Industry Perspectives on Counterfeit Medicines

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Beijing, 3 September 2007
About IFPMA


- Non-Profit, Non-Governmental Organisation in relations with WHO and other international agencies.

- Represents pharmaceutical industry associations & companies from developed & developing countries.

- IFPMA member companies are research-based pharmaceutical, biotech and vaccine companies, often having generic and self-medication medicines.
About PSI

- **Pharmaceutical Security Institute.**
- 21 R&D-based pharmaceutical companies from US, Europe and Japan
- PSI collects, analyzes and disseminates information to be shared with authorities.
- Members commit resources to work with investigators in national DRA’s, law enforcement agencies, WHO, Interpol and the WCO
About IMPACT

- **International Medical Products Anti-Counterfeiting Task Force.**
- Multi-stakeholder group (Governments, industry, health professionals, patients, etc…).
- Secretariat in WHO HQ, Geneva.
- Working through 5 sub-groups:
  - Legislative and Regulatory Infrastructure
  - Regulatory Implementation
  - Enforcement
  - Technology
  - Communication
Now is the Time for Concerted Action

- The WHO estimates that developed countries have a low proportion of counterfeits (<1%); BUT in developing countries a reasonable estimate ranges from 10% to 30%. The most counterfeited drugs (by volume) are older generic but effective antibiotic and pain-killer drugs.

- Thus, one important fact is that we have a counterfeiting gap:

  1. In developing and emerging countries in Africa, Asia, Eastern Europe and Latin America, the problem is already great – patients in these regions regularly encounter fake medicines. This is unacceptable.

  2. And in developed countries, the risks to patients today are still very small -- but counterfeit pharmaceuticals trade is very growing fast – and this is also unacceptable.
## Continuing Increase in the Detection of Counterfeit Medicines (PSI, 2006)

<table>
<thead>
<tr>
<th></th>
<th>2005</th>
<th>2006</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>No of counterfeiting incidents</td>
<td>1,123</td>
<td>1,371</td>
<td>22%</td>
</tr>
<tr>
<td>No of countries connected to counterfeiting incidents</td>
<td>101</td>
<td>100</td>
<td>-</td>
</tr>
</tbody>
</table>
## Continuing Increase in the Detection of Counterfeit Medicines (PSI, 2006)

<table>
<thead>
<tr>
<th>Type/Year</th>
<th>2005</th>
<th>2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Counterfeit</td>
<td>899</td>
<td>1,184</td>
</tr>
<tr>
<td>Diversion</td>
<td>151</td>
<td>133</td>
</tr>
<tr>
<td>Theft</td>
<td>73</td>
<td>54</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1,123</strong></td>
<td><strong>1,371</strong></td>
</tr>
</tbody>
</table>
Continuing Increase in the Detection of Counterfeit Medicines (PSI, 2006)

<table>
<thead>
<tr>
<th>Country</th>
<th>Seizures/Discoveries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Russia</td>
<td>160</td>
</tr>
<tr>
<td>China</td>
<td>142</td>
</tr>
<tr>
<td>Uzbekistan</td>
<td>79</td>
</tr>
<tr>
<td>South Korea</td>
<td>69</td>
</tr>
<tr>
<td>United States</td>
<td>66</td>
</tr>
<tr>
<td>Germany</td>
<td>61</td>
</tr>
<tr>
<td>Peru</td>
<td>60</td>
</tr>
<tr>
<td>Ukraine</td>
<td>47</td>
</tr>
<tr>
<td>Brazil</td>
<td>45</td>
</tr>
<tr>
<td>Israel</td>
<td>45</td>
</tr>
</tbody>
</table>
Today, is Just Too Easy for Counterfeits to Enter the Pharmaceutical Distribution Chain

- Counterfeits are **not** only those products deliberately manufactured as such.

- A legitimate product can also be transformed into a counterfeit.
  - Prolonged Expiration Dates
  - Mishandled (ex. Frozen Vaccines)
  - Diverted Donations, Re-packaging, Transhipping ...

- Traders may lack technical knowledge to handle medicines.
The Model Distribution Chain

Manufacturers → Wholesalers/Distributors → Hospitals & Pharmacy → Patient

(“Pharmacy” includes legal, accredited, online pharmacies and other legal points of dispensing)
Today’s Threats to the Distribution Chain Integrity

Legal Manufacturer

Wholesalers/Distributors

Mishandling of legal medicines…diversion & transhipping,

In informal markets

Internet

Patient

Hospitals & Pharmacy

Manufacturer

Illegal trader of CF final products

NB. Also threatening the supply chain: CF APIs, CF excipients, CF packaging materials, etc.

(“Pharmacy” includes legal, accredited, online pharmacies and other legal points of dispensing)

Legal medicines

Counterfeit medicines
Recently in the News

India: "Orders of drug supply issued to the established pharmaceutical companies that have been enlisted by the Central Government as well as state government for the supply of drugs, are being diverted to the illegal drug manufacturers. Drug supplied by the unscrupulous firms are much cheaper in comparison the authorized company".

The Hindustan Times, “Fake drug racket in government hospitals” (28.07.07)

China: “Medical investigators have found batches of a fake blood-boosting drug in northeastern China in the latest scandal to taint its pharmaceutical industry. More than 2,000 bottles of fake human albumin were discovered in Jilin province at 18 hospitals and 39 retail and wholesale drug outlets (…)

AFP, “Fake drug found in Chinese hospitals, outlets: report” (11.06.07)
Kenya: “A Chinese pharmaceutical firm plans to recall thousands of anti-malarial drugs supplied to Kenya after discovering a counterfeit syndicate (...). Duo-cotecxin is one of the artemisinin-based combination therapy drugs highly recommended by the WHO to treat malaria and is widely supplied in government and private hospitals in Kenya (...) An estimated 35,000 people die of malaria in Kenya each year.”

BBC, “Malaria drugs recalled in Kenya” (17.08.07)

China: “While China's tainted exports have attracted international attention, China's own citizens suffer most from the shortcomings of its drug regulators. Tens of thousands of crates of unsafe pharmaceuticals have reached the local market — from antibiotics to vaccines, from drugs to treat erectile dysfunction to ones to strengthen the immune system. The government does not know how many deaths and serious illnesses have resulted from faulty drugs.”

International Herald Tribune, “A Chinese reformer betrays his cause, and pays” (13.07.07)
Patients in Developing Countries Suffer the Most

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In 2006 anti-infectives were among the most common counterfeit medicines in Africa, Russia and Latin America (PSI).
Internet Trade Facilitates Flow of Counterfeits

Recent Study* of 3,100 Online Pharmacies

- “Traffic intended for legitimate websites diverted to suspicious sites”.
- “Online pharmacies fake their accreditation deliberately (...) is almost impossible for a visitor to know their provenance”.
- “Only four online pharmacies accredited with Verified Internet Pharmacy Practice Site – VIPPS”.
- “44% of spam landing sites hosted in the U.S.”.
- “38% of spam e-mails originated in China”.

* MarkMonitor “Brandjacking Index”, Summer 2007
“Canada’s first confirmed death from counterfeit drugs purchased over the internet reinforces long-stated concerns of the Canadian Pharmacists Association (CPhA). A BC Coroner’s report has concluded that pills bought from a fake online pharmacy are to blame for the March death of a Vancouver Island woman. These drugs were later determined to be contaminated with extremely high quantities of metal”.

Canadian Pharmacists Association, “Internet Drug Death a Warning to Canadians” (06.07.07)
Key Aspects in Play

- Countries are the worst affected where regulatory structures are weak, and control and oversight is difficult;

- **Regulation and organization of the distribution system is often weak:**

- Medicines prices vary widely across the world, and parallel trade is widespread, allowing counterfeit medicines to enter the supply chain;

- Branded and non-branded generics are also widely counterfeited as well as OTC: “price” not a warning-indicator of fake drugs

- Medicines counterfeiting has not been a high priority for many countries (cf., illegal drugs, pornography, etc.)

- In many countries, the risks of prosecution and penalties levied for counterfeiting are inadequate

- Low risk/high returns on investment in counterfeit drugs

- The way in which medicines reach the consumer is also different from other goods: “who knows what’s in the box – or blister pack?”
For the Pharmaceutical Industry, Counterfeiting is a Public Health Priority

- **Active support to the IMPACT/WHO**
  - Company experts interacting with Governments and other stakeholders across sub-groups.
  - IFPMA chairs Technology sub-group.
  - Active IFPMA advocacy for IMPACT in international Fora.

- **Pharmaceutical Security Institute (PSI):**
  - Shares information to prompt appropriate enforcement activities.
  - Active support to IMPACT.

- Important regional efforts through trade associations collaborating with local authorities: PhRMA, Efpiia, JPMA, PREMA, Fifarma.
IMPACT is a Big Move in the Right Direction…

- By December 2007 IMPACT will provide:
  - Good Pharmacy Practices (GPP) and Good Distribution Practices (GDP) adapted to counterfeit medicines;
  - General principles for legislation against anti-counterfeit medicines;
  - Platform for interaction and information between anti-counterfeiting technology providers and Governments;
  - Clear mechanism for collaboration between IMPACT/Interpol/WCO and local enforcement authorities;
  - Awareness material for enforcement authorities in Africa and Latin America.

- But in order to change history, IMPACT still needs further support from its partners.
Technology Responses to Counterfeiting???

- There is no such thing as a “worldwide” applicable technology
- No one global “solution” exists
- Developing countries should prioritize on (Good Manufacturing Practices, Good Distribution Practices, and Good Pharmacy Practices)
- There are currently multiple weaknesses (inc. costs) in the use of Radio Frequency Identification (RFID)
- Technologies already available (cheaper) are preferred (e.g., bar codes)
- Any technology needs to be sustainable in the longer term

WHO/IMPACT to establish ongoing dialogue between drug regulatory authorities, technology providers in order to permit to assess recent trends in anti-counterfeiting technologies:

- II International Conference, Feb. 2008 (Singapore)

http://www.who.int/impact
1. Police and judicial priorities are elsewhere.

2. Ignorance about the scope of the problem and its extent in sector of generic products.

3. Problem is not recognized as more than a “commercial issue”: association with “branded” products.


5. Sharp increase of uncontrollable INTERNET trade (including API).

6. Priority in global monitoring and control by police authorities given over to illegal drugs (heroin, etc.).

7. Refusal of some countries and companies to admit scope of problem.

8. Over-reliance on technical devices -- on the assumption that technical devices will solve the problem.

9. Insufficient resources: within countries and also in WHO.
1. Policymakers and enforcement authorities to take lead and prioritize the fight against counterfeiting of medicines -- political will to act now.

2. Enact and enforce tougher criminal penalties in national legislation.

3. Counterfeiting must be considered a serious criminal offense.

4. More appropriate resources to be allocated to investigation and law enforcement.

5. Tighter, compulsory control of the supply chain -- tackle counterfeiting at the source of entry into the distribution chain.
   a. Manufacturers, repackagers, wholesalers, distributors and pharmacies -- are all responsible.
   b. Repackaging to be reconsidered or further regulated.
6. International police collaboration to be operative, not only informative (especially with authorities in source countries).

7. High level commitment from all stakeholders with regularly scheduled information exchanges - already in IMPACT’s agenda.

8. Harmonization of reporting forms, in line with the WHO’s Rapid Alert System.

9. Seriously consider establishment of controls to the INTERNET trading in counterfeit medicines.

10. Engage in a public awareness campaign on a global scale that recognizes that counterfeiting is a “public health emergency”.

What We Need to Work Toward…
Thank you

www.ifpma.org
www.psi-inc.org
www.who.int/impact