

**OPPI Academia Programme – Sawyer School of Business Boston**  
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**I ABOUT OPPI**

Established in 1965, is a premier association of research based and large pharmaceutical companies in India and is also a scientific and professional body. It caters to the needs of Research based Pharmaceutical Industry thereby creating and sustaining an environment conducive to innovation and growth, simultaneously facilitating industry and stakeholders partnership through various advisory and consultative processes to achieve the Healthcare objectives of the Nation.

**OPPI Members follow :**

- GMP
- OPPI Code of Pharmaceutical Marketing Practices
- IPR

**OPPI Functions**

- Dialogue with stakeholders
- Knowledge creation & knowledge sharing with value addition
- Corporate Academia Interaction
- CSR
- IFPMA & WSMI Membership

## **Indian Pharmaceutical Industry**

- **Domestic Sales US \$ 8 billion growth, 13% exports US \$ 5 billion growth, 20% currently declined**
- **Net foreign exchange earner –  
60% of the population is within the age group of 30 years skilled English speaking manpower**
- **Good IT infrastructure entrepreneurial spirit**

## **II POLICY FRAMEWORK**

### **(a) Drug Policy – Ministry of Chemicals & Fertilizers**

**Pricing, reducing span of control**

- **2002 Policy yet to be announced**
- **Current products under Price Control 1976**
- **20% under cost based price control**
- **80% under price monitoring**

### **(b) Regulatory Policy – Ministry of Health & Family Welfare**

- **In the process of reform aligning itself to global standard**
- **Key issues – Clinical Trials of Phase I and Phase II by MNCs.**

### **(c) IPR Policy – Dept. of Industrial Policy & Promotion, Ministry of Commerce & Industry**

- **Patent Act (Amendment) 2005 heralds a new beginning**
- **Still some key issues :**
  - **Patentability**
  - **Patent Linkage**

- RDP
- Pre-grant Opposition
- Compulsory Licensing
- Patent Infrastructure

(d) **Biotech Policy – Dept. of Biotechnology, Ministry of Science & Technology**

- New Biotech Policy announced – some concerns being addressed
- Biosimilar Guidelines

(e) **Counterfeit Medicines**

- Magnitude of the problem
- Recent law enacted
- Definition of counterfeit medicines

(f) **Outsourcing Opportunities**

- Clinical Trials
- CRAMS

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