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Review Article

A REVIEW: EXPLORING BRANDED GENERIC DRUGS BY INDIAN PHARMACEUTICAL MULTINATIONAL COMPANIES AS A NEW PROSPECT

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ABSTRACT

With the increasing in pressure of healthcare costs all the large innovator companies as well as Indian MNCs drive up their business in generic market. In this context, markets like India are especially attractive, given their potential for higher growth. The pharma industry in India has over the last few years have seen some large inorganic investments by pharma MNCs and these acquisitions are likely to play a significant role in expanding the generic footprints of the MNCs concerned both in India and in other major markets. Moving forward, most pharma MNCs are likely to maintain their focus on the Indian market, strengthening their product basket and sales network.

Keywords: Generic, MNCs, Over-the-counter (OTC) drugs, Patents.

INTRODUCTION

The development of new drug typically takes about 10 to 12 years and can costs a company as much as \$359 million. Each year worldwide, only about 26 new chemical entities drugs enter into the market. These facts hence prove that indian pharmaceutical MNCs have a difficult road ahead for drug development and they need to invest more in R&D sector in between the drugs price issues and regulatory requirement. On the other hand, a generic drug is identical to and bioequivalent of a branded drug in dosage form, safety, route of administration, quality, performance characteristics and intended use which US food and drug administration (USFDA) also confirms. The procedure for approval of generic drug in respective country is as stringent as innovative drugs. Generic drugs

are cheaper in comparison to branded drugs because there is no need to make investments in R&D as in the case of new drugs. The prevailing fierce competition also makes the manufacturers keep to low prices.

Overview of Indian Pharmaceutical Industry

As of January 2009, the domestic sales stand at Rs 31,600 crores and the industry has 70,000 brands from over 20,000 units (Indian Pharma Market, 2009). The industry is highly regulated, essentially on patents, price and product quality (FICCI, 2005). Promotion efforts in pharmaceutical industry are distinctive, as it is not directed to the end user (a patient) but to the influencer (Physician). Promotion of pharmaceutical products may be done through personal selling by medical representatives (MRs), advertising, sales promotion and

publicity. Out of these promotional techniques, personal selling is the primarily used technique. Advertising of prescription drugs is permitted in United States with prior approval and permission of FDA but in India, advertising is restricted according to drugs and magic remedies (Objectionable Advertisements) Act, 1954 and can be used only to promote OTC (Over the Counter) drugs. Most of the good performing companies recruit fresh graduates with zero to three years of experience, hence lateral switching of sales person after 25-26 years of age is not common in Indian pharmaceutical industry. Job description of a MR involves ensuring availability of promoted brands at chemists and distribution level, sampling of promoted brands to doctors, demonstration of specific characteristics of their brands especially in the introductory phase viz., rapid dissolution of tablet in a glass of water, persuading the doctor to try pleasant fragrance/taste of liquid preparations and giving gifts with brand name inscribed on it to facilitate recollection of the brand leading to its prescription. Pharma companies subscribe to database of CMARC and ORGIMS that provide information on prescription data at molecule-level, brand-level and therapeutic-level from 7000 core specialist doctors from 20 different prescriber segments.

Pharma MNCs Facing Multiple Challenges in the Global Market

Over the last decades, the global pharmaceutical industry has been facing multiple pressures arising from increasing R&D costs, the implementation of cost control measures by developed countries, issues related to regulatory requirement, and the absence of a strong product pipeline. Many of the patent products of top innovator companies get expired at the end of 2014 and this one is the largest opportunity for the global pharmaceutical industry. Moreover, established drug prices are also being subjected to increasing pressure as part of the trend towards stricter pharmaceutical cost containment policies

with reference pricing schemes (regulating drug reimbursement levels using a reference price cap). All these reasons led down the MNCS companies to make focus on the pricing issues of drugs, and insurance reimbursement for, new drugs, given that these MNCs rely significantly on revenues from new drugs to offset the impact of patent expiries. This has led to pressure coming onto pharmaceutical R&D spends in a scenario in which product pipelines are shrinking even as the cost of bringing in a new product to the market stands at over US\$800 million on an average. All these factors are expected to restrict the annualized growth rate of the pharma MNCs to around 2.0% over the 2006-2020 periods, according to various industry estimates. This situation has led to pharma MNCs shifting from the traditional model of focusing on developed markets and patented products alone, to being present across the value chain and also entering newer markets to attain better growth

Proposed Growth Opportunity from Emerging Market

The growth in demand of generic and branded generics drugs has led to pharma companies reorganizing their strategies by focusing on the generic and branded generics business in developed as well as developing countries for higher growth. The pharma companies like Novartis, through Sandoz, remains one of the multinationals most committed to generics among the leading pharma such as Pfizer and Sanofi Aventis which have also in-house generic businesses. The emerging markets represent exciting opportunities as they are expected to grow at a rate of 15.2% during 2006-2020.

The emerging markets are expected to reach a size of US\$400 billion by 2020, with india being a key market. This scenario has led to pharma MNCs reorienting their strategies and resource allocation for emerging markets. Thus they are now seeking to build up a significant presence in branded generics and over-the-counter (OTC) drugs, launch off-patent products of other

innovator companies, and adopt the practice of local pricing for patented drugs so as to attain volumes and capture market share.

Indian MNCs Achieve Higher Growth by Focusing on Branded Generics

By way of entering into the domestic formulations market expected to grow to a size in excess of US\$40 billion by 2020, India has become one of the strategic markets for the pharma MNCs. Most of the pharmaceutical companies have a two-bilateral strategy for the Indian market, mass market via product localization and India-specific pricing to capture the branded generics segment and address affordability issues; and launch globally patented products in niche segments at a premium. Thus Pfizer has come out with “branded value offerings” (branded generics) like telmisartan and rabeprazole in the therapeutic segments of cardiovascular management (CVM) and gastrointestinal, respectively as well as similarly, GlaxoSmithKline (GSK) for instance has launched branded generics like Benitec A (Olmesartan in combination with Amlodipine) in

the cardiology segment, Meropenem in the antibiotic segment, and Calamine lotion in dermatology.

Further, the pharma MNCs are launching products from their global portfolios at a fraction of the global prices in the Indian market, with such products including, among others, Diovan (Novartis), Januvia (Merck Sharp & Dohme), Galvus (Novartis), and Crestor (Astra Zeneca); these are being sold in India at a discount of up to 80% to the global prices. Besides, the pharma MNCs are expanding their existing product portfolio in India through line extensions and lifecycle management of existing key drugs.

As Table 1 below shows, most pharma MNCs operating in India have reported healthy growth rates during the last three years. The growth rates are relatively low for some players because of the lacklustre performance reported by some of their non-pharma businesses; the pharma business has done well for most of the companies.

Table 1: Trend in Growth Rate of Pharma MNCs in India

Financial Year Ending	2009	2008	2007
Abbott	14%	12%	16%
Novartis	8%	2%	3%
GlaxoSmithKline	13%	5%	2%
Aventis	1%	17%	-1%
Merck	22%	24%	-5%
Astra Zeneca	13%	14%	13%
Pfizer	13%	0%	1%

Sales Effort Made by Pharmaceutical MNCs with New Product Launches

With the special significance increasing on new product launches and geographical expansion, the

pharma MNCs operating in India have been scaling up their field force to attain their strategic goals. Leading companies such as GSK, Pfizer, and Abbott have invested significantly in expanding their field force to widen the reach of

both their current products and the ones in their pipeline. Thus, for instance, Pfizer added 500 people to its field force in 2009, while Merck Limited had added 450 in 2008. Few of the pharma MNCs have also outsourced their sales and marketing function in remote rural areas to third parties, given that it is not cost effective for

them to have their own field force in such locations. The expenses made by pharma MNCs on promotional & marketing strategy have also increased, with the result that the operating margins of the pharma MNCs operating in India have shrunk, although they are still largely within the range of comfort.

Table 2: Drug Molecules Launches by Indian Pharma MNC's

Brand	Molecule	Launched by	Treatment Area	Innovator Company
Xyzal M	Montelukast+Levocetirizine	UCB	Respiratory	MSD
Mexcelol	Metoprolol tartrate	Sandoz	Cardiac	Astra Zeneca
Targit	Telmisartan	Pfizer	Cardiac	Boehringer ingelheim
Xparin	Enoxaparin sodium	Astra Zeneca	Cardiac	Sanofi-Aventis
Axeten	Telmisartan	Schering plough	Cardiac	Boehringer ingelheim
Obiglo MD	Voglibose	Abbott	Diabetes	Takeda
Above 5	Rabeprazole sodium	Pfizer	Gastro intestinal	Eisai

Indian Pharma MNCs Expansions with New Origin

Pharma MNCs have been looking at new origins like acquisitions, licensing arrangements with generic companies, and other inorganic growth options in emerging markets to gain access to large generic product portfolios and boost growth. Recent examples in this regard in the Indian space include the acquisition of Ranbaxy by Daiichi-Sankyo, of Shantha Biotech by Sanofi Aventis, and of Piramal Healthcare's domestic formulations business by Abbott. The deals are expected to drive growth for the innovator companies in the Indian market, especially in the segments in which they have little or no presence, by providing them with a ready prescription base, infrastructure, distribution network, and local management capabilities.

The pharma MNCs are also able to add value to the acquisitions by marketing their global product portfolio in India through the distribution networks of the acquired entities. While the recent M&As by pharma MNCs in India have all involved large size deals, smaller local

acquisitions and licensing arrangements that could advance their market shares and fill critical gaps in the portfolio may also be expected in future. Several global pharma MNCs have also entered into licensing arrangements with Indian companies in order to be able to dip into a ready basket of generic products. For instance, GSK and Pfizer have entered into such arrangements with Indian companies like Dr. Reddy's, Aurobindo Pharma, and Claris Lifesciences. These deals are likely to accelerate the launch of products in various generic markets while offering the MNCs the advantage of cost-effective manufacture by Indian companies.

Pharma MNCs Healthy Free Cash Flow with Less Resources Demanding Nature of Business

To maintain healthy free cash flows in business these MNCs these companies have been launching branded generics specific to Indian market, they have strong therapeutic focus owing to parents' drug discovery base resulting in strong marketing proposition to stakeholders. The number of MNCs access to parents' global research based product portfolio and scientific

promotion techniques leads to relatively higher margins compared to Indian peers. Most of the Pharma MNC companies have outsourced significant portion of manufacturing as like contract manufacturing to verified third party vendors and act as marketing and sales organization resulting in less capital intensive nature of operations.

CONCLUSION

With the increasing in pressure of healthcare costs all the large innovator companies as well as Indian MNCs drive up their business in generic

market. In this context, markets like India are especially attractive, given their potential for higher growth. The pharma industry in India has over the last few years have seen some large inorganic investments by pharma MNCs and these acquisitions are likely to play a significant role in expanding the generic footprints of the MNCs concerned both in India and in other major markets. Moving forward, most pharma MNCs are likely to maintain their focus on the Indian market, strengthening their product basket and sales network.

REFERENCES

1. <http://www.expresspharmaonline.com/> accessed on 24/12/2010.
2. (2007), Asia Business Generator Project, Overview of Indian Pharmaceutical Industry, Tata Strategic Management Group.
3. (2009), “**Journal of Intellectual Property Rights**”, Vol 4, 236-240
4. (2007), Opportunities for India in Generic Drug Space News.
5. <http://www.in.kpmg.com/pdf/> accessed on 18/1/2011
6. <http://www.usitc.gov/publications/> accessed on 13/12/2010
7. <http://www.eximbankindia.com/> accessed on 4/12/2010
8. <http://www.cdriindia.org/> accessed on 21/1/2011
9. <http://business.mapsofindia.com/pharmaceutical/> accessed on 24/1/2011

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