comply with the set standards, and benchmarking visits were conducted to already existing herbal manufacturing facilities to empower the new herbalists on how to manufacture their products effectively as illustrated in the picture below. This shows a stronger presence of local expertise or resources in herbal medicine production. Herbal medicines offer opportunities for indigenous knowledge integration and economic development.

Picture 2 shows the benchmarking visits conducted with local/domestic herbal manufacturers

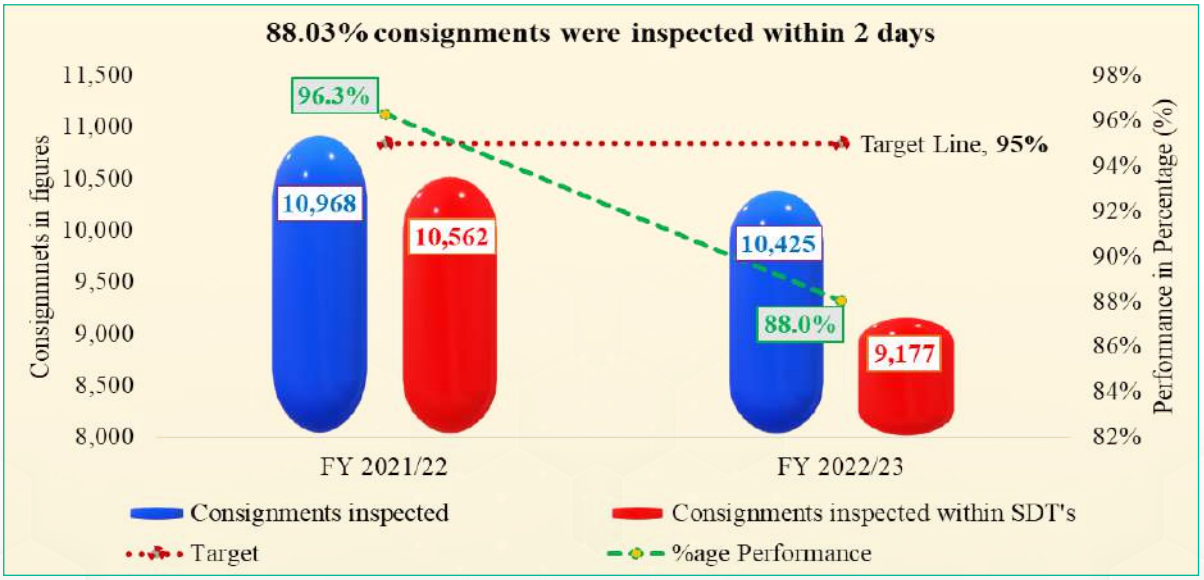
Benchmarking visits conducted with local/ domestic herbal manufacturers to support the development of herbal medicines and provide an avenue for capacity building of the domestic herbal manufacturing industry. The NDA herbal team visiting the Kazire manufacturing facility in Mbarara.

13.1.10. Development of the National Formulary

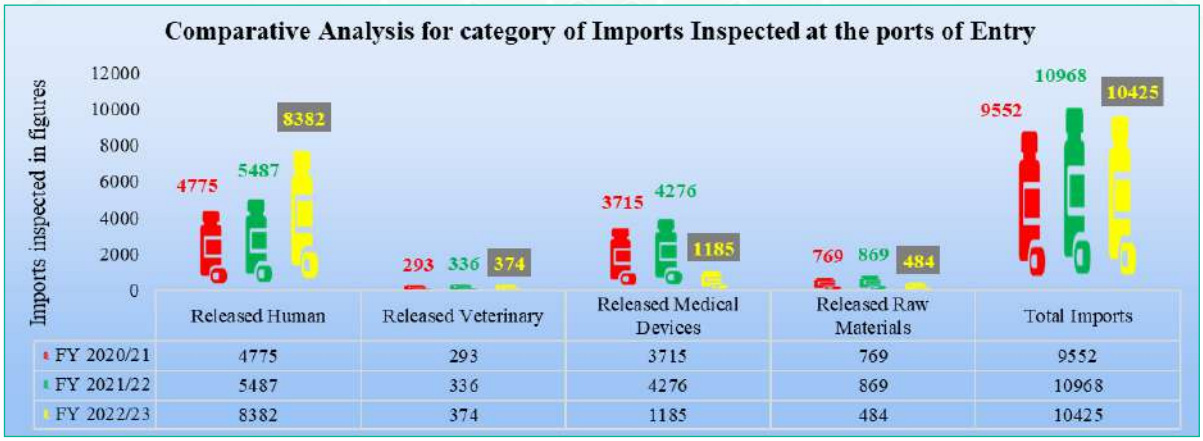
The Sixth Authority approved the first edition of the Uganda National Formulary for Human Drugs and shared it with the Ministry of Health.

13.1.11. 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 9,177 (88.03%) out of 10,425 consignments within two (2) days as compared a total of 10,562 (96.3%) out of 10,968 consignments for FY 2021/22. The graph below shows the comparative analysis for consignments inspected within two (2) days for FY 2021/22 and FY 2022/23.



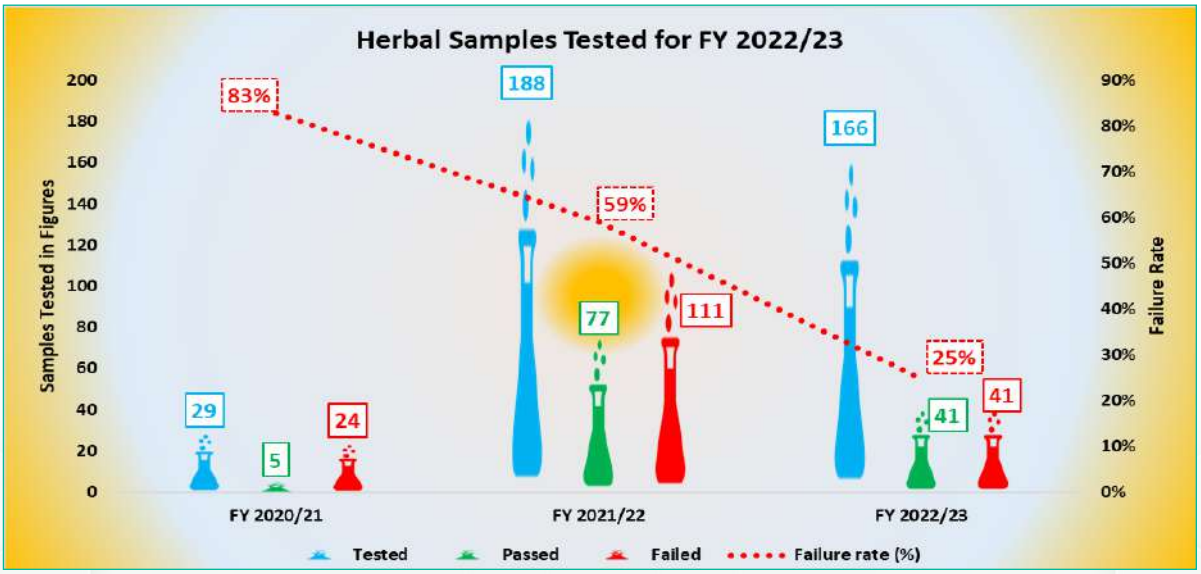
In addition, the category volume of imports inspected at the ports of entry comparative analysis for FY 2022-23 is illustrated in the chart below;



From the chart above, NDA registered a drop in the volume of imports inspected of 5% as compared to the volume of imports for FY 2021/22, and 156 (1.5%) of the consignments were sampled for quality control testing as compared to 251 (2.29%) for FY 2021/22 thus leading to improved quality product on the market. The drop in the number of imports reveals an increase in the number of products locally manufactured and there is a need for the Government of Uganda to reduce importation by giving subsidies and supporting the local manufacturing facilities to have a gradual increase in their production capacity.

13.1.12. Laboratory Testing of Herbal Products

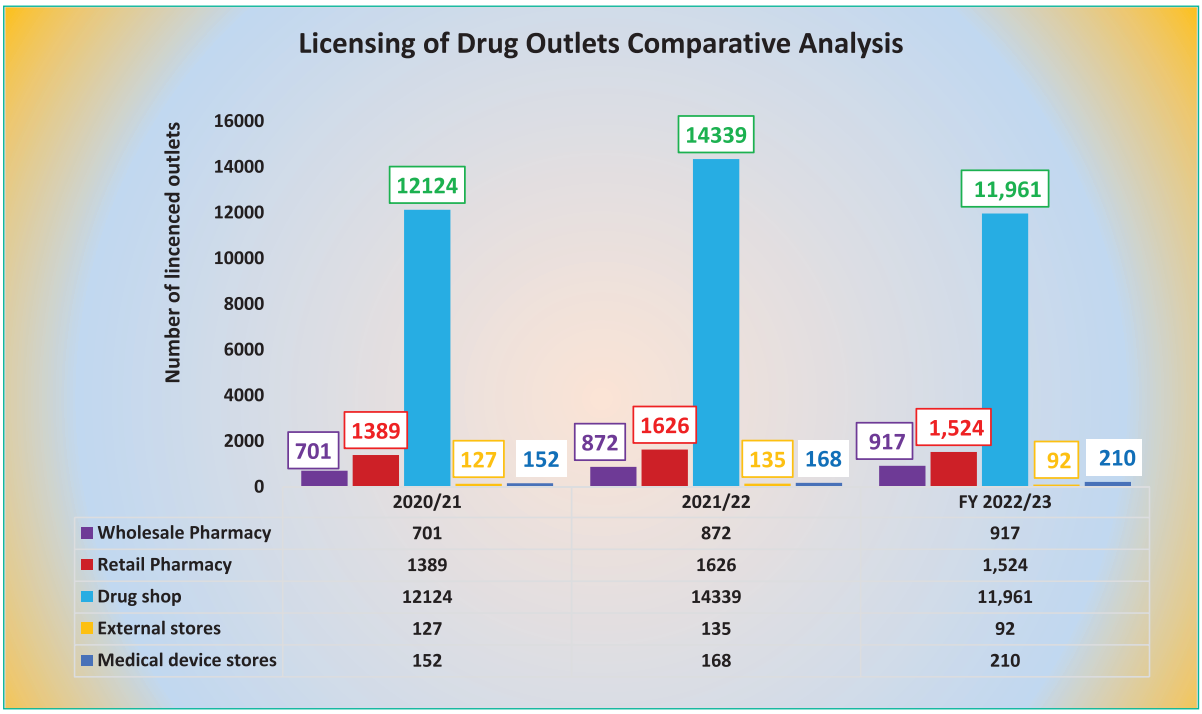
Acquired automated High-Performance Thin Layer Chromatography (HPTLC) equipment used in Herbal product testing. The table below shows the number of herbal products tested and the decrease in the failure rate from 59% for FY 2021/2022 to 25% for FY 2022/2023. The chart below shows the herbal samples testing analysis.



From the table above, the herbal failure rate has decreased from 59% (111 out of 188) for FY 2021/2022 to 25% (41 out of 166) for FY 2022/2023 implying that the quality of herbal products on the market has increased from 41% to 75%. The increase in the quality of herbal products is attributed to the 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 the Forty-one (41) samples of herbal medicine that did not comply with section 19 (5) of NDA Policy and Authority registration regulations, 2014, and most of these were manufactured locally.

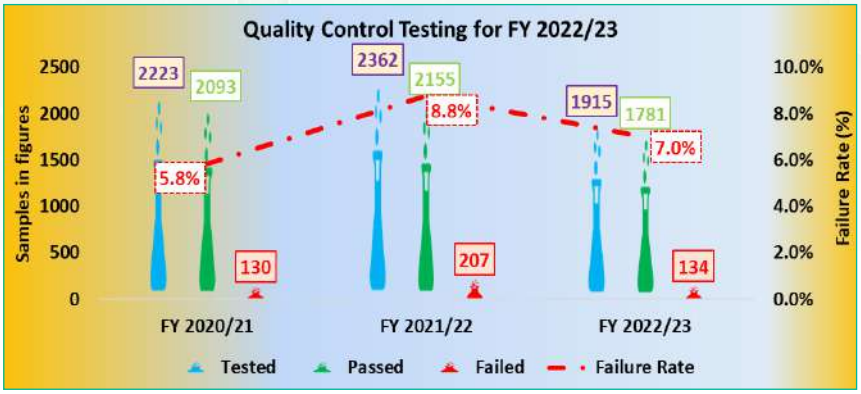
13.1.13. Licensing of Drug Outlets

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 917 against 929 applications received from wholesale pharmacies, approved 1,524 against 1541 applications received from retail pharmacies, approved 92 against 98 applications received from external stores, approved 210 against 214 applications for Medical device stores, and approved a total of 11,961 drug shops compared to 14,339 for FY 2021/22. Overall, NDA approved a total of 14,704 drug outlets of which 2,743 (19%) were pharmacies and 11,961 (81%) were drug shops. The licensing approval process conducted by the NDA ensures that the drug outlets meet certain standards of quality and safety. This helps to protect the public from counterfeit or substandard medications and ensures that they are receiving products that are safe and effective for their intended use.

13.1.14. Quality control Testing

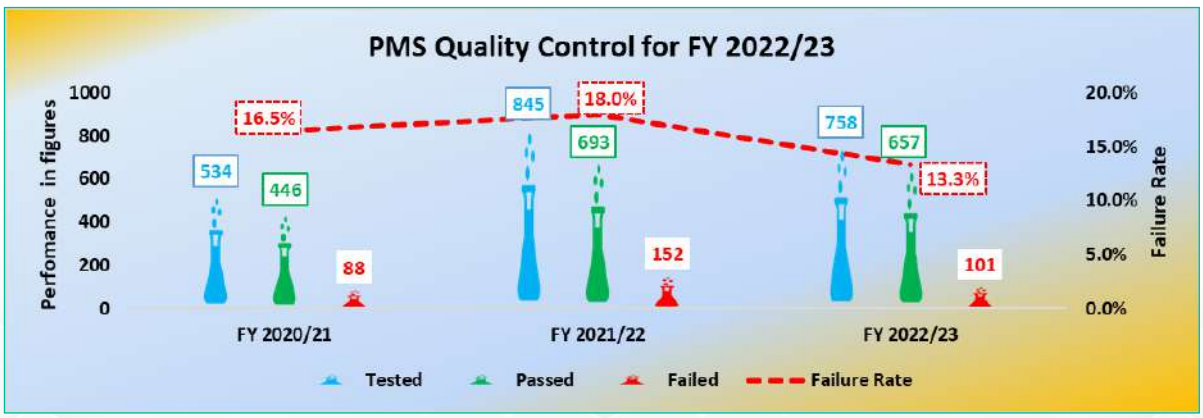


Samples tested mainly are drawn from three sources namely; routine Post-Market Surveillance, Pre-Market Samples, and Port of Entry. A total of 1,915 (79%) samples were tested out of 2,418 received against 2,810 planned samples. The planned target was not achieved because testing depends on the number of samples received from the market. The chart below presents the trend analysis of samples that passed the quality tests against those tested in FY 2022/23 and the previous two years back.

There was an improvement in the overall quality of pharmaceutical products from 91.2% for FY 2021/22 to 93.0% for FY 2022/23 thus leading to better health outcomes and reduced risks of adverse reactions or treatment failures. The quality percentage (%) improvement presented above is attributed to the increased surveillance of suspected substandard and falsified products on the market thus leading to the availability of safe products on the market. Samples were submitted to the laboratory for confirmation and the majority for example Hand Sanitizers, medical gloves, and herbal products were found to be substandard. These were recalled from the market and destroyed.

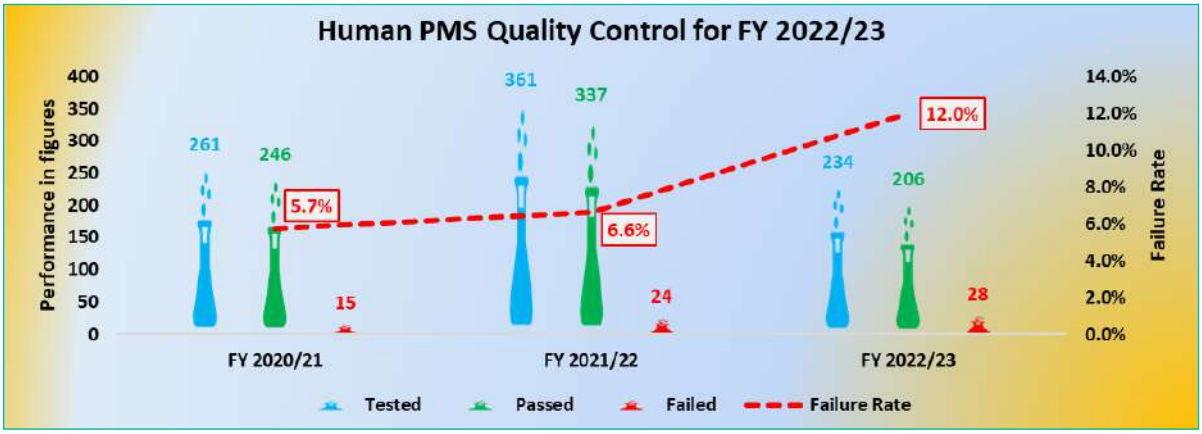
13.1.15. Overall PMS (Post Market Surveillance)

NDA Tested 758 samples for FY 2022/23 circulating in the market compared to 845 samples for FY 2021/22. There was an increase in the overall PMS pharmaceutical products quality from 82% for FY 2021/22 to 86.7% for FY 2022/23 thus leading to the availability of safe products on the market. The products that failed were recalled from the market and destroyed. The graph below shows the PMS comparative analysis.



13.1.16. Human Medicines under PMS

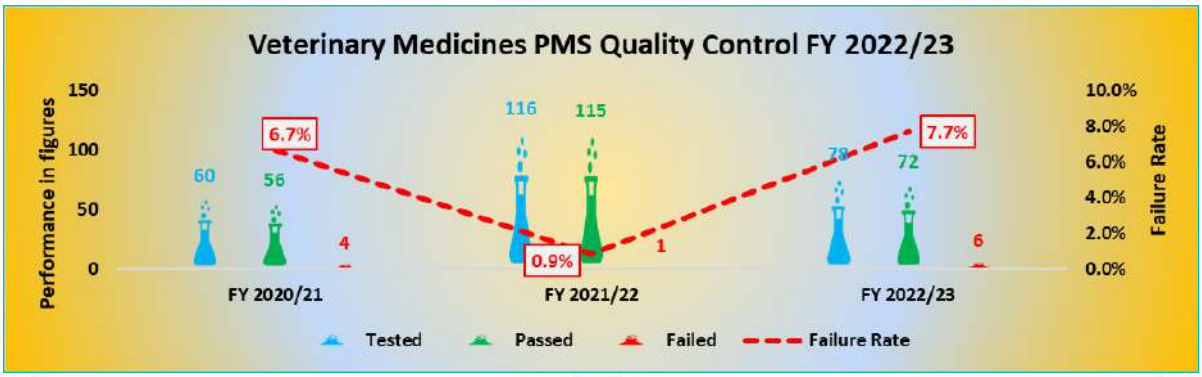
NDA tested 234 samples circulating in the market compared to 361 samples for FY 2021/22. There was an increase in the pharmaceutical quality failure rate up from 24 (6.6%) for FY 2021/2022 to 28 (12.0%) for FY 2022/23. Out of the overall PMS Quality failure of 13.3%, Conventional human medicine samples contributed (27.7%) to PMS sample failure. The graph below shows the Human PMS comparison analysis.



The increase in the failure rate above is attributed to the risk-based sampling that allowed NDA to conduct more thorough and frequent tests on high-risk categories, increasing the likelihood of detecting substandard products thus leading to enhanced protection of the public from substandard products and drugs.

13.1.17. Veterinary Medicines PMS

NDA conducted a quality test of 78 veterinary batches circulating on the market as compared to 116 batches for FY 2021/2022. There was an increase in the pharmaceutical quality failure rate from 1 (0.9%) for FY 2021/2022 to 6 (7.7%) for FY 2022/23. Out of the overall PMS Quality failure of 13.3% failure, Veterinary medicine samples contributed 5.9% of PMS sample failure. The graph below shows the Veterinary PMS comparative analysis.



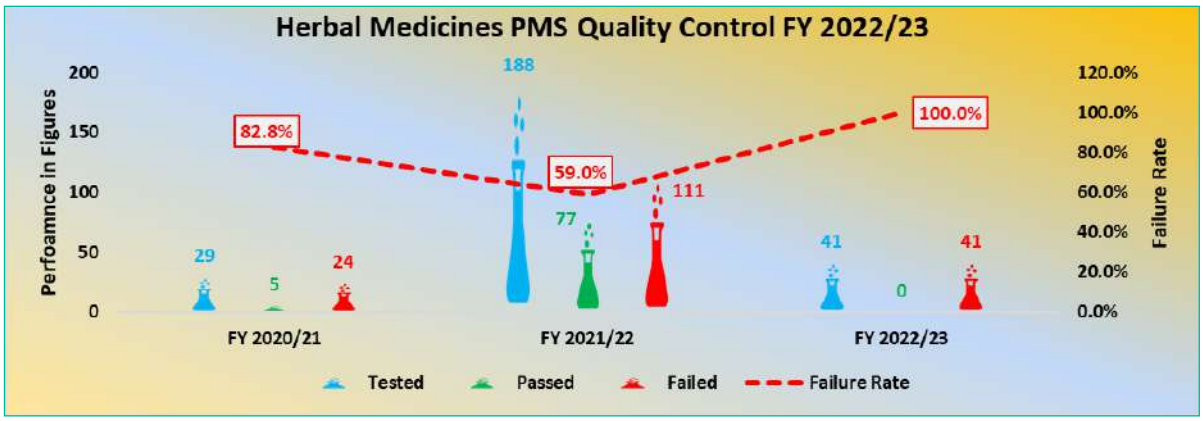
The increase in the failure rate above is attributed to the risk-based sampling that allowed NDA to conduct more thorough and frequent tests on high-risk categories, increasing the likelihood

of detecting substandard products thus leading to enhanced protection of the public from substandard products and drugs.

13.1.18. Herbal Medicines under PMS

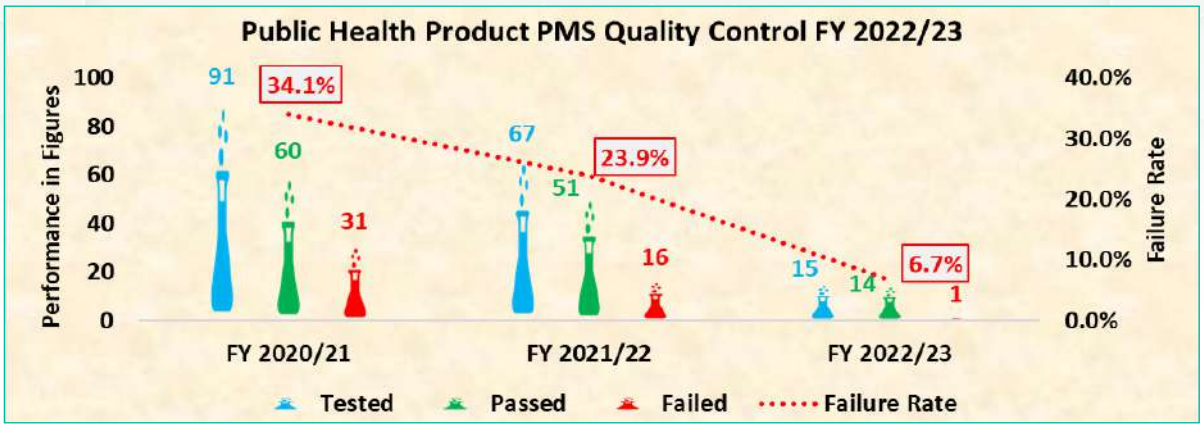
NDA Tested 41 batches circulating in the market as compared to 188 batches for FY 2021/22. There was an increase in the pharmaceutical quality failure rate from 111 (59%) for FY 2021/2022 to 41 (100%) for FY 2022/2023. Out of the overall PMS Quality failure of 13.3% failure, herbal medicine samples contributed 40% of PMS sample failure. The increase in the failure rate above is attributed to the risk-based sampling that allowed NDA to conduct more thorough and frequent tests on high-risk categories, increasing the likelihood of detecting substandard products thus leading to enhanced protection of the public from substandard products and drugs.

The graph below shows the Herbal PMS comparative analysis.



13.1.19. Public Health Products under PMS

NDA tested 15 batches of public health products and all the samples tested were face masks as compared to 67 samples of hand sanitizers tested for FY 2021/22 because of COVID-19. The pharmaceutical quality failure rate reduced from 16 (23.9%) to 1 (6.7%) for FY 2022/23 and they were all face masks. Out of the overall PMS Quality failure of 13.3%, Public health product samples contributed to 1% of PMS sample failure. This improves the availability of safe products on the market. The graph below shows the Public Health Product PMS comparative analysis.



13.1.20. Drug Recalls

In the period under review, 25 drug recalls were handled compared to 15 recalls for FY 2021/22. 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) reports to avoid the recurrence of the failure or defect in the future. The table below shows a list of products that were recalled from the market in FY 2022/23.

No.	Date Initiated	Brand Name	Batch Number/s	Local Technical Representatives (LTR)	Manufacturer	Reason/Problem
1	24-06-22	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
2	15-08-22	Mediworld Auto Disposable Syringes	210301	Mediworld Pharma Africa Ltd	Anhui Tiankang Medical Technology Co. Ltd - No 228 Weiyi Rd, Economic Development Zone, Tiankang City, Anhui, China	Failure of ISO 7886-4 Specification for Reuse Prevention Feature
3	19-08-22	Ad Syringe With 3ml Needle	2001k1	Biomed Africa Ltd	El Dawliaico International Company for Medical Necessities	Product batch failed the iso 7886-4 specification for the reuse prevention feature

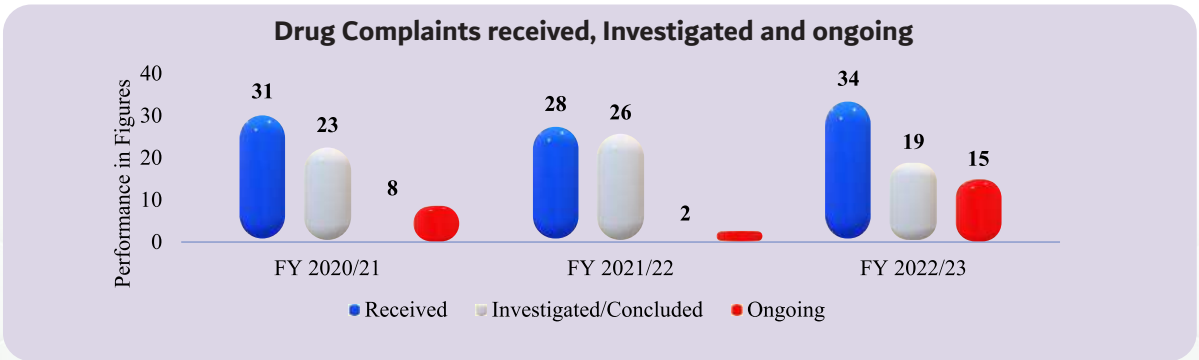
No.	Date Initiated	Brand Name	Batch Number/s	Local Technical Representatives (LTR)	Manufacturer	Reason/Problem
4	19-08-22	Oxytocin Injection 10 Iu	121016	Gittoes Pharmaceuticals Ltd	Sakar Healthcare Pvt Limited	Product Batch failed the USP Specifications for the Visible Particulate Matter.
5	22-08-22	Aspirin 300mg	All Batches	Harley's (U) Ltd and Royal Pharma 2011 Ltd	Laboratory & Allied Ltd	Recrystallization of Tablets
6	22-08-22	Toto Gripe Water	A21017 & A21018	Metro Pharmaceuticals Ltd	Kesar Pharma Pvt Ltd	Particulate Matter Present in Bottles
7	22-08-22	Oxytocin Injection 10 Iu	128109	Tata (U) Ltd	Gland Pharma-ceuticals Ltd - India	Product Batch failed USP Specifications for Visible Particulate Matter
8	22-08-22	Endospec 10% 1 Ltr Pack	2008019	Bimeda (U) Ltd	Medisel Kenya Limited	Product Batch Failed to Comply with Manufacturers and USP Specifications for Ph
9	22-08-22	Revital Syringes	215307	Maisha Medical Supplies Ltd	Revital Healthcare (Epz) Limited	Product Batch failed the Iso 7886-4 Specification for Re-Use Prevention Feature.
10	02-09-22	Revital Syringes	215307	Royal Pharma 2011 Ltd	Revital Healthcare (EPZ) Ltd	Failure to comply with iso 7886-4 specification for re-use prevention feature
11	21-09-22	BUZIRA CEFU HERBAL COUGH SYRUP	20191207	Buzira Herbal Company	Buzira Herbal Company	Products have misleading indications that is different from the samples that were approved for notification by the Directorate of Product Assessment and Registration

No.	Date Initiated	Brand Name	Batch Number/s	Local Technical Representatives (LTR)	Manufacturer	Reason/Problem
12	21-09-22	AD Auto Disposable Syringe and Needle	210625	Multiple Super Investments Ltd	Changzhou Medical Appliances General Factory Co. Ltd, Jiangsu - China	Failure to Comply with ISO 7864 & ISO 7886-4 Specifications for Re-use Prevention Feature
13	21-09-22	E-J Euroject Ii Syringe and Needle	2019207	Surgimed (U) Ltd	Jiangsu Zhengkang Medical Apparatus Co. Ltd	Product Batch Failed Iso 7864 & Iso 886-4 Quality Specifications for the Re-Use Prevention Feature
14	13-10-22	Ivanor	210508C & 210529C	Jubail Aggrotech Ltd	Hebei Hope Harmony Pharmaceutical Co Ltd	Failure to Comply with USP Specifications for Particulate Matter
15	02-11-22	Lecotrim Suspension 50ml	78247 And 79171	Royal Pharma 2011 Ltd	Laboratory & Allied Ltd	Failure to Comply with USP Specifications for PH tests
16	29-11-22	M-Forlin	JR1003	Metro Pharmaceuticals Ltd	Lincoln Pharmaceuticals Ltd	Failure to Comply with BP Specifications for Dissolution test.
17	01-02-23	Alphapor 500ml	BE21000371& BE21000733	Nile Services Ltd	Chimac S.A RUE De Renory 26/2, B-4102 Ougree - Belgium	Deformed Bottles
18	08-02-23	Sypertix 10%	2073510NKL	Norbrook (U) Ltd	Norbrook Kenya Ltd	Failure to Comply with CIPAC/In-House Specifications for Assay tests
19	09-02-23	Norotraz	2461 505NLK	Norbrook (U) Ltd	Norbrook Kenya Ltd	Failure to Comply with Specifications for Identification and Assay tests
20	09-02-23	Diprofos 7mg/Ml	W012878 And W025759	ERIS LTD	Organon Heist BV, Industrial Park 30 B-2220 Heist-OP-Den-Berg; Belgium	Presence of Particulate (Stainless Steel) Particles

No.	Date Initiated	Brand Name	Batch Number/s	Local Technical Representatives (LTR)	Manufacturer	Reason/Problem
21	28-02-23	Diprofos 7mg/Ml	W005050, W012878, W015902, W020203, W025759	Surgipharm (U) Ltd	Organon Heist BV Industrial Park - Belgium	Presence of Particulate Matter
22	03-03-23	Auto Disposable Syringe 10ML	220521	Mediworld Pharma Africa Ltd	Biomax Healthcare Pvt Ltd	Failure to Comply with ISO 7886-4 Specifications For Re-Use Prevention Feature
23	17-03-23	Auto Disposable 2ml Syringes	200120	Multiple Super Investments Ltd	NA	Failure to Comply with ISO 7864 And 7886-4 Specifications for Re-Use Prevention Feature
24	22-03-23	Revital Syringes	224703, 228704 and 223908	Maisha Medical Supplies Ltd	Revital Healthcare (EPZ) Ltd, LR. No. 5025/1239, Taking 80100 - Mombasa	Failure for Comply with ISO 7886-4 Specifications for Re-Use Prevention Feature
25	22-03-23	Medsunate -60	MAI-042207	Med Novation Enterprises Ltd	East African (India) Overseas	Failure to Comply with International Pharmacopoeia Specifications for Uniformity of Mass

13.1.21. Drug complaints

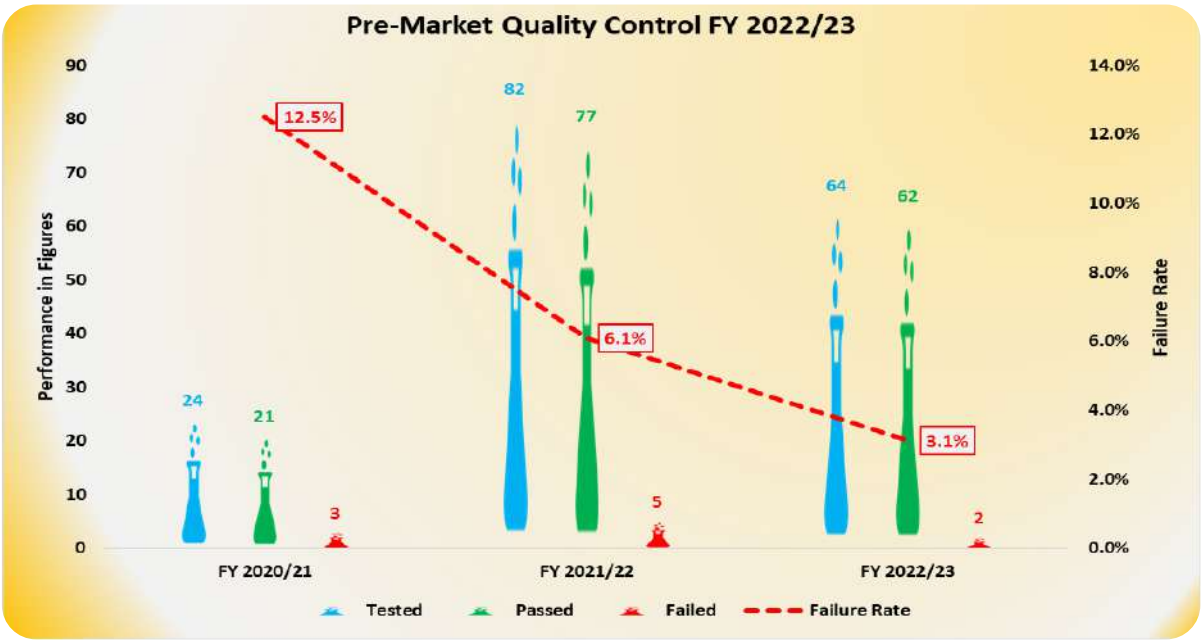
A total of 34 drug product-related complaints were received in FY 2022/2023, compared to 28 in the previous financial year. Of the complaints received accounted for 58.8% (20) were conventional human products, 17.6% (6) were medical devices, 11.8% (4) were herbal products, and 11.8% (4) were veterinary drugs as presented in the chart below.



As indicated in the chart above, the increase in total complaints from 28 to 34 suggests sharp vigilance and possibly an improvement in the reporting system. More complaints indicate that the public and healthcare providers are more aware and proactive in identifying and reporting potential issues with drug products, which is crucial for the early detection of public health risks. This helps in the effective allocation of resources for testing and monitoring human drugs, which constitute the majority of complaints, ensuring that these products meet safety and efficacy standards.

13.1.22. Pre-Market samples

NDA Tested 64 batches of drugs locally produced before they were allowed on the Ugandan market as compared to 82 samples for FY 2021/22. The failure rate dropped from 5 (6.1%) in FY 2021/22 to 2 (3.1%) for FY 2022/23. The medicines that failed included; two (2) samples of Chlorphenamine that failed Assay & Dissolution and in the FY 2021/22, the failed five (5) samples included the two (2) samples of Metronidazole and three (3) samples of Paracetamol both failing Assay test.



From the chart above drop in the failure rate of drugs from 6.1% to 3.1% is a positive development with far-reaching implications for the public, including improved patient safety, increased trust in medications, reduced healthcare costs, and enhanced quality of life. It emphasizes the importance of ongoing efforts to ensure the safety and efficacy of pharmaceuticals for the benefit of individuals and society as a whole.

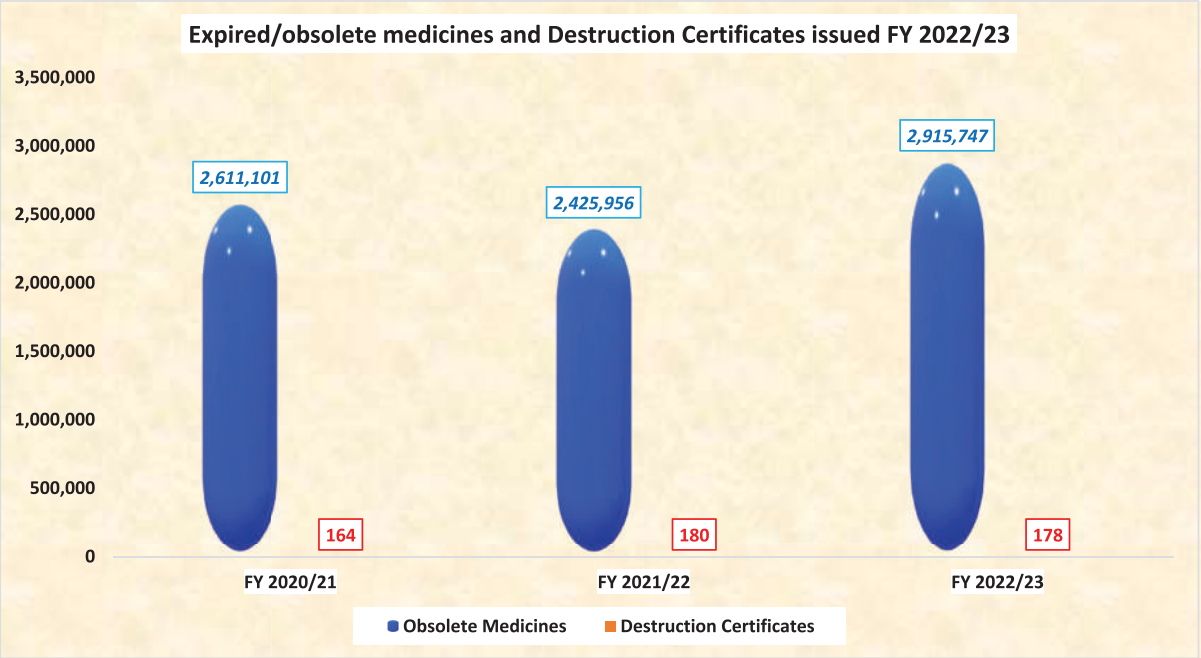
13.1.23. Port of Entry Samples

Medicine samples tested were 1,093 batches of which 31 (2.8%) failed the quality test (3 human medicine, 2 veterinary medicine, 5 condoms, 12 medical gloves, and 9 syringes) and all the failures were not allowed into the market for circulation as compared to 50 (3.5%) failure against

1,435 samples tested for FY 2021/2022. For medical devices, a total of 757 (110.3%) batches were tested out of the 686 batches received as compared to 950 batches that were tested the previous year FY 2021/22.

13.1.24. 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 2,915,746.76 kgs for FY 2022/23 from the public health facilities and PNFPs as compared to 2,425,956 kgs for FY 2021/22. A total of 178 destruction certificates were issued as compared to 180 for FY 2021/22 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. The chart below shows the analysis of expired products that were destroyed and certificates issued.

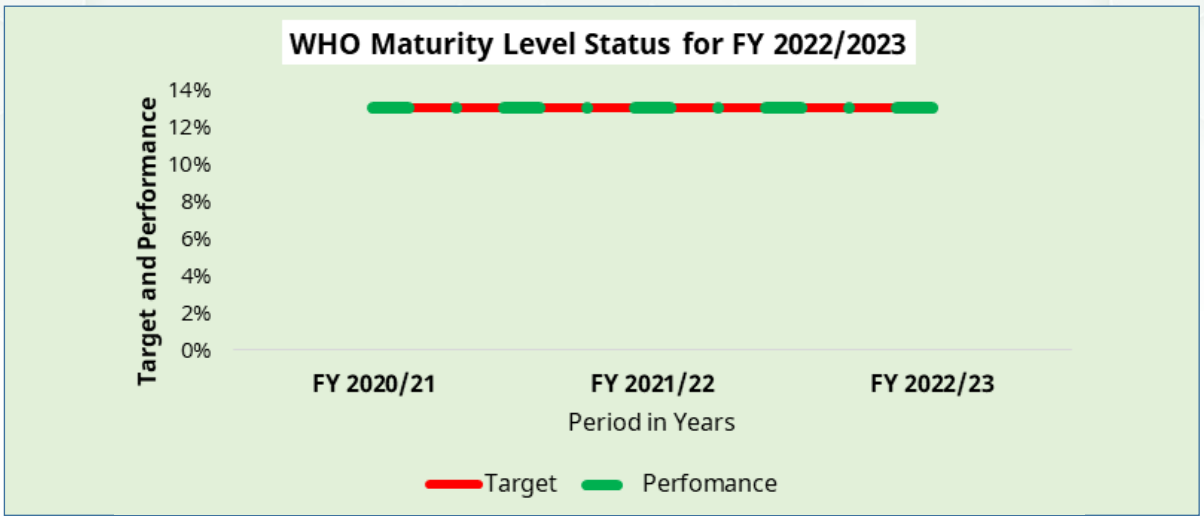


13.1.25. Strategic Plan Effectiveness Measurement under Focus Area 1

NDA has Key Performance indicators that are used in measuring the achievement of the strategic plan's effectiveness for the four focus areas including Core Service Delivery (Objective 1), Legal and Regulatory Framework (Objective 2), Awareness, Engagement, and Collaborations (Objective 3), and Institutional Development Objective (4).

Trend performance on KPIs Measuring the effectiveness of Strategic Objective 1 under Focus Area 1.

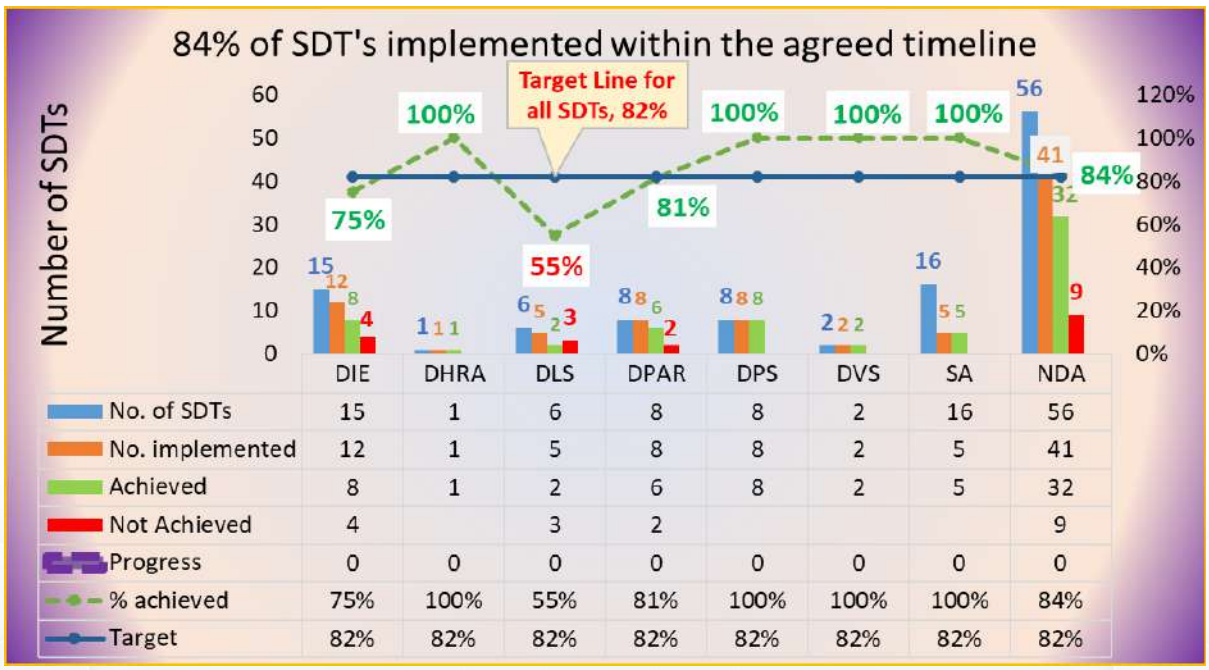
Percentage of regulatory functions meeting World Health Organization (WHO) Maturity Level 3. The chart shows the trend analysis for maturity level status for FY 22/23



The chart above shows that out of the eight (8) WHO regulatory functions, NDA has one (1) function of the Laboratory that reached and exceeded Maturity Level three (3). The seven regulatory functions are at maturity level two (2) and one because of the legal aspect of the NDA law. This implies that there are regulatory challenges or barriers within the NDA's legal framework that hinder the advancement of its seven (7) regulatory functions to higher maturity levels as defined by the WHO.

Proportion of SDTs implemented within the agreed timeline.

Currently, NDA has a total of fifty-six (56) Service Delivery Timelines. The graph below highlights the directorate performance in service delivery to the clients against the set targets or agreed service delivery timelines.



The Directorate of Inspection and Enforcement (DIE) achieved 75% against the set target of 82% in regards to the Service delivery timelines implemented and reported on during the FY 2022/2023. The directorate has a total of fifteen (15) SDT's but implemented twelve (12) contributing to a percentage implementation of 83%. The M&E unit didn't monitor the three (3) indicators because of system related issues that affected measurement. However, out of the twelve (12) implemented services, the directorate managed to implement eight (8) services within the agreed timeline and four (4) were implemented within a percentage variance of above 10% above the set timeline thus contributing to an average performance of 75% and there is a need for the directorate to develop a sustainability strategy and ensure 100% implementation of SDT's in the FY 2023/2024.

The Directorate of Human Resource and Administration (DHRA) achieved a performance 100% against the set target of 82% in regards to the Service delivery timelines implemented and reported on during the FY 2022/2023. The directorate has a total of one (1) SDT and implemented it contributing to a percentage implementation of 100%. The directorate managed to implement it within the agreed timeline and there is a need for the directorate to develop a sustainability strategy.

The Directorate of Product Safety (DPS) achieved a performance of 100% against the set target of 82% in regards to the Service delivery timelines implemented and reported on during the FY 2022/2023. The directorate has a total of eight (8) SDT's and implemented all contributing to a percentage implementation of 100%. However, out of the eight (8) implemented indicators, the directorate managed to implement all the indicators within the agreed timeline thus contributing to an average performance of 100% and there is a need for the directorate to develop a sustainability strategy in the FY 2023/2024.

The Directorate of Product Assessment and Registration (DPAR) achieved a performance of 81% against the set target of 82% in regards to the Service delivery timelines implemented and reported on during the FY 2022/2023. The directorate has a total of eight (8) SDT's and implemented all contributing to a percentage implementation of 100%. It was realized that out of eight (8) implemented indicators, the directorate managed to implement six (6) services within the agreed timeline and two (2) were implemented within a percentage variance of 10% above the set timeline thus contributing to an average performance of 81% and there is a need for the directorate to sustain the performance in the FY 2023/2024.

The office Secretary to the Authority achieved a performance of 100% against the set target of 82% % in regards to the Service delivery timelines implemented and reported on during the FY 2022/2023. The directorate has a total of sixteen (16) SDT's but implemented only five (5) contributing to a percentage implementation of 31%. The M&E unit didn't measure the eleven (11) services because there were no requests received that would be handled under these procurement methods. However, out of the five (5) implemented services, the directorate managed to implement all within the agreed timeline contributing to 100% and there is a need for the directorate to develop a sustainability strategy.

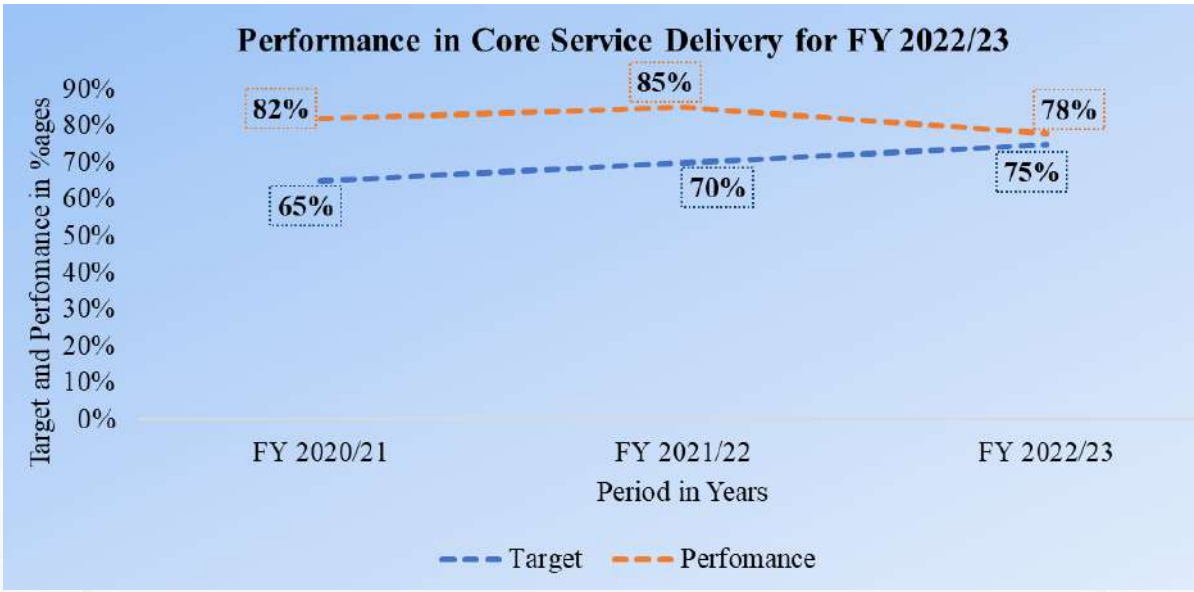
The Directorate of Laboratory Services (DLS) achieved 55% against the set target of 82% in regards to the Service delivery timelines implemented and reported on during the FY 2022/2023. The directorate has a total of six (6) SDT's and implemented five (5) services contributing to an implementation rate of 83%. However, out of the five (5) implemented services, the directorate

implemented two (2) services within the agreed timeline and three (3) services implemented within a percentage variance of 10% above the set timeline thus contributing to 55% and there is a need for the directorate to improve the performance for the FY 2023/2024.

Generally, NDA has an overall 56 Service Delivery Timeline Indicators. 41 (73%) out of 56 SDTs were implemented during the FY 2022/2023 and it was noted that 34.5 (84%) out of 41 were implemented within the agreed timelines. Fifteen (15) SDTs were not measured because of system related issues and there were no requests received that would be handled under these procurement methods and systems related issues for tracking performance. The 16% services were implemented beyond the agreed timelines because of the following reasons highlighted below

1. Some of the outliers result from a lack of timely response to client queries that led to untimely approval of registered product proforma.
2. Some inspections were scheduled late in the year because members had to attend other directorate activities.
3. Applications for facilities in Bangladesh that were not inspected due to delayed Visa approvals for the same country.
4. Delayed scheduling and completion of audits due to other departmental activities which affected the department in giving feedback within the agreed time.
5. Manual and late testing of samples for release due to challenges in LIMS handling data analysis affected the implementation of the service within the agreed timelines.
6. The samples reporting through LIMS were met with system errors that delayed release.
7. Also, the analysis involved an out-of-scope investigation which delayed the release.
8. More effort was put towards assessing variation additional information and the variation in SDT was also compounded by the grouping of different categories of variations by applicants.

Proportion of improved performance in core service delivery



NDA planned to achieve a total of seventy-seven (77) core outputs and by the close of the financial year, a total of fifty-nine core outputs were achieved reflecting a percentage achievement of 78% as compared to the set target of 75%. The set target was achieved during the year. However, there was a drop-in performance by 9% as far as achieving the core outputs is concerned from 85% (94 out of 105 implemented) for FY 2021/22 to 78% (58.9 out of 77 implemented). The organization experienced a drop-in performance due to various operational challenges arising from limited resources and manpower. These challenges included low staffing levels, insufficient capital reserves, delayed acquisitions, and inadequate staffing levels for internal controls, all of which have negatively affected service quality and delivery. Additionally, budget and resource constraints have impacted stakeholder collaboration. However, NDA is working to prioritize and allocate resources strategically to meet critical needs and minimize operational setbacks.

13.2. 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;

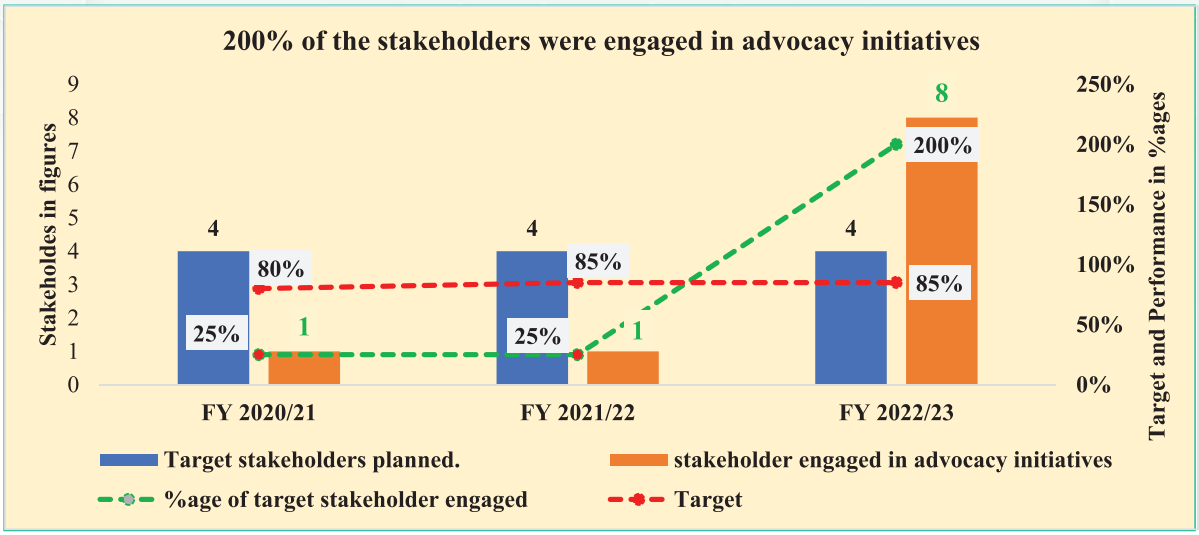
Strategic Intervention 2.1: Advocate for an improved regulatory framework.

13.2.1. Stakeholder Engagements in advocacy initiatives.

Trend performance on KPIs Measuring the effectiveness of Strategic Objective 2 under Focus Area 2.

Proportion of target stakeholders engaged in advocacy initiatives.

This focuses on the adequate delivery of regulatory services by the Drug Authority. The performance of 100% (8 advocacy engagements against the 4 planned) was achieved. There was a performance improvement for this financial year as compared to 25% for the previous year. However, 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 of stakeholder advocacy initiatives for FY 20/21 and FY 21/22.



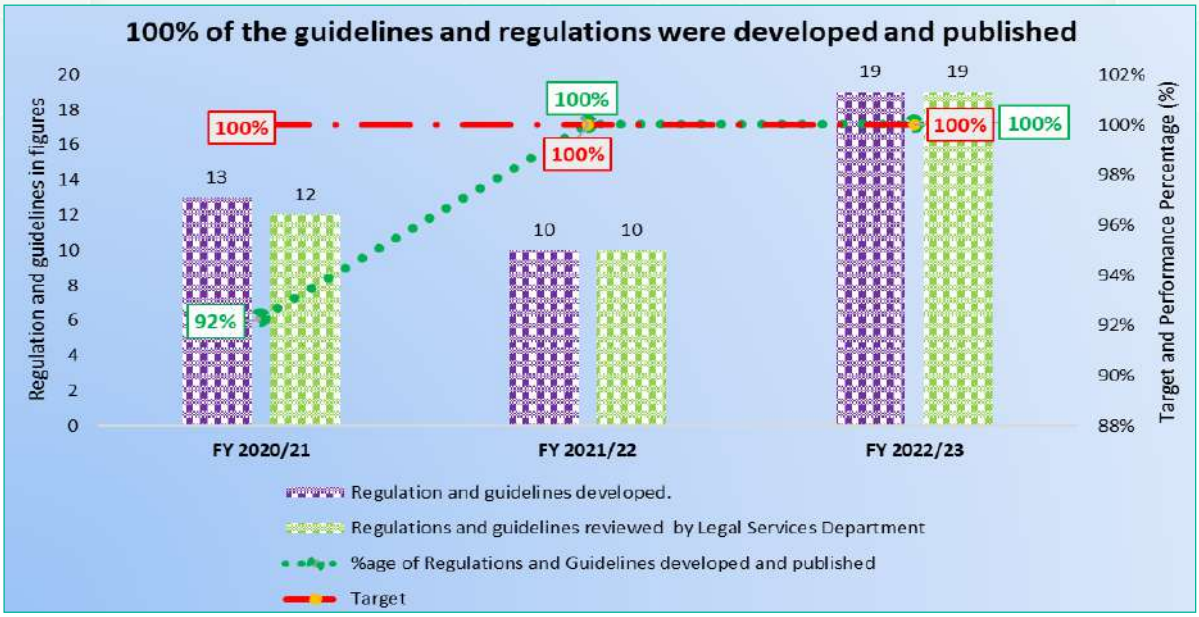
From the chart above, the performance represents a significant rise in the number of stakeholders actively involved in advocacy efforts. Additionally, the percentage of target stakeholders engaged also increased notably from 25% in FY 2021/22 to 200% in FY 2022/23, indicating an over-achievement of the engagement target. This suggests that advocacy efforts have been particularly successful in reaching and involving stakeholders. This implies that there has been a remarkable increase in stakeholder engagement.

Strategic Intervention 2.2: Strengthen the regulatory framework.

13.2.2. Regulations and Guidelines Developed and Published

Proportion Regulations or Guidelines developed and published.

NDA developed regulatory guidelines for different processes, which were shared with internal and external stakeholders to help clients comply with NDA's and international standards for medicines and health products. In FY 2022/23, NDA developed and published a total of 19 (100%) guidelines and regulations against 19 that were received as compared to 10 (100%) against 10 received for FY 2021/22. This performance improvement has resulted in a 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 22/23 and the previous years.



From the chart above the overall implication is that the data reflects positively on the NDA's regulatory efforts and its dedication to maintaining high standards in the oversight of medicines and health products thus contributing to enhancing public health and safety.

Transformation of NDP&A Act into UNFDA.

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

13.3. 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, and regional and international organizations to create visibility and enhance execution of the 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;

Strategic Intervention 3.1: Strengthen mechanisms for stakeholder awareness and engagement.

13.3.1. Stakeholders Engagement List.

NDA has also effectively engaged major stakeholders (Parliament, MOH, MAAIF, NMS, Police, Ministry of Finance, Planning and Economic Development, 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.

13.3.2. Veterinary Stakeholder, Engagements and Collaborations

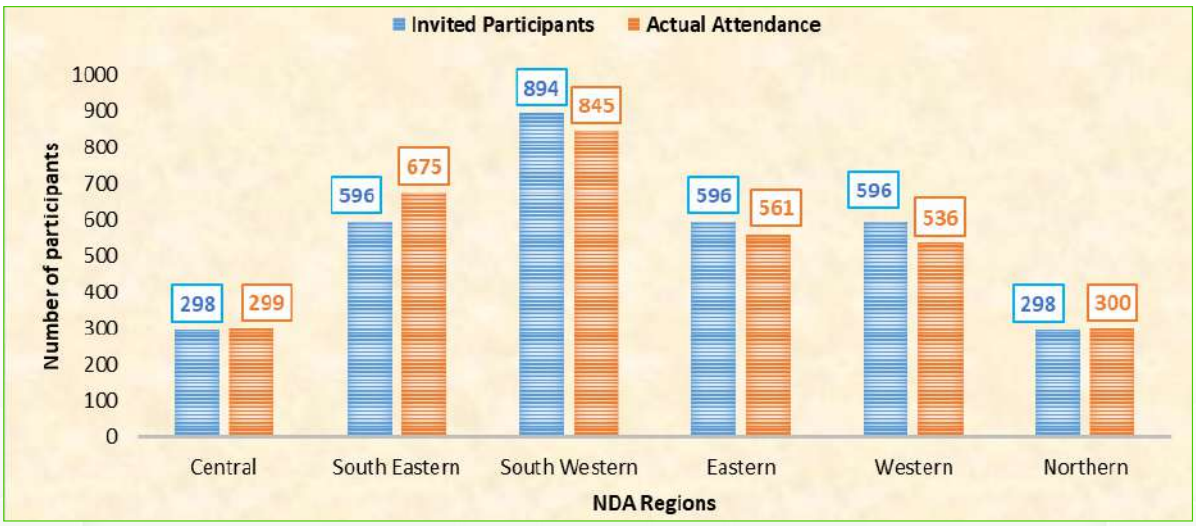
NDA has made strides in engaging veterinary stakeholders both national and international to ensure efficient veterinary medicines regulation. The different stakeholders are veterinarians, Para veterinarians, farmers, veterinary drug outlet operators, opinion leaders, academia, the East African Community (EAC), Codex Alimentarius, the World Organization for Animal Health (WOAH), Pan African Veterinary Vaccine Center of African Union (AU-PANVAC), the Global Alliance for Livestock Veterinary Medicines (GALV med) and many more.

During the financial year 2022/2023, several engagements were conducted- ed in various districts across all regions in the country and these included sensitizations, trainings, radio and TV talk shows, and farm visits. In an attempt to equip the public with relevant drug promotion, several I.E.C materials were distributed and these comprised posters, brochures, calendars, and notebooks.

13.3.3. Sensitization meetings at the county level

NDA conducted one hundred and seventy-seven (177) subcounty-level sensitization meetings in twenty-two (22) districts across all regions in the country. Engagements started with the district officials that included the Chief Administrative Officers (CAOs), the Resident District Commissioners (RDCs), Local Council V (LC5s), District Production Officers (DPOs), and the District Veterinary officers (DVOs). In each district, a total of 8 sub-counties and town councils were selected with the guidance of the respective DVOs for sensitizations. In attendance were selected farmers, the sub-county extension workers, sub-county chiefs, LC3s, and the Ministry of Agriculture, Animal Industry and Fisheries (MAAIF) zonal inspector of the relevant District.

Graph showing the level of participation of the invited stakeholders per NDA regional office.

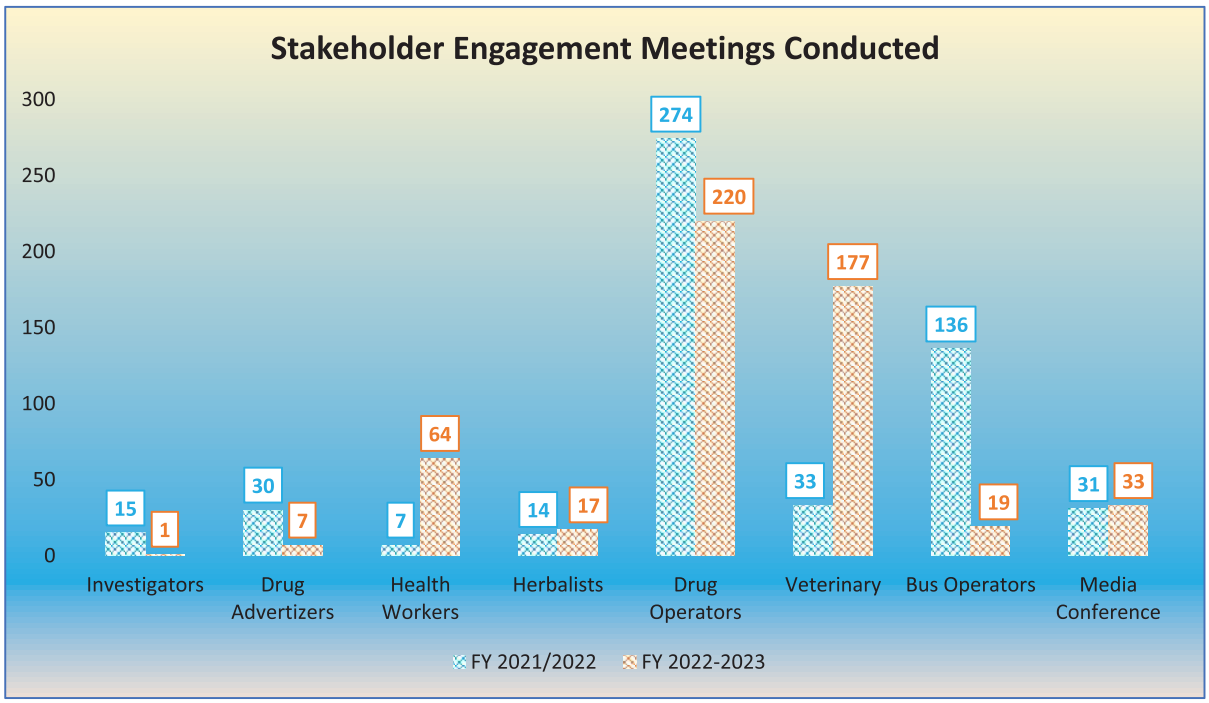


Southwestern being a cattle corridor region registered a higher level of stakeholder participation during the subcounty level engagements than other regions. This is attributed to the overarching issues and challenges that have remained a threat to both livestock production and public health. These include tick resistance to the available acaricides, irrational drug usage, and counterfeiting

Strategic Intervention 3.2: Enhance internal corporate and public relations functions.

13.3.4. Stakeholder Engagements Conducted.

NDA is cognizant of the need for accurate information flow with stakeholders through defined channels to enhance its image, reputation, trust, transparency, and integrity. There were 538 engagements with various stakeholders across the country compared to 540 in FY 2021/22 as indicated in this graph.



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

13.3.5. Publications for the National Drug Authority

The NDA's publications section is a vital resource for stakeholders, providing insights into the organization's activities, accomplishments, and plans. Through transparent reporting and dissemination of information, the NDA aims to foster trust, encourage collaboration, and ultimately ensure the health and well-being of the population. NDA made publications to the

public through three categories namely; the NDA website, Magazines, and Newspapers as illustrated in the table below.

No	Publication Name	Objective of the publication	Source	Date
1.	Annual Pharmacovigilance report 2022/23.	To provide a comprehensive overview of our activities in drug safety monitoring, highlighting the key achievements, challenges, and initiatives undertaken during the reporting period.	https://www.nda.or.ug/wp-content/uploads/2023/12/ANNUAL-PHARMACOVIGILANCE-REPORT-2022_23-1-1.pdf	FY 2022-2023
2.	NDA Pharmacovigilance Bulletin 2022 Volume 15 Issue 1,2,3 & 4.		https://www.nda.or.ug/directorate-of-product-safety/#DPSBulletins	
3.	Anti-hawking, substance, and drug abuse.	To contribute to a safer, healthier, and more informed community.	Independence Magazine	Oct-22
4.	Say no to drug hawkers.	To contribute to a safer and more informed community, ultimately protecting individuals from the dangers of unregulated drug sales.	Tahere Sita Magazine	Feb-23
5.	Say no to drug hawkers.		Officer Cadet magazine	Feb-23
6.	Say no to drug hawkers.		Habari Magazine	Oct-22
7.	Highlights of NDA Achievements in a year.	The publication aims to reinforce the NDA's role in safeguarding public health, demonstrate its effectiveness, and encourage ongoing support and collaboration from various stakeholders.	Fundamental publications	Feb-23
8.	Highlights of NDA Achievements in a year.		Visionaries of Uganda magazine	Nov-22
9.	Two articles on Reporting any side effects after the use of drugs to the National Drug Authority.	These articles likely aim to support the NDA's efforts to maintain a robust pharmacovigilance system and safeguard the population against harmful drug effects.	Daily Monitor and New Vision News Papers	Oct -09-22 and Feb-26-23

No	Publication Name	Objective of the publication	Source	Date
10.	2023 Annual Pharmaceutical Quality Control Convention.	This was a platform to interact and have technical discussions with local manufacturing partners and Over 50 representatives from Local Manufacturing companies were in attendance.	https://www.nda.or.ug/2023-annual-pharmaceutical-quality-control-convention/	June 8, 2023
11.	World Patient Safety Day	NDA joined the Ministry of Health and all Ugandans to celebrate World Patient Safety Day as our commitment is to ensure the availability of quality safe medicines that work well.	https://www.nda.or.ug/world-patient-safety-day-2/	September 15, 2022

In addition, other publications were uploaded on the NDA website (https://www.nda.or.ug) including 12 drug registers were uploaded to the website, along with 9 guidelines. Additionally, 9 tenders were posted to invite bids for large projects. The website also featured 32 forms for different services, 7 circulars announcing bans on various products, and 7 latest news sections. The helped NDA to foster trust, encourage collaboration, and ultimately ensure the health and well-being of the population.

Strategic Intervention 3.3: Enhance stakeholder collaboration and partnership at national, regional and international levels.

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

Activities Implemented during the contract period	FY 20/21	FY 2021/22	FY 2022/23
EAC MRH joint dossier assessment.	2	4	8
Expert Working Group meetings were held to review GMP inspection reports.	3	2	0
EAC joint GMP inspections.	8	1	14
Technical Committee meetings.	10	0	8
Steering Committee meetings.	9	3	0
Survey on the proportion of Substandard and Falsified (SF) medicines.	0	1	0

Activities Implemented during the contract period	FY 20/21	FY 2021/22	FY 2022/23
Expert Working Group Meetings (Finance, Clinical Trials, Pharmacovigilance, Medical Devices and IVDs).	9	0	0
EAC Regional Experts to develop a roadmap towards implementation of the EAC Technical Cooperation Framework Agreement.	1	0	0
Meetings were held for medicinal products, Africa Medicine Regulators, African Medicines Agency, policymakers, regulators, Industry, and other stakeholders.	0	4	0
Training sessions on access to medicinal products.	2	0	0

From the table above, at the Institutional level, the increase in the number of activities such as joint dossier assessments, expert working group meetings, and joint GMP inspections reflects growing collaboration among regulatory agencies within the East African Community (EAC) thus leading to the harmonization of regulatory standards, faster approvals of medicines, and better oversight of pharmaceutical products circulating in the region, ultimately enhancing public health by ensuring the quality, safety, and efficacy of medicines. Therefore, the performance shows the concentrated effort to strengthen regulatory systems, enhance collaboration, build capacity, and address public health challenges within the EAC region thus improving the quality and accessibility of medicines, regulatory agencies can contribute to better health outcomes and improved healthcare delivery for the population.

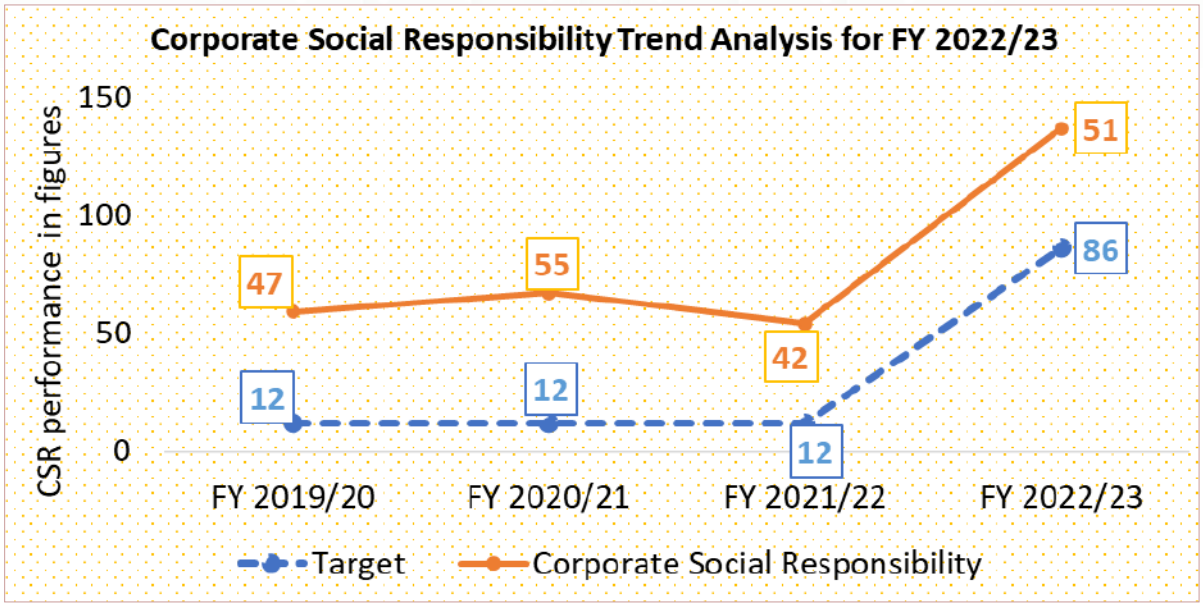
At the Country level, Harmonization contributed to the political integration and strengthened the EAC regional community which is part of the African Union Political Integration.

13.3.6. Stakeholder Meetings Conducted

The office of the Secretary to the Authority attended a total of thirteen (13) stakeholder meetings against a set target of twelve (12) meetings as compared to twenty (25) meetings for FY 2021/22. More stakeholder meetings were attended against the set target because of the need to resolve so many issues at hand. This highlights the importance of collaboration and engagement with stakeholders in addressing public health issues effectively and contributed to the 14% improvement in awareness, collaboration, and partnership overall performance of the strategic plan set commitments.

13.3.7. Corporate Social Responsibility.

NDA recognizes the importance of corporate social responsibility and contributes to society's wider goal of sustainable development and transformation alongside its normal business operations. A total of 51 Corporate Social Responsibility projects were financed against the set target of 86 as compared to 42 against the set target of 12 CSR projects as presented in the chart below.



From the chart above, there have been fluctuations in CSR performance over the years. For example, there was an increase from FY 2019/20 to FY 2020/21, followed by a decrease in FY 2021/22, and then another increase in FY 2022/23. These fluctuations were due to various factors such as changes in corporate strategy, economic conditions, or shifts in stakeholder priorities. 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, mentions good tonality/sentiments, interactions, potential impressions/reach, and influence.

Trend performance on KPIs Measuring the effectiveness of Strategic Objective 3 under Focus Area 3.

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

The KPIs were all captured in the Client Satisfaction Survey that is ongoing and the status of the three (3) KPIs is expected in the FY 2023-2024.

13.4. Focus Area 4: Institutional Development:

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

Strategic Objective 4

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

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

Strategic Intervention 4.1: Enhance the NDA infrastructure and facilities for her capacity growth.

13.4.1. Construction of an ultra-modern Quality Control Laboratory

The construction contract commenced on 11th October 2019 after all requirements had been in place, including handover and possession of the site. The actual overall progress on site was 100% in comparison to the planned progress of 100% based on the program with the practical completion achieved on 30th June 2022 and the Defects Liability Period (DLP) ending on 30th June 2023.

The scope of the consultancy services was to provide all necessary design reviews as well as project and contract management services required for implementing the construction of the NDA laboratory tower building which were to be carried out in the following phases and deliverables indicated: -

Phase 1: Pre-construction: Design and document review.

Phase 2: Construction stage: Supervision and monitoring of construction works.

Phase 3: Post-construction and project closure stage.

The works contract for the Construction of the NDA laboratory building included but not limited to the following: -

a) Construction of Tower building complete with curtain wall cladding
b) Construction of the Gate Houses.
c) External works which included roads & parking areas, boundary walls & gates, and a generator.
d) Platform, external surface water drainage, and external signage.
e) Electrical & mechanical installations.
f) ICT installation including Voice & data installations.
g) Air conditioning & fire fighting.

The final project accounts have been confirmed by both parties, including all project stakeholders and the final account price for the three phases highlighted above was UGX. 37,990,379,086 inclusive of VAT.

The construction of the laboratory tower project for public health implies the importance of timely completion, quality assurance, and effective management to ensure access to quality healthcare services and promote the well-being of the population.

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

13.4.2. Automation of the Business Processes for the Authority

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

No.	Process	Description
1.	Premises Module	The module has been designed to support the entire process of licensing Pharmacies and drug shops.
2.	Product Module	That module has been redesigned to support the process of Product Assessment and Registration for the generation of monthly Register.
3.	Imports/Exports Module	The module has been redesigned to ensure a comprehensive imports/Exports verification process and provide for the generation of reports progressively Integration with ASYCUDA World is underway
4	Inspection Module	This module has been developed to support the inspection of Premises & Imports/Export control at the various ports of entry
5.	GMP Module	The module was completed and integrated with the products Assessment and registration to 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 Payment Gateway & Mobile Money platforms has been achieved.
7.	Clinical trials Module	The module to support the process of Clinical Trials was completed and operational.

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

Strategic Intervention 4.3: Strengthen Corporate Governance practices and Human Resource capacity.

13.4.3. Internal Audit Engagements

Prepared audit engagement plans, programs, and notifications for the ten (10) audits that were conducted during the year and these include the Western region audit, Local Good Manufacturing Practice audit, Tenants receivables spot check audit, Human Resources and Administration audit, Eastern (Tororo) region audit, Kampala extra region audit, ICT Audit, DIE Audit, Good Manufacturing (Foreign) processes, QMS audit against a set target often (10) audits as compared to fourteen (14) conducted for FY 2021/22. This highlights the importance of maintaining adequate levels of audit activity to ensure robust oversight, compliance, and readiness in public health preparedness efforts.

13.4.4. Restructuring and staff establishment

The Eighth Authority improved staffing by 2.3% from 304 to 311 employees as of 30th June 2023. The Authority has ensured the recruitment of a balanced professional workforce in the technical regulatory areas by increasing the number of Veterinary Doctors from 17, recruitment of two (2) biomedical technologists, one (1) Dental Surgeon, twenty-three (23) Chemists, one hundred fifteen (115) Pharmacists and one hundred fifty-three (153) other professionals in support functions. This improved workforce capacity expansion, timely service delivery, and health outcomes.

13.4.5. Employment Gender Status

Overall National Drug Authority has a total of 311 staff of which 116 (37%) are females and 195 (63%) are males. However, NDA has put in place efforts to close the gender gap in employment including promoting women's education and skills training, addressing discriminatory practices in the workplace, and implementing policies that support work-life balance.

13.4.6. Staff Training and Development

The Authority has invested in training staff at all levels to ensure institutional knowledge enhancement and support succession planning. The institutional budget for staff training and development has increased from Two billion one hundred seventy-eight million (Ugx. 2.178 billion) FY 2021/22 to Two billion nine hundred eighty-eight million (Ugx. 2,988 billion) representing a percentage improvement of 37%. The Authority has also provided training for its members in key strategic areas of corporate governance, financial and risk management to better equip them to perform their over-sight functions and this has improved the performance of the drug Authority in meeting the set strategic plan commitments.

Strategic Intervention 4.4: Enhance the Institutional resource mobilization capacity and sustainability.

13.4.7. Resource Mobilization Function

The resource mobilization function has improved the capacity and sustainability of resource mobilization by conducting gap analysis, identifying funding sources, expanding resources, and collaborating with development partners. The NDA hosts its donors' conference every year to increase its pool of resources. These efforts have resulted in several achievements listed below.

- Secured a donation/grant of UGX 1,118,746.959 billion (USD 301,942) for the National Drug Authority (NDA) from Global Fund/Mistry of Health to monitor and ensure quality and safety of drugs used for managing diseases like Tuberculosis, HIV, Malaria, and COVID-19. The project is under the Directorate of Product Safety (DPS) and runs from July 1, 2022, to December 31, 2023.
- Coordinated and facilitated the signing of the Memorandum of Understanding (MOU) between NDA, Ministry of Health/Global Fund, Ministry of Finance Planning and Economic Development (MOFPED) and developed another MOU with the CUBA's Centre for the State Control of Medicines, Equipment and Medical Devices (CECMED) on technological transfer.
- Engaged the Bill and Melinda Gates Foundation (BMGF) and is currently the first chair of the NDA Development Partners Forum (NDADPF) on the 28th of June 2023 and who mobilized NDA to move towards WHO recommended Maturity Level (ML3) and is mobilizing funding for NDA.
- Continuous building of good relations with many development partners (potential donors) including USAID, CDC, WHO, Global Fund, UNICEF, FAO of the UN, CHAI, MSH, World Bank, GAVI, British High Commission, Marie Stopes, and Denmark.

Strategic Intervention 4.5: Strengthen the corporate planning and performance management systems.

13.4.8. Statistics Function

At its Tier 2 management review meeting dated 5th to 9th August 2019 at Golf Course Hotel Kampala, the authority resolved that a statistician be recruited. A statistician was recruited under the Department of Business Planning and Development in July 2022. The main objective of this unit is to analyze and interpret numerical data to enable informed planning and decision-making. The statistician is required to gather data, apply statistical and analytical techniques to data, and identify trends based on the results of calculations and projections to ensure the efficiency and effectiveness of the organization. Since the recruitment of a statistician, various statistical processes have been analyzed including data mapping and revenue analysis, and management has been provided with recommendations for action.

13.4.9. NDA Planning Function

The planning unit coordinated the work plan development with all Directorates and ensured that the organization's work plan for FY 2023-2024 was developed and aligned with the budgets for operational and financial monitoring. In addition, it also headed the revision of the fees through a consultative discussion with all the process owners, and the final agreed position of the organization was presented to the external stakeholders. The planning unit together with the internal and external consultancy firm conducted a mid-term evaluation of the current strategic plan and made recommendations targeted for performance improvement.

13.4.10. Monitoring and Evaluation Function.

NDA M&E function team with support from the M&E Coordinators conducted routine monitoring and evaluation of NDA strategic plan planned commitments quarterly, semi-annually, and annually for the FY 2022-2023. The team compiled the annual report to the public for the FY 2021-2022 which was published on the NDA's website for decision-making purposes and accountability to the stakeholders. The unit developed performance dashboards for different processes for performance progress tracking purposes. From the quarterly monitoring and evaluation reports generated and disseminated, several performance improvement recommendations were documented and shared with management and the Drug Authority for action. Therefore, the NDA is committed to monitoring, evaluating, and transparently reporting on its performance to ensure accountability, support decision-making, and track progress toward its strategic plan objectives achievement from 95% to 93.2% for FY 2021/22.

13.4.11. Risk and opportunity management

NDA's risk management function is in line with the 2018 Government of Uganda Risk Management Strategy. Under the policy statement section 2.2, provides that "All employees should understand GoU's position on risk-taking and managing risk. The risk policy statement should be implemented at the entity level i.e. at each Ministry, Department, Agency, Local Government, and Municipal Council".

The Public Finance Management Act (PFMA), 2015 of Uganda Part VII on Accounting and Audit, section 45 about accounting officers, sub-section 2 states that; "In the exercise of the duties under this Act, an Accounting Officer shall, in respect of all resources and transactions of a vote, put in place effective systems of risk management, internal control, and internal audit"

NDA adopted an Enterprise-wide Risk Management framework to create and maintain value for its stakeholders. Enterprise Risk Management Framework has been effective in ensuring that the Authority achieves its strategic objectives.

Risk management is well integrated into the overall core business activities including planning, budgeting, and decision-making processes.

The risk environment encompasses a mix of internal and external, strategic and operational factors that could potentially impact NDA's ability to achieve its objectives and goals. These factors can manifest as opportunities or threats, and their effective assessment and management are critical for ensuring the success and sustainability of our operations.

NDA's risk management approach is underpinned by our philosophy that risk management is every Employee's responsibility. All Employees are required to be competent and accountable to effectively manage risks within their area of responsibility. To ensure continuous improvement, of our risk management practices we have incorporated an agile risk management culture through: Conducting risk assessments for key investment projects before, during, and after implementation, minimizing third-party risks by conducting detailed due diligence on suppliers while keeping in check of our internal controls to ensure their adequacy and effectiveness.

Risk governance is well-structured with the board playing its oversight function and a well-defined risk reporting structure ensures that risks are communicated from the technical and process levels to the strategic level. Quarterly reports on the key risks facing NDA, along with relevant mitigation measures are communicated across the structure. The Authority, through the Audit, Risk & Legal committee, reviews the risks presented and directs management on how to address the risk exposures. It is a two-way (bottom-up and top-down) risk communication.

Risk management undertakes a structured and rigorous process starting with the identification of risks and opportunities, analysis and evaluation, treatment actions, recording and reporting, and monitoring and reviewing of the risks and the actions undertaken. This iterative process ensures that all organizational known risks are well managed and any emerging risks can be detected and managed.

Strategic Intervention 4.6: Strengthen the Quality Management Systems across the organization.

13.4.12. Quality Management System (QMS)

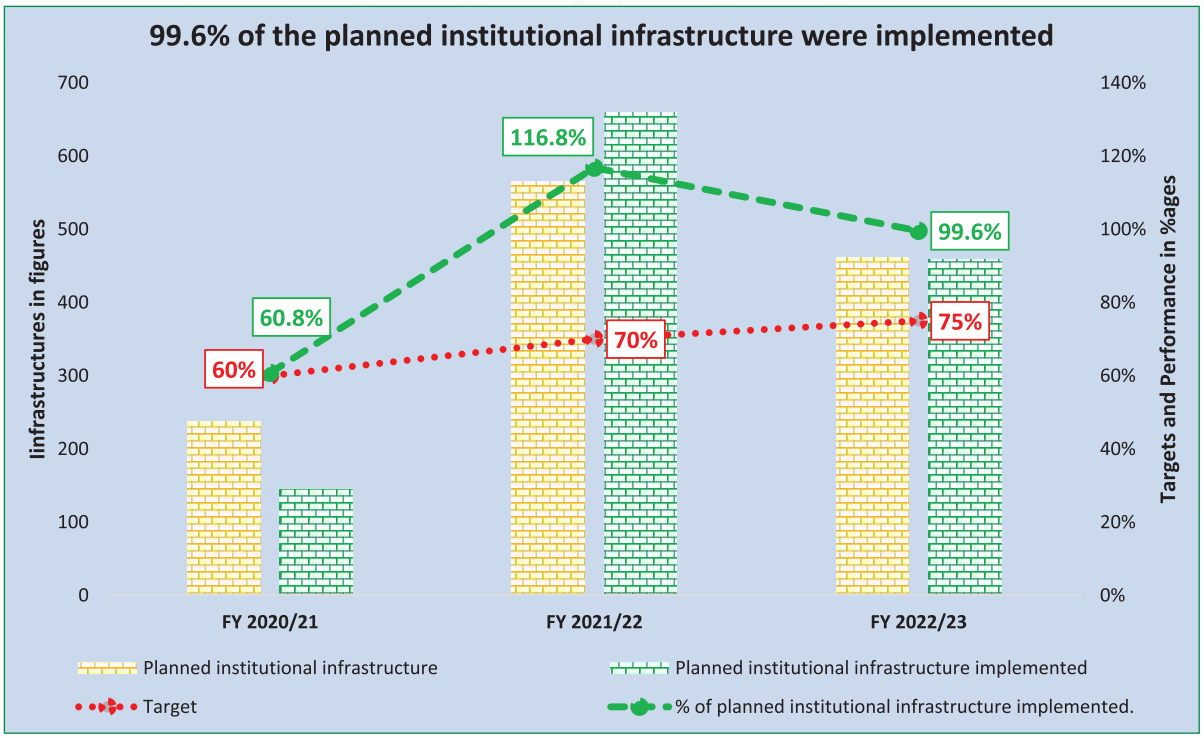
QMS has supported the National Drug Authority in Strengthen the Quality Management Systems across the organization. This has ensured that all processes have established quality objectives and standard operating procedures. QMS has prepared the Authority to ensure that the internal standards are met. NDA has maintained its certification ISO 9001:2015 International Standard for Quality Management System through annual surveillance audits carried out by SGS United Kingdom Ltd. QMS has implemented a computerized QMS compliance System called Q-Pulse, an Ideagen product from the United Kingdom. Q-Pulse has the following modules Documentation, Audit, Customer complaints, documentation of training, assets management, Supplier/Vendor Management, and Staff particulars and leave management. QMS has coordinated continual improvement through annual management reviews, regular internal quality audits, handling and investigation of customer complaints, and customer satisfaction surveys.

Trend performance on KPIs Measuring the effectiveness of Strategic Objective 4 under Focus Area 4.

%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, and laboratory

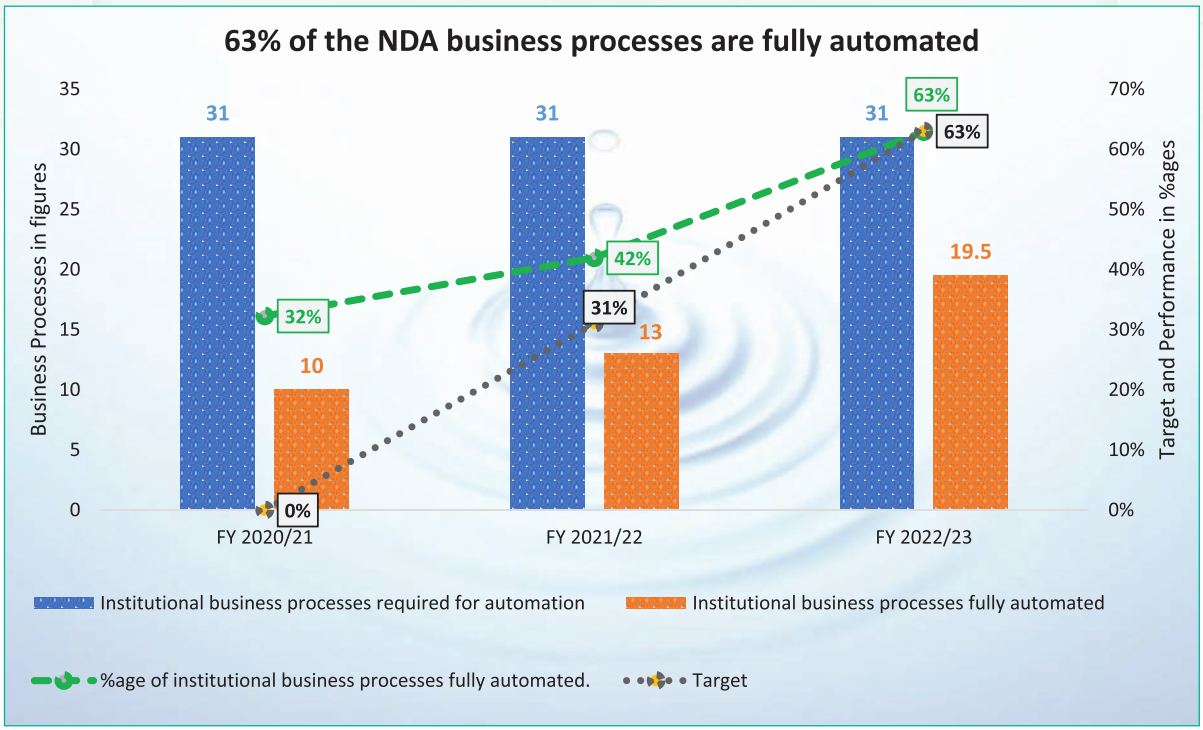
equipment that will enable its staff to perform the strategic plan commitments and meet the set strategic plan objectives for the third year of implementation. A total of 461 institutional infrastructures were planned to be procured of which 459 (99.6%) were availed in place for FY 2021/22 as compared to 565 institutional infrastructures were planned to be procured of which 660 (117%) were put in place for FY 2021/22. The chart below illustrates the comparative analysis for items procured against those planned for.



From the chart above, the NDA's ability to plan and execute infrastructure projects with such a high success rate reflects positively on the governance and administrative capabilities of the National Drug Authority. In addition, it reflects efficient coordination, decision-making, and implementation processes within the organizations.

Proportion institutional business processes fully automated.

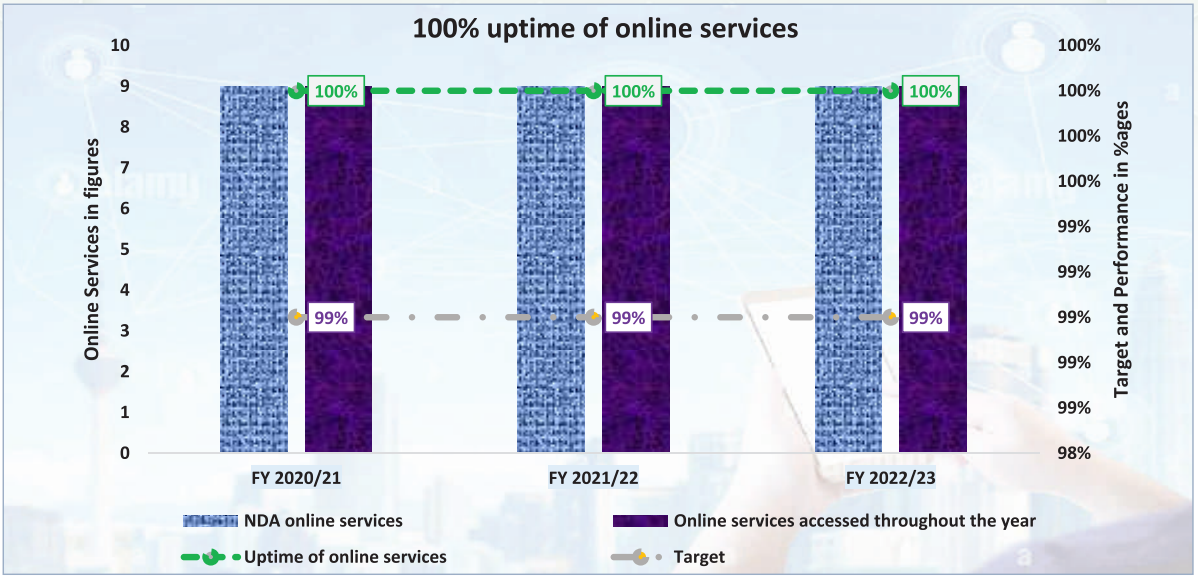
NDA planned to automate all 31 business processes as a way to improve timely service delivery and enhance organizational efficiency. In the FY 2022/23, NDA automated more six (6) business processes fully and one process partially (0.5) totaling 19.6 (63%) fully automated out of the planned 31 business processes and this is above the set target of 31% for the third year of implementation of the strategic plan. There is an improvement in automation as compared to the FY 2021/22 was only 42% (13 fully automated against 31 planned business processes). The chart below illustrates the comparative analysis of business processes partially and fully automated.



The chart above shows an improvement in automation of business processes within the NDA thus leading to increased efficiency and effectiveness in regulatory activities related to drug approval, monitoring, and oversight. This means that the NDA may be able to review and approve drugs more quickly, ensuring that safe and effective medications reach the market on time, which is crucial for maintaining public health. Therefore, there is a positive implication for public health by improving regulatory efficiency, enhancing monitoring and surveillance, promoting compliance with safety standards, and ultimately increasing access to essential medicines for the population.

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

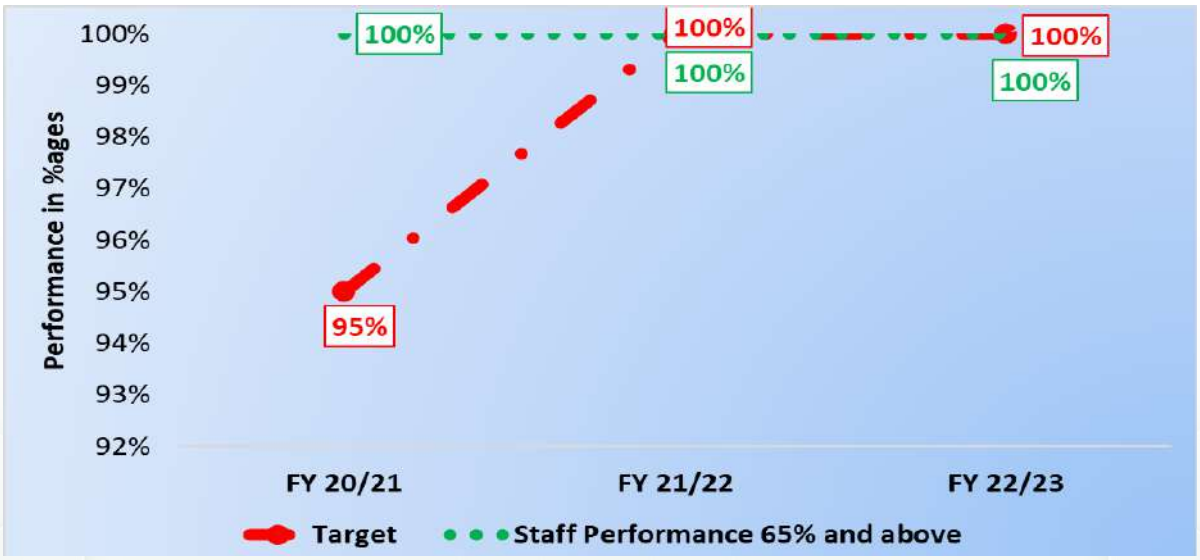
NDA transformed from hard copy review of applications to online services and these services are available and can be accessed for all working days. A total of nine (9) services including Email services, Drug Promotion (DPROM), the seven (7) NDAMIS modules including Product, Premises, Finance, GMP, IPMS, Import and Export, and reporting module. The uptime of the nine (9) services was maintained at 100% for the FY 2022/23. The graph below illustrates the comparative analysis for the uptime of online services.



The chart above shows that NDA maintained the uptime of its online services thus resulting in regulatory effectiveness, improving access to quality healthcare products, and strengthening public health interventions in Uganda.

Proportion of staff who attain 65% of approved performance targets

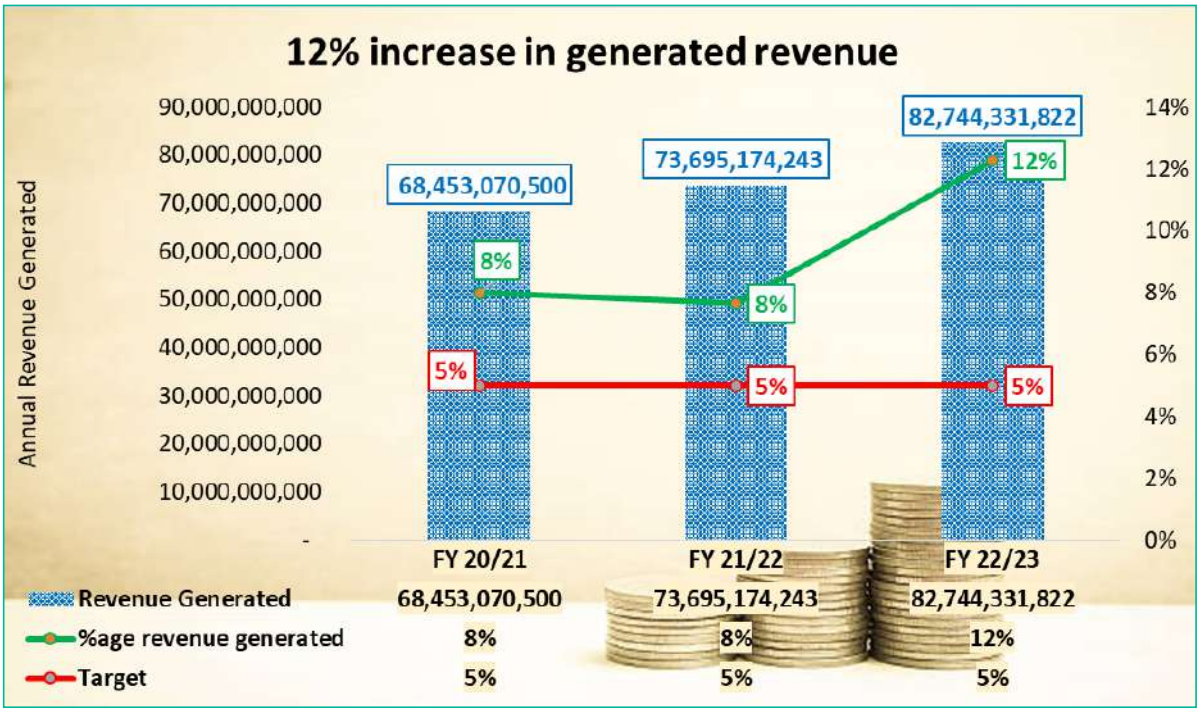
NDA has increased human resource productivity to deliver the NDA's regulatory mandate as evidenced by the performance of 100% (64 out of 64). All NDA-appraised staff have attained 65% and above in their performance targets against the set target of 100%. The average performance of 81% was registered during the reporting period and 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 were 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.



From the chart above, the high-performance appraisal suggests the NDA staff are effectively executing their regulatory duties. This efficiency has yielded quicker processing of applications, and timely inspections of pharmaceutical facilities, and other services, ultimately contributing to improved public health outcomes and delivery of services to clients at 84% against the set target of 82%. This signifies a dedication to regulatory excellence and public health protection in Uganda.

% increase in generated revenue.

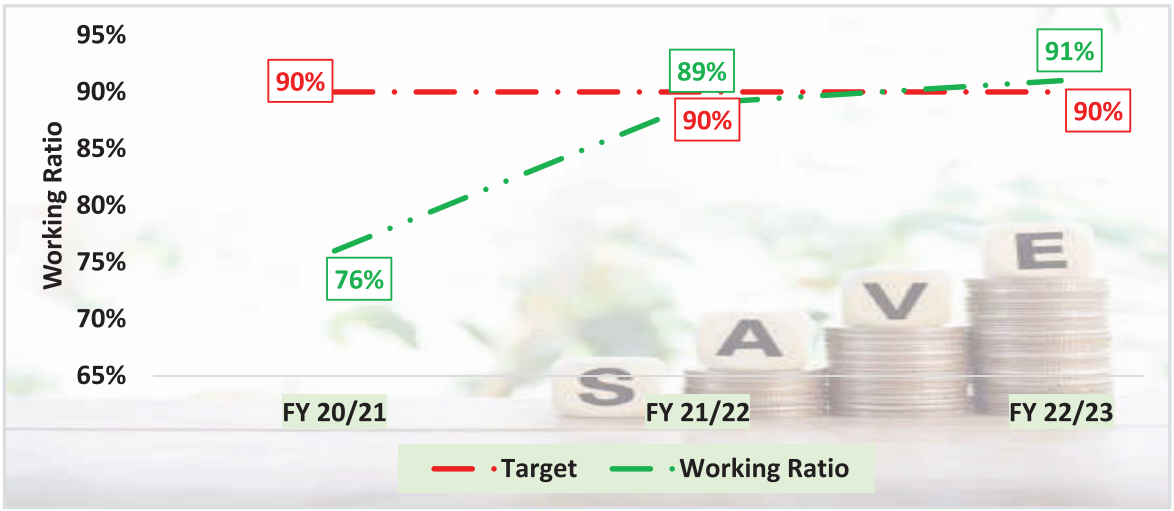
NDA generated a total of Ugx. 82,744,331,822 (105%) out of the projected amount of Ugx. 79,049,743,376. There is an increase in the revenue generated by 12% for FY 2022/23 as compared to Ugx. 73,695,174,243/= performance for FY 2021/22 and the increase in revenue generation is attributed to the increased importation that increased the Verification fees during the financial year. The chart below shows the Comparative analysis for revenue generation.



From the chart above, NDA has marked a tremendous increase in the total revenue generated from 10% to 12% thus resulting in improvements in healthcare services, financial sustainability, and health outcomes as evidenced by the strategic plan effectiveness performance of 95% as compared to 93.2% for FY 2021/22.

Working Ratio

The working ratio evaluates NDA's financial sustainability by gauging its ability to cover operating expenses with annual gross revenue. A ratio of less than one indicates expenses are covered, while greater than one suggests they are not fully covered. NDA implemented most of the activities for the FY 2022/23 resulting in an overall FY operational expenditure of Ugx. 75,697,239,936 as compared to Ugx. Ugx. 65,954,794,173 for the previous FY 2021/22. NDA's financial stewardship and sustainability stands at 91% (75,697,239,936 out of total revenue of Ugx. 82,744,331,822) as compared to 89% (65,954,794,173 out of total revenue of Ugx. 73,695,174,243) for FY 2021/22. This working ratio means that the Authority spent 91% of the generated annual revenue on planned FY operational activities against a set annual target of 90% and this proves that the Drug Authority has a moderate financial stewardship and sustainability. The working ratio trend for three years is illustrated in the chart below.



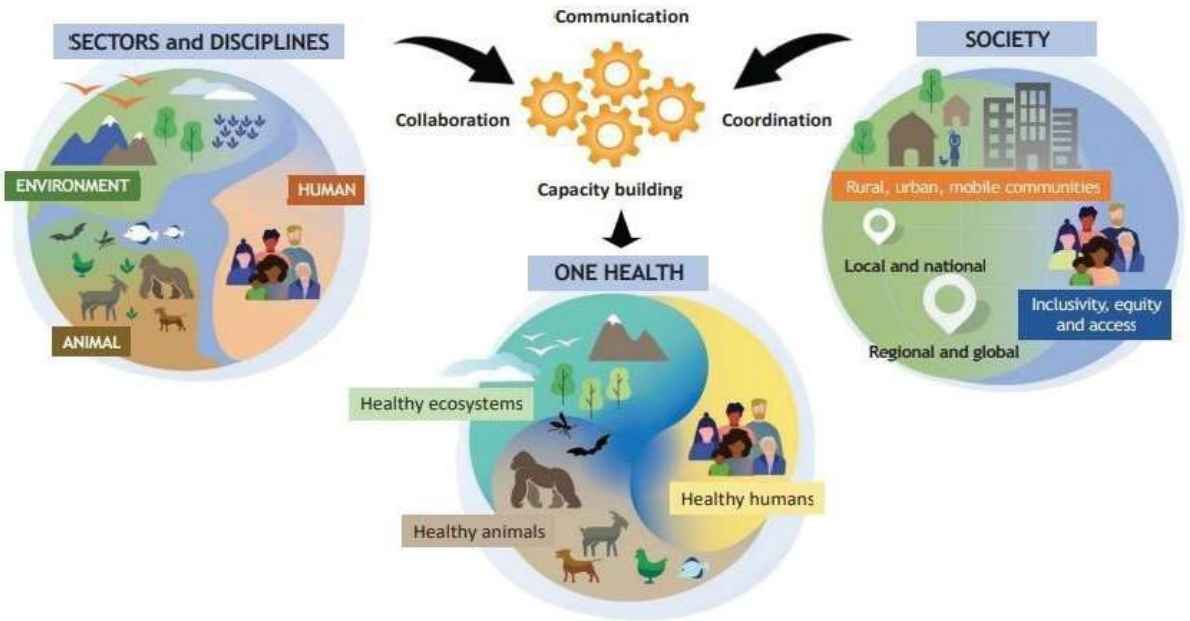
From the chart above, the NDA's increased operational expenditure was due to the need to enhance public health protection and ensure the availability of safe and effective medications thus NDA successfully implemented most of its planned activities and attained the health outcomes for the fiscal year 2022/23 as evidenced by the strategic plan effectiveness performance of 95% as compared to 93.2% for FY 2021/22.

14.0 ONE HEALTH APPROACH

The Quadripartite which includes the World Health Organization (WHO), World Organization for Animal Health (WOAH), Food and Agriculture Organization (FAO), and the United Nations Environment Program (UNEP) have embarked on the implementation of the one health concept.

One health is defined as an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals, and ecosystems. It recognizes the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) as a closely linked and interdependent system. The approach mobilizes multiple sectors, disciplines, and communities at varying levels of society to work together to foster well-being and tackle threats to health and ecosystems, while addressing the collective need for clean water, energy, and air, safe and nutritious food, acting on climate change, and contributing to sustainable development.

The collaboration across sectors and disciplines contributes to protecting health, addressing health challenges such as the emergence of infectious diseases and antimicrobial resistance, and promoting the health and integrity of our ecosystems.



One Health helps to address the full spectrum of disease control from disease prevention to detection, preparedness, response, and management, and to improve and promote health and sustainability.

15.0 THE FUTURE OF PHARMACEUTICAL COSTING

The process of pharmaceutical costing encompasses a complex interplay of factors, including research and development (R&D) expenses, manufacturing costs, regulatory requirements, market competition, and healthcare system dynamics. Understanding the economics of drug development and pricing is essential for stakeholders, including policymakers, healthcare providers, patients, and pharmaceutical companies, to ensure access to innovative therapies while maintaining sustainability and affordability within healthcare systems. NDA in FY 2024/25 is planning to start pharmaceutical valuation and then determine the pharmaceutical cost of all products on the market.

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