COMPETITION ASSESSMENT OF 
PHARMACEUTICAL SECTOR IN INDIA

INTERNSHIP PROJECT REPORT

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DISCLAIMER

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LIST OF ABBREVIATIONS

AIOCD - All India Organization of Chemists and Druggists
BICP - Bureau of Industrial Costs and Prices
CAF - Competition Assessment Framework
CAGR – Compound Annual Growth Rate
CBO - Congressional Budget Office
CCI – Competition Commission of India
CUTS – Consumer Unity and Trust Society
DCGI – Drug Controller General of India
DIPPCO – Department of Industrial Policy and Promotion
DPCO - Drug Prices Control Order
EC – European Commission
FDA - Food and Drug Administration
FERA - Foreign Exchange Regulation Act
FTC – Federal Trade Commission
NDP - National Drug Policies
NPPA - National Pharmaceutical Pricing Authority
TRIPS - Trade-Related Aspects of Intellectual Property Rights
WHO – World Health Organization
CHAPTER - 1

INTRODUCTION

The Indian pharmaceutical sector has come a long way, from being a small player in 1970, to becoming a prominent provider of healthcare products, meeting almost 95 per cent of the country’s pharmaceutical needs today. As per an estimate by Mckinsey & Co, the pharmaceutical industry in India has a unique and exciting opportunity to grow about from US $5.5 bn in 2000 to US $25 bn in 2020.

However, there are some doubts in some quarters if further growth and internationalization of the industry, in the changed scenario of a new patent regime and a deregulated environment, will benefit the common people by providing better access to affordable medicines. Since, 1970, the prices of essential drugs have been regulated by the Drug Prices Control Order (DPCO), with the National Pharmaceutical Pricing Authority (NPPA) fixing the prices of a range of drugs, since its establishment in 1997. Even though, over the last few years, a substantial decontrol of prices has taken place.\(^1\) The Drug Policy, 1994 needs to be revised to meet the challenges brought about the competitive international pharmaceutical industry in a globalised economic environment, as much as meeting the country’s requirements for safe and quality medicines at reasonable prices. Therefore, the government enunciates the National Pharmaceuticals Pricing Policy, 2011.

India accounts for 8 % of global pharmaceutical production. It is the third largest in terms of volume and fourteenth in terms of value. Indian firms produce about 60000 generic brands across 60 therapeutic categories and 500 active pharmaceutical ingredients (APIs) approximately. India boasts an export of generic drugs worth US $11 billion and the generic drug market is predicted to grow at a CAGR of 17 per cent between 2010-11 and 2012-13.\(^2\)

Pharmaceutical policy in India is perceived as industrial policy rather than health policy. The formulation of pharmaceutical policy, therefore, has traditionally been the responsibility of the

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Department of Petrochemicals in the Central Ministry of Chemicals and Fertilizers, with only limited input being provided by the Ministry of Health and the Bureau of Industrial Costs and Prices (BICP) of the Ministry of Industry.

In India, the pharmaceutical sector is affected by a complex variety of laws and policy instruments. Not all of these regulations, however, form part of the National Drug Policies (NDPs) that have been promulgated from time to time by the Ministry of Petroleum and Chemicals. In addition to the national drug policies, the Drug Price Control Orders (DPCOs), the National Industrial Policies, the Foreign Exchange Regulation Act (FERA), and the Indian Patents Act (IPA) also have an impact on the pharmaceutical industry.

Since 1947, the objectives of the Indian government regarding pharmaceuticals have remained the same: promotion of the domestic industry and ensuring adequate access to good quality drugs. The period between 1947-1969 was characterized by minimal government regulations, during which the multinational corporations (MNCs) dominated the sector. The second period, between 1970 and 1990 was a period of intense government regulatory oversight, with the MNCs being a particular target of the regulation. A number of public corporations also sprang up during this time. The 1990s, on the other hand, were a period that witnessed a substantial relaxation of government controls over the pharmaceutical industry.  

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India's pharmaceuticals industry

India to be one of the top 10 sales markets in the world!

Indian pharmaceuticals market (US$ bn)

CAGR = 14.5%

2005: 5.8
2009: 126
2010: 14.4
2015F: 284
2020F: 55.9

Source: India Pharma 2020, McKinsey & Company

Nature of the pharmaceuticals market

4 http://www.slideshare.net/aceglobal1/indian-pharmaceutical-sector-2011
Despite being highly fragmented, it is concentrated as well. Around 250-300 companies control 70% of the total market share.

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6 Supra note 4, also available at: http://www.kpmg.de/docs/Pharma_Summit_2009.pdf
Key Players (Indian and foreign) that enjoy a dominant position in the Indian pharmaceutical industry.

Source: Ace Global Consulting LLP

7 Supra note 4

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CHAPTER - 2

MARKET STRUCTURE AND COMPETITION ISSUES

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 while evidence seems to suggest that there is high market concentration in these markets.\(^8\) It needs no reiteration that consumer sovereignty simply does not exist in the pharmaceutical market. Since the consumers’ demand is essentially supply-driven (supplier-induced demand) in the pharmaceutical market, the physician or the pharmacist has no incentive to be price-sensitive\(^9\). It needs no reiteration that consumer sovereignty simply does not exist in the pharmaceutical market.

The usual assumption that market mechanisms stabilize prices does not hold entirely true for the pharmaceutical industry. This is because unlike consumer goods, drugs are not purchased by the consumer on the basis of his choice or preference. They are purchased on the advice of the medical professionals. Hence there is no escape when drug companies build a market for their drugs through their extensive marketing network that target medical professionals and chemists with a variety of marketing techniques. Consumers have little or no choice in such a ‘rigged’ market and buy what is prescribed by Doctors or what are sold by Chemists.\(^10\)

The main anti-competitive issues in the pharmaceutical sector are centered on anti-competitive agreements and collusive practices along the supply and distribution chains. There was an international cartel of bulk vitamins present for quite some time and cost in India about US$25mn, in the 1990s, as a result of overcharging. Although no domestic cartel in pharmaceuticals have been detected so far. For example, most pharmacy owners in India are members of a trade association, All India Organization of Chemists and Druggists (AIOCD).


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. Some of these unethical practices were pertaining to irrational drug prescriptions by doctors motivated by kickbacks received from pharmaceutical companies.

Another anti-competitive practice prevalent in the pharmaceutical sector is that of abuse of dominance. In 2005, India amended its Patents Act, 1970 to come into full compliance with its obligations under the TRIPS Agreement. Grave concerns were raised about access to affordable essential medicines and its heightened vulnerability to monopolistic abuse. The most common form of abuse of dominance is excessive or over-pricing. To illustrate this, we take the example of Novartis which exercised its exclusive marketing rights granted in India under the product patent regime. Novartis’ Glivec is used for treatment of Chronic Myeloid Leukaemia. There was an increase in the price of the drug from $90 to $2610 as a result of the exclusive marketing rights which put the drug out of reach of approximately 24000 patients in India who suffer from this disease. A big impediment to competition in the pharmaceutical sector is the high barriers to entry raised by market players abusing their monopoly for manufacturers of generic drugs.

**GENERICS 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. 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 prevent 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. 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.  

The third area of concern from a competition point of view is with regard to the growing trend of mergers and takeovers in the pharmaceutical sector.

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 Janumet (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.

While mergers and takeovers have their advantages their anticompetitive effects cannot be ignored. It is important here to assess the impact of combinations on innovation markets. ‘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.’

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Competition Assessment of Pharmaceutical Sector in India

may 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. 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-Synthelabo 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.14

The Drug Price Control Regime

Drugs are essential for health of the society and have been declared as essential under the Essential Commodities Act. All formulations containing these bulk drugs either in a single or combination form fall under the price control category. However, the prices of other drugs can be regulated, if warranted in public interest. For the purpose of implementing provisions of DPCO, powers of the Government have been vested in the National Pharmaceutical Pricing Authority (NPPA). A grave concern has been the decreasing number of drugs under statutory control in the wake of liberalization 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.15

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.

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. The Court held that even though 2010 parliamentary standing committee report as well as a 2005 standing committee report of the ministry of chemicals and fertilizers had admitted that essential medicines were not available to the poor at reasonable prices and had expressed concerns with regards to the gradual decrease in the number of essential medicines.
CHAPTER - 3

LEGAL PROVISIONS IMPEDING COMPETITION

a. Pharmaceutical Sector Laws, Regulations and Policies

DRUGS AND COSMETICS ACT AND RULES

Drugs and Cosmetics Act, 1940 is the law which regulates the import, manufacture, distribution and sale of drugs and cosmetics in this country. The main object of the Act, as it is observed by the Supreme Court in *Chimanlal Jagjivindas Sheth v. State of Maharashtra*\(^\text{16}\) is to prevent sub-standards in drugs presumably for maintaining high standards of medical treatment. The abovementioned act is to be read together with the Rules (Drug and Cosmetic Rules, 1945). Some of the rules also have the potential of being abused or implemented arbitrarily having detrimental effects on competition.

According to *Section 10A of Drugs and Cosmetics Act, 1940*: …If the Central Government is satisfied that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or any drug does not have the therapeutic value claimed for it …and that in the public interest it is necessary or expedient so to do then, that Government may, by notification, prohibit the import of such drug or cosmetic.

These provisions have been further strengthened in *Vincent Panikurlangara v. UOI*\(^\text{17}\) where the SC held that the government when prescribing adequate number of formulations to meet the requirements of public at large should totally eliminate injurious drugs from the market.

The provisions vest control in the government to make decisions to eliminate certain drugs from the market on grounds of public interest but have to be monitored carefully due to their potential to promote anti-competitive behaviour.

\(^{16}\) AIR 1963 SC 665
\(^{17}\) AIR 1987 SC 990
Section 16 and Schedule M to the Rules on Good Manufacturing Practices

Standards of quality

(1) For the purposes of this Chapter, the expression "standard quality" means--

(a) in relation to a drug, that the drug complies with the standard set out in the Second Schedule, and

(b) in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed.

(2) The Central government after consultation with the Board and after giving by notification in the Official Gazette not less than three months notice of its intention so to do, may by a like notification add to or otherwise amend the Second Schedule for the purposes of this Chapter, and thereupon the Second Schedule shall be deemed to be amended accordingly.

Here the provisions regarding standards of quality have often been abused to create artificial barriers to entry for others while creating favourable conditions for some.

According to Rule 85 of Drug and Cosmetic Rules, 1945 the Central Licensing Approving Authority may, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons thereof, cancel a license issued under this part, or suspend it for such period as he thinks fit either wholly or in respect of any of the drugs to which it relates (or direct the licensee to stop manufacture, sale or distribution of the said drugs and (thereupon order the destruction of drugs and) the stock thereof in the presence of an Inspector) if in his opinion, the licensee has failed to comply with any of the conditions of the licensee or with any provisions of the Act or rules made there under.

This rule has been abused in a recent instance where the Ministry of Health and Family Welfare suspended the manufacturing licenses of three vaccine manufacturing PSUs in 2008 and thereafter the government has only been purchasing vaccines from private players. The Parliamentary Standing Committee has demanded that this closure be revisited.
CHAPTER - 4

COMPETITION ASSESSMENT FRAMEWORK

CHECKLIST

Check is a statute, regulation, policy statement and practice have any of the following effects.

A. Limits the number or range of suppliers
B. Limits the ability of suppliers to compete
C. Reduces the incentives of suppliers to compete
D. Regulatory and policy barriers
E. Limits the choices and information available to consumers.

Application of Competition Assessment Framework (CAF) to the laws, rules and practices within the purview of the Drugs and Cosmetics Act and Rules

DRUGS and COSMETICS ACT, 1940

1. Sections 10A of Drugs and Cosmetics Act, 1940

Limiting Supply in Public Interest

The provisions vest control in the government to make decisions to eliminate certain drugs from the market on grounds of public interest. From a competition perspective, such provisions essentially allow the government to limit the number or range of suppliers in the relevant market therefore falling within the purview of condition A by potentially limiting the ability of some types of suppliers to provide a good or service by banning them on the grounds of public interest. Not to say that such policy objectives are not compelling or that injurious drugs should not be banned. But it is necessary to ascertain this clearly which can be done by demonstrating transparently the impact of such drugs and the harm arising out of them thereby justifying the reasons for such entry barriers. This would prevent undue dampening of competition in the relevant market in the instances that such provisions are abused in the garb of public policy rationales.
2. Provision: Section 16 of the Drugs and Cosmetics Act, 1940

Setting Arbitrary Quality Standards

The provision under Section 16 of the Act has the potential of abuse which has also been seen in practice. It has been implemented in the past in a manner to favour some firms over others thereby limiting the ability of suppliers to compete (Condition B) by setting standards for product quality that provide an advantage to some suppliers over others and are therefore arbitrary.

In the case of *Bharat Biotech International Ltd. v. A.P. Health and Medical Housing and Infrastructure Development Cooperation*\(^{18}\), 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.

Such barriers to entry in the relevant markets created with a justification to ensure quality need to be assessed carefully against the extent of the impact on consumers and producers.

3. Rule 64 of Drugs and Cosmetics Rules, 1945

The abovementioned rule deals with the power to grant and renew licenses. This provision also needs to be scrutinized closely due to its potential to be abused which can hamper market competition under condition A by limiting the number or range of suppliers that may be allowed to enter the market.

In the case of *Sagar Medical Hall v. State of Bihar*\(^{19}\), 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

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\(^{18}\) 2003 (1) ALD 463
\(^{19}\) Case decided on 7th December 2001, available at: http://www.indiankanoon.org/doc/806287/
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 is 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.

4. Rule 85: Authority to cancel/suspend a license

Closure of Vaccine Manufacturing PSUs

This may be a case of abuse of regulation on part of the Ministry which has led to a situation of
reverse competitive neutrality and a distorted level playing field for the public sector
competitors. It is important to note that 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.20 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.

20 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. Available

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DRUGS PRICE CONTROL ORDER, 1995

Section 7: Calculation of retail price of formulation

\[ R.P = (M.C + C.C + P.M + P.C) \times (1 + MAPE/100) + \text{Excise Duty} \]

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 cost.

This is the cost-plus fixed percentage approach. The problem with this approach is with regards to the ability to obtain accurate information on production marketing and other costs as reported costs can be manipulated. Such an approach also promotes inefficiency as producer has no incentive to reduce production costs and thereby affects competition. Similarly, while computing the price to be fixed, the cost of manufacture of generic drugs should be taken into account. In no case should the notified price be more than the average price of generic manufacture. This calculation also ignores the volatility in prices of raw materials, or the additional cost of ensuring quality.

Price of imported medicines is calculated on the basis of declared landed cost. However, there is no mechanism to verify whether the declared cost is true. One study revealed that MNCs are more interested in importing to India rather than producing in India because the transfer pricing loophole would give them an incentive to produce drugs elsewhere and then import them into India. This provision can therefore be abused by them to gain an advantage over others.

But now the regulation of prices of drugs in the National Pharmaceuticals Pricing Policy 2011 would be on the basis of regulating the prices of formulations only.\(^\text{27}\)

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\(^{21}\) Retail Price
\(^{22}\) MC is the material cost, including cost of bulk drugs/excipients.
\(^{23}\) CC is the conversion cost as per the dosage form.
\(^{24}\) PM is the cost of packaging material.
\(^{25}\) PC is the packaging charge, worked out in accordance with established costing procedures.
\(^{26}\) MAPE is the Maximum Allowable Post-manufacturing Expenses.
\(^{27}\) http://pharmaceuticals.gov.in/mshT2810/FTY2.pdf
Under Section 8(2) of DPCO, 1995: Where the Government fixes or revises the price of any bulk drug under the provisions of this Order and a manufacturer utilizes such bulk drug in his Scheduled formulations he shall, within thirty days of such fixation or revision, make an application to the Government, in Form-III for price revision of all such formulations and the Government may, if it considers necessary, fix or revise the price of such formulation.

However, in the case of downward revision in bulk drug prices, manufacturers seldom apply for price revision. It observes that “drug companies fail to furnish information as prescribed under DPCO ’95, but no specific provision for punitive actions are there in DPCO’95 to take action against errant companies/units”. As a result the manufacturers lack sufficient incentive to lower the drug prices.  

Sections 3, 8 and 9 of DPCO, 1995 deal with the fixing prices of Scheduled drugs

There are no provisions of fixing prices of substitutes of scheduled drugs as a result; companies continue to charge high prices through creating substitutes thereby hurting consumers who could otherwise gain through lower prices. An example of such a practice is the substitution of Psuedoephedrine with Phenylpropanolamine (PPA). Actifed, an international brand of Glaxo for cough and cold, contains psuedoephedrine. However, in India it contains PPA. In high doses, PPA has been found to enhance the risk of cerebrovascular accidents. Glaxo preferred to use PPA in India because while psuedoephedrine is under price control, PPA is not. It observes “in some cases, it has been noticed that whenever Government/NPPA fixes/revises ceiling or non-ceiling price of medicines/formulations some drug companies change the composition of the medicines/formulations and obtain new licenses from respective State Drug Controller/Licensing Authority. The State Drug Controller/Licensing Authority should not allow change in composition without any valid ground and without consulting DCGI and NPPA”.

29 Supra note 13
INdian medical council (Professional Conduct, Etiquette and Ethics) Regulations, 2002

In exercise of the powers conferred under section 20A read with section 33(m) of the Indian Medical Council Act, 1956, the Medical Council of India, with the previous approval of the Central Government, provides for regulations relating to the Professional Conduct, Etiquette and Ethics for registered medical practitioners as under these Regulations. But unfortunately, despite the serious medical malpractices that go on, there is little regulation on the actions of health care providers.

According to Regulation 1.5 Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002: 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.

Generic drugs are essential for effective competition and making medicines available at low prices to consumers. However, due to the various collusive arrangements, doctors often end up prescribing branded and expensive drugs instead of the cheaper generics.

This provision tries to guard against that but is weak and lacks teeth as it does not prescribe any punishment for failure to comply. One way, often suggested, of checking the rent-seeking behaviour of the doctors, as has been successfully experimented, even in neighbouring Bangladesh, is to mandate doctors to prescribe drugs with generic names. However, given the enormous clout of the pharmacists in India, this mandate has not worked. What is, thus, desperately required in India, is an effective mechanism to contain the rent-seeking behaviour of the doctors and pharmacists so as to check the anti-competitive practices in this market.
INDIAN PATENT ACT, 1970 AND THE TRIPS AGREEMENT

COMPETITION ANALYSIS

I. Section 3(d) of The Patents Act, 1970 and delay of generic medicines in the pharmaceutical sector

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. 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%.  

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 High Court.

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30 Section 3(d) of The Patents Act, 1970: The mere discovery of any new property of 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.

and the Supreme Court. And finally, the much controversial case of Novartis which had challenged Section 3(d) of the Indian Patents Act, 1970 claiming immunity for their drug Gleevec, a major drug for leukemia on the pleas that the new Gleevec was a major improvement over 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 Gleevec.32

II.  **Pre Grant oppositions under Section 25 and effects on competition**

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 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. It is important however to interpret this provision keeping in view the objectives of patent law and hence using these rights to ensure ex ante competition by allowing blocking patents to be appropriately screened. The provision has its limitations as its use depends on the ability of stakeholders to litigate in courts. Besides many may and have used it for strategic reasons rather than to ensure quality of patents and preserving competition.

III. Data exclusivity

India has not had a strict regime that protected secrecy of data submitted by pharmaceutical companies to regulatory agencies. Many MNCs hold the view that this has helped the generics industry immensely to reverse engineer and make cheaper versions of drugs. In fact it has been debated that in India, the absence of data exclusivity legislation has resulted in serious commercial clashes between researches based pharmaceutical MNCs and powerful local generic based companies.\(^33\)

Data exclusivity guarantees additional market protection for originator pharmaceuticals and prevents the regulatory authorities from assessing the safety and efficacy profile of a generic application for a period of time and therefore prevents authorities from accepting applications for generic medicines during the period of exclusivity.\(^34\) 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\(^35\)

C. INTERACTION WITH RELEVANT PROVISIONS OF COMPETITION ACT OF 2002

Since hospitals, health professionals, health insurers, pharmaceutical firms, pharmacists, etc. perform economic activities thus they can be considered to be undertakings and hence are subject to competition rules.

Competition is not an end in itself – it is a means to the objective of economic efficiency. It benefits consumers by restraining prices and encouraging companies to innovate to provide

\(^{33}\) M. Pugatch, “International political economy of intellectual property rights,” Edward Elgar Publishing, 2004. Available at: http://books.google.co.in/books?id=hLP13Ki7MhUC&pg=PA286&lpg=PA286&dq=M.+Pugatch,+%E2%80%9CInternational+political+economy+of+intellectual+property+rights,%E2%80%9D+Edward+Elgar+Publishing,+2004.&source=bl&ots=nQBh8jYhB&sig=9Oo5VDOOuUXyrmTmEl6jWzN94&hl=en&sa=X&ei=jnRT-nENc7wrQeIh9DLBw&ved=0CDoQ6AEwAQ#v=onepage&q=M.%20Pugatch%2C%20%E2%80%9CInternational%20political%20economy%20of%20intellectual%20property%20rights%2C%E2%80%9D%20Edward%20Elgar%20Publishing%2C%202004.&f=false


better quality for the price paid. However, in some circumstances a monopoly or coordinated network of companies may be the most efficient arrangement such as where there are substantial economies of scale. Competition laws usually allow the competition authorities to assess the trade-off between the costs or harm to consumers of permitting a monopoly, versus potential benefits (e.g. economies of scale, better coordinated service). The relevant geographic market of pharmaceuticals for the purpose of study would mainly mean national markets within India.

The main anticompetitive practices that occur in the pharmaceutical sector may be primarily categorized as breaches of intellectual property rights, anti-competitive agreements and anticompetitive mergers and takeovers.

**Anti-competitive agreements and collusive practices**

**Section 3** of Competition Act, 2002 deals with anti-competitive agreements. The specific anti-competitive practices of the pharmaceutical sector are covered under Section 3 of the Act are

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37 (1) No enterprise or association of enterprises or person or association of persons shall enter into any agreement in respect of production, supply, distribution, storage, acquisition or control of goods or provision of services, which causes or is likely to cause an appreciable adverse effect on competition within India.

(2) Any agreement entered into in contravention of the provisions contained in subsection (1) shall be void.

(3) Any agreement entered into between enterprises or associations of enterprises or persons or associations of persons or between any person and enterprise or practice carried on, or decision taken by, any association of enterprises or association of persons, including cartels, engaged in identical or similar trade of goods or provision of services, which—

(a) directly or indirectly determines purchase or sale prices;
(b) limits or controls production, supply, markets, technical development, investment or provision of services;
(c) shares the market or source of production or provision of services by way of allocation of geographical area of market, or type of goods or services, or number of customers in the market or any other similar way;
(d) directly or indirectly results in bid rigging or collusive bidding, shall be presumed to have an appreciable adverse effect on competition:

Provided that nothing contained in this sub-section shall apply to any agreement entered into by way of joint ventures if such agreement increases efficiency in production, supply, distribution, storage, acquisition or control of goods or provision of services.

Explanation.—For the purposes of this sub-section, "bid rigging" means any agreement, between enterprises or persons referred to in sub-section (3) engaged in identical or similar production or trading of goods or provision of services, which has the effect of eliminating or reducing competition for bids or adversely affecting or manipulating the process for bidding

(4) Any agreement amongst enterprises or persons at different stages or levels of the production chain in different markets, in respect of production, supply, distribution, storage, sale or price of, or trade in goods or provision of services, including—

(a) tie-in arrangement;
(b) exclusive supply agreement;
(c) exclusive distribution agreement;
collusive agreements including cartels, tied selling, exclusive supply agreements, exclusive distribution agreements, refusal to deal and resale price maintenance.

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 centers. 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.

Abuse of dominance

Section 4 of the Competition Act of 2002 prohibits abuse of dominance. It is to be noted here that it is not dominance per se that is prohibited but its abuse.

(d) refusal to deal;
(e) resale price maintenance,
shall be an agreement in contravention of sub-section (1) if such agreement causes or is likely to cause an appreciable adverse effect on competition in India.

Explanation.—For the purposes of this sub-section,—
(a) "tie-in arrangement" includes any agreement requiring a purchaser of goods, as a condition of such purchase, to purchase some other goods;
(b) "exclusive supply agreement" includes any agreement restricting in any manner the purchaser in the course of his trade from acquiring or otherwise dealing in any goods other than those of the seller or any other person;
(c) "exclusive distribution agreement" includes any agreement to limit, restrict or withhold the output or supply of any goods or allocate any area or market for the disposal or sale of the goods;

39 No enterprise shall abuse its dominant position.
There shall be an abuse of dominant position under sub-section (1), if an enterprise,—
(a) directly or indirectly, imposes unfair or discriminatory—
(i) condition in purchase or sale of goods or service; or
(ii) price in purchase or sale (including predatory price) of goods or service;

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An example of abuse of dominance by patent-holders can be seen in case of excessive or overpricing. An example may be taken from South Africa. In 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) in the domestic market. The SA Competition Act prohibits a dominant firm to charge excessive price to the detriment of the consumers and the Competition Commission ordered issuance of license to market generic versions of the patented ARV drugs in return for the payment of reasonable royalty.  

Mergers and Takeovers

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.” 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 laboratory 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

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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.

Due to the essential nature of pharmaceuticals markets which are innovation markets and also threat of excessive pricing due to abuse of dominance as a result of market concentration, there is a need to assess such mergers and takeovers in light of their impact on affordability and accessibility of drugs. 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 cartelization 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. As a result a High level Committee under the chairmanship of Arun Maiara was set up by the Planning Commission to look into the takeovers of pharmaceutical companies. The Committee is set to recommend approval by the Competition Commission of India (CCI) for all pharmaceutical merger & acquisition (M&A) deals.

Under the existing law, only M&A that involve target companies with a turnover of above Rs 750 crores and assets worth more than Rs 250 crores need to be vetted by the CCI.

As per the Maiara Report, the government will use the Competition Commission of India (CCI) and the Foreign Investment Promotion Board (FIPB) to keep a watch on acquisitions in the pharma sector to stave off the possibility of cartelization and dominance by multinational companies. It was decided to make antitrust rules tighter for such deals, bringing more pharma mergers and acquisitions (M&A) within CCI’s ambit.41

41 Sangeeta Singh and Aman Malik, “Pharma deals set to face closer scrutiny”. Available at: http://www.livemint.com/2011/10/10233455/Pharma-deals-set-to-face-close.htm
NEED FOR COOPERATION BETWEEN CCI AND SECTOR REGULATORY AGENCY

Nothing in the Act mandates the CCI not to intervene in price regulation only because of the existence of National Pharmaceutical Pricing Authority (NPPA) under the DPCO or issue of compulsory licensing under the Indian Patent Act. Lessons may be taken from South Africa Competition Commission in the case of excessive or overpricing by the CCI to intervene in such cases and authorize issue of compulsory licenses as a remedy in such instances. Competition issues are complex and matters having substantive competition content such as regulations of combinations, abuse of monopoly position leading to excessive pricing as well as anti-competitive agreements should be referred to the CCI even if it falls under the Department of Pharmaceuticals. The role of CCI in the pharmaceutical sector is critical due to the various competition issues prevailing in the sector as seen in this section especially given the trend of mergers and takeovers and likelihood of rise in prices, it is imperative that the NPPA and CCI work closely together to ensure affordability of drugs.
CHAPTER – 5

AGENDA FOR COMPETITION ADVOCACY

The primary objective of competition law is “to maintain and enhance competition in order ultimately to enhance consumer welfare”\(^{42}\) The role of consumers is important in determining the outcome of competition. Competition law gives the State’s competition authorities the power to prevent companies from acquiring a dominant share of the market or entering into agreements with other companies that restrict competition. It also gives the competition authorities power to take action against companies that abuse a dominant position in the market – such as charging excessive prices or restricting access by other companies that seek to enter the market and compete.\(^{43}\)

It is therefore important to ensure effective competition in the pharmaceutical sector where competition is also directly linked with the public health objectives.

Following are the few recommendations on setting the agenda for competition advocacy

1. **Addressing information asymmetry through advocacy**

   Competition depends on smooth and free flow of information. One of the major factors causing distortions in the pharmaceuticals markets is with regard to information asymmetry among consumers. While there is 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.

   The price control in the form of formulations only ensures more specific pricing control of the required medicine which is in the interest of the consumer from the point of view of the actual prescription by the Doctor. This aspect is more important for a country like India where there is

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\(^{42}\) [http://www.oecd.org/document/24/0,3746,en_2649_34753_1916760_1_1_1_1,00.html](http://www.oecd.org/document/24/0,3746,en_2649_34753_1916760_1_1_1_1,00.html)

large asymmetry in the information between the doctor and the patient. It is necessary to strengthen the public information system where simple drugs are known to consumers.

2. **Concerns regarding the Drug Price Control Regime**

   There have been growing concerns in the decrease in the number of drugs under price control as well as the shift in production by drug manufacturers from scheduled to non-scheduled drugs. This is a grave issue as it has adversely impacted the availability of essential drugs to the public at large. Currently there are 37 drugs out of 348 in the National List of Essential Drugs that are under the control of the National Pharmaceutical Pricing Authority (NPPA). Under the present price control regime, the prices of Non-Scheduled drugs are monitored, and in the case the prices of such drugs increase by more than 10% in a year, the NPPA is empowered to fix the prices of such drugs. Non-essential drugs should not be under a controlled regime and their prices should be fixed by market forces. There is a separate committee for finalizing the pricing of Patented Drugs, and decisions on pricing of patented drugs would be taken based on the recommendations of the Committee.

**Curbing anti-competitive agreements and collusive practices in the market**

Following recommendations may be looked into in this regard:

- Generating awareness among consumers about the different types of anti-competitive agreements and collusive practices prevalent among manufacturers, retailers and health-care providers.

- Enhanced role of CCI under Section 3 of the Act to curb anti-competitive agreements.

- Strict Penal provisions under the Medical Council of India Act and the Regulations on malpractices of health-care providers.

- Coordination of NPPA and CCI in monitoring price controls.

3. **Adopting measures to promote competition across the pharmaceutical value chain**

   Strengthening the implementation of the strict criteria for patentability incorporated in section 3 of the Indian Patent Act. There have been instances where patents have been

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wrongfully granted by the Patent Office to questionable/unworthy patents only to act as barriers for generic entry. 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.

4. **Strengthening the compulsory licensing system**

Flexibilities under TRIPS allow for issue of compulsory licenses. DIPP and patent offices must be advised for creating an effective and deterrent compulsory licensing mechanism to make drugs accessible under the essential facilities doctrine.

India’s Patents Act provides for it under Sections 84 (if initiated by a private party), 92 (notification by government that a Compulsory Licence needs to be issued for public non-commercial use, national emergency or extreme urgency), 92A (Compulsory Licence for generic exports) and 100 (for government use). However, nothing much has been done in this regard. 45

5. **Careful scrutiny of mergers and takeovers in the pharmaceutical industry**

As discussed earlier, the High Level Committee chaired by Arun Maiara has submitted recommendation for tighter rules for mergers and takeovers in the pharmaceutical sector by the CCI. This is a great step. This calls for greater role of CCI and NPPA in dealing with anticompetitive outcomes of mergers and closely monitoring the rise in prices (if needed) as a result of such a merger.

6. **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

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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.
CONCLUSION

Pharmaceutical manufacturers are demanding more liberalization, arguing that competition, and not price control, will improve availability and affordability of essential drugs. Even so, reducing the number of essential drugs on the DPCO will not be easy. The United Progressive Alliance Government’s national Common Minimum Program has promised to “take all steps to ensure the availability of life-saving drugs at reasonable prices”

The Indian Pharmaceutical regulatory regime has been quite hard on the manufactures, but has been extremely soft on the two other groups of important players: the doctors and pharmacists. Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 have sufficient provisions to ensure good behaviour on the part of the doctors. Be that as it may, it is more of a good endeavour rather than a binding rule. On the other hand, there is no effective monitoring or enforcement mechanism. Given the enormous clout of the pharmacists, what is badly required in India is an effective mechanism to contain the rent-seeking behaviour of the pharmacists.

The purchaser of bulk drugs are, after all, informed producers rather than helpless consumers. Like so, there is a need to study the behaviour of the bulk drug market, and, if desirable, there can be further decontrol in this regard. On the contrary, if we are talking about promoting competition in the Indian Pharmaceutical market, we also need to look at import competition. Currently, except a few specified life-saving products, the duty rate is quite high. For the scheduled (regulated) drugs, the protection is much higher, as the MAPE is 100 percent for domestically manufactured drugs and 50 percent for imported drugs. The issue needs a closer look.

It is essential for the Pharmaceutical sector in India to operate under a law that curbs anti-competitive activities. The new Competition Act, 2002 has all the required provisions. It would, anyhow, depend on how it is implemented.
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