The Indian Pharmaceutical Sector

The Indian pharmaceutical sector, a key science-based industry, has come a long way from a nominal and costly presence before 1970 to a prominent provider of pharmaceutical products, meeting more than 90 percent of the country’s pharmaceutical needs. Thanks to the thoughtful patent policy adopted by the government in 1970, among other things.

Indian pharmaceutical industry is one of the high-performing knowledge-based segments of the manufacturing sector. The pharmaceutical industry is a part of the larger chemicals industry. The ‘organised’ sector of India’s pharmaceutical industry consists of about 300 companies, which account for 70 percent of products on the market, with the top 10 firms representing 30 percent. However, the total sector is estimated at nearly 20,000 businesses, some of which are extremely small. There are about 8000 Small Scale Units, which form the core of the pharmaceutical industry in India (including five Central Public Sector Units).

Pharmaceutical companies in India manufacture bulk drugs in several therapeutic categories and the industry has amenities to manufacture various types of dosages namely capsules, tablets, injectables, orals, and liquids. Of the 400 bulk drugs in the Indian market, it is estimated that 300 are domestically produced. Moreover, India is emerging as the most favoured destinations for collaborative Research & Development (R&D), contract research and manufacturing, and clinical research as a result of growing compliance with internationally harmonised standards such as Good Laboratory Practices (GLP), current GMP (cGMP) and Good Clinical Practices (GCP).

India today has the distinction of producing high-quality generic medicines that are sold around the world. Further, India is poised to be one of the fastest-growing pharmaceutical markets in the world. Consequently, there are several trade associations in the industry representing different groups of producers, the Organisation of Pharmaceutical Producers of India (OPPI) representing big Indian pharma with high R&D base, Indian Pharmaceutical Association (IPA) a professional association of pharmacists in India, Indian Pharmaceutical Alliance (IPA); Confederation of Indian Pharma Industry (CIPA) – the apex body of small-scale manufacturers of drugs and pharma in India; Bulk Drug Manufacturers Association (BDMA); and Indian Drug Manufacturing Association (IDMA).

After signing the WTO accord, India became obliged by the World Trade Organisation’s Agreement on Trade Related Aspects of Intellectual Property Rights (WTO-TRIPs) and hence incorporated provisions to provide product patents since January 01, 2005 after making amendments in its Patents Act of 1970.
With increasing upper middle-class population base, improvements in healthcare infrastructure and penetration of health insurance, the Indian pharma industry is estimated to grow manifold.

Regulatory & Policy Framework

The pharmaceutical industry is an important source of health care for billions of population globally and in India. Hence, it is supposed to be a highly regulated sector. The pharmaceutical industry is influenced by a host of practices which may primarily relate to price regulations, insurance, drug procurement by government agencies, nexus among players in the pharmaceutical industry and service providers, patent laws, safety policies, drug regulation, drug promotion regulation, drug advertising regulation, etc. Hence, the regulatory mechanism plays a crucial role and has to work with all such diverse set of laws, policies and regulations governing the pharmaceutical sector.

Market Size & Growth

The US$12bn valued pharmaceutical industry in India is expected to grow at an annual compound annual growth rate (CAGR) of 10-11 percent. The industry spends around 18 percent of its revenue on R&D.

India is one of the most significant emerging markets for the global pharmaceutical industry. Moreover, India is expected to join the league of top 10 global pharmaceuticals markets in terms of sales by 2020 with the total value reaching US$50bn.

The domestic pharma market is expected to grow at a CAGR of 15 to 20 percent to reach a value anywhere between US$50 and US$74bn by 2020. The drugs and pharmaceuticals sector attracted FDI worth US$4.89bn between April 2000 and August 2011, according to the latest data published by the Department of Industrial Policy and Promotion (DIPP).

Number of Formulation and Bulk Drugs Manufacturing Units in India

Source: NPPA, 2007

### Key Feature of the Industry

| Supply | Higher for therapeutics segments, which is typical of a developing market |
| Demand | Very high for certain therapeutic segment. Will change as life expectancy, literacy increases and with increase in lifestyle diseases |
| Barriers to entry | Distribution network, patents and plant approval by regulatory authority |
| Bargaining power of supplier | Distributors are increasingly pushing generic products in a bid to earn higher margins |
| Bargaining power of customer | High, a fragmented industry has ensured that there is widespread competition in almost all product segments. (Currently also protected by the DPCO) |
| Competition | High, except in few therapeutic category. Very fragmented industry with the top 300 (of 24,000 manufacturing units) players accounting for 85 percent of sales value. Consolidation is likely to intensify |
In India, the drug manufacturers and exporters not only need to adhere to the standards imposed by the Drug Controller General of India (DCGI) but also standards set by the Drug Regulators of the countries to which the product is being exported. The regime of compliance is becoming stronger as regulators look for greater compliance from the industry given the mounting consumer pressures, and increasing healthcare standards. In addition, regulatory authorities are increasing the scrutiny related to patient safety and compliance.

The main regulatory body in India is the Central Drug Standard Control Organisation (CDSCO) under the Ministry of Health and Family Welfare (MoHFW). The CDSCO prescribe standards and measures for ensuring the safety, efficacy and quality of drugs, cosmetics, diagnostics and devices in the country and regulates the market authorisation of new drugs and clinical trials standards. It is responsible for the approval of licence of drugs at both Central and state levels. CDSCO is presided over by the DCGI.

The National Pharmaceutical Pricing Authority (NPPA) is responsible for fixing the prices of bulk and formulation of drugs within the National List of Essential Medicines (NLEM) under the Essential Commodities Act. It periodically updates the list under price control through inclusion and exclusion of certain drugs in accordance with established guidelines.

Along with the Health Ministry, the policy issues associated with the sector are looked upon by Department of Pharmaceuticals (DoP) formed in 2008 under the Ministry of Chemicals and Fertilisers. The MoHFW examines pharmaceutical issues within the larger context of public health while the focus of the DoP is on industrial policy.

The department give greater focus and thrust on the development of pharmaceutical sector in the country and to regulate various complex issues related to pricing and availability of medicines at affordable prices, R&D, protection of IPRs with DIPP and international commitments related to pharmaceutical sector which require integration of work with other ministries. All drugs and pharmaceuticals, unless specifically allotted to any other department, would come under the purview of the DoP.

However, other government department and ministries also play a role in the regulation process. These include:
- Ministry of Environment & Forests
- Ministry of Commerce & Industry
- Ministry of Science & Technology
- Ministry of Corporate Affairs etc.

Drugs and Cosmetics Act, 1940 is the law which regulates the import, manufacture, distribution and sale of drugs and cosmetics in this country. The Drugs and Cosmetics Act, 1940 and Drug and Cosmetic Rules, 1945 have elaborate provisions to check the production of spurious and substandard drugs in the country. The Act provides elaborate definitions of the term spurious, adulterated and misbranded drugs for the purpose of taking penal actions against the offenders. The Drugs and Cosmetics Act, 1940, has been recently amended under the Drugs and Cosmetics (Amendment) Act, 2008 providing very strict penalties for manufacture of spurious and adulterated drugs.

India has a bifurcated or dual drug regulatory control at Central and state levels. The Central Regulatory Authority undertakes approval of new drugs, clinical trials, standards setting, control over imported drugs and coordination of state bodies’ activities. State authorities assume responsibility for issuing licences and monitoring manufacture, distribution and sale of drugs and other related products.
Schedule M to the Drugs and Cosmetics Rules of 1945, provides requirements for GMP to make it at par with the international standards and it is mandatory for the manufacturers of drugs to comply with the requirements of this Schedule for quality control. It specify in detail the requirements of premises, surroundings, personnel, sanitation, storage of raw materials, documentation, records and quality control systems and site master files etc.

Schedule Y of the Drugs and Cosmetics Act governs the clinical trials legislative requirements of the Drugs and Cosmetics Act.

The other major acts and rule include Pharmacy Act of 1948, Drug and Magic Remedies Act 1954 and Drug Price Control Order (DPCO) 1995. Besides, the currently applicable Pharmaceuticals Policy, 2002, replaced the Drug Policy, 1986. A new Pharmaceuticals Policy, 2006, is on the anvil but is yet to be passed by the union government.

The drug prices in India are controlled under the Drugs Prices Control Order (DPCO). The DPCO is an order issued by the government under Section 3 of the Essential Commodities Act, 1955 empowering it to fix and regulate the prices of essential bulk drugs and their formulations. The order has been revised several times since then. The order includes a list of bulk drugs whose prices are to be controlled, the procedure for fixation and revision of prices, the procedure for implementation and various other guidelines and directions. The order is subject to the guidelines of Drug Policy and supposedly aims to ensure equitable distribution, increased supply and cheap availability of bulk drugs.

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

NPPA is entrusted with the task of recovering amounts overcharged by manufacturers for the controlled drugs from the consumers. It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels.

Patent Regime in India – India earlier had a product patent regime under the Patents and Designs Act 1911. However, in 1970, the government introduced the new Patents Act, reversing all previous legislations. With the changes brought about by the Patents Act of 1970, which provided only process patents for pharmaceutical products, Indian drug manufactures became experts in the field of reverse engineering and increased its production and supply of less expensive generic version of the world’s best-selling patent protected drugs.

Hence, with a regulatory system focusing on process patents and being in the grip of a rigid price control framework, the Indian pharmaceutical industry has emerged from an import dependent industry to having achieved worldwide recognition as a low cost producer of high quality generic pharmaceutical products.
The establishment of the WTO has led to a tremendous paradigm shift in world trade. India is thereby required to meet the minimum standards under the TRIPs Agreement in relation to patents and the pharmaceutical industry.

Drug Regulatory Environment in India in Transition: Proposed New System

The Central Cabinet approved the formation of the Central Drug Authority (CDA) in January 2007. The proposed organisational structure of the CDA would be similar to the US FDA. It would be a strong, well equipped, empowered, independent and professionally managed body expected to facilitate upgradation of the national drugs regulator, uniformity of licencing, and enforcement and improvement in drug regulations.

Regulatory Challenges

Drug Pricing

Ever since the evolution of the pharmaceutical industry, drug pricing in India is a huge issue. The high prices of drugs, access to medicines and procurement problems have made this issue even more crucial for the regulators. However, it is not simple to keep the interest of every stakeholder while arriving at a reasonable solution but it is not an excuse for the government and regulators who have so far not dealt with the issue in an efficient manner and are continue to mull over a reasonable solution. India’s government is facing stiff resistance from foreign and domestic pharmaceutical companies over its plan to limit prices for drugs severely.

The DoP comes out with a draft pricing policy last year, to bring all essential drug under price control. The new policy which has been pending since 2006 will set to replace the 15 year old policy. The Pranab Sen Committee of 2006 had recommended that pricing policy for drugs should move out of cost pay system and go to reference pay system especially in a market like India which is highly branded generics market. The new pricing policy proposed to cover at least 60 percent of drugs from only 20 percent right now. Also, all essential medicines, which are 348 drugs plus combination products making it to over 400 drugs, will come under price control after the policy is approved.

However, the draft National Pharmaceutical Pricing Policy (NPPP) triggered a serious debate on pricing of drugs in the country. It presented a contentious issue of moving the pricing mechanism to a market based model from the existing cost based model. The market based mechanism proposed to cap the prices of 348 essential drugs at the average price of the three best-selling brands in that category.

Though, the industry welcomed the move, others had objected saying it would lead to a rise in prices because the top three selling brands would usually be the more expensive ones. There is apprehension that this would lead to setting high prices for drugs.

The draft policy seen as government’s hasty response to the Supreme Court’s demand suggests a lack of clear thinking and coherence among the relevant authorities. Surrounding the policy disputes, DoP has decided to abandon its controversial ‘industry-friendly’ proposal. This comes as bad news for the bigger players in the market that have been lobbying to end the cost-based pricing model.

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<th>India’s Drug-Price Ceiling</th>
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<td>How India’s current price caps compare to the proposed system</td>
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<td>Reason for price control</td>
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<td>Medicine has large market share</td>
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<td>Number of compounds covered</td>
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<td>Formula to calculate ceiling price</td>
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Source: WSJ research

The Wall Street Journal
Opinions, as usual have been divergent between the industry, traders and healthcare activists/scholars. Some insisting on retaining the existing cost based mechanism, whereas others are pushing for the market based model.

After extensive deliberations spanning over a year, the GoM decided in favour of market-based pricing policy for essential drugs. Instead of earlier proposed weighted average price method they have recommended a simple average price method where the simple average price of all the brands in a segment with more than one percent market share by volume to determine the ceiling price of a particular drug in a therapeutic segment. Another major deviation from the original proposal of DoP, the GoM has now included even the dosages and other combination of drugs that consist of NLEM drugs under the price control.

However, there are still conflicts both in the industry and the public health groups. Policy makers face a daunting challenge ahead of balancing the interest of the pharma industry on the one hand, and preserving the already strained access to essential drugs of the average Indian.

National Pharmaceuticals Pricing Authority (NPPA) apart from fixing the prices of some of the commonly used medicines is also entrusted and authorised to levy fines on companies, which sell the medicines at higher prices than those fixed by NPPA. However, if one visits the NPPA website, it becomes obvious that NPPA has fined more than 300 companies but recovery of fine is partial. Irrespective of NPPA, one can easily find thousands of brands being sold in the market at much higher prices than those fixed by NPPA.

In November 2012, NPPA had imposed a cumulative penalty of Rs 2,462 crore on several pharmaceutical companies, a vast majority of which are multi-nationals, for overcharging Indian consumers for over 10 years, up to October 2011. Since then, however, the authority has been able to realise only a meagre Rs 220 crore from the drug manufacturers. Earlier in 2009, India’s drug prices regulator had failed to recover at least 90 percent of the Rs 1,800 crore in penalties it imposed on firms for overpricing medicines, due to long-drawn litigations and lack of administrative muscle. It clearly implies that the existing rules are toothless and pharma companies are taking undue advantage of existing system. However, to ensure long-term changes in the industry, the NPPA and the other regulatory bodies must also get their act together.

The authority has been hobbled by a weak cost analysing system, poor legal support and lack of infrastructure to track violations. It is urgently required that NPPA should be provided more power to enforce price control and undertake aggressive recovery measures.

**Collusion in Pharma Market**

Consumer choice in pharmaceutical products is limited by definition as consumers are constrained by their lack of medical knowledge and, thus, dependant on the advice of medical practitioners. The same lack of knowledge implies that there are information asymmetries between consumers and suppliers regarding medical services which cause the former to fall prey to low quality medical service or collusion among agents in the supply chain such as doctors and pharmaceutical companies. Such imperfections in the market for medical services (especially in the absence of proper regulatory oversight and strict enforcement) often lead to proliferation of market malpractices at various levels resulting in poor market outcomes. Such market failure calls for identification of necessary remedial action. Moreover, the punitive element in such remedial action would discourage such malpractices in the future.

The other extremely important point touches on access to medicines. Private (out-of-pocket) expenditure in healthcare constitutes 80 percent of the total healthcare expenses in India. Expenses made for buying medicines comprise 72 percent of the total out-of-pocket expenses on healthcare in India. Major issues arise with the possibility that drugs are prescribed or dispensed more for the financial interests of the prescribers and dispensers than the needs of the patient. Evidence for the existence of undue pressures on prescribers in India is abundant. It is hard to find any information about the effectiveness of the voluntary codes run by the larger pharmaceutical associations. In early 2009, government officials hinted at the creation of legal restraints on unethical promotion, but this seems to have been pre-election posturing rather than a serious proposal.

**Challenges Related to GMP**

One of the most important risks that pharmaceutical industry particularly the SMEs face is that of compliance to extremely stringent process standards of GMP. The industry is under the vigilance of multiple regulators that impose high standards, which increases efforts on the part of the industry but also builds up trust of its clients and the obligation on the regulatory bodies to ensure a healthy supply of quality drugs at affordable prices to the masses.
GMP compliance is necessary to enhance the industry's credibility within the domestic and international markets. There are still lacunae that need to be overcome, especially for the long-time survival of small scale industries (SSIs); both for producers of drugs as well as pharmaceutical machinery. It's been some time since the implementation of cGMP regulations in India, and still, thousands of SSIs or small and medium enterprises (SMEs) of India’s unorganised pharma industry have not complied to these preventive regulations put in place by state, WHO and the US Food and Drug Administration (FDA).

While most have shown resistance and have been demanding for more relaxations in the cGMP compliance list, others are simply unaware of the repercussions. Over the years, some of the barriers which have led to non-compliance of cGMP have been systematic conversions like from sample testing to instituting quality control procedures, failure of drug manufacturers to understand the cGMP norms and the logic behind them, changes or continuous improvement in the norms and regulations and lack of trained personnel.

In such a scenario, the government can take some proactive steps in this regard especially given its importance and can initiate training and technical capacity building and provide necessary know how to help them with GMP compliance. Under some schemes, the government grants loans to such pharmaceutical companies too. However, a serious problem faced by small companies is the inability to produce high collaterals for such loan approvals. This is an area where the government initiatives are required.

**FDI in Pharma Sector**

The Indian pharma industry has witnessed a lot of consolidation in recent years. Most of these acquisitions are tactical, largely to capture the growing Indian market. Many generic firms have been acquired in the process. Such consolidation is also witnessed due to change in patent regime which now allowing for product patents since 2005. Albeit a host of potential concerns is raised due to the potential effect on generic competition in the longer term. Some of the interest groups and even certain ministries have recommended restricting FDI to 49 percent in Indian companies citing the reasons that acquisition of Indian pharma companies (including generic companies) by foreign pharma companies would lead to a significant rise in the cost of the drugs in India.

Further, it was felt that if most of the generic companies are acquired by foreign companies, the option of compulsory licensing available under the Indian Patents Act, 1970, may not be availed by such companies. MoHFW was one of the concerned ministries in this regard, hence it suggested FIPB route for brownfield investments in pharmaceutical sector where ownership passes to a foreign firm (51 percent share or more). The rest of investment in the sector can continue to enjoy automatic route.

In the wake of this debate, government has set up a High Level Committee which after much consultation, came up with the prescription that the Competition Commission of India (CCI) is the body to keep a watch on brownfield investment through M&A activities in the pharma sector in order to avoid any dominance and other anticompetitive behaviour on the part of the MNCs. The automatic approval rule continues to apply to greenfield investment proposals of 100 percent FDI in the sector.

The proposed (CCI) approval requirements has been seen as a speed breaker by potential foreign investors as they may have to show that their intention is not to collude or undertake predatory pricing or any such anticompetitive practices.

The strengths of the CCI were the legal provisions that empower it to assess any proposed acquisitions for adverse impact on competition, consumer interest, and innovation among other issues. However, there are concerns that the threshold for action in the Competition Commission would tend to be high and also that the CCI's capacity, at least in the short run, in the domain areas may be less than optimal.

It is also believed that the moment there becomes a gap in domestic pharma sector vis-a-vis capacity to manufacture drugs under compulsory license because of acquisition of capable firms, the same would be filled up by upgradation of some smaller units operating in India. It would certainly make business sense for such smaller firms to keep aspiring to fill such gaps, if created. The strengthening of public sector drug manufacturing capacity also assumes importance in this regard, as this can be saviour for public health in cases of emergency.

After much debate between the government, interest groups and Industry, the CCI will finally be at the helm of the special dispensation for regulating brownfield mergers and acquisition (M&A) deals in the pharma sector. This means that even for the deals that do not meet the thresholds prescribed in the Competition Act, prior approval of the CCI would be required for investments by foreign firms in Indian pharma companies. The approval would be subject to compliance with a series of public health riders.

However, a multinational company with intent to acquire a domestic drug firm would take a commitment at the outset that it would not cut production of essential drugs and R&D spend in the
target company in years following the acquisition. The Competition Act will be amended for this purpose.

It remains a challenge whether this policy strengthens the Indian pharmaceutical sector, so as to ensure a vibrant, competitive and innovative pharmaceutical sector.

Supply Chain Challenges

While the pharma industry is mostly dominated by large MNCs and their blockbuster drugs, the brand owners themselves in most cases outsource the actual production and packaging to smaller specialised entities. Although compared to various industries in India, it is one of the most organised sectors, outdated and contaminated processes and lack of visibility through the supply chain impede efficiencies and add significant costs. The ever-changing market demands require flexibility in manufacturing schedule and shorter planning cycles. This apart from promotion decisions which are not in sync with actual demand.

Currently, in India (and in most other countries), the pharmaceutical firm serves as the key facilitator in this ecosystem. It promotes the product, plans the outsourced manufacturing and controls distribution to the outlets. In addition, the pharmaceutical company also takes responsibility for collecting the expired products from the outlets or stocking warehouses and its disposal. The above results in excess inventory at various points in the supply chain, and subsequently excess expiry which is ultimately dispensed to the environment causing undesired outcomes.

Understanding the stocking patterns of the distributors in comparison to the actual sales by these distributors, can give an indication of whether there is prevalence of unethical practices. Unnecessary inventory accumulation can be eliminated thereby reducing the likelihood of getting hit with large amounts of expired product.

Product Safety and Quality: Menace of Spurious Drugs

Ensuring safety and quality of the drugs produced and marketed by the pharmaceutical industry is a major concern. In recent times, a number of FDA approved blockbuster drugs had to be withdrawn from the market as questions were raised regarding their safety standards. In addition to safety and quality, in the Indian context, the problem of spurious drugs has become a cause of concern. The problem is more acute in remote and rural areas.

Traditionally, antibiotics, anti-malarial, anti-hormone and steroids were the candidates for fake drugs. Of late, even lifestyle drugs (such as nutritional, anti-diabetes, anti-hypertensives and cancer drugs) are also allegedly produced. Though, spurious drugs may not endanger the life, they can be ineffective in curing the patients. Re-usage of drugs past their expiry date is yet another menace. Filling spurious drugs in used medicine bottles is also allegedly prevalent. This calls for stricter safety and product quality regulations for the industry.

Unethical Clinical Trial and Research

The main legislation governing clinical trials is the Drugs and Cosmetics Act, 1940 and the Executive authority is the DCGI. Schedule Y to the Drugs and Cosmetics Rules, 1945 stipulates the regulations for importing and manufacturing new drugs for sale and to undertake clinical trials in India. Additionally, the Indian Council of Medical Research (ICMR) has issued Ethical Guidelines for Biomedical Research on Human Participants and the CDSCO has formulated Good Clinical Practices Guidelines (GCP Guidelines) in line with the international guidelines issued by World Health Organisation and International Committee on Harmonisation (ICHGCP), which provides operative guidelines for ethical and scientific standards for the designing of a clinical trial protocol including conduct, recording, safety and reporting procedures. It is compulsory for every organisation undertaking a clinical trial in India to strictly adhere to these guidelines.

Drug development is a process that calls for utmost care. An error can cause fatal result. Clinical trials are developed in such a way that it not only helps the discovery of new drugs but also ensures safety profile of such drugs. To determine the safety and efficacy of drug research on humans is always warranted, but one needs to be cautious and vigilant as to how the players in this field undertake the process. In India, compliance with GCP guidelines issued by the CDSCO is recommended.

However, in a recent shocking disclosure, by Parliamentary Standing Committee on Health & Family Welfare, some drug companies have been caught red handed writing scientific recommendations of their own products and submit them to the Central Drug Standard Control Organisation headed by DCGI after getting it endorsed by top doctors for a quicker marketing approval.

Another violation in relation is unethical drug trial on human body. Informed consent is an essential requirement of medical trials, which denotes that
the patient undergoing treatment as part of the study should be made aware of the trial being conducted, the drugs being administered on him and its possible side effects. But the country has, at several instances witnessed gross violations of human rights and ethical values while conducting trials.

In 2003, Mumbai-based Sun Pharmaceutical Industries Ltd. launched a promotional-cum-research programme by getting private doctors to prescribe the anti-cancer drug Letrozole to more than 400 women as fertility drug for ovulation induction. The company then publicised the doctors' reports to other doctors as 'research', using their network of medical representatives. The drug was prescribed despite the fact that it was known to be toxic to embryos.

Stricter regulatory measures are required to curb such nexus and unethical practices of drug. This is also a clear violation of the Code of Ethics of the Medical Council of India applicable to doctors. Lack of regulatory jurisdiction over private trial sites and absence of uniform application of the need for informed consent and proper ethics review have raised concerns about trials conducted in India.

Suggested that in the long run, functions of drug regulation and price control should be with the same agency, so that an integrated regulatory system exists in the economy.

Strngthening of regulatory system is also required in the context of new patent regime. There is a need to simplify procedures and shorten the timeline for various approvals. With India emerging as a major hub for contract research, particularly clinical trials, it is important to ensure good clinical practices in the country.

The pharmaceutical industry is one of the success stories of the Indian manufacturing sector. Favourable Government policies along with industry/firm level initiatives have helped the industry to post high growth rates over the years. Many Indian pharmaceutical companies have not only shown good performance domestically but have also been able to establish their foothold in overseas markets. The strategies being adopted by the industry are however to be strengthened along with an appropriate policy framework for shaping the future of the Indian pharmaceutical industry.

Conclusion

Regulatory framework of pharmaceuticals industry is panacea for its survival. It relates to the implications for public health, standard-setting, public accountability of regulatory agencies, procedures utilised by pharmaceutical companies for regulatory compliance, and addresses the complex web of regulatory requirements, application processes, and quality control issues influencing the pharmaceutical industry.

There are various policies that influence pharmaceutical industry which can be broadly categorised into healthcare policy, industrial policy and health safety policy. Some of the concerns of the industry, regulators and end users are addressed through such policy framework. These include: accessibility and affordability of medicine by common man, ensuring quality and efficacy of medicines, strengthening the growth of generic medicines, promoting R&D, technology transfer, strengthening industry-institutional linkages and capacity development.

At present, both Central and state governments regulate Indian pharmaceutical industry. While the state regulatory authorities are responsible for regulating manufacturing, sales and distribution of drugs, the national regulator approves new drugs and clinical trials, control import of drugs and also coordinate among the state bodies. Various committee reports and other recommendations
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