

NDA@25**New Vision**
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By Owen Wagabaza

Last Thursday, all roads led to Hotel Africana in Kampala as the National Drug Authority (NDA) celebrated 25 years of service to Ugandans. The dinner, which attracted the who is who in both human and animal health, was also attended by health minister Dr Jane Ruth Aceng, who was the chief guest.

"We are having this celebration dinner, as a mark of the great achievements, partnerships and contribution of NDA to essential health and related services, which promotes a healthy and productive life of our population," Dr Medard Bitekyerezo, the NDA board chairperson, said.

"It is a great landmark that NDA, as a government regulatory agency, has evolved into one of the most recognised drug authorities in Africa. NDA has international recognitions like the World Health Organisation prequalification, ISO/IEC 17025 accreditation, ISO/IEC 9001:2015 certification and is a centre of excellence for good manufacturing practice among the East African Community member states," Bitekyerezo added.

David Nahamya, the acting

NDA improves access to



Health Minister Aceng



David Nahamya



NDA has put in place mechanisms to control fake pharmaceutical products on the market. Some of these are the mandatory testing of condoms and gloves, among others

secretary to the authority, said 25 years is a major milestone for an organisation, as it is for an individual.

"Our celebration is a solemn

occasion to pause and look at this 25-year journey. It is a moment to look at the mountains that we must

climb and pay homage to the founders of this organisation that started with only seven people as staff," Nahamya said.

The authority was established in 1993 by the National Drug Policy and Authority Statute, which in 2000 became the National Drug Policy and Authority (NDP/A) Act, Cap. 206 of the laws of Uganda (2000 edition).

The entity is mandated to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda, as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs.

Dr Bitekyerezo attributed the achievement to the great support from President Yoweri Museveni, ministers who have worked tirelessly in the health ministry, technical teams and development partners, among others.

He also extended his appreciation to the current and previous drug authority members that have worked tirelessly in guiding the operations of NDA, despite several challenges.

"The current and previous staff of NDA are equally heroes," Bitekyerezo said.

The celebrations started last year, with the donation of 160 units of blood and continued this year with regional stakeholder engagements, as well as a free medical care camp in Kamuli district.

Government objective

Aceng said it is the Government's objective to ensure that all Ugandans and

LIKE OTHER NATIONAL REGULATORY AUTHORITIES IN THE WORLD, CRITICISM COMES FROM THE INCREASED PUBLIC DEMAND FOR QUALITY PUBLIC HEALTHCARE, TO WHICH NDA CONTRIBUTES

their livestock live a healthy life and have access to quality healthcare. Aceng said the Government has been striving to improve efficiency in health service delivery to the public, where NDA is one of the implementing agencies.

"Medicines are some of the most regulated commodities globally as they impact both human and animal health," Aceng said.

"There is increasing public demand for medicines regulation to ensure that safe, effective and quality drugs are accessed. It is because of this that NDA has had to evolve to meet this public demand," she added.

Aceng added that the Government has invested a lot of resources in medicines regulation on an ever-increasing scale to ensure that the population (human and animal) continues to have progressively better health outcomes.

"Medicines remain one of the critical inputs for the Government to deliver quality health services to its population and increased animal production," she said. Aceng also thanked NDA for its continued effort in

harnessing new information technologies to reach out to the masses with health information, like the NDA management information system, social media platforms and print and electronic media. She, however, urged on the organisation to ensure that the information is accurate, balanced and beneficial to the public.

On the criticism that the organisation regularly receives, Aceng said just like other national regulatory authorities in the world, criticism comes from the increased public demand for quality public healthcare, to which NDA contributes through the execution of its mandate. She said she was glad NDA is taking the criticisms positively by making strides to meet public expectations.

Achievements

During the dinner, Bitekyerezo highlighted several achievements registered by the authority. He named securing premises on Lumumba Avenue and on Buganda Avenue, which are currently undergoing development.

"The Authority has also put in place mechanisms to

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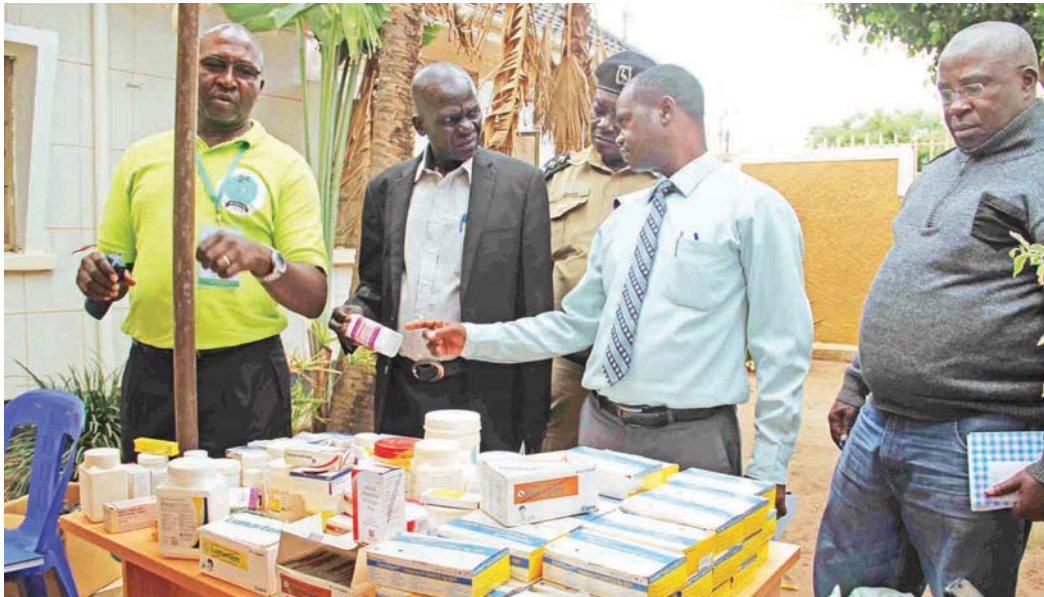
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quality healthcare



NDA officers displaying some of the government drugs found in private drug shops during an operation by the drug authority. Government drugs are meant to be free

control fake pharmaceutical products on the market that are dangerous to the population. Some of these are the mandatory testing of condoms, gloves and mosquito nets, a selected range of antiretroviral drugs and anti-malarials. The authority also carries out routine sampling and

testing of drugs on the market and testing of locally manufactured drugs before being introduced on the market," Bitekyerezo said. NDA has also registered a progressive improvement in staff capacity from seven in 1994/95 to over 300 now. Regional centres of NDA have also been set up, with

the authority having offices in seven regions and at many gazetted ports of entry. The authority has also equipped the National Quality Control Laboratory with capacity to test medicines, medical devices, herbal medicines and is expected to commence testing microbiology products.

"We are also participating and contributing to health sector harmonisation initiatives under the East African Community member states, and are managing pharmaceutical waste, which has been abused through adulteration with the herbal products, and re-use," Bitekyerezo said.

Plans
According to Bitekyerezo, the board, together with the management, are working on transforming NDA into National Food and Drug Authority (NFDA) to minimise the legal challenges faced with the existing National Drug Policy and Authority Act. In an effort to solve the

gaps in the NDA existing law, the National Food and Drug Authority Bill, 2017 has been developed and is currently before Cabinet for consultation. The Bill has proposed to expand the mandate of the NDA, to include regulation of food, medical devices and cosmetics.

"NDA is also in the process of constructing an ultra-modern laboratory that is expected to be the best in the sub-Saharan Africa. The lab will expand the range and quantity of tests conducted. This will further strengthen our capacity to prevent fake drugs from the Ugandan market," Bitekyerezo said.

The authority also has plans to construct offices, stores and laboratories for NDA regional offices, to improve the regulatory capacity and presence of NDA countrywide, which have been currently limited.

Bitekyerezo urged the public to continue being the eyes and the ears of the Government in the health sector, for a productive population.

Aceng pledged to continue encouraging investment in the domestic pharmaceutical manufacturing sector, especially for medicines for neglected human and animal diseases.

"We also encourage supporting local industries through the Buy Uganda, Build Uganda initiative. Our support to NDA in execution of its mandate is assured," Aceng said.



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Drug industry well regulated

By Owen Wagabaza

Twenty five years ago, the National Drug Authority (NDA) was established. The Government regulatory agency was set up in 1993 by the National Drug Policy and Authority Statute, which in 2000 became the National Drug Policy and Authority (NDP/A) Act, Cap. 206 of the Laws of Uganda.

The mandate of the NDA is to ensure the availability, at all times of essential, efficacious and cost-effective drugs to Ugandans as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs.

The authority has since been given additional mandates, like regulating medical devices, such as condoms, gloves and mosquito nets among others.

"Before 1993 when NDA was established, there was no regulation of the drugs industry and drugs were being sold on streets like potatoes. One would find stalls of drugs on the streets, people singing and selling. At that time, there were about two pharmacies in Kampala," David Nahamya, the acting secretary of the authority, says.

Over the years, courtesy of the strong regulations



Lira Resident District Commissioner Milton Odongo and the Police community liaison officer Michael Orech address a meeting after an NDA operation in the area

imposed by the NDA, the pharmaceutical industry has grown in leaps and bounds. Currently, there are up to 1,587 registered and licensed pharmacies, as well as 5,834 drug shops all over the country. Investors have also been attracted to the industry, with up to 15 large scale pharmaceutical industries operating in Uganda today.

Ensuring safe drugs

To ensure drug safety, NDA employs quality assurance

measures from manufacturing, import and export control, licensing, post market surveillance to clinical trials.

According to Nahamya, NDA audits manufacturers to ensure that the drugs are manufactured in accordance with the principles of good manufacturing practices.

"Quality is inbuilt, it cannot be tested. We, therefore, audit those processes involved in manufacturing. And here, we audit both local and manufacturing plants,"

Nahamya says.

NDA also does market authorisation, which involves registering the drugs. There is a full directorate mandated to do that. The authority gets dossiers/ documentations explaining all that there is to know about the drugs, how it is manufactured, safety of the drug, side effects and many others, and if the authority is contented, the drug is registered.

"We also do licensing of the drug outlets. We inspect to see whether the proprietor is fulfilling the set conditions. These include suitability of the premises, such as whether the place is well ventilated, the personnel, we look at equipment, such as freezers among other issues before issuing a license," Nahamya explains.

Nahamya also says, they make sure that drugs entering the country are the ones that were registered by the importer. Before one imports, they have to take their proforma invoice to NDA and if the importer brings different drugs, they are restricted from entering the country even when there is a slight change. If the proforma invoice says white tablet and you bring red ones, they will be rejected.

The Authority also does testing of the drugs to see whether they comply with the specifications. "We also do pharmacovigilance, this looks at the effects of the drugs after use. All these measures are put in place to ensure that drugs are safe for both human and animal usage," says Nahamya.

Operation against fake drugs

NDA in collaboration with the health ministry and the Uganda Police Force regularly conducts operations to clear the country of illegal dealers in the Government of Uganda drugs, substandard, and counterfeit medicines.

Fredrick Ssekanya, the NDA public relations officer, says the objective of such operations is to save the public from

unlicensed and unqualified personnel handling human and veterinary medicines, as well as intercept dealers in medicines intended for public health facilities with intentions to sell them to the private sector or export them to other countries.

"The operations are also aimed at clamping down on a racket involved in deliberate alteration/re-labeling of expired medicine and prevent its use by people, as well as cracking down on dealers in substandard and counterfeit medicines," Ssekanya says.

The risk averted by closing the drug outlets reduces the disease burden of unsuspecting population as a result of being conned by quacks or unqualified health personnel.

"This further promotes quality health service delivery resulting in better treatment of illnesses and prevention of diseases as the population accesses medicines from only licensed drug outlets manned by qualified health personnel," Ssekanya says.

This year alone, the operations have been conducted countrywide in 78 districts, leading to inspection of 1,684 targeted drug outlets (pharmacies and drug shops) of which 746 were issued with closure notices.

During the operation, 1,238 boxes of assorted medicines, estimated at sh430m were impounded, and 48 arrests effected. The entire operation to date has protected an estimated 349,938 unsuspecting persons of unlicensed and unqualified drug outlet operators.

During the operations in all regions covered, veterinary outlets inspected were 126, and impounded 183 boxes of assorted medicines estimated at sh82m.

Nahamya, however, says, that the biggest problem facing the pharmaceutical industry in Uganda is not necessarily fake drugs, but drug usage. According to Nahamya, people are not using the drugs as per the directions and for some medicines, this results into resistance.

"Some people do self-medication, and this makes it hard for drugs to work efficiently. When it comes to animals, people spray with pumps meant for crops, which do not have enough force to penetrate the hair, rendering the drug inefficient," Nahamya explains.

He also talks of policy issues, like financing mechanisms. "In Uganda, healthcare financing is mostly out of pocket and as such, because of poverty, patients bypass doctors and do self-medication and even when they go to a doctor and prescribes a dosage of 30 tablets, because of poverty, a patient will buy half or less, rendering the medicine ineffective," Nahamya says.

The inability of patients

Impact so far

Today, the industry is better regulated than ever before. There are over 1,587 pharmacies spread across the country and well over 5,838 drug shops.

NDA has also increased the testing equipment of the drugs and the range has increased.

"We have bought more equipment and our labs are World Health Organisation (WHO) pre-qualified, which means that our tests are recognised internationally. In the same vein, we are a centre of excellency recognised by NEPAD when it comes to manufacturing practices," David Nahamya, the acting secretary of NDA, says.

There has also been promotion and control of local production of essential drugs.

The number of local pharmaceutical manufacturers has increased from three when NDA started to 18 local manufacturers of which 12 are manufacturing human medicine, three medical devices while three are manufacturing veterinary medicine.

"Through Buy Uganda Build Uganda policy, a preferential fee was approved on 37 products that are locally manufactured as an incentive to manufacturers to increase local production of essential medicines. The policy has also attracted investors and this has led to establishment of two new local pharmaceutical industries, recently," Nahamya says.

to buy full doses is one our biggest challenges, because if drugs have resistance issues, they say that the drug does not work, yet they misused it earlier.

Nahamya calls for a speedy process of setting up the insurance scheme, because with insurance, even if one is poor, they can able to get quality services.

On herbal medicine, Nahamya says they are encouraging them to bring their drugs for registration. The authority is also helping them technically in the manufacturing of the drugs, encouraging them to try and meet the standards and doing a lot of sensitisation.

"We are also working with radio stations to see that they do not allow whichever herbalist comes up to advertise on their stations. Regulating herbal medicine is a challenge that is being given a lot of prioritisation now," he says.

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Why drug resistance is on the rise

By Owen Wagabaza

In July 2015, northern Uganda was hit by an unusual wave of malaria, which left thousands hospitalised, and many dead. The malaria strain was so severe that it caused convulsions even in adults. Despite the administration and absorption of drugs, the malaria parasites were able to survive and multiply.

"The parasites had resisted Artemether-Lumefantrine, the recommended first line treatment, but even after putting the patients on stronger doses, the parasites could not die," Dr Samuel Ssekindu, a general practitioner at Mulago Hospital, says.

Uganda has the world's highest incidence of malaria, with a rate of 478 cases per 1,000 people per year. About 100,000 people, mainly children and women, die of malaria every year. Many more remain unproductive for long periods due to the malaria-induced chills, fever, headaches, and diarrhoea. Any indication of malaria drug-resistance, therefore, causes major worries.

Unfortunately, there are hints that Uganda could be losing the simplest defences against



An NDA official impounding drugs from an illegal shop in Kole district. Uganda could be losing the fight not only against malaria, but also other infections as well

not only malaria, but other infections as well. Experts warn that many administered drugs can no longer offer protection against bacterial infections, such as typhoid and urinary tract infections. Yet these are the most prevalent health concerns that affect people throughout

the year. Doctors say some bacteria, parasites, fungi and viruses are now resistant to drugs.

What causes resistance?

Dr Ian Clarke, of Kampala International Hospital, attributes drug resistance to poor prescription of drugs by

National Drug Authority acting secretary, concurs with Dr Clarke, saying the biggest cause of bacterial resistance is the poor usage of drugs.

"People have a tendency of saying drug X and Y are fake, but all these drugs were put under a mandatory test and they passed," Nahamya says.

"People are not using the drugs as per the directions and for some medicines, this results into resistance. People are doing a lot of self-medication, and this makes it hard for drugs to work efficiently, because they don't know what exactly they are treating," Nahamya says.

"We also have the challenge of poverty, where patients cannot afford to complete the treatment doses as recommended by the doctor. A doctor prescribes a dosage of 30 tablets, but because of poverty, a patient buys only five tablets, rendering the drug ineffective," he adds.

According to Nahamya, when a disease is exposed to inadequate doses of drugs that cannot kill the bugs, they naturally mutate to eventually become immune to the drugs.

Tackling resistance

Drug resistance is a global threat and the World Health Organisation (WHO) estimates show that by 2050, 10 million people will have died from drug-resistant diseases worldwide.

To tackle it, experts recommend the use of drugs only when they are necessary and prescribed by a doctor, completing the full prescription, even if you feel better, and never sharing antibiotics with others or using leftover prescriptions.

According to the 2014 WHO Antimicrobial Resistance Report, there is also a need to develop new diagnostics, antibiotics and other tools to allow healthcare professionals stay ahead of emerging resistance.

Clarke says the emergence of superbugs, which are resistant to all antibiotics, is now a reality and, although only a few people are affected today, at some point in the future, we could all be attacked by superbugs.

"When this happens, we will succumb to simple infections and die, as was the case before the discovery of penicillin," Clarke says.

"If we continue with the current situation, where one can access the most powerful antibiotic over the counter, strong procedures like surgeries will be hard to do, as one will require too strong drugs for anaesthesia and the healing process," he adds.

So the next time you are told you have a 'bacterial infection', ask the doctor if he has carried out a culture and what is the specific infection. Antibiotics may not harm you, but future generations will suffer.



The first laboratory at Butabika in Kampala where NDA used to test drugs

doctors.

"One of the commonest diagnoses I see at present is 'bacterial infection' for which doctors' dole out lots of antibiotics," Clarke said in an article that has now gone viral online

"The patient is not only being given a drug they do not need, but the unnecessary treatment is promoting antibiotic resistance. When antibiotics are necessary, doctors should prescribe them according to a medically agreed hierarchy, known as first line treatment, second line and third line treatment. However, the current fashion is to jump straight to the third line treatment, especially when an insurance company is paying. This is poor medical practice," he says.

According to Clarke, healthy people do not get non-specific bacterial infections, there must be a site where the infection starts, such as the throat, which is tonsillitis, or the gut, which is gastroenteritis, or the

bladder, which is a urinary tract infection.

"Many of these so-called bacterial infections are self-limiting minor viral infections for which antibiotics are useless, but doctors still give antibiotics, because it is more satisfying, to both the doctor and the patient, to make a diagnosis for which there is a definite treatment," says Clarke.

In the past, patients diagnosed with 'malaria' would be treated with chloroquine, but due to the widespread administration of chloroquine for many fevers which were not malaria, the parasite was able to develop resistance, and, as a consequence, chloroquine treatment is no longer effective. Nowadays, the treatment of malaria is much more expensive and there is the real possibility that the parasite could develop resistance to the current treatment.

David Nahamya, the

Congratulations!

The Management and Staff of **LabX Scientific Ltd** wish **National Drug Authority - NDA** a **Happy 25th Anniversary Celebrations** and many years of dedicated service.



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