EVOLUTION OF COMPETITION ACT ON HEALTH CARE SECTOR AND PHARMACEUTICAL SECTOR
Chapter III
EVOLUTION OF COMPETITION ACT ON HEALTH CARE SECTOR AND PHARMACEUTICAL SECTOR

In common parlance, competition in the market means sellers striving independently for buyers' patronage to maximize profit or other business objectives. A buyer prefers to buy a product at a price that maximizes his benefits whereas the seller prefers to sell the product at a price that maximizes his profit.¹¹¹ So, in this context, it can be said that, “competition is not defined in law but is generally understood to mean the process of rivalry to attract more customers or enhance profit or both.”¹¹² Competition makes enterprises more efficient and offers wider choice to consumers at lower prices. This ensures optimum utilization of available resources. It also enhances consumer welfare since consumers can buy more or better quality products at lower prices. Fair competition is beneficial for the consumers, producers /distributors and finally for the whole society since it induces economic growth. The competition in market thus:

1. Promotes efficiency and innovation
2. Ensures abundant availability of goods and services of acceptable quality at affordable price
3. Offers wider choice to consumers.

The globalized and liberalized Indian economy is witnessing cut throat competition. To provide institutional support to healthy and fair competition, there is requirement of better regulatory and adjudicatory mechanism. To this effect, The Government appointed a committee in October 1999¹¹³ to examine the existing ‘MRTP Act’¹¹⁴ for shifting the focus of the law from curbing monopolies to promoting competition and to suggest a modern competition law. Pursuant to the recommendation

¹¹² Kumar Amitabh “Competition law at a glance” available at http://www.cci.gov.in/images/media/articles/competition-lawglance-20080409115746 pdf Visited on 27.06.2014
¹¹⁴ The Monopolies and Restrictive Trade Practices Act, 1969 is the first enactment to deal with competition issues and came into effect on 1st June 1970.
of this committee, the Competition Act, 2002 was enacted on 13th January 2003. Competition law deals with market failures on account of restrictive business practices in the market. Restrictive business practices can be of many kinds and include inter-alia agreements to restrict competition, cartelization, predatory pricing, tie-in sales, re-sale price maintenance, abuse of dominance etc. The Competition Act involves the formulation of a set of policies which promote competition in the local markets and are aimed at preventing anti-competitive business practices and unwanted government interference. Competition Act is also framed with the intention of curbing abuse of market power by a dominant company. Further, competition law aims at eliminating monopolization of the production process thereby encouraging new firms to enter into the market. The maximization of consumer welfare and an increase in production value are some of the main objectives of competition law. With this objective the competition law has also introduced the provisions relating to the establishment of Competition Commission of India. However, the competition law has given sufficient powers to CCI to ensure that an enterprise which indulges in anti-competitive practices suffers serious consequences. “The ambit of the Act encompasses every enterprise, other than those excepted, within its fold and enables the Commission to probe, investigate, inquire, regulate and adjudicate any activity/matter of any person or enterprise. All PSUs, Societies, Scientific Societies, Municipal Corporations etc., fall within the ambit of the Act.” The researcher has tried to do an analysis of anti-competitive practices prevalent in the Indian pharmaceutical sector and the role of Competition Act, 2002 in curbing the same.

3.1 THE INDIAN PHARMACEUTICAL SECTOR

The pharmaceutical sector is a high-technology and knowledge-intensive industry. This sector is dynamic and research-intensive that is fundamentally influenced by a web of regulations designed to:

a) promote research and innovation in the design and production of drugs;

b) protect consumers from potentially harmful effects of drugs; and

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115 It provides for different notifications for making different provisions of the Act effective including repeal of MRTP Act and dissolution of the MRTP.

116 The Competition Commission of India (CCI) is a body corporate having perpetual succession and a common seal, established under the Competition Act, 2002.

c) to control public and private expenditure on drugs.

The Government started to encourage the growth of drug manufacturing by Indian companies in the early 1960s, and with the Patent Act, 1970, enabled the industry to become what it is today. Up until the 1970s India’s pharmaceuticals market was mainly supplied by large international corporations. These state-run firms provided the foundation for the sector’s growth since the 1970s. Back then, India’s government aimed to reduce the country’s strong dependence on pharmaceutical imports by flexible patent legislation and to create a self-reliant sector. This made India a less attractive location for international companies, many of which left the country as a consequence.

3.2 ROLE OF PATENTS LAW IN THE PHARMACEUTICAL SECTOR

The pharmaceutical sector is heavily regulated. All aspects of the life-cycle of new drugs are regulated, from patent application, to marketing approval, commercial exploitation, patent expiration and competition with generics drugs. All the important factors in the pharmaceutical sector like the manufacturers, wholesalers, retailers and prescribing physicians are also subject to regulatory controls. The most significant change was the January 1, 2005 enactment of an amendment to India’s patent law that reinstated product patents for the first time since 1972. “The legislation took effect on the deadline set by the WTO’s Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which mandated patent protection on both products and processes for a period of 20 years.”118 The protection of intellectual property rights, especially patents, is fundamental for ensuring a continuing flow of innovative new drugs. There is evidence that the pharmaceutical industry is more reliant on patent protection for innovation than other industrial sectors. The research and development process for new drugs is costly and risky. Relatively few new chemical entities ever receive marketing approval. Of these, only a few are commercially successful. A sizeable proportion of pharmaceutical manufacturers’ revenue can come from relatively few products. Thus, the pharmaceutical market in India owes its current growth and success to the Patents Act, 1970 which brought in the concept of patents in the pharmaceutical sector.

The Patents (Amendment) Act, 2005 the following benefits emerged:

1. Reduce the manufacturing costs in terms of license fee
2. Reduce the costs involved in Research and Development (R&D)

3. Diffusion of technology and knowledge through Reverse Engineering (RE)

3.3 ANTI-COMPETITIVE AGREEMENT IN THE PHARMACEUTICAL SECTOR

As the increasing growth of the pharmaceutical sector and its growing importance, it is very necessary to examine the anticompetitive behavior therein, from the perspective of the provisions of the Competition Act, 2002. An anti-competitive agreement is an agreement having appreciable adverse effect on competition. Anti-competitive agreements include both, the horizontal and the vertical agreements.\(^\text{119}\)

\(^{119}\) Section 3 of the Competition Act 2002. Anti-competitive agreements.—

(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 sub-section (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;

(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 arrangements” includes any agreement requiring a purchaser of goods, as a condition of such purchase, to purchase some other goods;
Horizontal agreements: - these are between and among competitors who are at the same stage of production, supply, distribution etc. Examples- cartels, collusive bidding, bid rigging, sharing of markets etc. Vertical agreements: - these are between parties at different stages of production, supply, distribution etc. Examples- tie in agreements, exclusive supply or distribution agreements, refusal to deal. Pharmaceutical companies often enter into agreements and joint-venture arrangements at each stage of the manufacturing process – at the research and development phase (for example, to pool patented know-how) and/or at the marketing and promotion phase (for example, to exploit complementary marketing strengths). Thus, the pharmaceutical industry is most prone to anti-competitive practices.

The specific anti-competitive practices of the pharmaceutical system and the health delivery system, which are covered by Section 3 of the Act,\(^\text{120}\) are collusive agreements including cartels, tied selling, exclusive supply agreements, exclusive distribution agreements, refusal to deal and resale price maintenance. Some of these are discussed below. “A cartel is said to exist when two or more enterprises enter into an explicit or implicit agreement to fix prices, to limit production and supply, to allocate market share or sales quotas, or to engage in collusive bidding or bid-rigging in one or more markets. An important dimension in the definition of a cartel is that it requires an agreement between competing enterprises not to compete or to restrict competition.”\(^\text{121}\)

The Competition Act mandates that cartels would be presumed to be anti-competitive, but also provides for an efficiency defence, namely that nothing in the relevant subsection shall apply to any agreement, if such agreement increases efficiency

\(^{\text{120}}\) Ibid

\(^{\text{121}}\) Available at www.cci.gov.in/images/media/Advocacy/Awareness/cartels.pdf visited on 16.12.2014
in production, supply, distribution, storage, acquisition or control of goods or provision of services.\textsuperscript{122}

Pharmaceutical companies often enter into agreements which results in the boycott of manufacturer’s products till a favorable margin is arrived at and where the enhanced margins imply higher prices for the consumers. Hence directly or indirectly determine purchase or sale prices. This result of the increase in the price proves to be detrimental to consumers. In such a scenario, companies are in a position to lure the doctors or the chemists to sell their brand in lieu of commission or higher margin, respectively. However, this may also lead to position of the consumers vulnerable in the hands of the pharmaceuticalists pushing for brands with higher margins. Thus, there is a need for a competition law, to penalize and deter such behaviour, and ensure that all players play by the rules of free and fair competition and that the benefits of the same accrue to the economy and the consumers in general and are not cornered by a few. In this regard, mandatory generic prescription i.e. prescription by the common chemical name of the drug instead of the branded name, can be useful to check nexus between doctor and the pharmaceutical company.

\textbf{3.4 ABUSE OF DOMINANCE IN THE PHARMACEUTICAL SECTOR}

As patents confer a monopoly status on patent owners and there might be abuse of such monopoly status. Such abuse of dominance is one of the major competition concerns, which may well be set our pharmaceutical industry with the introduction of our new patent regime. “Dominance refers to a position of strength which enables an enterprise to operate independently of competitive forces or to affect its competitors or consumers or the market in its favour. Abuse of dominant position includes imposing unfair conditions or price, predatory pricing, limiting production/market or technical development, creating barriers to entry, applying dissimilar conditions to similar transactions, denying market access, and using dominant position in one market to gain advantages in another market.”\textsuperscript{123}

\begin{footnotesize}

\textsuperscript{123} Available at http://www.cci.gov.in last visited 19.03.2015
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In the case of *Hoffman-La Roche v Commission* (1979)\(^{124}\) it was held that large market shares may in themselves be evidence of a dominant position, save exceptional circumstances.

“A position of strength, enjoyed by an enterprise in the relevant market in India, which enables it to

(i) operate independently of competitive forces prevailing in the relevant market;

or

(ii) affect its competitors or consumers or the relevant market in its favour.”\(^{125}\)

In India, the Competition Commission of India (‘CCI’) is the authority which has established under the Competition Act, 2002 (Act) to eliminate practices having adverse effect on competition, promote and sustain competition, protect the interests of consumers and ensure freedom of trade carried on by other participants, in markets in India. It covers within its ambit all categories of 'markets' in India including the pharmaceuticals sector as well. Moreover, the Act is extra-territorial and assumes jurisdiction over acts even outside India that may affect a market within India. This research endeavors to throw light on the recent regulatory steps of CCI towards prevention of anti-competitive practices in the pharmaceutical industry and discusses some of its recent orders to regulate anti-competitive practices in the pharmaceutical market.

### 3.5 REGULATION OF COMBINATIONS IN THE PHARMACEUTICAL SECTOR AND THE COMPETITION ACT

Considering the growth of the pharmaceutical industry and the high profile mergers and acquisitions which are taking place in this area is leading to anti-competitive practices. Broadly, combination includes acquisition of control, shares, voting rights or assets, acquisition of control by a person over an enterprise where such person has control over another enterprise engaged in competing businesses, and mergers and amalgamations between or amongst enterprises where these exceed the thresholds specified in the Act in terms of assets or turnover.\(^{126}\)

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\(^{124}\) European Court reports 1979 Page 461

\(^{125}\) Section 4 of the Competition Act 2002.

\(^{126}\) 1) Section 5, which deals with what is denoted by a combination of enterprises and persons, delineating the specific circumstances as per which the acquisition of one or more enterprises by one or more persons or acquiring of control or merger or amalgamation of enterprise.

2) Section 6, which provides for regulation of combinations.

3) Section 20 which concerns inquiry into combinations.
3.6 HEALTH CARE AND COMPETITION ACT, 2002

Traditional competition in health care involves one or more elements (e.g. price, quality, convenience, and superior products or services); however, competition can also be based on new technology and innovation. A key role of competition in health care is the potential to provide a mechanism for reducing health care costs. Competition generally eliminates inefficiencies that would otherwise yield high production costs, which are ultimately transferred to patients via high health service and delivery costs.

The pharmaceutical industry is currently acknowledged as one of the leading industries in India. In fact, India is ranked among the top 15 drug manufacturing countries in the world. However, the Indian pharmaceutical sector is in a state of flux in the face of the sweeping changes in the patent regime and the increasingly de-regulated environment. Especially threatened in this new scenario is access to medicines for the poor. Moreover, though India has a vast health delivery system in place it is not comprehensive enough to serve a population of over one billion. Access to medicines and healthcare has five important aspects:

- Availability of supply;
- Price;
- Quality;
- Ability to pay; and
- Access to proper and affordable consultations.

All these aspects are adversely affected by a number of factors, which range from poverty and poor infrastructure to corruption, market malpractices, and lack of awareness. Market malpractices in general, and anti-competitive conduct in the pharmaceutical industry and health delivery system, in particular have serious implications for access to healthcare. Further exacerbating the situation are market distortions and skewed competition norms, unique to the pharmaceutical industry, with particular reference to market concentration, barriers to price competition, and lack of freedom in consumer choice (patients are guided by the advice of doctors and pharmacists). The health delivery system is also characterised by market failure uncommon in other markets, that is, consumers are mostly not involved in decision

4) Section 28, which allows for division of enterprises enjoying dominant position.
5) Section 29 and Section 30, which lays down the procedure for investigation of combinations.
6) Section 31, which enumerates the orders of the Commission on certain combinations
making regarding consumption, which in this case consists of medicines and healthcare facilities.

Anti-competitive practices in the pharmaceutical sector and the health delivery system include, amongst others, price fixing, abuse of dominance, collusive agreements, and tied selling. Even practices such as kickbacks to doctors and pharmacists may be deemed as anticompetitive, as they result in depriving patients of the best possible medicines and services at the lowest possible prices. The primary effect of anti-competitive practices on the health care sector is that medicines and services are rendered costlier. In order to deal with anti-competitive practices in the pharmaceutical industry and the health delivery system, there are multiple legal and policy options such as competition law, patent law and drug price control, which may be utilised effectively. It is to be noted that a number of anti-competitive practices pervade the pharmaceutical industry worldwide, including India. An issue of vital importance, however, is that consumers of formulations are very often not the decision-makers. They are, for the most part, guided by instructions from doctors and pharmacists. The significant role assumed by the doctors and pharmacists in influencing drug sales leads to manipulation of the system with drug companies seeking to exploit this influence, more often than not. Such practices result in patients being misled into purchasing more expensive medicines, or the prescribing of irrational or combinations of drugs, which may lead to medical complications, sometimes even causing death. This distorted guidance on the part of the doctor deprives patients from availing of the best possible healthcare.

Empowering consumers is a task fraught with difficulties, since medicine is a highly specialised field in which miscalculations in the decision making process may lead to severe adverse and sometimes even irreversible effects on health. Anti-competitive practices in the pharmaceutical sector may be categorised into primarily three classes: breaches related to intellectual property rights (IPRs); abuse of competition norms arising from mergers and acquisitions (M&A) and collusive and other anti-competitive practices. Collusive activities can range from cartelization to bid-rigging. However, existence of tendency towards collusive behaviour in certain segments, where there are just a few manufacturers, cannot be ruled out, particularly when an international cartel in bulk vitamins had been in existence in the country for quite a long time.
3.7 ANTI-COMPETITIVE PRACTICES IN THE HEALTH CARE SYSTEM

The anti-competitive practices which are widespread in the health care system, which includes doctors, hospitals, diagnostic laboratories and pharmacist. Given the anti-competitive practices in health delivery system, only 35 percent of Indians can access essential medicines. There are a number of factors, which would account for the lack of access to healthcare services and medicine. Anti-competitive practices are classified by type and the involved agent.

Giving enticement to doctors and pharmacist is one practice carried out by pharmaceutical companies, which blatantly violates free and fair competition. This may be motivated by a desire to create a large market share or to gain greater profits by pushing overpriced drugs and is achieved through aggressive promotional strategies aimed at doctors, and by providing lucrative margins to chemists. Many competition legislations around the world consider “incentive” as unfair trade practices (UTPs); and therefore prohibiting them.

There are companies, which use anti-competitive methods to create a market for their product. Novartis\(^ {127}\), a company that has a large market share in India has been recently accused of fuelling the misdiagnosis of Attention Deficit Disorder (ADD) through its close association with psychiatric associations and its presentations at their meetings, and conspiring thereby to carve a niche in the market for Ritalin, the drug for ADD. By expanding the use of the drug that has been responsible for millions of children misdiagnosed with ADD, Novartis has encouraged anti-competitive practices.

The most significant unethical practices engaged in by doctors are prescriptions which are motivated by the kickbacks received from pharmaceutical companies. Even if not influenced by incentives, doctors may continue prescribing a particular drug found to be effective, and do not bother to find out if there are existing less expensive alternatives. Another practice, which is rather prevalent among doctors, is to provide referrals that are motivated by commission. Doctors are quite often paid commission for referring the patient for further treatment or to any particular diagnostic, centre, pharmacist, or hospital. The anti-competitive practices most prominently engaged in by pharmacists are reflective of collusive behaviour. It may be concluded that pharmacy owners are banded together to form a huge cartel in the guise of a trade association named as the All India Organisation of Chemists and Druggists (AIOCD).

\(^{127}\) Novartis AG v. Union of India, Civil appeal No 2706 – 2716 of 2013
The AICOD is known to launch boycotts against companies to grab higher profit margins, which is ultimately passed on to the consumers.

Hospitals are an important part of the health care system. However, not much is known about their practices though random analysis reveals that they are known to exploit consumers, and enter into agreements with drug manufacturers. A case that was brought before a consumer forum in Andhra Pradesh revealed that a private hospital had entered into a contract with a drug manufacturer to supply drugs to the hospital at above the market price. A peculiar anti-competitive practice, common to all three of the aforementioned components of the health delivery system, is tried-selling. It basically means restriction of the choice of consumers, by a provider of a certain good or service, in the purchase of some other goods or services which may or may not be related. For instance, a doctor tying his services to the purchase of medicine from a particular medicine shop or ‘strongly recommending’ tests at a particular diagnostic centre in lieu of some commission is a case of tied-selling.

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

Competition Act apart, patent law and drug price control are crucial for efficacious elimination of competition violations in the pharmaceutical industry. The Patent (Amendments) Act, 2005 introduces product patents in India, invalidating Section 5 of the Indian Patent Act, which granted only process patents for food, medicines and other drug substances. Under the Patent (Amendments) Act, 2005, monopoly status is awarded to patent-holders. The Indian Patent (Amendment) Act, 2005, also provides compulsory licensing under Section 84 of the Patents Act.

128 Section 84 of the Patents Act - Compulsory licenses
(1) At any time after the expiration of three years from the date of the sealing of a patent, any person interested may make an application to the Controller alleging at the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not available to the public at a reasonable price and praying for the grant of a compulsory license to work the patented invention.

(2) An application under this section may be made by any person notwithstanding that he is already the holder of a license under the patent and no person shall be stopped from alleging that the reasonable
three years after a patent is granted (sealed), any interested party can allege that the invention is not reasonably available to the public and can request the grant of a compulsory license.

Price control is a tool that is used in a situation when maintaining a competitive market is extremely difficult. India has been following a price control regime for pharmaceutical products since the 1960s. However, there has been substantial decontrol in this regard since the 1990s, with the effect that prices of many medicines...
have seen an unprecedented rise. Under the Drug Price Control Order (DPCO) 1995, only 74 drugs are under price control. The DPCO is to be succeeded by the National Pharmaceutical Policy of 2002, which contains several important policy changes.

Competition law is an effective regulatory mechanism for addressing anti-competitive conduct in the health delivery systems. Hospitals are virtually ungoverned in this respect. In some states, there are laws that provide for mandatory registration and technical standards for clinical establishments including hospitals, nursing homes, or diagnostic centers. However, the coverage is not comprehensive. With the hospital industry growing, this gap needs to be addressed.

The new Indian Pharmaceutical Policy, 2002, has focused on liberalisation by further reducing the number of drugs subject to price control and opening up the market to foreign investment. The Competition Act provision offers some vital suggestions and recommendations for improvement in the healthcare and hospital delivery system.

3.8 PROMOTING GENERIC COMPETITION

Pharmaceutical companies often give incentives to doctors to push their brands of medicine, which may be more expensive than other alternatives available in the market. This vitiates the competition principle of "best possible goods and services at the least possible prices". The doctor-drug manufacturer nexus is to be viewed in the light of near complete dependence of patients on the doctors for information relating to drug purchase. In order to deal with this unholy nexus, there is a need to promote generic drugs\textsuperscript{130}. This promotion may be done by de-branding prescriptions for essential generic medicines. However, there are strong legitimate arguments against this proposition, which are beyond the scope of this paper. It is, therefore, recommended that only a selected number of most commonly used medicines be brought under the ‘de-branding of prescriptions’ scheme on an experimental basis.

3.9 APPLYING THE INDIAN COMPETITION ACT

The three focal areas of anti-competitive conduct covered by the Indian Competition Act, 2002, amended by The Competition (Amendment) Act, 2007, relate to anti-competitive agreements; abuse of dominance; and combinations - all three of which give rise to competition concerns in the Pharmaceutical industry and the health

\textsuperscript{130} A generic drug (generic drugs, short: generics) is a drug defined as "a drug product that is comparable to a brand/reference listed drug product in dosage form, strength, quality and performance characteristics, and intended use." It has also been defined as a term referring to any drug marketed under its chemical name without advertising or to the chemical makeup of a drug rather than to the advertised brand name under which the drug is sold.
delivery system. The specific anti-competitive practices of the pharmaceutical system and the health delivery system, covered by the Act are collusive agreements including cartels, tied-selling, exclusive supply agreements, exclusive distribution agreements, refusal to deal and resale price maintenance.

The Competition Act, 2002, as amended by The Competition (Amendment) Act, 2007 prohibits the abuse of dominance and, therefore, if pharmaceutical companies do engage in overpricing patented products or are unreasonable with respect to licensing terms and so on, the competition law may be resorted to for redressal.

The global health care industry is going through a period of “globalization,” a term that combines the words “globalization” and “localization” to describe the adaptation of global products or services to accommodate the needs of people in a specific locale. Typically associated with efforts by large consumer companies to boost sales by tailoring their products and menus to appeal to local tastes, globalization also applies to health care: Industry issues are global, even if care is usually delivered locally. And while the effects of these issues are influenced by local factors, many challenges are shared around the world to varying degrees, as are the opportunities to innovate to solve them. The growth of enormous pressure on governments, health care delivery systems, insurers, and consumers in both developed and emerging markets to deal with issues such as an ageing population, the rising prevalence of numerous chronic diseases, soaring costs, uneven quality, imbalanced access to care due to workforce shortages, infrastructure limitations, patient locations and disruptive technologies.

Across the globe there have never been more health care challenges than there are today. However, these challenges can push stakeholders to innovate in new and exciting ways and to generate scientific, medical, and care delivery breakthroughs that can improve the health of people worldwide. This 2014 global health care outlook examines the current state of the sector, describes the top issues facing stakeholders, provides a snapshot of activity in a number of geographic markets, and suggests considerations for 2014 and beyond. With ageing populations, an increase in those inflicted with chronic ailments that require more health care spending, government initiatives to increase the access to care in both industrialized and emerging markets, and treatment advancements expected to drive sector expansion, pressure to reduce health care costs remains and is escalating. Heavy government debts and constraints on tax revenue combined with the pressures of aging populations, are forcing health
payers to make difficult decisions on benefit levels. Europe remains under particular pressure, and not just in those countries most impacted by the regional economic crisis. After forcing through painful cuts to drug prices, wages and staffing levels, some governments are now using the crisis as a chance to push through broader reforms to health care funding or provision. The hope is that these reforms may make health care systems more sustainable in the future.

A large and growing population, a booming economy, rapid urbanisation which has expanded the middle class, rising diseases and increased awareness level has enable the sector to grow at much higher rate.

**GROWING HEALTHCARE DEMAND**

India is second largest populous country (after China) in the world having a population 1.21 billion\(^{131}\). The overall population grew at a rate of 1.76% per annum during the period 2001-2011 a decline from 2.13% per annum in the previous decade 1991-2001. The human sex ratio has shown a marginal improvement from 926 in the year 1991 to 940 in the 2011. Similarly, the birth rate has declined from 26.10 in the year 1999 to 22.50 in the year 2009. The Infant Mortality Rate (IMR) has decline significantly from 70 in 1999 to 50 in 2009 (per 1000 person) though there is a significant difference between rural and urban IMR of 55 and 34 respectively (per 1000 person).

\(^{131}\) 2011 provisional census, Ministry of Home Affairs, Gol
Further, emerging technologies called SMAC: social networking, mobile computing, analytics and cloud computing, are likely to play a crucial role in addressing these challenges, improving operational efficiencies and amplifying the performance of the pharmaceutical companies.

**SMAC TECHNOLOGIES**

![SMAC Technologies Diagram](image)

Though each of these technologies has a unique impact, they also complement each other in order to drive business transformation. These technologies jointly foster innovation through new ways of product development, customer service and interaction and partnerships, thereby creating value and stimulating success.

India has had an efficient pharmaceutical industry which has been making affordable drugs not just for the Indian markets but has also been exporting them to the world but off late, been facing rising FDA scrutiny for quality. US FDA has increased its scrutiny on the quality coming from India located manufacturing plants. Indian companies will have to raise their compliance to US FDA regulations as they drive their major share of exports from the US market. Addressing the challenges in a holistic way will strengthen the sector which constitutes a major part of the Indian economy. Pharmaceutical companies will have to think through suitable strategies to mitigate the risk emanating from the above discussed challenges and to sustain growth in the next decade.

### 3.10 REGULATORY CHALLENGES

The pharmaceutical regulatory environment across the world is getting more stringent. In order to compete in the global market, the Indian pharmaceutical market needs a strong regulatory set-up. But, the sector is currently grappling with a number of issues like delays in clinical trial approvals, uncertainties over the FDI policy, the new pharmaceutical pricing policy, a uniform code for sales and marketing practices and compulsory licensing all of which need immediate attention.
Safety and effectiveness of the medicines has to be established before regulatory approval is granted for new drugs. Clinical trials\(^{132}\) are the gold standard processes which determine the safety and effectiveness of these drugs. Clinical trials are also needed for the Indian pharmaceutical industry to develop cost effective therapies for diseases like tuberculosis, diarrheal diseases, malaria, leishmaniasis, and meningitis which affect India and the other developing countries and to capitalise on opportunities provided by bio-similars.

India also has aspirations of becoming a knowledge hub for Pharmaceutical. R&D in general and clinical trials in particular are an important aspect of this aspiration.

India has been considered as an attractive destination for conducting such clinical trials. This is mainly due to India's genetic diversity; increasing and varied disease prevalence rates; availability of medical, pharmaceutical and science graduates, clinical infrastructure and comparative cost advantage. However, the regulatory delays in the clinical trials are adversely affecting this possibility. The delays and regulatory uncertainty have severely derailed the innovation curve as well as the growth of the clinical trial industry. Ineffective regulatory oversight, need for safeguards for informed consent for vulnerable populations and compensation guidelines for patients for trial related deaths have emerged as major concerns. In terms of the clinical trials, where India could have been a leader, the country is losing out on opportunities because of the mentioned limitations.

Hundred percent FDI through the automatic route was possible in the Pharmaceutical sector in India. Given the high current account deficit, India requires FDI. The FDI policy\(^{133}\), however, gives confusing signals. 100% FDI in Greenfield investments is allowed by the automatic route but after November 2011, the Brownfield investments require the approval of the Foreign Investment Promotion Board (FIPB)

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\(^{132}\) Clinical trials are experiments done in clinical research. Such prospective biomedical or behavioral research studies on human participants are designed to answer specific questions about biomedical or behavioral interventions, including new treatments (such as novel vaccines, drugs, dietary choices, dietary supplements, and medical devices) and known interventions that warrant further study and comparison. Clinical trials generate data on safety and efficacy.

\(^{133}\) Foreign direct investment (FDI) is an investment in a business by an investor from another country for which the foreign investor has control over the company purchased. The Organization of Economic Cooperation and Development (OECD) defines control as owning 10% or more of the business.
which often comes with conditions. The time consumed in this process also acts a
deterrent.

FIPB conditions include the need to maintain production levels for the National
List of Essential Medicines (NLEM) at the highest level for three years preceding the
FDI, the need to maintain R&D expenses at the highest level for three years preceding
FDI, the need for information on the transfer of technology to the administrative
ministries and FIPB\textsuperscript{134} etc. The intention behind such restrictions may be good but it
discourages investment. We need a FDI policy which addresses these concerns while
ensuring the affordability as well as the availability of drugs in India

\textbf{3.11 NATIONAL PHARMACEUTICAL PRICING POLICY (NPPP)}

Pharmaceutical price controls are seen all over the world. Through NPPP 2012,
the government has enhanced the scope of the Drugs Price Control Order (DPCO) to
include all the drugs in the NLEM\textsuperscript{135}. Combination drugs in which one of the drugs is a
part of the NLEM were also brought under the ambit of DPCO. The government also
changed the formula to arrive at the ceiling price from a cost based method to a market
based method.

The Pharmaceutical companies are feeling the effects of the price controls
associated with NPPP which will have a negative impact on their top line in short term.
However, with well thought out strategies, a large part of this impact can be negated in
the medium to long term. While companies have accepted the reality of price controls,
one issue which has adversely affected the industry is the timeline for the
implementation of DPCO. The industry felt that the government did not provide
sufficient time for implementing the new packaging and labeling with the revised
prices. There was also lack of clarity about the location where such packaging and
labelling activities could be performed. Some companies had to go to court to get an
extension and the ones who couldn't do so in time are still suffering. This confusion
could have been easily avoided through consultation and by giving adequate time for
the implementation of the revised prices.

\textsuperscript{134} The Foreign Investment Promotion Board (FIPB) offers a single window clearance for applications
on Foreign Direct Investment (FDI) in India that are under the approval route. The sectors under
automatic route do not require any prior approval from FIPB and are subject to only sectoral laws.

\textsuperscript{135} The National list of essential medicines is one of the key instruments in balanced healthcare delivery
system of a country which inter alia includes accessible, affordable quality medicine at all the
primary, secondary, tertiary levels of healthcare.
In an attempt to streamline the marketing efforts, the Department of Pharmaceutical (DoP) has issued guidelines on a uniform code on sales and marketing practices which are applicable to the pharmaceutical companies. This is a laudable step aimed at preventing corruption. The DoP guidelines however, are different from the MCI guidelines on the sales and marketing practices. Tax authorities use the Central Board of Direct Taxes (CBDT) circular based on MCI guidelines to decide on permissible sales and marketing expenses. Because of differing standards between the DoP\textsuperscript{136} and MCI\textsuperscript{137} guidelines, there is an increased need for clarity both from the point of view of the industry as well as the tax authorities.

In countries like India, there should be a balance between the need for affordability of drugs and intellectual property (IP) protection. The intention of the government to ensure the availability of patented medicines at a reasonable price\textsuperscript{138} is noble but there are other ways of achieving the same goal. The indiscriminate use of compulsory licensing will undermine both the Indian as well as foreign pharmaceutical companies. The industry is also facing stricter regulations on manufacturing and quality practices in the domestic as well as international markets.

India is the biggest supplier of medicines to the US and according to the industry sources, pharmaceutical exports from India to the US rose nearly 32 % last year to 4.23 billion USD. With increase in exports, Indian companies are drawing greater FDA scrutiny for quality and manufacturing compliances.

For India to continue exporting to the foreign markets companies will have to step up their quality and manufacturing compliance programmes which are in line with the US FDA regulations. Increasing confidence in the drugs manufactured in India is important. The regulators need to set the standards at par with the global ones through appropriate legislation. They also have to ensure that these standards are effectively enforced and complied with.

India has an efficient pharmaceutical industry which has been making affordable drugs not just for the Indian market but has also been exporting them to the world. Addressing the above challenges in a holistic manner will strengthen the sector which constitutes a major part of the Indian economy. Pharmaceutical companies will

\textsuperscript{136} Department of Pharmaceuticals’ (DoP).
\textsuperscript{137} Medical Council of India’s (MCI)
\textsuperscript{138} 

\textit{Novartis v. Union of India & Others Civil Appeal 2706 – 2716 of 2013}
have to devise suitable strategies to mitigate the risk emanating from the above discussed challenges for a sustainable and compliant growth over the next decade.

Healthcare sector is a social sector, where 'access and equity' are as important as the need to have further investment. Not only right to healthcare has been recognised as a fundamental right in India, there are several international obligations for India to pursue 'access and equity' in this regard. The following excerpts from the Draft National Health Bill, 2009\(^{139}\) being promoted by the Ministry of Health and Family Welfare provides a near exclusive list of constitutional and international obligations for India with respect to healthcare.

**Fig no 5 Healthcare Market Segments**

139 A Bill to provide for protection and fulfillment of rights in relation to health and well-being, health equity and justice, including those related to all the underlying determinants of health as well as health care; and for achieving the goal of health for all; and for matters connected therewith or incidental thereto
3.12 MAJOR CHALLENGES THAT ON INVESTMENT AND CREDIT RATING AGENCY OF INDIA LIMITED (ICRA) FORESEE

- Small and Medium Enterprises (SMEs) can concentrate only in few cities and towns as they lack the infrastructure & funds for registering themselves at national level.
- Healthcare industry requires high initial investment and the entrepreneurs are unable to arrange such amount of capital investment hence this sector is growing at a fast pace.
- Due to limited capacity restriction these SMEs cannot operate beyond a certain level.
- Changing economic scenario is putting pressure on investors as sophisticated machinery needs to be imported and rupee devaluation is digging deeper hole in the packet of investors.
- Lack of information and market segmentation and demand makes SMEs handicapped in terms of planning and forgetting the profitable market.
- Lack of skilled human resources is one of the major challenges, faced by SMEs as the skilled resources are hired by big corporate at a lucrative pay package and the SMEs are left with no other option than compromising on quality.
- The Public Private Partnership (PPP) model is lacking in the SME sector, if PPP model is implemented intensively it can enhance the quality of health care services as funds required for improving the infrastructure will be provided by government and management skill can be given by the SME unit. This initiative will make healthcare facilities affordable for the middle and lower strata of the society.
- One of the major challenges which the industry as whole is facing is paucity of bed. India currently has 1 bed per 1050 people as compared to 1 bed per 250 people. Due to lack of infrastructure and investment the SMEs are unable to bridge this gap.\footnote{http://www.onicra.com/images/pdf/Healthcare-industry-report-Transparent.pdf visited on 27.06.2015}
3.13 MAJOR RISKS TO INDIAN PHARMACEUTICAL COMPANIES

- **Price control of drugs**
  Currently, MNC Pharmaceutical companies have higher exposure to price controlled products namely Glaxo SmithKline Pharmaceutical (GSK), Merck and Pfizer. The high exposure to the price controlled products has a direct impact on their EBIDTA margin.

- **Increasing scrutiny by US FDA**
  Increased scrutiny and stringency in norms by US FDA can be a deterrent to the planned growth for Pharmaceutical companies. Warning letters, import alerts and bans may seriously damage growth plans and also sentiment for the sector leading to value deduction/loss of momentum.

- **Fluctuations in currencies**
  Indian pharmaceutical companies derive a considerable portion of their revenues from the overseas market and hence have high exposure to foreign currencies. Hence, the companies have resorted to the hedging of currencies to minimize the risk but face stringent limits under laws (don’t want to get classified as currency arbitragers)

- **Elongated approval timings**
  Longer average approval timing for the ANDAs (Abbreviated New Drug Application).

- **Attrition is the biggest challenge**
  For the domestic Pharmaceutical industry attrition is a big challenge. The top talent of the Pharmaceutical industry is becoming more mobile moving between industries such as FMCG, Insurance, Banking and IT. Major attrition (over 20%) takes place among the Medical Representatives, who move for higher studies or to BPO/KPOs.

- **Risk from at-risk launches**
  At risk launches generally tend to bode well for companies and stock prices, but in two instance in the past (Sun Pharmaceutical : Protonix and Glenmark’s Tarka) courts in the US have rules against the Indian companies. Liabilities arising out of this can hurt cash flows as well as valuations.
Policy reforms

Policy changes by the Government of India could curtail some of the existing incentives for the players in the industry like the DEPB scheme, SEZs, Mauritius tax treaty advantages etc.

Counterfeit drugs

Counterfeit drugs are likely to pose a big threat to the global Pharmaceutical companies (Counterfeit drugs do not have active ingredients (placebos) or have lower amounts of active ingredients resulting in longer treatments with no recovery)

The Competition Act that require notification and screening of mergers above specified asset and turnover thresholds were brought into force only in mid-2011, and only six merger applications in the pharmaceutical sector have been reviewed since then. All of them have been approved because they did not pose competition concerns. In one case, the CCI forced the parties to modify their non-compete agreement. However, many other mergers in the sector were not reviewed because they fell below the notification thresholds. There is a case for reducing the thresholds for critical sectors like pharmaceutical, which will be possible only as and when a recently-tabled bill to amend the Competition Act is passed by Parliament. India has been imposing price controls on bulk drugs and their formulations since the 1960s, although the number of drugs under control has been progressively reduced and the pricing formula made more generous. A major change in the approach has been proposed in the National Pharmaceutical Pricing Policy (NPPP) 2012. Although it will greatly expand the number of drugs under control, it will cover only formulations. Most importantly, it will shift from the existing cost-based formula for fixing the prices to a market-based approach in which regulated prices will be determined by the average prices of all brands with market shares greater than 1%. There is an ongoing controversy over whether this will raise or lower drug prices and profits, and how manufacturers may evade its impact. There are weaknesses in the arguments of both sides, and many of the problems associated with price controls have not been adequately addressed. However, there is evidence that for many drugs, the range of existing prices and also the putative price under the new control formula are much higher than the competitive price that has been discovered by procurement mechanisms such as that of the Tamil Nadu Medical Supplies Corporation (TNMSC) and the central government’s Jan Aushadhi Scheme.
The solution therefore lies in unleashing the power of competition rather than in proliferating controls.

There is conflicting evidence on whether foreign firms have been acquiring a greater share of the Indian pharmaceutical market, or whether foreign takeovers have reduced the research and development spending of the acquired firms. However, it does seem that the performance of multinational drug companies is worse than that of their Indian counterparts in regard to investment, R&D and exports.

A further contentious area of debate is the impact of the product patent regime introduced in 2005 to comply with the TRIPS agreement. The evidence suggests that although R&D spending has increased subsequently, the number of patents granted has not. It is therefore not established that strengthened patent protection has stimulated innovation. On the other hand, there are encouraging recent signs of India beginning to use the flexibilities under the TRIPS agreement to attack patent monopolies head-on via compulsory licensing, denial of patents for incremental innovation (‘ever greening’) or for trying to patent known products, and post-grant opposition suits resulting in revocation of patents that were wrongly granted. Grey areas of the law that are yet to be explored include treatment of patents as essential facilities, which would bring them under the abuse of dominance provisions of the Competition Act, and parallel imports of drugs from other countries where they may be cheaper. In summary, the Indian pharmaceutical sector presents a range of practices that militate against competition. Many of these relate to the behaviour of producers and distributors, but they are in some instances reinforced by government policies. The solutions lie in recognizing the anti-competitive effects of such policies, reforming them so as to minimize the harm to competition while fulfilling their other objectives, and more actively deploying pro-competition policies in the areas of antitrust enforcement, exploitation of TRIPS flexibilities, and public production, procurement and distribution.