



# **REASONS FOR COUNTERFEIT DRUGS IN INDIA**

a part presentation from the on-going dissertation

**“Global Threat of Counterfeit Drugs –  
A Study Covering Extent of Problem and Anti-  
counterfeit Measures in Europe & India”**

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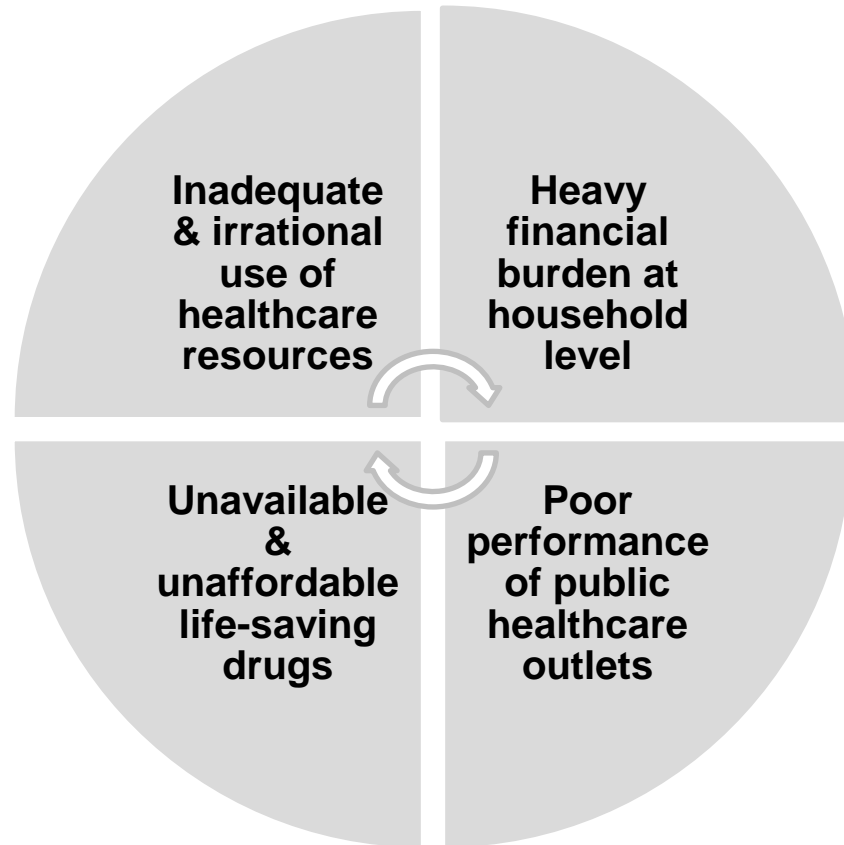


# Reasons for counterfeit drugs in India

- Poverty
- Inadequate health system
- Inadequate regulatory infrastructure
- Lack of enforcement of existing laws
- Weak penal actions
- Lack of coordination between various agencies
- Agglomerated and uncontrolled retail outlets
- Insecure distribution network
- Corruption and conflict of interest
- Internet sale of drugs



# Socioeconomic constrains & inadequacy of health system





# Socioeconomic constraints & inadequacy of health system

- Govt. Health spending LT 1% of GDP among the lowest in the world
- State budgetary allocation at minimal level
- 94% of healthcare expenditures are out-of-pocket at household level
- Near absence of social security system is impoverishing 20 million people annually just because of medical expenses
- The treatment of a single episode of TB costs 83 days of wages loses to a poor family



# Socioeconomic constraints & inadequacy of health system

- Irrationally framed national list of essential medicines which do not address real need (drugs for anemia, TB, malaria, ORS, vaccines are largely absent from the list)
- 40% of population do not have access to essential drugs. Three out of four public hospitals do not have life-saving drugs regularly available
- The performance & infrastructure of public health outlets even below WHO minimum standards
- Highly corrupt procurement system which makes quality compromised drugs easily available through public health outlets



# Corruption & conflict of interest





# Corruption & conflict of interest

- **Lentin commission report of 1986**

- Death of 14 patients in a Mumbai public hospital due to diethyl glycol poisoning. The liquid was actually a mixture of diethylene glycol 18%, polyglycol 51%, water 21% and glycerol 9%
- Lentin commission report concluded corruption in the procurement system, conflict of interest, favoritism, political interference and misuse of power to main causes of the tragedy
- After 25 years of the report, no actions were taken against responsible officials
- Mashelkar committee report of 2003 gave again the same reasons for the problem of counterfeit drugs in India
- Learned lesson: how to by-pass the prosecution!

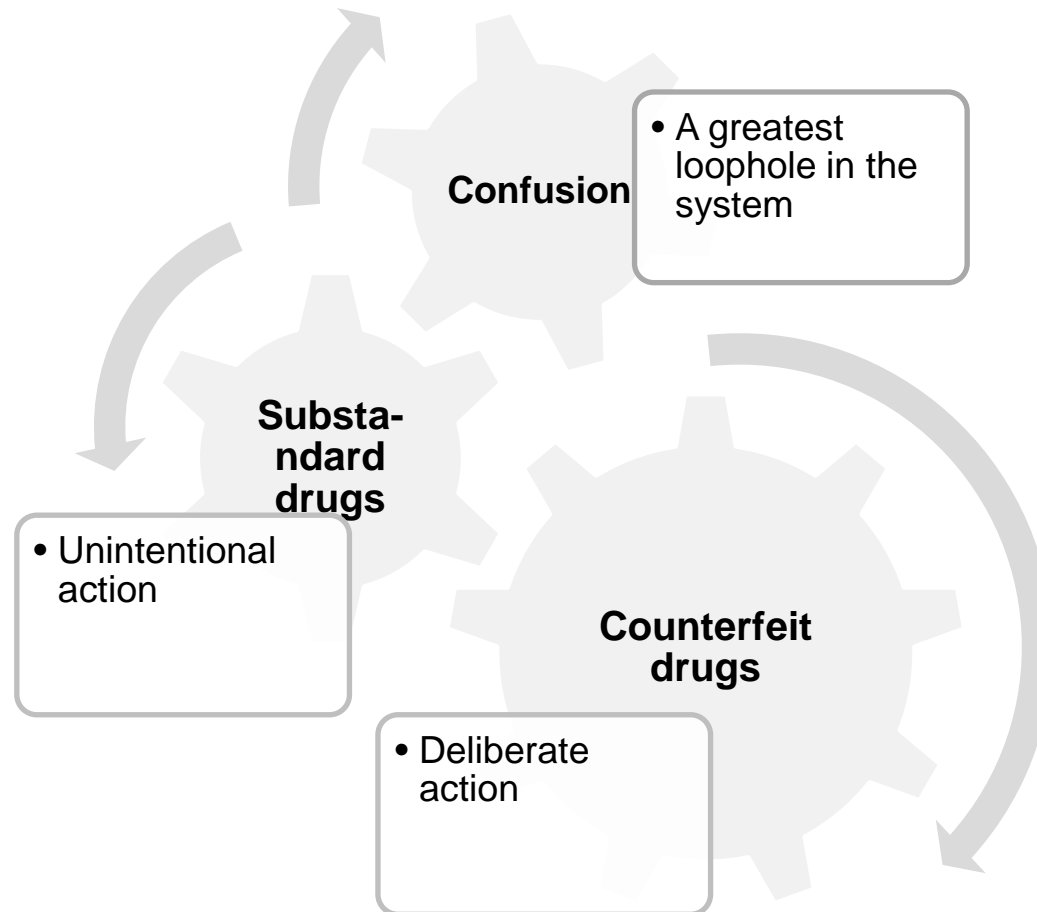


# Corruption & conflict of interest

- **Lucrative trade of recycled medical waste & expired drugs**
  - India produced 800 million syringes annually against which were used 3.7 billion times, meaning that each syringe was used more than four times!
  - In March 2009, 57 people were killed due to acquired Hepatitis B infection in Western state of India. The investigation leads to multi-million dollar racket of recycled medical waste
  - In April 2010 from the dump yard of two southern Indian cities police seized expired drugs from a leading pharmaceutical company worth millions
  - Since the state drug control authority has no system to monitor and assure that expired drugs are indeed being destroyed in an appropriate manner, no wonder that they are easily re-circulated in the market



# Inefficient drug regulatory system





# Inefficient drug regulatory system

## **Changes are NECESSARY**

- Gap analysis performed by Mashelkar committee show that current decentralized structure of the regulatory agency is the main reason for its malfunctioning
- Non-uniformity in the interpretation of the acts and norms fuels the problem
- In absence of even the national list of drugs manufacturer it is not possible to control the quality of drugs moving across the country
- Only 17 of the 31 states surveyed have functioning testing laboratories. Drug inspectors are in shortage
- Up to now not a single prosecution in fake drugs cases has resulted in any life-imprisonment



# Inefficient drug regulatory system

## **Changes DO NOT happen however**

- The idea of centralizing drugs regulatory agency by formation of National Drug Authority was first proposed by Hathi Committee Report in 1975. It is advocated by drug policies of 1986 and 1994, however it was not implemented
- The D&C Act 1940 has not been reviewed in a comprehensive manner since its inception
- In 2008 some provisions related to sub-standard drugs have been amended, but comprehensive revision of the D&C Act is still not done
- Control of retail outlets and distribution channels still a challenge



# Thank You