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In Focus: Fastest Growing Segment –Anti-Diabetic Therapy

Introduction

Diabetes is a symptom in which the body does not either produces enough, or does not properly respond to, insulin, a hormone which is produced in the pancreas. Insulin allows cells to absorb glucose in order to turn it into energy. It mainly helps glucose to accumulate in the blood, leading to various potential complications. Diabetes mellitus can be classified into three broad categories. They are:

- Type I
- Type II
- Gestational diabetes

Type I: Type I diabetic is a chronic disease. It is mainly caused due to failure to produce insulin from the pancreas. Presently most persons with type 1 diabetes take insulin injections. Type I diabetic is also called as Juvenile or insulin dependent diabetics. It can occur at any age, but it is most often diagnosed in children, adolescents, or young adults. The symptoms of this disease include Feeling tired or fatigued; Feeling hungry; Being very thirsty; Urinating more often; Losing weight without trying; Having blurry eyesight; Losing the feeling or feeling tingling in your feet.

Type II: Type 2 diabetes is a chronic disease marked by high levels of sugar (glucose) in the blood. It is the most common form of diabetes. When we have type 2 diabetes, the body does not respond to the insulin correctly. It is called insulin resistant. Insulin resistance means that fat, liver, and muscle

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cells do not respond normally to insulin. As a result blood sugar does not get into cells to be stored for energy. The symptoms are like blurred vision, erectile dysfunction, fatigue, frequent or slow healing infections, increased appetite, increased thirst and increased urination.

Gestational Diabetic: Pregnant women who have never had diabetes before but who have high blood sugar (glucose) levels during pregnancy are said to have gestational diabetes.

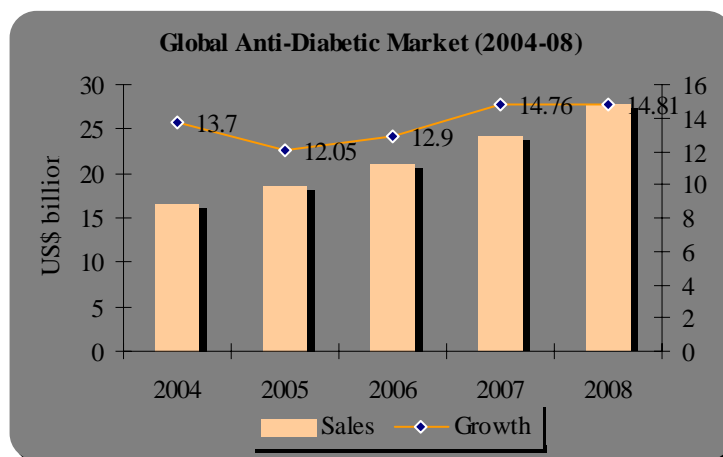
Market Overview

Global Market Overview

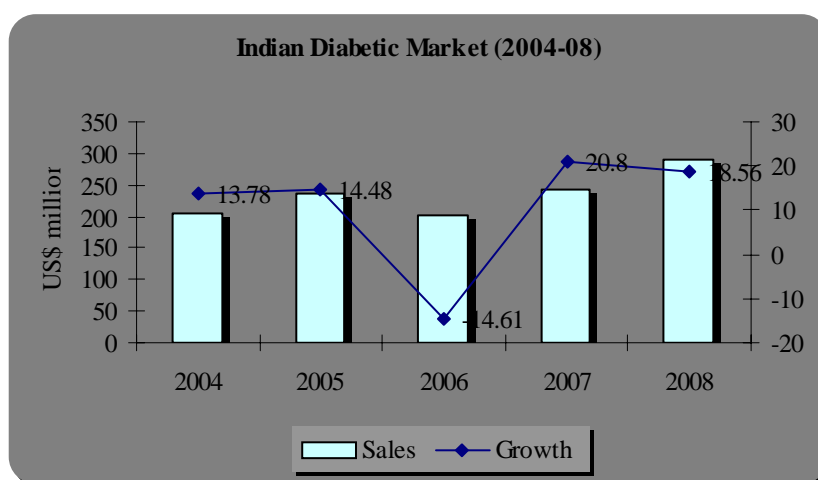
Over the past few years, diabetes drug market and insulin market have shown remarkable growth; it was mostly driven by increasing prevalence of diabetes globally and easily availability of insulin in other countries due to its access at an affordable price. The diabetes prevalence is increasing due to changing food habits in the western world leading to obesity. Diabetes is one of the largest therapeutic segments of global pharmaceutical sales and during the last 5 years it has grown double digit by a compound average growth rate of nearly 14% (2004-08), which was valued around US\$ 27.67 billion in 2008. It holds 4th place in top ten therapeutics segments. Diabetic segment holds 8% market share in top 15 therapeutic segments and 3.58% market share in global pharmaceutical market. Globally spending on diabetics treatment is expected to increase from US\$ 232 billion in 2007 to US\$ 303 billion in 2015.

Indian Market Overview

Indian pharmaceutical market is one of the fastest emerging pharmaceutical markets in the world. The market is driven by a large population, expanding GDP,



Source: IMS health; Cygnus Research



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and rapid epidemiological transitions. The market is expected to be the major player in the global pharmaceutical market both in terms of its large domestic market and also as a pharmaceutical export hub. Diabetic is one of the therapeutic segments in India which are recording rapid growth, due to more disease prevalence. Indian diabetic market holds around 1.05% of total global diabetic market. It has grown with double digit at 18.56 % YOY when compared to previous year. In 2008, Indian diabetic market was valued at US\$ 289 million. The market has grown at 9% CAGR over the last five years (2004-08).

Growth Drivers

Life style Disease

Diabetes is recognised as a major lifestyle disease in India, with the country having possibly the largest number of diabetics in the world. Ageing population, sedentary lifestyles, high stress levels, improper sleep and deteriorating eating habits are the factors contributing to India's dubious distinction as the world's diabetic capital.

According to Diabetes Atlas published in 2007, there are 246 million diabetics across the world, with 80% of them in the developing and underdeveloped countries. India, according to these statistics, has 40.9 million diabetics, closely followed by China with 39.8 million diabetics. It is predicted that by 2025 diabetics in India and China would increase to 69.9 million and 59.3 million respectively.

Ageing population

The increase in aged population is changing the healthcare scenario in India. Focus on preventive aspects such as vaccination and immunisation and shifting of disease patterns, will create new opportunities and drive healthy growth in pharmaceutical companies. People are looking forward to leading a longer, healthier and more productive life. This opens up new vistas of research into newer and better medicines. In 2005, nearly 64% of the population were in the age group of 15-65. As per Economic Survey, it will increase to 68% of the total population in 2030. The age group under 65+ will increase from 5% in 2005 to 15% of the total population in the year 2050. Indian has certainly seen progress in healthcare, which is evident from increased in life expectancy and reduced infant mortality Life expectancy during 1996-2008 increased from 60.6 to 69.2 years and has been the major contributor to the diabetic growth.

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Out look

Overall, global anti-diabetic drugs sales are expected to grow dramatically over the next five years to over US\$53.28 billion in 2013 at 14% CAGR as the addressable patient population continues to increase and obesity patients are increased and new, oral, injectable and pulmonary premium priced products enter the market to address high unmet clinical needs.

The Indian diabetes market is slated to grow big as awareness of the disease increases. Impact or any effect on each of the growth drivers i.e. aging population and lifestyle will influence the growth. Currently India is addressed as the diabetic capital of the world with 40.9 million with diabetics accounts for almost 16-20% of the world diabetic population; the market is estimated to reach US\$465 million, grown at CAGR 10% during 2009-13.

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News Briefs

MARKETING

America

USA: GE Healthcare Introduces Novel Device to Detect Tissue Stiffness

GE Healthcare introduced MR-Touch, a visual palpation technology that uses low frequency sound waves in combination with MRI to measure tissue elasticity. For centuries, clinicians have evaluated tissue stiffness—the physical property of tissue most affected by disease—through palpation. Based on technology invented at Mayo Clinic (Rochester, MN) and licensed to GE Healthcare, Recently FDA cleared, MR-Touch is a certified healthy imagination product and has been third-party validated to reduce costs and increase the quality of healthcare. MR Touch extends the principles of palpation with a precise, non-invasive and cost-effective way to evaluate tissue stiffness. GE Healthcare will also feature MR-Touch at the annual meeting of the Radiologic Society of North America (RSNA), at Chicago's McCormick Place from November 29-December 4, 2009. MR-Touch will be commercially available with the Optima MR450w 1.5T system and requires a modest software upgrade along with a hardware accessory to a conventional MR scanner.

USA: Wockhardt launches anti-hypertensive drug Nicardipine injections in USA

Pharmaceutical and biotechnology major, Wockhardt has received final approval from the United States Food & Drug Administration (USFDA) for marketing the 25mg/10 ml injection of Nicardipine HCl, which is used for short-term management of hypertension or increased blood pressure. Nicardipine is the generic name for the brand Cardene, marketed in the United States by EKR Therapeutics. The patents covering this product expired in November, 2009 and Wockhardt is launching the product immediately

USA: New ThermaFreeze subsidiary to offer healthcare products

ThermaFreeze Products Corporation, maker of refrigerant products for use in commercial shipment of perishables and as a consumer compress and chiller product, announced the formation of a majority-owned subsidiary named American Diversified Medical Corporation (ADM). This unit will offer products and services to the alternate site healthcare space, specifically homecare and clinics outside of the hospital environment and veterinarian market. ThermaFreeze and ADM plan to announce a portfolio of new therapeutic products called ThermaTherapeutics, based on ThermaFreeze technology, over the coming months. The patented polymers they utilise allow their products to enjoy some unique attributes that make them perfect for many healthcare and therapeutic applications.

USA: Six Pfizer-Wyeth R&D sites to close post merger

Pfizer will close six R&D facilities in the US and the UK, reducing its global capacity by over a third following completion of its acquisition of Wyeth. Units in Princeton, New Jersey; Rouses Point and Plattsburgh, New York; Sanford and Research Triangle Park, North Carolina, as well as two in Gosport and Slough in the UK, would cease operations. These changes are expected to bolster productivity and reduce costs, they will result in staff reductions. Pfizer did not specify how many employees the move would affect. However, when the multi-billion dollar Wyeth acquisition was completed earlier in November 2009 the firm said that as many as 20,000 of the combined 130,000-strong workforce would be cut. Drug, biologics and vaccine R&D will be focused at five main sites: Cambridge, Massachusetts; Groton, Connecticut; Pearl River, New York; La Jolla, California; and Sandwich in the UK. Other facilities in San Francisco, Cambridge, UK and Shanghai, China will conduct the development of monoclonal antibodies in a move that would transform the firm into the world's leading biopharma manufacturer. This new structure puts Pfizer in the best position to conduct cutting-edge research within and beyond our own laboratories and to deliver a portfolio of high-impact medicines to patients.

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USA: Catalent teams up with Endotis on oral oligo delivery

Catalent will work with Endotis Pharma on the development of orally-deliverable formulations of oligosaccharides under a deal. The accord will use drug delivery technology developed by the US contract manufacturing Organisation (CMO) on drugs being developed by Endotis, beginning with preclinical development of its candidate anticoagulant EP37151. The firm's hope to begin Phase I clinical trials of the drug in Q2 next year and anticipate that the collaboration will be extended to other drugs in Endotis' pipeline. This collaboration with Endotis, based upon a unique combination of complementary expertise, has been providing exciting results, proving that the various technical hurdles associated with the oral delivery of small-glycol drugs can be overcome.

CANADA: Ambrilia Biopharma Terminates License and Supply Teva Pharmaceuticals

Ambrilia Biopharma Inc. announced that its wholly-owned Canadian subsidiary, Cellpep Pharma Inc. has terminated the Licensing and Distribution Agreement granted to Teva Pharmaceuticals Europe BV ("Teva") by Cellpep S.A. (now Ambrilia Biopharma France S.A.) on April 24, 2002 and the Supply Agreement entered into by the same parties on May 6, 2002. These agreements were assigned by Ambrilia Biopharma France S.A. to Cellpep Pharma Inc. with the consent of Teva. The Initial Order issued on July 31, 2009 by the Commercial Division of the Superior Court of Montreal in favour of, inter alia, Cellpep Pharma Inc. under the Companies' Creditors Arrangement Act (Canada) ("CCAA") authorises Cellpep Pharma Inc. to repudiate any contracts as it deem appropriate.

USA: Biopharma Pushes for Online Advertising

As federal regulators take their first tentative steps toward policing the wild west of medical information online, pharmaceutical companies are pressing their case to market drugs via Google, Twitter and other Web sites. The Food and Drug Administration will convene a two-day meeting beginning November 12 to hear the drug industry's position on Internet marketing. The agency has agreed to consider developing rules for online advertising after companies complained that the current guidelines for traditional media - which require a detailed list of possible side effects - have left them hamstrung on the Web. Industry observers say companies have largely steered clear of the Web for fear of running afoul of FDA regulators, who have not defined the rules of operating online.

Canada: AVI BioPharma Inc-Therapeutic Competitors

AVI BioPharma Inc - Therapeutic Competitors includes a business summary, tabular representation of the number and percentage of products in each therapeutic indication, all AVI BioPharma Inc products listed with indication and stage of development, and competitors by therapeutic indication. The report also includes recent company news updates. Competitor Reports provide detailed analysis of a AVI BioPharma Inc's products by therapeutic indication, a summary of its overall pipeline as well as insight into the predicted likelihood of clinical success for each pipeline product. The Competitor Report of AVI BioPharma Inc compares the company against its primary competitors by individual therapeutic indication.

Europe**UK: Verizon Business Targets Healthcare Vertical with Collaboration Services**

Verizon Business (News - Alert) has pulled open the curtain to reveal a new suite of telehealth solutions. Verizon Telehealth Collaboration Services leverage videoconferencing to enable hospitals, physicians and other health care organisations to see patients at remote locations. The carrier will also offer consulting services to the medical vertical to help them access and implement these services. The company would seem to be in a plumb position to offer such services, given more than 90% of Fortune 1000 health care companies already rely on Verizon's IT solutions. These new IT capabilities will help hospitals, clinics and doctors' offices modernise the delivery of health care – a critical need throughout the U.S. health care system today.

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Asia-Pacific**India: GE Healthcare launches low-cost portable ECG**

GE Healthcare has launched MACi, a low-cost portable ECG device. Aimed at bringing down healthcare costs in rural India, the new hand-held device comes with a one-touch operation. It is capable of completing 250 ECGs for every 3-hour battery charge, and is particularly suited for rural India where healthcare is delivered through primary health clinics, said President & CEO GE Healthcare South Asia. GE Healthcare is already selling MAC-400 in India, a portable 3-channel ECG device. While MAC-400 costs about Rs50,000, the newly launched MACi is a single channel ECG device priced at Rs25,000. This stripped-down version of the MAC series is part of GE Healthcare's Rs280.00 billion "Healthy Imagination, Global Initiative" project. MACi is developed in GE Healthcare's R&D Centre in Bangalore and is being manufactured by the joint venture company Wipro GE Healthcare. As part of its strategy to expand its current IT India business, GE Healthcare also unveiled its initiatives.

China: Pfizer to build R&D capacity in China

Pfizer will expand its clinical services and biomedical presence in China as part of a worldwide effort to develop its R&D infrastructure. Working with the government, the US firm will partner with the Wuhan National Bioindustry Base Construction and Management office to establish a clinical R&D centre to provide support for ongoing trial programmes. The unit will be an integral part of Pfizer's global R&D operations while being closely aligned with the Chinese government's strategy on biopharmaceutical industry development. Pfizer also unveiled plans to expand its existing R&D facility in Shanghai. The US drug giant joins Germany's Merck KGaA which also announced plans for its own €150m (\$224m) clinical R&D hub in Beijing.

China: Sinovac forms vaccine manufacturing JV

Sinovac Biotech has formed a joint venture which will give it cost effective manufacturing capacity for 20m dose of live attenuated vaccines and 20m dose of vero cell cultured vaccines a year. Vaccines for rabies, mumps, varicella and rubella are in Sinovac's pipeline and by striking the deal with Dalian, which will provide land use rights, manufacturing facilities and established operating infrastructure; it believes it can support their production. The deal leverages the favourable investment environment to add an important manufacturing site for the company's vaccines. The joint venture is called Sinovac (Dalian) Vaccine Technology and will be headquartered in Dalian, Liaoning Province in North East China, occupying a 1m sq ft site and a 200,000 sq ft building. Housed in the headquarters is a 60,000 sq foot manufacturing and R&D facility with two vaccine production lines, one for live attenuated vaccines and another for vero cell cultured vaccines.

India: Jubilant inks JV to develop new drugs

Pharma company, Jubilant Organosys has formed a joint venture (JV) with the University of Alabama Birmingham (UAB) and Southern Research Institute, US to develop new drugs to treat oncology, metabolic and other infectious diseases. The partnership would involve development of promising biological targets—discovered by Jubilant and the two institutes, besides new drugs. They intend to develop the molecules from preclinical and to phase-II trials, and partner global pharma majors for the final trials and marketing. This academic and industrial collaboration demonstrates Jubilant's commitment to partner with globally renowned academia in order to identify and deliver affordable innovation and healthcare solutions to the patients worldwide.

India: Sanofi-aventis, MMV to launch largest antimalarial drug study

Sanofi-aventis and Medicines for Malaria Venture (MMV) announced that they have entered an agreement to launch the largest safety and efficacy study of an antimalarial drug. This field-monitoring programme on ASAQ, a fixed-dose combination of artesunate and amodiaquine, started in Côte d'Ivoire in October 2009. MMV is a not-for-profit drug research and development organisation dedicated to reducing the burden of malaria. ASAQ is the only fixed-dose combination of artesunate and amodiaquine prequalified by WHO in the treatment of Plasmodium falciparum uncomplicated malaria.

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India: Glenmark ties-up with Medicis Pharma to co-develop acne vulgaris drug

Glenmark Pharmaceuticals (GPL) has announced that it has entered into an exclusive agreement with Medicis Pharmaceutical Corporation to co-develop and commercialise a specialty pharmaceutical product in North America for the treatment of acne vulgaris. Pursuant to terms of the agreement, Glenmark will receive a one-time up-front payment of US\$5m from Medicis, and is eligible to receive additional payments upon achieving certain development milestones and royalty upon commercialisation.

India: Cipla launches flu pandemic drug oseltamivir

Cipla, the leading pharmaceutical company in India, has launched oseltamivir under the brand name of Antiflu. The only flu medicine from India to be prequalified by WHO, Antiflu would be sold under Schedule X category in India, like Virensa. These two Cipla drugs currently are the only to be widely recommended by various world health bodies. The launch comes in wake of WHO declaring flu as 'pandemic', which is anticipated to strike with the seasonal peak of winter.

India: NovaDel to get US patent covering its oral spray drug delivery technology

NovaDel Pharma Inc, announced that it received a Notice of Allowance from the United States Patent and Trademark Office (US PTO) for claims under US Patent Application No. 10/671,715, entitled 'Buccal, Polar and Non-polar Spray Containing Zolpidem', which covers a method of treating insomnia by administering zolpidem to humans utilising NovaMist Oral Spray technology. Once issued, this patent will expire in 2018.

India: Max Healthcare to build two hospitals in Punjab

Hospital chain Max Healthcare will invest Rs2 billion to set up two tertiary care hospitals in Bathinda and Mohali, both in Punjab. The hospitals, coming up in partnership with the state government, will have 300 beds each. The funds would be raised in a 1:1 debt equity ratio. The construction of the hospitals will begin on December 29 and they would be complete within 18 months. The hospitals will have speciality wings for cancer and heart treatments. The partnership is unique as it allows Max Healthcare to build and operate the hospital and ensures that the government gets a share of the revenue. The healthcare chain is ramping up its businesses around newly-created centres of excellence in areas like orthopedics, cancer and minimum invasive surgery among others. Max Healthcare is likely to open an organ transplant centre in one of its Delhi hospitals next year. Max Healthcare is a leading player in the national capital region with its six hospitals having cumulative bed strength of 800 and two out-patient centres. The company claims to have a base of over 1,250 doctors and 3,000 employees.

India: Apollo Hospitals plans facility in Nigeria

Apollo Group of Hospitals aims to come up with a hospital in Nigeria in Africa in the next two years, while it is eyeing opportunities in other countries in the continent. "While detailed plans are yet to be firmed up, we are looking to tie-up with a local partner to set up a hospital in the country. The investment could be made by the partner while Apollo could offer managerial expertise," said chief executive officer of Apollo Hospitals. The Nigerian government had approached the Group to modernise the healthcare infrastructure in the country. Apollo has just entered into a partnership to provide operational management services to Lagos-based Hygeia Nigeria, one of the largest health-care groups in west Africa. Hygeia Nigeria also owns the largest health maintenance organisation (HMO) in Nigeria with over 200 hospitals and clinics in the network. Apollo has also bagged a project consultant job for a 100-bed multi-speciality hospital in Ghana.

OPERATIONS**America****USA: Essent Healthcare to consolidate services at Texas hospital**

Essent Healthcare said that it is consolidating acute care services offered by its Paris Regional Medical Center in Paris, Texas, at one campus. Under the transition to be completed by next fall, the North campus will become home to an emergency department, women's services, the Heart Hospital at Paris Regional, pediatrics and labour and delivery among other operations. Officials are still deciding whether services such as accounting and human resources would remain at the South campus.

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USA: AstraZeneca sues Lupin to protect patent rights of anti-ulcer drug, Nexium

AstraZeneca, the Anglo-Swedish drug major, has filed a patent infringement lawsuit at the US District Court of New Jersey against the Mumbai-based Lupin Ltd and its US subsidiary to curb the latter's move to manufacture and market the generic version of its blockbuster acid reflux drug, Nexium.

USA: Dendreon seeks US approval for CRPC drug Provenge

Dendreon Corporation has completed the submission of the amended Biologics License Application (BLA) for Provenge (sipuleucel-T), the company's lead investigational product, to the US Food and Drug Administration (FDA). Dendreon is seeking licensure for Provenge for men with metastatic castrate-resistant prostate cancer (CRPC). If approved by the FDA, Provenge would represent the first product in the new therapeutic class known as active cellular immunotherapies.

Canada: Alder Biopharma inks US\$1bn deal for rheumatoid arthritis treatment

Alder Biopharma has entered a strategic partnership with Bristol-Myers Squibb, one that could result in the Bothell biotechnology company receiving more than US\$1 billion in milestone payments for a treatment for rheumatoid arthritis. Bristol-Myers has agreed to an upfront cash payment of US\$85 million to Alder, as well as milestone payments of US\$764 million. The deal also includes sales-related payments that could exceed US\$200 million, with Alder also reserving the right to have Bristol Myers purchase shares of Alder at the time of an initial public offering. As part of the deal, Bristol-Myers Squibb has secured development and commercialisation rights for Alder's ALD518 drug for all diseases except cancer. And Princeton, New Jersey-based Bristol-Myers appears to be excited with Alder's efforts in the rheumatoid arthritis arena, a disease that affects about one million people in the U.S.

Asia Pacific**India: Intas Biopharma to pump in Rs160m for facility for Monoclonal Antibodies**

Ahmedabad-based Intas Biopharmaceuticals said it has signed an MOU with Gujrat Government for setting up a Rs1600 million facility at Sanand in Gujarat. The company has acquired 23,000 sq metres of land at the Matoda village in Sanand and has initiated the Engineering Design Phase for the project. The facility will be dedicated to Monoclonal Antibodies (MAbs) and will take up large-scale manufacturing of the recombinant product in phases. Commercial production at the proposed MAbs facility is likely to commence by 2011. For research and development activities, the company is developing Novel Drug Delivery System for proteins and a cloning facility. IBPL is introducing novel production platforms as well as developing MAbs and recombinant products like cytokines, hormones and blood factors. It also takes up indigenous manufacturing and marketing of certain bio-therapeutic drugs like GCSF and Interferon.

Asia Pacific**Japan: Japanese NIH Research Reaffirms and Expands Pandemic Flu Protection**

Hemispherx Biopharma, Inc. announced that Dr. H. Hasegawa, Chief, Laboratory of Mucosal Vaccine Development Virus Research Center, Japanese National Institute of Infectious Diseases (JIID), expanded the data on Ampligen(R), an experimental immunotherapeutic, at the "Mucosal Immunity" session of the Japan-France Vaccine and Infectious Diseases Workshop in Osaka, October 10, 2009. Dr. Hasegawa provided an overview of intranasal pandemic flu vaccine (H5N1) and nasal immunity mechanisms. The data consist of both expanded clinical and anatomical findings in macaque monkeys exposed to the most virulent forms of pandemic influenza. Standard human seasonal influenza vaccines - given alone and having no benefit on H5N1 influenza virus pathology and clinical status - were nonetheless highly effective against pandemic virus when combined with Ampligen (R), an experimental therapeutic, applied

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intranasally in very small doses, in a prophylactic treatment setting. According to WHO's (World Health Organisation) Initiative for Vaccine Research, in some countries only 10% of the population will have access to pandemic vaccine.

Europe

UK: Cosmetic Surgery Procedures Might be Taxable under New Healthcare Bill

Under the new healthcare plan, which has been revamped to enable it to reach millions of more Americans, the Senate is looking to levy a tax on some cosmetic surgery procedures, and the plastic surgeons do not seem to be taking the news well as there are good chances that an added tax might reduce the number of people going in for cosmetic surgery greatly. Under the proposal, the 5% tax would be levied on everyone going in for procedures ranging from face-lifts to teeth whitening. For now, the new proposed tax is being called the "Botax", and it could raise as much as US\$6 Billion every year. President-elect of the American Society of Plastic Surgeons, has asserted that majority of women who nowadays receive corrective cosmetic surgery have earnings between US\$30,000 and US\$90,000.

Europe

Germany: EU review mechanism on customs laws not likely to cover drug seizure issue

Even as the repeated seizure of drugs by the European authorities raised resentment and the EU claimed to be reviewing the contentious regulatory clause relating to the issue, India has expressed apprehension about the review and its chances of resolving the matter permanently. European Union has learnt to be conveyed to India that it was reviewing the controversial regulation of EC 1383/2003 which has created the problem leading to the seizure of drugs in the recent past. However, Indian authorities view that the issue cannot be solved with the ongoing review.

UK: Cosmetic Surgery Procedures Might be Taxable under New Healthcare Bill

Under the new healthcare plan, which has been revamped to enable it to reach millions of more Americans, the Senate is looking to levy a tax on some cosmetic surgery procedures, and the plastic surgeons do not seem to be taking the news well as there are good chances that an added tax might reduce the number of people going in for cosmetic surgery greatly. Under the proposal, the 5% tax would be levied on everyone going in for procedures ranging from face-lifts to teeth whitening. For now, the new proposed tax is being called the "Botax", and it could raise as much as US\$6 Billion every year. President-elect of the American Society of Plastic Surgeons, has asserted that majority of women who nowadays receive corrective cosmetic surgery have earnings between US\$30,000 and US\$90,000.

Asia Pacific

India: Indian cos hold highest number of CEPs, bulk drug exports to EU rise

Indian exports of bulk drugs to European Union (EU) is growing at a higher pace, as the country has bagged the highest number of Certificate of suitability of European Pharmacopoeia monographs (CEPs), of late, according to a study released by the Pharmaceuticals Exports Promotion Council of India (Pharmexcil). According to the study, out of 48 countries globally pursuing the EU market, India received 21.47% of CEP approvals from The European Directorate for Quality Medicines and Healthcare (EDQM), followed by its closest competitor Italy (11%) and USA (10%). Almost 136 companies have received approval for CEPs from EDQM accounting for more than 200 different molecules.

India: Drug authorities file case against Shree Vinayak Trading Co for selling spurious drugs

The drug authorities have filed a case against Shree Vinayak Trading company, Mumbai for selling spurious Iviglob Ex. Injection, manufactured by Hualan Biologicals of China. The injection was imported and marketed by VHB Lifesciences Ltd, Mumbai.

China: PPD acquires BioDuro to expand drug development capabilities in China

PPD, Inc has signed an agreement to acquire BioDuro LLC, a drug discovery outsourcing company that provides a broad range of integrated services to biopharmaceutical companies. The acquisition will expand PPD's drug development capabilities in China. Founded in 2005, BioDuro operates a state-of-the-art, 110,000-square-foot laboratory in Beijing. Most of its approximately 660 employees are based in China, where it provides deep scientific expertise in medicinal chemistry, biology, pharmacology, drug metabolism, pharmacokinetic and safety services.

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India: SIRO enters pact with Mediscis to broaden early phase drug development expertise

SIRO Clinpharm, a global contract research organization (CRO) presents in India, US, Europe and Israel, announced their alliance with Mediscis, an early drug development company based in Poitiers and La Rochelle, France. The pact will widen SIRO's reach in western Europe clinical research market. Mediscis is an established expert in GCP compliant early phase drug development services including clinical trials and bioanalytics while SIRO offers expertise across all study phases for the pharmaceutical and biotech industry.

India: Drug control dept seizes imported diagnostic kits worth Rs1m from stockist

Following a complaint, the officers of the Drugs Control Directorate of Tamil Nadu has conducted a raid in a pharma stockist's office and godown at Perungudi in Chennai and seized Rs1m worth imported diagnostic kits meant for distribution in several parts of the state. The Perungudi zonal office of the department has received complaints about the importer-cum-stockist that he is engaged in illegal sale and distribution of diagnostic devices.

India: Indian drug cos need to focus on niche segments in US generic market

The Indian pharma companies should focus more on complex chemistry, biotech-based medicines and advance formulations to tap the lucrative US generic market in future, suggests a study conducted by Pharmaceuticals Exports Promotion Council (Pharmexcil) – the apex body governing pharma exports under the Union Ministry of Commerce. The study—Presence of Indian pharmaceutical industries in US market: An empirical analysis—conducted by Pharmexcil reveals that ANDAs from India are confined to small number of highly competitive molecules, the country has evident high hand in Abbreviated New Drug Application (ANDA) and Drug Master File (DMF) Filings.

India: SurModics, NuPathe enter license pact for drug delivery technology

SurModics, Inc, a leading provider of drug delivery and surface modification technologies to the healthcare industry, and NuPathe Inc, a neuroscience-focused specialty pharmaceutical company, have entered into a license agreement for drug delivery technology. The companies have been collaborating since 2007 on the development of a biodegradable sustained release formulation of an approved dopamine agonist. The result is NuPathe's NP201, the first long-acting treatment available in broadly acceptable dose form that maintains the potential to provide sustained relief from Parkinson's disease without motor response complications.

India: GE Healthcare expands US\$1.5bn global healthcare IT business in India

GE Healthcare launched the Indian expansion of its US\$1.5bn Global Healthcare IT business, pledging to offer strong healthcare connectivity and resources to a country that has lagged behind in this key area of healthcare delivery. India, with a population of 1.3bn, has fewer than 0.7 beds per 1000 people and an acute shortage of healthcare professionals. GE Healthcare IT solutions will help increase patient access and bridge the acute shortage of well-trained healthcare professionals. GE Healthcare also announced its first “managed” Indian partnership with DCA Imaging Centre, New Delhi. Under this alignment, GE Healthcare has installed Centricity PACS-IW solution at DCA Imaging headquarters in Delhi. With this brand new solution, DCA Imaging has already connected five imaging centres in India and will create a wider network in the near future. With GE's solution, DCA Imaging Centre can now offer diagnostic reports without delay, and without any upfront investment.

India: Max Bupa to provide health cover by March

Max Bupa, a joint venture between Max India and UK-based healthcare company Bupa, plans to enter the health insurance market in India by March 2010. They are targeting to be in the market in the first quarter next year (January to March). “We are building systems and training people. Premiums are being built and products developed to file with the regulator. We do not want to be very fast and get it wrong because that will severely damage our reputation,” Max Bupa chief executive officer said. The products for Indian market will be kept simple, accessible and affordable unlike other developed markets where health insurance is well understood and complex products are offered. Health insurance penetration in India is as low as 3%. Max Bupa will look at introducing portable group health insurance products to cater to the needs of people when they switch jobs.

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HUMAN RESOURCES**Asia-Pacific****Singapore: DIT programme to help un-employed reskill for a career in the booming**

In response to the identified need for up-skilling in the Bio-Pharmaceutical and related Life Sciences industries, DIT launched an innovative and cost effective way for retraining those recently unemployed for a new career in the Pharmaceutical industry. The aim of the class is to empower, enable and connect students with lecturers in global centres of excellence around the world using Internet technology. Students connect and meet live in a virtual classroom for an online interactive class that is delivered by BioPharmaceutical industry specialists from DPS in Ireland and in Singapore. It has been designed to provide participants with a stimulating, positive and enjoyable environment along with the opportunity to broaden and enhance employment prospects..

INVESTMENTS**Americas:****USA: Glades Healthcare Foundation Raises US\$56,000 for New Lakeside Medical Center**

Glades Healthcare Foundation Golf Tournament Raises US\$56,000 for New Lakeside Medical Center. Funds have supported state-of-the-art 50-acre medical campus opened in October. The first-annual Glades Healthcare Foundation Golf Tournament was held at prestigious Trump International Golf Club in West Palm Beach in Nov. 16 to raise funds for the new Lakeside Medical Center, which will improve access to quality healthcare for all western Palm Beach County communities bordering Lake Okeechobee and neighboring towns. One hundred forty-four golfers participated in the sold-out event sponsored and organised by airport concessionaire The Paradies Shops, raising over US\$56,000 for continued improvements to the recently-completed medical campus.

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USA: Eurotech Wins Contract with GE Healthcare for Medical Device Accessory

Eurotech Group, a leading supplier of embedded technologies, products, and systems, announced that it has signed a contract with GE Healthcare to provide the embedded computing platform, based on the TurboXb computer on module product, for a future data capture device accessory. The multi-year contract is worth over one million dollars for Eurotech. GE Healthcare is moving quickly to develop their device to improve patient care by minimising reporting error and recording health data accurately. The contract covers both hardware production units and engineering services centered on the TurboXb embedded computer from Eurotech that powers the GE Healthcare device accessory.

Asia-Pacific**Malaysia: KPJ Healthcare Aims RM2bn in Turnover By 2012**

Malaysia's largest private hospital group KPJ Healthcare Bhd aims to achieve an annual turnover of RM2 billion by 2012. The group is planning to achieve the target through its existing specialist hospital network and the services provided by several support companies within the group as well as opening new hospitals, takeover of other private hospitals already in operation and acquisition of sophisticated equipment. KPJ Healthcare now runs 19 hospitals nationwide including the one officiated by Penang Yang Dipertua Negeri Tun Abdul Rahman Abbas in Bandar Perda. It also has three hospitals overseas, namely in Indonesia, Bangladesh and Saudi Arabia.

MERGERS AND ACQUISITION**Americas:****USA: GE Healthcare and TeleHealth Services Partner to Bring Advanced Solutions**

TeleHealth Services, the nation's leading provider of on-demand patient education and communication solutions has become a Strategic Partner reseller of GE Healthcare Monitoring Solutions nurse call and communication systems including Telligence(TM), a platform designed for healthcare facilities to address patient communication challenges. By leveraging each organisation's industry-leading services and collective capabilities, GE Healthcare and TeleHealth will deliver comprehensive healthcare communication solutions. "The combination of each company's industry-leading solutions creates an extremely valuable offering that addresses some of today's most complex healthcare issues for patient safety and quality of care," said Steve Sholtis, TeleHealth Services' VP of Hospital Communications Systems.

USA: Mountain West Business Solutions Acquires Sunshine Biopharma

Mountain West Business Solutions, Inc. announced that it has acquired Sunshine Biopharma, Inc., a Colorado Corporation. The acquisition was in exchange for the issuance of 21,962,000 shares of common stock and 850,000 shares of Series "A" Convertible Preferred stock. Each Preferred share can be converted into 20 shares of common stock. The Company plans to change its name to Sunshine Biopharma, Inc. to reflect this acquisition and the Company's new direction. The Company's trading symbol will also be changed upon the name change taking effect.

Canada: Amarin Corp to Join SAFE-BioPharma Association

Amarin Corp, a clinical stage pharmaceutical company with R&D operations based in Mystic, Conn., has joined SAFE BioPharma Association, the non-profit association that created and manages the global SAFE-BioPharma® digital identity and signature standard for the pharmaceutical and healthcare industries. SAFE BioPharma digital signatures provide superior antiforgery and legal protection to electronic documents than conventional electronic signatures. The SAFE BioPharma standard also is used extensively for digital identity management and facilitates interoperability across different information systems. Amarin, which is scheduled to soon commence two Phase 3 clinical trials, joined SAFE-BioPharma in order to sign documents digitally, thus minimising the paper associated with drug development.

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Asia-Pacific

India: Philips eyes X-ray plant; to merge Alpha, Meditronics

Philips Electronics India Ltd plans to set up a manufacturing plant for CV (cardiovascular) and general X-ray system. The company also plans amalgamation of Alpha X-Ray Technology and Meditronics, acquired less than a year back, with itself. The move is expected to enhance value products with a competitive price band, which will help the company penetrate into tier-II and tier-III cities. Company is looking to make products under the Philips brand name in the new complex. The move is aimed at making India the hub for value products while maintaining its leadership position in the healthcare equipment market by penetrating into the mid and smaller cities, where the real healthcare infrastructure creation is going to take place over the years.

India: General Atlantic eyes stake in Strides arm

Private equity firm, General Atlantic (GA) is in advanced talks with Strides Arcolabs to buy a significant minority stake in the Bangalore-based company's injectables business arm for about \$100m. GA is eyeing between 30% and 40% in the Indian company's injectables business, which is housed in a subsidiary called Strides Specialties, and clarity on the exact structure of the deal would emerge in the next three weeks. There is still a gap between the valuation Strides is expecting for the business and the valuation arrived by private equity funds, which have evaluated the deal. There is a definite valuation gap, which has resulted in the deal negotiations, dragging on for close to two months.

Clinical Trials

Americas

USA: Human Genome and Aegera Therapeutics initiates clinical trial of lead IAP inhibitor

Human Genome Sciences, Inc and Aegera Therapeutics, Inc announced that HGS has initiated dosing in a Phase 1 clinical trial to evaluate the safety and tolerability of its lead IAP inhibitor, HGS1029, as monotherapy in patients with advanced lymphoid tumors. The company is pleased to initiate this first human study of HGS1029 in lymphoid malignancies, and look forward to continuing the study of its IAP inhibitors both alone and in combination with other anti-cancer agents, including mapatumumab, its agonistic antibody to TRAIL receptor 1. An additional Phase 1 clinical trial is currently ongoing to evaluate the safety and tolerability of HGS1029 in patients with advanced solid tumors.

Africa

South Africa: Synexus hails recruitment for vaccine trial

Synexus has recruited more than 2,000 children in three months for a Phase III rotavirus vaccine study, which it believes validates its methods and demonstrates they are particularly effective in late stage vaccine trials. The trial recruitment specialist's methods differ from many pharmas and contract research organisations (CRO), with the focus of the rotavirus study being on outreach campaigns. By launching these campaigns Synexus was able to target people that lack access to regular healthcare or information about clinical trials. Furthermore, the use of satellite clinics at community hospitals opened up the trial to people who are unable to travel to the main sites. These actions resulted in Synexus recruiting more than 2,000 of the 3,167 children, aged between five and 10 weeks, who participated in the trial in South Africa. Synexus has been operating in South Africa for several years, acquiring CRC SA in 2006 and starting building a further two sites last year, and it believes this experience and local knowledge helped its recruitment efforts. In addition Synexus has experience recruiting for late stage paediatric vaccine trials in South Africa. Feedback from pharma, CRO and NGO (non-governmental organisation) clients indicates that the company's model works particularly well for late stage vaccine trials.

Ivory Coast: Sanofi-aventis and MMV to launch study of an antimalarial drug

Sanofi-aventis and Medicines for Malaria Venture (MMV) announced that they have entered an agreement to launch the largest safety and efficacy study of an antimalarial drug. This field-monitoring program on ASAQ, a fixed-dose combination of artesunate and amodiaquine, started in Côte d'Ivoire in October 2009. MMV is a not-for-profit drug research and development organisation dedicated to reducing the burden of malaria. ASAQ is the only fixed-dose combination of artesunate and amodiaquine

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prequalified by WHO in the treatment of Plasmodium falciparum uncomplicated malaria. Under the terms of the agreement, MMV will provide \$1.5m towards the implementation of this large field-monitoring study developed by sanofi-aventis and the National Malaria Control Program of Côte d'Ivoire. Over a two-year period, approximately 15,000 patients afflicted by malaria are expected to be enrolled. All patients diagnosed with uncomplicated malaria at public health clinics in selected parts of the Agboville district (approximately 100km north of Abidjan) will receive a prescription of ASAQ. Within a week, patients will be visited at home by specially trained community health workers to assess treatment tolerability and compliance.

Approvals

Americas

USA: AstraZeneca submits US NDA for Ticagrelor (BRILINTA)™

AstraZeneca announced that it has submitted a New Drug Application (NDA) to the US Food and Drug Administration (FDA) for Ticagrelor, an investigational oral antiplatelet treatment for the reduction of major adverse cardiac events in patients with acute coronary syndrome (ACS). The proposed trade name for ticagrelor is BRILINTA(™), pending approval from the FDA. This submission is based on the results of a comprehensive program, including data from PLATO (A Study of Platelet Inhibition and Patient Outcomes), the Phase III head-to-head trial comparing ticagrelor plus aspirin with clopidogrel (Plavix®) plus aspirin. Ticagrelor is the first reversibly binding oral P2Y12 adenosine diphosphate (ADP) receptor antagonist. ADP receptor antagonists inhibit the action of platelets in the blood to prevent platelets from sticking together, thereby reducing recurrent thrombotic events.

USA: FDA approves Abilify (aripiprazole)

Bristol-Myers Squibb Company and Otsuka Pharmaceutical Co, Ltd. announced that the US Food and Drug Administration (FDA) has approved the supplemental New Drug Application (sNDA) for Abilify (aripiprazole) for the treatment of irritability associated with autistic disorder in pediatric patients ages 6 to 17 years, including symptoms of aggression towards others, deliberate self-injuriousness, temper tantrums, and quickly changing moods. While there is no approved treatment for the core symptoms of autistic disorder, irritability can be an associated behaviour of autistic disorder and is manifested as aggression towards others, deliberate self-injurious behaviours, temper tantrums, aggression and quickly changing moods. Behavioural problems such as irritability can be a source of impairment or distress to an individual with autistic disorder.

USA: FDA approves Revatio injection

Pfizer announced that the US Food and Drug Administration (FDA) has approved Revatio (sildenafil) Injection, an intravenous formulation of Revatio. Revatio is the only FDA-approved phosphodiesterase-5 (PDE5) inhibitor available in both tablet and intravenous formulations. It is indicated for the treatment of adult patients with pulmonary arterial hypertension (WHO Group I) to improve exercise ability and delay clinical worsening. The delay in clinical worsening was demonstrated when Revatio was added to background epoprostenol therapy. The efficacy of Revatio has not been adequately evaluated in patients taking bosentan concurrently. Revatio Injection is for the continued treatment of patients with pulmonary arterial hypertension who are currently prescribed Revatio Tablets but who are temporarily unable to take oral medication.

USA: BLA submitted for Zalbin

Human Genome Sciences, Inc announced that it has submitted a Biologics License Application (BLA) to the US Food and Drug Administration (FDA) for Zalbin (albinterferon alfa-2b) for the treatment of chronic hepatitis C. The BLA submission includes the results of two pivotal Phase 3 clinical trials showing that 900-mcg albinterferon alfa-2b dosed every two weeks met its primary endpoint of non-inferiority to peginterferon alfa-2a (Pegasys) dosed once each week.

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USA: Sun Pharma subsidiary gets FDA nod for anti-hypertension drug

Drug firm, Sun Pharmaceutical Industries said that its subsidiary, has received US Drug regulator approval for anti-hypertension drug. The subsidiary has received the US Food and Drug Administration (USFDA) approval for Nicardipine Hydrochloride injections, available in the strength of 25 mg/10ml, Sun Pharmaceutical said in a filing to the Bombay Stock Exchange. The injections are used for short-term treatment of hypertension when oral therapy is not feasible.

Asia-Pacific**China: Biolaxy secures IND approval for oral insulin**

Shanghai Biolaxy announced the Chinese State Food & Drug Administration (SFDA) has approved the investigational new drug application (IND) for its oral insulin project (Nodlin), an innovative insulin formulation to treat diabetes. This IND approval allows Biolaxy to initiate its first phase I clinical study. Diabetes is a disorder characteristic of high blood glucose and poor metabolism. The complications of diabetes often result in severe micro- and macro-vascular diseases, loss of vision, kidney failure, and amputation. Insulin, as an effective diabetic treatment, can slow down diabetic disease progression. However, insulin is given by multiple daily injections at present, which significantly hinders its use. Nodlin is developed with NOD technology, a patented bio-adhesive nano-particle oral delivery technology, to overcome the barriers of oral insulin. IND approval is a significant milestone achievement for Biolaxy.

OTHERS**Americas****USA: 'Pharma Crops' threaten Food Safety**

Medicine and farming are merging as genetically engineered (GE) maize and soy crops promise cheap drugs, but they also threaten to contaminate food and the environment, warn activists and experts. The United States has planted very small amounts of these experimental pharma crops since the early 1990s, including about 18 hectare in 2004, according to the U.S. Department of Agriculture. Although full-scale production is a few years away, a new report is warning that when it begins, the U.S. food supply will be contaminated sooner or later. A Union of Concerned Scientists (UCS), an environmental non-governmental organisation (NGO) that asked six independent scientists to prepare the report, is calling for an immediate ban on the field production of food or feed crops engineered to produce pharmaceuticals and industrial chemicals.

USA: Class Action Lawsuit Against Hemispherx Biopharma Is Without Merit

Hemispherx Biopharma, Inc said the recently filed lawsuit is without merit. The lawsuit is based upon the false claim that "... defendants failed to disclose that the FDA had requested several reports from the Company before the NDA could even be considered..." regarding the Ampligen® (Poly I : Poly C12U) investigational product. That claim is irrefutably false. On July 7, 2008 the Company received a letter from the Department of Health and Human Services, Food and Drug Administration.

USA: AVI BioPharma Presents Antisense Approach to Transplant Acceptance

AVI BioPharma, Inc. announced it presented data on its NeuGene® antisense approach to transplant acceptance at the 20th International Congress of the Transplantation Society, held in Vienna, Austria, Sept. 5-10, 2004. The presentation, titled "Antisense Inhibition of cFLIP Promotes Transplant Acceptance by Sensitising Responding T Cells to Undergo Activation Induced Apoptosis," was presented by AVI senior scientist Dan Mourich, Ph.D. The findings of the study indicate that specific transplant acceptance can be achieved using AVI's antisense approach and that a novel method for promoting transplant survival without long-term immunosuppressive therapy is possible. When the immune system responds to a foreign tissue transplant, specific immune cells, called lymphocytes, are activated, leading to transplant rejection. During this process a regulatory protein called cFLIP is produced, blocking apoptosis, or programmed cell death, in the activated lymphocytes.

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Asia Pacific

India: Karnataka Drugs Control issues show cause notices to 193 pharmacies

Karnataka drugs control department has issued 193 show cause notices to sales outlets for violations of Drugs & Cosmetics Act between September 1 and 31 October, 2009. During the period, 93 pharmacy trade licenses had been suspended and 36 sales licenses were cancelled. The reasons for issue of show cause notices are for not possessing a trade license, no issue of sales bills and for storing date expired drugs along with regular medicines. The Department issued show cause notices to seven manufacturing units for violations. These include the units not adhering to Schedule M norms like lack of record maintenance in batch production of drugs.

India: Six Indian pharma firms face ban in Sri Lanka for supplying substandard drugs

Even as India is fighting all out to redeem its image as a quality supplier of generic medicines across the world, as many as six pharma firms from India are facing the threat of ban in Sri Lanka for allegedly supplying sub-quality drugs, in an embarrassment to the domestic industry. The health authorities in the island nation have ordered withdrawal of supplies from six Indian pharma companies after a high-level panel found that they had supplied sub-standard drugs to the Medical Supplies Division and asked the companies to replace them with new stocks on their own expenses or face blacklisting for two years.

India: Public sector drug units improve production, sales turnover in 2008-09

The total production and sales turnover from the central public sector pharma undertakings including the ailing Indian Drugs and Pharmaceuticals Ltd (IDPL) have increased marginally during the last financial year, according to the data with the Pharmaceutical Department. The total production in the three CPUs - IDPL, Hindustan Antibiotics Ltd (HAL), Bengal Chemicals and Pharmaceuticals Ltd (BCPL)-and their joint ventures went up from Rs5.93 billion during 2007-08 to Rs6.41 billion during 2008-09, as per the data compiled by the department.

India: Indian pharmaceutical market is over Rs550bn

Indian pharmaceutical market, which has registered robust growth in last few years, was valued at over Rs550 billion in 2008-09. As per the information available with Pharmaceutical Department through ORG-IMS (market research agency), April 2009, moving annual total (MAT) value of Indian Pharmaceutical market is Rs554.54 billion. This includes retail pharmaceutical market at maximum retail price, companies not tracked by ORG, hospitals and institutional sales (except government procurement), direct doctor purchase, over the counter products and diagnostic chemicals. The average MAT value of Indian pharmaceutical market for the 2006-07 fiscal is around Rs439.04 billion, for 2007-08 is around Rs504.10 billion and for 2008-09 fiscal is Rs554.54 billion

RESEARCH AND DEVELOPMENT

Americas

USA: Hemispherx Biopharma Finds New Retrovirus in Chronic Fatigue Syndrome

Hemispherx Biopharma, Inc. has announced a discovery of a novel retrovirus in Chronic Fatigue Syndrome. The retrovirus light on the potential mechanism of action of Ampligen, an experimental therapeutic, in CFS. CFS is a debilitating disease of unknown etiology that affects 17 million worldwide. Hemispherx Biopharma found that In CFS patients Immunosuppression is often found and may be a feature of retroviruses in animal and man. Researchers from the Whittemore Peterson Institute, the National Cancer Institute and the Cleveland Clinic had reported a new retrovirus in the blood cells of 67% of CFS patients and 3.7% in healthy control subjects, in the October 8, 2009 issue of Science Express. The virus was greater than 99% identical to that previously detected in prostate cancer. Patients with the virus experience higher cancer rates and neurological pathology.

USA: Array BioPharma to Use Horizon Discovery's X-MAN Lines

Array BioPharma will use its X-MAN human isogenic cell lines to evaluate a target that could be used as a cancer treatment. Array will evaluate a panel of the X-MAN cell lines carrying specific mutant cancer genes with matched parental genetic backgrounds. Array aims to study the potential utility of its compounds and will share some of the data it generates over the course of the evaluation period, which starts this month.

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USA: CARS visualises lipids in cancer metastasis

Researchers have provided mechanistic evidence linking a high-fat diet to increased cancer metastasis by measuring the precise impact of fats on cancer cells using coherent anti-Stokes Raman scattering microscopy and a laser-based tool called intravital flow cytometry. For more than 30 years, doctors have observed a strong correlation between lipid-rich tumor biopsies from cancer patients and aggressive clinical cancer behaviors, including early death, according to Ji-Xin Cheng, who led the investigative team at Purdue University. Cheng said it has been widely observed that diet and obesity account for 30% of preventable causes of cancers, but that the relationship between diet and cancer incidence and mortality remains controversial.

EUROPE**UK: Nabi Biopharmaceuticals Initiates Pivotal Phase III Study for NicVAX**

Nabi Biopharmaceuticals has initiated the first of two pivotal phase III clinical trials for NicVAX (R) (Nicotine Conjugate Vaccine), the company's innovative and proprietary vaccine to treat nicotine addiction and prevent smoking relapse. This study is being funded in part with a US\$10 million grant from U.S. National Institute on Drug Abuse (NIDA), part of the National Institutes of Health. The FDA has agreed with Nabi on the study design, protocol and end points through a Special Protocol Assessment (SPA). The SPA forms a basic foundation to support approval of a New Drug Application. The Company also received scientific advice from the European Medicines Agency (EMA) that confirms and supports the trial protocol, increasing the possibility of a positive outcome.

Asia-Pacific**China: China biopharma shareholders approve Merger with with Neostem**

China Biopharmaceuticals Holdings, Inc, an integrated bio-pharmaceutical company, based in the People's Republic of China, announced that its shareholders have approved the acquisition of CHBP by NeoStem, Inc. by an overwhelming vote in favour of approximately 80% of all issued and outstanding shares. The approval was obtained at a Special Meeting of Stockholders held recently.

India: Biotech should seek inclusive innovation

The science of biotechnology offers a big opportunity for innovation and entrepreneurship, but innovators must keep in mind that India's billion plus benefit from it, said senior scientist and former director general of the Council for Industrial and Scientific Research Raghunath Mashelkar. The breakthrough ideas that biotechnology will seek should touch the lives of the country's masses and should not be confined to small groups of its people, Mashelkar said. India, particularly Maharashtra, has a significant advantage in terms of its natural and physical resources to leapfrog the development of biotechnology, but the task will have to be guided by three principles; speed, scale and sustainability, he said. The biotechnology-based solutions that we intend developing, according to him, should be relevant for all.

India: 21 M Pharm students selected for this year's M Pharm Scholarship Awards

Twenty one final year M Pharm students from various Colleges of Pharmacy in Tamil Nadu have been selected for this year's M.Pharm Scholarship Awards instituted by Tamil Nadu Pharmaceutical Sciences Welfare Trust. The scholarships are given for the project work undertaken by the students.

India: Indian Railways to establish 18 medical colleges, 7 nursing colleges along with its hospitals.

The Indian Railways will soon establish 18 new medical colleges attached to the existing Railway hospitals through the Public Private Partnership (PPP) programme. These proposed medical colleges will be opened in Chennai, Hyderabad, Bilaspur, Lucknow, Barasat, Bhubaneswar, Mysore, Kharagpur, Guwahati, Dibrugarh, Jodhpur, Gardenreach, Nagpur, Ahmedabad, B R Singh Hospital/Kolkata, Bhopal, Jammu and Thiruvanthapuram. The Railways will also establish seven Nursing Colleges attached to existing Railway Hospitals through the PPP programme. These places are Delhi, Kolkata, Mumbai (Kalyan), Chennai, Secunderabad, Lucknow and Jabalpur. Railways also propose to set up a training institute at Dankuni (West Bengal).

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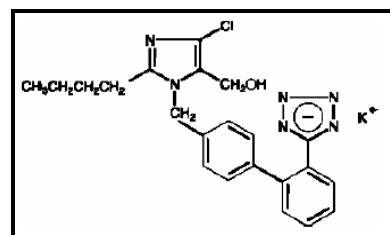
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Product Focus – Cozaar (Losartan Potassium)

COZAAR (LOSARTAN POTASSIUM)

Introduction

Cozaar (losartan potassium) is a prescription medicine that has been licensed to treat several conditions related to the heart and blood vessels. It is part of a class of drugs called angiotensin II receptor blockers (ARBs for short). Cozaar is manufactured by Merck & Co.



Uses

- High blood pressure (hypertension) control
- Diabetic nephropathy treatment

The medication is not a cure for high blood pressure or diabetic nephropathy. Although the medicine cannot cure either condition, it is effective in slowing down the progression of diabetic nephropathy and controlling high blood pressure. It has also been approved for use in children ages six and older to treat high blood pressure.

Working Mechanism

Cozaar is part of a class of drugs called angiotensin II receptor blockers. As the name of the drug class implies, the medication blocks angiotensin II receptors. This decreases the effectiveness of a chemical known as angiotensin II, which normally causes blood vessels to narrow (constrict). By blocking the effects of angiotensin II, Cozaar causes blood vessels to relax, which can lower blood pressure.

Side Effects

As with any medicine, side effects are possible with Cozaar. However, not everyone who takes the medicine will experience side effects. In fact, most people tolerate it well. If side effects do occur, they are often minor and either require no treatment or can easily be treated by healthcare provider. Serious side effects can occur, but are less common.

| Side Effects |
|---|
| ➤ Infection, such as the common cold or flu |
| ➤ Dizziness |
| ➤ Nasal congestion |
| ➤ Back pain |
| ➤ Diarrhoea |
| ➤ Fatigue |
| ➤ Anaemia |
| ➤ Increase in blood potassium levels |
| ➤ Low blood pressure |
| ➤ Weight gain |

Precautions

- ✓ Cozaar can cause low blood pressure, especially if the person is also taking a diuretic. Persons who are under this medication may feel light-headed or faint, especially during the first few days of therapy. If these symptoms occur, physician should be contacted at the earliest. The dosage needed to be adjusted or discontinued.
- ✓ Excessive sweating, severe diarrhoea, or vomiting could make the person lose too much water, causing a severe drop in blood pressure. The physician should be called if the person experiences any of these symptoms. Be sure to tell the physician about any medical conditions the person has, especially liver or kidney disease.
- ✓ Cozaar tends to increase the level of potassium in the blood. Check with your physician before taking potassium supplements or using a salt substitute.
- ✓ Cozaar can cause injury or even death to the unborn child when used in the second or third trimester of pregnancy. Stop taking Cozaar as soon as you are pregnant. If you are pregnant or plan to become pregnant, tell your physician before taking Cozaar. Cozaar may appear in breast milk and could affect the nursing infant. If this medication is essential to your health, the physician may advise you to stop breastfeeding while you are taking Cozaar.

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Recommended dosage

| Adults | Children |
|---|---|
| The usual starting dose is 50 milligrams once daily. However, Cozaar can also be taken twice daily, with total daily doses ranging from 25 milligrams to 100 milligrams. If the person's blood pressure does not respond, the physician may increase the dose or add a low-dose diuretic to your regimen. | The usual starting dose is 25 milligrams daily. The physician may adjust the dosage according to the person's response. |

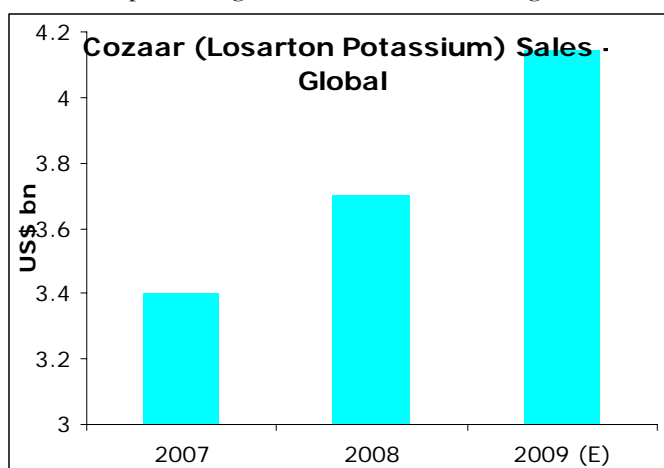
Market Scenario

Hypertension market

Hypertension is a leading risk factor for coronary heart disease, heart failure, heart attack, stroke and renal insufficiency. Hypertension is generally defined as blood pressure greater than 140/90mmHg. Risk levels are doubled in people with diabetes.

The global hypertension drugs market is currently valued at around US\$38.5 billion. The range of drug classes available to treat high blood pressure contributes to the competitive nature of a market were 12 blockbuster drugs in 2007, with combined sales of US\$23.7 billion.

Global sales of Merck's antihypertensive medicines, Cozaar and Hyzaar, were US\$891m for the fourth quarter of 2007, a 3% increase compared with the fourth quarter of 2006. Annual sales were US\$3.4 billion during 2007, a 6% increase compared with full-year 2006. Cozaar and Hyzaar are among the leading members of the angiotensin receptor blocker class of medicines. Cozaar and Hyzaar are registered trademarks of E.I. duPont de Nemours and Company, Wilmington, Delaware.



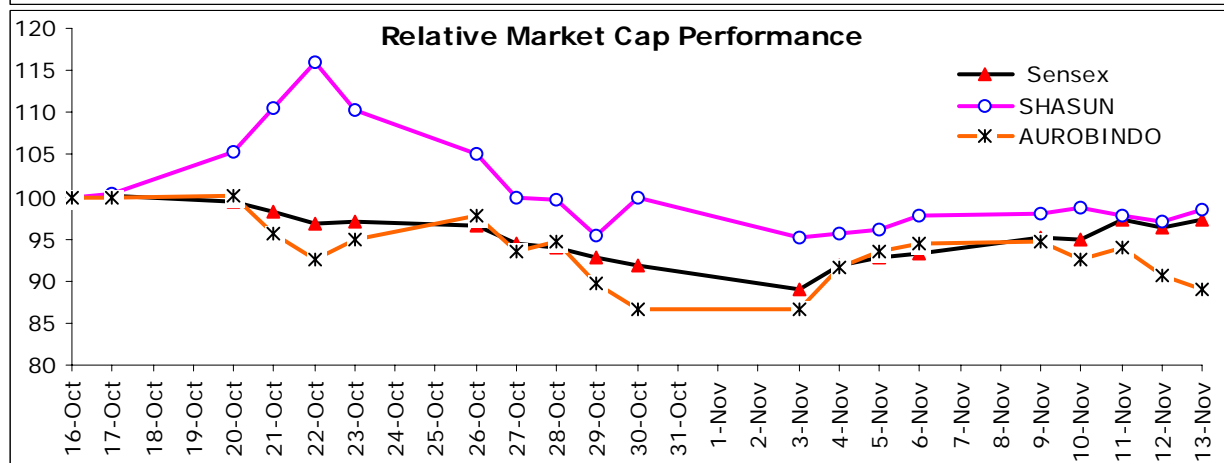
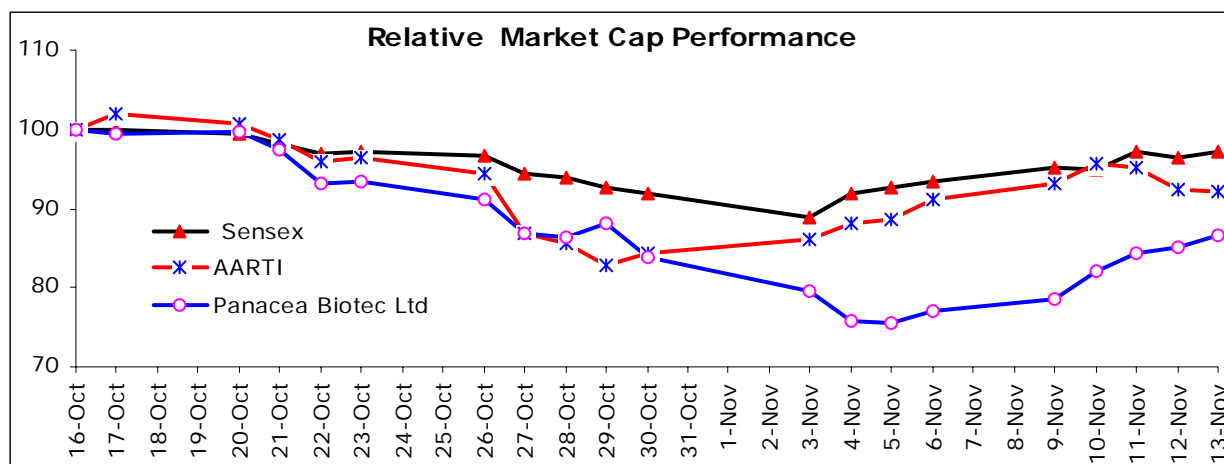
Source: Company Website; Cygnus Research

Outlook

The global revenue of hypertension market is likely to grow to nearly US\$30 billion per year by 2010. Approximately 30% of cases of essential hypertension are attributable to genetic factors. The worldwide sales of Cozaar were forecasted at US\$3.5 – 3.7 billion for 2008. It is estimated to register its net sales of 10-12% by the end of 2009.

The Indian drug retail market grew by a 29.24% in value terms in October 2009 over the year ago period, more than double the average monthly revenue growth rate of 13-14% in the recent past, as per market research firm ORG IMS. This sales audit by ORG IMS is based on the sales by stockists to chemists and not the actual sales by chemists to consumers. Domestic drug sales constitute about a third of revenues for pharma companies, who depend on exports for their overall business, besides selling directly to hospitals and institutions.

Stock Scan



Source: BSE India; Cygnus Research

| | Oct 16-Oct 24 | Oct 25-Oct 31 | Nov 01-Nov 07 | Nov 08-Nov 15 |
|---------------|---|--|---|--|
| SENSEX | Profit booking during this week in the oil & gas, and consumer durable stocks made the index slip into negative zone to 16810 points. | Sensex broke 16k mark and decreased to 15986 points due to the weak global markets and palpable nervousness ahead of the policy announcement by the banks. | This week the Sensex rose by 4.89% due to the recovery made by the PSU. | During this week the index which ended on a positive note, increased by 2.12% to reach 16848 points. This is mainly due to the capital infused by FII's in the market. |
| Aarti | This week the scrip followed sensex and declined by 4% to Rs88.80 from Rs92.05. | Negative sentiments in the market and the poor performance of the company made the scrip decline by 11% to Rs77.65. | Good positive move is seen by the scrip during this week. | This week the scrip remained flat. |

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| | | | | |
|------------------|---|---|--|---|
| Panacea | During this week the scrip declined by 7% and followed sensx. | Poor operational performance of the company made the scrip decline further by 8% to Rs149.15. | The scrip went against the indices and decline by 3% to Rs137.20. | Bulk purchases and the good market sentiments made the scrip increase by 10% to Rs154.30. |
| Shasun | The scrip went against the indices and increased by 10% to Rs35.80. | The negative sentiments in the market made the scrip decline by 5% to Rs32.45. | The scrip not made much movement during this week. | Scrip remained flat during this period. |
| Aurobindo | Poor operational performance of the company made the scrip decline by 5% to Rs821.30. | This week the scrip followed sensx and decline further by 11% to Rs749.25. | Some positive movement in the sensx made the scrip increase by 9% to Rs816.60. | This week the scrip ended on a negative note. |

Regulatory Issues

REGULATIONS

FDA Approves Kalbitor for Treating Potentially Life-Threatening Attacks of Hereditary Angioedema

The U.S. Food and Drug Administration approved Kalbitor (ecallantide) on Dec. 1 to treat sudden and potentially life-threatening fluid buildup that can occur in people with a rare genetic condition known as hereditary angioedema (HAE). HAE is caused by a defect in the blood protein C1 esterase-inhibitor, which plays a role in regulating how certain immune system and blood clotting pathways function. Decreased function of this protein can lead to rapid and serious swelling of the face or other parts of the body, which may result in permanent disfigurement, disability or death. Swelling of the digestive tract may cause excruciating abdominal pain, nausea, and vomiting, while airway swelling puts patients at risk of suffocation.

Voltaren Gel (diclofenac sodium topical gel) 1% - Hepatic Effects Labeling Changes

Novartis and FDA notified healthcare professionals of revisions to the Hepatic Effects section of the prescribing information to add new warnings and precautions about the potential for elevation in liver function tests during treatment with all products containing diclofenac sodium.

In Postmarketing reports, cases of drug-induced hepatotoxicity have been reported in the first month but can occur at any time during treatment with diclofenac. Postmarketing surveillance has reported cases of severe hepatic reactions, including liver necrosis, jaundice, fulminant hepatitis with and without jaundice, and liver failure. Some of these reported cases resulted in fatalities or liver transplantation.

NATIONAL

TN govt to appoint 25 new drug inspectors after a gap of 10 years.

The government of Tamil Nadu will appoint 25 new drug inspectors in 15 days to fill up the existing vacancies in various parts of the state. Further, it plans to speed up the procedures to fill up the vacancies of Pharmacists in the health department.

CDSCO to induct 200 drug inspectors by next year to equip itself for issuing CoPP

The Central Drugs Standard Control Organisation (CDSCO) is equipping itself for the smooth issuance of the CoPP by inducting more officials in the central machinery. Even as the fight for the control over Certificate of Pharmaceutical Products (CoPP) is going on in the court. By next year end, The CDSCO is planning to increase the number of drug inspectors across the country and is looking to depute at least 200 drug inspectors.

Upcoming Events

| | | |
|----------|------------------------|---|
| 1 | Event | Anti-Aging Conference & Exhibition – Las Vegas |
| | Date | Dec 09-12, 2009 |
| | Venue | Venetian Resort-Hotel-Casino, Las Vegas, United States of America |
| | Highlights | Anti-Aging Conference & Exhibition-Las Vegas will showcase many medicines and technologies that are at the cutting edge of this field and medicine in general. |
| | Contact Details | Tarsus Group Plc. 4th Floor, Metro Building, 1 Butterwick, Hammersmith, London, United Kingdom. Tel:+(44)-(20)-88462700; Fax:+(44)-(20)-88462801 |
| 2 | Event | Biomedical Optics |
| | Date | Jan 23-28, 2010 |
| | Venue | TBA, San Francisco, United States of America |
| | Highlights | It will provide an insight to the latest developments in the field of biomedical optics. BiOS will be displaying new innovations, developments and products in the field of optical coherence tomography, molecular imaging, and spectroscopy. The main exhibition of the biomedical optics will also host presentations and panel discussions on important topics in the industry. |
| | Contact Details | SPIE-International Society for Optical Engineering 1000, 20th Street, Bellingham, United States of America. Tel:+(1)-(360)-6763290; Fax:+(1)-(360)-6471445 |
| 3 | Event | Biomedical Optics |
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| 4 | Event | Clinical Outsourcing World Europe 2010 |
| | Date | Jan 26-29, 2009 |
| | Venue | TBA, London, United Kingdom |
| | Highlights | Clinical Outsourcing World Europe 2010 will address the major strategic and operational issues involved in outsourcing. Clinical Outsourcing World Americas builds on the success of the inaugural Clinical Outsourcing World Europe held in London in January 2010. |
| | Contact Details | Terrapinn Pte Limited 12, Prince Edward Road, 03-01 Podium A, Bestway, Singapore, Singapore. Tel:+(65)-(65)-62228550; Fax:+(65)-(65)-62263264 |
| | Event | Clinical Outsourcing World Europe 2010 |

| | | |
|----------|------------------------|--|
| 5 | Event | Military Health Management |
| | Date | Jan 26-28, 2010 |
| | Venue | Sheraton National Hotel, 900 S. Orme Street Arlington, Arlington, USA |
| | Highlights | Military health management is one of the most important issues facing the armed forces. Given that people are the most important resource in the United States military, it is an undisputed top priority to provide the highest quality of medical service and support to our men and women who serve. |
| | Contact Details | Worldwide Business Research. 535, Fifth Avenue, 8th, New York, United States Of America. Tel:+(1)-(888)-4826012; Fax:+(1)-(212)-8852798 |
| 6 | Event | International Conference on Drug Design & Discovery |
| | Date | Feb 01-04, 2009 |
| | Venue | Dubai Men's College, Dubai, United Arab Emirates |
| | Highlights | International Conference on Drug Design & Discovery (ICDDD) is the second major international conference and exhibition of this series, which aims to present cutting edge advances in various disciplines of drug design and discovery that have been recently achieved. |
| | Contact Details | Eureka Science Limited Executive Suite Y-26, P.O.Box:7917, Saif Zone, Sharjah, UAE. Tel:+(971)-(6)-5571132; Fax:+(971)-(6)-5571134 |
| 7 | Event | Pharma Con Davos |
| | Date | Feb 07-12, 2010 |
| | Venue | Davos Congress Centre, Davos, Switzerland |
| | Highlights | Pharma Con Davos Exhibition will be to bring together the manufacturers and suppliers of process plant and equipment, for this growing industry, all under one roof. The exhibition will provide an excellent platform for service providers to showcase their products and services to decision makers from leading Pharmaceutical manufacturers. |
| | Contact Details | Wuv (werbe- Und Vertriebsgesellschaft Deutscher Apotheker Mbh) Carl- Mannich- Strasse 26, Eschborn, Germany. Tel:+(49)-(61)-96928 |
| 8 | Event | Medicall-Hyderabad |
| | Date | Feb 19-21, 2010 |
| | Venue | TBA, Hyderabad, India |
| | Highlights | Medicall-Hyderabad is one of the prestigious events in India for medical & pharmaceutical industry. The exhibition attracts many visitors from different parts of the world. The fair is considered as the hospital needs supermarket where producers, dealers, buyers, suppliers etc. capitalise emerging opportunities of the pharma world. |
| | Contact Details | Medexpert Isha Homes, Np 74 1st Avenue, Indranagar, Adyar, Chennai, India. Tel:+(91)-(44)-32516661 |

| | | |
|-----------|------------------------|--|
| 9 | Event | World Generic Medicines Congress Europe |
| | Date | Feb 23-26, 2010 |
| | Venue | TBA, London, United Kingdom |
| | Highlights | World Generic Medicines Congress Europe is World's leading generic medicines strategy conference & expo. World Generic Medicines Congress Europe Speaker panel included representation. It is World's most compelling and influential scientific and strategic leaders, facilitating education, debate and business. Machinery & Materials, Lab Equipment, Analytical Instruments will be targeting Venture Capitalists, Investment Banks, CSOs, Equipment Providers, Delivery technology manufacturers. |
| | Contact Details | Terrapinn Pte Limited 12, Prince Edward Road, 03-01 Podium A, Bestway, Singapore, Singapore. Tel:+(65)-(65)-62228550; Fax:+(65)-(65)-62263264 |
| 10 | Event | Meditec Clinika 2010 |
| | Date | Feb 26-28, 2010 |
| | Venue | Chennai Trade Centre, Chennai, India |
| | Highlights | Meditec Clinika 2010 presents an opportunity in South Asia as the largest platform for the Medical Equipment and Technology industry. We envision Meditec Clinika to act as a catalyst to bring together a varied genre of medical professionals under one roof to interact, promote and transact business in this industry which will eventually lead to better healthcare for the common man in this densely populated region. |
| | Contact Details | Orbitz Exhibitions Private Limited 202, Navyug Industrial Estate, T J Road, Sewree, Mumbai, India. Tel:+(91)-(22)-24102801; Fax:+(91)-(22)-24102805 |