UNIVERSITY OF NOTTINGHAM

The Current and Future State of India's Pharmaceutical Industry

Management Project

Individual Report

by:

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Introduction

India's pharmaceuticals industry is growing at a very fast pace. At present, this industry is the second largest growing industry within the country, and in terms of size, it is the third largest in the world, crossing the US$20 billion threshold by the year 2015 (Kumar & Akhilesh, 2010). This paper is written with the intent to add value to our MBA group project exploring future scenarios for the generics drug industry within the European Union (EU). By 2030, India will more than likely be a dominant force to be reckoned with vis-à-vis the scenarios developed within our group project. Through the analysis of the facts and trends presented in this paper, comprehensive strategies which take into account the strong presence of Indian-based pharmaceuticals companies within the EU generics market can be developed by players (current and future).

Overview of the Global Pharmaceuticals Market

"The global pharmaceutical market can be classified into two categories: regulated and unregulated/semi-regulated" (Kumar & Akhilesh, 2010, p.13). Government regulations e.g. intellectual property protection and product patents are key features of the regulated markets, while the unregulated/semi-regulated markets comprise of no/lower levels of regulations. There is greater stability vis-à-vis prices and volumes in regulated markets while higher levels of competition and lesser entry barriers exist in the unregulated/semi-regulated environment. Numerous regulations related to safety, side effects and clinical evidence have been key trends in recent years. Additionally, other key trends include the shift in growth from mature markets to emerging economies, and the market drivers shifting from primary care to specialty care. Players in the market will become more integrated; numerous changes will occur in operations based on shifts in markets; strategies will change and business models will be reconfigured for further growth and expansion.

Brief History of the Indian Pharmaceuticals Industry

After India acquired independence in 1947, public policy initiatives have been mainly tailored towards encouraging investments into pharmaceutical research and development so as to ultimately make drugs available to all Indian citizens at affordable prices. The key policy measures have been "the Drug Price Control Order (DPCO), the Foreign Exchange Regulation Act (FERA) and the Industrial Trade Policy and Patents Act, 1970" (Chataway & Kale, 2009, p. 6). The patents act of 1970 was designed to bypass recognition of pharmaceutical product patents, and it was this act that propelled Indian firms towards developing generics through reverse engineering methods. Later, India signed up under the TRIPs Agreement of the WTO, and this led to adoption of product patents from 2005 onwards. Figure 1 below shows the three phases of development of the Indian pharmaceuticals industry over the past fifty years, and each of these phases is linked to patent acts. Firm level strategies evolved over this period, and the trajectory of the entire industry has shifted from firms being weak followers (in the 1970's) to partners of choice of large multinationals in drug research and development efforts.

Figure 1: Three phased development of the Indian Pharmaceutical Industry

Development Phase: Policy drivers	Technology/Knowledge	Domestic Market Ownership	Import-Export situation
Phase I (1950-1970) The Patents & Design Act 1911 Industrial Policy 1948 First DPCO*, 1970	Technology import, Capital investment, manufacturing facilities for formulations (mainly) and bulk drugs process technology encompassing fermentation, chemical synthesis and isolation form plant or animals	Dominated by Western MNCs Insignificant indigenous production (by large public firms and small private firms)	High import dependence for essential bulk drugs Market focus: domestic
Phase II (1970- 1990) The Patents Act 1970 NDP** 1978, 1986 Revised DPCO 1979, 1987 NIP*** 1991 (Liberalization)	Reverse engineering of known molecules, development and large scale production capabilities/ capacities for generics Few steps to develop non-infringing processes, complex fermentation and synthesis, backward and forward integration	Growth of a strong domestic Indian Pharmaceutical sector(mainly small medium and large private firms); Exit of several Western MNCs	Increased production of bulk drugs and formulations-import substitution Achieved self-sufficiency Started exporting to non- and semi-regulated markets
Phase III (since the 1990s) Transition to product patent regime DPCO 1995, Drug Policy 2002 TRIPs compliant since Jan 1 2005. Schedule M enforcement[1] Schedule Y[2] amendment	Greater investment into innovative R&D (Analogue research, NDDS, NCEs) Value-additions/innovations in generics Increased knowledge-base and R&D in Cardiovascular, Neurosciences, Oncology, Diabetes (Life style segment diseases and some neglected diseases)	Continued growth of the domestic sector (mainly large private firms); Reawakening of public research laboratories; Return of western MNCs	Net exporter of generics Moving from semi-regulated to regulated markets

Source: Chaturvedi, Chataway and Wield (2007)

Generic Drugs

The pharmaceutical industry in India has become the most important hub of generic drugs production in recent years. India is the 4th largest producer of pharmaceutical drugs in the world, and of all drugs exported by the country, 90% are generics (Sharma et. al., 2009). The table below shows the principle products of India's leading drug manufacturers, and looking at the last column (percent of sales) it is clear to see that most of these drug manufacturers have a significant emphasis on generic drugs vis-à-vis their product portfolios.

Principal products of India's leading drug manufacturers

Company	Principal products: API and generic drugs	Percent of sales
Ranbaxy Labs	Anti-infectives, cardiovascular, gastrointestinal, central nervous (diazepam, midazolan), ophthalmic & ointments, urologicals, nutritionals, sex hormones, analgesics, anti-asthma, cough & cold, vaccines.	API: 22%, Generic: 78%
Dr. Reddy's	Cardiovascular, gastrointestinal, anti-infectives, pain management	API: 40% Generic: 60%
Cipla	Antibiotics, anti-asthmatics, anti-AIDs and TB drugs, anabolic steroids, analgesics-antipyretics, antacids, anti-arthritis, anti-inflammatory, anticancer, antidepressant agents, anti-diabetic, anit-epileptic, anti-fungal, anti-malarial.	API 7%, Generic: 93%
Wockhardt	Anti-infectives, pain management, nutraceuticals	API : 19% Generic: 81%
Pfizer India	Nutritionals, cough syrup, anti-arthritis, anti-infectives, cardiovascular	Generic: 100%
Sun Pharma	Neuro-psychiatry, cardiovascular, gastrointestinal, diabetic, gynecological, anti-allergic, antidepressants, cholesterol reducers, anti-asthma, Parkinson, ADD, pain.	API: 18% Generic: 82%
GSK	Anti-infective, anti-inflammatory, analgesic, gastro-enterological, antiallergic, dermatological.	Generic: 100%
Lupin	Tuberculosis medication, antibiotics, cardiovascular.	Generic: 100%
Cadila	Cardiovascular, gastrointestinal, anti-inflammatory/analgesic, antibiotics/anti-infectives, vaccines/immunomodulators, anti-diabetics; vitamins.	Generic: 100%
Nicholas Piramal	Analgesics-anti-inflammatory, antibiotics, antifungal, antihistamines, antiseptics, cardiovascular, central nervous system, diabetic, dermatologic, endocrinologic, gastro-enterological, vitamins, pulmonary-respiratory, trauma-emergency, gastrointestinal, NSAIDs.	Generic: 100%
Aurobindo Pharmaceuticals	Antibiotics, anti-retrovirals, cardiovascular, central nervous system, gastroenterological, anti-allergy.	Generic: 100%

Source: Overview of Indian Pharmaceutical Industry by Tata Strategic Management Group (2009)

Strengths & Weaknesses of the Indian Pharmaceuticals Industry

The biggest advantage that Indian manufacturers possess is that they are the lowest cost producers in the world. Drugs can be produced in India at 40%-50% lower costs and this is mainly due to low levels of unit labour costs. Additionally, the skill level of the workforce is very high; "each year, roughly 115,000 chemists graduate from Indian universities with a master's degree and roughly 12,000 with a PhD" with the corresponding figures for Germany being just 3,000 and 1,500 respectively (Kumar & Akhilesh, 2010, p.204). These high levels of skilled workers translate into multinational companies saving 30% to 50% at

their Indian based R & D facilities. Cost advantages are also to be found in the area of clinical trials – these trials cost about 10% of similar costs incurred in the US. Skilled chemists who are specialists in process re-engineering also help Indian companies develop innovative and cost effective manufacturing processes. Indian pharmaceuticals manufacturers also have an excellent track record of development vis-à-vis chemical synthesis for various drug molecules, and this translates into enhanced cost-effectiveness as well. The existence of a good network of world-class educational institutions in information technology is also immensely beneficial. International consolidation within the pharmaceuticals industry has had a positive impact as many multinationals have found great opportunities to invest huge sums through joint ventures as well as mergers and acquisitions. The cost of capital investments is additionally lowered to the tune of 25%-50% with the presence of numerous local manufacturing firms who can build low cost and high quality manufacturing equipment (Kumar & Akhilesh, 2010).

With regard to weaknesses, there are serious issues around infrastructure that need to be addressed. Compared to western industrialised nations, manufacturing facilities in India face far more instances of power outages. The hot and humid climate is detrimental especially in cases where production facilities lack refrigeration capabilities necessary for the storage of certain finished products. Additionally, there is a serious concern vis-à-vis price regulations which are set for different drugs through the NPPA (National Pharmaceutical Pricing Authority). When prices are administratively set, profit margins are in fact determined as well, and those companies with the best cost advantages end up driving out competitors. Patent laws in India inhibit innovation and drug discovery, and additionally there are several issues around imprecise documentation systems and ambiguities in the interpretation and implementation of global regulatory and intellectual property protection standards. Multinationals operating in India also have to deal with confidentiality and data protection/exclusivity issues. Due to low barriers to entry, the Indian pharmaceuticals industry is highly fragmented “with about 300 large manufacturing units and about 18,000 small units spread out across the country” (Kumar & Akhilesh, 2010). The level of price competition is quite intense as a result of this, and this factor has reduced the growth of the industry in actual value terms. Safety concerns are also significant e.g.

Ranbaxy, a leading generics maker in India, conducted a recall of 73 million tablets in 2007 because of the presence of impurities in these tablets that exceeded specified limits (Sipkoff, 2008).

Current state of the Indian Pharmaceuticals Industry

Presently, India has "24,000 licensed pharmaceutical companies" with "more drug-manufacturing facilities that have been approved by the U.S. Food and Drug Administration than any country other than the US" (Kumar & Akhilesh, 2010, p. 22). In recent years, the Indian government has taken numerous measures to facilitate the rapid growth of the national pharmaceutical industry: there are tax break offered, new procedures for drug development, enhancements in clinical procedures, the implementation of the New Millennium Indian Technology Leadership Initiative as well as the Drugs and Pharmaceuticals Research Programme (Kumar & Akhilesh, 2010).

The Indian pharmaceuticals industry is currently going through a phase of re-orientation. The Indian government's signing of the TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights) in 1994 changed the landscape of the Indian pharmaceuticals industry. Traditionally, Indian drug firms simply copied foreign patented drugs using different manufacturing processes. With the signing of TRIPS, this approach had to be rethought, and therefore, Indian drug firms have now refocused their collective energies on increasing R & D for new drugs. Figure 1 below shows the shift from Process R & D to Product R & D. In the past, the emphasis was on reverse engineering, the development of generics, and new drug delivery systems (NDDS). The focus on Process R & D created certain rigidities within Indian pharmaceutical firms, the main ones being " a. imitative R&D organisational routines, b. in-house nature of R&D and c. organisational mindset shaped by short term vision of R&D investments and domestic market focused approach" (Kale, 2005, p. 23). Efforts have now shifted towards acquiring advanced capabilities and complex knowledge bases so as to promote new drug discovery research (NDDR).

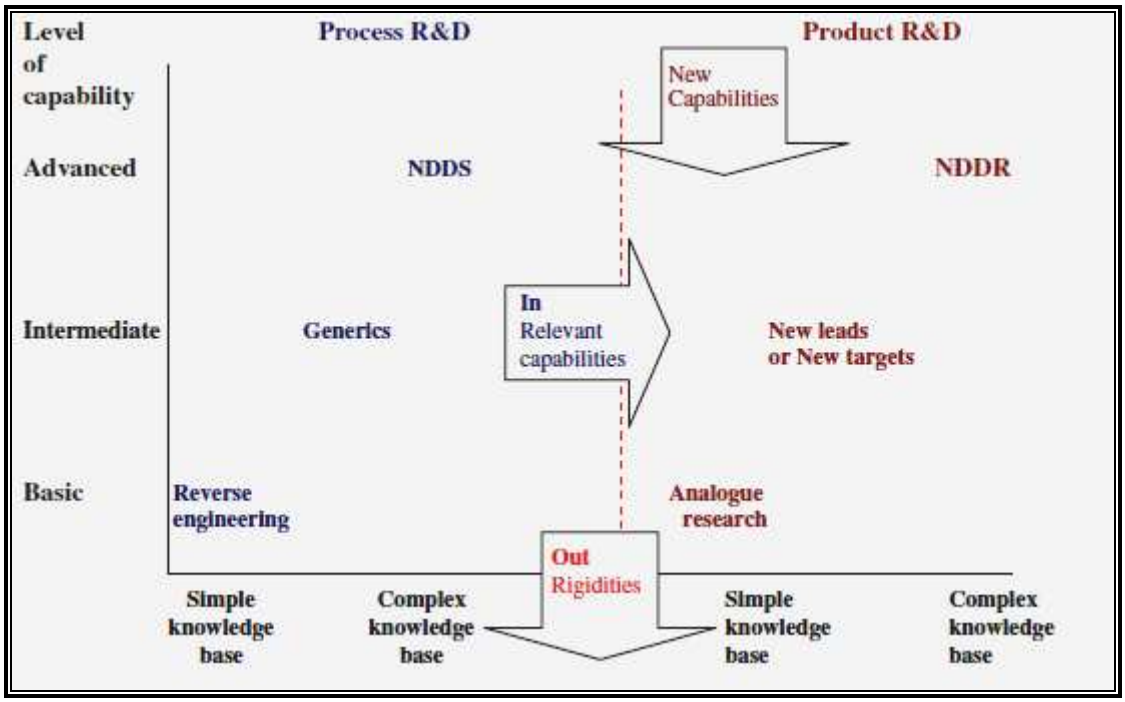

Figure 2: Changing skills and capabilities in the Indian pharmaceutical industry (Kale and Wield, 2008)

Additionally, numerous Indian pharmaceutical companies have started "acquiring brands, facilities and businesses overseas" as well as engaging in "local marketing in foreign markets" (Kumar & Akhilesh, 2010). The objective is geographic diversification with some companies looking for ways to penetrate developed regulated markets, while others expanding their presence in underdeveloped and developing markets. Partnerships are also being explored for the increased sales of bulk drugs and collaborations are being forged with innovators. In developed regulated markets, there is a focus on niche segments as well as offering of contractual research and manufacturing services to drug firms. There has also been an increase in M & A activity by Indian pharmaceutical firms because this can help these firms quickly become trans-national players.

The Indian government also recently (2006) enacted the set up of Special Economic Zones (SEZ's) within the country, and these zones have attracted foreign companies into setting up manufacturing facilities. The Draft National Pharmaceutical Policy (2006) "proposed to set up 25 pharmaceutical parks over five years in India" and "this kind of a development will strengthen India's competitiveness, develop world class infrastructure for the industry and fuel the growth of pharmaceutical exports considerably" (Kumar & Akhilesh, 2010, p.54).

Contract research is a budding industry in India at present with a growth rate of 20-25% per year and it is estimated that this industry will have grown to about US $380 million by the year 2010 (Kumar & Akhilesh, 2010). The Indian government has played a crucial role in revising policies to encourage growth within this area, and is granting "tax exemptions for a period of ten years and relieving customs and excise duties of all the drugs and materials imported and exported for clinical trials to promote innovative R & D" (Kumar & Akhilesh, 2010, p.52). Additionally, the Indian government has taken steps to ensure that the work done at contract research firms can meet International standards by "setting up of National Board for Accreditation of Testing and Calibration laboratories (NABL) and Indian Society for Clinical Research (ISCR) to look into the analytical, advisory and ethical issues associated with clinical trials in India" (Drabu, Gupta & Bhadauria, 2010, p. 420).

Another feature of the current Indian pharmaceuticals industry is the explosive growth of the clinical trials business in India. As the top pharmaceutical companies in the world have recently been very active in outsourcing human clinical drug trials to developing countries, the focus has been towards finding regions and countries with highly qualified English-speaking doctors and low labour costs. Because India meets these requirements, there are currently 400 clinical trials underway in India and this business "is expected to be worth $1 billion to $1.5 billion by 2010" because clinical trials in India are 50-60% cheaper; considering that the total cost of developing a single drug therapy "is estimated to be $800 million (excluding sales and marketing costs)" it just makes financial sense for multinational pharmaceutical companies to have Indian firms conduct their clinical trials for them (Petryna, 2009, p. 563).

Future of the Indian Pharmaceuticals Industry

For Indian pharmaceuticals to become competitive in the global marketplace in the long run, they will have to engage in innovative research, and develop new knowledge creation structures and environments. Additionally, they will have to expand into new markets e.g. the Indian pharmaceuticals company Ranbaxy exports its products to 125 countries, has subsidiaries in 50 countries and production facilities in 10 countries. There is an element of reluctance with regards to prescribing pharmaceuticals manufactured in India within certain western countries, and therefore, there is the added challenge of building confidence in these markets. This can be most effectively achieved through marketing strategies which enhance the perceptions of quality and safety of Indian pharmaceuticals within western markets. Moreover, as competition within the generics market gets increasingly intense, and the strategy of simply replicating existing drug formulas (already in widespread use amongst many manufacturers), Indian pharmaceuticals companies will have to focus their efforts on new molecules to diversify their revenue streams. This objective can be achieved by either their own efforts or through research alliances, and "this will entail a closer tracking of disease profiles and related therapies as well as keeping a close tab on the research programmes of rivals" (Kumar & Akhilesh, 2010, p.48).

One key trend occurring within the Indian pharmaceuticals industry at present is companies spinning off their R & D units as separate entities, and this is being done mainly as an attempt towards risk mitigation. "A spinout may be better positioned to work with best partners, expand its licensing business; can also mitigate the technical and commercial risk exposure of the parent company by isolating high-risk activities within the new entity" (Sharma & Goswami, 2009, p. 320). Another trend is the creation of superior bio-generics and superior versions of non-licensable products and technologies; diseases high on the list of targets by Indian pharmaceuticals companies with regard to these approaches include Parkinson's, Alzheimer's and other neural disorders (Sharma & Goswami, 2009).

Another key future trend in the Indian pharmaceuticals industry is the utilization of open source networks for the discovery of new drugs. "The Council of Scientific and Industrial

Research in India has recently initiated a novel comprehensive drug discovery programme termed 'Open Source Drug Discovery for Tuberculosis' (OSDD), a network project encompassing R & D institutions, academic institutes, Universities and Industries in a collaborative mode" (Taneja, et. al., 2009, np.). This approach is intended to replicate the benefits derived from open source networks in the IT and Biotechnology sectors. The Indian government has provided funding for this initiative to the tune of $30 million, and at the same time, donations for this initiative are also being solicited from private donors such as international agencies and philanthropists.

There is also a developing trend in the Indian pharmaceutical industry to exploit gains from traditional medicinal knowledge. "The Department of *Ayurveda, Yoga & Naturopathy, Unani, Siddha* and *Homoeopathy* (AYUSH) in collaboration with CSIR (Council of Scientific and Industrial Research) is creating a Traditional Knowledge library," and this library would "not only help in (re)exploring traditional medicines as pharmacophores but also help in preventing patenting of prior knowledge by MNCs" (Taneja, et. al., 2009, np.). There is an expectation in India that the knowledge gained from traditional medicinal fields such as *Ayurveda* can lead to the discovery and development of new drugs and the plan is to integrate traditional knowledge with modern scientific knowledge. The challenge that lies within this integrative approach will be "its ability to recognize, respect and maintain the respective identities, philosophies, foundations, methodologies and strengths of all systems" (Patwardhan, 2010, p. 13).

In the field of biotechnology, India is "undoubtedly a major player," and the country "is destined to boost biotech development" in the coming years (Chakraborty & Agoramoorthy, 2010, p. 5). The country ranks among the world's top 12 nations in biotech companies (Ernst & Young, 2004) and within the Indian biotech industry, the centre of concentration is biopharmaceuticals. In the field of Stem Cell Research, the country is ranked third in the world due to massive R & D investments into this field by the government as well as private investors (Acharya et al., 2004). Due to numerous ethical and moral concerns, the Government of India set up a bioethics committee, and at present, the law states that stem cells may be harvested (with full and informed permission from the donor) up to the 14th

day of gestation (Chakraborty & Agoramoorthy, 2010). Additionally, within the country "more than six stem cell banks have been established, and the current successes with stem cell R&D, especially stem cell transplantation (STC) provides an example for other developing countries to follow the model of India to enhance healthcare" (Chakraborty et al., 2009). It is clear that India is, and will continue to be, a major player in the Biotechnology sector, and this sector is bound to have a growing impact on the future of the pharmaceuticals industry in India as well as the rest of the world.

As India has established a global reputation for excellence in the fields of computer science and information technology, the competencies gained from these fields, in addition to the existence of a large pool of experts in the life sciences, have formed the foundation for a promising future for Indian firms in the global bioinformatics industry. The Advanced Technology Centre (ATC) in Hyderabad "has generated some of the important bioinformatics products and developments in India, including Bio-Suite™, Bio-Appliance™, and structure-based drug discovery" and despite the rapid growth of ATC, the research services provided by this subsidiary of the Tata Consultancy Services group represent "a fraction of the $55 billion spent in 2007 by the industry on global drug development" (Bannerjee, 2008, p.17). Heading into the future, the role of Indian bioinformatics firms and their research into drug developments is projected to grow tremendously, and life science industry reports suggest that bioinformatics is the "next growth engine" for India (Bannerjee, 2008, p.18).

Another field in which the future of the Indian pharmaceuticals industry looks bright is the field of vaccine manufacturing and this is mainly due to the fact that many multinational corporations have pulled out of this business due to low margins. India is on a fast track towards becoming a global leader in new vaccine development "enabled by abundant natural and human resources, ongoing R&D in multi-disciplinary subjects, application of information and communication technologies, and growth in collaboration between academic and research institutes in public and private domains" (Grace, 2004, p. 22). Experimental vaccines have been developed for numerous diseases e.g. Malaria and AIDS, and "once the FDA and the European Medicines Agency have defined a mechanism for

approval of bio-generics, India will be very well placed to dominate this field" (Grace, 2004, p. 23).

Heading into the future, Indian pharmaceutical firms will also have a big impact on the development of drugs for neglected diseases i.e. tropical diseases prevalent in developing countries e.g. malaria. "Of the 1,223 drugs introduced between 1975 and 1996, only 13 were aimed at tropical diseases" (Grace, 2004) and Indian pharmaceutical firms are well positioned towards exploring and exploiting drug treatments for these 'niche' diseases. As Indian pharmaceutical firms are mostly privately owned, and due to the fact that the neglected diseases segment has low competition from large western multi-national pharmaceuticals firms, there have been some Indian firms that have announced that their NCE research will be focused on developing products for this market segment. While referring to the establishment of the $250 million Drugs for Neglected Diseases Initiative, Dr. N.K. Ganguly, head of the IMRC stated that "Even in India, the commercial pharmaceutical companies focus mostly on products for the rich, such as drugs for hypertension, obesity, ulcers…we want to change that" (Grace, 2004, p. 41).

Another key trend heading into the future is the move towards consolidation in the Indian pharmaceuticals industry. As stated previously, the industry at present is heavily fragmented, and this scenario presents numerous problems e.g. negative effects on larger firms' reputations as a result of actions and practices by smaller firms. From January 2004 to October 2005, Indian firms made 18 international acquisitions with the biggest buyout being Matrix labs' acquisition of Belgium's *Docpharma* for $263 million (KPMG, 2006). It is important to note that many of the key acquisitions were in the EU where there is a wider price range of companies available, and the greatest future potential for growth in revenues from the sale of generics exists.

Risks faced by the Indian Pharmaceuticals Industry

As outlined in this paper, the Indian pharmaceuticals industry has several advantages as well as opportunities going into the future. Having said this, there are several risks facing the industry and these could pose as competitive threats to the industry over the coming years. The first of these risks lie in the fact that since generic drug makers are relatively new entrants into regulated markets, there are "concerns regarding their ability to manage large product portfolios, entailing numerous regulatory findings, scaling up manufacturing, forging alliances, and legal skills to win on patent litigations" (Grace, 2004, p.26). The industry will have to address these concerns effectively in order to be competitive in western markets such as the US and Europe.

Another major risk facing the Indian pharmaceuticals industry lies in the fact that certain players within the industry may cut corners with regards to laboratory or manufacturing practices, and if this results in lower quality products, then the industry as a whole will suffer a bad reputation within the marketplace. The example mentioned earlier whereby Ranbaxy conducted a recall of 73 million tablets due to the presence of impurities in these tablets likely led to a reputation crisis that affected the entire industry. If Indian pharmaceuticals companies are to succeed in the global marketplace, then, they will have to self monitor their practices within the industry so as to ensure that all players are working together to achieve the common goal of establishing a good reputation for the industry as a whole.

Related to the aforementioned risk vis-à-vis bad practices and subsequent effects on the reputation of the industry as a whole is the issue of counterfeit drugs manufactured in India that have proliferated the pharmaceutical drugs market in recent years. "Experts say the global fake-drug industry, worth about $90 billion, causes the deaths of almost 1 million people a year" and presently, "the Indian government says that 0.4 percent of the country's drugs are counterfeit and that substandard drugs account for about 8 percent", but "independent estimates range from 12 to 25 percent" (Lakshmi, 2010, p.1). This issue has to

be of great concern to not only the Indian government, but to Indian pharmaceutical companies as well, mainly because of the reputational risk as described previously.

There are also inherent risks in players pursuing the NCE (New Chemical Entities) strategy in that Indian pharmaceuticals firms lack skills in the area of patent writing. "It has been suggested that many existing patents written by Indian professionals can be easily circumvented; so even where an Indian company has produced an innovation, it may not be protected in international settings" (Grace, 2004, p. 27). Additionally, despite their strengths in chemistry, Indian pharmaceuticals firms are weak in biology, clinical research and development skills which are crucial for innovation within the NCE drugs category. As stated earlier, since generics will not be the main focus for Indian pharmaceutical firms going into the future and innovation in developing new drugs will be the main focus, firms will need to upgrade the aforementioned skill sets in order to gain competitive advantages within the global marketplace.

Another significant future risk being faced by players within the Indian pharmaceuticals industry is the risk of protectionism in developed countries. These countries have been instituting numerous non-tariff barriers (NTB's) in recent years in an attempt towards protecting their local industries. NTBs have mushroomed from a mere 389 in 1995 to 1,895 in 2009 (Dhar, 2010) and in general, exporters of Indian pharmaceuticals face numerous NTB's related to (i) packaging and labelling regulations (ii) standards, (iii) uniformity requirements, (iv) labour standards, (v) documentation and related procedures and (vi) company and product registration[1]. NTB's add significant costs to Indian pharmaceuticals manufacturers, and these costs can diminish the cost advantage that Indian firms have established in the global marketplace as well as erode margins vis-à-vis profitability.

Another risk facing the Indian pharmaceuticals industry is the growing threat of competition from China. Chinese firms have been gradually building "expertise in the production of active pharmaceutical ingredients (API's) and a wide range of raw materials for drugs" and in recent years, Chinese firms have become "a very important source of API's and bulk drugs

[1] The world isn't flat – *India Today (May 1st, 2010).*

for pharmaceutical companies in India" (Thomas, 2007, p. 35). Small scale bulk manufacturers in India are increasingly wary of the threat from Chinese manufacturers who are large scale producers of many of the intermediates for bulk drug manufacturing. "As a source of India's imports of medicinal and pharmaceutical products to India, China's share has been continuously increasing: from 6.2 per cent in 1993-94 to 34.6 per cent in 2005-06" (Thomas, 2007, p. 35). Additionally, many small Indian pharmaceutical firms are expressing fears that a transfer of technological skills and knowledge is taking place as a result of large Indian pharmaceutical firms establishing partnerships with their Chinese counterparts.

Conclusion

Over the coming years and decades, the impact of Indian-based pharmaceutical companies on the global pharmaceuticals and generics market will be immense. India has already established a significant cost and skills advantage over other nations but, having said so, there are still some glaring weaknesses that pharmaceutical companies and the Indian government will have to address over the coming years. From the government's perspective, these weaknesses mainly revolve around infrastructure, pricing regulations, and patent laws. From the companies' perspective, safety concerns and reputation issues are key concerns that will have to be effectively dealt with.

With the signing of the TRIPs agreement, the Indian pharmaceuticals industry is presently going through a phase of re-orientation whereby the previous strategy of process re-engineering to copy foreign patented drugs is gradually being replaced by a strategy of knowledge creation to facilitate new drug discoveries. There is tremendous potential within the industry over the coming years and decades in the fields of contract research, clinical trials, vaccine development, biotechnology and bioinformatics. Additionally, the industry is poised to exploit gains from traditional medicinal knowledge as well as utilization of open source networks for new drug discoveries. But, as Indian pharmaceuticals companies continue to make progress on numerous fronts, these companies also face numerous risks and challenges as they penetrate regulated markets. Their abilities in marketing, managing large product portfolios, maintaining high quality standards and writing patents will have to

be enhanced. Policymakers and strategists will also have to effectively deal with the threat of protectionism in developed western countries, as well as the rise of China within this industry.

Despite the fact that a reorientation is currently taking place within the Indian pharmaceuticals industry whereby the focus is slowly shifting from process engineering competencies in replicating patented drugs to product research and development, Indian pharmaceutical firms will continue to remain dominant players in the global generics marketplace. And from a more macro perspective, as long as the Indian government remains focused on its goal of attaining a superior competitive position on the global stage, and takes appropriate measures towards achieving this goal, the future of the Indian pharmaceuticals industry looks incredibly bright.

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