

A STUDY OF PHARMACEUTICALS IN INDIA AND KASHMIR ASPECT



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ABSTRACT

Keywords

Pharmaceutical
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The Indian pharmaceutical industry positions among the top five countries by volume (production) and accounts for about 10% of worldwide production. The industry's gross revenue has grown from a simple US\$ 0.3 bn in 1980 to about US\$ 21.73 billion in 2009-10. Stumpy cost of skilled manpower and innovation are some of the major factors taking sides of this growth. According to the Department of Pharmaceuticals, the Indian pharmaceutical industry employs about 340,000 people and an approximate 400,000 doctors and 300,000 chemists. The Indian pharmaceutical industry is disjointed with more than 10,000 manufacturers in the controlled and unplanned segments. The products manufactured by the Indian pharmaceutical industry can be generally classified into bulk drugs (active pharmaceutical ingredients - API) and formulations. Of the total number of pharmaceutical manufacturers, about 77% make formulations, while the remaining 23% make up bulk drugs. Bulk drug is an active constituent with medicinal properties, which acts as fundamental raw material for formulations. Formulations are precise dosage forms of a bulk drug or a mixture of bulk drugs. Drugs are available as syrups, injections, tablets and capsules. Based on the pharmaceutical consumer base, the Indian API manufacturing segment can be alienated into two sectors – innovative or branded and generic or unbranded. In 2009, the worldwide generic drug market was projected to be US\$ 84 billion, of which the US accounted for 42%. India's generic drug industry is approximate to be US\$ 19 bn and it ranks third globally, contributing about 10% to global pharmaceutical production. Pharmaceutical manufacturing units are mainly concentrated in Maharashtra and Gujarat. These regions hold for about 45% of the total number of pharmaceutical manufacturing units in India. Based on the elevated value plant species, J&K has a huge potential for establishing bio-pharmaceutical industry.

Contribution/ Originality: This study contributes in the existing literature by studying potential of Indian pharmaceutical industry in depth and finding the chances and areas of growth in this industry. This paper also studies the Swot analysis of the industry and the disease trends in India. The study provides detailed information about various states and their respective pharmaceutical industry and specifically of Kashmir. This original work will also provide the information about Kashmir's medicinal plantation resources.

1. INTRODUCTION

The narration of the progress of the Indian pharmaceutical industry can be alienated into four principal eras. The first era is from 1850 to 1945. The second age spans from 1945 to the late 1970s. The third era for development is from the early 1980s to the early 1990s, and the fourth epoch extends from the early 1990s to the present time.

1.1. *The Premature Stage of Pharmaceutical Evolution*

For ease, the early on stage of Pharmaceutical evolution has been divided into two distinctive phases viz., the pre-independence and the post independence developments.

1.2. *Pre-Independence Situation*

Before the arrival of British Rule, the original forms of medicine were in use (Ayurvedic or Unani) in India. The Central Government of British India first presented the allopathic form of medicine in the nation. However, there were no manufacture units in the country. Instead, the foreign companies exported raw materials from India, transformed it into finished products, and imported it reverse to India (Chaudhuri 1984) ¹. In spite of genuine hard work by a handful number of entrepreneurs to set up native companies, drug manufacture in the country was little and could barely meet only 13% of the total medicinal necessity of the country. The original industry, however, received force during the Second World War due to the fall in the deliver of drugs from overseas companies and many more Indian companies like Unichem, Chemo Pharma, Zandu Pharmaceutical Works, Calcutta Chemicals, Standard Chemicals, Chemical Industrial and Pharmaceutical Laboratories (now known as Cipla), East India Pharmaceutical Works and others were established. With the entrance of fresh firms in the market the making of drugs improved rapidly and indigenous firms were competent to satisfy about 70% of the country's medicinal obligation. During this stage, overseas companies across the globe as well as Indian companies were busy in production connected activities and the importance of R&D was strange to them

¹Concerned about the lack of domestic manufacturing facilities and the unequal pattern of trade, few scientists like Temin, Chandra Ray, TK Gajjar and AS Kotibhaskar laid the foundation of Bengal Chemical and Pharmaceutical Work in Calcutta (BCPW) in 1892 (see, BCPW 1941 for its activities in the early days) and Alembic Chemical Works by in 1907 in Baroda. The establishment of the Bengal Immunity in 1919 by a group of notable scientists and physicians, namely Nilratan Sircar, Kailash Chandra Bose, Bidhan Chandra Ray etc was yet another milestone in the history of the beginning of the Indian pharmaceutical industry. The company was founded with the sole aim of attaining self-sufficiency of the production of synthetic medicine and of sera and vaccines.

(Temin, 1976). Whichever novel inventions of drugs were made were largely owing to the individual efforts of scientists and the drug companies were not concerned in it (Chaudhuri 2005).

1.3. Post Independence Picture

The era spans from 1945 to roughly the mid 1970s. A major advance known as therapeutic revolution noticeable the beginning of this period and stemmed in a phenomenal growth of the global pharmaceutical industry situated mainly in Germany, Switzerland, the UK and also to some extent in the US. A notable accomplishment during this era was a transfer in drug therapy from treating the symptoms to treating the disease itself (Temin, 1976). At the same time there was a significant shift in the structure of the industry mainly because the global pharmaceutical industry instead of being mere production units also embarked on the path of massive investment in R&D (Temin, 1976). The commercialization of newly conceived pharmaceutical products like penicillin and other synthetic drugs also rotated out to be a lucrative business. The accounting rate of returns from a newly conceived drug between 1954 and 1978 averaged at around 20.9 for universal pharmaceutical companies. This encouraged firms to carry out more R&D to plug the potential emerging markets by inventing novel drugs in a methodical manner. Further, the public sector also extended its extraordinary support for health related research. In contrast Indian companies were however, not inclined by the wave of curative revolution. The lack of skill, capital and support from the government were the principal obstructions for Indian companies to go on board on the new flight of drug development. Worried about the lack of mechanized facilities and guided by the sensitivity that 'foreign technology' was an significant component for the growth of the pharmaceutical sector, the Government of India in its Industrial Policy

Statement of 1948 determined to take a moderate attitude towards MNCs and endorsed them to set up plants devoid of opposite the hurdle of licensing agreements. Such liberal approach of the government in the direction of MNCs led to a free stream of overseas capital and the sector witnessed fast growth. As prominent by the Pharmaceutical Enquiry Committee of 1954, the drug making of India witnessed a 3.5 times expansion in the production from just Rs. 10 core in 1947 to about Rs. 35 core by the closing stages of 1952.

However, in spite of the development made by the sector, it was detected that foreign companies did not establish any manufacturing unit in India, but were engaged in assembling bulk drugs (imported from their country) for manufacturing the ultimate product (Pharmaceutical Inquiry Committee, 1954)². MNCs were not keen to establish production units in the country because the production of bulk drugs required investment in plant and machinery whereas importing bulk drugs and processing them into the formulation was an easier and more profitable business (Pharmaceutical Inquiry Committee, 1954).

²Pharmaceutical Inquiry Committee (1954) To conquer the structural limitation that the sector was suffering from, the government in its industrial licensing policy of 1956 made it obligatory for overseas multinational companies to establish their production division in the country and produce drugs from the fundamental stage. The pharmaceutical industry was also incorporated in the core group of industries for the purpose of licensing because of the 'high social value' substance of medicinal products. Accordingly, the license was granted under the direction

of the Director General of Technical Development (DGTD) for setting up a new unit or expansion of the existing units keeping into description the medicinal need for the country. In order to fulfil authoritarian requirements many overseas companies started their production in India. During this period, a large number of domestic companies also entered the market mostly due to government hold up under the Industrial Licensing Act and started producing a wide range of products. Between 1952 and 1962, drug productions in the industry augmented from Rs. 35 crore to about Rs. 100 crore.

Besides, the capital investment for the segment was about Rs. 56 crore in 1962 as contrast to its value of Rs. 23 crore in 1952.

1.4. The Changing Scenario and Future: Post-GATT

Dramatic changes are inevitable as India moves toward 2005, when the country may be committed to honoring product patents by virtue of becoming a member of WTO and a signatory to the General Agreement on Tariffs and Trade (GATT). Indian companies have recognized that innovation and research are vital for success and survival. Present Indian R&D investment is 1.9% of business turnover, far below that of multinationals. It is impossible at present for any Indian company to command sufficient resources to take a product from discovery all the way to market. The government has stated support by allowing a 10-year tax holiday on profits for corporations investing in R&D. Top companies are gradually gearing up, with R&D investment quickly increasing. A latest success story is Dr. Reddy's licensing of two of its antidiabetic molecules to Novo Nordisk, a Dutch company, and the sublicensing of one to Novartis for circulation in the United States, Canada, and Mexico. The proceeds are expected to be pumped back into R&D. This strategy appears to be the foundation for a slow progression from novel drug delivery systems and analog research, including combinatorial and chiral chemistry, up the value chain to basic research.

The post-GATT scenario will witness a reduction in the number of companies, with many smaller companies shutting down. Multinational interest in India is bound to be rekindled, especially with the government now allowing 100% foreign direct investment (FDI) and making a commitment to honor intellectual property rights. Several Indian firms are preparing to turn into contract research organizations (CROs) and contract manufacturing organizations (CMOs). Skilled professionals can be employed in India for one-fifth to one-tenth the cost in the West, making subcontracting a profitable choice for multinationals. Thirty manufacturing facilities have already been approved by organizations such as the U.S. Food and Drug Administration, the Medicines Control Agency in the United Kingdom, and the Australian Therapeutic Goods Administration.

Another strategy in the post-GATT era is the building of strategic alliances with global giants for marketing and distribution as well as licensing. The established marketing networks and distribution systems of Indian companies have potential to be a valuable resource for multinationals. The industry in India will also create prospects to offer technical service, such as analytical and toxicology services. An additional area with potential is the development of international clinical trial centers based on good clinical practice (GCP).

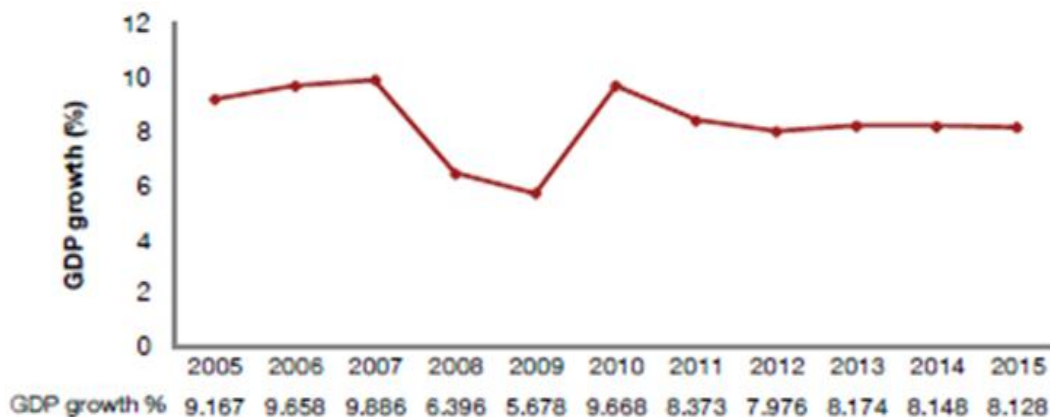
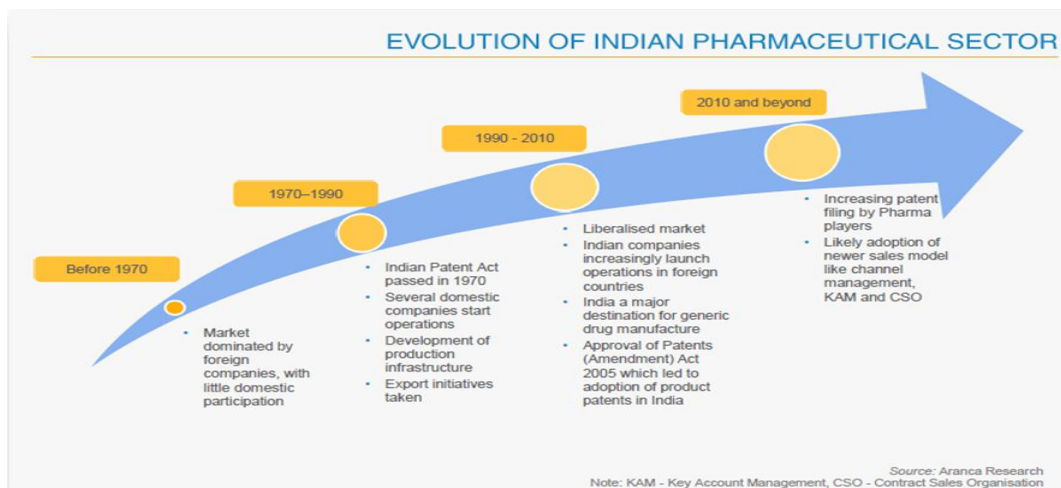


Fig-3. Indian's strong GDP growth rate

Source: IMF, World Economic Outlook, (October 2010)

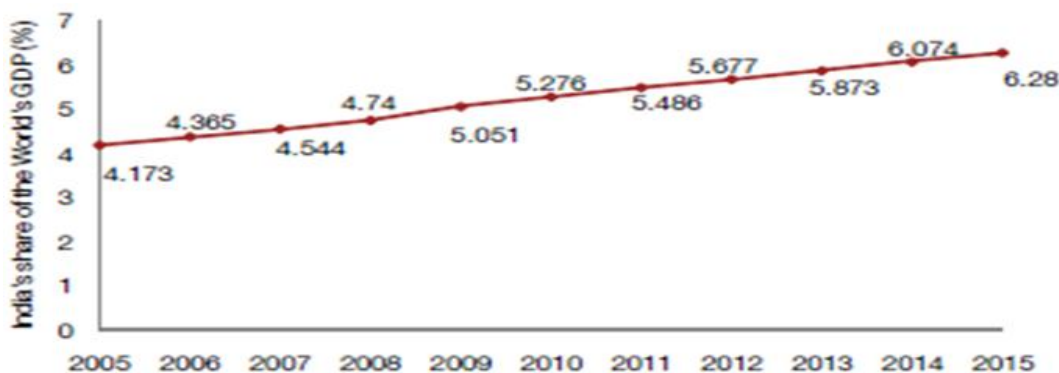


Fig-4. Growing global share of Indian's GDP (%)

Source: International Monetary Fund, World Economic Outlook, (October 2010)

2. LITERATURE REVIEW

2.1. Macro Factors Driving the Industry

2.1.1. The Growing Indian Economy

The Indian economy is rising fast, and is appreciated at US\$1.430 trillion in 2010. GDP growth, calculated on a Purchasing Power Parity basis has reached 9.66% in the year 2010, and the International Monetary Fund (IMF) anticipates it to continue consistently above 8% till 2015.

Furthermore, India's share in the global GDP has been gradually increasing, and is expected to reach 6.28% in 2015, up from 4.17% in 2005.

2.1.2. Rise of Middle Class with Higher Purchasing Power

India's population is currently just over 1.1 billion and is predictable to rise to 1.6 billion by 2050 – a 45.5% increase that will see it outshine China as the world's most populous state. Besides, India has a enormous middle class inhabitants (households with annual incomes of US\$4762 to US\$23,8 at 2001-02 prices), which has grown rapidly, from 25 million people in 1996 to 153 million people in 2010. If the economy continues to rise fast and literacy rates keep rising, around a third of the population (34%) is expected to join the middle class in the near future. The middle class population is quickly acquiring the purchasing power essential to afford quality western medicine due to an increase in disposable income. The Indian population spent 7% of its disposable income on healthcare in 2005; this number is expected to nearly double, to 13%, by 2025.

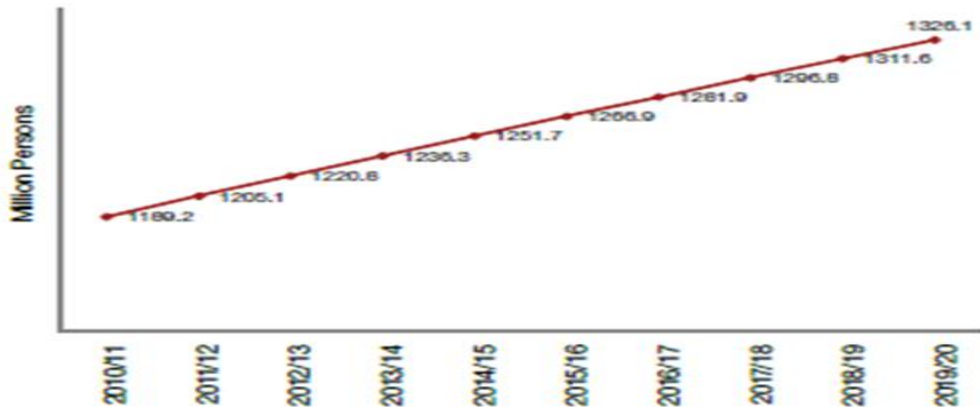


Figure-5. Population growth projections

Source: ISI analytics (2010)

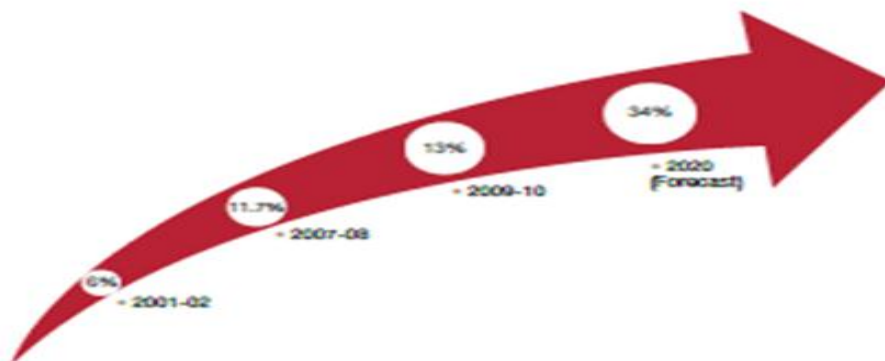


Figure-6. Ascent of the Indian Middle Class- Percentage of the population

Source: Economic Times (April 2009), PwC analysis

2.1.3. Changing Disease Contour

The Indian population is experiencing a swing in disease profiles (Figure). Conventionally, the acute disease slice held a major share of the Indian pharmaceutical market. This segment will carry on to breed at a solid rate, due to issues unfolding to public hygiene and sanitation. But, with boost in affluence, rise in life expectancy and the onset of lifestyle associated conditions, the disease profile is slowly shifting towards a enlargement in the chronic diseases segment. India has the largest group of diabetic patients in the world, with more than 41 million people suffering from the disease; this is projected to reach 73.5 million in 2025.

The growing dimension of the Indian geriatric population will be a major factor in influencing the growth of the chronic segment. By 2028, an projected 199 million Indians will be age 60 or older, up from about 91 million in 2008. Along with chronic, in the last year there has been a bounce back in sales in the acute diseases segment. This movement is likely to continue over the next few years, as we see companies widening their contact into newer markets, which have a relatively higher number of treatment immature patients requiring basic treatment, thus, creating new demand for drugs of the acute therapies segment.

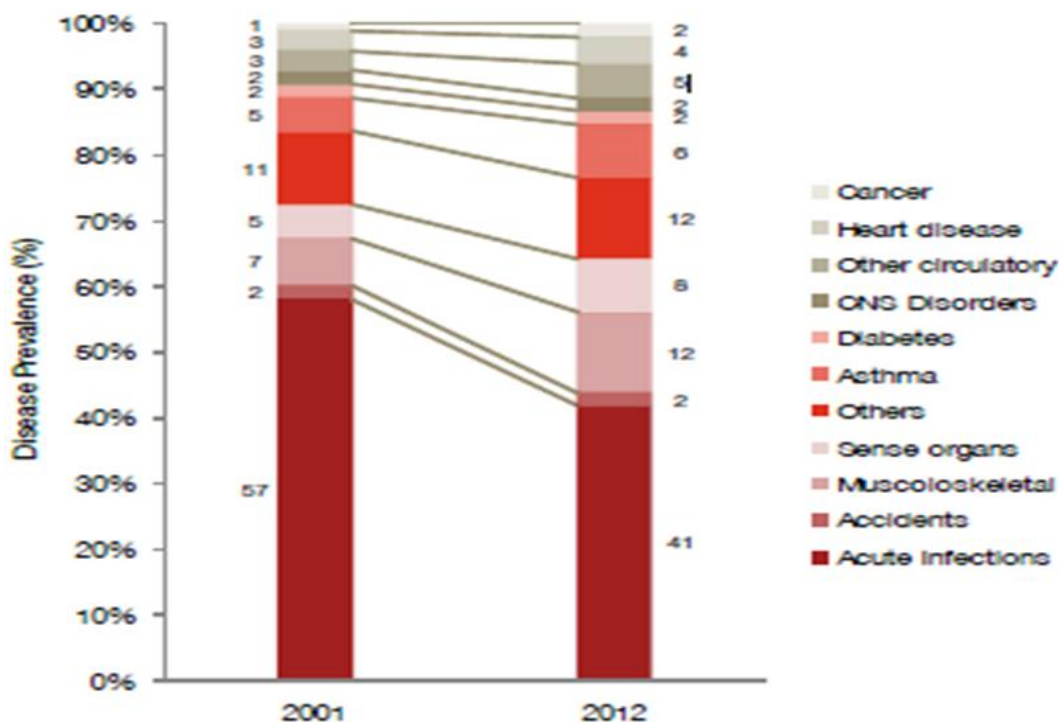


Figure-7. Shift in Disease Profile toward Chronic

Sources: IDFC International Securities, Indian Pharma (June 2010)

2.1.4. Government Policies

The Indian government has been making efforts to get better countrywide provision of healthcare. It has launched policies that are intended at:

- constructing more hospitals,
- boosting home access to healthcare,

- getting better the quality of medical education,
- escalating public expenditure on healthcare to 2-3% of GDP, up from a current low of 1%.

Some of the important government allocations on healthcare pay out include a five year tax break for opening hospitals anywhere in India, with an added focus on tier II and tier III markets, both in the 2008-09 Union financial plan. Going forward, the Indian government plans to spend US\$293 million on the promotion of healthcare through programmes for the prevention and cure of diseases such as cancer, diabetes, heart ailments and stroke in 2011-12. Diabetes, hypertension and non-communicable disease patients will be curtailed under the National Programme for Preclusion and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS). The agenda is likely to cover more than 70 million adults across 100 districts in 15 states and union territories of the India.

2.1.5. Healthcare Insurance

India's healthcare insurance industry is presently very trivial and imperfect, but is expected to raise at a CAGR of 15% till 2015. Around 80% of India's healthcare spending is financed out of pocket. This limits the tendency of Indians to spend on healthcare, particularly in lower and middle income groups which encompass around 95% of population. The little fraction of Indians who do have a number of insurance, the key provider is the Government-run General Insurance Company (GIC). Private insurance only emanated into the market post 2007, when the Insurance Regulatory and Development Authority (IRDA) removed tariffs on general insurance. Apollo was the first private healthcare insurance provider in the country; other private entrants are ICICI Lombard, Tata AIG, Royal Sundaram, Star Allied Health Insurance, Cholamandalam DBS and Bajaj Allianz Apollo.

The government runs a program called the National Rural Health Mission (NRHM), for the growth of the poor, allocating US\$2920 million in the 2008-09 budget, under the NRHM. A health insurance scheme called Rashtriya Swasthya Bima Yojna (RSBY) that provided US\$745 value of cover for every worker was also included. The total allocation of this inclusion was US\$51 million, which was increased in the subsequent budgets. The latest budget, 2010-11, incorporated a further 20% of the population covered under the NREGA (National Rural employment Guarantee Act).

The government, along with numerous in the industry believes that increase in insurance coverage is vital to take the market forward. But, other experts believe that the extent of health insurance could lead to a market wherein there is negligible differentiation between branded generics. An essential success factor for generic makers is separation of their products. While increased health insurance coverage may benefit generic drug manufacturers by increasing the market's affordability for medicines, it may, in combination with increased institutional sales cause a reduction in prices, owing to the rising influence of insurance companies.

Overall, dearth of insurance coverage still leftovers a challenge. Widespread use of health insurance could take many ages, not least because insurance companies lack the data they require to measure health risks precisely and the only products they sell graft on an indemnity basis –

that is, they compensate the patient after he or she has paid the healthcare provider's bill, making such policies less eye-catching.

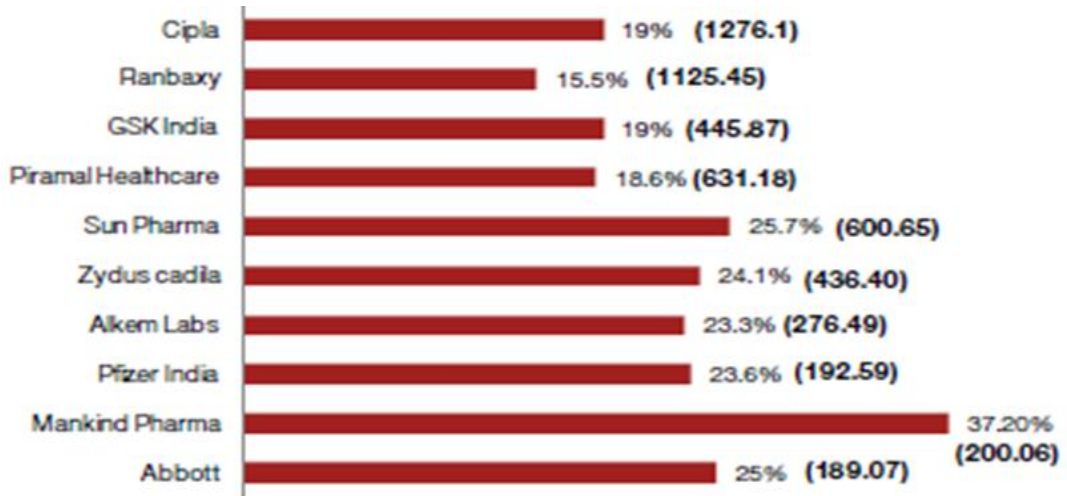


Figure-8. Indian Pharma top 10 players: 12 month growth rate ending July 2010 (09/10 Revenues in US\$ millions)

3. FINDINGS AND RESULTS

3.1. Industry SWOT

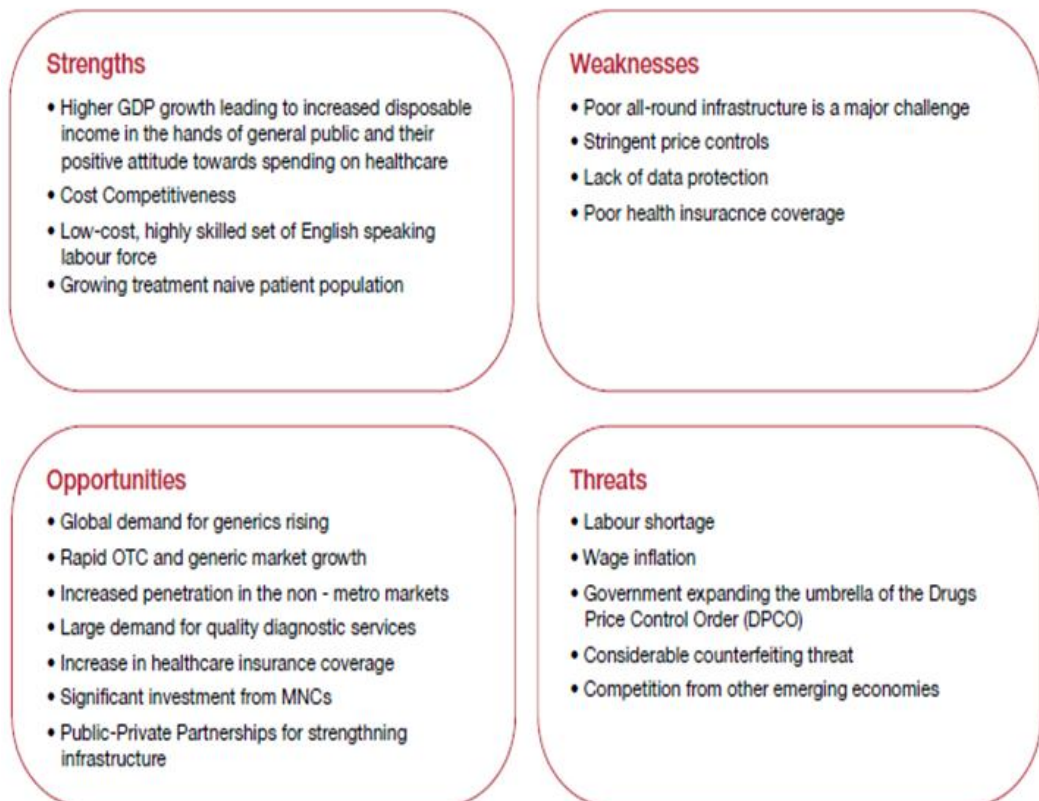


Figure-9. Indian Pharma Industry SWOT analysis

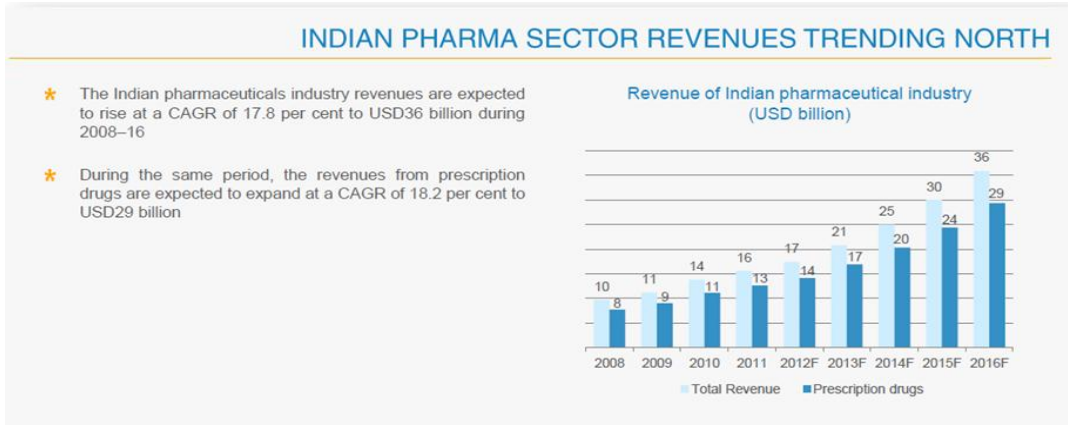


Figure-10.

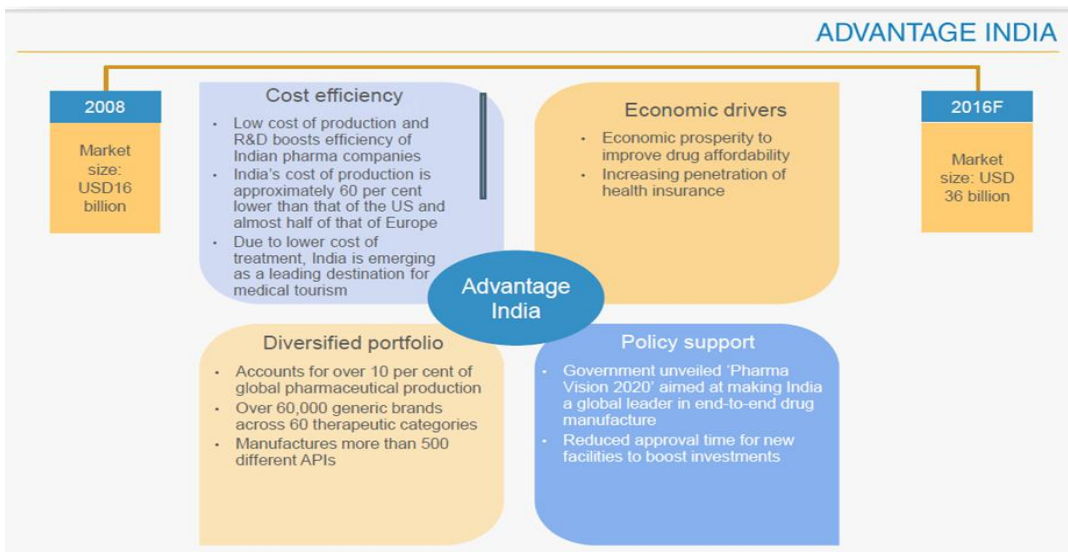


Figure-11.

3.2. Key Recent Trends

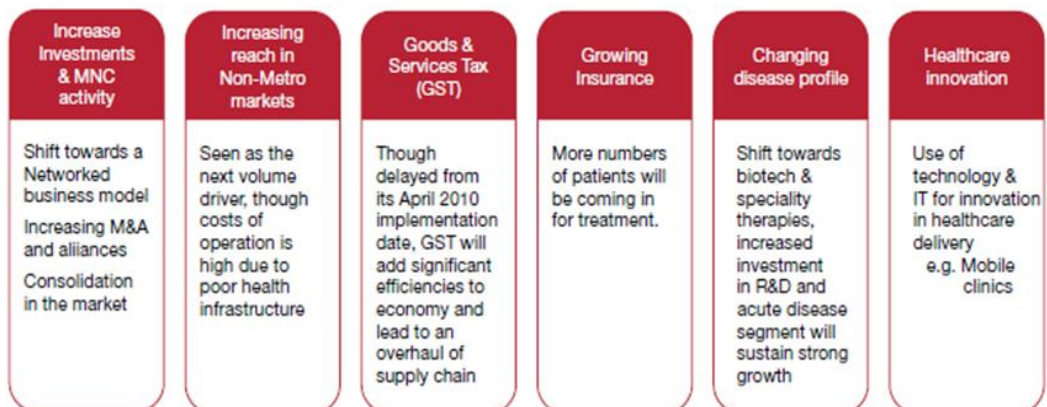


Figure-12. Industry trends and implications

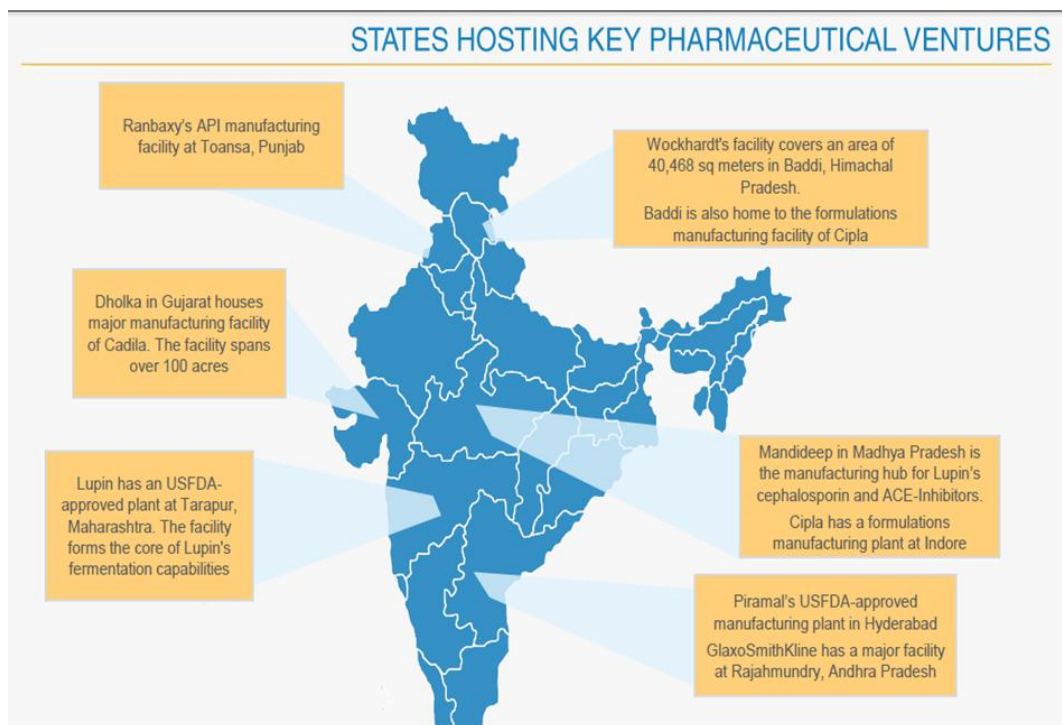


Figure-13.

4. KASHMIR ASPECT

4.1. Protection of Medicinal Plants

In-situ Conservation is usually the favoured conservation plan for capturing and conserving Medicinal Plant pockets in their natural habitats. Stress is laid on recognition of Medicinal Plant areas having rich biodiversity of genetic resources that have main concern, usually at the species level on the basis of current or potential socio-economic value of the species and their conservation importance in the ecosystem along with group of its associate species. The area-specific action plan and networking of natural sites has to be measured to be the most important aspects of in-situ conservation activities. The ecological necessity of many of the species is multipart. Hence moving them out of their own area of comfort to fresh area may for a while prove counterproductive. Hence by recuperating the protection, removing all kind of threats is one of the vital steps towards insitu conservation. Conservation units are not kept too small because this will cause unremitting loss of genetic diversity by the things of genetic drift and increased inbreeding. Considering this, the area has got to be large enough for maintaining the genetic integrity of the original inhabitants and for generating enough germ production. Some of the reserves like Achabal Conservation Reserve (Rakh) have dense forests and are denser compared to close compartments/forests.

The scientific management of forests can offer enabling environment for the medicinal plant species to prosper. It involves awning handling to provide light, governing of other unwanted species, control of Invasive species, removal of humus to provide ground contact to seeds of medicinal plants, soil and moisture conservation works to prevent soil erosion and to improve soil moisture regime etc. Enabling environment also involves achievement the public support for the

protection. As forest reliant communities are major stakeholders, it is very imperative that they get the benefit out of medicinal plant conservation programmes. Providing job opportunities and sharing economic profits with JFMCs can definitely help.

4.2. Ex-Situ Conservation of Medicinal Plants

Ex-situ conservation involves the procedure of protecting rare species and developing it remote its natural habitat. For medicinal plants, Ex-situ Conservation aims at the preservation concern by way of raising of nurseries, seedling supply, plantations and by establishing medicinal plant gardens. Establishment and Management of Ex-situ Conservation stands requires the total information of the forest trees, shrubs and herbs which have developed complex mechanism to uphold high level of genetic diversity, both inter-specific and intra-specific . It provides the structure blocks for future evolution, selection and human use in within and among populations of target species. It includes each simple seed collection, storage and field plantings or more rigorous plant breeding and development approaches. The vital aspect of ex-situ conservation is to uphold a broad range of phenotypic and genotypic range of diversity of a species and to spread the species outside its original natural provenance in a more guarded way. The choice of species for ex-situ conservation is made on the basis of the present local significance of the species, economic value for the subsistence of local population, ecological and geographic considerations and capacity for natural regeneration and the current protection status.

5. CHALLENGES

5.1. Price Controls

Price controls are generally cited as the most important challenge that companies face in the Indian market. India is one of the most price-controlled markets in the sphere, as under the DPCO, prices and margins are monitored sensibly. Price controlled drugs are vital medicines, such as antibiotics and painkillers, and drugs used for the treatment of diseases such as cancer and asthma. However, 90% of drugs are currently outside of any price controls in India. Consumer organizations uphold their stance of influence the government to carry on to expand the umbrella of the DPCO, but the industry believes that there is sufficient competition for the prices to be moderated by the market itself.

5.3. Infrastructure

Infrastructure has for all time been mentioned as a barrier to growth of the Pharma industry in India. Poor oomph and transport infrastructure has traditionally posed a difficulty for companies. Some areas lack elementary hotel facilities, preventing reach and infiltration. With the government gradually growing investment in infrastructure, the situation is taming, but it is still seen as an investment break in India.

5.4. Counterfeiting

Counterfeiting of drugs has been a key issue in the Indian Pharma freedom. The intrinsic nature of the Indian market makes it hard for a regular study that quantifies the extent of

counterfeiting, to be carried out. There have been numerous reports telltale plentiful figures as the rate of counterfeiting. A good indicator may be a large scale survey that was published in December 2009 by the health ministry that reported that false drug prevalence is much lower than otherwise put forward. The report found that only 0.046% of all medicines sold contained indication of being bogus. These reports suggesting lower numbers than earlier ones may be hopeful, but leading players are still tired of the threat of spurious drugs. Steps taken by the industry to pledge the threat of counterfeiting comprise investing in innovative packaging, using authenticity markers and sponsoring programmes to increase alertness amongst patients and healthcare workers.

5.5. Intellectual Property

India has acknowledged and made a promise to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995, and keeping with this promise, executed the Patent (Amendment) Act in 2005. Although this act does not apply for drugs patented before 1995, it is a major step advancing on the earlier patent scenario. Since then, endorsements have been made to the government regarding development and expansion of the Patent (Amendment) Act, by the Satwant Reddy committee and the Mashelkar report. These reports highlighted the need for data refinement and the prevention of 'ever greening'. Domestic and global Pharma companies are showing an augmented confidence in the patent laws, and we expect an increase in the number of presentations of patented products in the Indian market in the future. Resolution of data exclusiveness laws and capability building at patent offices will help in rising confidence among foreign companies.

6. CONCLUSION

Kashmir can turn into a 'hub for pharmaceutical industries in India.' There is a huge potential for developing bio-pharmaceutical industry in the state, given its conducive investment climate. Over 50 per cent of plant species described in British Pharmacopoeia were reported growing in Kashmir. Kashmir, is blessed with various medicinal plants that mostly grew on the mountains of the Valley, of which nearly 570 plant species were of huge medicinal importance. "Based on these high value plant species, Kashmir has a huge potential for establishing bio-pharmaceutical industry," adding that the herbal plants that were grown in Kashmir could not be replicated in other parts of the world.

7. RECOMMENDATIONS

1. With the second-largest inhabitants in the world, a highly educated population that is confident in English and with technical skills, and well-developed buying power, India has great prospective for industrial growth.
2. Since India has an advantage over China, tapping the world generics market before China is very important for Indian pharmaceutical industry.
3. Combining information technology with the pharmaceutical industry is also a good tool which can be used by the IPI.

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