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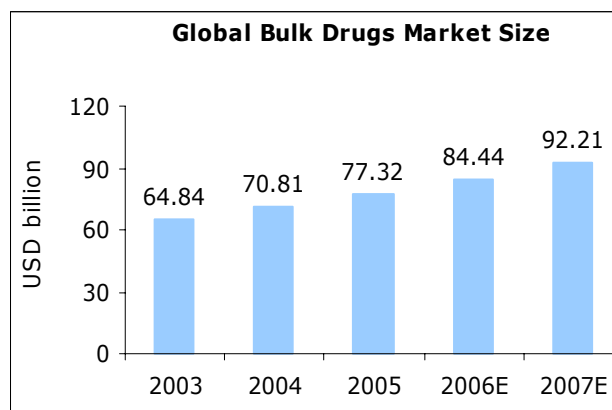
In Focus: “Indian Bulk Drugs Market – An overview”

Introduction:

According to USFDA, Bulk drug substance means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.

Global Bulk Drugs Market

The market size of the global bulk drugs was USD77.32 billion in 2005 and is estimated to be USD92.21 billion in 2007, growing at a CAGR of 9.2% during 2003-07. The bulk drug industry is highly-fragmented, with a large number of small players. The bulk drug producers can be classified into three categories: contract manufacturers, niche bulk drug



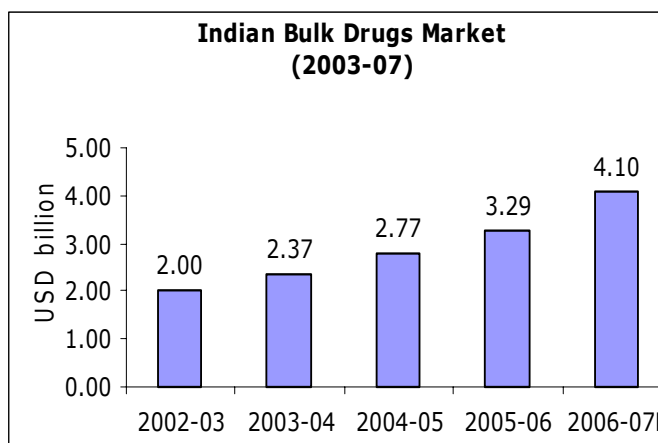
Source: Cygnus Research

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manufacturers and commodity bulk drug manufacturers. Of late, the generic prescription drugs segment has emerged as a promising market for bulk drugs. The contract manufacturing of OTC and nutritional products is the largest and fastest growing segment.

Indian Bulk Drugs Market

Bulk drug is the Indian name for Active Pharmaceutical Ingredients (API). India is ranked among the top 15 drug manufacturing countries worldwide. India is globally recognized as a low cost, high quality bulk drugs and formulations manufacturer and supplier. The Indian API manufacturing industry is the third largest in the world with sales of USD2.77 billion in 2005, and is estimated to be USD4.10 billion by



Source: BDMA, Cygnus Research
Figure includes 35% of production from unorganized market

2007, at a CAGR of 19.67%. The Indian bulk drug market is fragmented with about 1,333 pharmaceutical companies. Indian companies are capable of developing cost-effective technologies for the manufacturing of bulk drugs and intermediates in world standards in a very short time. Near about 70% of the bulk drug manufactured is exported to more than 50 countries. Indian bulk drugs exports revenue were USD2.65 billion in 2006-07, with a robust growth of 25% over the previous year.

Major Global players

The major bulk drug companies are Merck KGaA, Teva Pharmaceuticals, Novartis, Pliva Pharmaceuticals, Watson Pharmaceuticals, Barr Pharmaceuticals Inc, Mylan Laboratories Inc, Ranbaxy Laboratories, Actavis, Dr. Reddy's Laboratories and Aurobindo Pharma

Major Indian players

The list of companies include Aurobindo, Dr Reddy's Laboratories, Ranbaxy Dishman Pharmaceuticals, Lupin, Cipla, Matrix, Orchid Chemicals, Divi's laboratories Sun Pharmaceuticals, Ipca Laboratories, Cadila Healthcare, Alembic Ltd, GSK, Glenmark Pharmaceuticals, Nicholas Piramal, Torrent Pharmaceuticals, Unichem Laboratories, Merck India Ltd and Atul Ltd.

Growth Drivers

The major growth drivers for the Indian bulk drug market include:

- **High Growth of Generics/ Patent Expires**

The Indian pharma industry is well positioned to capture much of the USD65 billion new business expected to open up globally in coming years. Indian pharma industry accounts for 22% of the global generics market. Bearing in mind that USD65 billion of prescription medicines in Europe (USD25 billion) and the US (USD40 billion) are to lose their patents in 2007-08; India is ideally positioned to sweep up much of that new business. Indian firms are likely to take around 30% of the increasing global generics market in the coming years. Low production costs give India an edge over other generics-producing nations, especially China and Israel. In 2006, Indian firms now account for 44% of Drug Master File (DMF's) applications and one in four of all US Abbreviated New Drug Application (ANDA) filings submitted to the FDA. In related to ANDA approvals, India has gone up considerable from 15% in 2005 to 25% in 2007 (Jan-Jun). The loss of patent protection by 2009, which is expected to create almost USD80 billion worth of top selling drugs globally will be the main driver for the Indian Pharma industry.

- **New drug developments**

The major pharmaceutical companies in India are the main R&D investor in the country. The R&D expenditure of the 15 top 0companies has grown up by 8.9% to INR21.01 billion in 2006-07 from INR19.27 billion in 2005-06. Moreover the top Indian pharmaceutical companies have started the new business strategy of de-merging of their R&D activities into a separate company. So, companies can focus more on NCEs and Novel Drug Delivery Systems (NDDS). The model of R&D investment by Indian companies is shifting from core process research to new drug development and NDDS.

- **Contract manufacturing**

The global pharmaceutical contract manufacturing market was estimated to be USD16723.2 m in 2007 from USD13,661.4m in 2005, with a CAGR 11% and is estimated to grow to USD25,709.0m in 2011 at a CAGR of 11%. The year-on-year (YoY) growth in revenues is forecast to be marginally higher for each of the years from 2005 to 2011. The contract manufacturing market is expected to grow with a CAGR of 11% from 2004-2011.

- **Overall Pharmaceutical Growth**

The pharmaceutical industry in India meets around 80-90% of the country's demand for bulk drugs, drug intermediates, pharmaceutical formulations, chemicals, tablets, capsules, orals and injectible.

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Currently, Indian pharmaceutical companies produce about 20-22% of the world's generic drugs (in terms of value). Indian pharmaceutical market accounts for 1-2% of the global pharmaceutical market in value terms and 8% in volume terms. The market size comprises of domestic consumption of bulk drugs and formulations and does not include exports of the same. The pharmaceutical market has grown at a compounded annual growth rate (CAGR) of 13% during the last five years. In 2007 it has grown by 12.9% to reach USD8.14 billion. Market growth during 2007 was driven by a number of new product launches by both Indian and foreign companies. Exports grew at a higher CAGR of 20% to reach USD6.15 billion in 2007. So the overall growth of the pharmaceutical industry is also driving the growth of the bulk drugs industry.

Indian pharmaceutical industry is a major part of a country's giant economy which is predicted to become one of the top five economies by 2025. Current Indian pharmaceutical market is abuzz with all sorts of activity. It has strong competitive advantage in terms of low development cost, skilled and efficient manpower, and easy availability of raw materials.

Outlook

India has the highest number of USFDA approved manufacturing facility outside the US thus puts in a good position to manufacture bulk drugs and export to regulated markets in the coming years. By 2010, Indian bulk drugs market is expected to grow to about USD6.54 billion. Domestic companies are aggressively pursuing international market to the exports growth but competition from companies in Eastern Europe and China are emerging as a matter of concern. Rapid erosion of prices of generics, non-tariff barriers and appreciation of rupee are also seen as hurdles to exports. Increasing consolidation will erase the distinction between bulk drug companies and generic drug makers in the near future. China is becoming a major competitor to India, in the exports of active pharmaceutical ingredients (APIs). China's pharmaceutical industry ranks no.7 in the world and is expected to become the world's 5th largest by 2010. In the recent years Indian pharmaceutical companies have invested about 30% of their total global investment in generic manufacturing capacity. The market size is expected to grow at higher percentage in future years with more and more international companies are depending on India to meet their bulk-drug supply needs.



News Briefs

INTERNATIONAL

AMERICAS

USA: Self-confident children may be healthier as adults

Children who believe they have control over their lives may grow up to be healthier adults, study suggested. Locus of control is often viewed as a natural component of a person's personality. Researchers indicated that there is also evidence that it is shaped by childhood experiences including children's interactions with their parents. Parents who encourage independence and help children learn the connection between their actions and consequences tend to have children with a more internal locus of control.

USA: Vitamins improve tuberculosis treatment

Supplementing the diet with nutrients, including selenium and vitamins A, B complex, C, and E, improves the outcomes of patients being treated for tuberculosis, a study suggests. The nutritional status is a very important predictor of clinical outcomes in patients with infections. Nutrient supplements had no effect on death rates or on the progression of HIV disease, the researchers noted. Results from a single study are usually not sufficient to provide general recommendations. Researchers and doctors believe that the findings represent a true effect and nutrient supplementation could be an important (additional) therapy for patients with tuberculosis.

USA: Spectrum Pharmaceuticals announces expansion into Canada

Spectrum Pharmaceuticals, Inc announced the formation of a Canadian affiliate, Spectrum Pharma Canada, Inc. headquartered in the Province of Québec, Canada. The establishment of Spectrum Pharma Canada is another important milestone as the firm builds a global pharmaceutical organisation, Spectrum Pharmaceuticals spokes person said. The Canadian research infrastructure, highly qualified talent pool, and economic incentives provided by the individual provinces, especially the Province of Québec, were all factors in the establishment of this affiliate. The corporates were impressed with the receptiveness of Investissement Québec, and are currently working with this state-owned corporation to help Spectrum Pharma Canada succeed in its mission.

USA: Pfizer Inc and the University of Pennsylvania announce US\$15m partnership

Pfizer Inc announced that it has entered into US\$15m collaboration with the University Of Pennsylvania School Of Medicine. The partnership will include collaborations between Pfizer and the University in the areas of scientific research, clinical development and clinical care and policy. Project proposals will be solicited and reviewed by a committee with representation from both parties. The initial emphasis of the collaboration will focus on the neurosciences and oncology, but may expand to other areas. This collaboration provides an opportunity for Pfizer and the University Of Pennsylvania School Of Medicine to build and implement a new model for interactions between industry and academic medical centres.

USA: Javelin Pharmaceuticals, Inc. Announces New Patent Covering PMI-150 Intranasal Ketamine

Javelin Pharmaceuticals, Inc., a leading developer of specialty prescription medications for pain management, was granted a commercially important patent in the European Union that extends patent protection for Javelin's PMI-150 (intranasal ketamine) drug candidate into 2023. The extension of Javelin's intranasal ketamine patent portfolio in Europe is an important milestone for the company, Company's spokesperson said. The issuance of this European patent extends the term of commercial exclusivity for Javelin's intranasal ketamine by almost a decade. This extension in the

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market exclusivity for intranasal ketamine should significantly enhance the potential value of the PMI-150 franchise and further bolster their global partnership discussions.

USA: New Improved Dosing Approved for Pennsaid

Nuvo Research Inc, a Canadian drug development company focused on the research and development of drug products delivered to and through the skin using its topical and transdermal drug delivery technologies, and Paladin Labs Inc, a leading Canadian specialty pharmaceutical company, announced that Health Canada has approved a new dosing regimen for Pennsaid(R) (topical diclofenac). Paladin sells and markets Pennsaid in Canada, having acquired exclusive Canadian Pennsaid rights from Nuvo in August 2005. The new improved dosing regimen of Pennsaid(R) is a significant clinical advantage, the company CEO stated. Corporate people were eager to replicate Pennsaid's Canadian success in the U.S. market and continue to work diligently on obtaining U.S. FDA approval.

USA: Allergan Receives USFDA Approval for Trivaris(TM)

Allergan, Inc. announced that the U.S. Food and Drug Administration (FDA) has approved Trivaris™ (triamcinolone acetonide injectable suspension) 80 mg/mL, a synthetic glucocorticoid corticosteroid with anti-inflammatory action. Delivered via intravitreal injection, the ophthalmic indications for Trivaris™ include sympathetic ophthalmia, temporal arteritis, uveitis, and ocular inflammatory conditions unresponsive to topical corticosteroids. These are inflammatory conditions that can result in vision loss. The use of oral corticosteroids is not recommended in the treatment of optic neuritis and may lead to an increase in the risk of new episodes. Corticosteroids should be used cautiously in patients with a history of ocular herpes simplex because of possible corneal perforation. Corticosteroids should not be used in active ocular herpes simplex.

USA: Eli Lilly antidepressant approved for new use

Eli Lilly and Co. received the Food and Drug Administration approval to expand the use of its fastest-growing drug, the antidepressant Cymbalta. Regulators approved Cymbalta to treat fibromyalgia, a chronic pain disorder. The drug already is approved for diabetic nerve pain, major depressive disorder and generalized anxiety disorder. Lilly launched Cymbalta in 2004. It was the drugmaker's second-best seller last year, generating US\$2.1 billion in mostly U.S. sales behind Zyprexa's US\$4.7 billion. Cymbalta sales rose 37% in the first quarter to US\$605m. Fibromyalgia affects about 5m Americans. Researchers believe its cause may be related to genetics, stress and changes in brain and spinal cord chemistry and that it leads to increased pain sensitivity. Lilly developed the drug with Japan's Daiichi Sankyo Co., and some analysts following the drug maker expect it to generate at least US\$600m in annual revenue.

USA: Boca Pharmacal Receives FDA Approval for Carbinoxamine Maleate

Boca Pharmacal, Inc. announced that the U.S. Food and Drug Administration has granted final approval for the Company's Abbreviated New Drug Application (ANDA) to market its generic version of Pamlab's Palgic(R) 4mg Tablet. The Company plans to launch its product immediately. It is indicated to treat seasonal and perennial allergic rhinitis, vasomotor rhinitis, allergic conjunctivitis due to inhalant allergens and food, mild, uncomplicated allergic skin manifestations of urticaria and angioedema, dermatographism, as therapy for anaphylactic reactions to blood or plasma. Carbinoxamine Maleate 4mg Tablet is one more approval stemming from strong R&D and a robust product pipeline.

USA: Pfizer and UCSF Form Alliance to Advance a Broad Range of Research

In a novel experiment to advance new drug discovery and development, as well as stimulate basic research, Pfizer, Inc. and UCSF have launched a collaboration that spans many disciplines, several UC campuses and multiple Pfizer research units. The three year agreement, with research and other

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support up to US\$9.5m, establishes a university team to help identify promising areas of mutual interest and facilitate project management. The Pfizer-UCSF agreement will encourage collaborations between the company and UCSF's unit of QB3, the multi-campus California Institute for Quantitative Biosciences, headquartered at UCSF.

Europe:

UK: Denmark picks Merck's Gardasil for vaccine program

Denmark has chosen Merck & Co's cervical cancer vaccine Gardasil for its immunisation program, according to Sanofi-Aventis, which markets the drug in Europe as part of a joint venture with Merck. Sanofi announced the tender program to protect young girls against the human papilloma virus that causes cervical cancer. Vaccines are designed for girls and young women to protect them against cancer-causing strains of the HPV virus. Earlier this year the European Centre for Disease Prevention and Control said in a report that both vaccines could best help reduce cervical cancer when used with screening programmes. The disease kills 300,000 each year, mostly in developing countries. A handful of EU countries have introduced the vaccination into their national health programmes and most are considering it, according to the European Centre for Disease Prevention and Control.

UK: Big Progress in Government and Industry Drug Price Deal

The Government and the pharmaceutical industry announced a significant deal on parts of the new Pharmaceutical Price Regulation Scheme. The headline agreements with industry include: a saving of 5% in the cost of drugs sold to the NHS: In addition, a further price reduction of 2% will be available if growth in the drugs bill exceeds an agreed threshold. The 5% savings will be made up of a base price cut for all branded medicines of 2%, combined with measures to reduce the price of out of patent drugs (where a generic equivalent exists) and a further variable price cut to deliver 5% overall. In this system, patients have faster access to new medicines that are clinically proved and cost-effective.

UK: Pharmaceutical Price Regulation Scheme is a Win-Win Says Society

The pharmaceutical industry makes a big contribution to the UK economy and to patient care and they are fortunate to have such a vibrant research-based industry in the country. The Society believes this is a winning situation for all concerned - the National Health Service (NHS), patients and the industry. It is good news for the NHS as it will reduce the overall cost of medications and it is good news for patients as they should have faster access to new innovative medicines.

UK: PAREXEL reaches agreement to acquire ClinPhone

PAREXEL International Corporation, a leading global biopharmaceutical services organisation, announced the Boards of Parexel International and ClinPhone plc, a company traded on the London Stock Exchange, have reached agreement on the terms of a recommended proposal whereby a wholly owned subsidiary of PAREXEL will acquire the entire issued and to be issued ordinary share capital of ClinPhone. With headquarters in Nottingham, United Kingdom, ClinPhone is one of the world's leading clinical technology organizations. PAREXEL expects that the acquisition will be dilutive to earnings in its financial year ending June 30, 2009. Excluding amortization of intangibles, the acquisition will be accretive to earnings in that same period.

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Middle East

South African court bans AIDS vitamin trials

South African court issued an order banning unauthorised clinical trials of vitamin therapies for AIDS conducted by a team including a former adviser to President Thabo Mbeki. South Africa has one of the world's highest incidences of HIV, with an estimated 500,000 people infected each year. About 1,000 die every day from AIDS-related illnesses. The researchers promote vitamin pills and micronutrients, mainly minerals such as iron or iodine that can reverse the course of HIV/AIDS. The court said to researchers, two of 12 people mentioned in the suit, would be prohibited from conducting unlawful clinical trials in South Africa or from publishing advertisements for their products.

Africa: Zydus Cadila buys 70% in S. Africa's Simayla Pharma

Close on the heels of its recent acquisition in Spain, Cadila Healthcare Ltd (Zydus Cadila) announced acquiring 70% stake in Simayla Pharmaceuticals of South Africa, through its wholly owned subsidiary Zydus Healthcare SA Pty Ltd, for an undisclosed amount. As per the agreement reached between the two companies, the remaining stake will be held by the promoter of the company, Mr Ben Classen, who will continue to head the company's operations. Simayla recorded revenues of South African Rand US\$18.6m in 2007 and is expected to touch US\$40.5m in 2008, the company said. The Chairman and Managing Director of the Ahmedabad-based pharmaceutical company said the acquisition of Simayla, one of the fastest growing generic companies in South Africa, opens up opportunities for the group in a market that is estimated to touch US\$4.62 billion at consumer prices over the next three years.

Israel: Teva Announces Launch of Generic Wellbutrin XL(R) Tablets, 150mg

Teva Pharmaceutical Industries Ltd. announced that it has commercially shipping Bupropion Hydrochloride Extended-Release Tablets, 150 mg, the generic version of Biovail Corporation's antidepressant Wellbutrin XL® Tablets, pursuant to its March 2007 agreement with Anchen Pharmaceuticals, Inc. Wellbutrin XL® Tablets, 150 mg, marketed by GlaxoSmithKline, had U.S. sales of approximately US\$930m for the 12 months ended March 2008, according to IMS data.

Israel: Teva announces tentative approval of generic Diovan(R) tablets

Teva Pharmaceutical Industries Ltd announced that the US Food and Drug Administration has granted tentative approval for the company's Abbreviated New Drug Application (ANDA) to market its generic version of Novartis' hypertension treatment Diovan® (Valsartan) Tablets, 40mg, 80mg, 160mg and 320mg. Final approval of this product is expected upon expiry of patent protection for the brand product in September 2012, as well as any periods of marketing exclusivity that may be awarded. The brand product had US sales of approximately US\$1.5 billion for the twelve months ended March 30, 2008, according to IMS data.

Asia Pacific

Australia: Estrogen may protect against colorectal cancer

Female colon cancer patients who are 50 or younger have much better odds of surviving the disease than their male peers, but the opposite is true of older women with the disease, Australian researchers report. The researchers also noted that because women were more likely to have proximal tumours (i.e., those closer to the point where the colon joins the small intestine), flexible sigmoidoscopy, a colon cancer screening test that only examines the lower portion of the colon -- may be less effective in female patients than colonoscopy, in which the entire large intestine is viewed.

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China Cracks Down On Drug Companies

Chinese officials said that licenses had been revoked for three drugmakers, including one that sent human growth hormone to the United States, and that they had punished 125 other companies, mostly pharmacies, for making, selling or distributing performance-enhancing drugs. The move was heralded as evidence that China was determined to live up to its promise to host a clean Olympics. Officials also challenged claims by the United States that China accounted for 99% of the illicit performance-enhancing drugs in the largest drug-enforcement action in United States history, known as Operation Raw Deal, last year. The United States had asked China to investigate 37 drug manufacturers.

Japan: Daiichi Sankyo acquired stake control of Ranbaxy of India for up to US\$4.6bn

Daiichi Sankyo, a Japanese drug maker, will pay up to US\$4.6 billion to take control of Ranbaxy Laboratories of India, a leading producer of generic drugs, the latest in a string of international deals by pharmaceutical companies looking to bulk up and diversify to fend off aggressive rivals. Drug makers worldwide are searching for new and emerging markets to drive profit growth as sales of branded drugs in the United States, Europe and Japan start to slow. The deal values Ranbaxy, the largest drug maker by revenue in India, at US\$8.5 billion, with the offer price representing a 31.4% premium to its closing price. Generics are expected to play a pivotal role in accessing these large but relatively low-price markets, playing into the hands of Indian companies like Ranbaxy, which have unrivalled expertise in developing inexpensive versions of medicines that are no longer covered by patents.

National News

PCI to approve institutions for Pharm D course from Sept 2008

According to the notification by the government, the duration of the Pharm.D course is 6 academic years, which includes 5 years of study and 1 year internship or residency. In the one year internship, the students will be exposed to actual pharmacy practice and clinical pharmacy services and acquires skill under supervision to make them capable of functioning independently. The Pharm.D (post baccalaureate) course, another course in the draft, shall be for 3 academic years including 2 years of study and 1 year internship or residency. The Pharmacy Council of India (PCI) will publish the inspection form for approval in its website on July 15 and the institutions have to apply for inspection by July 31.

ICRI to launch 2-yr MBA course in healthcare management

Institute of Clinical Research India (ICRI), a leading institute in clinical research studies, has announced the launch of its healthcare division - ICRI Health-to focus on imparting education in healthcare services, covering both medical tourism and hospital operations management. ICRI Health will launch the two-year MBA course in healthcare management from September at its six existing campuses in the country,

India: Pharma firms bank on brand extensions to boost growth

Stiff competition in a highly fragmented market has led the domestic drug makers to depend on brand extensions rather than new product launches to corner a market share. A market intelligence study, organised by prescription audit company ORG IMS Health, has found that one in every three brands launched in the country is a brand extension. Such products comprise 18% of the Rs280 billion domestic pharmaceutical markets. The study found both multinational and domestic companies to be interested in introducing new medicines in such a manner in India. Brand extensions are common in industries such as automobiles and fast-moving consumer goods. But in the drug market, such a phenomenon is specific to India.

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India: Ranbaxy deal good news for Indian generic firms

With demand in the USD120 billion global generic, or off-patent, drugs market expanding at more than double the rate of growth in the patented pharma market, there will be several more cross-border buyouts among global and Indian drug makers on the lines of acquisition of Ranbaxy Laboratories Ltd by Japan's Daiichi Sankyo Co Ltd, experts say. This transaction will completely transform the outlook of Indian generic industry as it triggers a real global consolidation trend in the generic sector, says one of the directors at the international consultancy and audit firm PricewaterhouseCoopers. The deal will definitely change market dynamics and can expect more deals in the Indian generic industry soon.

India: Pharma firms boost Wal-Mart revenues

Ranbaxy, Cipla and other Indian drug makers are helping US retailer Wal-Mart sell drugs at low cost and boost revenue. Indian companies say the low-cost medicine revolution kicked off by Wal-Mart covers medicines meant for cholesterol and heart problems, diabetes, antibiotics, fungal infections, among others. Wal-Mart's US\$4 Prescription Program, which covers up to 95% of the prescriptions generated in majority of therapeutic categories in the US, provides its customers over 350 prescription medicines for just US\$4 for a month's dose. A few weeks back, Wal-Mart announced an extended prescription program, wherein the company offered 90 prescriptions for US\$10. The company says through such programmes, the US consumer has saved over US\$1 billion. Meanwhile, for Indian companies that have been waging a price war in the US generic business, supplies to pharmacy chains like Wal-Mart have turned more like their much-famed HIV/AIDS medicine supplies to developing countries in Africa and Latin America.

India: Ranbaxy deal good news for Indian generic firms

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Western Pharma cos shifting works to India, China

According to a study, cost pressures, the need to tap global talent, and growth opportunities in emerging markets has led Western pharmaceutical companies to shift substantial manufacturing and clinical-trial works to India and China. Pharmaceutical companies like Merck, Eli Lilly and Johnson and Johnson are counting the two countries for advanced research and development, the study sponsored by the Ewing Marion Foundation said. Indian and Chinese scientists are rapidly innovating and creating their own intellectual property as a result of Research and Development activities, the report entitled 'The globalisation of innovation: Pharmaceuticals. Can India and China Cure the global pharmaceutical Market?'. The study found that India is playing a more strategic role in early discovery and its drug companies have the most experience in selling generic drugs that meet FDA standards. Others are likely to follow suit as Chinese contract research organisations gain experience and Western companies trust in China's ability to protect intellectual property, researchers stated.

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India: Five Indians among 40 influential pharmaceutical faces

London based SPG Media, publishers of the bi-annual magazine 'World Pharmaceutical Frontiers' has included five Indians among the top 40 influential people in the global pharmaceutical industry in 2008, in its annual Pharma40 survey. These include former drugs controller M Venkateshwarlu, Ranbaxy CMD Malvinder Mohan Singh, Ranjit Shahani, India chief of Swiss pharma major Novartis AG, Ramaprasad Reddy, chairman Aurobindo Pharma and Rajesh Jain, joint managing director, Panacea Biotec. The reason for this refocus from finances to innovation is, in part, the result of a tightening marketplace, fiercer competition and the opening up of the increasingly dynamic emerging economies of India and China, Andrew Tunnicliffe, editor World Pharmaceutical Frontiers stated.

India: Contract Research and Manufacturing Services (CRAMS)

The global pharmaceutical industry is at the cross roads. With many of the blockbuster drugs getting off-patented and with increasing R&D costs, it's hard by the companies to maintain their bottom-line and remain unaffected. They have found recourse to outsourcing some of their research and manufacturing activities and saving cost in the process. This has led to the growth of contract research and manufacturing services or CRAMS making the companies in India to rejoice. Business of CRAMS has come as a boon to the mid-cap pharma companies in India, these companies are merrily embracing CRAMS taking full advantage of the features enjoyed by India as a country of diverse origin and strong manufacturing base in pharma for years. India could potentially capture 10% of the global CRAMS market of almost US\$168 billion by 2009. Overall, the CRAMS segment is expected to have grown at 40-50% in the last few years.

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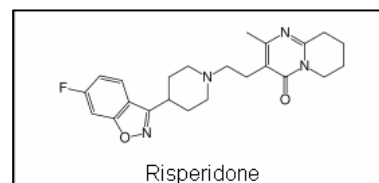
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Product Focus – Risperidone

Introduction

Risperidone is an antipsychotic medication. It works by changing the effects of chemicals in the brain. Risperidone is used to treat schizophrenia and symptoms of bipolar disorder (manic depression). It is also used in autistic children to treat symptoms of irritability. Risperidone may also be used for purposes other than those listed in this medication guide.



Drug Class and Mechanism

It works by interfering with the communication among nerves in the brain. The nerves communicate with one another by producing and releasing chemicals called neurotransmitters. The neurotransmitters attach to receptors on other nearby nerves, and the attachment of the neurotransmitter causes changes in the cells that have the receptor on them. Risperidone blocks several of the receptors on nerves including dopamine type 2, serotonin type 2, and alpha 2 adrenergic receptors and this blocks communication among nerves. Risperidone is a relatively new antipsychotic medication that probably has fewer side effects than many of the older medications.

Classification	
Brand Name	Risperdal
Generic Name	Risperidone
Therapeutic class	Antipsychotic
Manufacturer	Janssen Pharmaceutic Products
<i>Source: Cygnus Research</i>	

Drug Interactions

Risperidone may interfere with elimination by the kidneys of clozapine (Clozaril), a different type of antipsychotic medication, causing increased levels of clozapine in the blood. This could increase the risk of side effects with clozapine.

Side effects

Get emergency medical help if the person has any of these signs of an allergic reaction which includes hives difficulty in breathing; swelling of your face, lips, tongue, or throat. Stop using risperidone and tell the physician at once if the person has experienced the following side effects:

- Fever, stiff muscles, confusion, sweating, fast or uneven heartbeats
- Restless muscle movements in your eyes, tongue, jaw, or neck
- Feeling light-headed, fainting

Side Effects

Mild restlessness, drowsiness, or tremor
Sleepiness, dreaming more than usual
Blurred vision, headache, or weight gain
Problems with urination
Nausea, dry mouth, or constipation

Precautions

Risperidone is not for use in psychotic conditions that are related to dementia. Risperidone has caused fatal heart attack and stroke in older adults with dementia-related conditions. This drug is not applicable to the person, who is experiencing allergic while taking risperidone. Before taking risperidone, tell the physician if you are allergic to any of the following drugs:

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- Carbamazepine (Carbatrol, Tegretol)
- Phenytoin (Dilantin)
- Phenobarbital (Luminal, Solfoton)
- Clozapine (Clozaril)
- Fluoxetine (Prozac) or paroxetine (Paxil)
- Rifampin (Rifadin, Rimactane, Rifater)

Tell the physician about all the prescription and over-the-counter medications that the person has undertaken. This includes vitamins, minerals, herbal products, and drugs prescribed by other physician. Do not start using a new medication without informing the physician.

Supplied

It is available in 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg, 4 mg tablets; 1 mg/ml oral solution, and 30 ml bottles. Also available in 0.5 mg, 1 mg and 2 mg Risperdal M-Tabs (orally disintegrating tablets).

Adverse Event	Risperdal
Extrapyramidal symptoms	2.1%
Dizziness	0.7%
Hyperkinesia	0.6%
Somnolence	0.5%
Nausea	0.3%

Symptoms of overdose may include

- Drowsiness, upset stomach
- Pounding, or irregular heartbeat
- Blurred vision, fainting

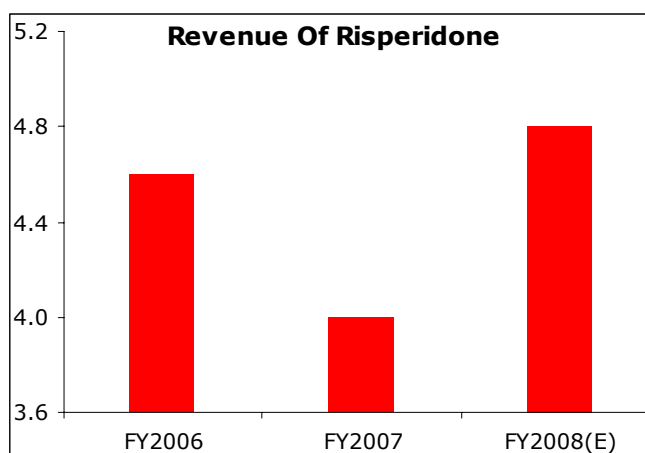
Storage: Tablets should be kept at room temperature, 15-30°C (59-86°F).

Patent Status

Janssen's patent on Risperdal expired on December 29, 2007, opening the market for cheaper generic versions of the drug from other companies; however, Janssen will continue to have exclusive marketing rights until June 29, 2008, as the result of a paediatric extension.

Revenue of Risperidone

Risperdal was launched by Janssen Cilag in June 1993. Risperidone had sold under the trade name Risperdal in the Netherlands, United States, Canada, the United Kingdom, Portugal and several other countries, Risperdal or Ridal in New Zealand, Rispolett in Eastern Europe. In 2007, sales of Risperdal manufactured by Janssen (a Johnson & Johnson subsidiary), decreased by 13% from US\$4.6 billion in 2006 to US\$4 billion in 2007. Total revenues for fiscal 2008 were US\$240.7m, compared to US\$240.0m for fiscal 2007.



Source: badpsych.com; Cygnus Research

Recent Highlights

Supplemental new drug application for Risperdal submitted to US Food and Drug Administration by Alkermes' partner, and Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

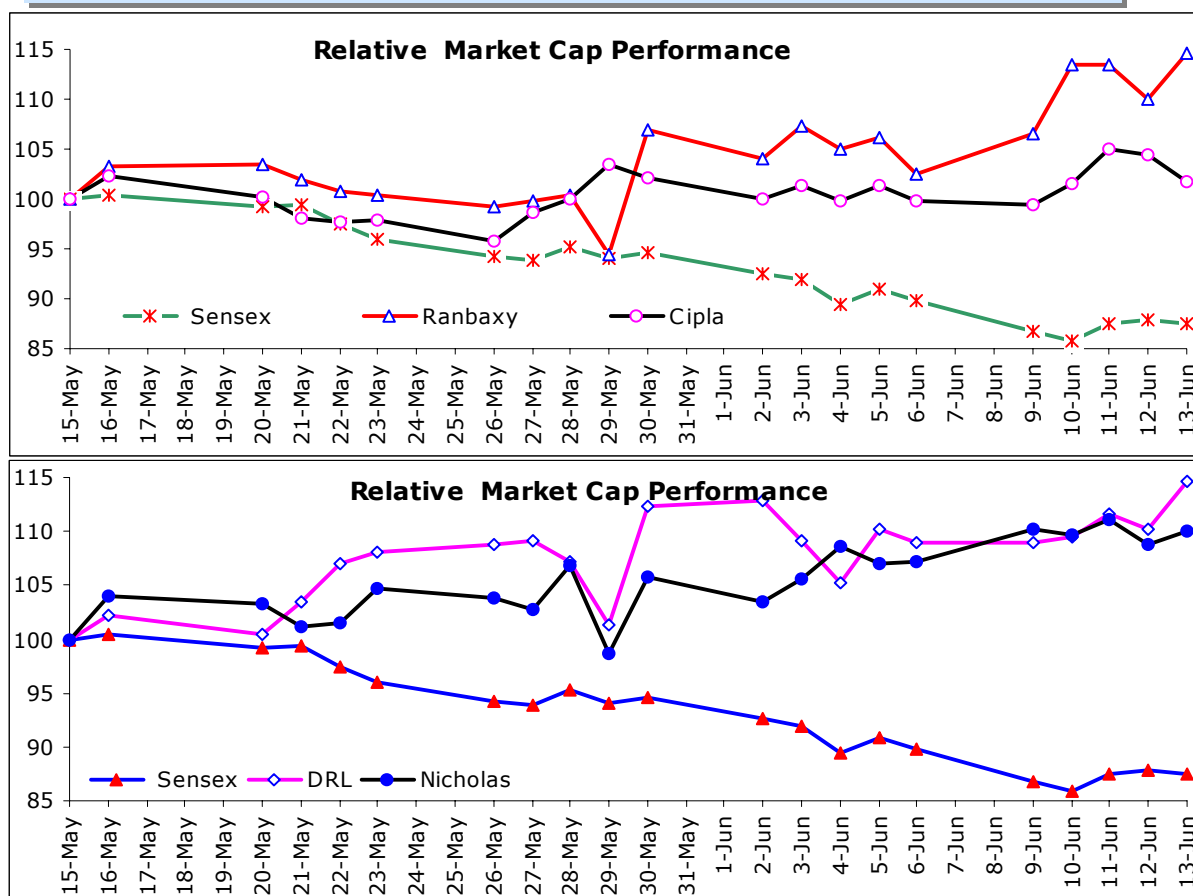
(J&JPRD), to seek the approval for adjunctive maintenance treatment to delay the occurrence of mood episodes in patients with frequently relapsing bipolar disorder (FRBD).

Outlook

The expected manufacturing revenues for Risperdal range from US\$106m to US\$114m by the end of 2009 and are based on a purchase forecast from Janssen. Corporate expects royalty revenues from Risperdal to range from US\$32m to US\$35m by end of the 2009. This expectation assumes continued sales growth in the US and around the world.

Risperidone is one of a new generation of antipsychotic drugs with relatively fewer side effects and equal efficacy for florid positive symptoms. Despite their higher direct costs of antipsychotic, which especially include risperidone has interesting economic arguments in their favour compared to earlier antipsychotics. With its recent strategies, it wants to be one of the top branded antipsychotics by its net sales and market size. It is expected to register its net sales by Rs7.5 billion by the end of 2009-10.

Stock Scan



Source: BSE India; Cygnus Research

	15 May – 24 May	25 May-31 May	1 Jun – 7 Jun	8 Jun – 13 Jun
BSE Sensex	There was a fall of 4.06% due to record high global crude oil prices which touched USD135 a barrel and spiraling inflation. The Sensex closed at 16694 points.	The Sensex registered a fall of 1.41% to reach 16415 during the period under consideration on the possibility of a hike in retail fuel prices and its impact on spiraling inflation.	A 10% hike in fuel prices and the possibility of a raise in inflation made the Sensex to drop by 5.14% to reach 15572, at the end of the period under consideration.	Soaring crude oil prices, high inflation and weak global cues hurting the sentiment of investors and Sensex lost around 2.46% during the period under consideration.
Ranbaxy	Remained flat under consideration.	The share price registered decline of 6.08% even though the company received the ICRA credit rating for	Decreased number of shares traded result in the fall in the stock prices from INR528.65 to INR506.80.	The stock price has increased by 7.69% as the company is planning to bring Daiichi Sankyo Company Limited,

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		short-term debt instruments in low credit risk. This however did not go well with investor's sentiments.		one among the largest pharmaceutical company in Japan, as majority partner; strategic combination creates innovator and generic pharma powerhouse, leading to positive sentiments among the investors.
Cipla	The stock price has declined by 2.26% as it moved in tandem with BSE Sensex.	The share price improved by 5.58% as the company is planning to sign a major long-term manufacturing and supply agreement with Australian drug company, Sigma Pharmaceuticals for over 100 over-the-counter (OTC) products, which led to rise confidence among the investors.	The share price decreased by 2.19% as major players did not performed well during this period.	The stock price increased by 2.25% as the company had received the tentative approval from USFDA for Lamivudine and Stavudine, which is indicated as antiretroviral agents for the treatment of HIV-1 infection, leading to positive sentiments among the investors.
DRL	Positive results from the company made its share move up by 6.99%.	The stock price closed at Rs644.75 showing decline of 6.21% as it moved in tandem with BSE Sensex.	Hike in fuel price prices made the share prices fall by 2.99%.	The stock price increased by 5.17% as the company had launched Atocor-R drug (combination of Atorvastatin and Ramipril) in India, which led to rise confidence among the investors.
Nicholas	Positive results from the company with 1.58% in the net profit gave boost to the share prices.	Lack of demand made share prices to fall by 5.72%.	The stock price increased by 1.28% as bullish as bullish sentiments prevailed in the market.	The stock price remained flat during this period.

Regulatory Issues

FDA Revises Process for Responding to Drug Applications

The U.S. Food and Drug Administration announced that it is revising the way it communicates to drug companies when a marketing application cannot be approved as submitted. Under new regulations that govern the drug approval process, FDA's Center for Drug Evaluation and Research (CDER) will no longer issue "approvable" or "not approvable" letters when a drug application is not approved. Instead, CDER will issue a "complete response" letter at the end of the review period to let a drug company know of the agency's decision on the application. These new regulations will help the FDA adopt a more consistent and neutral way of conveying information to a company when we cannot approve a drug application in its present form," said Janet Woodcock, M.D., director of the agency's Center for Drug Evaluation and Research (CDER). "Thorough and timely review of drug applications is a priority of the FDA, and these new processes will make our communications with sponsors of applications more consistent."

Taking the place of "approvable" and "not approvable" letters, a "complete response" letter will be issued to let a company know that the review period for a drug is complete and that the application is not yet ready for approval. The letter will describe specific deficiencies and, when possible, will outline recommended actions the applicant might take to get the application ready for approval. Currently, when assessing new drug applications, the FDA can respond to a sponsor in one of three types of letters: an "approval" letter, meaning the drug has met agency standards for safety and efficacy and the drug can be marketed for sale in the United States; an "approvable" letter, which generally indicates that the drug can probably be approved at a later date provided that the applicant provides certain additional information or makes specified changes (such as to labeling); or a "not approvable" letter, meaning the application has deficiencies generally requiring the submission of substantial additional data before the application can be approved. "Complete response" letters are already used to respond to companies that submit biologic license applications. The process for drugs and biologics will be consistent under the new regulations. The revision should not affect the overall time it takes the FDA to review new or generic drug applications or biologic license applications. These changes, which will become effective on Aug. 11, 2008, are not expected to directly affect consumers.

National

DCGI, industry agree to withdraw 138 FDCs from market

The year-long impasse over regulating marketing of fixed dose combinations in the market between the industry and the authorities is being finally settled after a fruitful meeting between the DCGI Dr Surinder Singh and the pharma associations. A consensus has been reached in the case of 138 combination drugs. At the meeting, described by the industry as one of the best ever with the authorities, it was agreed that 138 combinations out of the total 294 FDCs will be withdrawn from the market. The remaining 156 FDCs will be examined based on the scientific data and a final decision will be taken in course of time.

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NPPA revises prices of 21 formulation packs

The price regulator NPPA has fixed and revised the prices of 21 formulation packs including the monocomponent insulin products from multinationals Eli Lilly and sanofi aventis. As per the notification by the NPPA dated on July 4, two insulin products from sanofi and 13 from insulin products from market leader Eli Lilly came under the revision of prices by the authority under the powers conferred by sub-paragraph (1), (2) and (4) of Paragraph 8 of the Drugs Price Control Order, 1995. Prices of six products of Depo-Medrol / Solu-Medrol (Methyl Prednisolone) from Pfizer Products India Pvt. Ltd were also fixed. However, in most of the case, the MRP has been fixed at higher rates than the existing retail prices.

NPPA notifies overcharging cases involving 312 drugs, as companies fail to comply with orders

Manufacturers failing to furnish details of many of their products under one or other pretexts in prima-facie overcharging cases, the National Pharmaceutical Pricing Authority (NPPA) has for the first time notified the cases involving 312 drugs belonging to market leaders including Ranbaxy, Reddy's and Cadila.

Upcoming Events

1	Event	145th Annual Convention, American Veterinary Medical Association
	Date	Jul 19-22, 2008
	Venue	New Orleans, LA, USA
	Highlights	Sectors of domestic and international business and a new educational program format in 50 minutes sessions. The program will include lectures, interactive labs, special symposia, practice management, and technology classes for: veterinarians, veterinary technicians & students, practice managers and veterinary office staff.
	Contact Details	American Veterinary Medical Association Tel: 800-248-2862; Fax: 847- 925-1329 E-mail: convention@avma.org ; Web: www.avmaconvention.org
2	Event	9th Clinical Pharmacology and Therapeutics (CPT 2008)
	Date	July 27- August 1, 2008
	Venue	Quebec City Convention Centre, Canada.
	Highlights	Exclusive event for clinical pharmacology, clinical pharmacy, pharmacology and toxicology and improved therapeutics to support better health outcomes.
	Contact Details	The Organising Secretary, Canadian Society for Clinical Pharmacology (CSCP) Tel: +1 (613) 993-0414; Fax: +1 (613) 993-7250 Email: cpt2008@nrc-cnrc.gc.ca ; Website: www.cpt2008.org
3	Event	Drug Discovery & Development of Innovative Therapeutics
	Date	August 04-07, 2008
	Venue	World Trade Centre Boston & Seaport Hotel, USA
	Highlights	This is an ultimate goal of the pharmaceutical and biotechnology industries which is to bring innovative medicines to the marketplace. It will highlight how companies are moving from discovery to the clinic in creative ways and with less resource.
	Contact Details	The Organizing Secretary, IBC, 200 Seaport Boulevard, Boston, MA 02210 Tel: 617-385-5000; Fax: 617-385-5090 Email: custserv@ibcusa.com ; Website: www.drugdisc.com
4	Event	FICCI - HEAL 2008
	Date	Aug 07-08, 2008
	Venue	FICCI, New Delhi
	Highlights	FICCI endeavour, through this conglomeration of policy makers and leaders from healthcare and associated industries from India and abroad is to assess the Indian and global scenario, deliberate on the emerging opportunities, challenges and solutions to define a road map for growth of the health services sector. The aim is to arrive at workable strategies for expansion of quality healthcare provision at an affordable price from cities to towns and eventually to the villages through local and global collaboration and cooperation
	Contact Details	Shobha Mishra, Joint Director, FICCI Tel: +91-11-23722921; Fax: +91-11-23320714 Email: healthservices@ficci.com

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5	Event	Zak India Chem Pharma Expo (Zak ICPE)
	Date	Aug 13-17, 2008
	Venue	Singapore Expo, Singapore.
	Highlights	Zak India Chem Pharma Expo (Zak ICPE) will showcase the Indian chemical & pharma industries, products, companies and new offerings. This event will provide an excellent platform for business to business contacts and help producers, manufacturers, importers & exporters to network with bulk buyers of chemicals in the ASEAN region
	Contact Details	ZAK Trade Fairs and Exhibitions Private Limited, 49 (Old No. 27), Veerabadrin Street, Nungambakkam, Chennai, India., Tel: +(91)-(44)-28257722; Fax: +(91)-(44)-28254488
6	Event	Indonesia International Bio Pharma Expo
	Date	August 20-23, 2008
	Venue	Jakarta International Expo (JIExpo), Indonesia
	Highlights	Indonesia International Pharma Expo is an International Exhibition on Pharmaceutical, Raw Materials, Active Ingredients, Processing Machinery, Packaging Machinery, Equipments. The manufacturers and suppliers of process plant and equipment, for this growing industry, would attend the exhibition, all under one roof.
	Contact Details	The Organizing Secretary, Krista Media Pratama PT., Krista Exhibitions, Jln.Blandongan 28 DG, Jakarta, Indonesia., Tel: +(62)-(21)-6345861; Fax: +(62)-(21)-6340140, Website: www.kristamedia.com; Email: info@kristamedia.com;
7	Event	Saigon MediPharm & BioLab
	Date	Aug 21-24, 2008
	Venue	Ho Chi Minh City International Exhibition & Convention Centre, Ho Chi Minh City, Vietnam
	Highlights	The objective of the exhibition will be to bring together the manufacturers and suppliers of process plant and equipment, for this growing industry, all under one roof. The exhibition will provide an excellent platform for service providers to showcase their products and services to decision makers from leading Pharmaceutical manufacturers.
	Contact Details	F. A. S. T. System & Management Services 18 Richards Avenue, Singapore, Singapore Tel: +(65)-(9)-7380246; Fax: +(65)-(6)-68584490

8	Event	2008 Joint meeting of the UK HESG and Nordic HESG
	Date	Aug 27-28, 2008
	Venue	Aberdeen, Scotland, UK
	Highlights	<ul style="list-style-type: none"> • Research into economic approaches to health & health care; • Develop economic techniques to be readily applied by economists and/or health care personnel; • Demonstrate and test the approaches and techniques • Accumulate and make available to the health service a body of expertise in health economics.
	Contact Details	Health Economics Research Unit Foresterhill , Aberdeen Tel: +44 (0)1224 553733; Fax: +44 (0)1224 550926 Email: heru@abdn.ac.uk; Web: www.abdn.ac.uk
9	Event	Health India Expo
	Date	Sep 05-07, 2008
	Venue	Pragati Maidan, New Delhi, India
	Highlights	Health India Expo is a comprehensive showcase of opportunities emerging in India's burgeoning healthcare sector. The health care sector in India offers abundant collaboration opportunities for companies and medical practitioners from all over the world. India provides opportunities for global service providers to invest in curative and preventive services in primary, secondary and tertiary care. It also provides investment opportunities in medical infrastructure and medical tourism.
	Contact Details	Organiser: Exhibitions India Private Limited New Delhi - 110 020., India. Tel: +(91)-(11)-42795054; Fax: +(91)-(11)-5279 5098
10	Event	MEDi 2008
	Date	Sep 09-10, 2008
	Venue	Connecticut Expo Centre, Hartford, Connecticut, USA
	Highlights	MEDi 2008 is the most comprehensive medical device conference and exhibition in the Northeast. The educational content of MEDi 2008 will combine high-quality scientific research data with proven, validated industry case studies, proven strategies for bringing new devices to market, legal and regulatory issues and clinical applications.
	Contact Details	Designing Events, 10910 Resiterstown Road, Owings Mills, United States Of America , Tel: +(1)-(410)-6545525
11	Event	Medtec-China
	Date	Sep 09-11, 2008
	Venue	Intex Shanghai, Shanghai, Shanghai, China
	Highlights	For the first time, China's medical device and equipment manufacturers will have access to hundreds of leading medical OEM suppliers from around the globe providing a vast array of equipment, materials and services.
	Contact Details	Canon Communications, 11444 W. Olympic Blvd., Ste. 900, Los Angeles, United States Of America, Tel: +(310)-(4)-454200; Fax: +(310)-(4)-454299