The Republic of Uganda

Office of the Auditor General

VALUE FOR MONEY AUDIT REPORT
ON THE REGULATION OF MEDICINES IN UGANDA
BY NATIONAL DRUG AUTHORITY

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<th>Full Form</th>
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<tr>
<td>ADR</td>
<td>Adverse Drug Reaction</td>
</tr>
<tr>
<td>ARV</td>
<td>Antiretroviral Drugs</td>
</tr>
<tr>
<td>BMRs</td>
<td>Batch Manufacturing Records</td>
</tr>
<tr>
<td>bn</td>
<td>billion</td>
</tr>
<tr>
<td>cGMP</td>
<td>current Good Manufacturing Practice</td>
</tr>
<tr>
<td>CNF</td>
<td>Committee for National Formulary</td>
</tr>
<tr>
<td>DADI</td>
<td>District Assistant Drug Inspector</td>
</tr>
<tr>
<td>FY</td>
<td>Financial Year</td>
</tr>
<tr>
<td>GLP</td>
<td>Good Laboratory Practice</td>
</tr>
<tr>
<td>GMP</td>
<td>Good Manufacturing Practice</td>
</tr>
<tr>
<td>GoU</td>
<td>Government of Uganda</td>
</tr>
<tr>
<td>HPLC</td>
<td>High Performance Liquid Chromatography</td>
</tr>
<tr>
<td>HSSP</td>
<td>Health Sector Support Programme</td>
</tr>
<tr>
<td>INN</td>
<td>International Non-proprietary Names</td>
</tr>
<tr>
<td>INTOSAI</td>
<td>International Organisation of Supreme Audit Institutions</td>
</tr>
<tr>
<td>ISO</td>
<td>International Standards Organisation</td>
</tr>
<tr>
<td>LC’S</td>
<td>Local Councils</td>
</tr>
<tr>
<td>LLINs</td>
<td>Long Lasting Insecticidal Nets</td>
</tr>
<tr>
<td>NDA</td>
<td>National Drug Authority</td>
</tr>
<tr>
<td>NDPA</td>
<td>National Drug Policy and Authority Act</td>
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<tr>
<td>NDQCL</td>
<td>National Drug Quality Control Laboratory</td>
</tr>
<tr>
<td>NPC</td>
<td>National Pharmacovigilance Centre</td>
</tr>
<tr>
<td>OAG</td>
<td>Office of the Auditor-General</td>
</tr>
<tr>
<td>PAS</td>
<td>Professional Auxiliary Staff</td>
</tr>
<tr>
<td>RID</td>
<td>Regional Inspector of Drugs</td>
</tr>
<tr>
<td>RPC</td>
<td>Regional Pharmacovigilance Centre</td>
</tr>
<tr>
<td>Shs</td>
<td>Shillings</td>
</tr>
<tr>
<td>SIAMED</td>
<td>Model System for Computer-assisted Drug Registration</td>
</tr>
<tr>
<td>SMS</td>
<td>Short Message Service</td>
</tr>
<tr>
<td>URA</td>
<td>Uganda Revenue Authority</td>
</tr>
<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
</tr>
<tr>
<td>USP</td>
<td>United States Pharmacopeia</td>
</tr>
<tr>
<td>VFM</td>
<td>Value for Money</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
</tr>
</tbody>
</table>
EXECUTIVE SUMMARY

Introduction:
This Value for Money audit on Regulation of Medicines by the National Drug Authority (NDA) was conducted in accordance with Article 163(3) of the Constitution of the Republic of Uganda. This mandate is amplified by Section 21(1) of the National Audit Act 2008 which requires the Auditor-General to carry out value for money audits for purposes of establishing economy, efficiency and effectiveness in the operations of any department or ministry.

NDA was established by the National Drug Policy and Authority Act in 1993 (Cap 206 Laws of Uganda) 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 health care and safeguarding the appropriate use of drugs.

The Office of the Auditor-General instituted a Value for Money Audit to assess the operations of NDA regarding the Regulation of Medicines in Uganda; to identify the challenges, if any, and provide possible recommendations to mitigate them.

The audit was conducted in accordance with INTOSAI Auditing Standards and Guidelines. The focus of the audit was on the functions of Regulation of Medicines by NDA. The areas covered by the audit included NDA headquarters in Kampala, National Drug Quality Control Laboratory (NDQCL) in Mulago and 7 Regional Offices in Nakawa for the Central Region, Mbarara, for the South Western Region, Jinja, for the South-Eastern Region, Tororo, for the Eastern Region, Hoima, for the Western Region, Lira, for the Northern Region, and, Arua, for the North Western Region. We also visited 4 controlled entry points where mainly drug import verification takes place, namely: Nakawa, Busia, Malaba and Entebbe International Airport. Other entry points not staffed by NDA were also inspected to obtain views from Uganda Revenue Authority (URA) Customs staff on drug imports through these points. In addition, 8 Regional Pharmacovigilance Centres in Mbarara, Fort-Portal, Jinja, Soroti, Hoima, Lira, Arua and Mulago were also inspected.

To collect data, we reviewed documents, conducted interviews and carried out physical inspection/observation of NDA facilities and RPC’s. This report covers four years from July 2006 to June 2010.

Audit Findings:
The following audit observations were made:

Legal Mandate:
NDA has not gazetted guidelines into statutory instruments as required by law. This impairs the ability of the authority to execute its mandate.
Licensing Drug Outlets:

(i) NDA was unable to issue licences to all drug outlets by 31st January of each year as required by the law. This encourages illegal operators of drug outlets and poses a risk of exposing the people to sub-standard drugs on the market. NDA is also denied revenue from drug outlets as budgeted for service delivery.

(ii) NDA has not publicised licensed drug outlets. This limits access to vital information by the public as to the legal drug outlets from where consumers would confidently buy medicine with ease.

(iii) NDA did not close unlicensed drug outlets after 31st January each year as required by the Act. This encourages the prevalence of illegal operators, and, subsequently the circulation of sub-standard drugs which impairs NDA’s objective of ensuring that quality, safe and efficacious medicines are availed to the public.

Assessment/Evaluation, Registration and Updating the National Drug Register:

(iv) NDA delays the evaluation of dossiers. This may in turn reduce competition and result in increased prices and reduce the variety of essential medicines on the market.

(v) NDA was not updating the National Drug Register on a monthly basis which may result into entry of unregistered/unauthorized drugs in the country.

Drug Testing and Analysis:

(vi) NDA does not release all the test results in 2 weeks from the time samples are submitted. This may impair timely decision-making and lead to dissatisfaction by clients.

(vii) NDA did not test traditional/herbal medicines for the period under review. This may expose the public to sub-standard traditional/herbal medicines.

Drug Inspection:

(viii) All drug consignments entering the country were not inspected within a day as required, which may impair the image of NDA, compromise objectivity and delay critically needed drugs which may put the lives of people at risk.

Dissemination of drug information:

(ix) NDA had not completed statutory instruments for regulating the advertisement of pharmaceutical products. The public is exposed to the risk of getting misleading information about the drugs on the market.
NDA has not been vigilant in sensitizing the public on the rational use of drugs. Failure to provide vital information on drug use exposes the public to harmful effects of drug and substance abuse.

Monitoring and Control:
(xi) Apart from conventional western medicines, NDA does not approve all drug adverts and promotional materials. This has the potential of exposing the public to misleading information on drugs as evidenced by illegal adverts in the print and electronic media and the hawking of drugs.

(xii) ADR forms were not collected from health centres on a monthly basis, implying that cases of adverse drug reactions cannot be reported and followed up in time. This impairs timely reporting of ADR cases and affects proper management and timely corrective measures, thus risking the lives of the people.

(xiii) NDA was does not making timely feedback on ADR to international agencies, which in turn limits the information on the VigiFlow to enable proper decision making on drugs which impairs NDA’s role of proper identification of the signals necessary for evidenced based regulatory decisions.

Recommendations:

Legal Mandate:
(i) NDA should expedite the process of gazetting regulations to operationalise the NDPA Act.

Licensing of Drug Outlets:
(ii) NDA should make an evaluation of its human resource requirements and determine the optimal staffing levels to effectively carry out its mandate.

(iii) Management should ensure that regional offices are provided with appropriate transport facilities adequate to carry out pre-licensing inspection to aid timely issue of licenses.

(iv) NDA should finalise formal arrangements with all districts managements regarding DADIs by way of Memoranda of Understanding.

(v) Regular sensitisation meetings should be held to help the owners of drug outlets to understand the licensing requirements to avoid queries while processing application forms.

(vi) NDA should ensure that the public is availed free and timely access to information regarding licensed drug outlets.
(vii) NDA should liaise with local leaders in the respective areas when approving new operators, closing unlicensed premises, renewing licenses or carrying out inspections to obtain their cooperation so as to enhance the effectiveness of the inspections.

(viii) NDA should also strengthen and streamline the role of Inspectors to avoid the existing weaknesses in the process of authorisation, inspection and enforcement.

Assessment/Evaluation and Registration of Drugs:

(ix) NDA management should consider prioritising the funding of dossier evaluation.

(x) Where staff strength within the NDA structure does not match with the dossier applications received, management should consider the option of outsourcing to experts with the required skills and competencies to execute such tasks.

(xi) It is also necessary to evaluate and network with other drug regulatory agencies to share information on similar products that have been evaluated by reputable drug regulatory agencies to reduce on existing workload without compromising the quality of the products entering the Ugandan market.

Drug Analysis

(xii) Management should put in place a comprehensive plan to make use of Mini-Labs for testing samples at the regional offices. NDA should also prioritise the procurement of all laboratory inputs to avoid stock-outs and the delay of results.

(xiii) Government should take a leading role of ensuring that the NDA as a government drug regulatory body has adequate space, equipment and staff to execute its mandate.

(xiv) Steps should be taken to ensure the training of all the required staff in the testing of traditional/herbal medicines.

(xv) Management should prioritize the purchase of the equipment necessary for carrying out the testing of traditional/herbal medicines.

(xvi) A comprehensive system of regulating herbal medicines should be put in place to save the public from the quack products on the market, promote local research/production and save the lives of the people.

(xvii) More collaboration with the other agencies involved in traditional/herbal medicines, such as the Natural Chemothearapeutics Research Laboratory, should be encouraged with a view to sharing resources.
Drug Inspection:
(xviii) Management should put in place a proactive arrangement to ensure that all consignments are inspected within agreed timeframe and all key entry ports are staffed.
(xix) Provide testing equipment at designated ports of entry to reduce the time of inspecting consignments. This will also increase the number of samples tested.
(xx) NDA should formalise its working relationship with URA and ensure that customs staff are regularly sensitised and meetings held to enhance coordination.
(xxi) NDA should ensure that rejected consignments are destroyed or re-exported without delay.

Dissemination of Drug Information:
(xxii) Management should prioritise and expedite the legal drafting process to ensure that the guidelines are gazetted so as to disseminate drug information to the public.
(xxiii) Management should put more emphasis on public sensitisation to protect them against the harmful effects of drug and substance abuse.

Monitoring and Control:
(xxiv) To improve the system of approving adverts, NDA should take a leading role in coordinating with the other players involved in advertising, like media houses and their regulatory agencies, local councils, managers of public places, like markets or bus owners, to stop illegal adverts. Priority in resource allocation should also be given to monitoring adverts to safeguard the public from misleading information. Public awareness campaigns should be enhanced to empower the public and safeguard them against the effects of wrong drug information. NDA should assign and facilitate a dedicated person to monitor and report on advertisement of drugs and promotional materials.
(xxv) The Ministry of Health should streamline relationship with NDA to improve reporting and utilisation of information from adverse drug reaction reports.
(xxvi) It is also recommended that the ministry incorporates ADR reporting in the overall Health Information Management Systems so that the forms are collected with other routine documentation.
(xxvii) Sensitising health workers on ADR reporting and skills in filling the forms should be continuous with a view of encouraging health workers to record any possible drug reaction observed while allaying their fears on possible litigation.
(xxviii) NDA should improve feedback mechanisms to stakeholders to encourage them appreciate the benefits of ADR reporting.
(xxix) NDA should work hand in hand with the Ministry of Health to ensure that ADR reporting is prioritised and incorporated into other support supervision activities.

(xxx) While training centre coordinators on the use of VigiFlow should be emphasised, the sensitisation of health workers on observing ADRs and filling the forms properly should be continuous.

(xxi) Regional Inspectors of drug should be involved in Pharmacovigilance sensitisation activities.

(xxxii) Regional Pharmacovigilance centres should be facilitated with the necessary logistics like internet facilities to report ADR.
CHAPTER 1

INTRODUCTION

1.1 Background to the Audit:
This Value for Money audit on Regulation of Medicines by National Drug Authority has been conducted in accordance with Article 163(3) of the Constitution of the Republic of Uganda. This mandate is amplified by Section 21(1) of the National Audit Act 2008 which requires the Auditor-General to carry out value for money audits for purposes of establishing economy, efficiency and effectiveness in the operations of any department or ministry.

Motivation:
Drugs and pharmaceutical products constitute a big proportion of health care expenditure. At the national level, government spent 91% in 2008/09 and 86% in 2009/10 (projection) of the Ministry of Health recurrent budget on purchase of pharmaceutical supplies. In terms of value, the medical and pharmaceutical supplies imported in the country for the last 4 years have increased from US$ 123m in 2006 to US $213.8 in 2009 as shown in Table 1 below:

Table 1: Imports of Medical and Pharmaceutical products for the period 2006 – 2009 (in US $ million).

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<tbody>
<tr>
<td>Value of Imports</td>
<td>123.0</td>
<td>175.8</td>
<td>246.2</td>
<td>213.8</td>
<td>758.8</td>
</tr>
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</table>


These are essential components and are a government priority in a sector that is aimed at promoting a healthy and productive life. Drugs play an important role in saving lives and preventing the spread of diseases.

It is also common knowledge that households and individuals spend a big proportion of their incomes on health care by attending private clinics for treatment or acquiring drugs directly from private pharmacies and drug shops which are in close proximity to their homes.

Drug shops and Pharmacies are major drug distribution channels of drugs from the manufacturers to the final consumer since most Government Health facilities are prone to drug stock-outs. The public resorts to private drug outlets. Regular inspection of these

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outlets is important and necessary if their suitability is to be monitored to safeguard the public.

It is the responsibility of the Government and the mandate of the National Drug Authority as a drug regulatory agency to protect the health of the public by ensuring that the drugs available on the market are of the right quality, safety and efficacy through the regulation and control of their production, importation, distribution and use.

However, despite the efforts of NDA, cases of expired drugs on the market - others contaminated, outright counterfeits, prevalence of unlicensed drug shops and pharmacies (some of them managed by unqualified staff) have continued to increase. The above cases pose a major challenge in availing essential, efficacious and cost-effective drugs at all times to the entire population as a means of providing satisfactory health care. Some of the sub-standard and unauthorized drugs are imported into the country.

Some quack traditional healers may have also taken advantage of the flaws in dissemination of information on drugs and management of the formal health sector and human drug management in the country to fleece the population of money, encourage drug abuse and cause death through vices like human sacrifice.

It is against this background that the office carried out a Value for Money audit on regulation of medicines in Uganda by National Drug Authority.

1.2 **Description of the Audit Area:**
NDA has its headquarters in Kampala. It also operates a National Drug Quality Control Laboratory (NDQCL) based in Mulago Hospital (that is responsible for testing and analysing medicine samples for quality) and 7 Regional Offices responsible for decentralised activities of NDA e.g. inspection of drug outlets and market control. These centres are at Nakawa for the Central Region, Mbarara, for South Western Region, Jinja, for the South-Eastern Region, Tororo for the Eastern Region, Hoima, for the Western Region, Lira, for the Northern Region and Arua, for the North Western Region. It also has 4 entry points mainly for import verification purposes, namely: Nakawa, Busia, Malaba and Entebbe International Airport.
NDA also operates the NDQCL based in Mulago which is responsible for testing and analysing medicine samples for quality.

In addition, NDA has established a National Pharmacovigilance Centre (NPC) in Kampala, and 12 Regional Pharmacovigilance Centres in Gulu, Jinja, Mbarara, Arua, Kabale, Lira, Mulago, Soroti, Masaka, Hoima, Mbale and Fort-Portal Regional Referral Hospitals for receiving reports of suspected Adverse Drug Reactions (ADR). These are managed by coordinators who are not NDA employees but are staff of the respective hospitals.

1.3 **Statutory Mandate:**

NDA was established by the National Drug Policy and Authority (NDPA) Act in 1993 (Cap 206 Laws of Uganda) 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 health care and safeguarding the appropriate use of drugs.

1.4 **Vision, Mission, Goals and Objectives:**

The Vision, mission, goals and objectives of the NDA are:

**Vision:**

"A world-class centre of excellence in regulation of medicines and other health related products."

**Mission Statement:**

"To ensure quality, safety and efficacy of human and veterinary medicines and other health care products through the regulation and control of their production, importation, distribution and use."

**Goal:**

"To coordinate and oversee the medicines sector in order to protect public health."

**Functions of the National Drug Authority:**

The National Drug Authority is charged with the implementation of the national drug policy and, in particular, but without derogation of the foregoing, shall:

(a) Deal with the development and regulation of the pharmacies and drugs in the country;

(b) Approve the national list of essential drugs and supervise the revisions of the list in manner provided by the Minister;

(c) Estimate drug needs to ensure that the needs are met as economically as possible;
(d) Control the importation, exportation and sale of pharmaceuticals;
(e) Control the quality of drugs;
(f) Promote and control local production of essential drugs;
(g) Encourage research and development of herbal medicines;
(h) Promote rational use of drugs through appropriate professional training;
(i) Establish and revise professional guidelines and disseminate information to health professionals and the public;
(j) Provide advice and guidance to the Minister and bodies concerned with drugs on the implementation of the national drug policy.

**Strategic Objectives:**

- To ensure effective regulation of the human and veterinary Pharmaceutical sector.
- To promote and control local production of human and veterinary medicines.
- To ensure effective control over the quality, safety and efficacy of all human and veterinary medicines and other health related products available in the country.
- To provide drug information to stakeholders, pharmaceutical service providers and the general public.
- To combat drug and substance abuse in order to protect society against the associated harmful effects.
- To put in place mechanisms to ensure the financial sustainability and effective functioning of NDA.
- To promote/contribute to the accessibility and cost-effectiveness of human and veterinary (including traditional) medicines and other health related products.
- To ensure the establishment of an effective system for regulation and control of importation, advertising and sale of nutritional supplements, medical devices, diagnostics, medical equipment and sundries for human and veterinary use.
- To strengthen the regulation of traditional/herbal and complementary medicines.
- To ensure the establishment of an effective system for regulation and control of local manufacture, importation, advertising and sale of public health products and animal acaricides.

**1.5 Activities:**

To enhance the above strategic objectives, NDA undertakes the following activities:-

(i) Inspect all pharmaceutical premises (for new premises and renewals),
(ii) Eradicate unlicensed drug outlets and dealers with cooperation of police and LC’s,
(iii) Conduct regular inspections of all local manufacturing facilities,
(iv) Participate in GMP inspections of Local Manufacturing Facilities.
(v) Conduct current Good Manufacturing Practices (cGMP) inspection of foreign pharmaceutical manufacturing sites,
(vi) Inspection of drugs at ports of entry,
(vii) Inspect and License premises for manufacture and sale of public health chemicals and animal acaricides,
(viii) Initiate training of staff in human and veterinary medicines registration, regulatory activities for biological and other vaccines, registration of nutritional supplements/food fortificants/medical services/sundries and cosmetics.
(ix) Collaborate with relevant international bodies in drug registration matters.
(x) Dossier evaluation
(xi) Harmonize registration of public health products and acaricides with relevant international bodies.
(xii) Initiate the purchase and installation of additional equipment and spare parts of NDQCL.
(xiii) Test samples of medicines and health related products.
(xiv) Initiate a study of counterfeits and sub-standard medicines in Uganda.
(xv) Test condoms and other medical devices at the NDQCL.
(xvi) Test public health products and acaricides.
(xvii) Develop and review guidelines on drug promotion and advertisements of human and veterinary medicines.
(xviii) Sensitize stakeholders involved in advertising and promoting of human and veterinary medicines.
(xix) Review and publish training materials and ADR reporting forms.
(xx) Increase awareness about NDA activities.

1.6 **Organisation Structure:**

The Board of Directors (NDA Authority) is a policy and decision making organ and works through committees, namely: the NDA Commission, Committee on Pharmacovigilance and Clinical Trials, National Formulary, Human Resources, Medical Equipment and Devices, Finance and Audit, Legal/NFDA, Traditional/Herbal Medicines and Veterinary Medicines. At the management level, NDA has a secretariat headed by the Executive Secretary/Registrar and assisted by 5 Heads of Departments, namely: Drug Assessment and Registration, Drug
Inspectorate, Drug Information, Drug Quality Control and Finance. Other sections report directly to the Executive Secretary and they are: Legal Affairs, Human Resource, Procurement, Information Technology, Quality Management, Public Relations and Internal Audit. An organization chart showing the above relationships is attached as Appendix (i).

1.7 Financing:

NDA operations are mainly funded by internally generated revenue and support from development partners and these include HSSP, WHO and USAID. Details of funding by source is summarized in Table 2 below.

Table 2: Sources of National Drug Authority Funds – 2006/07 to 2009/10

<table>
<thead>
<tr>
<th>Source/Financial Year</th>
<th>2006/07 (Shs in bn)</th>
<th>2007/08 (Shs in bn)</th>
<th>2008/09 (Shs in bn)</th>
<th>2009/10* (Shs in bn)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NDA Income</td>
<td>9.19</td>
<td>10.36</td>
<td>13.06</td>
<td>13.12</td>
</tr>
<tr>
<td>Donor Funds</td>
<td>0.17</td>
<td>0.31</td>
<td>0.68</td>
<td>0.12</td>
</tr>
<tr>
<td>GoU Funds</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.014</td>
</tr>
<tr>
<td>Total Income</td>
<td>9.36</td>
<td>10.67</td>
<td>13.74</td>
<td>13.26</td>
</tr>
</tbody>
</table>

Source: NDA Audited Financial Statements 2006/07 – 2008/09
* NDA Performance and Activity Report July 2009 – June 2010

1.8 Scope:

The audit, which focused on regulation of medicines covered 4 financial years from July 2006 to June 2010. The audit covered NDA headquarters in Kampala, National Drug Quality Control Laboratory (NDQCL) in Mulago, NDA Regional offices based in Kampala/Nakawa, Jinja, Tororo, Mbarara, Lira, Hoima and Arua. Apart from the regional offices, where inspections are based, the team also visited Regional Pharmacovigilance Centres in Mbarara, Hoima, Lira, Arua, Fort-Portal and Jinja to understand the operations and systems of ADR reporting. Uganda Revenue Authority (URA) entry points at Nakawa, Malaba/Busia, Entebbe, Mpondwe, Mutukula and Vuura were inspected to obtain information on drug consignments entering the country.
CHAPTER 2

METHODOLOGY

The audit was conducted in accordance with International Organisation of Supreme Audit Institutions (INTOSAI) Auditing Standards and OAG Audit VFM Manual. Those Standards require that a Performance /VFM Audit should be planned in a manner which ensures that an audit of high quality is carried out in an economic, efficient and effective way and in a timely manner. In collecting data from the field, the team carried out interviews, reviewed documents and physical inspection/observation of the facilities.

2.1 Document review:
The team obtained and reviewed the documents shown in Appendix (ii), to obtain information relating to the legal framework and mandate of National Drug Authority, assess financial performance, obtain the organisation Vision, Mission, Goals and Objectives, financial forecasts and performance for the period under review.

2.2 Interviews:
The team interviewed the Executive Secretary, Head, Drug Assessment and Registration, Head, Drug Inspectorate, Head, Drug Information, Head, National Drug Quality Control Laboratory, Regional Inspectors of Drugs, District Assistant Inspectors of Drugs, Regional Pharmacovigilance Centre Coordinators, Manufacturers and URA staff at selected ports of entry.

2.3 Inspection:
The team inspected the NDQCL in Mulago, dossier and sample stores at NDA headquarters, Regional Pharmacovigilance Centres and selected pharmacies to assess adequacy and availability of facilities required for effective control and regulation of drugs.
CHAPTER 3

SYSTEMS AND PROCESSES IN REGULATION OF MEDICINES

3.1 Roles and Responsibilities of Key Players:

National Drug Authority – Committees:
The Authority is responsible for policy decisions and works through committees, namely: NDA Commission, Committee on National Formulary, Committee on Pharmacovigilance and Clinical Trials, Committee on Medical Equipment and Devices, Committee on Human Resource, Finance and Audit Committee, Legal/NFDA Committee, Committee on Veterinary Medicines and Committee on Traditional and Herbal Medicines. The Committees oversee activities in the respective departments.

Executive Secretary/Registrar:
At the Management level, NDA has a Secretariat headed by an Executive Secretary/Registrar assisted by five heads of departments. He/she is responsible for the day-to-day operations of the Drug Authority. In addition to other functions, he/she is responsible for the custody of the National Drug Authority Seal and keeping the records of the transactions of the Drug Authority.

Head, Inspectorate Department:
The Head of the Inspectorate Department is responsible for ensuring that all medicines manufactured locally and imported are of good quality. He/she does this by ensuring that medicines are inspected at all major ports of entry to minimize entry of substandard medicines into the country. He/she is also responsible for carrying out inspections and licensing of all pharmaceutical handling facilities and ensures that support supervision is done to rid the country of illegal operators of drug outlets.

Head, Drug Assessment and Registration Department:
He/she is responsible for ensuring that all medicines registered in Uganda meet internationally accepted quality, safety and efficacy standards. The department is also responsible for evaluating Dossiers, processing Amendments and maintaining an accurate Medicines register.
**Head, Drug Quality Control Department:**
The Head of Department is responsible for ensuring that medicine samples are tested and analyzed for their quality and safety. NDA’s main focus is to build the capacity of the laboratory to undertake its mandate through acquisition of adequate equipment and human skills.

**Head, Drug Information Department:**
The Head of Department is responsible for ensuring that all stakeholders have the right information on medicines and that public awareness of NDA is increased. The department is also responsible for Pharmacovigilance programs and Adverse Drug Reaction (ADR) reporting at the National Pharmacovigilance Centre (NPC) as well as project planning and management. He/she is responsible for ensuring that monitoring and approval of drug promotional materials is done as well as ensuring that misleading information on medicines is minimised, especially in the area of herbal medicines.

**Head, Finance Department:**
He/she is responsible for ensuring that adequate financial resources are realized, prioritized and properly used in the implementation of the Strategic Plan. The department also has a responsibility of updating the computerized accounting system to meet emerging needs of the organization and training of all finance staff in financial management and proper book keeping.

**Human Resource and Administration Officer:**
The Head of Unit is responsible for ensuring that employees are adequately equipped to undertake their work. He is also responsible for addressing problems like limited space and providing adequate logistical support to all departments.

**District Assistant Drug Inspectors (DADI’s):**
DADI’s are employees of the districts who carry out health/drug inspection and enforcement within the respective districts. They are facilitated by NDA with transport and stationery and report technical issues to NDA through regional offices. They also help NDA in inspection of drug outlets and issuing of application forms for renewal of licenses.
Manufacturers/Industry:
These make drugs within or outside the country. NDA participates in inspecting their premises to ascertain whether they comply with current good manufacturing practice (cGMP). NDA also inspects local drug manufacturers and encourages them through training programs and cGMP to promote local production of drugs.

Pharmacies, importers and distributors:
These import medicines into the country and also provide drugs to end users through prescription/dispensing. NDA collects fees and issues licenses to them annually.

Uganda Revenue Authority:
URA is a government body charged with the responsibility of enforcing export and import regulations, including collection of taxes from goods entering the country through the various ports of entry. In respect to drugs, URA officials at the customs entry points, collaborate with NDA drug inspectors to ensure that all drugs imported into and exported out of the country are inspected.

Ministry Of Health:
NDA is directly supervised by the Ministry of Health. The Minister responsible for Health appoints the Chairperson and the Board of NDA. The Minister is also responsible for making regulations, approval of NDA budget estimates and sources of funds.

Regional Pharmacovigilance Centre Coordinators:
These are medical staff based at Regional Referral Hospitals responsible for coordinating ADR activities in lower health units within the region which include: distribution, collection, recording and reporting ADR to the National Pharmacovigilance Centre. The equipment and facilities for recording ADR cases in the database are controlled by these coordinators.

3.2 Key processes:

i. Licencing:
All applicants collect application forms and banking slips from NDA offices at NDA headquarters, NDA regional offices and DADI’s based at the districts in the District Health Office. For renewal of licenses, application forms are required to be distributed to the applicants by 31st December each year and the completed forms accompanied by a letter of acceptance from the professional in charge (with a copy of certificate of
practice/registration/enrolment) returned not later than 31st January of each year. If an application for renewal is not received by 31st January, the premise is deemed to be subject to closure and operations would cease. The fees are payable to the bank within 30 days from the date of the invoice or approval letter. Pharmacies obtain their licenses from NDA headquarters but drug shops obtain theirs from Regional Inspectors of Drugs.

Late application/payment of fees attract a 50% surcharge of all total payable fees, but renewal fees for drug shops are required to be paid at the time of application.

The application should also bear the previous year’s license number. Certified copies of the memorandum and articles of association must be submitted together with application forms for all renewals, manufacturing and new applicants.

All new applicants are required to attach sketch plans of their premises. An applicant submits an application for pre-inspection of the location of the proposed premises which is done to ensure that there is no loss in case an application is rejected where financial and legal commitments have been made to the premises. This is expected to remain valid for a period of 3 months only and NDA may authorise a new applicant in the location.

Licenses shall be issued to applicants holding certificates of suitability of premises issued by the Registrar of NDA For retail pharmacies, at least one (1) of the partners or director must be a pharmacist resident in Uganda for partnerships and corporate bodies. For wholesale pharmacies, on the other hand, there must be a pharmacist who is an active member of the pharmaceutical society of Uganda and registered to practise in Uganda.

At the time of applying, a Pharmacist operating 2 pharmacy premises is required to indicate the time and duration he is expected to be physically present at each of the premises. He/she should also indicate name and qualification of the professional auxiliary staff (PAS) to deputise for him/her during hours of his/her physical absence.

ii. **Inspection Process:**
the activities done by the Inspectorate Department include: inspection of drug outlet premises i.e. pharmacies and drug shops (1 mandatory pre-inspection), processing and
issue of licenses of various drug outlets by 31st January and carrying out support supervision in all districts, at least once a year.

NDA inspectors inspect the premises and evaluate practices to ensure effective control over the quality, safety and efficacy of all human and veterinary medicines available in the country in order to protect the end user.

Inspections are done to ensure that the required provisions for licensing are complied with in the drug outlets. The Inspectorate Department also ensures effective regulation of the human and veterinary pharmaceutical sector, including traditional/herbal medicine, and promotes local production of essential human and veterinary medicines (including traditional/herbal medicine).

Inspection checklists are used to ensure standardized and comprehensive assessment of the drug outlets. Inspectors check on the location of premises, standards of construction, clean and tidy environment, good storage of drugs/protection against light, heat and moisture, sufficient space of pharmacy, among others. Outlets that do not comply are not licensed to operate. An inspection report is thereafter issued by the drug Inspector or Assistant Inspector of Drugs.

Specially trained Senior Drug Inspectorate staff visit pharmaceutical manufacturing facilities, both inside and outside Uganda, and carry out a detailed and comprehensive assessment of all manufacturing operations.

Current Good Manufacturing Practice (cGMP) Inspections are conducted to ensure that the manufacturing facilities of drugs to be imported into Uganda operate according to international standards for cGMP. Foreign manufacturers are supposed to pay GMP inspection fees to NDA prior to inspection. NDA also conducts cGMP inspections and monitors local pharmaceutical manufacturers to develop and maintain required technical capacity. Pre-licensing inspections are mandatory but technical assistance can be in form of training and re-inspection of manufacturing sites 3 times a year.
The inspection of imported drugs is done to ensure that they comply with NDA requirements (i.e. are registered drugs from approved sources), are of the identity, quantity and quality described on the relevant Pro-Forma Invoice and are of good quality.

The Inspectors based at the main ports of entry examine imported drug consignments to ensure that they comply with the requirements prior to granting NDA clearance of the shipment. Customs clearance must also be obtained before the drugs can be finally cleared for import into the country. Rejected consignments must be destroyed or re-exported to their countries of origin.

iii) **Drug Assessment and Registration Process:**

Drug Assessment and Registration is a control measure designed to ensure that only human and veterinary drugs of proven quality, safety and efficacy are licensed for importation into Uganda. The Department’s main function is to assess pharmaceutical products by evaluating documentary evidence in order to ensure that the product meets its intended purpose. Once a pharmaceutical product has been assessed and found to be compliant, it is included on a list of authorized drugs for use in Uganda.

The list of authorized drugs is often referred to as the National Drug Register (or the National Formulary) and the drugs are said to be registered (or have been granted marketing authorization). The register should be updated monthly.

Before a drug is authorized for use in Uganda, it must first be assessed and registered. Application forms are available from NDA headquarters or its website. A copy of guidelines as to how the application form should be filled accompanies the form.

The information required by NDA to assess a pharmaceutical product is stipulated in the application form which should be completely and accurately filled in.

The officer carrying out the Drug assessment checks/evaluates the dossier to check the information pertaining to the particulars of the applicant, manufacturer and the product being applied for (like brand name, INN name, pack size, and strength). This process should be completed within 3 months from the date applications are received by NDA if all the information has been supplied. Other features to be assessed include:
- Authorized Local Technical representative in Uganda, which should be a body corporate duly licensed to handle drugs in Uganda.

- Specifications of packaging materials and the composition of the product.

- Chemistry and Pharmaceutical information of the product

- Registration status of the product in other countries

- Pharmacology and toxicology of the product

- General information on the product (information on the product published in recognized international books, journal etc).

The data in the application forms is entered on SIAMED Program, (a software used for registering drugs). Information is then stored and samples of applications are retrieved and evaluation of dossiers done before presentation of drug applications to the Committee on the National Formulary (CNF) and the Authority, after which communication is made to applicants on the results of the evaluation.

During the registration process, processing of amendments is also done where information regarding any drug that may have changed (i.e. Brand name, strength, Pack size) needs to be updated. During registration, deletion of products from the National Drug Register is also done for the following reasons:

- A product profile may be undesirable,
- Adverse Drug Reactions reported (local or international),
- Non-payment of retention fees (the fee currently stands at US $300 for foreign manufactures or US $100 for local manufactures) or
- Non compliance to Current Good Manufacturing Practice (cGMP).

During the importation of drugs, data pertaining to a drug is scrutinised by Drug Inspectors to ensure that the information is similar to that contained in the application form earlier submitted and has been licensed for importation into Uganda.

iv) Drug Analysis Process:

NDA has an obligation to carry out testing of medicine and medical device samples according to international standards (BP, USP, Int.P, ASTM, ISO 4074) as per the National Drug Policy.
and Authority Act 1993 (Cap 206 Laws of Uganda) and NDA set a target to release results within 2 weeks.

All pharmaceutical products, whether locally manufactured or imported, are checked to ensure that they are of good quality and are safe for their intended use.

Medicine samples are collected from ports of entry into Uganda, hospitals, pharmacies, drug shops, and other drug outlets. On arrival at the Laboratory, drug samples go through a number of test procedures carried out by the Drug Quality Analysts and Laboratory Technicians. Tests include Physical Inspection, Weighing, Dissolution, Identification and Assay among others. Testing is done in accordance with Good Laboratory Practice (GLP).

After tests have been carried out, a report is written on whether a drug has passed or failed the test. This report is submitted through the Inspectorate Department to the Executive Secretary for communication to the client.

The Drug Analysts use Standard Operating Procedures to ensure that the samples are tested in accordance with International /WHO Standards. Substances used in the testing process include Chemical reference substances, Chemicals and Reagents obtained outside the country.

Mandatory post-shipment sample testing of male latex condoms, medical gloves and routine testing of insecticide treated mosquito nets (Long Lasting Insecticidal nets (LLINs), from the ports of entry, pharmacies and drug shops is also done.

Before local drug manufacturers avail products to the market, samples are first submitted to NDA for testing, vetting and approval. When the drug is approved, the manufacturer can then market the product. The NDQCL carries out pre-market analysis of the 3 initial consecutive batches of each new product formulation and reviews Batch Manufacturing records (BMRs).

NDQCL is also required to test 24 samples of traditional/herbal medicine.

V) **Drug Information Dissemination and Monitoring:**

The Department of Drug Information is responsible for disseminating drug information to all stakeholders to ensure that the public gets the right information on medicines and to increase public awareness of what NDA does.
The drug information dissemination process involves monitoring and approval of drug promotional materials like adverts to ensure that misleading information on medicines is minimised, especially in the area of herbal medicines.

The National Pharmacovigilance Centre and Regional Pharmacovigilance Centre are responsible for monitoring and reporting on Adverse Drug Reactions. They are involved in sensitizing health professionals on Pharmacovigilance and encouraging them to report ADR’s in various regions in the country. Reporting ADR’s starts by distributing forms to all Hospitals and Health Centres where every information on ADR is gathered and recorded by health workers. Follow up is then made and ADR forms collected on a monthly basis. The information is then entered onto the national adverse drug reaction database (VigiFlow) and sent to the Drug Information Department headquarters where the NPC is based. The information on the database is reviewed by expert reviewers and used to promote safe use of medicines at local, national and international levels, mainly by World Health Organisation (WHO), quarterly.
CHAPTER 4

FINDINGS

4.1 LEGAL MANDATE

4.1.1 Regulatory Framework:
Section 64 (1) of the NDPA Act requires the Minister in charge of Health, on the advice of the drug authority, to make regulations by statutory instrument for enforcing the provisions of the NDPA Act.

We noted that since 1993 when NDA was established, 21 guidelines have been made and some are currently in use. However, only 2 were gazetted\(^2\) into Statutory Instruments in 1995 and the rest have remained as guidelines. Apart from the two Regulations the rest of the guidelines are not legally enforceable; but used administratively for executing NDA work. A list of these regulations and the drafts is attached as appendix (iii).

The Board, at its sitting of 2\textsuperscript{nd} October 2008, recommended that a committee reviews all the guidelines in use with a view of making recommendations to the Board, which would be sent to the Minister in charge of Health for gazetting them into Statutory Instruments (Regulations). At the time of audit, they had not been gazetted.

Lack of relevant statutory instruments can be attributed to the slow pace at which NDA is developing these draft regulations. Since October 2008 when the Board recommended a review of the process, legal drafting has not been concluded.

NDA management however stated that the authority will forward the draft regulation to the Minister of Health for gazetting by January 2011.

Failure to have proper regulations impairs the ability of the Authority to execute its mandate of ensuring that only safe, efficacious and quality drugs are available to the public. NDA has also been involved in court cases arising out of inappropriate application of un-gazetted guidelines in carrying out enforcement activities.

4.2 LICENSING OF DRUG OUTLETS:

4.2.1 Issuing of Licences:

Section 14 (3) of the NDPA makes it an offence for one to operate a pharmacy or to sell drugs without a valid license. NDA is supposed to issue licences to drug outlets by 31st January every year and the license is valid until 31st December of that year.\(^3\)

Scrutiny of the database of operating drug outlets and the list of the licensed drug outlets as at 31st January of each calendar year revealed that no license had been issued within the stipulated timeframe. In addition, 100% of the respondents in regional offices confirmed that it had not been possible to issue licenses by 31st January, and believed that only 50% of the existing drug outlets may be licensed.

Our sample further revealed that licences are issued throughout the year from January to December as shown in the graph below.

**Figure 1:**

<table>
<thead>
<tr>
<th>NDA Regional Office</th>
<th>0-3 Months</th>
<th>4-6 Months</th>
<th>7-9 Months</th>
<th>10-12 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jinja</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Mbarara</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Tororo</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Lira</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

The main reasons advanced by NDA for the delays is lack of adequate staff to carry out mandatory (pre-licensing) inspections and issue licenses in time. Each regional office with an average of about 15 districts is managed by 1 person who cannot effectively handle the volume of work. At present, the Inspectorate Department is staffed with 18 Inspectors, including the Head of Department. We noted however that the existing structure does not

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\(^3\) NDA Strategic Plan July 2007 to June 2011 paragraph 1.2.6
reflect the required staffing levels for the Inspectorate Department and as such it is not possible to ascertain the optimal staffing levels to carry out its mandate.

Our interview with Regional Inspectors of Drugs revealed that such delays are also attributed to inadequate facilitation in terms of transport. The vehicles serving the regional offices have outlived their useful lives. We observed that 5 out of the 9 vehicles are as old as 7 or 5½ years instead of the expected four year cycle as shown in Table 3 below.

**Table 3: Vehicles for Regional Inspectors and their age.**

<table>
<thead>
<tr>
<th>Registration No.</th>
<th>Year of acquisition</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 UAA 848E</td>
<td>23/05/2005</td>
<td>Lira</td>
</tr>
<tr>
<td>2 UAA 506F</td>
<td>21/05/2005</td>
<td>Tororo</td>
</tr>
<tr>
<td>3 UAA 507F</td>
<td>21/05/2005</td>
<td>Mbarara</td>
</tr>
<tr>
<td>4 UAA 508F</td>
<td>21/05/2005</td>
<td>Hoima</td>
</tr>
<tr>
<td>5 UAJ 375X</td>
<td>27/01/2010</td>
<td>Central</td>
</tr>
<tr>
<td>6 UAJ 095X</td>
<td>14/08/2008</td>
<td>Central</td>
</tr>
<tr>
<td>7 UAA 805X</td>
<td>14/08/2008</td>
<td>Busia/Malaba</td>
</tr>
<tr>
<td>8 UAA 537E</td>
<td>05/03/2003</td>
<td>Jinja</td>
</tr>
<tr>
<td>9 UAJ 093X</td>
<td>05/03/2008</td>
<td>Arua</td>
</tr>
</tbody>
</table>

Source: NDA Administration Department

Delay in issuing licenses in time encourages illegal operators of drug outlets and poses a risk of exposing the people to sub-standard drugs on the market. NDA is also not able to collect all the revenue as budgeted from drug outlets to finance service delivery.

**4.2.2 Publicizing Licensed Drug Outlets:**

NDA is required to publicise a list of licensed drug outlets in the media and website by 31st March of every year. ⁴

Scrutiny of media records and the NDA website revealed that NDA did not fully comply with this requirement.

A review of the NDA website indicated that NDA displayed data on licensed Pharmacies for the year 2010 in November 2010. We further noted that NDA last publicised a list of licensed Pharmacies in the press in November, 2008 for the year 2008. For calendar years 2009 and 2010, a list of licensed drug outlets was not published. Efforts to have a list for the year 2009 published were halted by management preferring the use of booklets.

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⁴ NDA Strategic Plan July 2007 to June 2011, paragraph 1.2.7 page 23.
In 2009, NDA introduced a method of sending short messages on cell phone (SMS) to help the public identify licensed operators. Publicity of this initiative however is still low.

The reason advanced for stopping publications of licensed drug outlets was that the lifespan of a newspaper is limited compared to that of booklets. Management also indicated that newspaper adverts are costly. There was no evidence of the analysis on cost estimates for printing and distributing of the booklets to justify the change. Besides, the target population was not specified to compare the benefits of the proposed method. For drug shops, NDA management indicated that they would use journals and distribute them to various districts. To-date, no journal has been published and distributed to districts.

Failure to provide the public with information regarding legal outlets denies them vital information to decide where to buy drugs. Besides, publicising the list would encourage unlicensed outlets to strive to fulfil the requirements.

4.2.3 Closing of un-licensed Drug Outlets:
Paragraph 1.4 of the Licensing Requirements stipulates that unlicensed premises should be subject to closure and all operations to cease forthwith.

For purposes of licensing, drug outlets can be categorised as those already registered and have applied for renewal of license, registered but have not applied for renewal and unregistered (illegal outlets).

A review of the database of operating drug outlets revealed that no unlicensed drug outlet had been closed after 31st January as explained in 4.2.1 above.

Management explained that NDA has not been successful in identifying and closing all illegal outlets (especially drug shops) as they tend to suspend business immediately they are aware of NDA’s field inspections while others operate in hard to reach areas. While efforts were made to close some illegal drug outlets as and when identified, the success of this exercise was dependant on the level of inspections carried out by NDA. In the Northern Region (Lira), for example, illegal outlets for the 3 months in the third quarter of 2009
calendar year stood at 50% in July, 56% in August and 25% in September, which is high, in all the 3 cases.

Management further explained that they cannot close the unlicensed outlets that have submitted applications because the delay of issuance of licenses is partly due to their constraints in processing them. However, outlets that do not meet deadlines are always closed.

Audit also attributes laxity to close and eliminate illegal operators to lack of segregation of DADI’s roles in the current processes of distributing and collection of application forms, licensing, inspection and at times collection of fees, which functions are all performed by the same staff.

Failure by NDA to identify and close unlicensed drug outlets encourages prevalence of illegal operators who may not be easy to regulate, yet they serve many people especially in the rural/remote areas where alternative services may not be available. Besides, such operators may be a source of sub-standard drugs, which impairs NDA’s objective of ensuring that quality, safe and efficacious medicines are availed to the public.

4.3 ASSESSMENT/EVALUATION AND REGISTRATION OF DRUGS:

4.3.1 Assessment/Evaluation of dossiers:

NDA is required to assess pharmaceutical products by evaluating documentary evidence in order to ensure that the product meets its intended purpose. NDA is also required to evaluate 100% of dossiers submitted within 3 months.\(^5\) Once a pharmaceutical product has been assessed and found to be compliant, it is included on a list of authorized drugs for use in Uganda [National Drug Register].

A review of the register of dossier applications submitted for evaluation and status progress reports revealed that all dossiers were not evaluated within the prescribed timeframe.

\(^5\) [NDA Strategic Plan July 2007 to June 2011 paragraph 3.1.8 page 51].
A test-check of 215 dossier applications for a four year period (2006/07 to 2009/10) revealed that on average dossier evaluation took 5 months in 2006/07, 4 months in 2007/08, 3 months in 2008/09 and 5 months in 2009/10 resulting in delays of between 3 to 9 months between the date of application and completion of evaluation as shown in the graph below.

Figure 2:

NDA management attributed the delays to shortage of staff to handle the workload; inadequate facilitation, even when applicants have paid the relevant fees; increased number of dossier applications; and lack of specialised skills to evaluate different products (veterinary, human, biological, nutritional/food supplements, medical devices or public health products). The total funding received by the Department was only 44% of the required budget, yet NDA got over Shs. 9.5bn or 80% of its total revenue from the activities of this Department over the same period. Scrutiny of performance reports further revealed that in the FY2008/09 only Shs 62.9m or 40% was released for Dossier Evaluation activities against the budgeted amount of Shs 157.5m. Lack of prioritisation cannot be ruled out.

Interviews with NDA staff also revealed that use of SIAMED software for assessment and registration of drugs in recording and retrieval of data has proved to be problematic. The software (SIAMED) is not web-based, lacks adequate support from the vendor and easily hangs when many users are entering data simultaneously thus limiting speedy entry of
transactions, sharing and easy retrieval of data. However efforts are underway to procure a new drug assessment and registration program, with the help of development partners, according to management.

Delays in evaluation of dossiers may lead to complaints from importers since they pay a fee to be evaluated/assessed by NDA. The delays may compound illegal entry/importation of unregistered medicines on the market thereby denying consumers of an independent assessment of the safety, efficacy and quality of medicines. This may also cause drug stock-outs and the public may also be denied access to drugs required to save the lives of patients that may need those products. Fewer drugs on the market also limit consumer choice and may lead to high prices which also denies the public cheaper and quality medicines.

4.3.2 **Registration and Updating of the National Drug Register:**
Section 35 of the NDPA Act requires NDA to register or delete any drug on the Drug Register after scientifically examining any drug for purposes of ascertaining efficacy, safety and quality. The drug register should be updated monthly upon assessment of amendments/variations, payment of retention fees, cGMP compliance and ADR issues.

We noted that NDA registers drugs on the National Drug Register when evaluation of dossiers is complete. The analysis of records revealed that the registration of drugs in the Drug Register was taking an average of 4 to 10 months after completion of evaluation.

**Figure 3:**

<table>
<thead>
<tr>
<th>Months</th>
<th>2006/07</th>
<th>2007/08</th>
<th>2008/09</th>
<th>2009/10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time Taken to Register Drugs</td>
<td>10</td>
<td>6</td>
<td>4</td>
<td>6</td>
</tr>
</tbody>
</table>
Management explained that the use of SIAMED software delays registration/deletion of drugs from the register since it is not integrated to aid management in identifying items due for deletion for non-payment of retention fees.

The delays may increase entry of un-registered drugs into the country.

### 4.4 DRUG ANALYSIS:

#### 4.4.1 Time of releasing laboratory test results:

Chemical analysis should take 2 weeks from the time a consignment is sampled to when results are released.  

We reviewed a register of samples submitted to the lab and the test results released and noted that there were some delays in releasing laboratory test results. While NDQCL management indicated that releasing test results took them on average 2 to 14 days, analysis of test results for anti-malaria and anti-retroviral drugs for the period 2007 to 2009 however indicated that releasing test results was in a number of cases taking more than 2 weeks as shown below in Table 4.

| Table 4: Anti-malarials and ARVs Sample Test Results for the period 2007-2009 |
|-----------------------------------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Time (Weeks) | 2007 | 2008 | 2009 |
|               | Antimalarial | ARVs | Antimalarial | ARVs | Antimalarial | ARVs |
| Samples   | %age | Samples   | %age | Samples   | %age | Samples   | %age |
| Within 2 weeks | 469  | 79% | 389 | 88.4% | 187 | 46.5% | 206 | 64.0% | 38  | 57.4% | 39  | 57.4% |
| Above 2 weeks  | 125  | 21% | 51  | 11.6% | 215 | 53.5% | 116 | 36.0% | 164 | 42.6% | 29  | 42.6% |
| Total        | 594  | 100.0% | 440 | 100.0% | 402 | 100.0% | 322 | 100.0% | 202 | 100.0% | 68  | 100.0% |

Source: OAG Analysis of NDQCL data.

While more samples were tested in 2007, a higher percentage (79%) was also released within 2 weeks. The time of releasing results for subsequent years however was declining even when the samples submitted for both anti-malarials and ARVs had reduced.

Management attributed delays to lack of personnel, inadequate testing equipment and delays in procurement of chemical substances that may not be in stock at the time of

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6 Guidelines for Importation and export of drugs Paragraph 11 - Procedures for Importation.
submitting samples to the laboratory with emergency procurement taking up to 6 months. Lack of reference standards also contributes to delays in testing samples as some drugs may not be on the register. Management further explained that the board through the Committee of National Formulary changed the policy from mandatory analysis to risk-based analysis in 2008. The method enabled them to sample and test a wide range of medicines but other conditions like human resources, equipment and laboratory space remained the same.

Analysis of budget and actual expenditure for the same period revealed overall underfunding. We further noted that of the total required funds for key laboratory supplies like spares parts, chemicals and reference substances, calibration and maintenance of equipment were not fully funded as shown in Table 5 below.

**Table 5: Financing Laboratory operations for the year 2007/08 to 2009/2010**

<table>
<thead>
<tr>
<th>Item</th>
<th>2007/08</th>
<th>2008/09</th>
<th>2009/10</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Budget</td>
<td>Released</td>
<td>%age Released</td>
</tr>
<tr>
<td>Purchase of spare parts</td>
<td>153.6</td>
<td>87.9</td>
<td>57%</td>
</tr>
<tr>
<td>Purchase of columns for HPLC and GC</td>
<td>37.5</td>
<td>4.1</td>
<td>11%</td>
</tr>
<tr>
<td>Purchase of Chemicals and Reagents</td>
<td>83.2</td>
<td>60.9</td>
<td>73%</td>
</tr>
<tr>
<td>Purchase of chemical Reference Substances</td>
<td>60.0</td>
<td>76.8</td>
<td>128%</td>
</tr>
<tr>
<td>Calibration of equipment</td>
<td>27.0</td>
<td>0.0</td>
<td>0%</td>
</tr>
<tr>
<td>Maintenance of Lab Equipment</td>
<td>70.5</td>
<td>6.3</td>
<td>9%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>431.8</strong></td>
<td><strong>236.0</strong></td>
<td><strong>55%</strong></td>
</tr>
</tbody>
</table>

*Source: NDA Performance Reports 2007/08 to 2009/10.*

We also noted that NDA has not made a scientific study on the average time required to produce specific tests and monitor staff performance. Limited use of Mini-Labs which were intended to work as a stop-gap measure and provide quick results to inspectors in regional offices was also identified as another possible cause of delay.

Delays in releasing laboratory tests translate into dissatisfaction of clients. We noted that NDA spent Shs 9.3m in 2007/08, Shs 30.8m in FY2008/09 and Shs 19.9m in 2009/10 on outsourcing laboratory services outside the country, some of which could have been saved if all the necessary equipment, staff and other substances were in place. Benefits expected from use of minilabs cannot be realized.
4.4.2 **Capacity of the Laboratory:**

**(i) Personnel:**
Section 6.1 (part 1) of the WHO Good Practices for Pharmaceutical Quality Control Laboratories requires that laboratories for drug testing and analysis should have sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned functions.

We reviewed the NDA structure and current staffing levels and noted that the laboratory does not have sufficient staff as prescribed by WHO. We noted that NDQCL Department made an evaluation and presented a proposal of 52 staff to enable the proper functioning of the lab. Out of this number, the Department has only 11 officers.

Management attributed lack of sufficient personnel to failure by government to provide NDA with funding to fill existing posts. However a review of budgets and other correspondences, revealed that there was no evidence that NDA management had made efforts to secure government funding.

Inadequate staffing to test and analyse drugs impairs NDA’s objective of ensuring that only drugs of the required quality are accessed by the population. It also increases workload on existing staff and delays testing and release of sample results.

**(ii) Equipment:**
Section 8.2 and 8.3 (part 1) of the WHO Good Practices for Pharmaceutical Quality Control Laboratories stipulates that the laboratories for testing and analysis should have the required test equipment, instruments and other devices for the correct performance of the tasks and these should meet the relevant standard specifications.

Interviews carried out with the management of NDQCL revealed that the laboratory did not have the equipment required for key operations like micro-biology tests and traditional/herbal medicine testing. During inspection, we observed that some equipment, like the HPLC shown in Picture 1 below, required major repairs and had been out of use for more than 7 months. Some of the stock of lab equipment is as old 9 years and obsolete with frequent breakdowns.
Lack of sufficient funds to procure the necessary equipment was highlighted by management as a reason of inadequate lab equipment. NDA had failed to collect outstanding debts. The debt portfolio stood at Shs 2.5bn as at 30th June 2009 and Shs 3.3bn as at 30th June 2010 of which the line Ministry (Ministry of Health) alone owed NDA about 25% and 40% respectively. Part of the verification fees is meant to ascertain the quality of medicines by NDQCL before registration and market authorisation in Uganda.

Lack of equipment impairs the ability of the laboratory to test and provide sample results as required. Besides, NDQCL has not been able to carry out microbiology and traditional/herbal medicine testing which puts the public at risk.

(iii) Laboratory Space:
Section 7.9 part 1 of the WHO Good Practices for Pharmaceutical Quality Control Laboratories requires that the storage facilities of a laboratory should be well organised for the correct storage of samples, reagents and equipment.

We inspected the NDQCL based in Mulago and observed that the storage facilities for reagents inside the laboratory were well organised. However, some of the lab equipment and several boxes of samples were kept in the corridors due to limited storage space as shown in the picture 2 below. Space for keeping documents was also a challenge.
During the course of the audit, we inspected the on-going works by NDA to construct a bigger laboratory using internally generated funds to be completed in March 2011. Inadequate storage space can affect proper storage for ease of identification and retrieval of samples and equipment. It can also cause congestion, making it difficult to clean the premises. Effects of accumulated dust, poor aeration and effects of dampness and heat under such circumstances can also affect the lifespan of the samples which in turn impacts on test results.

4.4.3 Testing Traditional/herbal medicines:

NDA is supposed to test 24 samples of traditional/herbal medicine per year.\textsuperscript{7}

A review of operational plans and annual performance reports and interviews revealed that NDA did not test traditional/herbal medicines.

NDA’s failure to test these samples was attributed to lack of adequate space in the NDQCL to create a dedicated traditional/herbal testing unit, lack of equipment like Atomic

\textsuperscript{7} NDA Strategic Plan July 2007 to June 2011, paragraph 9.2.5 page 83.
Absorption Spectrophotometer (AAS), High Performance Thin Layer Chromatography (HPTLC) and Infra Red (IR). Lack of staff with technical skills in testing herbal medicine was another reason advanced by management. While NDA had planned to train 4 members of staff in testing traditional/herbal by December 2008, we noted, however, that none were trained until the end of the 2009/10 financial year (June 2010), when only 2 members of staff from the NDQCL were trained. Another reason given was lack of subsidiary legislation in place to enforce compliance.

As a result, the public may be exposed to medication which does not guarantee purity, safety, potency and efficacy. By their nature, traditional/herbal medicines are not regulated like other conventional medicines since they lack common standardization and scientific data to support the medicinal activity claimed and their assumed safety and efficacy. The benefit of testing to ascertain the purity, concentration or labelling claims of herbal medicines is not achieved. This may also expose the consumers to adverse reactions.

4.5 **DRUG INSPECTION**

4.5.1 **Inspection of Drug Consignments entering the country:**

NDA is required to inspect all consignments of drugs and pharmaceutical products entering the country on the same day\(^8\). All rejected consignments must be destroyed or re-exported to the countries of origin at the expense of the importer.

A review of weekly summary reports of consignments at entry points revealed that all consignments of drugs and pharmaceutical products entering the country are not inspected on the same day.

A sample of weekly reports on consignments each month for the 4 years under audit revealed that on average it took between 4 to 13 days as opposed to the stipulated period of same day as shown in the graph below.

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\(^8\) NDA Strategic Plan July 2007 to June 2011 page 29 paragraph 3.3.5
Through interviews, we noted that URA informs NDA of any drug consignment that may be at entry points. We, however, noted that this arrangement is not formal and is not supported by a memorandum of understanding between the 2 organisations. There are no meetings initiated by NDA to harmonise this relationship.

The results of inspection of consignments at entry points for the period July 2008 to June 2010 revealed that an average 2% of the consignments were rejected as shown in Appendix (iv). We were unable to obtain evidence to confirm that all rejected consignments were actually destroyed under NDA supervision or re-exported to their countries of origin.

The variations highlighted above were attributed to inadequate transport and lack of staff to inspect the consignments and verify relevant import documents. Busia and Malaba entry points along the Kenya/Uganda border are managed by only 1 person who moves from 1 station to another, which makes it difficult for him to inspect all consignments as and when they arrive in the country.

Failure to inspect consignments in time may result into importation of wrong drugs into the country. The delays experienced by importers may create undue pressure on NDA staff,
impair the image of NDA, compromise objectivity and delay critically needed drugs which may put the lives of people at risk. If rejected consignments are not destroyed or re-exported immediately, unscrupulous people may divert them into the market and increase a risk of sub-standard medicines in the market.

4.6 **DISSEMINATION OF DRUG INFORMATION:**

4.6.1 **Developing, reviewing and disseminating guidelines on of promotion and advertisement of medicines:**

Section 64 (1) (e) of the NDPA requires the Minister in charge of Health, on the advice of the drug authority, to make regulations by statutory instrument prohibiting, regulating or restricting the manufacture, sale or advertising of drugs, pharmaceutical preparations and therapeutic substances. NDA is supposed to develop, review and disseminate guidelines for promotion and advertising by June 2008. [NDA Strategic Plan July 2007 to June 2011 July 2006 to June 2011, 1.4.1 page 89].

Examination of the records availed during audit indicate that while NDA had developed guidelines for promotion and advertising, the guidelines had not been reviewed and disseminated by June 2008.

Delays in the legal drafting of guidelines into Regulations (see 4.1.1 above) was highlighted as the main reason for failure by NDA to disseminate information on advertising and promotion.

Failure to have proper guidelines on advertising and promotion of medicines and disseminating them to relevant stakeholders impairs the ability of the NDA to execute its mandate of regulating drug promotional activities.

The public is also exposed to the risk of getting misleading information about the drugs on the market.

4.6.2 **Public awareness on rational use of drugs:**

Section 59 (2) (a) of the NDPA requires NDA to promote public awareness and knowledge of the rational use of drugs.
A review of training reports revealed that NDA is not conducting public awareness programs on drug and substance abuse.

We noted that NDA was expected to carry out 6 sensitisation events on drug and substance abuse each year but no such event was organised by the Drug Information Department. Radio programs for purposes of sensitisation and radio awareness were suspended in 2007. NDA management attributes this lapse to inadequate funding.

Failure to sensitise the public on drug and substance abuse is an indication that NDA has failed to protect society against the associated harmful effects.

4.7 MONITORING AND CONTROL:

4.7.1 Monitoring and Approval of drug adverts and promotional material:
Section 33 (1), (a), (b) and (c) and the Fifth schedule thereto, of the National Drug Policy and Authority Act cap. 206 also prohibits the advertisement of drugs and descriptive matter likely to lead to the prevention or treatment of any disease for purposes of termination or influencing the course of human pregnancy, or for purposes of enhancing human potency and treatment of diseases like Hernia, Diabetes, Heart disease, cancer, goitre and many other diseases in the fifth schedule to the Act, unless a patent has been obtained for that purpose (S.33 (3) (c). All Drug promotions and adverts should be approved by NDA. ⁹

A review of documents revealed that promotional materials for conventional medicines are approved by NDA. Approval of adverts for traditional/herbal and complimentary medicines was however discontinued in 2008. Interviews conducted with NDA management also indicate that monitoring of adverts is not done. We also observed that sensitisation of stakeholders involved in the promotion and advertising of pharmaceutical products has not been done for the last 3 years.

The reason for discontinuing approval of adverts in this category was that NDA regulates the products only and not the practice. Audit noted that in November 2008, a joint statement was issued by NDA, Uganda Medical and Dental Practitioners Council, Media Council, and Broadcasting Council directing all media houses and the general public to stop

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⁹ NDA Strategic Plan July 2007 to June 2011 paragraph 1.4.2 page 89.
advertising and claiming that certain persons and/or medicines in their possession has the capacity to heal several diseases. Failure to monitor adverts was attributed to NDA’s failure to designate a dedicated person to monitor and report on adverts. Lack of funds and failure by NDA to gazette the guidelines into statutory instruments was also highlighted as another reason for limited sensitisation activities.

Failure to approve and monitor adverts and promotional materials has the potential of exposing the public to misleading drug information. This further poses a risk of using inappropriate medication, risking the lives of people and attendant effects of adverse reactions. Ensuring that promotion and advertising conform to appropriate procedures also becomes difficult. Besides, illegal adverts have continued unabated in the print and electronic media advertising prohibited services like treatment of acute medical conditions such as enhancing human potency, change of pregnancy, hernia, diabetes, syphilis and many other medical conditions. Hawking medicines ranging from over the counter drugs to herbal or food supplements in buses, markets and other public places or mounting public address system is on the increase. This practice exposes such items to extreme conditions like heat which can cause deterioration of their active ingredients and compromise their efficacy.

4.7.2 **Distribution and collection of Adverse Drug Reactions (ADR’s) forms:**

The National Pharmacovigilance Centre (NPC) is required to distribute ADR report forms and collect reports from health facilities. ADR forms should be distributed and collected on a monthly basis from hospitals and health centres.

Interviews with NPC and Regional Pharmacovigilance Centre Coordinators revealed that this is not the case.

We observed that ADR forms are distributed to hospitals and health centres or districts in bulk, usually once a year but collection of the forms by the Regional Pharmacovigilance Centre Coordinators is done on quarterly basis during other hospital support supervision activities. NPC staff also pick forms while conducting support supervision activities.

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11 NDA Strategic Plan July 2007 to June 2011 paragraph 3.4.11 page 94.
ADR forms are not collected regularly as required because they are not filled. Some health centre workers do not fill ADR forms even when there are patients under ADR observation because the forms are too detailed and complex to understand. They are also unable to fill the forms because of lack of knowledge. Failure to fill the forms was also attributed to fear of litigation since health workers attending to patients are the same people expected to fill the ADR forms. Meanwhile, distribution, filling, collection and reporting of ADR cases is not mandatory; it is persuasive and the staff handling these functions are not NDA staff. Enforcing compliance becomes difficult under these circumstances.

43% of the respondents from Regional Pharmacovigilance Centres indicated that lack of sensitisation was a cause of poor response, another 43% revealed that health centres failed to return ADR forms while 14% revealed that NDA does not provide them with facilitation to collect these forms from the health centres on a monthly basis. An operating imprest of Shs. 100,000 per month was only released once for 1 quarter in FY 2009/10 and stopped because of poor accountability. Further examination of estimates and actual releases for FY2008/09 revealed that of the Shs 25.4m that was budgeted for collection of ADR forms, only Shs 7.1m, representing 28% was released. This performance level impairs successful implementation of planned activities.

Failure to fill the ADR forms and submit them promptly impairs timely reporting of ADR cases. When existing or observed ADR cases are not reported, proper management and timely corrective measures may not be taken which puts the lives of the public at risk.

4.7.3 Reporting Adverse Drug Reactions:

The National Pharmacovigilance Centre is required to commit reports to WHO Drug Monitoring Centre in Uppsala, Sweden and to disseminate relevant information to Health Professionals, Policy makers and other stakeholders. NDA is also expected to give feedback on Adverse Drug Reactions (ADR) to International agencies on a quarterly basis.

It was noted that reports on ADR are recorded and filled in a software (VigiFlow) which relays this information to the World Health Organisation.

We visited the National Pharmacovigilance centre based at NDA headquarters and 9 out of the 12 Regional Pharmacovigilance Centres and noted that 4 of them carry out minimal

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12 A Guide to Detecting and Reporting Adverse Drug Reactions (paragraph 2.2 page 5), December 2008.
13 NDA Strategic Plan July 2007 to June 2011 paragraph 3.4.12 page 94.
activities and do not have facilities (e.g. space and equipment like computers) for use of VigiFlow. Arua, Jinja and Kabale do not have computers and only send ADR forms to the NDA National Pharmacovigilance Offices in Kampala. Although the Mulago National Referral Hospital Pharmacovigilance centre was provided with a computer, no records had been entered at the time of audit. Besides, the centre does not send any forms to NDA. Meanwhile NDA procured 7 modems for Hoima, Fort-Portal, Gulu, Mbale, Soroti and Masaka and pays for subscription for internet connectivity.

We noted that even after the forms have been collected, it took NDA 3 to 31 months on average to analyse and record them on VigiFlow.

**Figure 5:**

![Average Time Taken to Record and Report ADR Forms (2006-2009)](image)

OAG analysis of ADR reports by the National Pharmacovigilance Centre.

Further scrutiny of the ADR forms collected by the National Pharmacovigilance Centre from various health centres in 8 districts revealed that 66% of the forms had not been processed at all (Table 6 below refers).

**Table 6: ADR Forms Collected and Processed by the National Pharmacovigilance Centre**

<table>
<thead>
<tr>
<th>District</th>
<th>Forms Collected</th>
<th>Forms Processed</th>
<th>%age Processed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Kabale</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>Soroti</td>
<td>29</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>Gulu</td>
<td>32</td>
<td>10</td>
</tr>
<tr>
<td>4</td>
<td>Arua</td>
<td>36</td>
<td>24</td>
</tr>
<tr>
<td>5</td>
<td>Nebbi</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>6</td>
<td>Mbale</td>
<td>14</td>
<td>2</td>
</tr>
<tr>
<td>7</td>
<td>Mbarara</td>
<td>27</td>
<td>1</td>
</tr>
<tr>
<td>8</td>
<td>Masaka</td>
<td>30</td>
<td>21</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>174</strong></td>
<td><strong>59</strong></td>
<td><strong>34%</strong></td>
</tr>
</tbody>
</table>
Interviews conducted at National Pharmacovigilance Centre revealed that some Regional Pharmacovigilance coordinators are not able to use the VigiFlow software. The software is also slow and is associated with system overload which impairs speedy entry of data. Reports also indicate that about 80% of the forms submitted are not filled properly, have missing data leading to rejection by the system. This also delays data processing and analysis. Limited support supervision from the NDA to the regional centres also weakens the reporting process. Supervision of staff who are not employed by NDA is also a challenge as observed in 2 out of the 7 centres where coordinators have since left the stations without making proper accountability or even handing over the property entrusted to them.

Late reporting and analysis of ADR cases impairs NDA’s role of proper identification of the signals necessary for evidenced based regulatory decisions or follow-up action regarding changing lines of drugs, withdrawal of products or batch from the market. Spontaneous reporting by nature has its own weaknesses. Observing trends for informed decision making becomes difficult.
CHAPTER 5

CONCLUSIONS

From the audit findings outlined above, the following conclusions were made to highlight the opinions observed in the course of the audit.

5.1 LEGAL MANDATE

5.1.1 Regulatory Framework:
NDA has not gazetted guidelines into statutory instruments as required by law. This impairs the ability of the authority to execute its mandate.

5.2 LICENSING OF DRUG OUTLETS:

5.2.1 Issuing of Licences:
NDA does not issue licences to all drug outlets by 31st January of each year as required. This encourages illegal operators of drug outlets and poses a risk of exposing the people to sub-standard drugs on the market. NDA is also denied revenue from drug outlets as budgeted for service delivery.

5.2.2 Publicizing Licensed Drug Outlets:
NDA does not publicise licensed drug outlets. This limits access to vital information by the public as to the legal drug outlets where consumers would confidently buy medicine with ease.

5.2.3 Closing of un-licensed Drug Outlets:
NDA does not close all unlicensed drug outlets posing a risk to the population regarding the safety and efficacy of medicines available on the market. This encourages prevalence of illegal operators, and subsequently sub-standard drugs which impairs NDA’s objective of ensuring that quality, safe and efficacious medicines are availed to the public.

5.3 ASSESSMENT/EVALUATION AND REGISTRATION OF DRUGS:

5.3.1 Assessment/Evaluation of dossiers:
NDA takes too long to evaluate dossiers. This may in turn reduce competition and result in increased prices and reduced access of essential medicines on the market.
5.3.3 **Registration and Updating of the National Drug Register:**
NDA does not update the National Drug Register on a monthly basis which may result into entry of unregistered/unauthorized drugs in the Country.

5.4 **DRUG TESTING AND ANALYSIS:**

5.4.1 **Time of releasing laboratory test results:**
NDA does not release all laboratory test results in 2 weeks from the time a consignment is sampled. This may impair timely decision-making and lead to dissatisfaction by clients.

5.4.2 **Capacity of the Laboratory:**
NDA does not have the required laboratory capacity in terms of personnel, laboratory equipment and storage space. This compromises the ability of the lab to ensure the quality of the drugs consumed by the public.

5.4.3 **Testing Traditional/herbal medicines:**
NDA did not test traditional/herbal medicines for the period under review. This exposes the public to sub-standard drugs without proven safety, quality and efficacy.

5.5 **DRUG INSPECTION:**

5.5.1 **Inspection of Drug Consignments entering the country:**
NDA did not inspect all drug consignments at border entry points on the same day. This may impair the image of NDA, compromise objectivity and delay critically needed drugs which may put the lives of people at risk.

5.6 **DISSEMINATION OF DRUG INFORMATION:**

5.6.1 **Developing, reviewing and disseminating guidelines on promotion and advertisement of medicines:**
NDA has not made statutory instruments for regulating advertisement of pharmaceutical products. The public is exposed to the risk of getting misleading information about the drugs on the market.
5.6.2 **Public awareness on rational use of drugs:**
NDA has not been vigilant in sensitizing the public on rational use of drugs. Failure to sensitise the public on drug and substance abuse is an indication that NDA has failed to protect society against the associated harmful effects.

5.7 **MONITORING AND CONTROL:**

5.7.1 **Monitoring and Approval of drug adverts and promotional material:**
Apart from conventional medicines, NDA does not approve traditional/herbal drug adverts and promotional materials. Besides, monitoring of adverts is not done. This has the potential of exposing the public to misleading drug information as evidenced by illegal adverts in the print and electronic media and hawking of drugs.

5.7.2 **Distribution and collection of ADR forms:**
ADR forms are not collected from health centres on monthly basis, implying that cases of adverse drug reactions cannot be reported and followed up in time. This impairs timely reporting of ADR cases and affects proper management and timely corrective measures thus risking the lives of the people.

5.7.3 **Reporting Adverse Drug Reactions:**
NDA does not make timely feedback on ADR which in turn limits the information for informed decision making on drugs. This impairs NDA’s role of proper identification of the signals necessary for evidenced based regulatory decisions.
CHAPTER 6

RECOMMENDATIONS

Based on the findings and conclusions presented above, the following recommendations aimed at addressing the existing deficiencies have been suggested.

6.1 LEGAL MANDATE

6.1.1 Regulatory Framework:
Management should expedite the process of gazetting regulations to enable the authority to enforce its mandate effectively.

6.2 LICENSING OF DRUG OUTLETS:

6.2.1 Issuing of Licences:
NDA should fill existing positions and carry out a comprehensive evaluation of its human resource requirements and determine the optimal staffing levels to effectively carry out its mandate.

Management should ensure that regional offices are provided with appropriate transport facilities to enable them carry out pre-licensing inspection for timely issuance of licenses.

It is also advised that NDA starts the process of licensing early to avoid unnecessary delays.

6.2.2 Publicizing Licensed Drug Outlets:
NDA should ensure that the public is availed free and timely access to information regarding licensed drug outlets.

6.2.3 Closing of un-licensed Drug Outlets:
NDA should involve local leaders in their respective areas in approving new operators, closing unlicensed premises, renewing licenses or carrying out inspections so as to increase cooperation and effectiveness of inspections.
NDA should also strengthen and streamline the role of Inspectors to improve on existing weaknesses in the process of authorisation, inspection and enforcement. Management should also ensure that police officers of appropriate ranks are deployed whenever enforcement activities are taking place. NDA should encourage formation of Drug outlet owners towards self regulation.

NDA is advised to make formal arrangements with district management regarding DADI’s by way of Memorandum of Understanding, clearly stipulating the terms and conditions of such engagements.

6.3 ASSESSMENT/EVALUATION AND REGISTRATION OF DRUGS:

6.3.1 Assessment/Evaluation of dossiers:
NDA management should consider prioritising funding of dossier evaluation since it generates about 80% of NDA revenue whereas it is provided with only 44% of its budgeted requirements.

Where staff strength within NDA structure does not match with the dossier applications received, management should consider the option of outsourcing the activity.

NDA should also consider the option of establishing a dedicated information centre/front desk to guide applicants on NDA requirements, screen applications and provide timely advise on potential queries that may unnecessarily prolong evaluation of dossiers. It is also necessary to cooperate with other reputable drug regulatory agencies to share information on similar products that have been evaluated by their peers to reduce on existing workload, without compromising the quality of the products entering the Ugandan market.

6.3.2 Registration and Updating of the National Drug Register:
NDA should ensure that all user needs regarding identification of drugs for deletion and reminders on the respective due dates for payment of retention fees are taken into account by the software.

6.4 DRUG TESTING AND ANALYSIS:

6.4.1 Time of releasing laboratory test results:
Management should put in place a comprehensive plan to ensure that Mini-Labs are used for testing samples at regional offices.
NDA should improve procurement practices to ensure that laboratory inputs are available at all times to avoid delays of results.

They should also avail staff with the necessary reference standards to the laboratory to improve efficiency.

6.4.2 **Capacity of the Laboratory:**
Government, through the Ministry of Health, should play a leading role in ensuring that the NDA as a government drug regulatory body has adequate space, equipment and staff to execute its mandate.

6.4.3 **Testing Traditional/herbal medicines:**
- Steps should be taken to ensure that all the required staff in testing of traditional/herbal medicines are trained.
- Management should procure the equipment necessary for testing traditional/herbal medicines.
- A comprehensive system of regulating herbal medicines should be put in place by way of statutory instrument to save the public from quack products on the market, promote local research/production and save lives.
- Collaboration with other agencies involved in traditional/herbal medicines like Natural Chemotherapeutics Research Laboratory should be encouraged where capacity within NDA is inadequate.

6.5 **DRUG INSPECTION:**

6.5.1 **Inspection of Drug Consignments entering the country:**
- Management should put in place a proactive arrangement to ensure that all consignments are inspected within agreed timeframes and all key entry points are staffed.
- Provision of testing equipment at designated ports of entry should be prioritised to reduce the time of inspecting consignments and increase the number of samples tested.
- NDA should take a leading role to formalise its working relationship with URA and ensure that customs staff are regularly sensitised about the importance of quick notification of NDA and meetings held regularly to enhance coordination.
- NDA should liaise with other stakeholders to ensure that a system is put in place that would ensure that rejected consignments are destroyed or re-exported without delay.
6.6 DISSEMINATION OF DRUG INFORMATION:

6.6.1 Developing, reviewing and disseminating guidelines on promotion and advertisement of medicines:
Management should prioritise and expedite the legal drafting process to ensure that the guidelines are gazetted so as to disseminate drug information to the public.

6.6.2 Public awareness on rational use of drugs:
Priority should be given to awareness activities in order to protect the public against the harmful effects of drug and substance abuse. Management should harmonise Drug Information Department activities with those of the Public Relations Office to ensure harmony and coordination.

6.7 MONITORING AND CONTROL:

6.7.1 Monitoring and Approval of drug adverts and promotional material:
To improve the system of approving adverts, NDA should play a leading role in collaborating with other agencies involved in advertising, like media houses and their regulatory agencies, local councils managers of public places, like markets or bus owners, to stop illegal adverts. Priority in resource allocation should also be given to monitoring adverts to safeguard the public from misleading information. Public awareness campaigns should be enhanced to empower the public and safeguard it against the effects of wrong drug information. NDA should assign and facilitate a dedicated person to monitor and report on advertisement of drugs and promotional material.

6.7.2 Distribution and collection of Adverse Drug Reactions forms:
- The Ministry of Health should streamline the functions and activities relating to ADR reporting.
- It is also recommended that the ministry incorporates ADR reporting in the overall Health Information Management Systems so that the forms are collected with other routine documentation.
- Sensitising health workers on ADR reporting and skills on filling the forms should be continuous with a view of encouraging health workers to record all possible drug reaction observed. Their fears on possible litigation should be allayed.
• NDA should develop feedback mechanisms to stakeholders to encourage them appreciate the benefits of ADR reporting.

6.7.3 Reporting Adverse Drug Reactions:

• NDA should work hand in hand with the Ministry of Health to ensure that ADR reporting is prioritised and incorporated into other support supervision activities.

• While training centre coordinators on the use of VigiFlow should be emphasised, sensitisation of health workers on observing ADR’s and filling the forms properly should be continuous.

• Regional Inspectors of Drugs should be involved in Pharmacovigilance sensitisation activities.

• Regional Pharmacovigilance centres should be provided with the necessary logistics, like internet facilities, to enable them report ADR.

John F. S. Muwanga

AUDITOR GENERAL

KAMPALA

14th December, 2010
GLOSSARY OF TERMS:

Active Ingredient: An active ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.

Adverse Drug Reaction: A response to a medicine which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of diseased or for the modification of physiological function.

Clinical trial: Any investigation in human and animal subject intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s) and/or to identify any adverse drug to investigational product(s) and/or to study absorption, distribution, metabolism and excretion of an investigational product(s) with the objective of ascertaining its safety and/or efficacy.

Dossier: A dossier is a collection of papers containing detailed information about a particular product or subject.

Drug: Any substance or preparation used or intended to be used for internal or external application to the human or animal body either in the treatment or prevention of disease for improving physiological functions or for agricultural or industrial purposes.

Generic Drug: A generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. Drug products evaluated as "therapeutically equivalent" can be expected to have equal effect and no difference when substituted for the brand name product.

Herbal medicine: Consists of finished, labeled medicinal products that contain as active ingredients aerial or underground parts of plant, or other plant...
materials, or combinations thereof, whether in the crude state or as plant preparations. Plant material includes juices, gums, fatty oils, essential and any other substances of this nature. Herbal medicines may contain excipients in addition to the active ingredients.

**Hologram:** An image registered with use of coherent laser light. It allows to preserve the 3-D information of a holographed subject. With a single source of white light, the image is "played back" and appears in 3-D exactly as it was registered in the studio. Image can project deep inside, or "stick" out of the picture.

**Medicine:** Any substance used in treating diseases or illnesses; medicament; remedy.

**Pharmacovigilance:** A science and activities relating to the knowledge, detection and prevention of adverse effects or any drug-related problems.

**Post Market:** A stage when the drug is generally available on the market.

**Public Health Product:** A product or item or device used for public Health Programs for vector control or for other recognized health protection uses, including mitigation of viruses, bacteria or other micro-organisms (other than viruses, bacteria or micro-organisms on or in living man or other living animal) that pose a threat to public health.

**Traditional Medicine:** The sum total of all knowledge and practice whether they can be rationally explained or not, used in the diagnosis, prevention, elimination of physical, psychological and social imbalances and relying exclusively on practical experiences and observations handed down from generation to generation, either verbally or in writing.
Appendix (i)

NDA ORGANISATION STRUCTURE

NDA AUTHORITY

NDA Commission

Committee on National Formulary

Committee on Medical, Diagnostic, Devises & Equipment

Committee on Traditional and Herbal Medicines

Committee on National Pharmacovigilance

Committee on Human Resource

Committee on Veterinary Medicines

Committee on Clinical Trials

Committee on Essential Drugs

Executive Secretary/Registrar

Head, Finance Department

Head, Inspectorate Department

Head, Drug Quality Control Department

Head, Drug Assessment & Registration Department

Head, Drug Information Department

Legal Officer

Human Resource Officer

Procurement Officer

Public Relations Officer

Internal Auditor

Contracts Committee

Management Information Systems Officer

Pharmaceutical Advisor

Quality Systems Officer
## Appendix (ii)

### List of Documents Reviewed

<table>
<thead>
<tr>
<th>Document</th>
<th>Purpose</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDA – Certificate of Suitability of Premises (Regulations).</td>
<td>Get an understanding of processes and procedures followed in inspection of premises.</td>
</tr>
<tr>
<td>NDA – (Issue of Licenses) Regulations.</td>
<td>To understand regulations and guidelines followed in issuing licenses.</td>
</tr>
<tr>
<td>Training reports.</td>
<td>Obtain information about training activities</td>
</tr>
<tr>
<td>NDA Budget Estimates (2006/07, 2007/08 and 2008/09).</td>
<td>To establish how NDA operations are funded.</td>
</tr>
<tr>
<td>NDA Updates (January – March, April-June, July-September and October-December 2009).</td>
<td>To obtain updates and news on key NDA operation over the period.</td>
</tr>
<tr>
<td>NDA Pharmacovigilance News.</td>
<td>To obtain information relating to drug reactions and public awareness.</td>
</tr>
<tr>
<td>NDA Human Resource Manual.</td>
<td>To understand NDA Human resource needs, policies and obligations in execution of their mandate.</td>
</tr>
<tr>
<td>WHO assessment report and review of Medicines Regulatory authority of Uganda (July 2009).</td>
<td>To appreciate other independent assessments done on the performance of NDA.</td>
</tr>
<tr>
<td>Licensing Database.</td>
<td>Obtain information relating to licensed drug outlets.</td>
</tr>
<tr>
<td>Title</td>
<td>Status</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>---------------------------------</td>
</tr>
<tr>
<td>The National Drug Policy and Authority (Conduct of Clinical Trials)</td>
<td>Not Gazetted</td>
</tr>
<tr>
<td>The National Drug Policy and Authority (Detecting and Reporting Adverse Drug Reaction)</td>
<td>Not Gazetted</td>
</tr>
<tr>
<td>The National Drug Policy and Authority (Registration of Pharmaceuticals for Human Use in Uganda)</td>
<td>Not Gazetted</td>
</tr>
<tr>
<td>The National Drug Policy and Authority (Registration of Pharmaceuticals for Veterinary Use in Uganda)</td>
<td>Not Gazetted</td>
</tr>
<tr>
<td>The National Drug Policy and Authority (Registration of Traditional Medicinal Products for Human or Veterinary use in Uganda)</td>
<td>Not Gazetted</td>
</tr>
<tr>
<td>The National Drug Policy and Authority (Registration of Vaccines and Other Immunological Products for Veterinary Use in Uganda)</td>
<td>Not Gazetted</td>
</tr>
<tr>
<td>The National Drug Policy and Authority (Food or Dietary Supplements in Uganda)</td>
<td>Not Gazetted</td>
</tr>
<tr>
<td>The National Drug Policy and Authority (Public Health Products in Uganda)</td>
<td>Not Gazetted</td>
</tr>
<tr>
<td>The National Drug Policy and Authority (Restriction of medicine or Drug Promotion)</td>
<td>Not Gazetted</td>
</tr>
<tr>
<td>The National Drug Policy and Authority (Donation of Drugs)</td>
<td>Not Gazetted</td>
</tr>
<tr>
<td>The National Drug Policy and Authority (Procedure for Establishing a Pharmaceutical Enterprise)</td>
<td>Not Gazetted</td>
</tr>
<tr>
<td>The National Drug Policy and Authority (Procedure for Establishment of a Pharmaceutical and Medical Devices Manufacturing Company)</td>
<td>Not Gazetted</td>
</tr>
<tr>
<td>The National Drug Policy and Authority (Importation and Exportation of Drugs)</td>
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</tr>
<tr>
<td>The National Drug Policy and Authority (Conduct of Ectoparasiticides Field Trials in Uganda)</td>
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</tr>
<tr>
<td>The National Drug Policy and Authority (Preparation of a site Master file for Pharmaceutical Manufacturing facilities)</td>
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</tr>
<tr>
<td>The National Drug Policy and Authority (Introduction of New Formulation on the Ugandan Market)</td>
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<tr>
<td>The National Drug Policy and Authority (Import of Condoms)</td>
<td>Not Gazetted</td>
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<tr>
<td>The National Drug Policy and Authority (Establishment of warehouse for storage of Drugs and Medical Supplies)</td>
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</tr>
<tr>
<td>The National Drug Policy and Authority (Importation of Use of Hormones in Commercial Fish Production)</td>
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## Appendix (iv)

### Consignments inspected at entry points for the period 2008/09 to 2009/10

<table>
<thead>
<tr>
<th>Entry Point/Year</th>
<th>2008/09</th>
<th>2009/10</th>
<th>Average 2008/09 to 2009/10</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Consignments Handled</td>
<td>%age</td>
<td>Consignments Handled</td>
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<tr>
<td>Nakawa</td>
<td>Authorised</td>
<td>1,065</td>
<td>94.2%</td>
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<td></td>
<td>Queried</td>
<td>65</td>
<td>5.7%</td>
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<tr>
<td></td>
<td>Rejected</td>
<td>1</td>
<td>0.1%</td>
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<tr>
<td></td>
<td><strong>Sub-Total</strong></td>
<td><strong>1,131</strong></td>
<td><strong>100.0%</strong></td>
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<tr>
<td>Entebbe</td>
<td>Authorised</td>
<td>1,182</td>
<td>98.3%</td>
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<tr>
<td></td>
<td>Queried</td>
<td>20</td>
<td>1.7%</td>
</tr>
<tr>
<td></td>
<td>Rejected</td>
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<td>0.1%</td>
</tr>
<tr>
<td></td>
<td><strong>Sub-Total</strong></td>
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<tr>
<td>Busia/Malaba</td>
<td>Authorised</td>
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<tr>
<td></td>
<td>Queried</td>
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<td>9.7%</td>
</tr>
<tr>
<td></td>
<td>Rejected</td>
<td>28</td>
<td>7.3%</td>
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<tr>
<td></td>
<td><strong>Sub-Total</strong></td>
<td><strong>381</strong></td>
<td><strong>100.0%</strong></td>
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<tr>
<td>Average</td>
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<td>2,563</td>
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<td></td>
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<tr>
<td></td>
<td>Rejected</td>
<td>30</td>
<td>2.5%</td>
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</table>

*Source: OAG Analysis form NDA Inspectorate Department Data.*