



**Inside the Issue**

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- Stock Scan
- Regulatory Issues
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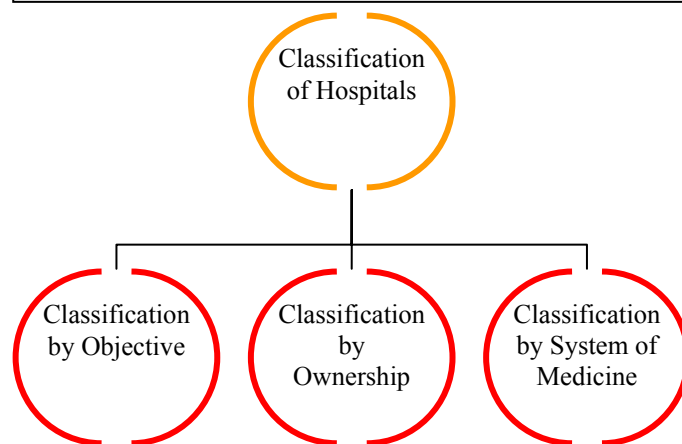


**In Focus: “Indian hospital industry – An overview”**

**Introduction**

Hospital industry structure is complex in nature, as the industry can be looked at from different angles. Each hospital is distinct in its characteristics since it differs in structure, functions, performance and the community it serves. Hospitals are normally classified into different types depending upon criteria like, objectives, ownership and system of medicine.

**Structure of Hospital Industry**



**Global Market**

**Market Overview**

Currently, Global healthcare market is on high growth. Global healthcare market is valued at USD7.72 trillion in 2007; it is growing at 7.5%, and estimated to reach USD8.30 trillion by the end of 2008.

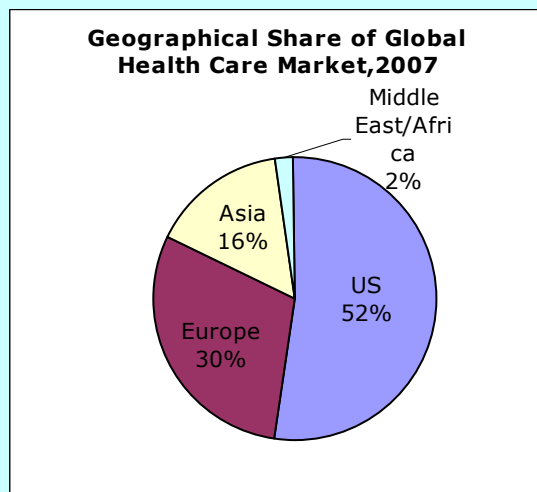
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### Geographical share of global healthcare market

Globally, healthcare industry is on a high-growth trajectory, with strong emphasis on the Asian and Middle Eastern markets. Economic growth, corresponding increase in standard of living, and aging population will continue to create a greater demand for better healthcare facilities globally. The major share of global healthcare pie is occupied by USA, which is valued at USD4.01 trillion of the global healthcare market, then followed by Europe, valued at USD2.32 trillion, Asia valued at USD1.24 trillion (16%) and Middle east/ Africa at USD0.15 trillion (2%).



Source: Cygnus Research

### Indian Market

The Indian healthcare industry is growing at an annual rate of 14%. The size of the Indian healthcare industry is estimated at INR1,717 billion in 2007, at 13% CAGR. The private sector accounts for nearly 80% of the healthcare market, while public expenditure accounts for 20%. The reasons behind the growth of private healthcare services include quality medical care, advanced technology, better service and attractive schemes. The private healthcare expenditure is financed through savings, debt, loans and sale of assets, which highlights need for health insurance and social security.

### Major Hospitals

The major hospitals include Apollo Group of Hospitals, Fortis Healthcare Group, Wockhardt Hospital, Christian Medical College, Bombay Hospital and Medical Research Centre, Lilavati Hospital, P.D Hinduja Hospital, and Jaslok Hospital.

### Key Trends

#### Mix of modern and traditional medicine

Currently, many hospitals and wellness centres are looking towards a comprehensive and holistic approach to treat the patients. Even hospitals are having tie up with holistic health centres to provide traditional treatment with conventional system. The following are the services offered in wellness centres:

- Diet and Nutrition
- Gym and Fitness
- Yoga

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- Tai Chi (Chinese therapy for improving flexibility, coordination and stress reduction)
- Herbal Medicine
- Humour therapy
- Healing Touch therapy
- Stress Management including relaxation, and meditation
- Biofeedback
- Acupuncture including techniques such as EFT (Emotional Freedom Technique)
- Pranic and Crystal Healing

A few well-being centres offering holistic treatment are as follows:

- The Golden Palms Spa and Resort in Bangaluru
- The Ananda Spa in Rishikesh
- The Ayurvedgram in Bangaluru
- The Vedic Village: spa and wellness centre in Kolkata
- Soukya in Bangaluru

### Health cities

Encouraging trends on improved healthcare facilities are initiating corporate hospitals to set up state-of-the-art health cities in India. Some of the major corporate hospitals are looking to invest and to provide better services to the large population in major Indian cities by offering facilities such as hotels, residential facilities, and recreational facilities of spa, gym and even golf courses. In the next five years, around 15-20 health cities are expected to come up in India. There are few health city plans in the pipeline which are:

- MIOT Hospitals, Chennai, have plans to set up a multi-specialty medical city
- Reliance ADAG has expressed interest in building a 60 acre health city in Kolkata
- CMCH, Ludhiana has initiated an USD12.2 million Medicity project in the state

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Upcoming Health Cities				
S. No.	Health city	No. of beds	Area (acres)	Investment (USD million)
1	Apollo Medicity, Gurgaon	700	33	243
2	Fortis Medicity, Gurgaon	600-800		293
3	Fortis Medicity, Lucknow	800	52	122-195
4	Dr Naresh Trehan's Medicity, Gurgaon	1,600	93	293
5	Nagpur Health City, Nagpur	2,000	100	NA
6	Chennai Health city, Chennai by Global Group	1,000	46	245
7	Bengal Health City	50,000	800	487
8	Narayana Health City	5,000	100	488
Source: IBEF, Cygnus Research				

### Hospotels

In the healthcare industry, Hospotels is an emerging trend and novel concept in India where hotels are being included in the hospital campus. It will provide comprehensive services to their visitors and patients attendants in addition to basic health services. Moreover, hotels and restaurant chains are actively getting into opening of food outlets at hospitals. Even many major hospitals have tie-ups with leading star hotels and airlines for their international patients.

### Outlook

The rising demand for healthcare services offers opportunities for corporates, medical equipment manufacturers and different service providers. Advanced technology in diagnosis and treatment, coupled with various systems of medicine, is attracting domestic and international patients. Private hospitals with super-speciality treatments are catering to patients from other countries. Moreover, top players are providing a blend of modern and traditional medical treatment to their patients by tying up with holistic health centres.

By 2025, the population of India will reach 1.4 billion, 45% of which will be urban adults (>15 years). To cater to this demographic change, the healthcare sector has to improve its contribution to GDP to 8-10%. By then, the top ten leading hospitals will capture as much as 30% of the market. The leaders in the Indian healthcare sector will be in a position to provide world-class services at affordable prices. Consequently, the total healthcare market will rise from INR1,717 billion in 2007 to more than INR3,163 billion in 2012, with 13% CAGR. According to CII-McKinsey report 2008, the healthcare sector can contribute 6-7% to the GDP and increase employment by at least 2.5 million by 2012.

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## News Briefs

### INTERNATIONAL

#### AMERICAS

#### Marketing

##### USA: MediGene sells Oracea's European rights to Galderma

MediGene AG has sold the European rights of the dermatological product Oracea, for the treatment of rosacea to Galderma Laboratories, Inc, the US holding company of Galderma Pharma SA, a global specialty pharmaceutical company focused on dermatology. MediGene AG will receive successive milestone payments totalling up to €32m. Depending on market launch and sales revenues achieved by Galderma with Oracea, MediGene will receive successive milestone payments totalling up to €24m. The sale of the rights to Galderma represents a major step in the implementation of MediGene's strategy of focusing on the areas of oncology and immunology.

##### USA: Santarus to promote Depomed's Glumetza products in US

Santarus Inc and Depomed Inc has entered into an agreement granting Santarus exclusive rights to promote Depomed's Glumetza (metformin hydrochloride extended release tablets) prescription products in the US. Glumetza is a once-daily, extended-release formulation of metformin that incorporates patented drug delivery technology and is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Glumetza may be used concomitantly with a sulfonylurea or insulin to improve glycemic control in adults. Glumetza is available in 500mg and 1000mg tablets.

##### USA: Santhera's Friedreich's Ataxia drug Catena gets approval

Santhera Pharmaceuticals, a Swiss specialty pharmaceutical company focused on neuromuscular diseases, announced that Health Canada has approved with conditions SNT-MC17/idebenone for the treatment of Friedreich's Ataxia. Health Canada's decision is the first marketing authorisation worldwide for any Friedreich's Ataxia therapy. The new drug will be marketed in Canada under the brand name Catena. Launch of Catena is anticipated for the end of October 2008.

##### USA: Taro receives final FDA approval for prescription Cetirizine Syrup ANDA

Taro Pharmaceutical Industries Ltd has received final approval from the US Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for prescription Cetirizine Hydrochloride Syrup (1mg /1mL) (cetirizine syrup). Taro had received tentative approval for this ANDA in October 2007. The company plans to market the product through its US affiliate, Taro Pharmaceuticals USA, Inc.

##### USA: Allergan receives USFDA for TRIVARIS(TM)

Allergan, Inc, US Food and Drug Administration (FDA) has approved TRIVARIS (triamcinolone acetonide injectable suspension 80mg/mL), a synthetic glucocorticoid corticosteroid with anti-inflammatory action. It is delivered through intravitreal injection; the ophthalmic indications for TRIVARIS include sympathetic ophthalmia, temporal arteritis, uveitis, and ocular inflammatory conditions unresponsive to topical corticosteroids. These are inflammatory conditions that can result in vision loss.

##### USA: Teva introduces first generic Lamictal(R) tablets in the United States

Teva Pharmaceutical Industries Ltd has introduced first of its generic version of Lamictal (Lamotrigine) Tablets, 25mg, 100mg, 150mg, and 200mg. Teva's Lamotrigine tablets are AB-rated generic equivalent of GlaxoSmithKline's Lamictal Tablets, and are indicated as adjunctive therapy in the treatment of partial seizures and the generalised seizures of Lennox-Gastaut syndrome, for conversion to monotherapy in adults with partial seizures who are taking certain other antiepileptic agents, and for maintenance

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treatment of Bipolar I Disorder. The brand products had annual sales of approximately USD2.2 billion in the United States for the twelve months that ended March 31, 2008.

#### **USA: Response Biomedical receives US FDA clearance for RAMP(R) NT-proBNP Test**

Response Biomedical Corporation has received regulatory clearance from the US Food and Drug Administration (FDA) to market the RAMP(R) NT-proBNP Test. It is an aid to the rapid diagnosis of heart failure (HF). NT-proBNP Test is emerging as superior marker for the diagnosis of HF. It has significant advance as it supports the drive for speed and accuracy of diagnosis for patients presenting in emergency rooms and for early detection in ambulatory care. Hospital can have standardised clinical decision points for NT-proBNP in both their emergency rooms and central laboratories. The addition of the innovative NT-proBNP Test expands the menu of the RAMP200 analyzer for the rapid assessment of patients with symptoms of cardiovascular disease.

#### **USA: Blood pressure drugs may protect against Alzheimer's**

The use of blood pressure drugs called angiotensin receptor blockers (ARBs) is associated with lower incidence and slower progression of Alzheimer's disease, according to researchers at the Boston University School of Medicine. The study found that people with Alzheimer's disease or dementia who took ARBs were up to 45% less risk to develop delirium, to be admitted to nursing homes, or to die. Patients who suffered strokes before or during being diagnosed with Alzheimer's or dementia seemed to especially benefit from taking ARBs. Patients who are suffering from dementia, with use of ARBs might delay deterioration of brain function.

#### **USA: FDA approves Energex Systems, Inc non-drug therapy for HIV Research**

Energex Systems, Inc, got approval from the Federal Food and Drug Administration (FDA) to utilise its experimental HemoModulation(TM) therapy in a clinical trial of HIV infected patients. The main purpose of the study will be to demonstrate safety and monitor viral load changes in patients who are not yet eligible for antiviral drug therapy. HemoModulation(TM) therapy is an extracorporeal treatment which involves in exposing a small amount of an infected subject's blood (3-4%) to a precise amount of ultra-violet light, for a precise amount of time. During this process, any pathogen in the blood that is directly exposed to the Ultra-Violet energy is inactivated. After exposure, the blood carrying the inactive pathogen is returned to the patient through the same portal it was drawn from. The hypothesis is that UV-inactivated virus will serve as an autologous vaccine and stimulate the patient's immune system against their own strain of virus.

## **CORPORATE**

### **M&A**

#### **USA: Dyax Corp and AVEO announce antibody library license agreement**

Dyax Corporation and AVEO Pharmaceuticals, Inc announced that Dyax has granted AVEO a non-exclusive license to Dyax's proprietary antibody phage display libraries for the discovery and development of therapeutic antibodies. Dyax's human antibody phage libraries combine gene fragments from human donors with strategically designed synthetic DNA, and are used to identify high-affinity human antibodies that bind to numerous therapeutic targets, including cell surface proteins such as tumour cell markers, viral antigens, enzymes, and glycoprotein.

#### **USA: Medivisor Inc new sales and marketing agreement with Cura Pharmaceutical**

Medivisor Inc has signed a new sales and marketing agreement with Cura Pharmaceutical for the marketing of Mucotrol(TM) in the United States. The groundbreaking drug Mucotrol(TM) is an oral gel wafer that received 510-K approval as a device from the FDA in late November 2004, as a treatment for mouth sores related to chemotherapy. Cura will supply and distribute Mucotrol(TM) with Medivisor handling the marketing and sales. Under the terms of the new agreement both parties agree to now share in the net profit.

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**R&D****USA: EpiCept, GNI partner to develop anti-viral hepatitis drug in Asia**

GNI Ltd, a leading biopharmaceutical company in Japan and China, and EpiCept Corporation, a US-based specialty pharmaceutical company, announced that they have reached agreement to develop a new therapeutic drug, EP1013, in Asia, Australia, and New Zealand, for late-stage viral infection-induced hepatitis. EpiCept will retain the rights in the rest of the world. GNI's wholly owned subsidiary, Shanghai Genomics, will start preparation for pre-IND and clinical development in China immediately. The corporate peoples are interested to establish this collaboration to accelerate the development of EP1013 for a therapeutic area which is outside the core focus areas in oncology and pain management. Caspase inhibitors may provide a new therapeutic modality for the treatment of degenerative diseases that involve apoptotic cell death, CEO said.

**Middle East****Israel: Teva acquired of Bentley Pharmaceuticals**

Teva Pharmaceutical Industries Ltd has acquired Bentley Pharmaceuticals, Inc, which will operate in Spain under the Teva name. Bentley consisted solely of its generic pharmaceutical operations, following the spin-off of its drug delivery business to its stockholders on June 30, 2008. The aggregate purchase price paid by Teva was approximately USD360m in cash, or approximately USD14.82 per Bentley share. After this acquisition, it is expected to provide Teva a platform to capture a leading position in the Spanish generic market. Bentley manufactures and markets of 130 pharmaceutical products in various dosages and strengths, as both branded generic and generic products, to physicians, pharmacists and hospitals.

**Europe:****UK: Orchid gets EU nod for piperacillin, tazobactam injections**

The Chennai-based generic pharma major, Orchid Chemicals & Pharmaceuticals Ltd has received Marketing Authorisation (MA) approvals for piperacillin and tazobactam injections for marketing in the European Union countries. Orchid filed the MA for this product with the UK MHRA through the DCP (de-centralised procedure) route enabling the company to launch the product across EU countries, corporate spokesperson said. The company has planned to launch this product through the exclusive marketing alliance with Hospira for the EU market and given the limited competition envisaged in this product.

**Germany: Cenix Bioscience signs research agreement with Regulus Therapeutics**

Cenix BioScience GmbH (Dresden), a leading specialist in advanced RNA interference (RNAi)-based research services today announced that they have signed a research agreement with Regulus Therapeutics LLC to advance the latter's efforts in the discovery of novel therapeutic miRNA modulators. Cenix use its well-established expertise in combining high through put applications of small RNA-based gene silencing with high content phenotypic analyses in cultured human cells. The company will thereby screen libraries of synthetic miRNA modulators designed and produced by Regulus, using multi-parametric assays to identify novel lead molecules offering highest therapeutic potential in the area of immunology and inflammation.

**UK: Janumet™ approved in the European Union for treatment of type 2 diabetes**

Merck & Co, Inc's new combination product for type 2 diabetes has been granted a marketing authorisation from the European Commission (EC). 'Janumet' (sitagliptin/metformin) helps patient lower their blood sugar levels to reach their treatment goal through the efficacy of sitagliptin, a DPP-4 inhibitor, and metformin, a mainstay of diabetes therapy. Janumet has a low risk of weight gain and hypoglycaemia compared with metformin alone and targets all three key defects of diabetes: insulin deficiency from pancreatic beta cells, insulin release, and overproduction of glucose by the liver. The product is now approved by the 27 member countries of the European Union.

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**UK: Wyeth and Progenics receive approval from European Commission for Relistor**

Wyeth Pharmaceuticals and Progenics Pharmaceuticals, Inc, have received marketing approval for Relistor™ (methylnaltrexone bromide) subcutaneous injection from the European Commission. Relistor is now approved in the 27 member states of the European Union as well as Iceland, Norway, and Liechtenstein for the treatment of opioid-induced constipation (OIC) in advanced illness patients who are receiving palliative care when response to usual laxative therapy has not been sufficient. Relistor is the first approved treatment for OIC in the European Union.

**Asia Pacific****Corporate****Policy and Regulations****US FDA commences surprise re-inspections of all approved facilities in India**

US FDA has commenced surprise inspections of all its approved facilities in India, as fallout of the recent allegations of exporting substandard drugs by Ranbaxy Labs. US FDA has already started surprise inspections in some plants in the country. There are more than 100 such plants in different parts of the country. Though the authorities and companies term plant inspections as a routine affair, what makes them different after the Ranbaxy-FDA imbroglio is that it has started inspecting the plants without any prior intimation to the companies. The origin of the present Ranbaxy-US FDA issue is attributed to such an inspection by the US agency in 2006, at the company's Paonta Sahib Plant in Himachal Pradesh. Ranbaxy is not the only Indian company that has had a run in with US FDA.

**China: Pharma Dept likely to sanction on-site inspection of Chinese mfg facilities**

The pharmaceuticals department is likely to approve the suggestion of sending a technical officials delegation for on-site inspection of the facilities in China supplying pharmaceutical ingredients to India, with a view to ensure quality of the products being imported. The department is learnt to have agreed to discuss the matter with the Drug Controller General of India (DCGI) office and take necessary steps in this regard, as repeatedly demanded by the industry, especially the bulk drug manufacturers who heavily depend on China for import of raw materials and ingredients. The bulk drug registration fee should be hiked to at least USD20,000 from USD2000 and registration be given only after sufficient inspections, the industry had demanded.

**Japan: Nu Skin enters joint R&D relationship with Toyo Bio-Pharma**

Nu Skin Enterprises, Inc announced that the company has signed a memorandum of understanding for a joint research and development relationship with Toyo Bio-Pharma, Inc. (a subsidiary of Toyo Shinyaku, Japan), a natural products manufacturer with facilities in the United States and Japan. To facilitate this relationship, the companies established a new joint venture, NU Toyo Research, Inc., in the United States. Toyo Bio-Pharma is a subsidiary of Toyo Shinyaku Co, Ltd, a research-driven manufacturer committed to providing consumers and clients with high-value ingredients derived from nature. With the most advanced instrumentation, continuous research and commitment to quality and integrity, Nu Skin Enterprises, Inc is a global direct selling company operating in 47 markets throughout Asia, the Americas and Europe.

**Japan: Cetuximab receives approval in Japan for use in advanced colorectal cancer**

ImClone Systems Incorporated, a global leader in the development and commercialisation of novel antibodies to treat cancer, Erbitux (Cetuximab) has received marketing authorisation in Japan for use in treating patients with advanced or metastatic colorectal cancer (mCRC). This approval allows for the use of Erbitux to treat patients with epidermal growth factor receptor. With this approval, Erbitux is the first ever EGFR-targeted monoclonal antibody to be submitted for and receive marketing authorisation in Japan.

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## National News

### Pharmacy Council of India notifies procedure and fees structure for pharmacy institutions to apply for Pharm D course

The Pharmacy Council of India (PCI), in the third face of launching the Pharm D course in the country from the year 2008-09, has notified the procedures and fees structure for pharmacy institutions to apply for the council's accreditation to commence the advanced course. The scheme, published in the website of the council along with the online application forum, insists that the institutions or individuals who apply to start Pharm D course should provide 300-bed hospital facilities as prescribed under the regulation. Further, the institution should provide necessary additional infrastructural facilities as prescribed by the PCI under Appendix - B of Pharm D regulations. However, the institutes cannot open the course in a hired or rented building.

### Employees State Insurance Corporation plans to set up 11 medical colleges, starting PG & diploma courses in medicine from April 2009.

With an initiative to meet the increasing demand of medical professionals in the country, the Employees State Insurance Corporation (ESIC) is firming up its plans to foray into the education sector on a big scale. The corporation plans to set up eleven medical colleges in various parts of the country including one in Tamil Nadu. As part of its new initiative, the ESIC will start post graduate degree (MD & MS) and diploma courses from next academic year. For the first time ESI Corporation is starting educational courses meant for good quality health care services. The new initiative will be in association with some super specialty hospitals in every state, Dr J P Bhasne, medical commissioner of the ESI Corporation told Pharmabiz.

### India, Brazil identify pharma as potential sector for greater cooperation

India and Brazil are expected to strengthen its bilateral trade relations in the pharmaceutical and health sectors and have identified health policies, sanitary regulations, traditional medicines, production of medicines and medical equipments as potential areas for cooperation. India has already an agreement with Brazil in 1998 in the field of health and medicine, to promote cooperation in the areas of biotechnology, health and pharmaceutical products, management of public health system, traditional medicines, infectious diseases, maternal and child healthcare and family planning.

### India: IDMA to meet chemicals ministry officials to expedite price hike of medicines

In an effort to convince the government to raise the formulation prices in view of the sharp increase in the cost of bulk drugs, intermediates and packaging materials, the Indian Drug Manufacturers Association (IDMA) has planned to meet the officials of the Department of Pharmaceuticals. IDMA has already submitted the data on raw materials and packaging materials price increase as per the directions of the ministry. The IDMA officials has earlier met the higher officials in the ministry to convey their apprehension on the increasing cost increase and the hardships in complying with the drug price control norms of National Pharmaceutical Pricing Authority (NPPA) in this context.

### India: Gujarat govt framing new industry policy, to benefit pharma, biotech sectors

Gujarat government is finalising the new industrial policy for the period 2009-2013 with a focus on industry friendly labour law and specific norms for the pharma Special Economic Zones. According to official sources, the new industrial policy is currently in the discussion stage and the draft policy is yet to be prepared. Now, the government is reframing the policy to include clear-cut and flexible norms for the special zones, informed industry sources. Savli Biotech Park, the prestigious project undertook by the GSBTM is also seeking SEZ status from the government, for the benefit of biotech industry in the state. The government is likely to announce special incentives and subsidies for the industry through the policy, expects the industry sources.

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**India: NPPA notifies overcharging cases involving 312 drugs, as companies fail to comply**

With manufacturers failing to furnish details of many of their products under one or other pretexts in prima-facie overcharging cases, the National Pharmaceutical Pricing Authority (NPPA) has for the first time notified the cases involving 312 drugs belonging to market leaders including Ranbaxy, Reddy's and Cadila. Himachal Pradesh has 27 and Delhi has 14 cases..

**India: Pharma majors focus on speciality, niche drugs to ride global boom**

Speciality and niche therapeutic segments are expected to increase their share in the global pharma market to corner up to 80% of the total 30 innovative new medicines introduced this year. Overall growth in the speciality driven market this year is pegged at 15% to reach a market size of USD300 billion. In this market, oncology is contributing upto 17%, apart from other high potential areas including bio-generics, peptides and penems. Top domestic companies like Dr Reddy's, Ranbaxy, Biocon and Glenmark are working on this speciality products by entering into alliances with innovator companies, to tap the huge opportunity.

**India: Apollo Hospitals to expand in Gujarat**

Apollo hospitals have a Joint Venture (50:50) with Cadila Pharmaceuticals and plan to invest INR2 billion over the next two years. The company's expansion plans call for a 1,000-bed capacity increase across hospitals in a variety of mid-sized and small cities. Most recently, Apollo Hospitals-Ahmedabad has initiated hospital projects in Gandhidham and Vadodara cities of Gujarat.

**India: Ranbaxy launches omeprazole capsules in US**

Ranbaxy Pharmaceuticals Inc (RPI), a wholly-owned subsidiary of Ranbaxy Laboratories Limited (RLI), Gurgaon, India, announced that under an agreement with Astrazeneca Pharmaceuticals it has launched an authorised generic of omeprazole 40mg capsules in the US healthcare system. Omeprazole 40mg is indicated for the treatment of acid-related disease, including gastric ulcer and Zollinger-Ellison syndrome.

## Product Focus – Monoclonal Antibodies

### Monoclonal Antibodies

#### Introduction

Antibodies are protein molecules that are used by immune system to identify and neutralise the foreign objects like bacteria and viruses. Each bacterium recognises a specific antigen as a target.

Types of antibodies
IgA
IgD
IgE
IgM
IgG

**Monoclonal Antibodies:** The monoclonal antibodies (mAbs) are produced by removing the B cells from the spleen of the vertebrate which is active or challenged with antigen and is fused with the myeloma tumour cells, which can grow indefinitely in a culture called as hybrid mass. This is further diluted to the considerable extent by developing colonies of different and specific antibodies. Monoclonal antibodies as drugs are mainly used for transplant rejection drugs, cardiovascular, Oncology, viral infection, inflammatory, etc.

**Polyclonal Antibodies:** If a foreign substance is injected into a vertebrate like mouse or human body, the immune system of the vertebrates will turn B cells into plasma cells and they start producing the antibodies, which bind to the antigens. Each B cell will produce a specific kind of antibodies. Different B cells produce different kinds of antibodies and these antibodies are called as polyclonal antibodies.

#### Classification of Therapeutic Monoclonal Antibodies

Monoclonal antibodies utilised in therapy are classified into murine antibodies; chimeric antibodies; humanised antibodies; and fully human antibodies. These different types of antibodies are distinguishable by the percentage of mouse to human parts making up the antibodies. A murine antibody contains 100% mouse sequence; a chimeric antibody contains approximately 30% mouse sequence, and humanised; and fully-human antibodies contain only 5-10% mouse residues.

#### Companies involved in the development of monoclonal antibodies

Company	Country
Immune system therapeutics, Patrys, Phylogica, Arena, Cytopia, CSL	Australia
AZ china, Aida pharmaceuticals	China
Sinomab	Hong Kong
Japan tobacco, Takeda, Ono pharmaceuticals, Jyowa Hakko kogyo, Daiichi sankyo, Kirin pharma, Eisai, Seikagaku corporation, Kureha corporation, Taisho pharmaceuticals	Japan
Daewoong pharmaceuticals	Korea
Serum institute of India, Glenmark pharmaceuticals, Biocon, Dr reddy's laboratories,	India
CP Guojian, Medipharm, Biotech, Tianguangshi, Welson, Hoist, Auam Human antibodomics	China

Source: Biospectrum ABLE; Cygnus Research

#### Comparison of monoclonal & polyclonal antibodies

Polyclonal antibodies	Monoclonal antibodies
Derived from different B Lymphocytes cell lines	Derived from a single B cell clone
Batch to Batch variation affecting Ab reactivity & titre	mAb offer Reproducible, Predictable & Potentially inexhaustible supply of Ab with exquisite specificity
Not powerful tools for clinical diagnostic tests	Enables the development of secure immunoassay systems

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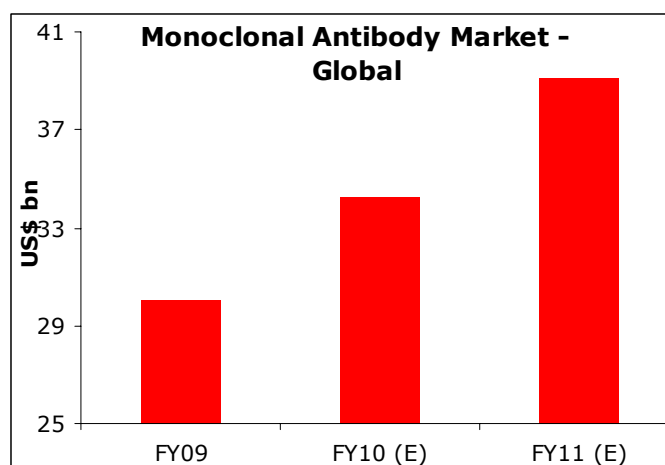
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## Monoclonal Antibody Market

**Global:** Monoclonal Antibody based therapies have been posting the fastest growth within the protein therapeutics market. The monoclonal antibody market is described as one of the most lucrative sectors of the pharmaceutical industry, registering a 14.2% growth in 2008-09 to USD20 billion. According to the industry estimates, the mAbs market will witness a two-fold increase in the next two-three years. This growth will continue in the coming years, boosted by a number of new mAbs on the market, new indications for successful medications, and their ability to treat conditions and diseases. It has the potential to increase in value over the years and reach USD30 billion in 2010, driven by technological evolution.



Source: Biospectrum Asia; Cygnus Research

**Asia:** The world monoclonal antibody market in Asia is estimated at USD200m in 2008-09. The favourable regulatory climate and mechanism that facilitates accelerated approval provides an attractive landscape for the development and production of innovative therapeutic antibodies in Asia for both the unique Asian market as well as the global market. With its high target specificity, monoclonal antibody is one of the most popular methods for diagnosis and treatment of various cancers as it offers reduced toxicity and side effects.

## Major Players and Their Contribution

Genentech, Biogen Idec, MedImmune, Johnson & Johnson and Abbott hold a major share in the global mAb market. The companies that were dealing with direct sales of monoclonal antibodies are expected to increase from 17 in 2004 to 36 by 2010, as new products and companies flood the market. It also forecasts that by 2012, a number of additional players will have significantly enhanced their presence in the mAb segment, with four companies—Biogen Idec, Amgen, Novartis and UCB Pharma—generating mAb sales in excess of USD1 billion each.

Over 150 companies are currently working on more than 400 antibody-based drugs that are in development for the treatment of cancer (solid tumours, non-Hodgkin's lymphoma), immune and inflammatory diseases, transplant rejection, rheumatoid arthritis, Crohn's disease, psoriasis, lupus, multiple sclerosis, asthma, age-related macular degeneration, HIV and Alzheimer's disease.

- BioTech Pharmaceutical, a high tech joint venture between China and Cuba, has successfully developed the first recombinant humanised monoclonal antibody for cancer treatment.
- A&G Pharmaceutical and Celltrion entered into an agreement for clinical production of a novel theranostic monoclonal antibody.

## Development Focus

The development focus of the industry is moving away from murine and chimeric antibodies, to humanise and, in particular, fully human technologies. The market is expected to continue to evolve as antibody engineering capabilities advance further, including more efficient manufacturing and alternative delivery methods, broadening the commercial viability of antibodies treatments in a wider range of diseases. A wave of fully-human products is expected to be launched from 2007 onwards, accounting for 12 of the 20 launches between 2007 and 2010. The attrition rate for monoclonal is not as high as small molecular drugs.

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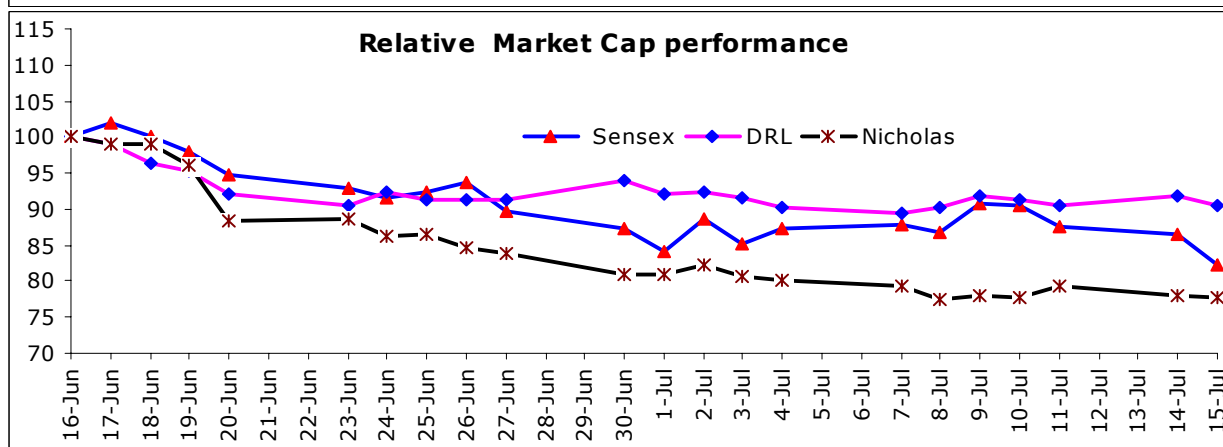
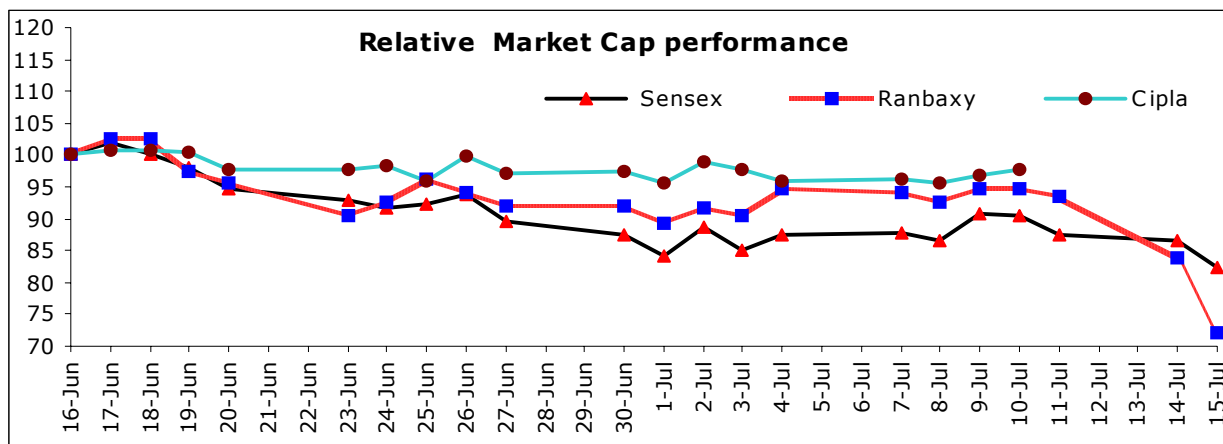
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## Outlook

The industry has the potential to double the number of approved mAbs, and also double the size of global mAbs market, as antibodies currently have no prospect of generic competition. The world's monoclonal antibody market is expected to be USD39.12 billion by 2012; 20% of new molecules in the approval pipeline at USFDA are monoclonal antibodies. The big pharma companies licensed 70% of their research molecules from small and medium biotech companies and there is a huge unmet medical need for life-threatening diseases. To bridge this gap, the industry needs to continue to develop with technology integration and market expansion. The market success will depend on strategies targeting shorter development times, higher success rates, innovative molecular engineering, robust intellectual property protection and the development of cost-effective manufacturing.

## Stock Scan



Source: BSE India; Cygnus Research

	16 June – 21 June	22 June – 28 June	29 June – 5 July	6 July – 15 July
<b>BSE Sensex</b>	The markets fell sharply by 618.33 points or 4.07% to reach 14571.29 points after inflation soared to 11.05%.	During this period under consideration, Sensex fell by 769.07 points or by 5.28% due to weak global markets and worries on domestic interest rates. Sensex down to 13802.22.	The Sensex slumped 348.22 points or 2.52% to reach 13454.00. Soaring Crude oil prices and weak global cue affected Index during this period under consideration.	Poor industrial output growth in May 2008, soaring crude prices and rising inflation made Sensex fall by 777.81 points or 5.78% during this period.
<b>Ranbaxy</b>	The Company and promoters signed agreement to sell of their entire stake 34.8% to the Daiichi Sankyo. And the share price fell to 4.42%	The share price has increased by 1.87% as the company has entered into agreement with Gurgaon based firm.	Positive sentiments in the market have increased the share price by 2.93%.	The share price has declined drastically 23.49% during this week. It is possible because American health regulator USFDA has filed a motion in a US court seeking certain documents from Ranbaxy.

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<b>Cipla</b>	The stock price decreased by 2.15% as major players did not perform well during this period.	The share price has declined by 0.73% as it moved in tandem with BSE sensx.	During this week, the share price has shown negative growth of 1.49%	Announcement of AMJ08 quarter results led to decrease in share price by 0.38%
<b>DRL</b>	The share price declined by 7.92% due to the bullish market	During this period, the company launched a new combination product. The share price has increased by 0.98%	The company announced the annual results of 2007-08; share price declined by 3.74%	During this period, the company got product approval from USFDA and signed agreement for global distribution. The share price increased by 1.12%
<b>Nicholas</b>	Share price has declined by 11.53% possibly due to the discussion with MPM capital and Orbimed to acquire 15% stake from the companies.	During this week, share price has decreased by 5.35% from INR329.9 to INR 312.3	The share price has declined by 0.76%. It is moved in tandem with BSE sensx.	The share price declined by 2% due to the bullish market

## Regulatory Issues

### International

#### FDA Announces Improved Policies Regarding Transparency, Public Disclosure for Advisory Committees

The Food and Drug Administration announced several improved policies and procedures strengthening its management of FDA advisory committees. The improvements include stricter limits on financial conflicts of interest for committee members, improved voting procedures, and improvements to the processes for disclosing information pertaining both to advisory committee members and to specific matters considered at advisory committee meetings. The FDA announced the availability of the guidance documents in today's Federal Register; copies of all of the guidances are available on FDA's website. Most of the changes in the final guidance documents will go into effect immediately, and all are expected to be fully implemented within 120 days.

#### FDA Approves 2008-2009 Flu Vaccines

The U.S. Food and Drug Administration (FDA) announced that it has approved this year's seasonal influenza vaccines that include new strains of the virus likely to cause flu in the United States during the 2008-2009 seasons. The six vaccines and their manufacturers are: CSL Limited, Afluria; GlaxoSmithKline Biologicals, Fluarix; ID Biomedical Corporation of Quebec, FluLaval; MedImmune Vaccines Inc., FluMist; Novartis Vaccines and Diagnostics Limited, Fluvirin; and Sanofi Pasteur Inc., Fluzone.

### National

#### New amendment to Schedule Y to strengthen pharmacovigilance protocols

The Union government is all set to amend the Schedule Y in a bid to strengthen the pharmacovigilance protocols further in the country. The office of the DCGI has initiated efforts to take a re-look at the current status of the Schedule Y. This regulation, enacted in 1998 and amended in 2005, has provided the necessary boost to the clinical trial business in India. The proposed amendment will now make pharmacovigilance in post marketing of drugs more stringent. A set of fresh rules are being made to ensure academia and industry partner with the regulatory authority for the management of risks associated with use of medicines.

#### NPPA hikes prices of ranitidine, metronidazole, cefotaxime and 3 other bulk drugs

The National Pharmaceutical Pricing Authority (NPPA) has revised upwards the prices of six bulk drugs ranging from 2 per cent to 13 per cent on Monday. The drugs include vitamin E acetate (dl tocopheryl acetate), metronidazole, ranitidine and cefotaxime sodium (sterile) and the new prices will be effective within 15 days. Under the sub-paragraph (5) of paragraph 3 of the Drugs (Prices Control) Order, 1995, NPPA fixed the new price of vitamin E acetate (dl tocopheryl acetate) at INR 768 which was INR.754. The price of parachlorometaxyleneol (PCMX) is revised to INR 273 per kg from INR. 248 and metronidazole price hiked to INR 526 per kg from INR.471.

#### Small Scale Industry upset over railways changed drug procurement norms in favour of large cos

The small and medium scale pharma manufacturers are upset over the recent changes in the terms and conditions for procurement of medicines by the railways and termed it as another move to 'kill the small scale sector'. Alleging that 'some vested interests' were playing behind the move, the small scale leaders have made representations to the railway minister Lalu Prasad Yadav and are trying to meet him personally, seeking to rescind the amendment which deprived the small scale units of level playing grounds.

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## Upcoming Events

<b>1</b>	<b>Event</b>	<b>Indonesia International Bio Pharma Expo</b>
	<b>Date</b>	August 20-23, 2008
	<b>Venue</b>	Jakarta International Expo (JIExpo), Indonesia
	<b>Highlights</b>	Indonesia International Pharma Expo is an International Exhibition on Pharmaceutical, Raw Materials, Active Ingredients, Processing Machinery, Packaging Machinery, Equipments. The manufacturers and suppliers of process plant and equipment, for this growing industry, would attend the exhibition, all under one roof.
	<b>Contact Details</b>	The Organizing Secretary, Krista Media Pratama PT., Krista Exhibitions, Jln.Blandongan 28 DG, Jakarta, Indonesia., Tel: +(62)-(21)-6345861; Fax: +(62)-(21)-6340140, Website: www.kristamedia.com; Email: info@kristamedia.com;
<b>2</b>	<b>Event</b>	<b>Saigon MediPharm &amp; BioLab</b>
	<b>Date</b>	Aug 21-24, 2008
	<b>Venue</b>	Ho Chi Minh City International Exhibition & Convention Centre, Ho Chi Minh City, Vietnam
	<b>Highlights</b>	The objective of the exhibition will be to bring together the manufacturers and suppliers of process plant and equipment, for this growing industry, all under one roof. The exhibition will provide an excellent platform for service providers to showcase their products and services to decision makers from leading Pharmaceutical manufacturers.
	<b>Contact Details</b>	F. A. S. T. System & Management Services 18 Richards Avenue, Singapore, Singapore, Tel: +(65)-(9)-7380246; Fax: +(65)-(6)-68584490
<b>3</b>	<b>Event</b>	<b>2008 Joint meeting of the UK HESG and Nordic HESG</b>
	<b>Date</b>	Aug 27-28, 2008
	<b>Venue</b>	Aberdeen, Scotland, UK
	<b>Highlights</b>	<ul style="list-style-type: none"> <li>• Research into economic approaches to health &amp; health care;</li> <li>• Develop economic techniques to be readily applied by economists and/or health care personnel;</li> <li>• Demonstrate and test the approaches and techniques</li> <li>• Accumulate and make available to the health service a body of expertise in health economics.</li> </ul>
	<b>Contact Details</b>	Health Economics Research Unit Foresterhill , Aberdeen Tel: +44 (0)1224 553733; Fax: +44 (0)1224 550926 Email: heru@abdn.ac.uk; Web: www.abdn.ac.uk
<b>4</b>	<b>Event</b>	<b>Health India Expo</b>
	<b>Date</b>	Sep 05-07, 2008
	<b>Venue</b>	Pragati Maidan, New Delhi, India
	<b>Highlights</b>	Health India Expo is a comprehensive showcase of opportunities emerging in India's burgeoning healthcare sector. The health care sector in India offers abundant collaboration opportunities for companies and medical practitioners from all over the world. India provides opportunities for global service providers to invest in curative and preventive services in primary, secondary and tertiary care. It also provides investment opportunities in medical infrastructure and medical tourism.
	<b>Contact Details</b>	Organiser: Exhibitions India Private Limited New Delhi-110 020.,India.,Tel: +(91)-(11)-42795054; Fax: +(91)-(11)-5279 5098

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<b>5</b>	<b>Event</b>	<b>MEDi 2008</b>
	<b>Date</b>	Sep 09-10, 2008
	<b>Venue</b>	Connecticut Expo Centre, Hartford, Connecticut, USA
	<b>Highlights</b>	MEDi 2008 is the most comprehensive medical device conference and exhibition in the Northeast. The educational content of MEDi 2008 will combine high-quality scientific research data with proven, validated industry case studies, proven strategies for bringing new devices to market, legal and regulatory issues and clinical applications.
	<b>Contact Details</b>	Designing Events, 10910 Resiterstown Road, Owings Mills, United States Of America , Tel: +(1)-(410)-6545525
<b>6</b>	<b>Event</b>	<b>Medtec-China</b>
	<b>Date</b>	Sep 09-11, 2008
	<b>Venue</b>	Intex Shanghai, Shanghai, Shanghai, China
	<b>Highlights</b>	For the first time, China's medical device and equipment manufacturers will have access to hundreds of leading medical OEM suppliers from around the globe providing a vast array of equipment, materials and services.
	<b>Contact Details</b>	Canon Communications, 11444 W. Olympic Blvd., Ste. 900, Los Angeles, United States Of America, Tel: +(310)-(4)-454200; Fax: +(310)-(4)-454299
<b>7</b>	<b>Event</b>	<b>Healthcare Facilities Symposium &amp; Expo</b>
	<b>Date</b>	Sep 09-11, 2008
	<b>Venue</b>	Navy Pier, Chicago, Illinois, USA
	<b>Highlights</b>	Healthcare Facilities Symposium & Expo is the longest-running conference and exhibition dedicated to the improvement of the overall health and welfare of patients and successful business outcomes through the design element.
	<b>Contact Details</b>	Organiser: JD Events LLC; 5520, Park Avenue, Trumbull, USA Tel: +(1)-(203)-3716322
<b>8</b>	<b>Event</b>	<b>Info Dental</b>
	<b>Date</b>	Sep 12-13, 2008
	<b>Venue</b>	Dusseldorf Exhibition Centre, Dusseldorf, Nordrhein-Westfalen, Germany
	<b>Highlights</b>	Info Dental is a great opportunity for all companies in the dental industry to promote their products and services to anyone involved in the business of dentistry. Professionals from the field of dental services, production, wholesale, scientific research, information/consulting services, educational establishment, health and medicine researcher would participate.
	<b>Contact Details</b>	Messe Dusseldorf GmbH, Stockumer Kirchstrasse, 61, Messeplatz, Germany Tel: +(49)-(211)-4560900; Fax: +(49)-(211)-4560668;
<b>9</b>	<b>Event</b>	<b>Pharmatex</b>
	<b>Date</b>	Sep 16-18, 2008
	<b>Venue</b>	Radisson Hotel, Cork, Cork, Ireland
	<b>Highlights</b>	Pharmatex will provide suppliers of production technology and knowledge solutions with an opportunity to address the needs of the pharmaceutical and bio-pharmaceutical manufacturing industry in Ireland.
	<b>Contact details</b>	Mediateam Limited; Media House Park Leopardstown, Dublin, Ireland Tel: +(353)-(1)-2947787; Fax: +(353)-(1)-2947799

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<b>10</b>	<b>Event</b>	<b>Drug Delivery Global Summit</b>
	<b>Date</b>	Sep 22-23, 2008
	<b>Venue</b>	Copthorne Tara Hotel, London, United Kingdom
	<b>Highlights</b>	Drug Delivery Global Summit will bring together key decision makers in the pharmaceutical, biotech, and drug delivery fields. It covers the latest in nanotechnology, inhalational drug delivery and the latest breakthroughs in drug delivery technologies; Presentations by internationally recognised industry experts are part of the submit.
	<b>Contact Details</b>	SMi Group Ltd, Unit 122, Great Guildford Business Square, 30 Great Guildford Street, London, SE1 0HS, United Kingdom Tel: +44 (0) 20 7827 6000; Fax: +44 (0) 20 7827 6001 Website: <a href="http://www.smi-online.co.uk/events/">www.smi-online.co.uk/events/</a>
<b>11</b>	<b>Event</b>	<b>PHARMACY</b>
	<b>Date</b>	Sep 30-Oct 02, 2008
	<b>Venue</b>	Lenexpo Fairgrounds, St. Petersburg, Russia
	<b>Highlights</b>	The international exhibition Pharmacy is the largest exhibition on public healthcare in the Northwest Region of Russia. The exhibition promotes the development of co-operation and the establishment of contacts in the area of medicine between the Russian and the international community and has a priority status for Saint Petersburg. Pharmacy 2005, expected to start with a full house of 140 exhibitors promising to showcase more new products and brands than seen in years previous.
	<b>Contact details</b>	Primexpo, Russia, Saint Petersburg, 23, Malaya Morskaya Street, "Belye noch" Business-Center, Belye Nochi, Russia Tel: +(7)-(812)-3806000; Fax: +(7)-(812)-3806001