

Pharmaceuticals: Regulatory & Policy Benchmarking

China and the USA have emerged as the two strongest forces in the global pharmaceutical industry. China has been backed by low cost of production, skilled labour and a large domestic market; while the USA has been backed by congenial R&D environment, and tax incentives. The two countries have been the most competitive and amongst the largest producers of pharmaceuticals in the world. As discussed in the earlier sections, the pharmaceutical industry in both countries possesses inherent strengths and enjoys immense support of their governments due to which the industry has witnessed huge success in recent times. However, there are certain constraints with respect to drug discovery process in India, which can be easily overcome through suitable policy measures. A comparative analysis of various factors determining industrial competitiveness has been done hereunder for India, China and other major competing countries like USA, Ireland and Japan to understand the sources of competitive advantages enjoyed by the competing countries and thereby formulate suitable recommendations for further improving competitiveness of the Indian pharmaceutical industry.

Fragmented Industry Structure: An obstacle in growth of industry

Indian pharmaceutical industry is highly fragmented, with presence of a large number of small and mid-sized players. Consequently, only a few large companies have been able to spend huge sums on research and development in new drug discovery. Additionally, various important facets of pharmaceutical industry such as intellectual property creation, facility design and maintenance, global regulatory affairs, legal compliances, etc. are being conducted by limited large players. Lack of resources restricts the ability of domestic pharmaceutical companies to compete with MNCs for new drug discovery, research and commercialisation of molecules.

Government's policy focus is a key to global success

Indian as well as Chinese governments have played a major role in development of pharmaceutical industries in their countries. The Chinese government has played an important role by laying new regulations and decrees regarding drug production and distribution, which enabled state owned pharmaceutical companies to become more market oriented. The Chinese government has also contributed in development of drug R&D capabilities by creating an innovation-oriented environment.

In the Indian pharmaceutical industry, price regulations, inadequate or weak drug control infrastructure etc. impacts the pharmaceutical industry. At present, pricing of 74 bulk drugs and their formulations, which account for a large share in the retail pharmaceutical market, are controlled by the Drug Price Control Order (DPCO)-1995. Therefore, the government needs to take a balanced approach towards price control, after taking into account its repercussions on drug availability on the one hand and drug affordability on the other.

The Japanese government deregulated the pharmaceutical industry during the 1960s and since then several reforms have taken place including FDI liberalisation in the sector, changes in the patent laws, and simplification of accreditation of drug manufacturers. The newly-created PMDA agency was introduced in 2004 with a view to improve drug approval times and bring them more into line with their US and European counterparts. The market is therefore increasingly open to overseas products, and many domestic companies are being forced into measures such as mergers and expansion of R&D facilities in a bid to ensure survival in the marketplace.

Investment measures have attracted FDI in the major markets

China has emerged as an attractive market to many multinational pharmaceutical companies owing to its large market size, increasing government spending on healthcare, government reform plans to restructure the highly fragmented industry, emphasis on encouraging innovation, and improved intellectual property protection. Moreover, the government provides various tax and other incentives to foreign investors in the sector. Although foreign enterprises are subject to 30% corporation tax and additional 3% local corporation tax, the foreign companies generally end up paying lower than full corporate tax due to various tax exemptions. The foreign companies enjoy similar tax concessions as domestic companies in the Special Economic Zones.

The Irish pharmaceutical industry has been a major international success story. Irish Industrial Development Agency (IDA) played a major role in attracting foreign investments in the sector. The sector that was almost non-existent until the 1960s, took off in the 1970s following the IDA's adoption of fine chemicals as one of its target sector, thereby leading to a series of manufacturing investments, notably by US and UK-based companies.

Although Indian pharmaceutical has globally recognized capabilities in generics production, it lacks in terms of investments in API production which requires inter-alia cheap power and other infrastructure facilities. Some of the areas where Indian industry is lacking are: inadequate GLP compliant animal facilities, lack of biological sample storage facilities and inadequate shared infrastructure for optimal capacity utilization.

Tax incentives and subsidies have improved competitiveness of players in major markets

As discussed in the earlier section, the Chinese government provides several incentives to the domestic pharmaceutical industry, such as tax reliefs and direct funding opportunities. The pharmaceutical firms are eligible for various tax incentives such as High/New Technology Enterprise (HNTE) incentive, CIT super deduction, IT exemption for transfer of technology, and tax refunds which may extend up to 100%

The government of the United States also has introduced several forms of tax credits over the years like Research Tax Credit, Orphan Drug Credit and Possessions and Puerto Rican Economic Activity Tax Credit etc. These have helped a large number of drug manufacturers engage in new drug discovery and prompted them to spend more on research than they otherwise would. The drug industry has been a leading beneficiary of the research credit: in 2006, it claimed \$902 million in research tax credits, or 12% of the total amount of such claims by all industries. Since the orphan drug credit was enacted in 1983 as one of a series of measures aimed at stimulating increased investment in the development of new drugs to treat rare diseases and conditions, at least 325 such drugs have gained regulatory approval in the United States.

Indian government too offers tax breaks to pharmaceutical industry in the form of weighted tax deduction for R&D expenditure, low customs duty and nil excise duty on specified lifesaving drugs. Government has also launched two schemes—New Millennium Indian Technology Leadership Initiative and the Drugs and Pharmaceuticals Research Programme—targeted at drugs and pharmaceutical research.



Various incentives are available for companies in Ireland to conduct their research and development activities. The incentives are available in the form of R&D Tax Abatement, R&D Financing, and Intellectual Property Stamp Tax. A major incentive to investors in Ireland is the highly competitive corporate tax rate of 12.5%. Further, no tax is paid on earnings from intellectual property where the underlying R&D work was carried out in Ireland. Ireland has also introduced a new R&D Tax Credit, designed to encourage companies to undertake new and/or additional R&D activity in Ireland. It covers wages, related overheads, plant/machinery, and buildings.

Trade barriers could affect competitiveness of Indian exporters

Trade agreements of developed markets with other countries could affect the prospects of Indian pharmaceutical exporters. For instance, USA has entered into FTAs with several developing countries (example Morocco-USA FTA) and there may be instances where such FTAs include provisions for extension of patent terms, which would affect exports of generics from India.

Indian exporters are also subjected to non-tariff barriers such as long transaction time for registration of drugs, insistence on completing long process for registration when the drug may actually have gone through the most rigorous process of registration such as the USFDA; insistence on allowing imports of only those drugs which are registered in some developed countries, etc.

Further, China and East European manufacturers are increasingly giving competition to Indian players. The Chinese government has made huge investments in the biotechnology sector to build up the manufacturing capabilities in the global pharmaceuticals market.

Investments in R&D boost competitiveness of pharmaceutical sector

Major competing countries have made huge investments in R&D for pharmaceutical sector, providing several tax and non-tax incentives and direct subsidies to the industry players. Besides incentives, the governments have also established specialized institutes and research facilities.

The pharmaceutical industry in the USA has been a pioneer in terms of the discovery of new cost effective and life-saving drugs. U.S. firms conduct 80% of the world's research and development in biotechnology and hold the intellectual property rights to most new medicines. According to the Pharmaceutical Research and Manufacturers of America (PhRMA), manufacturers spent nearly US\$67.4 billion on R&D in 2010. Programmes like Small Business Innovation Research (SBIR) and Small Business Technology Transfer program (STTR) have strengthened the role of small business in meeting Federal R&D needs for pharmaceutical industry. The program used small businesses to stimulate technological innovation and increased private sector commercialization of innovations.

In India, the overall spend of pharmaceutical industry on R&D is estimated at a mere 2% of sales as against 10-20% global average. The Indian government has taken several policy initiatives for strengthening R&D in the pharmaceuticals sector such as fiscal concessions, tax deductions for R&D expenditure, and has also established premier research institutes for the pharmaceuticals sector such as National Institute of Pharmaceutical Education and Research (NIPER).