



Strengthening the Legal Environment for the Elimination of Falsified and Substandard Medicines: Uganda Report



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Acronyms

ADR	Adverse drug reaction
API	Active pharmaceutical ingredient
AMRH	African Medicines Regulatory Harmonization
CEHURD	Center for Health, Human Rights and Development
CHAIN	Community Health and Information Network
CSO	Civil Society Organization
EAC	East African Community
GDP	Good distribution practices
GMP	Good manufacturing practice
HEPS	Coalition for Health Promotion and Social Development
IG	Inspectorate of Government
LEA	Law Enforcement Authority
MAH	Marketing authorization holder
MER	Medicine Evaluation and Registration
META	Medicines Transparency Alliance
MSM	Member State Mechanism
NDA	National Drug Authority
NEPAD	New Partnership for Africa's Development
NMS	National Medical Service
PMV	Pharmacovigilance
PSU	Pharmaceutical Society of Uganda
QMS	Quality Management System
SMS	Short message service
UNHCO	Uganda National Health Users' Organization
URA	Uganda Revenue Authority
UNCAC	United Nations Convention Against Corruption
UNTOC	United Nations Convention on Transnational Organized Crime
WHO	World Health Organization

Executive Summary

Falsified and substandard medicines (FS) are a known public health problem. FS medicines represent various threats to patients: they may contain an insufficient amount or no active ingredient, or dangerous ingredients. Drug resistance, treatment failure and death have been associated with these products. While the prevalence in developed markets is likely below 1%, it is estimated that up to and more than 15% of all drugs sold in developing countries constitute a threat to patients. Many factors facilitate the spread of FS medicines. One of the most important, in developing countries, is the need for strong national drug regulation. Added to the complexity in finding effective solutions is that falsified medicines are manufactured and sold by criminal individuals and organizations, exploiting weak national legislation and enforcement, and an unsuspecting and uninformed public.

Since the late 1980s the WHO and the global health community have been considering the problem of FS medicines. Despite challenges, some level of consensus is emerging on the actions and steps to be taken by the regulator and the obligations of one or more actors in the health system to manage the problem of FS medicines.¹ In short, these include prevention, detection, investigation and incident handling.

The goal of every medicines regulatory system is to ensure the health of the public, for whom access to affordable, safe, efficacious medicines of good quality is essential. To ensure the supply of such medicines, the health system and its government partners in law enforcement and criminal justice must perform a number of functions. These include preventing actual or suspected FS medicines from entering the medicines supply and, if they do enter, detecting their presence and containing them.

At a minimum, there must be a functioning regulatory authority: a national or regional drug authority that has the capacity to fulfill the main functions of the regulator. Though it is the case that “every regulatory function contributes to ensuring the safety quality and efficacy of drugs”,² some of these functions have specific roles to play with regards to FS medicines and these specific roles, in addition to the technical and scientific capacity, require particular legal authorizations and mandates. Effective management of the problem of FS medicines cannot happen unless there is a sufficient legal and regulatory framework that authorizes and mandates particular actions, and there are sufficient staff with the requisite skills who actually implement and enforce the legal framework.

This aspect of the solution set to the problem of FS medicines has not received significant attention, hence this initiative. Uganda was selected for this project as it is a member of the East African Community (EAC), and because of its commitment to boldly tackling the problem of FS medicines. No project of this type can be successful without the full participation and cooperation of the regulator, and Uganda has stepped up to this challenge. Tackling the legal and regulatory framework for FS medicines in Uganda in this pilot will serve the larger goals of harmonization in the region and pave the way for an East African Community (EAC)-wide strategy on FS medicines. This work is also very timely as the EAC harmonized medicine legislation and regulations are yet to be enacted in the EAC legal system and adopted in Uganda. As the harmonization work is ongoing, within it, the legal and regulatory provisions for any medicines regulatory matter including that of FS medicines should be considered.

Over the last two decades, Uganda has improved the availability of medicines and other essential health supplies. Nonetheless, like most countries, Uganda has challenges. Though the main functions of the regulator are present in the law, there are significant gaps in the legal and regulatory (civil, criminal and administrative) framework law that hamper the ability of

¹ Substandard/spurious/falsely-labelled/falsified/counterfeit medical products, Report by the Director-General, A68/33, 20 March 2015, available at: http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_33-en.pdf (accessed May 20, 2015). See also Countering the Problem of Falsified and Substandard Medicines <http://iom.nationalacademies.org/Reports/2013/Countering-the-Problem-of-Falsified-and-Substandard-Drugs.aspx>, Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, <http://conventions.coe.int/Treaty/EN/Treaties/Html/211.htm>

² Ratanawijitrasin, Sauwakon, Eshetu Wondemagegnehu, Effective drug regulation: A multi-country study. 2002 WHO, available at: <http://apps.who.int/medicinedocs/pdf/s2300e/s2300e.pdf> (accessed June 16, 2015).

the regulator to prevent, detect and respond to FS medicines. In the case of Uganda there is a significant staff shortage to manage all the pharmaceutical actors across the country.

The theory of change and structure of a national strategy to eliminate FS medicines is comprised of five parts; civil society, the national drug authority and the medicines law, the law enforcement and criminal justice sector, the private sector, and international and regional cooperation. This executive summary, report, and the draft national strategy are organized accordingly.

Civil society

Relevant civil society organizations include patients and consumer groups, advocacy organizations, and independent professional associations of medical practitioners and pharmacists. There is a need for all stakeholders to shift from the perception of civil society as simply consumers of medicines to the engagement of civil society as full partners in the national response to FS medicines. This reflects the human rights-based approach to health and development, which emphasizes participation, accountability, equality and nondiscrimination. This is particularly important as some communities still misunderstand the role of the National Drug Authority (NDA) and the importance of addressing FS medicines in Uganda. This misunderstanding has led to a lack of cooperation with government authorities in regulating FS medicines, and even hostility towards government inspectors responding to FS medicines. The general public needs to be empowered and provided with the information necessary to create the demand for appropriate, quality medicines. This includes for example ensuring that drugs are appropriately labelled, and expiry dates are checked.

Uganda has a vibrant and independent civil society sector, and there are several strong national civil society organizations which include health in their mandates. The role of faith-based communities and traditional leaders should also be considered. Civil society organizations should be engaged at all levels in the national response – including through representative participation in national structures. Trusted civil society champions and leaders should also be engaged in public education campaigns to inform people about the dangers of FS medicines. Finally, civil society engagement should be supported to extend to include regional and international collaboration regarding FS medicines.

Legal and Regulatory Environment

The following gaps have been identified:

- The National Drug Authority Act (the Act) is the main law governing medicines regulation, but its scope is limited to “drugs”. An amendment is in process to add medical devices, cosmetics, food safety, medical laboratory reagents, products for diagnosis, surgical supplies, blood, public health products and other products that are typically found in health systems as these too are often falsified or substandard and require regulatory oversight.
- The Act is accompanied by a set of nine regulations, all dated March 2014, - dated after the Act and covering essential topics of Licensing, the Suitability of Premises, Ectoparasiticides, Field Trials, Conduct of Clinical Trials, Control of Publication, and Advertisement, Fees, Pharmacovigilance, Importation and Exportation and Drug Registration.
- Regulatory inspectors, customs and border patrol and law enforcement officials are often not adequately equipped or authorized to identify FS medicines, properly prepare a file for prosecution, take immediate actions such as a preliminary seizure, and proceed through to conviction and sentencing. Law cannot implement itself and there must be adequate numbers of skilled staff to conduct the regulatory functions.
- There is a need to include a clear definition of FS medicines that is consistent throughout the legal system. Currently there is no definition of ‘counterfeit’ in the Act, though Art. 30 refers to impure drugs. The Regulation on Pharmacovigilance (PMV Regulation) defines “counterfeit drug” to mean “a drug which is deliberately or fraudulently mislabeled with respect to its identity, content or source.” A full definition of FS medicines could include elements that distinguish accidental substandard, negligent substandard, and intentional substandard, or accidental false label or packaging, as compared to intentional falsification (such as changing expiration dates).

- The ability of the NDA to prevent, detect and respond to FS medicines is hampered by the lack of reporting by pharmacists and health professionals, who are required to report adverse drug reactions and about FS medicines. These reports are critical to informing the post market surveillance system, however at present some stakeholders are not obligated to do so by law. These include wholesalers, manufacturers, marketing authorization holders, hospitals and clinics, and others.
- Correspondingly, the NDA requires efficient systems to respond and take action to any report it might receive. It has a pharmacovigilance (PMV) unit that does review adverse drug reaction reports, but more is needed so that operating procedures are in place to respond to alerts and reports of events that raise the matter of suspicious or actual FS medicines.
- Not all the actors in the supply chain are required to hold licenses, and there is no track and trace nor pedigree system. These facts make it difficult if not impossible to conduct a thorough investigation. The NDA has the authority to impose conditions on all license and permit holders during the licensing process (both on initial application and renewal). As licenses are renewed annually, this regulatory intervention can be accomplished immediately. All that the NDA need do is create a manual containing the requirements for reporting, storage, track and trace, among others and condition the license on their compliance. Of course these new conditions must be made transparent and communicated to license holders and enforced - meaning a rational, risk-based inspection system must be put in place to ensure compliance.

Law enforcement and criminal justice sector

From the criminal justice point of view, clear definitions that are consistent throughout the legal system are currently lacking. This hampers the ability of the NDA and criminal justice system to effectively manage the problem of FS medicines. Harmonization of definitions will also result in more harmonized data collection methodologies, allowing for the design of better policies in the response to FS medicines.

With regards to the law enforcement, apart from the lack of specialized human resources and the limited financial resources available, a number of challenges have been identified. Limited coordination and exchange of information among the agencies at the national level hinders proper enforcement of the existing legal and regulatory framework. Capacity building of the criminal justice sector actors to obtain successful investigations and meaningful sentences is also crucial. Furthermore, FS medicines are not currently an investigative priority for all law enforcement agencies, as in the case of customs and police. Also, uniform and standardized operating procedures are currently lacking, which would greatly increase the effectiveness of the interventions and uniformity of enforcement across the country.

Private sector Capacity Building and Engagement

Relevant private sector actors include drug importers, wholesalers, and retailers, and health sector corporations. They all need to be informed and engaged in the legal and regulatory reform to address FS medicines. Capacity building will be necessary, and public forums should include private sector representatives.

International and Regional Cooperation

International and regional cooperation is paramount in the fight against FS medicines. Opportunities exist for international and regional cooperation through the African Union (AU), East African Community (EAC), and other international forums. For example, the EAC Treaty addresses regional cooperation on health (art. 118). The EAC Ministers of Justice have approved the AU Model Law, and the EAC is considering a regional drug law to further enhance the regulatory systems that are in place.

Uganda has ratified both the United Nations Convention on Transnational Organized Crime (UNTOC) and the United Nations Convention Against Corruption (UNCAC). Uganda participates through INTERPOL, and is a member of the World Health Assembly, which has created the Member State Mechanism on substandard/spurious/falsely-labeled/falsified/counterfeit (SSFFC) medicines.

The Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health (Medicrime Convention) is open for ratification by States outside Europe, and could be a useful tool for Uganda. The Ugandan authorities should actively use the instruments provided for in these conventions to cooperate with other countries in investigating and prosecuting international cases involving FS medicines.

Introduction

This report on the Legal Environment for the Elimination of Falsified and Substandard Medicines is result of the pilot and preliminary phase of a larger initiative to build a knowledge base and collection of tools to support a whole-of-government approach to manage the public health problem of falsified and substandard (FS) medicines in any country. The initiative is designed to provide the pilot country, Uganda, with guidance on steps it can take to address the problem of FS medicines within its borders and with its neighbors. Also as a result of this initiative, an assessment tool and guide to developing a national strategy to address FS medicines were developed, which will be further tested and refined as this project continues, for use in other jurisdictions.

The findings of the pilot of the initiative, an assessment mission to Uganda in June 2015, are presented, as are recommendations and guidance on strategies and actions Uganda can take with regard to its legal system and regulatory approaches.

The initiative was jointly conceived and coordinated by four organizations: the World Bank, the International Development Law Organization (IDLO), the O’Neill Institute for National and Global Health Law at Georgetown University, and the United Nations Interregional Crime and Justice Research Institute (UNICRI). The National Drug Authority of the Government of Uganda partnered with the four organizations to ensure a successful pilot.

The initiative builds on prior related work and good practices, and international law. These includes the work of the World Health Organization and the World Bank, and the United Nations Convention against Transnational Organized Crime, the MEDICRIME Convention of the Council of Europe, and other sources.³ The project takes into account not only national but also cross border and regional solutions, as exemplified by the initiative of the East African Community (EAC). The project was financed with support from the World Bank through the Global Forum on Law, Justice and Development.

Terminology

In this report, the term ‘falsified medicines’ refers generally to all “spurious, falsely-labeled, falsified and counterfeit” products. These products have been defined by the World Health Organization as “medicines that are deliberately and fraudulently mislabeled with respect to identity and/or source.”⁴ Both branded and generic products are subject to falsification. When referring to the Uganda legislation and other sources, ‘counterfeit’ will be used when that is the term used in the legislation.

Medicines may also be ‘substandard’ for several reasons including manufacturing error, degradation and expiration. Not all errors leading to substandard medicines are intentional, or should result in regulatory action and criminal pros-

³ Uganda ratified the International Covenant on Economic, Social and Cultural Rights in 1987. This Covenant, and other international human rights treaties to which Uganda is a party, directly or indirectly address the right to health, and hence the issue of access to medicines. See Committee on Economic, Social and Cultural Rights, General Comment 14 ‘The Right to the Highest Attainable Standard of Health’ in E/C.12/2000/4. See also ‘Report of the Special Rapporteur on the right of everyone to the enjoyment of everyone to the highest attainable standard of physical and mental health, Anand Grover, on access to medicines’ A/HRC/23/42, 1 May 2013.

⁴ WHO defines “spurious/falsely-labeled/falsified/counterfeit” products as “medicines that are deliberately and fraudulently mislabeled with respect to identity and/or source.” WHO, Fact Sheet No 275 from May 5, 2012, available at: www.who.int/mediacentre/factsheets/fs275/en/. See also Institute of Medicine (US) study ‘Countering the Problem of Falsified and Substandard Drugs’ (2013). For this concept note, we have used the term “falsified and substandard” (FS) medicines rather than “spurious/falsely labelled/falsified/counterfeit” to clearly distinguish between medicines which are harmful to the public health—substandard and falsified—versus those which infringe on a registered trademark—counterfeit. As experts in the field have noted: “Stakeholders concerned with access to generic medicines fear that action against counterfeit drugs would mean stricter enforcement of intellectual property rights, thereby reducing the availability of inexpensive generics.” See, Lawrence O. Gostin et al., Stemming the Global Trade in Falsified and Substandard Medicines, JAMA, Vol. 309, No. 16, April 2013, 1693. The 2013 Institute of Medicine report *Countering the Problem of Falsified and Substandard Drugs* defines falsified drugs as “those drugs which carry a false representation of identity or source or both” and substandard drugs as “those that do not meet the specifications given in the accepted pharmacopeia or in the manufacturer’s dossier.”

ecution. In those cases where either negligence or some other lapse is the reason for the substandard quality, a warning and technical capacity building will be more appropriate. Hence penalties, may vary depending on the cause of the non-compliant product.

The Problem of FS Medicines

Falsified and substandard medicines (FS) are a known public health problem. FS medicines represent various threats to patients: they may contain an insufficient amount or no active ingredient, or dangerous ingredients. Drug resistance, treatment failure and death have been associated with these products. While the prevalence in developed markets is likely below 1%, it is estimated that up to and more than 15% of all drugs sold in developing countries constitute a threat to patients. Interpol estimates that 30% of medicines circulating in Africa are either falsified or of inferior quality. A 2011 World Health Organization study on the quality of anti-malarial medicines in sub-Saharan Africa found that 44% of samples from Senegal and 30% from Madagascar were of inferior quality.⁵

Many factors facilitate the spread of FS medicines. One of the most important, in developing countries, is the weakness of national drug regulation. According to the World Health Organization (WHO) only about 20% of 193 WHO member states are known to have well-developed regulatory and law enforcement capacity for medicines. Fifty percent of member states implement regulation at various levels and 30% have no medicines regulation in place or only very limited capacity that is hardly enforced.⁶

Falsified medicines are manufactured and sold by criminal individuals and organizations, exploiting weak national legislation and enforcement. Criminals often avoid prosecution by bribing corrupt officials or taking advantage of regulatory loopholes - both in the letter and implementation of the law. Even if convicted, the insignificant penalties which are often applied are seen as a cost of doing business, and do not destroy the large profit potential of this comparably low-risk business in many parts of the world.

Since the late 1980s the WHO and the global health community has been considering the problem of FS medicines. Despite challenges, some level of consensus is emerging on the actions and steps to be taken by the regulator and the obligations of one or more actors in the health system to manage the problem of FS medicines.⁷ In short these include prevention, detection, investigation and incident handling. The goal of the medicines regulatory system, and the entire health system in including its various actors, is to ensure the health of the public - for which access to affordable, safe, efficacious medicines of good quality is essential. To ensure a supply of medicines, the health system must perform a number of functions. These include preventing actual or suspected FS medicines from entering the medicines supply and, if they do enter, detecting their presence and containing them.

At a minimum, there must be a functioning regulatory authority, a national or regional drug authority (NDA) that has the capacity to fulfill the main functions of the regulator; medicines assessment and registration, inspection, pharmacovigilance, laboratory, licensing of manufacturing, wholesaling, distribution and retailing, control of advertisement and promotion, quality control laboratory testing and procurement. Though it is the case that "(e)very regulatory function contributes to ensuring the safety quality and efficacy of drugs",⁸ some of these functions have specific roles to play with regards to FS medicines. These specific roles, in addition to the technical and scientific capacity, require particular legal authorizations and mandates. Effective management of the problem of FS medicines cannot happen unless there is a sufficient legal and

⁵ WHO, Survey of the Quality of Selected Antimalarial Medicines Circulating in Six Countries of Sub-Saharan Africa, 2011.

⁶ WHO, FAQ on counterfeit medicines, available at: <http://www.who.int/medicines/services/counterfeit/faqs/QACounterfeit-October2009.pdf>

⁷ Substandard/spurious/falsely-labelled/falsified/counterfeit medical products, Report by the Director-General, A68/33, 20 March 2015, available at: http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_33-en.pdf (accessed May 20, 2015). See also Countering the Problem of Falsified and Substandard Medicines <http://iom.nationalacademies.org/Reports/2013/Countering-the-Problem-of-Falsified-and-Substandard-Drugs.aspx>, Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, <http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/211> (accessed 30 October 2015).

⁸ Ratanawijitrasin, Sauwakon, Eshetu Wondemagegnehu, Effective drug regulation: A multi-country study. 2002 WHO, available at: <http://apps.who.int/medicinedocs/pdf/s2300e/s2300e.pdf> (accessed June 16, 2015).

regulatory framework that authorizes and mandates particular actions, and there are sufficient numbers of staff with the requisite skills who actually implement and enforce the legal framework. This aspect of the solution set to the problem of FS medicines has not received much attention until this report and initiative.

Even if the legal and regulatory framework is sufficient, regulatory inspectors, customs and border patrol and law enforcement officials are often not adequately equipped or authorized to identify FS medicines, properly prepare a file for prosecution, take immediate actions such as a preliminary seizure, and proceed through to conviction and sentencing. Law cannot implement itself and there must be adequate numbers of skilled staff to conduct the regulatory functions.

Building effective regulatory systems for pharmaceuticals in developing countries is a major challenge, with scarce resources and technical expertise combined with other pressing health needs competing for priority. In many countries, the underlying legal framework (legal and judicial framework, procedural law and sanctions, etc.) is non-existent, weak or outdated. FS medicines are often treated by granting non deterrent penalties. General criminal laws may offer few options for punishing those who produce, distribute and sell falsified medicines. The same is true for medicines regulatory laws that inadequately define medicines-related crimes and regulatory offenses.

Most importantly, action to eliminate FS medicines should not undermine access to legitimate and lower-cost generic drugs.⁹ As a complex criminal activity involving regulatory offenses and several economic, social, legal and criminological sectors, FS medicines require multi-pronged, multi-sectoral solutions. Related government strategies include health, justice, organized crime, and in particular “medicrime” or crimes associated with falsified and fraudulent medical products and similar crimes, whether or not criminal organizations can be identified.¹⁰

Uganda and the Regional Context

Uganda was selected as the pilot country for this project due to its active role in addressing FS medicines and improving medicines regulation overall. It is a member of the East African Community (EAC) and the African Union (AU). Both the EAC and the AU have initiatives related to medicines regulation. One initiative is the African Medicines Regulatory Harmonization (AMRH) project, which was launched in 2009 with a goal to create a continent-wide medicines regulatory agency and system including harmonization. The EAC serves as a model for the continent-wide medicines regulatory harmonization and was the winner of the first in a series of grants to implement harmonization activities.¹¹ As Uganda is a member of the EAC and its harmonization pilot, and is actively involved in tackling the matter of FS medicines, it was a logical choice for a pilot country.

This is important as the EAC has made strides towards harmonizing registration procedures, a reality that is excellent for medicines access but which will increase the movement of medicines across borders including FS medicines. In September 2014, the EAC Council of Ministers approved regulations on medicine evaluation and registration (MER), good manufacturing practices (GMP) and quality management system (QMS) - all harmonized under the AMRH – and to be effective in the EAC as of January 2015.¹² Thus, tackling the legal and regulatory framework for FS medicines in Uganda in this pilot will serve the larger goals of harmonization in the region and pave the way for an EAC-wide strategy on FS medicines. This work is also very timely as the EAC harmonized medicine legislation and regulations are yet to be enacted in the EAC legal system and adopted in Uganda. As the harmonization work is ongoing, within it, the legal and regulatory provisions for any medicines regulatory matter including that of FS medicines should be considered.

⁹ “Counterfeit drugs: a growing global threat”, *The Lancet*, vol. 379, February 25, 2012, p. 685.

¹⁰The MEDICRIME Convention: criminalizing the falsification of medicines and similar crimes, *Generics and Biosimilars Initiative Journal*, vol. 1, August 20, 2012, p. 138 ff.

¹¹African Medicines Regulatory Harmonization Program (AMRH) Goals and Benefits [Internet] 2014 [cited: 2015 June 26]. Available from: <http://amrh.org/classifieds/strategic-plan> (accessed 30 October 2015).

¹²East African Community. Notice to Applicants: East African Community’s Procedure for Marketing Authorization for Medicinal Products [Internet] [cited 2015 June 26]. Available from: <http://pharmacyboardkenya.org/downloads/?file=NOTICE%20TO%20APPLICANTS.pdf>.

This same dynamic is also underway with the AMRH, which contemplates a continent-wide regulatory systems for medicines and an expansion of local manufacturing of medicines. The New Partnership for Africa's Development (NEPAD) has also made progress towards developing a model medicines law. It includes measures to address FS medicines so that medicines regulators and the law enforcement community are not constrained by the gaps in enabling legislation that exist in many countries today in medicines law.

Uganda, History, Government and Health Profile

Located in East Africa and within the African Great Lakes Region, the Republic of Uganda is the second most populous country in Africa with an estimated population of 37 million and an average growth rate of 3.4% (2015 figures). Presently, 88% of the population lives in rural areas¹³, and almost 50 % is under 15 years of age.¹⁴

In 1864, Uganda became a protectorate under British rule, and gained its independence in 1962. Since independence, Uganda has experience significant political and armed conflict, including a military coup and civil wars. The President, Yoweri Museveni, came to power in 1986 and is considered to have brought relative political stability, democratic progress, and economic growth to the country.

Uganda is a republic with a unicameral parliamentary system. The Constitution, which was adopted in 1995, provides for a central government divided into three branches: executive, legislative, and the judiciary and local government.¹⁵ The local government consists of five tiers of local authority (from highest to lowest): district councils, county and municipal councils, sub-county and town councils, parish councils and village (rural) or ward (urban) council.¹⁶ There are currently 112 districts.¹⁷ The Local Governments Act 1997 grants the Ministry of Local Government the authority to oversee the implementation of national policy and legislation with respect to local government.¹⁸

Districts are charged with the delivery of public health services (primary care, hospitals and health protection), although they are encouraged to delegate primary and health protection to lower councils. Meanwhile, trade and industry are within the scope of the central government's authority.¹⁹

There is also a traditional kingdom structure in Uganda. The kingdom structure is predicated on the King ('Kabaka') as the 'corporate soul' and a clan system (52 clans), chiefs, etc. However, these cannot undertake activities such as the leasing of land, financial ventures (e.g. investment) without the corporate identity of the Kabaka. The traditional structure is largely involved in promoting 'cultural' (and quasi-cultural) issues in the kingdom.

The health sector's strategic focus is currently guided by the National Development Plan 2015/2016 -2019/2020 and a Health Sector Strategic Plan 2015/16 to 2019/20.²⁰ The National Development Plan aims to foster socioeconomic transformation to reduce poverty, while the HSSIP seeks "the attainment of a good standard of health by all people in Uganda, in order to promote a healthy and productive life" and "reduced morbidity and mortality from the major causes of ill-health and premature death, and reduced disparities therein."

Infectious diseases represent the highest burden of disease in Uganda, although the prevalence of non-communicable diseases (NCDs), including mental health disorders, is rising. Neglected tropical diseases (NTDs) particularly affect the rural

¹³World Health Organization, "Country Cooperation Strategy: at a glance. Uganda", available at: http://www.who.int/countryfocus/cooperation_strategy/ccsbrief_uga_en.pdf?ua=1 (accessed 30 October 2015).

¹⁴Central Intelligence Agency, The World Factbook, Uganda, available at: <https://www.cia.gov/library/publications/the-world-factbook/geos/ug.html>. (accessed 30 October 2015)

¹⁵Chapter 11, Article 176 (1) of the Constitution of the Republic of Uganda.

¹⁶Commonwealth government forum, "The local government system in Uganda", available at: <http://www.clgf.org.uk/userfiles/1/files/uganda%20local%20government%20profile%202011-12.pdf> (accessed 30 October 2015)

¹⁷World Health Organization, Country Cooperation Strategy: at a glance (Uganda), cited.

¹⁸Local Governments Act 1997, Cap. 243, Sec. 97, available at: <http://www.ulii.org/ug/legislation/consolidated-act/243> (accessed 30 October 2015)

¹⁹Commonwealth government forum, "The local government system in Uganda", available at: <http://www.clgf.org.uk/userfiles/1/files/uganda%20local%20government%20profile%202011-12.pdf> (accessed 30 October 2015).

²⁰Available at: library.health.gov.ug (accessed 13 February 2016).

population and continue to be a growing concern.²¹ Life expectancy at birth in Uganda is 57 years for both sexes. Uganda has been lauded for its efforts to address HIV and AIDS during the 1990s, but recent years have seen a rise in the HIV prevalence in both sexes. Between 2007 and 2013, the estimated number of people living with HIV increased from 1.2 million to 1.5 million.²² Public health threats like Ebola outbreaks and cholera have incentivized the government to implement the International Health Regulations (IHR) (2005). Additionally, with a growing population of immigrants and refugees, there are concerns over the importation of diseases like polio.²³

Assessment Results and Analysis

Key Actors in the Uganda Drug Regulatory System

National Drug Authority (NDA)

Pharmaceutical Wholesalers

Pharmaceutical Importers and Exporters

Pharmaceutical Manufacturers

Pharmacies

Drug shops

Civil Society

Relevant civil society organizations include patients and consumer groups, advocacy organizations, and independent professional associations of medical practitioners and pharmacists. There is a need for all stakeholders to shift from the perception of civil society as only consumers of medicines to the engagement of civil society as full partners in the national response to FS medicines in Uganda.²⁴ This is consistent with the human rights-based approach to health and development, which emphasizes participation, accountability, equality and nondiscrimination.²⁵

This is particularly important as some communities still misunderstand the role of the NDA and the importance of addressing FS medicines. This misunderstanding has led to a lack of cooperation with government authorities in regulating FS medicines, and even hostility towards government inspectors responding to FS medicines.

Informants welcomed the proposed FS medicines project. There was a common belief that patients should have confidence that they will have access to safe, high quality and appropriate treatments. Informants identified the main problem as the shortage of medicines (one estimated that only 50-60% of the total medicines required is available). However it was also noted that in the public sector the situation has improved a lot.

²¹World Health Organization, "Country Cooperation Strategy: at a glance. Uganda", cited.

²²UNAIDS, 2013 Uganda HIV and AIDS Country Progress report, 4, available at: http://www.unaids.org/sites/default/files/country/documents/UGA_narrative_report_2014.pdf (accessed 30 October 2015).

²³ World Health Organization, Country Cooperation Strategy: at a glance (Uganda), cited.

²⁴ A description of relevant civil society organizations is contained in the Annexes.

²⁵ See <http://hrbaportal.org/> (accessed 30 October 2015).

Informants estimated that Uganda imports about 70% of medicines. However there is a lack of confidence in products imported from some countries e.g. China and India. There are six large local manufacturers among 15 NDA-accredited companies. One local producer (CIPLA-Quality Chemicals) produces antiretroviral drugs (ARVs) and also anti-malarial medications. Other local manufacturing is largely limited to basic, off patent drugs.

There is a lack of awareness about the nature and extent of the problem of FS medicines in civil society. Informants noted that people often don't distinguish falsified from substandard medicines. There is a lack of evidence of the extent of the problem. One informant suggested that up to 80% of medicines in Uganda were either falsified or substandard. Both local and imported medicines have been found to be substandard, including antibiotics and anti-malaria drugs. One case involved a local company ('Flamingo') which was closed down due to non-compliance to GMP standards. There are cases of companies which alter the amount of active pharmaceutical ingredients (APIs), or use cheaper APIs to reduce production costs. Thus, quality is a concern: it was reported that 'patients don't get well and we don't know why.'

Identifying FS medicines is a challenge even for people who are literate. However, most people are not sufficiently literate, and may even not know how to interpret an expiry date. In cases where the medicines are dispensed in an envelope with the instructions written on it there is no expiry date indicated.

Drug shop operators will sell half doses, according to what people can afford. Patients see this as convenient. However when patients become more aware (e.g. of drug resistance) they become more concerned. 'Stock outs' are also a problem. Clinics will sell what they have in stock rather than what the patient needs, even if it is not appropriate. Sometimes the doctor will look at what is in the pharmacy and then write the prescription on that basis.

Over-prescription is also a problem: clinics over-prescribe medications. The over use of antibiotics leads to resistance. Self-medication is also an issue. People go to the drug shops, e.g. for high blood pressure, and will be sold medication without a prescription. In the drug shops they will give half doses if requested.

People have lost confidence in the government health care system. This has been caused, in part, by long queues and the poor attitudes of health care workers. There is a conflict of interest in the mixed roles of pharmacists, who can diagnose, prescribe and treat.

Informants noted it is the same in the clinics. Monitoring of clinics is believed to be very poor. People borrow items from friends to equip a new clinic and then return them after the license is issued. So the clinic is poorly equipped, and there is no follow up monitoring for quality of service. The National Drug Authority has limited human resources to supervise the sector.

Medicines in Uganda are expensive – people die of preventable conditions because of the cost. Some medicines are three to five times the prices of the international retail cost. One informant recommended that the prices of medicines be fixed by the Ministry of Health. The MoH has recommended prices for certain medications.

Civil society is concerned about maintaining access to inexpensive generic drugs, and is worried that measures to address FS medicines, e.g. through anti-counterfeit legislation, will have a negative effect on access to generic drugs in Uganda. It is perceived as important that the problem not be addressed through strengthened legal protection for intellectual property.

The problem includes medical devices. It was not clear to the informants whether the NDA Act includes devices such as blood pressure meters, which can also be substandard.

Informants noted that there are multiple stakeholders involved. The Ministry of Trade is keen to protect the local industry. The Ugandan Revenue Authority (URA) is interested in tax revenues. Informants suggested that the President's Monitoring Unit, which is based in Nagulu, should be engaged. The Unit has impounded some medicines - most were antibiotics. The Unit also investigates the disappearance of drugs from public health units.

Informants noted that Uganda needs a forum where the multiple relevant institutions can address the issues. There are few opportunities to hold local manufacturers accountable to citizens. Informants complained that community involvement exists on paper – but was often minimal. Often community representatives are invited to a process that is almost ending. They are just expected to endorse it. However civil society networks need to be consulted earlier for meaningful participation.

Informants stated that prosecutors need to understand that FS drugs can kill. Enforcement needs to be improved, and penalties increased. Penalties for FS medicines are inadequate. For example, in one case a company imported substandard cancer medication. The Uganda Cancer Institute raised the alarm. Tests were done and about 20 substandard products were identified. The NDA visited the company in the country where the drugs were manufactured, and found that the standards were unacceptable. The penalty was only suspension for two years. Another case involved corruption in the NDA related to an anti-malaria drug which was improperly approved. Informants reported that the former the NDA head was imprisoned.

The NDA is perceived to lack the political will to address FS medicines. The NDA is also perceived to be reluctant to act because it has been sued by private sector companies.

Uganda has a vibrant and independent civil society sector, and there are several strong civil society organizations which include health in their mandates. The role of faith based communities and traditional leaders should also be considered. Civil society organizations should be engaged at all levels in the national response – including through representative participation in national structures. Trusted civil society champions and leaders should also be engaged in public education campaigns to inform people about the dangers of FS medicines. Finally, civil society engagement should extend to include regional and international collaboration regarding FS medicines.

Legal and Regulatory Environment

This section of the paper maps the Ugandan legal and regulatory system and compares it to the current best practices in addressing FS medicines. This section also notes opportunities for the Ugandan legal system to be strengthened to enhance the ability of the National Drug Authority, the Ministry of Health and other actors in the system to prevent, detect and investigate FS medicines so as to reduce their incidence in the country.

Ministry of Health

The Ministry of Health (MoH) is the lead authority for the health sector. It is responsible for “national planning and policy formulation, setting standards and guidelines, capacity building, training, monitoring and evaluation, provision of technical support and mobilization for the health sector.”²¹ The Ministry of Health is led by three cabinet members: a Minister of Health and two State Ministers of Health (State Minister of Health for General Duties and State Minister of Health for Primary Care).

National Drug Authority

The National Drug Authority (NDA) was established in 1993 by the National Drug Policy and Authority Statute, which in 2000 became the National Drug Policy and Authority (NDP/A) Act, Cap. 206 of the Laws of Uganda (2000 Edition) (the Act). The Act established a National Drug Policy and National Drug Authority to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda as a means of providing satisfactory healthcare and safeguarding the appropriate use of drugs.²⁶

²⁶A bill is pending to amend the Act that has been in process for some time. A copy was unavailable during the mission as it is in draft. See the NDA Official website: <http://www.nda.or.ug/> (last accessed 31 August 2015).

The Act is the main law governing medicines regulation in Uganda. The Act is accompanied by a set of nine regulations, all dated March 2014, covering Licensing, the Suitability of Premises, Ectoparasiticides, Field Trials, Conduct of Clinical Trials, Control of Publication, and Advertisement, Fees, Pharmacovigilance, Importation and Exportation and Drug Registration.

The scope of the Act is limited to “drugs”, which are defined as substances or preparations for humans and animals for treatment, prevention or for improving physiological functions or for agricultural or industrial purposes (Art. 1), including herbal medicines. Devices, cosmetics, foods, reagents, products for diagnosis, surgical supplies, blood and other products that are typically found in health systems are generally not defined or mentioned specifically in the Act.²⁷

The Act provides for the establishment of the NDA, control of the drug supply through restrictions on who can supply and dispense drugs and on narcotics; the licensing of sellers and other persons, the places where drugs may be supplied; and on who can conduct wholesale trade, provide transport, or import and export of drugs. The Act also grants the NDA the enforcement powers to enter and investigate premises, vehicles, vessels and documents.

Importantly, the Act provides for the licensing of (non-pharmacist) ‘sellers’, who may retail restricted drugs (other than Class A or B). These sellers operate the so-called ‘licensed drug shops.’ The NDA drug information department is responsible for authorizing drug advertisements, so for example herbal medicines require approval before being advertised.²⁸

Offenses, crimes and penalties are enumerated in the Act. In general the law of Uganda and related regulations empower the NDA to conduct the main functions of a regulator. Other relevant laws, regulations and guidance materials are noted in the Annex.

Functions of the National Drug Authority

The Act defines the functions of the National Drug Authority in Art. 5:

- › deal with the development and regulation of the pharmacies and drugs in the country;
- › control the importation, exportation and sale of pharmaceuticals;
- › control the quality of drugs;
- › promote and control local production of essential drugs;
- › encourage research and development of herbal medicines;
- › establish and revise professional guidelines and disseminate information to the health professionals and the public;
- › provide advice and guidance to the Minister and bodies concerned with drugs on the implementation of the National Drug Policy; and
- › perform any other function that is connected with the above or that may be accorded to it by law.

Location and Main Activities

The National Drug Authority has its headquarters in Kampala and has regional offices in in seven regions/ sub-regions:

- › Nakawa – Central Region
- › Hoima – Western Region
- › Lira – Northern Region
- › Tororo – Eastern Region
- › Arua – West Nile Sub-region
- › Jinja – Southeastern Sub-region
- › Mbarara – Southwestern Sub-region

²⁷ Art. 30(a)) prohibits the sale of any substandard ‘drug, medical appliance or similar article.’ This is the only reference in the Act to other health products.

²⁸It was reported that often, even when approval is not granted, the herbal medicines are often still advertised.

Each region has one drug inspector and each sub-region or zone has 1-2 pharmacy technicians. The main regulatory functions, which are to implement the Act, are regularly carried out by NDA officers, called “inspectors” in the regions and zones. They perform the following particular duties relative to the matter of FS medicines:

1. The central office licenses persons to operate pharmacies and drug shops and others but the regional and zonal inspectors inspect them to make sure they are in compliance with requirements. Pharmacies and drug shops sell different types of drugs, and there are different types of academic and professional qualification are required to operate them. For example, a drug shop can also be run by nurses, with a pharmacy diploma, without the need for a higher academic degree. In the Western Region, where there are currently 45 pharmacies, and about 1,500 drug shops, there are four NDA staff including two pharmacists, a secretary and cleaner.
2. Inspection of manufacturers in order to see if they comply with the Guidelines on Good Manufacturing Practice for Medicinal Products.
3. Inspection including Good Pharmacy Practice and Good Distribution Practice inspection.
4. Post market surveillance.

Part VII of the Act specifies the powers of entry and of investigation for NDA inspectors (Art. 50, 51). According to informants, the NDA draws a schedule for inspections to be carried out district by district, and inspects more frequently in districts with lower levels of compliance. The inspectors can check licenses and determine whether pharmacies and drugs shops are run by qualified people, and whether manufacturers have suitable premises. All the NDA inspectors use a check list which is standardized in order to harmonize the activities carried out by the Authority in the different regions. Inspectors are reported to have found significant drug quality issues in unlicensed drug shops. Under the law the NDA has the power to close unlicensed drug shops and any other actor in the sector that is subject to licensing but is not licensed. Indeed, drug shops and pharmacies are closed by the NDA. However, it appears there are numerous unlicensed shops in Uganda as there are simply too few NDA inspectors to address this regulatory challenge.

The NDA inspector can also check the qualification of the person running a pharmacy or the drug shop, but there are reports of fake academic and professional certificates, which make confirmation more difficult. NDA inspections of pharmacies and drug shops usually entail physical checks on the drugs on the premises, but do not include detailed checks of inventories.

Records and Databases

There is a national electronic database of licensed persons (pharmacists) or sellers (drug shops), wholesalers, manufacturers, importers or of any other actor in the medicines supply chain required to be licensed. It is not however, interoperable with existing regional databases, thus it is not possible to cross reference applicants, wrongdoers or for the purpose of coordinating inspections.

In addition, there are record keeping requirements in the law that make surveillance more effective. The Act requires pharmacists and drug sellers who supply class A, B or C Group II drugs keep specified details in a ‘Classified Drugs Book.’ Only some retail pharmacies have computerized data management systems. Details that are required to be maintained for two years include the name and quantity of the drug, the name and address of the person who requires the drug, and the purpose for which the drug is required. Signed orders for drug purchases are also required. Penalties include a fine of up to two million shillings and imprisonment for up to five years. Nonetheless, informants reported that correct book management is very hard to enforce.

Definitions

Clear definitions that are consistent throughout the legal system will be important to the ability of the NDA to manage the problem of FS medicines. Currently there is no definition of ‘counterfeit’ in the Act, though Art. 30 refers to impure drugs.

The Regulation on Pharmacovigilance (PMV Regulation) defines “counterfeit drug” to mean “a drug which is deliberately or fraudulently mislabeled with respect to its identity, content or source.” But as is the case for other regulations, their content has limited applicability from a legal perspective unless the content is grounded or referenced in the Act. The definition of counterfeit is not, thus unless a falsified medicine is also impure it cannot be the subject of regulatory action. Substandard drugs are not necessarily impure.

A full definition of FS medicines could include elements that distinguish accidental substandard, negligent substandard, and intentional substandard, or accidental false label or packaging, as compared to intentional falsification (such as changing expiration dates). Clear and comprehensive definitions in the law are also important because substandard drugs may result from deliberate or unintentional failure in manufacturing to follow good manufacturing practices and the requisite pharmacopeia. Or good medicines may degrade due to negligent transport and storage, or degradation may result from genuine error, with no criminal intent.

Drugs may also be illegal, though of good or adequate quality. For example, they may have been imported without an import license, or they may not be registered on the national formulary. It was reported that due to the high cost of importation and registration, importers are finding ways to circumvent the regulatory process and thus illegal drugs are in the market. While an inspector can take action if product is not registered this must occur along with the many other duties of the inspector.

These different situations require a different regulatory approach; for intentional cases the criminal law will apply as will punitive measures one would not use against an honest manufacturer who made a mistake. Regulatory systems can also accommodate a step between observation of a non-compliant condition and punishment and that step is remediation. However, regulatory systems including that of Uganda, need to develop a process to allow for remediation. Such a process can include empowering inspectors to grant time to honest actors that are willing to make corrections and give guidance and direction. If the actor continues to conduct itself in a manner that is not compliant with law and regulation, the inspector may then proceed to the steps that result in the application of sanctions.

The law of Uganda will need to be amended to clarify the definitions so that related actors and offenses can be comprehensively described and thus the legal gaps eliminated. During the amendment process, effort can be directed to ensuring that wherever terms and definitions are used remain consistent throughout the law and any regulations and are not in conflict with the intent of the law. Amendment to the law cannot be done with a regulation as gap in the law can only be corrected with a law. There are a number of regulations enacted after the Act that add requirements not defined in the Act thus the Ugandan regulations may be subject to challenge and not enforceable.

Prevention and Detection

Prevention begins with a functioning regulatory system that is able to ensure a safe medicines supply of good quality so that few to no FS medicines enter the supply. Prevention is the by-product of a functioning system. In Uganda, though the main elements of the regulatory system are present in the law and represented by the departments of NDA, a number of examples of poor enforcement and gaps in the law and conflict of interest cases were reported by various informants. Examples given included:

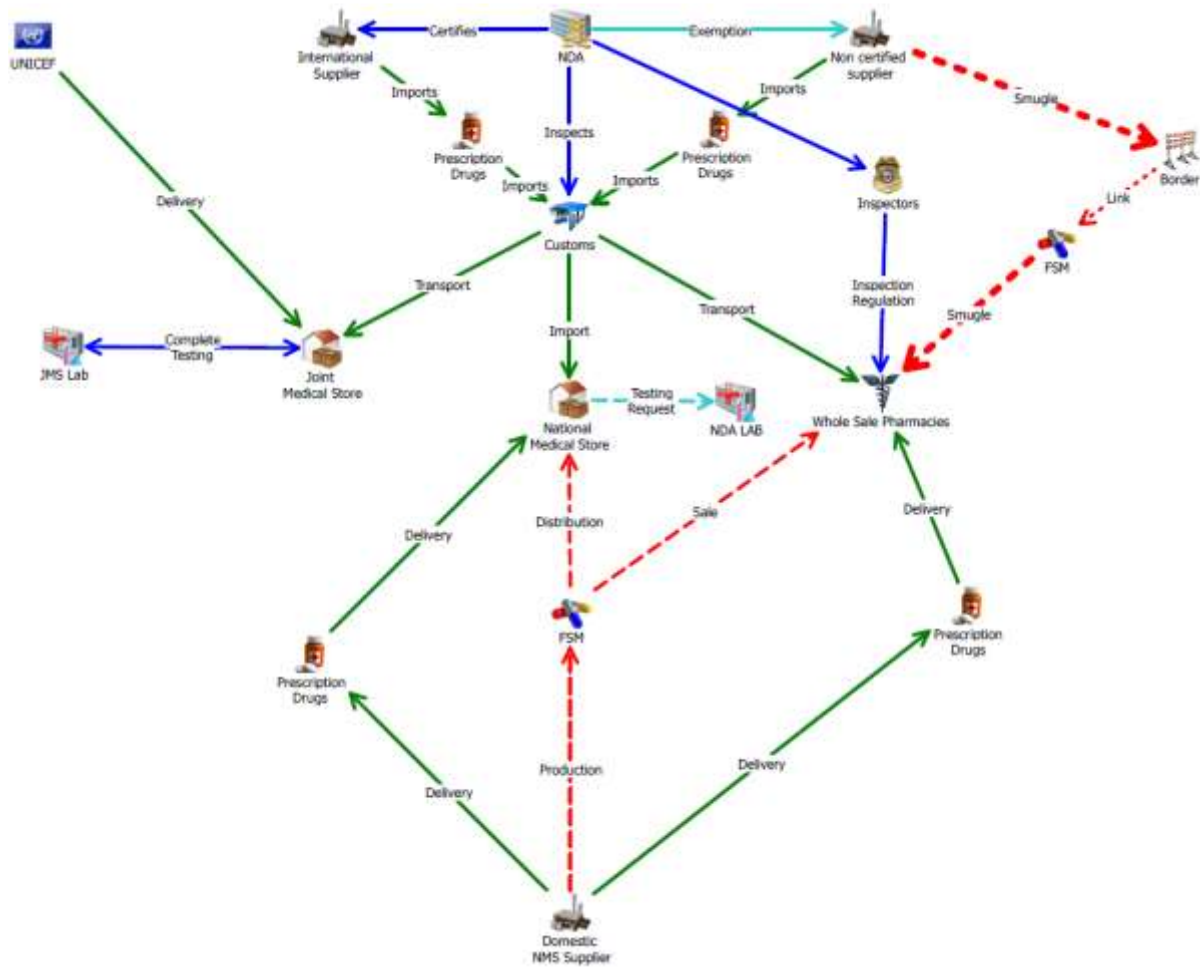
- influential persons who own pharmacies and hospitals and public sector health professionals are able to block inspections when faced with enforcement,
- inspection staffing is insufficient to manage the multiple actors in the system, and
- private hospitals and clinic pharmacies are not inspected on a regular basis, and then only in Kampala.

Some informants report the level of FS medicines to be as much as 50% of the medicines supply. The local WHO office noted the common complaint that “medicines are not working”, and that there is a plan in process to measure the failure rate of authorized medicines. These reports and the obvious challenge facing the central office team of just 14 inspectors for thousands of pharmaceutical actors confirm that systemic weaknesses are the key factors contributing to the presence

of FS medicines in Uganda. Also gaps in the law as described in this report hamper the NDA. Even though law does not implement or enforce itself; having the right laws clearly empowers inspectors, defines the rights, duties and limitations on all actors and prohibited behaviors. Perhaps most importantly for any country, once there is law to mandate any regulatory actions, Parliament must provide budget so the regulator can fulfill its mandates.

No country is exempt from the problem of FS medicines. No matter the level of prevention, detection is the second line of defense. Detection allows the regulator to manage the problem by preventing further circulation and additional entry of FS medicines in the country. Detection - the identification of actual or suspicious products - can occur at any point along the supply chain (both legal and illegal) from starting ingredients to the point of dispensing. The main process of detection is by quality monitoring. This occurs through inspections, pharmacovigilance, reports and with alerts. Each must be in effect and supported by law and regulations, and implemented and enforced by the regulator against public and private actors in the supply chain and by other branches of government, most notably Customs, police, law enforcement and judiciary.

The following graphic describes the ways in which FS medicines may enter the medicines distribution system in Uganda:



Credit: W. Koehling 2015

National Medical Stores

In public facilities it is rare to find falsified medicines because the procurement is managed by the Central Medical Stores. Approximately 40% of drugs in the country are purchased in this way. Informants stated that the problem of diversion of medicines from public hospitals has been reduced, as drugs sourced through the public procurement system are now labelled 'Republic of Uganda - not for sale'. Diversion of medicines from hospitals is still occurring, however. The stolen medicines may then be illegally exported to, for example, South Sudan and the Democratic Republic of the Congo.

Quality Monitoring (QM)

QM is the process of surveillance of the distribution chain, manufacturing and procurement. In general for the pharmaceutical sector, QM is conducted by the regulator of the public and private sector actors subject to its jurisdiction, by the regulator of national producers, and by any central medical store on public procurements. QM is also conducted by the private sector of products for which it is the marketing authorization holder (MAH) and for products that it procures, sells, or distributes. For the regulator, the process of QM is conducted according to good QM practices now often documented through an International Standards Organization (ISO) standard.

The NDA is in process of strengthening the capacity of quality monitoring, and has established a main QM department, which is responsible for all QM across the agency including the Inspectorate and the Pharmacovigilance Unit. The NDA QM system is based on ISO 9001. QM across the NDA covers

- a. documents – their management and control,
- b. internal quality audits of equipment, materials, personnel, methods and procedures, and the environment,
- c. non-conforming products – meaning those that either do not comply with authorization requirements during assessment or those that enter the country and do not comply, and
- d. preventive and corrective actions.

The legal basis of QM relevant to FS medicines is two-fold. The first part is the authority and responsibility of the NDA to conduct inspections on a periodic basis and in response to safety signals of regulated or licensed actors and activities and places, vehicles or vessels, or non-regulated actors, vessels when there is a suspicion of FS medicines. The second part is to require regulated actors to submit PMV reports, to conduct their own pharmacovigilance, and to respond to alerts such as for recall. For the overall QM system to function there must be some legal link to the regulated and non-regulated actors. As mentioned for non-regulated actors the link is a reasonable suspicion of FS medicines. For regulated actors, the strongest link is licensure, including permits or certification of some sort. Licensure is a legal privilege for which conditions can be imposed and the loss of which is a severe sanction.

A contract for procurement can also provide the legal authority for action. For the private sector, QM is part of good business practice and can be integrated into the procurement contract as a requirement for vendors. In this sense QM in a private sector contract is a function of the law between the parties, a concept discussed at length elsewhere. In Uganda the Joint Medical Stores, a not for profit private procurement and medical stores entity, conducts quality assurance actions on deliveries. JMS reports that 7% of deliveries fail visual screening, preliminary and full confirmatory screening tests even though JMS conducts supplier verification every three years and at the time of procurement. Response to failures are based on the procurement contract and include a rejection of the delivery, a query or an opportunity to correct depending on the nature of the failure. JMS is developing a new protocol to inform NDA if the non-conforming delivery is likely to cause harm to health so NDA can seize the products. JMS also conducts its own PMV through a customer service department and reports from clients.

Licensure

In Uganda the NDA Act only requires pharmacies and drug sellers (drug shops) (Art. 14, 15) and wholesalers (Art. 37) to be licensed. A Licensing Regulation requires manufacturers to be licensed, although this regulation has questionable enforceability. Actors such as transport operators are not required to be licensed. The Act only requires a premises such as a storage

facility to be certified as to suitability (Art 17), and this certificate is tagged by the NDA to a licensed company. The Act also requires an import or export to be authorized by a permit (Art. 44, 45).

Although there may be some aspect of Ugandan law that differs, in general a regulation such as the Licensing Regulation is insufficient to legally mandate manufacturers to be licensed operators if there is nothing in the legislation. This is especially important as wholesalers, manufacturers, importers and exporters, transport and storage operators are private sector actors who function under corporate umbrellas. Thus the law must act against the regulated actor for it to have optimal effectiveness. For many reasons this patchwork of licensure requirements should be harmonized and as is likely the case, must be corrected with an amended law and not another regulation.

Inspection

NDA inspectors are authorized by Part VII, Article 50 of the Act to enter and investigate, at all reasonable times,

- any premises for which a certificate of suitability has been issued,
- any premises, vessel or vehicle if the inspector has reasonable cause to suspect an offense under the Act has been or is being committed, or
- any premises where narcotic drugs are being manufactured or supplied.

In effect inspectors are granted wide scope to enter and inspect any actor or location where medicines may be located or be in production, on sale, under transport, or in storage. Once an inspector enters or investigates, he or she may inspect, require persons to furnish information as to the activities conducted there or in the vehicle or vessel, and to take away any drug or records or documents found (Art. 51).

For the purpose of periodic or as needed inspections of the places where medicines might be found, the law is sufficient in terms of inspections but is weak in terms of whether the inspector can “seize” permanently or temporarily the other items that are found concurrently with FS medicines such as production equipment or packaging materials. This gap in the law cannot be filled without legislation as the taking of property, even if used in illegal activity, affects legal property rights. Seizure, both temporary and permanent, should be authorized and circumscribed by law.

Seizure and confiscation of property

To take property - even if used in illegal activity - sufficient legislative authority is required. This should include the power to seize any and all property, including production equipment or packaging materials, labeling, starting materials and API related to a suspected FS medicine. It should include confiscation of the property in the event FS medicines are confirmed.

Wholesalers

Wholesalers are licensed to carry on a business of “supplying” restricted drugs by wholesale (Art. 37). ‘Wholesale’ is not explicitly defined in the Act. Informants indicated that some wholesalers are selling on a retail level, and visual observation of some outlets self-defined as wholesalers suggest that retail trade is underway.

Informants also noted that wholesalers do not keep records of what is sold and to whom. It was also reported that wholesalers have “branches”, which may be a euphemism for a retail sites operating without a license under Article 14 or 15 of the Act. A license under Art. 14 or 15 refers to the term “supply” defined in (Art. 1) to mean *administration of drugs*. A common understanding of administration of drugs refers to a clinical activity that is not the same as the common meaning of wholesaling which is to *sell goods in large quantities*. Further Art. 14 refers to supply by *retail*. As this term “supplying” is

used in reference to a wholesaler license, it does not cover the typical activity of a wholesaler. It is not clear if this definitional conflict has caused any challenges but if the Act is amended this should be cleared up so as to clarify the scope of who and what is regulated.



Credit: M Forzley 2015

Manufacturers

The Act declares that no manufacturing should occur in the absence of supervision by a pharmacist and that no product other than those on the national formulary are to be manufactured. The Regulation sets out requirements to obtain a license, including compliance with the Guidelines for Good Manufacturing Practice for Medicinal Products (June 2013), but does not require compliance with Good Distribution Practices (GDP). The Regulation can be amended to include the range of good practices guides.

Import and Export – Tack and Trace

The NDA has dedicated staff at the port of entry, together with Customs, in case an import is expected. The ASYCUDA²⁹ system used by Customs checks the code of the medication and informs the NDA. Unregistered medicines imports are allowed in case of emergency, but the manufacturer needs to be registered with the National Drug Authority of the country of origin. The NDA can also inspect foreign manufacturers, as drugs need to be registered before being imported.

The transactions of import and export are licensed for a period of one year under Articles 45 and 46. There is nothing in the law that circumscribes the activity of import or export other than the prohibition without a permit, the duration of the permit and that the “range of preparations” imported or the “drugs or range of preparations” to be stated to the NDA. The importer or exporter is not required to have a pharmacist on staff and there are no requirements to comply with nor is any system of ‘track and trace’ required.³⁰

For any country that imports medicines the importer is a primary actor in the system and should be required to comply with GDP and track and trace. Exporters should also be regulated - this will be very important as the regional harmonization

²⁹ Automated System for Customs Data. For more information, please see <http://www.asycuda.org/> (accessed on 18 June 2015)

³⁰See *WHO Good Distribution Practices for Pharmaceutical Products. WHO Technical Report Series, No 957, 2010, Annex 5*. Available at <http://apps.who.int/medicinedocs/en/d/Js18678en/> (accessed 31 August 2015).

systems are more established and products move more readily between countries. Tracking and tracing products will be essential to any capacity to recall or to send alerts, etc.

Transport and Distribution

Transport is mentioned in the Act as a subject of control but the Act provides no measures nor are there any applicable regulations. Thus though the vehicle used to transport products might be subject to inspection, the person or entity doing the transport is not subject to any limitations or requirements. The product could be seized but unless there is some requirement under which an offense can be found to take action against the transporter there is a wide opportunity for those engaging in FS medicines to operate without limitations.

Storage and Premises

There is an inconsistent mix of requirements for storage of medicines that does not provide a sufficient set of storage standards and which may then result in medicines becoming substandard. These standards and requirements need to be revised. There is no license requirement for those that store drugs though the facility where drugs are stored must hold a Certificate of Suitability as per regulation and the Seventh Schedule of the Act.³¹



Photo: M. Forzley 2015

The Seventh Schedule only requires a lock and key and separation of medicines from other products, two important requirements but by themselves insufficient storage standards. The Certificate of Suitability adds many more requirements and makes these applicable to wholesalers, retailers, manufacturers, and storage facilities. Meeting these requirements is a pre-condition for licensure except for manufacturers and storage facilities. A survey of drug shops and retail pharmacies on the road between the airport in Entebbe and the city of Kampala and the road from Kampala to Murchison Falls National Park indicates that many of the pharmacies and drug shops do not meet the standards of the regulation or schedule. This

³¹ Certificate of Suitability of Premises Regulation of, 2014.

factor alone may account for the presence of substandard medicines. Moreover, it is hard to imagine that many of these pharmacies and drug shops are even licensed as a quick visual observation while driving by along indicates many do not meet the minimum standards for suitability and therefore for licensure.

One example is the drug shop on the road to Paara Lodge. Though Art. 15 of the Act allows for the approval of a drug shop in a location not sufficiently served by existing facilities, it is hard to justify the approval of one such as this that is so clearly inadequate.

Pharmacies and Pharmacists

Pharmacists are regulated by the Pharmacy and Drug Act Chapter 280 of 1970 and the Standards of Pharmacy Practice of 2001. Pharmacists and pharmacies cannot be treated separately in this report as the regulatory requirements are inseparable: a pharmacist is essential to obtaining a license to open a pharmacy. Informants stated that the requirements are the same for private and public sector pharmacies and this would be the case if the pharmacy were in a public or private hospital or clinic or a stand-alone outlet. Pharmacists are also required on site for wholesale businesses.

The Pharmacy Council is the governing body of the Pharmaceutical Society, which was created under the Pharmacy and Drug Act. This Act contains a number of provisions important to managing the problem of FS medicines and requiring pharmacists to:

- keep records of sales and storage conditions,
- obtain product only through an authorized source of supply,
- appropriately store products,
- report suspected defective or counterfeit medicines,
- comply with recall warnings,
- comply with GMP if the pharmacist works for a manufacturer,
- sell to licensed outlets and keep records on sales only if the pharmacist works in wholesale and distribution (not defined),
- follow standards for disposal of unwanted and expired drugs, and
- ensure the Chief Inspector of Drugs witnesses destruction of such drugs.

Misconduct is defined in a schedule to the Act and lists a number of actions relevant to the management of FS medicines, including:

- imitating labels or other signs or symbols on products,
- misleading or exaggerating claims,
- not supplying drugs if the pharmacist has reason to suppose the drugs are destined for illicit channels, and
- applying proper pharmacopeia names to substances of different compositions.

These give the Pharmacy Council a power to discipline for actions that could be related to FS medicines through the cancellation or suspension of a license. No data on how many disciplinary proceedings are held each year was collected during the mission.

The on-site pharmacist is personally required by his or her license to comply with the Pharmacy Standards of Practice that include GMP (though not Good Distribution Practices (GDP)). Failure to do so may result in disciplinary proceedings that could result in license revocation or suspension. However, a pharmacist whether in a manufacturing facility or retailer or wholesaler is only required to be on site 40% of the time according to the Standards of Practice but not the law. Therefore there is ample opportunity for unsupervised activity and activity that falls outside the scope of any good practices. This may account for some of the substandard medicines in circulation.

As with any such requirement, there must be periodic inspection with sufficient frequency and in accordance with risk based inspection procedures to confirm compliance. For cases of non-compliance a procedure must be in place to impose

consequences. The Pharmacy Council has prescribed such a procedure, and set of penalties that it can impose on the pharmacist. It is not clear that the Council or the NDA inspectors are sufficiently monitoring compliance across the country for these measures to have the intended effect.

This indirect form of regulation can only work through and on the pharmacist. Most wholesalers and other actors operate in corporate name. This means the pharmacist might be punished but not the licensed actor. If corporate actors lose a pharmacist employee due to a contravention of the prescribed procedures, they can hire another pharmacist and carry on with business as usual. A simple change is to make add corporate liability and sanctions to the law.

Pharmacovigilance and Reports

Pharmacovigilance (PMV) is a set of activities undertaken by the medicines regulatory system – both the NDA and the various actors within –relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem after release on the market. Post-marketing surveillance is part of the process. Inspection and reports are two key tools of PMV. Both are important to identifying or detecting suspicious and actual FS medicines which is the essential step before further circulation can be prevented.

The reports are used to collect data, as are other data gathering means such as epidemiological studies, and these data are analyzed to identify safety signals of risks. Once the risks are evaluated and investigated incident handling and risk minimization efforts can be taken.

Without the data from reports and inspections the PMV system will be of no use in solving the problem of FS medicines. Most PMV systems are designed to capture data on adverse drug reactions (ADR), as defined as noxious and unintended effects resulting only from an authorized use at normal doses. They also capture data from medication errors, and uses outside the terms of the marketing authorization, including misuse and abuse. The challenge with the use of the PMV ADR system in terms of FS medicines is that health care providers or other actors who report ADR may not consider the possibility that an ADR is related to a FS medicine.³²

Reports can be voluntary or mandatory and can come from pharmacovigilance reports of ADRs or of FS medicines, from Customs and health officers at borders, MAH, pharmacies and pharmacists, patients, health care workers and professionals, procurement agencies and from the process of inspection and quality monitoring discussed above. The best practice for pharmacovigilance obligates *all* the varying actors in the system to report ADRs, and to develop a system to differentiate those ADR events that might be related to a FS medicine.³³ Correspondingly, the NDA is obligated to establish a PMV system that assesses reports, maintains an information data base, an office and to issue alert when significant risks are identified. The foundation of the system is however two part: the obligation to report ADRs to the NDA, and the NDA obligation and process to confirm and contain FS medicines.

There is a pharmacovigilance unit in the Ugandan NDA, following Regulation 37 of 2014, (PMV Regulation) but the Act does not specifically require or authorize PMV or reporting. Again we note the problem of the potential challenge to a regulation where there is no enabling law. The PMV Regulation defines adverse drug events and reactions. Both definitions seem adequate for the potential risks of exposure to a FS medicines. However the definition of a counterfeit drug does not include all the potential variations that result in a FS drug, such as being expired, not stored correctly or other condition but it does capture some of the elements that might confirm a product as a FS medicine.

Article 5 of the PMV Regulation *only obligates a licensed person* as defined in the Act Art. 14 as a pharmacy to submit safety reports. Pharmacy Standards of Practice require pharmacists to report defective and counterfeit medicines to the relevant authorities and pharmacists to comply with warnings or recall notices. No other actors are obligated in the regulation to

³² Forzley, M. The Nomenclature of Counterfeit Medicines Around the World, 2010 Report to WHO Director General, available at: <http://www.mich-eleforzley.com/counterfeit-medicines-counterfeit-goods-and-the-publicsquo-s-health-and-safety.html> (accessed 30 October 2015).

³³ See for example: Legal requirements related to the European Medicines Agency (EMA) pharmacovigilance system for human medicines are laid down in Regulation (EC) No 726/2004, Directive 2001/83/EC and Commission Implementing Regulation (EU) No 520/2012.

report. Licensed persons must submit periodic safety reports only annually and only on drugs that have been manufactured, sold or supplied in Uganda for less than ten years, and for those over ten years every three years.

The PMV Regulation suffers the same gap due to this reference to the Article 14 licensed person. Manufacturers, importers, doctors, NGOs, public health programs or any other person as may be determined by the authority are to have a pharmacovigilance system but are not obligated to report on the safety, efficacy and quality of drugs *unless requested*. In the case of a suspected *counterfeit drug* any person who suspects is to report to the NDA and not deal in the drug according to the PMV Regulation.

Health professionals are obligated to report any adverse event immediately, but the PMV unit reports there is little to no reporting from anyone. Based on informants' comments on the PMV system in Uganda, the challenge is to collect reports from anyone. The process is so difficult the staff actually go to the offices of the various actors to collect the reports. Clearly if the reports are not being submitted it makes little difference how effective the NDA investigation might be.

Alerts are another way the NDA gathers data to guide its investigations and incident handling. Alerts can come from regional or international partners such as WHO or Interpol, or other sources. To be a recipient of alerts a country must participate in regional and international organizations. Uganda does so as a member of the EAC harmonization initiative, the WHO Global Surveillance and Monitoring System (GSMS), and is a member of Interpol, among other organizations.

The three C's of Response to Surveillance Safety Signals

On receipt by NDA of a "safety signal", i.e., an inspection or PMV report, or an alert from any source, the next phase of managing an FS incident is to take the steps of investigation to confirm whether the item is an actual FS medicine and to determine the degree of risk the item presents. Incident handling follows investigation and involves containment and communication. One could use the shorthand of the three C's to manage FS medicines: confirm, contain and communicate. Sufficient legal authority and obligation by the various stakeholders is essential to the ability of the NDA to manage the three C's.

Confirmation: Investigate, inspect, sample, test, retain samples of batches, packaging, labeling, document and verify the chain of custody, cooperate with the police, prosecutor for potential crimes and collect evidence necessary to prosecute a criminal case or civil administrative proceeding.

Contain: Seize product, equipment, materials, packaging, labeling and related equipment, , close or suspend facilities or operators, arrest, destroy or dispose of FS medicines, remove from the market, alert members of supply chain.

Communicate: Recall, inform public and health care system, inform global WHO and regional EAC system and neighbors, share information and data.

The Ugandan NDA is not obligated by its enabling law to conduct investigations on receipt of a safety signal or take further actions. It *may* do so according to Articles 5 and 8 of the Pharmacovigilance Regulation. It is obligated however to control the quality of drugs, by Article 5 of the Act but the Regulation limits the obligation. A stronger, clearer statement on the elements or activities of control could be helpful in the new law if and when amended and may provide a basis to seek additional resources to carry out the mandate.

As part of the EAC harmonization initiative, there might be reason to require the NDA to investigate alerts of a certain type such as for public health medicines such as an anti-retroviral treatment. The legislation for such a mandate might flow from

any EAC system, or the NDA might adopt the operational guidance on how to handle investigations and incidents as outlined in the WHO Member State Mechanism (MSM) into an amended act and a regulation.³⁴ It is important to keep in mind however, that these are only operational guidelines; other elements must be added in order for the NDA to have sufficient legal authority to take certain actions and for the actors in the system to be obligated to report. Having a strong PMV system will be important as the EAC regional system evolves not just for FS medicines but for all medicines. The MSM operational steps note their limitations but as the NDA has a wider mandate, it must undertake actions that go beyond the operational steps. These are the three “C’s” of response to surveillance safety signals

Confirmation

With regard to confirmation, *the first “C”*, or investigation, the NDA at a minimum must be required to investigate those cases that are of such a nature as to reasonably conclude there is risk to the public’s health and safety. The dimensions of what such a risk looks like will hopefully be outlined in subsequent work of the MSM and until then this determination, once obligated by law, regulation, policy or national strategy, will have to be done according to the scientific and technical capacity of the NDA. To conduct an investigation or confirmation NDA must be able to take samples and retain them after analysis, without compensation to the person or entity from whom the samples were taken. The NDA has this authority in Article 51 of the Act.

The Act is deficient in that it only authorizes the taking of a drug, record or other documents but not labeling or packaging materials or finished ones, materials or production equipment. Falsified drugs are often, but not always, rudimentary, but as technical testing equipment is not generally used during inspections, a drug sample must be sent to a laboratory for analysis. This can delay regulator action and allow a wrong doer to hide evidence or leave the jurisdiction. Moreover, the laboratory only analyses composition, but does not trace for the source of the products. It is common to detect products with both falsified labels and contents. Moreover since Ugandan law does not have a pedigree³⁵ requirement or track and trace requirement³⁶, the documents that might be available may not lead to useful information on the source of finished FS medicines, API or excipients, packaging or labeling or equipment.

“Pedigree” means a record, containing information regarding each transaction resulting in a change of ownership of a drug, from sale by a manufacturer. A complete record that traces the ownership of and transactions relating to a pharmaceutical product as it is distributed through the supply chain.

Tracing illegal transactions and actors involved in the FS product is made more difficult if there is no documentation of the chain of custody. The record keeping requirements in the Licensing Regulation only refer to wholesalers who must keep records on the immediate source of the finished products imported or for immediate sales - not all the details for the entire chain of custody. For manufacturers, batch starting materials and other records must be kept according to Licensing Regulation Art. 22, but these are limited to the immediate process of production and immediate vendors and no information regarding subsequent buyers or sources earlier in the supply chain is required.

Manufacturers and importers are not required to comply with GDP, so the information they are required to keep is too limited to assist in tracing the sources of FS medicines. Solving the problem of FS medicines will require among other things that investigations up and down the supply chain can occur. To do this and to keep a tight supply chain, a pedigree and

³⁴ Substandard/spurious/falsely-labelled/falsified/counterfeit medical products, Report by the Director-General, A68/33, 20 March 2015, available at: http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_33-en.pdf (accessed May 20, 2015).

³⁵ See the definition of pedigree in World Health Organization WHO Technical Report Series, No. 957, 2010 Annex 5 WHO good distribution practices for pharmaceutical products. http://www.who.int/medicines/areas/quality_safety/quality_assurance/Good-DistributionPracticesTRS957Annex5.pdf (accessed 6 August 6 2015).

³⁶ Substandard/spurious/falsely-labelled/falsified/counterfeit medical products, Report by the Director-General, A68/33, 20 March 2015, available at: http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_33-en.pdf (accessed 20 May 20 2015).

track and trace system and clear guidance on the records to be kept by the actors in the supply chain should be implemented by law, regulation, standard or guidelines.

A full investigation will require more than the confirmation by scientific testing to demonstrate if a product is FS. It will also be necessary to collect or verify other information, such as a copy of a wholesaler license, which will give rise to a prima facie case that an administrative violation or offense under the Act has been committed. This list of information an inspector should collect does not need to be in the law, but the inspectors need to understand the elements of the offenses in order to collect relevant evidence. A list of the offenses under the Act is included in the Annex. The NDA can prepare a checklist of the types of information to collect or verify so inspections are more productive. Finally, the process of confirmation requires that the NDA cooperate with the police or prosecutor to collect evidence to establish the elements of a crime.

Contain

The second “C” is contain, which means to make sure the suspicious or actual FS medicine is blocked from circulation in the market. This step prevents any potential harm the FS medicine might cause. To contain the situation, there are two phases; first on arrival to the location where suspected FS medicine is found, the marketplace or the receiving dock or elsewhere. Here the NDA must be able to temporarily seize all suspicious goods, materials etc. pending confirmation by testing of the suspected goods.

The Act provides inspectors the right to ‘take away’ drugs, records or documents, but not the right to impound suspicious items where they are found (Art. 51). This means that the NDA has to immediately remove suspicious products, which may be in large quantities. This gap in the seizure authorization has caused NDA problems in the past and must be filled by legislation to authorize the best and most efficient means to hold the goods and other items pending testing. These powers include the facility closure, suspension of license, padlocking the door, posting a guard, and the right of seizure must be extended to the materials and equipment of production and those for packaging, labeling and other items used in relation to FS medicines. To ensure the good governance of such a procedure, a process to present the findings to a board or court for an order permitting final seizure and destruction should be included in an amended or new law.

Once the status of FS is confirmed, the next phase is to permanently remove the items from the market, or to ‘take away’ in the language of the Act. Following seizure, the next step is to dispose or destroy according to national and international guidelines for the hazardous or medical waste, after the conclusion of court proceedings. The Act does not authorize the NDA to destroy or dispose of FS medicines once confirmed. This authority, since it has an effect on title to goods, must be in the law otherwise there is a risk of claim of conversion, as has happened in Uganda. This process must also be done according to procedures that demonstrate good governance and rule of law. This means there is an opportunity to present the case to a board or court and for the owner of the products to defend after which the board or court will make a determination.

Communicate

The third “C”, communicate, means the NDA can and will alert members of supply chain, recall products, inform the public and health care system, inform global WHO and regional EAC system and neighbors, share information and data, and prosecutorial information. The power to recall is not in the NDA law. This power may be implicit in the power to issue a registration or authorization, which includes the power to revoke a registration, which to some extent what a recall order is. Rather than risk legal claims by a MAH, a legislative measure would be advisable, adding a measure to authorize removal of unregistered products from the market wherever found if they are confirmed to be FS medicine. Sharing data and other information relevant to prosecutions should also be authorized in the law.

Harmonization

The Act does not provide any authority to the NDA to enter into harmonization activities that result in reliance or recognition of the decisions of foreign regulatory agencies or any regional regulatory authority, should one be created in the EAC. Decisions could be for any of the regulatory functions of assessment, registration, inspection, pharmacovigilance analysis or

other. Uganda is bound by Article 118 of the East African Community treaty. Provisions for harmonization could be made clear in the new bill. Uganda is a member of the EAC harmonization initiative and has been participating in the voluntary joint assessment activities thereunder.

Should reform be undertaken through legislation or by regulation? Are there other options?

In general, any regulator including the Ugandan NDA has choices amongst a variety of legal instruments or regulatory approaches to manage the medicines sector and the matter of FS medicines. For any regulator and particularly for resource constrained environments adopting the choice with the least amount of associated work may be desirable, but not necessarily the best in the long run. A regulation is clearly fast to finalize than legislation as it can be implemented within the regulatory agency without approval from Parliament. Some regulatory options require a law; an existing law, an amendment to existing law or an entirely new law. The questions is a law required? Law is required when a right is granted or limited or a duty or responsibility imposed on any actor or the regulator. This includes regulatory offenses and crimes, the elements of and the upper and lower boundaries of sanctions of which must be in the law. Once the basic framework is in the law, then a regulation can be issued to provide the details, procedures, forms or other information to the regulator and the regulated.

An example is for licensure; the law must state who is to be licensed as this is the grant of a right and limitation on actions of citizens. Medicines regulation generally includes a prohibition to sell or market regulated products unless licensed or otherwise exempted by way of an exclusion such as for orphan drugs or in emergencies. The elements of the application to get a license and procedure can be the subjects of a regulation.

Once the law is in place, a variety of regulatory approaches can be implemented according to a reasonable interpretation of the law. Often regulators are not well guided or knowledgeable on how to reasonably interpret the law. Two examples demonstrate how important it is for regulators to be more fluent in the law in order to do their work. Example one is the question, “if a regulator can issue a license is it necessary to have a law that empowers the regulator to revoke it?” The answer is no as a reasonable interpretation of the right to issue is the right to revoke. Example two is the question “whether the license issuance and renewal process can be used to implement legally binding obligations?” In the case of Uganda and other countries, the law says a license can be issued with conditions as stated by the regulator. This provision in the law, permits the NDA to attach a set of conditions to the license that fill some of the gaps identified in this assessment. In effect license conditions are a third legal option in addition to regulations and legislation if the right to impose conditions is in the law. This becomes a management matter – first establishing a set of conditions that are published and transparent that are referenced in the license, and second that these are added them on license issuance or renewal. This is a regulatory approach totally within the control and capacity of the regulator. This is an immediate action that can be taken while waiting for Parliament to fill gaps in the law which is of course the optimum approach.

However, in the long run to serve the intended purposes of harmonization and for participation in any centralized system that may evolve, the bill to amend the Act should include measures to allow harmonization activities and to ratify the EAC Council Regulations. These Regulations are not self-implementing – a specific act of Parliament must be undertaken for these to have effect in Uganda and other EAC countries. Moreover, it is important to note that the measures currently in the draft NEPAD model medicines regulation law on harmonization are insufficient to legally empower the Uganda NDA or any NDA to take a legal action, such as recognition or reliance. Even with the recent version of the NEPAD model law, Uganda, like all other countries will have to align any model provisions with national law and regulation and also address the legal implications of harmonization.

Informants indicated there is an initiative underway to draft a mutual recognition agreement among the EAC members to effectuate some level of harmonization. This effort should be closely monitored to ensure the bill to amend the Act has sufficient language to permit the NDA to recognize the decisions of other EAC members according to the proposed agreement, in addition to the steps above mentioned.

Law Enforcement and Criminal Justice Sector

Customs Department – Uganda Revenue Authority

The Customs Department is administered by the Uganda Revenue Authority (URA). The priorities for Customs are related to fiscal matters. Though drugs are not taxed at entry into the country, import permits are routinely checked by Customs.

The Customs Department has a list of prohibited items which cannot enter the country, among which are ‘counterfeit items’ (including medicines). Customs officials most commonly conduct random checks as they lack the technical capacity to determine whether the imported medicines are falsified or substandard. Customs informally reports that a few interventions have taken place such as operations in the Eastern Region, where the Customs Department has created rapid response units.

The URA provides the NDA and other agencies at the borders access to the URA information system, including information on consignments entering the country. Imports need to be cleared by all agencies prior to entering the country.

The NDA and Customs have joint offices at some border crossings, e.g. at the Malaba border with Kenya. The Eastern border is the most porous. There are four Customs stations along this border, but there are many more roads that cross the country. There is only one international airport in Uganda, where the NDA inspects drugs imports. Informants suggested an approach to solve this issue is to form a task force on medicines, to aggregate data to indicate countries of origin known to be exporters of falsified and substandard medicines so as to profile flights arriving from countries on the list.

Directorate of Public Prosecutions

The Directorate of Public Prosecutions is established by the Constitution and is responsible for criminal prosecutions, including crimes related to falsified and substandard medicines. The NDA has held training workshops in which prosecutors have participated, either as participants or as trainers for inspectors on the prosecution of relevant crimes and offenses. Falsified medicines are found with both falsified packaging as well as with falsified or substandard content.

One of the main challenges for the prosecutor is that the evidence that needs to be collected in order to build the case is often insufficient. In June 2015, a case involving a big supplier and many small drug shops was investigated. However, as in a number of other previous cases, inspections leading to the prosecution of the case mainly involved small drug shops and retail pharmacies, rather than wholesalers and manufacturers.

Informants reported that on average a prosecutor receives about 4 cases every six months. However, as there are very few inspectors and police to investigate offenses, more cases could be investigated if there was more capacity.

There is currently no specific legislation regarding FS medicines in Uganda. A bill on counterfeits, the Uganda Anti-Counterfeiting Bill (2010), is currently in Parliament. The Bill addresses intellectual property law but expressly excludes medicinal products. The Bill does provide for a penalty which is 10 times the cost of the counterfeit product or a jail term of up to 20 years, which is greater than the penalties currently in the medicines law and regulations.

There are applicable offenses in both the National Drug Policy and Authority Act and the Penal Code Act. Conspiracy offenses carry substantially heavier penalties. One significant limitation of the provisions of the Penal Code is to consider the adulteration of drugs and the sale of adulterated drugs (which are, as said, limited categories of acts) as misdemeanors. One first step that might be taken with an adequate law reform process would be, for example, to consider these acts as felony.

Offenses related to falsified and substandard medicines in Uganda

Offenses relevant to falsified and substandard medicines exist in both the National Drug Policy and Authority Act and the Penal Code Act. As above mentioned, there is no specific provision for falsified medicines, (though substandard medicines are mentioned) therefore we take into consideration the possible criminal law provisions that, with their different limits, might be applied.

National Drug Policy and Authority Act (the Act)

The Act prohibits the sale of 'any drug, medical appliance or similar article which is not of the nature, substance and quality demanded or which... does not conform to the standards laid down in the authorized pharmacopoeia' (Art. 30(a).) The Act also prohibits the supply of 'any drug which is unwholesome or adulterated, or which does not conform to the prescription under which it is supplied...' (Art. 30(b)).

Any person who does so commits an offence and is liable to a fine not exceeding five million shillings or to imprisonment for a term not exceeding ten years or to both. 'Supply' includes, in relation to a drug, the administration of any such drug (Art. 1).

Part IX of the Act provides for offences and penalties (Art. 60):

1. A person contravening a provision of this Act commits an offence and, where no punishment is provided, is liable—
 - a) to a fine not exceeding one million shillings;
 - b) to a withdrawal of the license or permit for a period not exceeding five years;
 - c) to cause the items in contravention to be impounded, forfeited, destroyed or disposed of in a manner prescribed by the Minister;
 - d) to imprisonment not exceeding one year; or
 - e) to any two of the above punishments, and
 - f) for any subsequent offence under this Act, a person is liable to a fine not exceeding two million shillings or to a term of imprisonment not exceeding five years or to both.

2. A person who commits an offence under this Act and no other punishment is provided is liable—
 - a) where the offence relates to class A drugs, to a fine not exceeding two million shillings or to a term of imprisonment not exceeding five years or to both;
 - b) where the offence relates to narcotic drugs or psychotropic substances under international control and is a second or more subsequent offence, to a term of life imprisonment;
 - c) where the offence relates to manufacturing, smoking or having possession of any narcotic drug or psychotropic substance under international control and is a second or more subsequent offence, to a term not exceeding ten years.

Corporate liability and the liability of directors, secretaries and body corporate managers, and company partners, is envisaged in the section "Vicarious criminal responsibility" (Art. 61).

An example of the limits of the current legislation is that, for example, this provision does not include transport, manufacture, or storage. Similar limitations are identifiable in the following provisions of the Penal Code Act.

Penal Code Act

The Penal Code Act (1950) addresses the adulteration of drugs (Art.174) and the sale of adulterated drugs (Art.175).

Any person who adulterates any drug or medical preparation in such a manner as to lessen the efficacy or change the operation of such drug or medical preparation, or to make it noxious, intending that it shall be sold or used for or knowing it to be likely that it will be sold or used for any medicinal purpose, as if it had not undergone such adulteration, commits a misdemeanor (Art. 174).

Any person who, knowing any drug or medical preparation to have been adulterated in such a manner as to lessen its efficacy, to change its operation, or to render it noxious, sells the same or offers or exposes it for sale, or issues it from any dispensary for medicinal purposes as unadulterated, or causes it to be used for medicinal purposes by any person not knowing of the adulteration, commits a misdemeanour (Art. 175).

Both the above offenses in the Penal Code Act are misdemeanors, with a maximum penalty of imprisonment for two years (Art. 22). However, it is important to note that the offense of conspiracy to commit a misdemeanour (such as above) carries a more substantial penalty. It would also cover conspiracy in any part of the world to adulterate drugs or sell adulterated drugs (Art. 391).

Any person who conspires with another to commit a misdemeanour, or to do any act in any part of the world which if done in Uganda would be a misdemeanour, and which is an offence under the laws in force in the place where it is proposed to be done, commits a misdemeanour and is liable to imprisonment for five years (Art. 391).

Where an offence under the National Drug Policy and Authority Act or the Penal Code Act causes the death of a person, the offence of manslaughter may also be applicable.

Any person who by an unlawful act or omission causes the death of another person commits the felony termed manslaughter (Art. 187(1)).

There is no need for the prosecution to prove intention to cause death or bodily harm.

An unlawful omission is an omission amounting to culpable negligence to discharge a duty tending to the preservation of life or health, whether such omission is or is not accompanied by an intention to cause death or bodily harm (Art. 187(2)).

The Penal Code Act also provides for offenses of criminal recklessness and negligence, including specifically relating to medicines.

Any person who, by any rash or negligent act not amounting to manslaughter, causes the death of another person is liable to imprisonment for a term not exceeding seven years or to a fine not exceeding seventy thousand shillings or to both such imprisonment and fine (Art. 227).

Any person who, in a manner so rash or negligent as to endanger human life or to be likely to cause harm to any other person—

...

(e) gives medical or surgical treatment to any person whom he or she has undertaken to treat;
... commits a misdemeanour (Art. 228).

Transnational Organized Crime

Medicines counterfeiting is an activity that is mainly conducted with the clear involvement of organized criminals (both small and large scale groups), and involving perpetrators that are often connected and operate in different countries. At the international level, the United Nations Convention against Transnational Organized Crime (UNTOC) may play a crucial role to enhance the fight against medicines' counterfeiters.³⁷ Uganda has ratified both the United Nations Convention against Transnational Organized Crime (UNTOC)³⁸ and the United Nations Convention against Corruption (UNCAC).³⁹ Article 3 of the Convention identifies the scope of applicability of the UNTOC, affirming that it shall apply -- apart from the other forms of crime specifically mentioned -- to offences that are transnational in nature and involve an organized criminal group⁴⁰ as well as to 'serious crimes'.⁴¹ Furthermore, article 5 of the UNTOC also criminalizes the participation in an organized criminal group and its related activities.⁴²

The UNTOC contains several articles aimed at setting the basic standards for a series of very important matters related to organized crime investigation and prosecution. It is worth noticing that in this respect, specific provisions are dedicated to:

- Prosecution, adjudications and sanctions of the crimes indicated in the convention - among which, we have to remember, is the participation in an organized criminal group (Art. 11).
- Confiscation and seizure of: the proceeds of crime, the instruments and equipment used to commit such crimes, of the property into which proceeds of crime have been transformed or converted, income or benefits derived from proceeds of crime (Art.12).
- Extradition (Art. 16).

³⁷ It might be relevant to mention that there are specific international instruments currently developed in the field of counterfeiting of medical products. The Council of Europe drafted a convention which constitutes, for the first time, a binding international instrument in the criminal law field on counterfeiting of medical products and similar crimes involving threats to public health (MEDICRIME Convention). The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (CETS No.: 211) has not entered into force yet. The status of signatures and ratifications is available here: <http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=211&CM=8&DF=18/11/2014&CL=ENG>. The MEDICRIME Convention would establish as offences:

- the manufacturing of counterfeit medical products.
- supplying, offering to supply and trafficking in counterfeit medical products.
- the falsification of documents.
- the unauthorised manufacturing or supplying of medicinal products and the marketing of medical devices that do not comply with conformity requirements.

³⁸ See, United Nations Convention against Transnational Organized Crime, adopted by General Assembly resolution 55/25 of 15 November 2000, available at: <http://www.unodc.org/unodc/en/treaties/CTOC/index.html>

³⁹ See, United Nations Convention against Transnational Organized Crime, adopted by General Assembly resolution 55/25, annex I, available at: <http://www.unodc.org/unodc/en/treaties/CAC/index.html#UNCACfulltext>

⁴⁰ The Convention does contain a definition of 'organized criminal group'. In Article 2(a): a group of three or more persons that was not randomly formed; existing for a period of time; acting in concert with the aim of committing at least one crime punishable by at least four years' incarceration; in order to obtain, directly or indirectly, a financial or other material benefit. Since most 'groups' of any sort contain three or more people working in concert and most exist for a period of time, the true defining characteristics of organized crime groups under the Convention are their profit-driven nature and the seriousness of the offences they commit.

⁴¹ Serious crime is defined in article 2, subparagraph (b), of the UNTOC as meaning "conduct constituting an offence punishable by a maximum deprivation of liberty of at least four years or a more serious penalty."

⁴² UNTOC Article 5. Criminalization of participation in an organized criminal group: 1. Each State Party shall adopt such legislative and other measures as may be necessary to establish as criminal offences, when committed intentionally: (a) Either or both of the following as criminal offences distinct from those involving the attempt or completion of the criminal activity: (i) Agreeing with one or more other persons to commit a serious crime for a purpose relating directly or indirectly to the obtaining of a financial or other material benefit and, where required by domestic law, involving an act undertaken by one of the participants in furtherance of the agreement or involving an organized criminal group; (ii) Conduct by a person who, with knowledge of either the aim and general criminal activity of an organized criminal group or its intention to commit the crimes in question, takes an active part in: a. Criminal activities of the organized criminal group; b. Other activities of the organized criminal group in the knowledge that his or her participation will contribute to the achievement of the above-described criminal aim; (b) Organizing, directing, aiding, abetting, facilitating or counselling the commission of serious crime involving an organized criminal group.

2. The knowledge, intent, aim, purpose or agreement referred to in paragraph 1 of this article may be inferred from objective factual circumstances.

3. States Parties whose domestic law requires involvement of an organized criminal group for purposes of the offences established in accordance with paragraph 1 (a) (i) of this article shall ensure that their domestic law covers all serious crimes involving organized criminal groups. Such States Parties, as well as States Parties whose domestic law requires an act in furtherance of the agreement for purposes of the offences established in accordance with paragraph 1 (a) (i) of this article, shall so inform the Secretary-General of the United Nations at the time of their signature or of deposit of their instrument of ratification, acceptance or approval or of accession to this Convention.

- Mutual legal assistance (Art. 18).
- Protection of witnesses (Art. 24).
- Law enforcement cooperation (Art. 27).
- Prevention of crime through the development of national projects and best practices.

Regarding confiscations, UNCAC envisages the freezing, seizure and confiscation of proceeds of crime derived from offences established in accordance with the Convention (art. 31).

Since currently in Uganda there is no specific legislation regarding FS medicines, there is no corresponding regulation on confiscation of proceeds of crime in case of FS medicines. In the Anti-Money Laundering Act (2013), confiscation is envisaged in a dedicated section. Similar legal provisions might prove effective for FS medicines.⁴³

Inspectorate of Government

The Inspectorate of Government (IG) was initially established by the Inspector General of Government (IGG) statute in 1988. The Inspectorate of Government is now established by chapter 13 of the Uganda Constitution, which prescribes its mandate, functions and powers and other relevant matters. The Inspectorate of Government is an independent institution charged with the responsibility of eliminating corruption, abuse of authority and of public office. The powers enshrined in the Constitution and Inspectorate of Government Act include to; investigate or cause investigation, arrest or cause arrest, prosecute or cause prosecution, make orders and give directions during investigations; access and search – enter and inspect premises or property or search a person or bank account or safe deposit box among others.

The Inspectorate of Government has the mandate to oversee the work of the specialized agencies, including the National Drug Authority, to make sure that the public service is rendered in a proper and effective way.⁴⁴

Corruption

Informants reported corruption as being present at all levels and across institutions. Corruption in the court system was also reported, where a certain level of political pressure has also been perceived. Corruption in the media is also reported to be widespread. The mining sector is also reported to be most affected.

The relations of the Inspectorate with the Uganda Revenue Authority (URA) seem to be quite good. The Inspectorate has carried out a study on the link between corruption and distribution of vaccinations. The Republic of Uganda requires mandatory disclosure of financial records of individual candidates and political parties, which is carried out in collaboration with URA.

A limited number of investigations by IG seem to have been conducted in the sector of falsified medicines. One case was cited in which a magistrate was accused of not ordering the destruction of fraudulent medicines, which then disappeared. It is reported that sometimes seized drugs disappear, instead of being destroyed.

A major DFID-funded project, “Strengthening Uganda’s Anti-Corruption Regime (SUGAR)”, will explore how administrative sanctions can be used as a valuable tool against corruption, along with criminal sanction and confiscation.⁴⁵ This project represents a new approach, moving away from “single institution action” model towards strongly co-ordinated teamwork involving a range of agencies. The Whistle Blower Protection Act of 2010 will assist in the investigation and response to corruption.

⁴³The UNICRI study, “Confiscation of the Proceeds of Crime: a Modern Tool for Deterring Counterfeiting and Piracy” might serve as guidance to explore how sound legislation on confiscation of proceeds of crime and asset recovery can serve as an effective tool in counterfeiting cases. Available at: http://www.unicri.it/news/article/2013-04-25_Proceeds_of_Crime_Legislation (accessed 30 October 2015).

⁴⁴Activities to date appear to have been limited to investigating specific cases.

⁴⁵<https://www.gov.uk/government/world-location-news/international-anti-corruption-day-uk-working-with-uganda>, and <https://www.gov.uk/government/world-location-news/international-anti-corruption-day-uk-working-with-uganda> (accessed 30 October 2015).

Police and Interpol

During the June 2015 assessment mission there was no opportunity to meet with the local police. This should be remedied at the next opportunity, as this discussion is incomplete without the police perspective.

Interpol noted that organized crime syndicates were involved in the manufacture, distribution and sales of FS medicines. Many sales of FS medicines occur online. Operations such as Pangea VIII (June 2015), in which Uganda participated, aimed to address sales of illegal medicines online.⁴⁶ The NDA has been performing work and activities with Interpol. The contact point within the NDA is the Senior Inspector of Drugs in charge of Market Surveillance and Enforcement.

Interpol noted that counterfeiting of goods was extensive in Uganda, including of cosmetics, pesticides, food, electronics, and tires. However resources to address the issue are limited.

Interpol confirmed that multi-agency training on this issue would be very useful. Interpol has a training module on how to use Interpol tools (e.g. Red Notices, which seek the location and arrest of wanted persons, and can lead to extradition), and includes organized crime. Interpol has a strong commitment in combating illicit goods and counterfeit through its various activities, ranging from operations to capacity building and training, awareness raising and legal assistance provision.⁴⁷

Interpol has assisted with the coordination of transnational investigations (e.g. cases in which criminals operate under proxies, or where fake companies abroad are involved). This has included, for example, assisting in the identification of suspects and telephone numbers.

Example: Prosecution for operating an unlicensed drug shop

If an unlicensed drug shop is discovered by an NDA inspector, a warning letter to close the shop is issued to the owner or operator. If no compliance follows, after two weeks the NDA inspector requests the police to issue an arrest warrant, and to arrest and charge the person operating the unlicensed drug shop. NDA inspectors are also responsible for collecting the evidence. They may need, for example, to make photos, to keep records and to prepare a file for the case with the police. When the file is ready, the police forward the file to the Directorate of Public Prosecutions. The DPP then determines if the case is to be prosecuted, or dismissed.

The exchange of information with regulatory agencies in East Africa and neighboring countries is crucial to address the importation of FS medicines. Most cases of FS medicines are identified in the Eastern part of Uganda, near to the border with Kenya. There are performance indicators by region, with information on enforcement operations, and preliminary intelligence gathering. In 2008 - 2010 Uganda was part of the international Operation Mamba, led by Interpol, with the goal to disrupt the activities of transnational organized criminals involved in the trafficking of counterfeit medical products in Eastern Africa.⁴⁸

The criteria for international investigations are established at Interpol Headquarters. An operation to address FS medicines may start with an alert via text message from WHO Headquarters.⁴⁹ Local or international manufacturers might also inform the NDA.

⁴⁶See: <http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Pangea> (last accessed on 31 August 2015).

⁴⁷ For more information, see: <http://www.interpol.int/Crime-areas/Trafficking-in-illicit-goods-and-counterfeiting/Trafficking-in-illicit-goods-and-counterfeiting> (last accessed on 4 September 2015).

⁴⁸See Interpol, "Operations", available at: <http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Mamba>

⁴⁹ WHO Rapid Alert System for combating counterfeit medicine, available at: http://www.wpro.who.int/mediacentre/factsheets/fs_20050503/en/

Uganda has ratified both the UNTOC and the UNCAC. The Ugandan authorities may use the instruments provided for in these conventions to cooperate with other countries in investigating and prosecuting international cases involving FS medicines.

Private Sector Capacity Building and Engagement

Relevant private sector actors include drug importers, wholesalers, and retailers, and health sector corporations. They all need to be informed and engaged in the legal and regulatory reform to address FS medicines. Capacity building will be necessary, and public forums should include private sector representatives.

International and Regional Cooperation

International and regional cooperation is paramount in the fight against FS medicines. Uganda has participated in various international operations, including several of the Pangea operations. The official contact point of Interpol within the NDA to facilitate cooperation is the Senior Inspector of Drugs in charge of Market Surveillance and Enforcement.

From the legislative perspective, there is no regional treaty specifically dealing with FS medicines. Nevertheless, consideration has to be given to the Council of Europe (COE) Convention on the Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health (Medicrime Convention).⁵⁰ The Medicrime Convention is a recent response by the COE to the need to develop an international criminal justice instrument to fight counterfeiting of medical products and similar crimes involving threats to public health. Although it has been adopted in the framework of a regional organization, the Medicrime Convention is open for ratification by non-Member States and it could become a useful tool also for Uganda.

The MEDICRIME Convention requires State Parties to establish as criminal offences the following:

- the manufacturing of counterfeit medical products;
- supplying, offering to supply and trafficking in counterfeit medical products;
- the falsification of documents;
- the unauthorized manufacturing or supplying of medicinal products and the marketing of medical devices that do not comply with conformity requirements.

The Convention also lays down a framework for national and international cooperation between the competent health, police and customs authorities on both the national and international levels, measures for crime prevention by also involving the private sector, and the effective prosecution of crime and the protection of victims and witnesses. Furthermore, it provides for the establishment of a committee to follow up the implementation of the Convention by the signatory states.

In terms of prevention, it requires that States parties adopt measures to establish the quality and safety requirements of medical products and to ensure their safe distribution (art. 18).

Expressing the interest in signing the Medicrime Convention might help in showing the political will necessary to concretely reinforce the current legal framework and it will place Uganda among the Countries that actively show their commitment at the international level.

Another good example might come from cross-sectoral criminal justice treaties, specifically the two most relevant and nearly universally ratified instruments that are the United Nations Convention against Transnational Organized Crime (UNTOC) and the United Nations Convention against Corruption (UNCAC).

As mentioned in the report, Uganda has ratified both the UNTOC and the UNCAC. The Ugandan authorities should actively use the instruments provided for in these conventions to cooperate with other countries in investigating and prosecuting international cases involving FS medicines.

⁵⁰Available at: <http://conventions.coe.int/Treaty/EN/Treaties/Html/211.htm>

As mentioned in the relevant section in the report, the UNTOC contains several articles aimed at setting the basic standards for a series of very important matters related to organized crime investigation and prosecution. For example, the UNTOC outlines a broad legal framework for the identification, tracing, freezing and confiscation of instrumentalities and proceeds of crime (art. 12). This type of provision is currently missing in the current Uganda national legal framework.

The UNTOC provides for extensive provisions covering extradition, mutual legal assistance and law enforcement cooperation (art. 16-18, 27). Cooperation among all involved countries is key to make criminal investigations and subsequent prosecutions a success. International cooperation measures can be regarded as “bridges” between jurisdictions. On this regard, a fundamental role is played by data and information sharing initiatives at the international (and regional) level. In both UNCAC (art.48) and UNTOC (art. 27) States parties are required to strengthen the channels of communication among their law enforcement authorities, provide each other with items or substances for purposes of analysis, etc.

On secure communication channels and databases, INTERPOL is playing a vital role.

As regards the provision of secure global police communications services, operational data services and databases, these allow law enforcement from all member countries to communicate with each other securely, providing them with the means to share crucial information on suspected criminals, criminals and criminal activities.

The Member State Mechanism on substandard/spurious/falsely-labeled/falsified/counterfeit medicines of the World Health Organization provides an international forum for addressing the issues.⁵¹

⁵¹ See http://apps.who.int/gb/ssffc/e/a_msm1.html

Draft Uganda National Strategy and Recommendations to Eliminate FS Medicines

Introduction

This “*first draft*” national strategy to eliminate falsified and substandard medicines has been organized around the following five components:

- civil society,
- the national drug authority and the medicines law,
- the law enforcement and criminal justice sector,
- the private sector, and
- international and regional cooperation.

These components are related to the legal and regulatory environment necessary to support a national response to FS medicines. They are drawn from the literature, international best practices and the work of scholars and international organizations.⁵² The precise elements of each component were developed after a desk review of the law of Uganda and literature review and an assessment mission to Uganda in June 2015. As with any first draft, this draft strategy will require a more in-depth consultation with concerned stakeholders and further analysis of existing regulatory and legislative frameworks for it to be finalized. A comparative analysis of the current legal framework with international and regional legal provisions will also inform the strategy.

As is clear in this report, a number of critical gaps have been identified in the existing legal framework applicable to FS medicines which hamper the ability of the NDA to address the problem of FS medicine. This situation in addition to the sheer lack of sufficient staff make managing the problem very challenging and lead to an unacceptable level of circulation of FS medicines in the marketplace.

As underlined by the WHO there is no simple or standard solution that might be applicable worldwide to eliminate the FS medicines problem.⁵³ Each country has to develop a national strategy based on its own situation. Each relevant stakeholder has to be involved and the role of each party needs to be clearly defined to ensure accountability. The progress on the implementation of the strategy should be regularly monitored and evaluated to timely identify successes or failures and therefore to possibly take corrective measures. Political will and the feeling of a shared commitment (and consequent shared responsibility) in the elimination of FS medicines are a must for an effective design and implementation of a national strategy.

Civil Society

Relevant civil society organizations include patients and consumer groups, advocacy organizations, and independent professional associations of medical practitioners and pharmacists. There is a need for all stakeholders to shift from the perception of civil society as only consumers of medicines to the engagement of civil society as full partners in the national response to FS medicines. This reflects the human rights-based approach to health and development, which emphasizes participation, accountability, equality and nondiscrimination.

Uganda has a vibrant and independent civil society sector, and there are several strong civil society organizations which include health in their mandates. The role of faith based communities and traditional leaders should also be considered.

⁵² A guide to developing a national strategy is available for any country to use in the *Legal Information Repository*. See http://global-forumlid.org/themes/cops/health_law.htm

⁵³ WHO, Counterfeit Drugs. Guidelines for the development of measures to combat counterfeit drugs, 1999. Available at http://apps.who.int/iris/bitstream/10665/65892/1/WHO_EDM_QSM_99.1.pdf (Last accessed on 13 September 2015).

Civil society organizations should be engaged at all levels in the national response – including through representative participation in national structures. Trusted civil society champions and leaders should also be engaged in public education campaigns to inform people about the dangers of FS medicines. Finally, civil society engagement should be supported to extend to include regional and international collaboration regarding FS medicines.

In parallel, cross cutting and multidisciplinary awareness raising strategies need to be implemented targeting the various law enforcement agencies, health sectors’ professionals (e.g. hospitals, pharmacies, etc.) and local communities at large.

The existing awareness raising initiatives at the national, regional and international level have to be mapped in order to identify which experiences have been more successful. Proper assessment instruments to measure the impact of the implemented strategy and tools should be designed, tested and adopted, so as to make a proper financial and human resources planning and not to duplicate existing experiences/materials.

Civil society organizations focused on the health sector need to be supported to participate in related governance processes, such as on the National Drug Authority. Appropriate mechanisms of cooperation between public and the private actors, including the civil society organizations should be created on the basis of international good practices.

Civil society needs capacity building to understand the issues and where advocacy for reform needs to be focused. Capacity building for research, documentation, advocacy, and communications is needed.

National champions need to be identified who will ensure the issue of FS medicines is among the priority issues for government and civil society action in the coming years. Champions may be identified in both government and civil society.

Legal and Regulatory Environment

National Drug Authority and Medicines Legislation

The legislative and regulatory framework can be strengthened by: clarifying the actors and activities subject to medicines regulation; defining FS medicines clearly and consistently across all laws and regulations, prohibiting the production, sale, distribution, import, export, transport or warehousing of FS medicines, labels or packages and the manufacturing equipment, components, packaging or labeling materials used in the production of FS medicines, add or increase penalties for the violation of any prohibition and include severe penalties if FS medicines cause or could cause harm to humans or animals.

The Scope of the Medicines Law

The scope of the Act is limited to “drugs”, which are defined as substances or preparations for humans and animals for treatment, prevention or for improving physiological functions or for agricultural or industrial purposes (Art. 1), including herbal medicines. Devices, cosmetics, foods, reagents, products for diagnosis, surgical supplies, blood and other products that are typically found in health systems are generally not specifically defined by the Act. They should be added to ensure that such items, which can be and are falsified or substandard, are covered by law, and that there is regulatory oversight of these health products.

Expand Regulatory Infrastructure

1. The NDA must build a sufficient inspectorate to comprehensively cover the entire country and all its actors. The inspectors must be sufficiently trained and knowledgeable on how to conduct a proper inspection and what to look for in terms of compliance or lack thereof. The budget must be adequate to hire a sufficient number of inspectors who are trained on the requirements and their verification and what to do in case of a suspected FS medicine.

2. Improve the capacity of the laboratory system, in terms of the numbers of labs, the speed at which tests are completed and increasing the complexity of tests that can be conducted to determine if a product is substandard. Expand field testing of medicines through rapid tests, bar coding and use of mobile technologies to verify medicines.
3. Creating an integrated reporting and complaint mechanisms, with NDA as focal point (using various tools, e.g. apps and electronic platforms), including a toll free telephone hotline reporting and for answering to questions on FS medicines. Build an electronic platform for information sharing across agencies with a section dedicated to exchange of case law and best practices (possibly NDA can be the focal point).
4. Establish a specialized task forces comprised of the NDA, MOH, MOJ, and Customs among others and create a Joint Investigation Team, to track countries of origin of FS medicines to improve surveillance at border crossings, and to finalize develop and implement a national strategy to combat FS medicines.
5. Create coordination between the MOH and NDA to ensure that all actors in the system are in compliance. Harmonize operating requirements for public and private pharmaceutical actors, and private and hospital pharmacies and coordinate inspections with the NDA to ensure all pharmaceutical activities are correct.
6. Create an internal review board Uganda lacks an internal review board which the NDA should establish and operate either alone or in conjunction with the ministry of health. It can hear cases of suspected FS medicines, issue orders for final seizure and destruction, determine if the inspector is correct in observing non-compliance and sanction with license suspension or revocation for non-compliance.

Licensing

Review the licensing requirements and aligned these in the law and regulation so that all actors in the supply chain are required to be licensed including wholesalers, retailers, transporters, warehouseman, manufacturers, importers and exporters. The definitions in Articles 14 and 15 require revision so that there is internal consistency with the PMV regulations and all licensed actors and that the powers of inspection are clearly applicable to any and all actors in the legal and illegal supply chain.

It is also important to clarify the distinction between retail sales and wholesale activity, so that wholesalers cannot sell drugs to unlicensed persons (i.e. drug shops) and that their record keeping is extended beyond the immediate source of their supply. All actors must have a clear set of guidelines for their activities such as GDP and GMP. A realignment of the standards and scope of practice for all actors in the supply chain will be helpful to clarify gaps and ensure that a comprehensive set of standards are applicable to the relevant actors.

When considering manufacturers, as mentioned, they are licensed by the Regulation on Licensing, which sets out the requirements to obtain a license but does not require compliance with Good Distribution Practices (GDP). This sort of gap must be properly addressed.

Until such time as a new medicines law is enacted by Parliament the NDA can take action and do so immediately. The step it can take is to issue guidelines for each licensed actor and make license renewal and initial licensing contingent on an agreement to be compliant with the guideline. In this way the guidelines become legally binding as a function of the license. This approach is recognized in the existing law but underutilized by the NDA.

Supply Chain Security Monitoring and Reporting

Adequate provisions should focus on the supply chain security monitoring. The best practice for pharmacovigilance obligates all the varying actors in the system to report ADRs, and to develop a system to differentiate those ADR events that might be related to a FS medicine. Correspondingly, the NDA is obligated to establish a PMV system that assesses reports, maintains an information data base, an office and to issue alert when significant risks are identified. The foundation of the system is however two part: the obligation to report ADRs to the NDA, and the NDA obligation and process to confirm and

contain FS medicines. Mandate NDA and the National Medical Services (NMS) to report cases of suspected or actual FS medicines to the office of public prosecution.

With regards to the private sector, QM needs to be required by law and that is done by the procurement contract and as a prerequisite for vendors. It is important that the NDA consider how the ministry of health procures medicines and the specifications for them.

A second tier of gap is represented by the fact that manufacturers, importers, doctors, NGOs, public health programs or any other person determined by the authority must have a pharmacovigilance system, but are not obligated to report on the safety, efficacy and quality of drugs, unless requested. Due to the lack of proper enforcement of the system, useful intelligence and data might be therefore lost.

Another aspect to be considered concerns the compulsory on-site presence of the licensed pharmacist, which is currently limited to 40% of the working time, leaving ample space for unsupervised and possibly illicit activities. Periodic inspections should be compulsory and undertaken in accordance with risk-based inspection procedures to confirm full compliance. Consequences for non-compliance, currently not clearly specified, should also be foreseen.

In parallel NDA inspectors' powers should be enhanced and their authority extended so as to include, for example, testing of active pharmaceutical ingredients (APIs).

In the process of import and export, NDA has dedicated staff at the port of entry together with Customs. Currently, there is nothing in the law that circumscribes the activity of import or export other than the prohibition without a permit, the duration of the permit and that the "range of preparations" imported or the "drugs or range of preparations" to be stated to the NDA. The importer or exporter is not required to have a pharmacist on staff and there are no requirements to comply with nor is any system of 'track and trace' required. For any country that imports medicines the importer is a primary actor in the system and should be required to comply with GDP and track and trace. Exporters should also be regulated - this will be very important as the regional harmonization systems are more established and products move more readily between countries.

The storage requirements and who is subject to them can be amended to include the person or entity that stores and to expand their content to a more comprehensive technical level. As mentioned in the report, there is no license requirement for those that store drugs though the facility where drugs are stored must hold a Certificate of Suitability as per regulation and the Seventh Schedule of the Act. The Seventh Schedule only requires a lock and key and separation of medicines from other products, two important requirements but by themselves insufficient storage standards. Specific provisions on storage should be integrated in the national strategy to develop proper standards (considering also the regional experiences on this regard) with the goal of harmonizing the current regulation. The NDA is not obligated to conduct investigations on receipt of a safety signal or take further actions. It *may* do so according to Articles 5 and 8 of the Pharmacovigilance Regulation. It is obligated, however, to control the quality of drugs, by Article 5 of the Act but the Regulation limits the obligation. The national strategy should envisage a stronger, clearer statement on the elements or activities of control and provide as well for adequate resources. At a minimum, the NDA should be required to investigate those cases that are of such a nature as to reasonably conclude there is risk to the public's health and safety.

The powers of inspectors need to be expanded so that the Act authorizes the taking of labelling or packaging materials or finished ones, materials or production equipment in addition to what is permitted now but limited to taking drugs and records or other documents. While not a legal matter, providing inspectors with technical equipment that might aid inspections and investigations.

Manufacturers and importers are not required to comply with GDP, so the information they are required to keep is too limited to assist in tracing the sources of FS medicines. Clear guidance on the records to be kept by the actors in the supply chain should be implemented by regulation, standard or guidelines within the national strategy.

Uganda does not currently have a pedigree requirement or track and trace requirement in the law. This chain of custody recording requirements should be addressed a new law and until the law is passed the NDA can attach this requirement to license renewal and initial issuance.

With regards to reporting, the national strategy should envisage the creation of an integrated reporting and complaint mechanisms, with NDA as focal point (using various tools, e.g. apps and electronic platforms).

On the awareness component of the national strategy, hotline services for reporting and for answering to questions on FS medicines within the NDA should be enhanced with a toll free number.

Law Enforcement and Criminal Justice Sector

Definitions and Consistency in Both the Medicines Law and Criminal Law

As mentioned in the report, clear definitions are lacking, which need to be consistent throughout the legal system. Clear definitions that are consistent throughout the legal system will be important to the ability of the NDA and criminal justice system to manage the problem of FS medicines.

Currently there is no definition of 'counterfeit' in the Act, though Art. 30 refers to impure drugs. The Regulation on Pharmacovigilance (PMV Regulation) defines "counterfeit drug" to mean "a drug which is deliberately or fraudulently mislabeled with respect to its identity, content or source."

A full definition of FS medicines could include elements that distinguish accidental substandard, negligent substandard, and intentional substandard, or accidental false label or packaging, as compared to intentional falsification (such as changing expiration dates).

There are applicable regulatory prohibitions and criminal offenses in both the National Drug Policy and Authority Act (NDP/A Act -the Act) (mentioning impure drugs) and the Penal Code Act (addressing adulterated drugs). These different situations require a different regulatory approach; for intentional cases the criminal law will apply as will punitive measures one would not use against an honest manufacturer who made a mistake but for whom regulatory sanctions such as license suspension or financial penalties.

Finally, harmonization of definitions will also result in more harmonized data collection methodologies, allowing for the design of better policies in the fight against FS medicines.

Capacity building of justice sector actors to obtain convictions and meaningful sentences is also very much needed.

Penalties

The criminal provisions in the Act and the Penal Code Act generally provide an adequate basis for prosecutions to address FS medicines. Penalties need to be harmonized and should be effectively applied, specifically when imprisonment is applicable.

One significant limitation of the provisions of the Penal Code is to consider the adulteration of drugs and the sale of adulterated drugs (which are, as said, limited categories of acts) as misdemeanors. The offense of conspiracy to commit a misdemeanour carries a more substantial penalty (i.e. imprisonment for five years). The first step to be taken is to consider these acts as felony and raise, wherever necessary the severity of the applicable sanctions. In addition, the minimum level in existing penalties should be included along with the maximum (e.g. art.60 of the Act "...a fine not exceeding one million shillings" or "...imprisonment not exceeding one year").

Aggravating circumstances provisions are lacking as well and should be foreseen. The Medicrime Convention can be taken as a model: article 13 envisages aggravating circumstances when the offence involves:

- Death or physical or mental damage;
- Persons acting in their capacity as professionals;
- Manufacturers and suppliers;
- Resort to means of large scale distribution, such as information systems, including the Internet;
- A criminal organization;
- Previous conviction of offences of the same nature.

These considerations are extremely important in view of the possible applicability of provisions of the UN TOC Convention to FS medicines- related crimes in Uganda.⁵⁴

Corporate Liability

In the Act, corporate liability and the liability of directors, secretaries and body corporate managers, and company partners, is envisaged in the section “Vicarious criminal responsibility” (Art. 61). This provision does not cover however transport, manufacture, or storage, which instead need to be included along with specific penalties.

Financial sanctions are typically imposed for corporate liability, but a variety of other remedies has also demonstrated to be quite effective at international level and should be introduced in the Ugandan legal framework as well. The Medicrime Convention, for instance, mentions the temporary or permanent disqualification from exercising commercial activities, placing the legal person under judicial supervision, and subjecting it to a judicial winding-up order.

Confiscation of Proceeds of Crime

Since no specific legislation on FS medicines exists in Uganda, confiscation of proceeds of crime deriving from FS medicines is not foreseen specifically. In the Anti-Money Laundering Act (2013), confiscation is envisaged in a dedicated section. Similar law provisions have to be foreseen with regards to FS medicines. In addition, both the United Nations Convention against Transnational Organized Crime (UNTOC) and the United Nations Convention against Corruption (UNCAC), ratified by Uganda, include provisions dedicated to the issue of confiscation, which provide a useful model to draft specific provisions in this respect.

A clear definition of powers and of roles between inspectors and police (i.e. inspect, seize, shut down, arrest, citations, sample, remediate) has to be sought.

Regarding the power of inspection, for example, the current law seems to be adequate in terms of overall powers but does not permit impounding in place. An inspector must take away suspicious or actual FS medicines and does not have the legal option to impound in place. And inspectors cannot remove production equipment or packaging materials. A national strategy has to require that seizure, both temporary and permanent, is authorized and circumscribed by law. This is even more important considering that, as mentioned in the report, prosecutors have difficulties in initiating proceedings for crimes related to FS medicines because of the poor quality of the evidence collected. The final national strategy will need to include proper evidence collection and chain of custody management.

Another challenge is the storage of seized goods while the trial is pending. National authorities do not have space, nor appropriate facilities for these purposes. Goods need thus to be stored at the NDA premises, which might not be the perfect solution if there no proper requirements envisaged by law. The national strategy has to include relevant instructions for the storage and management of seized goods.

⁵⁴ UN TOC applies to serious crimes as defined by the Convention in article 2.b “Serious crime” shall mean conduct constituting an offence punishable by a maximum deprivation of liberty of at least four years or a more serious penalty”.

Data Sharing and Inter-Agency Cooperation

Not only data sharing is fundamental across agencies, but also within the same agency across the country. Access to different databases would greatly enhance and support stakeholders in the prevention of FS medicines.

One example is the NDA database with names of licensed persons/sellers: databases exist at regional level in Uganda, but they are not connected at national level (a person can therefore obtain more than two licenses in different regions). A key point of the final national strategy is to envisage the harmonization and interoperability of current existing instruments and provide for relevant regulations, access rights, data protection and information security provisions.

An example on good data sharing and common databases comes from pharmacovigilance that requires all actors to report adverse drug reactions (ADRs) and to develop a system to differentiate those ADR events that might be related to a FS medicine. Correspondingly, the NDA is obliged to establish a PMV system that assesses reports, maintains an information database, and to issue an alert when significant risks are identified. On the regulatory side, though, the PMV Regulation only obliges a licensed person to submit safety reports, no other actors are obligated and this might result in the loss of important data on various cases.

The national strategy should make the reporting by the NDA and National Medical Services (NMS) to public prosecution offices mandatory (details of circumstances and extent should be clearly defined by law). It should also envisage the creation of an apt system to manage complaints and cases, with the possibility to have different type of access with different privileges depending on the actor who has the authorization to accede.

Moreover, a focal person needs to be appointed in each agency (e.g. NDA, Inspectorate of Governments, etc.) to foster cooperation at national, regional and international level. The establishment of a permanent dedicated Task Force could facilitate the coordination and exchange of information across the different institutions. Legal issues related to the exchange of information among agencies should also be explored in the final national strategy, in order to overcome possible legal obstacles.

Enforcement

More coordination is required among the agencies at the national level to ensure proper enforcement of the existing legal and regulatory framework. At the same time, FS medicines should become an investigative priority for all law enforcement agencies, including customs and police.

In addition, to enhance law enforcement actions against FS medicines, specialized task forces and/or joint investigation teams among the various agencies shall be created, thereby enhancing exchange of information and cooperation across agencies, leveraging on existing expertise and minimizing conflicting competences.

The creation of an electronic forum/platform for information sharing across agencies with a section dedicated to exchange of case law and best practices, could be considered in this respect. Information sharing is not only about the quantity of the information that is exchanged, but it is especially about the quality of the information. Training should be developed as well on how to recognize FS medicines and therefore how to exchange the proper information.

Uniform and standardized operating procedures need to be established to increase the effectiveness of the interventions and uniformity of enforcement across the country. For instance, detailed checks on inventories and books in pharmacies are not very common but they should be compulsory. From a technical perspective and as noted during the assessment mission, enforcement agencies should be provided with adequate technical equipment to detect FS medicines also in remote areas. The number of testing labs should also be increased.

Overall and foremost, to make a national strategy realistic, sustainable and therefore effective, an adequate budget and well trained human resources in all agencies is crucial for their basic functioning as well as for their specific efforts in eliminating FS medicines.

Considering the NDA for instance, adequate number of trained staff need to present at all times in all departments. For instance as noted in the report, inspection staffing is insufficient to manage the multiple actors in the system. As a result, private hospitals and pharmacies are not inspected on a regular basis.

In parallel, priority needs to be given to capacity building activities for law enforcement and investigators, including officials of Inspectorate of Government, with specific focus on FS medicines- related issues and possible organized crime involvement.

Police are frequently rotated, so even if a specialized unit is created, the staff never really gets the adequate level of expertise to properly investigate. Rotation schemes within specialized units should be organized in order to ensure proper level of knowledge and awareness of the staff at all times.

The Customs Department in Uganda also suffers of limited human resources, not being able to be present at all crossing roads and border controls with neighboring countries. This issue must be properly addressed.

Capacity building of justice sector actors also has to become top priority to increase the number of convictions and meaningful sentences. Multidisciplinary and multi-agency training programs to foster both the knowledge and awareness, and the network building need to regularly carry out.

Private Sector Capacity Building and Engagement

Relevant private sector actors include drug importers, wholesalers, and retailers, and health sector corporations. They all need to be informed and engaged in the legal and regulatory reform to address FS medicines. Capacity building will be necessary, and public forums should include private sector representatives.

International and Regional Cooperation

International and regional cooperation is paramount in the fight against FS medicines.

Uganda has participated in various international operations, including several of the Pangea operations, but a proper official contact point of Interpol must be appointed within the NDA to facilitate cooperation.

From the legislative perspective, there is no regional treaty specifically dealing with FS medicines. Nevertheless, consideration has to be given to the Council of Europe (COE) Convention on the Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health (Medicrime Convention).⁵⁵ The Medicrime Convention is a recent response by the COE to the need to develop an international criminal justice instrument to fight counterfeiting of medical products and similar crimes involving threats to public health. Although it has been adopted in the framework of a regional organization, the Medicrime Convention is open for ratification by non-Member States and it could become a useful tool also for Uganda.

The MEDICRIME Convention requires State Parties to establish as criminal offences the following:

- > the manufacturing of counterfeit medical products;
- > supplying, offering to supply and trafficking in counterfeit medical products;
- > the falsification of documents; and
- > the unauthorized manufacturing or supplying of medicinal products and the marketing of medical devices that do not comply with conformity requirements.

⁵⁵Available at: <http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/211> (accessed 30 October 2015).

The Convention also lays down a framework for national and international cooperation between the competent health, police and customs authorities on both the national and international levels, measures for crime prevention by also involving the private sector, and the effective prosecution of crime and the protection of victims and witnesses. Furthermore, it provides for the establishment of a committee to follow up the implementation of the Convention by the signatory states.

In terms of prevention, it requires that States parties adopt measures to establish the quality and safety requirements of medical products and to ensure their safe distribution (art. 18).

Expressing the interest in signing the Medicrime Convention might help in showing the political will necessary to concretely reinforce the current legal framework and it will place Uganda among the Countries that actively show their commitment at the international level.

Another good example might come from cross-sectoral criminal justice treaties, specifically the two most relevant and nearly universally ratified instruments that are the United Nations Convention against Transnational Organized Crime (UNTOC) and the United Nations Convention against Corruption (UNCAC).

As mentioned in the report, Uganda has ratified both the UNTOC and the UNCAC. The Ugandan authorities should actively use the instruments provided for in these conventions to cooperate with other countries in investigating and prosecuting international cases involving FS medicines.

As mentioned in the relevant section in the report, the UNTOC contains several articles aimed at setting the basic standards for a series of very important matters related to organized crime investigation and prosecution.

For example, the UNTOC outlines a broad legal framework for the identification, tracing, freezing and confiscation of instrumentalities and proceeds of crime (art. 12). This type of provision is currently missing in the current Uganda national legal framework.

The UNTOC provides for extensive provisions covering extradition, mutual legal assistance and law enforcement cooperation (art. 16-18, 27). Cooperation among all involved countries is key to make criminal investigations and subsequent prosecutions a success. International cooperation measures can be regarded as “bridges” between jurisdictions. On this regard, a fundamental role is played by data and information sharing initiatives at the international (and regional) level. In both UNCAC (art.48) and UNTOC (art. 27) States parties are required to strengthen the channels of communication among their law enforcement authorities, provide each other with items or substances for purposes of analysis, etc.

On secure communication channels and databases, INTERPOL is playing a vital role.

As regards the provision of secure global police communications services, operational data services and databases, these allow law enforcement from all member countries to communicate with each other securely, providing them with the means to share crucial information on suspected criminals, criminals and criminal activities.

The Member State Mechanism on substandard/spurious/falsely-labeled/falsified/counterfeit medicines of the World Health Organization provides an international forum for addressing the issues.⁵⁶

⁵⁶ See http://apps.who.int/gb/ssffc/e/a_msm1.html

ANNEXES

Annex 1: Draft Theory of Change to Address FS Medicines in Uganda and Results Monitoring Framework

Proposed longer term goal (impact)

Reduction in morbidity and mortality in Uganda due to falsified and substandard medicines.

Proposed intermediate goal (intermediate impact)

Reduction in importation, manufacture, distribution and sale of FS medicines in Uganda.

Proposed outcomes (achievable within three years)

- 1) National FS strategy and legal and regulatory frameworks initiated, strengthened and implemented.
- 2) Enhanced capacity to eliminate FS medicines through legal sector engagement across government, judiciary, civil society, academia and media.
- 3) Established and functioning mechanisms for national cross-sectoral cooperation on initiatives to address FS medicines, including between government ministries, and between government, civil society and private sector.
- 4) Greater governmental (formal) engagement in inter-governmental cooperation on FS medicines.

Proposed outputs

- 1) Strengthened medicines regulatory framework and capacity

The above analysis reveals that the legislative and regulatory framework to address FS medicines in Uganda is basically sound, although there are still some significant gaps. Close the gaps with the methods proposed here. Much needed, however, are more trained NDA officers to inspect and implement the existing regulations. Support infrastructure, such as an interoperable national and regional databases of license holders, are also needed.

- 2) Strengthened criminal justice sector framework and capacity

The criminal provisions in the NDP/A Act and the Penal Code Act generally provide an adequate basis for prosecutions to address FS medicines. The maximum fines are inadequate however, and courts may be reluctant to impose the maximum terms of imprisonment. As a result, the penalties may not be a significant deterrent to criminal activity. Confiscation of equipment and the proceeds of crime would be additional useful deterrents. Capacity building of justice sector actors to obtain convictions and meaningful sentences is needed.

- 3) Strengthened government capacity and engagement in regional and international responses

Uganda needs capacity building and support to be more fully engaged in the East African Community harmonization process and other international efforts to address FS medicines.

- 4) Strengthened civil society capacity building and engagement

Civil society engagement, broadly defined, is key to any substantial progress to address FS medicines in Uganda. Civil society needs capacity building to understand the issues and where advocacy for reform needs to be focused.

Capacity building for research, documentation, advocacy, and communications is needed. Civil society organizations focused on the health sector need to be supported to participate in related governance processes, such as on the National Drug Authority.

5) Strengthened private sector capacity and engagement

Legitimate private sector actors, including private pharmaceutical and health sector corporations, need to be informed and engaged in the legal and regulatory reform to address FS medicines. Capacity building will be necessary, and public forums should include private sector representatives.

6) Champions for reform identified and engaged

National champions need to be identified who will ensure the issue of FS medicines is among the priority issues for government and civil society action in the coming years. Champions may be identified in both government and civil society.

Proposed activities:

- 1) Research and materials development
- 2) Capacity building
- 3) Communications
- 4) Networking
- 5) Technical assistance

Draft results monitoring framework

Proposed longer term goal (impact): Reduction in morbidity and mortality in Uganda due to falsified and substandard medicines.

Proposed intermediate goal (intermediate impact): Reduction in importation, manufacture, distribution and sale of FS medicines

Note: Risk analysis should include consideration of government engagement.

Outcomes	Results	Key Indicators	Data Sources
Outcome 1	Enhanced capacity to eliminate FS medicines through legal sector engagement across government, judiciary, civil society, academia and media	Reforms in laws and regulations, policies and practices. Positive judicial decisions. Statements and publications by civil society, academia and the media	Government sources. Case law. Newspaper and other reports
Outcome 2	National FS strategy and legal and regulatory frameworks initiated, strengthened and implemented	Development of a national strategy through participatory processes	Government sources
Outcome 3	Established and functioning mechanisms for national cross-sectoral cooperation on initiatives to address FS medicines, including between government ministries, and between government, civil society and private sector	Establishment of inter-ministerial and other platforms to support dialogue between stakeholders	Government sources
Outcome 4	Greater governmental (formal) engagement in inter-governmental cooperation on FS medicines	Formal government participation in regional and international structures	Government sources, reports of inter-governmental mechanisms
Outputs			
Output 1	Strengthened medicines regulatory framework and capacity	Legal and regulatory reform; capacity building events for key stakeholders	Government reports; reports of capacity building events
Output 2	Strengthened criminal justice sector framework and capacity	Legal and regulatory reform; capacity building events for key stakeholders	Government reports; reports of capacity building events
Output 3	Strengthened government capacity and engagement in regional and international responses	Number and type of government participation in capacity building events and regional and international responses	Meeting reports
Output 4	Strengthened civil society capacity building and engagement	Number and type of civil society participation in capacity building programs; private sector participation in structured dialogues	Reports of capacity building events, reports of structured dialogues
Output 5	Strengthened private sector capacity and engagement	Number and type of private sector participation in capacity building programs; private sector participation in structured dialogues	Reports of capacity building events, reports of structured dialogues
Output 6	Champions for reform identified and engaged	Number and type of champions identified, public statements	Government reports, newspaper reports

Annex 2: Current Laws and Regulations that Comprise the Uganda Legal and Regulatory Framework

CURRENT LAWS (2015)	PENDING LAWS
Constitution (1995)	
The National Drug Policy and Authority Act, 1993 (Cap 206)	The National Food & Medicine Authority Bill
<u>REGULATIONS</u> Licensing 2014 Certificate of Suitability of Premises 2014 Conduct of Ectoparasitocides Field Trials 2014 Conduct of Clinical Trials 2014 Control of Publication and Advertisement Relating to Drugs 2014 Fees 2014 Pharmacovigilance 2014 Importation and Exportation of Drugs 2014 Registration 2014	
> Guidelines on Good Manufacture Practice	
> Public Health Act, 1935	None
> National Medical Stores Act, 1993 (Cap 207)	None
> Pharmacy and Drugs Act, 1971 (Cap 280)	None
> Pharmacy Standards of Practice, The Pharmaceutical Council 2001	None
> The Health Service Commission Act, 2001	None
> Private Hospital Guidelines for the Construction, Establishment and Maintenance of Private Hospital and Day Procedure Facilities 1998	
> Penal Code Act, Cap 120 Penal Code (Amendment) Act, 2007	None
> None	Anti-Counterfeiting Bill, 2010
> None	The Indigenous & Complimentary Medicines Bill
> Leadership Code Act (2002)	None
> Anti-Corruption Act 2009	None

Annex 3: Offenses and Penalties in National Drug Authority Act

Article Section	Offense	Penalty
	Supply without registration	
14	Carry on pharmacy without a license	One million shillings/or one year jail
15	Carry on a drug shop without a license	License revocation
17	Failure to maintain a suitable premises	Revocation of the certificate
18	Failure to report loss of a class A or B drug	One million shillings or 5 years or both
24	Failure to maintain classified drug book	Two million shillings or five years or both
30	Sale of impure, adulterated or unwholesome drugs	Five million shillings or ten years or both
37	Wholesale without a license	Revocation of license
38	Manufacture without supervision of a pharmacist	
	Manufacture product not on national formulary or without approval of the authority	
42	Storage – failure to comply with Seventh Schedule	
42 (3)	Willful removal or alteration of label on any container	
45/46	Import or export without a license	
53	Failure to comply with the requirements of an inspector	
	Obstruction of an inspection	
Reg. # 27 licensing	Sale from a delivery vehicle prohibited by licensed persons (but not by unlicensed persons)	Suspension or revocation
Reg. # 9 PMV	Withhold safety information	
	Where no specific penalty is noted with the offense	Fine <=/= one million shillings Loss of license up to 5 years Items impounded, forfeited, destroyed or disposes Imprisonment up to one year To any two of the above For subsequent offenses, fines up to two million shillings or five years

Annex 4: Civil Society Organizations Responding to FS Medicines in Uganda

Uganda has a relatively vibrant civil society sector. Several NGOs focus on health, and have addressed issues related to FS medicines. The Medicines Transparency Alliance (MeTA) project in Uganda included many civil society organizations, and is also noted below. The civil society response to the issue of FS medicines is complex. It was reported that in some districts local populations may wish to protect unlicensed vendors from inspectors by informing the vendors of upcoming inspections. This occurs because the local population is afraid that the unlicensed vendors will be closed and drugs will be less accessible. They do not adequately understand the dangers of FS medicines.

Center for Health, Human Rights and Development (CEHURD)

<http://www.cehurd.org/>

The Executive Director is a Board member of the National Drug Authority. NDA Board Members are appointed by the Minister of Health. CEHURD is a member of the Global Forum on Law, Justice and Development.

The CEHURD website notes that:

CEHURD is an indigenous, non-profit, research and advocacy organization which is pioneering the enforcement of human rights and the justiciability of the right to health in Eastern Africa. CEHURD was founded in 2007. It was formed to contribute towards ensuring that laws and policies are used as principal tools for the promotion and protection of health and human rights of populations in Uganda and in the East African region. CEHURD realizes this through a set of programs: (1) Human Rights Advocacy; (2) Community Empowerment; and (3) Research and Documentation.

CEHURD focuses its efforts on critical issues of human rights and health systems in East Africa such as sexual and reproductive health rights, trade and health, and medical ethics...

CEHURD has a World Bank contract to draft the bill to create the first East Africa regional commission on drugs. This involves several components: regional law, regional policy, and law establishing the agency itself. CEHURD is working with UNDP to form civil society groups on health, with a focus on NCDs, law and rights. The funding has ended but the structure remains. CEHURD also has links with Georgetown University Law School.

Community Health and Information Network (CHAIN)

CHAIN has received funds from Pfizer to awareness among patient communities about falsified medicines. This helps patients to be aware of the risks of such medicines, and to understand why it is important to purchase medicines from licensed sources. It also helps patients to understand and appreciate the dangers of unregulated sources. Patients become more vigilant with medicines and are better able to report concerns about unregulated medicines to health professionals.

At national, regional and international level CHAIN advocates for more meaningful involvement of patients and patient groups in policy development and health systems. CHAIN also engages with other key stakeholders including MoH, WHO, NDA, industry, patient groups, village health teams (VHTs) and healthcare professionals. The latter have a valuable role in detecting and reporting falsified and substandard medicines, and can also empower patients through provision of accurate information.

CHAIN has held public hearings and had workshops with the NDA to raise awareness. It has developed groups of 'community self-medicine advocates'. They are trained to raise awareness in the community about where to get medication from a registered pharmacy. They are informed that they need to go to a health center when they are sick. They need to check the expiry date on their medications, and they are trained where to get medicines from. These advocates are drawn from the villages - local leaders and village health teams. They are well known to the communities. CHAIN also collaborates with CEHURD on issues related to FS medicines.

Coalition for Health Promotion and Social Development (HEPS)

<http://www.heps.or.ug/>

The HEPS website notes that:

HEPS-Uganda is a Health Consumers' Organisation advocating for health rights and responsibilities. The organisation is a coalition of health consumers, health advocates, health practitioners, Civil Society Organisations and Community Based Organisations. HEPS-Uganda was established as a not-for profit-organisation in 1999 out of concern for the lack of attention for health consumers in the country. HEPS stated its founding mission and guiding principles in the first strategic planning meeting in 2000. An office with a functional secretariat was opened in the same year. Initially, HEPS focused solely on Health Policy Advocacy. Subsequently, after conducting several advocacy activities on its own, the organisation started the Ugandan Coalition for Access to Essential Medicines in 2002. Members of the coalition include mainly national and international health CSOs and NGOs. The purpose of the coalition is to advocate for better healthcare through combined efforts. To this end, HEPS and the coalition started a constructive dialogue with the government of Uganda, (the Ministry of Health). Besides these Health Policy Advocacy activities, HEPS started a Community Empowerment programme in 2001. Outreach has been focusing on education with regard to health rights and responsibilities in rural communities in Uganda. Educating communities about health rights and responsibilities is aimed at ensuring that people make informed choices about health.

HEPS is involved in health rights advocacy, including access to medicines. They have two major programs: 1) the Health Policy Advocacy Program and 2) System Strengthening Program. HEPS analyses health related laws and bills to see the impact on access to medicines and how they are implemented in practice. HEPS has a longstanding collaboration with the Ministry of Health and with WHO. This led to involvement in the META Initiative, which comprises approximately 40 civil society organizations (CSOs).

HEPS also has a community empowerment program, educating the community on health rights and responsibilities. HEPS also informs communities on where to access medicines in 18 districts. They also have a project with accredited pharmacies, in which the community is empowered to actively monitor drug availability and quality.

In 2014, HEPS identified and surveyed 12 partners who play a role in monitoring of essential medicines:⁵⁷

1. Infectious Disease Institute (IDI)
2. Baylor College of Medicine Children's Foundation – Uganda
3. Strengthening TB and AIDS Response – Eastern Region (Star-E)
4. Strengthening TB and AIDS Response - East Central Region (Star-EC)
5. Uganda Protestant Medical Bureau (UPMB)
6. The Coalition for Health Promotion and Social Development (HEPS)
7. Strengthening Uganda's Systems for Treating AIDS Nationally (SUSTAIN)
8. Northern Uganda – Health Integration To Enhance Services (NU-HITES)
9. Northern Uganda Health Project (NU-HEALTH)
10. Strengthening TB and AIDS Response - South Western Region (STAR-SW)
11. Makerere University-John Hopkins University (MUHJU)
12. Securing Ugandans Right to Essential Medicines (SURE)

⁵⁷A review to assess the monitoring of the national pharmaceutical sector strategic plan NPSSP-II' available at http://www.heps.or.ug/system/files/attachments/report_on_the_review_of_npsspii_to_strengthen_monitoring_of_essential_medicines_final-01.12.2015.pdf

Medicines Transparency Alliance (MeTA)

<http://www.medicinestransparency.org/meta-countries/uganda/>

MeTA is a global program funded by DFID. The following information is drawn from the MeTA website.

MeTA 'brings together all stakeholders in the medicines market to improve access, availability and affordability of medicines for the one-third of the world's population to whom access is currently denied.'

MeTA Uganda was launched as a pilot in March 2009, and was the first multi-stakeholder initiative aiming to improve access to medicines in the country. The initiative was spearheaded by the Ministry of Health, and for the first time brought together the government, the private sector, faith based institutions and civil society together to discuss the need for more information and greater transparency in the Ugandan medicines market. The pilot phase ended in 2010.

Phase 2 (2012-2015) focused on access, availability, cost, quality and rational use by prescribers and users. It actively engaged CSOs – the Council included HEPS; the Uganda National Health Users' Organisation (UNHCO); the Uganda Protestant Medical Bureau; and the Uganda Catholic Medical Bureau. It also included participation from the Pharmaceutical Society of Uganda (PSU).

Annex 5: Key Informants and Contacts

Name	Position / Institution	Contact Details	Email
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Annex 6: Meeting Schedule Kampala, June 2015

Date & Time	Institution / Location	Contact	Team attending
Monday 1 June 9.00	National Drug Authority (NDA)	Mr. Huldah Nassali – Ag. Head, Drug Information Department Mr. Andrew Rutebuka–Ag. Head, IT Mr. Peter Ssali – Head, Quality Management Mr. Michael Mutyaba – Ag. Head, Drug Authorization Registry Mr. Solomon Onen – Regional Inspector of Drugs Ms. Diana Kabuzire – Ag. Head, Legal Services Mr. Fredrick Ssekyana – Ministry Public Relations Mr. Denis Mwesigwa - Senior Inspector of Drugs Mr. Agaba Edson Friday - Acting Head of NDA	Project Team: Dr. Henry Onoria, Mr. David Patterson (IDLO) Ms. Michele Forzley (O'Neill Inst.) Ms. Vittoria Luda (UNICRI) Dr. Wolfgang Koehling (WB) Ms. Galindo Aliyo (Legal Intern)
Monday 1 June 14.30	National Drug Authority (NDA)	Mr. Peter Ssali - Head, Quality Management Mr. Onen Solomon - Regional Inspector of Drugs Mr. Fredrick Ssekyana -Head, Public Relations	Michele Forzley Wolfgang Koehling Vittoria Luda David Patterson
Tuesday 2 June 9.00	National Drug Authority (NDA)	Ms. Grace Munyirwa - Vine Pharmaceuticals Mr. Opio (Sam) Samuel - Pharmaceutical Society of Uganda Mr. Denis Kibera - Coordinator, HEPS – Uganda / Medicines Transparency Alliance Mr. Peter Kalyango -Laborex Uganda Limited, pharmaceutical importer and distributor Mr. Anantharaman N - CEO, Abacus Pharma, also representing APDL the local manufacturing unit (importer, distributor, manufacturer) Mr. Denis Mwesigwa – Senior Inspector of Drugs	Project Team
Tuesday 2 June 11.00	National Drug Authority (NDA)	Dr. Huldah Nassal -Pharmacovigilance	Michele Forzley
Tuesday 2 June 14:30	World Health Organization (WHO)	Mr. Joseph Mwoga–Access, Quality and Use of Medical Products	David Patterson Michele Forzley
Tuesday 2 June 14.30	National Drug Authority (NDA)	Mr. David Dongo – Supervisor, Revenue Intelligence, Customs Dpt., Uganda Revenue Authority Mr. Ntambe Haruna – Assistant Commissioner, Police with Interpol	Wolfgang Koehling Vittoria Luda Henry Onoria
Wednesday 3 June 2.00-4.30pm	World Bank		Team Meeting

Thursday 4 June 8.30	Joint Medical Store	Mr. Emmanuel Higenyi – Head Quality Assurance	Michele Forzley
Thursday 4 June 9.00	Community Health and Information Network (CHAIN)	Ms. Regina Kamoga – Executive Director	David Patterson Henry Onoria
Thursday 4 June 9:30	National Medical Services NMS - Entebbe	Mr. Anthony Dddamba – Head of Sales, NMS in charge of customers Ms. Carol Abalo – Quality Assurance Officer Mr. Alfred Natamba – Head of Procurement	Vittoria Luda Wolfgang Koehling Diana Kabuzire Onen Solomon
Thursday 4 June	Directorate of Public Prosecution - Entebbe	Ms. Annette Namatovu – Resident Senior State Attorney	Vittoria Luda Wolfgang Koehling
Thursday 4 June 12.00	National Drug Authority (NDA)	Mr. Denis Mwesigwa – Senior Inspector of Drugs	David Patterson Henry Onoria
Thursday 4 June	Ministry of Health	Mr. Maurice Seru – Pharmaceutical Coordinator for the Ministry of Health	Michele Forzley
Thursday 4 June 4:00pm	Coalition for Health Promotion and Social Development (HEPS) & Medicine Transparency Alliance (MeTA)	Mr. Denis Kibira – Deputy executive Director, HEPS Uganda and MeTA Mr. Kenneth Mwehonge – Programs Officer – Advocacy & Networking (Health Policy Advocacy)	Vittoria Luda
Friday 5 June 9.00	Center for Health, Human Rights and Development (CEHURD)	Mr. Moses Mulumba – Executive Director	David Patterson Henry Onoria Galindo Aliyo
Friday 5 June	National Drug Authority (NDA)	Ms. Diana Kabuzire – Legal Advisor, NDA	Michele Forzley
Friday 5 June 10.00	Inspectorate of Government of Uganda	Mr. David Makumbi – Director Ombudsman Affairs, Inspectorate of Government	Wolfgang Koehling Vittoria Luda
Friday 5 June 11.30	United Nations Children’s Fund (UNICEF)	Dr. Flavia MpangaKaggwa - Health Specialist	Vittoria Luda Wolfgang Koehling
Friday 5 June 2.30pm	National Drug Authority (NDA)	Mr. Agaba Edson Friday - Acting Head of NDA Mr. Denis Mwesigwa - Senior Inspector	Project Team