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In Focus: Top Therapeutic Anti-Infective Segment

Introduction

Anti-infective drugs are classified as antibacterials, antiviral, or antifungal depending on the type of micro organism they fight. Anti-infective drugs interfere selectively with the functioning of a micro organism while leaving the human host unharmed.

- Antibacterial drugs, or antibiotics-sulfa drugs, penicillins, cephalosporins, and many others either kill bacteria directly or prevent them from multiplying, so that the body's immune system can destroy invading bacteria. Antibacterial drugs act by interfering with some specific characteristics of bacteria. On the spot they destroy the bacteria cell wall or interfere with synthesis of bacterial proteins.
- Antiviral drugs interfere with the life cycle of a virus by preventing its penetration into a host cell or by blocking the synthesis of new viruses. Antiviral drugs may cure, but often only suppress, viral infections; and flare-ups of an infection can occur after symptom-free periods. With some viruses, such as human immunodeficiency virus (HIV), which causes acquired immunodeficiency syndrome (AIDS), antiviral drugs can only prolong life, not cure the disease.
- Vaccines are used as antiviral drugs against diseases such as mumps, measles, smallpox, poliomyelitis, and influenza. Vaccines are made from either live, weakened viruses or killed viruses, both of which are designed to stimulate the immune system to produce antibodies, proteins that attack foreign substances. Mainly these antibodies protect the body against future infections.

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Kalina, Santacruz (E), Mumbai – 400 098.
Tel: 91-22-26671072; Fax: 91-22-26670744,
Email: ipacentre@ipapharma.org; www.ipapharma.org

Cygnus Business Consulting & Research Pvt. Ltd.
4th & 5th Floors, Astral Heights, Road No.1, Banjara Hills, Hyderabad-500034
Tel: +91-40-23430203-07, Fax: +91-40-23430201,
Email: info@cygnusindia.com; Website: www.cygnusindia.com

- Antifungal drugs selectively destroy fungal cells by altering cell walls.

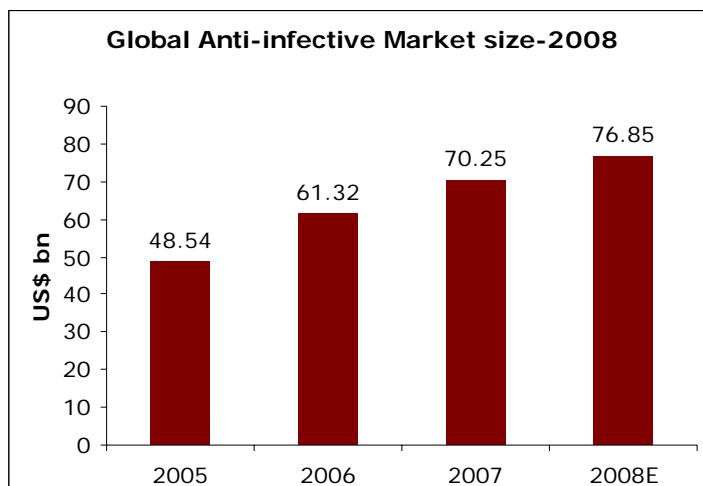
Market Size

In 2008, global anti-infective market is estimated to be about US\$77 billion and grow by 9.4% when compared with previous year where valued at US\$70.25 billion. In 2007, anti-bacterial sales accounted for 52.3% of the total market and valued at US\$36.3 billion. Major growth driver of the segment are cephalosporin and fluoroquinolones with sales of US\$14 billion and having 45% sales of total anti-bacterial revenues.

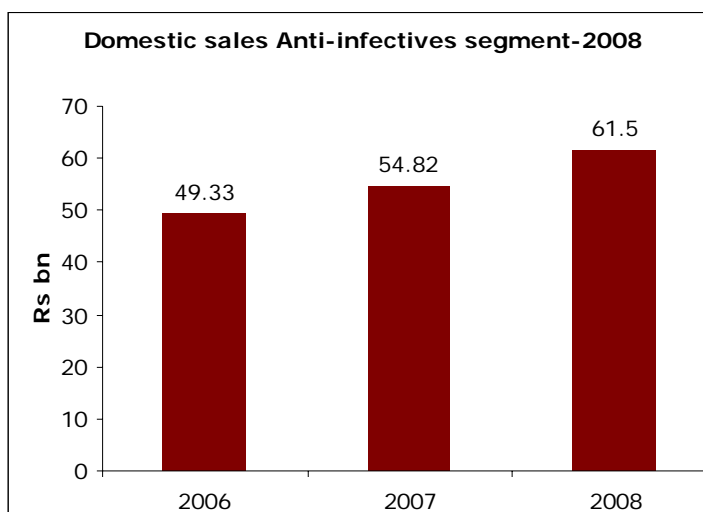
In domestic sales, anti-infective segment is the top therapeutic segment for the last few three years. In 2008, anti-infective segment is estimated to reach Rs61.50 billion with growth rate of 12.19% when compared with previous year. As per ORG IMS data, anti-infective segment grew by 11.13% and valued Rs54.82 billion in 2007 when compared with previous year value of Rs49.33 billion.

Geographic Segmentation

In geographic segmentation, US dominate the anti-infective market with 40% sales, and then second place is occupied by Europe with 21.1%, followed by Pacific Rim and others with 17% and 22% respectively.

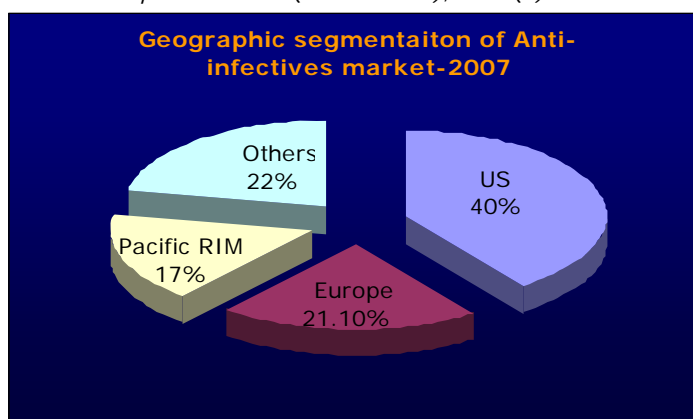


Source: Business Insights; Cygnus Research



Source: ORG IMS; Cygnus Research

Note: Data up to MAT Dec (2006 & 2007), 2008(E)



Source: Business Insights; Cygnus Research

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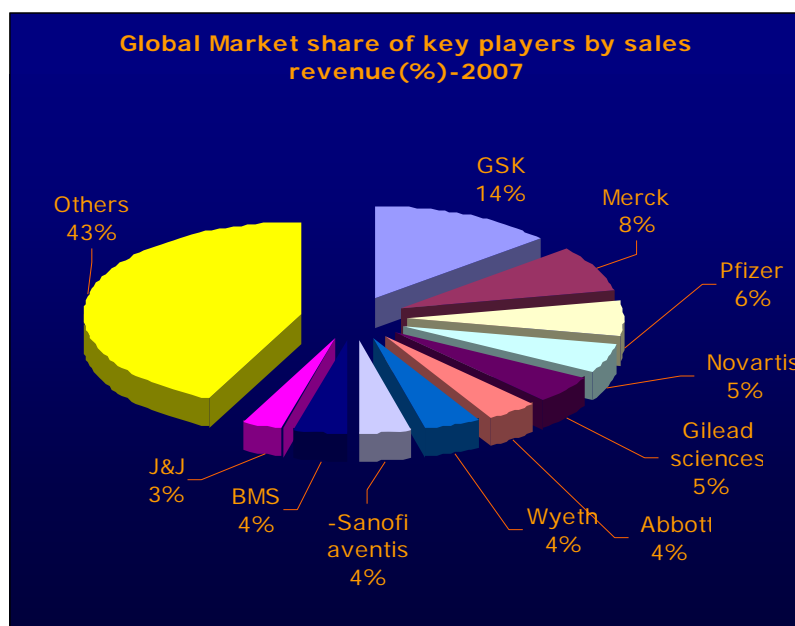
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Major Players

The top 10 companies in the anti-infective market contributed 57% towards the total market valued at US\$70.25 billion in 2007. The market is highly fragmented, market leaders both Merck and GSK holds around 22% of market share and GSK leads anti-infective market with a significant market share of 14%. Then followed by Merck, Pfizer, Novartis and Gilead Sciences with 8%, 6%, 5%, and 5%, respectively. The following table list out the top company's anti-infective brands:



Source: Business Insights; Cygnus Research

Top five global companies' anti-infective brands

Sno	Company	Top Brands
1	GSK	Augmentin, Zinnat, Valtrex, Combivir, Trizivir, Epzicom, Epivir, Lexiva, havrix Engerix B
2	Merck	Zienam, Invanz, Stocrin, Cancidas, Gardasail, varivax, Rotateq, pneumovax
3	Pfizer	Zyox, Azithromycin, Zithromax, Unasyn, Viracept, Vfend, Diflucan
4	Novarits	Amoxicillin, Azithromycin, Cefdinir, Famvir, Lamisil, Fluvirin
5	Gilead sciences	Truvada, Atripla, Viread, Hepsera, Emtriva, Ambisome

Outlook

The market for anti-infective disorders is set to become increasingly challenging as growing numbers of infectious pathogens become resistant to existing therapies. The resultant shift in R&D strategies has become a driving force behind market transformation, with many manufacturers now focused on developing drugs to counter resistance. Developmental focus has also shifted away from the anti-fungal and anti-bacterial markets due to increasing levels of genericization and comparatively shorter treatment regimens compared to other indications. By contrast, the anti-viral market contains large patient populations with chronic infections that require lifelong treatment, in addition to existing therapies that fail to provide adequate treatment. So in the coming years some of blockbuster drugs in anti-infective are going to be off patient. As per the Cygnus estimates, the global anti-infective market is estimated to reach US\$94.17 billion with a CAGR of 5.21% by 2012.

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News Briefs

MARKETING

Americas

USA: Pediapharm to market Ceragenix's EpiCeram in Canada

Ceragenix Pharmaceuticals, Inc, a medical device company focused on infectious disease and dermatology, has entered into an exclusive distribution and supply agreement with Pediapharm Inc, to commercialise EpiCeram, a prescription topical cream for treating atopic dermatitis and other dry skin conditions, in Canada. The agreement grants Pediapharm exclusivity in the territory for the distribution and marketing of EpiCeram while Ceragenix will be responsible for the manufacturing and supply of the product. Pediapharm is also responsible for obtaining regulatory clearance to market EpiCeram in the territory. Financial terms were not disclosed.

USA: Lilly receives temporary restraining order to halt launch of generic raloxifene

Eli Lilly and Company issued a communiqué after being granted a temporary restraining order to halt the launch of a generic version of Evista (raloxifene HCl tablets) by Teva Pharmaceuticals. Teva had indicated it was prepared to launch the generic version prior to the resolution of outstanding patent litigation currently being heard by the US District Court for the Southern District of Indiana.

USA: Halo Pharma to open branded product marketing company in Canada

Halo Pharmaceutical, a privately held specialty pharmaceutical company, is establishing a Canadian subsidiary to be called Halo Pharmaceutical Marketing (Canada) Ltd. This company will have its headquarters in Ontario, Canada, and its main purpose will be the marketing, sale and distribution of branded pharmaceutical products currently available in other major markets but not marketed in Canada. Halo is seeking, evaluating, and moving forward with opportunities for in-licensing and for the acquisition of branded products for both the US and Canadian markets from companies looking to rationalise their product portfolios.

USA: Arbor Pharma launches Xylarex for ear infections in kids

Arbor Pharmaceuticals, a specialty pharmaceutical company focused exclusively on paediatric medicine, has launched Xylarex - a first-in-class non-antibiotic for the dietary management of recurrent acute otitis media (middle ear infections). Xylarex is a novel oral solution intended to be administered daily to reduce the number of ear infections children experience. The primary ingredient in Xylarex has also been shown to reduce the amount of antibiotics prescribed to children affected by middle ear infections. Xylarex can be administered to children as young as six months of age.

USA: Spectrum Pharma acquires 100% control of RIT Oncology, to commercialise Zevalin

Spectrum Pharmaceuticals announced the closing of the transaction whereby Spectrum Pharmaceuticals acquired 100% control of RIT Oncology, LLC, to commercialise Zevalin ([90Y]-ibritumomab tiuxetan) in the United States. In connection with the closing, Spectrum Pharmaceuticals will pay its former partner a total of US\$16.5m, which is subject to further adjustments based on outstanding liabilities and obligations. Spectrum Pharmaceuticals now has 100% ownership of RIT Oncology, LLC, and will be responsible for all activities relating to Zevalin.

USA: The Ruth Group launches healthcare marketing communications unit

The Ruth Group, a full service investor and public relations agency dedicated to healthcare and technology, announced the expansion of its communications consulting services to include healthcare marketing. The initiative leverages TRG's strong track record and healthcare client portfolio focused on investor relations and public relations. TRG will provide existing and potential healthcare clients with

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marketing strategies for product launches, clinical trial recruitment, sales force support, patient advocacy programs, and physician outreach programs

Europe

France: Jubilant Organosys signs deal with French co Guerbet

Jubilant Organosys has signed an agreement with France-based Guerbet for the distribution of its nuclear medicine products in Europe. This was done via Jubilant's subsidiary Draximage, which specialises in radio pharmaceuticals business. Guerbet will become the exclusive distributor for the sale of Draximage range of products through its network of European subsidiaries. With this agreement, Guerbet strengthens its offering by expanding into nuclear medicine, a technology for diagnostic and therapeutic imaging that offers a highly complementary fit with x-ray and MRI line

France: Antigenics brain cancer drug Oncophage gets orphan drug status in Europe

Antigenics Inc announced that Oncophage (vitespen) has been granted a positive recommendation for orphan drug designation for the treatment of glioma by the Committee for Orphan Medical Products (COMP) of the European Medicines Agency (EMA). This designation provides Antigenics with, among other benefits, 10 years of potential market exclusivity if the product is approved for marketing in the European Union (EU). Subsequently, Antigenics submitted a Marketing Authorisation Application (MAA) to the EMA in October 2008 requesting approval for Oncophage in earlier-stage, localised renal cell carcinoma.

Asia Pacific

India: Wockhardt to launch generic version of ulcer drug Ranitidine syrup

Pharmaceutical and biotechnology major Wockhardt will be launching Ranitidine syrup in the United States. Wockhardt received final approval from the United States Food & Drug Administration (USFDA) for marketing the alcohol-free syrup containing 15mg/ml Ranitidine hydrochloride, which is used for ulcers and hyperacidity. Ranitidine is the generic name for the brand Zantac, marketed in the United States by GlaxoSmithKline. According to IMS, the total market for Ranitidine syrup in the US is US\$51m.

India: Bharat Biotech launches COMVAC5 vaccines

Drug firm Bharat Biotech has launched COMVAC5, a single shot pentavalent combination vaccine used for treating diseases such as Diphtheria, Pertussis, Tetanus, Hepatitis B and Haemophilus-Influenza type B (Hib). "COMVAC5 contains the first indigenously developed and manufactured Haemophilus type B vaccines in India and the only Hepatitis B vaccine in the world to be manufactured without the use of Cesium chloride," Bharat Biotech said. The company has invested around seven million dollars over the past four years in research & development (R&D) and manufacturing facilities for producing COMVAC5, it added.

India: Aurobindo gets USFDA nod for anti-depressant

Drug major Aurobindo Pharma said it has got tentative USFDA approval to market escitalopram oxalate tablets. They are the generic equivalent of Lexapro tablets, an anti-depressant manufactured by Forest Labs and are prescribed for the treatment of depression associated with mood disorders. The market size for this drug is approximately US\$2.6 billion, for the year ending September 2008, according to international research agency IMS. Aurobindo will manufacture these tablets in 5mg, 10mg and 20mg forms. The company now has 92 abbreviated new drug applications (ANDAs) that have been approved in the US market.

India: HLL forays into herbal healthcare

Hindustan Latex Limited (HLL), a major contraceptive manufacturer in the country, has launched 'Lactohil,' an Ayurvedic proprietary medicine and health tonic to address inadequate lactation after delivery in women. HLL would also take these products to the international markets, focusing on the merits and efficacy of traditional Ayurveda system that originated from India. By introducing healthcare

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products through ethical and over the counter (OTC) route, HLL is expanding its portfolio to benefit millions in the country and abroad, CMD of HLL M Ayyappan said.

India: BPL enters into marketing agreement with US-based Welch Allyn

BPL said it has entered into an agreement with the US-based medical products and solutions provider Welch Allyn to distribute its products in India. The company, through its group entity BPL Healthcare, has entered into a Memorandum of Understanding (MoU) with Welch Allyn to act as its master distributor in the country, the diversified business house said in a filing to the Bombay Stock Exchange. The e-clinic would have facilities for general health check-up and will be equipped with the products of both the companies, it further said.

Australia: Aurobindo Pharma's lisinopril gets Australian nod

Aurobindo Pharma Ltd said its wholly-owned Australian unit has received an approval from Australia's Therapeutic Goods Administration for the registration on lisinopril tablets. Lisinopril is used for the treatment of hypertension and congestive heart failure.

Australia: Ranbaxy gets approval to market anti-fungal drugs

Drug major Ranbaxy Laboratories said it has received approval from the Australian health regulator to market its anti-fungal tablets Serbifin Terbinafine in that country. Ranbaxy Australia, the wholly-owned subsidiary of the company, has received an approval from the Therapeutic Goods Administration (TGA) for the registration of Sebifin Terbinafine tablets in Australia, the drug manufacturer said in a statement. The approval was based on the assessment by the TGA that the Ranbaxy formulation of terbinafine is bioequivalent to Lamisil tablets of Novartis Pharmaceuticals Australia, it added.

INVESTMENTS

Europe

Netherlands: Dutch Stem cell co Cryo-Save plans expansion

Cryo-Save Group, the Netherlands-based stem cell company with a large Indian presence, plans to increase the number of stem cell donors in the country by opening more representative offices. The company expects this would increase the number of clients and also extend its reach beyond the current five cities, group CEO Rob Koremans told ET. Cryo-Save Group plans to invest €2m (about Rs130m) in its Bangalore-based subsidiary for over three years. Cryo-Save Group focuses on saving umbilical cords post deliveries for stem cell research that can be used to assist in curing medical problems of the same families in later years.

Asia Pacific

India: NH signs MoU with Gujarat government

Narayana Hrudayalaya signed a Memorandum of Understanding (MoU) with the Gujarat Government to set up a 5,000-bed Health City in Ahmedabad. The facility will be built on a 37-acre area at the site of Monogram Mills in Bapunagar, Ahmedabad and is Asia's longest hospital spread over half a kilometer, measuring 12.5 lakh square feet. In the presence of the honourable Chief Minister Narendra Modi, and Dr Devi Shetty, Chairman, Narayana Hrudayalaya, signed an agreement to establish this association was signed by Viren Shetty, and the Gujarat Government. Under this agreement, Narayana Hrudayalaya Health City plans to invest Rs4.80 billion and will begin operations with a 1,000-bed heart hospital.

MERGERS & ACQUISITIONS

UK

England: Vertex Pharma closes acquisition of ViroChem Pharma

Vertex Pharmaceuticals Incorporated has completed its acquisition of ViroChem Pharma Inc, a privately-held company with two investigational HCV polymerase inhibitors in clinical development. ViroChem shareholders received US\$100m in cash and approximately 10.7m shares of Vertex common stock. The

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shares issued in this transaction are expected to be available for resale upon filing of the registration statement. Vertex expects to begin clinical evaluation of novel combination regimens of its HCV protease inhibitor telaprevir, currently in phase-III clinical development, in the second half of 2009.

Asia Pacific

India: Piramal Healthcare completes acquisition of Minrad

Pharma firm Piramal Healthcare said that it has completed the acquisition of US-based Minrad International. In a filing to the Bombay Stock Exchange, Piramal Healthcare said shareholders of Minrad would receive US\$0.12 for every share held. As a result of acquisition, Minrad would be operated as a wholly-owned subsidiary of Piramal Healthcare. Further, Minrad's share would no longer be traded on the New York Stock Exchange Alternext Exchange.

RESEARCH & DEVELOPMENT

Americas

USA: Pfizer, PlaNet finance to study options for expanding access to healthcare

Pfizer Inc and PlaNet Finance announced that they will team up to conduct an in-depth research project on the healthcare needs of the working poor in China. The study will examine the availability and existing sources of medicines, patient purchasing patterns, and the level of access to medical services. The study ultimately aims to help both organizations identify models that may enhance and expand access to medicines and healthcare services for the working poor in China.

USA: Aeterna Zentaris & Sanofi-Aventis sign pact for BPH drug cetrorelix

Aeterna Zentaris Inc, a global biopharmaceutical company focused on endocrine therapy and oncology, signed a development, commercialisation and licensing agreement with Sanofi-Aventis for the development, registration and marketing of cetrorelix in benign prostatic hyperplasia (BPH) for the US market. Cetrorelix, a luteinising hormone-releasing hormone (LHRH) antagonist, is currently in a phase-III programme in BPH, a non-cancerous enlargement of the prostate, affecting more than 20m men in the US alone.

Asia Pacific

India: Bharat Biotech's rotavirus vaccine enters phase III of clinical trials

Bharat Biotech's rotavirus vaccine (116E) is entering phase III of its clinical trials. The vaccine treats severe dehydration and diarrhoea in infants and young children. The phase three trials will be mainly in India and will enroll 6,800 healthy infants, an official from Bharat Biotech said during the Drug Information Association conference recently held in Mumbai. The company is looking at launching the vaccine only in 2011, since the trials will conclude only two years after they commence. Bharat Biotech and its funding partners have already invested US\$28-30m in vaccine development so far and is looking to spend another US\$30m on phase three clinical trials alone, Bharat Biotech Vice President said.

GOVERNMENT INITIATIVES

Asia Pacific

India: Govt to invest up to Rs25bn in pharma R&D

In one of the biggest pharma R&D initiatives, the government has proposed to invest up to Rs25 billion with a similar amount from private players for promoting innovation. The focus will be on neglected diseases, for which developed countries are not investing enough till now, a senior government official told PTI. The government is planning to mobilise an investment of more than US\$1 billion in the next five years for promoting innovation here and half of this amount is expected to be contributed by the domestic pharmaceutical industry while the remaining would be provided by the Ministry of Chemicals and Fertilisers.

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India: Centre may inject US\$2bn/yr into drug research

The government plans to invest up to US\$2 billion, or Rs100 billion, annually to develop more effective medicines for diseases such as malaria and tuberculosis that hit thousands of Indians every year. Multinational drug makers with deep pockets are not interested in carrying out research for such afflictions prevalent among the poor in developing countries as medicines for these diseases do not fetch good profits. However, the proposed initiative is likely to give a major boost to new drug discovery in the country. The present pharmaceutical research spending of the government is Rs5 billion.

India: Centre to speed up Rs5bn revival plan for 3 PSU vaccine manufacturing units

Following widespread criticism and strictures from the Parliamentary panel, the health ministry is likely to accelerate the process of reviving the three public sector vaccine manufacturing units and may go for a Rs5 billion package to resume operations. The government has also categorically made it clear that it had not taken any decision to close down the units -- the Central Research Institute, Kasauli, Himachal Pradesh, the Pasteur Institute of India, Coonoor, Tamil Nadu and the BCG Vaccine Laboratory, Chennai, Tamil Nadu.

India: 39 drug firms under NPPA scanner for overcharging

National Pharmaceutical Pricing Authority (NPPA) has issued orders to recover penalty fee from 39 pharmaceutical firms for over pricing of drugs. The price regulator has asked various State Governments to collect the penalty amounting to Rs1100m. Dr Reddy's Laboratories, Wyeth, GlaxoSmithKline (GSK) Pharmaceuticals and Alkem Laboratories are among those companies on which the penalty has been imposed. These cases are referred on the basis of pendency of the case and the quantum of overcharging.

India: 263 medicines cheaper, 22 dearer: NPPA

The drug price regulator, National Pharmaceutical Pricing Authority (NPPA), has revised prices of 285 medicines leading to reduction in prices of 263 medicines. Prices of 22 other medicines have been revised upwardly, an NPPA official said. He said the exercise would make anti-allergic, antibiotics, multi-vitamins and eye drops cheaper, primarily marketed by companies such as Novartis, Pfizer Products and GlaxoSmithKline (GSK).

India: Govt to spend US\$2bn annually till '20 on drug discovery

The Department of Pharmaceuticals (DoP) will soon come out with a White Paper on Vision 2020. The purpose of the report is to promote drug discovery and innovation-based pharma industry in the country, and it entails government spending to the tune US\$1-US\$2 billion annually until 2020. The initiative will enable India capture about 10-20% share of the world's R&D business. The DoP initiative aims at creating India as a hub for cheaper drugs. "This is an advantage also for us, especially during the slowdown phase," Ashok Kumar, secretary, DoP, said, adding that our industry has lot of problems to face right from logistics, bank finance and exchange rates fluctuation. "In government, we do not understand business, but we are trying to sort it out," he remarked. Mr Kumar said about US\$103 billion worth of patented drugs will go off patent in the years to come. If India and China are able to secure even 30-35% of these, then the entire industry will be well off.

India: Tax-free bonds to fund drug research venture

The government is planning to issue tax-free bonds worth up to Rs10 billion (US\$2 billion) to the general public every year until 2020 as part of an ambitious plan to fund a massive drug discovery plan aimed at making India a global leader in new drugs. India accounts for less than 1% of the US\$130 billion spent worldwide on drug discovery, despite having the fourth-largest drug industry in the world by volume. Much of India's strengths in this sector are in making copycat versions of popular drugs discovered abroad and making medicines whose patents have expired. The government now aims to have one out of every five new drugs discovered by 2020 to be from India.

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Indian firms expect USFDA's local office to speed up approvals

The USFDA's new office in India could likely boost local pharma companies' efforts to process their applications and speed up approvals for marketing in the global market. The USFDA, the nodal drug authority, which certifies manufacturing facilities and approves products for the US market, opened its office in Delhi in January. Senior policy advisor at the USFDA's Centre for Drug Evaluation and Research (office of compliance) said that the agency's reports and findings would be shared with their counterparts across the world. This would eliminate the need for repetitive reviews, the policy advisor said.

FDA APPROVALS

Europe

Sweden: Orexo's insomnia drug Edluar gets USFDA approval

Orexo announces that the USFDA has approved Edluar (formerly Sublinox) 5mg and 10mg sublingual tablets for the short-term treatment of insomnia characterised by difficulties with sleep initiation. Orexo's partner Meda acquired the exclusive worldwide commercialisation license for Edluar last year and they expect to launch the product in the US market during the second half of 2009. Orexo will receive royalties on Meda's sales of Edluar.

Americas

USA: Genzyme gets complete response letter from USFDA on Lumizyme

Genzyme Corporation has received a complete response letter from the FDA regarding its application to market Lumizyme (alglucosidase alfa) for the treatment of Pompe disease. In its letter, the agency outlines the remaining items that need to be addressed before the application can be approved. Lumizyme is produced at the 2000 litre bioreactor scale at Genzyme's Allston Landing facility. In addition, Genzyme and the agency need to finalise the Risk Evaluation and Mitigation Strategy (REMS) for the product. Genzyme and the agency have been working closely and making progress toward these goals but were not able to reach them by the PDUFA date.

OPERATIONS

America

USA: MannKind to purchase Pfizer's insulin facility in Germany

MannKind Corporation has entered into agreements with Pfizer Inc to purchase Pfizer's insulin facility at Industriepark Hoechst, Frankfurt am Main, Germany and assets related to the production of bulk insulin, including the relevant real property rights, the production equipment, a quantity of bulk insulin and a license to manufacture bulk insulin for use in pulmonary delivery. The aggregate purchase price is US\$33 million, subject to certain adjustments. At MannKind's option, up to US\$30m worth of the company's common stock may be issued to Pfizer at closing and applied toward the full purchase price.

Middle East

Saudi Arabia: KIMS opens its third clinic in Gulf

The 500-bed Kerala Institute of Medical Sciences, (KIMS), Thiruvananthapuram, has launched its third GCC project as KIMS Qatar Medical Centre (KQMC) at Al Wakra after Bahrain and Al Jubail in Saudi Arabia. This new venture is a partnership between Coastal Healthcare Management, Doha and KIMS Hospital Group. KQMC will initially offer services in gynaecology, orthopaedics, and ENT. The Group aims to deliver world-class healthcare service to the inhabitants of Qatar at affordable costs.

Asia Pacific

India: AyurVAID hospital launches facility in Bangalore

AyurVAID Hospitals, a leading chain of Ayurveda hospitals promoted by Kochi-based Kerala First Health Services Private Limited, has opened its first facility in Bangalore. AyurVAID Hospitals' Bangalore

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facility is a 30-bed hospital with all modern amenities. The hospital offers full range of out-patient and in-patient medical services for treatment of serious medical conditions using classical Ayurveda.

India: Indrapastha Apollo conducts MICS for patients with CVD

Indraprastha Apollo Hospitals announced the introduction of Minimally Invasive Coronary Artery Bypass Grafting (MICS CABG) for patients suffering from cardio vascular diseases. This new technique offers benefits like shorter length of hospital stay, fewer blood transfusions, improved cosmetic outcomes and lower cost. The new technique brings down the cost of a bypass surgery by almost Rs50,000.

India: Yashoda cancer institute inaugurated

Yashoda Group has commenced its cancer institute which will incorporate the revolutionary Volumetric Modulated Arc Therapy (VMAT). Department of Radiation Oncology at Yashoda Cancer Hospital has been equipped with the world's latest and Asia's first Varian RapidArc Linear Accelerator, equipped with the most sophisticated 3D planning systems, a next generation system, superior to all other radiation delivery systems in terms of accuracy, speed and quality.

India: Apollo, Chennai introduces advanced Cyberknife

Apollo Speciality Hospitals, Chennai has introduced CyberKnife Robotic Radio Surgery System, the revolutionary treatment of cancerous and non-cancerous tumours, said Executive Chairman from Apollo Hospitals. The CyberKnife is a non-invasive alternative to surgery. The source of the therapeutic x-ray (the Linear Accelerator) is mounted on a computer controlled robotic arm. It's successful in the treatment of cancerous and non-cancerous tumours anywhere in the body, including the prostate, lung, brain, spine, liver, pancreas and kidney," explained Romesh Kaul, President and CEO, Advanced Medical Systems group PTE.

India: Microsoft initiative for Hyderabad pharma cluster

An E-Readiness Centre (ERC) has been set up by Microsoft under Project Vikas to facilitate adoption of information technology solutions by about 400 small and medium enterprises in Hyderabad Pharma Cluster. Under Project Vikas, a joint initiative of Microsoft India and the National Manufacturing Competitive Council (NMCC), the pharma manufacturers would be offered specially designed software tools, Mr Rajiv Sodhi, Director (Emerging Geographies), Microsoft India, told newsmen. About 400 SMEs in the pharma cluster would be offered Enterprise Resource Planning (ERP) and customer relationship management solutions developed by Microsoft's partners, city-based B2B Technologies and Bangalore-based Enzen respectively, Mr Sodhi said.

India: HLL Lifecare set to be major vaccine player

HLL Lifecare, which is metamorphosing from being a global leader in condom manufacturing to becoming a multi-faceted healthcare major, is poised to realise its largest-ever project – a 430-acre vaccine complex and medical park at Chengalpetu, near Chennai. The vaccine complex, which has a proposed outlay of Rs9 billion, will focus on value-added vaccines besides manufacturing the entire spectrum of vaccines for the central government's universal immunization programme, namely the BCG, DPT, DT and TT vaccines. Funding for the project is likely to be tied up within a month, and the complex is expected to be operating to full capacity five years after it is operational.

CORPORATE

Americas

USA: Enzo Biochem acquires Assay Designs for US\$12.2m

Enzo Biochem, Inc. announced the acquisition of substantially all the assets of privately-owned Assay Designs, of Ann Arbor, Michigan, for a purchase price of approximately US\$12.2m in cash, subject to post-closing purchase price adjustments based on Assay Design's working capital as of the closing date. The acquisition is expected to be accretive to operating results. This acquisition represents another important step in their strategy to build Enzo Life Sciences, said president of Enzo Life Sciences.

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Email: ipacentre@ipapharma.org; www.ipapharma.org

Cygnus Business Consulting & Research Pvt. Ltd

4th & 5th Floors, Astral Heights, Road No.1, Banjara Hills, Hyderabad-500034

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USA: Vertex Pharma to acquire ViroChem Pharma

Vertex Pharmaceuticals Incorporated, which is developing the hepatitis C virus (HCV) protease inhibitor telaprevir, will add two polymerase inhibitors to its HCV drug development portfolio through a definitive agreement to acquire privately-held ViroChem Pharma Inc in a stock and cash transaction. With the addition of these compounds, Vertex will advance its strategy to pursue novel combinations of Specifically Targeted Antiviral Therapies for hepatitis C (STAT-Cs)

USA: Merck to buy Schering-Plough for US\$41.1bn cash-&-stock deal

US-based Merck & Co said that it is acquiring Schering-Plough for US\$41.1 billion in a cash-and-stock deal, to create a US\$47 billion drug major. The deal comes just six weeks after Pfizer Inc gobbled rival firm Wyeth for a record US\$68 billion. Schering-Plough shareholders will get 0.57 shares of Merck and US\$10.50 in cash for each share they own. This values Schering-Plough at US\$23.61 a share, a 34% premium to Friday's closing price. Merck shareholders would own 68% of the combined company, a Merck release said.

USA: NanoViricides inks pact with one major pharma company

NanoViricides, Inc, has signed a material transfer agreement with a major pharmaceutical company (Party). The agreement initially entails evaluation of one of the company's nanoviricide drug candidates by an independent consultant chosen by the Party. This drug candidate has been designed to eradicate viral infections of the external eye, including those caused by adenovirus and herpes virus (HSV). It is the understanding of the parties that, should the testing results be favourable, they will enter into good faith negotiations for a potential long-term, exclusive, worldwide licensing agreement for the development and commercialization of the drug.

USA: Paladin files NDA for Trelstar 22.5mg to treat prostate cancer

Paladin Labs Inc, a leading Canadian specialty pharmaceutical company, has filed a new drug submission for Trelstar 22.5mg (triptorelin pamoate for injectable suspension). Trelstar 22.5mg is a six-month slow release, injectable, luteinizing hormone-releasing hormone (LHRH) agonist indicated for the palliative treatment of advanced prostate cancer. Trelstar is an important component of Paladin's urology franchise and this new dosage form will further strengthen this portfolio, said the president and CEO of Paladin Labs.

USA: Hi-Tech Pharmaco buys ECR Pharma for US\$5.1m

Hi-Tech Pharmaco Co, Inc announced the signing of a definitive agreement under which Hi-Tech acquired the assets of ECR Pharmaceuticals, a privately held branded specialty pharmaceutical company for US\$5.1m in an all-cash transaction, which will be paid over an eight month period. Additionally, Hi-Tech may pay up to US\$4.0m in performance incentives tied to future ECR product sales and profits.

USA: USFDA's PDUFA action date for GTx's toremifene 80mg NDA declared

GTx, Inc, announced that the USFDA will target a Prescription Drug User Fee Act agency action date on October 30, 2009 for the toremifene 80mg New Drug Application (NDA), which is within 10 months of the submission of the NDA. Toremifene 80mg is an oral selective estrogen receptor modulator which GTx seeks to market for the prevention of bone fractures in men with prostate cancer on androgen deprivation therapy (ADT).

Europe**Germany: Roche Diagnostics eyes India as key market**

Swiss-based Roche Diagnostics has outlined its 2009 business strategy that aims to strengthen its position in the Indian subcontinent and address key healthcare issues in the Indian diagnostics market. The company is part of the international F Hoffman-La Roche, which has just announced its global financial results for the year 2008. As the world's biggest biotech company and an innovator of products and services for the early detection, prevention, diagnosis and treatment of diseases, the group contributes on a broad range of fronts to improving people's health and quality of life.

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Germany: Roche acquires German based Innovatis AG for €15m

Roche announced that it has signed a definite agreement under which Roche will acquire 100% of Innovatis, a privately held company based in Bielefeld, Germany. Innovatis is a leading provider of automated cell analysis solutions, especially focussing on cell counting, viability testing, and cell function analysis in research, as well as bio-production. The purchase price for this transaction is €15m. This acquisition is a further step in the company's strategy to strengthen its position as a complete solution provider in the cell analysis research market, said CEO Division Roche Diagnostics.

UK**England: Allergy Therapeutics seeks EU approval for allergy vaccine Pollinex Quattro Grass**

Allergy Therapeutics (AGY), the specialist pharmaceutical company focused on allergy vaccination, has submitted its Pollinex Quattro Grass dossier for regulatory approval in the European Union (EU). The dossier has been submitted to the German Regulatory authority, the Paul Ehrlich Institut (PEI), recognised to be the European authority most expert in the allergy vaccine field. The PEI has agreed to act as 'Reference Member State' for Europe-wide registration under the European Union Mutual Recognition Procedure (MRP).

Asia Pacific**India: Piramal Healthcare bets on custom manufacturing**

Notwithstanding the spreading recession in the US and Europe, custom manufacturing for global innovator-pharmaceutical firms will remain a key growth driver for Piramal Healthcare. Asserting this, the CEO of the company said the current happenings on the global front had triggered cost-consciousness across the international innovator-pharmaceutical firms, resulting in consequential inventory correction. Nevertheless, the CEO anticipated a 10% growth in pharma solutions (custom manufacturing) business of the company, which fetched revenue of around Rs15 billion.

Japan: Astellas to terminate offer for CV Therapeutics

Astellas Pharma Inc. announced that it will terminate its US\$16 per share offer for CV Therapeutics, Inc and will not propose directors for the CV Therapeutics board of directors or make any other proposals at CV Therapeutics' 2009 annual meeting. According to an Astellas press release, the company also intends to withdraw a related lawsuit in the Delaware Chancery Court against CV Therapeutics and its directors.

India: Jubilant gets Canadian nod for generic Sestamibi

Jubilant Organosys Ltd, headquartered in India, announced that its subsidiary in Canada, Draxis has received approval for the generic Sestamibi from Health Canada. Draximage Sestamibi is a generic kit for the preparation of Technetium (Tc 99m) Sestamibi Injection, a diagnostic cardiac imaging agent used for the diagnosis and localisation of myocardial infarction; and for the diagnosis and localisation of ischemic heart disease and coronary artery disease.

India: Pfizer to license generics from India's Aurobindo

Pfizer Inc has agreed to license an array of generic pills and injectable medicines from India's Aurobindo Pharma Ltd as the world's largest drugmaker looks to off-patent medicines for growth. In the deal announced, Pfizer said it expected the products acquired to deliver more than US\$200m in annual revenue in 2013, according to David Simmons, general manager of Pfizer's established products business unit. The products expand Pfizer's growing generics portfolio and are versions of drugs originally made by companies other than Pfizer. Financial terms of the deal were not disclosed.

India: Pfizer, Sanofi vie for Wockhardt biotech

The world's largest drug company Pfizer and French drug company Sanofi Aventis are in the race to pick up a significant slice of Wockhardt's biotechnology business, said a person involved in the proposed deal. Analysts say if there is a complete buyout the deal could be in the region of Rs2.50 billion. "Both MNCs are doing due diligence on the company. This would be more in the nature of a strategic business tie-up instead of a complete sell-out," said the person on condition of anonymity. Wockhardt claims that the

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complex has the capacity to cater to up to 15% of global demand for major biopharmaceuticals that could be worth US\$100 billion by 2010.

India: Aurobindo gets Australia nod for anti-hypertension drugs

Drug maker Aurobindo Pharma said that its Australian subsidiary has received approval from the government agency for registering its anti-hypertension drug Auro-Linsinopril in that country. Aurobindo Pharma Australia, the wholly-owned subsidiary of the Indian firm, has received its first approval from the TGA of Australia for the registration of Auro-Linsinopril in three variants, the drug major said in a filing to the Bombay Stock Exchange. The company got approval from TGA for Auro-Linsinopril in the strengths of 5, 10 and 20 mg, it further said. These therapeutic products are used in the treatment of hypertension, congestive heart failure and acute myocardial infarction.

India: Ranbaxy gets USFDA nod for Ramipril

Ranbaxy Laboratories has received the final approval from the USFDA to sell Ramipril capsules (in 5mg & 10mg), a drug used to treat cardiovascular diseases. The application for the drug was submitted by Ranbaxy from its Ohm Laboratories (New Jersey), USA. The office of generic drugs, USFDA, had determined the Ranbaxy formulations to be bioequivalent and as having the same therapeutic effect as that of the reference listed drug, Altace by King Pharmaceuticals Inc, a Ranbaxy release said.

India: Ranbaxy says gets US nod for blood pressure drug

Ranbaxy Laboratories said that it had received the USFDA approval to make and sell blood pressure drug Quinapril Hydrochloride and Hydrochlorothiazide, a bioequivalent of Pfizer's Accuretic tablets. Ranbaxy said in a statement it had got approvals for the 10/12.5mg, 20/12.5 mg and 20/25mg versions of the drug. It said the application had been submitted from its OHM Laboratories facility in New Jersey.

India: CMG biz to drive Piramal Healthcare growth

The Rs28.70 billion Piramal Healthcare is upbeat on the business potential for its custom manufacturing vertical for global pharma innovator companies. Currently, contributing Rs15 billion to the total turnover, the CMG vertical is set to benefit from the recent mergers announced by Pfizer and Merck. Piramal Healthcare, which has 108 diagnostic centres across the country, is talking to a couple of players in Tamil Nadu to set up 20 to 25 centres by March 2010.

OTHERS

Americas

USA: Smoking costs America US\$101bn annually in healthcare

Though use of tobacco is declining in the US compared to developing countries, the habit still costs the country more than US\$101 billion in healthcare. Annual healthcare costs, both public and private, caused by smoking amount to US\$96 billion while US\$5 billion is spent on healthcare related to second-hand smoke. Premature deaths caused by smoking amount to US\$97 billion in productivity losses, according to the Tobacco Burden Facts on the US, released by the Campaign for Tobacco-Free Kids, at the 14th World Conference on Tobacco or Health in Mumbai.

Europe

Brazil: India, Brazil protest seizure of generic drugs by Dutch

India and Brazil have expressed their deep concern over the public health implications of the seizure of generic drugs in transit by European nations, and its systemic implications. The EU Customs regulations are in complete conformity of the TRIPS agreement and the WTO disciplines. The European Commission claimed that one-third of the four million counterfeit medicines seized by EU authorities come from India. Brazil stated that though both countries brought up what they considered was a serious violation of WTO rules at the General Council, as the TRIPS council was the forum dealing with intellectual property matters it could give a better analysis of the factual circumstances of the episode and legal implications.

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Asia Pacific

India: More investment needed to boost medical equipment production

Over the six past years, domestic medical equipment and devices producers have tried to promote their trademarks, still the sector has yet to fully exploit its domestic potential and launch a long-term strategy for training qualified staff. Deputy Prime Minister gave this assessment at a summarization conference held on March 10th and 11th to review the six-year implementation of the national policy on medical equipment and the three-year deployment of the national project on the research into and the production of medical equipment and devices. Delegates also agreed that the sector should invest more in research, production and training to meet the increasing demand of the domestic market, and as of 2010 the import of medical equipment and devices will be restricted to help domestic production.

India: Consolidation may drive growth in diagnostic sector

The country's diagnostics and path labs industry, which is pegged at around Rs45 billion and is growing at an annual rate of 10-12%, is expected to witness consolidation in the near term, according to industry experts. Fidelity International managing director Jasmin Patel said that consolidation is going to go up in the path labs space. Dr Lal Path Labs CEO OP Manchanda said that there has been no national player till now. Regional players are trying to go national, which requires a lot of time and investment. There is a pressure to decentralise and go closer to the patient, but economics doesn't allow that. The other option is to tie-up with like-minded players.

India's cure pill for global economic crisis

The healthcare sector will be India's "cure pill" for the ailing global economy, says the chairperson of the healthcare major Apollo Hospitals, Prathap C Reddy. Healthcare sector can be a cure pill for the current economic global crisis. It can prove to be the largest industry and in these times of layoffs, can provide millions of jobs. The CII recommends that the government introduce a stimulus package of an estimated Rs500 billion in the form of a health development fund that will push other funds and banks to come the healthcare way and accord healthcare sector a infrastructure or priority status.

India: Hospital chains eye robust growth

Slowing demand may be forcing India Inc to curtail investment plans, but corporate healthcare chains seem to suffer no such problems. The sector, led by Apollo Hospitals, Fortis Healthcare and Wockhardt Hospitals, has expansion plans worth more than Rs20 billion to increase their bed strength in response to robust demand. Fortis, which now manages 3,000 beds with a network of 26 hospitals, is planning to double capacity by 2012 with 40 hospitals. Fortis Healthcare Managing Director and CEO Shivinder Singh said, about 1,200 beds will be added soon at Vashi in Navi Mumbai, Shalimar Bagh in Delhi and Gurgaon, and the chain would be eyeing "opportunistic acquisitions" in the near future.

India: Demand for home medical equipment to exceed US\$10bn

US demand for home medical equipment is forecast to increase 5.5% annually to over US\$10 billion in 2012. Cost-saving products that reduce the need to treat or monitor chronically ill patients in hospitals, skilled nursing facilities and specialised clinics will command strong growth opportunities. Included in this group are CPAP machines and accessories, peritoneal dialysis equipment, IV pumps, ventilators and accessories, and blood pressure monitors. Demand for home patient monitoring equipment will increase 5.6% annually to US\$1.8 billion in 2012.

India: Biotech cos eye global JVs for R&D push

Biotech companies, Avesthagen and Biocon are in talks with global players to out-license various projects in their R&D pipeline, industry officials said. These initiatives are happening at a time when pharmaceutical companies, too, seem unable to find takers for their molecules in a challenging business environment. Since biotech companies, like many others, are facing a cash crunch, MNCs are likely to use this as a leveraging tool to get a better deal. Vice-president (biotechnology), Parexel Consulting, said, Biotech companies globally are facing a cash crunch and bigger companies would likely try and use this to

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their advantage. India, however, has a lot of expertise in biosimilars and that puts them in a strong position. It's not the same in the case of novel products.

India: Pharma cos focus on specialist therapies

Move over traditional block-busters (drugs), specialist therapies are now in. Clearly, the product portfolio is undergoing a major change worldwide, with MNCs like Roche, Genentech, Schering, and closer home, Dr Reddy's, Wockhardt and Lupin shifting towards specialised or targeted therapy, trailing after cancer molecules, monoclonal antibodies and vaccines. Specialist therapies are also marketed differently, and are prescribed by specialists (like oncologists) rather than general practitioners.

Australia: Aussie regulator puts Ranbaxy under scanner

The Australian drug regulator Therapeutic Goods Administration (TGA) said it is reviewing 62 drugs sold in the country which are made by Ranbaxy at its Paonta Sahib plant. But the regulator said it has so far not found any quality problems with these Ranbaxy drugs sold in Australia. Australia's TGA said it did not find any evidence in its earlier inspections that Ranbaxy's drugs did not meet the country's manufacturing standards. The last inspection by TGA was conducted in November 2008. The authority is now reviewing latest information from the USFDA and had sought more details concerning products sold in Australia.

India to be amongst top five pharma innovation hubs by 2020

A white paper drafted by the department of pharmaceuticals of the Union Government has projected India to be amongst top five Pharma Innovation Hubs by 2020, attracting an additional US\$20 billion (Rs100 billion) in terms of GDP, Secretary Department of Pharmaceuticals, Ashok Kumar said. India today accounts less than one per cent of the US\$130 billion in worldwide spending on pharmaceuticals research and development, despite its strength in process chemistry and abundant talent pool, Kumar said.

India: LatAm, CIS countries ask local drug cos to cut prices

Several companies in Latin America, Asia and the CIS countries that import Indian drugs and FMCG products are defaulting, deferring payments and asking the Indian suppliers to lower prices. This is because they are unable to meet payment commitments due to sharp depreciation of their respective currencies against the US dollar, making imports costlier in their local currency. Local currencies of Ukraine, Russia, South Africa and Brazil fell by around 50%, 37%, 45% and 40%, respectively, against the dollar in the last 4-5 months after the financial crisis broke out in September 2008.

India: SC asks Roche not to pursue Cipla case until patent examination

The Supreme Court (SC) has asked Swiss company Roche not to pursue the patent violation case against the generic version of Cipla's anti-infection drug Valcept until the Chennai patent office re-examines the patent granted to Roche. The Chennai patent office had granted patent to the Swiss company for Valcyte (Valganciclovir), a drug used for organ transplants and eye infection of AIDS patients, in 2007 despite opposition by an Indian NGO.

22 pharmacy colleges apply for starting Pharm D, TN tops list with 6 colleges

A total of 22 pharmacy colleges across the country have shown interest in starting the Pharm D course and have applied for the approval from the Pharmacy Council of India (PCI). This advanced pharmacy course, aimed to bring the pharmacists of the country on par with international standards, was introduced by the Union health ministry last year for the first time in the country. The PCI has examined the applications and has conducted physical verification of each of the colleges to ensure that these institutions fulfilled the required specifications to begin this advanced course. PCI president Dr B Suresh said that among the 22 colleges, six colleges are fulfilling all the criteria and therefore will be accorded permission forthwith. For the rest, the PCI has identified the deficiencies and has directed these institutions to rectify them as soon as possible so that these institutions also can start the course in this academic year. Among the 22 colleges applied for starting the Pharm D course, Tamil Nadu tops the list with six colleges followed by Andhra Pradesh and Karnataka with five colleges each showing interest. Two colleges each from Kerala, Maharashtra and Gujarat have also applied for starting the course.

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PCI to enter agreement with Association of America College of Pharmacy of US for faculty exchange programme

In order to improve the quality of pharmacy education in the country, especially the higher education, the Pharmacy Council of India (PCI) will soon enter into an agreement with Association of American College of Pharmacy (AACCP) under which the pharmacy colleges in US and India can exchange their faculties. AACCP is an association of several pharmacy colleges in the US. The agreement with AACCP will go a long way in improving the quality of education because Pharm D has been in existence in US for a long time now and the faculties in American colleges are well versed with the course. The By the faculty exchange programme, the Indian pharmacy colleges will get the much needed input in this regard

Indian Institute of Science's postdoctoral training provides job openings in Pharma-biotech industry

The Indian Institute of Science's (IISc) national postdoctoral training programme in biotechnology and life sciences is building a robust postdoctoral community and is providing the right candidates for research in the industry. A five-year review of the programme has revealed that the programme has been effective in building a robust postdoctoral community and providing qualified personnel to the academia, national laboratories and biotech industry, stated K Muniyappa, professor & chairman, Department of Biochemistry, IISc

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Product Focus – Risperdal

Introduction

Risperdal is used mainly in the treatment of two major psychotic disorders schizophrenia and bipolar mania. It is generically called as Risperidone. Risperdal is used separately or in combination with drugs called mood stabilisers, such as lithium or valproate for the treatment of acute manic or mixed episodes associated with bipolar mania. It is available as a tablet in 0.25mg, 0.5mg, 1mg, 2mg, 3mg and 4mg sizes, and as a 25mg, 37.5mg or 50mg ampoule Risperdal Consta, which is a depot injection administered once every two weeks. It is also available as a wafer Risperdal Quicklets.



Drug Mechanism

Schizophrenia and bipolar mania are thought to be caused by chemical imbalances in the brain. These neurotransmitter chemicals (transmitting messages between nerves) are called dopamine and serotonin. Dopamine may be responsible for delusions and grandiose symptoms, and serotonin for symptoms of anxiety and depression. Risperidone seems to work by interfering with these chemicals by muting them and maintaining a balance between dopamine and serotonin.

Drug Information	
Generic name	Risperidone
Brand Name	Risperdal
Therapeutic segment	Atypical anti-psychotics
Manufacturer	Janssen Pharmaceuticals
<i>Source: Industry Sources; Cygnus Research</i>	

Storage

Tablets should be stored at room temperature of 15–30°C (59–86°F). It should be kept away from moisture, light and heat. The liquid form of Risperdal should not be allowed to freeze.

Side Effects

Get emergency medical help if the person has any of these signs of an allergic reaction: hives; difficulty breathing; swelling of his face, lips, tongue, or throat. Stop using Risperdal and call the physician at once if the person has any of these serious side effects.

Side Effects
➤ Fever
➤ Stiff muscles
➤ Confusion, sweating
➤ Fast or uneven heartbeats
➤ Restless muscle movements in your eyes, tongue, jaw, or neck
➤ Tremor (uncontrolled shaking)
➤ Trouble swallowing; or feeling light-headed

Dosage

An intramuscular preparation, marketed as Risperdal Consta, can be given once every two weeks. It is slowly released from the injection site. It can be useful in patients who have difficulty taking oral medication for any reason. Some people prefer once-every-two-weeks injection to daily pills. It also helps the physician insure compliance. It is the only atypical antipsychotic available in this form. Doses range from 0.25mg to 50mg given as an intramuscular injection once every two weeks.

Other drugs that affect risperdal

Before the person takes Risperdal, tell the physician if the person regularly uses other medicines that make him sleepy (such as cold or allergy medicine, narcotic pain medicine, sleeping pills, muscle relaxers, and medicine for seizures, depression, or anxiety). They can add to sleepiness caused by Risperdal.

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

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Also tell the physician if the person is undertaking any of the following medicines:

- Carbamazepine (Carbatrol, Tegretol)
- Phenytoin (Dilantin)
- Phenobarbital (Luminal, Solfoton)
- Clozapine (Clozaril)
- Fluoxetine (Prozac) or paroxetine (Paxil)
- Rifampin (Rifadin, Rimactane, Rifater); or medicines used to treat Parkinson's disease such as levodopa (Dopar, Larodopa, Sinemet, Atamet, others), bromocriptine (Parlodel, others), pergolide (Permax), pramipexole (Mirapex), or ropinirole (Requip).

Psychotropic Drug Markets

The total antipsychotics market revenue in 2006 was worth US\$18.1 billion. A recent report predicted that total revenues in the antipsychotics market would reach US\$18.6 billion by 2007. Psychotropic drugs play a very vital role in patient welfare and therapy. Four major groups that come under the banner of psychotropic drugs are—hallucinogens, antipsychotics, depressants and stimulants, which may often cross overlap with other categories, as they produce more than one type of effect. Some of the well known drugs in the (antidepressant from GlaxosmithKline), Zyprexa (antipsychotic drug from Eli Lilly), and morphine (derived from opium for pain management).

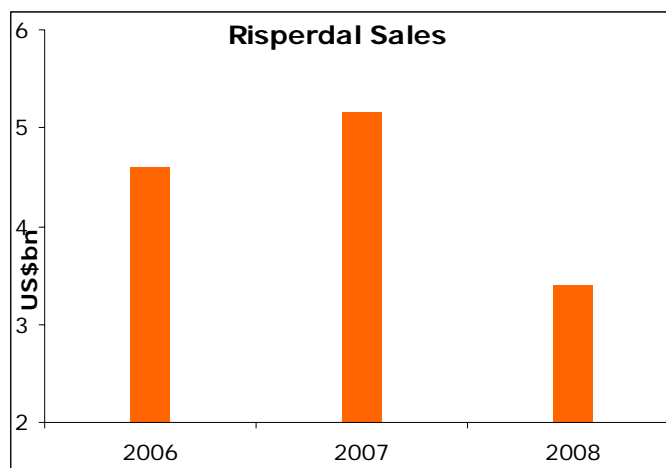
Globally, there are two sorts of psychotropic drug markets—open and closed. Open markets comprise countries with limited or no domestic capabilities that rely on imported narcotics. Closed markets comprise countries with adequate domestic sources of narcotic drugs that normally do not import and are generally inaccessible to foreign manufacturers, for instance Australia, Argentina, Belgium, Brazil, China, France, Hungary, Iran, Japan, Norway, Portugal, Slovakia, South Africa, Spain, Turkey, United Kingdom, and USA.

Global Scenario

In 2006, Risperdal (risperidone) achieved global pharmaceutical sales of US\$4.6 billion, contributing to total global antipsychotic sales of US\$18.2 billion (0.8% of total global pharmaceutical sales and a year-over-year sales increase of Risperdal - 12.3%). In 2008, sales decreased by 34% and reached US\$3.4 billion.

Risperdal was launched by Janssen Cilag in June 1993. Risperdal went off patent in June 2008, and the company started looking for cheaper generic Risperidone soon thereafter.

Until then, Janssen would actually price Invega slightly below Risperdal in order to encourage psychiatrists to prescribe Invega. Patent expiry has led to US\$1 billion-plus loss in revenues in 2008, due to generic sales erosion, according to analysts at market research firm.



Source: Janssen Pharmaceuticals Website; Cygnus Research

Global Competitors For Risperdal Drugs

Trade name	Company
Zyprexa	Elli Lilly
Seroquel	Astra Zeneca
Zeldox/Geodon	Pfizer
Abilify	Bristol Mayers

Source: www.drugmedia.com; Cygnus Research

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Email: info@cygnusindia.com; Website: www.cygnusindia.com

Recent Highlights

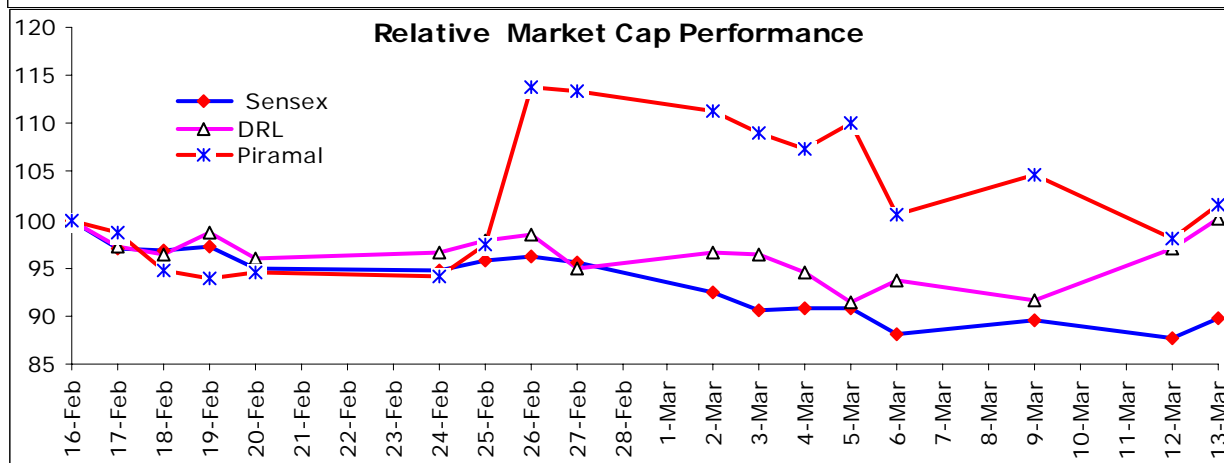
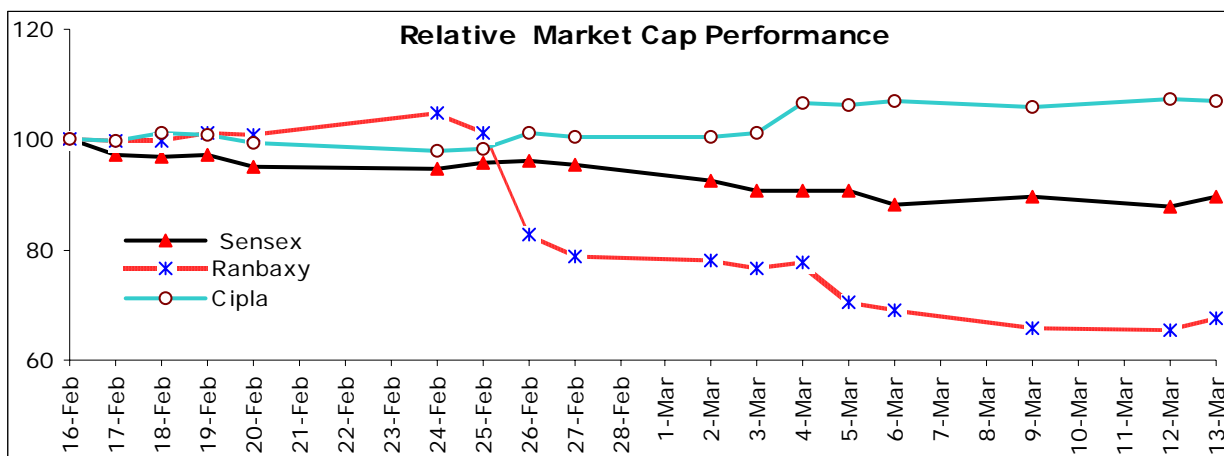
Supplemental new drug application for Risperdal consta submitted to the USFDA by Alkermes' partner, and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD), to seek the approval for adjunctive maintenance treatment to delay the occurrence of mood episodes in patients with frequently relapsing bipolar disorder (FRBD).

Outlook

Global anti-psychotics market is expected to expand to over US\$17.8 billion by 2011, before shrinking to US\$13.5 billion in 2012. Four of the top five leading atypical antipsychotics --Janssen's Risperdal, Eli Lilly's Zyprexa, AstraZeneca's Seroquel, and Pfizer's Geodon—will face generic erosion before 2012.

However, sales of Risperdal are estimated to slow considerably from 2008, as growth rates drop. In 2008, the growth rate is estimated to decline by 15% from the previous year due to patent expiration in 2008. Throughout the period, growth rates of the drug would continue to fall.

Stock Scan



Source: BSE India; Cygnus Research

	16 Feb – 22 Feb	23 Feb – 01 Mar	02 Mar – 08 Mar	09 Mar – 13 Mar
SENSEX	A disappointing interim budget and weak global cues made Sensex fall.	The falling inflation assisted the Sensex; It gained around 0.55%.	Due to worsening global economic outlook, the Sensex performed poorly and it lost around 6.35%.	Recovery of global markets helped the Sensex to gain 5.17% in the week. The market gained in two out of three trading days in the week. Low inflation also assisted a smart bounce back.

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RANBAXY	Increase in volume of shares traded resulted in the jump in stock price from Rs205.05 to Rs206.70.	Share price declined by 21.72% as the news that USFDA had put Ranbaxy Paonta Sahib ANDAs on hold did not attract the investors.	Sluggish trend on global markets made the share price fall by 12.67%.	Lack of demand on shares made the stock price fall by 1.98%.
CIPLA	Weak global cues made the share price move down by 0.55%.	Positive sentiments in the market made the share price move up by 1.16%.	Increasing demand of shares made stock prices move up by 6.38%.	The share price remained flat during this period.
DRL	Negative sentiments in the market made its share price fall around 4.12%.	The stock price further decreased by 0.89% due to the negative investor's sentiments.	Negative trend followed this week by 1.38% on par with Sensex.	The share price climbed by 6.92% as the company has crossed the milestone of US\$150m of revenues in the Russia/CIS region for the fiscal year 2009. This however attracted the investor's during this period.
PIRAMAL	Lack of demand on shares made the share price move down by 5.48%.	The share price gained by 19.95% as French drug major Sanofi-Aventis has emerged as the lead bidder to buy a sizeable stake in Piramal Healthcare at over 50% premium to the Indian company's current share price. This attracted the investors.	Negative sentiments in the global market made the share price move down by 11.39%.	The stock price witnessed a hike of 1.03% as the company acquired US based Minrad International, a provider of generic inhalation anesthetics. This strategy attracted the shareholder's during this period.

Regulatory Issues

FDA Imposes Restrictions on Coast IRB due to Violations

The U.S Food and Drug Administration today announced that Coast IRB, LLC of Colorado Springs, Colo., has agreed to voluntarily halt some aspects of its clinical trial oversight operations due to serious concerns about the company's ability to protect human subjects participating in clinical trials. According to the company's records, these actions may involve approximately 300 active human research studies conducted by some 3,000 clinical investigators.

FDA Adopts Interim Plan to Avoid Shortage of Medically Necessary Opioid

The U.S Food and Drug Administration today amended its March 30, 2009, action warning manufacturers to stop the production and distribution of certain unapproved prescription opioids, to allow the continued marketing and distribution of one particular type of opioid -- a high concentrate morphine sulfate oral solution -- on an interim basis.

The FDA took this action in response to concerns from patients and health care professionals in the palliative care community that the action taken on March 30 would cause a shortage of 20 mg/ml morphine sulfate oral solution. This product is widely used to alleviate pain in terminally-ill patients. The agency has determined that this dosage form is medically necessary, and should remain on the market until an approved alternative becomes available to the patients that need it.

Asia Pacific

India: Biotech cos await Canada's regulatory rules for next move

Biotechnology companies in the country have something to look forward to in the coming months. Health Canada, Canada's health regulatory body, will be coming out with its second guidance document on biologics by this month end. The US Food and Drug Administration (FDA) has also finished drafting its guidance for biologics and will release the same, subject to the approval of the Congress. The director general of the therapeutic products directorate at Health Canada said that they already have one guidance document out and have finished a second draft guideline on subsequent entry biologics which should be out next month. So companies can submit their applications to us for their subsequent entry biologics in the absence of a guidance document. They can still be reviewed and approved, if their documents are in order. The USFDA guidance has already been completed.

India: Pharma to get new regulatory regime

Drug makers in the country will get a new regulatory regime that is more friendly for investing heavily into high-risk research, testing experimental drugs on animals, protecting the costly research data shared with the regulators and everything needed to lead them to the global league of drug inventors. Regulatory reforms is attached to the pharmaceutical research funding plan of Rs10 billion every year that chemicals minister Ram Vilas Paswan announced a week ago before the model code of conduct for political parties and candidates kicked. Specific regulatory changes will be identified in a detailed project report to be prepared within six months after the Prime Minister clears the project, said an official.

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Upcoming Events

1	Event	Healthcare Ireland
	Date	Apr 01-02, 2009
	Venue	Main Hall & Serpentine Hall
	Highlights	Healthcare Ireland's international Exhibition contains all the latest products and services that will enhance efficiency, and improve care now and in the future. And by sharing experiences and information with colleagues from different departments, and across the country, we'll develop as individuals, and improve healthcare delivery
	Contact details	Healthcare Ireland Organizing Office, Step House, North Farm Road Tunbridge Wells, Kent UK TN2 3DR, Tel: +44 (0)1892 518877; Fax: +44 (0)1892 518811; E-mail: healthcare-ireland@stepex.com ; Web: www.healthcare-ireland.com
2	Event	Womens Healthcare
	Date	Apr 08-11, 2009
	Venue	Dubai International Convention & Exhibition Centre
	Highlights	Womens Healthcare is an event taking place alongside the very well established Bride Show in Dubai. Of the visitors of The Bride Show, more than 60% stated they are the decision maker regarding healthcare treatment in their family. It is vitally important that these women are educated on various health risks and most recent healthcare solutions.
	Contact Details	IIR Middle East P. O. Box, Dubai, United Arab Emirates Tel: +(971)-(0)-43365161; ax: +(971)-(0)-43365886
3	Event	Bangalore Bio
	Date	Apr 15-17, 2009
	Venue	Bangalore International Exhibition Centre, Bangalore, Karnataka, India
	Highlights	Bangalore Bio will offer an unrivalled opportunity in Asia Pacific region to meet with the who's who of the Biotech world in one place at one time. Bangalore Bio will be held at Bangalore International Exhibition Centre from 15 to 17 Apr 2009. In 2008, nearly over 600 delegates, 72 speakers, 150 exhibitors participated in this event.
	Contact details	M. M. Activ, Bangalore UNI Building, Thimmaiah Road, Millers Tank Bund, Bangalore, India Tel: +(91)-(80)-41131912; Fax: +(91)-(80)-41131914
4	Event	Pharmaceutical & Biotechnology Middle East (PABME)
	Date	Apr 20-22, 2009
	Venue	Dubai International Convention & Exhibition Centre, Dubai, Dubai, United Arab Emirates
	Highlights	Pharmaceutical & Biotechnology Middle East (PABME) is an exciting new networking platform for international industry players to converge, network and discuss new business alliances and joint ventures. The event will be a preferred destination for the international Pharma and Biotech Industries and an opportunity not to be missed!
	Contact details	IIR Middle East P. O. Box, Dubai, United Arab Emirates Tel: +(971)-(0)-43365161; Fax: +(971)-(0)-43365886

5	Event	PABME 2009
	Date	April 20-22, 2009
	Venue	Dubai International Convention and Exhibition Centre, UAE
	Highlights	It is a part of the Arab Health portfolio since 2001. Meet and network with the leaders of the industry and potential investors in a one stop shop for all Pharmaceutical and Biotechnology professionals in the unique and futuristic city of Dubai, the business hub of the Middle East.
	Contact details	Terri D'Elia, Exhibition Manager, Tel: +971-4-3365161 x 110; Fax: +971-4-3364021, Web : www.pabme.com; Email- pabme@iirme.com
6	Event	CPhI JAPAN 2009
	Date	April 21-23, 2009
	Venue	Tokyo Big Sight Exhibition Center, Tokyo
	Highlights	Currently the market of Bio-Pharmaceuticals as typified by antibody drugs has been a fascinating subject for both exhibitors and visitors at CPhI JAPAN. The market is forecast that the antibody drug will pull the market in the future, and it is in the increasing tendency the proportion of the biomedicine in the approved medicine.
	Contact Details	Event manager, CMP Business Media Co Ltd, Kanda 91 bldg., 1-8-3, Kaji-cho, Chiyoda-ku, Tokyo 101-0044, Japan Tel : +81-3-5296-1020; Fax : +81-3-5296-1018
7	Event	American Occupational Therapy Association Expo (AOTA Expo)
	Date	Apr 23-25, 2009
	Venue	Americas Center, St Louis, Missouri, USA
	Highlights	American Occupational Therapy Association Expo (AOTA Expo) advances the quality, availability, use, and support of occupational therapy through standard-setting, advocacy, education, and research on behalf of its members and the public. It is a meeting point for different professional and business figures, an occasion to update and to investigate topics ranging from research and new technology to marketing and the business outlook for the sector.
	Contact Details	National Trade Productions 313, S. Patrick, Alexandria, United States Of America Tel: +(1)-(800)-6877469; Fax: +(20)-(703)-8364486
8	Event	Pharmafest Premier Pharmaceutical & Medicine Techno-Trade Event
	Date	May 06-08, 2009
	Venue	Cape Town International Convention Centre (CTICC), South Africa
	Highlights	Pharmafest is purely dedicated to pharmaceutical industry and will bring together all the key players under one roof, providing exhibitors with an astonishing networking opportunity. The exhibition will provide an excellent platform for service providers to showcase their products and services to decision makers from leading pharmaceutical manufacturers. The event will be the pharmaceutical industry's esteemed source of innovation and knowledge.
	Contact details	Event Manager, Vantage Trade Fairs Private Limited, S. C. o 43, Sector 31, D, Chandigarh, India., Tel: +(91)-(172)-5049993; Fax: +(91)-(172)-5046645

9	Event	Diagno & Labfest South Africa
	Date	May 06-08, 2009
	Venue	Cape Town International Convention Centre, Cape Town
	Highlights	The event will be a great opportunity for all associated with diagnostics and laboratory business. It is a unique place to exchange ideas, share experiences, track the new developments and latest technologies. Diagno & Labfest, with its comprehensive product range and its outstanding expertise, is to become one of the most important meeting points for experts from this branch of industry.
	Contact Details	Vantage Trade Fairs (P) Limited. 23/21A, IInd Floor, East Patel Nagar, New Delhi, India. Tel: +(91)-(172)-30580444; Fax: +(91)-(172)-30581000

10	Event	Interphex China
	Date	May 12-14, 2009
	Venue	Xian International Exhibition Canter, Xian, Shaanxi
	Highlights	Interphex China is a must attend event for Chinese pharmaceutical manufacturers, and the best way to promote company image. It is the most reliable event to ensure your success in China's pharmaceutical industry.
	Contact Details	Reed Exhibitions China Head Office. Unit 4-5, Level 12, Office Tower E1, The Towers, Oriental Plaza, No.1, East Chang An Ave, Dong Cheng, Beijing, China. Tel: +(86)-(10)-851890707; Fax: +(86)-(10)-8518 9060 Email: enquiry@reedexpo.com.cn; Web: www.reedexpo.com.cn

11	Event	INTERPHEX Asia 2009
	Date	Jun 01-02, 2009
	Venue	Suntec Singapore International Convention & Exhibition Centre. Singapore
	Highlights	INTERPHEX Asia 2009 is the only event dedicated to the pharmaceutical manufacturing industry in Asia. Bringing together the pharmaceutical manufacturing professionals in the Asia-Pacific region and international suppliers, the event is the platform to network, meet industry suppliers and get updates on industry developments.
	Contact Details	Reed Exhibitions Pte Limited. 51 Changi Business Park Central 2, 07-01 The Signature, Singapore Tel: +(65)-()-67898800; Fax: +(65)-()-67897711 Email: ask@reedexpo.com.sg; Website : www.reedexpo.com

12	Event	Pharmaceutical Ingredients Japan 2009
	Date	Jul 01-03, 2009
	Venue	Tokyo International Exhibition Center (Tokyo Big Sight)
	Highlights	It is the most important pharmaceutical ingredients event of Japan. It is an international trade fair specialised in pharmaceutical ingredients. More than 63,000 visitors who deal with ingredients selection will be gathering at this show from all over the world for networking and business meetings. Through this show, exhibitors can enjoy the business expansion in Japan/Asia pharmaceutical market. It will bridge the needs between ingredients suppliers and pharmaceutical manufacturers.
	Contact details	Reed Exhibitions Japan Limited. 18F Shinjuku – Nomura Building, 1-26-2 Nishishinjuku, Shinjuku, Tokyo - 163-0570, Japan Tel: +(81)-(3)-33498501 ; Fax: +(81)-(3)-33498599 Email: info@reedexpo.co.jp; Website: www.reedexpo.co.jp

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13	Event	Hospitalar
	Date	Jun 02-05, 2009
	Venue	Expo Centre Norte, Sao Paulo
	Highlights	It will serve as a platform for medical suppliers, industry professionals, government bodies, hospital administrators, doctors, nurses and other healthcare professionals.
	Contact Details	Messe Dusseldorf GmbH, Stockumer Kirchstrasse, 61, Messeplatz, Germany, Tel: +(49)-(211)-4560900; Fax: +(49)-(211)-4560668 E-mail: infoservice@messe-duesseldorf.de Web: www.messe-duesseldorf.de
14	Event	Healthcare Travel Exhibition & Congress
	Date	Jun 28-30, 2009
	Venue	Fairmont Hotel, Singapore
	Highlights	Healthcare Travel Exhibition & Congress will be a platform which will bring together macro level decision makers on healthcare policy and payees of medical travel, specialised medical suppliers, travel providers, medical facilities and representatives from major medical tourism destinations.
	Contact Details	IIR Exhibitions Limited, 29 Bressenden Place, 5th floor, London, United Kingdom. Tel: +(44)-(20)-7017 7108; Fax: +(44)-(20)-73443890 Web: www.iirx.com.sg