The Indian Pharmaceutical Association

PHARMA PROFESSIONAL

Cygnus Business Consulting & Research Pvt.Ltd.
Knowledge Partner for Profitable Growth

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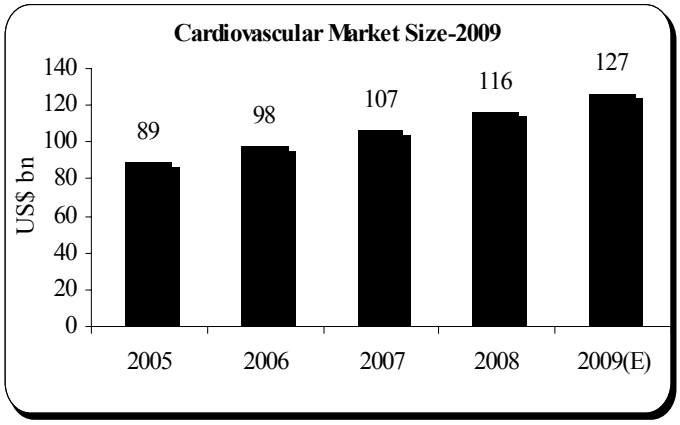
In Focus: Cardiovascular segment

.Introduction

The cardiovascular therapy areas extend a range of treatment classes including anti-hypertensives, anti-dyslipidemics, anti-thrombotics, haematological preparations and cardiac therapies. The cardiovascular market segmented into numerous subcategories, including anti-hypertensives, anti-dyslipidemics, anti-thrombotics, cardiac therapies and other cardiovascular agents. While established treatments are currently available for each of these therapeutic subcategories, these markets are large and significant unmet medical needs still exist.

Global Market

Global cardiovascular market size was estimated to value at US$127 billion in 2010. It has recorded a CAGR of around 9% during 2006-2010. Growth is driven by demographic changes and life style changes. It is also observed that growth is limited, which is mainly due to continued patent expires of the major brands and a shortage of novel therapies being introduced.



Source: Cygnus Research

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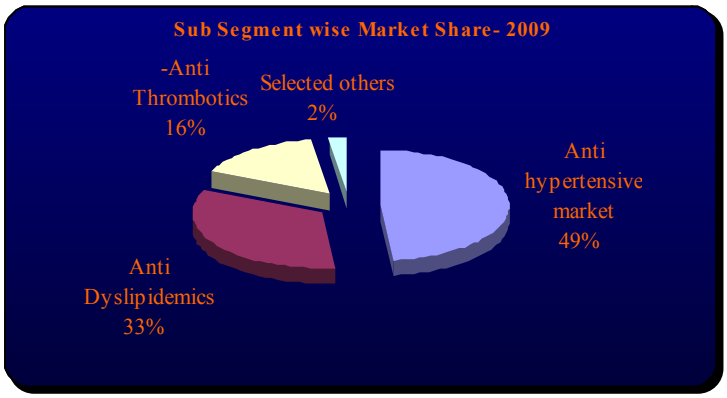
Sub Segment wise Market Share: Anti-hypertensive leads the race

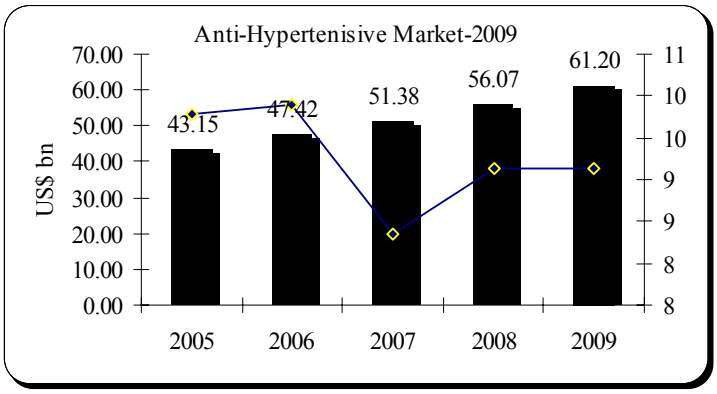
Globally, the cardiovascular market is dominated by anti-hypertensive market with 49% market share, followed by anti-dislipidemics with 33% market share. Anti-thrombotics has 16% market share in cardiovascular segment, while others have a 2% market share, which includes haematological preparations and cardiac therapies.



Source: Cygnus Research

Anti-hypertensive segment

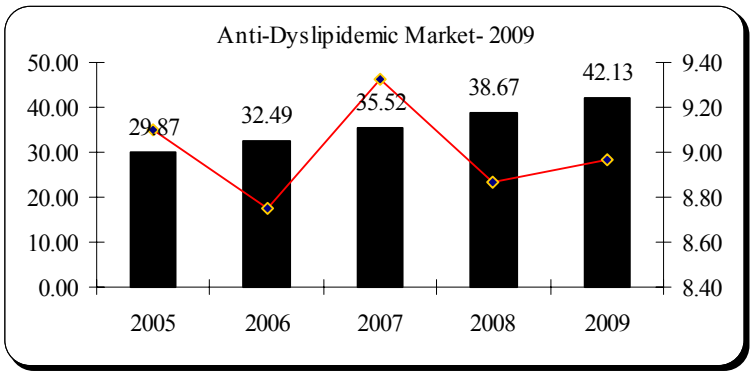
Anti-hypertensives are a class of drugs used to treat hypertension. It mainly includes adrenergic receptors (beta blockers and alpha blockers), calcium channel blockers, ace inhibitors and angiotension II receptor antagonists. The global anti-hypertensive market has increased by 9.14% in 2009 to US$61.20 billion. In this market, growth is limited as the top products are going patent off continuously. Top brands like Diovan/C0-Divan, Norvasc and Cozaar.



Source: Cygnus Research

Anti-Dyslipidemic Segment

Anti-Dyslipidemic is the second largest segment in cardiovascular segment. It is mainly dominated by statins and less by the other class of drugs. Global anti-Dyslipidemic market was valued at US$42.13 billion and grew at CAGR 8.98% during 2005-09.



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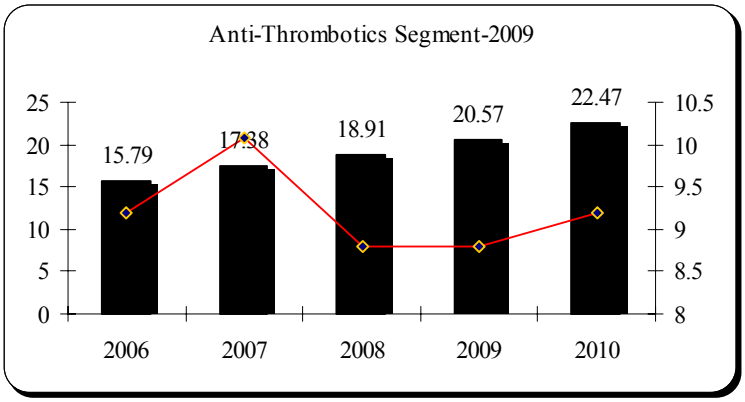
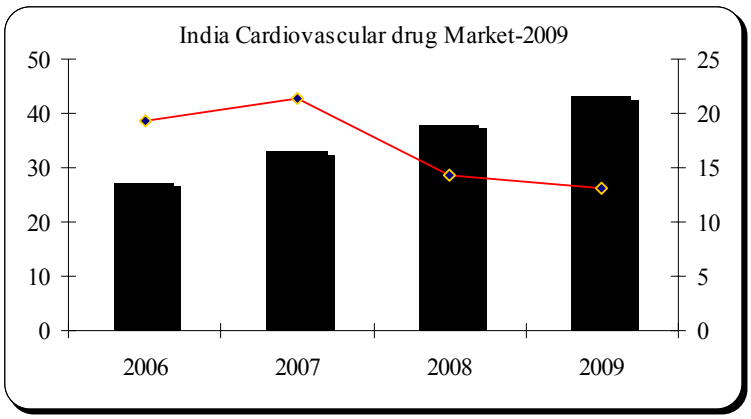
Anti-Thrombotic Segment



Source: Cygnus Research

Anti-thrombotic drugs, which include anticoagulants, antiplatelet drugs and thrombolytic drugs, are used in a wide range of indications for the prevention and treatment of ischaemic events. These include– –Acute Coronary Syndromes (ACS), Myocardial Infarction (MI), Stroke, Venous Thromboembolism (VTE) and Peripheral Arterial Occlusion (PAO). It is one of the fastest growing segments in the cardiovascular, with a share of around 16%. It was estimated to be around US$22.47 billion and grew at a CAGR of 9.22% during 2006-09.

Indian Cardiovascular Market



Source: Cygnus Research

Cardiovascular market is driven by demographic changes, lifestyle habits, increase in stress level. It is noticed that there will be clear limitations on sales from continued patent expires for major products. Additionally, company pipelines in the area appear to be woefully empty. Cardiovascular market was valued at Rs. 43 billion and grew at a CAGR of 16% during 2006-09.

Drivers of the Cardiovascular Market

- Demographic changes
- Life style habits
- Sudden cardiac deaths
- Increasing stress

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News Briefs

MARKETING

America

USA: Rite Aid, AAAAI team up to help allergy sufferers with free allergy guide

Rite Aid and the American Academy of Allergy, Asthma & Immunology (AAAAI) are again teaming up this spring to help allergy sufferers with free allergy guides available now in nearly 4,800 Rite Aid stores nationwide. According to the AAAAI, each year, allergies strike 50 million Americans, leaving many sidelined from favourite activities or even rushed to emergency rooms with potentially life-threatening reactions. But allergies are also one of the most treatable medical conditions. Rite Aid is offering several reward programs including a three-month program that offers customers US$10 or US$25 Rite Aid gift cards with either US$25 or US$50 purchases of select allergy and health products. Customers also can take advantage of a six-month Rite Aid Allergy Rewards program, earning a US$20 Rite Aid gift card by purchasing US$75 of Zyrtec and/or Benadryl.

USA: NAMI Launches Social Networking Site for Young Adults

National Alliance on Mental Illness (NAMI) has launched StrengthofUs.org, a new online community where young adults living with mental health concerns can provide mutual support in navigating unique challenges and opportunities during the critical transition years from ages 18 to 25. StrengthofUs.org is a user-driven social networking community where members can connect with peers, share personal stories, creativity and helpful resources by writing and responding to blog entries, engaging in discussion groups and sharing videos, photos and other news.

USA: Avaya helps Small Healthcare Companies enhance Customer Service

Avaya IP Office, a communications solution for small and medium enterprises (SMEs), is what many SMEs in healthcare are choosing to improve patient and client service with efficiency. It helps them use unified communications to increase mobility, speed responses and automate tasks to reduce human latency. Avaya recently launched a new version of IP Office that features enhanced unified communications capabilities and makes UC up to 40% more affordable for many small businesses. Companies such as IntrinsiQ, Bay Shore Medical and SPEAR Physical Therapy are just a few of the healthcare organizations using Avaya IP office to help enhance service to patients and clients, while improving operations through communications.

North America: Takeda Pharma to market Kapidex in US under new product name as Dexilant

Takeda Pharmaceuticals North America, Inc announced that Kapidex (dexlansoprazole) will be marketed in the United States under the new product trade name Dexilant (dexlansoprazole). The product is indicated for heartburn associated with symptomatic non-erosive gastroesophageal reflux disease, the healing of erosive esophagitis and the maintenance of healed EE. Dexilant will have a new National Drug Code (NDC) number associated with the product. Takeda anticipates that the newly named product Dexilant will be available toward the end of April 2010.

Europe

UK: The Harley Medical Group opens new clinic in Glasgow

The Harley Medical Group has revealed that Scottish people are five times more likely to have cosmetic surgery than the average person. 5% of Scottish men and women say they would have, or have already had cosmetic surgery, while one in ten would opt for non-surgical solutions, such as Botox. The Harley Medical Group adds a new Glasgow clinic – the fifth new clinic opening over the past year – to its UK and Ireland portfolio, bringing the total estate to 28 clinics, with Edinburgh and many other in the pipeline for 2010.

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Pairs: Menarini, Ipsen announce to launch of ADENURIC® in France
Ipsen, a global biotechnology specialty care group and Menarini, the first Italian pharmaceutical Group in the world with a significant pan-European presence, announced the launch of ADENURIC® (febuxostat) in France where they will co-promote the drug. Other launches by Menarini are planned shortly, notably in United Kingdom, Germany and Ireland. According to Deputy General Manager, Ipsen France Operations, Ipsen, the launch of Adenuric will provide patients and physicians with a new treatment alternative in a condition with high unmet medical needs. It also strengthens Ipsen's primary care franchise in France, the first country to launch the drug in Europe.

Italy: Leespharm to market Recordati's hypertension drug Zanidip in China
Lee's Pharmaceutical Holdings Limited announced in conjunction with Recordati S.p.A., a European pharmaceutical group, the execution of a license and supply agreement for Recordati's original product, Zanidip (lercanidipine), in China. The agreement grants Leespharm an exclusive license to market and sell, Zanidip (lercanidipine tablets) for the treatment of hypertension in the People's Republic of China.

London: GSK signs pact with GAVI Alliance to supply 300m doses of Synflorix vaccine
GSK has become one of the first manufacturers to sign a unique agreement with the GAVI Alliance (GAVI) that has the potential to save millions of children from dying in the world's poorest countries. GSK will supply up to 300 million doses of its vaccine Synflorix, for invasive pneumococcal disease, to GAVI over a ten year period. Pneumococcal disease is a leading cause of death in children under the age of five in developing countries. The agreement is funded by a ground-breaking mechanism called an Advance Market Commitment (AMC) and is the result of years of planning by GAVI, UNICEF, the World Bank and major donors, who recognised the potential of vaccines to prevent diseases in developing countries.

Asia Pacific
India: Mission Vivacare to launch dietary supplements in India
The Mumbai-based nutraceuticals and pharma company, Mission Vivacare, plans to launch its products in the Indian market by October this year. At present, the company is exporting its products to the United States, Canada and countries in West Asia under the brand name 'Vivaprime'. For the Indian market, the company plans to price its products in the range of Rs899-Rs 999, for what would work out to be a monthly dosage. Nutraceuticals, made out of vitamins, minerals, enzymes and herbs, are used as food supplements.

India: Herbal care products launched
Care and Care has introduced 14 herbal health care products made by aloe vera and noni in the Kerala market. According to Mr M.S. Sajeer, Managing Director, Care and Care, aloe vera and noni have many features with medicinal use. The company also introduced aloe vera juice for liver related problems, in three flavours such as ginger, lime and honey. The products hit the market after three years of research and the company plans to market them through franchise network. It is also in the process of setting up a corporate office in Kochi this month.

Malaysia: Promotes palmolein on health grounds
The Malaysian Palm Oil Council (MPOC) in league with Adani Wilmar Ltd, a 50:50 joint venture between the Adani Group and the Singapore-based Wilmar International Ltd, has launched a campaign to promote palmolein as healthy oil rather than a cheaper option. Adani has begun marketing palmolein under the "Alpha" brand in one-litre consumer packs. A few days ago, MPOC and Adani held an awareness campaign at Tirupathi in Andhra Pradesh. The Malaysian Government is willing to share the technology of palm oil production with India. Malaysian companies find Kerala a better option since it receives rain throughout the year. "Oil palm can be grown only between 10 degrees North and South of the Equator.

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India: GSK granded marketing authorisation from EC for Revolade

GSK confirmed that the European Commission (EC) has granted marketing authorisation for Revolade (eltrombopag) for the oral treatment of thrombocytopenia (reduced platelet count) in adults with the blood disorder chronic immune (idiopathic) thrombocytopenic purpura (ITP). Eltrombopag is indicated for adult chronic ITP splenectomised patients who are refractory (have not responded) to other treatments, such as corticosteroids and immunoglobulins. Eltrombopag was discovered as a result of a research collaboration between GSK and Ligand Pharmaceuticals, and developed by GSK. Ligand discovers and develops new drugs that address critical unmet medical needs of patients for a broad spectrum of diseases including hepatitis, muscle wasting, frailty, inflammatory diseases, anemia, asthma, rheumatoid arthritis and osteoporosis.

Lilly to acquire global license to Axiron testosterone solution from Acrux

Eli Lilly and Company and Acrux announced that they have entered into an exclusive worldwide license agreement for the potential commercialization of Acrux's experimental underarm testosterone solution (proposed tradename AXIRON(TM)). Under the terms of the agreement, Lilly will receive exclusive worldwide rights to commercialise Axiron. In exchange for these rights, Acrux will receive an upfront payment of US$50 million plus US$3 million on the transfer of manufacturing assets. Acrux is further eligible for US$87 million upon the issuance of marketing authorisation by the FDA, and up to US$195 million in potential commercialisation milestones, as well as royalty payments on future global sales if AXIRON is successfully commercialised. As a result of this transaction, Lilly expects to incur a charge to earnings in the first quarter of 2010 of approximately US$.03 per share.

India: AstraZeneca inks pact with Torrent for supply of branded generics

AstraZeneca has inked a license and supply agreement with Torrent Pharmaceuticals Ltd. Under the pact, Torrent will supply to AstraZeneca a portfolio of generic medicines for which the former has already licenses in a range of countries. Under the agreement AstraZeneca will initially purchase from Torrent the licenses and market authoriSations for 18 products in nine countries. The agreement allows the flexibility to add further products and new countries where AstraZeneca sees opportunities for growth.

Lupin launches osteoarthritis drug Hyalgan in India

Lupin has launched Hyalgan (sodium hyaluronate), an osteoarthritis drug, available in the form of an injectable through leading orthopaedics and physiotherapists across the country. Hyalgan is the original research molecule of the Italian pharma giant Fidia and is the world leader in HA therapy, marketed in over 60 countries globally. The drug, which is a natural liquid injected into the knees to relieve pain caused due to osteoarthritis, has been test-marketed by Lupin Hyalgan over the last six months across the country. Hyalgan is recommended for patients of stage 1 to 3 of OA to relieve the acute pain associated with it.

India: Dr. Reddy's Labs to move 25% more Betapharm production to India

Dr. Reddy's Laboratories is shifting production of more drugs from its German subsidiary, Betapharm, to India to remain competitive. Since all the medicine supply contracts it had managed to get in Germany were for products it sources from India, Dr Reddy's has decided to shift the production of 25% more of Betapharm's products to India in about six months. Shifting of more products to the low-cost manufacturing destinations in India will enable Dr Reddy's to be more competitive in future tenders. Currently, the bulk of Betapharm revenues come from the tender business.

GSK: Looking To Grow In India Via Buys, Core Business

GlaxoSmithKline PLC (GSK), the world's second-largest drug maker by prescription drug sales, is looking at expanding in India via both acquisitions and core business growth, according to its chief executive. "Opportunities will be evaluated based on a variety of factors, including the strategic nature of the fit," Andrew Witty told reporters on the sidelines of a company event. The company operates in the pharmaceutical market in India through unit GlaxoSmithKline Pharmaceuticals Ltd. (500660.BY) and in the consumer healthcare segment through unit GlaxoSmithKline Consumer Healthcare Ltd. (500676.BY).

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Waters, Daiso inks marketing pact for Bulk Process Chromatography Media

Waters Corporation and Daiso have entered into a collaborative agreement to globally market and supply Daisogel bulk packing materials for process chromatography. The combined purification expertise of both organizations will aid pharmaceutical and biopharmaceutical companies as they move from lab-scale purifications into pilot plant and process-scale manufacturing. As drug manufacturers invest significant amounts of money to manufacture new drug substances, they need solid commitments from established high quality process bulk suppliers with a long track record for synthesising chromatographic media for drug purification processes. Whether they need gram quantity amounts or hundreds of kilograms of bulk media, contract manufacturing organisations, innovator pharmaceutical, biopharmaceutical, natural product, and generic pharmaceutical laboratories can find the media they need in the right quantity and quality from Waters Corporation

INVESTMENTS

Europe

UK: Worldwide Supplier of Medical Equipment Level 1 Medical Opens for Business

Level 1 Medical are predicting a positive start to supplying its customers, as cost effective equipment combined with quality have demonstrated repeatedly new account development. Level 1 Medical is a medical supplies company distributes healthcare products and medical equipment throughout the UK and worldwide. Level 1 Medical has 25 years management experience in the industry and distributes to hospitals, GP surgeries and other healthcare professionals; additionally other personal well being devices for weight control, checking cholesterol levels and general fitness. Level 1 Medical aims to provide healthcare professionals with equipment for everyday use that will enhance patient care, and also work with customers to reduce costs.

Asia-Pacific

India: WACKER Starts Up New Production Facility for Pharmaceutical Proteins

Wacker Chemie AG officially opened a new production facility for pharmaceutical proteins (biologics) in Jena recently. The new plant is part of the Munich-based chemical company's investment program to enlarge its biotech operations. The expansion enables wacker to accommodate its customers' rapidly growing demand for biotechnologically manufactured pharmaceuticals. Biologics are used to treat, among other things, cancer, multiple sclerosis and hepatitis. The expansion, with the new building for process development and quality control brings Wacker's total investment in the Jena facility to some €18 million.

Aurobindo Pharma presents AuroSource, new division for CRAMS

Aurobindo Pharma Ltd has established AuroSource, a service oriented and customer-centric division with in the company that will provide custom R&D and manufacturing (CRAMS) services for large, mid-sized and emerging biotech and pharmaceutical entities globally. AuroSource will partner with these companies and cultivate opportunities to research, manufacture and develop compounds across the entire drug life cycle. The new devision will provide fully consolidated or customised manufacturing solutions for APIs, intermediates, pre-formulations and formulations across each stage of the pharmaceutical life cycle

MERGERS AND ACQUSITION

America

USA: Women's Lab Coat Pioneer Partners with the California Dental Association

Medelita, maker of breakthrough performance women's lab coats, doctor's lab coats and medical apparel, announced that it is an official corporate supporter of the CDA Foundation. The CDA Foundation is the philanthropic arm of the California Dental Association, whose mission is to improve the oral health of Californians by supporting dental health professionals and their efforts to meet community needs. Medelita will donate proceeds of all CDA member purchases to the CDA Foundation. CDA members will be able to purchase qualifying products at CDA events and exhibits and on a special web site for CDA members, which will be coming soon.

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St. Louis: Sigma-Aldrich enters pact to sell Pfizer's bioactive small molecule
Sigma-Aldrich has entered into an agreement with Pfizer under which Sigma-Aldrich will sell approximately 100 Pfizer-developed small molecule compounds to life science researchers for target characterisation, assay development, screening and in vivo animal model applications. Under the agreement between the two companies, the Pfizer compounds include patented and approved drug molecules such as atorvastatin, sildenafil and celecoxib, will be made available to the research community while still on patent, in some cases for the first time. The inclusion of these Pfizer compounds provides authentic material that will help advance researchers understanding of biological systems.

Washington: MDRNA acquires BNA technology from Valeant Pharma
MDRNA, INC, a leading RNAi-based drug discovery and development company, announced that it has acquired intellectual property for bridged nucleic acids from Valeant Pharmaceuticals North America. "The BNA technology provides MDRNA a unique position in the development of RNA therapeutics," stated Chief Scientific Officer of MDRNA. "BNA is highly complementary to our proprietary unlocked nucleobase analog (UNA) technology and enables MDRNA to tailor key characteristics of our UsiRNA constructs to impart greater versatility and specificity. Additionally, BNA strengthens MDRNA's proprietary meroduplex constructs and are directly applicable to alternative oligonucleotide constructs including single strand molecules and constructs which function outside of an RNAi mechanism."

Toronto: Biovail acquires Ampakine compounds from Cortex Pharma
Biovail Corporation, a specialty pharmaceutical company, has reported that its subsidiary, Biovail Laboratories International, or BLS, has acquired certain Ampakine compounds, including associated intellectual property, from Cortex Pharmaceuticals, Inc. (Cortex) for use in the field of respiratory depression, a brain-mediated breathing disorder. The acquired compounds include the phase-2 compound CX717, the preclinical compounds CX1763 and CX1942, and the injectable dosage form of CX1739.

Toronto: Transition acquires rights to diabetes pre-clinical compounds from Lilly
Transition Therapeutics Inc has acquired the rights to a series of preclinical compounds from Eli Lilly and Company in the area of diabetes. Under the licensing and collaboration agreement, Transition will receive exclusive worldwide rights to develop and potentially commercialise a class of compounds that, in preclinical diabetes models showed potential to provide glycemic control and other beneficial effects including weight loss. "Lilly's existing partnership with Transition pertaining to the exploration of gastrin-based therapies as potential diabetes disease-modifying agents continues to be productive," Said Lilly vice president of Endocrine and Cardiovascular Research. "…This new partnership with Transition supports that strategy for the development of a new class of agents for diabetes and related co-morbid conditions that was derived from Lilly's ongoing diabetes and biotechnology efforts."

Europe

UK: GSK joins global vaccine alliance to help prevent millions of children
GSK has become one of the first manufacturers to sign a unique agreement with the GAVI Alliance (GAVI) that has the potential to save millions of children from dying in the world's poorest countries. GSK will supply up to 300 million doses of its vaccine Synflorix, for invasive pneumococcal disease, to GAVI over a ten year period. Pneumococcal disease is a leading cause of death in children under the age of five in developing countries. The agreement is funded by a ground-breaking mechanism called an Advance Market Commitment (AMC) and is the result of years of planning by GAVI, UNICEF, the World Bank and major donors, who recognised the potential of vaccines to prevent diseases in developing countries. The mechanism is backed by the G8 and was officially launched by the AMC partners and donors on 12 June 2009.

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Netherland: Strides to acquire 50% of Aspen oncology business for Rs5.26bn
Strides Arcolab Limited and Aspen Pharmacare Holdings Limited have announced restructuring arrangements which deals with the oncology joint ventures between Aspen and Strides, Onco Therapies Limited, India and Onco Laboratories Limited. The Bangalore-based company will buy 50% of the oncology business of Aspen for a consideration of US$75m and Onco transaction of US$117. The transactions signal the strategic intent of Strides and Aspen in the oncology market. Acquisitions will increase the company's manufacturing and development capabilities in its pharma specialties business. The company will now has a world class sterile asset in India, Europe, and Brazil.

German Merck to acquire Millipore for US$ 7.2bn
In a major development in the life sciences space, Merck KGaA, a global pharmaceutical and chemical company, is set to acquire US based lab instrumentation major Millipore Corporation for a total consideration of US$7.2 billion. Millipore and Merck will create a US$2.9 billion world-class partner for the life science sector, achieving significant scale in high-margin speciality products with an attractive growth profile.

Sweden: BioInvent, HGSI enter collaboration to co-develop, therapeutic antibodies
BioInvent International AB and Human Genome Sciences, Inc. (HGSI) announced that they have entered into a collaboration to discover, develop and commercialise therapeutic monoclonal antibodies which specifically target antigens discovered by HGS. Under the terms of the agreement, BioInvent will apply its state-of-the art antibody discovery technology to generate and develop monoclonal antibody candidates. The collaboration will initially focus on the development of antibodies in the field of inflammation. BioInvent and HGS will each have the right to participate in development and global commercialisation of each antibody candidate, and will share research, development, manufacturing and commercialisation costs as well as future revenues.

SpePharm acquires global rights to Savene from TopoTarget
SpePharm Holding announced that it has acquired worldwide rights to Savene from TopoTarget A/S. As part of the acquisition SpePharm will also take on the European sales force of TopoTarget. Savene, which has been marketed by TopoTarget since its approval by the EMEA in July 2006, is approved product for the treatment of extravasations, or leakage out of the blood stream, of certain commonly used anticancer drugs known as anthracyclines.

Middle East
Israel: Teva to acquire German generic drug firm Ratiopharm
Teva Pharmaceutical Industries Ltd has entered into a definitive agreement to acquire Ratiopharm, Germany's second largest generics producer and the sixth largest generic drug company worldwide, for an enterprise value of €3.625 billion. This transaction is perfectly aligned with long-term strategy in which Europe is an important pillar and growth driver. The acquisition will position Teva as the leading generic pharmaceutical company in Europe, increasing its European business from sales of US$3.3 billion in 2009 to joint proforma sales of US$5.2 billion. Ratiopharm's robust portfolio includes 500 molecules in over 10,000 presentation forms covering all major therapeutic areas marketed in 26 countries.

Asia-Pacific
India: Strides to acquire Campos's facility in Brazil from Aspen for US$ 75m
Strides Arcolab has entered into an understanding with Aspen to acquire the facility in Campos, Brazil with related products and IPs for a total consideration of US$75m. The Campos facility is engaged in producing penems and penicillin. The facility is likely to generate income of US$40m on an annualised basis. Penems is a key domain for Strides. The acquisition of Campos facility is part of a well integrated strategy for Strides with licensing and supply agreements with global partners in place. Strides Arcolab, develops and manufactures a wide range of IP-led niche pharmaceutical products with an emphasis on sterile injectables.

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Tokyo: Astellas Pharma offers to acquire OSI Pharmaceuticals for US$3.5bn
Astellas Pharma Inc. (TSE: 4503), a global pharmaceutical company, will commence a tender offer to acquire all outstanding shares of common stock of OSI Pharmaceuticals for US$52.00 per share in cash, or an aggregate of approximately US$3.5 billion on a fully diluted basis. The acquisition of OSI - a biotechnology company primarily focused on the discovery, development and commercialisation of molecular targeted therapies addressing medical needs in oncology, diabetes and obesity - would support Astellas' growth strategy of becoming a Global Category Leader in oncology. OSI manufactures and sells Tarceva (erlotinib), a leading cancer medication and has several prospective new oncology medications in its R&D pipeline. The transaction would provide Astellas with a top-tier oncology business in the US and an expanded product portfolio and pipeline. OSI would also augment Astellas' strong existing franchises in urology and immunology.

Intas Pharma to introduce world's first Interferon Lozenges in tablet form for flu in India
Following the recent license and supply agreement signed between Amarillo Biosciences Inc. (ABI), a US biotechnology firm, and Intas Pharmaceuticals, Intas will soon market world's first Interferon Lozenges (tablet form) in India. Unlike vaccines, Lozenges (tablet form) has outstanding safety profile with minimal side effects at a much affordable price. Lozenges, being orally administered, offer treatment of Influenza which have unique advantages of less frequent visit to doctors and efficacy at low dose. In a breakthrough achievement, Australian scientists have also studied this drug that prepares the immune system to effectively resist flu infections.

India: Ranbaxy, Pfenex collaborate to develop biosimilar therapeutic protein
Ranbaxy Laboratories Limited and Pfenex Inc announced that Ranbaxy will develop an undisclosed biosimilar therapeutic produced in the Pfenex Expression Technology platform, a Pseudomonas-based recombinant protein expression technology. Under the terms of the agreement Pfenex is eligible to receive maintenance fees, milestone payments as well as royalty payments on any product sales derived from the agreement. Ranbaxy and Pfenex scientists will collaborate on developing the production strains and the process that will be used to produce product in support of clinical development and commercial production of the biosimilar product.

RESEARCH AND DEVELOPMENT

America

New York: Acorda launches Ampyra ER tablets in US & Puerto Rico
Acorda Therapeutics, Inc announced that Ampyra (dalfampridine) extended Release tablets, 10 mg available by prescription in the United States and Puerto Rico. Ampyra was approved by the US Food and Drug Administration as a treatment to improve walking in patients with multiple sclerosis. Ampyra is indicated for use in all types of MS, and can be used either alone or with existing therapies, including disease-modifying agents. The availability of Ampyra gives people with MS and their physicians an important new therapeutic option.

Cambridge: Cellzome enters second strategic drug discovery pact with GSK
Cellzome has formed a second strategic alliance with GlaxoSmithKline (GSK). This new collaboration gives GSK exclusive access to Cellzome's proprietary Episphere technology in the emerging field of epigenetics as applied to immunoinflammatory disease. Epigenetic mechanisms play a key role in controlling immune cell differentiation and inflammatory gene expression during an excessive inflammatory response. Under the terms of the agreement, the companies will work together using Cellzome's Episphere technology platform, to identify selective small-molecule drug candidates against targets from four different epigenetic target classes.

Vancouver: Tekmira and Pfizer Initiate New Research Collaboration
Tekmira Pharmaceuticals Corporation announced the initiation of a new research collaboration with Pfizer (NYSE:PFE). Tekmira and Pfizer will collaborate on evaluating Tekmira's stable nucleic acid-lipid particle (SNALP) technology to deliver small interfering RNA (siRNA) molecules provided by Pfizer.

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Tekmira will be responsible for preparing the SNALP formulations and Pfizer will evaluate the formulations in preclinical models. The collaboration combines Tekmira's expertise in the delivery of RNAi therapeutics with Pfizer's research excellence in nucleic acid therapeutics.

Pairs: BioAlliance Pharma's Loramyc approved in 13 additional European countries
BioAlliance Pharma SA, a company dedicated to the treatment and supportive care of cancer and AIDS patients, announced the approval of Loramyc in 13 additional European countries through a Mutual Recognition Procedure with France as reference member state. With this approval to a total of 26 European countries for Loramyc and the recent Setofilm approval in 16 European countries, BioAlliance is building an attractive cancer supportive care portfolio including this two complementary products.

Netherlands: Syntarga enters antibody-drug conjugate pact with two top pharma firms
Syntarga B.V has entered into research collaborations with two undisclosed top-15 pharma companies. These latest agreements, adding to a total of five collaborations with top-15 biopharma companies, exemplify the growing interest in Syntarga's Potent Payload technology to empower anticancer antibodies. Syntarga Potent Payload Technology combines extremely potent, proprietary duocarmycin toxins, a class of DNA minor groove binding agents, with unique, proprietary linker technologies. The company has generated a strong biological data package for its synthetic Linker- Drug payloads conjugated to various antibodies against a variety of tumor targets, including Trastuzumab/Her2.

Middle East
Compugen announces discovery platform to predict cell penetrating peptides for drug delivery
Compugen Ltd. Announced the development and validation of its Intracellular Drug Delivery (IDD) discovery platform for identification of cell penetrating peptides. Compugen also announced that as part of the validation process for the new platform, more than twenty novel peptides, predicted and selected in silico, demonstrated the predicted cell penetrating properties in initial experimental validation studies. The delivery of biological molecules across selectively permeable cell membranes and into the cells represents a major challenge for the pharmaceutical industry. Furthermore, important classes of biological drugs now under development, such as therapeutic peptides and siRNA, need to enter the cell to be effective. Since most are unlikely to cross the surrounding protective membranes of cells on their own, they will require some type of delivery methodology. Compugen's newly developed Intracellular Drug Delivery discovery platform enables the in silico identification of novel peptide sequences that are predicted to have the potential to penetrate the cell membrane. This new platform consists of various components from Compugen's existing computational biology infrastructure and a series of proprietary machine learning algorithms specifically designed for this platform.

Asia-Pacific
India: Venus Remedies gets product patent for Sulbactomax from IPO
Venus Remedies said that the company got product patent for Sulbactomax from Intellectual Property Office or IPO of Government OF India. Sulbactomax is a fixed dose combination of a beta lactam antibiotic Ceftriaxorte Sodium and a beta lactamase inhibitor Sulbactam Sodium in dry powder form for injection to be used after reconstitution with a super solvent. Product is used for combating betalactamase mediated antibiotic resistance of existing Ceftriaxone molecule with the aid of betalactamase inhibitor. It is one of the most potent combination, highly effective against betalactamase producing cephalosporin resistant pathogenic bacteria like K pneumonia, E.coli etc.

New process patent granted to IIT Madras and MIN
New process patent has been granted to IIT Madras and Madras Institute of Nephrology (MIN) for a life saving drug used in dialysis patients with chronic kidney disease. A successful collaboration between a medical doctor from Madras Institute of Nephrology (MIN) and an organic chemist from IIT Madras has resulted in the development of an improved single stage process for the synthesis of a polymeric phosphate binder and several softer derivatives of the phosphate binder. These phosphate binders are important in the treatment of dialysis patients with chronic kidney disease

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Indian researchers develops nano version of a cancer drug

For the first time, a nano version of carboplatin, used in chemotherapy treatment has been developed, wherein unlike the existing molecule, a higher concentration of the drug will attack the cancerous cells and increase the chances of survival of a patient. A group of five Indian researchers and doctors from the Indian Institute of Technology (IIT), Mumbai; LV Prasad Eye Institute, Apollo Hospitals, Hyderabad; and Tata Memorial Hospital, Mumbai; has researched and developed a nano version of an existing cancer drug, carboplatin. This will reach the cancerous cells at a faster pace, reduce toxicity levels of the chemotherapy drug and further increase chances of survival of the patient. Carboplatin is a chemotherapy drug used against some forms of cancer, especially against cancers affecting brain and central nervous system. If this nano drug is proved successful in human trials, this would be the first nano version of a carboplatin drug in the world.

Suven's NCE to treat CNS disorders gets US patent

India-based biopharmaceutical company Suven Life Sciences has received a US patent for one of their New Chemical Entity (NCE), which is indicated for the treatment of disorders associated with neurodegenerative diseases. With this new patent, Suven has a total of five granted US product patents for their NCEs in CNS therapy. According to the company, these granted patents are exclusive intellectual property of Suven and are achieved through the internal drug discovery research efforts. Products out of these inventions may be out-licensed at various phases of pre-clinical and clinical development.

FDA APPROVAL

US FDA approves VPRIV to Treat Gaucher Disease

The US Food and Drug Administration has approved velaglucerase alfa for injection to treat children and adults with a form of the rare genetic disorder Gaucher disease. Gaucher disease occurs in people who do not produce enough of an enzyme called glucocerebrosidase. Without this enzyme, harmful amounts of a certain fatty substance (lipid) can build up in the liver, spleen, bones, bone marrow and nervous system, and can prevent cells and organs from working properly. The approval of VPRIV will provide a safe and effective alternative treatment for patients with Gaucher disease.

Maryland: Vanda Pharmaceuticals Announces US Patent Allowance

Vanda Pharmaceuticals Inc. announced in a press release that the US Patent and Trademark Office has issued a notice of allowance for its patent application of a microsphere, long-acting injectable formulation of its antipsychotic product, Fanapt (iloperidone). Fanapt tablets are indicated for the acute treatment of schizophrenia in adults. The oral formulation is marketed in the US under the tradename Fanapt by Novartis Pharmaceuticals Corporation pursuant to an agreement between Vanda and Novartis Pharma AG. Novartis is responsible for the commercialisation and further clinical development activities of Fanapt in the US and Canada, including the development and commercialization of the long-acting injectable (or depot) formulation of Fanapt.

Glenmark Generics gets US FDA approval for ropinirole Hcl tabs

Glenmark Generics Inc has received ANDA approval from the United States Food and Drug Administration (US FDA) for ropinirole hydrochloride tablets 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg and 5 mg and will immediately commence marketing and distribution the approved products. Ropinirole Hydrochloride tablet is the generic version of GSK's Requip tablet in the US market. Ropinirole hydrochloride is indicated for treatment of the signs and symptoms of idiopathic Parkinson's disease as well as the treatment of moderate to severe primary restless leg syndrome.

Aurobindo gets Canadian approval for cefuroxime axetil tabs

Aurobindo Pharma Limited has received the approval for its Abbreviated New Drug Submission cefuroxime axetil tablets 250mg and 500mg from Health Canada. Cefuroxime axetil tablets 250mg and

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500mg is the generic equivalent of GlaxoSmithKline Inc, Canada's Ceftin tablets 250mg and 500mg. Cefuroxime axetil tablets are indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms and falls under the antibiotic segment.

CSL Behring gets US FDA approval to market Hizentra

US FDA has granted marketing approval to CSL Behring for Hizentra, Immune Globulin Subcutaneous (Human), 20% Liquid, for treating patients diagnosed with primary immunodeficiency. Hizentra provides effective protection against infection by maintaining a steady and normal level of immunoglobulin in the body. Hizentra is the first 20% subcutaneous immunoglobulin approved in the US by the FDA. Hizentra represents an effective, convenient choice of at-home Ig therapy allow people with PI to schedule treatment. With its high concentration, Hizentra is a new SCIg treatment option for patients managing primary immuno-deficiencies.

US FDA approves NerPharMa to manufacture Cell Therapeutics' drug pixantrone

Cell Therapeutics, Inc. (CTI) announced that the US Food and Drug Administration (FDA) has completed its inspection of the facility at NerPharMa (a pharmaceutical manufacturing company belonging to Nerviano Medical Sciences Srl, in Nerviano, Italy), which manufactures the CTI's drug pixantrone and has found the site in compliance and acceptable for continued manufacturing of the drug product. CTI has a New Drug Application (NDA) under review at the FDA for pixantrone to treat relapsed/refractory aggressive non-Hodgkin's lymphoma.

US FDA accepts Abbott 45-mg formulation of Lupron s NDA for review

The FDA has accepted for review the supplemental new drug application of a new six-month 45-mg formulation of Lupron Depot (leuprolide acetate for depot suspension) for use in the palliative treatment of advanced prostate cancer. Palliative treatment helps to relieve symptoms associated with advanced prostate cancer. Lupron Depot works by suppressing the production of the hormone testosterone. Abbott is seeking approval for a new six-month formulation to provide greater convenience and dosing flexibility to physicians and patients benefit from this medication. Lupron Depot is currently available in one-month (7.5 mg), three-month (22.5 mg) and four-month (30 mg) depot formulations.

Acucela, Otsuka Pharma get US FDA fast track status for ACU-4429

Acucela Inc., a clinical-stage biotechnology company focused on developing new treatments for blinding eye diseases, and Otsuka Pharmaceutical Co., Ltd., announced that they have received Fast Track designation from the US FDA for ACU-4429, an investigational oral treatment for dry age-related macular degeneration (dry AMD). The FDA's Fast Track programs are designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Fast Track designated programs may be eligible for priority regulatory review by the FDA.

Sun Pharma gets US FDA approval for generic Prometh syrup

Sun Pharmaceutical Industries announced that its subsidiary has been granted an US FDA approval for its ANDA for Promethazine Hydrochloride and Codeine Phosphate oral syrup of 6.25mg/5 ml and 10 mg/5 ml strengths. This is used to treat symptoms caused by common cold, flu, allergies or other breathing illnesses. The syrup is bio-equivalent to Prometh w/Codeine of Actavis Mid Atlantic LLC. The product has annual sales of about US$16 million in US.

Glenmark Generics receives US FDA approval for moexipril HCl tablets

Glenmark Generics Limited (GGL) announced that their United States subsidiary, Glenmark Generics Inc., USA (GGI), has received final ANDA approval for Moexipril Hydrocholoride 7.5mg and 15 mg tablets from the U.S. Food and Drug Administration (FDA) and will commence marketing and distribution of the product immediately. Moexipril HCl is the generic equivalent of Univasc® tablets, marketed by Schwarz. The product is indicated for the treatment of patients with hypertension and garnered total sales of over US$9 million for the 12 month period ending December 2009, according to IMS Health.

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US FDA approves CombinatoRx's NDA for Exalgo ER tabs
CombinatoRx, Incorporated announced that the US Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for Exalgo (hydromorphone HCl) extended-release tablets, for the management of moderate to severe pain in opioid tolerant patients requiring continuous, around-the-clock opioid analgesia for an extended period of time. CombinatoRx will receive a US$40 million milestone payment from Covidien based on Exalgo approval and is eligible to receive tiered royalties on Exalgo net sales. CombinatoRx's considerable product development expertise played a key role in facilitating this successful NDA submission, with the goal of providing much needed relief to those who suffer from chronic pain.

Somaxon Pharma gets US FDA approval for Silenor to treat insomnia
Somaxon Pharmaceuticals, Inc announced that the US Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for Silenor (doxepin) for the treatment of insomnia. Silenor is approved for the treatment of both transient (short term) and chronic (long term) insomnia characterised by difficulty with sleep maintenance in both adults and elderly patients. The approval of Silenor is an important milestone for Somaxon and will allow the company to provide physicians and patients with a highly differentiated treatment option for insomnia.

Mylan gets US FDA approval for generic Actigall
Mylan Inc has received final approval from the US Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Ursodiol Capsules USP, 300 mg, the generic version of Watson's gastrointestinal agent Actigall Capsules.

Aurobindo gets Canadian nod for antibiotic
Hyderabad-based Aurobindo Pharma has received an approval from Canada for its antibiotic, cefuroxime axetil ablets, which is the generic version of GlaxoSmithKline Ceftin tablets. Aurobindo has received approval to market 250 mg and 500 mg versions of the drug. Ceftin tablet is used to treat patients with mild to moderate infections.

Lupin receives USFDA tentative approval for Eszopiclone
Lupin's US subsidiary, Lupin Pharmaceuticals has received tentative approval for Eszopiclone tablets, 1 mg, 2mg and 3 mg from the US FDA. Eszopiclone tablets are the AB-rated generic equivalent of Sepracor's Lunesta tablets, indicated for the treatment of insomnia. The product will be introduced in the market through LPI's network of national wholesalers and pharmacy chains post patent expiry in 2012.

OPERATIONS

Global

World: Acupuncture Calms Highly Anxious Dental Patients, Study Suggests
Acupuncture can calm highly anxious dental patients and ensure that they can be given the treatment they need, suggests a small study published in *Acupuncture in Medicine*. A visit to the dentist provokes extreme fear and anxiety in an estimated one in 20 people, and can put them off going altogether, a condition termed odontophobia. And up to a third of patients report moderate anxiety at the prospect of dental treatment.

World: Non-Drug Techniques Reduce Pain in Hospitalized Patients
Non-traditional therapies relieve pain among a wide range of hospitalized patients as much as 50%. An inpatient integrative medicine program can have a significant impact on pain in an environment where pain management continues to be a major challenge, and traditional medications can have negative consequences. Roughly 80% of patients report moderate to severe pain levels after surgery and these therapies effectively reduce pain by over 50% across numerous patient populations. Furthermore, they can be clinically implemented in real time, across, and under the operational and financial constraints within an acute care hospital.

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America

USA: Alpha Pro Tech changes distribution strategy for disposable protective apparel

Alpha Pro Tech, Ltd., a leading manufacturer of products designed to protect people, products and environments, including disposable protective apparel and building products, today announced a strategic change in the Company's disposable protective apparel distribution strategy. Alpha Pro Tech has recently been informed that VWR, which has always been Alpha Pro Tech's largest distributor of disposable protective apparel, has decided to launch its own private label line of disposable protective apparel, and has made a business decision to transition away from selling Alpha Pro Tech's disposable garments to their own brand of apparel.

USA: Adoption of healthcare IT is on steady incline in small physician practice

Adoption of healthcare IT is on a steady incline in the small physician practice, reveals a survey by NaviNet, America's largest real-time healthcare communications network. In early March 2010, NaviNet conducted a survey of IT and electronic medical record (EMR). Survey results showed that the percentage of provider offices with plans to implement EMRs is growing. The two leading drivers for IT adoption are Centers for Medicare and Medicaid Services (CMS) mandates and administrative overhead reduction, with pending Federal incentives coming in a distant third.

USA: EPA's Action Plan on BPA: ACC issues statement

The Environmental Protection Agency (EPA) released an Action Plan on bisphenol (BPA). BPA is one of the most thoroughly studied chemicals in commerce and comprehensive scientific assessments recently conducted in Europe and Japan have affirmed that BPA is not a risk to the environment at current low levels. Numerous studies have found that BPA rapidly biodegrades, does not bioaccumulate and, if detected at all, is present in the environment only at trace levels that do not cause harmful effects.

USA: Premier Purchasing Partners announces new agreements for general urologicals

Premier Purchasing Partners, LP announced new agreements for general urologicals have been awarded to Bard Medical Division, C.R. Bard Inc. of Covington, Ga.; Nellcor Puritan Bennett, doing business as Covidien of Mansfield, Mass.; and Rochester Medical Corporation of Stewartville, Minn. Effective March 1, 2010, the agreements are available to acute care and continuum of care members of the Premier healthcare alliance Investment.

USA: Carestream Health now taking Orders for DRX-Mobile Retrofit Kit

Carestream Health announced it is taking orders for its CARESTREAM DRX-Mobile Retrofit Kit that will allow healthcare providers to upgrade selected mobile x-ray systems to wireless DRX-1 technology. This wireless DR system can help increase on-site productivity and deliver immediate access to images for improved patient care, especially for critically ill patients in emergency rooms, operating rooms and the ICU. The company is taking orders for the retrofit kit in countries where it has regulatory approval. The system will be available this summer. The DRX-Mobile Retrofit Kit can be installed quickly and is powered by Carestream Health's highly successful DRX-1 detector. The cassette-size detector's wireless capabilities allow users to capture and view images in seconds at the point of patient care.

Europe

UK: Optical Express Optometrist completes 7th Vision Aid Overseas Project

Optical Express Optometrist Ed Baldwin has successfully completed his seventh Vision Aid Overseas project, a trip to Burkina Faso to distribute eyeglasses and screen patients for cataract surgery. Vision Aid Overseas (VAO) sends teams of volunteer Optometrists and dispensing opticians to developing nations to screen and outfit patients with appropriate spectacles. Nearing its 25th anniversary, VAO has provided 300,000 individuals with spectacles, and conducted 600,000 eye tests.

Sweden: Swedish Orphan Biovitrum enters pact with Amgen to run additional Kineret drug

Swedish Orphan Biovitrum announced an agreement with Amgen to run an additional Kineret bulk drug campaign. In addition, Swedish Orphan Biovitrum will pay to buy-out previously agreed future sales

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milestones for Kineret and Kepivance. Under the agreement Amgen will run an additional Kineret campaign at its Boulder facility in Colorado, as well as manufacture drug product at its facility in Puerto Rico. The objective of this additional campaign is to meet an expected increased market demand of Kineret until Swedish Orphan Biovitrum has transferred manufacturing processes to new contract manufacturers.

Asia-Pacific

Singapore: SOHM expanding generic drug distribution in Southeast Asia

SOHM, a generic pharmaceutical manufacturer, announced that the company is expanding its generic drug distribution within the emerging pharmaceutical market in South East Asia; specifically in Indonesia, Thailand, the Philippines, and Malaysia. The Company's direct manufacturing of generic pharmaceuticals allows pricing advantages and distribution of quality drugs to consumers remaining underserved or with limited access to medicine in this region. SOHM is positioned to capitalise on the health issues not being addressed such as different contagious diseases and life style disorders such as cardiovascular, diabetes, musculoskeletal disorders and cancer to expand the market and serve the populations of these countries.

Japan: Neuland begins operations in Japan; makes entry into peptides

Neuland Laboratories has successfully started operations in Japan, making it one of the few Indian companies to have a presence in the highly regulated US$64-bn Japanese pharma market. Neuland has set up a wholly owned subsidiary and has signed deals with over 15 clients in Japan for supply of bulk drugs and APIs. The APIs are for the cardiovascular and anti infective segments. The company expects revenues from the Japanese market to contribute over 20% of their turnover in the next 4 years.

Dishman Pharmaceuticals and Chemicals Ltd. Announces Strategic Alliance with Codexis, Inc

Dishman Pharmaceuticals and Chemicals Ltd. have announced the formation of a strategic alliance with Codexis, Inc. The partnership covers the use of Codexis' proprietary enzymatic biocatalysis technology for the manufacture of building blocks, intermediates and API's for innovator pharmaceutical companies. The company will be a preferred contract manufacturer for Codexis and will be able to offer the technology to its own customers. In addition, the companies will work exclusively on certain select accounts. Codexis offers a wide selection of enzymes for the pharmaceutical synthesis of chiral compounds. With the majority of today's drugs containing at least one chiral centre, this technology is directed at the very heart of pharmaceutical manufacture. This alliance will benefit Codexis and its customers by enabling Codexis to offer production of both intermediates and final APIs in Dishman's manufacturing asset base.

Africa

Nigeria: NACA launches N756 Billion National HIV and Aids Response

The National Agency for Control of AIDS (NACA) has launched a comprehensive National Strategic Framework (NSF) response for six years, which, if fully implemented, would require an estimated N756 billion to implement. The NSF, which is made up of six thrust areas, comprising of prevention of new infection and behavioural change, treatment, care and support for those living with HIV & AIDS, policy advocacy, among others, is expected to provide at least 80% of HIV positive pregnant mothers free access to treatment.

Nigeria: NDA Tasks FG on Health Policy

The Nigeria Dental Association (NDA) wants the Federal Government to formulate national oral health policies based on the integration of oral health into the primary health programme of the nation. The association's partnership with pharmaceutical giant- GlaxoSmithKline is expected to help government minimised the persistent burden of oral disease in Nigeria occasioned by Poverty. The NDA has been pleading with the Federal Government through the Federal Ministry of Health to formulate national oral health policies based on integration of oral health into the primary health programme of the nation. If such is done, the partnership with GSK will support the government with capacity building programmes to ensure that each local government area in the country will have a dental unit where the people can regularly have their mouth checked.

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Asia Pacific

Chinese Wolfberries may improve Vision Imperfections Caused by Type-2 Diabetes

China: A Kansas State University researcher is exploring the use of Chinese wolfberries to improve vision deficiencies that are common for type-2 diabetics. Wolfberries are bright orange-red, oblong-shaped and grown in China. The fruit is known to help rebalance homeostasis, boost the immune system, nourish the liver and kidneys and improve vision. Wolfberries have high levels of zeaxanthin, lutein, polysaccharides and polyphenolics, which have been shown to improve vision, including the prevention of age-related macular degeneration and diabetic retinopathy

POLICY

Asia-Pacific

India: Shruthi Bulk Drugs of Secunderabad booked for exporting ketamine without drug license

The Drugs Control Administration in Andhra Pradesh has registered a case under Section 18 (c) of Drugs and Cosmetics Act, 1940, against the Secunderabad-based Shruthi Bulk Drugs Pvt Ltd for purchasing, selling and exporting 3300 kg of Ketamine Hydrochloride US P along with other drugs without possessing valid drug licenses. According to R P Meena, director general, Drugs and Copy Rights, government of Andhra Pradesh, the cost of 3300 kg Ketamine Hydrochloride USP in the country, as per the bill value, is Rs250 million. But the company sold it for Rs530 million and in international market it would cost around Rs330 million.

OTHERS

Indian firms overtake US in FDA drug filings

Indian drug makers are gearing up for the big opportunity coming up in the world's largest drug market, the US, as patents for several widely prescribed drugs are set to expire in the next few of years. They have filed the maximum number of drug master files or DMFs, accounting for 29.25% of the total 7,183 such filings with the US Food and Drug Administration (FDA) as on September 2009, almost double the filings by local companies. The US FDA data shows that a significant portion of these filings from India has been made since 2008 with 136 Indian drug makers filing DMFs with the US regulator for at least 450 drugs, including 10 most prescribed molecules such as metformin, amlodipine, simvastatin, omeprazole among others. The key reason for the aggressive filing by Indian companies is their preparation for exploring the imminent generic boom that is awaited in the world pharmaceutical market in the next two to three years, according to P.V. Appaji, executive director, Pharmexcil.

ICRI ties up with South Carolina Medical University to offer masters in Health Administration-Global

After the approval of the Foreign Universities Bill by the government, ICRI, the pioneers in healthcare and clinical research education, has entered into an academic/strategic alliance with Medical University of South Carolina (MUSC) to offer Masters in Health Administration-Global. Eminent faculty and administrative staff of MUSC were present during the launch. This alliance would help strengthen the roots of ICRI globally and further the cause of grooming professionals in upcoming healthcare administration Industry in India, to face exciting challenges posed by the Industry and also pave the way for new career opportunities in the field.

NIPER Ahmedabad to introduce PG diploma course for medical devices sector in July, 2010

The National Institute of Pharmaceutical Education and Research (NIPER), Ahmedabad, is all set to launch India's first dedicated course in medical devices segment from the new academic year starting from July, 2010. The institute is currently in talks with some of the major educational institutes conducting similar courses in the country for expert opinion and will finalise the curriculum soon.

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Product Focus – Levetiracetam

Levetiracetam

Introduction

Levetiracetam 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.

Dosage and Administration

Levetiracetam is indicated as adjunctive treatment of partial onset seizures in adults and children 4 years of age and older with epilepsy. Levetiracetam is indicated as adjunctive therapy in the treatment of myoclonic seizures in adults and adolescents 12 years of age and older with juvenile myoclonic epilepsy. Levetiracetam is indicated as adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in adults and children 6 years of age and older with idiopathic generalized epilepsy.

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

Source: mims.com; Cygnus Research

Drug Supply

- Levetiracetam 250 mg tablets are blue, oblong-shaped, scored, film-coated tablets debossed with "ucb 250" on one side. Levetiracetam are supplied in white HDPE bottles containing 120 tablets (NDC 50474- 594-40).
- Levetiracetam 500 mg tablets are yellow, oblong-shaped, scored, film-coated tablets debossed with "ucb 500" on one side. Levetiracetam are supplied in white HDPE bottles containing 120 tablets (NDC 50474-595-40).
- Levetiracetam 750 mg tablets are orange, oblong-shaped, scored, film-coated tablets debossed with "ucb 750" on one side Levetiracetam are supplied in white HDPE bottles containing 120 tablets (NDC 50474-596-40).
- Levetiracetam 1000 mg tablets are white, oblong-shaped, scored, film-coated tablets debossed with "ucb 1000" on one side. Levetiracetam are supplied in white HDPE bottles containing 60 tablets (NDC 50474-597-66).
- Levetiracetam 100 mg/mL oral solution is a clear, colourless, grape-flavoured liquid. It is supplied in 16 fl. oz. white HDPE bottles (NDC 50474-001-48).

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

Adverse effects of Drug

The most commonly reported adverse effects Levetiracetam in adults were somnolence (15% of patients), asthenia (15%), headache (14%), infection (13%), dizziness (9%) and ataxia (3%). These adverse effects were seen most frequently in the first month of therapy. The most frequent adverse effects in the children participating in that study were infection (33%), anorexia (25%), and somnolence (25%).

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

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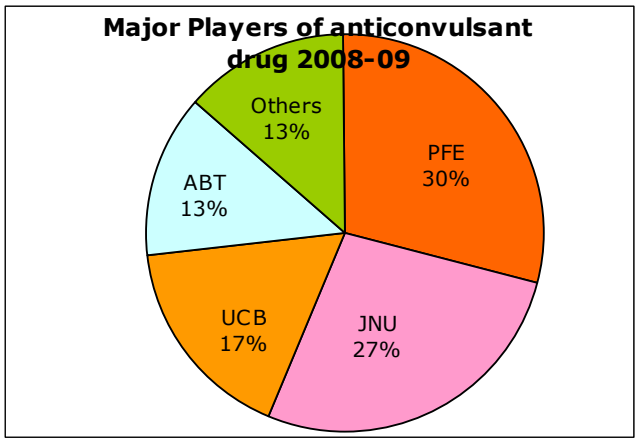
Drug Interactions

Probenecid (Benemid) reduces the elimination of levetiracetam by the kidneys, potentially doubling the concentration of levetiracetam in the body which lead to side effects from probenecid.

Market Scenario

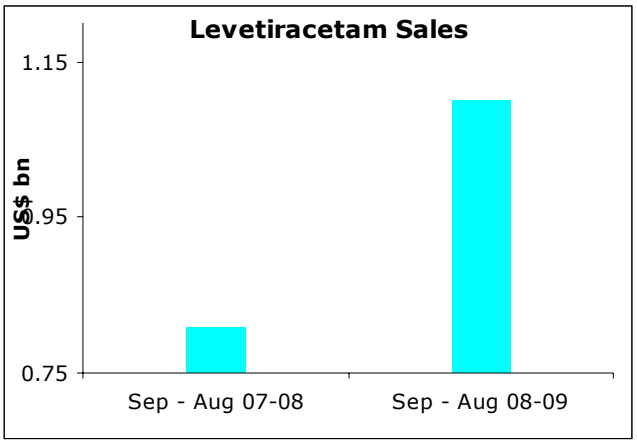
Anticonvulsant are therapies approved to treat patients with epilepsy, a brain disorder in which clusters of nerve cells signal abnormally, which can lead to seizures. Epilepsy affects approximately 2.5 million people in the United States, and results in an estimated annual cost of US$15.5 billion in healthcare. Epilepsy can be treated through both surgical and pharmaceutical intervention.] And the market for pharmaceutical treatment of epilepsy generated US$12 billion in 2008-09. The major players in the antiepileptic market include Abbott Laboratories, Cephalon, GlaxoSmithKline, Johnson & Johnson, Novartis AG, Pfizer, Sanofi-Aventis SA, Shire, and UCB Pharma. Pfizer maintains the largest market share in the antiepileptics market with 26% for its two products, Lyrica and Neurontin US$2.96 billion combined sales in 2008). Pfizer's antiepileptic products are also growing at the fastest rate among major competitors, with a sales growth of 31% from 2007 to 2008.



Source: wikinvest; Cygnus Research

Levetiracetam Sales

Glen mark 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 US 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 USFDA 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.



Source: BSE India; Cygnus Research

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Outlook

With a forecasted CAGR of 6.8%, anti-epilepsy sales are expected to double over the next decade, beginning to level off after 2008-09. 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 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 genericisation setting in. Major companies are looking at different strategies in addition to new indications to protect sales of their products from generics.

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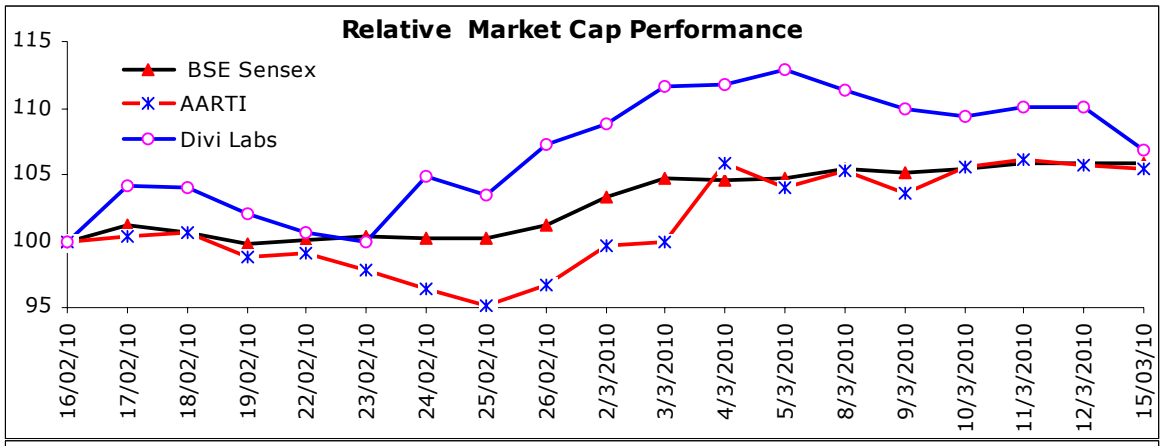
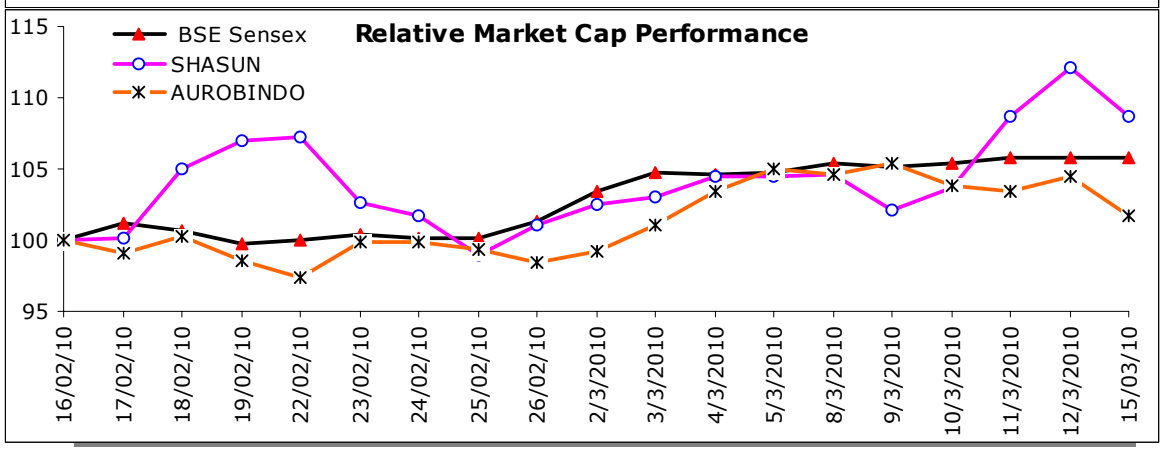
Stock Scan





Source: BSE India; Cygnus Research

	16 Feb-21 Feb	22 Feb-28 Feb	01 Mar- 07 Mar	08 Mar- 15 Mar
SENSEX	Sensex declined marginally by 0.22% or 35 points, due to the decline in basic goods, PSU, health care and metals indices.	The auto, infra stocks have built on their momentum during this week helped the Sensex to increase marginally by 1.19% to 16191 points; however, the overall verdict on the Budget was positive.	A positive Budget, surge of manufacturing and services activity in February and rise in exports for the third consecutive month in January 2010, aided the rally to the index rise by 221 points.	The increase of annual IIP figures and manufacturing output did not help the market to give the good positive boost. The midcap, smallcap index and Sensex remained unchanged during the week.

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AARTI	The companys share price declined by 1.23% from Rs93.45 to Rs92.30.	The companys share price declined by 2.54% from Rs92.65 to Rs90.30.	The companys share price increased by 4.35% from Rs93.15 to Rs97.20.	The companys share price increased by 0.05% from Rs98.45 to Rs98.50.
Divi Labs	The companys share price increased by 2.09% from Rs581.50 to Rs593.65.	The companys share price increased by 6.50% from Rs585.40 to Rs623.45.	The companys share price increased by 3.79% from Rs632.50 to Rs656.45.	The companys share price decreased by 3.97% from Rs647.25 to Rs621.55.
Shasun	The companys share price increased by 6.92% from Rs36.85 to Rs39.40.	The companys share price decreased by 5.70% from Rs39.50 to Rs37.25.	The companys share price increased by 1.99% from Rs37.75 to Rs38.50.	The companys share price increased by 3.89% from Rs38.55 to Rs40.05.
Aurobindo	The companys share price declined by 1.51% from Rs928.90 to Rs914.90.	The companys share price increased by 1.11% from Rs903.95 to Rs914.	The companys share price increased by 5.75% from Rs922.15 toRs975.15.	The companys share price declined by 2.70% from Rs971.30 to Rs945.10.

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Regulatory Issues

INTERNATIONAL

FDA Approves a Cellular Immunotherapy for Men with Advanced Prostate Cancer

The U.S. Food and Drug Administration today approved Provenge, a new therapy for certain men with advanced prostate cancer that uses their own immune system to fight the disease. Provenge is indicated for the treatment of asymptomatic or minimally symptomatic prostate cancer that has spread to other parts of the body and is resistant to standard hormone treatment.

Prostate cancer is the second most common type of cancer among men in the United States, behind skin cancer, and usually occurs in older men. In 2009, an estimated 192,000 new cases of prostate cancer were diagnosed and about 27,000 men died from the disease, according to the National Cancer Institute.

Abbott Receives FDA Approval for Creon to Include Dosing Information for Patients With Chronic Pancreatitis and Pancreatectomy

U.S. Food and Drug Administration (FDA) approved the supplemental New Drug Application (sNDA) for CREON® (pancrelipase) Delayed-Release Capsules that now includes dosing guidance in the prescribing information specific to patients with limited production of enzymes in the pancreas (exocrine pancreatic insufficiency) due to chronic pancreatitis (CP) or removal of the pancreas (pancreatectomy). Prior to this FDA approval, dosing guidance for medications such as CREON was based on patients with cystic fibrosis

NATIONAL

Drug regulatory agencies contemplating tightening of storage rules of trading outlets

The recent unearthing of expired drugs in Tamil Nadu has not only highlighted the necessity of a common incineration plant to destroy the drugs recalled from circulation, but also reinforced the need for proper storage facilities in pharmacies and in stockists' godowns as specified in the Schedule P of the D&C Act.

Registration delays with DCGI may lead to shortage of many essential drugs soon

The lethargic attitude of the Drugs Controller General of India's (DCGI) office in clearing applications for re-registration of import licenses for active ingredients and intermediates in time, is seriously affecting the drug supplies in certain therapeutic areas. The entire process of registration renewal, which could be executed within a month or two, is taking anywhere between six months to one year in several cases. The situation may lead to a serious shortage of certain life saving drugs at a time when the demand for the same is expected to be high.

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Upcoming Events

1	**Event**	**Dubai Pharmaceutical & Technologies Exhibition**
	Date	Mar 15-17, 2010
	Venue	Dubai International Convention & Exhibition CentreDubai, UAE
	Highlights	It has entered into its 15th edition and is emerged out as a viable annual event for pharma industry of both domestic and international arena. It is a pivotal event which helps in finding out new business avenues in pharmaceutical industry of throughout the world. It is 3 days event which is attended by over 299 exhibitors from all over the globe.
	Contact Details	INDEX Conferences & Exhibitions Organisation Est. Dubai Health Care City, Block B Office 203, 2nd Floor, Dubai - 13636, United Arab Emirates. Tel: +(971)-(4)-3624717: Fax: +(971)-(4)-3624718
2	**Event**	**World Pharma Trials Asia Expo**
	Date	Mar 16-19, 2010
	Venue	Raffles City Convention Centre, Singapore, Singapore
	Highlights	It is the exhibition for drug development offshoring and outsourcing opportunity for pharmas and biotech industry. The event will be taking place between 16 and 19 March 2010 at the Raffles City Convention Centre. For four days the expo is being organised by Terrapinn Pte Limited.
3	**Event**	**Belarus Medica**
	Date	Mar 23-26, 2010
	Venue	Roofed Soccer Arena, Minsk, Belarus
	Highlights	Belarus Medica 2010 is the largest medical exhibition in Belarus featuring all major branches of the medicine. The main objectives of the Exhibition are to demonstrate the latest achievements of the leading foreign and domestic manufacturers of medical preparations, cosmetics, optics, laboratory and diagnostic equipment, dental hardware, disposable materials and products.
	Contact Details	Technics And Communications, P. O. Box 34, Horki, Belarus. Tel:+(375)-(17)-3060606
4	**Event**	**AROGYA Kolkata**
	Date	Apr 09-12, 2010
	Venue	Science City Kolkata, West Bengal, India
	Highlights	The age old knowledge needs to be recast in a more acceptable modern, scientific idiom. Presenting the Research and Development efforts of Institutions and agencies and disseminating the same, projecting India's capabilities and requirements in health care and related spheres thereof like educational and employment opportunities.
	Contact Details	Federation of Indian Chambers of Commerce & Industry Federation House, 1, Tansen Marg, New Delhi - 110 001, India. Tel: +(91)-(11)-23738760; Fax: +(91)-(11)-23320714
	Event	**AROGYA Kolkata**

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5	**Event**	**Health Asia**
	Date	Apr 11-13, 2010
	Venue	Karachi Expo Centre, Karachi, Pakistan
	Highlights	The event shall be mainly divided into Exhibition and Conferences. Delegations from Ministry of Health of Asian Countries, Hospitals of International Repute, Medical Universities, Pharmaceutical Companies are major participants of Health Asia.
	Contact Details	E- Commerce Gateway Pakistan Private Limited. C-17, KDA Scheme - I Off: Kansas Road, Karachi, Pakistan. Tel:+(92)-(21)-111222444; Fax:+(92)-(21)-34536330
6	**Event**	**Med E Tel**
	Date	Apr 14-16, 2010
	Venue	Luxexpo Luxemburg, Luxembourg
	Highlights	It focuses on ehealth and telemedicine applications and a wide range of other medical ICT applications and on the convergence of information and communication technology with medical applications, which lead to higher quality of care, cost reductions, workflow efficiency, and widespread availability of healthcare services.
	Contact Details	LuxExpo, 10, Circuit de la Foire, Luxembourg, Luxembourg. Tel:+(352)-(43)-991; Fax:+(352)-(43)-99315
7	**Event**	**Tashkent International Healthcare Exhibition**
	Date	Apr 14-17, 2010
	Venue	Uzexpocentre Tashkent, Uzbekistan
	Highlights	It will bring together all the key players under one roof, providing exhibitors with a compelling networking opportunity-to precisely target relevant budget-holders in the shortest time possible and at an affordable cost.
	Contact Details	Organizer: ITE Uzbekistan, Mirobadsky Area, 20, Oibek Street, 3rd, Tashkent, Uzbekistan., Tel:+(998)-(71)-1130180; Fax:+(998)-(71)-2525164

8	**Event**	**Syria Lab**
	Date	April 15-18, 2010
	Venue	Damascus International Fairground, Damascus, Syria.
	Highlights	The Syria Lab gives a snapshot of Laboratory Technology and Equipment industry by displaying Auto-Back Devices, Bacteriological Isolation Rooms, Blood Gases Analysis Devices, Capillaries Analysis Devices and their Accessories, Cobalt Dyes Dehydrators, etc. It is 4-day event hosted by Arabian Group for Exhibitions & Conferences.
	Contact Details	Arabian Group For Exhibitions & Conferences P. O. Box 2683, Damascus, Syria. Tel: (963)-(11)-4433444; Fax:+(963)-(11)-4433666

9	**Event**	**World Vaccine Congress**
	Date	Apr 19-22, 2010
	Venue	TBA Washington, United States of America
	Highlights	It I s the largest vaccine industry event in North America. World Vaccine Congress continues to deliver a forum where the ever-changing dynamics of an industry in resurgence are discussed and acted upon by the industry's most senior figures. It is world's most compelling and influential scientific and strategic leaders, facilitating education, debate and business.
	Contact Details	Organizer: Terrapinn Pte Limited 12, Prince Edward Road, 03-01 Podium A Bestway, Singapore. Tel:+(65)-(2)-228550; Fax:+(65)-(2)-263264
10	**Event**	**CPhi Japan**
	Date	Apr 21-23, 2010
	Venue	Tokyo International Exhibition Center (Tokyo Big Sight), Tokyo, Japan
	Highlights	CPhi Japan showcases the rapidly progressing scenario of the pharmaceutical industry of Japan. Alongside Japanese 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	CMP Information Industrieweg 54, P.O. Box 200, 3600 AE, Maarsen, The Netherlands. Tel:+(31)-(346)-559444; Fax:+(31)-(346)-573811

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