UGANDA

NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

National Drug Authority

REPORT TO THE NATION

FY 2020–2021

Editorial Team:
Annet Ssenkindu
Dr. Victoria Nambasa Bukenya
Dr. Solomon Onen
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Dr. Mathias Lukwago
Dr. Willfred Opira
Fred Kalungi Kabuye
David Praise Angubua (PR Intern)
Abiaz Rwamwiri
Fredrick Ssekyana (Editor)
Barbara Najjemba (Reviewer)

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Denis Kajura

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Contents

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Chairperson's Statement

Dr. Medard Bitekyerezo

"To attain and maintain global best practices in drug regulation by 2025"

The National Drug Authority (NDA) is responsible
for assuring the safety, efficacy and quality of drugs in Uganda. The Report to the Nation provides an opportunity of not only being accountable,
but also our commitment to transform and execute our mandate through a stronger, effective and efficient Authority.

I wish to commend the commitment of stakeholders that continue to be part of our mission in promoting and protecting public health from drugs that are substandard and falsified.
These efforts facilitate access to reliable, effective, quality and affordable essential medicines, medical products and vaccines as was adopted in Agenda 2030 for Sustainable Development of the United Nations General Assembly in 2015.

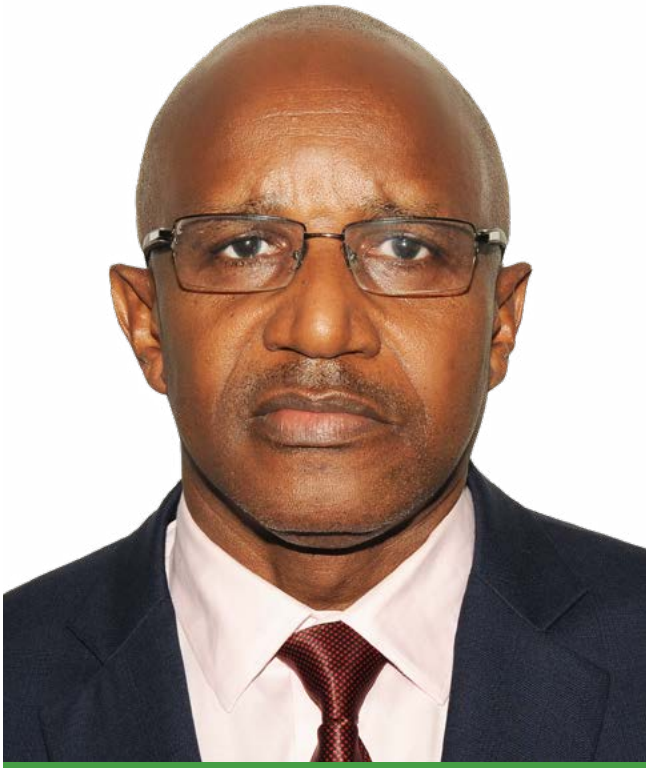
The main goal of the 2020 – 2025 NDA Strategic Plan is to attain and maintain global best practices in drug regulation by 2025. The Plan resonates with the National Development Plan III which focuses on modern, people centered, independent, integrated, resilient and self- sustaining economy.

To the public, you are our eyes and ears on the ground, and your role is to augment NDA operations in ridding the country of wrong elements in the pharmaceutical sector. I know NDA still has much to do, but with continued support from government, Ministry of Health, stakeholders and the public, a lot shall be accomplished for the betterment of our country.

For God and My Country

Authority Chairperson.

Secretary to the Authority Statement



Dr. David Nahamya

I am glad to present the financial year 2020/2021 account of the National Drug Authority performance in delivering on its core regulatory functions, that benefited the country to improve access and availability of safe and quality drugs (human and veterinary) and other healthcare products.

The availability of safe, quality and efficacious medicines is an important indicator of the quality of healthcare, and a key driver for attainment of the United Nations Sustainable Development Goals. In the advent of the Covid-19 pandemic that affected economies and business entities, it did present growth opportunities of our domestic pharmaceutical industry.

I am also glad to inform the public that we have developed a new Strategic Plan (2020/2021 - 2024/2025) to build upon the achievements that were realized during the period 2016 - 2021.

I take this opportunity to highlight some of the milestones achieved in the last financial year (FY 2020/2021).

- Tested 2,223 samples of medicines, medical devices and other healthcare products as compared to 2100 in FY 2019/2020.

- A total of 10,808 drug consignment imports were inspected of which 10,464 were released at the respective ports of entry in FY 2020/2021 as compared to 9,098 of which 8696 were released in FY 2019/2020.

- There was a significant increase of licensed pharmacies (2,369) and drug shops (12,124) compared 1,820 and 9,457 respectively in FY 2019/20.

- There was a rise of domestic pharmaceutical manufacturers licensed

The availability of safe, quality and efficacious medicines is an important indicator of the quality of healthcare, and a key driver for attainment of the United Nations Sustainable Development Goals.

(29) in the year under review as compared to 23 in FY 2019/20.

- Working with the Directorate of Industrial Training, we developed and launched the assessment training package to equip herbalists with skills in the processing of herbal medicinal products.

- A total of 30 herbal medicine manufacturers were inspected, and a total of 192 herbal products notified compared to 152 in FY 2019/2020.

- As we continuously improve our operations, I urge all stakeholders to be vigilant in order to promote and protect public health.

I extend our appreciation to the Government of Uganda, Ministry of Health, members of the Authority, staff, stakeholders and the public for your support that enabled us to deliver on our mandate.

Your safety is our priority. Safe Drugs Save Lives.

For God and My Country

Secretary of the Authority

01

Overview

1.0 Overview

A Glance at NDA's Performance FY 2020/2021

4,648
pharmaceutical products retained on the drug register compared to 4,881 (human - 4,043, veterinary -471, registered foreign human herbal products-134, and a foreign veterinary herbal – 1) in FY 2019/2020.

10,464 /10,808
drug consignment imports inspected and released for use in Uganda as compared to 8,696/9,098 in FY 2019/2020.

Drug outlets Licensed
2,369
Pharmacies and 12,124 Drug shops compared to 1,820 Pharmacies and 9,457 Drug Shops in FY 2019/20.

192
local herbal products notified compared to 152 in FY2019/2020.

29
Domestic pharmaceutical manufacturers licensed compared to 23 in FY 2019/20

2,552
adverse drug reaction reports received compared to 1824 reports received in FY 2019/20

349
foreign applications for inspections were assessed and issued with GMP certificates in FY 2020/2021 compared to 92 certificates issued in FY 2019/2020.

30
herbal medicine manufacturers inspected

26
drug recalls were effected compared to 22 in FY 2019/2020.

23/26
drug related complaint reports were handled to logical conclusion compared to 18/40 in FY 2019/2020

2,223
samples of drugs and other healthcare products tested as compared to 2100 in FY2019/2020.

189
clinical trial applications handled compared to 164 in FY 2019/2020.

187/253
drug promotions/ advertisements were approved to run in the media in FY 2020/2021

To improve animal health (better treatment of illnesses and prevention of diseases), yields, and economic gains for the farmers,

167 audits of veterinary cold chain facilities conducted in 82 districts, and 404 engagements held with stakeholders in veterinary sector at sub county level in 43 districts.

The National Drug Authority (NDA) was established in 1993 by the National Drug Policy and Authority Statute, which in 2000 became the National Drug Policy and Authority (NDPA) Act, Cap.206 of the Laws of Uganda (2000 Edition).

The Act established a National Drug Policy and National Drug Authority to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs.

The Drug Authority is composed of 20 members appointed according to the law. They have the diversity of professional expertise and academic discipline to effectively provide the oversight function required.

1.1 Vision

"A world class drug regulatory Agency"

1.2 Mission

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

1.3 Core Values

The following values guide culture and behavior of NDA in conducting business

- 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

1.4 Goals

To attain and maintain global best practices in drug regulation by 2025.

1.5 Functions of the Drug Authority

The Drug Authority is charged with the implementation of the National Drug Policy and, in particular:

i. Deal with the development and regulation of the pharmacies and drugs in the country;
ii. Approve the national list of essential drugs and supervise the revisions of the list in a manner provided by the Minister;
iii. Estimate drug needs to ensure that needs are met as economically as possible;
iv. Control the importation, exportation and sale of pharmaceuticals;
v. Control the quality of drugs;
vi. Promote and control local production of essential drugs;encourage research and development of herbal medicines;
vii. Promote rational use of drugs through appropriate professional training;
viii. Establish and revise professional guidelines and disseminate information to health professionals and the public.
ix. Provide advice and guidance to the Minister and bodies concerned with drugs on the implementation of the national drug policy; and
x. Perform any other function that is connected with the above or that may be accorded to it by law.

1.6 Quality Policy

The Drug Authority is committed to providing the highest standard of drug regulatory service to all customers.

Timely and reliable service, compliance to all applicable statutory and regulatory requirements, and meeting customer requirements underlie all our efforts in ensuring quality, safety and efficacy of all drugs and healthcare products used in Uganda. This is done through regulation and control of drug production, importation and distribution.

We are committed to implement a quality management system that complies with ISO 9001:2015 for the whole organization; WHO Good Practices for Pharmaceutical Quality Control Laboratories 2010 for the testing of drugs; ISO/IEC 17025:2017 for testing healthcare products; PIC/S 002 for pharmaceutical inspectorates; and maintaining an adequate workforce that is trained, motivated, facilitated and empowered to achieve results.

Quality objectives, processes, systems and procedures that support this quality policy are established and reviewed periodically for continuing suitability. The Drug Authority shall therefore commit adequate financial, human, physical and technological resources for implementing, maintaining and continually improving the quality management system to achieve set objectives.

1.7 Service Commitment

NDA engages stakeholders to ensure that they are satisfied with services provided and to understand their requirements. To assure them of our commitment, service delivery timelines were developed and are available on our website. We have a robust complaint handling process for both service and drug related complaints.

Client satisfaction surveys are conducted annually.

1.8 Our Environment

NDA is committed to a sustainable future of the environment through ensuring that drugs are safely disposed off in an environmentally friendly manner.

02

NDA Strategic Plan Objectives

2.0 NDA Strategic Plan Objectives

2.1 To improve the regulatory efficiency and effectiveness that ensure safe, efficacious and quality drugs and healthcare products.

Strategic interventions

- Strengthen systems and institute regulatory actions that support domestic pharmaceutical manufacturing.
- Strengthen systems and institute actions that support drug regulatory compliance by human and veterinary practitioners.
- Strengthen the research capacity for making evidence-based drug regulatory decisions.
- Strengthen the systems, processes and procedures for pre-market authorization of drugs and healthcare products.
- Strengthen the systems, processes and procedures for post-market authorization of drugs and healthcare products.

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

Strategic interventions

- Advocate for an improved regulatory framework.
- Strengthen the regulatory framework.

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

Strategic interventions

- Strengthen mechanisms for stakeholder awareness and engagement.
- Enhance internal corporate and public relations function.
- Enhance stakeholder collaboration and partnership at national, regional and international level.

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

Strategic interventions

- Enhance the NDA infrastructure and facilities for her capacity growth.
- Strengthen and ensure a sustainable management information system through automation and integration across the organization and other government Ministries Departments and Agencies.
- Strengthen Corporate Governance practices and Human Resource capacity.
- Enhance the Institutional resource mobilization capacity and sustainability.
- Strengthen the corporate planning and performance management systems.
- Strengthen the Quality Management Systems across the organization.

03

FY 2020–2021 Performance Highlights.

3.0 FY 2020-2021 performance highlights

3.1 Product Assessment and Registration

The Product Assessment and Registration directorate certifies that all drugs (human or veterinary) registered in Uganda meet national and internationally accepted quality, safety and efficacy standards for population use. This also applies to biological products and traditional medicinal products.

The cumulative pharmaceutical products retained on the drug registered (graph 1) were 4,648 in FY 2020/2021 compared to 4,881 in FY 2019/2020. These included human (4,043), veterinary (471), registered foreign human herbal products (134), and a registered foreign veterinary herbal product.

human
4,043

veterinary
471

registered foreign human herbal products
134

a registered foreign veterinary herbal product.
01

The trend of increasing herbal products manufactured (graph 2) in Uganda was due to engagements and training of herbal manufacturers to improve the quality of their products. This led to many herbal medicinal products being notified and manufacturers willingness to comply to regulatory requirements.

During the year under review 453 products were suspended from the register compared to 495 in FY 2019/2020. The product suspended were mainly due cGMP expiry, quality related issues and voluntary withdrawal.

Samples of herbal drugs at one of the local manufacturer's facility

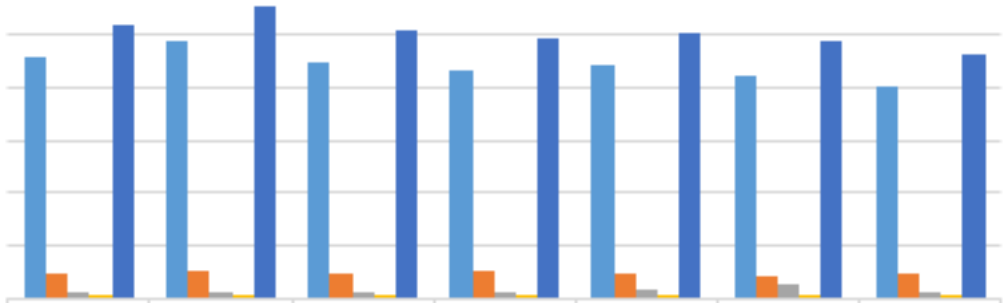
An assessment training package to equip herbalists with skills in the processing of herbal medicinal products was developed in partnership with Directorate of Industrial Training, Ministry of Health, Natural Chemotherapeutic Research Institute, representatives of herbalists and the academia.

Launch of the assessment training package to equip herbalists with skills in the processing of herbal medicinal products.

453

products were suspended from the register compared to 495 in FY 2019/2020.

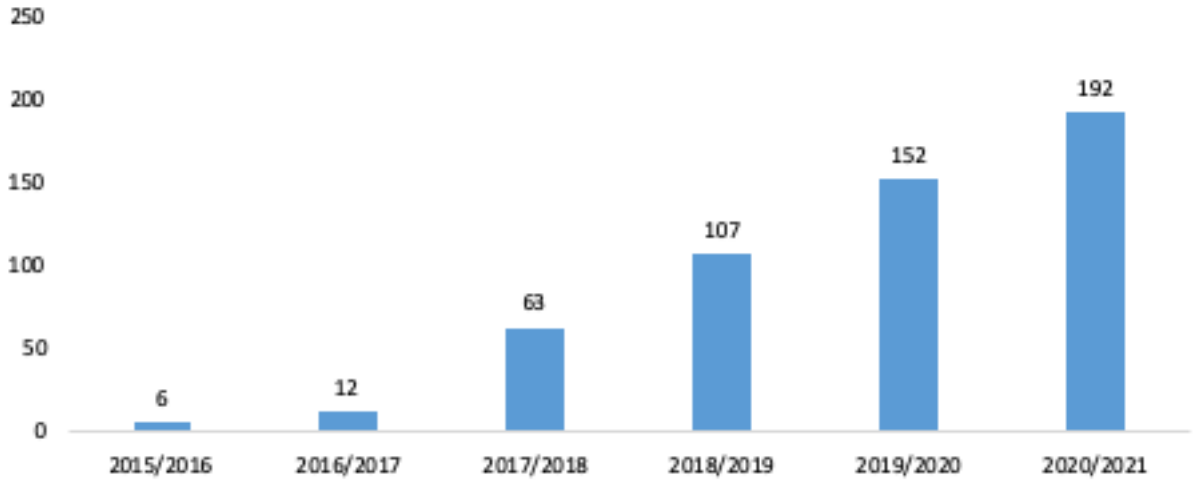
Trend of Products Registered



	2014/2015	2015/2016	2016/2017	2017/2018	2018/2019	2019/2020	2020/2021
Human	4587	4886	4483	4327	4407	4204	4043
Vet	461	513	493	498	460	414	471
Human Herbal	114	138	97	119	149	262	134
Vet Herbal	5	6	3	1	1	1	1
Total	5167	5543	5076	4945	5017	4881	4648

Graph 1

Trend of Local Herbal Notifications from FY 2015/2016 to 2020/2021



Graph 2

3.2 Inspectorate and Enforcement

Enforcement team sealing a box of drugs impounded from an illegal drug shop.

3.2 Inspectorate and Enforcement

The Directorate of Inspectorate and Enforcement ensures that all drugs manufactured locally and those imported into the country are of good quality, safe and efficacious, and properly handled throughout the distribution supply chain. This is achieved by ensuring that drugs imported into the country are from approved manufacturing sources, and properly handled to maintain quality and traceability.

3.2.1 Good Manufacturing Practice (GMP) Inspection

All pharmaceutical manufacturing facilities that wish to market their products in Uganda are inspected to ensure they comply with the current Good Manufacturing Practices (GMP). The inspection activity assesses the respective facilities' quality assurance systems and capability to produce quality drugs. It is only facilities rated compliant that are allowed to market drugs in Uganda.

In the year under review, a total of 349 foreign applications for inspections were assessed and issued with GMP certificates in FY 2020/2021 compared to 92 certificates issued in FY 2019/2020.

The Covid-19 pandemic saw a consequential rise in the number of domestic manufacturers of pharmaceutical products, as the country looked in-word for solutions to supply chain interruptions and shortages. A total of 30 herbal medicine manufacturers were inspected in the year under review. There was a rise of domestic pharmaceutical manufacturers licensed to 29 as compared to 23 in FY 2019/20 as indicated in graph 3.

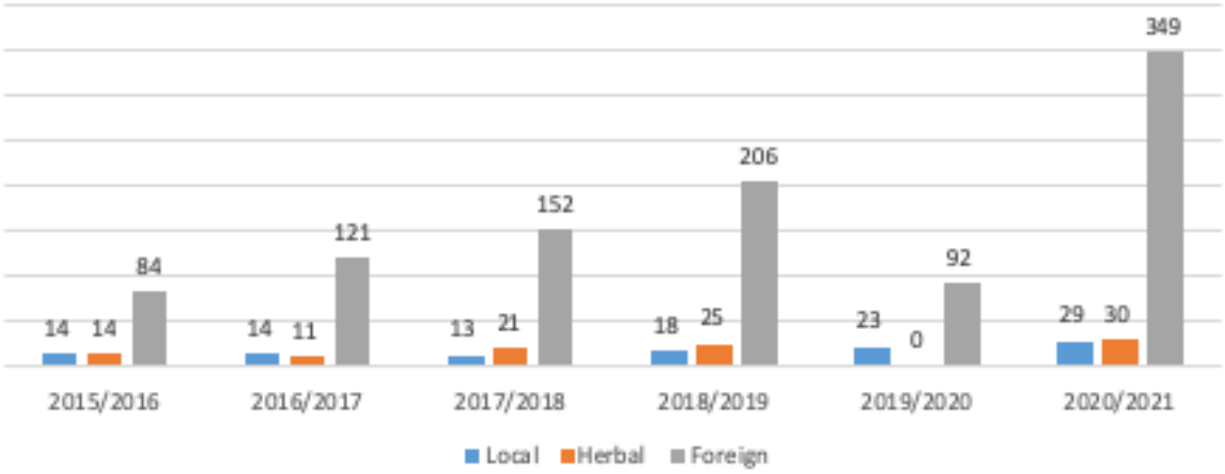
349

foreign applications for inspections were assessed and issued with GMP certificates in FY 2020/2021 compared to

92

certificates issued in FY 2019/2020

Trend of GMP Inspections conducted



Graph 3

Some of the drug consignments being inspected for conformance to stipulated NDA regulatory requirements at one of the Ports of Entry.

3.2.2 Import and export verification

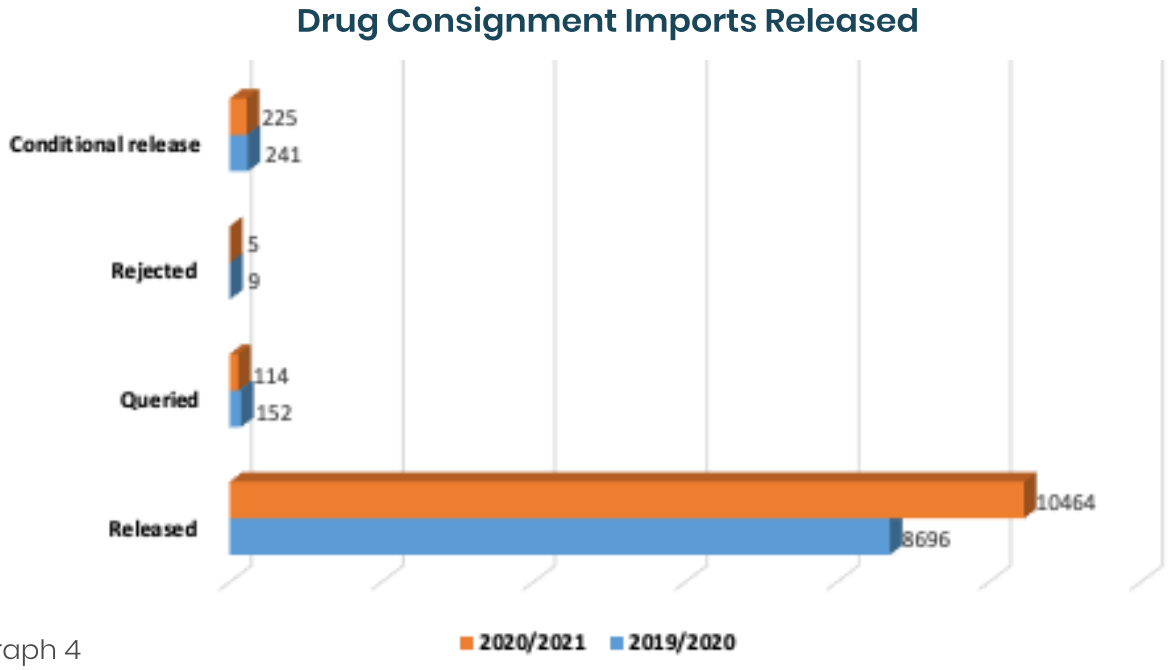
A total of 10,808 drug consignments imports were inspected at the respective ports of entry during FY 2020/2021 compared to 9,098 in FY 2019/2020 as indicated on graph 4. Of the drug consignments imported in FY 2019/2020 through the respective ports of entry, Nakawa inland port, Entebbe Airport, Busia and Malaba, 93.65% were released within two working days. This demonstrates NDA's efficiency at the respective ports of entry.

NDA ensures that all drugs imported in Uganda or exported are obtained from approved pharmaceutical manufacturing facilities. This is achieved through inspection of medicine and medical device consignments upon arrival at the ports of entry for conformance to stipulated quality regulatory requirements. Samples for some products are obtained and submitted to the quality control laboratory for testing as part of the final release decision making criteria. Where medicines are found not to meet the set quality requirements, they are rejected and the importer tasked to pay for their destruction at a National Environment Management Authority approved destruction site.

Nakawa inland port, Entebbe Airport, Busia and Malaba,

93.65%

were released within two working days.



Graph 4

3.2.3 Drug outlets distribution

The public is encouraged to buy drugs from human or veterinary outlets (Pharmacies or drug shops) licensed by NDA.

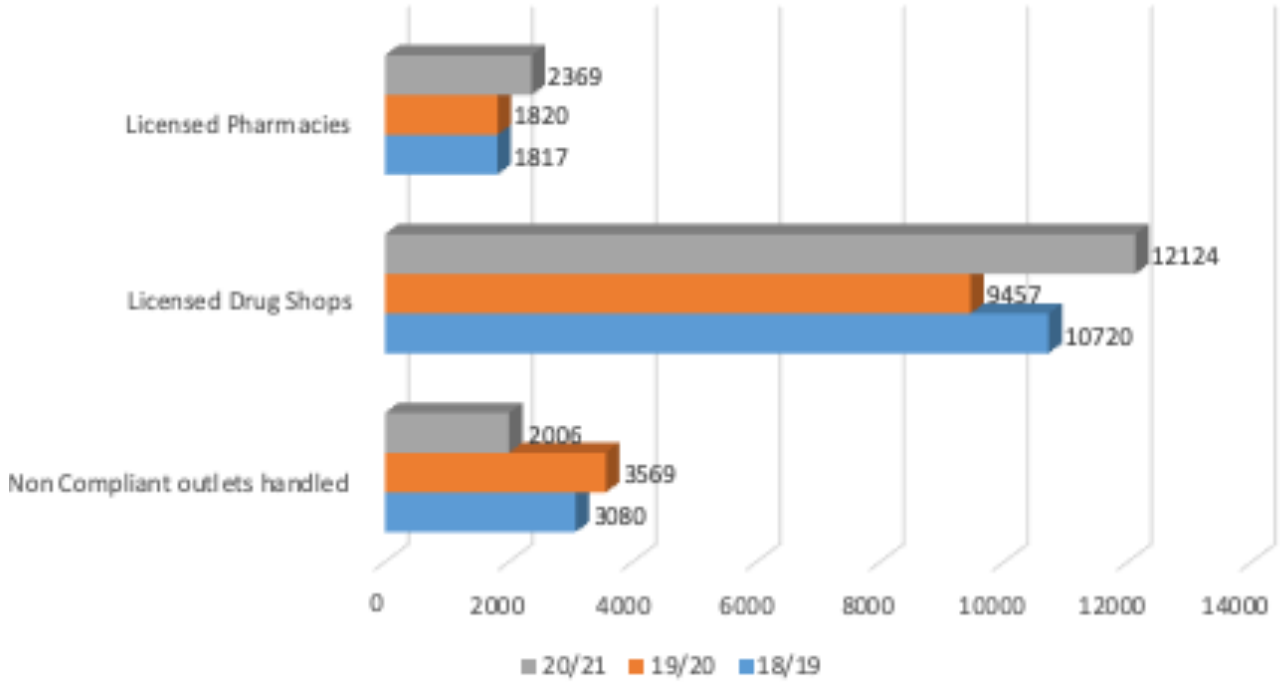
The regulation of drug outlets (pharmacies, drug shops and stores) is essential in ensuring that the integrity of drugs is maintained in the distribution supply chain. NDA adopted an internationally recognized standards of Good Distribution Practices (GDP) which it applies as a compliance benchmark.

In the period under review there was a significant increase in licensed pharmacies 549 (23.2%) and drug shops 2667 (22%) compared to FY 2019/20.

The significant increase in licensed drug outlets is attributed to general regulatory interventions like compliance visits, enforcement operations, and awareness programs. The increase in licensed pharmacies is further attributed to drug shops upgrade into pharmacies, easing licensing issuance to cover a period of three years, and provision of regulatory decision for new applicants within 25 days.

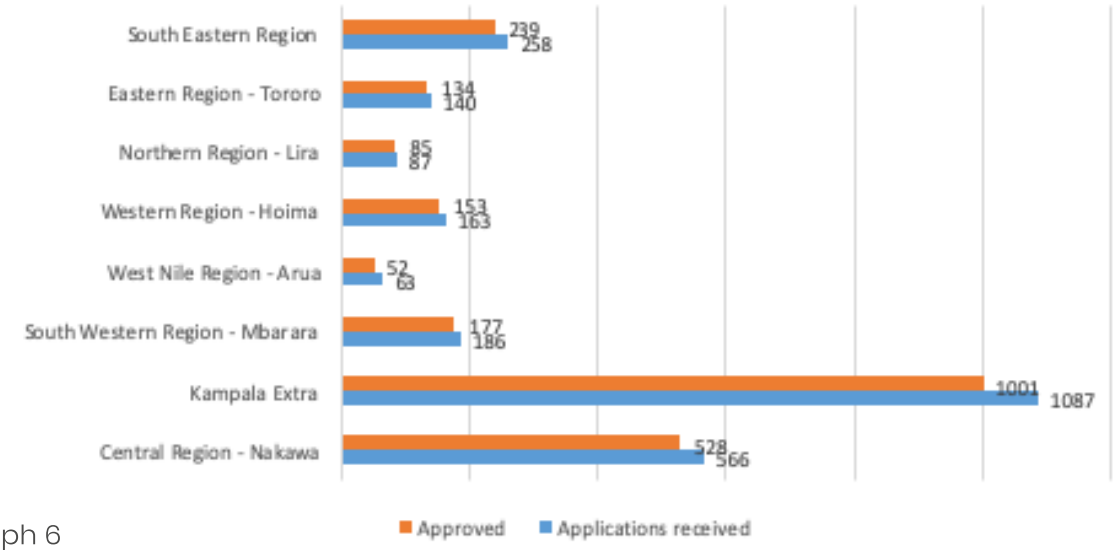
The above interventions led to many illegal drug outlets to comply with NDA licensing requirements in the year under review.

Trend of licensed Pharmacies/Drug Shops - FY 18/19-20/21)



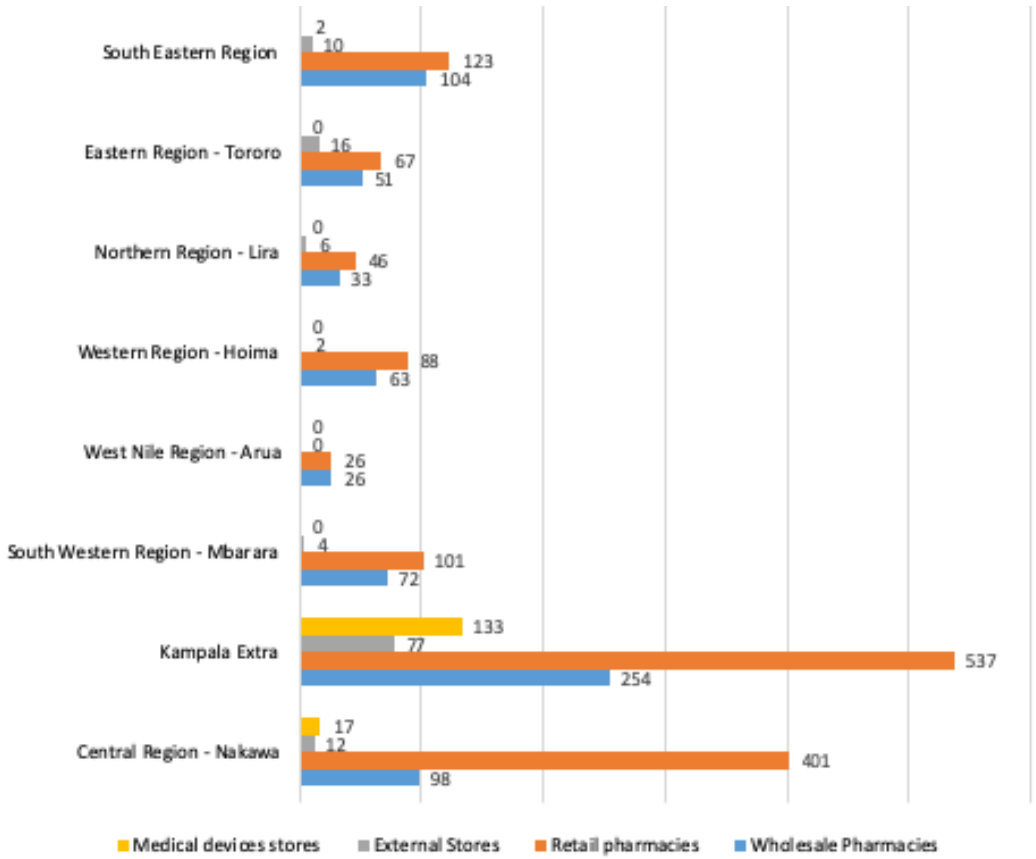
Graph 5

Licensed Pharmacies per Region FY 2020/21



Graph 6

Categories of Approved Pharmacies and Stores FY 2020/2021



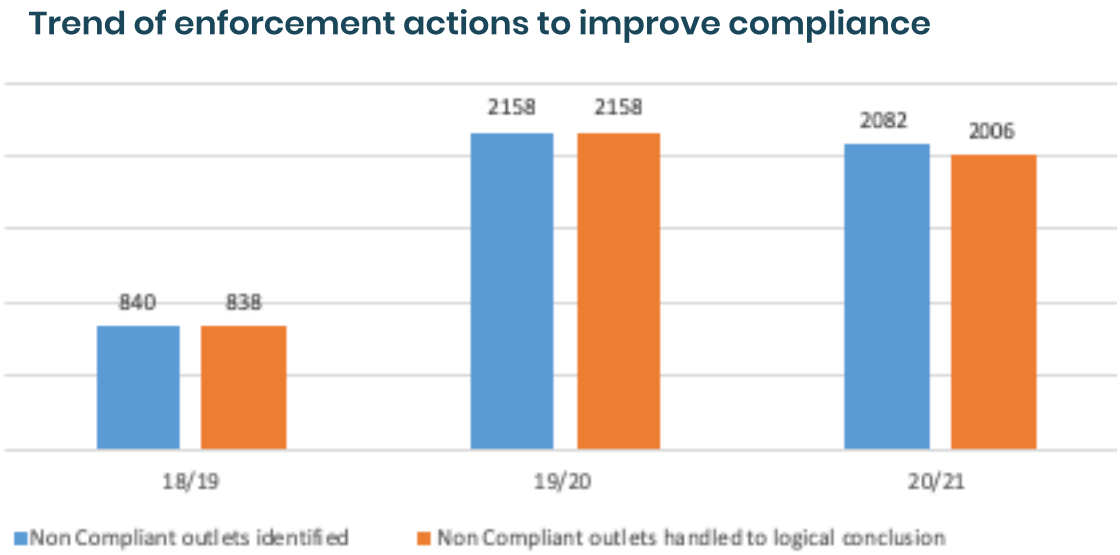
Graph 7

3.2.4 Enforcement

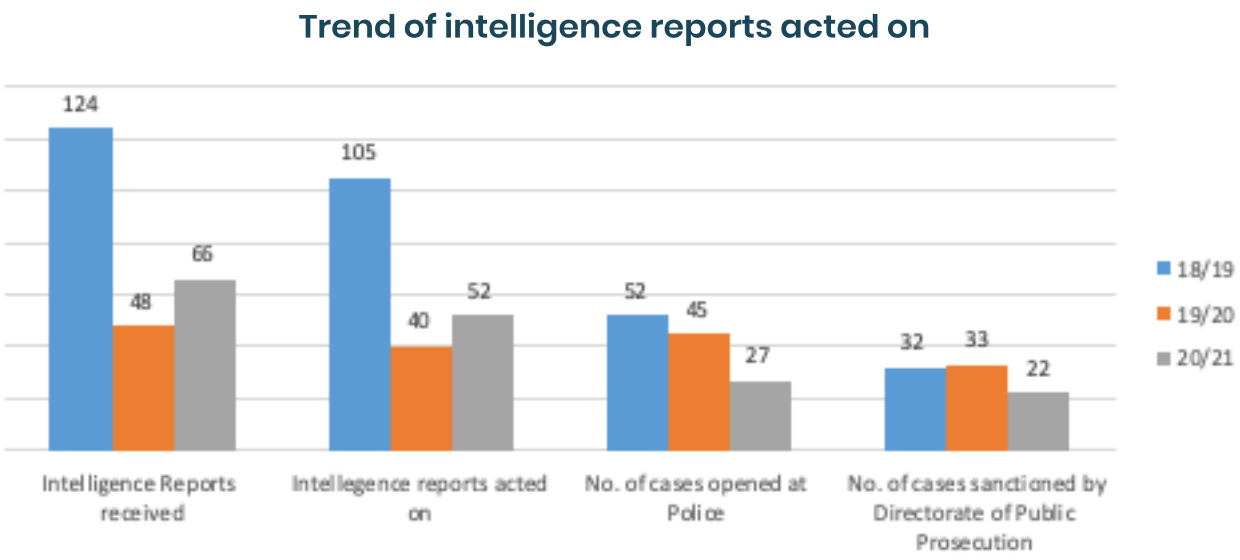
Some of the drugs impounded from non complying drug outlets during the enforcement operations.

Enforcement activities ensure that pharmaceutical operators comply with the National Drug Policy and Authority Act and Regulations which govern the sale and supply of drugs.

In FY 2020/2021 a total of **twenty seven (27)** police cases were opened **twenty two (22)** of which were sanctioned by the Director of Public Prosecution resulting into five (5) convictions. A total of forty two (42) police cases were opened and thirty three (33) convictions secured in FY 2019/2020.
The enforcement operations confirm that licensed persons maintain high quality standards, apprehend and encourage illegal operators to comply. In the year under review eleven (11) operations were held across the country that resulted in improved compliance levels to licensing requirements by operators of pharmacies and drug shops as shown on graph 8 and 9.



Graph 8



Graph 9

3.2.5 Destruction of obsolete pharmaceuticals

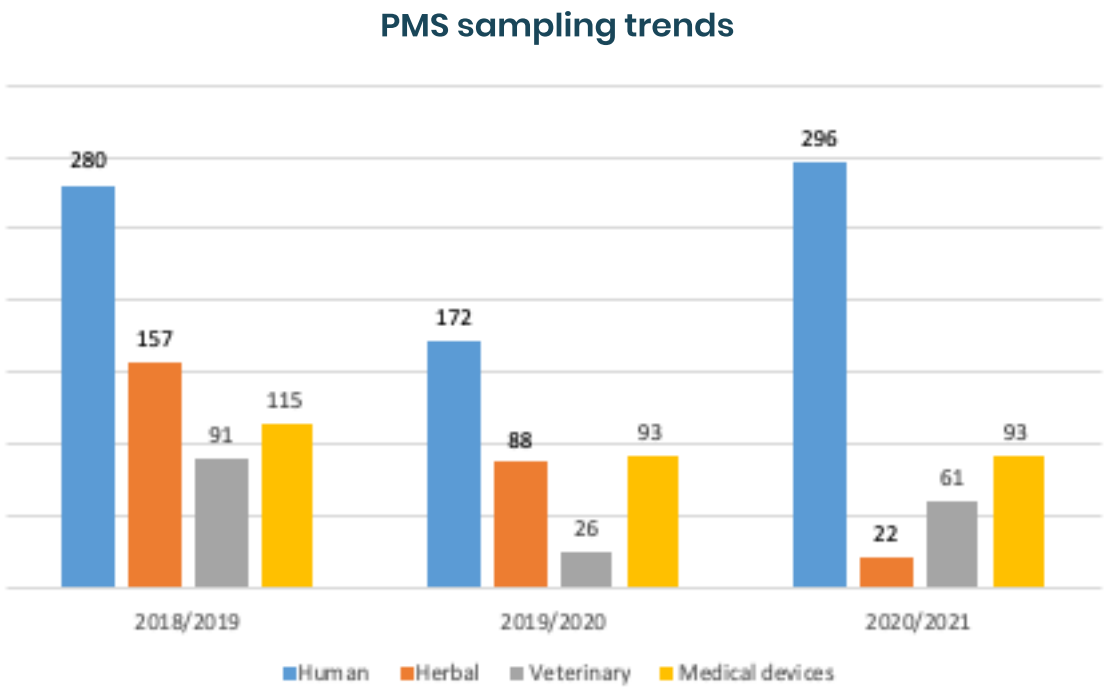
NDA issued 164 certificates for the destruction of 2,611.1 tons of obsolete pharmaceutical in the period under review, compared to 595.4453 that were incinerated in FY 2019/2020.

NDA continues to ensure that unsafe drugs and other health care products are effectively removed from the market and destroyed in an environmentally safe manner. The unsafe drugs included those that had expired, recalled and drug/healthcare products that failed laboratory tests or found not fit for human and veterinary use.

3.2.6 Post-Market Surveillance

i) Sampling and testing

Post-Market Surveillance (PMS) involves monitoring the quality of medical products on the market through ensuring the integrity of the drug supply chain, investigations on drug related complaints and recalling products off the market. NDA picks samples of drugs on the market for the laboratory analysis as indicated in graph 10.



Graph 10

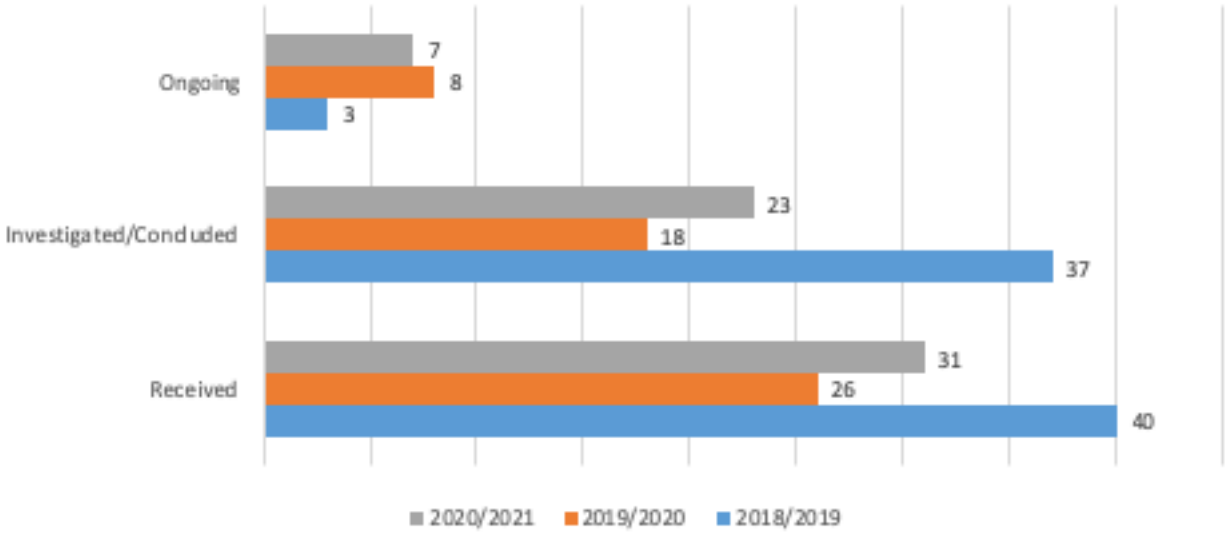
ii) Recalls

In the period under review, 26 recalls were effected compared to 22 in FY 2019/2020. The recalls arose from product defects, and others due to occurrence of adverse drug reactions.

iii) Drug related complaints

Drug related complaint reports received in FY 2020/2021 were 26 compared to 40 in FY 2019/2020. Of these, 23 were investigated and action taken while investigations are ongoing for the seven cases as indicated in the graph 11

Product complaints investigated/concluded



Graph 11

WE COUNT ON YOU FARMERS

Safe Drugs Save Lives

Report adverse drug reactions in animals following use of veterinary drugs to NDA.

Embrace reporting of adverse reactions to improve treatment outcomes and safe use of veterinary drugs.

Together we can strengthen Safety of Vet drugs.

3.3 Laboratory services

SAY NO

TO USE OF **TICK BURN** AND **MUTAMBIRA NTE**

IN CONTROL OF TICKS ON LIVESTOCK FARMS

UGANDA
NATIONAL DRUG AUTHORITY
Safe Drugs Save Lives

These are counterfeited crop pesticides, fumigants and household chemicals toxic to public, animal and environment health. They account for food chemical residues (meat and milk), livestock deaths, infertility, blindness and reduced livestock production.

Your Health is NDA noble concern.

Toll free:0800 101 999
0740 00 20 70
Med safety mobile app
druginfo@nda.or.ug
www.nda.or.ug

3.3 Laboratory Services

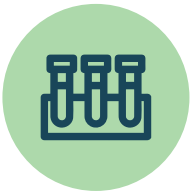
3.3.1 Testing

The Directorate of Laboratory Services houses a state of the art Quality Control Laboratory. It specializes in the quality assessment of drugs and medical devices using advanced pharmaceutical analytical techniques. The activity protects the human and animal population from drugs that are substandard and falsified.

The Laboratory is prequalified by World Health Organization and is also ISO 17025:2017 accredited. NDA continues to maintain an impeccable arsenal of resources and capabilities at its laboratories to facilitate scientific examination of a wide range of drugs as well as medical devices, in pursuit of her vision "A Uganda with safe, effective, quality drugs and health care products".

Despite the Covid-19 pandemic, NDA embraced the unprecedented challenges to pursue her mission "promoting and protecting public health through the effective regulation of human, animal drugs and health care products".

A total of 2,223 samples were tested at the Laboratory to ascertain their quality. The samples tested ranged from those collected from imports into the country before authorization of their sale – to ensure they are of the required quality. Those already on the market - to ensure that they meet the quality upon which they were approved for sale, and others from local manufacturers before authorization to ensure they meet the prescribed standard.



A total of

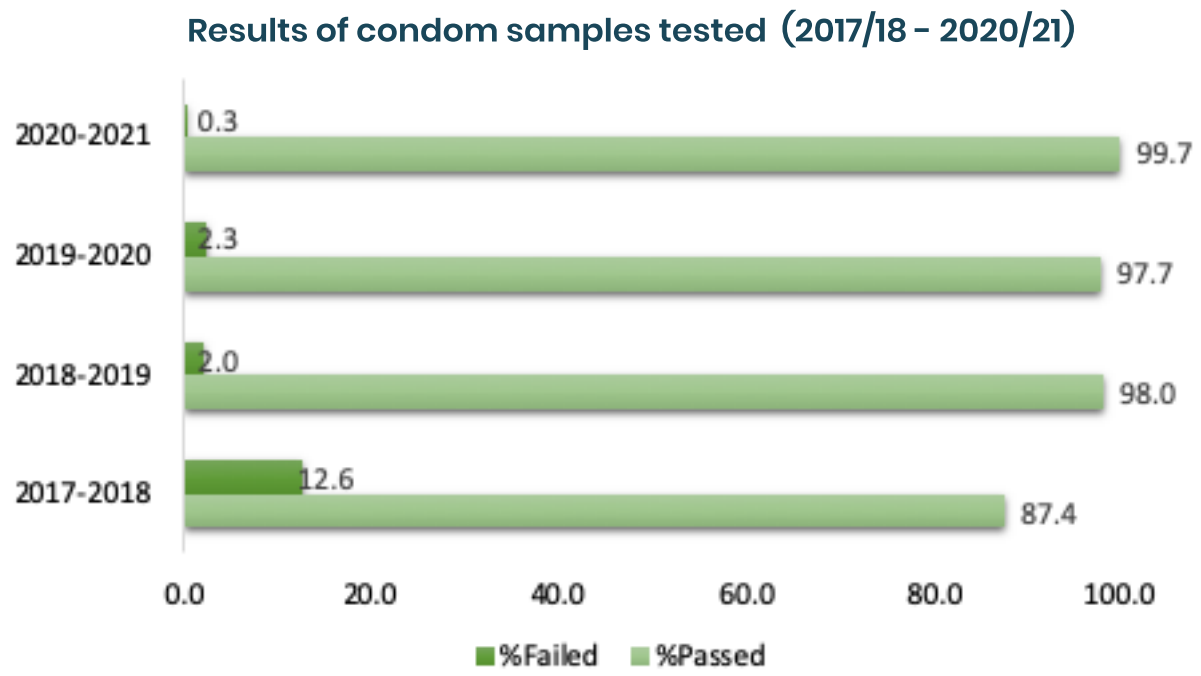
2,223

samples were tested at the Laboratory to ascertain their quality

3.3.2 Condom testing

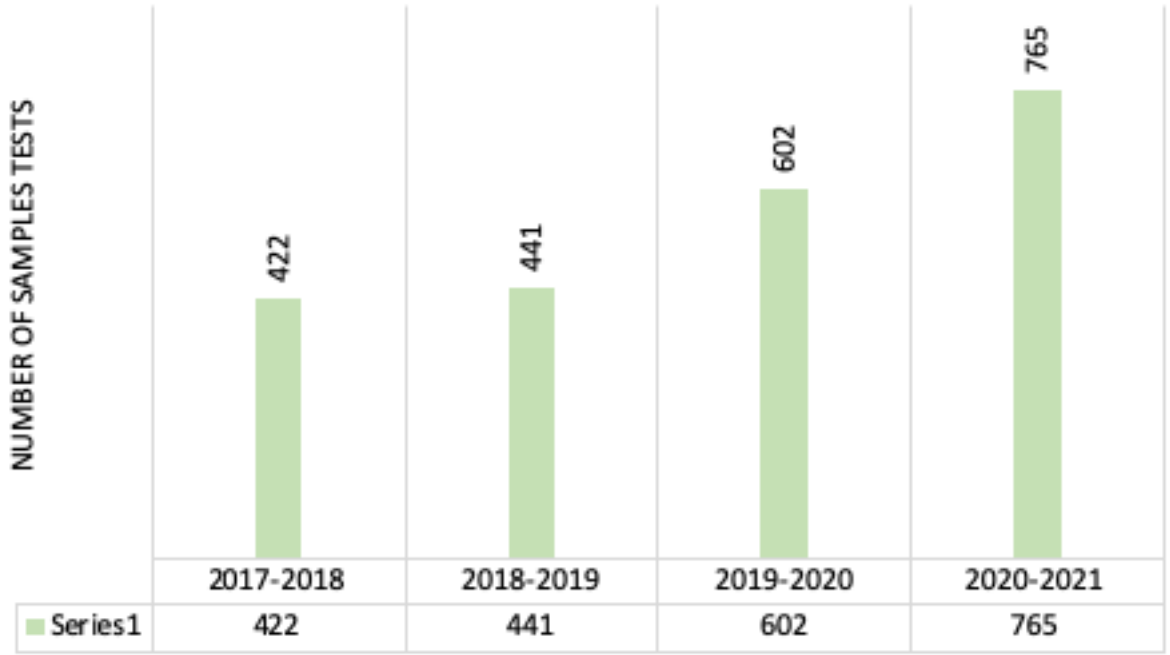
Testing condoms at the Quality Control Laboratory

Condoms have been at the forefront of curtailing the transmission of HIV/AIDS. NDA has registered a tremendous improvement in the quality of condoms imported into Uganda as indicated in graph 12. This has been due to the current mandatory testing before they are released onto the market to protect the population from fake condoms.



Graph 12

Trend of condom batches tested FY 2017/2018 -FY2020/2021



Graph 13

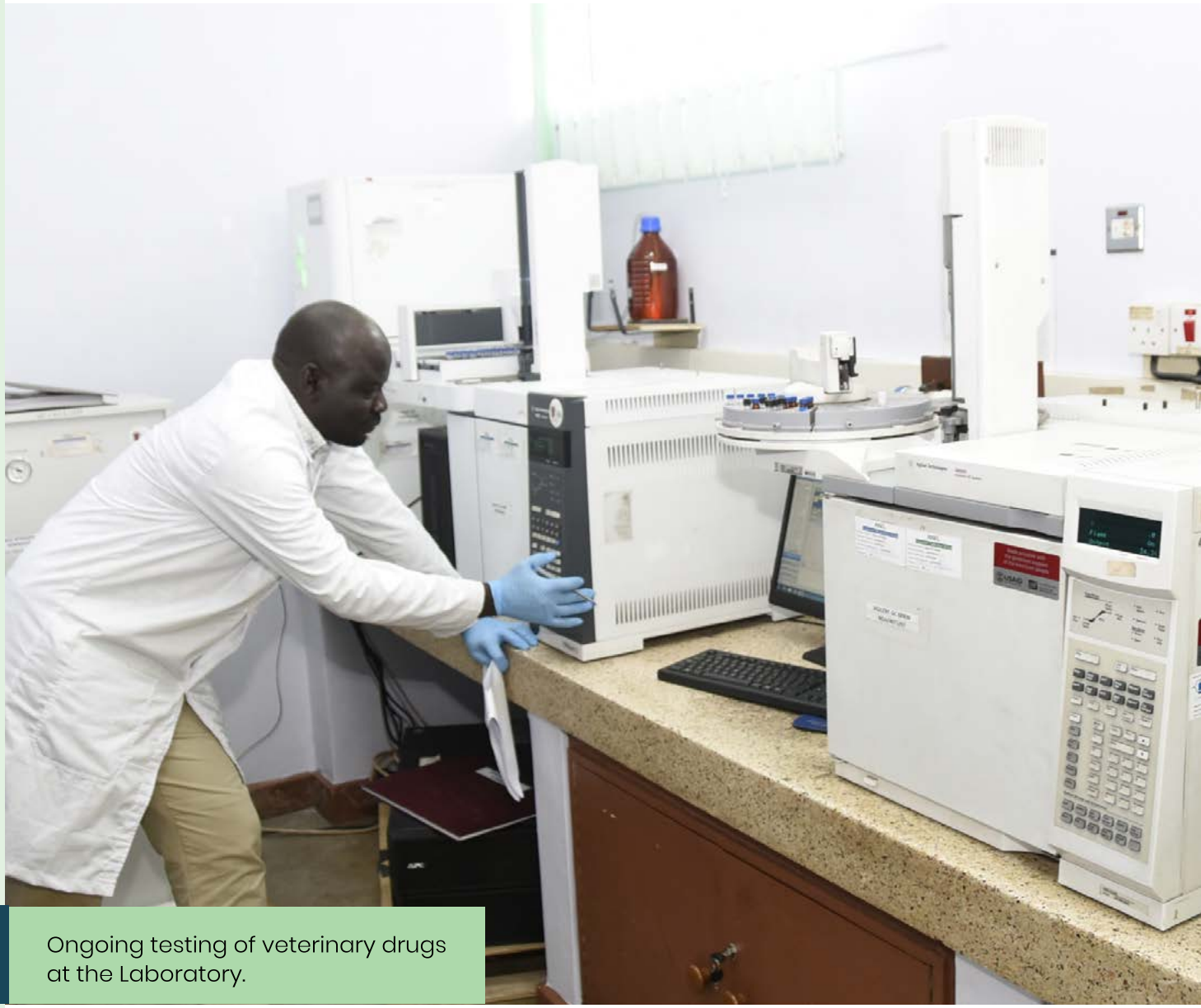
NDA's Laboratory success story in condom test results has led to suppliers of poor quality condoms removed from the UNFP – WHO prequalification list. This is attributed to NDA's improved capacity of the condom testing equipment that has further led to an all-time low failure rate of 0.3% in the FY 2020/21, compared to 12.6% in 2017/18.

This is attributed to NDA's enhanced capacity of the condom testing equipment that has further led to an all-time low failure rate of

0.3%
in the FY 2020/21, compared to

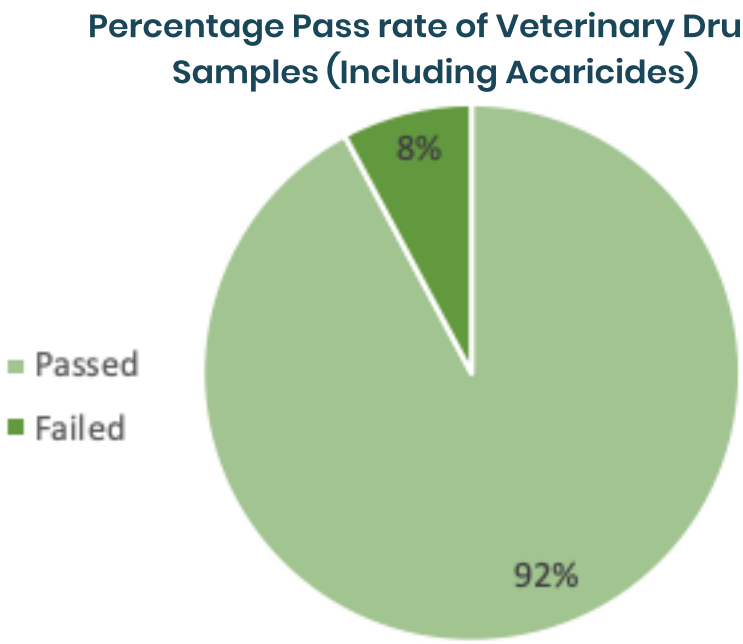
12.6%
in 2017/18

3.3.3 Veterinary drugs and acaricides analysis tests.



Ongoing testing of veterinary drugs at the Laboratory.

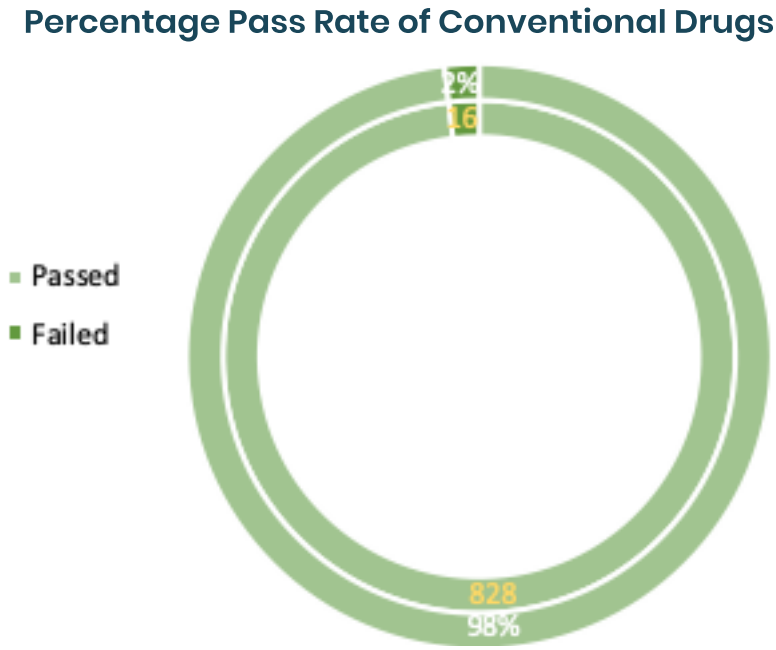
NDA is passionate about the people of Uganda and the health of their animals. To inform evidence-based interventions, NDA continues to assess the quality of acaricides and other veterinary drugs imported into Uganda. The Laboratory capabilities in veterinary drugs testing has grown to ensure that high-quality livestock inputs result in better yields for the sector. In the year under review, 8% (graph 14) of the veterinary drugs (including acaricides) tested at the Laboratory were substandard and were destroyed.



Graph 14

3.3.4 Capacity to detect substandard and falsified drugs

The vigilant surveillance of NDA led to 844 samples of different categories of drugs sampled and tested using advanced analytical techniques at the Laboratory. The results led to 98% of the samples passing the tests, and 2% (16) failing the test as shown on graph 15.



Graph 15

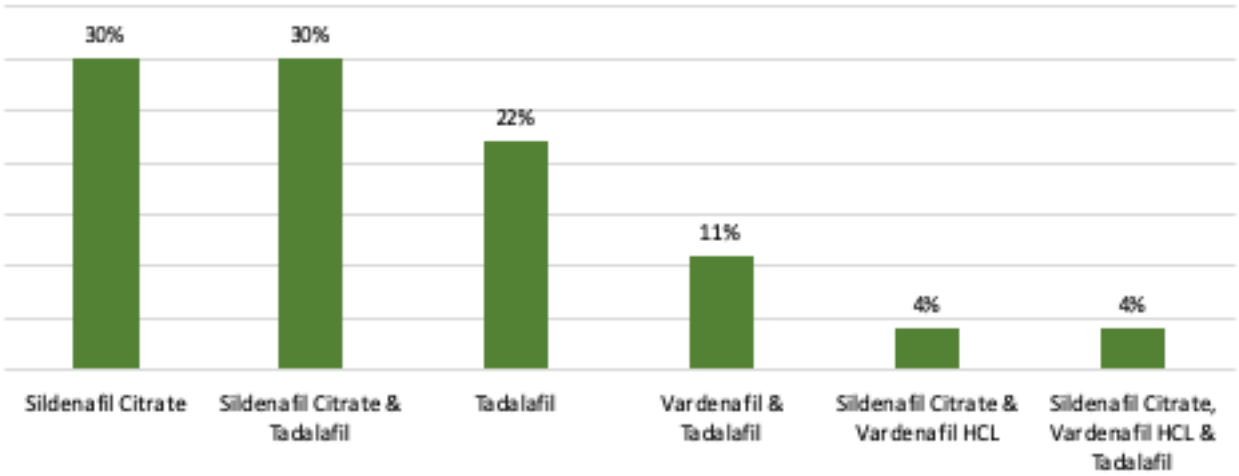
3.3.5 Quality of Herbal Drugs

Automatic Soxhlet Extractor for standardization of herbal medicine during testing

NDA has instituted mechanisms to facilitate the development of the local herbal drugs that are of good quality and safe for public use. Instruments to be used in the testing of herbal drugs to support the standardization and professionalization of the local herbal industry have been installed and are in service.

In the year under review, 30% of the herbal samples tested were adulterated with sexual potency drugs as shown in graph 16.

Conventional drugs found in herbal samples tested



Graph 16

Scope of testing

Testing of syringes and needles.

NDA continues to expand her capabilities and resources to enhance the ability to test all drugs on sale in Uganda.

A state of the art pharmaceutical microbiology laboratory is in place that will specialize in ensuring drugs and healthcare products meet the prescribed microbial standard. The Authority has expanded its testing scope to include Rapid Diagnostics Test kits, syringes and needles.

3.3.7 Progress on Laboratory Tower construction project.

Ongoing construction of the Laboratory Tower

Ground breaking for the state-of-the-art Quality Control Laboratory tower was held on 14th March 2019. When completed, NDA's capacity to carry out quality control tests on drugs, vaccines, medical devices, cosmetics, food and other chemicals will be greatly strengthened.

3.4 Product Safety

DRUGS

are very useful but can cause side effects in some patients

How to minimise side effects

- Read the Patient Information Leaflet(PIL).
- Ask your healthcare provider about the expected side effects.
- Report to National Drug Authority

3.4 Product Safety

The Directorate is responsible for promoting patient safety through monitoring adverse drug events (ADEs) to improve health outcomes. It monitors whether medicines available on the market result into better treatment of illnesses and prevention of diseases to protect and promote a healthy population.

3.4.1 Pharmacovigilance (monitoring safety of medicine).

Pharmacovigilance is a regulatory function that involves ongoing monitoring of drugs to ensure they remain safe for use, especially since previously undetected adverse events may occur. Monitoring safety of medicines during day- to- day use of medicines is essential for early detection of adverse reactions that could affect the optimization of treatment outcomes , early detection helps developing appropriate mitigation measures proportionate to the risks identified in the of the individuals or population associated with the long-term use or the intake at widely separated intervals.

Serious drug effects although rarely occur, often lead to public concerns and may erode confidence in medical products if not dealt with adequately. Such concerns

Ms. Sawlha Namanda (right) a health worker at KCCA, Kitebi Health Centre III, receives a token of appreciation (reporting adverse drug reaction cases to NDA) from Dr. Joseph Mwoga (WHO) and Dr. Helen Ndagija (Director Product Safety).

Director (right), Mbarara Referral Regional Hospital, receiving an award for the Best ADR reporting Hospital.

could have significant negative implications on public health, thus the need for a post-marketing vigilance system in place.
During the period under review, NDA collected 2552 adverse drug reaction reports compared to 1824 reports received in FY 2019/20, accounting for 39.9% increase. The rise in reporting is attributed to the online reporting platforms as well as the COVID-19 vaccination drive. Majority of the reported adverse drug reaction were consistent and known for the drugs involved, however a few reactions were investigated and regulatory action taken including recalls, and safety communication to healthcare workers . Since the roll out of
the COVID-19 vaccination, NDA has received a total of 651 AEFI reports on reactions to the Astra Zeneca Covid-19 vaccine of which, 202 were directly sent through the Immunization Programme from the COVID-19 Vaccination exercise. The most commonly reported reactions were headache , body weakness and injection site pain, which resolved in majority of the vaccine recipients within 2 days. The common and most reported events do not differ much from those that were seen in the clinical trials, experienced by other countries and are commonly experienced with vaccines generally. Of the cases reported, 11 were reported as serious and all have been investigated in collaboration with Ministry of
Health, Uganda National Expanded Program on Immunization (UNEPI) and World Health Organization. Almost all the serious events reported were unlikely not related to use of the vaccine but considered coincidental due causes other than the vaccine.

Awareness and sensitization activities provided to the public and health workers are key in enabling reporting of safety issues. In the reporting period 744 healthcare facilities around the country were engaged and 4,598 healthcare providers were trained as shown in

NDA collected

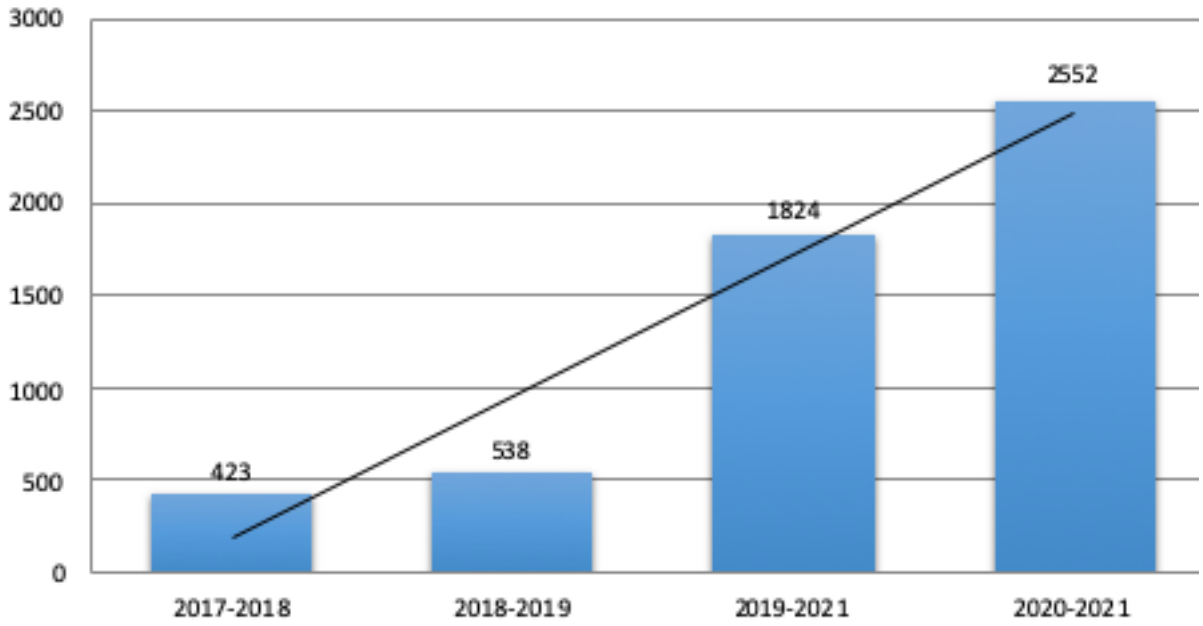
2552

adverse drug reaction reports accounting for

39.9%

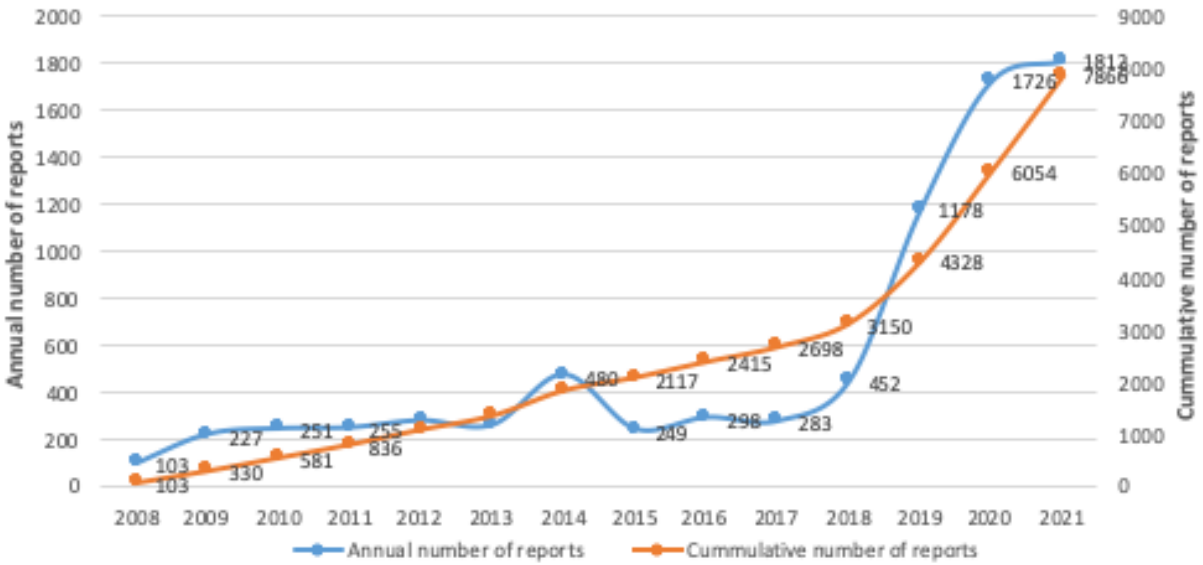
increase compared to 1824 reports received in FY 2019/20

Trend of Adverse Drug Reaction Reports received - FY 2017/18 - 2020/21



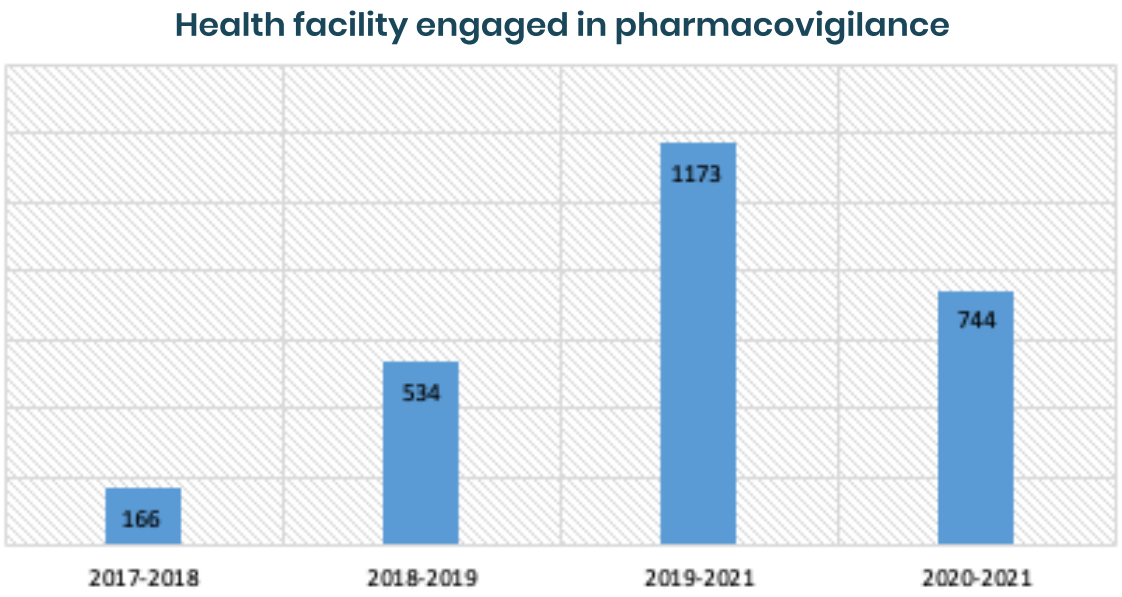
Graph 17

Cumulative ADRs



Graph 18

Awareness and sensitization activities provided to the public and health workers are key in enabling reporting of safety issues. In the reporting period 744 healthcare facilities around the country were engaged and 4,598 healthcare providers were trained as shown in graph 19.



Graph 19

3.4.2 Clinical Trial Evaluation

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

Currently, there are over 150 ongoing approved clinical trials on the register which NDA provides regulatory oversight. In the year under review, there was a 15% increase in volume of clinical trial applications (189) handled compared to 164 in FY 2019/2020. A total of 189 (93%) applications were evaluated and regulatory action issued within standard delivery timelines of 60 working days as show in table 1.

NDA organized stakeholder engagements with Investigators for the dissemination of Good Clinical Practices (GCP) guidelines. GCP sensitization meetings were held at some upcountry trial sites in compliance with the Ministry of Health Standard Operating Procedures for COVID-19.

Table 1. Clinical Trials

Activities	Number	Comment
Clinical Trial Applications evaluated (Initial applications, amendments and renewals)	189	161 were evaluated within standard delivery timelines
GCP inspections	21	21 inspections exceeded set target
COVID-19 Trials approved	7	Out of the 7 trials, 1 was a herbal clinical trial

Applications of COVID-19 related clinical trials were fast tracked as well as providing guidance to investigators. Guidelines for the conduct of Clinical Trials in children, pregnant women and lactating mothers were disseminated to provide guidance to Investigators when conducting trails in the respective population.

3.4.3 Control of publications and advertisement relating to drugs

The National Drug Authority through the Medicines Information unit, fulfills the mandate of control of all activities and materials for publications related to drugs or advertisements for drugs including promotions and promotion materials. This is to ensure that the information provided to the public is accurate, balanced and helps the public to make rational decisions about drugs.

Advertisements related to drugs are reviewed, vetted and approved before they are released/published to the public. For the year 2020/2021, 253 advertisements were submitted for vetting as indicated in table 2.

To enhance compliance on best practices of drug advertisements and promotions, several engagements with stakeholders were held including talk shows (radio and television). Together with Uganda National Bureau of Standards, and Uganda Communication Commission engagements on were held with district local government (Mbarara), manufacturers of 'Health Drinks', media owners and operators in the country to mitigate unauthorized drug related advertisements and promotions.

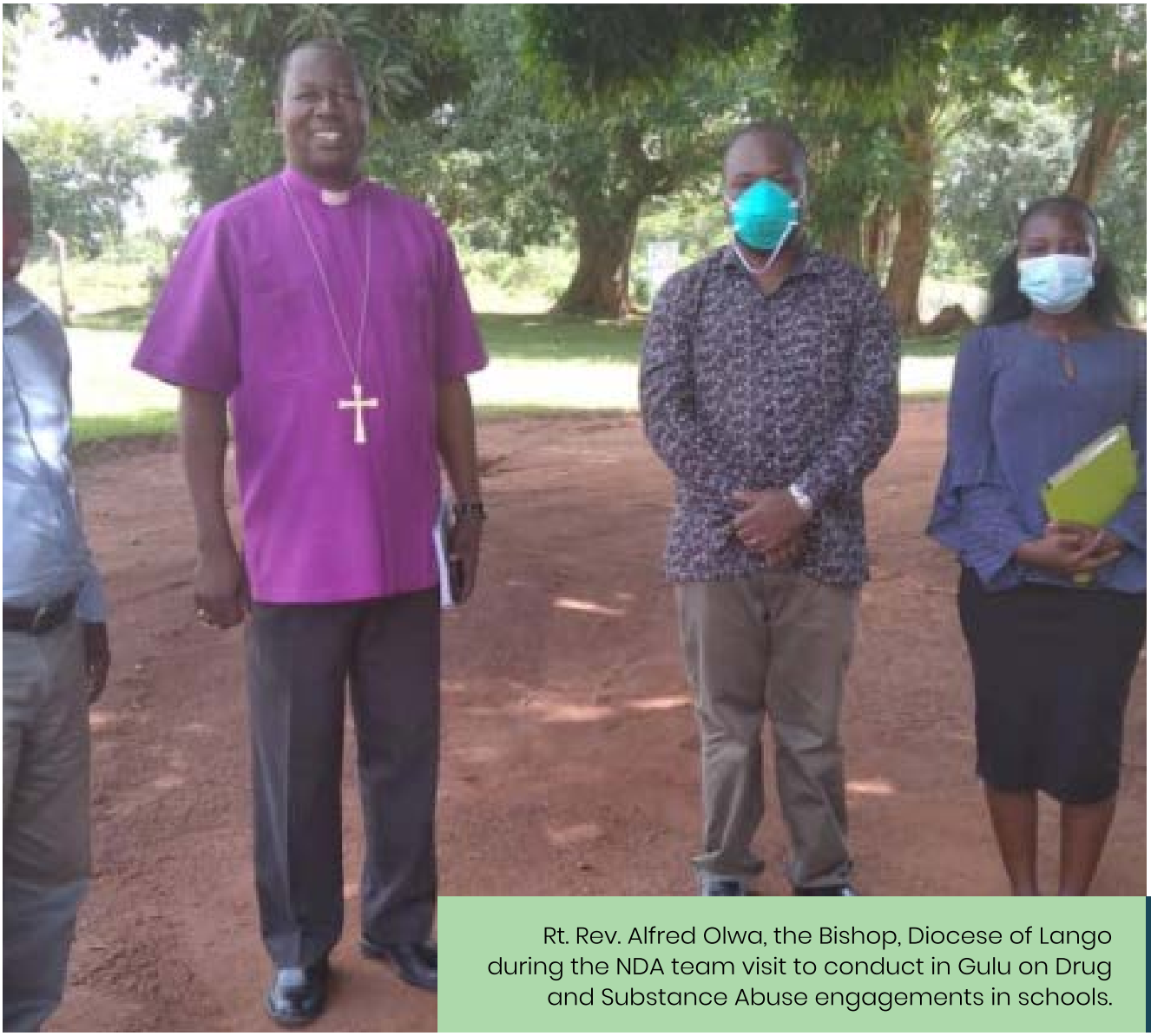
The publications and advertisements relating to drugs that NDA vets include notices, circulars, labels, wrappers or other document, and any announcement made orally or by means of producing or transmitting light or sound. Vetting of drug promotional materials involves receipt of application materials, sorting, data entry, database management, analysis and generation of reports, and approval of drug promotion/advertisement. NDA drug promotional materials reviews include the following:

- Correct target audience (children, public, health workers)
- Appropriate science (evidence, truth, undue advantage)
- Product classification
- Information is not misleading
- Information supporting rational decision making
- Nature of products (narcotics, psychotics, drugs for conditions specified in fifth schedule)

Table 2. Drug advertisements/promotions vetted in FY 2020-2021

Application type	Approved	Rejected	Queried	Total
Human drug products	157	32	18	207
Veterinary drug products	12	2	0	14
Herbal drug products	18	5	9	32
Total	187	39	27	253

3.4.4 Drug and Substance abuse



Rt. Rev. Alfred Olwa, the Bishop, Diocese of Lango during the NDA team visit to conduct in Gulu on Drug and Substance Abuse engagements in schools.

NDA has the mandate to prevent drug and substance abuse in Uganda. The public especially the youth were engaged through provision of information and education materials to prevent drug and substance abuse in their respective communities.

In 2020/2021, 19 secondary schools were engaged in collaboration with leaders of the Church of Uganda and the Gulu City. Radio Talk shows were held in Gulu, Lira, and Nebbi districts sharing information on prevention of drug and substance abuse among the public.

NDA participated in the international day against drug abuse and illicit trafficking organized by United Nation Office of Drugs and Crime.

4.0 Regulation of Veterinary Drugs

Engagement with veterinary stakeholders.

4.0 Veterinary Drugs

4.1 Veterinary Engagements

NDA instituted a new approach to enhance veterinary drugs regulatory capacity, in order not to expose the health of livestock and improve yields at various farm levels in the country.

In the year under review, engagements with stakeholders in the veterinary sector were held on post marketing surveillance, drug safety monitoring, animal health, to promote and protect public health.

The engagements (graph 21) did not only target technical teams, but included district/ opinion leaders to improve on their supervisory and collaborative role in distribution, handling and use of veterinary drugs regulatory capacity.

The technical teams included academia, veterinary drug shop and pharmacy operators, Veterinary Officers, Production Officers, extension workers, and the Ministry of Agriculture, Animal Industry and Fisheries (MAAIF) zonal inspectors. District/opinion leaders included Resident Commissioners, Chief Administrative Officers, Chairpersons, and Sub-County Chairpersons, and farmers among others.

4.2 Outputs of Veterinary engagements and collaborations

In the year under review, four hundred and four (404) sensitization meetings were held at the Sub-County level in forty three (43) districts (table 2) to improve handling of veterinary drugs.

During the engagements, various information materials on veterinary drugs was shared to empower stakeholders (graph 22) on their choices concerning various drugs. Information was disseminated through sensitization meetings, radio talk shows (table 3 and graph 23) and training of the technical staff in the respective districts. Promotional materials were also distributed to stakeholders in the form of posters, bulletins, brochures, books and calendars.

404

sensitization meetings were held at the Sub-County level in

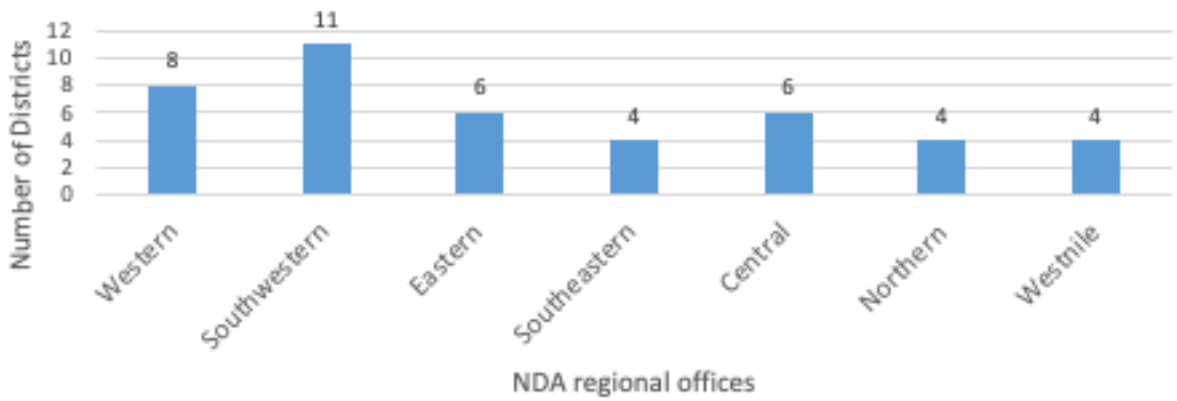
43

districts (table 2) to improve regulation of veterinary drugs handling for the benefit of high livestock yields and public health.

Table 3: List of districts covered during the Veterinary engagements

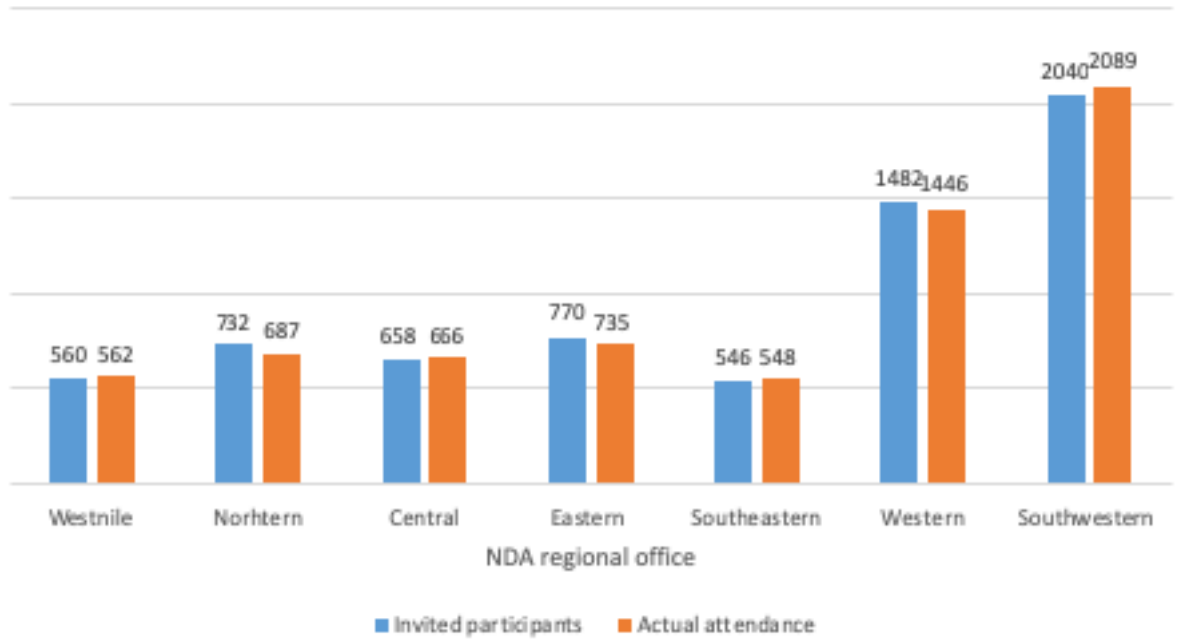
NDA Regional office	Districts covered
EASTERN	Soroti, Mbale, Napak, Moroto, Bukedea and Kapchorwa
WEST NILE	Adjumani, Arua, Pakwach and Maracha
CENTRAL	Bukomansimbi, Butambala, Nakaseke, Luweero, Kalungu and Mpigi
SOUTH WESTERN	Kanungu, Kisoro, Mitooma, Sheema, Rubanda, Rukiga, Kazo, Bushenyi, Sheema, Isingiro and Ntungamo
WESTERN	Masindi, Kagadi, Kyankwanzi, Kiboga, Kakumiro, Mubende, Kyenjojo and Kyegegwa
SOUTH EASTERN	Kamuli, Kaliro, Iganga and Luuka
NORTHERN	Gulu, Nwoya, Kaabong and Kotido

Districts covered per region during the stakeholder sensitization engagements



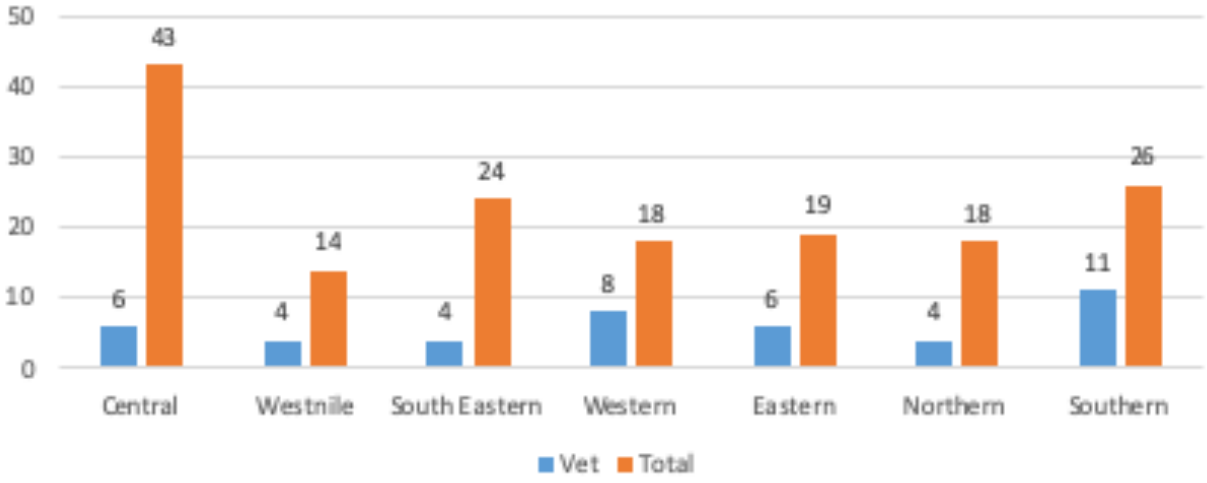
Graph 21

Stakeholder participation per region



Graph 22

Radio Shows - Veterinary shows against overall shows held



Graph 23

Table 4: Radio stations used to reach out to stakeholders in the different districts.

NDA Regions	District/Radio station
EASTERN	Soroti (Stop Radio), Mbale (Step fm), Moroto (Totore fm), Bukedea (Mama fm) and Kapchorwa (KTC fm)
WEST NILE	Adjumani (Radio Amani), Arua (Radio Pacis), and Pakwach (Pakwach fm).
CENTRAL	Masaka (Centenary fm), Buwama (Buwama fm), Nakaseke (Seke fm), and Kalungu (Buddu Broadcasting services)
SOUTH WESTERN	Kanungu (Kanungu Broadcasting Services), Kisoro (Voice of Muhabura), Mitooma (Voice of Ruhinda), Mbarara (Radio West), Kabale (Voice of Kigezi), Kazo (Kazo fm), Bushenyi (Bushenyi fm), Sheena (Hunter fm) and Ntungamo (Voice of Ankole).
WESTERN	Masindi (Kings Broadcasting Services), Kagadi (Kibaale Community radio), Kubota (Radio Kiboga), Kakumiro (KCR fm), Mubende (Point fm), Kyenjojo (Unique fm) and Kyegegwa (Britop fm)
SOUTH EASTERN	Kamuli Broadcasting Services, and Jinja (NBS radio)
NORTHERN	Gulu (Mega fm) and Kotido (Etoil Karamoja fm)

4.3 Findings raised from Stakeholder Engagements

The engagements enabled NDA get an in-depth understanding of the challenges faced by stakeholders in veterinary drug regulation and proposed mitigation measures towards better livestock yields and economic benefits as shown in Table 5.

Table 5. Identified challenges and mitigation measures.

Issue/problem	Risks	Possible remedies
1. Uncontrolled access to classified drugs by farmers.	• Increase resistance to drugs. • Non observance of drug withdrawal periods which results in drug residues in foods of animal origin and poses a risk to humans. • Poor treatment outcomes which lead to loss of confidence in registered drugs.	• Educate farmers on the value of seeking professional advice from veterinary practitioners. • Strengthen regulation of veterinary practices. • Increase support supervision.
2. Wide spread resistance of ticks to acaricides	• Overuse/misuse of acaricides. • Use of agrochemicals as pesticides • Counterfeiters and smugglers of unregistered drugs • Prevalence of tick borne diseases.	• Sensitize and educate stakeholders including farmers and veterinary practitioners on good practices in acaricide use. • Multipronged approach to tick population management.
3. Veterinary pharmacovigilance is not yet fully appreciated by the grass root practitioners	• Unreported drug complaints • Unreported adverse drug reactions • Defective and ineffective drugs on the market	• Increase sensitization and training on pharmacovigilance at grass root level • Disseminate ADR reporting tools at grass root level
4. Poor cold chain facilities and unreliable power supply.	• Deterioration of drugs in cold chain storage especially vaccines. • Outbreak of epidemics due to ineffective vaccination.	• Increase sensitization on cold chain management and vaccine handling. • Collaborate with development partners to assist in provision of cold chain equipment and power back up.

5. Lack of diagnostic facilities for veterinary diseases.	• Irrational drug use and poor treatment outcomes. • Over use of drugs • High cost of animals treatment.	• Partner with the private sector and development partners to build regional laboratories • Sensitize veterinary practitioners and farmers about the benefits of practicing evidence based medicine.
6. Some molecules used in the contral of pests in crops being used as acaricides to control ticks on animals.	• Exacerbated tick resistance to acaricides. • Presence of chemical residues in foods of animal origin that can cause cancers in humans.	• Increase sensitization on the public health effects of misuse of these chemicals. • Stringent regulation of agrochemicals.

4.5 Audit of veterinary cold chain facilities

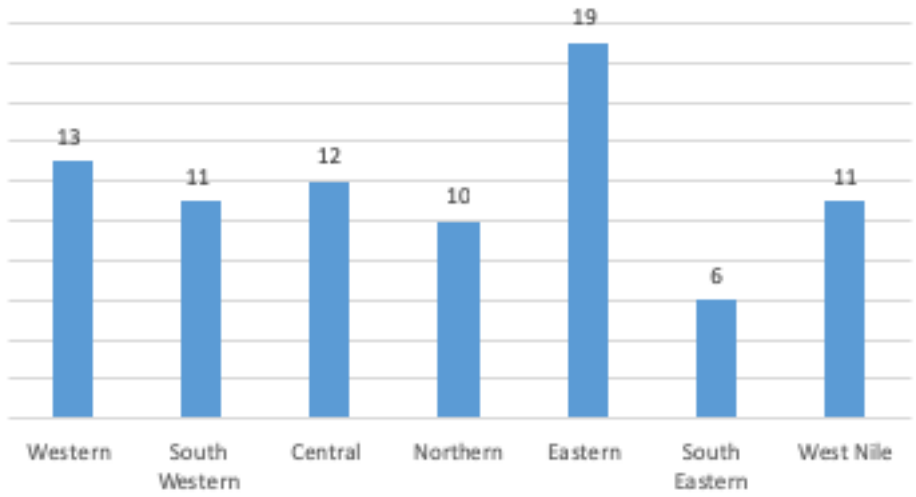
Drugs need to be properly handled in a distribution supply chain to maintain quality and traceability. Some drugs are sensitive to temperature changes or variations that may require a cold chain. A cold chain is a system used for transporting and storing drugs (e.g vaccines) that require refrigerated temperatures within recommended ranges.

NDA conducted an audit of 167 veterinary cold chain facilities (83 in public and 84 private) based in 82 districts in the year under review.

4.5.1 Findings in public cold chain facilities

The Eastern region had the highest number of districts covered 19/82 (23%), followed by Western 13/82 (16%) and shown in graph 24. The public cold chain facilities were mainly domiciled in the district veterinary office (78%). Due to shortage of space, some veterinary cold chain facilities were housed in the District health office cold chain store. Some districts (6%) made use of private veterinary drug shops or homes of officers to store Government vaccines, owing to absence of cold chain facilities in some districts.

Some districts (4%) kept their animal vaccines at the cold chain facilities of neighboring districts. The findings indicated the implications of the situation on access to animal vaccines and their integrity up to the end user.



Graph 24

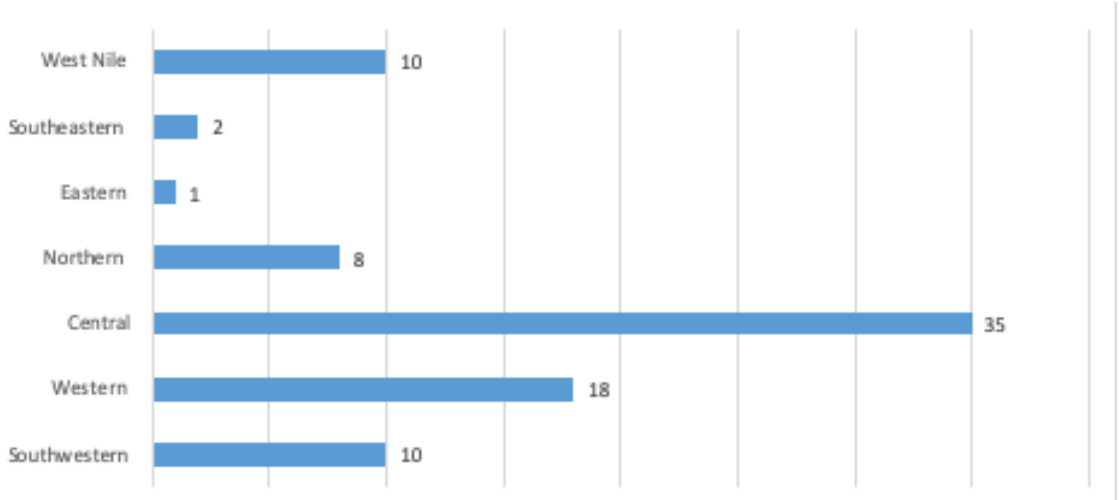
4.5.2 Findings in private cold chain facilities (Vet Pharmacies and Drug Shops)

Private veterinary drug outlets (pharmacies and drug shops) with cold chain facilities audited were 84. These were in 32/82 districts visited, and accounted for 39%.

Most districts (61%) visited had no private veterinary cold chain facilities. This implied that farmers relied on the public cold chain for provision of veterinary products that need special (cold) storage temperatures, that indicated a very big limitation to animal enterprise growth in the districts concerned.

Many of the private facilities audited were in Central region (42%), Western region (21%), South Western and West Nile each accounted for 12%, Northern (10%), South Eastern (2%) and Eastern
(1%) as indicated in graph 25.

Of the private drug outlets found with veterinary cold chain facilities majority were, drug shops (83.3%), followed by pharmacies (15.5%) and, a non-government organization (1.2%).



Graph 25

To safeguard vaccines and other animal drugs that require cold chain storage, there is need for special refrigerators designed for pharmaceutical use. Most of the audited outlets (81%) had domestic refrigerators, and a few (14%) had pharmaceutical refrigerators, while others (5%) had freezers for storage of vaccines.

Pharmaceutical refrigerators are recommended for cold chain storage, as opposed to the ordinary domestic refrigerators that can easily destroy freeze-sensitive drugs.

4.5.3 General audit observations

The commonly used domestic refrigerators were poorly insulated and, a good number of them were in poor hygienic condition.

Most power backups were found to be unreliable since they could not maintain uninterrupted power supply required for the vaccine refrigerators. Of the audited facilities 67% (public) and 43% (private) had power backups, while the rest mainly used ice blocks to store vaccines during power outage. Some facilities with power backups had generators that could not automatically switch on during power outage.

Among the facilities audited, 40% public and 48% private had temperature-monitoring devices installed in the vaccine refrigerator. However, very few of the facilities had evidence of monitoring the temperature daily and, only 8% (public) and 25% (private) facilities had up to date temperature monitoring charts for the vaccine refrigerators. None of the facilities audited did monitor vaccine temperatures during transportation. In the absence of the temperature monitoring charts, one is unable to know whether a refrigerator has been working within the recommended storage temperatures of the vaccines or not, which casts doubt on the integrity of the vaccines stored.
There were unauthorized products like fruits, sodas, drinking water, food, fruits, laboratory reagents, blood and tissue samples meant for laboratory analysis stored in the refrigerators. Mixing these unauthorized products with vaccines in the same refrigerator could lead to cross contamination of the products. This vice was noted both in private and public facilities.

A general training gap for the personnel in-charge of the facilities was identified, with only 10% (public) and 1.2% (private) having ever attended training in cold chain management. Many of the personnel in public sector (75%) that had ever been trained, were cold chain technicians employed under the District Health Office that assisted the District Veterinary Officer (DVO) to store animal vaccines. The gap in cold chain training and basic management knowledge, could be one of the main reasons why animal vaccines are poorly stored, transported and perhaps of reduced efficacy.

4.5.4 Implications of the status quo

Some vaccines are more sensitive to heat while others are more sensitive to freezing. Exposure of vaccines to extreme temperatures could cause loss of potency (quality of the vaccine required to produce an effect) thus rendering it inefficacious, unsafe and unusable.

The damage caused by extreme temperature to a vaccine is permanent, and leads to loss in potency and can never be restored. Use of damaged vaccines may lead to the outbreak of vaccine-preventable diseases and, affect the credibility of the vaccination programs. It is therefore important to note that, a break or failure in cold chain affects the potency of the product. Furthermore, good handling after

a break or failure in cold chain cannot restore the potency of a vaccine.

4.5.5 Mitigation measures of the identified constraints

The assessment activity of the veterinary cold chain storage facilities shall be a continuous NDA activity across the country as mitigation measures are being instituted to address the identified gaps.

Engage the Ministry of Agriculture, Animal Industry and Fisheries to seal these gaps in the public sector.

The different district local government administrations will be engaged for possible designation and specific training of officers that manage the cold chain at the district level.

Sensitization and training of the actors in both public and private sector is being done to acquire better and suitable cold chain facilities. Subsequently enforcement of the cold chain standards will be effected.

4.6 Veterinary Compliance Monitoring

Tick burn products recovered from a veterinary drug shop in Sheema District.

The compliance monitoring activities held in the period, targeted illegal dealers in veterinary pharmaceuticals. In the year under review, a total of fourteen (14) police cases were preferred by the Director of Public Prosecution that led to nine (9) convictions. The apprehended persons where charged or convicted before the Magistrate Courts in Ntungamo, Kampala, Sheema, Mbarara, and Fort Portal. Among the charges included, supply, sale and possession of unregistered, unauthorized and counterfeit veterinary products; and unlawful possession of classified drugs, selling classified drugs without a license as well as falsification (adulteration) of acaricides.

The success to curtail unscrupulous operators in veterinary drugs was attributed to close engagement of district leaders and farmers in the respective districts. The stakeholder engagements did improve effectiveness of veterinary drugs that reduce the burden of animal diseases which later translates into better human health.

Lack of prescribers, sub-standard and falsified are among the constraints leading to treatment failures and animal deaths in the cattle corridor areas. When effectively handled will improve animal health and production, improve economic gains for the farmers and safeguard public health.

4.7 Ticks and Acaricides

4.7.1 Ticks resistance to acaricides

Ticks and tick borne diseases constitute the biggest challenge to livestock production and productivity in Uganda and, cause both direct and indirect losses to farmers. Direct losses include low milk production, decreased live weight gain, mortality, hide damage and morbidity.

The two most prevalent cattle tick species are brown ear tick - Rhipicehpalus appendiculatus that causes East Coast Fever, and the blue tick - Rhipicephalus (Boophilus) decoloratus, that causes anaplasmosis, babesiosis and theileriosis. These ticks cause serious economic losses to farmers in Uganda.

Tick control in Uganda largely depends on the indiscriminate use of acaricides under the classes - synthetic pyrethroids, organophosphates and amidines, and of recent macrocyclic lactones. However such practices can lead to ticks developing resistance against these chemicals, a major challenge to sustainable livestock production. Recent studies in Uganda indicate that ticks have developed resistance to almost all acaricide classes available on the local market.

Amitraz a relatively affordable and a vital molecule for tick and tick borne disease control for small farmers was introduced in Uganda in 1991 to control organophosphate and synthentic pyrethroid resistant ticks. One in every 2 farmers in Southwestern and Central Uganda is reported to use Amitraz for tick control. It's mechanism of action is said to be an agonist of the octopamine/tyramine receptor.

It is recommended to use acaricides in a rotational manner placing Amitraz between organophosphates and synthetic pyrethroids as a management strategy for tick acaricide resistance.

STRICTLY BUY DRUGS

from Pharmacies and Drug shops licensed by National Drug Authority

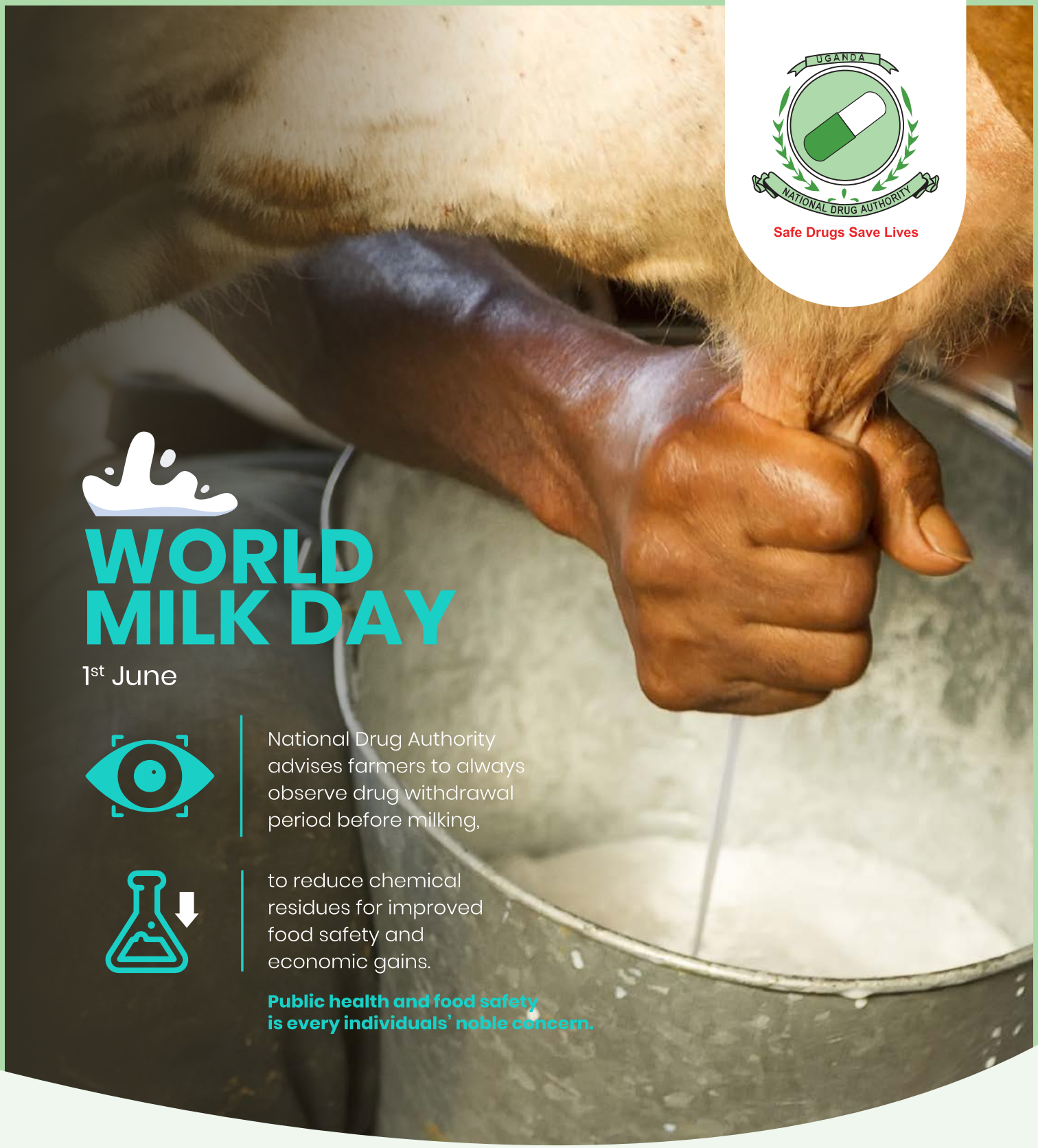
UGANDA
NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

Report drug related challenges to NDA via;

Toll free:0800 101 999 | 0740 00 20 70 | Med safety mobile app

druginfo@nda.or.ug | www.nda.or.ug



UGANDA

NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

WORLD MILK DAY

1st June

National Drug Authority advises farmers to always observe drug withdrawal period before milking,

to reduce chemical residues for improved food safety and economic gains.

Public health and food safety is every individuals' noble concern.

Toll free:0800 101 999 | 0740 00 20 70 | Med safety mobile app

druginfo@nda.or.ug | www.nda.or.ug

4.7.2 Strategies to control tick resistance to acaricides

- Rotation between acaricide classes to reduce or delay full emergence of resistance to a particular class of acaricides. Switching between acaricides should be done with guidance from a veterinary professionals and, the ideal situation is to switch after 2-3 years.
- Always follow the manufacturer's dilution rates.
- Spray the whole animal concentrating majorly around the ears, and tail.
- Spray all animals (including dogs) on the farm.
- Use proper equipment.
  - ✓ Measuring cylinder/cup: for correct measurement of the amount of acaricide to be added in water
  - ✓ Spray pump: to provide enough pressure while spraying.
  - ✓ Cattle crush: to hold the animals in one place while spraying.
  - ✓ Mixing cans/jerry cans of the proper size. Avoid swollen jerry cans.
- Examine and spray all newly introduced animals on the farm.
- Buy acaricides from NDA licensed drug outlets and, not agrochemical shops and hawkers.
- Practice controlled grazing to reduce risk of spread between farms.

4.7.3 Dangers of agrochemicals use in controlling ticks

The commonest agrochemical being used by farmers to control ticks in animals is Dudu acelamectin 2 in 1. This product contains a molecule called Abamectin that is present in another class of acaricide - the macrocyclic lactones - which is not yet widely used in Uganda. Abamectin falls under the avermectin family of the macrocyclic lactones.

The abamectin in agrochemicals is specifically formulated for use in plants but not animals. Inappropriate use in animals could lead to residues of abamectin in milk and meat which could pose a risk to public health.

4.7.4 Way forward

To improve veterinary drug regulation compliance in the country and high livestock yields, NDA shall continue with following interventions.

- Engage with veterinary practitioners to improve vet drug regulation compliance.
- Deliver on the memorandum of understanding (MoUs) with the Districts to better streamline roles for better veterinary services delivery.
- Train field veterinarians on NDA mandate especially new molecules, counterfeits, and pharmacovigilance to enable reporting of Adverse Drug Reactions in animals.
- Sensitize stakeholders on veterinary drug regulation.
- Support supervision and enforcement on veterinary drug outlets to improve the level of compliance to NDA regulatory requirements.

4.8 Guidance for opening a Class C Veterinary Drug Shop

A class C Drug Shop is licensed to sell class C drugs as laid out in the Third Schedule of the NDP/A Act. Class C drugs may also be referred to as Over-the-Counter drugs. These are drugs that treat simple ailments. Examples may include pain relievers, cough suppressants, dewormers, multivitamins, mineral licks (appetisers) and parasiticides among others.

4.8.1 Requirements for Application:

Applicants for a drug shop license should

submit the following at the time of application:

- Duly filled application forms for certificate of suitability of premises.
- Duly filled application forms for a license to operate a class C drug shop.
- Proof of payment of the prescribed fees in the bank or via mobile money.
- A certified copy of the certificate of registration of the qualified in-charge.
- A letter of commitment from the in-charge.
- Copy of the National identity card of the owner and the in-charge.
- A sketch plan of the premises taking into consideration the minimum floor area.
- Two recent passport size photos of the in-charge.

4.8.2 Timelines for renewal of Licenses for Drug shops

- Applications for renewal are required to be submitted at the respective regional offices or the District Veterinary Officer starting 01 October but not later than 31 October of the year in which the current license expires.
- License renewal shall only apply for drug shops, which had a license to operate for at least one of the two preceding calendar years in the same premises; if the reason for the previous non-renewal was communicated and approved by NDA.
- Incomplete application documents for licensing will not be accepted at the time of submission.

4.8.3 Supervision of Drug shops

- Drug shops shall only be run by professionals with approved veterinary qualification and must be registered with the professional council, the Uganda Veterinary Board.
- A Certificate/Diploma holder in Animal Husbandry shall be licensed to operate a veterinary drug shop.
- The premise must be operated by the licensed seller on a full- time basis, that is, throughout the entire opening hours of the drug shop. If the licensed seller must leave the premises for any reason, the drug shop must be operated by another suitably qualified person.

4.8.4 Recall of Veterinary Drugs

i) What is a recalled veterinary drug?

A recalled veterinary drug is a product that has been completely removed from circulation. It is important to note that these may be specific batches or all batches of a product that is recalled.

ii) Some of the reasons for a recall of a veterinary drug from the market.

Veterinary drug may be recalled from the market for the following reasons:

- Verified reports of serious adverse reactions not stated in the package insert of a particular product.
- Unacceptable frequency of adverse reactions which are mentioned in the package insert of a particular product.
- Falsified drug (e.g. incorrect labeling)
- Substandard drug (e.g. incorrect formulation)
- Failure to pass quality tests in the laboratory.
- Failure to comply with NDA regulatory requirements.

iii) What is a falsified veterinary drug?

A falsified veterinary drug is a product that deliberately or fraudulently misrepresents the identity, composition or source.

iv) What is a substandard veterinary drug?

Is an authorized product that fails to meet either the quality standards, or specifications, or both.

v) Why it is important to recall defective veterinary drug from the market?

The recall of defective products from the market safeguards the public from harmful effects caused by the use of unsafe, ineffective or poor quality drugs and other medical products.

vi) Why the public should not be alarmed when veterinary drug is recalled?

When veterinary drug is recalled, it is a means of safeguarding the public and animals from harmful products.

vii) What happens to recalled veterinary drug?

Veterinary drug recalled from the market are destroyed at National Environment Management Authority approved incineration sites.

viii) Who is responsible for recalling a veterinary drug from the market?

The local technical representative of a particular product is responsible for recalling the product from the market once a recall notice is issued. However, NDA is obliged to audit product recalls to rule out any inadequacies in the recall processes.

ix) Where can you find other lists of recalled pharmaceutical veterinary drugs from the market?

On the NDA Website at www.nda.or.ug

As a quality assurance mechanism, active post market surveillance culminates in recall of the registered and authorised veterinary drug that fail quality tests or other regulatory requirements. These recalled products are then either destroyed or re-worked and redistributed into the market.

4.8.5 Veterinary Pharmacovigilance

Pharmacovigilance (PV) is a process by which information is collected to detect and prevent unexpected or unwanted adverse effects following the use of a veterinary drug.

The scope of veterinary pharmacovigilance is mainly the safety and efficacy in animals and safety in people. It may include other events associated with the use of the product, such as lack of expected efficacy, residues exceeding the established safe limit, environmental issues and suspected transmission on infectious agents (for vaccines). The information collected allows for the on-going assessment of the risk-benefit of the veterinary drug in relation to its target population and throughout its life cycle.

Veterinary Pharmacovigilance is a shared responsibility involving a number of stakeholders who are expected to provide the required information through reporting of adverse drug events to the NDA.

NDA has a system in place to receive, record, collate, analyse and follow-up on adverse event reports. For a thorough evaluation of individual adverse event reports, a complete set of core data is critical. The minimum data required for an individual case report consists of:

- Identifiable reporter: this includes the name, address, phone number and email of the reporter.
- The treated animal: details of the number of animals treated, the sex, age and weight are important.
- Identifiable drug: provide the brand name of the product, batch number, dosage and route of administration.
- Adverse event description: for example abnormal findings (like swellings, hyper salivation, vomiting, death etc), other than the known clinical signs/symptoms. In order to evaluate a lack of efficacy, information on the dose used and method of administration should be given.

4.8.6 Veterinary Drug Promotion/ Advertisement

NDA regulates drug related information that targets different sections of society that includes the public, human or veterinary professionals. The NDP/A Act (Control of Publications and Advertisements Relating to Drugs) Regulation , 2014 states that "A person who seeks to make a publication or an advertisement for a drug shall make an application to the Authority using form 45".

i) What is an advertisement?

An advertisement is any notice, circular, label, wrapper or any other document; as well as any announcement made orally or by means of producing or transmitting light or sound.

ii) Drug promotion/advertisement application process

- Who can make an application? An application can either be made by the manufacturer of the drug, or a licensed person, or an agent authorised by the manufacturer or the holder of the patent of the drug.
- Documents required to be submitted: an application letter, samples of the materials to be advertised, and the prescribed fees.
- Language to be used in the advertisement: English is the preferred language, but where the materials are not in English, the material shall be presented with certified English translations.

Once an application has been accepted by NDA, it undergoes the vetting process which includes screening, uploading into the drug promotion (DPROM) system, review, making a regulatory decision and providing feedback to the applicant. The feedback may be an approval or rejection of the advertisement.

iii) Why control veterinary drug promotions/advertisements?

It is to ensure that all advertisements are reliable, accurate, truthful, informative, balanced and up-to-date and in good taste. They should not be misleading to induce unjustifiable drug use or give rise to undue risks. If the wrong information about a drug is exposed to the public, it is a potential source of harm to the animal and user.

4.8.7 Frequently Asked Questions on Veterinary Drugs

i) Who is responsible for regulation of agrochemicals?

Agrochemicals are chemicals used in agriculture and, are regulated by the Agricultural Chemicals Board under the Ministry of Agriculture Animal Industry and Fisheries.

ii) How long does NDA take to investigate a drug complaint?

Any drug complaint received at NDA is investigated and, feedback provided to the

complainant.

iii) Does NDA provide feedback to clients about investigation outcomes of drug complaints?

Upon completion of the drug complaint investigation process, feedback is provided either through SMS, email or written letter depending on the contact details that were provided by the complainant.

iv) What information does NDA require in drug complaint reports?

The most important information are the contacts of the complainant, the details of the drug being complained about, the description of the complaint about the drug and where the drug was brought. More information about what should be included on the report can be obtained from the Complaints Reporting Form. This form can be obtained from the NDA website or from the District Veterinary Officer at no cost.

v) How does the public know if a drug has been recalled from the market?

The public can know about a recalled drug by checking on the NDA website. Information about drug recalls can also be obtained through NDA bulletins and circulars to the public.

vi) What are the procedures for operating a veterinary drug shop?

Before opening up a vet drug shop, the intending operator should pick up and fill the NDA application forms. Then attach the qualification certificates of the would be supervising in charge. The qualification certificates include the academic and Uganda Veterinary Board (UVB) certificates. An evidence of payment of prescribed fees, commitment letter of the supervising in charge, National ID and Sketch map of the premises are also submitted together with the application forms. See more details in the section "Guidance Opening up a Class C Veterinary drug shop" in this bulletin.

How do fake drugs find their way into the market?

Through smuggling and counterfeiters within the country.

vii) How can you identify a fake drug from a genuine one?

- Check for unusual physical characteristics on the product including the colour, markings, shape and any other changes on the drugs.
- Check for altered manufacturing/expiry dates or labels. Take extra caution of products with short expiry dates.
- Be suspicious of drugs that are unusually cheaply priced.

viii) Why are ticks resistant to acaricides?

This is basically due to manufacturing and market dynamics which NDA has no control over.

ix) Why are ticks resistant to acaricides?

There are many factors contributing to the failure of acaricides to kill ticks. These include overuse of a particular class of acaricides, incorrect mixing (over or under dose), improper spraying (equipment and style) of animals, incorrect restraint of animals, and a lack of rotation between the classes of acaricides. It is a natural phenomenon for ticks to gain resistance to a particular type of acaricide, but this resistance is accelerated by all the above mentioned factors leading to failure of an acaricide to kill ticks.

For comments or feedback on any of the information in this issue of the bulletin, please feel free to send them via the email vet@nda.or.ug

5.0 Corporate Image

Secretary to the Authority installs a sticker (cautioning the public on risks associated with buying drugs from hawkers) on UTODA Awakuula Ennume bus.

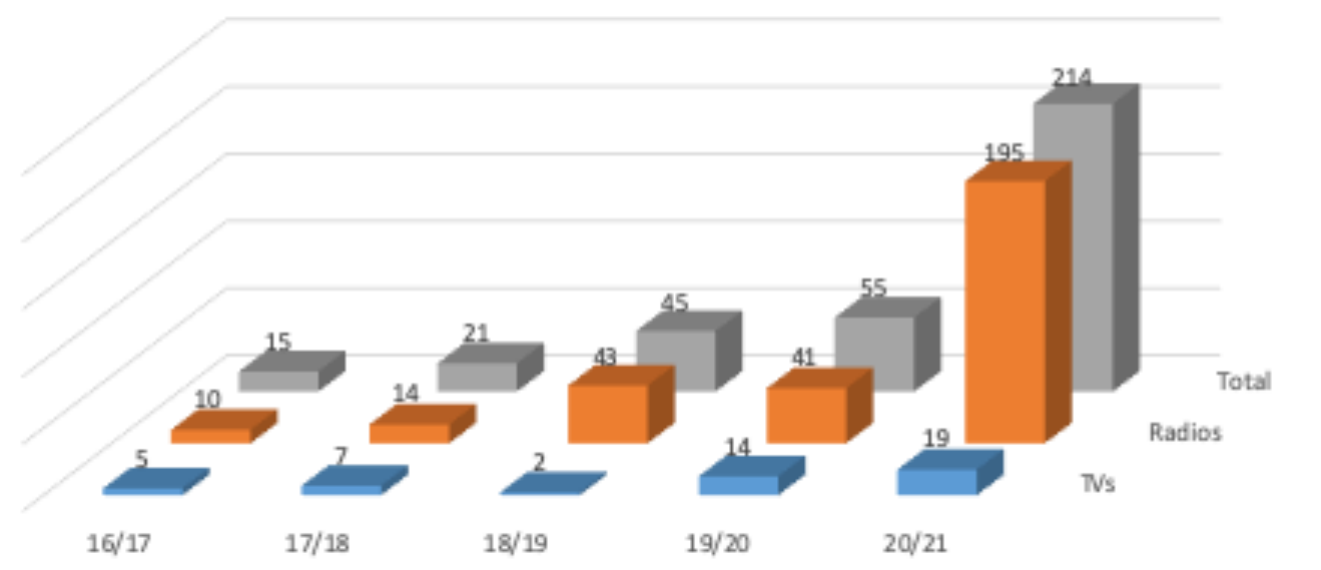
5.1 Communication

NDA recognizes the importance of communicating with the public through defined channels to enhance it's image, reputation, trust, transparency and integrity.

NDA's continued presence in the media shows (graph 28), and other media platforms exhibited solidarity with the population against irrational use of medicine, stockpiling, detecting unscrupulous pharmaceutical operators and use of personal protective equipment during the lockdown.

This flagged NDA's leadership on health related emergencies within it's mandate and minimized communication crisis.

Trend of Media Shows (FY 16/17 - 20/21)

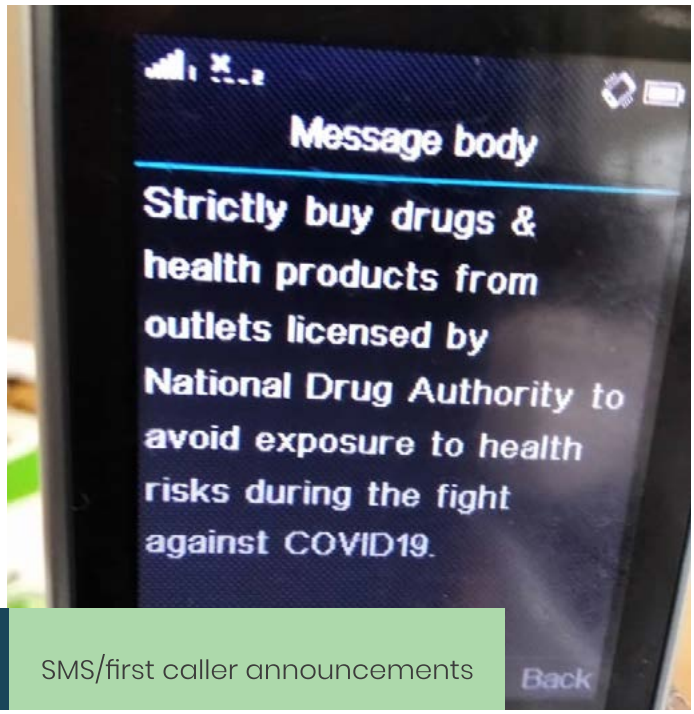


Graph 28

5.1.1 Communication channels

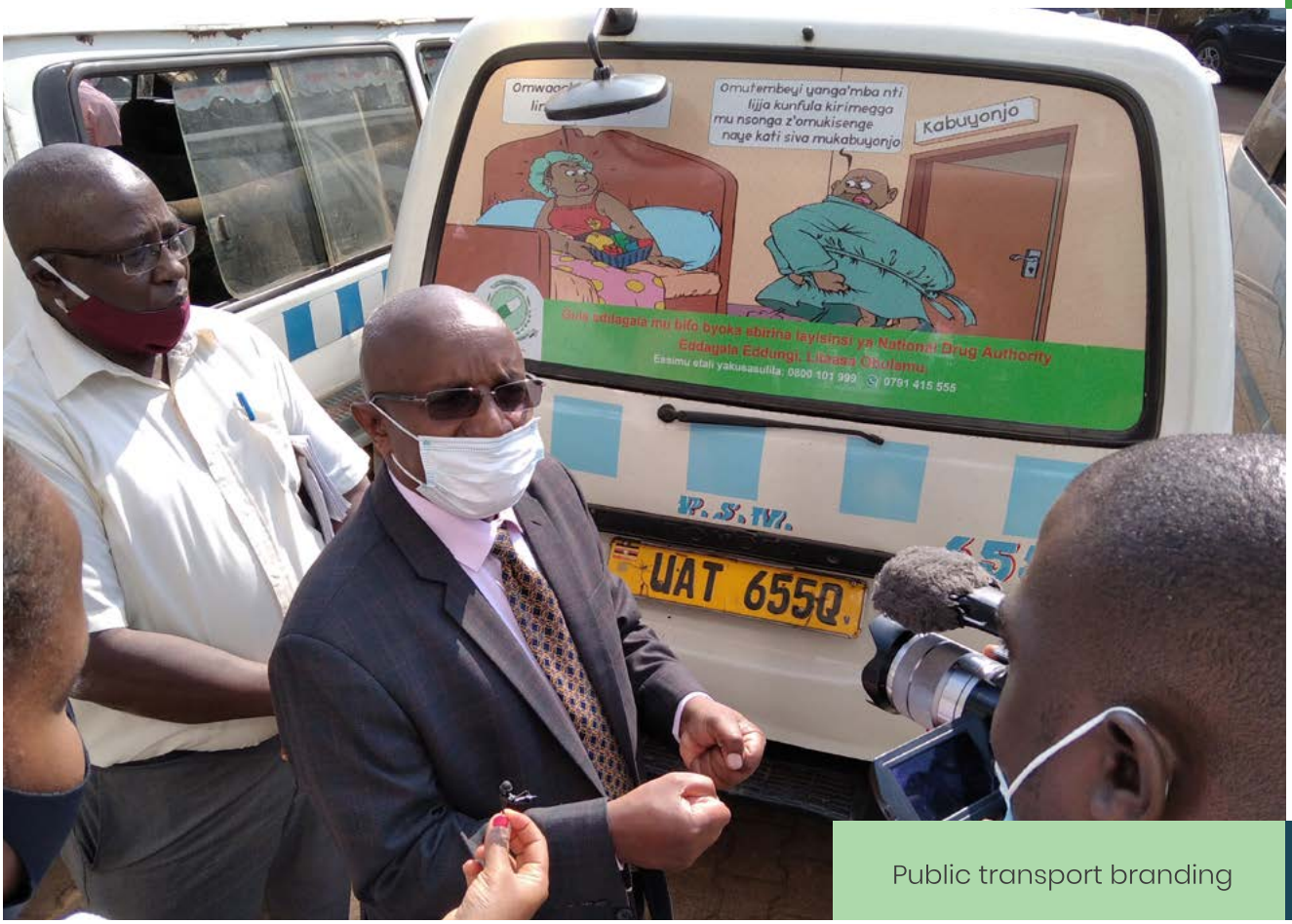
NDA increased visibility through use of various communication channels to improve levels of awareness and compliance on it's mandate.

Radio/TV appearances

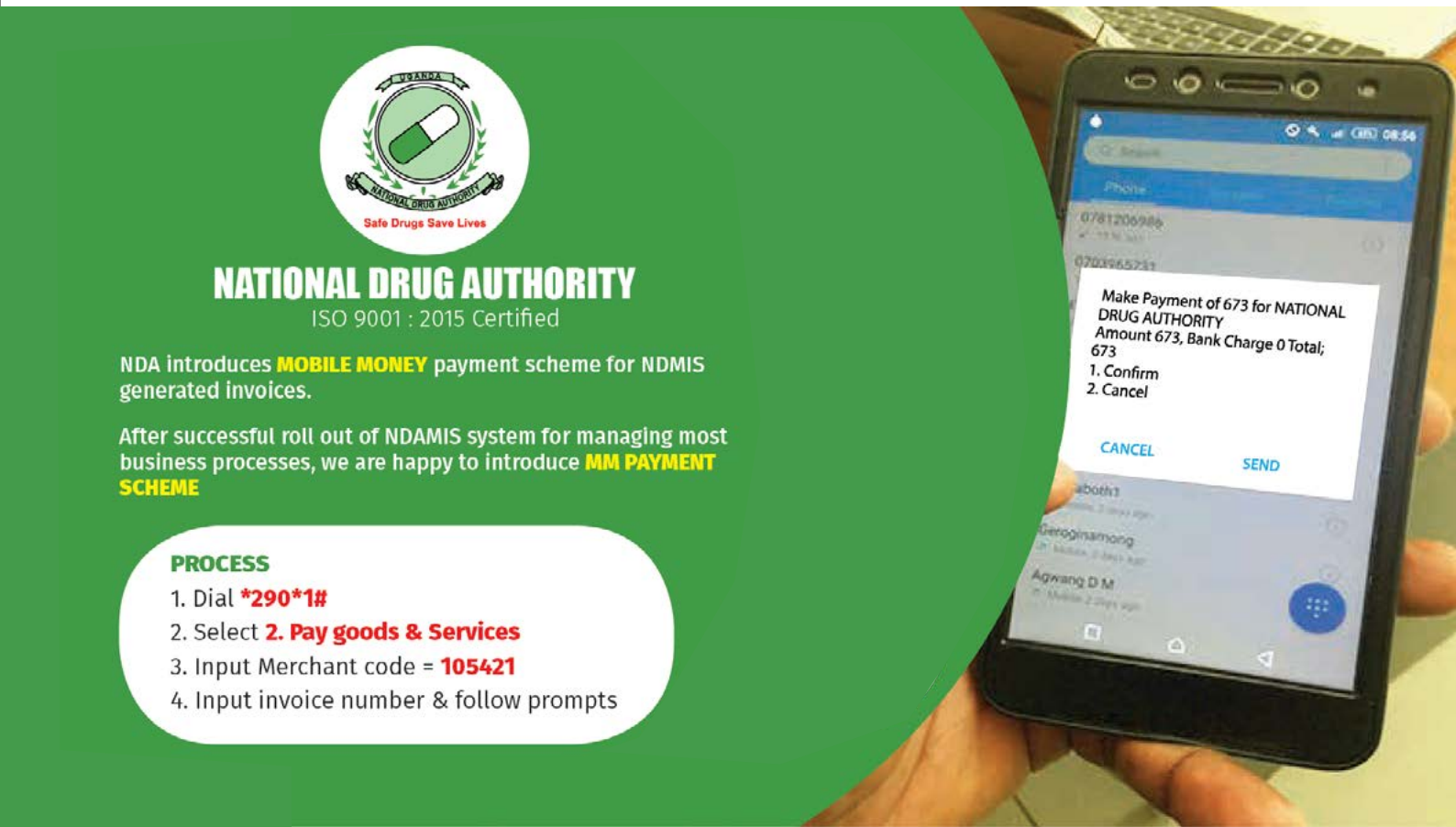


SMS/first caller announcements

Bill boards



Public transport branding

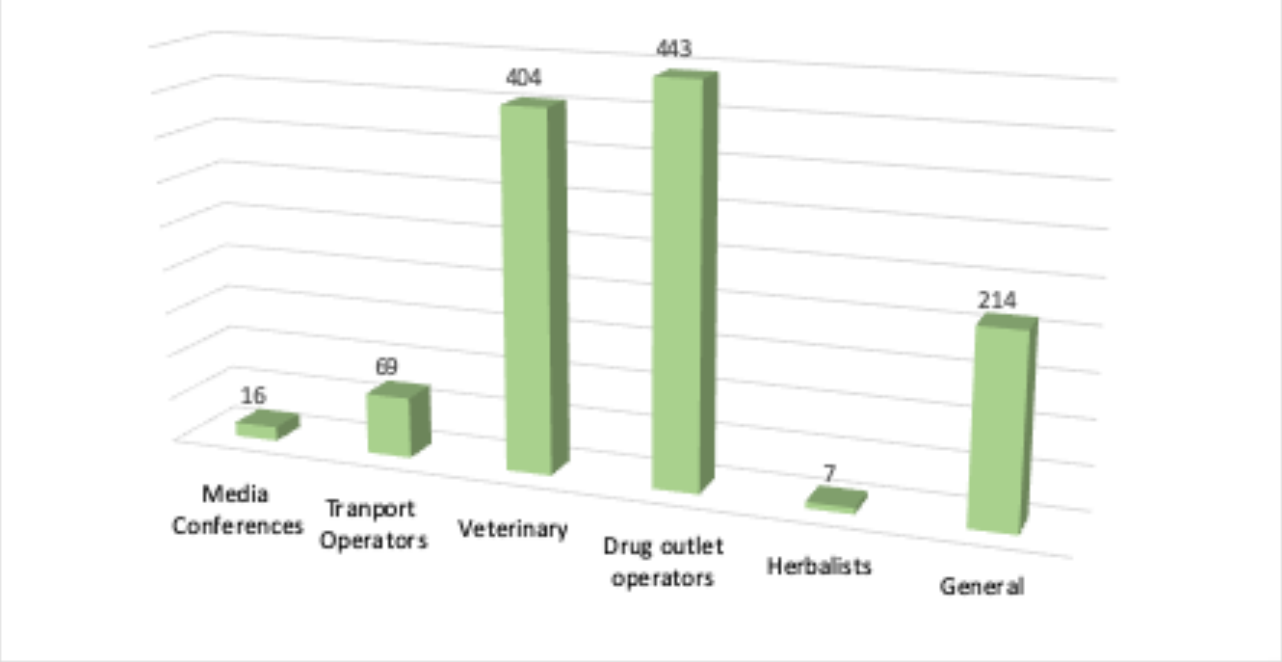


5.2 Stakeholder Engagements

5.2 Stakeholder Engagements

NDA held 1,153 engagements with various stakeholders across the country compared to 755 in FY 2019/2020 as indicated in **graph 27** These engagements foster a framework that favours the inclusion of stakeholders in the business of the Authority hence minimizing challenges in delivering on its mandate.

Stakeholder Engagements Held FY 2020/2021



Graph 27

Stakeholders engagement on rational use of veterinary drugs.

NDA is open and honest with stakeholders as it provides accurate and timely information, listens and responds to their views and concerns. Areas of engagements centered on NDA's activities like enforcement operations, veterinary drugs, acaricides, drug hawkers, drug promotions/advertising, adverse drug reactions, herbal drugs (covid-19 herbal remedies), and licensing among others.

5.3 Corporate Social Responsibility

5.3 Corporate Social Responsibility (CSR)

NDA recognizes the importance of corporate social responsibility as it manages social economic impact. As a corporate member of society NDA contributes to community' noble initiatives alongside its normal business operations.

NDA supported the national inaugural Heroes in Health Awards event that recognized health workers for their distinguished work in service. Health workers contribute to the overall quality of pharmaceutical products and, that is attributed to their vigilance, monitoring and reporting to NDA. Health workers positively impact millions of patients through providing solutions for better health outcomes.

Together with the Rotary club of Kampala, NDA supported planting of medicinal trees (moringa, gravella, prunus Africana and Giant Lira) and fruit trees in Nyenga Buikwe District.

Supported the Uganda Dental Association successful dental camp at the Makerere University Dental School in commemoration of World Oral Health Day 2021. Over 300 patients (including children) received free dental treatment at the camp.

Table 6 Indicating CSR projects supported under the different categories FY 2019/2020

No	Category	FY 19/20	2020/2021
1	Health	12	17
2	Education Institutions/Youth	21	9
3	Charity/Community/Environment	8	26
4	Faith based institutions	7	11
	TOTAL	**48**	**63**

6.0

International Accreditation, Certification and Recognition.

NDA's Quality Control Laboratory is prequalified by WHO: and accredited byANAB, USA to ISO/IEC 17025 standard. The Authority is also ISO 9001:2015 certified.

10.1 Pharmaceutical Inspection Co-operation Scheme

During a Pharmaceutical Inspection Cooperation Scheme training of staff after a pre-assessment audit of NDA's inspectorate system.

NDA is set to join the Pharmaceutical Inspection Co-operation Scheme (PIC/S). The two weeks assessment by a team of international experts reviewed NDA's inspectorate quality management systems, quality control laboratory and pharmacovigilance systems in addition to observing competence and technical knowledge of Good Manufacturing Practice (GMP) inspections.

The pre-accession stage will be followed by an on-site audit of NDA by the PIC/S auditors at a time to be agreed upon. NDA commenced its accession to the PIC/S in 2012 and completed the first pre-accession procedure in 2014. NDA was among the first Drug Regulatory Authorities to have completed the pre-accession procedure since the launch of the new PICS accession system.

PIC/S is a non-binding, informal co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use. It is open to any national drug regulatory authority having a comparable GMP inspection system.

It is made of 54 participating national drug regulatory authorities from Europe, Africa, America, Asia and Australia. Only South-Africa currently holds a PICS membership in Africa.

7.0 International Affairs

7.0 International Affairs

The International Affairs Unit serves as the focal point for NDA collaboration with international organizations involved in drugs regulation and counterpart drugs regulatory agencies. The period under review was quite challenging due to the prevailing conditions during the Covid 19 pandemic, however most of the planned activities were accomplished through virtual meetings.

8.1 Africa Drugs Regulatory Harmonisation (MRH) Initiative

The Africa Regulatory Taskforce comprised of the African Union Development Agency (AUDA-NEPAD), the Africa Centers for Disease Control and Prevention (Africa CDC), and the World Health Organization's (WHO) African Vaccine Regulatory Forum (AVAREF) was established to provide an effective regulatory framework for COVID-19 Vaccines in Africa. NDA is a member of the steering committed to this initiative.

To properly guide Member States, the Africa Regulatory Taskforce developed Guidance on Emergency Expedited Regulatory Authorization and Access to COVID-19 Vaccines In Africa - a framework for market authorization of COVID-19 vaccines.

8.2 East Africa Community MRH Initiative

The implementation phase of MRH initiative in EAC in 2015, has so far led to 21 joint assessment sessions resulting from 151 products received for assessment with 81 recommended for registration to date. The NMRAs have also conducted 30 joint GMP inspections.

The EAC-MRH programme implemented a scheme that enables certification of Active Pharmaceutical Ingredients (APIs) to avoid duplication of work and minimize different outcomes of evaluation in EAC. The Holder of the API certificate of acceptance may provide the certificate to the relevant applicant for the finished product consisting of the certified API who is seeking for marketing authorization in the EAC Partner States.

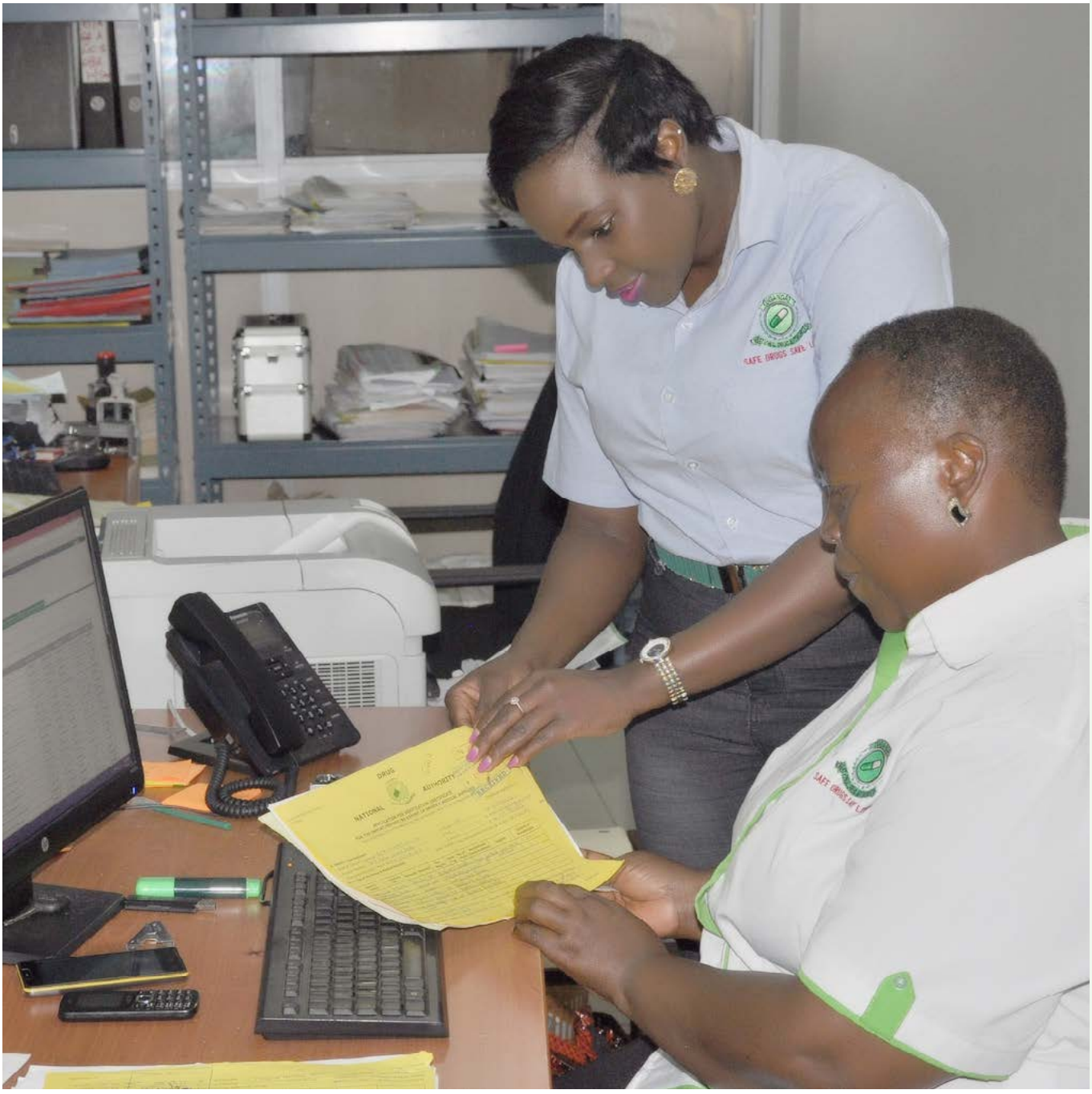
The EAC Harmonisation Initiative for Veterinary Medicinal Products (VMP):This is dedicated to VMPs whose implementation phase commenced in 2017 with immunological products. It has since been expanded to include pharmaceutical products and eight applications assessed and GMP inspections conducted

8.3 Inter-Government Authority on Development (IGAD) (MRH) Initiative

Implementation of theThe IGAD MRH Initiative commenced in 2020. A total of 48 products were assessed and recommended for registration

8.0

Brief on NDA Operational Procedures



8.0 Brief on NDA Operational Procedures

Market authorization

This applies to all **HUMAN** and **VETERINARY** pharmaceutical products including biological products, and traditional medicinal products.

Application for the registration of a drug shall be made only by:

The license/patent holder or the manufacturer

A distributor authorized by the manufacturer, license/ patent holder

Good Manufacturing Practices

All pharmaceutical-manufacturing sites at which human and veterinary drug used in Uganda are manufactured shall be subject to current Good Manufacturing Practices (cGMP) inspection by NDA before the drugs are registered and at least once every three years.

Import control

Any drugs to be imported in Uganda must be registered unless given special clearance by National Drug Authority (NDA) under section 8(4) of NDP/A Act. An importer must have a valid annual import permit issued by NDA, and may be issued to wholesale pharmacies, pharmaceutical manufacturers or any organisation that regularly imports drugs and other related substances. Ministry of Health of Uganda and its affiliated units may also apply for an annual import permit.

Procedures for importation.

An original proforma invoice for the consignment of drugs to be imported is presented to NDA for verification fees assessment and payment. The local technical representative should endorse on the pro-forma invoice if the drugs are registered.

Verification of submitted documentation to ensure compliance with NDA requirements

Issuing of verification certificate

Upon arrival at the ports of entry, the drugs are inspected by NDA to ensure that they comply with the approved specifications and regulations before they are released. Each batch must be accompanied by a corresponding certificate of analysis.

Re-export of rejected consignments

Drugs rejected for quality reasons must be re-exported to the supplier in the country of export within a stipulated period of one month after receiving a rejection report.

Drugs rejected because of being unregistered in Uganda or neutral labeling may be re-exported to a third country on special request with special clearance from the authorities of the importing country.

Procedure for re-export

Application for verification is lodged in by intending exporter, accompanied by the relevant invoice and documents related to the rejection indicating also the exact point of destination.

Regular export of drugs

This can only be done by licensed pharmacies or manufacturers of drugs in accordance with Section 45 of NDP/A Act Cap 2006. Where the exporter has no annual export permit a provisional export permit is issued pre consignment after presentation of the following;

Order from importer

Copy of the authority given to importer by competent authority in country of import

Copies of a proforma invoice prepared by exporter showing batch numbers, registration status of the products to be exported and quantities of drugs to be exported.

Application for both a provisional export permit, where applicable, and verification certificate.

Drug Donations

Donated drugs may be authorized from small scale private donations to individual health Units. However, donation of money to purchase drugs from reliable local sources is preferred.

Need for donation

All donations should be based on a specific need expressed by the receiving body or health facility.

Needs should be expressed in terms of the range of drugs and the quantities.

The quantified need should relate to the population to be served and the type of health facilities to receive the drugs.

Donations to districts must be assessed and justified by the District Medical Officer.

Allowable donations

Must follow the procedure for Verification of Drug Imports

Should be contained in the current edition of the Essential Drugs List of Uganda (EDLU) or in the current edition of the Uganda National Formulary (UNF) or its provisional lists.

Should have a remaining shelf life of at least one year after arrival in the country, with exception of vaccines or other biological products which should have at least three quarters of their stated shelf life remaining upon arrival.

Those commonly in use in Uganda.

Disposal of pharmaceutical waste

The disposal of pharmaceutical waste from the public is embedded in NDA's mandate of ensuring that only safe, efficacious and quality drugs are availed to the entire population of Uganda.

Recommended methods for disposal of drugs

The appropriate safe disposal method recommended will depend upon the pharmaceutical form of the drugs.

Operators must seek advice from relevant authority for the common methods used for the safe disposal of pharmaceutical waste.

Procedure

Original letter requesting for destruction is presented to NDA together with a detailed list of the obsolete items to be disposed off.

After inspection and assessment by an official of NDA, if the pharmaceutical waste is 100kg or less, the client is given a bank slip to pay for the weight specified.

If the pharmaceutical waste is more than 100kg, the client is advised to contact NDA accredited service provider for the destruction. In such an instance NDA shall provide an Inspector of Drugs who will supervise the safe disposal of the expired pharmaceutical waste.

Requirements for Operating a Drug Shop.

Process for opening a NEW drug shop
To operate a drug shop an applicant is required to submit the following documents before inspection by NDA.

- A completed application form.
- Two recent passport size photos of the qualified professional full-time in charge.
- A copy of the certificate of the qualified medical/pharmaceutical/veterinary
- profession in- charge.
- National ID Number (NIN)

The above requirements are the same for license renewal. It is a joint responsibility of the in-charge and the applicant/owner of the drug shop to ensure that the academic certificate of the in-charge submitted to NDA is valid and authentic.

Requirements for Operating a Pharmacy

Some of the requirements for establishing a PHARMACY in Uganda,

- The business must be registered with the Registrar of Companies.
- Have a suitable premises with space dimensions as stipulated in the licensing Guidelines.
- Commitment letter of Pharmacist (full time in charge).
- Employ professional auxiliary full time staff, with minimum qualifications of a pharmacy technician, Registered/Enrolled nurse or midwife with pharmaceutical training, Vet surgeon or Animal husbandry officer for vet pharmacies.
- Filled in application forms for suitability of premises and operating license.
- The forms can be obtained from headquarters, NDA Regional offices or accessed online (www.nda.or.ug).
- A Tax Identifi cation Number (TIN).
- Evidence of bank payment slip receipt.

Note: The applicant must apply to NDA, and a formal approval is given in writing.

Quality Control Laboratory

NDA has a WHO Pre-qualified and ISO/IEC 17025 accredited laboratory which carries out testing of medicine samples, medical devices, public health products, and other health care products.

Some of the approaches used in testing samples

Mandatory testing for some products (All medical devices and some selected drug products)

Risk-based testing of various categories of products.

Post Market Surveillance for most Essential Drugs

Samples are taken according to NDA approved sampling plans and acceptable world standards (United States Food and Drug Agency, and WHO guidelines).

Standards used in testing

For medicine samples NDA uses authorized pharmacopoeias, manufacturers specifications for non-pharmacopoeial products.

Authorized pharmacopoeias include British Pharmacopoeia, United States Pharmacopoeia, International Pharmacopoeia and European Pharmacopoeia.

Collecting samples?

Samples are taken according to NDA approved sampling plans and acceptable world standards (United States Food and Drug Agency, and WHO guidelines).

Collecting samples?

Appearance; Identification;

Dissolution or disintegration (for tablets and capsules);

Uniformity content for all Drugs

Weight variation for all drugs and friability

pH and microbial limits for the solutions (if in the specifications);

Sterility and bacterial endotoxin test (for injectables which are currently outsourced).

Particulate matter_(for injectables)

Medical gloves NDA_ASTM D3577, D3578 and D5151 Standards.

Male latex condoms (NDA uses ISO 4074 Standard, and WHO specifications)

Assay, and related substances and impurities

Drug compliant investigations Procedure

The procedure involves the following:

Sample collection of the concerned product complained about, from the market.

Testing in the Laboratory

Investigating the manufacturing facility

Inspection of the source of the active raw materials (active pharmaceutical ingredients) used for producing the product.

Investigation of information about bioequivalence studies

UGANDA NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

PROTECT YOURSELF & YOUR LOVED ONES FROM

FAKE OR DAMAGED DRUGS

01

Make sure your medicine does not look, smell or feel unusual.

02

Check the packaging for poor condition, spelling mistakes and unclear or altered labels.

03

Check the medicine for the manufacturer's name/ address, batch number and manufacturing/expiry dates.

04

Check whether the batch number and manufacturing/expiry dates on the inside package match what is on the outside package.

05

Report any bad reactions from your drugs to a healthcare worker.

06

Report unlicensed sellers and fake or damaged drugs to NDA on the toll-free line **0800 101 99** or by WhatsApp No. **+256 740 002 070**.

Toll free:0800 101 999 | 0740 00 20 70 | Med safety mobile app

druginfo@nda.or.ug | www.nda.or.ug

Frequently Asked Questions

What does NDA do?

NDA is responsible for protecting and promoting public health, by ensuring the population access quality, safe and efficacious human and veterinary drugs and other healthcare products from qualified health workers.

What does NDA regulate?

In general, NDA regulates: human and veterinary drugs including herbal (traditional) drugs, biologicals and vaccines, nutritional food substances, medical devices (like Condoms, Medical Gloves), public health products (like Long Last Insecticides Nets).

How does NDA regulate human and veterinary drugs?

NDA operationalizes its mandate through the following quality assurance mechanisms.

- Market authorization by reviewing and assessing the dossier to support a medicinal product.
- Subjecting pharmaceutical manufacturing facilities to current Good Manufacturing Practices inspection before registering the drug.
- Import control as prior to entry of drugs into the country, inspections are carried out at the ports of entry.
- Post market surveillance by monitoring the safety of a pharmaceutical drug or medical device after it has been released on the market.
- Pharmacovigilance by monitoring the effects of medical drugs after they have been licensed for use, especially in order to identify and evaluate previously unreported adverse reactions.
- Testing of drugs in the WHO pre-qualified laboratory to protect the population from substandard, falsified and counterfeit products in Uganda.
- Inspection and licensing of human/veterinary products drug outlets on suitability of premises to ensure quality and safety of drugs.

NDA conducts several kinds of inspections to protect Human and Animal population from poor quality, unsafe and ineffective drugs, and unscrupulous operators.

How can one use medicine safely?

- By getting medicine from only authorized licensed medicine outlets and not from hawkers or market stalls.
- Avoid self-medication and always seek for advice from a qualified health worker on
- How and when to take it, and for how long?
- Read and follow the instructions given by the health worker or on the product leaflet which is a paper found in the medicine packet with information about the medicine.
- Check the medicine expiry date before taking it and inspect the medicine for any contamination or change in appearance before taking it. Do not take expired medicine or medicine that seems to be tampered with.
- Report any medicine related problems to NDA or to your nearest health care center.

What information do you need to know about your medicine?

Patients should always understand what medicine they are about to take so that they get the most benefit from it. Ask your health care worker the following questions.

- The medicine's name, and what it is supposed to treat
- How and when to take the medicine
- For how long the medicine will be taken
- What to avoid while taking the medicine.
- Whether, the new medicine will work safely with other drugs you are already taking.
- Whether the medicine will work safely with any other medical conditions that you have like pregnancy or any disease.
- Side effects the medicine may cause and what to do when they occur?
- What you should do in case you miss a dose.
- Any written information available about the medicine. (At the very least, ask the health worker to write out complicated directions and medicine names).
- When to return to the health worker.

What is NDA's contribution to the Health Outcomes?

Drugs available on the market are efficacious for stated diseases and conditions resulting in better treatment of illnesses and prevention of diseases to protect and **promote a healthy human and animal population**.
Reduced treatment failures and number of deaths due to substandard, falsely-labelled, falsified and counterfeit human/veterinary drugs.

Improved animal health and production to safeguard public health and improved economic gains for the farmers

What NDA does not do?

NDA does not supply medicine to any institution or import or sell medicine or make decisions on the price of drugs. Once a marketing authorization has been granted, decisions about price are with the importer/ distributor. It does not licence clinics or hospitals.

How can a person detect a quack drug outlet operator?

The public is requested to seriously be vigilant and take note of the following signs in detecting quack operators.

- Avoid hawkers of drugs who are illegal, with outrageous claims of products that treat every disease leading to poor decision-making and late reporting of illnesses.
- Interested more in money and sale of medicine without asking for a medical prescription note or taking history of the patients health status e.g what one is suffering from, when it started, whether it is for a child or an adult, etc...
- Confuse patients with medicine brand pricing with countries of origin e.g China, United Kingdom, India, etc... with intention of fleecing them with unverified claims that drugs from certain countries are more effective than others.
- Do not explain to patients how the medicine is supposed to be taken, side effects and what to do when they occur?
- Open their outlets irregularly like late in the evenings, and close immediately close shop at sighting NDA Inspectors,...

How can I report a problem to or share my suggestions or ideas how can I get more information about NDA with NDA?

Anyone can report a problem or share their ideas with NDA through telephone, physical visits or online.

DRUGS

are very useful but can cause side effects in some patients

How to minimise side effects

- Read the Patient Information Leaflet(PIL).
- Ask your healthcare provider about the expected side effects.
- Report to National Drug Authority

Safe Drugs Save Lives

Tel: 01417 788 100

Med safety mobile app

druginfo@nda.or.ug

Toll free:0800 101 999

0740 00 20 70

www.nda.or.ug