Community of Practice on Health Law Concept Note

Description of Activities (based on the project proposal):

1) Identification of country for the pilot project, Communication and agreement with the World Bank Country Director and government counterpart/partner;

2) Agreement with GFLJD partners on respective tasks and deliverables, peer-reviewing mechanism and funding;

3) Procurement and launch of the project;
   a. **Assessment** of the existing legal, regulatory and policy framework on FS for the target country. This includes: a.1) Desk review of what has been done to date in country to address the problem of FS medicines; a.2) Draft the assessment tool to include interview questions and response grid to assess national challenges and opportunities. The grid will be improved throughout the assessment phase and based on existing research and as a deliverable for use in other countries.
   b. Inception mission to the selected country for **mapping** of the legal and institutional framework as well as judicial, prosecutorial, law enforcement and civil society’s competences on FS medicines and production of **gap analysis and recommendations**.
   c. **Development of a national FS strategy and engagement** of national champions: c.1) Draft framework tool for the development of a national strategy including for regional cooperation and assist the country in the process of drafting their national strategy for on FS medicines; c.2) Validation of the strategy through consultations; c.3) Identify and engage national champions to implement the strategy.
   d. **Design and implementation of an awareness campaign** including appropriate risk communication practices (possible small grants to NGOs/ government to carry out campaign).
   e. **Strengthened capacity** of the national authority and other key stakeholders (judges, prosecutors, police, defense lawyers, custom officials, healthcare workers, pharmacists, CSOs, NGOs, private sector) to prevent, identify and eliminate FS medicines:
   f. Development of materials on FS medicines for key stakeholders: Develop curriculum for: Judges, prosecutors, police, custom officers, government legal advisors and other relevant national authorities; Regulatory inspectors (with an emphasis on good law enforcement techniques and inspection practices in the case of suspicious goods); Lawyers and legal aid organizations.
   g. Develop capacity building materials for: Healthcare workers, pharmacists; Civil society and non-governmental organizations; Deliver capacity building workshops for key stakeholders.
   h. Increased cooperation at regional level to eliminate FS medicines: Co-host regional meetings; Support regional networking.
   i. Produce publications, including best practices and lessons learned, on FS medicines: Training curricula; Research and document national and regional best practices.

The following deliverables will be completed: points: 1), 2), 3a), 3b) and 3c1).
The pilot
This pilot presents the preliminary phase of a larger initiative to eliminate falsified and substandard (FS) medicines in any country, starting with Uganda, and will include national, cross-border and regional approaches. The project builds on the work of the World Health Organization and World Bank, as well as the United Nations Convention against Transnational Organized Crime, and the MEDICRIME Convention of the Council of Europe.

The initiative is jointly conceived and presented by three organizations: 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). All three organizations are members of the Global Forum on Law, Justice and Development. More importantly, IDLO’s expertise on the rule of law, the O’Neill Institute’s expertise in laws and regulations applicable to health and drug regulatory authorities and UNICRI’s work on organized crime make the team well-situated to support national and regional programming.

As requested by the World Bank, the three organizations have identified deliverables for which they will be separately contracted and responsible, however the work will be undertaken jointly and intensively coordinated. Each organization will take the lead in the work areas identified below, and will also provide input into the research undertaken by the other two organizations draft documents. At the end of this pilot, the main deliverable will be a single report that combines the work of each consulting organization. One section of the report will contain the assessment findings and draft national strategy for Uganda or other country as the case may be. A second section will contain a model assessment tool and an initial guide to developing a national strategy to eliminate falsified and substandard (FS) medicines. The model and initial guide are intended for use by other countries when added to this project as it continues with subsequent funding and ultimately to serve as stand-alone publications for use by anyone. These will be refined as additional countries are added. Each organization will lead in the area of its respective strength and technical competencies while each will have responsibility to complete a defined deliverable, all leading to a holistic country specific report and set of tools for wider use.

When combined, these outputs will provide the background and justification for a multi-year project to address FS medicines in Uganda. The approach modelled in Uganda can be adapted to other countries in the region, and in other regions.

The project will take approximately eight months and involves desk research and an assessment mission. A second mission may be undertaken if resources permit to hold discussions with national authorities on the findings of the research and next steps. The proposed budget is US $100,000, to be divided proportionately between the three organizations with part of the funding for travel related expenses.
ANNEX B

Context and Problem Statement

Falsified and substandard (FS) medicines[1] 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. Both branded and generic products are subject to falsification. While the prevalence in developed markets is likely below 1%, it is estimated that up to 15% of all drugs sold in developing countries constitute a threat to patients. This percentage can be higher in some regions. 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.[2]

Falsified medicines are manufactured and sold by criminal individuals and/or organizations, exploiting weak national legislation and enforcement. Criminals often avoid prosecution by bribing corrupt officials. Even if convicted, insignificant penalties are seen as a cost of doing business, and do not destroy the large profit potential of the trade in falsified medicines. The trade is a profitable and comparably low-risk business in many parts of the world. Criminal laws may offer few options for punishing those who produce, distribute and sell FS medicines. 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.

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 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.[3] 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 only as a trademark violation.

[1] 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, 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.”


Most importantly, action to eliminate FS medicines should not undermine access to legitimate and lower-cost generic drugs. As a complex criminal activity involving several economic, social, legal and criminological sectors, FS medicines require multi-pronged, multi-sectoral solutions. This project provides an opportunity to develop programmatic activities based on the extensive academic work to date. Related government strategies include health, justice, organized crime and in particular “medicrime”; crimes associated to falsified & fraudulent medical products and similar crimes whether or not criminal organizations can be identified.

The project will build on prior related work and good practices. For example, in Africa, the work of the African Union and NEPAD, and the initiative of the East African Community (EAC), supported by the World Bank Trust Fund.

ANNEX C
CoP Members to serve as Implementing Organizations and Deliverables

1. **IDLO:** The International Development Law Organization will provide overall project coordination and liaison with governmental and civil society organizations in Uganda, including communications support. IDLO may identify and recruit a local consultant to assist with research and the country missions. IDLO will lead in the areas of its technical expertise of civil society engagement, integrity and anti-corruption, and results-based program design, including process and outcome indicators, and a risk analysis and mitigation framework. IDLO will participate in the assessment mission and will lead on contacts with civil society organizations.

**Deliverable:**
Report sections containing the description of the country context, key stakeholder analysis, a theory of change, and a results monitoring framework with sample indicators for process and outcome results.

2. **O’Neill Institute:** The O’Neill Institute on National and Global Health Law will undertake a literature review, good practices review, and lead the drafting of the assessment tool and initial outline of a guide to a national strategy to address national challenges and opportunities. O’Neill Institute will participate in the assessment mission and will lead on contacts within the national health and drug authority.

**Deliverable**
Report sections containing legal literature review, good practices review, the mapping of the Ugandan legal and institutional framework, national challenges and Uganda specific opportunities for responding to FS medicines.

3. **UNICRI:** The United Nations Interregional Crime and Justice Research Institute will advise on the criminal and transnational aspects of the project, and will identify and liaise with other international

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partners such as UNODC, WHO, UNDP and the Council of Europe. UNICRI will participate in the assessment mission and lead on contacts with police and other law enforcement agencies.

Deliverable
Report sections on the mapping of the criminal legal and institutional framework and national strategy to address national challenges and opportunities in the criminal justice sector, including judicial, prosecutional, and law enforcement. The report will address the regional and international criminal aspects and propose solutions at national and regional levels, including law reform, capacity building, and national and regional professional networking.

CoP Members to serve as Implementing Organizations

IDLO (International Development Law Organization)
IDLO shall be the implementing organization. IDLO is an intergovernmental organization that offers legal expertise, resources, tools and professional support to governments, multilateral partners, and civil society organizations. IDLO enhances respect for human rights; encourages economic activity by providing a legal framework for business, trade and investment; and strengthens good governance through transparency and accountability of institutions. IDLO has its headquarters in Rome, Italy, a liaison office for the United Nations in New York, and Country Offices in Afghanistan, Kenya, Kyrgyzstan, South Sudan, Somalia (based in Nairobi) and Tajikistan. Since its establishment in 1983, IDLO has worked with over 20,000 legal professionals in 175 countries. Its growing worldwide network – consisting of 47 independent alumni associations and a roster of some 2,500 experts – gives the organization a unique possibility to draw on expertise from around the world. Its core staff includes highly experienced development professionals specialized in legal and judicial reform, human rights, health, international trade, intellectual property, environmental law and sustainable development. IDLO has a proven record of successfully managing a multi-donor portfolio of large, highly complex projects and fielding long-term, winning teams to both manage and implement sophisticated activities. Examples include programming in Afghanistan, Egypt, Kenya, Kyrgyzstan, South Sudan, and Tajikistan.

IDLO and FS Medicines
IDLO proposes a holistic, regional approach to law and capacity building, which includes prevention through supply chain management and criminal punishment of producers and distributors of FS medicines. This dual-pronged approach should be based on national contexts, and developed with the engagement of regional economic and political mechanisms, such as (in Africa) the East African Community and South African Development Community. The engagement of national and regional professional organizations and associations of police, pharmacists, and customs officers, as well as civil society organizations, will be essential. IDLO can offer tailored capacity development programs for the legal and regulatory sector, including seminars, multi-country video-conferencing and web-based networking, e-learning courses, direct technical support, mentoring, professional networking and South-South collaboration.

Examples of relevant current and recent procurement, judicial sector, health, and human rights programming in Africa include:

- Strengthening the capacity of public procurement professionals from Burundi, Central African Republic, Chad, Congo, Lesotho, Mali, Swaziland, Tanzania, Togo and Uganda to implement international standards of procurement of goods, works and services.
Capacity building to strengthen and expand HIV-related legal services in Benin and Burkina Faso (part of a global program reaching 21 countries).

Strengthening the capacity of the Justice Organs Professional Training Centre (JOPTC) of Ethiopia to deliver legal and judicial pre- and in-service training.

Providing capacity building and technical assistance to judicial professionals of Benin, Burkina Faso, Chad, Congo, Kenya, Mauritania, Namibia, Senegal and Uganda.

Providing technical assistance for constitutional reform, legislative drafting and the establishment of a Law Reform Commission in South Sudan.

Supporting the Committee of Experts during the Constitutional review process in Kenya, the implementation of the new Kenyan Constitution, and the establishment of an independent Judicial Training Institute in Kenya.

Providing technical assistance to the Ethiopian Human Rights Commission to develop its capacity to monitor and protect the rights of Ethiopian citizens.

O’Neill Institute for National and Global Health Law, Georgetown University Law School
The O’Neill Institute for National and Global Health Law at Georgetown University was established in 2007 to respond to the need for innovative solutions to the most pressing health concerns. Housed at the Georgetown University Law Center in Washington D.C., the O’Neill Institute reflects the importance of public and private law in health policy analysis. The institute is comprised of a multi-disciplinary network of faculty, fellows, staff, affiliates, and alumni with a diversity experience and expertise in the fields of law and health. The O’Neill Institute also draws upon the University’s considerable intellectual resources, including the School of Nursing and Health Studies, School of Medicine, the Public Policy Institute, the Kennedy Institute of Ethics, and the School of Foreign Service.

The essential vision for the O’Neill Institute rests upon the proposition that the law has been, and will remain, a fundamental tool for solving critical health problems in our global, national, and local communities. By contributing to a more powerful and deeper understanding of the multiple ways in which law can be used to improve health, the institute hopes to encourage key decision-makers in the public, private, and civil society sectors to employ the law as a positive tool to enable individuals and populations in the U.S. and throughout the world to lead healthier lives.

The O’Neill Institute is currently organized around seven thematic areas: food and drug law; global health governance; healthcare, health and human rights; infectious diseases; non-communicable diseases; and, trade, investment, and health. Each area combines elements of research, capacity building, and scholarship and draws upon the O’Neill Institute’s intellectual strengths, and those available through the broader university.

This project would be an ideal fit with the O’Neill Institute’s existing research portfolio, in particular with, food and drug law, global health governance, and healthcare. We have a number of subject matter experts, researching the intersection of fake medicines and public health law, regulation, and policy. The faculty director of the O’Neill Institute, Professor Lawrence O. Gostin, has significant expertise in this area, most recently chairing the Institute of Medicine’s committee on falsified and substandard drugs. The IOM Committee issued their findings and recommendations in the February 2013 report, “Countering the Problem of Falsified and Substandard Drugs.” Additionally, the O’Neill Institute has extensive experience drafting model health legislation, including public health laws at the national, state, and local levels.
Professor Michele Forzley, Senior Scholar with the O’Neill Institute, has been active in the field of counterfeit goods and health since 2003 when she wrote “Counterfeit Goods and the Public’s Health and Safety,” the first global study of the health effects of counterfeit goods consumed or used by humans. She then wrote “Combating Counterfeit Drugs: A Concept Paper for an International Framework Convention and Related Strategies” which was approved by the 11th International Conference of Drug Regulatory Authorities and later became the concept behind the work streams for the International Medical Products Anti-Counterfeiting Task Force. Subsequently she has written “Use of the Criminal Laws to Protect Public Health,” a guide to legislative drafting for crimes related to counterfeit goods and medicines, and most recently “Counterfeit Goods and the Public’s Health and Safety: A Study of Interventions,” a 10-year retrospective on what countries have done since 2000 to manage the problem of any counterfeit that could cause harm to humans, animals or plants. Professor Forzley has conducted trainings of law enforcement, judiciary, regulators and legislators worldwide on this topic.

Moreover, Professor Forzley is a consultant to the WHO, World Bank, SIAPS, Global Fund and others in the area of pharmaceutical capacity regulatory capacity building. She has worked in numerous countries around the world, most recently in Afghanistan. She is also a legal advisor to the African Union Regional Medicines Regulatory Harmonization Initiative and is advising on the model law on medicines regulation across the five countries in the initiative.

**United Nations Interregional Crime and Justice Research Institute**

UNICRI is a United Nations entity established in 1967 to support countries worldwide in preventing crime and facilitating criminal justice. UNICRI has a long tradition of research on organized crime in its different forms. UNICRI’s activities on counterfeiting started with “Counterfeiting, a global spread, a global threat,” a 2007 report which highlighted the economic and social impacts of counterfeiting, and extensively analyzed organized crime involvement in this illicit activity. With this report, UNICRI was among the first international organizations to present a complete and comprehensive picture of the seriousness of counterfeiting as an emerging threat led by criminal organizations. In 2008, UNICRI was awarded a High Commendation at the Global Anti-Counterfeiting Awards for the results obtained with this report and for UNICRI’s efforts in supporting the implementation of its proposed recommendations. Following a request from the United Nations Commission on Crime Prevention and Criminal Justice (UNCCPCJ) in 2010, UNICRI produced the 2011 edition of the report, which deepens the analysis regarding organized crime involvement in counterfeiting and presents a series of case studies. On 14 April 2011, UNICRI presented this report to the UNCCPCJ at its XX Session. In the 2012 UNCCPCJ session, UNICRI supported the negotiations led by Italy on the application of the United Nations Convention on Transnational Organized Crime (UNTOC) to counterfeiting activities, which resulted in the approval of a resolution dedicated to this important subject.

Based on recommendations of the 2007 report, UNICRI established a complete program against counterfeiting and organized crime which reflects the need to adopt a global, multidisciplinary and multifaceted approach. Two core elements were identified:

1) Examining organized crime involvement in various phases of the fake products trade, from the production to the distribution, highlighting: concrete cases and evidence of this involvement, the links that exist with other illicit trade including piracy both physical and digital, and activities performed by criminal organizations (i.e. the funding of other illicit activities and the laundering of proceeds of crime), and the functioning of transnational criminal networks;
2) Demonstrating the risks that the phenomenon creates for society at large by collecting cases showing that counterfeiting is far from being a victimless crime.

UNICRI has strong expertise in supporting developing countries to fight organized crime and to advance the respect of human rights, in particular the rights of crime victims. In this regard, UNICRI implemented several projects to fight trafficking in persons and to respond to the needs of victims of this crime. Apart from multidisciplinary training activities, these projects—implemented in countries such as Nigeria, Ukraine, Thailand and Costa Rica—supported shelters for victims and relied on strong cooperation with local NGOs, providing them with instruments to carry on the work after the end of the project activities. Awareness campaigns were also organized in cooperation with national authorities.

UNICRI also has considerable experience assisting Member States in reforming their national legislation to comply with the standards set by UN conventions. For example, UNICRI provided support to the Government of Serbia to advance the fight against organized crime and support proper implementation of the UNTOC and the United Nations Convention against Corruption.