

# COMBATING COUNTERFEIT DRUGS WITH PACKAGING TECHNOLOGY

Tapan Ray  
Director General  
Organisation of Pharmaceutical Producers of India



ALCAN PACKAGING UNIVERSITY  
OCT 8, 2009 -LONAVALA



# Content

- ❖ Counterfeit Medicines:
  - Definition
  - Perspective
  - Concerns
- ❖ Emerging trends: anti-counterfeit packaging
- ❖ The Way Forward
- ❖ “Do”





# Definition

# Counterfeit Medicines

## WHO Definition

“A medicine, which is deliberately & fraudulently mislabeled with respect to identity and / or source.

Can apply to both branded & generic products

Include products with correct / wrong ingredients; without active ingredients / with insufficient active ingredients / fake packaging”.

Source: WHO





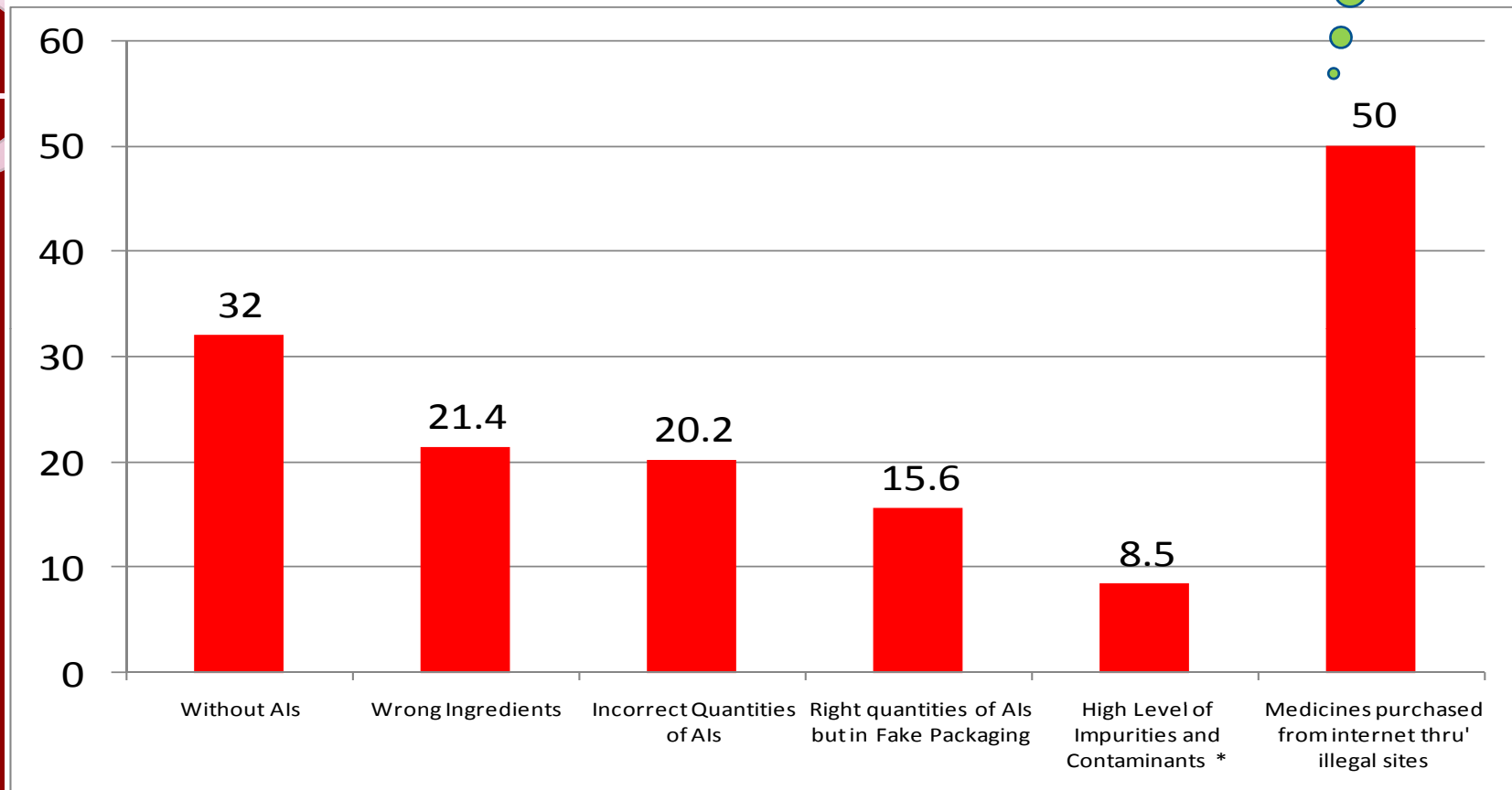
# Perspective



# Counterfeit Medicines

## *Various Types*

Growing threat to  
Global Public  
Health



AIs – Active Ingredients

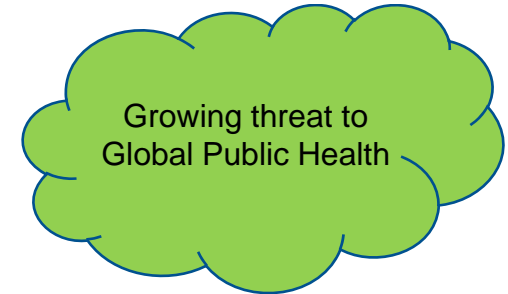
\*(Substituted ingredients could be from paracetamol to boric acid, talcum powder, rat poison or road paint)

Source: WHO



# Counterfeit Medicines

## *Magnitude of the Problem*



Developed Countries

**New Products Hormones, Steroids,  
anti-asthma, or anti-allergy medicines**

**World**

Developing Countries

**Malaria, Tuberculosis and HIV/AIDS**





## Magnitude of the Problem

- ❖ Higher incidence in countries where access to medicines is poor.
- ❖ 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.

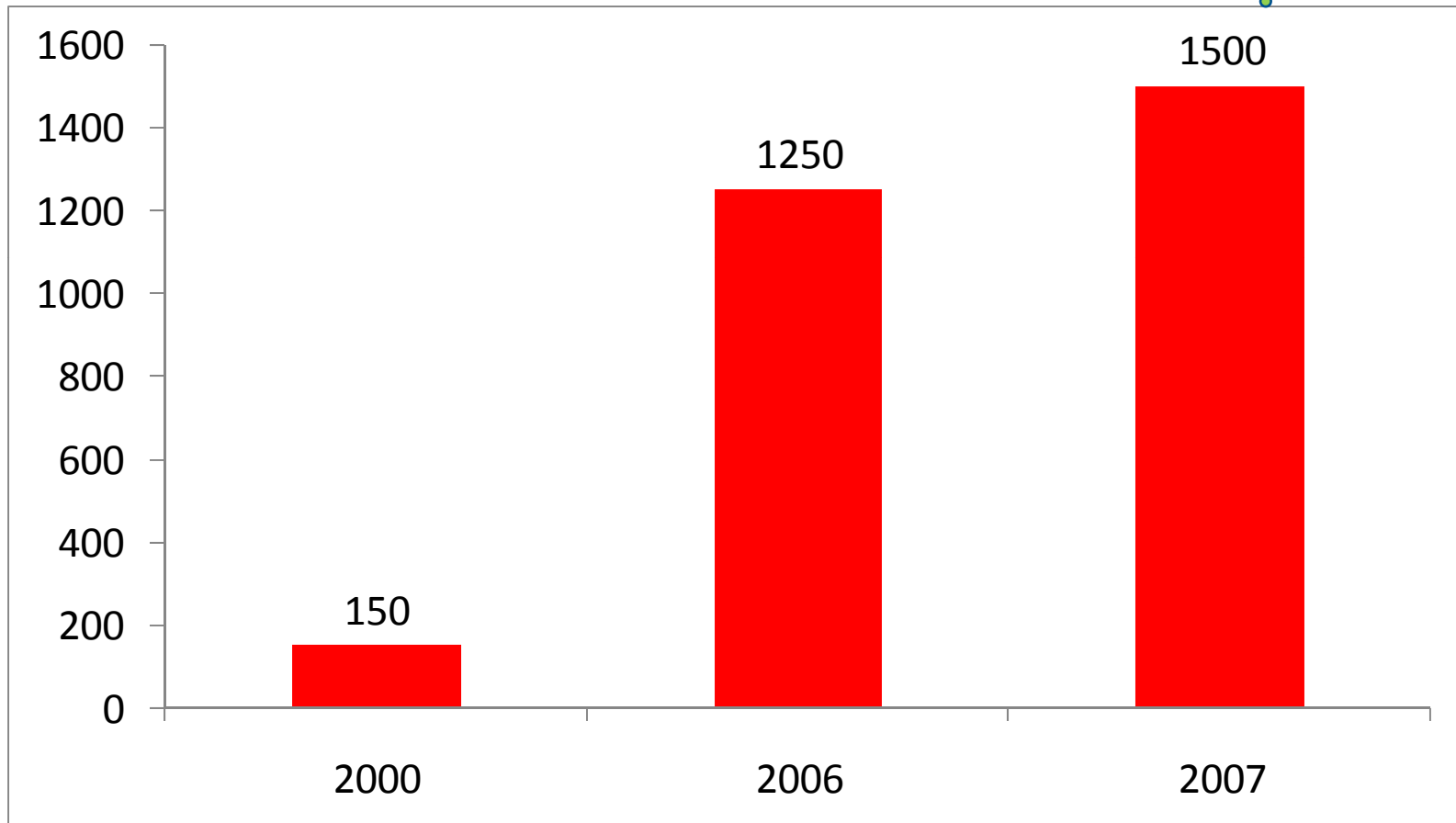
Source: WHO IMPACT 2006



# Counterfeit Medicines

## - Incidence of Detection

Growing threat to  
Global Public  
Health



Source: WHO Report

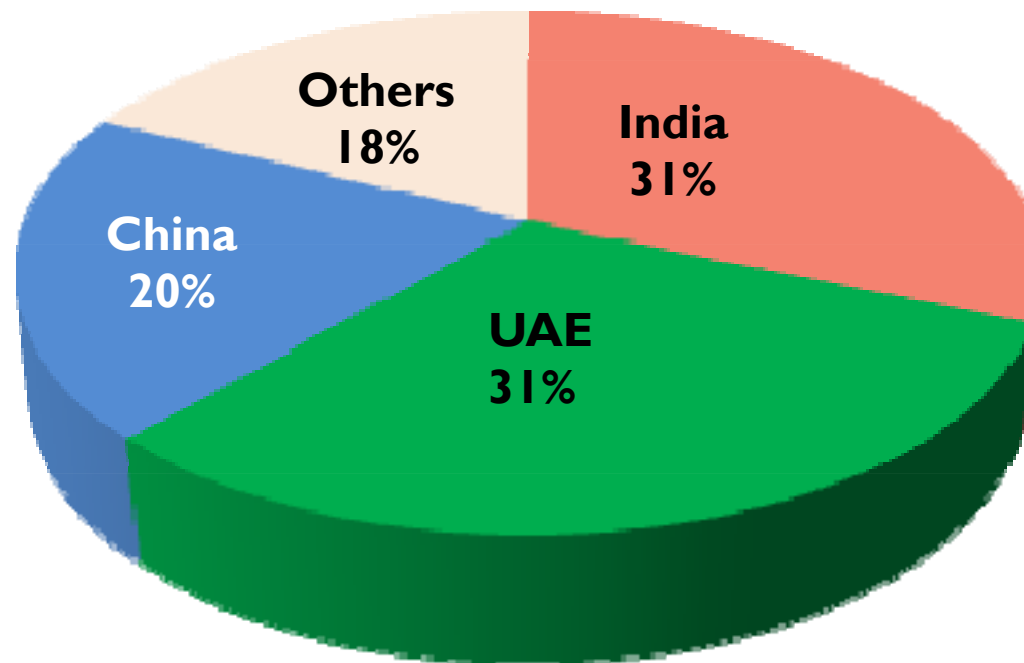


# Counterfeit Medicines

## *Seizures World over*

Growing threat to  
Global Public  
Health

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



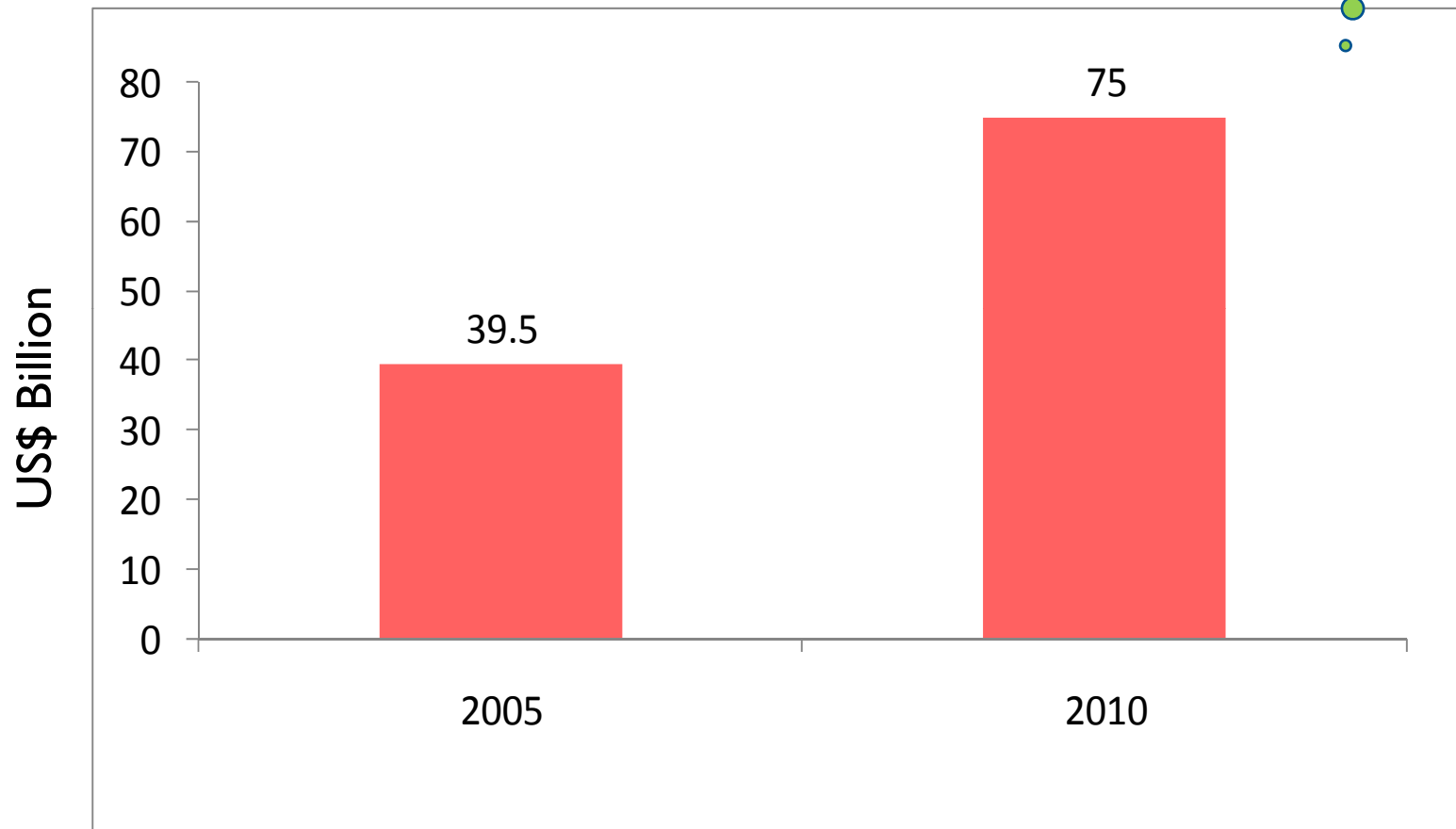
Source: WHO IMPACT



# Counterfeit Medicines

## *Global Forecast*

Growing threat to  
Global Public  
Health



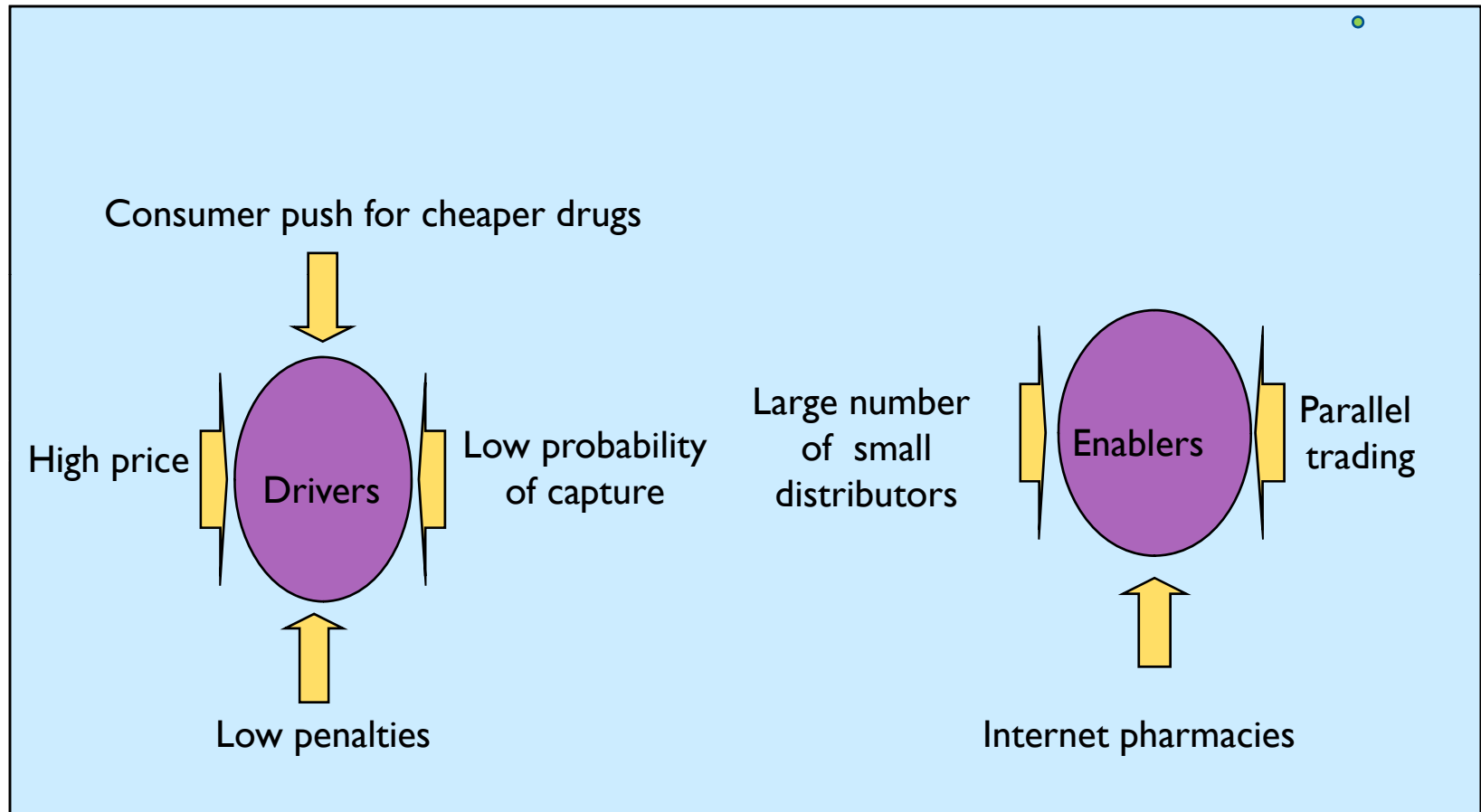
Source: Centre for Medicines in Public Interest - 2007



# Counterfeit Medicines

## Factors Influencing Flourishing Trade

Growing threat  
to Global  
Public Health



*Low risk/high returns on investment in counterfeit drugs*



# A Recent Report

## **The Economic Times**

(September 14, 2009)

### Exporters of drugs under govt lens

Amiti Sen

NEW DELHI

THE government has decided to initiate investigation against suspected exporters of substandard drugs on information provided by its missions abroad as it seeks to project the country as a reliable supplier.

The commerce department has advised missions in countries that import drugs from India to inform Centre of every complaint they receive on such dubious exports.

If the exporter is proved guilty, its import-export code will be revoked and the Drug Controller General of India (DCGI) will cancel its licence, DK Mittal, additional secretary in the commerce department, told ET.

After consulting the chemicals and petrochemicals department and the DCGI, the commerce department has decided to act promptly on complaints against exporters of substandard drugs to ensure that they do not hurt the country's image, he added.

In the normal course, action is initiated

against an exporter of substandard drugs after an official complaint by the importing country. However, the government will now investigate such cases and take action soon after it gets information from its missions abroad.

"India has always been a supplier of quality drugs. We want to ascertain that we take all possible measures to ensure that our ex-

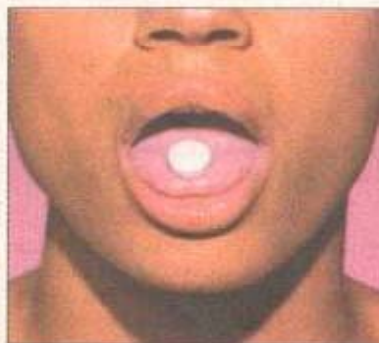
port standards are maintained," Mr Mittal said.

Recently, Nigeria confiscated a consignment of spurious medicines with made-in-India labels that had been shipped from China. Such incidents too hurt the country's credibility as a reliable supplier.

Beijing has assured New Delhi that action

would be taken against rogue exporters, and the Centre would continuously ensure that India's reputation is not affected, Mr Mittal said.

Of the Indian drug exports worth Rs 30,000 crore annually, about 15% are shipped to Africa. Other major markets for Indian medicines are South America and south-east Asia.





# Concerns

# Counterfeit Medicines

## *Emerging Views*

1. Innovator Companies : Generic Industry & Drug Regulators not very keen to resolve the issue.
2. Generic Companies & Drug Regulators :
  - Problem not as acute as projected by Innovator Companies.
  - Exploiting situation to fight against generics & parallel imports.
3. Other Group / NGOs :  
Global Pharmaceutical Companies trying to extend IPR to patients' safety issues and have gone to ACTA & WHO IMPACT.

IMPACT- International Medical Products Anti-Counterfeiting Task Force  
ACTA - Anti Counterfeiting Trade Agreement





# Counterfeit Medicines

## Concerns

- ❖ IPR being extended to the definition
- ❖ Even in India “misbranded” drugs are considered counterfeit under - Section 17 of the Drugs & Cosmetics Act.
- ❖ Estimated U.S.\$ 30 billion - 6% of global turnover.\*

\* Albany Law Journal 2006



# Counterfeit Medicines

## Concerns

### *Apprehension of Generic Pharma Industry*

- ❖ Attempt being made to bring generic drugs under counterfeit medicines.
  - 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

## - *Demands Immediate Action*

- Harmful effects on patients' health & can kill
- Frustrate efforts to deal with high burdens of disease
- Undermine health care systems

## Demands....

International collaboration

Simultaneous action on

- legislation
- regulations
- enforcement
- awareness
- innovative packaging technology



# Legislature in India

  
**THE TIMES OF INDIA**  
Powered by Indians

## Help seize fake drugs, get rewarded

### Whistle-Blower Policy Mulls Cash Prize Of Up To Rs 25L For Informer

Kounteya Sinha | [TNN](#)

**New Delhi:** Informing the government about spurious drugs could soon earn you big money. To tackle the menace of fake life-saving medicines, the health ministry has proposed a "whistle-blower" policy that would handsomely reward both the public and officers who inform and help seize spurious, adulterated and misbranded drugs, cosmetics and medical devices.

According to the policy, the reward—a maximum of 20% of the total cost of consignments seized—will be payable to the informer which should not exceed Rs 25 lakh in each case. In respect to an officer in the government or in the Central Drugs Standard Control Organisation (CDSCO), the reward will not exceed Rs 5 lakh for one case and a maximum of Rs 30 lakh in his or her entire service. Under the proposal, the reward will be given only when there is confirmation of the seizure of spurious drugs, cosmetics and medical devices by the designated officers of CDSCO.

According to Delhi minister Ghulam Nabi Azad, since spurious drugs affect the health of citizens as well as the prestige of the country's pharmaceutical trade interests, there will be a sense of urgency in taking on the menace on priority basis. "I propose to introduce a whistle-blower policy to involve public to provide information on any kind of unlawful activity in the manufacture of drugs. There is no dearth of good intentioned people who may wish to work for

**SHOT IN THE ARM**



- The whistle-blower policy proposes a cash reward for an informer that is maximum of 20% of the total cost of consignments seized. The limit shouldn't exceed **Rs 25 lakh**
- For a govt employee, the reward will not exceed **Rs 5 lakh** in a case and a maximum of **Rs 30 lakh** in his service
- For speedy trial, such fake drug cases will be filed before **designated special courts**

The country's interests as a whistle-blower in eradicating the menace. People's participation is imperative in this regard," Azad said.

The proposal says once fake drugs are seized, the government will engage senior advocates to help punish the guilty. To ensure speedy trials, these cases will be filed before designated special courts set up for the purpose of drug-related issues. The Drug Controller General of India will be the nodal officer who will oversee the functioning of the reward scheme. According to the DGCI, the size of India's pharmaceutical industry is Rs 86,000 crore. The health ministry estimates that 5% of drugs sold in India are counterfeit while 0.3% are spurious.



## **Emerging Trends- Pharmaceutical Packaging**

### **Anti-counterfeit measures**



# Anti-counterfeit

- What is Counterfeit?
  - Counterfeiting is manufacturing and selling Spurious drugs using the packaging similar to that of original drug manufacturer.
- Counterfeit leads to :
  - Health risks and lawsuits
  - Loosing consumer loyalty
  - Loosing sales and profits
- GSK is loosing 7% of Sales because of Counterfeiting.





# Anti-counterfeit



Original pack (old) on top and counterfeit pack on side



# Anti-counterfeit



Original pack (old) on top and counterfeit pack on side





# Anti-counterfeit

- Solution to counterfeit:
  - To do something either on the Product or Packaging, which makes the Brand different from its counterfeits and helps in authentication of its genuineness at the point of purchase



# Anti-counterfeit

## Hologram

- Dot Matrix 2-D, 3-D hologram
- Flip action, background text, kinetic movement, Micro text and a laser code



# Anti-counterfeit

## Clear to Cyan

- Patented 3M technology
- Multi-optical layers
- Changes colour to "cyan" during flip action



# Anti-counterfeit

## Retrogram

- "3M" offering
- Holographic images visible to the naked eye.
- Also, a "hidden" image that can be seen through a beam of light only



# Anti-counterfeit

## Confirm

- Patented "3M" technology
- Visible Image + Hidden Feature (visible through a beam of light) + Floating image





# Anti-counterfeit

## Securegram

- "3M" offering
- Visible Image + Hidden Feature (visible through a plastic verifier)



# Anti-counterfeit

## Tampergard

- 3M technology- mainly for carton seals
- Visible+ Hidden features- hidden messages can also be incorporated
- Coloured stickers with a "tamper evident feature"- cannot be put back once peeled off



# Anti-counterfeit

## Coloured Holograms

- All features like a hologram but in colour
- 3-D effect can be incorporated
- High resolution holograms with "nanotext features" can be done. Using E-Beam master





# Anti-counterfeit

## RFID

- RFID uses a semiconductor (micro-chip) in a tag or label to transmit stored data when that tag or label is exposed to radio waves of the correct frequency.
- Also helps in tracking of the product in supply chain



# Anti-counterfeit

## Cryptoglyph

- invisible mark printed on the outer surface of packaging with standard ink and using standard printing systems.
- The mark contains encrypted data in the form of indelible pixels.
- These are detected using an image scanning device, but are almost impossible to reproduce
- The solution also provides instant detection of possible grey market activity by means of camera phone and sms system.
- The security server reacts to the brands Crptoglyph labelling by identifying the coding and then sending an SMS back to the camera phone to confirm if the product is genuine or fake



# Conclusions

With enhanced consumer driven needs , packaging innovations to provide solutions to satisfy the consumers





# **The Way Forward**

# Combating Counterfeiting

*Corporate are part of the solution*



Every company needs to protect :

- ❖ Make it difficult for its products to be counterfeited.
- ❖ Enable authentication of products and its source.
- ❖ Train sales staff to spot counterfeit products
- ❖ Regular testing of samples from market
- ❖ Quick redressal of consumer complaints
- ❖ Storm signal ( mismatch sales figures Internal with ORG/IMS )
- ❖ Close liaison with regulatory authorities

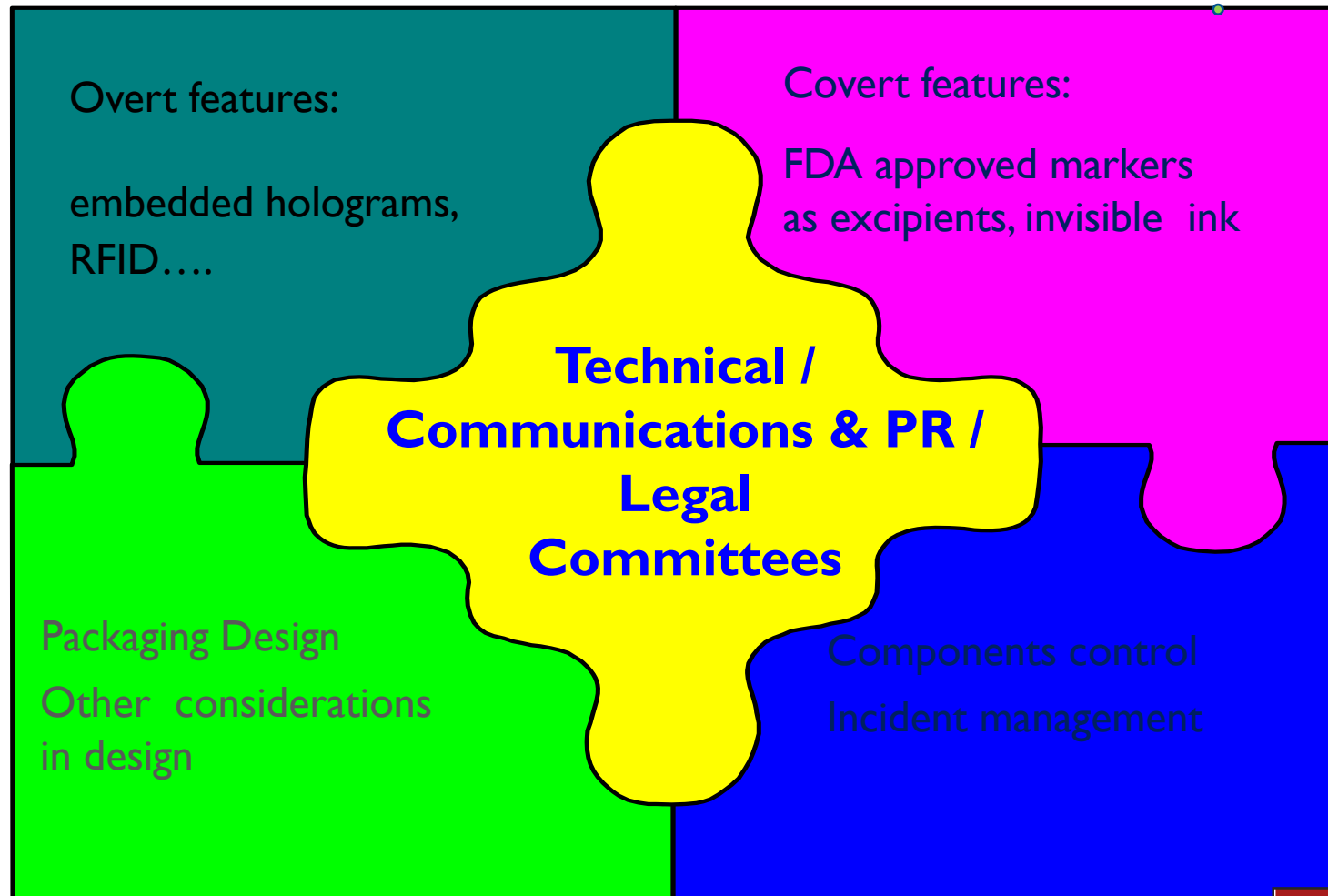
***Only 21% of large pharma companies had a dedicated anti-counterfeiting project team***



# Combating Counterfeiting

Requires an  
integrated  
approach

## OPPI Recommendations:



# 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.
- ❖ < 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 - 15<sup>th</sup> May, 2008



# Combating Counterfeiting

## *Summing up*

- ❖ Counterfeit Medicines : Growing menace against humanity.
- ❖ All stakeholders to join hands to address this public health issue.
- ❖ Packaging technology and creation of awareness play a major role to address this public health menace.







**Thank You**