

# **NDA sanitises the drug industry in Uganda**

**NDA Updates** had an interview with the Executive Secretary/Registrar, Mr. Apollo Muhairwe to explain NDA's development in sanitising the drug industry in Uganda.

**NDA Updates.** There has been discontent with delays in getting medicines into health centres in Uganda, what is your take on that?

**Executive Secretary/Registrar (ES/R).** No. NDA does not distribute medicines to hospitals, clinics, drug stores, pharmacies or health centres. NDA's mandate is to ensure that all human and veterinary medicines on the market and in all health units in Uganda are of good quality, safe and improve the health of the population. The role of medicines distribution is the responsibility of National Medical Stores.

**NDA Updates.** Tell us about the genesis of NDA into being.

**ES/R.** The law that established NDA dates as far as 1986 when an Adhoc Committee was constituted by the Ministry of Health to develop a National Drug Policy (NDP). In 1988 a Health Review Commission was established to incorporate the NDP into the National Health Policy report. Initial discussions on establishing the National Drug Authority and National Medical Stores (NMS) were held in 1991. In 1993, the National Drug Policy/Authority and NMS Statutes were passed by the then National Resistance Council. In 1994, NDA and NMS were inaugurated as implementing bodies of the Policy.

**NDA Updates.** What was the environment like before the coming of NDA?

**ES/R.** The coming of NDA has brought sanity and made a u-turn of the drug industry in Uganda compared to the past, when malpractices passed unchecked and perpetrators went scot free.

There was an obsolete section in the Pharmacy and Drugs Act 1970 that provided for any able-bodied persons being licensed to import and sell human and veterinary drugs in the country. The market would easily be flooded with substandard medicines.

There were also few pharmacists in the country, coupled with very few students being enrolled for diploma or degree courses in pharmacy. At the end of the courses these few graduates would opt for private practice or employment abroad.

The National Drug Policy and Authority Statute (1993) mandated NDA to regulate medicines and healthcare products quality, safety and efficacy, while NMS was given the mandate to procure, store and distributes Essential Drugs meant for all government health units.

**NDA Updates.** What are some of the key NDA achievements over the past 15 years?

**ES/R.** When you focus on the Laboratory where analysis of drugs imported or manufactured in the country is done prior to their release on the market.

- The total number of samples tested at the laboratory has increased from 430 (1998) to 1877 (2007) signifying an increase of approximately 320%.
- The number of sample failures has decreased from 112 (26.0%) in 1998 to 25 (1.3%) by the end of 2007.
- The number of samples (batches) of anti- malarial medicines tested has increased from 250 (1998) to 952 (2006) which is approximately 380%. Anti malarial drugs test failures have dropped from 40 batches (16%) in 1998 to 8 batches (1.3%) in 2007.
- Counterfeits batches detected have also dropped from 8 in 1998 to 1 (one) in 2007 (This batch was obtained from the field). The quality of anti malarial drug imports has also improved.
- NDA hosts a National Pharmacovigilance Centre (NPC) established in 2005 to promote patient safety by monitoring adverse drug reactions. Three regional pharmacovigilance centres were established in 2007 in Masaka, Gulu and Lira.
- NDA developed a Drug Register constituting over 2800 human and veterinary products, herbal products and notified food supplements by 2007.
- Growth in pharmaceutical outlets licensing continues with 440 Pharmacies and 4742 drug shops in the country by the end of June 2007/July 2008.
- During the same era we have seen the growth of medicines manufacturing facilities in Uganda from 1 to 14.
- These manufacturers contribute 15% of medicines consumed by the health sector compared to almost none before 1993.

**NDA Updates. How do you ensure the safety and quality of drugs on Uganda's market?**

**ES/R.** Before any pharmaceutical importer is permitted to import, he or she must have a valid import license. All importers seeking to import narcotic drugs or psychotropic substances under international control only for medical, dental or veterinary use must get a special import permit first. All products imported must be on the drug register.

There is a drug verification committee that is tasked with the responsibility of verifying all proforma invoices of drugs and healthcare products to be imported and their source and need. A verification certificate is then issued after the exercise. This certificate is valid for a period of six months and in case of part-shipment of the consignment, it can only be used twice. If it is full shipment, the verification certificate works only once for that consignment. Every time the importer wishes to import, the proforma invoices must be verified by NDA verification committee again even if it is the same product. Sometimes unregistered drugs under special circumstances are allowed to be imported into Uganda. Such circumstances may include cases where there are no alternatives to offer treatment for patients especially serious chronic illnesses like HIV/AIDS, TB, Cancers, cardiovascular diseases among others. Permission to import un registered drugs must be sought first before importing is permitted.

Drug Inspectors sample drug products whose efficacy, safety and quality is questionable according to an approved sampling plan and forward these to the National Drug Quality Control Laboratory for analysis before distribution and clinical use is approved.

**NDA Updates.** Then, how does NDA ensure quality of drug manufacturers locally and abroad?

**ES/R.** All pharmaceutical manufacturers must possess a valid manufacturing license. Our local manufacturers must first inform NDA in writing about the intention of producing any new product in their factories with accompanying information to support the application. NDA then evaluates the information provided in relationship to already licensed products of the manufacturer, if any, and verifies that the manufacturer is able to manufacture the product that will meet NDA standards. On approval the manufacturer is allowed to present proforma invoices for importation of raw and packaging materials. Drugs to be manufactured should be on the Essential Drugs List of Uganda. NDA issues annual manufacturing licenses to local drug manufacturers. At the end of this period the license has to be renewed following an inspection report by drug inspectors. The license can be cancelled and drug products suspended from the drug register if the manufacturer contravenes the conditions of the license.

**NDA Updates.** Under what conditions can a drug be deleted or suspended from the drug register?

**ES/R.** NDA has a National Drug Register which comprises authorized human and veterinary medicines that are supposed to be marketed and administered in Uganda. Suspension of a drug from the register occurs when a pharmaceutical industry fails to meet the standards of NDA following GMP inspection by our Inspectors, when the drug causes significant adverse effects in patients while on the market and when the license holder fails to pay retention fees. Deletions occur when it is proved that the drug is not safe for use. Importation of suspended products is halted until all issues pertaining the product are addressed.

**NDA Updates.** What kind of challenges do you encounter in regulating the industry?

**ES/R.** The challenges include,

- ensuring that substandard and counterfeit drugs do not find their way into Uganda's drug outlets,
- Coordinating with other government agencies to ensure public health safety.
- Presence of porous borders which lead to infiltration into the country of unauthorized products.
- Misuse of technology advancement to produce counterfeit products on the market.
- Building confidence among the general public to report illegal practices in the sector.

**NDA Updates.** How is NDA trying to address these challenges?

**ES/R.** NDA is trying to boost its human resource by increasing on the staffing levels especially Drug to meet the challenge of counterfeits on our market. Drug samples are picked from the market and quality control tests are done on them and appropriate action taken by NDA. Inspection of all pharmaceutical drug outlets in the country and our local and foreign industries making drugs for the Ugandan market.

We are also trying to increase our presence on the ground for example opening up regional offices and lobbying for support from government and other partners to enable us fulfill our mandate.

**NDA Updates. Your appeal to staff, stakeholders and the public.**

**ES/R.** I wish to thank all staff, the board of directors, development partners and all stakeholders for their input towards what NDA is today and urge them to continue being vigilant in their work on ensuring safety and quality of drugs in Uganda. I also urge the public to be vigilant by reporting to NDA wrong elements in the sector.