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In Focus: Innovation & Technology Drive the CT scanner Market

Introduction

Earlier known as EMI scan, Computed Tomography (CT) has evolved into a vital medical imaging technology. It is used in hospital imaging departments and even in outpatient clinics. It has a wide range of applications in the imaging and evaluation of brain, neck, spine, chest, abdomen, pelvis, sinuses, and various others parts of the body. CT scanning is more commonly used in trauma, oncology and cardiac cases.

Over the years, it has created its own niche market in the medical imaging, with the examination of internal body structures and diagnosis of diseases. There have been several improvements in the application of CT scanner.

Classification of CT scanner Market

The CT scanner market can be classified into five types:

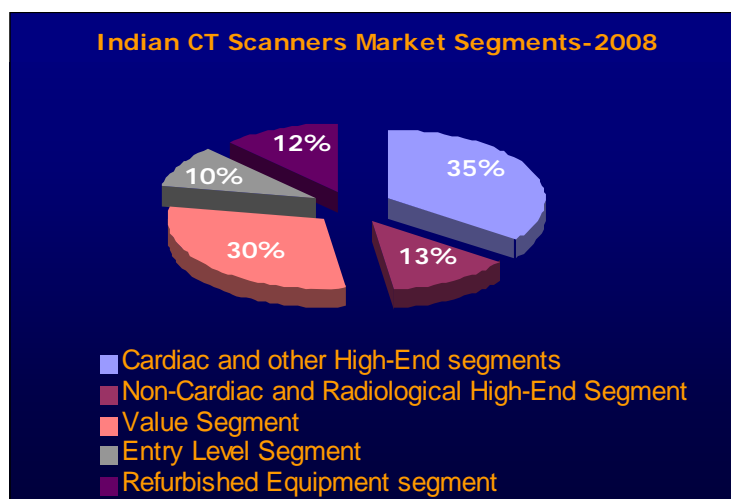
- Entry level (conventional CT)
- Low-end single-slice spiral CT
- High-end single-slice CT
- Entry level multi-slice (dual and quad) CT
- Advanced multi-slice (16-slice and 64-slice) CT

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Market Size

The market size of CT scanners in India was Rs374.85 crore in 2008, a growth of 19% over the previous year. The high-end CT scanner segment accounted for approximately 50% of the total market. Of this, Cardiac high-end segment accounted for a major share i.e 35%, amounting to Rs131 crore in values. The Non-Cardiac and Radiological high-end segment is valued at Rs48.36 crore and 13%

share. The Value segment has shown appreciable growth and accounted for 30% share of the total market, valued at Rs113 crore. The Entry Level segment held 10% of the market and valued at Rs37.49 crore. There is a major shift in demand towards high-end models in the Refurbished Equipment segment, which is valued at Rs45.36 crore.



Source: Medical Buyer; Cygnus Research

Growth Drivers

Technology and innovation drive the growth

India's medical imaging sector is poised for a new accelerated phase of growth, fuelled by the availability of advanced technology and digital information. CT scanner market continues to be one of the more progressive markets in Asia in terms of technology adoption. The enhancements in technology have seen the growing adoption of new imaging technology that combine high levels of accuracy with rapid, user-friendly product formats. Along with pressures to improve the quality of healthcare while keeping the medical treatments affordable, new "Greenfield" opportunities are emerging for suppliers to provide innovative cost-effective equipment.

Rising demand for quality healthcare

With its huge population of over a billion people, India's public health sector is unable to provide the basic healthcare facilities to the majority. Hospitals in the cities are overburdened, while those living in the rural areas have minimal access to quality healthcare. Inefficiency has given way to a booming private healthcare industry, which now takes care of three-quarters of the nation's needs. At the same time, rising income and health consciousness amongst the urban Indian population are urging people to seek specialised care. The urban consuming class is expected to grow from 78 million in 2001 to 250 million in 2010. India's increasing affluent middle class is demanding access to better healthcare; many Indians are

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now choosing health insurance with either full or partial coverage. This is one of the growth drivers of CT scan.

Opportunities in India's public healthcare sector

Despite the unfavourable situation in the public health sector, the Indian government has stated in its National Health Policy that it hopes to increase the number of healthcare centres in remote areas and to improve supply of essential healthcare services by boosting the public healthcare expenditure to 2.0% of the gross domestic product (GDP) by 2010. This provides a substantial market for the public sector and for the potential collaborations between private sector and government. This could translate into opportunities for use of medical equipment.

Increase in healthcare expenditure

The healthcare industry is currently one of the largest service sectors in India, delivering through both the public and private sectors. In 2007, revenues from the healthcare sector accounted for 5.2% of the GDP, making it the third largest sector in India. Currently, the government spending on healthcare is 0.9% of India's GDP. The government has set a target to increase this figure to 2–3% of the GDP by 2012.

Upgradation of medical services, devices & equipment

The Government of India is improving health infrastructure by upgrading and increasing the total number of hospitals, clinics and clinical laboratories in urban and rural areas. Moreover, the healthcare delivery and infrastructure are going through structural changes after the entry of corporate hospitals. Significant investments have been made in setting up pharmacy chains and private hospitals.

Major Players

GE Healthcare, Philips Healthcare and Siemens together account for the major share of the market. GE Healthcare holds leadership position in value and entry level equipment segments. Philips continues to lead in high-end segment. Other players include Blue Star, Shimadzu, Toshiba and Trivitron. The Indian manufactures and suppliers include Sanrad Medical, Cura Medical, Bhram Systems, Electromed, Electrochemical and Master Medicals.

Outlook

According to Cygnus estimates, CT scanner market is estimated to grow to Rs656 crore by 2012 with CAGR of 15%. Evolution of technology in this field has led to the development of several products that are getting well accepted in India and other countries. Cardiac applications of the CT scanners are driving the high-end market; introduction of new machines for new applications, demographic changes in population and growth of the oncology market are leading to growth in the mid-range segment. Moreover, several new hospitals are being set up across the country, which will contribute to the sales of CT scanners in a big way. The market is expected to witness substantial growth, owing to several technological Upgradation.

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News Briefs

MARKETING

Americas

USA: Ethex recalls prescription prenatal & iron supplements products

Ethex Corporation, a subsidiary of KV Pharmaceutical Company, is issuing a voluntary nationwide recall of prescription prenatal and iron supplements products (all lots within their expiration dates) at a wholesale level. The company is taking this action as a precautionary measure, because the products may have been manufactured under conditions that did not sufficiently comply with current Good Manufacturing Practice (cGMP). Patients who may have these products in their possession should continue to take them in accordance with their prescriptions, as the risk of suddenly stopping needed medications may place patients at risk.

USA: IBPL- Apotex to develop biosimilar version of pegfilgrastim

Apotex Inc. of Canada and Intas Biopharmaceuticals Limited (IBPL) of India have extended their business agreement to develop a biosimilar version of pegfilgrastim, a protein that is used to treat neutropenia (a side effect of cancer chemotherapy). Both companies, IBPL and Apotex are eyeing a significant share of total Peg GCSF market in North America, which is currently estimated to be around US\$3.5 billion annually. This collaboration gives Apotex the rights to market the product in North America (US and Canada), Europe and selected other countries.

UK

Switzerland: Novartis gains worldwide rights for anti-clotting agent

Novartis has gained the exclusive worldwide rights to elinogrel, a promising anti-clotting agent in phase II clinical trials that has shown potential to offer clinical improvements over current anti-clotting medications in helping patients avoid heart attacks and strokes. As part of the agreement with the US biotechnology company Portola Pharmaceuticals, Inc, Novartis will have responsibility for the phase III development, manufacturing and commercialisation of elinogrel. Under the terms of conditions, Novartis will make an upfront payment of US\$75m to Portola for the exclusive worldwide rights to elinogrel.

Europe

Switzerland: Novartis gains worldwide rights to anti-clotting agent elinogrel

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Asia Pacific

India: Dr. Reddy's launches 5 products in US market

Dr. Reddy's Laboratories announced that it has launched five new products in the US market. According to a release issued recently, the company launched the products in the US market in January 2009. The products launched were Levetiracetam tablets with IMS annual sales of US\$1.1 billion, Omeprazole capsules with IMS annual sales of US\$168m, Lamotragine CD chewable tablets with IMS annual sales of US\$87m, Divalproex capsules with IMS annual sales of US\$126m, and Lamotrigine tablets with IMS annual sales of US\$2.3 billion.

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India: Dr Reddy's, Ranbaxy line up to sell low-cost drugs

Dr Reddy's, Ranbaxy and a few other reputed drug companies are seeking empanelment in a government programme to sell unbranded low-cost drug to poor people, a government official said. The Department of Pharmaceuticals will announce a list of drug makers and non-governmental organisations (NGO) next week to supply medicines to Jan Aushadhi, a new low-priced medicine store chain promoted by the Central government.

India: Trumount launches 20 products with US, Europe FDA approval

Trumount Cosmoceuticals, a Pune based company launched 20 different beauty products that meet the standards set by the food and drug administration (FDA) in the Europe and the US. Ludhiana based pharmaceutical firm Wind Trust Pharma Ltd, Trumount would market these products under the brand name Votre. With an investment of about Rs10m so far, Trumount conducted its clinical trials in Barcelona and tested across India under various climatic conditions before the launch.

India: Wockhardt launches Sanofi's Lantus generic in India

Drugmaker Wockhardt Ltd said it has launched new insulin, Glaritus, in India for the treatment of diabetes. Glaritus is a generic version of Sanofi-Aventis' Lantus, which is a recombinant long-acting human insulin analogue, Wockhardt said. The domestic market for the product is about Rs1.2 billion and is growing at 37% per year, the company said. Wockhardt's range of Glaritus cartridges, pens and disposable pens will be cheaper by 10%, 63% and 34% respectively than the branded Lantus, a company spokesman said.

India: Quest launches Leumeta test to detect tumour

In a major effort to save time in diagnosing the leukaemia and lymphoma cancers, Quest Diagnostics with its novel test 'Leumeta' will now help to detect biomarkers of leukaemia and lymphoma using minimally invasive blood analyses rather than painfully extracted and risky bone-marrow biopsies. It helps to detect certain blood cancer markers and assist the physician in monitoring the impact of treatment. They are the first diagnostic assays available to doctors that directly measure tumour load and identify markers in blood plasma, said Dr Maher Albitar, director, Haematology & Oncology, Quest Diagnostics' Nichols Institute.

India: Cord Blood banking facility comes up in kolkata

Kolkata-based Strassenburg Pharmaceuticals, the leading pharma manufacturing company of the region, has diversified to set up Eastern India's biggest 'umbilical cord blood stem cell banking' facility in partnership with a Singapore based firm. The company hopes this futuristic knowledge based venture will help to keep pace with the changing needs of the pharmaceutical industry. Set-up at a cost of Rs100m, the umbilical cord blood storage facility has come up on Diamond Harbour Road adjacent to Strassenburg manufacturing facility. This advanced facility has a storage capacity for up to 1,50,000 cord blood units to support such stem cell therapies. Licensed by the Drug Controller General of India, CordLife is able to collect cord blood units from across the country.

India: NPPA fixes prices of formulation of Atorvastatin

Drug price regulator, National Pharmaceutical Pricing Authority (NPPA) has fixed the price of formulation of Atorvastatin, Clopidogrel and Aspirin capsules used in the cardiovascular segment. The regulator has fixed the maximum retail price of the combination of Atorvastatin, Clopidogrel and Aspirin Capsule of different strengths at Rs37.89 per strip of 10, according to the information available on its website. NPPA has fixed the price of the combination using the power conferred by Drug Prices Control Order 1995, the regulator said in a statement.

India: Piramal Life may unveil new chemical entity by 2011

Piramal Life Sciences, the listed research and development (R&D) subsidiary of Piramal Healthcare, is hoping to hit the market with its first New Chemical Entity (NCE) by 2011. The company is currently developing drugs in oncology, diabetes, inflammation disorders and anti-infectives. Piramal Life Sciences was hived off as a separate entity in May 2008. This was done to segregate research from the company's contract manufacturing and generic businesses. There is no drugs which treat head and neck cancer with

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minimum side-effects and their aim is to tap this market worldwide, managing director of Piramal Life Sciences told ET.

INVESTMENTS

Europe

Belgium: UCB to build new biologics pilot plant

UCB has announced its plans to build a biologics pilot plant on its site of Braine-l'Alleud in Belgium, further executing its strategy to become the next generation biopharma leader focusing on central nervous system (CNS) and immunology. This planned investment should amount to EUR65m and is supported by the Walloon Government. The biologics pilot plant is expected to become operational early 2012 and around 100 new job opportunities should be created in the medium-term. Advanced feasibility studies are currently ongoing.

Asia Pacific

India: Central government to fund Bio-IT facility in Bangalore

The central government would fund the setting up of a Bio-IT facility in India's tech hub to conduct research in genome sequencing and analysis, Karnataka Chief Minister said. The Bio-IT facility will be set up in the newly-built biotech park by the ministry of communications and IT in collaboration with the Centre for Human Genetics (CHG), the Jawaharlal Nehru Centre for Advanced Studies and Research (JNCASR) and leading biotech firm Strand Life Sciences. A major chunk of financial support for the Bio-IT Centre will come from the central government, while the state government will initially contribute Rs50m in fiscal 2009-10, Karnataka Chief Minister BS Yeddyurappa said.

Asia Pacific

India: Accel India to invest US\$2.5m in healthcare portal

HealthcareMagic, a medical consultation and referral portal, allows users to interact live with doctors. Rx HealthCare Magic, which runs a healthcare portal HealthcareMagic.com, has raised Series A funding of US\$2.5 million from Accel India, VCCircle has learned. Kunal Sinha, founder and CEO of Rx HealthCare Magic, has confirmed the investment. The funding will be released in tranches as company meets its milestones. Bangalore-based HealthcareMagic is a medical consultation and referral portal which allows users to interact live with doctors. It currently has around 50 employees, which include 34 doctors. While some of these doctors are full time employees, others are consultants on contract. The company earns its revenues through medical consultations online and via telephone. While payment for online consultations is done through credit cards, for telephone, it has signed up with network operators. The mobile phone consultations are done at charges of Rs8-10 per minute, said Sinha.

India: Gujarat govt to invest Rs3bn for healthcare

All the primary hospitals and community health centres in Gujarat are set to undergo a sea change, with the state government taking initiatives to ensure quality healthcare services. As part of a memorandum of understanding (MoU) signed by the government of Gujarat with the Quality Council of India (QCI), about 1000 primary health centres and 270 community health centres across the state will get a facelift through various capacity building exercises of QCI. The Gujarat government has come up with a big plan to improve the quality of services of 1000 primary health centres and about 270 community health centres across the state. In this regard, the state has signed a Rs3 billion MoU during and plan to start its operations after February 15.

India: Max Healthcare to set up cancer hospitals in Punjab

Punjab government has approved the major projects to set up two Super Specialty Cancer Hospitals— one at Mohali and another at Bathinda in the public-private partnership mode. A spokesman of the Punjab government said that these projects had been awarded to Max Healthcare, which had already deposited up front charges of Rs45m and Rs15m for these mega-hospital projects at Mohali and Bathinda respectively. Besides, the company would also offer 5% of its gross turnover every year to the state

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government. These projects would be completed within 18 months. To strengthen the Health sector, the Punjab government had already initiated a mammoth project for the modernisation of Amritsar Medical College at a cost of Rs1.5 billion besides upgrading the Guru Gobind Singh Medical College and Hospital Faridkot at a cost of Rs680m.

India: Himachal to get Rs20bn nano-tech park

Himachal Pradesh will soon emerge as a nano-business valley as the state government has proposed to set up a Nano-Biosym technology park in collaboration with the department of science and technology of the Union government. Multi-purpose project such as pharomic (DNA diagnostic kit), incubator, health, medical, education activities and BT-based units will be carried out effectively in the park. It will have a critical mass of creative minds that can attract and create a technological culture so that the hill state can compete in global nanobusiness race. After business plan is finalised, the state government will take help of the department of biotechnology, government of India for its seed funding to complete construction of this park. The state has tied up with a US-based company NBS Inc and private investors to set up the proposed park with an investment of about Rs20 billion on 400 acres at Aduwal near Nalagarh in Solan district. Official sources claimed the land had already been provided for the park.

Vietnam: HCMC plans to invest VND2.2tril in health care

HCMC this year plans to invest VND2.2 trillion in the health care sector with an aim to ease the current overloading at State-owned hospitals by constructing new ones, said the director of HCMC's Health Department. HCMC is now a hub of health care service with 39 State-owned and 26 privately-run hospitals, and 322 district-level medical clinics. Nguyen Van Chau said that this would be huge investment for the sector in an effort to improve health care quality for local residents. According to Chau, the city's healthcare sector is mandated not only to meet the demand of its citizens but also to serve people from neighbouring provinces. Thus, hospitals in the city are always under pressure to provide treatment, so it is imperative now to build new clinics.

MERGERS & ACQUISITIONS

Americas

USA: WIL Research Labs acquires Midwest Bioresearch

WIL Research Laboratories, LLC and WIL Research Holding Company, Inc have announced the acquisition of Midwest Bioresearch, LLC. Together, Midwest Bioresearch and WIL Research shall integrate their service offerings through scientific collaboration, sharing of best practices and marketing to provide a seamless bridge between these two highly regarded scientific organisations. Midwest Bioresearch's significant expertise in immunoanalytical and bioassay techniques and small molecule bio analysis, supporting both clinical and nonclinical research, and their expertise in genetic toxicology, complements WIL Research's contract research service offerings that include expertise in chronic, neuro-, inhalation, and intravenous toxicology, developmental and reproductive toxicology, safety pharmacology, bio analytical chemistry and metabolism.

RESEARCH & DEVELOPMENT

Asia Pacific

India: CCRAS to launch database on traditional medicines research

The Central Council for Research in Ayurveda and Siddha (CCRAS), the research body under the Department of Ayush to find new inroads on Indian Systems of Medicines (ISM), will soon launch a national research database with comprehensive information on the research in the traditional medicines. The research database, which is under preparation by the council, is an effort to collect and comprehend the information of all the research projects underway in various parts of the country. The database will consist of research details in Ayurveda, Siddha, pharmacology, pharmaceutical sciences, medicinal plant cultivation related projects and related fields pertaining to Indian Systems of Medicine, informed Dr G S Lavekar, director, CCRAS.

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India: World's first cloned buffalo calf born in Karnal

In a path-breaking development, Indian animal scientists had announced the birth of the world's first cloned buffalo calf. It has been developed by using an indigenously evolved advanced, yet relatively simple, "hand-guided cloning technique", rather than the conventional cloning technology followed elsewhere in the world for producing cloned sheep and cattle. But another cloned calf is expected in about two months, scientists at the Karnal-based National Dairy Research Institute (NDRI) said. The cloned buffalo calf was born on February 6. This development assumes significance because the buffalo is an important milch animal only in India, Pakistan and, to a considerably less extent, in some east-Asian countries.

India: ICMR to start testing of AIDS vaccine

The Indian Council of Medical Research (ICMR) will start phase I clinical trials to test a combination of two AIDS vaccine candidates. The trials will be conducted at the National AIDS Research Institute (NARI) in Pune and the Tuberculosis Research Centre (TRC) in Chennai. The combination drug will combine two AIDS vaccines Advax and TBC-M4 in a prime-boost regimen, which essentially means the two vaccine candidates will get better response from the body's immune system than giving either vaccine candidate alone. The partnership with IAVI is helping to achieve the aim by not only bringing new vaccines but also in capacity development and infrastructure strengthening.

CORPORATE**Americas****USA: USFDA raised concerns on Taro's quality control systems**

The USFDA has raised concerns about Taro Pharmaceuticals' quality control systems and had recently written to the Israeli company about its Canadian manufacturing facility. The concerns also included Taro's failure to complete investigations of quality issues in a timely manner. Taro said it plans to respond to the letter from USFDA within 30 days, as required. It also said that it has already corrected many of the observations cited during the July 2008 inspection of its Canadian facility.

USA: Synta achieves US\$10m elesclomol milestone from GSK

Synta Pharmaceuticals Corp, a biopharmaceutical company focused on discovering, developing, and commercialising small molecule drugs to treat severe medical conditions, announced that it has achieved an operational milestone triggering a US\$10m payment from GlaxoSmithKline (GSK) under its collaboration agreement for the development and commercialisation of elesclomol. Elesclomol is an investigational first-in-class oxidative stress inducer that triggers apoptosis (programmed cell death) in cancer cells. Elesclomol is not yet approved for any indication in any market.

USA: Merck talking to 10 pharma companies for tie-ups

Global pharma major Merck & Co Inc is planning to expand its research collaboration with Indian companies and is currently in talks with 10 major and minor firms. "While I cannot name the companies with which we are talking, I can say that the discussions are highly promising and something concrete may happen soon," Director of Licensing and External Research (India), Merck & Co Inc., told Business Line. He, however, declined to give any time frame. The companies included some small companies in Hyderabad. "We are not interested in people engaged in contract research and manufacturing services but are looking for partners in innovation," the Director said.

USA: Novelos, Mundipharma sign exclusive collaboration pact for cancer drug

Novelos Therapeutics, Inc., a biopharmaceutical company focused on the development of therapeutics to treat cancer and hepatitis, announced that Novelos signed an exclusive collaboration agreement with Mundipharma International Corporation Limited to commercialise in Europe and Asia/Pacific (excluding China) Novelos' lead compound, NOV-002, which is in a pivotal phase 3 trial for non-small cell lung cancer under a Special Protocol Assessment (SPA) and Fast Track. NOV- 002 has also demonstrated positive results in phase 2 trials for other cancer indications.

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Americas**USA: Santarus submits NDA for Zegerid tablet formulation**

Santarus, Inc., a specialty pharmaceutical company, has submitted a New Drug Application (NDA) to the US Food and Drug Administration (FDA) for a new tablet formulation to add to its Zegerid family of branded prescription pharmaceutical products. The new formulation is an immediate-release tablet that combines omeprazole, a proton pump inhibitor (PPI), with a mix of buffers. The company's objective is to have the new Zegerid tablet product commercially available in the US in the fourth quarter of 2009.

USA: US FDA accepts GTx's toremifene 80mg NDA for review

GTx, Inc. announced that the United States Food and Drug Administration has accepted for filing and review the New Drug Application (NDA) for toremifene 80mg, an oral selective estrogen receptor modulator, which GTx seeks to market for the prevention of bone fractures in men with prostate cancer on androgen deprivation therapy (ADT). The NDA is supported by results from a two year, double blind, placebo controlled, randomised phase III clinical trial of 1,382 men with advanced prostate cancer on ADT.

USA: Mylan gets US FDA nod for generic Lamictal tabs & Lamictal CD

Mylan Inc. announced that its subsidiaries Mylan Pharmaceuticals Inc. and Genpharm ULC received final approvals from the US Food and Drug Administration (FDA) for their Abbreviated New Drug Applications (ANDAs) for lamotrigine tablets. Genpharm also received final FDA approval for its ANDA for a separate lamotrigine product, lamotrigine tablets chewable dispersible (CD). Mylan Pharmaceuticals' and Genpharm's ANDAs were approved for the 25mg, 100mg, 150mg and 200mg strengths of the generic version of GlaxoSmithKline's Lamictal tablets. This product had annual U.S. sales of approximately US\$2.5 billion for the 12 months ending September 30, 2008, for the same strengths according to IMS Health.

USA: US FDA to review Sirion's ophthalmic gel ganciclovir NDA

Sirion Therapeutics, Inc, a privately held ophthalmic-focused biopharmaceutical company, announced that its New Drug Application (NDA) for ganciclovir ophthalmic gel, 0.15%, has been accepted for review by the US Food and Drug Administration (FDA). Sirion Therapeutics is seeking approval for ganciclovir as a treatment for herpetic keratitis, an ocular disease caused by the herpes simplex virus. The FDA has issued an action date in late fall of 2009, under the Prescription Drug User Fee Act.

USA: Taro receives US FDA nod for lamotrigine tablets

Taro Pharmaceutical Industries Ltd. has received final approval from the US Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for lamotrigine tablets 25mg, 100mg, 150mg, and 200mg. Taro had received tentative approval for this ANDA in March 2008. Lamotrigine is a prescription product used for the treatment of seizures and is bioequivalent to GlaxoSmithKline's Lamictal tablets. According to industry sources, lamotrigine tablets had annual US sales of more than US\$2 billion.

Canada: Cipher gets tentative US FDA nod for tramadol ER capsules

Cipher Pharmaceuticals Inc announced that it has received tentative approval from the US Food and Drug Administration (FDA) for CIP-Tramadol ER, the company's extended-release formulation of the analgesic tramadol, which is indicated for the management of moderate to moderately severe chronic pain such as osteoarthritis. While the product meets all the FDA's requirements for manufacturing quality, clinical safety and efficacy, the company must resolve certain patent issues related to the reference product, Ultram ER, before CIP-Tramadol ER is commercialised.

Europe**Sweden: Vitrolife's human oocytes collection needle gets US FDA approval**

Vitrolife has received approval from the American Food and Drug Administration, so-called 510(k) clearance, for its new needle for the collection of human oocytes, Swemed Sense (patent pending), which

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reduces the risk of tissue damage and pain. The needle, which has previously received European approval, a so-called CE mark, and which was launched at ESHRE in 2008, has received a very positive response and publicity. Swemed Sense will now be launched in the USA. "This is the first product that applies a new technical principle for oocyte collection needles. We believe in this principle very much," says Anette Jäderberg, marketing director at Vitrolife.

Asia Pacific

Japan: US FDA nod for Takeda's dexlansoprazole capsules for GERD

Takeda Pharmaceutical Company Limited and its wholly-owned subsidiary, Takeda Pharmaceuticals North America, Inc., announced that the US Food and Drug Administration (FDA) approved Kapidex (dexlansoprazole) delayed release capsules for the once-daily, oral treatment of heartburn associated with symptomatic non-erosive Gastroesophageal Reflux Disease (GERD), the healing of erosive esophagitis (EE) and the maintenance of healed EE. Kapidex (30mg and 60mg) is the first proton pump inhibitor (PPI) with a Dual Delayed Release (DDR) formulation designed to provide two separate releases of medication.

India: Educomp Pharma gets US FDA nod for Tenofovir

Aurobindo Pharma Ltd said it has got tentative approval from US Food and Drug Administration for Tenofovir Disoproxil Fumarate tablets, which fall under the anti-retroviral segment. The firm has obtained a license from Gilead for marketing Tenofovir products in 95 countries, it said in a statement.

India: Alembic gets USFDA nod for Meprobamate tablet

Alembic, a leading pharmaceutical company in India, announced that it had received an approval for a new drug, Meprobamate Tablet from USFDA (United States Food and Drug Administration). The said generic drug, Meprobamate Tablet will be available in the strengths of 200mg and 400mg. Meprobamate is used in the treatment of anxiety.

India: Glaxo, Sanofi chasing Piramal – source

GlaxoSmithKline PLC and Sanofi Aventis SA have emerged as bidders for Indian drug company Piramal Healthcare Ltd, with the sale price perhaps going as high as US\$1.5 billion, a source familiar with the situation said. A deal for Piramal Healthcare could further Glaxo's strategy to build its presence in emerging markets. The British drugmaker plans to explore small and medium-sized deals, rather than "be distracted by large-scale M&A," CEO Andrew Witty said. Analysts have predicted Sanofi will target medium-sized companies to boost its growth after recent moves by Sanofi to acquire vaccines maker Acambis and Czech generic drug group Zentiva.

India: GSK Pharma scouts for domestic buys

GlaxoSmithKline Pharmaceuticals (GSK), the Indian arm of global drug major GlaxoSmithKline, is scouting for acquisitions in the domestic market to consolidate its Indian business. It is speculated that GlaxoSmithKline Plc is in talks to acquire leading Indian drug major Piramal healthcare, in a deal valued over US\$1.5 billion. Piramal Healthcare had denied the reports as 'market speculation'. The new launches will include Cervarix, GSK's much touted cervical cancer vaccine. Another drug in the pipeline from the parent's stable will include a Streptococcus pneumonia vaccine, to be launched by 2010.

India: Aurobindo pharma gets USFDA nod for viral drug

Hyderabad-based drug maker Aurobindo Pharmaceuticals said in a filing with the Bombay Stock Exchange that has received temporary approval for Tenofovir Disoproxil Fumarate tablets, 300mg from the US Food and Drug Administration. Tenofovir Disoproxil Fumarate tablets, 300 mg are the generic equivalent of Gilead Science Inc's Viread Tablets 300mg and falls under the anti-retroviral segment. It is indicated in combination with other anti-retroviral for the treatment of HIV-1 infection in adults. Aurobindo has obtained a license from Gilead to market Tenofovir products in 95 developing and least developed countries.

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GOVERNMENT INITIATIVES

Asia Pacific

India: Industry may soon start supplying low cost medicines to generic stores

Private pharmaceutical companies will soon be part of the central government's initiative to make quality medicines available at affordable prices. The department of pharmaceuticals (DoP) has received 76 applications from domestic drug makers who are interested in supplying generic medicines at a lower price to the generic drug stores recently being set up by the government in several states. At present, only pharma public sector undertakings (PSUs) are supplying medicines to these stores. The government plans to launch 40 such stores by March in Punjab, Haryana, Rajasthan, Delhi and Andhra Pradesh.

India: Small drug companies oppose central licensing agency

The proposed Central Drug Authority (CDA) Bill, likely to be passed in the upcoming Parliament session this month, is posing a threat to about 5,000 small drug-making units, the association of these players said. The bill has proposed the Centre would take over from the states the authority to clear manufacturing licences of pharmaceutical companies to ensure high standards. At present, state drug controllers approve manufacturing sites, and give licenses for sale and distribution of medicines. The bill is framed in favour of big multinational companies. Small players cannot incur such huge costs to get clearances from the Centre.

India: DCGI withdraws WHO-GMP certification, COPP made mandatory

The Drugs Control General of India (DCGI) has taken a decision to discontinue issuance of WHO GMP certificate for both pharma products and plant audits. The decision comes in the wake of objection raised by the World Health Organisation on handing over these certificates at random. The WHO GMP had been a mandatory requirement for global markets entry and specifically for countries which had no dedicated regulatory authority. The Indian pharma regulator has been issuing the Certificate of Pharmaceutical Products (COPP) which is on par with the WHO-GMP certificates. For the marketing of drugs within the country only Schedule M certification is required.

India: New norms for MNC drug prices

In a move that would prevent MNCs such as GlaxoSmithKline (GSK), Eli Lilly, Roche and Pfizer from selling their drugs at a huge premium in India, the government may soon finalise norms for monitoring prices of costly imported patented medicines for diseases such as diabetes, arthritis, obesity, cancer and heart diseases. Under the new norms, the government will negotiate prices for imported medicines for identified diseases based on prices of the same medicine in other markets and the cost of production estimated by it, an official said. At present, imported brands circumvent price control norms as the drug price regulator, National Pharmaceutical Pricing Authority (NPPA), has no means of verifying their production cost. The proposed pricing mechanism for patented drugs would ensure that essential medicines not available here due to patent protection are affordable.

India: Tweaking inputs no ground for raising drug prices: NPPA

The drug price regulator has ruled that pharma companies cannot unilaterally increase prices of medicines that are under price control by merely tweaking their composition. Any company seeking to change an approved composition of a price-controlled drug will now have to follow the ceiling price of drugs with similar composition, or get a separate price approved for the new composition, according to a notification by the National Pharmaceutical Pricing Authority (NPPA). "Companies not complying with the ceiling shall be liable to deposit the overcharged amount along with interest. The idea is to block the loopholes so that companies cannot escape norms specified in the Drug Price Control Order (DPCO)," an NPPA official told ET.

India: 40 Generic drug stores to be opened by March

The Minister for Steel, Chemicals and Fertilizers Shri Ram Vilas Paswan has said that 40 generic drug stores under the brand Jan Aushadhi will be opened by the end of March this year. The stores are to

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dispense generic drugs at a fraction of the price of branded drugs in the market. The stores to remain open round the clock are being set up with the participation of State Governments and NGOs. The Minister said the government is trying its best to provide affordable health services to everybody.

India: Clinical trials for new ayurvedic formulations find few takers

The proposals for clinical trials of new ayurvedic formulations have come under scrutiny with a major chunk of ayurvedic companies particularly those belonging to small and medium category feeling that it could kill the industry if not properly implemented. Also, there is a lurking fear that it could lead to a rise in the prices of ayurvedic drugs. The ayurvedic doctors feel such regulations should be dropped for ayurvedic drugs other than those containing hazardous ingredients (those concerning heavy metals). The pre-clinical and clinical trials for new ayurvedic drug formulations have been prescribed by the Department of Ayush with the intention of providing appropriate evaluation methods to facilitate the development of regulation and registration in ayurveda and other traditional systems of medicines.

India: ICMR comes out strict draft norms on clinical trials

Mothers undergoing clinical trials which harm their unborn child may soon be able to demand compensation from researchers conducting the trial. According to Indian Council of Medical Research's draft guidelines for compensation to participants for research related injury in India, compensation will have to be paid to a child injured in-utero through the participation of the parent in clinical research. According to ICMR, these guidelines apply to all clinical research whether sponsored by the pharmaceutical or medical device industry, government or academia.

India: K'taka drug control dept issues 323 show cause notices to pharmacy outlets

Karnataka drugs control department has issued 323 show cause notices for violations in the pharmacy trade outlets. The department has cancelled 85 sales licenses and suspended another 151 sales licenses. The licenses were cancelled for not maintaining the accounts, disbursement of bills and keeping stocks of expiry drugs along with the medicines which are on sale. The Drugs Control Department, at the same time, has also issued 278 fresh licenses. In Karnataka, there are around 22,003 sales premises, 170 blood banks and 241 manufacturing units. In the drug test laboratory of the state, 288 samples were analysed of which 26 samples were declared as not of standard quality drugs and investigation is being carried out, stated Dr BR Jagashetty, Karnataka drugs controller.

FDA APPROVALS

Americas

USA: Takeda's febuxostat gets US FDA nod for hyperuricemia with gout

Takeda Pharmaceutical Company Limited and its wholly-owned subsidiary, Takeda Pharmaceuticals North America, Inc., announced that the United States Food and Drug Administration (FDA) has approved Uloric (febuxostat) 40mg and 80mg for the chronic management of hyperuricemia in patients with gout. This once-daily, oral medication is the first new treatment option in more than 40 years for the more than five million patients who have hyperuricemia associated with gout. Uloric was discovered by Teijin Pharma Limited (Teijin Pharma) of Tokyo and licensed to Takeda for the US market.

USA: Glenmark Pharmaceutical unit gets approval for Lithium Carbonate Tablets

Glenmark Generics Inc. USA (GGI), a subsidiary of Glenmark Pharmaceutical, has received ANDA approval from the United States Food and Drug Administration (U. S. FDA) for Lithium Carbonate 150mg, 300mg and 600mg capsules. The company plan to immediately commence marketing and distribution of these products in the U. S. Market. Lithium is indicated in the treatment of manic episodes of Bipolar Disorder. It is also indicated as a maintenance treatment for individual with a diagnosis of Bipolar Disorder. According to IMS Health, Lithium Carbonate capsules had annual sales of US\$10m for the period ending September 2008.

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USA: Impax receives US FDA approval for generic Solodyn

Impax Laboratories, Inc. confirmed that the US Food and Drug Administration (FDA) has granted final approval of the company's Abbreviated New Drug Application (ANDA) for generic versions of Solodyn (minocycline HCl) 45mg, 90mg and 135mg extended-release tablets. Medicis markets Solodyn for the treatment of moderate-to-severe acne. According to Wolters Kluwer Health, US sales of Solodyn were approximately US\$340 million across all strengths for the 12 month period ending December 2008.

USA: Taro's lamotrigine chewable tablets get US FDA approval

Taro Pharmaceutical Industries Ltd. reported that it has received final approval from the US Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for lamotrigine tablets (chewable dispersible), 5mg and 25mg (lamotrigine chewable tablets). Lamotrigine chewable tablets, marketed by GlaxoSmithKline as Lamictal CD tablets, are a prescription pharmaceutical product used in treating seizures. Taro previously filed a "Paragraph IV" certification challenging GlaxoSmithKline's patent protection on Lamictal. According to industry sources, lamotrigine chewable tablet products had annual US sales of approximately US\$70m.

Europe**Germany: Sandoz receives European nod for biosimilar filgrastim**

Sandoz has received final approval for its third biosimilar, filgrastim, paving the way for this important oncology medicine to be made available to patients across the European Union. Filgrastim is indicated for the treatment of neutropenia, a condition characterized by a lack of neutrophils - one of the most common types of white blood cells - whose role is to fight infection in the body. Neutropenia is often associated with chemotherapy or bone marrow transplants, as well as advanced HIV infections. Filgrastim is a natural protein produced commercially by recombinant DNA technology, which stimulates production of white blood cells.

Asia Pacific**Thailand: FDA certifies quality of Indian-made heart drug**

Thailand's Food and Drug Administration (FDA) has certified the quality of the Indian-made generic heart drug Clopidogrel which is 23 times cheaper than its patented alternative Plavix, media reports said. "We confirm that every lot of Clopidogrel imported from India has been tested, with its quality and efficacy approved by the Department of Medical Science before being distributed to hospitals," FDA deputy secretary said. Thailand has already imported 6m Clopidogrel pills from India under its Compulsory Licensing scheme that allows the government to import generic pharmaceuticals to treat major diseases prevalent in the country.

OTHERS**UK****Britain: Drugs giant GSK to slash thousands of jobs: reports**

British drugs giant GlaxoSmithKline will announce it is cutting up to 10,000 jobs when it posts full-year results this week, reports said. The Sunday Telegraph reported that 6,000 jobs would go, while the Observer put the figure at 10,000, which would represent 10% of the group's worldwide workforce. The global pharmaceuticals giants are facing a growing commercial challenge from cheap, generic drugs as dozens of high-selling medicines lose patent protection. GSK's rival AstraZeneca said it would axe more than 6,000 jobs by 2013, extending a cost-cutting programme that had already shed about 8,000 positions since 2007.

India: Drug makers' net profit down 24%, M-cap drops 21%

The Indian drug industry, generally considered resistant to economic downturns, suffered in the December quarter, as net profits fell by 23.7% and market capitalisation declined by 21.4% compared with the year-ago period, its worst performance in 12 quarters. However, the decline in earnings was largely due to currency fluctuations and a weak capital market. High mark-to-market losses due to

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currency hedging and higher interest costs on foreign currency loans due to currency fluctuation were the key factors that dragged down profits for most firms.

India: Global drug majors slow R&D offshoring to India

New drug discovery and contract research have taken a back seat as global drug majors have slowed down their research and development offshoring to India. The domestic players could only manage three small deals in January 2009 since September 2008. These three are between Intas Biopharma and Canadian generic major Apotex, Biocon subsidiary Syngene International and US biotech firm Sapiient Discovery, and Jubilant Biosys' drug discovery partnership with US-based BioLeap. Experts and analysts attribute the slowdown to global recession causing multinational players to reserve cash and cut down R&D expenses in the wake of dwindling profits.

India: 200kgs of fake Viagra tablets seized in Haryana

Haryana Police have claimed to have recovered more than 200kg of fake tablets of Viagra, the drug for erectile dysfunction. The fake Viagra was recovered from a unit in Udyog Vihar in Haryana in a raid conducted jointly by the Haryana crime branch and Haryana State Drug Controller Organisation. According to the police, the fake drugs were being manufactured for the past six months and were being sent to countries like the UK, US and Canada. A case has been registered against the company, Chem Pharma Company, and its owner SC Bhardwaj.

India: Drug companies to launch anti-AIDS medicine

Prices of popular anti-Aids medicine Tenofovir could soon fall as several Indian drug companies plan to launch their low-cost versions in the next few months. US-based Gilead Sciences, the innovator company which sells the drug under the trade name Viread is launching its original drug in India through a marketing tie-up with Piramal Lifesciences. Others such as Ranbaxy, Alkem, Aurobindo Pharma and Hetero may launch their generic versions soon. Viread and its combination drugs, which are used as second line medication in India when patients developed resistance to first line drugs, raked in revenues of about US\$4 billion in 2008 for Gilead.

FDA's nod key to Indian drug companies' growth in US

Ranbaxy, Dr Reddy's and other Indian drug makers, which earn a third of their earnings from selling products in the US, need higher drug approvals from the Food and Drug Administration (FDA) of that country in the next financial year to maintain 20% sales growth. The requirement comes at a time when the US, the world's biggest drug market, is facing a slowdown and one of India's leading drug makers, Ranbaxy, is being investigated by US FDA for violating rules. Ranbaxy and Lupin, which currently face regulatory issues with the US FDA, might find it tough to achieve this target, the report said. Indian generic companies account for more than 40% of marketing applications in the US. Drug companies with a good product pipeline in the US and Europe will not suffer in near or long-term future.

India: Pharma companies eye new markets to drive sales

Indian pharmaceutical companies whose global revenues were affected by their exposure to foreign currencies and slump in the US sales have seen significant revenue growth in the newer or emerging markets across continents. "Emerging markets will continue to show the fastest growth for Indian drug companies as they are introducing new products in these markets. Product registration is a continuous process and hence growth," Ranjit Kapadia of broking firm Prabhudas Liladhar said. A recent KPMG report has highlighted the growth opportunities in the newer markets. "Indian companies are now also looking towards emerging markets such as Russia and other CIS nations, Eastern Europe, Brazil and other Latin American countries and South Africa. These markets, similar to Indian market, have branded generics and high entry barriers that leads to less competition and higher profitability," the report said.

India seeks easy entry for drug cos in Japan

India is set to ask Japan to facilitate the entry of Indian pharmaceutical companies in the world's second-largest drug market. Indian companies say their penetration of the US\$66 billion Japanese drug market is restricted due to a host of reasons. Indian companies are the world's largest suppliers of generic drugs,

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which are low-cost versions of off-patent drugs. Currently, the generic drug penetration in Japan is about 5%, which translates to a US\$3 billion market. The Japanese government is making regulatory changes to promote generic drugs to reduce healthcare costs and expects generic drug penetration to reach 30% in volumes by 2012-13. Only a few Indian companies currently have subsidiaries in Japan. While Lupin, Dr Reddy's and Zydus Cadilla have wholly-owned units, Ranbaxy Laboratories, now owned by Japan's Daiichi Sankyo, has a 50:50 joint venture with another local player and a marketing subsidiary.

India: Stress on collaboration to beat slowdown in pharma sector

There is a greater need for collaboration between pharma companies across the globe in research and licensing in view of the present economic slowdown. This was the opinion expressed by panelists at a discussion on business drivers leading to collaboration and licensing at the on-going BioAsia 2009. Alliances and collaboration in the global pharma industry are necessary as there has been a phenomenal increase in spending on licensing procedures and shortage of capital, especially for smaller yet innovation-driven companies.

India: Some companies register profit despite slowdown

Defensive sectors like pharma and FMCG tend to perform better than others during a downturn. This was proven to be true in the December quarter, given the performance of Dr Reddy's Laboratories (DRL), Unichem Laboratories and the tea company McLeod Russell. DRL's net margin was primarily boosted by the exclusivity enjoyed by one of its authorised generic drug. To sustain its growth, the company is also undertaking a shift in its various business models. In German market, which is changing from branded generic market to a tender based generic market, the company intends to emerge as a high volume, low margin player. In India, the company is changing from a supply-push model to a replenishment-based (demand-pull) model to boost its stagnant business.

India: Malaysia eyes strong bio bonds with India

In a move to boost the bilateral trade relationship between Malaysia and India, Malaysian Biotechnology Corporation (BiotechCorp), the lead development agency for the biotechnology industry in Malaysia, kicked off their first business development engagement for 2009 in Hyderabad and Chennai with the Indian media members and industry participants. Fresh collaboration announcements are expected from the meetings scheduled with key players of the Indian biotechnology and life sciences companies. In the 2009 Budget, the Malaysian government has allocated a RMB13.7 billion (US\$3bn) to enhance healthcare, which include increasing the supply of medicine, intensifying research and enforcement activities as well as further strengthening the growth of healthcare biotechnology.

India: State drug authorities to oppose centralising of WHO-GMP certification

Some of the states are likely to oppose the recent move by the Drug Controller General of India (DCGI) to centralise the WHO-GMP certification process as it further takes away the powers of the state licensing authorities, besides making it tougher for the small scale units across the country. Though the industry has in principle welcomed the move to do away with the WHO-GMP certification by making the Certificate of Pharmaceutical Products (COPP) mandatory, the industry associations have taken up the matter with the SLAs to write to the DCGI for a corrective step. "The states have no control over the COPP as it is issued by the CDSCO headquarters. It is not easy for us to go to the centre for certification each time," a senior industry leader disclosed, after interacting with a number of state drug controllers on the matter.

India: Short-term hit seen for pharma outsourcing

The global economic slowdown may help boost pharma outsourcing to India but not just yet. Industry watchers say that contract research and manufacturing services (CRAMS), in which companies such as Piramal Healthcare and Dishman Pharmaceuticals and Chemicals are major players, is likely to see a slowdown in the coming 1-2 quarters. In the long run, however, the economic headwinds are likely to boost the CRAMS business. This is because multinational drugmakers' distribution cycle for formulations has been impacted by the slowdown. According to estimates, such outsourcing helps multinationals cut costs by 30-50% due to the availability of cheap labour in India.

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Walden University offers 3 new courses; MS in leadership, BS in instructional design & tech and BS nursing

Walden University, one of the leading providers of online degrees, is offering three new degree programmes designed to meet increasing demands for qualified professionals in the fields of nursing, instructional design and technology, and management leadership with the addition of its Bachelor of Science in Nursing, B.S. in Instructional Design and Technology, and M.S. in Leadership programmes.

AICTE puts on hold decision to increase student intake for B Pharm course

The All India Council for Technical Education (AICTE) is learnt to have backtracked from its decision to give permission to increase the number of student intake in the pharmacy colleges from the existing 60 to 90 students for B Pharm course as there was no demand from other states except Andhra Pradesh to increase the number of seats. The AICTE late last year had taken the in-principle decision to allow the colleges to increase the student intake for B Pharm course.

Product Focus – Levetiracetam (Keppra)

Levetiracetam (Keppra)

Introduction

Levetiracetam (INN) is an anticonvulsant medication used to treat epilepsy. It is S- enantiomer of etiracetam, structurally similar to the prototypical nootropic drug piracetam. Levetiracetam is marketed under the trade name Keppra. Keppra is manufactured by UCB Pharmaceuticals Inc.



Drug Class and Mechanism

Levetiracetam is an antiseizure (antiepileptic) drug. Its mechanism of action is unknown, but it inhibits the spread of seizure activity in the brain. In studies, addition of levetiracetam to other antiseizure drugs reduced the frequency of seizures more than placebo. The FDA approved levetiracetam in November 1999.

Dosage and Administration

Treatment should be initiated with a dose of 1000mg once daily. The daily dosage may be adjusted in increments of 1000mg every 2 weeks to a maximum recommended daily dose of 3000mg.

Drug Interactions

In vitro data on metabolic interactions indicate that KEPPRAXR is unlikely to produce, or be subject to, pharmacokinetic interactions. Levetiracetam and its major metabolite, at concentrations well above C_{max} levels achieved within the therapeutic dose range, are neither inhibitors of, nor high affinity substrates for, human liver cytochrome P450 isoforms, epoxide hydrolase or UDP-glucuronidation enzymes. In addition, levetiracetam does not affect the in vitro glucuronidation of valproic acid. Levetiracetam circulates largely unbound (<10% bound) to plasma proteins; clinically significant interactions with other drugs through competition for protein binding sites are therefore unlikely.

Preparations: Tablets (immediate release): 250, 500, 750, and 1000 mg. Tablets (extended release): 500 mg. Oral solution: 100 mg/ml. Injection solution: 100 mg/ml.

Storage: Levetiracetam can be stored at 25 degree C (77 F). Brief storage at 15-30 degree C (59-86 F) is acceptable.

Side Effects

Side effects cannot be anticipated. If any develop or change in intensity, inform the Physician as soon as possible. Only the Physician should determine if it is safe for the person to continue taking Keppra.

Market Scenario

Epilepsy Market:

Epilepsy, one of the oldest conditions known to mankind, is a neurological disorder characterised by recurrent, transient seizures caused by a disturbance in the electrical activity of the central nervous system. According to the World Health Organisation, up to 50 million people worldwide, equating to a

Brands	Manufacturers
Levroxa	Ranbaxy
Epictal	IPCA (Innova)
Levecetam	Psycorem
Levtam	Neu Foreva
Torleva	Torrent

Source: mims.com; Cygnus Research

Side effects
➤ Depression
➤ Dizziness
➤ Drowsiness
➤ Headache
➤ Infection
➤ Loss of muscle coordination
➤ Nervousness
➤ Pain
➤ Runny nose
➤ Sore throat
➤ Weakness

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prevalence of at least 50 per 100,000 of the general population will have epilepsy at any one time. The seven major markets for epilepsy revenues grew strongly at a compound annual growth rate of 11.7% to reach almost US\$3.8 billion in 2007.

Characterised by a tendency to recurrent seizures and defined by two or more unprovoked seizures, the clinical manifestations of seizures will vary depending on where in the brain the disturbance first starts and how far it spreads. Transient symptoms can occur, such as loss of consciousness and disturbances of movement, sensation, mood or mental function. While the condition can develop at any age, it is most often diagnosed before the age of 20 and after the age of 60, and can be due to any one of several conditions, including:

- Genetic
- Hippocampal sclerosis
- Congenital disorders
- Cerebrovascular disorders
- Alcohol/drugs & metabolic disorders
- Cerebral infection
- Brain tumours

Levetiracetam Sales

Glenmark Generics Inc., USA (GGI), the subsidiary of Glenmark Generics Limited (GGL), has commenced marketing and distribution of Levetiracetam 250 mg, 500 mg and 750 mg tablets in the U.S. market. According to IMS Health data for the 12

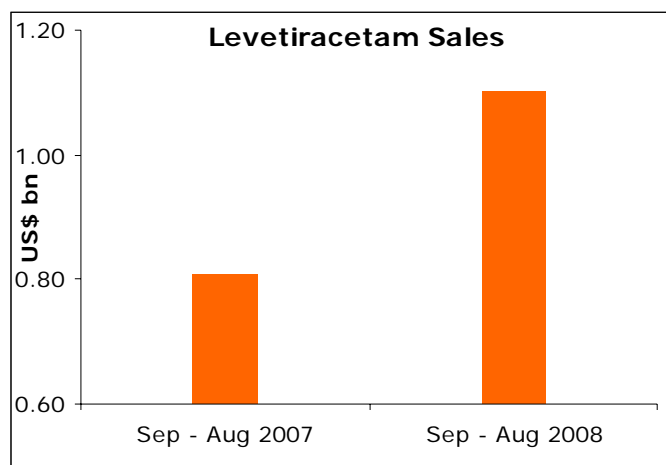
month period ending September 2008, Levetiracetam tablets recorded sales of US\$ 1.1 billion, growing at a rate of 36% over the corresponding period for the previous year. For the 12 month period ending September 2008, Levetiracetam is ranked within the top 5 oral solid anti-epileptic (N3A) products.

Glenmark initiated shipping immediately upon final ANDA approval for Levetiracetam tablets from the U.S. FDA through its longstanding partnership with Invagen Pharmaceuticals Inc. Based on the terms of this collaboration Glenmark will exclusively market and distribute the product while Invagen will be responsible for the manufacture and supply.

Outlook

With a forecasted CAGR of 6.8%, anti-epilepsy sales are expected to double over the next decade, beginning to level off after 2008. Significant events depressing market growth will be the potential dominance of generics as unbranded gabapentin, topiramate and lamotrigine become available, each capturing around 70% of brand volume in the US. The approval of anti-epileptic drugs for new indications, use as monotherapy, and in children, will potentially provide growth however, along with the availability of already marketed anti-epileptic drugs in countries such as Japan.

The seven major epilepsy market is forecast to grow to over US\$5.5 billion by 2017. It is forecast to become a fiercely competitive indication over the forecast period with heavy genericization setting in. Major companies are looking at different strategies in addition to new indications to protect sales of their products from generics

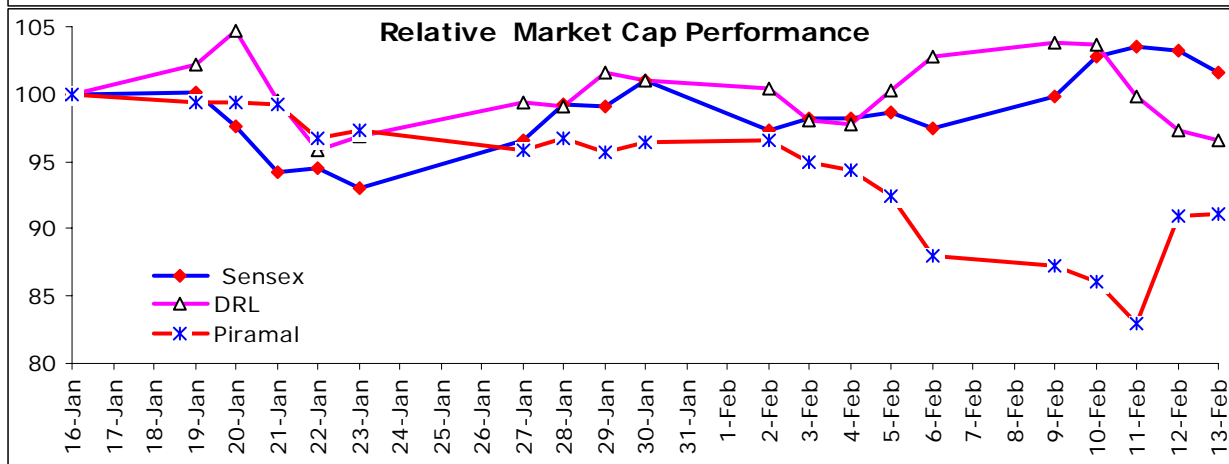
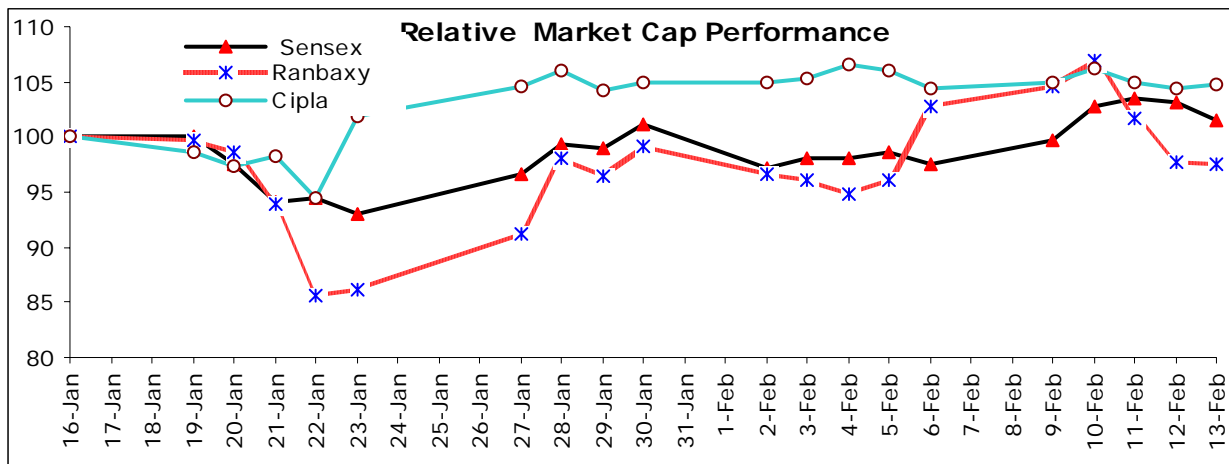


Source: BSE India; Cygnus Research

Competitors

- Wockhardt
- Dr.Reddy's
- Taro Pharmaceutical Industries Ltd
- Actavis
- Lupin
- GSK

Stock Scan



Source: BSE India; Cygnus Research

	16 Jan – 24Jan	25 Jan – 31 Jan	01 Feb – 07 Feb	08 Feb – 13 Feb
SENSEX	BSE Sensex declined by 6.9% due to the troublesome situation of the world economy and subdued OND08 quarter earnings of the Indian companies.	Obama's stimulus plan boosted sentiment across financial markets during the past week. Metals, realty, oil & gas led the charge in a week where Sensex rose around 8.6%.	Weak global cues made Sensex to lose 1.3%	Stock markets rose by 3.6% on expectations of further stimulus measures

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	performance its share price decreased by 13.83%	Rs215.70 registering an increase of 15.04% due to the bullish sentiments prevailing in the market.	company received the USFDA approval to market the Umatriptan Succinate Tablet to treat attacks of migraine headaches, which then attracted the investors.	prevailed in the market
CIPLA	Due to the company's poor financial performance its share price decreased by 1.94%	Bullish sentiments prevailed in the market. Stock moved in tandem with BSE Sensex.	Stock price remained flat under consideration	Stock price remained flat under consideration
DRL	Weak global cues made the share price fall by 3.18%	As the company's net soared 2.54 times, it impacted on share price and raised by 4.31%.	The share price inflated by 1.81% as the company received five Abbreviated New Drug Application (ANDA) approvals and launched generic product in the US market, which then attracted the investors.	The stock price opened at Rs459.30 and closed at Rs431.30 registering an increase of 6.10% due to the bearish sentiments prevailing in the market.
PIRAMAL	As the net profit declined by 47.62% in OND08 as against OND07, it impacted on share price and fell by 2.67%.	Lack of demand on shares made the stock price fall by 0.88%	Bearish sentiments prevailing in the market. Stock moved in tandem with BSE Sensex.	Increase in the volume of the shares traded resulted in the jump in the stock price from Rs194.40 to Rs201.20.

Regulatory Issues

FDA Takes New Regulatory Action against Ranbaxy's Paonta Sahib Plant in India

The U.S. Food and Drug Administration today announced that a facility owned by India-based Ranbaxy Laboratories falsified data and test results in approved and pending drug applications. The facility, Paonta Sahib, has been under an FDA Import Alert since September 2008. The FDA is continuing to investigate this matter to ensure the safety and efficacy of marketed drugs associated with Ranbaxy's Paonta Sahib Site. To date, the FDA has no evidence that these drugs do not meet their quality specifications and has not identified any health risks associated with currently marketed Ranbaxy products.

FDA Advises Public of Serious Adverse Event with Psoriasis Drug Raptiva

The U.S. Food and Drug Administration today issued a public health advisory concerning three confirmed, and one possible report of progressive multifocal leukoencephalopathy (PML), a rare brain infection, in patients using the psoriasis drug Raptiva (efalizumab). Three of those patients have died. All four patients were treated with the drug for more than three years. None of the patients were receiving other treatments that suppress the immune system.

Asia Pacific

India: Guidelines issued on Ayurveda, Siddha and Unani medicines

The Ministry of Health and Family Welfare has issued guidelines on pre-clinical and clinical studies for the Ayurveda, Siddha and Unani (ASU) medicines through a notification of draft rules adding new rule in the Drugs and Cosmetics Act, 1945. In a notification, the ministry has inserted new rules following the rule 169 of the Drugs and Cosmetics Act 1945 as guidelines for evaluation of Ayurveda, Siddha and Unani drugs and other traditional medicines of India. The government through the guidelines has suggested extensive safety evaluation procedures for approval of ASU medicines including sub-chronic toxicity tests, genotoxicity studies and clinical trials.

Australia: Health care funds to be divided according to population

A report into Australia's health care system recommends funding be distributed to regional areas depending on population size. The National Health and Hospitals Reform Commission says current funding arrangements don't serve the needs of local communities and aren't fairly distributed. The Commission also proposes that more undergraduate and post graduate healthcare places be allocated to regional areas. Doctor Jenny May, chair of lobby group the National Rural Health Alliance, says the report is a good first step.

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Upcoming Events

1	Event	Medtec Stuttgart
	Date	Mar 03-05, 2009
	Venue	Messe Stuttgart, Stuttgart, Baden-Wurttemberg, Germany
	Highlights	Medtec Stuttgart is Europe's premier exhibition and conference for medical device development and manufacturing. MEDTEC enables thousands of senior medical manufacturing professionals, representing Europe's most innovative medical device producing companies to meet with over 400 new suppliers of the medical grade raw materials manufacturing technology and outsourcers.
	Contact Details	Organizer: Canon Communications 11444 W. Olympic Blvd., Ste. 900, Los Angeles, USA. Tel: +(310)-(4)-454200; Fax: +(310)-(4)-454299
2	Event	Medical Equipment & Technology Exhibition
	Date	Mar 10-12, 2009
	Venue	Shanghai Exhibition Center, Shanghai, China
	Highlights	Medical Equipment & Technology Exhibition showcases the rapidly progressing scenario of the pharmaceutical industry of China. Alongside Chinese companies a large number of International companies will provide the global overview of this sector with new innovations and research techniques that are already on or in the anvil.
	Contact Details	Organiser: Top Repute Co. Limited, Fu Fai Commercial Center, 27 Hillier Street, Hong Kong, China Tel: +(852)-(852)-28518603; Fax: +(852)-()-28518637
3	Event	UAE Dental Exhibition
	Date	Mar 10-12, 2009
	Venue	Dubai International Convention & Exhibition Centre, Dubai, UAE
	Highlights	There will be an International conference presented by well-known speakers from around the globe, which will offer the most up-to-date knowledge to all dental professionals in the region and make use of the scientific resources that will benefit the dental community.
	Contact Details	Organiser: Index Conferences & Exhibitions Org. Dubai Health Care City Block B, Dubai, United Arab Emirates Tel: +(971)-(4)-3624717; Fax: +(971)-(4)-3624718
4	Event	Healthcare Ireland
	Date	Apr 01-02, 2009
	Venue	Main Hall & Serpentine Hall
	Highlights	Healthcare Ireland's international Exhibition contains all the latest products and services that will enhance efficiency, and improve care now and in the future. And by sharing experiences and information with colleagues from different departments, and across the country, we'll develop as individuals, and improve healthcare delivery
	Contact details	Healthcare Ireland Organizing Office, Step House, North Farm Road Tunbridge Wells, Kent UKTN2 3DR, Tel: +44 (0)1892 518877; Fax: +44 (0)1892 518811; E-mail: healthcare-ireland@stepex.com; Web: www.healthcare-ireland.com

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5	Event	Womens Healthcare
	Date	Apr 08-11, 2009
	Venue	Dubai International Convention & Exhibition Centre
	Highlights	Womens Healthcare is an event taking place alongside the very well established Bride Show in Dubai. Of the visitors of The Bride Show, more than 60% stated they are the decision maker regarding healthcare treatment in their family. It is vitally important that these women are educated on various health risks and most recent healthcare solutions.
	Contact Details	IIR Middle East P. O. Box, Dubai, United Arab Emirates Tel: +(971)-(0)-43365161; ax: +(971)-(0)-43365886
6	Event	Bangalore Bio
	Date	Apr 15-17, 2009
	Venue	Bangalore International Exhibition Centre, Bangalore, Karnataka, India
	Highlights	Bangalore Bio will offer an unrivalled opportunity in Asia Pacific region to meet with the who's who of the Biotech world in one place at one time. Bangalore Bio will be held at Bangalore International Exhibition Centre from 15 to 17 Apr 2009. In 2008, nearly over 600 delegates, 72 speakers, 150 exhibitors participated in this event.
	Contact details	M. M. Activ, Bangalore UNI Building, Thimmaiah Road, Millers Tank Bund, Bangalore, India Tel: +(91)-(80)-41131912; Fax: +(91)-(80)-41131914
7	Event	Pharmaceutical & Biotechnology Middle East (PABME)
	Date	Apr 20-22, 2009
	Venue	Dubai International Convention & Exhibition Centre, Dubai, Dubai, United Arab Emirates
	Highlights	Pharmaceutical & Biotechnology Middle East (PABME) is an exciting new networking platform for international industry players to converge, network and discuss new business alliances and joint ventures. The event will be a preferred destination for the international Pharma and Biotech Industries and an opportunity not to be missed!
	Contact details	IIR Middle East P. O. Box, Dubai, United Arab Emirates Tel: +(971)-(0)-43365161; Fax: +(971)-(0)-43365886
8	Event	PABME 2009
	Date	April 20-22, 2009
	Venue	Dubai International Convention and Exhibition Centre, UAE
	Highlights	It is a part of the Arab Health portfolio since 2001. Meet and network with the leaders of the industry and potential investors in a one stop shop for all Pharmaceutical and Biotechnology professionals in the unique and futuristic city of Dubai, the business hub of the Middle East.
	Contact details	Terri D'Elia, Exhibition Manager, Tel: +971-4-3365161 x 110; Fax: +971-4-3364021, Web : www.pabme.com; Email- pabme@iirme.com

9	Event	CPhI JAPAN 2009
	Date	April 21-23, 2009
	Venue	Tokyo Big Sight Exhibition Center, Tokyo
	Highlights	Currently the market of Bio-Pharmaceuticals as typified by antibody drugs has been a fascinating subject for both exhibitors and visitors at CPhI JAPAN. The market is forecast that the antibody drug will pull the market in the future, and it is in the increasing tendency the proportion of the biomedicine in the approved medicine.
	Contact Details	Event manager, CMP Business Media Co Ltd, Kanda 91 bldg., 1-8-3, Kaji-cho, Chiyoda-ku, Tokyo 101-0044, Japan Tel : +81-3-5296-1020; Fax : +81-3-5296-1018

10	Event	American Occupational Therapy Association Expo (AOTA Expo)
	Date	Apr 23-25, 2009
	Venue	Americas Center, St Louis, Missouri, USA
	Highlights	American Occupational Therapy Association Expo (AOTA Expo) advances the quality, availability, use, and support of occupational therapy through standard-setting, advocacy, education, and research on behalf of its members and the public. It is a meeting point for different professional and business figures, an occasion to update and to investigate topics ranging from research and new technology to marketing and the business outlook for the sector.
	Contact Details	National Trade Productions 313, S. Patrick, Alexandria, United States Of America Tel: +(1)-(800)-6877469; Fax: +(20)-(703)-8364486