

4. Pharmaceuticals Sector and Opportunity Ahead

In general, there are several reasons which justify focusing on pharmaceutical exports. The most important of these reasons is the size of the industry, the growth potential of this sector and the advantage India enjoys in pharmaceutical manufacturing and services. Indian pharmaceutical industry has evolved in the last 20 years to position itself to global envy. It has the capacities of addressing needs of countries at different levels on the development ladder. Comparisons are some time drawn between the information technology and information technology-enabled services, 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. However, it may be necessary to note that pharmaceuticals all over the world are heavily regulated products. Comparisons with information technology will be miss-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.

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, bio-pharmaceuticals and Indian systems of medicines. It is even more necessary that this branding is 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. 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.

4.1 The Goal of Sector - Built on Track Record & Comparative Advantage

India can achieve significant revenue streams from exports by becoming a global centre for Pharmaceutical Generics, APIs and Innovative Formulations, an emerging New Chemical Entities (NCE) hub, service management centre for Multinational Pharmaceutical Companies (MPCs) such as, contract research/ custom synthesis, clinical trials, bioequivalence studies, biological studies, data management, etc. (refer Appendix V on comparative advantage of Indian pharmaceutical exports).

The main opportunities for the Indian pharmaceutical industry are in the areas of:

- ❖ Generics/ Bio pharmaceutical generics
- ❖ Contract manufacturing services for MPCs
- ❖ Contract R&D services like custom synthesis, clinical trials, clinical data management, bioequivalence testing, Stability testing, chemistry and biology services,

4.2 Generic Pharmaceuticals

The domain of generic pharmaceuticals includes pharmaceutical/biopharmaceutical intermediates, Active Pharmaceutical Ingredients and Finished dosage formulations. India's capabilities in various market segments have been presented (in bold letters) in Exhibit 1 below:

EXHIBIT 1: INDIAN CAPABILITIES IN DIFFERENT SEGMENTS OF PHARMACEUTICALS INDUSTRY

Geographical Segment

US generic market	EU market
Japan generic market	Latin America
Australian market	Africa and ROW

Generic Product Segment

Tabs and caps	Injectables and infusion
Ointments & creams	Oral solutions

Business lines Segment

CRAMS of API/formulations	API manufacture
Cuts synthesis / chemistry work in drug discovery	Formulation manufacture
Clinical trials/ data mgt etc, in drug discovery & development	NDDS/ Specialty generics development

Customer

MNCs of USA	MNCs of Europe
Generic Cos. /USA	Generic Cos. of Europe
Pharmacies / distributors	Other markets regulated

Therapeutic Segment

CVS, CNS	Antibiotics
Oncology	Derma/opthal
Steroids and Hormones	Controlled and subs

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4.2.1 Generics 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 of generic products are at risk of losing patents by 2012 (refer table 19, 20 & Chart 18). Even at a conservative estimate of 15% opportunity this translates into US\$18.4 billion opportunity for India.

Country	Pharmaceutical Market Size	Generics Market Size (US\$ man)	Generics Penetration (%)	Generics CAGR (%) (2004A-2008E)
Germany	34,913	13,451	38.5	15.6
UK	24,829	9,963	40.1	18.3
France	35,011	6,993	19.8	28.8
Italy	23,141	5,972	25.8	31.9
Spain	15,200	1,254	8.3	15.1
Netherlands	4,717	2,423	51.4	28.1
Belgium	5,406	380	7.0	16.5

Source: Wall Street Research, IMS, Datamonitor and Deutsche Bank

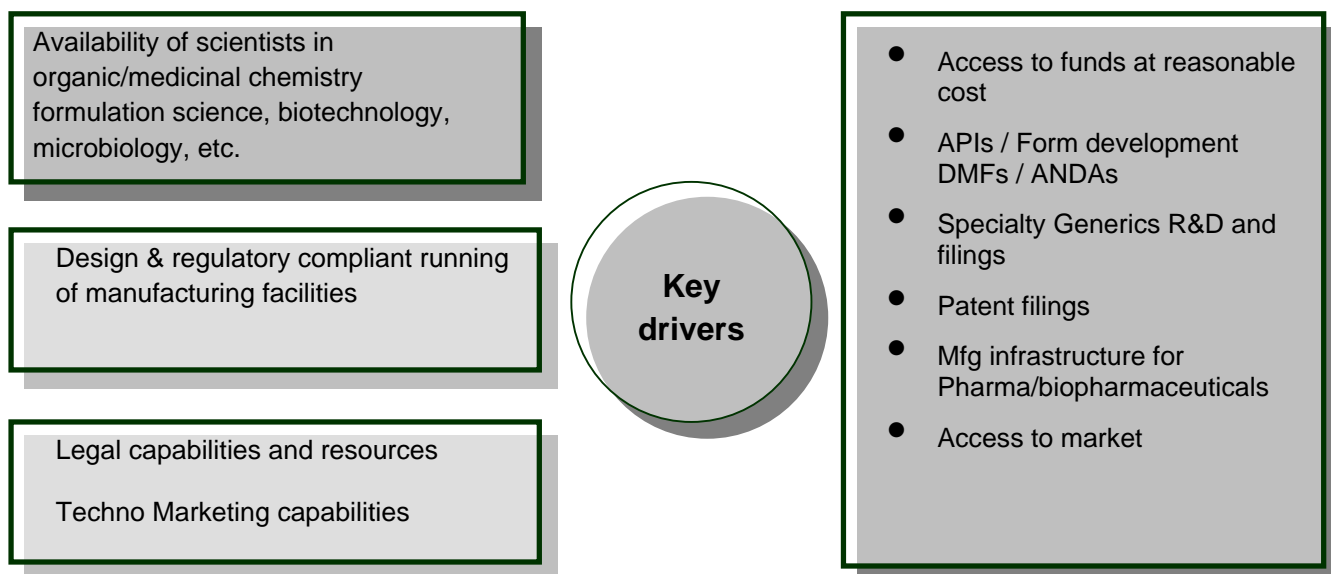
Year	Value of Products at Risk
2002	17
2003	10
2004	16
2005	14
2006	19
2007	20
2008	20
2009	20
2010	28
2011	28

Source: IMS Health Market Prognosis Sep. 2007

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The key drivers for growth of Indian generic pharmaceutical industry are presented in Exhibit 2.

Exhibit 2: Key Drivers for Promoting Indian Generic Pharmaceutical Industry



4.2.2 Opportunity in Developing Economies

A number of countries pursue self-reliant policies and create non-tariff barriers. In the new era of stricter regulation & enhanced understanding of drug quality, countries are learning the importance of economies of scale, strengthening of R&D and manufacturing. Lately, the structure of the industry has become capital-intensive with stringent requirements to set up dedicated manufacturing and R&D facilities for different varieties of drugs to ensure drug safety and quality. Further, importing is far cheaper than revamping manufacturing for several product classes in countries with small populace and/or underdeveloped industry. As the infrastructure is technology and human skill-intensive, the cost of setting up and running such facilities to serve small populations has become uneconomical.

Further, the Declaration on the TRIPS Agreement and Public Health, at the 4th Ministerial Conference in Doha on the 14th of November, 2001 which the WTO adopted, has serious implications for world trade in pharmaceuticals and offers Indian companies specific export opportunities. Art. 31 of the TRIPS, which originally put in place the provisions regarding compulsory licensing, is understood as per paragraph 5b of the Doha WTO Ministerial Declaration on TRIPS and Public Health. This provides that "each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted." Usually these conditions are those of national emergencies and health crises when

Strategy for Increasing Exports of Pharmaceutical Products

nations are permitted to grant compulsory licenses on patented compounds to generic manufacturers who will produce the drug at low cost.⁵

This is important in the context of pharmaceutical exports because, as shown by the examples of Thailand⁶ and South Africa⁷, there are situations when patented pharmaceuticals become too expensive for developing countries and consequently, they import cheaper copies of these drugs. Indian companies such as *Cipla* and *Aurobindo* have been at the forefront of exporting drugs in these situations. This is specifically because there are very few countries, which have the manufacturing capacity to cater to situations. AIDS, etc are national emergencies and since India is one of the countries which has significant manufacturing capacity as well as a past record of providing for such situations, an important opportunity as well as social responsibility emerges for Indian companies⁸.

Public health commitments of developing countries are increasing manifold in order to provide better health coverage to populations due to rising expectations and improved living standards. National commitments are also manifested in governments resolving to fight disease and malnourishment to improve productivity and mitigate poverty; and take up the challenges posed by occurrence in epidemic proportions of diseases such as AIDS, tuberculosis, malaria and many others. As populations in developing countries improve their living standards and get into the mainstream of economically productive modern living, emerging 'epidemics' such as diabetes and cardiac diseases, place new challenges before these countries, opportunities unfold for India in providing inexpensive but quality medicines to these developing countries.

As business in developed markets despite higher entry costs offers better returns today, most exporters are tempted to export to developed markets, at times, neglecting the less developed markets. Regulatory processes in such markets are also not adequately evolved thereby discouraging many exporters. However, there is a need to look at these markets with a renewed interest particularly because they are bound to evolve over time and today's entry investment may prove to be a seed investment offering better returns over time, secondly an entry at a later date may simply not leave any space for Indian drugs as the first mover's advantage might elude us, thirdly pharmaceutical exports may be a good strategic investment in these areas as it creates foundations for long term strategic relationships.

4.2.3 Opportunity in Developed Economies

US, Europe and Japan are the most significant economies in global pharmaceutical market. Developed markets such as USA, Top 5 EU countries and Japan are estimated at US\$295-305bn, US\$135-145bn,

⁵ Art. 5(c), Doha Declaration.

⁶ The Economist, "A Gathering Storm", June 7th, 2007. This mentions initiatives by Malaysia and Brazil to pursue compulsory licensing.

⁷ The Economist, "The Price of Africa's Cheap Drugs", April 19th, 2001.

⁸ Duncan Matthews, "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?", 7 J. Int'l. Econ. L. 73, (2004).

Strategy for Increasing Exports of Pharmaceutical Products

and US\$64-68bn respectively with single digit growth rates (refer chart 23 & Table 4). The generics opportunity within this market is relevant for India. Around ten percent of this market estimated between US\$49.4 – 51.8 billion can be taken as the size of the opportunity for Indian generics.

Generics need not be promoted to doctors in many markets such as USA and assume character of a commodity in these countries. The cost of promoting to doctors and setting up drug promotion structures would otherwise be very high for Indian firms and the only entry cost in generics markets in these countries is limited to the cost of developing a DMF (Drug Master File) or ANDA (Abbreviated New Drug Applications) and the filing costs. In view of this, many developed economies are important target opportunities for pharmaceutical generic manufacturers.

Emerging markets (Brazil, China, India, Mexico, Russia, South Korea and Turkey) are estimated at US\$85-90bn. (12-13%) and rest of the world is estimated at US\$125-135bn growing at 7-8 percent in the coming years. Emerging markets have significant generic component due to historic reasons of patents applicability.

4.2.4 Bio-generics Opportunity

Bio-generics are nothing but generic versions of biological products. With around 200 companies, India's biotechnology sector is growing fast and is in the early stages of development with initial emphasis on vaccines and bio-services. The break-up of Indian domestic biotechnology market is given in chart 19. This industry grew by 37 percent in the year 2006-07. Total biotechnology exports stood at US\$763 million during 2006-07 with 75 percent of it coming from biopharmaceuticals.

IMS estimates that biotechnology products accounted for over 10 percent of global pharmaceutical sales, 20 Patents on the first generation of blockbuster biopharmaceuticals are beginning to expire. Sales of bio-generics are flourishing in the unregulated markets. The only regulated-market approvals so far are in Australia, granted in October 2004 for the recombinant DNA growth hormone Omnitrope, manufactured by Sandoz, as well as in the EU, granted in April 2006.

Table 21: India's Domestic Bio-Technology Market Segmentation (2006-07) (figs. in US\$ mn. & %)

Bio-pharmaceuticals	76
Bio-agriculture	8.4
Bio-services	7.7
Industrial Products	5.5
Bio-informatics	2.5
Source: Pharmexcil	