



Indian Compliance Best Practices Roundtable

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Panelists:

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Parichay Mittal, Sanofi Aventis ,India



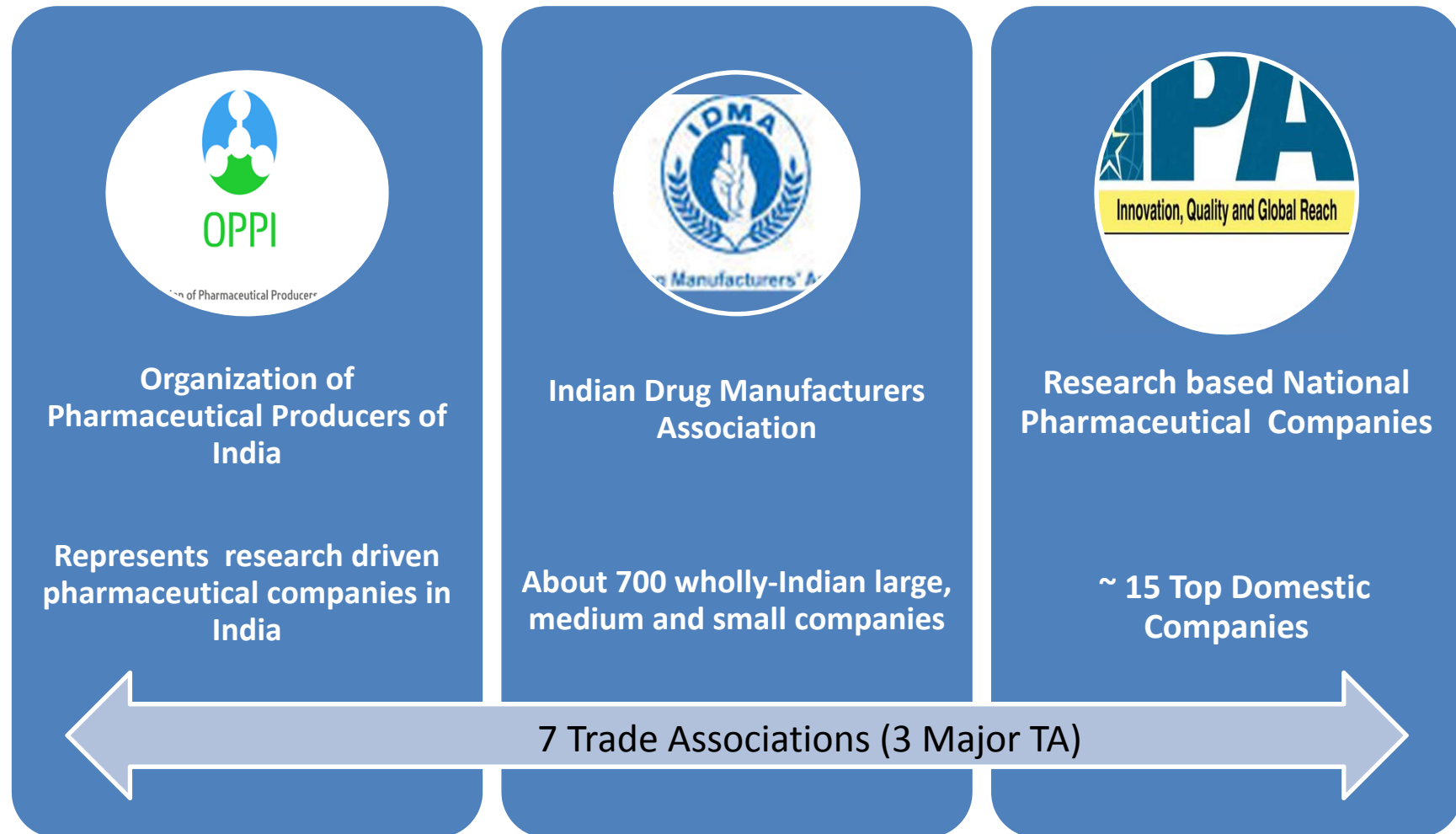
Indian Diversity

INDIAN PHARMACEUTICAL INDUSTRY

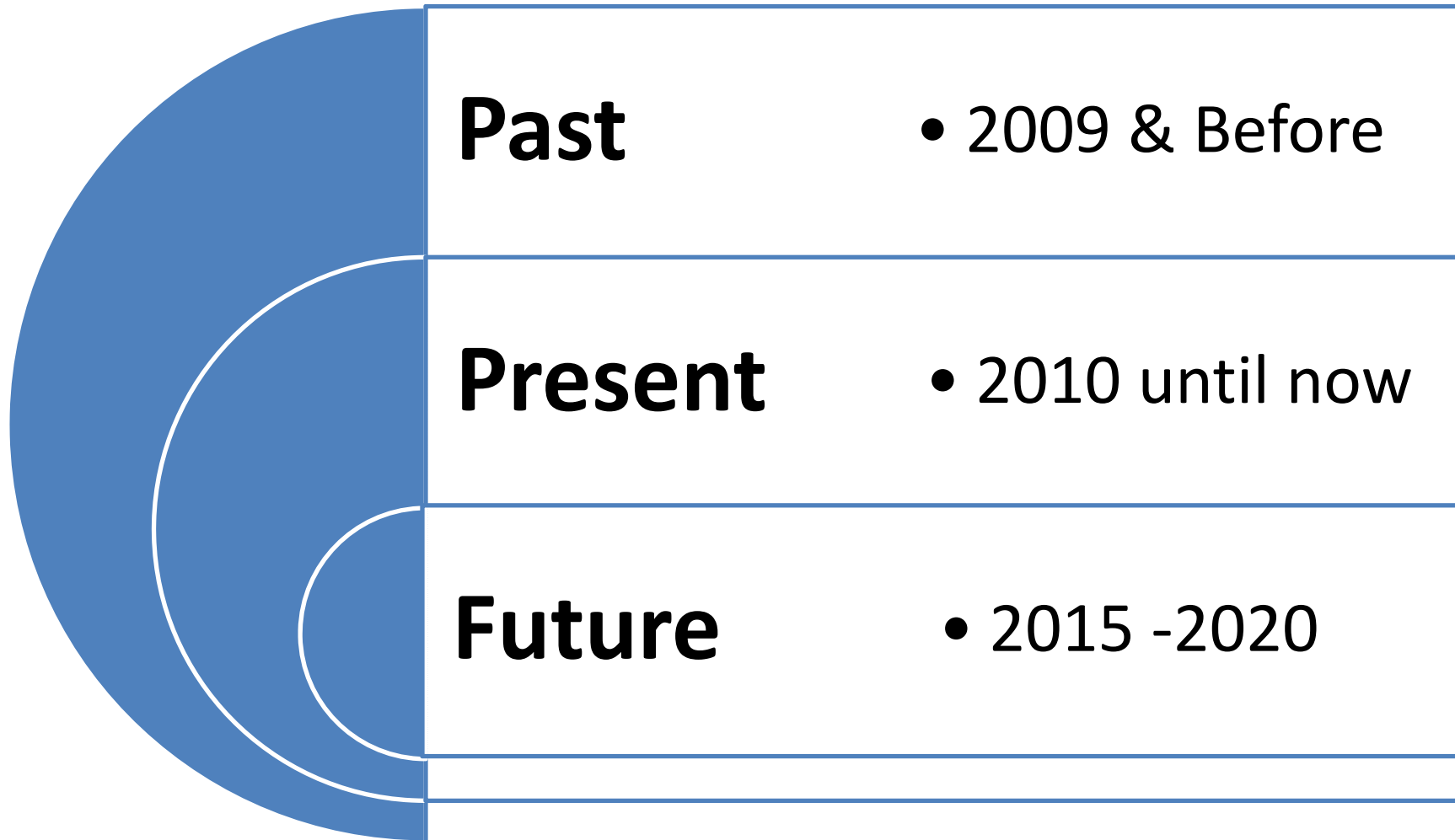
- ❖ The Indian pharmaceutical sector is highly fragmented, with more than 20, 000 registered companies.
- ❖ Branded generics account for 70–80% of total market.
- ❖ Share of Indian companies in the country's pharmaceutical market is expected to be 77% by 2015.

Compliance Environment in Indian Pharmaceutical Industry will be a reflection of conduct of Indian Pharmaceutical Companies.

INDIAN PHARMACEUTICAL INDUSTRY



Compliance Environment : India



Compliance Environment: India

PAST

PRESENT

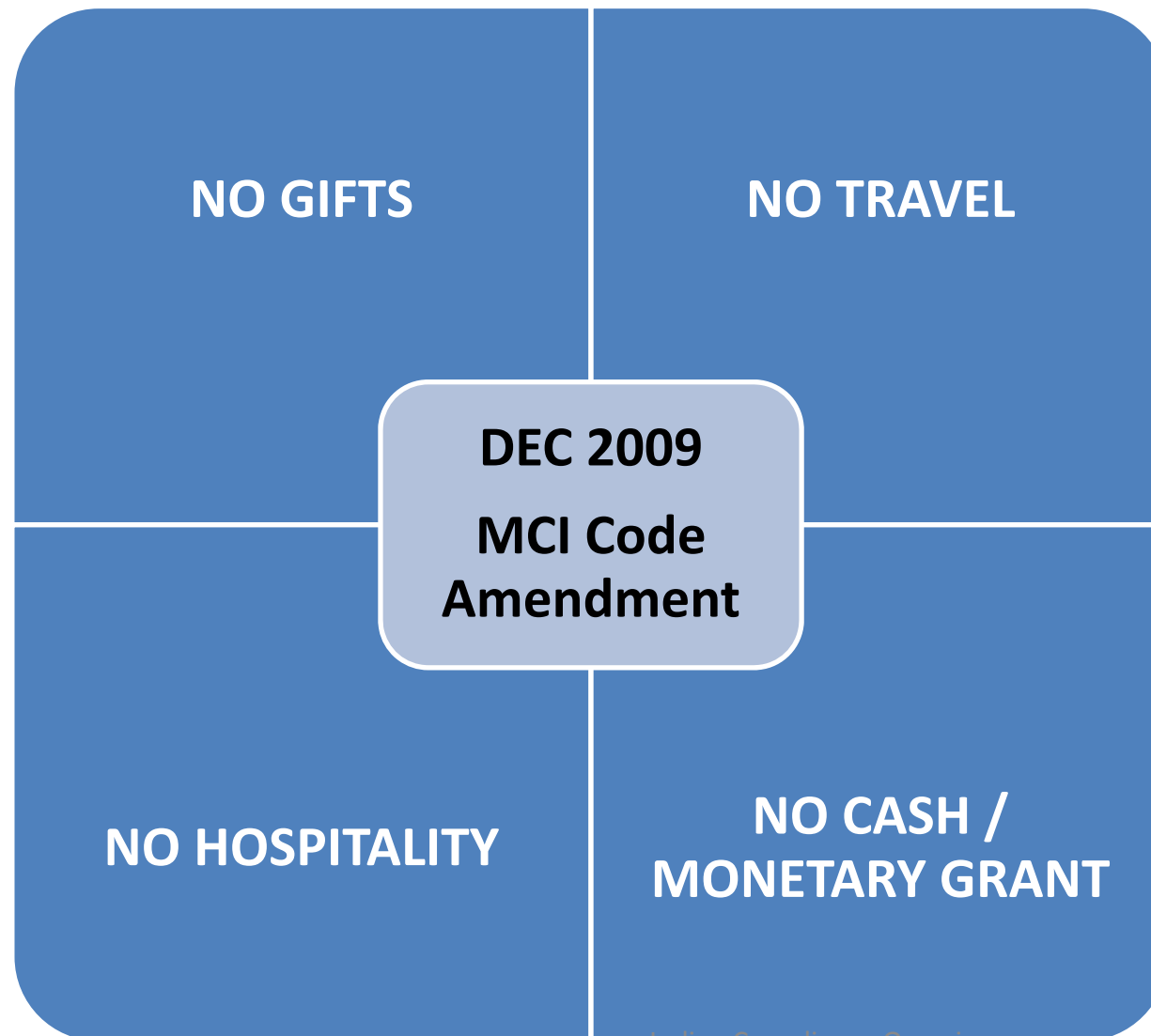
FUTURE

Marketing Support Activities	1990-2000	2000-2009	MCI CODE Dec 2009
Sampling	+ + + + +	++	
Brand Reminders	+ + + + + (Modest Value)	+ + (High Value)	
Customary & Edn Gifts	+ + +	+ + + +	
Individualized Gifts	+ + (Low Value)	+ + + + + High Value/ROI	
HCP Sponsorship for Congresses.	+ +	+ + + + +	
Company organized overseas events /Ent	+	+ + + + +	
Price Discounts to Dispensing HCP's	+ + + + +	+ +	
FFS	-	+ + +	

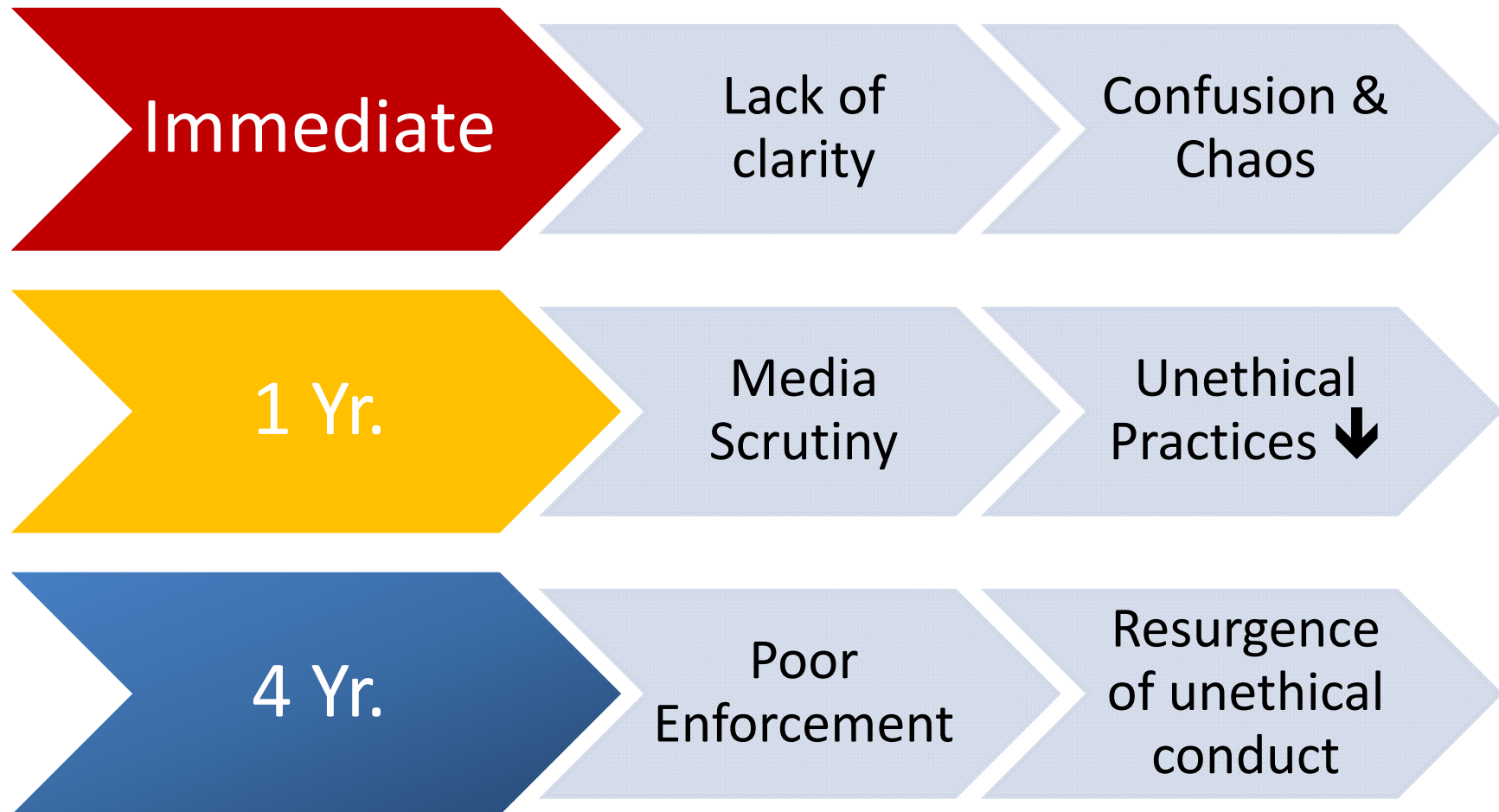
Infrequent
unethical practices

Rampant
Unethical
Practices

Water Shed Moment for Indian Pharmaceutical Industry



Outcome: MCI Code Amendment



Compliance Environment



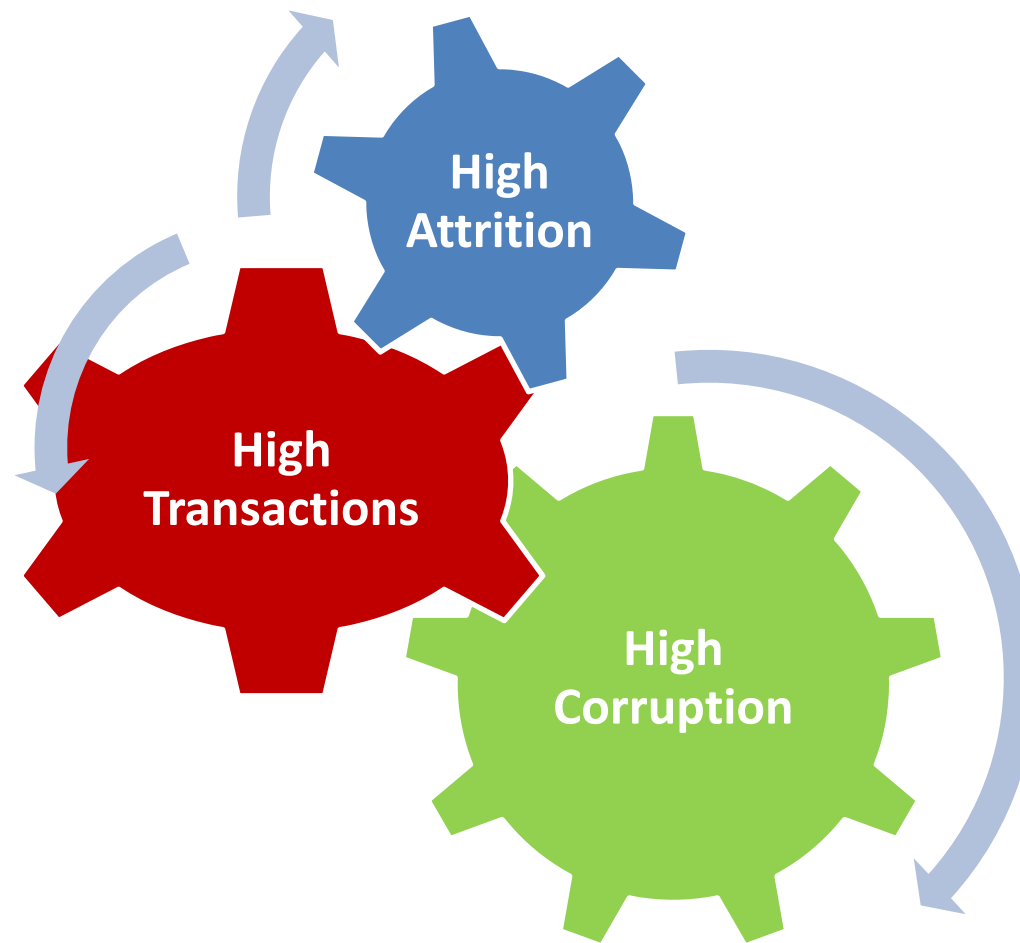
- ❖ MCI Code not legally binding to pharmaceutical firms in strict sense (Companies can only be accused of abetting HCP's)
- ❖ No uniform Industry code as of today.
- ❖ Different Pharma Trade associations(OPPI/IDMA/IPA etc.) have their own codes which vary significantly.
- ❖ All these codes are voluntary in nature and not legally binding.

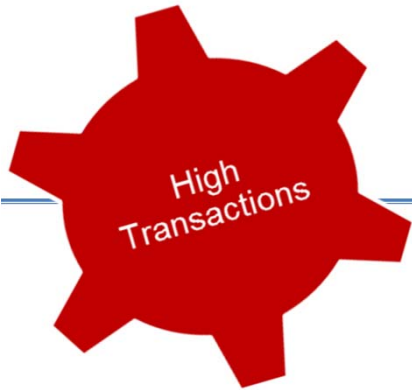
Low enforcement ⇒ **inconsistent ethical behavior**

Compliance Environment : Current

Marketing Support Activities	1990-2000	2000-2009	2010-2014
Sampling	+++++	++	++
Brand Reminders	+++++ (Modest Value)	++ (High Value)	+ (Modest Value)
Customary & Edn Gifts	+++	++++	+
Individualized Gifts	++ (Low Value)	+++++ High Value/ROI	+ (Discreetly if any)
HCP Sponsorship for Congresses.	++	+++++	++ Consultant / 3 rd P.
Company organized overseas events /Entertainment	+	+++++	+ (3 rd Party)
Price Discounts to Dispensing HCP's	+++++	++	+
FFS	-	+++	+++++

Compliance Challenges: INDIA





High Transactions

- India is 3rd in terms of volume of drugs produced (and 10th globally in terms of value).
- High disease burden (World Capital for Diabetes, Cardiac and many other diseases.)
- Humongous no of high risk HCP interactions /Events / Patient Programs.
- Hundreds /000's of distributor for most pharmaceutical companies.

**Monitoring / 3rd Party Due Diligence
Need Consideration**



High Corruption

- ❖ India ranked 94th on corruption Index by T.I.
- ❖ Low paid Govt. HCP's , high patient load and inadequate infrastructure.
- ❖ Hierarchical Society –**Speak Up Culture** missing.
- ❖ Lack of Whistle Blower protection
- ❖ Low enforcement of A.C legislations.



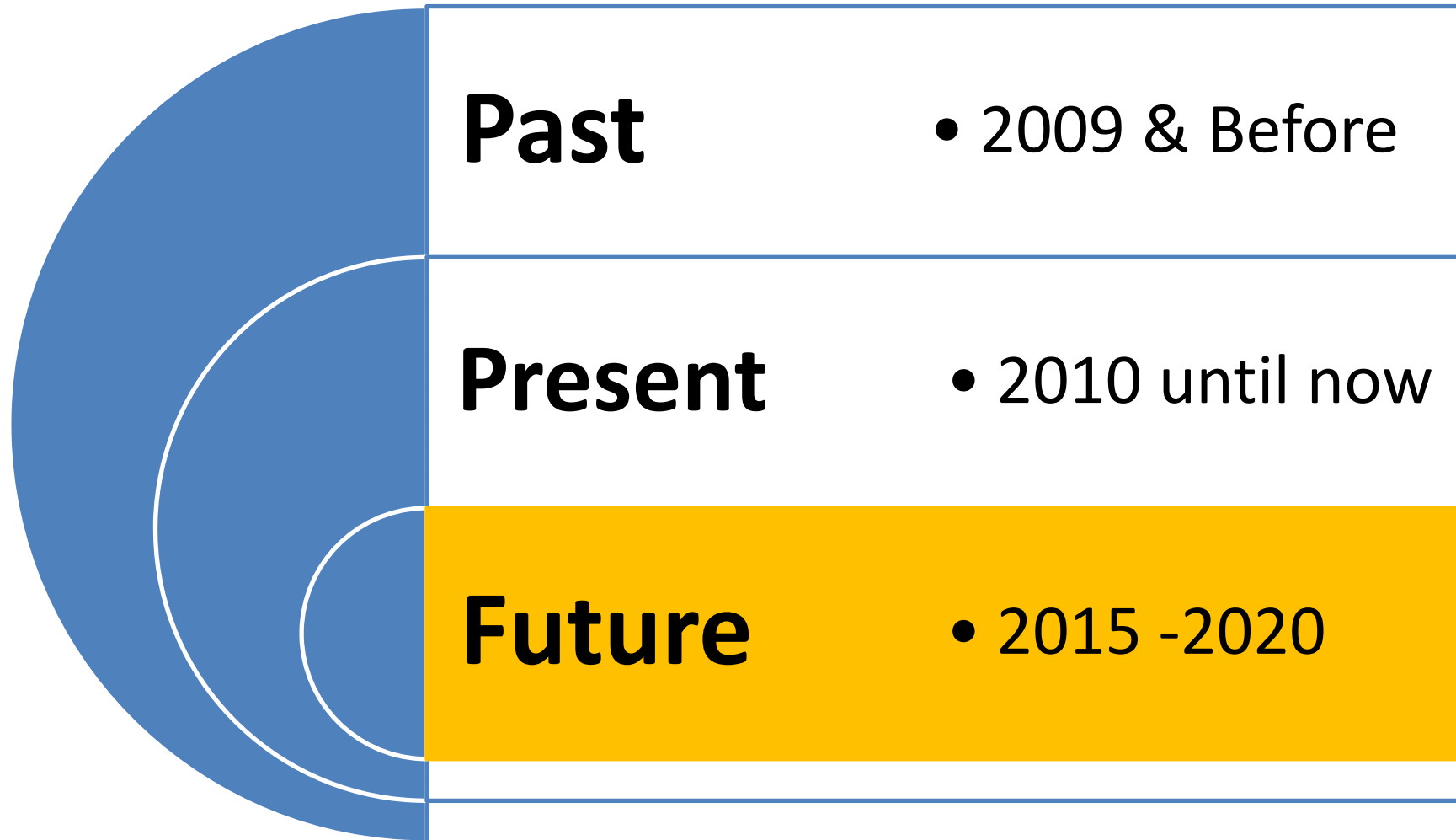
High Attrition

- ❖ Indian Pharmaceutical Industry growth in double –digit in recent years.
- ❖ Limited trained manpower leading to frequent poaching and high attrition.
- ❖ New Employee, unable to adapt to different culturePose Risk
- ❖ Recurrent training intervention a necessity.

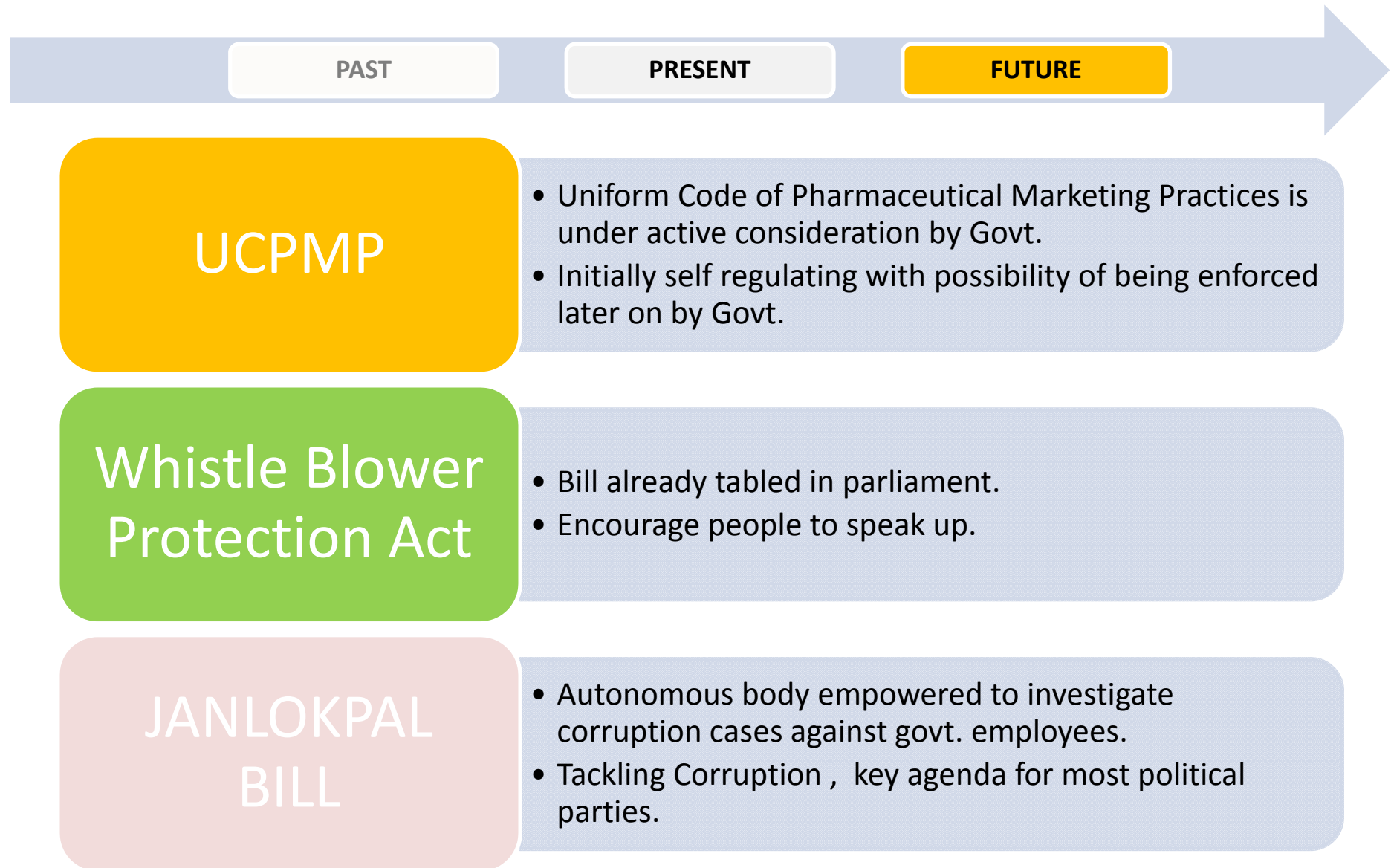
Other Risk Area: Patient Privacy/Privacy

- ❖ HCP's often share their patient P.I with the field staff.
- ❖ Many HCP's expect field staff to provide adequate patient services/counseling to their patients with lifestyle diseases e.g. Diabetes / Hypertension.
- ❖ Large Geographies and inequitable distribution do not allow deployment of nursing support for PEP's.

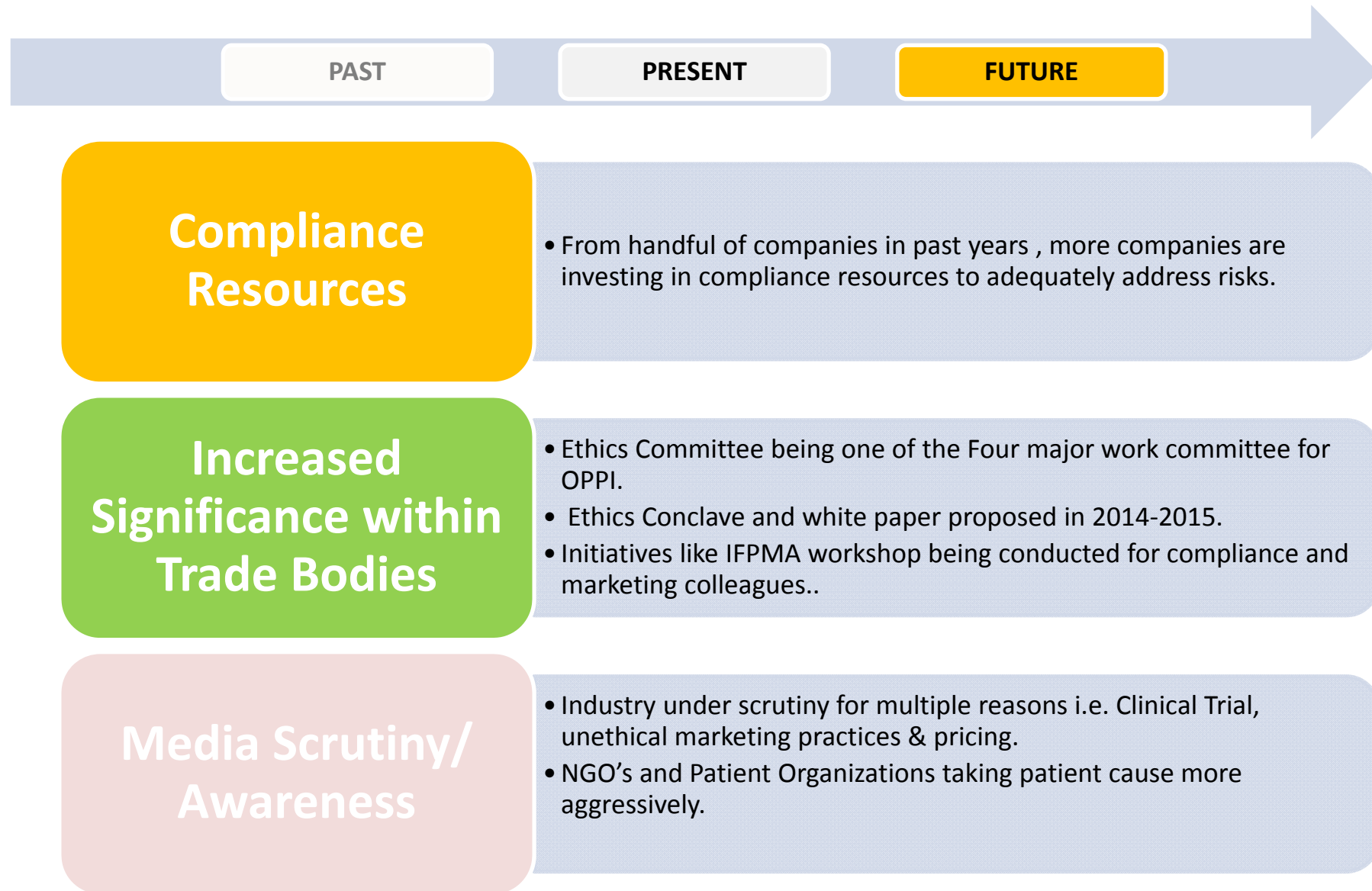
Compliance Environment : India



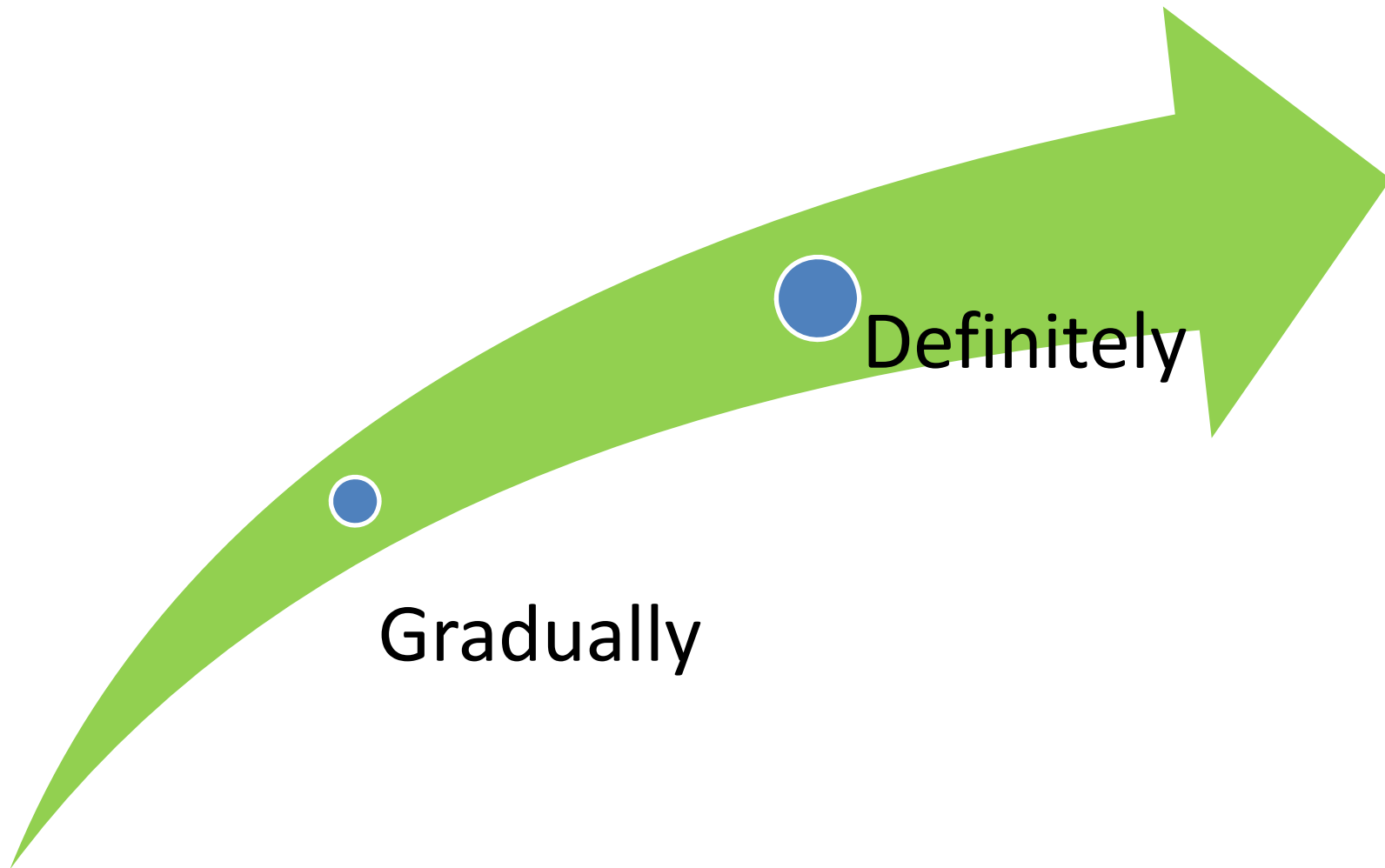
Compliance Environment India



Compliance Environment India



Compliance Environment Trend





Indian Compliance Best Practices

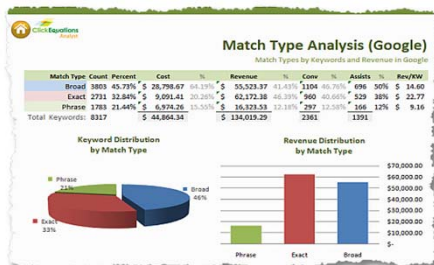


Compliance Analytics

Compliance Analytics

What is Compliance Analytics?

- A Powerful & fast analytical tool to view compliance outliers and Risk Areas.
- Built with the following in mind – Analysis, Presentation, Usability & Performance.
- Can be executed as a desktop application or a web application



Analysis

Quick and comprehensive Analysis of all sales practices, Promotion Compliance areas through data analysis

Presentation

Simple Dashboard

Usability

Comprehensive Details on demand, drill down visualizations, filters, dynamic parameters



Impact

Early red Flags & remediation to mitigate compliance risks.

Compliance Area for analysis & Review

- **Sales Activities**

1. Gross to Net Sales & Trend
2. Sales by Product and by Customer
3. Trade Discounts
4. Commercial Free Goods
5. Credit Notes/Returns
6. Payments to Sales Customers
7. Distributor Interactions
8. Government Intermediaries (Distributors)

- **HCP Interactions**

1. Fees for Services
2. Sponsorships (Including Meetings)
3. Travel and Entertainment
4. Samples

- **Disbursements**

1. Grants, Donations and Charitable Contributions
2. All Other Third Party Payments
3. Other Government Intermediaries

- **Other Compliance Activities**

1. Compliance Training
2. Audit Remediation
3. Travel and Entertainment (T&E)

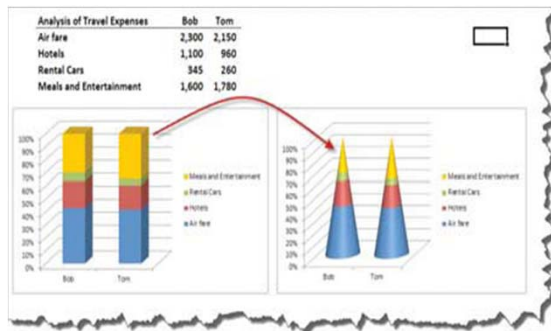
- **Dashboard Tabs**

1. Sales Activities
2. Sampling
3. HCP
4. Audit Commitments
5. Compliance Training
6. Promotional Materials
7. Government Intermediaries

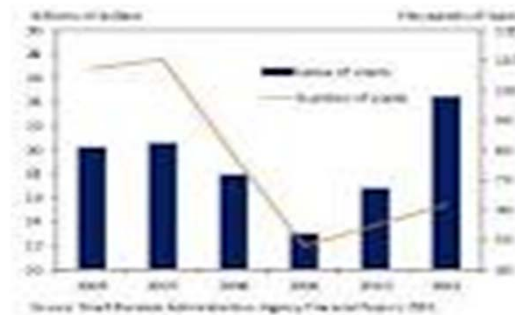
Compliance Dashboards

Monitoring Activities and Behaviors in Key Risk Areas:

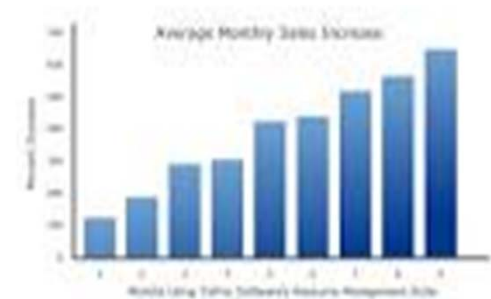
Travel & Entertainment



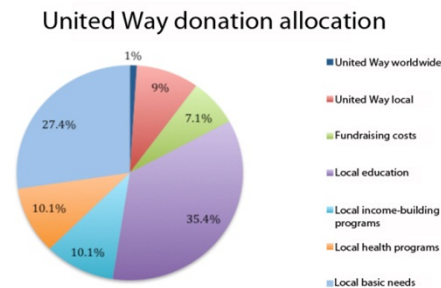
Government Intermediaries



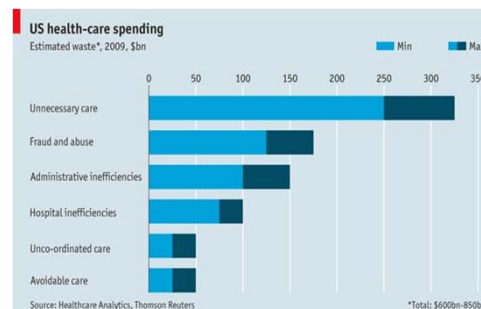
Distributors



Grants and Donations



Payments to HCP's



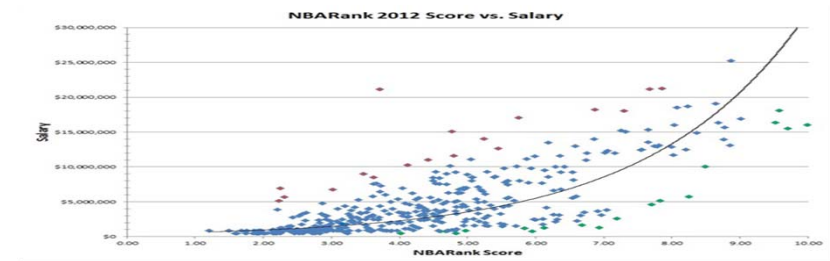
Compliance Training



Outlier examples

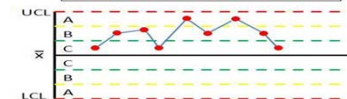
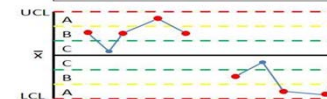
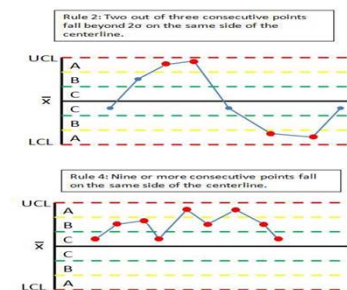
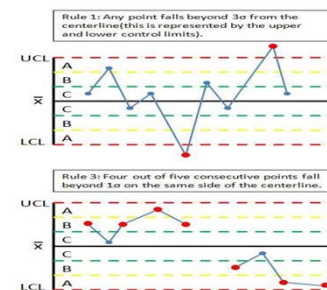
T&E SPEND

- High frequency of claims
- Claims with high value amounts



SAMPLES

- Understand the local policy in terms of a guidance for number of samples that can be distributed per HCP in a given period
 - *Limit line per doctor that can be customized by market*
 - *Limit line per rep that can be customized by market*



Governance Overview

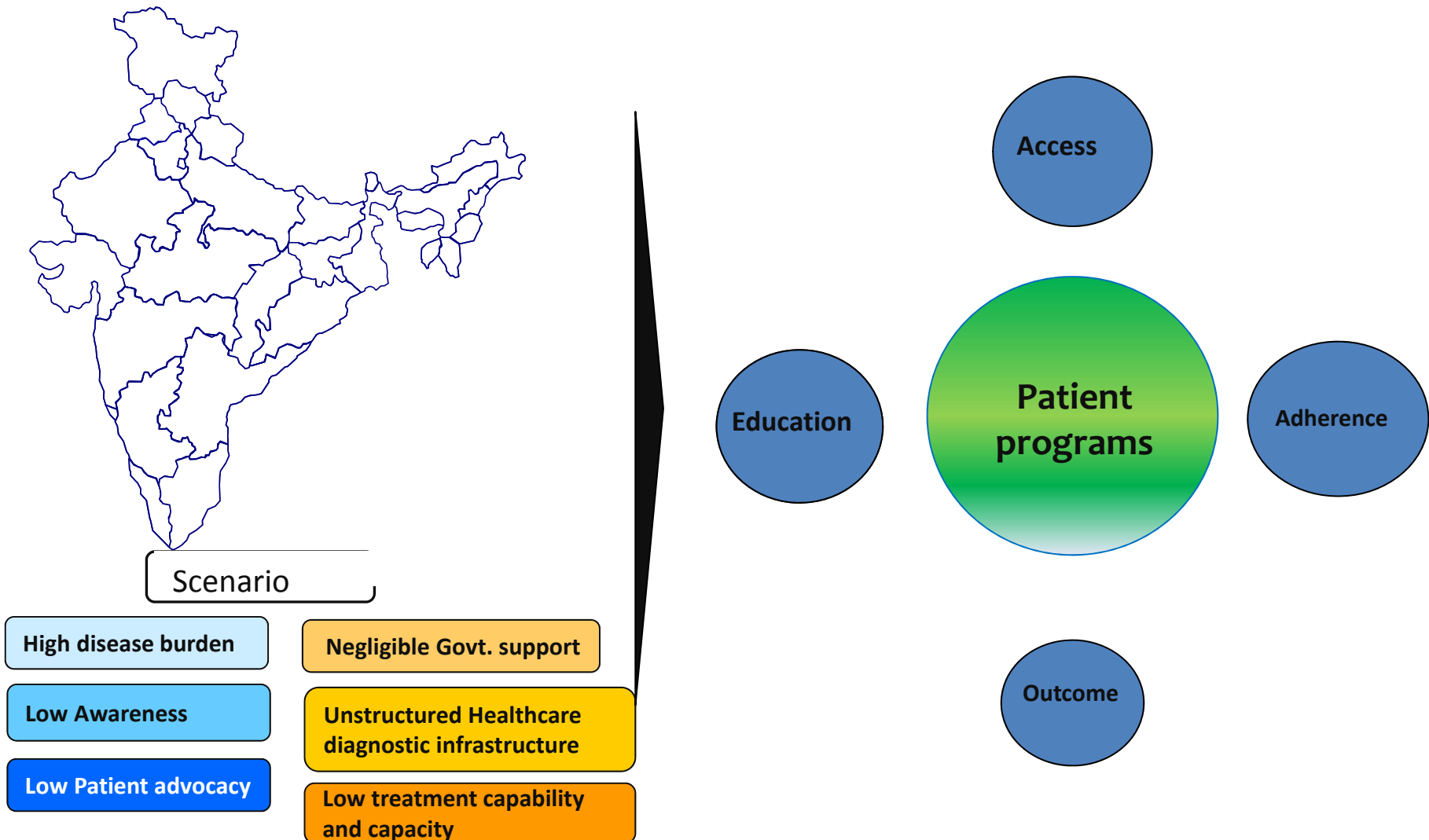


- **Business Leaders are the owner of the Dashboard**
- **Compliance provides training & oversight and facilitate the self review Mechanism**
- **Steering Committee to ensure remediation & implement suggestion.**
- **Access restricted to Management level so that, they themselves get involved into the process rather delegating .**
- **High visibility at global & regional level**

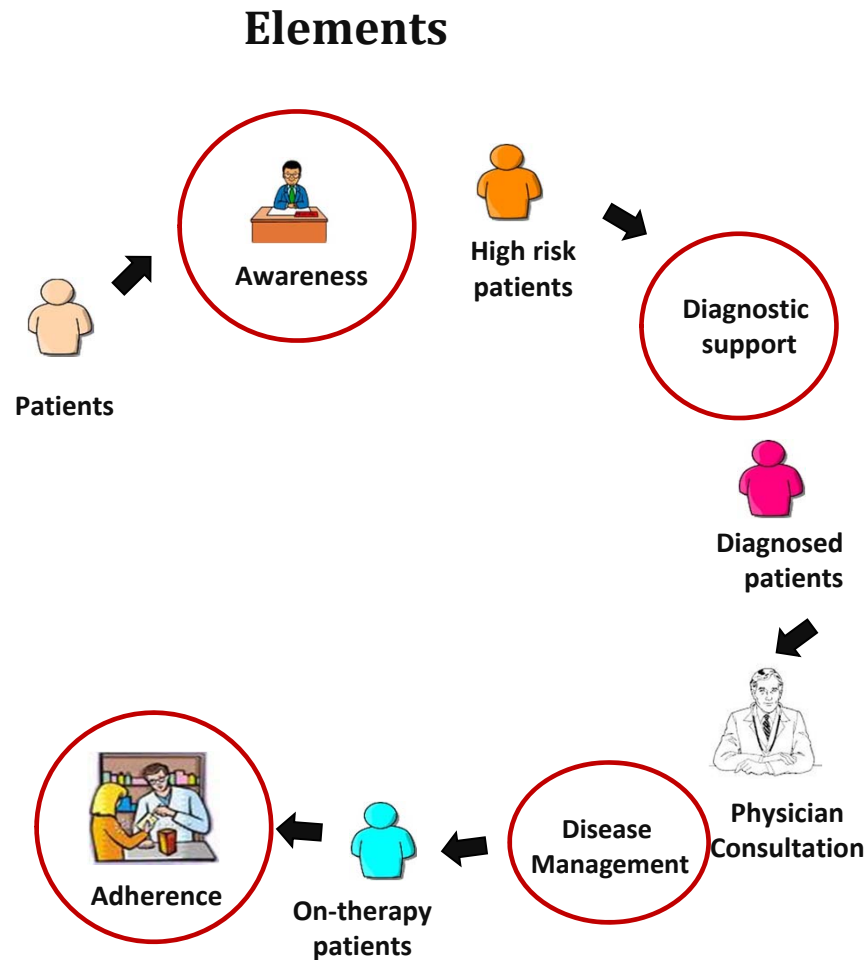


Patient Programs

Patient Programs – India perspective



Elements of Patient Programs



Patient Education Programs

- Awareness Camps
- Educational Material/Display

Patient Diagnostic Programs

- Screening
- Risk Assessment

Disease Management

- Diabetes Management
- Counseling

Adherence

Interaction/Guidance post prescription.

Key Principles and Compliance Controls

- The patient program must relate to medical improvement of patient outcomes, and not be intended only to increase patient convenience or comfort.
- Programs should not be a substitute for the role of the HCP in treatment decisions.
- The program should not lead to directly / indirectly benefitting or supporting HCP/Clinic as an offset of their routine and normal business expenses.
- The program must not be used to help create 'billing opportunities' or offset expenses that the HCP or practice would otherwise have to pay.
- Any involvement by Company must be disclosed and transparent in the conduct or support of the activity.

Key Principles and Compliance Controls

- The involvement of sales representatives shall be limited – Primarily Logistic.
- Unbranded with the only reference of being the supporter of the program.
- Information or support to patients delivered through a qualified HCP or third party, and not directly by Company.
- Patient confidentiality, collection and management of any personal information - Privacy Regulations, Procedures and Corporate Policy.
- Adverse event reporting must follow established procedures.



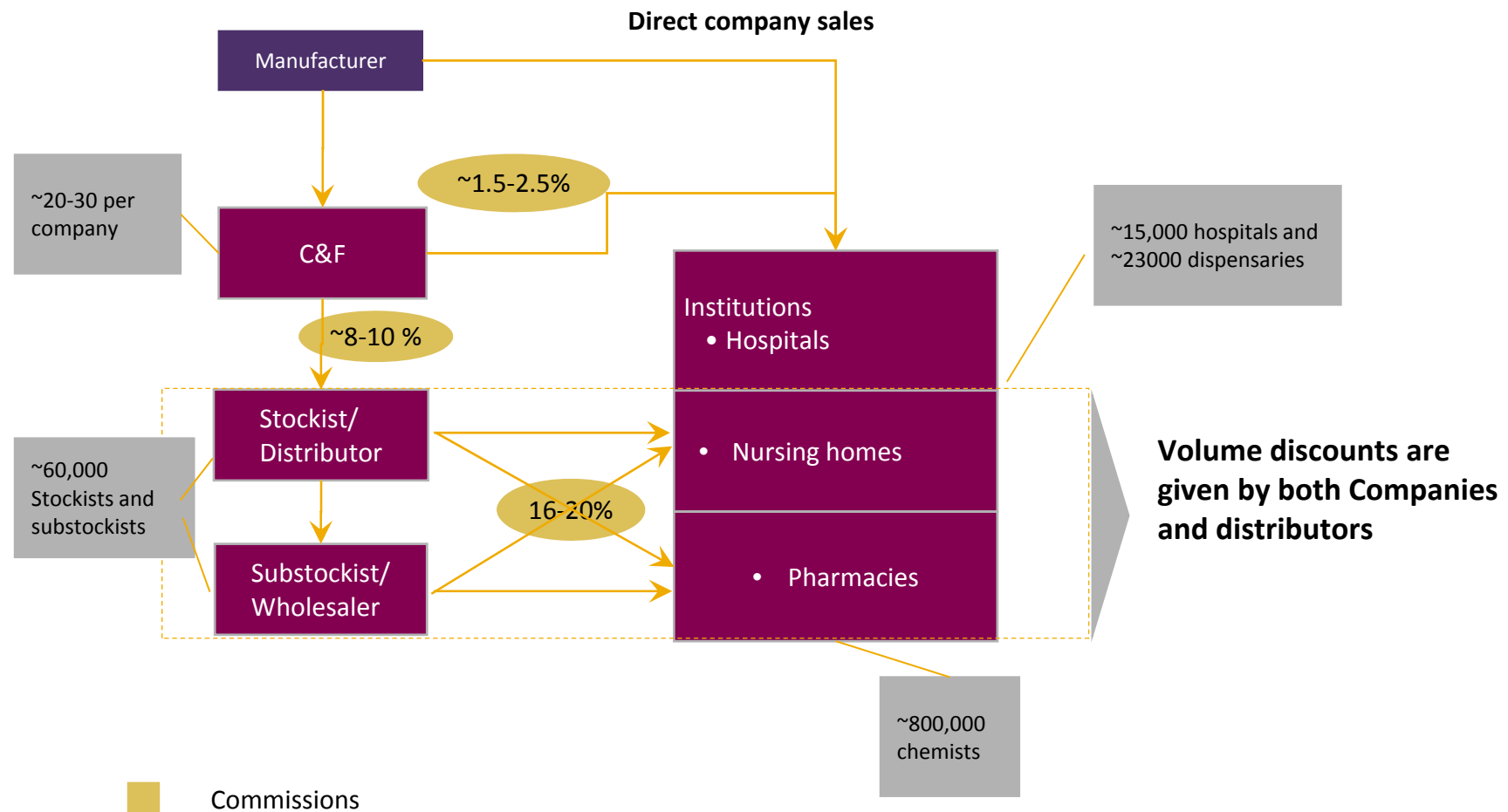
Distribution Channel-India

Distribution : Background and numbers

Brick level data of product sales not available

Large volume based play

Limited IT infrastructure (~ 80% of retailers are still not computerized)



Challenges

- The relationship is one of P2P and transactions carried out on these terms.
- The distributor is not exclusive. The Companies have many distributors and the distributors have many company lines.
- The competition for retailer order is very high leading to instances of distributor parting with part of their commission (Volume/frequency based discount)
- Mostly family run businesses and hence no established processes and policies (mom and pop store model and none are listed on stock exchanges)
- The distributor is largely a logistics partner – does not promote, is a principal and not an agent, does not pay on behalf of the Company and hence difficulty in making them aware of the need to follow Company expectations
- Highly fragmented and local operations(typically one city/town operations) and hence do not have exposure to global norms and hence difficult for them to comprehend Company requirement for policies/process

Process in the fragmentation

- All active Distributors identified and dormant distributors blocked
- As none of the Distributors have a policy based approach, a complete slide set involving the key principles of Anti bribery/corruption and methods to escalate rolled out as training and enhancing awareness of the distributors
- Contracts renewed with adequate Anti Bribery clauses inserted
- High risk distributors (such as distributors supplying products to Govt institutes etc) put through a more rigorous due diligence including financial, taxes, court cases, etc
- Acknowledgments of understanding the ethical standards and abiding by them sought from the distributors
- Monitoring of adherence to the principles, in particular for discounted sales introduced for better visibility and assurance
- Stringent due diligence (not just financial but reputation based too) prior to new appointment of a distributor. Multiple internal stakeholder approvals (finance, legal, procurement, Compliance etc) sought prior to issuing the appointment letter.



Team- India