Tackling the Menace of Counterfeit Medicines
- A Public Healthcare Issue

International Seminar on
“Consumer Safety Through Anti-Counterfeiting Technologies
- A Pharmaceutical Perspective”
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Counterfeit Medicines
- 3 Clearly Emerging Global Views

1. Innovator Companies: Generic Industry and Drug Regulators not very keen to resolve the issue.

2. Generic Companies and Drug Regulators:
   - The problem is not as acute as projected by the Innovator Companies.
   - Exploiting the situation to fight against generics and parallel imports.

3. Other Group / NGOs: Global Pharmaceutical Companies trying to extend Intellectual Property Rights (IPRs) to patients’ safety issues and have gone to ACTA and WHO IMPACT.
Counterfeit Medicines - Addressing the Concerns
IPR being extended to the Definition of
Counterfeit Medicines

- Even in India “misbranded” drugs are considered counterfeit under Section 17 of the Drugs & Cosmetics Act.

Magnitude of the Problem with Counterfeit Medicines has been inflated

- Less than 1% in developed countries like USA, EU, Japan, Australia, Canada and New Zealand.
- More than 30% in developing nations like parts of Asia, Latin American and Africa.
- 33-53% of artesunate for malaria are counterfeit in S.E. Asia.

Source: IMPACT 2006
Counterfeit Medicines

- Apprehension of Generic Pharma Industry

- Apprehension: Attempt to bring generic drugs under counterfeit medicines.

- Apprehension unfounded: No threat to non-patent infringing generics anywhere in the world.

- Generic Industry is growing much faster than patented drugs in the developed markets.
Counterfeit Medicines
- An Unexplained Similarity

- Incidence of counterfeit medicines are higher in those countries where access to medicines is poor.

- Counterfeit versions of all types of products from tropical diseases to life-threatening to lifestyle - all available as counterfeit.

Source: WHO
Counterfeit Medicines - Various Types

<table>
<thead>
<tr>
<th>Type</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Without AIs</td>
<td>32%</td>
</tr>
<tr>
<td>Wrong Ingredients</td>
<td>21.4%</td>
</tr>
<tr>
<td>Incorrect Quantities of AIs</td>
<td>20.2%</td>
</tr>
<tr>
<td>Right quantities of AIs but in fake packaging</td>
<td>15.6%</td>
</tr>
<tr>
<td>High Level of Impurities and Contaminants *</td>
<td>8.5%</td>
</tr>
<tr>
<td>Medicines purchased from internet thru illegal sites</td>
<td>50%</td>
</tr>
</tbody>
</table>

AIs – Active Ingredients

*(Substituted ingredients could be from paracetamol to boric acid, talcum powder, rat poison or road paint)*

Source: WHO 2006
Counterfeit Medicines – Factors for Influencing Flourishing Trade

- Low manufacturing costs, thus higher margin.

- High pricing ratio of counterfeit medicines compared to branded products (Albany Law Journal).

- Risk of detection of fake medicines is lower and penalties lenient e.g. India

Source: WHO IMPACT
Counterfeit Medicines – Global Forecast

Source: Centre for Medicines in Public Interest - 2007
Counterfeit Medicines
- Incidence of Detection

Source: WHO Report 2006
Counterfeit Medicines
- Volume of Seizures Worldover

In 2005 and 2006, 2.7 million articles of counterfeit drug seizures took place, which originated from the following countries:

- India: 31%
- UAE: 31%
- China: 20%
- Others: 18%

Source: WHO IMPACT
Counterfeit Medicines
– Some Points to Ponder

• One in 5 medicines sold in India is fake.
• 75% of drugs supplied world over have their origin in India.
• As per Lancet 10 to 30% of medicines are counterfeit in India.
• Less than 1% of the drugs manufactured in India are tested.
• 26 Government labs. Test 2,500 drugs samples annually. Each has backlog of 6-9 months.
• WHO estimates that 200,000 of 1 million malaria death annually are due to fake drugs.

Source: The Times of India 0 15th May, 2008
Counterfeit Medicines - Conclusion

• Counterfeit Medicines: growing menace against humanity.

• All stakeholders to join hands to address this public health issue.

• Thugs and criminals should not be allowed to run to their banks with sacks full of money from this illicit trade at the cost of innocent patients.

• Technology plays a great role to address this public health issue.
Thank You