

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

## 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.<sup>1</sup> 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”,<sup>2</sup> 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

<sup>1</sup> 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](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>

<sup>2</sup> 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 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 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.

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