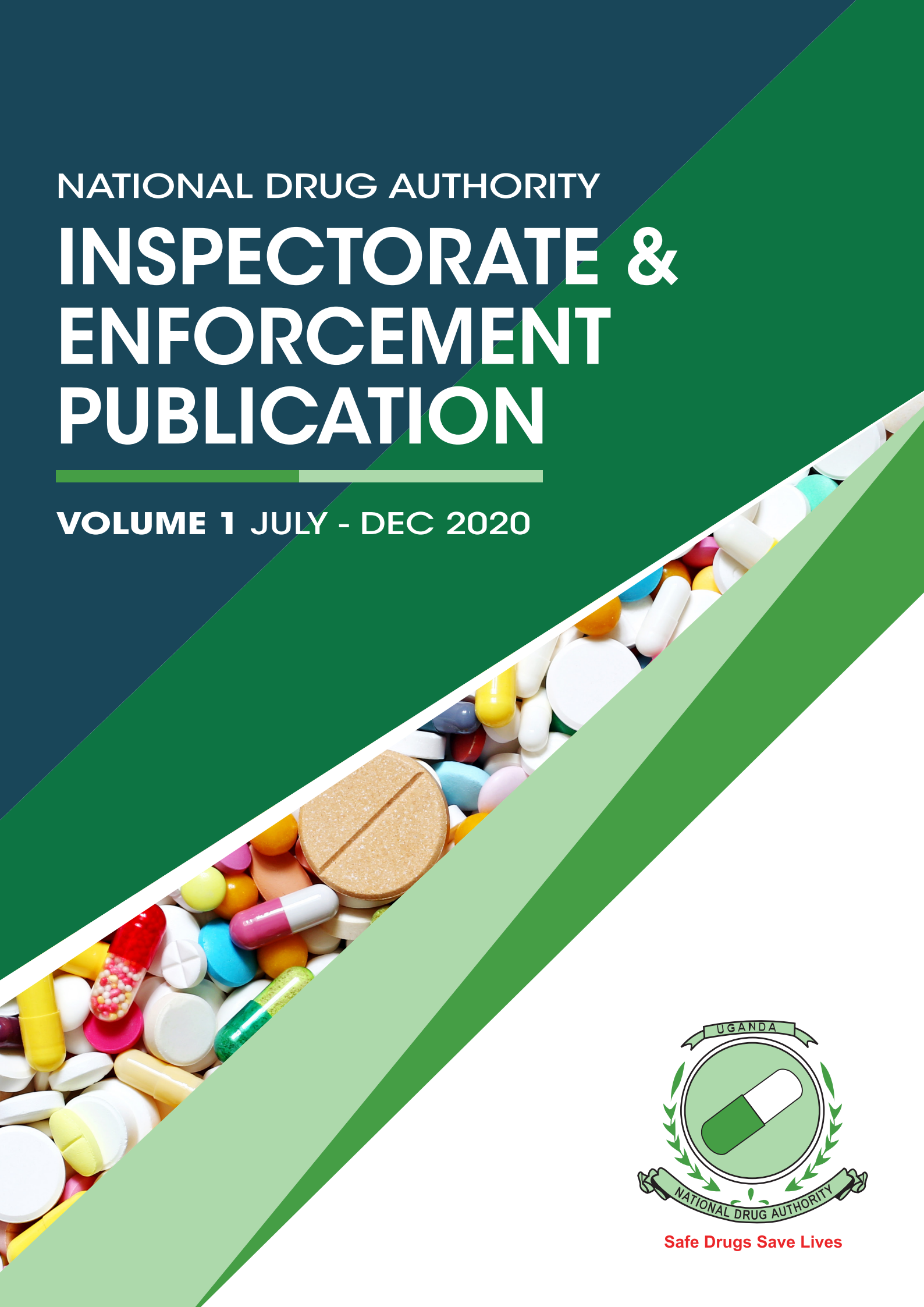
NATIONAL DRUG AUTHORITY

INSPECTORATE & ENFORCEMENT PUBLICATION

VOLUME 1 JULY - DEC 2020



UGANDA

NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

The Secretary to the Authority at the commissioning of East Africa Medical Vitals (manufacturers of both surgical and examination gloves

NDA management providing technical guidance to Domestic manufacture

MESSAGE FROM THE SECRETARY TO THE AUTHORITY

On behalf of the Authority, I am happy to present to you this report that highlights the results of the directorate of inspectorate and enforcement for the first half of the financial year 2020/2021. This performance report of the Directorate of Inspectorate and Enforcement, provides a detailed accountability of our commitment towards ensuring that the citizens of Uganda access only safe, effective and quality medicines.

This period has been challenging globally with the out-break and rapid spread of the COVID-19 pandemic which tremendously challenged the healthcare systems including the drug regulatory systems. Amidst these challenges, the National Drug Authority (NDA) has demonstrated flexibility and adaptiveness in dealing with pandemic-related challenges. Despite the challenges, new opportunities have arisen out of adversity. For instance, the country has seen a significant rise in the number of domestic pharmaceutical and

medical device manufacturers, which offer us an opportunity to secure the supply chain for quality essential medicines and consumables. At the same time, it has created employment opportunities and supported import substitution of medical products.

The Directorate of Inspectorate and Enforcement supported the work of the Authority by monitoring and certifying compliance to the established national drug regulatory standards, as well as providing technical assistance to domestic manufacturers. This report highlights the contribution of the Directorate in the achievement of our strategic objectives over the first half of the financial year 2020/2021, and points out potential opportunities for improvement going forward.

As an organisation, we are looking towards streamlining our processes and adopting evidence-based decision-making approaches to regulation. In addition, we look forward to strategically leveraging our stakeholders' participation in promoting regulatory compliance. Further to this, we encourage research and development of herbal medicines and promote local production of essential drugs.

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 Authority and the leadership of the Ministry of Health for the support and guidance granted to us in the execution of NDA mandate. I also appreciate all our stakeholders, professional bodies, the pharmaceutical industry, strategic and development partners.

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

For God and my Country

David Nahamya
SECRETARY TO THE AUTHORITY

“As an organisation, we are looking towards streamlining our processes and adopting evidence-based decision-making approaches to regulation.”

FOREWORD FROM THE DIRECTOR, INSPECTORATE AND ENFORCEMENT

I am delighted to present to you the first comprehensive publication of the Directorate of Inspectorate and Enforcement, aimed at shining a spotlight at our work and results for the first half of financial year 2020/2021. This publication has been prepared with a view of giving our stakeholders and the public an account of our efforts in protecting public health as envisaged in the National Drug Policy and Authority Act, and to make good on our commitment to be transparent and accountable to the people of Uganda.

In many ways, our work for the first half of FY 2020/2021 was largely affected by the organisation's response to the COVID-19 pandemic, and this report is evidence of the sacrifice and hard work that our field and office teams in the Directorate of Inspectorate and Enforcement were able to endure to uphold the implementation of the NDA mandate in the face of the public health crisis. Like many organisations, NDA was able to adapt to the rapid changes brought about by the pandemic, to continue to provide the necessary support to stakeholders, communities, and the public. I appreciate every member of our team for contributing in various ways towards ensuring the fulfilment of our Vision: A Uganda with safe, efficacious and quality medicines and healthcare

products". I also appreciate the resilient efforts and sacrifice made by frontline health workers who have had to continue to step forward in the noble pursuit of saving and preserving lives.

Despite the disruptions associated with the COVID-19 pandemic, the directorate has posted resilient performance in the areas of licensing, manufacturing, import/export control, post-market surveillance and enforcement, through implementing the Authority's mandate in regulation of pharmaceuticals across the distribution chain.

As a directorate, we believe in continuous improvement to further consolidate our gains and improve our performance. Moving forward, we shall be focusing on strengthening systems for ensuring the quality of medicines on the market including compliance to Good Distribution Practices, controlling the transportation of drugs, establishing a regulatory framework for online supply of drugs, enhancing automation of business processes, and deepening the use of risk-based approaches to medicines regulation.

We will also support domestic production of essential drugs; encourage the development of herbal medicines; build the technical capacity of our staff; and leverage the local, regional and international partnerships and cooperation.

I take the opportunity to thank the Authority and Management of NDA for creating an enabling environment for the directorate to deliver the results published in this report. I would also like to wholeheartedly thank the Directorate staff for their dedicated work and commitment during this period amidst a myriad of challenges.

I thank you.

For God and my Country

Denis William Mwesigwa
DIRECTOR, INSPECTORATE AND ENFORCEMENT

"As a directorate, we believe in continuous improvement to further consolidate our gains and improve our performance."

EDITORIAL

National Drug Authority was established in 1993 by the National Drug Policy and Authority (NDP/A) Statute which in 2000 became the NDP/A Act Cap 206 . The objective of the National Drug Authority is to ensure availability, at all times, of essential, efficacious, and cost-effective drugs to the entire population of Uganda as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs. The legal framework for drug regulation is also embedded in the National Veterinary Drug Policy, whose vision is to have quality veterinary drugs accessed by all stakeholders for sustainable animal health and production. Pursuant to this mandate, National Drug Authority put in place a strategic plan. The 2016-2021 strategic plan focused on three priority areas of safety, efficacy, and quality; collaborations and partnerships; and institutional capacity.

As the enforcement arm of the Authority, the Directorate of Inspectorate and Enforcement is responsible for delivering compliance monitoring and enforcement of these priority areas. The directorate achieves this mandate through a number of core activities (see table 1 below). These activities were integrated into annual work plans which were approved with the budget. The annual work plans were further subdivided into quarterly workplans.
This report showcases the accomplishments and the challenges faced during the first two quarters of the 2020/21 financial year (July to December 2020). The most outstanding challenges were as a result of restrictions caused by Covid-19 pandemic which disrupted the normal supply chains threatening the availability of critical health supplies.

From a patient perspective, patients and caregivers increasingly made use of ubiquitous health information online and actively sought out new therapies to confront the pandemic which had no approved treatment. These challenges brought opportunities in e-commerce and increased domestic manufacture of essential

Editorial team

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

Review team

1. Mr. Abiaz Rwamwiri
2. Ms. Barbara Najjemba Musoke

[1] The National Drug Policy and Authority Act and the regulations can be retrieved from https://www.nda.or.ug/ndpa-act-regulations/

Editorial team

Amos Atumanya
Lead Editor

Frank Kaleebu
Senior Regulatory Officer

Brenda Kitimbo
Principal Regulatory Officer

Moses Akampurira
Senior Regulatory Officer

Mohammed Lukwago
Manager Central Region

Solomon Onen
Manager GMP

Review team

Abiaz Rwamwiri
Manager Public Relations

Barbara Najjemba
Administrative Officer

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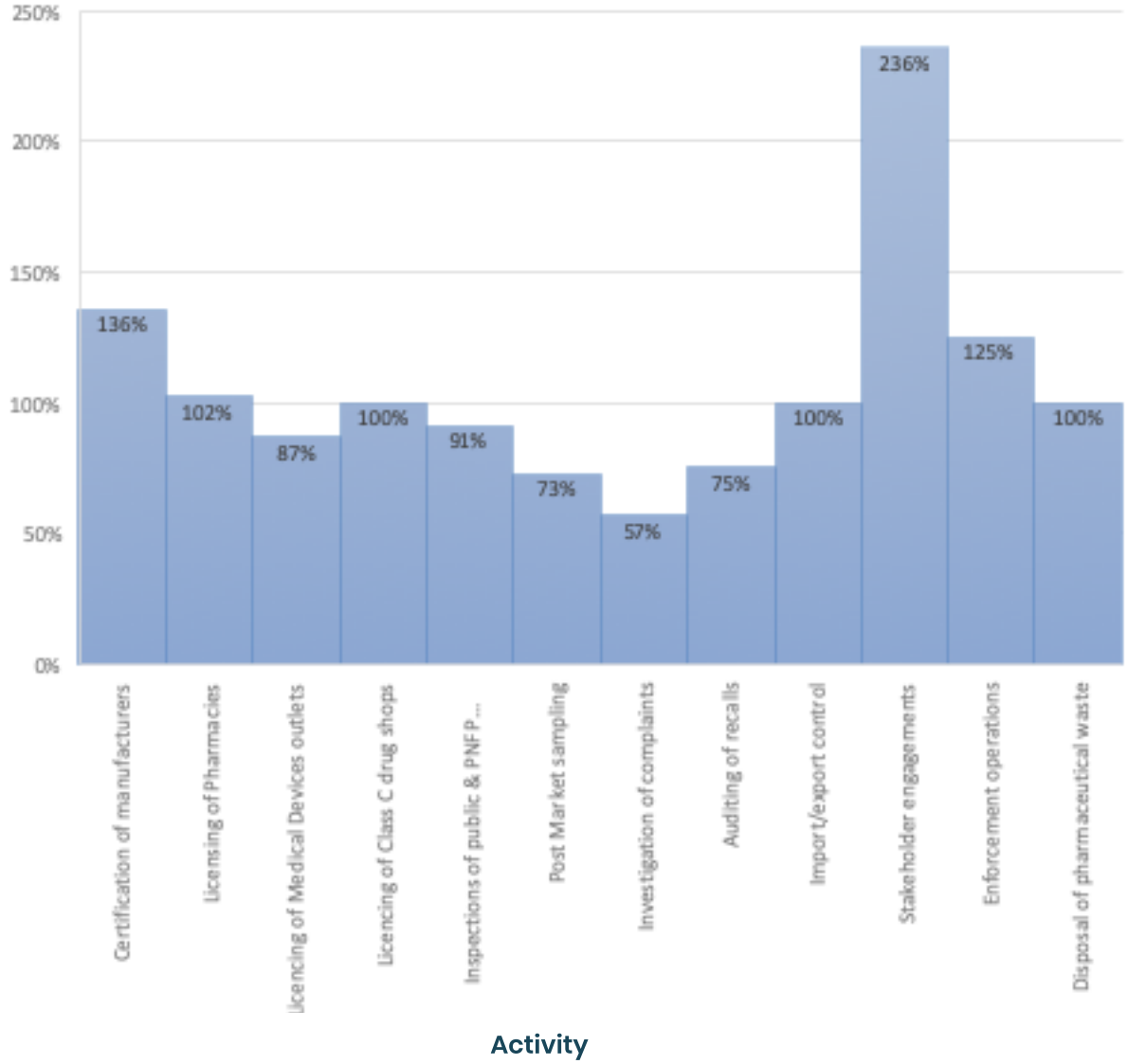
1.1 Executive Summary

The directorate of Inspectorate and Enforcement conducted a wide range of compliance and enforcement activities in the July to December 2020 period. These activities helped to ensure the availability at all times of essential, efficacious and quality drugs to the entire population of Uganda. The performance is summarised in the chart below.

Inspectorate and Enforcement Performance Summary for the July to December 2020.



Activity

This chart indicates that certification of manufacturers, licencing of pharmacies, import and export control, stakeholder engagements, enforcement operations and disposal of pharmaceutical waste met or exceeded performance targets. While licensing of medical device outlets & drug shops, inspection of public and PNFP facilities, post market sampling, investigation of complaints and auditing of recalls 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 are summarised in the table below:

Table 1: Summary of the directorate activities

Core activity	Sub-activities	Target	Done	Perfor-mance	Compliant	Non-com-pliant	Compli-ance rate
Good Manufacturing Practices	Pre-inspection of manufacturers	17	17	100%	Not rated	N/A	N/A
	Certification of domestic manufacturers	16	16	100%	16	0	100%
	Certification of foreign manufacturers	170	236	138.9%	217	19	91.9%
	Domestic herbal manufacturers	20	14	70.0%	Not rateda	N/A	N/A
	Pre-market authorisation	29	29	100%	Not rated	N/A	N/A
	Pre-market sampling	88	74	84%b	48	26	64.9%
Inspections of Pharmacies	Pre-inspection of pharmacies	664	613	92.3%	367	246	60%
	Licensing of Pharmacies	527	539c	102.3%	500d	13	92.8%
	Licencing of Medical devices	38	33	86.8%	29	4	88%

Core activity	Sub-activities	Target	Done	Performance	Compliant	Non-compliant	Compliance rate
Inspections of Pharmacies	Pharmacy compliance monitoring visits	1,246	837	67.2%	618	219	73.8%
	Good Distribution Practice inspections	556	361	64.9%	19	342	5.3%
Inspections of Licensed sellers (Class C drug shops)	Pre-inspection of Class C drug shops	2,202	1989	90.3%	1,429	560	72%
	Licencing of Class C drug shops	8,040	8,023	99.8%	7,589	434	94.6%
	Drug shop compliance monitoring visits	9,062	8,982	99.1%	5867	3,115	65.3%
Public and Private not for profit facilities	Inspections of public & PNFP facilities for GPP	182	165	90.7%	91	74	55.2%
	Inspection of blood banks	12	12	100%	Not rate-da	N/A	N/A
Post market surveillance	Post Market sampling	1,682	1,221	72.6%b	901	36	96.2%
	Investigation of complaints	21	12	57.1%	N/A	N/A	N/A

Post market surveillance	Auditing of recalls	20	15	75%	0	15	0%
	Market surveillance operations	2	3	150%	Not rated	N/A	N/A
Control of imports and exports	Import/export verification	7,700	7,700	100%	7,575	22e	98.4%
	Port clearance	5,044	5,044	100%	4,886f	01	96.9%
Stakeholder engagement of stakeholders	Radio/television talk shows	63	76	120.6%	Not rated	N/A	N/A
	Stakeholder engagements	93	300	322.6%	N/A	N/A	N/A
Enforcement activities	Enforcement operations	4	5	125%	N/A	N/A	N/A
	Implementation of intelligence recommendations	80%	76.2%	95.3%	N/A	N/A	N/A
Supervision of pharmaceutical waste disposal	Disposal of pharmaceutical waste	1,007, 662.15 kg	1,007,662.15 kg	100%	Not rated	N/A	N/A

[a]Inspections of herbal manufacturers and blood banks were not rated because it was determined before inspection that they were to provide technical assistance to improve the capacity of the herbal manufacturers and to benchmark for making guidelines respectively.
[b]The testing of samples is done by the DLS and was still ongoing for some of the batches
[c]12 applications were brought forward from the previous period.
[d]26 applications were queried.
[e]103 applications were still pending issuance of a verification certificate
[f]45 consignments were queried and 112 conditionally released

NDA members during a familiarisation tour of a domestic veterinary manufacturer.

2.0 MANUFACTURING FACILITIES

National Drug Authority is mandated to promote and control local production of essential medicines as a means of ensuring the availability, at all times of essential, efficacious and cost-effective drugs to the entire population of Uganda. In the execution of this mandate, NDA undertakes several strategies to support domestic manufacturing of medical products. These include but are not limited to;

- Providing technical support to domestic manufacturers, from conception to licensing and commercialization of their products.
- Routine GMP inspections to drive continual improvement in the quality systems of pharmaceutical manufacturers.
- Zero fees on importation of raw materials and equipment, which reduces the overhead operational costs for manufacturers.
- Lower fees for inspections and registration of products
- Expedited approvals for pre-market and marketing authorization of their products
- Implementation of the 'Buy Uganda Build Uganda (BUBU) policy that provides for a price competitive advantage for selected locally manufactured products, by charging imported equivalents, a higher (12 percent) verification fee.

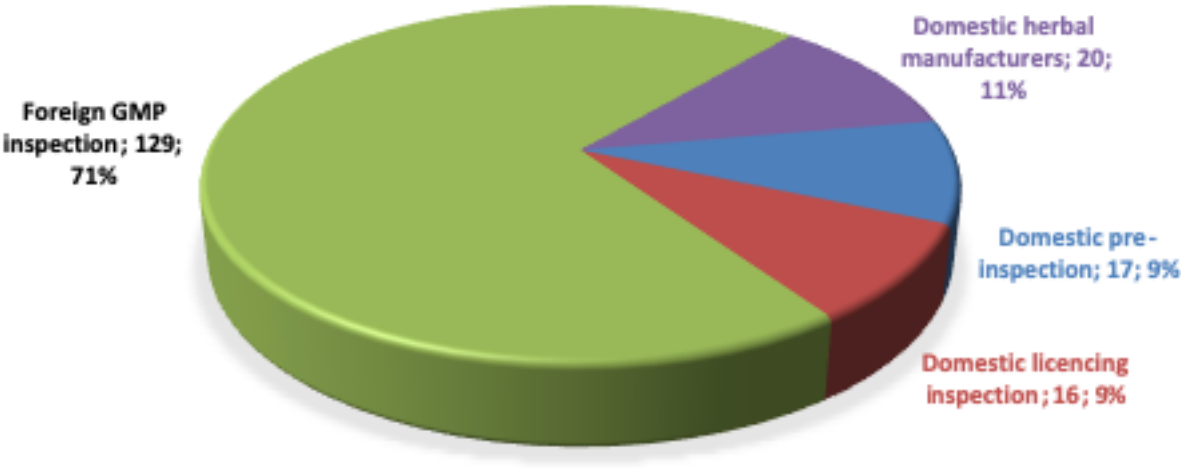
The Inspectorate performs an initial pre-inspection of a domestic manufacturer within 20 days. It then conducts a licensing inspection within 20 days of receipt of a licencing application. Domestic manufacturers are licenced every 3 years while foreign manufacturers are inspected for GMP compliance once every 3 years. 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. Manufacturers are required to apply for renewal of their GMP status six months before their expiry. The annual work plan is built on risk-based approach. 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.

NDA Members providing technical support during a familiarisation tour of a domestic herbal manufacturer.

2.1 Manufacturing inspection statistics and results

Figure 1: Distribution of manufacturing applications received

Distribution of manufacturing applications received



This chart shows that 71% of all the manufacturing applications received were foreign based while 9% were for pre-inspection of the proposed domestic facilities. If all the proposed facilities were to proceed to licensing, it would double the number of domestic manufacturers.

71%

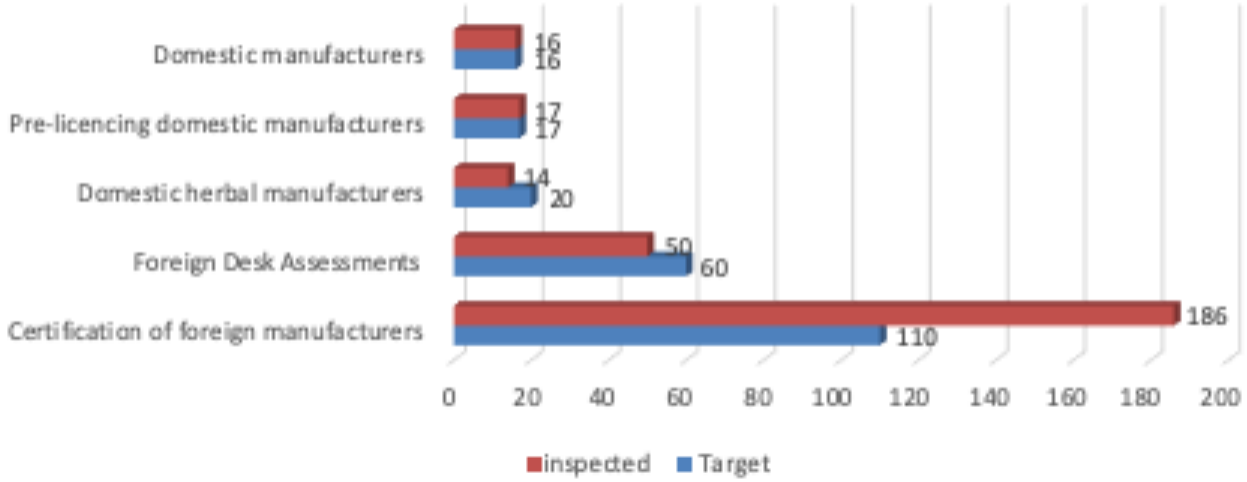
of all the manufacturing applications received were foreign based while

9%

were for pre-inspection of the proposed domestic facilities.

Figure 2: Distribution of Good Manufacturing Practice inspections done

Distribution of Good Manufacturing Practice Inspections

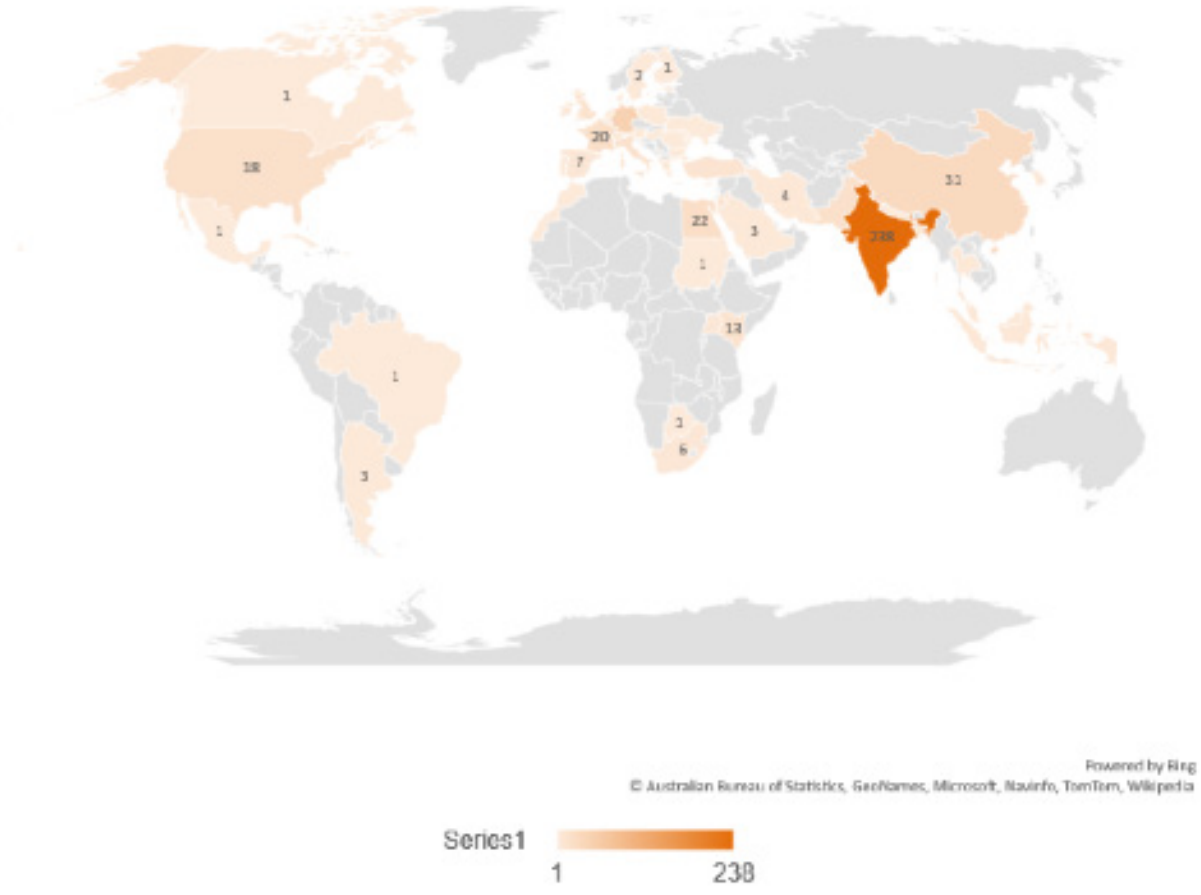


The target for foreign manufacturer inspections was surpassed because onsite inspections could not be conducted due to the disruptions caused by the Covid-19 pandemic. The resultant national and international safety measures and travel restrictions prevented the conduct of onsite inspections related to good manufacturing practice (GMP). 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 will be conducted as soon as the situation allows.
- New GMP applications from countries with stringent regulatory authorities (SRA) were desk-assessed.

Figure 3: Distribution of GMP certified facilities as at Dec 31, 2020

Distribution of GMP Certified Manufacturers as at Dec 31, 2020



There were 583 GMP certified facilities. India 238 (40.8) had the highest number followed by Germany 46 (7.9%) and China 31 (5.3%).

583

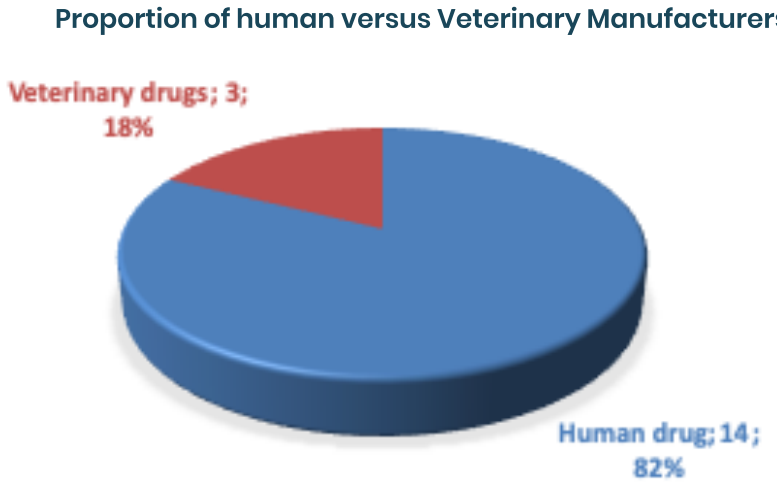
GMP certified facilities India **238 (40.8)** had the highest number followed by Germany **46 (7.9%)** and China **31 (5.3%)**.

2.2 Manufacturing pre-inspection statistics and results

NDA performs pre-inspections of proposed manufacturing facilities to provide technical assistance as part of support to promote domestic manufacture of essential drugs. These inspections were not compliance rated

In July to December 2020 period; 17 pre-inspection applications were received and all were inspected.

Figure 4: Distribution of manufacturing pre-inspections

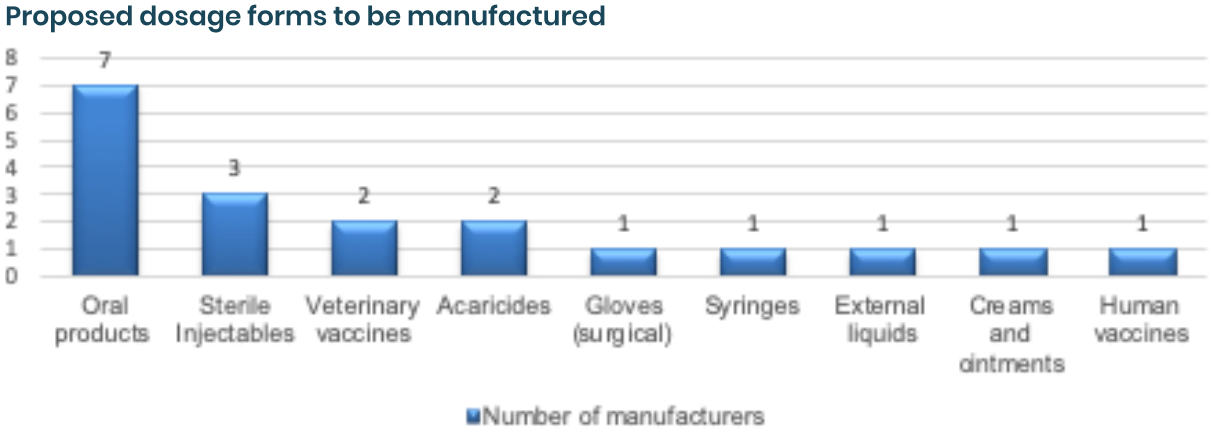


Majority (82%) of the proposed manufacturing facilities are for drugs for human use.

82%

of the proposed manufacturing facilities are for drugs for human use.

Figure 5: Distribution of manufacturing pre-inspections dosage forms



This chart shows that the majority of the proposed products are oral followed by injectable preparations.

2.3 Inspection statistics and results for licensing of manufacturers

47 (71.2%) of the manufacturer inspections resulted into compliant rating, 1 (1.5%) was non-compliant and 18 (27.3%) were awaiting additional information.

Most common observation

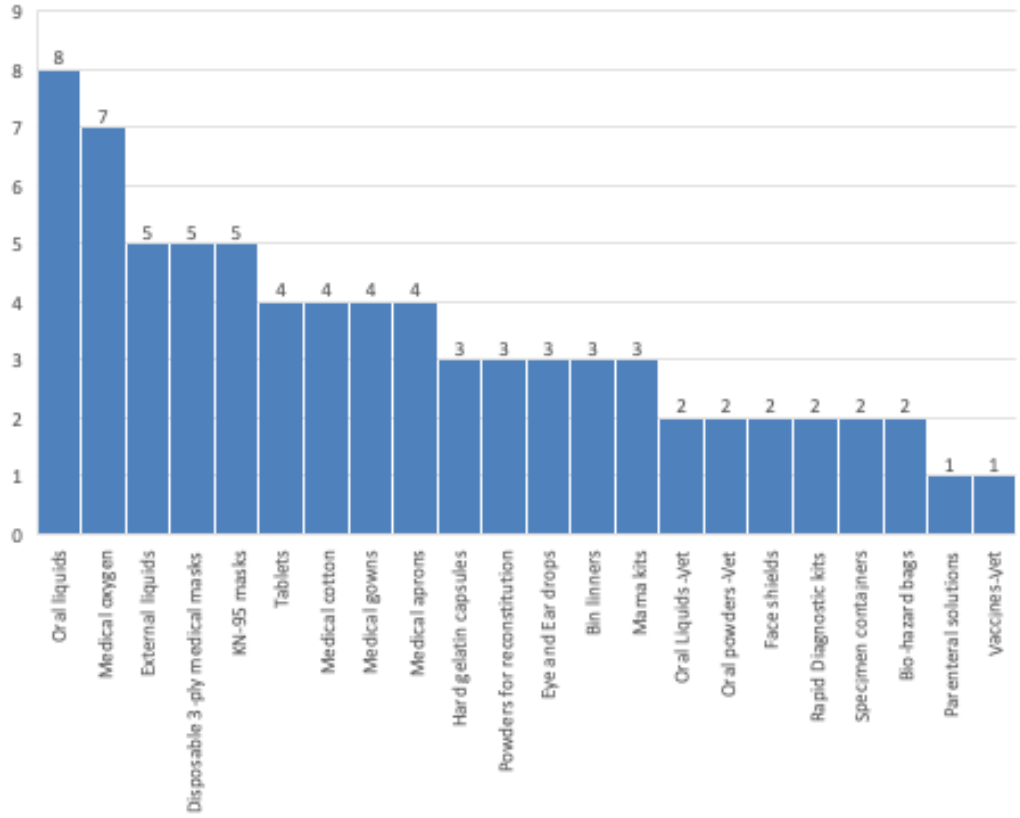
- Lack of supporting documentation

Action taken

- The non-compliant applications were recommended for physical inspection
- The deferred applications were requested to submit additional information

Figure 6: Domestic manufacturers dosage forms as at Dec 31, 2020

Number of inspected manufacturers

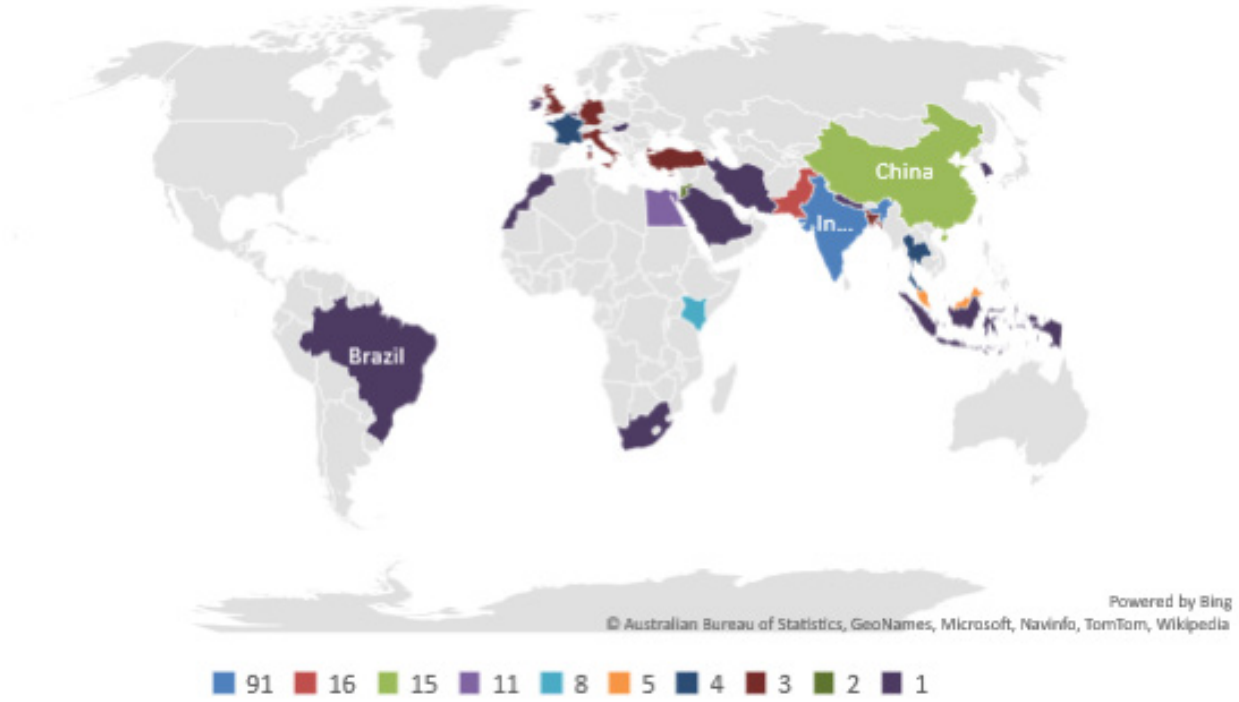


Oral liquids followed by medical oxygen were the most prevalent dosage forms manufactured during the July to December 2020 period

NDA management providing technical guidance to Domestic manufacture.

Figure 7: Distribution of foreign facilities re-certified for GMP

Distribution of foreign facilities re-certified for GMP



186 facilities were re-certified. India had the majority with 91 (48.9%) facilities followed by Pakistan with 16 (8.6%) and China with 15 (8.1%).

India had the majority with **91 (48.9%)** facilities followed by Pakistan with **16 (8.6%)** and China with **15 (8.1%)**

2.4 Domestic herbal manufacturers inspection statistics and results

NDA conducted inspection of domestic herbal manufacturers as part of our technical support to promote the development of herbal medicines. The inspections are aimed at building the capacity of herbal manufacturers to meet the requirements of Good Manufacturing Practices (GMP) and consequently the quality of herbal drugs. These inspections were not for compliance rating but to provide technical assistance to improve the capacity of the herbal manufacturers.

In the July-December 2020 period;

- 20 herbal manufacturers were planned
- 14 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); raw material, intermediate and finished product specifications or records including Batch Manufacturing Records (BMRs).
- There was lack of suitable premises and equipment for pharmaceutical

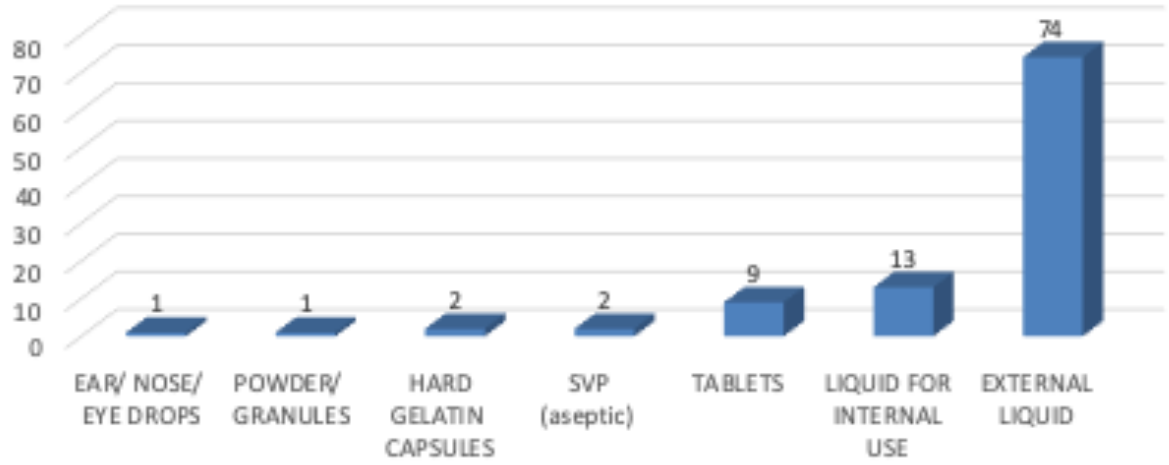
manufacture
- There was no system or evidence to show that quality control tests were done.

2.5 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 figure below summarises pre-market authorisation statistics.

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

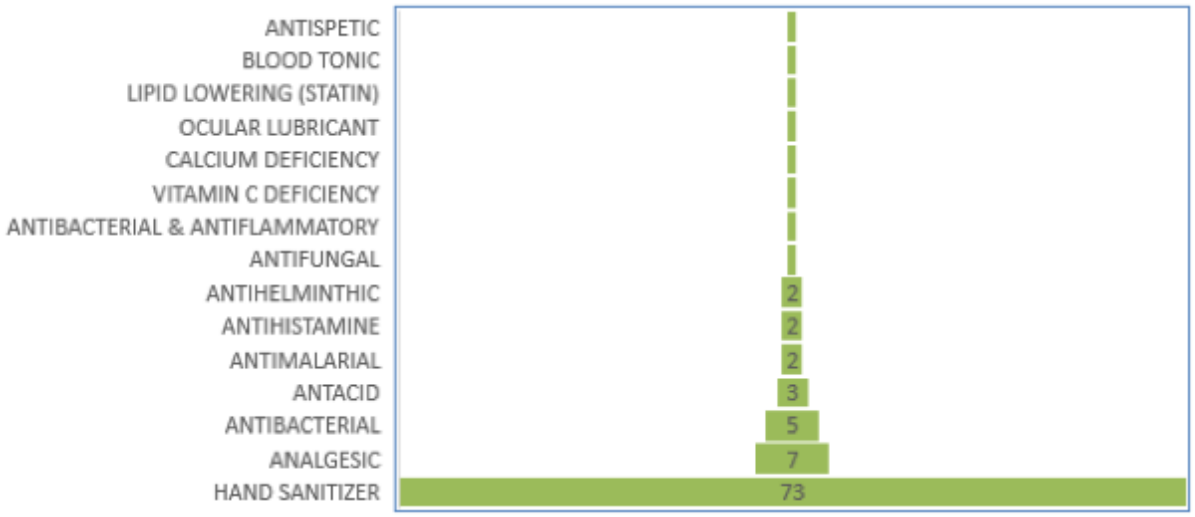
Distribution of pre-market authorisation of products applications by dosage form



In the July to December 2020 period; 102 applications for approval of new products for manufacture by domestic manufacturers were received and reviewed. 56 were granted permission to manufacture pre-market batches and 46 were queried and requested to submit addition information. The most common dosage form were external liquids due to the increased manufacture of hand sanitizers.

Figure 9: Pre-market authorisation of product applications by therapeutic category

Pre-market authorisation of product application by therapeutic category

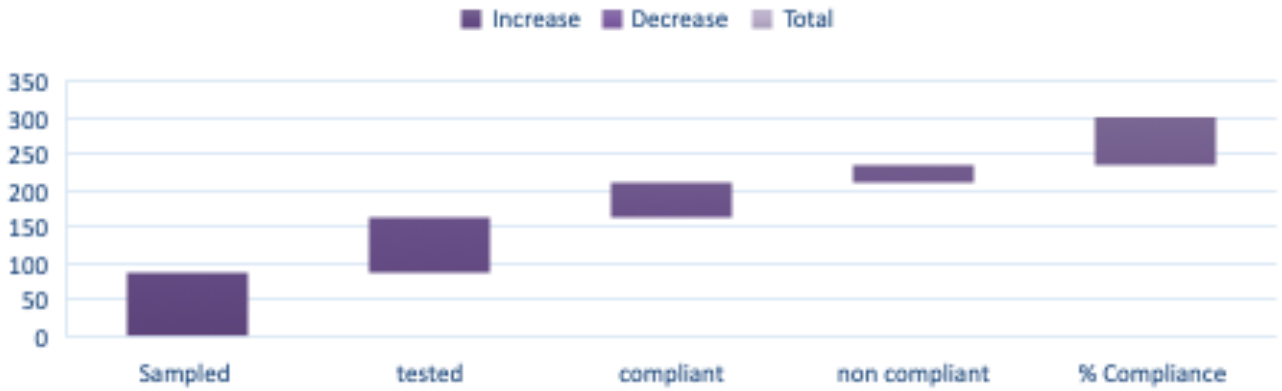


71.6% (73 of the 102) pre-market authorisation of product applications were hand sanitisers.

2.6 Pre-market sampling statistics and results

Figure 10: Status of pre-market batches sampled

Status of pre-market samples tested



64.9% of the pre-market samples tested complied with the specifications while 35.1% did not comply. 88.5% (23 of the 26) of the non-compliant samples were hand sanitisers.

64.9%

of the pre-market samples tested complied with the specifications while **35.1%** did not comply.

[2] 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.

Pre-market sampling of domestically manufactured gloves.

NDA officers following up on a veterinary outlets.

3.0 PHARMACIES AND MEDICAL DEVICE OUTLETS

National Drug Authority inspects pharmacies 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. Some of the requirements include suitable premises, qualified personnel and records of receipt and supply.

The Inspectorate performs an initial pre-inspection of a new pharmacy (wholesale or retail) premises within 15 days of receiving an application. It then conducts a licensing inspection within 20 days of receipt of a licencing application. Pharmacies licenses are valid for 3 years. After the licencing inspection, 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

3.1 Inspection statistics anda Figure 11: Distribution of Pharmacy inspections results

Distribution of Pharmacy inspections

25%

all pharmacy inspections were pre-inspections for new pharmacies

25% of all pharmacy inspections were pre-inspections for new pharmacies.

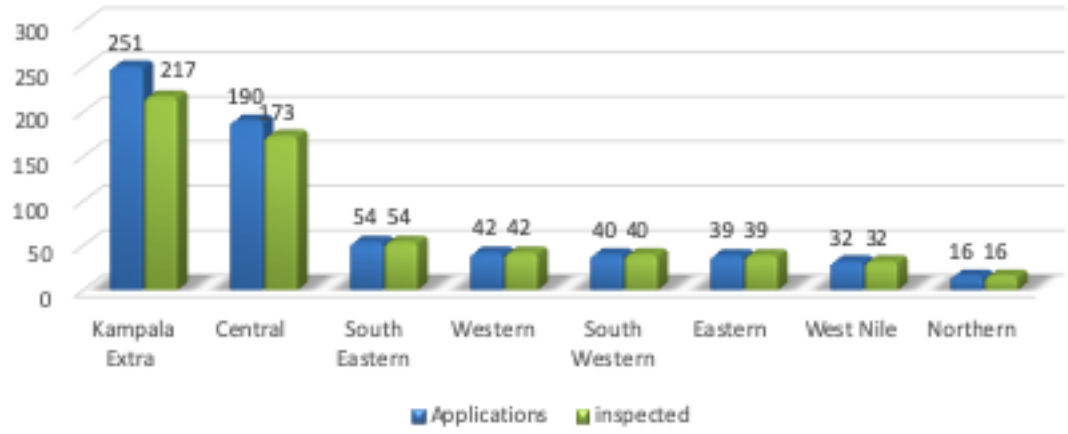
[3]The National Drug Policy and Authority Act and the regulations can be retrieved from https://www.nda.or.ug/ndpa-act-regulations/

3.2 Pharmacy pre-inspection statistics and results

NDA performs pre-inspections to guide clients on the suitability of the location for the proposed outlet before they can commit resources. This ensures that clients do not commit resources to a facility whose location makes it impossible to meet the licencing requirements. It also helps to increase the probability of a licence application being successful. The pre-inspections are currently provided at no cost to the clients. In the July to December 2020 period:

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

Distribution of pharmacy pre-inspections applications by region



Two regions received 66.4% (441 of the 664) of the pre-inspection applications for new pharmacies. Kampala Extra region with 251 (37.8%) received the highest number followed by central region with 190 (28.6%) applications.

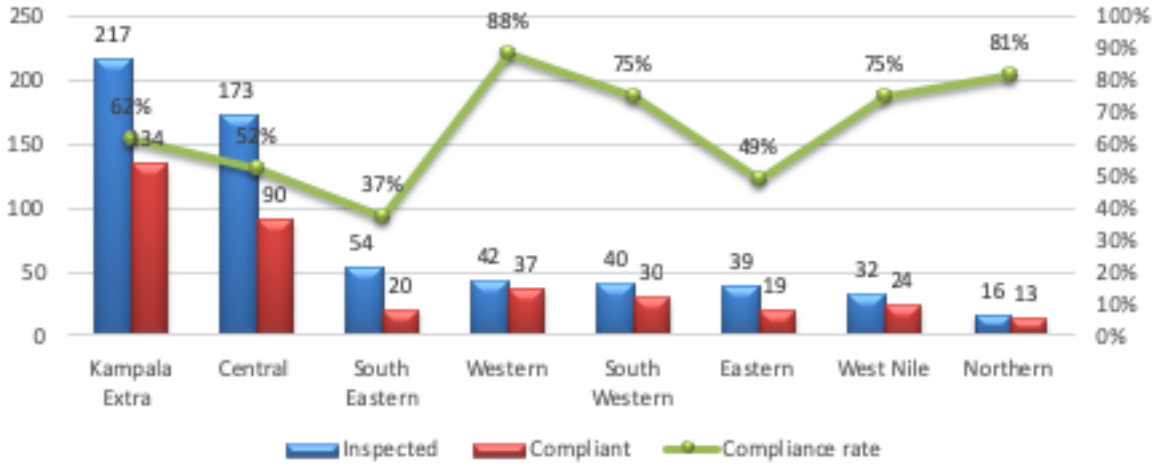
Two regions received

66.4%

(441 of the 664) of the pre-inspection applications for new pharmacies.

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

Compliance rating of pharmacy pre-inspections



367 (60%) of the pre-inspections resulted into compliant rating while 246 (40%) resulted into a non-compliant rating. The compliance rate was lowest in South Eastern region (37%), followed by Eastern at 49% and Central at 52%. However, the highest number of non-compliant facilities were in Kampala Extra and Central regions with 33.7% (83) apiece, which is more than the number of applications received in any other region.

Most common observation:
Non-compliance with the distance to the nearest like outlet as specified in the Professional licencing guidelines for pharmacies.

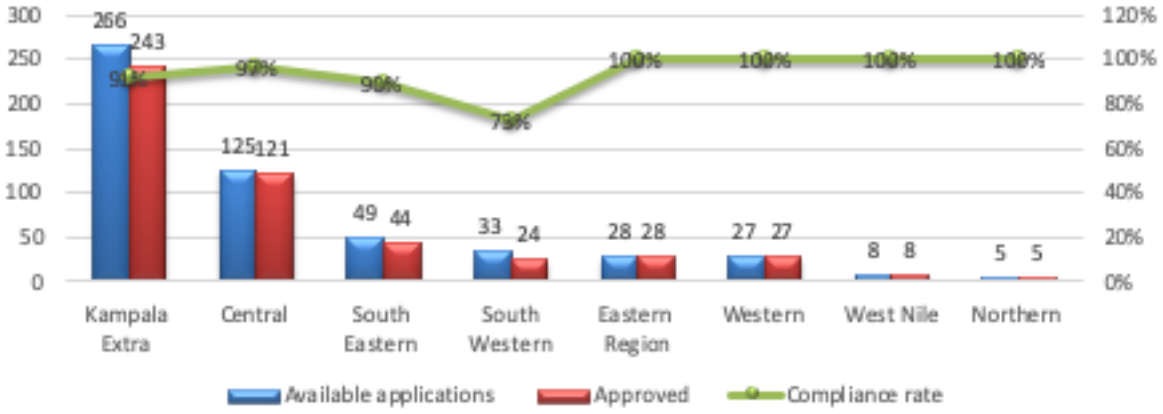
Action taken:
Non-compliant applications were denied login credentials into the NDAMIS system thus they could not apply for a licence.

3.3 Pharmacy licencing inspection statistics and results

National Drug Authority conducts licencing inspections to verify if the proposed pharmacy has the premises, facilities, personnel and systems to assure the safety, efficacy and quality of the drugs. This inspection is required for issuance of a certificate of suitability of premises and licence to operate.

Figure 14: Compliance rating of pharmacy licencing applications by region

Compliance rating of pharmacy licensing applications



In the July to December 2020 period; 527 pharmacy applications were received with 14 others brought forward from the previous period. 539 inspections were conducted with 500 resulting into a compliant rating, 26 (4.8%) were queried, 13 (2.4%) were rejected and two applications were carried forward. The compliance was lowest in South Western (73%) followed by South Eastern (90%) and Kampala Extra (91%).

527

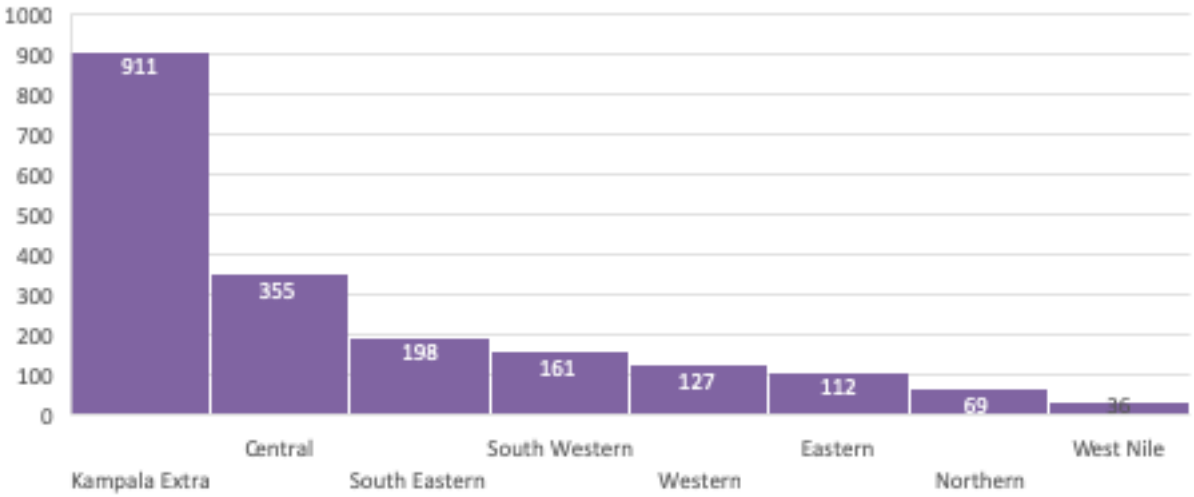
pharmacy applications were received with **14** others brought forward from the previous period

539

inspections were conducted with **500** resulting into a compliant rating, **26 (4.8%)** were queried, **13 (2.4%)** were rejected and two applications were carried forward

Figure 15: Distribution of pharmacy licencing status as at Dec 31, 2020

Distribution of pharmacy licencing status as at December 31, 2020



There were 1969 licensed pharmacies; 46.3% (911) of them in Kampala Extra region.

1969
licensed pharmacies

Most common observations

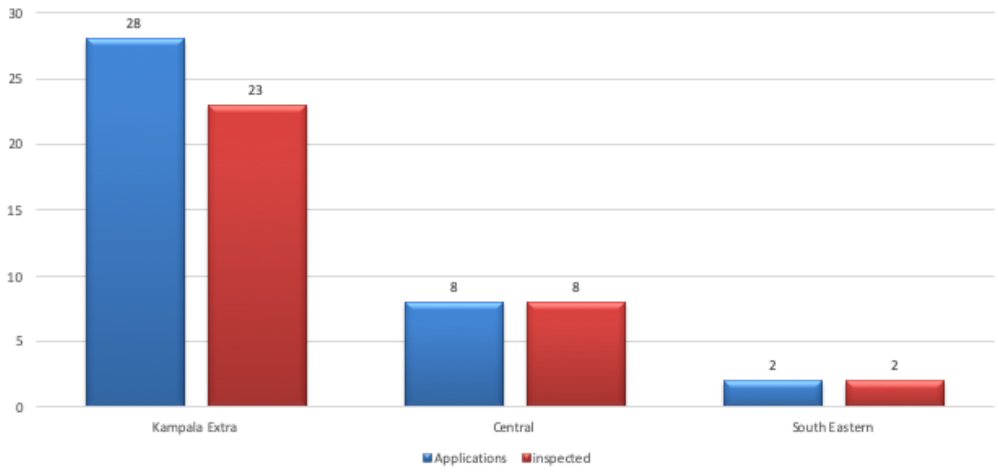
- Poor documentation including lack or inadequacy of standard operating procedures and inadequate records of purchase, sales and room temperature monitoring.
- Inadequate cold chain systems
- Low presence levels for pharmacists
- Inadequacy of technical reference materials
- Unclean and untidy premises

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.

Figure 16: Medical devices licencing inspections by region

Distribution of Medical device licensing inspections



38 medical devices outlets applications were received. 33 inspections were conducted with 29 (88%) of the inspections resulting into compliant rating and 4 (12%) resulted into non-compliant rating. 73.7% (28 of 38) medical devices outlet applications were in Kampala Extra region.

38

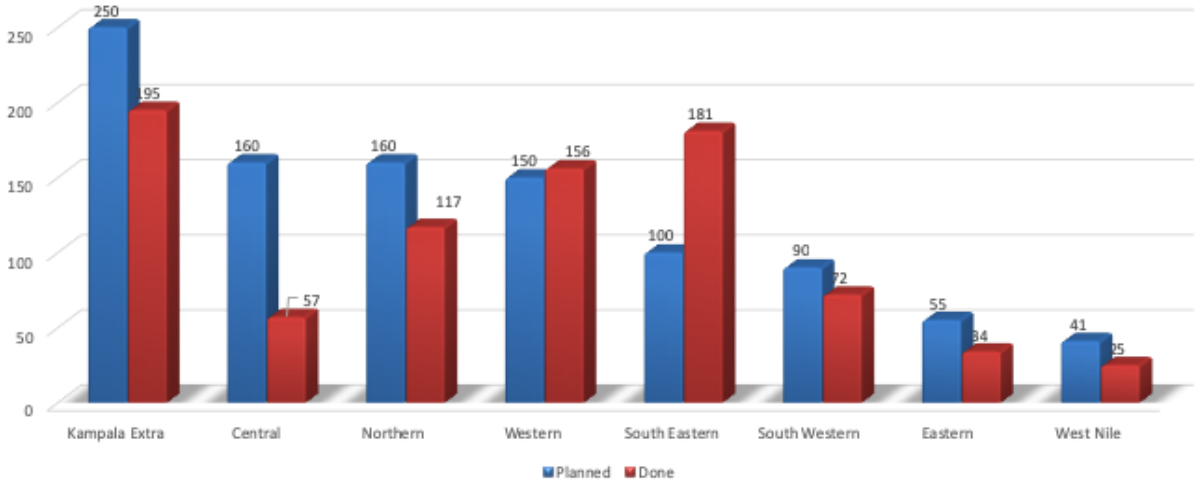
medical devices outlets applications were received.

3.4 Pharmacy compliance monitoring visits statistics and results

NDA conducts inspections of authorised establishments to promote compliance and assure the safety, efficacy and quality of drugs. These inspections constitute part of our routine monitoring and support to the authorised establishments to exhort them to comply and elucidate the requirements. These visits present an opportunity for inspectors to personally sensitize the operators on the requisite standards for a pharmacy and any developments from NDA. They also offer an opportunity to get feedback on the policies, practices and work methods for purposes of continuous improvement.

Figure 17: Distribution of compliance monitoring visits by region

Distribution of pharmacy compliance visits by region



In the July to December 2020 period; 1,246 compliance monitoring visits for pharmacies were planned, 837 visits were conducted with 618 resulting into compliant rating and 219 rated non-compliant. Central region (35.6%) had the lowest monitoring rate which was attributed to the lack of the District Assistant Drug Inspector in Wakiso district which diverted the regional team to conducting pre-inspections for drug shops in the district.

1,246

compliance monitoring visits for pharmacies were planned, **837** visits were conducted with 618 resulting into compliant rating and **219** rated non-compliant.

Most common observations:

- Sale of prescription-only drugs without prescriptions
- Absence of pharmacists
- Poor record keeping
- Poor cold chain systems.

Action taken:

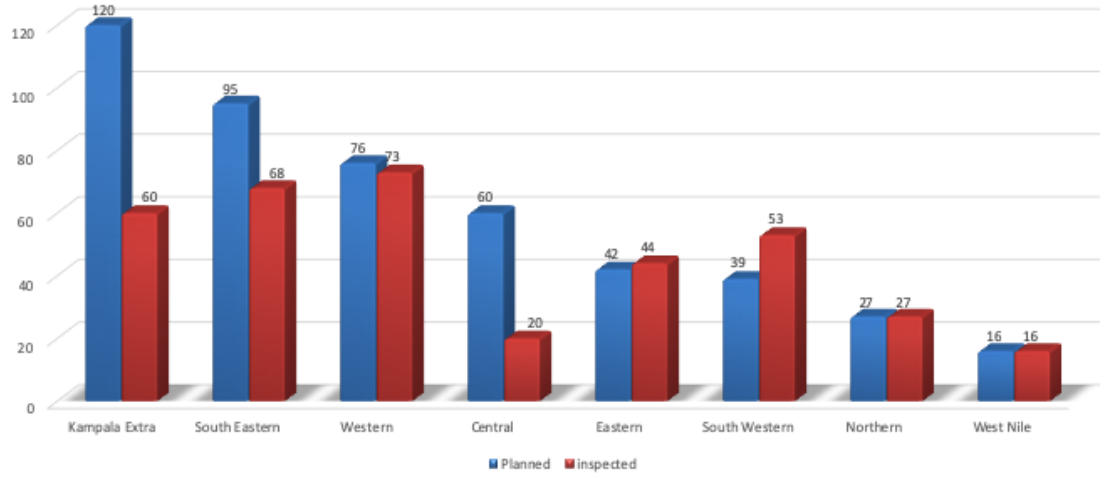
- Sensitization meetings have been undertaken to guide pharmacies on the minimum standards and how they can put systems in place to address the non-compliances
- One-on-one meetings with the pharmacists have been held to guide them on possible steps to address the non-compliances
- In exceptional cases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

3.5 Good Distribution Practices (GDP) inspection statistics and results

NDA conducts inspections of drug distributors to verify compliance with the requirements of Good Distribution Practices (GDP). GDP is part of quality assurance that ensures that there are adequate controls in place to maintain the quality of drugs throughout the numerous activities which occur during the distribution process. This is being implemented in a phased manner beginning with wholesale pharmacies

Figure 18: Distribution of GDP inspections by region

Distribution of GDP inspections by region



In the July to December 2020 period: 556 GDP inspections of wholesalers were planned; 361 GDP inspections were conducted with 19 inspections resulting into a compliant rating. Central region (33.3%) had the lowest GDP inspection rate which was attributed to the lack of the District Assistant Drug Inspector in Wakiso district which diverted the regional team to conducting pre-inspections for drug shops in the district.

556

GDP inspections of wholesalers were planned; **361** GDP inspections were conducted with 19 inspections resulting into a compliant rating

Most common observations:

- Poor or 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

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.
- Due to the low compliance during GDP inspections, a follow up meeting was planned with the biggest wholesalers to agree on the way forward.

Head Veterinary products providing technical support to a veterinary outlet.

Buy drugs from NDA licensed drug outlets (drug shops and pharmacies).

4.0 LICENSED SELLERS (CLASS C DRUG SHOPS)

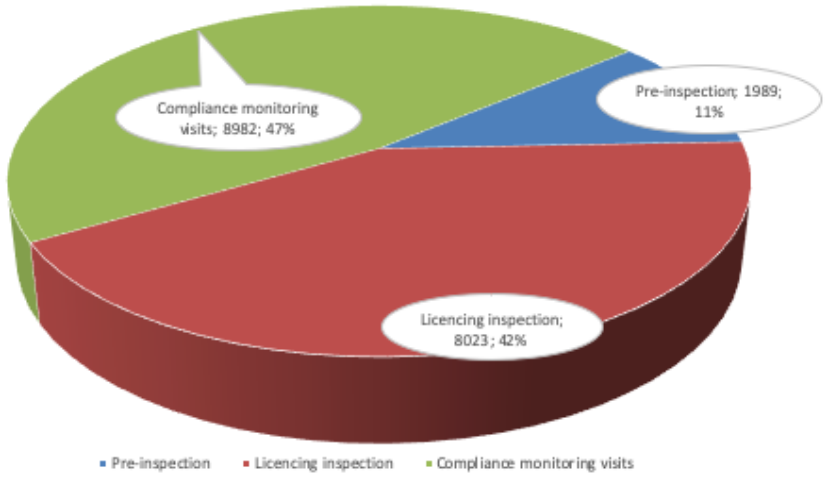
National Drug Authority inspects licensed sellers (Class C drug shops) to verify compliance with the requirements of the National Drug Policy and Authority Act and the National Drug Policy and Authority Licencing and certificate of suitability of premises Regulations, 2014. Inspections are done sequentially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

The Inspectorate 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.

4.1 Inspection statistics and results

Figure 19: Distribution of drug shop inspections by inspection type.

Distribution of drug shop inspections



A total of 18,994 inspections were done with 1,989 (10.5%) pre-inspections, 8,023 (42.2%) licensing inspections and 8,982 (47.3%) compliance monitoring visits

18,994

inspections were done with **1,989 (10.5%)** pre-inspections, **8,023 (42.2%)** licensing inspections and **8,982 (47.3%)** compliance monitoring visits

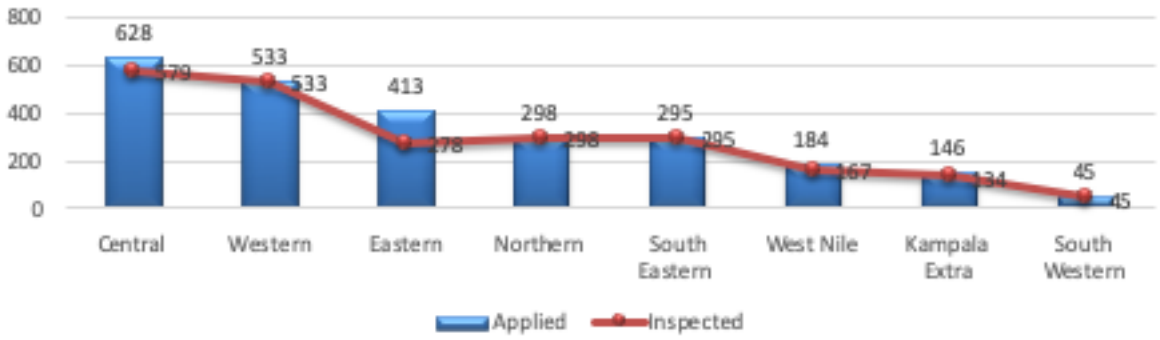
[4]Licensed seller (Class C drug shop) is a drug outlet licensed under section 15 of the Act for retail sale of class C (over the counter) drugs only and not those of Class A or B.

4.2 Drug shop pre-inspection statistics and results

NDA performs pre-inspections to establish that the proposed location is compliant with the provisions of the prevailing licensing guidelines. In July to December 2020 period:

Figure 20: Distribution of Class C drug shop pre-inspections by region

Distribution of drug shop pre-inspections by region



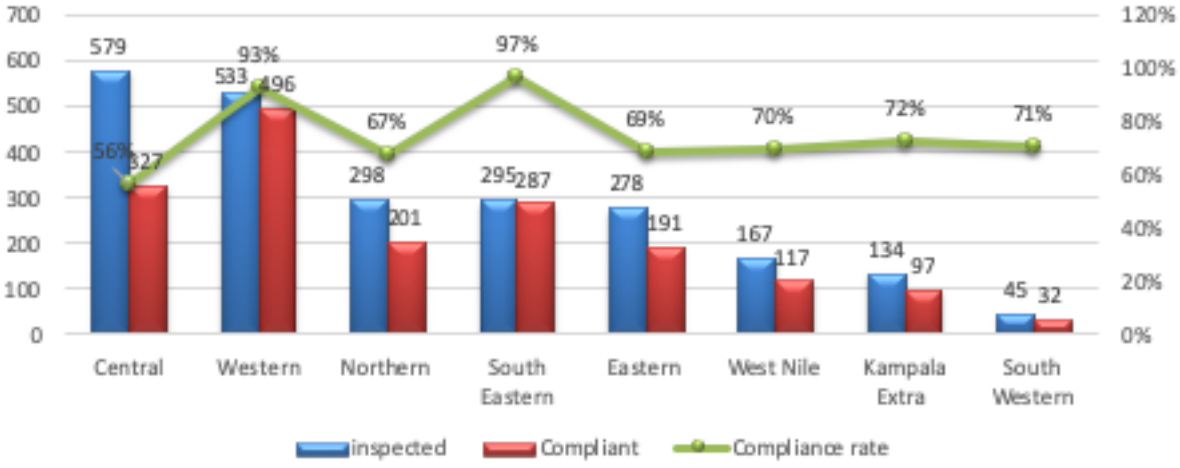
A total of 2,202 pre-inspection applications for class C drug shops were received and 1,989 pre-inspections conducted. The highest number 628 (28.5%) were received in central region, followed by Western region with 533 (24.2%) and Eastern region with 413 (18.8%).

2,202

pre-inspection applications for class C drug shops were received and **1,989** pre-inspections conducted.

Figure 21: Compliance rating of drug shop pre-inspections

Compliance rate for class C drug shop pre-inspections



1,989 pre-inspections were conducted with 1,429 (72%) resulting into compliant rating and 560 (28%) resulting into a non-compliant rating. The lowest compliance was in Central region at 56%, followed by Northern region at 67% and Eastern at 69%. Central region accounted for 45% (252 of 560) of the non-compliant drug shop pre-inspections.

1,989

pre-inspections were conducted with **1,429 (72%)** resulting into compliant rating and **560 (28%)** resulting into a non-compliant rating.

Most common observation: Non-compliance with the distance to the nearest like outlet as specified in the Professional licencing guidelines for class C drug shops.

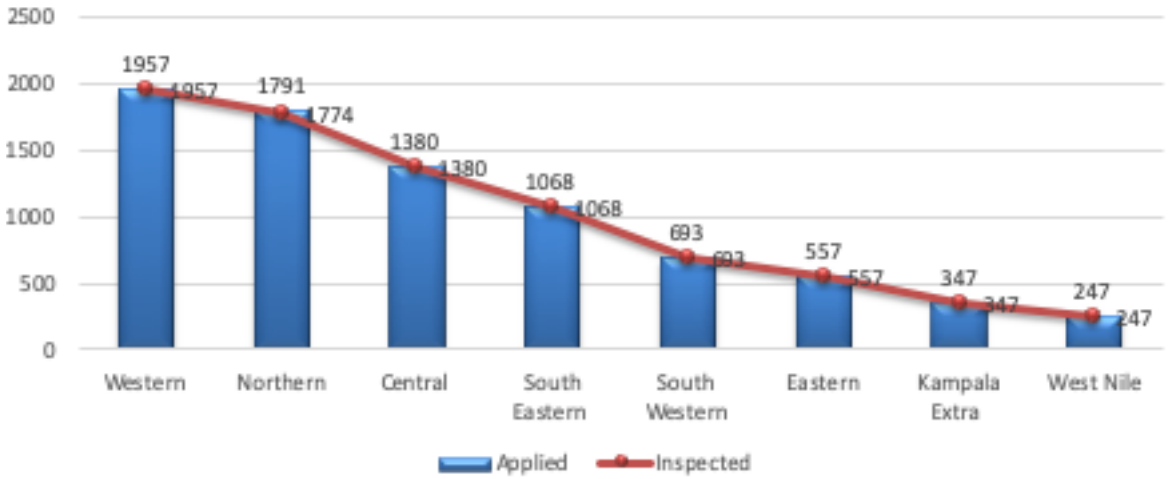
Action taken: Non-compliant outlets were denied an opportunity to apply for a certificate of suitability of premises.

4.3 Drug shop licencing inspection statistics and results

National Drug Authority conducts licencing inspections to verify if the proposed drug shop has the personnel, premises, facilities and systems to assure the safety, efficacy and quality of the drugs. This inspection is required for issuance of a certificate of suitability of premises and licence to operate.

Figure 22: Distribution of drug shop licencing inspections by region

Distribution of drug shop licencing inspections by region



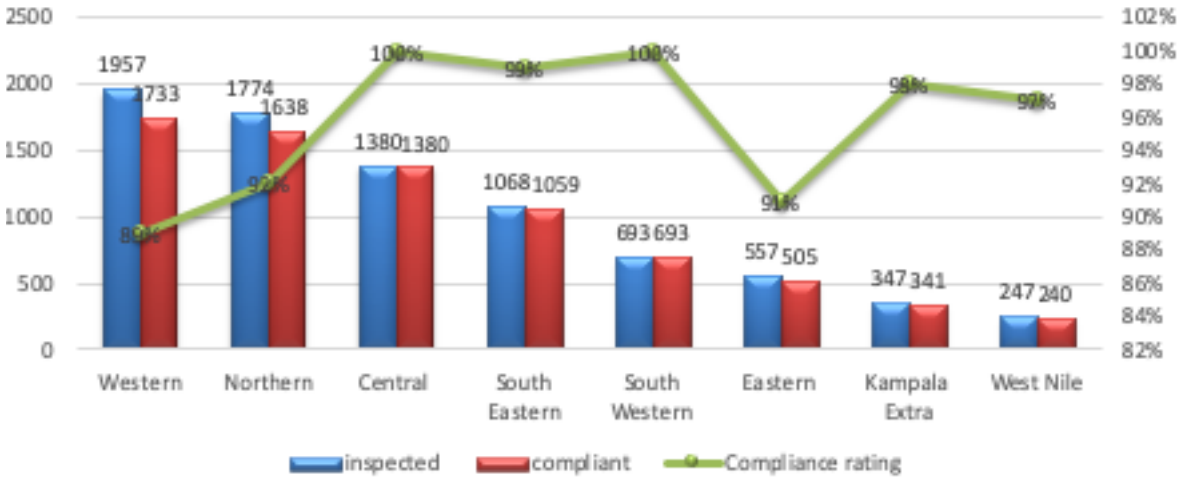
In the July-December 2020 period; 8,040 licencing applications for class C drug shops were received and 8,023 inspections conducted. Only Northern region at 99.1% had not inspected all drug shop applications.

8,040

licencing applications for class C drug shops were received and **8,023** inspections conducted.

Figure 23: Compliance rating of drug shop licencing inspections by region

Compliance rating of drug shop licencing inspections by region



94.6% (7,589 of 8,023) of the inspections resulted into a compliant rating and 434 (5.4%) resulted into a non-compliant rating. Western region had the lowest compliance rating at 89% followed by Eastern at 91% and Northern at 92%.

94.6%

(7,589 of 8,023) of the inspections resulted into a compliant rating and **434 (5.4%)** resulted into a non-compliant rating.

Most common observation:

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

Action taken:

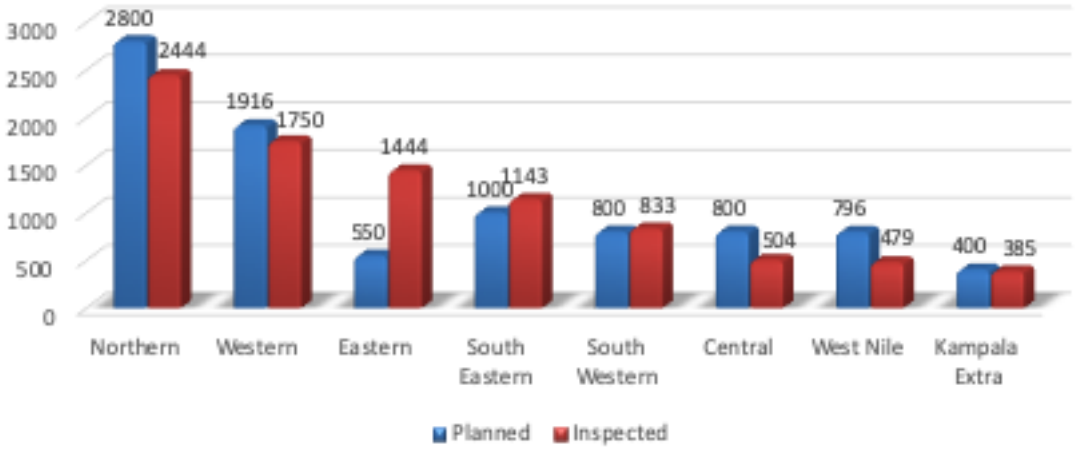
Non-compliant outlets were denied a licence until the non-conformances were addressed.

4.4 Class C drug shop compliance monitoring visits statistics and results

NDA conducts inspections of authorised establishments to verify if they still comply with the licencing requirements. These visits present an opportunity for inspectors to personally sensitize the operators on the requisite standards for a drug shop and any developments from NDA. They also help inspectors to get feedback on the challenges in the community such as emerging illegal outlets.

Figure 24: Distribution of drug shop compliance monitoring visits by region

Distribution of drug shop compliance visits by region



In the July to December 2020 period; 9,062 compliance monitoring visits for drug shops were planned; with 8,982 visits conducted and 5867 (65.3%) rated compliant. West Nile region had the lowest monitoring rate at 60.2% followed by Central region at 63%.

9,062

compliance monitoring visits for drug shops were planned; with **8,982** visits conducted and **5867 (65.3%)** rated compliant.

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 have 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. NDA has also increased vigilance on compliance to GDP requirements by wholesale pharmacies.

Training on how to conduct remote GMP inspections.

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

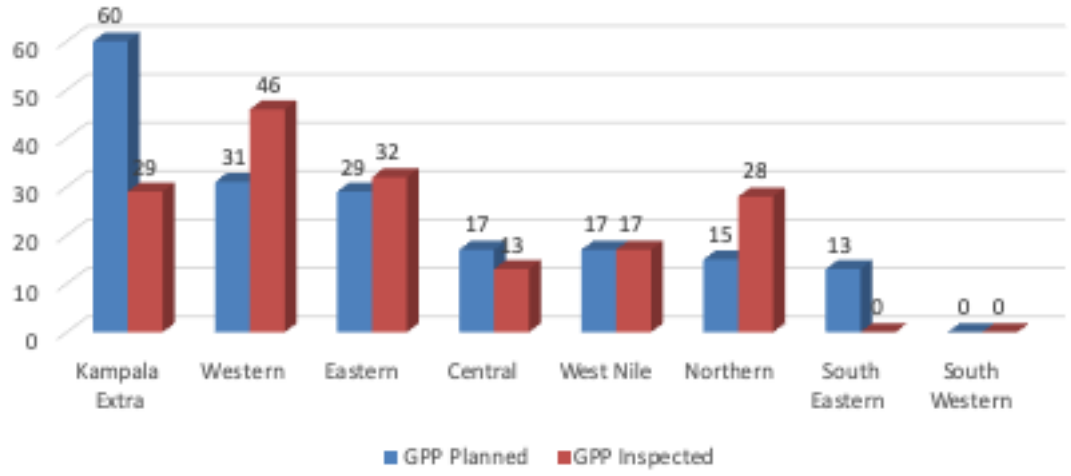
NDA inspects public and private not for profit facilities as part of the technical support and provide independent assessment of the systems in place. The outcomes of these inspections are shared with the management of the health unit, the district and the ministry for corrective and preventive actions. In the period under review, NDA planned to inspect pharmacy departments of health facilities and blood banks.

5.1 Good pharmacy practices (GPP) inspection statistics and results

NDA inspects pharmacy departments of public and private not for profit health facilities to assess their compliance with Good Pharmacy Practices (GPP). This is part of the NDA technical support to these facilities to ensure the quality and traceability of drugs.

Figure 25: Distribution of GPP inspections by region

Distribution of GPP inspections by region



In the July-December period; 182 good pharmacy practice (GPP) inspections were planned; 165 inspections were conducted with 91 resulting into compliant rating. South Eastern conducted no GPP due to other commitments. South Western region had scheduled their GPP inspections in the third and fourth quarters of the financial year.

Most common observations:

- Absence of specialized pharmacy staff
- Unsuitable premises: The public facilities especially health center 3 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.

5.2 Blood banks inspection statistics and results

NDA inspected Blood banks and the associated blood collection centres as part of our support to ensure the quality of blood and provide independent oversight to the Uganda blood transfusion services (UBTS). The purpose was to establish a baseline and assess the applicability of the PIC/S GMP Guide for Blood Establishments in assessment of compliance of Uganda Blood Transfusion Services Regional Blood Banks to good practices in blood collection, component preparation, quality control and distribution of blood and blood components.

In the July to December period;

- 12 blood banks and blood collection centres were planned
- 12 inspections were conducted.
- All these inspections were not compliance rated because it was determined before inspection that they were to provide benchmark for making guidelines and would not be rated.

Most common observations

- Lack of sufficient resources: The blood banks and collection teams did not have sufficient resources (including measuring equipment for vital signs) to effectively and reliably carry out their activities
- Lack of adequate personnel: The regional blood bank did not have sufficient personnel to carry out all the technical duties
- Inadequate record keeping; The records of activities done were not readily available to assure that all activities were done as per the procedures.

Action taken

- The Uganda Blood Transfusion Services (UBTS) was required to provide a corrective action and preventive action (CAPA) plan which shall be verified during the next inspection.
- A follow up meeting was planned with UBTS to agree on the implementation of the CAPA.
- Exploring modalities for establishing a system for licencing

Inspection of pharmacies

6.0 POST MARKET SURVEILLANCE

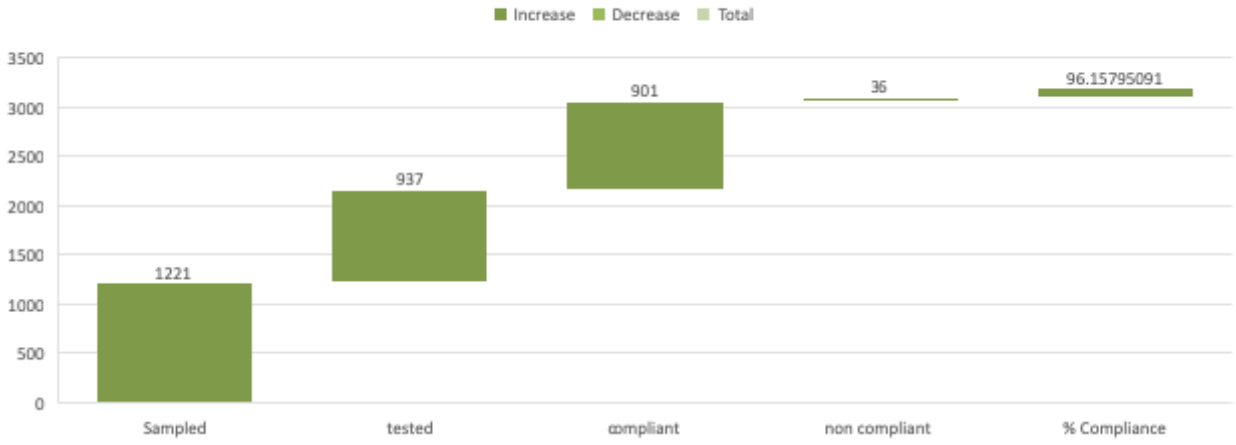
Post market surveillance (PMS) is important in fighting substandard and falsified medicines and ensuring that the drugs circulating on the market are of acceptable quality. The PMS strategy is premised on three priority areas adopted from the World Health Organization Global Surveillance and Monitoring System, namely; Prevention, Detection and Response to Substandard and falsified medical products. In Uganda, this strategy is implemented through post market sampling, management of complaints and recalls and market surveillance.

6.1 Post marketing sampling statistics and results

Post marketing sampling is a critical part of the post market surveillance strategy. Post market sampling is done at the port of entry and on the market. The market and port of entry sampling were conducted as per the annual plan and sampling protocol approved at the beginning of the financial year as part of the annual work plan. All batches of imported long-lasting insecticide-treated mosquito nets, condoms and gloves underwent post shipment mandatory sampling for analysis, while a risk-based sampling plan was followed for the rest of the products.

Figure 26: Post market sampling and testing statistics

Post market sampling and testing



In the July to December 2020 period; 1221 batches were sampled (982 ports of entry and 239 market), 937 batches were tested (763 port of entry and 174 market), 901 batches were compliant (746 port of entry and 155 market) and 36 batches were non-compliant (17 port of entry and 19 market). The overall compliance rate was 96.2%

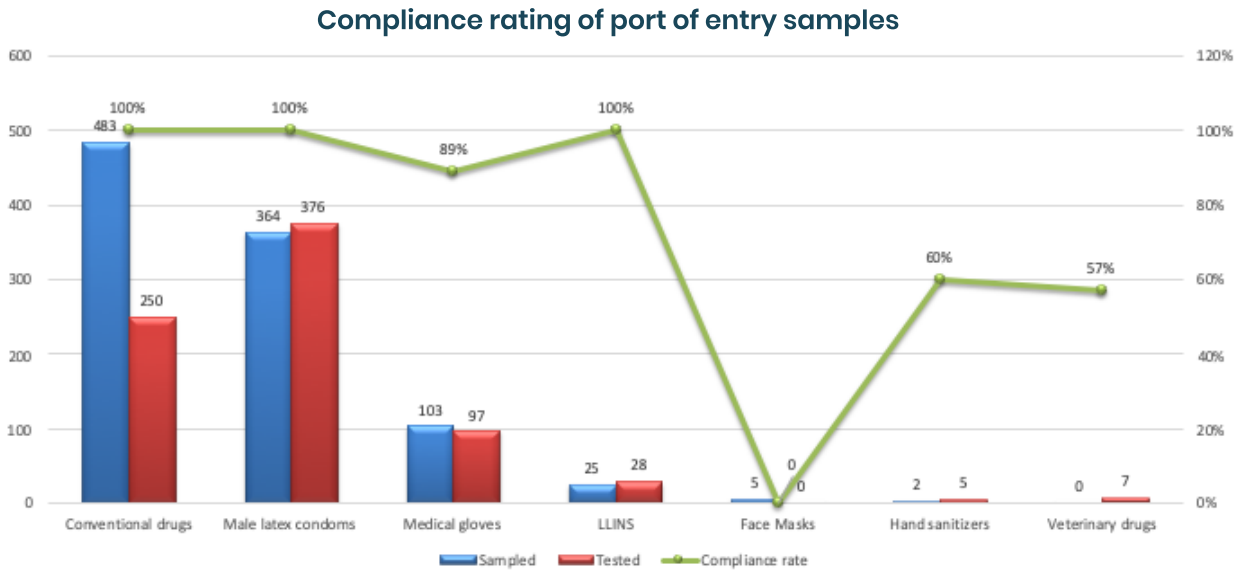
1221

batches were sampled (**982** ports of entry and **239** market), **937** batches were tested

[5] Post 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 routine monitoring of the products on the market.

6.2 Port of entry sampling statistics and results

Figure 27: Distribution and compliance rating of ports of entry samples



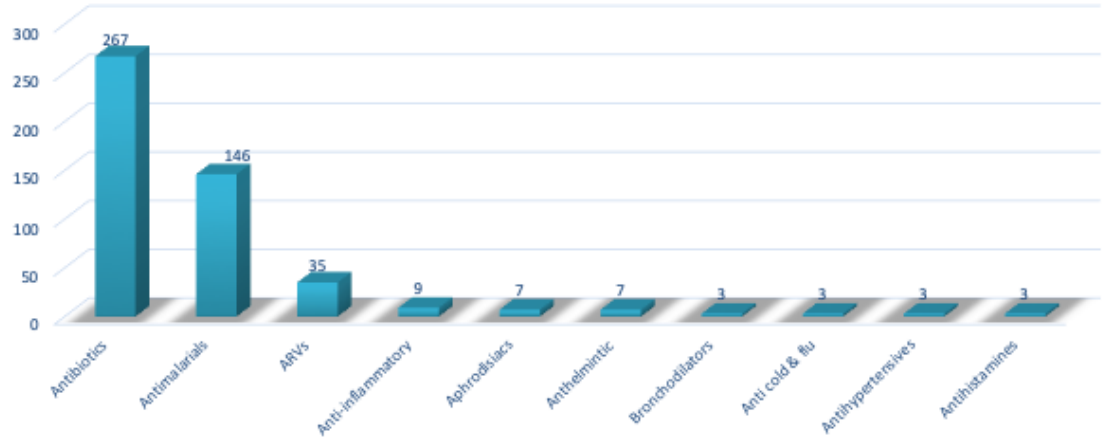
The port of entry samples consisted of 483 batches of conventional drugs, 364 of male latex condoms, 103 of medical gloves, 25 of long-lasting insecticide treated mosquito nets (LLINS), 5 of face masks and 2 of hand sanitizers. Face masks were not tested in the review period. However, samples of male latex condoms, LLINS, hand sanitisers and veterinary drugs from the previous period were tested. The overall compliance rate for port of entry samples was 97.8% (746 of the 763 batches tested).

483

batches of conventional drugs, **364** of male latex condoms, 103 of medical gloves, **25** of long-lasting insecticide treated mosquito nets (LLINS), **5** of face masks and **2** of hand sanitizers.

Figure 28: Distribution of conventional drugs sampled at the ports of entry

Distribution of conventional drugs sampled at the ports of entry

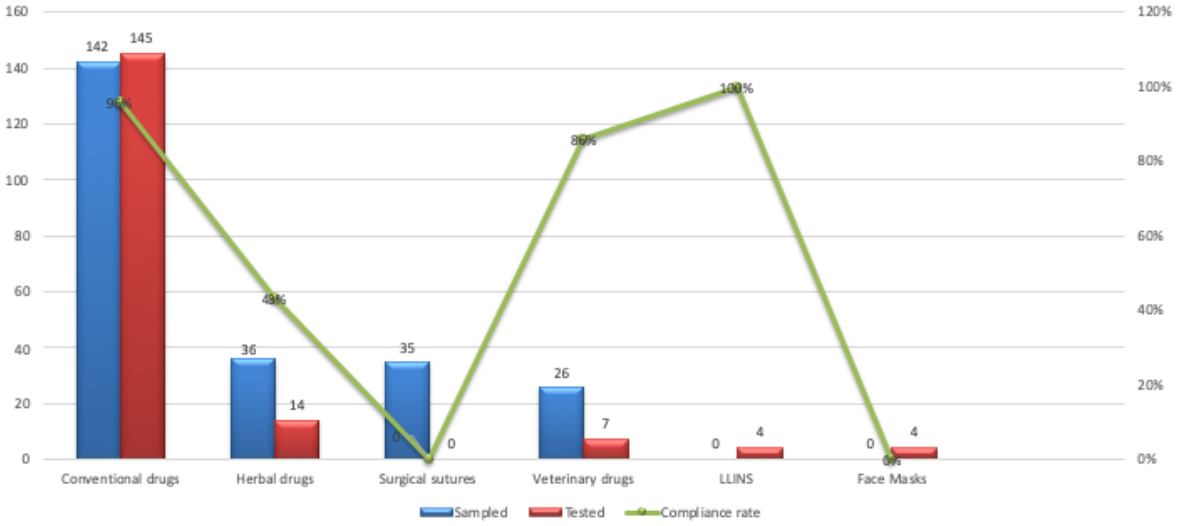


Two therapeutic categories contributed 85.5% of the conventional drugs sampled at the port of entry with 55.3% (267 of 483) being antibiotics and 30.2% (146 of 483) antimalarials.

6.3 Market sampling statistics and results

Figure 29: Distribution and compliance rating of samples from the market

Compliance rating of market samples



A total of 700 batches were planned for the July-December 2020 period. 239 batches were sampled from the market consisting of 142 batches of conventional drugs, 36 of herbal drugs, 35 of surgical sutures and 26 of veterinary drugs. A total of 174 batches were tested comprised of 145 batches of conventional drugs, 14 of herbal drugs, 7 of veterinary drugs and 4 each for LLINS & face masks. The overall compliance rate for market samples was 89.1% (155 of the 174 batches tested).

700

batches were planned for the July-December 2020 period. **239** batches were sampled from the market consisting of **142** batches of conventional drugs, **36** of herbal drugs, **35** of surgical sutures and **26** of veterinary drugs.

Most common observations

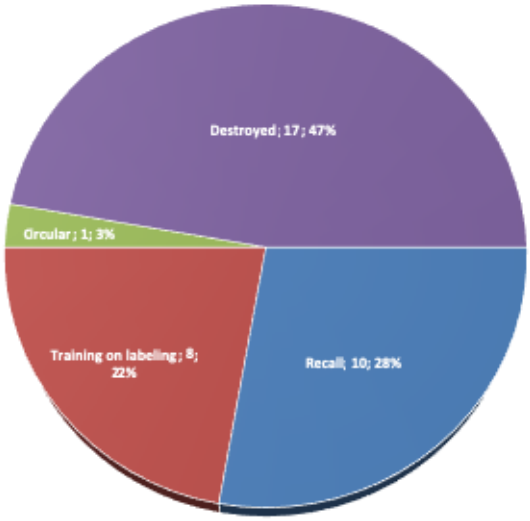
- For ports of entry samples; Veterinary drugs had the lowest compliance rate at 57% followed by hand sanitisers at 60% and medical gloves at 89%.
- For market samples; Facemasks had the lowest compliance rate at 0% followed by herbal drugs at 43% and veterinary drugs at 86%.

Actions taken on non-compliant batches

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

Figure 30: Action taken on non-compliant batches of drugs

Action taken on non-compliant batches



6.4 Product Complaints statistics and results

NDA conducts investigation of complaints registered against medical products (drugs and medical devices). They are investigated to establish the veracity of the complaint, identify the probable cause and take the necessary actions.

The directorate conducted investigation of product complaints related to the identity, quality, durability, reliability, safety, efficacy or performance of a medical product (Human, Veterinary, Herbal and Medical Devices) after release for distribution. The complaints are received by NDA from health workers and members of the public through Standard NDA form for pharmacovigilance or an online reporting platform . Other reporting platforms include toll free telephone number +256 800 101 999, WhatsApp line number +256791 415 555 or the Med safety mobile app downloadable from Google play store for android or the app store for iOS.

Figure 31: Categories of products for which complaints were received

Categories of products for which complaints were received

[6]online reporting platform is available at https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=UG

In the July to December 2020 period; 21 product related complaints were received consisting of 8 (38.1%) for Human conventional products, 5 (23.8%) for medical devices and healthcare products and 4 (19%) each for Veterinary products and Herbal products. 57.1% (12 out of 21) of the complaints received were investigated and regulatory action taken.

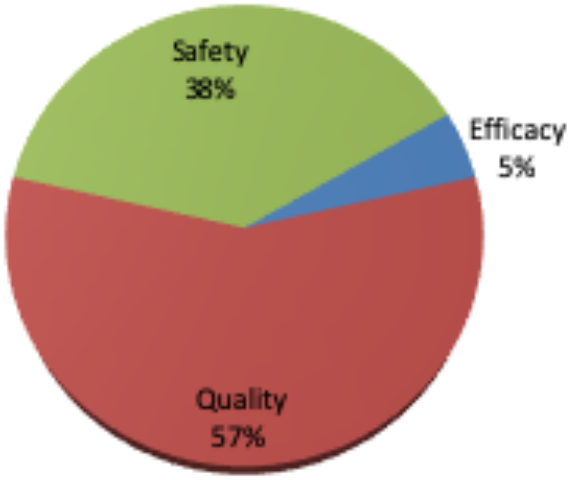
21

product related complaints were received consisting of **8** (38.1%) for Human conventional products, **5 (23.8%)** for medical devices and healthcare products and **4 (19%)** each for Veterinary products and Herbal products.

Most common observations

Figure 32: Showing the nature of product complaints

Nature of product complaints



57.1% of the complaints related to the quality of the product, 38.1% related to the safety of the product (adverse events) and 4.8% related to lack of efficacy.

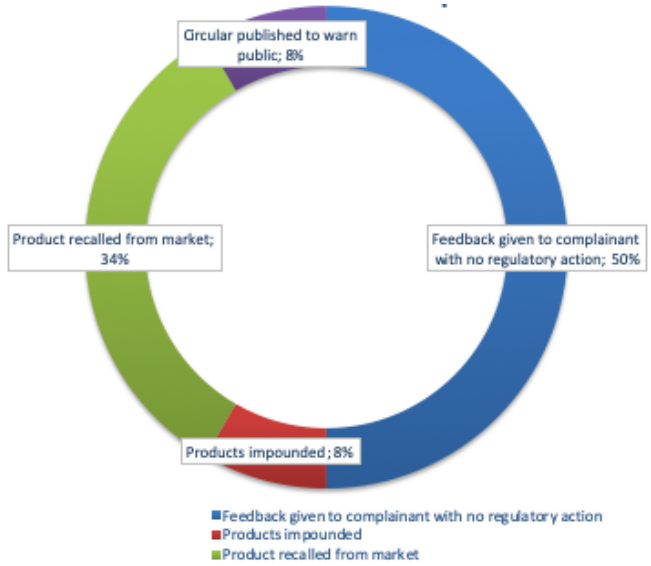
57.1%

of the complaints related to the quality of the product, **38.1%** related to the safety of the product (adverse events) and **4.8%** related to lack of efficacy.

Action taken

Figure 33: Showing action taken on complaints

Action taken on complaints



12 complaints where investigations were complete resulted into; 6 feed back to the complainant (i.e. did not require regulatory action), 4 product recalls, 1 impounding of the product and 1 circular to warn the public.

12

complaints where investigations were complete resulted into; **6** feed back to the complainant (i.e. did not require regulatory action),

6.5 Recall statistics and results

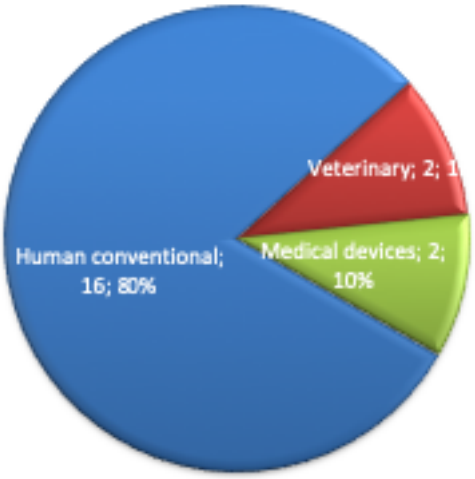
A recall is an official order to remove from the market, a product that does not meet the requirements of the marketing authorisation and return it for appropriate action. Drug recalls are made by NDA or the marketing authorisation holder as a result of complaints, surveillance or sampling and testing results.

Upon confirmation of a defective product on the market; NDA can institute a product recall through the importer/LTR of the product. Recalls are classified with regard to the relative health hazard associated with the use of or exposure to the recalled product.

Upon recall of the defective products on the market, the LTRs/importers/ manufacturers are required to submit root cause investigation to explain the occurrence of the observed non-conformance as well as corrective and preventive action (CAPA) to avoid recurrence of the defect. The directorate evaluates the recall report and the proposed CAPA for appropriateness before providing feedback and audit of the recall. Between July and December 2020, the directorate instituted recalls for products (medicines and medical devices) that did not meet the requirements of safety, efficacy or quality. 20 products were recalled from the market as shown in the figure below.

Figure 34: Category of products recalled

Category of products recalled



16 (80%) of the recalls were for human conventional drugs; 2 (10%) for Veterinary drugs and 2 (10%) for medical devices

16 (80%)

of the recalls were for human conventional drugs; **2 (10%)** for Veterinary drugs and **2 (10%)** for medical devices

Most common observations

- 15 out of 20 (75%) recalls were audited and traces of these products were found on the market.
- 16 (80%) of the recalls were due to quality defects, 3 (15%) due to safety arising from adverse drug reactions and 1 (5%) was unauthorized (unregistered) drug.

Figure 35: Reasons for recall of products

Reasons for recall

Action taken

- Recalled products were destroyed.
- Review of the guidelines to institute punitive measures for LTR whose recalls are considered ineffective.

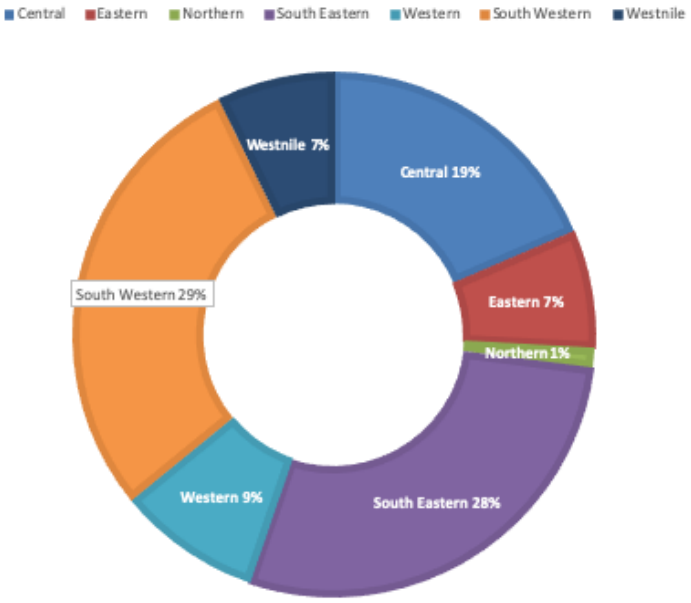
6.6 Market Surveillance statistics and results

NDA carries out surveillance activities to detect any unauthorized /smuggled, substandard and falsified products (medicines and medical devices) including products recalled from the market. This is done to protect the public from potential harm caused by these products. This is done through random sampling of outlets and intelligence led targeted operations. The directorate planned one surveillance operation per quarter.

In the July to December 2020 period, 3 surveillance operations were conducted where 45 substandard products and 30 recalled products (which had remained on the market) were found on the market and impounded. A total of 159,046 units of substandard and recalled products were recovered from the market.

Figure 36: Regions where Substandard and recalled products were recovered

Regions where substandard and recalled products were recovered



According to the 3 surveys conducted, 28.8% of Substandard were recovered from South Western, followed by 28.4% from South Eastern and 18.4% recovered from central excluding Kampala (Kampala was not surveyed during this period).

Most common observations

- 28.8% of the products were recovered from South Western region.
- 97,600 tablets (units) of Mykoff mentholated tablets were the biggest individual amount of the recalled product recovered during surveillance.

Actions taken

- Show-cause letters were written to 100 pharmacies found in possession of the substandard and recalled products.
- 5 suspects linked to smuggled drugs were arrested (one in Bugiri and two each in Kampala and Mubende/Fortportal).
- Three suspects of smuggled drugs were arrested along William Street.

An inspector inspecting a consignment of vaccines at the Port of entry.

7.0 CONTROL OF IMPORTS AND EXPORTS

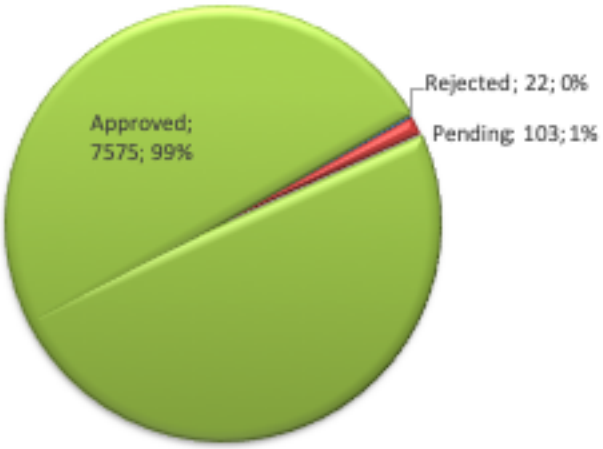
The Inspectorate performs verification of applications for importation of registered drugs within 3 working days and verification of unregistered drugs within 10 working days. Port of entry inspection and release are to be performed within 2 working days after submission of an inspection request to the National Drug Authority.

7.1 Verification statistics and results

All imports and exports of drugs into and out of Uganda must be verified by NDA prior to importation/exportation to verify that the drugs comply with the national regulatory framework, which includes registration pursuant to the Regulations on Registration of Drugs and Compliance with Good Manufacturing Practice Standards prescribed by the National Drug Authority from time to time. The outcome of this verification activity is issuance of a verification certificate, which is issued only to consignments that are compliant with national requirements, and hence authorized for importation into Uganda. This activity is done for every consignment to be imported into Uganda by any importer.

Figure 37: Status of applications for verification certificates as at Dec 31st 2020

Status of applications for verification certificates



In the July to December 2020 period; 7,700 applications for verification certificates were received, 7,575 (98.4%) were approved, 22 (0.3%) were rejected and 103 (1.3%) were pending

7,700

applications for verification certificates were received, **7,575 (98.4%)** were approved, **22 (0.3%)** were rejected and **103** (1.3%) were pending

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

1. Rejected: These were rejected for various reasons (see Figure 39 below). There were 22 in number accounting for 0.3% of the total applications.
2. Approved: These were granted verification certificates and were 7575 in number, accounting for 98.4% of the total count. This count includes verification certificates for consignments which had not been imported or released by 31st December 2020 or those which were cleared outside the single window system.
3. Pending: These are applications which were queried pending additional information. These were 103 in number accounting for 1.3% of the total count.

Most common observations

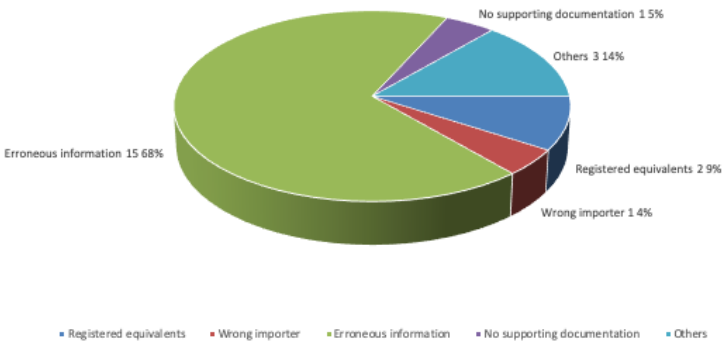
- 7,337 (95.3%) of the applications for verification certificates were for importation of drugs into Uganda.
- 363 (4.7%) of the applications for verification certificates were for exportation of drugs out of Uganda.
- Erroneous information was the most common reason for rejection

Action taken

Non-compliant verification certificate applications were rejected.

Figure 38: Reasons for rejection of applications for verification certificates

Reasons for rejection of VC applications



68.2% (15 of 22) of verification applications were rejected for erroneous information.

68.2%

(15 of 22) of verification applications were rejected for erroneous information.

7.2 Ports of entry inspection statistics and results

When a verified consignment arrives at the port, it is physically inspected to verify compliance with regulatory requirements prior to entry/exit of/ from Uganda. This may also involve sampling of imported consignments for laboratory analysis as part of the mandatory analysis program or on a risk-based approach, depending on the criticality of the product and perceived risk of the products imported.

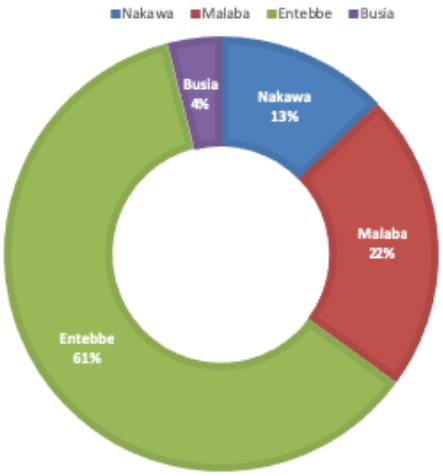
NDA operates four port of entry offices in Entebbe international airport, Nakawa (within the vicinity of the inland container depots), Busia and Malaba one-stop border posts.

Each of these ports of entry/exit is manned by inspectors of drugs to carry out inspection in compliance with the law, prior to entry/exit of the drugs.

In the July to December 2020 period; 5,044 import and 8 export consignments of drugs were received and inspected at the ports. 4886 import consignments were rated compliant and approved, one was rated non-compliant and rejected, 45 were queried and 112 were conditionally released

Figure 39: Distribution of consignments at ports of entry

Consignments received at port of entry



The distribution of import consignments at the ports of entry/exit was;

Nakawa **645** (accounting for **12.8%** of total consignments), Malaba **1125** (accounting for **22.3%** of total consignments), Entebbe 3071 (accounting for **60.9%** of total consignments) and Busia **203** (accounting for **4.0%** of total consignments).

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

Figure 40: Trend of consignments released at Busia OSBP within 2 days

Busia OSBP: % consignments released in 2 days

Figure 41: Trend of consignments released at Entebbe airport within 2 days

Entebbe airport- % released in 2 days

Figure 42: Trend of consignments released at Malaba OSBP within 2 days

Malaba OSBP: % released in 2 days

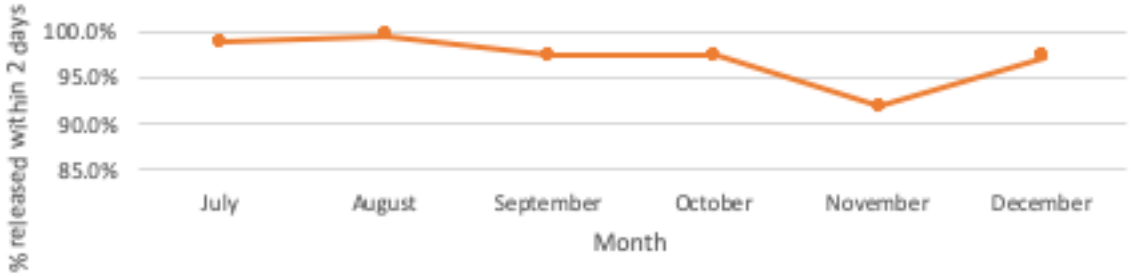


Figure 43: Trend of consignments released at Nakawa port of entry within 2 days

Nakawa- % released in 2 days

Note: There was a gradual decline in the number of consignments received and inspected through Nakawa over the period of July-Dec. 2020, and this could be attributed to truck restrictions at the Busia/Malaba border during the COVID-19 interventions.

Most common observations

- Variations in the particulars of the registered product
- Products undergoing mandatory analysis were conditionally released pending analysis results from DLS.
- Frozen and clinical trial products were conditionally released for physical verification at importer's premises

Action taken on non-compliant

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

Stakeholder engagement.

8.0 ENGAGEMENT OF STAKEHOLDERS

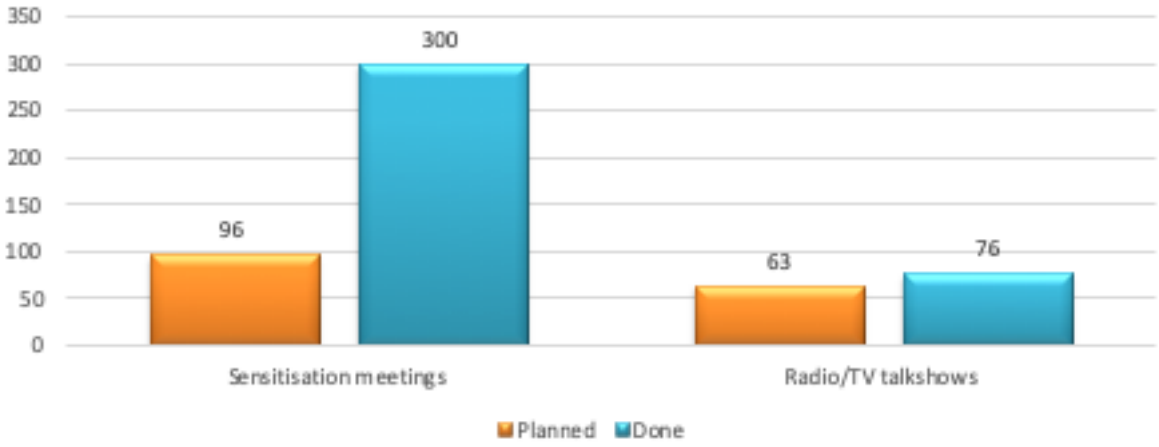
In a bid to promote voluntary compliance and ensure an informed and empowered public, NDA conducts sensitization of selected stakeholders and the public. The sensitization is geared towards building public confidence in the products we regulate and the services we provide. The sensitization is embedded in each activity of NDA that interfaces with clients or members of the public. The directorate conducts sensitization of public through radio & TV talk shows and the targeted stakeholders through meetings and one on one engagement during routine inspection and support supervision activities.

The Inspectorate conducts regular sensitization programs as indicated in the work plan and budget at the beginning of the financial year. The annual work plan is further broken down into quarterly work plans.

Stakeholder engagement statistics and results

Figure 44: Summary of stakeholder engagement activities

Summary of stakeholder engagements



In the July to December 2020 period; the target for stakeholder engagement meetings was 96 while the target for radio and TV talk shows was 63. 300 stakeholder engagement meetings and 76 radio and TV talk shows were held.
The stakeholder engagement meetings were exponentially increased by the Veterinary department's sub county sensitization meetings. Additionally, a healthcare workers' stakeholder engagement meeting was held in Jinja on substandard and falsified (SF) drugs identification and reporting, as well as a sensitization meeting of youth group in Rubindi– Mbarara.
The radio and TV talk shows were increased by the free shows provided by government through the PR office, the district radio talk shows by the veterinary department and the 4 radio talk shows on substandard and falsified drugs.

Most common observations during stakeholder engagements

The most common issues raised were:

- The most commonly highlighted roles of NDA by the participants included; checking quality of drugs, import/export control of drugs, regulation of manufacture of drugs, licensing of drug outlets, enforcements action of non-compliant individuals, confiscating expired and substandard drugs, sensitizing the public on proper use of drugs among others.
- Widespread advertising of herbal drugs with exaggerated and misleading claims
- Self-medication was reported to be widely practiced as farmers opted to treat their animals without consulting veterinary professionals.
- Acaricides were ranked as the most commonly used category of drugs. Acaricide ineffectiveness was the most predominant complaint raised by farmers.
- Due to the purported ineffectiveness of the acaricides, several farmers confessed that they had resorted to use of crop pesticides like Dudu Acelamectin and 2-in-1 Ocelamectin.
- Some farmers claimed they used to spray animals with Larva (Diclorvos) but stopped due to serious and severe adverse effects like death of animals, blindness, loss of milk production and skin rashes.

Action taken

- The directorate also developed audio-visual materials on SFs to be aired on radios and TVs (in English and local languages) and posters sensitising the public and health care professionals on reporting SF products with guidance from WHO experts.
- Mandatory sampling and analysis of acaricides at the ports of entry
- Promoting domestic manufacture of acaricides and other essential drugs

Enforcement operation

Christopher Luzinda-Manager Western Region addressing the press after an operation in Western region on 22102020 at Hoima regional office-In attendance were DPC-Hoima, Representative of CAO.

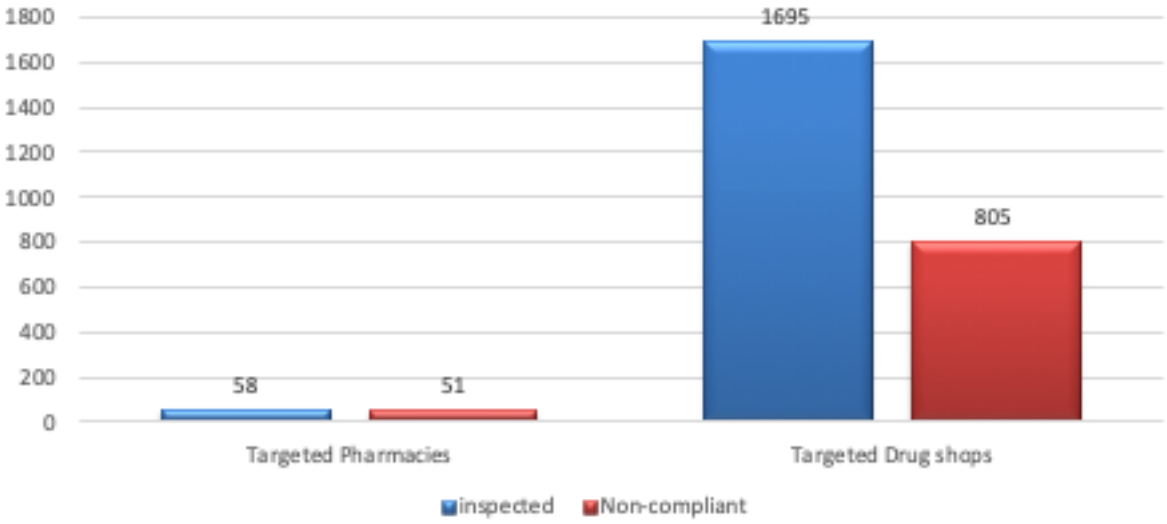
9.0 ENFORCEMENT STATISTICS AND RESULTS

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.

Figure 45: Distribution of outlets visited during enforcement operations

Outlets inspected during enforcement operations



In the July to December 2020 period; 42 intelligence reports /recommendations were received and 32 were acted upon with enforcement actions effected in line with the intelligence recommendations. 5 operations (including one night-operation in Kampala metropolitan area and aimed at illegal sale of government drugs) were conducted. 1,695 drug shops and 58 pharmacies were inspected with 805 drug shops and 51 pharmacies found unlicenced thus rated non-compliant

Most common observations
The most common observation was operating without a licence and lack of qualified personnel.
Actions taken on non-compliant

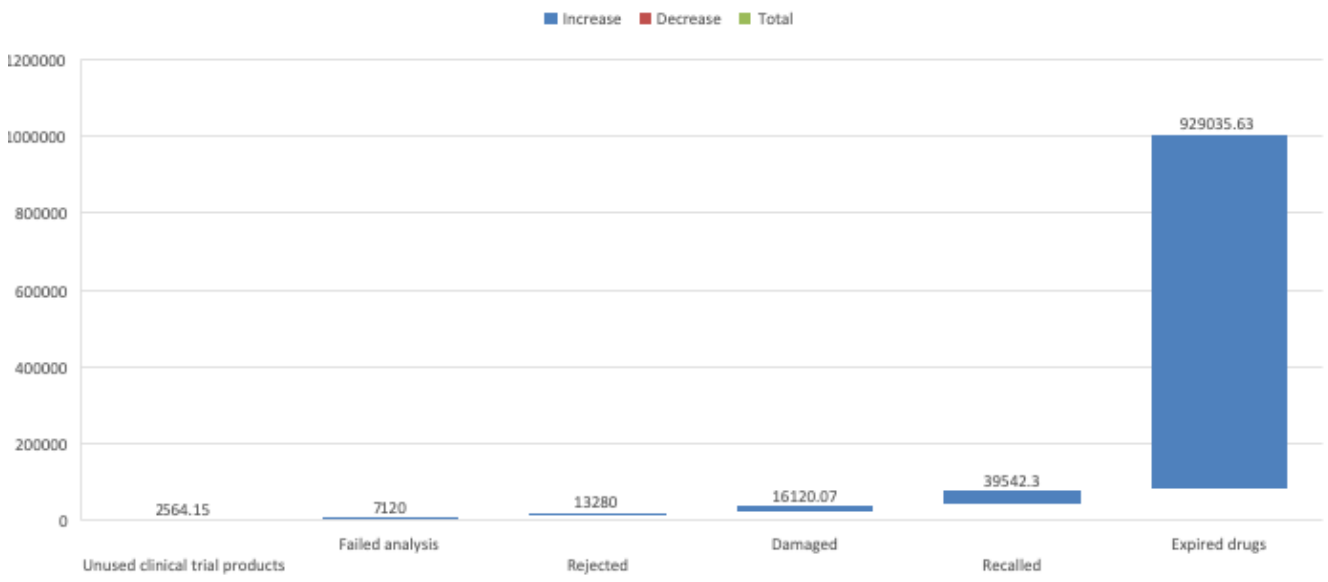
- 904 boxes of drugs were impounded with 858 boxes from drug shops and 46 boxes from pharmacies.
- 69 boxes were impounded from the night operation.
- 16 case files were submitted to the Director of Public Prosecutions
- 13 case files were sanctioned by DPP to proceed to court.
- 5 convictions were secured. Other court cases are ongoing.

Loading drugs from an illegal drug shop from Kyenda TC-Mubende district-20102020- Putting on the mask is Lawrence Kyagera-Driver Western Region and the second person is a client loading.

10.0 SUPERVISION OF 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).

Figure 46: The quantity of drugs disposed of with the reason for destruction



In the July to December 2020 period; 81 applications for the supervision of destruction of drugs were received and processed. The directorate also supervised the destruction of internally generated pharmaceutical waste (from the directorate of laboratory services). 1,007,662.15 kg of pharmaceutical products was destroyed. The chart shows that 92.2% of the disposed drugs were expired.

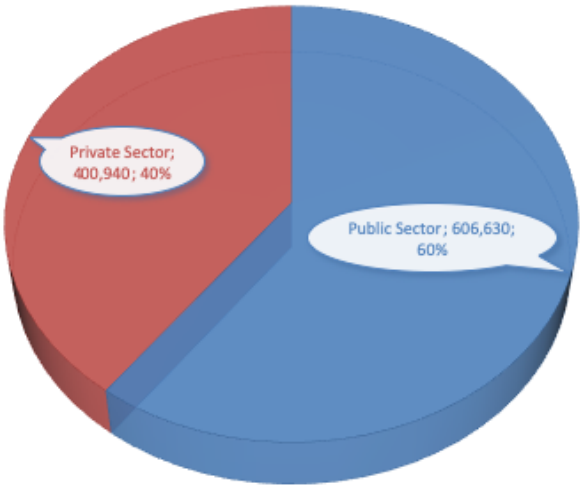
81

applications for the supervision of destruction of drugs were received and processed.

Most common observations

Figure 47: Sources of disposed pharmaceutical waste

Distribution of the source of disposed pharmaceuticals by quantity (kg)



60% (602,130 kg) were expired and obsolete drugs from public sector including 4500kg of laboratory waste from the National Drug Authority directorate of Laboratory Services (utilized sampled products after analysis) and 40% (400,940 kg) was from the private sector

60%

(602,130 kg) were expired and obsolete drugs from public sector

Radio talk show at VOT FM- Fortportal City on 17/11/2020-R to L-Christopher Luzinda-Regional Manager, John Twasiima-DDI-Bunyangabu district and Stephen Ssemakalu-Regulatory Officer.

11.0 TOP PRIORITIES MOVING FORWARD

The top priorities moving forward are:

a. Strengthening systems for ensuring the quality of medicines on the market: We envisage to continue to strengthen compliance to Good Distribution Practices, control the transportation of drugs and establish a regulatory framework for online supply of drugs. These will help to ensure the quality of drugs during the various activities involved in the distribution.

b. Automation of business processes: Due to the fast-changing landscape in the regulation of drugs and the ever-increasing need of Ugandans to access information, NDA is looking to enhance automation of its business processes. The directorate will be taking advantage of that environment to have all its business processes automated. This shall facilitate the provision of services, generation of reports, determination of risk rating and measurement of service delivery timelines.

c. Risk-based approach: The regulation of drugs has become increasingly complex, fast-paced and innovative with a rapidly changing environment. Consequently, NDA is developing a risk-based framework to help identify and assess the risks for the facilities and activities it regulates. This will enable a shift from regular inspection cycles to a more flexible risk-based approach. This flexible approach will be continuously updated based on the risk rating of the activity. The directorate shall then prioritize activities and facilities and determine the frequency and scope of inspections based on the risk rating. This should encourage compliance and enable the directorate to focus resources to the activities deemed to be higher risk.

d. Support to the domestic pharmaceutical industry: We will strengthen support to the local industry especially in product development to ensure that locally manufactured products are competitive in international markets, as well as comply with internationally acceptable standards of efficacy, quality and safety. We will continue to support prospective investors in the pharmaceutical industry to establish facilities that are compliant with international standards of Good Manufacturing Practices (GMP) which would position them to market their products successfully on the international market. We will also encourage the development of herbal medicines.

e. Evidence based decision making: The directorate will continue to monitor the environment to identify emerging issues for the facilities and activities we regulate in order to be able to take steps to address them. Decisions will be guided by the intelligence information generated through these monitoring activities and operational research. For example, enforcement operations and import authorisations will be guided by intelligence information and data from research.

f. Leveraging local, regional and international partnerships and cooperation: NDA is looking at ways to increase active dialogue and collaboration with local, regional and international regulatory partners and trade associations. The directorate will look towards harnessing this synergy. We will continue to play our part in supporting the East African Community medicines regulatory harmonization activities related to inspectorate and enforcement. At a strategic level, the participation of inspectors in the African Medicines Agency medicines harmonization activities will also be given priority, as well as pursuing accession to the Pharmaceutical Inspection Co-operation Scheme (PIC/S). Once realized, these partnerships and cooperative arrangements will improve resource utilisation through minimization of duplication of regulatory efforts and will make the Ugandan pharmaceutical sector attractive for investment. This will enable the sector to play a greater role in Uganda's economic development.

g. Technical capacity building of staff: As a directorate we believe that our strength lies in competence of our people. To continue positioning the NDA inspectorate as a center of excellence in East Africa and Africa as a whole, we shall prioritise the technical and professional development of staff to enable them to be at par with the cutting-edge developments in the regulatory and pharmaceutical sciences. The COVID-19 pandemic has highlighted the need for the country to build technical regulatory capacity for face masks, medical gases, e-commerce, personal protective equipment, new drug molecules and technologies as well as herbal remedies. For regulatory personnel to be proficient enough in their work, we believe that they must be ahead of the industry in technical knowledge and competence.

NDA management providing technical guidance to EAMVL.

Safe Drugs Save Lives

Regional offices

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 70

www.nda.or.ug