International Federation
of Pharmaceutical
Manufacturers & Associations

IFPMA

UNODC
Conference on Fraudulent Medicines

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15 February 2013

Outline

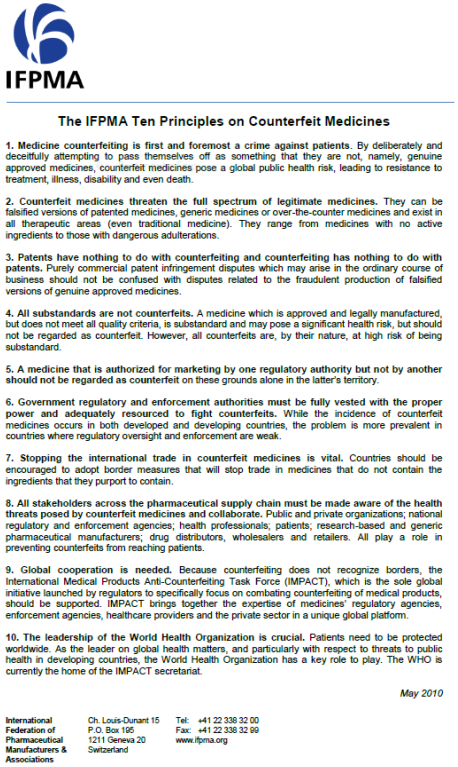
1. Our engagement
2. Current challenges in fighting counterfeit medicines
3. Case studies
4. Conclusions

Our Engagement

- Anti-counterfeiting is an industry priority
  - ✓ IFPMA Ten Principles
  - ✓ Partnerships
  - ✓ Policy research
  - ✓ Awareness raising

- Support to WHO initiatives

Our Ten Principles



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The IFPMA Ten Principles on Counterfeit Medicines

1. Medicine counterfeiting is first and foremost a crime against patients. By deliberately and deceitfully attempting to pass themselves off as something that they are not, namely, genuine approved medicines, counterfeit medicines pose a global public health risk, leading to resistance to treatment, illness, disability and even death.

2. Counterfeit medicines threaten the full spectrum of legitimate medicines. They can be falsified versions of patented medicines, generic medicines or over-the-counter medicines and exist in all therapeutic areas (even traditional medicine). They range from medicines with no active ingredients to those with dangerous adulterations.

3. Patents have nothing to do with counterfeiting and counterfeiting has nothing to do with patents. Purely commercial patent infringement disputes which may arise in the ordinary course of business should not be confused with disputes related to the fraudulent production of falsified versions of genuine approved medicines.

4. All substandards are not counterfeits. A medicine which is approved and legally manufactured, but does not meet all quality criteria, is substandard and may pose a significant health risk, but should not be regarded as counterfeit. However, all counterfeits are, by their nature, at high risk of being substandard.

5. A medicine that is authorized for marketing by one regulatory authority but not by another should not be regarded as counterfeit on these grounds alone in the latter's territory.

6. Government regulatory and enforcement authorities must be fully vested with the proper power and adequately resourced to fight counterfeits. While the incidence of counterfeit medicines occurs in both developed and developing countries, the problem is more prevalent in countries where regulatory oversight and enforcement are weak.

7. Stopping the international trade in counterfeit medicines is vital. Countries should be encouraged to adopt border measures that will stop trade in medicines that do not contain the ingredients that they purport to contain.

8. All stakeholders across the pharmaceutical supply chain must be made aware of the health threats posed by counterfeit medicines and collaborate. Public and private organizations; national regulatory and enforcement agencies; health professionals; patients; research-based and generic pharmaceutical manufacturers; drug distributors, wholesalers and retailers. All play a role in preventing counterfeits from reaching patients.

9. Global cooperation is needed. Because counterfeiting does not recognize borders, the International Medical Products Anti-Counterfeiting Task Force (IMPACT), which is the sole global initiative launched by regulators to specifically focus on combating counterfeiting of medical products, should be supported. IMPACT brings together the expertise of medicines' regulatory agencies, enforcement agencies, healthcare providers and the private sector in a unique global platform.

10. The leadership of the World Health Organization is crucial. Patients need to be protected worldwide. As the leader on global health matters, and particularly with respect to threats to public health in developing countries, the World Health Organization has a key role to play. The WHO is currently the home of the IMPACT secretariat.

May 2010

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- **Medicine counterfeiting is first and foremost a crime against patients**
- **Counterfeit medicines threaten the full spectrum of legitimate medicines**
- **Patents have nothing to do with counterfeiting and counterfeiting has nothing to do with patents**
- **Global cooperation is needed**
- **WHO leadership is critical**

Our Recent Initiatives

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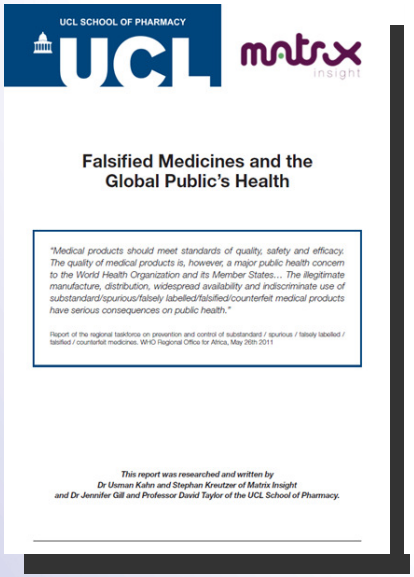

UCL SCHOOL OF PHARMACY

UCL

matrix insight

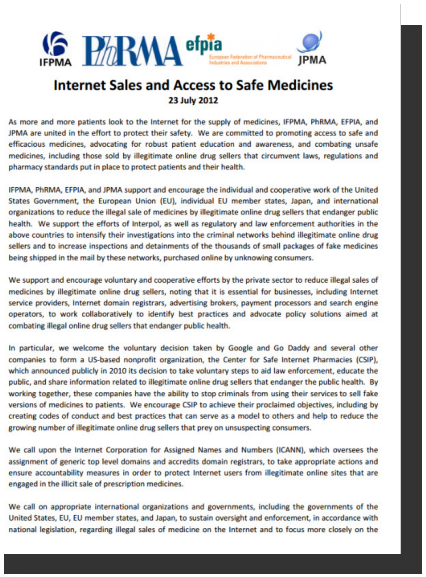
Falsified Medicines and the Global Public's Health

"Medical products should meet standards of quality, safety and efficacy. The quality of medical products is, however, a major public health concern to the World Health Organization and its Member States… The illegitimate manufacture, distribution, widespread availability and indiscriminate use of substandard/spurious/falsely labelled/falsified/counterfeit medical products have serious consequences on public health."

Report of the regional taskforce on prevention and control of substandard / spurious / falsely labelled / falsified / counterfeit medicines. WHO Regional Office for Africa, May 26th 2011

This report was researched and written by
Dr Usman Kahn and Stephan Kreutzer of Matrix Insight
and Dr Jennifer Gill and Professor David Taylor of the UCL School of Pharmacy.

UCL policy report: Falsified medicines and global public's health


IFPMA PhRMA efpia JPMA

Internet Sales and Access to Safe Medicines

23 July 2012

As more and more patients look to the Internet for the supply of medicines, IFPMA, PhRMA, EFPIA, and JPMA are united in the effort to protect their safety. We are committed to promoting access to safe and efficacious medicines, advocating for robust patient education and awareness, and combating unsafe medicines, including those sold by illegitimate online drug sellers that circumvent laws, regulations and pharmacy standards put in place to protect patients and their health.

IFPMA, PhRMA, EFPIA, and JPMA support and encourage the individual and cooperative work of the United States Government, the European Union (EU), individual EU member states, Japan, and international organizations to reduce the illegal sale of medicines by illegitimate online drug sellers that endanger public health. We support the efforts of Interpol, as well as regulatory and law enforcement authorities in the above countries to intensify their investigations into the criminal networks behind illegitimate online drug sellers and to increase inspections and detainments of the thousands of small packages of fake medicines being shipped in the mail by these networks, purchased online by unknowing consumers.

We support and encourage voluntary and cooperative efforts by the private sector to reduce illegal sales of medicines by illegitimate online drug sellers, noting that it is essential for businesses, including Internet service providers, Internet domain registrars, advertising brokers, payment processors and search engine operators, to work collaboratively to identify best practices and advocate policy solutions aimed at combating illegal online drug sellers that endanger public health.

In particular, we welcome the voluntary decision taken by Google and Go Daddy and several other companies to form a US-based nonprofit organization, the Center for Safe Internet Pharmacies (CSIP), which announced publicly in 2010 its decision to take voluntary steps to aid law enforcement, educate the public, and share information related to illegitimate online drug sellers that endanger the public health. By working together, these companies have the ability to stop criminals from using their services to sell fake versions of medicines to patients. We encourage CSIP to achieve their proclaimed objectives, including by creating codes of conduct and best practices that can serve as a model to others and help to reduce the growing number of illegitimate online drug sellers that prey on unsuspecting consumers.

We call upon the Internet Corporation for Assigned Names and Numbers (ICANN), which oversees the assignment of generic top level domains and accredits domain registrars, to take appropriate actions and ensure accountability measures in order to protect Internet users from illegitimate online sites that are engaged in the illicit sale of prescription medicines.

We call on appropriate international organizations and governments, including the governments of the United States, EU, EU member states, and Japan, to sustain oversight and enforcement, in accordance with national legislation, regarding illegal sales of medicine on the Internet and to focus more closely on the

Position on Internet Sales and Access to Safe Medicines


fip IFPMA

THE THREAT OF FALSE FRIENDS

Joining efforts to protect patients against online sales of fake medicines

FIP-IFPMA Document: The threat of false friends


International Federation of Pharmaceutical Manufacturers & Associations

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Geneva Pharma Forum

The Threat of False Friends
Fake Medicines - Imminent Risks to Global Health

Tuesday, 11 December 2012
Centre de Conférence de Varembé, Room B

The falsification of medicines is first and foremost a crime against patients and public health. This growing issue requires a concerted multi-stakeholder effort, including the World Health Organization, governments, healthcare providers, patients, and the private sector. Addressing this problem successfully requires collaborative action and the creation of a global policy environment that recognizes, prioritizes, and effectively addresses the major aspects of the falsification of medicines The IFPMA invites you to the next session of the Geneva Pharma Forum for a panel discussion on how the issue of fake medicines is being addressed. This session will also feature the launch of a study by the School of Pharmacy at the University College of London in conjunction with Matrix Insights. This study offers suggestions for coordinated actions against falsified medicines to foster the general public and governments' action. Participants will include representative of national missions from UN member state missions in Geneva, key decision-makers from health-related intergovernmental and nongovernmental organizations plus senior pharmaceutical industry executives.

Program

Moderator
Jamil Chade, Journalist

10.00 – 10.05
Introduction & Welcome
Mario Ottiglio, IFPMA

10.05 – 11.45
Discussion
David Taylor, UCL School of Pharmacy
Robert Johnstone, IAPO
Luc Besancon, International Pharmaceutical Federation
Martin Bernhardt, Sanofi

11.45 – 12.30
Questions and Answers

Lunch

Workshop: The threat of false friends Fake medicine - Imminent Risks to Global Health

Current Challenges

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a. Detection of counterfeit medicines requires control of supply chain and enhanced regulatory capacity

b. Lack of global data and health impact assessment require regular reporting from competent authorities and other organizations

c. Robust and adapted legislative and regulatory frameworks require continuous enforcement efforts at national and international level

Case Studies

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a. Scope: global, multiple therapeutic areas, patented and generic medicines
b. Illegitimate Internet sales
c. Unregulated API
d. Legislative challenges: Jurisdictional alignment, statutory limitations, domestic resource constraints
e. Opportunities: New technology & tools, growing awareness and actions, shared commitment to patient safety

Conclusions

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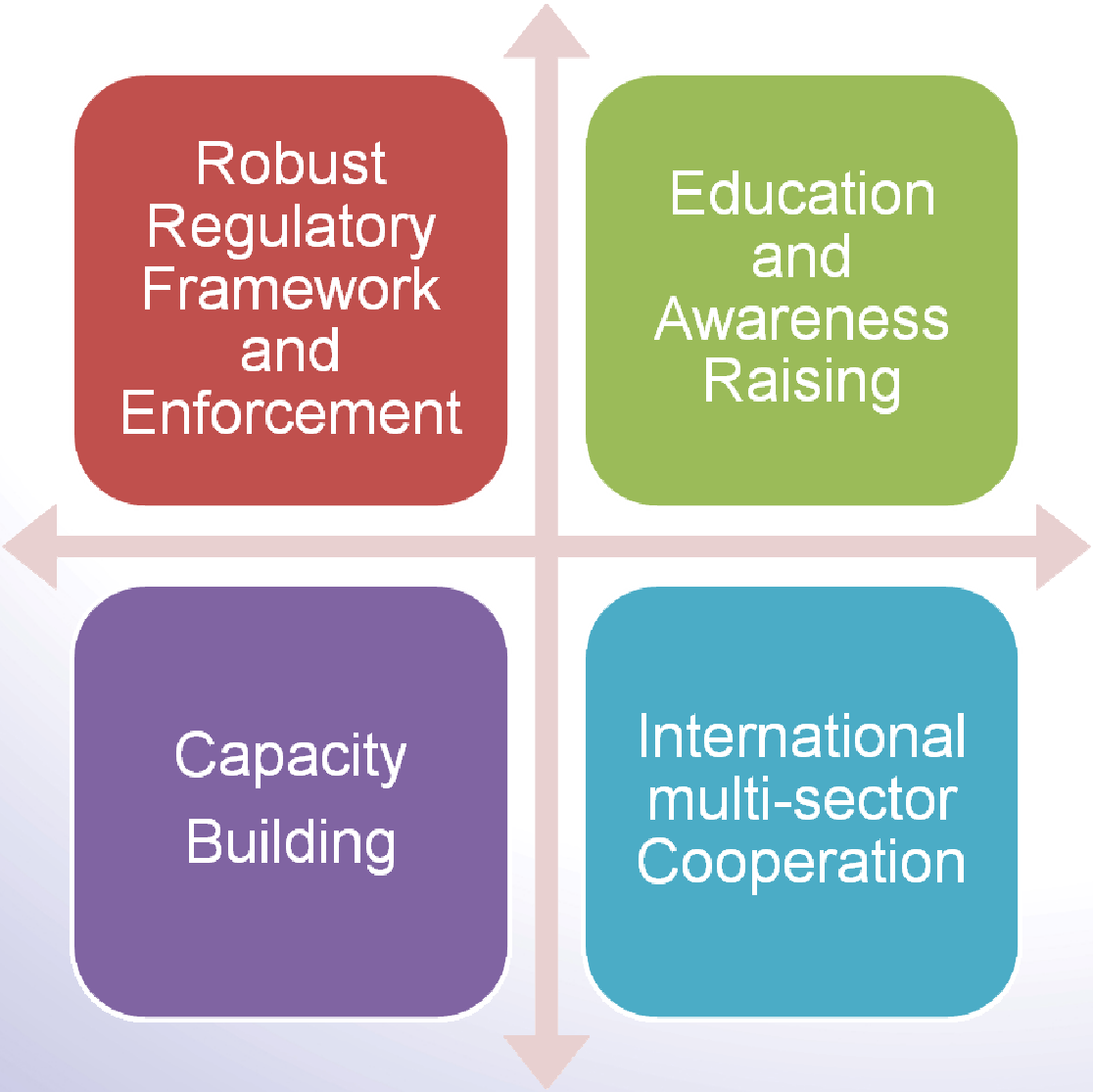

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Thank you