With reports of alleged fake drugs in the country and unqualified health attendants giving wrong prescriptions and focusing on making money, I sat down with Dr. David Nahamya, the Secretary to the Authority of the National Drug Authority (NDA). Dr. David Nahamya highlighted issues on how NDA has contained the challenge of falsified drugs (which many refer to as fake drugs) in Uganda. He also noted the high demand of reproductive health-related products on sexual enhancement and birth control pills, among others as some of the falsified drugs not only in Uganda but globally. Below are our interactions:

Q. What are some of the challenges the NDA faces as it carries out its mandate of regulating drugs in the country?

A. National Drug Authority (NDA) is a drug regulatory authority established in 1993 under the National Drug Policy and Authority Act, Cap. 206 (2000 Edition) with the mandate to ensure 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.

Overtime, the regulatory landscape has changed and many products used in public and veterinary
health which were not explicitly provided for under the National Drug Policy and Authority Act Cap 206 have become critical to the delivery of health services. These include medical and veterinary devices, cosmetics, among other substances. They are a regulation challenge to NDA due to the ambiguity in the existing law. Therefore, the legal framework turns out to be our biggest challenge.

Other challenges include inequitable distribution of drug outlets with close to 70% of the outlets based in the Kampala metropolitan area, which is partly attributed to the high out-of-pocket payment for healthcare.

**Q** Does a health worker in a pharmacy, supposed to examine a patient before giving her the drug?

**A** In Uganda, drugs are classified into three groups of A, B and C, where two groups (B and C) have subgroups. The classification determines how they are used. Class A and Class B group I drugs are prescription only drugs and must only be issued on presentation of a valid prescription. Class B group II drugs are Pharmacist initiated drugs, while Class C drugs are over the counter drugs.

The person dispensing has to take adequate care to ensure that the right drug is given to the patient with the appropriate information about its use. This is why we require the pharmacies to have qualified staff.

A health worker in a pharmacy or drug shop, has to interview the patient, who provides historical information regarding the personal health condition to be treated. For example whether the patient has visited a medical facility or when the condition started, among others, to enable proper treatment.

**Q** What is the risk of pharmacies selling drugs to unlicensed drug shops?

**A** The risk is that all drugs are poisons, and all poisons are potential drugs. What differentiates a drug from the poison is the benefit-risk ratio. If the benefit outweighs the risk, it is a drug, and if the risk outweighs the benefit, it is a poison. For the ratio to be maintained beneficial, the right drug must be used for the right patient and in the right conditions of use, otherwise it can cause harm to a patient.

The quality of the drug can deteriorate if it is not stored as per the recommended storage conditions. The licensing process ensures availability of suitable premises and qualified personnel to ensure the safety and quality of the drug. With unlicensed outlets, the safety, efficacy and quality of the drugs cannot be assured.

Such drug shops don’t meet NDA licensing requirements. The premises may be unsuitable for drug storage, hence affecting their safety, efficacy and quality. The operators of such unlicensed drug shops may be unqualified medical attendants, who eventual expose patients to over/under dosage, wrong medication for wrong conditions.

This may lead to drug resistance in users, and poor health, and sometimes death of animals or people. Because these drug shops are unlicensed they cannot be easily traced. Therefore we advice pharmacies to always sell drugs to licensed drug shops otherwise their licenses will be withdrawn.
**What is your advice to pharmacies selling drugs to unlicensed drug shops or clinics?**

**A** First of all, it contravenes section 22 of the NDP/A Act, and the respective pharmacy may be prosecuted or their license suspended or revoked. However, for now we continue to sensitize wholesalers to implement Good Distribution Practices (GDP); one of whose requirements is qualification of customers to ensure that they are person to whom drugs may properly be supplied as required by Section 22 of the NDP/A Act. We advise all wholesalers to implement GDP to ensure the quality of drugs, and traceability of the supply chain to eliminate falsified drugs which can harm patients.

Pharmacies should always confirm whether the drug shop is licensed before selling drugs to it, to protect and promote a healthy human and animal population. Reduce treatment failures, and improve animal health and production, to safeguard public health and improve economic gains for the farmers in the country.

**What is your advice to the public when accessing medicine?**

**A** Avoid self-medication before visiting or seeking treatment from a health provider or practitioner regarding your health condition. In most cases, people who self-medicate, treat symptoms and pain but not the cause of the problem. This oftentimes masks the cause of the problem and may lead to complications.

Follow the right procedures for accessing medication such as visit a health provider for assessment. Buy prescribed drugs from pharmacies or drug shops (class C drugs) licensed by NDA. Take the medicine as directed by the health provider. And also report unscrupulous operators in your respective communities to avoid causing health risks to the population.

**Do you test some drugs that enter the country?**

**A** We have a robust system for assuring the quality of drugs imported into the country. The system involves assessment and registration of the information on the safety, efficacy and quality of the drug. As part of the quality assessment, we inspect the factory where the drug is manufactured to ensure compliance with Good Manufacturing Practices (GMP). When an application for importation is lodged with us, we verify whether the drug is on our register. When the drug reaches the port of entry, our inspectors inspect them to ensure that they conform to the approved drug.

For purposes of testing, we have a robust risk assessment system used to determine which drugs are sampled and tested from the port of entry. We also routinely monitor, sample and test drugs from pharmacies, drug shops, hospitals, clinics and health centres to ensure that their quality is maintained. Drugs are also sampled and tested following complaints from the public. So, there is sampling and testing happening at different points of the distribution chain.

**What is your medicine testing trend over the years?**

**A** There has been a rise in the samples of medicine tested over the years. For instance, in the financial year 2020/2021, we tested 2,223 samples of medicine, medical devices, and other health care products compared to 2,100 samples in FY 2019/2020.

**A** All drugs imported in Uganda or exported are obtained from NDA approved pharmaceutical manufacturing facilities. This is achieved through inspection of drug consignments upon arrival at the ports of entry for conformance to stipulated
quality regulatory requirements. Samples for some products are obtained and submitted to our Quality Control Laboratory (pre-qualified by WHO) for testing as part of the final release decision making criteria.

In 2021, we received 10,808 consignments of drugs through different ports of entry into the country, and out of these 10,464 consignments were released for use in the country. Where medicines are found not to meet the set quality requirements, they are rejected and the importer tasked to pay for their destruction at a National Environment Management Authority approved destruction site.

**Q** But why do we continue to have fake drugs on the market despite all that effort, you do to test them?

**A** What you call “fake drugs” is termed as “falsified drugs” in the pharmaceutical language. A falsified drug is one which is deliberately and fraudulently mislabeled with respect to identity or source. They often contain wrong ingredients or wrong quantity of the active ingredients.

There are unscrupulous operators that try to smuggle such falsified drugs through border points. However, NDA has the capacity to detect any falsified drug that infiltrates the market and remove them. This has been possible due to our rigorous post market surveillance, intelligence led operations, inter agency cooperation, laboratory tests and public vigilance.

Our post-market surveillance mechanism monitors the quality and safety of medical products on the market, conducts investigations on drug related complaints and recalls defective products from the market. We also promote patient safety through monitoring adverse drug events (ADEs) to improve health outcomes.

This system ensures that falsified products (which you call fake) and substandard products (those which do not meet prescribed standards) are removed from the market.

In other words whatever we do is to ensure that drugs on the market are of good quality, safe and efficacious. And as we perform our mandate the system takes care of fake drugs too.

But also patients complain that drugs are fake when they don’t get cured yet they do not take medicine as directed by the healthcare providers. Therefore we urge the public to always follow advice provided by healthcare providers for stated diseases and conditions which results in better treatment.

**Q** What are common fake products on market?

**A** Unscrupulous operators normally falsify (counterfeit) fast moving drugs. For instance, sexual enhancement, birth control pills among others.

**Q** What can be done to avoid fake drugs on the market?

**A** Falsification of drugs is a criminal offence which is a challenge the world over. It is minimised through securing the supply chain from manufacturing to the patients to deny entry of falsified products into the genuine supply chain. That is why we exhort all distributors to implement GDP. Other methods used are tracking and tracing of products, from the point of manufacture to the patient, and combating smuggling.

We also continue to engage stakeholders like health practitioners (human or veterinary) to play an active role to ensure that medicines regulations is in the public interest. Increase public awareness with bus operators to mitigate hawkers of drugs on the buses and bus parks. Working on the legal framework to improve on the penalties.

**Q** Have you tried to review this penalty with the judiciary?

**A** The law is in the process of being revised to improve on the penalties. We are certain that the initiative will result into heavy penalties that would deter others getting involved in dubious pharmaceutical related business.

**Q** Many people are selling herbal concoctions in different trading centers across the country, are they cleared by NDA?

**A** NDA clears herbal medicines through a notification mechanism. But we do not approve hawking of herbal medicines in markets, parks or buses. All med-
icines including herbal products have to be sold in places that have been certified as suitable for storage and supply of drugs and licensed by NDA.

**Q: What are your plans for herbal dealers in the country?**

**A:** The trend of local herbal notifications with NDA is on the rise from 6 products in FY 2015/2016 to 191 in FY 2020/2021. The rising trend is due to engagement with herbalists to improve the quality of their products.

We hold sensitization meetings with herbalists through their associations and advise them to notify NDA and improve the quality of their products in manufacturing, storage, and distribution for safe human use.

Together with the Directorate of Industrial Training, an assessment training package was developed to improve herbalists with skills in processing, distribution and supply of herbal medicinal products.

**Q: Is it true that some herbals are adulated with other medicines and chemicals to deceive clients that they are working?**

**A:** Through our post-marketing surveillance, several herbal products have been tested, and some were found adulterated with conventional drugs. These were especially herbals that deal with erectile dysfunction, which were adulterated with sildenafil (the drug in Viagra) claiming that they work. Sildenafil is a synthetic chemical which does not exist naturally.

**Q: What is your advice to herbal hawkers in the Bus parks and buses?**

**A:** Hawking of medicines is unauthorized. Whoever is doing so, does so illegally. We have an ongoing campaign with bus operators to stop hawkers selling herbal medicines in buses and bus parks. Most hawkers of herbal drugs make unverified claims, which are a risk to public health. However, genuine herbalists do not hawk their products or advertise themselves.

We call on hawkers of herbal drugs to establish a permanent location for suitability of their products and public safety.

**Q: What is the difference between NDA and National Medical Stores (NMS)?**

NDA is a drug regulator responsible for ensuring the safety, efficacy and quality of drugs while NMS is a government parastatal responsible for procuring, storage and distribution of drugs and other health supplies to public health facilities.

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NDA is a government statutory agency responsible for ensuring that the population has access to safe, effective and good quality drugs (human and veterinary) as a means of promoting good health in the country.

**2,369**

Pharmacies and 12,124 Drug shops compared were licensed to 1,820 Pharmacies and 9,457 Drug Shops in FY 2019/20.

In FY2020/2021 National Drug Authority tested 2,223 samples of medicines, medical devices and other healthcare products as compared to 2,100 in FY2019/2020.