Chapter 2

INDIAN PHARMACEUTICAL INDUSTRY

2.1 Evolution of Indian pharmaceutical industry

The Allopathic system of medicine made its entry into India sometime during the early part of the 19th Century. Medicines were imported by the British for their personal use and this lead to the formation of the Pharmaceutical industry in India. For the first few decades, pharmaceutical products were being imported mostly from Germany and the United Kingdom (Chaganti, 2005).

Scientists in India undertook research in tropical diseases like malaria, typhoid and cholera. But the real stimulus to the domestic production of pharmaceuticals was given during First World War. There was a steep rise in demand and drastic cut in imports during this period. By 1941, the production of several formulations based on imported bulk drugs also showed a significant expansion. The estimated value of production of pharmaceuticals in 1947 was around Rs. 10 crores. From a mere Rs. 10 crore in 1947 to a whopping Rs. 26,540 crore in 2002-03, the pharmaceutical industry in India has come a long way. Today there are over 400 bulk drug manufacturers and around 60,000 formulations (Chaganti, 2005).

2.2 Indian pharmaceutical market: An Overview

The Indian pharmaceutical market is in a phase of transition. Companies are converging their resources and redefining their value chain to face the challenges poised by the product patent. Domestic pharmaceutical companies have been churning out new drugs at a never seen before frequency and have gone on a brand acquisition spree to strengthen their market position.

The Indian pharmaceutical market is estimated to be $ 5.1 billion in year 2004 which is approximately 1.3 percent of the global pharmaceutical sales that stand at USD 317.2 billion. India has 8 percent value share of the global pharmaceutical production market and stands fifth in volume terms. The Indian patent laws (1970) gave Indian companies the opportunity to reverse engineer molecules that were under patent (without payment of royalty) and to sell them at 8-15 percent of the price of the patented drug. The benefits given to SSI units resulted in a mushrooming of small units and this has resulted in the industry being highly fragmented (there are nearly 20,000 licensed companies). The top 10 companies control 30 percent of the market, eight of these are Indian companies. By comparison, the global top ten companies account for about 45 percent of the International market (Parmar, 2005).

Indian pharmaceutical market is now moving up the value chain. From being a pure reverse engineering industry focus to a basic research driven, export oriented industry with both domestic and global firms competing to provide better quality of drugs and services. The industry can also be classified by the therapeutic sectors. The major

therapeutic sectors include Analgesics and Anti-pyretic, Antacids and Anti-ulcerant, Antibiotics, and Anti-tuberculosis.

2.3 Therapeutic Segmentation

The most important way of segmenting the Indian pharmaceutical market is by the therapeutic groups. The major therapeutic segments in the Indian pharmaceutical market in 2004 are explained in Table 5.

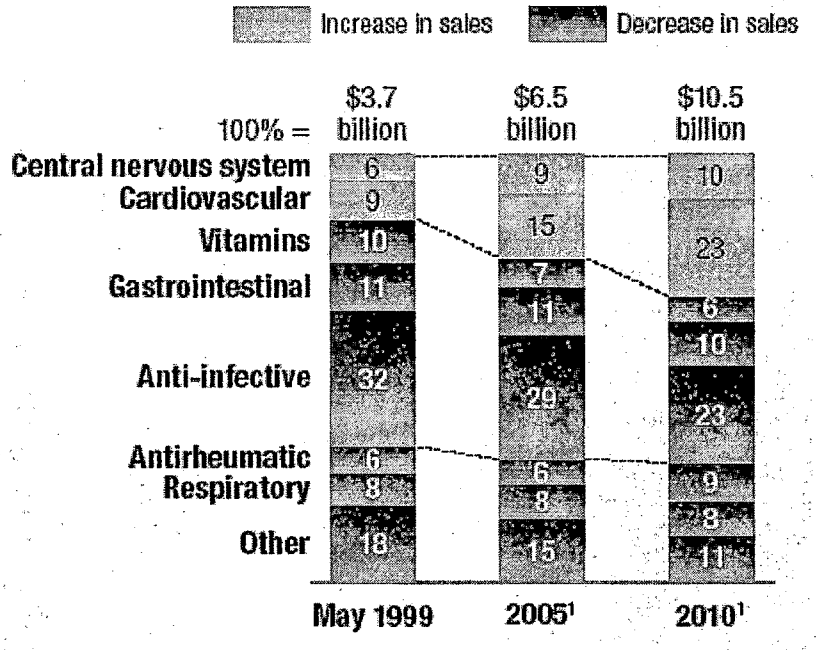
Table 5: Major Therapeutic segments in Indian Pharmaceutical Market in 2004

Sl. No.	Therapeutic Segments	Rs. in Millions	Market Share (%)	Change (%)
1	Anti-Peptic Ulcerants	923	4.6	7.9
2	Antibiotic, Systemic	3,282	16.4	4.4
3	Quinolones	724	3.6	–
4	Tuberculostatic*	314	1.5	(4.0)
5	Cardiac Therapy	769	3.8	9.7
6	Anti-Diabetic Therapy	882	4.4	11.1
7	Anit-Rheumatic, Non-Steroial Anti-inflammatory	1041	5.2	7.9
8	Analgesics, Non-Narcotic	343	1.7	10.4
9	Anti-Asthmatic Therapy	500	2.5	9.2
10	Cough and Cold Preparations	982	4.9	7.9
11	Neuro-Psychiatry Therapy	1245	6.2	10.9
12	Vitamins	1155	5.7	5.0
	Total	***12,160***	***60.5***	***6.7***

** Except Streptomycin*
Source: ORG Retail Store Audit, 2004.

Chart 2: Therapeutic segments in Indian Pharmaceutical Market by 2010

Composition of therapeutic treatments, percent



[1]Forecast.
Source: ORG-MARG; interviews; McKinsey analysis

The rising incomes and a growing number of elderly people, sustained by advances in hygiene and medicine, are driving a shift in the market away from sales of vitamins and anti-infective and gastrointestinal treatments and toward sales of treatments for cardiovascular problems, central-nervous system disorders, and other complex ailments (Adarkar, et al. 2001). By 2010, cardiovascular and central-nervous-system treatments, which accounted for only 15 percent of the market in May 1999, are expected to account for 33 percent (chart 2).

2.4 Bulk drugs

Over 60 percent of the India's bulk drugs production is exported. The balance is sold locally to other formulation manufacturers. Most of the domestic players are involved in bulk manufacturing.

2.5 Formulations

The top ten companies in the market account for nearly 30 percent of the market share, Glaxo being the market leader in this category.

2.6 Export and Import

Though India is a net importer of goods, pharmaceutical is one of the few industries, which is a foreign exchange earner for the country. Total exports from the Indian pharmaceutical industry during FY2001 amounted to Rs. 8 billion, of which formulations contributes about 55 percent and the balance 45 percent came from bulk drugs. This represents a year-to-year growth of about 21 percent. Indian companies are focusing on exports of formulations to semi or non-regulated markets and gearing up for exports of bulk drugs to regulated markets (www.indiastat.com).

Table 6: Leading Exporters (2001-2002)

Company	Exports (Rs. in millions)	Growth (%)
Ranbaxy	10,291	28.3
Dr Reddy' Labs (DRL)	9,537	133
Cipla	4,942	92
Wockhardt	1,712	41.25
Sun Pharma	1,396	18.2
Lupin Laboratories	2,314	65
Torrent Pharma	274	19.75
Cadila Pharma	958	40

Source: www.indiastat.com

Imports of medicinal and pharmaceutical drugs for the last three years have been as under:

Table 7: Imports of Medicinal and Pharmaceutical products

Year	Import of Medicinal & Pharmaceutical products (Rs. in Crore)
2000-01	1701.46
2001-02	2026.58
2002-03	2717.82 (*prov.*)

Source: D.G.C.I.S., 2003.

Import of drugs and pharmaceuticals are allowed freely, except those in the restricted list of import under the current EXIM policy, which can be imported under an import license.

2.7 Environmental Analysis of Indian pharmaceutical market

Acquisitions and alliances have increased as companies' pool their resources to consolidate product portfolios and distribution. The therapeutic profile is changing. Cardiovascular and anti-diabetics are gaining market share while older therapeutic areas like anti-infective are experiencing a negative growth. By 2010, cardiovascular and central nervous system treatments which accounts for only 15 percent of the market in May 1999, are expected to account for 33 percent (ORG-MARG survey; Mckinsey analysis 2004).

The disease management techniques within the therapeutic segment are also changing. Older antibiotics like ampicillin/ amoxicillin are losing market share to the new cephalosporins and quinolones as more people are developing resistance to the older drugs and the newer antibiotics offer better coverage.

There is an increase in research spending of the big Indian players. India will comply with GATT-TRIPS agreement in 2005. Product patents will be enforced and reverse engineering, an area where Indian companies have built expertise, will no longer be possible. The number of drugs under Drug Price Control Order (DPCO) has been coming down consistently, from 74 drugs under it in 1995, the number is expected to fall to 16 in the new amendment. The companies can charge prices that the market will be able to bear and improve their profitability margins.

The generic markets are expanding. The cost-containment measures of managed care in the US have resulted in substitution of branded drugs with generics; Europe generics market is also increasing because of cost containment efforts and new regulations.

2.8 Indian Pharmaceutical industry and Porter's five forces model

2.8.1 Entry barriers

The major barriers to the pharmaceutical market are the product access, reach and relationship and Production.

2.8.2 Intensity of rivalry

Rivalry is extremely high because of regulations that permit process patents and due to the lifestyle drugs that has great revenue potential and the prescriber base. Intensity of rivalry is high in reverse engineering as well, till 2005 one can reverse engineer products; therefore everyone is building capabilities in the drugs coming off patent. Multinationals are taking more interest in the Indian market; consolidating their brands, setting up manufacturing and R&D facilities and they will become more aggressive in the coming years. Lobbying with regulatory authorities to stop launches and approvals so that the competitor does not have a first to market advantage are quite common.

2.8.3 Substitutes

The potential substitutes for allopathic medicines in Indian pharmaceutical market are the medicine treatments based on household, Unani, Homeopathy and Phytomedicine.

2.8.4 Bargaining power of the Suppliers

The bargaining power is relatively low with the Bulk drug suppliers and is high with the Multinationals and Indian majors due to the support of patent and Novel drug delivery system (NDDS).

2.8.5 Bargaining power of the buyers

The bargaining power of the patients is low. The market is prescription driven and the faith on the doctor is tremendous. Institutional buyers enjoy high bargaining power as they control almost 10 percent of the Indian market. Prescriber bargaining power is very high as they eventually control product sales.

2.9 Regulatory Framework

Regulation is a very significant factor in pharmaceutical business. There are two reasons for that. First, since drugs affect the health and well being of the masses, the government has an interest in assuring their adherence to medical standards and availability. Second, in light of the fact that patentable research can represent a important part of a given drug

company's cost structure, IP protection is essential to provide firms with incentives to develop new drugs.

2.10 The Indian Patent Act (IPA)

Prior to 1970, India employed western-style patent legislation, and recognized product patents in addition to process patents on drugs. Under that environment, MNCs prospered while local companies lacked the resources to enter the industry (Chaganti, 2005). By ignoring product patents, the 1970 Patent Act permitted companies to reverse engineer their competitor's products. In addition to India, such products are freely sold in Russia, the Commonwealth of Independent States (C.I.S), Africa, China, and South America. Furthermore, Indian companies were free to ship reverse engineered drugs to patent recognized countries on or after the day of expiry (with no lag time).

2.11 Intellectual Property Rights (IPR)

The agreement on trade related aspects of Intellectual Property Rights (TRIPS) provides for minimum norms and standards in respect of the following categories of intellectual property rights:

1. Copyrights and related rights
2. Trademarks
3. Geographical indicators
4. Industry designs
5. Patents

6. Layout designs of integrated circuits

7. Protection of undisclosed information (trade secrets)

The Agreement sets out minimum standards to be adopted by the parties, though they are free to provide higher standards of protection.

2.12 Drug Price Control Order (DPCO)

In 1970, the government introduced the Drug Price Control Order (DPCO) to guarantee public access to "essential" drugs, to provide a reasonable rate of return to companies, and to ensure quality. In 1995 DPCO declassified 70 out of 146 drugs, dropped some clauses that favored small companies, and exempted newly (locally) produced products from price controls.

2.13 National Pharmaceutical Pricing Authority (NPPA)

The NPPA was established in 1997, to improve the speed and transparency of the process of fixing the prices of bulk drugs and formulations. It is expected to reduce the time lag between price revisions, thereby providing stable margins for formulations, and revise the list of bulk drugs under price control within a reasonable time.

2.14 WTO policies and its implications on Indian pharmaceutical market

In 1995, the government amended the 1970 Patent Act to conform to the TRIPS accord of the Uruguay round of GATT. After 2005, India will have to comply with GATT/TRIPS requirements, or risk a return to isolation. Since the second scenario is unlikely and undesirable, the industry can probably look forward to product patent protection in 2005.

2.15 Insurance and Healthcare market in India

Till recently, there was no participation permitted by the private sector. There is limited payer mechanism available through government schemes (GGHS, ESI etc) and through corporate reimbursements. The Indian government has only recently allowed private participation in the Insurance sector.

2.16 Political Risks

The political constraints may prove to be a very significant factor in deciding the stand of the Indian government on the patents in 2005. This has to be seen in the light of the multi party system that India has and also the fact that a lot of political observers suggest that the coming years are the years of coalition politics. In spite of the commitments, the political compulsions may force the government to delay/ modify the processes.

2.17 Indian Pharmaceutical Supply Chain: An Overview

The supply chain of the pharmaceutical industry is quite complex and the roles played by various partners, are undergoing drastic changes worldwide. This trend is expected to be followed in India in the next few years as well. The supply chain has various players; the complexity in the chain is because of the fact that the decision making for the products is made by multiple players. The supply chain of pharmaceutical industry includes the Distributor, Wholesaler and Retailer. The chain also includes the channel between drug company and the physician, through the Medical Sales Representatives (MSRs). This is a relationship driven area where the MSRs contact the doctors and make the sales.

2.17.1 The future Supply Chain

As the role of managed care rises in the Healthcare, managed healthcare partners and third party administrators will play an increasingly important role in the supply chain.

2.18 Prescription process of Medical Practitioners

The pharmaceutical market is prescription driven as the end consumer is not the main client. Regulations in India ban direct marketing to the end customers. It is, therefore, important to reach out the doctors who play a pivotal role in the sale of drugs as they prescribe the desired drug for a specific disease.

Table 8: Growth in Prescriptions

Total Prescriptions	*75.3 crore*
Average Doctors	*1.3 lacs*
Prescription Growth	*1.3 %*
P/D	*472*

Source: Cmarc, 2004.

The Over-the-Counter (OTC) market segment is just about $0.5 billion (www.indiastat.com). In India, a significant segment of the market is based on self medication but the majority of the sale still comes from prescriptions.

2.19 Emerging Trends

Pharmaceutical industry has achieved an increase in performance and efficiency across various parts of the existing value chain i.e. from production planning to distribution. Focus is now on key therapeutic areas and to develop and nurture the doctor relationship with the companies in those areas.

2.20 Bio-technology

Although Indian pharmaceutical companies have forayed into biotechnology, they are still in a nascent stage of research and development. Some of the Indian players have started via the hepatitis B vaccine route before moving on to more complex technology and products.

2.21 Contract Manufacturing

Research and Development eats up more than half of the 20-year exclusivity period granted to patented drugs. Manufacturing of the drugs may lead to bottlenecks caused by infrastructure problems etc. Hence, a company may decide to outsource production of that drug to another country, instead of creating a manufacturing base there.

2.22 Mergers and Acquisitions (M&A)

The fragmentation in the industry shows the scope of M&A activity that exists in India. The total deals in the pharmaceutical market still remain low which can be attributed to the gray areas in the patent laws and the unpredictability of the Indian government towards the pricing mechanisms. The total size of Mergers and Acquisitions business in Indian pharmaceutical market in 2000 was about Rs. 320 crores (www.indiastat.com).

2.23 Alternative Systems of Medicines in India

Ancient civilization allowed India to develop various kinds of medical and pharmaceutical systems. In addition to the allopathic system, which is prevalent in the US, Japan, and Europe, the following types of medical and pharmaceutical systems are used in India:

- Ayurvedic medicines
- Unani medicines
- Siddha and
- Homeopathy.

Ayurveda is believed to be more ancient than the Allopathic system. The word 'Ayurveda' has genesis in two Sanskrit terms: 'Ayush' meaning 'life' and 'Ved' implying two meanings; 'to know' and 'to achieve'. Thus Ayurveda is defined as a science through which the knowledge of healthy life is obtained, more of health is achieved and the healthy life so achieved is not destroyed (Sharma, 1968). Ayurveda has two purposes: (1) To eradicate diseases, and (2) To protect the health. Ayurveda did not only deal with the health of human beings; it also dealt with health of animals and plants.

Homoeopathy is another alternative system of medicine originated in Germany during the eighteenth century. Dr. Albrecht von Haller recorded (Swiss Pharmacopoeia, 1755) that drugs must be proved on healthy persons to determine the effects they produce. Dr. Hahnemann, an allopathic physician, worked on this concept and recorded their results in the form of a book called *'Materia Medica Pura'*. He advocated the principles of 'law of similars' (Gala, 1995).

Siddha is also an ancient Hindu system of traditional medicine mainly practiced in the state of Tamilnadu and surrounding areas. This system mainly employs minerals and metals and also products of animal and vegetable origin. It advocates the principle of *Panchbhutas*, comprising gold, lead, copper, iron and zinc (Sharma, 1968).

Unani system of medicine originated from Greece, and later spread over Arabian regions who made it popular. They also gave it a scientific base. This system based on the principle of the balance of blood (Dam), phlegm (Balgham), yellow bile (Safra) and

black bile (Sauda). Unani system also advocated surgery and employed its own surgical instruments in the ancient times.

All these systems, which developed in different geographical territories during different times, had one thing in common. Initially, during the evolutionary period, the professions of medicine and pharmacy were simultaneously practiced by the same person. The evolution of separate professions of medicine practice and pharmacy is not clearly defined in other systems, as is in allopathy (Gala, 1995). Nevertheless, it can be observed that as each of the systems of healthcare developed, the intricacies of formulating the medicines increased; calling for special expertise of compounding of medicines. This expertise was developed by persons other than the physicians, who later on practiced the profession of pharmacy.

2.24 Pharmaceutical Marketing in India

Pharmaceutical marketing is a complex process which involves multifarious activities at different levels and starts from the need realization for a new drug and ends when the product is exchanged for a price.

2.25 The Pharmaceutical Marketing Model

The marketing process starts with the need realization for a new drug or a new treatment method for a disease. A marketer can judge the need from the feedback received from the physicians. This need is converted into a viable product idea. Product development efforts in India are restricted mainly to formulation development. The product is first

developed and tested at the laboratory, and then scaled up to the commercial production level. The next stage is product promotion. The active promotion leads to the awareness among the medical practitioners. The product is distributed through the wholesale and retail channels and is offered for the final sale to the consumers. Medicines being non-durable consumer products, minimal after sales service are required.

In case of most consumer products; the buying decision is made by consumers. But in case of pharmaceutical products, the buying decision for prescription products is made by the physician. The consumer of medicines, the patient, has no significant role in deciding the drug or the brand. The physician makes the final choice of the drug brand for his or her patient. Thus the major proportion of promotions is directed towards the physician.

2.25.1 Pharmaceutical Product

The Indian pharmaceutical industry is currently congested and flooded with over 60,000 products which are competing with each other for market share of the Rs. 165 billion strong Indian pharmaceutical market in different therapeutic categories (Chaganti, 2005). Only 300 products accounts for over 46 percent of the total sales volume.

A product provides bundle of benefits and is a need satisfying entity. While a generic product is an undifferentiated product, a branded is promoted and differentiated for capturing both market share and mind share.

In the Indian pharmaceutical industry, product augmentation is essential for the survival and growth of brands. This is not because research and development (R&D) activity is

high but the main reason is the licensing policy of the government. It encourages the small-scale sector even in the knowledge based industry like Pharmaceuticals. The result is the mushrooming of the pharmaceutical companies churning out innumerable brands with little scope of improved efficacy over other brands in the same category. Thus, end up flooding the market with undifferentiated products. Companies, which consider that branding means augmenting the product by creating and communicating the value additions effectively, are bound to succeed.

Branding by product augmentation, in the Indian pharmaceutical industry, is primarily achieved by creating differentiation in the manufacturing process, changes in the formulations, packaging, communication, and by using memorable and appropriate brand name for the formulation.

Product Mix Decisions

Product mix decision is a crucial and essential product policy decision that a company has to take. It reflects not only the nature of the market and the resources with the company, but also the underlying philosophy of the company.

It is extremely difficult to define an ideal or optimal product mix for any industry. Company's current product mix is optimal, only if no further adjustment will enhance their chances of achieving its objectives and improving its performance (Kotler, 2005).

The major strategic options available for achieving an optimal product mix are:

- Deletion: Deletion strategy involves decisions regarding product discontinuance or abandonment of individual product or the entire product line
- Product modification: Product modification can be achieved by changing either tangible or intangible product attributes. Reformulation, redesigning, changing the pack size, or shape, changing the taste or flavour and removing certain features, are some of the commonly adopted methods in the product modification strategies. By successfully planning and implementing the product modification strategies, a number of companies have extended their life cycles.
- Introduction of new products: Developing new product is a very expensive and risky proposition. Expensive because huge investment required in research and development (R&D) for the development of new products; risky because of the high degree of uncertainty and high rate of failure of new products. Developing new product involves a disciplined approach of creative planning, innovation and managing the task effectively.

2.25.2 Pricing

The Indian pharmaceutical industry is highly regulated. The government controls the prices of a number of bulk drugs and formulations. There is very little for the pharmaceutical marketer in India to decide as far pricing is concerned. There is a price ceiling fixed for as many as 162 bulk drugs and 585 formulations (Chaganti, 2005). The only choice available for a pharmaceutical marketer is whether he can manufacture and

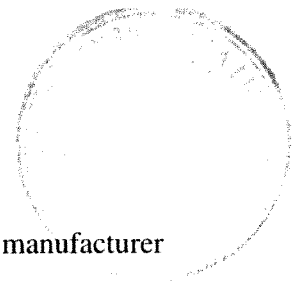
market profitably the drug within those prices fixed by the government. Even the conversion norms and packaging norms are fixed for the formulations. The government has a definite say in the pricing of drugs and medicines, through the pricing mechanism regulated by the Drug Price Control Orders (DPCO).

The pricing is fixed by using one or more of the basic pricing methods: the cost based pricing, the demand based pricing, the competition based pricing and the market based pricing. Depending on the objectives of an organization, various pricing strategies are employed like: skimming pricing, penetration pricing or marginal cost pricing.

Traditionally, price has been an important communicator in India. The consumers typically believe that higher price reflects the better quality. It is largely believed by the pharmaceutical marketers in India that while marketing a new drug, the price communicates the efficacy and brand identity to the customers.

2.25.3 The Place: Distribution

Distribution activity is concerned with placing the goods and services when they are needed and where they are wanted. Place or distribution is a crucial ingredient of the marketing mix. Distribution channels are pathways through which the product flows from the place of manufacturer to the place where consumers can buy them. There are two major distribution channels: Wholesalers and Retailers. Wholesaler channel comprises of C&F/ C&A agents, Superstockists, Stockists etc., whereas the retailers necessarily have to employ the services of registered pharmacists for dispensing of drugs. Distribution



margins are regulated under the Drug Price Control Order (DPCO). The manufacturer also pays the transportation charges up to the place of destination.

2.25.4 The Promotion

Pharmaceutical promotion is mainly aimed at generating prescriptions from the practitioners. Pharmaceutical products are believed to be high technology products whose advantages and disadvantages cannot be deciphered by a consumer. The physician decides the medicine to be purchased by the consumer.

Personal selling is the main tool employed by the pharmaceutical marketer for promoting pharmaceutical products to the medical profession. Although costly, it is the most successful and universally acclaimed tool for pharmaceutical promotion. Pharmaceutical companies employ medical representatives (MRs) to communicate their drug categories to the medical practitioners. Promotion is the marketing communication that informs and reminds the target audience and persuades them to accept, recommend or use the product. Pharmaceutical companies also, to some extent, use other promotional tools like advertising, sales promotion, publicity and public relation campaigns for promoting pharmaceutical products.

Packaging had been recently started recognized as another important ingredient of the marketing mix of the pharmaceutical products. Medicines need to be packed not only for aesthetic appeal, but also to protect them from environmental effects. Packaging also plays an important role in advertising the pharmaceutical products.

2.26 Prescription Behaviour

Prescription certainly is the prime-mover of goods and services in pharmaceutical marketing. Prescriptions have been used to study treatment patterns and analyze markets for various therapeutic categories in many countries. In today's highly competitive pharmaceutical market, marketers are increasingly concentrating on studying the prescription trends and the prescribing behaviour of physicians (Chaganti, 2005).

2.26.1 Prescription behaviour: Rational or emotional?

A rational buyer makes purchase, theoretically, in a logical manner with clear cut objectives. Rational buyers evaluate all the alternatives available and match their needs with the product attributes and make the final choice decision. The emotional buyer, on the contrast, may be swayed by the product attributes or advertising appeals, that may not be actually delivered in the product or service. Physician's choice is more logical and rational while choosing a therapy but when it comes to selecting a particular brand of formulation, his decision may be more inclined towards emotional and less rational prescription. It may depend upon a number of factors like the confidence, pleasant mannered, friendly, and persuasive approach of medical representatives, reputation of the company, easy to remember brand name, and many more other factors.

2.27 Prescription process

The physician is concerned with the patient well being and therefore tries to select the best therapy and drug for treatment. Prescription is a reflection of a physician's choice set

of drug for a treatment. There are some major factors that contribute to the prescription process:

- Behavioural characteristics of the patient
- Expectations and attitude towards the prescriber's treatment
- Trust level on the prescriber's treatment
- Level of knowledge and expertise of the prescriber
- Prescriber – patient relationship

2.28 Prescriber motivation

Physician's prescription decision involves a very high degree of conscious choice set and concern for patient's well being. They rely on certain sources, to select a particular drug treatment, like medical representative relations, medical journals, direct mails, peer advice, conferences and seminars, workshops etc.

Some of the major observations, propositions and findings on prescription behaviour proposed by many studies are (Chaganti, 2005):

- Physicians use and rely more on professional sources, like colleagues, while treating serious illness and where efficacy of a drug therapy are relatively less clearly defined.
- Specialists and well informed physicians are likely to use more of newer drugs early in the course of treatment.

- Advertising and promotions are likely to have high influence on prescription choice set.
- Most of the drug choices a physician makes through the prescription are habitual.

Convenience and availability of information sources are two crucial factors influencing the physician's prescription behaviour.

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