

**OPTIONS FOR USING COMPETITION LAW/POLICY
TOOLS IN DEALING WITH ANTI-COMPETITIVE
PRACTICES IN THE PHARMACEUTICAL INDUSTRY
AND THE HEALTH DELIVERY SYSTEM**

Report Prepared For

**WORLD HEALTH ORGANIZATION
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By

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LIST OF ABBREVIATIONS

ADD:	Attention Deficit Disorder
AIDS:	Acquired Immune Deficiency Syndrome
AIOCD:	All India Organisation of Chemists and Druggists
AMAI:	Alkali Manufacturers' Association of India
AMTC:	Affordable Medicines Treatment Campaign
ANSAC:	American Natural Soda Ash Corporation
API:	Active Pharmaceutical Ingredient
BPL:	Below the Poverty Line
CCI:	Competition Commission of India
CII:	Confederation of Indian Industry
CIMS:	Current Index of Medical Specialities
CL:	Compulsory Licensing
CML:	Chronic Myeloid Leukaemia
CPI:	Consumer Price Index
DCA:	Drugs and Cosmetics Act 1940
DCI:	Drug Controller of India
DCR:	Drugs and Cosmetic Rules
DDPF:	Drug Development Promotion Foundation
DPCO:	Drug Price Control Order
DSF:	Delhi Science Forum
EMA:	European Agency for Evaluation of Medicinal Products
EMRs:	Exclusive Marketing Rights
EU:	European Union
FCA:	Finnish Competition Authority
FDA:	Food and Drug Administration
GDP:	Gross Domestic Product
GOI:	Government of India
GSK:	GlaxoSmithKline
HMOs:	Health Management Organisations
ICESCR:	International Covenant on Economic, Social and Cultural Rights
IDMA:	Indian Drug Manufacturers' Association
IPRs:	Intellectual Property Rights

M&As:	Mergers and Acquisitions
MAPE:	Maximum Allowable Post-manufacturing Expenses
MIMS:	Monthly Index of Medical Specialities
MNC:	Multinational Companies
MRP:	Maximum Retail Price
MRTPA:	Monopolies and Restrictive Trade Practices Act
MRTPC:	Monopolies and Restrictive Trade Practices Commission
NABL:	National Accreditation Board for Testing and Calibration Laboratories
NERA:	National Economic Research Associates
NGOs:	Non-Governmental Organisations
NHS:	National Health Service
NIAF:	National Illness Assistance Fund
NIH:	National Institutes of Health
NPPA:	National Pharmaceutical Pricing Authority
OPPI:	Organisation of Pharmaceutical Producers of India
OTC:	Over-the-counter
PMPRB:	Patented Medicine Prices Review Board
PPP:	Purchasing Power Parity
PPRS:	Pharmaceutical Price Regulation Scheme
PRDSF:	Pharmaceutical Research and Development Support Fund
R&D:	Research and Development
RTP:	Restrictive Trade Practices
SA:	South Africa
SC:	Supreme Court
SIAF:	State Illness Assistance Fund
SMEs:	Small and Medium-Sized Enterprises
TNCs:	Trasnational Corporations
TRIPS:	Agreement on Trade-Related Aspects of Intellectual Property Rights
UDHR:	Universal Declaration of Human Rights
UK:	United Kingdom
US:	United States of America
WHO:	World Health Organisation
WTO:	World Trade Organisation

EXECUTIVE SUMMARY

The right to health is recognised in a number of international legal instruments. In India too, there are constitutional commitments to provide access to healthcare. However despite the existence of any number of paper pledges assuring the right to health, access to health remains a problem across the world. In India, according to one estimate, only 35 percent of the people have access to essential medicines.

There are several factors that are responsible for such deprivation. Market malpractices in general, and in particular, anti-competitive conduct in the pharmaceutical industry and the health delivery system are also among them. Examining legal and policy options to effectively eliminate or curb anti-competitive practices in the health sector is the focal point of this study.

The pharmaceutical industry and the health delivery system

The pharmaceutical industry is currently acknowledged as one of the leading industries in India. India is ranked among the top 15 drug manufacturing countries in the world. However, today, the Indian pharmaceutical sector is in a state of flux, in face of the sweeping changes in the patent regime and the increasingly de-regulated environment. Especially threatened in this new scenario is the access to medicines by the poor. Further exacerbating the current situation is the market distortions and skewed competition norms, unique to the pharmaceutical industry, with particular reference to market concentration, barriers to price competition and lack of independent consumer choice (patients are guided by the advice of doctors and pharmacists).

India currently has a vast health delivery system in place though not comprehensive enough to serve a population of over one billion. For the purpose of this report the health delivery system has been taken to comprise of doctors, pharmacists and hospitals. 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.

Competition concerns

Apart from the distinct competition scenario, it is to be noted that a number of anti-competitive practices pervade the pharmaceutical industry worldwide, including in India. Such practices may be categorised into primarily three classes: intellectual property rights related breaches, abuse of competition norms arising from mergers and acquisitions and collusive and other anti-competitive practices. 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.

Anti-competitive practices in the health delivery system range from receiving kickbacks by doctors from pharmaceutical companies for influencing drug sales, to tied selling. With specific reference to doctors, suggesting more tests than necessary and accepting commission for referrals are practices, which may have anti-competitive implications. With particular reference to pharmacists, the anti-competitive practices most commonly engaged in are reflective of collusion.

Legal and policy options

There are multiple legal and policy options, which may be utilised to deal with anti-competitive practices in the pharmaceutical industry and the health delivery system. These options have been considered herein in light of facilitating access to medicines and healthcare by the poor. Using competition law is the obvious choice of legal remedy to deal with anti-competitive practices in the pharmaceutical industry and health delivery system. The key element in successfully enforcing the provisions of competition law is building the capacity of the competition agencies.

Competition law apart, patent law and drug price control are crucial for efficacious elimination of competition violations in the pharmaceutical industry. Price control is a tool that is used in a situation when maintaining a competitive market is extremely difficult. India has been following a price control regime for pharmaceutical products since 1960s. However, there has been substantial decontrol in this regard since 1990s, with the effect that prices of many medicines have seen unprecedented rise.

The report critically analyses the strengths and weakness of all three areas of legal remedy and examines whether there is any need for change in the law.

Apart from competition law, there is no concrete regulatory mechanism addressing anti-competitive conduct in the health delivery system. With specific reference to doctors, the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 may also be used to deal with anti-competitive practices.

Suggestions and recommendations

Apart from identifying areas of concern in existing legislations, the report provides certain recommendations which encompass both legal and policy considerations. The salient recommendations of this report may be summed up under the following heads:

Promoting Generic Competition

Pharmaceutical companies often give incentives to doctors to push their brand of medicine, which may be more expensive than other alternatives available in the market. This vitiates the competition principle, “best possible goods and services at the least possible prices”. The doctor-drug manufacturer nexus is to be viewed in light of near complete dependence of patients on their doctors for information relating to drug purchase. This report focuses on the need to deal with the aforementioned nexus by promoting generic drugs. This promotion may be done by debranding of prescriptions for essential generic medicines. However, there are strong arguments against this proposition, which to some extent are legitimate concerns. It is, therefore, recommended in this report that a selected number of most commonly used medicines be brought under the ‘debranding of prescriptions’ scheme on an experimental basis.

Dealing with IPR Related Issues

The monopoly rights which patents award to patent holders, which in the case of the pharmaceutical industry are the pharmaceutical companies, is susceptible to abuse, especially in the form of excessive pricing. Compulsory licensing is an effective way to deal with such abuse of monopoly rights. The experience in India’s previous product patent regime indicates that the practical aspect of license issuance needs to

be given due attention if there is to be any likelihood of actualising the grant of compulsory licenses.

It has been recommended in this report that it would be more appropriate to give the competition authority the responsibility of granting compulsory licenses in consultation with the patent office rather than the other way around.

This report is in agreement with the proposed policy of mandatory price negotiations of patented drugs before the grant of marketing approval. It is recommended that while framing guidelines in this respect, India may look at the experiences of other countries, which follow such practices, such as Canada, France, Germany, Italy, Japan and the UK.

The IPR related agreements have been exempted in the Competition Act even if they contain anti-competitive provisions which are reasonable, without defining what is reasonable. This will create confusion. Moreover, some of them can be purely anti-competitive and cannot be justified in the interests of promoting innovation and hence should not be exempted even with a rider of reasonableness.

Checking Collusive Activities

Collusive activities among Indian manufacturers of pharmaceuticals have not yet been discovered. However, their prevalence cannot be ruled out. Pharmacies engage in collusive practices in India to ensure higher trade margins. The government has created deterrence mechanisms. However, these have their own limitations and need to be re-examined. The report emphasizes the need to eliminate collusive practices by pharmacies to ensure growth of the industry, and a fair deal for the consumers. There are many questions for regulators to consider. Should the manufacturers be also allowed to engage in collective bargaining with the pharmacists? Should there be a trade margin fixation regime? Should there be a negotiated settlement in the short run? These options need to be considered in light of existing law, the practicalities involved and long-term implications.

Controlling Tied Selling

Tied selling in the health delivery system, although anti-competitive in effect may partly be driven by safety considerations as well rather than profit concerns only. Although, there is regulatory framework to ensure genuine medicines in the market, the report stresses that there is significant scope for improvement in its enforcement. In the area of diagnostic testing, however, the regulatory framework is almost non-existent. The report recommends that regulatory authorities at the state level should be properly empowered to ensure standards of medicines and services offered at the diagnostic laboratories. Consumer forums ought to be actively involved to ensure that patients are not exploited. Accreditation of diagnostic laboratories is another way in which diagnostic laboratories may be effectively regulated. Once safety and reliability issues in the health sector are addressed, dealing with tied selling will become easier.

Regulating the Health Delivery System

Given the predominance of the private sector in the health delivery system and the lack of any regulatory regime to monitor the functioning of private hospitals, nursing homes and other medical care establishments in the country, this report identifies an urgent need for licensing and regulating private health providers. Hospital accreditation is another method, which may be used to regulate hospital conduct. There is also a need for a programme of stricter licensing of medical practitioners.

Bridging the huge information gap, which exists between consumers and persons responsible for health delivery, may also assist in stemming the incidence of anti-competitive practices in the health delivery system.

Health Insurance

The most pernicious effect of nearly all anti-competitive practices in the health sector is medicines and health services being rendered costlier. Health insurance is one way to lessen the impact of high prices on the consumer. However, health insurance itself causes market distortion in the health sector. Ultimately patients end up bearing the cost of market inefficiencies. Health insurance thus has a multi-dimensional impact.

This report arrives at the conclusion that with respect to insurance driven public health coverage as per the proposed government scheme that will benefit only families below the poverty line, other alternatives ought to be explored, which will

benefit a wider range of health consumers. In this regard, it is recommended that the government explore the possibility of replicating the Rajasthan model of Medicare Relief Societies, and enhancing the coverage and effectiveness of National Illness Assistance Fund. The issue of health insurance can be left to the market. It is further suggested that lessons may be drawn from other countries where health coverage through insurance is more prevalent than presently in India.

Promoting Innovation

With the transition of India to the product patent regime, it is imperative for our domestic pharmaceutical industry to accelerate its efforts in research and development. This study emphasises that total price decontrol as suggested by industry representatives, is unnecessary to promote R&D and suggests a carrot and stick approach to encourage R&D by companies. There has to be incentives and disincentives directly linked with R&D efforts.

Furthermore this report emphasises the need to not only focus on private R&D, but also to actively promote public R&D. This report also advocates that Indian companies should file as many patents for herbal medicine as they can. The Indian Government should actively support such initiatives in whichever way possible.

Creating Awareness

The implementation of many of the aforementioned policies and measures will require the involvement of all stakeholder groups. The report suggests that there should be capacity building of all involved groups through awareness campaigns through the media on all of the aforementioned issues and other means as well. The central government, the state governments and all interested NGOs need to be involved in creating awareness.

Conclusion

Given the peculiarity of the market, ensuring competition is easier said than done. The new Competition Act, 2002, is better equipped than the earlier law to deal with the anti-competitive practices prevalent in the health sector. Currently the regulatory regime has been quite hard on manufacturers, but extremely soft on two other groups of important players, the doctors and pharmacists. This situation needs to be given

due consideration by the relevant authorities. Finally, it may be mentioned that to deal with anti-competitive practices in the pharmaceutical sector and the health delivery system in order to facilitate access to health, taking recourse to the legal and policy options available is not sufficient; there is need for efficacious implementation of appropriate policy tools as well.

CHAPTER I INTRODUCTION

“The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being.”

- *Preamble to the WHO Constitution*

It is undeniable that access to healthcare is one of the most basic needs, an inviolable right of every human. Healthcare is an intrinsic component of the development process. Limitations in healthcare may be immediately associated with a lack of adequate public or private health facilities or the inability to afford what is available, but the impact of the same lies in the lack of freedom to live healthy lives, free from preventable ailments and untimely death.¹

International human rights law recognizes the right to health in a number of legal instruments, significantly the Universal Declaration of Human Rights (UDHR) and the 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR). The Declaration of Alma Ata has expressed the need for urgent action by all governments, all health and development workers and the world community to protect and promote health of all the people in the world. In India, the right to health is recognized as a derived fundamental right, under Article 21 of our Constitution², the cornerstone of our nation. The report of the Bhore Committee submitted in 1946 embodied a lofty vision of India’s health services, enunciating the principle that there should be access to health for all, free of charge³.

In theory, there are constitutional commitments to provide access to health to the nation’s population. The arguments justifying such a commitment are also watertight. Yet there is a stark difference in what is and what ought to be. The reality echoes what Rudolf Virchow had said in 1848, “that health is politics and politics is health, as if

¹ See generally, Jean Dreze, Amartya Sen, *India Development and Participation*, Oxford University Press, New Delhi, 2002, p. 5

² ND Jayal v. Union of India [2004 (9) SCC 362]

people matter”.⁴ Despite the plethora of promises made to the people of India assuring them access to medicines and health services, such promises have not yet been transformed into tangible actuality.

Access to healthcare is not a problem confined to India and may easily be ranked as a crisis of global dimensions. Over one-third of the world’s population lacks access to healthcare and pays a heavy price in terms of poor health and elevated mortality⁵. Lack of access to healthcare also increases poverty. One of the main factors driving families below the poverty line in India is financing their own healthcare⁶. There is a widely held assumption that healthcare for the poor is very inexpensive given their reliance on welfare driven government institutions. However, in reality, the poor are often compelled to avail of more expensive private services due to a range of factors and government hospitals also have many hidden costs.

In developing countries, a large proportion of the population has no access to necessary medicines. In the poorest parts of Africa and Asia, the picture is even worse, with over 50 percent of the population lacking access to even the most basic essential drugs.⁷ In India, according to one estimate, only some 35 percent of Indians can access essential medicines.⁸

The matter of healthcare, like most other development issues, is simply so enormous in magnitude that the government alone cannot be expected to provide the perfect panacea to resolve all issues in the area. The involvement of the people and relevant industries is essential to transform the paper pledges into reality.

There are two institutions of vital importance in ensuring access to medicines and healthcare. Firstly, there is the health delivery system, which is inclusive of doctors,

³ Debabar Banerji, *Politics of Rural Health in India*, Economic and Political Weekly, July 23rd, 2005, P.3253. Also see, KR Nayar, *Rural Health: Absence of Mission or Vision?*, Economic and Political Weekly, November 6th, 2004, p 4872.

⁴ Rosen G, *History of Public Health*, MD Publications, New York, 1958, p 7.

⁵ Nitya Nanda and Ritu Lodha, *Making Essential Medicine Affordable to the Poor*, Wisconsin International Law Journal, Vol. 20, No. 3, p. 581, 2002

⁶ See generally Report of the National Commission on Macroeconomics and Health, September 2005, p. 33

⁷ Ibid

⁸ Prabodh Malhotra and Hans Lofgren, India’s pharmaceutical industry: hype or high tech take-off?, *Australian Health Review*, Vol. 28, No. 3, p. 183

hospitals (both public and private), diagnostic labs, pharmacists and primary health centres, to mention only a few of its components. Also to be considered is the pharmaceutical industry, which manufactures and markets medicines and invents new medicines.

Access to medicines and healthcare has five aspects: availability of supply, price, quality, ability to pay and access to proper and affordable consultations. All these aspects are vitiated in our country by a number of factors, which range from poverty and poor infrastructure to corruption, market malpractices and lack of awareness. Market malpractices in general and in particular, anti-competitive conduct in the pharmaceutical industry and the health delivery system, have serious implications for access to healthcare by people. Examining legal and policy options to effectively curb such anti-competitive practices will be the focal point of this study.

Anti-competitive practices in the pharmaceutical sector and the health delivery system include, amongst others, price fixing, abuse of dominance, collusive agreements and tied selling. Even practices such as kickbacks to doctors and pharmacists may be deemed as anti-competitive as they result in depriving patients of best possible medicines and services at the lowest possible prices. The primary effect of anti-competitive practices on the health sector is that medicines and services are rendered costlier.

In the context of India's new patent regime and the increasingly deregulated environment, new concerns arise with respect to access to medicines and healthcare⁹. Will there be abuse of the monopoly rights of the patent-holder, causing an increase in prices? Will relaxation in price controls lead to rising prices? Will the inevitable increase in MNC presence, post-TRIPS, usher in the many anti-competitive practices? Will the current spurt in mergers and acquisitions create market structures, which may result in abuse of dominance? These are a few of the many questions arising in the wake of a series of changes in the pharmaceutical industry.

⁹ The differing implications of the process patent regime and product patent regime and the impact of the transition from one patent regime to the other is discussed in the second and third chapters.

One issue, which now renders it essential that there be careful monitoring of anti-competitive practices in the health sector, is that the Government is presently emphasising on promoting the private sector and such anti-competitive practices as outlined above are believed to be more prevalent in the private sector than in the public sector.

Many of the issues to be discussed in this report, including the anti-competitive practices prevalent in the health sector and the very need to efficaciously regulate and monitor the pharmaceutical industry and the health delivery system, are all underpinned by the basic conflict arising from private profit-driven institutions being major providers of health related products and services having enormous public good implications.

The emerging competition regime in India is likely to deal with some of these practices. However, competition law and policy will alone not be able to ensure adequate access to medicines and healthcare. Many problems need to be effectively addressed, at least to an extent, (for instance our endemic poverty and inadequate distribution mechanisms), if access to health is to become a reality. Nevertheless, effective control of anti-competitive practices in the health sector will go a long way in facilitating such access.

The methodology adopted for this study comprised of analysis of primary and secondary data. Primary data utilised for the report consisted of survey results, opinions culled from interviews, legislations, case law, the Current Index of Medical Specialities (CIMS) and Monthly Index of Medical Specialities (MIMS). A survey was conducted of five survey groups, namely, doctors, hospitals, pharmaceutical industries, pharmacists and consumer-oriented NGOs. In total, one hundred and thirty-three (133) doctors, one hundred and three (103) hospitals, fifty-four (54) pharmaceutical companies, one hundred and twenty-three (123) pharmacists and one hundred and eight (108) consumer-oriented NGOs were surveyed. The survey of all five sectors was carried out in four metro cities, namely, Delhi, Mumbai, Kolkata and Chennai, except in the case of pharmaceutical companies, where Chennai was substituted with Ahmedabad. Information generated through a survey conducted by CUTS earlier was also used wherever relevant, particularly the results of the survey of

consumers. Personal interviews were conducted with experts. An analysis of mergers and acquisitions related statistical data has been conducted and incorporated into the report. Secondary data were sourced from books, journals, newspapers, magazine and websites.

The structure of the report has been organized as follows: Chapter II provides a brief overview of the pharmaceutical industry and the health delivery system in India. Chapter III discusses existing and probable anti-competitive practices, at the local as well as cross border level, in the context of both the pharmaceutical industry and the health delivery system and the impact of such practices on the access to medicines and healthcare. Chapter IV presents an in-depth critical analysis of the existing legal and regulatory framework germane to dealing with the competition concerns in the health sector. Chapter V recommends certain measures and strategies to deal with anti-competitive practices in the pharmaceutical industry and the health delivery system, facilitating thereby access to medicines and healthcare. Chapter VI comprises of the conclusion to the report. The experience of different countries and lessons India could learn from such experiences, have been included throughout the report as and where deemed appropriate.

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 market¹³. 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 needs¹⁴. 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 in¹⁵:

- 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

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 industry¹⁶. 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 people¹⁷.

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 companies¹⁷. 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

¹⁷ Supra n. 8 at p.3-4

¹⁸ Ibid at p.4

key strengths is its expertise in manufacturing generic drugs¹⁹. 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 percent³⁰, 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&D³¹.

➤ *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

only³². Of the top ten companies in India today, only two are MNCs³³. MNC market presence is, however, expected to grow now in view of the introduction of the new patent regime³⁴.

Table 2.1: Top ten companies in the Retail Pharmaceutical Market

1. Cipla
2. <i>GlaxoSmithKline (MNC)</i>
3. Ranbaxy
4. Nicholas Piramal
5. Sun Pharma
6. Dr. Reddy's
7. Zydus Cadila
8. Aristo Pharma
9. <i>Abbott India (MNC)</i>
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 a unique and exciting opportunity to grow from about US\$5.5bn in 2000 to US\$25bn in 2020³⁵. 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 markets³⁶.

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 range³⁷. 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 players³⁸ and accounts for 70 percent of the industry in terms of value³⁹, with the largest player having a market share of approximately 6 percent⁴⁰. 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 market⁴¹

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 annum)	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 annum)	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 annually⁴⁴.

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 following⁴⁵ 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 laboratories⁴⁶

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 equipment⁴⁸.
- 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 insurance⁴⁹.

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 years⁵⁰.

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 country⁵³. Estimates predict that at its current pace of growth, healthcare tourism alone can bring in over US\$2bn as

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.

CHAPTER III COMPETITION CONCERNS

In the last chapter, it was noted that the pharmaceutical industry and the health delivery system are afflicted by a range of market failures, the condition exacerbated by the prevalence of anti-competitive practices in the market. This particular chapter focuses on the various violations of competition norms in the pharmaceutical industry and the health delivery system.

THE PHARMACEUTICAL INDUSTRY

Intellectual Property Rights Related

The level of competition in the pharmaceuticals market is inextricably linked to a range of issues relating to intellectual property protection. The crux of the matter is that patents confer monopoly status to pharmaceutical companies as patents by their very definition grants the patent-holder exclusive rights to make, use or sell a product for a specified period. Often such monopoly rights are misused to the detriment of consumers, with companies abusing their dominant position by pricing their patented products at monopolistic profit-maximising levels, thereby severely circumscribing access to affordable medicine.

In India, with the process patent regime in place, the above-mentioned abuse of monopoly power was easily avoided. Now, however, since India has made the transition to the product patent regime from 2005, any patented products entering the market will essentially be marketed by a monopolist. This means that in the new patent regime, abuse of dominance, which was almost non-existent earlier, may become quite frequent.

The tendency of patent holding companies to abuse their dominant position in the market has particularly deleterious repercussions on developing countries. While overpricing a patented drug, companies usually do take into consideration the paying capacity of the consumer.⁵⁹ However, in developing countries, there would possibly not be substantial adherence to this policy of overlooking purchasing ability, because

to make medicines available to a large segment of the population, drug companies would have to drastically lower their prices, which they would not be willing to do.

Their unwillingness would conceivably stem from primarily two reasons. The first being that given their profit-oriented strategies, this level of reduction in prices would not be acceptable to them, and the second reason being that if they did adopt such a policy, the price differences would be so glaring that they would conspicuously reveal the extent of profits involved leading to pressure to reduce prices in developed countries as well, especially for life-saving drugs or drugs of mass consumption. Thus, it is highly likely that patented drugs in developing countries will be greatly overpriced, depriving underprivileged people in these countries from the benefits of these drugs.

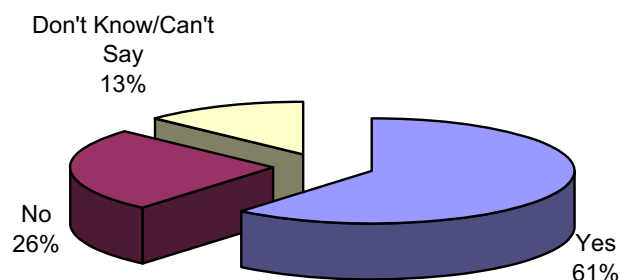
Patents and Pricing

It is difficult to predict whether or not the new patent regime will result in an increase in drug prices in India. The product patent regime having come into force only in 2005, with only one product patent having been granted till date,⁶⁰ the regime is still too new for its effect on prices to be discernible now. But consideration of certain facts, issues and situations may give us the ground to draw certain tenuous conclusions on this matter.

Firstly, let us consider the survey results. Majority of the pharmaceutical companies surveyed believe that a price rise is to be expected in the new patent regime. 40.7 percent of respondent companies predict that MNCs will price their products high in the new patent regime, with only 25.9 percent of respondents asserting that pricing policies will be based on the affordability principle. These statistics are particularly significant considering that these are impressions carried by representatives of the pharmaceutical industry itself and not consumer or NGO perceptions.

⁵⁹ See generally, Pradeep Agarwal and P. Saibaba, *TRIPS and India's Pharmaceutical Industry*, Economic and Political Weekly, September 29th, 2001

Figure: 3.1
Expected Price Rise in the New Patent Regime –
Perceptions of the Pharmaceutical Industry



In the context of patents and pricing it becomes imperative to discuss the grant of exclusive marketing rights (EMRs) in India⁶¹. Out of the seventeen applications filed for grant of EMR so far, only four have been granted in the pharmaceutical sector to Novartis's Glivec, Wockardt's tropical antibiotic Nadoxin, United Phosphorous' pesticide product Saaf and Eli Lili's Tadalafil.⁶² But the manner in which Novartis exercised these rights gives cause for concern with respect to what might be expected in the new patent regime. Novartis' Glivec is used for treatment of Chronic Myeloid Leukaemia ('CML'). There was an increase in the price of the drug from \$90 to \$2610 after the grant of EMR, which will effectively put the drug out of reach of 24,000 patients in India who suffer from CML.⁶³

This shows clear abuse of dominance through excessive pricing. It also shows the ramifications of the elimination of the process patent regime. In line with the pre-WTO practice, the Indian company NATCO Pharma Ltd. had launched in early 2003

⁶⁰ The first product patent was granted to Roche India Pvt. Ltd. - *Roche gets first product patent in India*, Financial Express, 1st March, 2006.

⁶¹ Please see p. 79 for an understanding what is meant by exclusive marketing rights.

⁶² Archa Saran, *India: A Changing Regime - India's Tryst with January 1, 2005*, 15 November 2004 at <http://194.88.95.39/article.asp?articleid=29573&searchresults=1>

⁶³ Ibid

an alternative version (named Veenat) of the aforementioned drug of Novartis. This generic version was made available to patients at one tenth the price set by the original manufacturer (estimated annual cost of treatment for Glivec at \$27000 and for Veenat at \$2700)⁶⁴.

Interestingly, Novartis now offers a programme for poor patients to whom Glivec is provided free of cost. It almost seems as if the programme is a bargaining chip to enforce their EMR,⁶⁵ so that they do not come off looking ruthlessly profit oriented. Of course, it might be that this is a truly altruistic effort and it certainly cannot be denied that the programme increases access to healthcare, but time will only tell whether the programme is philanthropic or merely a tactic designed to distract public attention away from excessively high prices.

An oft-repeated argument by pharmaceutical companies supportive of the new regime is that very few essential medicines are covered under the patent regime and, therefore, the fear that the high prices of patented drugs will block access to medicines is far greater than the situation mandates. However, essential drugs do not cover all the major prevalent diseases. For instance, the drugs used by cancer patients are not listed as essential drugs. However, a recent research publication has concluded that, out of 7.5. million new cancer cases, estimated to have occurred worldwide in 1985, the share of developing countries was 52 percent. The number of new cancers in India is estimated to be around 800,000 in 2001. The incidence among the poor also is large. In such a situation, simply because it is not treated with drugs considered as essential drugs, in no way means that there is any less need to ensure anticancer drugs at economical prices⁶⁶.

There is another case, which may be noted here. Natco Pharma is now manufacturing a generic version of AstraZeneca's Iressa, which is an anti-cancer drug. The drug priced at Rs 325 per tablet of 250 mg is at 1/10th of the cost of the international brand presently available in the market. It is conceivable that Natco could face a litigation problem as AstraZeneca is considering the drug for EMR and is in consultation with

⁶⁴ AD Damodaran, *EMR for Glivec: A TRIPS-dedicated 'Cure'?* available at <http://www.financialexpress.com>

⁶⁵ Ibid

the government agencies to do so. In all probability, the price set by Astra Zeneca will be higher than that at which Natco is currently selling the drug.⁶⁷

Box 3.1: Do Prices increase in Product Patent Regimes?

One study (1995) on Italy found that prices of new drugs increased sharply after the introduction of product patent protection in 1978. However another study (2001) arrived at the conclusion that the implementation of patent protection in South Korea, Mexico, Hungary, Taiwan and Brazil did not result in any significant rise in prices. But the latter study did not make a distinction between the new patented and the existing generic products. In fact the study did not address the vital issue, namely, were the prices of the products introduced after the product patent regime was in place higher than what they would have been in the absence of product patents.

However, the following points were raised by the chairman of the OPPI in a recent speech in contradiction to assertions that patents lead to higher drug prices.

- Patents can never be awarded retrospectively. Patents can only apply to new discoveries. Since patents of over 95 percent of the drugs available in India have expired and there are no patented drugs in the WHO List of essential Drugs, these drugs will continue to be available at current prices.
- The NPPA has power to control prices of even decontrolled drugs if found excessive

To buttress his point further, he cited studies (Study by the National Economic Research Associates-NERA, Washington-January 1998 and the Study by Dr. Heinz Redwood entitled 'New Horizons in India'-1994), which show that prices do not rise in a stricter patent regime. A study of prices in 6 therapeutic categories in 9 countries demonstrates that strengthening IPR does not have a measurable impact on real or nominal prices of existing drugs.

He also noted that at any point of time only 5-7 percent of drugs in the world market are under patent protection. The rest 93-95 percent market is of generics. For any new patented medicine, there are a minimum of 6-10 percent generic equivalents available. The price difference between the two itself acts as a control on patented drugs. Newer products, being more effective, ultimately lead to lower per day cost therapy to the patient.

In contrast to the views of the chairman of OPPI, some studies, which attempted to find out the likely effects of product patent protection on drug prices and welfare losses, came to the conclusion that the product patent regime will increase the average prices. But the extent of the price rise predicted varies a great deal. In the case of India, it varies between 12 per cent and 200 per cent.

Sources: *Sudip Chaudhuri*, The WTO and India's Pharmaceuticals Industry, *Oxford University Press*, New Delhi, 2005, p. 226; and Effect of the new patent regime on prices of medicines, speech delivered by Mr ZH Charna, Director, OPPI, India Habitat Centre, 2005

The difference in prices of generic versions of drugs and the original product is huge and this alone is indicative of increased prices in the new product patent regime. Prices of drugs may go up by 5 –10 times as is evident from the prices of drugs in India (generic versions) and the prices of drugs in other countries where product patents have been in force, such as Pakistan. To give just one example, the drug

⁶⁶ Ibid

Aciclover costs Rs. 33.75 in India while the same drug is sold in Pakistan at Rs. 363.00.⁶⁸ Therefore, that there will be a rise in prices in the wake of the new regime is, in all probability, an inevitability to be expected.

Blocking Entry of Generics

The abuse of dominance aspect of intellectual property rights in the pharmaceutical industry, which has been discussed in quite some detail above, also has certain other aspects, which include strategies adopted by companies marketing patented drugs to frustrate entry of generic rivals. Given the difficulty of ensuring access to affordable medicines, especially in developing countries, the presence of competition in the markets, particularly though generic products, is essential. Considering India's strength in the generics market, the current existence of patent holding drug manufacturers in the industry and the predicted increase in MNC patent holders in the new patent regime, the barring of generics is a definite competition concern of the present as well as the future.

Artificial barriers to block competition from generic companies would include among others the following methods aiming to lengthen market exclusivity after the expiry of a patent:

- Innovator companies having their own generics arm to stem the possible loss of business once their drugs go off patent (Pfizer's Greenstone, Novartis' Sandoz; Glaxosmithkline, Sanofi-Aventis have also developed in-house generics companies).⁶⁹ To protect their overall profits, they go to the extent of undercutting their own brands by manufacturing cheaper generic equivalents in-house or through partners.⁷⁰ While this may have predatory pricing and market pre-emption effects, often, it does facilitate access to affordable medicines.
- Injunctions to prevent legal challenges to patents, since litigation is one method used by generic producers to strip away patent rights.
- Suing (there may or may not be a legitimate cause of grievance) generic manufacturers for patent infringement so as to increase the cost of generics entering the market and discourage entry.

⁶⁷ Dr. HPS Chawla and Nalin Diwan, *The Story of EMRs-India's Response under TRIPs*, Business Briefing, Pharmatech, 2004

⁶⁸ D.P. Dubey, *Globalisation and its Impact on the Indian Pharmaceutical Industry*, available at, <http://revolutionarydemocracy.org>

⁶⁹ Bhuma Shrivastava, *US drugs going off patents in 3 years*, Business Standard, 31st August, 2005

⁷⁰ Andrew Jack, *Patently Unfair? Makers of branded drugs struggle to counter the generic onslaught*, Financial Times, November 22nd, 2005.

- Applying for excessively broad patents in order to block research carried on by competitors.⁷¹
- Launching combinations of two existing drugs as well as resorting to reformulations, modifications and new applications, gaining fresh patents in each case. The innovator companies thus keep filing for more patents of different types on their drugs to continue to enjoy exclusive rights, ‘evergreening’ in this way their existing products. The process of ‘evergreening’ of patents is accomplished by methods ranging from developing newer delivery systems and reducing side effects to shifting the drugs to over-the-counter (OTC) and identifying additional uses of the drug, not evident when the drug was first approved and priced.⁷²
- The use and aggressive marketing of brand name to increase barriers to entry for generic drug manufacturer

Box 3.2: Block or delaying generic competition –Certain Cases

Recently, the European Commission has started investigating pharmaceutical companies in Denmark, Hungary and Italy. The firms are suspected of abusing their dominant positions by engaging in collusive conduct to delay or exclude generic competition. (*Source: Dow Jones International News, AFX International Focus, 25th October, 2005*).

Aventis Pharmaceuticals Inc. is currently facing a federal lawsuit on the charge of firstly filing a patent infringement suit against Andrx, to delay their marketing of the generic version of Aventis’ popular heart drug Cardizem CD and thereafter using another delaying tactical arrangement by paying Andrx Corp., not to market their generic alternatives. This case has originated in the United States, but practices such as these may well pervade the Indian market as well, if it has not already given that companies such as Aventis have a substantial foothold in the Indian pharmaceutical market. Aventis is ranked third amongst the MNC pharmaceutical companies of India in terms of market share. (*Source: Financial Express, May 16th, 2001*)

The pharmaceutical company Schering-Plough Corp spent US\$90mn in pay offs to generic drug manufacturers as part of a scheme to avoid facing generic competition in the market, which not only distorts the competitive process but also has serious repercussions on access to affordable medicines. (*Source: Financial Express, May 16th, 2001*)

Bristol-Myers Squibb, which has very recently set up a subsidiary company in India (Bristol-Myers Squib India Pvt. Ltd), has been indicted in the United States for using tactics, which prevented patient access to lower priced generic versions of Taxol, a treatment for breast and ovarian cancer. (*Timeline of Paclitaxel Disputes, available at www.cptech.org/ip/health/taxol/taxol-timeline2001.html*)

This practice of deterring generic competition may intensify in incidence in today’s context, as blockbuster drugs going off patent in the next three years is expected to open up a \$50bn opportunity for generic companies⁷³ and companies in possession of

⁷¹ Barbara Rosenberg, *Market Concentration of the Transnational Pharmaceutical Industry and the Generic Industries in the World: Latest trends on Mergers, Acquisitions, and other Transactions*, ICTSD-UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines, Bellagio, 12-16 October, 2004, p.10.

⁷² Supra n. 70

⁷³ Ibid

these patents are gearing up to protect their terrain by engaging in a number of competitive and anti-competitive practices.

Co-Marketing and Co-Promotion Agreements

In the context of disrupting competition from generic rivals, the matter of generic market pre-emption needs to be considered. In relation to this, examining the effects of co-promotion⁷⁴ or co-marketing⁷⁵ agreements becomes pertinent.

There is an emerging trend in India to participate in co-promotion and co-marketing agreements. Certain illustrative examples would be Aventis Pasteur's co-promotion agreement with Ranbaxy for a cluster of vaccine brands,⁷⁶ Ranbaxy and Glaxo's co-marketing agreement in the Cephalexin market covering India and Nepal⁷⁷ and Wockhardt's co-marketing agreement with Bayer AG for the marketing of the anti-diabetic drug Acarbose⁷⁸. Also INFAR India Ltd, still a 51 per cent subsidiary of the Dutch company Organon Participation BV, has initiated a dialogue with other pharma companies for co-promotion and co-marketing of products⁷⁹. Many market reports have suggested entering into such agreements in the strategies they have outlined for the purpose of strengthening the industry.

The moot question here is whether co-marketing and co-promotion agreements are pro-competitive or anti-competitive, since there exists a line of thought which considers the primary *raison d'être* of such agreements to be a strategy of innovator companies to block generic competition.

⁷⁴ Co-promotion consists of sale and marketing of a defined product under a single trademark, where the parties co-operate in managing the overall process of commercialisation, from manufacture through to sale to the ultimate consumer. (See Carlo Piria, *The Position of Co-Marketing and Co-promotion between EU regulatory and Competition Rules*, Regulatory Affairs Journal, Volume 13, No. 8, p. 653,4)

⁷⁵ Co-marketing is the sale and marketing of a defined product, which is to be conducted independently and under different trademarks by each party. (See Carlo Piria, *The Position of Co-Marketing and Co-promotion between EU regulatory and Competition Rules*, Regulatory Affairs Journal, Volume 13, No. 8, p. 653,4)

⁷⁶ <http://www.contentlinks.asiancerc.com>

⁷⁷ Pharmaceutical Sector: April 2000 Review, at www.ipan.com/reviews/archives/apr2000ph.htm - 28k - Supplemental Result

⁷⁸ Pharma-Future Diagnosed, at <http://www.equitymaster.com>

⁷⁹ Infar India in talks for marketing, promo pacts at <http://www.blonnet.com>

Analysis reveals that these agreements have both pro-competitive and anti-competitive repercussions. For example, if the alliance is between a generic drug company and a branded drug company, on one hand, it allows both companies to pool together different and often complementary skills and resources in order to compete more effectively and reduces costs, but on the other hand, these kinds of alliances may discourage other generic companies from entering the market given the much higher risks and costs created by this kind of co-operation. The single most significant competition concern in this context is market pre-emption.

It is necessary to note that evidence shows that brand name companies tend to enter such agreements with generic companies when the patent protection of a well known brand name product is about to expire. In this way the former protects itself from probable losses.

Another area of concern relating to generics' market pre-emption is that as the production of generic drugs requires some level of technology, if generic companies become only distributors of brand name products, by means of co-marketing or co-production agreements, they might stop investing in research and will not be able to *produce* its own generics. This might have a negative effect in the market if a compulsory license is granted and there is no company capable of producing the drug.

Furthermore an issue to be considered is that *any* agreement among current or potential competitors – even among generic producers – may lead to higher prices or less innovation, especially when they imply a coordination of policies that include pricing.⁸⁰

GlaxoSmithKline recently entered into licensing agreements with two American generic producers - allowing them to produce “authorized generics” - right after the announcement of a poor result for the first semester of 2004, caused by generic competition that knocked US\$1.4bn off sales of its two blockbusters. Even though such deals provide the company with modest revenue, half of its losses may allegedly

⁸⁰Supra n. 71

be recovered due to them, as well as by the introduction of Glaxo's own generic, as this strategy is supposed to deter entry of other generics.⁸¹

Therefore, while co-marketing and co-promotion agreements can, on one hand, reduce barriers and accelerate generics entry in the market, on the other, they are likely to prevent long run entry as well as reduce real competition among brand names and generic firms –which may be truly costly particularly for developing countries.

The generic drug market exemplifies a competitive market (there being many players involved and a homogenous product range) and the affordability of generic products mandates that these markets be particularly sheltered from the prevalence of anti-competitive practices.

The eminent economist, Joseph E. Stiglitz has said, “Intellectual property protection strengthens dynamic efficiency and competition, but often at the expense of static efficiency and competition. If overly strong, it can actually hinder both dynamic and static efficiency and competition.”⁸² Another key statement which exemplifies the dynamics existing between patents and competition is as follows: “While patent law attempts to protect the monopoly right of excluding third parties from exploiting the patent, antitrust law attempts to prevent monopolies, encouraging competition.”⁸³ It is important to note that all this need not necessarily mean that the two fields are in conflict. IPRs promote dynamic efficiency and thereby improve welfare while fair and free competition improves overall market efficiency.

Considering that the research and development process for new drugs is costly and risky, without a minimum protection of their initial investment in creating a new molecule, there would be no incentive for drug manufacturers to engage in R&D work. All this is especially vital in the context of increasing resistance to existing drugs and new diseases being discovered. It is necessary to appreciate both the positive and negative aspects of intellectual property rights without being overwhelmed by the dimensional considerations of either. The crucial issue here is

⁸¹ Ibid

⁸² Joseph E Stiglitz, *Public Policy Towards Intellectual Property*, International Computer Law Adviser 6, June 1991, p. 6.

⁸³ Supra n. 71

how to achieve the perfect balance in interpreting and implementing IPRs and competition law so as to facilitate access to medicines and enhance both static and dynamic efficiency. This is proving a challenge to competition agencies across the world. In India, this issue remains largely unexplored. However, given the new patent regime, a close examination of all modalities involved and associated with this issue must be done soon.

Mergers & Acquisitions

As of now, the Indian pharmaceuticals industry is highly fragmented. It is expected, however, that the coming years will see intense consolidation activities. In fact, most of the top global pharmaceutical companies are consolidating their market positions, either through product rationalisation, brand acquisitions, or company acquisitions. Companies are re-evaluating their strengths and emphasising product segments that are profitable.

Whilst many domestic companies are enhancing their product portfolios by expanding therapeutic reach through product launches in new high margin segments, many others are trimming their portfolios to focus on particular therapeutic segments. Aventis, Glaxo SmithKline, Wockhardt and Ranbaxy have cut down their product portfolios in order to be more focused. Sun Pharma, Nicholas Piramal and Dr. Reddy's Labs have opted for brand/company acquisitions to increase their therapeutic reach and market penetration. Large Indian pharmaceutical companies are also expanding their reach overseas through acquisitions abroad. Examples include Ranbaxy's acquisition of RPG Aventis; and Wockhardt's acquisition of CP Pharmaceuticals.⁸⁴

Pressure to reduce drug prices has made pharmaceutical TNCs resort to mergers and alliances, in a bid to reduce R&D duplication & costs, combine product portfolios and increase reach. The total number of alliances increased from 120, in the mid-1980s, to nearly 400 in the mid-1990s. These alliances often allow pharmaceutical companies to draw upon each other's research expertise, and bring products to market more rapidly and more effectively. The mega-mergers in the global pharmaceuticals industry, in the

⁸⁴ Supra n 10 at p. 198

last few years, have been Sanofi-Aventis, Glaxo-Wellcome-SmithKline Beecham; Hoechst-Marion-Merrell Dow-Roussel; Pfizer-Warner Lambert; Ciba-Sandoz (to form Novartis); and Hoechst Marion Roussel-Rhone Poulenc (to form Aventis). The trend is expected to continue, and such mega-mergers in the global market are likely to raise competition concerns in several markets, including India.⁸⁵

Expectedly, Indian pharmaceutical industry has seen several cases of M&A over the last few years, both as a direct fall out of mergers of global players, as well as M&A of domestic players, and in some cases between global and domestic players. Several of these cases involved companies that had medicines that were used for the same therapy and hence were competing directly. The following table cites few such cases where the companies involved were a dominant or a major player before or/and after the merger. It was not possible to infer if the market power was pre-existent or achieved after the merger due to non-availability of historical data.

Table 3.1: Companies in M&A and their competing medicines

M&A & Companies	Therapeutic Category/Therapy	Company	Medicines
Nicholas Piramal (India) (NPI) Boehringer Mannheim (BM)*	Cardiovascular System: <i>1. Cardiac Disorders</i>	BM	Calaptin, Calaptin INJ
		NPI	Mono Sorbitrate 20/40
		BM	Calaptin, Calaptin INJ, ISMO-20
	<i>2. Aginal Drugs & Coronary Vasodilators</i>	NPI	Cardules, Sorbitrate
		BM	Calaptin, Calapin INJ, Calaptin-240 SR, Sembrina-250
	<i>3. Anti-hypertensive</i>	NPI	Cardules
		NPI	Aquaviron B-12, Multigesic
	Hormones: <i>Gonadal Hormones</i>	BM	Euglucon
	Nutrition: <i>Vitamins</i>	NPI	Betavite Forte
	Metabolism: <i>Poisoning & Metabolic Dysfunction</i>	BM	Mittavin
NPI		Bezalip	
Pharmacia (Boots Pure Drugs- Boots Company (India) Limited - Boots Pharmaceuticals Limited - Knoll Pharmaceuticals Limited - Abbott India Limited) Pfizer	Nutrition: <i>Vitamins</i>	Abbott	Bevidox Injection
		Boots	Betonin, Kinetone
		Pfizer	Becosules
	Musculo-Skeletal Disorders: <i>Non-steroid Anti-inflammatory Drugs</i>	Pfizer	Dolonex
		Boots	Brufen, Froben, Froben-SR
	Respiratory System: Expectorants, cough suppressants, mucolytics & decongestants	Pfizer	Corex
Boots		Protussa Plus	
Nicholas Piramal (India) (NPI)	Cardiovascular System: <i>1. Aginal Drugs & Coronary Vasodilators</i>	RP	Sectral-200
		NPI	Cardules, Sorbitrate

⁸⁵ Ibid

M&A & Companies	Therapeutic Category/Therapy	Company	Medicines
Rhône Poulenc*	2. <i>Anti-hypertensive</i>	RP	Sectral-400
		NPI	Cardules Retard
Glaxo India Burroughs Wellcome (India) Limited - BWIL	Infections & Infestations: <i>Antibiotics</i>	BWIL	Aerosporin, Cefizox
		Glaxo	Ceporan, Crystapen, Fortum, Phexin, Supacef, Supacef Captabs
	Respiratory System: 1. <i>Bronchospasm relaxants</i>	Glaxo	Salbutamol Inhaler, Ventorlin
		BWIL	Theo-PA
	2. <i>Expectorants, cough suppressants, mucolytics & decongestants</i>	Glaxo	Piriton Expectorant, Ventorlin Expectorant, Protussa Plus
		BWIL	- Actifed, Actilex
	Skin: <i>Topical Steroid Preparations</i>	Glaxo	Benovate, Benovate, Scalp Application, Benovate-C, N, Eumosome, Tenovate-M, Tenovate Skin cream
		BWIL	Neosporin Oint.
	Cardiovascular System: 1. <i>Cardiac Disorders</i>	Glaxo	Sotagard
		BWIL	Lanoxin/Digoxin
2. <i>Aginal Drugs & Coronary Vasodilators</i>		Glaxo	Sotagard
		BWIL	Cardilate
Hindustan CIBA Geigy Ltd. – HCGL Sandoz (India) Ltd. - CLARIANT (INDIA) LTD.*	Cardiovascular System: 1. <i>Cardiac Disorders</i> 2. <i>Aginal Drugs & Coronary Vasodilators</i>	HCGL	Lopresor Tablets, Trasicor
		Sandoz	Visken
	3. <i>Anti-hypertensive</i>	HCGL	Adelphane, Adelphane-Esidrex, Esidrex, Lopresor Tablets, Nepresol, Serpasil, Trasicor
		Sandoz	Brinaldix, Visken

* Both the companies involved were highly active in some other therapeutic categories. However, further details were not available.

Source: CIMS, Manish Agarwal, *Analyses of Mergers in India*, MPhil Dissertation, University of Delhi, 2002, Websites of the companies.

What then are the anti-competitive practices, which may be expected as a result of mergers and acquisitions? Why is it essential to examine all the modalities and possible repercussions of a desired merger before sanctioning the process? Mergers are not necessarily anti-competitive and may lead to creation of efficiencies. The trends of mergers and acquisitions in the global pharmaceutical market seem to reveal that for the pharmaceutical industry, these transactions are an appropriate way of counteracting competition and achieving more profitable returns and high market shares.⁸⁶

However, the concern is whether the mergers, the acquisitions or the joint ventures will enable parties to achieve or strengthen a dominant position in the markets in which they compete and whether there will be abuse of dominance leading to higher prices, reduced output or less innovation. To cite just one example of possible anti-

competitive ramifications: such transactions may eliminate a significant direct competitor in a relevant therapeutic category, particularly where there are few substitutes and new entry is difficult. This is often the case in many pharmaceutical markets, due to technological and regulatory impediments to entry.

As not permitting the establishment of dominant structures in the market is an effective preventive method, mergers and acquisitions should be subjected to careful scrutiny. A particular cause of anxiety is that these processes often lead to patent pooling, which gives rise to the possibility of abuse of dominance with respect to their combined intellectual property rights.

Mergers and acquisitions can raise competition concerns, whether they combine two producers of competing branded products, producers of branded and competing generic products or two products of competing generic products.

In this context, it is worth mentioning that the particularities of the pharmaceutical market require that attention is given not only to transactions involving companies competing in the same market, but also to transactions that may be inhibiting future competition, either by increasing barriers to generic entry or causing potential harm to innovation.⁸⁷

Till date there has been no outright ban on any proposed merger. In a few cases the mergers did result in the parties to the merger acquiring too much market power for some of the products involved. The parties, however, eased the concern demonstrated by the authorities by means such as offering partial divestitures, and delivering on promises to outlicense relevant products. Such accommodations were involved in the case of the merger involving Rhone Poulenc and Hoechst and also in the merger involving Glaxo Wellcome/Smithkline Beecham.⁸⁸ The latter case, of course, has many other dimensions as well and has been discussed subsequently in more detail.

⁸⁶ Supra n. 10

⁸⁷ Ibid

⁸⁸ Mario Monti, *EC antitrust Policy in the Pharmaceutical Sector*, 2001, available at europa.eu.int/comm/competition/speeches/text/sp_2001_013_en.pdf

At present, it would appear that mergers and acquisitions cannot easily lead to the creation of a dominant position as globally no one company has a market share of more than 11 percent. In fact, there is only one company, Pfizer which has a percentage share of the global market in excess of a two-digit figure⁸⁹. However, data relating to market shares at a global scale are hardly indicative of absence of concentration, since when one studies the relevant markets, i.e., therapeutic categories of medicines; there are several cases of high levels of concentration.

Significantly, the consolidation in the global generic industry following Teva's acquisition of Ivax and Sandoz's takeover of Hexal has created a huge gap between the top two generic players and the rest of the industry⁹⁰. Analysts have opined that if Ranbaxy can takeover or tie up with a large company, it could become the third-generics company in the world⁹¹. Whether the gap between these companies and the others in the generics market may in the future give rise to anti-competitive concerns remains to be seen.

In India, the new competition legislation provides for merger review beyond a threshold level. As the threshold level is reasonably high, only the big deals will come under the scrutiny of the competition authority. This does not necessarily mean that all such deals need to be blocked. The deals, however, will require complex analysis to examine the impact of the deal on different therapeutic segments. For example, Glaxo-Wellcome-SmithKline Beecham was allowed to merge by the EU, on the condition that they divested product categories where competition concerns could arise. The deal went unchallenged in most developing countries. However, South Africa, who closely cooperates with the EU, imposed similar conditions before it allowed the merger of their local subsidiaries. This shows how India can deal with merger and acquisition cases, not only of domestic companies but also of global companies, with local presence in India.⁹²

⁸⁹ Supra n. 16

⁹⁰ Javed Sayed, *Pharma cos snap up \$ 500-m buys in 18 months*, Economic Times, September 4th, 2005

⁹¹ Ibid

Box 3.3: Mega-merger – Glaxo Wellcome and SmithKline Beecham

Two large pharmaceutical giants, Glaxo Wellcome, and SmithKline & Beecham, merged to become GlaxoSmithKline (or GSK). This merger created a leading global pharmaceutical company, with sales of £18.1bn in the year 2000. Headquartered in the United Kingdom, GSK supplies products to 140 markets in the world. Obviously, the merger created competition concerns in several countries, yet it went unchallenged in most of them. India did not have a merger review provision in its extant competition law, the MRTPA, so the merger was not investigated. In Sri Lanka, the competition authority did not even take up the case of merger between Glaxo Wellcome and SmithKline Beecham, saying that that it did not have jurisdiction, even though both the companies had commercial presence in the country!

The handling of the merger case by South Africa is quite illustrative. Upon investigation and evaluation of the merger, the Competition Commission reached the conclusion that the transaction should be prohibited, on competition and public interest grounds. In particular, the Commission was concerned that the merger would result in the merging parties having high market shares in two therapeutic categories. The Commission stipulated that there would be unacceptable levels of concentration with respect to Bactroban, Zelitrex and Famir, and there were no appropriate substitutes to counter any price gouging, or ease of entry, to offset the concern.

Upon prohibition of the merger by the Commission, the merging parties volunteered to out-license some of their products identified, by the Commission, to be the cause of the competition concerns. The merging parties, and the Commission, reached an agreement and the merger was allowed, conditionally. Interestingly, the conclusion of the Commission, in making its recommendations to the Competition Tribunal, was substantially the same as the conclusions of the EC, in so far as the overlap of products was concerned. This may partly be due to the fact that the Commission sought, and received, extensive cooperation from both the US and EC. However, it may be noted that the Commission completed its investigation long before the case was decided by the EC.

Source: Nitya Nanda and Amirullah Khan, Competition Policy for the Pharmaceutical Sector in India, in “Towards a Functional Competition Policy for India”, Pradeep Mehta (ed), Academic Foundation, New Delhi, 2006.

Notwithstanding all of the above while mergers may or may not have anti-competitive effects, they are necessary for many companies to remain in the competition. Consider the key drivers of the increasing tendency to merge, rising R & D costs, decline in the number of new product launches, pressure from expiry of patents on existing products, need for improvement in sales and marketing, access to new markets, healthcare cost-containment efforts of governments affecting the pricing power of the company and the desire to achieve economies of scale.⁹³

⁹² Supra n. 10

⁹³ Amul Gogna, *It can provide companies access to new markets*, The Financial Express, June 27th, 2005.

In the new product patent regime, while the bigger Indian companies, such as Ranbaxy and Dr. Reddy's can afford to develop and market their own brand of drugs in the highly competitive regulated markets, the same is not the case with small and middle-rung companies. They do not possess the financial capacity to survive in the rapidly changing market environment and takeovers, strategic tie-up, mergers and marketing alliances allow them to survive⁹⁴. While the bigger companies undergo mergers and acquisitions for further expansion and profits, SMEs do the same to remain competitive. With almost all multinationals expected to set up their facilities in India or start marketing their patented products, it is predicted that competition will become intense⁹⁵.

Given that the bulwark of the Indian pharmaceutical sector, the process patents system, is now in the past, it is essential to develop sound survival strategies and for the Indian pharmaceutical sector, mergers and acquisitions is one route being resorted to. In fact, since January 2004, Indian pharmaceutical companies have made 18 international acquisitions with an aggregate deal value of more than \$500mn approximately. And with companies of the likes of Ranbaxy and Wockhardt predicted to seek "big-ticket" M&As, the figure is set to rise⁹⁶.

It is necessary to mention that bigger companies often seek M&As to maintain or increase their market shares, which may in the long run have possible anti-competitive effects if a dominant position is created; examples in this particular context would be Teva scouting for a big acquisition in India which will help it in regaining its top position in the global generic pharmaceutical market. Teva lost this position after Novartis bought over Hexal in a \$8.3bn deal.⁹⁷

Keeping in mind the slew of mergers happening and slated to occur, the benefits such mergers entail and the possible anti-competitive effects, competition authorities need

⁹⁴ P Vinod Kumar, *Drug companies go for second rung of foreign acquisitions*, Financial Express, 19th August, 2005.

⁹⁵ See generally, *M&As can help launch new molecules*, The Financial Express, June 27th, 2005. Also see Giteesh Chandra Prasad & Javed Sayed, *Pharma MNCs to have strategic tie-ups here soon*, Economic Times, April 7th, 2005.

⁹⁶ Supra n. 90

⁹⁷ Rajesh Unnikrishnan, *Global generic drug cos descend on India*, Financial Express, March 13th, 2005.

to carefully analyse the probable repercussions of a proposed merger before permitting or for that matter disallowing the process to go ahead.

Collusion and Other Anti-Competitive Practices

Collusion

Collusive activities can range from cartelisation to bid rigging. Collusive activities among Indian manufacturers of pharmaceuticals have not yet been discovered. However, existence of a tendency towards collusive behaviour in certain segments, where there are just a few manufacturers, cannot be ruled out, particularly when an international cartel in bulk vitamins was in existence for quite a long time. According to one estimate, this vitamins cartel cost India about US\$25mn, in the 1990s, due to overcharging.⁹⁸ There may have been the incidence of other cartels as well affecting the pharmaceutical industry which have remained undiscovered till date. Further pernicious effects of cartels, international or domestic, may be felt in the future.

Box 3.4: Collusive Practices – A Brazilian Case Study

The following case study illustrates collusive conduct in the pharmaceutical industry and is significant, because most of the companies involved in this case have a foothold in the Indian industry as well. Twenty pharmaceutical laboratories were recently fined by competition authorities in Brazil, for participating in a cartel, which allegedly attempted to boycott the entry of new generic medicines. The laboratories involved include large multinational groups such as Roche, Aventis, Bayer, GlaxoWellcome and AstraZeneca. The intention of the cartel was to establish a joint action- involving general practitioners-to develop an information campaign against generics, thereby spreading what was regarded as, “distorted information”. This case reveals collusion between pharmaceutical companies and doctors on the matter of barring generics, an issue of grave concern since patients usually implicitly rely on the advice meted out by their physicians and in such a case may be deprived of quality products at less expensive prices.

Source: 20 Pharma Laboratories Fined for Cartelisation, Folha News, 13th October 2005.

One case illustrates the kind of price fixing practice companies engage in. In the United States, Mylan, a maker of generic drugs was accused of price fixing with its suppliers pushing up the cost of medicines 3000 percent.⁹⁹ This might be a problem in India as well, with companies making their stance against the fixing of trade margins for generic drugs apparent. In another case the US State of Pennsylvania sued a slew of pharmaceutical companies for artificially inflating prices and the use of deceptive

⁹⁸ Supra n 10

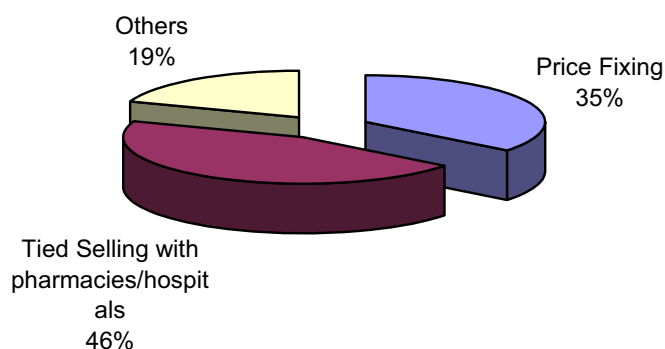
⁹⁹ Mylan and others-Another Drug Cartel, available at Antitrust Regulators Crack Down on Health Industry, Los Angeles Times, December 22nd, 1998

sales practices.¹⁰⁰ These companies include a number of MNCs, which have a significant presence in Indian markets, such as AstraZeneca, Bayer, GlaxoSmithKline, Pfizer and Bristol-Myers. Cartelisation through cross licensing is another practice, which exists in the industry and affects fair and free competition.

Table 3. 2: What Pharmaceutical Industry Thinks

	Yes	No	(Percent) Can't say/ Don't Know
Aware of collusive practices in the industry	57.4	42.6	
Liberalisation increased the threat of collusive practices of MNCs	31.5	25.9	42.6
Felt the impact of such collusive practices	24.1	75.9	

Figure 3.2: Kind of Existing Collusive Practices - Pharmaceutical Industry



In our sample of respondents, the majority of pharmaceutical companies surveyed claimed awareness with respect to the existence of collusive practices in the pharmaceutical industry and a high 32.3 percent of respondents asserted that such practices prevail in the industry to a great extent. As Figure 3.2 indicates, tied selling was ranked as the most frequently occurring anti-competitive conduct in the pharmaceutical industry. Only 24.1 percent of the respondents admitted to having directly felt the impact of collusive practices. Given the notoriety of MNCs of

¹⁰⁰ Bayer and others defraud Medicaid Drugs, available at

engaging in anti-competitive practices and that their presence in the Indian market is predicted to increase substantially in the new patent regime, there may well be an increased incidence of collusive and other anti-competitive practices. This is a matter of concern. Industry perceptions on this issue revealed that a high percentage of companies surveyed, believe that liberalisation has increased the threat of collusive practices of MNCs.

Although there has been no documented evidence of such activities in India, the results of the survey and interviews conducted indicate that collusive behaviour is quite common in pharmaceutical markets. The vital question to consider is whether or not the absence of proof of collusive conduct in our industry reflects the reality of industry functioning or simply reveals the incompetence of our investigative institutions.

Other Practices

Providing Incentives

Giving incentives to doctors and pharmacists is one practice engaged in by companies, which blatantly violates free and fair competition. This may be motivated by a desire to create a larger market share or to gain greater profits by pushing overpriced drugs and is achieved through aggressive promotional strategies aimed at doctors, and by providing lucrative margins to chemists. Incentives to pharmacists to induce them to buy large quantities of prescription drugs have become commonplace in India, where thousands of drug manufacturers compete for shelf space, and the country's half-million pharmacists wield an unusual amount of clout. Hence, often there is a huge gap between the wholesale price and the retail price. A study by the Mumbai-based market-research firm, Interlink Healthcare Consultancy, found that all but one of the top 25 drug companies, in India, offered heavy discounting deals at least once a month. A letter to pharmacists from Blue Cross Laboratories Ltd, a Mumbai company, outlined a deal that offered pharmacists up to a 103 percent profit margin on a variety of prescription drugs.¹⁰¹

<http://www.uow.edu.au/arts/sts/bmartin/dissent/documents/health/pharmfraud.html>

¹⁰¹ See generally, Daniel Pearl and Steve Stecklow, *Drug Firms' Incentives Fuel Abuse by Pharmacists in India*, Wall Street Journal, 2001.

Box 3.5: Discounts to Pharmacists Anti-competitive?

Discounts admittedly allowed by Synbiotics Ltd., a pharmaceutical company, to its pharmacists, was held by the competition authorities in India, to be according to the mercantile practice prevailing and permissible under the law for promoting the sale of their pharmaceutical products. [2001 CTJ 45 (MRTP)] Whether discounts and rebates of this kind have an adverse effect on competition in the pharmaceutical sector is a matter of debate.

The Finnish Competition Authority has held that rebates commonly granted by pharmaceutical companies to pharmacies violate the Finnish Act on Competition Restrictions and EU competition rules. Accordingly, the FCA requested that the pharmaceutical companies concerned inform it by December 22, 2005, of measures to be taken in order to remove the unlawful features of the rebate agreements. According to the FCA's investigation, the rebates granted on the wholesale prices of pharmaceutical products restrict competition between pharmaceutical companies and curtail the choice available to pharmacy customers, particularly in respect of prescription drugs. As regards prescription drugs, the rebates relate primarily to pharmaceutical products that are substitutable with generics. According to the FCA, there are rebates in practice, which have a tying effect and limit the opportunity for competing pharmaceutical companies to obtain shelf space for their products. As of February 1, 2006, the Finnish Act on Medicines has been amended to provide that any medicinal product sold exclusively in pharmacies shall be sold at the same wholesale price to pharmacies. This means that rebates and other benefits will no longer benefit individual pharmacies, but shall be applied in respect of all pharmacies. (*Rebates by Pharmaceutical Companies Found Unlawful*, International Law Office, 2006)

Pharmacists in developed countries have little influence over the volume of prescription-drug sales¹⁰². There, the marketing push usually targets doctors, the main legal conduit for prescription drugs and give kickbacks, which can range from free airline tickets to cars.

Misdiagnosis

There are companies, which use anti-competitive methods to create a market for their product. Novartis, a company that has a large market share in India has been recently accused of fuelling the misdiagnosis of Attention Deficit Disorder (ADD) through its close association with psychiatric associations and its presentations at their meetings, and conspiring thereby to carve a niche in the market for Ritalin, their drug for ADD through expanding the use of the drug by being responsible for millions of children being misdiagnosed with ADD.¹⁰³

¹⁰² Supra n 10

¹⁰³ Novartis-Diagnosing for Profit, Writing May Be on Wall for Ritalin, InsightMag.com October 16, 2000

The major anti-competitive practices prevailing in the pharmaceutical industry having been delineated, it is necessary now to briefly overview the violations of competition principles occurring in the health delivery system.

ANTI-COMPETITIVE PRACTICE IN THE HEALTH DELIVERY SYSTEM:

The three components of the health delivery system, which has been prioritised for the purpose of this report, are doctors, pharmacists and hospitals. Diagnostic laboratories are also brought into the picture as they are very often collusively linked with other components of the health delivery system. This section shall examine the anti-competitive practices widespread in their domains.

Doctors

The most significant unethical practice engaged in by doctors is irrational drug prescription. Ideally the cheapest, most readily available drugs should be prescribed. But usually the more expensive drugs are prescribed. The doctors are motivated by the kickbacks received from the pharmaceutical companies. Even if not influenced by incentives, doctors may continue prescribing a particular drug found to be effective and simply not bother to find out if there are any less expensive alternatives with the same effects. A rough estimate of irrational drug use would be 50-60 percent.¹⁰⁴ The reason why this practice is considered anti-competitive is because it impinges upon one of the basic tenets of competition policy, which is to avail of the best possible services at the lowest prices feasible.

Another practice, which is rather prevalent among doctors, is accepting commission for referrals. This may be interpreted to be anti-competitive in effect. Rational decision-making is an important principle of competition. Here the doctor is making the decision on behalf of the patient as to where best to send the patient for further treatment. Profit considerations would obviously vitiate such decision-making and herein lies the impingement on free and fair competition. However, although such practices are generally known to prevail, 76.7 percent of doctors surveyed denied being offered commission upon referral. A high percentage of 59.5 percent of doctors mentioned that other doctors take commission for referrals and 48.9 percent of these respondents felt that this practice adversely affected healthcare.

The aggressive strategies followed by the big multinational companies producing branded formulations leads to the entire branded versus generics debate in context of prescription drugs. Ensuring generic prescriptions may resolve to a great extent this practice of pharmaceutical companies influencing doctors.

Doctors as substitute consumers are certainly in a position to abuse the implicit faith many patients vest in them. Many sources confirm that this often does happen. But it must also be recognised that the choices many doctors make on behalf of their patients are motivated by welfare considerations rather than on the basis of kickbacks. Profit need not be the driving factor behind doctors not prescribing the least expensive medicine on the market or the reason for referring their patients to particular diagnostic centres, pharmacies or to other doctors. It might also be because of their awareness of greater effectiveness of a particular drug, because even if two drugs are same, their might be significant differences, for instance in their bioavailability¹⁰⁵. Certain diagnostic centres may be preferred not because of any commission consideration, but because the doctor has knowledge of comparatively superior quality services offered.

Whatever be the motivation, the vital question here is do these choices of the physician provide patients with the choice of quality goods and services at the best prices? If not, then such choices of the physician may be termed as anti-competitive.

Pharmacists

The anti-competitive practices most prominently engaged in by pharmacists are reflective of collusive behaviour. Pharmacy-owners may be considered to have banded together to form a huge cartel in the guise of a trade association, All India Organisation of Chemists and Druggists (AIOCD).¹⁰⁶ A high percentage of 64.25 percent of all pharmacists surveyed are members of the AIOCD The AIOCD is known to launch boycotts against drug companies to grab higher profit margins.

¹⁰⁴ Interview with Mr. Barun Kanjilal

¹⁰⁵ Bioavailability is a measurement of the rate and extent of a therapeutically active drug that reaches the systemic circulation and is available at the site of action.-See L Shargel, L. & A.B. Yu, *Applied biopharmaceutics & pharmacokinetics*, McGraw-Hill, New York, 1999.

¹⁰⁶ Supra n 10

As indicated by Figure 3.3, in our sample of respondents from the pharmaceutical industry, more than half of the companies admitted to facing demands from pharmacies for greater margins. Figure 3.4 shows that a high percentage of these respondents believed that these demands were on the higher side.

Figure 3.3: Companies facing demands from pharmacists for greater margins

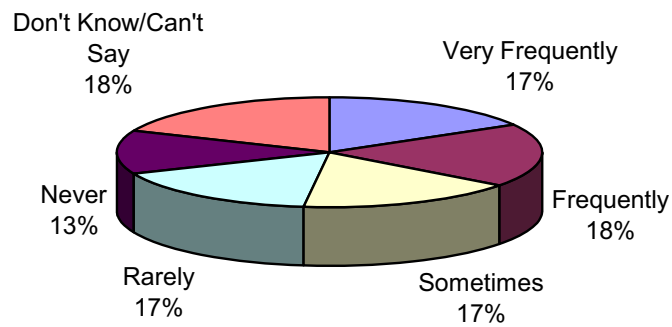
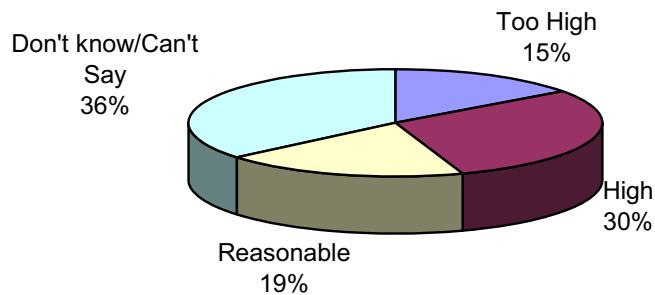


Figure 3.4: Are the demands for greater trade margins from pharmacists too high?



On the other hand, in our survey of pharmacists, not surprisingly, 79.7 percent of the respondents thought that the level of profits sought from companies was reasonable. A mere 10.5 percent of the pharmacists surveyed admitted that the profit margins sought from companies were on the higher side.

Pharmacist associations have been known to demand that drug companies obtain a "no-objection letter" from each state trade association, before a new drug could be sold there. Otherwise it would be excluded from the pharmacists' stock lists. For each new drug, the trade groups usually solicit a cash donation. AIOCD has also forced some drug companies to sign "memorandums of understanding" in which they agree to increase profit margins of pharmacies¹⁰⁷.

Box 3.6: Rent-seeking by Pharmacists: A Few Cases

Strong-arm tactics of the pharmacists' associations (at state level as well as national level) are nothing new. In 1984, a case came before the MRTP Commission as the Retail and Dispensing Chemists Association, Bombay, directed all the wholesalers and retailers to boycott a Nestle product, till the company met its demands.

The Commission observed that the impact of the chemists' boycott could, by no stretch of the imagination, be considered negligible. The boycott represents an attempt to deny the consumers certain products, which they are used to and, therefore, the hardship to such consumers is indisputable. The Commission accordingly passed a 'cease and desist' order (RTP Enquiry No. 10/1984).

Even before that, in 1982, the All India Organisation of Chemists & Druggists, had to face a similar stricture in a similar case (RTP Enquiry No. 14/1982, order dated 25-9-1984).

AIOCD was brought before the Commission once again, in 1983. It issued a circular to various pharmaceutical companies, threatening that if they dealt with the State cooperative organisations and appointed them as Stockists, granting them sale rights, it would expose the companies to a boycott by its members. The case was decided in 1993, and the Commission observed this to be the restrictive trade practice of refusal to deal (RTP Enquiry No. 37/1983, decided on 25-6-1993).

Nevertheless, undeterred, AIOCD decided to boycott the "Septran" range of products, manufactured by Burroughs Wellcome (India) Ltd. When the case came up before the Commission, AIOCD pleaded that it did not issue any such circular to the dealers, threatening to boycott the products. However, the Commission observed that a boycott could be conducted by way of an understanding among those perpetrating it, or by word of mouth among them. Merely because of the absence of a circular, calling upon the sellers to boycott, it could not be said that there was no boycott (1996, 21 CLA 322).

Recently, the MRTP commission again issued a cease and desist order against a boycott. In this case the material published in the bulletin of Retail and Dispensing Chemists Association read in one part as 'it is necessary that all retailers suspend dealing in Wander (pharmaceutical company) and ensure no retailer sells even the other products of Wander Ltd...'. The Commission held that a boycott of such nature might go against public interest by not making available an essential commodity. [1999 CTJ 436 (MRTP)].

¹⁰⁷ Supra n. 101

Price decontrol has led to greater trade margins for pharmacists. It just might be that the benefits of price decontrol, of several drugs, are going to the pharmacists disproportionately, more than the manufacturers. This defeats the very purpose of the deregulation that is meant to provide the manufacturers with the ability to spend more on R&D. By giving extra profits to the pharmacist, instead of reducing the retail price, manufacturers are keeping medicine prices higher than necessary for Indian patients.

Box 3.7: Trade Margins to Pharmacists

Statistics reveal the high level of trade margins, which pharmaceutical companies give to pharmacists. Cipla reportedly sells a strip of 10 pills of its painkiller Nicip to the retail dealer at Rs. 2 a strip. The retailer then sells it to the customer at Rs. 25 at a profit of 1,150 percent. According to information provided by Business World, Ranbaxy's anti-allergic Stanhist costs retailers Rs. 1.80 a strip. This is sold to the customer at Rs. 26. Web information provides further accounts of huge trade margins. A few instances would be as follows: 10-tablet strip of Methygin costing Rs. 5.75 sells at Rs. 54, Nimesulide in a 10-tablet strip costing Rs. 1.85 sells at Rs. 10. The following chart by NPPA gives further conclusive data in the matter of massive trade margins to pharmacists.

Company	Brand	Price printed on the strip	Purchase price of retailers
Ranbaxy	Stannist	26	1.80
Cadila Healthcare	Ceticad	26	1.60
Lyka Labs	Lycet	25	1.44
Wockhardt	Setride	25.2	1.70
Cipla	Cetcip	27.5	2.00
Ranbaxy	Pyrestat-100	25	1.50
Lupin	Lupisulide	24	1.94
Welcure Drugs	Omejel Caps	33	4.50
Wockhardt	Merizole-20	39	6.48
All figures in Rs.			

SOURCE: NPPA, as cited in FT, July 27th, 2004

It is the consumer who ultimately bears the brunt of the pharmacists receiving such high trade margins.

It is to be noted that higher trade margins are usually given in the case of generics. Drugs sold as generics maintain a large margin to compete with successful brands although they have a small market share. Typically the gap between retailer's procurement price and the retail price of drugs sold –through prescription or sales promotion through medical practitioners-vary between 5-16 per cent. But it is much higher for generic sales (direct to retailer). The cases of at least three drugs –Nimesulide (for fever and pain), Omeprazole (antacid) and Cetrizine (anti-allergic) have come to the notice of the ministry of chemicals and fertilizer. The government is now trying to rectify the situation. A meeting with NPPA was followed by a survey by the Drug Controller who discovered that the consumer was being overcharged for these three formulations

Generally see: MV Kamath: Pharmaceuticals are cheating citizens. Also see, *Govt Asks why Drug Cos are Overcharging*, Financial Times, July 27, 2004

This issue has engaged the attention of the Government. In December 2004, the Ministry of Fertilisers & Chemicals tried to bring in curbs on trade margins of pharmacists. This move was strongly resisted by AIOCD. On the contrary, they demanded for the lowering of Maximum Retail Prices, which are under the control of manufacturers. The AIOCD added that it would be impossible for them to survive on a maximum gross margin of 20 percent, excluding excise duty.¹⁰⁸ Indeed, there is some sense in the argument of the pharmacists and the manufacturers cannot avoid the responsibility, as they are the ones who control MRPs. In fact, high trade margin is not only due to bargaining power of the pharmacists but also due to manufacturers strategy to capture greater market shares through providing incentives to doctors and pharmacists.

Informal collusion by pharmacists at local level must also be considered. For example, printing of maximum retail price (MRP) is mandatory under the Standards of Weights and Measures (Packaged Commodities) Rules, 1977. MRP needs not be the actual selling price and the retailers are expected to sell at prices lower than MRP. However, in practice, the retailers do not compete and the MRP becomes the reference price for them to collude informally.¹⁰⁹

Dealing with such collusive behaviour of pharmacists will be one of the biggest challenges for the competition authority.

Hospitals

Hospitals are an important part of the health delivery system. However, not much is known about their practices, though random analysis reveals that there have been cases of agreements entered by hospitals with drug manufacturers to exploit consumers. A case that was brought in a consumer forum in Andhra Pradesh revealed that a private hospital had entered into a contract with a drug manufacturer to supply drugs to the hospital at prices, which were above the market price. 27.2 percent of the hospitals surveyed for this study confirmed that hospitals and manufacturers did enter into agreements to exploit consumers. However, a high 72.8 percent of hospitals

¹⁰⁸ Supra n 10

¹⁰⁹ Ibid

denied knowledge of such practices. Of those respondents who answered in the affirmative, 41.3 percent believed that such practices existed to quite some extent.

Figure 3.5: Hospitals and Manufacturers enter into agreements to exploit consumers-perceptions of hospitals

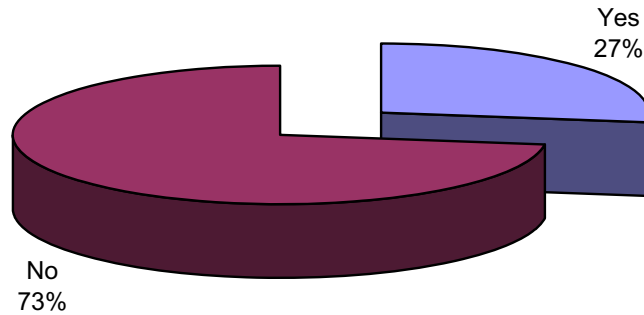
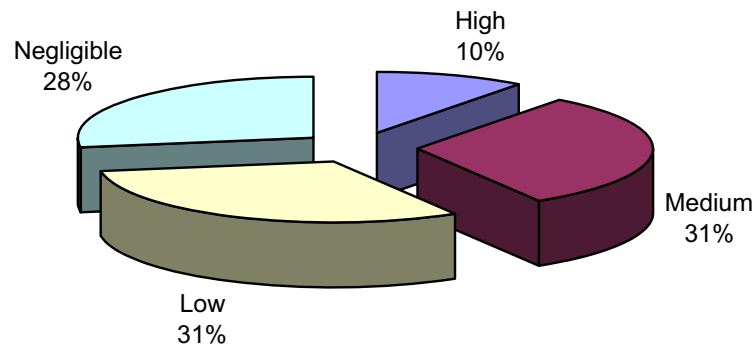


Figure 3.6: Extent of collusive agreements between hospitals and drug manufacturers



Our survey of doctors indicated that 19.5 percent of the physicians surveyed believed that hospitals and drug manufacturing companies entered into agreements to exploit consumers, with a high 51.1 percent of respondents unable to express an opinion on the matter. Of those who responded in the affirmative, 61.5 percent felt that it was quite a prevalent practice in the health sector.

Hidden costs, which is an issue in many hospitals is also anti-competitive in nature as the consumer pays more than warranted.

Tied Selling

A particular anti-competitive practice, common to all three of the aforementioned components of the health delivery system is tied selling. It basically means restricting choice of consumers by a provider of goods or services, in some other goods or services which may or may not be related. Tied selling occurs normally when there is monopolistic dominance or general scarcity in the market for some goods or services. However, it can also occur even otherwise if the market players act in collusion and all the players force such tied selling.

Overall, tied selling of medicines was not found to be a major problem as only about 15 percent of consumers surveyed claimed that they have been asked to buy medicines from a particular shop. However, in some cities the situation seems to be against the trend. On an average, those visiting private doctors or private hospitals reported a higher incidence of tied-selling of medicine. This was, however, not reflected in the responses of service providers who indicated that such practices may be equally prevalent.

Nearly half of the people who were asked to buy medicines from a particular medicine shop found prices to be reasonable there. However, this was not enough a reason to buy medicines from there and people mostly bought from there to follow doctor's advice or not to annoy him/her. Interestingly, less than two percent of the consumers could go against the advice of the doctors and buy the medicines from some other shop. It should also be mentioned here that more than half of these people thought that the issue here was of better or genuine medicines and only about 36

percent of them thought that their doctors advice was motivated by profit considerations.

The perceptions of consumer-oriented NGOs, however, differ substantially from the impressions consumers seem to have on the incidence of tied selling in the medical profession. In respect of the four cities of Delhi, Mumbai, Kolkata, Chennai, a high percentage of respondents, 54.9 percent claimed knowledge that doctors suggested buying medicines from a particular shop. They attributed the usual adherence to the recommendations given by the doctor to the implicit trust patients reposed in their doctor. Although a greater percentage (43.9%) considered tied selling to be expressive of the doctor's concern to ensure safe and reliable medicines, a high percentage of 31.6 percent of NGOs believed tied selling engaged in by doctors were motivated by profit considerations.

Figure 3.7: Motives behind tied selling of medicines-NGO perceptions

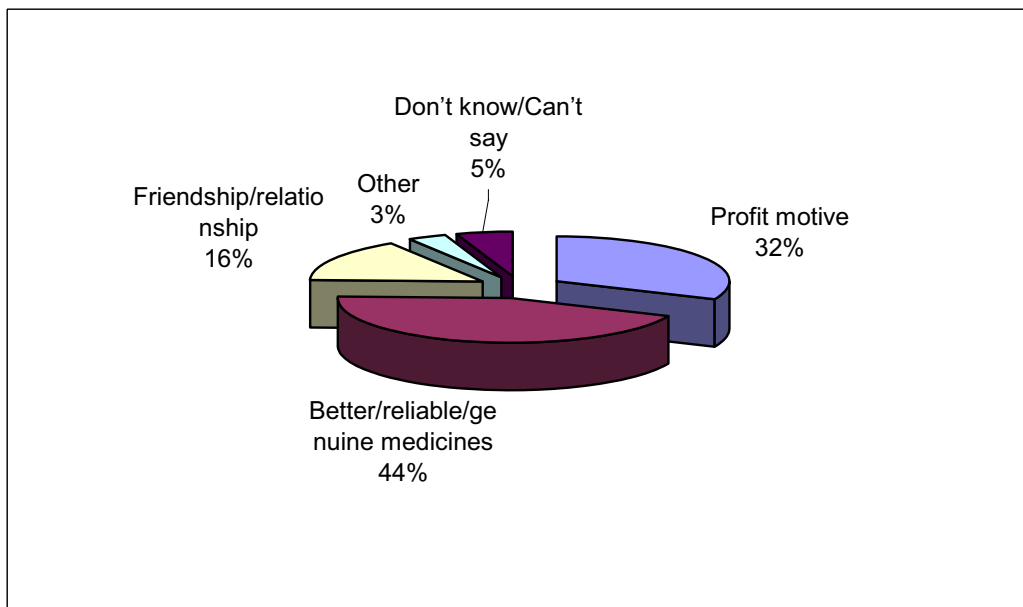
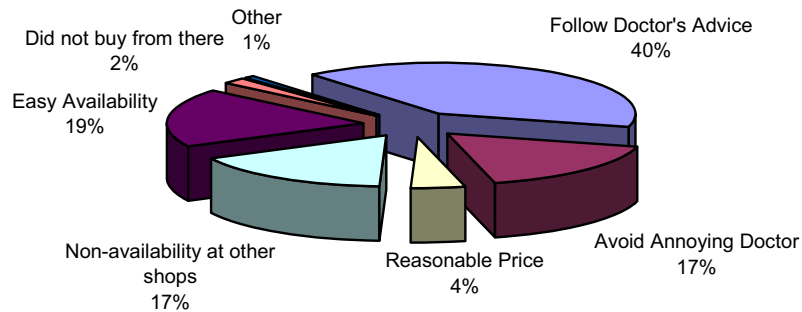


Figure 3.8: Reasons for Accepting Tied-selling of Medicines - Consumers



When doctors were asked about tied-selling of medicines, only 28.6 percent admitted that they ever resorted to such practices. And among them, none admitted to being motivated by profit considerations, 92.1 per cent asserting that they do it to ensure genuine and reliable medicines for their patients. When they were asked about whether other doctors gave such specific instructions, 52.6 percent responded in affirmative and 19.4 percent of them thought that the motive behind others resorting to such a practice was profit or commission considerations.

In our survey of hospitals, only 33 percent of respondents would admit to engaging in tied selling and among these respondents, 70.6 percent asserted that their reason for doing so was ensuring reliable and genuine medicines. Interestingly enough, only 44.1 percent of respondents believed that ensuring genuine and reliable medicines was the reason prompting tied selling in other hospitals. 26.5 percent attributed tied selling by their peers to profit making considerations.

49.6 percent of pharmacists surveyed admitted to having tie-ups with doctors and hospital; a small percentage of 19.5 percent of pharmacists denied the existence of such a practice. It may be noted in this context that there have been several media reports on the issue, including one investigative reporting by tehelka.com.

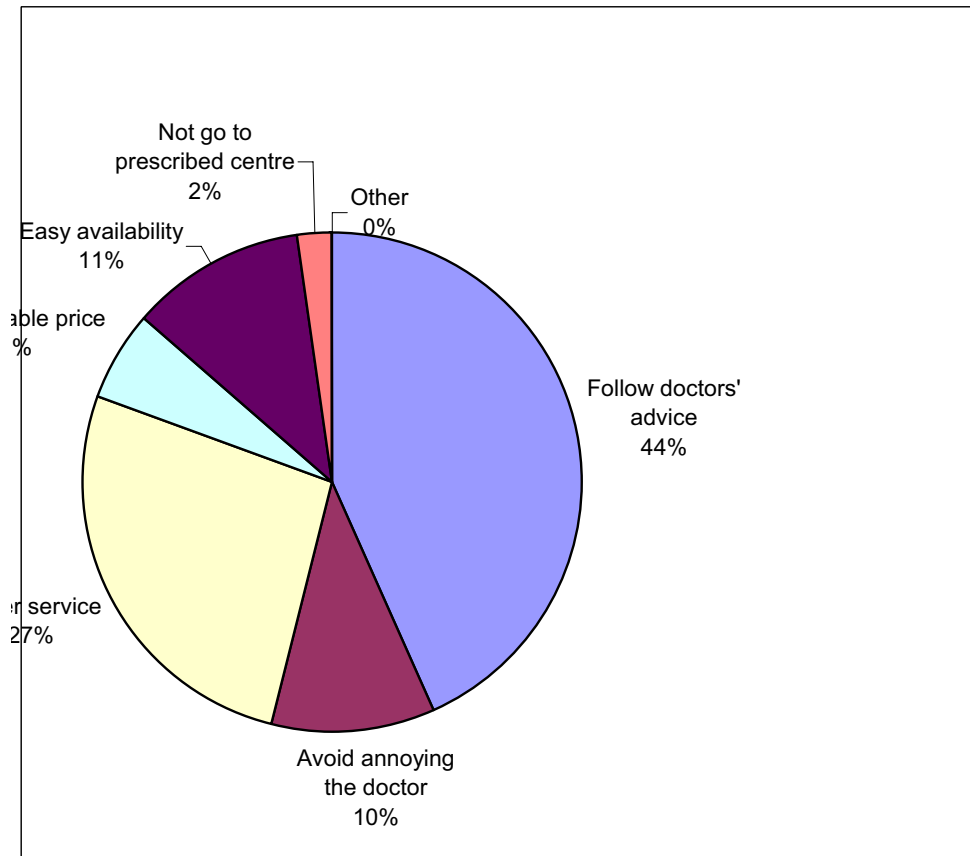
Recently, some pharmaceutical companies have entered into hospital business as well. Some of them are also getting into the business of retailing of medicines. It has also been reported that the chemists' association is forming a corporate entity in response to these plans. All these can have serious competition concerns.

Tied Selling of Diagnostic Tests

In our sample of respondents, slightly more than half of the people were asked to undergo some diagnostic test. Among these people, about half were instructed by the doctors to undergo the test at a particular laboratory. As with the medicines, people visiting private doctors or private clinics reported higher incidence of tied-selling of diagnostic tests.

Among the people who went to the prescribed laboratory, more than half went simply to follow doctor's advice or not to annoy the doctor. A quarter of them cited better and reliable service as the reason. A section of these people of course might have been influenced by their doctors to think so. Slightly more than five percent said the charge being reasonable was the reason, while for about 11 percent it was easy accessibility. Just about two percent of the people went against the advice of the doctor and got the testing done from a different laboratory.

Figure: 3.9: Reasons for Accepting Tied-selling of Diagnostic Tests - Consumers



It is, however, interesting to note that though about 35 percent of people thought that profit motive on the part of the doctors could be the reason for prescribing a particular test centre, an overwhelming 55 percent thought doctors advised so to ensure reliable services. It is quite surprising to see that a higher percentage of consumers than the service providers think that tied-selling of diagnostic testing is done to ensure reliable testing. Interestingly, about 43 percent of all the people interviewed thought tied selling practices by doctors are not ethical or justified. A high 30 percent could not give their opinion on this, while about 21 percent did not have any problem with such practices.

The survey shows that the people with higher income have relatively less problems with such practices. This may be due to the fact that price differentials have less significance for richer people and easy availability of the goods and services are important for them. They might also feel that paying slightly more may be worthwhile if the doctors have more confidence in a particular shop or a test laboratory.

Table 3.3: Views on Tied-selling by Income Groups

	Lower	Lower middle	Upper middle	Higher
Ethical & Justified	19	18.56	19.89	45
Unethical & Unjust	44.67	46.22	53.89	28.5
Not sure	36	33.89	26.22	21.5

Consumer oriented NGOs were also surveyed on this matter of tied selling of diagnostic tests. 75.5 percent of respondents believed that doctors ask their patients to go to a particular centre for diagnostic testing and cited that the primary reason as to why patients adhered to the recommendations given by their doctors was the implicit trust patients repose in their physicians. While a higher percentage of NGOs suggested that the doctors were motivated to make such recommendations in their concern to guide their patients to centres that provided reliable services, 27.3 percent of the respondents attributed these recommendations to profit-making considerations.

Regarding tied-selling of diagnostic tests, about 92.8 percent of doctors surveyed admitted that they suggested that their patients undergo diagnostic tests of which 56.7 percent recommended their patients to go for diagnostic testing at a particular centre. A high 93.1 percent of them argued that it was important to do so because of reliable testing services. Only 2.8 percent divulged that tied selling occurred for the purpose of garnering profits. More than half of them thought that other doctors/clinics do resort to such practices. However, in this context, a much higher, 20.2 percent of the respondents thought profit or commission consideration was the main motive, though more than half held the view that reliable service was the main motive. About 55 percent of doctors surveyed believed that such practices were justified and ethical, while a close 44 percent thought otherwise.

One form of anti-competitive practice (similar to full line forcing) which may be adopted by medical professionals is suggesting more tests than necessary which may be indicative of a profit arrangement scheme between doctors and diagnostic centres which breaches the basic competition principle of making available to consumers the best possible goods and services at the lowest possible prices. 30.8 percent of doctors surveyed categorically denied that medical professionals ever recommend more tests than strictly necessary while an almost equal, but slightly higher percentage, 33.1

percent of respondents responded in the affirmative to the question as to whether or not doctors recommend more tests than necessary at times. In contrast, a much higher percentage of 61.8 percent of the NGOs surveyed asserted that doctors insist on more tests than necessary and half of these respondents stressed that they believed this practice to be unethical.

That tied selling of diagnostic testing is prevalent in hospitals as well, is evident from 95.1 percent of hospitals surveyed mentioning that they recommend their patients to go for diagnostic testing of some sort, of which 46.9 percent admitted that they suggested that their patients undergo the tests from a particular centre. 73.9 of these respondents cited reliability of services as their motivations behind such recommendations. As to why other hospitals recommend that their patients visit a particular diagnostic centre, 76.5 percent of respondents asserted that such tied selling is prevalent, however, a high percentage of 57.3 percent attributed reliable services being the cause behind such recommendations for other hospitals as well. However, 25.3 percent of these respondents attributed tied selling by other hospitals to profit-making considerations. 39.8 percent of all hospitals surveyed felt that the practice of tied selling of both medicines and diagnostic testing is unethical.

CHAPTER IV AVAILABLE LEGAL OPTIONS- A CRITICAL ANALYSIS

There are multiple legal and policy options, which may be utilised to deal with anti-competitive practices in the pharmaceutical industry and the health delivery system. These options are to be considered in light of facilitating access to medicines and healthcare by the poor. Competition law apart, patent law and drug price control are crucial for efficacious elimination of competition violations in the health sector.

COMPETITION LAW

The competition law regime in India has a rather convoluted history. The Monopolies and Restrictive Trade Practices Act was the first competition related legislation in India¹¹⁰ and was enacted in 1969. The Act was framed to deter and also dismantle any concentration of economic power to the common detriment, for the control of monopolies, for the prohibition of monopolistic and restrictive trade practices and for related matters¹¹¹. The Act provided for the formation of a MRTP Commission. This Commission dealt with the functional aspects of the Act and implemented its provisions. The MRTP Act was periodically amended as and how deemed appropriate.

In the course of time however, finding the ambit of the MRTP Act inadequate for fostering competition in the market and eliminating anti-competitive practices in national and international trade, the Government of India in October 1999 appointed a high level committee on Competition Policy and Law (the Raghavan Committee) to advise on the competition law.¹¹² The Raghavan Committee concluded that there was a need for new competition legislation, whereafter the MRTP Act would be repealed and the MRTP Commission wound up. The Committee recommended that the new competition law would not cover unfair practices as its predecessor did, since such practices came under the purview of the Consumer Protection Act, 1986. A commission was to be formed under the new Competition law and was to be denominated as the Competition Commission of India. All monopolistic trade

¹¹⁰ Atul Chitale, *India: Overview and Recent Developments*, available at http://www.globalcompetitionreview.com/apar/ind_overview.cfm

¹¹¹ See generally, Preamble of The Monopolies and Restrictive Trade Practices Act, 1969.

¹¹² Debashree Dutta, *New Competition Regime in India* available at <http://www.legalserviceindia.com/articles/new.htm>

practices and restrictive trade practices cases pending before the MRTP Commission would be taken up by this new Commission.

The new law, entitled the Competition Act, 2002 received presidential assent on January 13th, 2003. However, the entire Act has still not come into force¹¹³. The implementation of the Act was stalled by public interest litigation (Mr. Brahm Dutt v. Union of India¹¹⁴) relating to certain issues concerning the Competition Commission of India. The Supreme Court has ruled on the matter and given recommendations which need to be suitably incorporated in the Act, before it may be deemed enforceable.

At present, the MRTP Act is still in operation. Interestingly, the Competition Commission of India has been established under the Competition Act 2002 and exists alongside the MRTP Commission. However, till date it is the MRTP Commission, which passes orders, the Competition Commission being handicapped in that respect due to the Supreme Court case. The Competition Act, 2002 (hereafter referred to as the Act), being the law of the immediate future, shall be focused on extensively henceforth.

Regulating the Pharmaceutical Industry

1. Prevalent Anti-competitive Practices and Competition Law

The three focal areas of anti-competitive conduct covered by the Act relate to anti-competitive agreements, abuse of dominance and combinations, all three of which give rise to competition concerns in the pharmaceutical industry and the health delivery system, as is evident from the previous chapter.

Anti-Competitive Agreements

The main provisions dealing with anti-competitive agreements are as follows:

- Section 3, which prohibits such agreements.
- Section 19, which provides for inquiry into anti-competitive agreements.
- Section 27, which concerns orders, passed by the Commission after inquiry into agreements or abuse of dominant position.

¹¹³ Anurag K. Agarwal, *Competition Law in India: Need to go Slow and Steady* at www.iimahd.ernet.in

¹¹⁴ WP(C) No. 490 of 2003 decided on 20.1.2005

The specific anti-competitive practices of the pharmaceutical system and the health delivery system, which are covered by 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. Matters relating to two such practices are considered below in more detail.

The prohibition of cartel agreements (price fixing, output restricting, market sharing or bid rigging) between enterprises is considered to be the strongest provision in the Act.¹¹⁵ The Act mandates that cartels would be presumed to be anti-competitive, but also provides for an efficiency defence, namely that nothing in the relevant subsection shall apply to any agreement, if such agreement increases efficiency in production, supply, distribution, storage, acquisition or control of goods or provision of services.

However, while cartels may translate into increased efficiency, they may also result in increased prices, which would be detrimental to consumers. The provision may be allowing far too wide an exception. While the efficiency defence is certainly justifiable, perhaps it might be prudent to have a safeguard ensuring that the increased efficiency envisaged does not impose a burden on consumers.

Surprisingly, while anti-competitive practices in the areas of combinations and abuse of dominance may be condoned on ‘development’ considerations, this latitude has not been allowed for cartels.¹¹⁶

However, the law seems to be too generous to agreements that are related to enforcement of IPR but can have anti-competitive effects. Though the law says that an IPR-holder can impose reasonable conditions, as may be necessary for protecting any of his rights, it is not defined what is reasonable. Moreover, the Act does not specifically provide for any remedies if the conditions imposed are unreasonable. IPR related licensing agreements can contain anti-competitive provisions which are purely unreasonable and hence they should have been made clear instead of creating

¹¹⁵ Aditya Bhattacharjea, *Do away with flaws before enforcement*, Financial Express, January 28th, 2005

¹¹⁶ Ibid

confusion by using terms like “reasonable restrictions”. If a licensing agreement contains conditions like tie-in arrangement to buy other products or technology, fixing of minimum price for licensed products, restriction on buying products or technology from others or if the firms in a manufacturing industry decide to pool their patents and agree not to grant licenses to third parties, at the same time fixing quotas and prices, then the practices are simply anti-competitive and there is no point in engaging in a debate if they reasonable or unreasonable. Such situation may exist when firms decide to make joint R&D efforts and invent something jointly. It seems that the Act has not taken the advantage of flexibilities allowed under Article 40 of TRIPS.

The provisions relating to anti-competitive agreements, except probably the one on exemption on IPR-related agreements, are for the most part well framed. However collusive conduct, especially if cross-border, in cases such as international cartels, need very adept investigative skills and only time will tell whether the Commission can do justice to the framing of the law.

Abuse of Dominance

The main provisions dealing with abuse of dominance are as follows:

- Section 4, which prohibits the abuse of dominant position.
- Section 19, which provides for the procedural aspect of inquiry into the dominant position of an enterprise.
- Section 27, which mentions the orders, which may be passed by the Commission after inquiry into the practice of abuse of dominant position.
- Section 28, which concerns division of enterprise enjoying dominant position.

As has been discussed in Chapter Three, patents confer a monopoly status on patent owners and there might be abuse of such monopoly status. Such abuse of dominance is one of the major competition concerns, which may well beset our pharmaceutical industry with the introduction of our new patent regime.

Box 4.1: Explicit embargo on Excessive Pricing-the case of South Africa

In South Africa, the pharmaceutical companies, GSK and Boehringer, patent owners of ARV (HIV/AIDS) drugs set unjustifiably high prices of these drugs in South African markets. AZT (300 mg) sold at US\$0.92 as compared to the WHO generic price US\$0.25. Compulsory licensing negotiation under their patent Act proved futile as the companies demanded 25 percent royalty on sales as compared to the international rate of 4-5 percent. The Competition Commission took action under Section 8 of the SA Competition Act, which prohibits ‘a dominant firm to charge an excessive price to the detriment of the consumers’, ordering the issuance of licenses to market generic versions of the patented ARV drugs in return for the

payment of reasonable royalty to be decided by the Competition Tribunal. (See generally, Mr. Anand Grover, *Anti-competitive practices in Patent Licensing Arrangements and the scope of competition law/policy in dealing with them*, AMTC, National Workshop on Patent & Public Health, Ministry of Health, April 11th, 2005.)

This case reflects that however much power is exercised by TNCS, a clearly articulated legislation and an effective competition authority can efficiently protect the interests of the consumers and facilitate access to health. Although the Indian Act does not mention excessive pricing expressly, it prohibits unfair or discriminatory prices, which may be construed to include overpricing within its ambit. Given the prevalent fears that prices of medicines will rise, this provision assumes significance in the access to health issue.

The Act prohibits abuse of dominance in Section 4. If, therefore, pharmaceutical companies do engage in overpricing patented products or are unreasonable with respect to licensing terms and so on, our competition law may be resorted to for redressal. It is interesting to note that while intellectual property rights are expressly excluded from the purview of anti-competitive agreements in sec 3 (with the qualification that conditions imposed as a result of such rights are to be reasonable), there is no such exclusion provided in sections dealing with abuse of dominant position and combinations.

Box 4.2: Drug Pricing and the MRTP Commission

The Director General (Investigation & Research) [investigation authority under the MRTP Act] brought to the notice of the MRTP Commission that pricing of certain drugs manufactured by Stangen Pharmaceutical Ltd was unreasonable and unjustified and that the pricing pattern of the respondent did not appear to have any relationship with the cost of the inputs. The DG asserted that this unreasonable increase in the prices of drugs imposed unjustified costs on the consumers. The DG however failed to establish in the Commission's opinion that such a trade practice has the effect of preventing, distorting or restricting competition in the market, which the wording of the relevant provision mandated.

It was held in Director general (I&R) v. Jagson Pal Pharma Ltd. [2002 CTJ 151 (MRTP)] as well that excessive pricing or pricing pattern having no relationship with the cost of the input not anti-competitive if such a trade practice does not have the effect of preventing, distorting or restricting competition in the market. Increasing prices of drugs per se is therefore not an anti-competitive practice. The new Act maintains this position. This position however may perhaps be reviewed in light of the peculiarity of the pharmaceutical market as discussed in the previous chapters and the fact that consumers are not free to choose the lowest price medicines For instance, say that there is a drug on the market and there are generic substitutes of the same. If the former drug was overpriced, it can be assumed that because of the substitutes there would be no major effect on competition. However given the powerful marketing strategies of large pharmaceutical companies, say that the company marketing the former drug, managed to convince a number of doctors of the superiority of their product and the doctors prescribed accordingly. Although market statistics would not indicate that the pricing was affecting the market in any way, the manufacturers of the former drug would be in a monopoly position with respect to those patients whose doctors they had successfully influenced. This is how increased pricing can have anti-competitive effects even if such effects are not overtly apparent.

Another point to consider is why a company would overprice its products when there is fair

and free competition, given that it would only lose business. Were factors such as the patent status of the drugs concerned, market share of the drug in question in context of the relevant therapeutic segment, the existence of a sufficient number of generic substitutes, considered at all? It is of course difficult to ascertain these questions from the judgment. In case the DG cannot establish a case satisfactorily, is a summary dismissal the extent to which the Commission will deign to act in the matter?

See generally: Director General (I&R) versus Stangen Pharmaceutical Ltd. [2005 CTJ 82 (MRTP)] and also Director general (I & R) v. Jagson Pal Pharma Ltd. [2002 CTJ 151 (MRTP)]

Whether it would be correct to consider that this silence is intentional and designed to make it easier for the Competition Commission to deal with IPR related anti-competitive practices in the particular areas of dominance abuse and combinations is a question to be considered. However, there is enough justification to empower the competition authority to grant compulsory licence or take any other appropriate action in case of abuse of IPR right through explicit provisions.

While Section 4 of the Act prevents an enterprise from abusing its dominant position by imposing unfair or discriminatory conditions of purchase or pricing, an exception clarifies that if such practices are adopted “to meet competition”, they will not qualify as abuse. The significant fallout of this is that a dominant enterprise will not be subjected to unfair disadvantage while competing with smaller enterprises.¹¹⁷ Where does one draw the line though, when deciding what is meant by meeting the competition? The exception allows for a broad defence and may be used as a loophole by enterprises strategising to drive out competition. In the pharmaceutical sector and the health care system, because of the entire access to health issue, this is a matter of special concern.

The Act enumerates several factors to be taken into account while ascertaining whether a firm enjoys a dominant position. One such criterion reads as follows: “Relative advantage, by way of contribution to the economic development, by the enterprise enjoying a dominant position having or likely to have an appreciable adverse effect on competition”. A similar criterion is listed for the purpose of determining whether a merger or acquisition would have an adverse effect on competition.¹¹⁸ These clauses are pointless and may even be potentially dangerous.¹¹⁹

¹¹⁷ Hemant Sahai and Srinivas Parthasarathy,, *Breathing Space*, The Economic Times, January 18th, 2003

¹¹⁸ Section 19 (4)(l) and Section 20(4)(m), The Competition Act, 2002

The very concept of economic development is questionable because of the inherent difficulty of interpretation. For instance, say a merged entity in the pharmaceutical sector will serve to make our industry more competitive globally and lead to growth in exports. However, the merger may also give rise to serious competition concerns and access to health issue. Its positive and negative repercussions are linked intrinsically to core development concerns. Which then would take precedence over the other and on what criteria would this be decided?

These clauses allow the competition authority, perhaps influenced by the government for whom promoting FDI will be an important consideration, to condone anti-competitive activities by large corporations that purport to be promoting development. Also the wording of the criterion is so broad and lacking in any specificity that it remains open to varying interpretations, based on the subjective understanding of ‘development’, which leads to unnecessary uncertainty in the law.¹²⁰

The aforementioned issues need to be addressed to strengthen the law against abuse of dominance and facilitate thereby the effective restraint or elimination of this kind of practice in the pharmaceutical sector and the health delivery system.

Mergers And Acquisitions:

The main provisions dealing with mergers and acquisitions are as follows:

- Section 5, which 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 enterprises by one or more persons or acquiring of control or merger or amalgamation of enterprise
- Section 6, which provides for regulation of combinations.
- Section 20 which concerns inquiry into combinations
- Section 28, which allows for division of enterprises enjoying dominant position.
- Section 29 and Section 30, which lays down the procedure for investigation of combinations
- Section 31, which enumerates the orders of the Commission on certain combinations

The Act provides for merger review beyond a threshold level. As the threshold level is reasonably high, only big deals will come under the scrutiny of the competition

¹¹⁹ Supra n. 115.

¹²⁰ Ibid

authority. Prior to the new Act, an acquisition or merger that involved a group of companies whose combined turnover exceeded the specified amounts would be a combination. At present, however, only the turnover of the group to which the enterprise would belong to after the completion of the acquisition or merger determines whether the resultant entity is a ‘combination’ or not. The new position appears more in tune with the corporate economic reality and allows for strategic planning.¹²¹

Regulation of combination is a soft regime under the Act. Merger notification is voluntary¹²², a result probably of the inevitable compromises which are required to be made in creating new legislation. By contrast, most countries favour a compulsory notification regime.

One matter which is giving rise to some anxiety in our domestic pharmaceutical industry, especially in light of the recent spate of mergers and acquisitions is that as the threshold level for regulation is quite high, the Indian industry may become an easy target for MNCs for acquisition. Only those companies with assets more than Rs.1000 crore or a turnover of over Rs.3000 crore would come under the regulatory provision when they either singularly or in combination go for acquisition. Only 100 of the 6000 Indian companies were beyond this threshold limit and the new provisions do not prohibit size of investment.¹²³

There is a concern that the Commission may have lack of experience to evaluate mergers. But the Act provides for this by empowering the Commission to draw upon the knowledge of external experts.

Box 4.3: Incapacity cripples Law

At the time of the merger of Glaxo Laboratories Pakistan Limited, and Wellcome Pakistan Limited, the Pakistani Monopoly Control Authority (MCA) took initiative to investigate. But the MCA failed to take any action and the case was abandoned halfway. The reason provided by the MCA for this abandonment, is that calculating market shares of individual products with the identification of their substitutes, as required in the case, was a complicated matter, and the MCA did not have qualified and trained staff for this exercise.

Source: Pulling Up Our Socks: A Study of Competition Regimes of Seven Developing Countries of

¹²¹ Supra n. 9

¹²² Amitabh Kumar, *Creating a culture of competition*, The Financial Express, January 28th, 2005.

¹²³ *Competition Bill passed*, Times News Network, December 17th, 2002

The key element in successfully enforcing these provisions is capacity building of the Commission. Without investigative competence the Commission may not be able to efficaciously deal with the complexities of determining the ostensible and the remote possibilities of the combination having an anti-competitive effect on the market. India did not have any provision for merger review in the MRTP Act since 1991, and hence lacks experience in this area. However, considering that many high profile mergers and acquisitions are taking place in the pharmaceutical industry as has been discussed in the previous chapter, it is essential that the Commission does all that it can to overcome this lack of experience and engage in efficient review.

The Functional Aspect of Competition Law

Jurisdictional Reach

One important aspect to consider while deliberating on various dimensions of the competition law is the jurisdictional reach granted. The law has extra-territorial jurisdictional reach with respect to anti-competitive agreements, abuse of dominance and combinations (both cross-border and wholly beyond borders) and any other matter or practice or action arising out of such an agreement, dominant position or combination outside India, but having an effect on competition in India. This empowerment has been conferred by the effects doctrine, which has been given expression in section 32 of the Act. The framing of Section 32 gives rise to a contentious issue. The provision ends with empowering the CCI to enquire into an alleged anti-competitive agreement or practice but does not mention explicitly the option to pass an order if such is deemed appropriate in keeping with this Act. This silence is rather inexplicable given that the power to pass orders in domestic matters has been stated clearly in the Act. Of course, it could be interpreted that the power to pass an order is implied, but in matters concerning extra-territorial jurisdiction, it is better not to leave such a crucial area of the legislation unclear.

Given that India's strength lies in its generic markets and that an onslaught of generic competition from China is expected, to just cite one relevant example, matters such as predatory pricing, dumping and injunctions against imports in relation to the powers of the CCI, assume importance. Relevant case law has been taken up which remain

germane to our understanding of the aforementioned matters despite the case being decided under the MRTP Act and not the Competition Act, 2002 which is the principal focus of this study.

In the case of AMAI (Alkali Manufacturers' Association of India) and ANSAC (American Natural Soda Ash Corporation), the MRTP issued orders, which effectively resulted in injunctions against imports. The Supreme Court, however, in its judgment in *Haridas Exports v. All India Float Glass Manufacturers' Association*, which subsumed the ANSAC vs. AMAI case, set aside both the injunctions on the ground that the MRTP Commission lacked jurisdiction. Now the CCI is empowered by law to impose injunctions against imports¹²⁴ and therefore there has been a substantial change rendered with respect to this particular matter.¹²⁵

One aspect of this case, which is vital in the context of today, is its reflections on predatory pricing and anti-dumping. In the float glass case, where the question of predatory pricing was central, the importers had contended that the complaint was essentially one of 'dumping' of exports for which there was a specific remedy under the anti-dumping provisions of the Customs Tariff Act. The MRTPC, therefore, had no jurisdiction. The other side contended that the anti-dumping laws did not implicitly repeal the relevant provisions of the MRTPA, to which the SC agreed. Therefore, it was decided that no conflict of jurisdiction as such existed between the MRTPC and the anti-dumping authority.¹²⁶ As a sidebar, it may be mentioned here that it is easier to prove anti-dumping cases than predatory pricing and most cases in such situations would probably take recourse to anti-dumping law.

To return now to the present competition authorities being enabled to impose injunctions against imports, the stoppage of imports could be a remedy that strangles competition as such action translates into one less competitor in the market.¹²⁷ It may also clash with the WTO commitments and that the provision in question may just be invoked by domestic manufacturers who fear competition from efficient rivals. But

¹²⁴ See Section 33 of the Competition Act 2002.

¹²⁵ Aditya Bhattacharjea, *India's Competition Policy: An Assessment*, Economic and Political Weekly, August 23rd, 2003

¹²⁶ Ibid

¹²⁷ Supra n. 126

given that the competition authorities would not pass such an order without heeding the consequences, it does not seem that having such a provision itself would lead to any harm. It would simply have limited applicability.

Inter-Agency Linkages

Another important aspect of the functioning of competition authorities is the linkages they have with other statutory authorities. Section 21 of the Competition Act is vital in this respect, being perhaps the only explicit mention of cross-linkages with other agencies in the Act. This provision provides that when a party objects that any decision which a statutory authority has taken or proposes to take, is or would be, contrary to any of the provisions of the Act, then such statutory authority may make a reference in respect of such issue to the Competition Commission, who after hearing the parties shall give its opinion to such statutory authority which shall thereafter pass such order as it deems fit. An amendment to this section proposed in The Competition (Amendment) Bill, 2005 proposes that this provision shall additionally provide that any statutory authority may *suo moto* also make such a reference to the Commission, without any party before it asking for such a reference.

While this provision is commendable that it establishes a firm connection between agencies, it does not settle the question of precedence and is actually of little use because after all what weight does a reference carry? It may be completely ignored. Competition issues are complex and matters having a substantive competition content, even if comes under the jurisdiction of the Drug Controller or the NPPA or the Patent agency (speaking here only of those statutory authorities which are relevant to the pharmaceutical industry and the health delivery system), should be referred to the Competition Agency whose decision or opinion on competition related issues, for instance say excessive pricing due to abuse of monopoly by the patent holder, should be held binding.

Box 4.4: Jurisdictional Conflict with NPPA?

In one case¹²⁸ before the MRTP a particular company was accused of increasing the prices of its products, namely, Dygiene Tablets, Dygiene Syrup, Cremaffin and Eptoin by 120 percent, 70 percent, 45 percent and 86 percent respectively. The case as such will not be reviewed here, merely a portion of the order shall be highlighted for its relevance to the issue being discussed.

¹²⁸ Director General (I & R) v. Knoll Pharmaceuticals Ltd. [2001 CTJ 250 (MRTP)]

This case is rather strange in what it indirectly conveys rather than directly says. It mentions twice, for instance, that the company has contended that the matter of fixation of prices and monitoring of prices of drugs is the function of the NPPA and does not fall within the ambit of the Act, if the essential ingredient of impact on competition is missing. A jurisdictional conflict may have been hinted at since the commission did not respond to this argument. But then nothing explicit was said on the matter. The Commissioner never said that since a separate authority had been created for monitoring the retail prices of drugs, the Commission would not go into that question. They simply left the matter of jurisdiction unaddressed. The case was dismissed on grounds of the accused company having negligible market share. Can the matter of fixation of prices and monitoring of drug prices be considered to be solely under the preview of the NPPA if there is no impact on competition issue involved? But mere increase of prices may have anti-competitive effects, whether such effects are apparent in the market or not. In such a case, the expertise of competition authorities may be required.

While considering inter-agency linkages, it may be mentioned that it is commendable that provisions have been made for the Commission to enter into arrangements with foreign agencies, which is vital for dealing with cross-border anti-competitive activities. Such empowerment is especially important since trans-border anti-competitive activities are likely in the pharmaceutical sector with the significant presence of MNCs and also for that matter in the health delivery system, with the opening up of the hospital sector and the growing popularity of medical tourism.

A Wake Up Call - Likely obstacles to Effective Implementation

- In the implementation process of the Act, in particular reference to the pharmaceutical sector, MNCs with far greater experience in fighting competition cases in countries across the globe, have a decided advantage over their Indian rivals who will have to hire expensive lawyers and consultants to counter them¹²⁹.
- The following has been mentioned before, but needs reiteration. Various sections lay down multifarious criteria, which the Commission has to take into account. These criteria require proficiency in modern industrial economics as well as statistical analyses of the economic conditions of the industry under consideration. It is crucial to build up the capacity of the Commission and its staff. It should be equipped with multi-disciplinary professionals at senior levels. The required skills would be those of lawyers, managers, economists, statisticians, chartered accountants and even people with a police backgrounds to investigate the conspiracy elements of a cartel. The flaws in the Competition Act if combined with inadequate professional and financial resources in the Commission, will lead to vexatious and costly litigation, inconsistent verdicts, legal uncertainty, and possible retaliation by other WTO members. This, at all costs, should be avoided and concrete measures should be taken to avert such a situation.¹³⁰

¹²⁹ Supra n. 115

¹³⁰ Ibid

The Patent Regime – A TRIPS Specific Overview

TRIPS will be examined herein from the perspective of its impact on competition, with specific reference to the pharmaceutical sector and the health delivery system. As has been mentioned previously, product patents as introduced by TRIPS unlike process patents, give a complete monopoly to the patent holder, which in turn may possibly give rise to the abuse of such monopolistic position. Therefore, we will consider those provisions of the TRIPS agreement which award exclusive rights to the patent holder, the extent of such rights, and the flexibilities provided such that the law does not circumscribe too severely the access to health issue afflicting millions.

Patents and the Pharmaceutical Sector – An Introduction

It is necessary, however, to note at the outset that the alarm triggered by the new patent regime and the possible impact on the affordability and the accessibility of medicines ought to be defrayed to some extent by the fact that currently over 95 percent drugs produced in India are off patent and even by 2010, 90 per cent of the drugs trade in India will continue to be in generics¹³¹. Also, every year, up to forty medicines go off patent.¹³² It may, therefore, be concluded that most drugs in current usage are not under patent and thus in case of most medicines there can be no abuse of monopoly to deprive the masses of medicine by overpricing.

Why then is TRIPS such an issue? Is the anxiety engendered by TRIPS on the matter of access to health, unwarranted? Not really. Given that there has been cogent evidence revealing a connection between patents and high prices and that there is growing drug resistance, emerging new diseases and endemic poverty in many of the countries, which are signatories to TRIPS, the agreement may well prove to substantially deprive millions of availing new drugs that are both effective and safe.

It may be borne in mind that industry conduct in the past has revealed that it is not just recovery of costs that concern pharmaceutical companies, but profits on a very large scale. Patents by allowing a monopoly position to be created for a drug block out

¹³¹ Effect of the new patent regime on prices of medicines, Speech delivered by Mr. ZH Charna, Director, OPPI AT THE national Workshop on Patent and Public Health, New Delhi, 2005

¹³² Ibid

competition. Market forces, therefore, can play no part in levelling prices. This is unfortunate since the difference in prices that can be brought about by effective competition from generic competitors is striking. It was only when Cipla, a generic company from India, offered to sell the requisite therapy for AIDS patients at US\$350, that the originator company offered to slash prices from more than US\$10,000 to US\$931 and then further to US\$727. Against this price of US\$727 of the originator company, the therapy is now available from Hetero at \$201.¹³³

TRIPS can be easily manipulated to engage in anti-competitive practices in the pharmaceutical sector, impacting the health delivery system as well. Even if the patent regime is deemed justifiable, there should be sufficient flexibilities allowed thereunder to stem any access problem arising in the wake of the Agreement. TRIPS does provide such flexibilities, which shall be considered here later.

THE COMPETITION DIMENSIONS

Monopoly Rights to the patent holder

TRIPS provides that patents shall be available ‘for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.’¹³⁴ The term of protection at the most minimum is twenty years. The monopoly position awarded to patent holders is with respect to rights, including the making, using, offering for sale, selling or importing of the invention.

Apart from patents, two other TRIPS related concepts relevant to the present context are those of ‘mailbox’ and ‘exclusive marketing rights’. Although countries like India had till January 1, 2005 to introduce full product patents protection for pharmaceuticals and agricultural chemicals, they were required to introduce ‘mailbox’ and ‘EMR’ provisions from January 1, 1995. The first pertains to putting through applications for grant of patents, the first step to attaining a monopoly position and the second concept confers rights akin to those granted by a patent. EMRs are awarded to the patent applicant in the interim period between patent review and actual grant of a patent.

¹³³ Supra n. 16

¹³⁴ TRIPS Agreement

Mailbox

Mailbox, at a very simplistic level, would denote a facility to receive and hold product patent applications in the fields of pharmaceuticals and agricultural chemicals till the new patent regime is slated to function. The mailbox has in fact been opened in 2005 to the apprehension of generic manufacturers across the country since many Indian generic companies are producing and marketing a number of drug products for which MNCs have filed mailbox applications.

The question of the moment is that if and when a product patent is granted to any mailbox application, what will happen to the generic companies, which may be producing the product at present? Under the Act of 2005, 'enterprises which have made significant investment and were producing and marketing the product concerned prior to January 1, 2005, need not suspend production. They can continue to produce on payment of reasonable royalty to patent holders. It has not been specified, however, what is meant by the term reasonable. Also if there were no agreement in their interpretation of the term reasonable, then who would intervene? Would that be sufficient to invoke a compulsory license in light of existing provisions? All these questions are matters of uncharted territory, such situations not having arisen as yet.

Exclusive Marketing Rights

Exclusive Marketing Rights can be obtained for an application in the mailbox if a patent has been granted in some other WTO member country and the application has not been rejected in the country as not being an invention.

The Saving Grace

TRIPS in its literal interpretation at least, is not focused solely on the profit concerns of drug manufacturers. However, although development provisions have been incorporated in the agreement, it is doubtful, to what extent they are protective of infringements committed in protection of health concerns. Be that as it may, an examination of these provisions is necessary to examine their utility as legal options to deal with anti-competitive practices in the pharmaceutical sector and facilitate access to health.

The preamble of any agreement embodies the philosophy of an agreement. The preamble of TRIPS recognises the underlying public policy objectives of national systems for the protection of intellectual property.

The objective of the agreement delineated in Article 7 stresses that the protection of intellectual property rights should be to the advantage of both producers and users of technological knowledge and in a manner conducive to social and economic welfare. In practice, however, this altruistic aspect of the objective is more a hollow platitude than a guiding principle for countries and pharmaceutical companies. Government and industry conduct in the cases of Brazil, South Africa and Thailand (see box 4.6 and 4.7) stand testament to this.

Article 8 is more specific in articulating a sense of commitment to development and health issues. Article 8 provides that countries may adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development. The scope of this provision is seriously curtailed by the proviso that such measures may be undertaken only in harmony with the provisions of the TRIPS Agreement. The provision further provides that appropriate measures may be taken to prevent the abuse of intellectual property rights by rights holders, but such measures must also be in consonance with the Agreement.

Within the scope of TRIPS, the following are the flexibilities, which developing countries can use¹³⁵:

- Exemptions from grant of patents in certain cases;
- Exceptions to product patent rights in certain cases;
- Limited Data Protection;
- Government use in certain case
- Use by non-patentees in certain cases.

The specific provisions for controlling anti-competitive practices in the pharmaceutical sector are embodied in the following sections of TRIPS:

¹³⁵ Supra n 16 at p. 70

Art 40(1): Understanding that licensing practices or conditions relating to intellectual property may restrain competition and may impede transfer of technology.

Art 40 (2): Legislation may provide for licensing practices and conditions in case of abuse of IPRs having an adverse effect on competition in the relevant market, and for control of such practices

Art. 31(k): Voluntary licensing need not be resorted to in case a practice is judicially or administratively determined to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases.

India's Patent law Regime

There has been reference to the history of India's patent law in the previous chapters. After signing the TRIPS Agreement, the 1970 Act was accordingly revised to achieve compatibility with WTO requirements. The alterations were made in four stages: The Patents (Amendment) Act, 1999, The Patent (Amendment) Act, 2002, the Indian Patent Ordinance of 2004 and the Indian Patent (Amendment) Act, 2005.

The Patents (Amendment) Act, 1999, introduced the mailbox system and set up a system of exclusive market rights (hereafter, EMRs) to be retrospective from January 1, 1995, in conformity with the TRIPS Agreement. The Patent (Amendment) Act, 2002 introduced 64 changes to the Patent Act of 1970, the most important ones of these being the extension of patent term from 14 to 20 years, and the reversal of burden of proof from patent holder to alleged infringer. The final set of changes to make India's patent regime comply with the TRIPS Agreement *in toto* were first contained in the Indian Patent Ordinance of 2004, that has now been replaced by the Indian Patent (Amendments) Act of 2005.¹³⁶

It is expected that the new patent regime may take about two to three years to be fully implemented.

¹³⁶ Supra n 31 at p. 33

The Competition Aspects of the Indian Patent Act

The 2005 Act introduced product patents in India, invalidating Section 5 of the Indian Patent Act, which granted only process patents for food, medicines and other drug substances. Under the Indian patent law of today, monopoly status is awarded to patent-holders. However, there are a number of provisions in the Act utilizing the flexibilities allowed by TRIPS.

The general principles in our patent law, both applicable to the working of patented products and relevant to our study are as follows:

- Patents do not impede protection of public health (section 83(d))
- Patents granted do not prohibit Governments to take measures to protect public health [Section 83(e)]
- Patents make the benefit of the invention available at reasonable affordable prices [section 83 (g)]

Certain areas of the Act will be particularly examined for their relevance to this study.

Box 4.5: Encouraging generic competition- The Hatch-Waxman Act

Under the Hatch-Waxman Act, the first generic firm to file an application for a new drug is granted 180 days of marketing exclusivity if the generic firm certifies that its product does not infringe any of the brand-name company's patents on the drug product or if the generic firm challenges the validity of the brand-name company's patent. During this 180-day exclusivity period the US Food and Drug Administration (FDA) may not approve subsequent generic applications for the same drug. The exclusivity provision has provided increased incentives for a generic firm to be the first to file an application to market its product. As the first to file, a generic has the potential to "reap the reward" of being the only generic product in the market for a set period of time. The provision also provides more incentives for companies to challenge patents and develop alternatives to patented drugs. India may well consider incorporating such a provision in her laws, given that it encourages generic competition and India's strength lies in generics.

Two issues may be highlighted with respect to this 180-day exclusivity provision. Firstly, case laws indicate that it may be manipulated to aid in anti-competitive practices, in particular, collusive agreements. Secondly, in a recent judgment, the US Federal Appeals Court has upheld the FDA's decision to allow pharmaceutical companies to launch 'authorized' generics of their patent stripped drugs during the 'exclusivity period' granted to generic companies which have successfully challenged a patent. The marketing of such authorized generics during the exclusivity period would reduce the financial incentive to undertake patent challenges risking significant litigation costs. The ruling obviously gives the MNCs a huge advantage because creating a generic substitute of a drug to which a company owns a patent is a process they may initiate long before the patent on their drug expires. Thus, the generic competitor does not get the privilege of sole marketing that the period provided earlier. As it is, generic companies are facing major pricing pressure in the US market, with prices of generic drugs dropping by about 80-95 percent within days of ending the 180-day exclusivity period.

Source: James Mathew, 'Authorised' generics granted permission, Financial Times, June 8th, 2005

Patentability Criteria

Art. 27 (1) of TRIPS mandates that patents shall be granted for any inventions provided such invention is new, involves an inventive step, and is capable of industrial application. None of the terms defining the criteria for awarding a patent have been defined. This provides a leeway, which developing countries can use to their advantage. The terms may be interpreted in a manner, which would restrict the number of patents.

In India, this flexibility afforded by the TRIPS Agreement has been utilized. In this context, it is necessary to understand what ‘primary patents’ and ‘secondary patents’ mean. Primary patents are granted to new chemical entities involved in the new drugs. Secondary patents are awarded to new formulations, new combinations and new uses of existing chemical entities. In the USA, both kinds of patents are granted. A recent research report in the USA has found most of the new products provided have no clinical benefits. Given the strong pharmaceutical lobby in that country, this would be no surprise. The grant of secondary patents where there is no therapeutic benefit is unjustifiable on two grounds: Firstly, it delays generic entry and secondly, patents are granted due to the high cost and effort involved in drug development, but mere tweaking of products usually involves neither cost nor effort to an extent which would warrant monopoly rights. Secondary patents are often used as a tool for evergreening patents¹³⁷.

The Patent Amendment Act of 2005 in its delineation of patentability criteria, takes advantage of the broad wording in the analogous provision of the TRIPS Agreement and has excluded salts, esters, polymorphs, particle size, combinations and other derivatives of known substances from patentable products unless they differ significantly in properties with regard to efficacy (Section 3). There is no scope, therefore, under the law for patentees to be granted secondary patents on frivolous grounds and assume an unwarranted monopoly.

¹³⁷ See generally Supra n 16 at p. 71

Pre-Grant and Pos- Grant Opposition

Given that upon grant of patents, there exists a probability of abuse of exclusive rights and that there may be negative implications on public health concerns, a procedure to properly screen patent applications and eliminate the frivolous ones is essential.

The new patent Act 2005 allows for both pre-grant and post-grant opposition. Any interested person can oppose the grant of patents on specified grounds; and finally a patent is granted only after entertaining such opposition. The advantage of such a procedure is that any wrongful claims can be detected before the patent is granted. For example, in the event of a secondary patent application, which is pertaining to an innovation not therapeutically significant, the pre-grant scrutiny can detect such applications for secondary patents and protection can be denied. The inclusion of post-grant opposition ensures an opportunity to deny a patent after its grant in case of initial oversight of grounds for refusal.

Surprisingly, while detailed procedure has been laid out for the hearing and passing of an appropriate order for post-grant opposition, similar procedure for pre-grant opposition has not been specified, the only reference being that rules may be prescribed in this regard. This may lead to unnecessary confusion and is undesirable. It is important to facilitate pre-grant opposition as much as possible since succeeding in post-grant opposition is difficult and involves more costs, direct and indirect.

Exceptions to Rights Conferred

Article 30 of TRIPS embodies an explicit flexibility in allowing for limited exceptions to the exclusive rights conferred by a patent, but its scope is limited by the necessity that the flexibility must not be used in conflict with the normal exploitation of the patent and must not unreasonably prejudice the legitimate interests of the patent owner. Nevertheless, this provision is certainly useful and justifies practices and policies such as parallel imports, the Bolar provision and usage by non-patentees for research purposes. These practices existed in many countries even before TRIPS came into existence. But the heavy conditionality of Article 30 of TRIPS causes legal uncertainty with respect to the extent this provision allows exceptions to patent rights.

Under TRIPS, the use of exceptions by a country can be contested by any other country and in that case the former cannot use it unless the dispute is resolved in its favour.

Parallel Imports

Under Article 28 of TRIPS, the patent owner has the exclusive right to prevent others not only from making, using or selling the invented product or process in the country, but also importing from other countries. This is, however, subject to Article 6 ‘on exhaustion’. What it basically means is that the patent holders in a country cannot legally stop imports of patented products offered for sale in another country. Such imports of patented products without the consent of the patent holder in the importing country are known as parallel imports. This is very important in the pharmaceutical industry because the same patented medicine is often sold at different prices in different countries and hence parallel imports permit a country to shop around for the lowest price. The underlying justification of allowing parallel imports is that since the innovator has been rewarded through the first sale of the product, its patent rights have been exhausted and hence it should have no say over the subsequent resale. Under Article 6 of TRIPS, as clarified by the Doha Declaration [paragraph 5 (d)], each country is ‘free to establish its own regime for such exhaustion without challenge.’¹³⁸

Under the original 1970 Act, importing was not mentioned as an exclusive right. This has been amended to conform to TRIPS. But unlike Article 28 of TRIPS, Section 48 of India’s amended Patents Act provides no qualification about exhaustion of patent rights. Instead another section (107Ab) has been inserted which says that ‘importation of patented products by a person who is duly authorized under the law to produce and sell or distribute the product shall not be considered as an infringement of patent right.’ This permits parallel imports. In case of abuse of monopoly position by patent holders, this practice may be resorted to for facilitating access to medicines.¹³⁹

¹³⁸ Supra n. 16

¹³⁹ Ibid

Bolar Provision

The Bolar provision or early working provision is prevalent in the US. In the US, before 1984, generic producers had to conduct their own studies and submit data about the safety and the efficacy of the product. Generic producers hardly had the resources to undertake such consuming and costly studies. Moreover, under the then existing patent law, they could start the process of testing and submitting data to the Food and Drugs Authority only after the patents had expired. These circumstances made generic entry into the market very difficult. The Hatch-Waxman Act was created to resolve both problems. Under the Bolar provision of the patent Act, non-patentees could start using the patented product for regulatory purposes even before the expiration of the patents. Moreover, generic applicants were no longer required to repeat the clinical studies to prove efficacy and safety of the product. They were permitted to rely on the innovator company's safety and efficacy data and could file only an Abbreviated New Drug Application. This speeds up the process considerably.

It is to be noted that in a recent dispute, the WTO has upheld that the Bolar exemption is in conformity with TRIPS.¹⁴⁰

The amended Patents Act in India provides for Bolar Exemption. Under Section 107(A), use of a patent for development and submission of information for regulatory approval will not be considered as an infringement of the patent right. Thus, in the new patent regime, as innovator companies introduce new drugs in India and enjoy exclusive patent rights, such Bolar provisions can be used to introduce generics immediately after the expiry of patents.

Research and Experimentation

Section 47 of the Patents Act, 1970, which remains unchanged in the Act of 2005 provides that any patented product may be made or used by any person for experimentation or research including the imparting of instructions to pupils. This is a vital provision for strengthening the research base of our own industry, which will strengthen indigenous capacity in the long run. Having a strong domestic industry is

¹⁴⁰ Prabodh Malhotra, *TRIPS-plus: Free Trade Agreements jeopardizing Public Health in Developing Nations*, Presented at the conference on Enlarged ASEAN: Issues in Trade, Development and Integration, 24-25th November, 2005, p. 11.

mandatory for successfully coping with the new patent regime, the increased presence of MNCs in the market and the increased likelihood of anti-competitive practices. Herein lies the importance of this provision.

Data protection and data exclusivity

Article 39(3) of the TRIPS Agreement places a requirement upon member countries to provide protection to regulatory data under specific circumstances. Data exclusivity, a relatively new form of protection, is one such form of protection and it refers to the protection of pharmaceutical registration files that contain data submitted by pharmaceutical companies to regulatory agencies, such as the US Food and Drug Administration and the European Agency for the Evaluation of Medicinal Products (EMA), for the purposes of obtaining market approval of patented drugs.

Grant of data exclusivity prevents generic companies from using the test data submitted by the original patent holder to regulatory authorities to prove bioequivalence of the generic version of the products. In practice, data exclusivity terms, since they are granted from the date of introduction of a particular product in a given market, may have the effect of extending the monopoly term of the patent holder beyond the term of the patent and delaying the entry of generics. The general practice in the USA is to grant five years of data exclusivity, whereas the EU grants a ten year data exclusivity period.¹⁴¹

Assuming hypothetically that a developing country like India granted data exclusivity of five years, this would mean the following in reality. A product for which a patent was granted in 1995 is valid until 2015. But if this product is introduced in the Indian market in 2013, then data exclusivity in Indian law would protect the regulatory data submitted by the company until 2018 (5 years from introduction), thus delaying the entry of generics (and extending the product monopoly) by three more years than the twenty years granted under the patent. Furthermore, a reading of Article 39(3) of the TRIPS Agreement shows that although there is a requirement to provide protection to regulatory data under specific circumstances, it is not necessary that this protection is granted in the form of data exclusivity.¹⁴²

¹⁴¹ Supra n 31 at p. 37

¹⁴² Ibid

The provision gives countries the choice to decide upon the form of protection. India has not had a strict regime that protected secrecy of data submitted by pharmaceutical companies to regulatory agencies. Many MNCs hold the view that this has helped the generics industry immensely to reverse engineer and make cheaper versions of drugs. The general practice amongst Indian generic companies has also been to use the data submitted by the original manufacturer to prove bioequivalence. Presently, a committee set up by the Government of India is examining the extent of data protection that should be afforded to the pharmaceuticals industry.¹⁴³

Compulsory licensing

An invaluable tool to deal with anti-competitive practices in the pharmaceutical sectors, which lead to overpricing, is the issuance of compulsory licensing. Although TRIPS does not specifically use the term, ‘compulsory licensing’, the practice may be deemed to be sanctioned by TRIPS, under Article 31 and Article 40, which provide for use without authorization of the patent-holder.

India did provide for compulsory licensing in the 1970 Act and the 2005 Act also allows for compulsory licensing, although substantial alterations have been made. In India, as per the Section 84 of the Patents Act, any time after the expiry of three years from the date of grant of a patent, any person interested may make an application to the Controller on the basis of specified grounds and request for the grant of a compulsory license to work the patented invention. These grounds are as follows:

- That the reasonable requirements of the public with respect to the patented invention have not been satisfied,
- That the patented invention is not available to the public at a reasonably affordable price
- That the patented invention is not worked in the territory of India

Under similar grounds, the Controller, upon request of the Central Government, may endorse a patent with the words “Licences of Rights” (section 88). Such endorsement will enable any person who is interested in working the patented invention in India may require the patentee to grant him a licence for the purpose on such terms as may be mutually agreed upon, notwithstanding that he is already the holder of a licence under the patent. If the parties are unable to agree on the terms of the licence, the Controller can decide the terms on which the licence shall be granted by the patentee. If the Controller is satisfied that that the reasonable requirements of the public with

¹⁴³ Ibid

respect to the patented invention have not been satisfied or that the patented invention is not available to the public at a reasonable price, even after granting compulsory licence or licence under the endorsement with the words “Licences of Rights”, the patent concerned may even be revoked after two years from the first compulsory licence or the licence under Section 88.

However, in India’s previous product regime, a lot of problems were faced in implementing the provision providing for issuance of compulsory licensing and it is feared that history might just repeat itself.¹⁴⁴

Box 4.6: Hazards of Compulsory Licensing

Despite elaborate provisions relating to compulsory licensing in the Patents and Designs Act, 1911, patent-holders could take advantage of the cumbersome procedure and frustrate the efforts of interested enterprises to get compulsory licences. A government research institute (Haffkine Institute) applied for compulsory licence. In response to the notice, the patent-holder suggested that they were willing to give the licence voluntarily on the basis of royalties to be fixed through negotiations. They demanded an absurdly high rate of 25 percent. As there was no limit on the time taken, it took more than four years to reduce it to 10 percent, which was still higher than the limit of five percent stipulated by the Reserve Bank of India at that time. By that time, the Institute decided to abandon the project (Joint Committee on Patents Bill, 1969, p. 452).

Similarly, Neo-Pharma Industries Ltd sought a licence from Parke Davis to manufacture a drug. But whereas the subsidiary company in India pointed out that the matter was beyond its jurisdiction, the parent company in the US insisted that the Neo-Pharma should first discuss the matter with local subsidiary. It took more than two years to decide as to who would negotiate. At last, when negotiations started with the parent company, they did not formally refuse to grant the licence but simply sat over the proposal. Finally, when a compulsory licence was sought and granted, Parke Davis went to court and obtained a stay order (Joint Committee on Patents Bill, 1966, p. 493).

Source: Sudip Chaudhuri, *The WTO and India’s Pharmaceuticals Industry*, Oxford University Press, New Delhi, 2005, p. 94

In light of all of the above-mentioned flexibilities which may be used to circumvent the product patent regime, one may now legitimately ask then where lies the problem with TRIPS? Access to health appears to be addressed to some extent at least and

remedies for anti-competitive practices are provided. The truth is that these measures while appearing to be the saving grace of the agreement are actually rather limited in scope, given that they are required to be consistent with the provisions of TRIPS. Thus, there can be no infringement of the Agreement even when public health concerns of a nation may legitimately mandate such violation. Also to be considered is the reality of the global power imbalance and that the pro- intellectual property protection countries are the ones with the leverage in the power game.

One major threat to utilising TRIPS flexibilities is the ‘TRIPS Plus’ provisions, which the TNCs and the US Government seek to impose on nations across the world, notably through regional and bilateral trade agreements. These agreements, while legally enforceable are blatantly anti-competitive in effect, by allowing the creation of rigid monopolistic positions in the market with few, if any exceptions, prohibiting many of the flexibilities provided by TRIPS. A number of complex issues come under the TRIPS Plus heading, including conditions under which compulsory licensing is to be allowed and the issue of data exclusivity. The inherent double standards of the agreements are evident in many instances. To cite just one example, data exclusivity clauses in the agreements so actively entered into by the US, do not provide for the Bolar exemption, but the US law does.¹⁴⁵

All free trade agreements embodying the agenda to set higher IP standards than required by TRIPS, require an extension of the patent term to offset delays caused by host nations’ regulatory authorities in granting marketing rights for new drugs, some agreements additionally call for extensions to compensate for delaying the granting of patents. (For example, US-Australia, US-Bahrain, US-Chile, US-Morocco and US-Singapore).

These conditions delay the introduction of generics in the market. There are agreements, which even facilitate the evergreening of patents. It is to be noted that such requirements are not mandated by TRIPS. Eminent economist Joseph Stiglitz suggests that in all its bilateral agreements, the US is using its economic muscle to

¹⁴⁴ Supra n. 16

¹⁴⁵ Supra n. 8 at p. 6

help big drug companies protect their products from generic competitors.¹⁴⁶ A further threat to the flexibilities available under TRIPS is now emerging from the agenda pursued by the US within the World Intellectual Property Organisation with the ultimate objective of global patents that would preclude consideration of national circumstances and do away with the need for most national patent offices.¹⁴⁷

Box 4.7: Never Practice what you Preach

There are a number of instances that indicate that the flexibilities afforded by TRIPS may well be defeated by a number of factors such as the imposition of TRIPS Plus provisions and the power imbalance in international affairs. A few such instances have been cited below.

It has already been mentioned that in Korea, after Glivec was awarded a patent, it was priced at a level, which put it beyond the reach of most Koreans. Compulsory Licensing could have been a tool for Korea to alter the situation for public welfare. This, however, was not possible. In face of the US threatening a serious trade dispute over drug pricing, the Korean Government, was compelled to reject the application for compulsory license that would override the patent for Glivec in 2002.

Thailand is another country, which forfeited its right to use certain flexibilities in the TRIPS Agreement upon being pressured by the US Government. A report from the Medecins sans Frontieres details the US Government's pressure on Thailand to reduce its use of parallel imports and compulsory licensing. The Thai Government passed a law banning parallel imports in 1992, under threat from the US to limit textile imports. (Parallel imports are allowed again after amendments to the patent law, which came into force in 1999). Although patent law in Thailand provides for compulsory licensing, MSF reports that the Thai government, this time under threat of high tariffs on imports of wood products and jewellery, passed ministerial regulations in 1998 to restrict the use of compulsory licenses.

Bilateral agreement is another method used to restrict nation's ability to take advantage of TRIPS flexibilities. The US agreements with Australia, Jordan, Singapore and Vietnam restrict compulsory licensing to emergency situations. Except the Vietnam and Jordan agreements, all other agreements prevent marketing approval of generics during the patents protection period without the consent of the patent-holder rendering compulsory licensing ineffective in those countries including Australia and Oman. One of the most shocking instances of arm-twisting through the means of bilateral agreements is the IP Agreement between the US and Sri Lanka.

The Sri Lankan agreement limits the issue of compulsory licensing to the three situations specified below:

- if adjudicated violation of competition law occurred
- during existence of a declared emergency
- to enable compliance with national air pollution standards

Two of these situations are such that their inclusion is a mockery of the rationale of providing flexibilities. Firstly, under the current Sri Lankan Competition Law, intellectual property rights is excluded altogether, there can be no adjudication on IP related matters under competition law. The second exception allowed is far too qualified and rigid to have practical use. Not only will an emergency have to be declared, but the CL will have to be issued within the period of emergency. Therefore, a CL may not be issued in anticipation of an emergency such as bird flu.

¹⁴⁶ Supra n. 140

¹⁴⁷ Nitya Nanda, *WIPO Patent Agenda: As if TRIPS was not Enough*, Economic and Political Weekly, September 25th, 2005

It would appear from the above that the US is against the practice of issuing compulsory licensing. However, following a curious “Never practice what you preach” philosophy, the US is one of two countries which have used CL the maximum number of times. The US’ own patent regime is far more liberal than what it is trying to impose on developing countries. Under the US law, if the government wants to use a patent, it can do so without negotiating with the patent-holder. The patent-holder can ask for compensation but has no other rights. In addition, the Bahy Dole Act gives the government wide ranging powers to issue CL.

In India, although the new Patent Act does not take advantage of TRIPS flexibilities as comprehensively as it might have, nevertheless, it does incorporate a number of provisions, which may be utilized as safeguards if patent-holders in the pharmaceutical industry abuse their monopoly position. The capacity of the Patent Office in India, and the awareness of patent examiners of issues concerning the interface between patent law and competition law, will play a key role in determining how these provisions in the Patent Amendments Act of 2005 will be interpreted and enforced and how the flexibilities in the Act may be used to deal with anti-competitive practices in the pharmaceutical industry and health delivery system.

Box 4.8: The Brazilian and South African Experience

In Brazil, the government decided to take measures to facilitate access to drugs in the context of the HIV/AIDS crisis. This includes, for instance, a strong compulsory licensing regime. The US government objected to the requirement that unless it is economically unfeasible, inventors have the duty to manufacture the product in Brazil. A WTO dispute was initiated by the US in February this year but was withdrawn in June. Interestingly, the US specifically indicated that it was not targeting another section relating to national emergencies. The possibility to provide easier compulsory licensing in case of national emergencies is recognized under TRIPS.

Brazil has, however, gone much further and adopted a decree establishing rules concerning the granting of CL in cases of national emergency and public interest. Public interest includes public health, nutrition, the protection of the environment, and elements of primordial importance for technological, social or economic development. This broad coverage will allow issuance of CL in most situations of need. These grounds are not TRIPS compliant *per se*. Nevertheless, they have been incorporated in the nation’s legislation and are even deemed acceptable by the world community. India also faces health emergencies like Brazil and may draw lessons from the Brazilian experience that laws may be redrafted to take into account the needs of the local population.

In South Africa, the 1997 Medicines and Related Substances Control Amendment Act had created much controversy. This amendment was partly a reaction to the severe HIV/AIDS crisis that the country has been facing and the lack of access to drugs because of their unaffordability. One section in particular was deemed very controversial. It authorizes the government to determine to what extent a specific drug patent will apply. This provision was a direct challenge to the pharmaceutical industry, which reacted by moving the courts, but ultimately the petition was dropped in face of strong public opposition. It is unlikely this provision will be challenged again and it has now been accepted. This goes to show that for the benefit of its population, a nation may, in its adherence to TRIPS, avail of some latitude

even beyond flexibilities allowed, if this is imperative for public welfare.

Source: Patents Bill, TRIPS and Right to Health, Economic and Political Weekly, October 27, 2005

PRICE CONTROL

Many of the anti-competitive practices in the pharmaceutical sector leads to high drug prices as has been seen in Chapter III. One of the most effective options to deal with such anti-competitive practices is drug price control. Drug price control entails a mechanism or a policy that ensures that essential and life saving medicines are available at reasonable prices.¹⁴⁸

Control over cost of medicines exists in one form or the other in most countries. In Australia, since 1993, new drugs, with no advantage over existing products, are offered at the same price. Where clinical trials show superiority, incremental cost effectiveness is assessed to determine whether a product represents value for money at the price sought. In the UK, there exists the pharmaceutical price regulation scheme (PPRS) - a voluntary agreement between UK's Department of Health and the Association of the British Pharmaceutical Industry, in which companies negotiate profit rates from sales of drugs to the National Health Service (NHS). The PPRS regulates profits to a band of 17 to 21 per cent on historic capital or the initial capital used to begin the venture with a 25 per cent variation on either side. Companies are free to set prices, provided the rate of return is within the band. If the profits are higher, the companies have to reduce profits the next year and if the profits are lower, they can raise prices. In France, Italy and Belgium, prices are set in relation to relative cost, prices elsewhere in the EU and the contribution made to national economy.¹⁴⁹

Globally, drug companies are being forced to reduce the cost of medicines. Pressure is being mounted by Health Insurance Companies, Health Management Organisations (HMOs) and Governments (in countries like the UK and Canada, where the State provides Health Insurance cover) all over Europe and North America. These pressures have become stronger in recent years, with the realisation that spiralling drug costs are

¹⁴⁸ *What is drug price control system?* Economic Times, September 26th, 2005

¹⁴⁹ *Supra* n. 10

making health insurance cover (whether state funded or privately managed) unsustainable and obstructing access to medicines.¹⁵⁰

In India, drugs and formulations have been subjected to price control for more than three decades now, though recently there has been a trend towards decontrol. In fact, significant decontrol was introduced in 1995. Drug prices vary from country to country, for a number of reasons, including patent regulations, government controls, purchasing power, currency exchange fluctuations, etc. Due to the price control and patent regime, drug prices fell considerably, in India, and were among the lowest in the world. The main regulatory mechanism, which enforces price control, is the Drug Price Control Order, which is revised periodically.

The History of Price Control in India

Till 1962, the drug industry was bereft of any price control. In 1962, there was Chinese aggression on India and Emergency was declared. The Government feared that, as a result, drug prices might rise. Accordingly, for the first time, under the Defence of India Act, 1915, statutory control was imposed on the prices of drugs and pharmaceuticals, when the Drugs (Display of Prices) Order, 1962, and the Drugs (Control of Prices) Order, 1963, were promulgated. Under the Drugs Prices (Display and Control) Order of 1966, it was made obligatory for the manufacturers to obtain prior approval from the Government, before increasing the prices of any formulation.¹⁵¹

In 1970, the Drug Prices Control Order (DPCO) was passed. The DPCO is an order issued by the Government, under Section 3 of the Essential Commodities Act, 1955¹⁵², empowering it to fix and regulate the prices of essential bulk drugs and their formulations. The order incorporates a list of bulk drugs whose prices are to be controlled, the procedure for fixation and revision of prices, the procedure for implementation, the procedure for recovery of dues, the penalties for contravention, and various other guidelines and directions. The order is subject to the guidelines of

¹⁵⁰ Ibid

¹⁵¹ Ibid

¹⁵² The Essential Commodities Act, 1955 was enacted for the control of production, supply, distribution, trade and commerce in certain commodities that were declared essential by the Central

the Drug Policy and supposedly aims to ensure equitable distribution, increased supply, and cheap availability of bulk drugs.¹⁵³

The DPCO, which aims towards the availability of essential drugs at affordable prices, has played a vital role in directing the pharmaceutical industry's fortunes. The DPCO of 1970 effectively put a ceiling on prices of all mass-usage bulk drugs and their formulations. Its primary objective was to protect the interests of consumers, and ensure a restricted but reasonable return to producers. The order was a landmark regulation and has had several implications in shaping the Indian pharmaceuticals industry.¹⁵⁴

DPCO, 1970

The DPCO was first passed in 1970 and then revised in 1979, 1987 and 1995. In its introductory form, DPCO was a direct control on the profitability of a pharmaceutical business, and an indirect control on the prices of pharmaceuticals. It stipulated that a company's pre-tax profit from its pharmaceutical business should not exceed 15 percent of its pharmaceutical sales (net of excise duty and sales tax). In case profits exceeded this sum, the surplus was deposited with the Government. So, a pharmaceutical company had the freedom to decide the prices of its products. Product-wise margins were also flexible, so long as the overall margin did not exceed the stipulated norm. Since individual product prices did not require approval from the Government, bureaucratic hurdles were low.¹⁵⁵

DPCO, 1979

In 1974, the Government of India (GOI) appointed a committee under the chairmanship of Rajya Sabha MP, Mr Jaisukhlal Hathi, to inquire into the conditions prevailing in the sphere of pharmaceuticals in the country. The DPCO, 1979 was loosely based on the recommendations of the Hathi committee. The revised DPCO stipulated ceiling prices for controlled categories of bulk drugs and their formulations.

Government. The Act defines "Essential Commodities" to include drugs since they are considered essential for the health of society.

¹⁵³ Supra n 10

¹⁵⁴ Ibid

¹⁵⁵ Ibid

The retail prices of controlled formulations were decided by applying the concept of MAPE (Maximum Allowable Post-manufacturing Expenses).

The pricing formula was: Retail price¹⁵⁶ = (MC+CC+PM+PC) x (1+MAPE/100) + excise duty. MC was the material cost, including cost of bulk drugs/excipients; CC was the conversion cost as per the dosage form; PM was the cost of packing material suitable to dosage form; and PC was the packaging charge calculated in accordance with established costing procedures. The DPCO, 1979 put 370 drugs under price control. These drugs were segregated into three categories, having different MAPE. The most important drugs, including life-saving drugs were put in Category I, which had the least MAPE. Through this DPCO, around 80 percent of the Indian pharmaceutical industry (in value terms) was brought under strict price control. However, 13 TNCs challenged the order and succeeded for some time (see box).¹⁵⁷

Box 4.9: Drug Price Control in Practice

Indian consumers were cheated of over Rs.400 crores, which the Supreme Court defined as diabolical profiteering. 13 TNC drug manufacturers, after obtaining a stay on the DPCO, 1979, from our 'convenient' High Courts, had ignored the prices fixed under this. Ultimately, the Government of India had to appeal to the Supreme Court, which upheld the validity of its action and directed the Government to assess and recover the amounts.

In its judgement on April 10, 1987, the Supreme Court made a shocking observation. It discovered that Hoechst India Ltd had fraudulently priced Baralgan Ketone, a non-essential drug. While Hoechst had applied for a price level of Rs. 3,500 per kg. The Government, after analysing the cost, fixed it as Rs. 1,810.20 per kg. Before the DPCO, Hoechst was charging a price of Rs. 24,735.38 per kg. But instead of reducing it to Rs. 1,810.20, or even Rs. 3,500, as requested of them, they continued to sell the drug for Rs. 24,735.38, under the protection of the High Court's stay order.

The angered Supreme Court observed:

“We see that the price, of Rs. 24,735 per kg; at which the manufacturer was previously selling the drug, and at which he continues to market the drug to this day because of the quashing of the order fixing the price by the high court; is so unconscionably high, even compared with the price claimed by itself, that it appears to justify the charge that some manufacturers do indulge in 'profiteering'”.

Little money was recovered, and in spite of various parliamentary interventions, the matter languished in our courts. Whatever little that was recovered, was put into the Drug Price Equalisation Fund to subsidise public sector manufacturers.

Source: All About GATT- A Consumers Perspective, CUTS, February 1983

¹⁵⁶ This retail price is different from the Maximum Retail Price (MRP) as applicable to all other packaged goods. While MRP for other goods are inclusive of all taxes, in case of medicines local taxes are not included in MRP.

¹⁵⁷ Supra n. 10

DPCO, 1987

In 1984, the Kelkar Committee released its report, in which it recommended the exclusion of a number of drugs from the purview of price control. Various suggestions were made for determining the criteria for inclusion and exclusion. The DPCO, 1987 was based on the Drug Policy of 1986, and the Kelkar Committee Report. In the DPCO, 1987, the number of bulk drugs under price control was significantly reduced from 370 to 142. In addition, the categories of control were reduced to two, and higher MAPE was provided for each category of controlled drugs (75% and 100% respectively). However, around 75 percent of the pharmaceutical industry was still under price control.¹⁵⁸

The Drug Policy of 1994

In September 1994, the New Drug Policy was announced. The New Drug Policy liberalised the criteria for selecting bulk drugs and formulations for price control. In addition, industrial licensing was abolished for all bulk drugs. All hindrances to capacity expansions were removed, and it was expected that, as a result, supply would rise, resulting in higher competitive pressures. Foreign investment up to 51 percent was also permitted in the case of all bulk drugs, their intermediates and formulations. FDI above 51 percent could also be considered on a case to case basis. Nevertheless, five bulk drugs; Vitamin B1, Vitamin B2, Folic Acid, Tetracycline and Oxy-tetracycline were reserved for the public sector till 1998.¹⁵⁹

Table 4.1: Market share of drugs under the DPCO, 1979–2004

Year	Number of drugs	Approximate market share (%)
1979	347	80
1987	142	60
1995	74	> 40
2004	38*	20

* Not yet effective

Source: Prabodh Malhotra and Hans Lofgren, India's pharmaceutical industry: hype or high tech take-off?, Australian Health Review, Vol. 28, No. 3, 2004

¹⁵⁸ Ibid

¹⁵⁹ Ibid

Currently the Drug Price Control Order, 1995 governs the price control regime in India. For the purpose of implementing the provisions of the DPCO, powers of the Government have been vested in National Pharmaceutical Pricing Authority (NPPA).

DPCO, 1995

Under the DPCO 1995, just 76 drugs are under price control. Of these, two drugs have been removed from price control and as of today, only 74 drugs are under price control in India.

The Pricing of Bulk Drugs: The methodology, through which prices of DPCO-controlled bulk drugs are fixed, is as follows. While fixing the maximum sale price of a bulk drug, the Government has to provide either a post-tax return of 14 percent on net worth, or a return of 22 percent on capital employed.¹⁶⁰ Each company can choose one of the two methods mentioned above as per its own volition. So, the choice of method is company-specific and not product-specific. Based on the chosen method, each company submits to the Government, a detailed working of the prices of various bulk drugs that it requires. The Government subsequently studies the applications made by the major players for every bulk drug and cost audits reports of manufacturers before arriving at the final price. The price so decided will be binding on all manufacturers irrespective of their actual cost of production.¹⁶¹

The Pricing of Formulations: The methodology, through which prices of formulations are fixed, is as follows. In the new system, the retail price of a DPCO formulation is fixed equal to $(MC+CC+PM+PC) \times 2 + \text{excise duty}$. In order for the Government to decide the price of a controlled formulation, each manufacturer is supposed to submit to the Government, details of material cost, manufacturing process, etc. For imported drugs and formulations, the landed cost, including customs duty and clearing charges, is the benchmark to fix prices. A margin of 50 percent is allowed to the importer to cover the selling and distribution expenses, including interest and profit.¹⁶²

¹⁶⁰ In respect of a new plant, an IRR of 12% based on long-term marginal costing is allowed and where production is from basic stage, a post-tax return of 18% on net worth or a return of 26% on capital employed is allowed. (See Supra n. 1)

¹⁶¹ Supra n.10

¹⁶² Ibid

It is also to be noted that this DPCO grants a uniform MAPE (Maximum Allowable Post-manufacturing Expenses) of 100 percent to all controlled formulations.¹⁶³

National Pharmaceutical Pricing Authority

NPPA is an organization of the Government of India, which was established to fix/revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of the medicines in the country under the Drugs (Prices Control) Order, 1995. It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels.

The functioning of the NPPA is crucial to the effectiveness of the DPCO. However, The NPPA is handicapped in its functioning by a lack of a credible database on market price data. Currently, the determination of the prices of bulk drugs are based on cost studies and techno-economic estimates, market price data obtained from reliable sources and import price data from government agencies. It is felt that price fixation should be based on market price data and not cost and techno-economic studies. Since there is no single source of data for actual price related information, the government needs to work towards evolving a credible system.¹⁶⁴

Box 4.10: Refunding Illegal Excess to the NPPA

One of the responsibilities of the NPPA is to recover amounts overcharged by manufacturers for the controlled drugs. In one instance, the drug, Carbamezapine 200 mg, a product of Sun Pharmaceuticals, was being sold under the brand name 'Zeptol' and was excessively priced. However, upon receiving a notification issued by the government of India under the Drug (Price Control) Order, 1995 under the Essential Commodities Act, 1955, Sun Pharmaceuticals reduced the price of Zeptol 200 mg and swore in an affidavit stating therein that the excess amount charged over and above the retail price from January, 1997 to 21st May, 1997 would be refunded as soon as the NPPA issues the demand notice. [Source: 2003 CTJ 292 (MRTP)]

At present, there is no penalty as such which the NPPA can impose if companies are caught overcharging. Now companies charging more are simply asked to deposit the over-charged amounts with the NPPA. This is set to change, however, with the new Pharmaceutical Pricing Policy.

[Source: Nithya Subramaniam, *Drug Companies may be allowed to fix prices*, *Business Line*, February 26th, 2006]

¹⁶³ Ibid

¹⁶⁴ KG Narendranath, '*Pharmaceutical companies must realise that they cannot thrive by not having the government as a friend*', Interview with Mr. Arun Kumar, Chairman of NPPA, available at <http://www.pharmabiz.com>

NPPA has initiated steps to overcome the knowledge lag and has assigned a drug codification project to the National Institute of Pharmaceutical Education and Research. Currently, the codification of drugs in the country is not complete as the drugs are covered under the wider term of fine chemicals. NPPA resorts to the ORG-MARG for the retail price data. However, the chairman of the NPPA feels that there should be a parallel way to collect actual market price data that is crucial for price determination.¹⁶⁵

Box 4.11: Patented Medicine Prices Review Board (PMPRB) of Canada

Created in 1987, under the Patent Act, as an independent quasi-judicial tribunal, the PMPRB limits the prices set by manufacturers for all patented medicines, new and existing, sold in Canada, under prescription or over the counter, to ensure they are not excessive.

As an independent quasi-judicial body, the PMPRB carries out its mandate independently of other organisations, such as Health Canada, which approves drugs for safety and efficacy; and public drug plans, which approve the listing of drugs on their respective formularies for reimbursement purposes.

The PMPRB has a dual role:

Regulatory: To protect consumers, and contribute to Canadian health care, by ensuring that prices charged by manufacturers for patented medicines are not excessive.

Reporting: To contribute to informed decisions and policy making, by reporting on pharmaceutical trends and on the R&D spending by pharmaceutical patentees.

This agency is unique in the sense that it was set up exclusively to monitor the prices of patented drugs. Besides it also analyses the therapeutical contribution of the patented drugs and documents the pharmaceutical R&D investment in Canada. Though the data provided by this agency are rich, the PMPRB's area of operation is restricted to the patented medicines marketed or distributed under voluntary licenses. It does not regulate the prices of generic drugs and prices charged by wholesalers or retailers. Thus PMPRB regulates the price of each patented product on the first and last month of every year.

The price of a patented product in Canada can at no time exceed the highest price for the same drug in countries such as France, Germany, Italy, Sweden, Switzerland, the UK and the US. Sale of patented drugs accounted for 67 percent of total sales in 2001 as compared to 43 percent in 1990. Of the 933 patented drugs reviewed by this body till 2001, 827 drugs have been within the price guidelines. This may imply that the PMPRB does keep the prices of patented drugs under control. Lexchin (1997) observes that the prices of drugs, which had voluntarily surrendered patents, were above the prices of patented medicines. Once this was brought to the notice of PMPRB, the rules were changed and now, even if companies voluntarily surrender their patents, such products still come under the scrutiny of PMPRB until the expiry of patents.

Canadian regulators have ordered the local subsidiary of US-based ICN Pharmaceuticals to cut the price of its Virazole, anti-infection, drug by almost 90 percent, and pay a C\$1.2mn (US\$876,000) penalty for excessive pricing. It found ICN had sold Virazole at "an excessive price" since January 1994, and ordered the company to reduce the price of a 12-hour dose from C\$1540 to about C\$200. (SAWTEE newsletter, August-December, 1996)

¹⁶⁵ Ibid

The ruling is the first, since the establishment of the Patented Medicine Prices Review Board in 1987, under reforms to extend patent protection on brand-name pharmaceuticals. However, the Board has reached 100 “voluntary” settlements, which it claims have saved consumers about C\$110mn.

Source: Sawtee newsletter, August- December, 1996

The National Pharmaceutical Policy of 2002

The 1995 DPCO is to be succeeded by the National Pharmaceutical Policy of 2002. The National Pharmaceutical Policy of 2002 contains several important policy changes.

The new Indian Pharmaceutical Policy, 2002, has focused on liberalisation by further reducing the number of drugs, subject to price control, and opening up the market to foreign investment. The new Pharmaceutical Policy, 2002, further reduced the number of drugs under price control to just 38. The key features of the Pharmaceutical Policy, 2002 are:

- Reduction in the number of drugs under price control to 28 percent (19% of the market) from 74 drugs (40% of the market) under the 1995 policy.
- A Drug Development Promotion Foundation (DDPF), and a Pharmaceutical Research & Development support Fund (PRDSF), to be established to boost research and development.
- Foreign investment up to 100 percent to be permitted, subject to stipulations laid down from time to time in the industrial policy.
- Abolition of industrial licensing for all bulk drugs, intermediates and formulations.¹⁶⁶

The implementation of this policy is presently in a state of limbo. Triggered off by a stay on the application of the 2002 Policy within the state of Karnataka by the State High Court, a petition to investigate the validity of the judgment is pending in the Supreme Court. The ultimate implementation date and effectiveness of the policy when implemented will both be determined by the decision of the Supreme Court in this regard.¹⁶⁷ Meanwhile, the government has come out with the Draft National Pharmaceuticals Policy, 2006. But only Part A of the Policy that contains issues other than statutory price control has been put in the public domain. Nothing is known

¹⁶⁶ Supra n. 31 at p. 24

¹⁶⁷ Ibid.

about the Part B that might be dealing with statutory price control, presumably due to the pending Supreme Court case.

But a close reading of the Pharmaceutical Policy 2002, gives rise to certain questions. Is decontrol to this extent justified? In an attempt to balance protection of industry efficiency and access to health, is such a liberal regime not tilting the scales towards the industry?

It is necessary to examine this issue more closely by considering the arguments for and against price decontrol.

Dismantling the Decontrol Rationale

The two main contentions

Two arguments are primarily put forth to justify price decontrol in relation to the pharmaceutical industry.

1. It is asserted that market forces are best suited to stabilise drug prices. The validity of this argument is suspect. Market forces do tend to be a leveller when it comes to prices in other industries, but given the high concentration in different therapeutic segments and the low elasticity of demand in the pharmaceutical sector, market forces are usually not effective in controlling prices. This reality in conjunction with the fact that the welfare implications of industry conduct is far greater for the pharmaceutical sector than most other industries counters the industry's stand that when price control has been abolished in a large number of industries, it is unfair to continue to stifle the pharmaceutical industry with rigorous price control.

Studies and statistics bolster the assertion that market forces do not control drug prices.¹⁶⁸ This would be illustrated by the pricing patterns of different brands in a particular therapeutic segment. In almost all segments, the brand leader for a particular drug is usually one of the most expensive. That costlier products sell well is inevitable given that because a costlier product can spend more on market promotion and incentives to doctors. It may be mentioned here that for prescription drugs such as these the resistance to price increase must come from prescribers, on whose consultation patients are more often than not blindly reliant. Needless to say the price hike is not influencing to any significant extent the choices made by doctors, which is indicative of the need for more stringent regulation of physician's conduct as well.

¹⁶⁸ Wishvas Rane, *Prices of Prescription Drugs*, Economic and Political Weekly, August 17th, 2002

The IDMA holds that the practice of controlling medicine prices in India has become redundant due to growing competition in the industry. It, in fact, cites statistics that intense competition itself has brought down medicine prices by almost 2-3 percent in the last three years as against the general inflationary growth of 3-4 per cent during the same period.¹⁶⁹ The Indian Pharmaceutical Association points out that a study of price movement for the 12 month period ending March 2003 reveals that the prices of many commonly used medicines such as antibiotics (-9%), antidiabetics (-4%), Tuberculostatics (-8%) etc, have declined during the period¹⁷⁰.

There exists, however, a wide range of statistical data, which contradicts this contention. Prices have been seen to rise steeply after removal of price control.

According to government authorities, price rise in prices of medicines that are under price control is only one percent, whereas drugs that are not under price control have an average price rise of around seven percent in the past decade.¹⁷¹

A recent study shows that the prices of many life saving bulk drugs have gone up steeply. Is decontrol to blame, at least to an extent? Statistics appear to support an affirmative response. Below are the prices of twelve essential drugs before the liberal decontrol of DPCO in 1995 and 1998.

Table 4.2: Impact of Decontrol of Drug Prices

Name of the drug	For Treatment	Price 1995	1998	Percentage increase
Diazepam	Depression	3.13	9.50	204
Ampicillin	Antibiotic	12.85	23.15	80
Cephalexin	Antibiotic	45.07	113.15	151
Ethambutol	Anti T.B. drugs	5.92	33.00	457
Rifampicin	-do-	24.00	64.00	167
Pirazinamide	-do-	17.01	46.95	176
Lignocaine Hcl	Anaesthetic	4.16	12.40	198
Promethaxine Hcl	Anti Allergic	1.25	3.23	158
Antacid liq.	Gastritis	13.00	23.00	77
Oxyfedrine Hcl	Angina pectoris	10.44	21.41	105
Discopyramide Phospate	Cardiac problems	16.50	50.46	206
Dipyridamole	Anti angina	2.00	4.73	137

Source: D.P. Dubey, *Globalisation and its impact of the Indian Pharmaceutical Industry-* at <http://revolutionarydemocracy.org>

¹⁶⁹ Remove medicine price control: IDMA, December 18th, 2004

¹⁷⁰ P.T Jyothi Data, *Fluctuating Drug Prices*, Business Line, August 10th, 2004

¹⁷¹ Supra n. 31 at 61

It may be noted that the above list is indicative. Hundreds of such examples may be given.

Further telling statistics are provided by a comparative study of drug prices between February 1996 and October 1998 which revealed that the price increase for drugs under price control was negligible, while prices for drugs out of control were up by an average 14.94 per cent. Sporidex was up from Rs 54.25 in 1996 to Rs 61.10 in 1998; Digene was up from Rs 16.55 to Rs 27.10; Crocin went up from Rs 3.89 to Rs 5.88. It may well be inferred that medicine prices are expected to increasingly and silently creep up, as against a one-time escalation.¹⁷²

2. The second justification used to support drug price decontrol is that the industry must be made more profitable in order for it to increase investment on R&D and be globally competitive. A successful drug must pay for its own research, as well as the research on the unsuccessful ones, on which the company also risked money. Citing from the insights of a DSF study post-DPCO (1995), the DSF discounts this theory. "In the past, price controls were slashed from 166 drugs to 74. In the last decade, it was diluted to about 30 per cent of the market to spur R&D activity. But R&D investments in the drug industry is still less than 2 per cent of sales,"¹⁷³. Also even with price control, the pharmaceutical industry remains a highly profitable one. The argument that total price decontrol is necessary so as to have funds ready for R&D, does not hold much water, as a Pharmabiz study finds that pharmaceutical industry in India is the second highest profitable only after IT. The study also mentions, "And a hard truth behind this excellent performance is that a major part of these profits came from overcharging of several drugs by large units."¹⁷⁴ This could happen even in a situation of partial decontrol and hence one can imagine what can happen in a regime of total decontrol.

Lowest Prices in the World

There exists an argument that there are many drugs which are not under price control and which are not overpriced. The pharmaceutical industry emphasised time and again that drug prices in India are amongst the lowest in the world. This may no longer be true. Drugs that are still patent protected are much cheaper in India due to India's earlier Patent Act of 1970. Off-patent drugs (which account for 80-85% of current sales in the country) are not necessarily cheaper in India. In fact, generally drug prices are higher in India than those in neighbouring Sri Lanka and Bangladesh. Even more disturbing is the fact that prices of some top selling drugs are higher, in India, than of those in Canada and the UK. This comparison is on the official foreign

¹⁷² PT Jyothi Datta, *Few Takers for drug cos' claim on prices*, Hindu Business Line, February 11th, 2002

¹⁷³ Ibid

exchange conversion rate. If one takes the purchasing power parity (PPP), then the disparity is stark.¹⁷⁵

Table 4.3: International Cost Comparison of Select Drugs

Drug	Dose	Canada	UK	India
Amoxicillin	250 mg	1.75	2.59	2.89
Ampicillin	250 mg	1.75	2.42	3.18
Erythromycin	250 mg	1.25	2.87	3.28 - 4.17
Cephalexin	250 mg	3.00	7.74	4.46
Propranolol	40 mg	1.25	0.25	1.39
Atenolol	50 mg	--	2.65	1.29
Prednisolone	10 mg	1.50	1.09	1.32
Paracetamol	500 mg	1.25	0.32	0.49
Haloperidol	0.25 mg	0.13	1.60	0.55
Phenobarbitone	30 mg	0.25	0.28	0.50

Note: Single units, tab/cap/vial, has been taken for all drugs. Prices are in Indian Rupees. Conversion rate is \$1=Rs42.52, 1 Canadian dollar = Rs25, 1 Pound = Rs70. Based on the figures available in British Columbia Children's Hospital Formulary, British National Formulary, No.35, March 1998, MIMS India, March 1998

(Source: Nitya Nanda and Amirullah Khan, *Competition Policy for the Pharmaceutical Sector in India*, in "Towards a Functional Competition Policy for India", Pradeep Mehta (ed), Academic Foundation, New Delhi, 2006.)

Plans on the Anvil

The government plans to step up monitoring of even small price hikes of drugs and pharmaceutical products. Currently, the NPPA seeks explanations from companies on price hikes of over 20 percent in a year. This cap is likely to be brought further down. The Ministry of Chemicals and Fertilizers clarifies that this would be applicable to drugs outside price control.¹⁷⁶

It is probable that in the Pricing Policy likely to be introduced, there will be different models to regulate prices of different category drugs. For instance, hospital supply medicines will not be subject to price control although some of the selected drugs will be subject to cost-based price control. For the remaining medicines in the essential drug list, the Government is planning to cap the ceiling prices based on the weighted average of the maximum retail price (MRP) of the top three brands in both volume

¹⁷⁴ <http://www.pharmabiz.com/article/detnews.asp?articleid=12357§ionid=47>

¹⁷⁵ Supra n. 10

¹⁷⁶ Nithya Subramaniam, *Govt to step up monitoring of small hikes in drug prices*, Business Line, January 1st, 2006

terms and value terms. Also prices of drugs for cancer and HIV/AIDS will be kept affordable and those for patented drugs will be pre-negotiated.¹⁷⁷

Under the new Pharmaceutical Pricing Policy, companies may be given greater flexibility in fixing prices. Instead of the NPPA fixing the prices of certain drugs based on the cost of raw materials, the companies may be allowed to do so. However, they would have to file pricing structure with the Authority. The Authority would then choose a few applications for further inspection. Also the government plans to impose stiff penalties on companies apprehending overcharging and the penalties will increase with every offence. The penalties, however, have not yet been finalized. This would be a marked change from the current liberal regime where companies are merely notified to refund illegal excesses.¹⁷⁸

Another measure the government is considering is to cap trade margins of drugs not under price control. However, the generic industry is concerned about the margin cap. Big generic players such as Cipla, Ranbaxy and Wockhardt have met to work out a strategy. This policy has the triple effect of price control through restraint on trade margins, curbing the anti-competitive practices engaged in by pharmacists and paving of way for generic prescriptions. The last needs some explaining. One of the policy tools, which will be suggested in the next chapter to deal with the prevalent anti-competitive practices in the pharmaceutical sector and the health delivery system, is enforcing generic prescription for select drugs to address the specific problem of pharmaceutical companies giving incentives to doctors. But the core concern underlying this recommendation is that the focus of the pharmaceutical companies will simply shift to pharmacists and they will offer higher trade margins to pharmacists in return for pushing their drug.

The industry argues that this recent arbitrary imposition of ceiling on trade margins would shift the sales from branded generics to branded products and thus give boost to the sales of leading brands. The action would harm small and medium units in sales with no corresponding benefit to the consumer.

¹⁷⁷ Ibid

¹⁷⁸ Nithya Subramaniam, *Drug Companies may be allowed to fix prices*, Business Line, February 26th, 2006

The Government of India has presently constituted Sandhu Committee that is looking to reinforce accessibility of drugs in the post-2005 scenario by re-defining the categories and basis for price control. Whether or not price control is gradually phased out, there are certain lacunae in the present system, which need urgent attention and this is the mandate of the Sandhu Committee. To illustrate two such problems:

The Price Control Order relies mainly on ORG data to assess prices, which takes into account only retail prices. Institutional sales, such as those to hospital segments are completely left out. Therefore, prices of drugs for very important diseases, such as AIDS and cancer, are left out of the scope of the Order, since most of the drug supply in the case of these diseases is institutional and escapes the economic criteria of the Order.¹⁷⁹ The experiences of South Africa and Brazil in the matter of drug prices and AIDS are indicative that this current weakness in the price control regime be addressed at the soonest.

Secondly, the price control mechanism as it operates today, does not effectively control the prices of imported drugs. The practice under the Order for imported drugs had been to allow a margin over “landed” costs (cost of the drug/ API when it lands on Indian territory). This practice has been problematic in the past because it is hard to monitor price collusions between the Indian importer and exporter of the raw materials/drug. Previously, subsidiaries of MNCs operating in India have used this loophole to claim inflated prices for raw materials imported from their parent companies into India. This problem will become much more acute from 2005 onwards, since patented products do not have to be produced locally.¹⁸⁰ Therefore, solutions need to be created to resolve this oversight of the system.

These and many other issues impinge upon the efficacy of the price control regime and it is to be hoped that the Sandhu Committee is successful in designing effective remedies.

¹⁷⁹ Supra note 31 at p. 61

¹⁸⁰ Ibid

OPTIONS IN THE HEALTH DELIVERY SYSTEM

The Competition Act, 2002 can obviously be used to redress violations of competition law committed by doctors, hospitals and pharmacists. The discussion on the competition law provisions in this chapter would apply for the most part to the health delivery system as well, apart from those cases where the anti-competitive conduct is unique to the pharmaceutical industry. But while anti-competitive practices are far more prevalent in the pharmaceutical sector than in the health delivery system, the former is much better regulated as well.

Apart from competition law, there is no concrete regulatory mechanism addressing anti-competitive conduct in the health delivery system. Hospitals are virtually ungoverned in this respect. In some states, there are laws that provide for mandatory registration and technical standards for clinical establishments including hospitals, nursing homes or diagnostic centres. However, the coverage is not comprehensive and even, not to mention about proper implementation. With the hospital industry growing as it is, this gap needs to be addressed. However, as of today and as has been seen in Chapter III, breach of competition principles is committed far more by doctors and pharmacists than by hospitals and legal options to control anti-competitive behaviour will be examined in more detail with specific reference to these two components of the health delivery system.

Box 4.12: A Case on the Health Delivery System

Tabre Treatment Clinic is engaged in providing health services and more especially treatment for arthritis. Consumers desirous of using its services were previously required to endorse certain conditions in writing, the most striking of which is, "I ...agree and undertake not to hold TTC liable in any manner whatsoever, whether for refund, damages or otherwise in respect of this contract or the aforesaid treatment. It was held that this requirement tended to impose unjustified costs on the consumer. The practice being prejudicial to public interest, the respondent was directed by the MRTP Commission to cease the practice by deleting the condition in question and desist from repeating the same in the future. [2000 CTJ 1 (MRTP)]

See generally Tabre treatment Clinics Madras: In re:

Regulating Prescribing Doctors

As has been mentioned many times before in this study, for the purchase of most pharmaceuticals, it is not the health consumer who decides which medicines to consume – a prescribing physician typically makes this choice. The pharmaceutical companies spend large sums in an attempt to influence the prescribing practices of

doctors. Collusion (tied selling) with pharmacies or diagnostic centres is another practice, which is common in the medical profession. Taking commissions on referrals is another practice, which may be interpreted as having anti-competitive effects.

Box 4.13: Regulating Physicians in the US

The types of conduct within the health care professions that have been deemed anti-competitive over the decades include agreements on price and price-related terms, agreements to obstruct the entry of innovative forms of health care financing and delivery, and restraints on advertising and other forms of solicitation. Since the 1970s, the Commission has had an active law enforcement program targeting anti-competitive practices among physicians and other health care professionals.

Since 2002, the Commission has entered into 17 consent agreements with physicians, their organizations, or their non-physician consultants and agents, settling charges that the respondents have engaged in unfair methods of competition - primarily different forms of price-fixing.

Source: Improving Healthcare: A Dose of Competition, A Report by the Federal Trade Commission and the Bureau of Justice, 2004

Apart from competition law, the only other regulation, which may be resorted to as recourse for anti-competitive conduct, is the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (hereafter termed as the Regulation).

This Regulation strongly emphasises the duty aspect of the medical profession and that the prime object of the medical profession is to render service to humanity and that reward or financial gain is a subordinate consideration. Therefore, accepting incentives to promote particular brands would be against the very philosophy of the code of ethics.

There is a prevalent trend of thought, which will be discussed in more detail in the next chapter, which believes that the practice of pharmaceutical companies giving kickbacks to doctors to push their drugs, might be stemmed by making generic prescriptions mandatory at least in case of selected medicines. The Regulation, in fact, mandates that every physician should, as far as possible, prescribe drugs with generic names and that every physician should ensure that there is a rational prescription and use of drugs. There is explicit mention in the Regulation that drugs

prescribed by a physician or brought from the market for a patient should explicitly state the proprietary formulae as well as generic name of the drug.

Referral on the basis of commission has also been addressed by the Regulation, which provides that a physician shall not give, solicit, or receive, any gift or commission in return for the referring or recommending of any patient for treatment. It further provides that a physician shall not directly or indirectly, participate in or be a party to act of division, transference, assignment, subordination, rebating, splitting or refunding of any fee for medical, surgical or other treatment.

The Regulation stresses on the fact that the practices mentioned as unethical or misconduct under its provisions are not exhaustive and that the Council would consider any other practice which may be construed as professional misconduct. Therefore, other anti-competitive practices for instance tied selling, which are not expressly mentioned by the Regulation may still be redressed by the Medical Council. Does a Regulation have the same weight as legislation? What would be the punishment meted out to a practitioner found guilty? The appropriate Medical Council may award such punishment as deemed necessary or may direct the removal altogether or for a specified period, from the register of the name of the delinquent registered practitioner. Deletion from the Register is widely publicized in local press as well as in the publications of different Medical Associations.

But the Regulation has little effect in practice. That its provisions are not implemented in reality is evident from prevalent practices. Doctors tend to mention the brand name of drugs in prescriptions rather than the generic name of drugs. Doctors, of course, are not always motivated by incentives offered by companies. But this system renders it very difficult to identify doctors who are prescribing on the basis of bribes offered by drug companies among other criteria.

Difficulties in implementation will continue in all probability, as the decision-making authority under the Regulation is the Medical Council, which usually chooses to protect the medical fraternity.

A few countries have evolved a regulatory framework to regulate doctors' prescribing practices. Prescription audit is one method to make a post-facto analysis, which creates an incentive for doctors to be careful. Some countries have sought to create financial incentives for doctors to maintain a high level of rationality and cost-effectiveness in their prescribing behaviour. But to effectively control anti-competitive practices in the health delivery system, it is essential that there be more stringent regulation of physicians' conduct.

Regulating Pharmacists

Again apart from competition law, there is little governance of this component of the health delivery system. As has been seen in the third chapter, collusive behaviour and arm-twisting drug companies into giving higher margins are practices commonly engaged in by pharmacists. As per the provisions of the new Competition Act 2002, however, only trade unions are allowed to engage in collective bargaining. Hence, the activities of the pharmacists' association to extract higher margins would stand illegal. There is a legislation pertaining specifically to pharmacies, namely The Pharmacy Act, 1948. This, however, is not a useful legal option in controlling anti-competitive practices engaged in by pharmacists. The only provision therein which may possibly be used is that a pharmacist stands to be deregistered if found guilty of any infamous conduct in any professional respect.

The MRTPC, however, has been quite active in controlling anti-competitive practices engaged in by pharmacists. Such cases have been previously discussed. (See Box 3.6).

Box 4.13: The Effect of the MRTPC Commission

In one case, a pharmaceutical company alleged that a pharmacist association had issued oral instructions to its members not to deal with the complainants and to buy or sell medicines to them. In reply the association not only denied the allegations but also issued a circular to its members mentioning that an allegation has been made that there exists a boycott against the company in question, but that the allegation was untrue and to remove all trace of doubt in the matter, the circular was issued to make clear that there was no such boycott and all members were free to deal with the company and the company with them. Upon this the Commission saw no ground to continue proceedings.

Comments: Now it may very well be that this was exactly what happened. But it may have been that that there was an oral boycott and the complaint served the purpose of getting the boycott turned on its head. [2002 CTJ 124 (MRTP)]

In another case, upon initiation of an enquiry by the Commission into the Utkal Chemists and Druggists Association issuing a circular to boycott the products of Lupin Laboratories, the Chemists and Druggists Association informed the Commission that they had resolved the matter with the company and would not repeat such an action in the future. [(1997) 5 CTJ 350 (MRTPC)]

Most countries have separated the role of physicians and pharmacists to ensure that physicians do not have a financial interest in the pharmaceuticals they prescribe. Japan and Korea are exceptions. Japan has a very high rate of pharmaceutical consumption per capita, even taking into account the high average income. Korea is currently in the process of separating the roles of physician and pharmacist. In some countries, the pharmacist also has some degree of control over the drugs actually consumed. For example, one US study found that 77 percent of physicians asked by a pharmacist, to switch prescriptions, consented to do so. In India, the pharmacist-doctor nexus remains strong and it is to the benefit of the consumer that their relationship be monitored.

Regulating Hospitals and Diagnostic Centres

As noted above hospitals and diagnostic centres often engage in a range of anti-competitive practices. It has also been observed that the types of market failures are so special that it is not possible to tackle them simply by a competition law. Yet, there is no appropriate law to regulate or monitor the functioning of private hospitals, nursing homes and other medical care establishments in the country in relation to requisite level of facilities, space, equipments, doctors and nurses.

There are state level laws in this regard only in a few states like West Bengal, Maharashtra, Tamil Nadu, Andhra Pradesh and Pondichery, while some states like Kerala and Jammu & Kashmir are considering such a law. The Central Government is also considering a legislation called the Clinical Establishments Regulation Act in consultations with the State Governments with the objective of regulating the establishment of private hospitals/clinics and prescribing uniform minimum standards. As of now, however, in most states, any person can open a nursing home or a hospital or a diagnostic laboratory just by obtaining a trade or a municipal license.¹⁸¹ Most damaging aspect of the situation is that very little is known about these establishments and people are very often cheated.¹⁸²

¹⁸¹ Parliament of India, *Hundred and Twenty Sixth Report on the Petition Seeking Legislative Measures Inter Alia to Provide a Regulatory Mechanism for Private Nursing Homes/Clinics and Stringent Penal Provisions For Production/Distribution*,

Even in states where such a law exists, the provisions are quite rudimentary and implementation is quite poor. Moreover, these laws deal with technical regulations only. On economic regulation front, some laws specify only free treatment to a certain percentage of patients. However, there is no effective mechanism to monitor such provisions. The hospitals in the public sector, however, operate under the regulatory mechanism as may be specified by the Central Government or the State Governments concerned. In practice, however, there are several hospitals and health centres run by governments who do not conform to their own standards. Moreover, though the fees charged by government hospitals are quite reasonable and often free or subsidised, they are also prone to anti-competitive practices.

etc. of Spurious Medicines, Committee on Petitions, Rajya Sabha Secretariat, New Delhi, December 2005.

¹⁸² K V Narayana, *Changing Health Care System*, Economic and Political Weekly, March 22-29, 2003, p. 1230-1241

CHAPTER V SUGGESTED STRATEGIES AND MEASURES

In this chapter, we try to explore some approaches or strategies that could be used to deal with anti-competitive practices in the pharmaceutical as well as health services industry. However, due to peculiarity of the market conditions, many common marketing practices that are followed in most other industries, can actually promote non-competitive or inefficient outcomes. As opposed to any other market, in health services, very often the seller decides what a customer would buy, and often the customer has little choice regarding the seller as well. For example, a patient with a sudden health problem may just visit the nearest hospital. But once in a hospital, it is for the hospital to decide on everything, ranging from what diagnostic tests to take, what kind of treatment to receive, what medicines to take, whether to go for a surgical operation, to how many days to stay in the hospital. Obviously, in such a situation, a profit-oriented hospital, would in all probability place very little premium on ethical values and impose huge and unnecessary costs on the patient.

Thus, the focus here would be on promoting competitive outcomes and efficiency rather than promoting competition *per se*, by evolving appropriate rules of the game or regulatory framework. The approaches and strategies outlined below are intended to promote competitive outcomes and efficiency in the health care industry including the pharmaceuticals sector, enhancing thereby access to affordable healthcare for the people, through promotion of competition as well as appropriate regulation where necessary.

As may be seen below, several policies and measures will be required to be implemented. This will require appropriate involvement of all stakeholder groups. Capacity building through awareness campaigns through print and electronic media on all relevant issues outlined below need to be carried out on a sustained basis for which the government need to provide adequate budgetary resources to the relevant authorities, existing and forthcoming. A dedicated website need to be created which would disseminate all relevant information. In addition to English language, publicity

should also be carried out in other Indian languages. State governments as well consumer organizations and other interested NGOs need be involved with this work.

Promoting Generic Competition

The market for pharmaceuticals is different from other markets in the fact that consumers do not make their buying decisions. They buy medicines as suggested by their doctors. The problem here is to ensure that the doctors make the best possible decisions for the patients. However, this is not easy. In economics, the problem of motivating one party to act on behalf of another is known as ‘the principal-agent problem’. The principal-agent problem arises when a principal engages an agency for performing certain acts which are useful to the principal, and where there are elements of the performance which are costly to observe. This is the case to some extent for all contracts which are performed in a world of information asymmetry, uncertainty and risk. In the case of a patient-doctor relationship, information asymmetry is rather extreme as the patient’s ignorance on the issue is often near total.

Here, principals do not know enough about whether (or to what extent) a contract is or has been satisfied. The chances of a doctor making a sub-optimal decision get higher as there is the problem of moral hazard as well, as pharmaceutical companies entice the doctors to push their medicines by offering huge incentives. The solution to this problem is to ensure (as far as possible) the provision of appropriate incentives so that agents act in the way principals wish them to. In terms of game theory, it involves changing the rules of the game, so that the self-interested rational choices which the principal predicts the agent will make, coincide with the choices the principal desires.

In this kind of a situation, the only way the rules of the game can be changed seems to be through promoting generic drugs.¹⁸³ This has been suggested by the Task Force formed under the chairmanship of Dr. Pronab Sen. Though opinion is divided on this issue, similar experiment has been quite successful in neighbouring Bangladesh. However, the idea was floated in India even in the past, by a committee formed in 1974, under the chairmanship of Rajya Sabha MP, Mr Jaisukhlal Hathi, to inquire into the conditions prevailing in the sphere of pharmaceuticals in the country.

¹⁸³ Generic drugs, in this particular context, would mean drugs popularly sold under their chemical names only.

Interestingly, though the idea could not take off in India, it inspired Bangladesh to adopt a policy to make generic prescription mandatory for a select list of essential drugs.¹⁸⁴

Presently, branded drugs dominate the market in India and there is a very small presence of the generic drugs. It is also seen that generally generic drugs are priced lower than the branded ones. Generic competition of bio-equivalent medicines is essential in order to arrive at the lowest and most sustainable prices for essential medicines. The promotion of generic drugs, as against branded drugs, will help the consumer to break free from the biased counselling of physicians.

However, as mentioned above, there is strong opposition to the proposal as well. One opinion is that the power the doctors hold today will simply shift to the pharmacists, as they will try to sell the more expensive brands. This is partly true, as the patients will move from a “no choice” to a “some choice” situation that might be influenced by the pharmacists. However, relatively more aware consumers will benefit as they will search for cheaper brands. Moreover, consumers can be made more aware through media interventions.

Another concern is related to the quality of drugs as it has been argued by some that brands are important indicator of quality. However, it may be noted that de-branding can be done with sole reference to prescriptions by doctors, and the market will not be de-branded as the drugs will continue to carry manufacturers’ names. The issue of spurious medicines should not be linked with this issue as reputed brand names are very often used to market spurious medicines. The only solution to this is to ensure that spurious medicines are not injected into the distribution channel. In any case, utmost effort must be made to ensure that only medicines of certain minimum standards can enter the market. The French safety arrangement in this regard is worth studying.

¹⁸⁴ Zafrullah Chowdhury, *The Politics of Essential Drugs: The Makings of a Successful Health Strategy: Lessons from Bangladesh*, Zed Books Ltd. London, 1995

Box 5.1 Distribution of Medicines: French Safety

The distribution chain for medicines in France offers outstanding safety in the quality of products. The activities of the pharmaceuticals industry in France operate under a very strict regime laid down by the Public Health Code. A medicine may only be marketed after it has received a marketing permit (an AMM) from the Medicines Agency (the competent government authority), issued following studies to confirm the quality, safety and efficacy of the product. The Medicines Economic Committee is responsible for fixing the price of the product (France has the lowest pharmaceuticals prices in Europe) and the rate of reimbursement under the sickness insurance scheme.

To be marketed by pharmacies, the medicine produced by a pharmaceuticals group will then be stored at the premises of wholesale distributors. These form the sole link in France between the factory and the pharmacy: a closed system synonymous with security at a time when the world traffic in counterfeit pharmaceutical products is estimated to be some \$8bn dollars.

Source: http://www.diplomatie.gouv.fr/label_france/english/ECONOMIE/pharmac/pharmac.html

De-branding of prescription for essential generic medicines thus seems to be an option worth exploring. This is the only way competition in real sense can be promoted at least in the generic segment of the market. However, considering the opposition from different quarters, a relatively smaller number of most-commonly used medicines can be brought under this scheme on an experimental basis.

Box 5.2: Promoting Generic Drugs – Experiment in Bangladesh

Under pressure from the civil society, the Bangladesh Government promulgated its Drug Policy in June 12 1982, to promote use of generic drugs only (Although the policy has now been diluted, for reasons not fully clear, there are useful lessons to be learnt). The main purpose of this policy was to restrict the marketing of unnecessary and harmful drugs and:

- to ensure a strict quality control of medicines;
- to control the pricing of drugs;
- to make quality medicines available to the people at a fair price;
- to break the monopoly of multinational companies and encourage local producers;
- to use generic names only for essential medicines and avoid enticing brand names.

The law provided a penalty of 10 years imprisonment or a fine of up to two hundred thousand Taka, or both in the event of a violation

Substantial benefits were derived from Bangladesh's National Drug Policy. The gains are evident when prices, production figures and quality indicators, at the time the policy was introduced (1982), are compared with those of a decade later (1992).

1. Essential drugs increased from 30 to 80 percent of local production;
2. Drug prices stabilised, increasing by only 20 percent, compared with an increase of 180 percent in the consumer price index. The drop in price in real terms made drugs more affordable;
3. Bangladesh companies increased their share of local production from 35 percent to over 60 percent and overall local production increased by 217 percent;
4. Less dependence on imports and prioritisation of useful products saved the country approximately US\$600mn;

5. The quality of products improved – the proportion of sub-standard drugs fell from 36 percent to 9 percent.

Source: Nitya Nanda and Ritu Lodha, Making Essential Medicine Affordable to the Poor, Wisconsin International Law Journal, Vol 20, No 3, 2002

Dealing with IPR Related Issues

As mentioned previously, in the new patent regime, any new product entering the market would essentially be marketed by a monopolist. This means that in the new patent regime, abuse of dominance, which was almost non-existent earlier, is likely to become quite frequent. India, thus, needs to learn the art of dealing with abuse of dominance, in which its experience is almost non-existent. Moreover, the related provisions in the Competition Act (2002) are not strong enough.

The major way of dealing with abuse of dominance by a patent-holder is through compulsory licensing. India was not in need of using this since 1970 as its patent regime did not grant product patent. However, it would be worth recalling its experience in this regard prior to 1970, when a product patent regime was in place, under its old patent law of colonial vintage. Unfortunately, the experience was far from satisfactory as granting compulsory license proved to be almost impossible. The legal provisions regarding compulsory licensing as per the new amended patent law are hardly any different from those of its 1911 law. It is hence quite doubtful if providing compulsory licence under the new patent regime would be easy.

It is also quite unfortunate that the competition authority would hardly have any role in granting compulsory licence. In any case, patent offices are created to look into issues of patentability and granting of patent on ground of ‘innovativeness’. Hence they are unlikely to have the capacity to understand if a patent holder is abusing its monopoly status granted through patent rights. Considering this, it would be more appropriate to give the competition authority the responsibility of granting compulsory licence in consultation with the patent office rather than the other way round. In fact, this is how the issue is handled in most developed jurisdictions.

Box 5.3 Balancing IPR and Competition: A Canadian Case Study

On November 2005, the Federal Court of Appeal of Canada delivered an interesting judgment in the case of Eli Lilly et al v. Apotex Inc., on the matter of achieving balance between competition law and patent laws. The crux of the ruling was that an assignment of patent may, as a matter of law, unduly lessen competition. As the privilege of assigning patents is a right granted to a patentee in India as well, this case is being highlighted.

One of the key questions in the case was if a company already owns patents that would give it a monopoly in the relevant market upon assignment of other related patents by another company/s, would such an assignment of patents be considered as anti-competitive or valid in light of the exclusive rights granted to a patentee to assign patents to whomsoever the patentee wishes.

The court held that rights granted to the patentee under patent law does not immunise an agreement to assign a patent from the purview of competition law [Sec 45 (1) of the Competition Act which is analogous to Sec 3 of the Competition Act, 2002 of India], when the assignment increases the assignee's market power in excess of that inherent in the patent rights assigned.

In India, this may well be an issue, but there has been no such case or even discussion on this matter. The Eli-Lilly case may serve as an useful future reference as the principle facilitates access to medicines and healthcare. The case also is indicative of the fact that any consolidation of patent rights by way of an assignment or license between two parties, when the assignment or license potentially transfers more market power than that inherent in the patent assigned or licensed, should now be carefully considered from a competition law perspective by the relevant authorities and also by parties to ward off possible allegations of anti-competitive conduct.

Source: Fasken Martineau DuMoulin, Federal Appeal Court Gives its Verdict in Eli Lilly Case, available at <http://www.internationallawoffice.com/Newsletters/Detail.aspx?r=11922&I=1049738>

It is worth noting that the patented drugs (formulations under product patent) that are launched in India in the new patent regime are proposed to be subjected to mandatory price negotiations before granting them marketing approval. It has been proposed that the Department of Chemicals and Petrochemicals in consultation with the Department of Health would lay down necessary guidelines for determining the negotiated prices. While framing such guidelines, India can look at the experiences of other countries particularly Canada, France, Germany, Italy, Japan and UK and some other countries in this regard who follow such practices of price negotiations. In determining prices of patented medicines, countries look at different factors, ranging from prices of existing drugs used to treat the same disease, prices in other countries, to the therapeutic value of the new drug as well as control on maximum profits.

Box 5.4: Pricing of Patented Drugs in Select Countries

To determine the price of a patented drug sold in Canada, the PMPRB applies factors set out in the *Patent Act* and in its price guidelines as:

- Most new patented drug prices are limited so that the cost of therapy is in the range of the cost of therapy for existing drugs sold in Canada used to treat the same disease;
- Breakthrough drug prices are limited to the median of the prices for the same drugs charged in other specified industrialized countries that are set out in the *Patented Medicines Regulations* (France, Germany, Italy, Sweden, Switzerland, U.K. and the U.S.).
- Existing patented drug prices cannot increase by more than the Consumer Price Index (CPI);
- In addition, the Canadian prices of patented medicines can never be the highest in the world.

The French pricing system allows pharmaceutical companies to sell their products at any price. However, if these companies want the national health care system to reimburse patients for the cost of the drug, the companies must agree to a lower, negotiated price. These negotiated prices and reimbursement rates paid by the healthcare system are based on;

- the therapeutic value of the drug, and
- the price of the drug in other countries.

Italy's national health care system allows manufacturers to sell their drugs at any price. However, if these drugs are to be eligible for reimbursement under the national health care system, pharmaceutical companies must set the price of the drug at a cost that does not exceed a twelve country European average price.

Japan, like most other developed countries, has a national health care system. The prices paid by this health care system are generally determined via a reference system. Prices for new drugs are determined by comparing them with similar drugs that are already on the market. Prices are based upon the safety and effectiveness of the drug; drugs that are shown to be more effective or innovative than existing drugs are priced higher. If there is no comparable drug on the market, the price of the drug is determined by factors such as manufacturing cost and the price of the drug in other countries.

Source: "Prescription Drug Prices in Canada, Europe, and Japan" Prepared by Minority Staff, Special Investigations Division, Committee on Government Reform, US House of Representatives, April 2001.

The proposal for negotiated price for patented medicines has attracted criticism from certain sections of the industry arguing that it will dampen R&D efforts in the country. However, the experience of France shows otherwise. France is considered to have the toughest regulatory regime for pharmaceuticals with the lowest pharmaceuticals prices in Europe. Yet, France is now the country ranked third as discoverer of drugs and the world's third largest exporter of medicines. In fact, the US and Germany have now become major markets for French medicines. One may wonder, if strict regulatory regime has forced French pharmaceutical industry to be more efficient and internationally competitive!

Under the Competition Act, IPR related agreements have been exempted if they impose only reasonable restrictions without defining what is reasonable. This will create unnecessary confusion. Moreover, many of the anti-competitive provisions that may enter into IPR related agreements are purely anti-competitive and cannot be justified that they are in the interest of promoting innovation. These practices should be treated like normal anti-competitive practices rather than testing their reasonableness. The Competition Act should be amended accordingly.

Checking collusive activities

As previously indicated, collusive activities among the Indian manufacturers of pharmaceuticals have not yet been discovered. However, existence of such a tendency in certain segments, where there are just a few manufacturers, cannot be ruled out.

Collusive behaviour of the pharmacies in India in ensuring higher trade margins is a matter of grave concern. As mentioned before, the issue has engaged the attention of the Government. The issue of trade margins has been the subject of intense debate from time to time and different views have been expressed on this issue.

To create deterrence, the government is charging excise duties on the basis of MRP rather than ex-factory prices. However, such a strategy has its own limitations. Such deterrence can work only when the rate of excise duty is reasonably high. But high excise duty on such essential goods like medicines will ultimately harm the ordinary people. Moreover, as has been noted before, high prices need not necessarily imply loss of consumers due to peculiar nature of the market. Thus, the strategy of collecting excise duty on the basis of MRP can be a cure worse than the disease itself from the viewpoint of ordinary people.

Whatever course of action is taken, it is not going to be easy to take strong action when about half a million pharmacists are involved. Should the manufacturers be also allowed to engage in collective bargaining with the pharmacists; Should there be a trade margin fixation regime; Or should there be a negotiated settlement in the short run? - may be the questions that will dog the regulators. In any case, such collusive

behaviour must be done away with, in the long run, to ensure growth of the industry, and a fair deal for the consumers.

Controlling Tied Selling

Tied-selling is a genuine concern in health services as came out in the survey of stakeholders. However, the issue is far from being a simple one. Quality of medicines and reliability of testing services are serious issues. Although there is regulatory framework to ensure genuine medicines in the market, there is significant scope for improvement in its enforcement. In the area of diagnostic testing, however, the regulatory framework is almost non-existent. It seems that the regulatory failure in one area can create difficulties in enforcing appropriate regulation in another area. Thus, before any serious attempt is made in removing tied selling of testing services, it would be important to put in place an appropriate regulatory framework to promote and maintain service standards in testing laboratories.

One thing that came out of the survey is that people with relatively lower income are more bothered about the anti-competitive practices that occur at grassroots level. The survey was done at major cities and some smaller ones. There are indications that such practices are more prevalent in smaller cities and town. It would not be surprising if they were even more prevalent in smaller towns and rural areas. However, it is unlikely that the implementation mechanism envisaged in the Competition Act would be able to deal with such problems. Nevertheless, if the competition policy of the country is to be made pro-poor such issues cannot be ignored and appropriate alternatives need to be explored.

A way forward could be regulatory authorities at the state level are properly empowered to ensure standards of medicines and services offered at the diagnostic laboratories. This should be complemented with encouraging the consumer forums both at district and state levels to take up such cases to ensure that patients are not exploited. Voluntary consumer organisations should also be made more aware and active on these issues to prevent them from happening.

Regulating the Health Delivery System

The level of health care spending in India is currently at over 6 per cent of its total GDP. More than three-quarters of this spending includes private ‘out-of-pocket expenses’. Almost all of this private spending is on curative care: consultations, diagnostics and in-patient care. Despite such a high share of expenditure by individuals, the provision of health care, that is adequate in terms of quality and access, is becoming more and more problematic. Currently, there is no appropriate law to regulate or monitor the functioning of private hospitals, nursing homes and other medical care establishments in the country. Some states have state level laws, however, with limited mandate for regulation and poor implementation.

The private health sector will continue to be a major player in providing health services, especially curative health care. Given that private sector health care is predominant in India, and that it is likely to grow even more under the liberalised environment, there is an urgent need for recognition of its far-reaching impact on the health of the people. This means, there is an urgent need for licensing and regulating private health providers.

The absence of regulation not only means that there are no minimum standards, it also implies that consumers do not have adequate information in taking the right decisions. One of the essential conditions in promoting or maintaining competition in a market is availability of sufficient information on the goods and services that are offered in the market. However, as noted before, lack of information is a serious problem here. People, by and large, depend on private health facilities for their health care needs. Yet, little is publicly known about the quality and type of services as well as prices of different private hospitals. Patients normally collect such information through informal channels, which often lead to huge costs on their part. Thus, making information on types of services provided by different hospitals and other medical establishments (including government establishments) and their quality and prices easily available, is essential to promote competition in the health services sector. Even the insurance companies are unable to establish criteria for appropriate reimbursements for treatment at different levels of facilities.

There is need for a programme of strict licensing of all hospitals, nursing homes, and medical practitioners. Regulatory authorities should be established at both central and state levels with appropriate division of responsibilities and mechanism for coordination. The fee structure at private facilities should be formalised and monitored, mainly to avoid exploitation of uneducated patients but also to facilitate the establishment of appropriate reimbursements for specified procedures by insurers.

Hospital accreditation

Health services monitoring agencies can be created at the state as well as the central level that will collect relevant information from all hospitals within their jurisdiction. It should be made mandatory for all hospitals to provide the necessary information to the monitoring agencies. Directories of hospitals with their rating can be prepared and made widely available. Directories for ordinary hospitals can be maintained at district level, while directories for speciality and super-speciality hospitals can be maintained at state and central levels respectively. Such directories can be made available through websites of central and state government health departments and district administrations. They can also be made available through market as well as different government health centres and NGOs.

Regulation of diagnostic laboratories

In diagnostics, quality assurance and accuracy of test results are critical, as the doctor's diagnosis and patient's treatment are dependent on the results. Yet, there is hardly any mechanism to ensure quality and standards of services offered by the diagnostic laboratories all over the country. Shocking but true — all it takes to start a diagnostic laboratory is a municipal corporation licence, which essentially equates a clinical laboratory with a general merchandise store or even a garment shop. In some States such as Uttar Pradesh, even this is not required. Some of the practices followed by the laboratories are questionable. Moreover, absence of standards leads to tied-sales as many doctors use this as a pretext to send patients to their chosen laboratories. However, in reality, even doctors are not well aware of the quality of services provided by these laboratories.

There is a system of accreditation with National Accreditation Board for Testing and Calibration Laboratories (NABL) which comes under the Union Ministry of Science

and Technology. However, the accreditation process is non-mandatory and as a result, of the more than 25,000 clinical laboratories in India, barely 59 are accredited with the NABL as on 28.02.2006, and only about two per cent of the people get their tests done at accredited laboratories.

There are other reasons for accreditation not becoming popular. Red tape and the expensive nature of the process of NABL accreditation, being forced to meet associated expenditure not strictly linked to the professional aspects of the process, like the use of specified colours of paint on the walls of a laboratory, air-conditioned facilities, are some of them. If the NABL standards were strictly enforced, more than 80 per cent of the laboratories would be closed. Hence, there is a need for accreditation for different grades of services. However, a well-enforced system of certification and meaningful regulatory legislation are simply essential.

Dealing with Health Insurance

Often one source of market distortion in health care services is health insurance. Since insurance-holders do not pay their medical bills directly, they care less about the choices they make. Even doctors or hospitals when come to know that a particular patient is insured, care less (or probably more) about the financial implications of their counselling or treatment to the patients. Thus, the healthcare market with prevalence of health insurance is faced with severe moral hazards that promote inefficiency in the market. Ultimately, of course, the patients bear the costs of this inefficiency. Though prevalence of insurance in India is quite low at present, it is growing as public health coverage is quite poor in the country.

However, the issue has become quite important as the government is planning to provide public health coverage to poor people in the country through the insurance route rather than through creating a better healthcare infrastructure of its own. Thus, it would be useful to look at the experiences in this regard, especially in other countries where health insurance is widely prevalent. This essentially takes us to the US as it is the only developed country that does not guarantee universal health coverage. Most Americans receive health insurance through their employer, with government paying the insurance bill for the poor (through Medicaid) and the elderly (through Medicare), though a huge number of people remain uninsured and vulnerable.

The American system has a distinct advantage as it gives wider choice to consumers, compared to other developed countries where public health coverage is public health facilities driven. However, per capita expenditure on health in the US is almost double of that of other rich countries. It is also estimated that about 30 percent of US health spending is simply wasted. In fact, in the US, there are serious concerns that the healthcare system is in need of a thorough revamp. Many also believe that, in the longer run, US may have no choice other than to accept a more overtly European-style system.¹⁸⁵ These lessons should be kept in mind while promoting health insurance in the country.

A new health insurance scheme by the name of ‘Rashtriya Swasthya Bima Yojana’ is proposed to be launched in the country for providing free healthcare to the families below the poverty line (BPL). The scheme would include benefit of hospitalisation cost upto Rs15000 and costs for medicines as outpatient upto Rs5000 per annum per family. The Government of India would pay the full cost of the premium amount for all BPL families. The Scheme is to be implemented by the four public sector insurance companies in the country.

Under this scheme, the BPL families would approach any government doctor in the area. Based on the prescription of the government doctor the BPL cardholder would approach the authorized chemist shop for obtaining medicines free of cost. The chemist would send the bill to the insurance company which would reimburse him for the amount of the medicines purchased by the BPL family

However, in any insurance scheme, the company would fix the premium in such a way that the total premium collected would be more than the total of expected claims. That being the case, the government would be paying much more to insurance companies than the actual costs that these BPL families would incur on hospitalisation and medicines. Buying an insurance policy is sensible for an individual or family to cover the risks. However, buying a group insurance for such a huge population could be really expensive.

¹⁸⁵ *America's headache: How to start fixing the world's costliest health-care system*, The Economist, January 28, 2006.

Thus, it would be a far better option if the medicines are provided free of costs to the BPL families through the government health centres only, especially when the patients need to visit government doctors anyway. Moreover, government can buy in bulk for all its clinics and can get the medicines at much better price compared market prices that would be charged by the private chemists.

What is more worrying is, there seems to be no credible safeguard to limit corruption in the scheme. It is almost a certainty that a nexus would develop among the government doctors, chemists and the BPL families. This would ensure that all these families would avail their full quota for accounting purposes though actual medicines or hospitalisation services sold would be much much less. The claimed transparency of accounts through computerised statements would be of no use to stop such deals. This would be quite likely as the beneficiaries would not share any burden of the insurance costs and would have no incentive to be honest.

Even the basic objective of the scheme may not be fulfilled as many families might avail their full quota early in the year getting just a small share, conceding the rest to the doctors and the chemists; and when they actually fall ill, they would have no treatment. Access to healthcare would still remain a problem if instead of reinforcing the system of health centres, government launches insurance scheme which is unlikely to help develop health facilities in rural areas. The question arises, whether a developing country like India should tolerate US-type inefficiency and wastage just to have more consumer choice. In fact, majority of the poor being in rural areas would not have much choice any way, particularly when they have to consult a government doctor. In any case, an insurance-oriented healthcare system, though generally promotes choice, does not make the system competitive or efficient.

Revamping and reinforcing the existing public healthcare system can be a better option than the proposed insurance scheme. A better public healthcare system would help even the non-BPL families. Moreover, it is well known that targeting of such scheme based on poverty line has its own problems as many families with higher income make into the BPL list, while many people with actually lower income fail to make it to the list.

Box 5.5: Rajasthan Model of Medicare Relief Societies

In Rajasthan Medicare Relief Societies have been set up in all the government hospitals at State, Divisional, District and sub-division level for the purpose of –

- better maintenance and upkeep of the hospitals;
- providing cheaper medicines to the common man through outlets known as life-line fluid stores opened within the hospital premises.
- providing medicines free of cost to BPL families.

These Medicare Societies mainly comprise of the doctors in the hospitals. Their source of income is primarily the user charges levied by them for the services provided in the hospitals. Through these medicare societies several critical medicines, injections, antibiotics, IV Fluids etc. are purchased in bulk through open tender from the manufacturing companies and sold through the lifeline fluid stores in the hospital premises. As a result the prices are reduced considerably and some of the medicines are sold at prices as low as or even lower than 50 percent of the prevailing market rates.

An example is the Intra-venous (IV) fluid, a bottle of which is being sold to patients between Rs.10 to Rs.11 as against its ceiling price of Rs.17. Running of the Stores is contracted out and these are generally open all the 24 hours.

Thus, it could probably be a better idea to explore other alternatives instead of insurance-driven public health coverage that will benefit only the BPL families but others as well who are not rich anyway. In this regard, the government can explore the possibility of replicating Rajasthan model of Medicare Relief Societies, and enhancing the coverage and effectiveness of National Illness Assistance Fund. The issue of health insurance can be left to the market. In any case, an insurance-driven health care system cannot ensure universal health care as the government is willing to pay the bill for the poor only and most Indians are employed in the informal sector unlike in the US where employers play important role in paying the insurance bill.

Box 5.6: National Illness Assistance Fund

The Central Government under the Ministry of Health and Family Welfare operates the National Illness Assistance Fund (NIAF) through which financial assistance is provided to states for the medical treatment of people living below poverty line and other poor families. Out of this fund assistance is provided to States upto 50 percent of their share in the State Illness Assistance Fund (SIAF). Also revolving funds have been set up in some of the leading Government Hospitals for providing financial assistance to BPL families upto Rs 50,000. A Rashtriya Arogya Nidhi has been set up for this purpose. Some states are making good use of these schemes for the BPL families while some have not yet set up the State Illness Assistance Funds.

Promoting Innovation

With the advent of the product patent regime it is imperative for the Indian pharmaceutical industry to accelerate its efforts in R&D. This is because the share of

generic market upon which most Indian companies depend is going to shrink and they would be able to introduce generic drugs only after they go off patent. The present level of spending on R&D (about 1.9% of turnover) is much lower as compared to most of the developed countries (10 to 16%).

Globally, the sophisticated, research-based part of the global pharmaceutical industry, is highly concentrated in a handful of countries, notably the USA, the UK, Germany, and Switzerland, and is composed of just a few companies. However, some developing countries have made significant progress over the last couple of decades. According to some experts, countries can be classified into five categories, according to the stage of development of their pharmaceutical sector, as outlined in Table 5.1. India is considered to be in the second category, just after the group of sophisticated industry, and is recognized to have significant innovative capabilities.

Table 5.1: The Structure of the Global Pharmaceutical Industry

Stage of development	Number of countries		
	Industrial	Developing	Total
Sophisticated pharmaceutical industry with a significant research base	10	Nil	10
Innovative capabilities	12	6 (Argentina, Brazil, China, India, Korea and Mexico)	18
Those producing both therapeutic ingredients and finished products	6	7	13
Those producing finished products only	2	87	89
No pharmaceutical industry	1	59	60
Total	31	159	190

Source: Nitya Nanda and Ritu Lodha, Making Essential Medicine Affordable to the Poor, Wisconsin International Law Journal, Vol 20, No 3, 2002

In India, it is not only that some top companies have taken R&D efforts seriously, the country is also emerging as the most favoured destinations for collaborative R&D, contract research and manufacturing, clinical research and R&D base of some big foreign companies. The future of pharmaceutical R&D in India, thus, seems to be quite bright and it should be promoted.

It has been made clear in Chapter IV that there is no need to make the industry further profitable to promote R&D through the route of price decontrol. What is needed is a carrot and stick approach. There has to be incentives (or disincentives) directly linked with R&D efforts. This is what is done in most developed countries where companies take substantial R&D initiatives. Some fiscal incentives are already available for R&D. These incentives are at present available only up to March 31, 2007. However, since R&D activity has to be carried over long periods of time, they should be made available over a longer period or even permanently, with provisions for periodical review. The required incentives should also be made available with some safeguards to ensure that these are available to the deserving cases only.

Though the patent regime gives adequate incentives for investing in R&D, it may not be possible for some companies to make such investment, if those companies do not have patents or are not likely to have patents in the near future, though they may be keen to graduate to a patent-holding company. It may be noted in this context that the Pharmaceutical Research and Development Committee headed by Dr R A Mashelkar in its report submitted to Government in November 1999, recommended that R&D intensive companies fulfilling certain conditions should be given price benefits for the drugs under DPCO. This recommendation may be taken up for implementation though with caution.

Although private R&D should be promoted, it cannot be a substitute for public R&D. They should be complements rather than substitutes. It may be noted in this context, that some public laboratories have made significant inventions that have helped the pharmaceutical industry immensely.¹⁸⁶ Moreover, private companies may not be interested in making substantial investment on diseases that affect mostly the poor. Even in developed countries, it has been observed that many pharmaceutical companies are more interested in new 'slimming tablets' that rich people are interested in, rather than finding out new medicines for diseases. Furthermore, private companies would be more interested in curative medicines, rather than preventive medicines. The benefits that preventive medicines provide through reduced chances of infection, and even eradication of certain diseases, cannot be fully captured by

¹⁸⁶ Supra n. 16

‘profits’. Government intervention in this regard is, thus, necessary. In fact, such an approach is followed in many developed countries including the US. For example, the National Institutes of Health (NIH), the national agency in the United States, spends about \$27bn per year on research, a substantial amount of which is directed towards drug development, including clinical trials.¹⁸⁷

At present, the Pharmaceutical Research and Development Support Fund (PRDSF) has a corpus of Rs.150 crores (where only interest income is available for spending) is utilized for funding R&D projects of research institutions and industry in the country. It is not adequate to meet the present day and the emerging requirements of this sector. It needs to be sufficiently augmented over years. This process of augmentation has already been initiated with the government’s decision to utilize the entire Rs.150 crore drug research corpus fund this year itself. With this, public funded research is expected to witness a spurt in the country.¹⁸⁸

The Indian companies should try to exploit the Indian traditional knowledge in ayurveda and herbal cures. They should engage in R&D in herbal medicine and file as many patents for herbal medicine as they can. For this, the Government should set up R&D laboratories undertaking research exclusively in the area of herbal medicines and support the companies in their research and patent filing. Efforts should also be made to integrate use of herbal medicines into allopathic methods of treatment.

Box 5.7: Highlights of the Recommendations

- Promoting generic drugs in select categories, along with better quality control
- Mandatory price negotiations for patented drugs
- Monitoring of prices of all drugs outside price control
- Giving the Competition Commission of India the authority to grant compulsory licence for patented drugs
- No data exclusivity should be granted as it is not in the best interest of the country and it is not required under TRIPS
- Checking collusive practices, particularly of the pharmacists and monitoring trade margins
- Checking anti-competitive practices like tied-selling at local level and empowering consumer forums to deal with such cases.

¹⁸⁷ Tim Hubbard and James Love, “A New Trade Framework for Global Healthcare R&D”, Plos Biology, Vol 2, No 2, 2004.

¹⁸⁸ Gireesh Chandra Prasad, *Drug Cos to get more funds for research*, Economic Times, January 25th, 2006.

- Regulation, accreditation and rating of hospitals and diagnostic centres with appropriate mechanism at state and central levels
- Monitoring and checking anti-competitive practices arising from availability of health insurance
- Finding alternatives to the proposed government sponsored health insurance cover, like replication of Rajasthan model of Medicare Relief Societies or National Illness Assistance Fund
- Providing adequate incentives for R&D, including in herbal medicines
- Creating awareness involving all stakeholders, namely, central and state governments and NGOs

CHAPTER VI CONCLUSION

The pharmaceutical industry, which till now has been characterised by its complexity, intense competition, low prices, and high level of fragmentation, is on the verge of a major shift as it prepares to meet the challenges of the forthcoming product patent regime. Post-2005, the pharmaceutical industry will see a major shakeout, with a lesser number of players, and an increasing focus on higher value areas like drug discovery, drug delivery systems and technology licensing. The top bracket companies, having a strong R&D focus to deliver better products to the consumer, and innovate cost-efficiency, will survive and become even stronger.

It is estimated that in the next five years, over US\$50bn worth of drugs will go off-patent. This will enable Indian companies to launch their generic equivalents in these markets. The global generics market is widely expected to grow faster than the global pharmaceutical market, in the next few years.

The prices of vital medicines, under patent, are bound to go up manifold in the new patent regime. The Government should be careful and must take all the precautions to protect the rights of the third party, and the party affected i.e. the public at large. The pharmaceutical manufacturers are demanding more liberalisation, arguing that competition, and not price control, will improve availability and affordability of essential drugs.¹⁸⁹ Several arguments are advanced as to why price controls would hurt, not help, consumers.

There is a definite trend towards price decontrol today, however, it is another matter as to whether or not such a trend can sustain. Given that only about 74 drugs are under

¹⁸⁹ The Indian Pharmaceutical Alliance (IPA), comprising 11 big companies, said that they would oppose any restriction on the prices of 'branded' drugs manufactured by them. The pharmaceutical industry has assured the Government of a price-freeze till March 31, 2005. This has been echoed by the Indian drug manufacturers' association (IDMA), as well as the Organisation of Pharmaceutical Producers of India (OPPI). The IDMA is a premier association of the Indian pharmaceutical industry and has come to be regarded, in different circles, as the 'Voice of the National Sector.' IDMA members comprise large, medium and small companies from all over India, manufacturing bulk drugs and formulations. The OPPI is another premier organisation of pharmaceutical manufacturers in India. Its membership consists of companies with international collaboration, and large Indian companies. It represents primarily research-based companies in India.

price control, the entire issue of price decontrol is not really of much significance. But given the likely increase in prices in the new patent regime, it is of paramount importance that the government not give in to industry pressure but maintain some semblance of regulation. India prides itself on its low drug prices. But there were two primary reasons responsible for such pricing patterns. Process patents and price control. Process patents have now been consigned to a practice of the past and decontrol is steadily gaining ground in the pharmaceutical sector. What then is in store? That industry interests must be protected is justified. But these interests need to be balanced with adequate access to health.

However, despite Finance Minister P. Chidambaram's indication that the Government will reduce the rigours of price control, where it has become counter-effective, reducing the number of essential drugs on the DPCO will not be easy. Firstly, the United Progressive Alliance Government's National Common Minimum Programme has promised to "take all steps to ensure the availability of life-saving drugs at reasonable prices". Secondly, any move to reduce the number of drugs in the DPCO may be considered to be in contravention of the Supreme Court order. This is relating to the K.S. Gopinath case ruling on March 10, 2003, in which the Government was directed to ensure that "... essential and life-saving drugs do not fall out of price control" ¹⁹⁰

In most developed countries, the regulation of drug prices is considered necessary to contain public expenditure due to the government's role in funding social health and insurance schemes that cover hospitals and outpatient drugs. In these countries, a substantial portion of the population is covered through health insurance and public health schemes. As a result, consumers are not affected directly by the high prices of drugs or the high costs of medical services but are made to pay for the increased costs through a high insurance premium. As opposed to this, a substantial portion of the population in India is market-dependent and has to meet all their expenses on this account out of their own pocket, making price regulation of pharmaceutical products unavoidable.

¹⁹⁰ Siddarth Narrain, *A Life Saving Order*,
<http://www.flonnet.com/fl2115/stories/20040730004110300.htm>

Given the peculiarity of the health market, ensuring competition is easier said than done. The Indian pharmaceutical regulatory regime has been quite hard on the manufacturers, but has been extremely soft on the two other groups of important players: the doctors and the pharmacists. Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, have sufficient provisions to ensure good behaviour on the part of the doctors. However, it is more of a good endeavour rather than binding rules. Moreover, there is no mechanism to monitor if the doctors are following them.

One way, often suggested, of checking the rent-seeking behaviour of the doctors, as has been successfully experimented, even in neighbouring Bangladesh, is to mandate doctors to prescribe drugs with generic names. Even the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 state that, “Every physician should, as far as possible, prescribe drugs with generic names.” However, given the enormous clout of the pharmacists in India, this mandate may not work, and could even make the situation worse. What is, thus, desperately required in India, is an effective mechanism to contain the rent-seeking behaviour of the pharmacists as well.

If it is difficult to promote and maintain competition because of the peculiarity of the market, in the sense that consumers do not decide their purchases, then the same may not be true for bulk drugs. It has, in fact, been indicated previously that more archetypal competition prevails in the bulk drug industry. There is a need to study the behaviour of the bulk drug market more closely and, if desirable, to further decontrol the sector.

It is essential for the pharmaceutical sector in India, to operate under a law that curbs anti-competitive activities. Despite ubiquitous regulations, competition is not entirely excluded from this industry. Competition is the key driving force behind the development of new innovative drugs, and a significant factor in keeping down the prices and production costs of off-patent drugs. Few aspects of the pharmaceutical industry, even though highly regulated, are unaffected by regulatory controls. The MRTP Act, 1969, did not have adequate provisions to deal with a large number of anti-competitive practices, like collusion or cartelisation, mergers and acquisitions,

and abuse of intellectual property rights, which is a very common practice in the pharmaceutical industry, if viewed globally. The new Competition Act, 2002, is a much improved law, and has the required provisions, including extra territorial jurisdiction, though the provisions on IPRs is rather weak. This needs to be buttressed.

The fact that the private healthcare market that is expected to cross a turnover of US\$40bn by 2012 is completely unregulated, despite quality and standards being serious and complex issues for the industry, does not augur well. India is also keen on promoting the country as a destination for medical tourists from neighbouring countries and the West, and it is estimated, at its current pace of growth, healthcare tourism alone can bring in over US\$2bn as additional revenue by 2012. However, just a few medical accidents can frustrate this effort. Hence, the government must take the issue of regulating the healthcare industry seriously, not only to ensure quality services to its own citizen, but also to realize its ambition of becoming a global player in the field.

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ANNEXURE I

Report on

NATIONAL WORKSHOP ON OPTIONS FOR USING COMPETITION LAW/POLICY TOOLS IN DEALING WITH ANTI-COMPETITIVE PRACTICES IN PHARMACEUTICALS AND THE HEALTH DELIVERY SYSTEM

8 September, 2006, New Delhi

BACKGROUND

CUTS CCIER conducted a study entitled “*Options for Using Competition Law/Policy Tools in Dealing with Anti-competitive Practices in Pharmaceuticals and the Health Delivery System*”. The World Health Organisation (WHO) and the Ministry of Health and Family Welfare, Government of India, supported the project.

The overall objective of this project was to identify competition concerns in the pharmaceutical sector and health delivery system; examine the scope of competition policy and law in dealing with such concerns; and suggest an implementation strategy to enhance access to medicines and enhance the efficiency of health delivery systems.

The purpose of this workshop was to share the findings of this study with various stakeholders consisting of consumer organisations, health and competition experts, academia, consumer and other NGO activists and representatives of business associations and seek and incorporate their comments and observations on the report.

The workshop was divided into three sessions. Nitya Nanda, the Principal Investigator of the study from CUTS made a presentation on the study in the first session. This was followed by a panel discussion between experts from the Voluntary Health Association of India (VHAI), Indian Drugs Manufacturers Association (IDMA) and Competition Commission of India (CCI). In the third session, the participants raised their concerns on the issue.

DETAILS OF THE PROCEEDING

Welcome Note

Ujjwal Kumar (UK), National Consultant from the Ministry of Health and Family Welfare welcomed the participants on behalf of the Ministry and the WHO, India, and enlightened them about their work. A World Trade Organisation (WTO) cell has been set up in the Ministry of Health and the said project was implemented under its mandate. The main aim of the workshop was to discuss the outcome of the study, which has been commissioned by the Ministry to CUTS. Idea of this study was conceived under a new sub-programme area of WHO on Trade & Health which among other things endeavours to document the impact of globalisation on public health and public health policy and also to enhance coherence between trade policy and health policy. While flagging the studies commissioned and workshop organised for this purpose, UK briefly outlined on:

- Impact of Trade Related Intellectual Property Rights (TRIPS) on pharmaceutical prices in India carried out by the National Institute for

Pharmaceutical Education and Research, Chandigarh, institution under Ministry of Chemicals & Petro-Chemicals

- Implication of the WTO agreement on Sanitary and Phyto-sanitary Standards (SPS) & Technical Barriers to Trade (TBT) on access to health, carried out by Rajiv Gandhi Foundation
- Impact of offshoring of clinical trials in India carried out by National Law School, Bangalore
- Impact of mailbox patent application on access to health, just commissioned to Centre for Technology & Development, New Delhi

Access to health care is very high on the government's Agenda and this study is an attempt to know as to how competition law and policy can be used to enhance access to health.

With the advent of privatisation since 1991, more and more reliance is being put on private sector for meeting public health needs. Anti-competitive practices in the market place will surely pose hurdle in meeting such needs. Therefore, understanding the competition dynamics of pharmaceutical sector and health delivery system is *sine-qua-nun* for taking any law policy measure to rectify any adverse situation. In the post-TRIPS and post-Product Patent era, the common logic is, we will slowly move towards more monopolistic market situation in the pharmaceutical sector. The current spurt of mergers and acquisitions will further aggravate the situation.

In India, where the consumer meets around 80 percent of health expenses, allowing an unregulated profit motive monopoly could be detrimental to an access to health. The government and respective regulators will have to keep a close eye on the competition situation and proactively take necessary action where any abuse is apparent. In this regard, expectations from the upcoming competition regime under the new competition act, which has been devised to suit the changed economy architect of India, are high.

The present study is a first of its kind in India that has seen the access to health issue from the competition policy perspective. The study has, apart from secondary literature, also used primary data through survey in four metros and Ahmedabad and has taken opinions from stakeholders like doctors, hospitals, pharmaceuticals companies, chemists, and consumer organisations. UK congratulated CUTS and reinforced that this is not the end. The recommendations made in the study are to be implemented for desired results. For this, there is a need to debate and further streamline the recommendations and come out with an action plan.

Outlining the sessions of the programme, UK preceded further, requesting Nitya Nanda, the Principal Investigator, to share the findings of the study with the participants.

Pradeep S Mehta, Secretary General, CUTS, took this opportunity to introduce Mr. P Venkatash, Director, Ministry of Consumer Affairs, himself a participant – to the other participants.

Session I – Presentation on Research Findings, Nitya Nanda

CUTS' Work on Competition Policy Issue

Nitya Nanda (NN) started with a brief introduction about CUTS' work on competition policy issues in the last several years, in India as well as other countries. CUTS has already worked on pharmaceutical sector (among other sectors) vis-à-vis competition policy under one of its' study viz. "Towards a Functional Competition Policy for India" i.e. *FunComp* and this study is an extension of that. Findings of the earlier studies have been largely incorporated in the present one.

Overview of the Indian Pharmaceutical Industry

Giving an overview of the pharmaceutical industry in India, NN explained that the pharmaceutical industry in India was almost non-existent before 1970. As on date, India is a prominent producer and is able to meet 95 percent of its requirements. Prices of drugs in India are much lower compared to other countries, the reason being an absence of a patent regime in India, so far. Globally, the Indian pharmaceutical industry garnered attention during the debate on TRIPS and public health. Indian companies are now producing drugs at one-tenth the price of other countries'. In spite of the presence of big multinationals, the market leaders are some of the Indian companies. Though there is a presence of large number of pharmaceutical industries, some drugs are dominated by a handful of companies.

Peculiarities in the Sector

Highlighting the fact that it is not consumers, but doctors and sometimes chemists who are the decision makers the pharmaceutical industry including the health delivery system, is most prone to anti-competitive practices. While, in developed countries like Japan, US, and EU, where the cost of medicines or treatment are borne either by the government or the insurance companies, in India, the cost is borne out of the consumer's pocket.

In such a scenario, companies are in a position to lure the doctors or the chemists to sell their brand in lieu of commission or higher margin, respectively. In this regard, mandatory generic prescription i.e. prescription by the common chemical name of the drug instead of the branded name, can be useful to check nexus between doctor and the pharmaceutical company. However, this may also lead to position of the consumers vulnerable in the hands of the pharmacists pushing for brands with higher margins. Further, tied selling also exists in cases of hospitals and diagnostic centres.

Most developed countries have adequate provisions to regulate the doctors, pharmacies and the industries to keep a check on the prices. Briefly touching upon the history of price control mechanisms adopted and subsequently revised in India, NN observed that while there are provisions to keep a check on the pharmaceutical industries, there is an inadequacy of provisions to regulate doctors and chemists.

Competition Concerns

Though there has been no evidence of cartelisation in the pharmaceutical industry, the chemists or pharmacists operate as an association or cartel under All India Organisation of Chemists and Druggists (AIOCD). AIOCD is known to launch boycotts against drug companies to grab higher profit margins.

A rising awareness as to Intellectual Property Rights (IPRs) in India has also raised competition concerns in the form of the patent holder exercising or imposing unjustifiable condition on the licence holder. In this context, it was suggested to bring IPR related abuses and the responsibility of granting compulsory licences under the Competition Commission of India (CCI). Mergers & Acquisitions (M&As) on the national and international arena, which lead to dominance of the market share by few, may also raise competition concerns.

Recommendation was made to standardise and accredit the diagnostic centres and hospitals to ensure quality output to the patients.

NN shared the survey results conducted on the doctors, pharmaceutical industry, consumer organisations, hospitals and the pharmacists with the participants bringing to the lights various facts at the ground level.

On the issue of data protection and data exclusivity, it was observed that granting a long period to data protection/exclusivity could be detrimental to consumer interests.

The study also called for proper and overall monitoring at the distribution level to check entry of spurious drugs in the market. An account of how anomalies exist in the pricing of the drugs was also made.

Session II - Panel Discussion

1. Gajanan Wakankar

With a brief note of thanks, Gajanan Wakankar (GW) appreciated the timeliness of the workshop when several things are happening with regard to pricing, date exclusivity and competition law of India. GW also complimented the work done in the form of exhaustive study under the project especially in the situation where different players with conflicting interests exist. Further, GM emphasised on the fact that he is representing indigenous pharmaceutical manufacturers only and not the multinationals.

He highlighted some observations from the study. Pointing to the recommendation made in the main report, while he agreed to most of them, there were reservations on a few.

Data Protection & Data Exclusivity

Multinational pharmaceutical manufacturers were able to introduce data protection and data exclusivity during the Uruguay round. Although, at present, the text available requires only the protection of data, it does not require data exclusivity. The current regulation in India satisfies the TRIPS agreement requirements i.e. protection of data from people for unfair commercial use.

The term 'Data Exclusivity' does not form any part in the TRIPS agreement. This was demanded by the US delegation during Uruguay round. It was discussed and rejected time and again in the ministerial conferences. Hence, there should not be any provision for data exclusivity in the country.

Pricing

GW presented a CII study reflecting that only 15 percent of total expenditure on health care is spent on medicines indicating that prices of medicines in our country are quite low. Most of the expenditure is incurred on hospitalisation, diagnostic centres, doctor's fees, etc.

Japan and India are the only two countries where multinational pharmaceutical corporations do not have control over the market. This has been achieved in India due to 1970 Patents Act, prior to which, multinational pharmaceutical corporations controlled nearly 80 percent market share of the Indian market. Now their market has come down to 15 percent only, the rest being controlled by the indigenous generic drug industry.

Indigenous drug manufacturers are providing the drugs at the lowest and economical prices, which form one of their ultimate goals. While pursuing the goal, there are many players in the field and the government and consumer organisations, hold different opinions, and therefore the procedure of pricing face lot of controversies.

The Drug Prices Control Order 1995 is the operating system at the moment, which regulates the pricing. It has a system of scheduled drugs, which covers up to 28-30 percent of the market with about 74 molecules and non-scheduled drugs covering the rest.

GW highlighted one of the tables prepared in the CUTS report, a comparative analysis of the prices of drugs before and after the decontrol of DPCO in 1995 and 1998, pointing to a steep increase in the prices after decontrol.

In response to the inference drawn, GW clarified that the drugs mentioned in the table are basically bulk drugs. In the present WTO regime, facilitating import and exports, prices of the bulk drugs are more or less at par with the international level. When the prices of the bulk drugs in the domestic market go up, more imports take place and vice versa. What has happened in 1995 and 1998 is no longer applicable now, as the mechanism of open export and import has changed the whole scenario. Further, rise in prices is more due to inflation at the compounded rate of four percent. Considering all this, prices have either not increased or if it has, not risen by more than five percent.

Another table indicating the prices of certain drugs as more in India than in Canada and the UK was also questioned. GW observed that the prices mentioned are the government procurement prices in UK and Canada and these prices are generally 50 percent of the actual retail prices.

Further, with the constant monitoring by the National Pharmaceutical Pricing Authority in India (NPPA) over prices, it is very unlikely that the companies raise the prices. Even if they do, they are mandated to lower the prices by NPPA. Prices of drugs in India are still the lowest.

Competition is the best way to bring prices down to a reasonable level. Rigid price control will drive out good medicines from the market. Also, it will adversely affect exports to the tune of 20,000 crore, mainly done by the indigenous industries.

Miscellaneous Issues

Generic Drugs Prescription: GW was doubtful if this would work in lieu of some practical difficulties faced in maintaining quality control over the non-branded drugs.

Declining Access to Health: Access to health according to GW has been improving as indicated by the factors such as increased life expectancy.

Collusive & Anti-competitive Practices: GW assured of co-operating with the government, opposing such practices.

Access to Health to BPL Population: GW assured co-operating with the government in providing access to health to the population below poverty line.

Role of the CCI: GW opined that the role of CCI as an impartial referee would be diluted if it were conferred with the power to grant compulsory licensing.

2. G R Bhatia

G R Bhatia (GRB), from the CCI emphasised on the necessity of creating awareness among the consumers and manufacturers regarding the usefulness and benefits of the Competition Law. The government has enacted the Competition Act in 2002, through which the CCI came into being. India is not new to the Competition law regime. The instrumentality of the new law makes it more efficient than the Monopolies & Restrictive Trade Practices (MRTP) Act. But, the CCI is yet to become fully functional and substantive provisions of the law are yet to be made operational, as now it is only permitted to undertake the competition advocacy.

The new competition law strikes a balance between the two stakeholders, of consumers and businessmen, as it protects the interests of the consumers as well as ensures freedom of trade to the market participants.

GRB stressed on the need to promote competition and competition law, because it makes possible the abundance of goods at an affordable price to the consumer. Further, anti-competitive practices like cartelisation and price-fixing not only affect the consumers, but also the business houses that are the consumers of inputs for producing their product.

With regard to anti competitive agreements in IPRs, GRB observed that IPRs do confer monopoly and there is a need to confer monopoly to provide incentive to the innovator of the formulation of medicine. He, however,

emphasised that the new law is an improved version of the MRTP Act. Under the MRTP Act, there was no specific provision to deal with the abuse of IPRs. Any IPR holder exercising unreasonable restrictions on the licence holder will be guilty of anti-competitive practice. It is left to the wisdom of CCI to decide as to what is unreasonable. This will take care of anti-competitive practices emanating from IPRs.

He also pointed out categorically that the new competition law is not against healthy competition or dominance. But the new law is against the abuse of dominance. With regard to mergers and acquisitions, GRB agreed that mergers lessen competition, but as per the provisions of the new competition law, competition is no longer related to the number of players. In this context, he gave the examples of Pepsi and Coke. In this case, though the number of players is two, yet consumers are benefiting from the rivalry between the two. It is the responsibility of CCI to ensure that such rivalry exists.

He also dismissed the charge against the new competition law that it delays the process of a merger. CCI has been provided with 90 working days to raise objections, if any on the merger, after the voluntary notification has been served. If no objection is raised, the merger is deemed to be solemnised.

Citing the example of the HLL & TOMCO merger, as post-merger consequences, shareholders have benefited, as market value of shares have gone up and even the financial institutions have benefited due to the enhanced financial soundness of the company. But, the government has suffered as the tax liability of the merged entity has gone down. Further, the merger has not even benefited consumers by way of increased volume or better quality or decreased prices. Hence, mergers need to be regulated.

GRB agreed that the pharmacists and druggists have been a hindrance between the manufacturing sector and the ailing patients. This is due to the fact that the MRTP Act has been a reformatory law, while the new competition law is not only reformatory, but also will act as deterrent.

GRB also mentioned that CCI has an Expert Advisory Committee headed by Vijay Kelkar and eminent legal experts who will from time to time evaluate the new findings, as law is an ever-evolving thing. He also cautioned the audience that the CCI should not be confused with agencies like Securities and Exchange Board of India (SEBI) & Insurance Regulatory Development Authority (IRDA). This is because the former are market regulators who can issue licence, while the CCI is only the referee who decides how to play and not who will play.

3. Mira Shiva

Mira Shiva (MS) opined that though the CCI exists and even if there is a lot of hue and cry on the drug pricing issue, what is most unfortunate is that a vast number of people in India are without medicine. MS expressed her concern over affordability of prices of drugs falling outside the purview of essential drugs. Moreover, the production pattern of a pharmaceutical industry should

be structured to ensure sufficient production of price-controlled drugs. MS raised the question that as elementary drugs are not available to the people, the central concern should be as to how to handle this denial.

She recommended uniform pricing of drugs. Holding that she is not against profitability of the pharmacists and druggists and that they are free to maximise their profit she emphasised that such profits should come through economies of scale and not by malpractices.

In India, only 0.9 percent of the Gross Domestic Product (GDP) is put on health. 80 percent of the price for the medicine has to be paid out of the pockets of the consumers. Moreover, there is a 'Medical Mafia', which is controlling the medicine price in India, which literally implies 'pharmaceuticalisation' of medicine prices. So, if this price fixation is left to the market forces, then this will adversely affect the public health system in India. Hence there has to be a price control order in India. Competition alone is not the solution. Aggressive competition may lead to wiping out of certain healthy options.

MS emphasised that health education is must for the consumers in making right choices. This will help to prevent unethical behaviour and will promote a healthy consumption practice as well.

She also emphasised the need for medical, social, and prescription audits to check unscrupulous behaviour of doctors.

4. Anurag Bhargava

Virtually, every country in the world regulates drug prices. This mechanism is not unique to India. However, what is unique is the partial control, putting few drugs under price control. Only 13 percent of the drugs are under price control.

Though there are thousands of producers, for a particular disease, there are very few players. This creates oligopoly in the market, which renders consumers with little or no choice. In this highly privatised system, the government when it is not able to provide drugs, should, in all necessity, protect consumers from the distorted market.

Despite having an industry producing 40,000 crore worth of drugs in India, India is a country with the largest number of people who lack access to drugs, as per the WHO report, 2004. 649 million people in the country cannot access drugs for common ailments and others. . Considering this state of affairs, health care should form the top most priority among the policy makers, which unfortunately is not happening.

The drug policy in India is formulated by the Ministry of Chemicals and not by the Ministry of Health, which is again very peculiar. Policy is thus not guided by a health objective.

The consumer is paying many times more than he should pay. There have been many instances where same drug or formulation is sold at substantially different prices under different brands. The final price paid by the consumer has no relation to the cost of the manufacturer. Drug companies are allowing exorbitantly high trade margins upto 1000 percent, to the retailers, which do not happen in any other commodity.

Addressing the dichotomy existing between the terms essential and life saving, Anurag Bhargava (AB) recommended that there cannot be any difference between the two, as essential drug can be life saving and vice versa.

AB raised the issue of exorbitant amount spent by the drug companies to promote their products. According to an estimate, the top 50 companies in India have spent an amount to the tune of Rs 5840 crore on their drug promotion, which ultimately falls on consumers and this needs to be regulated.

Session III - Floor Discussions

One of the participants from the Consumer VOICE observed that while free competition in consumer products is desirable for consumer welfare, drugs cannot be left to unfettered market forces. Regulation is absolutely necessary to keep a check on spurious drugs.

Also recommended was the revelation of the first point price by the pharmaceutical companies for a consumer's understanding on both cost of production and the subsequent margins thereof.

G C Mathur from Binty urged to bring transparency in justifying the maximum retail price of a drug. Consumers should know the amount and rate of taxes they are paying to buy a medicine. It is evident in many cases that retailers are pocketing some four-six percent of drug price in the name of taxes.

One of the participants questioned the relevance of competition policy and law in a scenario where 80 percent of the population in rural and tribal areas are denied access to health. Family primary health centres in some areas do not even have basic sulphur drugs. Competition policy and law may help in reduction of retail prices of the drugs, but cannot ensure access of medicines to the poor and people in remote areas.

GM called for reconciling the differences existing on state tax, municipal tax and VAT between various states to bring in more transparency and uniformity of pricing of the drugs.

Tarun Das from *Institute of Integrated Learning in Management* insisted to include the subject of access to medical education and training in the report. Further, proper management of hospitals and health centres is also an important issue, which India lacks.

UK made a vote of thanks to the participants, requesting them to mention their concerns, which were not flagged during this workshop due to time constraint, via letters and emails.

ANNEXURE II

NATIONAL WORKSHOP ON

OPTIONS FOR USING COMPETITION LAW/POLICY TOOLS IN DEALING WITH ANTI-COMPETITIVE PRACTICES IN PHARMACEUTICALS AND THE HEALTH DELIVERY SYSTEM

8 September, 2006, New Delhi

PARTICIPANTS IN ATTENDANCE

1. P. N. Anand, DCM, New Delhi
2. Nupur Anchlia, CUTS Mumbai Resource Centre, Mumbai
3. H. K. Awasthi, Consumer VOICE, New Delhi
4. Anurag Bhargava, Jan Swasthya Sahayog, Bilaspur
5. G. R. Bhatia, Competition Commission of India, New Delhi
6. Aditya Bhattacharjea, Delhi School of Economics, New Delhi
7. Thaneshwar Bir, National Institute of Health & Family Welfare, New Delhi
8. Bhaswati Das, Council for Social Development, New Delhi
9. Tarun Das, Institute of Integrated Learning in Management, New Delhi
10. S. Deepa, British High Commission, New Delhi
11. Priyanka Dutta, CUTS Calcutta Resource Centre, Calcutta
12. Savita Hanspal, Consumer VOICE, New Delhi
13. Shobha Iyer, Citizen Consumer & Civic Action Group (CAG), Chennai
14. Smita John, CUTS International, Jaipur
15. Surendra U. Kanstiya, Surendra Kanstiya Associates, Mumbai
16. Ujjwal Kumar, Ministry of Health & Family Welfare (MoH&FW), New Delhi
17. Savita Madan, Chetna Consumer Club, New Delhi
18. G. C. Mathur, BINTY, New Delhi
19. R. Mehrotra, Ministry of Health & Family Welfare (MoH&FW), New Delhi
20. Pradeep S Mehta, CUTS International, Jaipur
21. Nitya Nanda, CUTS International, Jaipur
22. Sanghamitra Sahu, The Indian Council for Research on International Economic Relations (ICRIER), New Delhi
23. K. Satyamurty, Consumer Guidance Society, Ahmedabad
24. Mira Shiva, Voluntary Health Association of India, New Delhi
25. Paramjit Singh, Consumer VOICE, New Delhi
26. Siddharta Singh, ASSOCHAM, New Delhi
27. M. C. Verma, ITLI, New Delhi
28. Gautam Vohra, Development Research and Action Group (DRAG), New Delhi
29. P. Venkatesan, Department of Consumer Affairs, New Delhi
30. G. Wakankar, Indian Drug Manufacturers' Association (IDMA), New Delhi