Combating Counterfeit Medicines
Challenges & Solutions

XXXIII
ALL INDIA STEEL MEDICAL OFFICERS’ CONFERENCE

VISAKHAPATNAM STEEL PLANT
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Presented by M & M Technologies P. Ltd.
— Meenaxee Padhy
Combating Counterfeit Medicine

- A Boon for Manufacturers.
- A relief for the Society.
- A challenge for the public health.
- A determination for the Government.
- An empowerment to the Regulatory Authority.
- An enhancement to ethical growth.
- A fierce battle against the criminalism to survive with dignity.
Objective

Definition of Counterfeit Medicine

Public Health challenges

Threat and Consequence

Impact on Stakeholders

Global Scenario

The Grim situation in India

Smart Solution by M&M

Overview of Technology

Q & A
Today’s presentation aims at very clear and distinctive objectives.

1. Raise the awareness level among the Stakeholders on how grave is the counterfeit trade of medicine.
2. It’s challenges and Solutions
3. Highlighting on the Technology for solution.
4. Identifying the role of Each Stakeholder in support and help to mitigate the problem.
Definition

- No **Unified** definition of counterfeit.
- **Empirical, Reliable and Transparent statistic** about drug counterfeiting virtually non-existent.
- In absence of the universally accepted definition; it makes difficulty in –
  - Exchanging information between the countries
  - To gauge the magnitude of the problem globally.
WHO was categorised the counterfeit Drugs as under:

1. Products without active ingredients (API)
2. Products with incorrect quantities of active ingredients (API)
3. Products with wrong ingredients.
4. Products with correct quantities of active ingredients but with fake packaging.
5. Copies of an original product.
6. Products with high levels of impurities & contaminants.
Threat & Consequence

- Violets copyright of **IP (Intellectual Property).**
- Constitute Crime against **Humanity.**
- Dismantle **Public Healthcare System.**
- Paralyses **Cross Border Legal System.**
- Jeopardize **Regulatory System.**
- Betrays the vulnerability of **Pharmaceutical Supply Chain System.**
- Loss of confidence in **Drug Control & Enforcement of Drug Law.**
- Failure in **Therapeutic efficacy.**
- Worst Case Scenario – **FATAL**
# Impact of Counterfeit Medicine

## Impact

<table>
<thead>
<tr>
<th>Category</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumer</td>
<td>• Damage to health and safety</td>
</tr>
<tr>
<td></td>
<td>• Increase in Treatment Cost</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>• Lost Sale &amp; Revenue, Loss of Brand Values</td>
</tr>
<tr>
<td></td>
<td>• Damage to Public Image</td>
</tr>
<tr>
<td></td>
<td>• Decreased incentive to Invest on R&amp;D,</td>
</tr>
<tr>
<td>Government &amp; Regulatory Authority</td>
<td>• Loss of Tax Revenue, Cost of IP Enforcement</td>
</tr>
<tr>
<td></td>
<td>• Risks of Infiltration by illegal trade</td>
</tr>
<tr>
<td></td>
<td>• Civilian safety &amp; National Security at stake</td>
</tr>
<tr>
<td>Economy as a whole</td>
<td>• Lower Economy Growth</td>
</tr>
<tr>
<td></td>
<td>• Lost Revenue from declining legitimate Trade</td>
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Intention That **KILLS** !!

- **No respect for Human life**
  - Opportunists and criminals operating globally
  - **Least Regard** for Public Health

- **Easy Money Earning**
  - Easy Money.
  - Low manufacturing cost,
  - No safety standard, no quality control...
  - Leads to Huge earning !!
How Do They Look Like!!

Counterfeit Metakelfin: Uganda

Source: Counterfeit Metakelfin: Uganda

Source: Caribbean Poison Information Network

Source: Pfizer Inc.

Contd..
How Do They Look Like!!

Can you make out the difference?

Source: Caribbean Poison Information Network

Source: Pharmaceutical Research Manufacturers Association in Taiwan

Source: IPI-USPTO-EAC Conference on Anti-Counterfeiting 2010
Why, How and Where?

- Easy Money
- Illegal Internet Trade
- Inadequate Legislation, Regulation and Enforcement.
- Ineffective cooperation among Stakeholders.
- Corruption and conflict of interest
- Lack of Awareness
- High cost of medicines
- Demand exceed supply
- Lack of political will
- Weak law Enforcement
Filthy environment, even garages .....  

Clandestine setup  

No quality check  

No FDA approval  

No safety measures  

No GMP (Good Manufacturing practice)  

All imitation : Look Alike
Why, How and Where?

Counterfeit Manufacturing Facilities

Source: Pharmaceutical Research Manufacturers Association

Source: Instituto Nacional de Medicamentos – ANMAT, 2008

Source: Caribbean Poison Information Network

Source: Instituto Nacional de Medicamentos – ANMAT, 2008
The methods of storage and production (cement mixer) discovered during a raid on a counterfeit drugs manufacturer in Haryana State, India, 2008.

Source: A Safe Medicines Chest for the World
Why, How and Where?

Counterfeit Medicines Flows

<table>
<thead>
<tr>
<th>Route</th>
<th>Source</th>
<th>Vector</th>
<th>Destination</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>China &amp; India</td>
<td>Sea &amp; Air</td>
<td>South – East Asia &amp; Africa</td>
</tr>
</tbody>
</table>
Why, How and Where?

Source: A Safe Medicines Chest for the World
Killer Internet Pharmacy

Sources: Interpol
Global Scenario

- Counterfeit Trade is no more a closed door practice.
- The Lucrative criminal activities spread over Globally in varied percentage.
- Difficult to ascertain the Accurate, Empirical Statistics.
- WHO has been spearheading the movement against this deplorable Practice.

Contd ..
The Center of Medicines in the Public Interest in United States estimate the Global Counterfeit Drug sale up to **US$75 Billion in 2010**.

An Increase of **90%** from 2005

**Source:** WHO (Report 2006) (INCB Report: Press Release)

Contd...
Global Scenario

- In developed countries it is most frequently new & expensive lifestyle medicine.

- In developing countries the counterfeit of medicine mainly attributed to life saving drugs like – Anti malarial, Tuberculosis and HIV/AIDS including children Cough Syrups.

- The condition is worse in poor countries where regulatory and Legal oversight are the weakest.

Contd . .
Global Scenario

**Incidents - Regions of the World**

- **Asia**: 1073 incidents
- **Latin America**: 348 incidents
- **Europe**: 327 incidents
- **Eurasia**: 255 incidents
- **N. America**: 201 incidents
- **Near East**: 138 incidents
- **Africa**: 48 incidents

**Total No. of Incidents by Year**

- **Y 2002 – Y 2010**

Source: Confederation of Indian Industry (CII)

**Online Pharmacy Host Location 2009**

- **USA**: 50%
- **Russia**: 17%
- **Panama**: 11%
- **Canada**: 5%
- **U.K.**: 5%
- **India**: 6%
- **New Zealand**: 6%

Source: Pharmaceutical Security Institute (PSI)

The European Commission EC 2006 – On Counterfeit Seizure

The report states “in the medicines sector, India is the number one source, followed by the United Arab Emirates and China.”
Back at Home – India

- VERY GRIM.
- Blooming export market share of $8.5 Billion.
- A Hub of Illicit Trade of medicine and narcotics: INCB
- World’s largest manufacturer of generic drugs, has become the Center for Counterfeit and Substandard Medicines - The Washington Post

Contd..
Fake medicines are being paddled to different countries with an **Indian Tag**.

In 2010 a huge fake drug racket was being exposed in Chennai selling **expired medicines**.

Various state Drug Control authorities reveal the circulation of counterfeit drug – **0.3%**.

Independent estimation goes up to **20% - 25%**.

WHO reports **35%**.
The Drug and Cosmetic Act 1940 been amended to Drug & Cosmetics (Amendment) Act, 2008.

Stringent penalties and punishment for those found guilty.

DGFT implemented Traceability for All Stage of pharma packaging.

At par with Global Requirement.

Industries focus on Newer Technologies to Control Counterfeit.
Flow Chart of Pharma Distribution Network

- Manufacturer
- Warehouse
- C&F Agent
- Distributor
- Stockiest
- Intermediary Trade
- Internet Trade
- Pharmacy
- Sub Stockiest
- Pvt. & Public Hospitals
- Unwitting Customer
- Legitimate
- Illegitimate
- Counterfeit & Genuine

Flow: Manufacturer to Warehouse to C&F Agent to Distributor to Stockiest to Intermediary Trade to Internet Trade to Pharmacy to Pvt. & Public Hospitals to Unwitting Customer

Legitimate: Manufacturer to Warehouse to C&F Agent to Distributor to Stockiest to Intermediary Trade to Internet Trade to Pharmacy

Illegitimate: Counterfeit Manufacturer to Counterfeit Distributer to Internet Trade to Pharmacy
solution

Nuts & Bolts
Who holds the key to the solutions?

The Stakeholders

- The Manufacturers
- The regulatory Authorities
- All Intermediaries in Supply Chain Network
- The Pharmacies
- The Doctors
- Hospitals

Contd . .
Each stakeholder holds the KEY to the solution in different magnitude !!

Role of Each Stakeholder is Remarkable significant.
Measures & Solution

- Monitoring & Evaluation
- Appropriate legislation
- Empowering the Judiciary
- Strengthening Political Will & Commitment
- Enforcing Drug Control Laws

At all International, National, Regional and Sub Regional Level.

Contd . .
Measures & Solution

- Fostering Partnership.
- Sharing Responsibilities.
- Mobilizing the Community
  - Importer, Custom Officers
  - Intermediary.
  - Health Professionals
  - Consumers.
New Thinking - Streamlining

Environment

Good outcomes

- Safe, effective, good quality drugs available
- Appropriate information
- Rational prescribing
- Appropriate dispensing practice

Drug regulatory structures + Drug regulatory processes

Drug regulation outcomes

- Substandard, counterfeit, toxic and useless drugs
- Inappropriate information
- Irrational prescribing
- Inappropriate dispensing practice

Health outcomes

- Better treatment of illness
- Better prevention of disease
- Decreased morbidity and mortality

Bad outcomes

Drug regulation outcomes

- Drug resistance
- Treatment failure
- Adverse drug reaction
- Increased morbidity and mortality

Environment
SMART
SOLUTION
BY
M & M

Simple Multipurpose Adaptable Reliable & Tested
SMART Solution from M&M

Features of ‘I – Key’

- Unique Distinctive identification Code
- Secured, Coveted Taggant System
- Innovative, Proven & Commercialized
- Maintained in GAD System

Contd . .
SMART Solution from M&M

Unique Distinctive Identification Code?

- Designed & Developed by Denso
- Public & Private data encoded
- Secured and Dynamic
- Difficult to copy / clone
- Authenticate Product Before Buying.

Contd ..
SMART Solution from M&M

It is the simple answer to the Big Question:

How do we know it is – What it claims to be?

QR Code + Security Function = Security QR Code (SQRC)

Contd ..
GAD System – Global Authentication Database System

How does **GAD System by M & M** Work?

1. GAD System is **Inaccessible** to everyone.
2. Only Authorized Person in Plant have access.
3. GAD records movement of products from plant to pharmacy outlet in **Pre-determined** manner.
4. Provides market **Intelligence Report**.

Contd . .
SMART Solution from M&M

Effective Tool for Supply Chain Systems.

Unfold Real Time / Geographic Zone.

GAD prohibits unofficial transport Route.

GAD System identifies Wrong Location identity.

Maintains Parent-child relation.
SMART Solution from M&M

GAD assist Stakeholders in

1. Supply Chain Management
2. Authentication Management
3. Recall System Management
4. Traceability Management
How does it Work?

- How does GAD Communicate with Stakeholders?

INFO

Consumer - Camera Mobile
Distributor - Scanner
Manufacturer - Scanner
Authority - Scanner
How GAD System Works!!

1. Manufacturer
   - Code generation Request for a batch
   - With all details CODE Generated are sent to the Code Printing System
   - Packing and dispatch Notify to Server

2. Code Printing System
   - Distributer confirm receipt of package

3. Distributer
   - Confirm receipt of package
   - Send Secret code to server for Validation / Verification / receiving return response

4. Packager

5. Application Server
   - Incase of investigation & verification

6. Web Server

7. Database Server

8. GAD System By M&M

9. FireWall

10. Pharmacy

11. Consumer

12. Regulator

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ROLE OF STAKEHOLDERS

Patients

Government
Pharmacy
Hospital
Doctors
Manufacturer
FDA
Role of Manufacturer

STANDARD QUESTIONS . .

? Will it Work?

? Will it Worth Investment?

SIMPLE ANSWER:

✓ The Key Issue is not just adopting the technology, But the Right Technology.

Contd . .
Role of Manufacturer

- The key to the solution **Starts with the Manufacturer.**

- Strong Business **Code & Conduct.**

- To adopt and implement the **Right technology.**
  - To empower **product level authentication.**
  - To provide clear asset in **terms of Anti – counterfeiting Impact.**
  - To portrait **Brand Protection** in terms of **Brand Evolution.**
Role of Doctors

• Play **Proactively** in their role to eliminate counterfeit drug.

• Doctors wield an awesome influence on patient’s healthcare.

• Uphold ethical practice.

• Work for **ultimate good** of patients.
Role of Doctors

- Ensure to source the medicine from **Credible Source**.
- Counsel the patient to check the authentication measure before buying.
- Educate them to report any deviation in case of **falsified** medicine intake.
- Encourages your patient to take up issue with **FDA / Any Grievance Cell**.
Role of Hospitals / Hospital Pharmacies

- Play important role at his Critical time.
- Ensure the supply source to be Genuine / Credible sources.
- Be aware of the problem of counterfeit medicine.
- Ensure the safety of medicines administered to the patients.
- Educate the patients / Staff / Pharmacies to use the anti-counterfeiting Tools to ensure the Patients safety.

Your Pharmacist: A Partner in Drug Safety
Need to be alert for the act of miscreants.

Play crucial role in control of counterfeit supply.

Can insist on strictly following the Anti counterfeit Tools by the manufacturing source.
Technology can not stand alone.

It is a Big Task!

- Massive load on Government to Comprehend and Formulate.
- Drug Control Authority to Comply With
- Manufacturers to Adhere.
- The Consumers to be Alert.
- Respect to LIFE.
Not Just adopting the Technology,

Adopting The Right Technology

THANK YOU