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In Focus: An overview of Indian Biopharma

Introduction:

The life science sector is emerging as a key industrial segment in the national economy. The past performance of the industry indicates that it has surpassed the growth rate of many other industries. India is counted among the top 12 global biotech hotspots and is the 3rd largest in Asia Pacific (in terms of number of biotech companies). Biopharmaceuticals are complex macromolecules (Large molecules) created through the genetic manipulation of living organisms using gene cloning, recombinant DNA (gene splicing), or cell fusion technologies. The major opportunity segments for the Indian biopharma are the clinical research in India. The Indian biopharmaceutical industry is poised to witness a healthy growth within the short to medium term.

Market

The biotech industry continued to grow at almost the same rate as it did in the previous fiscal despite a growing base. The industry recorded 30.98% YoY growth accounting to INR 85.41 billion compared to the 2005-06. The total Biopharma industry, comprising of vaccines, therapeutics, other products like statins, and diagnostics registered 26.9 % growth in 2006-07 and the segment still is the single largest contributor to the Indian biotech industry. The total Biopharma industry grew from INR47.08 billion in 2005-06 to INR 59.73 billion in 2006-07 (See Chart 1).

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Table 1 : Segmental Revenue in Bio Pharma Sector 2006-07

Bio Pharma	Revenues INR Billion (2005-06)	Revenues INR Billion (2006-07)	% Growth
Vaccines	23,410	30,530	30.41
Diagnostics	9,050	9,500	4.97
Therapeutics	6,400	7,250	13.28
Others	8,220	12,450	51.46
Total	47,080	59,730	

Source: ABLE BioSpectrum Survey 2007

Share of exports vs. Domestic

In 2006-07 exports accounted for 61.49 % of the Biopharma sales, while domestic and imported sales account for the rest. Bioservices had 95.46% of its revenue from exports. There was an increase in the share of exports, in their contribution to the Biopharma sales from 53 % in 2005-06 to 61.49 % in 2006-07 (See Chart 2).

Biopharma Industry Segments

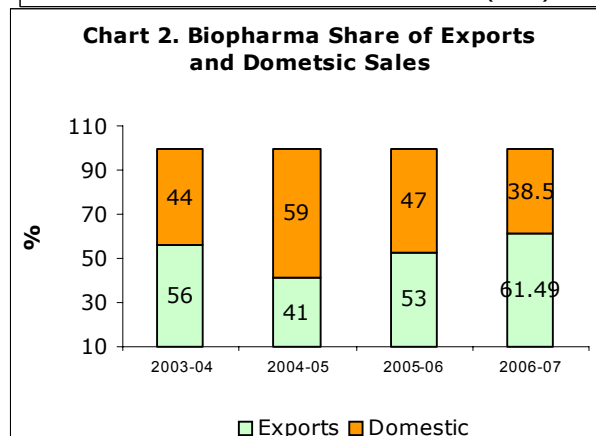
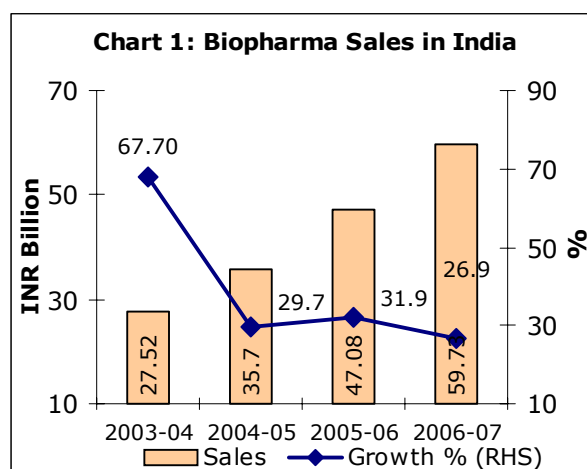
In Bio Pharma Diagnostics, vaccines and recombinant therapeutic proteins are the three main segments. (refer table 1).

Vaccines

Vaccines are the largest segment accounting for 51% of the sectoral revenue. The vaccines sales market in India in 2006-07 was INR.30.53 billion registering a 30.41% growth over the previous year. India's huge population makes it among the world's largest markets for vaccines of all types

Diagnostics

Diagnostics is also one of the largest contributors to the sector contributing 16 % of the total sectoral value. Diagnostics sales market was estimated at INR. 9.50 billion in 2006-07. Diagnostics registered a growth of 4.97 % in 2006-07



Source: Cygnus Research

Therapeutics

Therapeutics is the fourth largest contributor to the sector. It accounted for 12 % of the total biopharma sales with INR. 7.25 billion in revenues. Therapeutics registered a growth of 13.28 % in 2006-07. Companies like Biocon, Eli Lilly and Wockhardt have established their mark to manufacture these products.

Major Indian Players:

Rank	Company	Turnover in 2005-06	Turnover in 2006-07	Growth % in 2006-07
1	Serum Institute of India	7.03	9.50	35.27
2	Biocon	6.88	7.28	20.73
3	Panacea Biotec	4.38	6.60	37.04
4	Novo Nordisk	1.75	2.22	26.86
5	Venkateshwara Hatcheries	2.80	1.90	-32.1
6.	Indian Immunologicals	1.02	1.57	54.50
7	GlaxoSmithKline	0.94	1.20	27.66
8	Aventis Pharma	1.15	1.19	4.50
9	Shantha Biotechnics	0.82	1.15	39.90
10	Bharat Serums	0.78	1.08	39

Source: ABLE Biospectrum Survey 2007; Cygnus Research

Further, the Indian (home grown) manufacturers today account for 62 % of the total BioPharma sector (excluding the diagnostics market which is valued at INR9.05 billion). Among the top five companies, Novo Nordisk is the only MNC. Most of the biotech companies today are focusing on discovery-led innovation and investing in infrastructure and R&D. Biological E has invested about 36 % of its total turnover on infrastructure and R&D. Panacea has recently developed and launched several other vaccines which include Recombinant Hepatitis B (Enivac HB), Enivac HB Safsy, Ecovac (DPT+Hib B), Ecovac safsy, Easy Four (DPT+Hib) and Easy Five (DPT-Hib-HepB). It also entered into collaboration with UK-based Cambridge Biostability, for manufacturing of vaccines in India using the Stable Liquid Technology.

Emerging Trends in Biopharma

Big Pharmaceutical Companies Are Scouting For Biopharma Partners

Now, more than ever, pharmaceutical companies must outsource research and development works to their biotechnology counterparts - and they are doing so in record numbers. Nearly one third of new pharmaceutical products are developed through such alliances. Pharmaceutical companies are not the only ones that stand to gain from these partnerships; opportunities abound for biotechnology companies as well. These puny biotechnology companies often lack the marketing muscle to launch a new drug. Biotechnology companies need the backing of major pharmaceutical companies to achieve rapid sales uptake and boost peak annual sales.

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Increasing Demand for Biogenics

The large Indian firm has recently ramped up production of biogenics and is already producing biogeneric equivalents of two patented drugs. Biogenics is the generic versions of pharmaceutical preparations involving a biologically active substance that has generally been created using modern biotech tools. These products are still in their infancy due to the relatively recent patent expirations of the first branded set of biotech products. Lack of clear regulatory guidelines, potential shortage of bulk active biopharmaceuticals obtained through non-patent-infringing routes and, most critically, the belief that minor modifications of the bioprocess may lead to variation in product quality or safety, pose significant challenges. The FDA and industry need to work together to ensure that follow-on products will not risk patient safety.

R&D Spend On the Rise

Leading companies like Biocon, Ranbaxy, Dr Reddy's Laboratories, Nicholas Piramal, Lupin and Wockhardt have increased their focus on R&D. The R&D activities at these companies are targeted both at New Drug Development (NDD) as well as Novel Drug Delivery Systems (NDDS). The R&D expenditure of leading Indian pharmaceutical companies has crossed INR 15 billion during 2007. In value terms companies like Ranbaxy and Dr Reddy's Labs led the way in R&D spending. Contrary to the pharmaceutical companies, most of the biotechnology companies are still engaged in R&D activities depending on government support for funds.

Increasing Outsourcing by Pharmaceutical Companies

Pharmaceutical companies are also outsourcing more drug development processes. As more molecules come out of the drug discovery pipeline, it has become increasingly difficult for any single R&D organisation to handle the complete synthesis for each new molecule. Today, it is not uncommon for pharmaceutical companies to involve one or more outsourcers - process R&D companies that design production processes - to complete the work on any new drug. Outsourcing of discovery research, clinical trials and formulation manufacturing provides pharmaceutical companies with a highly effective approach to declining productivity and the pressure for consistent, high-growth financial returns. Outsourcing allows these companies to pursue potential new revenue streams outside their core focus areas, and to benefit from improved productivity, emerging technologies, in-license opportunities and increased growth.

Opportunities in Clinical Research

India is fast emerging as a favoured destination for clinical trials by global pharmaceutical and biotech companies that are looking for partnerships or setting up new operations. New pharmaceutical strategies pursue increased Research and Development (R&D) investments ranging 15-20% in contrast to late 80's period where classical model across was 10%. The annual budget allocation spent with clinical research organizations (CRO) is approximately USD12 billion in an attempt to increase throughput, which has predominantly benefited CRO's who have seen their turnover boost growth of 20-30% year on year.

Outlook

The Indian biopharmaceuticals is in the development stage with about 134 players currently. The growth rate is expected to be around 13.6% between 2006 and 2010, taking the Indian biopharma market size up to INR 160 billion by 2009-10. In order to sustain the future growth, Indian companies must achieve the right product-mix. Patent law changes have propelled the industry to explore newer avenues of drug development which in turn will lead to higher capital investment in the industry in near future.

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News Briefs

INTERNATIONAL

AMERICAS

USA: Celator Pharmaceuticals uses nanoparticles to administer hydrophobic drug combinations

Celator Pharmaceuticals reported a novel approach designed to deliver drugs that are incapable of dissolving in water (hydrophobic drugs) in nanoparticles to enhance and control drug circulation. These findings allow the company to combine hydrophobic drugs such as paclitaxel with other anti-cancer drugs, based on the company's proprietary, CombiPlex technology. The company has applied this technology to approve and widely used anti-cancer drugs using liposomes. By expanding the formulation platform to include nanoparticles for hydrophobic drugs gives greater flexibility in delivering synergistic drug combinations with widely varying chemical properties, thus potentially leading to more product opportunities.

USA: Brahms receives FDA clearance to market automated Procalcitonin test

Brahms Inc announced that it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market its patented Procalcitonin (PCT) Kryptor (R) test. The automated test will be used in critically ill patients on the first day of ICU admission as an aid to assess their risk for progression to severe sepsis and septic shock. PCT levels are undetectable in healthy individuals. However PCT levels rise rapidly when there is the presence of a bacterial infection. The quick results provided by the Kryptor will aid healthcare professionals to make faster and better patient management decisions.

USA: BioSeek and Lexicon join hands in drug discovery

BioSeek has initiated research collaboration with Lexicon Pharmaceuticals for BioMAP Systems for further evaluation of selected compounds with drug discovery programs. BioMAP Systems are a series of human primary cell-based assay systems designed to replicate the intricate cell and pathway interactions present in human disease biology. BioSeek CEO stated that by providing predictive preclinical human data on the pharmacological properties of Lexicon's compounds, the BioMAP platform can help to discern the relevant physiologic pathway impacted by the compounds and identify appropriate cellular assays for their further optimisation.

USA: North Park Aesthetics acquires exclusive rights to fluridil

North Park Aesthetics has signed an agreement with Biophysica and Interpharma Praha. North Park has acquired exclusive worldwide rights to develop and commercialise products containing fluridil, a novel antiandrogen for topical administration. Fluridil is the primary ingredient in NP-619, North Park's Phase II product for androgenetic alopecia (pattern baldness). The company also acquired an option for existing markets associated with two fluridil-containing products, Eucapil and Care.

USA: ImaRx announces agreement with Abbott for thrombolytic drug

ImaRx Therapeutics signed an agreement with Abbott Laboratories for its acquisition of urokinase, a thrombolytic drug of about US\$15m. As a result, full title to the urokinase assets, including the remaining inventory of finished product, all regulatory and clinical documentation, validated cell lines, and intellectual property rights, now resides unencumbered with ImaRx. ImaRx CEO stated that the agreement ensures to have complete ownership of the asset, which will enable the company to continue to commercialise this product as important therapeutic.

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USA: Multivitamins are top diet supplement for teens

Researchers revealed that multivitamins and vitamin C, top the list of dietary supplements which is supporting the lack of health risks among US adolescents. The study stated the adolescents who used prescription medications were more likely to use dietary supplements, and doctors and pharmacists should be sure to ask their young patients about supplements to avoid the possibility of harmful interactions. Researchers found obese individuals were 51% more likely to be using non-vitamin or mineral herbal supplements, as were older teens. Researchers concluded for future studies of culturally diverse groups with different clinical conditions should include a broader range of dietary supplements such as those used in folk remedies, foods and medicinal teas and ask about common health conditions.

USA: Cutting phosphate may protect kidney patients from heart trouble

A study revealed that phosphate-binding drugs could help prevent heart disease in people with chronic kidney disease (CKD). Researchers at Washington University noted that patients with chronic kidney disease (CKD) are at high risk of death from cardiovascular disease, and that recent studies have shown that a high level of phosphate in the blood is a major source of cardiovascular death risk in these patients. Elderly osteoporosis patients and people with diabetes have high rates of cardiovascular disease and high levels of vascular calcification. Researchers concluded that drugs which reduce phosphate levels may help protect CKD patients from cardiovascular disease.

USA: AMN Healthcare Service acquires RX Pro Health and Pharmacy Choice

AMN Healthcare Services Inc announced the acquisition of Rx Pro Health Inc and Pharmacy Choice Inc, the leading providers of pharmacy staffing, workforce technology solutions, and on-line educational services for hospital-based and retail pharmacies and pharmaceutical companies. The total cash consideration of upto US\$17.3m consists of an initial purchase payment and potential additional earn-out payments through 2009.

USA: Watson files FDA application for Generic Yasmin

Watson Pharmaceuticals Inc, confirmed that it has filed an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA), seeking approval to market its Drospirenone and Ethinyl Estradiol tablets (3.00mg/0.03mg) combination oral contraceptive product prior to the expiration of patents owned by Bayer HealthCare Pharmaceuticals, Inc. Watson's Drospirenone and Ethinyl Estradiol product is a generic version of Bayer's Yasmin tablet indicated for the prevention of pregnancy.

Europe:**UK: FDA approves Rotarix (R) Rotavirus Vaccine**

GlaxoSmithKline (GSK) has received approval from the U.S. Food and Drug Administration (FDA) for Rotarix (R), for the prevention of rotavirus gastroenteritis in infants. Rotarix will offer protection against the most commonly circulating rotavirus types in the U.S. and allow infants to complete the vaccination series by four months of age. The U.S. Centres for Disease Control and Prevention currently recommends that children complete the rotavirus immunisation series by six months of age. Rotarix may help prevent many of the 55,000 – 70,000 hospitalisations by young children that result from rotavirus in the U.S. each year.

UK: Glaxo and Pozen receive FDA approval for migraine drug

Companies announced that GlaxoSmithKline PLC and Pozen Inc have received approval from the U.S. Food and Drug Administration for their long-delayed migraine drug. The drugmakers stated that FDA approved Treximet, a combination of an anti-inflammatory drug for the acute treatment of migraine attacks with or without aura in adults.

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UK: EU extends marketing authorisation for Bayer's Zevalin

Bayer Schering Pharma has announced that the European Commission has extended the marketing authorisation for Zevalin in Europe. The decision for extending the Zevalin market authorisation is based on data from the pivotal Phase III First-Line Indolent Trial. Zevalin can be used in the course of a first-line therapy after remission induction in previously untreated patients with follicular lymphoma. This is why that many patients with follicular lymphoma will now have access to Zevalin's proven clinical benefits. The approval in first-line consolidation treatment will help to further exploit the potential of Zevalin.

Switzerland: Addex initiates Phase I formulation study of GERD drug

Addex Pharmaceuticals has started Phase I testing of two formulations of ADX10059. The Phase I trial in 30 healthy volunteers has two parts: A single-dose, three-way crossover study in 12 healthy volunteers measuring pharmacokinetics, safety and tolerability of two formulations of ADX10059 and the active pharmaceutical ingredient in capsule, which was used in Phase IIa testing, and a multiple ascending-dose pharmacokinetics, safety and tolerability study in 18 healthy volunteers. This Phase I testing will enable us to identify the optimal formulation to take into Phase IIb and could provide important additional efficacy data for ADX10059 in the indication of GERD.

Europe: MRI studies provide new insight on early Parkinson's disease

Researchers from Stavanger University and University of Bergen have shed new light on the early development of Parkinson's disease (PD) through the neurology and imaging project using advanced magnetic resonance imaging (MRI) technologies available at the Buffalo Neuroimaging Analysis Centre (BNAC). The researchers can identify brain regions linked to Parkinson's disease based on images showing the status of both white and grey matter. Researchers studied a case-control investigation, compared brain MRI scans and scores on the Mini-Mental State Examination (MMSE), a standard mental screening test, of 155 patients diagnosed with early Parkinson's disease with those of 101 normal subjects. The relationship between higher white matter hyperintensities and lower MMSE scores in PD provide a possible explanation for cognitive impairment in PD.

Europe: Pine bark naturally reduces osteoarthritis

Phytotherapy Research shows Pycnogenol (pic-noj-en-all), an antioxidant plant extract from the bark of the French maritime pine tree, was shown to reduce all osteoarthritis symptoms by 56%. The study revealed a particularly high efficacy of Pycnogenol for lowering joint pain by 55%. In addition to the osteoarthritis results, 76% of the patients in the Pycnogenol group showed visible ankle and foot edema at inclusion of the study. Evaluation of data demonstrated a decrease of gastrointestinal complications of 64% in the Pycnogenol group. The exclusive worldwide distributor of Pycnogenol has filed for several patents for Pycnogenol's application for COX-1, COX-2 and treating osteoarthritis.

UK: 2 Merck medicines recommended for approval in the European Union

Merck announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has recommended two medicines for marketing approval in the European Union (EU). The CHMP issued its positive opinions following a review of comprehensive data supporting the efficacy, safety and tolerability profiles of Tredaptive and Janumet. EU marketing authorisation by the European Commission is expected within 67 days from the date of the CHMP recommendations. If authorised, the decisions will be applicable to the 27 countries that are members of the EU, plus Norway and Iceland.

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Asia Pacific

Singapore: Alcon to build pharmaceutical plant

Alcon is planning to build a facility in Singapore that will manufacture pharmaceuticals to be distributed throughout most of Asia. The company plans to break ground in 2009 with the plant being fully functional by 2012. Alcon expects to manufacture at a rate of more than 53m units per year at this facility by the end of the third year of operation. Over the recent past, its sales of pharmaceuticals that treat diseases and conditions of the eye have risen at a CAGR of more than 20% in Asian markets. This growth has been driven by many of company's major brands such as Travatan, Patanol and Vigamox ophthalmic solutions, Tobradex ophthalmic ointment, and Systane eye drops. By building this plant, the company is expected to be able to more efficiently and cost-effectively distribute pharmaceuticals in the high-growth countries in Asia.

China's gastric cancer drug market to triple by 2012

Researchers has predicted that the Chinese gastric cancer drug market will nearly triple between 2007 and 2012. According to the new Emerging Markets report, this growth will be fuelled by increased access to health insurance and greater patient spending power, leading to increased usage of targeted therapies. Additionally, the prevalence of gastric cancer in China is said to be among the highest in the world. The Chinese government plans to insure close to 100% of the Chinese population by 2010, through three government-sponsored insurance schemes: Basic Medical Insurances, Urban Resident Basic Medical Insurance and new Rural Cooperative Medical Scheme. These initiatives will increase gastric cancer diagnosis and drug-treatment rates in China and present an opportunity for multinational companies to reach a larger patient population.

Australia: Children should not take antihistamines for chronic cough

Chronic cough can cut into children's sleep and fray parents nerves. Although antihistamines can alleviate cough, possible side effects outweigh their benefits, researchers said. The older antihistamines, benadryl have more anticholinergic activity, these older drugs therefore can work when the cause of the upper airway cough is not due to allergies and they can also work if the cause of the cough is due to allergies. Also the new drugs such as cetirizine and loratadine don't have much anticholinergic activity; they will work only if the cause of the upper airway cough is due to allergies. Beyond the research, parents continue to seek treatment for their children, spending billions of dollars worldwide on cough and allergy medications every year.

Nagai Foundation keen to tie up with Indian universities for pharma research

Nagai Foundation, the Tokyo-based non-profit organisation for promoting pharmacy research, education and alliance, may soon commence its operations in India for research, co-operation and exchange of students between the universities of Japan and India. The initiative would come up as the part of increasing interest of Indo-Japanese collaboration in pharmaceutical sector.

National News

Symogen to commence certificate course in pharmacovigilance from Sept,08

The UK based Symogen, which has expertise in all aspects of pharmacovigilance and pharmacoepidemiology, will be conducting certificate course at New Delhi from September 2008. The company has designed part-time course of four months. The course is designed for Doctors/Physicians of all disciplines, post graduates in pharmacy and bio-sciences (both M.Sc and PhD) and junior professionals in Pharmaceutical and IT Industry, clinical research organizations, BPOs, academia and regulatory agencies. Symogen will conduct classroom teaching on all Saturdays from 9.00 a.m. to 6.00 p.m. The company will be conducting mini workshops as part of the teaching process to include practical examples for specific modules. The admission will be based on

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candidate's merit and short interview with the panel of Symogen India. The course is supported by the WHO-Uppsala Monitoring Centre, Sweden and the International Society of Pharmacovigilance. It has arranged specialist's faculty in Medical and Pharmaceutical industry, which are reputed academicians and trained and qualified pharmacovigilance experts from UK, Sweden, USA, Thailand and India. It has recommended that the candidates who are wishing to join the course are required to submit their CVs to Symogen India at info@symogen.net

Biological E Ltd, U.S. companies Heparinex LLC and Choncept LLC Sign Option/License Agreements

Biotechnology companies Heparinex LLC and Choncept LLC announced that option and license agreements with Biological E., Limited (BE), a leading biopharmaceutical company based out of India. The agreement provides BE with an option for novel production technologies for both heparin and chondroitin related carbohydrate compounds. The combined strengths and unique advantages of the Heparinex and Choncept core technologies have potential applications in multiple high-yield markets. This agreement with Biological E. is a prime example of Emergent Technology focus on establishing long-term partnerships with market leaders in segments of strategic significance to portfolio companies.

Indian government slashes drug prices

According to the Union Budget 2008 announcement, the government has reduced the prices of more than 150 life-saving drugs in over 1,000 formulations as per the price cuts. According to the National Pharmaceutical Pricing Authority, the budget's reduction in countervailing duty (CVD) rate from 16% to 8% has lowered the prices of 36 of the 64 price-controlled bulk drugs which are imported into India. The 2008-09 budgets also reduced customs duty from 15% to 10% for certain life-saving medicines and the bulk drugs used in their manufacture and exempt them from excise and CVD. The newly-announced regulation, which will also reduce the prices of imported drugs marketed by multinational drug makers like Eli Lilly, Pfizer and Sanofi-Aventis, includes products such as betamethazone, carbamazepine, insulin, ranitidine, rifampicin and salbutamol.

India's public healthcare in serious decline

A Planning Commission report said that India's public healthcare is in serious decline due to non-availability of medical and paramedical staff, diagnostic services and medicines. The report noted that hospitalised treatment has gone down in government hospitals while the reverse has happened in private ones. But they have been on a serious decline in the last two or three decades. It also noted that critical shortage of health personnel, inadequate incentives and poor working conditions, lack of transparency in posting of doctors in rural areas, absenteeism, long wait, inconvenient clinic hours, poor outreach, time of service, insensitivity to local needs, inadequate planning, management and monitoring of service are the other reasons for low turnout in government hospitals.

US based MakroCare to open 3 clinical trial centres in India in 6 months

The US-based MakroCare, a multidisciplinary knowledge and technology driven clinical research organisation (CRO), is all set to open three more offices in various parts of the country. In India, the company currently operates from a facility located at Hyderabad. The company has already invested Rs40m for its Hyderabad facility. As per the company, which offers multiple trials to the customers, support to pharmaceutical, biotechnology and medical device industries, it has a good pipe line for the year of 2008-09.

Indian pharmaceutical companies making inroads into Japan

Indian pharmaceutical companies in now making deep inroads into Japan, the third largest pharma market in the world. The Pharmaceutical Export Promotion Council Director stated that the growing interest in Japan for Indian companies has been evident for the last one year as Japan has been

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liberalising norms pertaining to foreign companies reeling under the burden of heavy healthcare costs. Japan is an important traditional market. If it is opening up, it could be a major development for formulations business, according to Bulk Drug Manufacturers Association (BDMA) President of India. The Japanese market would offer good space to Indian pharma companies but the margins might not be very attractive.

Study highlights heart disease risk in India

India, expected to account for 60% of the world's heart disease cases by 2010, could prevent many deaths by ensuring the poor get better access to treatment. Heart disease is the leading cause of death globally, killing about 7.1m people each year. It is caused by fatty deposits that harden and block arteries, high blood pressure which damages blood vessels, and other factors. Strategies to reduce delays to access to hospital, and to improve the affordability of urgent care could reduce morbidity and mortality.

Indian biotech companies need to generate profit from IPR

Indian biotech sector needs to look at profit generation from Intellectual Property (IP) products and processes. Visible trends are seeking upfront payments, milestones and equity from patented products and processes. The growth potential for Indian biotech companies is huge and there is also an increasing focus to commercialise and profit from IPs. In the last two years, monoclonal bodies showed a steep growth in seeking IP protection as compared to other biological drugs. However, profit from IPs depended on commercial feasibility. Indian companies are realizing the need to profit from IPRs.

Italian biotech companies scout for alliances with Indian bio-pharma majors

Cross border collaborations, platform technologies and market opportunities are motivating biotech companies from Italy to scout for partnerships in India. The collaboration is initiated due to the growing demand for diagnostic tools in India, scientific instrumentation, development of real time microscopy, and new biologic analysis methods of investigations in biology based on probe microscopes. Italian Trade Commission stated that the government is looking for future collaborations and strategic partnerships and a possible 50:50 stake in many of the Indian biotech and life sciences companies.

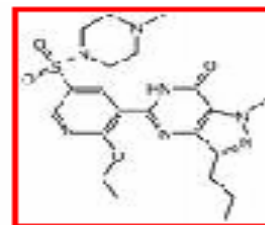
Siemens to launch Petnet services in India

Siemens Medical Solutions has announced the launch of its project to set up the company's first molecular imaging biomarker production facility in Chennai. The new facility will enable the healthcare providers in and around Chennai to access the PET.CT technology for diagnosis of patients with life-threatening diseases such as cancers, cardiac and neuro ailments. With this facility, Siemens makes another significant contribution to strengthen healthcare infrastructure in the country.

Product Focus – Sildenafil Citrate

Introduction

Viagra is an oral drug for male impotence, also known as erectile dysfunction (ED). It works by dilating blood vessels in the penis, allowing the inflow of blood needed for an erection. Sildenafil citrate, sold under the names of Viagra, Revatio, is a drug used to treat impotence and pulmonary arterial hypertension (PAH). Its primary competitors on the market are tadalafil, and vardenafil. It was initially studied for use in hypertension and angina pectoris. The drug was patented and approved in 1996 for use in erectile dysfunction by the Food and Drug Administration on March 27, 1998, becoming the first pill approved to treat erectile dysfunction in the United States.



Sildenafil citrate

Mechanism of action

Sildenafil is a potent and selective inhibitor of cGMP specific phosphodiesterase type 5 (PDE5), the molecular structure of Sildenafil is similar to that of cGMP and acts as a competitive binding agent of PDE5 in the corpus cavernosum, resulting in more cGMP and better erections. Sildenafil is metabolised by hepatic enzymes and excreted by both the liver and kidneys. If taken with a high-fat meal, there may be a delay in absorption of sildenafil and the peak effect might be reduced slightly as the plasma concentration will be lowered.

Contraindications: Hypersensitivity, Patient using organic nitrates.

Safety Profile: Severe renal or hepatic impairment, cardiovascular disease retinitis pigmentosa. In elderly peoples, use with extreme caution.

Dosage and administration

Doses range from 25mgs to 100mgs, depending on the drug's effect. The usual dose is 50mgs. If age is over 65, have liver or kidney problems, or are taking erythromycin, ketoconazole, itraconazole, ritonavir, or saquinavir a dose of 25mgs may be sufficient. Physician will adjust the dosage if the drug is not working properly. Viagra should be taken only before sexual activity.

Classification	
Brand Name	Viagra
Generic Name	Sildenafil citrate
Therapeutic class	Leukotriene Modifiers
Manufacturer	Cipla
<i>Source: Cygnus Research</i>	

Major Players

- Ranbaxy
- Torrent
- Alembic
- Sun
- Lupin
- Cadila Pharma
- Cipla

Side effects

- Sudden severe loss of vision, blurred vision
- Sudden decrease or loss of hearing
- Erection that is painful or lasts longer than 4 hours
- Dizziness, fainting
- Chest pain
- Rash, itching or burning during urination

Storage: Keep this medication in a tightly closed container, and out of reach of children. Store at 25°C (77°F); excursions permitted to 15-30°C and away from excess heat and moisture.

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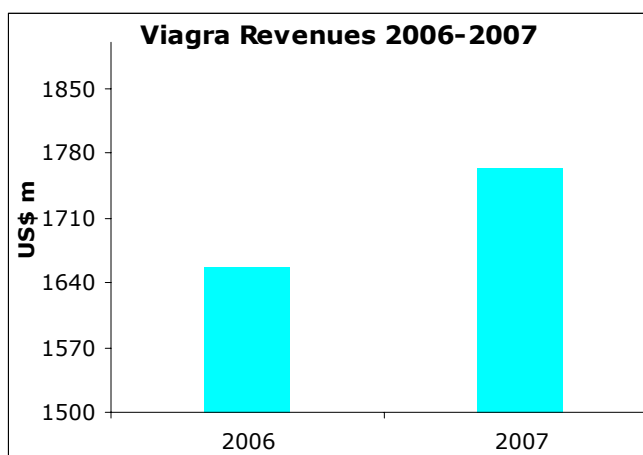
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Precautions

- Tell the physician and pharmacist about the allergic may be caused due to sildenafil or any other medications.
- Do not prefer to take sildenafil if you are in the medications of nitrates such as isosorbide dinitrate (Isordil), isosorbide mononitrate (Imdur, ISMO), and nitroglycerin (Nitro-BID, Nitro-Dur, Nitroquick, Nitrostat, others).
- Tell the physician and pharmacist about prescription and non-prescription medications, vitamins, and nutritional supplements that you are planning to take in future. Be sure to mention about alpha blockers such as alfuzosin, doxazosin, prazosin, tamsulosin, and terazosin.
- Also tell the physician, if you already had pulmonary veno-occlusive disease (PVOD; blockage of veins in the lungs); a stomach ulcer; heart, kidney, or liver disease; a heart attack; an irregular heartbeat; a stroke; chest pain; high or low blood pressure; high cholesterol; a bleeding disorder; blood circulation problems.
- Be sure to tell at the time of pregnancy, plan to become pregnant, or are breast-feeding.

Global Sales

Viagra remains the leading treatment for erectile dysfunction and one of the world's most recognized pharmaceutical brands. Viagra revenues grew 6.4% worldwide, with U.S. revenues flat and international revenues increasing 13% in 2007, compared to 2006. The growth in Viagra international revenues was driven by foreign exchange, as well as a combination of other factors, including strengthening of value proposition to key customers and growth in the erectile dysfunction market.

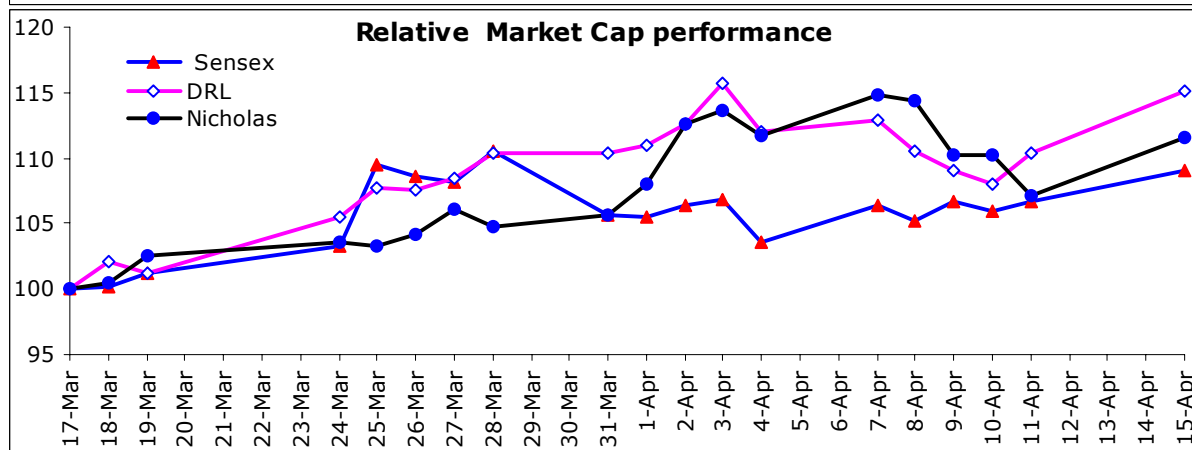
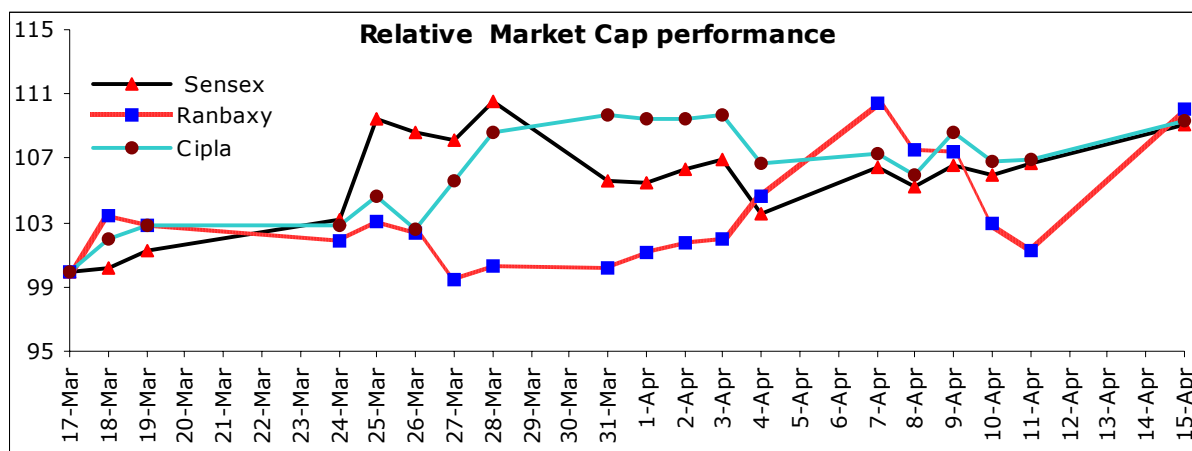


Source: Company Report; Cygnus Research

Outlook

Most men experience ED at some points in their lives usually by the age of 40; some even experience chronic and complete ED. Over, 150m men worldwide are unable to achieve and maintain an erection adequate for satisfactory sexual intercourse. Analysis expects this figure to double by 2020. In order to control the Erectile Dysfunction (ED), Viagra, is the most popular and recognised brand in the market. The market estimations also indicate that in coming decade globally its revenue will touch by US\$2020m within two years.

Stock Scan



Source: BSE; Cygnus Research

	Mar16 – Mar22	Mar23 – Mar29	Mar30 – Apr05	Apr06 – Apr15
BSE Sensex	The Sensex ended the week with loss of 765.69 points or 4.86% lower at 14994.83 points. The reason being weak was due to global cues, which led to selling in capital market. Volatility was high during the week.	The Sensex ended the week with gain of 1376.46 points or 9.18% higher at 16,371.29 points. Mid- and small-cap stocks did better. With firm global cues, buying was seen across both Mid- and small-cap companies.	The Sensex fell by 1,028.17 points or 6.28% to touch 15,343.12. The reasons for the fall in the Sensex included selling by foreign institutional investors, low level of participation by domestic institutions and fears of monetary tightening by RBI as inflation touched a three-year high of 7%.	The Sensex rose 810.54 points or 5.28% to 16153.66 points. The markets ended higher for the period under consideration due to firm Asian and European indices. During this period Sensex posted smart gain.

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Ranbaxy	The share price increased by 2.80% as the company signed an agreement with CD Pharma to market the Inersan brand in India and Nepal, leading to rise confidence of the investors' sentiments.	The share price closed at Rs439.10 showing a decline of 1.60% due to the investors' negative sentiments.	The stock price increased by 4.44% as the company had launched Bonista-Teriparatide injection in collaboration with Virchow Biotech, India, which led to rise confidence of the investors' sentiments.	The stock price remained flat during this period.
Cipla	The share price moved up by 2.79% due to performance of the major players during this period.	The stock price registered 5.53% as the company was planning to develop combination drugs for allergic rhinitis, asthma and cardiac-problems, and to develop markets in US and Europe, which led to rise confidence of the investors.	The share price declined by 2.71% as it moved in tandem with BSE sensex.	Positive results from the company with 87.7% in the net profit gave boost to the share prices.
DRL	The stock price increased by 1.16% due to positive sentiments of the investors.	The share price further increased by 4.58% as bullish sentiments prevailed in the market.	The share price rose by 1.40% as the company signed an agreement with the Dow Chemical Company for Dowpharma small molecules business at Mirfield and Cambridge, United Kingdom, which led to rise confidence among the investors.	The share prices registered positive trend as the company was planning to launch the generic version of Nexium, Plendil, Prilosec for treatment of intestinal ulcers in the US, leading to positive sentiments among the investors.
Nicholas	The share price increased by 2.52% as it moved in tandem with BSE sensex.	The share price further increased by 1.24% as the company had launched a pilot project at Rajasthan, for sending its drugs to rural markets to create proper public health system, leading to positive sentiments among the investors.	Increased number of shares added the result jump in the stock price from Rs303.20 to Rs320.80.	The share price fell down by 2.91% even though the company had signed an agreement for purchase of Anafortan and CEFI brands groups from Khandelwal Laboratories for Rs1, 160m. This, however, did not go well with the investors' sentiments.

Regulatory Issues

FDA Approves New Formulation of Coagulation Therapy

The U.S. Food and Drug Administration today approved a new formulation of the genetically engineered version of Factor VIIa, a plasma protein essential for the clotting of blood. The new formulation allows the product to be stored at room temperature (up to 77 degrees Fahrenheit) for up to two years. NovoSeven RT shares the same uses as the earlier NovoSeven product. These uses include the treatment of bleeding and the prevention of surgical bleeding in patients with hemophilia A or B, who have antibodies that neutralize the action of clotting Factors VIII or IX; the treatment of bleeding and the prevention of surgical bleeding in patients with congenital Factor VII deficiency; and the prevention of surgical bleeding in patients with acquired hemophilia.

National

WHO expert calls for reduction of taxes on medicines to make them affordable

India has the highest tariff rates on medicines, a number of experts including WHO expert Richard Laing and industry leaders have called for cut in duties on drugs to make them affordable in the country. The regulation of mark-ups is another measure to avoid excessive add-on costs in the supply chain. However, maximum percentage mark-ups would provide incentive to sell higher priced products to obtain a higher return

WHO facilitates CDSCO tie up with Health Canada to modify Indian drug regulatory system

Perturbed by the lacunae in the Indian drug regulatory system which could jeopardise the global supply of vaccines, the World Health Organisation has facilitated a tie-up between CDSCO and Health Canada to modernise and improve the regulatory mechanism here. Under the collaboration, which would run till the end of next year, a series of interactions between the officials on both the sides and workshops would be held and know-how on administration would be imparted. Fully-funded by WHO, the partnership would also cover extending assistance to improve the functioning of public sector vaccine manufacturers. The UN agency was also seriously concerned about the matter as India was supplying vaccines to 150 countries, accounting for almost 60 per cent of global supply. Any lapse in the Indian system could jeopardise the world situation and the collaboration would thus indirectly ensure smooth supply of vaccine ahead

DCGI preparing guidelines to link patent status to marketing approval of drugs

Sticking to his stand on linking patent status with marketing approval for drugs, the Drugs Controller General of India (DCGI) is preparing a guidance document to deny licences for copycat versions of medicines that have product patent in the country, even as discontent is growing in the industry over the move. However, the DCGI would give marketing approvals to the drugs that have only process patents in the country while denying permission to the low cost Indian versions of product-patented drugs. The policy document, to be finalised in consultation with the industry, would be in place within a few months time to give concrete shape to the proposal.

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Upcoming Events

1	Event	Interphex China 2008
	Date	May 20 - 22, 2008
	Venue	Dalian World Expo Center, Xinghai Bay, Dalian, China
	Highlights	Overview of China National Pharmaceutical Market Trends in the World Pharmaceutical Ingredients Market Policy Advices on Centralized Drug Purchase by Tender Developing & Implementing 'Effluent Standards of Pollutants from Pharmaceutical Industries' Intellectual Property Protection of New Drug in China Focus on Drug Price Administration in China
	Contact Details	The Organising Secretary, Reed Exhibitions China Unit 4-5, Level 12, Office Tower E1, The Towers, Oriental Plaza, No.1, East Chang An Ave, Dong Cheng District, Beijing 100738 , China Tel: +86 10 8518 9070, Fax: +86 10 8518 9060 Email: zhen.tan@reedsinopharm.com, Website: www.interphexchina.com
2	Event	Biotech China 2008
	Date	May 28 - 30, 2008
	Venue	Intex Shanghai, 88 Loushanguan Rd, Shanghai 20036, China
	Highlights	The event is the only international exhibition in China that focuses on biomedicine, gene-technology and life science. It has become the well-known and highly professional expo in this particular field with widely acknowledged fame in both China and the whole Asia region. Serving as an international fair which facilitates technology discussion, trade negotiation and business cooperation, it has been a not-to-be-missed purchasing platform for manufacturers, suppliers and end-user.
	Contact details	The Organising Secretary, SMIE - World Expo (Group) Shanghai Modern International Exhibition Co Ltd Ms. Maggie Lau, Tel: (+86) 21 6238 8899, Fax: (+86) 21 6374 9188 , E-mail: info@biotech-china.com, Website: www.biotech-china.com
3	Event	Interphex India
	Date	May 29-31, 2008
	Venue	Bombay Exhibition Centre - NSE Exhibition Complex, Mumbai, India
	Highlights	Interphex India is internationally renowned for bringing together the pharmaceutical sectors' most innovative technologies, equipment, products and services, and the highest level education and insights into international standards, practices and regulation.
	Contact details	The Organising Secretary, Reed Exhibitions India, Gurgaon, India. Tel: +(91)-(124)-4686300, Fax: +(91)-(124)-4686309 Email: india@reedexpo.co.uk, Website: www.reedexpo.in;

4	Event	Interphex Asia
	Date	Jun 02-08, 2008
	Venue	Suntec Singapore International Convention & Exhibition Centre, Singapore
	Highlights	Interphex Asia is the only event dedicated to the pharmaceutical manufacturing industry in Asia. The event is the platform to network, meet industry suppliers and get updates on industry developments.
	Contact Details	The Organising Secretary, 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.sg
5	Event	Active Pharmaceutical Ingredients
	Date	June 2-4, 2008
	Venue	NH Amsterdam Centre Hotel, Netherlands
	Highlights	This course is for individuals working in all phases of human and veterinary Active Pharmaceutical Ingredients (API) production and control including: Pilot and commercial production, QA/QC, Regulatory affairs, Process development, Engineering and Management.
	Contact details	NH Amsterdam Centre Hotel, Stadhouderskade 7, 1054 ES Amsterdam, The Netherlands, Phone: +31/20/6851351, Fax: +31/20/6851611 E-mail clientsite@cfpa.com; Website: www.cfpa.com
6	Event	Pharma Westafrica
	Date	Jun 04-08, 2008
	Venue	Shehu Yaradua Center, Nigeria
	Highlights	<ul style="list-style-type: none"> ➤ Project the latest developments in pharmaceuticals ➤ Drugs and formulations Project the status ➤ Facilities and services on R & D, quality control, ➤ Govt. regulations. Showcase the latest products, machinery
	Contact Details	The Organising Secretary, Global resources & Projects Nig. Ltd. 40, Adegbola Street, Anifowose, Ikeja, Lagos, Nigeria. Tel: +(234)-(1)-4800305; Fax: +(234)-(1)-2557542 Email: info@westafricanhealth.com; Website: www.westafricanhealth.com
7	Event	Organic Process Research & Development
	Date	June 23-26, 2008
	Venue	Montréal, Canada
	Highlights	<ul style="list-style-type: none"> ➤ Presenting important and detailed case studies ➤ Learn to design for efficiency and optimise your development objectives ➤ Discover the strategies are evolving to meet the challenges ➤ Current developments, future trends and meet and network with key people working in the chemical and pharmaceutical industries
	Contact Details	Contact: Kate Laird, Scientific Update LLP, Maycroft Place, Stone Cross, Mayfield, TN20 6EW, UK, Tel. +44 (0)1435 873062; Fax: +44 (0)1435 872734, Website: http://www.scientificupdate.co.uk E-mail: sciup@scientificupdate.co.uk

8	Event	Cardiology Update in Primary Care Medicine:
	Date	Jun 23-27, 2008
	Venue	Hyatt Sarasota, Florida, USA
	Highlights	This presentation will teach both medical device therapies for such common patient complaints as CHF, HTN, Tachy and Brady arrhythmias. It will also teach the skills of ECG "first-read" and management options that are most needed in the settings of rural office and emergency rooms, as well as after-hours interpretation in any clinic or urgent care settings.
	Contact Details	Organiser, American Medical Seminars, Inc P.O. Box 49947, Sarasota, Florida Tel: 1-941-388-1766; Fax: 1-941-365-7073 Email: mail@ams4cme.com; Web: www.ams4cme.com
9	Event	Critical Care Symposia 2008
	Date	Jul 01-04, 2008
	Venue	Alexander Fleming Building, Imperial College, London
	Highlights	<ul style="list-style-type: none"> • An update on the latest developments in the overall ICU management of acute organ failure • A forum to share and exchange views with leading experts within the field of renal, respiratory and cardiac medicine • An opportunity to gain a raised awareness of the impact of acute organ failure on the ICU
	Contact Details	MA Healthcare Ltd, FREEPOST SO6080, Salisbury, UK Tel: +44 (0)1722 716007; Fax: +44 (0) 1722 716926
10	Event	Pharmaceutical Portfolio & Product Life Cycle Management
	Date	July 2-3, 2008
	Venue	The Hatton, London, United Kingdom
	Highlights	<ul style="list-style-type: none"> • Strategic portfolio management and planning, pairing in-house and alliance products • Emerging markets and therapy areas, pricing analysis • Future Mapping Commercial Opportunity
	Contact Details	The Organising Secretary, Simon Curtis, The Hatton, London Email: scurtis@smi-online.co.uk
11	Event	Medicare Expo
	Date	July 10-12, 2008
	Venue	Kenyatta International Conference Center, Nairobi, Kenya
	Highlights	Medicare Expo is focusing on medical equipment, Scientific and Laboratory equipment, Hospital furniture and Pharmaceutical products, to be hosted by the Health Watch magazine. Medicare Expo will enable to launch new products in a forum consisting of potential clients drawn from all over the world.
	Contact Details	The Organising Secretary, Design Initiative Limited., P.O Box 4030-00506, Nairobi, Kenya., Tel: +(254)-(2)-600815; Fax: +(254)-(2)-609348 Email: owachi@todaysonline.com

12	Event	International Bio Expo Japan 2008
	Date	Jul 02-04, 2008
	Venue	Tokyo International Exhibition Center (Tokyo Big Sight), Tokyo, Japan
	Highlights	The event includes 250 sessions/seminars, attracts strong attention as the best place for enhancing knowledge on life science. This event is widely known as a comprehensive bio event gathering all bio-related people, products, technologies and information from all across Asia.
	Contact details	The Organising Secretary, Reed Exhibitions Japan, 18F Shinjuku - Nomura Building, Tokyo, Japan, Tel: +81 (0)3 3349-8501; Fax: +81 (0)3 3349-8599 Email : bioexpo@reedexpo.co.jp; Website: www.bio-expo.jp;
13	Event	145th Annual Convention, American Veterinary Medical Association
	Date	Jul 19-22, 2008
	Venue	New Orleans, LA USA
	Highlights	New Orleans is consistently hosting successful and important meetings in all 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
14	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