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In Focus: “Opportunities in Indian Generic Market”

Introduction

A generic drug is a pharmaceutical drug which is produced and distributed without patent protection. A generic drug is bioequivalent to a drug that has a brand name, also called an innovator drug. It is intended to be interchangeable with an innovator product, which is manufactured without a license from the innovator company and marketed after the expiry date of the patent or other exclusive rights. A generic must contain the same active ingredients as the original formulation. According to the US Food and Drug Administration (FDA), generic drugs are identical in dose, strength, route of administration, safety, efficacy, and intended use. Generic drugs are marketed under a non-proprietary or approved name rather than a proprietary or brand name and are much cheaper than brand-name drugs. A brand name is a name given to a drug by the manufacturer. The use of the name is reserved exclusively to its owner.

Market Overview

The generic segment comprises drugs that are either not patented or the patent-expired ones. The market is generally led by increased outsourcing and a large number of drugs going off-patent. According to Cygnus estimates, the global generics market registered a growth rate of 13.35% in 2007 to reach US\$81.79 billion and will sustain the growth at a CAGR of 13.62% during 2006-10. India has strong presence in global generic market. In 2002, Indian companies accounted for less than 7% of all generic drugs approved by FDA for products marketing, but in 2006 they accounted for over 20%. Moreover,

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India's share in total DMF (Drug Master Files) filings has increased from 14% in 2000 to about 50% in 2007 (Jan-Jun). With regard to ANDA (Abbreviated New Drug Application) approvals, India's share has gone up from 15% in 2005 to about 25% in 2007 (Jan-Jun). As per IMS Health, the Indian generic manufactures will grow to more than US\$70 billion as drug worth approximately US\$20 billion in annual sales will face patent expiration in 2008. The Indian generic manufacturing companies are positioning themselves to take advantage of this situation.

India is expected to hugely benefit from the growth in this segment owing to its cost advantages, large number of FDA-approved manufacturing facilities and process chemistry skills. It has become a strategic necessity for global Pharma companies to make India an integral part of their manufacturing value chain to maintain lean cost structures and combat intense competition in the global generics industry. Global generic companies are increasingly aiming to leverage low-cost contract manufacturing facilities in countries such as India and China to speed up their time to market. Strategic agreements between companies operating in different countries are expected to provide benefits of synergy.

Factors Driving Generics Market in India

The Indian generics market is witnessing rapid growth with the opening of immense opportunities for Indian companies. Other important factors include the popularity of outsourcing non-critical business functions to India by MNCs, the reintroduction of product patents for pharmaceuticals, growing importance of R&D related to drug discovery, and the growing demand for generic drugs in developed markets.

Low production costs

India's competitive advantage lies in its lower production and research costs, its large pool of low-cost technical and scientifically-trained personnel, and the large number of FDA-certified plants. Low production costs give India an edge over other generics-producing nations, especially China and Israel. Indian companies are strongly positioned to grab the new opportunities in the generic drug market as they have the benefit of low-cost manufacturing, world-class production skills and availability of quality human resources. Domestic production costs in India are almost 50% less compared with developed countries. The Indian pharmaceutical companies have been doing extremely well in developed markets such as the US and Europe, notable among these being Ranbaxy, Dr. Reddy's Labs, Wockhardt, Cipla, Nicholas Primal and Lupin.

Drugs going off patent

Generic medicines are gaining significance with the increase in ageing population and the expensive drugs driving healthcare costs upwards. The governments are under tremendous pressure to reduce healthcare

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expenditure. In this scenario, generics are widely regarded as the best method to allow access to safe, effective and high quality drugs at affordable prices to a vast majority of patients. Prescription drugs worth US\$40 billion in the US and US\$25 billion in Europe are due to lose patent protection during 2005-2008. With the patent expirations of blockbuster drugs, Indian companies are expected to actively participate in the production of generic version of these products. Indian companies are also ready with generic version of biotech drugs.

Rising healthcare expenditure

BRIC countries (Brazil, Russia, India and China), supported by favourable economic conditions, are anticipated to foster growth in various sectors of the pharmaceutical industry, especially generics. In Asia Pacific, low purchasing capacity of the population and escalating healthcare spending are increasing the sales of generic drugs. Despite the differences in the healthcare delivery systems in various countries, rising healthcare costs is a common predicament that most governments face. Exploding healthcare costs and lack of affordable healthcare coverage will continue to affect the generic drug industry over the next few years. As the global population ages, many experts have predicted that healthcare costs are going to escalate further in the coming decades. Global healthcare costs are likely to triple in the next 15 years, which is likely to lead to more consumption of generics drugs. The US and Europe will continue to promote generics production, basically to overcome the rising healthcare expenses, and so will India.

Growing population

Asia's population is growing rapidly and aging at that. The limited purchasing power is fuelling demand for less expensive drugs. Currently, 25% of Asia's population is above 55 years. In the present scenario, there is no adequate governmental coverage for health insurance. Thus, majority of the population is shouldering the burden of healthcare costs. The low purchasing power of the majority of the population in developing Asian countries creates a situation for increased uptake of low-priced generic pharmaceuticals. The patent expirations will force generic manufacturers to replenish product pipelines with new generic versions. Generic business is a 'low price, high volume' model and high volume is the biggest attraction for the Asian countries, particularly India and China. The 70 million-strong middle class is expected to grow even faster, accounting for a higher share of total population. Increase in standard of living will lead to longer life expectancy and higher consumption of drugs and healthcare services.

Emerging lifestyle diseases

In the recent years, the focus on what are termed as "lifestyle diseases" has increased. Basically, lifestyle diseases (also called diseases of longevity or diseases of civilization) are diseases that appear to increase in frequency as countries become more industrialised and people live longer. These are diseases that occur

as a result of unhealthy lifestyle – sedentary habits or low physical activity, preference for unhealthy “junk foods” and indulgence in tobacco, alcohol and drug abuse.

Higher incidence of lifestyle diseases will increase the demand for biopharmaceutical products, which in turn will drive the demand for cheaper drugs. This will trigger the growth of generics drug manufacturing. Indian companies are poised to gain as they have world-class plants and formidable chemical synthesis skills to compete in the market.

Future Outlook

Generic drugs market is witnessing rapid growth, fostered by the need for providing low-cost alternative to expensive life saving drugs. The vast potential of this market is attracting multinationals to foray into the production and marketing of generic versions of patented pharmaceutical products. Increasing production of generics in developing countries, often involving patent violations, is allowing local consumers to gain access to drugs that were earlier out of reach for them. With several patents set for expiry in the near future, approximately US\$123 billion worth of generic products are at risk of losing the patent globally by 2012. Indian generics market accounts for around 15% of the patented drugs, which converts into an opportunity worth US\$31.2 billion.

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News Briefs

INTERNATIONAL

MARKETING

Americas

USA: NYC Health Department donates blood pressure monitors

As part of an awareness campaign for hypertension, the New York City Health Department has donated blood pressure monitors to pharmacies in areas where there are high rates of hypertension. The NYC Health Department purchased LC300 blood pressure monitors, which automate blood pressure and heart rate monitoring, from Burtonsville, Md-based Lifeclinic International. The monitors will be distributed and maintained by Lifeclinic's dealer, New York Blood Pressure, Inc, to pharmacies in east and central Harlem, the south Bronx and north and central Brooklyn. The business is about supporting programs such as this by providing state-of-the-art technology and solutions that enable individuals to become proactive in managing their own health, NYBP President said.

USA: Piedmont Healthcare launches US\$525m plan

Piedmont Healthcare will spend US\$525m over five years as it launches a bruising battle for market share in three high-octane medical services. The strategic plan, expected to generate up to 750 new jobs, involves muscling up Piedmont's cardiology, oncology and neuroscience services, CEO of Piedmont said. The company has planned to make the institutions a place, where the doctors can practice and patients want to come. Swooning reimbursement, new competitors and a slumping economy, however, could derail the Piedmont Express.

USA: Cincinnati's AssureRx forms partnership with Diamond Healthcare

Biotech Company AssureRx has entered a development/marketing partnership with Diamond Healthcare Corp of Richmond, Virginia, the country's largest privately held behavioural health and management consulting firm. Cincinnati-based AssureRx's personalised medicine platform, based on technology from the Mayo Clinic and Cincinnati Children's Hospital Medical Centre, helps physicians determine the right drug and right dose for patients suffering from behavioural health conditions. The relationship, the terms of which were not disclosed, will provide AssureRx access to Diamond's managerial and clinical expertise and industry relationships. It will accelerate the commercial introduction of AssureRx's first personalised medicine product, according to a press release. Studies of the AssureRx product with several large hospitals will start this quarter, and the company expects to begin commercial sales early next year.

Brazil to produce generic AIDS drug

Brazil's health minister says Latin America's biggest country will produce an inexpensive generic version of an AIDS drug made by Merck & Co. The company's CEO said the decision to produce efavirenz, a generic version of Stocrin, was taken because Merck refused to reduce its price. Production should begin in the first half of 2009. Last year, the Brazilian government rejected Merck's offer to sell the drug at a 30% discount - for US\$1.10 per pill, down from US\$1.57. The country was seeking to purchase the drug at US\$0.65 per pill, the same price Thailand pays. In May of 2007, Brazil bypassed the patent on efavirenz when the government issued a compulsory license, a legal mechanism that allows a country to manufacture or buy generic versions of patented drugs while paying the patent holder only a small royalty.

USA: Roxane Laboratories announces the launch of protriptyline HCl tablets, USP

Roxane Laboratories, a subsidiary of Boehringer Ingelheim, announced recently the approval of its abbreviated new drug application for protriptyline HCl tablets, USP, 5mg and 10mg. The product is available in bottles of 100 tablets for immediate shipment to wholesalers and pharmacies nationwide. Roxane Laboratories protriptyline HCl tablets, USP are AB rated to Vivactil (protriptyline HCl).

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Canada: Ambrilia Biopharma develops one-month formulation of goserelin

Ambrilia Biopharma has succeeded in manufacturing a final one-month formulation of goserelin intended for the treatment of prostate cancer and several gynecological indications. Ambrilia's goserelin formulations are indicated for hormone-sensitive prostate cancer and several gynecological indications such as fibro-myomas and endometriosis. President and CEO of Ambrilia Biopharma said, "With the addition of a one-month goserelin formulation we now offer to interested acquirers a complete generic Zoladex package which includes a potentially first-to-market three-month generic version. "This further enhances the value of the goserelin product offering focused on European market and maximises potential deal terms. All efforts are being made in order to conclude an agreement by the end of 2008."

USA: Pfizer to withdraw global marketing applications for Dalbavancin

Pfizer has announced that it will globally withdraw all Dalbavancin marketing applications for the treatment of complicated skin and skin structure infections in adults, including the US new drug application and the European marketing authorisation application. Dalbavancin, a member of the glycopeptide class of antibiotics, was acquired by Pfizer in September 2005 as part of its acquisition of Vicuron Pharmaceuticals. After careful consideration of feedback and ongoing dialogue with regulatory authorities, Pfizer has decided to study Dalbavancin further in patients with complicated skin and skin structure infections.

USA: Xoma wins US\$65m federal contract for botulism drugs

Xoma announced that it has been awarded a US\$65m multiple year contract from the National Institute of Allergy and Infectious Diseases, a component of the National Institutes of Health, to support the company's ongoing development of drug candidates towards clinical trials in the treatment of botulism poisoning, a potentially deadly muscle paralyzing disease. This award furthers Xoma's plans to develop anti-botulism antibody products to protect against natural, accidental or intentional human exposure to botulism. The project is fully funded under federal contract and Xoma expects to receive US\$65m in revenues as work is conducted over a six-year period.

USA: Gliknik locks up licenses to develop cancer drugs

Gliknik, a Baltimore biotechnology firm, has secured the rights to develop two cancer vaccines. The biotech firm, creating drugs for autoimmune diseases and cancer, reached an agreement with the University of Maryland, Baltimore and the Mayo Clinic for the drugs, which are now in clinical trials for head and neck cancer. "We are encouraged by the novelty and clinical trial results to date of the drug candidates and pleased to become a clinical stage development company early in the progress of the company's growth," said CEO of the company.

USA: Dr Reddy to enter US specialty business through its subsidiary Promius Pharma

Dr Reddy's Laboratories has set up a wholly owned subsidiary Promius Pharma in US to undertake specialty business. The subsidiary will initially focus on the branded dermatology market and it is based on a platform of strategic licensing initiatives and internal product development activities. Its product portfolio currently comprises of there in-licensed and co-developed dermatological products that are scheduled to launch within calendar years 2008-09. The company is committed to establish a leading position in the US dermatology market by providing innovative solutions to patients and physicians that leverage Promius Pharma's current portfolio and future additions.

Europe**UK: HC&B Healthcare Communications expands to London**

Seven years after it launched as a multi focus advertising agency, HC&B Healthcare Communications has zeroed in on the medical industry across the United States and is looking to capture that sector's growth in Great Britain. Austin-based HC&B's first satellite office has opened in London. Many clients have worldwide operations and require partners who can operate effectively on an international scale, HC&B President said. Strengthening its global capabilities will help the company better serve it's existing and future clients. Being based in Austin also enables the advertising firm to bring the latest technology platforms to its clients — an attractive attribute in the rapidly growing medical sector.

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Denmark: Basilea's eczema drug wins marketing approval

Basilea Pharmaceutica had announced that Toctino, a new once-daily oral treatment for adults with severe chronic hand eczema unresponsive to potent topical corticosteroids, has received approval from the Danish Medicines Agency. Marketing applications for the use of Toctino (alitretinoin) in the treatment of severe chronic refractory hand eczema are also under regulatory review in Canada and in Switzerland.

Germany: Bayer to launch thinnest needle Betaferon for MS patients in US

Bayer will launch a 30-gauge needle for its multiple sclerosis (MS) treatment Betaferon (interferon beta-1b) in the US. This will be the thinnest needle of any injectable disease-modifying therapy for people with MS. The needle is as thin as those commonly used for insulin and paediatric injections. Betaferon (Interferon beta-1b), marketed as Betaseron in the US and Canada, was the first MS medication with proven efficacy on the underlying course of the disease. It is indicated for the treatment of relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations.

INVESTMENTS**Americas****USA: Frost Group invests US\$10m in Seattle biopharma company**

Cocrystal Discovery, a Seattle-based privately held biopharmaceutical company, has completed a US\$10m private placement with an investor group led by Phillip Frost. The company will focus initially on hepatitis and influenza, diseases that affect millions of people in both developed and underdeveloped countries. Since its formation in October 2006, the Frost Group has invested more than US\$160m in various companies and technologies in the U.S. and other countries.

Asia Pacific**India: Cipla to invest Rs8bn for SEZ**

Cipla has drawn up a Rs20 billion capex over the next two years, a top company official said recently. Significant investments have been made and utilised in expansion of facilities and creation of new plants. The company will continue to pursue an aggressive expansion policy to cater to the increased volume growth, both locally and internationally, MD said, adding that the company expects a 12-15% growth in sales in 2008-09. Investments of Rs1-1.5 billion each have been made in the Patalganga and Kurkumbyh units. Over Rs300m has been invested in Bangalore while Rs2 billion has been invested in a plant in Sikkim which is already in production. He said Rs8 billion will be spent on its new facility at the Indore SEZ plant. The company is expecting to maintain their leading position in the domestic market and also keep up the momentum on the export front. Exports will go up to 60% from the present 50%.

MERGERS & ACQUISITIONS**Americas****USA: Rockdale Medical Centre inks sale to LifePoint**

LifePoint Hospitals Inc will buy Rockdale Medical Centre (RMC) in metro Atlanta in a deal worth up to US\$110m. LifePoint's offer includes an US\$80m price tag and US\$30m in new capital over the next six years. The deal still needs the review and approval of the state of Georgia. RMC is a non-profit community-owned hospital with 138 beds in Conyers, Georgia, that provides acute care, diagnostic, emergency and outpatient services. It put itself on the market after having difficulty with debt from the recent expansion of the hospital. Corporates believe that this partnership will enable the hospital to surmount the difficulties all standalone community hospitals face in today's challenging healthcare environment and continue to provide the best healthcare possible to the citizens of Rockdale County.

USA: Antares Pharma signs development agreement with Dr Reddy's

US-based specialty pharmaceutical company Antares Pharma has signed a development agreement with Dr Reddy's Laboratories for the development of an innovative, topically applied product, using Antares's ATD gel platform, targeting specific receptor sites within the skin. As part of the overall understanding between the parties, Antares will be responsible for development and commercial manufacturing of the

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product and Dr Reddy's will be responsible for clinical development and marketing. Dr Reddy's will market the product through Promius Pharma, its US based specialty dermatology business, upon final approval.

USA: Dr. Reddy's signs agreement with Cosmederm Tech

Dr. Reddy's Laboratories Ltd has announced a licensing and distribution agreement with Cosmederm Technologies, a US based specialty pharmaceutical company focused on dermatology and aesthetic medicine. The agreement grants Dr. Reddy's exclusive rights to distribute Cosmederm Technologies unique skin care products throughout India. Through this partnership Dr. Reddy's enters the aesthetic dermatology segment and consolidates its position in cosmeceuticals. The company is very excited to offer these unique products throughout the Indian market and expects the lines to quickly become leaders in the area of chemical peels and anti-aging.

USA: Shionogi acquires US-based Sciele Pharma

Shionogi & Co, Ltd and US-based Sciele Pharma, Inc have signed an agreement under which Shionogi will make a cash tender offer for Sciele shares and subsequently acquire Sciele by executing a cash merger. Under the terms of the agreement and pursuant to a tender offer, Shionogi intends to acquire through a wholly-owned US subsidiary all of the outstanding shares of Sciele's common stock at a price of US\$31 per share, for a total purchase price of approximately US\$1.1 billion. Upon completion of the acquisition, Sciele will become an indirect wholly-owned subsidiary of Shionogi and will continue operations in Atlanta, GA as a standalone business unit. This acquisition is subject to clearance under the Hart-Scott-Rodino Antitrust Improvement Act and other customary conditions. This transaction will not result in any reduction of Sciele employees.

USA: Actis Biologics completes two acquisitions in US

Actis Biologics Pvt Ltd, the Mumbai-based biotech research and technology incubator company, has acquired patented technology platform for effective treatment of hepatic cancer, from CellPoint Diagnostics, USA. This platform technology is based on Ligand Linker Drug Delivery [LLD] system, and can be of tremendous value in reducing the toxicity of chemotherapeutic agents. In this mode of therapy, the attached Ligand directs the chemotherapeutic agent like 5FdU to the target cell, and so the drug is delivered to malignant cells through the hepatic asialoglycoprotein receptors, where it only affects rapidly growing cells, namely cancer cells. This mode of action explains the low toxicity of the drug. This spacer is designed in such a way that it delivers about 40% more drug to the patient than from the leading spacers available in the market.

HUMAN RESOURCES

Americas

USA: United Healthcare says job cuts won't stop its plans to expand local business

United Healthcare's work force reduction will have virtually no impact in the Pittsburgh area, where the insurer continues to try to make inroads, company officials said. The Minnetonka, Minn-based company had announced a nationwide work force reduction of 4,000 employees, or almost 6%, which includes only one person in Pennsylvania. As part of the downsizing, the company reduced its reliance on contracted workers and moved some employees into units that are growing, according to company sources. The insurer employs some 2,400 people statewide including an estimated 800 employees added with United Healthcare's acquisition of Unison Health Plan. The deal was completed in June.

USA: HR Policy Association Certifies Pharmacy Benefit Managers

HR Policy Association announced recently it has certified 3 new pharmacy benefit managers (PBMs) and recertified 12 PBMs that have agreed to do business in a fully transparent manner. The certified and recertified PBMs are Aetna Pharmacy Management, Blue Cross and Blue Shield of Alabama, CVS Caremark, Express Scripts, Inc, Humana Pharmacy Solutions, informedRx, an SXC company, Medco Health Solutions, MedImpact Healthcare Systems, Inc, Prescription Solutions, Prime Therapeutics, LLC ProCare Rx, RESTAT LLC, United Health Pharmaceutical Solutions, Walgreens Health Initiatives, Inc.

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WellPoint NextRx. These PBMs have committed to meet the HR Policy Association Pharmaceutical Coalition's standards, which provide employers with the most rigorous level of drug purchasing transparency available in the marketplace.

RESEARCH & DEVELOPMENT

Americas

USA: First Coast Oncology to offer proton therapy

First Coast Oncology had started offering the proton therapy services to its patients in the region. The oncology group will add the Monarch250 Proton Therapy from Still River Systems Inc at its Mandarin location. The addition will make First Coast Oncology the first private practice in the Southeast to add this treatment to its comprehensive cancer treatment. The Monarch250 is a compact system that offers precise, non-invasive treatment at a much smaller scale than larger systems like the University of Florida Proton Therapy Institute, which boasts four proton therapy rooms. This is available only because of recent developments in super technology, medical director said at First Coast Oncology. First Coast Oncology invested about US\$30m in the project and hopes to be able to treat about 30 patients per day once the unit is operational in early 2011.

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USA: Neurotech wins fast track designations for intraocular drug

Neurotech Pharmaceuticals, a biotechnology company focused on the development of sight-saving therapeutics for chronic retinal diseases, has announced that the FDA has granted fast track designations for NT-501 for the treatment of visual loss in two indications - retinitis pigmentosa and the dry form of age-related macular degeneration. NT-501 is an intraocular, cell containing polymer implant designed to provide continuous, long-term release of the therapeutic protein ciliary neurotrophic factor directly into the back of the eye by means of the company's proprietary encapsulated cell technology. The company's CEO said that the receipt of fast track designations for NT-501 in these indications is an important component in the ongoing product development strategy, allowing them to potentially accelerating their two clinical development programs to provide much needed treatment options for patients facing these devastating diseases.

USA: Algeta's pain palliation drug Alpharadin meets endpoint in Phase II trial

Algeta ASA, the Norwegian cancer therapeutics company, has announced the primary objective of its BC1-03 Phase-II pain palliation study was met. The study showed that even single doses of Alpharadin in patients with painful bone metastases could produce increasing clinical benefit with increasing dose. Pain palliation is an important quality of life benefit in metastatic cancer patients. The trial also confirmed Alpharadin's benign side-effect profile and, importantly for a drug in this clinical setting, no significant bone marrow toxicity was observed. This international study will evaluate Algeta's targeted therapeutic Alpharadin in advanced, hormone-refractory prostate cancer (HRPC) that has metastasized to the skeleton. Approximately 750 patients are expected to be enrolled at more than 125 medical centres in Europe, Asia, South America and Canada.

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USA: Cell Therapeutics receives FDA nod for submission of lymphoma drug sBLA

Cell Therapeutics, Inc has announced that following a meeting with the U.S. Food and Drug Administration (FDA) data from the First-line Indolent Trial (FIT) would be sufficient to support a submission for a supplemental Biologics License Application (sBLA). The sBLA will propose a label expansion to include use of the Zevalin therapeutic regimen ([90Y]-ibritumomab tiuxetan) as consolidation therapy after remission induction in previously untreated patients with follicular non-Hodgkin's lymphoma. The Company plans to submit the sBLA in the fourth quarter and request priority review, which if granted, would result in a six month review period. CTI gained access to the FIT data through an agreement with Bayer Schering Pharma who used the data to obtain approval for Zevalin as first-line consolidation treatment in Europe.

Europe**Switzerland: Glenmark files molecule for Phase I trials**

Glenmark Pharmaceuticals had announced that it has filed its molecule GBR 500 for Phase I trials with the USFDA. The filing of this crucial IND (Investigation New Drug Application) signifies the successful molecule, GBR 500, a monoclonal antibody, is an antagonist of the VLA-2 (Alpha2 Beta 1) integrin. The company expects to complete Phase I trials for GBR 500 in this financial year immediately followed by several proof of concept Phase IIA studies in patients with multiple sclerosis and another common human inflammatory disease. The company is excited about the progress that they made with the antibody. The company also has completed preclinical data package at hand to present to the FDA. The company is very much looking forward to bringing this molecule into the clinic, President, Biologics, Glenmark said.

Germany: Bayer Group scientists receive 'Otto Bayer Medal' award for outstanding research

Scientists working for the Bayer Group have been awarded the 'Otto Bayer Medal' for their excellent achievements in three research projects. The award of the Otto Bayer Medal is much more than just a symbolic gesture. It is an element of our corporate and research culture, a culture that promotes creativity and innovation, supports achievement, and rewards success, said the Board member responsible for research. This prize is awarded for successful research work related to new products or applications and new developments for future markets. Werner Wenning, chairman of the Board of Management of Bayer AG, and Dr Wolfgang Plischke, the member of the Bayer Board of Management responsible for innovation, technology and environment, presented the awards to the winners at a ceremony held in the Palladium in Cologne in September 2008.

PATENTS**Americas****USA: Formatech awarded patent for new drug formulation**

Formatech, a provider of contract development services for pharmaceutical companies, has received a new US patent which covers novel formulation methods to enhance the solubility of hydrophobic compounds. According to the company, the patented technology effectively solubilizes pharmaceutical compounds in micellar formulations containing fatty acids or fatty alcohols. The CEO of Formatech said that this novel technology is ideal for application to commercially successful drugs that call for a safer, more effective drug product formulation, including Taxotere, Taxol, Diprivan and Cyclosporin. The formulation technology is also applicable to many novel hydrophobic pharmaceutical compounds and new chemical entities.

USA: Trubion wins patent opposition against Genentech and Biogen Idec

US-based biopharmaceutical company Trubion Pharmaceuticals has announced that the opposition division of the European Patent Office has revoked Genentech and Biogen Idec's European patent, in its entirety. This patent was generally directed to the use of an anti-CD20 antibody for the treatment of rheumatoid arthritis. Trubion's CEO said, "We are extremely pleased with the European Patent Office's decision as it supports the continued development of new and innovative therapies that have the potential to improve patient outcomes for autoimmune and inflammatory diseases. Continued innovation will ultimately provide patients with more effective, convenient, and safer therapies."

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USA: Ocimum granted new US patent for molecular toxicology

Ocimum Biosolutions, an integrated genomics company, received new US patent that describes elucidation of the global changes in gene expression and identification of toxicity markers in tissues or cells exposed to a known renal toxin. The invention includes a database of genes characterised by toxin-induced differential expression that is designed for use with microarrays and other solid-phase probes. CEO of Ocimum Biosolutions said that the company has consistently been in the forefront of genomics innovation over many years and this patent reiterates the strong commitment to continue as a leader in this space

USA: Claris Lifesciences and Xcleris Labs files a Joint Patent in Biotherapeutic Protein

Claris Lifesciences has filed its first Patent Co-operation Treaty (PCT), for Novel Delivery of a Biotherapeutic Protein, in collaboration with Xcleris Labs, a specialty contract research organisation. The filing, which comes within a short time of Claris foray into the sunrise sector of Biotechnology, is a significant breakthrough for the Company. The PCT is distinctly different from a regular patent application which is a global application, granting the Applicant rights over the product, all over the world. With biotechnology being billed as the future of pharmaceuticals, the company's strategy as a pharma major is to consistently orient and dedicate towards building on the existing niche areas, which is the injectable domain and at the same time, extending efforts and expertise into naturally synergistic, high potential segments like biotechnology, Claris Lifesciences, said the CEO Claris Lifesciences.

POLICY/ REGULATIONS**Asia Pacific****India: Pharma Dept prepares scheme to set up generic drug store in each district**

The Department of Pharmaceuticals has drawn up a scheme to set up generic drug stores in each district of the country to ensure affordable medicines to the poor sections of the society. The department has prepared the draft of the scheme, which is also likely to give boost to the manufacturers of unbranded generic drugs, and it is launching consultations with the industry including suppliers. The meeting will suggest the modalities to facilitate the sales of unbranded generic medicines in different districts and government hospitals primarily for the poor people, sources said. The government will be seeking the support of the industry, especially the manufacturers of generic drugs for production of essential medicines that would be sold through these planned stores. Besides, the government would also consult chemist associations and NGOs to take their suggestions.

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CORPORATE

Americas

USA: Mylan wins FDA approval for generic Risperdal tablets

Mylan Inc has announced that its subsidiary Mylan Pharmaceuticals Inc has received final approval from the FDA for its abbreviated new drug application for risperidone tablets USP, 0.25mg, 0.5mg, 1mg, 2mg, 3mg and 4mg. Risperidone tablets, used to treat schizophrenia and bipolar disorder, are the generic version of Janssen's Risperdal tablets. Mylan will ship the product shortly. Currently, the company has 109 abbreviated new drug applications pending FDA approval, 22 of which are potential first-to-file opportunities.

USA: Alte Bioscience files patent for new inflammatory bowel disease drugs

Alte Bioscience, a development stage pharmaceutical company, has filed a provisional patent for a new class of drugs that may benefit patients with inflammatory bowel disease. Pharma Directions, under contract to Alte Biosciences, developed these molecules to treat inflammatory bowel disease (IBD). Each molecule consists of two mutual pro-drugs that release medicines that are well known in the treatment of IBD. Pharma Directions will develop specialised formulations to deliver these molecules in ways that will improve their anti-inflammatory, anti-microbial and cytoprotective properties. The company's CEO stated that they were pleased that their research efforts resulted in the identification of new chemical entities that have the potential to benefit patients with inflammatory bowel disease.

USA: Barr Receives Approval for Generic Version of Razadyne(R) ER Capsules

Barr Pharmaceuticals, Inc. recently announced that its subsidiary, Barr Laboratories, Inc., received final approval from the USFDA to manufacture and market a generic version of Ortho McNeil Janssen's Razadyne (R) ER (galantamine hydrobromide extended release capsules), equal to 8mg, 16mg and 24mg. Barr also announced that it is the first company to file an Abbreviated New Drug Application (ANDA) with the U.S. Food & Drug Administration (FDA) containing a Paragraph IV certification for a generic version of Razadyne ER capsules, and therefore is entitled to 180-days of marketing exclusivity, as provided for under the Hatch Waxman Act. The Company intends to launch its product shortly.

USA: Pro-Pharma gets FDA nod for Davanat combo for breast cancer

Pro-Pharmaceuticals, Inc has announced that the US Food and Drug Administration (FDA) has granted an Investigational New Drug application for use of Davanat in combination with 5-FU to treat a breast cancer patient at the Brown Cancer Centre in Louisville, Kentucky. Davanat is also being administered in Phase II clinical trials for first-line treatment of colorectal and biliary cancer patients. Davanat is a proprietary carbohydrate drug that is administered with chemotherapies and biologics to treat cancer.

USA: Oculus launches topical wound drug in China

US-based biopharmaceutical company Oculus Innovative Sciences had launched its Dermacyn product in China through one of its Chinese distributors, Sinopharm. According to the company, Dermacyn is a topical formation based upon the Microcyn technology platform that is capable of producing a potent broad-spectrum antimicrobial designed to treat a wide range of pathogens, including viruses, fungi, spores and antibiotic-resistant strains of bacteria such as Methicillin-resistant Staphylococcus aureus and Vancomycin-resistant Enterococcus, all of which cause disease or inhibit the healing in both acute and chronic wounds.

Europe

France: Merck wins EU positive opinion for new formulation of diabetes drug

Merck Serono, a division of Merck KGaA, Darmstadt, Germany, has announced that Glucophage powder for oral solution in sachet - metformin hydrochloride in 500mg, 850mg and 1000mg strengths - has received a positive opinion recommending approval for the first-line treatment of type 2 diabetes through a decentralised procedure with France as the reference member state. This will be rolled out in the coming months following the delivery of the national marketing authorisations. The company's CEO said, "The new formulation of Glucophage powder for oral solution in sachet allows for a rapid dissolution of the drug. It has been developed to offer patients a convenient alternative to tablets."

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Asia Pacific

India: Star Health, Sankara Nethralaya to offer eye care

Star Health & Allied Insurance Company is planning to launch a health insurance product called Eye Care for eye diseases. This is in association with Chennai-based eye hospital Sankara Nethralaya. It will be a co-branded product.

India: Dr Batra to set up 10 new centres across globe

The Mumbai based leading homeopathy clinics chain Dr Batra's Positive Health Clinic Private Limited (DBPHCPL) is expanding its presence in domestic as well in the international market. The company has planned to invest Rs60m for setting up 10 new centres. All the centres are expected to become operational by the current fiscal. Recently, DBPHCPL has opened world's first tele-homeopathic clinic at its newly opened 55th multi-speciality clinic at Mumbai. With the help of this facility, Dr Batra can continue to enhance its expertise in homeopathic healthcare to benefits patients across globe. The company is also planning to enter into the skin care market. At this moment five to seven products are under different stage of completion at the manufacturing unit in Mumbai

India: Aurobindo Pharma gets nod for Abacavir Sulfate / Lamivudine tablets

Aurobindo Pharma has received the tentative approval to manufacture and market Abacavir Sulfate / Lamivudine tablets 600mg/300mg from the US Food & Drug Administration (USFDA). Abacavir Sulfate / Lamivudine tablets 600mg/300mg are the generic equivalent of Epzicom tablets 600mg / 300mg of SmithKline Beecham Corporation and falls under the Anti Retro Viral (ARV) segment. This product has been reviewed under the President's Emergency Plan for AIDS Relief (PEPFAR). This is Aurobindo's 76th ANDA approval from USFDA.

India: Cadila gets USFDA nod for Ramipril capsules

Zydus Cadila has received an approval from the USFDA to market Ramipril capsules in the strengths of 1.25mg, 2.5mg, 5mg and 10mg. The drug falls in the ant-hypertensive segment. The sales of Ramipril capsules as per NDC were estimated at US\$1.06 billion. The group now has 41 approvals and has so far filed 79 ANDAs since the commencement of filing process in the FY04.

India: Strides Arcolab wins USFDA approval for two new drugs

Strides Arcolab has received two ANDA approvals for Dexamethasone Injection USP, 4mg/ml, and Dexamethasone Sodium Phosphate Injection USP, 10mg /ml. The products are licensed to Akorn-Strides LLC, which is a Joint Venture that was formed in 2004 by Akorn Inc and the company, Strides Arcolab said.

India: Aurobindo gets tentative nod for hypertensive drug

Aurobindo Pharma has received a tentative approval from the US Food & Drug Administration (USFDA) to manufacture and market Losartan Potassium tablets in the strengths 25mg, 50mg and 100mg. Losartan Potassium tablets are the generic equivalent of Merck Research Laboratories' Cozaar tablets 25mg, 50mg and 100mg and falls in the anti-hypertensive segment. The branded sales of Losartan range of products was US\$1.23 billion for the year ended December 2007, according to Merck Financial Disclosures. This is Aurobindo's 75th ANDA approval from USFDA.

India: Unichem Lab gets USFDA approval for Hydrochlorothiazide tab

Unichem Laboratories Ltd has received an approval from the US Food & Drug Administration (FDA) for Hydrochlorothiazide tablets in the strengths of 25mg and 50mg.

India: Dr Reddy's wins FDA approval for dementia drug

Indian-based pharmaceutical company Dr Reddy's Laboratories has announced that its US subsidiary has received tentative approval from the FDA for galantamine hydrobromide tablets in the strengths of 4mg, 8mg and 12mg. Galantamine hydrobromide is indicated for mild to moderate dementia associated with Alzheimer's disease.

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TRADITIONAL SYSTEMS OF MEDICINE

Asia Pacific

China: Tianyin Pharmaceutical wins Chinese approval for asthma drug

Tianyin Pharmaceutical, a manufacturer and supplier of modernised traditional Chinese medicine based in Chengdu, China, has received approval from the Chinese State Food and Drug Administration to produce Laonian Kechuan tablets in the dosage form of 0.25 gram/tablet. Tianyin said that Laonian Kechuan tablet is a traditional Chinese medicine drug that effectively treats asthma in people aged 60 or above. The company plans to launch Laonian Kechuan tablets in the domestic market and begin recording revenue in November 2008. The company maintains the capacity to produce approximately one million tablets of this product monthly. As China's elderly population is rising so rapidly, the company anticipates this new drug will be another significant contributor to growth of the revenue and net income.

China: Genesis Pharmaceuticals receives US\$12m new purchase orders

Genesis Pharmaceuticals Enterprises, a pharmaceutical company in the People's Republic of China, has received purchase orders for a total value of approximately US\$12m over the next 12 months from over 800 wholesale distributors. According to the company, Radix Isatidis dispersible tablets, a herbal-based traditional Chinese medicine, received the highest number of orders, over 60% of the total value of the purchase orders. The company's CEO said the company believes in new purchase orders from the distributors and it will increase the presence in the Chinese over-the-counter pharmaceuticals market. He said the company will expand the market share and get even greater brand recognition in China in the future by bringing new and innovative products to market.

FINANCE

USA: Sagent secures additional US\$30m in Series A financing

US-based specialty injectables company Sagent Pharmaceuticals has closed a US\$30m extension to the US\$53m Series A financing of 2007. The round was led by Vivo Ventures. Proceeds from the financing will be used to fund near-term product launches, product development activities and strategic business initiatives. The CEO of Sagent Pharmaceuticals said that this additional financing round would allow to advance the additional products to market and to avail the discovered product acquisition opportunities.

OTHERS

Americas

USA: Stark introduces new healthcare IT bill

Congressman Pete Stark (D-Calif) and eight co-sponsors introduced the Health-e Information Technology Act 2008. The bill is designed to promote the adoption and meaningful use of health information technology. The bill builds on measures already proposed in the PRO (TECH) T Act, H.R. 6357, introduced by John Dingell (D-Mich) and under consideration by the House Energy and Commerce Committee. Stark's new bill includes measures that would provide clear deadlines and standards to spur development of healthcare IT systems, incentives to drive healthcare IT adoption and strong rules to protect the privacy of personal health information. According to Electronic Health Records Association chairman, there are some good points in the bill around HIT adoption incentives and the privacy and consent language is much better than the PRO (TECH)T Act.

USA: Experts push transparency, P4P, and healthcare IT for healthcare reform

Transparency in healthcare, pay-for-performance (P4P) and healthcare IT are among the top ways of the country could overhaul its healthcare system to not only improve care, but also reduce costs. At a Senate Finance Committee, providers and experts from the private sector urged the federal government to take the lead on reform. The government should create comparative performance information not just for providers, but for treatments that will be used in payment and incentives. The government should also rebalance medicare payments to reward care coordination, and establish a new payment review process

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under the Centers for Medicare & Medicaid Services that is physician-informed and patient-centered, executive vice president of clinical health policy said. The chief medical officer at WellPoint, Inc said this type of healthcare reform will call for widespread adoption of healthcare IT and e-prescribing.

USA: Medical Home model receives US\$1.7m shot in the arm

The Johns Hopkins Bloomberg School of Public Health will apply a US\$1.7m grant to help primary care practices boost care for older patients with chronic illnesses. Older adults with chronic conditions are a critical and growing medical challenge in need of new solutions, said Charles E Boulton, MD. If this demonstration is successful, the medical home could become the new standard for treating the chronically ill. With funding from the Hartford grant, the Lipitz Centre will develop and provide primary care practices with online courses for physicians and nurses, a practice implementation manual and technical assistance in meeting the Medicare Medical Home Demonstration's requirements. The centre will team with the American Academy of Family Physicians/TransforMED, the American College of Physicians, the Medical Group

Asia Pacific

India: Government needs to build on capacities created in health sector: PM

The Universal Health Insurance Scheme (UHIS), to cover 1m people from families below the poverty line, has been liberalised further to take medical care to rural India, according to the Indian Union Finance Minister. Medical insurance is now available for a small premium. For an individual, the annual premium under the UHIS has been reduced to Rs300 from Rs365; for a family of five, it is reduced to Rs450 from Rs548; and for a seven-member family, it is to Rs600 against Rs730 earlier. Addressing the launch of Apollo Reach Hospitals, a chain of hospitals planned in rural and semi-urban centres, the minister said the centre has also decided to increase the age limit eligible for cover under UHIS to 70 years from 65 previously. The premium will include pre-existing diseases, which were not covered till now. The policy will also be extended to maternity cases.

India: SBI offers loans for heart patients

There is now a bank loan for poor heart patients. The SBI launched its new loan product, said to be the first of its kind, on a pilot scale. SBI Hrudaya Suraksha is currently available to those being treated at Narayana Hrudayalaya Health City in Bangalore. The loan amount will cover 80% of the total medical expenditure or Rs50,000 whichever is lower. There is no collateral on the loan sanctioned jointly in the names of the patient and spouse or kin. The amount is to be repaid within six months. The bank will charge an interest of 8.5% on the loan and aims to disburse the loans the same day through its new branch at the hospital. The hospital will pay the interest for the first three months. Narayana Hrudayalaya treats many patients via telemedicine, would consider a 5,000-bed health city in Dhaka with Grameen Bank's help, combining micro credit and a network of primary health centre.

Ayurveda Siddha Unani Drug Manufacturers Association urges PCI to include ISM as part of syllabi for Pharm D course

The manufacturers, traders, research scholars and traditional doctors of the Indian Systems of Medicines in Tamil Nadu have demanded that manufacturing and regulatory systems of Ayurveda, Siddha and Unani should be incorporated in the syllabi of the advanced Pharm D course starting from this academic year. Regarding the issue, Vijay A.Mehta, president of Ayurveda, Siddha and Unani Drug Manufacturers Association (ASUDMA) has approached the Pharmacy Council of India and the Union Health Ministry.

PCI approves four more colleges to start pharma D course

The Pharmacy Council of India has given approval to four more colleges to start the advanced Pharma D course from this academic year by bringing the total number of colleges selected for the programme to 26, according to Dr Suresh, president of the PCI. They are KLE College of Pharmacy-Belgaum, Vinayaka Missions's College of Pharmacy-Salem, Bharti Vidyapeeth University-Pune and Shri Ramnath Singh Institute of Pharmaceutical Sciences & Technology- Gwalior. Earlier the Council had given green signal only to 22 colleges in various parts of the country to proceed with the new programme this year.

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All India Council Technical Education to allow private pharmacy colleges to hike seats for B Pharm from 60 to 90

The All India Council for Technical Education (AICTE) is learnt to have decided to give permission to hundreds of private pharmacy colleges in the country to increase the number of student intake in the pharmacy colleges from the existing 60 to 90 students for B Pharm course. However, the AICTE did not take a final decision on the private pharmacy colleges' demand to increase the number of student intake for the M Pharma course.

Product Focus – Paroxetine Hydrochloride (Paxil)

Introduction

Paroxetine (trade names- Seroxat, Paxil, Parotin, Aropax, Xetanor, ParoMerck, Rexetin) is a selective serotonin reuptake inhibitor (SSRI) antidepressant. It was released in 1992 by the pharmaceutical company GlaxoSmithKline. In 2006 it was the fifth-most prescribed antidepressant in the United States retail market, with more than 19.7m prescriptions. The prescription of this drug is controversial because of side effects such as suicidal ideation (thoughts of suicide) and withdrawal syndrome which have resulted in legal proceedings against the manufacturer.

Paxil has also been approved as treatment for obsessive-compulsive disorder. Obsessions are recurrent and persistent thoughts that are intrusive and inappropriate, as well as distressing or anxiety-provoking. Compulsions are repetitive behaviours such as hand-washing or mental acts such as repeating words silently, and are aimed at reducing the distress or preventing some dreaded event.

How anti-depressants work

Selective Serotonin Reuptake Inhibitors (SSRIs) affect the brain's use of the neurotransmitter chemical serotonin, which is thought to have a role in regulating body heat. Increased serotonin use by the brain can also improve pre-menopausal mood swings and irritability.

Pharmacology

Paxil is an orally administered psychotropic drug. It is the hydrochloride salt of a phenylpiperidine compound. The molecular weight is 374.8 (329.4 as free base). Paroxetine hydrochloride is an odourless, off-white powder, having a melting point range of 120° to 138° C and a solubility of 5.4 mg/mL in water.

Paroxetine is the most potent and one of the most specific selective serotonin (5-hydroxytryptamine, 5-HT) reuptake inhibitors (SSRI). This activity of the drug on brain neurons is thought to be responsible for its antidepressant effects.

Tablets

Each film-coated tablet contains paroxetine hydrochloride equivalent to paroxetine as follows: 10mg–yellow (scored); 20mg–pink (scored); 30mg–blue, 40mg–green. Inactive ingredients consist of dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, polyethylene glycols, polysorbate 80, sodium starch glycolate, titanium dioxide, and one or more of the following: D&C Red No. 30, D&C Yellow No. 10, FD&C Blue No. 2, and FD&C Yellow No. 6.

Contraindications

Do not take paroxetine if the person is taking a monoamine oxidase (MAO) inhibitor (isocarboxazid [Marplan], phenelzine [Nardil], selegiline [Eldepryl], tranylcypromine [Parnate], or linezolid [Zyvox]) in the past two weeks. Do not start taking an MAO inhibitor within two weeks of stopping paroxetine. If it persists, it may develop confusion, agitation, restlessness, stomach or intestinal symptoms, sudden high body temperature, extremely high blood pressure, or severe convulsions.

Classification

Brand Name	Paxil
Generic Name	Paroxetine Hydrochloride
Therapeutic Class	Antidepressants
Manufacturer	GSK

Source: Cygnus Research

Other Brands of Paroxetine Hydrochloride

- Pexeva
- Paroxetine
- Paxil CR Controlled-Release Tablets
- Paroxetine
- Pexeva
- Paxil
- Paroxetine
- Paroxetine

Source: Drugs.com; Cygnus Research

Commonly Observed Adverse Events

- Major Depressive Disorder
- Obsessive Compulsive Disorder
- Panic Disorder
- Social Anxiety Disorder
- Generalized Anxiety Disorder
- Posttraumatic Stress Disorder
- Major Depressive Disorder

Source: rxlist.com; Cygnus Research

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Paroxetine may cause a serious condition called Serotonin Syndrome when taken with certain medicines such as linezolid (Zyvox), lithium, tryptophan, St. John's Wort, or some pain medicines (tramadol [Ultram], sumatriptan [Imitrex], zolmitriptan [Zomig], or rizatriptan [Maxalt]).

Side Effects

Get emergency medical help if the person has experienced any of these signs of allergic reaction,

- Skin rash or hives
- Difficulty breathing
- Swelling of your face, lips, tongue, or throat

Contact the physician promptly if the person has the following side effects, especially if they are new symptoms or if they get worse: mood changes, anxiety, panic attacks, trouble sleeping, irritability, agitation, aggressiveness, severe restlessness, mania (mental and/or physical hyperactivity) and thoughts of suicide or hurting themselves.

Most Common Side Effects

Weight loss or gain; Headache

Nausea; Dry mouth

Increased sweating

Drowsiness/Somnolence or Insomnia

Increased or decreased appetite

Constipation or Diarrhoea

Inability to achieve orgasm, manifested at low dosage as diminishment of premature ejaculation

Partial or complete loss of libido (sexual desire)

Erectile dysfunction; Tremor

Vertigo/Dizziness/Motion sickness

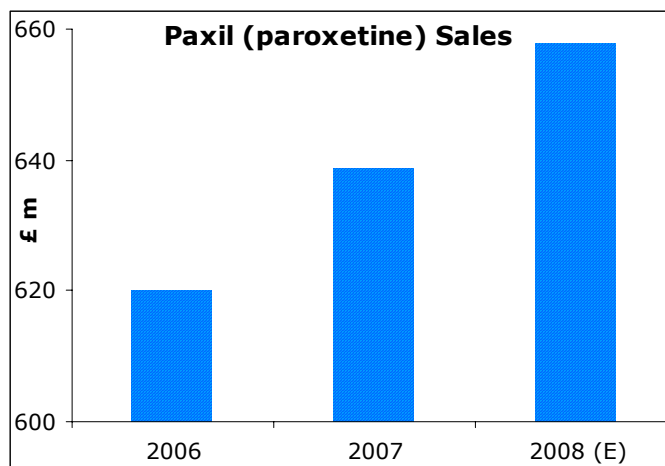
Source: Wikipedia; Cygnus Research

Dosage

Paxil is available in 10, 20, 30, and 40 mg tablets. For the treatment of panic disorder, the recommended target dose of Paxil is 40mg per day. The starting dose is 10mg per day, and dosage should not exceed 60mg per day. The recommended dosage of Paxil in the treatment of obsessive-compulsive disorder is 40 mg daily. The starting dose is 20 mg per day, and dosage should not exceed 60 mg per day.

Precautions

- While using this medicine, if the person is pregnant, it can harm the unborn baby. Use an effective form of birth control to keep from getting pregnant
- Be sure to tell at the time of pregnancy, plan to become pregnant, or are breast-feeding
- Tell the physician right away that if the person develops any allergic reactions, such as skin rash or hives, while taking paroxetine
- Paroxetine may cause some people to be agitated, irritable, or display other abnormal behaviours. It may also cause some people to have suicidal thoughts and tendencies or to become more depressed
- Do not suddenly stop while having this prescription. If the person has been instructed to stop taking paroxetine, ask the physician how to slowly decrease the dose. This is to decrease the chance of having discontinuation symptoms such as agitation, breathing problems, chest pain, confusion, diarrhoea, dizziness or light-headedness, fast heartbeat, headache, increased sweating, muscle pain, nausea, restlessness, runny nose, trouble in sleeping, trembling or shaking, unusual tiredness or weakness, vision changes, or vomiting



Source: Company Website; Cygnus Research

Market Scenario

Paxil registered 1% growth in 2006 as compared to 2005 sales. The sales increased from £620m to £638.60m. It is estimated to show the same positive growth of 3% at the end of 2008. The sales growth was due to strong growth of Paxil CR in the USA and Paxil IR in Japan and partly offset by generic competition to Paxil IR in Europe.

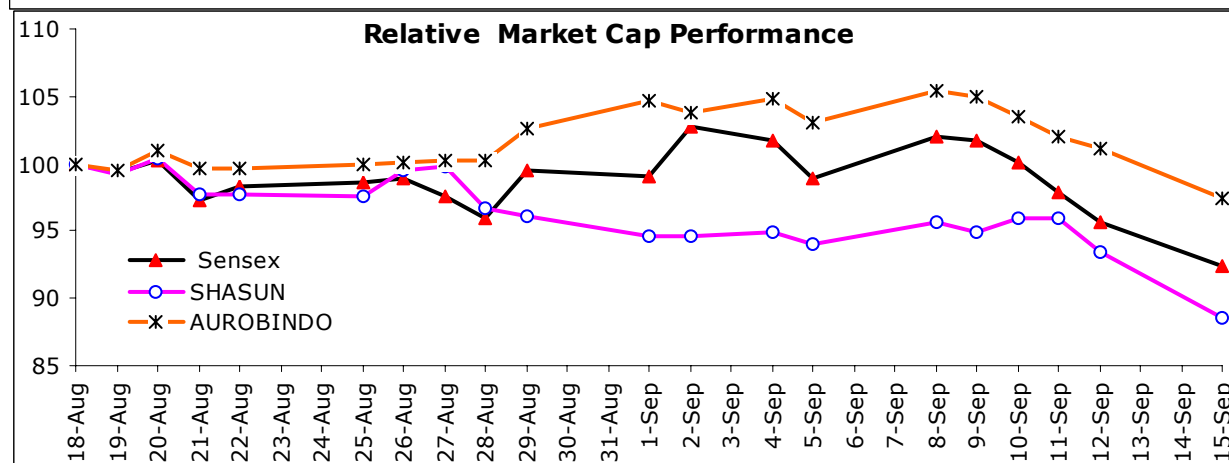
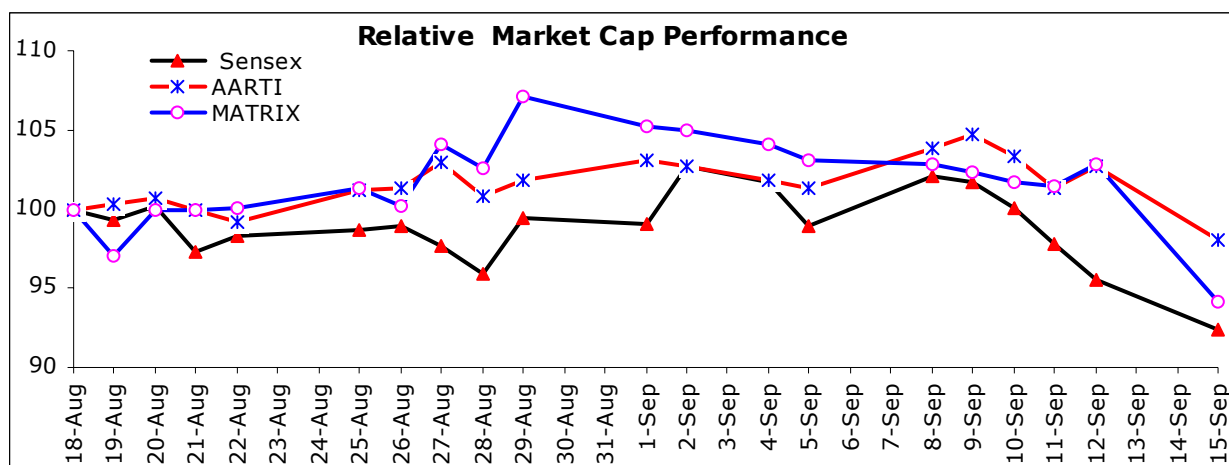
Outlook

Depression is taking a major place in the world with increase in work and family pressures. In the future, research programmes may permit the identification of specific receptor regions and receptor subtypes involved in depression, and novel non-receptor targets and signalling pathways, in order to develop drugs with more specific mechanisms of action and fewer side-effects. In addition, a greater understanding of differences in patient etiology, and how these can be identified with gene or biochemical markers, will allow tailored treatments.

In Indian scenario, Ranbaxy, Sun Pharma, Cadila and Innova Pharma will take major market positions in India. Paxil will face stiff competition from these companies. By the end of 2010, many medium and small companies are set to produce brands in this segment.

Brand Name	Generic Name	Manufacturer
Paxil	Paroxetine	GlaxoSmithKline
Zoloft	Sertraline	Pfizer
Effexor	Venlafaxine	Wyeth
Wellbutrin	Bupropion	GlaxoSmithKline
<i>Source: USFDA; Cygnus Research</i>		

Stock Scan



Source: BSE India; Cygnus Research

	17 Aug – 23 Aug	24 Aug – 30 Aug	31 Aug – 06 Sep	07 Sep – 15 Sep
BSE Sensex	Sensex lost 2.19% to 14,401.49 during the period under consideration due to inflation, resurgence of crude oil prices to US\$121 per barrel and sluggish trend across global markets.	Sensex gained in three trading sessions. Sensex gained around 1.13% during this period to reach 14564.53 points as India's GDP growth rate i.e. about 7.9% in AMJ08, was taken as a positive surprise.	The Sensex declined by 0.55% to reach 14,483.83. Oil prices fell below the US\$105 mark during this period and the inflation reached 12.34%.	The Sensex lost around 6.58% to reach 13531.27 points in this period due to selling pressure seen during the period. FIIs have sold shares worth Rs15254m.
AARTI	Lack of demand on shares made the stock price fall by 0.76%.	The share price closed at Rs53.55, showing an increase of 0.66%, as it moved in tandem with BSE sensex.	The stock price decreased by 1.66% as major players did not perform well during this period.	Decreased number of shares traded resulted in a fall in the stock prices from Rs54.65 to Rs51.55.

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MATRIX	The stock price remained flat during this period.	The share price improved by 5.68% as the company had received tentative approval from the USFDA to market Lamivudine tablets (300 mg) and Tenofovir disoproxil fumarate tablets (300 mg) for the treatment of HIV infections in adults, attracted the investor during this period.	The share price fell down by 2.03% as bearish sentiments prevailed in the market.	The share price further declined by 8.41% due to the negative investor sentiment
SHASUN	Weak global cues in the market made the share price fall by 2.33%.	Negative sentiments in the market made its share prices register a drop of 1.49%.	The share price further declined by 0.62% as it moved in tandem with BSE sensenx.	The share price fell down by 7.46% as bearish sentiments prevailed in the market.
AUROBINDO	The share price remained flat during this period.	The stock price improved by 2.81% as the company received the tentative approval from the US Food & Drug Administration (USFDA) for Losartan potassium tablets in the strengths of 25mg, 50mg and 100mg, attracted the investor during the period.	The share price fell down by 1.53% as bearish sentiments prevailed in the market.	Negative sentiments in the market made its share prices register a drop of 7.52%.

Regulatory Issues

International

FDA Approves Toviaz, a New Drug to Treat Overactive Bladder

The U.S. Food and Drug Administration have approved a new drug to help patients suffering from overactive bladder (OAB). Toviaz (fesoterodine fumarate) works by relaxing the smooth muscle tissue of the bladder, thus reducing the urinary frequency, urge to urinate, and sudden urinary incontinence (leakage of urine), that are characteristic symptoms of OAB. Patients who suffer from overactive bladder face quality of life issues that can hamper their ability to enjoy life to its fullest. This new drug will provide an additional treatment option to help them manage problems with an overactive bladder

FDA Approves Lung Valve to Control Some Air Leaks after Surgery

The U.S. Food and Drug Administration approved an implantable and removable valve system designed to control some air leaks in the lungs that persist after certain kinds of lung surgery. While air leaks are generally common after lung surgery, prolonged air leaks, which are leaks present seven days after surgery, occur less frequently and make it difficult for patients to breathe. Prolonged leaks also can increase the length of hospital stays and require additional surgeries to close. This device is approved for use in patients who have undergone partial or total removal of a lung lobe or lung volume reduction surgery and who experience prolonged air leaks or significant air leaks that may become prolonged.

National

Drug Control General India orders strict compliance of pharmacopoeia norms on imported products of MNCs

Drug Controller General of India (DCGI) has started enforcing standards under Indian pharmacopoeia on imported drugs also as is the case of domestic products, amid apprehensions that some foreign multinationals were trying to evade Indian standard parameters while following the norms in their own countries. DCGI has asked his drug inspectors across the country to make sure that all drugs imported and products manufactured by multinational companies here adhere to the standards set in the latest IP 2007. He has issued orders to zonal and sub-zonal offices of CDSCO to mount inspections on regular basis to verify if the imported drugs had followed the norms. Taking the matter very seriously, he also asked them to intimate the action taken in this regard to his office at an early date

Industry urges government to define substandard drug in D&C (Amendment) Bill

The industry has urged the government to rectify the Drugs and Cosmetics (Amendment) Bill, 2005 by incorporating certain provisions defining the word 'substandard drugs' which is missing in the Bill at its present form. An industry delegation met the DCGI in this regard. Industry sources said that representatives of major industry associations like IDMA, FOPE and CIPI met DCGI Dr Surinder Singh and urged him to take up the issue with higher authorities in the government. The industry expressed its view that if the Bill is implemented in its present form in letter and spirit, it will adversely affect the industry as even the genuine manufacturers can be falsely framed in the absence of any definition on substandard drugs.

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Upcoming Events

1	Event	Pharmacy Days
	Date	Nov 14-16, 2008
	Venue	Helsinki Fair Centre, Helsinki, Finland
	Highlights	Pharmacy Days is the largest national education event in the pharmaceutical sector. The programme is addressed to professionals from various related fields: pharmacy personnel, hospital pharmacists, medical industry, authorities, commerce and academia.
	Contact details	The Finnish Fair Corporation; Rua Oscar Freire, 379, 19th Floor, Helsinki, Finland; Tel: +(358)-(9)-15091
2	Event	PHARMTECH
	Date	Nov 25-28, 2008
	Venue	Crocus Expo, Moscow, Russia
	Highlights	PharmTech is a unique exhibition in Russia and the CIS is exclusively dedicated to pharmaceutical production: substances, raw materials, production machinery, packaging, turn-key projects, clinical research, and lab equipment.
	Contact Details	ITE Group Plc, 105, Salusbury Road, London, United Kingdom Tel: +(44)-(207)-5965000; Fax: +(44)-(207)-75965111
3	Event	CPhi India
	Date	Nov 28-30, 2008
	Venue	Bombay Exhibition Centre - Mumbai, Maharashtra, India
	Highlights	The attendee may be the CEO of an API manufacturer, engaged in formulations development, a quality control specialist or responsible for the purchasing of specialist ingredients for your organisation. CPhi India is an event to attend.
	Contact Details	CMP India; Sagar Tech Plaza A., 6th Floor, 615-617 Andheri Kurla Road, Saki Naka Junction, Andheri East, Mumbai, India Tel: +(91)-(22)-66122600; Fax: +(91)-(22)-66122626
4	Event	Anti-Aging Medicine & Medical Spa expo
	Date	Nov 29-Dec 01, 2008
	Venue	Al Bustan Rotana Hotel, Dubai, UAE
	Highlights	Anti-Aging Medicine & Medical Spa expo attracts the professionals related to apparel and accessories, aromatherapeutic products, body treatments, education and training, health and organic food, massage oils and cream, music and sounds, nail and foot care, body and skin care, spa equipment and anti-aging medicine.
	Contact Details	IIR Middle East; P. O. Box 21743, Dubai, United Arab Emirates Tel: +(971)-(4)-3365161; Fax: +(971)-(4)-3352711
5	Event	Hanoi MediPharm & BioLab
	Date	Dec 04-07, 2008
	Venue	GiangVo Exhibition Centre & Fairground, Hanoi, Vietnam
	Highlights	The objective of the exhibition will be to bring together the manufacturers and suppliers of process plant and equipment, for this growing industry, all under one roof. The exhibition will provide an excellent platform for service providers to showcase their products and services to decision makers from leading pharmaceutical manufacturers.
	Contact Details	F. A. S. T. System & Management Services 18 Richards Avenue, Singapore, Singapore Tel: +(65)-(9)-7380246; Fax: +(65)-(6)-68584490

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6	Event	Medifest' 08
	Date	Dec 05-07, 2008
	Venue	Pragati Maidan, New Delhi, India
	Highlights	The fair will provide the global overview and comprehensive information of the developments in the field. As this region has huge requirements of healthcare related products and services, it offers great opportunity to all related with this industry, under one roof.
	Contact Details	Vantage Medifest (P) Limited SCO 43, Sector 31-D, Chandigarh, India Tel: +(91)-(172)-5049993; Fax: +(91)-(172)-2613702
7	Event	Anti-Aging Conference & Exhibition-Las Vegas
	Date	Dec 11-14, 2008
	Venue	Venetian Resort-Hotel-Casino, Las Vegas, USA
	Highlights	Anti-Aging Conference & Exhibition-Las Vegas will showcase many medicines and technologies that are at the cutting edge of this field and medicine in general. This is practiced worldwide that ensure quality of service in this sphere.
	Contact Details	Tarsus Group Plc; 4th Floor, Metro Building, 1 Butterwick, Hammersmith London, United Kingdom Tel: +(44)-(20)-88462700; Fax: +(44)-(20)-88462801
8	Event	International Hospital Industry Exhibition - 2008
	Date	Dec 23-26, 2008
	Venue	Kish International Exhibition Center, Kish Island, Iran
	Highlights	International Hospital Industry Exhibition - 2008 will feature the Supply Equipment, Technology & Services in the field of Building modern Hospitals. Professionals from Hospitals, Importer/Exporters/Manufacturers of Medical facilities/appliances/single use materials, Doctors, Nurses, Wholesale buyers, Cleaning service companies, Hospital builders, Architects, interior designers & engineering consultants, Contractors are the Highlight for this event.
	Contact Details	Organiser: ExpoKish Flat # 25-5th Floor # 60, Tehran, Iran Tel: +(98)-(21)-77529214; Fax: +(98)-(21)-77657133
9	Event	Arab Lab
	Date	Jan 10-13, 2008
	Venue	Dubai International Convention & Exhibition Centre, Dubai, UAE
	Highlights	Arablab, The Expo, the only dedicated trade fair for laboratory and instrumentation in the Arabworld and MENA region. It focuses on six mainstream sectors: biotechnology, instrumentation, laboratory technology, automation, robotics and diagnostics. This is a powerful global show attracting buyers and sellers from 70+ countries.
	Contact details	The Arablab Group, P. O. Box 125303, Dubai, United Arab Emirates Tel: +(971)-(4)-3975418; Fax: +(971)-(4)-3975419

10	Event	Arab Lab
	Date	Jan 10-13, 2009
	Venue	Dubai International Convention & Exhibition Centre, Dubai, UAE
	Highlights	Arablab, The Expo, the only dedicated trade fair for laboratory and instrumentation in the Arabworld and MENA region. It focuses on six mainstream sectors: Biotechnology, Instrumentation, Laboratory Technology, Automation, Robotics & Diagnostics.
	Contact Details	The Arablab Group, P. O. Box 125303, Dubai, United Arab Emirates Tel: +(971)-(4)-3975418; Fax: +(971)-(4)-3975419
12	Event	MedWorld 2009
	Date	Jan 16-18, 2009
	Venue	Bombay Exhibition Centre - NSE Exhibition Complex, Mumbai, Maharashtra
	Highlights	Med World 2009 is International Medical trade fair & congress, a must attend event for the healthcare domainz. This is the right place to showcase your equipment & technologies and reach out to the fastest growing healthcare market. Professionals from more then 30 countries will be participating in this mega trade event. MedWorld 2009 will help position you on the world map treading the path of growth, sucess & being witness to the best in the world of Medical technologies.