

### Chapter 5

#### Findings and Policy Recommendations

The preceding analyses bring together the pattern of growth in the pharmaceutical industry in India before and after the implementation of TRIPS Agreement and examine the export performance and competitiveness of the sector during the period. Although, at the cost of repetition, it is important to briefly recapitulate the main points.

With the introduction of Indian Patent Amendment Act- 2005, the Indian pharmaceutical industry has undergone major shift from process patent regime to a modern and WTO compatible regime under TRIPS Agreement. The period witnessed remarkable growth in Indian pharma sector led by domestic firms and foreign collaborations. Intense competition, high volumes and lower prices characterize the domestic market of the Indian pharma sector. India exports half of its total production of pharmaceuticals. Exports to US and other regulated markets account for over 50 percent of Indian global exports. In recent years some Indian firms like Sun Pharma, Lupin, Reddy's Lab and Cipla have established manufacturing units in the United States.

Today, Indian pharma industry accounts for 3.5 percent of the global pharma industry in value terms and 10 percent in volume terms. Branded

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generics have dominated the market. The sector is expected to generate immense employment opportunities and foreign exchange earnings in the coming years. The Indian pharma firms have entered into highly regulated and the same time highly profitable markets of Europe and North America.

**The present study** makes an attempt to analyse the implications of TRIPS Agreement on the Indian pharmaceuticals industry for the period 1995-2015. It focuses on the export performance and competitiveness of Indian pharma sector during the study period. Foreign direct investment in pharma firms in pre and post Indian Patent Amendment Act- 2005 period has also been examined. The final impact of IPR-2005 on the industry will largely depend on the developmental status and growth path followed by the country.

The study gives a brief review of the evolution of the Indian pharmaceuticals industry under different patent regimes, the TRIPS Agreement of WTO and the Indian Patent Amendment Act 2005 in compliance with TRIPS. It discusses the structure of Indian pharma industry. It highlights policy measures adopted by the government for the growth of this sector, particularly after the implementation of TRIPS Agreement.

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A **review** of the earlier studies related to the TRIPS Agreement of WTO and its impact on pharmaceuticals industry has been done in Chapter 2 of the study. The issues discussed in their studies and the findings have been stated briefly. Attempt has also been made to find the research gaps in the reviewed work.

Since export potential is one of the key strengths of pharmaceutical sector, the present study analyses the trends and growth rates in Indian pharma exports during 1995-2015 period. The share of Indian pharma exports in global pharma market has also been analysed. The chapter highlights major competitors of India in global pharma market. Changing trend in the export of the two major categories of pharma products of India, bulk drugs and formulations, during pre and post IPA has been explained.

**The present study** also examines the competitiveness of Indian pharma sector by using revealed comparative advantage Index of Balassa in Chapter 4. It shows and analyses the pattern of FDI inflows in pharmaceuticals as an important factor influencing the profitability of Indian firms and expansion of this sector in the changing international scenario.

The findings of the study and policy recommendations for the Indian pharma industry have been given in this last chapter.

### Findings of the Study

- Pre TRIPS era was characterised by Process Patent Regime. Indian pharma firms used ‘reverse engineering’ process to manufacture drugs. This led to the growth of a strong generic drugs industry and Indian pharma companies began to move aggressively into the international market. After the implementation of TRIPS Agreement in 1995, India took 10 years transition period and enacted ‘Indian Patent Amendment Act’ (IPA) in 2005 introducing Product Patent Regime.
- The share of India pharma exports has shown a significant increase in global exports after IPA 2005. It remained approximately 1.0 percent from 1995 to 2005. This share doubled and stood at 2 percent in 2011.

Germany's market share has been highest since 1995 while Switzerland, Belgium, US & UK have been competing very closely.

- Annual growth rate of pharmaceutical exports of India shows that the exports have increased gradually in pre IPA and increased rapidly after post IPA. An improvement in Compound Annual Growth Rate (CAGR) after 2005 is clearly observed in the analysis. CAGR has increased from 15.04 percent during 1995-2005 to 18.11 percent in the period 2006-2015.

There was sudden dip in annual growth rate of exports in 2009-10 which may be attributed to the impact of world financial crisis.

- Paired t-test has also been applied in order to analyze whether there is any improvement in export performance of Indian pharmaceutical industry. The obtained |t| value (5.95) is significant at 5% level of significance. It indicates that there is much

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improvement in export performance of Indian pharmaceutical industry after the introduction of IPA.

- The export-import ratio of Indian pharmaceutical products was 10.45 in 1996-97. It has continuously declined to 4.73 in 2009-10. There have been greater imports of raw material and intermediates during this period. Moreover, small R&D expenditure, increasing regulatory concerns and pricing issue could have been the other reasons. Eventually this ratio began to improve from the year 2010-11 when mergers and acquisitions in pharmaceutical sector, greater R&D and improvement in productivity as well as clinical research began to be adopted by the Indian pharmaceutical firms. The export-import ratio of pharmaceutical products further improved and stood at 7.87 in 2015-16. It demonstrates rising export intensity.
- Though 3<sup>rd</sup> largest in terms of volume, Indian pharma is 13<sup>th</sup> in terms of value. This is largely due to India's focus on generic drugs. To rise in value chain, companies have to invest in R&D on speciality and differentiated products. Indian companies can tap huge high value market for biosimilars in developed nations. This will enable them to come out of generic manufacturing to grow, develop and market their own pharma products using robust R&D which allow them to expand globally.
- The RCAI index for measuring export competitiveness of Indian pharmaceutical industry from the year 1995–2012 is found to be greater than unity for all the years. Thus, India has comparative advantage in pharmaceutical exports. However this ratio has almost stagnated during the study period. It needs to be raised under the new patent regime. It is an indicative of large productivity improvements required in this sector.

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- The share of pharmaceuticals in India's total exports has increased from 2.01 percent in 1996-97 to 2.41 percent in 2001-02 and 2.47 percent in 2004-05. During the above mentioned period, it has shown only a gradual increase. In post-IPA (from 2005-06 to 2015-16), the share of pharmaceuticals in India's total exports has increased from 2.37 percent in 2005-06 to 4.92 percent in 2015-16.
- Comparison of the trends of FDI inflows into Indian pharmaceutical industry before and after Patent Act-2005 shows that the process patent regime had been a constraint in attracting FDI into Indian pharmaceutical industry. India's liberalized policy regime and government's decision to permit 100 percent FDI in manufacturing and research & development has led to increased investment in pharmaceutical sector. There has been a significant improvement in FDI inflows after the introduction of Patent Act-2005. During 2000 to 2014 the drugs and pharma sector has attracted one of the highest FDI inflows although with some years of downswings, more so during world economic crisis period.
- The World's leading Pharma companies have been expanding their manufacturing footprints in India. Several other global companies source pharma through contract manufacturing or wholly owned units in India. Several big companies Pfizer, Glaxo Smith Kline, Novartis, Wyeth, Abbott and Sanofi, have set up base in India. Most of the companies mentioned above have entered into supply agreements with local pharma companies for domestic requirements and long term sourcing needs.
- The new patent era has forced many MNC pharma firms to find India as an attractive destination not only for R&D but also for contract manufacturing, clinical trials, co-marketing alliances and generic drugs.

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- Pharmaceutical production costs are much lower in India than in the western countries, while overall R&D costs are one-eighth and clinical trial expenses around one-tenth of western levels. Research and Development efforts and patenting activity have been stimulated after the signing of TRIPS Agreement. Almost a decade back, investment in R&D was around 3 percent of the sales turnover. This investment in R&D has increased to the tune of 11-15 percent in last few years.
- Till 1990s, the MNCs did not dominate the production network in India, but in the second half of 2000s the industry has witnessed significant structural changes with an increase in Mergers and Acquisition activities. They were supported by a liberal credit regime and the corresponding recognition by the international community as credible global competitor. Companies like Sun Pharma, Wockhardt, Zydus, Cadila have acquired several companies and entered into alliances with those companies in various markets. A matter of interest has been the acquisitions by large global pharma companies of some of the leading Indian companies in the recent past. Recent takeovers of Ranbaxy by Daiichi, Matrix and Mylan, NPIL and Abbotts etc. are illustrative of this phenomenon.
- According to Mc Kinsey propriety pharma operations benchmarking, the cost of manufacturing formulations remains 30-40 percent lower than the other manufacturing hubs including China and Eastern Europe notwithstanding low productivity levels. India's labour cost advantage is going to sustain well in the coming years, especially if the Indian companies can improve productivity through operational excellence and digital initiatives. The supply of local talent into the pharma sector of India is quite strong.

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- In the field of generic drugs, Indian companies are facing generic competition from “Authorized Generics” in the developed markets. Authorized Generics are the generic version of patented molecule marketed by the patent holder itself once the patent on the molecules expire. In addition, to the woes of the pharma companies, Drug Price Control Order (DPCO) continued to hamper the growth of the industry and erodes the profitability. Thus lack of enough return on investment due to DPCO may be ascribed as one of the reasons Indian companies were unable to invest heavily in R&D.
- Moreover, in the post TRIPS era, it has been observed that MNCs undertake “Evergreening Strategies” to maintain and extend patents and thereby they try to control the flow of medicines through either new formulations of patented drugs by combining it with already available drugs or increasing the period of patent while they apply for second medical use of the same drug.
- China’s has made massive expansion of bulk drug industry and its influx in the Asian and African countries. China brought in world class Patent Act and data protection laws years before it was required to for similar reasons. Germany, Singapore, Thailand and Korea are also in the forefront of knowledge economy. Russia’s self-sufficiency in the pharma sector and Nigeria’s ban on some specific drugs and formulations to protect its domestic industry are other potential challenges.

### **Policy Recommendations**

For the Indian economy, pharmaceutical industry is of great importance as it is the fifth largest export item in country’s export basket. Given this



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significance and competitive advantage some policy recommendations for the expansion of Indian pharma industry in the new patent regime are as follows:

1. Attaining high level of efficiency in production, marketing and supply of diversified drugs and pharma products is extremely important. Indian firms have focused more on large domestic demand rather than accessing international market.
2. The market of generic drugs is price sensitive. In view of this, Indian pharma firms have to be more strategy oriented in near future to stay competitive internationally.
3. Developed countries would see stronger international patent regime as a vehicle for opening worldwide market for their products or to further increase their commercial benefits. India can reap advantage of economies of scale since comparatively higher labour cost in developed nations will inevitably lead them to relocate their labour intensive manufacturing and research activities to the developing world, if stronger patent regime is in place in these nations.
4. Developing economies need not be apprehensive about stronger patent laws but now they have to recognize that the IPR regime is key to scientific, technological and economic progress. Without such protection much fewer drugs would be developed and the flow of standard medicines to the public would be hampered to the detriment of public health and economic development throughout the world.
5. There is ample scope of expanding the range of generic products as more molecule come off- patent. Indian companies can continue to

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market and export such generic drugs that are off-patent. US, being one of the largest markets for generic drugs, is the ideal destination for Indian companies. In US and Europe major blockbuster drugs are going off patent in the next few years. The cost of production will hold the key to success in the generic market. This will depend on the scale. Indian pharma companies need to build global scale to sustain in the global generic market.

6. Along with R&D investment in traditional chemical based screening, firms can look for breakthrough in bio-technology research. Indian companies will have to acquire the skills of exploring research areas that offer excellent revenue and profit potential. This will require a close track of disease profiles and related therapies as well as keeping a close watch on research programs of rival firms. Further, amount for R&D can be invested for NDDS (Novel Drug Delivery Systems), Analogue Research, NDDR (New Drug Discovery and Research), etc. Many European countries are keen to tie up with the Indian pharmaceutical companies for research and development of new drugs.
7. It is difficult for Indian companies to come out with totally new molecules at a fast pace due to prohibitive cost of developing a new molecule. But companies can enter licensing agreements with multinational pharmaceutical companies for the development of molecule. Some Indian companies have already entered into these licensing agreements. “Torrents Pharmaceuticals” has entered into an exclusive licensing agreement with “Reliance Life Sciences” in marketing.
8. The growing concern that dominance of the MNCs will once again surface as a result of these takeovers may not adversely affect the Indian industry since with larger resources, it is possible for these

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new entities to invest into drug discovery and contract research/clinical trials which in any case is the lifeline for their survival.

9. The option of contract research is very important for Small and Medium Enterprises (SMEs) to survive in post TRIPS era in India. Contract research is spreading in India at a rapid pace and many Contract Research Organizations are providing services to various companies.
10. Indian pharma companies have the opportunity to take advantage of its rich bio-diversity. Firms are increasingly focusing on herbal products and products that are used as alternative medicines. India has vast potential to expand manufacturing and export of Herbal products. Patanjali Ayurved, Dabur, etc have already shown the way in this field. It is required to further greatly expand in this direction.
11. There is immense scope for outsourcing in post IPA-2005 and can be grabbed mainly by players with economies of scale in terms of production. This would require huge capital investment in fixed capital assets and create technological capabilities to sustain operations.
12. A product-patent system that is now enforced may lead to monopolies and these, in turn, to high prices. Pricing of drugs in India is a cause of concern unless safeguard measures are implemented to prevent this. TRIPS do not specify or enforce anything regarding the prices of drugs and national governments are free to enact the measure within the ambit of TRIPS provisions to curb the increase in prices of drugs.
13. The country has at times shown inadequate regulatory framework along with weak enforcement regime reflected in occurrences such as production of spurious or low quality drugs. This can be a

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stumbling block for the Indian Pharmaceutical Industry. Rapidly rising cost of skilled manpower such as scientists and pharma lawyers needs to be taken care of. Investment in innovative R&D is strongly recommended.

14. Although India has comparative advantage in pharma exports as revealed by RCA index but its stagnant nature during the study period is suggestive of need to diversify operations and large productivity improvements.

15. Since pharma sector is highly intensive in skilled labour there is utmost need to train people for the industry in collaboration with educational institutions. Therefore industry – academia link is important in product patent era.

16. Development of Special Economic Zones (SEZ) and their successful working significantly influences the export potential of a particular industry. However, it has not been a success story in India so far which needs to be addressed.

17. Opportunities for outsourcing are immense in post IPA-2005 and would be grabbed mainly by players with economies of scale in terms of production. This would require huge capital investment in fixed capital assets and create technological capabilities to sustain operations.

Globally, the pharmaceutical industry is undergoing a transitional phase with shifts in demand patterns, realignment of supply chains and global regulatory changes. The changing dynamics of this sector at international and domestic level call for the Indian pharma companies to redesign their strategies, make investments in market creation, focus more on R&D, maintain the momentum of new product launches and enlarge their

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presence in the global market. Over the next decade, the market will proliferate presenting an array of opportunities for the Indian pharmaceutical firms.