





PHARMACY TO THE WORLD

India is emerging as a major global pharmaceuticals hub, attracting international drug giants who are keen to set up research and development (R&D) labs and other facilities here. Domestic pharma majors are also expanding their global presence as drugs worth US\$ 135 billion are going off-patent, presenting tremendous opportunities, says **N B Rao**.

INDIA is fast emerging as the pharmacy to the world, with domestic and international drug producers investing huge sums in setting up manufacturing units, research and development laboratories and other related facilities.

The international pharmaceuticals industry is undergoing dramatic changes, with governments – both in the developed and developing world – focussing on slashing their ballooning healthcare budgets. With a growing number of popular drugs going off-patent over the

coming years, many countries would be opting for generic products that would be available at far lower prices, to save on costs.

IMS Health, the US-based global healthcare information and consulting firm, estimates that during the next five years, products that currently generate an unprecedented US\$ 137 billion in sales are expected to face generic competition. These products include blockbuster drugs (each with annual sales of more than US\$ 1 billion) such as Lipitor (manufactured by Pfizer, one of the largest pharma compa-

'INDIAN PHARMA COMPANIES CAN LOOK FORWARD TO A SIGNIFICANT SPURT IN GROWTH'

An interview with **Kiran Mazumdar-Shaw**, chairman and managing director, Biocon Ltd, India's leading integrated healthcare company.

How do you view the prospects for the Indian pharma sector over the next few years, especially with billions of dollars worth of drugs likely to go off-patent?

Indian pharmaceuticals companies are well-positioned to leverage the opportunity provided by blockbuster drugs going off-patent over the next few years. Not only do Indian pharma players have a US Food and Drug Administration-approved pipeline, but they are also equipped with a strong, cost-effective production ecosystem.

Indian generics manufacturers can make huge gains with the US, the world's largest pharma market, turning to generics to decrease pressure on the healthcare budget costs and the pipeline of new drugs in the US drying up as

the FDA becomes cautious in granting approvals.

Moreover, global companies are adopting cost-cutting strategies to increase margins after the economic meltdown. They are striving to discover and develop drugs at lower costs by embracing outsourcing and contract research, which will help India's price-competitive clinical research and manufacturing activities thrive.

Apart from exports, the domestic consumption of medicines is slated to increase with rising income levels of India's growing middle-class. So, overall Indian pharma companies can look forward to a significant spurt in growth.

Do you see multi-national companies (MNCs) taking advantage of

this trend and setting up research and development (R&D) facilities, manufacturing plants and distribution networks in India?

I see more partnerships and alliances on the generics front like those forged between Pfizer and Aurobindo, Claris and Strides, and GlaxoSmithKline and Dr Reddy's Laboratories. I do not envisage the need for MNCs to set up R&D or manufacturing facilities in India for generics since they already have the marketing infrastructure, which they may use to roll out generics.

Emerging markets such as India are certainly a large generics opportunity which MNCs are keenly eyeing. Collaborative partnerships with Indian companies are a win-win for both parties and give MNCs a cost-effective entry point

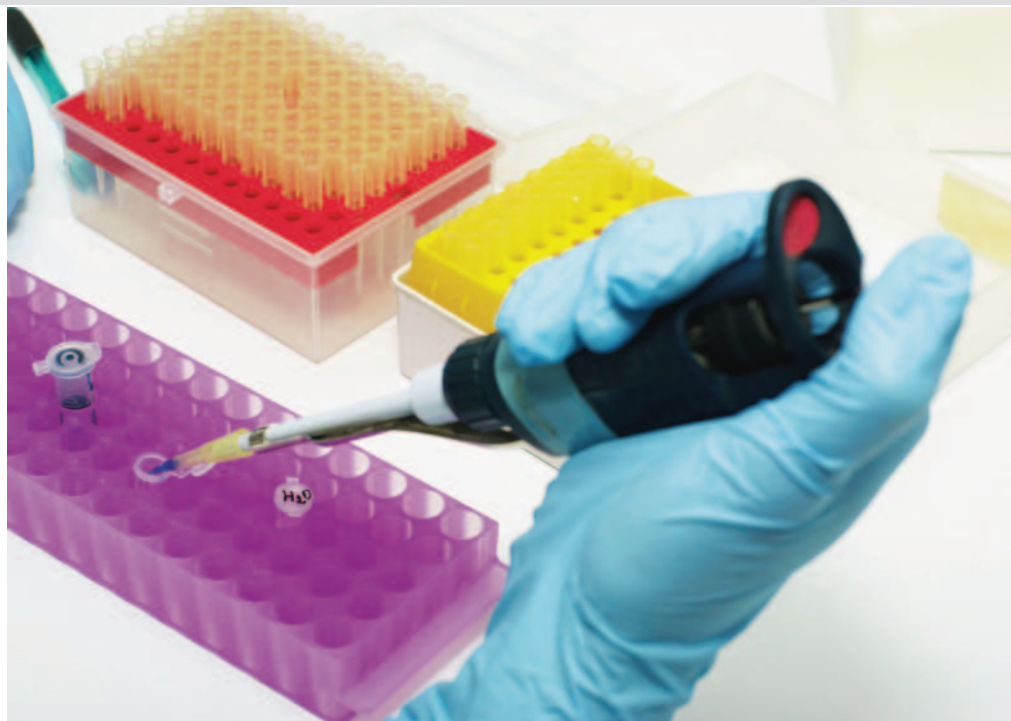
nies in the world), Plavix (Bristol Meyer Squibb, Sanofi-Aventis) and Seretide/ Advair (GlaxoSmithKline – GSK).

Lipitor, the cholesterol-lowering drug, fetched US\$ 12 billion in sales for Pfizer last year, but faces generic competition from 2011. Plavix, an anti-clotting drug – which earned Bristol Meyer Squibb more than US\$ 6.1 billion in sales in 2009 – will lose patent protection in 2012. The drug is being co-marketed by Sanofi-Aventis.

GSK, which earns US\$ 4 billion from its asthma treatment drug, Seretide/Advair, will see its patent expire in 2010.

But non-branded (or generic) drugs are expected to continue strong growth over the coming years. According to IMS data, global prescription sales growth of generic drugs was up by 7.7 per cent for the 12-months ended September 2009, as against 3.6 per cent in 2008.

IMS Health expects the global pharmaceuticals market to grow by four to six



through their existing marketing network.

What about exports of Indian pharma products? Are you bullish about Indian companies expanding their overseas presence?

As I said, Indian pharma exports are going to scale new heights in the next few years. Indian companies already have a substantial presence in the United States, the biggest pharmaceuticals market in the world, and in several European countries.

We also enjoy a favourable presence in emerging markets like Russia, Latin America and Africa, which are also critical for growth. The pharmaceuticals sector has seen increased volume of exports in recent years. Indian companies and their subsidiaries have also secured approvals for several Abbreviated New Drug Applications (ANDAs) in the US.

Do you expect Indian pharma companies to step up their international presence, continuing with acquisitions abroad?

Even as MNCs enter into tie-ups with Indian companies for our domestic market, Indian players are likely to continue expanding their global foot-



Kiran Mazumdar-Shaw

print through mergers and acquisitions (M&As). These acquisitions may not be transformational – instead, they will add to strategic capabilities by helping the player gain intellectual property assets or access to marketing and distribution networks.

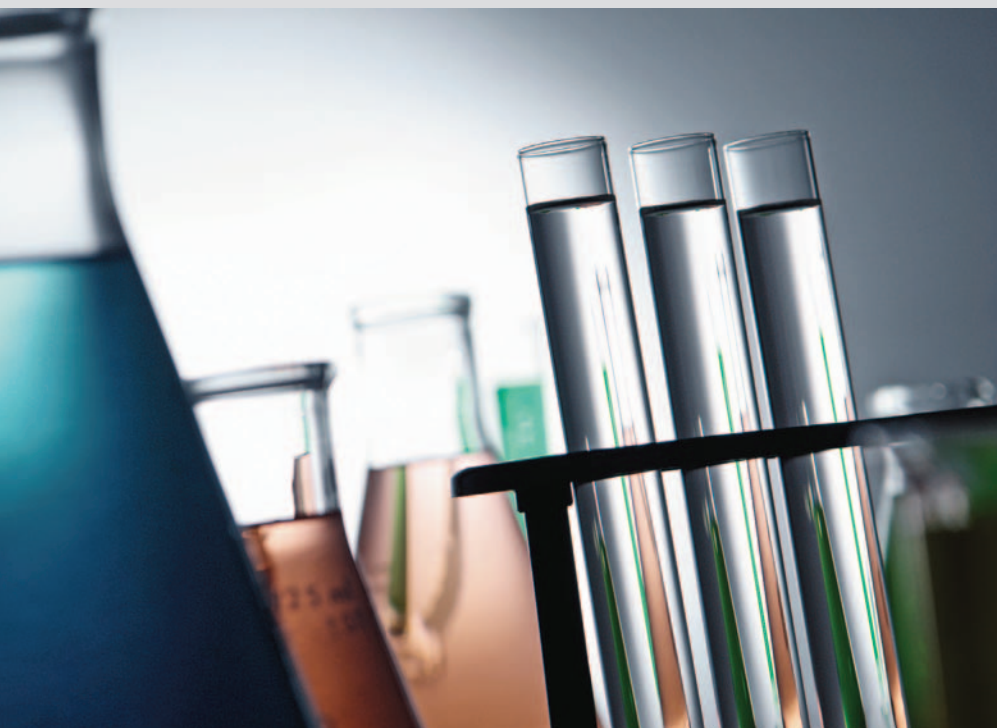
A good example is Biocon's acquisition of our partner, Nobex Corporation, an intellectual property (IP) company in the US. The acquisition provided us a valuable IP platform as well as ownership

of our oral insulin and oral brain-type natriuretic peptide (BNP) programmes for the treatment of cardiovascular disease.

What are the global trends you perceive in the international pharma business? What is the impact of bio-technology likely to be on the sector?

There are four clear trends, which indicate that the industry is recalibrating to the present-day challenges of poor R&D productivity and emerging market opportunities by opting for strategies that involve:

- Portfolio diversification to include products with shorter regulatory timelines. For example, diagnostics, devices, new drug delivery systems, vaccines, generics, bio-similars, etc
- Focusing on emerging markets to deliver top line growth
- Acquisition of late stage R&D assets to fill depleting R&D pipelines with programmes that can accelerate time to market
- Reducing the risk and cost of R&D with new models of risk sharing, co-development programs and outsourced research services.



per cent in 2010, exceeding total sales of US\$ 825 billion. Last year, global generic products accounted for sales of less than US\$ 85 billion.

While generics accounted for just 17 per cent of total sales in the US in 2009, it added up to 72 per cent in terms of volumes, an all-time high.

The US consulting firm predicts global pharma market sales to grow at a four to seven per cent compound annual growth rate (CAGR) through 2013, with the value of the global pharmaceuticals market expected to expand to nearly US\$ 1 trillion in three years.

India features among the seven 'pharmerging' markets – along with the other BRIC nations including Brazil, Russia and China, besides Turkey, South Korea and Mexico – which are expected to drive growth of the global pharmaceutical industry in the coming years.

"The seven pharmerging countries

'INDIA WELL-PLACED TO DEVELOP AFFORDABLE GENERIC PRODUCTS'

Gaurav Khungar, sector head for pharmaceuticals, KPMG, India, dwells on various issues relating to the pharma sector. His views on:

Growth prospects for the sector:

Indian pharma is well-placed to develop affordable generic products for the regulated and semi-regulated markets globally. Indian companies are likely to benefit from a low cost manufacturing base, good understanding of regulatory standards and strong chemistry skills. However, the above applies only to select companies in India who have built a presence in the regulated markets and developed an understanding of IP/regulatory complexities.

MNCs are already taking advantage of the favourable situation in India. This is the underlying reason for growth in Contract Research and Manufacturing (CRAM) and impetus of MNCs to grow in the domestic market.

Overseas expansion plans of the Indian pharma industry:

Indian companies exporting or considering acquisitions are subject to significant regulatory barriers both in the US and European markets on account of manufacturing capability or reference pricing of products.

Indian companies are more likely to enter into alliances with MNCs, starting

by building confidence in the semi-regulated markets, gradually extending to regulated markets for select therapeutic areas. Acquisitions will be opportunistic and not based on a broad based strategy.

Global trends in the pharma industry:

There are some major trends that are evident:

- Indian and emerging markets expected to grow 12 to 15 per cent. Developed markets two to four per cent
- The US continues to present an opportunity over the next five years. It will protect innovation closely. Earlier, patents could not be challenged for five years - this is moving to 12 years for bio-similar products. Additional regulation will pose challenges and higher costs. Settlement between MNCs and generic companies around IP, patents to launch approved generics will be increasingly difficult due to pressure to bring costs down for the end-consumer
- European markets stressed on account of revamp in healthcare, which is in progress. There is a global push to bring the cost of drugs down by all governments. Reference pricing is in place
- Emerging markets: good growth; however, higher currency risk and high debtor cycles causing larger working cap requirements

Bio-technology potential:

Bio-technology is seen as a significant opportunity for generic companies as large bio-technology products are expected to go off-patent over the next five years. However, only select players will try to target this opportunity since it involves complex manufacturing capability, clinical trial costs and potential IP challenges with innovators.





are expected in aggregate to grow by 12 to 14 per cent in 2010, and 13 to 16 per cent over the next five years," says IMS Health's projection for the global pharmaceuticals market.

The four BRIC countries alone are expected to account for eight per cent of the global pharma market by 2011. The absolute value of growth of the seven pharmerging markets will equal that of the top five European markets (Germany, France, Italy, the UK and Spain).

Interestingly, the Indian pharma market is expected to grow at a much faster pace. International consultancy firm, McKinsey & Company, estimates that the domestic market will grow at between 10 and 14 per cent annually, with total revenues topping US\$ 20 billion by 2015.

The overall pharma sector in India – including domestic sales, exports, off-shoring by global firms, contract manufacturing and R&D – is also expected to double to US\$ 40 billion by 2015.

A report by Credit Suisse research projects that Indian generics manufacturers will see annual growth of nearly 20

The industry now produces bulk drugs belonging to all major therapeutic groups requiring complicated manufacturing technologies.

Mr Srikant Kumar Jena,
Minister of State for Chemicals and Fertilizers

per cent over the coming years.

Leading Indian pharmaceutical manufacturers including Cipla Ltd, Dr Reddy's Laboratories, Ranbaxy Labora-

tories Ltd, Sun Pharmaceutical Industries Ltd, Lupin Ltd, Piramal Healthcare, Glenmark Pharmaceuticals Ltd and Jubilant Organosy Ltd are among the companies that are expected to gain significantly because of the switchover to generic drugs over the coming years.

Demand for generic drugs is expected to grow not just in the US, but even in countries such as Japan, Russia and emerging markets in Africa and Latin America.

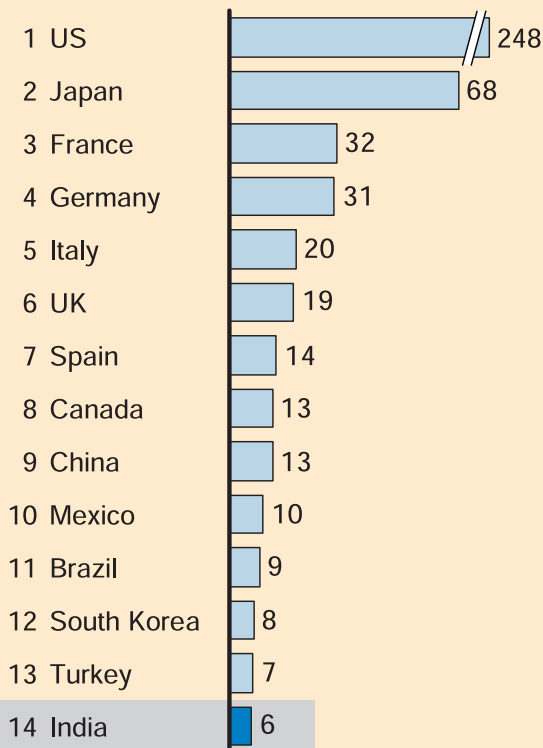
Addressing the eighth Pravasi Bharatiya Divas conference in New Delhi in January 2010, Union Minister for Health and Family Welfare, Mr Ghulam Nabi Azad, also referred to the huge opportunities available for non-resident Indians (NRIs) to invest in the pharmaceuticals sector, especially considering the fact that billions of dollars of drugs were on the verge of going off-patent.

According to Mr Srikant Kumar Jena, the Minister of State for Chemicals and Fertilizers, the Indian pharmaceuticals industry has shown tremendous progress in terms of infrastructure development,

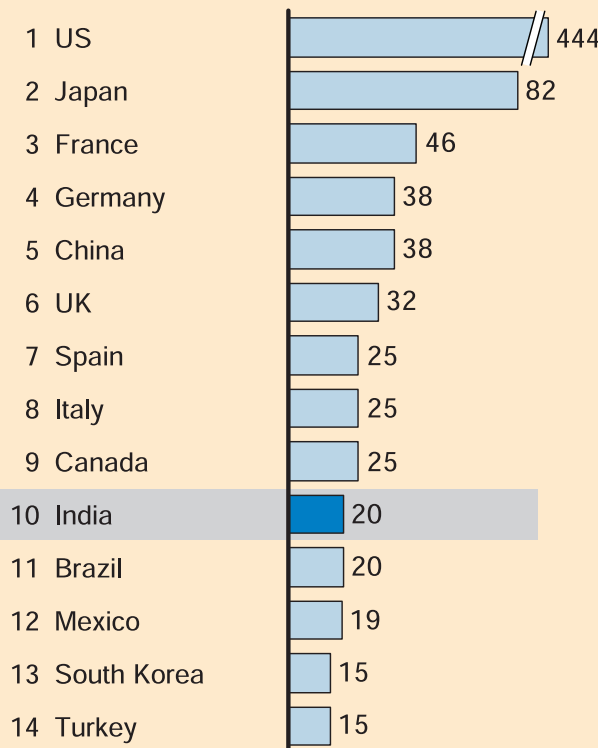
INDIA IS PROJECTED TO BE THE 10TH LARGEST MARKET BY 2015

US\$ billion

Top 14 pharmaceuticals markets, 2005



Top 14 pharmaceuticals markets, 2015



Source: IMS World Review; analyst projections; McKinsey India Pharmaceutical Demand Model

technology base creation and a wide range of products.

“The industry now produces bulk drugs belonging to all major therapeutic groups requiring complicated manufacturing technologies,” he notes. “Formulations in various dosage forms are being produced in good manufacturing practice-compliant (GMP compliant) facilities.”

India now ranks third worldwide by volume of production – accounting for 10 per cent of the world’s production – and 14th by value (1.5 per cent of world production), according to the minister. “Globally, it ranks fourth in terms of generic production and 17th in terms of export value of bulk actives and dosage forms.”

Indian drug manufacturers export their products to more than 200 countries around the globe including regulated markets of the US, western Europe, Japan

**This investment
 further
 strengthens our
 R&D partnership
 network in
 Asia and its
 emerging market
 countries.**

Rod MacKenzie,
 senior vice president, Pfizer Inc.

and Australia.

The growing presence of Indian drug-makers in the US has resulted in the US Food and Drug Administration approving about 175 pharmaceutical manufacturing facilities in India. The US FDA has also opened offices in New Delhi and Mumbai to coordinate its activities in the country.

Indian pharma companies today have a significant and growing presence in the US. In 2009, for instance, of the 483 generic products approved by the US FDA, Indian companies accounted for 138 abbreviated new drug applications (ANDAs).

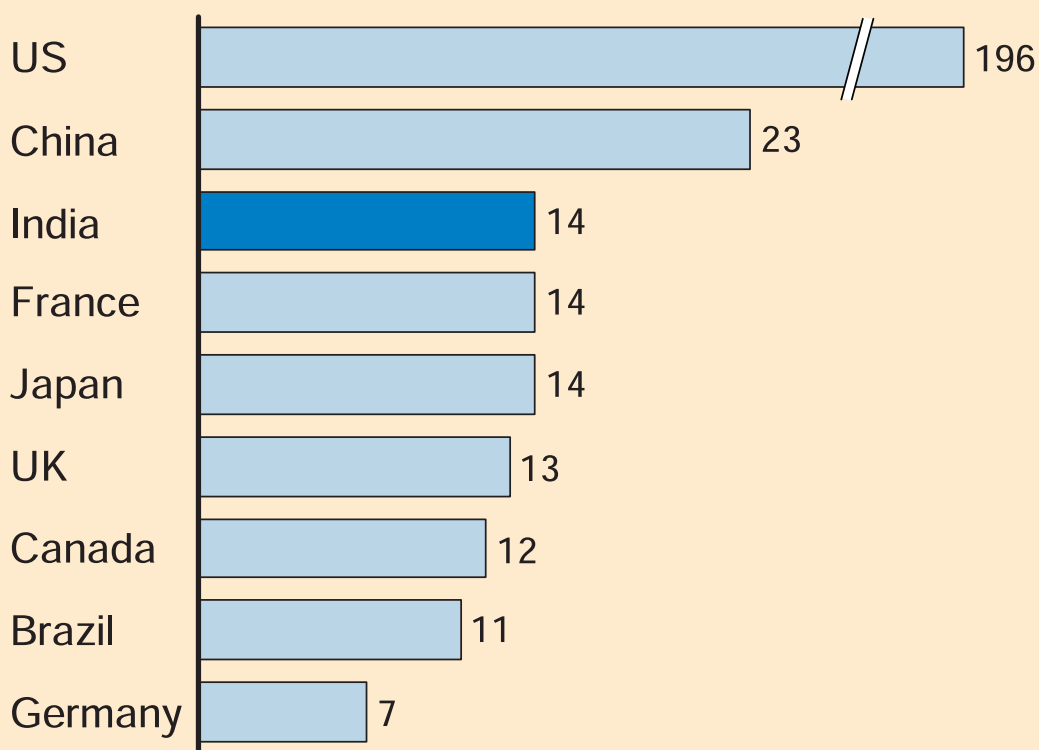
Aurobindo Pharmaceuticals and Dr Reddy’s Laboratories – both Hyderabad-based firms – won about 40 ANDA approvals.

In fact, over the last three years, Indian drug majors accounted for over 400 of the

BY ABSOLUTE GROWTH, INDIA WILL BE AMONG THE TOP 5 MARKETS GLOBALLY DURING 2005 TO 2015

Incremental growth (2005-2015)

US\$ billion



Source: IMS World Review; analyst projections; McKinsey India Pharmaceutical Demand Model

nearly 1,400 approvals granted by the FDA.

International drug companies are also expanding their presence in India, seeking to leverage the R&D skills and the expertise of Indian scientists and technicians. Companies such as Pfizer, Eli Lilly, AstraZeneca and Merck are increasingly seeking collaboration with Indian partners, or carrying out research in the country. With India being a signatory to the Trade-Related Aspects of Intellectual Property Rights-compliant patent regime, international pharmaceutical companies are enhancing their presence, both in the manufacturing and R&D segments.

In January 2010, for instance, Pfizer entered into an exclusive collaboration with TCG Lifesciences Ltd (TCGLS), the clinical research organisation that is part of the Chatterjee Group, to develop a portfolio

Our collaboration with Jubilant has resulted in the identification of promising pre-clinical candidates in important therapeutic areas.

Dr William Chin,
senior vice-president for
discovery and clinical research, Eli Lilly

of pre-clinical molecules for discovery of new drugs. TCGLS will develop the compounds up to the nomination of pre-clinical candidates, encompassing medicinal chemistry, parallel medicinal chemistry, in-vitro absorption, distribution, metabolism and excretion (ADME), in-vivo pharmacology, and preliminary safety and toxicology. Pfizer will own the compounds, and TCGLS will receive research funding and will be eligible to receive research milestone payments as part of the partnership arrangement.

“By combining Pfizer’s scientific leadership and drug discovery experience with TCGLS’ project management and scientific capabilities, we continue to expand our discovery capabilities and increase the likelihood and speed of developing new medicines for patients in need,” points out Rod MacKenzie, senior vice president,

HUGE GROWTH POTENTIAL

THE pharmaceuticals and medical products practice of McKinsey & Company, estimates that India pharma market (domestic) will top the US\$ 20 billion-mark by 2015, up from US\$ 6.3 billion in 2005, implying a compound annual growth rate of 12.3 per cent.



The Indian pharma market is expected to rank among the top-10 in the world, up from the 14th rank in 2005. Importantly, the incremental growth during the 2005-15 decade, of US\$ 14 billion, would propel it to among the top-three, after the US and China.

The McKinsey report identified six trends that are influencing growth of the Indian pharma sector:

- Doubling of disposable incomes and the number of middle-class households
- Expansion of medical infrastructure
- Greater penetration of health insurance
- Rising prevalence of chronic diseases
- Adoption of product patents, and
- Aggressive market penetration driven by relatively smaller companies.

The McKinsey report states that while the therapy mix will gradually move in favour of speciality and super-speciality therapies, mass therapies such as anti-infective and gastrointestinal drugs will continue to comprise half the market by 2015. Generics will continue to dominate, while patent-protected products are likely to constitute 10 per cent of the market.

head of worldwide research, PharmaTherapeutics, Pfizer Inc. "This investment further strengthens our R&D partnership network in Asia and its emerging market countries, which is an important component of our R&D strategy."

According to Swapan Bhattacharya, managing director, TCGLS: "This agreement serves as a testament to our growing capacity and capabilities to provide high-end integrated drug discovery services in the global arena and to align our strategic focus with the goals of our partners."

The company operates three laboratories in Kolkata, Delhi and Pune, employing over 1,000 professionals.

It has also announced a strategic collaboration with ENDO Pharmaceuticals, another American pharma major, to discover novel small molecule drug candidates for the treatment of pain. Working closely with ENDO scientists, the collaboration will focus on an integrated approach involving medicinal chemistry, biology and animal pharmacology capabilities of Chembiotek.

ENDO will have full ownership of the compounds developed under the collabo-

This is a testimony of collaborative efforts of scientists at Lilly and Jubilant and demonstrates the value of this pioneering effort.

Sri Mosur,

ceo and president, global drug discovery and development, Jubilant.

ration with exclusive worldwide rights, and will fund all subsequent drug development and commercialisation activities. It will also provide research funding and make success-based discovery milestones payments to TCG Lifesciences.

Bengaluru-based Jubilant Organosys

Ltd, which has had a four-year research collaboration with Eli Lilly & Company, also got a five-year extension and an expanded portfolio collaboration with the multinational.

Under the terms of the new five-year agreement, Jubilant will receive research funding and success-based discovery and development milestones.

"Our collaboration with Jubilant has resulted in the identification of promising pre-clinical candidates in important therapeutic areas," points out Dr William Chin, senior vice-president for discovery and clinical research, Eli Lilly "We look forward to continuing our joint efforts to discover and develop novel medicines for patients." The two pharma companies also set up a joint venture, Vanthys Pharmaceuticals, for early stage drug development in 2008.

"The extension with Lilly is a testimony of collaborative efforts of scientists at Lilly and Jubilant and demonstrates the value of this pioneering effort in networked R&D and its true impact on global pharmaceuticals industry," explains Sri Mosur, ceo and president, global drug discovery and development, Jubilant. "We also appreciate Lilly's guidance and



support to the partnership and Jubilant's aspiration to become India's most innovative pharmaceutical research and development company, accelerating drug development and enabling affordable patient care worldwide."

Jubilant Organosys is India's largest custom research and manufacturing services (CRAMS) company and a leading drug discovery and development solution provider.

The global market for contract pharmaceutical research is estimated at around US\$ 40 billion, with more than a quarter going towards the drug discovery and development process. The rest is apportioned for clinical trials.

Other international giants including Aventis, Novartis, GSK and Novo Nordisk have also begun clinical trials in India.

India is indeed emerging as a major healthcare market, especially with the rapid roll-out of medical insurance and the proliferation of top-class tertiary-care facilities in many cities. According to a McKinsey study, total consumer spending on healthcare products and services in India grew at a CAGR of 14 per cent between 2000 and 2005.

'The Bird of Gold: The Rise of India's Consumer Markets,' a report by the McKinsey Global Institute, noted that spending on healthcare will witness the highest growth rate among all spending categories over the next 20 years.

Healthcare spending rose from four per cent of average household income in 1995 to seven per cent in 2005 and is projected to grow to 13 per cent by 2025, according to the McKinsey study.

The international consulting firm says six trends will influence growth of the Indian pharmaceuticals market: doubling of disposable incomes and the number of middle-class households; expansion of medical infrastructure; greater penetration of health insurance; rising prevalence of chronic diseases; adoption of product patents; and aggressive market penetration drive by relatively smaller companies.

The healthy growth of the pharmaceuticals sector in India will continue to attract huge investments, both from international and domestic players, over the coming years. And the world will increasingly come to depend on India as a major source for affordable and quality drugs. 🌱

DOMESTIC PHARMA SECTOR UP BY 17 PER CENT

ORG IMS, a joint venture between international major IMS Health and AC Nielsen ORG-MARG, closely monitors the Indian healthcare sector. The research outfit comes out with monthly reports pertaining to the size of the Indian domestic pharma sector, ranks companies in terms of revenues and compiles other relevant information.

According to ORG IMS moving annual total (MAT) data, the domestic pharma market in December 2009 saw year-on-year growth of 17 per cent, adding up to more than US\$ 8.75 billion.

The top five companies accounted for 22.5 per cent of the domestic market. Cipla Ltd was the largest company, with a 5.4 per cent share of the total market. It was followed by Ranbaxy Laboratories (4.9 per cent share), GlaxoSmithKline (4.4 per cent), Piramal Healthcare (4.1 per cent) and Zydus Cadila (3.7 per cent).

The top five products in the domestic market (each with sales of over Rs1 billion and with a market share of 0.3 per cent and 0.5 per cent) included Corex from Pfizer, Voveran from Novartis, Phensedyl from Piramal Healthcare, Augmentin from GlaxoSmithKline and Zifi from FDC Ltd.

Seven Indian companies got approvals from the US FDA for their Abbreviated New Drug Applications (ANDAs). They include Lupin Ltd, Unichem Labs, Torrent Pharmaceuticals, Sun Pharmaceuticals, Matrix Laboratories, Zydus Cadila and Glenmark Generics.