

Tackling the Menace of Counterfeit Medicines - A Public Healthcare Issue



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- 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.
- Albany Law Journal 2006 estimated a loss to industry towards counterfeit medicines of U.S.\$ 30 billion - 6% of global turnover.



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.



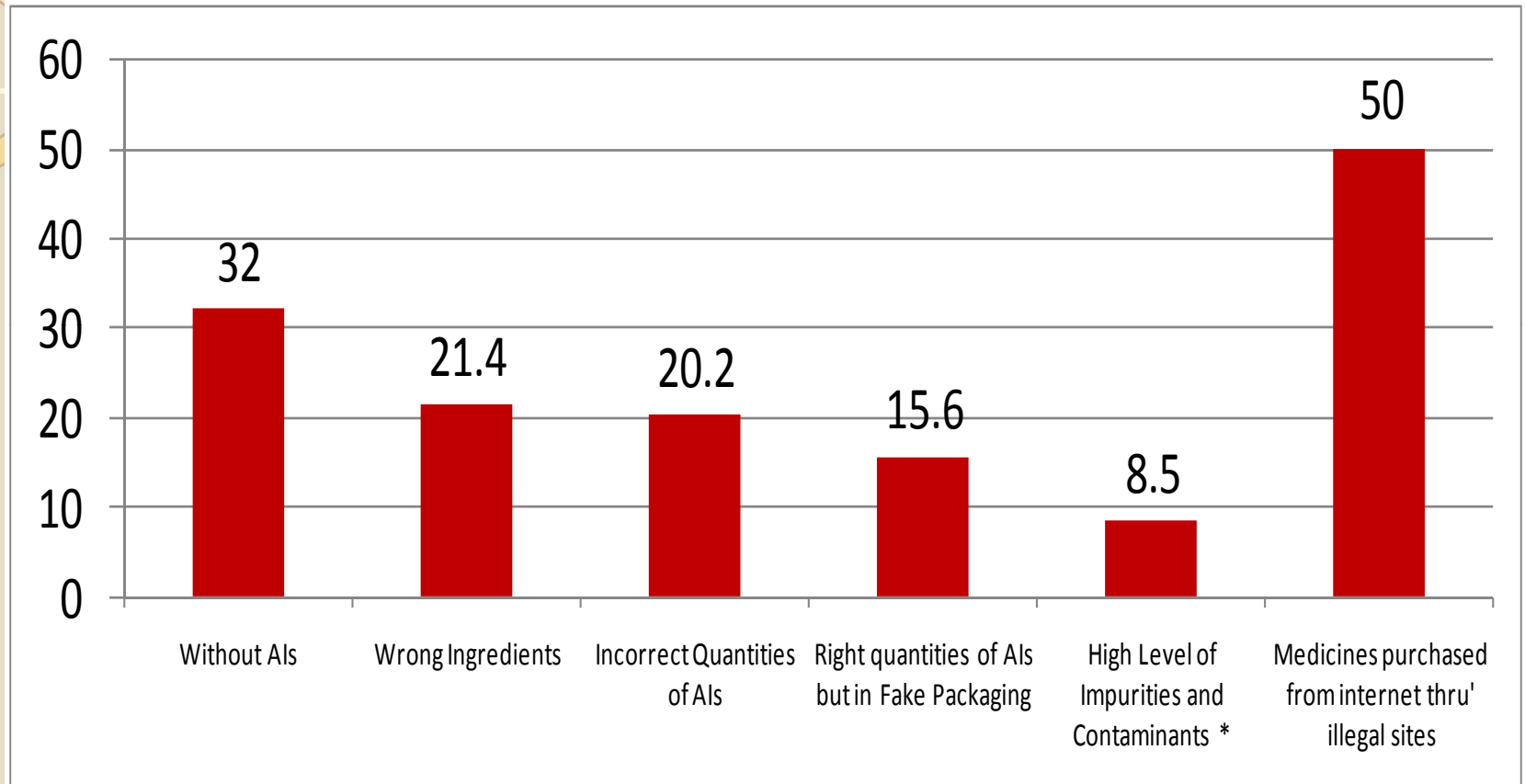
Counterfeit Medicines - An Unexplained Similarity

- 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



AIs – Active Ingredients

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

Source: WHO 2006



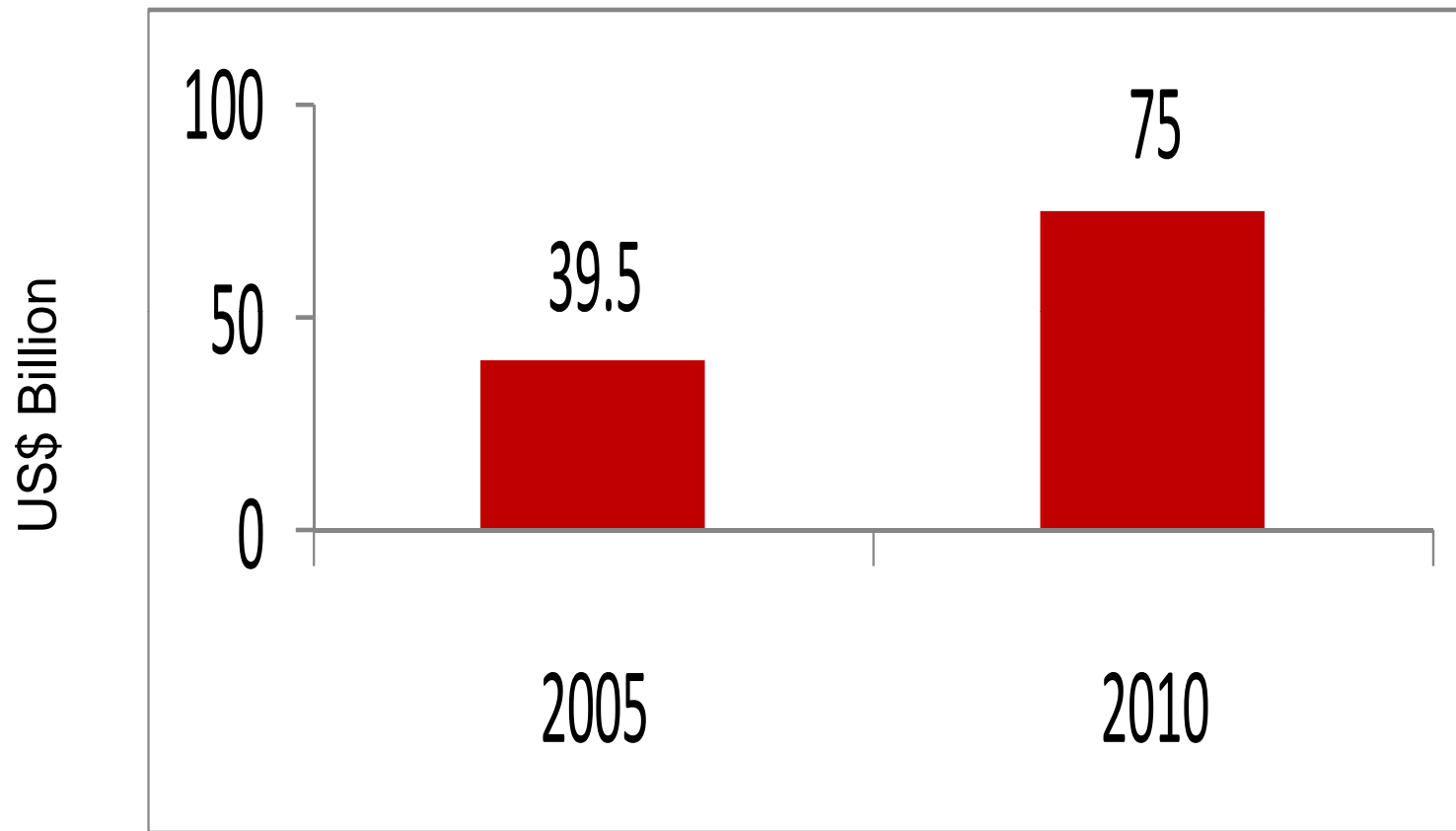
Counterfeit Medicines – Factors for Influencing Flourishing Trade

- 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



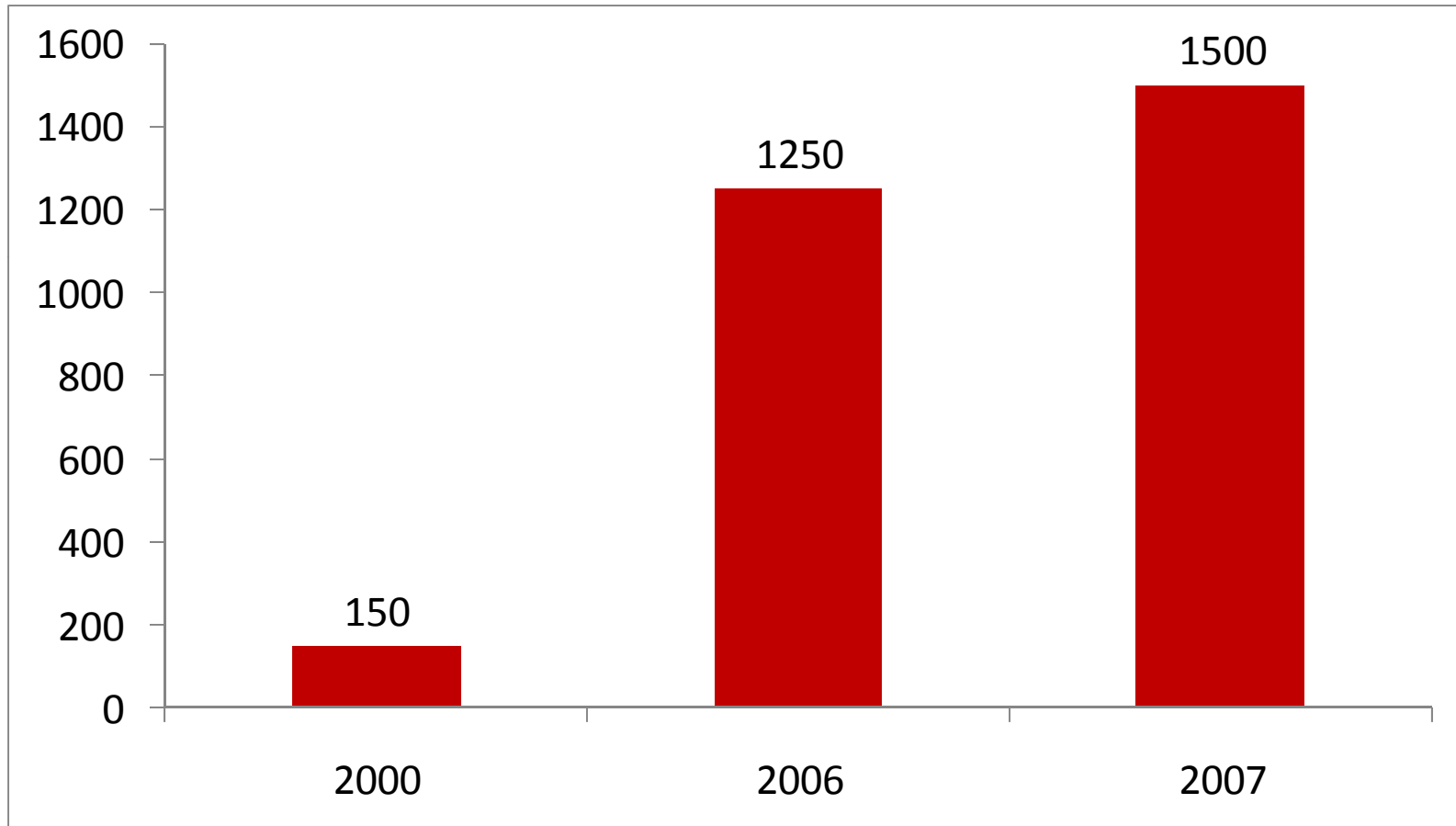
Counterfeit Medicines – Global Forecast



Source: Centre for Medicines in Public Interest - 2007



Counterfeit Medicines - Incidence of Detection



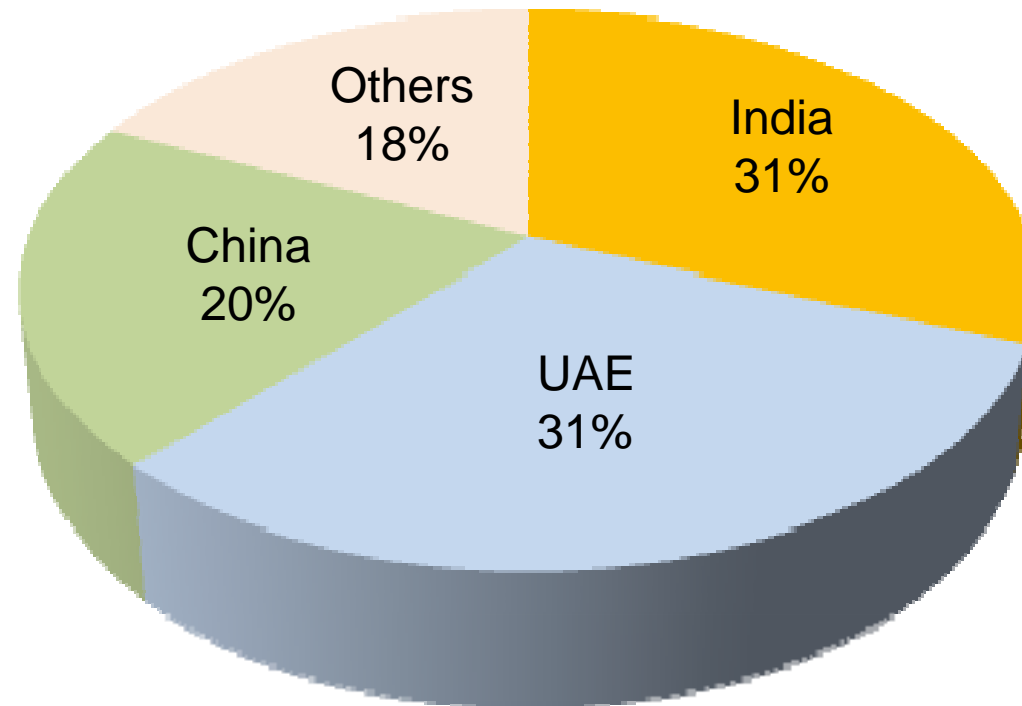
Source: WHO Report 2006



Counterfeit Medicines

- Volume of Seizures Worldwide

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



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