COMPETITION IMPEDIMENTS IN THE PHARMACEUTICAL SECTOR IN INDIA

Authored by:
Natasha Nayak

Supported by:

सत्यमेव जयते
Ministry of Corporate Affairs
Government of India

EXECUTIVE SUMMARY

The purpose of the study is to identify the impediments to competition existing in the legislative provisions, rules, regulations, policies and practices emanating from such provisions within the pharmaceutical sector in India. The relevant market for study has been defined as the pharmaceutical market as a whole across India not including the ayurvedic and unani medicines. The assessment tool for such analysis is primarily the competition assessment toolkit developed by OECD to identify competition distortive government regulations and policies.

The study has identified key competition concerns to be in the area of: anticompetitive agreements along the pharmaceutical supply and distribution chain; abuse of dominance by patent monopolies at the domestic and international levels; growing mergers and acquisitions and drug pricing.

The Constitution of India guarantees Right to Health as a fundamental right under Right to Life (Article 21). Availability, accessibility and affordability of drugs remains to be a prime objective. The study is also mandated with the broad objective of addressing potential threats to this right posed by competition distortions in the sector.

Since the study has been commissioned to set the agenda for advocacy initiative for the National Competition Policy once it is adopted, it recommends the role of the National Competition Policy Council when operationalized, to address the identified concerns in addition to the Competition Commission of India's role on some issues.

The paper is divided into four main sections. The first section introduces the mandate and methodology. The second section provides an overview of the market structure with the industry profile and recent trends, a SWOT analysis and the existing regulatory framework. The section also highlights briefly, the critical competition concerns in the sector. The third section provides the provisions under various relevant statutes and policies annexed as a matrix to the study (Annex. A). The identification and analysis of the provisions has been done with the guidance of the Competition Assessment Toolkit developed by the OECD for the most part. The section also provides some recommendations to address specific issues. The last section sets out broad recommendations and the way forward.

1. INTRODUCTION

1.1 Mandate

Ministry of Corporate Affairs, Government of India, vide notification F.No.5/15/2005-IGC/CS dated 8th June 2011, constituted the Committee on National Competition Policy and Related Matters (C-NCP) for:

a) Framing of a National Competition Policy (NCP)
b) Strategy for competition advocacy with government and private sector
c) Changes required in Competition Act for fine tuning it and
d) Any other matter relation to competition issues

After submitting a draft report on the National Competition Policy, the Committee is currently working on the Competition Advocacy Strategy for the National Competition Policy.

The Pharmaceutical Sector Research Study (hereinafter referred to as "the study") gathers an account of evidences to set the agenda for the advocacy initiative. The mandate of this study is to identify and analyze those laws, regulations and policies within the pharmaceutical sector and outside to the extent that affect competition in the pharmaceutical market.

1.2 Methodology

The methodology for the study is a combination of primary and secondary data. Primary data has been gathered through various structured and unstructured meetings among representatives of Department of Health and Family Welfare, Ministry of Corporate Affairs and various institutions such as Indian Drug Manufacturers Association (IDMA), Organization of Pharmaceutical Producers of India (OPPI), civil society organizations such as CIRC and sector experts. Consumer surveys have also been employed to draw attention to some critical issues.

Secondary data includes statutes, case laws, CCI orders, Reports of the Planning Commission, the Ministry of Chemicals and Fertilizers, Ministry of Health and Family Welfare, DIPP and international organizations such as WHO, UNDP and World Bank as well as many scholastic articles. Country reports for United States, European Union, South Africa, Brazil and Japan have been referred for comparative analysis in relevant places.

This report seeks to discuss few significant issues of pharmaceutical industry through the lens of competition which broadly include:

- Anticompetitive agreements along the pharmaceutical value chain,
- Competition distortive provisions in the sectoral laws and rules that raise entry barriers for domestic players and affect their ability to compete fairly,
- Growing trend of mergers and acquisitions by foreign MNCs of domestic companies that promotes monopoly as well as threatens innovation, and

- international "obligations" and non-tariff barriers read trade politics or backdoor measures for monopoly protection that block/delay entry for Indian generic drugs

These issues and challenges cannot be studied in isolation without looking at the predominant issue of ensuring availability, affordability and accessibility of medicines to the public which is part of the fundamental right to life under Article 21 of the Indian Constitution and a consideration that motivates the pricing decisions of medicines under the National List of Essential Medicines in accordance with the Essential Commodities Act and the Drug Price Control Order, administered by the National Pharmaceutical Pricing Authority.

Balancing the entrepreneurial interests with the objective of consumer welfare is a critical challenge unique to the pharmaceutical industry and therefore the study cannot be complete without getting a closer look at drug pricing policies and how they impact market competition. The study in fact attempts to guide the policy makers towards achieving this equilibrium through some of its findings in the larger scheme.

Whereas the study tries to address most of the issues which were brought before it by stakeholders and were considered significant for the purpose of this study, there is a likelihood of some of the issues having been missed out. In most cases it could be because of inter-se prioritisation leaving out the lesser of the issues to save on space and maintain the focus.

1.3 Data Collection and Analysis

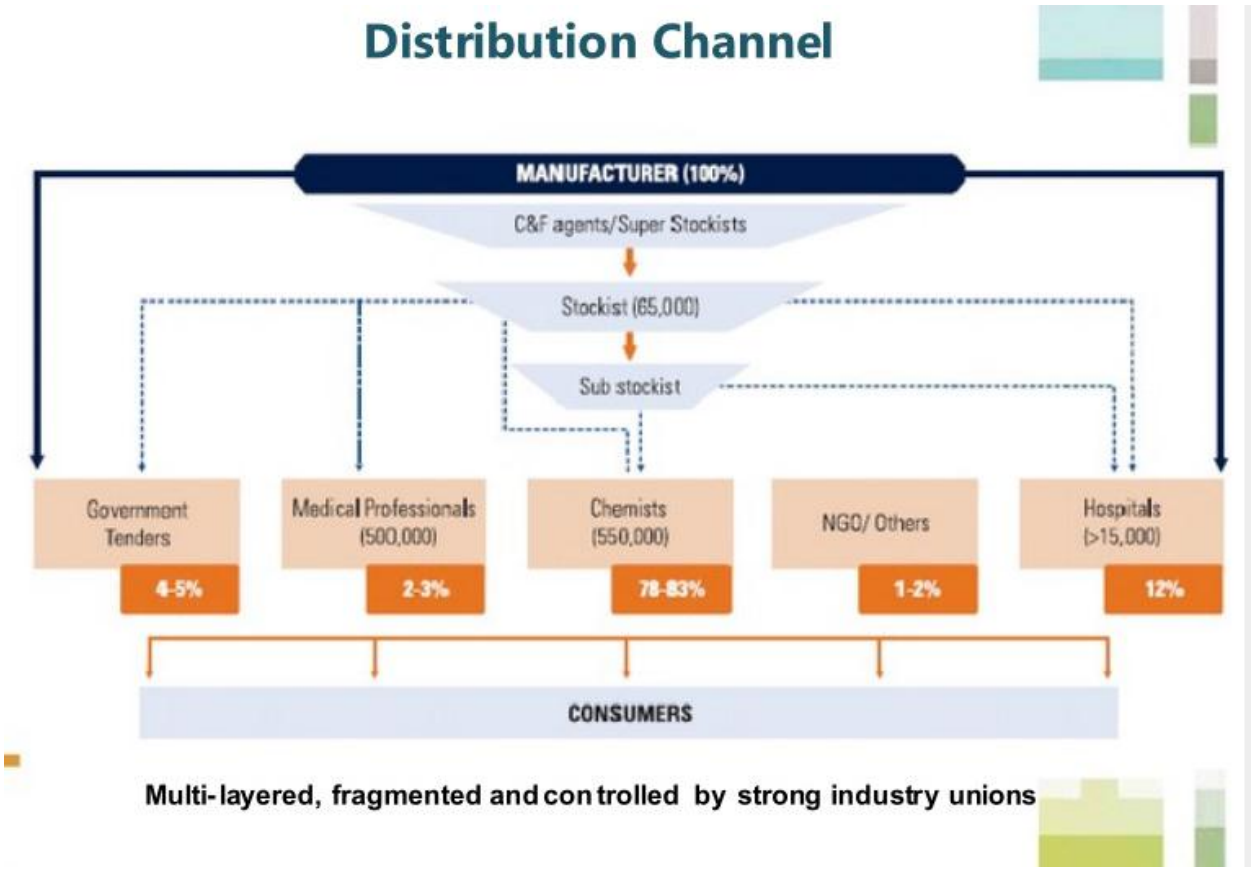
Stakeholder interviews, questionnaires and surveys have been used to reach at useful findings. The legal inventory of competition distortive laws, rules and policies has been prepared and analysed to assess how they impact competition by employing the Competition Assessment Toolkit developed by OECD.

2. MARKET STRUCTURE AND COMPETITION ISSUES

With a population of nearly 100 crores, India accounts for 16 per cent of the global population. WHO says that 65% of the population still lacks regular access to essential medicines. With the rise in health care cost, over 23 % of the sick don't seek treatment because they are not having enough money to spend. Healthcare costs are high and are increasing further. Expenditure on drugs constitutes about 50 % of the health care cost which increases up to 80 % in rural areas and healthcare expenditure is the second most common cause for rural indebtedness in India. Our national objective is to ensure affordable and accessible medicines for Indian citizens. However, there are bottlenecks in this process created by monopolistic situations and unreasonable upward pressure on prices that result from forces that emerge from within and outsides the market. The objective of the study is to identify and analyse these competition concerns existing the sector and suggest ways to address the same.

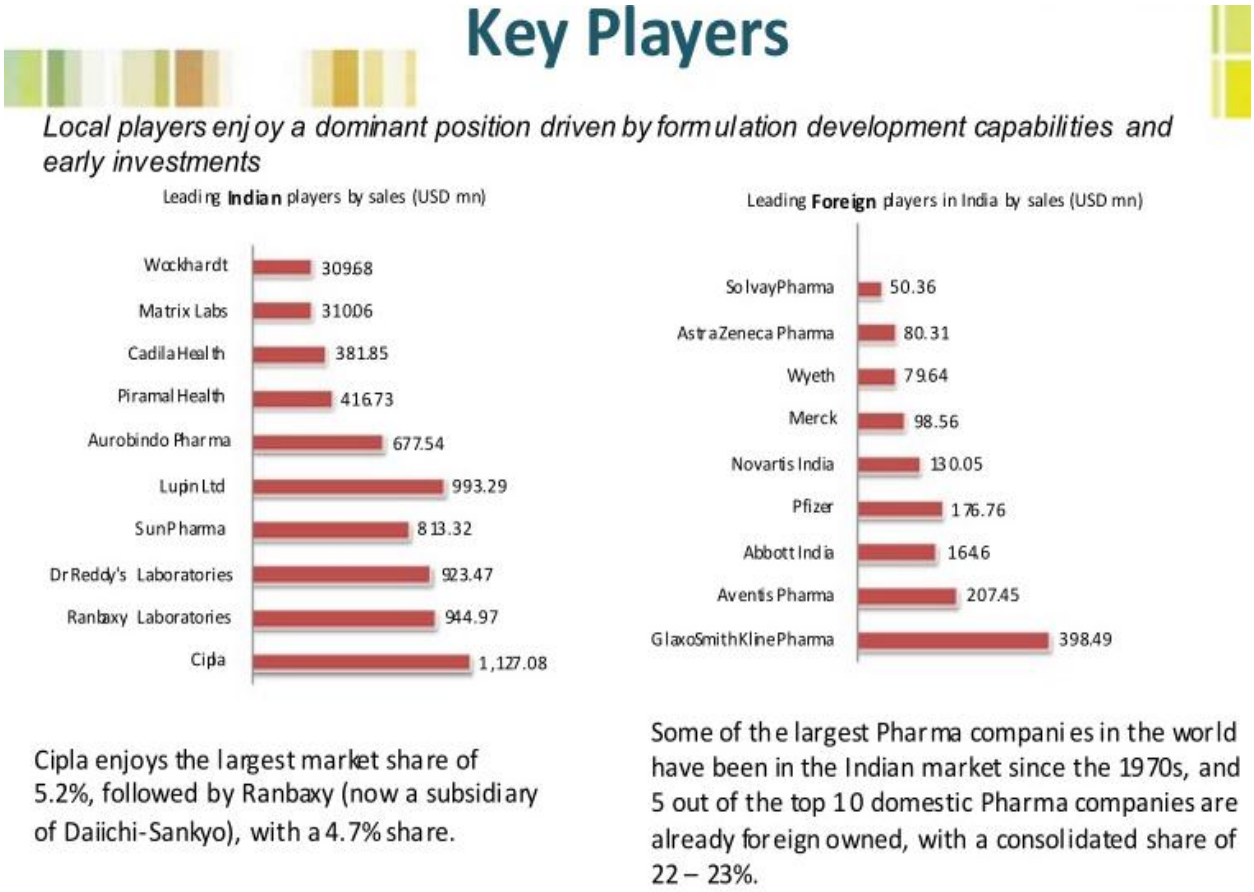
2.1 Industry Structure

It is often argued that India's drug market is a competitive one with nearly 20,000 companies competing in various therapeutic segments. This is said to have kept the drug price at low level. However, it is a highly contestable claim as evidence suggests that despite being highly fragmented, there is high market concentration in these markets ***(Sakthivel, 2005).*** Around 250-300 companies control 70% of the total market share.



Source: KPMG India Pharma Summit 2009

Key Players (Indian and foreign) that enjoy a dominant position in the Indian pharmaceutical industry.



Source: Ace Global Consulting LLP

2.2 Industry Profile and Recent Trends

The Indian pharmaceutical sector is one of the leading sectors in terms of the country's economic growth. It has grown significantly in past five years and is expected to continue to show double digit growth in 2012. Indian pharmaceutical industry ranks very high in the third world, in terms of technology, quality and range of medicines manufactured. It is the third largest in terms of volume and fourteenth in terms of value. As per the IMS Prognosis Report of 2011, India's pharmaceutical spending has been steadily increasing. It ranked 15 in 2005, 12 in 2011 and is expected to escalate upto 8 by 2015. Some statistics as of mid 2011 are as below:

PHARMACEUTICAL STATISTICS	
Total turnover in US$	26 Billion
Total Value of domestic market in US$ in 2010	12 Billion
Total exports in US$: Formulation exports API exports	13.9Billion 5.8Billion

	8.1Billion
%Volume of global production	10%
%Value of global production	1.5%
Employment generation (direct and indirect)	Approx. 42 lakh
FDI Between April 2000-2010 in US$	1707.52 million

INDUSTRY SWOT ANALYSIS

Strengths	Weaknesses	Opportunities	Threats
• High GDP growth and increasing disposable income	• Information asymmetry and inelastic demand to changes in price makes collusion conducive and profitable	• Generics worth over USD 40 bn going off patent in the near 2-5 years.	• Global pressure for data exclusivity, TRIPS plus provision that hampers generic competition
• Increasing healthcare expenditure	• Capacity constraints for CCI to scan pharmaceutical mergers and takeovers	• TRIPS Flexibilities	• International developments on "counterfeit" medical products to threaten Indian generic entry to global markets
• Increasing old age population and rise in per capita demand for health services	• Non tariff barriers imposed globally	• Rising opportunities for contract research and manufacturing (CRAMS) especially beneficial for SMEs with limited	• Growing acquisitions of domestic pharma companies by foreign ones potentially leading to monopoly/oligopoly and threatening innovation in

Strengths	Weaknesses	Opportunities	Threats
		options to grow in a product patent regime	some cases
• Lean cost structure	• High market barriers for SMEs with limited financial and technical capacity constraints to enter the larger market due to lack of technical know how and inability to comply with GMP	• Rapid generic market growth	• Competition from other emerging economies such as China with lower cost of APIs compared to India
• Global competitiveness enhanced by recent amendment to Schedule M (GMP)of Drugs and Cosmetics Act and Schedule Y (new drug discovery)	• Product patent regime does not favour the generic industry as much as process patent regime did	• Increasing Public Private partnerships for strengthening healthcare infrastructure	
• Governmental initiatives to boost Small and Medium Pharmaceutical Enterprises such as Credit Linked Capital Subsidy (CLCS), Pharma Technological Upgradation Assistance (PTUA),	• Linking regulatory issues with IPR issues	• Increasing foreign direct investments by MNCs	

Strengths	Weaknesses	Opportunities	Threats
setting up of SEZs, tax holidays etc.			
• Increasing usage of pro competitive provisions such as Section 3D of the Indian Patent Act to fight against ever greening strategies employed to promote monopoly by big players	• Inability to use TRIPS flexibilities • Absent guidelines on regulation of bio-similars	• Growing bio-similar industry in light of a large chunk of biotech pharmaceuticals going off patent by 2015	
	• Low R and D		

2.3 Regulatory Framework

1. Relevant legislations (includes but not limited to the following):

- Drugs and Cosmetics Act, 1940.
- Drugs and Cosmetics Rules, 1945.
- Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954.
- The Indian Medical Council Act, 1956.
- Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002
- Drug Price Control Order, 1995.
- Essential Commodities Act (Section 3)

2. Some Relevant policies

- Draft National Pharmaceutical Pricing Policy, 2011

3. Regulatory agencies

- Central Drug Standard Control Organization (CDSCO).
- Drug Controller General of India (DCGI)
- Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers
- National Pharmaceutical Pricing Authority (NPPA)
- State level: State Drug Controllers and Inspectors.

Other key laws that affect pharmaceutical sector include:

- Competition Act of 2002
- Indian Patent Act, 1970
- TRIPS Agreement

2.4 Key Competition Concerns

1. Anti-competitive practices along the pharmaceutical value chain for profits and high trade margins

A survey conducted on the doctors, pharmaceutical industry, consumer organisations, hospitals and the pharmacists in India bring to light various facts about collusion along the pharmaceutical distribution chain at the ground level.

In a CUTS study, the majority of the pharmaceutical companies surveyed claimed awareness with respect to the existence of collusive practices in the pharmaceutical industry and a high 32.2 per cent of respondents asserted that such practices prevail in the industry to a great extent. Some of these unethical practices were pertaining to irrational drug prescriptions by doctors motivated by kickbacks received from pharmaceutical companies. As a result they prescribe expensive drugs that may not be necessary either. What encourages such rent-seeking behaviour is the information asymmetry and low elasticity of demand to changes in prices because here the doctors are the influencers and not the consumers.
Collusion also takes place along the distribution between drug companies, stockists, retailers, Medical Representatives (M.R.) which disproportionately inflates the cost of medicines & the overall treatment. Consumers have little or no choice in such a 'rigged' market and buy what is prescribed by Doctors or what are sold by Chemists (Sengupta, 2010).

Below is a study that throws light on such exorbitant trade margins.

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

Source: CUTS Study, 2006

2. Abuse of dominance by patent monopolies

India operated a process patent regime until not so long ago which scholars have expressed helped the Indian pharmaceutical industry flourish into a world class generics industry. However, in 2005, India amended its Patents Act, 1970 to come into full compliance with its obligations under the TRIPS Agreement and became a product patent regime. The product patent regime as the term indicates is the granting of patent to the 'final' product irrespective of the process used for obtaining the product. Once you obtain a patent on the product, then one is precluded from manufacturing that product, even though with a different process.

It is only obvious that this has given rise to grave concerns were about access to affordable essential medicines threatening competition by delaying generic entry into the market and enhancing the industry's vulnerability to monopolistic abuse.

Economics of Generic Drugs and Price Effects

According to the U.S. Food and Drug Administration (FDA), generic drugs `are identical or within an acceptable bioequivalent range to the brand name counterpart with respect to pharmacokinetic and pharmacodynamic properties. By extension, therefore, generics are considered identical in dose, strength, route of administration, safety, efficacy, and intended use. In most cases, generic products are available once the patent protections afforded to the original developer have expired.

When generic products become available, the market competition often leads to substantially lower prices for both the original brand name product and the generic forms.

The principal reason for the relatively low price of generic medicines is that competition increases among producers which prevents any single company from dictating the overall market price of the drug. With multiple firms producing the generic version of a drug, the profit-maximizing price generally falls to the ongoing cost of producing the drug, which is usually much lower than the monopoly price.

There are many studies on the effects of generic competition on prices in the USA following adoption of the ***Hatch-Waxman Act*** in 1984 and also studies in Canada, some EU countries, and Australia that have been discussed in greater detail in the forthcoming sections.

The big pharma players adopt various strategies to eliminate competition from generics by adopting measures described as evergreening, creation of patent thickets etc.

A remedy against that lies under the flexibilities adopted by India and developing countries that are TRIPS compliant is that of Compulsory Licensing under Section 84 and 92 of the Indian Patent Act, 1970. However while countries like Brazil and South Africa are leading in their use of such flexibilities, in India there have been just one case so far. The fault lies jointly with pharmaceutical companies as well as the government.

3. Backdoor monopoly protection and trade politics affecting competition from generics market: Defining "Counterfeit" drugs and TRIPS plus measures

Data exclusivity

In 2006, the USA placed India on the Special 301 Priority Watch List for not granting monopoly rights for clinical trial data (data exclusivity). It asked the patent holder be given 5 years of exclusive monopoly rights. Pharmaceutical companies also pressurized India to do this. Recently, data exclusivity has become an issue in the FTA with EU where EU is pushing for India to give data exclusivity for clinical trial data submitted by a pharmaceutical company for ten years. This means that regardless of whether a patent is regarded, a generic version of that drug cannot be registered during that period. Hence the impact of this on generic entry into the market is monstrous. Besides such a provision is TRIPS plus because TRIPS nowhere talks about exclusivity of data for any period even though it talks about data protect under Article 39.3. India must firmly resist such global pressures to block entry of generics and promote patent monopolies of multinational players.

Counterfeit drugs

The new global initiative on the need to define "counterfeit" drugs by an alleged WHO initiated anti-counterfeiting taskforce, IMPACT has created major problems. It seeks to alter the older definition provided by WHO to make it more ambiguous such that it risks causing confusion between fake drugs with legitimate generics. WHO'S older definition uses the terms "deliberately and fraudulently" to define what constitutes counterfeiting. But the new definition by IMPACT does away with these words which creates confusion as in the absence of fraudulent intent it is easy to find infringement even when there is none. The seizure of drug consignments in transit from India to South America at various European ports on the pretext of patent infringement is a glaring example. India has to be careful that this does not become a non-tariff barrier for Indian generics that may be confused with fake and substandard drugs which is a safety regulation issue with an intellectual property issue.

4. Growing trend of mergers and takeovers in the pharmaceutical sector

Acquisitions of local players by large MNCs illustrate their increasing level of interest in the Indian market.

Cumulative FDI Inflow in Drugs and Pharmaceuticals sector	**USD 1851**	Apr 2000 to Nov 2010
M&A Deals *(Inbound deal value – USD4.6bn and Outbound deal value – USD0.1bn)*	**19** Inbound (8); Outbound (4); Domestic (7)	Jan 2010 – Oct 2010

FDI of up to 100 per cent in drugs and pharmaceuticals is permitted through the automatic route. For licensable drugs and pharmaceuticals manufactured by recombinant DNA technology and specific cell/tissue-targeted formulations, FDI requires prior government approval.

In 2010, Abbott bought Piramal Healthcare in a deal worth US$3.7 billion, a valuation that was **nine times** the value of Piramal's sales revenue.

Key deals				
Deal type	Acquirer	Target	Total value (US$ million)	Completion date
Inbound	Abbott Laboratories	Piramal Healthcare Ltd	3,712.8	September 2010
Inbound	Taro Pharma	Sun Pharma India	332.4	September 2010
Outbound	Strides Arcolab Ltd	Aspen Pharmacare Hldg Ltd	75.0	July 2010
Outbound	Solvay Pharma India Ltd	Abbott Capital India Ltd	66.8	April 2010
Inbound	Hospira, Inc	Orchid Chemicals Injectible business	400.0	March 2010

Source: Ace Global Consulting LLP

Over the last couple of years, Indian pharmaceutical companies have been increasingly targeted by multinationals for both collaborative agreements and acquisition. During the first half of 2011, Bayer and Zydus Cadila agreed to set up a joint venture called Bayer Zydus Pharma (BZP), for the sales and marketing of pharmaceutical products in India. Other recent collaborations include Sun Pharma working with MSD (Merck & Co) to market and distribute Merck's Januvia (sitagliptin) and Janumat (sitagliptin+metformin) under different brand names in India. In May 2011, Par Pharmaceutical Companies entered into a definitive agreement to acquire privately-held Edict Pharmaceuticals, a Chennai-based developer and manufacturer of solid oral dosage generics. Hikma Pharmaceuticals announced in April 2011 that it had agreed to acquire a minority interest in Unimark Remedies, a privately-held Indian manufacturer of active pharmaceutical ingredients and API intermediaries ***(Espicom Business Intelligence Report, 2011)***. Pharma MNCs are projected to capture a 35 per cent market share of the market by 2017, compared with 28 per cent in 2009.

Foreign companies in almost all industries—automobiles, retailing, telecom, etc—have strategies to enter and grow in India and other emerging markets. We should take advantage of this attraction of our market to bring in technologies and investments that will accelerate the development and growth of our country, expand our innovation experience and expertise and improve the conditions of our people. However we must ensure that the influx of foreign companies improves the condition of industry in India and provides benefits to Indian citizens. While companies will develop strategies to suit themselves, we must ensure that their strategies do not result in acquisition of power by them to distort competition, and the pricing and availability of medicines in India. Therefore the Indian Government must have the ability to evaluate any major moves by foreign companies into India that could create adverse conditions for Indian consumers. This is the genesis of the recent alarm, rightly raised by the Ministry of Health, about the recent acquisitions of Indian pharma companies by large foreign MNCs (Maira Committee Report, 2011).

5. Drug Pricing

Currently 37 drugs out of the National List of Essential Medicines of 348 are under price control pursuant to the Drug Price Control Order (DPCO), 1995. A grave concern has been the decreasing number of drugs under statutory control in the wake of liberalisation and economic reforms. Currently 60% of the top-selling 300 drugs which accounted for nearly 80% of the retail sales are not to be found in the national essential drug list (Srinivasan, 2011).

Major efforts need to be made in bringing all essential medicines under price regulation. In response to a petition brought in by All India Drug Action Network, on October 11, 2011, the Supreme Court directed the secretaries of ministry of health and ministry of chemical and fertilizer to file affidavits in four weeks stating whether the Union government wanted to bring the essential medicines under the ambit of price control. The petitioner had stated that medicines are not being available to the poor at affordable prices.

Drug Price Control Regime in India over decades until recently

1962	The control on prices of drugs and pharmaceuticals in India was introduced for the first time in the wake of the Chinese aggression and declaration of emergency and accordingly the Drug (Display of Prices) Order, 1962 and the Drug (Control of Prices) Order, 1963 were issued under Defence of India Act.
1966	The Govt. introduced a system of allowing increases in prices by issuing Drug Prices (Display and Control) Order making it obligatory for the manufacturers to obtain price approvals from Govt. before increasing prices of any formulation.
1970	In suppression of all orders issued earlier, The Drug (Price Control) Order, 1970 (DPCO,1970) was issued on 16thMay 1970 under sec 3 of The Essential Commodities Act, 1955 with an objective to bring down prices of essential drugs, curbing excessive profit, promoting R&D and diversification of future development of the drug industry.
1979	DPCO 1979 was issued empowering Govt. to fix maximum sale price of 347 indigenous manufactured scheduled drug, new bulk drugs, imported scheduled drugs and to fix retention price, common sale price and pooled price of scheduled bulk drug and to fix leader price of specified formulation as per schedule I & II.
1987	On the basis of Drug policy 1986, DPCO 1987 was issued where no. of bulk drugs under control was reduced to 142. The leader price concept in 1979 was renamed as Ceiling Price. The power to recover overcharged amount from the companies was also incorporated.
1995	DPCO 1995 (at present in force) was introduced under which the no. of drugs under price control was reduced to 76 (2 omitted and at present 74) and the GoI has been empowered to fix and revise the price of non-scheduled formulation also.

Source: Pharmaceuticals Export Council of India

Recently, the Draft National Pharmaceutical Pricing Policy was proposed in 2011, which introduced two significant changes to the existing system of drug pricing. Firstly, the methodology for calculating drug prices would be the market based rather than the earlier cost based approach which would depend on the weighted average of the prices of the top three branded drugs. Secondly, the controls have been lifted from bulk drug manufacturers. There is apprehension that this would lead to setting high prices for drugs because the top three branded drugs would be the expensive ones making huge profits. While this has been welcomed by the industry at large, it may not serve the purpose of affordability. Secondly, decontrol of bulk drug manufacturers might lead to increase in the prices of inputs while keeping control over the formulations which might reduce the margins and further promote anticompetitive behavior and collusion along the value chain.

III. LEGAL PROVISIONS IMPEDING COMPETITION

See Matrix attached as Annexure A.

IV. RECOMMENDATIONS AND SOME LESSONS FROM ABROAD

1. Adequate Usage of Section 3(d) and delay of generic medicines in the pharmaceutical sector.

One of the key drivers of competition in the pharmaceutical market causing prices of drugs to fall is the entry of generics. There are many studies on the effects of generic competition on prices in the USA following adoption of the Hatch-Waxman Act in 1984 and also studies in Canada, some EU countries, and Australia.

The Hatch-Waxman Act in the USA facilitated generic entry in return for an extended period of patent protection. Since this law was adopted, some originator brands lost half their market share in a year after generic medicine entry (Grabowski, 1992). Various US studies estimating the discount in price offered by the first generic entrant find discounts in the range of 15%-40% during the period when there is only one generic competitor, and that prices of generics drop lower as more generic companies enter the market and compete (CBO, 2004). The EU adopted regulation to promote the uptake of generic medicines in 2004, which included some similar features to those in the USA. A European Commission (EC) inquiry into a sample of 219 medicines found that generic prices were on average 25% lower than the originator brand price before loss of exclusivity, falling to 40% lower on average two years later. Generic market share was about 30% after a year, and 45% on average after two years. But in some EU countries, prices fell by up to 80%-90% (EC Pharmaceutical Inquiry Report, 2009).

There is extensive good quality evidence from OECD countries, and some evidence from LMIC that competition can reduce prices for essential medicines (WHO/HAI Working Paper, 2011). One source of evidence is the large body of studies evaluating the effect of laws that countries have adopted to encourage generic medicine entry and generic competition after patent expiry. A Congressional Budget Office (CBO) study attempted to quantify the magnitude of this effect by analyzing retail pharmacy data from 1993 and 1994. The study found that, for drugs that are available in both generic and brand-name versions, the average price of a generic prescription was approximately half of the average price of a brand-name prescription (Lee, 2007). The CBO estimated that, in 1994, the availability of generic drugs saved purchasers between $8 billion and $10 billion (Vickers, 2005). The broader empirical economics literature also points to a number of competitive effects associated with the introduction of generic drugs.

One of the main impediments to competition in the pharmaceuticals market is strategies employed by big players to delay generic entry into the market. Ever-greening has oft been used as a routine business strategy by monopolistic patentees to delay generic competition. Patents are issued on pharmacological compounds quite early in the drug development process, which sets the clock running. In due course, drug companies may seek new patents on the production of specific forms of these compounds, such as single enantiomers of drugs which can exist in both “lefthanded” and “right-handed” forms, different inactive components in a drug salt, or a specific hydrate form of the drug salt. If granted, these patents ‘reset the clock’ on patent expiration and extends the lifetime of the patentee (Dahiya, 2007). Originator companies many times resort to practices to extend the commercial life of patents. This contributes to the generic delay and restricted competition. The EC conducted a pharmaceutical sector inquiry under the EC competition rules in 2008, based on information that suggested restriction of competition in these markets leading to a reduction in the number

of innovative medicines reaching the market and delays in generic entry. The inquiry found that originator companies used a range of strategies to extend exclusivity and delay generic entry as long as possible such as filing up to 1300 patents for a single medicine (creating "patent thickets"), and engaging generic companies in costly litigation, even though the courts upheld originator patent litigation claims in only 2% of cases. It estimated that faster generic entry could reduce public expenditure on medicines by over 5% (EC Pharmaceutical Inquiry Report, 2009).

Such strategies have been witnessed in India as seen in the number of litigations filed under Section 3 (d) which has been held as a pro-competitive provision to safeguard ever greening of patents. For instance, Delhi High Court rejected the petition of Bayer Healthcare (German) preventing the Drug Controller General of India giving marketing approval to Indian company Cipla for the generic version of the cancer drug Nexavar. Similarly, Cipla in another case won the right to manufacture and market the generic version of the anti-cancer drug Tarceva originally patented by the Swiss pharma company Hoffman La Roche both in Delhi Court and the Supreme Court. And finally, the much controversial case of Novartis which had challenged Section 3(d) of the Indian Patents Act claiming immunity for their drug Gleevic, a major drug for leukemia on the pleas that the new Gleevic was a major improvement over a older version whose patent was over. This was disputed by Indian companies such as Natco Pharmaceuticals. The plea of Novartis was rejected consequently enabling manufacture by Indian generic companies. Cost estimates of the new generic drug place it at one tenth the price of Gleevic (Gauri, 2010).

While Section 3(d) is one of the most pro-competitive provisions in the Patent Act and as seen above, is being used in the country, its success depends on the manner in which it is interpreted and implemented by the Patent Office. A UNDP Report of December 2010 has revealed a dismal picture of the Patent Office lacking in capacity which can be seen as one of the biggest bottlenecks in the path of effective and optimum utilization of such provisions. For example:

- a significant number (16 patents, or 19 percent of the sample) of patents reviewed were formulated as composition claims but were in fact 'new use or 'method of treatment' claims 'in disguise'.

- A number of patents relating to other secondary features, such as the salt form, ester prodrug, enantiomer, etc., were also granted (8 patents, or 10 percent of the sample).

- Patents that were selected largely on the basis of Title and Patentee, some patents that appeared to be secondary product patents in fact turned out not to be so. E.g. The patent titled "A pharmaceutical composition for therapy of interstitial cystitis," turned out not to have any product claims, and only process claims relating to the process for manufacturing such composition.

- Indian Patent No. 208357, granted from Application No. 512/MUMNP/2005, claims oxybutynin, a known compound, in gel formulation for topical application. Thus, given the "new form" of oxybutynin that is being claimed, the applicants presumably had the burden of establishing that there was an enhancement of "therapeutic efficacy" in this new form. However, the specification describes the therapeutic efficacy of the gel form in this manner: "…the number of incontinent episodes for those individuals treated by the non-oral method of the present invention is nearly

identical to the number for those treated with the oral formulation." Thus, in establishing "therapeutic efficacy," the applicants showed that this new form was 'nearly identical'. A correct interpretation of Section 3(d), however, would appear to require a much higher showing of significant enhancement.

- A patent granted for the γ-crystal polymorphic form of a known substance-perinpodril contains a claim covering a pharmaceutical composition comprising the γ-crystal form "in combination with one or more pharmaceutically inert nontoxic carriers." In view of section 3(e) that excludes 'mere admixtures,' it is unclear what 'synergistic' effect was demonstrated that was deemed to overcome this exclusion.

- Many patents granted in India are rejected by the USPTO and EPO that have much more liberal patentability criteria. For example, Indian Patent No. 211807, granted from Application No. 952/CHENP/2003, claims the combination of two known compounds, amlodipine and benazepril. This application, filed in 2003 and granted in 2007, contains 13 claims covering the combination of these two drugs. The equivalent US application (US Application No. 10/450,344), however, was abandoned after the USPTO issued a non-final rejection for lack of novelty.

The above are instances where patents have been wrongfully granted by the Patent Office to questionable/unworthy patents only to act as barriers for generic entry. What is necessary therefore is:

- Have greater transparency in the patent granting procedures so that civil societies and other stakeholders can effectively contribute through patent grant oppositions.
- Sensitize the Patent Office, DIPP and other ministries on the anti-competitive effects of granting questionable patents where NCPC would play a crucial role.
- Enhance the capacity of the Patent Office so that it is able to examine the large number of filings carefully and avoid errors in judgment.

There is evidence that the international norms for intellectual property rights in the pharmaceutical industry may be going too far towards protecting the monopolies of the inventors and hurting consumer interests. Therefore India must not go any further than what it has already committed to under WTO and TRIPs, and not succumb to the pressure being brought on it to yield regarding modifications to Section 3(d) (Maira Committee Report).

2. Making Use of Compulsory Licensing

India has incorporated liberal provisions for compulsory licensing. India's Patents Act provides for it under Sections 84 (if initiated by a private party), 92 (notification by government that a CL needs to be issued for public non-commercial use, national emergency or extreme urgency), 92A (CL for generic exports) and 100 (for government use). However, nothing much has been done in this regard (Srinivasan, 2011). On the other hand, there are great lessons to learn from global best practices in this regard as well. For example, as mentioned earlier in the case of South Africa, the pharmaceutical companies, GSK and Boehringer, patent owners of Antiretroviral (HIV/AIDS) drugs set unjustifiably high prices of these drugs (over and above the WHO generic price). The Competition Commission ordered

issuance of a compulsory license to market generic versions of the patented ARV drugs in return for the payment of reasonable royalty (CUTS Report, 2006).

Compulsory licensing was brought to the forefront of the international debate about intellectual property and public health policy in January 1998, after the Executive Board of the World Health Assembly adopted a resolution urging the member states to put public health above commercial interests and to review their options under TRIPS to safeguard access to essential drugs (World Health Assembly, 1998). This provision enables countries to address the adverse impact created by patent monopolies and the resulting exorbitant price of drugs on public health grounds to ensure their affordability, accessibility and availability through their generic versions.

Both Brazil and South Africa have fought considerable opposition from American pharmaceutical companies and invoked compulsory licensing in the past. Both Indian companies and the government with its vast majority of population that is denied access to essential medicines could draw some lessons from these and make better use of the existing provisions under compulsory licensing. Unfortunately, till date there has been just one case of compulsory licensing in India which lies pending with the Mumbai High Court due to several procedural complexities that only delay the entire procedure defeating the very premise on which the need for a compulsory license is sought. The case pertains to the application by Natco for issuing a compulsory license for a patent by Bayer that is marketed under the name of Nexavar. The approach of Natco to the issue of compulsory licensing can be a good reference point to understand the lack of capacity and awareness on the part of pharmaceutical companies in using this provision adequately.

3. Adopting other measures to promote generic entry by lowering market barriers: Experimental use, parallel imports.

The United States enacted the Hatch-Waxman Act in 1984 to facilitate generic entry. Before Hatch-Waxman was enacted, a generic company could not begin the required FDA approval process until after patents on the relevant brand-name product had expired; to begin earlier would typically have infringed the brand-name company's patents. To enable earlier generic entry, the Amendments provided that certain conduct related to obtaining FDA approval that would otherwise constitute patent infringement would be exempt from infringement liability under the patent laws. In addition, generic applicants were permitted to rely on the brand-name company's trade secret data demonstrating the safety and efficacy of the brand-name drug product. As one federal appellate judge explained, the Amendments "emerged from Congress's efforts to balance two conflicting policy objectives: to induce brand-name pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market."

Similarly, lowering geographical barriers and making use of the doctrine of international exhaustion that India operates, it is possible to import generic versions of drugs where they cost low and the patent rights (both product and process) have been exhausted.

Provisions to this effect already exist within the Indian Patent Act under Section 107 on experimental use and parallel imports, respectively. Unfortunately, they rarely receive any attention despite being significantly pro competitive.

4. Delinking IPR with regulatory issues: Counterfeit and Data Exclusivity

Medicines fall under two separate legal and regulatory systems: the intellectual property system and the drug regulatory system. These systems have different objectives, are administered separately and function independently. Recent efforts to integrate these two systems via data exclusivity, "linkage" or other means are likely to have negative implications for access to medicines. Thus, (developing) countries would be well advised to keep these systems separate, and to reject any and all efforts to make connections between them. (WHO Briefing Paper, 2006).

a. Data Exclusivity:

This has been discussed at length in past and the existing position of the MOHFW is towards providing data protection with reliance and avoid data exclusivity (i.e. data protection for a fixed period without reliance).

The Satwant Reddy Report on Data Protection has recommended in the case of pharmaceuticals that India should pursue "data protection with reliance" for time being and gradually shift towards "data protection without reliance for 3 years, with prescribed safeguards" in due course of time. The matter was then entrusted to the MOHFW for amending the Drug and Cosmetics Act accordingly.

The Committee constituted on Article 39.3 of the TRIPS Agreement (Protection of Undisclosed Information) in 2004 rightly interpreted the same to mean data protection and not data exclusivity. Protection for a fixed period, the Committee held, amounted to data exclusivity which was a TRIPS plus provision not part of the WTO. The final report of the Committee on appropriate inclusion of data protection in the Indian pharmaceutical industry has proposed a calibrated approach with a transition period. The Committee has recommended the existing practice of approving new drugs as per the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945 with suitable modification for a transition period. After the transition period is over, it has been recommended that in long run it would be in national interest to provide a fixed-term data exclusivity with safeguards. During the transitional period, the minimum requirements under Article 39.3 of TRIPS can be implemented. Also, this period can be utilized to educate the public and industry so as to allay their apprehensions on the issue. Over time, the standards may be increased.

On the issue of data exclusivity there has been considerable pressure on India to implement the same. In fact it has been debated that in India, the absence of data exclusivity legislation has resulted in serious commercial clashes between research based pharmaceutical MNCs and powerful local generic based companies (Pugatch, 2004). Many MNCs hold the view that

this has helped the generics industry immensely to reverse engineer and make cheaper versions of drugs. However, data exclusivity provides protection to the technical data generated by innovator companies to prove the usefulness of their products. In pharmaceutical sector, drug companies generate the data through expensive global clinical trials to prove the efficacy and safety of their new medicine. By gaining exclusive rights over this data, innovator companies can prevent their competitors from obtaining marketing licence for low-cost versions during the tenure of this exclusivity. While it however does not legally prevent other companies from generating their own registration. But in practice the vast financial resources and extended time required for gathering and generating pharmaceutical registration data for a new drug may create a market barrier for generic based companies (Pugatch, 2004)

India's stance that data exclusivity is a TRIPS plus provision is correct. On a plain reading of the relevant portion of the TRIPS Agreement, Article 39.3,(2) only requires protection of expensive, undisclosed data submitted to drug regulatory agencies against "unfair commercial use" . Nowhere does TRIPS state that exclusive rights must be provided for a given period. In fact, TRIPS makes clear that countries may decide for themselves what constitutes "unfair commercial use" and that there are many possible approaches to satisfy this requirement.

The World Health Organization's Commission on Intellectual Property Rights, Innovation, and Public Health also reinforced the view that TRIPS does not require data exclusivity:
Article 39.3, unlike the case of patents, does not require the provision of specific forms of rights. It does not create property rights, nor a right to prevent others from relying on the data for marketing approval of the same product by a third party or from using the data except when unfair (dishonest) commercial practices are involved.

The effect on access to affordable medicines is clear. India can learn from the countries that have preceded it down this path instead of committing this mistake. Jordan brought in data exclusivity as part of a trade deal with the US. A study by Oxfam found that of 103 medicines registered and launched since 2001 that had no patent protection in Jordan, at least 79% had no competition from a generic equivalent as a consequence of data exclusivity. The study also found that prices of these medicines under data exclusivity were up to800% higher than in neighbouring Egypt. This is the reason why India is dead against data exclusivity while it respects data protection even while EU is pressing hard to include data exclusivity in the proposed Bilateral Trade and Investment Agreement (BTIA). The Indian Trade and Commerce Minister, Shri Anand Sharma said that India today said it was against the inclusion of 'data exclusivity' provision in any of its free trade agreements (FTAs) as it would hurt the interests of the domestic generic drugs industry and so there was no question that it would accept data exclusivity in any (free trade) agreement with any country.

b. Counterfeit

The whole confusion regarding the counterfeit of drugs emerges from the issue that counterfeiting is a term used in relation to infringement of trademarks. A draft resolution on counterfeit of medical products presented at the 61st World Health Assembly in May 2008 was the subject of intense discussion, as was a WHO Secretariat report (A61/16) on this issue. The term "counterfeit" entered the WHO forum using the quality argument which is the mandate of the WHO and not the infringement of IPRs. The draft resolution

(A61/A/Conf. Paper No. 1) was initially sponsored by Gambia, Ghana, Nigeria, Tunisia and United Arab Emirates. During a meeting at the Committee level, the European Union also became a co-sponsor.

The WHO defines counterfeit medicines as "medicines which are deliberately and fraudulently mislabeled with respect to identity or source. Counterfeiting occurs both with branded and generic products and counterfeit medicines may include products with the correct ingredients but fake packaging, with wrong ingredients, without active ingredients or with insufficient active ingredients".

IMPACT, International Medical Products Anti-Counterfeiting Taskforce an alleged WHO initiative, proposed a new definition of counterfeit as "a medical product as counterfeit when there is a false representation in relation to its identity, history or source. This applies to the product, its container, packaging or other labeling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components, with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging."

However, this definition has not yet been adopted by the WHO members and negotiations are ongoing on the definition.

The experts in India are warning against adopting any definition of "counterfeit drugs" that might create non-tariff barriers for Indian generic exports. This definition poses huge concerns as in the words of Shamnad Basheer, an IP lawyer and professor, ""The IMPACT definition is certainly problematic in that it uses the term 'when there is a false representation in relation to its identity, history or source'. If the word 'false' is defined quite loosely, it could potentially even catch legitimately approved generics, whose brands are similar to the innovator" (as reported by Live Mint, 2008)[1]. The Indian Drug Manufacturers Association also shared it view that they apprehend that this could be abused to prevent manufacture and supply of medicines to countries where patents are not granted/sought or granted but invalidated or found to be non-infringing. Many originator companies classify generic versions in India of their drugs under patent outside India as "counterfeits". Furthermore, in light of the drug seizures of Indian shipments in transit by EU, it said that empowering countries other than the country of origin and the recipient country to intercept a consignment in transit would create unwarranted hardships as the intervening country may not be aware of the patent status in the country of the origin and the recipient country.

At the 64th World Health Assembly (WHA), the much debated issue of the relationship between WHO and IMPACT was sought to be put to rest.
Following a general discussion there was no consensus on WHO's relationship with the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). The positions ranged from disengagement from, to continued engagement with, IMPACT. Some Member States suggested a moratorium on WHO's involvement in IMPACT activities until this issue is duly assessed by the Working Group, while other Member States supported WHO's continued involvement. Some Member States proposed an intergovernmental mechanism to discuss the issue of spurious/falsely labelled/falsified/counterfeit medical products. Some

[1] Lison Joseph, "Shipment Seizure: India's drug makers may avoid EU routes", Livemint, 12 December 2008

Member States acknowledged the need to reform IMPACT. However, it was noted that WHO cannot unilaterally change the terms of reference of IMPACT. Several Member States recognized that there have been benefits to some countries; several Member States, however, expressed their concerns about the controversial nature of the work of IMPACT and confusion between public health goals and commercial interests.

The WHA discussed the report from the working group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products on improving access to quality and affordable medical products. They also approved the decision to extend the working group to resume its work and report to the next World Health Assembly.

While the authenticity of IMPACT remains rather ambiguous, there remain crucial concerns in light of the generic seizures under suspicions of being counterfeit. It is important here to understand that at the heart of the problem lies the domestic ambiguity with respect to the definition of "counterfeit" or the lack thereof within the Indian drug regulatory regime which has serious implications for our generics exports. The Drugs and Cosmetics Act that sets the drug regulatory regime for the country does not use the term "counterfeit" anywhere. However, it defines "spurious drug" under Section 17B which may be understood as raising safety and efficacy concerns in a manner in which "counterfeit" is globally understood except when used in the context of trademarks which is an IPR issue. However, the definition defines "spurious" so loosely as to include legitimate generics well within its ambit. No surprises therefore when a German pharmaceutical company wanted to challenge the regulatory approval of a generic version of its drug by Cipla on grounds that it fell within the definition of "spurious" (SpicyIP, 2009).

5. Pharmaceutical Mergers and Acquisitions to be scanned by Competition Commission of India

Section 5 of the Competition Act prescribes the thresholds under which combinations shall be examined. Section 6 states that "No person or enterprise shall enter into a combination which causes or is likely to cause an appreciable adverse effect on competition within the relevant market in India and such a combination shall be void." These sections were notified earlier this year and came into effect as of June 1. Besides this, The CCI also has the power to order a demerger under Section 28 of the Competition Act, 2002 if the merged entity is abusing its dominant position. This means that if the merged entity engages in any form of exploitative or exclusionary practice, the CCI can take suitable action including asking the merged firm to break up. So far, no case of a demerger has come up before the CCI.

Mergers and Takeovers in the pharmaceutical sectors have grown considerably in the past few years. Matrix lab. Was acquired by US based Mylan Inc in August 2006, Dabur Pharma acquired by Singapore based Fresenius Kabi in April 2008, Ranbaxy labs. Ltd. Acquired by Japan based Daiichi Sankyo in July 2009, Shantha Biotech by France based Sanofi Aventis in July 2009, Piramal Healthcare acquired by US based Abbott Labs in May 2010 are some such examples. It has been a common trend that large pharmaceutical companies which enter into transactions with effectively or potentially competing companies, in many cases are found to do so patents are about to expire, so as to maintain their market share and try to reduce competition with other new generation drugs. The large number of Pfizer's acquisitions during past years, for instance, is possibly based in the fact that.

New trends of mergers and acquisitions in the transnational pharmaceutical market may suggest that, for the drug industry, this may be a good way of neutralizing competition and getting high market shares. Given the peculiarities of the marker, it is important to pay particular attention to whether such mergers are creating barriers to generic entry or causing potential harm to innovation. The former issue of generic entry is of particular relevance to developing countries where generic competition is necessary to ensure low cost medicines to the public at large.

It is apprehended that mergers would lead to increased prices of drugs. Similar concerns were raised by the health ministry that acquisition of Indian pharmaceutical companies by multinationals could orient them away from the Indian market, thus reducing the domestic availability of drugs produced by them. The ministry argued the trend of takeovers may result in cartelisation and concentration of market shares by few and a clutch of companies dictating prices of drugs critical for addressing public health concerns.

Nonetheless, to add to this is the grave issue that many mergers and takeovers in this sector would not attract CCI scrutiny as they may not meet the prescribed financial threshold requirements. Under the existing law, only M&As that involve target companies with a turnover of above Rs 750 crore and assets worth more than Rs 250 crore need to be vetted by the CCI.
A High Level Committee was constituted to study the recent acquisitions of Indian pharma companies by large foreign MNCs by the Planning Commission on June 30 2011 under the Chairmanship of Mr Arun Maira. The report submitted by the Committee in September mentions that the threshold criteria for target companies is on the higher side. This is especially true when compared to small pharmaceutical companies. Therefore it is likely that a strict compliance with the rules may not catch many of the small pharmaceutical mergers and take overs. This can be a serious problem. From the consumer perspective, whose interests the antitrust laws are supposed to safeguard, medicines are among the most important products consumed. Given the potentially serious implications of overlooking the loss or delay of new and improved medical treatments as a result of a merger, it is submitted that the law should specifically empower and require the antitrust enforcement agencies to review and respond to concerns arising from combinations in the pharmaceutical industry, whatever the current size of the merging companies happens to be (Dror Ben-Asher, 1999). Consistent with this argument is the Committee's recommendation that pharmaceutical companies be exempt from such threshold requirements for these reasons. This would bring about two thirds of the pharmaceutical mergers under the careful scrutiny of the CCI.

Furthermore, it is important also to assess the impact of combinations on innovations. 'An innovation market consists of the research and development directed to particular new or improved goods or processes, and the close substitutes for that research and development' (U.S. Antitrust Guidelines on Licensing of IP, 1995). Mergers and acquisitions in innovations markets such as pharmaceuticals, pose a threat for subsequent entry of products by stifling competition at the R&D and product development stage. It is a concern that acquisitions that involve takeover of generic companies may lead to change in priorities of these companies and adversely impact the competition in generic markets. This has been well noted by competition agencies in other countries such as USA and EU.

The USA and EU competition authorities have reviewed several mergers of large multinational pharmaceutical companies that took place in the last decade. Their reviews

examined whether the mergers would reduce competition in research and development, including clinical trials in particular therapeutic areas, as well as whether the mergers would lead to excessive concentration of the markets for particular therapeutic groups and products. For example, the review of the 2004 merger between Sanofi-Synthélabo and Aventis was found to reduce competition in three pharmaceuticals in the USA. As a condition of the merger, the FTC required divestment of products that were still at the clinical trials stage of development. It required divestment of manufacturing facilities to a competitor (GlaxoSmithKline), and required the companies to help GlaxoSmithKline to complete clinical trials and gain regulatory approval. The FTC also required divestment of clinical studies, patents and other assets related to cytotoxic colorectal cancer medicines to Pfizer (FTC, 2006).

In the words of Arun Maira:

"We must pay attention to the acquisitions and mergers taking place in the pharmaceutical sector. We do not want to be in a position where acquisitions are distorting the industry and oligopolistic or monopolistic conditions are created," We have created sophisticated mechanisms like the CCI where the necessary gate-keeping could be done before such takeovers or acquisitions take place. Therefore, we no longer need to follow the FIPB (Foreign Investment Promotion Board) route when there are other instruments to scrutinise a deal."(Matthew and Basu, 2011).[2] *While CCI is relatively new, concerns remaining regarding its capacity to scan such mergers. Lessons from other countries serve a useful guide in this regard:*

Merger approvals on conditionalities
China whose Anti-Monopoly Law came into being only in 2008 has approved 6 pharmaceutical mergers with conditionalities till date.

Public interest Criteria in Merger Clearance
While clearing pharmaceutical merger transactions, the South African Competition Tribunal has considered the question of the likely impact on public interest and cleared the merger once it raised no such concerns. To quote an excerpt from the clearance of a merger between Clicks Pharmaceutical Wholesale (Pty) Ltd and New United Pharmaceutical Distributors is as below:

"No deregulation has occurred as yet and we cannot speculate into the future. As to when this might happen. It suffices for the purposes of this merger, that we conclude that the merger will not lead to a substantial lessening of competition.
The Tribunal therefore is justified in approving the transaction unconditionally. There are no public interest concerns which would alter this conclusion since the NUPD business is being acquired as a going concern"

6. Anti-competitive agreements along the pharmaceutical value chain

[2] The above issue has met with some dissent by the Ministry of Health which argues that the FIPB is better equipped to scan mergers in the pharmaceutical sector given their better understanding of the issues.

Evidences of tie-in arrangements in the pharmaceutical (and healthcare sector) are many. Several surveys have revealed that consumers visiting private doctors or private hospitals witnessed tied selling of medicine as well as diagnostic tests. Doctors would instruct patients to buy prescribed medicines from particular shops or go to specific diagnostic centres. Sometimes doctors suggest several unnecessary tests which may not be relevant as part of their arrangements. These practices are anti-competitive in nature and impose heavy costs on consumers. In a survey conducted by CUTS International, only 15% of the respondents claimed that they had been asked to purchase medicine from a particular shop. On an average, those visiting private doctors or private hospitals, reported a higher incidence of tied selling of medicines. When healthcare service providers were asked about tied selling of medicines, only 11% admitted that they had ever resorted to such practices while 35% of them believed that other doctors resorted to tied selling practices with a profit or commission consideration.

Countries world over have shown several inspiring examples of the same and the CCI could gain some inspiration from these competition agencies. For example, twenty pharmaceutical laboratories were fined by competition authorities in Brazil, for participating in a cartel, which allegedly attempted to boycott the entry of new generic medicines in 2005. The laboratories involved include large multinational groups such as Roche, Aventis, Bayer, GlaxoWellcome and AstraZeneca. The intention of the cartel was to establish joint action involving general practitioners, to develop an information campaign against generics, thereby spreading what was regarded as, "distorted information". This case revealed 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. Several OECD country competition authorities have also taken action against associations of pharmacies or pharmacists for coordinating prices or restricting entry to the profession. For example, in a series of decisions in the 1990s, the FTC found that associations of pharmacies and pharmacists had attempted to fix prices and other terms and conditions of dealing with third-party payers (health insurance plans). In some cases, the associations threatened to boycott government programmes for indigent patients unless they were paid higher fees and restricted the ability of individual pharmacists to deal with third party payers individually. The FTC issued orders prohibiting these restrictive agreements (WHO/HAI Working Paper, 2011).

Although no domestic cartels in pharmaceuticals have been detected so far, there are associations that function just as such. For example, most pharmacy owners in India are members of a trade association, All India Organisation of Chemists and Druggists (AIOCD) which controls 95% of India's pharma trade and over 5.5 lakh members. This association is nothing short of a cartel with almost 64.25% of all pharmacists are members of AIOCD. The AIOCD is known to launch boycotts against drug companies in order to grab higher profit margins. In fact price decontrol has led to greater trade margins for the pharmacists in fact this actually beats the purpose of decontrol of prices i.e. to allow the manufacturers to be able to spend more on R&D. The suffering lies with the consumers ultimately. CCI in recently initiated an investigation to assess alleged anticompetitive practices of the AlOCD on the

complaint by an Orissa drug stockiest, Santuka Agencies which complained that its supply contract had been terminated by USV following a spat with the AIOCD which coerced USV to terminate its contract with Santuka.

More such investigations are needed to detect the many anticompetitive practices along the chain. So far, about 5.2% of the total cases that CCI has undertaken pertain to the pharmaceutical sector. There is need for better enforcement of competition laws in terms of vertical restraints among the pharmaceutical industry.

Competition advocacy to address information asymmetry
One of the major factors causing distortions in the pharmaceuticals market is with regard to information asymmetry among consumers. While there is a range of choice open to consumers, the exercise of choice is determined by several factors but the critical factor is on the availability of information. It is necessary to strengthen the public information system where simple drugs are known to consumers.

7. Drug Pricing

The greatest conundrum in the pharmaceutical sector is to balance consumer welfare with entrepreneurial interests. What health plans view as necessary to maintain equitable access to medicines, industry views as inimical to R&D and innovation. A recent case study by Australia proves that the claims of pharmaceutical companies that Australia's pricing and reimbursement policies suppress drug prices and reduce profits, are misguided. This case study was conducted via a narrative review that examined Australia's experiences balancing health and industrial policy objectives in the pharmaceutical sector. The review included electronic databases, grey literature and government publications for reports on relevant Australian policy published over the period 1985-2007. The results reveal that Australia appears to have secured relatively low prices for generics and "me-too drugs" while paying internationally competitive prices for "breakthrough" medicines. Simultaneously, Australia has focused efforts on local pharmaceutical investment through a variety of industry-targeted R&D incentive policies (Morgan S. et.al., 2008).

Such case studies are good indicators to put the fears of the industry regarding drug price controls at rest.

Therefore, the recent notice by the Supreme Court asking secretaries of ministry of health and ministry of chemical and fertilizer to file affidavits in four weeks stating whether the Union government wanted to bring the essential medicines under the ambit of price control is a welcome state towards attempts to bring essential medicines under price regulation and ensuring its accessibility. It is hoped that measures will be taken to address the matter (Mahapatra, 2011).

A draft National Pricing Policy was introduced recently in 2011. The Draft Policy states that “the span of control is likely to go up to 60%” in the new Policy (Re: Pg 14, Clause 3.3.iv).

However, the IMS Health data as presented below shows that the span of control could effectively be as high as 75%. This is more than *four* times the current span of control and more than *twice* the span of control as per NLEM 2011:

Span of Control

No	Reference Document	No of Drugs	No of Formlns	Data Available For		
				No of Drugs	No of Formlns	Span of Control %
1	**DPCO 1995**	**74**	**1,550**	**38**	***800**	**18.0**
2	**NLEM 2011**	**348**	**654**	**270** **78**	**351** **303**	**(a)18.1** **(b)11.9**
3	**NPPP 2011** Additions to NLEM 2011:					
	a. (Ex-1) Non-specified Strengths/Dosage Forms	-	-		1,389	9.7
	b. (Ex-2) Combinations of NLEM+NLEM	-	-		395	8.1
	c. (Ex-3) Combinations of NLEM+Non-NLEM		-	1,154	4,657	26.7
	Total Additions (a+b+c)	**-**	**-**	**1.154**	**6,441**	**44.5**
4	**NPPP 2011 (2 + 3)**	**-**	**-**	**1,502**	**7,095**	**74.5**

Source: NPPP 2011 and IMS Health MAT Mar 2011 * Estimated

(a) This is based on the data available for 351 out of 654 formulations included in the NLEM 2011. The actual span may further increase after the requisite data is collected, which is estimated at 11.9%.

(b) Estimate.

Responses to the Draft NPPP 2011:

Stakeholder consultations reveal a mixed response to this policy that has proposed some significant changes to the existing policy mainly regarding the methodology to calculate drug prices using the weighted average of the top three brands and decontrolling the bulk drug manufacturers. On the issue of decontrol of bulk drugs from price control, there was consensus that this was a welcome decision as this would reduce the growing reliance on imports from China. On the contrary, on the methodology adopted for pricing there is no consensus. An expert has remarked that the market based pricing criteria should be avoided

since the ethical drug industry (prescription drug) is structurally flawed with reference to free market conditions. There is no free market in case of ethical drugs because the drugs are priced based on the ability of the brands to project as better in terms of quality to the doctors and not to the ultimate consumers. Considering market based pricing will mean that the criteria of judging a higher mark up price which is fixed due to information asymmetries becomes the standards for price controls. The prices of prescription drugs even under price control are essentially going to rise significantly. However, the Indian Pharmaceutical Association had a different view: "The IPA lauds the proposal to move away from the archaic system of "uniformity of prices" based on normative costs irrespective of variations in the age, size and location of the plant, the level of GMP standards and the product quality. The current system rewarded companies with the lowest standards and penalized those with the higher standards of GMP. It is opaque and prone to corruption."

8. Transparency and Accountability in the Drug Regulatory Regime

There has been an observed lack of consistency between the actions undertaken under the Drugs and Cosmetics Act and their intended purpose to "ensure quality" under Section 16 of the Drugs and Cosmetics Act. Some of them have had grave consequences from the viewpoint of competition. Some of these cases are as below:

- **In Bharat Biotech International Ltd- v. A.P. Health and Medical Housing and Infrastructure Development Cooperation,** the High Court concluded that the government's order in inviting tenders for the supply of Hepatitis-B Vaccine only from the primary manufacturers in India with further condition that such primary manufacturers of vaccine should possess 'WHO pre-qualification was arbitrary and excludes some more manufacturers, suppliers and importers of the vaccine while favouring select ones. The Court went on to hold that instead of rectifying the implementation of the Act, the State cannot seek shelter in such a manner and set the prequalification aside.

- Another example of arbitrary rules imposed by the governments to "ensure quality" that have in fact been questionable as they were found to favour some specific firms in the year 2010 where bending the rules governing procurement of medicines, the Directorate of Ayurveda in Ajmer added riders in its tender call to buy medicine worth `5 crore INR for state-run hospitals. The move, it seems, was made to benefit a handful of companies. The decision was taken in accordance with a letter from the Union Ayurveda ministry dated June 9 2010. Though the purchase committee had decided to invite public sector undertakings and cooperatives, with GMP compliance, for the purchase bid, later, in its advertisement, it inserted a condition that the manufacturer must have a five-year experience, a condition which was not mentioned in the letter received from the Union ministry of Ayurveda. Of the existing PSUs and co-ops that manufacture Ayurvedic medicines, only eight have an experience of five years and more. Also, operations of most of these companies are managed by the

same set of people. "The move is an attempt to prevent new players from entering the fray, the officials have colluded with them [manufacturers] to block them [new entrants] by adding erroneous riders," an official source reported to one of the news dailies. It is therefore necessary to ensure that such riders acting are not enforced to block potential entry of new suppliers and benefit a handful of favoured players in the relevant market.

- Similarly, a much controversial case is with regards to the curious closure of the only three PSUs that manufactured vaccines on GMP grounds. Following the closure, the Vaccine Procurement Cell under the relevant ministry has placed orders with private firms producing vaccines and a bulk of purchase orders to one unit in particular – Biological E. Ltd Hyderabad. The Parliamentary Standing Committee on Health and Family Welfare in the 34th Vaccine Report has stated that in the two lists of functioning and non-functioning vaccine manufacturing units, furnished by the Ministry, the name of Biological E. Ltd Hyderabad is found in both the lists. The Committee would like to note here that either the Ministry had failed to provide complete information on the unit or had chosen not to do so. In either case, it is of the opinion that more transparency in the matter is required. The Committee is also not aware about the status of all the private units with which the Vaccine Procurement Cell has placed the orders alone. The Committee has demanded that it would like to be apprised as to whether all these units are GMP compliant. The Committee believes that since the CRI, Kasauli, BCG VL, Chennai and PII, Coonoor are in the public sector, vaccines were available to the people at cheap price, but once the manufacturing goes into the private hands as it has, there is every likelihood that the cost of the vaccines could go up in future, thus, defeating the very objective of providing highly essential drugs like vaccines to the people at affordable prices. (Department Related Parliamentary Committee on Health and Family Welfare, 34th Report, 2009).

Grant/renewal of licenses under Rule 64 of the Drugs and Cosmetics Rules:

In **Sagar Medical Hall v. State of Bihar**, a petition was filed against the order of the State government restraining the regional licensing authorities from issuing/renewing licence for the wholesale and retail sale of drugs. Here in the present case, grant and renewal of licence was refused only on the ground that as a matter of policy, the State Government has temporarily decided not to grant licence on the ground that number of shops available in the State is sufficient to meet the demand of the public. As stated earlier, the grant and renewal of drug licence is governed by the Rules and it nowhere provides that the licence can be declined or renewal can be refused on the ground that in the opinion of the State Government, the number of shops are sufficient to meet the demand of the public. The High Court therefore held that when grant or renewal of licence is governed by the statutory rule, decision of such a question has to be governed by the provisions of the Rules and executive decision taken by the State Government, cannot override the same. The decision of the state

can clearly be viewed as one hindering competition by limiting the number of suppliers that can operate in the market and therefore again assessed against the likely public benefits resulting from the operation of such a policy. In this case, the answer may be rather easy: Given the need for accessibility of medicines at affordable prices, a policy that limits its accessibility by limiting the number of shops is clearly anticompetitive and not backed by policy justification.

9. Other recommendations:

- Absence of provisions on regulation of biosimilars

  Manufacture and marketing of biosimilars, generic versions of biotech drugs in India are currently governed by the Environment Protection Act of 1970 and the Drugs and Cosmetic Act. Even though biosimilars is regulated under these provisions of these acts, there is no specific set of rules this sector in the country today. There is need to have a proper set of guidelines on regulation of bio similar which are growing market in India and will be more so after 2015 when patents on many biotech drugs will expire. Biogenerics space is being reviewed in a fresh context the world over. But specific guidelines on the same are missing. In light of the huge potential it holds in India's endeavor to grow as a powerful generics capital in the world, it is necessary that specific guidelines and regulations are formulated under the respective ministries without further delay. The domestic drug makers complain that in the absence of a time bound process of clearance as well as complex and tedious procedures for approval of biologics, they find themselves chasing their application from one ministry to the other and within one ministry.

  In view of India's potential to emerge as a key player in the biosimilar segment, the current lack of clear guidelines which address the issues at hand, poses a serious concern in terms of ensuring the safety of patients in India. There is an urgent need to establish robust guidelines which provide for the approval of biosimilars in India in an expedited manner whilst also ensuring that biosimilars which are developed, manufactured and marketed in India demonstrate safety, quality and efficacy in patients. Meeting global standards for safety and efficacy, will also allow for export of these products to other developed nations.

- Transferring the Department of Pharmaceuticals under the Ministry of Health and Family Welfare

  The Planning Commission's high-level experts' group on universal health coverage, headed by Dr K. Srinath Reddy in its report has said that public interest would be served best by transferring the department of pharmaceuticals to the health ministry. This recommendation should not be ignored as it is only appropriate that pharmaceuticals should be placed directly under the ministry which is responsible for

ensuring quality, safety and efficacy of drugs and is accountable for unhindered availability of all essential drugs in the public healthcare system.

- Assisting SMEs in overcoming entry barriers posed by GMP compliance requirements

GMP compliance is necessary to enhance the industry's credibility within the domestic and international markets. Different countries are now complying with the same. Other developing countries such as South Africa and Brazil have higher standards than us. China recently released its GMP Compliance Policy in 2011 which had taken five deliberations given the impact felt by SMEs who lack the financial and technical capacity to comply with these norms. The situation in India is not too different where SMEs have to struggle with this market barrier . The government can take some pro active steps in this regard especially given its importance and the fact that It already has undertaken initiatives through NIPER to engage with SMEs and build their technical capacity to help them with GMP compliance. Under some schemes, the government grants loans to such pharmaceutical companies too. However, a serious problem faced by small companies is the inability to produce high collaterals for such loan approvals. This is an area where the government initiatives are required. A representative from IPA has recommended that government needs to take on modernization and upgradation schemes in the manner that it did for textile sector.

REFERENCES

1. Espicom Business Intelligence Report, 2011.
2. CUTS International, "Unholy alliances in healthcare sector", June 2011.
3. WHO/HAI Report on Medicine Prices and Affordability, May 2011.
4. Amit Sengupta, "Study of National Health System in India with Regards Access to Health Care and Medicines," April 2010.
5. CCI Survey Report, "A Brief Report on Pharmaceutical Sector in India", January 2011.
6. CENTAD, "Competition Law and Indian Pharmaceutical Industry", 2010.
7. UNDP Report, "Five Years into the Product Patent Regime-India Response," December 2010.
8. McKinsey and Company Report, "India Pharma 2020: Propelling access and acceptance, realizing true potential,"2010.
9. Chirantan Chatterjee, "New Suppliers in Global Pharmaceuticals: Evolution of the Modern Pharmaceutical Industry in India - Policies & Case Studies," Doctoral Dissertation Proposal submitted to H. John Heinz III College School of Public Policy and Management, 2009.
10. 34th Report on the Functioning of the three Vaccine Producing PSUs, namely CRI (Kasauli), PII (Coonoor) and the BCGVL (Chennai), Department Related Parliamentary Standing Committee Report, February 2009.
11. Pharmaceutical Sector Inquiry: Final Report. Brussels, European Commission, DG Competition Staff Working Paper. Adoption Date: 8 July 2009.
12. CUTS Report, ""Options for Using Competition Law/Policy Tools in Dealing with Anti-competitive Practices in Pharmaceuticals and the Health Delivery System", September 2006.
13. Centre for International Public Health Policy, "Pharmaceuticals Distribution in India", University of Edinburg, 2007.
14. How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry. Washington DC, Congressional Budget Office, 1998.
15. *PHARMAC Annual Review 2001*, Wellington (New Zealand), Pharmaceutical Management Agency, 2001.
16. Overview of FTC Antitrust Actions in Pharmaceutical Services and Products. Washington DC, Federal Trade Commission (FTC), Healthcare Services and Products Division, Bureau of Competition, 2006.
17. Waning B, Maddix J, Tripodis Y, Laing R, Leufkens HGM, Gokhale M. Towards equitable access to medicines for the rural poor: analyses of insurance claims reveal rural pharmacy initiative triggers price competition in Kyrgyzstan. *International Journal for Equity in Health*, 2009.
18. Framework for the Design and Implementation of Competition Law and Policy, Washington DC, World Bank-OECD, 1999.
19. S. Narayan, "Price Controls on Pharmaceutical Products in India", ISAS Working Paper No. 20, 2007.

20. S. Srinivasan, " 'Medicines for All', the Pharma Industry and the Indian State", Economic and Political Weekly, June 2011.
21. Joe C Mathew and Nayanima Basu, "CCI should clear pharma M& As," Business Standard, September 27 2011.
22. Sangeeta Singh and Aman Malik, "Pharma deals set to face closer scrutiny", Mint, October 11 2011.
23. Dhanajay Mahapatra, "Centre gets Supreme Court notice on drug prices," The Times of India, October 12 2011.
24. Naveen Dahiya, "Competition Law as Patent Safety Net in the Pharmaceutical Industry", Competition Commission of India.
25. Geeta Gauri, "Competition issues in the Generic Pharmaceutical Industry in India," Competition Commission of India, April 2010.
26. Vasudha Wattal, "Identification of Competition Issues in Healthcare Sector in India," Competition Commission of India, 2010.
27. DIPP Draft Discussion Paper on Compulsory Licensing, August 2010. Available at: **dipp**.nic.in/CL-**DraftDiscussion**.doc
28. Sakthivel Selvaraj, "How Effective is India's Drug Price Control Regime?", Harvard School of Public Health, 2007.
29. Lee C. Model competition laws. In: Cook P, Fabella R, Lee C eds. , "Competitive Advantage and Competition Policy in Developing Countries", Cheltenham (UK), Edward Elgar Publishing, 2007.
30. Reddy and Sandhu, "Report on Steps to be taken by the Government of India in the context of Data Protection provisions of Article 39.3 of the TRIPS," Ministry of Chemicals and Fertilizers, 2007.
31. Vickers J. Abuse of market power. *The Economic Journal*, June 2005.
32. The 7th Report of the Standing Committee on Chemicals and Fertilizers on Availability and Price Management of Drugs and Pharmaceuticals, 2005.
33. M. Pugatch, "International political economy of intellectual property rights," Edward Elgar Publishing, 2004.
34. Cook P, Fabella R, Lee C, eds. Competitive Advantage and Competition Policy in Developing Countries. Cheltenham (UK), Edward Elgar Publishing, 2007.
35. Report of the European Generic Medicines Association, 2004.
36. UNCTAD Model Law on Competition. Geneva, United Nations Conference on Trade and Development, 2003.
37. Jean Lanjow, "The Introduction of Pharmaceutical Product Patents in India:
38. 'Heartless Exploitation of the Poor and Suffering?'Economic Growth Center, Yale University, 1997.
39. Fuchs, V. R., "Physician-Induced Demand: A Parable," Journal of Health Economics, Vol. 5, 1996.
40. Labelle, R. G. Stoddart and T. Rice, " A RE-Examination of the Meaning and Importance of Supplier-Induced Demand, *Journal of Health Economics*, Vol. 13, 1994.
41. Grabowski H, Vernon J. Brand loyalty, entry and price competition in pharmaceuticals after the 1984 Drug Act. *Journal of Law and Economics*, 1992.

42. World Health Assembly, Executive Board, 101st Sess., Resolution No. EB101/R.24, Revised Drug Strategy (January 27, 1998).
43. WHO Briefing Note, "Access to Essential Medicines", 2006 http://www.searo.who.int/LinkFiles/Global_Trade_and_Health_GTH_No3.pdf
44. SpicyIP, "Spuriousness of the Indian Law: Delinking IP from Drug Regulation", September 25 2009
45. Morgan S. et.al." Balancing health and industrial policy objectives in the pharmaceutical sector: lessons from Australia", Health Policy, Aug; 87(2):133-45, Mar 4 2008

ANNEXURE A

LEGISLATIVE PROVISIONS LIKELY TO IMPEDE COMPETITION

DRUGS AND COSMETICS ACT, 1940

	Provision	Enforce-ment Authority	Checklist Code	Impact on Competition	Recommendation
1.	Schedule M :Legislation ensuring Good Manufacturing Practices	Ministry of Health and Family Welfare	B4, B6	B4: The provision limits the ability of suppliers to compete as it sets standards for product quality that provide an advantage to some suppliers. A significant percentage of SMEs that are important because they produce affordable life saving drugs especially in rural areas are unable to comply with the requirements laid down in this schedule and the introduction of this requirement has led to closure of many of these units. This is a big entry barrier for SMEs to enter the market. B6: Another concern with these compliance standards is the ability to use the same by the government to act arbitrarily in procurement bids. The study highlights case studies where the government was found to have erroneously used such standards to discriminate in: a.Procurement process b.favouring private sector over public unjustly and thereby distort competitive neutrality	Many countries (developing) have enacted GMP such as China which introduced GMP Compliance Policy in 2011 after 5 deliberations because of the adverse impact on SMEs. Brazil and South Africa maintain higher standards of GMP than the current standards in India. GMP standars are necessary not only to ensure safety but also necessary for getting global market access. • Government support to boost SMEs through modernisation and upgradation schemes, ease in loan approvals etc. Government had taken initiatives through NIPER to provide technical support to SMEs. While it has also provided financial support, they have not come through as desired because the banks demand very high collateral security which small companies cannot afford. There is need to simplify the procedures for providing financial support to the SMEs. With enhanced technical upgradation and financial capacity, the SMEs will be able to lower these market barriers and gain easy entry. • Need for transparency in bidding processes.
2	Section 17B(b)	Ministry of Health and Family Welfare	A4, E3	A4: While it is good that significantly enhanced penalties have been prescribed for manufacture, sale and distribution of spurious drugs, a strong recommendation by the Mashelkar Committee, it is still a concern that the definition of spurious/counterfeit is ambiguous to a fault. The term “spurious drugs” has	In light of India’s applaudable efforts to not adopt the attempt by a WHO-led anti-counterfeiting task force (IMPACT) to expand the meaning of “counterfeit” to even catch legitimate generics, India’s very own definition of spurious drugs remains problematic. • Revisit the definition and clearly define or clarify that spurious relates to substandard drugs that pertains to safety and efficacy consideration

	Provision	Enforce-ment Authority	Checklist Code	Impact on Competition	Recommendation
				been defined so loosely so as to also include legitimate generics within its ambit. This is a problematic legal ground when assessed from the point of entry of generics into the market. The definition of "spurious drugs" as prescribed in section 17B(b) in particular is a market barrier that limits the ability of manufacturers and suppliers of generic drugs to operate freely in the market. E3: In cases where generic manufacturers use names similar to the original name, consumers may be confused and be led into thinking that the generic version may be an imitation used in a manner likely to deceive the consumer into believing that it is the original drug when in fact it is fake or spurious as under the definition 17B (b). The consumer would then mistakenly reject cheap generic drugs thinking them to be fake and substandard. Since generics are a lot cheaper than the original patented ones, in this manner, it limits the choices and information available to consumers by changing such important information needed by buyers to shop effectively.	• Delink IP with Regulatory issue • NCPC to build an advocacy agenda for a delinkage that facilitates backdoor monopoly protection strategies (data exclusivity and counterfeit issues)
3	Rule 64 Conditions to be satisfied before a licence in Form[20, 20-B, 20-F,20-G 21 or 21-B] is granted	Ministry of Health and Family Welfare	A2 & A3	According to sector study report rule 64 of The Drugs and Cosmetics Rules, 1945 licensing authority has used the power to refuse or renew the licences, on the ground other than what has been provided therein. The study comes out with conclusion that in practice the power to grant or renew licences has been used arbitrarily by government to limit the number or range of suppliers	Deviations from principles of competition are justifiable on grounds of social and environmental objectives provided they are notified and this requires to be done transparently and publicly (one of the principles advocated by the Australian National Competition Policy) • Need for such transparency and accountability to be ensured.

	Provision	Enforce-ment Authority	Checklist Code	Impact on Competition	Recommendation
				A2: These licensing requirements have been seen to create natural barriers affecting prospective entrants. A3: They have been used to limit the number of firms permitted to enter the market	

DRUG PRICE CONTROL ORDER 1995

	Provision	Enforcement Authority	Checklist Code	Impact on Competition	Recommendation
	Section 3 Fixation of maximum sale price of bulk drugs in the First Schedule	National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilizers	B1	Limits the ability of bulk manufacturers to set prices of bulk drugs (Price fixing per se anticompetitive under US Antitrust) and poses barrier to entry for a potential entrant since constrained to sell at fixed prices and prefer to sell to existing buyers (NPPP Draft 2011).	• A step has already been taken in this direction by the draft National Pharmaceutical Pricing Policy 2011 which should be welcomed and implemented. • The government should uphold this recommendation in its attempts at balancing entrepreneurial interests with consumer welfare together with the NPPA.
	Section 7 Calculation of retail price of formulation>The retail price of a formulation shall be calculated by the Government in accordance with the following formula namely: R.P. = (M.C. + C.C. + P.M. + P.C.) x (1 + MAPE/100) + ED. Where "R.P." means retail price; "M.C." means material cost and includes the cost of drugs and other pharmaceutical aids used including overages, if any, plus process loss thereon specified as a norm from time to time by notification in the	National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilizers	B1	This provision per se limits the ability of sellers to set the retail prices for formulations. According to sector study report Section 7 of Drugs (Price Control) Order, 1995 the cost-plus fixed percentage approach is with regards to the ability to obtain accurate information on production marketing and other costs as reported costs can be manipulated. Sector Study Report comes with a conclusion that such an approach also promotes inefficiency as producer has no incentive to	• Need for effective pricing mechanism is a must. • The draft National Pharmaceutical Pricing Policy has been circulated in 2011 that introduces the market based pricing approach looking at the weighted average of the top three brands to set the MRP. While this has been welcomed by the industry, there is apprehension that it would not address the affordability issue as it would only increase the prices considering the top three brands would have the highest selling drugs with huge profits.

	Provision	Enforcement Authority	Checklist Code	Impact on Competition	Recommendation
	Official Gazette in this behalf; "C.C." means conversion cost worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf; "P.M." means cost of the packing material used in the packing of concerned formulation, including process loss, and shall be fixed as a norm every year by, notification in the Official Gazette in this behalf; "P.C." means packing charges worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf; "MAPE" (Maximum Aflowable Post-manufacturing Expenses) means all costs incurred by a manufacturer from the stage of ex-factory cost to retailing and includes trade margin and margin for the manufacturer and it shall not exceed one hundred per cent for indigenously manufactured Scheduled formulations; "E.D." means excise duty: Provided that in the case of an imported formulation, the landed cost shall form the basis for fixing its price along with such margin to cover selling and distribution expenses including interest and importer's profit which shall not exceed fifty percent of the landed			reduce production costs and thereby affects competition. Sector Study Report suggests, while computing the price to be fixed, the cost of manufacture of generic drugs should be taken into account. This calculation also ignores the volatility in prices of raw materials, or the additional cost of ensuring quality. The Report comes out with the finding that price of imported medicines are calculated on the basis of declared landed cost. However, there is no mechanism to verify whether the declared cost is true.	

	Provision	Enforcement Authority	Checklist Code	Impact on Competition	Recommendation
	cost.				
2	Section 8 Power to fix retail price of Scheduled Formulations: 1. The Government may, from time to time, by order, fix the retail price of a Scheduled formulation in accordance with the formula laid down in paragraph 7	Ministry of Chemicals and Fertilizers Department of Chemicals and Petrochemicals	B1 & C1	This provision per se again limits the ability of sellers to set prices for goods and services. Furthermore, it reduced the incentive of suppliers to compete by creating a self-regulatory or co-regulatory regime. According to Sector Study Report Section 8 of Drugs (Price Control) Order, 1995 Government has power to fix retail price and there is scope for informal collusion of the pharmacists at the local level. National Pharmaceutical Pricing Authority (NPPA) price is the ceiling on the retail price and need not be the actual selling price. However report suggests that retailers do not compete and the MRP becomes the reference price for them to collude informally.	There is need to promote competition across the pharmaceutical value chain. Need to promote competition among wholesalers and retailers.

THE INDIAN MEDICAL COUNCIL PROFESSIONAL (PROFESSIONAL CONDUCT, ETIQUETTE & ETHICS) REGULATIONS, 2002

	Provision	Enforcement Authority	Checklist Code	Impact on Competition	Recommendations
1	Section 1.5: Use of Generic names of drugs. - Every physician should, as far as possible, prescribe drugs with generic names and he/she shall ensure that there is a rational prescription and use of drugs.	Medical Council of India	E1 & E3	According to sector study the provisions of Section 1.5 of The Indian Medical Council (Professional, Conduct, Etiquette & Ethics) Regulations 2002, tries to guard against that but is weak and lacks teeth as it does not prescribe any punishment for failure to comply. There have been several evidences where doctors act contrary to this and prescribe only the branded drugs even when cheaper versions of generics are available and thereby	• Need to attack information asymmetry through advocacy. • Necessary to strengthen the public information system where generic drugs are known to consumers. • Need to promote non branded generics through Jan Aushadhi Scheme • Educating doctors and holding them accountable • Greater Accountability for irrational prescriptions

	Provision	Enforcement Authority	Checklist Code	Impact on Competition	Recommendations
				limit the choices and information available to consumers who go solely by what the doctors have prescribed and do not buy cheaper generic medicines. This also changes all the necessary information that they require in order to shop effectively by not revealing anything about the existing generic versions.	

INDIAN PATENT ACT 1970

	Provision	Enforce-ment Authority	Checklist Code	Impact on Competition	Recommendations
1	Section 3 : What are not inventions (d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. (e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance; (i) any process for the medicinal, surgical, curative,	Controller General, Ministry of Commerce and Industry, Departmen t of Industrial Policy and Promotion	A1, A4	According to sector study report, Section 3 provisions especially Section 3(d) are seen as a safeguard against ever-greening of patents but is much in debate due to the large number of efforts on part of big pharmaceutical companies to delay generic entry into the market and prolong monopoly status in the pharmaceuticals market. There is therefore great pressure on India for modifications to the same. According to sector study report if this act is vigorously applied, these provisions have the potential to make a substantial portion of "new" drugs open to generic competition by removing patent barriers. The Sector Study report notes that concerns remain regarding its implementation and interpretation by the Indian Patent Office which has in some instances been erroneously applied to	• Need to sensitize Patent Office and DIPP on the anticompetitive effects of granting questionable patents where the government could play a role.

	Provision	Enforce-ment Authority	Checklist Code	Impact on Competition	Recommendations
	prophylactic [diagnostic, therapeutic] or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.			grant exclusive rights when there was no invention (A1) and results in limiting the ability of some types of suppliers to provide a good or service.	
2.	Section 25 Pre Grant Opposition	Controller General, Ministry of Commerce and Industry, Departmen t of Industrial Policy and Promotion	A1, A4	This provision gives an opportunity to further examine and oppose the grant of a patent monopoly so as to prevent exclusive rights being granted for a supplier wrongly and as a result limit the ability of generic suppliers to provide cheap low costing drugs.	Granting patents of questionable validity which happens when patent examiners do not carefully evaluate the patents due to the large number of applications has been seen to stifle innovation and delaying generic entry. US FTC in a 2003 report highlighted that questionable patents can deter or raise the costs of innovation, defensive patenting and licensing. This may prove anticompetitive. This provision addresses many abuses of anticompetitive nature such as the problem of patent clusters i.e. filing numerous patents for the same medicine which is used as a strategy to delay/block generic entry into the market and create uncertainty as to when generic competitors can start developing a generic medicine which does not infringe the patents. Through pre-grant oppositions under Section 25(1) such wasteful litigation could be avoided at a later stage. While the pre-grant oppositions can delay the entire procedure, in the longer run it would serve better to make the market more competitive.
3.	Section 84 Compulsory Licensing	Controller General of Patents, Ministry of Commerce and Industry	A1, A4, E1	At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory licence	This provision is one major opportunity to ensure availability, accessibility and affordability of medicines on public health grounds but unfortunately has not been utilized. Critical attention has to be paid to this where CCI has a

	Provision	Enforce-ment Authority	Checklist Code	Impact on Competition	Recommendations
				on patent on grounds of public health. Therefore, if this provision is not used effectively then it would not only provide exclusive rights to some suppliers(A1), it would limit the ability of generic suppliers to compete (A4) and in the end limit the choices available to consumers giving them no option but to purchase the high priced patented drugs (E1)	big role to play in ensuring that generic competition is promoted and public health objectives are served.
4.	Section 92 If the Central Government is satisfied, in respect of any patent in force in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, that it is necessary that compulsory licenses should be granted at any time after the sealing thereof to work the invention, it may make a declaration to that effect	Controller General of Patents, Ministry of Commerce and Industry, Departmen t of Industrial Policy and Promotion	E1	This provision is significant again in terms of public health grounds and while the Government has been empowered to do so, there have been no cases where it has invoked compulsory licensing despite over half of the population that is denied access to critical medicines. This has led to consumer welfare loss and has limited their choices to the available high cost patented drugs.	Ministry of Health to ensure that the effective tool of compulsory licensing is utilised wherever to break the patent monopoly and open markets to competition and the introduction of generics.
3	107A Certain acts not to be considered as infringement: any act of making, constructing, [using, selling or importing] a patented invention solely for uses reasonably relating to the development and submission of information required under any law for the time being in force,	Controller General of Patents, Ministry of Commerce and Industry, Departmen t of Industrial Policy and Promotion	A4, E1	Commonly known as the Bolar provision, the research exemption generally enables manufacturers of generic drugs to use a patented drug to get marketing approval without the patent owner's permission before the patent expires. The generic manufacturer can then market their own version of the patented drug once the patent expires. This provision has not been	Use of Bolar provision is limited in India which is unfortunate considering how many other developing and developed countries have introduced the same in their patent regimes and there have been several cases on this too. In a case Ono pharmaceuticals v. Kyoto Pharmaceuticals, Japanese Supreme Court rightly reasoned that to read this exception narrowly so as to allow patentees to prevent experiments required to allow others to market a medicine that had been the subject of patent

	Provision	Enforce-ment Authority	Checklist Code	Impact on Competition	Recommendations
	in India, or in a country other than India, that regulates the manufacture, construction, [use, sale or import] of any product			used much in India even though it is a pro competitive provision as it facilitates the process of generic manufacture. Not using this provision adequately would have a limiting impact on manufacturers of generics and eventually the final consumers who are denied the choice of low cost generic medicines as a result once a patent expires.	protection until after the patent had expired would have the effect of extending the effective life of the patent. In China, in the case of Sankyo Pharmaceutical v. the Beijing Wansheng Drug Industry the Beijing Second Intermediate People's Court ruled that clinical trials conducted by Sankyo alleged to have infringed Wansheng's PRC patent were not for "immediate" commercial purposes or direct sales. Instead, the court found that the limited production of these pharmaceuticals was intended to establish the safety and efficacy of the drug for an eventual application for administrative approval to the PRC's State Food and Drug Administration (SFDA) and therefore found them not to have infringed the patent, applying correctly the research exemption.
4.	Section 107A(b) Parallel Imports	Controller General of Patents, Ministry of Commerce and Industry, Departmen t of Industrial Policy and Promotion	A6	The provision on parallel imports is a TRIPS flexibility that can be well used for lowering georgraphical barriers for entry of low cost drugs. Since this allows India to be able to produce generic versions of a patented drug in a country and import the same in India and thus ensure lower priced patented goods for its own consumers, it enables such pharmaceutical companies to supply generic low cost drugs in different countries that are authorised to sell and manufacture those patented products once the patent rights are exhausted.	India operates under an international exhaustion doctrine that makes such parallel imports possible and useful. Furthermore, what is not known is that parallel imports have been interpreted by Courts to apply to exhaustion both of product patents as well as process patents. This opens many options to make available low cost drugs through imports from other countries that fall within the ambit of the prescribed law. It is therefore time to visit this provision and make use of the opportunity that it presents to contribute towards making affordable health care possible by lowering geographical barriers.

TRADE RELATED INTELLECTUAL PROPERTY RIGHTS, 1995

	Provision	Enforcement Authority	Checklist Code	Impact on Competition	Recommendations
	Article 39.3 Protection of Undisclosed Information	Controller General of Patents, Ministry of Commerce and Industry, Department of Industrial Policy and Promotion	A1, A4	On a plain reading of the relevant portion of the TRIPS Agreement, Article 39.3(2) only requires protection of expensive, undisclosed data submitted to drug regulatory agencies against "unfair commercial use" . It does not state that exclusive rights must be provided for a given period. In fact, TRIPS makes clear that countries may decide for themselves what constitutes "unfair commercial use" and that there are many possible approaches to satisfy this requirement. Therefore interpreting this provision in such a fashion would be TRIPS plus and guarantees additional market protection for originator pharmaceuticals by prevents authorities from accepting applications for generic medicines during the period of exclusivity regardless of whether patent is eventually granted. The impact of this on generics goes without saying. It grants additional exclusive rights to originator company and these companies can prevent their competitors from obtaining marketing licence for low-cost versions during the tenure of this exclusivity. While it however does not legally prevent other companies from generating their own registration. But in practice the vast financial resources and extended time required for gathering and generating pharmaceutical registration data for a new drug may create a market barrier for generic based companies and limiting their ability to produce low cost generics.	India has been against inclusion of data exclusivity despite the pressure from USA earlier and now by EU under the Free Trade Agreement demanding data exclusivity for clinical trial data for a period of ten years. Shri Anand Sharma has rightly called this a TRIPS plus obligation that we need not comply with in any way including any free trade agreements. The impact of such inclusion would be monstrous on the generic manufacturing companies.

COMPETITION ACT, 2002

	Provision	Enforcement Authority	Checklist Code	Impact on Competition	Recommendations
	Section 3: Anticompetitive agreements	Competition Commission of India	E1, E3	Consumers are hit by high prices as a result of such collusion.	• CCI to undertake more investigations and inquiries along the pharmaceutical supply and distribution chain.
	Section 5 and 6: Regulating Combinations	Competition Commission of India	E1	Acquisitions of generic companies might change their priorities and dictate high prices of medicines.	• Arun Maira Committee recommendations: Exempt pharma companies from the threshold requirements which would bring two thirds under CCI scrutiny • Introduce Public Interest Criteria for merger clearance like South Africa .e.g. Clicks Pharmaceutical Wholesale Ltd and New United Pharmaceutical Distributors was also viewed against its impact on public interest and when none was found "to alter the conclusion", it was cleared. • Give merger approvals on conditionalities like China has done for 6 mergers since its newly constituted Anti-Monopoly Law in 2008 • Concerns regarding CCI's capacity to scan pharma mergers given technicalities remain – Need for coordination