PART-III REVIEW OF RELATED LITERATURE:

3.1 Need to follow policy framework:

Marketing of pharmaceutical products need to follow policy framework where set rules as international guideline must be followed and respected, while local guidelines which are country specific in accordance with global rules should also be taken care. Many a time it has been observed and recorded that organizations facing serious consequences for not following the guideline, as a result either heavy financial penalty has been imposed or banning the company operation from the respective country. Situation might be outcome of so many companies with too many brands trying to capture maximum market share with various marketing practices. In the process of capturing market share companies intend to inform, influence or even induce stake holders where medical practitioners are major stake holders, as explained in chapter one. Present work will further focus on this process which ultimately effect marketing practices. Under this context researcher could search relevant literature to justify and substantiate the discussion.

Mickey C. Smith, in his book titled Principles Of Pharmaceutical Marketing explained with elaboration on identification of intervention of marketing strategists and market in while initiating the research and development activities. His proposition and view point further provided a framework to initiate academic work in Indian context reason being organizations adopting practices which are only market driven. With the help of academic debate point can well be established that drug resistances cases almost in all categories like antibiotic to anti-tuberculosis to mention few increasing rapidly. Under this context usage of a particular molecule in terms of overuse can always be well established and adequate number of studies have been conducted on same.

3.2 Review of Gap in Marketing Practices:

Relevant and related literature of the present study has been reviewed with the view point on dividing them in two academic arguments to understand the gap further:

1. Global pharmaceutical marketing and prevailing practices along with models.
2. Specifics of Indian pharmaceutical market and practices with models adopted by the organizations.

Jain & Saxena in their study Lifestyle and general could classify pharmaceutical products in two categories namely lifestyle and general. Further, in their study could elaborate the need of different promotional tool or mix as strategy which subsequently effect marketing practices of companies. In a comparison they could mention that lifestyle medicine carries higher value for pharmaceutical company because of their long term use and as a result higher revenue generation[1]. Consequently lifestyle medicines being voluminous for organizations became attractive therapeutic segment for marketing strategists.

In global context Joan Buckley could evaluate and highlight about the need to monitor marketing practices. In his work with title "The need to develop responsible marketing practice in the pharmaceutical sector", could elaborate the problem at global level. In the present work argument has been put forward for greater vigilance with regard to pharmaceutical industry marketing practice[2].

Socially Responsible Pharmaceutical Marketing Practices: The Case Of Egypt, the case developed by Salma, Ehab and Noha is another instance why study of marketing practices in pharmaceutical industry is of great concern. Present case has successfully pinpointed significant unethical conducts practiced by both pharmaceutical companies and physicians[3].

Brian Smith (2007) in his work published in Journal of medical marketing with title Marketing Masterclass could evaluate marketing excellence and the organizational conditions that are the precursors to achieving it. He could summarize these precursors to marketing excellence as leadership commitment, idea importation, authentic behavior & theorizing. His present work could elaborate upon the fact that organizations missing link of any precursors cannot achieve marketing excelling while same is a strategic choice for the organizations[4].

Kalman Applbaum (2006) could illustrate in PLos Medicine the need of developing a "culture of marketing" by the pharmaceutical companies in the essay title "Pharmaceutical Marketing and the Invention of the Medical Consumer". Present work could further elaborate ethical justification for marketing by pharmaceutical companies by quoting "doing good while doing well"[5].

In editorial of British Medical Journal Volume 328, 3 April 2004 challenges has be mentioned with the title "Marketing of Medicine in India". It is quite clear from the article that though India is having a large pharmaceutical industry, the major expansion started in the early 1970s. Indian government decided to permit domestic manufacturers to produce generic versions of patented molecules without permission from overseas innovators provided a different manufacturing process was employed[6].

Vijay Bhangale in his work with title Emerging Markets Pharma Marketing in India: Opportunities, challenges and the way forward Volume 8, 3 205-210 Journal Of Medical Marketing could explain the point that many multinational companies have established the Global policy on interactions with healthcare professionals that introduced new guidelines to meet the needs of healthcare providers effectively[7].

In a difficult and challenging operating environment like India, one may feel that it is virtually impossible to adhere to these guidelines. This feeling is quickly dispelled once one realizes that ethical promotion is paramount and benefits all stakeholders including patients, healthcare practitioners, regulators and corporation. The industry should take cognizance of this and adopt good ethical marketing practices that will be beneficial in the long run. After all, there is nothing better than self-regulation! [8]

Janice MacLenna and David MacKenzie in their work Strategic market segmentation: An opportunity to integrate medical and marketing activities published in International Journal of Medical Marketing Volume 1,1 40-52 raised the point under the heading what are the biggest hurdles to companies doing what we propose ? The explained further under current practices which is our point of concern with two examples of current practices characterize this issue:

1. When developing a new drug, companies delay significant expenditures until there is a reasonable certainty that the product will be approved for commercial launch
2. If a product does reach the market and demand takes off, then there is little time to think about segmentation; the goal at this stage is to sell as much as you can as quickly as you can[9].

Guenther IIIert and Ralf Emmerich in their work with title Marketing Strategy the need for new promotional models published in Journal of Mediacl Marketing Volume 8, 1 23-30 could explain the need for new marketing recipes. They could elaborate the point with citation that with the changing healthcare environment, the focus in pharma marketing needs to adapt to new stakeholders needs. They could observe and increasing influence of payers and patients on prescribing decision whereas physician’s influence is decreasing. Marketing recipes that worked

in the past will not guarantee future success-patient centricityand focus on health outcomes need to be at the heart of the pharma value proposition in future. Direct interactions between pharmaceutical companies and payers will open the door for further market mechanisms[10].

Online marketing and e-Detailing: In-depth report from an eye for pharma conference published by Andree K. Bates in Journal Of Medical Marketing Volume 6, 4 298-300 could examine how European physicians are using the internet, and in turn, how the pharmaceutical industry is using the e-channel in response. E-Detailing was a significant topic of focus at the conference. Given the high cost and decreasing impact of the traditional salesforce model, eDetailing is expected to become a viable alternative to the salesforce arms race. Moreover, the deployment of digitally enabled representatives enhancing customer visits with e-Detailing technologies is steadily becoming an industry trend[11].

Richard B. Vanderveer and Noah M. Pines in their work Customer-Driven Positioning published in Journal Of Medical Marketing volume 7, 71-76 could elaborate the point the process by which physicians truly want to engage and learn about a new pharmaceutical product. In pharmaceutical marketing practices the next generation approach to positioning will be customer-Driven positioning or CDP[12].

Christoph Burman, Jorg Meurer and Christoper Kanitz could emphasize enough on their work Customer Centricity as a key to success for pharma published in Journal Of Medical Marketing 1-11. They explained new unique selling propositionswill become indispensable for future pharmaceutical competition. Even though in the 1960s the customer was identified to be one major bottleneck, only a few companies are customer-oriented. Their work could explain three-step approach of customer centricity which are 1) customer segmentation and segment

strategies 2) redesign of customer contacts and the marketing logic and 3) adjustment of control mechanism and cultural change[13].

Kalpana Chaturvedi and Joana Chataway on their work with title Innovation in the Post-TRIPs regime in Indian pharmaceutical firms: implication for pharmaceutical innovation model could explain in detail with the focus that innovation does not happen merely by chance. The findings of their analysis suggest that in the new policy and knowledge intensive environment, one company can identify a new compound, another can process and develop it, a third can carry it through clinical development and still fourth can launch it[14].

Anil Kotwani with title will generic drug stores improve access to essential medicines for the poor in India? Published in Journal of public health policy (2010) 31, 178-184 could initiate the discussion with the point that policymakers in developing countries are challenged to increase the availability and affordability of essential medicines. Ideally, medicines available at generic drug stores should be the same as the national list of essential medicines or the state essential medicine list. Given these facts, one is forced to ask the question-are these new stores being opened for the benefit of low-income populations or for the sustenance of government-owned drug companies?

To summarize the resulting advice:

- Start with awareness and advocacy for generic equivalents of medicines for the public.
- Publicize evidence-based results about the quality of generic medicines available at generic drug stores.
- Stock the generic drug stores with all the essential medicines.

- Open stores in the private sector, not only in urban areas but also in villages and small towns. If quality medicines at affordable prices are accessible to the general public in the private sector, then access to essential medicines will improve.
- In its current form, the Jan Aushadhi campaign will increase the affordability of very few medicines for a very small population[15].

3.3 Associations and Industry perspective:

White paper on Indian pharmaceutical industry quest for global leadership published by ASSOCHAM on November 14, 2006 could quote about future trends of industry: some of the major trends that are expected in the future include-mergers and acquisitions in the industry: new product launches by MNCs and Indian companies; in-licensing of patented products by Indian companies to launch them in the Indian market and increase in the number of contract research organizations. The industry will also face stricter regulatory norms in order to maintain its competitiveness in the global space[16].

Vincent Aurentz, Bernhard Kirschabaum and Markus Thunecke could elaborate the point in Revitalizing portfolio decision-making at Merck Serono S.A.-Geneva published in Journal of commercial Biotechnology, Vol 17, I, 24-36. They explained the point which is of in direct relation with our present study that is limitations of current practices. Companies often get stuck in a vicious cycle that locks in a lack of productivity, which poor portfolio management reinforces. When short-term productivity goals produce sub-optimal project resource allocation, companies experience a decrease in project quality and increase in attrition[17].

Rajesh Dubey and Jayashree Dubey on their work with title Pharmaceutical product differentiation: A strategy for strengthening product pipeline and life cycle management published in journal of medical marketing volume 9, 2, 104-118 could elaborate the point sustaining growth of pharmaceutical sector and need of new strategies. These are the most difficult times ever faced by pharmaceutical companies across the world. The industry that had flourished with varied business model is finding itself at crossroads, facing a future riddled with uncertainty. Until recently, research and development had been the main growth engine of pharmaceutical industries, though its objective differed in different geographies. Although the organizations in developed countries invented new molecules and drug delivery technologies, organizations in developing countries researched to reverse engineer and manufacture drug products innovated by their peer counterparts. This dichotomy polarized the global pharmaceutical sector in two parts, the poor world inhabited by generic players selling cheap copied version drugs, and the rich world ruled by monopolistic research-oriented players offering innovative therapy at premium price[18].

Key Account Management (KAM) though practiced in Indian pharmaceutical industry but in overall scenario KAM could not take much momentum, however quite useful for sustainable growth of the organization and industry. Brian D Smith with title Myth, reality and requirements in pharmaceutical key account management published in journal of medical marketing, Vol 9, 2, 89-95 could explain further the term. As cited in his work, in contrast to most models of marketing which have their origins in consumer markets, the roots of KAM lie in business-to-business marketing (or Industrial Marketing, as it used to be known). In Indian context many organization do practice same even run separate business unit to manage key account many a time they term them as institutional business or even special task force. Key account

management is having certain advantages like key accounts create more than financial value, key accounts are key to both partners, key accounts have multiple relationships, key account managers facilitate rather than sell, and key accounts have longevity[19].

As mentioned in Atos consulting's report under the title trends and issues in pharmaceutical sector-the market share of generic medicines is increasing. The generic medicines can be marketed for a substantial lower price than the original product, because the discovery and research is already done by the branded company. Further, they mentioned because of financial pressure (earnings of top companies have fallen by 25%, since 2002), pharmaceutical companies have to manage two challenges at once: Improve the efficiency of IT and Use IT to enhance business innovation and operational efficiency[20].

An in-depth analysis by Dr. R B Smarta with title "Forces Shaping Indian Pharmaceutical Industry" could provide further insight to the Indian way of developing pharmaceutical marketing practices. Finally, he could name same as medico-marketing model with reference to Indian context. To put forward argument and viewpoint when we consider the forces which could shape Indian pharmaceutical Industry as six basic forces which are:

1. The Government as a force trying to regulate the industry
2. The trade as a force to facilitate the availability
3. The medical profession as a force to stimulate the demand for different types of fixed dosage formulations
4. Technology as a force to create or eliminate competition
5. The status of country in terms of its industrial development, population, hygiene, health awareness, and per capita income

6. Influence of international development and its impact

According to his study and analysis late 1980s witnessed the emergence of two additional forces-the ‘forces of patients’, legitimate but recent, and the ‘force of medical representatives’.

His further compilation could provide the eight major forces that will act on the Indian pharmaceutical industry are:

- Core strength of the Indian pharmaceutical industry
- Disease pattern
- Doctors
- Patients
- Alternative medicine
- Health infrastructure
- Information technology
- Health insurance

Indian pharmaceutical industry include its good blend of Eastern and Western styles of management, well-educated, low-cost and abundant workforce, low-cost bulk drugs and formulations, large and growing market for the next 25 years, and alternate medicine for masses at lowest cost.

Looking at the impact of the eight major forces, one can identify 10 critical success factors which may emerge:

1. Product-portfolio related
    - New products

- The ability to be the first to enter the market
- The right kind of portfolio mix as per the prevalent disease pattern
- The product portfolio base
- Right positioning

2. Well-trained sales force(MRs)
3. Integration to widen business opportunities
4. R&D efforts to provide competitive advantage
5. Information technology to derive cost advantage and to be the customer responsive
6. Good manufacturing practices to provide competitive advantage in terms of quality
7. Strong over-the-counter (OTC) brands
8. Exports-allopathic and ayurvedic products
9. Strategic alliances
10. Business design and strategy

His concluding remark is of our prime importance in context to our study where he mentioned the point "it is very important to develop sustainable and innovative marketing approaches and practices to get results in the pharmaceutical industry"[21].

3.4 Global perspective:

International Federation of Pharmaceutical Manufacturers & Associations popularly known as IFPMA (www.ifpma.org) set a standardized code of marketing practices that should be followed by all the companies operating in the market place. Following are the points which can bring a regulation in marketing practices adopted from year 2012 publication:

1) The healthcare and well-being of patients are the first priority for pharmaceutical companies.
2) Pharmaceutical companies will conform to high standard of quality, safety and efficacy as determined by regulatory authorities.
3) Pharmaceutical companies' interactions with stakeholders must at all-time be ethical, appropriate and professional. Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence.
4) Pharmaceutical companies are responsible for providing accurate, balanced, and scientifically valid data on products.
5) Promotion must be ethical, accurate, balanced and must not be misleading. Information in promotional materials must support proper assessment of the risks and benefits of the product and its appropriate use.
6) Pharmaceutical companies will respect the privacy and personal information of patiens.
7) All clinical trials and scientific research sponsored or supported by companies will be conducted with the intent to develop knowledge that will benefit patients and advance

science and medicine. Pharmaceutical companies are committed to the transparency of industry sponsored clinical trials in patients.

8) Pharmaceutical companies should adhere to both the spirit and the letter of applicable industry codes. To achieve this, pharmaceutical companies will ensure that all relevant personnel are appropriately trained.

Wendel Barr, Chief Operating Officer, Covance with title Tactical To Strategic-the evolution of drug development outsourcing wrote in his concluding part of the manuscript as, recently, the chief executive officers of large sponsor companies, such as Wyeth, Merck, Pfizer, GSK, and others, have made public announcements that the era of investing in "bricks and mortar" has ended. They candidly speak of the value of strategically partnering with CROs, biotechs, and other organizations as part of their drug development strategy. Some firms, such as Wyeth, are making dramatic moves by outsourcing entire functions including data management to outside vendors. Others, such as Solvay, are strategically outsourcing entire clinical programs to single CROs[22].

Surveys from Center Watch, Contract Pharma, Wall Street securities firms, and other industry analysts have acknowledged that CROs have greatly improved operational efficiency, begun to understand the value of excellent customer service and are delivering complex, high-quality global studies on-time and within budget-often surpassing the performance of large pharma's internal R&D.

A recent study by the Tufts University Center for the study of Drug Development stated that pharmaceutical and biotechnology companies will increasingly include strategic outsourcing partnerships and alliances in their operating model to improve R&D productivity in drug

development. Survey results by contract pharma indicate that today more that 50% of pharmaceutical companies see themselves as strategic outsourcers and more that 60% view CRO as partners.

The emergence of strategic outsourcing involved more than an impulsive response to market and financial issues-while those issues have certainly proved to be catalysts, it is clear that CROs and the service and expertise they offer have evolved to a point where they are fit to be strategic partners. While there will be some bumps in the road ahead, as such arrangements play out and are evaluated for success, the path is clear: large biopharmaceutical companies have embarked upon strategic outsourcing as part of their plans for drug development and future growth[23].

John Watson, corporate Vice President, Marketing & Sales, Covance in manuscript with title Strategic Partnering-an R&D solution that makes sense in conclusion mentioned, Biopharmaceutical sponsors have much to offer in the form of new molecules and biologics, but they need to improve R&D productivity if the best compounds are to come to market faster and more economically.

A combination of mounting external pressures and increasing CRO capabilities will result in more partnerships between sponsors and CROs positioned to take on global development programs. As part of the process, sponsors will recognize the importance of executive involvement in decision making as it relates to selecting the right outsourcing partners, and the need for a strong governance agreement and ongoing communication. This approach will help both parties learn new skills in partnering, build trust and encourage more innovative ways to leverage the expanding capabilities of broad based global CROs for mutual benefit.

Market demands are going to continue driving sponsors to challenge conventional thinking about outsourcing. Only when conventional thinking is challenged and traditional practices are replaced by innovative ideas will the fruits of this new paradigm begin to blossom.

Through strategic partnering. Honda was able to maintain quality while reducing material cost. Once strategic partnering becomes a common practice within the biopharmaceutical industry, the potential impact could be much more significant-improved health worldwide by delivering much-needed medicines to patients around the world[24].

Many Indian researcher and business personalities like Kiran Mazmudar-Shaw is having high opinion on Biotechnology. Her article in The Hindu with title Biotechnology-strong bas to build on could explain a business segment for India has the potential of generating revenus of $5 billion and creating sufficient number of jobs.

The Government had identified biotechnology as a thrust area for development way back in 1986 when it set up a dedicated Department of Biotechnology (DBT) that had well-defined objectives of establishing several centres of excellence by way of research and academic institutions focused on biotechnology based programmes. In addition, universities were also encouraged to introduce graduate and post-graduate programmes specializing in biotechnology. Although Indian biotechnology has received global recognition for its biotech capabilities, Government policies have thus far lagged behind[25].

V Y John's publication in Indian Journal of Finance, June, 2009 with title Potential Risk Factors Influencing the Indian Pharmaceutical Industry could elaborate the point through his analysis. Risk analysis and management in the pharmaceutical industry in India is a different exercise compared to that of other industries.

Indian's present budgetary allocation is just 1% if the GNP towards the health-care sector. There should be a substantial scale-up in this figure and the government should look to providing at least 4% of the GNP for tackling the healthcare issues. Given the Indian lead in strategic sectors like education, IT and communications, the government should make sincere efforts to scale-up operations in the health-care sector. There are special nuances in this sector like the excessive price controls in indigenous market, global consolidation, presence of counterfeit drugs, compliance with global standards and long drawn process of research. It takes about 10-12 years for the discovery and development of a new medicine and the average effective patient life for a new drug is roughly less that 10 years. The cost of developing a new drug can be in excess of $1 billion. That is because 1 out of 10 drugs that start human clinical trials reach the market.

The Indian industry is subject to many risks s it is functioning amidst such constraints which ensures that the fittest survive. In his work he could summarize the risk in eight categories like finance risk, research and development risk, regulatory risk, market risk, quality risk, strategic risk, technology risk and operational risk[26].

A Deutsche Bank research with title India's pharmaceutical industry on course of globalization published on April 9, 2008 could summaries like: The pharmaceutical industry is expanding worldwide. For some years now, it has been benefiting from the particular dynamics of the Asian economies as both purchasers and producers. It is not only the markets in China and India that register high growth rates. Annual growth rates are also impressive in Singapore, Malaysia, Thailand and Indonesia.

Thanks to low costs, qualified staff and extensive production and research units in India is becoming more and more of a major pharmaceutical location. Drivers of growth are the growing

population, which at 1.5 bn should exceed that of China already in 2025, as well as the larger number of older people with markedly higher demand for medicines. Add to this the increase in middle-class households which have considerably higher incomes at their disposal that the population on average.

As a result of the new patent legislation, the country's pharmaceutical industry is reorienting itself and focusing on self-developed medicines and/or contract research and production for western drugs companies. Also the expansion of Indian firms abroad looks set to continue- preferred target markets are the US and European countries.

Despite the positive outlook India will lose market share in the Asian market in future. The winner, first and foremost, will be China, which will remain the No1 thanks to its expected higher sales growth and volume, as Indian companies' strategic reorientation away from generics to original preparation is still in its infancy. The sooner India manages to close the infrastructure gap, the higher growth will be in the country's pharmaceutical industry[27].

3.5 Future Outlook:

Dinar Kale & Steve Little in their work with title From Imitation to Innovation: The Evolution of R&D Capabilities and Learning Processes in the Indian Pharmaceutical Industry published in Technology Analysis & Strategic Management Volume 19, Issue 5, pages 589-609, 2007Special Issue: The Indian Pharmaceutical Industry Before and After TRIPS :

Since the mid1990s the Indian pharmaceutical industry has emerged as a leading supplier of generic drugs to both developing and developed countries. The movement of the Indian pharmaceutical industry along the R&D value chain represents a remarkable shift from an importer to an innovator of drugs.

The Indian government's industrial and technology policies along with changes in regulation of intellectual property rights played a crucial role in shaping this development of R&D capability. Using the 'capability creation model' this paper discusses the learning processes and stages involved in this dramatic accumulation of technological capability. This analysis shows that the Indian pharmaceutical industry has followed a trajectory from duplicative imitation to creative imitation to move up the value chain of pharmaceutical R&D. Finally as a result of changes in patent law the industry is learning to develop capabilities in innovative R&D.

The basic and intermediate technological capabilities gained from imitative learning gave these firms a solid base for development of competence in advanced innovative R&D. These findings have implications for government policies as well as firm strategies in other developing countries albeit with some limitations due to global harmonization of patent laws being promoted by the World Trade Organization.

Indian Pharmaceutical Industry in WTO regime- A SWOT Analysis work by N Lalitha published in Economic & Political Weekly, August 24, 2002. A SWOT analysis of the Indian pharmaceutical industry (IPI) in the WTO regime reveals that the much acclaimed IPI's expertise in process development skills were made possible by amendments made to the Indian Patents Act 1970. This strength should be utilised to the hilt to benefit from opportunities that arise from vertical disintegration of research, clinical trials and manufacturing by the multinationals.

IPI faces threats in the form of competition from other Asian giants, particularly China. This paper argues that the IPI should adopt various strategies like producing off-patented products, new patented products by acquiring compulsory licensing or cross licensing, collaborate with multinationals not only in R and D and manufacturing, but also in marketing new patented products and improving the standards of production to widen the export market[28].

This paper addresses three main questions on Indian pharmaceutical firms that have integrated biotechnology in their marketing, production or research activities:

1. What kind of labour stocks of the knowledge base have an impact on market sales?
2. Which components of the R&D strategy are strategic substitutes and which are strategic complements?
3. What are the distinguishing features of firms that have already integrated biotechnology in their research activities?

The paper shows that market sales are an increasing function of qualified labour stocks. Internal R&D and foreign collaborations are strategic substitutes, while patents and publications are strategic complements. Firms that are active in biotechnology research are likely to be younger and implementing more aggressive learning strategies.

Rossen Kazakov and title between stragety and change: reformulating the medicines industry in an enlarged Europe published in the Journal of Medical Marketing Volume 7, 3 245-253 in 2007. The questions as how to achieve competitive advantage through a genuine and innovative set of strategic principles and tools is even present in the business repertoire of all industries. Yet few manage to reorder their way of doing things to achieve the perfect correlation between business goals and external customers' expectations.

With modern economics rejecting the existence of a perfect equilibrium between supply and demand, the job of the business strategy planner is harder than never before. The key to successful strategy creation, as his work shows, lies in an understanding of three strategic perspectives:

1. The purchaser of health care services-patient and government-as investor in health as an asset.
2. Of customer perceived value as a distortion of the product 'eidos', due to market imperfections and asymmetries of information.
3. Of the effective management of the dynamics between suppliers' and customers' interests.

Present work could address the point how can industry maintain sustainable growth?

Some ideas in terms of how to develop a new and effective strategy have been developed throughout the present research work. The first is the effective management of the dynamics of the 'point of intersection' between industries and customer interests (cumulative of values, expectations, needs). The second is managing customers' price-sensitive thinking as investors in health. The third is managing agency relationship phenomena, market asymmetries and

imperfections and their exploitations. The fourth is understanding the 'eidos' nature of the customers' perceived product value and the fifth is managing local time and place (dynamics of local policy and culture).

The future of medicine industry can be drawn in two main directions-standard strategic direction and a more innovative strategic direction. Specialization of product portfolio, product differentiation, getting closer to the consumer and adding value constitute the standard direction which still has a huge potential to achieve industry growth. [29]

Neetu Dubey, R.K. Sharma, Himanshu Gupta, Nitin Dubey and Nidhi Dubey with title: Performance of the Indian Pharmaceutical Industry Pre and Post TRIPS Era: A Study published in Asian Journal of Pharmacy & Life Science, Vol. 1 (2), March-June, 2011. Globally the pharmaceutical market is undergoing a transformation led by change in demand patterns, realignment of supply chains, and global regulatory shifts. The Indian Pharmaceutical Industry is entering an era where the value chain components are reassessed and redesigned to realize optimum value.

While the cost of doing business is increasing, the customers are demanding more innovative pharmaceutical products at more competitive prices. The change in patent regime has also become heralded for a change in the industry dynamics. On one hand,patents on blockbuster drugs are expiring and on the other hand, there are insufficient drugs in the pipeline. The changing industry dynamics both at the domestic level as well as the international level has forced the pharmaceutical players to rethink their traditional business strategies.

The pharmaceutical industry needs to focus more on R&D and better productivity to capitalize on the immense existing opportunities. India, with its inherent competitive advantages and cost-effective manufacturing capabilities, has now become one of the most preferred

destinations for Contract Research and Manufacturing Services (CRAMS). As per the KPMG report, India holds huge potential to tap the $20 billion CRAMS business, which is expected to reach $ 31 billion by 2010. India with its essential competitive advantages remains as one of the most preferred outsourcing destinations and is now playing a vital role in manufacturing as well as drug development value chain of various innovator companies.

The pharmaceutical industry in India is expected to grow from $5.5 billion now to $25 billion by 2010 and $75 billion USD by the year 2020. By 2020, global integration of most sectors in the world economy would be much more pronounced, and the pharmaceutical industry will not be an exception. In fact the Indian pharmaceutical industry, which currently has strong linkages with the global pharmaceutical market, will become even more strongly integrated[30].

The future will be extremely promising with many more milestones to come in the journey of the Indian pharmaceutical industry.Jyoti Nair with title : Performance Analysis And Solvency Prediction Of Indian Pharmaceutical Companies published in International Journal of Marketing, Financial Services & Management Research Vol.2, No. 5, May (2013). The Indian pharmaceutical industry is growing at about 8-9% annually. In 2011, the growth was pegged at 15%.

According to McKinsey & Co.‟s report, "Indian Pharma 2020: Propelling access and acceptance, realizing true potential." Indian pharmacy market will grow to USD 55 billion by 2020. It also ranks India 3rd in terms of volume among the top 15 drug manufacturing countries. Patent laws are also expected to boost development of pharmaceutical products. Demand for pharmaceutical products in India is also growing due to various factors. Market research firm Cygnus forecasts that Indian bulk drug industry will grow annually @21%. McKinsey report

also mentions that household spending on health care will grow from 7% to 13% by 2025. All these factors will contribute to growth of pharmaceutical sector in the coming years[31].

3.6 Options for Organizations:

According to CARE research, demand triggers for the growth are:

1. Patent drugs worth USD170 billion are expected to go off patent leading to huge market for generic drugs.
2. Exports of pharmaceutical products enjoying high margin is expected to grow at a higher rate than domestic market.
3. Increased M&A activities will consolidate the market leading to development of specialized segments
4. There are currently approx.175 UDFDA and 90 UK- MHRA approved pharma plants in India which can supply high quality pharmaceutical products globally.
5. Rural demand is expected to surge given the rising income level and awareness.
6. Change in life style has contributed to a shift from chronic diseases to lifestyle diseases.

Government has also taken positive steps to promote this sector by focusing on improvement of medical infrastructure, rural health care etc. Increased budgetary allocation to National Rural Health Mission (NRHM) is another step in this direction. With 100% FDI being allowed health and medical services through automatic route, an increased inflow of investment in pharmaceutical sector is visible. Allowing a weighted deduction of 200% for in house research will encourage research and development of Indian pharmaceutical companies[32].

Amit Shovon Ray and Saradindu Bhaduri with title: Competing through Technological Capability the Indian Pharmaceutical Industry in a Changing Global Landscape published in J N U New Delhi, September 2012.

They have attempted to portray the unique policy space that India had created for itself to foster technological capability of the domestic pharmaceutical industry. We have shown how endogenously determined home grown policy models have helped this industry to become self-reliant, not only in manufacturing but also in technology, and eventually compete successfully in global markets through technological capability.

A few imminent questions arise from this discourse. First, why the success of Indian pharmaceuticals could not be replicated in other sectors in India? As already mentioned, India made a concerted effort in the 1970s to create a new policy paradigm (especially in terms of IPR regime) for its pharmaceutical sector only, leaving the rest of the manufacturing industries operate within the earlier IPR framework. Hence, it is of little surprise that we fail to see replication of India's pharmaceutical success in other sectors. The policy attention on pharmaceuticals may perhaps be understood in the light of India's public health concerns and rising drug prices, but there is very little by way of research to explain India's policy priority for pharmaceuticals over other manufacturing industries.

Second, is it possible to replicate this pharmaceutical policy framework elsewhere? It has been adequately highlighted by the innovation systems literature that policies need to develop various systemic linkages in order to be effective. Synchronisation of policies with other institutional and organisational factors determines, to a large extent, the fate of policy outcomes and one cannot deny the importance of historicity and path dependence in technological learning. India's historical roots of pharmaceutical production dating back to the pre-independence era

coupled with its long standing tradition of science education, especially skills of analytical chemistry in this particular context, perhaps contributed to the policy success in building pharmaceutical technological capability. Therefore, one must contextualise the policy lessons to be able to replicate this success in other countries.

In addition, the creation of a policy space is influenced by national and international political economic interests. For instance, the pressure lobby from global pharmaceutical giants have often influenced policy making in developing countries to the detriment of indigenous capability building. It is believed that in the 1970s, India could succeed in resisting such pressures to a large extent to pursue its primary goal of technological self-reliance. Similar attempts by other developing countries to create this policy space have often been foiled by political economy pressures created by pharmaceutical MNCs and their home governments.

We would like to note that the space for endogenous policy making by national governments have been shrinking over the last couple of decades with the emergence of a new world order driven by neo-liberal institutions like the WTO. Accordingly, the present global landscape does pose a rather challenging environment for the Indian pharmaceutical industry to continue to compete and emerge through its technological capability. We have seen how it is becoming increasingly difficult to create a favorable policy environment for this industry to flourish. For one thing, its transition to a new paradigm of technological trajectory through successful drug discovery research does not appear to be imminent. At the same time, the niche that it has created for itself as global generic producer is also under major threats. It is our contention that, at this juncture, any policy move that may hurt the generic industry inIndia must be resisted. A vibrant generic industry in India will go a long way in serving the cause of global access to

affordable medicines, upholding the spirit of the Doha Declaration, and its mandate to give priorities to public health concerns over trade interests[33].

With the context of present work and title pertinent to put forward the outcome of a report published by price water house cooper with title pharma 2020: Challenging business models which path will you take? Interesting to note certain questions has been raised for senior management which are quite relevant to our present work.

Key questions for senior management

1. What is our current business model?
2. Does it play sufficiently to our strengths?
3. What kind of company do we want our company to be?
4. Will our current business model enable us to expand intonew markets – be these new products, services or countries and satisfy the expectations of our customers in 2020? If not, what sort of business model will we need?
5. What is the size of the gap and how can we reduce it as rapidly as possible?
6. Do we have a clear picture of the opportunities and risks entailed by each of the alternatives available to us?
7. Do we have a plan in place that will enable us to move forward quickly, while maximizing the opportunities and minimizing the risks?

The transition will not be easy for collaborative business models are far more complex than the integrated model that has previously prevailed. Moreover no one model will suit every company. Each will need to assess its position. Options and future course in light of its individual strengths and needs.

However, the prospects for any pharmaceutical company that can make the switch are very promising. The potential for reallocating resources to deliver better outcomes and maximize the effectiveness of expenditure on healthcare is considerable in most healthcare systems. Research recently completed by Britain's Audit commissions how for example, that annual spending on the treatment of diabetes ranges from less than £8 to over£30 (US$11.9-US$44.6) per head. But differences in the prevalence of diabetes account for only 8%ofthis variation –and higher expenditure does not result in fewer emergency hospital admissions.

To date Pharma has focused on the profits it can earn from the estimated 10-15% of the health budget that goes on medicines. Yet there are many opportunities to generate revenues by improving the way on which the remaining 85-90%is spent. It is these opportunities the industry will need to address in the brave new world of 2020[34].

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