1.1 Introduction

The pharmaceutical market is knowledge driven and is heavily dependent on research and development for new drugs. The competitive and technological changes in the pharmaceutical industry from powerful new drug discoveries to the innovative R&D partnerships and marketing plans are reshaping the business strategies of many pharmaceutical companies. Patent laws play a very important role in encouraging the clinical trials and drug discoveries. The new WTO rules imply that Indian pharmaceutical companies have to switch to a product patent regime\textsuperscript{*} post 2005 from the currently prevailing process patent regime\textsuperscript{†}.

Pharmaceuticals are medicinally effective chemicals, which are converted into dosage forms suitable for patients to imbibe. In its basic chemical form, pharmaceuticals are called Bulk drugs and the final dosage forms are known as Formulations. Doctors to cure specific diseases normally prescribe formulations and these are called the Ethical drugs. However, some formulations such as pain balms, health tonics etc., can be purchased directly by customers from the pharmacists. These are called Over-the-counter (OTC) drugs.

\textsuperscript{†} Product patent is a form of protection which gives the discoverer, a period of exclusivity to exploit the invention or permit others to do so under a licensing agreement.

\textsuperscript{*} Process patent allows a manufacturer to produce the same formulation without paying any royalty or license fees to the original producer if they use a different process.
Formulations could be categorized according to the method of administration as:

1. **Orals**: tablets, syrups, capsules, powders etc., taken through the mouth.
2. **Topical**: ointments, creams, liquids, aerosols that were applied on the skin.
3. **Parenterals**: sterile solutions injected in an intravenous or intramuscular fashion.
4. **Others**: such as eye drops, surgical dressing and materials etc.

Bulk drugs were prepared by chemical reactions of natural or synthetic intermediaries under controlled conditions. Formulations were manufactured in a batch mixing process in which the dosage of the bulk drugs (active ingredients) was compounded with compatible substances to make the formulation palatable (Kshirsagar, 2003).

The origins of the modern pharmaceutical industry can be traced to the 19th century. Pfizer and Merck in America, Roche, Ciba-Geigy and Sandoz in Europe – all started out as family chemical companies. Slowly but steadily many companies moved into synthetic pharmaceuticals and eventually to global players. During the 1940's and 50's, research and development become firmly established within the pharmaceutical industry. Discovery of penicillin in 1940's was a major sensation throughout the scientific community and Pfizer made medical history when it became the first company to successfully mass-produce penicillin (Rodengen, 2000).
In the 1960's, the industry expanded, benefiting from new discoveries. The healthcare spending boomed as economies prospered. There were no strict controls over research and development (R&D), drug approvals and marketing. However, during this time, the new legislation was passed in the USA that completely transformed the pharmaceutical industry worldwide. By 1978 the average time needed to discover and develop new drugs to meet the FDA's expanded requirements and then undergo regulatory review had reached 14 years or more (Rodengen, 2000). Thus, consuming an increasing percent of the 17 years - the length of time then covered by patents. As a consequence, it became much harder for the pharmaceutical companies to recoup their investment in order to fund future research. By year 2000, the time taken for drugs to share by adhering to specific "laws" when activating a specific purchase motive in the customer's mind. They are called "Growth Codes", which form the basis of a new approach to brand marketing (Buchholz and Wördemann, 2000). The authors arranged the "Growth Codes" behind five portals in the consumer's mind: benefits and promises; norms and values; perceptions and programs; identity and self-expression; and emotions and love. According to the authors, the success of "migration principle" (e.g. to "migrate" into a different or even unexpected "mental drawer" where your brand can better unfold) can be replicated in any market, any product, service, or institutions.

Pharmaceutical companies today face a series of significant challenges that are affecting their ability to maintain growth and sustain earnings levels. These challenges include competing against generic products - drugs whose patents have lapsed and which are typically 60% to 70% cheaper than the 'branded' version - and the drying up of the
research and development pipeline that has led to a reduction in the rate of new compound discoveries. In addition, pharmaceutical companies have to operate in a complex industry environment. For prescription-only medicines, the relationship between consumer (patient) and pharmaceutical company is highly regulated and subject to government intervention. Governments and private insurance companies determine the price consumers pay. Furthermore, pharmaceutical companies are severely constrained in what they can communicate directly to consumers. In response to these challenges, the pharmaceutical industry has undergone, and continues to undergo, a period of consolidation and rationalization to control costs and maintain R&D rates per company. (Cleland, et.al. 2004)

Pharmaceutical marketing, which is primarily targeted at physicians, has been criticized because it may distort physician prescription and thus potentially raise costs and/or worsen health (Calfee, 2002). However, he also proposed that, a successful marketing of pharmaceuticals can improve consumer welfare by increasing incentives for research and development (R&D) investment and by providing guidance to R&D to make it more consistent with the consumer preferences.

1.2 Pharmaceutical marketing

Pharmaceutical marketing is a complex process. It involves multifarious activities at different levels and spans over the entire area where the products are made available for use. It starts from the need realization for a new drug and ends when the product is exchanged for a price (Chaganti, 2005).
Pharmaceutical marketing and its consequences are strongly affected by the unique environment in which pharmaceutical marketing takes place. It starts with the need realization for a new drug or a new treatment method for a specific disease. A marketer can gauge the need from the feedback received from the physicians. This need requires to be converted into a viable product idea. The next stage is product promotion. Active promotion leads to the awareness among the medical practitioners. The product is distributed through the wholesale and retail channels and is offered for retail sale to the consumers, in this case the patients. The marketing process is completed when the product is demanded at the retail store by the patient.

1.2.1 Physicians as Gatekeepers

The most distinctive characteristics of pharmaceutical market is the dominant role of physicians. The physician is not merely a gatekeeper, but also provides authoritative advice on the role of drug therapy in the treatment of illness and medical conditions (Calfee, 2002). Patients have always sought the advice of physicians on medical matters even when it is not required, and they are reluctant to use powerful drugs without the advice of the physician. In less developed nations, with no prescription requirement largely because of the scarcity of physicians and trained pharmacists, consumers were reluctant to use drugs without professional guidance (Peltzman, 1987).
Sufficient literature is available to support the central role of physicians in drug usage and is reflected in the fact that the bulk of pharmaceutical promotion is directed at physicians rather than consumers (Rosenthal, 2002).

1.2.2 Estimating Potential Demand

The marketing process begins with the estimation of potential demand. The benefits from advances in drug therapy and other medical technology, measured in terms of consumer willingness to pay for improving and extended life (Nordhaus, 2002). The nature and magnitude of demand for specific therapies require estimation to guide research and development (R&D) investment.

1.2.3 Advertising and Promotion

Advertising and promotions are, by design, the integral parts of marketing. These activities necessarily focus on information, because the pharmaceutical industry is largely an information industry. Pharmaceutical drug characteristics mean very little without persuasive information. Physicians are often slow to alter their prescription behaviour, and they commonly fall far short of adhering to evidence-based practice guidelines (Calfee, 2002).

Physicians also, quite reasonably, pay more attention to diagnosing conditions when they know there are effective drug treatments (Pincus et.al., 1998; Elliott, 2002). These set of
literatures propose that faster dissemination of information about new pharmaceuticals or new usage can improve health. Economic research in other markets has found that advertising improves markets by disseminating valuable information with the goal of increasing sales for individual brands.

Promotion is likely to be valuable especially in pharmaceutical markets because information plays a dominant role, is highly technical and widely dispersed, and changes rapidly. Also equally important is the consumer interest in taking the initiative in seeking diagnosis and treatment (National Health Council, 2002). Consumer advertising can also be an effective tool for improving patient compliance with the drug therapy. This suggests that consumer welfare can be improved by promoting prescription drugs directly to consumers (process of purchase of prescription drugs remains unaltered). A recent empirical study found strong support for the fact that physician detailing is primarily an information tool rather than a means for increasing market power (Gönül, et. al., 2002).

Thus, pharmaceutical advertising and promotion play a dual role of disseminating information about the benefits of new therapies while also shifting the focus of the healthcare system towards the individual needs of consumers and patients.

1.2.4 Feedback from Marketing to Research and Development (R&D)

Successful advertising and promotion increases the returns from past pharmaceutical research and development (R&D). This increases incentives to explore market demand
and in turn increases incentives to pursue research and development (R&D) based upon the estimated demand. Hence, there is a feedback from marketing to research and development.

This process works through two distinct paths. Firstly, by supplying information and emphasizing it for physicians and healthcare organizations. Secondly, to stress upon the consumer willingness to pay for the new technology, thus increasing derived demand (Kleinke, 2001).

Thus, marketing affects the research in two ways. Firstly, by increasing overall research incentives and secondly by shaping the research and development (R&D) so as to make it conform more closely to consumer preferences.

There is substantial evidence that the linkage from marketing back to research has become much stronger in recent years (Galambos, 2001; Galambos et.al., 1995). Marketing is, thus, a powerful force that stimulates the feedback from marketing to research and development (R&D).

1.3 Global Pharmaceutical Market

1.3.1 Introduction

Over the past few years, the pharmaceutical business environment has changed significantly, which has transformed the market dynamics. While Multinational pharmaceutical firms indulge in consolidating their positions through mergers,
acquisitions and strategic alliances, the generic manufacturers are gearing up to meet the opportunities created by blockbuster drugs going off patent.

Though the pharmaceutical industry remains one of the most profitable and stable industries, several macro-level variables are influencing fundamental changes in the industry structure. The chief variables are: the increasing role of substitutes-generic pharmaceuticals threat; the threat of new entrants-emergence of bio-pharmaceuticals and genome revolution; increasing buyer power of third party payers, government buyers, and health maintenance organizations, and increased health awareness amongst patients and changing suppliers-enhanced outsourcing in manufacturing and R&D. Additionally, changing world demographics (increasing graying of world population), stringent regulatory environment, declining R&D productivity, worldwide compliance of General Agreements on Tariffs and Trade (GATT) and Trade Related Intellectual Property Rights (TRIPS) and emergence of e-pharmaceuticals is likely to reshape the industry.

According to a soon-to-be-released report from Business Communications Company, Inc. (www.bccresearch.com) RB-191 World Pharmaceutical Markets, the global pharmaceuticals market has demonstrated consistent strong growth patterns in the last five years generating total revenues of US$ 534.8 Billion in 2005. This industry accounts for 24% of the healthcare sector and been growing handsomely at the double-digit-rate mainly driven by the demographic shifts (i.e. increasing elderly population), changing epidemiological patterns, increase in healthcare awareness amongst the masses and finally, by the ability of the industry to provide innovative cures for various ailments.
The Indian pharmaceutical industry is comprised of 4 major sectors: ethical, generic, OTC and biopharmaceutical. Ethical pharmaceuticals sector is growing at double-digit rates but is under increasing pressure owing to the strong competition from generic and biopharmaceutical sectors. The ethical sector is increasing by relying on blockbusters and innovative medicines to drive its growth. Life-style diseases\(^1\) will continue to drive the growth of this sector. The change in the life-styles would fuel demand for cardio-vascular agents, CNS (central nervous system) and alimentary/metabolism products. The generic pharmaceutical sector is expected to increase its penetration in the world pharmaceutical market to 7% by 2008. The sector's growth will continue to be fueled by patent expirations worth $80 billion through 2010.

Increasing health awareness, patent expiration, and increasing marketing activities by the OTC manufacturers have fueled the growth of the OTC pharmaceutical sector. The OTC pharmaceutical sector is expected to reach $101 billion by 2008. Biopharmaceuticals are an increasingly becoming popular mode of treatment owing to their efficacy and ability to treat hard-to-treat conditions. The sector is growing at double the rate of the ethical sector.

The industry is witnessing continued consolidation. Companies are increasingly focusing on mergers and acquisitions, in-licensing activities, co-development, and co-marketing activities in order to remain competitive and create value for their share holders. Leading

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\(^1\) A disease associated with the way a person or group of people lives. Lifestyle diseases include atherosclerosis, heart disease, and stroke; obesity and type 2 diabetes; and diseases associated with smoking and alcohol and drug abuse. (www.medterms.com)
ethical pharmaceutical companies are increasingly venturing into biopharmaceuticals, generic pharmaceuticals, etc. as a mode for organic growth. Generic pharmaceuticals are increasingly becoming a formidable force in the market. They are increasingly becoming global in nature, segmenting (super generics, bio generics, specialty generics, etc.) in their quest for survival. Biopharmaceutical companies like Amgen and Genetech are competing head-on with the big pharma in the market place.

Table 1: Worldwide Pharmaceutical Market in 2008 by Sectors (in $ Billions)

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Ethical</td>
<td>317.1</td>
<td>363.4</td>
<td>401.0</td>
<td>437.6</td>
<td>677.8</td>
<td>9.1</td>
</tr>
<tr>
<td>Generics</td>
<td>24.0</td>
<td>27.0</td>
<td>30.5</td>
<td>37.0</td>
<td>64.0</td>
<td>11.6</td>
</tr>
<tr>
<td>OTC</td>
<td>70.5</td>
<td>73.8</td>
<td>78.5</td>
<td>82.0</td>
<td>101.0</td>
<td>4.3</td>
</tr>
<tr>
<td>Biopharmaceuticals</td>
<td>22.1</td>
<td>26.3</td>
<td>31.0</td>
<td>36.5</td>
<td>58.6</td>
<td>9.9</td>
</tr>
<tr>
<td>Total World Market</td>
<td>433.7</td>
<td>490.5</td>
<td>541.0</td>
<td>593.1</td>
<td>901.4</td>
<td>8.7</td>
</tr>
</tbody>
</table>

Source: BCC, Inc., IMS Health, 2006

Chart 1: Worldwide Pharmaceutical Market in 2008 by Sectors
(in $ Billions)

Source: RB-191 World Pharmaceutical Markets, Published: March 2004
This changing environment presents complex challenges like shrinking market exclusivity, R&D productivity, price pressures, patent expiry and generic competition.

The global pharmaceutical majors who have relied on patented molecules are facing onslaught from the generic market. The top pharmaceutical majors are expected to lose upto $40 billion of global sales because of patent expiry of their leading brands, world’s top ten brands are going off patent within the next ten years, the global market for generic drugs is predicted to increase to $30 billion by 2005. As global pharmaceutical market expands, the growth of the developed and matured markets tends to be overshadowed and this leads to the emerging of developing markets with opportunities of investment in the form of technological tie-ups and strategic alliances. (Bhardwaj, 2005)

The global pharmaceutical market had experienced a sustainable growth with world’s leading markets showing decent growth despite economic challenges during the year (Table 2).

<table>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sales by year</td>
<td>292.0</td>
<td>294.8</td>
<td>304.2</td>
<td>338.0</td>
<td>373.0</td>
<td>406.9</td>
<td>438.0</td>
<td>469.4</td>
<td>505.8</td>
</tr>
<tr>
<td>IMS global sales</td>
<td>337.2</td>
<td>354.0</td>
<td>392.0</td>
<td>403.0</td>
<td>469.4</td>
<td>505.8</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IMS audited sales</td>
<td>295.9</td>
<td>321.8</td>
<td>364.2</td>
<td>400.6</td>
<td>466.3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sources: Global Pharma Forecasts and IMS

The world pharmaceutical sales by regions had registered a decent growth of 8 percent and stood at US $ 317 million in 2004 (Table 3)
Table 3: Pharmaceutical Sales by regions in 2004

<table>
<thead>
<tr>
<th>Country</th>
<th>in US$m</th>
<th>% growth (ref. to US$)</th>
<th>% growth at constant exchange rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>World</td>
<td>317,948</td>
<td>14</td>
<td>8</td>
</tr>
<tr>
<td>USA</td>
<td>163,157</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>Canada</td>
<td>8,862</td>
<td>23</td>
<td>11</td>
</tr>
<tr>
<td>Germany</td>
<td>22,748</td>
<td>27</td>
<td>7</td>
</tr>
<tr>
<td>France</td>
<td>18,793</td>
<td>27</td>
<td>6</td>
</tr>
<tr>
<td>Italy</td>
<td>12,933</td>
<td>22</td>
<td>2</td>
</tr>
<tr>
<td>UK</td>
<td>13,177</td>
<td>20</td>
<td>10</td>
</tr>
<tr>
<td>Spain</td>
<td>8,980</td>
<td>34</td>
<td>12</td>
</tr>
<tr>
<td>Japan (incl. hospitals)</td>
<td>52,825</td>
<td>11</td>
<td>3</td>
</tr>
<tr>
<td>Mexico</td>
<td>6,220</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Brazil</td>
<td>4,266</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>Argentina</td>
<td>1,594</td>
<td>48</td>
<td>48</td>
</tr>
</tbody>
</table>

source: IMS Strategy Group

Global pharmaceutical market witnessed a sales growth due to the therapeutic categories like Blood agents, Muco skeletal, CNS, Cytostatics and Diagnostics (Table 4).

Table 4: World Pharmaceutical Sales by therapeutic category in 2004

<table>
<thead>
<tr>
<th>Therapeutic area</th>
<th>in US$m</th>
<th>% growth (ref. to US$)</th>
<th>% growth at constant exchange rates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular</td>
<td>61,788</td>
<td>15</td>
<td>7</td>
</tr>
<tr>
<td>CNS</td>
<td>57,921</td>
<td>19</td>
<td>14</td>
</tr>
<tr>
<td>Alimentary/ metabolism</td>
<td>46,598</td>
<td>13</td>
<td>7</td>
</tr>
<tr>
<td>Respiratory</td>
<td>28,185</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Anti-infectives</td>
<td>27,025</td>
<td>12</td>
<td>6</td>
</tr>
<tr>
<td>Muco skeletal</td>
<td>19,972</td>
<td>19</td>
<td>12</td>
</tr>
<tr>
<td>Genito urinary</td>
<td>17,543</td>
<td>9</td>
<td>4</td>
</tr>
<tr>
<td>Cytostatics</td>
<td>14,816</td>
<td>18</td>
<td>10</td>
</tr>
<tr>
<td>Dermatologicals</td>
<td>9,585</td>
<td>11</td>
<td>5</td>
</tr>
<tr>
<td>Blood agents</td>
<td>10,892</td>
<td>23</td>
<td>14</td>
</tr>
<tr>
<td>Sensory organs</td>
<td>6,428</td>
<td>15</td>
<td>8</td>
</tr>
<tr>
<td>Diagnostic agents</td>
<td>5,788</td>
<td>18</td>
<td>10</td>
</tr>
<tr>
<td>Hormones</td>
<td>5,046</td>
<td>17</td>
<td>9</td>
</tr>
</tbody>
</table>

source: IMS Strategy Group
The word ‘brand’ originated from the word ‘brandr’, meaning ‘to burn’. With the development of trade, buyers would use brands as a means of distinguishing and brands quickly became associated with quality and reliability. Thus, brand provided buyers with a guide to choice (Kumar, 2005).

Globally, brand building is the top priority for pharmaceutical majors as sizeable amount of investments and years are spent before the blockbuster drugs emerge from their research. These drugs through proper positioning and effective promotions ensure long period of returns for these companies.

The pharmaceutical market has come relatively late to branding. During the 1980’s and 1990’s the pharmaceutical industry has enjoyed success over an extended period of time, achieving relatively easy double digit growth on a consistent basis (Schuiling and Moss, 2001). By and large this was through using traditional methods. The success factors for the industry were three fold:

1. Strong research and development (R&D)
2. Aggressive defense of patents, and
3. Use of dominant promotional tool i.e. sales force management.

The industry is witnessing a consolidation phase, out of a series of significant mergers and acquisitions and an increased attention towards accelerating the R&D activities.
Traditionally, when a pharmaceutical product is launched the product positioning is based on the product license i.e. its indicators and the established efficacy, safety and tolerability seen in registration clinical studies. Post launch studies then tend to lead to a broadening of the indications, the development of the new dosage forms and the strengthening of the claims versus the competition (Moss, 2001).

1.3.2 Changing Market Dynamics

The economic, structural, political and health dynamics that impact growth are rebalancing the worldwide pharmaceutical market, driving global growth of 5–6% for 2007, according to IMS Health. This compares to 6-7% in 2006 and will see global pharmaceutical sales reach $665–685 billion in 2007 (www.imshealth.com).

According to the IMS Health, in 2007, the market will still be absorbing changes that have defined a new economic reality, one in which growth is shifting from mature markets to emerging ones; new product adoption is not keeping pace with the loss of patent protection by established products; specialty and niche products are playing a larger role; and regulators, payers and consumers are more carefully weighing the risk/benefit factors of pharmaceuticals.

1.3.3 Revised world map

The geographic balance of the pharmaceutical market continues to shift away from the US toward the world’s emerging markets, countries with a per-capita Gross National Income of less than $20,000, where the availability of healthcare is expanding and there
is an increasing need for treatments associated with chronic diseases more typically found in developed countries. Emerging markets currently represent 17% of the global market, but will contribute 30% of growth next year. The US will account for about 36% of the total growth in 2007, significantly less than the 54% it contributed five years earlier (IMS Health, 2006).

1.3.4 Reduced contribution of new products

The number of new product launches in 2007 is expected to be in the range of 25 to 35, comparable to the anticipated 30 launches in 2006. However, increasing emphasis on the development of products that serve niche markets and treatments that are initiated by specialists means that new products are contributing less to overall market expansion than they have in the past (IMS Health, 2006).

Moreover, market expansion from new products is not keeping pace with the loss of patent protection by older products. Generic erosion is more aggressive than ever before. Following a busy year for patent expirations in 2006, a number of important therapeutic classes will also be affected in 2007, including antipsychotics, calcium antagonists and beta-blockers. In 2007, marketed products with a value of more than $16 billion are likely to lose patent protection, which comes on top of $23 billion of products that lost protection in 2006. Consequently, branded products are making up a smaller percentage of the world market volume, a phenomenon that is dragging down overall market value.

Notwithstanding this, the cumulative number of blockbuster products on the market continues to grow and is expected to reach 112 in 2007, up from 94 in 2005. Potential
blockbuster products in 2007 will be paliperidone for schizophrenia, desvenlafaxine for depression and vildagliptin for diabetes.

1.3.5 Further cost containment initiatives

The need for public and private payers to limit their expenditure on drugs is the most powerful force tempering growth worldwide. Unfortunately, most payers are managing their drug expenses in a silo, without full consideration of a therapy's impact on total healthcare costs. In Europe, their tactics include price freezes, across-the-board cost cuts, incentives for using generics and scrutiny of comparative effectiveness between drugs.

Patients influence is offsetting much of the growth that stems from rising demand and innovation. Pharmaceutical manufacturers increasingly must strengthen the evidence that their therapies deliver value based on direct health outcomes.

1.3.6 Pockets of robust growth

Selected pockets of the market will experience high levels of demand and rapid expansion in 2007. Key amongst these will be biotechnology products, with estimated growth of 13-14%, generics with 13–14% growth, and specialist-initiated products with 10–11% growth (IMS Health, 2006). Generics growth will stem from opportunity in several key therapeutic areas and from increased volume as cost control efforts intensify.

1.3.7 Regional forecasts

In the US, 2007 market growth is forecast to slow to 4-5%, compared with the 6–7% expected in 2006. The Medicare Part D prescription drug benefit has expanded the
overall US market by nearly 1% in 2006, with a further uplift of 1–2% expected through 2007 while formularies remain relatively unrestricted (IMS Health, 2006).

However, the loss of patent protection for several key brands valued at $10 billion will significantly impact the US market next year, following the patent expiry of $19 billion in branded products in 2006. Growth from new products will not be sufficient to offset the volume of branded drugs that shift to generics. In Europe, the top five markets (France, Germany, the UK, Italy and Spain) combined are expected to grow at 3 to 4%, down from the 4 to 5% expected in 2006. While these countries are seeing increased demand from an ageing population, growth is being affected by cost-containment measures, incentives for using generics and increased scrutiny of the cost/benefit of drugs. “Governments will continue to emphasize on cost-effectiveness in 2007 and with cost benefit assessors now established in all key European markets, success for pharmaceutical industry will increasingly depend on the provision of clear and targeted evidence to support the value propositions of their innovations” (Lewis 2006, IMS Health).

The forecast has suggested that the Japan market will grow at 5 to 6% in 2007, up from an estimated 1 to 2% in 2006 resulting from the government’s biennial price cuts imposed on April 1, 2006. Emerging markets, including China and India, are growing by more than 10% in 2006 and will do so again in 2007, largely due to their expanding economies and broader access to medications. Growth in China will be 15–16% and the market size will reach $15-16 billion in 2007. Generally, locally manufactured generics dominate these markets (IMS Health, 2006).
1.3.8 Therapeutic classes

An ageing population and improved diagnostics have increased demand for oncology treatment — a challenge that the industry has met with a strong flow of innovation. Science has changed the face of the disease; survival rates are improving and some cancers are now considered chronic illnesses or even preventable conditions.

Products used in the treatment of oncology are expected to reach $40-45 billion in value in 2007, contributing nearly 20% of total market growth. Through 2007, this class will expand rapidly as more patients gain access to treatment from a growing range of therapies. But oncology products will eventually be subject to tighter pricing and usage parameters as payers deal with their mounting costs (IMS Health, 2006).

Among other major therapy classes, the lipid-lowering class (including statins as well as Zetia and Vytorin) will grow to $30-33 billion, reflecting an estimated 1–2% growth in 2007, down from 7-8% this year. While the 2006 patent losses for Zocor and Pravachol will continue to affect growth, increased public awareness of the efficacy of lipid-lowering agents, broader patient screening and new combination therapies will continue to drive demand (IMS Health, 2006).

1.3.9 Getting ahead

Pharmaceutical companies have started to reinvent themselves in response to market challenges, and they look very different than they did just five years ago but it is no longer enough just to be responsive. To succeed, companies need to get ahead of the dynamics that are rebalancing the market. This requires a greater reliance on scenario-
based planning, a sharper focus on realizing productivity gains from sales and marketing expenditures, and proving the value of medications as never before.

1.4 Pharmaceutical Branding

Brands and branding, as traditionally understood, were subject to continuous review and redefining. There are number of definitions of brand. According to American Marketing Association, brand is "a name, term, sign, symbol, or design, or a combination of them, intended to identify the goods and services of one seller or group of sellers and to differentiate them from those of competitors" (Kotler, 2000). A more universally applicable definition describes brand as a "cluster of functional and emotional values which promises stakeholders a particular experience" (de Chernatony and Dall'Olmo, 1999). In its simplest form, a brand represents the promises that the product makes (Blackett, 2004).

The concept of *branding* has developed over the years. Within traditional branding model, the goal was to build the brand and to create brand image, which derived short-term results (Aaker and Joachimstaler, 2000). The modern concept of branding can be applied to anything “from product and services to companies and even countries” (Clifton, 2004). The branding can be stated as “a major issue of product strategy” (Kotler, 2000).

The value of the brand comes from “Its ability to gain an exclusive, positive and prominent meaning in the minds of a large number of customers” (Kapferer, 1997).
Combinations of four factors determine the perceived value of the brand for the consumer: brand awareness, perceived quality, confidence, and image.

**Figure 1: Perceived Value of a Brand**

![Diagram showing the relationship between brand awareness, perceived quality, confidence, and image]


Pharmaceutical branding has traditionally led to considerable returns through: (Datamonitor, 2006)

- Intense advertising activity has led to pharmaceutical brand recognition, rapid uptake and blockbuster sales
- Brand awareness is a key tool for protecting against new competition
- Unique selling points can be key to brand success

In the recent past, some pharmaceutical companies have been investigating how to develop brands but there is still much confusion in the way brands are defined. Some believes that giving a name to a certain product will make it a brand. Others believe that adding a bit of symbolism to a product will be sufficient to create a brand (Chandler and Owen, 2002).
One of the factors that have added to the debate for pharmaceutical branding is the significance of direct-to-consumer (patient) communication on the prescription behaviour. The promotions termed as DTC (direct-to-consumer) are strictly regulated worldwide.

The early years of DTC have proven difficult with only few individual brands benefited. The DTC spending now accounts for approximately 15% of the budget for prescription drug marketing according to the FDA (the Pink Sheet, 2003). Some therapy areas appear to respond better than others e.g. antihistamines (Claritin, Zyrtec), irritable bowel syndrome (Zelnorm), and erectile dysfunction brands (Viagra, Levitra). In general, according to the Kaiser Family Foundation study (Erickson, 2001), the DTC appears to increase the size of the market. The study focused on antidepressants market and suggested that physician detailing still made differences about which antidepressant was prescribed but more patients identified themselves for consultation as a result of the DTC.

Despite the lack of brand focus in the pharmaceutical market, pharmaceutical product has got all the necessary ingredients that make it a brand. It represents in consumers’ mind as a set of tangible and intangible benefits. It does not only deliver efficacy (tangible) but it also offers additional value such as trust (intangible). The brand has an existence in both the doctor and patients mind that goes beyond the product itself. Pharmaceutical companies develop molecules but doctor’s prescription results in brands (Kapferer, 1991).
Branding of pharmaceutical drugs can help sustain brands against generics after the patent expiration. A strong brand will be benefited from a high consumer loyalty (Aaker, 1991; and Kapferer, 1991). The brand would therefore be in a better position to sustain sales after the patent expiry. A strong base of loyal consumers would give an additional time to maximize the return on investment (Blackett 2001).

Prescription drugs are increasingly being branded and sold to consumers with traditional marketing tactics such as advertising and promotion (Ono, 1994). In the 1990s, a host of prescription drugs became available over the counter and were backed by sizable marketing budgets like Pepcid, Tagamet, and Zantac heartburn remedies (Weisz, 1996). In 2000, a number of brands received more than $100 million in promotion, including Merck’s Vioxx arthritis treatment, Schering-Plough’s Claritan antihistamine drug, and Pfizer’s Viagra erectile dysfunction treatment.

Some authors have also highlighted the possibility for better protection of the branded drugs versus generics from the legal perspective when they are branded (Blackett 2001). Brands will have a stronger influence on the behaviour and attitudes of patients and doctors. Doctors can be convinced by arguments other than the purely rational ones (Chandler and Owen 2002). Various studies have shown that doctors may get influenced in their prescription behaviour due to the factors such as ‘trust’ or the ‘quality image’ of the pharmaceutical manufacturer (Schuiling and Moss 2001).
In addition, they need reassurance and in similarity to many consumer purchases they operate on a basis of limited information. They also make prescription decisions for emotional reasons, besides rational ones.

It is important to note that there is not just one pharmaceutical market, but around a hundred different ones. Firms do not compete with each other within the total pharmaceutical market, but within therapeutic markets, defined by afflictions. Examples of such therapeutic markets are the markets for drugs against ulcers, hypertension and depression. Within these therapeutic markets substitutability of one product for another exists, but between such markets substitutability is low.

If there is competition between therapeutically substitutable drugs, the quality of the drug is an important decision factor. The quality of a drug is multi-faceted; the important characteristics are efficacy, safety, side effects and ease of use. In the early stages of the product life of a drug, when it is protected by a patent, its only competitors are drugs with different active ingredients. These therapeutic substitutes may differ in their efficacy, safety characteristics and side effects. After expiration of the patent, other producers can enter the market with generic copies of the drug. In general, prices of generic copies are lower than the branded precursor.

It is clear that there is an important role for promotion in the market for pharmaceuticals. Because another company may introduce a better drug and because the patent period is limited, the period to earn back the R&D (and other) investments is limited. Therefore,
drug producers have to make sure that their products reach high sales levels as soon as possible. (Frank Windmeijer et.al, 2004)

1.5 Pharmaceutical Value Chain

The value chain of the global pharmaceutical industry contains five basic steps.

| Research & Development | Clinical Trials | Approvals | Drug production & Commercialization | Sales & Distribution |

Figure 2: Pharmaceutical Value Chain
(Source: Pharma Industry in India, EVALUESERVE, 2001)

Post 2005, the value chain will mirror those of global MNCs since process patents will not be permitted.

1.5.1 Value Drivers

The major value driver in the pharmaceutical industry has been a strong research and development environment (Figure 3). This was not true in India due to lack of proper Patent laws.
1.6 Conclusion

In India, the pharmaceutical marketplace is dominated by doctors and patients. They have a large choice in terms of medication and procedures. This requires a greater reliance on scenario-based planning, a sharper focus on realizing productivity gains from sales and marketing expenditures, and proving the value of medications. Prescription drugs are increasingly being branded and sold to consumers with traditional marketing tactics such as advertising and promotion. Thus, brands will have a stronger influence on the behaviour and attitudes of patients and doctors.
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