Confederation of Indian Industry

CII Southern Region

Industry and Economic Update

Pharmaceuticals & Biotechnology

October-December 2009

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INDUSTRY PROFILE

Pharmaceuticals and Biotechnology Industry in India

The Indian pharmaceutical industry has emerged as a key science based industry in the last four decades. At Rs. 680 billion, the industry is estimated to contribute around 1% to the total GDP. Typically spread across the western and central regions of the country, the industry is now emerging as a key growth sector for several southern states. Apart from increased ease of doing business in terms of policies and infrastructural facilities provided by the state governments, factors that have helped the spread include existing strength in organic chemicals synthesis and process engineering, low cost manufacturing base, presence of educational institutions and trained personnel, development of technology oriented facilities, use of cost effective technologies, and adoption good manufacturing practices in compliance with international standards.

The industry manufactures a range of products from chemicals, active pharmaceutical ingredients (API), bulk drugs and formulations to vaccines, tablets, capsules, orals and injectibles. The range of medicines s has also increased over the years to include medicines for headaches, antibiotics, complex cardiac compounds, therapeutic medicines for oncology, human immunodeficiency virus (HIV)/acquired immunity deficiency syndrome (AIDS), and lifestyle diseases including arthritis and diabetes. Most of these had to be imported earlier. The biotechnology industry is primarily based in the southern region and is highly technology dependent. While vaccines are the key products as of now, this industry is fast emerging as a key sector with research and development thrust on producing high value therapeutic drugs and contract manufacturing.

The pharmaceuticals market is highly fragmented with about 24,000 units. Of these, there are about 300 large units and around 8,000 small scale units, which form the bulk of the industry. These units produce about 350 bulk drugs and related formulations. Also, there is severe price competition in drugs not falling under the government's Drug Price Control Order, 1995 (DPCO) list. The DPCO list covers 74 bulk drugs in the cure segments including analgesics and antipyretics, anti-asthamatic, antibiotics, anti-diabetic, anti-dysentery, anti-histamines, anti-malarial, cardiovascular drugs, corticosteroids, diuretics, gastrointestinal medications, vitamins and anti-bacterial drugs whose prices are fixed by the central government's National Pharmaceuticals Pricing Authority (NPPA). Since many of these drugs relate to common diseases in the domestic market, industry profitability is severely restricted in the domestic market, thereby adding to the price competition in the decontrolled drug categories, also monitored by the NPPA.

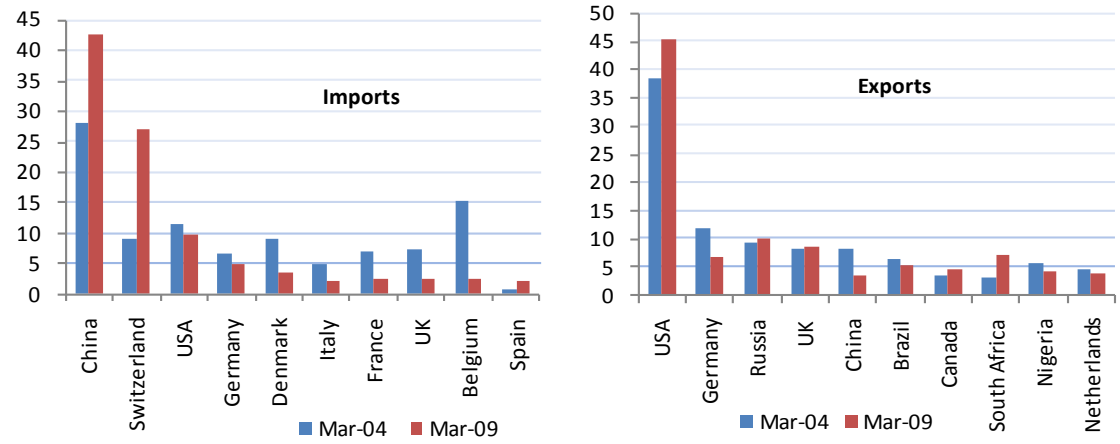
Progressive de-licensing of the pharmaceutical industry since the 1990s has resulted in removing industrial licensing for most of the drugs and pharmaceutical products. Manufacturers are free to produce any drug approved by the Drug Control Authority. Foreign direct investment (FDI) of 100% has been allowed since 2001. The total FDI inflow to the sector since 2000 has been about Rs. 65.95 billion, which is about 1.67% of the total FDI inflows in all industrial sectors. The inflow was about Rs. 11 billion each in 2007 and 2008 and about Rs. 1.48 billion during the first three months of 2009.

India adopted changes in its patent regime in January 2005 to include product patents, thus complying with the World Trade Organization's Trade Related Aspects of Intellectual Property (WTO-TRIPS)

agreement. This change in the intellectual property norms has prompted many companies to realign their strategies towards innovative research programs. The drug policies have been revised to accommodate new developments in the fast developing sector. The currently applicable Pharmaceuticals Policy, 2002, replaced the Drug Policy, 1986. A new Pharmaceuticals Policy, 2006, is on the anvil but is yet to be passed by the union government because of severe opposition from the industry on issues like inclusion of 354 drugs under the DPCO list and others that could affect the industry adversely. New developments like the growth of contract manufacturing and increased outsourcing of clinical trials by international companies also need to be provided for in the new policy.

Country-wise Drugs & Medicines Exports & Imports as Percentage of Total

(%)



Source: CMIE, IMaCS Research

Drugs and pharmaceuticals exports account for over 40% of industry sales. It is important to note that despite slowdown in exports in the other sectors, drugs and pharmaceuticals industry is expected to maintain its 3% share in total exports in FY2010 as it has done in FY2009. The global advantage of the industry arises from factors like a competent work force, proven track record in cost effective chemical synthesis, a well established legal framework, growth of information technology sector and a general acceptance of the principles of globalisation. Although Europe and accounts for a large share of the overseas drugs and medicines markets, many Indian companies have diversified their international market base in the recent years by starting marketing or manufacturing facilities in other regions like Asia, CIS and Russia, and Africa.

The biotechnology sector in India is at a nascent stage and hence has a small but growing contribution to the economy. Many Indian biotechnology firms started by targeting the vaccine market for which there is significant local expertise and limited competition from foreign players. These firms continue to leverage revenue from the sale of vaccines to develop more innovative products including vaccines, therapeutics and drug administering technologies. There is expertise and efficiency in the sector, which is recognized globally, but that has to be sustained with innovation, performance standards, and by converting the knowledge into products. The sector has particular use in developing therapeutic medicines for both domestic as well as international healthcare markets, improving agricultural products, preventing environmental degradation by industrial processes using chemicals and increasing the use of genetics in the animal husbandry sector and genomics. The Department of

Biotechnology, functioning under the Ministry of Science & Technology has formulated The National Biotechnology Development Strategy, 2007.

The Indian oncology market is estimated to be about Rs. 4 billion with an annual growth rate of 30%. India, China and the USA account for 30% of the total global diabetic population. In India, the growth rate is estimated to be more than 5% per annum between year 2000 and 2030. Vaccines are one of the fastest growing markets in India and estimated to be around Rs. 40 billion with 65% exports market. The market for hepatitis-B virus vaccine is expected to grow to ten times more between 2007 and 2012. Biotechnology firms are working on a range of vaccines against virus including hepatitis, measles, diphtheria, pertussis and tetanus, cholera, human rabies, Japanese encephalitis, meningitis, malaria, rotavirus, tuberculosis and HIV. Cardiovascular diseases kill an estimated 1.9 million people, annually. The global market is estimated to be about Rs. 90 billion.

The average research and development (R&D) expenditure of Indian pharmaceuticals companies in low at 5% of total revenue as compared to about 15% internationally. Domestic market for drugs is predominantly in the traditional therapeutic segments as compared to growing lifestyle segment in the developed countries. The new patent regime and requirement of plant approvals by several domestic and international authorities acts as a barrier to entry. Distribution is affected by competition in large number of drugs in similar categories and regional concentrations are high. Distributors generally push generic drugs to earn higher margins.

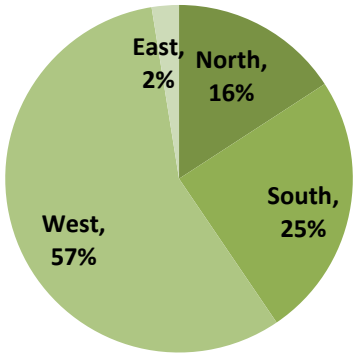
Future challenges to the pharmaceuticals and biotechnology industry include development of a research base for manufacturing new products developed indigenously, countering domestic and international competition either through use of sophisticated technology or through consolidation, maintaining its low cost and good manufacturing practices advantages to counter international competition in the generic drugs market and increasing profitability of their overseas operations.

Drugs, Pharmaceuticals & Biotechnology Market in South India

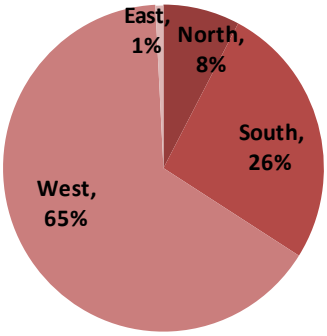
Of the 24,000 companies operating in India in the drugs, pharmaceuticals and biotechnology sector, there are about 300 companies in the organised sector. The leading 200 manufacturers control over 75% of the market. Of the 160 companies tracked, about 25% have their registered office in the southern region. Most companies of the south were set up in the last 25-28 years.

Together, these companies account for 25% of the gross sales and 41% of revenue in foreign exchange earned by the sector. The cumulative share of the southern companies in the total industry gross block is about 34%. Companies may have plants in locations other than in the south and also manufacturers registered in the other regions may have plants located in the southern states. The average return on capital employed by companies registered in the south is about 18% as compared to 16.8% for the overall industry. The average debt to equity is close to one as compared to industry average of 1.70.

Regional Distribution of Companies
(%)



Distribution by Sales
(%)



Source: Capitaline, IMaCS Research

Some of the established pharmaceutical and biotechnology firms in the southern region include Divis Laboratories, Krebs Biochem, Aurobindo Pharma, Dr. Reddy's Laboratories, Natco Pharma, Indian Immunological, Biocon, Shasun Chemicals, Orchid Chemicals, and Arvind Remedies.

Selected Company Profiles of Southern States

Company	Major Segment	State	Sales H1FY09 (Rs million)	Gross margin H1FY09 (%)	Sales H1FY10 (Rs million)	Gross margin H1FY10 (%)
Arvind Remedies	Formulations	Tamil Nadu	1,080.8	8.7	1,351.8	10.5
Aurobindo Pharma	Bulk drugs & formulations	Andhra Pradesh	13,330.5	17.3	16,093.1	24.1
Biocon	Biotechnology	Karnataka	4,678.8	23.7	5,349.4	30.5
Divis Lab	Bulk drugs	Andhra Pradesh	5,972.9	47.0	4,256.4	74.1
Dr Reddy's Labs	Bulk drugs & formulations	Andhra Pradesh	20,440.0	22.7	23,298.5	28.0
Hindustan Bio Science	Biotechnology	Andhra Pradesh	12.3	-	23.8	11.8
Jupiter Bioscience	Biotechnology	Karnataka	20.5	6.8	39.6	17.2
Natco Pharma	Bulk drugs & formulations	Andhra Pradesh	1,187.0	29.0	1,368.1	30.5
Orchid Chemicals	Bulk drugs	Tamil Nadu	6,216.9	7.8	6,106.6	23.8
Shasun Chemicals	Bulk drugs	Tamil Nadu	2,257.7	-0.9	2,478.7	10.0

Source: Capitaline, IMaCS Research

Company Profiles – South India

Arvind Remedies

Established in 1988, Arvind Remedies was set up to manufacture and market both allopathic and ayurvedic pharmaceutical products. The company has its manufacturing facility and R&D centre at Chennai. This factory manufactures pharmaceutical products in various dosages, like tablets, capsules, liquids, ointments, creams, suspensions, dry syrups, ayurvedic and herbal medicines. Formulations include analgesic, anti-inflamatory, anti-infective, anti-oxidant, anti-rheumatic, anti-spasmodic, haematinic, cough expectorant, nasal decongestant, nutritional supplements and vitamins. Current research focus of the company is on formulations and novel drug delivery systems in diabetology, cardiology and nephrology, nutraceuticals and anti infective segments. The domestic market primarily consists of defense establishments, employees' state insurance corporation, central government

health scheme, central and state government institutions, public sector companies, post and telegraph, railways and World Bank sponsored projects. International markets include Africa, Commonwealth of Independent States and Asia. Arvind Remedies has commenced the process of registering its products in several countries including Malaysia, Tanzania, Sri Lanka, Ukraine, Nigeria and Nepal. It plans to set up a second state-of-the art manufacturing facility which will measure up to the requirements of United States Food and Drug Administration (USFDA), United Kingdom Medical Control Agency (UKMCA) and Australian's Therapeutic Goods Administration (TGA) standards. Plans are also there to identify and tie up with foreign companies for introduction of new products as well as manufacturing and co-marketing. The stock is listed in exchanges of Mumbai, Ahmedabad and Chennai.

Aurobindo Pharma

Established in 1986, Aurobindo Pharma commenced operations in 1988-89 with a unit manufacturing semi-synthetic penicillins at Pondicherry. The company is the market leader in this product and has presence in therapeutic segments like cephalosporins, antivirals, central nervous system (CNS), cardio-vascular, anti-allergic, anti-diabetic and gastroenterology. It has competence in bulk actives and has entered the high margin speciality generic formulations segment. The company has five units for APIs and four units for formulations that are designed for the regulated markets. The units have approvals from USFDA, the Medicines and Healthcare Products Regulatory Agency of UK (UKMHRA), the World Health Organisation (WHO), the Medicines Control Council of South Africa (MCC-SA), and Agencia Nacional de Vigilancia Sanitaria, Brazil (ANVISA-Brazil) for both APIs and formulations. The product portfolio consists of over 250 finished dosage formulations and 200 APIs in therapeutic areas such as anti-allergic, anti-diabetic, anti-emetic, anti-fungal, anti-malarial, anti-obesity, anti-pyretic, anti-retroviral, anti-viral, antibiotic, cardiovascular, CNS, GI-tract, histamine, lifestyle, osteoporotic, over the counter (OTC) products, pain management, respiratory, urology, and organic intermediates. Aurobindo has overseas marketing offices located in Ethiopia, Tanzania, Kenya, Uganda, Ghana, Italy, Vietnam and the UK. The company is listed on Mumbai and National Stock exchanges.

Biocon

Established in 1978, Biocon is arguably the first Indian biotechnology firm of India. Apart from bio-pharmaceuticals and biological, the company established custom and clinical research services to international pharmaceutical and biotechnology firms through subsidiary companies, Syngene and Clinigene. It has a fully integrated business model spanning pre-clinical discovery to clinical development and through to commercialization. The company's original strengths lie in statins while it has now commercialized insulin, immuno-suppressants and a range of biogenerics. Current research focus of the company are in two collaborative projects for the development of novel medicine, including oral insulin and T1h. Biocon has a USFDA approved facility in Bangalore to manufacture of lovastatin, a cholesterol-lowering molecule. Its proprietary bioreactor, the PlaFractor™ has received a US patent. It full product range includes b**io-pharmaceutical APIs** for anti-diabetes, anti-Inflammatory, anti-oxidants, cardiovascular, anti-obesity, digestive-aid enzymes, anti-hypertensive, haemostatic, hepato-protective, immune-suppressants, gastro-intestinal, and nutraceuticals; biologicals like insulin, streptokinase, monoclonal antibodies; and branded formulations for o**ncology, nephrology, cardiology, and diabetology. The company is listed on the Mumbai and National Stock exchanges and has representative offices in** Abu Dhabi, London and New Jersey.

Divi's Laboratories

Established in 1990, Divi's Laboratories focussed on developing new processes for the production of APIs and intermediates for generics. It has manufacturing facilities at Hyderabad and Visakhapatnam. The Visakhapatnam plant has seven multi-purpose production blocks. Both the Hyderabad and Visakhapatnam comply with current good manufacturing practices (cGMP) guidelines and have been inspected by USFDA. Divi's also undertakes contract research on process development for discovering new compounds for MNCs across the world and has partnered with them for the supply of APIs. Divi's competencies are in manufacture of protected amino acids, the protecting reagents themselves, peptide condensing agents, totally synthetic, natural and novel unnatural amino-acids and oligopeptides; stereo selective synthesis using chiral ligands, high yield resolutions using chirally active resolving agents, recovery of resolving agents and ligands, recycling of undesirable isomers, resolutions involving enzymes and manufacture of novel ligands like binol and binap; and multistep total synthesis of important carotenoids like Betacarotene, Lycopene, Astaxanthin, and Canthaxanthi. The company has submitted drug master files to USFDA for over 25 compounds, The European Directorate for the Quality of Medicines (EDQM) for 10, European drug master file for 40, and with Health Canada, Korea FDA, China SDA, Japan Pharmaceuticals Medical Devices Agency (PMDA) and Health Protection Branch (HPB) Canada for over 15 compounds. The company has marketing offices in New Jersey and Switzerland. Its stock is listed on the Bombay and National Stock exchanges.

Dr. Reddy's Laboratories

Established in 1984, Dr. Reddy's Laboratories is listed on the Bombay, National and New York stock exchanges. It is a fully integrated pharmaceutical company with USFDA approved manufacturing facilities in India, UK and Mexico. The company manufactures APIs, custom pharmaceuticals, generics, formulations and biopharmaceuticals. Dr. Reddy's is one of the few pharmaceuticals companies that have dedicated biotechnology facilities also. The company manufactures more than 140 APIs and has 20 products under development. Branded generics include over 200 products in therapeutic areas of gastro-intestinal, cardiovascular, pain management, oncology, anti-infective, paediatric and dermatology. The company's new chemical entity (NCE) research areas include metabolic disorders, cardiovascular, anti-infective and inflammation. Dr. Reddy's key markets include India, US, Venezuela, Romania and Russia and CIS countries. It has offices located in Russia, Brazil, Dubai, Malaysia, Johannesburg and China. Dr. Reddy's entered into a 10-year agreement with Rheoscience A/S of Denmark for the joint development and commercialization of Balaglitazone, a molecule for the treatment of Type-II diabetes. Rheoscience holds this product's marketing rights for the European Union and China. It has several other such tie ups including a marketing agreement with Eurodrug Laboratories, a pharmaceutical company based in the Netherlands, for improving its product portfolio for respiratory diseases. The biologics development centre has dedicated development and manufacturing suites for both E.coli and mammalian cell culture. The company has developed a generic biopharmaceuticals, filgrastim, a cancer drug that stimulates bone marrow to replace white blood cells lost due to chemotherapy, in-house from the molecular biology phase up to commercial manufacturing.

Hindustan Bio Sciences

Established in 2001, Hindustan Bio Sciences is based in Hyderabad and is a relatively new entrant to the biopharmaceutical industry. The aim is to provide treatment of life threatening diseases at affordable cost. It has been active is identifying Recombinant DNA (RDNA) based biopharmaceutical products for marketing in India. The company has outsourced the manufacturing activity and is setting up a research and development facility for developing the RDNA based biopharmaceuticals. The

company has finalized a technical consultation tie-up with the Centre for Cellular and Molecular Biology. Hindustan Bio Sciences has obtained the approval of Genetic Engineering Approval Committee for import and marketing of Recombinant Human Erythropoietin from China. The protocol submitted by the company to conduct clinical trials has been approved by the Drug Controller General of India and ethics committees of concerned Hospitals. The company is in the process of conducting phase III clinical trials since March 2005. It has entered into a memorandum of understanding with Shenyang Sunshine Pharmaceutical Company, China, for custom manufacture of Interleukin-2 and Interferon alpha 2A for marketing in the domestic market.

Jupiter Bioscience

Established in 1985, Jupiter Bioscience has manufacturing facilities located at Bidar in Karnataka, and Cheriyal, Kazipally and Cherlapally in Andhra Pradesh. These facilities manufacture speciality and fine chemicals, drug intermediates, active pharmaceutical ingredients (API), peptide re-agents, coupling re-agents, protected amino-acids, raw materials and custom peptides. It has offices at Secunderabad, US, Japan and Switzerland. The company's competency is synthesis of peptides. The company's stocks are listed on the Bombay and National stock exchanges. It has a strategic alliance with Ranbaxy for APIs and formulations. In 2008, Jupiter acquired a manufacturing facility in Switzerland. Current research focus of the company is targeted towards peptide chemistry, chiral chemistry, biotechnology and organic chemistry. Its key products are APIs for human use, drug intermediates and fine chemicals, biopharmaceuticals, generic peptide APIs, non-peptide generic APIs, peptide and DNA micro arrays, enzymes, formulations and rapid diagnostic kits.

Matrix Laboratories

Matrix Laboratories started operations in 2002. The company manufactures APIs and solid oral dosage forms. Matrix Labs has manufacturing facilities at four locations in and around Hyderabad and Visakhapatnam. The solid oral dosage facility is located near Nasik. All facilities are USFDA approved. In 2005, Matrix acquired controlling stake in Concord Biotech, an Ahmedabad-based biotechnology company, with fermentation and bio-catalytic technology capabilities and USFDA approved API manufacturing facilities and controlling stake in Docpharma of Belgium. In 2003, Matrix Labs signed an agreement with the Clinton Foundation for the supply of antiretroviral for the treatment of HIV and AIDS patients in Sub-Saharan Africa, South Africa and the Caribbean countries. In contract research, the company offers its capabilities to global companies engaged in full-scale drug discovery, development and commercialization of new molecular entities. Its product portfolio includes anti-bacterial, CNS agents, anti histamine, anti-asthamatic, cardiovascular, anti viral, anti diabetic, anti fungal, proton pump inhibitors and pain management. The company is listed on Bombay and National stock exchanges.

Natco Pharma

Established in 1981, NATCO Pharma started operations in Andhra Pradesh with production of an anti-anginal drug. The company now has competency in cardiovascular, anti-cold, anti-asthmatic and antibiotic segments. NATCO claims to have pioneered the time release technology in India. It manufactures products on contract for other companies like Ranbaxy, Dr. Reddy's Labs and John Wyeth. It has a parental manufacturing facility at Nagarjunasagar, a bulk drug manufacturing and research centre, a USFDA and TGA approved intermediates facility at Mekaguda, and a speciality formulations facility at Kothur. It has US patent for manufacturing Omeprazole and has launched anti-cancer drug developed in-house. Other branded products include antibiotics, anti-malarial, amoebicides, analgesics, anti-pyretic, peripheral vasodilators, anti-anginal, anti-hypertensive, anti-

asthmatic, tranquilizers, anti-depressant, oncological, anti-emetic, anti-anaemic, nutritional supplement, bio-technology based drug forms and health products of natural origin.

Orchid Chemicals & Pharmaceuticals

Established in 1992 as a 100% export oriented unit, Orchid Chemicals & Pharmaceuticals is today an integrated pharmaceutical company with core competencies in the development and manufacture of APIs, finished dosage forms and in drug discovery. The company has two manufacturing sites for APIs at Alathur and at Aurangabad, and three manufacturing sites for dosage forms at Irungattukottai and Alathur near Chennai. Orchid's facilities have international regulatory approvals including USFDA and UKMHRA. It has a joint venture in China for manufacturing sterile APIs. It has offices in South Africa, Japan, China, Russia, London, South America and US. The company has long-term exclusive marketing alliances with global companies such as Apotex, Actavis, Dava and Hospira for distribution of its products in the US and Europe. For drug discovery, it has subsidiary research laboratories at Chennai and the US. Orchid's APIs include oral cephalosporins, sterile cephalosporins, sterile veterinary cephalosporins, non cephalosporins – betalactams, speciality nutraceutical and dietary ingredients. Formulations include anti-infective, anti-inflamatory, anti-oxidants, anti-ulcer, cardiovascular, nutraceuticals and oral anti-diabetic drugs. The stock is listed on exchanges at Mumbai, Madras, Luxemborg and Singapore.

Shasun Chemicals and Drugs

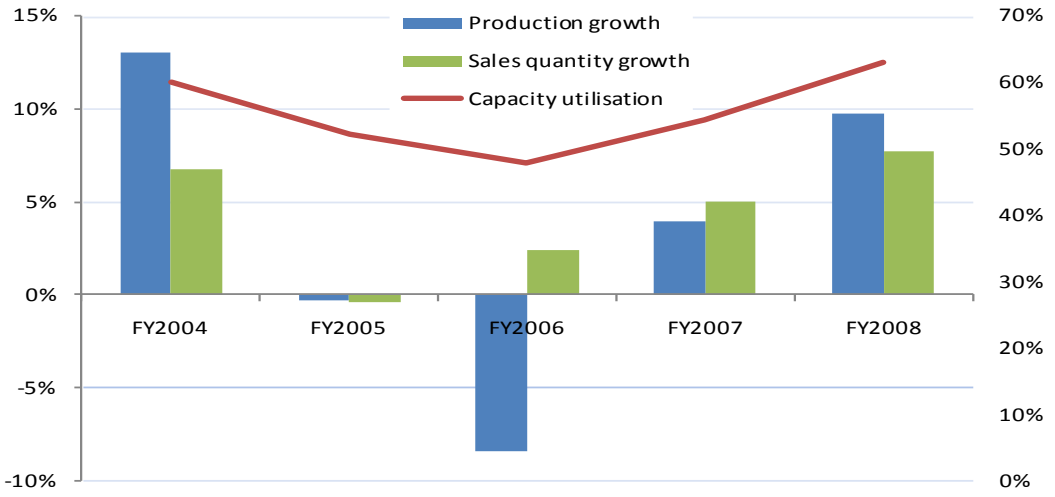
Shasun Chemicals was incorporated in 1976 at Chennai. It manufactures APIs, intermediates and enteric coating excipients. Shasun is one of the largest producers of Ibuprofen worldwide. Other key products are Ranitidine and Nizatidine. Its products are exported to countries across North America, Europe, Asia and Latin America. Shaun has a API and formulations manufacturing facility Puducherry, a multi-product facility at Cuddalore, a biotech facility at Velacherry. The formulations plant at Puducherry is USFDA approved. The company is strengthening its offer of contract research, custom synthesis, contract manufacturing and contract formulation services. The company is setting up a multipurpose and multi-product contract manufacturing facility at the special economic zone of Pharma-city, Visakhapatnam. It has recently added finished formulations capability as forward integration, and has invested in large facility to cater to the international regulated market. It has tied up with multinational companies in the formulations space for developing and supplying products for the US market. The recent acquisition of the business and facilities of Rhodia Pharma Solutions by Shasun's wholly owned subsidiary Shasun Pharma Solutions, UK, is intended to evolve as a technology based service provider. The company is listed on Bombay and National stock exchanges.

Trends in Production and Sales – Southern Region

A look at 39 companies involved in the drugs and pharmaceuticals manufacturing with registered offices in the southern region indicates that while Karnataka has a strong biotechnology industry, Tamil Nadu and Pondicherry have companies producing mainly formulations although there are some bulk drug manufacturers too. Andhra Pradesh, the leading manufacturer among all southern states, has companies in all the three segments – bulk drugs, formulations and biotechnology. Kerala has a strong Ayurveda products base but the presence of pharmaceuticals industry in the state is small and limited to plants of companies headquartered elsewhere.

Average Production and Sales Growth – Bulk Drugs & Intermediates

(%)



Source: Capitaline, IMaCS Research

Average production growth trends in bulk drugs and intermediates, by far the largest segment, indicate a steady recovery in FY2008 after negative growth in FY2006. Average capacity utilisations have also improved from about 50% during FY2006 to 63% during FY2008. However, unlike FY2007 where sales volume growth was higher than production growth, in FY2008 sales growth lagged production growth lower drug releases as well as exchange rate fluctuations were two main reasons for this lag. An economic slowdown overseas also helped the Indian manufacturers exporting generic drugs because of price competitiveness.

A further slowing down of western economies, rupee depreciation in the recent months, increased demand for cheaper generic drugs, and outbreak of swine flu in April 2009 are some of the reasons that continue to help the Indian pharmaceuticals industry. In general, both the drugs & pharmaceuticals segment and the biotechnology segment are fairly non-cyclical with growing demand. However, factors like local government policies, mergers and divestments, legal delays and irregular product pipelines can be disrupt production and sales in a particular state.

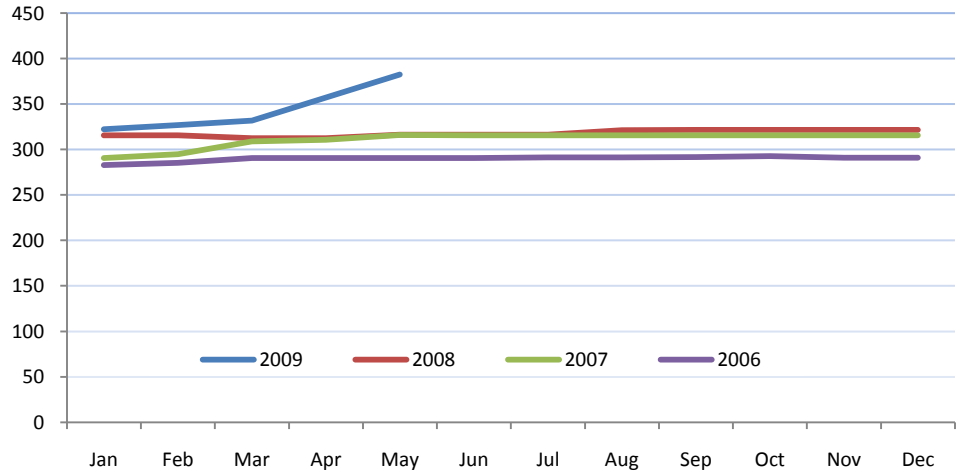
Pricing Trends

Drugs and pharmaceutical pricing for the medicines included in the DPCO list is determined by the NPPA. The usual method is to provide for an annual escalation on costs, set the retail and wholesale distribution margins, which along with taxes and duties result in a retail price. Conversion, packaging and packing materials account for over 20% of the production cost. The retail and wholesale margins are generally fixed at about 16% and 8%, respectively, of the total cost. The central excise duty for most bulk drugs are at 4% and for formulations at 8%. In the overall pricing scenario the difference in taxation between tax free zones and the non-tax free zones has eroded over the years because of lower duties and cenvat credit facilities.

However in drugs that are not on the DPCO list there is little regulation on prices and the variation among producers as well as different demand centres may be high. This is because of unregulated distribution margins that may be as high as 400-500% for some commonly sold drugs. As a result, while there is severe price competition between manufacturers of similar drugs, the retail prices tend to be high because of the margins paid to the distributors. Also, retail pricing can be pushed upwards by changing the composition of drugs slightly to provide some value addition. However, such differentiation does not last long as competition catches up. Although it is difficult to assess drugs prices in different regional markets, the monthly whole sale price index (WPI) on drugs and medicines indicates a steady rise in prices since 2004 and a comparatively steeper rise since March 2009.

WPI – Drugs & Medicines

(%)

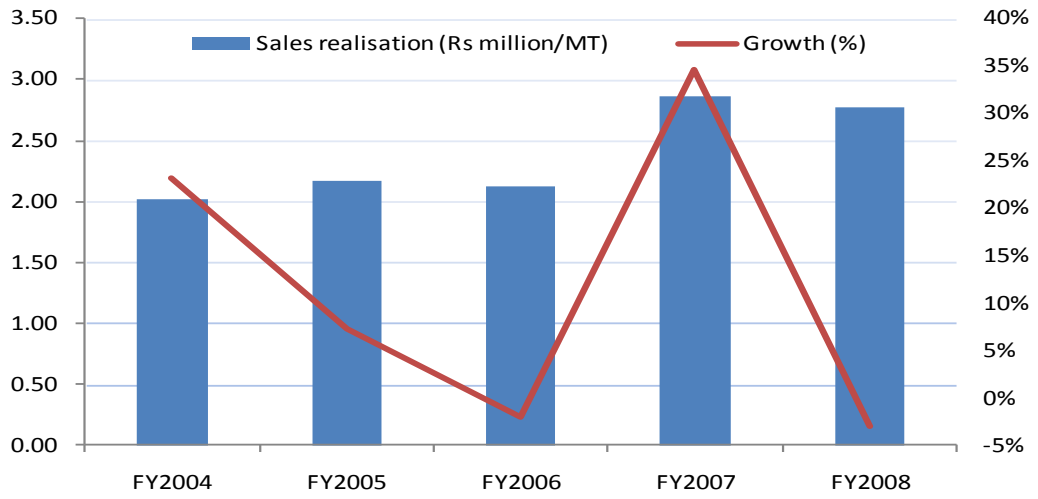


Source: Ministry of Statistics and Programme Implementation

Taking sales realisations on bulk drugs and intermediates as an indicator of factory price trends over the five years to FY2008, it is observed that realisations were slightly lower during FY2008 as compared to the previous year although much higher than that in FY2004-06. Slowdown in realisations even as WPI increased during FY2008, again point towards severe competition in a fragmented market on the one hand and high margins on the other. The other factor was a fall in sales of multinational companies in FY2008. Sales fell because of lower low number of new product launches, trade related issues, and divestments.

Sales Realisations from Bulk Drugs and Intermediates – Southern Companies

(Rs million/MT)



Source: Capitaline, IMaCS Research

NPPA's Retail Pricing Formula

The retail price of a formulation shall be calculated by the Government in accordance with the following formula namely:

R.P. = (M.C. + C.C. + P.M. + P.C.) x (1 + MAPE/100) + ED

"R.P." is retail price;

"M.C." is material cost and includes the cost of drugs and other pharmaceutical aids used including overages, if any, plus process loss thereon specified as a norm from time to time by notification in the Official Gazette in this behalf;

"C.C." is conversion cost worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf;

"P.M." is cost of the packing material used in the packing of concerned formulation, including process loss, and shall be fixed as a norm every year by, notification in the Official Gazette in this behalf;

"P.C." is packing charges worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf;

"MAPE" (Maximum Allowable Post-manufacturing Expenses) represents all costs incurred by a manufacturer from the stage of ex-factory cost to retailing and includes trade margin and margin for

the manufacturer and it shall not exceed one hundred per cent for indigenously manufactured Scheduled formulations;

"E.D." is excise duty: Provided that in the case of an imported formulation, the landed cost shall form the basis for fixing its price along with such margin to cover selling and distribution expenses including interest and importer's profit which shall not exceed fifty percent of the landed cost.

"Landed cost" is cost of formulation import including customs duty and clearing charges.

Investment Trends

There are 22 projects under construction across India that are expected to be completed by March 2010. The projects together have a cost of Rs. 23,846 million. Increasingly new projects or research and development (R&D) centres are being constructed in special economic zones (SEZ) announced by various states to attract foreign investments. The location of such projects in SEZs provides benefits like infrastructural support in terms of buildings, information technology, power supply and such facilities as also tax and duty benefits because of being free trade zones. Southern states have also special zones to attract investment from this sector.

State wise investments announcements in pharmaceuticals and biotechnology indicate that there are many projects under construction or being planned with total project cost of, at least, Rs. 45,613 million. As of December 2009, Andhra Pradesh had the maximum number of projects under construction with mostly Indian private investors developing facilities for bulk drugs, formulations, R&D centres, bio-pharmaceuticals, vaccines, and active pharmaceutical ingredients.

Investments in Pharmaceuticals and Biotechnology Industry – Southern States

Project name	Promoter	Cost (Rs million)	Implementation stage	Location
Andhra Pradesh				
R&D Centre	Sigma-Aldrich Corp.	1,250.0	Deferred	Hyderabad
Formulations (JN Pharma city)	Sai Adventium Pharma	600.0	Deferred	Visakhapatnam
Lab-cum-Production Complex (ICICI Knowledge park)	Sigma-Aldrich Corp.	360.0	Deferred	Hyderabad
Bulk Drugs (Thangadapally) - Expansion	Discovery Intermediates	70.0	Deferred	Nalgonda
Bulk Drugs (Thukkapuram)	Denisco Chemicals	40.0	Deferred	Nalgonda
R&D Centre (Hyderabad)	Honeywell Technology Solutions		Deferred	Hyderabad
Formulations (JN Pharma city)	Aurobindo Pharma		Deferred	Visakhapatnam
Bio-technology (Hyderabad)	Avestha Gengraine Technologies		Deferred	Hyderabad
R&D Centre (Cherlapally)	Zyden Gentec		Deferred	Ranga Reddy
API (Pharma city)	Shasun Chemicals & Drugs		Deferred	Visakhapatnam
Formulations (Choutuppal)	Vivimed Labs		Nascent	Hyderabad
Biotech Facility (Orissa)	SPC Biotech	5,000.0	Planning	Warrangal

Project name	Promoter	Cost (Rs million)	Implementation stage	Location
Bulk Drugs (Pharma city)	Suven Life Sciences	1,000.0	Planning	Visakhapatnam
Biological Containment Lab-IV	Centre for Cellular & Molecular Biology	1,000.0	Planning	Hyderabad
R&D Centre (Pashamylaram)	MSN Laboratories	300.0	Planning	Medak
Technology Development Centre (Hyderabad)	Sai Adventive	250.0	Planning	Hyderabad
Injections (Andhra Pradesh)	Sven Genetech	80.0	Planning	Andhra Pradesh
Bulk Drugs (Veliminedu)	Elbs Pharma	80.0	Planning	Nalgonda
Bulk Drugs (Brahmanakodur)	People's Biological Drugs	40.0	Planning	Guntur
Bulk Drugs (Dnagaram) - Modernisation	Yegna Manojavam Drugs & Chemicals		Planning	Nalgonda
Vaccine & Formulations Facility (Karkapatla)	Indian Immunologicals		Planning	Hyderabad
Bulk Drugs (JN Pharma city)	Vaya Jayanthi Drugs		Planning	Visakhapatnam
Bulk Drugs (Tupakulagudem)	Vensar Laboratories		Planning	West Godavari
Red Cross - NMDC Centre (Andhra Pradesh)	NMDC		Planning	Andhra Pradesh
Bulk Drugs (Parawada)	Granules		Planning	Visakhapatnam
Chemical Substances (Kongavanipalem)	Divi's Laboratories		Planning	Vijayanagaram
Bulk Drugs (Nalgonda)	SPICA Laboratories	20.0	Stalled	Nalgonda
Bulk Drugs (Visakhapatnam)	Esai Pharmatechnology & Manufacturing	5,000.0	Execution	Visakhapatnam
Formulations (Polepalli)	Aurobindo Pharma	1,800.0	Execution	Mahaboob Nagar
Bulk Drugs (Khazipally)- Expansion	Jupiter Biosciences	939.0	Execution	Medak
Bulk Drugs (Nakapally)	Hetero Drugs	800.0	Execution	Visakhapatnam
Allopathic Pharmaceuticals (Nellore)	Vinkem Labs	720.0	Execution	Nellore
Bio-Pharmaceuticals (Shamirpet)	Pochiraju Industries	600.0	Execution	Hyderabad
API (Vishakhapatnam)	Anu's Laboratories	550.9	Execution	Visakhapatnam
Formulations (Mulugu)	Globion India	420.0	Execution	Medak
Biotechnology (Genome Valley)	Celestial Labs	400.0	Execution	Hyderabad
Allopathic Pharmaceuticals (Jedherla)	Lessa Life Sciences	400.0	Execution	Mahaboob Nagar
API (Kandivalsa)	SMS Pharmaceuticals	400.0	Execution	Vijayanagaram
R & D Centre (Pashamylaram)	MSN Laboratories	350.0	Execution	Medak

Project name	Promoter	Cost (Rs million)	Implementation stage	Location
Biotech Cephalosporin (Medak)	Maanya Biotech	320.0	Execution	Medak
Bio-Pharmaceutical ingredients (Turkapally)	Saamya Biotech	280.8	Execution	Ranga Reddy
Bio-Technology Incubator	Indian Institute of Chemical Technology	270.0	Execution	Ranga Reddy
Biological Fermentation (Ongole)	J C Biotech	250.0	Execution	Prakasam
Bulk Granules (Visakhapatnam)	Lee Pharma	250.0	Execution	Visakhapatnam
Pharmaceuticals (Chandrapadiya) - Expansion	Nutra Specialities	200.0	Execution	Nellore
Formulations (Dommarpochampally)	Mars Therapeutics & Chemicals	200.0	Execution	Ranga Reddy
Vaccines (Pashamylaram) - Expansion	Brilliant Bio Pharma	200.0	Execution	Medak
API (Nalgonda)	Mantena Laboratories	180.0	Execution	Nalgonda
Formulations (Velimineduu)	Chinamilli Drugs	150.0	Execution	Nalgonda
Clinical Research Centre (Uppal)	Centre for Cellular & Molecular Biology	110.0	Execution	Hyderabad
Allopathic Pharmaceuticals (Parawada)	Stilbene Biopharma	100.0	Execution	Visakhapatnam
Bulk Drugs (Medak)	Bajaj Organics	30.0	Execution	Medak
R&D Centre (SP Biotech park)	Issar Pharmaceuticals	-	Execution	Hyderabad
Formulation (JN Pharma City)	Emmennar Bio Tech	-	Execution	Hyderabad
Injectables (Pashamylaram)	Trident Life Sciences	-	Execution	Medak
Formulations (Nemaragomula)	Dano Vaccines & Biologicals	-	Execution	Nalgonda
R&D Centre (Ranga Reddy)	Passura Lifescience	-	Execution	Ranga Reddy
API (Parawada)	Avra Laboratories	-	Execution	Visakhapatnam
API (Parawada)	Alkali Metals	-	Execution	Visakhapatnam
API (Sedipet)	Arch Pharmalabs	-	Execution	Hyderabad
Karnataka				
Formulations (Bidadi)	Himalaya Drug Co.	1,650.0	Deferred	Bangalore
Surgical Products (Kanakapura)	Pradeep Surgical Dressings	50.0	Nascent	Bangalore
Bulk Drugs (Vasantha)	Anugraha Chemicals	-	Nascent	Tumkur
Formulations (Nelamangala)	Kemwell Biopharma	3,000.0	Planning	Bangalore
Oral Formulation (Belgaum)	HLL Lifecare	300.0	Planning	Belgaum
Ayurvedic Medicines (Kasaba)	Ayurpark Health Care	173.0	Planning	Kolar
Formulations (Tumkur)	Kaseb Healthcare Pvt. Ltd.	170.0	Planning	Tumkur

Project name	Promoter	Cost (Rs million)	Implementation stage	Location
Herbal Extraction & Research Centre (Thandya)	Siddartha Medical Educational Research & Cultural Trust	80.0	Planning	Mysore
API (Dobbospet)	Bio-Gen Extracts	50.0	Planning	Bangalore
R & D Centre (Bangalore)	Avestha Gengraine Technologies	-	Planning	Bangalore
Enzyme & Neutraceutical Formulation (Malur)	Richcore India	-	Planning	Bangalore
Formulations (Hassan)	Medreich	-	Planning	Hassan
Herbal Extraction (Hassan)	Sami Labs	-	Planning	Hassan
Bulk Drugs & Intermediates (Hassan)	Arvee Chem Pharma	-	Planning	Hassan
Liquid Formulation Unit (Dobaspet)	Tejkamal Pharmaceuticals	-	Planning	Bangalore
Allopathic Pharmaceuticals (Anekal)	Micro Labs	1,000.0	Execution	Bangalore
Formulations (Tumkur)	Himalaya Drug Co.	400.0	Execution	Tumkur
Pharmaceutical Liquids (Dobaspet)	Tejkamal Pharmaceuticals	100.0	Execution	Bangalore
Formulations (Hassan)	Kaseb Healthcare	80.0	Execution	Hassan
Ayurvedic Formulation (Hassan) - Expansion	Pentacare Ayur Pharma	40.0	Execution	Hassan
Bulk Drugs (Karnataka)	Shilpa Medicare	-	Execution	Karnataka
Bulk Drugs (Jigani)	Intermed Labs	-	Execution	Bangalore
Intermediates & Bulk Drugs (Mysore)	Arvee Chem Pharma	-	Execution	Mysore
Bio-Formulations (Mysore)	Sun Formulations	-	Execution	Mysore
Tamil Nadu and Puducherry				
Capsules (Irungattukottai)	Arvind Remedies	2,500.0	Planning	Kancheepuram
Vaccines (Chinglepet) - Phase I	HLL Lifecare	2,500.0	Planning	Chennai
Formulations (Siruseri)	Xechem International	1,000.0	Stalled	Kancheepuram
R & D Centre (Siruseri)	Xechem International	500.0	Stalled	Kancheepuram
Formulations (Chennai)	Medopharma	-	Stalled	Chennai
R&D Centre (Red Hills)	Bafna Pharmaceuticals	-	Execution	Chennai
Vaccine (Coonoor)	Pasteur Institute of India	-	Execution	Nilgiris
Kerala				
Nano Tech City (Thiruvananthapuram)	Government of Kerala	-	Planning	Thiruvananthapuram
Chitin Based Glucosamine (Alappuzha)	Kerala State Co-operative Federation for Fisheries	-	Planning	Alappuzha
Formulations (Mavelikkara)	Agstya Biopharma	3,000.0	Execution	Alappuzha
Formulations (Chandra Nagar)	Agstya Biopharma		Execution	Palakkad

Project name	Promoter	Cost (Rs million)	Implementation stage	Location
		2,010.0		
Formulations (Palakkad)	Agastya Biopharm	2,000.0	Execution	Palakkad

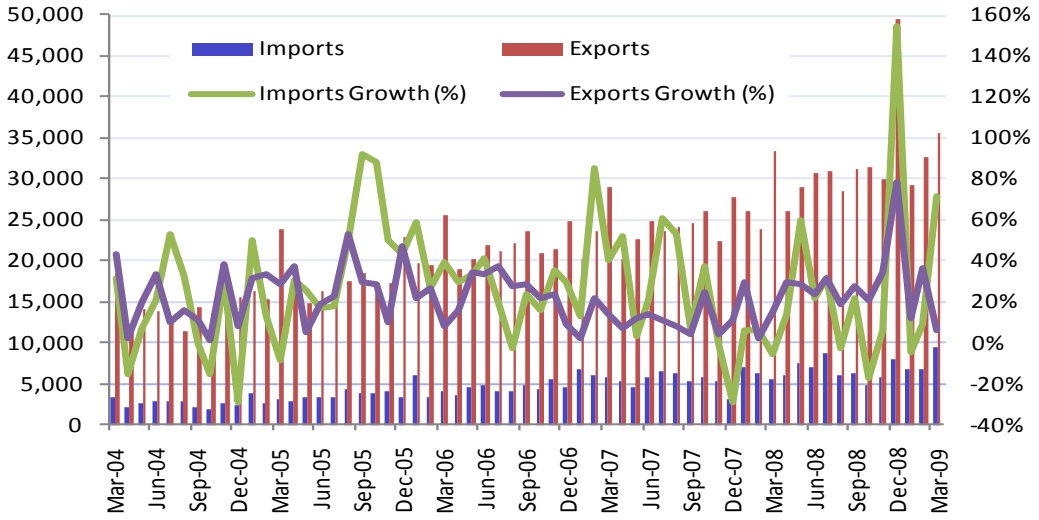
Source: Projects Today, IMaCS Research

RECENT DEVELOPMENTS

Production of bulk drugs grew 10% at Rs. 152.04 billion and formulations were up 22% at Rs. 667.96 billion. Despite recent slowdown in exports in the other segments, pharmaceuticals products exports were robust in FY2009. On an average, the exports were at about 2.88% of total exports during FY2009 as compared to 2.55% in FY2008.

Drugs & Medicines Exports

(%)



Source: CMIE, IMaCS Research

The US healthcare bill, which has been passed by the US House of Representatives and is awaiting nod from the Senate holds a lot of promise for generic drug manufacturers from India. With emphasis on increasing the coverage and reducing healthcare costs, the bill is going to provide a big fillip to the usage of low-cost generic drugs. Besides, the bill seeks to bring an additional 40 million US citizens under medical insurance coverage. This will open up a big market for generic drug makers. Even for the existing population under insurance coverage, there is likely to be a shift in the usage from patented to generic drugs.

Indian pharma companies — most of them being exporters of generic drugs and intermediates to the US, the world's largest drug market — are going to gain by passing of this bill. While the impact is long term in the form of increase in procurement of generic drugs by the US, it is nevertheless a positive

sign. One other major aspect of the bill, which is likely to be important for Indian pharma companies, is the provision in the bill on bio-similars.

The bill has provided for a data exclusivity protection period of 12 years for biologics innovator companies. This is much longer than the period of five years, provided by the US government in case of chemical drugs. This provision, while throwing some light on the pathway to launch bio-similars in the US, will slow down the long-term growth of bio-similars in the US.

However, the good news is that this would not impact the immediate pipeline of Indian biotech players. Most biologic drugs were developed between 2000 and 2004 in the US. Indian companies, which are developing bio-similars for these biologics, will just be ready with their products by 2016 — the time when the 12-year protection period ends for the biologics in the US. However, Indian companies may have to go slow on future product development in bio-similars.

While the potential of drugs going off patent was high in the US markets, the economic slowdown has resulted in significant pricing pressures, especially in new molecules facing patent expiry with more than 10 players launching their generic versions on the first day of patent expiry. The price erosion on the base business remained stable and volumes largely drove growth in the US generics market.

The government may make it compulsory for all hospitals and medical institutions to report adverse drug reactions to keep a stringent check on the quality and efficacy of drugs sold in the country. About 12,000 adverse drug reactions have been reported in the country in the past three years, according to official estimates. The ministry has also asked the Medical Council of India (MCI) to approve only those medical colleges that have a pharmaco-vigilance centre.

Stricter penalty under the amended Drugs and Cosmetics Act, 2008, which has become effective from August 2009 has given rise to fears that ambiguity over the definition of the terms 'adulterated' and 'spurious' drugs could affect Indian generic drug players also. While the amended law has provided for stricter punishment for companies charged with manufacturing adulterated or spurious drugs, the evidence of both adulteration and manufacture of spurious drugs needs to be established for a person to be convicted. However, the punishment has been increased to 10 years imprisonment from five years now (extendable to life in prison), the fine amount has also been increased to Rs. 100,000 from Rs 10,000.

The fear is that the existing definition could be interpreted to even catch within its fold legitimately-authorised generics of good quality. The loophole identified by intellectual property lawyers and companies, particularly in the recent Bayer versus Cipla case Bayer, in the recent drug patent case, suggested that Cipla's generic version of Nexavar would qualify as spurious.

The Economic Survey, 2008-09, has called for decontrol of prices. According to the survey, high growth has been achieved in the pharmaceuticals industry through the creation of required infrastructure, capacity building in complex manufacturing technologies of active ingredients and formulations, drug discovery through original and contract research and manufacturing (CRAM) and clinical trials and product specific strategies of acquisition and mergers.

The national pharmaceutical policy, pending since 2002, may be put under the scrutiny of another Group of Ministers (GoM), without any change to the draft prepared by the previous regime. The Chemicals Ministry has stuck to the old draft and has submitted it to the Cabinet secretariat with a recommendation to be examined by a GoM. The crux of the draft policy was to bring in price control over 354 drugs instead of existing 74 medicines and it was contented by the industry, especially the large players, leading to inordinate delay in the finalization of the policy. After it was placed among the priority tasks within the next three months, the ministry decided against delaying by making any change to the draft National Pharmaceutical Policy, 2006 originally submitted in December 2006.

According to a study by FICCI and Ernst & Young, India's cost advantage is attracting global pharmaceutical companies to shift their contract research and clinical trials business to here. The ability to offer end-to-end services in clinical research covering trials, data management, biostatistics and central laboratory services makes the country a preferred destination for trials and research. A clinical trial conducted in India costs 50-60% lower than in the developed markets. Also, the number of companies engaged in drug development has increased the most in India amongst the countries in Asia, Latin America and Eastern Europe. The industry-sponsored, Phase-II,-III clinical trial study sites in India have grown by 116% cent over the last 15 months. India participates in 7% of the global Phase III trials and 3.2% in the Phase II trials.

The health ministry is planning to introduce e-governance for clinical trials in four years. The move will enable drug companies that want to carry out clinical trials in India to register online from any part of the world. Once the required approval for conducting trials is obtained, the companies can also submit research data online to the drug regulator, Drug Controller General of India (DCGI), seeking marketing approval for their drug. The drug regulator would deliver online approvals to companies after validating all the information submitted by companies. It would take about four years to put the system in place and e-governance is expected to be implemented in the country by 2013. The government also intends to make use of information technology to discourage volunteers to enrol into more than one clinical trial resulting in adverse drug reactions. The government is using finger printing software available through which clinical trial centres can be interlinked. The drug regulator has also asked companies to install the software so that they can enrol first time volunteers and avoid drug reactions during trials.

Indian biotechnology companies that were aiming to launch cheaper drugs in the US market may have to contend with a bigger challenge after a change in legislation ensured protection for the biotech companies that originally discovered the drugs. The US Energy and Commerce Committee recently approved a legislative amendment that would give a 12-year data exclusivity and protection from biosimilars to innovator biotech companies. The exclusivity begins from the time the product is launched in the market, thus making it difficult for Indian companies to copy them. However, industry experts point out, that biotech products which are likely to lose patent protection soon will not be impacted. Companies would have to adapt themselves to the new regulations. The change in ruling is however, unlikely to affect those companies engaged in innovative research.

Southern States

Andhra Pradesh

Hyderabad-based Dr Reddy's Labs is planning to launch new generic drugs in various therapeutic segments to give a push to its domestic operations and get back to among the top ten firms in the country. It is currently ranked 13th with a 2.7 per cent share in the domestic pharmaceuticals market. The company will launch new products in the domestic market particularly in therapeutic areas like cardiovascular, diabetes and dermatology that have a larger market share, he said without specifying details. It will also focus on different regions where it doesn't have a strong presence. The company also plans to buy brands in Russia to scale up businesses in key emerging markets

Biocon has announced in December 2009 that it would acquire the bulk pharmaceutical business undertaking of IDL Specialty Chemicals Limited, located near Hyderabad.

The Medicines Control Council of South Africa has permitted Aurobindo Pharma to manufacture and market five products there. They include Auro-Abacavir (anti-retroviral) and Auroprozil, Auro-Cefotaximme and Auro-Cefalexin (anti-infectives). The company has also received final approval from USFDA for Fosinopril sodium and hydrochlorothiazide tablets. The drug is the generic version of Bristol Myers Squibb's Monopril HCT tablets and is useful in treating hypertension. In August 2009, Aurobindo Pharma also received the final approval for Carisoprodol tablets from the USFDA. Also, its tentatively approved ANDA for Sumatriptan Succinate tablets received the final approval from the USFDA. The company also received final approval for Clindamycin Hydrochloride capsules from the USFDA. Clindamycin Hydrochloride is generic equivalent to Cleocin Hydrochloride of Pharmacia & Upjohn Company and is indicated in the treatment of serious infections caused by susceptible anaerobic bacteria and Aurobindo now has a total of 101 ANDA approvals (73 final approvals and 28 tentative approvals) from USFDA.

In another development, the board of Aurobindo Pharma approved the proposal to acquire 100% stake of Trident Life Sciences (TLSL). TLSL was incorporated in 2004 and has an established clinical research organization. It is in the process of implementing a liquid injectables facility in Medak district near Hyderabad. In July 2009 Aurobindo Pharma had announced that it has received the final approval for Zidovudine tablets and tentative approval for Lamivudine and Zidovudine tablets from the USFDA. The company's US joint venture Cephazone Pharma LLC received approval for its original Abbreviated New Animal Drug Application (ANADA) for Ceftiofur Sodium Sterile Powder from the USFDA Centre for Veterinary Medicines. Aurobindo Pharma Australia Pty, a wholly owned subsidiary of Aurobindo Pharma received approval in May 2009 from Therapeutic Goods Administration (TGA), government of Australia for the registration of Simvastatin tablets in multiple strengths. Earlier, in March 2009, Pfizer had extended an agreement with Aurobindo whereby it acquired rights to sell 39 generic drugs in the US, 20 in Europe and 11 in France.

In August 2009, Dr Reddy's Laboratories approached the USFDA to overcome impediments in making the generic version of Revlimid, an expensive drug used to treat leukaemia. US-based biotech firm Celgene, the innovator, has declined to make the drug samples available to DRL for bio-equivalence studies. The company also launched 'Strea Professional', its first product in the non-invasive

aesthetics segment in India. It is the first bi-phasic superficial peel for specific imperfections. The product has been licensed from Gruppo Phitogen, Italy.

Drug manufacturing companies such as Cipla, Ranbaxy, Johnson & Johnson and Dr Reddy's may have to pay over Rs. 20,380 million to the government for overcharging consumers on price-controlled medicines. Through a nation-wide survey and other tools of inspections, the drug price regulator National Pharmaceutical Pricing Authority (NPPA) has found that these pharmaceutical companies were overcharging consumers for several medicines or selling them without a price approval from NPPA. Unlike decontrolled drugs, the prices for which can be hiked by up to 10% annually, manufacturers do not have the liberty to increase prices of drugs under price control on their own.

Drug costs to fight HIV/AIDS are likely to go down further with the launch of a new, second line regimen by Matrix Labs and the Clinton Foundation. The cost-effective once-daily HIV/AIDS treatment regimen of four anti-retrovirals will be available for under $500 annually. The Clinton HIV/AIDS Initiative (CHAI), Mylan Inc., and Matrix Laboratories have signed an agreement for this. However, Matrix Laboratories has recently been issued a notice by the World Health Organisation (WHO) for failure to meet the quality norms in the pharmaceutical sector. The notice is in relation to the anti-retroviral (ARV) drugs that Matrix supplies to WHO for its HIV/AIDS programme. A suspension of such a status could impact Matrix to the extent of its sales to WHO for these products. In another development, Matrix Labs received the first tentative approval from the USFDA in March 2009 under the President's Emergency Plan for AIDS Relief (PEPFAR) for its abbreviated new drug application for Emtricitabine and Tenofovir Disoproxil Fumarate tablets. In January 2009, the company had assigned its parent company, MP Laboratories, purchase rights to a part of the equity of Astrix Laboratories. Matrix will purchase the equity stake from Aspen Pharmacare Holdings, a South African company. Matrix and Aspen have 50:50 joint ventures in Astrix and Fine Chemicals. MP Labs will purchase 49% of Aspen's stake in Astrix. Matrix will purchase the remaining 1% and will then control 51% of the company.

In August 2009, the government put Zanamivir, the only swine flu drug that is freely available in the market. It is currently, under restricted sale category. This is being done to bring it on par with the more widely used swine flu drug Oseltamivir, which will be available in the retail market in the next 10-15 days. Cipla is the only company that sells Zanamivir, the generic version of GSK's drug Relenza, under the brand Virenza. The government has given approval for marketing Oseltamivir to six pharmaceutical companies - Ranbaxy, Cipla, Natco Pharma, Strides Arcolab, Hetero Drugs and Roche India. The government has asked drug manufacturers such as Ranbaxy, Hetero, Natco Pharmaceuticals, Cipla and Strides Arcolab to stock about 7.2 million oseltamivir anti-viral tablets to handle any emergency situation. It has also decided to store additional 10 million tablets to treat swine flu patients, a ministry of health and family welfare official said.

July 2009, Natco Pharma had to recall its breast cancer drug Albupax following an order from the Drug Controller General of India, which said that the drug might cause damage to liver. Natco has since then stopped the production, distribution and marketing of the drug and is in the process of recalling stocks. Albupax - a nanotechnology-based generic version of a drug by US based company Abraxis BioScience had been launched in September 2008 after the clinical trial data were found satisfactory. However, three months ago, the US firm filed a written complaint citing

serious side-effects that the generic may cause. The original drug, Abraxane, is distributed in India through Biocon, but the drug is costlier than the Natco version by around Rs. 5,000 per vial.

In April 2009 Dr Reddy's and Natco announced that they would together develop generic oncology products for registration and global commercialization. Natco would exclusively manufacture and supply the products for global commercialization by Dr Reddy's. As per the agreement, Dr Reddy's would pay an upfront fee to Natco for securing rights to the product portfolio and the capacity required to make the products. In addition, both parties would have a profit sharing mechanism in their respective designated territories. Natco also formed an alliance with Mumbai-based Lupin to sell Lanthanum Carbonate tablets, a generic version of US based Shire PLC's Fosrenol tablets is used for treating kidney failure and facilitate phosphate absorption.

Hyderabad-based Anu's Laboratories is planning to raise Rs. 2,500 million to fund its expansion after six months. The company is planning to set up a USFDA-compliant API manufacturing facility at Visakhapatnam in Andhra Pradesh at an investment of Rs. 630 million to be completed by October 2009.

Lonza Group, the Switzerland-based bio-pharmaceutical company plans to infuse Rs. 7,050 million in setting up a facility to be located at the outskirts of Hyderabad, Andhra Pradesh. The facility is expected to be set up in two phases. Phase I will comprise of a small-scale multi-purpose manufacturing plant for biopharmaceuticals, bio-therapeutic media manufacturing plant labs for biologics and bioinformatics etc. Phase II will see the expanded large-scale manufacturing plant for biopharmaceuticals and media manufacturing capacity for bio-therapeutic media. The two phases are expected to be completed between 2011-2013 and 2014-2015 respectively.

Hyderabad based Biological E's new biopharmaceutical and vaccines manufacturing campus was inaugurated in February 2009. The new facility is spread over 75 acres at SP Biotech Park, Hyderabad. The company has invested over Rs. 3,000 million in setting up Phase I. The plant has facilitites to manufacture vaccines and biopharmaceuticals to prevent childhood diseases. In the next phase, the company will invest further Rs. 2,500 million over the next two to three years, in expanding capacities and creating infrastructure for the future pipeline products of the company.

Shantha Biotechnics, the Chennai based bio-pharmaceuticals company is setting up a new vaccine manufacturing complex near Hyderabad. The company plans to invest Rs. 500 million initially and later invest another Rs. 500 million. The complex is expected to be developed on 40 acre land in the Genome Valley Biotech Park in Ranga Reddy district, and will have a capacity to manufacture over 100 million doses of vaccines per year. The complex will address the capacity constraints of the existing facilities to manufacture a range of enteric vaccines and the new generation pneumococcal vaccines under development

Karnataka

Biocon is expecting significant improvement in sales from the oral insulin drug is scheduled for launch in March 2010. Now that the markets are picking up, the company would also look at listing its research division Syngene. The NPPA recently brought Biocon's newly launched Basalog under price control. However, the company avers that Basalog does not come under the purview of NPPA and has been wrongly classified as there is a provision under the DPCO, which exempts biotech drugs five

years, especially if they are developed and commercialized in India. The NPPA has brought Wockhardt's Glaritus and Biocon's Basalog, the two local versions of Lantus, under price control after the companies were found to be violating pricing norms. Glargine is an altered form of insulin that stays in blood stream longer than other forms of insulin. The NPPA has fixed the price of the insulin at around Rs 130 for a 3-ml vial. Currently, a 3-ml vial of Wockhardt's Glaritus is priced at around Rs. 435, whereas Biocon's brand Basalog costs around Rs. 500.

In June 2009, Biocon announced that the company had executed a definitive agreement with Mylan Inc. for an exclusive collaboration on the development, manufacturing, supply and commercialization of multiple, high value generic biologic compounds for the global marketplace. In May 2009, Biocon launched its biosimilar version of human insulin analog glargine, brand named Basalog. The basal insulin is meant for type-1 and type-2 (non-insulin dependent) diabetics. The company is also keen to develop its market in Germany, where Biocon has acquired distribution company AxiCorp. In the next two years, the product should be in many global markets, and in the US, in 2015-16, once the product goes of patent. In March 2009, Syngene and Bristol-Myers Squibb announced the opening of a fully dedicated research and development facility for Bristol-Myers Squibb at Biocon Park, Bangalore.

Bharat Biotech International has announced plans to set up an animal vaccine manufacturing units near Bangalore in Karnataka at an investment of Rs. 1,000 million. The new unit expected to be commissioned by September 2009 will have a production capacity of 100 million doses of vaccine for cattle and other animals. The main product of the new venture, to be called BIO-VET International, will be a vaccine for the foot and mouth disease prevalent among cattle.

Bangalore-based Kemwell is planning to develop a biopharmaceutical manufacturing plant in Bangalore at an investment of about Rs. 2,350 million. The company has joined hands with German pharmaceutical firm Boehringer Ingelheim for technical and marketing collaboration. Boehringer Ingelheim will provide technical know-how and marketing support to Kemwell for its contract manufacturing services. The new facility is likely to be developed on 15,000 sq.m. It is designed for process development, fermentation, purification, and formulation of biologicals for clinical studies. The plant will consist of a cGMP compliant drug manufacturing facility and, a sterile fill and finish facility for drugs. It will house process development laboratories to support production of protein therapeutics.

GE Healthcare has invested Rs. 1,250 million to set up R&D facility at Bangalore. The new 40,000 sq.ft R&D facility has a replicated hospital work environment and will be used for development of products catering to the Indian as well as foreign healthcare market. The laboratory, which will become operational by June 2009, will be used to develop latest technology including software applications as well as development of next generation products. The lab is part of a new "green" centre that has cost GE an additional Rs. 2,500 million.

Syngene International, a subsidiary Biocon and Bristol-Myers Squibb Company has inaugurated its fully dedicated R&D facility for Bristol-Myers Squibb in Biocon Park, Bangalore. Spread over 20,000 sq.ft, the R&D facility is devoted to advancing Bristol-Myers Squibb's work in discovery and early drug development and has 270 researchers.

Biotech companies like Avesthagen and Biocon are in talks with global players to out-license various projects in their R&D pipeline. Avesthagen is in talks with several companies for partnerships in the nutrition space. The first molecule in nutrition has completed clinical trials while others are in the pipeline. But instead of retailing it directly, the plan is to licensing them to other retail companies. Avesthagen in partnership with Danone in metabolic disorders is through with its pre-clinical testing. As part of the agreement between the two companies, Danone will start clinical trials of the molecules and later into the market. Avesthagen has four bio-pharma molecules in the pre-clinical stage and is looking for partners for further development. With its IPO currently on hold, Avesthagen is counting on strategic partnerships and milestone payments from its out-licensed molecules to tide over shortage of funds.

Tamil Nadu

The Chennai-based Sanmar Group announced, in December 2009, the sale of the closely held Bangalore Genei (India) (BGIP), a part of the speciality chemicals business of the Sanmar Group, to Merck Specialities. BGIP specialises in the development, production, marketing and sales of products for proteomic and genomic research. With its more than 100 employees, the company generated total revenues of Rs 20.2 crore in 2008-09. This sale would help Sanmar Speciality focus on its core business of fine chemicals, intermediates for agrochemicals and pharmaceutical industries, contract research and phyto-chemical based active pharma-ingredients. Bangalore Genei is India's leading company in the field of biotechnology based reagents and would be helped by Merck's strong market presence, worldwide.

Orchid Chemicals and Pharmaceuticals, which sold off its generic injectable pharmaceuticals business to US-based diversified healthcare group Hospira for US$ 380 million, plans to use the funds to retire its debt and pursue new growth opportunities. About US$ 260 million of the US$ 380 million are expected by March 2010 and would be used to settle its short-term debts of US$ 110 million and US$ 150 million FCCBs that are maturing in 2012. The balance cash component would be deployed for pursuing new growth opportunities and to fill gaps in working capital.

In August 2009, Orchid Chemicals announced that it has received the final approval from the USFDA for Sumatriptan Succinate tablets. The company also received tentative approval from USFDA for Desloratadine tablets. The drug is the generic version of Schering-Plough's allergy medication, Clarinex and is used for treating allergic rhinitis and chronic idiopathic urticaria. Orchid Chemicals & Pharmaceuticals settled the patent litigation with Schering-Plough for Clarinex. Orchid has the rights to market Desloratadine tablets in the US market from July 2012. In July 2009, Orchid received approval from USFDA for Amlodipine Besylate tablets in multiple strengths. Amlodipine is indicated for the treatment of hypertension, for the symptomatic treatment of chronic stable angina, and for the treatment of confirmed or suspected vasospastic angina and is a generic version of Pfizer's Norvasc tablets.

Shasun Chemicals stopped operations of its multi-product facility in Cuddalore in late August upon receiving notice from the Tamil Nadu Pollution Control Board for closure of plant located at the SIPCOT Industrial complex in Cuddalore, Tamil Nadu. The facility in Cuddalore is spread over 64,000 sq meters and manufactures anti-ulceratives, Nizatidine, Ranitidine and Excipients.

In July 2009, Shasun Chemicals had launched a recombinant streptokinase, a clot dissolving drug used during heart attacks in collaboration with Council of Scientific and Industrial research (CSIR). The drug would be marketed by two other Indian companies Lupin and Alembic. Shasun expects to capture 15-17% of the Rs. 800 million market segment in the first year. The drug will be priced at Rs. 2,200- 2,400 per injection for retail market which is comparable with its competitors.

In April 2009, Shasun closed its contract manufacturing facility at Annan in Scotland and shifted production to locations in the US, the UK and India. Manufacturing locations in India can produce drugs at a fourth of cost of production in the west, where strict environmental rules and overheads are causing multinational drug makers to discard facilities. Shasun Chemicals is likely to set up an Active Pharmaceutical Ingredient (API) manufacturing facility in Visakhapatnam, Andhra Pradesh, at an investment of Rs. 1 billion by 2012.

Trivitron, the medical technology company has entered into a partnership BioSystems of Spain to manufacture in vitro diagnostic (IVD) reagents. BioSystems plans to set up a manufacturing facility of IVD reagents for diagnostic lab use at Trivitron's Medical Technology Park in Chennai. The company plans to invest Rs. 400-500 million in Phase I of the project and production is expected to commence in 2010. The park is coming up on a 23 acre land at Sriperumbudur, near Chennai, on which Trivitron has already invested Rs. 1,700 million.

The union government has sanctioned the proposal to set up Rs. 2,500 million plasma fractionation centre with a capacity to process more than 150,000 litres of plasma at Chennai as part of the ongoing National AIDS Control programme - Phase-III to ensure access of plasma derivatives to needy patients at affordable prices. The state-of-the-art facility with the latest technology and equipment is expected to reduce the dependence to imports of factor VIII and factor IX derivatives and save foreign exchange. The time frame for setting up this facility will be co-terminus to Phase-III of National AIDS Control Programme during 2007-12. The import of plasma products accounts for an estimated foreign exchange Rs. 800-900 million, annually.

Two companies from south India are in the final stages of establishing pre-clinical trial facilities in Malaysia, which has been aggressively promoting biotechnology. The Malaysian government has been promoting biotechnology, which is expected to contribute 5% of the overall GDP. In the Budget, 2009, the Malaysian government had announced US$3 billion allocation to enhance healthcare and strengthening biotechnology. The Kuala Lumpur-based BiotechCorp, established in 2005 as a not-for-profit organisation, has been facilitating biotechnology development by targeting countries like India, which are seen as a knowledge economy. Investments from 55 new bionexus companies in Malaysia are expected to touch US$143 million by this year. “Bionexus” is a status that makes firms eligible for privileges contained in the Bionexus bill of guarantees. There are 97 bionexus status companies with a total approved investment of US$360 billion involved in areas such as agriculture, healthcare and industrial biotechnology. India is the fourth largest investor within Bionexus.

POLICY AND REGULATIONS

The National Strategy for Manufacturing prepared by central government's National Manufacturing Competitiveness Council has identified the 20 sectors as having immediate potential for growth and employment in the country. These include drugs and pharmaceuticals and biotechnology. The Department of Pharmaceuticals functioning under the Ministry of Chemicals and Fertilisers is responsible for formulating policies at the national level for the pharmaceuticals industry. The key policies of the union government that drive the sector are The Pharmaceuticals Policy, 2002, and the Drugs (Price Control) Order, 1995.

The Pharmaceuticals Policy, 2002, was formulated to accommodate new changes and the effect of new obligations brought in by the WTO agreements. These challenges were to accelerate growth of the industry, making it more internationally competitive and to develop it as knowledge based industry. The government has abolished industrial licensing in the manufacture of all drugs and pharmaceuticals except bulk drugs produced by the use of recombinant DNA technology, bulk drugs requiring in-vivo use of nucleic acids, and specific cell/tissue targeted formulations. Reservation of five drugs for manufacture by the public sector only was abolished in 1999. Foreign investment through automatic route was raised from 51% to 74% in 2000 and then to 100%. Automatic approval for Foreign Technology Agreements is given in the case of all bulk drugs, their intermediates and formulations except those produced by the use of recombinant DNA technology. Drugs and pharmaceuticals manufacturing units in the public sector are being allowed to face competition including competition from imports. Wherever possible, these units are being privatized. There is a facility of weighted deductions of 150% of the expenditure on in-house research and development to cover as eligible expenditure, the expenditure on filing patents, obtaining regulatory approvals and clinical trials besides R&D in biotechnology. Most importantly, the policy also introduced the Patents (Second Amendment) bill in the Parliament for the extension in the life of a patent to 20 years. The obligation under TRIPs has been addressed in the policy through improved incentives for research and development and the promise of reducing price control.

The objectives of the policy are as follows:

- Ensuring abundant availability at reasonable prices within the country of good quality essential pharmaceuticals of mass consumption;
- Strengthening the indigenous capability for cost effective quality production and exports of pharmaceuticals by reducing barriers to trade in the pharmaceutical sector;
- Strengthening the system of quality control over drug and pharmaceutical production and distribution to make quality an essential attribute of the Indian pharmaceutical industry and promoting rational use of pharmaceuticals;
- Encouraging R&D in the pharmaceutical sector in a manner compatible with the country's needs and with particular focus on diseases endemic or relevant to India by creating an environment conducive to channelizing higher level of investment into R&D in pharmaceuticals in India;
- Creating an incentive framework for the pharmaceutical industry which promotes new investment into pharmaceutical industry and encourages the introduction of new technologies and new drugs.

In order to strengthen the pharmaceutical industry's research and development capabilities and to identify the support required by Indian pharmaceutical companies to undertake domestic R&D, the Pharmaceutical Research and Development Committee (PRDC) was set up in 1999 by this Department under the Chairmanship of Director General of Council of Scientific and Industrial Research (CSIR). PRDC suggested the following standards for qualifying as a R&D intensive company:

- Invest at least 5% of turnover per annum in R&D
- Invest at least Rs.100 million per annum in innovative research including new drug development, new delivery systems in India
- Employ at least 100 research scientists in R&D in India
- Has been granted at least 10 patents for research done in India
- Own and operate manufacturing facilities in India

The Drugs and Cosmetics (Amendment) Act, 2008, has come into force from August 10, 2009. The amended Act states that if the central government is satisfied that a drug is essential to meet the requirements of an emergency arising due to epidemic or natural calamities and that it is necessary in the public interest to do so, then the government may regulate or restrict the manufacture, sale or distribution of such drug. The punishment for manufacturing spurious drugs has been increased from five to ten years 9extendable to life in prison) and the fine levied has been increased from Rs. 10,000 to Rs. 1 million or three times the value of confiscated drugs, whichever is higher.

On price controls, the guiding principle for identification of specific bulk drugs for price regulation should continue to be: (a) mass consumption nature of the drug and (b) absence of sufficient competition in such drugs. The "Retail Store Audit for Pharmaceutical Market in India" published by ORG-MARG, and the Indian Pharmaceutical Guide have been considered as data sources for ascertaining the mass consumption nature and addressing absence of sufficient competition with reference to a particular bulk drug. The policy also delineates methodology for pricing, its components and NPPA's role as the price regulating and monitoring agency, education and training of personnel and related issues.

The Department of Biotechnology, functioning under the Ministry of Science & Technology has formulated The National Biotechnology Development Strategy, 2007. According to the strategy, the government recognises biotechnology as a sunrise sector that needs focussed attention in terms of fully using currently available manufacturing and services facilities while laying the foundation for discovery and innovation for potential to contribute to agriculture, animal productivity, human health, environmental security and sustainable industrial growth. The purpose is to address challenges like building research and development capabilities, attracting investment capital, facilitating technology transfer, absorption and diffusion, handling intellectual property rights and regulatory issues, and developing human capital.

The key deliverables identified under the strategy are setting up of a National Biotechnology Regulatory Authority as a single window for bio-safety clearance of genetically modified products and processes; setting up of an inter-ministerial coordination committee to coordinate the development of the sector; promoting biotech industry by investing up to 30% of the department's budget on public-private partnership programmes by the end of the Eleventh Plan period - this would promote innovation, pre-proof-of-concept research, and accelerated technology and product development; building human capital through identified colleges and courses at the graduate and post graduate levels, setting up of a UNESCO Regional Centre for Science, Education and Innovation in

Biotechnology, attracting scientists from overseas, creating centres of excellence in biotechnology; developing technology clusters; initiating capacity building for technology transfer and intellectual property related issues; and other such initiatives.

The key highlights of the recent Union Budget, 2009-10, that are likely to directly or indirectly affect the pharmaceuticals industry include the following proposals:

- Customs duty on 10 specified life saving drugs/vaccine and their bulk drugs to be reduced from 10% to 5% with nil counter veiling duty (CVD). Excise duty exempted. These drugs/vaccines include influenza vaccine and nine specified life saving drugs used for the treatment of breast cancer, hepatitis-B, rheumatic arthritis etc.
- Customs duty on specified heart devices, namely artificial heart and Patent Ductus Arteriosus/ A*trial Septal Defect* (PDA/ASD) occlusion device, to be reduced from 7.5% to 5% with nil CVD. Excise duty exempted.
- 4% excise duty maintained for drugs and pharmaceutical products falling under Chapter 30.
- Scope of provisions relating to weighted deduction of 150% on expenditure incurred on in-house R&D to all manufacturing businesses being extended except for a small negative list.
- Allocation under National Rural Health Mission (NRHM) increased by Rs. 20.57 billion over interim B.E. 2009-10 of Rs. 120 billion.
- All BPL families to be covered under Rashtriya Swasthya Bima Yojana (RSBY). Allocation under RSBY increased by 40% over previous allocation to Rs. 3.5 billion.

While reduction of customs duties could act as a threat to the domestic manufacturers as vaccines are primarily manufactured in the small to medium enterprise sector, excise duty exemption benefits the local manufacturers. Biotechnology firms trying to raise money for research through vaccine revenues may have to contend with increased competition. However, India is one of the largest vaccine markets as well as manufacturer in the world. Spending increase in NRHM along with derived benefit from income generating programmes like NREGA and unorganised workforce security scheme are likely to increase long term demand for medicines.

State Policies – Southern Region

The state governments, in turn, have their specific policies regarding the development of the industry in their respective states. Andhra Pradesh leads in terms of number of companies incorporated and is followed by Tamil Nadu, Karnataka and Kerala. However, there are distinct hubs, for instance, Karnataka is an established biotechnology hub and is moving towards high end research facilities, while Tamil Nadu is an established bulk drug manufacturing centre. Andhra Pradesh has also attracted biotechnology companies because of the research and training institutions established for this sector. While almost all states have stated their intent to develop the pharmaceuticals and biotechnology sectors, the two states that have followed concrete strategies to develop either of these or both the sectors are Andhra Pradesh and Karnataka. Tamil Nadu's focus has mainly been on providing infrastructure support to the industry in terms of industrial parks while Kerala's focus has been on developing the ayurveda industry.

In 2003, the Andhra Pradesh government announced its plans to develop the state as a one of the largest manufacturing centres in the country by 2020 for bulk drugs, intermediates, formulations and R&D activities. It aimed to be the preferred destination for investments in this area along with

pharmaceutical healthcare, education and research. The strategy was followed with action to create a dominant position among the states. It is estimated that the pharmaceuticals industry in Andhra Pradesh accounts for about 33% of the bulk drugs manufactured in the country.

The distinct advantages provided by the state included an established pharmaceutical base starting with central government owned Indian Drugs & Pharmaceuticals Limited (IDPL) and a strong R&D base with reputed institutions like Indian Institute of Chemical Technology (IICT), The Centre for Cellular and Molecular Biology (CCMB), Centre for DNA Fingerprinting & Diagnostics (CDFD) and National Institute of Nutrition (NIN). It also has a strong academic base with 22 degree colleges and 18 diploma colleges turning out about 2,000 students annually. The state government was quick to recognise the need for change in the industry as per the WTO requirements and created environment for innovation and discovery. The key initiatives were to create hubs for discovery, and institutions to support the industry. The new industrial policy simplified labour laws and provided for single window clearances to attract more investments in the sector. The State Investment Promotion Board was designated to regularly review the progress in giving clearances for matters pertaining to the industry. The government also supported the creation of pharmaceutical and biotech parks in key cities of the state. Thus the Pharma City near Visakhapatnam, The genome Valley with Biotech and ICICI knowledge parks, as well as a formulation park in SEZ came up in the sector. To exploit the potential for clinical research and trial, the government approached the central government for initiating necessary legal measures in tune with international requirements. Other infrastructural facilities were also developed to attract foreign and domestic investors from other states. The state government also worked towards locating the Pharmexil, the special export promotion council, at Hyderabad.

Karnataka focussed on developing the biotechnology industry. The state government brought out the Millennium Biotech Policy, 2000. The policy focussed on genomics, bio-fuels, bio-informatics and contract research. Incentives and concessions included exemption from entry tax on certain capital goods, concession on stamp duty and registration charges, rebate on cost of land, exemption from electricity tax for five years on captive generation, continuous and uninterrupted supply of power at industrial rates, simplified procedures and laws for urban planning and zonal regulations, relaxation in labour laws, single window agency, and encouragement to venture capital funds for biotech industries. The cluster approach was adopted to set up biotech parks in Bengaluru and Dharwad; marine biotech park in Karwar; and biotech corridor in Bengaluru. Other institutions such as Centre for Human Genetics and Institute of Agri-Biotechnology were also planned. The state government is expected to announce a revised biotech policy soon, to attract more investments in the tier II and tier II cities of the Karnataka.

The Tamil Nadu government's annual industrial policy of 2006-07 state that the Tamil Nadu Industrial Development Corporation received in-principle approval from the central government for establishing a multi product SEZ in an area of about 1,055 hectares in the Hosur and Denkanikotta taluks of Krishnagiri district in December 2005. Market survey and preliminary feasibility study for the proposed SEZ project had been completed. TIDCO had requested government of Tamil Nadu for Administrative Sanction to acquire and alienate the lands for developing the SEZ at a cost of Rs. 5 billion. This SEZ is expected to generate employment for about 70,000 persons over 8-10 year period in IT/ITES, Pharmaceuticals, Apparels, Electronics and Food processing Industries. The government is now working on widening the scope of the project and restructuring the project company for speedy implementation.

REVIEW OF FINANCIAL PERFORMANCE

Overall Drugs & Pharmaceuticals Industry

The pharmaceutical industry's profitability improved in H1FY2010 as compared to H1FY2009 on a 7.5% increase in operating income. Financial data of a sample set of pharmaceutical companies indicates that fall in costs as percentage of sales resulted in just 3.0% increase in cost of sales. A fall of 11.4% in net interest resulted in a 23.3% increase in net profit, despite a 51.1% fall in other income.

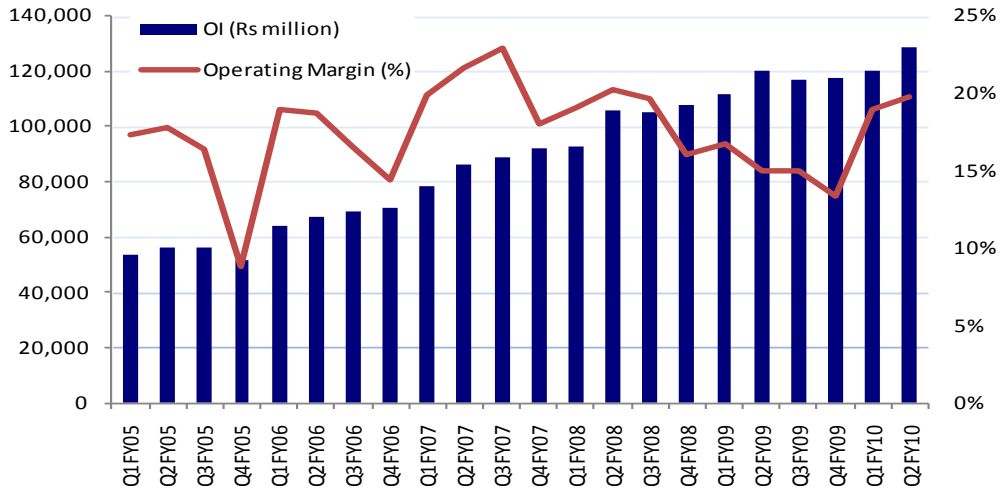
Financial Performance

Rs. Million, except percentages

	Rs. Million		Change	% of OI	
H1FY	2010	2009	(%)	2010	2009
Net Sales/OI	248,886	231,580	7.5	100.0	100.0
Raw Material Cost	121,772	118,502	2.8	48.9	51.2
Employee Costs	23,397	20,596	13.6	9.4	8.9
Power & Fuel	476	533	-10.7	0.2	0.2
Other Operating Costs	55,077	55,216	-0.3	22.1	23.8
Cost of Sales	200,722	194,847	3.0	80.6	84.1
OPBDIT	48,164	36,733	31.1	19.4	15.9
Interest	5,678	6,406	-11.4	2.3	2.8
Depreciation	9,554	8,226	16.1	3.8	3.6
OPBT	**32,931**	**22,101**	**49.0**	**13.2**	**9.5**
Other Income	2,663	5,443	-51.1	1.1	2.4
PBT	**35,594**	**27,544**	**29.2**	**14.3**	**11.9**
Tax	8,149	5,289	54.1	3.3	2.3
PAT	27,445	22,255	23.3	11.0	9.6

On a quarterly basis, operating margins improved from 15.0% in Q2FY2009 to 19.7% in Q2FY2010.

Trends in Operating Income and Operating Margins



Drugs & Pharmaceuticals Industry - Southern Region

The financial performance of the pharmaceutical industry in the southern region improved as sales increased by 9.1% in H1FY2010. Operating profit improved 38.5% mainly, because of a 13.3% fall in power and fuel costs. A 37.7% fall in net interest combined with just 2.8% increase in overall cost of sales further improved net profits by 47.3%. Profitability improved to 12% in H1FY2010 as compared to 8.9% in H1FY2009.

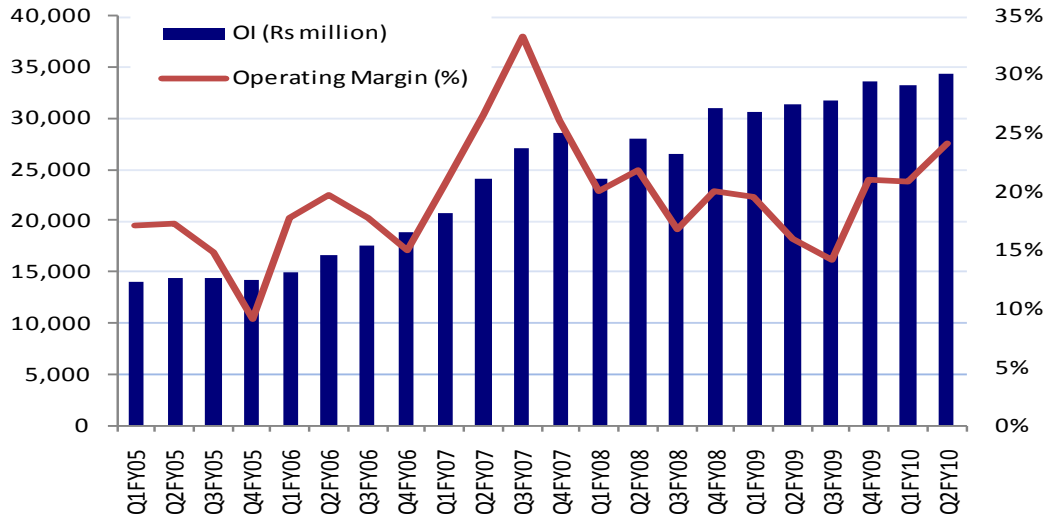
Financial Performance

Rs. Million, except percentages

	Rs. Million		Change	% of OI	
H1FY	2010	2009	(%)	2010	2009
Net Sales/OI	67,609	61,955	9.1	100.0	100.0
Raw Material Cost	31,435	31,671	-0.7	46.5	51.1
Employee Costs	6,040	5,138	17.6	8.9	8.3
Power & Fuel	353	407	-13.3	0.5	0.7
Other Operating Costs	14,589	13,770	5.9	21.6	22.2
Cost of Sales	52,418	50,987	2.8	77.5	82.3
OPBDIT	15,191	10,968	38.5	22.5	17.7
Interest	1,803	2,896	-37.7	2.7	4.7
Depreciation	3,510	3,052	15.0	5.2	4.9
OPBT	**9,878**	**5,021**	**96.7**	**14.6**	**8.1**
Other Income	855	2,018	-57.6	1.3	3.3
PBT	**10,733**	**7,039**	**52.5**	**15.9**	**11.4**
Tax	2,647	1,550	70.8	3.9	2.5
PAT	8,086	5,489	47.3	12.0	8.9

On a quarterly basis, operating margins improved significantly from 15.9% in Q2FY2009 to 24.1% in Q2FY2010.

Trends in Operating Income and Operating Margins



INDUSTRY OUTLOOK

Global pharmaceutical industry is on the decline with its sales growth declining to 4.8% in terms of constant dollar during 2008 from 6.6% in the previous year, according to IMS Healthcare report. The growth of the sector is likely to deteriorate further to 2.5-3.5% in 2009. The lower growth in pharmaceutical sales, worldwide, is attributed basically to global economic slowdown, patent expirations, price restrictions and slowdown in innovative product launches. However, Asia, Africa and Australia markets recorded high pharmaceutical sales growth of 15.3% during 2008. Similarly, Latin America achieved double digit growth in sales of 12.6%, but the growth in Europe was restricted to only at 5.8%.

Drugs having estimated sales of over US$28 billion are expected to go off patent in the US between 2008 and 2010. With the governments in the developed markets looking to cut down healthcare costs by facilitating a speedy introduction of generic drugs into the market, domestic pharmaceuticals companies are likely to benefit. However, despite this huge promise, intense competition and consequent price erosion would continue to remain a cause for concern. The IMS report notes that unprecedented level of potential patent expirations in 2011 and 2012 will curb sales growth. The global compounded annual growth rate for pharmaceutical market is forecasted at three to 6% through 2013.

North America continued to be the largest pharmaceutical market with sales of $311.8 billion in 2008 contributing around 40.3% to total sales. It was followed by Europe with sales of $247.5 billion at about 32.1% of total market. Asia, Africa and Australia had sales of $90.8 billion or 11.7%, Japan $76.6 billion or 9.9% and Latin America $46.5 billion or 6%.

In India, the life style segments such as cardiovascular, anti-diabetes and anti-depressants will continue to be lucrative and fast growing owing to increased urbanisation and change in lifestyles. Growth in domestic sales in the future will depend on the ability of companies to align their product portfolio towards the chronic segment. In the exports market, the industry has achieved a leadership position as a world class cost effective generic drugs manufacturer of AIDS medicines. Many Indian companies are part of an agreement where major AIDS drugs based on Lamivudine, Stavudine, Zidovudine, Nevirapine are being supplied to Mozambique, Rwanda, South Africa and Tanzania which have about 33% of all people living with AIDS in Africa. Yet another US scheme envisages sourcing antiretrovirals from some Indian companies whose products are USFDA approved. Increasing number of Indian pharmaceutical companies have been getting international regulatory approvals for their plants from agencies like USFDA, UKMHRA, TGA (Australia), MCC (South Africa) and Health Canada.

Innovation is increasingly becoming a key requirement for the industry. New drug discovery has to keep pace with the emerging pattern of diseases as well as responses in managing existing diseases where target organisms are becoming resistant to existing drugs. But it is an expensive activity and takes years to become a finished product with no guarantees of success for every molecule. Now, at least 10 Indian companies are involved in new drug discovery in the areas of infections, metabolic disorders like diabetes, inflammation, respiratory, obesity and cancer and many more are giving more focus on developing their research capabilities. Most of these companies have increased their R&D spending to over 5% of their respective sales turnovers.

There is notable success from some Indian companies in out licensing new molecules in the asthma and diabetes segments to foreign companies. Introduction of product patent for pharmaceuticals has also gained importance resulting in increased confidence of multi-national companies towards collaborative R&D for new drug discovery. Some Indian companies have also got USFDA approvals for their new molecules as innovative new drugs. What attract the multi-national companies is low cost scientific manpower, excellent infrastructure, reliable quality with capability to conduct modern research under good laboratory practice (GLP) and good clinical practice guidelines. Many of them have set up independent R&D centres also. Clinical trials conducted to establish safety and efficacy of drugs constitute nearly 70% of R&D costs. Considering the low cost of R&D, several multi-national companies as well as global clinical research organizations are increasingly making India a clinical research hub.

Contract manufacturing and research is expected to gain momentum going forward. India's competitive strengths in research services include English-language competency, availability of low cost skilled doctors and scientists, large patient population with diverse disease characteristics and adherence to international quality standards. Both global innovators and generic majors are finding it profitable to outsource production because of cost cutting requirements. This is a positive development for domestic manufacturers as India has the highest number of USFDA approved plants outside the US. Top multi-national companies like Pfizer, Merck, GSK, Sanofi Aventis, Novartis, and Teva are largely depending on Indian companies for many of their APIs and intermediates. The Boston Consulting Group estimated that the contract manufacturing market for global companies in India would touch US$900 million by 2010.

Biotech companies are seeking possible partnerships with overseas companies. At a time when pharmaceutical companies are finding it difficult to find takers for their molecules, the Biotechnology sector has gained more acceptability in this regard. Since biotech companies are relatively newer than the established pharmaceutical companies, they face cash crunch, especially for funding their research programs. MNCs stand to gain from this disadvantage to negotiate better valuations given that the biotechnology sector in India is fairly knowledge intensive.

Overall, the Indian industry is expected to grow at about 14% per annum in the next two to three years given its competitive advantage in terms of low cost manufacturing, chemical synthesis expertise, number of USFDA approved plants, new collaborations and contract research opportunities.

Industry and Economic Update has been prepared by ICRA Management Consulting Services Limited (IMaCS) for the Confederation of Indian Industry (CII).

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