

Intricacies of Investigation Under Drugs & Cosmetics Act (Case Studies)

All India Drugs Control Officer's Confederation Academy

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**Omprakash Sadhwani
Former Joint Commissioner &
Drugs Controller, FDA Maharashtra.**

Agenda



- Value chain



- Regulatory Framework



- Menace of counterfeit drugs



- Counter – Counterfeit Strategy



- Investigation- Vital Ingredients



- Assets of Investigators

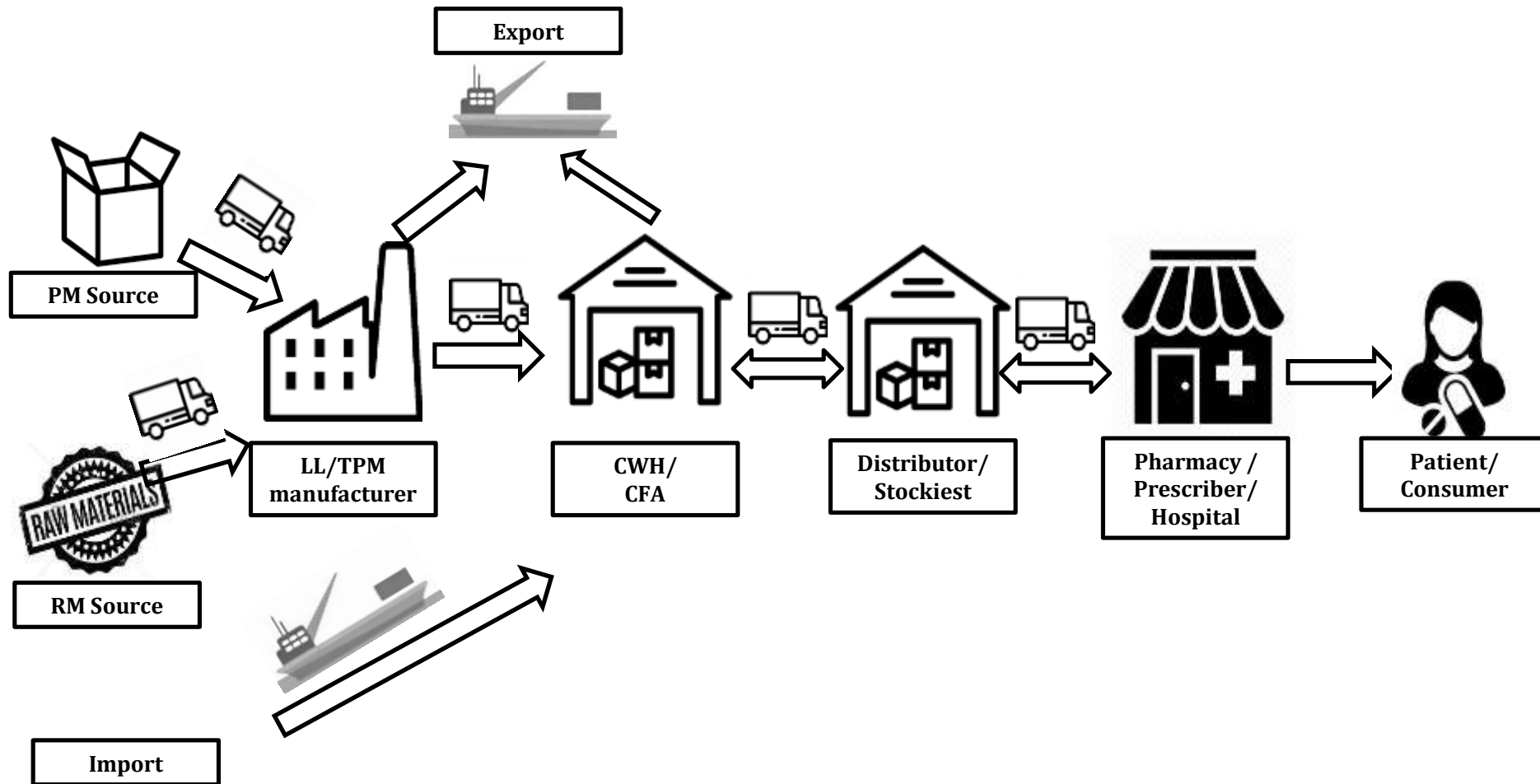


- Essential Skills



- Review and conclusion

Value Chain



Regulatory Framework - India



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

Manufacture and sale



Prohibition

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

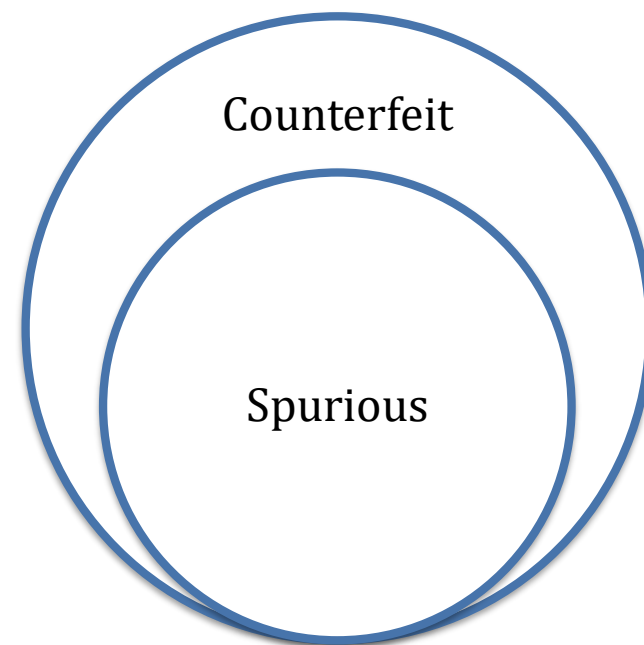
- Except under license
- In accordance with the conditions of license

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
 - Trade mark or copy right violations
 - Manufacture at / Distribution through unauthorized factories/channels
- Counterfeits carry financials and reputational costs for all stakeholders (manufacturer, regulator, consumer, prescriber, government at large)



Extent of counterfeits

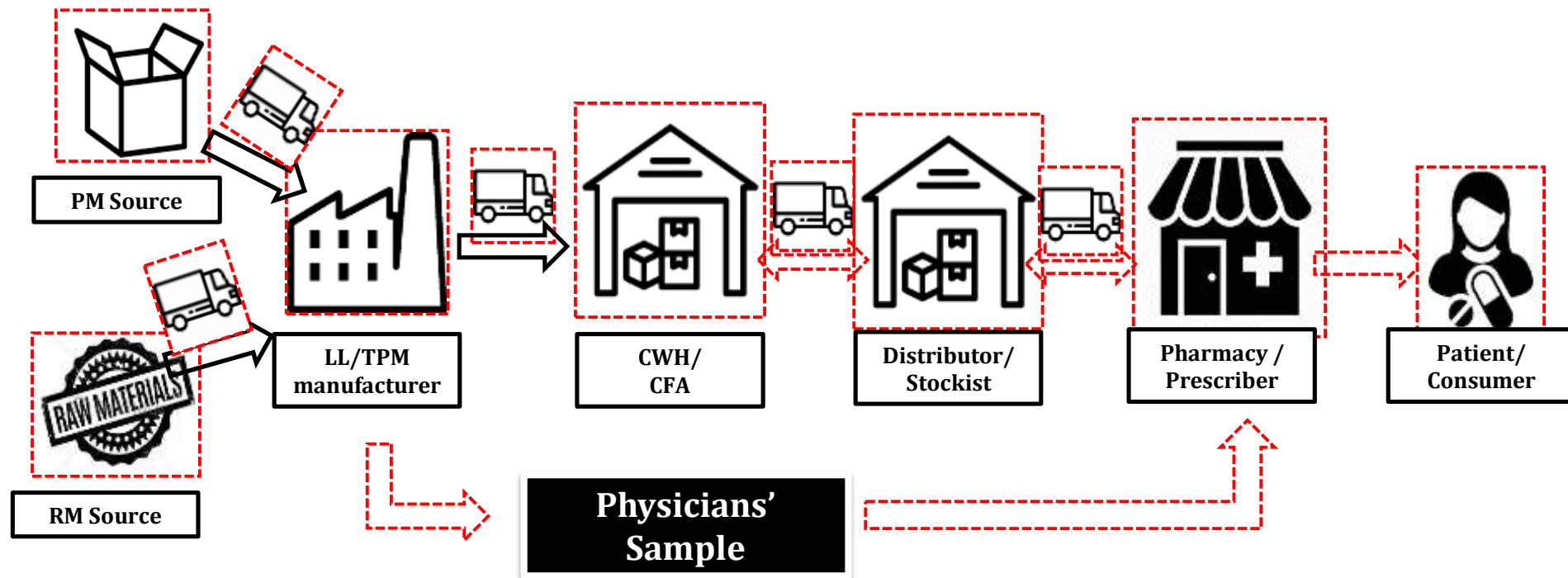
- Perceptions (lacking evidence) vary across a spectrum with some sources citing a rate of incidence up to 12-14%
- There has been no expansive or authoritative survey for counterfeits; however surveys for spurious drugs exist
- Most recent findings are from National Drug Survey:2016-18

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

Vulnerability across the value chain

- Negligence, Ignorance
- Expired, recalled, rejected goods – recycling



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

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

Assets of Investigator

Ability to secure information

From Person indulging in offences

Other investigating Agencies

Not to overlook even trifle

Manufacturer /Companies –Wood word

Gripe water case

Associations - small scale soap
manufacturer Association.

UNBELIEVABLE



Speed in Investigation

Spurious Corex case

- Received information
- Rushed to spot
- Interrogated the person
- Seized stock of spurious corex with invoice
- Proceeded to manufacturing /residential premises of accused
- seized stock along with pp caps, colored Xerox label, jar of cough syrup
- Accused arrested
- Completed investigation of label, p.p. caps
- Proceeded to investigate bogus invoice of firm at Satara

Assets of Investigator

- Ability to cultivate informant
- Ability to treat the informant fairly regardless of his character.
- Ability to conceal Informants identity not only from his business rivals/associates but also from other officers

Skills to sift Information

- Investigate all the tips
- Evaluate reliability of Information
- Don't be mislead by fabricated information.

Speed in Investigation

Godrej Hair Dye case

- During search at Mahavir communication center transport receipt of dispatch were found
- Scrutiny of T.R. revealed that Godrej Hair dye was sold to Calcutta, Bangalore, Surat, Delhi
- Team rushed to Batco transport, and withheld stock ready for loading to Surat, Delhi
- Communicated Batco Branch Surat not to make delivery of earlier supply
- Visited to Surat - Seized stock at transport and shopkeeper's premises

Essential Skills

Attitude of Investigator:-

Never give up
Look for clues

R- cin Case

- Accused absconded ,Telephone bill- frequent std call gave clue to Ladawa Kurukhetra
- Telephone No display on wall in police station help to identify Mr. Ashwin Maheshwari

Glaxo case --

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

Essential Skills

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 .

Essential Skills

Communication and coordination

Mascot Laboratories Ahmedabad

- Stuck– up to get transporter address
- Informed A.C.(I.B.) Mumbai
- Officer made inquiry at transporter's premises at Mumbai
- Communicated details - Not only address but code No.--
modus operandi

Essential Skills

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

Essential Skills

Team Work -

R- cin case

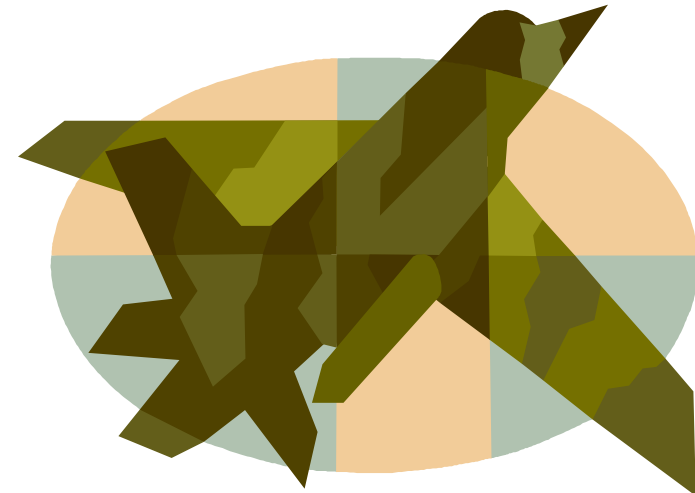
- Officers assigned to get help from Lupin Laboratories determine R-cin caps are spurious
- I.O. gave FIR, Police Custody transit remand of accused secured
- Co I.O. to make up mind of mediator to go to Delhi who knows culprit– Ravi Sharma.
- Other officers coordinated to get air ticket



Essential Skills

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



Essential Skills

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 reveled true M.P. of Sulpha methoxy pyridazine



Essential Skills

Patience

Stock of rejected drugs was seized

Person arrested disclosed name of Bhavesh as a person who had purchased rejected drugs.

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

Essential Skills

Patience

Case of Anoop Hair Oil

- Watch maintained for twenty days
- Suspected person was moving on cycle in crowded area of Moh.Ali. road
- Residence located at Andheri
- Not much stock found –officers not disheartened
- Interrogation led the team to dealer at Santacruz

Essential Skills

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.

Ability to remain cool

Accused arrested at 19.00 hrs at Orai

Put in lockup

Accused reported chest pain 22.00hrs

Admitted to Civil Hospital

Sent for admission to Medical College Hospital

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

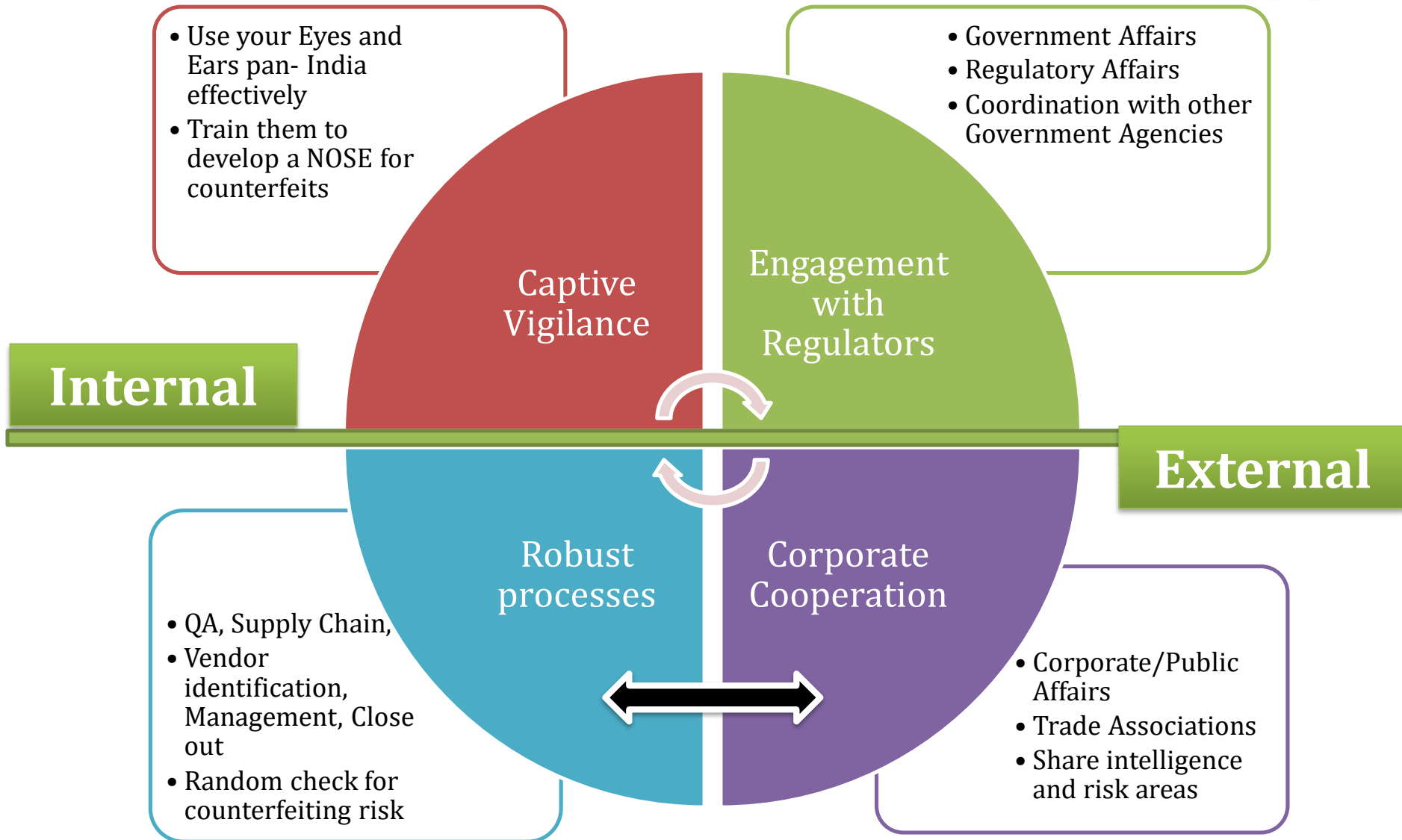
CJM Jhansi refused to transit remand

Accused was brought to Orai contacted PP

Accused was present before CJM Orai

Ultimately CJM Orai gave transit remand.

Four Pronged Counter- Counterfeit plan



Watch



Dealers
without
license

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



Undercutting
supplies

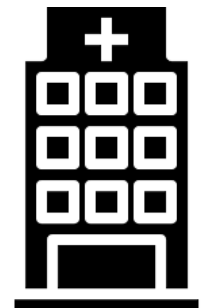
**Be Alert!
Watch out for these
Warning Signs!!**

Unusual incidents!!

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

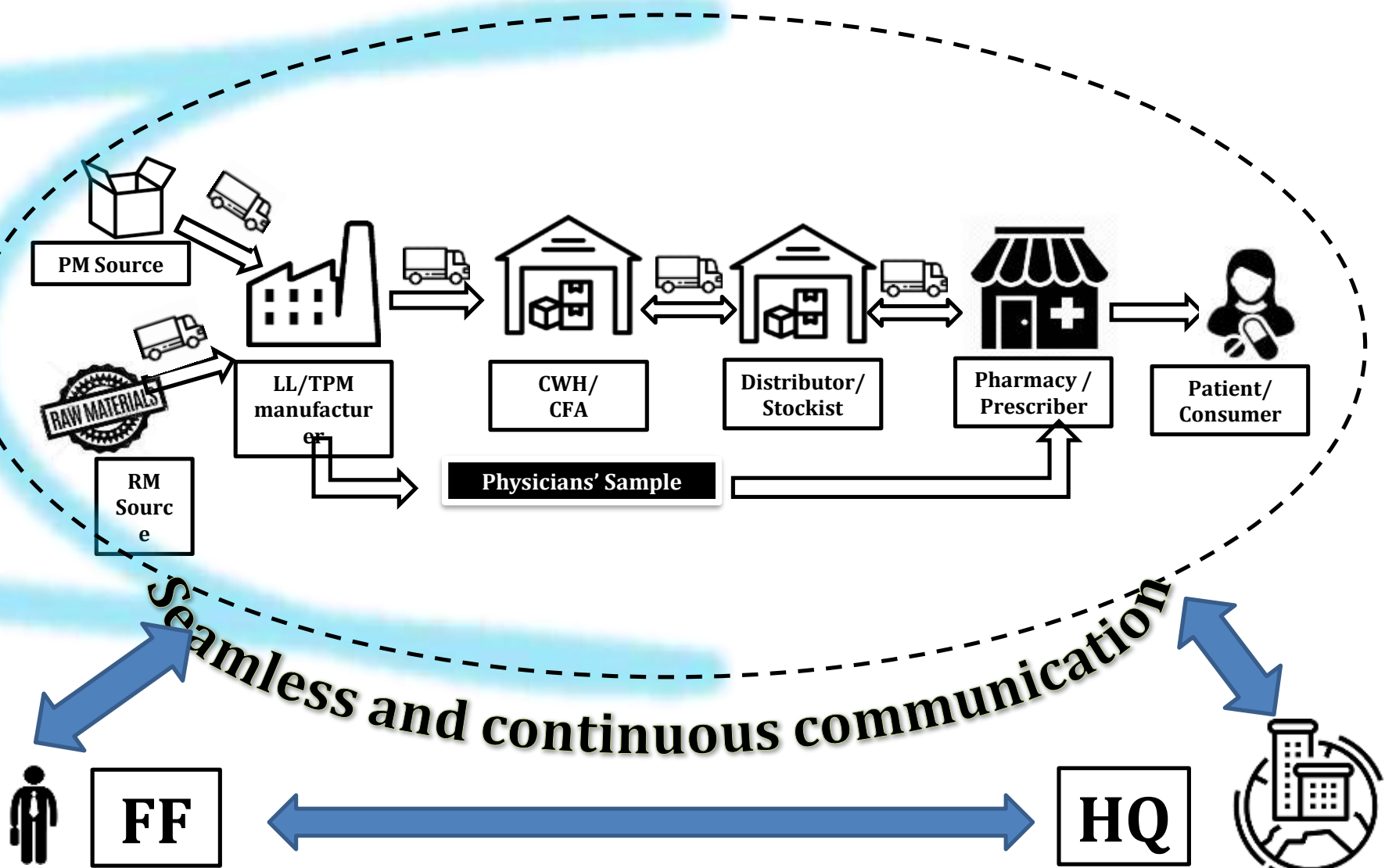


Direct
supplies to
Doctors

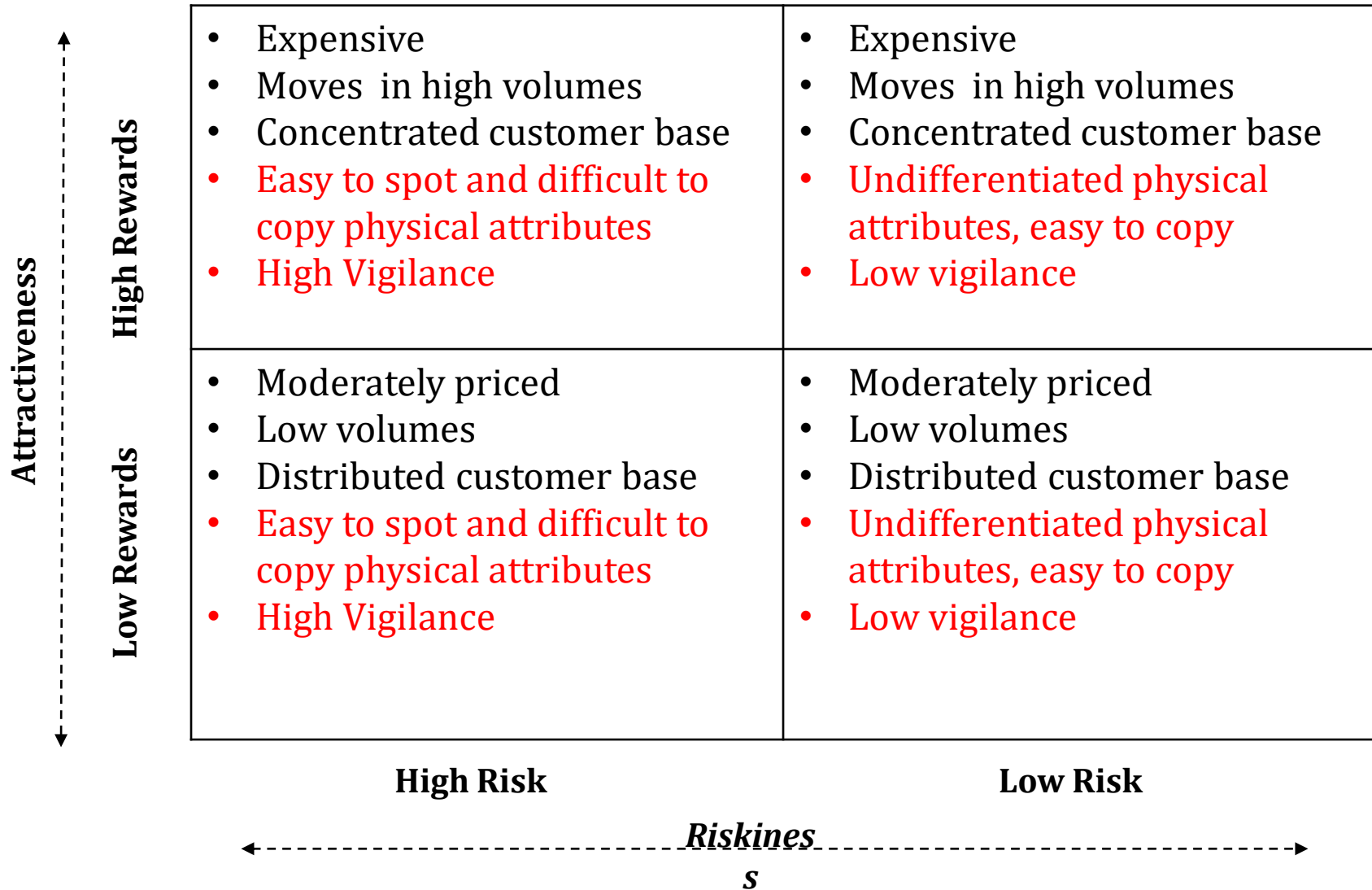


Institutional
Supply

Communicate seamlessly



Counterfeiting Risk Assessment Matrix



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**

Conclusion

The Skills discussed so far coupled with attitude & above all the commitment to the job will certainly curb the menace of spurious drugs.

If you want to be a winner, you have to be willing to give it your all.

*Thank
you!*

Email : ossadhwani@rediffmail.com

Cell : +91-9867325648