UGANDA

NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

VETERINARY MEDICINES UPDATES

BULLETIN

Issue 6, October 2021

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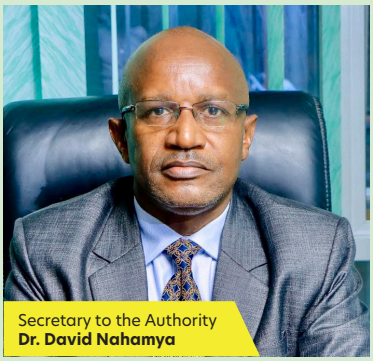

Secretary to the Authority
Dr. David Nahamya

Warm greetings from the National Drug Authority! It is with great pleasure that we bring to you this sixth issue of the Veterinary Medicines Update Bulletin and we hope that you find the content therein informative and beneficial.

The world is facing one of the most challenging times in history due to the COVID 19 pandemic with so much fear in the hearts of the people, and yet life has to move on. A lot has changed, from having to go from a free world to a restricted one. It is no longer business as usual, but the good news is - human beings were created dynamic and creative, ready to adapt and adopt in any situation.

The National Drug Authority was able to successfully engage various veterinary stakeholders in the financial year 2020/2021 through a number of activities which included post marketing surveillance, drug safety monitoring, stakeholder sensitizations, training of animal health practitioners, radio and TV talk shows, and farm visits in order to promote and protect public health.

A new model of stakeholder engagement was adopted, since the lockdown, which saw us carry out sensitization meetings at sub county level in forty three (43) districts spread across all the regions of Uganda. We ably covered four hundred and four (404) sub counties and reached approximately six thousand and seven hundred (6700) people during the sensitizations alone. We assessed the knowledge and practices of veterinary practitioners and farmers in distribution, handling and use of veterinary medicines; and from this great feedback was obtained. With these feedback, newer models of operation shall be generated in order to enhance our regulatory capacity and serve the country better.

In addition to the district technical teams and the farmers, key service delivery and leaders within the districts were engaged including the Resident District Commissioners (RDCs), Chief Administrative Officers (CAOs), Local Council V (LC5s), Local Council III (LC3s), District Veterinary Officers (DVOs), and the District Production Officers (DPOs) of each district.

We appreciate every institution that contributed to the success of these activities and we thank you for your invaluable continued support and cooperation.

For God and my Country.

Dr. David Nahamya
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STAKEHOLDER ENGAGEMENTS AND COLLABORATIONS

The National Drug Authority has actively engaged veterinary stakeholders to ensure that veterinary drug regulation is efficient and effective. Both our national and international stakeholders have made great contributions through their various expertise and feedback in regard to veterinary drugs regulation.

The veterinarians, para veterinarians, farmers, veterinary drug shop and pharmacy operators, opinion leaders, academia, the East African Community (EAC), Codex Alimentarius, the World Organization for Animal Health (OIE), Pan African Veterinary Vaccine Center of African Union (AU-PANVAC), the Global Alliance for Livestock Veterinary Medicines (GALVmed), to mention just a few have greatly contributed to the improvement of veterinary drugs regulation in Uganda.

During the financial year 2020/2021 several engagements were carried out in a number of districts where materials and information pertaining to drugs was shared. NDA is committed to promoting public accessibility to relevant drug information that is needed to empower the people on their choices concerning medicines. Information in the form of posters, bulletins, brochures, note books, T-shirts, head caps and calendars were distributed to the target groups during sensitization meetings, radio and TV talk shows and training of the technical staff in each district.

District engagements and collaborations

Sensitization meetings at Sub County level

The National Drug Authority has put in much effort to ensure that veterinary drugs are well regulated, but despite the efforts, veterinary drug regulation has faced a number of challenges, putting both the livestock and human population in jeopardy.

In a bid to address some of the challenges, NDA carried out approximately four hundred (400) Sub County sensitization meetings in forty three (43) districts between July 2020 and April 2021. A maximum of ten (10) sub counties per district were selected to engage farmers, sub county veterinary extension workers, district and sub county opinion leaders in collaboration with the District Production's Office and the Ministry of Agriculture, Animal Industry and Fisheries (MAAIF) zonal inspectors.

The opinion leaders included the Chief Administrative Officers (CAOs), Resident District Commissioners (RDCs), LC5s, LC3s and SACAOs. The table below shows the districts that were reached including the participation level in each district.

Table 1: List of districts covered during the stakeholder engagements between July 2020 and April 2021.

NDA Regional office	Name of District	Total number of administrative units reached by NDA per district	Total number of administrative units per district	Total number of participants invited by NDA per district	Actual attendance of participants per district
EASTERN	Soroti	10	14	140	138
	Mbale	10	27	140	122
	Napak	9	14	126	119
	Moroto	6	11	84	80
	Bukedea	10	16	140	138
	Kapchorwa	10	15	140	138
WEST NILE	Adjumani	10	11	140	141
	Arua	10	13	140	140
	Pakwach	10	10	140	140
	Maracha	10	19	140	141
CENTRAL	Bukomansimbi	5	5	70	77
	Butambala	6	6	84	88
	Nakaseke	10	15	140	139
	Luwero	10	18	140	120
	Kalungu	7	7	98	109
	Mpigi	9	9	126	133
SOUTH WESTERN	Kanungu	10	23	140	148
	Kisoro	10	17	140	139
	Mitooma	10	13	140	140
	Sheema	10	14	140	162
	Rubanda	10	11	140	140
	Rukiga	6	6	140	143
	Kazo	10	10	240	270
	Bushenyi	10	17	240	229
	Sheema	10	14	240	227
	Isingiro	10	35	240	242
	Ntungamo	10	34	240	249
WESTERN	Masindi	10	10	140	144
	Kagadi	10	14	140	142
	Kyankwanzi	9	13	126	132
	Kiboga	10	14	140	141
	Kakumiro	10	24	240	204
	Mubende	9	19	216	193
	Kyenjojo	10	27	240	245
	Kyegegwa	10	18	240	245
SOUTH EASTERN	Kamuli	10	15	140	140
	Kaliro	10	15	140	140
	Iganga	11	11	154	153
	Luuka	8	12	112	115
NORTHERN	Gulu	10	10	140	148
	Nwoya	8	8	112	108
	Kaabong	11	17	264	222
	Kotido	9	9	216	209

The sub counties were selected with the help of the District Veterinary Officers of each district and the criteria for selection depended mainly on the availability of animals in a particular sub county among other factors.

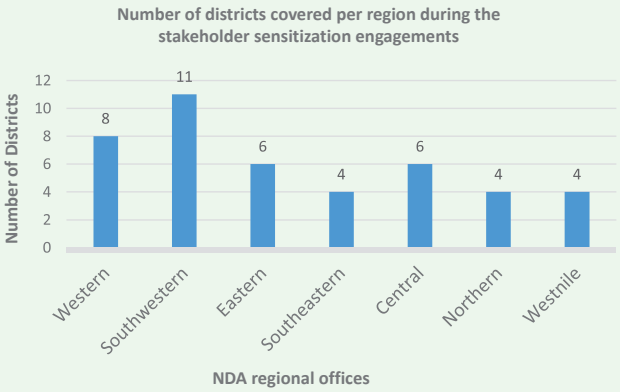


Figure 1: *The number of districts that were covered per NDA regional office during the sub county stakeholder engagements between July 2020 and April 2021*

There were more districts covered in the Southwestern and Western regions because of the high cattle density and the challenge of tick resistance to available acaricides which has led to acaricide counterfeiting in these parts of the country. We observed that there is no much complaints about acaricides in the Northern and Westnile regions and not many farmers spray their animals.

Figure 2: *Graph showing the level of participation of invited stakeholders per NDA regional office. Overall, there was a good turn up of the stakeholders at the meetings.*

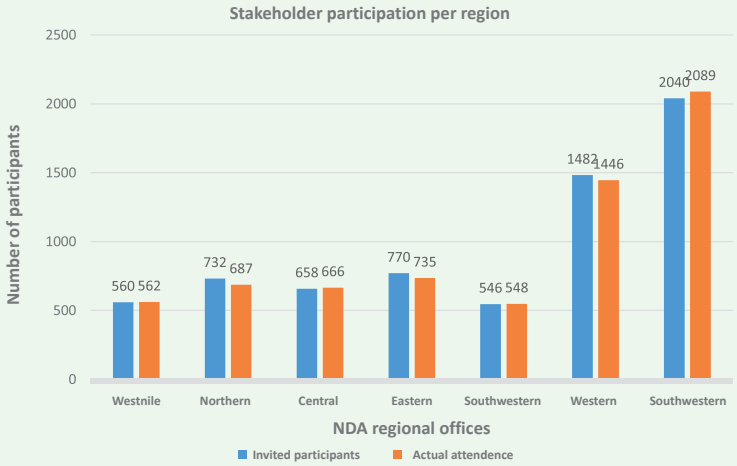


Figure 3: *Photograph of a sensitization meeting that took place in Adjumani District.*

Figure 4: *Photograph of a sensitization meeting that took place in Adjumani District.*

Figure 5: *Sensitization meeting in Pakwach District*

Figure 6: *Sensitization meeting in Masindi District*

Figure 7: *Sensitization meeting in Ntungamo District*

Training of veterinary practitioners

The National Drug Authority conducted trainings of veterinary practitioners in forty three (43) districts between July 2020 and April 2021. These trainings were organized after the sub county sensitization meetings with the farmers. A total of twenty (20) practitioners per district were invited including ten private and ten government practitioners. The other participants of the trainings included the DVOs, DPOs, CAOs, LC5s, RDCs and the MAAIF zonal vet inspectors. The topics covered included:

- NDA legal frame work, mandate, vision, mission, and role in veterinary drug regulation.
- NDA regulatory challenges.
- Rational and irrational veterinary drug use.
- Veterinary pharmacovigilance.
- Reporting of veterinary drugs related issues.
- Best practices in acaricide use.
- MAAIF presentation on policy issues.
- Giving feedback to the technical personnel following the sensitization meetings.

The trainings were of great importance because most of the issues that were raised by the farmers were practice related and therefore the practitioners had the chance of being notified about what is happening in their areas of practice.

Figure 8: *Veterinary practitioners training in Kyankwanzi District*

Figure 9: *Veterinary practitioners training in Ntungamo District*

Figure 10: *The NDA team having a discussion with a farm owner on the challenge of ticks on his farm*

Figure 11: *NDA team demonstrating the proper use of a spray pump on a farm in Mitooma District*

Figure 12: *Veterinary practitioners training in Isingiro District*

Figure 13: *Veterinary practitioners training in Sheema District*

Radio talk show engagements

The National Drug Authority conducted radio talk shows in forty three districts between July 2020 and April 2021. The most widely listened to radio stations were selected for this exercise. There were some districts that did not have any radio stations and the nearest station was used to reach the community.

The radio hosts moderated the talk shows centering the discussions on NDA legal mandate in medicines regulation, the role of NDA in veterinary drug regulation and rational drug use. The feedback and the questions from the public were varied ranging from regulation, practice and policy issues.

The guests included the NDA staff and the District Veterinary Officer or his representative. The table below shows the radio stations that were used to reach the community in the different districts.

Table 2: List of radio stations used to reach out the veterinary stakeholders in the different districts where stakeholder engagements were carried out

NDA Regional office	Name of District	Radio station
EASTERN	Soroti	Etop radio - Soroti
	Mbale	Step Broadcasting and Communication services - Mbale
	Napak	Totore FM - Moroto
	Moroto	Totore FM - Moroto
	Bukedea	Mama FM - Bukedea
	Kapchorwa	KTR FM - Kapchorwa
WEST NILE	Adjumani	Radio Amani - Adjumani
	Arua	Radio pacis - Arua
	Pakwach	Pakwach FM - Pakwach
	Maracha	Radio Pacis - Arua
CENTRAL	Bukomansimbi	Centenary FM - Masaka
	Butambala	Buwama FM - Buwama
	Nakaseke	Seke FM - Nakaseke
	Luwero	Seke FM - Nakaseke
	Kalungu	Buddu Broadcasting services - Kalungu
	Mpigi	Radio Buwama - Buwama
SOUTH WESTERN	Kanungu	Kanungu Broadcasting Services - Kanungu
	Kisoro	Voice of Muhabura – Kisoro
	Mitooma	Voice of Ruhinda - Mitooma
	Sheema	Radio west - Mbarara
	Rubanda	Voice of Kigezi - Kabale
	Rukiga	Voice of Kigezi - Kabale
	Kazo	Kazo FM - Kazo
	Bushenyi	B FM - Bushenyi
	Sheema	Hunter FM - Sheema
	Isingiro	Voice of Ankole - Ntungamo
	Ntungamo	Voice of Ankole - Ntungamo
WESTERN	Masindi	Kings Broadcasting Services - Masindi
	Kagadi	Kagadi Kibaale Community radio - Kagadi
	Kyankwanzi	Radio Kiboga - Kiboga
	Kiboga	Radio Kiboga - Kiboga
	Kakumiro	KCR FM - Kakumiro
	Mubende	Point FM - Mubende
	Kyenjojo	Unique FM - Kyenjojo
	Kyegegwa	Britop FM - Kyegegwa
SOUTH EASTERN	Kamuli	Kamuli Broadcasting Services - Kamuli
	Kaliro	Kamuli Broadcasting Services - Kamuli
	Iganga	NBS radio - Jinja
	Luuka	NBS radio - Jinja
NORTHERN	Gulu	Mega FM - Gulu
	Nwoya	Mega FM - Gulu
	Kaabong	Etoil Karamoja FM - Kotido
	Kotido	Etoil Karamoja FM - Kotido

Figure 14: *NDA team during a radio talk show in Kazo District*

Findings from the stakeholder engagements.

The National Drug Authority obtained useful feedback and questions (addressed in the FAQs section of this bulletin) through the sensitization meetings, trainings and radio talk shows. There were also observations made by the organisation that need urgent attention and corrective measures.

Table 3: Showing the issues observed during the stakeholder engagements, their associated risks and the possible solutions for the problems.

Issue/problem	Risks	Possible remedies
1. Uncontrolled access to classified medicines by farmers.	• Increased Resistance to drugs. • Non observance of drug withdrawal periods which results in increased drug residues in foods of animal origin and poses a risk to humans. • Poor treatment outcomes which leads to loss of confidence in registered drugs.	• Educate the farmers on the value of seeking professional advice from veterinary practitioners. • Strengthen regulation of veterinary practice. • Increased support supervision.
2. Wide spread resistance of ticks to acaricides	• Overuse/misuse of existing acaricides. • Use of agrochemicals • Falling prey to counterfeiters and smugglers • High prevalence of tick borne diseases.	• Sensitization and education of all stakeholders including farmers and vet practitioners on good practices in acaricide use. • Multipronged approach to tick population management.
3. Veterinary pharmacovigilance is not yet fully appreciated by the grass root practitioners	• A lot of drug complaints go unreported. • Potential adverse drug reactions go unreported. • Potential defective and ineffective drugs on the market	• Increased sensitization and training on pharmacovigilance at grass root level • Disseminate reporting tools at grass root level
4. Poor cold chain facilities in both the private and government sector. And unreliable power supplies in the rural areas.	• Deterioration of cold chain medicines in storage especially vaccines. • Increased outbreak of epidemics due to ineffective vaccination.	• Increased sensitization on cold chain management and vaccine handling. • Partnering with development partners to assist in provision of cold chain equipment and power back up.
5. Strong perception that Asian manufactured drugs are of poor quality.	• Loss of confidence in available and registered drugs.	• Increased sensitization of stakeholders to demystify myths. • Strengthen pharmacovigilance to improve reporting of drug related issues • Increased market surveillance on complained about drugs.
6. Lack of diagnostic facilities for veterinary diseases.	• Blind treatment of diseases leading to irrational drug use and poor treatment outcomes. • Over use of drugs • Increased cost of treating animals.	• Need to partner with the private sector and development partners to build regional laboratories • Sensitize veterinary practitioners and farmers about the benefits of practicing evidence based medicine.
7. Some molecules used in the treatment of pests in crops are being used as acaricides to control ticks on animals.	• Exacerbated tick resistance to acaricides. • Presence of chemical residues in foods of animal origin that can cause cancers in humans.	• Increased sensitization on the public health effects of misuse of these chemicals. • Stringent regulation of agrochemicals.

The greatest out cry from the public is the issue of tick resistance to available acaricides on the market.

Tick resistance to acaricides

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

The most prevalent tick species are the *Rhipicephalus* (Boophilus) *decoloratus* and *Rhipicehpalus appendiculatus*. They vector some of the costliest cattle diseases like anaplasmosis, babesiosis and theileriosis among others.

Tick control in Uganda largely depends on the indiscriminate use of acaricides under the classes - synthetic pyrethroids, organophosphates and amidines, and of recent macrocyclic lactones. Recent studies in Uganda have indicated that ticks have developed resistance to almost all acaricide classes available on the local market.

The recommendation today is to use acaricides in a rotational manner placing amitraz between organophosphates and synthetic pyrethroids as a management strategy for tick acaricide resistance.

Figure 15: *Showing the different classes of acaricides on the Ugandan market. Under each class are the registered brands on the market*

Strategies to control tick resistance to acaricides

1. Rotation between acaricide classes: the strategy of rotating between the classes of acaricides is to reduce or delay full emergence of resistance to a particular class of acaricide. Switching between acaricides should be done following guidance from a veterinary professional. The ideal situation is to switch after 2-3 years, but depending on the Ugandan situation, this time period may be shorter. A farmer should always seek professional advice to have success.
2. Always follow the manufacturer's dilution rates.
3. Spray the whole animal concentrating majorly around the ears and tail areas.
4. Spray all animals on the farm including dogs.
5. Use proper equipment.
    - Measuring cylinder/cup: for correct measurement of the amount of acaricide to be added in clean water
    - Spray pump: to provide enough pressure while spraying.
    - Cattle crush: to hold the animals in one place while spraying.
    - Mixing cans/jerry cans of the proper size. Avoid swollen jerry cans as these give inaccurate measurements.
6. Examine and spray all newly introduced animals on the farm.
7. Buy acaricides from NDA licensed drug outlets to avoid counterfeited products. Avoid buying acaricides from agrochemical shops and from hawkers.
8. Practice controlled grazing to reduce risk of spread between farms.

Dangers of using agrochemicals in controlling ticks in animals

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

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

Antimicrobials intended for use in animals in uganda for the year 2020

Antimicrobials are agents that kill microorganisms or inhibit their growth. The misuse and overuse of antimicrobials are considered drivers in the emergence and spread of antimicrobial resistance (AMR).

Antimicrobial resistance refers to the ability of microorganisms (such as bacteria, fungi, viruses or protozoa) to nullify the effects of antimicrobial drugs, resulting in the drugs becoming ineffective. Therefore the routine collection and analysis of data on the use of antimicrobial agents is necessary as it forms the basis for reporting information on antimicrobial resistance.

Since 2015, the World Organization for Animal Health (OIE) has set priority in the development of a global database on the use of antimicrobials in animals. Uganda as a member of the OIE is required to annually report on the amounts of antimicrobial compounds intended for use in animals that enter the country.

The National Drug Authority hosts the OIE focal point person for veterinary products and therefore annually compiles import data in terms of volumes (in kilograms) of antimicrobials intended for use in animals for purposes of reporting to the OIE through the Ministry of Agriculture Animal Industry and Fisheries.

The shared data is used by the OIE to establish global trends over time and to evaluate actions to be taken to ensure responsible and prudent use of antimicrobial agents in animals.

Volume of antimicrobials imported into Uganda since 2019

There has been an increase in volume of antimicrobials intended for use in animals imported into Uganda since 2019. The amount increased from 70,688 Kg in 2019 to 90,520 Kg in 2020 as shown in the figure below.

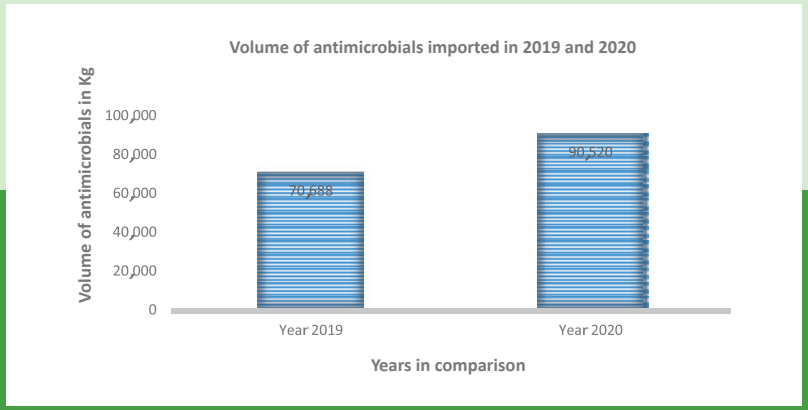
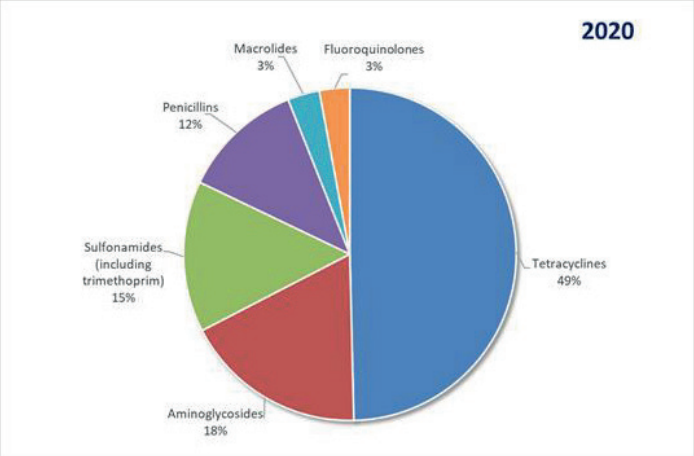


Figure 16: *Graph showing the total amount in Kilograms of antimicrobials intended for use in animals imported since 2019*

Overall amount of antimicrobial classes imported in 2020

Antimicrobials are broken down into different classes among which are the tetracyclines, aminoglycosides, sulphonamides, macrolides and fluoroquinolones. Tetracyclines accounted for the biggest quantity (49%) of antimicrobials imported followed by aminoglycosides (18%), sulphonamides including trimethoprim (15%), penicillins (12%), macrolides (3%) and fluoroquinolones (3%).

Figure 17: *Showing the percentage of the classes of antimicrobials intended for use in animals imported in 2020*



Opportunities for collaboration

1. There is a need for more engagement of the veterinarians in the field to strengthen veterinary pharmacovigilance and reporting of adverse drug reactions to the National Drug Authority and the District veterinary office.
2. More media engagement is required for wider dissemination of information to the public.
3. Establishment of MoUs between NDA and the Districts to better streamline roles.

VETERINARY MEDICINES REGISTRATION

The National Drug Authority has strived to see that it makes available medicines to the entire population through a rigorous registration process ensuring that only good quality medicines are registered within the country.

Current statistics of registered medicines in Uganda

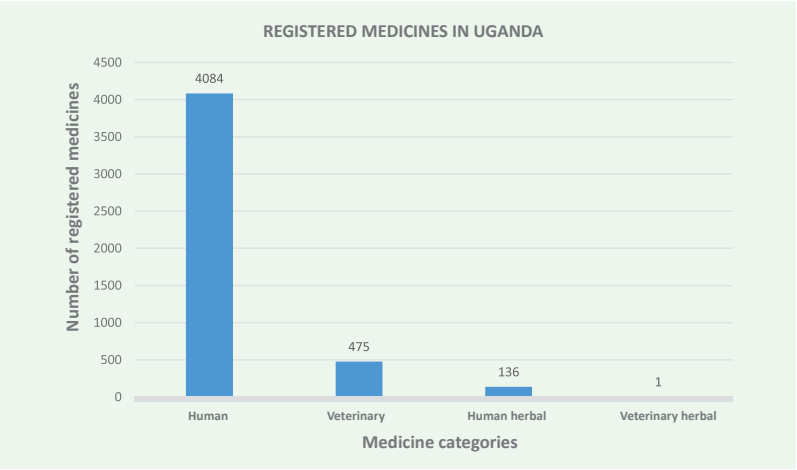


Figure 18: *The number of medicines registered in Uganda per category: Human, Veterinary, Human herbal and veterinary herbal. Source: The Uganda National Drug Register (27 July 2021)*

Procedure for Drug Registration

Submitting an application and product samples

The basic procedure involves a company submitting an application (that includes two CDs, two samples of the product, plus the registration fees) for registration of a veterinary product.

Assessment of Application

The assessment of the application is handled on a first come first served basis except for veterinary immunological products that are handled under first track. All applications undergo a first (involving screening) and second assessment for quality assurance purposes. If it is found that the application meets all requirements, then the product is recommended for registration. However, if an application is found to be lacking some information, the Authority writes back to the applicant requesting for additional data. When the applicant submits additional data to the Authority, it is assessed and if found acceptable, the product is recommended for registration.

Guidance for opening up a Class C Veterinary drug shop

Registration and Approval

All products recommended for registration should be manufactured by facilities that meet NDA cGMP (Current Good Manufacturing Practices) requirements. The products are presented to the Committee on National Formulary (CNF) for approval. The CNF is the statutory committee that approves drugs for Market Authorization (MA). All products that have been approved by the CNF have to be ratified by the Authority. Upon ratification, the approved products are assigned registration numbers and included on the NDA register.

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

Requirements for application

Applicants for a drug shop license should submit the following at the time of application:

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

Timelines for renewal of licenses for drug shops

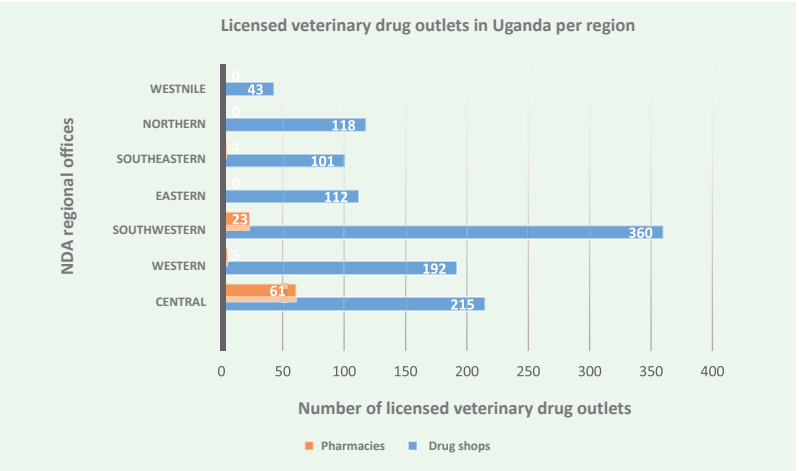
1. Applications for renewal are required to be submitted at the respective regional offices or the District Veterinary Officer starting **01 October** but not later than **31 October** of the year in which the current license expires.
2. License renewal shall only apply for drug shops, which had a license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

Supervision of drug shops

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

Current statistics of registered/licensed veterinary drug outlets

Figure 19: *Graph showing the current number of licensed veterinary drug outlets by region in Uganda as of 27 July 2021*



The highest number of veterinary drug outlets is in the Southwestern, Western and Central regions with the lowest number being in Westnile region. The farmers in the Westnile and Northern regions do not use a lot of drugs and the community is largely not aware of the requirements to open drug outlets. During our field surveys, it became clear that not so many people know about the process of opening up a drug outlet. This knowledge gap has been exploited by unscrupulous people who have resorted to hawking drugs and also selling them in open markets.

POST MARKET SURVEILLANCE

Introduction

Post market surveillance is the practice of monitoring the quality, safety and efficacy of pharmaceutical drugs or medical devices after they have been released on the market.

Licensed and regulated distributors, wholesalers and retailers have a responsibility to comply with good storage and distribution practices and are subject to periodic inspections by the National Drug Authority.

Distributors and retailers are therefore obliged to keep and maintain purchase records of medicines and medical devices indicating the source, supply dates and batches for proper traceability.

Veterinary medicines cold chain facility audit

Medicines are a delicate commodity that have to be properly handled through the supply chain in order to maintain their quality. Ensuring the quality of cold chain medicines is a complex undertaking that mandates precisely coordinated events in temperature controlled environments during storage, management and transportation of these products. A classic example of a cold chain product are the vaccines.

The National Drug Authority carried out several veterinary cold chain facility audits in the public and private sectors to ascertain the storage, handling and transportation of vaccines on the market and the findings are as follows.

A total of 167 (83 in public sector and 84 in private sector) veterinary cold chain facilities were audited in 82 districts during the FY 2020/2021. The districts were spread across all the seven NDA regional offices and each of the districts were audited for both the public and private cold chain facilities. The public facilities were located at the district local government headquarters whereas the private facilities were at pharmacies and drug shops. There were some districts that neither had a public or private cold chain facility to keep their vaccines therefore making them to keep their cold chain supplies in the neighboring district.

Cold chain facility audit findings in the public sector

1. Number of districts covered per region

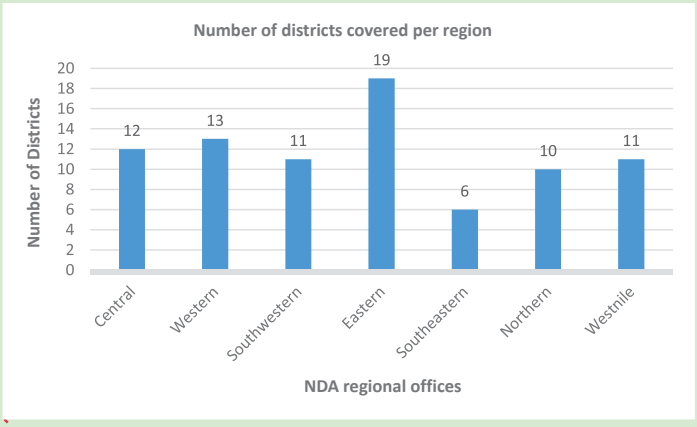
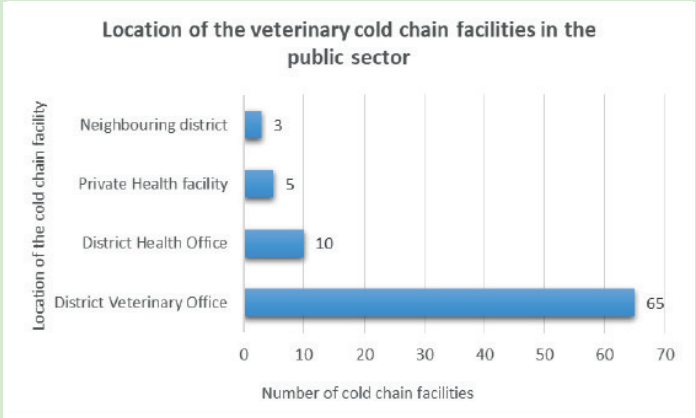


Figure 20: *Graph showing the number of districts covered per region during the cold chain facility audit exercise in the public sector in the FY 2020/2021*

2. **Location of the facility:** The public cold chain facilities were considered to be located at the district local government headquarters, however there were some districts where the vaccines for public use were stored either in private facilities or in neighboring districts. A total of 83 facilities were audited under the public setting.

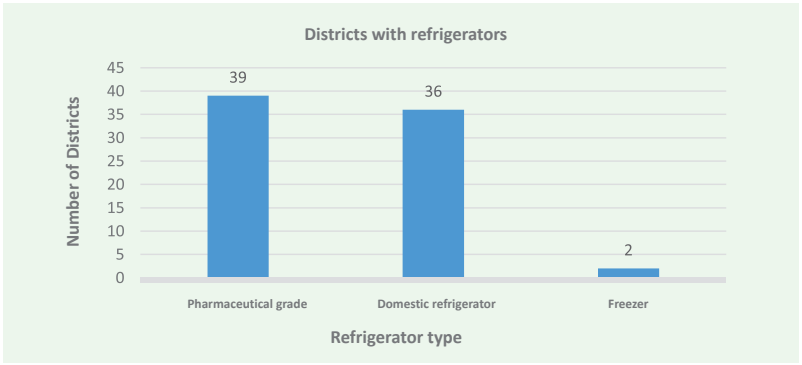
Figure 21: *Showing the location of the public cold chain facilities. The facilities were either located at the District Veterinary Office, District Health Office, Private Health facility or a neighbouring district.*



Parameters audited during the cold chain audit exercise in the public sector

a. Availability of recommended refrigerator for storing vaccines: the recommended refrigerator for keeping of vaccines is the pharmaceutical grade refrigerator. The figure below shows the type of refrigerators that were found in the districts. There were six districts that either did not have a refrigerator or the refrigerator in place was nonfunctional.

Figure 22: *Showing the type of refrigerators being used in the various districts.*



b. Availability of a power backup: power backups are important to maintain the power supply in the event of power interruption. Only fifty six districts had a power back up in their facilities.

Availability of power backup	Number of districts
Present	56
Absent	27

c. Availability of a temperature monitoring device for the vaccine refrigerator: temperature monitoring devices help in ensuring that the vaccines are being kept at recommended temperature range. Only 33 districts had temperature monitoring devices.

Availability of temperature monitoring device	Number of districts
Present	33
Absent	50

d. Availability of a temperature monitoring chart: a temperature monitoring chart is used for recording daily temperature readings from the thermometer. Only 7 of the districts had temperature monitoring charts.

Availability of temperature monitoring chart	Number of districts
Present	07
Absent	76

e. Absence of unauthorized products in vaccine refrigerator: products other than the vaccines are a potential source of contamination for the vaccines. Findings showed the presence of unauthorized products like fruits, soft drinks, drinking water, food, laboratory reagents, blood and tissue samples stored in the vaccine refrigerators.

Unauthorized products in vaccine refrigerator	Number of districts
Present	11
Absent	72

f. Vaccine refrigerator cleanliness: dirt is a source of contamination to vaccines. We registered the presence of clean refrigerators in only 35 districts.

Cleanliness of refrigerator	Number of districts
Clean	35
Dirty	45

g. **Personnel trained in cold chain management:** training in cold chain management ensures that the custodian of the cold chain facility maintains the vaccines in the recommended temperature ranges whilst encouraging the same during distribution. Majority of the personnel in-charge of the cold chain facilities were not trained in cold chain management.

Training in cold chain management	Number of districts
In charge trained	08
In charge not trained	75

Cold chain facility audit findings in the private sector.

1. **The National Drug Authority audited 84 private cold chain facilities** located in pharmacies and drug shops in the Central, Western, Southwestern, West Nile, Northern, Southeastern and Eastern regions. The graph below shows the proportion of the cold chain facilities audited per region.

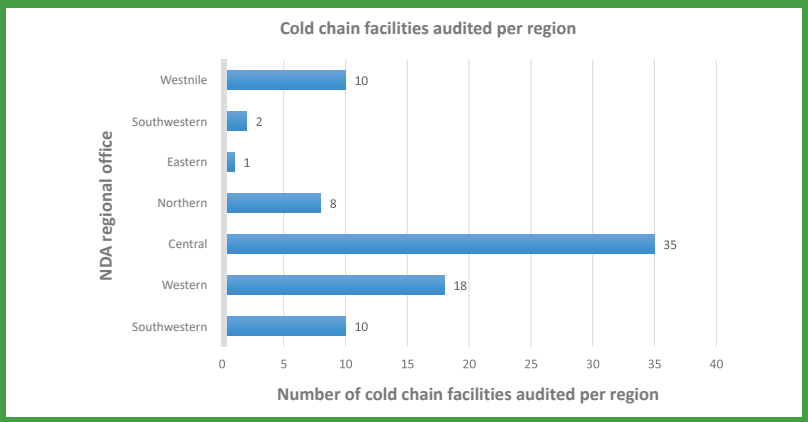
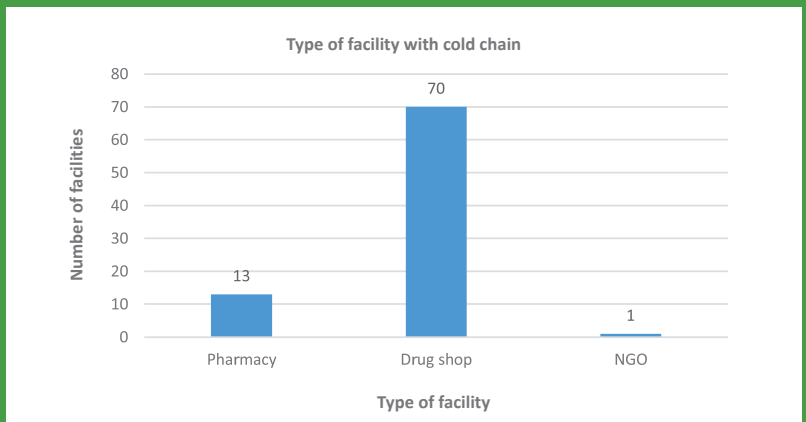


Figure 23: *Showing the number of cold chain facilities that were audited per region during the cold chain facility audit exercise conducted in the private sector*

2. **Type of the facility with cold chain:** the facilities were either a pharmacy or a drug shop. We noted that vaccines are also stored by non-governmental organizations. Majority of the private veterinary cold chain facilities were found in drug shops, followed by pharmacies and then the NGO.

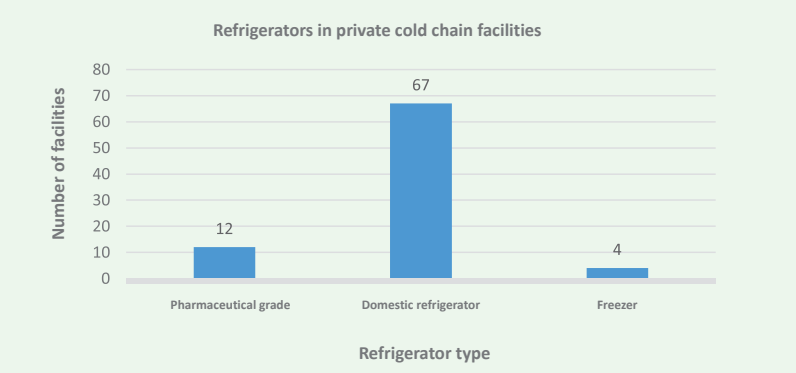
Figure 24: *Showing the number of the type of cold chain facilities in the private sector within the audited districts.*



Parameters audited during the cold chain audit exercise in the private sector

a. Availability of recommended refrigerator for storing vaccines: majority of the facilities stored vaccines in domestic refrigerators. Domestic refrigerators are known for forming frosts that can easily destroy freeze sensitive vaccines.

Figure 25: *Showing the number of facilities with the different type of refrigerators*



b. Availability of a power backup: a few facilities had power backups.

Availability of power backup	Number of facilities
Present	36
Absent	48

c. Availability of a temperature monitoring device for the vaccine refrigerator:

Availability of temperature monitoring device	Number of facilities
Present	40
Absent	44

d. Availability of a temperature monitoring chart:

Availability of temperature monitoring chart	Number of facilities
Present	21
Absent	63

e. Absence of unauthorized products in vaccine refrigerator: the unauthorized products in the 17 drug outlets included food, soft drinks, yoghurt, drinking water and fruits.

Unauthorized products in vaccine refrigerator	Number of facilities
Present	17
Absent	67

f. Vaccine refrigerator cleanliness: dirt is a source of contamination to vaccines. We registered the presence of clean refrigerators in only 46 facilities.

Cleanliness of refrigerator	Number of facilities
Clean	46
Dirty	38

g. Personnel trained in cold chain management: we observed a huge knowledge gap in cold chain management in almost all the facilities audited.

Training in cold chain management	Number of facilities
In charge trained	01
In charge not trained	83

Discussion

Vaccines must be continuously stored in a precise temperature range from the time they are manufactured until the moment of vaccination. Storage and transport equipment such as cold rooms, refrigerators, freezers, cold boxes and vaccine carriers must comply with performance standards in order to maintain the cold chain. This is because temperatures that are too high or too low can cause the vaccine to lose its potency; and once a vaccine loses its potency, it cannot be regained or restored. As a result, use of damaged vaccines may lead to the outbreak of vaccine preventable diseases due to vaccine failure.

The findings showed that majority of the audited facilities were not fully functional in terms of the minimum equipment requirements for a cold chain facility. The absence of any one of the minimum requirements (frost free refrigerator, power back up, thermometer, temperature monitoring chart and a trained in-charge) for a cold chain facility leads to a breakage in cold chain therefore affecting the quality of the vaccines.

It was observed that majority of the audited facilities were using domestic refrigerators to store vaccines whereas some were using freezers. A few had the pharmaceutical grade refrigerators which are the recommended type. Domestic refrigerators are not recommended to keep vaccines because they are usually poorly insulated, have no good temperature control and they cannot keep vaccines cool during electricity cuts of more than one or two hours. In addition, the cabinet of domestic refrigerators have a number of zones, each with a different temperature and temperatures often fall below freezing in areas close to the freezing compartment.

The best refrigerator for storing vaccines is a purpose-built vaccine refrigerator. These are designed and built for vaccine storage and have the following features:

- Stable, uniform and controlled cabinet temperature, unaffected by ambient temperature.
- Good temperature recovery after the lid or door is closed.
- Nearly all of the internal space can be used for storing vaccine.
- Most have standard alarm and safety features alert.

Secondly, all facilities must have a power back to cater for power interruptions that are almost inevitable. Only Sixty-seven (67%) of public and 43% of private facilities had power backups. The rest were mainly using ice blocks to store vaccines when electricity goes off. Some of the facilities with power backup had generators which could not automatically switch on when electricity goes off. Like mentioned earlier, vaccines must be kept in specific temperature ranges from manufacture until vaccination. The absence of a power back in a facility cannot achieve this goal.

Thirdly, a facility must have a functional temperature monitoring device. We noted that only 40% of the public and 48% of private facilities had temperature-monitoring devices installed in the vaccine refrigerator. Even with the presence of thermometers, only 8% of the public and 25% of the private facilities had up-to-date temperature monitoring charts for the vaccine refrigerators. None of the facilities audited had been monitoring vaccine temperatures during transportation.

In regards to training in cold chain management, only 10% of the personnel in public sector and 1.2% of the private sector had ever attended training in cold chain management. The gap in cold chain training and basic knowledge in cold chain management could be one of the main reasons why animal vaccines are poorly stored and transported.

The presence of other products in the vaccine refrigerator are a potential source of contamination for vaccines. A few facilities out of the whole stored soft drinks, drinking water, food, fruits, laboratory reagents, blood and tissue samples in the vaccine refrigerators.

Another source of contamination for vaccines is dirt. Only 44% of the public and 55% of the private vaccine refrigerators were found to be clean at the time of audit. Maintenance of vaccine refrigerator cleanliness is vital to avoid contamination.

Conclusion

There is inadequate veterinary cold chain facility in both the public and private sector across the country. Lack of purpose built vaccine refrigerators, power backups, temperature monitoring devices and charts, and a lack of knowledge/training in cold chain management needs to be addressed to ensure that animal vaccines are of quality, are safe and efficacious.

Recommendations for improvement in cold chain management

There is need for the National Drug Authority to continually monitor, supervise and sensitize cold chain facilities personnel to ensure that cold chain medicines retain their quality. The facilities are therefore encouraged to:

i. Install purpose built cold chain/vaccine refrigerators for safe storage of cold chain products.
ii. Install reliable power backup systems to maintain uninterrupted power supply to the vaccine refrigerator.
iii. Daily clean the vaccine refrigerators including maintaining a clean environment.
iv. Install calibrated temperature monitoring devices to monitor temperature of cold chain products in the refrigerator and
v. Monitor the temperature of vaccines/cold chain products during transportation.
vi. Obtain a temperature monitoring chart and daily fill it in. A chart can be a book where one records temperatures or sheets that are stuck on the refrigerator.
vii. Avoid mixing vaccines with other products.
viii. Keep an up-to-date stock inventory of vaccines.
ix. Train the personnel in-charge of the cold chain facility.

Compliance monitoring and support supervision

Through regular sampling and surveying of both the regulated and unregulated supply chains, substandard and falsified veterinary pharmaceutical products have been identified on the market.

The National Drug Authority conducted compliance monitoring and support supervision in ninety four (94) districts distributed across all the seven NDA regions in the FY 2020/2021.

Figure 26: *Showing the number of districts that were covered in the different NDA regional offices*

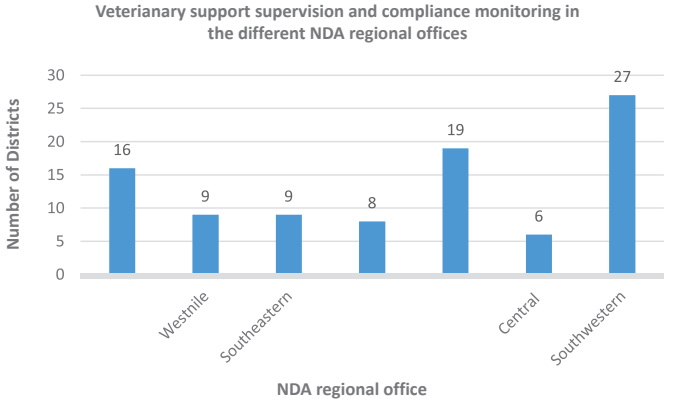
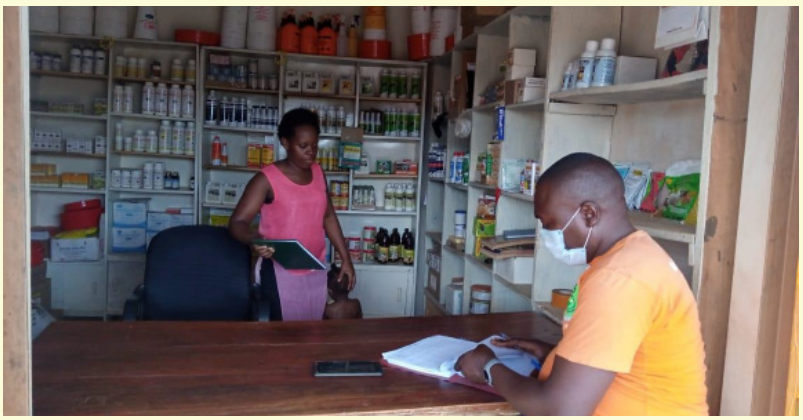


Figure 27: *NDA team conducting a surveillance exercise in an open market located in Kyenjojo District.*

Figure 28: *Compliance monitoring and support supervision in Kamuli District*



Key findings from compliance monitoring and support supervision activities

- Poor record keeping making traceability of products difficult. This poses a challenge during complaints investigations by NDA. Several drug shops receive purchase receipts that do not show the batch numbers and expiry dates of the medicines.
- Increased sale and distribution of unregistered products by licensed operators.
- Sale of drugs in unlicensed milk outlets/cooperatives especially in Southwestern region.
- Stocking of agrochemicals in veterinary drug outlets.
- Stocking of veterinary drugs in agrochemical drug outlets.
- Sale of veterinary drugs in hardware and general merchandise shops especially in greater Luwero area.
- Sale of medicines by un-qualified persons which exposes the population to wrong prescription, drug resistance, loss of income and other related risks including death of animals.
- Class C drug shops stocking beyond the recommended class to be handled.
- Lack of proper cold chain storage facilities. Most cold chain facilities do not have power backups and temperature monitoring devices. Domestic fridges are being used instead of pharmaceutical grade refrigerators.
- Mushrooming unlicensed drug outlets.
- Rampant hawking of veterinary drugs in the districts of Kyankwanzi, Kiboga, Sembabule, Kyegegwa, Gomba, Kiruhura including the districts in the Eastern region.
- Selling of drugs in open markets and general merchandise shops in Karamoja and Eastern region.
- Piles of expired drugs at the local government headquarters.
- Increasing sale of nutritional supplements with therapeutic claims.

The regulatory action that ensues from compliance monitoring and support supervision activities is enforcement where non-compliant citizens are forced to face the law.

Enforcement Activities

The enforcement operations are intelligence led with collaborative efforts from key grassroots stakeholders within districts. Intelligence information on counterfeiters, marketers and distributors of counterfeited/falsified veterinary pharmaceuticals are shared for regulatory action(s) to be taken.

A number of veterinary products counterfeiters have been made to face the law with the help of Uganda Police Force, Directorate of Public Prosecution and the Magistrate court. The table below shows a summary of the court cases that were handled in the last financial year.

Table 4: Summary of court cases handled on falsified/counterfeited veterinary drugs for the FY 2020/2021

SN	COURT CASE	DISTRICT, LOCATION	COUNTERFEIT PRODUCT/ OFFENSE	MAGISTRATE COURT	STATUS
1.	Uganda Vs Gideon Ntwirenabo	Bushenyi, Kyamutunga LC	Tick Burn Spray	Buganda Road	Pleaded guilty Convicted
2.	Uganda Vs Bonabaana Bernadette	Bushenyi, Ishaka TC	Tick Burn Spray	Buganda Road	Pleaded guilty Convicted
3.	Uganda Vs Paulson Kakuru	Ntungamo, Mahwa Cell	Tick Burn Spray	Ntungamo	Pleaded guilty Convicted
4.	Uganda Vs Richard Ahabwe	Mbarara, Ntakanoni LC and Kyenjojo, Butunduzi LC	Tick Burn Spray	Buganda Road	Pleaded guilty Convicted
5.	Uganda Vs Hussein Rwabona	Mbarara City, Pearl Dairy	Tick Burn Spray	-------	Escaped and still on the run.
6.	Uganda Vs Ssemanda Mukasa Benard	Ntungamo, Kagarama TC	Acaricide repackaging (Adulteration)	Ntungamo	Pleaded guilty Convicted.
7.	Uganda Vs Dr. Wilson Kafeero and Olive Kafeero	Mitooma, Kabwohe TC	Tick Burn Spray	Sheema	Trial ongoing
8.	Uganda Vs Denis Kakuru	Mbarara City, Nile services Pharmacy	Tick Burn Spray	Mbarara	Trial ongoing
9.	Uganda Vs Eridadi Tumwebaze	Mbarara City Rubiri Cell	Tick Burn Spray	Mbarara	Trial ongoing
10.	Uganda Vs Bernard Nuwahereza	Sheema, Shuku Dairy	Tick Burn Spray	Sheema	Trial ongoing
11.	Uganda Vs Godfrey Tumwebaze	Sheema, Sheema Dairy	Tick Burn Spray	Sheema	Pleaded guilty Convicted.
12.	Uganda Vs Rwamigina Asaph, Winnie Rwamigina, Tumwebonire Benon, Mubezi Godfrey.	Kyegegwa, Rwensasa Market	Mutambira Ente, Cataract Remover	Fort portal	Pleaded guilty Convicted.
13.	Uganda Vs Dr. Atlkor John and Mrs. Atikor	Kiboga TC	BELEMYCIN – Unregistered product. Unlawful possession of classified drugs	Buganda Road	Pleaded guilty Convicted.

VETERINARY PRODUCT RECALLS

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

What are some of the reasons for recalling products on the market? Veterinary pharmaceutical products may be recalled from the market for the following reasons:

1. Verified reports of serious adverse reactions not stated in the package insert of a particular product.
2. Unacceptable frequency of adverse reactions which are mentioned in the package insert of a particular product.
3. Falsified product (e.g. incorrect labelling)
4. Substandard product (e.g. incorrect formulation)
5. Failure of quality tests in the laboratory.
6. Failure to comply with the regulations of the National Drug Authority.

What is a falsified veterinary product? Is a product that deliberately or fraudulently misrepresent their identity, composition or source.

What is a substandard veterinary product? Is an authorized product that fails to meet either the quality standards, or specification, or both.

Why is it important to recall defective products from the market? It is important to recall defective products from the market to safeguard the public from harmful effects which may be caused by the use of unsafe, ineffective or poor quality medicines and other medical products.

Why shouldn't the public be alarmed when products are recalled? The public should not be alarmed when products are recalled because it is a way of safeguarding the public from harmful products.

What happens to recalled products? Recalled products are destroyed

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

Where can you find other lists of recalled pharmaceutical products from the market? From the NDA Website at www.nda.or.ug

As a quality assurance mechanism, active post market surveillance culminates in recall of the registered and authorised products that fail quality tests or other regulatory requirements. These recalled products are then either destroyed or re-worked and redistributed into the market. The table below gives a list of recalled veterinary pharmaceutical products between July 2020 and June 2021.

Table 5: List of recalled veterinary products from the market between July 2020 and June 2021

Name of Product	Batch details	Reason for recall	Regulatory Action Undertaken
Alamycin 10 injection	9231-600A	Failed quality laboratory test	Destruction
Vet Fungicare	All batches	Not registered	Destruction
Vet tick clean spray	All batches	Not registered	Destruction
Vet healer spray	All batches	Not registered	Destruction

VETERINARY PHARMACOVIGILANCE

Pharmacovigilance (PV) is a process by which information is collected to detect and prevent unexpected or unwanted adverse effects following the use of a veterinary medicinal product [source: Health for Animals]

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

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

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

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

An adverse drug event that occurred in puppies following the use of diminazene diaceturate

Background

The National Drug Authority received a report of a serious adverse event from Namugongo, Kira division, Wakiso District, about the death of 10 puppies within 36 hours following use of diminazene diaceturate and phenazone granules. Before the death of the puppies, they were reported to make noise, limping, stomach swelling, and swelling of legs, salivating, weakness and collapse.

Figure 29: *Showing healthy puppies before treatment with Dimi-nazene Diaceturate and Phenazone granules*

Figure 30: *Showing dead puppies after treatment with Diminazene Diaceturate and Phenazone granules*

Summary of investigation

Affected puppies: 10 puppies of Pugs and Husks breeds weighing 2 kg on average.
Suspected condition: Canine babesiosis - is a tick-borne, protozoal, haemoparasitic disease that can cause haemolytic anaemia, splenomegaly and fever.
Suspected product: Diminazene diaceturate - is an antiprotozoal medicine. It is administered at a dosage rate *1mL per 20 kg* body weight.
Treatment given: 0.5mL of diminazene diaceturate administered per average body weight of 2 kg.

Conclusion: There was an overdose of diminazene diaceturate administered to the puppies. The dosage rate as per manufacturer is 1mL per 20 kg body weight. The puppies were therefore supposed to receive 0.1mL each. The investigation showed that the attendant was not qualified to treat the puppies.

Toxicity of diminazene diaceturate

Diminazene has a narrow clinical safety margin and can induce fatal nervous complications after 24-48 hours of overdose. The clinical signs of toxicity include depression or stupor, continuous vocalization, ataxia, nystagmus, seizures and opisthotonos.

Caution to the public

- Always consult veterinary professionals for proper diagnosis and treatment of animal diseases.
- Always consult veterinary professionals on guidance on which drug to use for treatment of animal diseases.
- Always be vigilant and report any suspected drug events or misuse of drugs to the National Drug Authority or to your District Veterinary Office for onward submission to NDA.

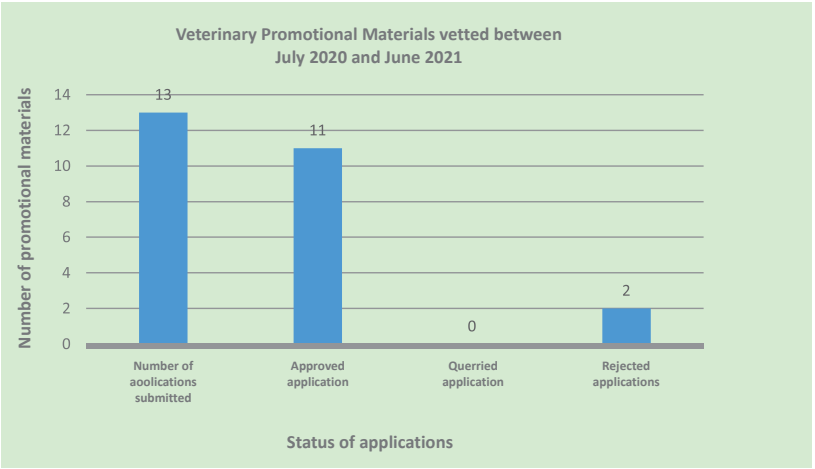
VETERINARY DRUG PROMOTION/ADVERTISEMENT

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

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

The process of making an application for a drug promotion/advertisement

Figure 31: *Showing the statistics of veterinary promotional materials submitted to NDA between July 2020 and June 2021*



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

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

Reason for controlling veterinary drug promotions/advertisements

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

DID YOU KNOW

Reporting Adverse Drug Events

The adverse drug events that you report to NDA contribute to regulatory decisions and actions for improved safe use of veterinary medicines. An Adverse Drug Event is any observation in animals, whether or not considered product related, that is unfavorable and unintended and that occurs after any use of a veterinary medicinal product. Examples include lack of expected efficacy, injection site sarcomas, reduced yield in production, adverse reactions in the person administering the product, and environmental incidences such as aquatic animals, insects and plants dying. An example of an environmental incidence is Cypermethrin killing fish. All persons including veterinary surgeons, veterinary nurses, farmers and pet owners can report adverse events. Reports can be sent to the National Drug Authority via email on druginfo@nda.or.ug or WhatsApp 0740 002 070 or on our toll free number 0800 101 999.

Licensing of veterinary drug outlets in 2020

Every veterinary professional intending to open up a veterinary drug outlet should have a valid certificate of registration from the Uganda Veterinary Board, without which no license or renewal thereof will be made. Licensed drug outlet supervisors should not leave unqualified personnel to attend to farmers. Unqualified personnel are a source of wrong information that has contributed to misuse of veterinary drugs and has consequently resulted into disease resistance, loss of income and death of animals.

Resistance is the ability of microbes to grow in the presence of a drug that would normally kill them or limit their growth. Overuse and misuse of medicines are among the practices that have contributed to the development of drug-resistant microbes.

Dispensing of antimicrobials

According to the OIE requirements of access to antimicrobials, drug outlets are required to only dispense antimicrobials on prescriptions written by qualified and licensed veterinarians. The National Drug Authority reminds all drug outlets to keep and maintain records of these prescriptions for inspection purposes.

Good Distribution Practices

The distribution chain (manufacturer to user) is key in maintaining the wholesomeness of veterinary medicines. Keep proper purchase, sales and prescription record books to be presented at inspection to aid in traceability and monitoring use of drugs. Store drugs according to the manufacturer's instructions. Please note that Class C drug shops are only allowed to stock class C drugs.

FREQUENTLY ASKED QUESTIONS

1. **Who is responsible for regulation of agrochemicals?** Agrochemicals are regulated by the Agricultural Chemicals Board under the Ministry of Agriculture Animal Industry and Fisheries. It is important to note that Agrochemicals are chemicals used in agriculture. The current mandate of the National Drug Authority is limited to human medicines, veterinary medicines, human and veterinary herbal medicines, vaccines and biologicals and medical devices (needles, syringes, gloves).
2. **How long does NDA take to investigate a drug complaint?** Every received drug complaint is investigated within 15 working days after which a preliminary report is written and feedback sent to the complainant. The complaint is then either resolved or further investigations conducted for those whose investigations are unsatisfactory.
3. **Does NDA provide feedback to clients about investigation outcomes of drug complaints?** Yes. After investigating a drug complaint, feedback is given to the complainant either through SMS, email or written letter depending on the contact details that have been provided by the complainant.
4. **What information does NDA need included in drug complaint reports?** The most important information are the contacts of the complainant, the details of the drug being complained about, the description of the complaint about the drug and where the drug was brought. More information about what should be included on the report can be obtained from the Complaints Reporting Form. This form can be obtained from the NDA website or from the District Veterinary Officer at no cost.
5. **How does the public know if a drug has been recalled from the market?** The public can know about a recalled drug by checking on the NDA website. Information about drug recalls can also be obtained through NDA bulletins and circulars to the public.
6. **What are the procedures for opening up a veterinary drug shop?** Before opening up a vet drug shop, the intending operator should pick up and fill the NDA application forms. Then attach the qualification certificates of the would be supervising in charge. The qualification certificates include the academic and Uganda Veterinary Board (UVB) certificates. An evidence of payment of prescribed fees, commitment letter of the supervising in charge, National ID and Sketch map of the premises are also submitted together with the application forms. See more details in the section "Guidance Opening up a Class C Veterinary drug shop" in this bulletin.
7. **How do fake drugs find their way into the Ugandan market?** Through smuggling and counterfeiters within the country.
8. **How can a lay person identify fake drugs from genuine drugs?**
    - Check for unusual physical characteristics on the product including the colour, markings, shape and any other changes on the medicines.
    - Check for altered manufacturing/expiry dates or labels. Take extra caution of products with short expiry dates.
    - Be suspicious of medicines that are unusually cheaply priced.

9. **Why are the prices of veterinary drugs very high?** This is basically due to manufacturing and market dynamics which NDA has no control over.

10. **When is the Government instituting the policy of zoning acaricides?** NDA cannot tell when Government shall institute zoning of acaricides, but we can inform policy through sharing reports of our field findings with the Ministry of Agriculture, Animal Industry and Fisheries who are responsible for policies affecting animals.

11. **Why are acaricides no longer killing ticks?** There are many factors contributing to the failure of acaricides to kill ticks. These include the over use of a particular class of acaricide, incorrect mixing (over or under) of acaricides, incorrect spraying (equipment and style) of animals, incorrect restraint of animals, and a lack of rotation between the classes of acaricides. It is a natural phenomenon for ticks to gain resistance to a particular type of acaricide, but this resistance is accelerated by all the above mentioned factors leading to failure of an acaricide to kill ticks.

12. **What happens to recalled drugs?** Depending on the reason for recall, a recalled product can either be reworked or destroyed.

13. **Why are some drugs put off the market suddenly?** Withdrawal of products from the market follows different reasons which may include regulatory decisions such as suspensions, deregistration and recalls. On the other hand, products may leave the market due to market forces which may not require notification.

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