

**SITUATION ANALYSIS OF THE
PHARMACOVIGILANCE CAPACITY OF
KENYA
TANZANIA
UGANDA**

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Part 1: Summary of Findings from Kenya, Tanzania and Uganda

I. Background Information

The situation analysis includes data for Kenya, Tanzania and Uganda. The respondents interviewed from these countries were all directly responsible for managing pharmacovigilance (PV) efforts in their countries, and had been working in their present capacity for several years, except in the case for Tanzania, where the individual had been posted in this capacity for a few months.

II. PV Policy Framework

None of the countries have a national policy or legal framework governing PV. However, Kenya and Tanzania both have policies that regulate medicines (quality, efficacy, prescription). In Kenya, an act of parliament regulates pharmacists' practice, and includes a section on safety and quality of medicines. In Tanzania, documentation speaks about the control of ADRs.

Although we make a distinction in the questionnaire between a strategic plan and an action plan, it appears that the annual plan is often a subset of the former. The National Drug Administration (NDA) in Kenya and Tanzania already have their annual operating plans, while Uganda's is under development. Tanzania's strategic plan, was updated in 2006.

III. Organizational Structure and Capacity for PV

All three countries have a department that is specifically responsible for managing and coordinating PV efforts. These departments became active in mid-2004, and thus are relatively new and quite small with only one to two full time professionals.

- In Kenya, the Department of PV reports to the Registrar of the Pharmacy and Poison Board (NDA equivalent).
The number of staff in the department has recently increased from 1 to 2 persons. The requested budget for 2007 was 7.5 million Kenyan Shillings or approximately US\$112,500¹, although it was not indicated what percent of this amount had been granted. There are several external organizations that are planning on funding pharmacovigilance in Kenya, although exact amounts were not available at this time; examples include WHO, Gates Foundation, Health Action International/Africa, World Bank and PEPFAR.
- In Tanzania, after organizational restructuring in early 2008, the department will be named Pharmacovigilance and Clinical Trial Control Department, and will report to the Director of Medicines and Cosmetics, which is one of the 4 Directors supervised by the Director General of the TFDA.

¹ Estimated exchange rate is USD1 = 65 Kenyan Shillings

There are currently 2 full time staff in the department.

Its budget for 2007 was 5 million Tanzanian Shillings, or about USD 5,000².

[Authors comment: This figure is extremely small but has been verified by the head of the pharmacovigilance department. However, further discussions need to be undertaken to ensure each of the respondents are using the same definition of the department's budget and including the same 'line-items.']. External donors, namely the Global Fund has also provided \$50,000 to the department.

- In Uganda, the head of DID reports to the Executive Secretary/ Registrar (ES/R) of the NDA, who in turn reports to the Chairman of the Board, who reports to the Minister of Health. The national centre for PV was established in the Drug Information Department (DID) at NDA. DID is one of the 5 core departments of NDA. Apart from the head of DID, there is a Drug Information pharmacist, 2 drug information technicians (nurse, pharmacy diploma) who handle PV activities. There is also a PV Advisory Committee of the NDA Board which is the strategic and decision making arm of the NDA. External sources of funding include approximately USD320,000 from USAID and WHO. The exact amount of internal sources was not available at this time.

All departments work with public health programs in the areas of malaria and HIV/AIDS control. Kenya is also planning to conduct some assessments of ADR and quality in TB.

In terms of capacity building, all three departments have had staff attend the two 2-week PV training either at UMC or in one of the African countries. With an average of less than one training per year, and HR strength of 1-2 people, it is therefore not surprising that these countries are struggling to scale-up their pharmacovigilance efforts.

IV. PV Process

All three countries have a formal ADR form for collecting data, although Kenya hasn't yet started collecting ADR data but plans to start in 2008.

At the outset, Kenya is focusing more of its efforts in malaria and eventually HIV/AIDS. Within these categories, they are focused on collecting information from vulnerable groups, specifically use of ACTs in pregnancy.

Kenya plans to roll-out a common nation-wide system of ADR reporting and monitoring ("passive reporting"), but also plans to initiate "active" reporting for newer medicines and medicine use in high risk groups (like ACTs in pregnancy). Their main goal is a

² Using current exchange rate of USD1 = 1123 Tanzania Shillings

national PV system for the passive reporting and sentinel sites-based pharmacovigilance approach for the active reporting.

Tanzania has more systems in place and has been collecting ADR forms and entering some of them into UMC's Vigiflow software. The information is mostly reported by medical doctors and medical assistants and sent to the center through their regional centers of health.

For Uganda, the most common methodology for capturing pharmacovigilance data is 'passive surveillance'; various other methodologies are also used including, passive pharmacovigilance, active research, cohort event monitoring, case control studies, etc. Generally the passive surveillance is voluntary; however when pharmacovigilance is conducted for a research project, then pharmacovigilance data collection is mandatory.

Data is collected by all types of health professionals and not just by doctors and nurses. The ADR forms are then entered into UMC's Vigiflow software for data analysis.

V. Quality, Efficiency and Outcomes

All three countries have a nationally approved ADR form and are implementing a passive pharmacovigilance system based on voluntary reporting of adverse drug events.

- In Kenya, PV sensitization training has just recently been rolled out at the national and regional levels. The plan is now to train at the district level. Proposed guidelines for the system are available in draft form, and the department has requested to license Vigiflow, and link up to the UMC. The aim is to start reporting in 1 year's time, and in 4-5 years become a center of excellence for PV in Africa.
- In Tanzania, the PV system is functioning, and an estimated 900 reports have been collected since the inception of the program, with 217 reports collected between June 2006 and July 2007. There is a process for sending the reports from the regions, and once they arrive at the central level, they are expected to be reviewed within 5 working days (in the case of emergencies they are attended to upon arrival). The priority objectives for the department are to 1) promote health providers' responsibility to report ADRs, and 2) sensitize patients to also report ADRs, although there is no process for recording ADRs from patients directly. The system uses Vigiflow and is linked to UMC. So far only 67 ADR reports were entered into Vigiflow, in the e2b format, and another 580 ADR reports were entered into Vigibase (the older format).

- A total of approximately 200 ADR reports have been collected since the inception of the pharmacovigilance program and of these, 167 have been entered in Vigiflow. During the past 12 months, 122 ADRs were collected. It is estimated that the time required for ADR forms to move from the health professional to being fully analyzed is about 3 months, and the NDA is expecting this to improve. [Authors comment: we should also collected more information in terms of what types of analyses were conducted with this data] The assessments have yielded some early results already; for example, some quinine batches have been recalled and Hedex (Paracetamol / Caffeine / Acetyl Salicylic Acid) has been reformulated as a result of the pharmacovigilance activities.

VI. Coordination and Collaboration for PV

All countries appear to be quite similar in terms of collaboration and coordination for pharmacovigilance:

- All have received support from WHO in terms of capacity building
- All have been trained at UMC, and are/will be using Vigiflow for analyzing their ADR reports
- All are coordinating with the Malaria and HIV/AIDS Control Programs for ADRs, but less so with the TB program at the moment. The Malaria Control Program seems of greater interest at present with the introduction of ACTs in both countries.
- All are also working with other technical and donor organizations.

VII. Challenges and Future Scale Up

In terms of challenges, the PV officers highlighted a greater need for commitment and buy-in from key government stakeholders, which should also then result in additional resources being invested in the pharmacovigilance program—viz additional HR and financial resources.

Where pharmacovigilance programs are being implemented, the ‘returns’ are low—few ADR forms are completed and returned, and when received, the subsequent steps of data entry and data analysis are difficult to complete as there is not sufficient technical capacity in the country. Building capacity through training and more importantly, by retaining trained staff has always been a challenge.

The interviewees cited the following components to help strengthen their pharmacovigilance programs:

- Technical advice on implementation and scaling up of PV programs
- Training, with Kenya specifically mentioning the need for regional training, and all countries mentioning the need for data entry and analysis of ADR information for detecting and following up on signals

- An approach where the countries could have quick results while also strengthening their existing systems; provision of training while required was considered to be a long-term solution.
- Additional sources of funding for scaling up efforts

Conclusions:

The challenges cited by Kenya, Tanzania and Uganda appear to be quite similar. These efforts require a lot of political, financial, human and technical support, which must all be sustained over a long period of time. As it stands today, most PV officers receive 1-2 weeks of training from UMC and WHO and then return to their countries to initiate or scale up a national pharmacovigilance program. The challenge is how can these individual ‘Pharmacovigilance Ambassadors’ now transform the system and process of doing pharmacovigilance in their country? The challenge is even more significant as it relies on the *hope* that health professionals understand and will complete the ADR forms after a brief exposure to pharmacovigilance discussions by the NDA staff.

And while the challenge of getting completed ADR forms is critical, it is only a small part of the challenge. Once these forms reach the center the PV department must have the technical capacity and “bandwidth” to conduct causality and signal analysis. If done right, each country should receive several thousand reports each year and this should keep growing in number.

To support this kind of effort, the PV program of each country will need to establish at least a 4-5 person team; provide regular training to health workers; receive additional training in how to establish and operate a PV center; implement what they have learned, and where possible coordinate with global experts. This will require several years of sustained effort before most countries would reach a state of proficiency in conducting and implementing PV programs.

It is during this interim period, while the countries are in the process of strengthening their capacity that they require external assistance to catalyze their ongoing programs and also to explore some short-term options that can supplement their ongoing activities.

As appropriate and if requested by the countries, the RaPID approach will be presented and discussed with the various NDAs.

Part 2: Detailed findings (completed questionnaires) from countries regarding their pharmacovigilance capacity

Kenya's Capacity in Pharmacovigilance

I. Background Information	
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II. PV Policy Framework	
Is there a national policy, legal framework for PV?	Although there is no direct legal mandate, there is an act of parliament which regulates pharmacists' practice, and includes a section on quality, safety and efficacy of pharmaceutical products.
Is there a national action plan (strategic plan or operating annual plan)? If no, confirm if drug safety is being monitored today?	There is a National Strategic Plan and an Annual Operating Plan. Yes, drug safety is being monitored, see details below.
III. Organizational Structure/Capacity for PV	
Are there a National center/ department/ unit dedicated to PV only? If no, is there any other center/department/unit responsible for PV?	There is a department within the Kenyan Pharmacy and Poisons Board (PPB), dedicated to PV. Jayesh heads it.
What is the name of center/department/unit for PV?	Department of Pharmacovigilance
When was it created?	Mr Pandit was hired in October 2004 and the department began its activities in January 2005.
What is the overall organizational structure of the center/department/unit? Where does it fit in, what is the reporting structure? (simple organogram)	The head of PV reports to the Registrar of the Pharmacy and Poison Board, which in turn reports to its Board of Committee Members. The Chairman of this committee is the Director of Medical Services (MOH), who reports to the Minister of Health. The Secretary of the Board is the Chief Pharmacist/Registrar.
Is there any specific focus area for PV within national health programs (HIV/Malaria/other)?	Yes, actively within the Division of Malaria Control. There is also interest within the National AIDS and STD Control Program (NAS COP), which has requested meetings with the PV Department (this week). Possibly also within the National Leprosy and TB Programs.
Annual budget for center/department/unit for PV (provide % share of the budget of parent)	The budget requested for 2007 was 7.5 million Kenyan Shillings (over USD 100,000), but it was not clear how much was actually being granted.

	Ministry/Authority)	
	Is there any contribution from external funding source/Private sector (as PPP)? How much? Who is/are the donor agency/ies?	There are contributions from sources other than the MOH. For example, WHO provides funding for PV? Other donors also provide funding through national programs, such as Malaria and HIV/AIDS. The proportion of funding from outside sources is not known. Donor agencies include: Malaria: WHO, Gates, Health Action International (HAI)/Africa HIV/AIDS: World Bank, PEPFAR (USAID) Donors are realizing the need for PV in their programs, and starting to put financial resources in the health programs for this purpose.
	Is there any increase/decrease in budget in last two years? How much? Provide one to two critical reason/s for significant changes	Budget has increased over the past years, as the department is new and the first year was dedicated to exploring the level of awareness and knowledge of PV within the health sector.
	How many staff are dedicated only to PV? Full time equivalent? What are their areas of responsibility? (brief)	Only one staff until very recently, who is the Head of Department for pharmacovigilance. Now there is one new staff member who is a pharmacy technician and comes from Drug Registration Department. He will be appointed as the Deputy Head of Pharmacovigilance.
	Is there any capacity building activity for staff for PV? How many existing staff for PV are trained for PV? What were the training topics? When were the trainings carried out? By whom? What are the plans for future training?	Mr. Pandit was trained in clinical pharmacy sciences at Mysore, India, part of that covered basic PV concepts. He attended the WHO sponsored 2-week course in PV at Uppsala Monitoring Center in 2007. The course covered all PV related topics. Attended the WHO training in Rational Use of Medicines at IIHMR, India. Recently attended WHO/UMC training for PV consultants in Ghana as East Africa representative (Kenya, Uganda, and Tanzania).
IV.	PV Process	
	Is there a nationally approved ADR form? What system of PV is used? How are adverse drug reactions and other drug related problems detected (e.g. drug abuse, poisoning, medication errors)? [List ways: Passive PV/Active research/Cohort event Monitoring (CEM)/Follow up, prescription event monitoring, case control studies, any other]	Yes, the ADR form was just recently approved. 1. Spontaneous reporting is being rolled out at a national level. PV Sensitization Training at the central and provincial levels was conducted in June 2007, with ~ 100 people trained (7 people from each of the 8 provinces, + many from central level.) There is a plan now to roll out at the district levels. 2. Planned: Active monitoring (with mandatory reporting) of use of ACTs during pregnancy at sentinel sites with the Division of Malaria

		Control. (Small cohort, with inclusion/exclusion criteria) 3. Proposal expected: ARVs
	Is reporting mandatory or voluntary or both? If mandatory, as part of which health program?	Reporting has not started yet. Will be both. See above. *Proposed guidelines for the implementation of the PV system are written. (Jayesh will send them to us.) However no SOPs or TORs have been developed.
	Who fills out the reports – Doctor/Nurse/Pharmacist/other?	*See above.
	How are data entered, processed, analyzed, shared? Which database are used – Vigiflow/Aris G/Other? Since when?	*See above. PV Department is looking to license Vigiflow and link up to UMC.
	How data quality is ensured?	*See above.
	Is there specific target population for PV - pregnant women, children, elderly, and patients with HIV/AIDS, Malaria /other?	With Division for Malaria Control, sentinel sites will monitor use of ACTs in pregnancy. HIV/AIDS Division is interested in implementing PV with ARVs.
	Are target populations/patient groups involved in the process? At which stage? How?	*See above.
V.	PV Efficiency, Quality, and Outcomes	
	How many individual reports have been collected since the last 12 months? What are the total number of reports that you have? How many have been analyzed?	None. The aim is to start reporting to UMC in one year's time, and for Kenya to be a center of excellence in PV in 4-5 years.
	How would you rate the quality of the final reports? [Completeness of forms, quality of reporting]	N/A
	How would you assess the institutional capacity to detect signals? Establish causality? Do you rely on outside sources to do this? (which ones)	N/A
	How long does it take to fill reports/forms to: transmit to centre -> enter into database -> analyze -> share with parent institution?	N/A
	Have any ADR problem/s been detected? Any other drug related problem/s?	There have been reports of "lack of efficacy" and "poor quality" and counterfeit medicines routinely. The pharmacovigilance dept has been proactive and updated their reporting tool. (<i>Author's comment: get a copy of the modified tool</i>)
	How is ADR information disseminated	N/A

	to policy makers, doctors, pharmacists, nurses and other paramedics, health system, institutions, other – confidential letters/conferences/mass media? How soon and how often?	
	Is there any instance of policy decision as a result of PV? Has there been any drug withdrawal/s?	Dept of pharmacovigilance has assisted in recalling some antibiotic injections and in withdrawing some molecules as per WHO updates- like Nimesulide in pediatric populations, Gatifloxacin etc.
	How do you measure outcomes/impact of PV program?	N/A
	Is there an ADR advisory committee? Review panel?	Not yet, but will be announced shortly.
VI.	Coordination/Collaboration for PV	
	Name the centers/departments/units with which the PV information/reports/analysis are shared apart from the parent institution/authority? Why? How?	*See above.
	Is there any exchange of information or communication with UMC? What kind?	Yes, mostly through training. Expectation is to link with UMC once system is up and running.
	Is there any coordination/collaboration any organization at national/regional/international levels - for e.g., with MSF/PSI/CHAI/FHI/other? Briefly describe the area/s and nature of coordination/collaboration.	See proposed guidelines, which list organizations in the acknowledgments. Divisions of Malaria Control and STD/AIDS Control, WHO, Health Action International (HAI)/Africa, Missions for Essential Drugs and Supplies (MEDS), MSH, and more.
	Any other programs, organizations doing PV? Which ones? What areas? Highlight if there are any organizations for HIV/AIDS, Malaria control involved in PV. Provide salient activities; any coordination/collaboration initiative?	See what is mentioned earlier.
VI I.	Challenges and Future Scale Up	
	What are the challenges in implementation of PV including capacity constraints; responding to signals of ADR; assessing events, severity, causal relationships, etc?	<ul style="list-style-type: none"> - Human resources: up to recently, has been a one-man show - Lack of vehicles for rolling out training - Commitment to program (at the time of training in June, money requested to pay training participants was not available, he had to pay some out of pocket until they released the budget) - Not all PHPs are as active in PV as the Malaria

		<p>Control Division. Other programs suffer from bureaucracy and lack of commitment. (Many in MOH don't know that PV is taking place; others feel they can do without.)</p> <ul style="list-style-type: none"> - After collection of data, then what, how do we proceed effectively - If we would like to become the Center of Excellence, how can we achieve this goal, quickly?
	<p>What would you suggest for improving and scaling up PV, especially in HIV/AIDS, malaria?</p>	<p>Too soon to say.</p>
	<p>What assistance (technical/financial) would be needed to establish an efficient and effective PV system?</p>	<ul style="list-style-type: none"> - More advisory and supervisory support (for example for development of SOPs and TORs), and support from global experts - On site WHO/UMC training, to train more people and save costs. Training he received was only for him. He could host for ex. 20 people from each country/location: Kenya, Uganda, and Tanzania. - More financial support to fund two more people, to roll out trainings faster. - Infrastructure support as the department grows - Exchanges with other PV programs - Data collection must be followed by data entry, analysis and ensuring safer, more effective and better quality products are on the market

Tanzania's Capacity in Pharmacovigilance

I. Background Information	
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II. PV Policy Framework	
Is there a national policy, legal framework for PV?	Although there is no national policy dedicated specifically for pharmacovigilance, there is documentation that addresses control of ADRs.
Is there a national action plan (strategic plan or operating annual plan)? If no, confirm if drug safety is being monitored today?	The TFDA has a strategic plan, which was updated last year. Each year an annual operating plan is developed, the annual PV plan is a component of this.
III. Organizational Structure/Capacity for PHARMACOVIGILANCE	
Is there a National center/ department/ unit dedicated to PV only? If no, is there any other center/department/unit responsible for PV?	The main activity of the Risk Assessment and Product Promotion Control is PV. In addition, pharmacovigilance is also the responsibility of Product Promotion Control (drug advertising, etc.). It is linked to 4 regional centers: Kilimanjaro, Bugando, Muhimbili, and Mbeya. There are plans to open new zones in Dodoma and Mtwara *In Jan/Feb 2008, the structure of the department will change and the Department will be renamed the Pharmacovigilance and Clinical Trial Control Department, which will include all the PV functions. It will report to the Director of Medicines and Cosmetics, who is one of the 4 directors who report to the Director General of the TFDA. The reason for this change is the expected increase in PV activities. It is also with the intent to implement a product-oriented structure, rather than a function-oriented structure. [<i>Author's comment: it will be important to examine the success of this approach vs. other approaches.</i>]
What is the name of center/department/unit for PV?	Risk Assessment and Product Promotion Control Will be renamed to be the Pharmacovigilance and Clinical Trial Control Department
When was it created?	July 2003, active in 2004
What is the overall	Now, the dept. reports to the Director of Product Evaluation and

	<p>organizational structure of center/department/unit? Where does it fit in, what is the reporting structure? (simple organogram)</p>	<p>Registration. (discussed above)</p>
	<p>Is there any specific focus area for pharmacovigilance within the national center (HIV/Malaria/other)?</p>	<p>Yes, within the Malaria and HIV/AIDS programs.</p> <p>With Malaria program, plan is to do a cohort study to monitor use of antimalarials.</p> <p>Two projects are being discussed with the National AIDS Control Program.</p> <p><i>[Author's comment: collect more information on these projects]</i></p>
	<p>Annual budget for center/department/unit for PV (provide % share of the budget of parent Ministry/Authority)</p>	<p>For 2007/08 it is 5 million Tanzanian Shillings (about US\$ 5,000). These funds are available directly to the department but there are other activities that complement the PV activities which are budgeted for in other directorates such as procurement.</p> <p><i>[Author's comment: given this level of 'fragmented funding' which is per line item and sometimes in different departments, it is difficult to accurately determine the level of funding for pharmacovigilance in Tanzania. Needless to say, it is greater than the figure provided above].</i></p>
	<p>Is there any contribution from external funding source/Private sector (as PPP)? How much? Who is/are the donor agency/ies?</p>	<p>Three sources of funding:</p> <ol style="list-style-type: none"> 1) MOH 2) TFDA's own resources 3) GFATM: \$50,000 for PHARMACOVIGILANCE
	<p>Is there any increase/decrease in budget in last two years? How much? Provide one to two critical reason/s for significant changes</p>	<p>An increase in budget is planned, as the overall plan is to "activate" the current PV system for the collection of ADRs. It is expected that the budget will increase three-fold.</p>
	<p>How many staff members are dedicated only to PV? Full time equivalent? What are their areas of responsibility? (brief)</p>	<p>Currently there are 2 full time staff members within the department. They share responsibilities across PV and product promotion control, with more focus on PV.</p> <p>The head of department can also call upon other pharmacists within the TFDA, though this is in practice quite difficult.</p> <p>Regional center staff members also have responsibilities other than PV.</p>
	<p>Is there any capacity building activity for staff for PV? How many existing staff</p>	<p>Mr. Mtenga has recently joined and has not yet been trained. Training has been discussed with his supervisor.</p>

	for PV are trained for PV? What were the training topics? When were the trainings carried out? By whom? What are the plans for future training?	Two staff attended UMC PV training. Three staff attended the WHO PV training in Ghana this year
IV.	PV Process	
	Is there a nationally approved ADR form? What system of PV is used? How are adverse drug reactions and other drug related problems (drug abuse, poisoning, and medication errors) detected? [List ways: Passive PV/Active research/Cohort event Monitoring (CEM)/Follow up, prescription event monitoring, case control studies, any other]	Yes Currently, use passive system, with spontaneous reporting. Any report on ADR is evaluated.
	Is reporting mandatory or voluntary or both? If mandatory, as part of which health program?	Voluntary
	Who fills out the reports – Doctor/Nurse/Pharmacist/other?	MD and Medical assistants, Pharmacist, and Nurses, at the hospitals, dispensaries and health centers
	How are data entered, processed, analyzed, shared? Which database are used – Vigiflow/Aris G/Other? Since when?	ADR report is sent by mail either to the regional center, or to the department. Staff evaluate all reports received and the reports for serious problems are followed -up appropriately. Since July1, the department has received 1 report. Data is entered into Vigiflow.
	How data quality is ensured?	This is done through the SOPs for Quality Assurance of ADR reports at the regional centers and at the TFDA. Staff evaluates the reports and ADRs in relation to the drug (subject/product.)
	Are there specific target population for PV - pregnant women, children, elderly, and patients with HIV/AIDS, Malaria /other?	Don't know.
	Are target populations/patient groups involved in the process? At which stage? How?	Yes, attended meetings organized by people living with HIV/AIDS to discuss safety of some ARVs Plan for the future is to 1) encourage health providers to feel more responsible for reporting ADRs, and 2) sensitizing patients to also report ADRs. And to “activate” the existing system.
V.	PV Efficiency, Quality, and Outcomes	

	<p>How many individual reports have been collected since the last 12 months? What are the total number of reports that you have? How many have been analyzed?</p>	<p>From June 2006 to June 2007, 217 reports were collected and evaluated. 67 reports were entered into Vigiflow (those that were found to have 'real' ADRs. Total number: 905 since the start of the program out of those 617 have been analyzed since the start of the program.</p>
	<p>How would you rate the quality of the final reports? [Completeness of forms, quality of reporting]</p>	<p>Poor. The key difficulty is the health providers' ability to differentiate ADRs from other events</p>
	<p>How would you assess the institutional capacity to detect signals? Establish causality? Do you rely on outside sources to do this? (which ones)</p>	<p>This is an area where additional training is needed.</p>
	<p>How long does it take to fill reports/forms to: transmit to centre -> enter into database -> analyze -> share with parent institution?</p>	<p>1-2 weeks to receive the reports. Reports are screened within 24 hours, and an emergency response is given to reports that indicate a serious problem.</p>
	<p>Have any ADR problem/s been detected? Any other drug related problem/s?</p>	<p>Probably, examples are not known though.</p>
	<p>How is ADR information disseminated to policy makers, doctors, pharmacists, nurses and other paramedics, health system, institutions, other – confidential letters/conferences/mass media? How soon and how often?</p>	<p>ADR information is disseminated either in person or in writing to the regional centers. WHO sends regular information bulletins regarding drug safety. This has resulted in drug withdrawals. It is unknown though whether the decision is based on ADR reporting.</p>
	<p>Is there any instance of policy decision as a result of PV? Has there been any drug withdrawal/s?</p>	<p>Unknown</p>
	<p>How do you measure outcomes/impact of PV program?</p>	<p>By drugs withdrawn, unknown how many though have resulted from ADR reporting.</p>
	<p>Is there an ADR advisory committee? Review panel?</p>	<p>Yes</p>
VI.	Coordination/Collaboration for PV	
	<p>Name the centers/departments/units with which the PV information/reports/analysis are shared apart from the parent</p>	<p>Public health programs. WHO/UMC NGOs most likely, though no names mentioned.</p>

	institution/authority? Why? How?	
	Is there any exchange with UMC? What kind?	Yes, through training and Vigiflow.
	Is there any coordination/collaboration any organization at national/regional/international levels - for e.g., with MSF/PSI/CHAI/FHI/other? Briefly describe the area/s and nature of coordination/collaboration.	Yes--Management Science for Health (MSH), Ifkara Health Research and Development Center. Malaria control program, National Aids Control Program. Department of TB & Leprosy at the Ministry of health and Social Welfare.
	Any other programs, organizations doing PV? Which ones? What areas? Highlight if there are any organizations for HIV/AIDS, Malaria control involved in PV. Provide salient activities; any coordination/collaboration initiative?	Unknown

VII. Challenges and Future Scale Up		
	What are the challenges in implementation of PV including capacity constraints; responding to signals of ADR; assessing events, severity, causal relationships, etc?	<ol style="list-style-type: none"> 1. Lack of buy-in from all stakeholders, particularly health providers and product registrants 2. “Low” technical capacity of staff and small number of staff—gathering ADR reports and doing the causality and signal analysis is challenging 3. Financial constraints to accomplish all activities 4. Shortage of human resource
	What would you suggest for improving and scaling up PV, especially in HIV/AIDS, malaria?	Not able to comment as Mr Mtenga has only recently taken over this position.
	What assistance (technical/financial) would be needed to establish an efficient and effective PV system?	<ol style="list-style-type: none"> 1. Training: <ul style="list-style-type: none"> - At central level, lessons learned from other countries - On use of ADR information, and detecting and following up on signals 2. Advice/guidance on how to scale up PV activities. 3. How to manage in the ‘limited’ financial and HR environment that we are operating in

Uganda's Capacity in Pharmacovigilance

I.	Background Information	
	Name	Helen Byomire Ndagije
	Designation	Head Drug Information Department
	Department, Ministry	National Drug Authority (NDA)
	Address	P.O.Box 23096 Kampala, Plot 46/48 Lumumba Ave
	Email	hbyomire@nda.or.ug , helenbyomire@yahoo.co.uk
	Phone; Mobile; Fax	256- 414 -2556655/ 347391/2; 256- 772 – 469094; 256- 414 - 255758
II.	PV Policy Framework	
	Is there a national policy, legal framework for PV?	There is no national policy or legal framework at this time.
	Is there a national action plan (strategic plan, operating plan)? If no, confirm if drug safety is being monitored today?	The national plans are in the process of being developed. Yes
III.	Organizational Structure/Capacity for PV	
	Is there a national center/ department/ unit dedicated to PV only? If no, is there any other center/department/unit responsible for PV?	The national centre for PV was established in the Drug Information department (DID) at NDA.
	What is the name of center/department/unit for PV?	The Uganda National Pharmacovigilance Centre
	When was it created?	October 2004
	What is the overall organizational structure of center/department/unit? Where does it fit in, what is the reporting structure? (simple organogram)	The head of DID reports to the Executive Secretary/ Registrar (ES/R) of the NDA, who in turn reports to the Chairman of the Board, who reports to the Minister of Health. The national centre for PV was established in the Drug Information Department (DID) at NDA. DID is one of the 5 core departments of NDA. Apart from the head of DID, there is a Drug Information pharmacist, 2 drug information technicians (nurse, pharmacy diploma) who handle PV activities. There is also a PV Advisory Committee of the NDA Board which is the strategic and decision making arm of the NDA.
	Is there any specific focus area for pharmacovigilance within the national center (HIV/Malaria/other)?	All areas are handled
	Annual budget for	PV budget is 30.6% of the DID (department) budget and

	center/department/unit for PV (provide % share of the budget of parent Ministry/Authority)	0.7% of the overall NDA budget. The nominal amount in Ugandan Shillings or USD is still pending.
	Is there any contribution from external funding source/Private sector (as PPP)? How much? Who are the donor agencies?	Most of the money comes from external sources like: WHO, Malaria Consortium, prospects from PEPFAR/USAID, for example: WHO- USD20,000, USAID - USD300,000, Malaria Consortium/ DID funded our recent pharmacovigilance symposium.
	Is there any increase/decrease in budget in last two years? How much? Provide one to two critical reason/s for significant changes	There is an increase (data is still pending for how much the increase is)
	How many staff are dedicated only to PV? Full time equivalent? What are their areas of responsibility? (brief)	There is no staff totally dedicated to PV activities. They all do PV and other activities such as vetting drug promotional materials, reviewing applications for clinical trials, various regulatory activities like cGMP inspections, dossier evaluations etc. Altogether, there are two full time equivalent staff.
	Is there any capacity building activity for staff for PV? How many existing staff for PV are trained for PV? What were the training topics? When were the trainings carried out? By whom? What are the plans for future training?	2 people have been trained so far by the WHO Collaborating Centre for International Drug Monitoring in Uppsala, Sweden in 2005 and 2007 for two weeks each. One received training in 2005 at the pre-FIP conference in Egypt. They plan to train the new staff in basic skills and after that send them for more advanced training in pharmacovigilance.
IV.	PV Process	
	Is there a nationally approved ADR form? What system of PV is used? How are adverse drug reactions and other drug related problems (drug abuse, poisoning, and medication errors) detected? [List ways: Passive PV/Active research/Cohort event Monitoring (CEM)/Follow up, prescription event monitoring, case control studies, any other]	Yes Passive surveillance Various methodologies are used including, passive pharmacovigilance, active research, cohort event monitoring (CEM)/Follow up, case control studies, etc.
	Is reporting mandatory or voluntary or both? If mandatory, as part of which health program?	Generally it is voluntary; however it is mandatory for research
	Who fills out the reports – Doctor/Nurse/Pharmacist/other?	All health professionals
	How are data entered, processed, analyzed, shared? Which database are	Vigiflow software is used for data analysis.

	used – Vigiflow/Aris G/Other? Since when?	
	How is data quality ensured?	The process used is a 'double data entry' at the national PV centre and after discussions with PV advisory committee it is committed to UMC (WHO centre). <i>(Authors comment: The process appears to be thorough and it would be valuable to obtain further details of the this process)</i>
	Are there specific target population for PV - pregnant women, children, elderly, and patients with HIV/AIDS, Malaria /other?	Most HIV systems have a system of reporting- TASO, PEPFAR, various research centers.
	Are target populations/patient groups involved in the process? At which stage? How?	For research there may be depending on their selection criteria.
V.	PV Efficiency, Quality, and Outcomes	
	How many individual reports have been collected since the last 12 months? What are the total number of reports that have been collected? How many have been analyzed?	122 200 167 [<i>Author's comment: need to collect more information in terms of what types of analyses conducted</i>]
	How would you rate the quality of the final reports? [Completeness of forms, quality of reporting]	Fair; some missing information is still a problem and the quality can be improved.
	How would you assess the institutional capacity to detect signals? Establish causality? Do you rely on outside sources to do this? (which ones)	Not well developed; capacity is there but time is limited to conduct all the components Yes. The department is supported by the NDA Advisory Committee mainly made up of lecturers/ experts in clinical pharmacology and epidemiology.
	How long does it take to fill reports/forms to: transmit to centre -> enter into database -> analyze -> share with parent institution?	About 3 months; it is expected to improve as regional centers , 3 so far, have been trained to use Vigiflow.
	Have any ADR problem/s been detected? Any other drug related problem/s?	Yes. Yes. Quality issues like defective drugs, etc. (<i>Authors comment: collecting additional data here would be useful</i>)
	How is ADR information disseminated to policy makers, doctors, pharmacists, nurses and other paramedics, health system, institutions, other – confidential letters/conferences/mass media? How soon and how often?	Through various methods: NDA Bulletin; the pharmacovigilance department intends to publish Pharmacovigilance Bi-annual Report. Conferences: the first was held on 28-29 th Aug 2007. Intend to also use mass media soon.
	Is there any instance of policy decision as a result of PV? Has there been any drug withdrawal/s?	Yes. For example, Quinine- batches were recalled; Hedex (Paracetamol / Caffeine / Acetyl Salicylic Acid) reformulated.
	How do you measure outcomes/impact of	Still low; But with the recent commitment from public

	PV program?	health programs, the center is expected increased level of activities and data capture.
	Is there an ADR advisory committee? Review panel?	Yes <i>(Authors comment: it would be useful to capture how these operate)</i>
VI	Coordination/Collaboration for PHARMACOVIGILANCE	
	Name the centers/departments/units with which the PV information/reports/analysis are shared apart from the parent institution/authority? Why? How?	NDA- especially Inspectorate National Referral Hospitals Regional Referrals Health professionals –letters Media- case by case , also depending on funds.
	Is there any exchange with UMC? What kind?	Yes. Various; E-mails for information, reports,
	Is there any coordination/collaboration with any technical organizations at national /regional /international levels - for e.g., with MSF/PSI/CHAI/FHI/other? Briefly describe the area/s and nature of coordination/collaboration.	No
	Any other programs, organizations doing PV? Which ones? What areas? Highlight if there are any organizations for HIV/AIDS, Malaria control involved in PV. Provide salient activities; any coordination/collaboration initiative?	Uganda Malaria Surveillance Program/ USAID-CDC doing cohort event monitoring, active research. UNEPI- routine passive/ some active vaccine surveillance, Malaria Consortium & Malaria Control Program- training for PV in private sector health workers. Various Research and donor funded projects for HIV.

VII.	Challenges and Future Scale Up	
	What are the challenges in implementation of PV including capacity constraints; responding to signals of ADR; assessing events, severity, causal relationships, etc?	Limited capacity; human, financial Poor culture of reporting ADRs Limited skills of causality assessment at the regional centers as well as national level.
	What would you suggest for improving and scaling up PV, especially in HIV/AIDS, malaria?	A policy for mandatory reporting in the PHPs.
	What assistance (technical/financial) would be needed to establish an efficient and effective PV system?	<ul style="list-style-type: none"> • Set up and use Vigiflow as a data management tool in all the 11 regional centers plus 2 national referrals • Train core teams in these regions to do causality assessment and fill in ADR reports • Mass campaigns – on drug safety • Continuous sensitization; support supervision • Having accessible focal points in the health units where forms can be availed or picked. • Exploring ways to make forms more available. • Incorporating PV into the Health Service Delivery. • Incorporating PV into CPD and CME and pre-service training • Making the forms simpler • Promoting pharmacovigilance: Use of posters and reminders.

Part 3: Visual Representation of Pharmacovigilance Findings and Country Comparison – Kenya, Tanzania and Uganda

A visual representation of the findings has been developed to provide a quick ‘snapshot’ of similarities and differences among the three countries. The visual representation is also useful in determining for which variables the countries have achieved greater success—further left implies countries have achieved more, while further right, implies countries have recently started these activities or have not achieved much yet.

For example, in the section of ‘Organization Capacity’ the three countries are grouped together for most of the variables, e.g. in terms of number of people, when the program was founded, amount of funding, etc. What is also interesting to note is that while they are grouped on the far left for several variables, they are grouped to the far right (weaker) in terms of level of funding they are receiving, number of people employed by the department, etc.

The same is observed for ‘Process’ section, where again, the three countries are grouped together in terms of having developed their ADR from, conducting spontaneous reporting, more with HIV and malaria than with TB, etc. Although there is intent and coordination with the HIV and in some cases TB programs, for the moment there is no data being captured from HIV and TB health programs (hence they are plotted on the far right).

In terms of ‘Efficiency, Quality and Outcome’, a greater variation is observed—while Kenya is embarking on an ambitious pharmacovigilance program but hasn’t collected any ADRs yet, Uganda has collected a few hundred, and Tanzania has collected almost 1000. These are still very few, but it gives a sense of range order and inter-country comparison. For most of the other variables, Tanzania and Uganda appear to be grouped together.

For ‘Collaboration’, again, there is a lot of grouping and the profiles of the 3 countries are quite similar—all appear to be collaborating closely with the HIV and malaria program, and less so with the TB program, as indicated earlier too.

This visual representation will be more useful as more countries are mapped on the same analytical grid to compare their activities, processes, outputs, etc.

Visual representation of pharmacovigilance findings and country comparison—Kenya, Tanzania and Uganda					
		Degree of 'Implementation'			
Components of Pharmacovigilance		More Favorable	----->		Less Favorable
			K	U	T
I. Policy/Planning	Policy/Legal Framework	Exists		U	Does Not Exist
	National FDA Strategic Plan	Exists	K	U	Does Not Exist
	PV Annual Operating Plan	Exists	K	U	Does Not Exist
II. Organization Capacity	Dedicated Department to PV	Yes	K	U	No
	When Founded	5-10 years		U	0-2 years
	Number of FT Staff	more than 5		U	1
	Attended pharmacovigilance training at UMC	Yes	K	U	No
	Attended pharmacovigilance training--other	Yes	K	U	No
	Total Annual Funding	\$5million		U	< \$1 million
	Recent Increase in Annual Budget	Yes	K	U	No
	MOH Funding	Yes	K	U	No
	Donor Funding - Other	Yes	K	U	No
	III. Process	Nationally approved ADR form	Yes	K	U
Passive Reporting System in Place		Yes	K	U	No
Monitoring Spontaneous Reporting					
for Malaria Control		Yes	U		No
for HIV/AIDS		Yes		U	No
TB		Yes		U	No
Vigiflow being used?		Yes	U		No
Interaction with UMC?		Yes	K	U	No
IV. Efficiency, Quality, Outcomes	Number of Reports Collected (Kenya--N/A)	>5000		U	<100
	% of reports analyzed (Kenya--N/A)	most (>90%)		U	<10%
	Quality of data (Kenya--N/A)	Excellent		U	Poor
	Feedback Mechanism in Place	Yes	U		No
	Resulted in Changes in Policy	Many examples		U	Few examples
	ADR Advisory Committee	Yes	U		No
	V. Collaboration	With other PHP			
HIV/AIDS		Yes	K	U	No
Malaria		Yes	K	U	No
TB		Yes		K	U
Global Organizations	Yes	K	U	No	

Color coding	
Kenya	K
Uganda	U
Tanzania	T

Part 4: Illustrative Example--Assessment of Level of Activity of Public Health Program

In addition to assessing the PV program for each country, it will be important to assess the disease specific public health program for each country too. By understanding the public health structure, current level of treatment and care provided to patients, availability of health staff, etc, the PV program of the country should be able to develop better strategies for coordination and gathering of ADR data. The below questionnaire was conducted for Kenya as an example, and specifically for HIV/AIDS.

Program: HIV/AIDS

Country: Kenya

Date: September 2007

I. Respondent: Background Information	
Name	Dr. Jayesh M. Pandit
Designation	Head of Department
Department, Ministry	Department of Pharmacovigilance, Pharmacy and Poisons Board, Ministry of Health.
Address	P.O. Box: 27663-00506, Nairobi, Kenya.
Email	pv@pharmacyboardkenya.org jayesh@mapandit.com
Phone; Mobile; Fax	+254-20-2716905 / 6- Office +254-721348503 / +254-733733349- Mobile +254-41-2225898 / +254-20-2713538- Fax

II. Country and Public Health Information	
Country Population	31.3 million
Number of States/ <u>Provinces</u>	8 provinces
Number of Districts	72
Number of:	
National Hospitals	2 Nationally recognized Referral Hospitals
State/Provincial Hospitals	8 Provincial General Hospitals (PGHs)
District Hospitals	65 District Hospitals
Primary Health Centers (approx)	Approx 4000 HCs

III.	HIV/AIDS Treatment Information	
	Number of Antiretroviral Treatment Centers in the -- - Public Sector - Private Sector	Approx. 266 centers 202 64 (Mission/Faith based= 43, Private=17 and NGO= 4)
	What is the estimated number of people taking ARVs? What % are pediatrics patients taking ARVs?	160,000 patients 12,000 pediatric patients currently on ARVs
	What is the estimated number of DAILY visits to the ART centers in- -Larger and busy ones -Smaller and less busy ones	This depends per site, but on approximation: 250 patients per month < 50 patients per month
	Which types of staff are operating the ART Centers? Provide data for a 'large' and a small ART center	Staff includes Medical Officers, Clinical Officers, Nurses, Pharmacists and Pharmaceutical technologists. This may be seen at the "high volume" sites, typically. However, at the very small "low volume" sites, the nurse may be the only person available.
	--Type of health professional? (medical officers, nurses, pharmacists, lab technician)	As above
	--Estimated % of Posts that are vacant?	Majority of sites always complain that they are understaffed! High volume of work is the reason in most cases! In the "low volume sites", nurses will be the sole healthcare provider.
	--Estimated salary Level in US\$ for each type of health professionals?	Approximation per month in US \$: Medical officers: 1300-1800 Clinical officers: 800-1000 Nurses: 500 Pharmacists: 1000-1500 Pharmaceutical technologists: 400-600
	What are the operating hours of the ART centers? --Which days of the week? --Typical hours of work each day?	The "high volume" sites are open Mon to Fri from 8am to 5 pm The "low volume" sites would have their clinic days once or twice a week... days chosen per site.

IV	Human Resources availability (Nurses and Pharmacists)	
	<p>Hiring of Nurses</p> <p>If one needs to hire nurses, how easy would it be to find 25 nurses in the country?</p> <p>What type of nursing degrees are available in the country? (Diploma, bachelors, masters, etc.)</p> <p>How many years do each of the above nursing programs take to complete?</p> <p>What is the average monthly salary for these different types of nurses? In different settings (public hosp, private clinic or hospital, other settings)</p>	<p>Very easy for research purposes especially from the public sector</p> <p>BSc Nursing Diploma Community Enrolled Nurse Registered Nurse</p> <p>BSc Nursing- 4 years Diploma- 3 years Community Enrolled Nurse- 2 years Registered Nurse- not sure</p> <p>Approx salary in US\$: BSc Nursing- 400-500 Diploma- 250-300 Certificate: 150-200</p>
	<p>Hiring of Pharmacists</p> <p>If one needs to hire pharmacists, how easy would it be to find 25 pharmacists in the country?</p> <p>What type of pharmacy degrees is available in the country? (diploma, bachelors, masters, etc.)</p> <p>How many years do each of the above pharmacy programs take to complete?</p> <p>What is the average monthly salary for these different types of pharmacists? And in different settings (retail pharmacy, private hospital, public/government hospital, industry sales person)</p>	<p>Very easy for research purposes especially from the public sector</p> <p>Diploma in Pharmacy, Bachelor in Pharmacy, Master in Pharmacy and PhD Diploma in Pharmacy- 3 years Bachelor in Pharmacy- 4 years Master in Pharmacy- 2 years and PhD- 2-3 years</p> <p>There is no major distinction between the different sectors though private may often be a little higher. On average the following are the salaries, in US \$.</p> <p>Diploma in Pharmacy- 600 Bachelor in Pharmacy- 1000-1400 Master in Pharmacy- 1000-2000 PhD- 2000-3000</p>

V	Communications Networks	
	<p>Is Internet available?</p> <ul style="list-style-type: none"> - In capital, Major cities - Major towns 	<p>Yes</p> <p>Yes</p>

	Are cell phones available? -What is the degree of coverage in the country (most of it, small part of it)	Yes Most of the country at present is connected (60-70%) through one mobile provider or another and the network is expanding!
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VI	Other Contacts/Information	
	Who is the Head of National Malaria Program	Dr. Willis Akhwale Head- Division of Malaria Control (DOMC)
	Who is the Head of National HIV/AIDS Program	Dr. Ibbrahim Mohammed Head- National AIDS and STD Control Program (NASCO)
	Who is the Head of National TB Program	Dr. Joseph Sitienei Division of Leprosy, Tuberculosis and Lung Disease (NLTP)
	Is there an operational and active CCM?	Yes there is.

Appendix 1: Agreement for Performance of Work (APW) excerpts

For purposes of the EC/ACP/WHO Pharmaceutical Project, the preliminary workplan will focus on assessment of situation in 3 EAC countries and formulation of plans.

Specific Activities:

1. Visit some of the EAC group of countries to conduct an assessment of the current pharmacovigilance system, public health programs and pharmacovigilance activities, including activity of the pharmacovigilance center—number of people, number of reports collected/analyzed, etc.
2. Where appropriate, determine how the RaPID program must be tailored to meet the countries needs (3 countries or more)—including customizing the ADR report form for that country/program, number of people required to collect data, etc. (next phase)
3. Help write proposal for funding pharmacovigilance activities for country (next phase)

Deliverables:

1. Assessment reports of at least 3 EAC countries and their pharmacovigilance capabilities
2. If appropriate, a customized approach for RaPID to work with these countries (next phase)

Appendix 2: People Contacted During the Pharmacovigilance Assessment Project (September 2007)

Uganda

Name	Title/Position	Organization	Contact Details	Intro by
Mr. Apollo Muhairwe	Head NDRA	NDRA	Apollo5000x@yahoo.com Plot 46-48 Lumumba Avenue PO Box 23096, Kampala, Uganda.	Dr Matsoso
Joseph Mwoga	NPO, WHO	WHO	Mwogaj@ug.afro.who.int	Dr Matsoso
Helen Byomire-Ndagije	Head, Drug Information Department National Drug Authority	NDRA	Tel: + 256 41 347391/2 Cell-phone: + 256 772 469094 Email address: hbyomire@nda.or.ug Web address www.nda.or.ug Email ID given by Apollo: ndaug@nda.or.ug	Mr. Apollo Muhairwe
Elizabeth Madraa	Head HIV AIDS National Program		077 2 695 109	

Tanzania

Name	Title/Position	Organization	Contact Details	Intro by
Margareth Ndomondo-Sigonda	Head of NDRA	NDRA	Mnsigonda@yahoo.co.uk +255 754 333 308	Dr Matsoso
Adelard Mtenga	Focal point for pharmacovigilance		Amtengab@yahoo.com	Dr Margareth Sigonda
Rose Shija	NPO--EDM Officer	WHO	Shijar@tz.afro.who.int EDM/NPO c/o WR/Tanzania, PO Box 9292, Dar Es-Salaam Tel: (255) 22 21 34244, Fax: (255) 22 211 3180 Cell: (255) 74 422 2263	Dr Matsoso

Kenya

Name	Title/Position	Organization	Contact Details	Intro by
Dr. Fred M. SIYOI	Registrar , Head of NDRA	NDRA - which is known as the Pharmacy and Poisons Board of Kenya, MOH	PO Box 27663-00506, Nairobi, Kenya. Cell-phone: + 254 724255934 Email Address: fmsiyoi@yahoo.com	
Jayesh M. Pandit	Lead for pharmacovigilance	Pharmacy and Poisons Board of Kenya, MOH	Jayesh@mapandit.com 2716905/6. Ext No.224 0721 348503	Fred Siyoi
Regina Mbindyo	NPO	WHO	Tel: 254 202 717 902 Fax: 254 2 2719 141 Cell: 254 733 678 332 Mbindyor@ke.afro.who.int	Dr Matsoso

WHO AFRO

Name	Title/Position	Organization	Contact Details	Comments
Ossy Kasilo	NPO, Regional Advisor Essential Medicines	AFRO	Kasiloo@afro.who.int	Dr Matsoso

Notes (intentionally left blank)