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# *Fourth Asia Pacific Pharmaceutical Compliance Congress*

## MINI SUMMIT VII- September 17, 2014

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# Industry Overview

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# *Market value and industry performance*

- ***The Indian Pharma market (IPM)*** is valued at USD 12,012 Millions in 2013 as against USD 10,942 Million in 2012. The growth rate is slow currently due to the new pricing policy and other regulatory challenges.
- The ***top 10 companies*** contributed to 41% of total Indian Pharma market sales in 2013 up from 39% in 2010
- The ***top 10 therapy areas*** of the Indian Pharma market contribute to approximately 90% of the IPM sales
- Increased access to healthcare, improved infrastructure and greater penetration of pharma companies into extra urban regions has led to an enhanced contribution and a higher growth from lower town classes in the IPM.
- India is the biggest supplier of medicines to the US and according to the industry sources, pharmaceutical exports from India to the US rose nearly 32 % last year to 4.23 billion USD.

*Source: India Pharma Inc. -Changing landscape of the Indian pharma industry available at www.pwc.com*

# *The top 10 companies in the IPM contribute to 41% of sales and are growing at 11%*

***Highly fragmented market – over 20,000 companies of which 200 account for 80%***

| Company | Sales (USD Million) | Growth % | Market Share % |
|---|---|---|---|
| **IPM** | **12,012** | **10%** | **100%** |
| Abbott | 817 | 7% | 6.8% |
| Sun | 440 | 20% | 5.1% |
| Cipla | 601 | 7% | 5.0% |
| Zydus | 536 | 20% | 4.5% |
| GSK | 530 | 4% | 4.4% |
| Ranbaxy | 497 | 7% | 4.1% |
| Mankind | 436 | 20% | 3.6% |
| Alkem | 414 | 12% | 3.4% |
| Pfizer | 369 | 6% | 3.1% |
| Lupin | 362 | 11% | 3.0% |
| **Others** | **7010** | **10%** | **59%** |

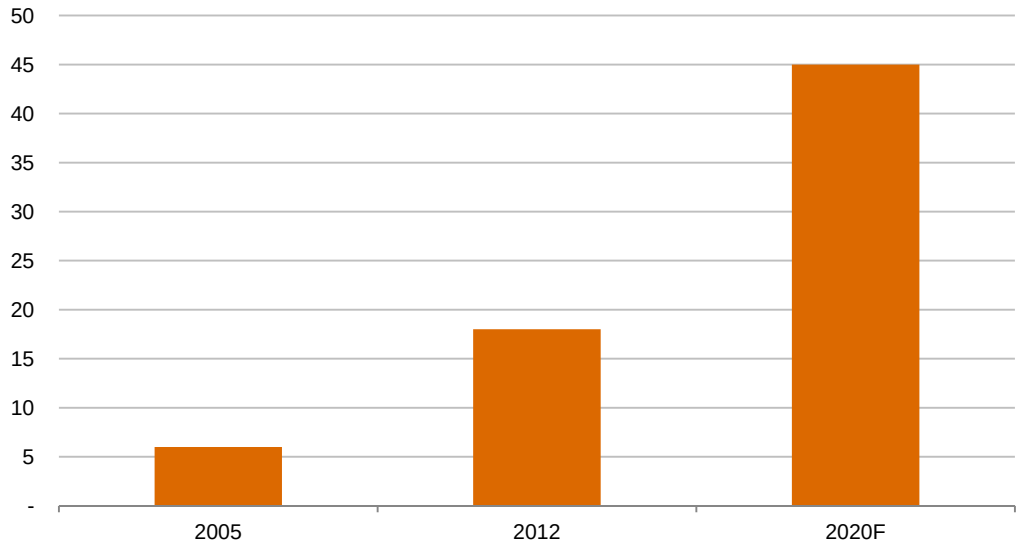
- The Top 10 companies are all above the USD 333 Million mark in terms of sales
- Sun Pharma has added the highest incremental value among the top 10 companies at USD 101 Mn, followed by Zydus (USD 88 Mn.) & Mankind (USD 71 Mn.)
- Sun Pharma, Zydus & Mankind have gained rank in the IPM over previous year while Cipla, GSK, Ranbaxy & Alkem have dropped ranks. Ranks of Abbott, Pfizer & Lupin have remained unchanged over 2012

# *Industry Outlook*

- The Indian pharmaceuticals market grew at a CAGR of 17.0 per cent in 2012 from only USD 6 billion in 2005 and is expected to grow at a CAGR of 12.1 per cent to reach USD45 billion in 2020

- By 2020, India is expected to be within the top 3 pharmaceutical market by incremental growth and sixth largest market globally in absolute size

**Revenue of Indian Pharmaceutical industry (USD billion)**

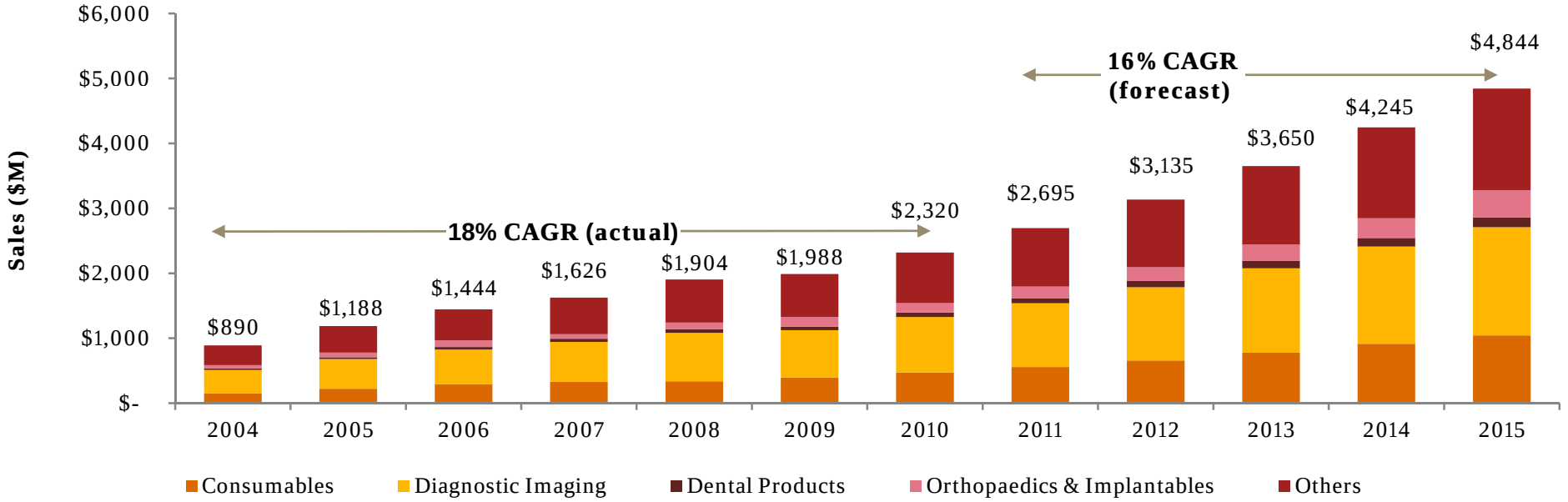



*Source: IBEF March 2014*

# *India Medtech market is poised for major growth*

## *Growth in economy and growth in delivery models to continue to power Medtech market*

### India Medtech Market Growth[1]




- 23 out of the 25 top medical device firms have established at a minimum a direct sales and marketing presence in India
- Higher-end medical devices such as orthopaedics and other implantables are projected to grow at 19% CAGR until 2015[2]

1. PRTM Emerging Markets Supply Chain Survey, MDISCC 2011
2. EPSICOM India Medical Device Report, 2010

# *Current scenario in India*

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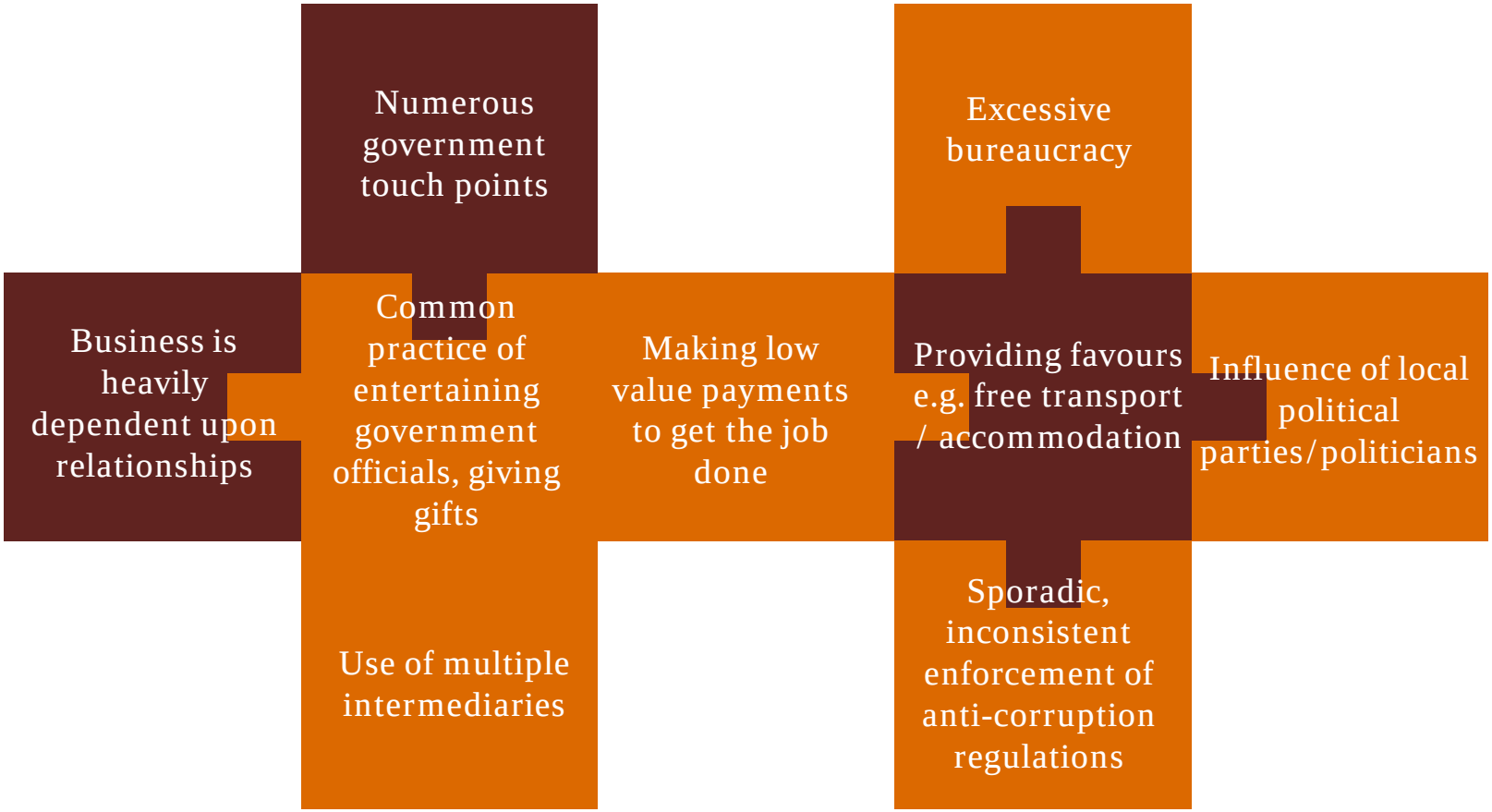
# *Risk Factors - Bribery and Corruption in India*




*India was ranked among the world's highly corrupt nations at the 94th spot out of 177 countries in Transparency International's* ***Corruption Perception Index 2013.***

# *Current scenario in India*

**In an attempt to market/promote products, pharmaceutical companies regularly interact with HCPs and government officials. Some areas of concern in this regard are as follows:**

## *Interaction with HCPs*

- Inappropriate benefits to HCPs through sponsorships, travel facility, per diem provided during international conferences, donations etc.
- Providing expensive gifts to HCPs or incurring lavish expenses on meals or entertainment with HCPs
- Payments to HCPs or profit margin sharing for recommending the company's product

## *Government Officials*

- Inappropriate payments to government authorities during bidding, approvals for clinical trials or product licensing.

## *Distributor/ Liason agents*

- Free products meant for poor patients sold in the grey market.
- Fake orders created by distributors to generate slush funds

# *Current scenario in India* *(contd….)*

- Strict enforceability of voluntary pharma codes is challenging.
- Multinational pharma companies adopting safer approach to ensure compliance with law of the land.
- Local companies yet not completely in compliance with the codes.
- Indian Government taking steps towards better implementation of the draft Uniform Code.
- Change in Indian Government might lead to faster results.

# *Challenges*

- Concerns of US FDA with regards to manufacturing quality of Indian plants and concerns of MNCs and Indian companies with regards to selling practices will dominate client thinking.
- Growth in Pharma sector was slow in CY13 with regulatory changes namely – new National Pricing Policy, FDI restrictions, compulsory licensing issues.
- National Pharmaceutical Pricing Authority, country's drug price regulator's move to control the price of commonly used diabetes and heart diseases drugs in addition to changing the formula to arrive at the ceiling price from a cost based method to a market based method.
- Differing standards between the Department of Pharma (DOP) guidelines and Medical Council of India (MCI) guidelines requiring a need for clarity from industry point of view.
- Delays in clinical trial approvals in India leading companies to rethink their plans for conducting clinical trials in India.

# Regulatory scenario in India

## *Prevention of Corruption Act, 1988*

- Central statute applies to all of India
- Intends to curb bribery and corruption in the context of civil servants of the central and state governments

## *Central Board of Direct Taxes ("CDBT") circular*

- 2012 circular disallows expenses incurred by pharma and life science businesses in providing freebies to medical professionals
- Value of freebies will be treated as taxable income

## *The Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002, ("MCI Code")*

- Prohibits medical practitioners and their professional associations from accepting any gift, travel facility, hospitality, cash or monetary grant from the pharma and life science companies

## *Code of Marketing Practice for Indian Pharmaceutical Industry ("Draft Uniform Code")*

- Voluntary code relating to promotion of pharmaceutical products and interactions between health care professionals (HCPs) and the pharma industry
- Prohibits freebies to HCPs or their families

## *OPPI Code of Pharmaceutical Practices, 2012*

- Voluntary code for pharmaceutical companies in India
- Prohibits freebies to HCPs; provides guidance on (i) appropriate venues for meetings / events; (ii) engaging health care professionals as consultants / advisors; and (iii) prohibition of promotional aids / brand reminders

# *Trends in the Indian Pharma industry*

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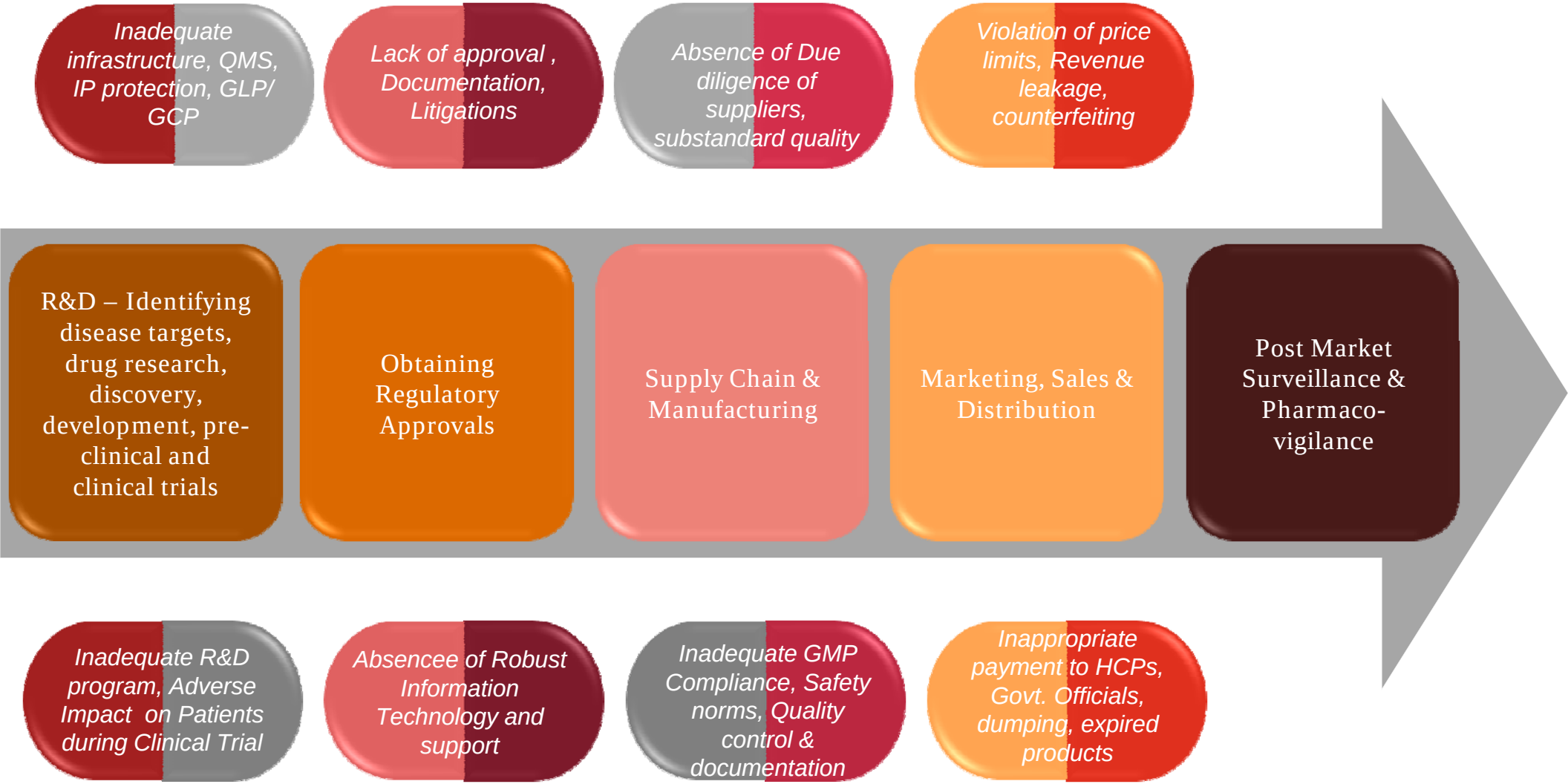
# Pharma Value Chain – Risk and Challenges



# *Pharma R&D and Clinical Trial*

## CHALLENGES

1. Successfully developing innovative drugs and enhancing R&D productivity.
   *Companies need to move new products into existing and new markets quickly to obtain sufficient benefit from a limited patent life and to compensate for development costs which can exceed $800 million per drug*
2. Leakage of insider information on discovery of new drugs
3. Lack of adequate mechanisms to safeguard illiterate and vulnerable patients, prevent informed consent violations and ensure proper functioning of institutional ethics committees

## Some recent action/ enforcement by Regulators

### New Regulatory Regime

Jul 2013: Supreme Court directed Central to come up with new regulatory regime for clinical trials that reflects the concerns of all stakeholders, including those who volunteer to undergo tests at risk of adverse health effects and even death.

Deaths from trials stood at 2,644 in last 5 years. Additionally, 11,972 cases of adverse effects were reported, with 506 cases being directly attributable to the trials. Adverse effects included dementia, psychiatric problems, heightened blood sugar levels, chest pain and heart problems.

# *Pharma Manufacturing*

## CHALLENGES

1. Violations in Safety of drugs
2. Lapses in GMP
3. Lapses in US FDA
4. Environmental norms violations: *Storing Bio-medical waste beyond prescribed period and non-disposal of waste in specified time*
5. Manufacture and Sale of Adulterated & Spurious Drugs
6. Issues on Data Integrity

## Some recent action/ enforcement by Regulators

### Safety of Marketed Drugs

1. December 2009: A UK based large Pharma company was levied a fine of $1 billion for birth defect associated with use of anti-depressant drug during pregnancy.
2. July 2010: One of the Global Top 10 Pharma company (US based) settled suit of $4.8 billion for numerous deaths of patient following heart attack induced by a painkiller.
3. **September 2013**: US regulators banned one of the Largest Indian Pharma company's 11 drugs from entering US over safety concerns.

### Lapses in GMP & US FDA

1. Several Indian Top Pharma companies have faced FDA action in the recent years.
2. **May 2013**: A large Indian Pharma company Pleads Guilty and Agrees to Pay $500 Million to Resolve False Claims Allegations, cGMP Violations & False Statements to FDA
3. In the year **2013,** there were around 34 reports of GMP non-compliance and most of the plants were based in India and China.

### Other Compliance Issues

1. Manufacture and Sale of Adulterated Drugs: October 2010: A UK based large Pharma company was levied a fine of US $750 million for manufacturing and sale of certain adulterated drugs.
2. Data Integrity Issues: **1 Feb, 2014**: US FDA banned products from an India based Pharma company's biggest drug ingredient plant at Toansa due to alleged data integrity violations.

# *Pharma Distribution & Sales*

## CHALLENGES

1. Illegal off-label marketing and sale of drugs
2. Violation of Price Limits
3. Unlawful Promotion of Drugs
4. Bribery/Unlawful Influence on doctors and other clinics for sale of drugs
5. Objectionable Advertisement of Drugs

## Some recent action/ enforcement by Regulators

### Objectionable Advertisement of Drugs

1. FDA shut off 15 companies globally, including Gujarat-based Life Care company, for illegal sale of drugs labelled as dietary supplements and ayurvedic products for treating diabetes
2. Sept 2009, one the Top 10 global US based Pharma company inked $430 million settlement for misbegotten promotions of seizure drug. The company pled guilty for promoting drug to treat acute pain at dosages FDA had previously deemed dangerously high.
3. May 2012, one of the Top 10 US based Pharma company was fined $1.5 billion for illegal promotion of a drug. The company admitted to training special sales force to target nursing homes, and market the drug for control of aggression and agitation in elderly dementia patients.

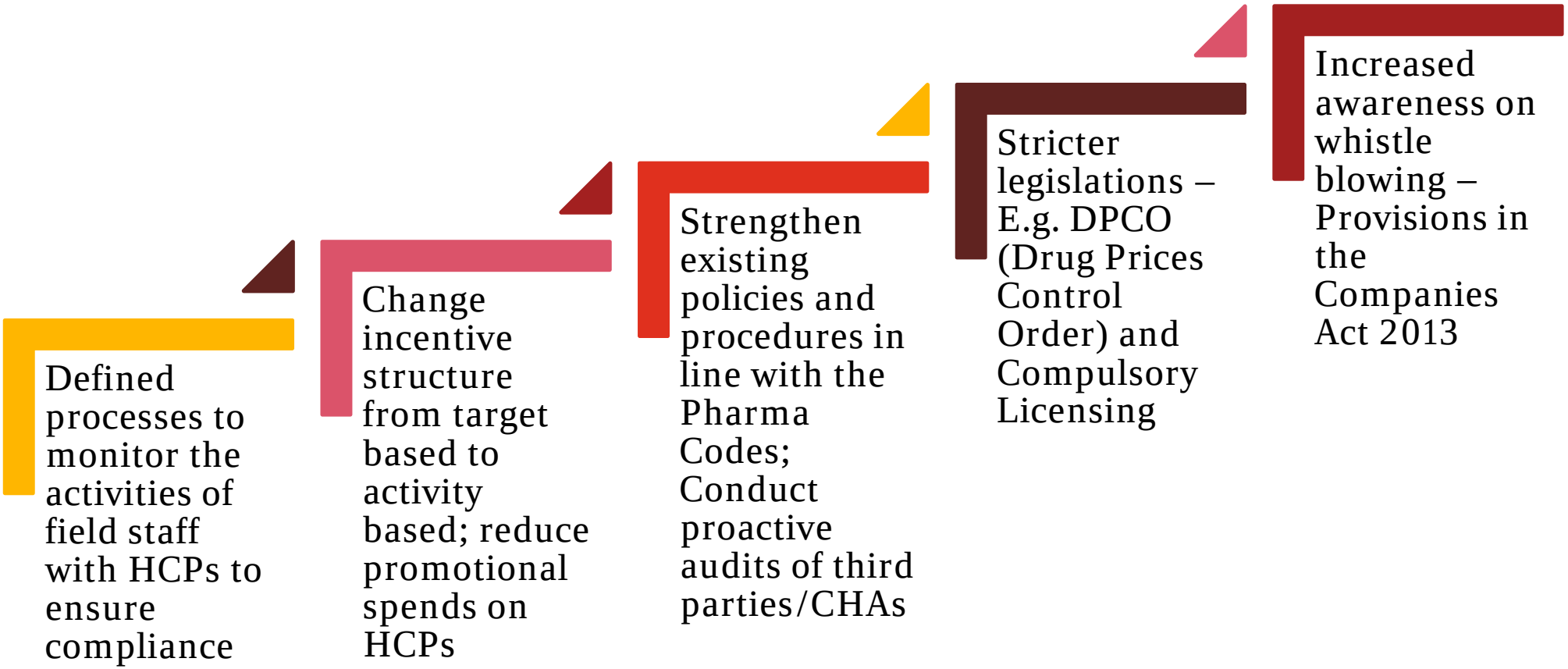
### Other Compliance Issues

**Violation of Price Limits:** In ***December 2013***: Apex court in a ruling against a UK based Pharma company's appeal held that unsold medicine stocks from previous batches cannot be sold at higher unrevised prices after the cut-off date fixed by the drug price regulator. NPPA has thereafter asked companies to pay the overcharged dues with 15 per cent interest.

**Bribery / Unlawful Influence on doctors and other clinics for Sale of Drugs:** In **Dec 2012:** One of the France based top 10 Pharma company agreed to pay $109 million to resolve allegations that company gave doctors free units of their medicine to encourage those doctors to buy their product.

# *Landscape of institutional business in India*

# *Recent trends witnessed in the Indian Pharma industry*



# Robust internal compliance programme

## Critical questions to consider while setting up an internal compliance programme

- Are all dealings with healthcare professionals as well as government and regulatory agencies conducted in the mosttransparent and ethical manner?
- Do you really know who your third-party and business agents are?
- In the race to optimize profits, have you compromised any aspect of compliance or controls?
- Do you have adequate controls over your contract manufacturing facilities?
- Are you aware of the business practices adopted by your CFA, stockist or distributor? Are they in line with your compliance standards?

# *Enabling Technology in Sales, Marketing and Distribution*

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# *Enabling technology to gain better visibility and control over sales, marketing and distribution*

**Pharma companies are resorting to technology by taking assistance from data analytics etc. in performing the following activities:**

- Using CRM to monitor the field operations/activities of field staff
- Data analytics on sales by location, product, division for red flags/alerts
- Proactive risk management review of CFA operations
- Implementing mobility solutions such as smart phones/tablets for recording and monitoring activities of field force
- MIS dashboards analyzing consumption patterns and billings

# *Thank You!*


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