Counterfeit Medicines Toolkit

1. Nature and Magnitude of the Problem

Materials developed in collaboration with:

Pharmaceutical Security Institute

The Partnership for SAFE MEDICINES
✓ 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 illness, disability, resistance to treatment and even death

✓ The R&D pharmaceutical industry believes in the principle that protecting patients’ health is, and should be, the most important objective of combating counterfeit medicines
Counterfeit medicines jeopardize health. They can be any, or all, of the following:

- too strong or too weak
- missing key ingredients
- made with dangerous ingredients
- contaminated with foreign, even toxic, materials
- made in unsanitary or unsterile conditions
- created using unsafe standards
- improperly labeled, stored or handled
- expired (out-of-date)
Today it is Just Too Easy for Counterfeits to Reach Patients

- In many developing countries, regulation and organization of the health care system and medicine supply chain are weak
  - Poor health infrastructure
  - Prevalence of street markets
- Counterfeits often also make it into the legal supply chain
- Today more than ever, Internet trade facilitates the flow of counterfeits
Extent of the Problem

- Unknown, difficult to measure due to criminal nature, and evidence is often consumed
- Deaths related to counterfeits are often recorded as due to the patients underlying disease
- No systematic collection of information at the global level by any international organization, including the World Health Organization
- Within the private sector, the Pharmaceutical Security Institute (PSI) tracks incidents reported by its members
The Pharmaceutical Security Institute (PSI)

- An initiative of the R&D based pharmaceutical industry; currently 24 members.
- PSI collects, analyzes and disseminates information concerning counterfeiting incidents.
  - Begun by security directors in 1992 it began rigorous collection of data in 2002 after a major reorganization.
  - Central point of contact for multi-national enforcement efforts
  - Provides strategic reporting and regional reporting through the Counterfeit Incident System
    - Maintains supporting files regarding illegal diversion and theft of medicines.
- PSI conducts briefings and training for drug regulators, law enforcement and customs authorities around the world.
Key findings by the Pharmaceutical Security Institute (PSI) for 2009

- 2,003 Incidents – up 9.2%
- 1,693 Counterfeit incidents – up 6.8%
- 118 countries impacted
- 808 different medicines – up 36%
- 1,468 arrests – up 60%
- 48% of seizures are 1,000+ dosage units (commercial size)
- Counterfeit medicines are a threat to the health and well-being of people around the world

☑ Each PSI Member reported/experienced a counterfeit, theft or illegal diversion incident
☑ Total incidents include reports by PSI members plus those identified by PSI analysts using open source information
Continuing increase in pharmaceutical crimes, including counterfeiting

<table>
<thead>
<tr>
<th>Type/ Year</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Counterfeit</td>
<td>1,513</td>
<td>1,585</td>
<td>1,693</td>
</tr>
<tr>
<td>Diversion</td>
<td>188</td>
<td>188</td>
<td>245</td>
</tr>
<tr>
<td>Theft</td>
<td>58</td>
<td>61</td>
<td>65</td>
</tr>
<tr>
<td>Total</td>
<td>1,759</td>
<td>1,834</td>
<td>2,003</td>
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Total Incident Trends: Counterfeiting + Diversion + Theft
For the fifth consecutive year, PSI data revealed that medicines in the following therapeutic categories were most frequently counterfeited:

1. Genito-urinary
2. Anti-infectives
3. Central nervous system
Highest percentage increase per therapeutic category 2008/2009

- **Alimentary**: 57%
- **Anti-Infective**: 48%
- **Musculo-Skeletal**: 35%
- **Cytostatic**: 32%
- **CNS**: 28%
- **Cardiovascular**: 23%
48% of incidents were of “commercial size” (1,000+ units)
Most arrests took place in Asia and Latin America.
Sixty-eight (68) illegal pharmaceutical manufacturing facilities disrupted through searches and seizures in eighteen (18) countries.

In 531 incidents, counterfeit products reached licensed wholesale distributors and/or pharmacies in forty-eight (48) different countries.
What are the Main Obstacles?  
Industry’s View

- Problem is perceived as a “commercial issue”, for “branded” products
  - Lack of recognition of health hazard of counterfeiting of medicines
  - Need to enact and enforce tougher criminal penalties in national legislation
  - Counterfeiting must be considered a serious criminal offense
- Priority in global monitoring and control by police authorities given over to illegal drugs, people trafficking, etc.
- Ignorance about the scale of the problem
- Refusal of some countries to admit scale of the problem
- Lack of political will to act now
- Insufficient resources: within countries and also in the World Health Organization
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