CHAPTER II
THE PHARMACEUTICAL INDUSTRY AND HEALTH DELIVERY SYSTEM IN INDIA

THE PHARMACEUTICAL INDUSTRY

The pharmaceutical industry is currently acknowledged as one of the leading industries in India. The growth rate has been significant and has recently accelerated substantially due to new products launched in recent years. Almost 3000 new products were launched between 2002 and 2004, with sales estimated at US$280mn.[10] The domestic pharmaceutical output has increased from Rs.4bn in 1970-1971 to Rs.290bn in 2003 at a compound growth rate of 13.7 percent per annum.[11]

India is ranked among the top 15 drug manufacturing countries in the world. Globally, the output of India ranks 4th in terms of volume and 13th in terms of value.[12] The Indian pharmaceutical industry, however, only has a one percent share of the world pharmaceutical export market[13]. India's export market is expected to strengthen substantially in the coming years.

At the domestic level, the Indian pharmaceutical industry is self-reliant in drug manufacture, evident in its ability to meet 95 percent of the country's pharmaceutical needs[14]. One vital characteristic of the industry is that drug prices in India are arguably amongst the lowest in the world.

The industry is today being recognised globally for its strengths in[15]:

- Availability of a large pool of low-cost and highly skilled pool of scientists and medical professionals
- Chemistry and synthesis skills
- Successful scaling up of laboratory processes to plant scale

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[10] Nitya Nanda and Amirullah Khan, *Competition Policy for the Pharmaceuticals Sector in India*, CUTS International in Pradeep Mehta (ed.), Towards a Functional Competition Policy for India, 2004, p. 189.
[11] *Industry Overview: Drugs and Pharmaceuticals* at http://www.directories-today.com/drugs.html
[12] Ibid
[13] *International Trade Statistics*, WTO, Geneva, 2005
[14] Supra n. 10 *at* p. 189
[15] Ibid

- Cost effective and commercially viable non-infringing processes
- Manufacturing facilities of international standards
- Quicker adoption of new technology

Notwithstanding all the encouraging indicators and the substantial promise of the pharmaceutical industry in India, the sector is today in a state of flux. Many domestic companies are being confronted by the very issue of survival in face of the sweeping changes introduced in the patent regime and the increasingly de-regulated environment. Especially threatened is the issue of access to medicines by the poor. However to clearly appreciate the crossroads at which the industry stands today, it is essential to briefly understand the history of the pharmaceutical industry.

A Brief History

India and Japan are the only two countries in the world where western multinational companies (MNCs) do not dominate the pharmaceutical industry[16]. For India, this is a remarkable achievement considering that until the 1970s, the market was dominated entirely by foreign transnational companies and characterised by relatively high drug prices. Domestic firms supplied less than 25 percent of the total market. During that time public sector companies would supply cheaper, essential medicines. These state owned companies alongside the public sector organisations, notably, the Council of Scientific and Industrial Research, set the foundation for a strong pharmaceutical industry by developing indigenous technical capacities. This vitally contributed to the striking growth the pharmaceutical industry is demonstrating today. Public sector companies no longer play any significant role in delivering healthcare to people[17].

The history of the patent regime is crucial to understanding the pharmaceutical industry in India. India's transition from the product patent regime for medicines to that of process patents in 1970 is one of the key factors to which the current success of the industry may be credited. In the context of the pharmaceutical industry, product patents protect the patent-holders' rights to the new drug or molecule invented while process patents protect the method used to create a drug or molecule, but not the product itself. A process patent, therefore, allows manufacturers to produce the same or similar molecule, if they are able to devise an alternative method of developing the

[16] Sudip Chaudhuri, *The WTO and India's Pharmaceuticals Industry- Patent Protection, TRIPS, and Developing Countries*, Oxford University Press, 2005, p. 18

molecule. This patent regime gave latitude to Indian manufacturers to substitute the development processes of patented drugs by employing a technique known as reverse engineering and in this way manufacture different versions of patented drugs.

Since the companies manufacturing such copies of patented drugs did not have to recover any substantial research and development cost, these medicines could be priced such that they were affordable to the common people. The affordability of these alternate versions was the principal benefit of process patents and a matter of vital significance in a country with such a high percentage of underprivileged citizens. Based on the flexibilities of the process patent system and a range of protectionist measures, a self-reliant domestic drug industry emerged with the capacity to manufacture and provide at a low cost a wide array of bulk and finished drugs.

The milieu against which the industry achieved its success is now set to radically change. The era of liberalisation and integration with the global markets in India has ushered out the earlier protectionist measures. Since 2001, automatic approval has allowed up to 100 percent foreign equity in the pharmaceutical sector and the Indian law now treats TNCs as equal to Indian companies[18]. The process patent regime was largely responsible for the domestic industry maintaining its competitive edge. At present, even that is set to change with India reverting back to the product patent regime in accordance with the mandate given by the TRIPS Agreement, which India signed in 1994.

Presently, the pharmaceutical industry of India stands at the cusp of developments that presents in its wake both compelling opportunities as well as stiff challenges.

Nature of the Pharmaceutical Industry

The pharmaceutical sector in India today is a high technology and knowledge-intensive industry with wide-ranging capabilities in not only drug manufacturing technologies, but also in the area of research and development. One of the industry's

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[17] Supra n. 8 at p.3-4

[18] Ibid at p.4

key strengths is its expertise in manufacturing generic drugs[19]. A widely quoted industry estimate places the number of companies at 20,000.[20] However as against this figure, the Mashelkar Committee has identified 5877 companies, based on the number of production (licensed) units in the country.[21]

Box 2.1 The Approval Process for Manufacturing and Marketing
The pharmaceutical industry is regulated by the Drugs and Cosmetics Act 1940 (DCA), and the Drugs and Cosmetics Rules (DCR) made there under. This legislation applies to the whole of India and all products, whether imported or made in India. The office of the Drug Controller of India (DCI) has the primary responsibility of enforcing the law. However, at the field level, enforcement is done by the individual State governments through their Food and Drug Administrations. Matters of product approval and standards, clinical trials, introduction of new drugs, and import licenses for new drugs are handled by the DCI. However, the approvals for setting up manufacturing facilities, and obtaining licenses to sell and stock drugs are provided by the State Governments. There is no requirement for any registration of a drug in India. However, there is need for approval from the DCI to import, market, or manufacture a "new drug." All new drugs (drugs not previously used in India or in use for less than four years) proposed to be introduced must be approved for import or manufacture in India by the DCI. The application for permission to import or manufacture must be accompanied by the appropriate dossier on the following aspects: • Introduction: description of drug and therapeutic class • Clinical and pharmaceutical information • Animal pharmacology • Animal toxicology • Human/ clinical pharmacology (Phase I)

[19] The term generics will be often used in the course of this study. It is necessary therefore to provide a precise definition. Unfortunately there is no precise definition. Generics is a term, which is used in a number of different contexts, primarily three. A drugs generic name is the pharmacological name of the compound assigned either by WHO's International Non-proprietary Names Committee or by the US Adopted Name Council. Drugs whose patents have expired are also included in the category of generics. (See Zafrullah Chowdhury, *The Politics of Essential Drugs: The Makings of a Successful Health Strategy: Lessons from Bangladesh*, Zed Books Ltd. London, 1995, p. 8). Also copies of patented drugs in the erstwhile process patent regime in India were loosely termed as generic copies of patented drugs. Generic drugs are broadly classified into commodity generics and branded generics.
Commodity generics, which have been on the market since 1950s are simply generic name products marketed by a wide variety of companies. Branded generics are either unpatented drugs sold under a brand name or patent-expired products sold under a generic name prefixed by the company's initial(s)- a practice which helps differentiation from other generic manufacturers and is supposed to provide an assurance of quality. (See Zafrullah Chowdhury, *The Politics of Essential Drugs: The Makings of a Successful Health Strategy: Lessons from Bangladesh*, Zed Books Ltd. London, 1995, p. 8)

[20] Report of the Expert Committee on A Comprehensive Examination of Drug Regulatory Issues, including the Problem of Spurious Drugs, Ministry of Health and Family Welfare, Government of India, 2003 p.3, paragraph 13. Also see, *Pharmaceutical Industries in India* available at http://www.economywatch.com/business-and-economy/pharmaceutical-industry.html, Richard Gerster, *Indian Pharmaceutical Industry: An Overview* available at http://www.pharmaceutical-drug-manufacturers.com/pharmaceutical-industry, Ajit Ranade and Sanchita Basu Das, *Pharmaceutical Industry-Update*, Sector Report, ABN-AMRO, 2003.

[21] Report of the Expert Committee on A Comprehensive Examination of Drug Regulatory Issues, including the Problem of Spurious Drugs, Ministry of Health and Family Welfare, Government of India, 2003 p.3, paragraph 13.

• Exploratory clinical trials (Phase II)
• Confirmatory clinical trials (Phase III)
• Special studies
• Regulatory status in other countries
• Marketing information

In case the drug is already approved and marketed abroad, then only Phase III trials may be required in India. Further, such trials would need to be conducted on at least 100 persons spread over 3-4 locations in the country. However, the DCI may agree to dispense with the need for local clinical trials, if it is in the public interest and if it can use the data of trials carried out in other countries.

All manufacturing of drugs in India requires a license. A license is required for each such location at which drugs are to be manufactured, and also for each drug to be manufactured. The license has to be renewed periodically.

As per the law in the country, each unit of a single company not only needs a license for production, but also for drugs manufactured. Could it be that the estimate of 20,000 companies is merely an unauthenticated statistic quoted arbitrarily? If this estimate is correct, then that would mean that there are a huge number of illegal and unregulated manufacturing units in the country which in turn leads to any number of issues relating to spurious drugs, correct manufacturing techniques and so on. The latter issues being beyond the scope of this study will not be further pursued herein, but this may well be a matter meriting close consideration by the authorities.

Firms in this industry may be classified on the basis of diverse criteria, which would include the following:

- *Formulation production and bulk drug production*

The pharmaceuticals market is roughly divided into *bulk drugs*[22] *(20%) and formulations*[23] *(80%)*[24]*,* the industry producing about 60,000 formulations and roughly 400 bulk drugs.[25] India is among the top five producers of bulk drugs in the world.[26] This segment of the market has increased in the past decade at around 20

[22] A bulk drug is any pharmaceutical, chemical or biological product including its salts, esters, stereoisomers and derivatives, conforming to pharmacopoeia or other standards and which is used as such or as an ingredient in a formulation. (Source: The Drugs Prices Control Order, 1995)
[23] A formulation is a medicine processed out of bulk drug/s for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or animals, but shall not include any medicine included in the Ayurvedic, Homeopathic or Unani system of medicines. (Source: The Drugs Prices Control Order, 1995)
[24] Supra n. 10 at p. 191
[25] Supra n. 11
[26] Ibid

percent annually, while the production of formulations has increased by around 15 percent.[27] Companies either specialise in the production of bulk drugs or formulations or may manufacture both.

Firms specialising in formulations may be further classified into *innovating firms and non-innovating firms.* Innovating firms are those, which engage in research and development of new medicines, and the firms, which do not, are represented as non-innovating firms.

Globally, the pharmaceutical industry has a two-tier structure. The largest firms account for the majority of the R& D investment in the industry and hold the majority of the patents.[28] A small number of MNCs dominate the global pharmaceutical industry, the top twenty-five MNCs having accounted for 64.5 percent of the world market in 2003.[29] A large number of smaller firms manufacture off-patent products (generic drugs); or are license to a patent holder.

In India too, this tiered structure does exist. However, given that R&D is still not that prominent a feature in the Indian pharmaceutical industry evident from the fact that R&D expenditure (as a percentage of turnover) by the domestic industry is only 1.9 percent when compared global giants' expenditure of 10-16 percent[30], this division may be considered tenuous at best. However, it may well become more rigidly tiered in the new patent regime, especially since some Indian pharmaceutical companies (for instance, Ranbaxy and Cipla, to quote just two companies) are now making major investments in R&D[31].

- *Domestic Companies and Multinational Companies*

As has been mentioned previously, domestic companies dominate the pharmaceutical industry in India, while the MNCs' market share is currently around 23 percent

[27] Supra n. 8 at p. 5
[28] Supra n. 10 at p.191
[29] Supra n. 16 at p. 4
[30] *Pharmaceutical Industries in India* available at http://www.economywatch.com/business-and-economy/pharmaceutical-industry.html. Also see, supra n. 12
[31] Padmashree Gehl Sampath, *Economic Aspects of Access to Medicines after 2005: Product Patent protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry* , CIPIH, WHO, 2005, p. 26

only[32]. Of the top ten companies in India today, only two are MNCs[33]. MNC market presence is, however, expected to grow now in view of the introduction of the new patent regime[34].

Table 2.1: Top ten companies in the Retail Pharmaceutical Market
1. Cipla
2. GlaxoSmithKline (MNC)
3. Ranbaxy
4. Nicholas Piramal
5. Sun Pharma
6. Dr. Reddy's
7. Zydus Cadila
8. Aristo Pharma
9. Abbott India (MNC)
10. Alkem Labs
Source: ORG-MARG, 2004

Growth of the Pharmaceutical industry

As per an estimate by McKinsey & Co., the pharmaceutical industry in India has an unique and exciting opportunity to grow from about US$5.5bn in 2000 to US$25bn in 2020[35]. The industry has grown substantially over the last three decades. The Indian generic market in particular is witnessing rapid growth with the opening of tremendous opportunities for firms. The industry's export performance is steadily rising. Aggregate numbers, for about 50 of India's top pharmaceutical companies, show that they get over a third of their sales from overseas markets[36].

Table 2.2: The Key Statistics of the Indian Pharmaceutical Industry

	Growth Indicators		
	US$mn		Growth %
	1965-66	1999-2000	CAGR
Capital Investment	31	549	9
Production			
-Formularies	33	3508	14
-Bulk Drugs	4	830	17
Import	2	756	19
Export	1	1457	25
R&D Expenditure	1	70	14

Source: Nitya Nanda and Amirullah Khan, *Competition Policy for the Pharmaceuticals Sector in India*, Academic Foundation, in Pradeep Mehta (ed.), Towards a Functional Competition Policy for India, 2004, p. 189.

The Competition Aspects of the Pharmaceutical Industry

The competition aspects of the pharmaceutical industry are very distinct from those in most markets. There are certain unique characteristics of the pharmaceutical industry, which account for a distinctive competition scenario, although this is pertaining to

[32] Supra n. 16 at p. 18-19
[33] Ibid at p. 20
[34] Supra n. 8 at p. 4
[35] Supra n. 10 at p. 191

primarily the formulations sector and not the bulk drugs industry. The bulk drugs sector has archetypal competition primarily due to two reasons. Firstly, there are a large number of players with none enjoying market dominance, and secondly, the sector is characterized by a homogenous product range[37]. In addition, the buyers from the bulk drugs sector being pharmaceutical companies are very aware consumers and there is less scope for the prevalence of anti-competitive practices. All three of the aforementioned characteristics of the bulk drugs industry are conducive to free and fair competition.

Market Concentration

The organised sector (which is primarily responsible for the formulation production in the country) comprises 250-300 players[38] and accounts for 70 percent of the industry in terms of value[39], with the largest player having a market share of approximately 6 percent[40]. The top ten companies account for 30 percent of total sales. The individual market shares of companies are small. However, this does not mean that there is intense competition in the market. This is because pharmaceutical products are not single homogenous goods, and there are several "relevant markets" within the industry. These 'relevant markets' are termed as therapeutic segments. There are high levels of concentration in some of the segments as demonstrated by the following table, which provides an overview of the major therapeutic segments in the Indian pharmaceuticals sector. These segments account for nearly 80 percent of the domestic formulation market[41]

[36] *Pharmaceutical companies venture into Export Markets*, 2004, available at http://news.indiamart.com/news-analysis/pharmaceutical-compa-7195.html
[37] See generally, Supra n. 16 at p. 15
[38] Supra n. 10 at p.189
[39] Ibid at p.191
[40] Supra n. 10
[41] Ibid at p. 192

Table 2.3: The Nature of Competition in Different Therapeutic Segments

Product category	Patent Coverage	DPCO Coverage	Market size and growth (per anum)	Players	Comments
Analgesics & Anti-pyretics	Most of the popular drugs like Aspirin, Analgin and Paracetamol are off-patent.	High	Rs.4bn and growing at 17-18%	Major players in formulations are Burroughs Wellcome, SmithKline Beecham, Hoechst and Wockhardt. A large number of local players	Margins are low
Antacids and Anti-ulcerants	Large number of new under-patent molecules, due to ongoing R&D on developing more effective ways to combat acidity/ulcers	High	Antacids: Rs1.8bn, growing 8-9%. Anti-ulcerants: Rs2.3bn growing at 17-18%	Antacids: Knoll and Parke Davis. Anti-ulcerants: Glaxo, Cadila, Ranbaxy, Dr Reddy's Labs etc.	
Antibiotics	The earlier generation drug groups such as Penicillins (eg Amoxycillin) and Macrolides (eg Erythromycin) have mostly gone off-patent. Newer generation groups like Quinolones (eg Ciprofloxacin) and Cephalosporins (eg Ceftriaxone) are still largely under patent	The latest generation drugs	Rs21.6bn and is growing at 13.5%.	Glaxo, Ranbaxy, Cipla, Hoechst, Alembic, Burroughs Wellcome, Ambalal Sarabhai etc.	A vast range of drugs
Anti-tuberculosis products	All popularly used drugs are off-patent.	Only Rifampicin is covered	Rs2.9bn, growing 11%.	Lupin (dominant), Hind. Ciba., Cadila, Glaxo and Hoechst	
Anti-parasitic & Anti-fungal products	Most of the popular drugs are off-patent.	Relatively low	Rs3.9bn and growing at 19-20%	Anti-protozoal: Nicholas Piramal[42], SmithKline Beecham Pharma, Ranbaxy, and Cipla. Anti-fungal: Bayer, Fulford, Glaxo etc.	Presence of a multitude of players keeps margins low.
Cardiac Therapy	New drugs are continually introduced by TNCs abroad. However, most of the drugs popularly used in India are off-patent.	Low	Rs5.6bn and is growing 17-18%.	Sun Pharma, Torrent, Cadila, ICI etc.	The world's top therapeutic segment. Share of TNCs is relatively low.
Corticosteroids	All drugs popularly used in India are off-patent.	Key drugs Betamethasone and Dexamethasone	Rs3.6bn, growing 16.5%.	Glaxo, Crosslands, Wyeth, Fulford, Merind. etc.	TNCs have been dominating but now local players are increasing their presence.
NSAIDs, Anti-rheumatic	All major drugs used in India are off-patent	High, due to inclusion of major	Rs5.2bn, growing at 15%.	Knoll, Roussel, Hind Ciba, Pfizer etc.	Local players have higher

Product category	Patent Coverage	DPCO Coverage	Market size and growth (per anum)	Players	Comments
products		drug, Ibuprofen			presence in topical formulations.
Respiratory System ailments	Very low.	Very low.	Cough & cold formulations market: Rs5.6bn (75% are anti-cough preparations), growing 24.5% Anti-asthmatics: Rs2bn, growing 15.5%.	Anti-cough: Pfizer, Parke Davis, Nicholas Piramal. Anti-cold: Burroughs, Alembic etc. Anti-asthmatics: Cipla (dominant)	
Vitamins	All drugs are off-patent	Very high	Rs5.7bn growing 14%.	E-Merck, Pfizer, Glaxo, Abbott etc.	Local players have poor presence in the segment.

Source: *Report on the Pharmaceutical Sector in India*, Presented to International Trade Centre, Geneva, CII, 2000.

It is clear from the collated data in Table 2.3 that in the case of many drugs, there are only a few large suppliers in a particular therapeutic category. Many of the drugs mentioned in Table 2.3 are off patent. But in the case of patented drugs, with the patent-holder companies exercising monopoly rights over those drugs, substitutability is often close to zero, especially after the implementation of TRIPS. Now a manufacturer cannot produce a rival's drug even through a different process since the product patent regime is in place.

In addition, there are other factors as well, which enhance concentration in the market, or at least in a particular therapeutic segment and consequent profits for individual companies. These factors include brand loyalty (of not just consumers, but more importantly of doctors as well) and packing the product space (by producing a wide range of products with similar therapeutic qualities), as well as the requirement of millions of dollars to research and develop new drugs. [43]

Apart from this aspect of distinctive competition in the formulations market, the prevalence of other skewed competition norms prevailing in the sector must also be considered.

[43] Competition News, 5th Edition, 2001.

The Barriers to Effective Price Competition

In a normal product market, firms try to boost sales, and consequently, profits, by reducing prices. Competition between firms to provide the highest quality product for the lowest price ensures efficient allocation of resources in the economy. It also means that the benefits of increased efficiency are shared between consumers, in the form of lower prices and higher quality; and firms, in the form of profits. However, this is not the case in the pharmaceutical sector with specific reference to formulations.

The very essentiality of the product being sold, namely medicines, is facilitative to distortion in competition in the pharmaceutical market. Consumption patterns are not affected by prices and, therefore, firms do not have any incentive to keep prices low. In developed countries consumption patterns usually remain unaffected not just because of the essentiality of the product, but also because drug consumers are not directly impacted as such, as they are usually covered by either private or public insurance. In many countries, it is the government that bears most, or all, of the costs of medicines, which may result in reasonable drug pricing, since as a monopsonist, the government may be able to control drug prices, at least to some extent, and prevent drug companies from exploiting the market. However, in India and most developing countries, the situation is quite different. Majority of people are covered neither by public nor private insurance. The coverage of public provisioning of healthcare services and medicines is also limited.

However, this does not imply that pharmaceutical companies compete with each other through prices in developing countries. Instead they compete through innovation. Product markets for drugs – defined by 'therapeutic classes' (medicines with the same therapeutic purpose) tend to be highly concentrated, with one or two firms accounting for the bulk of sales in each sector.

Consumer Choice –The Dependence Involved

Another issue of vital importance is that consumers of formulations are very often not the decision-makers. They are for the most part guided by instructions from their doctors and pharmacists. The significant role assumed by the doctors and pharmacists

in influencing drug sales, leads to manipulation of the system, with drug companies seeking to exploit this influence, sometimes via huge incentives. Such practices result in patients being misled into purchasing more expensive medicines, or the prescribing of irrational (or combinations of) drugs, which may lead to medical complications, sometimes even causing death. This vitiated guidance on the part of the doctor deprives patients from availing the best possible products at the lowest possible prices, which is a basic competition principle. Empowering consumers is a task fraught with difficulties, since medicine is a highly specialized field in which miscalculations in the decision making process may lead to severe repercussions on health. These are issues, which are more extensively explored in subsequent chapters.

Anti-competitive Practices

A number of anti-competitive practices pervade the pharmaceutical industry worldwide including in India. Such practices include, amongst others, collusive activities, merger and acquisition related anti-competitive practices and abuse of dominance. To contain the distorted competition in the pharmaceutical industry practically all countries in the world have mechanisms to regulate the industry, particularly drug prices.

In the Context of Access to Medicines

Skewed competition notwithstanding there is no doubt as to the technological sophistication, entrepreneurial flair and export success of the pharmaceutical industry. But in the context of one yardstick, namely, the contribution of the pharmaceutical industry in facilitating access to drugs, despite significant contribution by the industry, the overall situation has been disappointing. As mentioned previously, only some 35 percent of Indians can access essential drugs. There are a number of factors, which would account for the lack of access to drugs. However, accountability lies with the industry as well. The health delivery system shares a large part of the responsibility for ensuring access to affordable medicines and healthcare to the people and will be briefly examined hereafter.

The Health Delivery System

India currently has a vast infrastructure in place for primary, secondary and tertiary healthcare in government, voluntary and private sectors. This infrastructure serves a population of over one billion, growing at about two percent annually[44].

A broad definition of the health delivery system would encompass a complex tiered structure comprising of multiple establishments and a range of personnel in diverse designations. However, for the purpose of this report, the health delivery system shall be considered to consist of four components only, namely, doctors, hospitals, diagnostic laboratories and pharmacists, not only since these are the vital elements of the system, but also because anti-competitive practices are comparatively more prevalent in their domain than in other segments of the health delivery system.

The following[45] gives an approximate estimate of the numbers involved in the health delivery system:

- 15,000 hospitals,
- 875,000 hospital beds
- 633,108 doctors (1 for 1676 persons) with 18,000 new every year
- 350,000 retail chemist outlets
- 25,400 diagnostic laboratories[46]

How far has India traversed in improvement of healthcare delivery? What have been the key milestones in fashioning the health delivery system as it stands today? Are there structures and practices prevalent in the system, which are conducive to anti-competitive conduct? These are questions, which have been addressed herein.

A Brief History

Health care facilities and personnel increased substantially between the early 1950s and early 1980s. Due to fast population growth, the number of licensed medical practitioners per 10,000 individuals had fallen by the late 1980s to three per 10,000 from the 1981 level of four per 10,000. Today however, there are approximately six licensed practitioners per 10,000 people. The fast pace of development of the private medical sector and the burgeoning middle class in the 1990s have led to the

[44] Healthcare, Ernst & Young, p. 2, available at http://www.indianembassy.at/content/india/documents/Healthcare.pdf
[45] Ibid

emergence of a new concept in India of establishing hospitals and health care facilities on a for-profit basis.[47]

Two events in the history of the health delivery system are of particular significance:

- During the mid 1980s, the government formally recognised private healthcare as an industry and offered several incentives to private players such as land allocation at subsidised rates for new hospital projects and reducing import duties on medical equipment[48].
- The health insurance market was opened up to private competition for General Insurance Corporation's mediclaim in April 2000. Both general and life insurance companies can now offer health insurance[49].

Nature of the Health Delivery System

The Indian healthcare delivery market (overall and not just the four elements singled out for this study) is estimated at US$18.7bn and is growing at about 13 per cent annually, with market forecasts predicting a growth at 15 per cent over the next four to five years[50].

It may be mentioned, in India, more than 50 percent of the total health expenditure comes from the individual, as against state level contribution of below 30 percent.[51] Currently only about 0.2 per cent of the population are covered under voluntary medical insurance.[52] The insurance aspect of the health delivery system is very important, being inextricably linked with a number of competition related issues, as will be discussed in subsequent chapters.

Of late, India is becoming a preferred healthcare destination for neighbouring countries and the West due to low cost and high quality of treatment available, giving rise to the phenomenon of medical tourism in the country[53]. Estimates predict that at its current pace of growth, healthcare tourism alone can bring in over US$2bn as

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[46] A study conducted by Speciality Ranbaxy Ltd (SRL,) gives this figure.
[47] *Health Care in India-Primary Services*, available at http://www.indianchild.com/health_care_in_india.htm
[48] Supra n. 44 at p. 3
[49] Ibid
[50] Ibid at p. 6
[51] *The Indian Healthcare Sector* available at www.ambnewdelhi.um.dk/NR/rdonlyres
[52] *The Indian Health Care Industry* available at http://www. directories-today.com/health_care.html
[53] Ibid

additional revenue by 2012.[54] While this will enhance the growth prospects of the industry, it may have significant trade-offs in the form of increased costs of healthcare, which in turn will affect access to healthcare.

The components of the health delivery system may be classified on the basis of diverse criteria, which are mainly confined to the following:

Urban and Rural

The health delivery system is heavily tilted in favour of the urban and semi-urban areas. Of concern is the abysmal quality of services provided at the rural periphery by a large number of unqualified persons. One survey by the Ministry of Health and Family Welfare in eight middle-ranging districts revealed a highly skewed distribution of resources, with 88 percent of towns having healthcare facilities compared to 24 percent in rural areas.[55] The scope of this paper is primarily limited to the health delivery system in the urban areas, as information pertaining to rural areas is not readily available and would need large-scale primary survey to be conducted. In any case, most facilities are located in urban areas, and even people from rural areas use these facilities.

Public and Private

Nearly 65 percent of the healthcare services market has been captured by the private sector.[56] The private sector today has gained a dominant presence in all the submarkets of the healthcare delivery system. Currently, private sector health services range from those provided by large corporate hospitals, smaller hospitals, nursing homes and clinics run by qualified personnel.

The aforementioned survey conducted by the Ministry of Health and Family Welfare reveals that 75 percent of the specialists and 85 percent of the technology are in the private sector. 49 percent of the hospital beds were in the private sector but bed occupancy is only 44 percent against 62 percent in the public sector.[57] A recent CII-

[54] Supra n. 44 at p. 20
[55] Supra n 6
[56] Supra n. 44 at p. 6
[57] Supra n 6

McKinsey study predicts that in 2012, the healthcare market may well be estimated at US$45bn. Private healthcare is expected to account for 75 percent of this spending.
The scope of this report extends to examining both the public and private health delivery systems. Anti-competitive practices may be found in both the private and public sector with the difference that the practices in the private sector are mostly institution-driven, while in the public sector, the practices stem from individual corruption. This conceivably is because of the varying approaches of the two sectors, the private sector being motivated by profit and the public sector being welfare oriented.[58]

The structural and growth aspects of the health delivery system having been briefly overviewed, certain functional aspects of the healthcare delivery market may now be examined.

Market Dynamics

As in the pharmaceutical industry, the health delivery system is also characterised by a market failure uncommon in other markets, that is, consumers are mostly not involved in the decision making process of their purchase of goods and services, which in this case are medicines and healthcare facilities. Patient choices are dictated mainly by doctors, pharmacists or hospital staff.

In the health delivery system, however, the matter extends beyond just medicines, to healthcare facilities and diagnostic testing, with a similar impact on competition. For instance, a doctor may send a patient to a particular diagnostic centre in return for incentives received in the form of a commission and patients may end up paying higher fees for testing than if they had gone elsewhere. Such instances shall be discussed in more detail in the next chapter where specific anti-competitive practices in the pharmaceutical sector and the health delivery system shall be highlighted.

In all matters, patients tend to rely on the advice of the medial establishment. It is to be reiterated that such reliance is expected and indeed necessary in the complex field

[58] From interview with Dr. Barun Kanjilal.

of health. However, this excessive dependence of the consumer does render the health delivery system vulnerable to misuse by the players in the system.

The above market distortion apart, anti-competitive practices, which may be commonly found in other markets, pervade the health delivery system as well. Such practices would include, among others, collusive activities, specifically price fixing and promoting of irrational drug use and abuse of dominance.

In the context of the access to healthcare

The health delivery system in India is a study of contrasts. An excellent growth rate and the promise of becoming an international destination for healthcare belie statistics citing that a very low percentage of the Indian population can access healthcare facilities. This anomaly is due to the industry's growth and expansion being skewed and confined mainly to the private sector, in that the growth registered is confined mainly to big hospitals and private urban facilities which are accessed mostly by the elite section of the society. The private sector is flourishing in sharp contradistinction with a highly inadequate and inefficient public sector.

The public sector although welfare-oriented is not remotely equipped to handle the mammoth task of efficient health delivery to millions of Indian citizens. Is the situation set to improve? The market reports, which provide encouraging estimates of growth of the health delivery system, concern the private sector. There is no indication at the moment, of substantial growth in relation to the public sector. The private sector's continued growth and the stagnation of the public sector may very well end up in there being an overall increase of prices and diversion of budget allocation making it more difficult for government concerns to remain competitive, worsening thereby, the access to healthcare situation.