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## Pharma advertising- Is it deceptive?.

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### ABSTRACT

Ethics is considered to be extremely important in advertising as to the reputations, credibility and success of the company depends upon the same. The advertising in pharmaceutical industry takes the form of direct-to-consumer advertising, sales promotion to physicians, pharmacists and other health care professionals. Promotional activities are performed by sales personnel of pharmaceuticals manufacturer and advertisement of the product is initiated through electronic or print media. All promotional claims should be current, accurate, balanced and not misleading either directly by implication or omission. In the pharmaceutical sector, bribery and corruption has emerged as one of the key compliance risks to pharma companies. Developing markets are becoming more exposed to the three problems of corporate governance— fakes, fraud and forgery. A preventive-check method to make an anti-fraud situation and proactively facing the risks is the necessity of the present world, while there are ever-increasing set of laws for global pharmaceutical companies in the developed markets.

**Keywords:** Pharmaceutical advertising, ethics, legislations, deceptive advertising and health care professionals

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## INTRODUCTION

Ethics generally means a set of moral principles and values which governs the behaviour of individuals in day to day life. The actions and decisions of individuals depend on these moral values. The preference between the good and bad is governed by the moral values which are in consistent with the values and customs of the society. Due to the demographic and psychographic diversity of the population, ethics is always a subjective concept. Ethics in advertising governs the method of communication between the seller and buyer. An ethical advertisement should not make any false claims and should be within the limits of decorum. Ethics is considered to be extremely important in advertising as to the reputations, credibility and success of the company depends upon the same. The advertising in pharmaceutical industry takes the form of direct-to-consumer advertising, sales promotion to physicians, pharmacists and other health care professionals. The spending on advertising may increase the cost of medicines to the consumers. Many pharmaceutical companies exhibit the truth but partially. The companies create awareness among the customers regarding the medicines for their cure but do not reveal the side effects of those medicines.

### Scenario of Indian Pharma Industry:

The Indian pharma industry is on the threshold of becoming a major global market by 2020. It is expected to grow at 15% to 20% Compound Annual Growth Rate (CAGR) to touch US\$50 billion and US\$74 billion in the next decade. India has a large pool of scientific manpower which can be used in drug discovery, development and clinical trials. Its diverse genetic pool of treatment-naïve population is attractive for clinical trials. Alongside, economic growth has increased the buying power of India's middle class for healthcare services in general, particularly medicines. Emergence of lifestyle diseases such as diabetes, cardiovascular disease and cancer has increased the demand for medicines. Leading Multi National Companies (MNCs) from Europe, the US and Japan have established a local presence.[1]

As per 'Pharma Vision 2020', the Government of India aims to make India a global leader in end-to-end drug manufacturing. Manufacturing costs in India are approximately 35-40 per cent of those in the US due to low installation and manufacturing costs. The projected human resource requirement in the Indian pharma sector is estimated to be about 21,50,000 by 2020. India is home to 10,500 manufacturing units and over 3,000 pharma companies.

The growth in Indian domestic market will be on back of increasing consumer spending, rapid urbanisation, raising healthcare insurance and so on. Going forward, better growth in domestic sales will depend on the ability of companies to align their product portfolio towards chronic therapies for diseases such as such as cardiovascular, anti-diabetes, anti-depressants and anti-cancers are on the rise. Moreover, the government has been taking several cost effective measures in order to bring down healthcare expenses. Thus, governments are focusing on speedy introduction of generic drugs into the market. This too will benefit Indian pharma companies. In addition, the thrust on rural health programmes, life saving drugs and preventive vaccines also augurs well for the pharma companies.[2]

India accounts for 36.9 per cent (3,411) of the 9,296 Drug Master Files (DMFs) filed with the USA, which is the highest outside of the USA (as on December 31, 2013). Higher spending on research and development (R&D), owing to products patents have made India a major destination for generic drug manufacturing. India's pharma exports stood at US\$ 15 billion in 2013-14. Pharmaceutical exports from India have grown at a CAGR of 21 per cent over the last decade. India ranks fourth in terms of the total pharma market share in the Asia Pacific. Approximately 70 per cent of the patients in developing countries receive Indian medicines through NGOs like The Clinton Foundation, Bill & Melinda Gates Foundation, Doctors Without Borders, the UNCTAD (United Nations Conference on Trade and Development) etc.[3]

The top ten companies commanded a 40% market share with seven domestic players in the list. Cipla led the Indian tally with sales of Rs.4,571 crore in CY14, with a growth of 19%. Macleods Pharma registered the highest growth of 21%, followed closely by Mankind Pharma at 17%. Sales of drugs included in the National

<sup>1</sup> <http://www.pwc.in/industries/pharmaceuticals-and-life-sciences.jhtml> (accessed on 21-7-15)

<sup>2</sup> [http://indiainbusiness.nic.in/newdesign/index.php?param=industryservices\\_landing/347/1](http://indiainbusiness.nic.in/newdesign/index.php?param=industryservices_landing/347/1) (accessed on 4.8.15)

<sup>3</sup> <http://www.brandindiapharma.in/infographic-on-pharma-sector-business/>(accessed on 21-7-15)

List of Essential Medicines (NLEM) grew at 0.4% in December 2014, compared with a 14.8% growth for the same period recorded by non-NLEM drugs. The lower sales were not compensated by higher volumes, with volumes declining 4% in the NLEM segment for the same period. In July 2014, The National Pharmaceutical Pricing Authority (NPPA) capped the prices of 108 diabetes and cardiac drugs under the auspices of the Drug Pricing Control Order, which amounts to approximately Rs. 5,500 crore, or 6% of the Indian pharmaceutical market.

In addition to having Good Manufacturing Practice (GMP), World Health Organisation (WHO), several Indian companies have also been getting plant approvals from international regulatory agencies like Food and Drug Administration (FDA) United States, Maritime and Coastguard Agency (MCA) United Kingdom, Therapeutic Goods Administration (TGA) Australia, Medicines Control Council (MCC) South Africa. India possesses the highest number of US FDA approved manufacturing facilities outside the USA and currently tops in filing the drug master files (DMF) with the US FDA. This has also facilitated the domestic industry to attract contract manufacturing opportunities in the rapidly growing generics market.(Exhibit No:1)[4]

**Some Key Characteristics of the Indian Pharmaceutical Industry**

*Highly Regulated:* The industry faces price regulation, quality regulation and patent regulation.

*Research Oriented:* The industry is highly research driven having to regularly invent novel drug delivery system (NDDS), discover new molecules, invent innovative production processes.

*Low price-elasticity:* Being a necessity, consumers are less sensitive to price movements for most products; substitutes can however make a difference in certain segments.

*Limited consumer choice:* Consumers are not decision-makers; Doctors & medical representatives play an important role.

*Highly dependent on development of health infrastructure:* The presence of hospitals and other health facilities and medical practitioners play a key role in driving consumption.

Exhibit No: 1

Indian Pharmaceuticals sector is classified into Bulk drugs, Formulation and Contract Research and Manufacturing Services (CRAMS). The drug and pharmaceuticals industry in India meets around 70% of the country's demand for bulk drugs, drug intermediates and formulations. There are about 500 corporate players with more than 20000 players in general and thus fragmented Indian pharmaceutical industry. The bulk drugs and pharmaceuticals manufacturers produce complete range of pharmaceutical formulation and about 350 bulk drugs. (Exhibit No: 2)[5]



Exhibit No: 2

<sup>4</sup> Source: <http://www.dnb.co.in/pharmaceutical/overview.asp> (accessed on 21-7-15)

<sup>5</sup> <http://www.pharmatutor.org/articles/indian-drug-regulatory-system-moving-new-era> (accessed on 4.8.15)

The move came a year after the NPPA added 348 drugs to the NLEM in May 2013. The foreign drug companies have suffered the maximum adverse impact of this change in policy. Foreign drug players, which constitute 30% of the Indian Pharmaceutical Market (IPM), underperformed the market and Indian companies almost throughout the year. However, the top company by value in the IPM was Abbott India with a market share of 6.5% and sales of Rs. 5,630 crore. Drugs for infectious diseases continued to dominate therapies with sales of Rs. 1,009 crore for the period. India with the largest population of diabetics in the world registered a growth of 20% in sales of anti-diabetes drugs with sales of Rs. 615 crore. Sales in the dermatology segment followed closely with a growth of 19% to Rs. 509 crore in the 12 months. (Exhibit No: 3)[6]

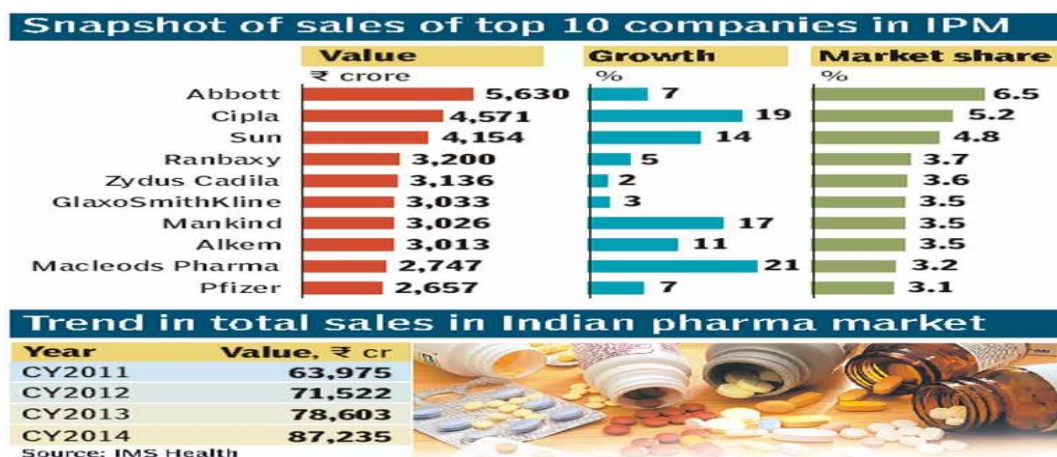


Exhibit No: 3

**Legal regulations of Indian Pharma industry in India:**

Pramod Kumar (2013) has said that drug & pharmaceutical industry plays a vital role in the health care of any country. The pharmaceutical industry in India is among the most highly organised sectors. This industry plays an important role in promoting and sustaining development in the field of global medicine.<sup>7</sup> Central Drugs Standard Control Organization (CDSCO), Ministry of Health & Family Welfare, Government of India provides general information about drug regulatory requirements in India. Drugs (Price Control) Order 1995 and other orders enforced by National Pharmaceutical Pricing Authority (NPPA), Government of India controls the prices of drugs. The Drugs & Cosmetics Act, (D&C Act) 1940 regulates the import, manufacture, distribution and sale of drugs in India. Schedule M of the D&C Act specifies the general and specific requirements for factory premises and materials, plant and equipment and minimum recommended areas for basic installation for certain categories of drugs. Schedule T of the D&C Act prescribes GMP specifications for manufacture of Ayurvedic, Siddha and Unani medicines. The clinical trials legislative requirements are guided by specifications of Schedule Y of The D&C Act. The Ministry of Health, along with Drugs Controller General of India (DCGI) and Indian Council for Medical Research (ICMR) has come out with draft guidelines for research in human subjects. These GCP (Good Clinical Practice) guidelines are essentially based on Declaration of Helsinki, WHO guidelines and ICH (International Conference on Harmonisation) requirements for good clinical practice.

The Pharmacy Act, 1948 is meant to regulate the profession of Pharmacy in India. The Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954 provides to control the advertisements regarding drugs; it prohibits the advertising of remedies alleged to possess magic qualities. The Narcotic Drugs and Psychotropic Substances Act, 1985 is an act concerned with control and regulation of operations relating to Narcotic Drugs and Psychotropic Substances.[8]

<sup>6</sup> <http://www.financialexpress.com/article/industry/companies/generics-beat-trend-in-cy14-clock-14-4-pct-growth-in-sales/29742/> (accessed on 4.8.15)

<sup>7</sup> Pramod Kumar (2013), Marketing Mix of Pharmaceutical Industry in India: An Exploration, KBSCMR's Journal of Management Research, 1(1):50-70.

<sup>8</sup> <http://www.ipapharma.org/regulations.aspx> (accessed on 21-7-15)



In India, the system of regulation, in order to provide checks and balances with regard to the advertisement of drugs, is provided in the Drugs and Magical Remedies (Objectionable Advertisements) Act, 1954 ("Act"). Section 3 (d) of the Act provides that "no person shall take part in the publication of any advertisement referring to any drug in terms which suggest or are calculated to lead to the use of that drug for the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule, or any other disease, disorder or condition (by whatsoever name called) which may be specified in the rules made under this Act." It can be devised, from the above provision that publication of advertisement of drugs are subject to scrutiny of the above mentioned section 3 (d) of the Act in India. Therefore, publication of any advertisement referring to any drug in terms which suggest or are calculated to lead to the use of that drug for the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition specified in the Schedule or Rules of the Act are prohibited in India.[9]

The Foreign Corrupt Practices Act (FCPA) has become an enforcement priority for regulators and major compliance issue for the US companies. There are increased investigations by the Securities and Exchange Commission (SEC) and the Department of Justice (DOJ) for prosecuting business corruption raising financial risks to companies. Pharmaceutical companies in the developing countries have to maximise the generic opportunity as a large number of drugs are expected to lose patents. These drugs represent \$80 billion in innovator sales between the years 2011 and 2013. Developing countries are coming together for an anti-fraud mechanism which can prevent patent infringement. This can also stop the allegations made by a few global pharmaceutical companies which have apprehensions to outsource to developing countries like India.

#### **Ethics in Pharma advertising:**

After inaugurating the 71st World Congress of Pharmacy and Pharmaceutical Sciences organised by International Pharmaceutical Federation (FIP) and Indian Pharmaceutical Association at Hyderabad, President Pratibha Patil said "it is the responsibility of every health care provider and health care organisation to ensure that quality and safety of medicines are not compromised. There are instances of spurious drugs, which are harmful, being produced. This is a crime and an unethical practice. It should not be left to the Government alone to identify such unscrupulous producers. The industry must also have a wing to find out such practices and bring it to the notice of the Government".[10]

Promotional activities are performed by sales personnel of pharmaceuticals manufacturer and advertisement of the product is initiated through electronic or print media. All promotional claims should be current, accurate, balanced and not misleading either directly by implication or omission. Promotional information should be in good taste and comparative and must conform to approved product information on the specific literature.

The code of conduct restricts many activities including those prescribed by legislation. Following steps can be brought to ethical code of advertisement and promotion of drugs:-

- Prescription medicine i.e., "Schedule-H drugs" cannot be promoted to the general public
- Manufacturer or traders cannot promote their product for indication that is not listed in the approved product information.
- Pharmaceutical representative or sales personal cannot promote the product over telephone unless the promotional material is marked urgent attention.
- Unsolicited reprint of journal articles must be consistent with the product information and the word "safe" cannot be used unless it is substantiated.[11]

A new code drawn up recently by the MNC-led industry body, Organization of Pharmaceutical Producers of India (OPPI) with 50-odd members, which has roughly 35% market share includes standards for ethical promotion of pharmaceutical products to doctors and healthcare professionals (HCPs) and seeks to

<sup>9</sup> <http://www.mondaq.com/india/x/265212/food+drugs+law/advertisement+of+drugs+in+india+an+overview> (accessed on 21-7-15)

<sup>10</sup> <http://www.thehindu.com/sci-tech/health/medicine-and-research/ensure-no-unethical-practices-in-pharma-industry-president/article2423932.ece> (accessed on 21-7-15)

<sup>11</sup> <http://www.pharmabiz.com/article/detnews.asp?articleid=31150&sectionid=50> (accessed on 21-7-15)

ensure that companies' interactions with HCPs and other stakeholders such as medical institutions and patient organizations, are appropriate and transparent.[12]

#### **Deceptive advertising in pharma industry:**

Lober CW (1993) has stated that the content of many symposia and medical journals as well as physician prescribing decisions seems to be influenced by the promotional efforts of pharmaceutical companies.[13] John A.Rizzo (1999) has revealed that consumers pay higher prices as a result of the advertising that occurs in this pharmaceutical industry.[14] Michael Veronin (2011) reveals that the prescription container label is the only source of instructions for the patients.[15] Shivkar YM (2009) have stated that the main aim of the package inserts or leaflets is to provide information essential for the safe and effective use of the drugs and hence reducing the number of adverse reactions resulting from medication errors.[16] Srivastava B et al. (2011) reveals that drug labelling refers to all of the printed information that accompanies a drug, including the label, the wrapping and the package insert.[17] Saeed Abbas Shah and Hyder Ali Khawaja (2013) have stated that pharmaceutical companies initiate unethical marketing activities and health specialists/doctors accept gifts and help companies to continue unethical marketing activities.[18] Nobhojit Roy, Neha Madhiwalla and Sanjay A Pai (2007) have revealed that misleading information, incentives and unethical trade practices were identified as methods to increase the prescription and sale of drugs.[19]

Ashish Chandra and Gary A Holt (1999) has said that drug marketers should always try to follow the unwritten rules of marketing ethics and consider what is best for their consumers before developing a particular advertising strategy. Increased participation of health care professionals in developing these strategies are likely going to be beneficial to all parties involved which are directly and even indirectly associated with the promotion of drug products.[20]

Lal A (2001) have revealed that the pharmaceutical industries (PI) throughout the World are heavily involved in aggressive drug promotions, with a clear aim to change the prescribing habits of physicians and to encourage the self-medication of patients. Broadly, drug promotion refers to all the informational and persuasive activities of the PI, the effect of which is to induce prescription, supply, purchase, and use of medicinal drugs. It includes the activities of medical representatives, drug advertisements to physicians, provision of gifts and samples, drug package inserts, direct-to-consumer advertisements, periodicals, telemarketing, holding of conferences, symposium and scientific meetings, sponsoring of medical education and conduct of promotional trials.[21]

Personal and healthcare companies are major offenders when it comes to misleading consumers through advertisements, according to the Advertising Standards Council of India (ASCI). In November last year, out of 113 advertisements against which the ASCI upheld complaints, 61 belonged to the personal and healthcare category. For instance, the advertisement of Goodnight, a mosquito repellent brand by Godrej Consumer Products, shows "a child stands near the mosquito vaporizer", whereas the product's leaflet

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<sup>12</sup> Rupali Mukherjee, Pharma companies adopt tough ethical norms, The Economic Times, 9<sup>th</sup> January, 2013.

<sup>13</sup> Lober CW (1993), Ethics in pharmaceutical advertising, *Dermatol Clin*, 11(2):285-288.

<sup>14</sup> John A.Rizzo (1999), Advertising and Competition in the Ethical Pharmaceutical Industry: The Case of Antihypertensive Drugs, *Journal of Law and Economics*; 42(1): 89-116.

<sup>15</sup> Michael Veronin (2011), Packaging and labelling of pharmaceutical products obtained from the internet, *Journal of Medical Internet Research*, Jan-Mar; 13(1): e22.

<sup>16</sup> Shivkar YM (2009), Clinical information in drug package in India, *Journal of Postgraduate Medicine*, 55(2): 104-107

<sup>17</sup> Srivastava B, Prakash Cand Sinha AK et al( 2011), Errors in Drug Labelling and Medico-Legal Awareness, *Journal of Indian Academy of Forensic Medicine*, 32(3): 228-230.

<sup>18</sup> Saeed Abbas Shah and Hyder Ali Khawaja (2013), Unethical marketing practices of pharmaceutical companies in Pakistan: A case study of Sukkur Division, *Handbook on the Economic, Finance and Management Outlooks*.

<sup>19</sup> Nobhojit Roy, Neha Madhiwalla and Sanjay A Pai (2007), Drug promotional practices in Mumbai: A qualitative study, *Indian Journal of Medical ethics*, 4(2): 57-61.

<sup>20</sup> Ashish Chandra and Gary A Holt (1999), Pharmaceutical advertisements: How they deceive patients, *Journal of Business Ethics*, 18 (4):359 – 366.

21 Lal A (2001), Pharmaceutical drug promotion: How it is being practiced in India?, *Journal of the Association of Physicians of India*, Feb 49; 266-273.

includes a precaution that the electrical liquid vapourizing machine should be kept away from the reach of children. The advertisement features a dangerous practice, manifests a disregard for safety and encourages negligence, ASCI said in a statement. Apart from being misleading or false, a lot of claims in advertisements by popular brands also could not be adequately or scientifically substantiated. ASCI found that the advertisement in which Lifebuoy (Hindustan Unilever) claims to provide "10 x more germ protection" and "10 x more skin care" than any other soap was not substantiated.<sup>[22]</sup>

Fraud management has different facets such as bribery investigations, counterfeits, conducting due diligence activities in high-risk countries, etc wherein compliance becomes mandatory by the companies for adherence. A report released by the Organisation for Economic Co-operation and Development (OECD) says that 75% of fake drugs supplied world over have some origins in India, followed by 7% from Egypt and 6% from China. A data on counterfeit medicines are difficult to obtain by virtue of its very nature, a recent WHO report estimates the prevalence to be around 1% of sales in developed countries to over 10% in some developing countries.

Fraud incidences occur in countries where access to medicines is poor. A study by the WHO's International Medical Products Anti-Counterfeiting Taskforce (IMPACT) indicated in 2006 that in countries like the US, EU, Japan, Australia, Canada and New Zealand, the incidence of spurious/counterfeit drugs is less than 1%. On the other hand, in parts of Asia, Latin America and Africa, more than 30% of the medicines are counterfeits.<sup>[23]</sup>

In the pharmaceutical sector, bribery and corruption has emerged as one of the key compliance risks to pharma companies. This is due to situations ranging from the fact that procurement teams at hospitals in India can manipulate prices in return for kickbacks from pharma companies. So also, medical practitioners have been accused of accepting gifts from pharma companies in return for promoting drugs made by them. Independence of regional regulatory bodies can be compromised to provide favourable reports overlooking malpractices.<sup>[24]</sup>

The pharmaceutical giant, Ranbaxy, is fined with 500 million US dollar (approximately Rs. 2750 crore) by the US Justice Department for selling adulterated drugs in US market. The company is charged with making false, fictitious and fraudulent claims for winning US FDA approval. This has raised serious concern among the health professionals and in the minds of consumers. The case is related to manufacture and distribution of adulterated drugs made at two of its units located in Himachal Pradesh and Madhya Pradesh. A pharma major Panacea Biotec has reported to have recalled a batch of easy five TT vaccine from the market following a controversy. This is a pentavalent vaccine meant for prevention of diphtheria, pertussis, tetanus, hepatitis and haemophilus influenza type B in children. The vaccine is recently introduced into the immunization programme in selective states. The controversy arose when the Tamil Nadu Drugs Control Department seized a batch of this vaccine for alleged re-labelling of the products. The vials of this batch of vaccine are re-labelled by pasting a new label over the old one extending the expiry date.

The company initially claimed that it has received permission from national drug regulatory authority Central Drugs Standard Control Organization (CDSCO) to re-label the products with extended shelf life. This has been denied by the office of Drug Controller General of India (DCGI). There has been reported death of a child after administration of the pentavalent vaccine. The Drugs Price Control Order (DPCO) (1995) was expected to control the price of scheduled drugs. But the companies continue to violate the norms of DPCO. The National Pharmaceutical Pricing Authority failed to even completely recovering the over charged amounts. During 2011-12 alone 26 fresh cases were raised for overcharging. The spurious drugs not only affect the health of the people but also the prestige of Indian's pharmaceutical trade. The Government of India introduced a whistle blower policy on dealing with spurious drugs (2009). The policy intends to reward both the public and the officials who provide information and help seizure of spurious, adulterated, misbranded drugs, cosmetics and medical devices. It proposed to a maximum of 20 per cent of the total value of seized items limiting the

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22 <http://timesofindia.indiatimes.com/business/india-business/Healthcare-ads-most-misleading-says-ASCI/articleshow/45770783.cms> (accessed on 27-7-15)

23 <http://www.safemedicinesindia.in/others6.php> (accessed on 31.7.15)

24 <http://archivepharma.financialexpress.com/latest-updates/1424-bribery-corruption-key-compliance-risks-to-pharma-cos-kpmg-india-fraud-survey-2012> (accessed on 4.8.15)

amount not exceeding Rs. 25 lakh for each case. For officials, the reward value does not exceed Rs. 5 lakh in each case limiting the total value of Rs. 30 lakh in full career.[25]

Even though the pharmaceutical industry is the most regulated and controlled industrial segment, it is well nigh impossible to continuously monitor the activities of companies which number several thousands and deal with the manufacturing and marketing of tens of thousands of drug formulations and several hundred Association of Physicians of India (APIs). In 2012, the US government raked up over \$ 6 billion by way of penalties from such companies more than double that of the previous year. In the US, during the period 2010 to 2012, 14 companies were fined by States and 5 by the Federal Agency for major offences. The list of companies included GlaxoSmithKline, Johnson & Johnson, Pfizer, Abbotts, Amgen, Allergen, Serono, Bristol Myers Squibb and Merck, all reputed companies with an excellent track record of providing quality products to global markets. The fines ranged from \$ 500 million to \$ 3.8 billion, not counting settlement with patient groups. In fact companies whose products are banned or withdrawn due to unacceptable adverse effects detected post-marketing, make provisions for payment of product liability claimed by patients particularly if there is evidence that relevant information during pre-clinical and clinical studies was suppressed. For example, in the case of Vioxx, the anti arthritic drug, Merck has provided for payment of up to \$ 1 billion to settle claims from patients.

Major offences by the companies were related to promotion of off label usage of drugs (for indications other than those which were approved for use), bribery and kick backs for members of the medical profession, insurance frauds of diverse nature, defrauding Government health programmes, manipulating pre-clinical and clinical trial data, suppressing information on adverse effects, non-compliance with statutory requirements under GLP (Good Laboratory practices), GCP (Good Clinical Practices) and GMP, price manipulations, anti-competitive practices etc.

The heaviest fine so far imposed on a pharmaceutical company has been in the case of GlaxoSmithKline, where two products Paxel and Welbutrin both anti psychotic drugs as well as Avandia the anti-diabetic drug were implicated and the total fine amounted to \$ 1 billion on criminal fines and \$ 2 billion in Civil penalties following a nine year investigation into the company's activities. The charges levelled against the company which were admitted to by the company included bribing doctors, false reporting on effectiveness, fabricating safety data, defrauding Medicare and Medicaid schemes and National Government Health Programmes.[26]

The industry has seen tremendous progress in terms of infrastructure development, technology base and the wide range of products manufactured. Demand from the exports market has been growing rapidly due to the capability of Indian players to produce cost-effective drugs with world class manufacturing facilities. Bulk drugs of all major therapeutic groups, requiring complicated manufacturing processes are now being produced in India. Pharma companies have developed GMP compliant facilities for the production of different dosage forms.

The Department of Consumer Affairs (DoCA) is one of the two Departments under the Ministry of Consumer Affairs, Food & Public Distribution. The mandate of the Department is consumer advocacy. In its endeavour to address the problem of misleading advertisements, the Department of Consumer Affairs has launched this portal for registering online complaints for Grievances Against Misleading Advertisements (GAMA). Tackling Unfair Trade Practices and Misleading Advertisements requires mobilization of all agencies viz. State Governments, Voluntary Consumer Organizations (VCOs), Grahak Suvidha Kendras, Advertisement Standards Council of India (ASCI), Indian Institute of Public Administration (IIPA) and various Regulators of the Central Government.

The focus will be on Six Key Sectors viz. Food & Agriculture, Health, Education, Real Estate, Transport and Financial Services. Regulators for each of these sectors will be key partners in the success of the effort to prevent the problem. (Exhibit No: 4)[27]

<sup>25</sup> <http://www.pharmabiz.com/NewsDetails.aspx?aid=75714&sid=9> (accessed on 4.8.15)

<sup>26</sup> <http://www.pharmabiz.com/NewsDetails.aspx?aid=76626&sid=9> (accessed on 4.8.15)

<sup>27</sup> <http://gama.gov.in/Default.aspx> (accessed on 4.8.15)





Exhibit No:4

The obnoxious practice of drug companies giving costly gifts such as gold chains, cars and foreign junkets to doctors may come to an end if the government accepts recommendations made by the parliamentary standing committee on health. Such gifts make doctors prescribe drugs of companies dishing out freebies and also contribute to higher marketing costs, which in turn, add to the consumer price of such drugs, the committee observed in its latest report. The practice needs to be banned by enforcing legal - not voluntary - code of conduct for doctors and drug makers. The department of pharmaceuticals has in place a code of conduct for drug companies to restrict such unethical practices, but it is voluntary in nature. The parliamentary panel has recommended that this code be made mandatory. The Medical Council of India (MCI) too had formulated rules for doctors to oversee marketing of drugs in 2009. (Exhibit No:5)[28]



Exhibit No:5

**CONCLUSION**

Fraud in the pharmaceutical industry have become an unavoidable constituent in the pharma industry because of the mounting research and development overheads and promotional costs. Developing markets

<sup>28</sup> <http://www.dailymail.co.uk/indiahome/indianews/article-2143268/Costly-gifts-doctors-push-drug-prices.html#ixzz3EEFsESDK> (accessed on 4.8.15)

are becoming more exposed to the three problems of corporate governance namely, fakes, fraud and forgery. A preventive-check method to make an anti-fraud situation and proactively facing the risks is the necessity of the present world, while there are ever-increasing set of laws for global pharmaceutical companies in the developed markets. The technological innovation in pharmaceutical industry has made the pharmacists and the corporate to follow the strong ethical codes in advertising and promotional methods. A pharmacist is always expected by the society to ethical as the people believe them as health care professionals.

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- [4] Source: <http://www.dnb.co.in/pharmaceutical/overview.asp> (accessed on 21-7-15).
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