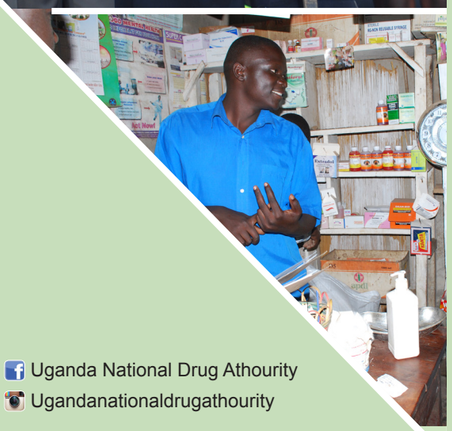

National Drug Authority Head Office and Regional Office Contacts

NATIONAL DRUG AUTHORITY
Head office, Plot 46-48 Lumumba Avenue
P.O. Box 23096, Kampala, Uganda
Tel. +256-414 255 665, +256 414 347 391/2
+256 417 788 100/1, +256 417 788 124/9
Toll Free: 0800 101 999

NATIONAL DRUG QUALITY CONTROL LABORATORY
Tel: 256 414 540067

CENTRAL REGION, NAKAWA
Premier Engineering Works Ltd.
Premier Complex, Plot 1-2, Enterprise Close
Jinja Road, Ntinda Industrial Area,
Tel. 256 393 261548/ 312261548

WEST NILE REGION, ARUA
Plot 1 Mount Wati Avenue, Arua Municipal Council, Tel 256 414 671033

NORTHERN REGION, LIRA
Plot 48, Ogwalanjulgu Road, Lira, Junior Quarters.
Tel. 256 414 671032

WESTERN REGION, HOIMA
Plot 29/31, Main Street Hoima
Tel. 256 465 440688

SOUTH EASTERN REGION, JINJA
Plot 6 Rippon Garden, Jinja town
Tel. 256 434 122176

EASTERN REGION, TORORO
Plot 27 Kwapa Road, Tororo
Tel. 256 454 445195

SOUTH WESTERN REGION, MBARARA
Mbaguta Estate House 29, Kamukuzi,
Mbarara District Local Government Premise,
Tel. 256 414 671034

Follow us on:

www.nda.or.ug
ndauganda.or.ug
Uganda National Drug Athourity
+256 791 415555
@UNDAuthority
Ugandanationaldrugathourity

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NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

National Drug Authority

Strategic Plan

July 2016 - June 2021

Peace * Harmony * Progress

Members of the NDA Authority after bidding farewell to Hon. Jane Ruth Aceng on completion of her term as a member of the Authority, June 2016

National Drug Authority

Strategic Plan

July 2016 - June 2021

Peace * Harmony * Progress

Message from the Authority Chairman

Dr. Sam Zaramba
Authority Chairman

The NDA Strategic Plan 2016-2021 comes at an opportune time when NDA is striving to transform the way we deliver services to the public. The plan has been developed out of a highly participatory process that involved members of the Authority's strategic planning task force, key stakeholders, senior management, and all staff.

The message from all these stakeholders has been very clear; an urgent need for the National Drug Authority to adopt an outward orientation with a primary focus on the client, who ultmately is an ordinary Ugandan who needs medicine for themeselves on their animals.

Therefore, the primary objective of this strategic plan, in line with the national aspirations set out in Vision 2040 and the National Development Plan II, is to enhance service delivery to our clients. Over the next five years, we will focus on ensuring that we deliver on our mandate as set out in the law to the satisfaction of our clients and stakeholders. This will be coupled with developing the institutional capacity to deliver the level of services required to meet stakeholder expectations.

We intend to make it our habit to constantly communicate with our stakeholders, highlighting challenges that we may encounter in execution of our mandate, and taking every opportunity to use stakeholder feedback to shape our plans and programs.

The Authority takes pride in being part of this journey, and we pledge our full support and commitment towards the implementation of this strategic plan.

The Authority takes pride in being part of this journey and we pledge our full support and commitment towards full implementation of the plan.

Dr. Sam Zaramba
Authority Chairman

Message from the Secretary to the Authority

Donna Kusemererwa
Secretary to Authority

The Strategic Plan 2016-2021 marks a new era in NDA's history as we embark on the journey of transformation. The next five years will come with a number of challenges as the demands from our clients increase and the medicines regulatory landscape evolves locally and internationally. Still, therein also lies an opportunity for us to demonstrate our innovation, leadership, and commitment to the highest standards of service in medicines regulation.

The overall goal of the plan is to transform NDA into a high performing, results oriented institution with specific focus on the client.

It presents a paradigm shift in the way NDA operates. Over the next five years, the focus will be on three priority areas: safety, efficacy, and quality of medicines and health care products; collaborations and partnerships; and institutional capacity building. NDA's mandate as enshrined in law is to ensure medicines and health care products available to the Ugandan population are safe, efficacious, and of high quality. What we will do differently is to focus on increased surveillance and coverage, efficient, effective and standardized services, promotion of voluntary compliance, and an informed and empowered public. All of this will be geared towards building public confidence in the products we regulate and the services we provide.

We further intend to collaborate and establish effective partnerships with other agencies both locally and internationally to create synergies that are beneficial to our clients and will enhance our efficiency and effectiveness.

The third arm of this strategy, enhancing our institutional capacity, will enable us to deliver on these ambitious goals through applying new approaches such as integration and automation of our business process as well as creating a conducive working environment for staff to excel.

We will make additional and renewed efforts to address the regulatory issues related to herbal, veterinary medicines and human medicines as well as support the development process for a comprehensive legal framework for food safety, medical devices, and other health care products.

The NDA management and staff are committed to the successful implementation of the plan, and we call upon all our stakeholders and partners to support us in whatever way they can. We have committed to reporting on progress to the Authority every quarter and to our stakeholders annually, not only as a good corporate governance practice but also as part of our commitment to being accountable.

Donna Kusemererwa
Secretary to Authority

Acronyms

Acronym	Meaning
ADR	Adverse Drug Reaction
AIDS	Acquired Immune Deficiency Syndrome
API	Active Pharmaceutical Ingredient
EAC	East African Community
EAC-MRH	East African Community Medicines Regulatory Harmonization
EMHS	Essential Medicines and Health Supplies
GoU	Government of Uganda
HC	Health Centre
HIV	Human Immunodeficiency Virus
HRA	Human Resource and Administration
HSDP	Health Sector Development Plan
ICDRA	International Conference of Drug Regulatory Authorities
IT	Information Technology
IVDs	In vitro diagnostics
KCCA	Kampala Capital City Authority
MDG	Millennium Development Goals
MOH	Ministry of Health
NDA	National Drug Authority
NDP	National Development Plan
NDP/A	National Drug Policy and Authority
NDQCL	National Drug Quality Control Laboratory
NeSW	National electronic Single Window
NFDA	National Food and Drug Authority
NPSSP	National Pharmaceutical Sector Strategic Plan
QMS	Quality Management System
SDG	Sustainable Development Goals
SEQ	Safety, Efficacy and Quality
SF	Substandard and Falsified
TB	Tuberculosis
TFR	Total Fertility Rate
URA	Uganda Revenue Authority
WHO	World Health Organisation
Y on Y	Year on Year

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Acknowledgments

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- Dr. Bildard Baguma
- Mr. Moses Mulumba

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Finally, to Ms. Martha Embrey, thank you for the comprehensive technical and editorial review of the plan.

Executive Summary

The NDA Strategic Plan 2016-2021 provides a paradigm shift in the way NDA provides services to the clients. The overall goal of the strategy is to transform NDA into a high-performing institution. The strategy has been informed by stakeholder expectations of NDA over the next five years; the need to contribute to attainment of national development priorities in Uganda's Vision 2040 and National Development Plan II; as well as emerging issues from the regional and global arenas. To this end, the new strategic agenda focuses on three priority areas: i) safety, efficacy, and quality, ii) collaborations and partnerships, and iii) institutional capacity, which covers the investments needed in NDA's capacity to deliver on its mandate.

Fifteen inherent strategic objectives will be pursued across the three priority areas resulting in a number of outcomes over the period including: efficacious and quality products, increased public confidence, increased domestic manufacturing of essential medicines, value-adding partnerships, high-performing staff, automated business processes, timely and standardized services, financial sustainability, construction of the NDA towers, and the drafting of the National Food and Drug Authority (NFDA) bill, among others.

To realize the above results, a number of strategic interventions will be implemented to address the key constraints and service delivery gaps including:

- Strengthening systems for herbal medicines production and registration.
- Strengthening pharmacovigilance and ethical medicines promotion.
- Setting up a track and trace systems along the supply chain and other mechanisms for assuring quality of medicines (e.g., field testing of medicines).
- Sensitizing the public to create awareness about regulation as well as disseminating drug information to the public facilitating local manufacturers to increase production of essential medicines.
- Establishing value-adding partnerships through operational memorandums of understanding (MOUs) and other formal collaborative mechanisms.
- Constructing the NDA towers, microbiology laboratory and setting up and equipping regional offices.
- Automating key business processes.
- Strengthening Quality Management Systems (QMS), performance management, and reward systems.

To be successful, implementation of the plan will require; ownership by all, effective annual business planning, commitment of resources, behavioural change, institutional cohesion and harmony, and an effective performance monitoring unit. Monitoring and reporting on progress will be done through quarterly reports to the Authority and regular stakeholder forums to ensure effective feedback.

1.0 Background and Introduction

The NDA was established in 1993 by the National Drug Policy and Authority (NDP/A) Statute which in 2000 became the NDP/A Act. The objective of the National Drug Policy was to ensure the availability at all times of essential, efficacious, and cost-effective drugs to the Ugandan population as a means of providing satisfactory health care and safeguarding the use of drugs. The legal framework for drug regulation is also embedded in the National Veterinary Drug Policy, whose vision is to have quality veterinary drugs accessed by all stakeholders for sustainable animal health and production.

In line with these policies, NDA's strategy for the period of 2016 to 2021 builds on the foundations laid down by previous strategies. The vision and strategy, respond to the need to modify, refocus, and build capacity to meet existing and new challenges and opportunities.

This plan presents the three key priorities that NDA will focus on over the next five years:

i) Safety, efficacy, and quality of medicines and health care products for both human and animal populations.

ii) Strengthening NDA's institutional capacity to deliver the required services.

iii) Collaboration and partnerships with other agencies both locally and internationally to leverage synergies.

This strategic plan has been developed through a consultative process with a wide range of stakeholders owing to the breadth and reach of NDA's regulatory functions and cognizant of the observations in the mid-term strategic plan review.

Towards the end of 2015, the Authority set up a task force to lead the strategic planning process. NDA management requested technical assistance from the World Health Organization (WHO) to develop the strategy with a team of consultants from Kampala Capital City Authority (KCCA). Consultations were conducted at different levels including with staff, key stakeholders, the Authority, and policy makers. During these engagements, stakeholders were given an opportunity to identify the challenges to address and the key areas they would want NDA to focus on over the next planning period.

The outputs of this process were validated by various meetings with staff and stakeholders. The views obtained from these engagements and the findings of the 2011-16 mid-term review formed the basis for the objectives and strategies in this plan. Care was taken to align the strategic agenda with the regional medicines regulatory frameworks as well as national and relevant sector plans.

This plan is divided into seven parts. Part one provides for background and introduction. Part two provides a situational analysis outlining the operating context at international, regional, national and sector levels. Part three focuses on the organizational assessment including external stakeholder expectations and summary of the emerging challenges and gaps that need to be addressed. Part four provides an outline of the strategic foundations, the vision, mission, core values, mandate, and functions. Part five addresses strategic agenda priority areas, outlining strategic objectives, interventions and expected strategic outcomes. Part six outlines the implementation, monitoring, and evaluation mechanisms, institutional arrangements for strategic implementation and progress reporting and review of results. Part seven describes the financing mechanisms to deliver the strategy effectively.

2.0 Situation Analysis

2.1 Context

2.1.1 Geography and People

Uganda is a landlocked country in Eastern Africa, bordered by Kenya to the east and Rwanda and Tanzania to the south. To the north lies South Sudan and to the west the Democratic Republic of Congo. This region for years, has been affected by geopolitical challenges resulting in mass migration and porous borders. The population of Uganda in 2016 is estimated at 36.6 million with an annual growth rate of 3.03%[1]. 48% of the total population is below 15 years, making it one of the youngest and most rapidly growing populations in the world. An estimated 72% of the population lives in rural areas as compared to 28% in urban centres. The high population growth rate, high fertility, and high youth population present several development opportunities and challenges for the country in the short and medium term.

2.1.2 Political Context

Administratively, the country is divided into 112 districts and the capital city of Kampala[2]. The districts are spread across four administrative regions of Northern, Eastern, Central, and Western. Although Uganda has enjoyed relative political stability over the last three decades, political conflicts in the neighbouring countries of South Sudan, Democratic Republic of Congo, and Burundi have led to social instability and population displacement into Uganda. Uganda is an active member of several important political groupings and development organizations at the global, regional, and sub-regional levels including the United Nations, the African Union, and the East Africa Community (EAC).

2.1.3 Socioeconomic Context

Uganda operates a liberalized economy with several ongoing reforms geared at encouraging active participation of the private sector in the economy. The country is estimated to have realized 4.6% economic growth in 2016/17[3]. One of the measures that the government introduced to boost trade in 2015/16 is the National electronicSingle Window (NeSW) Project. The project provides a platform in which all parties involved in trade and transport lodge standardized information into linked databases to fulfil all import and export regulations. Under the leadership of the Uganda Revenue Authority, NDA is one of a number of agencies that is part of the initial project implementation[4]. During the last 20 years, Uganda's increased population growth coupled with rural–urban migration led to overstretched infrastructure (i.e., water, electricity, housing and access to health services). In recent years, Uganda has seen a rapid rise in institutions offering higher education, particularly universities. Graduating health professionals are responsible for ensuring that they adhere to the code of conduct and ethical standards of their profession.

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[1] *Uganda Bureau of Statistics National Housing and Population Census 2014*

[2] *February, 2016*

[3] *Background to the Budget FY 2016/17*

[4] *Background to the Budget FY 2016/17*

2.1.4 Technological Context

Global advancement in technology has created new opportunities for production and distribution of medicines and other health products. Technology has also enhanced access to information. Research in medicines is a focal point for improving and promoting technological advancements in medicines assessments and studies. The medicines market in Uganda has become more liberal and competitive, requiring methodologies and protocols for product safety and efficacy to be evaluated continuously. Evidence accumulated from these reviews is required to address public safety and efficacy concerns. Technology also provides opportunities for process automation for enhanced services. The wide access to and use of mobile phones in the country for example provide new opportunities to disseminate public information through short messaging and social media.

2.1.5 Policy, Legal, and Regulatory Context

The legal and regulatory environment still poses the biggest challenge to medicines regulation in Uganda. This has been recognised in the National Development Plan (NDP II) and in the health sector plans. The current NDP/A Act was enacted in 1993, but over time has been overtaken by globalization, which directly affects the protection and promotion of public health care everywhere. Medicinal products distributed and used in domestic markets are increasingly global commodities. The manufacturing and distribution supply chains are complex, multi-faceted, globally integrated, and may at times be difficult to understand. The ability of any domestic regulator to assure the safety, efficacy, and quality of a medicinal product requires knowledge of and confidence in these supply chains and regulatory oversight at all stages. For the last nine years, NDA has struggled to seek this assurance legally through the drafting of the National Food and Drug Authority bill.

The policy and legal framework for appropriate veterinary medicines regulation and management are contained in the NDP/A Act, the National Veterinary Drug Policy 2002, and the Veterinary Surgeons Act. From the NDP/A Act, a number of regulations pertaining to; veterinary drugs registration, importation, licensing of drug outlets, pharmacovigilance, and conduct of pre-registration field trials for arcaricides have been introduced.

Global trends in veterinary drug regulation and the local institutional context further compound NDA's challenges to regulate veterinary drugs. The broad goals of regulating drugs used on animals are to preserve the health of the animals, improve animal production, and protect public health. Veterinary drug control is however only one aspect of these broad aspects of public policy. The scope of veterinary drug regulation in the NDA/A Act is to guarantee the quality, safety, and efficacy of veterinary drugs. The human health consequences of chemical residuals in animals is a subject that is hotly debated between different stakeholders internationally.

NDA regulates within an extremely complex domain; legally, technically and recognizes that the effectiveness of its plans and approaches depends on strategic-level leadership and political will. New ways of working and certain governance and legal issues positively affect the performance of NDA, especially around processes.

2.1.6 Ecological Context

The country is prone to frequent disasters from natural hazards, including disease epidemics, drought, and floods. In addition, due to the persistent threat of landslide, affected populations have

had to be resettled. The displaced populations from different types of hazards have stretched the existing health and social services in the host communities.

2.2 Health Situation

2.2.1 Health Status of the Population

The Constitution of Uganda recognizes health as a Human Right and the health sector is considered a development priority. The health sector has recorded tremendous improvement in recent years. The life expectancy of Ugandans at birth increased from 44 to 57 years for males and 57 to 61 years for females from 1990 to 2013 respectively. The infant mortality rate dropped from 81 to 45 deaths per 1,000 live births from 1995 to 2014. Also, under-five mortality rates dropped from 147 to 54 deaths per 1,000 live births in 2015. Similarly, stunting rates dropped from 38.3% in 1995 to 33% in 2011. In the area of maternal health, the maternal mortality ratio has dropped over the period 1995 to 2014 from 506 to 360 deaths per 100,000 live births respectively. Although maternal mortality rates have decreased, they fell short of meeting the Millennium Development Goals target.

2.2.2 Health System in Uganda

The Ministry of Health (MOH) is responsible for the overall leadership and governance of the sector with responsibilities for policy formulation, strategic direction, setting standards, disease surveillance, quality assurance, and resource mobilization. The decentralized local governments are responsible for district level planning, budgeting/resources appropriation, passing of health-related by-laws, recruitment and management of personnel, and service delivery. The health system is comprised of both the public and the private sectors, and health services delivery is decentralized to districts and health sub districts. The government health system provides 44% of services; 56% of health services are provided by not for profit, private health practitioners, and the traditional and complementary medicine practitioners.

The government has undertaken several initiatives to strengthen community health services including training and deployment of village health teams. These community health workers are entrusted with managing sick persons within their communities including distributing medicines to them at no charge. Nonetheless in Uganda, medicines typically account for high out-of-pocket expenditure for poor households.

There is limited local pharmaceutical production in Uganda, thus the country imports 90% of its essential medicines and health supply needs. Regulation of the pharmaceutical sector, including import and export controls and post marketing surveillance, is critical to ensure that the public is protected from harmful medicines.

2.2.3 Animal Health Situation

Over 69% of Uganda's population indicate that agriculture is their main source of livelihood[5]. Animal husbandry is very important in generating income and supporting food security in Uganda. Over the last decade, the livestock population has been rapidly increasing as supported by a near doubling of Uganda Bureau of Statistics figures in year 2011 compared to 2000: cattle (5.60-

[5] *Background to the Budget FY 2016/17*

12.84 million), goats (3.50-14.01 million), sheep (1.30-3.84 million), pigs (1.00-3.58 million), and poultry (23.00-42.13 million).

Sustainable farming can only be achieved if the available livestock population can equitably generate income, food, and economic prosperity. Trade in livestock and livestock products is largely hampered by high prevalence of diseases including; foot-and-mouth disease, contagious bovine pleuropneumonia, tick-borne diseases, lumpy skin disease, rabies, brucellosis, African swine fever, and New Castle disease, among others. It is therefore not possible to access lucrative regional and international markets unless appreciable investments are made in controlling livestock diseases. This is the reason why only three countries in Africa; Swaziland, Botswana, and South Africa, can export meat only from disease-free zones.

Resistance to commonly available arcaricides in some parts of the country is also emerging as an obstacle to the control of ticks and tick-borne diseases. A national task force has been put in place to look at addressing this problem by coming up with short-, middle-, and long-term interventions. Among the long-term interventions, the task force is developing a policy on control of ticks and tick-borne disease.

Among others, the Ministry of Agriculture Animal Industry and Fisheries is responsible for improving livestock health, production, and marketing. In the past, delivery of veterinary services in Uganda was a domain of the central government as a public good. However, the 1995 Constitution and the Local Government Act of 1997 divested the central government's role in the delivery of veterinary services. Since 1987, the Uganda government has pursued macro economic policies of liberalization and privatization aimed at eradication of poverty. In line with the new macro-economic policies, the Ministry of Agriculture Animal Industry and Fisheries formulated a new policy that categorizes veterinary services into those that are public, private, and shared, with appropriate implementation strategies that will promote efficient, cost-effective, and sustainable livestock development. The central and local governments make up the public sector, whereas, the private sector is composed of individual private veterinary practitioners, community animal health workers, drug companies, nongovernmental organizations, paraveterinarians, and feed manufacturing companies.

In June 2016, there were 520 registered veterinary medicines, 6 notified herbal veterinary products, and 24 notified veterinary food and dietary supplements on the national register. In January 2015, NDA enlarged its role in regulation of veterinary vaccines by beginning the process of registering them. Previously all veterinary vaccines were specially imported as unregistered products.

2.3 National Development Agenda

2.3.1 Vision 2040

To consolidate and accelerate this development growth momentum, the government developed and launched a 30-year vision reflecting the country's aspiration of transforming from a predominantly peasant and low-income country to a competitive upper middle-income country by 2040. Vision 2040 is to be operationalized through three 10-year plans, six 5-year national development plans and other sub-national level frameworks to address development bottlenecks including; weak collaboration with the private sector, underdeveloped human resources, inadequate infrastructure, and underdeveloped services sector, among other priorities.

2.3.2 National Development Plan II

The National Development Plan 2016-21 lists weak policy, legal, and regulatory frameworks, including the NDP/A Act of 1993, the Pharmacy Profession and Practice Bill, the Traditional and Complementary Medicine Bill, and the Food Safety Bill among the constraints of performance under the health and nutrition sector. It also mentions that National Drug Authority has limited capacity to enforce legislation and policies. It therefore proposes under objective 1 to strengthen the organisation and management of the national health system by ensuring that essential, efficacious, safe, good quality, and affordable medicines are available and used rationally at all times through the following interventions:

(i) Promote regional and international collaboration on medicine regulation and bulk purchasing.

(ii) Encourage local production of medicines and ensure compliance with standards of current Good Manufacturing Practices (cGMPs).

(iii) Strengthen the existing regulation and its enforcement in the pharmaceutical sector.

(iv) Support the National Drug Authority to ensure safety and efficacy of medicines, including traditional medicines.

It also proposes under Objective 5 to; improve the policy, legal, and regulatory framework by reviewing and developing relevant acts and regulations governing health in Uganda through the following interventions:

(i) Strengthen relevant institutions including National Drug Authority and professional councils to develop and enforce health and related legislation.

(ii) Support and implement an effective regulatory environment that will enforce existing legislation and policies, including inspections by regulatory bodies, and ensure that high quality services are provided.

(iii) Support the development of an effective regulatory environment and mechanisms for clients who seek redress for poor service provision.

(iv) Support the development and enforcement of by-laws and regulations at local level.

2.3.3 The Health Sector Development Plan

The Health Sector Development Plan (HSDP) 2015-2020 acknowledges that the regulation of medicines has been strengthened through NDA in the last five years; however it points out the inadequate funding for NDA to carry out its regulatory function. The focus for NDA for the next five years under the HSDP is to:

(i) Strengthen legal and policy frameworks to assure quality medical products and health technologies and food safety.

(ii) Strengthen postmarketing surveillance and pharmacovigilance for medicines and health supplies.

(iii) Promote domestically produced essential medicines of good quality.

2.3.4 National Pharmaceutical Sector Strategic Plan

The National Pharmaceutical Sector Strategic Plan (NPSSP) 2016-2021 development affirmed that a reasonable legislative and regulatory framework is in place, but owing to some weaknesses and the move to extend its mandate, the law establishing NDA is up for amendment. It also determined the following critical gaps:

(i) Unclear activities, roles, mandate of various players currently involved in medicines regulation, and no mechanism to evaluate the contribution of each of the players.

(ii) Significant deficiencies in the enforcement of regulations governing prescription- only medicines; traditional and complementary medicine products; veterinary medicines; medicine handling including retailing in clinics, transportation, distribution, research; community drug distributors; and village health teams.

(iii) Ineffective postmarketing surveillance and pharmacovigilance systems, especially in the private sector.

(iv) Ambiguous policy and regulatory framework for authorization and licensure of “persons” who handle medicines.

Since a number of laws are in the pipeline for amendment or enactment, emphasis is placed on pursuing the bills that are already in the pipeline, thereby strengthening the legislative and regulatory framework to improve the systems for quality assurance of pharmaceutical products.

The following strategies are identified:

1. Identify, establish, and maintain collaboration with relevant regional and international bodies.
2. Develop and maintain a strong system for post marketing surveillance.
3. Develop and enforce regulations on medical devices, traditional and complementary products, and other relevant areas as required.
4. Promote the development and growth of domestic production of pharmaceutical products of assured quality, safety, and efficacy and effectively engage the private sector in policy implementation.

Currently the regulation of medical devices and in vitro diagnostic products is not appropriately provided for in the legislation. The draft NFDA bill makes provisions for the effective regulation of Public Health Products (PHPs), in vitro diagnostics, medical devices, and cosmetics. The bill also strengthens the provisions for regulation of herbal medicines, focusing on commercialized herbal products.

2.3.5 The Veterinary Drug Policy

The Veterinary Drug Policy has the following areas of focus:

- Veterinary drug supply
- Veterinary drug legislation and inspection
- Licensing of veterinary drug outlets
- Disposal of expired or otherwise unwanted veterinary drugs and veterinary waste materials

- Monitoring of drug residues in foods of animal origin
- Quality assurance of veterinary drugs
- Veterinary drugs information management system
- Research in veterinary drugs and ethno veterinary medicines
- Correct and safe use of veterinary drugs.

The responsibility of policy implementation from a government perspective is shared primarily between the Ministry of Agriculture Animal Industry and Fisheries and the National Drug Authority. However, given the decentralization of veterinary services to the districts, the district local governments directly impact service delivery.

2.4 Regional and International Regulatory Issues

Regulatory authorities are continually faced with new issues such as globalization and extension of free trade. Increased responsibilities from market expansion and increasingly sophisticated products place heavy demands on regulatory systems and knowledge bases. The development of cutting-edge technologies and health care techniques and extensive use of the Internet impose further challenges.

The African Union heads of state agreed to the formation of the African Medicines Agency (AMA). A task force is in place to ensure that the AMA is established by 2018. AMA will be the custodian of the model law on medicines regulation and will assist countries with their legislative frameworks. It will also provide regulatory guidance on complex or innovative therapies, developing policies, guidelines, and standards, GMP inspection of active pharmaceutical ingredient (API) manufacturing sites and control of substandard/spurious/falsely labelled/falsified/ counterfeit (SSFFC) products.

The model law on medicines regulation has been developed by the New Partnership for Africa's Development Agency and adopted by the African Union. The model law provides a framework for the regulation of medical products and requires countries to domesticate those provisions that may be missing from their legislative framework.

EAC has responded to these challenges at a regional level by requiring that partner states cooperate on matters of health by developing common medicines policies and harmonizing medicines regulation through Chapter 21, Article 118 of the EAC Treaty. The East African Community Medicines Regulatory Harmonization Program was launched in 2012 and the 29th meeting of the EAC Council of Ministers in September 2014 approved the harmonized medicines registration guidelines, requirements, and procedures and subsequently the use and domestication by EAC partner states commenced 1 January, 2015.

The Council of Health Ministers also adopted a mutual recognition procedure for registration of veterinary vaccines. National medicines regulatory authorities of the member countries are expected to fast track the registration of drugs within the region, facilitate easy movement of products within the community, and establish systems for joint EAC drug evaluations and inspections to build capacity within their institutions.

Uganda has adopted international standards, guidelines, and recommendations under the World Organization for Animal Health, the Codex committee on residues of veterinary products and pesticides, and the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products, which is a trilateral programme comprising the European Union, Japan, and the United States. NDA was accepted as a member of the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products Outreach Forum in June 2016. It is hoped that by benchmarking these countries with stringent drug regulatory agencies, the capacity of NDA to meet its mandate will be enhanced. NDA also hosts the Focal Point of Veterinary Products of the World Organization for Animal Health.

International Conference of Drug Regulatory Authorities (ICDRA)

ICDRA provides drug regulatory authorities of WHO member states with a forum to meet and discuss ways to strengthen collaboration. ICDRA has been instrumental in guiding regulatory authorities, WHO, and interested stakeholders in determining priorities for action in national and international regulation of medicines, vaccines, biomedicines, and herbals.

The 2015 16th ICDRA made the following recommendations for member states:

- Strengthen national medicines regulatory systems as a component of the health system by establishing the necessary governance and legal frameworks that will enable NRAs exercise this role, and ensure effective implementation of core regulatory functions; and promote the greater participation of national regulatory authorities in existing international and regional initiatives and networks for collaboration and cooperation.
- Prevent and reduce the risk to public health from SSFFC medical products by participating in the WHO member state mechanisms on SSFFC medical products and put in place strategies and procedures to prevent, detect, and respond to emerging SSFFC products.
- Implement pharmacovigilance as an integrated service that supports regulatory decisions, informs public health programs and improves health-care delivery; establish, strengthen, and effectively enforce regulations of herbal medicines; develop capacity for regulation of biotherapeutic products; establish regulation of whole blood, blood components, and plasma derivatives within the national regulatory authority; strengthen regulation of medical devices, including in vitro diagnostics; strengthen capacity of regulatory authorities' oversight of clinical trials; and ensure that appropriate regulatory pathways are in place to provide rapid but effective regulatory oversight of products to be used in public health emergencies.
- Establish transparent regulatory systems based on internationally agreed-upon standards that will assure quality and safety of APIs manufactured by regulated manufacturers and used in and/or exported from their borders, while ensuring that all API producers, suppliers, and brokers are regulated; support and encourage the use of information sharing mechanisms for ensuring the quality and safety of APIs e.g. WHO prequalification, International Generic Drugs Program (IGDRP).
- Ensure that all inspections are done in a consistent manner and that inter-inspector variability is measured and managed.

3.0 Organizational Assessment

3.1 Strategic Plan Period 2011-2016 Review

NDA Strategic Plan 2011-2016 was informed by and aligned to the National Veterinary Drugs Policy, National Health Policy (NHP), Health Sector Strategic Plan, and NPSSP. The plan was based on five strategic priorities as follows:

(i) Ensure that essential, safe, efficacious, and cost-effective drugs and other health care products are made available to the entire population to provide satisfactory health care.

(ii) Ensure that appropriate information on the correct use and storage of drugs is readily available, widely disseminated, and used accordingly.

(iii) Support the development of efficient local production of essential drugs of good quality relevant to national needs and resources.

(iv) Ensure that adequate financial, physical, technical, and human resource capacity is available so as to maintain efficient and effective operations of NDA and to satisfy customers.

(v) Contribute to the process of transforming NDA into NFDA.

A midterm review of the 2011-2016 strategic plan conducted in April 2015 observed that the successful implementation of measures that support the core regulatory functions of the NDA had benefited the country by improving access to and availability of pharmaceuticals for both human and veterinary use. As a result, the nation's health outcomes have also improved. The key results from the review are presented in the table that follows. The status of these results has not changed significantly since the midterm review with the exception of the work environment for staff. The Authority, since its appointment towards the end of 2013, has made significant strides in addressing staff concerns by recruiting additional staff at both operational and managerial levels, clarifying human resource policies and procedures, and reviewing staff remuneration.

3.2 NDA Financial Performance review 2011-2016

NDA continued to register notable performance improvement in the strategic plan implementation period 2011 - 2016; Revenue increased by 115%, The Accumulated Reserves increased by 182% and the Operating Expenditure remained stable at 1.2% increase. The increase in revenue was due to a stable macro economic factors. The projected annual revenue growth in 2013/14 was 12%, which was affected by change in the governance structure of the Authority. The financial indicators are shown in the table below;

Indicator	Financial Performance review 2011-2016					
	Baseline 2010/11	2011/12	2012/13	2013/14	2014/15	2015/16
Annual Revenue	18.7	21.5	24.8	27.7	33.3	46.3
Operating Expenditure	15.1	16.2	19.4	23.2	24	16.4
Net Surplus before Depreciation	4.4	6.4	6.9	6.0	11.2	31.8
Net surplus after depreciation	3.6	5.3	5.4	4.5	9.3	29.9
Projected Revenue Growth		15%	15%	12%	20%	39%
Accumulated Surplus Reserves	14.2	19.5	24.6	29.3	38.6	55.0

PROGRESS ON IMPLEMENTATION OF NDA STRATEGIC PLAN 2011 – 2016

FINDINGS OF THE MIDTERM REVIEW APRIL 2015

A. Fully attained goals of the strategic plan

1) NDA successfully executed its core mandate of regulating allopathic human and veterinary medicines in terms of quality, safety, and efficacy.
2) The success of NDA regulatory functions increased the availability of human and veterinary medicines as well as contributed to positive national health outcomes.
3) On institutional reforms, the NDA attained its strategic goal of increasing its financial sustainability.
4) NDA attained its goal of expanding the infrastructure required to support the execution of its core regulatory functions.

B. Partially attained goals of the strategic plan

1) Although the NDA has a mandate to regulate traditional/complementary medicines as well as nutrition supplements, not much work had been done to develop appropriate regulations and guidelines.

C. Areas not achieved as set out in the strategic plan

1) Although there is a Policy Directive on Food Safety on the role of the NDA, this directive has not been translated into a mandate with appropriate regulations, which has hampered NDA's ability to attain its goal of becoming NFDA.
2) NDA had set itself an important goal of improving the work environment of its staff, but this was substantially hampered by the absence of a board (2011-2013)

Note: *Except for the great strides made since appointment of the Fifth Authority in 2013, the position on the other strategic areas had not changed significantly by the end of the strategic planning period in June 2016.*

3.3 SWOT Analysis

The SWOT covers the strengths, weaknesses, opportunities, and threats that need to be recognized to enhance the quality of NDA's service delivery. The 2016-2021 strategic plan outlines strategies to address the weaknesses and threats identified and to consolidate the strengths identified in the analysis.

Results of NDA SWOT Analysis

Strengths	Weaknesses
a. Set up by statute with a defined mandate, regulations and guidelines. b. Committed leadership to transform the institution. c. Competent and knowledgeable staff. Organisation has over 23 years of experience in the field of drugs regulation. d. Secure funding as the law empowers NDA to collect revenue and spend at source. e. WHO-prequalified laboratory. f. High-value assets such as the equipment in the laboratory and NDA- owned land and buildings.	a. Gaps in the governance structure e.g. overlap of roles between Authority and management. b. Lack of performance management systems and weak performance appraisal system. c. Inadequate staff remuneration. d. Insufficiently developed occupational health and safety systems. e. Limited stakeholder engagement. f. Lack of an organisation structure. g. Limited staffing leading to limited presence beyond the headquarters h. Insufficient infrastructure relative to the scope and nature of operations. i. Lack of adequate and effective business process automation. j. Limited awareness of NDA services by the public. k. Weaknesses in enforcement. l. Lack of detection technologies at the ports and in the field. m. Reliance on district drug inspectors who are not NDA employees n. Gaps in the existing laws (NDA/P Act)
Opportunities	**Threats**
a. Renewed political will from government to transform the country, promote business and strengthen the health sector. b. Supportive regional and international collaborative mechanisms with EAC, African Medicines Regulatory Harmonisation Project, WHO, International Organization for Standardization (ISO), Pharmaceutical Inspection and Certification Scheme (PICS). c. Collaboration with ministries, departments, and agencies and other relevant institutions to execute NDA functions. d. WHO prequalification provides an opportunity for commercialisation for laboratory testing. e. Development partners interest in increased quality and safety of Medicines. f. Increased scope of products to be regulated under NFDA bill g. Global shift towards self-financing mechanisms to support regulatory activities.	a. Gaps in other laws that create conflicts that hamper regulation b. Conflicting and duplication of roles with other ministries, departments and agencies c. Policy shifts that lead to loss for revenue to NDA (e.g. Pharmacy Council taking over the licencing of pharmacies in the proposed bill) d. Litigation from clients that threaten image and financial sustainability. e. Mushrooming drug shops and pharmacies manned by unqualified health personnel. f. Porous borders that allow inflow of unregulated products. g. Limited access by the population to health services. h. Increased public concern about drug quality and safety.

3.4 Stakeholder Analysis and Expectations

To establish the expectations of stakeholders, consultations were conducted with different groups through focused group discussions as well as individual consultations. NDA stakeholders were broadly categorized as follows:

(i) Policy makers with supervisory function over NDA.

(ii) National regulatory agencies within and outside the health sector.

(iii) International and regional bodies with whom NDA works to achieve shared goals.

(iv) Players in the medicines supply chain (drug importers, manufacturers, wholesalers and distributors, retail outlets, public and private medical facilities, health marketing agencies, traditional medicine promoters, medical device suppliers).

(v) Civil society and patient organisations.

(vi) Academia and research organisations.

(vii) The media

The focus under the stakeholder analysis was to assess how NDA services, stakeholder relationships, and image compound to inform client expectation and the extent to which these expectations were being met. The following were the major observations and expectations from stakeholders.

Major Observations and Expectations by Stakeholders

1. Secure the quality of medical and veterinary products throughout the entire supply chain including the underserved markets.
2. Strengthen the regulation of Veterinary medicines working together with other partners in the Veterinary sector.
3. Respond to epidemics by conducting early registration procedures for possible drugs, speeding up clinical trials and the study phases for drugs for emerging epidemics.
4. Facilitate local production of medical products.
5. Align and harmonise service delivery with other relevant government entities such as Uganda Revenue Authority, Uganda National Bureau of Standards, and Uganda National Council of Science and Technology.
6. Standardize NDA services to minimise inter-staff variability and increase efficiency.
7. Promote the use of ICT in the delivery of service.
8. Update and revise the drug schedules to cater for policy shifts and sector trends e.g. community medicines usage.
9. Increase NDA laboratory capacity to test a wide range of products to reduce costs and save time.
10. Prioritize client expectations and provide regular and standardized feedback about regulatory decisions and expectations.
11. Increase awareness of the public about drug regulation.
12. Facilitate the implementation of a pro-active ethical research agenda on medicines and health care products that is meaningful for Uganda.
13. Make and follow through with commitments to strengthen the regulation of medicines and medical devices.
14. Continually build the capacity of NDA to regulate and extend its reach countrywide.
15. Increase stakeholder collaboration and partnership with a focus on meaningful engagement.

3.5 Summary of Emerging Issues and Critical Gaps

The table below provides a summary of the key issues and gaps identified from a synthesis of the observations from the internal and external stakeholder consultative engagements, the mid-term review of the previous strategic planning period, delivery requirement on sector and national priorities and obligations to regional and international mechanisms.

Summary of Emerging Issues and Critical Gaps

Key Issues	Gaps Identified
Legal and Regulatory	1. Existing gaps in current law in regard to regulation of medical devices, food, blood and blood components, traditional medicine, vaccines, and biological products. 2. Lack of harmonization of different institutional mandates (conflicting mandates) and limited collaboration with other agencies. 3. Weak veterinary medicine regulation in collaboration with players in the veterinary sector. 4. Several government policies and bills that would complement NDA are still at the draft stage including the pharmacy profession and practice bill, the national health insurance scheme bill, the traditional and complementary medicine bill.
Infrastructure, Facilities, and Equipment	1. Inadequate working environment and facilities (e.g. current headquarters building, regional offices, central lab and regional lab facilities including services to cater for veterinary vaccines) to minimize delays and costs. 2. Limited investment in infrastructure expansion to support service delivery.
Human Resources	1. Understaffing and lack of alignment of the structure to deliver strategies including limited staffing levels at regional offices to handle decentralized services. 2. Weak performance management and reward systems. 3. Weaknesses in regulation by professional councils and limited availability of skilled last-mile professionals such as drug dispensers and pharmacy technicians, leading to unqualified practitioners.
Service Delivery	1. Inadequate management systems leading to unnecessary delays in decision making. 2. Limited standardization, integration, and automation of procedures, systems, and business processes. 3. Inadequate post marketing surveillance and weak enforcement and pharmacovigilance on medicines and medical products. 4. Inadequate footprint of NDA services including weak capacity at regional and border entry points. 5. Lack of proactive mechanisms to respond to emergencies (e.g., early/speedy registration of drugs and clinical trials during epidemics). 6. Weak enforcement mechanisms particularly for traditional medicines and drug promotion and advertising. 7. Poor internal interdepartmental and functional coordination.

Supply Chain	1. Lack of proactive promotion of domestic production of essential medicines and health care products. 2. Slow registration processes and long registration lead times. 3. Proliferation of unregulated products and counterfeits and smuggling of drug and medical products from neighbouring markets including falsification of documents due to advances in technology. 4. Mushrooming of drug shops and pharmacies across the country staffed by unqualified health personnel.
Collaborations and Partnerships	1. Weak collaboration mechanisms with other agencies to leverage synergies, efficiency in service delivery, and resource optimization. 2. Inadequate participation in regional initiatives and collaborations including harmonization of policies, regulation guidelines, practices and standards to increase efficiency in the regulatory environment. 3. Limited information dissemination including public awareness of medicines use and safety and community level support for inspection and surveillance.
Financing	1. Lack of diversification of revenue sources and overreliance on regulatory fees.

3.6 Rationale for National Drug Authority Strategic Plan 2016-2021

The National Drug Authority Strategic Plan has been developed to address the challenges identified above, meet stakeholder expectations, and enhance delivery of the NDA mandate. The plan has also been designed to maximize NDA's contribution to the attainment of sector, national, and international development agendas. It provides the Authority's strategic focus for the next five years in alignment with the National Pharmaceutical Sector Strategic Plan, the Health Sector Development Plan, and the National Development Plan, and highlights how NDA will contribute, within its mandate, to improving the pharmaceutical sector and overall health sector performance by supporting the National Veterinary Drug Policy and Strategy, Vision 2040, and the Sustainable Development Goals.

4.0 Strategic Foundations

The strategic foundations (vision, mission, core values, mandate, and functions) of NDA guide all strategy discussions for the organisation and provide the context for how the organisation operates on a day-to-day basis. The vision, mission and core values were reviewed as part of the organizational assessment and were aligned to NDA's new strategic direction.

4.1 Vision

A Uganda with safe, effective and quality medicines and health care products

4.2 Mission

Promoting and protecting public health through the effective regulation of human and animal medicines and health care products

4.3 Core Values

Values are critical in guiding behaviour. The following are the values that NDA has chosen to guide the culture and behaviour of Authority management and staff.

- **We care for the people of Uganda,** striving for excellence in service underpinned by professionalism and fairness.
- **We take pride in what we do,** motivated and passionate about achieving the highest standards of service.
- **We serve with integrity** and are honest, transparent, and accountable at all times.
- **We continuously nurture team spirit,** respecting and supporting each other, working together to achieve common objectives.
- **We take advantage of new opportunities for learning** and use our knowledge and skills to innovate, creating value for our clients and the public.

4.4 Mandate

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

4.5 Functions

The law prescribes the functions of NDA to include the following:

(i) Address the development and regulation of pharmacies and drugs in the country.

(ii) Control the importation, exportation, and sale of pharmaceuticals.

(iii) Control the quality of drugs.

(iv) Promote and control local production of essential drugs.

(v) Encourage research and development of herbal medicines.

(vi) Establish and revise professional guidelines and disseminate information to health professionals and the public.

(vii) Provide advice and guidance to the MOH and bodies concerned with drugs on implementing the National Drug Policy.

(viii) Perform any other function that is connected with the above or that may be accorded to it by law.

The current legal mandate of NDA does not cover emerging products such as medical devices, food and nutritional supplements, blood and blood products. Although there are efforts to bring the above elements into the regulatory scope through the National Food and Drug Authority bill, this is not yet enacted into law.

5.0 Strategic Agenda

The contextual analysis, organizational assessment, stakeholder expectations, aspirations of the Authority and staff call for a transformational approach to the way NDA delivers its service to stakeholders. NDA seeks to leverage opportunities and honour obligations presented by the existing agreements at national (NDP, HSDP, NVDP, NPSSP) and regional levels (EAC drug harmonisation) as well as with international best practices.

The goal of the 2016-2021 strategic plan is to transform NDA into a high- performing regulatory agency that maximises public human and animal health while delivering value to its clients

5.1 Strategic Priorities

In response to the identified emerging issues, critical service delivery gaps and the need for NDA to deliver on national goals and aspirations as defined in Vision 2040, the NDP II, and relevant sector plans, three strategic priorities have been identified to form the focus for the next five years:

Strategic Priority 1: Safety, Efficacy, and Quality

Safety, efficacy, and quality is the core of NDA's mandate. All medicines and health care products to be used in Uganda must be safe, efficacious, and of good quality to ensure the health of the Ugandan population. Having the strategy focus on saftety, efficacy, and quality means that all interventions will be directly linked to NDA's mandate. The overall goal under this priority area is to enhance the effectiveness and quality of medicines on the Ugandan market and increase public confidence in the quality of medicines by strengthening the pre and post-marketing regulation for all medicines and health care products imported, manufactured, distributed, and used in the country.

As an Authority, we are more concerned about effective drugs which produce the desirable stringent outcomes within our clinical settings.

Strategic Priority 1 Objectives

1.1 Increase compliance to the NDP/A Act and Regulations

NDA will ensure that its clients comply with the provisions under the NDP/A Act. It will seek to build voluntary compliance to policies and legal regulations. This will include improving the standards of Drug Shops and Pharmacies throughout the whole country through accreditation of drug outlets: Good Pharmacy Practices (GPP) for public and PNFP health facilities and Good Distribution Practices (GDP) for wholesale Pharmacies.

1.2 Promote domestic production of human and veterinary medicines and health care products

NDA will promote the local production of medicines and health care products to reduce reliance on imports and contribute to the national development aspirations on industrialisation.

1.3 Strengthen the systems, processes, and procedures for pre-market regulatory activities on medicines and health care products

NDA will build its capabilities to improve on pre-market regulatory activities with emphasis on efficient & effective registration processes.

1.4 Strengthen the systems, processes, and procedures for post-market regulatory activities for medicines and health care products

NDA will build its capabilities to address challenges associated with post-marketing follow up of medicines and health care products along the supply chain and the impact of those products on the health of both humans and animals.

1.5 Provide relevant and appropriate drug and health care product information to the public

NDA will promote public accessibility to relevant drug information that is needed to empower the people on their choices concerning various medicines and health care products. The focus under this objective is to have an informed public on the issues of safety, efficacy and quality.

Strategic Priority 2: Collaborations and Partnerships

NDA will strengthen collaboration with stakeholders within the country, region, and globally to improve service delivery. The focus will be on actively identifying strategic partners and formalizing partnership arrangements, participating in regional harmonization efforts as well as building and strengthening all other partnerships.

Strategic Priority 2 Objectives

2.1 Participate actively in EAC and other harmonization initiatives

NDA will promote EAC harmonisation of various medicines regulation processes and exchange of critical information amongst the region's medicine regulatory agencies.

2.2 Harness the synergies available through national, regional, and international partnerships and collaboration

NDA will promote synergies to reduce duplication of efforts and costs of service delivery. This will include the development of local capabilities to exploit economies of scale and support local, regional, and international partnerships in drug regulation management of quality and increased public awareness.

2.3 Facilitate the improvement of the legal and regulatory framework for food safety, medicines, and other health care products.

NDA will promote improvements in the legislative framework to minimise gaps and flaws in the current law in order to align with current business development in the sector. Under this objective, NDA will seek out relevant stakeholders to engage with the goal of transitioning from NDP/A law to National Food and Drug Authority (NFDA) law.

2.4 Engage all external stakeholders effectively

As a government regulatory agency, NDA will seek out all other agencies and institutions that are central to the improvement of the medicine and health care product regulation in the country and region.

Strategic Priority 3: Institutional Capacity

NDA will invest in the people, infrastructure, systems, and technologies that together will translate into an efficient and effective organisation. Decentralization will be key to bringing service delivery closer to those who need it and have a direct impact on Uganda's human and animal populations. NDA will also improve its infrastructure by building both administration offices and specialized laboratories to support operations.

Strategic Priority 3 Objectives

3.1 Develop the requisite human resource capacity to deliver NDA's mandate
NDA will develop the requisite human resource capabilities and deployments needed to deliver its strategy. NDA will also develop the human resource management systems needed to address the functioning of the new organisation structure.

3.2 Avail the requisite infrastructure and equipment
NDA will develop the much-needed functional and administrative infrastructure that is central to the provision of a productive office environment for staff.

3.3 Ensure that all business processes are efficient and effective
NDA will seek to re-engineer all business processes and strengthen its quality management system. NDA will also seek to enhance the automation and integration of supporting processes to enhance institutional efficiency.

3.4 Provide good financial stewardship and promote financial sustainability
NDA will develop a revenue mobilisation strategy built on the current revenue streams while identifying other revenue sources needed to make NDA a self-sustaining agency. NDA will also put in place prudent financial procedures that promote good financial stewardship.

3.5 Promote knowledge management across NDA
NDA build systems that support research and innovation to become a more knowledge-based organisation. This will include building the capacities needed to retain institutional knowledge and support succession planning management

3.6 Attain the highest practicable standards of corporate governance
NDA will adopt and promote sound corporate governance principles that enhance transparency and accountability, while seaking to promote the effective functioning of the Authority and its represantation.

5.2 Strategic Objectives and Interventions

The table below summarizes the strategic priorities, their objectives, and related interventions needed to achieve the objectives.

Strategic Priority 1: Safety, Efficacy, and Quality				Time frame
No	**Strategic Objective**	**No**	**Strategic Intervention**	
1.1	**Increase compliance to the NDP/A Act and regulations.**	1.1.1	Develop effective and efficient mechanisms to increase compliance to NDP/A act and regulations.	Y5
		1.1.2	Strengthen enforcement mechanisms.	Y5
		1.1.3	Sensitise the public about the NDP/A Act and regulations..	Y on Y
		1.1.4	Implement accreditation systems for Drug Shops and Pharmacies to improve standards.	Y5
		1.1.5	Promote compliance with Good Pharmacy Practice (GPP) by public and PNFP health facilities.	Y on Y
		1.1.6	Promote compliance with Good Distribution Practices (GDP) by wholesale Pharmacies.	Y on Y
1.2	**Promote domestic production of human and veterinary medicines and health care products.**	1.2.1	Support domestic manufacturers to comply with cGMP and maximise production outputs.	Y5
1.3	**Strengthen the systems, processes and procedures for pre-market authorization activities for medicines and health care products.**	1.3.1	Regulate clinical and field trial approvals to maximise safety while facilitating access to new medicines and health care products.	Y on Y
		1.3.2	Establish systems for timely product quality evaluations.	Y on Y
		1.3.3	Strengthen systems for registration of herbal medicines and other health care products.	Y on Y
1.4	**Strengthen the systems, processes, and procedures for post-market authorisation of drugs and health care products.**	1.4.1	Establish systems for inspection and licensing of herbal medicine manufacturing and sales premises.	Y3
		1.4.2	Strengthen systems for effective licensing and certification of premises.	Y on Y
		1.4.3	Review and improve systems for effective control of imports and exports.	Y2
		1.4.4	Increase the range and outputs of NDA laboratory services.	Y on Y
		1.4.5	Establish systems for field testing of medicines and health care products.	Y3

Strategic Priority 1: Safety, Efficacy, and Quality				Time frame
No	**Strategic Objective**	**No**	**Strategic Intervention**	
		1.4.6	Establish strong track and trace systems along the entire supply chain.	Y5
		1.4.7	Increase the effectiveness and visibility of the pharmacovigilance systems.	Y2
		1.4.8	Foster ethical medicines promotion (herbal & conventional).	Y5
		1.4.9	Facilitate the prudent and safe disposal of expired or otherwise unwanted medicines.	Y on Y
		1.4.10	Strengthen the systems for quality control testing of medicines, medical devices, and other health care products.	Y5
		1.4.11	Strengthen The Rapid Alert System To Manage SF.	Y on Y
1.5	**Provide relevant and appropriate drug information to the public.**	1.5.1	Establish and maintain systems for effective drug information dissemination.	Y on Y
		1.5.2	Disseminate public information on relevant drug laws and regulations.	Y on Y

Strategic Priority 2: Collaboration and Partnerships				Time frame
No	**Strategic Objective**		**Strategic Intervention**	
2.1	**Participate actively in EAC and other harmonisation initiatives.**	2.1.1	Institute measures in support of regulatory harmonisation and identify additional areas for harmonisation: • Legal framework, policies, and guidelines • Advocacy and capacity development • Mutual recognition cooperation agreements	Y on Y
		2.1.2	Undertake joint activities with other regulatory agencies.	Y on Y
2.2	**Harness the synergies available through national, regional, and international partnerships and collaboration.**	2.2.1	Establish strategic partnerships with all agencies/ bodies central to delivery of NDA mandate.	Y on Y
		2.2.2	Establish mechanisms for collaboration and joint working with health regulatory bodies and other stakeholders.	Y on Y
		2.2.3	Strengthen existing partnerships and collaborations.	Y on Y
2.3	**Facilitate the improvement of the legal and regulatory framework for food safety, drugs, and other health products.**	2.3.1	Establish and facilitate development of a relevant legal and regulatory framework covering NDA's extended mandate.	Y4
		2.3.2	Establish and implement an effective advocacy programme.	Y2

Strategic Priority 2: Collaboration and Partnerships				Time frame
No	**Strategic Objective**		**Strategic Intervention**	
2.4	**Effectively engage all external stakeholders.**	2.4.1	Set up effective communication, information dissemination, and feedback mechanisms for different stakeholder groups.	Y on Y
		2.4.2	Establish sustainable fora for sharing information on regulatory activities and quality of medicines and health care products at various levels.	Y on Y

Strategic Priority 3: Institutional Capacity				Time frame
No	**Strategic Objective**		**Strategic Intervention**	
3.1	**Develop the requisite human resource capacity to deliver NDA's mandate.**	3.1.1	Foster on values-based culture (inculcate core values into the work force).	Y on Y
		3.1.2	Continually invest in learning/training and skills development.	Y on Y
		3.1.3	Align the performance management and reward systems to the strategy.	Y on Y
		3.1.4	Develop effective and accountable leadership across the organisation.	Y on Y
		3.1.5	Put in place clear workforce planning and human resource management systems.	Y on Y
3.2	**Avail the requisite infrastructure and equipment.**	3.2.1	Construct NDA towers.	Y5
		3.2.2	Complete construction of the microbiology lab at National Drug Quality Control Lab (NDQCL) and acquire laboratory equipment.	Y2
		3.2.3	Set up fully equipped field offices.	Y4
		3.2.4	Implement an integrated management information system across the organisation.	Y2
		3.2.5	Provide information and communication technology infrastructure (software and hardware) connecting all NDA offices.	Y2
		3.2.6	Implement the One Stop Border Point (OSBP) at Mombasa.	Y3

Strategic Priority 3: Institutional Capacity				Time frame
No	**Strategic Objective**		**Strategic Intervention**	
3.3	**Ensure that all business processes are efficient and effective.**	3.3.1	Implement QMS compliant to ISO and on other international standards across the whole organisation.	Y3
		3.3.2	Decentralise all key technical functions to regional offices (except cGMP and product evaluation).	Y2
		3.3.3	Automate and integrate all business processes.	Y3
		3.3.4	Implement a comprehensive organisational monitoring performance system.	Y on Y
		3.3.5	Strengthen procurement systems.	Y3
		3.3.6	Implement an effective administration system.	Y on Y
		3.3.7	Establish mechanisms for timely service delivery.	Y on Y
3.4	**Provide good financial stewardship and promote financial sustainability.**	3.4.1	Strengthen systems for efficient resource allocation, utilisation, and provision of value for money.	Y3
		3.4.2	Strengthen financial accountability systems.	Y3
		3.4.3	Expand and diversify sources of revenue.	Y on Y
3.5.	**Promote knowledge management across NDA.**	3.5.1	Put in place systems and incentives to support research and innovation.	Y on Y
		3.5.2	Establish an integrated resource centre.	Y on Y
		3.5.3	Publish and disseminate information generated at NDA.	Y on Y
		3.5.4	Analyse and share statistics arising from information flowing through the organisation.	Y on Y
3.6	**Attain the highest practicable standards of corporate governance.**	3.6.1	Put in place mechanisms to regularly review employee and authority performance.	Y on Y
		3.6.2	Strengthen systems for independent objective assurance audit and advisory services.	Y on Y
		3.6.3	Put in place environmental and social safe guard systems.	Y4
		3.6.4	Invest in corporate image and visibility.	Y on Y
		3.6.5	Strengthen the enterprise risk management system.	Y3

5.3 Regulatory and Health Strategic Outcomes

In line with the defined strategic priorities, specific outcomes are expected to be achieved and these will be measured annually through specific indicators as detailed below.

Strategic Priority	Strategic Objectives	Regulatory & Health outcomes	S/N	Key Indicators	Target
Safety, Efficacy, and Quality	Strengthen the systems, processes and procedures fo pre-market activities for medicines and health care products.	Increased access to the regulated products	1	Percentage of medicines batches that are tested before they are sold	40%*
		High Quality products	2	Percentage of foreign & Local GMP Inspections conducted on time	75%
		Products available at the time they are needed	3	Percentage of additional Information evaluated on time	95%
			4	Percentage of applications for product registration received and assessed within twelve months	95%
		Efficacious Products	5	Percentage of Clinical Trial applications evaluated on time	95%
	Increase Compliance to the NDP/A Act and regulations	High Quality products	6	Percentage of Unlicensed (Non-Compliant) Drug Outlets	5%
			7	Percentage of Licenses eligible for renewal issued by 1st January every year	100%
			8	Number of Product Recalls initiated by NDA	Trends
	Facilitate domestic production fo human and veterinary medicines and health care products.	Increased domestic manufacturing of quality essential medicines	9	Number of domestically manufactured essential medicines	50
			10	Percentage of domestically manufactured herbal medicines notified	40%

**The target is subject to review.*

	Strenghen the systems, processes, and procedures for post-market authorisation of drugs and health care products.	High Quality products	11	Percentage of substandard and falsified Pharmaceutical products on the market	5%
Collaborations and Partnerships	Participate actively in EAC and Other Harmonisation initiatives	Value addition from collaboration and partnerships	12	Number of Publications and joint activities undertaken with stakeholders	20
Institutional Capacity	Ensure that all business processes are efficient and effective	Institutional effectiveness	13	Percentage of services delivered within the agreed time lines	80%
	Effectively Engage all external stakeholders	Increased public condidence in product safety, efficacy and quality.	14	Percentage of Client Satisfaction Index	85%
	Provide good financial stewardship and promote financial sustainability	Strong financial stewardship and sustainability	15	working ratio	80%
	Avail the rquisite infrastructure and equipment	Institutional effectiveness and business process efficiency	16	Percentage completion of the NDA tower	
			17	Percentage of Business Processes Automated	75%
	Develop the requisite human resources capacity to deliver NDA's mandate.	High performing staff	18	Proportion of staff who attain 80% of their performance targets	95%
	Attain the highest practicable standards of corporate governance.	Good Corporate governance and compliance	19	Number of new cases arising from NDA staff exposing the Authority to avoidable litigation	0

6.0 Implementation, Monitoring, and Evaluation Mechanisms

Annual implementation plans will be prepared to guide the operationalization of the NDA strategic plan. The plans will outline how the strategic objectives and strategic priorities will be realized by indicating what will be done, by whom, when, and how and will serve as a checklist that will be regularly updated, monitored, and shared among the stakeholders. The plans will also help coordinate and integrate planned actions, support coordinated and collaborated efforts, minimize duplication, and promote synergies.

Monitoring and evaluating of how well strategy is being implemented will be aided by constant tracking of key strategic outcomes and outputs as detailed in the previous section.

Successful implementation of this strategy will require the following:

(i) Ownership of the strategy by staff, management, and the Authority
(ii) Effective annual implementation planning and commitment of resources
(iii) Behavioural change, minimal conflict, institutional cohesion, and harmony
(iv) Effective M&E to support strategy implementation

6.1 Institutional arrangements for strategy implementation

The implementation of this strategy will be carried out by NDA directorates departments and units, which will require changes in the current organization structure, systems, and procedures to improve efficiency and effectiveness. Also it is envisaged that the regional offices will gradually become semi autonomous with respect to implementation of approved Plans. While the NDA headquarters will have exclusively over certain functions such as authorization of clinical trials and product assessments, the bulk of regulatory functions will over time be shifted to the regions in as much as they relate to the geographical areas covered by the regional office. While the National Drug Quality Control Lab will continue to be the centre for quality testing of both medicines and health care products during this strategic period, efforts are to be made to strengthen field testing to support screening and eMS activities. Implementation therefore requires the shared responsibility of all concerned. To harness synergies, ensure holistic and sequenced approach to implementation of the strategic interventions, and facilitate the coordination of cross-cutting issues, the establishment of a Corporate Performance Management Unit is proposed. The unit will coordinate the development of annual work plans and budgets and bring together relevant stakeholders for joint implementation planning. Specifically, the responsibilities of the Corporate Performance Management Unit will entail the following:

(i) Ensuring congruence of institutional, department, project and other work plans with the strategic plan.

(ii) Ensuring that a sound framework for effective coordination of strategy implementation is adhered to at all levels.

(iii) Establishing mechanisms to coordinate intra-departmental linkages in implementing cross-cutting interventions.

(v) Periodically organizing strategy performance review meetings to ensure that the strategy is translated into operations.

(vi) Developing guidelines and reporting formats and databases to support M&E.

6.2 Progress reporting and review of results

NDA management will develop and put in place a work plan and corporate M&E framework that will provide the foundation for tracking performance against set targets. Directorates, Departments and units shall report monthly and quarterly on key expenditures, actions, outputs, and progress towards outcomes, where outcome data is available. This will guide the production of a quarterly performance report which will be presented to the Authority for discussion and approval. The quarterly performance reports will be consolidated into the NDA annual report. The annual report shall be presented at stakeholder forum to provide feedback on progress towards implementation of the strategy.

To align the strategy with the ever-changing environment, a mid-term and end of term perfomance review shall be conducted to assess the performance of NDA towards overall targets and the relevance of the strategic interventions to address emerging challenges.

The staff performance management system shall be aligned with the institutional work plans to help translate the strategy into every staff member's job responsibilities. Staff performance contracts at all levels will therefore be developed and signed off together with the unit, departmental and directorate work plans.

6.3 Assumptions

For Successful implementation of the Strategic Plan, NDA has made a number of Assumptions below:

- The NFDA bill is enacted into law.
- A fully resourced organisation structure is fully implemented.
- The political environment remains stable.
- The National Drug Authority continues to remain as an independent Authority.
- The National and International Macro Economic Factors remain stable.

7.0 Financing Mechanisms

Delivering this strategy will require a significant amount of financial resources. NDA will develop an effective revenue mobilization strategy and also raise additional funds from development partners to finance strategic interventions. Effective annual and capital investment planning procedures and processes will be put in place to ensure both allocative and spending efficiency.

Existing revenue sources will continue to be key and efforts will be made to ensure that they are fully optimised.

The table below shows the projected funding requirement to finance the strategy over the five-year period.

Projected Funding Needs and Sources: 2016–2021 (Billions of Uganda shillings)

	2016/17	2017/18	2018/19	2019/20	2020/21
Total Income					
Own source revenue	48.14	55.36	64.77	77.73	89.39
Accumulated reserves	29.94	20.52	16.57	14.69	6.60
Other (grants/loans)	0.43	0.50	0.58	0.69	0.80
Investment Needs					
Operations & maintenance (O&M)	37.16	42.73	50.85	61.03	72.62
Capital expenditure (CAPEX)	18.63	14.55	14.48	23.23	23.23

8.0 Annexes

Annex 1: References

1. EAC Medicines Registration Harmonisation Project document, 2010
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6. Ministry of Health Uganda. 2002. National Pharmaceutical Sector Strategic Plan for Uganda (NPSSP) 2002/3−2006/7MoH, Kampala Uganda
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14. www. vichsec.org

Annex 2: List of External Stakeholders Consulted

NO.	NAME	Institution
1	Citra Rehema	Abacus Pharma
2	Patrick Mpiima	Allied Health Professional Council /MOH
3	Nabbanja Annet	Allied Health Professional Council /MOH
4	Mr. Kassagga	Allied Health Professionals Council
5	Rogers Sekabira	Baylor - Uganda
6	Regina Kamoga	Community Health and Information Network
7	Prof. Kabasa	College of Veterinary Medicine, Animal Resources and Biosecurity (COVAB)
8	Dr. Nakavuma Jesca	College of Veterinary Medicine, Animal Resources and Biosecurity (COVAB)
9	Edward Mugirwa	Eram Uganda
10	Dr. Edward Okwori	Food and Agriculture Organisation of the United Nations
11	Dr. Mucunguzi Richard	Globalvet (U) Ltd
12	Okwir Ricky Okello	Gorilla Doctors
13	Fahad Sadiq	Health Care Ltd
14	Kenneth Muhoye	HEPS Uganda - Coalition for Health Promotion and Social Development
15	Denis Kibira	HEPS Uganda - Coalition for Health Promotion and Social Development
16	Nannono Monica	Hospice Africa Uganda
17	Eve Agnes Laker	Infectious Disease Institute
18	Kaboggoza J. P	Infectious Disease Institute
19	Dr. Peter Mugyenyi	Joint Clinical Research Centre (JCRC)
20	Dr. Bildard Baguma	Joint Medical Store
21	Joanita Lwanyaga	Joint Medical Store
22	Eric Musyoki	Kampala Pharmaceutical Industries
23	Doreen Basangwa	Kampala Pharmaceuticals Industries
24	Col BNN Rao	Kwality Afro Asia Limited
25	Kiryowa Uthman	Laborex (U) Ltd
26	Nabbanja Grace	MacNaughton Ltd
27	Sowedi Muyingo	Medical Access Uganda Limited
28	Dr. Kenneth Mugabi	Ministry of Agriculture Animal Industry & Fisheries
29	Dr. Asuman Lukwago	Ministry of Health
30	Dr. Sebisubi Fred	Ministry of Health
31	Dr. Isaac Kadowa	Ministry of Health
32	Dr. Sebidde Bernard	Mountain Gorilla Veterinary Project
33	Alex Natukunda	MTK (U) Ltd
34	William Nanyanga	National Livestock Resources Research Institute (NaLIRRI)
35	Moses Kamabare	National Medical Stores
36	Okuna Neville	Pharmacy Board MOH
37	Stella Mwesige	Quality Chemicals Ltd

NO.	NAME	Institution
38	Le-Marin Okiror	Rene Industries
39	Grace Bbosa	Sekalala Ltd
40	Fredrick Kisembo	Surgipharm
41	Dr. Christine Ondoa	Uganda AIDS Commission
42	Brian Sekayombya	Uganda Health Supply chain (UHSC)
43	Dr. Margaret Wandera	Uganda Medical and Dental Practitioners Association
44	Denis Kimalyo	Uganda National Association of Private Hospitals
45	David Mugisa	Uganda National Association of Private Hospitals
46	Geoffrey Bakiyi	Uganda National Association of Private Hospitals
47	Joel Oryang	Uganda National Bureau of Standard
48	Patricia Ejalu	Uganda National Bureau of Standards
49	Beth Mulaba	Uganda National Council for Science & Technology
50	Nalunkuma Edith	Uganda Nurses and Midwives council
51	Dr. Dominic Venture Mundrugo	Uganda Veterinary Association
52	Dr. Lawrence Mugisha	Uganda Veterinary Association
53	Dr. Seguya Andrew	Uganda Wildlife Authority
54	Denis Tugume	United Health Care Distributors
55	Gugu N. Mahlangu	World Health Organisation

Annex 3: Own Source Revenue Projections 2011-2021

Projected Revenue Streams											
GL Acc	Name	2011/2012	2012/2013	2013/2014	2014/2015	2015/2016	2016/2017	2017/2018	2018/2019	2019/2020	2020/2021
11999	Licensing Fees	1,325,300,880	1,269,296,511	2,427,905,967	2,402,677,750	2,118,893,972	2,330,783,369	2,680,400,875	3,136,069,023	3,763,282,828	4,327,775,252
12399	GMP Audit Fees	1,977,158,346	2,426,565,066	3,178,752,712	2,358,276,848	3,317,883,512	3,649,671,863	4,197,122,642	4,910,633,492	5,892,760,190	6,776,674,219
12599	Retention Fees	2,635,694,041	2,487,812,020	4,124,726,487	5,129,345,753	6,295,745,500	6,925,320,050	7,964,118,058	9,318,018,127	11,181,621,753	12,858,865,016
13199	Verification Fees	13,004,027,923	12,867,453,986	15,803,656,876	17,066,401,472	22,912,654,171	25,203,919,588	28,984,507,526	33,911,873,805	40,694,248,566	46,798,385,851
14399	Drug Registration Fees	1,457,691,868	2,228,688,028	712,837,577	1,521,549,933	3,436,966,473	3,780,663,120	4,347,762,588	5,086,882,228	6,104,258,674	7,019,897,475
15299	Notification	22,013,840	87,680,700	90,628,490	130,652,850	116,975,750	128,673,325	147,974,324	173,129,959	207,755,951	238,919,343
16199	NDA Publications	14,994,500	15,211,019	28,402,500	33,450,000	33,837,727	37,221,500	42,804,725	50,081,528	60,097,833	69,112,508
17399	Laboratory Analysis Fee	177,713,250	191,201,580	174,434,819	75,180,547	203,593,872	223,953,259	257,546,248	301,329,110	361,594,932	415,834,172
18199	Miscellenous	581,482,253	2,261,287,546	816,034,902	4,182,159,018	5,327,676,134	5,860,443,748	6,739,510,310	7,885,227,062	9,462,272,475	10,881,613,346
19199	Grants	334,527,073	978,483,846	365,246,445	392,293,543	391,354,265	430,489,692	495,063,146	579,223,880	695,068,657	799,328,955
		21,530,603,973	**24,813,680,302**	**27,722,626,773**	**33,291,987,713**	**44,155,581,376**	**48,571,139,514**	**55,856,810,441**	**65,352,468,216**	**78,422,961,859**	**90,186,406,137**
		Projected Growth	**15%**	**12%**	**20%**	**33%**	**10%**	**15%**	**17%**	**20%**	**15%**

Assumptions

a) NFDA Bill in place leading to additional revenue from 2017/2018
b) Target to Double revenue projections by 2020/2021 in the next five years
c) NDA will continue to rely on internally generated funds. i.e will not become a Vote