NATIONAL DRUG AUTHORITY

Safe Drugs Save Lives

NATIONAL DRUG AUTHORITY

THE VETERINARY MEDICINES UPDATES

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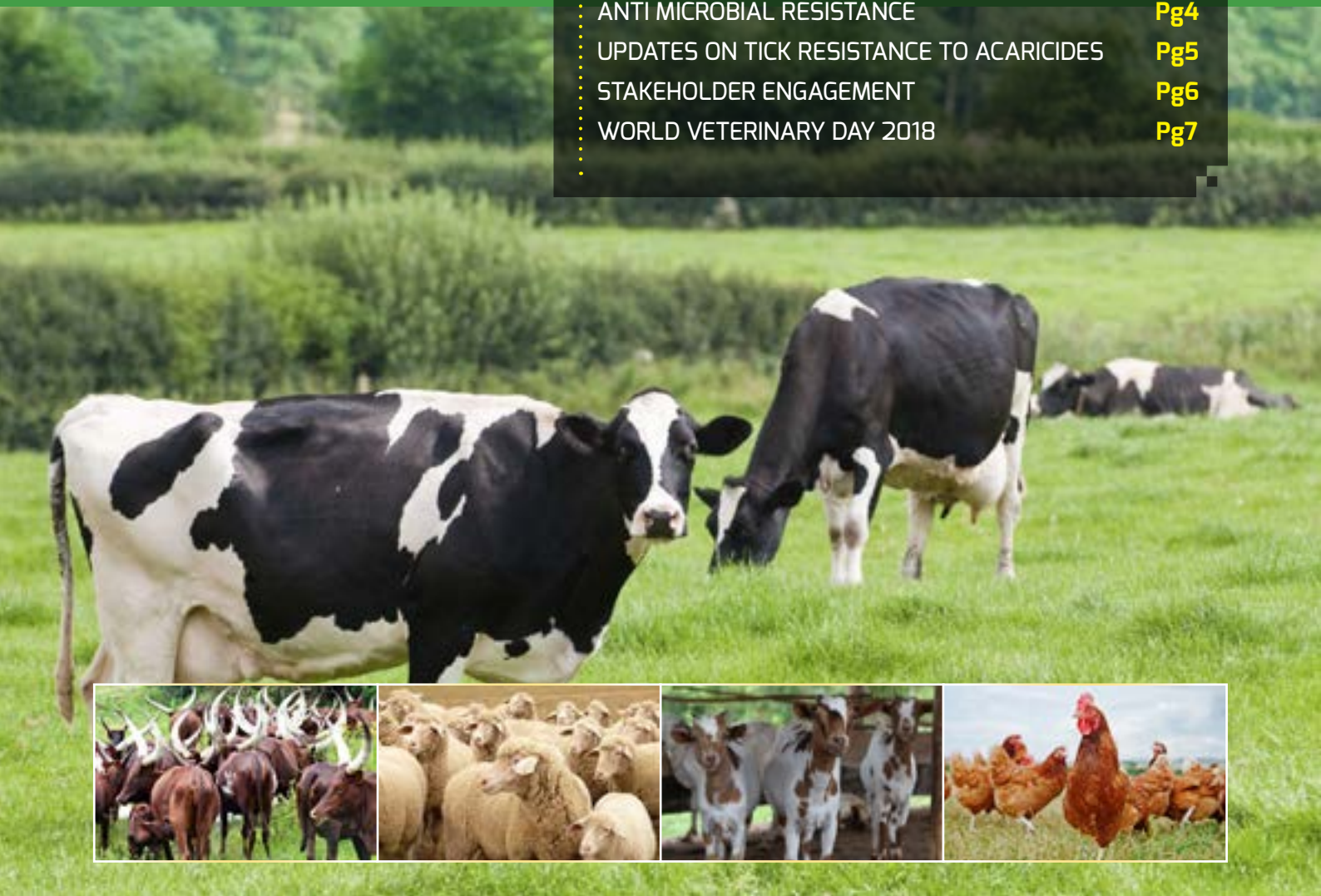

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EDITORIAL

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Dear readers,
There is a fundamental overlap between the health of human and animals, hence animal health plays a significant role in the life of humans. Over 60% of infectious diseases are shared between human and animals.

This close health linkage requires working together towards achieving satisfactory "One health" for both human and animals.

This year, 2018, National Drug Authority is celebrating 25 years of service. This issue of the Uganda Veterinary Medicines Updates outlines the historical background on the formation of NDA and the policy amalgamation that brought both veterinary and human drugs under one regulatory body.
National Drug Authority is therefore mandated to provide satisfactory health care for both human and animals by ensuring availability at all times of safe, efficacious and good quality drugs.

As we commit to executing this mandate, we appeal to the public to be vigilant and report any drug related problem to NDA to make sure that the drugs we have are effective, of high quality and safe.

Thank you
HELEN BYOMIRE NDAGIJE
Director Product Safety

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VETERINARY DRUGS REGULATION & HISTORY ON FORMATION OF NDA

THE MACROECONOMIC REFORMS

At the time of formation of the National Drug Authority (NDA), the country was implementing the structural adjustment policies as recommended by the World Bank (WB). The WB's aim was to bring macroeconomic reforms to improve service delivery and empower the private sector to invest in service delivery. The public sector was to remain with planning, regulatory and policy formulation functions. With regard to drugs, the objective was to improve efficiency and availability, which was a problem for both human and veterinary medicines at the time.

THE LAWS ON DRUGS BEFORE FORMATION OF **NDA**

Until the formation of the National Drug Authority in 1993, there were no specific laws and regulatory agencies regulating drugs in Uganda. The first law regarding drugs was the Food and Drugs Act of 1959, Cap 278. This law mainly established offenses related to drugs and food, but gave no responsibility to any agency, office or Ministry to administer it. The definition of drug in that law excluded veterinary medicines.

THE IDEA OF FORMING NDA IS BORN

The Danish Development Cooperation (DANIDA) was an active development partner in Uganda at that time. Early support (1987-1992) was focused on essential human drug supplies and management. Having identified gaps in the country's drug management system, DANIDA caused stakeholder discussions on the issue. In July 1987, a brainstorming meeting was held at Crested Crane Hotel in Jinja, on the formation of a government agency to regulate drugs in the country. Two European experts were subsequently hired to draft the law on regulation of drugs, based on benchmarking regulatory frameworks in different countries. The drafting committee realised that human drugs could not be regulated alone and leave out the veterinary drugs since their poor regulation would also have bearing on public health through the food chain.

SUPONA SCARCITY AND PROF. KAGONYERA'S REPORT

In 1990, following scarcity of acaricides (Supona), H.E. Yoweri Kaguta Museveni, the President of the Republic of Uganda instituted a special committee, chaired by Prof. Mondo Kagonyera, to advise government on the way forward on the management of veterinary drugs in the country. Farmers had resorted to use of agro-chemicals (e.g. Ambush®) to spray cattle, which resulted in seroius skin reactions. The findings and recommendations of the committee helped in refining the already drafted National Drug policy and Authority Bill to cater for both human and veterinary drugs.

FORMATION OF **NDA**

On 3rd December 1993, The Minister of Health passed The National Drug Policy and Authority Statute, leading to creation of NDA with a mandate of regulation of human and veterinary drugs; to control the manufacture, importation and distribution of both human and veterinary drugs in the country.

ACARICIDES REGULATION BROUGHT UNDER **NDA**

It is important to note that there was the Control of Agricultural Chemicals Act, 1989 Cap 29, which included acaricides. This law was reviewed to be the Agricultural Chemicals (Control) Act of 2006 to exclude acaricides so that NDA takes up its control as per the National Drug Policy and Authority Act of 1993.

NDA CELEBRATES **25 YEARS** OF SERVICE

This year 2018, NDA celebrates 25 years of dedicated service to the nation, and several milestones have been registered in both human and animal drug regulation. This has made NDA a center of excellence in several drug regulatory functions in East Africa and beyond.

ANTIMICROBIAL RESISTANCE

Antimicrobial resistance (AMR) refers to the ability of microorganisms, such as bacteria, viruses, fungi and other parasites, to stop an antimicrobial from working against it. Antimicrobial Resistance happens when microorganisms gain genetic ability to survive when exposed to antimicrobial drugs. As a result, standard treatments become ineffective, infections persist and may spread to others.

DEVELOPMENT OF **AMR**

Resistance in microorganisms is a natural phenomenon which may occur as organisms adapt to their environments. However, overuse and misuse of antimicrobial agents in humans, animals and plants has dramatically accelerated the emergence of AMR (OIE, 2016). Misusing and overusing antibiotics puts us all at risk and this calls for a multi-actor approach.

THE ROLES OF **NDA** IN COMBATING **AMR**

One of the causal components of AMR is low quality medicines. Falsified and substandard medicines can contribute to antimicrobial resistance by being partially or completely ineffective at treating illnesses and infections—providing enough exposure to surviving microbes to breed drug resistance. It is within the mandate of NDA to ensure that drugs available on Ugandan market are of good quality, safe and effective. National Drug Authority advocates implementation of international standards and recommendations by the World Organisation for Animal Health (OIE), for responsible and prudent use in animals.

What the veterinarians can do:

As custodians of animal health, Veterinarians should use antimicrobials responsibly and prudently, and advise their clients to desist from practices that constitute misuse of antimicrobials.

When and how should antimicrobials be used?

1. Only after clinical examination of the animal and on recommendation (s) by a qualified veterinarian or trained animal health professional.
2. Only in addition and never in replacement of good animal husbandry practices, hygiene, biosecurity and vaccination programmes.
3. Only by making an appropriate choice of antimicrobial agent based on clinical experience and diagnostic laboratory information when and where possible.
4. Always followed by provision of clear information on treatment protocols and withdrawal periods.

What to do if first-line treatment fails?

1. Second-line treatment should be based on results of diagnostic tests including sensitivity testing.
2. In the absence of test results a different class or sub-class should be used.

Can combinations of antimicrobials be used?

Only if supported by scientific evidence.

What should be written on the prescription for antimicrobials?

1. Dosage regimen (dose, treatment intervals, duration of treatment).
2. Withdrawal times for meat, milk and eggs.
3. Amount of antimicrobial (to be) provided, depending on dosage and number of animals.
4. Identification of the prescriber (signature name and contact)

References
World Organisation for Animal Health, (November, 2016). The OIE Strategy on Antimicrobial Resistance and the Prudent use of Antimicrobials.

UPDATES ON TICK RESISTANCE TO ACARICIDES

BURDEN OF TICK RESISTANCE TO ACARICIDES IN UGANDA

Uganda is currently faced with severe burden of tick resistance to acaricides which has been recorded as the worst in the history of the country. Recent findings have indicated emergence of multi-acaricide resistant ticks in western and central regions of Uganda where there is intensive acaricide application (Vudriko et al., 2016). The resistance was confirmed across all molecules of acaricides in the market with highest resistance recorded against synthetic pyrethroids (SP), 90% and Co-formulations of organophosphates and SP, 43.3% (Vudriko et al., 2016).

High tick infestation in the ear of a heifer

What to do if first-line treatment fails?

The major effect of tick resistance is an upsurge of tick-borne diseases. This culminates into huge economic losses due to the death of livestock, production losses and losses associated with treatment of sick animals.

NDA'S CURRENT FINDINGS ON FARMERS' PRACTICES IN THE CONTROL OF TICKS

Out of desperation, many farmers have resorted to bad practices in the control of ticks, most of which are against food safety objectives;

- Concocting acaricides with agro-chemicals (Larva and Rocket) is a common practice among farmers. It is common to find empty bottles of acaricides and agrochemicals littered within farms which are indicative of the practice.
- Most farmers have shortened acaricide application intervals to twice a week for acaricides recommended to be sprayed weekly. This practice only increases the selection pressure in favour of resistant ticks and is not helpful.
- Improper reconstitution (doubling concentrations) of acaricides is rampant. Apart from putting the life of the livestock and the handlers in danger of exposure to high concentrations of the chemicals, this results in higher residues in the food (meat and milk) and in the environment that further poses long term health risks.
- Buying acaricides from non-licensed premises like cattle markets, hawkers, and homes of fellow farmers. This has opened ground for opportunists to cheat farmers with fake products.
- Use of improper handling facilities: Most farmers use poorly constructed crushes for spraying their animals, while others spray their animals in bomas. In some farms proper crushes are available but never used for spraying but rather for treatments only. This makes acaricide application less effective thus precipitating resistance.
- Use of concoctions: farmers are concocting different acaricides and applying them at one go.

For example, Amitraz compounded with Organo -phosphate - pyrethroid co - formulation acaricides.

In some instances also adding agrochemicals and herbicides. Some unscrupulous individuals have made business by making these concoctions and selling to farmers in unlabelled containers with claims that they are new molecules imported from neighbouring countries.

Rocket Metazachlor and 1, 2 -benzisothiazol - 3 (2H) - one is the commonest herbicide used.
According to the label, this chemical is believed to be very toxic to aquatic life with long lasting effects and is also feared to have carcinogenic potential. Spraying this chemical on animals and harvesting the milk for human consumption is therefore, viewed as a very risky practice.
The habit of concocting acaricides is said to be adversely affecting those involved in the practice. It is reported that one counterfeiter was admitted to hospital in critical condition following continuous exposure to chemicals he was mixing to which he personally confessed.

There is therefore no point in fighting to kill the ticks at the cost of human life. National Drug Authority condemns this practice and advises the farming communities to be patient as the Government works to come up with safe solutions to the acaricide resistance challenge.

Veterinary Medicines Committe members on a fact finding mission on reports use of agrochemicals as acaricides. The small bottle displayed is Lava.

Veterinary Medicines Committee members in Gomba districts interacting with farmers on the issue of acaricide resistance.

CURRENT DEVELOPMENT IN THE MANAGEMENT OF TICK RESISTANCE TO ACARICIDES

In October 2017, H.E the President of the republic of Uganda set up a Presidential Technical Advisory Committee to propose a way forward to the management of tick resistance to acaricides in the country. The committee (of which NDA was part) produced a report which was presented to H.E the President in December 2017 and later to Cabinet in January 2018.

The committee recommended herd cleansing intervention with concurrent studies using three acaricides. The acaricides have so far been cleared by NDA and imported between December 2017 and February 2018 upon request by Ministry of Agriculture, Animal Industry and Fisheries (MAAIF). The committee advised on the zoning policy after the herd cleansing process.

On 22nd January 2018 cabinet directed that the three products be scientifically tried as per regulations in all geographical locations for three months and a final report presented to cabinet on 23th April 2018 indicating the best product for use.

As we wait for the ministry to advise on the next molecule to use;

WAY FORWARD

- Farmers should be advised to shun from use of concocted acaricides as they may worsen the situation of resistance.
- NDA requests that all users of drugs should report all problems/complaints related to use of drugs.
- Farmers are also discouraged from drugs from premises not licenced by NDA to buying avoid being cheated.

UPDATES ON STAKEHOLDER ENGAGEMENT

Stake Holders' Meeting

National Drug Authority engages its stakeholders in order to give updates on different aspects of drug regulation and improve service delivery. In February, 2018, NDA organized two meetings: one for veterinary drug importers, and the other for veterinary clinical research stakeholders.

National Drug Authority is part of the inter-ministerial initiative to curb illegal dealership in agro-inputs. Together with the Ministry of Agriculture, Animal Industry and Fisheries, joint operations, inspections and community engagements will see a significant reduction in the incidences of counterfeiting and concocting of agrochemicals and acaricides across the country. This is considered to be a strategic move as it is expected to register great strides in food safety.

It is through such meetings that the Authority listens to the stakeholders for improvement of service and also communicates new developments.

Arising out of the two meetings, the stakeholders proposed further engagement of the Uganda Veterinary Board to discuss ways of effective distribution of veterinary drug outlets across the country, updating the registration of veterinary products that did not have up to date dossiers on file, formation of veterinary importers association, and the need to streamline the policy on acaricide distribution (zoning) by the Ministry of Agriculture, Animal Industry and Fisheries.

NATIONAL DRUG AUTHORITY PARTICIPATES IN WORLD VETERINARY DAY CELEBRATIONS 2018

The World Veterinary Day (WVD) is an international day celebrated worldwide on April 28th every year and spearheaded by the World Veterinary Association (WVS) and World Organization for Animal Health (OIE). The day is celebrated to highlight the contribution of the veterinary profession towards animal health, animal production, public health and improving people's livelihoods.

The official celebration for this year in Uganda was organized by the Uganda Veterinary Association (UVA) and held on April 27th, 2018 in Rwebisengo Town Council, Ntoroko District. The theme for this year's celebration was "The role of the Veterinary Profession in sustainable development to improve livelihoods, food security and safety".

The President UVA addressing the gathering; Second right is the Commissioner Livestock Health. Both of these are NDA Board members

The event started with a procession through the town of Rwebisengo Town Council. This was followed by speeches from delegates and exhibition from the different stakeholders in animal health and production, mainly pharmaceutical companies and farmers. The Guest of Honor was the Minister of State for Agriculture, Hon. Kibazanga Christopher who represented the Minister of Agriculture, Animal Industry and Fisheries.

In his remarks he encouraged improvement of traceability of veterinary products in order to curb counterfeits and working together as government agencies to improve service delivery.

The Guest of honor Hon. Christopher Kibazanga addressing the gathering

National Drug Authority participated fully in these activities, and the delegation was headed by the Secretary to the Authority, Mrs. Donna Kusemererwa. She encouraged all stakeholders to report to NDA all suspected cases of counterfeit drugs and illegal trade in medicines so that the culprits can be brought to book. She explained that NDA cannot achieve its goals except through closely working with the communities as NDA staff cannot be everywhere.

The Secretary to the Authority Mrs. Donna Kusemererwa addressing the gathering

The team visited schools (e.g. Rwebisengo Secondary), drug shops and a clinics to get feedback on what they think about NDA, increase awareness about NDA and sensitized them about safe use of drugs and dangers of drugs and substance abuse. In the school, five NDA ambassadors (led by head prefect, Musisi Godfrey) were identified and these will be empowered to sensitize the community and fellow youth about safe use of drugs and staying away from drug/ substance abuse. The criterion for choosing the ambassadors was based on individual's participation during the Q/A sessions about NDA and each ambassador received an NDA T-shirt.

VMC members visit NDA Mbarara regional offices.

If you have any comments, questions or feedback on the contents of this bulletin, please contact us on our address below.

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