

The World's Pharmacy

Pharmaceutical exports from India are booming as manufacturers make their presence felt in global generics market. Indian drug-makers are also driving the contract manufacturing clinical research segment, says **Rajeshwari Adappa Thakur**.

PHARMACEUTICAL exports from India are currently booming on the back of low-cost innovation and manufacturing coupled with skilled manpower and cutting edge R&D. Indian drug makers are anticipating greater export opportunities for their generics business as an increasing number of patented drugs worth \$60-70 billion will go off patent in the next four to five years.

The pharma sector has been a major source of foreign exchange for the country. "As per estimates, the Indian pharma exports market, valued at around \$5.3 billion, is growing at a rate of over 20 per cent," says a Ranbaxy spokesperson.

Ranbaxy Laboratories, Dr Reddy's Laboratories, Cipla, Sun Pharma, JB Chemicals, Aurobindo Pharma, Wockhardt, Nicholas Piramal, Orchid and Lupin are some of the leading pharma exporters of India.

"India's low cost manufacturing expertise, presence of the highest number of US FDA approved plants outside the USA, availability of a large talent pool with superior chemistry skills at relatively low cost are among the key factors contributing to the global success of Indian pharma sector," points out Hitesh Gajaria, sector leader, pharmaceuticals, KPMG India.

Indian exports have grown at an astounding rate over the past few years

and this growth is expected to continue in the future as well. According to Crisil Research, total formulation exports were valued at \$3.2 billion in 2006-07. They have grown at a CAGR (compounded annual growth rate) of about 24.6 per cent since 2001-02 and are expected to continue to grow at the same rate up to 2011-12.

The total bulk drug exports were valued at \$3.7 billion in 2006-07. They have

grown at CAGR of almost 32.7 per cent over the last five years and are expected to grow between 28 and 30 per cent over the next five years.

Interestingly, in 1980-81, exports constituted only five per cent of the total bulk drug production. "This figure grew rapidly to touch 19 per cent by 1986-87 and by 1994, of the total bulk drug production, around 50 per cent was exported,"



SUPERIOR SKILLS: The large talent pool in India contributes to the success of the pharma sector



cadmach

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says Gajaria. "Today almost 80-90 per cent of the total bulk drug production is exported."

The export growth is driven by growing dependence on generics across the world, acceptance of Indian generic drugs, aggressive expansion of Indian companies in international markets and entry of smaller companies into exports. Generics have been the mainstay of the Indian pharma industry. "At this point in time, the India story is a generics, branded generics and active pharmaceutical ingredients (API) story," notes a Sun Pharma spokesperson.

Governments worldwide are under severe pressure to curb the soaring health-care budgets and as a result, are increasingly promoting the shift towards generics consumption. The outlook for the global generics pharmaceutical industry is positive and encouraging. "It is expected that the years 2006-2010 will see a strong global generics market opportunity unfold with an estimated \$60-70 billion worth of branded products expected to go off patent," adds the Ranbaxy spokesperson.

India is well placed to take advantage of this opportunity for various reasons. Indian generics companies are now moving up the value chain and are increasingly focusing on building niche and speciality product portfolios that offer higher and more stable margins.

Also, Indian pharma players have adopted the inorganic route too to attain scale, gain access to new geographies and increase their product portfolios.



MOVING UP THE VALUE CHAIN: Indian generics companies are focusing on building niche product portfolios

Both large as well as small and medium players have chosen to grow through mergers and acquisitions (M&As), targeting companies with strengths in marketing and distribution.

Apart from Europe, which has been the favourite hunting ground for Indian companies, South Africa, Brazil and Thailand too have seen some M&A action involving Indian pharma majors.

Besides, India today has a dominant market share in the total Abbreviated New Drug Application (ANDA) approvals received as well as in the total Drug Master Files (DMF) filings.

India has an edge over China in the

pharma sector as the latter lacks the specialisations required in key areas such as finished formulations. "India is ahead of China in terms of US FDA approved plants today," points out Gajaria of KPMG India. "China lags in the total DMF filings as well. India filed 110 DMFs, nearly thrice that of China's filings in the first half of 2007 itself."

While consolidating their position in the established markets, Indian pharma companies are targeting new markets like the emerging and semi regulated markets that offer better opportunities in terms of profitability than the regulated markets. The US is the largest generics market in

the world and is likely to remain attractive due to the significant patent expiries expected over the next few years.

Among the other regulated markets, Japan and many European markets such as Italy, Belgium, Spain and Germany are emerging as highly remunerative markets on the back of regulatory reforms favouring the use of generics.

Each market has different regulatory requirements and presents different challenges. Japan, the world's second largest pharmaceutical market was valued at \$65.2 billion in 2006. A rapidly ageing population, increasing health-care expenditure and government reforms are likely to aid the growth of generics in Japan.

Semi-regulated markets are also being increasingly viewed as very promising markets. Emerging markets such as South Africa, Brazil and the Latin American nations as well as Russia and the other CIS countries are gaining traction as a result of improved demographics, enhanced health-care infrastructure, increased health-care spending and positive regulatory environments.

Indian pharmaceutical exports to Russia are on an upswing, having more than doubled from about \$150 million in March 2004 to over \$300 million in March 2007. The estimated size of the Russian market (at manufacturer's prices) is about \$ 4.5 billion. Of this, Indian pharma exports enjoy a six to seven per cent share of the Russian market.

"The Russian pharma market continues to grow explosively with growth estimated at over 22 per cent at retail value in the first half of the current fiscal," says Bahadur S. Avari, senior vice-president – international division, J. B. Chemicals & Pharmaceuticals Ltd. "This is on the back of a blistering growth of over 33 per cent in 2005 and over 20 per cent in 2006. With per capita consumption still at less than \$30, the Russian pharma market can only grow higher as disposable incomes continue to rise."

For branded generics, markets that are similar to India, across South East Asia, Africa, Latin America and the Middle East would continue to look attractive. "Breadth of the product range, quick speed to market, alternatives to the innovator product at a sensible price point are features that work in our favour,"



STEPPING UP R&D: Leading Indian players have about 50 molecules under various stages of development

Indian companies will achieve significant success in drug discovery research and could potentially launch about five to 10 drugs in the global market.

explains the Sun Pharma spokesperson.

Generics apart, India today stands at the threshold of opportunities like Contract Manufacturing and Clinical Research. Thanks to the competitive cost advantage, India is the country of choice for global pharmaceutical companies that are outsourcing operations to competitive destinations.

"Contract manufacturing is the new trend," adds the Sun Pharma spokesperson. "Over time, delivery system products should be interesting as well." Clinical research is also an area that promises a bright future. Many MNC pharma companies have made India their research and development (R&D) hub especially for clinical trials.

Besides, leading Indian pharma companies are also stepping up their investments in R&D, which now accounts for as much as seven to nine per cent of their sales. It is estimated that leading Indian players have about 50 molecules under various stages of development.

"It is expected that Indian pharma companies will achieve significant success in drug discovery research and could potentially launch about five to 10 drugs in the global market over the next decade," says the Ranbaxy spokesperson. The company hopes to come out with its first new chemical entity (NCE) molecule by around 2011.

Currently India ranks among the top 20 pharmaceutical exporters in the world. It has a share of around two per cent in

THE EXPORT SAGA

Indian pharma export's success story was first scripted in the early 1970s. Today, industry can confidently say "this is not the end. It is just the beginning."

Ranbaxy's first brush with globalisation was in the early 1970s when the company started exporting to the developing markets of Asia and Africa. Ranbaxy was also among the first Indian companies to set up a plant in Nigeria through a joint venture in the late 1970s. This opened up opportunities in other African countries. In 1982, the company set-up a joint venture in Malaysia and later in Thailand in 1984.

"Even as far back as the late 1980s and the early 1990s, we were acutely aware that 99 per cent of the pharmaceutical market was outside India and therefore internationalising our business made sense," says a Ranbaxy spokesperson. One of the top 10 global generic companies, Ranbaxy is considered an Indian multinational corporation today.

It has a ground presence in 49 countries, sells products in 125 countries, has manufacturing facilities in 11 countries and is present in 23 of the top 25 pharma markets of the world; it has a 12,000 strong staff comprising 50 nationalities.

About 80 per cent of Ranbaxy's \$1.33 billion (2006) turnover comes from its international operations.

Dr Reddy's Laboratories entered the international markets in 1986 with exports of Methyldopa and commenced formulation exports to Russia in 1991. The company has posted consolidated revenues of \$1.62 billion in fiscal year 2007; 86 per cent of this revenue came from geographies outside of India.

the US generics market and around 2.7 per cent in the European generics market. Going forward, India is expected to have a higher market share in the key generics market in the world.

Indian pharma companies have set up ambitious targets for the future. Ranbaxy — one of the top 10 global generics companies at present — for instance, aims to be a \$5 billion company and one of the top five

Of this, 44 per cent came from North America, 23 per cent from Europe, seven per cent from Russia and 12 per cent from rest of the world markets.

Cipla Ltd., India's third largest pharma firm, was the first company in 2001 to radically bring down the price of anti-AIDS triple combination drugs. Cipla reported exports of more than \$450 million for the financial year ended March 31, 2007. JB Chemicals is a leading exporter across the world and also a major player in Russia; it first began exports to the country in the mid-1980s. Of the total sales of about \$135 million in 2006-07, Russia/CIS accounted for about \$55 million, and the balance was from the domestic market and exports to other countries.

JB Chemicals employs about 160 people in its Russian office. *Doktor Mom* range of cough and cold products are the mainstay of JB Chemical's Russia/CIS product portfolio.

Sun Pharma made its first foray abroad, in a modest way, in the early 1990s with branded generics in the neighbouring markets such as Sri Lanka. "We now have over 1,500 active registrations in 30 markets across South East Asia, Russia, China, some countries in Africa, the Middle East and Latin America," says a company spokesperson. "We offer a selection of the same speciality brands that we market in India, across these countries."

Sun Pharma's largest international market is the US, where it is present as a generics company, through its subsidiary Caraco Pharm Labs. Currently international markets account for 43 per cent of Sun Pharma's turnover of \$570 million.

global generics players by 2012. "This will be driven by strong organic growth, well supplemented by acquisitions," adds the spokesperson.

Success is about being at the right place at the right time and Indian companies are enjoying their triumph as the world turns to them to source their pharmaceutical requirements. India, it appears, is all set to become the world's pharmacy. 