COUNTRY REPORT

India

The economy in India is worth US$1,243bn and growing fast – real GDP reached 9 per cent in the year ending March 2008 (IMF World Economic Outlook Database, October 2009). The pharmaceutical sector, which is the country’s leading science-based industry, makes a significant contribution to this growth, ranking fourteenth in the global league table with sales of approximately US$19bn in March 2009 (Department of Pharmaceuticals, Third Round Up of Developments in the Pharmaceutical Sector, July 2009).

After five years of major expansion in the early 2000s, growth in India’s biotech sector fell from 50 per cent to 20 per cent, according to the Association of Biotech Led Enterprises (ABLE), only to rise again between 2010 and 2011 to 21.5 per cent, breaching the US$4bn mark.

By 2020, the pharmaceutical market is expected to realise its true potential and reach US$55bn, according to India Pharma 2020: Propelling Access and Acceptance, a report from McKinsey & Company; a dramatic rise from US$12.6bn posted in 2009. According to the consultancy group, the pharma sector has the potential to reach US$70bn by 2020 in an aggressive growth market.

HEALTHCARE SYSTEM

India, like many other countries in Asia uses out-of-pocket payments as a financing mechanism for healthcare. Private health insurance cover is limited and just 2-3 per cent of the population has cover; the rest are forced to pay for care at the point of need. There are few alternatives for uninsured people; many prefer to turn to private practitioners, who reportedly cost US$30-US$35, rather than use state-run facilities that have poor infrastructure and limited capacity.

Healthcare provision in India is split between the public and private sectors and heavily polarised both by geography and by ability to pay. Some 75 per cent of public health facilities are concentrated in...
urban areas. Rural communities have little or no access to hospitals or pharmacies, relying instead upon care provided by government-subsidised Primary Health Centres (PHCs).

For almost a decade healthcare provision in India has been a priority for the government and in 2005 the National Rural Health Mission (2005-2012) was launched to improve access to medicines and care in rural communities. In addition, the government pledged to build more hospitals, improve the quality of medical training and increase public spending on health to 2-3 per cent of GDP, from a low of 1 per cent.

Through the 2008-09 Union Budget, the government introduced a five-year tax holiday for establishing hospitals across India. In the 2009-10 budget it allocated US$76m (an increase of US$25m from 2008-09) to establish a new health insurance scheme, under which every worker below the poverty line would receive health cover to the value of US$745.

In the most recent budget (2010-11), coverage was extended through the National Rural Employment Guarantee Act (NREGA) to include another 20 per cent of the population.

The government has been criticised for not doing enough despite its renewed focus on healthcare provision in rural areas, cover for the most vulnerable sections of the population and investment in national programmes, such as those for TB, polio among children and AIDS awareness. Those who can afford it are turning to the private sector for treatment.

**DISEASE BURDEN**

Like many other South Asian countries, India is experiencing a continuous and rapid increase in the incidence of heart disease. In
Pharmaceutical Market Europe
July 2011

fact, it is reported to have the highest burden of acute coronary syndrome in the world and it was estimated that 60 per cent of the world’s heart patients were in India in 2010 (Lancet, 2008 Apr 26;371[9622]: 1435-42). At one time communicable diseases were more prevalent there than non-communicable diseases, but now more patients die from heart disease than infection.

Even more concerning is that it is the younger population with cardiovascular disease, rather than the older population. Cardiovascular diseases, including congestive heart failure, atrial fibrillation, angina and stroke, are driven by increased risk factors, particularly dyslipidemia, hypertension and obesity related to increased adoption of Western lifestyles, affluence and a diet high in carbohydrates.

An estimated 920,000 people in India will have a stroke this year, up from 580,000 in 1996, plus it is estimated that 1.6 million Indians will suffer a stroke in 2030, according to Epi Database (India, Stroke), from Kantar Health. While the incidence as a percentage of the total population is below that of the US, the age distribution of those suffering a stroke is quite different between the two regions. In India, three-quarters of all strokes occur in those younger than 75, while in the US only half of strokes occur in this younger age cohort.

Factoring into this disparity is the fact that average life expectancy for Indians is lower than that of Western patients. The average life expectancy in India is 68 years, which means that the age cohort at greatest risk for stroke in the West, those older than 75, is largely excluded for the population.

Hypertension is a major risk factor for stroke. In 2011 it is estimated that 194 million people, or 26 per cent of India’s population, have hypertension lead to hypertension if preventive steps are not taken, according to the Epi Database (India, Hypertension), from Kantar Health. As with stroke, a much larger percentage of the hypertensive population falls within the younger patient cohorts in India versus Western countries. In India, a quarter of those with hypertension are younger than 40, while in the US only 8 per cent are in the younger age cohort. Likewise, over half of the pre-hypertensive population in India are younger than 40, compared with less than 40 per cent in the US.

“Hypertension is a major risk factor for stroke. In 2011 it is estimated that 194 million people, or 26 per cent of India’s population, have hypertension”

Heart failure is another major cause of hospitalisation. An epidemic of heart failure is feared in the next 20 years in India because of the high prevalence of coronary artery disease and hypertension, according to the article Heart Failure in India, by Anil Kumar (J Cardiac Failure. 2006 Oct;12(8):S157). The age distribution of the population with heart failure follows the same pattern as the other cardiovascular diseases in India: 94 per cent of congestive heart failure patients are younger than 70, compared with 43 per cent in the US, according to Kantar Health’s Epi Database (India, Congestive Heart Failure). Again, India’s shorter life expectancy may affect overall prevalence of congestive heart failure as the older population is simply much smaller than in other parts of the world.

“Hypertension is a major risk factor for stroke. In 2011 it is estimated that 194 million people, or 26 per cent of India’s population, have hypertension”

INDUSTRY LANDSCAPE
The pharmaceutical market in India is highly fragmented, with more than 20,000 registered businesses. Manufacturers in the region produce high-quality, low-cost medicines, mostly in the generics market. There are high levels of aggressive price competition and stringent government controls on the price of treatments on the Essential Medicines List (EML).
The leading 250 pharma companies control 70 per cent of the market with the market leader claiming 7 per cent. Domestic outputs meet around 70 per cent of the country’s demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals and injectables. Imports are estimated at 10-12 per cent, with supplies coming from Switzerland, China, the US, Germany, Italy, Denmark, France and the UK. Imported goods include raw materials and finished products.

The country’s first pharma company, Bengal Chemicals and Pharmaceutical Works, was established in Calcutta in 1930 and is still operating today as one of five government-owned drug manufacturers. The other government-owned companies are Indian Drugs and Pharmaceuticals, Hindustan Antibiotics, Bengal Immunity and Smithstanistreet Pharmaceuticals.

The strongest players in the market represent a mix of domestic and multinational companies including Cipla, Ranbaxy, Sun Pharma, Abbott, Zyds Cadila, Alkem Laboratories, Pfizer, GlaxoSmitKline (GSK) India, Piramal Healthcare and Lupin. Some companies which have entered India recently, like Merck (MSD) and Bristol-Myers Squibb are performing well and look strong for the future. Equally, Pfizer, GSK, Sanofi and Novartis, all of which have introduced an appropriate pricing strategy in India, are maximising opportunities in the marketplace.

“The Drugs and Cosmetics Act, which was passed into law in 1940 ... covers the manufacture, distribution and marketing of pharmaceutical products”

REGULATION

In India, the pharmaceutical industry is not classified under healthcare but under the chemical and fertilisers sector. That is not to say that the industry is not regulated: the Medical Council of India (MCI), a government body, and the Drug Controller General of India (DCGI) have regulatory jurisdiction over pharma companies operating in the region. Both are influential in deciding policies regarding marketing of pharmaceuticals (see Education & Promotion, below).

The MCI is a statutory body with responsibility for establishing and maintaining high standards of medical education and recognition of medical qualifications in India. It registers doctors to practice in order to protect and promote the health and safety of the public by ensuring proper standards in the practice of medicine. DCGI is responsible for approval of licences of specified categories of drugs such as blood and blood products, IV fluids, vaccines and sera.

The Drugs and Cosmetics Act, which was passed into law in 1940 and amended most recently in 2008, covers the manufacture, distribution and marketing of pharmaceutical products.

Under the Act, the regulation of manufacture, sale and distribution of drugs is primarily the concern of state authorities, while the central authorities are responsible for approval of new drugs, clinical trials in the country, laying down the standards for drugs, control over the quality of imported medicines, coordination of the activities of state drug control organisations and providing expert advice with a view to bringing uniformity to the enforcement of the Drugs and Cosmetics Act.

INTERNATIONAL COMPANIES AND THE LAW

The degree to which global pharma companies have been dominant figures in the marketplace has varied significantly in 150 years. From the late 1800s until independence in 1950, multinational corporations loomed large in the market thanks to bias shown to them by the colonial Patent and Designs Act 1911. ‘Between 1947 and 1957, 99 per cent of the 1704 drugs and pharmaceutical patents in India were held by foreign MNCs,’ DP Dubey stated in Globalisation and its Impact on the Indian Pharmaceutical Industry (2008).

The introduction of two public sector bodies, Hindustan Antibiotic and Indian Drugs and Pharmaceutical Limited (IDPL) in 1954 and 1961, respectively, removed this bias. Favouring domestic manufacturers boosted the availability of lower-priced medicines and, as a result, India became self-sufficient in producing drugs.

The landmark reforms announced by the Hathi Committee under the Drug Policy 1978 pledged to make drugs widely available at low cost. However, many elements of the policy could not be implemented and in 1986 the Drug Policy was revise to include the following objectives:

- To ensure abundant availability of reasonably priced, essential life-saving drugs
- To strengthen quality control in drug production
- To promote the rational use of drugs
- To create an environment conducive to channelling new investment, encouraging cost-effective production and introducing new technologies
- To strengthen indigenous capabilities.

“The Patent Bill was first debated in Parliament in 1967 ... and came into force in 1972. It favoured domestic companies by removing the patent rights that multinationals had previously enjoyed”

PATENT ACT 1970

The Patent Bill was first debated in Parliament in 1967, ratified in 1970 and came into force in 1972. It favoured domestic companies by removing the patent rights that multinationals had previously enjoyed. The act did not support product patents on medicines, agricultural products or atomic energy. The act removed composition patents and, although process patents remained, they were valid for just five to seven years.

The lack of patent protection made the Indian market undesirable and untenable for multinational companies and they left the region, a move that enabled domestic producers to flourish. They carved a niche in both the domestic and world markets with their expertise in reverse-engineering and new processes for manufacturing medicines at low costs. Although some of the larger companies have taken small steps towards drug innovation, the industry as a whole has been following this business model up to the present day.

The Patent Act was amended in 1995 and 2000, but it was not until 2005 that it was finally amended to include product patents for pharmaceuticals, signalling a resurgence in multinational interest.
EDUCATION AND PROMOTION

There is a set protocol on how companies must market drugs, with two methods, one ethical and the other for OTC products. Most prescription medicines are ethically promoted and the government does not allow product advertising (The Drugs and Magic Remedies Act 1954).

Reps still meet face-to-face with doctors and promote product brands, often leaving free samples and gift bags. However, there are restrictions on the types of gifts that pharma companies can offer doctors. In line with moves in other countries, including the UK and the US, India is expected to strengthen restrictions surrounding gifts in an attempt to encourage, if not force, companies to focus on providing scientific and educational materials and present the benefits of a treatment in improving patient outcomes and quality of life.

All brands are marketed to the medical organisations through continuing medical education (CME), sponsorship of conferences and research papers. However, the use of social media is almost non-existent. Access to the internet is limited and despite social media being seen as something of a time-saving channel in the West, many doctors in India are simply too busy to log on for information, preferring instead the traditional personal selling approach. The internet and social media channels are still mostly considered as, and used for, entertainment, not as business tools, and there is still some way to go before pharma companies start using these channels to promote drugs.

MARKET ACCESS

Establishing a foothold in India is not without its challenges. In its report Global Pharma Looks to India: Prospects for Growth, PwC suggests two potential routes to access. The first centres on the increasing in-country expertise in biotechnology, bioinformatics and clinical testing. By shifting R&D and clinical trials to India, companies can form collaborations and achieve cost savings, all without compromising intellectual property. The second approach focuses on collaborative networks across the value chain – from sourcing and manufacturing to marketing and distribution – that would enable companies with a broad portfolio to bring new products to India. However, to maximise this approach, companies would still need to adopt competitive pricing strategies.

“A report estimates that at least 60 million Indians ... can already afford to buy Western medicines. However ... companies will need to adopt aggressive pricing strategies”

A report by Deutsche Bank (India’s Pharmaceutical Industry on Course for Globalisation, April 2008) estimates that at least 60 million Indians – a market equal in size to the UK – can already afford to buy Western medicines. However, in order to gain access to greater patient numbers and unlock the forecasted potential of the market, companies will need to adopt aggressive pricing strategies to be competitive in this price-sensitive environment.

Regulatory authorities in India are very sensitive to pricing and for many companies adopting differential pricing will be key to their access strategy. Within this they will need to evaluate access to medicines, look at volume-based pricing and consider per capita income increases in the coming years to arrive at a price palatable to the authorities.

There is already evidence of multinationals taking this type of approach to pricing in India; Merck & Co is using differential pricing for diabetes treatment Januvia, setting the price at US$1 per dose – a mere fraction of the price in the US (S. Harachand, India-specific Pricing Bucks Trend, ContractPharma, August 2008). Domestic manufacturers, such as Biocon, have also adopted similar pricing strategies.

GAINING ENTRY THROUGH OTC

The over-the-counter (OTC) market in India, in stark contrast to the domestically dominated generics market, is comparatively undeveloped. It represents an opportunity for multinationals to increase their presence and build brand awareness at the same time.

With the government facing budgetary constraints and patients used to paying for the majority of their medicinal products, it is likely that access to OTC products will continue to improve and the market will expand.

According to PwC, the OTC market was worth US$1.8bn in 2009 and Biocon has predicted that the market will grow 18 per cent each year, to reach US$3bn in 2012. The government is now discussing plans to increase the list of drugs that can be sold outside pharmacies, a move that would significantly boost the potential of the OTC market.

“In 2006, through its draft pharmaceutical policy, the government made attempts to expand the scope of essential drugs, a move that met with fierce industry opposition”

PRICING

India’s federal government currently mandates price controls on drugs on the Essential Medicines List (EML) and has been subject to intense criticism in recent years (Journal of Pharmacology & Pharmacotherapeutics, July-December 2010, Volume 1, Issue 2) for failing to update the list in line with World Health Organisation recommendations, which suggest revision every two years.

Despite evidence to suggest that the EML has improved availability of medicines, helped reduce prices and improved product safety, the government and the Ministry of Health and Family Welfare have not revised the list for seven years. The government has also been criticised for its ‘lack of attention to detail, disregard for the exacting finer points of medicine and indifference to the potential harmful consequences the mistakes in the list could generate’, according to the Journal of Pharmacology & Pharmacotherapeutics (July-December 2010, Volume 1, Issue 2). This has prompted fears that mistakes in the EML, which is used for procurement, to inform formularies and as a reimbursement list for insurance purposes, could have numerous negative implications, including patients being denied reimbursement.

The National Pharmaceutical Pricing Authority (NPPA) controls the pricing of some drugs through the Drugs Price Control Order (DPCO). In 1979 there were 347 price-controlled drugs. This was reduced to 143 in 1987 and currently covers 74 bulk drugs, including high-consumption products such as antibiotics.

In 2006, through its draft pharmaceutical policy, the government made attempts to expand the scope of essential drugs, a move that met with fierce opposition from the industry, which argued that such a move would compromise R&D activities in India and discourage
companies from investing in new drugs. Companies are free to decide the prices of other drugs not on the EML. However, this ‘pricing freedom’ is somewhat meaningless, given that the Drug Control General Office, to which companies must submit relevant documents, bio-equivalence studies and a recommended or requested price, approves products for use based on price. Once a product has been approved, the manufacturers can begin manufacturing.

The NPPA monitors prices and legislation states that companies cannot increase the prices of the products by more than a certain percentage in a given timeframe. Any price increases must be negotiated.

**RESEARCH & DEVELOPMENT**

Until now, India’s drug discovery process has been almost non-existent mainly due to cost and capacity; many companies do not have money or expertise to take a molecule to phase III trials. The country has suffered something of a brain drain in recent years too: many of India’s top-flight scientists choose to be educated in US, with a significant number seeking employment there when they graduate. There are signs, however, of a shift in this trend thanks to increased outsourcing of research and clinical trials by multinationals and emphasis on collaboration (see Market Access, above) in R&D and across the value chain.

Collaborations are likely to focus on developing treatments in oncology, CVD, diabetes and HIV, along with major developments in drug delivery systems.

**SUPPLY CHAIN**

There are a large number of distributors in the market, with around 18,000 linked to 300,000-400,000 pharmacies. The supply chain is fairly regulated but requires investment to improve distribution at a local level.

It is littered with stops and product passes through a number of different hands between leaving the production facility and arriving at its final destination. It is hoped that the introduction of Goods and Services Tax (GST) will encourage streamlining as companies look to reduce costs by cutting out the numerous ‘middle men’. According to DHL, there are more than 1,000 carrying and forwarding agents across the country that supply about 6,000 stockists, serving about 550,000 pharmacies and 20,000 hospitals. A majority of pharmacies are independent companies, with 90 per cent being members of the All India Organisation of Chemists and Druggists (AIOCD).

High margins (ranging between 18 and 22 per cent) at the pharmacy level have led to an increase in companies shipping product direct to the patient, reducing their financial burden. More expensive drugs, such as oncology treatments, are commonly delivered directly to the patient.

**THE FUTURE**

There is no doubt that the Indian market is an attractive proposition and one that multinationals cannot afford to ignore. According to PwC’s report Global Pharma Looks to India: Prospects for Growth: ‘The country, many predict, will be the most populous in the world by 2050. India will make its mark as a growing market, potential competitor or partner in manufacturing and R&D, and as a location for clinical trials.’

The opportunities are tremendous thanks to the rising socioeconomic status of the population. The increase in the number of high earners is likely to open a potential $1tn market by 2015 for companies selling expensive drugs, according to a report by Ernst & Young, Compelling Reasons for Doing Clinical Research in India.

India has a long-established democracy, a solid legal framework and strong financial markets. It has an established international industry and business community, a good network of world-class educational institutions and established strength in information technology.

**The Authors**

Clare Bates, editorial director at PMGroup, wrote this report with content from Liz Wells, deputy editor of PM, who interviewed Gauri Pathak, general manager, Kantar Health India and Swati Shankar (left), senior project director, Kantar Health India.

David Robinson (right), vice president, Epidemiology Services, Kantar Health, supplied the piece on Disease Burden.

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**TOP 10 PHARMACEUTICAL COMPANIES IN INDIA**

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<th>Rank</th>
<th>Company</th>
<th>Revenue 2007 (Rs crore)</th>
<th>Revenue 2007 (Rs billion)</th>
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<tr>
<td>1</td>
<td>Ranbaxy Laboratories</td>
<td>4,198.96</td>
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<td>Dr Reddy’s Laboratories</td>
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<td>3</td>
<td>Cipla</td>
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<td>4</td>
<td>Sun Pharmaceutical</td>
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<td>Lupin Ltd</td>
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Source: various