

**Indian Pharmaceutical
Industry and Laws
Governing Manufacture
and Sale of Drugs**

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Indian Pharmaceutical Industry

Pharmaceutical Industry

- 108 Year Old
- First Indian owned firm – The Bengal Chemical and Pharmaceutical Works (1901, Prof P.C Ray)
- Alembic Chemical Works (1907, Baroda) by T. K Gaffar and Rafmitra B. D Amine
- Sarabhai Chemical Works
- Bengal Immunity Laboratory
- Government Laboratories

- Ancient times – Ayurvedic and Unani medicines
- Allopathic medicines – offered immediate relief
- Nine firms had been existing before 1915
- Small and medium sized plants engaged in making formulation from imported bulk drugs
- World War I – stimulus for domestic productions of pharmaceuticals
 - Rise in demand and reduction in imports

- Quinine salts, stilbamine, caffeine and surgical dressings. Biological products like vaccines and sera
- World War II – Blessing in disguise, production of plant based, synthetic and biologics
- By 1941 the industry took up manufacture of new drugs like iodochlor as well as alkaloids
- Arsenicals and antileprotic

- Modern Drug research India in 1920 Sir Ram Nath Chopra – Indian Medicinal plants, School of Tropical Medicine, Calcutta.
- Dr. Upendra Nath Brahmachari, Campbell Medical School, Calcutta – Urea stibamine in 1922 for Kala-azar.
- World War-I – Local Demand for allopathic medicines increased

- Production of Quinine salts-Govt. factories
- 1930 – Manufacture of Sera and Vaccines and anesthetics
- World War II – Was blessing in disguise, It started undertaking the production of plant based, synthetic and biologics
- CSIR (March 12, 1942) – Promotion, Guidance and coordination of Research and Development activities in India.

Post Independence

- Few drugs were produced from intermediates.
- 1948 survey was undertaken of the country's industrial potential in all the sectors and a program of development was undertaken in the first five year plan
- 1950's – Pharma Industry was dependent mainly on imported technology
- In 1951 the Industries (Developments and Regulations) Act was passed

- The pharmaceutical Enquiry Committee which examined the structural imbalances of the industry had submitted its report in 1954.
 - Its recommendations included various aspects like licensing, foreign collaborations, production of bulk drugs and selling and distribution of drugs and medicines.
- HAL, 1954, Pimpri

- Special Incentives were provided by the Govt
- IDPL, 1964 – Bulk drugs and Formulations
- 1970's – Upsurge of R&D – Liberal Tariff, Tax exemptions and financial incentives.
- Special Provision in Patent Act, 1970 to exclude product patents – provided the right climate for technology innovation
- 1980 – 1990, Number of Drug manufacturing units

Present Scenario

- Production of Bulk Drugs and Intermediates
- Formulations Production
- Fermentation Products
- Clinical Research
- Collaborative research
- Exports

SWOT

STRENGTH

- Cost Competitiveness
- Well developed industry with strong manufacturing base
- Well established R&D infrastructure
- Third largest English speaking scientific and technical manpower in the world
- Strong marketing and distribution network
- Rich biodiversity

WEAKNESS

- Low investments in innovative R&D
- Volume driven but low priced markets
- Low healthcare spends
- Highly fragmented industry
- Inadequate regulatory standards
- Spurious and counterfeit drugs

OPPORTUNITIES

- Significant export potential
- Licensing deals with MNCs for NCE and NDDS
- Marketing alliances with MNCs to sell their products in domestic market
- Contract Manufacturing for MNCs
- Opening up of the health insurance sector
- Centre for clinical trials
- Exploiting generic segment

THREATS

- 2005 IPR regime
- Pricing pressure imposed by DPCO
- Threat from China
- Loopholes in the patent bill

Laws Pertaining to Manufacture and Sale of Drugs in India

- The Drugs and Cosmetics Act, 1940
- The Pharmacy Act, 1948
- The Drugs and Magic Remedies Act, 1954
- The Narcotic Drugs and Psychotropic Substances Act, 1985
- The Medicinal and Toilet Preparations Act, 1956

Recent Amendments

- The penalty for manufacture, stock and sale of spurious drugs has been enhanced to 10 years or life imprisonment and fine not less than Rs. 10 Lakhs (It is distributed to patients/consumers affected)
- Marketing adulterated drug – seven years imprisonment and fine of Rs. 50,000
- Spurious Ayurveda, siddha and Unani drugs – one year with a fine of Rs. 20,000
- Separate judicial courts – adulterated and spurious drugs

THANK YOU

??Questions??