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Chapter 1 : Pharmaceutical Products - Koshambh Multitred Private Limited

The evolution of the Indian pharma industry since independence into a powerhouse supplying 20 per cent of the global demand for generic drugs The Financial Express is an online Business and Financial Newspaper providing news from Stock Markets, Companies, Insurance, Automobiles and more through Mobile Apps; iPhone, iPad and Android.

This article has been cited by other articles in PMC. India exports medicines to more than countries worldwide. Pharmaceutical market in India consists of more than 20, manufacturers and is termed as the 3rd largest market in the world, by volume. In spite of that, more than half of its population has no access to essential medications in government hospitals due to heavy dependence of a majority of patients on private sector. A significant proportion of the Indian population pays for their health care expenditures by shelling money out of their own pockets. Pharmaceutical policy in India is perceived to be favouring the industry rather than the public. The main focus of pharmaceutical health policies in India is to focus on the progression of the industrial sector while the issues of availability, pricing, and affordability of drugs remain ignored. Although, it is a common notion that drug prices in India are relatively low, studies have reported that medications in India are overpriced and unaffordable. To promote the domestic industry and manufacture good quality drugs. However, the promulgation of law and policy from time to time has severely affected the progress toward these goals. In , the National Pharmaceutical Pricing Authority NPPA was established under the ministry of chemicals and fertilizers, Government of India with the aim of controlling the prices of medicines and ensure its availability. This drug list has been revised and cut down considerably over the years and finally in , the Drug Price Control Order DPCO included only 76 drugs that were subjected to price control. The efforts of NPPA were widely acknowledged nationwide by the public as NPAA was viewed as an organization making a paradigm shift its industry-friendly policy to health policy. On September 20, , the NPPA announced to cap the prices of 36 more drugs to increase their affordability to the public. However, just 2 days later, on 22 September, , the Department of Pharmaceuticals, Ministry of Chemical and Fertilizers, Government of India issued a notification in which the internal guidelines given by NPPA on May 29, regarding the inclusion of drugs under price control policy were withdrawn with immediate effect. The implication of this policy has already seen an unbelievable rise in pricing of some of the commonly used drugs as shown in Table 1. Table 1 Open in a separate window As health care professionals, we urge the stakeholders to review the necessity of their policy of excluding drugs from price control list. The extremely essential medications that are needed by the majority of the Indian population should be reconsidered for inclusion in the drug price control list. Another possible solution could be to negotiate drug pricing with the manufacturers to keep prices under control and in return, the manufacturers could be provided with tax benefits. Pharmaceutical companies should be brought on board to partner with the government to achieve the vision of healthcare access for all. There is a wide variation in the prices of different branded drugs and generics that are available in the market. There is a wide variation even among the branded or generic drugs manufactured by different companies, even though they might represent the same drug molecule. Medical professionals should be urged to prescribe cost-effective medications in the interest of the patients without being influenced by pharmaceutical companies. Consumer knowledge about generics could be enhanced through effective educational interventions. The issue of pricing needs a holistic solution generated by the synchronized efforts of stakeholders, pharmaceutical companies, and healthcare professionals in order to catalyze equity in access to healthcare. Availability, cost and affordability of antimalarial medicines in India. Int J Pharm Clin Res. Harvard School of Public Health; Responding to the threat of chronic diseases in India. Burden of non-communicable diseases in India: Setting priority for action. Prices and availability of common medicines at six sites in India using a standard methodology. Indian J Med Res.

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Chapter 2 : History - Alembic Pharmaceutical Limited

Before Independence Indian pharmaceutical industry has grown over a period of time and has seen many ups and down during its evolution. The architect of the Indian pharmaceutical industry would be Acharya calendrierdelascience.com

Patents Regime in India: Issues, challenges and opportunities in Pharmaceutical Sector. With India adhering to TRIPS requirements it is feared that prices of new drugs in India may shoot up and drugs may become out of reach of common man. But TRIPS agreement provides some inherent flexibilities and with prudent application by the government will benefit the society. Flexibilities like Compulsory Licensing, Parallel Imports, and Bolar Exemption can be used judiciously by Indian government to make drugs affordable to masses. Indian companies have some challenges ahead in product patent regime, as multinational pharma giants will launch products in India from their portfolio of global products, which may have higher prices. History Patent Act in India is more than years old. The Patent Act was first enacted in the year under the rule of British and subsequently amended several times. India had inherited The Patents and Designs Act from the colonial times that provided for protection of all inventions except those relating to atomic energy and a patent term of 16 years from the date of application [1]. After Independence of India there was a need to revise The Patents and Designs Act to facilitate the local industry and in accordance with the stage of development of the country. The Patents Act in India was framed after years of consideration and on the basis of the recommendations made by the Justice Rajagopal Ayyangar Committee [2]. The Patent Act , provided for process patents for pharmaceuticals and agro-chemical products and for a short period i. This enabled the growth of a strong local generic drug industry, which produced the same drugs as the MNCs at relatively low prices. India, since , had a Patent law that was proclaimed by many as a model for other developing countries. One of the important factors that contributed the growth of Indian pharma industry was the fact that The Patent Act did not provide for monopoly rights in the area of drugs and agro-chemicals [3] as only process patents and not product patents were recognized. Thus, by allowing only process patent India today witnesses a thriving generic pharmaceutical industry that is capable of exporting generic drugs to certain developed countries. India being a developing country was given a grace period of ten years - January 01, to December 31, - to fully comply with TRIPS requirements. These amendments in and did not completely comply with the WTO requirements and so there was a need to frame an Act that was more compatible with the requirements of TRIPS. With the third amendment of The Patents Act in March by the Indian government, Indian pharmaceutical companies were prohibited to market a generic drug - a drug patented elsewhere by using a different process. But amended Indian Patents Act has provided measures and safeguards that will not be detrimental to Research and Development activities in the country, specifically in the field of pharmaceutical products. Evergreening refers to extending patent life of a product beyond its stipulated term of 20 years. Growth of pharmaceutical industry since India has achieved tremendous progress in science and technology since independence. It ranks very high in the third world, in terms of technology, quality and range of medicines manufactured. From simple pills to complex medicines requiring complex steps to manufacture, medicines for almost all type of ailments are manufactured in India [6]. India today is considered to be global powerhouse of generic drugs. As a result, the Indian pharmaceutical industry grew rapidly by developing cheaper or economical versions of a number of patented drugs and supplying these cheaper versions to Indian market and eventually moved aggressively into the international market with generic drugs once the international patents expired [7]. Thus, India has had a vibrant generic industry since when it lawfully amended its existing Patent Act to disallow patent protection for pharmaceutical products. This move catapulted India from a country importing most of its medicines at some of the highest prices in the world before Independence, to a country that was self-reliant in producing life-saving medicines [8] although it took several years for Indian pharmaceutical companies to make their mark in global pharmaceutical field and being recognized as producer of quality medicines at affordable prices. According to pharmaceutical industry

statistics, nearly 70 percent of production is by the top firms and about a third of that is exports, which are rising 25 percent a year [10]. Prices of Drugs in India So far India was regarded as a supplier of low cost generic version of patented drugs to countries, which do not have sufficient manufacturing capacity and to some low income and least developed countries in Africa. If the government does not establish measures to bring prices down, the cost of new drugs remains very high, because patents allows monopoly power and prevents competition. Although least-developed countries are not obliged to grant patents on pharmaceuticals until , these countries do not have the technical and financial capacity, nor the economies of scale to produce generic medicines [11]. TRIPS implementation in India and other manufacturing countries will eventually cut the lifeline of affordable drugs unless safeguard measures are implemented to prevent this. TRIPS agreement does not specify or enforce anything regarding the prices of drugs and national governments are free to enact the measure within the ambit of TRIPS provisions to curb the increase in prices of drugs. India should think in this direction and should control the prices charged by the pharmaceutical companies. It is evident that Indian drug maker Cipla offered and supplied anti-retroviral drugs to some African countries at a fraction of price charged by the Multinational companies MNCs. In India it is feared that if certain antiretroviral drugs are granted patent, prices of these drugs will rise making it unaffordable to the general public. And in India, a vast majority of population spends for the medicines out of pocket and provision of medical insurance schemes is not in vogue. TRIPS declaration to meet public health in least developed countries and countries with insufficient manufacturing capacity Paragraph 6 of the Doha declaration on the TRIPS agreement and Public health provides certain flexibilities to be used by the countries to protect public health concerns. It states that member countries can use compulsory license, incase of emergency to address supply problems that can arise during health crises. The Decision is made up of eleven main paragraphs in addition to an annexure; setting out the determination of manufacturing capacities in pharmaceutical sector. In paragraph 2, the General Council explicitly waived the obligation of member countries under Article 31 f [16]. Paragraph 2 expressly permits export of pharmaceutical products to eligible importing member upon the fulfilment of certain conditions. These conditions include notification to the TRIPS Council by eligible importing members of specific names and quantities of the products needed, confirmation of lack of sufficient manufacturing capacity, obligation imposed on the exporting country to ensure that the amount of products produced under compulsory licenses are to meet the health needs of the eligible importing members and that all the products are exported to the member which has notified its need of such a product to the TRIPS Council [17]. Mailbox was essentially a mechanism for accepting patent applications till a product patent regime was actually put in place. Experts assume, therefore, that most of those patent requests are for already known medicines that have been only slightly modified. When the Patent Office of India opened the mailbox, there were a total of 8, patent pleas in the mailbox; a majority of 7, belonged to foreign entities. This clearly shows how pharmaceutical companies can have several patents for the same molecule. While US based entities put 2, applications including 2, for pharmaceuticals, Indian companies submitted only 1, filings including 1, for Pharma sector. Among the pharma companies Pfizer, worlds number one pharma company, emerged as the biggest patent applicant with applications. Johnson and Johnson with applications followed Pfizer in filing mailbox pleas. Among Indian companies Dr. Thus it is evident from the mailbox applications is that the multinational pharmaceutical companies were more interested in getting patent protection in India than the Indian pharmaceutical companies. The mailbox applications filed by some multinational and Indian pharmaceutical companies is shown in Table 1. Figure 1 Table 1: The Agreement does not limit the grounds upon which compulsory licenses may be granted and only sets forth the conditions to be applied in the case of granting. This includes specification of grounds of compulsory licensing and the reasonable rate of licensing fees to the patent holder [21]. According to the TRIPS agreement, WTO member countries can use the subject matter of a patent or permit such use by a third party without the authorization of the patent holder [22] in certain cases of national emergency, public non commercial use or extreme emergency. Indian patent law already includes a compulsory license provision that can be invoked under certain circumstances, including a

lack of working the patent in India [23]. The use of compulsory license is restricted to limited period and under certain conditions. This may be attributed to non recognition of product patent in India as Indian pharma companies can manufacture generic versions of patented molecules and can export to countries, which do not recognize product patent. Bolar Provision Article 30 of TRIPS agreement allows members to provide for limited exceptions to the exclusive rights conferred by a patent, that is, to define acts that would not be deemed as infringing when made without the authorization of the patent owner. Such exceptions may include, for instance, acts of experimentation and the request for marketing approval of a pharmaceutical product before the expiration of the patent [25]. The Bolar exemption strikes a careful balance between promoting invention and ensuring that consumers have timely access to cheaper generics, after the expiry of the patent [26]. This is a TRIPS compliant safeguard and many countries outside the European Union including the US, Canada and Israel allow for the early development and testing of generic medicines to enhance competition in the off patent sector immediately after the basic patent of an originator pharmaceutical product expires. Bolar provision in many ways has facilitated improved affordable access to anti retroviral for AIDS [27]. Parallel importation Parallel importation is one such flexibility that can be used by countries to make available certain drugs at lower price compared to what is charged by the patent holder. Under the Agreement, countries can overcome the high price of a patented medicine by either making or importing generic versions of pharmaceuticals by issuing a compulsory license or importing a more affordable version from another country through parallel importation [28]. Challenges for Indian Pharmaceutical Industry Product Patent regime implies that Indian pharma companies cannot make generic versions of the patented molecule from January 1, Indian government while drafting the Patents Bill, has taken due care to ensure that drugs that were on the market can be sold in India after by providing reasonable royalties to the Patent holder. Thus, Indian pharma companies have no experience of developing a new molecule. Considering this fact, it may be difficult for an Indian company to come up with a new molecule. Indian companies are going to have tough competition form Multinational Corporations who were waiting for implementation of Product Patents in India. Authorized Generics are the generic version of patented molecule marketed by the patent holder itself once the patent on the molecules expire. Indian pharma industry and some experts believe that in addition to the woes of pharma companies, Drug Price Control Order DPCO continues to hamper the growth of the industry and erodes the profitability. Opportunities for Indian pharma companies in Patents regime Despite challenges and hurdles faced by Indian Pharma companies in post TRIPS era, Indian companies could capitalize on the strengths that they have developed for over three decades. Generic Drugs Indian companies can still continue to market and export generic drugs that are off patent. US, being one of the largest markets for generic drugs, is the ideal destination for Indian companies. In US alone major blockbuster drugs are going off patent in next few years. This is a good sign for Indian pharma companies. Licensing Agreements It is difficult to imagine Indian companies coming out with totally new molecule in near future due to prohibitive cost of developing a new molecule. But companies can enter licensing agreements with Multinational pharma companies for development of molecule. Indian companies can garner royalties out of these licensing agreements. Indian companies can either opt for Out-licensing of molecules for royalty payments or they can In-license some promising molecules. Thus, In-licensing and Out-licensing of potential and promising molecules is a lucrative option. Some Indian companies have already entered into these licensing agreements. Licensing agreements can be arrived at early stage of product development or at a later stage of development of molecule depending on the potential of molecule. Mergers, Acquisitions and Alliances Pharma companies in India can merge with overseas companies and market the generic drugs in those markets. Further Indian companies can enter into alliances for marketing and distribution of their products in foreign markets. Acquisitions of companies abroad will help Indian companies make inroads to less penetrated and unpenetrated markets. Companies like Sun Pharma, Wockhardt, Zydus Cadila have acquired several companies and entered into alliances with those companies in various markets. Consolidation and Integration of Business Activities To achieve cost effectiveness Indian companies have to constantly look for integration of business activities and consolidation

of the business functions. Consolidation of business functions will reduce the operations cost and help compete successfully. Pharma companies need to consolidate their business activities in order to stay focused. The consolidation and integration of business activities will help sustain Indian pharma companies. Leveraging Biotech Boom Biotech sector in country is fast growing. Companies have to look for development of biotech drugs apart from traditional drugs. Although proper regulatory guidelines are not in place for development and marketing of biotech drugs, coming days will witness launching more number of products based on biotechnology. Biotechnology companies are increasingly involved in licensing deals for their products with some big pharmaceutical companies to develop and market biotechnology derived products.

Chapter 3 : Drugs and Pharmaceuticals in India - Pharma Industry India, India Pharmaceutical Companies

Article shared by. Indian pharmaceutical industry is one of the fastest growing industries since independence comprised of state owned enterprise, locally owned firms and affiliation of major M.N.C's drug companies combines to provide better healthcare for our society.

Theory and Research Tags: Such strategies have lifted the fortunes of China, Malaysia and Brazil in industries such as consumer electronics, automobiles and chemicals. Today fast-growing Indian pharmaceutical firms such as Dr. Before the early s, the Indian pharmaceutical industry had no choice but to focus on knock-off drugs, since government policies discouraged imports. While India had no shortage of bright scientists graduating from its government-funded universities, most of them just worked on reverse-engineering established drugs to produce generic variants. The researchers saw the proof in the number of U. The study demonstrates that Indian domestic pharmaceutical companies soon followed this government lead. Not all innovation flows from bigger, more established companies. But the Indian pharmaceutical industry shows that things can evolve differently, and raises some important questions for research, economic policy, and corporate strategy. To nurture innovation in research-intensive industries such as pharmaceuticals, governments in emerging countries must invest in the tertiary educational infrastructure that is the source of new scientists. By Kristin Brandl, Ram Mudambi and Vittoria Giada Scalera Abstract Over the second half of the 20th century, Indian pharmaceutical firms were nudged by government policies to focus on import substitution. In response, MNE strategies in India became strongly focused on intellectual property IP protection, most typically implemented through the avoidance of collaboration with domestic firms. Hence, domestic firms in the industry developed mostly independently from the influence of foreign firms but with a strong guidance from governmental policies. A significant number of domestic firms recognized that the returns to imitative, re-engineering oriented innovation would inexorably decline under the new regime. These firms implemented aggressive new strategies aimed at generating world- class product innovation. In this paper, we document the rise of these Indian domestic innovation champions. Introduction In most cases, emerging market firms catch-up processes are significantly influenced by knowledge spillovers from foreign multinational enterprises MNEs. However, the Indian pharmaceutical industry evolved differently and as we document here, it is at odds with the traditional development trajectory. This development has arisen through the often uncoordinated co-evolution of government policies and MNE strategies. High skilled human capital, governmental support and global linkages based on personal relationships were the recipe for the fast development of the Indian pharmaceutical industry, activating a virtuous circle of knowledge creation that connects India with the rest of the world. This case study establishes that innovation catch-up, the most sophisticated component of the catch-up process, need not necessarily be sparked by knowledge flows from foreign entities. India is changing and so is the Indian pharmaceutical industry. Waves of products developed, produced and exported by ever-growing Indian pharmaceutical firms such as Dr. But as we will document below, Indian pharmaceutical firms were not always innovation-driven. In fact, for most of the second half of the 20th century, Indian pharmaceutical firms were nudged by government policies to focus on import substitution based on imitation. To this end, they were encouraged to develop capabilities in process technologies aimed at producing generic variants of the branded drugs developed by foreign MNEs. In particular, these foreign firms stressed the prevention of knowledge spillovers to domestic firms. This meant that MNE subsidiaries in India were given very little freedom to pursue local innovation activities and were also discouraged from collaborating with local partners. Hence, domestic firms in the industry developed mostly independently from the influence of foreign firms but with strong guidance from governmental policies. The Indian Pharmaceutical Industry The Indian pharmaceutical industry is one of the oldest industries in the country, with the first locally owned modern firms established in the early s. With independence in , the government took steps to encourage the domestic sector including setting up public

sector firms. In spite of strenuous efforts, for many decades Indian firms were confined to the lower-unit-value bulk drugs segment. They struggled to innovate and develop new drugs, the requisite for entering and competing in global markets. The Indian pharmaceutical industry developed in several stages influenced by government policies implemented to address diverse objectives: However, with heavy government investments in the domestic science and engineering education system and in the scientific infrastructure, times began to change. The domestic scientific workforce began to expand and world-class research institutions, such as the Council of Scientific and Industrial Research CSIR arose. Only after the adoption of the Patent Act, were domestic firms incentivized in their efforts to innovate. This Act encouraged firms to patent drug manufacturing processes, but not the complete products. As a consequence, domestic firms were motivated to develop generic equivalents of extant drugs with new production processes and methods through reverse engineering. However, the local IP protection standards were considered sub-par by foreign MNEs, so they undertook virtually no local knowledge creation and innovation. With the ratification, the Indian pharmaceutical industry underwent a fundamental change, from a rather loosely regulated industry to one governed by a rigorous product patent regime. The Indian government amended the Patent Act and began a process of implementing rigorous legal protection for product patents and related IP rights, with the objective of reaching the standards of the developed world by Consequently these firms renewed their emphasis on the Indian pharmaceutical market. They brought new and improved products and knowledge into the market, increasing awareness among domestic firms of the opportunities in new drug developments. This awareness caused many Indian firms to set up research facilities and laboratories as part of drug discovery and innovation programs. Our study is based on the output of patents granted by the U. Patent and Trademark Office USPTO , generally accepted to be a crucial and internationally accepted metric of global innovative excellence. For instance, between and , subsidiaries of foreign MNEs produced U. During this decade, domestic Indian firms produced no U. A closer look into the innovative trajectory of the Indian pharmaceutical market demonstrates quite clearly that the innovative profile of the industry changed dramatically with its accession to the global innovation system following its entry into the WTO and acceptance of the provisions of TRIPS. The government led by example in terms of moving toward world-class innovation outputs and this shows up in the steep increase in the production of U. Our analysis reveals several Indian firms now show world-class innovative capabilities, and the genesis of all of these outputs is in the period immediately following the ratification of TRIPS in see figure below. It filed its first U. The graph below shows a significant increase in innovation output from onwards and another spurt starting from , which we attribute to the end of the year TRIPS transition period in In addition to Dr. These include firms like Biocon Ltd. The recent performance of Cadila is particularly notable and it has produced an impressive upward trajectory in patent output over the last five years to amass the second largest patent stock among Indian pharmaceutical companies. Ranbaxy was acquired by Daiichi Sankyo in and subsequently returned to local ownership when the Japanese firm sold a controlling stake to Sun Pharmaceuticals in April In recent years, Sun has become an active innovator in its own right â€” it obtained its first U. The combination of Sun and Ranbaxy has created the largest Indian pharmaceutical company and the fifth largest specialty generics company in the world. Our data indicates that the combined firm may soon surpass Dr. However, our data shows that their patent output from their Indian labs is far smaller than that of Indian pharmaceutical companies see the Figure. Among the top twelve innovating firms in the Indian pharmaceutical industry based on U. Our study of trajectories indicates that the growth rate of patent output of the locally based firms is significantly higher than that of the MNE subsidiaries. This suggests that within a very short time, the dominance of local firms on the patent output scoreboard is likely to increase even further. The firm is now known as Sanofi India and has no local patent output. Summary Firms learn from firms. Smaller firms and less advanced emerging market firms are able to capitalize on the knowledge of firms based in advanced market economies, be it on a national or international level. Firms tend to cluster in and around certain locations, source knowledge externally and collaborate internationally even with competitors. However, the Indian pharmaceutical industry has not followed this

traditional path of catch-up through collaborating and working within the global value chains of advanced economy firms. The knowledge-intensive firms like Dr. The growth of a few big Indian pharmaceutical firms reveals the change undergone within the national pharmaceutical industry, emphasizing the strong link between innovation and competitiveness â€" especially in high tech sectors. This case study throws up important questions for research, policy and corporate strategy. Are these costs associated with eschewing collaboration with foreign MNEs? How generalizable is this experience to other high technology industries and other emerging market contexts? How does this model of government intervention compare with one that is more market driven? It is clear that MNEs in the pharmaceutical industry are repositories of an enormous store of knowledge. However, industry insiders view IP as a key source of competitive advantage. Hence these MNEs jealously guard their IP and are reluctant to collaboration with partners in situations and contexts where they fear knowledge leakage. This is especially true when they do not expect to gain much in terms of reciprocal knowledge flows. Thus, while we expect that the costs of non-collaboration with knowledge-rich MNEs are probably fairly low in the pharmaceutical industry, this result may not generalize to industries that have a more open approach to innovation. However, we believe that our findings are generalizable to other emerging market contexts. For instance, in an ongoing related study, we find that foreign MNEs are NOT the major source of knowledge inflows into the Chinese pharmaceutical industry. Similarly, in the wind turbine industry, we find that emerging economy firms have been able to source knowledge by acquiring component manufacturers in advance economies Awate et al. The knowledge threshold for entry into such industries is extremely high and innovation processes rely on very highly educated scientists. Hence the government has key role to play in funding tertiary educational institutions and research labs. In contrast, industries like information technology and metal fabrication are less reliant on basic research, so that market players like venture capitalists and larger firms assume a more important role. EMNE catch-up strategies in the wind turbine industry: Global Strategy Journal, 2 3: Journal of International Business Studies, 46 1: Publicly funded science and the productivity of the pharmaceutical industry. Clusters, connectivity and catch-up: Bollywood and Bangalore in the global economy. Journal of Economic Geography, 13 3: Catch-up strategies in the Indian auto components industry: Journal of International Business Studies, 43 4: Location, control and innovation in knowledge intensive industries. Journal of Economic Geography, 8 5:

Chapter 4 : The Spectacular Rise of the Indian Pharmaceutical Industry | calendrierdelascience.com

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Even though the Drugs Act was passed by the Indian Parliament in and the Drug Rules became official in , the effective implementation commenced only many years later, after independence in The Drugs Act, was later amended to include cosmetics in late 60s and further amended to include Ayurvedic preparations in the 80s. Even though, the Act and Rules for drug formulations were already in place during independence, the enforcement was extremely weak and slow in implementation. Pharmacy Act, was the most important legislation post-independence. After Pharmacy Council of India and various State Pharmacy Councils were formed in the s and s, consequent to the linguistic division, the states of Maharashtra and Gujarat were born in The states of Karnataka and Madras were born too. It is around this time that the implementation or enforcement of Drugs and Cosmetics Act, commenced in India. Bombay Maharashtra and Gujarat emerged as pharma pioneers during to period. While Haffkine Institute vaccines and Cipla were industry leaders in Bombay, Alembic, Sarabhai and Gujarat Pharmaceuticals took lead in pharma industry growth in the western region. It is noteworthy that the hand-holding, industry-friendly, problem solution approach of industries in Maharashtra and Gujarat helped the growth of pharma industry in western India. In early years, it was the regulators who used to take a lead in resolving quality related problems of the industry. Regulatory agencies working closely in tandem with the industry, catalytically promotes the healthy quality growth of the industry. Team of experts must be appointed in each divisions to interact with industry and provide guidance and assistance for them to contribute to the National Healthcare needs and global leadership of India in respective fields. Patents Coming back to patents, need for amending the Patents and Designs Act of was felt, post-independence. There was no modern medicines or packaged foods or basic fertilizers available in India, because everything was under patents and only available through imports. Various committees, including Parliamentary Committees were appointed, culminating in the Ayyangar Committee Report of Justice Rajagopala Ayyangar Report which based itself on an earlier Swan Committee Report of The Bill for Patents Act amendment lapsed in Parliament more than once. All was quiet on the patent front for nearly 10 years. It is then, that the famous landmark judgement by Justice Vimadalal was delivered in the Bombay High Court on July 11, While Hoechst had an Indian Patent No. Unichem was injuncted and found to infringe the product patent of Hoechst. As per the amendments to Patent Act , only process patents on Drugs, Foods and Chemicals were allowable. Product patents on these fields were not eligible to be granted. The rest was history. There were full supportive initiatives from the government, through Hathi Committee report implementation, ratio parameters Bulk drugs to formulation ratios were fixed company-wise , import substitution incentives etc. Patent term got enhanced uniformly to all fields of technology to 20 years on May with retrospective effect for valid patents. Full-fledged product patent regime returned to India in leading to opening of flood gates to product patents and infringement litigations. The year period of and has seen a large number of patent infringement suits, most of them in Delhi High Court. A large number of ex parte ad-interim injunctions were granted in pharma patent litigations between and Major reforms in Narcotic Control provisions have also been enacted. Meeting global standards India is substantially on track to meet global standards on pharma regulatory framework. At a time when the industry leaders are being adversely impacted by the negative attitude of US FDA inspection audits, the industry need to take these challenges as opportunities for further upgradation and compliance. However, these positive measures are bound to impact profits of market leaders due to the sandwiching effect from stringent squeeze of DPCO.

Chapter 5 : Evolution of Indian Pharma Regulatory Framework - BPD

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Indian Pharmaceutical scenario: Since Independence the Indian Pharmaceutical Industry has shown momentous growth, progressing from the Multinational monopoly stages to the present R&D revolution.

Chapter 6 : India Pharma Inc's Tryst With Destiny - BPD

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Chapter 7 : the indian pharmaceutical sector | Download eBook PDF/EPUB

*The Indian pharmaceutical industry since independence [P. K Ravindranath] on calendrierdelascience.com *FREE* shipping on qualifying offers.*

Chapter 8 : Internet Scientific Publications

Description: This study analyzes the impact of the revision of the Indian Patent Act () on the Indian pharmaceutical industry, which has been achieving healthy growth over the past 30 to 40 years or more. As of , the Indian pharmaceutical industry was ranked as No. 4 in the world in terms of volume and 15th in terms of value.

Chapter 9 : Indian Institute of Toxicology, Pune - INDIA

Before the early s, the Indian pharmaceutical industry had no choice but to focus on knock-off drugs, since government policies discouraged imports. While India had no shortage of bright scientists graduating from its government-funded universities, most of them just worked on reverse-engineering established drugs to produce generic variants.