

# **INVESTIGATIONAL SKILLS FOR COUNTERFEIT DRUGS**

**Drug Control Officers (I) Welfare Association**

**&**

**Drug Control Administration, Jammu & Kashmir**

**Date: 13<sup>th</sup> May 2023**

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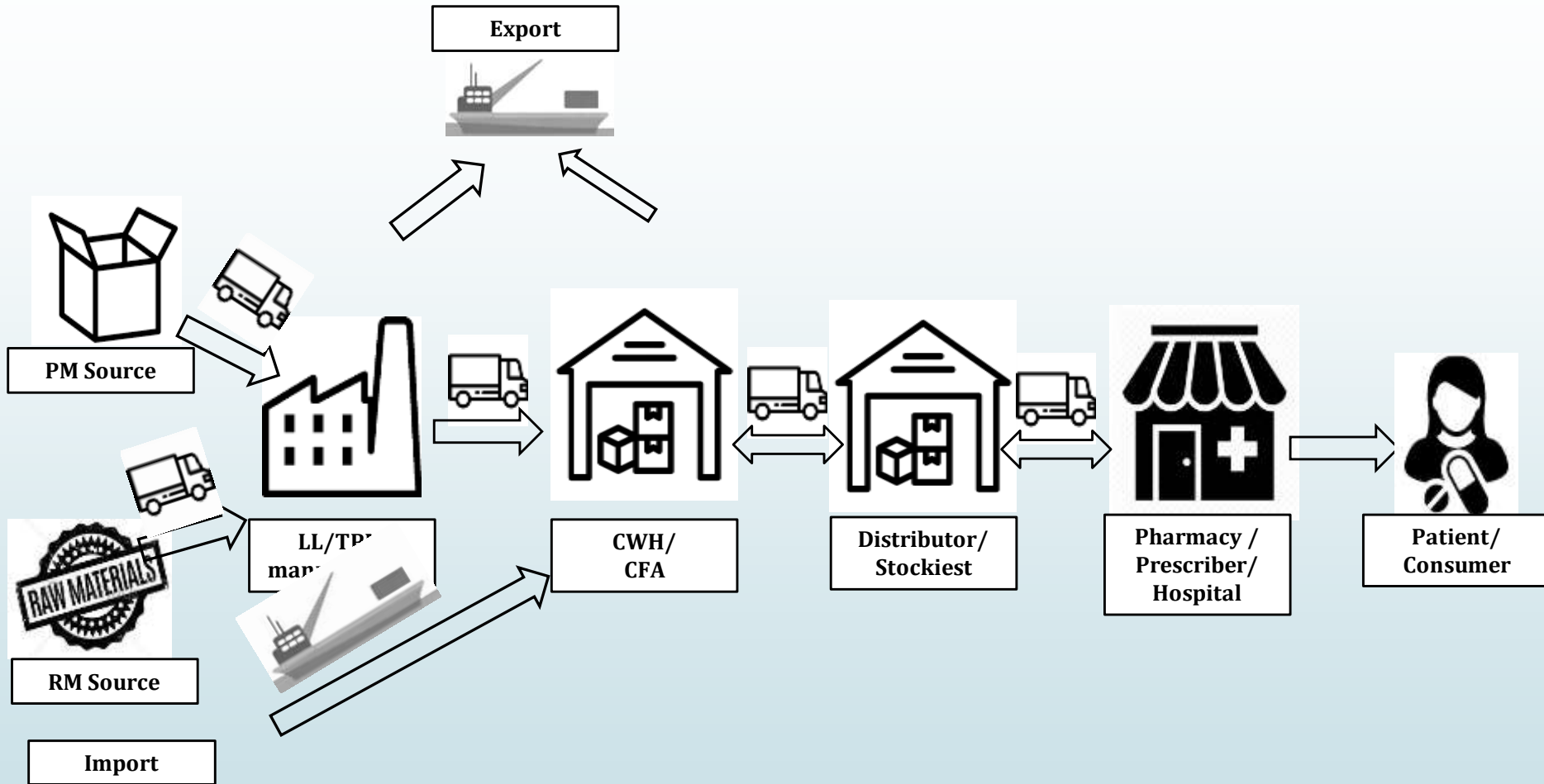
**Drugs Controller, FDA Maharashtra.**

# Agenda



- Value chain
- Regulatory Framework
- Investigation- Vital Ingredients
- Destruction of Evidence, Absconding accused/Impersonation/Health issues
- Refusal to provide information ,Obstacles from Authorities.
- Vexatious Search and Seizures, Good Faith, Obstruction to Govt Servant.

# Value Chain



Tiblo Consultancy Services

# Regulatory Framework - India



Regulator	CDSCO/DCG(I)	State FDA
<b>Division of responsibilities</b>		
Legislation	✓	
International Trade	✓	
Clinical Trials	✓	
New Drug Approvals	✓	
Manufacturing License	✓	✓
• Biologics	✓	✓
• Medical Devices	✓	✓
• Other Drugs	✓	✓
Retail/Distribution License		✓
<b>Investigations</b>	Merits pan-India co-ordination/authority	✓
<b>Consumer Complaints</b>		✓

# Manufacture and Sale

## Prohibition

Manufacture for sale, sell or stock or exhibit or offer for sale or distribute any drug

- Except under license
- In accordance with the conditions of license

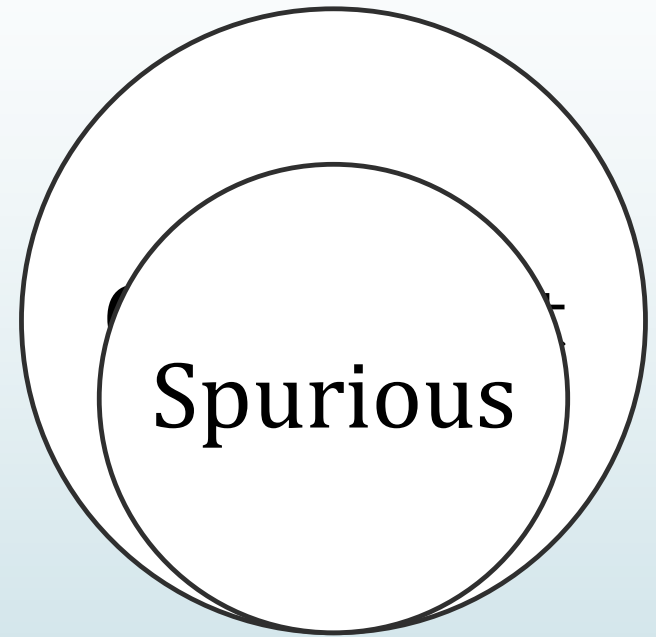
# Present Regulatory System



- Organized system for health care management.
- System to keep away entry of spurious, misbranded or adulterated drugs in the market
- Avoid self medication, enable use of medicines with utmost care so as to minimize the risks to the health of the patients
- Ensure the traceability of the medicines from the manufacturer, distributors, retailers up to the point of use to enable effective recall, wherever and whenever required

# Menace of Counterfeits

- Current regulatory framework focuses on spurious drugs, not on counterfeits
- **Spurious Drug:** A drug which does not contain any active medicine or is manufactured by unlicensed/unauthorized/fictitious manufacturer or is not of standard quality
- **Counterfeits:** May contain a valid active and or may be manufactured by a licensed factory. But are still illegitimate on account of
  - Trademark or copy right violations
  - Manufacture at or Distribution through unauthorized factories/channels
- Counterfeits carry financials and reputational costs for all stakeholders (manufacturer, regulator, consumer, prescriber, government at large)



# Extent of counterfeits

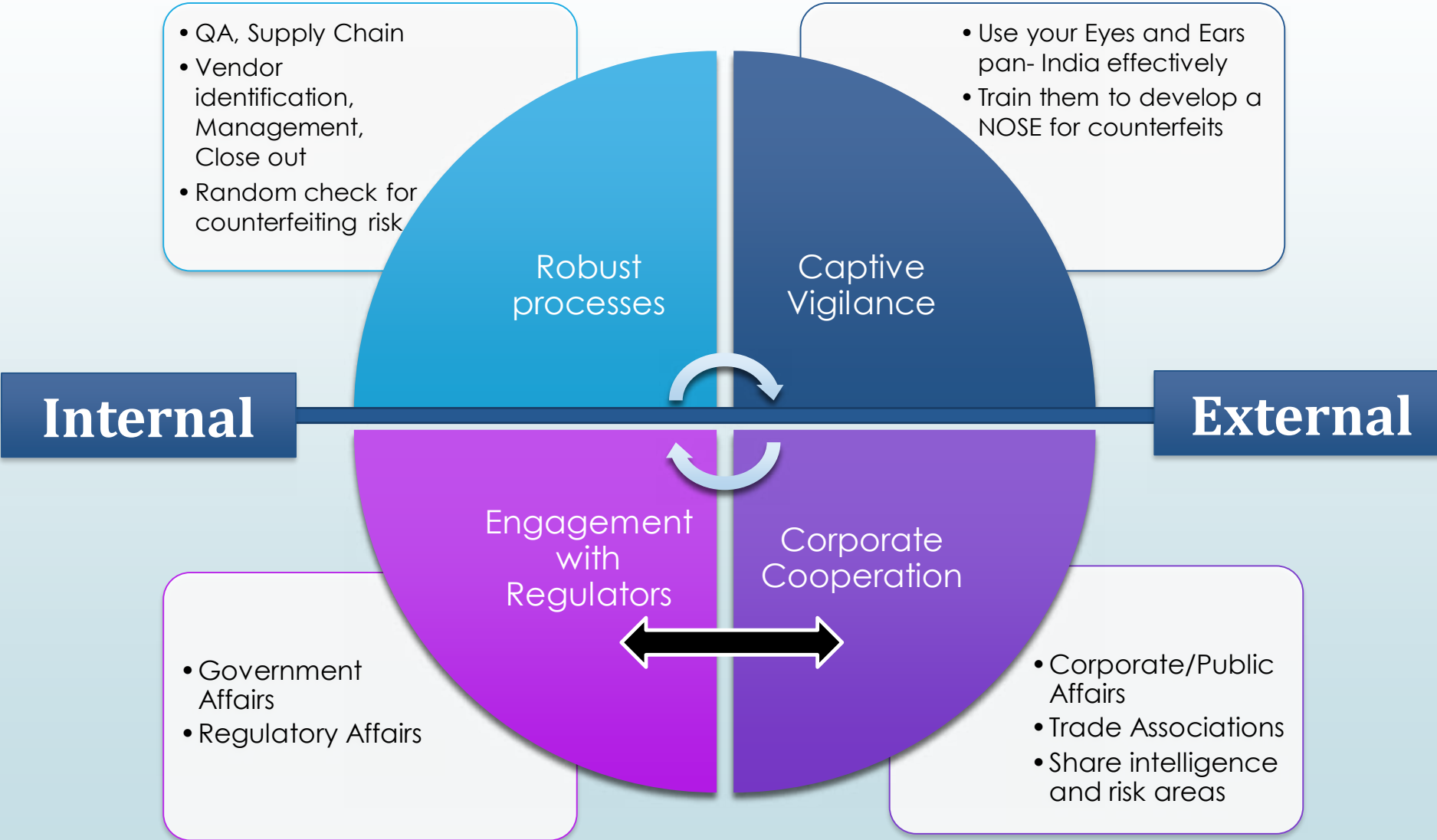
- Perceptions (lacking evidence) vary across a spectrum with some sources citing a rate of incidence up to 12-14%
- There has been no expansive or authoritative survey for counterfeits; however, surveys for spurious drugs exist
- Most recent findings are from National Drug Survey:2016-18

Parameter	Finding
Samples Drawn	47,000
Not of Standard Quality	3.16%
Spurious	0.245%

- While the national average  $\sim 0.25\%$  may seem low
  - Counterfeits will always exceed spurious (by definition)
  - Counterfeiting risk will be high for brands with equity/pricing power
- This makes quality produces more vulnerable to counterfeits than the market average



# Four-Pronged Counter-Counterfeit plan



# Watch



Dealers without license

Observable drop in sales in a geography and/or particular brand



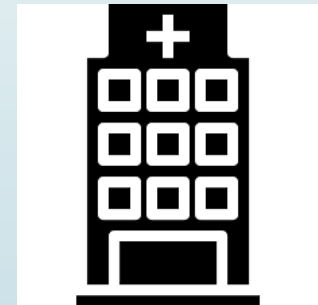
Undercutting supplies



**Be Alert!**  
**Watch out for these Warning Signs!!**

**Unusual incidents!!**

- Attempts to create cylinder/moulds/stamps for brands
- Attempts to print/copy packaging materials



Institutional Supply



Direct supplies to Doctors

# Attributes of a counterfeiting target



**Pricing Power**



**Very High Volume**



**High Recall at Rx level**



**High Recall with Consumers**



**Undifferentiated Physical Attributes  
e.g. Any white pill in a featureless strip**

# Investigations - What it means?



- All proceedings for collection of evidence.
- It is a systematic, minute and thorough attempt to learn facts about ***something complex or hidden.***
- It starts when the information in respect of an offence is received

# Steps Involved



- Gathering of intelligence
- Sifting of information
- Verification
- Documentation of Information
- Commencement of investigation

# Investigation



## Investigation consist of following steps

- Proceeding to spot
  - Ascertainment of facts and circumstances of facts
  - Discovery and arrest of offender
  - Collection of evidence relating to commission of offence-
- 
- i. Purposeful recording of Nature of Drug Viz. spurious, Misbranded and reasons to believe.
  - ii. Recording of statements
  - iii. Search
  - iv. Seizure

# Methodology

- **Confidential purchase of drugs suspected to be spurious**
- **Confidential testing of these samples**
- **Comparison with original product**
- **Wherever possible obtaining opinion of original manufacturer**
- **Following suspect with the help of watcher or by officer himself**
- **Decision taken to raid the place or places with or without help of police**

# Supporting Methodology

- **Shortlist medicines that are likely candidates**
- **Undertake survey sampling on our own or through NGOs**
- **Keep track of retailers and wholesalers not doing good business**
- **Watch activities of dealers with bad antecedents**
- **Frequent inspections of such dealers**
- **Ideally, study the modus operandi and keep profile on offenders**



# Complex Issue

## Remember

- ❖ Manufacture ,sale and distribution of spurious drugs is a clandestine activity
- ❖ Cases are not noticed during routine inspections
- ❖ Normally, complaints do not result in detection of such cases
- ❖ Therefore most important pre-requisite is gathering of intelligence of such activities



# Vital Ingredients

- **Dedicated officers with aptitude for investigation**
- **Information**
- **Informants**
- **Skills of sifting Information**
- **Speed in investigation**
- **Interrogation Skill**
- **Co-ordination Skills**

# Vital Ingredients

- ❖ **Team Work**
- ❖ **Presence of Mind**
- ❖ **Ability to follow clues**
- ❖ **Attention to minor clues**
- ❖ **Patience**
- ❖ **Ability to remain cool**

## Glaxo case -

- No stock found at Welcome Hindu Hotel.
- Son of accused detained & interrogated
- Stock seized from Andheri Lokhandwala creek

# Refusal to Provide Information



## Glaxo Case –

- Commissioner wanted information about Head of Glaxo UK.
- Information denied by Glaxo India management.
- We pressed for information as inherent power of inspector.
- Tactical handling lead to success.

# Accused Absconding

Ability to Interrogate to elicit information/ clues

❖ **Interrogation is an Art – because no set of Rule guide one to successfully investigation of case .**

**R-cin case -**

Accused absconded , Persuasion /pressurization of his brother( Licensee) made him produce accused before us.

**Wyeth Lab case -**

Recovery of 80 gms Prednisolone

❖ **Innovative approach -Mascot Lab Ahmedabad case –**

▪ Accused absconded, Visit to premises, instructed watchman not to open market, publicity in local news paper helped to get accused surrendered .

# Accused Absconding /Persistence



Commitment to solve the case and Coordination paid dividends

## Satya Narayan Hyderabad Case

- First visit -Accused absconded.
- After one year visited Hyderabad for another investigation,
- Accused was located,
- Informed Mumbai office who coordinated with CB II
- C.B. Police arrived at Hyderabad
- Coordination of local Drug Control was sought
- Accused arrested with huge stock of spurious drugs
- Accused was convicted in the case



# Obstacles From Authorities

## R- cin case

- Officers assigned to get help from Lupine Laboratories determine R-cin caps are spurious
- I.O. gave FIR, Police Custody transit remand of accused secured
- Co I.O. to make up mind of mediator to go to Delhi who knows culprit– Ravi Sharma.
- Commissioner instructed team to travel by train.
- Officers discussed and decided to travel by air.





# Cooperation From Other Agencies



- **Team Work – Presence of Mind**
- Officers with mediators managed to board plane in time
- Police team with accused on way to arrive to air port
- Plane was delayed for 10 minutes
- Till the police boarded the plane



# Persistence & Ability to Follow Clues



## Godrej Hair Dye Case -

- Main accused absconded
- Stuck up to get manufacturing premises
- Telephone bill found in drawer of table
- Interrogate person, Premises was found in vicinity of FDA office with full fledged activity of spurious cosmetic mfg.

## Franco Italian case -

- Rough note book of Analyst revealed true
- M.P. of Sulpha methoxy pyridazine

## Non Cooperation by Other State Agencies.

### Framycetin case -

- Neomycin is labeled as Framycetin.
- Jurisdiction issue

# Instructions/Orders from High Court



## ❖ MAPL Case-

- Accused at Latur
- Order from High Court not to arrest till further orders.
- Accused Non Co-operative
- Team from IB Mumbai investigated & Traced Rubber stamp vendor.
- New FIR launched at Indapur pune .
- Lady partner (Wife of the Accused) arrested.
- Accused started co-operative to case solve.

## ❖ MAPL Case-

- FIR against Director of Health Services.

## ❖ Prosecution against Director of Public Sector Undertakings.

# Impersonation



## Patience

- Stock of rejected drug was seized.
- Person arrested disclosed name of Bahvesh as a person who had purchase rejected drug.
- Bhavesh came to know of raid.
- Decision taken not raid his place.
- He was allowed to believe that he has managed to avoid arrest.
- Watch continued for almost fifteen days and then raid was carried out.

# Impersonation

## UNBELIVABLE - What is this?

Compounds mfg by Bhavesh -  
Ampicillin Trihydrate,  
Rifampicin, Erythromycin Stearate



## Ability to remain cool

Bhavesh was present during raid.  
But pretended to be his brother.  
His mother and sister also supported the  
story.

At 19.30 the informant informed the fact-  
Bhavesh ran away.

What happened next ?

Good example of remaining cool.

# Accused Pretending Health Issues



Accused arrested at 19.00 hrs at Orai

Put in lockup

Accused reported chest pain 22.00hrs

Admitted to Civil Hospital

Send to admit to Medical College

CJM Orai refused to give transit remand in absence of accused person.

CJM Jhansi refused to transit remand

Accused was brought to Orai contacted PP

Accused was present before CJM Orai

Ultimately CJM Orai gave transit remand.

# Review and Discussion

- Glaxo – Instructions of Commissioner shri Arun Bhatia.
- R-cinex - Commissioner Shri Sanjay Narayan. Go by train
- DMR – China issue of interference
- Delay- HC & Supreme Court Issue section166 IPC.
- Orai – MLA Jhansi medical college issue
- Bhavesh Parekh / pandya absconding issue
- Satyanarayan Hyderabad absconding issue
- Welcome Hindu Hotel destruction of evidence issue
- Lady of Kandivali - Throwing away stock from rear side
- Gulati – Mulund Zopadpatti issue

- Interference by minister - Medical device, Nutra, Ketamine
- Glaxo suite issue- Action takes in good faith
- Mob psychology - Banarase Wadala Bogus Dr. issue
- Creating Records to avoid/ prevent allegations about vexatious search and seizure.
  
- Anticipate who can interfere-
  - Associations
  - Administration
  - Ministers/ politicians
  - Courts
  - Legislature
  - Press
  - Peer pressure





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