

We continue with our series on India's success in different spheres; in this edition we have chosen to highlight the pharmaceutical industry.

The Indian pharmaceutical sector has come a long way, being almost non-existing during 1970, to a prominent provider of health care products; meeting almost 95% of the country's needs. Currently the Indian pharma industry is valued at approximately \$8 billion. It ranks 3rd by volume of production (10% of global share) and 14th by value (1.5% of global share). Nearly 40% of the world's bulk drug requirement is met by India. Today the Indian pharma industry is truly global—evidenced by some big ticket acquisitions of foreign companies like Sun Pharma's acquisition of Taro Pharma, Wockhardt's acquisition of Negam Labs, Nicholas-Piramal's acquisition of Abbott Labs, DRL's acquisition of Betapharm, etc.

Generics are the backbone of Indian pharmaceutical industry with India accounting for 22% of generics in the world market. This has been possible due to 30-50% lower production costs, expertise of Indian firms in reverse engineering processes and lower personnel & capital construction costs. Generics make it possible for a large segment of the world's population (in India, Africa and the poor in the developed West) to buy affordable health care for themselves.

The Indian pharma industry has been witnessing many changes in the recent years. The size of exports has increased from 19% to 52% during the period 1996-97 to 2008-09. This indicates greater dependence of our domestic industry on international fortunes. With rise in global mortality rates and increase in incidence of "lifestyle" diseases, comprehensive yet affordable health care reforms have become the top priority of many nations. In such a scenario, the comparative advantage of Indian cheap and high quality drugs signals expanding horizons for the domestic industry. This coupled with development of 'medical tourism' through development of world class hospitals and well trained medics—can see India emerge as a medical hub of the world.

This, however, requires the Indian companies to do their homework properly. Despite being the country with the highest number of US FDA approved plants outside US, there have been many instances in the recent past of drugs manufactured at Indian sites being rejected on parameters of stringent quality control by international inspection authorities. Similarly, there was much negative publicity generated by English medical circles on a superbug "ND Mettalo-1" detected by them in India that is believed to be resistant to antibiotics. Additionally, instances of export by other countries of counterfeit drugs using Indian drug makers' label is on the rise that tarnish the reputation of Indian companies in the world market. Apart from strengthening internal systems by the Indian manufacturers, the issue of rising fraud has to be taken up at the appropriate fora by Indian authorities. It is imperative that India also resolve the matter of seizure of exported drugs in transit before reaching their destination (in violation of WTO guidelines).

As with the nature of market forces, the success story has attracted many foreign pharma majors to acquire Indian firms both to access the large market as also to reap the benefits of high quality R&D prevalent here (e.g. Daiichi Sanyo's acquisition of Ranbaxy). It is feared that this might discourage Indian arms of the foreign companies from producing generic drugs since the MNCs will only be interested in pushing costly drugs for greater profits. This is leading Indian policymakers to mull the option of restricting FDI norms.

Another issue is that of issue of patents. The number of patent filings by Indian companies has increased manifold. India enjoys process patent under compulsory licensing as per WTO norms. While this has spurred the production of essential medicines at economical rates (made possible due to reverse engineering), which would otherwise have been beyond the reach of the millions of the country's poor; India is under constant pressure from the developed nations to scrap compulsory licensing.

While this issue is one of negotiation at the global forum, an equally pressing prerequisite is of encouraging greater R&D. Though R&D in Indian pharma is a world beater and Indian companies have been hiking their R&D expenditure from 2% of their annual sales to 10% during the last 10 years, the country is often criticized of only incremental innovation without any major breakthroughs. Apart from greater outlays by the government to the area of research, financial incentives to the drug companies by way of tax exemptions to foster research which would otherwise be unviable for the companies is essential. To breed an atmosphere that encourages R&D it is also essential to develop global capabilities of scale (which requires higher capital), more skilled manpower, and clinical trials.

Benefits of scale can be enjoyed by greater inflows of FDI (examined above), becoming cost effective, and through consolidation. Currently, the Indian pharmacy industry has over 20,000 units; around 260 constitute the organized sector, while others exist in the small scale sector. This fragmented nature of the industry indicates the opportunity for consolidation in order for the industry to become scalable. During the ten year period 1996-97 to 2006-07, the Indian domestic pharmacy industry has become more concentrated with share of the 10 largest companies rising from 10% to 20%. Collaborations and alliances in discovery research and product development tie-ups like that of Ranbaxy-Eli Lilly, Ranbaxy-Bayer, Torrent-Novartis, Dr.Reddy's-Novartis etc. are some cooperative strategies that Indian companies have to undertake to adapt to the dynamic times.

As the new patent regime comes into force, prices of controlled drugs will escalate which will endanger the lives of the poor and aam aadmi. Hence, in the new scenario, cost optimization becomes very important. Outsourcing of clinical trials, contract manufacturing for active pharmaceutical ingredients (API) from independent manufacturers in the country are some methods adopted for cost reduction. Our Cost and Management Accountant friends can through their expertise in costing techniques—play a crucial role in taking the Indian pharma sector to the top.

Wishing our readers a cracking and colourful Diwali.