UGANDA

NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

VETERINARY MEDICINES REPORT 2021/22








A SKETCH MAP OF UGANDA SHOWING

NATIONAL DRUG AUTHORITY (NDA) REGIONAL OFFICES

THE NATIONAL DRUG AUTHORITY
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Head Enforcement

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A Message from THE SECRETARY to the Authority

Secretary to the Authority
Dr. David Nahamya

Compared to the FY 2020/21, we registered more sub county level participation of stakeholders during the sensitization meetings with a near 100% turn up in all the districts covered. A total of 33 districts and 284 sub counties were reached across all the regions attracting 4,884 veterinary stakeholders.

Your safety is our priority. Safe drugs save lives

Dear readers,

It is my great pleasure that I welcome you to this publication of the annual report. The publication is intended to share the activities performed by the veterinary products department in the National Drug Authority (NDA) during the financial year (FY) 2021/2022. I therefore urge you to utilize the information shared herein for improved veterinary medicines regulation.

The department conducted a number of activities which included sub county sensitization meetings, training of veterinary professionals, radio talk shows, TV shows, compliance monitoring and support supervision, cold chain facility audits, field trial inspections among others. Compared to the FY 2020/2021, we registered more sub county level participation of stakeholders during the sensitization meetings with a near 100% turn up in all the districts covered. A total of 33 districts and 284 sub counties were reached across all the regions attracting 4,884 veterinary stakeholders.

We are happy to report that the public is increasingly becoming aware of their roles in veterinary medicines regulation as a result of these stakeholder engagements. For example, there has been an increase in reporting of adverse drug events occurring in animals to NDA, which has led to the dissemination of targeted information materials and trainings for animal health workers (AHW) in the various districts. We developed and disseminated 6 sets of materials on rational drug use during the trainings of the 660 AHW conducted in 33 districts.

The public has also risen up to support NDA in the fight against counterfeiting of veterinary drugs. Some unscrupulous individuals in the community were reported to be counterfeiting veterinary drugs and vaccines. These were consequently arrested, tried before the courts of law and convicted after being found guilty. It is a sad event because these products once used can lead to massive economic loss due to increased morbidity and mortality.

I extend our sincere appreciation to all the stakeholders on whose expertise we leveraged on for the success of these activities.

EDITORIAL TEAM

Stakeholder Engagements & Collaborations

Stakeholder engagement is a crucial element in medicines regulation and the National Drug Authority has played an active role in engaging veterinary stakeholders to ensure that veterinary medicines regulations are in the public interest. The national and international stakeholders include 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 (WOAH), Pan African Veterinary Vaccine Center of African Union (AU-PANVAC), the Global Alliance for Livestock Veterinary Medicines (GALVmed) to mention just a few.

During the Financial Year 2021/2022, several engagements were conducted in a number of districts that included sensitizations, trainings, radio and TV talk shows and farm visits. Information materials pertaining to medicines stewardship were distributed as a way to promote public accessibility to relevant drug information that is needed to empower people on their medicines consumption. Posters, brochures, calendars, note books, T-shirts and head caps were distributed to the target groups.

District Engagements & Collaborations

Sensitization meetings at Sub County level

We conducted two hundred and eighty four (284) sub county sensitization meetings in thirty three (33) districts. Within each district were engagements made with the Chief Administrative Officers (CAOs), the Resident District Commissioners (RDCs), LC5s, District Production Officers (DPOs) and the District Veterinary Officers (DVOs).

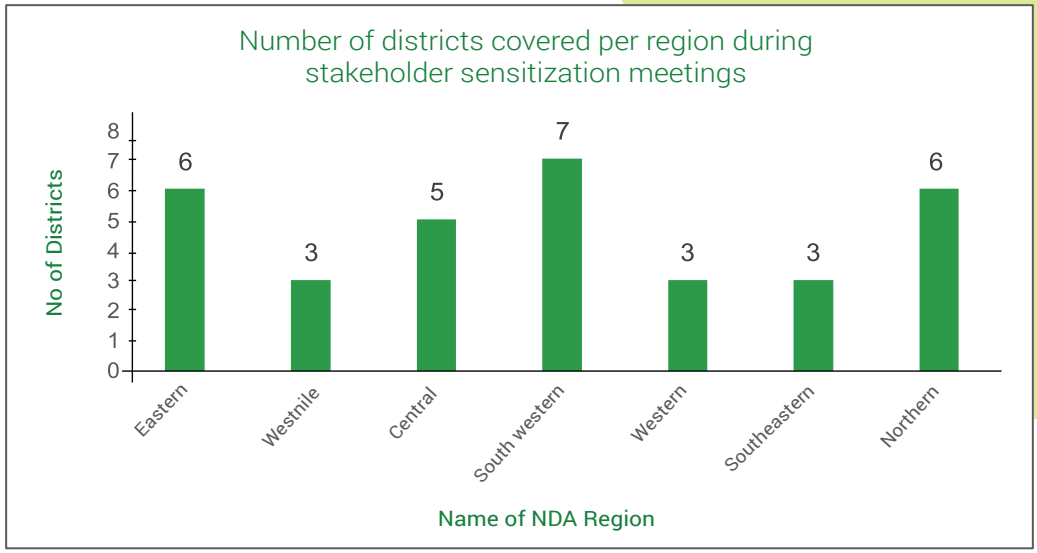
Each district selected eight (8) sub counties to sensitize farmers, the sub county extension workers and sub county opinion leaders (LC3s and sub county chiefs). Another important stakeholder was the Ministry of Agriculture, Animal Industry and Fisheries (MAAIF) zonal inspector of each district.

The table below lists the districts reached and their participation levels.

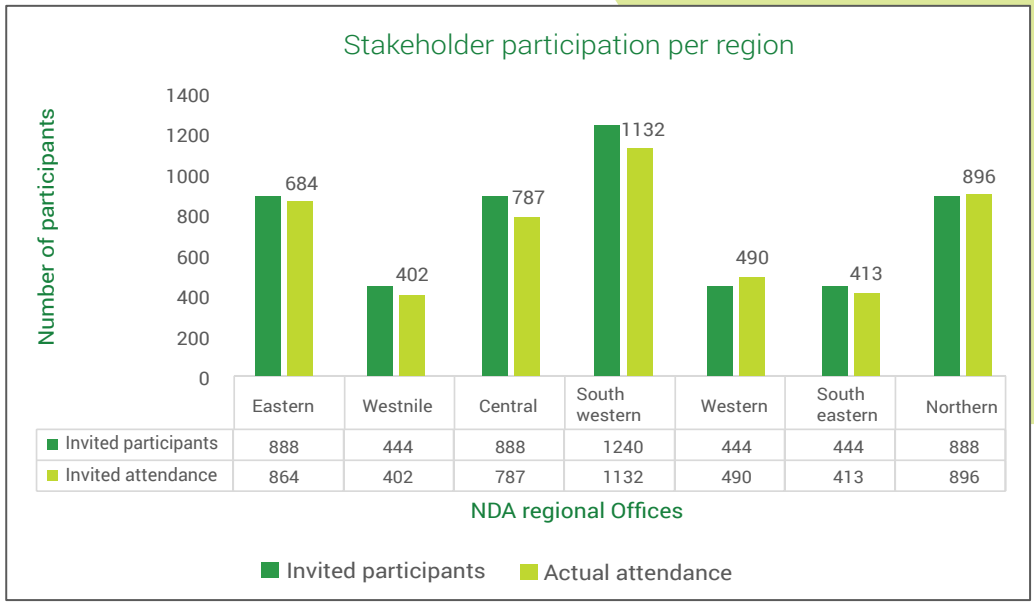
Table 1: List of districts covered during the stakeholder engagements between July 2021 and May 2022.

NDA Regional office	Name of District	Total number of participants invited by NDA per district	Actual attendance of participants per district
EASTERN	Kumi	148	147
	Ngora	148	144
	Serere	148	145
	Tororo	148	151
	Busia	148	134
	Manafwa	148	143
WEST NILE	Zombo	148	146
	Nebbi	148	138
	Pakwach	148	118
CENTRAL	Rakai	148	137
	Kyotera	148	137
	Lwengo	148	133
	Masaka	148	173
	Sembabule	296	206
SOUTH WESTERN	Mbarara	148	116
	Rwampara	148	131
	Isingiro	148	121
	Kiruhura	352	368
	Ntungamo	148	118
	Rukungiri	148	144
	Kabale	148	134
WESTERN	Kabarole	148	190
	Ntoroko	148	155
	Mityana	148	145
SOUTH EASTERN	Kayunga	148	149
	Buikwe	148	134
	Mukono	148	130
NORTHERN	Kitgum	148	147
	Lamwo	148	153
	Apac	148	153
	Pader	148	147
	Oyam	148	149
	Kwania	148	147

The number of districts that were covered per NDA regional office during the sub county stakeholder engagements between July 2021 and May 2022



Graph showing the level of participation of invited stakeholders per NDA regional office.



Meeting with the Chief Administrative Officer of Buikwe District

Stakeholder meeting with participants from Seeta Namuganga and Kasawo sub counties

Sensitization meeting with participants from Nkokonjeru Sub County and Ssi Sub County in Mukono District

Stakeholder meeting in Rukungiri District

Stakeholder engagement in Manafwa District.

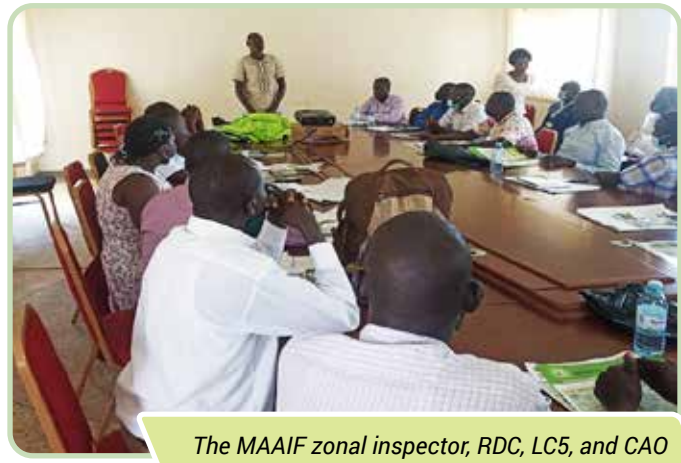
Stakeholder engagement in Manafwa District.

Training of **Veterinary Practitioners**

The National Drug Authority conducted trainings of veterinary practitioners in 33 districts between July 2021 and May 2022 attracting 660 practitioners. A total of twenty (20) practitioners per district were invited including ten private and ten government practitioners. Other participants who attended the trainings included the CAOs, RDCs, LC5s, DPOs, DVOs 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.

Group photo after Vet practitioners training in Buikwe district.



The MAAIF zonal inspector, RDC, LC5, and CAO officiating the Veterinary practioners training in Pakwach district

Radio talk show engagements

NDA team during a radio talk show in Tororo District

The National Drug Authority conducted radio talk shows in twenty six (26) districts between July 2021 and May 2022 and radio stations with the widest listenership within the districts were selected. The guests included the NDA staff and the District Veterinary Officer or his representative.

Discussions were on NDA legal mandate in medicines regulation, the role of NDA in veterinary drugs regulation and rational drug use.

The feedback and questions from the public were varied ranging from regulation, practice and policy issues.

Table 2: List of radio stations used to reach out the veterinary stakeholders in the different districts where stakeholder engagements were carried out from July 2021 to April 2022

NDA Regional office	Name of District	Radio station
EASTERN	Kumi	Radio Continatal
	Ngora	Aisa FM
	Serere	Voice of Serere
	Tororo	East FM
	Busia	Jogo FM
	Manafwa	Step FM
WEST NILE	Zombo	Paidha FM
	Nebbi	Rainbow FM
	Pakwach	Pakwach FM
CENTRAL	Kyotera	Buddu broadcasting services
	Lwengo	Buddu broadcasting services
	Sembabule	Mbabule FM
SOUTH WESTERN	Mbarara	Radio West
	Kiruhura	Radio 5
	Ntungamo	Radio Ankole
	Rukungiri	Radio Boona
WESTERN	Kabarole	Voice of Tooro
	Mityana	Mboona FM
SOUTH EASTERN	Kayunga	Sauti FM
	Buikwe	Mukono FM
	Mukono	Mukono FM
NORTHERN	Kitgum	Tempo FM
	Lamwo	Mighty Fire FM
	Apac	Divine FM
	Oyam	Unity FM
	Kwania	Divine FM

Findings from the stakeholder engagements.

The overall response of the stakeholders was good with many of them becoming increasingly aware of their roles in regard to veterinary drugs regulation. Compared to the previous years (2020 and 2021), the challenges are still related to irrational drug use, inadequate facilities for disease diagnosis and many people masquerading as veterinary professionals. The issues and their associated risks are listed in the table below.

***Table 3:** Showing the issues noted during the stakeholder engagements, their associated risks and the possible solutions.*

Issue/problem	Risks	Possible remedies
1. Uncontrolled access to classified medicines by farmers and unqualified persons.	• Increased resistance to drugs (antimicrobial resistance) • Non observance of drug withdrawal periods which results in increased drug residues in foods of animal origin thereby posing a risk to human health • 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 especially in the western and southwestern regions of the country.	• Overuse/misuse of existing acaricides • Use of agrochemicals with acaricidal activity • Falling prey to counterfeiters and Smugglers of acaricides • 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 maintained on the market	• Increased sensitization and training on veterinary pharmacovigilance of veterinary practitioners • Disseminate Adverse drug events and drug complaints reporting booklets up to the grass root level (sub counties)
4. Poor cold chain facilities in both the private and government sectors coupled with unreliable power supply	• 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 to badly affected regions
5. 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.
6. Some molecules used in the control of crop pests 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 have a gross effect on human health	• Increased sensitization on public health effects of misuse and use of agrochemicals on animals • Stringent regulation of agrochemicals.

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. These tick species are reservoirs for some of the costliest cattle diseases namely, anaplasmosis, babesiosis and theileriosis.

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 leading to farmers resorting to the use of agrochemicals with acaricidal activity. The latter has resulted into damaged animal skins, blindness, decreased milk production, presence of drug residues in milk and decreased meat quality.

NDA team assessing drug usage patterns at farm level. Red arrow indicates evidence of misuse of a crop pesticide (Dudu acelamectin mixed with Duo Dip) acaricide in the control of ticks

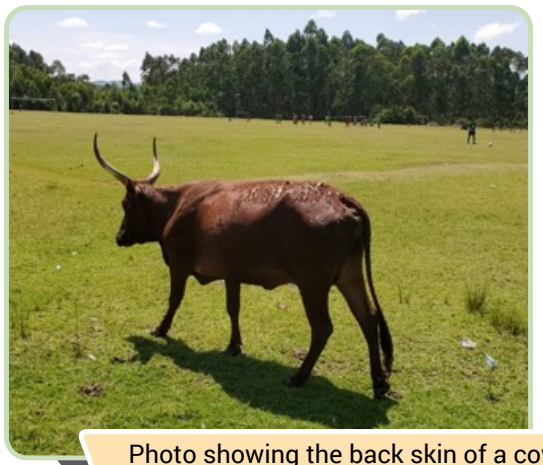


Photo showing the back skin of a cow peeling off after application of an agrochemical in Rwampara District"

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 on the predilection sites namely: ears, neck, interdigital spaces, perineal and inguinal region.
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.

Farm visits to some **selected farms** in the **sub counties**

Following the stakeholder engagements at the sub counties, some farms with serious drug complaints were visited to assess their drug handling practices, farm records on drug use pattern, farm structures and equipment that aid drug administration. A total of 38 farms were visited as shown in the table.

Name of District	Number of farms visited
Kiruhura	22
Rukungiri	1
Ntungamo	2
Kabale	1
Sembabule	12
Total	**38**

Farm visit in Kiruhura district to assess acaricide use practices

Farm visit in Kiruhura district to assess acaricide use practices

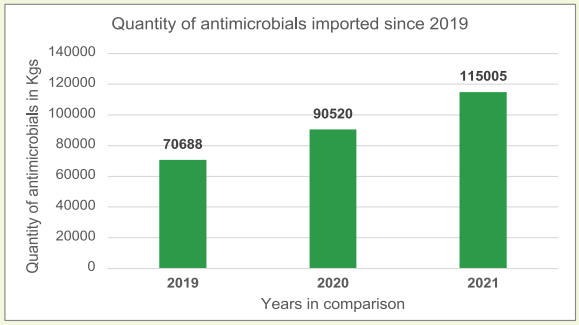
A photo showing the storage of veterinary drugs in the bush on a farm in Rukungiri District. The farmer was advised on proper drugs storage.

Quantity of Active Ingredients of **Antimicrobials Imported** into Uganda since 2019 to 2021

Antimicrobials play a critical role in the treatment of diseases in animals (aquatic and terrestrial) and their use is essential for food safety and for the well-being of the animals. However, their overuse and misuse promotes the emergence and spread of microorganisms resistant to these antimicrobials thereby leading to a serious compromise in food safety, food security and sustainable economic development.

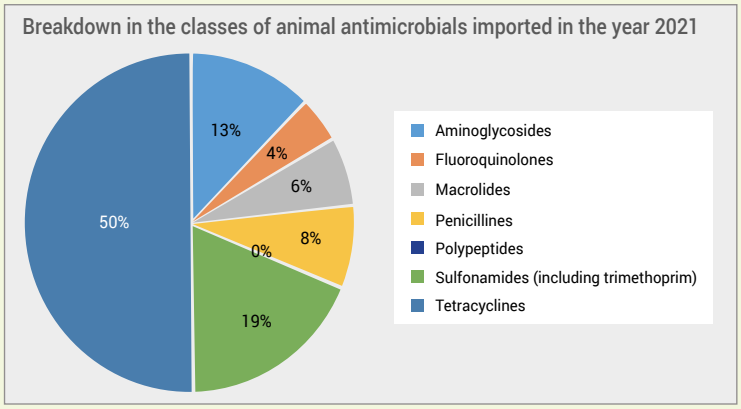
The World Organization for Animal Health (WOAH) member countries are annually required to monitor and report to the WOAH, the quantities and usage patterns of antimicrobial agents intended for use in animals. In Uganda this data is currently being collected at the point of importation. The National Drug Authority hosts Uganda's WOAH focal point for veterinary products who compiles and submits the report to WOAH through the WOAH country delegate, the Commissioner Animal Health, Ministry of Agriculture Animal Industry and Fisheries (MAAIF). The graph shows the trend of quantity of antimicrobials intended for use in animals imported in Uganda from 2019 to 2021. The data shows that there has been a steady increase in the imported quantities of antimicrobials in Uganda since 2019 which is a direct indicator that antimicrobial use in animals has increased. There is need for a multistakeholder approach to promote disease preventive measures and alternatives to antimicrobials as a way to reduce the pressure on use of antimicrobials. The National Drug Authority has continued to prioritize stakeholder engagement on proper use of antimicrobials as a measure to contribute to the global effort against antimicrobial resistance

The graph showing the total quantity in kilograms of active ingredients of antimicrobials intended for use in animals since 2019 to 2021



Classes of **antimicrobials** for animal use imported in the year 2021

Antimicrobials (antibiotics, antivirals, antifungals and antiparasitics) are broken down into different classes among which are the tetracyclines, aminoglycosides, sulphonamides, macrolides and fluoroquinolones. Tetracyclines accounted for the biggest quantity (50%) of antimicrobials imported in 2021 followed by the sulfonamides (19%).



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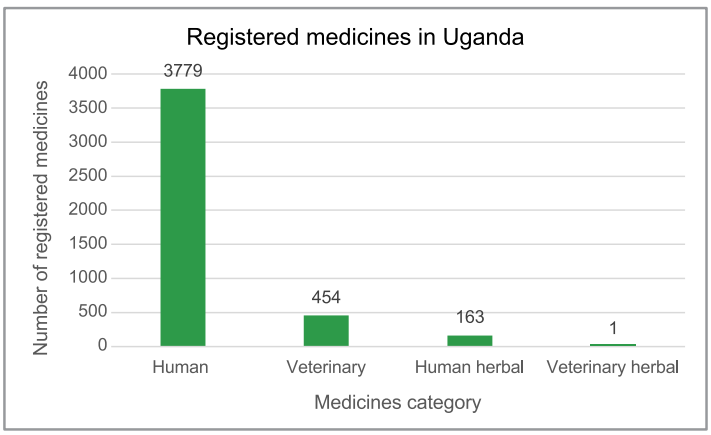
Veterinary Medicines

Registration

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

Current statistics of registered medicines in Uganda

The number of registered medicines in Uganda. Source: The Uganda National Drug Register (28 June 2022)



Procedure for Drug Registration

Submission of an application and product samples

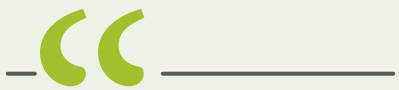
The basic procedure involves a company submitting an application (that includes two CDs, two samples of the product, plus the registration fees) for registration of a veterinary product in Uganda.

Assessment of the 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.

Registration and Approval

All products recommended for registration should be manufactured by facilities that meet NDA cGMP (Current Good Manufacturing Practices) requirements. Upon recommendation for registration approval, the products are presented to the Committee on National Formulary (CNF) to grant 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.



If it is found that the application meets all requirements, then the product is recommended for registration.

Proper veterinary medinces handling and storage

All veterinary medicines must be stored well and handled only by a qualified person. A qualified person to handle veterinary medicines is one who is recognized by the Uganda Veterinary Board and has obtained a license from the National Drug Authority to operate a veterinary medicines drug outlet.

Did you know that veterinary medicines are sensitive to extreme temperatures, moisture and light? It is therefore imperative to observe the following conditions to secure the quality of these medicines.

1. Always keep the medicines in lockable shelves or boxes away from light, heat or water
2. Have temperature and humidity monitoring devices and keep daily records of the premises
3. Separate medicines for external use from those for internal use.
4. Have sufficient space to store the medicines in an orderly manner.
5. Keep the premises clean and dry.
6. Have the premises in a permanent building with well painted walls.
7. The premise should have a ceiling made of leak proof material and should be maintained in good condition.
8. The floor should be well cemented or tiled (free of holes) for easy cleaning or disinfecting.

Also,

1. Keep medicines away from reach of the public and children.
2. Keep medicines in a place only accessible by the qualified person and they should be under lock and key.

A veterinary drug outlet with lockable shelves, well painted walls and ceiling being attended by a qualified personel. Farmers having an opportunity to consult the attendant before purchase of the medicines

The head veterinary products doing an on-farm sensitization of farmers on best practices in drug handling and storage.

NDA Officer assessing drug storage practices at farm level.

Guidance for opening up a Class C Veterinary drug shop

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 of which include pain relievers, cough suppressants, dewormers, multivitamins, mineral licks (appetisers) among others.

Requirements for application

Applicants requesting to open up a veterinary drug shop should submit the following at the time of application:

1. A duly filled application form for certificate of suitability of premises.
2. A duly filled application form 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 professional 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 body, the Uganda Veterinary Board.
2. The premise must be operated by the licensed seller on a full- time basis, 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.

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

Medicines are a delicate commodity that have to be properly handled throughout 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, handling and transportation. A classic example of a cold chain product are the vaccines.

Requirements for a good cold chain facility

The National Drug Authority continually monitors and supervises both public and private cold chain facilities as well as sensitize personnel on cold chain management to ensure that cold chain medicines retain their quality. Several gaps have been identified in cold chain management which include; use of non-pharmaceutical refrigerators, lack of power backup to maintain uninterrupted power supply, lack of temperature monitoring, inadequate vaccine records, unqualified personnel handling vaccines among others. The personnel incharge of the cold chain facilities are therefore encouraged to:

i. Install purpose built (pharmaceutical) 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

v. Monitor the temperature of vaccines/ cold chain products during storage and transportation. Obtain a temperature monitoring chart and daily fill it in.

vi. Avoid mixing vaccines with other products.

vii. Keep an up-to-date stock inventory of vaccines.

viii. Train the personnel in-charge of the cold chain facility.

Images showing the presence of unauthorized items in a vaccine refrigerator.

The presence o f other items in the vaccine refrigerator are a potential source of contamination for vaccines. They may include soft drinks, drinking water, food, fruits, laboratory reagents, blood and tissue samples among others.

Compliance monitoring and support supervision

Compliance monitoring and support supervision is to ensure that the NDA laws, regulations and guidelines are being adhered to. The activities were geared towards creating awareness of the best practices in handling and storage of veterinary medicines especially vaccines through onsite sensitization.

We carried out compliance monitoring and support supervision in 85 districts, conducted 13 follow up surveys to identify unauthorized veterinary products and audited 122 private and 45 public cold chain facilities.

Key findings from compliance monitoring and support supervision activities

1. Good distribution practices (GDP) were not being followed in majority of the drug out lets (both pharmacies and drug shops).
2. Some Class C drug shops were wholesaling, stocking beyond the legal class while most were not adhering to storage conditions in accordance to section 42, 7th schedule of the NDA/P Act and the manufacturers' instructions. For example light sensitive products displayed on open shelves.

3. Onsite sensitization on good drugs storage and handling yielded great results as the drug outlet operators started to adopt the recommendations immediately. The positive outcome to the professional side is that farmers have began to seek professional as a result of non-display of drugs on open shelves.
4. Implementation of the requirements for prescription to enable acquisition of veterinary drugs is still far from being achieved. This is due to a lack of enough qualified and licensed veterinary surgeons/practitioners.
5. Veterinary drugs are still being sold in shift markets. Business owners and veterinary clinicians are encouraged to erect suitable structures at the locations of the shift markets to help alleviate the problem.

A veterinary drug shop in Sembabule Town council stocked with restricted drugs and on open shelves, exposed to light, dust and full view and access to farmers. (Before)

The veterinary drug shop in Sembabule Town Council that responded to the NDA team support supervision and compliance monitoring advise by fixing lockable shelves for the restricted vet drugs. (After)

Compliance monitoring and support supervision availed intelligence information that supported enforcement. This led to the arrest of 6 suspected counterfeiters in the districts of Mbale, Bushenyi, Kalisizo, Mbarara and Sheema. More enforcement activities and achievements have been registered including 7 more cases and destruction of 4.8 tonnes of counterfeit drugs.

Enforcement Activities

Investigations into a suspected counterfeiter of Albafas 10% through relabeling.

Engaging police to apprehend the suspected counterfeiter in Mutukula Town Council.

Joint NDA and Police press release after the crack down operations in Mutukula Town Council.

Joint NDA and Police press release after a crack down operations in Ishaka Town Council, Bushenyi district.

Table 4: *Summary of court cases handled on falsified/counterfeited veterinary drugs for the FY 2021/2022*

SN	COURT CASE	DISTRICT, LOCATION	MAGISTRATE COURT	STATUS
1.	Uganda Vs Philly Kikawa	Kalisizo	Kalisizo magistrates court	Pleaded guilty Convicted
2.	Ug Vs Deomax Mubangizi & others	Bushenyi	Bushenyi magistrates court	Case ongoing
3.	Uganda Vs Bernard Nuhawereza	Kakango	Kakango magistrates court	Case ongoing
4.	Uganda Vs Eldard Tumwebaze	Mbarara	Mbarara magistrates court	Case ongoing
5.	Uganda Vs Denis Kakuru	Mbarara	Mbarara magistrates court	Case ongoing
6.	Uganda Vs Jennifer Najjuka	Lyantonde	Lyantonde magistrates court	Convicted

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.

Compliments to reporters

National Drug Authority wishes to recognize the following reporters that have sent reports to the Authority in no particular order over the years:

1. Dr Nuwagira Fred - Kiruhura District
2. Dr. Godfrey Kahuta – Kyenjojo District
3. Kalungi Derick - Kampala
4. Dr. Joseph Amanya - Sheema District
5. Dr. Abel Mukasa – Norbrook Uganda Limited
6. Mugyenyi William – Kakumiro District
7. Dr. Kivumbi John - Jubaili Agrotech
8. Dr. Sseguya Bill - The Big Fix– Uganda, Gulu City
9. Dr. Ssemwogerere Daniel – Lusanja Wakiso
10. Dr. Lutaaya John – Kyotera District
11. Dr. Kibaya Yusuf – Kasese District
12. Tweshengyereze Apollo – Kiruhura District

An adverse drug event that occurred in puppies following the use of a cocktail parvovirosis vaccine

Background

The National Drug Authority received a report of a serious adverse event from Gulu City following the vaccination of 8 weeks old puppies with a cocktail vaccine containing live attenuated parvo virus, canine distemper, leptospirosis, canine influenza, kennel cough, and infectious canine hepatitis. It was reported that all the vaccinated puppies succumbed to the clinical signs of parvovirosis after 1 week of administration. The cocktail vaccine was administered as a booster for plain parvovirosis vaccination that was done at week 6 as per the puppies' vaccination program.

Summary of investigation

Affected puppies: 10 German shepherd puppies at 8 weeks old.

Suspected condition: Canine parvovirosis – a highly contagious virus that causes gastro intestinal complications in young, unvaccinated dogs. The incubation period of the virus is 3–7 days post exposure

Suspected product: a live attenuated cocktail vaccine containing parvo virus, canine distemper, leptospirosis, canine influenza, kennel cough and infectious canine hepatitis. Each puppy was vaccinated with 1ml of the vaccine subcutaneously at the back.

Treatment given: supportive treatment was given which included fluid therapy and antibiotics.

Reporter observations: when the reporter of the adverse event stopped vaccinating clients' puppies with the suspected cocktail vaccine, there were no further complaints. However, after a while, the reporter vaccinated a resident puppy with the suspected cocktail vaccine which led to development of overt signs of parvovirosis and death after one week.

Investigations done by NDA: we conducted a facility check at the reporter's premises including the cold chain facility which was found to be operating at an acceptable standard; and the vaccine was handled and administered by a qualified person. Further investigations were done at the district veterinary office and the supplier's premises.

Conclusion: this case is highly suspected to be a vaccine associated enhanced disease (VAED). This scenario usually occurs when live attenuated vaccines such as the parvo vaccines undergo inadequate attenuation which results in immune responses that exacerbate the disease associated with the pathogens in the vaccine. Considering the fact that the event occurred within the incubation period of the disease (3-7 days), it is reasonable to conclude that the adverse event is certainly associated with the vaccine in question.

Regulatory actions: the vaccines were quarantined and samples submitted to the NDQCL LAB for onward analysis.

An adverse drug event that occurred in Goats and sheep following the use of Ivermectin injection

Background

The National Drug Authority received a report of a serious adverse drug event from a farmer in Kikatsi sub county, Kiruhura district. This followed the treatment of 95 goats and 63 sheep with Ivermectin injection. It was reported that all goats reacted negatively to this product 4 to 5 days after administration. A causality assessment was done and the following was the investigation summary:

Affected species: 95 goats and 63 sheep of varying age.

Suspect condition: Ivermectin toxicity following misuse in contraindicated species.

Suspected product:

- Brand / Proprietary name – IVER PLUS injection.
- Generic name – Ivermectin + Clorsulon
- Pack size – 100mL amber vial (with a broached silver metallic seal).
- Batch Number: 202112001
- Manufacture Date: 12/2021
- Expiry Date: 12/2024
- Dosage administered: 1mL per 60kg body weight, 0.5mL for 30kg body weight and 0.4mL for 25kg body weight.

Treatment given to avert the adverse event: Following occurrence of the adverse event, the sub county vet practitioner intervened by administering Dexaphan injection, an anti-inflammatory to reduce swellings. In addition he administered Penstrep injection as an antibiotic to check bacterial infections.

Reporter observations: The farmer reported that the suspected product was administered on his farm to 95 goats and 63 sheep as dewormer on 04/May/2022. From 09/May/2022, the animals started showing signs of swollen necks, weakness and mortalities averaging 3 deaths per day. As a result, 23 goats and 1 sheep died.

Investigation findings: The investigation activities were geared towards assessing the relationship between the serious adverse drug event and the drug product administered. Further evaluation on possible confounding factors such as qualification of attendants, farm management systems, drug storage, handling and source of the product was also conducted.

Conclusion: The suspect product used, IVER plus® - as per the manufacturer's instructions - is indicated for use in cattle and contra-indicted in other species. Therefore, its use in goats and sheep is most probably responsible for the occurrence of the reported serious adverse drug events observed.

In addition, considering the fact that the event occurred within 4 days after treatment, there is a close temporal association between the use of the suspect product and the emergence of the adverse events.

Regulatory actions: Causality assessment report made and feedback given to the stakeholders.

The Journey Of The National Drug Authority In Monitoring the Safety of Animal Drugs

The National Drug Authority has over the years built the function of monitoring of the safety of veterinary drugs, the science referred to as veterinary pharmacovigilance especially in the area of adverse drug events reporting. The duty to report adverse drug events following use of drugs in animals falls on the shoulders of each one of us as a collective effort.

The key milestones so far achieved include the following:

a) Drawing of the Veterinary Pharmacovigilance Strategy as part of the new NDA strategic plan. This is set to guide the implementation and monitoring of progress of veterinary pharmacovigilance in the country. It spells out the roles of the different stakeholders plus the key activities and responsibilities in veterinary pharmacovigilance.

b) Development of the veterinary pharmacovigilance guidelines. The guidelines spell out the process of recognition, reporting and assessment of veterinary Adverse Drug Events in line with the framework of veterinary services delivery in the country.

c) Adverse drug event reporting tool: having been developed, the critical issue is making it available to the reporters across the country. The Authority intends to make adverse drug reporting cheap and convenient through user friendly and easily accessible reporting tools.

d) Veterinary pharmacovigilance platforms have been created by use of interactive social media (WhatsApp). This has created an easy way to capture adverse drug events that occur across the country, and to provide feedback and advice to animal health workers on drug related matters and animal health issues in general. They are avenues for consultation since these platforms include members with different levels of training in veterinary science.

Common adverse drug events and signals

Adverse events following vaccination tops the number of adverse drug events so far reported. These include – hypersensitivity reactions, lack of desired effect (protection), and injection site abscesses. Reports on ivermectins are also significantly increasing, pointing mainly to medication errors since this class of drugs has a narrower safety margin. Animal health workers are encouraged to always read product information leaflets and adhere to the recommended routes of administration.

Reports have also been received of misuse of agrochemicals on animals. This practice is widespread among farmers and several adverse events have been registered arising out of this misuse.

The extensive use of Abamectin-based agrochemicals for tick control in cattle is further suspected to be the cause of the increasing blindness of animals on farms. Since these are food animals, it is highly suspected that there could be public health ramifications of this practice especially in communities that consume this milk on a daily basis.

The long term effect on humans consuming milk daily from treated animals is not yet documented but believed to be significant. The Codex Alimentarius established the acceptable daily intake (ADI) at 0-2 µg/kg body weight. Since the dose for use as an ectoparasiciticide is not established, it is likely that this ADI is exceeded for several days post-application.

The Codex Alimentarius established the Acceptable Daily Intake (ADI) at 0-2 µg/kg body weight.

Activities to focus on 2022/2023

1. Development of more IEC and training materials for reporters (e.g. the veterinary pharmacovigilance training manual for animal health workers, posters, brochures and fliers) to deepen the science of pharmacovigilance among veterinary professionals.
2. Availing reporting tools to the reporters and encouraging reporting through building the reporting network and support to the district veterinary offices.
3. Aligning the process of receipt, handling, assessing and feedback for reported adverse drug events to the national veterinary services system.
4. Identification of collaboration centers for veterinary pharmacovigilance.
5. Allocation of human and financial resources for specific training of animal health workers in pharmacovigilance.

Some of the goats that died after treatment with Ivermectin contraindicated in the species

Veterinary Drug **Promotion/ Advertisement**

The National Drug Authority regulates drug related information that targets different stakeholders in the community. 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".

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.

	National Drug Authority Rumee Tower, Plot No. 19 Lumumba Avenue, P.O. Box 23096, Kampala, Uganda Email: ndaug@nda.or.ug, Tel: +256-414-255665, +256-414-347391, +256-414-347391	**FORM 45**

APPLICATION FOR PUBLICATION OR ADVERTISEMENT FOR A DRUG

The National Drug Policy and Authority (Control of Publication and Advertisement Relating to Drugs) Regulations, 2014; Regulation 6(1)

1. PARTICULARS OF APPLICANT

(1) Name of applicant ……

(2) Physical address/location……

(3) Plot No……Street……..…City/town……..……Country ……..

(4) Box No…… ……..……Telephone No ……..

(5) Email: ..... Mobile. Tel. No.: .....

(6) Signature…….....

(7) Full name and title of signatory ……..…..

2. DESCRIPTION OF PUBLICATION OR ADVERTISEMENT

(1) Type of activity for which application is made (*for example launch, advertisement, talk-show, exhibition*) ……..…… ……..…..

2) Type of material to be used (for example, posters, literature, bags, calendars) *(applicant to attach 2 samples of materials)* ……..…..

(3) Drug product name ……

(4) Language of the publication or advert ……..…..

(5) Date of submission of application……

(6) Intended target group ……

3. FOR OFFICIAL USE ONLY

(1) Fees payable……

(2) Receipt No……Date…….. NDA entry No……

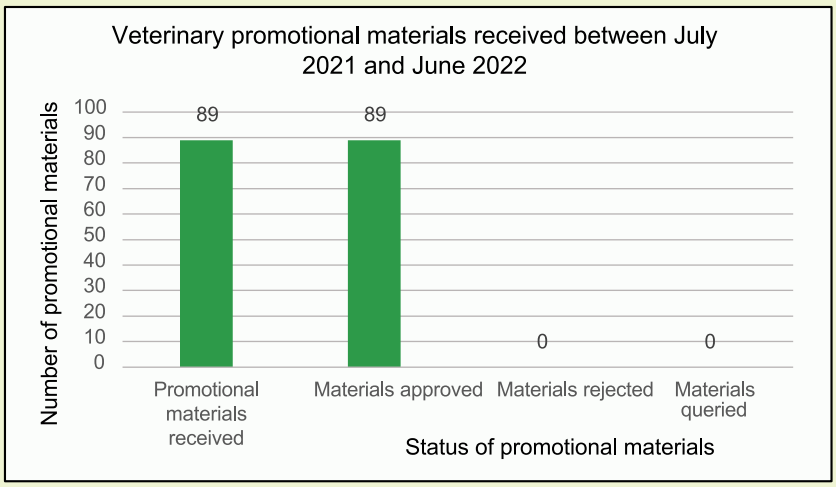
(3) Samples received and assessed by (name)……

Signature……Date……..…..

Sample application form for publication or advertisement for a drugs

FORM 45 that can be obtained on the NDA website, ***https://www.nda.or.ug/application-forms/***

The process of placing an application for a drug promotion/advertisement at the National Drug Authority



***A graph** Showing the statistics of veterinary promotional materials received at NDA between July 2021 & June 2022*

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 authorized by the manufacturer or the holder of the patent of the drug.

2. **Submission requirements:** an application letter, samples of the materials to be advertised, and the prescribed fees.

3. **Language requirement:** 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 received by the National Drug Authority, it undergoes the vetting process which includes screening, uploading into the drug promotion (DPROM) system, and subsequent review. After review of the materials, a regulatory decision is made which includes approval, query or rejection. This decision is communicated to the applicant within 15 working days after submission.

Reason for controlling veterinary drug promotions/advertisements

Veterinary drug promotions are controlled to:

i. Ensure that all advertisements are reliable, accurate, truthful, informative, balanced and up-to-date and in good taste; to

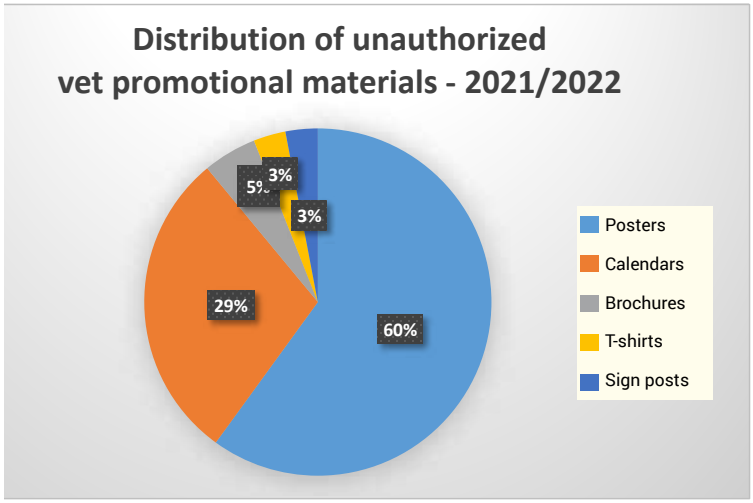
ii. Ensure that it is not misleading to induce unjustifiable drug use or give rise to undue risks.

If wrong information about a drug is exposed to the public, it is a potential source of harm to the animal and the user.

Compliance monitoring of **Veterinary Drugs Promotional Materials.**

Several non authorized promotional materials were identified in drugs shops as shown below.

Type of materials recovered	No. Materials	Status / Remarks
Posters	23	All were not approved
Calendars	11	All were not approved
Brochures	02	Contained misleading information
T - shirts	01	Not approved
Sign posts	01	Contained misleading information
Total	**38**	



Conclusion:

The monitoring of the accuracy of information on promotional materials in various drug outlets revealed that a number of materials were circulating on the market in total contravention of the NDA regulatory requirements. The biggest percentage of unauthorized promotional materials in circulation was found to be posters at 60% followed by calendars at 29%, brochures at 5%, signposts at 3% and T-shirts at 3%.

Did You Know???

Reporting Adverse Drug Events

The adverse drug e v en ts 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 002070 or on our toll free number 0800101 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.

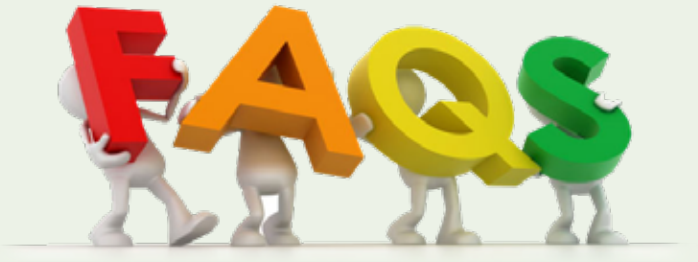
Resistance is the ability of microbes to grow in the presence of a drug that would normally kill them or limit their growth. Overuse and misuse of medicines are among the practices that have contributed to the development of drug-resistant microbes.

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 t o user) is key in main training 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.

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 that can be obtained on the NDA website . 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?**

   TThe 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 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.

8. Why are the prices of veterinary drugs very high?

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

9. Why are some acaricides no longer killing ticks?

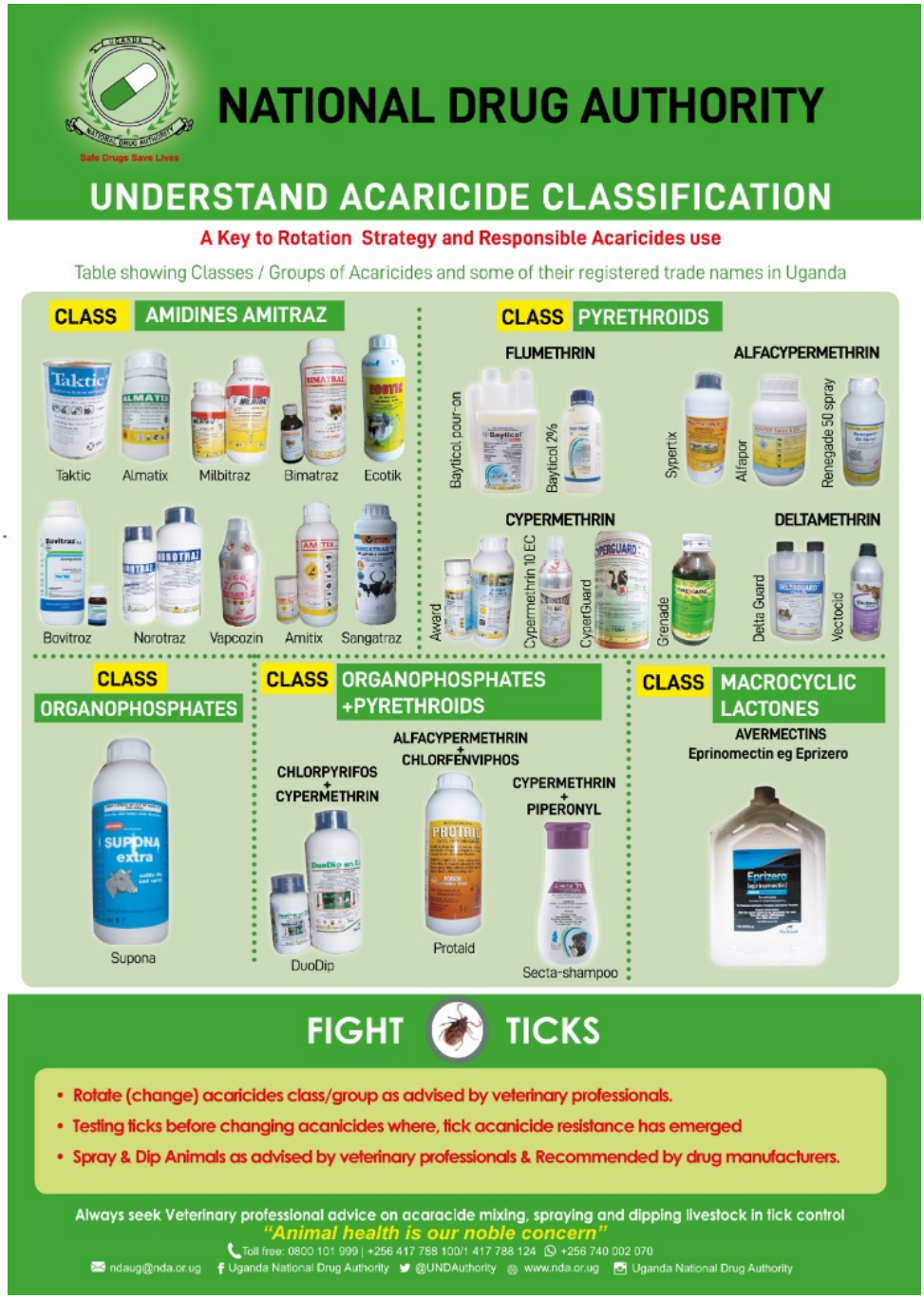
There are many factors contributing to the failure of acaricides to kill ticks. These include the over use of a particular class of acaricide, incorrect mixing (over or under) of acaricides, incorrect spraying (equipment and style) of animals, incorrect restraint of animals, and a lack of rotation between 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..

10. What happens to recalled drugs?

Depending on the reason for recall, a recalled product can either be reworked or destroyed.

11. 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.



Aposter showing the different classes of acaricides on the Ugandan market. There are several brands under each class

A poster showing the role of different stakeholders in the fight against antimicrobial resistance

NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

GOOD PRACTICES IN ECTOPARASITICIDE USE

Acaricides (Ectoparasiticides) are chemical formulations applied on animals for control and prevention of ectoparasitic infestation by dipping, spraying or application of shampoos. Much as these are beneficial, their use is constrained by concerns about chemical residues in food, environment, human exposure and high mortality due to diseases that follow failure to sustain their intensive application, high cost and resistance to them by ticks and other ectoparasites.Parasites such as ticks following prolonged use naturally gain resistance to acaricides and genetically pass it to their offsprings leading to the generations of resistant parasites naturally selecting out the susceptible ones.

Therefore by the time we realize that a certain acaricide is no longer effective, the problem has been on for a long time. However good practices in acaricide use, can greatly slow down the development of acaricide resistance, minimise chemical residues and maximise production benefits

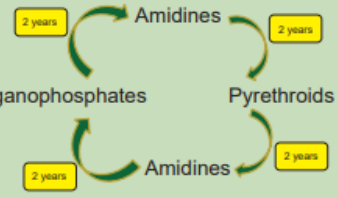
✓ Plunge Dip

RECOMMENDATIONS TO THE FARMERS AND VETERINARIANS

1. Buy acaricide products from NDA licensed drug outlets.
2. Use only those ectoparasiticides recommended and approved for use on livestock (Refer to the veterinary drug register available online). http://www.nda.or.ug/vet_list.php
3. Always follow the label instructions regarding dilution, storage and handling.
4. Always spray all animals on the farm including dogs
5. Spray the whole animal concentrating on parasite (tick) predilection sites.
6. Use proper measuring and application equipment and animal handling facilities e.g. cylinders, pumps , dips and crushes (old jerricans and bottle tops should be discouraged).
7. For dips, premix the dip before application / re-dip the first animals
8. Report any lack of efficacy of ectoparasiticides to the area veterinary officer or to NDA.
9. Practice controlled grazing to reduce tick challenge
10. Examine and treat newly introduced animals to avoid introducing resistant ticks.
11. Safely dispose off all empty containers and used diluted ectoparasiticide to avoid contamination of the environment.
12. Use one type or class of ectoparasiticide for a definite period of time (recommended 2years) and seek professional veterinary advice as you change to another class. (Acaricide Rotation) as illustrated below.

ACARICIDE ROTATION STRATEGY

CPD



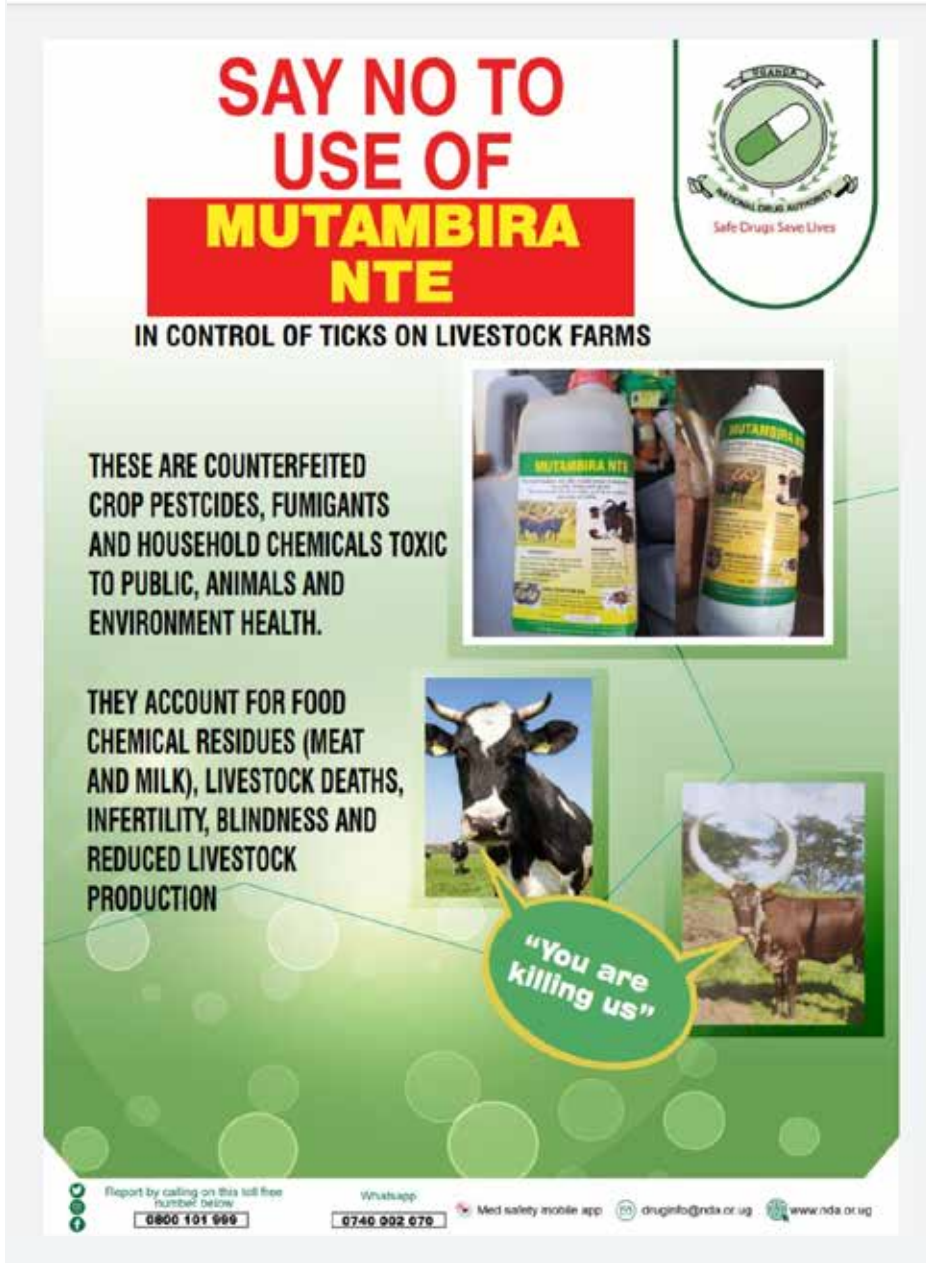
Always seek Veterinary professional advice on acaracide mixing, spraying and dipping livestock in tick control

"Animal health is our noble concern"

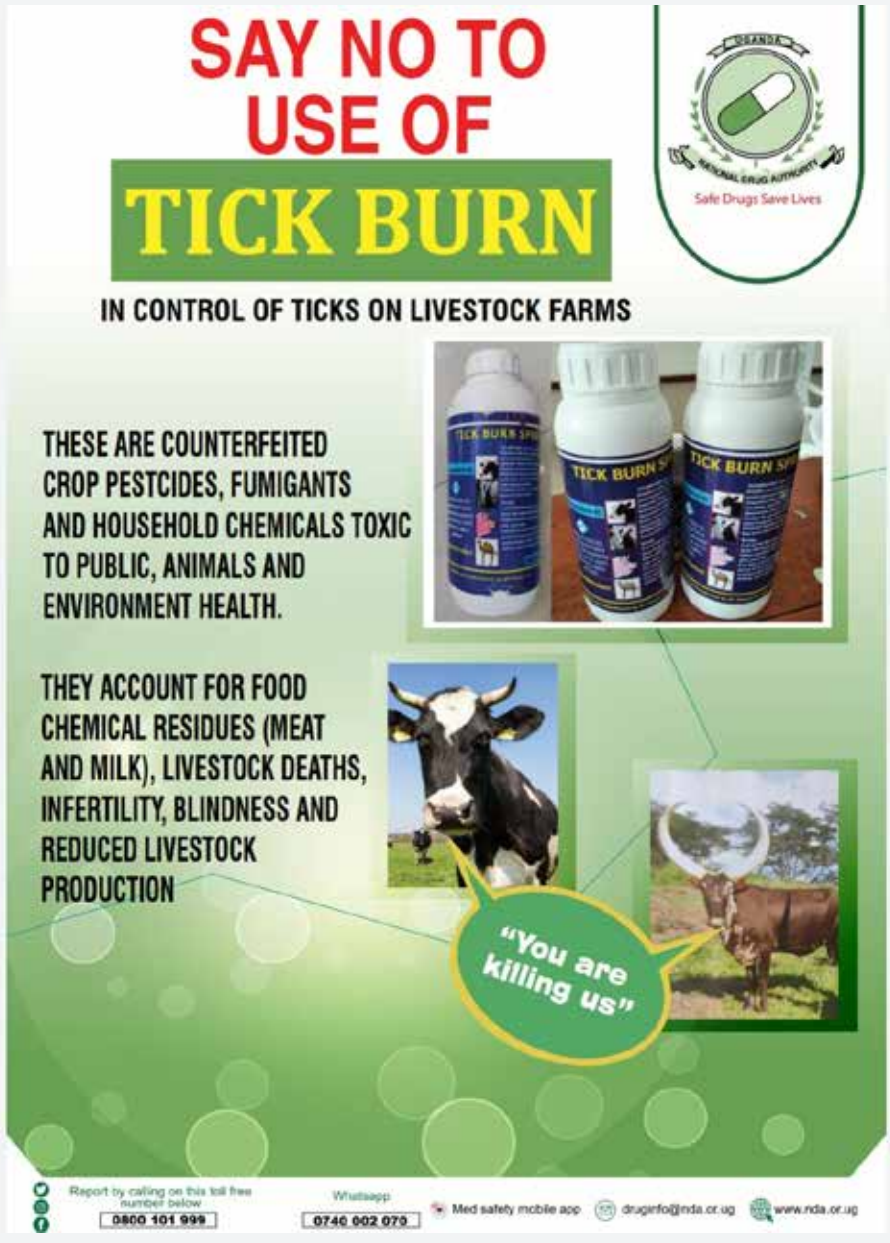
Toll free: 0800 101 999 | +256 417 788 100/1 417 788 124 0791 415 555

ndaug@nda.or.ug Uganda National Drug Authority @UNDAuthority www.nda.or.ug Uganda National Drug Authority

A poster on good practices in octoparasiticide use



An information, Education and communication material on discouraging the use of **"MUTAMBIRA NTE"** *in cattle.*



An information, Education and communication material on discouraging the use of agrochemicals in animals.

A poster showing the minimum requirements/standards for a veterinary drug shop

An information, Education and communication material on veterinary pharmacovigilance

An information, Education and communication material on veterinary pharmacovigilance

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NATIONAL DRUG QUALITY CONTROL LABORATORY

Tel: +256 414 540 067 or +256 414 583 095

1. **KAMPALA EXTRA - NAKAWA**
   Premier Complex, Jinja Road, Nakawa.
   Tel: +256 393 261 548

2. **SOUTH EASTERN REGION - JINJA**
   Plot 64, Gokhale Road, Jinja
   Tel: +256 434 122 176

3. **EASTERN REGION - TORORO**
   Plot No. 27, Kwapa Road, Tororo
   Tel: +256 454 445 195

4. **NORTHERN REGION - LIRA**
   Plot 48 Ogwal Ajungu Road, Lira.
   Tel: +256 414 671 032

5. **WESTERN REGION - HOIMA**
   Muganwa Centre, Plot 30, Old Toro Road, Hoima
   Tel: +256 465 440 688

6. **SOUTH- WESTERN REGION - MBARARA**
   Plot 26, Johnstone Road, Boma, Mbarara.
   Tel: +256 414 671 034

7. **WEST NILE REGION - ARUA**
   Plot 1 Mt. Wati Road, Anyaflo – Arua
   Tel: +256 414 671 033

8. **SOROTI**

9. **CENTRAL REGION**
   Akamwesi Mall, Gayaza Road
   Tel: .....

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**