# Guide to the Development of a National Strategy for Strengthening the Legal and Regulatory Environment for the Elimination of Falsified and Substandard Medicines

*and*

# Assessment Tool to Evaluate National Actions to Address Falsified and Substandard Medicines

## Overview

The Global Forum on Law, Justice and Development's Community of Practice (CoP) on "Health Law" has developed a pilot project to address falsified and substandard (FS) medicines. The members of the Project Team, who co-lead, are the International Development Law Organization (IDLO), the United Nations Interregional Crime and Justice Research Institute (UNICRI) and the O'Neill Institute for National and Global Health Law at Georgetown University.

The project aims to reduce the negative impact of falsified and sub-standard medicines in developing countries where the tools and guides developed in the project are utilized. Beginning with a pilot project, the tool and guide will be developed and refined so as to build a wealth of knowledge on content and process for use by anyone. At the invitation of the Uganda National Drug Authority the project was piloted in Uganda, between April and October 2015 and concluded with a country specific report on Uganda and a draft national strategy for the benefit of Uganda.

To assist the Project Team and later country lead teams, the project has devised this assessment tool and guide to the development of a national strategy to reduce the negative impact of falsified and substandard medicines, including through regional cooperation. The assessment tool and strategy guide are designed to examine the current legal, regulatory and policy framework on FS medicines. It includes instructions on how to conduct an assessment, collect background information, the interview questions and a response grid, sample letters and other resources and the guide to strategy.

This project sits within the Global Forum on Law, Justice and Development and its Community of Practice on Health. A key purpose of the forum is to develop and disseminate knowledge. Therefore a key goal of the project is to finalize the tool and guide, encourage countries to use them so that country studies may be generated and experiences shared on which knowledge can be built and confirmed for use by others. Underscoring the project is the view that law is the critical enabler and cross cuts solutions that are within the national response to the public health problem of falsified and substandard medicines. Therefore the Project is focused on the law as the framework to understand weaknesses, strengths and opportunities for national response.

IDLO

unicri
United Nations
Interregional Crime and Justice
Research Institute

O'NEILL INSTITUTE
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GEORGETOWN LAW

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On a more practical level this tool is to assist national project teams, starting with the Project Team, to carry out assessments of the legal, policy, regulatory, law enforcement environment with regard to falsified and substandard medicines, so that solutions and interventions can be identified and implemented as part of a national strategy. The starting point in developing a national strategy is of course a thorough assessment, however, experience has shown that briefing the Project Team with a look ahead at national strategy is an aid to assessment. Thus this tool begins with that look ahead at the national strategy.

## The Guide to the Development of a National Strategy (version 1)[1]

The starting point in developing a national strategy is a thorough assessment of the current situation involving all the concerned stakeholders. This guide therefore has two parts, first the introduction that follows and the guide and the second is an assessment tool.

The deadly implications of falsified and substandard (FS) medicines are well understood to be a central challenge to the integrity of public health systems around the globe, as well as a direct threat to our individual health and welfare. What is often less understood is that the profits from this ominous crime are increasingly being used by a wide range of organized criminal groups to fund their operations around the world. As such, FS medicines might also pose a direct threat to national and international security.

The lack of strict monitoring and regulatory mechanisms allows for easy access to legitimate channels of distribution, making FS medicines an appealing source of illicit revenue. Usually counter-trafficking initiatives primarily target narcotics, therefore FS medicines might encounter fewer obstacles to infiltrating the pharmaceutical supply chain. Since the legal implications are routinely much lower in comparison to, for instance, illicit drug trafficking—even though profits and consequences can be equally high—FS medicines are becoming the chosen illegal imports/exports for both international and national criminal elements.

Due to the complex and global nature of FS medicines threat, effective responses will require a wider array of inter-agency involvement from within government and enhanced cooperation between governments, as well as improved partnerships with legitimate private pharmaceutical and supply chain industry actors.

In general terms, the construction of a sound national strategy against FS medicines requires consensus-building through a national consultation process involving all relevant stakeholders.

While developing a national strategy, it is important to consider the need for involvement of many different key stakeholders and their commitment from the beginning of the program (national and local authorities, public and private institutions, academia, civil servants, nongovernmental and civil society organizations, consumers and others). In particular, the national strategy will have to be discussed and agreed with those stakeholders that will be called upon to apply it, as law enforcement, regulatory authorities, private sector representatives, etc. A broad and heterogeneous participation in the decision-making process will favor the elaboration of appropriate legislation and will more accurately meet the objectives set by relevant international treaties. Finally, the process involves consideration of the manner in which the laws and policies will be implemented and enforced and then doing just that.

An important aspect is to raise awareness not only on FS medicines and their consequences, but the key element for the design and implementation of a good national strategy also needs to increase public awareness about ethical and transparent leadership and good governance. Without a strong public engagement component, there may well be resistance to legal and regulatory measures to reduce access to 'pharmaceutical products' – whether falsified and substandard, or genuine. The rational use of medicines must be a component of the strategy, both in addressing antimicrobial resistance and reducing other harms from the inappropriate use of medicines.

Challenges in developing and implementing a national strategy may include like political instability and changes in government, resistance to change of the different stakeholders, lack of adequate monitoring and evaluation tools, and lack of integration of the strategy within existing efforts in the same area both at national and at regional level.

[1] The Guide will be further revised in phase II of the project.

The national strategy should be as much as possible pragmatic and have realistic goals that are attainable with the available human and financial resources.

## Civil Society

- Identification of relevant civil society organizations, which may include, but are not limited to, patients and consumer groups, advocacy organizations, and independent professional associations of medical practitioners and pharmacists.
- The contribution of faith-based organizations and traditional leaders should also be considered.
- Identification of how civil society organizations are engaged in the national response – including through representative participation in national structures.
- Civil society engagement should be supported to extend to include regional and international collaboration regarding FS medicines.

## Medicines Regulation

- A national strategy to eliminate falsified and substandard medicines begins with a comprehensive legal frameworks that supports all the activities of a medicines regulator.
- Within the legal framework specific legal measures should include that enable the steps to:
    - Detect: includes market surveillance and post marketing surveillance, and reporting, comprehensive definition of falsified and substandard medicines that is uniform across the legal system, powers to inspect, investigate, sample, test, retain samples of batches, packaging, labeling, document and verify the chain of custody,
    - Prevent: license all operators in the pharmaceutical supply chain and condition licensing on standards and requirements,
    - Contain: by authorizing the seizure of product, equipment, materials, packaging, labeling and related equipment, the closure or suspension of facilities or operators, arrest, destroy or dispose of FS medicines, remove from the market, and alert members of supply chain. It also means the drug authority can cooperate with the police, prosecutor for potential crimes and collect evidence necessary to prosecute a criminal case or civil administrative proceeding and it will be able to communicate with the public and recall, inform public and health care system, inform global WHO and regional EAC system and neighbors, and share information and data.
- The medicines agency is adequately staffed and has sufficient budget.

## Criminal Justice

A sound strategy in the criminal justice area should be based on a clear understanding of the following elements:[2]

- Whether there is a comprehensive and integrated legal framework prohibiting illicit production and trade of FS medicines in national legislation and that there are appropriate sanctions (criminal or non-criminal);
- Whether law enforcement agencies (LEAs) are equipped with adequate tools to ensure successful prosecutions;

[2]Reference is made to Interpol "Countering Illicit Trade in Goods: A Guide for Policy-Makers", Legal Handbook Series, June 2014. Available at: http://www.interpol.int/Crime-areas/Trafficking-in-illicit-goods-and-counterfeiting/Legal-assistance/Legal-publications (Last accessed 13 September 2015).
The list of questions do not intend to be exhaustive and it can be adapted to different geographical and sector related contexts.

- Whether the necessary procedures are in place to enable the confiscation of FS products, manufacturing equipment, packaging, labeling, other instrumentalities and proceeds of sale FS medicines related offences.

## Law Enforcement Sector

- Whether there is substantial knowledge within the law enforcement authorities on FS medicines production and trade, and on convergence of threats;

- Whether information sharing initiatives and platforms are in place and they can be considered adequate.

## Private Sector

- Whether public private partnerships (PPP) initiatives exists and which activities are carried out within these initiatives (e.g. in the awareness raising and prevention fields-roles of the stakeholders on the development of a transparent and verifiable chain of custody from point of production to point of sale);

- Whether there are multidisciplinary and cross-sector capacity building initiatives.

## International and Regional Cooperation

- What the international legal framework requires and how it enables States to cooperate with one another more effectively;

- What laws and institutions are already in place at the national level reflecting the requirements of the international legal framework.

**FURTHER INFORMATION**

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# Assessment Tool to Evaluate National Actions to Address Falsified and Substandard (FS) Medicines
## Version 1 (October 2015)[3]

Use this tool to evaluate national actions and laws related to address FS medicines. The process of collecting information in order to design and implement a national strategy is not a onetime event; rather it is iterative. As each element of a strategy is designed, some of the questions and prompts will have more relevance.

| **This column is a set of prompts you can convert to a question to answer in the next column where you can record your findings. If not already a question, treat the content as a prompt to a question.**<br><br>**Example - Prompt: *Participation in global or regional initiatives*. The question is "Is the government participating in any regional or international forums on the matter of FS medicines? If so what forums?** | **Responses are placed in this column.** | **This column is space for your notes on next steps which will inform the national strategy, or gaps and other areas of further investigation or actions in this column.** |
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| **International** | | |
| Participation in global initiatives at international organizations | | |
| Int'l Classification of Disease Revision | | |
| WHO Member State Mechanism | | |
| Data and information sharing, establish common data sets | | |
| INTERPOL, World Customs Organization | | |
| **Regional** | | |
| Participation in regional activities | | |
| Participation in bi-lateral activities | | |

[3] This tool will be further refined in phase II of the project.

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| **International Best practices and standards** | | |
| Accreditation | | |
| **LEGISLATIVE** | **CURRENT LEGISLATIVE STATUS** | **Next Steps** |
| International Standards Organization | | |
| ***Conduct a comprehensive assessment of existing laws and policies and how these are implemented and enforced*** | | |
| The Constitution - what provisions establish the regulatory system and powers? | | |
| Is there power to issue regulations and what is the source? Does the law provide the executive branch of the government with the power to formulate the detailed requirements of medicine regulations for the implementation of the legislation, etc. | | |
| Identify all legislative subjects and operational functions at all governmental levels relevant to the matter of FS medicines | | |
| Identify all existing domestic legislation, regulations and other instruments relevant to each of the subject areas and functions. | | |
| Specify any legislation, regulations and other instruments which may potentially interfere or conflict with full or efficient strategies to manage the problem of FS medicines. | | |
| Specify any necessary enabling or authorizing legislation which may be relevant for the government to exercise rights or fulfil obligations: note the rights and obligations particularly relevant to your State's individual context, profile; and economic and geographical characteristics, including public health infrastructure and priorities; trade, | | |

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| transport and travel profile; and economic and geographical characteristics. | | |
| What products are covered if FS? Agriculture, veterinarian, devices, cosmetics, foods, consumer products, other? | | |
| Are your laws harmonized with international law and any regional groupings to which your country is a member? | | |
| Is there an adequate budget and human resources to perform all basic functions related to regulatory control? | | |
| Define the type of products to be regulated by the national medicines authority. | | |
| ***Is there legislation on these specific subjects?*** | | |
| ***Law enforcement provisions*** | | |
| Definitions: what are the terms used to describe FS medicines? Are the use of the term or terms selected consistent in the laws? Is the definition functional in civil and criminal law and is it as uniform or harmonized as possible? | | |
| Is the type of medical product the criminal law mentions the same as that which is regulated? | | |
| Is any activity related to a FS product that can cause harm the subject of a crime? Consider warehouse, transport, manufacturing, packaging, labelling, selling, importing, exporting, actual or potential harm or if on a commercial scale, other? | | |
| Is there a coordinator/coordination agency or focal point? | | |
| Who is authorized to inspect? | | |

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| Are the powers of the regulator and the inspectors across the whole of government; to inspect, seize, shut down, arrest, citations, sample, require remediation, more? | | |
| Are there prevention measures, victim and witness protections, and universal jurisdiction? | | |
| Does Customs have enhanced powers with ex officio authority and the ability to impose administrative penalties such as seizure until title/authenticity/import authority is established? | | |
| Are there other measures such as supplier verification, certificates of compliance with standards for imports, mandatory and optional recall powers, ability to bar imports for history of non-compliance with GMP? | | |
| ***Sanctions*** | | |
| Sanctions - are they substantial enough to deter wrong behavior? In the case of potential harm to health or just actual? | | |
| Is there penalty relief for voluntary disclosure | | |
| Is there a penalty for exporters of FS products? | | |
| ***Additional Regulatory provisions*** | | |
| Is the supply chain regulated with track and trace and a strong pharmacovigilance? Are inspectors following a code of good practice for inspections? Is good manufacturing practices enforced? Is there cooperation between law enforcement and regulatory agencies? | | |
| ***Data Collection, Monitoring and Evaluation - all agencies*** | | |
| Mandate data collection and evaluation. | | |

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| Do all branches of government have national budget for M&E? Required to monitor and evaluate and collect relevant data? | | |
| Office for data collection and/or research to evaluate data | | |
| **REGULATORY ACTIVITIES/FUNCTIONS** | **CURRENT LEGISLATIVE STATUS** | **Next Steps** |
| ***Adopt a National Policy and Strategy*** | | |
| Is there a national strategy and policy and plan of action to reduce the negative impact of FS medicines to protect public health? Does it include: | | |
| Inter- ministerial cooperation and collaboration | | |
| A specialized agency or department or coordinator? | | |
| To close regulatory loopholes - compare your system to that of others | | |
| That all model desired behavior - e.g. government and contractors to use genuine products | | |
| Category for goods that can harm humans, animals and plants? | | |
| Is there an official organizational chart (Organigram) | | |
| Does the organizational chart show the various divisions/departments within the authority that are responsible for the different activities and provide names of the officials supervising the divisions/departments and the contact address for each? | | |
| Are all the main regulatory functions supported by adequate legislation, authorization and relevant regulations: Registration of medicines, Licensing of pharmaceutical business, Inspection of establishments, post marketing vigilance, Control of medicine promotion, | | |

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| Control of clinical trials, Selection of essential medicines, Procurement of medicine, Distribution of medicines | | |
| Are the main functions being implemented and enforced? What is not being implemented and enforced and by whom? | | |
| Is the supply chain regulated with track and trace and a strong pharmacovigilance? | | |
| Are inspectors following a code of good practice for inspections? | | |
| Is good manufacturing practices enforced? | | |
| Is there cooperation between law enforcement and regulatory agencies? | | |
| ***Enhancements to regulatory powers*** | | |
| Sufficient police powers to regulatory staff and inspectors | | |
| Define the administrative measures and legal sanctions to be applied when provisions of medicine legislation are violated. | | |
| Is there testing according to published standards? Is it mandatory? | | |
| Does local law enforcement have the power to enforce national rules? | | |
| Tools: are there appropriate forms, instructions, standards, guidelines and procedures to be used as tools for the application of all regulatory processes? | | |
| ***Manage the Supply Chain*** | | |
| Inspection of labs that certify standards compliance | | |

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| Are foreign plants inspected as import condition and for marketing authorization | | |
| Is consent to jurisdiction required as import condition | | |
| Are track and trace/supplier verification and supply chain integrity principles used? | | |
| Are known violators subject to follow up audits? | | |
| Are certificates of compliance with standards required for procurements? | | |
| Set the terms and conditions under which licenses to import, manufacture, export, distribute, sell, supply and promote medicines will be issued, suspended, revoked or cancelled. | | |
| ***Behaviour Change Communications*** | | |
| Messages - who is the messenger, what is the message? | | |
| Encourage consumer cooperation, reporting mechanisms | | |
| Guides for consumers | | |
| Media campaigns - print, posters, TV, films, web | | |
| Trade and professional associations | | |
| ***Data-driven regulation and governance*** | | |
| Is data collection, and monitoring and evaluation mandated by all agencies of government? | | |
| Harmonize data fields, categories | | |
| Create data fields& category for goods that when counterfeited harm | | |
| Code and count for injuries | | |

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| Mandate that all interventions, programs, trainings are evaluated | | |
| Employ data dependent strategies | | |
| Risk Assessment mechanisms, use of trend analysis | | |
| Use data to target strategies, reverse management data | | |
| ***Destruction - Safe Methods*** | | |
| Establish national protocols, reference int'l standards | | |
| ***Use of Technology*** | | |
| Coding and cell phones to check bar codes or other indicators of authenticity | | |
| ***The internet*** | | |
| Focus foreign websites that sell FS medicines | | |
| Facilitate cooperation to reduce sale of FS medicines over internet | | |
| Regulate internet vendors of products that can harm and internet pharmacies | | |
| ***Quality management and staff development*** | | |
| Does the authority have a quality management manual that defines the vision, mission and objectives of the authority and the responsibilities, policies, procedures, processes, standards and resources required to deliver quality medicine regulatory services? | | |
| Is there a staff development program and staff recruitment guideline? | | |
| ***Qualified and trained staff*** | | |

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| Does the regulator have sufficient staff with competencies in the policy, legal, scientific and technical areas and management? | | |
| ***Appeals and complaints system*** | | |
| Is there administrative and legal appeals system to ensure that there is rule of law and fairness in the regulatory decision-making process? | | |
| ***Change Consumer Behavior with Behavior Change Communication (BCC)*** | | |
| Use BCC know how to influence consumer behavior | | |
| Let law enforcement be the powerful voice it is | | |
| Demonstrate seriousness of national plan - publicly profile successes | | |
| ***Audit, monitoring and evaluation system*** | | |
| Is there an internal monitoring and evaluation system and also an external audit or peer review system to provide independent opinion on how the system is operating and its weaknesses and strengths? | | |
| **LAW ENFORCEMENT** | | |
| ***Stick to the Basics of Law Enforcement*** | | |
| Enforce the law and impose sanctions | | |
| Use any and all means | | |
| ***Develop a national law enforcement strategy and plan of action*** | | |
| Assess laws and law enforcement weaknesses | | |
| Add ex officio authority at least for public health concerns | | |

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| Cooperate with regional and int'l law enforcement/customs | | |
| Implement laws with a view to protecting the public's health | | |
| Capacity build as needed - adapt existing int'l trainings/handbooks | | |
| ***Enhance Law Enforcement*** | | |
| *Target enforcement* | | |
| Establish specialized police units and court | | |
| Does your law target medical products with potential to harm health if substandard, illegal or falsified? Or if so can these cause harm to humans, plants or animals? | | |
| ***Sanctions*** | | |
| Impose full measure of all sanctions | | |
| Make counterfeiting a serious gravity crime | | |
| Seek the full measure of all sanctions | | |
| If harm to individual or population health | | |
| If conscious or reckless risk of serious bodily harm | | |
| Administrative detention | | |
| ***Use better data as a driver of decision making*** | | |
| *Improve data* | | |
| Harmonize data fields, categories for comparison with others | | |
| Combine trademark registries | | |

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| Mine prosecution files for useful data | | |
| *Use data and trend analysis to target strategies* | | |
| Track and report enforcement activities | | |
| Share exclusion order enforcement data | | |
| Use risk assessments as PREDICT or ID intrinsically dangerous goods | | |
| *Assess, monitor and evaluate* | | |
| All Interventions, programs, trainings, initiatives | | |
| **Situation in Uganda and strategic perspective** | | |
| How National Authorities perceive the phenomenon | | |
| Is Uganda mainly an Origin/Transit/Destination country? | | |
| FS medicines Trafficking flows regarding neighboring countries | | |
| Existing cooperation with neighboring countries | | |
| FS medicines main means of transportation/entry methods into Uganda | | |
| Have investigation on organized crime involvement in FS medicines being conducted? If so, with which result? Have commonly used operation modalities by organized crime been identified? | | |
| Which are the main investigative strategies implemented by prosecutors/police forces/relevant competent authorities | | |
| **Specific information responses and on FS medicines in Uganda (addendum to previous parts)** | | |

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| Are there methods in place to register cases and, in particular, to communicate registered cases to the WHO operative database? | | |
| Is the falsification activity dedicated more to the packaging or the medicine itself or both? | | |
| Did national authorities register cases of falsified medicines using original packaging? | | |
| Did national authorities register cases in which expired products (also coming from hospitals) were reinserted into the supply chain after simple modification of the expiration date? | | |
| Are there cases of FS medicines presence into the legitimate supply chain? If so, which are the insertion modalities? If not, is a parallel and illicit market being created? | | |
| Regarding consumers, are they usually deceived or are there also aware buyers that purchase FS medicines without knowing the risks? | | |
| Are online pharmacies legal in Uganda? Have problems been registered with online pharmacies? Did they register cases of FS medicines sold by online pharmacies? Which are the main investigative methods in this regard? | | |
| **Prevention and detection** | | |
| Methods and difficulties encountered in detecting falsified medicines? | | |
| Is there a cooperation with legitimate manufacturers in place for this purpose? If so, how does it work in practice and how could this be improved? | | |

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| Did the national authorities register cases where anti-counterfeiting technologies (if in place for some products) were counterfeited? | | |
| More information on risk assessment modalities implemented by the Customs | | |
| Is inter-agency cooperation working well in the country? If so, could they provide some example? | | |
| Are there examples of cooperation with the private sector? | | |
| Would they be interested in establishing an informal cooperation working group on FS medicines bringing together various national authorities in charge for fighting the phenomenon (and representatives of producers associations?) | | |
| **Civil Society Engagement** | | |
| Are there formal mechanisms for civil society engagement to address FS medicines? If so, please specify | | |
| Which health NGOs are addressing the issue? | | |
| Which human rights or legal rights NGOs are addressing the issue? | | |
| Are there other NGOs which are addressing the issue? | | |
| Has there been any engagement with professional associations of doctors, nurses, pharmacists or other health professionals? | | |
| Have there been relevant media reports in the last five years? If so, specify. | | |
| Are there formal structures for government civil society dialogue on health issues which might address FS medicines? | | |

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| ***Communications between ministry and citizens*** | | |
| Is there a two-way communication system for routine communication between the ministry and citizens? | | |
| Are decisions made by management, minutes of meetings, etc. easily accessible to all stakeholders, including staff? | | |