IDENTIFICATION OF COMPETITION ISSUES IN THE HEALTHCARE SECTOR IN INDIA

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Abstract

Competition Law is vital to the efficient functioning of markets in a free market economy. In the absence of such laws or policies there may be either anti competitive practices prevailing or lack of an incentive mechanism to promote competition. The healthcare sector comprising of hospitals and allied services such as medical education, equipment, diagnostics and pathological laboratories and medical insurance is a complex market, distinct from other sectors. Its distinct nature arises because of the asymmetries of information in this sector. Usually it is the doctors and pharmacists who are the final decision makers and not the consumer for the latter lacks medical knowledge.

There are a number of issues in the healthcare sector that may curb or foster competition. For instance consider entry barriers created by the regulatory framework in the medical education sector thereby restricting effective competition and thus effecting the quality of medical education. Similarly absence of an effective regulatory body in hospitals/nursing homes leaves the question open about the quality of services delivered in this segment. Thus policies can often restrict or promote competition. Besides these there are also issues of anti competitive practices prevalent in the sector. Practices on the part of doctors, pharmacists, hospitals and pharmaceutical firms can often be to the detriment of consumers. Issues of tied selling, exclusive supply and distribution agreements etc. have come up in nations across the world however the challenge posed in most of the cases is establishing a practice to be an anti competitive under the relevant competition law. The informational barrier in the healthcare sector makes it difficult to identify whether the act is anti-competitive or not. It has been a matter of debate in several nations whether the competition law is applicable at all to the healthcare sector or not, owing to the peculiarity of the sector. One argument favouring competition law in the sector goes on to say that competition law is not harmful since it aims at protecting the patient. However the argument against it goes on to say that competition does not affect this sector as it effects the other sectors.

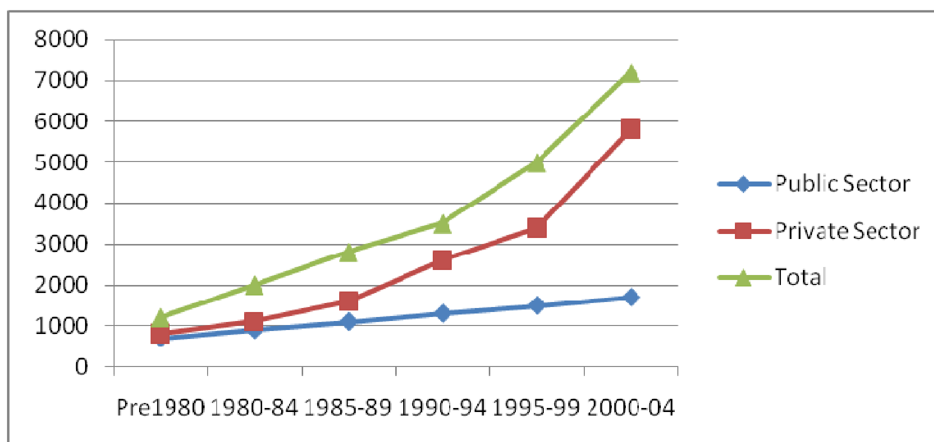
This paper seeks to identify the various competition related issues and anti-competitive practices in the Indian Healthcare Sector. Compared to various other nations the Indian population has one of the lowest insurance coverage thus the issues that affect the Indian healthcare sector are often to be much different. A look at the Competition Act,2002 shows that several practices are in fact in the purview of the competition authorities however the hurdle is in identifying these practices at the micro level.

CHAPTER 1

THE INDIAN HEALTHCARE INDUSTRY

The Healthcare Sector in India comprises of hospitals and allied sectors such as; diagnostics and pathology, medical equipments and supplies, medical tourism and private medical insurance. According to YES Bank and ASSOCHAM Report, from the current estimated size of US $35 billion it is projected to grow at 23% p.a. to touch US$77 billion. During the period 2000-09, the sector has registered a growth of 9.3%, comparable to the sectoral growth rate of other developing nations such as China, Mexico and Brazil. According to the report, the growth of the sector will be driven by healthcare facilities in private and public sectors, medical diagnostic centres and pathlabs and the medical insurance sector.

The share of private expenditure as to the total expenditure on health has grown from about 60% to almost 80% over the last decade. The current share of public expenditure on health is 20%. With a view to raise government expenditure on health as a proportion of GDP from 0.9% to a target of 2-3 % by 2012 and the government launched the National Rural Health Mission [NRHM] in 2005. At present the central government and the state governments cumulatively contribute 0.34% and 0.56% of GDP respectively to healthcare and related services.



GROWTH OF PUBLIC AND PRIVATE FACILITIES, INDIA

There are an increasing number of private players changing the nations' health delivery landscape beyond recognition. New hospitals are mushrooming even in Tier II and Tier III Cities and leading healthcare entrepreneurs with deep pockets are expanding their empires, often overseas. At the root is the new age patient who is ready to undertake the best possible treatment that money can buy. State of art technology, wonder drugs and five star facilities are now the hospital mantra. It is booming industry both in terms of

revenue and employment. Currently the industry employs over 4 million people making one of the largest service industries in the economy.

The key issues driving growth in the healthcare industry have been identified as follows:

1) *Population Growth*- this is the prime driver of growth in the healthcare sector. With the population currently at 1.1 billion and increasing at the rate of 2% p.a., it is estimated that by 2050 the population will reach 1.6 billion.[1] This massive population is due in part to a decrease in infant mortality (in turn a result of better medical facilities and government emphasis on eradicating diseases such as hepatitis and polio among infants), a general increase in life expectancy, greater affluence among people and better hygiene. This way a growing elderly population will soon place an enormous burden on India's healthcare infrastructure.
2) *Expanding Middle Class*-Parallel to India's thriving economy is rapid urbanization and creation of an expanding middle class with more disposable income to spend on healthcare. With women entering workforce, purchasing power and thus affordability has increased and people can buy western medicines.
3) *Rise of Disease*-Two kinds of diseases are largely prominent among people these days-one is communicable diseases and the other chronic degenerative diseases. While infectious/communicable diseases such as polio, hepatitis, tuberculosis, pneumonia were thought to have been brought under control via the extensive government programmes however now they seem to have resurfaced or have developed a rather stubborn resistance to drugs. Another problem that seems to be on the rise these days is AIDS. Among the urban population there have been a significant number of health problems which may be called lifestyle diseases. Unhealthy diets, sedentary work and affluent lifestyle has given rise to hypertension, cancer, diabetes, obesity etc. Lifestyle disorders are expected to grow in the future at a faster rate than infectious diseases in India and to result in an increase in cost per treatment.
4) *Medical Tourism*-With specialty and super specialty hospitals equipped with the latest equipment and the best surgical procedures at relatively inexpensive charges on the rise has made India a hub for people from the west to get treatment here-giving birth to a concept called Medical Tourism. With the healthcare costs increasing in many developed nations and the time for waiting for a procedure also increasing, especially in Britain, it is expected that the medical tourism industry will grow.

[1] IBEF(verify)

The Public Healthcare in India

The public health infrastructure of India has grown since independence, but it is yet to match the basic healthcare facilities in many other countries. While in 1947 the number of hospital beds was 3.2 per 10,000, the present number of 9 per 10000 is commendable, but still far behind those of other developing countries. The healthcare system consists of primary, secondary and tertiary healthcare centres, and the focus of public healthcare has been on Primary healthcare [NRHM] as well as centres providing healthcare services and education.

Health is a state responsibility, however the central government does contribute in a substantial manner through grants and centrally sponsored health programs/schemes. Various public health schemes taken out by the central government include the Rashtriya Swasthya Bima Yojana which provides health insurance to poor families who are unable to afford medical care or hospitalization or cannot afford private medical insurance. As a part of the public healthcare scheme, there are a number of hospitals who offer free services to the poor who are unable to pay for their treatment.

Drawbacks of the public health system:

1) There is a fragmented approach since the conceptualization and planning of the all the programs is centralized and the specific needs of the local area are not taken into account.
2) Accessibility, utilization and acceptability of the programs is low because the infrastructure set up by the government is based on population norms rather than habitation.
3) There is a gap between the demand and supply of human resources thereby causing people to waste time waiting in queues for treatment or consultation.
4) Though there is implementation of infrastructure but the quality of service offered is not consistent.

Private Healthcare in India

Compared to nations such as EU and Japan where major spending in healthcare sector comes from the government India is an exception here insofar that it has one of the highest private spending on healthcare. With a significant proportion of the Indian population still below the poverty line public facilities are largely to cater to this segment however in the urban and sub-urban areas private healthcare facilities are preferred. With rising income levels and exposure to international standards/ quality has raised the demand for quality private healthcare facilities.

The private health sector consists of the 'not-for-profit' and the 'for-profit' health sectors. The not-for-profit health sector includes various health services provided by

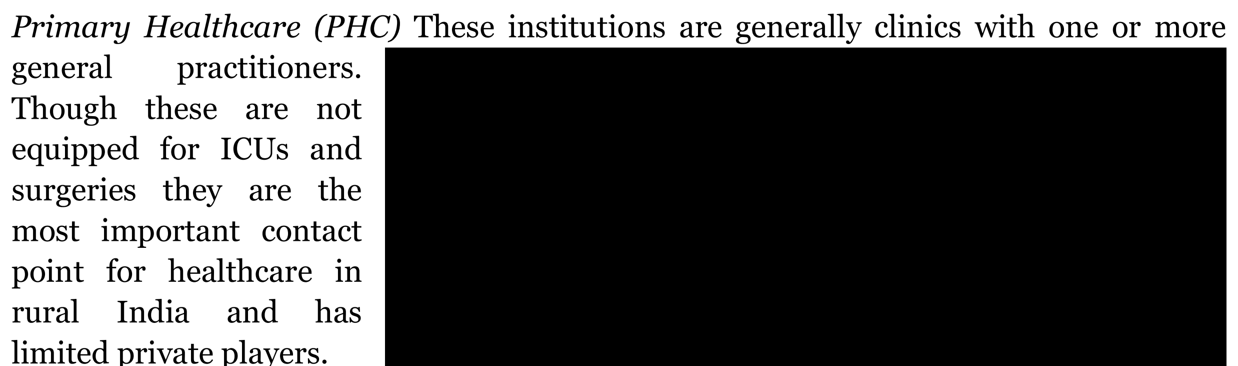
Non Government Organisations (NGO's), charitable institutions, missions, trusts, etc. Health care in the for-profit health sector consists of various types of practitioners and institutions. The licensed practitioners range from general practitioners (GPs) to the super specialists, various types of consultants, nurses and paramedics, licentiates, and rural medical practitioners (RMPs).

The out-of pocket spending on healthcare by Indians is one of the highest, constituting 94% of the total spending in the private health industry.[2] Out of pocket is the direct outlay of households, including gratuities and payments in kind, made to health practitioners and suppliers of pharmaceuticals and other goods and services, intended is to contribute to the restoration or to the enhancement of the health status of individuals or population groups.[3] According to estimates an average household contributes 4 -6% of its household income to healthcare with close to 80% going to the private sector.

The advantage to the private sector comes from little government interference and unlike many developed nations, the healthcare policies do not work on a reimbursement model. The widespread demand for quality healthcare has resulted world class quality of such facilities at cost competitive rates. Although health insurance is still in its infancy and has not percolated to all sections of the society but it has been predicted that with more complicated services being offered and increased demand for better quality, the insurance sector will boost the private healthcare market.

On the basis of infrastructural requirements and the types of services offered hospitals can be broadly classified into the following categories:

Primary Healthcare (PHC) These institutions are generally clinics with one or more general practitioners. Though these are not equipped for ICUs and surgeries they are the most important contact point for healthcare in rural India and has limited private players.



Nursing Homes can have one or more doctors and at least 20 beds. There are various types of nursing homes such as ophthalmic, orthopeadic, cardiac, dental clinics, Ear Nose Throat (ENT) clinics and maternity homes.

Secondary Care Hospitals are bigger hospitals with typically 100-300 beds with surgical wards and ICU facilities. They can be further classified as general hospitals and specialty

[2] Source:WHO

[3] Healthcare Services in India 2012:The Path Ahead-Report by YES Bank and ASSOCHAM

hospitals. While general hospitals offer inpatient facilities along with radiology, emergency care, general surgery and a few departments such as obstetrics, paediatrics, gyneacology etc. and dedicate 10% of their beds to ICU use. On the other hand specialty care hospitals, apart from general hospital departments also offer at least one specialty care such as cardiology, neurology, dermatology etc. Moreover these hospitals dedicate 25% of their beds to ICU usage. There are secondary care hospitals in certain cities but none have pan India presence. Examples include-Manipal Specialty Hospital, Bangalore.

Tertiary Care Hospitals have around 300 beds and doctors offering top of the line facilities in specific specialties. Examples include Sankara Nethralaya (Chennai), Escorts Heart Institute and Research Centre (New Delhi), National Institute of Mental Health and Neuro Sciences (NIMHANS)etc. While these are single specialty hospitals there are multi specialty tertiary hospitals as well which offer a number of specialty services under one roof. Some prominent examples are the Manipal Hospital, Bangalore and Max Hospital, Noida.

Quaternary Care Hospitals are tertiary care hospitals offering super specialty surgical procedures including advanced cardiac, joint replacement, neurological etc. Osmania General Hospital (Hyderabad) and Apollo Children's Hospital (Chennai) are examples.

PUBLIC PRIVATE PARTNERSHIP (PPP)

Recognizing the increasing demand for better quality of healthcare, the government has devised a strategy for health development through public private partnerships. With the objective to improve the health of the population PPPs are seen in the context of viewing the medical sector as a national asset with health promotion as a goal of health providers public as well as private.

The utilization of hospital services in public and private sectors varies greatly from one state to another. The private sector has provided useful contribution in improving the healthcare provision besides the role of the public sector in of the states of Kerela and Tamil Nadu .The private sector too is keen to enter into PPP since it's the easiest route for them to enter into the market as well as to expand in lesser time. Since private players are faced with infrastructural constraints thus entering into PPP serves their purpose through leveraging public assets.

Models for Partnership:

Franchising: In such a model the franchiser develops specialized skill, knowledge and strategies for franchisees who in return contribute resources of their own to set up a clinic and pay membership to the franchiser.

Contracting Out: In this model the private providers receive a budget to provide certain services and manage a government health unit. The parties concerned agree on the quantity, quality and the duration of the agreement.

Contracting In: The government hires an individual on a temporary basis to provide services such as maintenance of buildings, utilities, housekeeping, meals, medicine stores, diagnostic facilities, communications etc.

Build, Operate and Transfer (BOT): BOT requires financing of projects by the government, financial guarantees, subsidized land and assurance of reasonable returns on investment. These models are useful for establishing large hospitals.

Joint Venture Companies: Companies launched with equity participation from the government and the private sector. This model has not succeeded in India due o the lack of understanding, trust, and appropriate governance.

Examples:

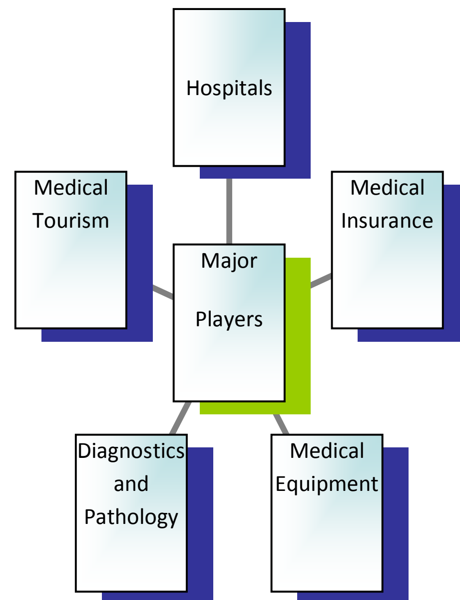
The Rajiv Gandhi Super Specialty Hospital at Raichur, Karnataka is the result of a partnership between the Government of Karnataka with Apollo Hospitals Group with the financial support from the OPEC Fund for International Development. It has a mission to provide low cost specialty care to families below the poverty line.

The Uttaranchal Mobile Hospital and Research Centre is a three way partnership among the Technology Information, Forecasting and Assessment Council (TIFAC), the Government of Uttaranchal and the Birla Institute of Scientific Research (BISR) with a motive to provide health care and diagnostic facilities to poor and rural people at their doorstep in difficult and hilly terrains.

However there still remain a number of challenges faced by PPPs. A major reason for this lies in the gap between the priorities between the government and the private sector. Moreover operational and structural issues also act as a deterrent for the private players to enter a PPP such as lack of enabling infrastructure, project management, shared decision making, lack of appropriate governance and accountability for delayed payments by the Government.

Allied Health Services:

Diagnostics and Pathology



Parallel to the healthcare industry growth, the Indian diagnostics and pathology testing market is set for steady growth. The market is valued at close to INR 6000Cr in 2008 and is growing at 20% per annum. The industry is highly fragmented and encompasses over 40000 laboratories, very few of which are accredited. These include:

- Pathological laboratory chains (corporate laboratories)
- Regional laboratories
- Hospital run diagnostic facilities

While there is a high demand for clinical pathological tests however the rampant supply leads to intense competition with respect to pricing, which directly has an impact on profitability. The advent of new techniques has stimulated the need for more accurate and wider test parameters and laboratories are trying to differentiate themselves by offering specialized services. Key players include SRL Ranbaxy, Dr. Lal Path Labs, Apollo Clinics and Piramal Diagnostics.

Medical Equipments

The Indian market for medical equipment and supplies estimated at US$2.7 billion has been ranked among the world's top in 20 in 2009. Out of the total market size of India, more than 85% equipment is imported from other countries. The Indian companies with strong domestic presence in this sector include Medived innovations, Opto Circuits, Trivitron Healthcare etc. These companies manufacture niche products with international accreditations; they are mostly export oriented rather than supplying the Indian market.

Medical Insurance

The recent liberalization of the Indian healthcare sector has led to the emergence of a much needed health insurance industry. Post 1991, with the passing of the Insurance Regulatory Development Authority Bill (IRDA) the insurance sector was opened to private and foreign participation, thereby paving the way for the entry of private health

insurance companies. The Bill also facilitated the establishment of an authority to protect the interests of the insurance holders by regulating, promoting and ensuring orderly growth of the insurance industry.

In India, the penetration of insurance remains very low, with only about 10% of the population having some sort of health insurance coverage in 2007-08. However in the private sector the no. of insured account for only 3.5% of the population.[4]

Major insurance companies offering health insurance schemes in the private sector include Bajaj Alliance, ICICI, Royal Sundaram, Cholamandalam. Public Sector companies including New India, United India, National Insurance and Oriental Insurance have a combined market share of 62%, of which New India Assurance has the largest market share of 24%. ICICI Lombard has the second largest market share of 17%.

Over the years however the rising costs of healthcare and the prospering middle class has supported a significant increase in the average household consumption in healthcare. This has stimulated a greater awareness of the benefits associated with insurance coverage.

Medical Tourism

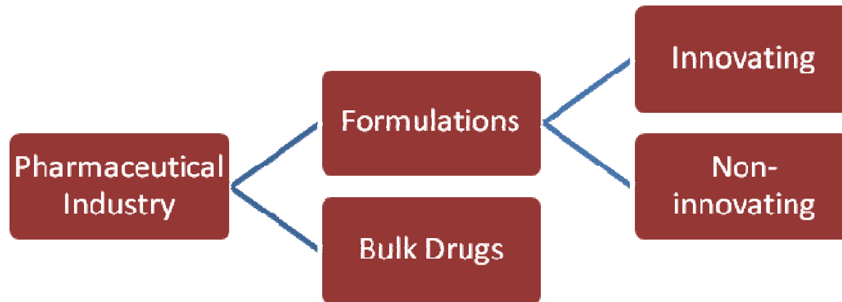
This is a developing concept where people from all over the world come to India for their medical and relaxation needs. India is becoming a hub for medical treatment owing to its low costs and superior quality of services. The most common treatments include knee transplant, heart surgery, cosmetic surgery and dental care. Studies have in fact indicated that with an increasing number of foreign patients coming in, India could make Rs. 100 million through medical tourism by 2012.[5]

Pharmaceutical Industry:

As one of the leading industries in India, the Indian Pharmaceutical Industry represents 8% of the global total industry by volume and 13% by value.[6] The “organized” sector of India's pharmaceutical industry consists of 250 to 300 companies, which account for 70% of products on the market, with the top 10 firms representing 30 %. India’s a leading producer of generic drugs and at the domestic level is self-reliant as it meets

[4] Healthcare Services in India 2012:The Path Ahead; ASSOCHAM and YES Bank report (2009)
[5] http://www.medical-tourism-india.com/medical_tourism_articles.htm
[6] http://www.kpmg.com/IN/en/WhatWeDo/Industries/Documents/IM/Indian%20Pharma%20Outlook.pdf

95% of the country's pharmaceutical needs. Some of the leading brands in the retail pharmaceutical market are Cipla, Ranbaxy, GlaxoSmithKline, Nicholas Piramal, Sun Pharma, Zydus Cadila etc.



The pharmaceutical industry is roughly divided into formulations and bulk drugs. Firms specializing in pharmaceuticals may be further classified as innovating and non-innovating. Innovating firms are those which engage in research and development of new medicines and the firms which do not do so are called non-innovating firms.

India is among the top 5 producers of bulk drugs in the world and has a share of 20% in the pharmaceutical market. The Indian sector produces about 60000 formulations and 400 bulk drugs. The Indian market for over-the-counter medicines (OTCs)[7] is worth about $940 million and is growing 20 percent a year i.e. double the rate for prescription medicines and recent government initiatives have been towards widening the availability of OTCs to outlets other than pharmacies.

The Indian sector is highly technology as well as knowledge intensive and has wide ranging capabilities not only in drug manufacturing but research and development as well. However R&D is not a prominent feature in the domestic industry as the expenditure on R&D stands at 1.9% whereas that of global counterparts at 10-16%. But with the product patent regime now in place some major domestic pharmaceutical companies are making huge investments in R&D. According to ASSOCHAM, the new patent regime will lead to development of innovative new drugs, which will lead to increased profitability for MNCs and also force domestic players to focus on R&D.

[7] Over the Counter medicines are those which can be bought without a prescription. Some of these medicines relieve aches, pains and itches.

CHAPTER 2

THE PRESENT REGULATORY FRAMEWORK

THE PHARMACEUTICAL INDUSTRY

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. 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.

MEDICAL EQUIPMENT

The Indian Medical Devices industry is still largely unregulated.Most importantly quality of medical equipment is still not under the radar of authorities.

The authority principally responsible for regulating medical devices in India, is the Central Drugs Control Organization (CDSCO) under Ministry of Health and Family Welfare (MoHFW). Foreign as well as Indian Companies must register with the CDSCO before the company's products can be introduced into the Indian market. Both the sellers as well as manufacturers have to register with the CDSCO and the Indian importer has to obtain a no objection certificate to import and sell in India. In 2008 the DCG(I) prepared a list of 160 medical devices which require registration.

MEDICAL EDUCATION

The Medical Council of India (MCI) is the regulatory authority for medical education. According to its guidelines only government or trust hospitals can set up education facilities. They also have specifications as to the amount of land required, the number of classrooms, and on their size before the hospitals can actually be set up. For instance, there is a restriction of a 500-bed care unit on hospitals for getting permission to set up training colleges. The healthcare education facility is required at a minimum have a 10-acre campus. However there arise a number of issues since such a framework creates a supply bottlenecks. The Nursing Council of India requires 50 beds minimum and large size campus but trains only 50 nurses while much smaller buildings with 10,000 square feet for example in Singapore are training 500 nurses a year.

Likewise, the Nursing Council of India's regulations are also seen to be arcane. The Nursing Council does not allow private players to enter into nursing education unless they form trusts. Hospitals need to tie up with another organization in order to grant a PG diploma in hospital administration. Again, there are requirements on land and

infrastructure, such as requiring a 500 seater auditorium, 25 acres of contiguous land, conditions which are difficult to fulfill in first tier cities.

MEDICAL INSURANCE

Less than 10% of India's population today is covered by health insurance, either voluntary or as part of the Employees State Insurance, Central Government Health Scheme or Community Insurance. The low share of insured patients is seen as one of the main reasons that healthcare services have not grown as much as they could in India. There is also an allied problem of low awareness about medical/ health insurance. Thus, there is considerable scope for increased market penetration. The growth of the medical insurance industry also depends on the presence of a capable regulator that will through various initiatives boost the penetration of private medical insurance products. For example the IRDA in 2007 eliminated tariffs on general insurance to encourage scientific rating and independent pricing for each line of business so that the premiums are based on actual risks and costs. Currently, the IRDA is focused on standardizing medical definitions to ensure consistent pricing and products and is providing incentives for standalone insurance companies to attract private players into the industry.

HOSPITALS/NURSING HOMES

The government does not have a proper framework to guide the setting up of hospitals and nursing homes. The government does not set benchmarks for service delivery or demand players to comply with basic norms, and also does not do any kind of local or zone based marked needs assessment before allowing new facilities to register. It was noted that without a uniform disclosure policy and sharing of information by hospitals, a mature healthcare delivery system cannot materialize. Government needs to insist on getting proper information from all establishments in order to ensure adherence to norms it lays down. Independent regulatory bodies are required to ensure standards are maintained through frequent audits and disclosure of information. The lack of a regulatory framework for setting up establishments and monitoring their standards adversely affects quality, creates unwarranted competition for manpower, and also results in excess supply of medical facilities in some zones, making some players unviable.

The current private health sector is highly unregulated and there is a need for establishing an accreditation body because of (i) the increased competition in the health sector (ii) no advantage enjoyed by hospitals maintaining certain standards (iii) the realisation that standards needs to be improved and updated and (iv) the emergence of health insurance.The body will ensure quality health care through,

1. assessing hospitals for compliance to set standards,
2. providing assistance to hospitals to upgrade their standards,
3. ensuring proper patient care, and

4. aiding to upgrade standards of hospitals through education, training and consultation.

Accredited hospitals need to be monitored for standards, quality, price and consumer satisfaction.

DIAGNOSTICS AND PATHOLOGY

In India, this industry lacks a regulatory framework and hence has a low entry barrier with the only requirement being registration under the Shop and Establishment Act. The National Accreditation Board for Testing and Calibration Laboratories (NABL) is the sole accreditation body with the criteria assuring accuracy, reliability and conformity of the tests results. Since it is an autonomous body under the Ministry of Science and Technology with limited prowess thus the speed of accreditation is slow and a few laboratories are accredited by NABL or CAP.

CHAPTER 3

MAJOR PLAYERS

Apollo Hospitals Enterprise Ltd.

Apollo Hospitals Enterprise Ltd. was launched as a single hospital in Chennai in 1983 and today it has expanded its global reach with the opening of Apollo Bramwell hospital in Mauritius. Apollo Hospitals secured $50 million worth of loan from International Finance Corporation (IFC), a member of the World Bank Group, to set-up high quality hospitals in remote areas of India and is planning to add 2,000 beds within the next two years for an investment of Rs 1,500 crore to Rs 1,600 crore.[8] Currently it manages a network of 43 specialty hospitals and clinics with a bed capacity of 7543 across country and abroad.
The Hospital chain has recently launched a healthcity in Hyderabad and intends on doing so pan India. It has also tied up with Indian Oil Corporation to set up pharmacies at its petrol stations.

Fortis Healthcare Ltd.

Fortis Healthcare Limited, a leading healthcare delivery company in India was formed with the vision of "creating a world-class integrated healthcare delivery system in India, entailing the finest medical skills combined with compassionate patient care". Fortis Healthcare will acquire nearly 23.9% strategic stake in Singapore-based healthcare group, Parkway Holdings from TPG Capital (formerly Texas Pacific Group), in an off-market deal, estimated to be around USD 685.3 million. The company's net sales and operating profit are expected to grow at CAGR of 28.67% and 48.07% from 2008 to 2011.[9]

Max Healthcare

Max Healthcare operates 18 healthcare facilities in National Capital Region (NCR) of Delhi, has a bed capacity of around 865 beds and is expected to increase to 1,500–1,600 beds in the next few years. Has collaborated with Singapore General Hospital in the areas of medical practices, nursing, paramedical research and training. It plans to raise US$ 85.36 million to expand its hospital.

Narayana Hrudalaya

This super specialty hospital is the first of its kind offering cardiac care facilities and is located in Bangalore. It was set up by the Asia Heart Foundation with the ability to

[8] First Call Research-Sectoral Report: Indian Healthcare Sector
[9] Ibid

perform 25 cardiac surgeries a day. The hospital is based on a model that facilitates social inclusion by charging each patient based on his affordability.

Tertiary Hospitals and Medicities

Large corporations such as the Reliance ADA Group and Aditya Birla Group have entered the industry to capitalize on the attractive growth that corporate hospital chains have been experiencing. The Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute at Mumbai, a tertiary multispecialty hospital has been set up by the Reliance ADA Group. Lately, health cities aimed at catering to larger populations and the medical tourism industry by offering multiple specialties, alternative therapies, research and development centres, educational institutions and residential facilities; have been setup by corporate hospital groups. Dr. Naresh Trehan's Medicity, a large area catering to the medical and recuperative aspects for patients, is an example of health cities in India.

CHAPTER 4

COMPETITION RELATED ISSUES IN THE HEALTHCARE SECTOR

In theory, competition ensures provision of best possible goods and services at the lowest possible prices. It is in the absence of effective competition that efficiency of markets is hampered. Different government policies may encourage or adversely affect competition, and hence consumer welfare, particularly in the context of the present globalising environment.[10]In addition, sector specific policies in various areas such as health, electricity, telecommunications, financial services etc., also affect competition in the economy.

The market for healthcare services is quite distinct in its functioning with asymmetries of information and market power prevailing in the industry .The complexity of the market for health services arises because of three reasons:

- Asymmetry of Information
- Complexity of production-since each patient requires different treatment procedures and standardization of such procedures is not feasible.
- Local market power due to economies of scale and costs of travel-In urban areas there are economies of scale since they cater to a larger segment of the population compared to the rural segment and hence have significant local market power.

It is such complexity of market for health services that makes it even more difficult yet essential to ensure free and fair competition and thus efficiency in the market.

Competition issues in the healthcare sector can be looked upon by segregating them into issues at domestic level and those at international level.

Domestic Issues

Entry barriers to private players in the medical education sector: Until very recently only government and charitable trusts could set up medical colleges. Private players were not permitted by the MCI to start such facilities. This created major supply bottlenecks since there were only about 13500 post graduate vacancies and many students had to go abroad to pursue their post graduation. Moreover the entire approach is infrastructure and volume based rather than value based and does not focus

[10] "Towards a Functional Competition Policy for India: An Overview" Pradeep Mehta, CUTS International.

on quality and functional excellence since the MCI had land requirements and area specifications for the medical colleges.

Ironically, the Medical Council has not permitted corporate hospitals to set up training facilities, which would benefit them and the healthcare sector at large, it has permitted a plethora of substandard private medical colleges, many of which lack basic faculty, equipment, and infrastructure and are unable to provide relevant and quality training. It is only very recently in March 2010 that the MCI has permitted hospital chains such as Apollo Hospitals, Fortis Healthcare and Max Healthcare to start medical colleges in the light of acute shortage of seats for post graduate medical students.

Issues in the Medical Insurance sector: 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. The poor and lower middle class strata of the society cannot afford corporate hospitals while the state of public hospitals is disappointing. Even among the middle class people only those with insurance go to corporate hospitals and the others go to government hospitals or small nursing homes. In India, more than 50 percent of the total health expenditure comes from the individual, as against state level contribution of below 30 percent. Currently only about 0.2 per cent of the population are covered under voluntary medical insurance while 3% to 5% of Indians are covered under any form of health insurance.

The Indian health insurance scenario is a mix of mandatory social health insurance (SHI), voluntary private health insurance and community-based health insurance (CBHI). The main provider of health insurance in the public sector is the government-run General Insurance Company (GIC), along with its four subsidiaries, The New India Assurance Company, Oriental Fire and Insurance Co., National Insurance Co., and The United India Insurance Co. While over 75 per cent of private health insurance is concentrated with six leading players —ICICI Prudential, SBI life, Bajaj Allianz, Reliance Life, Birla Sun Life and HDFC Standard. The existing mandatory health insurance schemes in India—the Employees' State Insurance Scheme (ESIS) and the Central Government Health Scheme (CGHS)—were first started as pilot projects in 1948 and 1954, respectively in the context of achieving universal coverage via the SHI.

The reasons for the lack of penetration of health insurance among the masses:[11]

1. *Lack of regulations or control over provider behaviour*- The unregulated environment and a near total absence of any form of control over providers regarding quality, cost or data-sharing, makes it difficult for proper underwriting and actuarial premium setting. This puts the entire risk on the insurer as there could be the problems of moral hazard and induced demand. Most insurance companies are therefore wary about selling health insurance as they do not have the data, the expertise and the power to regulate the providers. Weak monitoring systems for checking fraud or manipulation by clients and providers, add to the problem.
2. *Unaffordable premiums and high claim ratios*-Increased use of services and high claim ratios only result in higher premiums. The insurance agencies due to

[11] Financing and delivery of healthcare services in India; ch 4-Health Insurance in India, K. Sujatha Rao(http://whoindia.org/LinkFiles/Commision_on_Macroeconomic_and_Health_Health_insurance_in_India.pdf)

lack of adequate information also tend to overestimate the risk and fix high premiums. Besides, the administrative costs are also high— over 30%, i.e. 15% commission to agent; 5.5% administrative fee to TPA; own administrative cost 20%, etc. Patients also experience problems in getting their reimbursements including long delays to partial reimbursements.

3. *Reluctance of health insurance companies to promote their products and the lack of innovation*- Since health insurance is not exclusive as a product by itself therefore insurance companies do not take any initiative at promoting it. This is so because insurance companies cannot sell both life and non-life insurance products and hence finding non-life insurance such as theft, fire, health more profitable .Insurance companies tend to compete by adding a low incentive such as a premium health insurance to select clients thereby cross-subsidizing the resultant losses. With a view to get the non-life accounts, insurance companies tend to provide health insurance cover at unviable premiums. Thus, there is total lack of any effort to promote health insurance through campaigns regarding the benefits of health insurance and lack of innovation to make the policies suitable to the needs of the people.
4. *Too many exclusions and administrative procedures*- Apart from delays in settlement of claims, non-transparent procedures make it difficult for the insured to know about their entitlements, because of which the insurer is able to, on one stratagem or the other, reduce the claim amount, thus demotivating the insured and deepening mistrust. The benefit package also needs to be modified to suit the needs of the insured. Exclusions go against the logic of covering health risks, though, there can be a system where the existing conditions can be excluded for a time period—one or two years but not forever. Besides, the system entails equity implications.
5. *Inadequate supply of services*- There is acute shortage of supply of services in rural areas such as there are very few hospitals where even basic surgeries are performed and barely one or two for specialist treatment .So an orthopedic or cardio consultancy one might have to make a trip to the nearest town/city.
6. *Covariate risks*- If the prevailing level of risks that could affect a majority of people is high more so in a nation like India where the incidence of communicable diseases is high, the insurance industry would become non-viable. There would be no gains from forming large pools and the premiums would be high as well again restricting the affordability of health insurance.

Another issue with the health insurance sector is the existence of a number of failures that characterize the insurance market. Firstly, it is the asymmetry in information that puts both the patient and the insurer at a disadvantage due to their inability to resist or challenge medical opinion regarding an existing condition or future treatment. Another is that in the absence of knowledge of prices the provider can actually overcharge. Moreover a cashless insurance creates disincentives to control costs as the patient as well as the provider start perceiving it as a free good often resulting in excessive treatment by the producer for example he may increase the hospital stay of the patient or for that matter the patient may actually go to the hospital for a condition that could have been cured by a home remedy (moral hazard). Thirdly, it is only the patients who

know their health status. Since it is normally those in need of health care who tend to subscribe to health insurance, this puts the risk on insurance agencies to resort to extensive processes of risk selection, such as medical examination, before being given admittance as an enrollee and focusing on low risk groups, such as the young or healthy. Risk selection in individual-based policies however results in increasing the loading fee and consequently the cost of premium. For these reasons private insurance companies take only select consumers-young, rich and healthy while leaving the bad risks to the government.

Market Failure due to information asymmetry: The market failure arises in this case due to the fact that the consumers play no role in deciding the kind of goods and services to be purchased in this case medicines and healthcare facilities since they lack the knowledge to make such decisions and rely on the decision taken by their doctor or pharmacist. This sort of market failure does not characterize the market for bulk drugs because the buyers of the same are pharmaceutical companies who are very aware consumers. The competition in the formulations sector is distinct. In any market producers compete to sell the best quality product at the lowest possible price however in the formulations sector this is not the case since the demand for medicines is highly price inelastic and hence the producers have no incentive to keep their prices low. In most developed nations most individuals are covered by either public or private insurance and hence it is the government which bears most of the cost of the medicines. Thus the government in its role as a monopsonist will regulate prices and try to keep them reasonably low. However in the developing nations most patients are neither covered by public nor private health insurance. Companies in such nations do not compete via prices but rather through innovation.
In such cases where consumers are not the decision makers are often misguided by doctors and pharmacists into purchasing expensive medicines and sometimes even irrational combinations of medicines leading to medical complications. It is here where the efficiency of the market is lost with patients not being provided with the best possible treatment/medicines at the lowest possible prices.
Alternatively, this market failure can be addressed in a similar situation of self referral, a doctor may refer a patient to a particular diagnostic centre in return for incentives say in the form of a commission even though it is expensive and the patient could have availed similar services at much lower charges elsewhere.

Low FDI in the healthcare sector: post 1991- the healthcare industry has completely opened up to FDI in hospitals however actual statistics show that there is very little presence of FDI in the industry. Out of 90 FDI projects approved for hospitals and diagnostic centres between the years 2000-2006 only 21 were for the hospitals.[12] In fact private equity funding turns out to be more prevalent than FDI in the sector. This shows that there are definitely issues curtailing long term FDI to be an attractive and beneficial investment. Possible factors at work are of both types domestic as well as external.
Domestic factors include

- Massive upfront costs of setting up as a result of infrastructural constraints

[12] Foreign Investment in Hospitals in India: Status and Implications Rupa Chanda

- The Indian Medical Device industry largely relies on imports and capacity for local manufacturing is very low and thus the costs are huge.
- The medical education sector being inappropriately regulated is a major cause for shortages of medical professionals among other inadequacies of the medical education sector.
- Healthcare is still inaccessible for a large section of the Indian population largely due to the low penetration of private health insurance and absence of mandatory public health insurance .
- Absence of an adequate regulatory framework for maintaining quality and standards of services provided.

External factors such as the limitation in the developed countries on the number of private players who can invest abroad; lack of localized information about the market of the country where the investment is to be made influence the investors decision to invest.

International Issues

International Cartels**:** India has been a victim of an international cartel once which costs the nation a grossing US $ 3 million. This was the case of the bulk vitamins cartel. Other issues in this regard arise from export cartels as well as import cartels. Although most countries exempt export cartels from their antitrust laws so long as they don't distort the domestic market. Import cartels formed by domestic importers, or buyers and similar arrangements(such as boycotts of, or collective refusal to deal with, foreign competitors), may be a threat to maintaining competition in the market.

THE VITAMINS CARTEL

Leading producers of vitamins including Roche AG and BASF of Germany, Rhone-Poulenc of France, Takeda Chemical of Japan formed a cartel dividing up the world market and price fixing for different types of vitamins during the 1990s. The cartel was operated for ten years and later prosecuted with the help of Rhone-Poulenc which defected from the cartel and cooperated with US authorities. India incurred overcharges of more than US$25 million as a consequence.

Source: Abir Roy and Jayant Kumar (2008), Competition Law in India, Eastern Law House.

Cross border Mergers in the Pharmaceutical Sector: Large pharmaceutical companies often in order to get a foothold in market of another country or to adopt a quick

growth strategy enter into cross border mergers and acquisitions. India known for its generics, cost effectiveness and cost competitiveness is a favourite destination when it comes to mergers. Recently cross border mergers into India have been on a rise. The year 2009 saw the biggest merger in the generic market when Japan's 3rd largest drug maker Daiichi Sankyo took over India's Ranbaxy Laboratories.

Cross-border mergers place Indian companies on the global map. Being a significant part of the global pharmaceutical sector will help the Indian companies to take further steps in maintaining the global pharmaceutical standards which would be beneficial for them in all segments including exports, increased profitability, increase in the R&D laboratories, funding received by the companies, increased number of patented products, expansion of their market share etc. This in turn will be beneficial to the global pharmaceuticals as well since the cost effective techniques used by Indian companies and the huge market India provides to this sector can help enhance the research and creation of newer and improved drugs. However this is so long as such mergers do not hamper the efficiency and competitiveness of the domestic market.

High import duty on pharmaceuticals: Barring a few life saving drugs that face an import duty of 5 %, all other pharmaceuticals are levied at 10%. Such high rates of duty hamper import competition and thus reduce access to affordable medicine. It is thus suggested that lowering of import duty will help promote competition.

CHAPTER 5
ANTI-COMPETITIVE PRACTICES IN THE PHARMACEUTICAL AND THE HEALTH DELIVERY SYSTEM

The Pharmaceutical Industry:

The Indian Pharmaceutical industry is highly fragmented and there is no single market. It is divided into therapeutic segments i.e. vitamins, respiratory disorders, cardio ailments, anti-fungal etc. It is highly technology and knowledge intensive sector ad its capabilities are not limited to only drug manufacturing but research and development as well. As already mentioned in the previous section the market is very different from others in that it is characterized by market failure particularly in the formulations sector. The organized sector majorly responsible for the formulations comprises of some 250-300 players and accounts for about 70% of the total value of production.[13] The top ten companies account for 30% of the total sales.[14]Even though the individual market shares of companies is small this does not however imply that the market is characterized by intense competition. This again is primarily due to the fragmented nature of the market and that there are several relevant markets.

Apart from the distinct competition scenario, it is to be noted that a number of anticompetitive practices pervade the pharmaceutical industry worldwide, including in India. Such practices may be categorised into primarily three classes:

- Collusions
- Mergers and Acquisitions (Horizontal or Vertical)
- Abuse of Dominance (intellectual property rights related)

Though knowledge about most anti-competitive practices is not in plenty, as India did not have an effective competition regime, several mergers and acquisitions have taken place in recent years and many of them might have had serious implications for competition in the market.

Collusions: Collusions in the pharmaceutical sector can range from cartelization, cross licensing to bid-rigging.[15]Though there haven't been as such cases of collusions in the Indian pharmaceutical sector but there for sure is scope and tendency for such a possibility. There was an international cartel of bulk vitamins present for quite some time and cost India about US$25mn, in the 1990s, as a result of overcharging. While the cartel was penalized in all rich country jurisdictions, but not in a single developing

[13] Cuts-International Report-*Options for using competition law/policy tools in dealing with Anti-competitive practices in the Pharmaceutical and Health Delivery system.*

[14] Ibid

[15] Bid Rigging is a form of fraud in which a commercial contract is promised to one party even though for the sake of appearance several other parties also present a bid. This form of collusion is illegal in most countries.

country. Cartelization through cross licensing may also be anti-competitive since by doing so competitors allocate territories among themselves and create entry barriers. In fact with India now having adopted the product patent regime it is more vulnerable to collusive practices more so because of the increasing presence of MNCs in the Indian industry.

Mergers and Acquisitions: At present the market for pharmaceuticals is highly fragmented and mergers and acquisitions could lead to consolidation of market shares. Such consolidation of market position can be done via brand acquisition, company acquisition or product rationalization. Recently Nicholas Piramal has taken the ownership of 17% of biosyntech that is a major pharmaceutical packing organization in Canada. Matrix has acquired Docpharma, a major pharmaceutical company of Belgium. While,Sun Pharmaceutical Industries had announced its plans for acquisitions in the US and had earmarked $450 million for this purpose.[16]

However such acquisition becomes anti-competitive in nature when it leads to creation of a dominant position in the market in which they operate and if there is abuse of such a dominant position leading to higher prices and reduced output.

Abuse of Dominance: The ownership of an IPR grants the company exclusive rights to produce and sell their drugs in the market for a limited period of time. Such rights are particularly important for the pharmaceutical products since the manufacturing process is easy to replicate and can be copied with a fraction of the investment of that required for research and clinical testing. It is often believed that the patent law is an exception to the general rule in favour of competition but the argument for patent is that without granting a temporary monopoly, there would be no incentive for the firms to invest in research and development. However patentees often such misuse these rights to the detriment of the consumer by selling the medicine at monopolistically profit maximizing price levels and thereby curbing access to affordable medicine. Till such time India had a patent regime protecting the process involved there was no threat of abuse of dominance. With India adopting product patient regime in 2005 such instances may become frequent as producers resort to monopolistic practices. Another strategy used in abuse of dominance is that of restricting the entry of generics in the market. This can be very detrimental to the consumers as they'll lose access to affordable medicines. Often companies with patented products create artificial entry barriers for generic drug manufacturing companies by setting up their own range of generics so as to recover the losses that they would have to bear upon expiry of the patent. Other practices resorted to by patentees include refusal to license, resale price maintenance and patent pooling.

In the health delivery system we shall limit ourselves to the anti-competitive practices widespread among doctors, pharmacist, hospitals and diagnostic labs.

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[16] Express Healthcare Management Issue dated 15th September 2005

DOCTORS:

One of the most rampant unethical practices witnessed among doctors these days is irrational drug prescription. Doctors sometimes motivated by the kickbacks received from the pharmaceutical companies and sometimes simply do not make any effort to find cheaper alternatives and continue prescribing the expensive drug. This practice is seen often is because of the market failure that exists here with the patient who is not at the deciding end. Since such a practice violates the basic competition policy i.e. provision of the best possible services at the lowest possible prices, thus it is anti-competitive. Moreover doctors often accept commissions for referrals which does not lead to rational decision making again impinging upon a basic tenet of competition policy. Therefore do not practice free and fair competition.

Having said this does not take away from the fact that it is not always the case that there is a profit motive behind the doctor prescribing an expensive drug or referring their patients to a particular diagnostic centre. At times it is also the case that they are aware that the prescribed drug is more effective or has fewer side effects than its cheaper counterpart. Similarly, the doctor may send his/her patient to a certain diagnostic lab due to the superior quality of services offered there.

PHARMACISTS:

Most pharmacy owners in India are members of a trade association, All India Organisation of Chemists and Druggists (AIOCD). This association is nothing short of a cartel with almost 64.25% of all pharmacists are members of AIOCD.[17] The AIOCD is known to launch boycotts against drug companies in order to grab higher profit margins. In fact price decontrol has led to greater trade margins for the pharmacists in fact this actually beats the purpose of decontrol of prices i.e. to allow the manufacturers o be able to spend more on R&D. In fact this manner while the pharmacists grab greater profits the retail price continues to be higher with the consumer being the ultimate sufferer.

[17] CUTS-International report –*"Options for using Competition Law/Policy Tools in Dealing with Anti-Competitive Practices in the Pharmaceutical Industry and the Health Delivery System"*

COMPANY	BRAND	MRP	PURCHASE PRICE OF RETAILERS
Ranbaxy	Stannist	26	1.80
Cadila Healthcare	Ceticad	26	1.60
Cipla	Ceticip	27.5	2.00
Lupin	Lupisulide	24	1.94
Wockhardt	Setride	25.2	1.70
Lyka Labs	Lycet	25	1.44
Ranbaxy	Pyrestat-100	25	1.50
Welcure Drugs	Omejel Caps	33	4.50
Wockhardt	Merizole-20	39	6.48

Source: CUTS-International report, 2006

However high trade margins are not only due to the bargaining power of the pharmacists but also due to manufacturers strategy to capture greater market shares through providing incentives to doctors and pharmacists.

Another instance of anti-competitive practices to be considered is the informal collusion of the pharmacists at the local level. For example consider this, the Maximum Retail Price (MRP) that is set by the manufacturers under the guidelines of the National Pharmaceutical Pricing Authority (NPPA) , is the ceiling on the retail price and need not be the actual selling price. However retailers do not compete and the MRP becomes the reference price for them to collude informally.

HOSPITALS:

There is not much that is known about the practices of hospitals. Though there have been cases now and again about hospitals entering into agreements with drugs manufacturers to exploit consumers. There was a case brought in front of the consumer forum in Andhra Pradesh In which a private hospital had entered into an agreement with a drug manufacturer to supply drugs to the hospitals at prices above the market price. Such hidden costs are anti-competitive in nature as the consumer pays more than warranted.

An anti-competitive practice that is particularly prevalent in the healthcare system is that of **Tied Selling.** Tied Selling refers to situations where the sale of one good is conditioned on the purchase of another good. Tied selling is sometimes a means of price discrimination. It may foreclose opportunities for other firms to sell related products or may increase barriers to entry for those who do not offer a full-line of products. Tied selling can occur if market players act in collusion and all the players force such tied selling. Several surveys have revealed that consumers visiting private doctors or private hospitals witnessed tied selling of medicine as well as diagnostic tests. Doctors would

instruct that their patients to buy the prescribed medicine from a particular shop or to get a test done from a particular laboratory. Though there is a chance the doctor advise their patients to take the test at a particular diagnostic centre due to greater reliability of its services however profit motive cannot be ruled out as a motive. Often what is also done by doctors is suggesting more tests than necessary which may again be because of some arrangement for profit between the doctor and the diagnostic centre. This also violates the basic tenet of competition as it fails to provide the best possible service at the lowest possible price and hence is anti-competitive in nature.

In a survey conducted by CUTS International, only 15% of the respondents claimed that they had been asked to purchase medicine from a particular shop. On an average, those visiting private doctors or private hospitals, reported o higher incidence of tied selling of medicines. When healthcare service providers were asked about tied selling of medicines, only 11% admitted that they had ever resorted to such practices while 35% of them believed that other doctors resorted to tied selling practices with a profit or commission consideration.

Consumers with higher income have relatively less problems with such practices since the price differentials may have lesser significance for richer people and easy availability may be a greater concern. However it is the poor who suffers here since he has to pay a price beyond his means and little resources to spare for finding alternative solutions.

Chapter 6

COMPETITION LAW AND THE HEALTHCARE SECTOR

IS THE COMPETITION LAW APPLICABLE TO THE HEALTHCARE SECTOR?

Healthcare sector is distinct from other sectors in that there exists an inherent asymmetry of information that renders it difficult for the sector to compete in the manner that other sectors do. For this reason it is often believed that the competition law may not be applicable to healthcare in the way it is applied in other sectors. However the ultimate purpose of any competition law is to protect the interest of the consumer and to ensure efficiency and competitiveness in the market.

The competition law is applicable to healthcare players if they can be considered as undertakings. Since hospitals, health professionals, health insurers, pharmaceutical firms, pharmacists, etc. perform economic activities thus they can be considered to be undertakings and hence are subject to competition rules. Even in countries where there is little competition among the health care players due to excessive regulation, a hospital entering into an agreement with another hospital or pharmaceutical firm would have to comply with the competition law.[18]

THE ROLE OF COMPETITION LAW IN ENSURING QUALITY PROVISION OF HEALTH SERVICES

The application of competition law improves the quality of care by protecting the patient against unfair and anticompetitive practices such as abuse of dominant position, distribution agreements, etc. At times practices that restrict competition may themselves be quality enhancing in that case competition law may make an exception. In the United States competition law has opened the door to alternative practitioners and forms of practice and enhanced quality by maximizing choice in the marketplace.

COMPETITION LAW IN INDIA AND THE HEALTHCARE SECTOR

The competition policy in India is laid out in the Competition Act, 2002.When the Competition Act replaced the MRTP Act, 1969, there was a shift in the focus from curbing monopolies to promoting competition.
The Competition Act 2002 aims to prevent practices having an adverse affect on competition and abuse of dominance of enterprises either by entering into anti competitive agreements, or combinations.

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[18]Diego Fornaciari ;International Journal of Environmental Research and Public Health (2009); "Quality healthcare in European Union thanks to competition law "

The Act typically focuses on four areas:

a) Anti-Competitive Agreements (Section 3)
b) Abuse of dominance (Section 4)
c) Combination Regulation (Section 5)
d) Competition Advocacy (Section 49)

The first three areas mentioned above give rise to competition concerns in the pharmaceutical and the health delivery system as seen earlier.

Anti-Competitive Agreements: Section 3 of the Competition Act deals with the prohibition of agreements, which have an adverse effect on competition. It states that no enterprise or association of enterprises or person or association of persons shall enter into any agreement in respect of production, supply, distribution, storage, acquisition or control of goods or provision of services, which causes or is likely to cause an appreciable adverse effect on competition within India.

The specific anti-competitive practices of the pharmaceutical and health delivery system covered under Section 3 of the Act are collusive agreements including cartels, tied selling, exclusive supply agreements, exclusive distribution agreements, refusal to deal and resale price maintenance.

The prohibition of cartel agreements (price fixing, output restricting, market sharing or bid rigging) between enterprises or persons is the strongest provision in the Act however the act shall not apply in case such an agreement increases efficiency in production, supply, distribution, storage, acquisition or control of goods and provision of services. Having said this it must be noted that cartels may increase efficiency but alongside may also increase prices that may be detrimental to the consumers. However there is an exception in the law for IPR-related agreements. Section 3(5) states that under reasonable conditions that an IPR holder may apply to protect his rights may not be regarded as anti-competitive, although what is reasonable has not been defined well.

Abuse of Dominance: The Competition Act does not prohibit the mere possession of a dominant position but only the abuse of such dominance by the way of imposition of unfair or discriminatory conditions of purchase/sale or unfair/ discriminatory pricing.

Abuse of dominance may arise in the pharmaceutical industry in the case of abuse of monopoly status granted by patents. Thus in case pharmaceutical companies engage in overpricing patented products or are unreasonable with respect to licensing terms etc then the competition law may be resorted to for redressal.

Excessive Pricing of a patented drug-South African Case

In South Africa (SA), the pharmaceutical companies, GSK and Boehringer, patent owners of Antiretroviral (HIV/AIDS)drugs set unjustifiably high prices of these drugs (over and above the WHO generic price) in the domestic market. The SA Competition Act prohibits a dominant firm to charge excessive price to the detriment of the consumers and the Competition Commission ordered issuance of license to market generic versions of the patented ARV drugs in return for the payment of reasonable royalty to be decided by the Competition Tribunal.

Source: CUTS-International report, *"Options for using competition law/policy tools in dealing with Anti-competitive practices in the Pharmaceutical and Health Delivery system"*

It is important to note that increasing prices of drugs per se is not an anti-competitive practice however considering the peculiarity of the pharmaceutical industry wherein the consumer cannot choose the lowest price medicines it may actually be anti-competitive. This can be understood in the following manner- in case a drug is overpriced and there are generic substitutes available then there'll no impact on competition. However if the pharmaceutical firm manages to convince a number of doctors of the superiority of their drug and doctors prescribed accordingly then the drug in question would attain a monopoly position. In this manner overpricing can actually have anti-competitive effects.
The Indian Act has provisions for unfair or discriminatory pricing however excessive pricing is not mentioned expressly and hence it is considered to be a part of the former. This is an important provision considering the issue of accessibility to medicines under the recently adopted product patent regime.

Mergers and Acquisitions: Section 5 of the Competition Act deals with what is denoted by a combination of enterprises and persons, delineating the specific circumstances as per which the acquisition of one or more enterprise by one or more persons. The Act provides for merger review beyond a certain threshold level which would be defined as the turnover of the group to which the enterprise would belong after the completion of the acquisition or merger.
Unlike most other countries merger notification in India is not compulsory and is only voluntary. Moreover since the threshold level for regulation is quite high, the Indian industry may become an easy target for MNCs for acquisition.

Cross border competition issues: The Competition Act, 2002 has extra-territorial jurisdiction reach with respect to

a) Anti-Competitive Agreements
b) Abuse of Dominance
c) Combinations

having an effect on competition in India. However the provision only empowers the commission to enquire into such an agreement, it does not mention anything about the option to pass an order in this regard.

CHAPTER 7

CHALLENGES AHEAD

Notwithstanding the sector's rapid growth and potential, in many respects, India's healthcare sector falls well below international benchmarks for physical infrastructure and manpower, and even falls below the standards existing in comparable developing countries. The total number of doctors (all kinds included) per thousand persons stood at only 1.27 in 2006 and 0.5 physicians per thousand persons in India, compared to a world average of 1.5. The number of nurses per thousand persons stood at 0.9 in 2006 compared to a world average of 1.2. Added to this deficiency is the mal-distribution between rural and urban areas and shortages of specialized personnel. These ratios are projected to remain below the existing world averages even in 2016. The current ratio of beds per thousand persons is a mere 1.03 (well below the WHO norms) compared to an average ratio of 4.3 for developing countries like China, Korea, and Thailand, and in the best of circumstances is projected to reach 1.85 per thousand persons by 2012. It is estimated that over a million beds have to be added to attain this 1.85 ratio, which translates into a total investment of $78 billion (Rs. 350,830 crores) in health infrastructure. An additional 800,000 physicians are required over the next 10 years, which in turn translates into huge investments in training facilities and equipment. In order to reach even 50-75 percent of the present levels of other developing countries, the sector will require an estimated investment of $20-30 billion. Thus, India's healthcare sector needs to scale up considerably in terms of the availability and quality of its physical infrastructure as well as human resources so as to meet the growing demand and to compare favourably with international standards.

There are numerous opportunities and yet untapped areas in the healthcare sector. Some suggestions are given below:

Increase in government spending: Level of public expenditure needs to be enhanced considerably. Moreover regional disparities existing in the provision of health services also need to be brought down. On a priority basis government should fill up vacant seats of medical professionals, improve quality of infrastructure and availability and accessibity to medicines.

Establishment of an industry body: The healthcare sector is highly fragmented and thus there needs to be formed a common industry body comprising of the representatives from all the segments of the industry. The body can address the issues faced by the industry; provide frameworks for improvements in the level of services provided and achievement of higher industry standards.

Increase PPPs: There is surely a need to increase the number of PPPs alongside efforts should be made to strike a good balance between the objectives of the public and the private sector. This can be ensured by building a scalable and financially sustainable business model as well as providing equitable healthcare services.

Besides these, the anti competitive practices cited in the above chapters some of which even though not much prevalent in India in the present day context pose as a potential threat to the efficient provision of medical services to the common man. The tied selling of medicines and diagnostic tests often is detrimental to patient who is largely uninformed and thus easily falls prey to such practices.

Following are some issues that need to be addressed not only to tackle anti-competitive practices but also to foster competition in the sector and ensure quality healthcare services to the consumers.

I. Absence of a regulatory framework to monitor rent seeking behaviour of doctors and pharmacists.

II. With the product patent regime now in place, mergers and IPR related abuse of dominance will raise competition concerns in time to come and thus there is a need for preparedness to tackle such problems.

III. Identification of anti-competitive practices in the sector that are not explicit. Since competition does not affect the healthcare sector the way it does other sectors there is a need to devise a mechanism to ensure identification of such issues.

IV. A provider information disclosure needs to be put into place so as to reduce the asymmetries of information for consumers and insurers. Ensuring that information about procedures and ailments reach consumers will help reduce the informational barrier to some extent. This can be done through media and internet.

V. Regulatory barriers in the medical education sector need to be looked into to ensure adequate supply of well trained professionals.

VI. Reduction of the present high import duty in order to foster effective import competition and ensure accessible and affordable medicine to all.

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