VETERINARY MEDICINES

UPDATES BULLETIN

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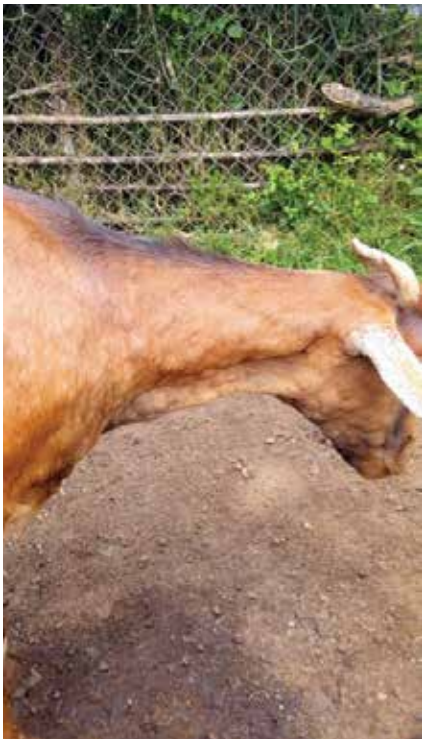

UGANDA

NATIONAL DRUG AUTHORITY

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On behalf of the National Drug Authority, I take this opportunity to thank all our stakeholders for entrusting the National Drug Authority with the mandate of ensuring that the animal population gets access to safe, efficacious and quality veterinary medicines. There have been tremendous achievements in veterinary medicines regulation over the past 26 years of the Authority's existence, there have been tremendous achievements in veterinary medicines regulation through her different technical Directorates.

The country currently boasts of four hundred and twenty one (421) registered veterinary medicines, [as of May 29, 2020], used in treatment and prevention of diseases in the animal sector. There are one thousand one hundred and twenty five (1125) licensed veterinary drug outlets distributed in all the regions of the country to ensure that the public consumes quality medicines.

Before a veterinary product is licensed for use in Uganda, manufacturing facilities are subjected to current Good Manufacturing Practices (cGMP) inspections; which are principles that must be observed during manufacturing to ensure that products from a particular manufacturing facility are of good quality, and are safe. Not only are manufacturing facilities inspected, but also product dossiers are submitted to NDA for further scrutiny of the manufacturing processes. At entry into Uganda, the products are verified for compliance with the Authority's regulatory guidelines.

The products are continuously monitored once on the market through NDA's post market surveillance activities and inspection of facilities where these products are distributed. Every facility where veterinary drugs are distributed must be licensed by the National Drug Authority. Market surveillance activities have resulted into submission of suspicious products to the National Drug Authority Quality Control Laboratory [WHO prequalified] for quality testing. By the results, interventions have led to illegal operators and counterfeiters being apprehended and taken to the courts of law whereas the substandard and falsified medicines are recalled from the market for destruction.

Through pharmacovigilance activities, veterinary medicines are also actively monitored after use to determine the risk benefit of these products. We are happy to report that the public is increasingly, vigilantly, collaborating with NDA by reporting of adverse drug reactions occurring in animals, illegal veterinary drug operators; and forwarding of quality and safety complaints.

We are particularly grateful for the cordial interaction and feedback obtained from the different veterinary stakeholders during sensitization meetings in the different regions of the country.

May you enjoy reading this Fifth Edition of the Veterinary Medicines Update bulletin.

Dr. Helen Ndagije Byomire

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STAKEHOLDER ENGAGEMENTS

The National Drug Authority actively collaborates with veterinary stakeholders at all levels to ensure efficiency and effectiveness in veterinary drug regulation. There is a wide range of stakeholders who include veterinarians, para veterinarians, farmers, veterinary drug shop and pharmacy operators, local government extension workers, district and opinion leaders as well as the International community that includes the East African Community (EAC), Codex Alimentarius, the World Organization for Animal Health (OIE), PANVAC, GALVmed among others.

NATIONAL COLLABORATIONS

There were local engagements at regional level from November 2019 to March 2020 in which six regions (Acholi sub region, Bugisu sub region, Central region, Lango sub region, Teso sub region and Western region) were covered. The discussions were on issues to do with the principles of post marketing surveillance and pharmacovigilance, rational use of veterinary medicines, the role of local government and NDA's mandate in veterinary drug regulation. The meetings are normally well attended, thanks to the good mobilization of the District Veterinary Officers.

The category of participants for these meetings include veterinary extension staff, farmers, veterinary drug outlet operators, district local government officials and opinion leaders.

Table showing stakeholder participation in the different regions of the country from November 2019 to March 2020

Region	Total number invited by NDA	Actual attendance	Percentage attendance
Western region	260	258	99.2%
Bugisu sub region	100	99	99%
Acholi sub region	80	70	87.5%
Lango sub region	100	87	87%
Teso sub region	100	80	80%
Central region	400	168	42%

Figure 1: Graph showing number of participants from four districts in the Western Region. A total number of 260 participants were invited of which 258 participants turned up. The meetings were held in February and March 2020.

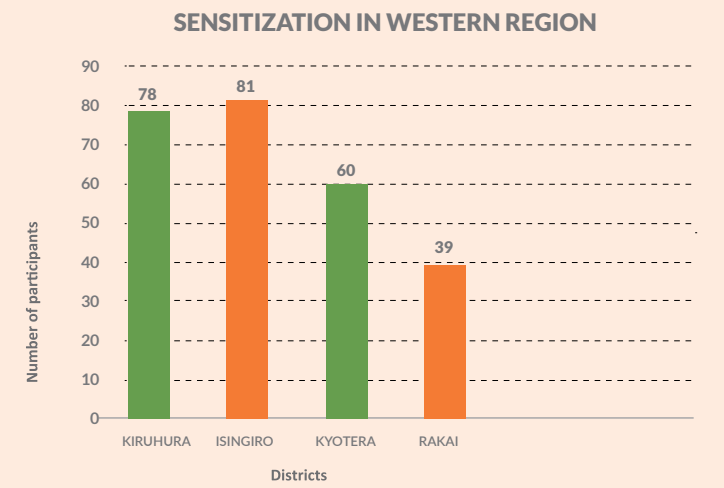


Figure 2: Graph showing the number of participants from five districts in the Central region. A total number of 400 participants were invited of which 168 participants turned up. The meetings were held in December 2019.

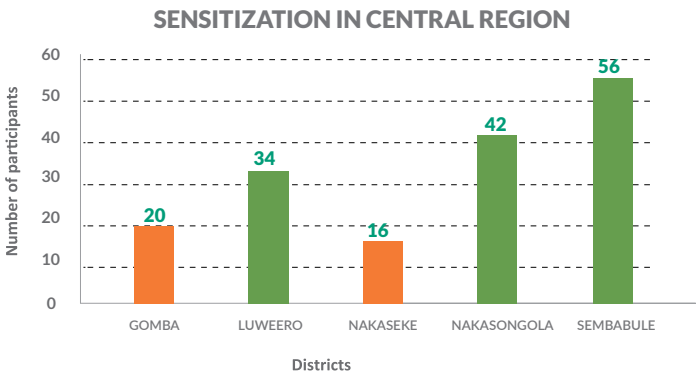


Figure 3: Graph showing the number of participants from six districts of Lango sub region for a sensitization meeting that took place in November 2019 at Good News Hotel in Lira District. A total attendance of 87 participants was realised out of the 100 invited participants

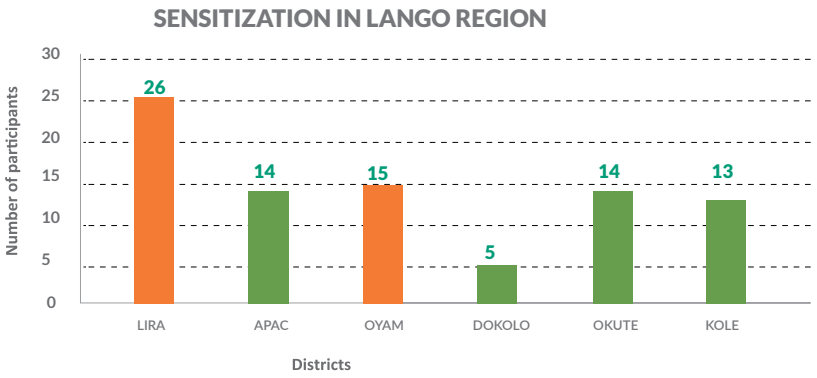


Figure 4: Graph showing the number of participants from four districts of Acholi sub region for a sensitization meeting that took place in November 2019 at Kakanyero Hotel in Gulu District. A total attendance of 70 out of 80 participants was realized

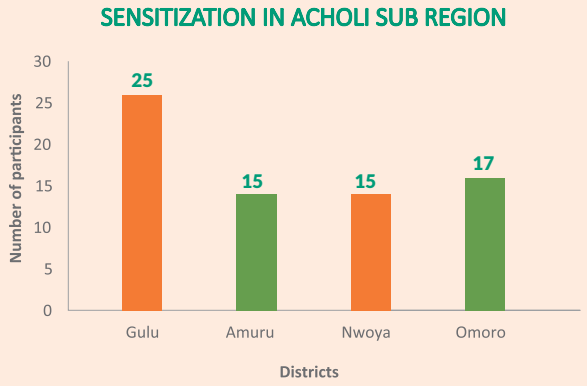


Figure 5: Graph showing the number of participants from six districts in Bugisu sub region for a sensitization meeting that took place in November 2019 at Reliance View Hotel in Mbale District. A total attendance of 99 out of 100 participants was realized.

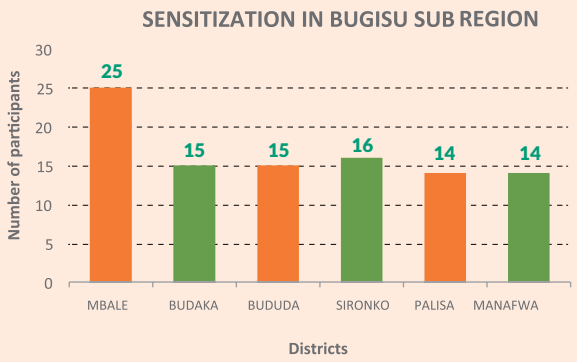
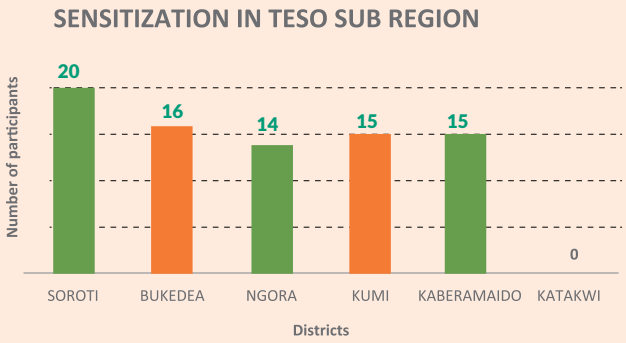


Figure 6: Graph showing the number of participants from six districts of Teso sub region for a sensitization meeting that took place in November 2019 at Akello Hotel in Soroti District. A total of attendance of 80 out of 100 participants was realized



Photograph of the stakeholders meeting in Gulu District

NDA regulatory officer conducting a stakeholder sensitization meeting in Mbale District

The DVO Mubende and two NDA Regulatory Officers on Tropical FM – Mubende in a collaborative engagement to reach out to the wider public on NDA regulatory roles and rational use of veterinary drug use. The main stream media is the other platform employed to sensitize the stakeholders including the public.

FINDINGS FROM THE STAKEHOLDER ENGAGEMENTS

The activities of the stakeholder engagements include formal meetings, post marketing surveillance as well as pharmacovigilance at farm level. Together, these activities have resulted into an in depth understanding of the challenges faced in drug regulation.

SAFETY, EFFICACY AND QUALITY ISSUES	GENERAL ISSUES
There is an increasing use of ARVs in animals (especially pigs) with the aim of fattening the animals.	There are imposters claiming to be NDA staff thereby fleecing the unsuspecting drug shop operators of money.
Crop pesticides are being widely used as acaricide.	Unqualified personnel left to manage some drug outlets. These people cannot advise farmers on proper use of the drugs leading to misuse of these medicines.
There is the practice of repackaging pesticides as new acaricides for sale to the farmers.	Some farmers are being supplied directly by importers of veterinary drugs.
Acaricide concoctions are being made to spray animals against ticks as well as mixing of agrochemicals with acaricides to spray animals against ticks.	There are drug shops stocking Class B drugs instead of Class C drugs only.
Veterinary drug shop operators are increasingly dispensing small volumes of veterinary drugs in empty bottles of human drugs.	It is challenging to farmers to differentiate between authorized and unauthorized medicines on the market.
There are complaints from the field of ineffectiveness of some dewormers on the market.	Presence of misleading advertisements on the market as complained about by the farmers.
Expired drugs were found on shelves of some drug outlets during the surveillance activities.	Farmers do not have good knowledge about the best practices for tick control.
Use of dirty water to reconstitute acaricides.	Self-medication by farmers of their animals without any veterinary consultation.

OPPORTUNITIES FOR COLLABORATION

1. 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 for wider dissemination of information to the public.
3. Establishment of MoUs between NDA and the Districts to better streamline roles.

RECOMMENDATIONS

1. District Veterinary Offices to register all veterinary practitioners and coordinate their reporting of Adverse Drug Events ad suspected substandard and falsified drugs to NDA
2. In depth training by NDA of the field veterinarians on pharmacovigilance to enable reporting of Adverse Drug Reactions.
3. Continuous sensitization of stakeholders regarding veterinary drug regulation, proper handling and rational use of veterinary drugs.
4. Intensify support supervision of veterinary drug outlets to improve the level of compliance to NDA regulatory requirements.
5. Continued enforcement activities to ensure that unqualified drug outlet operators are managed.

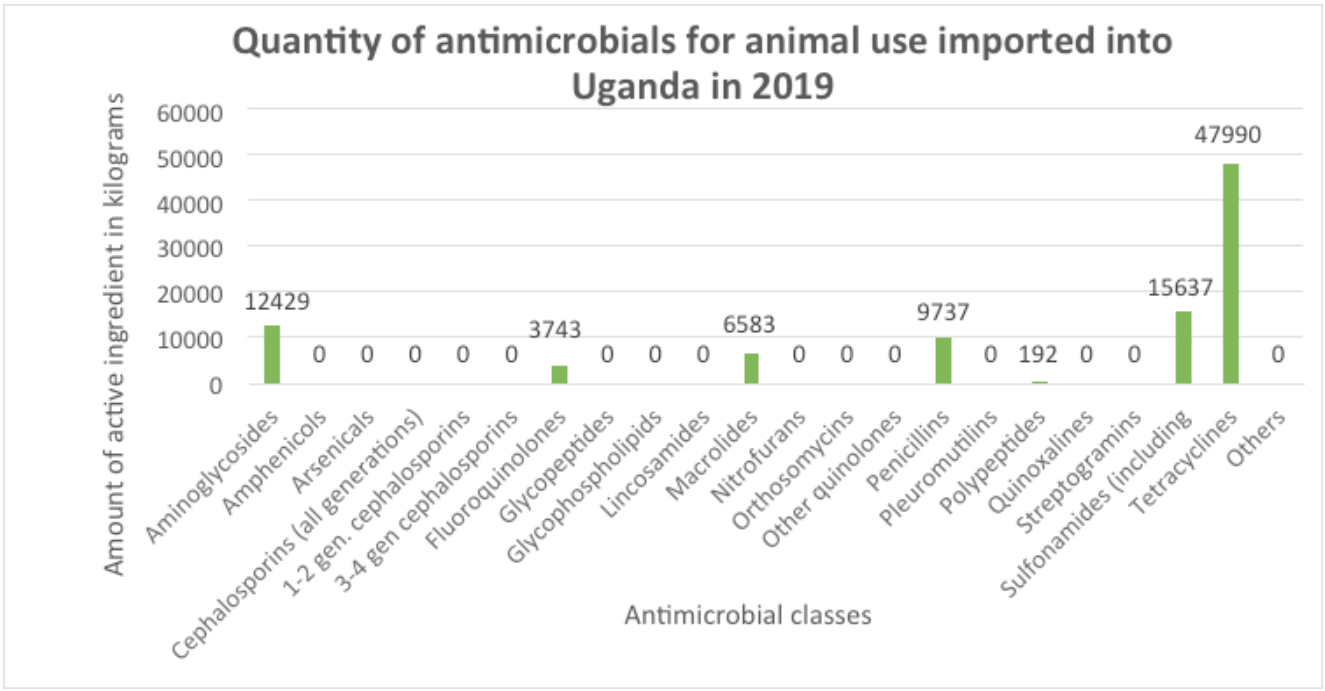
INTERNATIONAL COLLABORATIONS

The National Drug Authority collaborates with various international organisations including the World Organisation for Animal Health (OIE) that is responsible for safeguarding world trade by publishing health standards for international trade in animals and animal products. The OIE develops normative documents relating to rules that Member Countries can use to protect themselves from the introduction of diseases and pathogens. The OIE also provides technical assistance in disease control and eradication to member states that request for such assistance.

In her latest engagement, NDA participated in a training workshop on the database on antimicrobial medicines intended for use in animals in Eastern and Southern Africa. This training that was held in Mombasa, Kenya in October 2019, majorly focused on antimicrobial use data collection, collation, and harmonisation of the system. Uganda is required to submit to the OIE quarterly reports on antimicrobial consumption and use.

Delegates to the OIE training held in Mombasa, Kenya in October 2019. From Left to Right: Dr. Wilfred Opira of the National Drug Authority, Dr. Winfred Amia of Mott MacDonald/Fleming Fund, Dr. Engelbert Bilashoboka of the Tanzania Drug Authority, Dr. Jeanne Muhindo Bukeka of National Drug Authority and Dr. Richard Sam Erechu of Ministry of Agriculture, Animal Industries and Fisheries – the AMR Focal Point person in Uganda.

Figure 7: Graph showing the quantity of antimicrobials imported into Uganda in 2019 for animal use.



VETERINARY MEDICINES REGISTRATION

Procedure for Drug Registration

SUBMITTING AN APPLICATION & 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

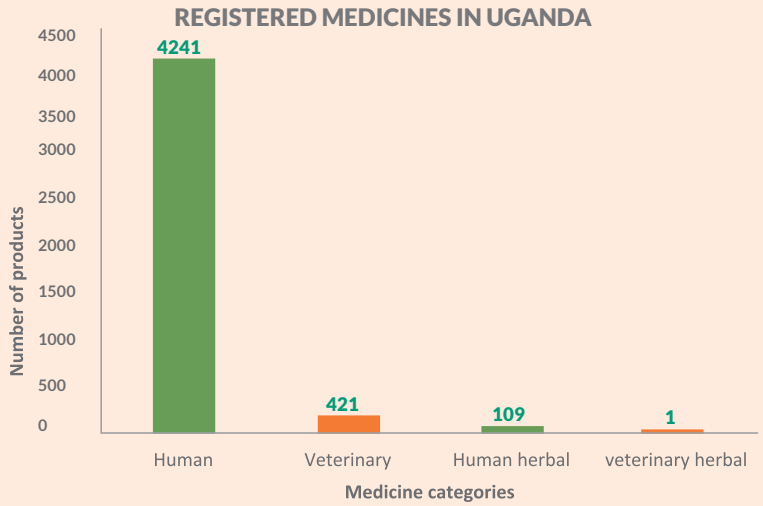
The assessment of the application is handled on a first come first served basis except for veterinary immunological products that are handled under first track. All applications undergo a first (involving screening) and second assessment for quality assurance purposes. If it is found that the application 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.

REGISTRATION & 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.

Current statistics of medicines registered in Uganda

Figure 8: Categories of medicines registered in Uganda including the numbers of each category.



Source: Uganda National Drug Authority Register (26 May 2020)

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

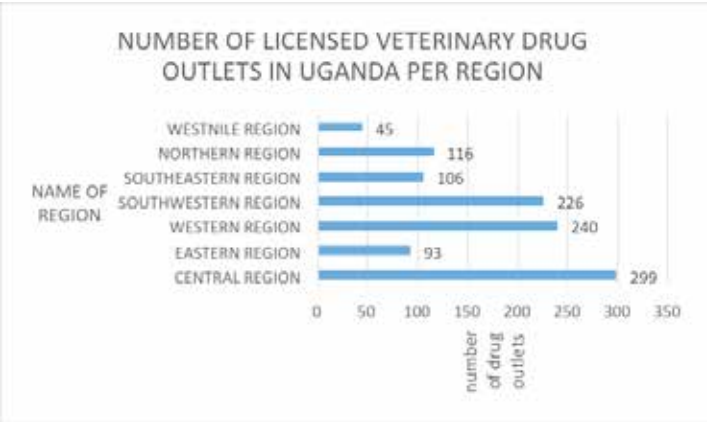
Timelines for renewal of Licenses for Drug shops

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

Supervision of Drug shops

- 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.
- A degree holder in veterinary medicine and a diploma holder in veterinary sciences shall be licensed to operate a VET drug shop.
- The premise must be operated by the licensed seller on a full- time basis, that is, throughout the entire opening hours of the drug shop. If the licensed seller must leave the premises for any reason, the drug shop must be operated by another suitably qualified person.

Figure 9: Graph showing the current number of licensed veterinary drug outlets by region in Uganda as of March 26, 2020



The Uganda Veterinary board has been consulted on how to make the licensing of veterinary drug outlets better.

POST MARKET SURVEILLANCE

Post market surveillance is the practice of monitoring the quality, safety and efficacy of a pharmaceutical drug or medical device after it has been released on the market.

Licensed and regulated distributors, wholesalers and retailers have a responsibility to comply with good storage and distribution practices, and should be subject to periodic inspections by the National Drug Authority. Distributors and retailers are therefore, obliged to keep and maintain purchase records indicating the source, supply dates and batches for proper traceability.

Through regular sampling and surveying of both the regulated and unregulated supply chains, substandard and falsified veterinary pharmaceutical products have benn identified on the market. Distributors, wholesalers and retailers should remain vigilant and report any challenges or suspicious Substandard and Falsified veterinary medicines to NDA.
As a quality assurance mechanism, Active Post market Surveillance culminates in a recall of the registered and authorized products that fail quality tests or other regulatory requirements. The table below gives a list of recalled veterinary pharmaceutical products between.

NDA regulatory officer inspecting the records of a veterinary drug outlet during post market surveillance. Good record keeping through sales receipts help in traceability of pharmaceutical products on the market

NDA regulatory officer inspecting the storage conditions of a veterinary product. It is good to adhere to the manufacturer's storage conditions in order to maintain the quality of the product.

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.

Why is 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.

What are some of the reasons for recalling products on the market? Veterinary Pharmaceutical products may be recalled 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 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 either:

1. Destroyed
2. Re-worked and re-distributed depending on the nature of the defect

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 by NDA. 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.

List of recalled veterinary pharmaceutical products of 2018 and 2019.

Name of Product	Batch details	Reason for recall	Regulatory Action Undertaken
1. Sequzole 2.5%	LQ/16047/01 LQ/16050/01	Illegible labels and easily erased manufacturing and expiry dates	Destruction
2. Bimatraz	B031117A	Failure to comply with USP specifications for the Assay test	Destruction
3. Albevet	170724	Failure to comply with USP specifications for the Assay test	Destruction
4. Sypertix 10% EC	8384-515NKL	Failure to comply with CIPAC/WHOPES specifications for assay	Destruction
5. Erazole 2.5	0014	Failure to comply with specifications for the Assay test	Destruction
6. Albendastar 10%	170428	Failure to comply with specifications for the Assay test	Destruction
7. Ecotik E.C	358215 358216	Failure in assay test.	Destruction
8. Norotraz	8123B-505 NKL (1 litre) 8124-501 NKL (40 mL)	Did not comply with the USP specifications for assay test	Destruction
9. Wormita	80504	Failure to comply with the specifications for pH tests	Destruction

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.

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 GOATS AFTER VACCINATION WITH THE PESTE DES PETITS RUMINANTS VACCINE (PPRV)

Background: ***Mr. B.M, a farmer, reported to the National Drug Authority a case in which his goats developed adverse drug reactions of skin rash, swellings and death 4 to 7 days after being vaccinated with the Peste des petits ruminants (PPR) vaccine. A follow-up physi- cal examination of the goats that survived revealed the presence of skin rashes and swollen lymph nodes on some of the goats, but the rest of them had recovered.***

Peste des petits ruminants (PPR): ***Peste des petits ruminants (PPR), also known as goat plague, is an acute contagious disease that affects mostly sheep and goats and occasionally small ruminants living in the wild. The clinical disease resembles Rinder- pest in cattle.***

Causative agent: ***PPR is caused by the Peste des petits ruminant virus (PPRV) classified in the family Paramyxoviridae, genus Morbillivirus. It represents one of the most economically important animal diseases in areas that rely on small ruminants. Outbreaks tend to be associated with contact of immuno-naïve animals with animals from endemic areas. In addition to occurring in extensive-migratory populations, PPR can occur in village and urban settings though the number of animals is usually too small to maintain the virus in these situations.***

Transmission: ***is by aerosols or direct contact between animals living in close quarters. Fomites (bedding, feed and water troughs) may be a means of spread of the infection. There are outbreaks that are more frequent during the rainy season or the dry cold season.***

Incubation period: is typically 4–6 days, but may range from 3–10 days.

Prevention and Control of PPR

PPR in goats is controlled by vaccination of non-infected animals. In the event of disease, there is no specific treatment, however supportive care and treatment of bacterial and parasitic coinfections may decrease mortality. Antibiotics may prevent secondary pulmonary infections.

Photograph showing a goat with swellings around the head and neck

Photograph showing a goat with swellings on the whole body

AN ADVERSE DRUG EVENT CAUSED BY TICK BURN SPRAY – A COUNTERFEIT AND UNREGISTERED MEDICINE.

Background

The National Drug Authority received reports of circulation of counterfeited and unregistered "Tick Burn Spray" which was causing serious adverse effects to both the animals and the human population exposed to this suspicious product. A particular report from Kyenjojo indicated that a farmer had lost a milking cow following use of the Tick Burn Spray.

Photo of a dead milking cow after using Tick Burn Spray in Kyenjojo District

Picture of the counterfeit and unregistered Tick Burn Spray used on the farm where the death of the milking cow occurred

This report prompted a causality assessment by the National Drug Authority, which confirmed that the suspected product used on the farm was indeed Tick Burn Spray – an unregistered product with NDA.
A targeted operation covering the districts of Kyenjojo, Bushenyi, Mbarara, Kiruhura, Kazo, Ntungamo, Rukungiri and Kampala was conducted in February 2020 to ascertain the source of this product. Drug shops, agrochemical shops, general merchandise shops and dairy facilities were inspected.

Outcomes of the investigations

- Tick Burn Spray was discovered and obtained from the facilities inspected.
- It was confirmed that Tick Burn Spray and other agrochemicals were being sold to farmers to control ticks on their farms.
- There was evidence of relabelling DDForce and Boom Super 1000 EC (both of which have pesticide and fumigant activity) as Tick Burn Spray.
- Seven suspects were arrested and four were aligned in court.

Items recovered from the inspected facilities

Product Name	Pack size	Quantity recovered
Tick Burn spray	1000 mL	30 bottles
	500 mL	11 bottles
	100 mL	86 bottles
Tick Burn spray labels		1600 stickers
DDForce	1000 mL	4 bottles
	100 mL	3 bottles
Assorted stickers of DDForce and Tick Burn Spray		3 sacks
Ocelamectin (2 in 1)	500 mL	3 bottles
	250 mL	6 bottles
	100 mL	4 bottles

Possible side effects and risks to humans, animals and environment after the use of Tick Burn Spray

- Death of livestock.
- Reduced milk production in dairy animals.
- Skin allergies to humans exposed to the product.
- Contamination of animal food products with chemical residues.
- Cancer in humans and animals.

Advice to the public

- Only buy veterinary drugs from NDA licensed drug outlets.
- Consult veterinary professionals for proper advice and guidance on which drug to use from the available alternatives registered for use in Uganda.
- Be vigilant and report any suspected drug event or misuse of drugs to NDA or to the District Veterinary Office.

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 vet@nda.or.ug or WhatsApp 0791 415 555 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.

The adverse drug events reportec to NDA contribute to regulatory decisions and actions for improved safe use of veterinary medicines.

Every veterinary professional intending to open up a veterinary drug outlet should have a valid certificate of registration from the Uganda Veterinary Board

The distribution chain - manufacturer to user, is key in maintaining the wholesomeness of veterinary medicines

VETERINARY DRUG PROMOTION/ADVERTISEMENT

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

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

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.

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.

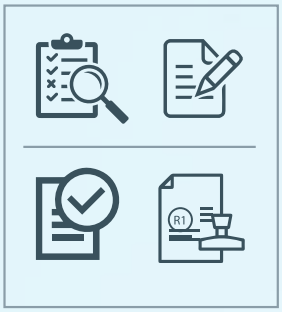
Inspection of acaricide field trial at Aswa Ranch, Pader District (in pink T-shirt - Dr. Eseru David, NDA).

Dr. Muhindo Jeanne, (Head Veterinary Products, NDA) sensitizing herdsmen using NDA posters on good rotational practices for acaricides at a farm in Isingiro District.

Group photo with NDA veterinary stakeholders during a sensitization meeting on veterinary drugs regulation and rational use of drugs in Isingiro District

Sharing information with the public at the Harvest Money Expo held at Namboole Stadium.

The National Drug Authority at the launch of the Med Safety Mobile App used for reporting adverse drug reactions and any other drug related issues in human patients. Such technology shall soon be adopted for reporting of adverse drug reactions in animal patients.



If you have any comments or feedback on any of the articles in this issue of the bulletin, we would be pleased to receive them via vet@nda.or.ug

Safe Drugs Save Lives

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Toll free: 0800 101 999
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National Drug Quality Control Laboratory Tel: (+256) 414 540 067
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Premier Complex, Jinja Road, Nakawa. Tel: +256 393 261 548

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

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

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

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

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

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