Available online on 15 Dec 2018 at http://ijdra.com/index.php/journal

International Journal of Drug Regulatory Affairs

Open Access to Pharmaceutical and Medical Research

Review Article Open Access

Corporate strategies adopted by Indian Pharmaceutical Industry for restructuring

Bhuvana Madhuri Chokkakula*, Venkata Ramana Murthy Kolapalli, Vijaya Ratna Jayanti

Pharmaceutical Management and Regulatory Affairs, A.U. College of Pharmaceutical Sciences, Andhra University, Visakhapatnam, Andhra Pradesh, India.

ABSTRACT

The Indian pharmaceutical industry has developed rapidly over the last few decades. Before TRIPS, the Indian regulatory system recognized only process patents. The Indian Pharmaceutical companies were engaged in the development of new processes for manufacturing drugs. They mainly concentrated on the domestic markets and unregulated markets. The Indian companies focused very little on Research & Development (R&D). Even large pharmaceutical companies showed little interest on innovation and R & D. They mostly depended on imitation and reverse engineering of the patented products. But after TRIPS, product patent was reintroduced and the companies spent their expenditure on R&D, synthesis of new chemical entities (NEC), and on modification of already existing entities to develop new formulations and development of generics to obtain regulatory approvals for marketing already patent expired drugs. The multinational companies have turned to contract manufacturing and research services (CRAMS), marketing alliances, collaborative research and clinical trials to save time and cost. The main advantage of the Indian firms lies with their capability for low cost of production, and in their highly skilled technical labour. The manufacturing cost is less in India when compared to the US and the European countries. The Indian Pharmaceutical industry developed different types of strategies in order to survive and expand in the international pharmaceutical sector which involve collaborative strategies, business strategies, and overall corporate growth strategies.

Keywords: TRIPS (Trade Related aspects of Intellectual Property Rights), Indian Pharmaceutical industry, corporate strategies, business strategies, R&D, CRAMS (Contract Research and Manufacturing services).

Article Info: Received 30 Nov. 2018; Review Completed 10 Dec. 2018; Accepted 12 Dec. 2018

Cite this article as:

Chokkakula BM, Kolapalli VRM, Jayanti VR. Corporate strategies adopted by Indian Pharmaceutical Industry for restructuring. International Journal of Drug Regulatory Affairs [Internet]. 15 Dec. 2018 [cited 15 Dec. 2018]; 6(4):33-41. Available from: http://ijdra.com/index.php/journal/article/view/282

DOI: 10.22270/ijdra.v6i4.282

Corresponding author Tel.: +91-8332004151

E-mail address: bhuvanamadhuri369@gmail.com (Bhuvana Madhuri)

1. Introduction

The Indian pharmaceuticals market is the third-largest in terms of volume and thirteenth-largest in terms of value. It has established itself as a global manufacturing and research hub. The Indian pharmaceutical industry is expected to grow at a compound annual growth rate (CAGR) of 22.4 percent to touch US$ 55 billion by 2020.

India is the largest supplier of generic drugs globally (20 to 22 percent of global export volume). The main vision is to modify the Indian pharmaceuticals industry to play a number one role in the global market and to ensure abundant availability, at reasonable prices within the country, of good quality pharmaceuticals of mass consumption. At present, India is in a good position with respect to the global pharmaceutical sector. The country has highly skilled scientists who have the potential to run the industry ahead to an even higher level. Presently, most of the life-saving drugs used globally are supplied by the Indian companies.

The Union Cabinet has given its nod for the modification of the existing Foreign Direct Investment (FDI) policy in the pharmaceutical sector. FDI allows up to 100 percent under the automatic route for manufacturing of medical devices subject to certain conditions. The Department of Industrial Policy and Promotion (DIPP) released information that, the drugs and pharmaceuticals sector attracted cumulative FDI inflows worth US$ 15.59 billion between April 2000 and December 2017. In 2017, Indian pharmaceutical sector witnessed 46 merger & acquisition (M&A) deals worth US$ 1.47 billion.

- The Government of India is planning to set up an electronic platform to regulate online pharmacies under a new policy, in order to stop any misuse due to easy availability.

- The Government of India revealed 'Pharma Vision 2020' aimed at making India a number one global leader in end-to-end drug manufacture. In order to boost investments, the approval time for new manufacturing facilities has been reduced.
- The government brought mechanisms like the Drug Price Control Order and the National Pharmaceutical Pricing Authority to take action with the issue of affordability and availability of medicines.

The Indian Pharmaceutical market is dominated by generic drugs which constitute nearly 70 percent of the market, whereas Over the Counter (OTC) medicines and patented drugs make up to 21 percent and 9 percent respectively (1).

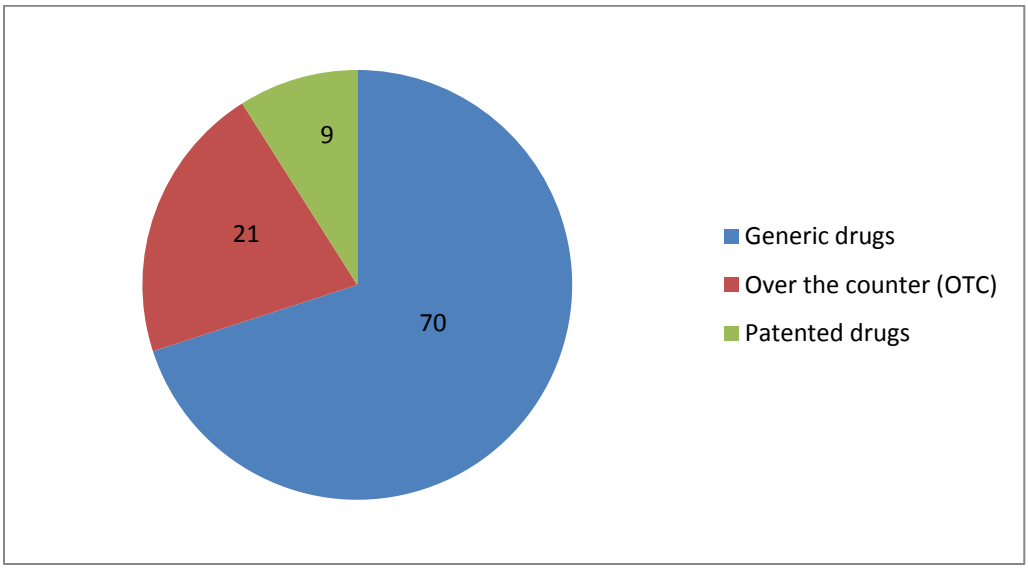

Figure 1. Comparison over Generics, OTC and Patented drugs

Evolution of the Industry

The Indian pharmaceutical industry has come across the time of independence when multinational corporations dominated the industry. Under the new patent regime, the pharmaceutical industry has established itself as a major supplier of not only generic products but also of new formulations.

The Indian pharmaceutical industry has evolved and currently, it is in a position to export a crucial volume of pharmaceutical products to highly regulated markets, including the developed markets of USA, EU and Japan. The evolution of the Indian pharmaceutical industry can be classified into the following stages:

Pre-1970s

- During this stage, the Indian Pharmaceutical industry was highly dominated by the multinational companies as most of the bulk drugs and formulations were imported from abroad.
- The domestic firms were engaged in the repacking of the formulations and production was mainly controlled by the MNCs.
- The first pharmaceutical business began in India with the establishment of Bengal Chemical and Pharmaceutical Works in Calcutta in 1901.
- Later, many entrepreneurs came forward and lead to the establishment of Alembic chemical works in 1907 and Bengal Immunity in 1919.
- The Design and Patent Act 1911 which provided protection for the product patent prevented the domestic firms from manufacturing those patented products.

1970- 1995

- Until the 1970s, the Indian pharmaceutical market was dependent on the multinational companies and only a small portion of drugs were produced domestically.
- This stage plays a significant role in the history of the Indian pharmaceutical industry.
- The government in order to encourage the drug manufacturing by Indian companies amended the Patent Act in 1970s and introduced only process patent but not the product patent.
- The patent protection span was shortened to a period of five to seven years.
- The lack of patent protection allowed the Indian firms to develop new processes by reverse engineering at low costs.
- It also recognized the grant of compulsory licensing after three years of the patent.
- The domestic firms introduced cost-effective processes and supplied the domestic markets with inexpensive but quality drugs.

1995-2005

- This stage witnessed a major regulatory policy change with respect to the Indian pharmaceutical industry.

- Since the mid- 1990s, the Indian pharmaceutical industry has faced several new challenges on account of the WTO-TRIPS agreement.
- India signed TRIPS agreement and became a member of the WTO in 1995. A transition period of 10 years was given to amend their patent law in order to comply with the new patent regime.
- India amended its Patent Act in 1999, 2002 and 2005. India and some other developing countries were given exemption until 2005.
- They mandated to set up a mailbox facility for product patent applications filed before 2005 and to assign each filing date. A five year period, starting from the day they granted, of exclusive marketing rights, was given to the inventors.
- This patent regime threw a new challenge to the Indian pharmaceutical industry to maintain its competitiveness and profitability. The Indian drug manufactures can no longer manufacture and market reverse- engineered drug products patented by foreign drug makers (2,3).

2. Strategies adopted by Indian Pharmaceutical industry

The Indian pharmaceutical industry has developed rapidly over the last few decades. Before TRIPS, the Indian regulatory system recognised only process patents. The Indian Pharmaceutical companies were engaged in development of new processes for manufacturing drugs. They mainly concentrated on the domestic markets and unregulated markets. The Indian companies focussed very little on Research & Development (R&D). Even large pharmaceutical companies showed little interest on innovation and R & D. They mostly depended on imitation and reverse engineering of the patented products. But after TRIPS, product patent was reintroduced and the companies spent their expenditure on R&D, synthesis of new chemical entities (NEC), modification of already existing entities to develop new formulations and development of generics to obtain regulatory approvals for marketing already patent expired drugs. The multinational companies have turned to contract manufacturing and research services (CRAMS), marketing alliances, collaborative research and clinical trials to save time and cost. The main advantage of the Indian firms lies in their low cost of production and the availability of highly skilled technical manpower. The manufacturing cost was less in India when compared to US and European countries. The Indian Pharmaceutical industry develops different type of strategies in order to survive and expand which involve collaborative strategies, business strategies and overall corporate growth strategies (4-6).

2.1 Collaborative strategies

This strategy is being adopted by major pharmaceutical companies for various reasons even though some of the companies have huge capabilities for development of compounds. The reasons mainly include increasing demand for new chemical entities (NCEs) and to decrease the cost of research and development. Most of the pharmaceutical firms form collaboration with universities which helps them in researching the problems that cannot be solved individually. When pharmaceutical companies need compounds for drug development and research, custom synthesis providers satisfy demand.

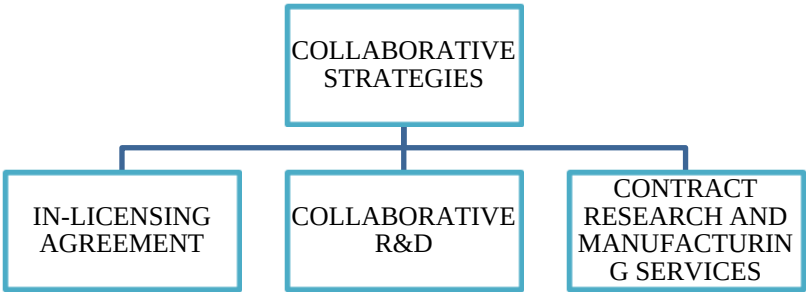

Figure 2 Collaborative Strategies

In -licensing agreement

Licensing is considered as an essential element of technology transfer to developing countries. A licensing agreement is a legal contract between two parties; generally the licensor and the licensee. The licensor allows the licensee to produce or sell the products, use a brand name or trademark or use the patented technology with series of conditions. The licensor agrees to pay royalties to the licensor. Indian companies do not have sufficient new drugs to introduce into the domestic market. So they depend on the MNCs and form in-licensing agreement with them. The Indian firms market their products in India and share a portion of the profit with MNCs. These agreements make the regulatory approval procedures easier and faster.

Companies that have already signed in-licensing agreements with foreign drug makers are companies such as Ranbaxy laboratories Ltd, Dr Reddy's Laboratories Ltd, Nicholas Piramal India Ltd, Cipla Ltd, Wockhardt ltd, Torrent Pharmaceuticals Ltd.

This strategy helps Indian firms to bring new medications to the country at affordable prices. As these products are already approved in other countries for marketing, the regulatory approvals are easier and faster as they directly undergo a bio-equivalence study or a Phase –III trails (6).

Collaborative research and development

Collaborative R&D are strategic partnerships is a type of partnership dedicated to the research and development of new products and services. This type of collaboration is made up of limited partners who can contribute funds to pay for certain research and development opportunities. They bring about valuable innovations and often provide the only way organization can stay ahead of their competition in the long run.

The global pharmaceutical industry is highly research oriented and innovative firms spend on average about 15 per cent sales turn over in R&D. However, the Indian pharmaceutical industry spends less than 2 percent of its sales turn over in R & D. The report of the Hathi Committee (Government of India 1975) noticed that R&D intensity was only 1.1 per cent in 1973. The Indian companies were engaged in imitation of drug products rather than new drug development, which involves high investments. The 1970 Indian Patent Act allows the Indian firms to develop reverse engineering products and development of non- infringing processes. When India became member of WTO, product patent was reintroduced. The R & D intensity began to rise from 2000-01 and reached its peak in 2005-06 (6,7).

Contract Research and Manufacturing Services (CRAMS)

Contract Research and Manufacturing Services (CRAMS) is one of the fastest growing sectors in the pharmaceutical and biotechnology industry. They provide research services/ manufacturing products with world class standards and international regulatory norms such as USFDA, TGA, MHRA, and EMEA. Traditionally, pharmaceutical industries have been outsourcing APIs, intermediates, and formulations. Indian CRAMS companies are the preferred players for the global pharmaceutical companies due to their research services and technology services at low and affordable cost. India offers an abundant pool of skilled professionals in the areas of drug development and research.

The pharmaceutical market uses outsourcing services from low cost providers in the form of CROs and CMOs. CRAMS plays a significant role in the areas like preclinical, clinical trials, drug discovery, R&D and pharmaceutical manufacturing. CRAMS mainly carry out two activities.

- Contract research
- Contract manufacturing

Contract Research Organisation (CRO) is an organisation that provides services to the pharmaceutical and biotechnology industries on a contract basis in the form of Research services Outsourcing. A CRO may provide services such as biopharmaceutical development, pre- clinical and clinical services, clinical data management and pharmacovigilance.

Contract Manufacturing Organisation (CMO) is an organisation that makes pharmaceutical products under the contract and delivers them with wide range of services to its clients. This helps the client to focus on core competencies and high- value projects.

Key drivers – CRAMS

- Higher number of USFDA approved manufacturing plants.
- High- end research services and complex technology services at low cost.
- Large and growing talent of professionals in the area of drug development and research (5,8).

Significance of CRAMS

Many pharmaceutical companies outsource their clinical trials and manufacturing to CRAMS companies with focus on managing costs and shortening time to market. They provide services such as drug discovery, pre- clinical and clinical trials.

Table 1 Selected CRAMS, contract research and outsourcing deals in India

INDIAN COMPANY	CRAMS PARTNER	CRAMS PRODUCT
Lupin Labs	DMS (US) Apotex (Canada)	API for cephalosporins Cefuroxime Axetil
Wockhardt	Ivax (US)	Anti-ulcer
Nicholas Piramal	Allergan (US) AstraZeneca (Sweden)	Bulk drugs and formulations Intermediates and APIs
Sun Pharma	Eli Lilly (US)	Cardiovascular products, anti-infective drugs and insulin
Matrix	GSK (US)	APIs
Biocon	BMS Pfizer	Contract research for bulk drugs
Cadila Healthcare	Altana Pharma	Intermediates and APIs

Source: Greene W. The emergence of India's pharmaceutical industry and implications for the US generic drug market**.**

Table 2 Collaborative Strategies adopted by Indian firms

Strategy	Examples
In- licensing agreement	Elder Pharmaceuticals one of the growing pharmaceutical companies in India has signed an in- licensing agreement with Israeli biotech company Enzymotec for the marketing of Cardio Beat (9). Wockhardt Ltd. is a Global pharmaceutical and Biotechnology company form in-

	licensing agreement with Syrio Pharma SpA for a range of dermatology products. It in- licensed Kelocate used to treat scars (10).
Collaborative R&D	Ranbaxy an Indian Pharmaceutical company expanded the scope of its existing research alliances with global pharmaceutical major Glaxo SmithKline (GSK). The agreement shows a unique opportunity to demonstrate the India- centric advantages of high quality research and development (11). Torrent Pharmaceuticals enters into Research collaboration deal with AstraZeneca for discovering a novel drug candidate for the treatment of hypertension (12).
CRAMS	Lupin Laboratories supply API of Cefuroxime Axetil to Apotex (13). Nicholas Piramal India Limited entered into an agreement with Allergan Inc., for the manufacturing of two Glaucoma APIs for Allergan's (14).

2.2 Business Strategies

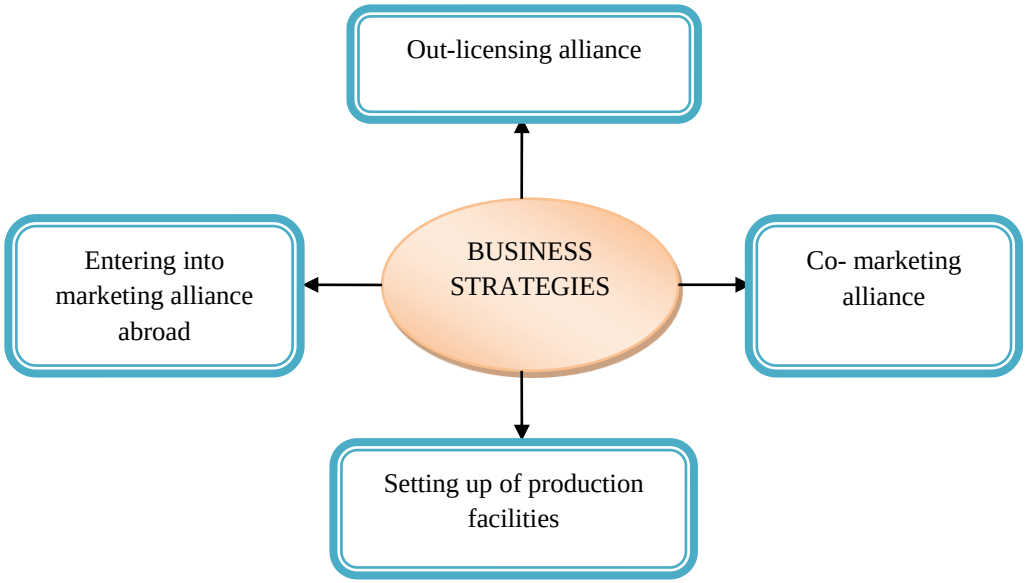

Figure 3. Business Strategies

Out- licensing alliances

Drug discovery and development of new drugs requires high investments and expertise. Some Indian firms have focussed on the development of new chemical entity (NEC). Due to lack of resources to conduct clinical trials and also as they are not ready for start- to- finish model for NEC research, so smaller firms out-license these drugs to a larger pharmaceutical firms (MNCs). Outsourcing is the most widely adopted strategy by the Indian pharmaceutical industries. In out- licensing, the firms develop the molecules up to certain stage and then out- license them to MNCs for further development. Indian companies receive milestone payments and royalty, on successful marketing of the drug.

Co- marketing alliances

Co –marketing alliance are a form of partnership defined by Anderson and Narus (1990) as the "mutual recognition and understanding that the success of each firm depends in part on the other firm". The partnership involves one or more aspects of marketing and may also extend into research and development and even production. This type of alliance provides access to new complementary products or technologies (15).

Setting up of production facilities

In order to meet the increasing demand and to cut cost, many of the Indian Pharmaceutical industries set up new production facilities abroad. This new facility helps to increase production quality and also speed up production times. The domestic firms are searching for manufacturing hubs on the foreign lands due to regulatory delays, increased land and labour cost. Many pharmaceutical companies such as Glenmark, Lupin and Biocon have manufacturing units outside India (6).

Entering into marketing alliance abroad

A marketing alliance is a formal relationship between two or more organizations to achieve collective business objectives. It mainly involves co-ordinating the strengths of different companies in order to meet a market demand. These types of agreements are generally seen between non- competing firms. Several firms depend on marketing alliance instead of setting new production facilities (6).

2.3 Overall corporate growth strategies

The expansion of firms takes place either by internal or external expansion. Generally, in the case of internal expansion, a firm grows through acquisition of new assets, replacement with advanced equipment and introduction of new products. But in the case of external expansion, a firm forms collaboration with the running firms through corporate combinations. These combinations include mergers, amalgamations, acquisitions and takeovers. These strategies become an important feature in the corporate restructuring.

Indian Pharmaceutical industry showed a significant rise in the number of mergers and acquisitions, joint ventures and other type of alliances. They are becoming strategic choices for their organizational growth and are most commonly done to gain market share, reduce cost of operations, or to get entry into new markets.

Table 3 Business Strategies adopted by Indian firms

Strategy	Examples
Out- licensing agreement	• Strides Acrolab, an Indian Pharmaceutical company form an out- licensing and supply agreement of generic oncology products to Pfizer (16). • Ranbaxy form licensing agreement to manufacture and supply finished formulation of the drug, used for the treatment of benign prostate hyperplasia to Schwarz Pharma (17).
Co- marketing alliance	• Lupin entered into co- marketing alliance with Novartis for its asthma drug, Onbrez, in India (18). • Dabur Pharma in deal with Abbott of US (19).
Setting up of production facilities	• Lupin having 18 manufacturing facilities globally, out of which six are outside India. • Aurobindo Pharma Limited set up production facilities in USA, Brazil and China. • In order to expand its operations, Dr. Reddy's Laboratories Ltd set up manufacturing facilities in Mexico, USA, India and UK (6).
Entering into marketing alliance abroad	• Lupin Pharmaceutical Inc., entered into an alliance with cornerstone BioPharma, Inc., for its Suprax. • Glenmark signed supply agreement with Lehigh valley Technologies Inc (6).

A number of smaller Indian pharmaceutical companies have been acquired or merged by larger companies. Similarly, firms with excess capacity and high R&D investment depend on M&A to restructure their position in the industry (6,20).

Joint venture

Joint venture is an entity formed between two or more parties to undertake economic activity together. JVs are becoming more common for the foreign companies to capitalise on the opportunities presented in India. Generally foreign firms form JVs with the local partners in order to increase their market in India. The local firms are experts in business environment, knowledge support and the network capabilities of other local pharmaceutical companies. The western pharmaceutical companies make use of India due to the availability in India of low production costs, skilled labour and faster drug development. R & D joint ventures are also growing rapidly to enhance the development capabilities.

Types of Joint Ventures:

Contractual Joint Venture

Equity based Joint Venture

- Contractual Joint Venture (CJV)

In a contractual joint venture, a new joint agreement to work together is there; but there is no agreement to give birth to an entity owned by the parties who are working together.

- Equity Based Joint Venture (EJV)

In equity based joint venture, a separate entity is established and owned by both the parties. There would be a joint ownership by two or more parties.

Mergers and Acquisitions

Liberalization facilitated Indian firms to enter into the US and other western European countries to market generic drugs. India exports its products to more than 65 countries worldwide; the US being the largest customer.

Indian pharmaceutical market is changing under the light of the below three arguments:

- Cost effective manufacturing being implemented by developed economies.
- Growing importance of emerging markets.
- Changing significance of India's domestic market.

Indian firms face several challenges from Chinese and Eastern European manufacturers. The Indian firms are aiming to produce super generics and branded generics. Indian companies will involve new strategies and innovation in order to compete with the global pharmaceutical companies.

India having a large domestic market and highest number of US FDA approved manufacturing facilities outside the US, is trying to capture the opportunity through strategic alliances and M&A.

The corporate sector is restructuring its operations through different strategies in order to face various challenges posed by the new patent regime. Mergers and acquisitions (M&A) are defined as consolidation of companies. M&A is one of the major aspects of corporate growth strategy where two separate companies together create more value compared to being an individual company. In order to expand and survive, companies keep evaluating different opportunities through the merger or acquisition. The main objective behind these mergers and acquisitions is to penetrate overseas markets and expand their network channel globally, R&D capabilities, enhance their product portfolios in order to survive in the post-TRIPS era.

Benefits of mergers and acquisitions

- To provide improved capacity utilization
- To make use of the existing sales force in a better way.
- To gain economies of scale.
- To reduce managerial staff and tax obligations.
- To gain access to new suppliers, distributors, customers, products and creditors.
- To get access to new technology (20).

Acquisition

Acquisition is an art of acquiring effective control of one firm by another firm over assets or management without any combination of firms. It is a corporate strategy in which a company buys most of another firm's ownership stakes to assume control of it. The Indian pharmaceutical firms are pursing foreign acquisition with the following goals:

- Improved global competitiveness
- Creation and entry to new markets
- Acquire assets and new products
- Consolidate their market shares
- Move up the value chain

Merger

A merger is a legal agreement by which two or more companies are joined together to form a new entity. The main aim to form mergers is to expand into new markets or to gain market share. In India, mergers are regulated under the Companies act and also the SEBI act. With the enactment of the Competition Act, 2002, mergers also come under this legislation.

In the Companies Act, a merger between companies tries to protect the interests of the secured creditors. In the SEBI Act it tries to protect the interests of the investors. In the Competition Act, it aims at protecting the appreciable adverse effects on trade and prevents anti- competitive agreements.

Types of mergers

Horizontal mergers: This type of merger exists between two companies who compete with the same product in the same industry segment. The two companies combine their operations and show improved performance, increased assets and enhanced profits.

Vertical mergers: This type of merger exists between companies in the same industry, but at different stages of production process.

Conglomerate merger: This type of merger exists between two or more companies belonging to different industrial sectors which are in no way related to the kind of business and product line. They rather overlap each other's business lines.

Table 4 Corporate Strategies adopted by Indian firms

Strataegy	Examples
Joint venture	• Granules India and Ajinomoto Omnichem form Joint Venture to market the products to third- party companies. • Sun Pharmaceuticals Industries form a 50:50 joint venture with US- based drug maker Merck and Co Inc. (21).
Acquisition	• Abbott laboratories, an US based Pharma giant acquires Piramal Healthcare Solutions unit for $ 3.72 billion. It marked as second largest deal in the Indian Pharmaceutical sector (22). • Sun Pharma to acquire Ranbaxy in a US $4 billion landmark transaction (23).
Merger	• Strides Shasun merge its Australian generic business with Apotex.

Indian pharmaceutical market posted a double digit growth of 12.8% in the month of October 2018.The top 10 companies contributed to 42.9% of the market. The chronic medicines segment showed better growth than the acute medicines segment. This difference was very prominent in the following three cases (24):

Table 5 Comparison between acute and chronic sale value in Crores

Company name	Acute sales value in Crores	Chronic sales value in Crores
Lupin	28	55
Torrent	25	54
Intas	26	53

Pharmaceutical companies are feeling extremely constrained in the case of many medicines because of the extremely low prices fixed by the Drug Price Control Order (25). The Government of India must think of giving a boost to this extremely promising sector by reducing the limitations of price control on drugs which are expensive in their production. It must think of measures which can give a boost to the innovative capabilities of the pharmaceutical companies. They may promise an exemption from price control for a given period of ten years for a drug product which shows a clear innovative step.

3. Conclusion

- The Indian pharmaceutical industry has evolved from an almost non- existent player to a dominating and

impacting producer. India emerged as an innovation driven developing country in the global market. The government of India has employed a variety of policy tools to protect the Indian companies from multinational firms' dominance.

- It experienced a golden period after the introduction of the Indian Patent Act, 1970. This Act allowed the pharmaceutical firms to produce products of already patented drugs by reverse- engineering. Indian firms have evolved to gain the position of leader of the world in the production of high-quality but low-cost generic drugs.
- India signed TRIPS agreement and became a member of WTO in 1995. A transition period of 10 years was given for developing countries to become compliant with the TRIPS agreement. With the re-introduction of product patents in 2005, a strong patent regime has thrown new competitive challenges for the pharmaceutical sector.
- The pharmaceutical industry was forced to adopt new strategies in order to survive in the global markets. It slowly began shifting from generic drugs to becoming a regional hub for strategies like R&D, drug discovery, contract research and manufacturing services (CRAMS), licensing and marketing alliances.
- Since, Indian firms do not have enough investments to develop innovative products; they form in-licensing agreements with foreign firms. This helps to bring novel medications to the country at reasonable and affordable prices. The majority of alliances in the pharmaceutical industry are through university alliances and contract research, which helps in the early development stages of innovation.
- Indian CRAMS companies are the preferred players for the global pharmaceutical companies, due to their research and technology services at low and affordable cost.
- Many pharmaceutical firms are strengthening their geographical presence by starting their own subsidiaries in different overseas markets. Indian Pharmaceutical industry also employed strategies like marketing alliances, contract manufacturing, and R&D collaboration.
- There has been a significant rise in the number of mergers and acquisitions, joint ventures and alliances in the Indian pharmaceutical industry. The main motive behind these strategies is to penetrate the overseas market and widen their global presence. This may be a good way of neutralising competition and getting high market shares. These acquisitions are expected to enable Indian companies to gain a foothold in western regulated markets, diversify their portfolios and gain R&D capabilities. Many Indian companies have spent millions of dollars, filing ANDAs with the USFDA, to gain production rights in United States for patent expired drugs.
- The Indian government has taken several policy measures for enhancing growth in the pharmaceutical sector. Several regulations came into existence in order to maintain fair competition between the pharmaceutical firms. It must now encourage this industry be offering incentives in terms of reduced price control on drug products involving innovation.
- The main significance of the study is to bring out certain realities that :
    - IPI is undergoing restructuring in order to survive and grow.
    - MNCs are also collaborating in this process so as to expand and dominate.
    - Different stakeholders in the field are operating to ensure that the drug sector flourishes.

Acknowledgments

We take this opportunity to express deep sense of gratitude to A.U. College of Pharmaceutical Sciences, Andhra University for continuous support.

Conflict of interest

The authors declare that there are no conflicts of interest.

References

1. Indian Pharmaceutical Industry. IBEF [Internet]. India Brand Equity Foundation; 2018 [Cited 2018 Oct 02]. Available from: https://www.ibef.org/industry/pharmaceutical-india.aspx.
2. Lalitha N. Indian pharmaceutical industry in WTO regime: a SWOT analysis. Economic and political weekly. 2002 Aug; 24:3542-55
3. Ghai D. Patent protection and Indian pharmaceutical industry. International Journal of Pharmaceutical Sciences Review and Research. 2010 Feb 23; 3(2):43-8.
4. Lalitha N. Indian pharmaceutical industry in WTO regime: a SWOT analysis. Economic and political weekly. 2002 Aug; 24:3542-55.
5. Reddy CD, Gupta NV. Overview on contract research and manufacturing services (CRAMs) and its present status in India. Asian Journal of Pharmaceutical and Clinical Research. 2013; 6(2):33-7.
6. Rai RK. Battling with TRIPS: Emerging Firm Strategies of Indian Pharmaceutical Industry Post-TRIPS. Journal of Intellectual Property Rights. 2008; 13:301-17.
7. Kale D, Little S. From imitation to innovation: The evolution of R&D capabilities and learning processes in the Indian pharmaceutical industry. Technology Analysis & Strategic Management. 2007 Sep 01; 19(5):589-609.
8. Drabu S, Gupta A, Bhadauria A. Emerging trends in contract research industry in India. Contemporary clinical trials. 2010 Sep 01; 31(5):419-22.
9. "Elder Pharma, Enzymotec ink in- licensing deal" .The Economic Times [Internet]. 2007 Apr 25 [Cited 2018 Jan 02]. Available from: https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/elder-pharma-israel-co-enter-in-licensing-deal/articleshow/1952096.cms.

10. "Pharma firms eye in-licensing opportunities". Business standard [Internet]. 2013 Feb 05 [cited 2018 Jan 02]. Available from: https://www.business-standard.com/article/companies/pharma-firms-eye-in-licensing-opportunities-107042601094_1.html.
11. "GSK and Ranbaxy expand R & D pact". Business Standard [Internet]. 2013 Feb 26 [cited 2018 Jan 04]. Available from: https://www.business-standard.com/article/companies/ranbaxy-gsk-expand-r-d-pact-107020701067_1.html.
12. "Torrent and AstraZeneca enter into R&D deal". Business Standard [Internet]. 2013 Jan 19 [cited 2018 Jan 25]. Available from: https://www.business-standard.com/article/companies/torrent-pharma-astrazeneca-in-r-d-deal-105022200003_1.html.
13. "Lupin US arm in Cefiximealliance". Business Standard [Internet]. 2013 Feb 06 [cited 2018 Feb 10]. Available from: https://www.business-standard.com/article/companies/lupin-us-arm-in-cefixime-alliance-105012801001_1.html.
14. Nicholas to rake in $30m sales via 2 contract deals". Business Standard [Internet]. 2013 Feb 06 [cited 2018 Feb 16]. Available from: https://www.business-standard.com/article/companies/nicholas-to-rake-in-30m-sales-via-2-contract-deals-104110501077_1.html.
15. Bucklin LP, Sengupta S. Organizing successful co-marketing alliances. The Journal of Marketing. 1993 Apr; 1:32-46.
16. "Strides Acrolab signs two licensing and supply agreements with Pfizer". IIFL [Internet]. 2010 May 14 [cited 2018 Mar 05]. Available from: https://www.indiainfoline.com/article/market-equity/strides-arcolab-signs-two-licensing-deals-with-pfizer-113101200276_1.html.
17. "Ranbaxy gets $4 million from Schwarz Pharma". Business standard [Internet]. 2013 Feb 06 [cited 2018 May 06]. Available from: https://www.business-standard.com/article/companies/ranbaxy-gets-4-million-from-schwarz-pharma-104062401033_1.html.
18. "Lupin, Novartis in marketing tie-up". Business Standard [Internet]. 2013 Jan 20 [cited 2018 May 20]. Available from: https://www.businessstandard.com/article/companies/lupin-novartis-in-marketing-tie-up-112073000039_1.html.
19. "Dabur Pharma in deal with Abbott of US". The Economic Times [Internet]. 2003 Oct 22 [cited 2018 Jun 10]. Available from: https://economictimes.indiatimes.com/dabur-pharma-in-18bn-deal-with-abbott-of-us/articleshow/245641.cms.
20. Vyas V, Narayanan K, Ramanathan A. Determinants of mergers and acquisitions in Indian pharmaceutical industry. Eurasian Journal of Business and economics. 2012; 5(9):79-102.
21. "Merck, Sun Pharma enter JV for emerging markets". Business Standard [Internet]. 2013 Jan 20 [cited 2018 July 01]. Available from: https://www.business-standard.com/article/companies/merck-sun-pharma-enter-jv-for-emerging-markets-111041200083_1.html.
22. "Abbott Acquires India's Piramal Health for $3.72 bn". The Times of India [Internet]. 2010 May 22 [cited 2018 Aug 18]. Available from: https://timesofindia.indiatimes.com/business/india-business/Abbott-buys-Piramals-pharma-arm-for-3-7bn/articleshow/5960176.cms.
23. "Sun Pharma to acquire Ranbaxy in a US $4 billion landsmark transaction". IIFL [Internet]. 2014 April 06 [cited 2018 Sep 15]. Available from: https://www.sunpharma.com/sites/default/files/pressreleases/Press%20Release%20Sun%20Pharma%20to%20acquire%20Ranbaxy.pdf.
24. "AIOCD AWACS" monthly report; 2018 Oct.
25. "National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers" [Internet]. 2014 [cited 2018 Sept 20]. Available from: http://nppaindia.nic.in/