Can India be the Leader in Global Generics

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NURAY CHEMICALS PVT. LTD. USFDA Approved
R&D and Manufacturing of API

Sai Mirra
R&D and Manufacturing Formulations

Ethics Bio Lab Pvt. Ltd. USFDA Approved
CRO & Bio-equivalence

Numen Healthcare Pvt. Ltd. Singapore
International Marketing

Delvin Formulations
Domestic Formulation Marketing

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Indian Pharma Industry
Before 1970

- Depending on MNC from USA and Europe for supply of Medicines
- Hardly few Indian Companies in Top 25
- 1970 the Indian Patent Act removed the Product Patent and implemented Process Patent

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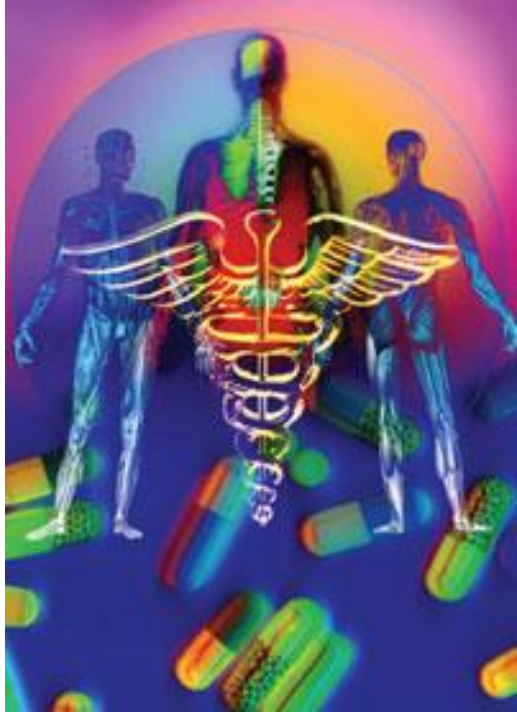
Indian Pharma Industry
1970 - 2005



- Many Indian Companies emerged
- In 80's many Indian companies started launching the latest drugs in India at affordable price since there was no product patent
- In 90's India adopted liberalized economical policies and so, Indian pharma industry entered in to Exports aggressively

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Indian Pharma Industry
1970 - 2005

- Due to the free liberal economy ,foreign companies partnered with Indian companies and taught the technology of US FDA and other global standards.
- Foreign Direct Investment was one of the main reason for making India as a leader in global exports to regulated markets
- By 2000 more than 20 Indian companies reached the Top 25 slot

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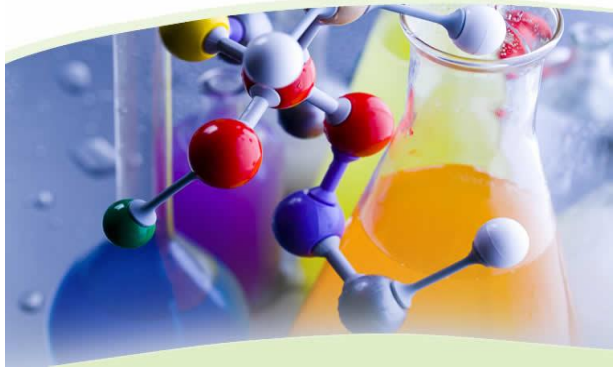

Indian Pharma Industry

After - 2005

- We accepted for patent regime and so process patent changed into product patent
- No Indian companies could launch new molecules
- Many MNC entering back to Indian market and launching new drugs with unaffordable price
- Indian companies are forced to invest in R&D and launch value added old drugs

Patent → **Patient**

Core Factor

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Indian Pharma Industry – Current Scenario

- India is the pharmacy for the world
- Every 3rd pill taken in the world is from India
- Domestic Pharma market value is around 70,000 crores ($11.5 billion) from 18000 crores ($3 billion) in 1995 with growing by 14% annually
- The exports of pharmaceuticals from India grew to 90,000 Crores ($14.6 billion) from nowhere in 1990 with growth rate of 25% .
- Total growth of the Pharma Market is around 22%.

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Indian Pharma Industry – Current Scenario

- Highest number of USFDA approved facility (550 Plants)
- Accounts for 40% of Generic drugs in USA
- India was recognized as global leader in supply of generic UNICEF
- India is the manufacturing hub for most of the countries
- Every 3rd DMF filed in US is from India

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Indian Pharma Industry – Current Scenario

- India's pharmaceutical sector will touch 270000 crores (US$ 45 billion) by 2020, according to a major study by global management and consulting firm, McKinsey & Company.
- Its steady growth is positively affecting the Indian economy.
- The country accounted for 8 percent of global production Most of the domestic pharmaceutical drug requirements are met by the domestic industry.
- Indian owned firms currently account for 70 percent of the domestic market, up from less than 20 percent in 1970. In 2005, nine of the top 10 companies in India were domestically owned, compared with just four in 1994

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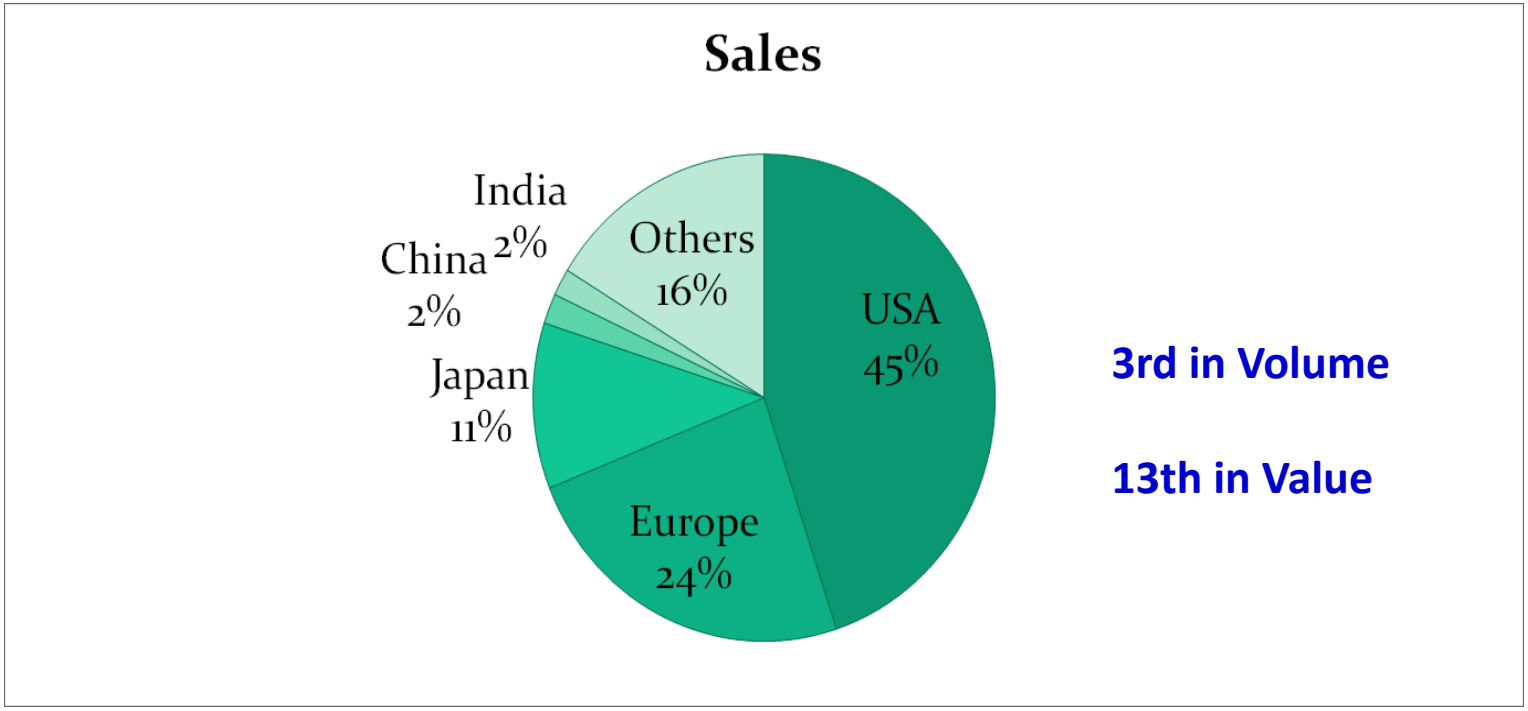
Indian Pharma Industry – Current Scenario

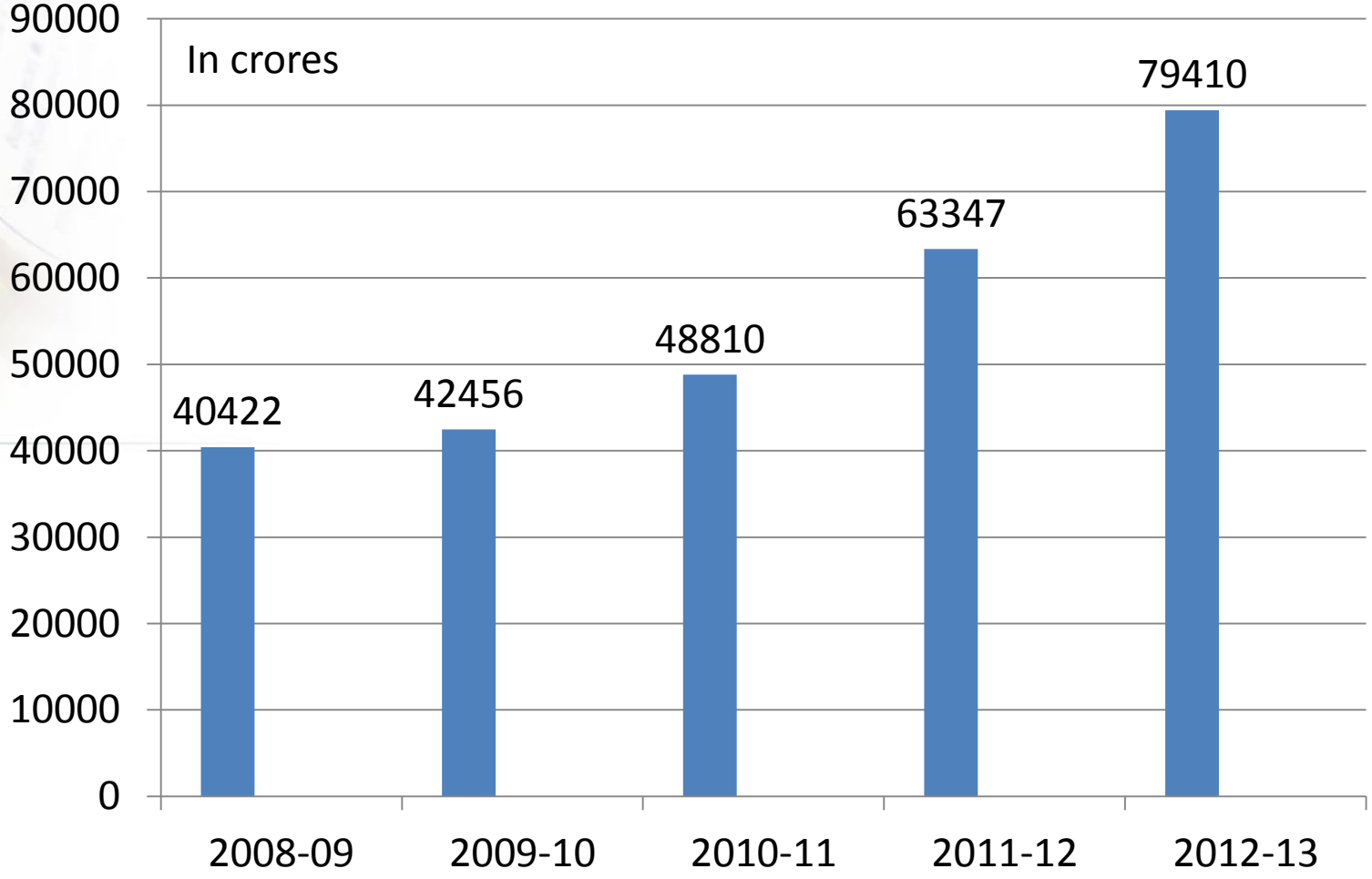


3rd in Volume

13th in Value

Inference – The most economical medicine provider in the World

Pharmaceutical Exports of India



India is 5th Largest export country accounting to 4.83% and growth rate of 25%

Source : Pharmexcil

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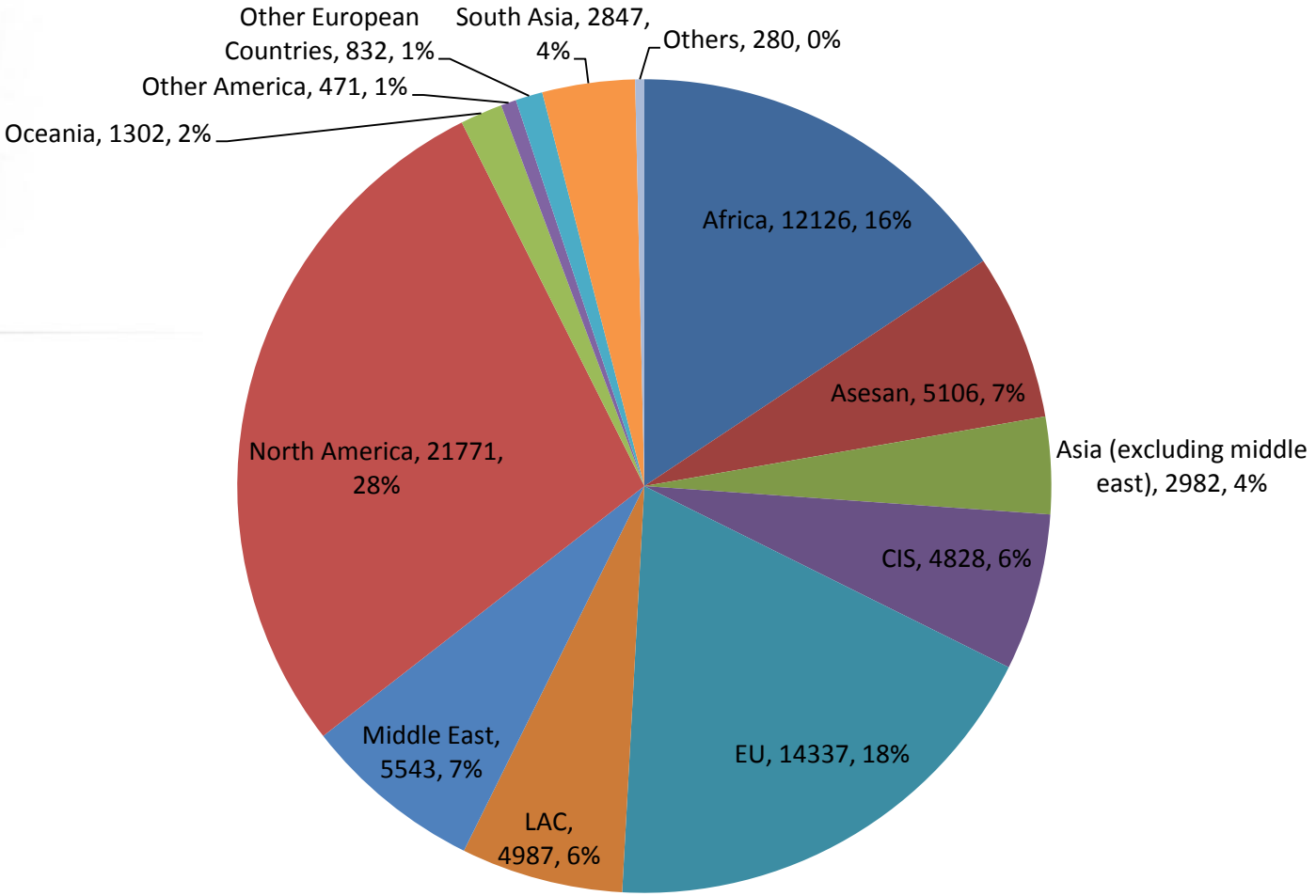
Pharmaceutical Exports of India



India's Pharmaceutical exports region wise in 2012-13

Source : Pharmexcil

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Pharmaceutical Exports of India

Top 25 Designation Countries of India's Exporting during 2012-13				
Rank	Country	2012-13	Gr%	Cont%
1	USA	20239.15	29.33	25.49
2	RUSSIA	3092.61	57.28	3.89
3	UK	2785.18	18.32	3.51
4	GERMANY	2525.18	13.77	3.18
5	SOUTH AFRICA	2397.43	30.50	3.02
6	NIGERIA	1854.61	24.59	2.34
7	BRAZIL	1771.42	32.67	2.23
8	CANADA	1532.02	23.80	1.93
9	KENYA	1371.32	24.47	1.73
10	NETHERLANDS	1354.77	22.69	1.71
11	VIETNAM	1093.97	23.34	1.38
12	TURKEY	1072.16	22.79	1.35
13	AUSTRALIA	1016.36	22.77	1.28
14	SINGAPORE	1013.65	25.15	1.28
15	GHANA	1006.35	41.54	1.27
16	FRANCE	988.10	18.41	1.24
17	ISRAEL	974.80	17.59	1.23
18	JAPAN	964.91	32.94	1.22
19	SPAIN	943.55	-1.38	1.19
20	IRAN	855.86	80.52	1.08
	TOTAL OF TOP 25	48853.40	26.67	66.66
	TOTAL EXPORTS	79410	25.03	100.00

Source : Pharmexcil

- USA remains the top export destination with a share of 24.6% amounting to 20,239 crs and growth of 29%.

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SWOT Analysis of the Indian Pharmaceutical Industry

Strength

1. Qualified English-speaking manpower

2. Fair protection of intellectual property rights.

3. India has skilled scientists / technicians / management personnel at affordable cost leading to low cost of innovation / manufacturing / capex costs / expenditure to run cGMP compliance facilities and high quality documentation and process understanding

4. Data management functions for clinical trials

5. Strength in Chemistry which are essential for drug discovery.

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SWOT Analysis of the Indian Pharmaceutical Industry

Weaknesses

1. Low investments in innovative R & D

2. Majority of companies lack the ability to compete with MNCs for New Drug Discovery, Research and Commercialization of molecules on a worldwide basis due to lack of resources.

3. Rapidly increasing costs of skilled manpower such as scientists / regulatory compliance personnel / pharmaceutical lawyers / International business development

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SWOT Analysis of the Indian Pharmaceutical Industry

Opportunities

1. India has significant export opportunities. US$40 billion worth of drugs in the USA and US$25 billion worth of drugs in Europe are going off patent .

2. This translates to an opportunity of additional export of US$19.5bn

3. Cost advantage in contract manufacturing & Research multi-national companies find it compelling to shift their production bases to countries offering such cost advantage.

4. India has a very high potential for developing as a centre for international clinical trials due to rich diversity.

5. A rise in geriatric population making the nations to move to cheaper APIs and formulations which are India's forte.

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SWOT Analysis of the Indian Pharmaceutical Industry

Threats

1. Product patent regime poses serious challenge to domestic industry unless it invests in research and development.

2. Improper systems and issues complicates conducting clinical trials scope in India

3. MNCs play different strategies to pull down Indian companies

4. Drug Price Control Order puts unrealistic on product prices and profitability

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Strategies and Challenges created by MNCs

- Indian companies were innovating fixed dose combinations which are followed now world wide

- Since their growth in US and Europe is very less the MNCs is trying to penetrate other semi regulated market, where India is leader already.

- Issues in regulatory approvals. Eg. Ranbaxy, Wockhardt

Reason for success of Indian Industries

- 1970 Patent Act and liberation of economy
- Adherence to GMP helps it become a global out sourcing hub for Manufacturing
- Ability to meet global regulatory expectations
- Supplies of High Quality, Low Cost generic drugs
- Speed – Recruitment of patients & conducting clinical trials
- Also dependable outsourcing supplies
- India has strong IT skills for Clinical data Management

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India is the Leader in Global Pharma Generics

THANK YOU FOR LISTENING TO A PHARMACIST