Implementation and enforcement of Good Manufacturing Practice (GMP) regulations in Uganda: Implications for access to quality medicines.

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Background
For medicines to be put on the national drug register (NDR), they must comply with current Good Manufacturing Practice (GMP); to ensure their quality, safety and efficacy. Uganda is obliged to use international standards for GMP inspection, and it's medicines regulatory body, the National Drug Authority (NDA), uses its guidelines in reference to World Health Organisation (WHO) standards. Effective GMP regulation requires legal enforcement and adequate human, financial and infrastructural resources. This paper describes the implications for access to quality medicines basing on the resources available to NDA to conduct GMP regulation.

Methods
Document review and qualitative data from key informant interviews. Interviews were conducted with purposively selected representatives from the NDA and professional Councils, including Medicines/Pharmaceutical regulators, and Ministry of health officials. The interviews addressed issues such as; capacity of the NDA, challenges to regulatory activities; any cases of non compliance to GMP and how enforcement to non-compliance is carried out; and differences in regulatory practices between local and international manufacturers.

Findings
Uganda imports >95 of its medicines. Inspection for GMP is done by the NDA, using WHO guidelines, for every plant applying to register medicines on the NDR. Only 11% of the brands of medicine on the EML, were WHO GMP prequalified. One local plant was prequalified by WHO, as an alternative site for Cipla’s antiretroviral therapies and Lumartem®. The NDA inspection unit and Quality control (QC) laboratory operate at about 50% and 20%, respectively, of their human resource capacity. The laboratory has limited facilities, and is not accredited by WHO for Good Laboratory Practice. There were reported cases of non-compliance to GMP, and high percentage of products failing quality testing. NDA has not gazetted its GMP inspection guidelines into statutory instruments as required by law. The NDA budget (with ≥95% funds internally generated, ≤5% from donors, and minimal from government), is constrained, with high expenses on foreign inspections.

Conclusion
NDA should strengthen QC, review its financing priorities for foreign inspections, and be pro-active in harmonization of inspection and regulatory activities at regional, continental and international level. Government should strengthen the NDA law to enforce regulation, and engage relevant stakeholders to improve funding, human resource and QC capacity.

Key words: Essential Medicines, GMP regulation, Quality, Access, Uganda.
The National Drug Authority (NDA) is mandated by the National Drug Policy and Authority (NDP&A) Act to control the quality of drugs sold on the Ugandan market. It has to ensure that for medicines to be registered and put on the national drug register (NDR), they must comply with current Good Manufacturing Practice (cGMP). cGMP is “that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization”. It covers all aspects of the manufacturing process: defined manufacturing process; validated critical manufacturing steps; suitable premises, storage, transport; qualified and trained production and quality control personnel; adequate laboratory facilities; approved written procedures and instructions; records to show all steps of defined procedures taken; full traceability of a product through batch processing records and distribution records; and systems for recall and investigation of complaints.

Inspection of local and foreign drug manufacturing sites for GMP compliance, by the NDA, is based on the NDA current GMP Guidelines. The guidelines were developed with reference to the World Health Organization (WHO) and Pharmaceutical Inspection Cooperation/Scheme (PIC/S) guidelines on GMP. WHO and PIC/S have in place stringent mechanisms and requirements, for regulating medicines, which are often used as models for developing countries.

The Government of Uganda can use accredited manufacturers under the WHO GMP prequalification program/standards, thereby circumventing the need to do its own GMP inspection; but there are circumstances where the government of Uganda has to procure medicines from manufacturers that are not WHO prequalified. Medecins Sans Frontier’s (MSF) has highlighted that many medicines on the Uganda Essential Medicines List (EML) do not have a WHO prequalified supplier. WHO prequalification project mainly focuses on medicines for TB, HIV/AIDS, malaria, influenza and reproductive health. This implies that those pharmaceutical products that are not WHO GMP prequalified have to satisfy the inspection requirements of NDA before they are registered on the Ugandan market. Likewise, all the international manufacturing plants for medicines that are imported for use in the country, have to be inspected and meet the requirements of the NDA.

This situation places an extra burden on the NDA inspection unit in terms of finances and human resource needs for the regular inspections of both the local and international drug companies that provide medicines on the Ugandan market. The NDA has experienced a number of constraints in executing its mandate of regulation of drug inspection, including: (i) Gaps in the NDP&A Act, which does not explicitly provide for the regulation of some products and for effective enforcement and deterrent penalties; (ii) Infiltration into the country of unauthorized medicinal products through the numerous unregulated border points; (iii) Inadequate funding amidst widening mandate, and (iv) Inadequate office space and storage facilities.

A WHO report published in 2002 documented the serious lack of human and financial resources available to the NDA (Ratanawijitrasin & Wondemagegnehu, 2002). A serious public health hazard, related to inadequacies in drug inspection, is the presence of substandard drugs on the Ugandan market. A 1998 survey in Kampala showed that 55% of tablets and 62% of injection forms of chloroquine failed the quality test (Ogwal-Okeng et al., 1998). In a large-scale USAID-funded, Promoting the Quality of Medicines Program, implemented by the US Pharmacopoieal Convention, in which antimalarial medicines were tested for quality in ten countries it was found that 26% of samples from Uganda were substandard (USAID, 2010). Quality control/assurance and testing of medicines and health supplies is the responsibility of...
the National Drug Quality Control Laboratory (NDQCL), which is one of the four departments of the NDA. The NDQCL provides services for the analysis, assessment and quality assurance of pharmaceutical products on the market, to ensure that whether locally manufactured or imported, they are of good quality and are therefore safe and suitable for their intended use. This paper sets to describe the implementation and enforcement of GMP regulation in Uganda and its implications for access to quality medicines basing on resources available to NDA for GMP inspection.

METHODS

Study design
Document and Literature review and qualitative data from the key informant interviews. Analysis of the NDR was done to determine the countries of origin for medicines on the NDR; drugs on the Uganda Essential Medicines List are that WHO prequalified; WHO prequalification status of local pharmaceutical industries; the process that NDA follows when assessing a manufacturer’s compliance to GMP, and if there were any cases of non-compliance to GMP. We also wanted to find the capacity of NDA, funding, and the barriers and constraints to conduct GMP inspections.

Document and Literature review
A comprehensive document and literature review to identify key points and gaps regarding the drug regulatory structures and bodies responsible for GMP inspection in Uganda. This review included an analysis of the National Drug Register (NDR), the Essential Medicines List (EML), and the Tracer Medicines’ (TM) brands and compare them with the WHO list of prequalified Medicinal products. A literature search to describe the GMP process in Uganda, including determination of data on capacity of GMP inspection; the number of inspectors, adequacy of facilities for quality control and budgets. The review strategy included internet search, websites and reports of relevant institutions including the NDA, WHO, donor agencies, the Ministry of Health, and other government agencies.

Key informant Interviews
Purposive sampling using a Key informant interview guide included selected representatives from the NDA and professional Councils, including Medicines/Pharmaceutical regulators (drug inspectorate of the NDA, registrars of professional medical councils) and Ministry of health officials. These interviews addressed issues such as; capacity of the regulatory agency, challenges to regulatory activities; any cases of non compliance to GMP, and how enforcement to non-compliance is carried out. We also interviewed international donor agencies including WHO, United Sates Agency for international Development (USAID), President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund to Fight AIDS, TB and Malaria (GFATM), and Clinton Health Access Initiative (CHAI), to find out if there was any donor support for GMP inspection activities. More clarification on data obtained from the KI interviews was sought by using e-mail inquiries, telephone conversations, and occasionally face to face short meetings.

Data management and the approaches to analysis
Key informant interviews were transcribed, entered into MAXQDA (version 10) software and then coded with reference to study aims. Thematic content analysis was performed. The variables explored in results included the following: The number of medicines (brands) on the EML that are WHO prequalified; the process that NDA follows when assessing a manufacturer’s compliance with GMP; the capacity of the NDA to conduct GMP inspections;
and the funding and resources available for GMP inspection. We also examined the availability of Medicines inspection guidelines and harmonization with global, international and regional best regulatory practices; availability and accessibility of Medicines inspection reports; and comparison of the local versus international GMP inspection processes.

Ethical considerations
Ethical approval was obtained from the Institutional Review Board (IRB) of Mbarara University of Science and Technology; and the Uganda National Council for Science and Technology (UNCST). Signed informed consent was obtained from each study participant before the interviews.

RESULTS

Countries of origin for medicines on the National Drug Register (NDR)

Analysis of the current Uganda NDR (2013), shows that >95% the medicines on the Uganda NDR are imported mainly from India (57%), Kenya (7%) , China (4%), and a few from a number of European countries including UK (3%), Germany (3%), etc; as shown in figure 1. below:

Figure 1: Countries of origin for medicines on the Uganda National Drug Register
Medicines on the Uganda EML that are WHO prequalified

Among the medicines (brands/formulations) on the Uganda EML, only 11% are on the WHO list of prequalified medicinal products, as shown on table 1.

Table 1: Number of medicines (brands/formulations) on the Uganda EML that are WHO prequalified

<table>
<thead>
<tr>
<th>WHO Prequalification</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>536</td>
<td>88.74%</td>
</tr>
<tr>
<td>Yes</td>
<td>68</td>
<td>11.26%</td>
</tr>
<tr>
<td>Total</td>
<td>604</td>
<td>100%</td>
</tr>
</tbody>
</table>

The 68 brands of medicines on the EML that are WHO prequalified cover 4 main therapeutic areas including HIV/AIDS, TB, Malaria, and Reproductive Health as shown below:

<table>
<thead>
<tr>
<th>Therapeutic area</th>
<th>Brands/formulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV</td>
<td>39</td>
</tr>
<tr>
<td>TB</td>
<td>9</td>
</tr>
<tr>
<td>Malaria</td>
<td>12</td>
</tr>
<tr>
<td>Reproductive Health</td>
<td>8</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>68</strong></td>
</tr>
</tbody>
</table>

Source: EMHSL for Uganda (2012) & WHO List of prequalified medicinal products

Among the Tracer medicines brands of interest in this study only Artemisinin, Lamivudine, and Rifampicin are on the WHO list of prequalified medicinal products. No brands of fluoxetine, metformin, and oxytocin are included on the list.

WHO GMP prequalification status of local pharmaceutical industries

Among the local drug manufacturing companies in Uganda (listed in table 2 below) only Quality Chemicals Industries Limited (QCIL) has been prequalified by WHO, as an alternative manufacturing site for Cipla’s Lamivudine, Nevirapine and Zidovudine fixed dose tablet preparation.

Table 2: Pharmaceutical manufacturers in Uganda (2009)

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Type</th>
<th>Ownership</th>
<th>District</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. K.P.I (1996) Ltd</td>
<td>Large Scale</td>
<td>Foreign/India</td>
<td>Kampala</td>
</tr>
<tr>
<td>2. Quality Chemical Industries</td>
<td>Large Scale</td>
<td>Foreign/India</td>
<td>Kampala</td>
</tr>
<tr>
<td>3. Mavid Pharmacy</td>
<td>Large Scale</td>
<td>Local</td>
<td>Kampala</td>
</tr>
<tr>
<td>4. Medipharm Industries</td>
<td>Large Scale</td>
<td>Joint (Ugandan &amp; Kenyan)</td>
<td>Kampala</td>
</tr>
<tr>
<td>5. Rene Industries</td>
<td>Large Scale</td>
<td>Foreign/India</td>
<td>Kibale</td>
</tr>
<tr>
<td>6. Abacus Parenteral Drugs</td>
<td>Large Scale</td>
<td>Foreign/India</td>
<td>Mukono</td>
</tr>
<tr>
<td>7. NEC Pharmaceuticals</td>
<td>Large Scale</td>
<td>Local</td>
<td>Kampala</td>
</tr>
<tr>
<td>8. Uganda Pharmaceuticals</td>
<td>Large Scale</td>
<td>Joint (Ugandan &amp; Indian)</td>
<td>Jinja</td>
</tr>
<tr>
<td>9. Sev Pharmaceuticals</td>
<td>Small Scale</td>
<td>Local</td>
<td>Kampala</td>
</tr>
<tr>
<td>10. Kwality Afro-Asia</td>
<td>Small Scale</td>
<td>Foreign/India</td>
<td>Kampala</td>
</tr>
<tr>
<td>11. Uganda Kwefuga African Industries</td>
<td>Small Scale</td>
<td>Local</td>
<td>Kampala</td>
</tr>
<tr>
<td>12. Kiwakye Pharmaceuticals</td>
<td>Small Scale</td>
<td>Local</td>
<td>Kampala</td>
</tr>
</tbody>
</table>

(Source - Pharmaceutical Sector Profile: Uganda 2010)
The company was established in 2007 and the inspection (requested for by Cipla Ltd., India) took place in January, 2010. The facility was found to operate at an acceptable level of compliance with WHO GMP and final approval was announced by WHO in June 2010 (Kaplan & Laing, 2005; http://www.unido.org, http://www.eac.int). QCIL also produces the generic ACT Lumartem which is a fixed dose combination of Artemether Lumefantrine (AL), which is also WHO GMP prequalified. According to the WHO Head of Pharmaceutical division in Uganda, interested companies apply to WHO for prequalification and those that meet the requirements get approved, but it has been of interest mainly to those that target funding from global health initiatives (GHIs).

"Those companies that manufacture products that are not of frequent interest to donors may have less incentive to seek for it. The rest have not applied. So interested companies apply to WHO for prequalification and those that meet the requirements get prequalified". The processes that NDA follows when assessing a manufacturer’s compliance with GMP

Inspectors follows the NDA cGMP Guidelines for foreign and local pharmaceutical manufacturing plants of medicines for use in Uganda (revised March 2011), (http://www.nda.or.ug/drug-insp). Though the NDA has not gazetted these guidelines into statutory instruments as required by law (www.oag.go.ug/ Auditor general Report 2010), the policy clearly spells out criteria for compliance, approval and resolving of deficiencies. According to data from KI interviews, inspections are done for every plant applying to the NDA. Standard formats are to be followed whether big or small plants.

“Two or three inspectors perform inspection using a pre-approved GMP checklist. They usually cover a big area. They plan a visit which takes a month or so, this will cover a number of institutions; for example they may have 5 applications from India, 3 from China and may be one from Germany. They will plan a routing and cover that whole range of facilities”. [Head of Pharmacy Division, Ministry of Health]

Each site is scored for compliance in quality management and personnel, standard operating procedures, premises and equipment, warehousing areas, and Quality control/Assurance; according to the NDA guidelines (http://www.nda.or.ug/drug-insp). Confidentiality of this information is assured.

“Inspection reports cannot be shared with other firms, due to disclosure reasons. The reports are within NDA, and can only be shared as and when necessary, especially for purposes of government statistics [Chief Inspector of Drugs, NDA]”. 

Recently, the NDA has started implementing random, unannounced GMP inspections of manufacturing facilities for medicines on the Ugandan market. The new initiative is meant to strengthen the inspectorate’s ability to understand the real situation at the manufacturing sites when inspection is carried out abruptly without first alerting the facility (According to Executive Secretary NDA, personal communication, November 16, 2012). As a result of this initiative, one of the foreign manufacturing sites in Mumbai India, where an impromptu inspection was done in June 2012, was found non compliant on some aspects of GMP inspection and this led to cancelling of their license and suspension of their products from the Ugandan market (National Drug Authority, Notice 957/SR/NDA/06/12; June 2012). In another move, NDA conducted a three-day special inspection of a "local pharmaceutical company in Kampala’s Industrial Area", beginning June 21, 2012. The company was found to be non-compliant with the “cGMP requirements” as per NDA guidelines at the time of audit, and a directive was given to halt all importation of its products (www. observer.ug / index.php).
“The NDA, through the inspectorate department, conducts routine post-market surveillance of all products on the NDR that are being marketed in Uganda. Part of this surveillance includes random sampling of the products and laboratory testing to determine if the products meet their specifications. So in this case if a given product fails the test, we carry out investigations to find out the cause and whether the whole batch is affected. That’s how we can decide to recall a given batch. Thus products recalls are batch specific. But on the issue of ‘this company in Mumbai’ we got complaints from clinicians and customers about a whole range of their products and then we decided to investigate through lab analysis and impromptu visits. So we found that the problem affected multiple production lines. That’s why many batches and products were recalled.” [NDA Senior Inspector of Drugs].

**Capacity of the NDA to conduct GMP inspections**

**Human resource:** The NDA inspection unit operates at a low and variable human resource capacity, the drug inspectorate at or below 50% (Head Drug Inspectorate NDA, Executive Secretary NDA) and the NDQCL Department at about 20% (www.oag.go.ug/ Auditor general Report 2010). There are collaborations with USFDA, WHO, and Securing Ugandans Right to Essential Medicines (SURE) to train staff, and make sure that capacity constraint is quickly addressed.

"The WHO is the main technical adviser for NDA. We train their inspectorate staff, we help in preparing guidelines and tools for medicines inspection and assessment, and we also assist in capacity building for the laboratory and quality control staff. The NDA would not exist without WHO. We do not advance cash because we are not donors. Instead we are funded to do our work by the rich countries through USAID, EU, DFID, etc." [Head of Pharmaceutical Division, WHO].

"We work with the NDA on a number of projects especially relating to capacity building of staff as well as evaluation tools for work done. I do not think that NDA should carry out inspections of manufacturing sites outside of Uganda. It is very expensive. But they seem to have much interest in doing that. I think compliance can still be ensured through rigorous testing and quality control procedures, and by working with local regulatory bodies based in those countries. The NDA budget is constrained and the key regulatory aspect of their work here in Uganda suffers because of that." [Chief of Party, SURE].

**Financing:**
NDA operations are mainly funded by internally generated revenue with some support from development partners.

"NDA doesn’t get funding from government, it gets zero shillings. The major sources of income, 98% come from funds generated from NDA activities i.e. fees for assessing dossiers and registering medicines and GMP inspection fees. There are different rates for the different regions (local-Uganda, Africa and the rest of the world)" [Executive Secretary, NDA].

According to the Auditor General (www.oag.go.ug/ Auditor general report 2010), >95% of NDA funds are internally generated and about ≤5% is support from development partners include HSSP, WHO and USAID (table 3 below).

<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 (98%)</td>
<td>10.36 (97%)</td>
<td>13.06 (95%)</td>
<td>13.12 (99%)</td>
</tr>
<tr>
<td>Donor Funds</td>
<td>0.17 (2%)</td>
<td>0.31 (3%)</td>
<td>0.68 (5%)</td>
<td>0.12 (0.9%)</td>
</tr>
<tr>
<td>GoU Funds</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>0.014 (0.1%)</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*
From the money that is collected;

"We pay employees, buy air tickets for inspectors to go and inspect abroad (this constitutes about 70% of our expenditures). We also use this money to test drugs. Importers pay 6000USD yet we use much more than that to test their products. We also have to finance routine checking (inspectors) in the fields" [Executive Secretary, NDA].

Quality control: The Auditor General report showed that NDQCL Department had made an evaluation and presented a proposal of 52 staff to enable the proper functioning of the lab. Out of this number, the Department had only 11 officers. There were also issues of inadequate equipment and laboratory space (www.oag.go.ug/ Auditor general Report 2010).

"60% of antimalarials had failed quality tests and it was not clear if inspection reports were shared with other regulatory agencies" (Registrar UMDPC).

"We have very well trained people in the labs but they are very few and usually overwhelmed. We expect to buy some more equipment. We have applied for WHO prequalification"[Executive Secretary, NDA].

Harmonization:
The East African Community (EAC) has recently launched the East African Medicines Registration Harmonization (EAC–MRH) project. The planned activities of the EAC MRH project include a Technical working group on GMP to develop GMP inspection guidelines and manuals for the EAC partner states (http//www.eac.int:)

"With regard to sharing of information within the East African region, the DRAs are working on frameworks on how to share information, e.g. if a plant was inspected by NDA, it probably was not inspected by the other regulatory bodies. The question being addressed in this framework is that if NDA has inspected a site, can it be recognized by the other regulatory bodies? The current practice is that if NDA inspects, Kenya Medicines & Poisons Board, also inspects and then Tanzania Food and Drugs Authority (TFDA) also inspects"[President Pharmaceutical Society of Uganda]” .

DISCUSSION

Uganda imports more than 90% of its medicines, mainly from India, Kenya, China, and a few from several European countries (http://www.unmillennium project. org; UNIDO [2010, NDR register 2013]. NDA has to ensure that those medicines are of high quality, safety, and effectiveness. Therefore, GMP inspections by NDA staff are mandatory for all manufacturers, both local and international, seeking registration of their products in the country. Inspectors follow NDA current GMP guidelines, which were developed with reference to the WHO and PIC/S guidelines on GMP. The analysis, in this study, shows that among the medicines brands on the Uganda EML only 11% were WHO GMP prequalified. Only QCIL, one out of 12 pharmaceutical manufacturing companies in Uganda considered, has been prequalified by WHO, as a manufacturing site for antiretroviral therapies and antimalarials. Therefore, all the other products on the EML and those which are currently manufactured by QCIL are not WHO prequalified. This implies that those pharmaceutical products, that are not WHO GMP prequalified, have to satisfy the inspection requirements of NDA before they are registered on the Ugandan market. Likewise, all the international manufacturing plants for medicines that are imported for use in the country, have to be inspected and meet the requirements of the NDA. The NDA, therefore, is expected to be autonomous, to have their own registers and systems of approval/market authorization. This situation places an extra burden on the NDA inspection unit in terms of finances and human
resource needs for the regular inspections of both the local and international drug companies that provide medicines on the Ugandan market.

If inspection is not done well, coupled with inadequate resources and equipment for drug testing, there is a possibility of lots of substandard or defective products coming in the country. According to the Promoting the Quality of Medicines Program report (USAID, 2010), products in the public sector are, usually, purchased with donor funds from suppliers that have been prequalified by WHO. Interestingly, products sampled from the public sector all passed quality control tests, while a high percentage of those in the private sector failed. Those in the private market are obtained from either local companies or foreign companies that have not been certified by WHO as GMP compliant. Likewise, most of the local pharmaceutical companies do not meet the stringent GMP criteria of WHO or regulatory authorities from developed markets (PIC/S, USFDA, EMA, etc.). A high percentage of antimalarials, on the Uganda market, were reported failing quality tests. This observation calls for further evaluation of the efficiency and cost-effectiveness of foreign inspections conducted by the NDA. Due to disclosure reasons, it was not possible, in this study, to obtain details of the inspection reports from the NDA. It is also possible that counterfeit and substandard products find their way into the Ugandan market, due to problems associated with poorly regulated import channels, whereby wholesalers and pharmacies can also import medicines directly; and where the NDA is unable to designate Inspectors of Drugs at all border points into Uganda due to inadequate staffing levels. There is also need for the expedited approval of the NDA’s application for WHO GLP prequalification of its quality control laboratories. Therefore the capacity of quality control testing labs, in terms of human resources, finances, equipment, laboratory space, and quality assurance mechanisms needs to be strengthened. Also, the status of NDA law will need to be strengthened to enforce regulation. There are gaps in the NDA’s Act, which does not explicitly provide for the regulation of some products and for effective enforcement and deterrent penalties; the penalties are not sufficiently deterrent and this has partly encouraged recurrent breach of the law. Regarding the recently introduced unannounced GMP inspections to find out cases of non-compliance, the NDA will need to mobilize additional resources for effective implementation and sustainability of this initiative as the costs involved are high. Inadequate funding amidst widening mandate remains one of the most pressing challenges facing NDA. NDA operations are mainly financed by internally generated revenue with some funding from development partners and very minimal support from government. The internally generated funds are grossly inadequate to support NDA’s budget and the key regulatory aspect of their work in Uganda suffers because of high expenses of foreign inspections. NDA, through exchange of information and working experience over time, can identify sites with consistent high profile of cGMP compliance and DRAs/Institutions with cGMP inspection procedures and competencies that meet NDA guidelines for the purpose of establishing mutual recognition agreements (MRAs) or using their regulatory decisions. NDA can thereafter either conduct joint inspections with, or recognize cGMP inspection reports from, such willing DRAs/Institutions. For the purposes of these guidelines the DRAs of countries of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S), the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (Todo); including the European Union Medicines Agency (EMA), Japan and the United States Food and Drug Administration (USFDA) are considered stringent. Instead of foreign inspections, its recommended that NDA should strengthen rigorous testing and quality control procedures, and by harmonizing operations with local regulatory bodies based in other countries.
Acknowledgements
This paper results from research funded by the European Union Seventh Framework Programme Theme: Health-2009-4.3.2-2 (Grant no. 242262) under the title ‘Access to Medicines in Africa and South Asia [AMASA]’. The project team includes partners at the Swiss Tropical and Public Health Institute at the University of Basel (Switzerland), University of Edinburgh (UK), The Queen Mary University (London), University of Ghent (Belgium), Makerere University (Uganda), Mbarara University of Science and Technology (Uganda), University of the Western Cape (South Africa), and the Foundation for Research in Community Health (India). Neither the EU nor any of the partner institutions is responsible for views advanced here.

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