Indian Pharmaceutical Industry

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Introduction

The pharmaceutical Industry around the world is one of the fastest growing industries and a major contributor to the world economy.

India & the World Market size

Currently India’s contribution to the world market stands at 1.4 per cent in value terms and 20 per cent in volume terms. The Indian pharmaceutical industry is however expected to grow at CAGR of 15 per cent as against the world CAGR of 5 per cent between 2015 and 2020 and thereby become the sixth largest pharmaceutical market globally in absolute size. In 2016, IPI registered revenue of USD 33 billion. This is expected to grow to around USD 55 billion by 2020.

World Scenario

The world market is dominated by countries like USA, EU and Japan and the contribution of Phrmerging\(^1\) countries is expected to be more in coming years. According to IMS health report, it is projected that, US will contribute to about 41 percent of total sales of medicine in the word by 2020, followed by EU5 and Chain which are projected to spend about 13 percent and 11 percent respectively. Brazil, Russia and India put together contribute about 6 percent of global consumption of the medicine.

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\(^1\) Phrmerging nations- Twenty-one countries are considered by IMS to be “emerging” within the pharmaceutical world. This category is defined as countries that are expected to see more than $1 billion in absolute spending growth from 2014 to 2018 and which currently have GDP per capita of less than $25,000. The biggest of these is China, followed by Brazil, India and Russia; after them comes the “Tier 3” group of smaller emerging markets, including Mexico, Turkey, Venezuela, Poland and 13 others.
The future of the world pharmaceutical sector will be dominated by medicines for non-communicable diseases and original branded medicines.

**Indian Pharmaceutical Industry (IPI)**

The IPI is a highly fragmented sector, with about 20,000 registered units with severe price competition and government price control. There are approximately 250 large units and about 8000 small scale units which form the core of this industry in India (including 5 Central Public Units). The countries production cost is the lowest in the world. According to IBEF, the cost of production in India is approximately 60 per cent lower compared to US and almost half when compared to Europe.

This has given rise to the increasing export contribution. India derives 50 per cent of its revenues from exports. America is India’s largest buyer accounting for 40.6% of estimated exports of USD 16.8 billion in 2016-17. Europe (19.7%), Africa (19.1%), Other Asian countries (18.8%) are the other major buyers.

Please refer below for the structure of the IPI

The IPI is dominated by the generic drugs segment which makes up for almost 70 per cent of the total revenues followed by Over the Counter (OTC) medicines (21 per cent) and patented drugs (9 per cent)
API/Bulk Drugs: India supplies 20 per cent of global generic medicines, in terms of volume, making the country the largest provider of generic medicines globally and the same is expected to expand even further in coming years. Growth will be driven by increasing number of Abbreviated New Drug Applications (ANDA) approvals.

IPI accounts for the second largest number of ANDA approvals, and is the world’s leader in Drug Master Files (DMFs) applications with the US. The significant share of approvals to India of the total approvals by USFDA (31.8 per cent in FY16) can be attributed to the Indian Pharma companies’ efficiency to make high-quality medicines at competitive prices.

Formulations: In the formulations business as well, India is largest exporter in terms of volume, with 14 per cent market share and 12th in terms of export value. Domestic market size currently valued at USD11.2 billion. A double-digit growth expected over the next five years

Biosimilars: Biosimilar’s sector in India is expected to increase from $186 million in 2016 to $1.1 billion in 2020, according to industry estimates. Indian life science firms are investing in biosimilar development to tap this growing opportunity. They are also establishing manufacturing facilities in other countries to serve the local and export markets. The government plans to allocate USD70 million for local players to develop biosimilars

CRAMS: CRAMS industry is estimated to reach USD18 billion in 2018 and expected to witness a strong growth at a CAGR of 18-20 per cent between 2013-2018. The sector will benefit on account of branded drugs going off patent during 2017-19 which will create an opportunity for CRAMS segment.

Indian Pharmaceutical Market segment by Value

![Pie chart showing market segments]

Source: IBEF
Trends in the Indian Pharmaceutical Sector

- **Focus on Research & Development:** R&D expenditure across the globe is around 15% of sales turnover. While it is much lower in India at around 8-11%, (was less than 2% per cent in early 2000s), the same is expected to increase due to the introduction of product patents; companies need to develop new drugs to boost sales. R&D expenses of top five Indian pharma companies has increased from 5.1 per cent of total revenues in FY 10 to 8.9% in FY17.

<table>
<thead>
<tr>
<th>Companies</th>
<th>R&amp;D Spend</th>
<th>Revenues</th>
<th>R&amp;D spend as % of revenue</th>
<th>Net Profit</th>
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<th>Net Profit</th>
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<tbody>
<tr>
<td>Sun Pharma</td>
<td>208.2</td>
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<td>6964.3</td>
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<td>4773.6</td>
<td>7.2</td>
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<td>17119.6</td>
<td>13.3</td>
<td>2557.4</td>
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<tr>
<td>Aurobindo Pharma</td>
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<td>2.7</td>
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<td>3.7</td>
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<td>Cipla</td>
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<td>5859.5</td>
<td>4.3</td>
<td>1082.5</td>
<td>1071</td>
<td>14280.8</td>
<td>7.5</td>
<td>1006.3</td>
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<tr>
<td>Dr Redys Labs</td>
<td>379.3</td>
<td>7027.7</td>
<td>5.4</td>
<td>106.7</td>
<td>1595</td>
<td>14080.9</td>
<td>13.9</td>
<td>1257.2</td>
</tr>
<tr>
<td>Total</td>
<td>1256.6</td>
<td>2448.4</td>
<td>5.1</td>
<td>3785.3</td>
<td>8024.8</td>
<td>90590.4</td>
<td>8.9</td>
<td>14086.3</td>
</tr>
</tbody>
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Source: Economic time, Bloomberg

- **Increasing Exports:** Indian Pharmaceutical export market is thriving due to the strong presence in the generic market, which supplies about 20 percent of the global market in terms of volume. Furthermore, exports to US, which is already the largest export destination for India, will witness a boost. This will be backed by about USD 55 billion expected sales gain to generics drugs on account of branded drugs going off patent during 2017-19.

- **Joint venture:** The focus on joint venture in pharmaceutical sector is increasing. Many foreign companies joining hands with Indian companies to develop new drugs. The advantages seen in the R&D is contributed by cost effectiveness, availability of skilled employees and government incentives and so on.
  - Cipla signed exclusive partnership with serum institute of India to sell the vaccines in south Africa.
  - LAZOR an alliance of six leading pharmaceutical companies was formed to share best practices and improve their efficiency and reduce operating costs.

- **Favourable amendments in rules & regulations:** In order to compete with global market, the drug approval process has been simplified and approval time for new plant has been reduced. In the draft Patent (Amendment) Rules 2015, the time period of patent grant has been reduced from 12 months to 4 months. Furthermore.

**Future Outlook**

The government wants to control drug prices to ensure its availability at reasonable rates. This is expected to have a continued impact on the prices. However the industry will benefit from the steady growth in the formulations segment on the domestic front, backed by growth in presence of chronic diseases, increasing per capita income, improvement in access to healthcare facilities and penetration of health insurance. Furthermore, while the Indian generic drug segment on the export front will have competition pressure from other countries to get ANDA Approval, and pricing pressure in the US generics market due to consolidation of distribution channels and increase in competition, it will benefit from the expected increase in business from several drugs going off-patent in 2017-19 which will create opportunities in the CRAMS segment. Indian companies are also increasingly developing niche portfolios in various segments such as high margin injectables,
dermatology, respiratory, biosimilars, complex generics etc. Major companies have increased their R&D spend to build pipeline of niche drugs. This in turn will help the companies to optimize growth and margins. Thus, post patent cliff, the companies which have developed their product basket in the niche category will be ahead in the curve.

While the implementation of GST has no major impact on prices of medicines, it has resulted in savings in logistic cost for drug makers as they now have where they can prefer not to have warehouses in each state thus reducing their dependency on CFA. The companies can therefore set up warehouses keeping in mind the logistics benefits rather than considering CST.
Challenges faced in the Pharmaceutical Industry

The Pharmaceutical Industry is rapidly changing on the regulatory, R&D, people, technology fronts. Companies face numerous challenges such as

- Meeting Government policies and compliance
- Increasing costs
- Supply chain issues
- Lack of skilled manpower and training systems as the company scales up
- Inefficient internal systems such as information management

How we can help

NMS provides a wide range of professional services to help overcome these challenges.

- Statutory Cost auditing
- Process costing
- Productivity improvement
- Strategic sourcing, logistics
- Vendor & Customer review & assessment
- Process & HR advisory
- Streamlining sales, HR, IT processes
- Organisation assessment and transformation
- Budgeting & Forecasting
- Information technology solutions covering data and process automation, assisting in the identification and implementation of software, ERP, etc.
- Enterprise risk management enabling organizations to help identify, control and mitigate / manage risk across the organization
- Company law compliance and commercial documentation
- GST Compliance Management & ASP Offerings
- Credit Rating advisory