National Drug Authority

NDA improves service delivery through automation

On June.27, National Drug Authority marked the 25 years of existence in Uganda. The entity, established in 1993 by the National Drug Policy and Authority Statute that in 2000 became the National Drug Policy and Authority (NDP/A)Act, Cap. 206 of the laws of Uganda (2000 Edition), is mandated to ensure availability, at all times, of essential, efficacious and cost-effective drugs to the entire Uganda's population, as a means of providing satisfactory health care and safeguarding the appropriate use of drugs.

NDA officials and Board Chairman Mr. Medard Bitekyerezo at the 25years celebrations at Hotel Africana

NDA, in fulfilling its mandate, has registered numerous milestones and include the following:-

1) Regulation of pharmacies and drug shops. To-date there are 1587 pharmacies and 5838 drug shops that have been licensed.
2) Promotion and control of local production of essential drugs. The number of local pharmaceutical manufacturers has increased from 3 when NDA started to 18 local manufacturers. Through Buy Uganda Build Uganda policy, a preferential fee was approved on 37 products that are locally manufactured to provide with 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.
3) Control of quality of drugs. NDA has been able to institute measures to ensure quality of medicines in Uganda as follows:-

i. Assessment and registration of drugs before they are granted marketing authorisation.
ii. Under clinical trial authorisation, NDA has adopted a new web-based online review platform in order to improve efficiency in clinical trial activities before marketing authorisation.
iii. Inspection of pharmaceutical manufacturing facilities (both local and foreign).
iv. Inspection of consignments of medicines at ports of entry to detect defective and substandard medicines and also to ensure that medicines have been manufactured in factories that have been inspected and approved by NDA.

4) Strengthened enforcement activities to get rid of counterfeits and substandard drugs, illegal outlets and smugglers.
5) NDA has built a quality control laboratory located in Mulago that has been prequalified by WHO and accredited by ISO international standards. This laboratory is able to test all types of samples for human and veterinary drugs to rule out substandard drugs from reaching the public. The laboratory is also able to test condoms, surgical and examination gloves, hypodermic syringes and needles and other medical devices; acaricides and mosquito nets.
6) Vetting of promotional materials to prevent inaccurate and misleading information on promotional and advertisement materials and products.
7) Strengthened the monitoring system for adverse events and reactions to medicines. Over 3500 ADR forms have been received and reviewed and as a result some treatment regimens in HIV and TB have been changed to improve safety. NDA has established National Pharmacovigilance Centres in Referral hospitals in several districts in Uganda through which ADRs are received.
8) Increased veterinary stakeholder engagement, pharmacovigilance and post marketing surveillance on acaricides and other veterinary products.
9) Dissemination of information to health professionals and public in terms of publications like bulletins, Dear Doctor Letters and face-to-face engagements through training workshops and meetings.
10) Promotion of rational use of drugs in terms of treatment guidelines, newspaper articles and talk-shows. Sensitisation of farmers and veterinary officers on the proper use of acaricides.
11) Control of herbal medicines. NDA has produced guidelines on herbal medicines and held sensitisation meetings with herbalists on the role of NDA and what the herbalists need to do to comply with the law and improve the quality of herbal medicines. NDA has started inspections of local herbal medicine manufacturing facilities.
12) A web-based on-line management information system (NDAMIS) has been developed to handle processes like drug registration, licensing of pharmacies, import authorization and GMP. This made these functions much more efficient and convenient to the customers.
13) EAC Medicines Regulatory Harmonization. NDA is recognised as a centre of excellence in good manufacturing practice inspections in the East African Community.
14) NDA became the International Harmonisation for Registration for Veterinary Products (VICH) outreach forum member in 2016. It has so far adopted and used 24 VICH guidelines to streamline veterinary medicine operations.
15 Increase in human resource capacity (7 in 1994 to 300 to-date) which is multi-disciplinary in nature.

Dr. Jane Ruth Acheng the Minister for Health delivering her speech at the NDA 25years celebrations at Hotel Africana.

Secretary to the Authority Mr. David Nahamya at the 25years dinner Celebrations at Hotel Africana.

Future plans

However, as the NDA strives to fulfil its obligation, more challenges have continued to emerge. And in a bid to cope with this, NDA has outlined the following future plans.

- Strengthen testing of drugs by constructing an ultra-modern quality control laboratory tower on Buganda Road and laboratories at the NDA regional offices.
- Continue to promote investment in the domestic pharmaceutical manufacturing sector, especially for medicines for neglected diseases with the ultimate aim of reducing our dependence on imported drugs and medical devices.
- Conduct more collaborative intelligence based operations to mitigate unethical operators in the pharmaceutical sector.
- Strengthen systems for herbal medicines production and registration.
- Strengthen pharmacovigilance and ethical medicines promotion to include herbal medicine.
- Set-up track and trace systems along the medicines supply chain including field testing of medicines.
- Strengthen systems and processes by embracing ICT in the operations of NDA.
- Transformation of NDA into NFDA to regulate food, drugs, cosmetics, medical devices and household chemicals.

National Drug Authority

NDA automates licensing process to boost service delivery

NDAMIS Launch Dinner: Delegates from Partner Institutions (EAC, TMEA, URA and NDA)

Uganda's National Drug Authority has unveiled an online portal that will enable the pharmaceutical industry's stakeholders to access trade and drug retention services.

Daniel Kalibbala Head of IT, said the innitiative is expected to boost the pharmaceutical sector by easing access to services provided by the regulator to the pharmaceutical industry.

The development of the online portal dubbed National Drug Authority Management Information System (NDAMIS) has been facilitated by TradeMark East Africa as part of its efforts to promote regional trade and economic integration.

Through the online portal https://portal.nda.or.ug stakeholders will be able to apply for operational licenses, renew existing operational licenses, make e-payments, facilitate customer's clearance and apply for drug exports and imports.

The new system will be linked to the Uganda Electronic Single Window to enable import/export data exchange for all medicine products and facilitate paperless transactions at customs boarder posts.

The new initiative will also fasten the licensing exercise, fastening delivery of drugs to various stakeholders countrywide. For instance, prospective pharmaceutical owners will now take just 14 days to acquire an operating licence, down from 60 days, with the possibility to print licences for themselves.

Inspection of pharmacies will also experience a reduction in the number of days from 45 days to 5 days, with the possibility of scheduling and report filling done online.

Retention of drugs of drugs will now be done in one day, down from 30 days before while authorisation for import and export will see days reduce from the current 14 days to two days.

Customs declaration and clearance will be done in just three hours, down from the usual two days.

Overall, end to end automation will facilitate transparency, accountability, service delivery timelines improvement but most importantly cost reduction regarding transport to and from NDA offices, stationary (both to NDA and clients), and accurate reporting.

This comes at the time that the regulation of medicines and harmonization of technical standards and legislative frameworks have emerged as important components of the regional economic integration efforts mainly because countries in Africa are struggling to produce, procure and make safe and essential medicines available to their populations.

The online portal was developed in close partnership with TradeMark East Africa (TMEA) who provided technical and financial support to NDA.

NDA 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) to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population (human and animal) as a means of providing satisfactory health care and safeguarding the appropriate use of drugs.

NDA ONLINE

THROUGH THE ONLINE PORTAL **URL: https://www.nda.or.ug** STAKEHOLDERS WILL BE ABLE TO APPLY FOR OPERATIONAL LICENSES, RENEW EXISTING OPERATIONAL LICENSES, MAKE E-PAYMENTS, FACILITATE CUSTOMER'S CLEARANCE AND APPLY FOR DRUG EXPORTS AND IMPORTS.

NDA awards partners who participated in NDAMIS system development: L-R Michael Mitheu Programme Manager ICT for Trade and Transport Facilitation, TradeMark East Africa Eng. Daniel Kalibbala the Head of ICT NDA and Eng. Daniel Murenzi Principal Information Technology Officer of EAC

BACKGROUND OF THE ONLINE SYSTEM

NDAMIS was received as a project deliverable of the East African Community Information Management System (EAC IMS) within the East African Community Medicines Regulatory Harmonization EAC/MRH program.

The EAC IMS project is a key component of the African Medicines Regulatory Harmonization (AMRH) Project.

The main goal of the EAC IMS project is to support the five EAC Partner states and six regulatory authorities which are part of the MRH Project, to achieve EAC wide harmonization of national regulatory processes and to facilitate data and information exchange among NMRAs and EAC.

The system is developed by Trademark East Africa with support from various funders.

The East African Community Medicines Regulatory Harmonization (EAC-MRH) project aims at improving access to safe, efficacious, affordable and good quality medicines by harmonizing medicines regulation systems, requirements and procedures in accordance with national and international policies and standards.

This initiative is in line with the provisions of the Treaty establishing the East African Community; Chapter 21 Article 118, which provides for Partner States to corporate and collaborate in health matters

The 10th Ordinary Meeting of EAC Sectoral Council of Ministers of Health that was held in Arusha, Tanzania, Oct.16, 2014 (Report Ref: EAC/Health/SCM-10/Decision 035), welcomed TMEA to collaborate with EAC Secretariat in Implementation of IMS system and also approved the EAC roadmap for installation and operationalization of the Information Management system (IMS) for the Minimum Harmonized System and Processes Requirements for Regulation of Medicines.