Safe Drugs Save Lives

25 March 2022

NATIONAL DRUG AUTHORITY

INSPECTORATE & ENFORCEMENT PUBLICATION

VOLUME 2 JANUARY–JUNE 2021

The Director Inspectorate and Enforcement attending the launch of the Assessment Training Package for the occupation of herbalist

Launch of the Assessment Training Package for the Occupation of Herbalist

Physical stakeholder meeting SERERE

Physical stakeholder meeting SERERE

MESSAGE FROM THE SECRETARY TO THE AUTHORITY

On behalf of the Drug Authority, I take this opportunity with great pleasure to present to you the second performance report of the Directorate of Inspectorate and enforcement for the second half of the financial year 2020/2021.

This report represents our continued commitment to provide a detailed accountability of the progress and efforts made by the Authority towards ensuring that the citizens of Uganda access only safe, effective and quality medicines.

The second half of the year 2020/21 remained a challenging period globally, as different variants of the Covid-19 virus continued to ravage across the World, putting a heavy burden and strain on the already fragile healthcare systems, including the regulatory systems for approval and monitoring the quality of medicines and other healthcare products.

Amidst these challenges, National Drug Authority demonstrated leadership, flexibility and a progressive approach in dealing with the pandemic related challenges and their impact on the regulatory system and availability of quality essential medical products. The NDA has continued to expeditiously support emergency importation and use of new therapies for the Covid-19 treatment, the set-up of domestic pharmaceutical and medical device manufacturing facilities especially those much needed and in shortage during this pandemic period. The Authority also adopted flexible measures to ensure business continuity of regulatory functions during the continued lock down and movement restrictions.

The National Drug Authority continues to play a key role in furthering the opportunities presented during the covid-19 pandemic, specifically with regards to promoting the domestic manufacture of medical products. NDA has proactively continued to offer technical support to the upcoming domestic pharmaceutical and medical device manufacturing facilities within Uganda. It is against this initiative that I am pleased to report that during this period, the NDA issued licenses to two new domestic manufacturers;

one medical gloves facility and one veterinary pharmaceutical products facility. This milestone achievement places Uganda in prime position as a leading actor in the pharmaceutical manufacturing space within the region and a key ally in securing the supply chain for essential medical products within the region. It is anticipated that these facilities will greatly contribute to access to quality medical gloves and veterinary products within the country and East African region. Furthermore, these facilities are expected to contribute to the employment opportunities within the country, and support import substitution, while improving the trade deficit on medical products. National Drug Authority will continue to work with the various manufacturers currently setting up within the country to ensure they comply with the National standards for manufacture.

The Authority further looks to leveraging the gains made over the past period and building on these successes towards realizing its vision of *a Uganda with safe, effective, quality medicines and healthcare products*.

As I conclude, the successes achieved during this period would not have been possible without the support from various stakeholders. In this regard, I would like to thank the Ministry of Health and the Authority board for the leadership, support and policy guidance provided to the NDA secretariat to enable us achieve and deliver successfully on all the objectives of our mandate during this period. I would also like to wholeheartedly thank the NDA staff for their dedicated work and commitment during this period amidst a myriad of challenges. Finally, I wish to thank all our development partners, professional bodies, and the pharmaceutical industry.

I take this opportunity to renew our commitment to ensuring all Ugandans live healthy lives through the access of safe, effective and quality assured medical products.

For God and my Country

David Nahamya
SECRETARY TO THE AUTHORITY

As the Authority moves forward during this challenging period, we continue to adapt our work methods to focus on risk-based approaches, reliance and collaborations with competent Authorities worldwide and the World Health Organization in order to arrive at well informed regulatory decisions.

FOREWORD

It is my honour to present to you yet another comprehensive publication from the Directorate of Inspectorate and Enforcement containing our results and experiences for the second half of financial year 2020/2021.

As reported in July to December 2020 publication, the activities of the Directorate continued to suffer effects of the COVID-19 pandemic. Despite the challenges, our efforts continued to be aimed at ensuring uninterrupted service delivery and integrity of the health sector supply chain in the interest of public health.

In the second half of 2020/2021, we continued to receive applications for domestic manufacturing pre-inspections, an indicator of increasing interest in domestic pharmaceutical manufacturing, which is good for the economic development of the country. The Directorate continued to uphold standards in pharmaceutical manufacturing by both foreign and domestic pharmaceutical manufacturing companies. As a COVID-19 countermeasure, risk-based approaches were utilised to ensure that the drugs supplied to Uganda were of appropriate quality despite the travel restrictions that hampered physical inspections of drug manufacturing facilities. Other important trends include significant improvements in performance regarding licensing of pharmacies and medical device outlets from the first half of the financial year, as well as continued efforts in securing the supply chain through enforcement, market surveillance and public sensitization.

As a COVID-19 countermeasure, risk-based approaches were utilised to ensure that the drugs supplied to Uganda were of appropriate quality despite the travel restrictions that hampered physical inspections of drug manufacturing facilities.

Going forward, the directorate shall continue to consolidate its achievements to further improve service delivery and protect the health of the public through ensuring the safety, efficacy and quality of drugs. Key

interventions shall include strengthening systems for ensuring the quality of medicines on the market, automation of business processes, risk-based decision making, supporting the domestic pharmaceutical industry to manufacture quality drug products, evidence-based decision making, and leveraging local, regional and international partnerships and collaborations to improve regulatory service delivery. In addition, the Directorate shall continue to strengthen the technical capacity of personnel to ensure that they acquire relevant skills that will enable NDA to effectively regulate the products under the ambit of the National Drug Policy and Authority Act.

Going forward, the directorate shall continue to consolidate its achievements to further improve service delivery to protect the health of the public through ensuring the safety, efficacy and quality of drugs.

I appreciate the Authority and management of NDA for supporting the work of the Directorate and enabling the publication of this report. I also thank all our stakeholders without whose cooperation, we would not effectively do the work we do. I thank my team at the Directorate of Inspectorate and Enforcement for making every positive result in this publication a reality.

I therefore warmly invite you to read this publication and feel free to give feedback through our established contact platforms.

I thank you.

For God and my Country

Denis William Mwesigwa
DIRECTOR, INSPECTORATE AND ENFORCEMENT

We are delighted to present this second publication of the Directorate of Inspectorate and Enforcement (DIE). This publication builds on the DIE publication for July to December 2020 period. It seeks to give the reader a complete picture on the performance of the directorate in the entire July 2020-June 2021 financial year. This is done through the summary statistics and results for each subtopic. However, the detailed reporting including figures and tables have been focused on the January to June 2021 performance.

We have also tried to clarify certain areas based on the feedback received for the previous publication. We invite the readers to give their comments or seek clarity for further improvement.

We sincerely hope that you will enjoy reading this publication as we look to improve further.

Editorial team

1. Amos Atumanya, Lead Editor
2. Muhammad Lukwago
3. Solomon Onen
4. Moses Akampurira
5. Brenda Kitimbo
6. Frank Kaleebu
7. Nashira Asiimwe

Review team

1. Mr. Abiaz Rwamwiri
2. Mrs. Barbara Najjemba Musoke
3. Mrs. Joy Byarugaba

Editorial team

Amos Atumanya
Lead Editor

Muhammad Lukwago
Manager Central Region

Solomon Onen
Manager GMP

Moses Akampurira
Senior Regulatory Officer

Brenda Kitimbo
Principal Regulatory Officer

Frank Kaleebu
Senior Regulatory Officer

Nashira Asiimwe
Regulatory Officer

Review team

Mr. Abiaz Rwamwiri
Manager Public Relations

Mrs. Barbara Najjemba Musoke
Administrative Officer

Mrs. Joy Byarugaba
Manager Administration

CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF ABBREVIATIONS

Abbreviation	In full
CAPA	Corrective Action and Preventive Action
EAC	East African Community
FY	Financial Year
GDP	Good Distribution Practices
GMP	Good Manufacturing Practices
GPP	Good Pharmacy Practices
IGAD	Inter-Governmental Authority on Development
NDA	National Drug Authority
NDAMIS	National Drug Authority Management Information System
PMS	Post Marketing Surveillance
PNFP	Private Not for Profit
PoE	Port of Entry
WHO	World Health Organisation

EXECUTIVE SUMMARY

The Directorate of Inspectorate and Enforcement conducted a wide range of compliance and enforcement activities in the July 2020 to June 2021 period. These activities helped to ensure the availability at all times of essential, efficacious and quality drugs to the entire population of Uganda.

The implementation of activities in this period was significantly affected by Covid-19 pandemic. Consequently, some activities were not fully implemented while the others had to be adjusted to the new normal. The foreign manufacturers' inspections could not be conducted due to the national and international safety measures and travel restrictions which prevented the conduct of onsite inspections related to Good Manufacturing Practices (GMP). To ensure continued availability of essential drugs while maintaining good manufacturing standards, the Authority approved mitigation measures as follows:

1) The validity of GMP certificates which were due and had applied for renewal were extended for an additional three years on condition that onsite inspections would be conducted as soon as the situation allows.
2) New GMP applications from countries with stringent regulatory authorities (SRA) underwent rigorous document review in collaboration with other drug regulatory agencies to ascertain compliance with GMP standards.

Post market sampling was also significantly affected during the period of total national lockdown affecting the overall annual performance.

The annual performance statistics and results for the July 2020 to June 2021 period are summarised in Figure 1 below.

To ensure continued availability of essential drugs while maintaining good manufacturing standards, the Authority approved mitigation measures as follows:

The validity of GMP certificates which were due and had applied for renewal were extended for an additional three years on condition that onsite inspections would be conducted as soon as the situation allows.

New GMP applications from countries with stringent regulatory authorities (SRA) underwent rigorous document review in collaboration with other drug regulators to ascertain the GMP standards.

[1]As defined by the World Health Organisation (WHO), a Stringent Regulatory Authority (SRA) is a regulatory authority which is:

- a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015); or
- an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or
- a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015).

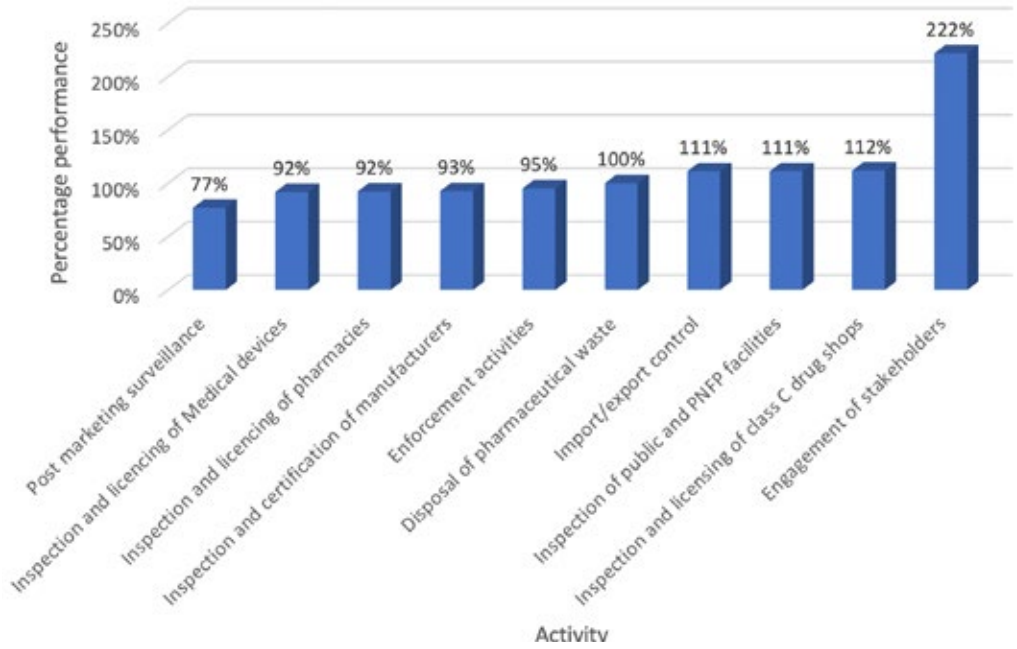


Figure 1: Summary of the directorate Jul 2020 to Jun 2021 annual performance.

Disposal of pharmaceutical waste, import/export control, inspection of public and PNFP facilities, inspection and licencing of class C drug shops and stakeholder engagements met or exceeded performance targets. While post market surveillance, inspection and licencing of pharmacies & medical devices, inspection and certification of manufacturers and enforcement activities did not meet the performance target. Stakeholder engagements were exponentially increased by the Veterinary stakeholder engagements at the subcounty level.

The activities of the Directorate during the July 2020 to June 2021 period are summarised in the table below:

Table 1: Summary of the directorate activities

Core activity	Sub-activities	Target	Done	Performance	Compliant	Non-compliant	Compliance rate
Good Manufacturing Practices	Pre-inspection of manufacturers	23	23	100%	Not rated	Not applicable	Not applicable
	Certification of domestic manufacturers	22	22	100%	22	0	100%
	Certification of foreign manufacturers	340	374	110%	340	34	91%
	Domestic herbal manufacturers	40	28	70%	Not rated[a]	Not applicable	Not applicable

Core activity	Sub-activities	Target	Done	Performance	Compliant	Non-compliant	Compliance rate
	Pre-market authorisation	39	39	100%	Not rated	Not applicable	Not applicable
	Pre-market sampling	118	89	75%[b]	66	26	74%
Inspections of Pharmacies	Pre-inspection of pharmacies	1359	1257	92%	779	478	62%
	Licensing of Pharmacies	1082	1094	101%	966	102	88%
	Licencing of Medical devices	61	56	92%	52	4	93%
	Pharmacy compliance monitoring visits	2023	1903	94%	1457	448	77%
	Good Distribution Practice inspections	720	588	82%	32	556	5%
Inspections of Licensed sellers (Class C drug shops)	Pre-inspection of Class C drug shops	4388	3938	90%	3023	915	77%
	Licencing of Class C drug shops	18725	18501	99%	17482	1019	94%
	Drug shop compliance monitoring visits	12303	18044	147%	11122	6922	62%

Core activity	Sub-activities	Target	Done	Performance	Compliant	Non-compliant	Compliance rate
Public and Private not for profit facilities	Inspections of public & PNFP facilities for GPP	250	306	122%	150	156	49%
	Inspection of blood banks	12	12	100%	Not rate[d]	Not applicable	Not applicable
Post market surveillance	Post Market sampling	1,050	518	49%	391 of 453[c]	62	86%
	Investigation of complaints	31	23	74%	Not applicable	Not applicable	Not applicable
	Auditing of recalls	25	21	84%	16	5	76%
	Market surveillance operations	4	4	100%	Not rate[d]	Not applicable	Not applicable
Control of imports and exports	Import/export verification	14,632	14,483	99%	14438	45	99%
	Port clearance	9553	9553	100%	9260[e]	4	97%
	Port of entry sampling	1350	1816	135%	1637 of 1679[c]	42	97%

Engagement of	Radio/television talk shows	84	122	145%	Not rated	Not applicable	Not applicable
	Stakeholder engagement meetings	134	400	299%	Not applicable	Not applicable	Not applicable
Enforcement activities	Enforcement operations	8	10	125%	Not applicable	Not applicable	Not applicable
	Implementation of intelligence recommendations	66	52	79%	Not rated	Not applicable	Not applicable
	Number of case files submitted to DPP that were sanctioned for prosecution	27	22	81%	Not applicable	Not applicable	Not applicable
Supervision of pharmaceutical waste disposal	Disposal of pharmaceutical waste (kg)	2450 016.3	2450 016.3	100%	Not rated	Not applicable	Not applicable

[a]Inspections of herbal manufacturers were not rated because it was determined before inspection that NDA was to provide technical assistance to improve the capacity of the herbal manufacturers.

[b]Pre-market samples depend on the applications received from domestic manufacturers and the target was based on expected applications but the actual were less than the expected. Three of the tested were brought forward from the previous period.

[c]Shows the total number of samples tested since some of the sampled batches were still under testing.

[d]Market surveillance in the Jan to June period concentrated on the performance of the cold chain facilities.

[e]54 consignments were queried and 78 conditionally released

NDA officers inspecting and providing technical advice to domestic herbal manufacturers

1.0 MANUFACTURING FACILITIES

National Drug Authority is mandated to control the manufacture of drugs as a means of ensuring the quality of drugs available for use in Uganda. In the execution of this mandate, NDA inspects domestic and foreign manufacturers. Domestic manufacturers are inspected for licencing and certification for compliance with Good Manufacturing Practices (GMP) while foreign manufacturers are certified for compliance with GMP.

For domestic manufacturers, the directorate performs an initial pre-inspection within 20 days. It then conducts a licensing inspection of receiving an application within 20 days of receipt of a licencing application. They are licenced every 3 years.

The foreign manufacturers are inspected for GMP compliance once every 3 years. They are required to apply for renewal of their GMP status six months before their expiry. There are two inspection pathways; desk assessments for low risk facilities and onsite inspections for high risk facilities. A low risk facility is one whose manufacturing site is located in a country with a Stringent Regulatory Authority (SRA) as defined by the World Health Organisation. This process relies on the regulatory approval by the SRA.

After that, the date of further inspections depends on the plan set out for the activity which is approved as part of the annual work plan. The annual work plan is built on risk-based approach.

1.1 Manufacturing inspection statistics and results

The target for manufacturing inspections in the July 2020 to June 2021 financial year was 220 foreign physical inspections, 120 desk assessments, 40 domestic herbal manufacturers and all domestic pre-and licensing inspections as per the service delivery timelines. There were 23 pre-inspection and 22 domestic licensing applications. Seventeen of the domestic pre-inspection applications were received in the July to December 2020 period and 6 in the January to June 2021 period. Sixteen of the domestic licensing applications were received in the July to December 2020 period and 6 in the January to June 2021 period.

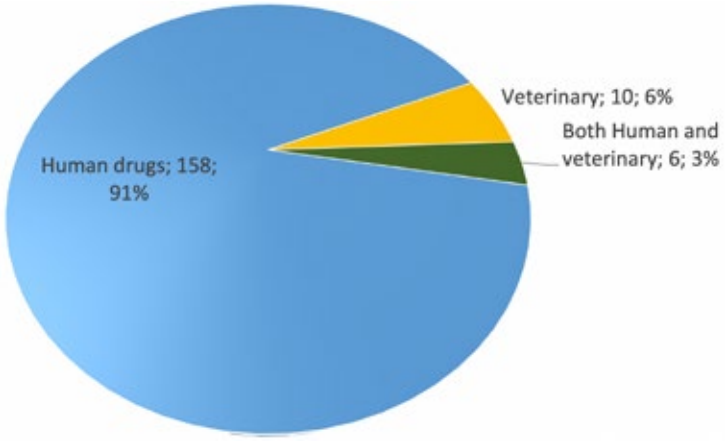
A total of 450 inspections were conducted; 286 in the July to December 2020 and 164 in the January to June 2021 period. Overall 106% (450) of the 425 inspections planned for the year were conducted.

Note: Some of the applications inspected were brought forward from the 2019/2020 financial year.

The statistics and results for manufacturing inspections for the January to June 2021 period are indicated in Figures 2-4 below.

A total of **450** inspections were conducted; 286 in the July to December 2020 and **164** in the January to June 2021 period. Overall 106% (450) of the 425 inspections planned for the year were conducted.

Figure 2: Distribution of manufacturing applications received by drug category



A total of 174 applications were received during the January to June 2021 period. Out of which 158 (91%) were for human drugs, 10 (6%) for veterinary drugs and 6 (3%) were for both human and veterinary drugs.

91% (158)

of the 174 manufacturing applications received were for human drugs, 6% (10) for veterinary drugs and 3% (6) for both human and veterinary drugs.

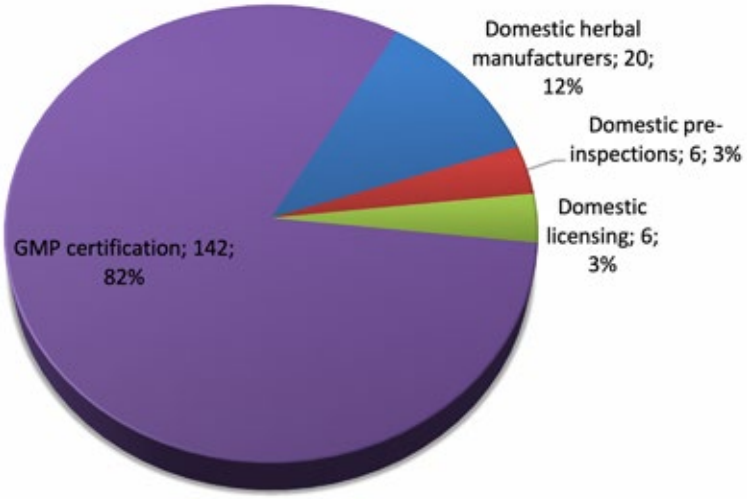


Figure 3: Distribution of manufacturing applications received by licence type.

In the January to June 2021 period; 82% (142) of the 174 applications received were for Good manufacturing Practices (GMP) certification, 12% (20) from domestic herbal manufacturers and 3% (6) apiece for domestic pre-inspection and domestic licensing. 98.6% (140 of 142) of the applications for GMP were from foreign manufacturers.

98.6% (140 of 142)

of the applications for GMP were from foreign manufacturers.

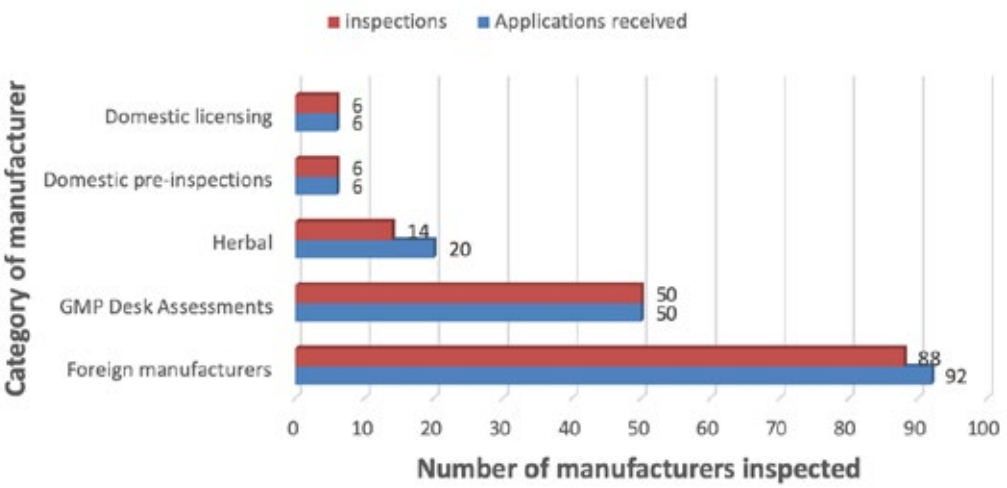


Figure 4: Distribution of Manufacturing inspections conducted.

A total of 164 inspections (out of the 174 applications) were conducted during the January to June 2021 period. The inspections consisted of 6 apiece for domestic pre- and licencing inspections, 14 domestic herbal manufacturers, 50 desk reviews and 88 recertifications.

A total of

164

inspections (out of the 174 applications) were conducted during the January to June 2021 period.

1.2 Manufacturing pre-inspection statistics and results

The target for pre-inspection of manufacturing facilities in the July 2020 to June 2021 financial year was all the received applications (100%) as per the service delivery timeline. 23 applications were received; 17 in the July to December 2020 period and 6 in the January to June 2021 period. All the 23 applications were inspected.

All the 6 pre-inspection applications received in January to June 2021 period were for manufacture of drugs for human use.

1.3 Manufacturing licencing inspection statistics and results

The target for licensing inspections of manufacturing facilities in the July 2020 to June 2021 financial year was all the received applications (100%) as per the service delivery timeline. 22 applications were received; 16 in the July to December 2020 period and 6 in the January to June 2021 period. All the 22 applications were inspected.

All the 6 licensing inspection applications received in January to June 2021 period were approved for licensing. Five of those manufacturers were for drugs for human use while one was for veterinary drugs.

All the 6 pre-inspection applications received in January to June 2021 period were for manufacture of drugs for human use.

All the 6 licensing inspection applications received in January to June 2021 period were approved for licensing. Five of those manufacturers were for drugs for human use while one was for veterinary drugs.

The licensing statistics and results for domestic manufacturers are summarised in Figures 5 below.

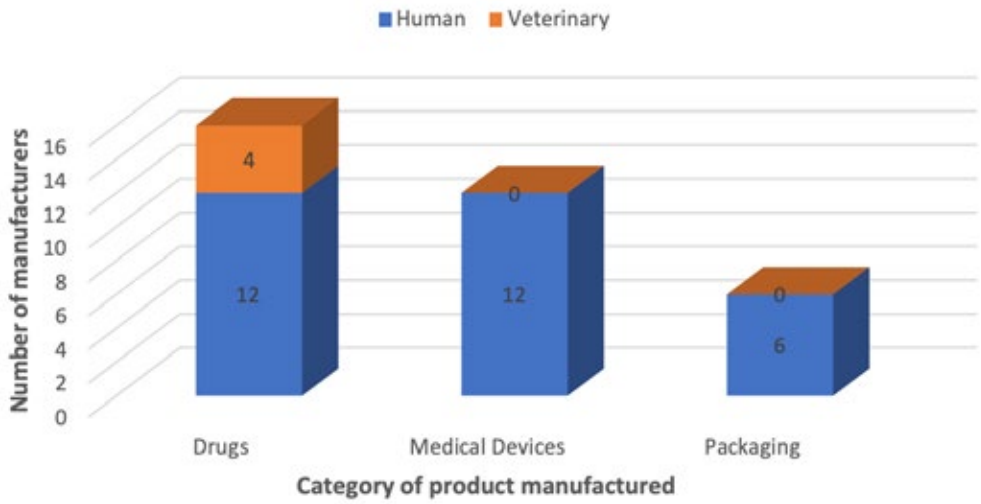


Figure 5: Licensing status of domestic manufacturers as at June 30, 2021.

A total of 34 manufacturing facilities were licenced as at June 30, 2021; out of which 16 were for drugs, 12 for medical devices and 6 for packaging. By category, 88% (30 of 34) of the manufacturers were for human medical products while 12% (4 of 34) were for veterinary products.

A total of
34
manufacturing facilities were licenced as at June 30, 2021; with 16 for drugs, 12 for medical devices and 6 for packaging

1.4 Certification of foreign manufacturers for Good Manufacturing Practices

The target for GMP inspections in the July 2020 to June 2021 financial year was 220 foreign physical inspections and 120 desk assessments
.

271 GMP applications were received;129 in the July to December 2020 period and 142 in the January to June 2021 period.

A total of 374 GMP certification assessments were conducted; 236 in the July to December 2020 and 138 in the January to June 2021 period. Of the 138; 88 were re-certifications of foreign facilities and 50 were desk assessments.

Overall 110% (374) of the 340 GMP inspections planned for the year were conducted. Some of the applications inspected were brought forward from the 2019/2020 financial year.

The statistics and results for Good Manufacturing Practices for the January to June 2021 period are indicated in Figures 6 & 7 below.

Overall
110% (374)
of the 340 GMP inspections planned for the year were conducted.

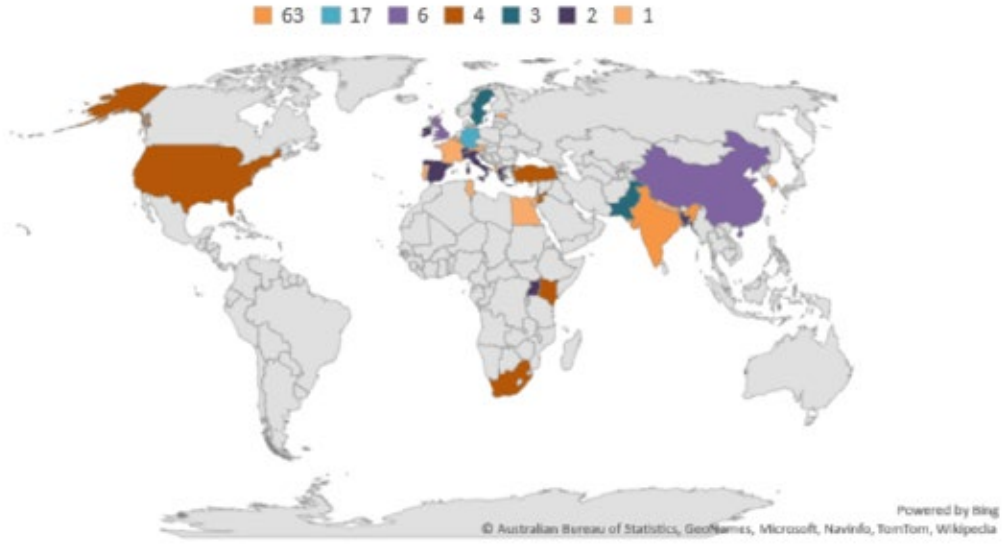


Figure 6: Distribution of applications for GMP certification.

There were 142 GMP applications received in the January to June 2021 period. Of the applications received, 44% (63) were from India, 12% (17) from Germany and 4% (6) from United Kingdom and another 4% (6) from China. Only two of the 142 GMP applications were from Uganda.

Only two of the
142
GMP applications
were from Uganda

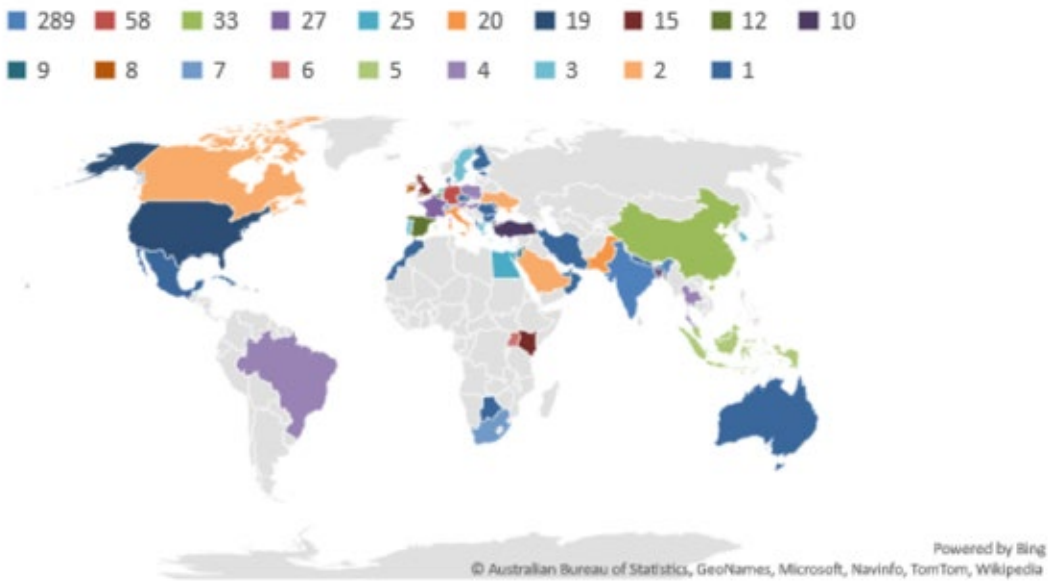


Figure 7: Distribution of facilities certified for GMP as at June 30, 2021.

[2]The desk assessment process involves submission of documentary evidence by the manufacturer to NDA in order to demonstrate the conformity of the manufacturing facility to GMP.

There were 692 facilities certified for Good Manufacturing Practices (GMP) as at June 30, 2021. India had the majority with 42% (289) of the 692 GMP certified facilities followed by Germany with 8% (58) and China with 5% (33). There were 6 GMP certified facilities in Uganda.

India had the majority with

42% (289)

of the **692** GMP certified facilities followed by Germany with **8% (58)** and China with **5% (33)**. There were 6 GMP certified facilities in Uganda.

Observation

- All the deferred applications were GMP desk assessments which lacked sufficient supporting documentation.

Action taken

- Some of the non-compliant applications were recommended for physical inspection.
- Other applicants whose applications were deferred were requested to submit additional information.

1.5 Domestic herbal manufacturers inspection statistics and results

The target for inspection of herbal manufacturers in the July 2020 to June 2021 financial year was 40 facilities. 14 facilities were inspected in the July to December 2020 period thus the target for the January-June 2021 period was 26 facilities. 14 facilities were inspected. Overall 70% (28) of the 40 domestic herbal manufacturing facilities planned for the year were inspected.

Overall

70% (28)

of the **40** domestic herbal manufacturing facilities planned for the year were inspected

Most common observations

- Most herbal manufacturers did not have basic quality assurance systems and documentation in place such as Standard Operating Procedures (SOPs), specifications for raw materials, intermediates and finished products, or records including Batch Manufacturing Records (BMRs).
- There was lack of suitable premises and equipment for pharmaceutical manufacturing.
- There was no quality control system or evidence to show that quality control tests were done.

Actions taken

The Directorate is working with the herbal unit to provide training and support supervision to the domestic herbal manufacturers.

1.6 Pre-market Authorisation of Products statistics and results

NDA carries out pre-marketing review and authorisation of products for initial local manufacture to facilitate the generation of the data required for registration of the product. It is part of the technical support to the local manufacturers to ensure quality by design which would facilitate the sale of those validation batches if they meet the pre-defined specifications.

The target for pre-market authorisation of products in the July 2020 to June 2021 financial year was all the received applications as per the service delivery timeline. 102 applications were received in the July to December 2020 period and 10 in the January to June 2021 period. All the 112 applications were inspected with 63 authorised and 49 required to submit additional information. Overall 100% applications received for the year were inspected.

The statistics and results for pre-market authorisation for the January to June 2021 period are indicated in Figures 8 & 9 below.

All the **112** applications were inspected ; out which 63 authorised and 49 required to submit additional information.

The statistics and results for pre-market authorisation for the January to June 2021 period are indicated in Figures 8 & 9 below.

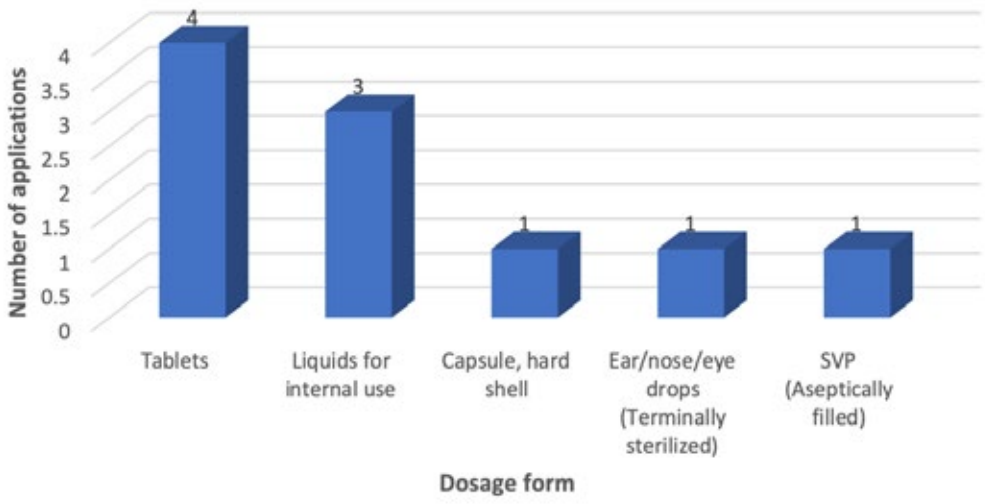
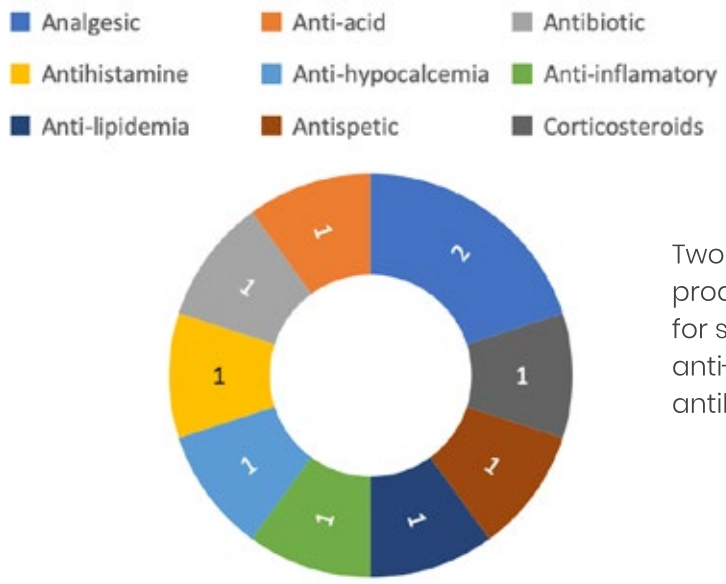


Figure 8: Pre-market authorisation applications by dosage form category.

In the January to June 2021 period; 10 applications for premarket assessment were received and all were assessed. Of the 10 pre-market authorisation applications received, 7 were authorised to manufacture while 3 were required to provide additional information.

Of the **10** pre-market authorisation applications received, **7** were authorised to manufacture while **3** were required to provide additional information.



Two of the applications were for analgesic products while there was one each for steroids, antiseptic, anti-lipidemic, anti-inflammatory, anti-hypocalcemic, antihistamine antibiotic and antacid.

Figure 9: Pre-market authorisation applications by therapeutic category.

1.7 Pre-market sampling statistics and results

The target for pre-market sampling of domestically manufactured products in the July 2020 to June 2021 financial year was all the products authorised for pre-market manufacture. A total of 103 pre-market batches were sampled with 88 batches in the July to December 2020 period and 15 in the January to June 2021 period. Overall 89% (92) of the 103 pre-market batches sampled in the financial year were tested and results communicated; with 66 compliant and 26 non-compliant.

Overall **89% (92)** of the **103** pre-market batches sampled in the financial year were tested and results communicated; with 66 compliant and **26** non-compliant.

The pre-market sampling statistics and results for the January to June 2021 period are summarised in Figure 10 below.

Figure 10: Status of pre-market batches sampled in the January to June 2021 period.

A total of 15 batches of pre-market products were sampled in the January to June 2021 period. 18 batches were tested with all 18 passing. The overall compliance rate was 100% (18 of the 18 batches tested). some of the samples tested were carried from the previous period.

Most common observation:

- 23 of the 26 batches that failed analysis were hand sanitisers which were manufactured by new entities in response to the covid-19 pandemic during the July to December 2020 period and are detailed in the previous publication.

Actions taken:

- The affected batches were rejected and the manufacturers were encouraged to establish a strong research and development (R&D) for formulations and analytical methods and to ensure testing capacity as part of the product concept.

[3]Pre-market sampling is the practice of picking a scientifically determined quantity of a drug or medical device for testing to ascertain the quality as part of the process for validation of the product for sale.

NDA officers interacting with drug shop operators during an enforcement exercise

NDA officers interacting with drug shop operators during an enforcement exercise

2.0 PHARMACIES AND MEDICAL DEVICE OUTLETS

The Directorate conducted various inspections in pharmacies and medical devices outlets for purposes of approval of new premises, renewal of licenses and certificates of suitability of premises and follow up inspection to ensure continual compliance. Majority of the inspections conducted in the review period were compliance visits in licensed and illegal premises, followed by pre-inspections for prospective new premises, inspections for renewal of licenses and lastly GDP inspections. The license renewal inspections were fewer because most pharmacies received three-year licenses that will be expiring at the end of December 2022.

2.1 Inspection statistics and results

The target for inspection of pharmacies in the July 2020 to June 2021 financial year was 2023 compliance monitoring visits, 720 Good Distribution Practices (GDP) inspections and all the pre-and licencing applications received as per the service delivery timelines. A total of 1359 pre- inspection and 1082 licensing applications were received.

A total of 4,842 inspections were conducted; 2,350 in the July to December 2020 and 2,492 in the January to June 2021 period. Forty three percent (1,066) of the 2492 inspections were compliance monitoring underscoring the value of the three-year licence in freeing up time for follow up inspections.

Overall 93% (4,842) of the 5,184 inspections planned for the year were conducted. Some of the applications inspected were brought forward from the 2019/2020 financial year.

Overall
93% (4,842)
of the 5,184 inspections planned for the year were conducted.

The pharmacy inspection statistics and results for the January to June 2021 period are summarised in Figure 11 below.

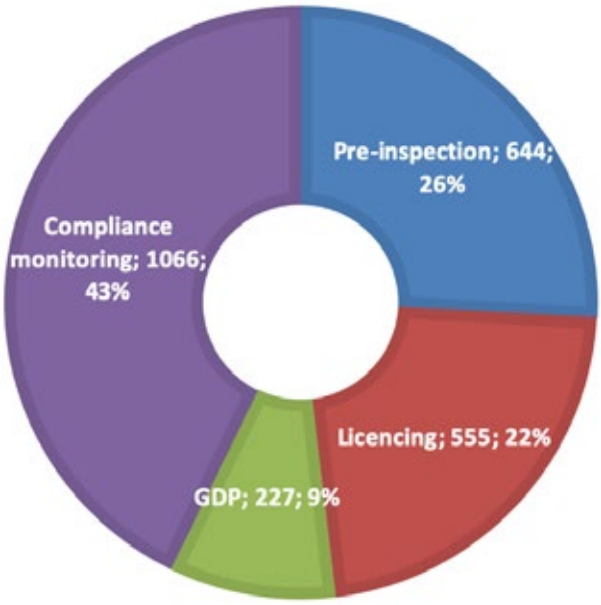


Figure 11: Distribution of Pharmacy inspections in the Jan to June 2021 period.

A total of 2,409 pharmacy inspections were conducted; 43% (1,066) of which were compliance monitoring (follow up) inspections, 26% (644) were pre-inspections for new premises, 22% (555) were pharmacy licencing inspections and 9% (227) were GDP inspections.

A total of
2,409
pharmacy inspections were conducted; 43% (1,066) of which were compliance monitoring (follow up) inspections, 26% (644) were pre-inspections for new premises, 22% (555) were pharmacy licencing inspections and 9% (227) were GDP inspections.

2.2 Pharmacy pre-inspection statistics and results

The target for pre-inspection of pharmacies in the July 2020 to June 2021 financial year was all the applications received as per the service delivery timelines. 1,359 pre- inspection applications were received; 664 in the July to December 2020 period and 695 in the January to June 2021 period.

A total of 1,257 inspections were conducted; 613 in the July to December 2020 and 644 in the January to June 2021 period. Overall 92% (1,257) of the 1,359 pre-inspection applications received in the financial year were conducted and outcomes communicated.
The enthusiasm for new pharmacy openings was highest in urban areas compared to rural areas, and as such, Kampala-Extra, Central and South Eastern regions registered the highest number of applications in the review period. It should however be noted that a proportion of pre-inspections were for existing pharmacies seeking relocation to new premises.

Overall
92% (1,257)
of the 1,359 pre-inspection applications received in the financial year were conducted and outcomes communicated.

The statistics and results for pharmacy pre-inspections for the January to June 2021 period are indicated in Figures 12 & 13 below.

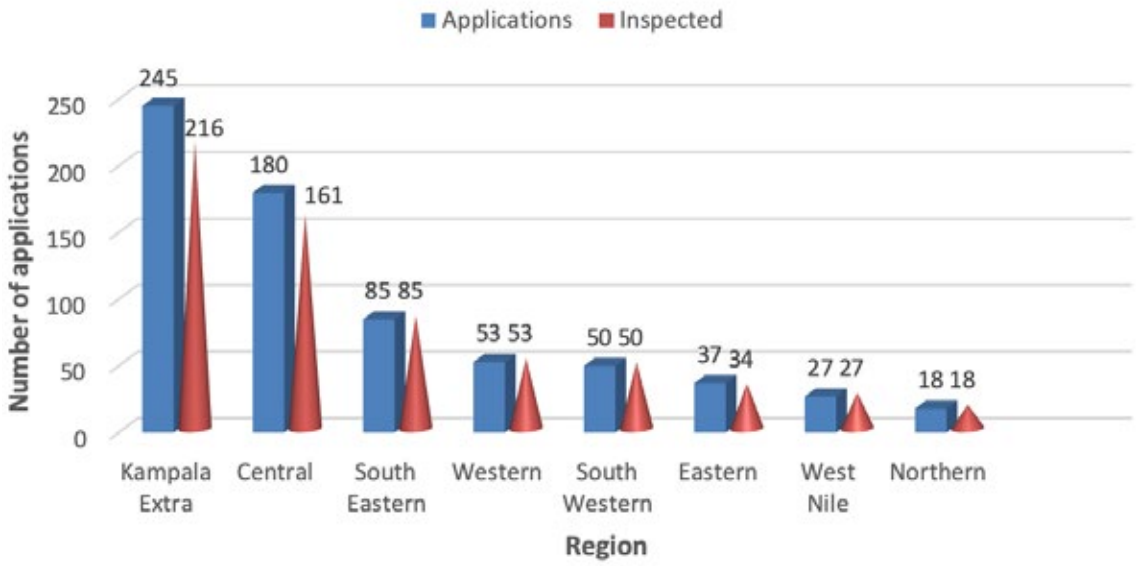


Figure 12: Distribution of Pharmacy pre-inspections applications by region.

In the January to June 2021 period, there were 695 pre-inspection applications. Out of which 644 (93%) were inspected. Kampala Extra region with 35.3% (245) of the 695 pre-inspection applications had the highest number followed by central region with 25.9% (180). The two regions received 61.2% (425 of the 695) of the pre-inspection applications for new pharmacies.

Kampala Extra region with
35.3% (245)
the 695 pre-inspection applications had the highest number followed by central region with 25.9% (180). The two regions received 61.2% (425 of the 695) of the pre-inspection applications for new pharmacies.

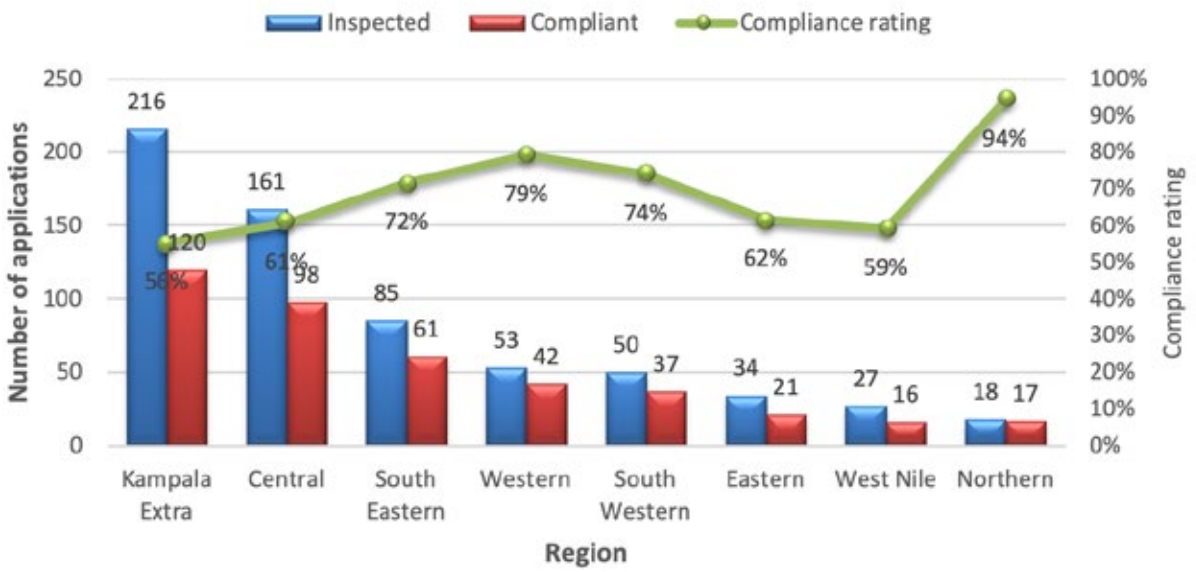


Figure 13: Compliance rating of Pharmacy pre-inspections by region.

Sixty four percent (412 of 644) of the pre-inspections resulted into compliant rating while 232 (36%) resulted into a non-compliant rating. The compliance rate was lowest in Kampala Extra (56%) followed by West Nile at 59% and Central at 61%. The highest number of non-compliant applications were in Kampala Extra (96) and Central regions (63), which is more than the number of applications approved in any other region.

64% (412 of 644)

of the pre-inspections resulted into compliant rating while 232 (36%) resulted into a non-compliant rating.

Most common observation:

Non-compliance with the distance to the nearest like outlet as specified in the Professional Licensing Guidelines for Pharmacies.

Action taken:

Non-compliant applications were communicated to the applicants; who were denied login credentials into the NDAMIS system thus they could not apply for a licence.

2.3 Pharmacy licencing inspection statistics and results

The target for inspection of pharmacies in the July 2020 to June 2021 financial year was all the licencing applications received as per the service delivery timelines. A total of 1082 licensing applications were received; 527 in the July to December 2020 period and 555 in the January to June 2021 period.

A total of 1,094 licensing inspections were conducted; 539 in the July to December 2020 and 555 in the January to June 2021 period. Overall 101% (1,094) of the 1,082 licensing applications were inspected. Some of the applications inspected were brought forward from the 2019/2020 financial year.

Overall

101% (1,094)

of the 1,082 licensing applications were inspected.

The statistics and results for pharmacy licensing inspections for the January to June 2021 period are indicated in Figures 14-19 below.

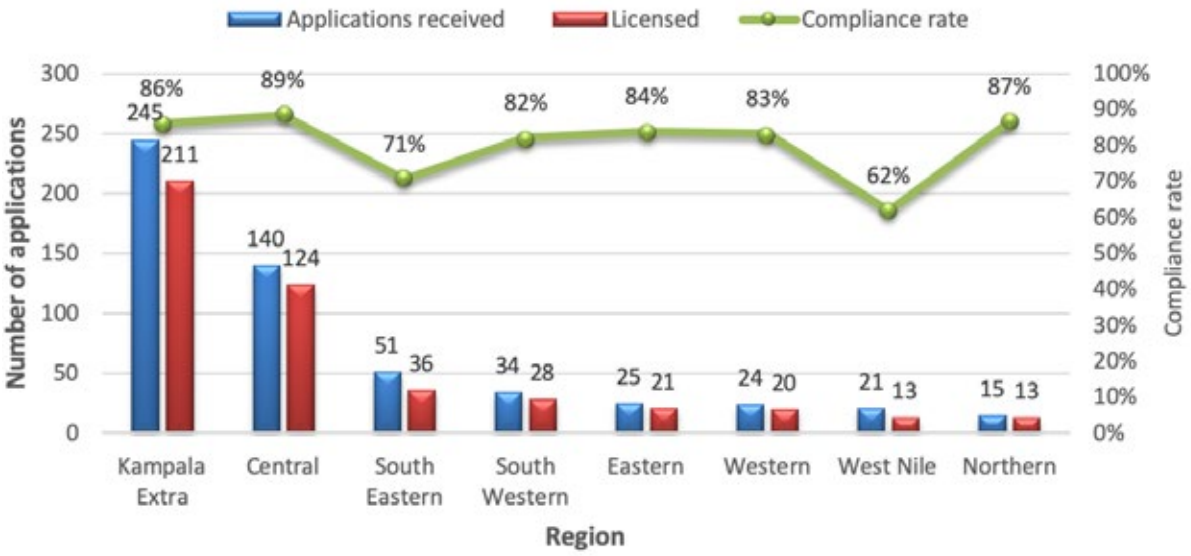


Figure 14: Compliance rating of licencing inspections by region.

In the January to June 2021 period; 555 pharmacy licensing applications were received and inspected; with 53% (294) of the applications being for new outlets while 47% (261) were renewals. 84% (466) of the inspections resulted into a compliant rating and were licensed while 16% (89) were rated non-compliant and queried. The compliance was lowest in West Nile (62%) followed by South Eastern (71%) and South Western (82%). 421 of the approved applications were for human drugs while 45 were for veterinary drugs.

In the January to June 2021 period; 555 pharmacy licensing applications were received and inspected; with 53% (294) of the applications being for new outlets while 47% (261) were renewals.

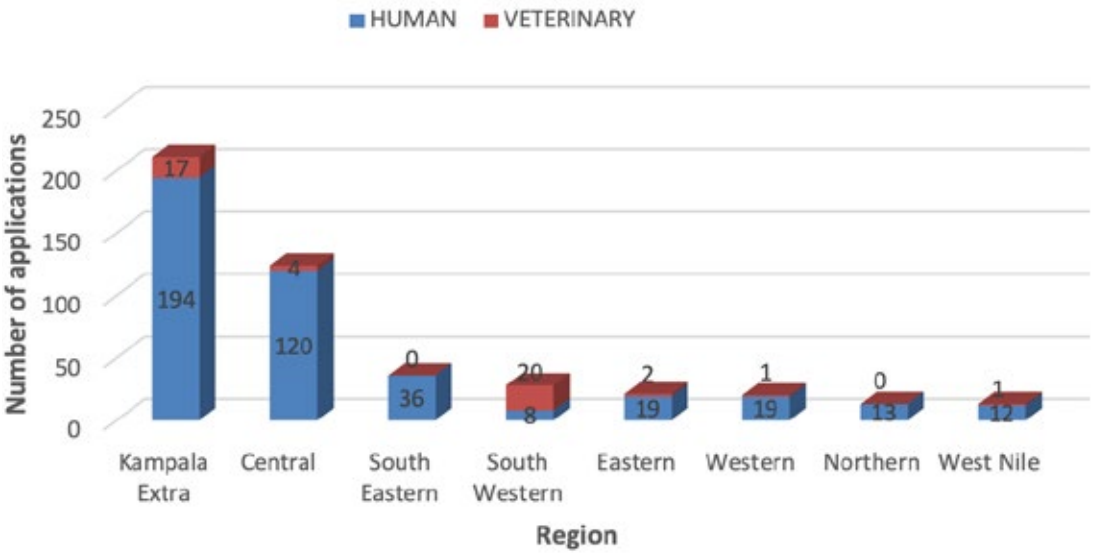


Figure 15: Distribution of licencing approvals by product category.

90.3% (421) of the 466 licenses approved in the period were for human products while 9.7% (45) were for veterinary products.

90.3% (421)

of the **466** licenses approved in the period were for human products while **9.7%** (45) were for veterinary products.

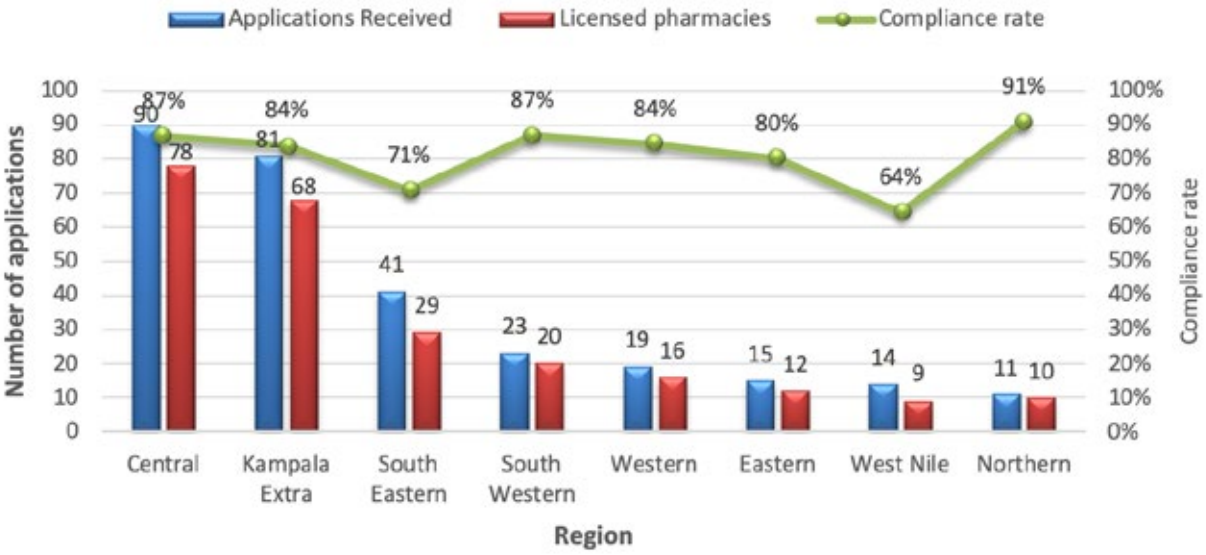


Figure 16: Distribution of new licencing applications by region.

In the January to June 2021 period, there were 294 applications for new outlets. 82% (242) of the 294 applications for new outlets were compliant and approved for licensing while 18% (52) were non-compliant and queried. The compliance was lowest in West Nile (64%) followed by South Eastern (71%) and Eastern (80%).

82% (242)

of the **294** applications for new outlets were compliant and approved for licensing while **18%** (52) were non-compliant and queried.

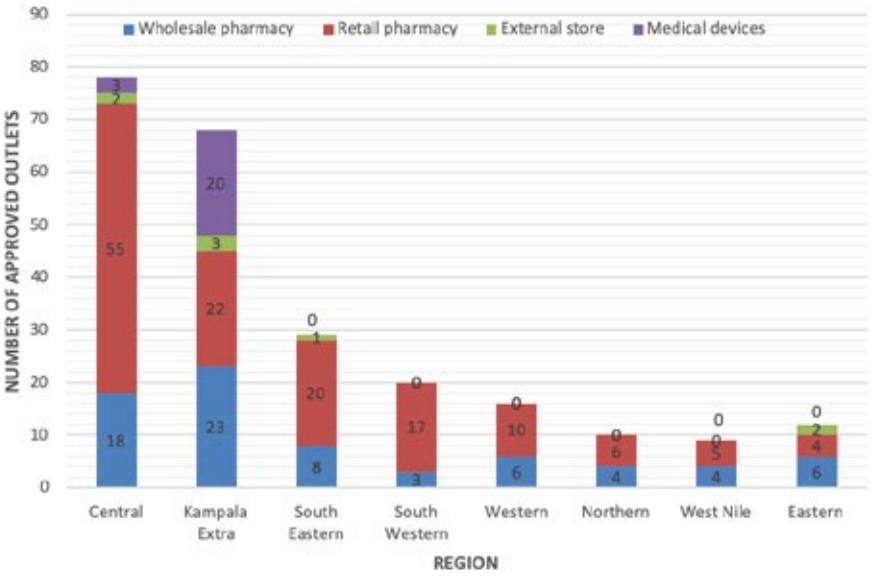


Figure 17: Distribution of newly licenced outlets by type.

In the January to June period, there were 242 approvals of new outlets. 57% (139) of the 242 new outlets were retail pharmacies, 30% (72) wholesale pharmacies, 10% (23) medical device outlets and 3% (8) external stores.

57% (139)

of the **242** new outlets were retail pharmacies, **30%** (72) wholesale pharmacies, **10%** (23) medical device outlets and **3%** (8) external stores.

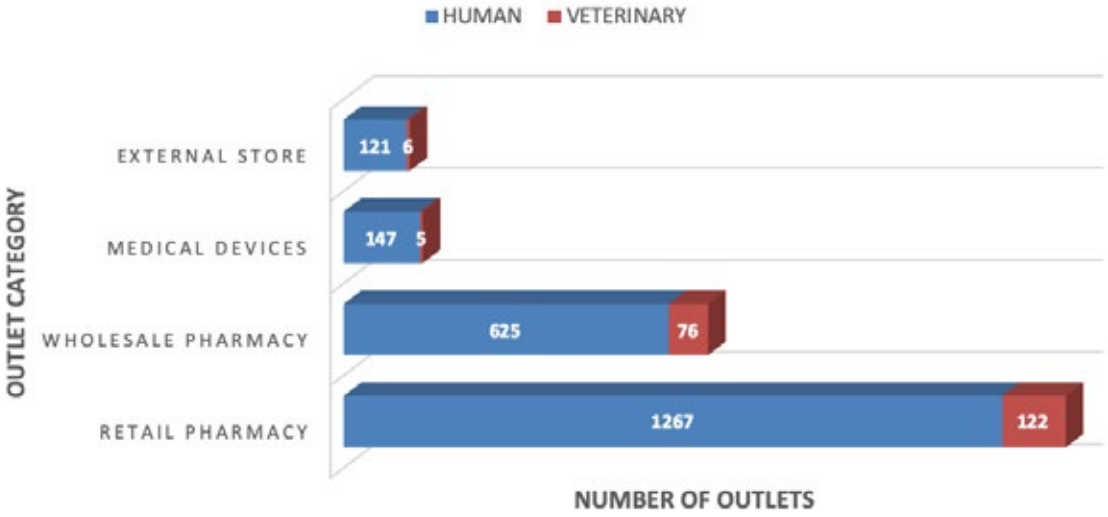


Figure 18: Licencing status as at June 30, 2021.

As at June 30, 2021; there were 2,369 pharmacy and medical device licensed premises consisting of 1,389 retail pharmacies, 701 wholesale pharmacies, 152 medical devices outlets and 127 external stores. 91% (2,160) were for human drugs and 9% (209) were for veterinary drugs.

As at June 30, 2021; there were **2,369** pharmacy and medical device licensed premises consisting of 1,389 retail pharmacies, 701 wholesale pharmacies, 152 medical devices outlets and 127 external stores. 91% (2,160) were for human drugs and 9% (209) were for veterinary drugs.

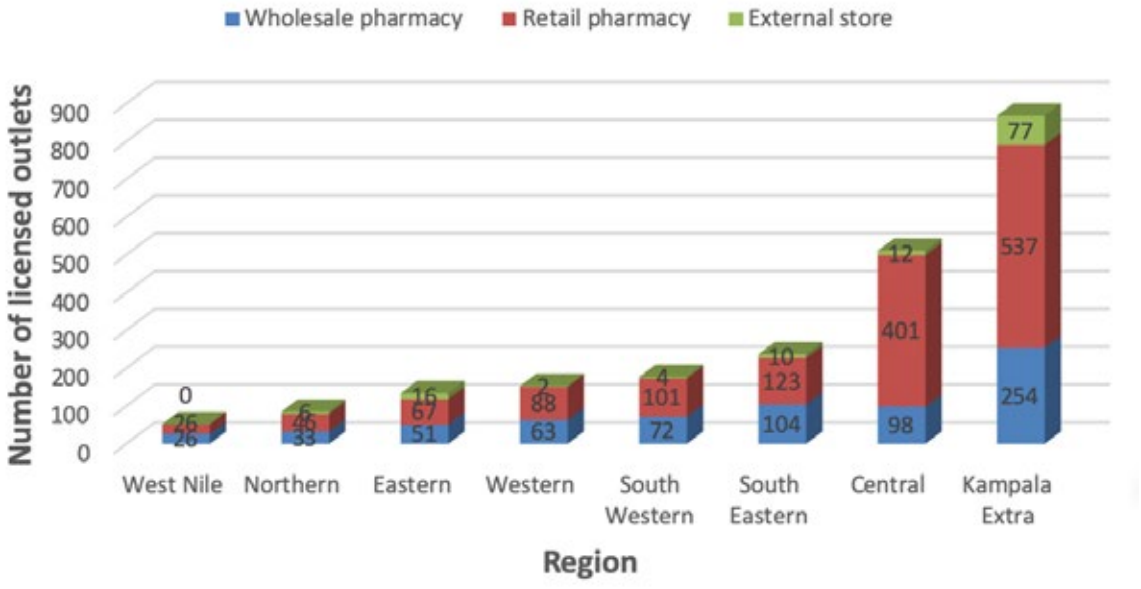


Figure 19: Distribution of pharmacy licencing by outlet category and region.

There were 2,217 licensed pharmacy premises (including external stores). 62.7% (1,389) were retail pharmacies, 31.6% (701) were wholesale pharmacies and 5.7% (127) were external stores. Kampala extra region had 39.2% (868) of the 2,217 licensed pharmacies followed by Central region at 23% (511) while West Nile region had the least at 2.3% (52) followed by Northern at 3.8% (85).

Kampala extra region had **39.2%** (868) of the **2,217** licensed pharmacies followed by Central region at **23%** (511) while West Nile region had the least at **2.3%** (52) followed by Northern at **3.8%** (85).

Most common observations

- Poor documentation practices, including lack of or inadequacy of standard operating procedures and inadequate records of purchase, sales and storage temperature monitoring.
- Inadequate cold chain systems.
- Low presence levels for pharmacists at the premises during operating hours.
- Inadequacy of technical reference materials such as treatment guidelines.
- Unclean and untidy premises.

Action taken

- One-on-one meetings with the pharmacists were held to guide them on steps to address the non-compliances.
- Some pharmacies were initially queried and licenses withheld until non-compliances were addressed and written compliance reports submitted.

2.4 Licencing of medical devices outlets statistics and results

The target for inspection of medical device outlets in the July 2020 to June 2021 financial year was all the licencing applications received as per the service delivery timelines. 61 licensing applications were received; 38 in the July to December 2020 period and 23 in the January to June 2021 period.

A total of 56 medical devices outlets licensing inspections were conducted; 33 in the July to December 2020 and 23 in the January to June 2021 period. Overall 92% (56) of the 61 medical devices licensing applications were inspected and results communicated.

Overall **92%** (56) of the **61** medical devices licensing applications were inspected and results communicated.

The licensing status of medical devices' outlets as at June 30, 2021 is indicated in Figure 20 below.

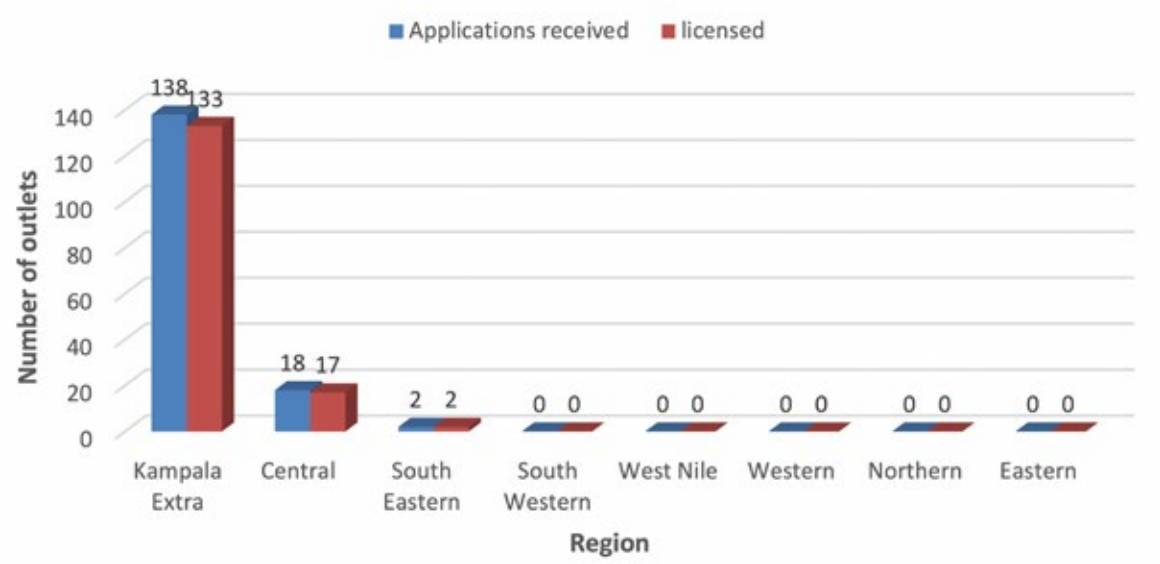


Figure 20: Licencing status of Medical devices outlets as at June 30, 2021.

A total of 158 medical devices outlets applications were received and 152 outlets licensed and 6 were still under processing. Only three regions of Kampala Extra, Central and South Eastern had ever received applications for medical device outlet. 87.3% (138 of 158) of the medical devices' outlet applications were in Kampala Extra region.

87.3% (138 of 158)

of the medical devices' outlet applications were in Kampala Extra region.

2.5 Pharmacy compliance monitoring visits statistics and results

The target for pharmacy compliance monitoring in the July 2020 to June 2021 financial year was 2,023 inspections. 837 inspections were conducted in the July to December 2020 period thus the target for the January-June 2021 period was 1,186 inspections. A total of 1,066 inspections were conducted.

Overall, 94% (1,903) of the 2,023 inspections planned for the year were conducted. This was because some regions did not meet their annual target despite others exceeding the annual target.

Overall

94% (1,903)

of the 2,023 inspections planned for the year were conducted.

The statistics and results for pharmacy compliance monitoring visits for the January to June 2021 period are indicated in Figures 21-24 below.

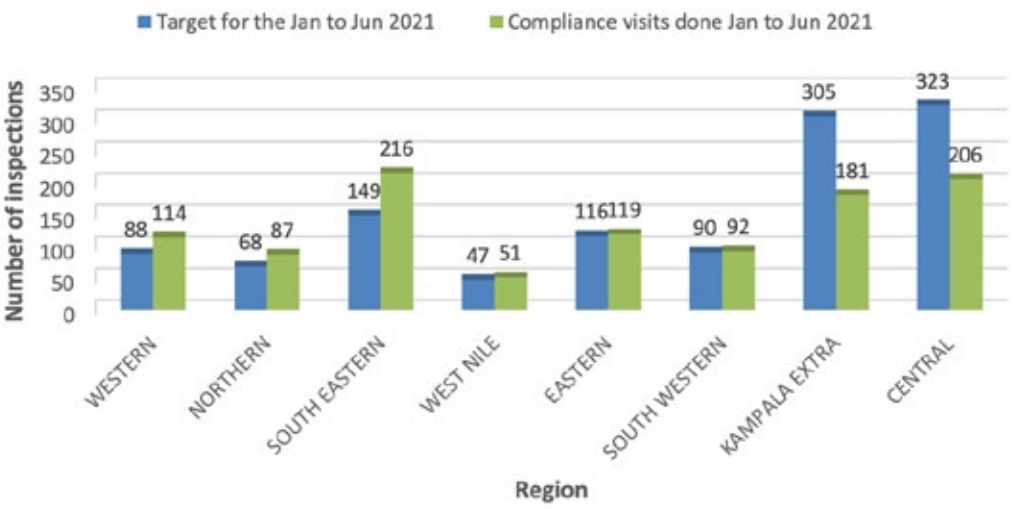


Figure 21: Distribution of pharmacy compliance monitoring visits by region.

Six of the eight regions exceeded the target while the two regions of Central and Kampala Extra did not meet the target. This was attributed to the high number of pre-inspection applications received in the two regions.

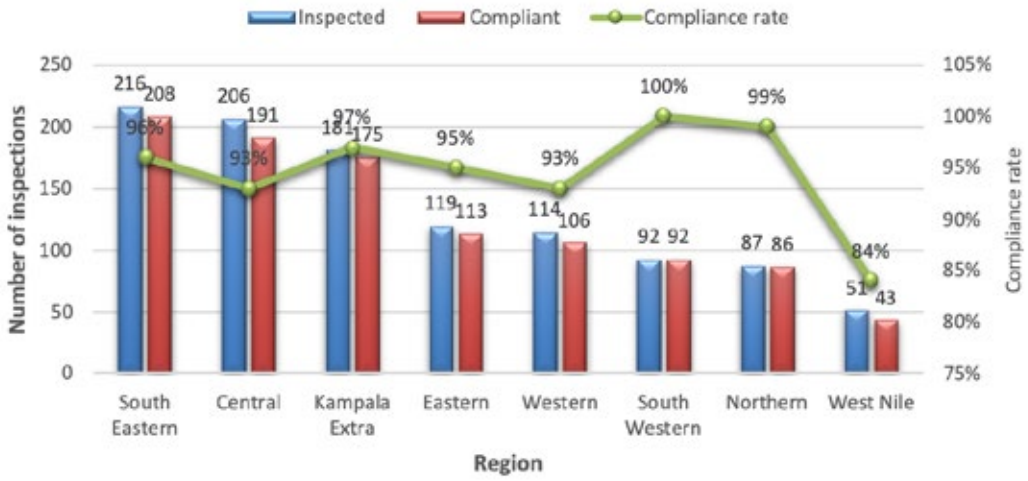


Figure 22: Compliance rating of pharmacy monitoring inspections by region.

In the January to June 2021 period; 1,066 compliance monitoring inspections for pharmacies were conducted with 1,014 resulting into compliant rating and 52 rated non-compliant. West Nile region had the lowest compliance rate at 84% followed by Central region at 92.7% and Western region at 93%.

In the January to June 2021 period;

1,066

compliance monitoring inspections for pharmacies were conducted with 1,014 resulting into compliant rating and 52 rated non-compliant.

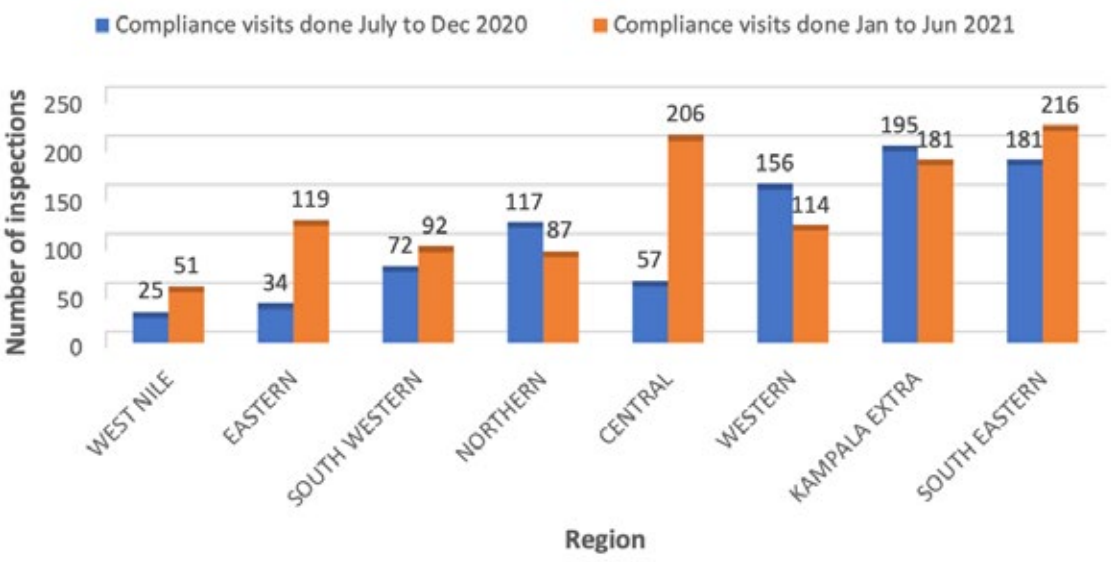


Figure 23: Comparison of the two half-year performances by region.

Five of the eight regions did most of the pharmacy monitoring visits in the second half of the financial year (January to June 2021 period). Northern, western and Kampala Extra did most of their pharmacy monitoring in the first half of the financial year.

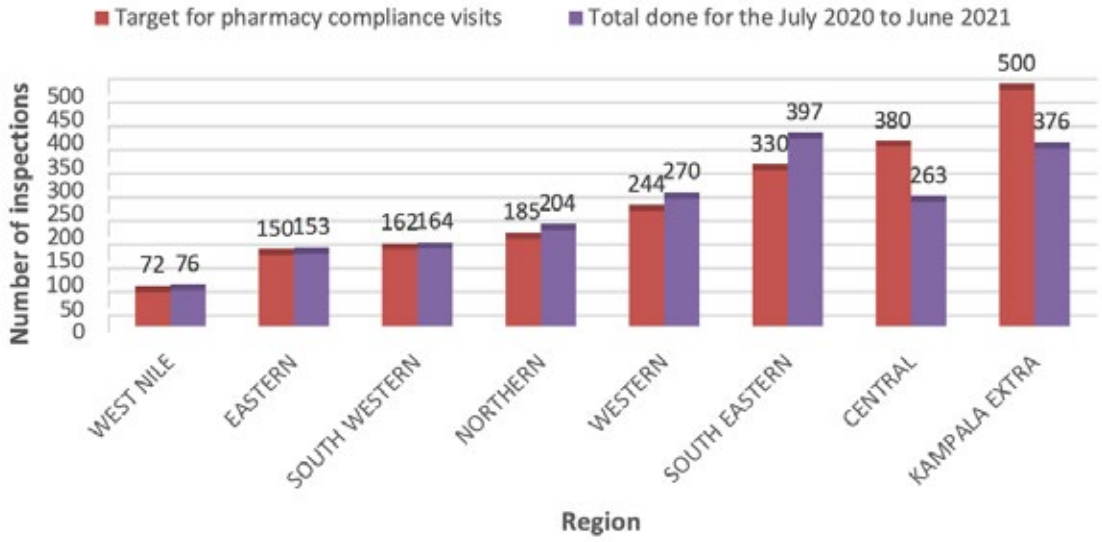


Figure 24: Distribution of annual pharmacy compliance monitoring by region

Six of the eight regions surpassed the annual target for pharmacy compliance monitoring. Kampala Extra and Central regions which have 39.2% and 23% of the pharmacies respectively did not meet the annual target (as indicated on figure 24. This is attributed to the high number of pre-inspection and licensing applications received in the two regions.

Most common observations:

- Sale of prescription-only drugs without prescriptions.
- Absence of pharmacists at the premises during operating hours.
- Frequent resignation of pharmacists on short notice.
- Poor record keeping.
- Poor cold chain systems.
- Mass facility closures on spotting NDA teams, especially in semi-urban areas.

Action taken:

- Sensitization meetings have been undertaken to guide pharmacies on the minimum standards and how they can put systems in place to address the non-compliances.
- One-on-one meetings with the pharmacists have been held to guide them on possible steps to address the non-compliances.
- In exceptional cases enforcement action was taken and some pharmacies closed until the non-compliances were addressed.
- The cold chain verification was assigned to PMS for a centralized assessment.

2.6 Good Distribution Practices (GDP) inspection statistics and results

As per the annual work plan, the target for GDP inspections in the July 2020 to June 2021 financial year was 720 inspections. 361 inspections were conducted in the July to December 2020 period thus the target for the January-June 2021 period was 359 inspections. 227 inspections were conducted.

Overall 81.7% (588) of the 720 GDP inspections planned for the year were conducted. This was because some regions did not meet their annual target even though others exceeded the annual target.

In the January to June 2021 period: 359 GDP inspections of wholesalers were planned; 227 GDP inspections were conducted with 13 inspections resulting into a compliant rating and 214 non-compliant.

Overall
81.7% (588)
of the **720** GDP inspections planned for the year were conducted.

The statistics and results for GDP inspections for the January to June 2021 period are indicated in Figures 25-26 below.

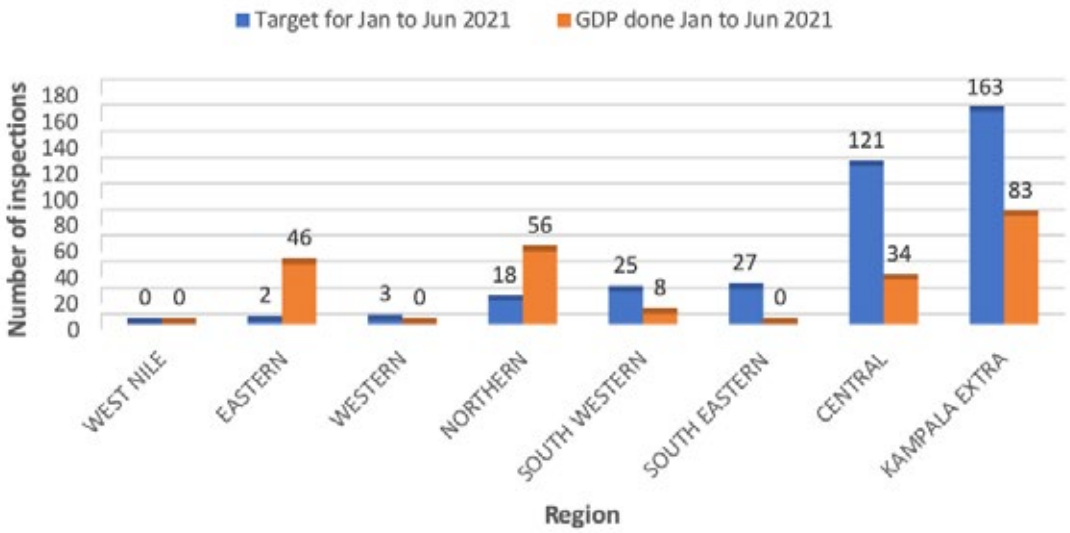


Figure 25: Distribution of GDP inspections by region

West Nile region had met the annual target for GDP inspections in the July to Dec 2020 period thus had no obligation for the Jan to June 2021 period.

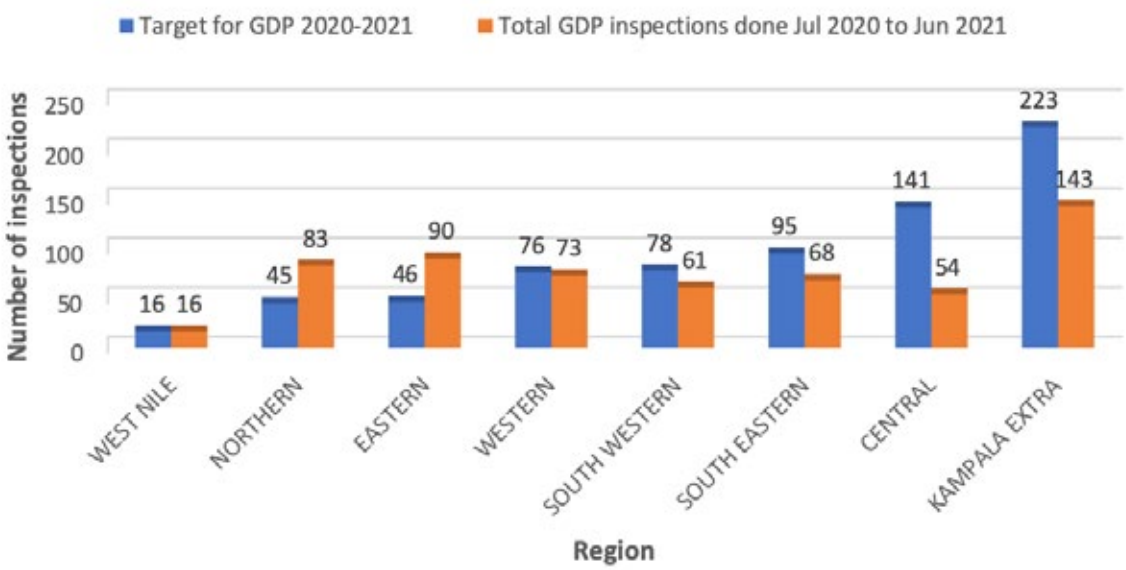


Figure 26: Distribution of annual GDP inspections by region

Only three of the eight regions met or surpassed the GDP target for the 2020-21 financial year.

Most common observations:

- Poor record keeping or complete absence of records of receipt and sale of drugs: Purchase and sales records lacked batch numbers and names of customers; and where batch numbers were available, in many cases they did not correspond with the actual batch numbers on the medicines.
- Unsuitable premises: The storage premises were congested and dirty with poor records for temperature monitoring.
- Inadequate cold chain: most outlets did not have a power back-up, continuous temperature monitoring system or an alarm system for the temperature excursions.
- Lack of appreciation for GDP by technical and business teams at facilities, despite sensitization.
- Inadequate CAPA responses both technically and timeliness.

Action taken:

- The non-compliant pharmacies were required to provide a corrective action and preventive action (CAPA) plan which would be verified during the next inspection.
- A follow up meeting was held with the biggest wholesalers but implementation of the agreed actions was hampered by the uncertainty due to Covid-19 and the attendant lockdowns.

Drugs impounded during an operation in Eastern Region

3.0 LICENSED SELLERS (CLASS C DRUG SHOPS)

National Drug Authority inspects licensed sellers (Class C drug shops) to verify compliance with the requirements of the National Drug Policy and Authority Act and the National Drug Policy and Authority Licencing and Certificate of Suitability of Premises Regulations, 2014. Inspections are done sequentially as pre-inspections followed by licencing inspections and finally compliance monitoring visits.

The Directorate performs an initial pre-inspection of a licenced seller within 15 days of receiving an application. It then conducts a licensing inspection within 20 days of receipt of a licencing application. Class C drug shops are licenced annually. After that, the date of further inspections depends on the plan set out for the activity which is approved as part of the annual work plan.

3.1 Inspection statistics and results

The target for inspection of class C drug shops in the July 2020 to June 2021 financial year was 12,303 compliance monitoring visits and all the pre-and licencing applications received as per the service delivery timelines. A total of 4,388 pre- and 18,725 licensing applications were received; 2,202 & 8,040 in the July to December 2020 period and 1949 & 10,478 in the January to June 2021 period respectively. Overall 35, 416 inspections for drug shops were planned for the July 2020 to June 2021 financial year.

A total of 40,483 inspections were conducted; 18,994 in the July to December 2020 and 21,489 in the January to June 2021 period. Overall 114% (40,483) of the 35,416 drug shop inspections planned for the year were conducted. This was because several regions exceeded the target for compliance monitoring visits.

Overall
114% (40,483) of the **35,416** drug shop inspections planned for the year were conducted.

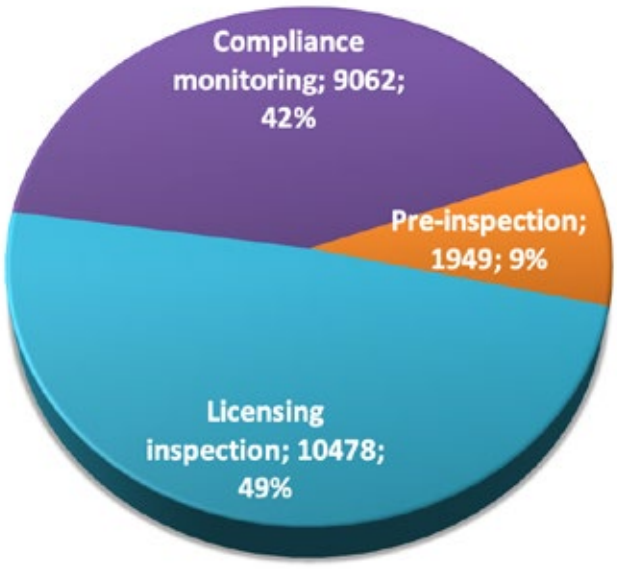


Figure 27: Distribution of drug shop inspections by inspection type.

In the Jan-June 2021 period, a total of 21,489 inspections were done with 1,949 (9%) pre-inspections, 10,478 (49%) licensing inspections and 9,062 (42%) compliance monitoring visits. This is the main licencing period for class C drug shops thus the share of licensing inspections.

In the Jan-June 2021 period, a total of
21,489
inspections were done with 1,949 (9%) pre-inspections, 10,478 (49%) licensing inspections and 9,062 (42%) compliance monitoring visits.

[4]Licensed seller (Class C drug shop) is a drug outlet licensed under section 15 of the Act for retail sale of class C (over the counter) drugs only and not those of Class A or B.

3.2 Drug shop pre-inspection statistics and results

The target for pre-inspection of class C drug shops in the July 2020 to June 2021 financial year was all the applications received as per the service delivery timelines. A total of 4388 pre- inspection applications were received; 2,202 in the July to December 2020 period and 2,186 in the January to June 2021 period.
A total of 3,938 pre-inspections were conducted; 1989 in the July to December 2020 and 1,949 in the January to June 2021 period.

Overall 90% (3,938) of the 4,388 pre-inspection applications received in the 2020/21 financial year were inspected while 10% were pending inspection.

Overall
90% (3,938)
of the 4,388 pre-inspection applications received in the 2020/21 financial year were inspected.

The statistics and results for drug shop pre-inspections for the January to June 2021 period are indicated in Figures 28-29 below.

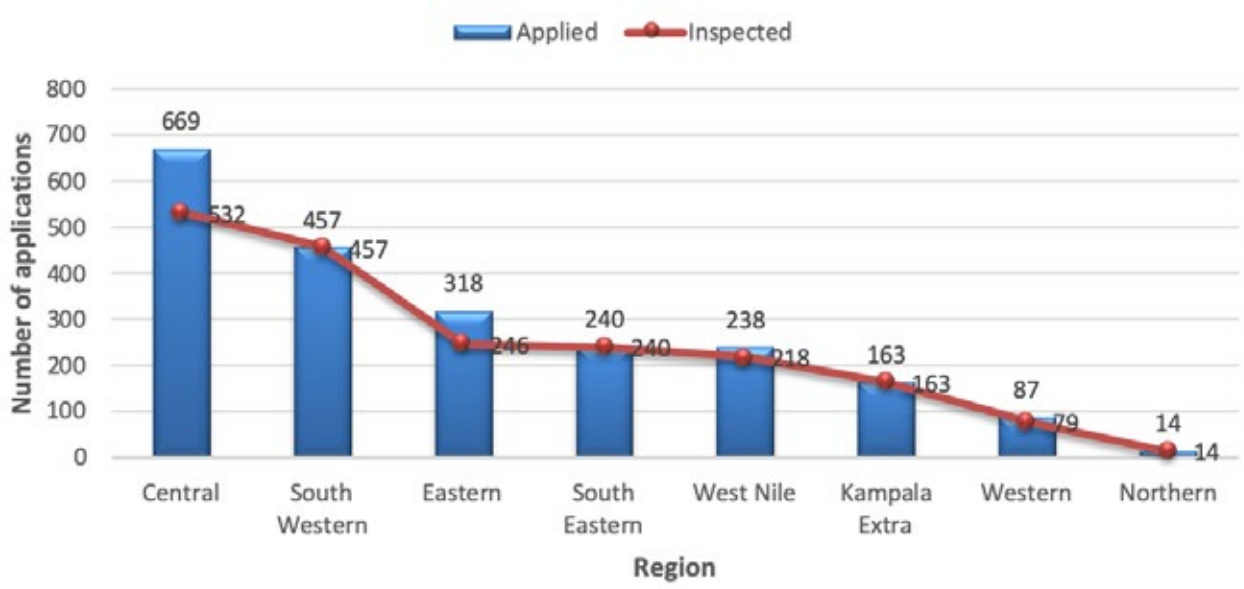


Figure 28: Distribution of Class C drug shop pre-inspections by region

In the Jan to June 2021 period, a total of 2,186 pre-inspection applications for class C drug shops were received and 1,949 pre-inspections conducted. The highest number 669 (30.6%) were received in central region, followed by South Western region with 457 (20.9%) and Eastern region with 318 (14.5%).

In the Jan to June 2021 period, a total of
2,186
pre-inspection applications for class C drug shops were received and 1,949 pre-inspections conducted.

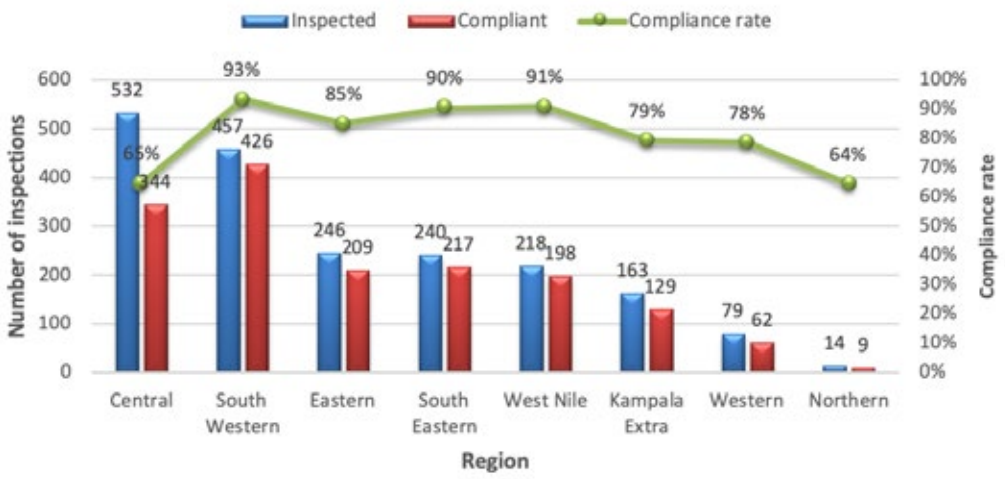


Figure 29: Compliance rating of drug shop pre-inspections

1,949 pre-inspections were conducted with 1,594 (81.8%) resulting into compliant rating and 353 (18%) resulting into a non-compliant rating. The lowest compliance was in Northern region at 64%, followed by Central region at 65% and Western at 78%. Central region accounted for 53.3% (188 of 353) of the non-compliant drug shop pre-inspections.

1,949

pre-inspections were conducted with 1,594 (81.8%) resulting into compliant rating and 353 (18%) resulting into a non-compliant rating.

Most common observation:

- Class C shops were already operational at time of application.

Action taken:

- Non-compliant outlets were informed in writing about the outcome and advised to close.
- Those who did not heed the advice faced appropriate enforcement action.

The statistics and results for drug shop licensing inspections for the January to June 2021 period are indicated in Figures 30-32 below.

3.3 Drug shop licencing inspection statistics and results

The target for licensing inspection of class C drug shops in the July 2020 to June 2021 financial year was all the applications received as per the service delivery timelines. 18,725 licensing applications were received; 8,040 in the July to December 2020 period and 10,685 in the January to June 2021 period.

A total of 18,501 inspections were conducted; 8,023 in the July to December 2020 and 10,478 in the January to June 2021 period. Overall 99% (18,501) of the 18,725 licensing applications received in the 2020/21 financial year were inspected with 1% pending inspection.

Overall

99% (18,501)

of the 18,725 licensing applications received in the 2020/21 financial year were inspected.

The statistics and results for drug shop licensing inspections for the January to June 2021 period are indicated in Figures 30-32 below.

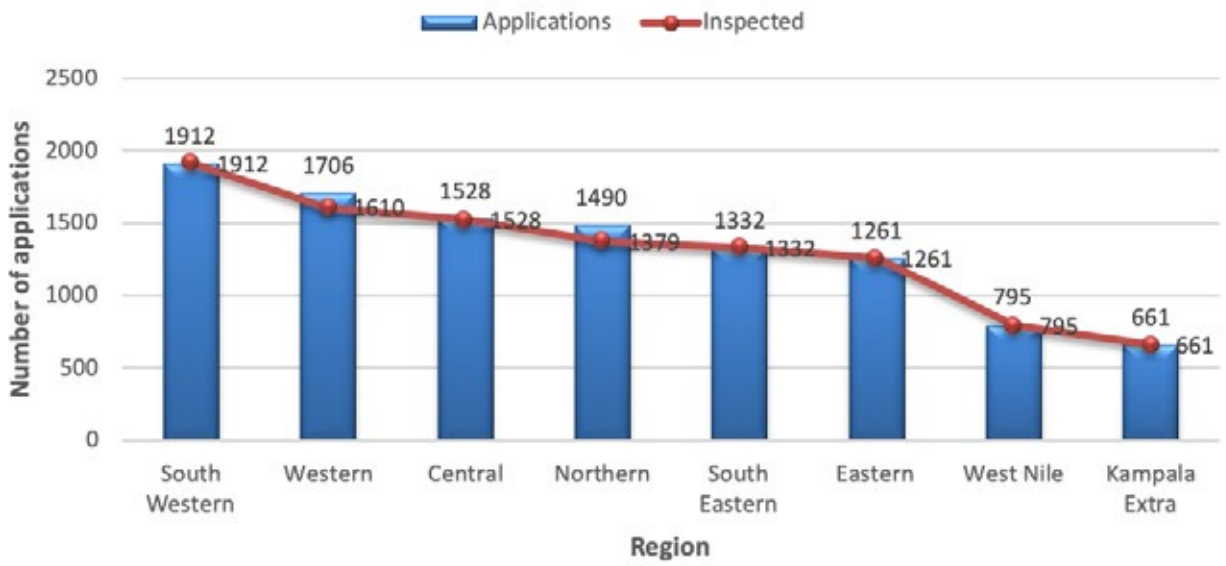


Figure 30: Distribution of drug shop licencing inspections by region

In the January-June 2021 period; 10,685 licencing applications for class C drug shops were received and 10,478 inspections conducted. Only Northern (111) and western (96) regions had not completed the inspection of the drug shop applications.

In the January -June 2021 period; **10,685** licencing applications for class C drug shops were received and 10,478 inspections conducted.

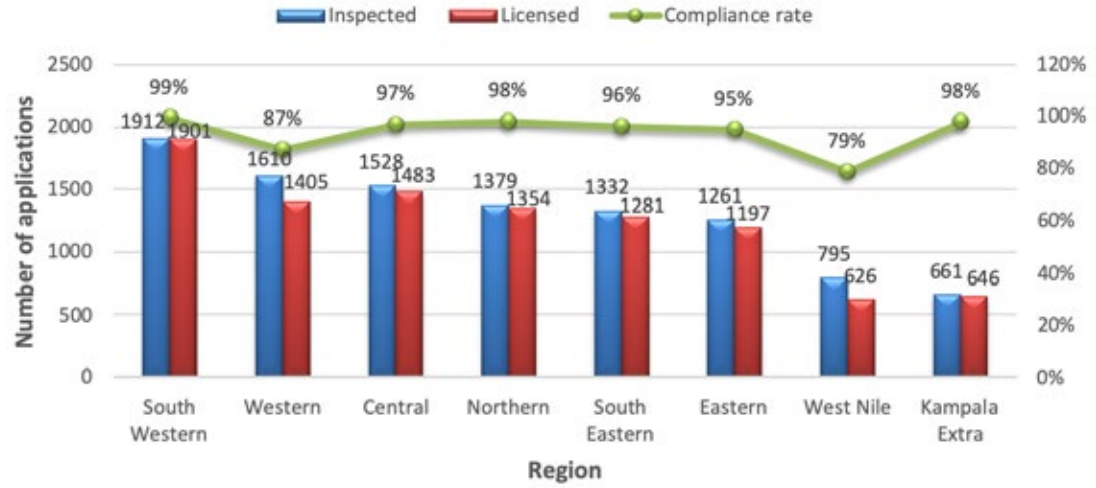


Figure 31: Compliance rating of drug shop licencing inspections by region

94% (9,893 of 10,478) of the licensing inspections resulted into a compliant rating and were licensed while 585 (6%) resulted into a non-compliant rating and were queried. West Nile region had the lowest compliance rating at 79% followed by Western at 87% and Eastern at 95%.

94% (9,893 of 10,478)

of the licensing inspections resulted into a compliant rating and were licensed while **585** (6%) resulted into a non-compliant rating and were queried.

Most common observation:

- Poor records of purchase and sales.
- Absence of qualified in-charges.
- Unclean and untidy premises.

Action taken:

Non-compliant outlets were denied a licence until the non-conformances were addressed.

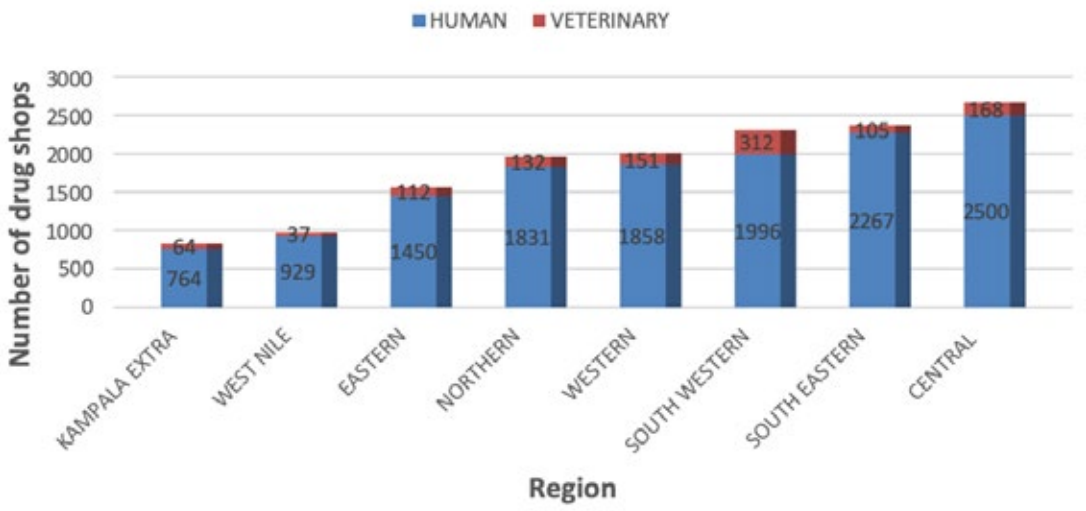


Figure 32: Licensing status of Class C drug shop as at June 30, 2021

A total of 14,676 Class C drug shops were licenced; 93% (13,595) were for human drug products while 7% (1081) were for veterinary drug products. Central region had the highest number at 18% (2668) followed by South Eastern at 16% (2372) while Kampala Extra had the least at 5.6% (828) followed by West Nile region at 6.6% (966).

A total of
14,676

Class C drug shops were licenced; **93%** (13,595) were for human drug products while **7%** (1081) were for veterinary drug products.

3.4 Class C drug shop compliance monitoring visits statistics and results

The target for drug shop compliance monitoring in the July 2020 to June 2021 financial year was 12,303 inspections. 8,982 inspections were conducted in the July to December 2020 period thus the target for the January-June 2021 period was 3,321 inspections. 9,062 inspections were conducted.

Overall 147% (18,044) of the 12,303 monitoring visits planned for the year were conducted. This was despite some regions not meeting the annual target because other regions exceeded the target.

Overall
147% (18,044)

of the **12,303** monitoring visits planned for the year were conducted.

The statistics and results for drug shop compliance monitoring for the January to June 2021 period are indicated in Figures 33-36 below.

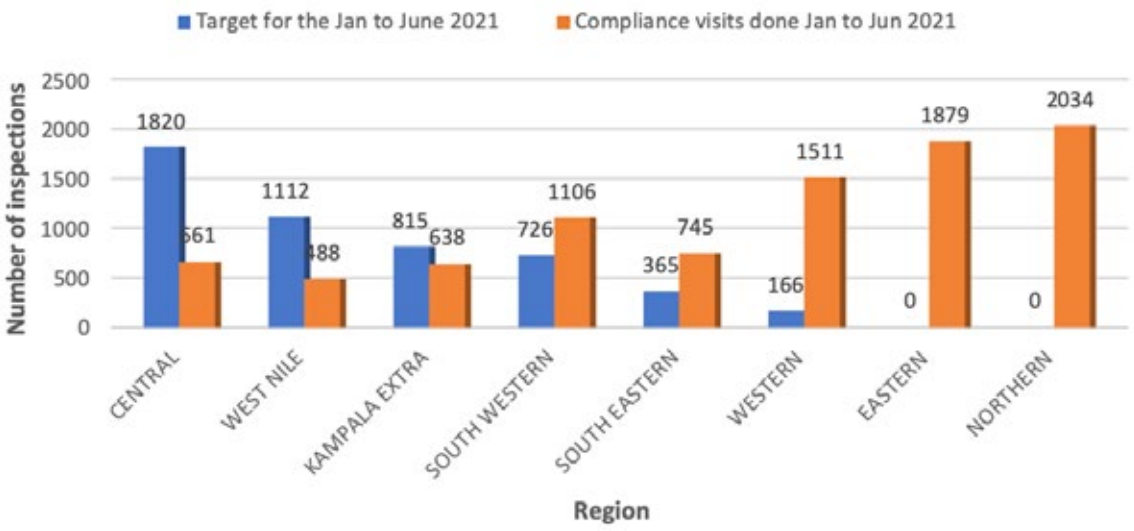


Figure 33: Distribution of drug shop compliance monitoring visits by region.

Some of the regions met or exceeded the annual target within the first half of the year thus had no obligation or target for this activity in the period under review. Their target is thus indicated as zero but they still carried out the activity.

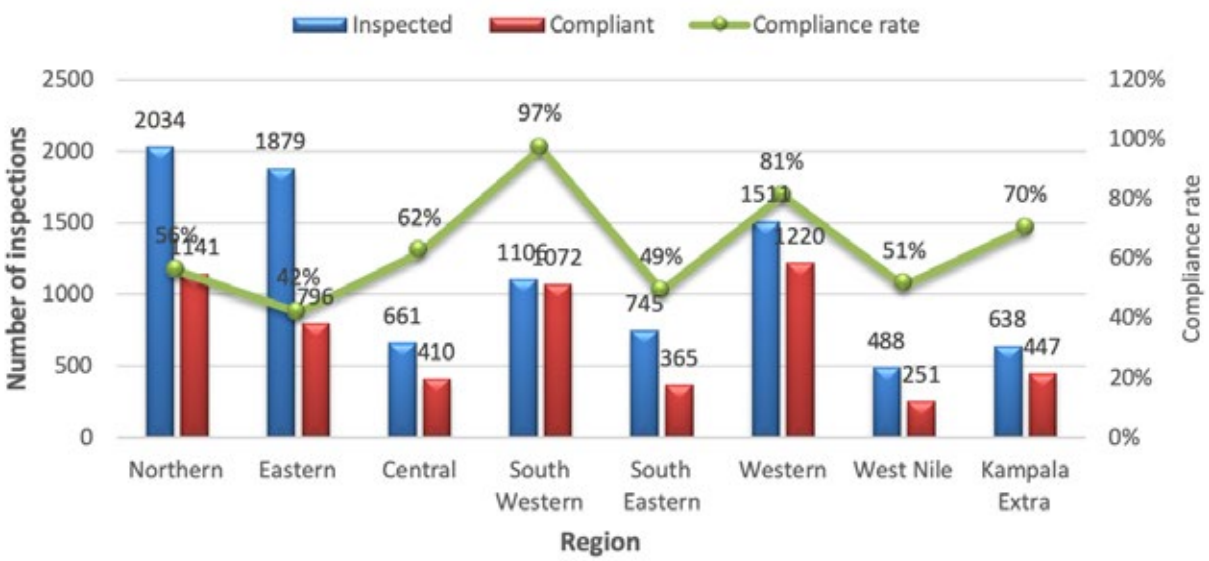


Figure 34: Compliance rating of drug shop monitoring visits by region

In the January to June 2021 period; 9,062 compliance monitoring visits for drug shops were conducted with 5,702 resulting into a compliant rating while 3,360 were non-compliant. South Western region had the highest compliance rate at 97% followed by Western at 81% and Kampala Extra at 70% while Eastern region had the lowest compliance rate at 42% followed by South Eastern at 49% and West Nile at region at 51%.

In the January to June 2021 period; **9,062** compliance monitoring visits for drug shops were conducted with 5,702 resulting into a compliant rating while 3,360 were non-compliant.

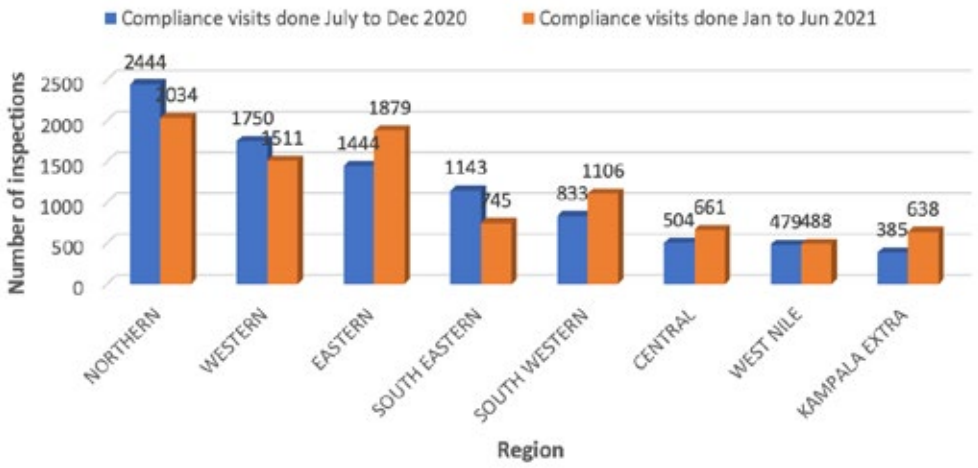


Figure 35: Comparison of the two half-year performances by region

All the regions distributed their drug shop compliance monitoring throughout the year

Figure 36: Distribution of annual drug shop compliance monitoring by region

Five of the eight regions surpassed the annual target for pharmacy compliance monitoring. Kampala Extra, West Nile and Central regions did not meet the annual target. This is attributed to the high number of pre-inspection applications received in the two regions.

Most common observations:

- Illegal possession of class B drugs.
- Unqualified personnel as attendants.
- Dusty/dirty premises.
- Conducting of clinical services.
- Unlicenced outlets (illegal & unauthorised relocations).

Action taken:

- Sensitization meetings were undertaken in most districts to educate the operators on the minimum standards and how to meet them.
- Local leaders were engaged to assist with monitoring of drug shops and to curb unlicensed drug outlets.
- Radio talk shows were held to sensitize the masses about the danger of accessing pharmaceutical services from unlicensed outlets and how to identify and report them.
- Enforcement operations were carried out in various parts of the country to apprehend illegal operators and illegal practices.
- Wholesale pharmacies were warned about selling Class B medicines to drug shops.

Suspected impostor arrested in Bukwo district

4.0 PUBLIC AND PRIVATE NOT-FOR-PROFIT (PNFP) FACILITIES

Uganda's health system comprises public, private-not-for-profit (PNFP) and private-for profit (PFP). These facilities dispense drugs to patients. In order to ensure that the public and Private not for profit facilities that stock drugs meet standards for suitability of premises, NDA inspects these premises in health centers.

The inspections are a way of providing technical support and independent assessment of systems in place. Reports from the inspections are shared with the Unit management and Ministry of Health for corrective and preventive action.

4.1 Good pharmacy practices (GPP) inspection statistics and results

The target for GPP inspections in the July 2020 to June 2021 annual work plan was 250 inspections. In the July to December 2020 period 165 inspections were conducted thus the target for the January-June 2021 period was 85 inspections. A total of 141 inspections were conducted.

Overall 122% (306) of the 250 GPP inspections planned for the year were conducted. This was because some regions exceeded the annual targets while others did not meet their annual target.

Overall
122% (306)
of the **250** GPP inspections planned for the year were conducted.

The statistics and results for GPP inspections for the January to June 2021 period are indicated in Figures 37-39 below.

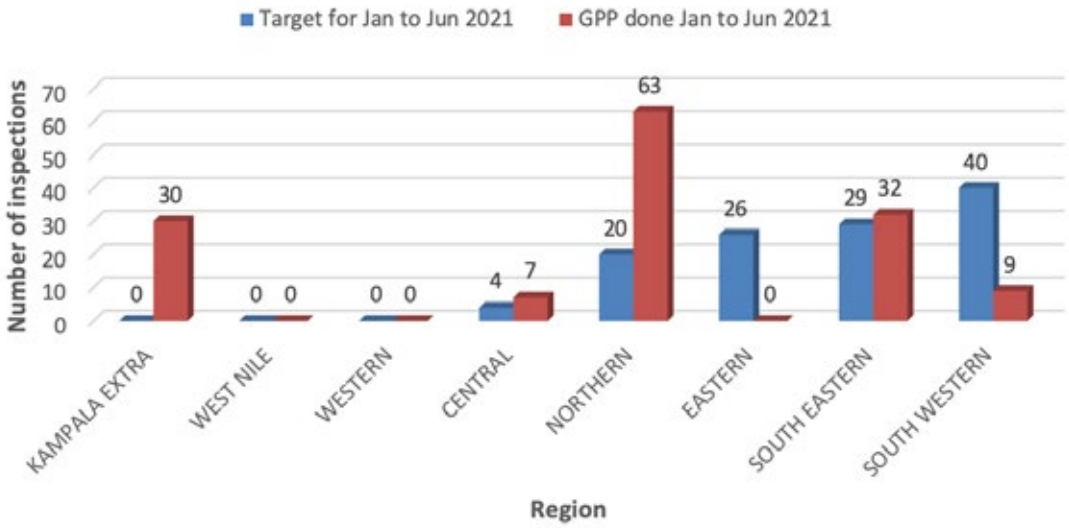


Figure 37: Distribution of GPP inspections by region

In the January-June 2021 period; 85 good pharmacy practice (GPP) inspections were planned; 141 inspections were conducted with 59 resulting into compliant rating while 82 were non-compliant. Kampala Extra, Western and West Nile regions had met the annual target for GPP inspections in the July to Dec 2020 period thus had no obligation for the Jan to June 2021 period.

In the January -June 2021 period;

85

good pharmacy practice (GPP) inspections were planned; 141 inspections were conducted with 59 resulting into compliant rating while 82 were non-compliant.

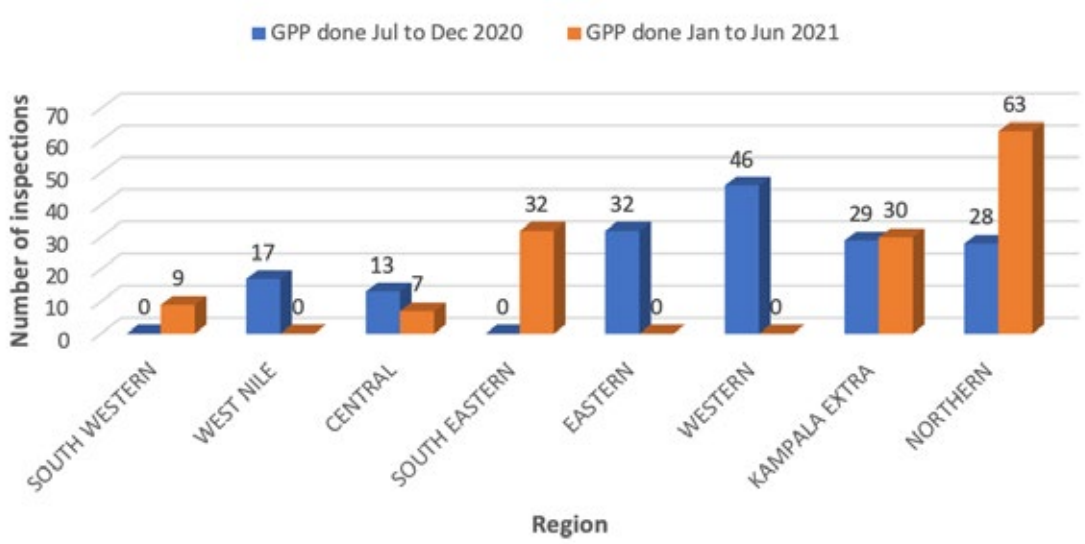


Figure 38: Comparison of the two half-year performances by region

Three of the eight regions did all their GPP inspections in the first half of the year (July to December 2020 period) while another two regions did all in the second half of the year (January to June 2021 period).

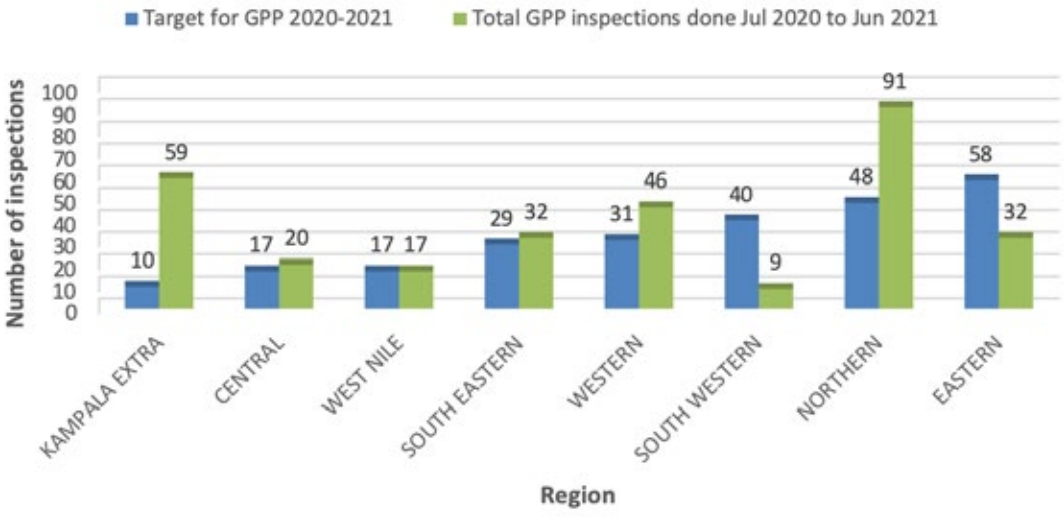


Figure 39: Distribution of annual GPP inspections by region

Six of the eight regions met or surpassed the annual target for GPP. Only South Western and Eastern regions did not meet the target partly because some health centre teams did not receive the NDA inspectors on account of Covid-19 Presidential directives at the peak of the second wave.

Most common observations:

- Absence of specialized pharmacy staff.
- Unsuitable premises: The public facilities especially health center III and below were in a poor state with dirty walls, fallen ceilings, poor toilet facilities and inadequate storage space.
- Poor record keeping.

Action taken:

- The individual facility reports were compiled and findings submitted to the individual facilities to address the non-compliances.
- The consolidated district reports will be submitted to the District Health Officers and local government leadership.
- The consolidated national report will be submitted to the Ministry of Health to support the facilities in addressing infrastructural challenges that require huge budgetary support.

Refresher training of NDA officers on post marketing surveillance

5.0 POST MARKET SURVEILLANCE

The quality of any medicine or healthcare product is determined by its effectiveness, safety and ultimately the health outcome of a patient. If that quality is disputed, then any efforts and investment into public health systems and medicines regulatory systems will be compromised.

The aim of NDA's Post-Market Surveillance is to identify whether medicines and healthcare products continue to be as safe, effective as when originally approved for market entry or registered.

The PMS program focuses on 4 activities:

1. Risk-based selection of medicines to be tested, in order to prioritize those that pose risks to public health.
2. Sampling and testing of prioritized medicines on the market, as routine surveillance of the quality of medicines.
3. Manage reported complaints and regulatory actions proposed including recalls
4. Undertake proactive post-market surveillance that is based on data from other Regulatory agencies and international organizations like WHO, IGAD and EAC .

Consumers are important stakeholders in NDA's fight against substandard and falsified regulated products. Stakeholders play a critical role and are encouraged to report information concerning one or more of the following:

- Incidents that cause the medicine and healthcare product or its labeling to be mistaken for or applied to another medicine and healthcare product;
- Any significant chemical, physical, or other change or deterioration in the distributed medicine and healthcare product;
- Any failure of one or more distributed batches of the medicine and healthcare product to meet the specifications established in its marketing authorization.

To facilitate reporting, in addition to walk in complaints, NDA has developed a standardized reporting format that may be used to submit electronically or in paper form by mail. Other reporting platforms include toll free telephone number +256 800 101 999, WhatsApp line number +256740 002 070 or the Med safety mobile app downloadable from Google play store for android or the app store for iOS

5.1 Post marketing sampling statistics and results

The target for sampling from the market (PMS) in the July 2020 to June 2021 financial year was 1,050 batches consisting of 400 conventional human drugs, 100 veterinary drugs, 200 samples of herbal drugs, 100 samples for microbiology, 150 samples of surgical instruments (Sutures, syringes & needles) and 100 samples of Rapid Diagnostic Tests (RDTs).

239 samples were picked in the July to December 2020 period; thus, the target for the January to June 2021 period was 811 samples.

279 batches were sampled consisting of 158 conventional human drugs, 28 of herbal drugs, 36 of veterinary drugs, 25 samples of Rapid Diagnostic Tests (RDTs) and 32 samples of surgical instruments (Sutures, syringes & needles).

Overall sampling rate for PMS was 49.3% (518) of the 1050 planned samples. 453 batches were tested with 391 compliant and 62 non-compliant. The overall compliance rate for PMS samples was 86.3%.

Overall sampling rate for PMS was **49.3% (518)** of the 1050 planned samples.

The overall compliance rate for PMS samples was **86.3%.**

The low sampling rate was attributed to;

1. Lack of laboratory capacity (microbiology samples were not sampled because the laboratory was not ready to carry out the required tests).
2. The COVID-19 pandemic lockdown and the attendant restrictions affected the activity. Some of the post market surveillance (PMS) samples were deferred to the 2021/2022 financial year including herbal antihistamines, condoms, cosmetics, ivermectin injection and levamisole Injection.

The statistics and results for post marketing sampling for the January to June 2021 period are indicated in Figures 40-41 below.

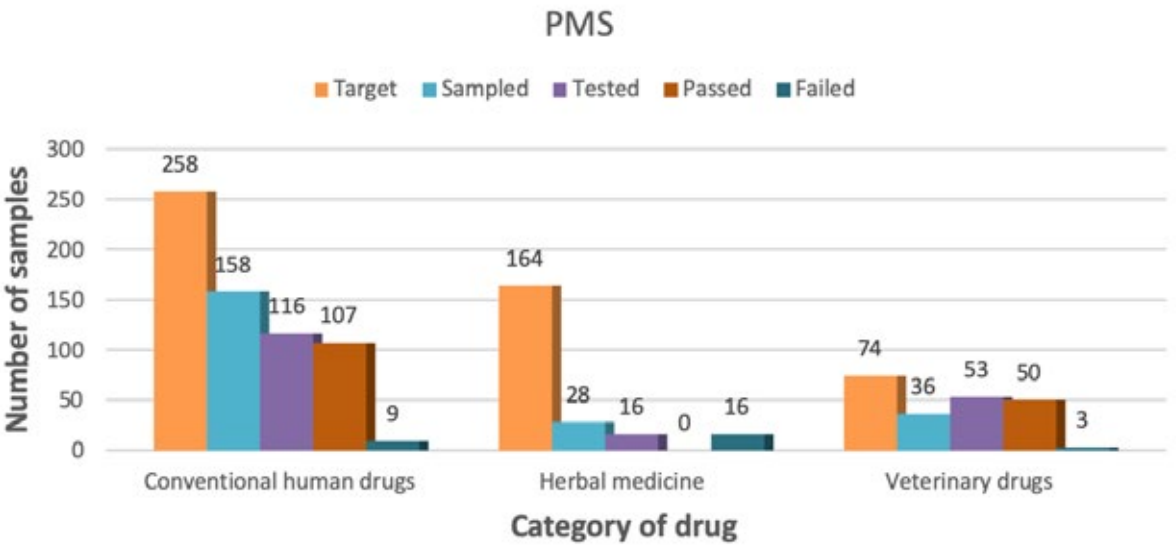


Figure 40: Distribution and compliance rating of drug samples from the market

The PMS target for the January-June 2021 period was 596 drug samples (including 100 microbiology samples). 222 batches were sampled from the market consisting of 158 batches of conventional human drugs, 36 of conventional veterinary drugs and 28 batches of human herbal drugs. A total of 185 batches were tested comprised of 116 batches of conventional human drugs, 53 of veterinary drugs and 16 of herbal drugs. The overall compliance rate for PMS drug samples was 85% (157 of the 185 batches tested).

Note: some of the tested batches were carried forward from the previous period and that explains why the numbers of veterinary drugs tested are higher than those sampled.

222

batches were sampled from the market consisting of **158** batches of conventional human drugs, 36 of conventional veterinary drugs and **28** batches of human herbal drugs.

The overall compliance rate for PMS drug samples was

85%

(**157** of the **185** batches tested).

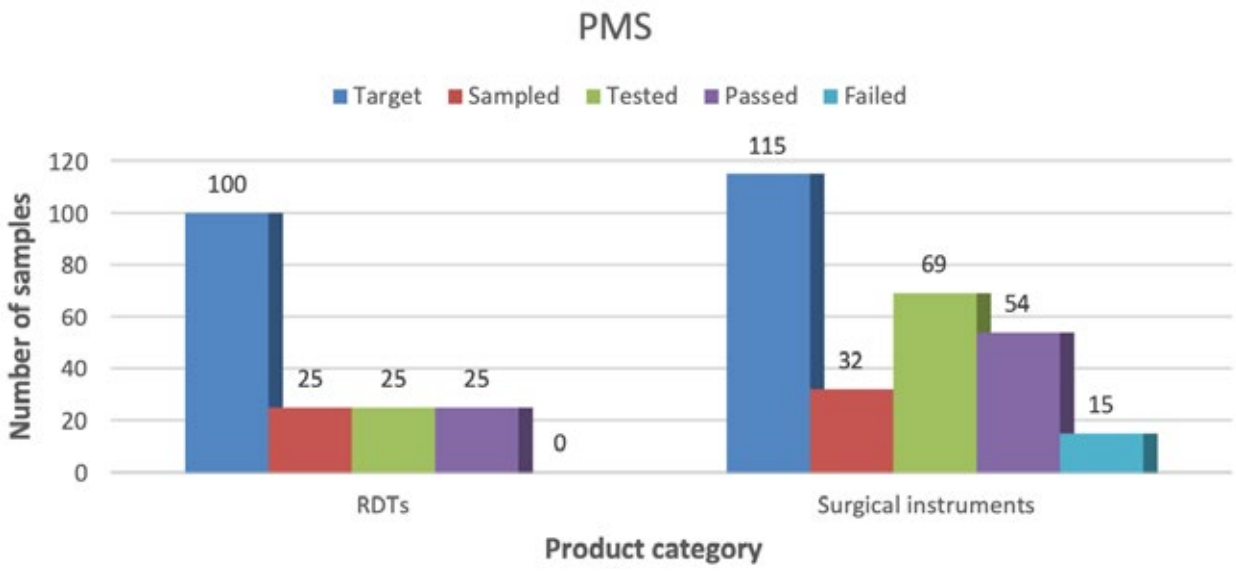


Figure 41: Distribution of other medical products sampled from the market

A total of 215 batches of medical devices consisting of 100 batches of rapid diagnostic tests (RDTs) and 115 batches of surgical instruments were planned for the January-June 2021 period. 57 batches were sampled, 94 tested with 79 passing and 15 failing. The overall compliance rate for PMS medical device samples was 84% (79 of the 94 batches tested).

Note: some of the tested batches were carried forward from the previous period and that explains the numbers for surgical instruments.

The overall compliance rate for PMS medical device samples was

84%

(79 of the 94 batches tested).

Most common observations

1. There were confirmed falsified products as follows;
   - Cialis (Tadalafil tablets) batch 05668, failed identity as it was discovered to contain Sildenafil;
   - Quinine Bisulphate Tablets Batch 8421 and Quinine Bisulphate had Metronidazole instead.
   - Postinor-2 (Levonorgestrel) tablets batch T86232V had no active pharmaceutical ingredient
   - One herbal aphrodisiac product was found adulterated with Sildenafil (a synthetic conventional drug).

2. There were substandard products as follows;
   - Vermakil (Albendazole chewable tablets) manufactured by Synokem Pharmaceuticals Ltd, India had six batches failing dissolution tests as per the International Pharmacopeia specifications.
   - Alzol (Albendazole Tablets) Batch 01619 manufactured by Rene Industries Ltd, Uganda also failed dissolution.
   - Two batches of Endospec (Albendazole) 10% suspension batch numbers 1911013 and 1907042) manufactured by Medisel Kenya Ltd failed pH.
   - Doxyrone-100 (Doxycycline Capsules) Batch 000780 manufactured by Africure Pharmaceuticals Ltd, India failed uniformity of dosage forms.
   - Auto disable syringes batch number 20BA3 manufactured by Guangdong Haiou Medical Apparatus Co. Ltd-China failed the needle point test.
   - Herbal products failed labelling requirements.
   - Surgical sutures failed labelling requirements.

Actions taken on non-compliant batches

Non-compliant batches during sampling and testing were recalled and destroyed; issued with a circular explaining the non-compliance or training to address the cause of the non-compliance as follows:

- Vermakil (Albendazole chewable tablets) batches manufactured by Synokem Pharmaceuticals Ltd, India, were recalled and the product was suspended from the register by the Authority due to the persistent dissolution test failures.
- Other substandard products that were confirmed by analysis were recalled from the market.
- The public was warned about the falsified and adulterated products through posters and talk shows.
- A circular was issued to all importers and manufacturers of surgical sutures regarding the labelling requirements for surgical sutures.
- Efforts are underway to provide training and support supervision visits to the herbalists to improve the labelling of their products to meet requirements.

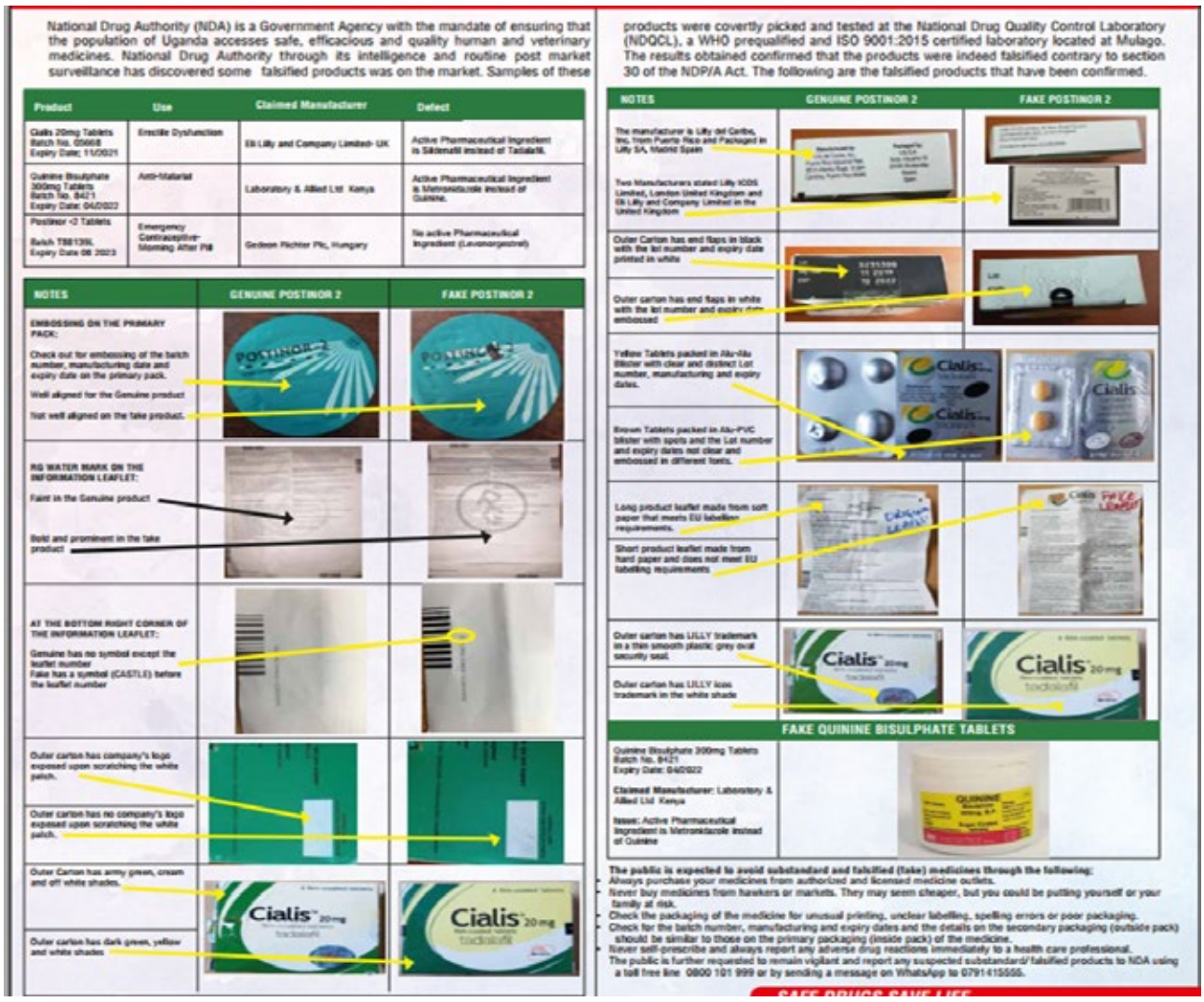


Figure 42: Poster warning the public about falsified Cialis on the market

5.2 Product complaints statistics and results

The target for handling product complaints in the July 2020 to June 2021 financial year was all complaints received as per the service delivery timelines. 31 complaints were received; 21 in the July to December 2020 period and 10 in the January to June 2021 period.

A total of 23 complaints were investigated and completed; 12 in the July to December 2020 and 11 in the January to June 2021 period. Overall 74% (23) of the 31 complaints were investigated and communicated.

Overall
74% (23)
of the **31** complaints were investigated and outcome communicated.

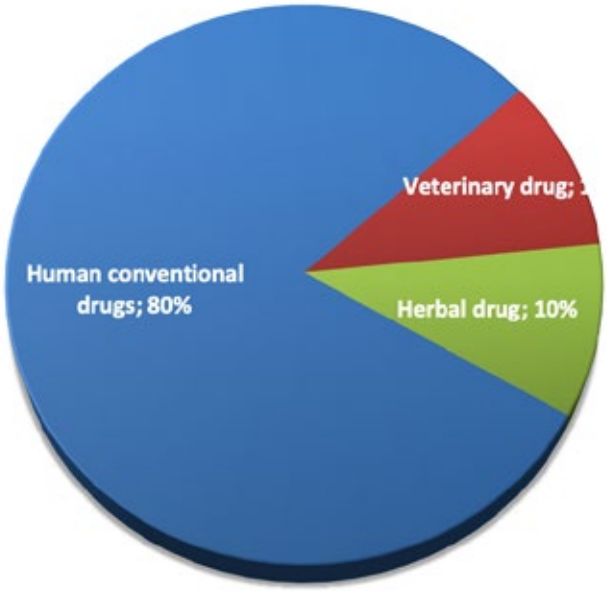


Figure 43: Categories of products for which complaints were received

In the January to June 2021 period; 10 product related complaints were received consisting of 8 (80%) for Human conventional products and 1 (10%) each for Veterinary and Herbal products.

In the January to June 2021 period; 10 product related complaints were received consisting of 8 (80%) for Human conventional products and 1 (10%) each for Veterinary and Herbal products.

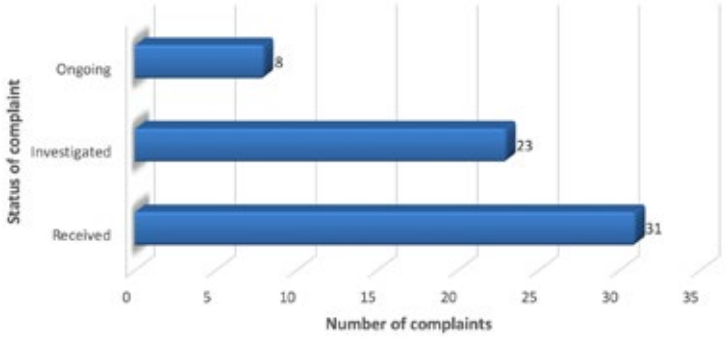


Figure 44: Product complaints investigated in the 2020-21 financial year

Overall 74.2% of the complaints received in the 2020-2021 financial year were investigated and regulatory action taken. The remaining 8 complaints were still undergoing investigation as the end of June 2021 as shown in the figure above.

Overall **74.2%** of the complaints received in the 2020-2021 financial year were investigated and regulatory action taken.

The statistics and results for market complaints are indicated in Figures 43-45 below.

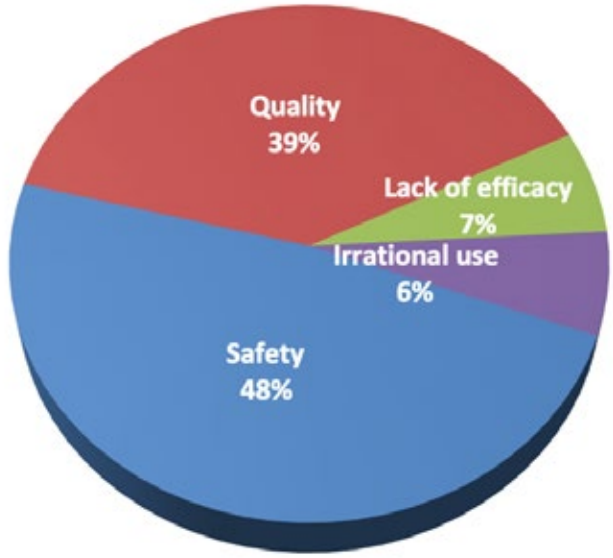


Figure 45: showing nature of the product complaints

Overall, 48.4 % of the complaints received related to the safety of the product, 38.7% were related to the quality of the product and 6.5% apiece of the complaints related to lack of efficacy of the product and irrational use.

48.4 %

of the complaints received related to the safety of the product, 38.7% were related to the quality of the product and 6.5% apiece of the complaints related to lack of efficacy of the product and irrational use.

Most common observations

- 80% of the complaints were related to human conventional drugs.
- 74.2% of the complaints received in the 2020-2021 financial year were investigated and regulatory action taken.
- 87.1% of the complaints received were related to the safety or quality of the products (48.4% for safety and 38.7% for quality).

Table 2: Summary of complaints and action taken

Category	Product	Investigation and Regulatory Action
Complaints Substantiated	Lidocaine Injection 2%	Lidocaine Injection 2% caused serious adverse drug reactions and was recalled
	Medeplast protective face masks	Medeplast protective face masks were inappropriately labelled. Manufacturer was required to improve on labelling to distinguish between Medical and Non-Medical Masks
	Nana Herbal Mouth Wash	Nana Herbal Mouth Wash caused adverse drug reactions. It was discovered that there are two manufacturers of the product. The original manufacturer was inspected but efforts are underway to establish the counterfeiter.
	Quantum Analysers	Quantum Analysers used for wrong diagnosis- Clinic in Ishaka was raided and equipment impounded.
	Spamcil dry powder for suspension	Spamcil dry powder for suspension had dark brown particles. Product was recalled from the market
	V8 Antiviral Veterinary solution	V8 Antiviral Veterinary solution in Ibanda - Unregistered drug found to have been supplied by a Pharmacy in container village. The pharmacy was required to show-cause in writing.
	Vitaglobin Syrup	Vitaglobin Syrup had no information leaflet and pharmacy that sold the syrups was issued with a show-cause letter.
	Vet fungi care sprays	Vet fungi care sprays – Unregistered products were recalled from the market.
	Xymex drops	Xymex drops with brown particles were recalled from the market.
	Zenvac Injection	Zenvac Injection: Numerous complaints were received from medical practitioners regarding the adverse drug reactions following use of Zenvac for spinal anesthesia during caesarian section. Investigations are ongoing to conclude on the matter.
Complaints for which we failed to substantiate the claim	Artesun	Artesun claims of inefficacy were not confirmed.
	CCPP Vaccine	CCPP Vaccine claims of causing adverse drug reactions were not confirmed but attributed to poor cold chain storage of the vaccine.
	Newcastle-IB Vaccine	Newcastle-IB Vaccine claims of causing adverse drug reactions were not confirmed but attributed to poor cold chain storage of the vaccine.
	Samaka hand sanitizer	Samaka hand sanitizer causing burns to the hands. Product could not be traced on the market.

	Slim burn for weight loss	Slim burn for weight loss. Food supplement not under NDA mandate.
Complaints for which samples were submitted in the lab for analysis	Embaluka samples	Embaluka samples were confirmed to be adulterated and a circular was published and product withdrawn from the market.
	Kalaso sonsomola	Kalaso sonsomola passed analysis for absence of adulteration.
	Buyinza Natural Tea	Buyinza Natural Tea – Best for Men failed labelling but passed adulteration.
	Metformin	Metformin Tablets passed analysis.

5.3 Recall statistics and results

The target for audit of recalls in the July 2020 to June 2021 financial year was all the recalls instituted in the review period as per the service delivery timelines. 25 recalls were instituted; 20 in the July to December 2020 period and 5 in the January to June 2021 period.

A total of 21 recalls were audited; 15 in the July to December 2020 and 6 in the January to June 2021 period. Overall 84% (21) of the 25 recalls instituted were audited.

Overall
84% (21)
of the **25** recalls instituted were audited.

The statistics and results for recalls are summarised in Figures 46-48 below.

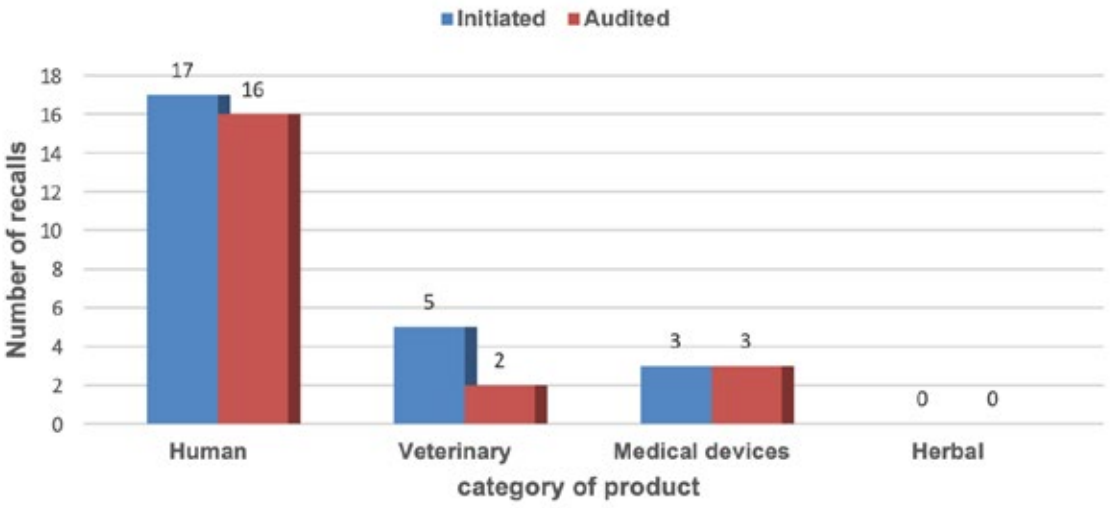


Figure 46: Recalls initiated and audited in the 2020/2021 financial year.

17 (68%) of the recalls were for human conventional drugs; 5 (20%) for Veterinary drugs and 3 (12%) for medical devices. 76% of the product recalls were statutory recalls (ordered by NDA) following laboratory failures or discovery poor quality products on the market while 24% were voluntary recalls.

17 (68%)
of the recalls were for human conventional drugs; 5 (20%) for Veterinary drugs and 3 (12%) for medical devices.

Table 3: List of product recalls for the FY 2020/2021

Name of product	Batch	Reason for recall
Netvaicaine	Sx-19352	Severe neurological adverse drug reactions
Piritex junior	All	Presence of crystalline particulate matter in the syrup.
Easy pill	EUG 007	Failure to comply with specifications for dissolution tests.
Valcontin	9318, 9319, 9320, 9321, 9322, 9323, 9352, 9353, 9355, 9247, 9248, 9249, 9250, 9251, 9252, 9253, 9254, 9255, 9256, 9257	Tablets squashed, molten and stuck to the primary packaging.
E-J Euro ject-x auto disposable syringes	20190319	Failure of the re-use feature.
Revital syringes	205401	Failure of the re-use feature.
Phenobarbital 200mg/ml	0124892, 0122830, 0124140, 0122142	Degradation due to inappropriate environmental conditions while in transit.
Vermikil	E9SGCT005, E9SGCT008	Failure to comply with USP specifications for dissolution tests.
Abpara	28b05620	Severe adverse drug reactions.
Vet fungicare spray, vet tick clean spray, vet healer spray	All	Unregistered veterinary products.
Alzol-400	01619	Failure to comply with specifications for dissolution tests (international pharmacopeia).
Doxyrone	000780	Failure to comply with BP specifications for uniformity of dosage forms.
Spamcil	MO210, MO 211, MO 213, MO 214, MO 216, MO 218	Presence of brown lumps in the powder.
Gynozol ovules	201111, 201463, 201464, 201465	Capsules melt before use.

Ascorbic acid tablets	2001047	Color change of tablets from orange to brown.
Xymex drops	C90124	Formation of black/brown smudges inside the liquid.
Norotraz 12.5% 40ml	8265-501NKL, 8494-501NKL, 9133-501 NKL	Crystallization of liquid.
Fluphenazine decanoate injection usp 25mg/ml	70327	Stability study failure showing out of specification (OOS) for the impurity-free fluphenazine content.
Lidocaine injection 2%	GM804, GM805, GM809	Adverse drug reactions due to use of the product.
Unibrol	5806675 & 5806897	Color change of tablets from white to yellow.
Norotraz 12.5%	Resource codes: 151001000 & 151001100	Presence of crystalline particulate matter.
Ext set 200cm p-disc (g30402m) & gp series infusion set 2 ssy singles (60093e)	556518 & 1015275	Compromised sterility.
Endospec 10 % 1 litre batch numbers 1911013 and 1907042	1911013 and 1907042	Failure to comply with specifications for pH.
Medisolone syrup	MS 01.20	Relabeling of product batch number, manufacturing and expiry dates contrary to GMP requirements.

Most common observations

- Eighty four percent (21 out of 25) of the product recalls conducted for the year were audited.
- Eighty percent of the recalls were due to quality defects, 15% due to safety arising from adverse drug reactions and 5% was unauthorized (unregistered) drugs.

Reasons for recall

Figure 47: Reasons for recall of products

Eighty percent of the recalls were due to quality related defects mainly non-compliance with the specifications or labeling requirements.

80%

of the recalls were due to quality related defects mainly non-compliance with the specifications or labeling requirements.

Action taken

- Recalled products were destroyed.
- Actions taken following audit of the recalls are indicated in the Figure below;

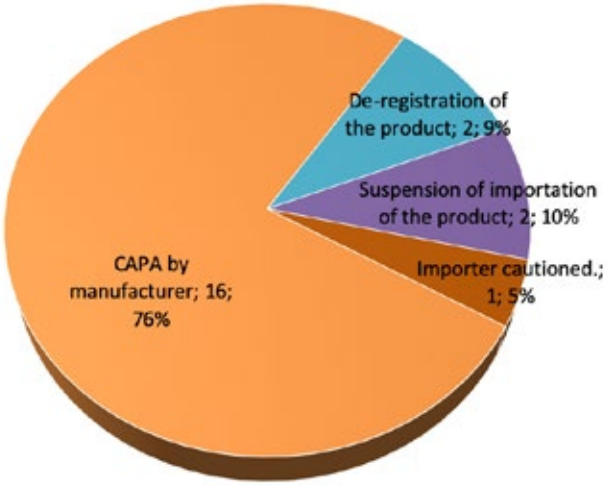


Figure 48: Actions taken following audit of recalls

Seventy six percent (16) of the 21 recalls audited resulted into corrective and preventive actions by the manufacturers, 10% (2) apiece resulted into resulted into de-registration and suspension of importation of the product and one resulted into a caution to the importer.

5.4 Market Surveillance statistics and results

The target for market surveillance in the July 2020 to June 2021 financial year was four surveillance operations (one per quarter). 4 surveillance operations were conducted; 3 in the July to December 2020 period and 1 in the January to June 2021 period.

Overall 100% (4) of the 4 surveillance operations were conducted.

In the January to June 2021 period, the surveillance operation focused on an exploratory study to assess the suitability of premises for storage of cold chain products. A total of 325 facilities were audited for cold-chain storage in the eight NDA regions.

A total of 325 facilities were audited for cold-chain storage in the eight NDA regions.

The statistics and results for market surveillance for the January to June 2021 period are summarised in Figures 49-56 below.

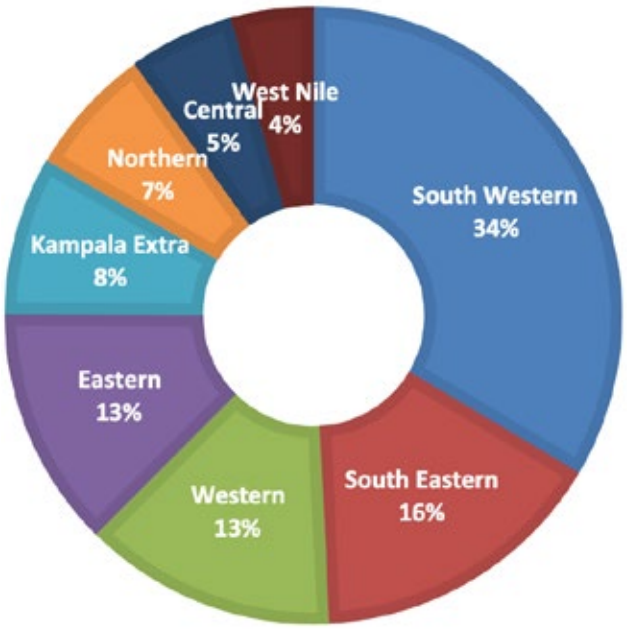


Figure 49: Distribution of facilities surveyed by region

A total of 33.54% were from South western, 15.69% from South Eastern, 13.23% from Western, and 12.62%, from Eastern. The others were Kampala Extra with 8.31%, Northern with 6.77%, Central region with 5.54% and West Nile with 4.31%.

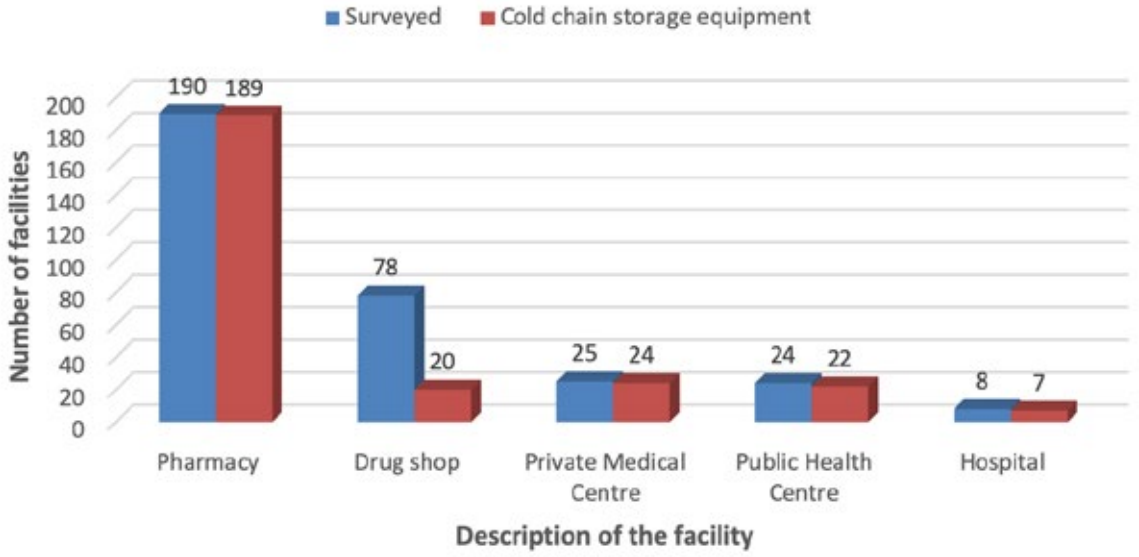


Figure 50: Distribution of health facilities surveyed by outlet type

The facilities surveyed included 190 pharmacies, 78 drug shops, 25 private medical centres, 24 public health centres and 8 hospitals.

The facilities surveyed included

190 pharmacies, **78** drug shops **25** private medical centres, **24** public health centres **8** hospitals

- Ninety-nine percent of the pharmacies surveyed, had at least one of the cold chain storage equipment seen in figure above. Only one did not have cold chain storage equipment yet they had cold chain products.
- Seventy four percent of the drug shops did not have and did not deal in cold chain products. The other drug shops (26%, n=20) were veterinary drug shops which had one of the forms of equipment indicated.
- Eighty-eight percent of the Hospitals visited which routinely handle cold chain products had equipment for handling those products. One hospital did not have the necessary equipment.
- Ninety six percent of the private medical centres surveyed had sufficient cold chain handling equipment whereas 4% did not have equipment yet they routinely handle cold chain products.
- Ninety two percent of the public health centers surveyed, had sufficient equipment to deal with cold chain products. 8% (n=2) of the health centers did not have equipment at the time of the audit.

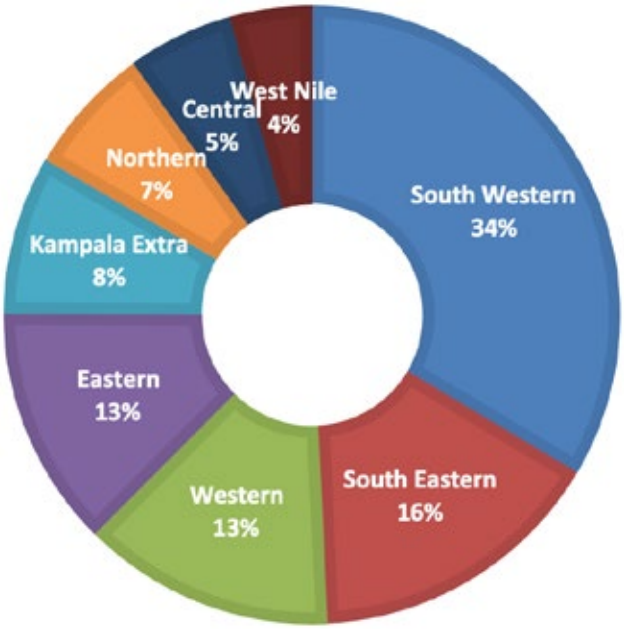


Figure 51: Cold chain storage facilities found

The facilities authorized to supply cold-chain products had a range of equipment used for this purpose. Refrigerators used alone were the most common equipment found in the premises accounting for 87.40% (229 of the 262 facilities), 10.31% (27 of the facilities) combined use of both the refrigerator and cold-boxes, whereas 1.53% (4) used a combination of Refrigerators, cold room and cold boxes. The remaining 0.76% (2) used only Cold boxes.

Refrigerators used alone were the most common equipment found in the premises accounting for 87.40% (229 of the 262 facilities), 10.31% (27 of the facilities) combined use of both the refrigerator and cold-boxes, whereas 1.53% (4) used a combination of Refrigerators, cold room and cold boxes.

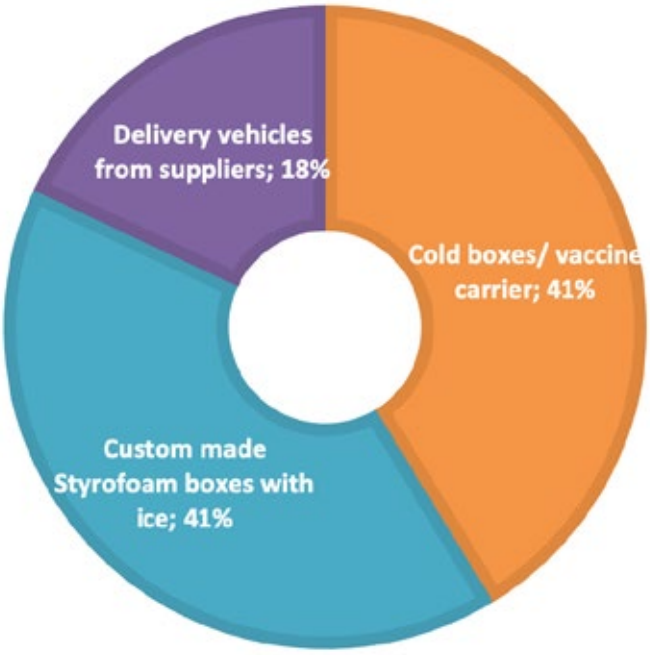


Figure 52: Equipment for delivery of cold chain products to pharmacies

The most common mode of transportation of cold chain drugs in the facilities visited was cold boxes/vaccine carrier (41.3%) followed by custom made Styrofoam boxes with ice (40.87%). The rest of the facilities (17.83%) reported that delivery vehicles from suppliers deliver the products.

The most common mode of transportation of cold chain drugs in the facilities visited was cold boxes/vaccine carrier **(41.3%)** followed by custom made Styrofoam boxes with ice **(40.87%)**.

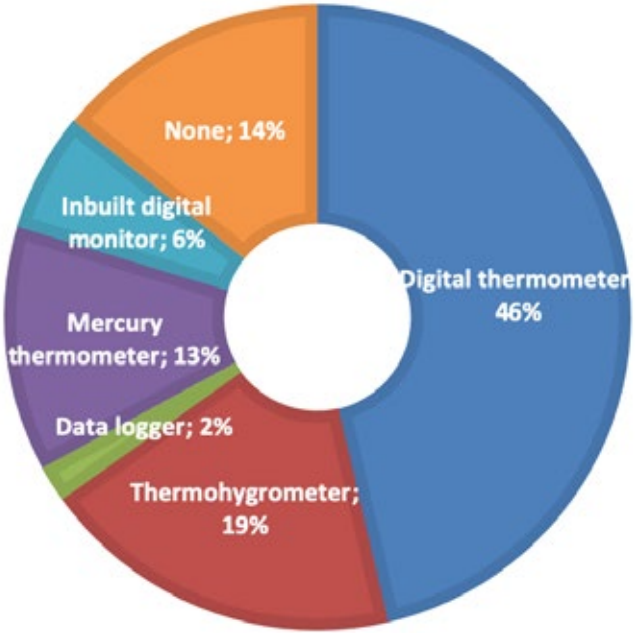


Figure 53: Types of temperature Monitoring Devices used

Temperature monitoring devices (TMDs) are used to monitor the cold chain storage conditions and to detect deviations for correction. In the surveyed facilities, digital thermometers accounted for 46.2% of commonly used thermometers, followed by Thermohygrometers comprising 18.8%. 14.3% of the facilities inspected did not have appropriate temperature monitoring devices.

In the surveyed facilities, digital thermometers accounted for **46.2%** of commonly used thermometers, followed by Thermohygrometers comprising **18.8%.**

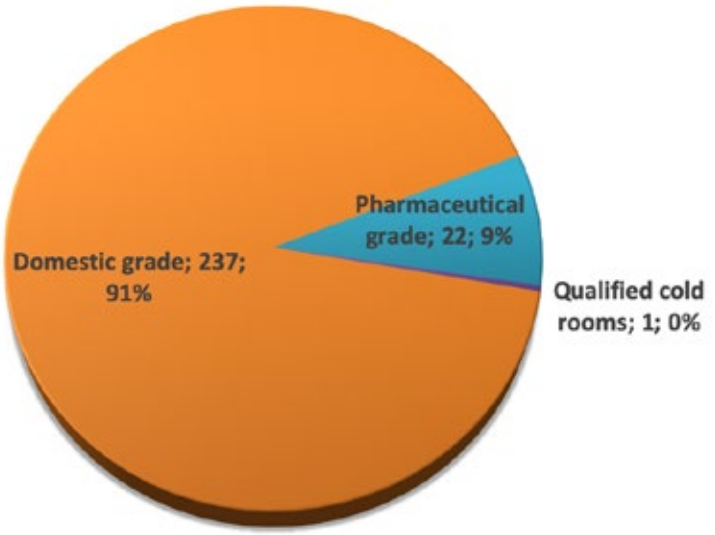


Figure 54: Types of cold chain facilities

Of the 260 facilities that had refrigerators , 237 (91.1%) used domestic grade refrigerators 22 (8.5%) had pharmaceutical grade refrigerators with alarm systems and 0.4% had qualified cold room.

91.1%

(237 of the 260 facilities that had refrigerators used domestic grade refrigerators to maintain the cold chain.

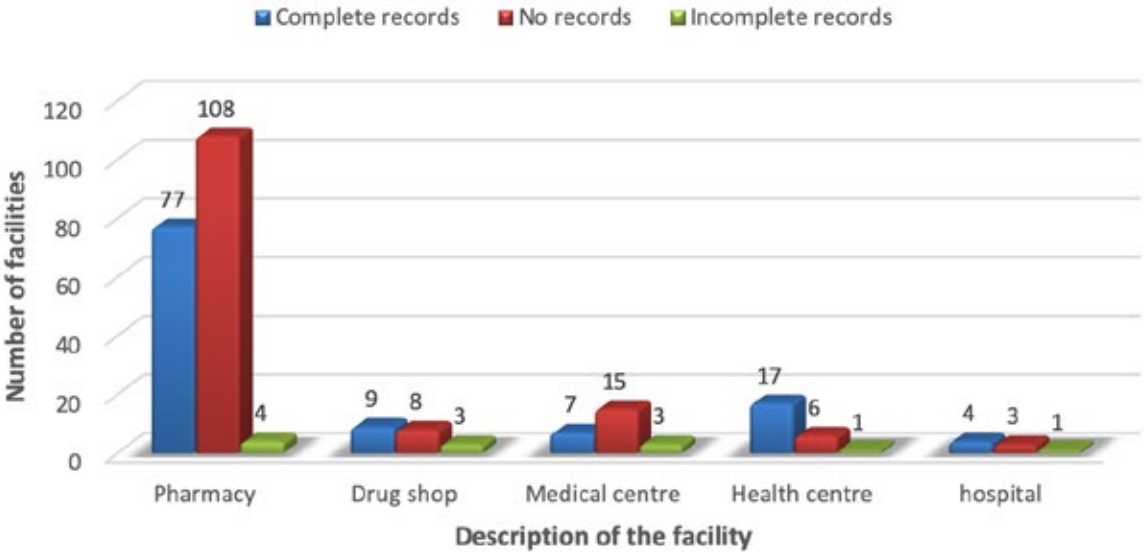


Figure 55: Cold chain monitoring records

Of the 266 surveyed facilities that dealt with cold chain products114 (42.9%) had up-to-date records of monitoring the cold chain; 52.6% did not maintain records of monitoring of storage conditions whereas 12 (4.5%) had incomplete records at the time of inspection.

42.9%

(114 of the 266 surveyed facilities that dealt with cold chain products) had up-to-date records of monitoring the cold chain; 52.6% (140) did not maintain records of monitoring of storage conditions whereas 4.5% (12) had incomplete records at the time of inspection.

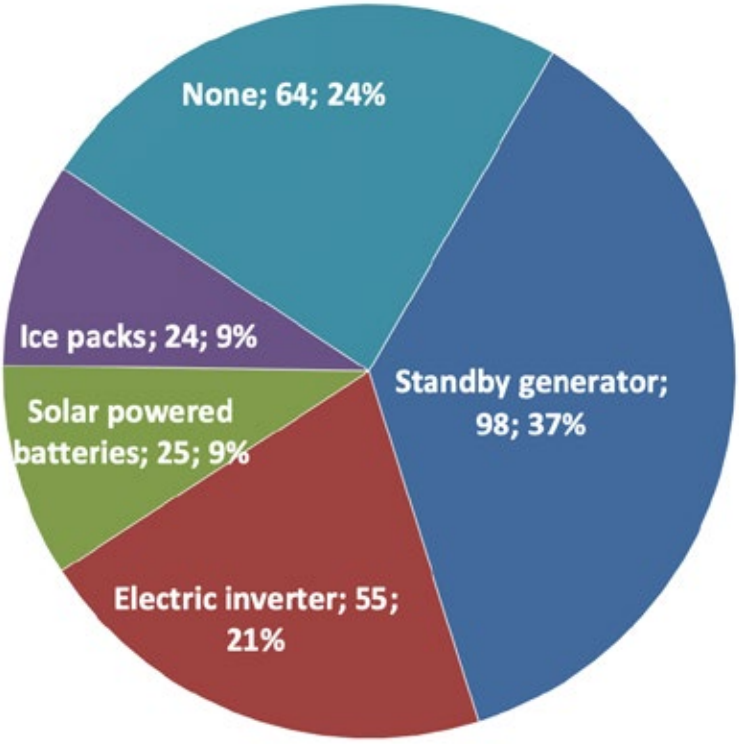


Figure 56: Power backup systems

Of the 266 surveyed facilities, 98 (37.0%) had standby generator, 20.6% had electric inverter, 9.4% had solar powered batteries and 9.1% relied on ice-packs as alternative (power back-up system) source of cooling. 23.9% of the facilities surveyed had no alternative power back-up system in the event of national grid failure.

37.0%
(98 of 266)

had standby generator, 20.6% had electric inverter, 9.4% had solar powered batteries and 9.1% relied on ice-packs as alternative (power back-up system) source of cooling

Actions taken

The observations were communicated to the inspected facilities for corrective and preventive actions. Follow up inspections will be conducted to verify the implementation of the corrective actions.

The Director Product Assessment and Registration leading a team of NDA officers on an engagement with URA

The Head of Regions and Manager, Imports and Exports interacting with inspectors and URA officials during support supervision at the ports of entry

6.0 CONTROL OF IMPORTS AND EXPORTS

The Directorate of Inspectorate and Enforcement is responsible for monitoring compliance and enforcement activities related to medicines and health products in order to verify that regulatory requirements are being applied appropriately. NDA has an MoU with the Uganda Revenue Authority (URA) that ensures that medicines and health products are released from the ports of entry with NDA's intervention.

All drugs imported into Uganda are required to meet the laws and regulations as set out by the National Drug Policy and Authority Act Cap 206. All drugs and medical devices are required to be safe, effective and of good quality with useful and truthful labeling in English.

Following an application for import or export through our online management information system (NDAMIS), medicines and healthcare products are subjected to a desk assessment prior to importation and a physical inspection upon arrival of the consignment into Uganda. Products may be refused entry if found, from inspection, laboratory testing or otherwise, to violate NDA requirements. Selected products are subject to sampling and testing due to a past history of violations or as part of the post market surveillance program and these are identified in the port of entry sampling memos.

After completion of the desk assessment, a verification certificate is issued and upon successful physical inspection, an imported goods authorization report is issued. The imported goods authorization report permits distribution and supply of the imported medicines and health products.

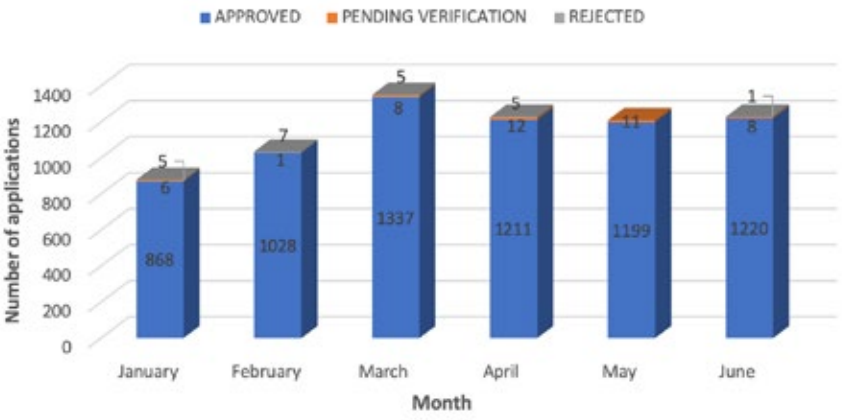
6.1 Verification statistics and results

The target for verification of imports/exports in the July 2020 to June 2021 financial year was all the applications received as per the service delivery timelines. 14,632 applications were received; 7,700 in the July to December 2020 period and 6,932 in the January to June 2021 period.

A total of 14,483 verifications were conducted; 7,597 in the July to December 2020 and 6,886 in the January to June 2021 period. Overall 99% (14,483) of the 14,632 verifications were completed.

Overall
99% (14,483)
of the 14,632 verifications were completed.

The verification statistics and results for the January to June 2021 period are summarised in Figures 57-63 below.



In the January to June 2021 period;
6,932
applications for verification certificates were received, 6863 (99%) were approved, 46 (0.7%) were pending verification and 23 (0.3%) were rejected.

Figure 57: Distribution of verification certificate applications by month

In the January to June 2021 period; 6,932 applications for verification certificates were received, 6863 (99%) were approved, 46 (0.7%) were pending verification and 23 (0.3%) were rejected. The month of March had the highest number of applications at 1,350 (19%) followed by June 1,229 (18%) and April 1,228 (18%). January had the lowest number of applications 879 (13%) followed by February 1,036 (15%) and May 1,210 (17%).

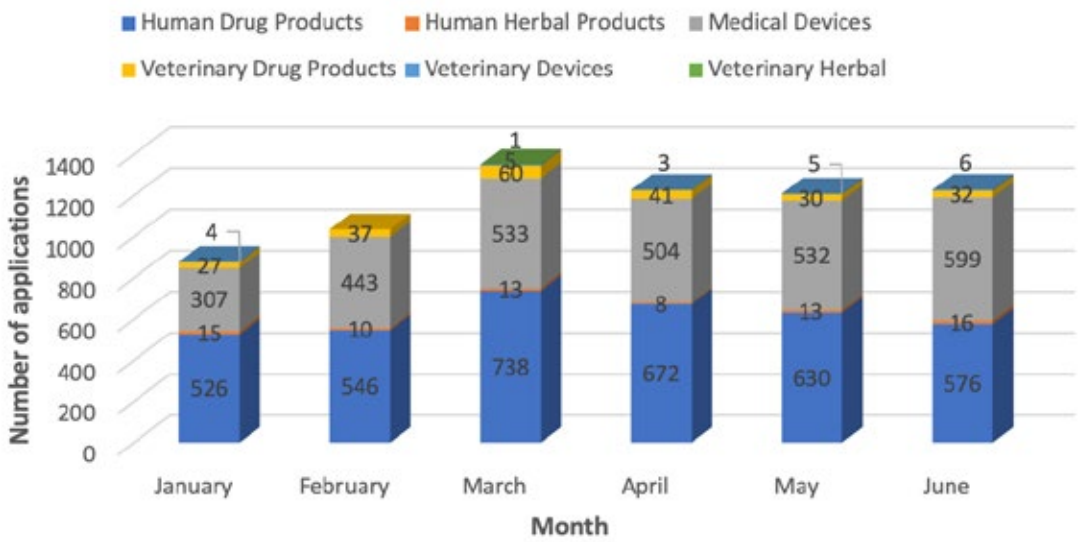


Figure 58: Distribution of verification certificate applications by product type

Of the 6,932 applications for verification certificates, 3,688 (53%) were for human drug products, 2918 (42%) for medical devices, 227 (3%) for veterinary drug products, 75 (1%) for human herbal products, 23 for veterinary devices and 1 for a veterinary herbal product.

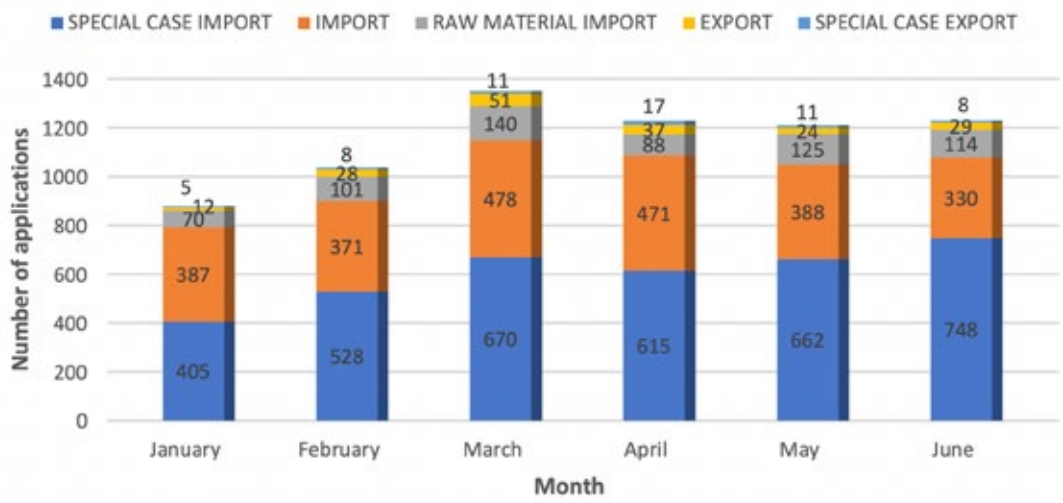


Figure 59: Distribution of verification certificate applications by permit type

Of 6,932 applications for verification certificates, 3,628 (52%) were special case import, 2,425 (35%) were ordinary import, 638 (9%) were raw material import, 181 (3%) were ordinary exports and 60 (1%) were special case exports.

Note: The following explains the different terminologies used in the above figure:

1. Special case import/export: These were applications for verification of products which were not registered in Uganda (mostly medical devices for which registration was being done in a phased manner).

3,628 (52%)

of the applications were special case import, 2,425 (35%) were ordinary import, 638 (9%) were raw material import, 181 (3%) were ordinary exports and 60 (1%) were special case exports.

2. Import/export: These were application for verification of products registered for sale in Uganda.
3. Raw material: These are applications for verification of materials for use in the manufacture of regulated products.

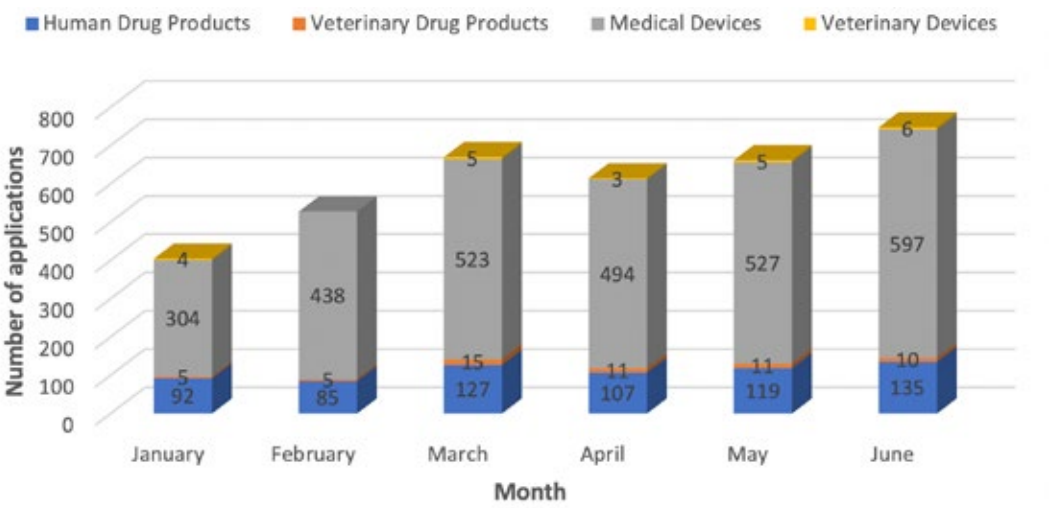


Figure 60: Distribution of Special case import applications for verification

Of the 3,628 applications for special case import verification certificates received, 2,883 (79%) were medical devices, 665 (18%) were human drug products, 57 (2%) were veterinary drug products and 23 (1%) were veterinary devices.

3,628

applications for special case import verification certificates were received, **2,883** (79%) were medical devices, **665** (18%) were human drug products, **57** (2%) were veterinary drug products and **23** (1%) were veterinary devices.

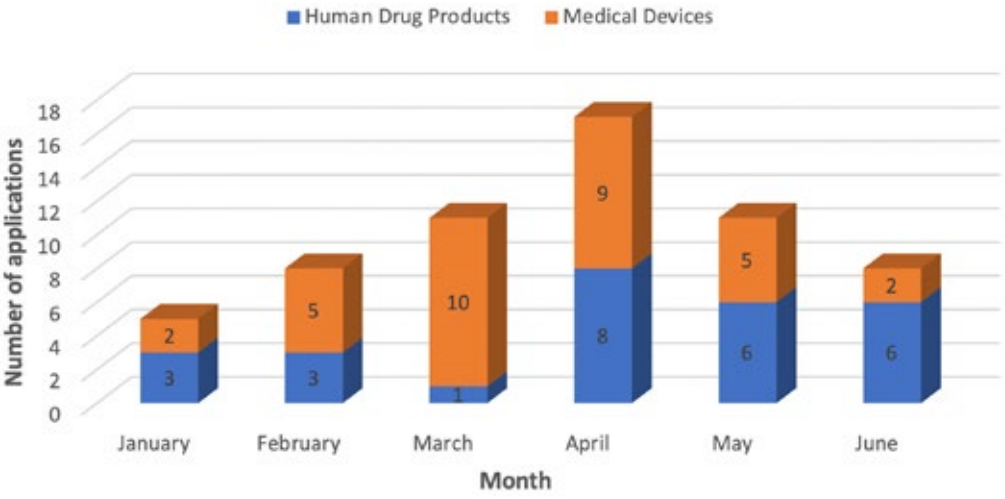


Figure 61: Distribution of Special case export applications for verification

Of the 60 applications for special case export verification certificates received, 33 (55%) were medical devices and 27 (45%) were human drug products.

60

applications for special case export verification certificates were received, **33** (55%) were medical devices and **27** (45%) were human drug products.

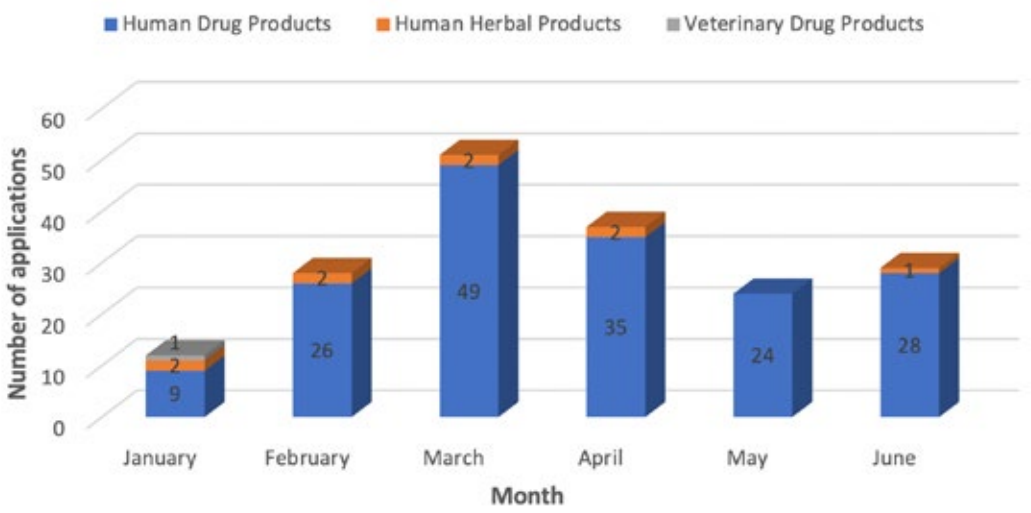


Figure 62: Distribution of export applications for verification

Of the 181 applications for export verification certificates received, 171 (94%) were human drug products, 9 (5%) were human herbal products and 1 (1%) was a veterinary drug product

181 applications for export verification certificates were received, 171 (94%) were human drug products, 9 (5%) were human herbal products and 1 (1%) was a veterinary drug product.

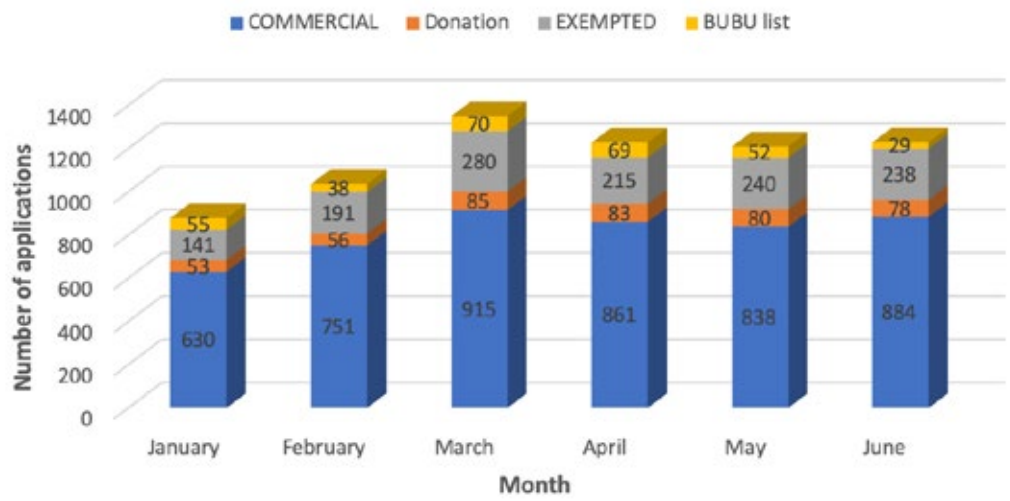


Figure 63: Distribution of verification certificates applications by reason for import/export

Of the 6,932 applications for verification certificates received , 4,879 (70%) were commercial consignments, 1305 (19%) were exempted, 435 (6%) were donations and 313 (5%) were on the BUBU list of products.

70% (4,879 of the 6,932) applications for verification certificates received were commercial consignments, **1305** (19%) were exempted, **435** (6%) were donations and **313** (5%) were on the BUBU list of products.

Note: The following explains the different terminologies used in the above figure:

1. Commercial: These were applications for verification of consignments for sale in Uganda.
2. Donation: These were applications for verification of consignments for donation.
3. Exempted: These were applications for verification of consignments which are exempted from verification fees.
4. BUBU list: These were applications for verification of consignments for products which are protected for local manufacture thus attract higher verification fees.

Most common observations

- Ninety-nine percent (6,863 of 6,932) of the verification certificates were approved; 87% (6,053) were for importation of finished products; 53% (3688) were for human drug products and 52% (3,628) were special case import.
- Seventy nine percent (2,883) of the applications for special case import verification certificates were for medical devices
- Seventy percent (4,879) of the applications for verification certificates were for commercial consignments

Action taken

Non-compliant verification certificate applications were rejected.

6.2 Ports of entry inspection statistics and results

The target for inspection of consignments at the ports of entry/exit in the July 2020 to June 2021 financial year was all the consignments received as per the service delivery timelines. A total of 9,561 consignments were received; 5,052 (5,044 import & 8 export) in the July to December 2020 period and 4,509 in the January to June 2021 period.

Overall 100% of the consignments received were inspected with 9,268 rated compliant and approved, 04 rated non-compliant and rejected, 99 queried and 190 conditionally released.

Overall 100% of the consignments received were inspected with 9,268 rated compliant and approved, 04 rated non-compliant and rejected, 99 queried and 190 conditionally released.

The statistics and results for port of entry inspection for the January to June 2021 period are summarised in Figures 64-68 below.

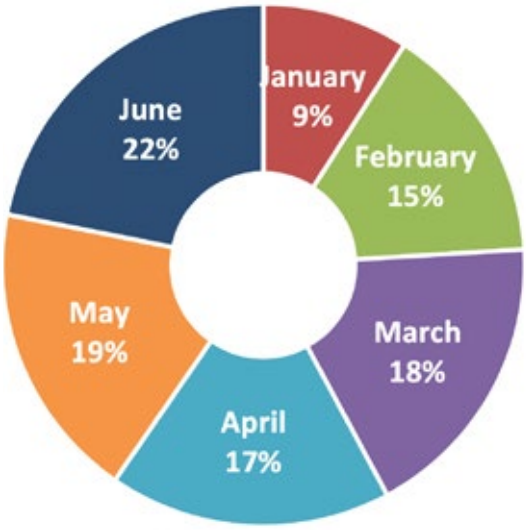


Figure 64: Monthly distribution of consignments inspected at the ports of entry

In the January to June 2021 period; 4,509 consignments of drugs and medical devices were received and inspected at the ports. 4,374 consignments were rated compliant and approved, three (03) were rated non-compliant and rejected, 54 were queried and 78 were conditionally released. The highest number of consignments was received in June (22%) followed by May (19%) while the least were in January (9%) followed by February (15%).

4,374 consignments were rated compliant and approved, three (03) were rated non-compliant and rejected, **54** were queried and **78** were conditionally released

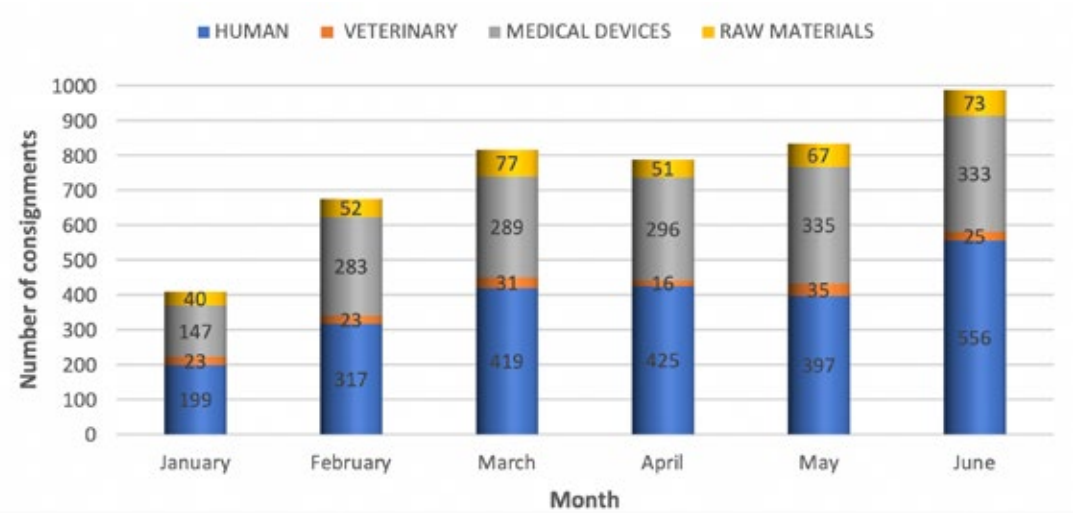


Figure 65: Distribution of consignments by product category

Of the 4,509 consignments received, 2,313 (51%) were for human drugs, 37% (1,683) for medical devices, 8% (360) for raw materials and 3% (153) for veterinary drugs.

51% (2,313) of the consignments were for human drugs, **37%** (1,683) for medical devices, **8%** (360) for raw materials and **3%** (153) for veterinary drugs.

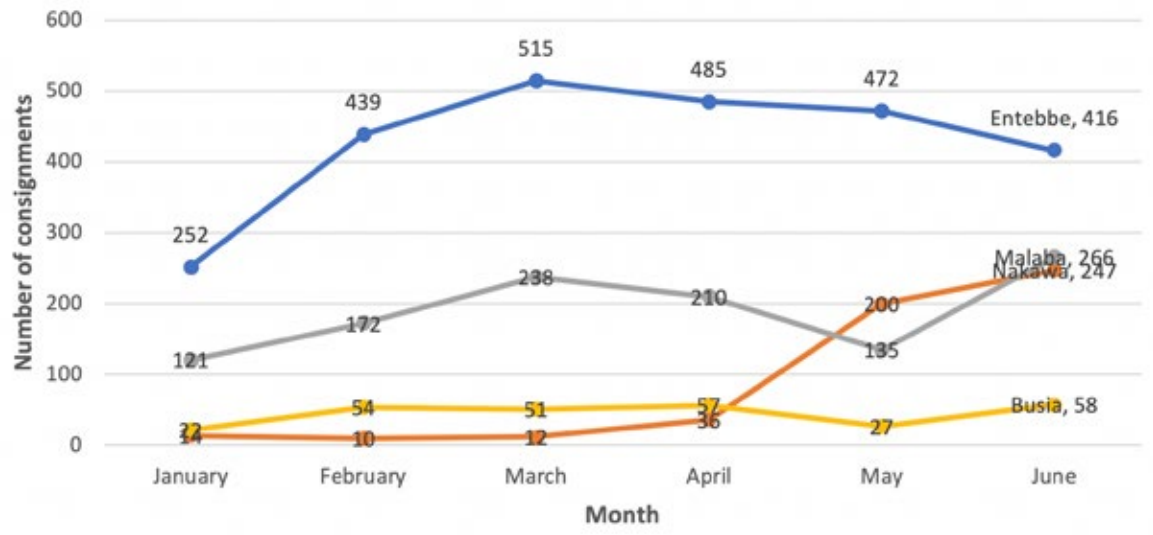


Figure 66: Trend of consignments received at ports of entry

Of the 4,509 consignments received, 2,579 (57%) were at Entebbe International Airport, 25% (1,142) at Malaba One stop border post (OSBP), 12% (519) at Nakawa and 6% (269) at Busia

57% (2,579)

of the consignments were at Entebbe International Airport, **25%** (1,142) at Malaba One stop border post (OSBP), **12%** (519) at Nakawa and **6%** (269) at Busia.

Note: A consignment is defined as contents of a single verification certificate whether delivered in part or in full.

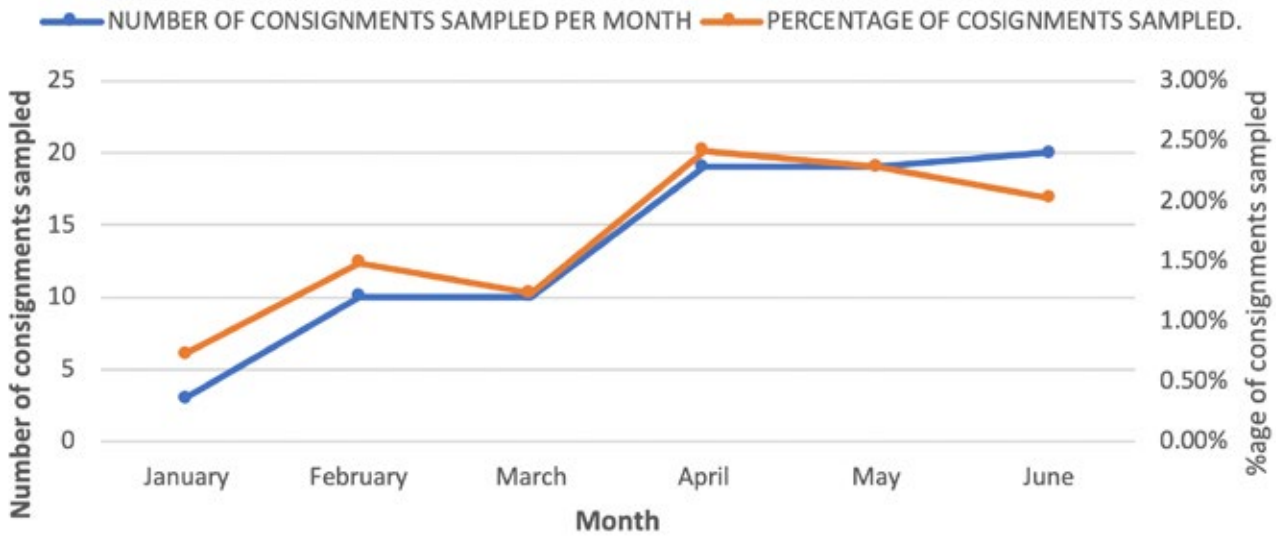


Figure 67: Trend of consignments sampled at the port of entry

The number of consignments sampled at the ports of entry increased over the 6 months from 3 to 20 while the percentage also increased over the same period from 0.73% in January to 2.41% by April 2021 then decreased slightly to 2.03% by June 2021. The percentage decrease is due to the increased number of consignments in May and June 2021.

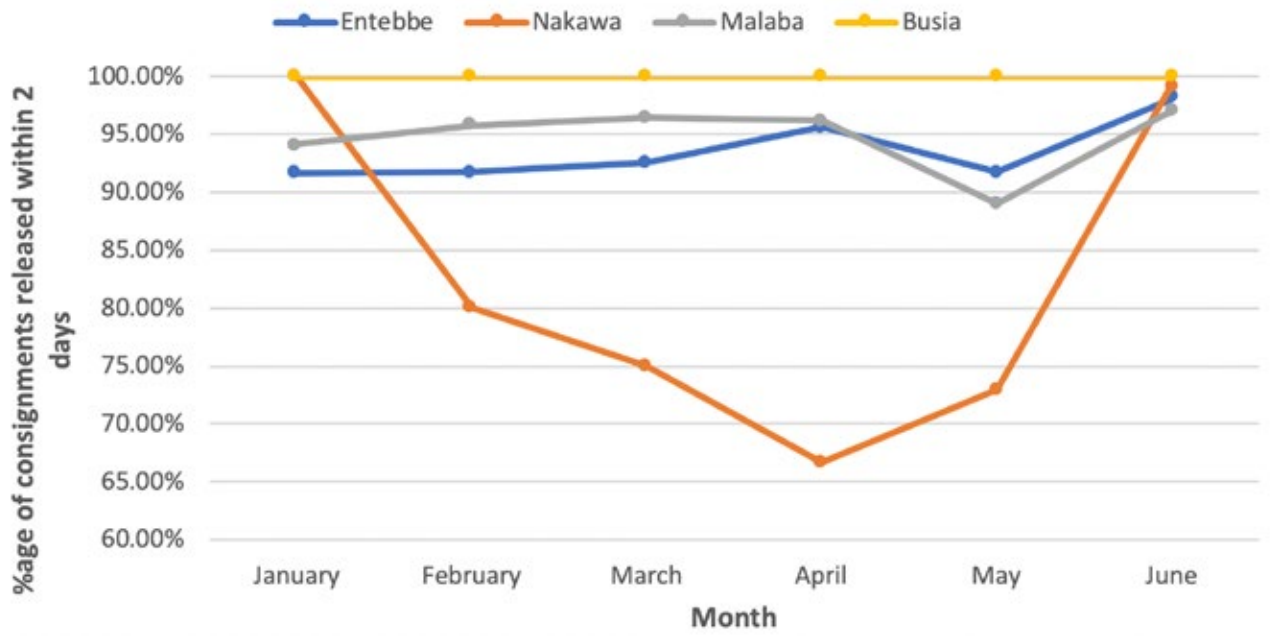


Figure 68: Trend of consignments released within 2 days

There was a slowdown in the release of consignments received and inspected through Nakawa port of entry over the period of January to June 2021, and this could be attributed to a change in the customs workflow during that time. The NDA inspection was carried out prior to processing of customs (IM4 -Entry for home use) assessments, after which some of the clearing agents took long to return to NDA for clearance due to travel challenges caused by the pandemic-related

restrictions.

6.3 Port of entry sampling statistics and results

The target for sampling at the ports of entry in the July 2020 to June 2021 financial year was 1,350 batches consisting of 400 conventional human drugs, 200 veterinary drugs, 200 samples of gloves, 450 samples of male latex condoms and 100 samples of Public Health Products (LLINS, Hand sanitizers & Face Masks).

982 samples were picked in the July to December 2020 period including 483 of human conventional drugs. The target for the January to June 2021 period was 451 batches consisting of 200 veterinary drugs, 86 male latex condoms, 97 gloves and 68 public health products. This was because the annual target for human conventional drugs was exceeded in first half of the year.

A total of 834 batches were sampled from the ports of entry consisting of 110 batches of conventional human drugs, 119 of conventional veterinary drugs, 452 batches of male latex condoms, 125 batches of gloves and 28 batches of public health products.

The overall sampling rate for port of entry was 135% (1,816) of the 1350 planned samples. 1,679 batches were tested with 1,637 compliant and 42 non-compliant thus the overall compliance rate for PoE samples was 97%.

The overall sampling rate for port of entry was 135% (1,816) of the 1350 planned samples. 1,679 batches were tested with 1,637 compliant and 42 non-compliant thus the overall compliance rate for PoE samples was 97%.

The statistics and results for port of entry sampling for the January to June 2021 period are summarised in Figures 69-70 below.

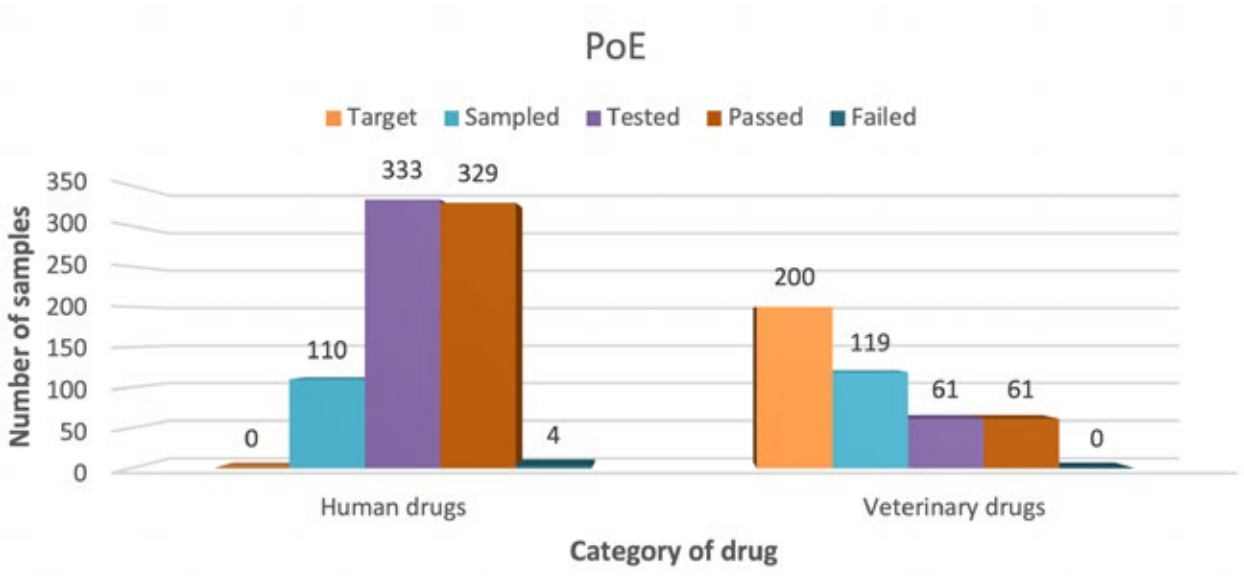


Figure 69: Distribution and compliance rating of ports of entry drug samples

The target for ports of entry drug sampling for the January-June 2021 period was 200 batches of veterinary drugs. 229 batches were sampled consisting of 110 batches of conventional human drugs and 119 of conventional veterinary drugs. A total of 394 batches were tested comprised of 333 batches of conventional human drugs and 61 of veterinary drugs. The overall compliance rate for port of entry drugs was 99% (390 of the 394 batches tested).

In the January to June 2021 period, **229** batches were sampled consisting of 110 batches of conventional human drugs and 119 of conventional veterinary drugs.

The overall compliance rate for port of entry drugs was **99%** (390 of the **394** batches tested).

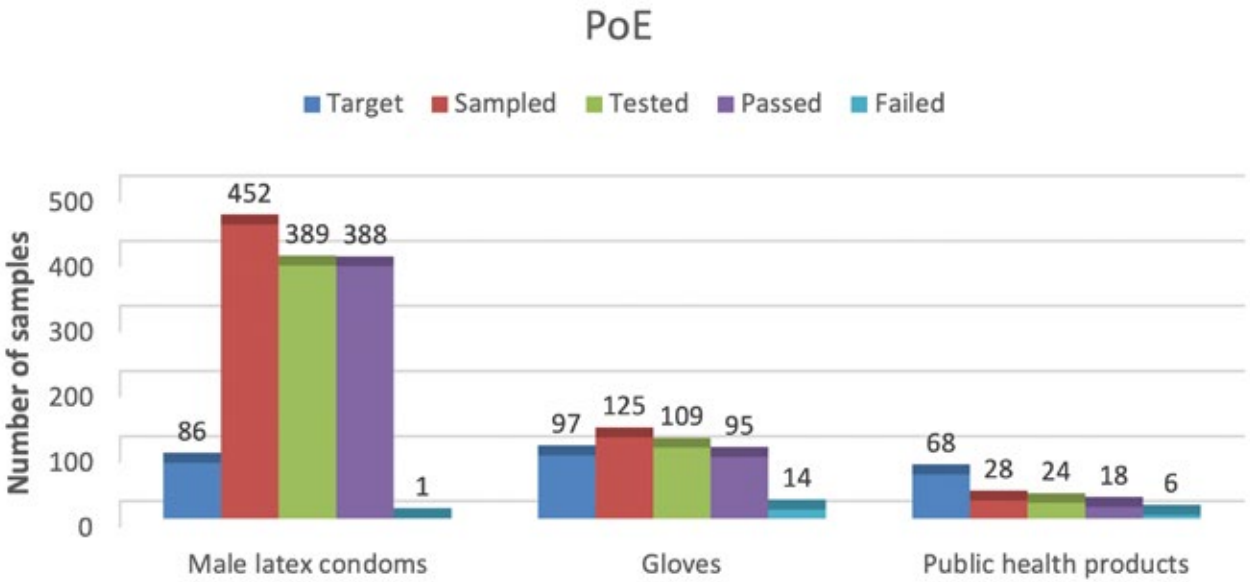


Figure 70: Distribution of other products sampled at the ports of entry

A total of 251 batches (including 86 of male latex condoms, 97 of gloves and 68 of public health products) were planned for the January - June 2021 period. 605 batches were sampled from the ports of entry consisting of 452 batches of male latex condoms, 125 batches of gloves, 28 batches of public health products. A total of 522 batches were tested comprised of 389 of male latex condoms, 109 batches of gloves, 24 batches of public health products. The overall compliance rate for other medical products was 96% (501 of the 522 batches tested).

605 batches were sampled from the ports of entry consisting of **452** batches of male latex condoms, **125** batches of gloves, **28** batches of public health products.

The overall compliance rate for other medical products was **96%** (**501** of the **522** batches tested).

Note: some of the tested batches were carried forward from the previous period and that explains the numbers of tested batches for surgical instruments.

Most common observations

The most common reasons for objection to import were;

- Products from manufacturing facilities with no evidence of GMP compliance acceptable to NDA.
- Unregistered products without evidence of marketing authorization in the country of origin.
- Donated products with a short shelf life.

Action taken on non-compliant

Non-compliant consignments were either queried for further investigation or rejected.

GDP Stakeholder meeting MBALE Wash and Wills Hotel

7.0 ENGAGEMENT OF STAKEHOLDERS

Generally, majority of the activities that NDA staff carry out on a day-to-day basis while in contact with clients form part of stakeholder engagement. Of particular interest and importance are the following: they reach several targeted individuals and require special arrangements/ plans.

- Sensitization meetings usually target a group of NDA stakeholders with a common background/ interest. The meetings are routinely scheduled to answer many commonly asked questions about a topic at hand, give feedback about previously fronted issues, update stakeholders about the status quo, i.e., in cases of change in guidelines or consultation with the stakeholders.
- Radio/ TV talk shows; are more often organized according to need since they are easier to organize and reach a vast range of stakeholders. They are mainly organized to throw more light at any NDA-related hot topic, with seasonal variations focusing on NDA visibility.
- Meetings with the District Assistant Inspectors; District Assistant Drug Inspectors are not NDA employees but form part of a collaboration NDA has with the local governments. So, it falls within the NDA mandate to equip them with the correct information that they can disseminate while back on duty in their respective districts. NDA synchronizes the information and work as a team towards ensuring the availability of safe, quality, and efficacious medicines to the whole of Uganda.

The relevance of all forms of stakeholder engagement include educating clients about their rights within the NDA's mandate. Informing them of new developments, echoing what is likely to be missed, simplifying processes and procedures, enabling clients to identify imposters, and, most importantly, improving NDA visibility efficiently.

7.1 Stakeholder engagement statistics and results

The target for stakeholder engagements in the July 2020 to June 2021 financial year was (130) 164 stakeholder engagement meetings and 84 radio/TV talk shows. 300 stakeholder engagement meetings and 76 radio/TV talk shows were conducted in the July to December 2020 period thus the target for the January-June 2021 period was 23 radio/TV talk shows. This is because the target for meetings was already exceeded in the first half of the year.

100 stakeholder engagement meetings (87 external stakeholder engagement meetings and 13 DADI meetings) and 46 radio/TV talk shows were held.

Overall 244% (400) of the 164 stakeholder engagement meetings and 123% (122) of the 99 radio/TV talk shows were held.

This was because some the stakeholder engagement meetings were increased by the Veterinary department's sub county sensitization meetings while the radio/TV talk shows were increased by the free shows provided by government through the public relations (PR) office.

Overall

244% (400)

of the **164** stakeholder engagement meetings and **123%** (122) of the 99 radio/TV talk shows were held.

The stakeholder engagement statistics and results for the January to June 2021 period are summarised in Figure 71 below.

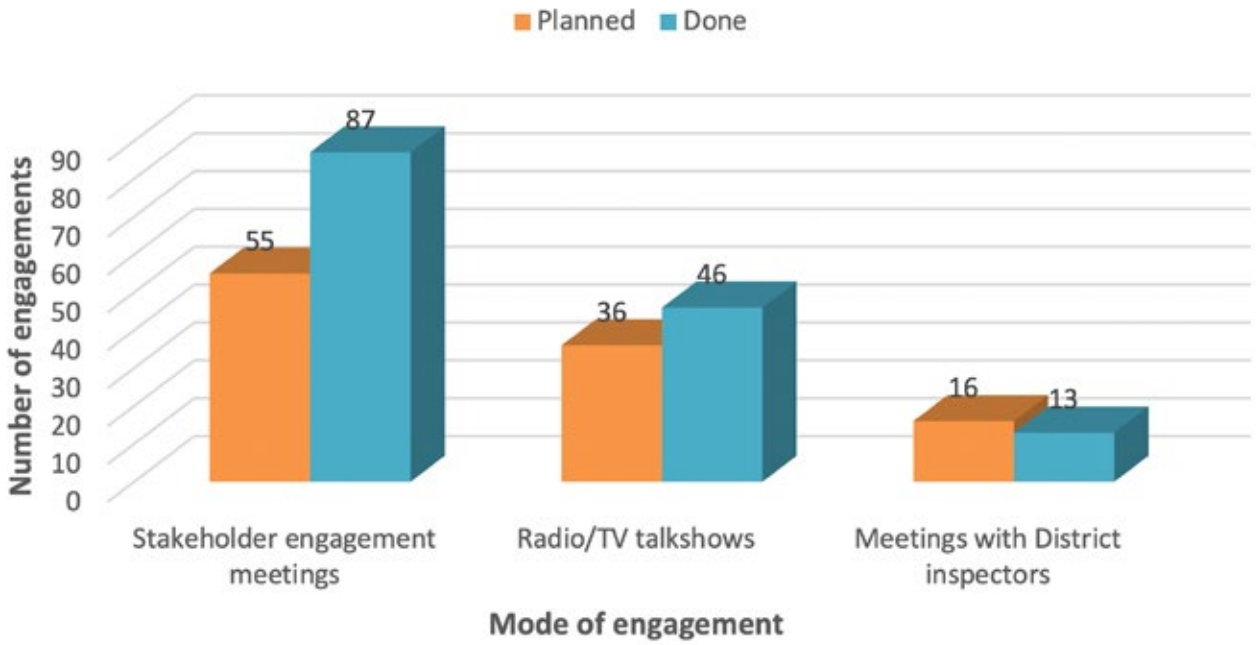


Figure 71: Summary of stakeholder engagement activities

In the January to June 2021 period, stakeholder engagement activities consisted of meetings with external stakeholders, meetings with the district assistant drug inspectors (DADI) and radio/ TV talk shows. The target for external stakeholder engagement meetings was 55, that for DADI's meetings was 16 while the target for radio and TV talk shows was 36. 87 external stakeholder engagement meetings, 13 DADI meetings and 46 radio and TV talk shows were held.

87

external stakeholder engagement meetings, 13 DADI meetings and 46 radio and TV talk shows were held.

Most common observations during stakeholder engagements

- Clarity on whether there is need to involve NDA in relocation of a licensed outlet.
- NDA's stand on Nursing Assistants still working in drug shops.
- Uncertainties about drug classification.
- Unscrupulous people who request funds on behalf of NDA.

Action taken

Clarity was provided as follows:

- All relocations of licensed premises must be applied for and approved by NDA prior to the relocation. The approval is based on the National Drug Policy and Authority (Licensing) (Amendment) Regulations 2021.
- Nursing Assistants were phased out of drug shops and should not independently work in the drug shops.
- The drug classification schedules were amended by statutory instrument, the latest being on 8th February, 2021. The new schedules are available on the NDA website.
- All payments to NDA are made in the bank and receipt given for future reference.

Authority members during a familiarisation tour of Kampala Extra region, Central region and Nakawa ports of entry.

Authority members during a familiarisation tour of Kampala Extra region, Central region and Nakawa ports of entry.

8.0 ENFORCEMENT

National Drug Authority inspects any premises or vehicle where it is suspected that an offence under the National Drug Policy and Authority Act has been or is being committed.

These enforcement visits help the directorate to identify illegal outlets and other offenders and take the actions necessary to ensure compliance with the Act and the regulations.

Enforcement operations are planned at the beginning of each financial year and incorporated in the directorate work plan and budget. Further enforcement operations depend on the outcome of the inspection and intelligence gathered about the existence of illegal operations.

8.1 Enforcement statistics and results

The target for enforcement in the July 2020 to June 2021 financial year was to conduct 8 enforcement operations, conduct enforcement action in line with inspectorate and intelligence recommendations (80%) and ensure that case files submitted to the Director of Public Prosecutions (DPP) are sanctioned for prosecution (80%).

In the July to December 2020 period; 5 enforcement operations were conducted, 13 of the 16 case files submitted to the DPP were sanctioned and 76% (32) of the 42 inspectorate/intelligence recommendations were implemented.

The target for the January-June 2021 period was 3 enforcement operations. 5 enforcement operations were conducted, 9 of the 11 case files submitted to the DPP were sanctioned for prosecution.

Overall, 125% (10) of the 8 enforcement operations were conducted, 81% (22) of the 27 cases submitted to the DPP were sanctioned and 79% (52) of the 66 inspectorate and intelligence recommendations were effected through enforcement actions.

In the 5 operations conducted in the January to June 2021 period; 3,540 outlets consisting of clinics, pharmacies, veterinary drug shops, herbal outlets and human drug shops were inspected during enforcement operations. 1349 were operating illegally and were either impounded or closed. A total of 1984 boxes were recovered from the impounded outlets.

South Eastern region had the highest non-compliance rate at 49% (279 of 567) followed by South Western at 44% (285 of 645) and West Nile at 40% (174 of 434). Western had the lowest non-compliance rate at 31.9% followed by Central at 32.4%.

The enforcement statistics and results for the January to June 2021 period are summarised in Figures 72-73 below.

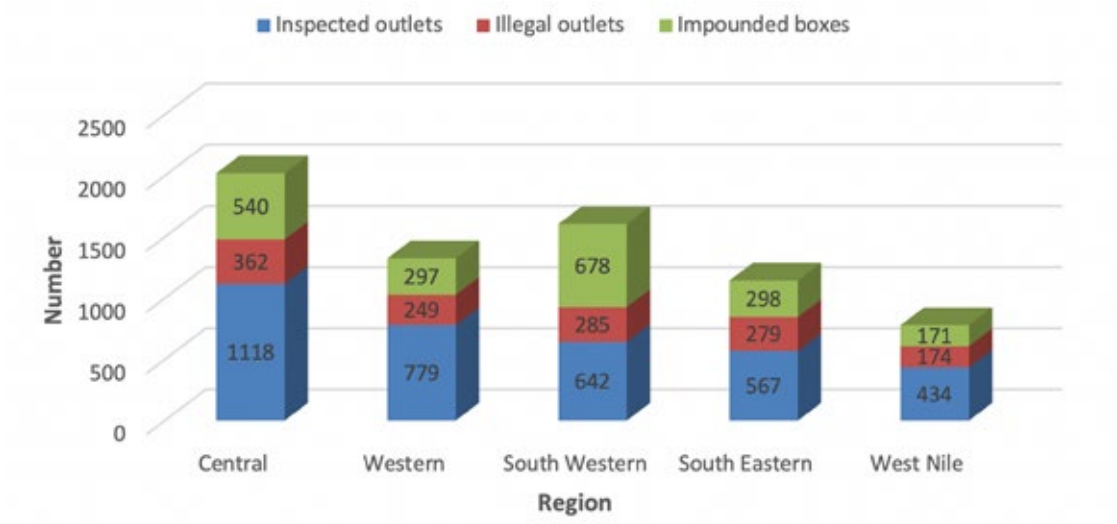


Figure 72: Distribution of outlets visited during enforcement operations

32% (1118 of 3540) of the facilities inspected during inspection were in Central region, followed by 22% (779) in Western region and 18% (642) in South Western region. South Western had the highest number of impounded boxes at 678; this was because one illegal outlet in Mpondwe town council had big stock which accounted for two Hundred eighty-eight (288) of the boxes impounded

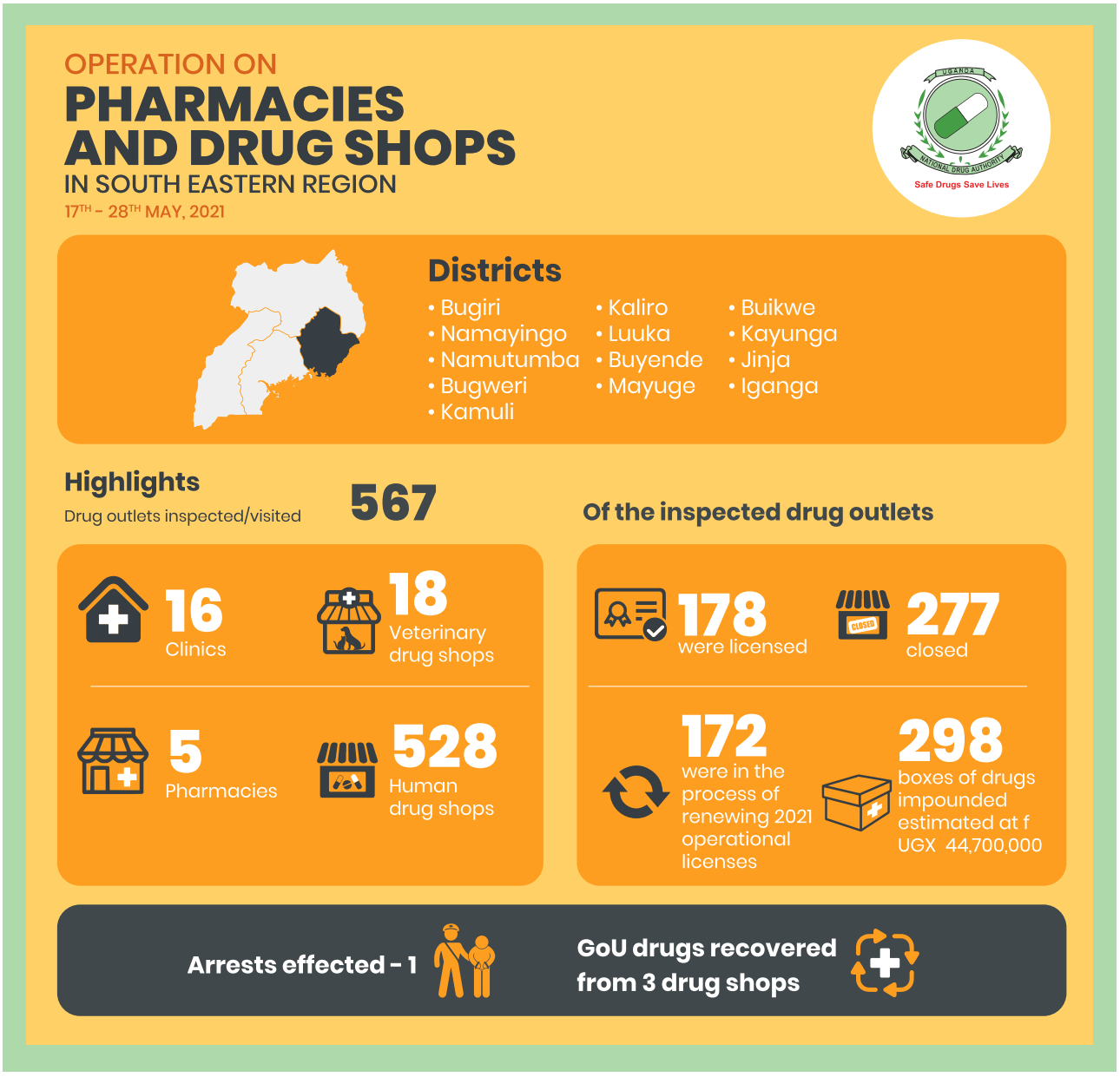


Figure 73: Summary of the enforcement report for South Eastern region

Of the facilities inspected in the South Eastern region, 93.1% were human drug shops, 18 were veterinary drug shops, 16 were medical clinics and 5 were pharmacies.

Most common observations

1. Rampant closure of outlets in various trading centers. Most centers known for illegalities were found closed during the operation.
2. Manning of drug shops by unqualified persons.

Actions taken on non-compliant

- Eleven case files were opened at Police for prosecution of the offenders.
- Nine of the 11 files were sanctioned by the Director of Public Prosecution.
- Two convictions were secured. Other court cases were ongoing.

Items impounded during an enforcement operation

9.0 DISPOSAL OF PHARMACEUTICAL WASTE

The Directorate supervises the destruction of expired, recalled, substandard and obsolete pharmaceuticals to ensure that they are safely disposed of. Applications are expected from both public and private pharmaceutical handling facilities including pharmacies, clinical trial sites, clinics, medical centers and hospitals. The Directorate also supervises the destruction of internally generated pharmaceutical waste (from the Directorate of Laboratory Services, NDA enforcement activities and items impounded at ports of entry that are not claimed).

9.1 Disposal statistics and results

The target for disposal of pharmaceutical waste in the July 2020 to June 2021 financial year was all the applications received as per the service delivery timelines. 160 applications for disposal of pharmaceutical waste were received; 81 in the July to December 2020 period and 79 in the January to June 2021 period.

All the applications were supervised for the requisite disposal. Overall 100% (160) of the 160 applications for disposal were inspected.

Overall
100% (160)
of the 160 applications for disposal were inspected.

In the January to June 2021 period; 79 applications for the supervision of destruction of pharmaceutical waste were received and processed. In total 1,442,354.10 kg of pharmaceutical waste was destroyed in the Jan-June 2021 period.

In total
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pharmaceutical waste was destroyed in the Jan-June 2021 period.

The disposal statistics and results for the January to June 2021 period are summarised in Figures 74-75 below.

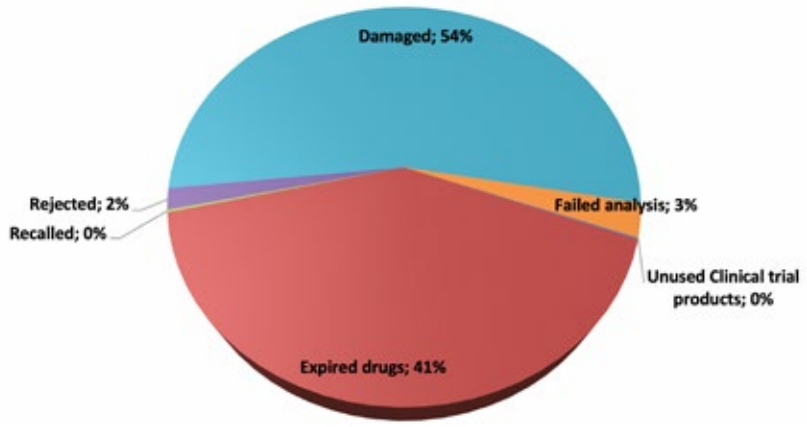

Figure 74: The quantity of drugs disposed of with the reason for destruction

54% of the disposed drugs were damaged, 41% expired, 3% failed analysis and 2% were rejected. A small quantity was due to unused clinical trial and recalled products.

54%

of the disposed drugs were damaged, 41% expired, 3% failed analysis and 2% were rejected.

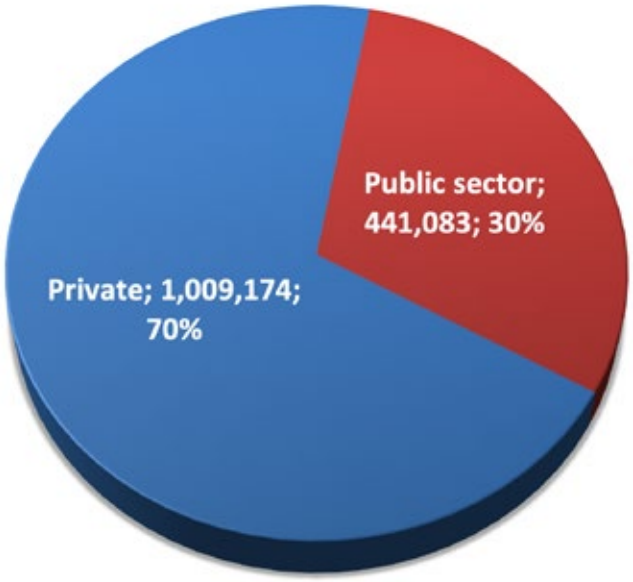

Figure 75: Sources of disposed pharmaceutical waste

Of the 1,442,354.10kg of pharmaceutical waste received for destruction, 1,009,174kg (70%) was from private sector; including 786,340 kg from the Joint medical store burnt warehouse at Madhivani complex industrial area. The 30% from the public sector includes the 7,903 kg of laboratory waste from the National Drug Authority Directorate of Laboratory Services (utilized sampled products after analysis).

70% (1,009,174 kg)

of the pharmaceutical waste was from private sector;

Head Enforcement leading his team on a ferry to Kalangala district

The Head of Enforcement and the Manager, South Western region assessing the drugs impounded during an enforcement operation

10.0 PRIORITIES MOVING FORWARD

1. Strengthening systems for ensuring the quality of medicines on the market:
The Directorate has strengthened the systems for ensuring the quality of medicines on the Ugandan market through a deliberate initiative to foster compliance with good distribution practices among wholesale pharmacies and good pharmacy practice among retail pharmacies in Uganda, through the routine inspection of these premises against NDA guidelines for GDP and GPP respectively. This is a routine activity that is undertaken throughout the calendar year with the aim of fostering continuous improvement among actors in the distribution chain. Furthermore, the statutory instrument for the control of transportation of drugs and the guideline for online supply of drugs are in draft phase and are undergoing public consultation. It is envisaged that the two documents will establish a regulatory framework that ensures quality of medicines are maintained during transportation and online supply respectively.

2. Automation of business processes:
Automation of all business processes remains a key priority for the National Drug Authority. This is in an effort to better serve our clients with efficiency and to meet the expectations of doing business in the current digital world, but also to allow for the generation of data and analytics. The Directorate automated its import control and licensing of premises regulatory functions in the year 2017, with updates on these modules to improve their functionality currently being undertaken.

The GMP module is currently under development and expected to be fully functional within a couple of years. Once fully functional, it is expected that this automation enhancement will improve the ease of doing business for our clients, but also enable the Directorate to generate important data that may be used to improve decision making and the quality of our services.

3. Risk-based approach:
The adoption of a risk-based approach to all key regulatory activities is of high-level importance in ensuring the appropriate use of the Directorates` limited resources to achieve the highest level of impact. The risk-based approach is already practiced during the inspection of manufacturing facilities. However, an all-inclusive and consistent approach is required to ensure all activities are approached in this manner. Consequently, the Directorate is in the process of revising its standard operating procedures in order to incorporate a risk-based approach in the conduct of its activities. This is envisaged to ensure that the limited resources of the Directorate yield the most impact.

4. Support to the domestic pharmaceutical industry:
The Directorate is committed to ensuring sustainable domestic production of quality essential medicines in Uganda. As part of this initiative, the Directorate has supported the set up and licensing of two domestic manufacturers; East African Medical Vitals Limited (EAMVL), licensed to manufacture surgical and examination gloves, and Sanga Vet licensed to produce veterinary pharmaceutical products including acaricides.

Furthermore, the Directorate routinely inspects all domestic manufacturers to ensure they are complaint with the Good Manufacturing Practice guidelines. The Directorate will work with all manufacturers to put in place a GMP compliance road map for all manufacturers that need to implement continuous improvements at their manufacturing premises. This will ensure the standards of the domestic manufacturers is lifted continuously towards full compliance with GMP.
Regarding herbal medicines, the Directorate is actively engaging domestic herbal manufacturers through sensitization meetings, trainings and routine inspections to uplift the

standards of their manufacturing premises and also improve the quality of their products.

5. Evidence based decision making:
The Directorate has prioritized the use of evidence-based decision making to support its regulatory policies, decisions and activities. Accordingly, the Directorate is currently undertaking research in collaboration with the NDA research unit into the impact of the 12 percent verification fees on the domestic pharmaceutical industry. Once completed and published, the evidence from this piece of research will be used to guide the policies made to support the growth of the domestic pharmaceutical industry.

Additionally, the Enforcement Department of the Directorate is focusing its efforts more on intelligence guided operations to deal with counterfeit, smuggled and substandard medicines. This has enabled the department lead successful enforcement operations and effectively deal with this vice. The Directorate will continue to use information, research and intelligence in its routine operations.

6. Leveraging local, regional and international partnerships and cooperation:
The covid-19 pandemic has severely hampered efforts in this area due to the restricted travel opportunities that have affected meetings and collaborative activities. Nevertheless, the Directorate has continued to engage in several regional and international online activities aimed at promoting collaboration with key stakeholders, including but not limited to; EAC meetings and activities, WHO collaborative procedures for medicines registration and IGAD medicines harmonization initiative.

The Directorate has also been working closely with the WHO to address the gaps identified in its regulatory framework during the most recently conducted WHO benchmarking exercise conducted in 2019.

7. Technical capacity building of staff:
The NDA Strategic Plan 2021-2025, strategic objective 4 mentions, "to strengthen NDA institutional capacity to effectively and efficiently implement its functions". In line with this provision, the Directorate of Inspectorate and Enforcement has identified key skills and knowledge areas of training that the Directorate will focus on for this strategic period in order to ensure the training of its staff in a structured manner in various regulatory and support function areas that will ensure a competent Directorate that is able to address the evolving and dynamic needs of regulation.

The training areas are highlighted below, and the Directorate shall provide regular updates on its implementation throughout the strategic period 2020-2025.

- Regulatory Officers in Licensing: skills in public health, pharmaceutical policy and regulation
- GMP Inspectors: skills in pharmaceutical technology, pharmaceutical analysis, pharmaceutical microbiology, medical gases testing, pharmaceutical sciences, pharmaceutical engineering, biotechnology, vaccinology, biopharmaceuticals.
- Regulatory Officers in PMS: skills in public health and drug regulatory affairs
- Regulatory Officers in the Import and Export Unit: skills in quality assurance and regulation, drug regulatory affairs.
- Regulatory and Police Officers in the Enforcement Unit: skills in investigative interviewing skills for law enforcement, law enforcement management and leadership, improving police and community relations, processing evidence in criminal investigation, emotional intelligence and creative reframing skills for innovative policing, training in detection and response to counterfeits.
- Regulatory Officers in the Medical Devices Unit: ISO 13485 certification, Regulatory Affairs Professionals Certification.
- Administrative Officers and Officers in leadership positions: skills in leadership, management or business administration.

The Director Inspectorate and Enforcement leading a team of NDA officers during the launch of Assessment Training Package (ATP) for the occupation of herbalist by the Directorate of Industrial Training (DIT)


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Central Region +256 312 261 584
South Eastern Region +256 434 122 176
Eastern Region +256 454 445 195
Northern Region +256 473 420 652
Western Region +256 465 440 688
South Western Region +256 485 421 088
West Nile Region +256 372 260 087

Med safety mobile app druginfo@nda.or.ug

Toll free:0800 101 999 0740 00 20 80

www.nda.or.ug