4. THE OPPORTUNITIES AND CHALLENGES TO PHARMA INDUSTRIES

4.1 Overview of Global Pharmaceutical Industry

The global pharmaceutical industry, after experiencing a shrink during the past 2 years, is now in its recovery period, which will be followed by its growth. Decline in global pharmaceutical market was largely due to the economic recession. Meanwhile, pharmaceutical markets in some developing regions, like Asia and Latin America have been continuously witnessing huge growth rate for the last few years on account of increasing prevalence of diseases, rising healthcare spending, and increasing affordability. IMS Health reports that the total value of the global pharmaceutical market is expected to grow by 5-7% in 2015 to US$1880 billion, compared with a 4-5% pace in 2010. United States is still the largest pharmaceutical market in the world with a market size of around $300 billion and it is expected to reach $370 to $390 billion by 2015.

![Figure 4.1.1: The Share of Global Pharmaceutical Market (2012)](image)

Today’s major pharmaceutical markets consisting of 17 countries are slated to grow in the range of 15-17% in 2014, representing sales of $570-$680 billion. China, which is now the third largest market in the world, is expected to grow 25-27% to more than $50 billion in 2014. As far as developed markets are concerned, Japan is slated to grow 5-7% in 2014. Major European markets like the UK, Germany, France, Italy and Spain are expected to deliver combined growth of 13%. Figure 4.1.1 shows the global market share of the various countries.
According to Global Pharmaceutical Market Forecast to 2012, global pharmaceutical industry is projected to grow at a CAGR of around 6.5% during 2014-2015. The growth will be driven by low cost factor, increasing prevalence of diseases worldwide, and rising per capita income of consumers. The current recovering pharmaceutical market is still dominated by US as it remains at the top position globally, and then followed by the European Union and Japan. Figure 4.1.2 shows the expenditure of top countries.

![Figure 4.1.2: Top Pharmaceutical Expenditure in GDP by Country (2009)](image)

The US, which accounts for about 28 percent of global sales in 2009, followed by the EU, accounting for nearly 15 percent, and Japan for 12 percent. Together, these three markets represent nearly 55 percent of the global market. While the performance of the global pharmaceutical market is more positive in 2010 than in 2009, the fundamental dynamics of the innovation cycle and funding pressures will result in mid single-digit growth over the next five years. Notwithstanding the improved prospects in the US market, the pressure on pharma companies to adapt to the longer-term marketplace trends and evolving patient needs remains undiminished. Due to much patent expiration, the generic drug industry has experienced great growth in the past few years. The global market for generic drugs was worth $107.8 billion USD in 2009 and is projected to reach $129.3 billion USD by 2014 with a CAGR of 9 percent. Rising cost pressure on healthcare has resulted in an increase in generic pharmaceutical usage generic drugs cost 30 to 80 percent less than their original equivalents. Figure 3.1.3 shows the same. The pharmaceutical environment of today differs considerably to that of only a decade ago. Key events shaping the market have been:

- Rising healthcare costs leading to inevitable payer pressure in the pharmaceutical market which coupled with the ongoing financial crisis has tipped the emphasis from
slowing pharma spend growth to actually cutting pharma spend in many mature markets

Figure 4.1.3: Global Pharmaceutical Market Estimate

- Significant number of small molecule generalization events in the primary care market, leading to the demise of many blockbusters: 12 out of the world’s leading 20 blockbuster products are small molecules which either have or will lose their protection by 2016. The remaining 8 products are all biologics, which even if they lose patent protection will probably maintain much of their sales at least for the next 5 years.
- The rise of specialty care, and as a subset of this, biologics, which combined with the previous trend, means the companies thriving in this new environment are more dependent on specialty care than primary care.
- A flattening off in the true number of blockbusters with fewer launches achieving blockbuster status.

Pharma has attempted to diversify over the last decade to compensate for many of the above events, shying away from pure innovation and moving into areas such as diagnostics and devices, generics and consumer health, to broaden their portfolios and strengthen their balance sheets in the run up to Loss of Exclusivity (LoE) of key blockbusters. There has also been a whole series of mega mergers and acquisitions over this decade (Sanofi-Aventis, Bayer-Schering, Pfizer-Wyeth, Roche-Genentech, and Merck-Schering-Plough), leading to consolidation amongst the largest players. Yet
Despite this continuous deal making and apparent consolidation, the pharmaceutical industry remains remarkably fragmented. In comparison to the automotive industry which sees the Top 10 players account for 80% of global production, or the mobile phone market which sees the Top 10 players account for 66% global production, the Top 10 pharmaceutical companies have never managed to break the 50% market share threshold their grip on the global pharma market has remained remarkably static over time, consistently around the 40% mark. This consistent global market share is equally true of the patent protected market, often thought of as the stronghold of big pharma. Although the Top 10 were disproportionately affected by the patent cliff (many attained their Top 10 ranking as a result of blockbusters which have been the source of the largest losses in the protected market), the amount spent on four "mega mergers" in 2009-2010 alone equated to $200bn and despite this outlay, the Top 10 have only managed to retain share of the protected market, rather than increase share (Figure 4.1.4). This thwarted consolidation goes hand in hand with another key event for the Top 10 in 2012: The arrival of Teva into the elite Top 10. Replacing Lilly as a Top 10 player, this makes Teva the first non-US or European based pharmaco, and the first pharmaco that did not start as a traditional R&D based company, to enter the Top 10 (Figure 4.1.5). Teva therefore changes the face of the Top 10 pharmacos forever. Prior to Teva’s entry it was a given that all Top 10 companies i) originated in the mature markets of US or Europe and ii) were primarily R&D driven i.e. most of their sales came from protected products. Teva originates from Israel and has been primarily dependent upon unprotected products, although its protected portfolio is a key driver of profit and now accounts for 40% revenue.

![Figure 4.1.4: Protected Revenue of Top 10 Firms Vs Protected Pharma Market](image_url)
Big pharma unsurprisingly view today’s pharmaceutical market environment as highly challenging, which it is. But how much is the perception of an adverse environment a product of reliance on a single model of focus on R&D, on protected products, and on the mature markets? IMS believes that today’s prescription medicine environment is the most diverse ever in terms of geography, stakeholders, product offering opportunities, pricing/value choices and commercial model options that the industry has ever experienced, giving the big players in the prescription medicines industry more opportunities and options than they have ever had before to become or to remain a Top 10 player.

The pharmaceutical industry has historically been highly conservative, and that default mode is not going to be an asset in the next few years; out of the box thinking and a willingness to discard many of the fondly held beliefs of the past will be the crucial asset.

4.2 The Growth & Opportunities to Indian Pharmaceutical Industries
Global pharmaceutical markets are in the midst of major discontinuities. While growth in developed markets will slow down, emerging markets will become increasingly important in the coming decade. The Indian pharmaceuticals market, along with the markets of China, Brazil and Russia, will spearhead growth within these markets. The Indian pharmaceutical sector has come a long way, from being almost non-existent before 1970 to a prominent provider of healthcare products at present. The
Pharmaceutical industry has grown from mere US $0.3 billion turnover in 1980 to about US$ 21.73 billion in 2009-10. The country now ranks 3rd in terms of volume of production (10 per cent of global share) and 14th largest by value (1.5 per cent of global share).

The Indian pharmaceuticals market has characteristics that make it unique. First, branded generics dominate, making up for 70 to 80 per cent of the retail market. Second, local players have enjoyed a dominant position driven by formulation development capabilities and early investments. Third, price levels are low, driven by intense competition. While India ranks tenth globally in terms of value, it is ranked third in volumes. These characteristics present their own opportunities and challenges.

In 2010, India exported $10.3 billion worth of pharmaceutical products, registering 17.5% growth over 2009. By March 2012, pharmaceutical exports from the country have touched a growth of 20%. The largest export destination continues to be the US, followed by the UK, Germany, South Africa, and Russia. Segment wise, generic drugs account for 58% of total exports, APIs account for 40% and traditional medicines account for the remaining 2%.

Table 4.2.1: Export of Drugs and Pharmaceuticals by Indian Pharma Companies

<table>
<thead>
<tr>
<th>Year</th>
<th>Exports (In Billion US$)</th>
<th>Growth (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007-08</td>
<td>6.3</td>
<td>36.51</td>
</tr>
<tr>
<td>2008-09</td>
<td>8.6</td>
<td>5.81</td>
</tr>
<tr>
<td>2009-10</td>
<td>9.1</td>
<td>13.19</td>
</tr>
<tr>
<td>2010-11</td>
<td>10.3</td>
<td>22.33</td>
</tr>
<tr>
<td>2011-12</td>
<td>12.6</td>
<td>20.00</td>
</tr>
<tr>
<td>2012-13</td>
<td>15.12</td>
<td>36.57</td>
</tr>
<tr>
<td>2013-14</td>
<td>20.65</td>
<td>69.49</td>
</tr>
<tr>
<td>2014-15</td>
<td>35</td>
<td>Projected</td>
</tr>
</tbody>
</table>

Many pharmaceutical firms have already established themselves as leading API manufacturers and generic players in the US and European markets. Thus the Indian firms have made their presence felt in developed markets and continue to maintain the
quality of its APIs and generic formulations. The country’s commerce ministry has set an ambitious export target of $35 billion by 2014–2015. More than 50 per cent share of exports is by way of dosage forms. Indian companies are now seeking more Abbreviated New Drug Approvals (ANDAs) in USA in specialized segments like anti-infective, cardio vascular and central nervous system groups.

India currently exports drug intermediates, Active Pharmaceutical Ingredients (APIs), Finished Dosage Formulations (FDFs), Bio- Pharmaceuticals and Clinical Services to various parts of the world. Export of drugs and pharmaceuticals by Indian Pharma Companies from 2007-08 to 2009-10 are given in Table 4.2.1.

Table 4.2.2 outlines the Top 10 destinations of Indian pharma products all over the world

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Importing Country</th>
<th>Amount (US$ million)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>USA</td>
<td>1791.1</td>
</tr>
<tr>
<td>2</td>
<td>UK</td>
<td>263.9</td>
</tr>
<tr>
<td>3</td>
<td>Germany</td>
<td>243.6</td>
</tr>
<tr>
<td>4</td>
<td>South Africa</td>
<td>226.8</td>
</tr>
<tr>
<td>5</td>
<td>Russia</td>
<td>221.4</td>
</tr>
<tr>
<td>6</td>
<td>Brazil</td>
<td>165.3</td>
</tr>
<tr>
<td>7</td>
<td>Nigeria</td>
<td>154.1</td>
</tr>
<tr>
<td>8</td>
<td>Kenya</td>
<td>137.3</td>
</tr>
<tr>
<td>9</td>
<td>Netherlands</td>
<td>131.7</td>
</tr>
<tr>
<td>10</td>
<td>Turkey</td>
<td>119.5</td>
</tr>
</tbody>
</table>

All these financial figures to Indian pharmaceutical industries are possible due to the following key strengths of pharma sector:

- Low cost of innovation/manufacturing/Capex costs/expenditure to run a CGMP compliance facility.
- Low cost scientific pool on shop floor leading to high quality documentation.
- Proven track record in design of high tech manufacturing facilities.
- Excellent regulatory compliance capabilities for operating these assets.
- Recent success track record in circumventing API/formulation patents.
• About 95 per cent of the domestic requirement being met through domestic production.
• India is regarded as a high-quality and skilled producer in the world.
• It is not only an API and formulation manufacturing base, but also as an emerging hub for: Contract research, Bio-technology, Clinical trials and Clinical data management.
• The country has the distinction of providing quality healthcare at affordable prices.

The Indian Pharmaceutical Industry today is in the front rank of India’s science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. It ranks very high in the third world, in terms of technology, quality and range of medicines manufactured. From simple headache pills to sophisticated antibiotics and complex cardiac compounds, almost every type of medicine is now made indigenously. The core strength of Indian pharmaceutical industry today is its huge export potential. The industry is making adequate returns from the domestic sales but bulk of its profits come from the export of generics and active pharmaceutical ingredients to the developed markets. The industry has been exporting more than half of its total production, which is estimated to be more than 20 billion dollars currently.

4.2.1 The drivers of growth
As the market becomes more diverse, the drivers of growth are proliferating and becoming more nuanced. They fall into four main categories:

Epidemiological factors: Population growth of around 1.3 percent per year and a steady rise in the prevalence of disease (with an increase of 25 to 40 percent in diabetes and cancer, for instance) are expected to increase the patient pool by nearly 20 percent by 2020.
Figure 4.2.1: Expansion of Health Insurance

Affordability: As incomes continue to grow and insurance coverage increases, drugs will become more affordable. With real GDP growing at nearly 8 percent over the next decade, income levels should rise steadily, elevating 73 million households into the middle and upper income segments. As health insurance spreads in parallel, more than 650 million people should enjoy coverage by 2020 (Figure 4.2.1).

Accessibility: The growth in medical infrastructure, increased government spending on health care, new business models for tier II towns and rural areas, and launches of patented products should make drugs accessible to more people. More than $200 billion is likely to be invested in creating and upgrading medical infrastructure, with more than 160,000 hospital beds added every year, a total increase of 1.9 million by 2020. The annual growth of 18 percent in government spending on healthcare since 2005–2006 (Figure 4.2.2) should create a $4.5 billion segment of pharma products within the government’s public health spending.

Figure 4.2.2: Rising of Government Spending
Acceptability: Modern medicines and treatments should become more prevalent as a result of therapy-shaping investments by pharma companies, a growing acceptance of biologics and vaccines among patients and physicians, and patients’ increasing propensity to self-medicate. Companies are likely to invest in physician education and patient awareness campaigns to improve diagnosis, treatment, and compliance rates, especially for chronic therapies such as cardiovascular and neuropsychiatry. Vaccines are expected to grow by more than 20 percent per year, while biologics should become a $3 billion segment by 2020. As self-medication becomes more widespread, consumer healthcare could grow at more than 14 percent a year if companies are able to make larger over-the-counter brands easily available and differentiate their products through deeper connections with patients.

Thanks to these drivers, Indian pharma is expected to grow more than fourfold, from $12.6 billion in 2009 to $55 billion by 2020. With more optimistic assumptions, it could reach $70 billion; under a pessimistic scenario, the value would fall to $35 billion (Figure 4.2.3).

Figure 4.2.3: Rising of Government Spending

The government increases its healthcare spending to 1.5 percent of GDP by 2020, while pharma companies step up their investments in consumer health care, biologics, and vaccines and increase awareness and treatment, boosting the patient pool by 15 percent. At least 25 percent of patented products launched worldwide are launched in India in this scenario, resulting in seven to nine launches per year. The contribution made by different growth drivers undergoes a shift in this scenario. The analysis in 2007 showed that
between 2005 and 2015, rising affordability should account for 60 percent of the incremental $14 billion market opportunity, but between 2009 and 2020, accessibility should become equally important. Together these two factors should account for some 70 percent of the incremental $42 billion market opportunity, while increased acceptability should account for another 25 percent.

In terms of scale, the Indian Pharmaceutical market is ranked 14th in the world. By 2015, it will rank among the top 10 in the world, overtaking Brazil, Mexico, South Korea and Turkey (Figure 4.2.4). More importantly, the incremental market growth of US$14 billion over the next decade is likely to be the third largest among all markets. The US and China are expected to add US$200 billion and US$23 billion respectively. India, Japan, Canada and the UK are expected to be the next in line, with growth expectations in the range of US$13–14 billion during this timeframe (Figure 4.2.5).

Underpinning the market projection of US$35 billion is the assumption that the growth drivers will change significantly by 2015. Real GDP will grow at the compounded annual rate of 7.3 per cent.5 per capita disposable income will rise from US$463 in 2005 to US$765 in 2015. Twenty-seven million households currently in the low-income category will move up. The middle-income category will witness the steepest rise, with the addition of 59 million households.

<table>
<thead>
<tr>
<th>Top 14 pharmaceuticals markets, 2005</th>
<th>Top 14 pharmaceuticals markets, 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 US</td>
<td>1 US</td>
</tr>
<tr>
<td>2 Japan</td>
<td>2 Japan</td>
</tr>
<tr>
<td>3 France</td>
<td>3 France</td>
</tr>
<tr>
<td>4 Germany</td>
<td>4 Germany</td>
</tr>
<tr>
<td>5 Italy</td>
<td>5 China</td>
</tr>
<tr>
<td>6 UK</td>
<td>6 UK</td>
</tr>
<tr>
<td>7 Spain</td>
<td>7 Spain</td>
</tr>
<tr>
<td>8 Canada</td>
<td>8 Italy</td>
</tr>
<tr>
<td>9 China</td>
<td>9 Canada</td>
</tr>
<tr>
<td>10 Mexico</td>
<td>10 India</td>
</tr>
<tr>
<td>11 Brazil</td>
<td>11 Brazil</td>
</tr>
<tr>
<td>12 South Korea</td>
<td>12 Mexico</td>
</tr>
<tr>
<td>13 Turkey</td>
<td>13 South Korea</td>
</tr>
<tr>
<td>14 India</td>
<td>14 Turkey</td>
</tr>
</tbody>
</table>

Figure 4.2.4: Indian Pharmaceutical Market by 2015
Driven largely through private investments, the number of hospital beds and physicians in the country is expected to double by 2015 (i.e., additional 2 million hospital beds and 0.4 million physicians). A close examination of the growth drivers indicates that rising disposable incomes and an upward shift in income demographics will be the dominant growth factor and will account for nearly 40 per cent of the projected market growth. Improvements in medical infrastructure come next, accounting for 20 per cent. Greater health insurance penetration will account for nearly 15 per cent of the growth. A gradual shift in disease profile will account for another 10 per cent of the growth. Finally, population growth and other factors will make up the remaining 15 per cent (Figure 4.2.6).

![Figure 4.2.5: India by Absolute Growth](image)

Changes in the relative importance of mass and specialty therapies, metro and rural markets, and hospital and retail channels are likely to have major implications for pharma companies in the next few years.

![Figure 4.2.6: Affordability and Accessibility Drive Growth](image)
As the market grows in size and diversity, several emerging opportunities should reach their full potential. The most promising five, patented products, consumer health care, biologics, vaccines, and public health, are currently worth $5 billion and should grow to $25 billion in the base case (Figure 4.2.7). They play a major role in the optimistic growth scenario too: more than half of the gap that separates it from the base case is predicated on growth at much higher than expected rates in these five areas.

![Figure 4.2.7: Emerging Opportunity Reach Scale](image)

To make the most of these proliferating opportunities over the next decade, pharma companies should modify their business models and take part in multiple arenas. Most major multinationals have already set bold aspirations for their India business, invested in their local organization, and adopted a local model that involves ramping up their sales force and launching branded generics. Meanwhile, leading local players have invested in market creation, developed differentiated business models, and maintained the momentum of new product launches. All these are steps in the right direction, but as competition intensifies and the market evolves, much more needs to be done.

India’s pharmaceuticals market has grown in confidence and moved onto an accelerated growth path. The question is whether it can achieve its full potential. Backed by solid fundamentals, the market is giving rise to a multitude of business opportunities. By pursuing the right ambitions, making appropriate investments, and adopting the actions outlined above, companies should be able to underpin future growth and help take Indian pharma into the global top rank.
4.2.2 The Top Indian Pharmaceutical Companies

Looking back into history reveals that it was in 1930 when the first pharmaceutical company in India came into existence in Kolkatta. It is called the "Bengal Chemicals and Pharmaceutical Works". This Indian company is still there and today it is the part of five drug manufacturing companies that are owned by the government. Till the period of 60 years the pharmaceutical industry in India was overshadowed by the foreign drug manufacturing companies but with the Patent Act in 1970, the whole scenario of pharmaceutical companies in India had changed since then. With this the Indian market was more open to Indian pharmaceutical companies than the MNCs. So with this pharmaceutical companies in India started to grow in number. At present there is a cut throat competition among top pharmaceutical companies in India with the native as well as MNCs. But there are certain issues that are concerning the growth of pharma companies in India. These are:

- Mandatory licensing and failure of new patent system.
- Regular power cuts and inadequate infrastructure.
- Restricted funding.
- Regulatory hindrances that lead to the delays in the launch of new drug or pharma product.
- Too many small as well as big pharmaceutical companies and excessive competition.

In the list of top pharmaceutical companies in India it is not the Indian companies but also the MNCs that are becoming the part of the race. Indian pharmaceutical market in 2008 was $7,743m and if compared to year 2007 it was 4% more than that. It is expected that Indian pharmaceutical market will grow more than the global pharmaceutical market and will become $15,490 million in 2014. Today Indian pharmaceutical industry is the second most fastest growing industry displaying the revenue of Rs 25,196.48 crore and growth of 27.32 percent. Top pharmaceutical companies in India are also acquiring the small companies worldwide to further expand the market. Pharmaceutical drugs injections, tablets, capsules; syrups are the products of pharma companies in India along with many more.
Find below the list of latest Top 10 pharma companies in India by Net Sales (BSE):

1. Ranbaxy Labs: With total net sales of Rs 7,686.59 crore, Ranbaxy is the largest pharmaceutical company in India.
2. Cipla: With total net sales of Rs 6,977.50 crore Cipla is the second largest pharmaceutical company in India.
3. Dr Reddys Labs: With total net sales of Rs 6,686.30 crore Dr Reddys Labs is the third largest pharmaceutical company in India.
4. Lupin: Lupin is the fourth largest pharma company in India with the total net sales of Rs 5,364.37 crore.
5. Aurobindo Pharma: Aurobindo Pharma is on 5th position with the total net sales of Rs 4,284.63 crore.
6. Sun Pharma: Net Sales revenues stood at Rs 4,015.56 crore makes it the sixth largest pharmaceutical company in India.
7. Cadila Health
   Cadila Health is the seventh largest pharma company with the total sales revenue of Rs 3,152.20 crore.
8. Jubilant Life: Eight largest companies have the total sale revenue at Rs 2,641.07 crore.

9. Wockhardt: Wockhardt has the total net sales of 2,560.16 crore and the ninth largest pharmaceutical company in India.

10. Ipca Laboratories: Revenue of Rs 2,352.59 crore makes Ipca India’s 10th largest pharma firm by sales.

4.3 The Challenges to Pharmaceutical Industry

When we look back at the close of the 21st century’s first decade, we’re likely to view the global financial crisis as the final blow that pushed the pharmaceutical industry into a period of upheaval. Human resources executives are being asked to design talent strategies as the business playbook changes daily. Most of the research identified the competencies needed to lead an HR transformation and suggests that now is the time for pharma companies to try new ways to develop change leaders.

Indian Pharmaceutical industry is going through a very interesting phase. On the one hand it is rapidly achieving a distinctive position in the global pharmaceutical space with generics, CRAMS and clinical trials while on the other hand the fragmented domestic market is poised for a major consolidation. The common thread in this scenario is increased competition on the basis of speed to market, cost competitiveness, quality, customer orientation and distribution reach & penetration in the domestic markets. With these challenges, Indian Pharmaceutical industry is seriously evaluating the ways and means to improve the productivity and work effectiveness.

Over the last decade organizations across the world started adopting effective manpower management philosophy to improve effectiveness of their business. Initiatives like – TQM, Six-Sigma, TPM, JIT, TOC, business process engineering, Kaizen, QC Circles and 5S etc are proven to be helping companies eliminate waste and hence are considered as “Lean Initiatives” With this increased complexity and formidable challenges Indian domestic Pharmaceutical industry is moving ahead and thriving for effective human resource practices in order to compete in domestic and international market.

As competitive pressures intensify, more drug makers would be launching ‘Operations excellence’ programs to stay in the race. Companies can leverage human resource
management as tools and techniques to improve service levels. The surveyed Pharmaceutical Companies have realized a host of benefits by embracing improvement initiatives. Improvement initiatives in Pharmaceutical companies have yielded maximum benefits in terms of improved quality, increased profitability & improvement in service levels.

Scientific and humanistic thinking is at the heart of productivity and other operations excellence tools and hence the application of such tools in Pharmaceutical is beneficial from the regulatory view-point as well.

Considering this rapid pace of development, HR departments in pharma companies face the challenge of supplying different skill sets as per the requirements of the industry. Further, in areas like R&D, which are the heart of the pharmaceutical industry, attracting and retaining R&D professionals is an important task for the HR department. Moreover, research professionals demand a continuously evolving environment and opportunities to work on innovative research projects where they can explore their knowledge and skills. Hence, understanding these requirements and providing them with an appropriate work environment would help in retaining this talent group. Retaining the best talent remains the topmost priority for most HR managers, especially quality talent in areas where knowledge and expertise plays an important & critical role.

To thrive in an upbeat competitive environment, it will also be essential for them to continuously update these policies in line with industry trends and analysis.

When asked to define the challenges facing pharma today, most industry executives would likely list these:

1. Major regulatory authorities undergoing change following a great deal of adverse publicity and skepticism.
2. Governments challenging and imposing price controls wherever possible.
3. The difficulty and ever-rising expense of developing new small molecules and converting them into potential blockbusters.
4. The clock marching ever forward toward patent expiry, with no imminent drug replacements in sight.

The four listed challenges have been coming for many years, and the industry has, in some ways, had sufficient time to react. But, the impact of this recession has many
companies, despite their huge cash reserves, balancing cost pressures with the need to continue high levels of top-line growth. To cope, many have imposed unprecedented cost cutting, and, when that has been insufficient, they have engaged in rounds of mega mergers. However, there is a bright spot. The pharmaceutical industry has turned to new sources of revenues in emerging markets outside of North America, a move that help maintain sales growth of at least three percent and will ultimately support the industry’s resurgence thereafter. But, since most companies face talent shortages in these high-growth markets, will they be able to seize the opportunity? Human resources functions in many of the world’s top pharma companies are facing game-changing pressures, which perhaps is a relatively new phenomenon for them. For an industry that is relatively high tech, pharma is not one that is synonymous with change. Why would it be when, with margins hovering around 40 percent for the past few decades, there has been little need for pharma to reinvent itself? And then, the HR function, as with most other functions in this industry, has tended to hire from within, limiting its experience in dealing with so many outside challenges. So, how are HR leaders in the pharmaceutical industry responding to cost controls, lack of talent, and a changing marketplace?

HR needs to operate as an equal with other functions, with the same accountability to deliver business value. In order to keep its seat at the table, the focus of HR needs to shift from administration to consultative problem solving. Regarding HR transformation in the pharma industry, several interrelated themes and drivers for change, could be grouped as follows:

- Globalization
- Efficiency and Driving Performance
- Strategic Change Management
- Talent Management

Figure 4.3.1: Challenges to Pharmaceutical Industries

The above mentioned two issues were already addressed in the sections of this chapter. The third one, strategic change management is synonymous with the term “transformation” came the term “change management.” Every HR function we encountered was in the process of some degree of driving change, not only within the function, but also by being the catalyst for new thinking within their organizations. GSK
has developed various work streams across the company and one of them is entitled “accountability.” According to GSK, “HR needs to be the catalyst for change in an organization, and we are questioning how we release the capability and energy in our employees so that they can break out of the mould that has been successful for the past decade and adapt to meet the challenges of the future.” There is need to help managers take risks and become more instinctive, as opposed to being analytical and scientific in their day-to-day decision making.

A casual observer from outside the industry would look at the issue of talent management in the pharma industry with some disdain. Pharma HR, therefore, faces talent challenges on two fronts: established traditions that discourage developing people outside the standard career progressions and the inability to attract external talent.

Perhaps an answer to these challenges is for the industry to revert back to development models perfected by the likes of GE and P&G who moved young managers into more challenging management roles in different divisions and locations internationally early in their careers. It would certainly address a need for a more flexible workforce, more leaders in emerging markets and the ability for organizations to think globally.

![Figure 4.3.2: Forces Shaping the Future of Pharma](image)

At least six major forces are poised to overtake Pharma during the next few years. Indeed, they are already at work in the industry with profound implications for HR. In short, these six forces will clearly present Pharma with many challenges over the next few years, and they are powerful arguments in favour of developing a HR function that is strategically aligned with the business itself. The need for new sources of human capital,
new skills, new methods of recruitment, retention, management and development, new social and environmental sensitivities: all these issues will demand a HR function that can make a major contribution to the direction of the business, not one that simply does the housekeeping. We need a very different way of thinking about people in pharmaceutical organizations.

4.3.1 Techno-Commercial Challenges to Indian Pharmaceutical Industry

The main challenges for drug companies come from four areas. First, they must deal with competition from within and without. Second, they must manage within a world of price controls that dictate a wide range of prices from place to place. Third, companies must be constantly on guard for patent violations and seek legal protection in new and growing global markets. Finally, they must manage their product pipelines so that patent expirations do not leave them without protection for their investment.

- Competition

The pharmaceutical industry currently represents a highly competitive environment. One can distinguish three layers of competition for Indian pharma companies:

First, obviously, Indian pharma companies compete among themselves. Although not all leading pharmaceutical companies cover all segments of pharmaceutical market, almost all of them are active in R&D and production of drugs in the segments with the highest potential – such as treatment of infectious, cardiovascular, psychiatric or oncology diseases.

Secondly, Indian pharma companies experience significant profit losses due to competition from the generic drug manufacturers. Opposite to the research-oriented pharmaceutical companies, which invest significant financial resources and time to develop new medicines, generic drug manufacturers spend minimum resources on R&D, and start manufacturing already developed by other companies drugs after their patent expiration. Because generic drug manufacturers do not have to recoup high R&D costs, prices of their products are usually much lower than those of major pharmaceutical companies; as the result, after patent expiration, generic drugs manufacturers capture significant market share, dramatically decreasing revenues of the Indian pharma companies.
Finally, the whole pharmaceutical industry competes with other health care industries. In this case, pharmaceutical companies should not only demonstrate high efficiency of their products, but also provide obvious proof of cost advantages in comparison with other forms of care.

- Price control

Pharmaceutical companies have to operate in a highly regulated environment; the degree of regulation to a significant extent depends on the country and type of the product. One of the most important aspects of government regulation for pharmaceutical companies is price regulation, and different countries have different policies on this issue. In the United States, the largest and the most attractive pharmaceutical market, currently there is no direct price control for non-government drug sales. At the same time, it is expected that Medicare Prescription Drug Improvement and Modernization Act will potentially increase downward price pressure.

The majority of European countries control drug prices, and this downward pressure on prices has been increasing during last year’s. Japan has even stricter price controls than European countries; all prices are controlled by the government, and they are subject to a periodic price review.

As the result of price control, prices of the same products can significantly differ in different countries.

- Protection of patents

Generic drugs manufacturers represent a significant threat to research-based pharmaceutical companies. For example, Dr. Reddy’s Claritin patent expired in 2012; as the result of generic drug competition, sales of Claritin by Dr. Reddy’s declined from $3.2 billion in 2011 to $1.8 billion in 2012 and to $0.37 billion in 2013.

Moreover, generic drugs manufacturers sometimes start production of patent-protected drug analogues even before a patent expires. Although research-oriented companies in many cases are able to protect their patents, they do suffer from lost revenues.

Therefore, protection of patents is one of the key conditions necessary for further development of the Indian pharmaceutical industry. At the same time, non-efficient legislation that does not provide the necessary level of patent protection is one of the
factors that hamper expansion of Indian pharmaceutical companies to the developing countries.

- **Drugs portfolio management**

Drug portfolio management is one of the most important determinants of long-term prosperity of research-oriented pharmaceutical companies. First, it takes an extremely long time to develop a new drug, and only a very small portion of all projects is successful. Projects that the company starts today will determine its financial performance 10-15 years later. Therefore, careful planning of R&D projects is very important for the long-term stability of the company.

Second, insofar as patents keep exclusivity of drugs only during a limited time, and soon after the expiration of the patent the sales of the drug sharply go down, the company has to carefully monitor its patent expiration dates, and insure that new products become available by that date. Otherwise, we are reminded of the case of Dr. Reddy’s, when after expiration of its major drug patent the company did not have a new product of similar value and the company experienced losses in 2012 and 2013.

Definitely, planning errors or rapidly changing demand in the industry can be corrected by acquisition of smaller research companies or patents from competitors, but in any of these cases the company will have to pay a premium price, thus reducing its profitability.

### 4.3.2 Human Resource Management Challenges

In the context of Indian industries, talent management has been of paramount importance in industries like pharma & biotech, where knowledge is the name of the game. Hence, attracting and retaining the much-needed talent & preventing them from migrating to greener pastures have been a major challenge for HR professionals in pharma. As per the survey of Business Today, training, commemoration and empowerment were considered as the most popular way to manage talent in pharma industries.

Indian Pharmaceutical firms show great propensity to provide training to employees. This is more frequent in the case of knowledge exploitation. In general, firms combine internal and external sources of training, in an effort to capture the synergistic effects between the two types of training. The local industry acts in the same manner as observed at global level. Pharmaceuticals firms are strongly inclined to train personnel across operations
Training ranges from a few hours of on-the-job training to years of formal education, including job experience. Training not only includes the development of general skills, but also those needed to carry out specific projects, develop particular processes, conduct specific analyses, handle specialized equipment and so on.

Firms frequently train in safety, environmental and quality control and technological advances. Training in marketing and sales is expected to increase the market success of a product. It can thus be concluded that the provision of training could have a positive influence on the likelihood that firms perform R&D.

In India, remunerations in the pharmaceutical industry are higher than in other manufacturing industries, and are even higher in firms that conduct in-house R&D. As a mechanism to motivate and retain workers, remunerations are frequently limited to adjustment without altering the firm’s structure of compensations as a whole. These considered, remunerations can be expected to positively influence learning through R&D.

Workers in the Indian pharmaceutical industry have limited opportunities to participate in decision-making with regard to working conditions and, whenever that happens, it is of limited relevance to the firm. In this regard, it must be acknowledged that strict regulations faced by the industry could reduce opportunities to modify the working conditions. In fact, these are already among the best throughout manufacturing activities. Manufacturing processes and operations, in general, must comply with strict current good manufacturing practices (GMPs) and other industry standards, and work closely with regulatory authorities.

Regarding R&D, literature documents that drug development activities, such as those underpinning the formulation of generic drugs, may be more structured and defined in terms of timing, nature of tasks, formality in the organization, conduction of activities, and so on. Exploratory interviews with the local industry revealed that R&D staff may frequently succumb to the needs of manufacturing and quality control departments. Nevertheless, empowering employees is expected to positively affect the probability of R&D performance.

A number of elements will be critical in dealing with these challenges. They include strong leadership to provide a sense of direction when the conditions in which a company
is operating are extremely fluid. They also include giving HR professionals sufficient authority to engage fully in strategic planning for their businesses. This is still a sensitive issue, as is clear from the results of *HR Benchmarking 2000*, a survey of HR departments in 977 European and Middle Eastern companies conducted by PwC. Only 19% of the respondents reported that they felt satisfied with the influence of HR on the development of the business strategy. And only 32% had a HR executive on the top management team, suggesting that the function still struggles to gain board recognition. The ability to understand, and respond to, the needs of different employees will be equally vital. Many senior managers assume that the only reason someone might leave a company is for more money even in Pharma, where the nobility of the purpose is so important a motivation. Their response is thus to match, or better, bid for people they want to keep, an approach that often ends up boosting compensation for a particular class of workers without increasing the value they deliver. In fact, recent surveys show that most employees would leave an organization to follow a good mentor; and that most believe being hired into an organization provides a better opportunity to realize their potential than being groomed for a new role. So money is not necessarily the answer. Another option is to look for people with raw talent, develop their skills and recognize their worth at an early stage. This means creating a culture that stimulates learning, with knowledge management systems, mentors, coaching, e-learning and so forth. It also means acknowledging the acquisition of new skills promptly in both financial and non-financial ways.

Over 1.25m people work in the pharmaceutical industry. And whether they work for giants like Merck and GlaxoSmithKline or minnows like the many biotech and genomics companies springing up in the wake of the Human Genome Project, most people entering the sector have something in common: they want ‘to make a difference’. But Pharma companies are not philanthropic ventures staffed by saints and despite any noble intentions they remain under pressure to satisfy the commercial expectations of their shareholders.

Issues of work-life balance and ethics are already recognized as key considerations for ‘knowledge workers’. The ‘spirit’ of an organization captured in its brand values can be a crucial factor in deciding where to work. Getting it wrong can have serious implications for companies already facing skills shortages. The published objectives of some of the
industry leaders indicate the importance of communicating the nobility of the purpose. AstraZeneca aims ‘to deliver revolutionary medical advances worldwide’; Aventis to ‘provide the human race with the ability to increase its living standards worldwide’; Bristol-Myers Squibb to make medicines for ‘extending and enhancing human life’.

<table>
<thead>
<tr>
<th>Employer wants</th>
<th>Employee wants</th>
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<tr>
<td>Pharma wants to maximise return on investment in expensive new technologies and costly capital plant with round-the-clock, round-the-year cover</td>
<td>Many employees want to work agreed hours; they do not want to be on call all the time and at any time</td>
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<tr>
<td>Pharma wants a mobile workforce</td>
<td>Most employees, especially those with families, want to stay put or be properly compensated for the upheaval</td>
</tr>
<tr>
<td>Pharma wants to reduce fixed costs, for example, by outsourcing non-core activities</td>
<td>The majority of employees want job security rather than short-term contracts</td>
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<td>Pharma wants to employ people with the right skills – and, given the nature of those skills, it will need to assume a greater role as ‘post-graduate’ learning centres</td>
<td>Highly educated employees are often happy to acquire new skills, but they want to be valued for those skills. If the company is slow to recognise the increase in value or believes they should first repay the investment, they will move elsewhere</td>
</tr>
<tr>
<td>Pharma wants to shake out the poor performers and retain the best, with pay structures that reflect the skills it most prizes</td>
<td>Employees want transparency and equity. They also want to share in the big wins – even though they may not have chosen to work in a high-risk environment</td>
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Figure 4.3.3: The Demands of Employers & Employees in Current Situation

Although the precise words vary, the same spirit pervades the sector. People often join such organizations because they share the same emotional commitment, but arguably, people are questioning the reality behind these objectives. As the sector comes under pressure to deliver shareholder value, the ethics of organizations can come under scrutiny and impact on the image of the sector. Sir Richard Sykes, non-executive chairman of GlaxoSmithKline, said recently: ‘Of course, there’s a part of our business that’s important about making money. But we also have to be cognizant of the fact that we have a responsibility in society.’ (In Business, BBC Radio Four, UK, 8 February 2001.) One of the continuing themes of this briefing is the way in which both organizations and individuals are responding to these pressures. The demands of satisfying shareholders and competing for funds are driving some of the changes the industry is now experiencing. New technology is driving scientific advances, enabling the modeling and analysis of complex processes. These forces are reshaping Pharma; they are behind the consolidation of the industry, the growth in the number of alliances and the increase in outsourcing. Such changes are also contributing to the growing divergence between what Pharma companies need to achieve and what their employees want (see Figure 4.3.3). This
briefing examines the effect of these changes on the people working in the industry both now and in the future.

All knowledge industries and Pharma is no exception, recognize that ‘intellectual capital’ is a key business resource and that their strategies are a major factor in the ability to compete for, and retain, the most talented individuals. But tomorrow’s employees may well expect more and different benefits from those that are typically on offer today.

![Figure 4.3.4: Factors Influencing Job Satisfaction of Pharmaceutical Industries](image)

Nevertheless, experience shows that size can boost a company’s scientific power and strength in its markets – and that strategic HR plays a key role in making big companies successful, just as poor HR practices contribute to large-scale failures. The most successful Superpharmas of the next few years will be those which integrate the creativity and originality that are often found in biotech operations with all the advantages of scale and global reach that belong to Big Pharma.

### 4.3.3 Significance of Human Resource Management to Indian Pharmaceutical Industries

“One machine can do the work of fifty ordinary men. No machine can do the work of one extraordinary man” (Elbert Hubbard). Our great Earth is, dominated by human beings. Human race that evolved throughout the great ages of struggle and development has brought about civilizations of spectacular and tremendous developments in all the fields of human activity. Scientific developments and splendid techniques have contributed to
the development and progress in agriculture, industry, engineering, medicine and pharmacy. To meet the requirements of human beings for their existence and qualitative living, human resources have been nurtured and developed. Industry thrives not only on money, machines and materials but more especially on human endeavours. Mother India has been marching along the path of progressive independence. Along with industrial and economic development, health care and quality of human life, have been emphasized as a “must” for the promotion of human welfare. Pharmaceutical industry plays “a key-role in promoting quality in health-care. Human ailments physical mental are caused by the exigencies and circumstances of urbanized life-styles.

Cut throat competition, struggle for survival in rat race, non-moving jobs, addition, oily, spicy and to enhance life-expectancy and promote healthy living, the research and development departments in the organizations of pharmacy and medicine need tremendous boost in terms of trained and talented and committed human resources. This requirement which is increasing day by day necessitates the development of human resources. The parameter of progress of pharmaceutical productivity consists of the excellence of human resources in pharmaceutical industry. This encircles readily available, economically affordable with consistent standard quality, without side effect and result oriented medicines. Proximity and accessibility of medicines is in tune with existing need of the user. The lives saving medicines are as important as food, water, air and sunlight. The government should create a regulatory body for monitoring the affordable price, availability and quality.

Even though technology may gallop and triumph still human effort is indispensable. Well-trained personnel can man the machines for achieving productive results. Human Resource Development is a continuous phenomenon that is dependent on training feedback and counselling, career planning, job-rotation and performance appraisal. In pharmaceutical industry development of skilled and technical manpower is of paramount importance. HRD should fundamentally aim at the development of the individual in the context of his job and responsibility. Development of team-work and the inter-team collaboration is essential. The recognition of talent, skill, funding of knowledge and commitment are imperative for effective performance. The health of an organization gets promoted if the superior-subordinate relationship is safe-guarded with the ultimate
objective of promoting the capabilities of all the employees. Technical and managerial along with promotion of appropriate result-oriented research can positive lead by the Indian Pharmaceutical industry to greater heights of performance and peaks of perfection. It is also imperative to enhance creativity. Creativity is thinking in different way. Creativity capsules a combination of materialism’s approach along with spiritualization. This undoubtedly encircles ceaseless efforts in proper direction and leads to tightening the belt and putting the heart and soul in the cause of good.

The growth of drug manufacturing industries actually; or accelerated during the 1960s, even though way back in 1930, the Bengal Chemicals and Pharmaceutical works, in Calcutta started drug manufacturing activity in India. Further the Planets Act in 1970 paved the way for progress. Human Resource talents contributed to the growth of the Indian and world markets with their expertise in. reverse-engineering new procedures for manufacturing drugs at comparatively low costs. Development of human resources in the pharmaceutical industry lead to rapid strides in drug innovation, especially in large drug manufacturing companies in India. Noticeable changes in the life style, spectacular pay hike in certain sectors [e.g. IT industry] unscheduled working hours during long night hours [e.g. BPO service centres], nuclear families, craze for fast food, and addiction etc leads to ill health. To restrict repercussions new drugs are to be invented. The role of Human Resource Development in the Pharmaceutical Industry is paramount importance when these companies have to score higher on effective economy efficiency and innovation from their present levels. Indian Pharmaceutical Companies should move from comparative to competitive advantage in the health care industry. Just as the Indian IT and BPO exports are seeking tax sops in order to compete against other software exporting countries, Indian Pharmaceutical sector by raising its levels of qualitative human resources management can contribute remarkably to enable India to be the third largest economy after China and US by 2050. In this respect organizational effectiveness in the Pharmaceutical Companies that depend on the R & D and innovative efforts of Scientists, Managers, Executives, Supervisors, Workers, Systems and Technology, has to be geared up.

Human Resource Development is concerned with people, dimensions of the organization. The organization objectives can be best achieved by acquiring human resources, develop
them, cast them for our need & motivate them for still better performance and ensure that they continue to maintain their involvement, commitment, loyalty to the organizational. The Human Resource Development basically consists of three c’s i.e. competencies, commitment and culture. During 1980 it was Larsen and Turbo Ltd. who introduced the concept of Human Resource Development and Practice in Indian Industry. Earlier to that personnel functions were used traditionally i.e. to look after salary, administration, absenteeism, new employment and maintenance of industrial relation. The employee was viewed in terms of laws and procedures laid down by personnel management but the management realized the importance of man above money, machine and material. Hence the concept of HRD was introduced and gained ground.

There are as such no standard guidelines laid down by government authorities and private organizations. Standard HR policies and practices differ from organization to organization depending upon size, type, purpose, classification and location of the organization.

These guidelines are designed and tailored as per the need of the hour and also organization as well as government regulations. The data groups of industries have laid down the standard guidelines for their organizational set up. They do not follow the guidelines set up by other organizations as the other organizations follow their own guidelines. This is so because; these organizations have laid down their own guidelines on the basis of their own experience, expectations and to serve their primitive purpose. Hence as said earlier no standard guidelines have been laid down and as such they differ from organization to organization. In the wake of globalization and privatization policy, the organizations have to adopt innovative ways to survive and to remain in competition. It is being realized that "Human factor" gives competitive advantage to the organization. If human resources are treated as assets and by carefully nurturing their creativity, competence, the organization can successfully accept the challenges and encounter in a fast changing business environment, all organizations with enterprising, enthusiastic, competent, motivated and satisfied work force will remain successful. Creation of human assets calls for formulating appraisal, policies and practices in every developmental stage viz. planning, acquisition, nurturing, developing, motivating, rewarding and retaining of manpower. It calls for integrated policies, with a strategic planning of the organization.
and also aligning with a conclusive culture and climate. The policies have been such that it develops a culture of learning, encourages teamwork and result in enhanced performance. The practices should be such that the employee remains committed to the organization and adds value to the business. In the formal analysis, the HR policies and practices should have impact on bottom line of the organization. Although an earlier study on the subject has been made, there is still a large and wide scope for scientific study over the HR policies and practices in the pharma industries. Pharmaceutical industries play a major role in the annual turnover of Indian economy. These industries not only prove backbone to the economy but also play vital role in the maintenance of public health. If the working of these pharma industries is not smooth and well organized then there is a possibility that these organizations may collapse resulting in bottlenecks of career of the employees working in these industries. Also it will affect the well being of the consumers since pharma industries are directly related to the public health. Over the HR policies & practices was done however the study did not stretch up to the pharmaceutical industries. Due to globalization liberalization and liberal polices of Indian Government the small, middle as well as the large scale Pharmaceutical companies are on the way of expansion, amalgamation, joint ventures, enriching present market with penetration and concentration therein. Hence there is a growing need for skilled and scientific study of Human Resource Management in these Pharmaceutical companies. Privatization, introduction of new technology, latest machinery are all responsible for the expansion of the companies however the HRM study focuses on the utilization of manpower which is the need of the Day. Proper utilization of manpower helps in the growth, expansion and success of the company and study of HRM policies and practices deals with this utilization of manpower and hence the need of the Day. It was observed from the above that, HRM is the prominent success factor of an organization. The following functional areas are associated with effective HRM: staffing, human resource development, compensation and benefits, safety and health, and employee and labour relations, training & development. The quality of work life is broad concepts of HRM by which the phama companies can achieve the excellence and grow as per the expectations. Hence, the study is undertaken to find out the impact of QWL interventions on the selected pharmaceutical companies.