



# Report

On the

## Uganda Pharmaceutical Sector Scan

Part of Component 1 of MeTA Baseline Assessments

**JUNE 2010**

**Drafted by consultants:**

1. Samuel Balyejjusa, B.Pharm., MPH
2. Paschal Mujasi, B.Pharm., MBA
3. Eleanor Babirye, Dip. Pharm

***Note:** Comments from the WHO Harvard Collaborating Centre in Pharmaceutical Policy, who have provided technical support to countries for the pharmaceutical sector scan, have not yet been incorporated in this report.*

## **1. Introduction**

From 17<sup>th</sup> May to 4<sup>th</sup> June 2010, a pharmaceutical Sector Scan was conducted in order to assemble a core set of existing information about Uganda's pharmaceutical sector and to highlight key information gaps. A range of public and private sector institutions were scanned by a team of three consultants to assemble existing country-level data, assess their validity, flag inconsistencies between sources, and provide the most up-to-date summary of existing information. Key data was entered in a structured format using data forms which were classified according to the following domains:

1. Country Profile
2. Medicines Policy and Regulatory Framework
3. Medicines Market
4. Medicines Financing
5. Medicines Trade
6. Medicines Supply System
7. Medicines Access
8. Medicines Use

## **2. Key findings**

The key findings and gaps in each of the domains mentioned in section 1 above are summarized in the following sections

### **2.1 Country Profile**

#### **2.1.1 Key findings**

- Total population – 30.7 million
- Total annual per capita expenditure on health – 76,890/=
- Percent of MOH budget to total govt. budget – 9.8%
- Annual per capita government expenditure on health – 15,610/=
- Govt. annual expenditure on health as percentage of total health expenditure – 26.2%
- Annual per capita private expenditure on health – 36,795/=
- Private out-of-pocket expenditures as percent of total health expenditure – 51%
- Percent of total population covered by national, social or private insurance – 3%
- Physicians/10,000 population – 1
- Licensed Pharmacists/10,000 population – 0.12
- Licensed pharmacies/10,000 population – 0.14

### **2.1.2 Key issues for MeTA stakeholder group**

- Increase in Health Insurance coverage
- Increase in percentage of health budget versus total national budget
- Increase in number of licensed pharmacists and pharmacies

## **2.2 Medicines Policy and Regulatory Framework**

### **2.2.1 Key findings**

- NMP last updated in 2002
- NPSSP updated in 2009
- Legal provisions establishing NMS exist
- Legal provisions for marketing authorization exist
- NDA regulatory staff – 60
- Legal provisions for code of conduct in regulatory work non-existent
- NDA actively involved in regional harmonization
- NDA has a website: [www.nda.or.ug](http://www.nda.or.ug)

### **2.2.2 Key issues for MeTA stakeholder group**

- Legal provisions requiring transparency and accountability and promoting a code of conduct in regulatory work.
- Update national medicines policy?

## **2.3 Medicines Market**

### **2.3.1 Key findings**

- Number of registered pharmaceutical products – 6,810
- No information on total annual market by value
- No data on market share by value of generics and locally manufactured medicines
- No list of top 20 medicines by value

### **2.3.2 Key issues for MeTA stakeholder group**

- Total annual market by value
- Market share by value of generics and locally manufactured medicines
- Top 20 medicines by value

## **2.4 Medicines Financing**

### **2.4.1 Key findings**

- Ministry of health budget for medicines - 300 billion
- Percent of MOH budget for medicines – 47%
- Total medicines expenditures per capita – 11,150/=
- No data on total medicines expenditure
- No data on percent govt. medicines expenditures
- There is no social or national health insurance – bill in process
- Medicines are obtained free at public health care facilities
- No user fees charged at all public health facilities except at private wings of referral hospitals.

### **2.4.2 Key issues for MeTA stakeholder group**

- Support the NHI bill
- Quantification of total medicines expenditure

## **2.5 Medicines Trade**

### **2.5.1 Key findings**

- An explicit and transparent process exists for assessing applications for registration of pharmaceutical products.
- A formal committee assesses applications for registration of medicines.
- Medicines registration fees exist.
- Samples are not tested as part of the registration process.
- An appeal process exists for medicines registration decisions
- Medicines register publicly available
- The list and application status of products submitted for registration are not publicly available.
- The lists of GMP compliant manufacturing plants and that of the type and number of sanctions following inspections are available on request from NDA.
- Legal provisions exist for licensing domestic and multinational manufacturers and importers.
- Legal provisions exist to inspect premises and collect samples, detect counterfeit medicines and to ensure quality control of imported and locally manufactured medicines.

- In the last year, 1,440 samples were tested for quality, out of which 80 samples failed the test. The list giving detailed results of quality testing is however not publicly available.
- Uganda does not have a policy to regulate medicine prices.
- There is no national medicine price monitoring system for retail/patient prices. However data on retail prices is collected by HAI in collaboration with MOH and WHO and supported by MeTA on a quarterly basis.
- There are no regulations mandating retail medicine price information to be made publicly accessible.
- The government does not charge duty on imported raw materials, imported finished products or VAT and other taxes on medicines.
- The consumer prices of medicines in the public sector are much lower than those in the private sector.
- Legal provisions exist to control promotion and/or advertising of prescription medicines.
- There are no legal provisions to control gifts from the pharmaceutical industry to prescribers.
- Regulatory pre-approval is required for medicines advertising and/or promotional materials. Committee procedures in guidelines and membership adhoc.
- There are no SOPs governing behavior of public procurement agencies in their interactions with sales representatives/wholesalers.
- Complaints, violations and sanctions relating to advertising of medicines are not systematically recorded.
- There is no professional code of conduct to limit gifts that physicians can accept from the pharmaceutical industry.
- There is no national code of conduct concerning advertising and promotion of medicines by pharmaceutical manufacturers.
- Pharmaceutical companies report their promotion and advertising budget in tax disclosures (as part of sales and marketing disclosures)

### **2.5.2 Key issues for MeTA stakeholder group**

- List and application status of products submitted for registration to be made public
- GMP compliant and non-compliant manufacturing plants and type and number of sanctions following inspection to be made public
- Results of quality testing not publicly available
- Policy on medicines price regulation
- National medicines price monitoring system for retail prices
- Legal provisions to control gifts from pharmaceutical industries to prescribers.
- SOPs governing public procurement agencies in their interactions with sales representatives/wholesalers.

- Recording of complaints, violations and sanctions relating to advertising of medicines.
- Professional code of conduct to limit gifts that physicians can accept from the pharmaceutical industry.
- National code of conduct concerning advertising and promotion of medicines by pharmaceutical manufacturers.

## **2.6 Medicines Supply System**

### **2.6.1 Key findings**

- National Standard Treatment Guidelines (STGs) exist for most common illnesses.
- Uganda Essential Medicines List (EML) exists.
- The process and criteria for selecting medicines on the EML are clearly documented and public.
- List of national EML members publicly available
- There is no national medicines formulary manual.
- There is a tender committee overseeing public procurement that is independent from the procurement office.
- Suppliers for public procurement are prequalified using explicit criteria and a list of prequalified suppliers and those who failed is available on request.
- Public sector tenders and winning bids are publicly available however there is no electronic bidding process.
- Results of quality testing during procurement process are available on request.
- There are no National guidelines for GDP and list of GDP compliant distributors is not available
- NMS uses software tools for management of medicines supply.
- Routine procedures exist to track expiry of medicines at NMS
- There are legal provisions for licensing wholesalers and a list of wholesalers is publicly available
- There are 190 wholesalers in the market

### **2.6.2 Key issues for MeTA stakeholder group**

- Introduce an electronic bidding process in the public sector tenders.
- National guidelines for GDP and list of GDP compliant distributors.

## **2.7 Medicines Access**

### **2.7.1 Key findings**

- 29% of patients travel more than one hour to reach a primary health care facility.
- 47% of the households obtain medicines for recent illness at a public health care facility.
- Key medicines are available at 47.5% of public health care facilities and only about 75% of prescribed medicines are actually dispensed
- 65% of households in the lowest socioeconomic quintile face monthly catastrophic expenditures on medicines
- 51% of households in the lowest socioeconomic quintile have a chronically ill member who requires medicines but has no medicines at home.
- The average monthly cost of medicines for the most frequent chronic disease in households in the lowest SE quintile is about 7,181/=.

### **2.7.2 Key issues for MeTA stakeholder group**

- Increase availability of key medicines in public health care facilities
- Reduce household catastrophic expenditures on medicines
- Increase access to medicines for chronic illnesses.

## **2.8 Medicines Use**

### **2.8.1 Key findings**

- There is a national program in the MOH to monitor and promote rational use of medicines.
- Public education campaigns about rational medicines use have been conducted by the MOH
- A written strategy does not exist to contain antimicrobial resistance and there is no dedicated national medical laboratory to coordinate epidemiological surveillance and promote rational use of medicines.
- About 80% and 33% of public health care facilities have copies of the national STGs and national EML respectively.
- Legal provisions exist to govern the licensing and prescribing practice of prescribers and health facilities.
- There are no legal provisions restricting dispensing by prescribers.
- There is no professional code of conduct to govern professional behavior of prescribers.

- An average of 3 medicines is prescribed per patient in a public health care facility. Of the prescribed medicines, 71.5% are prescribed by INN names, 96.8% are from the EML, 66.7% are antibiotics and 16.7% are injections.
- Legal provisions exist to govern licensing and dispensing practice of pharmacists and pharmacy establishments
- Legal provisions restrict prescribing by dispensers.
- A professional code of conduct governs professional behavior of pharmacists.
- The dispensing of antibiotics, injections, narcotics, psychotropic drugs and precursors is not allowed without a prescription.
- At public health care facilities, only 3% of dispensed medicines are adequately labeled and 76% of patients know the correct dosing of all dispensed medicines.
- 75% of prescribed medicines are actually dispensed at facility where they were prescribed.

### **2.8.2 Key issues for MeTA stakeholder group**

- A written strategy to contain antimicrobial resistance
- A dedicated national medical laboratory to coordinate epidemiological surveillance and promote rational use of medicines.
- Increase dissemination of the EML.
- Legal provisions restricting dispensing by prescribers.
- A professional code of conduct to govern professional behavior of prescribers.

## **3. Conclusion**

The key findings presented in section 2 above reflect a core set of existing information about Uganda's pharmaceutical sector and highlight areas where key information gaps exist. We hope that this data shall be paramount in assisting the national MeTA stakeholder groups in their efforts to improve transparency in the pharmaceutical sector and to set priorities for future activities.

## KEY REFERENCES

1. Essential Medicines List of Uganda, MOH, 2007
2. Medicines Transparency Alliance 2010: *Uganda Medicine Price Monitor 2009*, Kampala
3. Ministry of Finance and Economic Development of Uganda, 2009: *National Budget Framework Paper FY2009/10 – FY2013/14*, Kampala.
4. Ministry of Health of Uganda, 1999: *Uganda National Health Policy*, Kampala
5. Ministry of Health of Uganda, 2008: *Access to and use of medicines by households in Uganda*.
6. Ministry of Health of Uganda, 2008: *Pharmaceutical Situation Assessment – Level II – Health Facilities Survey in Uganda*.
7. Ministry of Health of Uganda, 2009: *Annual Health Sector Performance Report 2008/2009*, Kampala.
8. Uganda Bureau of Statistics, 2006: *Uganda Demographic and Health Survey*, Kampala
9. Uganda Clinical Guidelines, MOH, 2003
10. World Health Organisation, 2009: *Uganda Health Profile*, Geneva
11. World Health Organisation, 2010: *WHO World Health Statistics*, Geneva
12. World Intellectual Property Organisation, [www.wipo.int/treaties/en/summary.jsp](http://www.wipo.int/treaties/en/summary.jsp). Accessed 27th May 2010