

## **Interaction with NDA Executive Secretary/Registrar (ESR) on the performance of the National Drug Authority July 2008/June 2009**

***Reporter: Is NDA responsible for distribution of drugs to health centers in Uganda ?***

**ESR:** No, NDA does not distribute drugs nor medicines to hospitals, clinics, drug stores, pharmacies or health centers. What NDA does is to ensure that human and animal drugs supplied in Uganda 's health facilities, whether produced locally or abroad, are of good quality and safe. We also ensure that these drugs are handled and administered by qualified personnel to minimize occurrences of misuse.

***Reporter: In the course of last financial year how did you ensure the quality and safety of drugs in the country in the course of the last financial year (July 2008/June 2009)?***

**ESR:** NDA inspected 5877 drug outlet applicants' premises throughout the country – 5417 drug shops and 460 pharmacies. Of the inspected premises, 5643 met our operational requirements and were licensed. These were 5200 drug shops and 443 pharmacies.

NDA also licensed **13** local manufacturers.

We inspected **109** pharmaceutical factories abroad for verification of their compliance to current Good Manufacturing Practices, NDA Regulations and Guidelines and International Standards.

In the course of last year 644 drug applications, of which 610 were human drugs and 34 veterinary drugs, were received. Of all the applications evaluated 446 human drugs and 19 veterinary drugs met the NDA registration requirements.

Received **62** dietary (food) supplement applications of which 53 products were approved.

All the **697** products approved were placed on the National Register for Drugs and food supplements.

**479** amendments were made with changes in product label, additional pack size, change in packages, revision of information size, shelf life, to mention a few.

**Eight** (8) foreign herbal products and **four** (4) public health chemical products were registered.

***Reporter: How does an ordinary person tell whether a Pharmacy or Drug Shop sells good medicine?***

**ESR:** For any approved pharmacy or drug Shop, there should be a certificate of registration displayed publicly. However, soon we shall introduce a system through

which the public will be able access drug information on their mobile phones regarding licensed drug outlets, drugs registered and authorized for sell in Uganda , and also send health alerts. We are soon launching a new communication system using mobile phones.

This system will enable anybody with a mobile phone in Uganda to send an sms text and receive prompt response on the status of a pharmacy, drug shop, medicine, condom, food supplement or public health chemical. The system is simple, all one has to do is enter any of the above by typing **NDA** name of any of the above and sending to 7197 and a prompt reply will let you now whether the pharmacy or drug shop is licensed or not, tell whether the drug/food supplement/public health is authorized to be marketed in Uganda by NDA or not. This will apply across all mobile telephone networks. For example the name of the pharmacy is XYZ Limited type NDA space XYZ Limited press ok to send message to 7179.

**Reporter: Suppose the response on the drug shop or pharmacy is not licensed what should one do?**

**ESR:** One should not buy medicine from such outlet. We have also provided details to the users to alert NDA through our hotline so that corrective measures are taken.

**Reporter: How do you ensure that drugs which are counterfeit, substandard or not on the register are not imported in Uganda through the 52 border ports?**

**ESR:** Our major challenge is supervising all the 52 border points to ensure that all medicines into Uganda are approved and certified. NDA has Drug Inspectors based at the main ports of entry through which almost all drug imports pass. Namely; Nakawa Inland port, Entebbe International Airport , Busia and Malaba. However we work closely with other government agencies (Uganda Revenue Authority and Uganda National Bureau of Standards) to alert us in case they come across drug consignments being imported or exported through points that we do not cover.

The Drug Inspectors examine and verify imported drugs on whether they comply with import requirements (i.e. are registered drugs from approved sources), and are of the identity, quantity and quality described on the ProForma Invoice previously approved by NDA.

For instance in the financial year under review NDA issued 5390 verification certificates for drug imports into and for export to other countries.

We also inspected 2,431 consignments of medicines at ports of entry of which 2290 (94.2%) were approved, 112 (4.6%) queried and 29 (1.2%) rejected.

**Reporter: What measures do you have in place for the upcountry and rural population to counter unscrupulous operators?**

**ESR:** NDA has endeavored to extend services nearer to the upcountry and rural population through its seven regional offices namely Arua ( West Nile ), Lira (Northern), Tororo (Eastern), Jinja (South Eastern), Mbarara (South Western), Hoima (Western)

and Nakawa (Central). In all these offices NDA has Drug Inspectors who work closely with respective local district administrations through District Assistant Drug Inspectors to ensure that drugs are of good quality and safe and are handled and administered by qualified personnel to minimize occurrences of misuse.

Our officers also conduct post market surveillance in the regions through buying drug samples from the market and testing them again using mobile mini-labs to test for quality and safety. In the last financial year **247** drug samples were picked and tested of which **236** samples passed the test and 17 failed. The failures were due to irregular white coating, appearance and powder not flowing freely.

The NDA Quality Control Department analyzed 513 drug samples (ARVs, anti-malaria, antibiotics, vet medicines and others) and 240 medical devices (condoms and gloves). Of the analyzed drug samples 13 samples failed the tests e.g physical appearance (anti-malarials), dissolution tests of antibiotics and diclofenac. And of the 102 condom batches only one failed, and of the 138 batches of gloves 14 failed the test.

However, I would want to assure the public that once these failures are observed, NDA communicates to the manufacturers or importers to institute recalls for destruction is done under the supervision of NDA Drug Inspectors.

***Reporter: What is this new development regarding adverse drug events?***

***ESR:*** An adverse drug event is a response to a medicine which is harmful and unintended.

It is not easy to assign a figure to the frequency of medicine reactions because in most cases they often go unnoticed and unreported by the prescriber and patient respectively. Secondly there is no appropriate denominator. For instance, the total number of patients exposed to a particular medicine is difficult to establish.

You also have to note that medicines have side effects which occur because of its nature (the way it interacts with the body to exert its effects). The side effects may be harmful or just unpleasant. Side effects are very common.

NDA has established 7 pharmacovigilance centres in major referral hospitals of Mulago, Hoima, Soroti, Kabarole, Mbale, Arua and Mbarara, and we have so far had 500 adverse drug event reports from these hospitals.

***Reporter: Any major challenges experienced in the course of the year!***

***ESR:*** Even though we are trying our best to counter counterfeit medicines, the problem is still big. Funding for our activities is still small and we cannot recruit the manpower that we need for the regions and districts we have to continuously monitor. We require facilitation in terms of equipments for the laboratory, specialized training, etc. The good thing is that our presence is felt in the country, as incidents of medicines that are substandard and counterfeited are being countered.

- Currently we have 7 Zonal Inspectors of Drugs which is quite a small number to efficiently cover the entire country.
- Districts are also phasing out District Assistant Drug Inspectors in their structures yet they have been very instrumental in facilitating NDA meet its mandate in the respective districts.
- Media houses aiding unethical advertisements by herbalists misinformation of the public leading to poor decision making – (late reporting of the illnesses, interactions of herbal medicines with conventional ones, wasting income on unverifiable benefits – enlargement of body parts.
- Mushrooming illegal drug dealers and operators.
- Ensuring that fake and counterfeit drugs do not find their way in Uganda , health units, pharmacies, drug stores and shops.
- Lack of vigilance from the public in being our eyes and ears wherever they come across unscrupulous persons.
- Need for the judicial officers to grant tougher sentences to illegal and unscrupulous drug operators because one taking expired drugs, counterfeits, and not receiving any effects is murder of the unsuspecting public.
- Low levels of reporting encountered adverse drug events.

***Reporter: How do you envisage overcoming these challenges?***

**ESR:** NDA will continue to work closely with Uganda Medical and Dental Practitioners Council, Uganda Media Council and the Uganda Broadcasting Council to ensure that the general public is not fleeced by quacks, herbalists/traditional medicines healers.

NDA had 44 cases forwarded to court for prosecution regarding contravention of the NDA Act. There is need to sensitize judicial officers to grant tougher sentences against convicted culprits. Imagine one caught selling drugs that are expired, counterfeits, substandard or packaging cassava flour as drugs, to be given 6 months sentence compared to the people that might have been affected is absurd.

Raising awareness in partnership with religious institutions, civil societies with grass root presence, local district administrations and the media.

***Reporter: Your last word to the public.***

**ESR:** Through this new sms text facility on trial, NDA is looking forward to creating simple solutions for the public in curbing unlicensed drug operators, unapproved condoms, and unregistered medicines in the country through the use of the sms mobile phone communication.

We therefore request the public to be vigilant about their health and that of others through utilizing the sms facility on their mobile phones to check whether the outlet they

are buying medicine from is licensed by NDA or the drug prescribed by the health professionals is on our drug register and also report any irregularities to minimize unscrupulous individuals.

For instance on any network to check whether drug outlet/medicine/condom/food supplement is licensed or registered or approved, you type **NDA** space followed by name of either **drug outlet/medicine/condom** and then send to **7197** and, an immediate response will be received on your phone.