



OPPI

Organisation of Pharmaceutical Producers of India

## India Compliance Best Practices Overview

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*Disclaimer: This presentation represents views of the members of OPPI Working Group on Ethics and Compliance in respect of compliance best practices in the pharmaceutical industry in India*

# OPPI

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**OPPI** (Organisation of Pharmaceutical Producers of India) was established in 1965 and leads in:

- Innovation
- Ethical marketing
- Adherence to Good Manufacturing Practices (cGMP)

Currently have 47 members.

## **Objectives (To Make a Difference)**

- **Intellectual Property Protection:** promoting innovation for the good of India
- **Access to Healthcare:** partnering with stakeholders to enable physical reach, quality and affordability
- **Ethics and Compliance: reinventing ourselves and committing to high ethical standards and compliance**



# Overview of India

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- GDP per Capita: 1,489 USD<sup>1</sup>
- Inflation : 8% for 2014<sup>2</sup> (expected)
- GDP Growth: 5.4% for 2014<sup>3</sup>(expected)
- Population : 1.2 Billion (approx.)
- Young Vibrant population<sup>4</sup>  
( >50% population below the age of 30)
- Burgeoning middle class<sup>5</sup> ( 41% of the total population by 2025 vs. just 14% today)
- World's largest democracy, multi cultural, free speech, fiercely independent media
- Anti-corruption agitations in recent years



Source : 1: World Bank

2: RBI

3: IMF

4: UN World Population prospects, May 10, 2011

5: Mckinsey Global Institute, The Rise of India's Consumer Market, May 2007

# Indian Pharma Industry

- Pharmaceutical industry in India is expected to continue the strong growth momentum with CAGR: 12-14%<sup>1</sup>
- India has the largest FDA approved manufacturing plants outside of the USA (more than 175)
- India is the third largest pharmaceutical market by volume
- Product Patents recognized since 2005
- Highly fragmented and price sensitive market with over 56,000 brands and 10,000 companies
- Share between MNC: India is 28:72<sup>2</sup>
- Essential Medicines under price control
- 75% healthcare spend is Out of pocket
- 12th five year Plan envisages doubling of HC spends by Government (TBD in building infrastructure)
- More than 750,000 chemists (Retailers and wholesalers)

Source : 1: IMS Data  
2: IMS December 2013 Data



Map of India presented on this slide is to compare other countries based on population and does not portray the real political & territorial boundaries of India.

# Why Compliance ?

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## Expectation

- Society expectation and sensitiveness to business integrity are very high to cater patients needs

## Law and regulations

- Stringent regulatory rules introduced in India (MCI Code in 2010 and OPPI Code in 2012)

## Operational Excellence

- Long term sustainable growth
- Fair competition

**Above all our responsibility**

# OPPI Focus Areas for Compliance

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- Development of OPPI Code of Pharmaceutical Practices 2012 based on IFPMA Code. OPPI code also cover Indian law / guidelines issued by Medical regulators, e.g. MCI and DOP
- Provide platform for Industry to have dialogue with Government and other regulatory bodies, e.g. MCI, Health Ministry etc.
  - To create level playing field MNCs VS INDIAN players
- Aligned with national health care objectives
- Addresses the concerns / violation of OPPI code reported by the member companies as per operating procedure set in the code
- Created specific OPPI Working Group on Ethics and Compliance in the year 2012

# India Compliance Best Practices

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- **Evolving Compliance Structure & Program**
- **Key Industry Practices – A Risk based Approach**
  - Awareness
  - Third Party Relationship
  - Health Care Professional and Health Care Organization Relationship
  - Anti- Bribery and Corruption
  - Complaint Management

## Evolving Compliance Structure & Program

Designing and Implementation of Compliance Program with independent governance structure

### Prevent

- SOP - Defining standards to comply with laws
- Training - Awareness to change mindset
- Tone at the top - Required on all levels

### Detect

- Monitoring & Auditing – Continuous improvement and effectiveness
- Communication – Identification of issue/s at early stage

### Respond

- Correction – Swift and effective
  - Well Defined Process
  - Disciplinary Action



## Awareness

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- Why, what and how - *Changing the mindset of people*
- Adoption of global best practices – *One policy globally with due respect to local laws*
- Collaborative approach (everyone responsible) - *Using diversity to strengthen controls*
- Regionalisation of compliance message – *Speak in their language*

## Third Party Relationship

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- Due Diligence (Know your partner) – *Go extra mile (limited data available online)*
- Evolving the process – *Dynamic approach (identify the change)*
- Education - *Communicating the benefit of being compliant*

## Health Care Professional and Health Care Organisation Relationship

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- Transparency (Documentation) - *Focus of Patient benefit and to avoid wrong perception*
- Ethical Marketing practice – *Level playing field for everyone*
- Communication & education - *Communicating the benefit of being compliant*

## Anti- Bribery and Corruption

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- Adoption of International Laws – *One policy globally with due respect to local law*
- Gifts – *Clearly defined policy for gifts (trade/cultural/customary)*
- Persistence and Perseverance – *Don't give up attitude (It's a chain reaction and impossible to stop later)*

## Complaint Management

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- Culture of raising concern - *The World suffers a lot not because of action of bad people but because of silence of good people*
- Whistle blower protection – *Feeling secure*
- Neutral Approach – *Rules are same for everyone*

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# Questions?