

‘Fight against Counterfeit Goods and why it matters to us?’



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Seminar on
Counterfeit Products & Their Impact on Consumer Safety
15th Sept, 2009 – New Delhi

Content

Counterfeit Medicines -

- ❖ Definition
- ❖ Perspective
- ❖ Concerns
- ❖ The Way Forward





Definition

Counterfeit Medicines

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



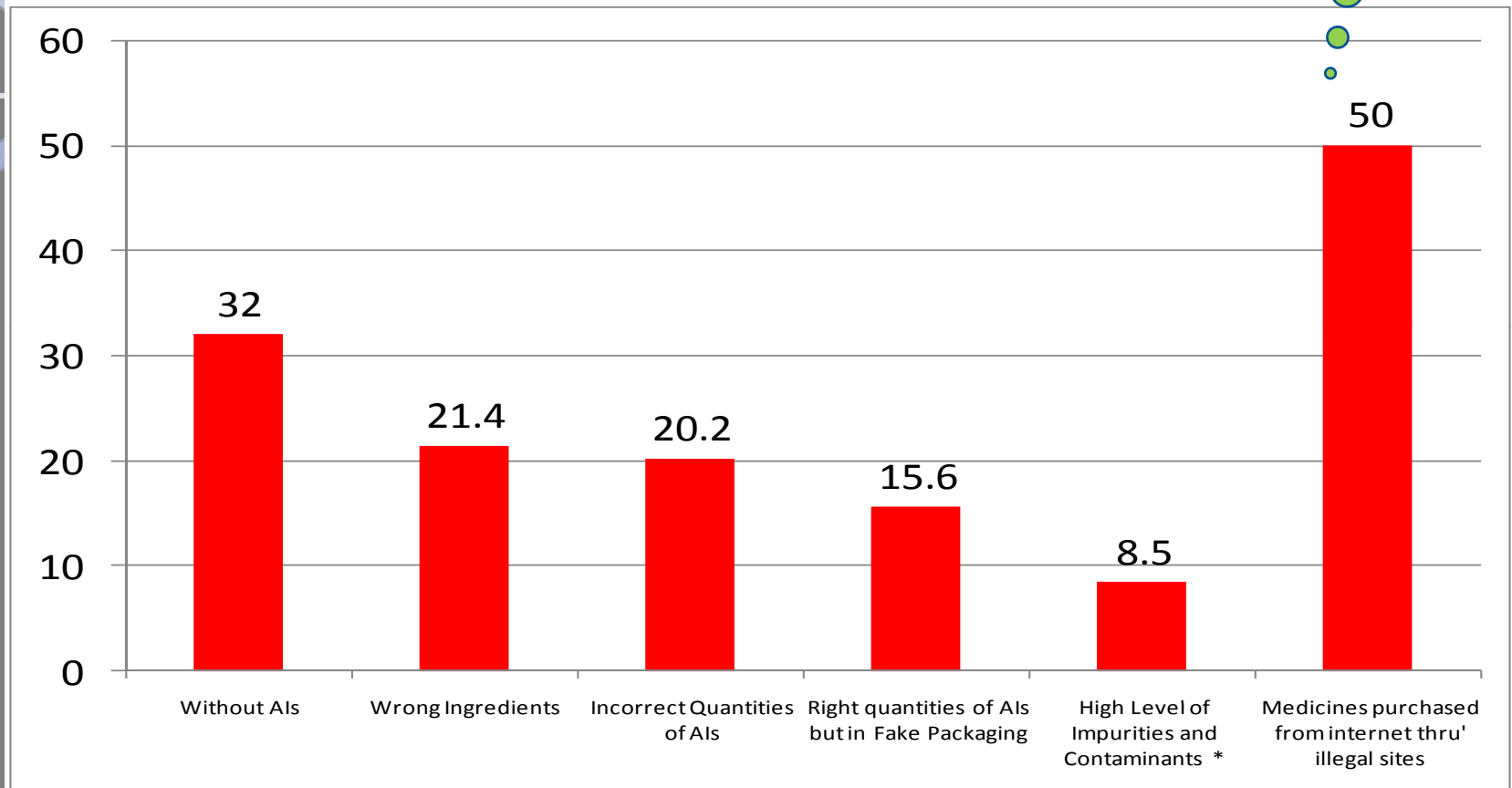


Perspective

Counterfeit Medicines

Various Types

Growing threat to
Global Public
Health



AIs – Active Ingredients

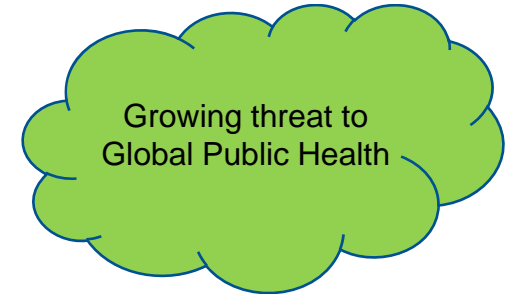
*(Substituted ingredients could be from paracetamol to boric acid, talcum powder, rat poison or road paint)

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.

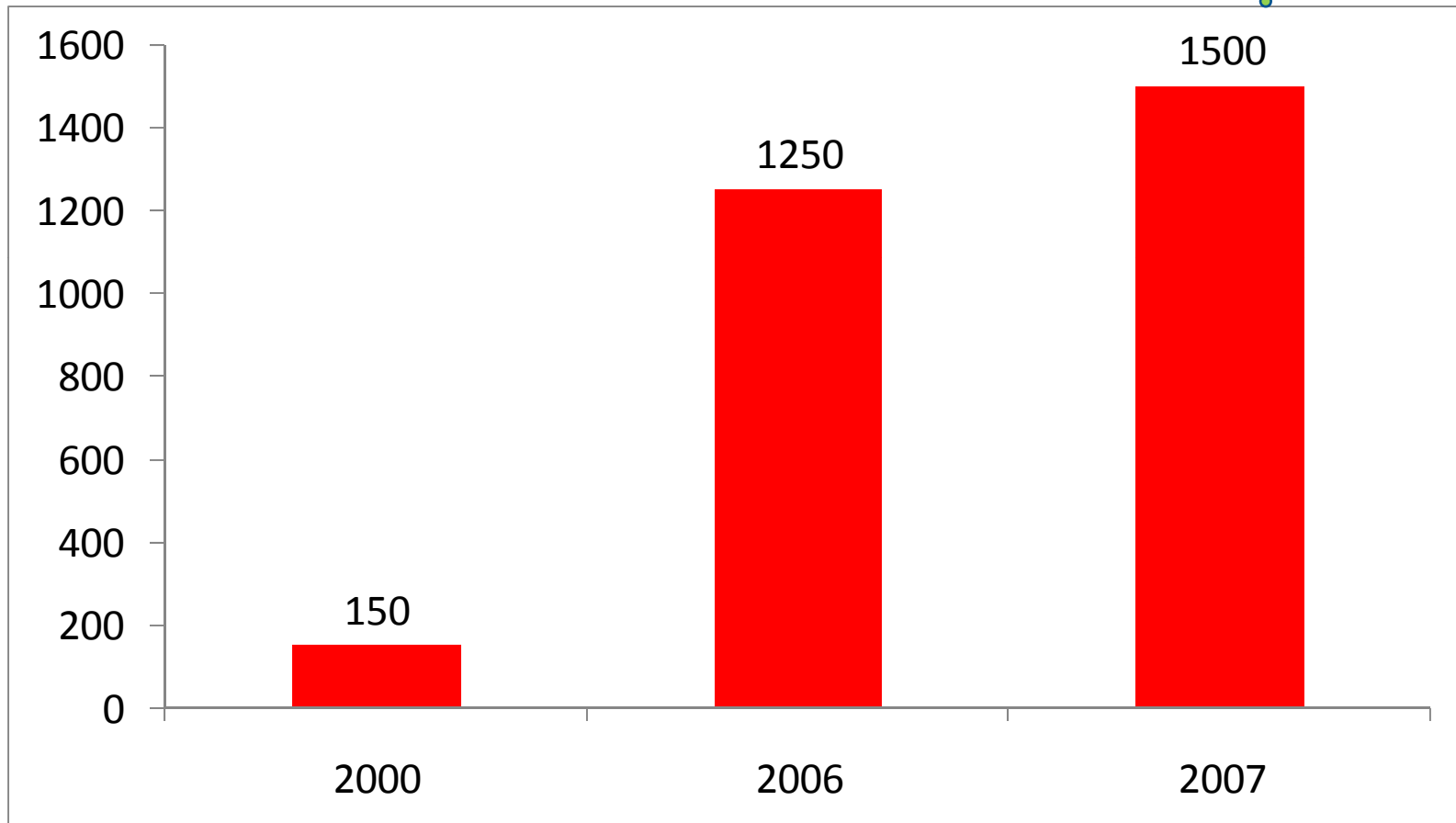
Source: WHO IMPACT 2006



Counterfeit Medicines

- Incidence of Detection

Growing threat to
Global Public
Health



Source: WHO Report

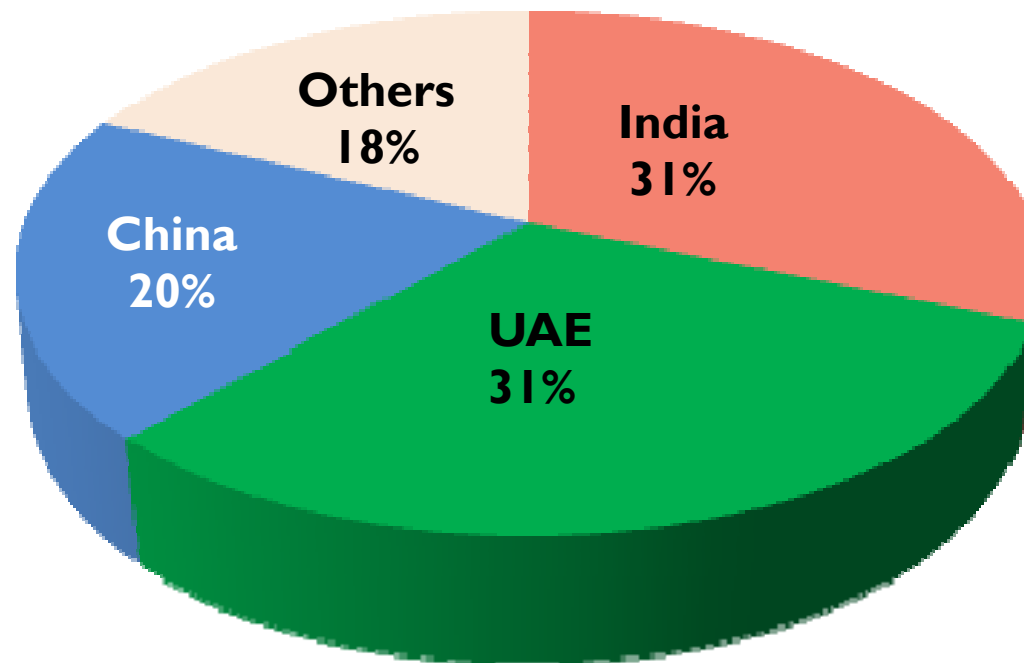


Counterfeit Medicines

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:



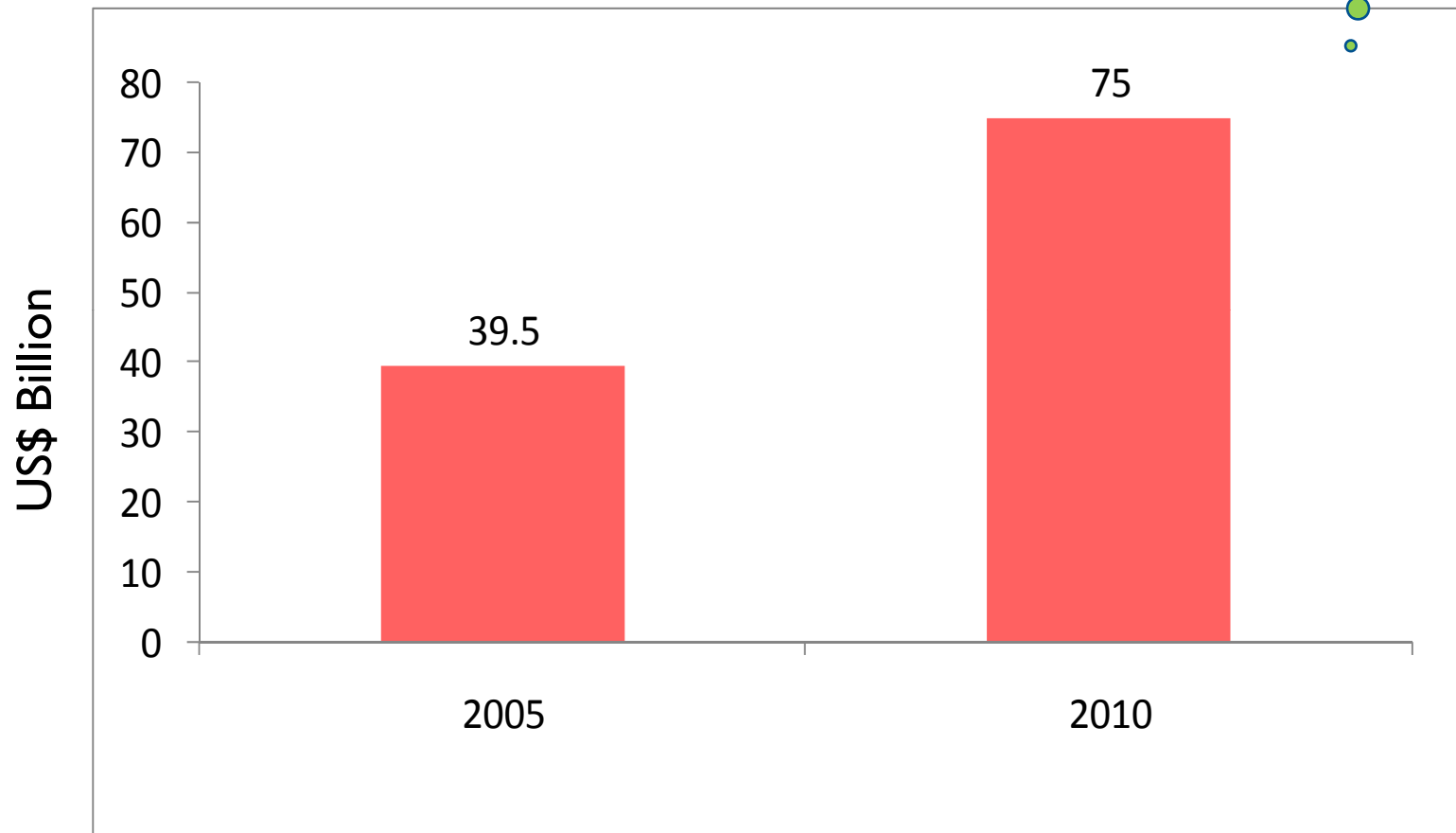
Source: WHO IMPACT



Counterfeit Medicines

Global Forecast

Growing threat to
Global Public
Health



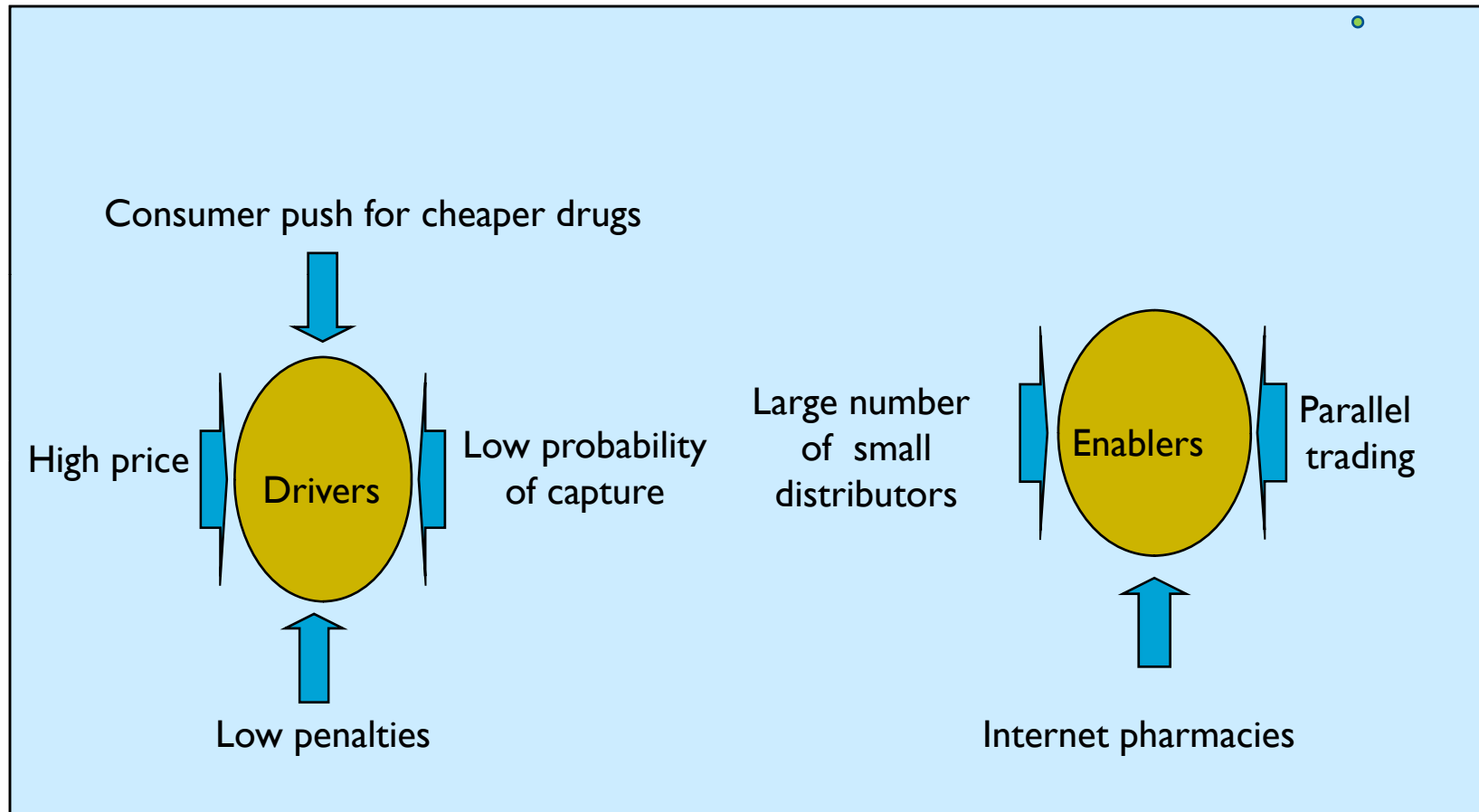
Source: Centre for Medicines in Public Interest - 2007



Counterfeit Medicines

Factors Influencing Flourishing Trade

Growing threat
to Global
Public Health



Low risk/high returns on investment in counterfeit drugs



Counterfeit Medicines

China selling fake 'Made in India' drugs



- ❖ Dented image of industry.
- ❖ No regulatory control :
Quality checks, data on the small scale units making medicines, the location of such drug units, trade is growing unchecked.
- ❖ Copies of well-known brands but contents deadly.
- ❖ Drugs look genuine with good packaging so passed on as genuine .



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



In-transit issues



Monday, December 15, 2008

In-Transit Pharma Consignments, IP Forum Proliferation and the WHO

A very [well researched story](#) from Lison Joseph of the Mint, which I reproduce in full below (critical portions of the piece have been marked in bold).

In my interview to the Mint for this story, I stated that the "in-transit" seizures of Indian consignments (of Pharmexcil member companies) in the EU appear to implicate "patent" rights of EU patent owners. And have nothing to do with trademark issues (since the exports were unbranded API's) or counterfeiting (as traditionally understood) or the WHO's recent moves to expand the definition of counterfeiting (under its IMPACT initiative). Nonetheless, there may be cause to worry about the current trend towards more expansive IP enforcement measures worldwide (through ACTA etc) and the proliferation of international agencies that wish to jump into the IP bandwagon.



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-

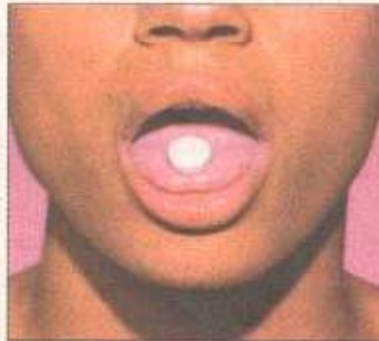
port standards are maintained," Mr Mittal said.

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
- technology and
- communication strategies



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.





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

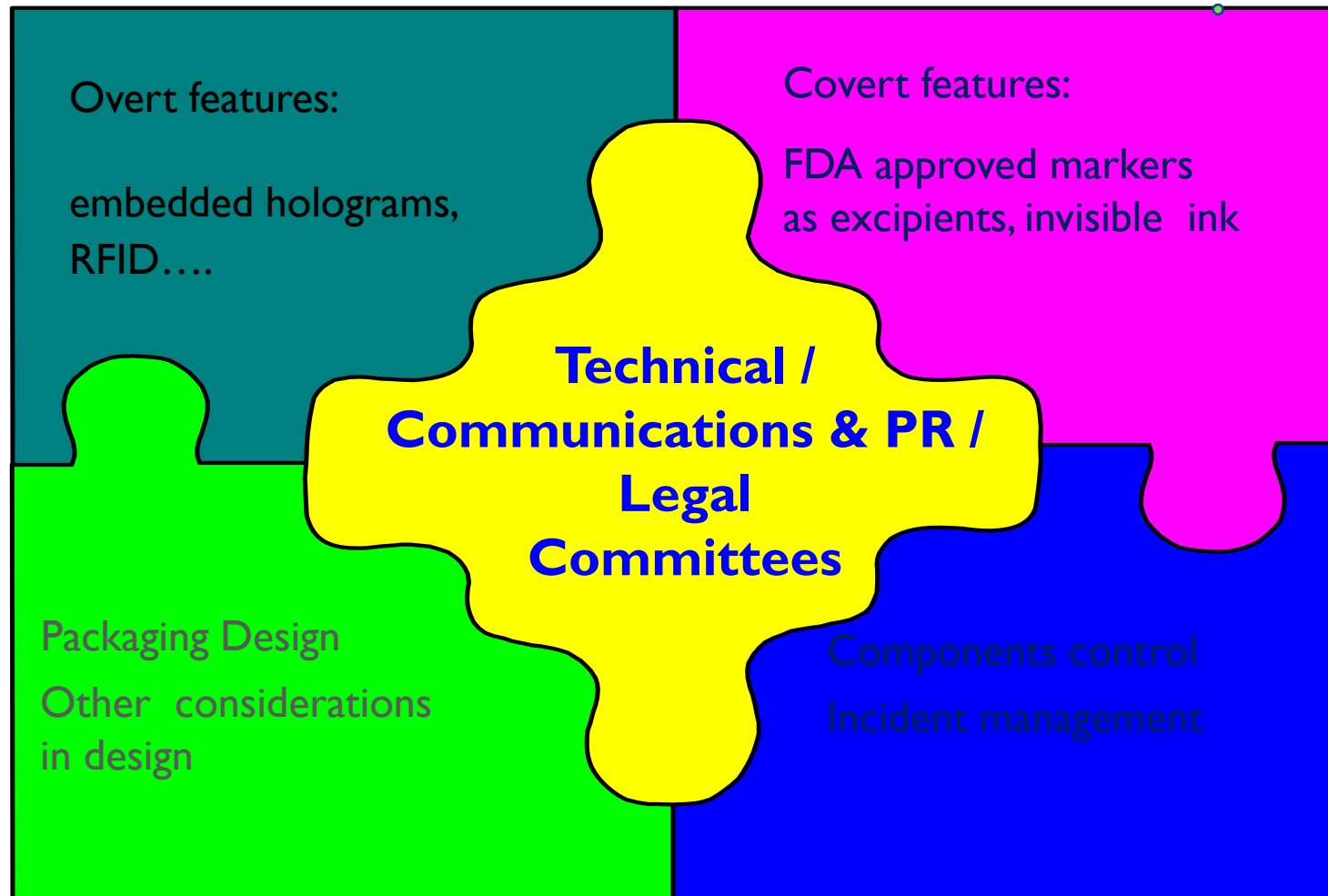
Only 21% of large pharma companies had a dedicated anti-counterfeiting project team



Combating Counterfeiting

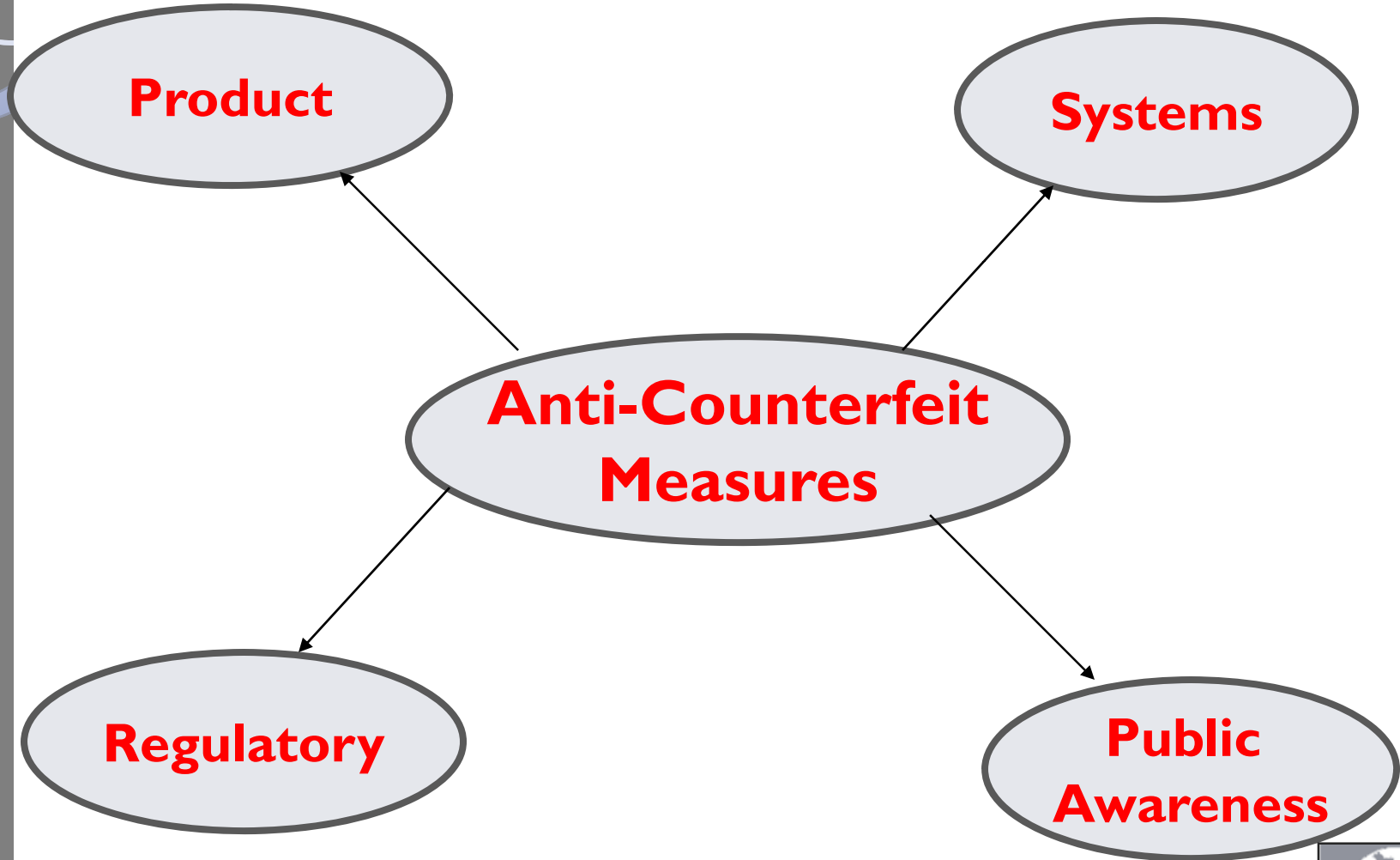
Requires an
integrated
approach

OPPI Recommendations:



Combating Counterfeiting

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 - 15th May, 2008



Combating Counterfeiting

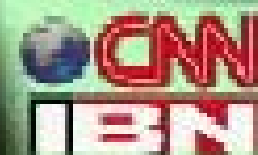
Summing up

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





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Thank You