

Panel Discussion on Counterfeiting Pharmaceuticals: A Crime Against Humanity

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An Ostrich Syndrome

“The extent of spurious drug in retail pharmacy is much below the projections made by various Media CDSCO.”



Almost one in three drugs (36%) found "not of standard quality" from across India last year were from Maharashtra (23%) and Tamil Nadu (13%) alone. – Times of India, August 22, 2012



‘Spurious’ and ‘Sub-standard’ Drugs in India

	2011-12	2010-11	2009-10
Raids / Samples Size	48,082	49,682	39,246
Not of Standard Quality	2,186 (4.5%)	2,372 (4.7%)	1,942 (4.9%)
Spurious / Adulterated	133 (0.27%)	95 (0.19%)	117 (0.29%)
Prosecution for Crime	NA	NA	138
Persons Arrested	141	72	147

Source: TOI 22 Aug 2012



'Spurious' and 'Sub-standard' Drugs in India

States	% Share of Inferior quality drugs
Maharashtra	23
Tamil Nadu	13
Kerala	9.2
Gujarat	8.5
Karnataka	7.2
UP	6.9
J&K	6
Rajasthan	5.8

Health Ministry officials say more than 10,000 drug manufacturers make – and more than six lakh outlets sell-fake drugs



1 in 3 dodgy drugs from Maha, TN

Besides Leading Pack In Sub-Standard Pills, Maha Is Second In Fake Medicines

Kounteya Sinha | TNN

New Delhi: Almost one in three (36%) of “not of standard quality” drugs from across India last year were from Maharashtra (23%) and Tamil Nadu (13%) alone.

Among the other states, Kerala accounted for 9.2% of sub-standard drugs, Gujarat for 8.5%, Karnataka for 7.2%, Uttar Pradesh for 6.9%, Jammu & Kashmir for 6% and Rajasthan for 5.8%.

Union health minister Ghulam Nabi Azad said on Tuesday that of the 48,082 drug samples tested by state drug controllers between 2011 and 2012 (till now), 2,186 samples, or around 4.5%, failed the

NEED FOR STRONG MEDICINE



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quality test. Of these, around 133 samples — almost 6% — were found to be spurious or adulterated, the minister said.

In comparison, 4.9% of the samples tested in 2009-10 and 4.7% in 2011-11 were sub-standard. The maximum number

of samples tested were from Maharashtra (6,928), followed by Karnataka (5,268), Andhra Pradesh (4,758), Tamil Nadu (4,110), Kerala (3,904), Punjab (3,031) and Gujarat (2,874).

Very few samples (283) were tested in Delhi of which

only 13 — around 4.5% — were found to be sub-standard.

As far as spurious or adulterated drugs are concerned — which have no active ingredient or are expired drugs that have been re-labelled and sold — Gujarat recorded the highest number of such samples (64), followed by Maharashtra (19), UP (11) and Delhi (9). Union health ministry officials say there are more than 10,000 drug manufacturers and more than six lakh outlets that sell fake drugs.

Experts say acute shortage of drug inspectors (DI) is hampering the nation's fight against spurious drugs.

The Central Drug Standard Control Organization

(CDSCO), which lays down standards for drugs, estimates that the nation requires 3,200 DIs for its six lakh chemists, but only about 1,000 are available. The size of India's pharmaceutical industry is pegged at Rs 90,000 crore of which 40% is exported.

Azad said “spurious drugs not only affect the citizens' health but also the prestige of the country's pharmaceutical trade interests.”

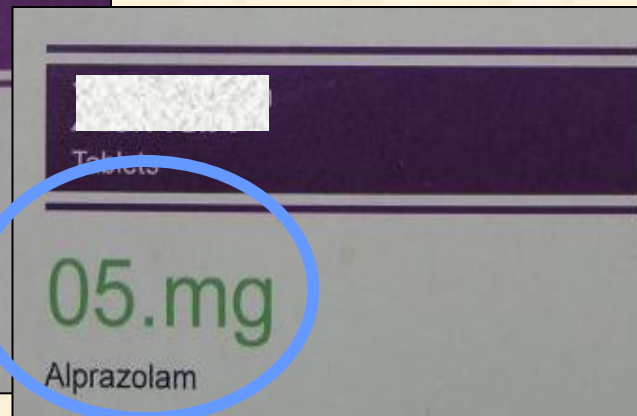
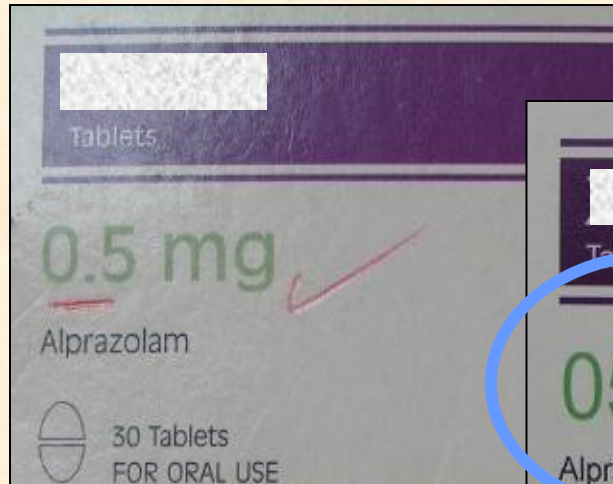
The working group on health for the 12th five year plan has recommended setting up of eight new Central Drugs Testing laboratories for Rs 320 crore, besides upgrading the six existing ones for Rs 15 crore each.



Examples of Counterfeits



Examples of Counterfeits: Less Sophisticated



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

Indian Drugs and Cosmetics Act says...

Manufacturing or selling of following types of drugs are punishable offence:

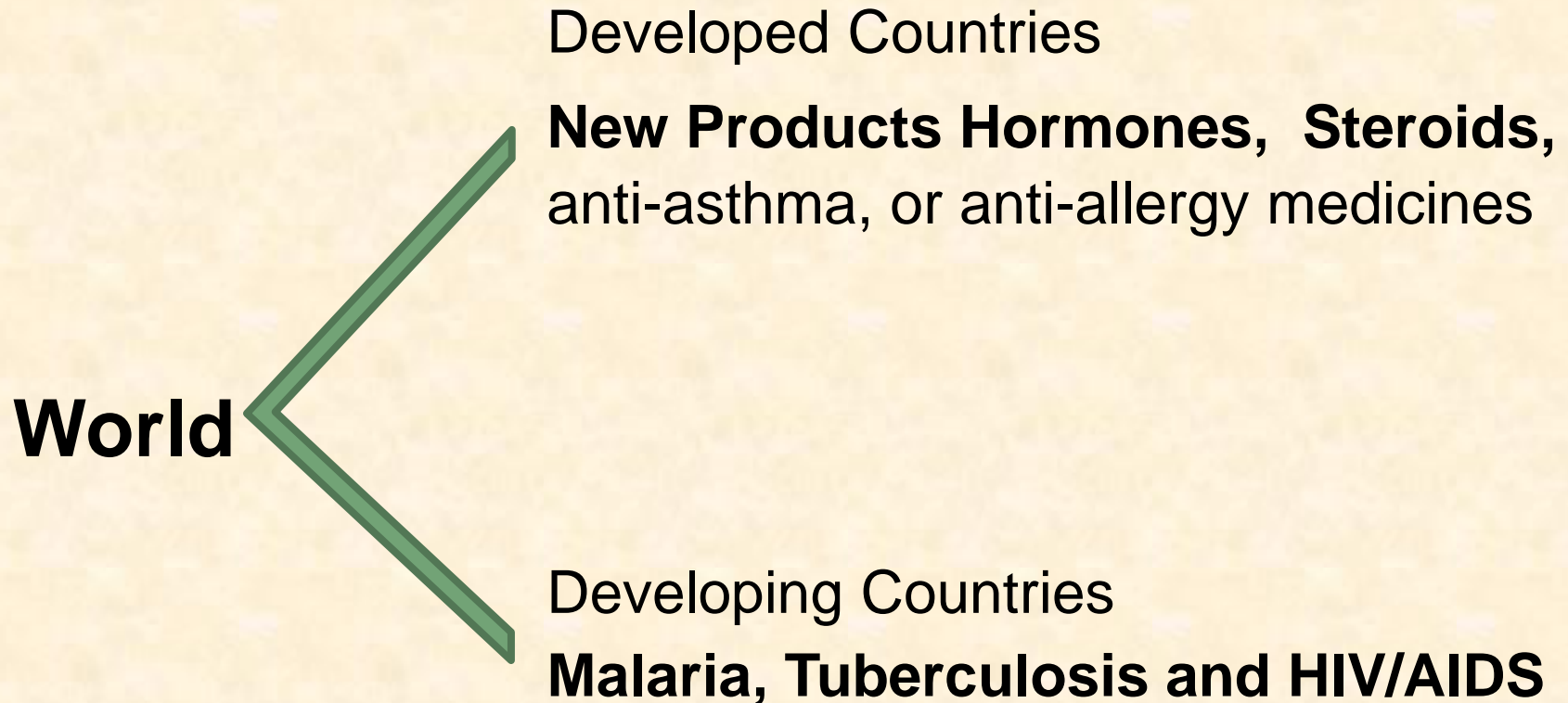
Section 17 : Misbranded drugs

Section 17-A : Adulterated drugs

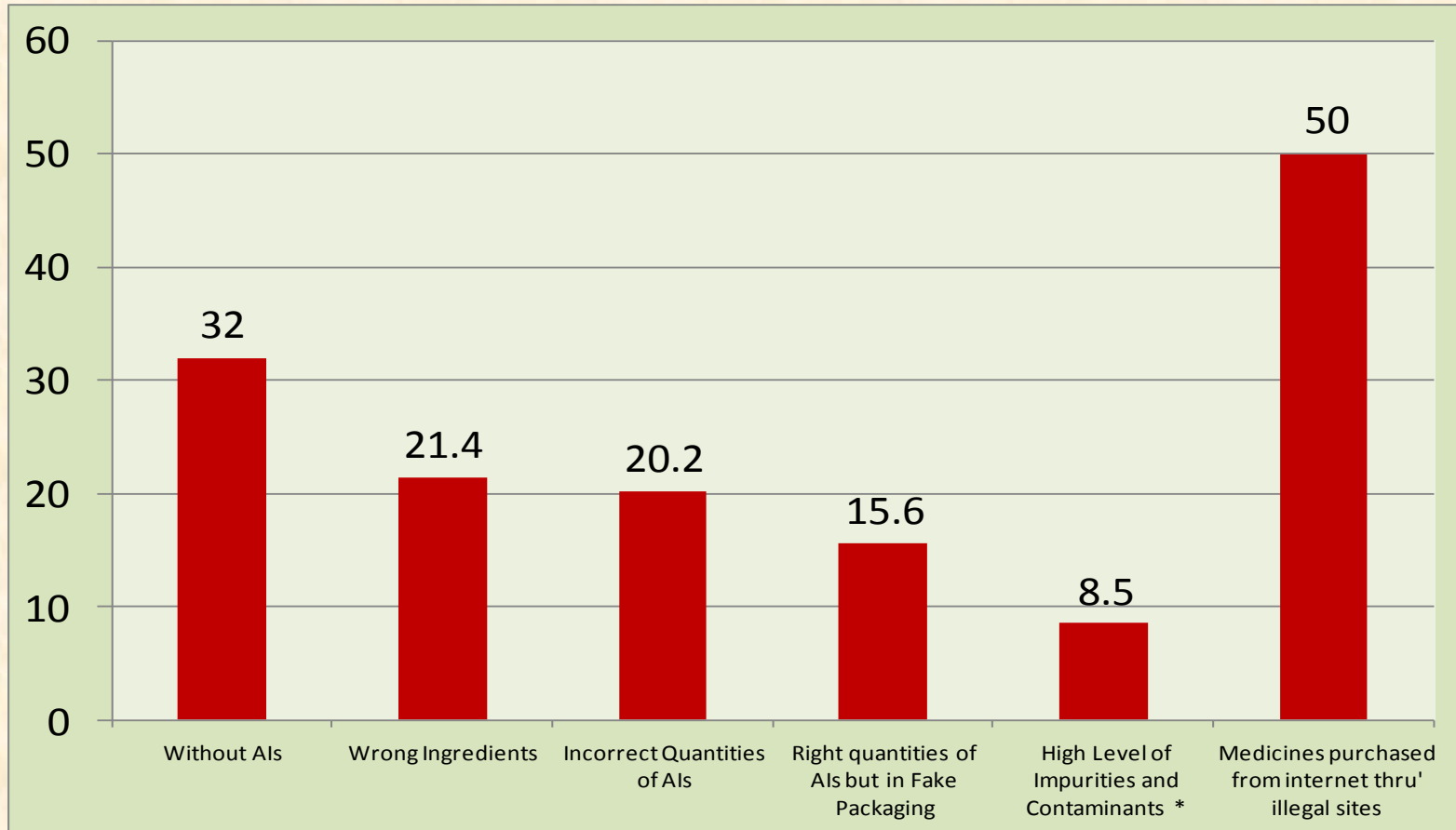
Section 17-B : Spurious drugs



Counterfeit Medicines : Perspective



Counterfeit Medicines : Various Types



AIs – Active Ingredients: * Substituted ingredients could be from paracetamol to boric acid, talcum powder, rat poison or road paint



Counterfeit Medicines : Emerging Global Views

1. **Innovator Companies:**

2. Generic Industry and Drug Regulators not very keen to
3. resolve the issue.

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 Intellectual Property Rights (IPRs) to patients' safety issues and have gone to ACTA and WHO IMPACT.



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.
- ❖ < 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.



Counterfeit Medicines : Demands Immediate Action



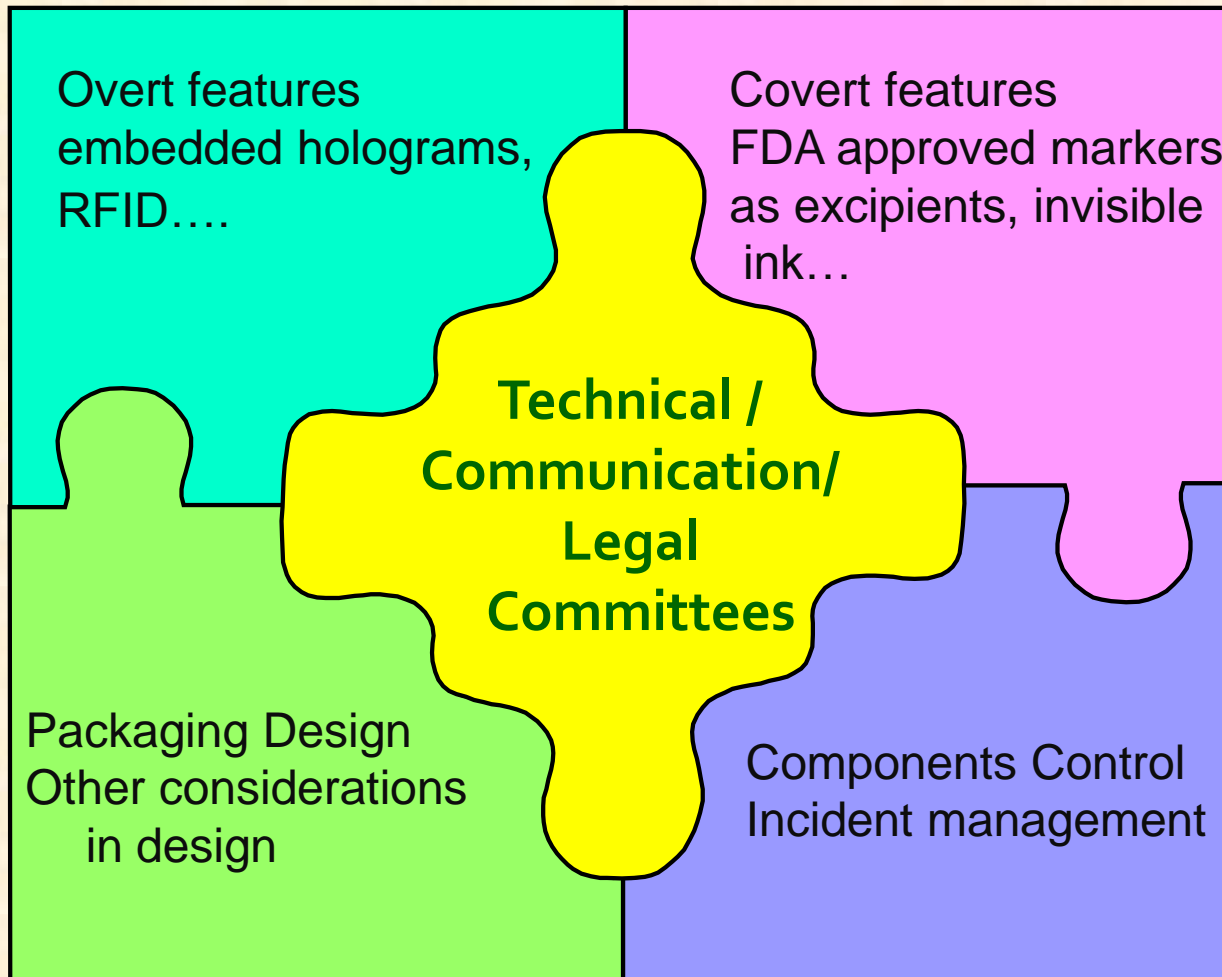
- ❖ Legislation
- ❖ Regulations
- ❖ Enforcement
- ❖ Technology and
- ❖ Communication Strategies



Combating Counterfeiting

Requires an integrated approach

OPPI Recommendations



Recent Steps Taken by the Government

- ❖ The MoH amended Anti-counterfeit Law of the Drugs and Cosmetics Act in 2009:
 - a. Maximum penalty of life imprisonment and fine of INR 1 Mn. or 3 times the value of the confiscated goods, whichever is more.
 - b. Offences are non-bailable.
 - c. Specially designated courts for trial of offences
 - d. Provision for compounding of minor offences.
- ❖ Whistle Blower Policy



Counterfeit Medicines

- Allahabad High Court's Directive

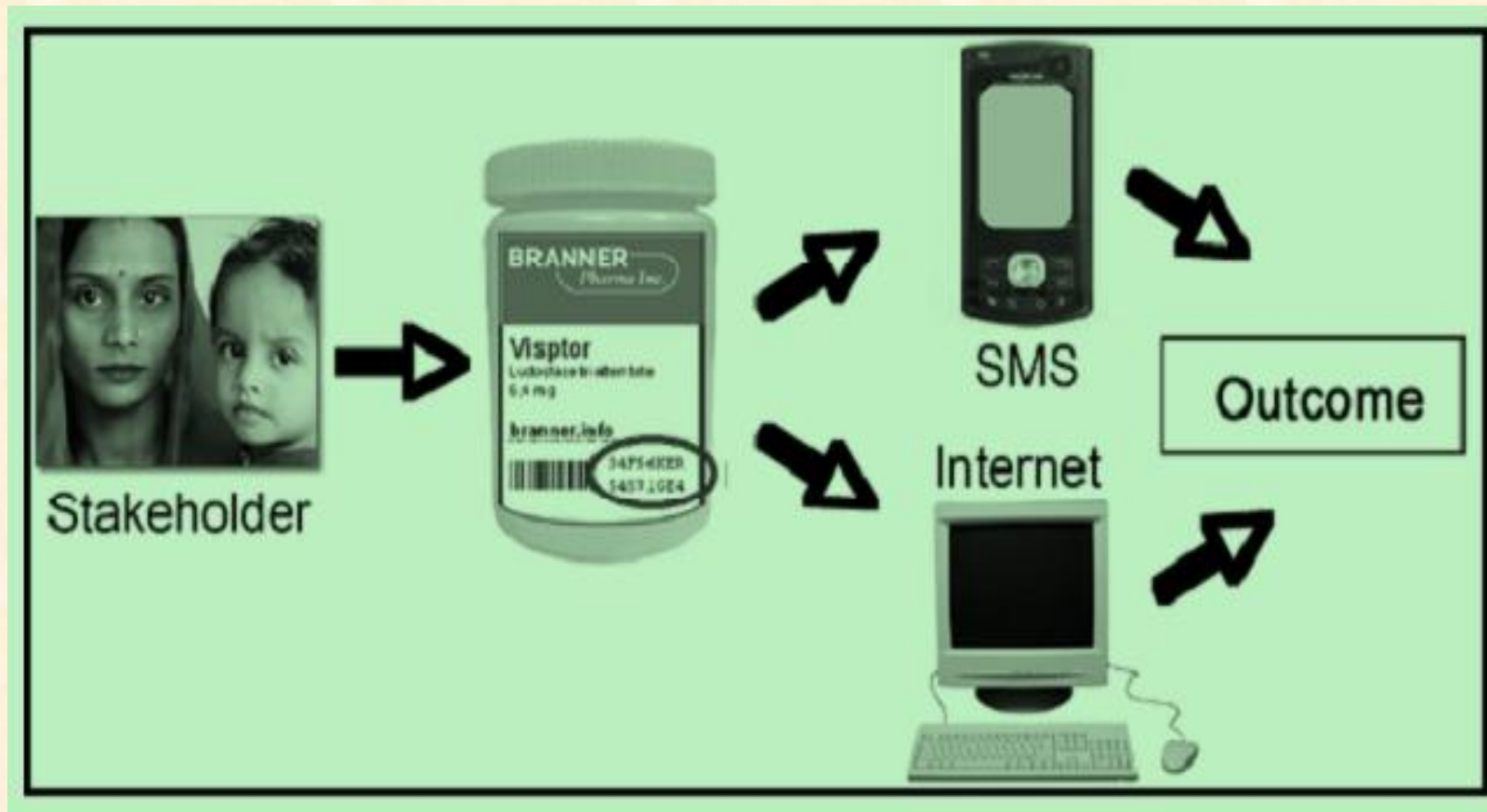
On all Pharmaceutical Product Packs in India:

- ❖ A unique ID
- ❖ Bar coding for all pharmaceutical products in India including exports

Being worked out by the 'Central Drugs Standard Control Organization (CDSCO)' of India.



Use of “Unique Identifier Code”



'Track & Trace Technology' for Pharmaceutical Exports from India

- ❖ Use of barcode technology as per GS 1 global standards at primary, secondary and tertiary level packaging.
- ❖ Encoding unique product identification code (GTIN), Batch Number, Expiry Date and Serial Number of the Primary pack.
- ❖ 'The track and trace technology' will come into effect from 1st July, 2011.



Recommendations of the Sub-Group

Sub-group on spurious and adulterated drugs three meetings in 2011 - Chairmanship of Dr. A. K. Panda, Jt. Secy., MoHFW

- I. Regular Testing of Drugs as Survey Samples:
- II. Strengthening of Central and State Drugs Control Departments including Laboratories
- III. Special Training Programmes for Regulatory Officials
- IV. National Network of Enforcement
- V. Nomination of Nodal Officers for States, UTs and CDSCO
- VI. Regular sampling of drugs U/S 23 of the D&C Act through Notified Drug Inspectors
- VII. Registration of Printers of Pharmaceuticals Packaging Material
- VIII. Setting up of a Special Intelligence Cell in Drugs Control Department
- IX. Awareness Programme for all Stakeholders
- X. Special Designated Courts
- XI. 'Whistle Blower' scheme



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