CHAPTER – 3

INDIAN PHARMACEUTICAL MARKET AT A GLANCE

3.1 INTRODUCTION

The Indian pharmaceutical industry ranks among the top five countries by volume (production) and accounts for about 10% of global production. The industry’s turnover has grown from a mere US$ 0.3 bn in 1980 to about US$ 21.73 bn in 2009-10. Low cost of skilled manpower and innovation are some of the main factors supporting this growth. According to the Department of Pharmaceuticals, the Indian pharmaceutical industry employs about 340,000 people and an estimated 400,000 doctors and 300,000 chemists.

3.2 MARKET STRUCTURE

The Indian pharmaceutical industry is fragmented with more than 10,000 manufacturers in the organized and unorganized segments. The products manufactured by the Indian pharmaceutical industry can be broadly classified into bulk drugs (active pharmaceutical ingredients – API) and formulations. Of the total number of pharmaceutical manufacturers, about 77% produce formulations, while the remaining 23% manufacture bulk drugs. Bulk drug is an active constituent with medicinal properties, which acts as basic raw material for formulations. Formulations are specific dosage
forms of a bulk drug or a combination of bulk drugs. Drugs are sold as syrups, injections, tablets and capsules. Source:[ Pharmaceuticals – Industry Structure,D&B, https://www.dnb.co.in]

Figure 3.1 : therapeutic groups in the Indian formulations market

SOURCE: D & B RESEARCH

Based on the pharmaceutical customer base, the Indian API manufacturing segment can be divided into two sectors –innovative or branded and generic or unbranded. In 2009, the global generic drug market was estimated to be US$ 84 bn, of which the US accounted for 42%. India’s generic drug industry is estimated to be US$ 19 bn and it ranks third globally, contributing about 10% to global pharmaceutical production. Pharmaceutical manufacturing units are largely concentrated in Maharashtra and Gujarat.
These states account for about 45% of the total number of pharmaceutical manufacturing units in India.

Figure 3.2 : concentration in pharmaceutical manufacturing unit in India (%)

Source: Annual Report 2012-13, Department of Pharmaceuticals, Govt. of India.

3.3 INVESTMENT IN THE INDIAN PHARMACEUTICAL MARKET

100% foreign direct investment (FDI) is allowed under automatic route in the drugs and pharmaceuticals sector, including those involving use of recombinant technology. Also, FDI up to 100% is permitted for Brownfield investments (i.e. investments in existing companies), in the pharmaceuticals sector, under the Government approval route. The drugs and
The Indian pharmaceutical industry enjoys certain advantages, which attract FDI in the country: a) low cost of innovation and capital expenditure (to operate good manufacturing practices-compliant facilities) which provides leverage in pricing of drugs b) transparency in the regulatory framework c) proven track record in bulk drug and formulation patents d) strong domestic support in production, from raw material requirements to finished products.
goods and e) India emerging as a hub for contract research, bio-technology, clinical research and clinical data management.

3.4 FACTOR INFLUENCING GROWTH OF THE MARKET

The Indian pharmaceutical industry ranks 14th in the world by value of pharmaceutical products. With a well-established domestic manufacturing base and low-cost skilled manpower, India is emerging as a global hub for pharma products and the industry continues to be on a growth trajectory. Moreover, India is significantly ahead in providing chemistry services such as analogue preparation, analytical chemistry and structural drug design, which will provide it ample scope in contract research and other emerging segments in the pharmaceutical industry. Some of the major factors that would drive growth in the industry are as follows:

• Increase in domestic demand: More than half of India’s population does not have access to advanced medical services, as they usually depend on traditional medicine practices. However, with increase in awareness levels, rising per capita income, change in lifestyle due to urbanization and increase in literacy levels, demand for advanced medical treatment is expected to rise. Moreover, growth in the middle class population would further influence demand for pharmaceutical products.
• Rise in outsourcing activities: Increase in the outsourcing business to India would also drive growth of the Indian pharmaceutical industry. Some of the factors that are likely to influence clinical data management and bio-statistics markets in India in the near future include: a) cost efficient research vis-à-vis other countries b) highly-skilled labor base c) cheaper cost of skilled labor d) presence in end-to-end solutions across the drug-development spectrum and e) robust growth in the IT industry.

• Growth in healthcare financing products: Development in the Indian financial industry has eased healthcare financing with introduction of products such as health insurance policy, life insurance policy and cashless claims. This has resulted in increase in healthcare spending, which in turn, has benefited the pharmaceutical industry.

• Demand in the generics market: During 2008-2015, prescription drugs worth about US$ 300 bn are expected to go off patent, mostly from the US. Prior experience of Indian pharmaceutical companies in generic drugs would provide an edge to them.

• Demand from emerging segments: Some of the emerging segments such as contract research and development, biopharma, clinical trials, bio-generics, medical tourism and pharma packaging are also expected to drive growth of the Indian pharmaceutical industry.
3.5 FOREIGN TRADE IN PHARMACEUTICAL PRODUCT

The Indian pharmaceutical industry’s growth has been fuelled by exports. Its products are exported to a large number of countries with a sizeable share in the advanced regulated markets of the US and Western Europe. India currently exports drug intermediates, active pharmaceutical ingredients, finished dosage formulations, bio-pharmaceuticals and clinical services to various parts of the world. The top five export destinations of Indian pharmaceutical products are USA, Germany, Russia, UK and China. Indian exports of drugs and pharmaceuticals grew at a CAGR of 16.5% to Rs. 451.4 bn over FY02-FY12 (up to Dec 2011).

Figure 3.4: export of drugs and pharmaceuticals from India

Source: Directorate General of Commercial Intelligence and Statistics (DGCIS) Kolkata
Import of drugs and pharmaceuticals into India recorded a CAGR of 17.6% during FY02-FY12 (up to Dec 2011). During FY12 (up to Dec 2011), pharmaceutical products worth Rs. 102.2 bn were imported into India. India is almost self-sufficient in formulations; its imports mostly comprise bulk drugs and some intermediaries. These imports are freely permitted, except those that are restricted in the foreign trade policy. Import restrictions are mostly on drugs that contain narcotics and psychotropic components.

Figure 3.5: import of drug and pharmaceutical in India

Source: Directorate General of Commercial Intelligence and Statistics (DGCIS) Kolkata

3.6 MAJOR CHALLENGES FACED BY THE INDUSTRY

The Indian pharmaceutical industry was on a strong growth trajectory in the last decade. It has achieved several milestones and is well positioned to
leverage emerging opportunities. However, the industry needs to tackle various issues related to its operations and regulations. It faces several challenges in the form of pricing of pharmaceutical products and impact of Some agreements. This section touches upon several key issues and challenges faced by the industry:

• Impact of GATT-TRIPS agreement: The General Agreement on Tariffs and Trade1 (GATT) and Trade Related aspects of Intellectual Property Rights (TRIPS) have an adverse impact on pricing of pharmaceutical products. Pharmaceutical companies are not allowed to re-generate existing drugs and formulations and change the existing process and manufacture the same drug. New investments are required to perform research. This is a major obstacle for pharma companies, especially the micro, small and medium enterprises. Moreover, transfer of technology from abroad is difficult and expensive. Consequently, revenue of the pharma companies is impacted. Hence, adequate measures should be taken to support the industry’s revenue and minimize losses.

• Pricing: At present, pricing of 74 bulk drugs and their formulations, which account for a large share in the retail pharma market, are controlled by the Drug Price Control Order (DPCO)-1995. The Government had considered reducing the number of regulated drugs, but it has not been implemented.
There is a need to reduce the number of regulated drugs to facilitate the growth of the pharmaceutical industry.

• Drug diversions by institutions: Most of the institutional clients of the Indian pharmaceutical companies comprise government hospitals, the Indian defence service and private hospitals; the defence sector is mandated to buy drug stocks through tenders in quantities twice as large as the projected demand for those drugs in the following year at a discounted price. At the year-end, surplus available at the institutions is pushed to regular channels by leveraging the price discounts, resulting in a loss for companies through the regular distribution channel.

3.7 INDIAN PHARMACEUTICAL INDUSTRY SWOT ANALYSIS

Indian pharmaceutical industry: SWOT analysis

The SWOT analysis of the industry reveals the position of the Indian pharmaceutical industry in respect to its internal and external environment.

Strengths

• Low cost of innovation, manufacturing and operation.

• Low cost of skilled manpower and proven track record in design of high technology manufacturing devices.
Weaknesses

• Stringent pricing regulations affecting the profitability of pharma companies.

• Presence of more unorganized players versus the organized ones, resulting in an increasingly competitive environment, characterized by stiff price competition.

Opportunities

• Opening of the health insurance sector and increase in per capita income – the growth drivers for the pharmaceutical industry.

• India, a potentially preferred global outsourcing hub for pharmaceutical products due to low cost of skilled labor.

Threats

• Other low-cost countries such as China and Israel affecting outsourcing demand for Indian pharmaceutical products.

• Entry of foreign players (well equipped technology-based products) into the Indian market.

3.8 TREND IN INDIAN PHARMACEUTICAL MARKET

It is not sufficient for companies to imitate the market leader’s products but to align marketing strategies for maximizing the customers’ satisfaction by the product and the service provider. This trend is also equally witnessed in
the pharmaceutical industry as this cannot be simply isolated from the mainstream. The paradigm shift to create loyal customer as a strategic business plan has become a very important criterion of customer satisfaction research. In this light, Berry (1995) has rightly given his breakthrough by quoting “it will not suffice to have customers that are merely satisfied.”

The literature considers elements of the marketing mix (Gatignon & Hanssens 1987; Capon et al. 1990; Narayanan et al. 2004) and describes the way in which the promotion process can be evaluated with respect to spending. A recent study by Gagnon and Lexchin (2008) looks at allocation of spending across a number of different promotional modes (samples, detailing, DTCA, meetings/conferences, e-promotion, journal advertising and unmonitored promotion). This is important because the promotional process in the pharmaceutical industry differs from that of other industries, such as automobiles. Indeed, it was estimated that pharmaceutical companies spent US$1 billion or £20,000 per physician, per year in Canada alone (foss 2001). However, the global figure is estimated to be much higher. In the US, total spending on pharmaceutical promotion grew from US$11.4 billion in 1996 to US$29.9 billion in 2005. During that time, although spending on DTCA increased by 330%, it made up only 14% of total promotional expenditures in 2005 (Donohue et al. 2007). Some argue that, in the US, the
amount spent on pharmaceutical promotion may be as much as double what it spends on research and development (R&D) and double what is reported in the literature (Gagnon & Lexchin 2008), but regardless of the actual figures, it is a tremendous amount.

In the pharmaceutical industry, the promotional process involves the exchange of drug information between the ‘buyer’, who for this industry tends to be the ‘physician’, and the ‘seller’, otherwise referred to as a ‘medical sales representative’ (MR). The pharmaceutical promotion process requires medical representatives to visit doctors in the workplace to provide information about the MR companies’ products using a process known as ‘detailing’ (Narayanan 2004). Detailing constitutes one means of obtaining product information. Physicians receive their information about products via three key promotional routes. First, a large proportion of product information comes from the detailing effort, which is provided by medical representatives. Representatives from each company will provide specific clinical information about product efficacy. This information is reiterated through the use of promotional leaflets. Second, conference attendance offers an alternative method for receiving training and product education and, third, in countries where it is permitted, there is direct-to-consumer advertising (DTCA). The importance that is attached to MR promotion is
illustrated by the fact that most companies employ a large number of MR staff to facilitate the promotional process. In 1998, it was estimated that, in the US, 65% of the sales budget was spent on MR promotion, with some 57,500 medical representatives detailing in North America (Wright & Lundstrom 2004). Despite the advancements in e-technology, the field force size of medical representatives continues to increase. In the post-2000, the number of medical representatives in the US is believed to be around 80,000 (Wright & Lundstrom 2004).

Detailing is the other factor that characterizes the promotional process of this industry, meaning that the number of visits that a medical representative may make to a given hospital/doctor in a particular time frame may also vary. In theory, if detailing effort is to be used as a method for analyzing promotional success and a tool for developing promotional strategy, the detailing effort of an MR needs to consider not only the product life cycle (PLC) of the product but also the more immediate marketing parameters which may influence sales, such as hospital size and geographical spread, as well as the country-specific determinants embedded in the regulatory procedures that determine promotional style between different countries.

However, despite the differences in field force size, the method used to detail products, with respect to the way the information is presented and
exchanged between the physician and the MR is fairly consistent throughout the industry. This has made it possible to analyze promotional performance against expenditure. A number of studies have sought to evaluate the return on investment gained through the pharmaceutical promotion system. Comparison of data on detailing effort against the number of prescriptions prescribed offers one way of measuring performance. For example, in a recent study, Neslin (2001) analyzed the investment return on 391 branded products, and showed that detailing is beneficial to the pharmaceutical promotional process.

In a different study, Wittink (2002) presented data that compared the effectiveness of the detailing effort with respect to brand size. Narayanan et al. (2004) concluded that detailing products exert a positive effect on brand share, and suggested that the traditional method of detailing products for pharmaceutical promotional purposes is more effective than DTCA campaigns because the mechanism used to exchange product information is more ‘targeted’ to specific buyer groups. Based on the literature reviewed thus far, pharmaceutical promotion has largely assumed a ‘push’ orientation. Of late, the value of traditional ‘push’ promotional methodologies has been questioned, as DTCA with its associated consumer ‘pull’ orientation has been considered to be the future marketing tool on which to position and
promote pharmaceutical products (Auton 2004). Interestingly, though, promoting products is often not the sole focus of DTCA. Especially in those countries that do not permit DTCA of prescription drugs, DTCA is often used to creatively communicate the existence of diseases through a process often referred to as ‘disease mongering’ or ‘disease branding’ (Parsons 2007). Here the aim is to increase market share, not by promoting specific pharmaceutical products, but by selling to the consumer the idea that there is a new disease about which one has to be concerned, or by looking at diseases in a new way that makes consumers feel they might actually suffer from the advertised condition. Medawar (2001) directly at odds with the reality of pharmaceutical industry practices such as that of increasing brand penetration through identifying new ailments that may be treated by existing drugs (thus extending the brand’s target markets base and potentially its sales).

The concepts of knowledge-based economy, trade liberalization and patent harmonization have introduced a major shift in the strategies and direction for research, development and commercialization at firm level. In part this is driven by new policy developments in intellectual property protection and TRIPs. External forces do not determine the direction though. Internal resources and capabilities provide the basic direction for a firm’s strategy. It
is clearly evident that the existing technology and knowledge base of a firm (trajectories followed in the past and capabilities created) was a key element in deciding the direction of growth and innovation for successful pharmaceutical companies. However, there is a revelation that the leading firms have adopted gradual but deliberate strategic deviations to help them move from past strategies. Thus, concentrated and mindful strategic effort helped firms to overcome ‘stickiness’, as identified in the resources based view as overtime some firm-specific assets have expanded with increased knowledge based capabilities.

Therefore, knowledge is treated by the pharmaceutical industries as the most critical resource to gain competitive advantage over others and is fully exploited as the most important strategic intent in the recent period in the Indian pharmaceutical industry. As per a recent research report, a shift from a purely resource-based static approach of the 1970’s to a knowledge based dynamic approach by leading Indian pharmaceutical companies is the order of the day. The presence of key elements of the dynamic capabilities and strategic management framework developed by Teece et al. (1997), wherein the competitive advantage of firms is defined as distinctive processes (of coordinating and combining), shaped by firm’s asset positions (such as difficult to trade knowledge assets and complementary assets), and the
evolution path(s) it has adopted or inherited’. Identifying new opportunities and organizing effectively and efficiently to embrace them are more fundamental to knowledge and wealth creation in the present dynamic environment of pharmaceutical marketing of 21st century. It is apparent that the notion of path dependence (which is a part of the resource based approach) and path creation to produce new products and processes amidst changing knowledge, policy and market environment (dynamic capability approach) have taken primacy in the present day pharmaceutical industries. Turbulent markets prompt firms to think beyond the internal resources and paths followed in the past. The focus of path dependence, which could be accurate, is often incomplete for understanding changing environments. To ascertain how capabilities evolve in environments of substantial change, the path dependence view is usefully complemented by the research literature on dynamic capabilities. Facets associated with path renewal and creations are implicit in several bodies of work. In the economic literature, for instance, creation is implicit in notions of dynamic efficiency and dynamic equilibrium. Path creation pertains to the organization’s competencies to achieve new and innovative forms of competitive advantage despite constraints of path dependencies. Path creation does not mean unbounded strategic choice rather it is embedded in structures that are created in the
past, from which firms deliberately deviate. Together, path dependence and creation have been useful in understanding the transformation processes that create new paths by re-using, modifying or totally moving away from the old paths.

3.9 CONCLUSION

Overall growth outlook for the Indian drugs and pharmaceutical market appears positive. Pharma manufacturers are likely to benefit from rise in demand for generic products. Some of the factors that would drive growth in the domestic pharma industry are: 1) low cost operations 2) research-based processes 3) improvements in API and 4) availability of skilled manpower. The domestic formulations and bulk drugs markets are currently facing price pressure as benefits of cheaper drugs have been shifted to end-users and trade channels. Hence, consolidation, partnership and alliances are expected together momentum in the near future. Off patenting of branded drugs would increase demand for generic drugs. This provides immense opportunities to the Indian pharmaceutical companies especially given their prior experience in generic drug development. Some other factors such as high penetration in the global markets and increase of share in Abbreviated New Drug Application (ANDA) filings are likely to power growth of the formulations market. Major growth drivers for the Indian bulk drug industry include rise
in demand for contract manufacturing, increase of share in Drug Master Files (DMF) filings and process innovation. Furthermore, initiatives of the Government will act as a backbone for growth. Some such initiatives include: a) allowing 100% FDI under the automatic route in drugs and pharmaceuticals including those involving use of recombinant technology b) increasing weighted tax deduction on expenditure in in-house R&D activities to 200% in the Budget 2012 and c) setting up a US$ 639.56 mn venture capital fund to support drug discovery and strengthen pharmaceutical infrastructure.