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A NEW PHARMACEUTICAL ENVIRONMENT IN INDIA: MARKETING IMPACTS

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ABSTRACT

For nearly 55 years, Indian Pharmaceutical market has been a closed and centrally controlled one. Although some initiatives have been introduced during the last decade, yet the system is characterized as a closed one and lacks real competition. The current situation of drug in India may be characterized as intense price control by the Drug Authority i.e. DPCO, National Pharmaceutical Pricing Authority (NPPA). Ministry of Health, ban of drug import when an item is manufactured in the country, compulsory generic production policy, currency allocation by the government in reduced rate for drug production and importation, subsidization of many items by the government and irrational use of drugs.

Keywords: Medical Practitioners, bioequivalence, Chronic Illness, Cost Efficiency

INTRODUCTION

The pharmaceutical industry is expected to expand rapidly, benefiting from new open market policies. Regulatory controls on development and marketing are going to be negligible and as the economy prospers, health care and drug expenditure are expected to increase. When the market opens up for different competitors, be it local or big pharmaceutical companies from overseas, to secure a high market share, new marketing strategies and approaches are required. It is well known that the final consumer (i.e. the patient) has little or no say in the choice of drug and treatment. Specialists and general practitioners are the customers of the pharmaceutical companies, because they are ultimately responsible for purchasing decisions. Therefore, it is expected that marketing efforts target medical practitioners and specialists, building on individual representatives that will alert practitioners of new products through one-to-one sessions at the practitioner's office. This sales approach, known as "muscle marketing", is proven to be a successful approach for a fragmented customer base, while increasing the number and spread of sales representatives is an effective way to overcome challenges posed by high mobility of specialists, cramped appointment schedules and general practitioners' geographic expected. We are already noticing this impact. There is a noticeable shortage of pharmacist in the country.

The second impact is expected to be on the generic concept, a "generic" product is a drug bioequivalent to the brand item, manufactured by another pharmaceutical company and usually sold at a cheaper price. Generics are identical in virtually every respect to the branded original and their prices are normally at the bottom of the market. Generics are neither developed nor manufactured by the original company and as such, are not backed by the manufacturer's quality control and

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medical information department (Chaturvedi K. and Chataway J, 2006; IMS Health, 2004; Organisation of Pharmaceutical Producers of India, 2004).

To a lot of medical practitioners, difference is irrelevant, whereas for others the difference is important thus an opportunity to have "branded generics" opens up. Branded generics are generic products offering small advantage, of being sold at a price above the lowest-priced generics.

The immediate effect of legislation allowing branded generics and proprietary products is that pharmaceutical companies start to develop better products by investing in research and development activities. This may have some impacts on drug prices; however, quality improvements are real consequences. Pharmaceutical investments in R & D, quality control and quality assurance activities are going to increase significantly. Even clinical trials and bioequivalency studies are to increase markedly. We therefore expect to see an increased demand for pharmacy graduates in this sector as well. Therefore small but highly advanced and scientific pharmaceutical companies specialized in R & D and marketing activities should be established to provide services for drug manufacturing companies. I think pharmacy schools are not prepared for these changes. We need to take these emerging challenges into consideration and be prepared to meet the requirements of the new environment (Indian Government National Pharmaceuticals Policy, 2006; Pharma Review, 2005; Indian Pharma Machinery Manufacturers Association, 2003).

India's pharmaceutical sector is currently undergoing unprecedented change. Much of this is due to the country's introduction, on January 1, 2005, of a system of product patents; before that, only patents for processes were permitted to be issued, a fact that has been instrumental in the domestic industry's huge success as a worldwide exporter of high quality generic drugs.

The new patent regime has also led to the return of the pharmaceutical multinationals, many of which had left India during the 1970s. Now they are back, and looking at India not only for its traditional strengths in contract manufacturing but also as a highly attractive location for research and development (R&D), particularly in the conduct of clinical trials and other services (Tufts Centre for the Study of Drug Development, 2000; Indian Government National Pharmaceuticals Policy, 2006; Associated Chambers of Commerce and Industry of India Report to Government, 2005).

Both multinational companies (MNCs) and domestic players are also examining the prospects offered by the local market as the government moves forward with initiatives aimed at providing India's more than one billion inhabitants, for the first time, with access to the life-saving drugs they need. A further huge boost to the local market is coming from the rise of India's new affluent consumers, who lead more Western-style lives and are demanding innovative drugs to treat the chronic illnesses that these changing lifestyles may produce (Center Watch Data, 2006; Associated Chambers of Commerce and Industry of India Report to Government, 2005).

India's leading drug manufacturers are becoming global players, utilizing both organic growth, through the gradual development of their business, and mergers and acquisitions (M&A) as they seek to boost their presence in existing markets and open up new ones.

The Indian Pharmaceutical Industry

India represents just U.S. $6 billion of the $550 billion global pharmaceutical industry but its share is increasing at 10 percent a year, compared to 7 percent annual growth for the world market overall.

Also, while the Indian sector represents just 8 percent of the global industry total by volume, putting it in fourth place worldwide, it accounts for 13 percent by value, and its drug exports have been growing 30 percent annually. The “organized” sector of India's pharmaceutical industry consists of 250 to 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. Approximately 75 percent of India's demand for medicines is met by local manufacturing.

According to the German Chemicals Association, in 2005, India's top 10 pharmaceutical companies were Ranbaxy, Cipla, Dr. Reddy's Laboratories, Lupin, Nicolas Piramal, Aurobindo Pharma, Cadila Pharmaceuticals, Sun Pharma, Wockhardt Ltd. and Aventis Pharma. Indian-owned firms currently account for 70 percent of the domestic market, up from less than 20 percent in 1970. In 2005, nine of the top 10 companies in India were domestically owned, compared with just four in 1994.

India's potential to further boost its already-leading role in global generics production, as well as an offshore location of choice for multinational drug manufacturers seeking to curb the increasing costs of their manufacturing, R&D and other support services, presents an opportunity worth an estimated $48 billion in 2007. India's US$ 9.4 billion pharmaceutical industry is growing at the rate of 14 percent per year. It is one of the largest and most advanced among the developing countries. The Indian pharmaceutical industry has reached a market size of US$ 11.6 billion by 2009.

Over-the-Counter Medicines

The Indian market for over-the-counter medicines (OTCs) is worth about $940 million and is growing 20 percent a year, or double the rate for prescription medicines. The government is keen to widen the availability of OTCs to outlets other than pharmacies, and the Organisation of Pharmaceutical Producers of India (OPPI) has called for them to be sold in post offices.

Developing an innovative new drug, from discovery to worldwide marketing, now involves investments of around $1 billion and the global industry's profitability is under constant attack as costs continue to rise and prices come under pressure. Pharmaceutical production costs are almost 50 percent lower in India than in Western nations, while overall R&D costs are about one-eighth and clinical trial expenses around one-tenth of Western levels. India's long-established manufacturing base also offers a large, well-educated, English-speaking workforce, with 700,000 scientists and engineers graduating every year, including 122,000 chemists and chemical engineers, with 1,500 PhDs. The industry provides the highest intellectual capital per dollar worldwide, says OPPI (The Economic Times of India and Pharma Market letter, 2006).

The industry's exports were worth more than $3.75 billion in 2004-05 and they have been growing at a compound annual rate of 22.7 percent over the last few years, according to the government's draft National Pharmaceuticals Policy for 2006, published in January 2006. The Policy estimates that, by the year 2010, the industry has the potential to achieve $22.40 billion in formulations, with bulk drug production going up from $1.79 billion to $5.60 billion: "India's rich human capital is believed to be the strongest asset for this knowledge-led industry. Various studies show that the scientific talent pool of 4 million Indians is the second-largest English-speaking group worldwide, after the USA (Technology Forecasting & Assessment Council. Intellectual Property Rights, 2005; India Raising the Sights, 2001).

India's other advantages for off shoring

• Low-cost skill base
• Current Good Manufacturing Practice (cGMP) and U.S. FDA compliance levels
• High visibility in generics
• High-quality, compliant manufacturing
• Strong financial position with ability to scale up
• Manufacturing capacity
• Access to new technologies
• Cost efficiency and track record
• Industry position
• Recognition of product patents

Table 1. India's top branded drugs

India's top branded drugs 2004	India's top branded drugs 2011
Corex (chlorpheniramine maleate, codeine phosphate)	Corex (chlorpheniramine maleate, codeine phosphate)
Human Mixtard (insulin)	Huminsulin
Voveran (diclofenac sodium)	Voveran
Becosules (vitamin B complex, vitamin C)	Augmentin
Taxim (cefotaxime	Phensedyl

Table 2. The Indian Pharmaceutical Industry

	The Indian Pharmaceutical Industry in 2004	The Indian Pharmaceutical Industry in 2010
Turnover:	$6.02 billion, up 6.4 percent year over year	US$ 26 billion, up 9% year over year
Exports:	$3.72 billion	US$ 13.9 billion
Imports:	$985.3 million	US$ 12.1 billion
Bulk drug production	$2.10 billion, with over 400 bulk drugs produced. Over 60,000 formulations produced, in 60 therapeutic categories	US$19 billion
Capital investment:	up 14.8 percent to $1.16 billion	Rs.8,829 crore
Employment	5 million direct, 24 million indirect	US$ 53 billion

CONCLUSION

There has never been a more important time for India's government and its drug producers, both multinational and domestic, to work together in partnership for the good of the industry and the nation. With its enormous advantages, including a large, well-educated, skilled and English-speaking workforce, low operational costs and improving regulatory infrastructure, India has the potential to become the region's hub for pharmaceutical and biotechnology discovery research, manufacturing, exporting and health care services within the next decade. For foreign investors, collaborations with India present a huge opportunity both in terms of joint production for the global market and supply of the growing domestic market.

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