

## **Executive Summary**

The Indian pharmaceutical sector is emerging as one of the major contributors to Indian exports with export earnings rising from a negligible amount in early 1990s to Rs.29,139.57 crores (US\$7.24bn) by 2007-08. The exports of Drugs, pharmaceuticals & fine chemicals of India have grown at a compounded annual growth rate (CAGR) of 17.8% during the five-year period 2003-04 to 2007-08. The Indian domestic pharmaceutical market size is estimated at US\$10.76bn in the year 2008 and is expected to grow at a high CAGR of 9.9% percent till 2010 and thereafter at a CAGR of 9.5% till 2015.

However, this is still miniscule in comparison to the opportunity existing in the global market or with the exports cornered by major pharmaceutical exporting countries. The global pharmaceutical markets were estimated at US\$712bn in the year 2007 growing at 6.4 percent. The market size of USA is estimated at US\$295-305bn (growing at 4-5 percent) followed by Top 5 European countries (EU-5) with an estimated market size of US\$135-145bn (growing at 4-5%), emerging markets, viz., Brazil, China, India, Mexico, Russia, South Korea & Turkey with an estimated market size of US\$85-90bn. (growing at 12-13%) and Japan with an estimated market size of US\$64-68bn (growing at 1-2%).

India is undisputedly an acknowledged leader in the global pharmaceutical industry (other than drug discovery) measured by any yardstick say number of facilities filing DMFs or facilities inspected by US FDA or number of patent challenges or volume of APIs & formulations exported, etc. In spite of considerable achievements, several untapped business segments and markets exist and the room to enhance the country's pharmaceutical exports is vast. The sophisticated chemistry capabilities, lateral thinking abilities in developing non-infringing processes, disciplined approach to adhere to any stringent guidelines, dedication for manufacturing excellence, etc., make India as a most favourite destination to source or outsource various components of value chain. Although various government institutions are working with great zeal to boost the industry, there exist multi-departmental issues arising out of globalisation and challenges, which need to be addressed. In addition, despite our success, we are still at the periphery of this vast opportunity.

A number of leading drugs go off patent every year and the generic pharmaceuticals penetration is increasing in all the countries of the world further raising the opportunity for exports in this segment. Approximately US\$123 billion worth of generic products are at risk of losing patents by 2012. Even at a conservative estimate of 15% opportunity, this translates into US\$18.4 billion opportunity for India. Intense science, good understanding of patents and manufacturing to the stringent requirements of access regime are key requirements for future success in this opportunity. India has the requisite capabilities. Hitherto most opportunities emanated from synthetic chemistry. The opportunities in biopharmaceuticals will be the major attraction in the next decade. New technologies and enhanced regulatory requirements are changing the rules of the game making production migrate to east.

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The global market for contract manufacturing of prescription drugs is estimated to increase from a value of \$26.2 billion to \$43.9 billion. India and China could potentially account for 35 percent to 40 percent of the outsourced market share for active pharmaceutical ingredients, finished dosage formulations and intermediates. Costs of clinical trials in India are around one-tenth of their levels in the U.S. and it is estimated that they could be worth US\$300 million to India by 2010. There has been a great deal of interest in alternate remedies for some time now. World market for natural products is estimated at US\$62 billion and is exhibiting double-digit growth rate.

India with its significant advantage of low cost of innovation, low capital requirements and lower costs in running facilities, well established manufacturing processes, R&D infrastructure, is strategically well positioned to emerge as 'Health Keeper' of the world. Third world countries are increasingly looking towards India as an alternative source for affordable medicines to solve their increasing healthcare costs. The recent antiretroviral revolution to help millions of aids patients in the world was possible only due to India, which is clearly acknowledged world wide.

Pharmaceutical industry can help India transform itself into a knowledge driven economy with firm routes in science and intricate knowledge of production and manufacturing engineering. The industry has risen in its importance from a sector to an important part of development process. The country has to look at pharmaceutical sector as a strategic & flagship industry. The Current success is due to amalgamation of R&D (developing non infringing processes and reverse engineering), manufacturing excellence (designing and running world class facilities with economies of scale), globalisation ability ( establishing presence/ acquisitions/ mergers in the international markets). Such multidimensional excellence will make Pharma the torch bearer of the nation paying way for R&D led global market leadership in various goods and services.

Comparisons are some time drawn between the Information Technology/Information Technology-Enabled Services (ITES) and pharmaceutical industry to prove that state intervention and support may not be necessary as private sector is capable of spearheading itself. There is no doubt about the capacity of Indian pharmaceutical sector in taking the big leap forward. Comparisons with information technology will be mis-founded for several reasons. Primary among them are the fact that pharmaceuticals serve survival needs in all societies and traditionally the sector got its momentum from government policies, which developed its inherent strength. It may be necessary to note that pharmaceuticals all over the world are heavily regulated products.

India needs a very strong pharmaceutical industry if it has to provide affordable medicines to its over one billion population. The country with out strong drug discovery capabilities would be at the mercy of foreign pharmaceutical MNCs in the future for new & innovated drugs. The next decade is crucial in finding a

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viable strategy to maintain the current dominance in chemistry, develop biology and to create drugs that could help the nation.

Today, the whole world acknowledges the supremacy of Indian pharmaceutical capabilities in chemistry, manufacturing and adhering to stringent guidelines of most advanced nations. In addition to generating revenues and securing appropriate medicines for its citizens, the pharmaceutical industry propels the country to emerge as a knowledge economy. Intricate science, technology, legal aspects and regulations involved in pharmaceuticals industry creates a great scientific and business tempo that propels the nation. The diffusion impact of such knowledge economy will help various sectors to think of global dominance following the example of pharmaceutical industry and would provide means and drive in such achievement. Due to excellent regulatory and fiscal climate, we have travelled a significant distance. India needs to protect what it has achieved, and draw key milestones, road maps and measure our success with conscious effort to emerge as an alternate power in the global health sector.

Government of India needs to more proactively nurture this sector by addressing the missing links and strengthening the policy environment to encourage industry to find its rightful place sooner than later. India is also exposed to the threat of takeovers from global big pharmaceutical companies under the new IPR regime. Indian pharmaceutical industry being fragmented with small balance sheet sizes; takeover by global pharmaceutical companies would adversely affect the health interests of the nation. Hence there is a case to promote internal consolidation and develop stronger companies that have width and depth in market access, manufacturing and R&D.

It may be recalled that Information Technology industry while emerging in the country produced some professionals who evolved to be world class leaders in Information Technology establishing Indian credentials in the sector. The emergence of these leaders helped in spear heading the Indian Information Technology industry globally. At the same time, these leaders had the charisma of consolidating and re-energizing not just the IT sector, but the new industry in India as a whole. In the pharmaceutical sector while some corporate entities have evolved as global leaders from developing countries, there is relative absence of individual pioneers, role models and leaders in the industry. It is not that they do not exist but their adequate projection with a view to consolidate the sector in the global context, position it at a platform of potential dominance and lead the sector from the front in order to catapult the sector into the higher orbit is lacking. It is, therefore, necessary that such icons need to be adequately recognized and projected as leaders of industry and consolidators of the sector.

There is another reason to contend that pharmaceutical industry deserves a greater focus today. A 'brand India' has gradually evolved around Indian pharmaceutical sector with the emergence of new segments of the industry, such as contract manufacturing, contract research services, biopharmaceuticals and Indian systems of medicines. It is even more necessary that this branding be

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adequately strengthened. This would require investments in brand building. It is perceived that government needs to prepare an action plan for brand building around pharmaceutical sector. This will also help in creating several spin-off benefits such as for dealing with the problem of counterfeit drugs.

The Task force enunciated a vision for Indian pharmaceutical R&D as:

- ❖ *"To provide intellectual capital to make available safe, cost-effective, contemporary, quality therapeutics to the people of India and help reduce percentage of mortality and morbidity while emerging as a significant player in the global market place."*
- ❖ In consonance with this vision, a grand dream for production, export and investment in pharmaceutical R&D was evolved. This report suggests the measures by which such a dream and vision could be realised.
- ❖ Priority areas for Indian pharmaceutical R&D have been identified. India's expertise in developing new and innovative processes for known molecules needs to be exploited in a greater measure. While India forged ahead in conventional pharmaceutical technologies, it lagged behind in complex technologies, specialty pharmaceuticals and new drug delivery systems. Investment impetus required in these areas has been specified.
- ❖ Priority needs to be given for initiation of new drug development for diseases of relevance to the Indian population, while at the same time seizing opportunities to become a global player by introducing globally competitive products based on new molecules. Currently India is at a nascent stage in drug discovery and the industry is focusing on strategies to earn while learn. Key building blocks in the value chain could be focused to facilitate the drug discovery. These have been discussed.
- ❖ A key factor to retain competitiveness is low cost of innovation and process management. In the current context of rapidly rising wages for select skilled population, efforts to widen the skill base and strategies to generate the skill base have been discussed.
- ❖ To achieve such objectives, the existing human resources in conventional methods of drug discovery need refurbishing alongside acquisition of newer tools of drug discovery. A larger team of experts comprising chemistry, biology, biotechnology, etc., need to find select viable strategies for India in drug discovery. Drug discovery is a product of strong efforts at universities, public institutions and industry. The direction of effort has been specified.
- ❖ Citing the unique opportunity for India to become a leading centre for clinical trials, the report suggests basic changes in the legislation allowing import of animals, contract research and a legal status for institutional animal ethics committee. Establishment and operationalisation of a cGMP, GLP and GCP monitoring authority has been recommended.

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- ❖ Recognising the crucial role played by the Indian systems of medicine in the health care needs of world population, the Task Force has recommended initiatives to strengthen and modernise the existing infrastructure. Proper scientific documentation of India's traditional knowledge base in the internationally accepted format and media has been suggested as a priority. For any industry to succeed and become globally competitive a strong home market is essential. Certain initiatives have been specified to foster the progress of the industry.
  
- ❖ A higher level of innovation and IPR management coupled with strategic manufacturing and aggressive marketing will largely determine Indian pharmaceutical industry's future. Specific measures for strengthening the IPR system with action points for the Government, judiciary and the legal system, industry, Department of Science & Technology and educational system have been suggested. Some suggestions for enacting a TRIPS compatible IPR legislation, which protects the interest of the consumers and allows a platform for the growth of Indian pharmaceutical industry, have been made.
  
- ❖ This Report identifies concrete action points for various stakeholders, particularly the government agencies and departments over the next few years. The expanse of recommendations is wide and deep. It ranges from action in the sphere of linkages to be sought between academics, research and industry; evolving a new regulatory regime in view of emerging concerns of the industry in its multi-faceted dimension; mechanisms for coordination on a multi-disciplinary platform; the front end of export policies and incentives required to facilitate exports; capacities both at the scientific level within the industry and at regulatory and administrative level for developing the industry; identifying infrastructure required for the purpose, etc. The section on key recommendations summarizes the discussion in the previous sections to give concrete suggestions. Further a role analysis of promotional institution such as Pharmexcil has been carried out and recommendations made