

# Addressing the risk of fraud and misconduct in the Pharmaceutical sector



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# Common Fraud in Pharmaceutical Sector

1. Accounting
2. Bribery and Corruption
3. Medical Promotion: MCI Guidelines
4. Supply Chain:
  - Sourcing: Heparin Tragedy
  - Trade Related
5. Clinical Trials:
  - Ethical
  - Regulatory
  - Misuse of Discretionary Power
6. Manufacturing:
  - Regulatory: Ranbaxy
  - Counterfeiting



# Some Examples of Counterfeits (1)





# Some Examples of Counterfeits (2)



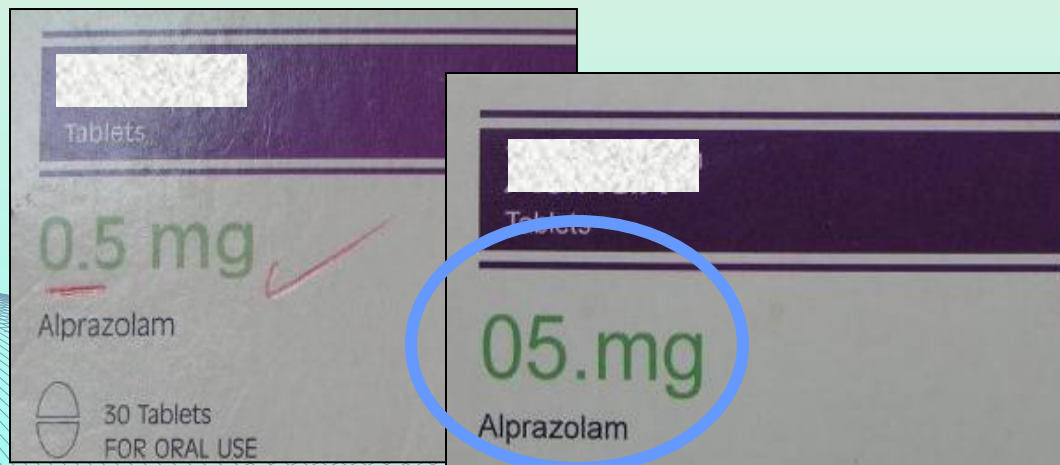
Source: ANVISA, Brazil



# Some Examples of Less Sophisticated Counterfeits



Picture courtesy of GSK, cannot be reproduced without written permission





# Examples of Manufacturing Facilities

This is how medicines should be produced...



# Examples of Manufacturing Facilities

... This is how counterfeits are produced



*Picture courtesy of PSI. Operation Cross Ocean, China.*





# Counterfeit Medicines

## - 3 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.





# ‘Spurious’ And ‘Sub-standard’ Drugs in India:

Year	Drugs samples tested	% of sub-standard drugs	% of spurious drugs	Prosecution for crime	Persons arrested
2006 – 07	34,738	5.8	0.22	115	12
2007 – 08	39,117	6.2	0.19	120	122
2008 – 09	45,145	5.7	0.34	220	133
2009 -10	39,248	4.95	0.29	138	147
TOTAL	1,58,248	5.66	0.26	593	414



# Counterfeit Medicines

## - 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.



# Counterfeit Medicines

## - Magnitude of the Problem

- 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.





# 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.



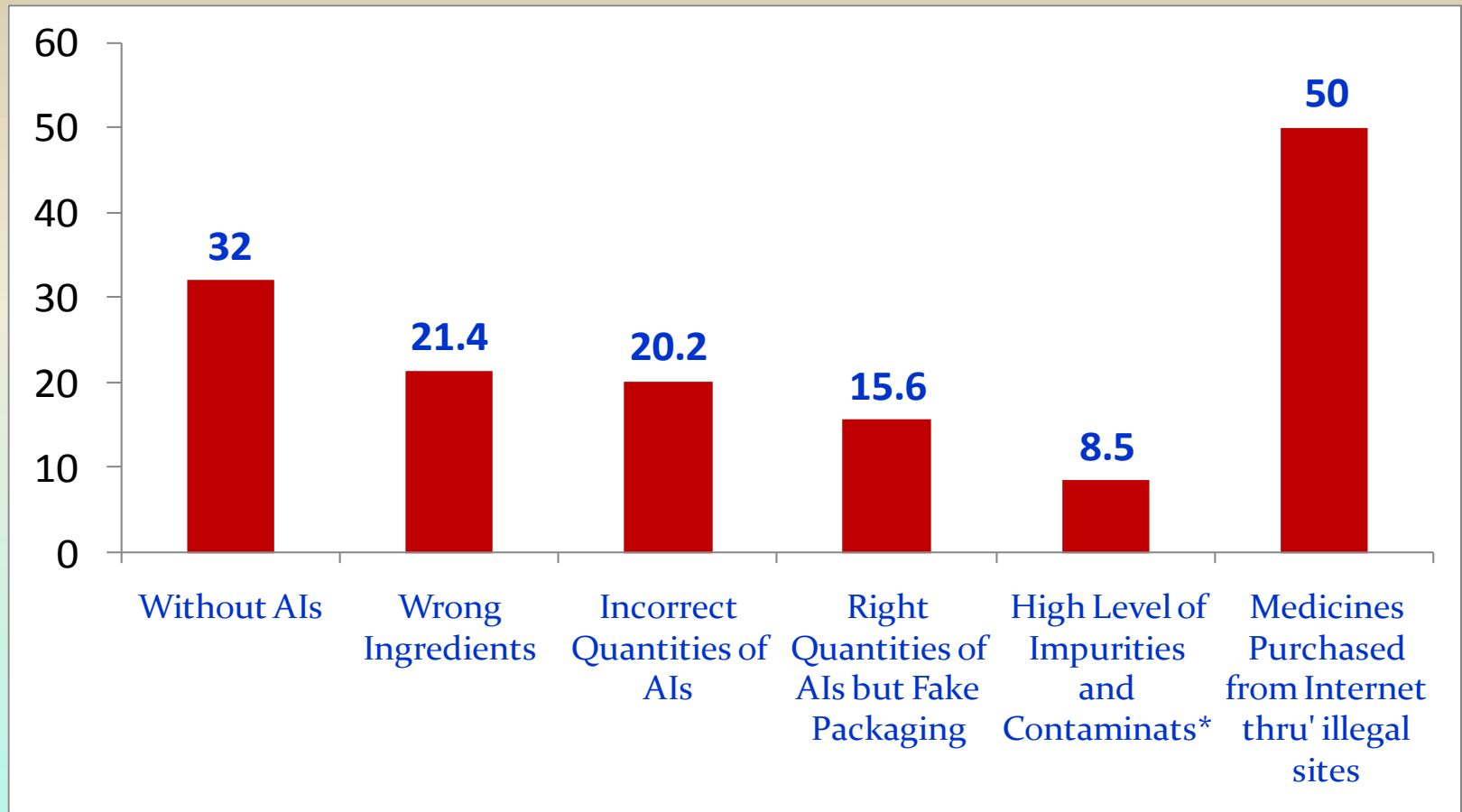
# Counterfeit Medicines

## - 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.



# Counterfeit Medicines - Types



AIs – Active Ingredients

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





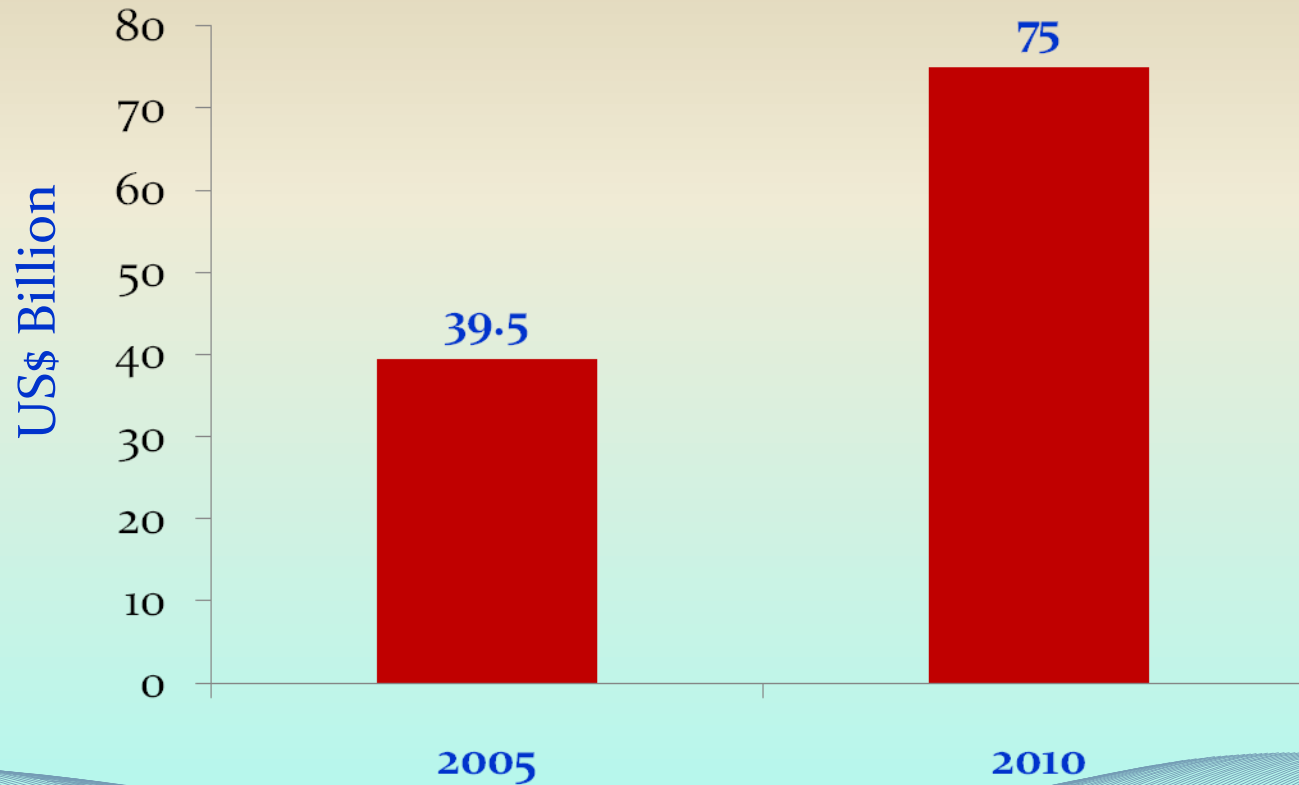
# Counterfeit Medicines

## – Factors 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 not commensurate.



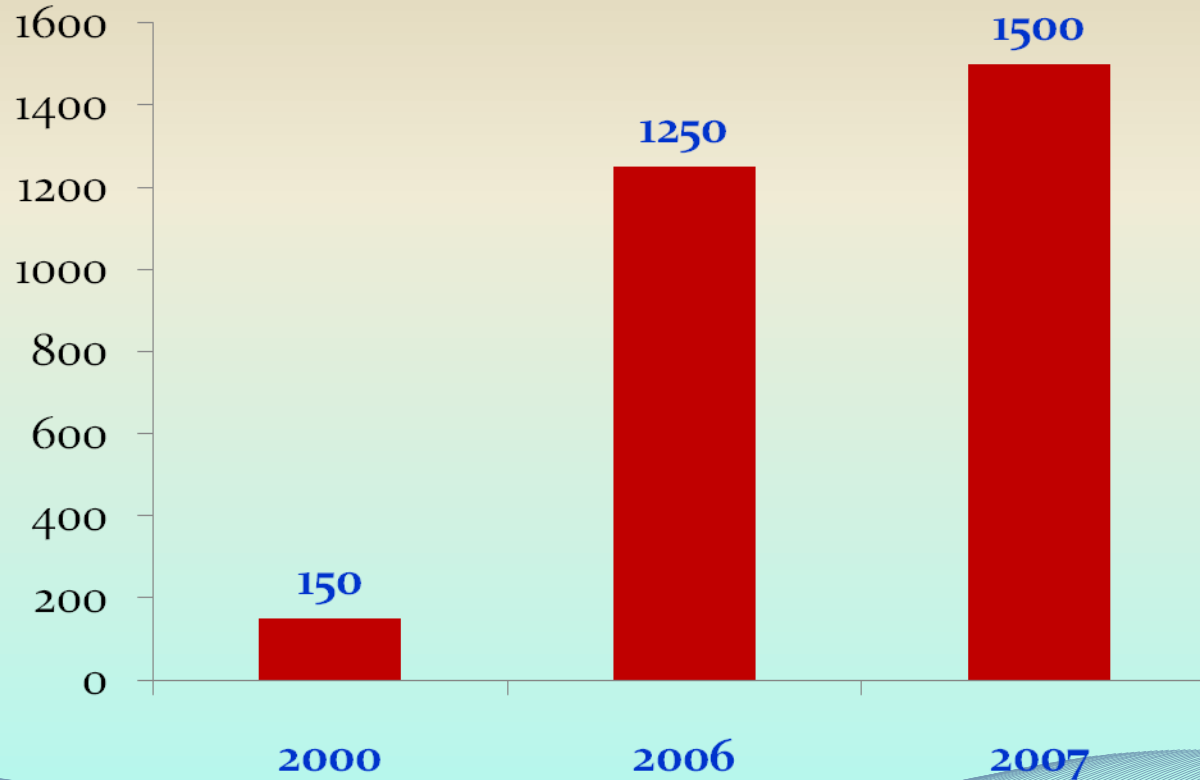
# Counterfeit Medicines – Global Forecast



Source: Centre for Medicines in Public Interest - 2007



# Counterfeit Medicines - Incidence of Detection



Source: WHO Report 2006

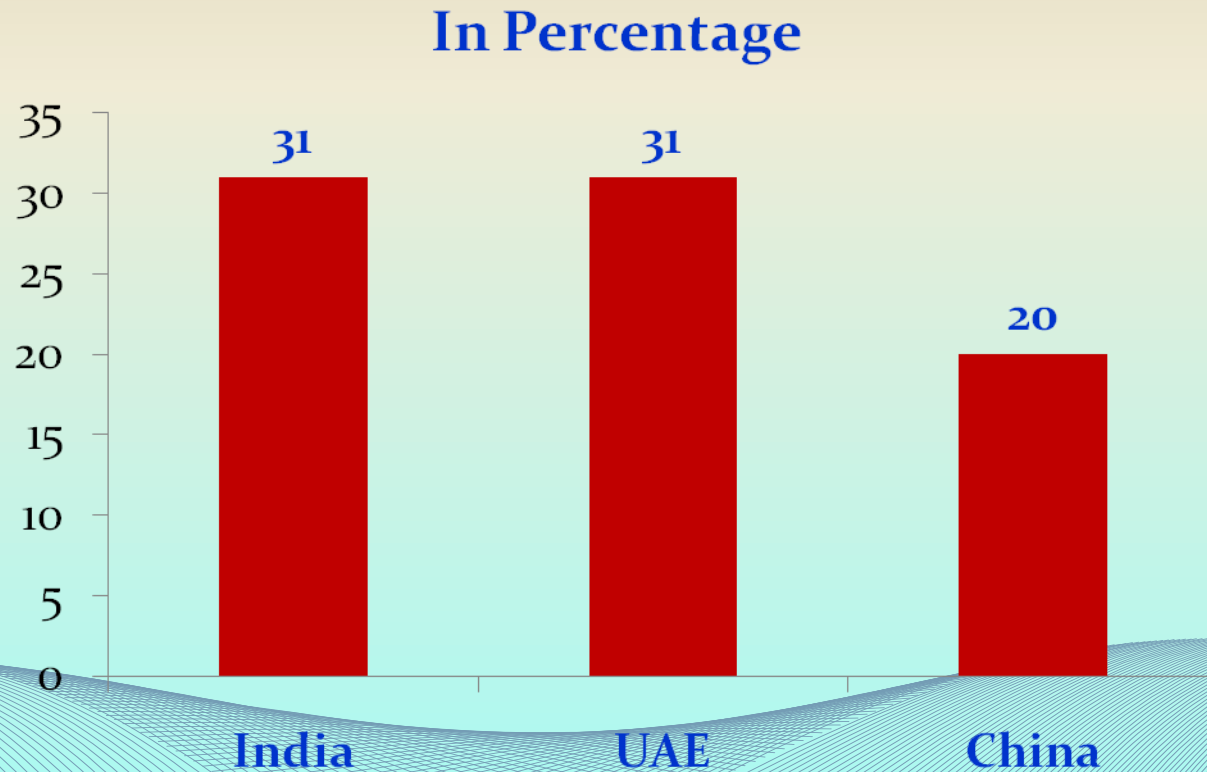




# Counterfeit Medicines

## - Volume of Global Seizures

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



# Counterfeit Medicines

## China selling fake 'Made in India' drugs



THE ECONOMIC TIMES

www.economictimes.com

MONDAY 3 AUGUST 2009

### FIGHTING FAKES

Talks for preventing fake drugs with 'Made-in-India' tag reaching Nigeria

### AFRICAN SAFARI

Govts to help Indian drugmakers set up manufacturing units in Nigeria

### RETAIL DETAIL

Setting up pharmacies in Nigeria with govt licence to be discussed

# India set to sign pharma export deal with Nigeria

Sushmi Dey & Gireesh Chandra Prasad  
NEW DELHI

THE government is set to sign an exhaustive deal with Nigeria to boost pharmaceutical exports to its eighth-largest global consumer, where the reputation of Indian drugs was recently dented by fake drugs from China bearing 'Made-in-India' labels.

The department of pharmaceuticals and the ministries of commerce, external affairs and health will start talks with a visiting Nigerian delegation on Monday on ways to prevent fake drugs from other countries bearing fabricated 'Made-in-India' labels from reaching the Rs 1,000-crore West African market for Indian generic drugs.

Orchid Chemicals and Pharmaceuticals and Medo Pharma are the biggest Indian exporters to the region.

To salvage the reputation of Indian generic drug exporters and to promote sales of Indian generics, India is likely to use resources from the 'challenge India fund' maintained by the commerce ministry.

"Both the governments (India and Nigeria) will also discuss setting up a network of retail pharmacies in Nigeria operating with government licence, and putting an end to the existing unregulated medicine outlets," the official, who asked not to be named, said.

The move will enable the government to

put in place a fool-proof system to ensure that fake drugs are not passed off as imported generic drugs from India.

Recently, a delegation of Indian authorities led by officials from the commerce ministry also visited Johannesburg to discuss the issue of fake drugs.

At the proposed talks, both the governments will identify steps to encourage Indian drug companies to set up manufacturing units in Nigeria and explore whether Indian public sector drugmakers can supply low-cost quality drugs to the Nigerian government.

The African country had seized a large consignment of fake anti-malarial drugs labelled 'Made in India' in May this year that was later traced to China. Three such consignments from China were also seized by the Indian authorities at the Chennai Port. India has also demanded that China should take strict action against the manufacturers whose names and addresses were printed on the confiscated cartons.

"Supply of spurious drugs to Africa is on the rise. Urgent steps have to be taken to ensure that India's reputation as a reliable supplier of high-quality, low-cost medicines is not ruined. The sooner we act, the better for us," the official said.

Africa accounts for over 15% of India's total generic exports worth Rs 30,000 crore annually. sushmi.dey@timesgroup.com





# Counterfeit Medicines

## In Transit issues

### Belgians seize Africa-bound drugs

More than two million counterfeit drugs destined for Africa have been seized in Belgium, customs officials say.

They said the shipment from India, including copies of an anti-malaria drug, was the biggest seizure of fake medication ever made in Europe.

Customs officers at Brussels airport became suspicious when they noticed spelling mistakes on the labels.

The UN says fake medicines represent 10% of the world market and up to 30% of the African market.

The seizure, made last week, was made public on Thursday night.

Hidden in large bags, the pills were copies of a strong painkiller made by a German company, and a Swiss-made anti-malarial treatment.

The confiscated medicines had been sent in three shipments by an Indian company in Mumbai, and were bound for two unnamed companies based in Togo.



The shipment included drugs to treat malaria - a big killer in Africa

“ Thanks to this seizure, we have saved lives

”

Lieven Muylaert  
Customs department





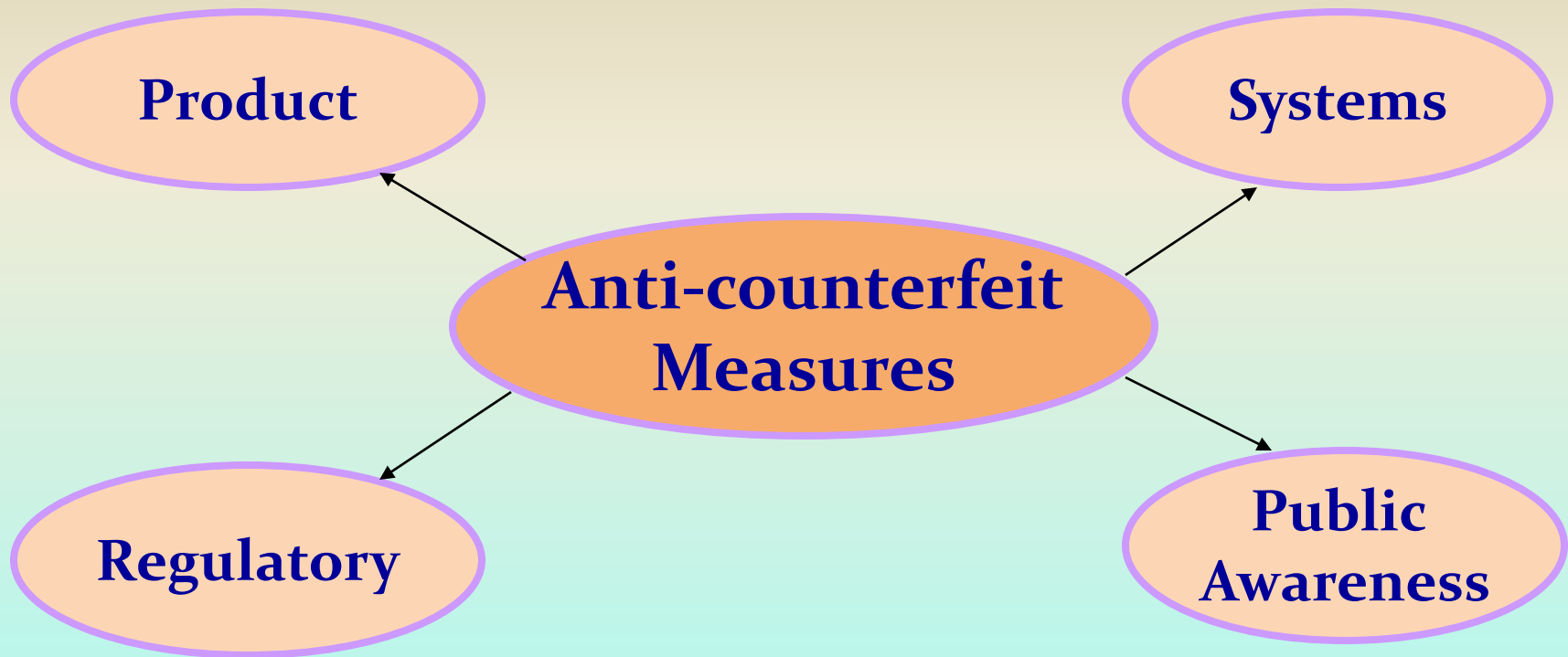
# Counterfeit Medicines

## –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.



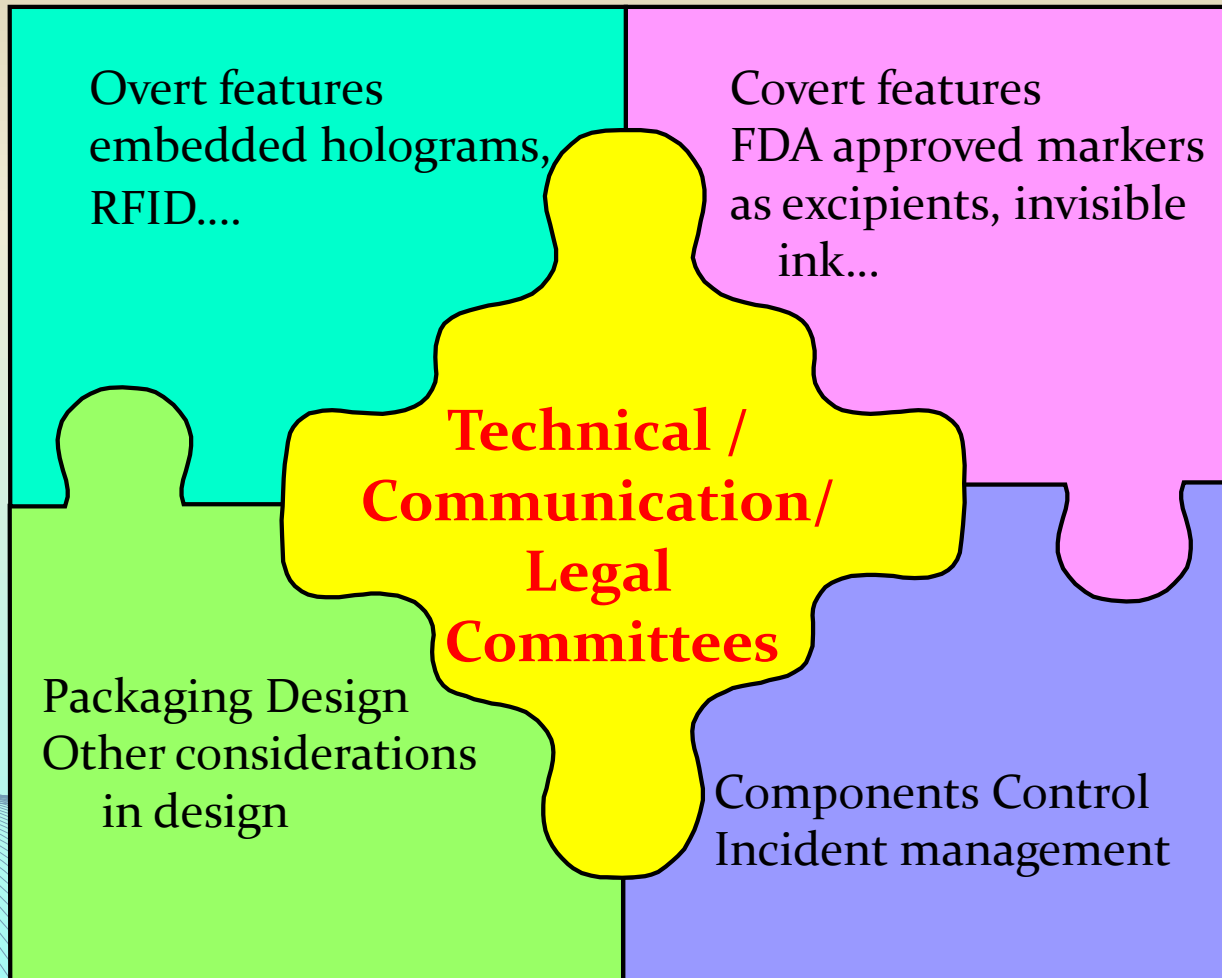
# Combating Counterfeiting



# Combating counterfeiting

## OPPI Recommendations

requires an  
integrated  
approach





# The Chinese example

## 39 Companies Are Combining Forces: The China Anti-Counterfeiting Coalition

**Adidas**  
**American Standard**  
**Anheuser-Busch**  
**Aventis**  
**BAT**  
**Bayer**  
**Bestfoods**

**Glaxo Wellcome**  
**Henkel**  
**Johnson&Johnson**

**L'Oreal**  
**Logitech**  
**Louis Vuitton**  
**Mars**  
**Nike**  
**Philips**

**Bosch**  
**Caterpillar**  
**Coca-Cola**  
**Colgate-Palmolive**

**CACC**

**Philip Morris**  
**Prada**  
**Procter&Gamble**  
**Reebok**

**DaimlerChrysler**  
**Dell**  
**Dow Corning**  
**Energizer**  
**Epson**  
**Gillette**

**Kimberly-Clark**  
**Kodak**  
**Levis**

**S.C.Johnson**  
**Siemens**  
**Unilever**  
**Van Melle**  
**Westvaco**  
**Yamaha**



# Conclusion :

Counterfeit Medicines – A fraud against humanity and the industry

- Awareness
- Technology
- Amendment of D&C Act
- Whistleblower Policy

All stakeholders to join hands to address this  
Public health issue



**Thank You**

