Objectives
This knowledge sharing workshop aims to contribute to a multidisciplinary understanding of the global phenomenon of “Counterfeit Medicines” and solutions. For the purpose of this event, we use the WHO definition of Spurious/falsely-labeled/falsified/counterfeit (SFFC) as “medicines are medicines that are deliberately and fraudulently mislabeled with respect to identity and/or source”.

The workshop will be open to all interested stakeholders, including students, with no fees. The panelists will present and discuss the scale and trend of the phenomenon, its public health and economic impact and the potential solutions from legal, regulatory, technology and enforcement perspectives. The workshop is promoted by the Global Forum on Law, Justice and Development (GFJLD) and hosted at the World Bank Headquarters in Washington DC. GFJLD’s goal is to facilitate networking and cooperation between relevant stakeholders and establish a Community of Practice on this topic.

Background
There is no reliable data on the real scale of the problem of counterfeit medicines. While the prevalence in the developed markets is below 1%, it is estimated that up to 15% of all drugs sold in developing countries constitute a threat to patients. The situation is most severe in the poorest countries: Interpol estimates that 30% of medicines circulating in Africa are either counterfeit or of inferior quality. Likewise, a recent study on the quality of anti-malarial in Sub-Saharan Africa conducted by the WHO revealed a high failure rate. The study found that 44% of samples from Senegal and 30% from Madagascar could be qualified as of inferior quality.

Counterfeit Medicines represent various threats to patients; they may contain no active ingredient, an insufficient quantity, or even dangerous ingredients. Drug resistance, treatment failure and death have

1 WHO, Fact Sheet No 275 from May 5, 2012: http://www.who.int/mediacentre/factsheets/fs275/en/
2 WHO, Survey of the Quality of Selected Antimalarial Medicines Circulating in Six Countries of Sub-Saharan Africa, 2011
been associated with these products. They are manufactured and sold by criminal individuals or organizations, exploiting the relatively weak legislation and enforcement that make the trade in counterfeit medicines a profitable and comparably low risk business in many parts of the world.

Many factors facilitate the spread of Counterfeit Medicines but one of the most important, in developing countries, is the weakness of national drug regulation. According to WHO, out of the 193 WHO member states, only about 20% are known to have well-developed medicines regulation and enforcement. 50% of the member states implement regulation at various levels and 30% have no medicines regulation in place or only very limited capacity that is hardly enforced. Building effective regulatory systems for pharmaceuticals in developing countries is a major challenge, because resources and technical expertise are scarce, and many other pressing health needs are competing for priority.

In many countries, the underlying legal framework is non-existent, weak or outdated. Counterfeiting is often treated only as a trademark violation with very limited possibilities for punishing those who sell fake medicines resulting in people unnecessarily dying from treatable diseases; or law enforcement is not equipped to recognize counterfeit medicines. Corrupt officials may tip off wealthy counterfeiters for a bribe or let them out of jail after a short time.

At the international level, the issue is surrounded by confusion about the definition of counterfeit medicines. It is important to differentiate the issue of intellectual property rights (IPRs) and trademark protection from the issue of authenticity, correct representation of content and quality. From a public health perspective, the discussion of IPRs in the pharmaceutical field needs to be strictly separated in order to not create the impression that the issue of counterfeit medicines is used to undermine access to legitimate and lower-cost generic drugs, which are indispensable to ensure access to essential medicines for patients in developing countries.

This global threat requires global, regional and national solutions. Various approaches have been recently initiated at the international level, such as:

- The Medicrime Convention adopted by the Council of Europe in 2010 and opened for signature in October 2011 to all States aims to criminalize the illegal trade of counterfeit medical and veterinary products.
- The 65th World Health Assembly (May 2012) addressed a new mechanism for international collaboration among the 193 WHO Member states. This initiative follows a public health perspective, excluding trade and intellectual property considerations, regarding “substandard/spurious/falsely-labeled/falsified/counterfeit medical products”.
- At a regional level, the development of initiatives to harmonize medicines registration and regulatory activities is one approach to overcoming resource constraints. Regional harmonization initiatives such as the African Medicines Regulatory Harmonization Initiative (AMRH) with its first implementation project in the East African Community (EAC), can help participating countries to support each other, lift up their standards, avoid duplication and thereby making the best use of scarce regulatory resources.

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5 cf. WHO EB Resolution EB130.R13, 21 January 2012
6 See www.amrh.org
At national level, there have been successes in fighting back counterfeiters by using modern technology, such as screening devices for field use and authentication of medicines packaging through “scratch codes” that consumers can send via text message to a given telephone number. Initial results are promising (example Nigeria) and several Africa medicines regulators are now in the process of building up such technological capacity.

**Audience**
The workshop is addressed to an audience of development actors already active in this field, including development agencies, health specialists, economists, universities, foundations and legal/judicial professionals.
# Agenda

**OCTOBER 2**  
8:30 – 9:00  
Registration/Light Breakfast

9:00 – 9:20  
**Welcome and Setting the Stage**  
Anne-Marie Leroy, Sr. Legal Vice President and Group General Counsel, World Bank, and Cristian Baeza, Director, Health, Nutrition and Population, World Bank

9:20 – 10:15  
**Public Health and Economic Aspects**  
Chair: Andreas Seiter (World Bank)  
Panel: Patrick Lukulay (USP), Jeffrey Gren (US Department of Trade), James Fitzgerald (PAHO)  
- Working definition, prevalence and trends  
- What is drug quality and how is it ensured?  
- Health impact of counterfeit and sub-standard drugs  
- Counterfeit and substandard APIs

10:15 – 10:45  
**Speaker: Roger Bate, American Enterprise Institute, “The Global Trade in Fake Drugs”**

10:15 – 10:45  
Coffee break

11:00 – 12:30  
**Criminal Aspects: Counterfeit Pharmaceuticals as a Strategic Threat**  
Chair: Louise Shelley, Criminologist  
Panel: Xavier Raufer, Criminologist, French institute of criminology (Département de Recherche sur les Menaces Criminelles Contemporaines); Matthew Levitt, Washington institute for Middle East Policy  
- What interest for organized crime?  
- Pharmaceutical crime in the new world disorder.  
- The Counterfeit-Terrorism Threat

12:30 – 2:00  
**Luncheon Speaker:** To be announced

2:00 – 3:30  
**Legal Aspects and Solutions**  
Moderator: Michele Forzley, Co-Chair ABA SIL Life Sciences and International Health Law Committee and Prof. Global Health Law Widener School of Law  
Panel: Speaker from Council of Europe To be Confirmed, Marco Musumeci UNICRI (via VC)

The legal panels will focus on international, regional and national legal frameworks that underpin regulatory and law enforcement approaches in the fight against this global phenomenon.  
- The role of international, regional and national law in the fight against counterfeit medicines; relevant law from other sectors including, among others, criminal law,
customs, and law enforcement.

- The legal foundation for cooperation between national authorities to combat the problem and for information sharing and alerts.
- Legal mechanics to ensure the fight against counterfeit medicines does not impede access to generic and affordable medicines
- Effective mechanisms for developing countries

3:30 – 3:45  Coffee break

3:45 – 5:00  Regulatory Aspects/Solutions (global and country level)
Chair: Murray Lumpkin (US FDA) (TBC)
Panel: Andreas Seiter, World Bank (Chair), Margareth Sigonda (NEPAD) (TBC), Anthony Boni (USAID) (TBC), James Fitzgerald

- Capacity-building strategies in developing countries and south-south cooperation in the field of safety and quality of pharmaceuticals regulation (global pharmaceutical standards, regional harmonization initiatives)
- African Medicines Regulatory Harmonization Initiative (AMRH)

OCTOBER 3
8:30 – 9:00  Registration/Light Breakfast

9:00 – 11:00  Enforcement and Technical Solutions
Chair: Aline Plancon (Interpol)
Panel: Pierre Delval, Executive Director of the WAITO Foundation, Mike O’Neil, Executive Director of NASPO, Pierre Viaud (SICPA), Tom Woods (Woods International)

- Effective enforcement in a national and international context
- ISO Standards development and TC 247
- Innovative technologies to identify fake and substandard drugs in resource-limited settings:
  - Supply chain related technologies
  - Technologies that enable consumer identification

11:00 – 11:15  Coffee break

11:15 – 12:30  Discussion and closing remarks
Panel: Michele Forzley (American Bar Association, Widener Law Institute), Susanne Keitel (Council of Europe), Marco Musumeci (UNICRI), Andreas Seiter (World Bank), Aline Plancon (Interpol), Murray Lumpkin (US FDA)

- What could be the role of development partners in assisting countries in the global fight against counterfeit medicines?
- What can GFLJD’s partners do?