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In Focus: INDIAN OTC Market

OTC Market

Introduction

'OTC Drugs' are drugs sold legally 'Over the Counter', i.e. without any prescription of a registered medical practitioner. India does not legally recognise this phrase. Those drugs that are not included in the list of prescription, are considered as non-prescription drugs or OTC drugs. Prescription drugs fall under two schedules of the Drug and Cosmetics Rules, 1945: Schedule H and Schedule X. Drugs falling under Schedule G require the following mandatory text on the label: Caution: It is dangerous to take this preparation except under medical supervision. These drugs are not advertised to the public voluntarily by the industry. OTC market is segmented into –

- Vitamins, Minerals & Supplements
- Cough, Cold & Allergy
- Gastrointestinal
- Analgesics
- Dermatological

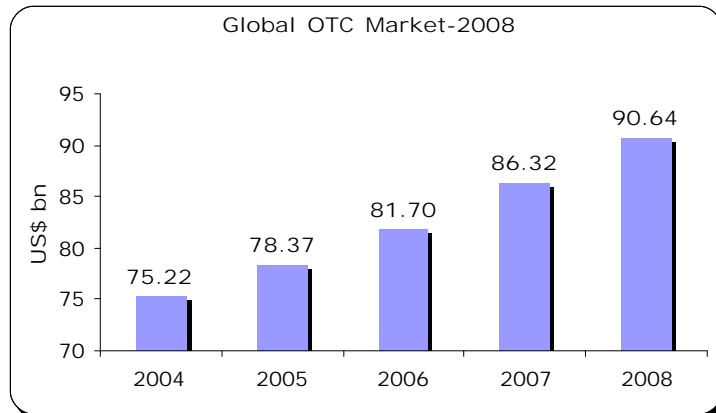
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Global OTC Market

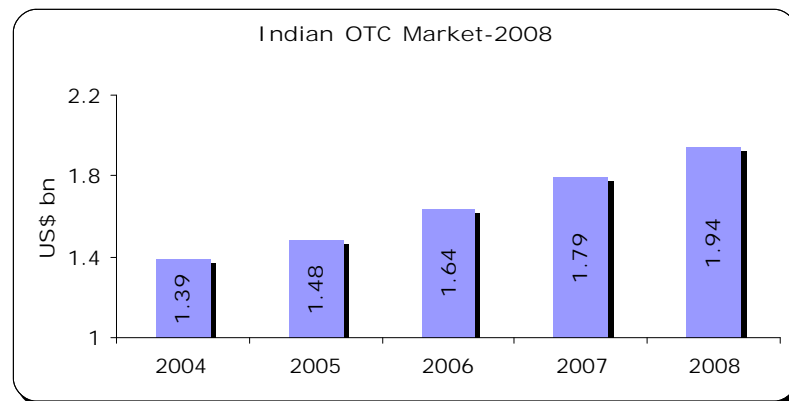
The sale of global OTC market in 2008 is estimated to be US\$ 90.64 billion, growing at a CAGR of 5% from 2004 to 2008. It is expected to reach US\$ 110.17 billion by 2012 at a CAGR of 6% during 2008-12. OTC market is driven by increase in the number of OTC consumers, especially the elderly, due to increasing population of the world and rapid economic growth in emerging markets such as India and China. Many consumers will be shifting from prescription drugs to OTC drugs.



Source: Cygnus Research

Indian OTC Market

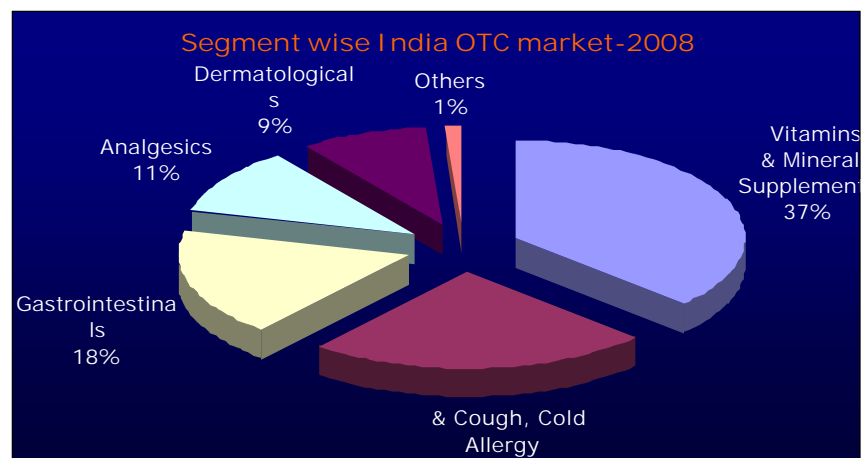
The increase in consumer spending and prevention is better than cure concept, is really driving the Indian OTC market. Indian OTC market is estimated to be US\$ 1.94 billion in 2008, growing at a CAGR of 9% from 2004 to 2008.



Source: Cygnus Research

Segment wise India OTC Market

In Indian OTC market, vitamins, minerals and supplements segment has major share at 37%; grew at 10% YoY in 2008. Cough, cold and allergy segment



Source: Cygnus Research

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occupies second place at 24%; recorded a yoy growth of 6.45% in 2008. The third segment is gastrointestinal, with an 18% share in total market and YoY growth at 6%. Analgesics segment has shown double-digit YOY growth at 12.23% in 2008 and has 11% market share. Dermatological and Others segments have market shares of 9% and 1% respectively.

OTC Products

The following are the OTC products in the Indian Market:

Sno	Brand	Major Category
1	Abdec, A -to-Z, Alamin Forte, Antoxid, Aquisol-A, Aquisol-Ceezed, Astymin	Vitamins, minerals and supplements
2	Actifed DM and Acetified & Actifed plus, Alday, Alex, Allerga, Ascoril, Avil, Benadryl	Cough, cold and Allergy
3	Anacin , Amrutanjan pain Balm, Aspro, Calpol	Analgesics
4	Ascabiol, Anovate, Arcolane Scalp, B-Text, Band-Aid, Betadine Antifungal	Dermatological
5	Nu life, Refresh tears, Tear Plus	Others

Growth driver- Consumer Awareness

The following are the growth drivers of OTC Market:

- Increased Education
- Lifestyle
- Urbanisation
- Increasing Middle class
- Pending Regulatory changes
- Consumer Awareness

Future Outlook

Demographic trends, lifestyles changes and clinical advances are transforming medicine and creating opportunities for therapeutic areas and drug types in OTC pharma. Consumers are increasingly willing to self-medicate, for convenience and cost savings in particular. New regulations are changing OTC retail channels and sales processes, including the range of products on offer. Importantly, governments and healthcare providers are promoting self-medication, viewing the process as a tool to help contain healthcare expenditure. Therefore the OTC pharma market holds high potential for continued growth in both mature and emerging geographical markets. According to Cygnus, Indian OTC market is estimated to grow to Rs. 2.84 billion by 2012 with a CAGR 10%.

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News Briefs

MARKETING

Americas

USA: Glenmark launches hypertension drug fosinopril sodium in US

Glenmark Generics Inc, USA (GGI), the US subsidiary of Glenmark Generics Limited and a leading company in the manufacture, marketing and distribution of high-quality, low-cost generic pharmaceutical products in the US, initiated the launch of fosinopril sodium and hydrochlorothiazide tablets in the US market. Fosinopril sodium and hydrochlorothiazide (HCTZ) tablets are available in both 10mg/12.5mg and 20mg/12.5mg strengths and are indicated for the treatment of hypertension

Europe

Germany: Bayer to launch OTC Omeprazole in Germany

Bayer Vital, the marketing arm of Bayer HealthCare, is to launch the proton pump inhibitor omeprazole as an over-the-counter heartburn treatment. It will first be brought to the German market next month under its existing prescription-only brand name Antra, and Bayer is expected to make it available as an OTC treatment in other European countries soon.

UK

Switzerland: New drug moxidectin being tested in Africa for river blindness

A clinical trial is being launched in three African countries of a drug that could eliminate onchocerciasis, or river blindness, one of the leading infectious causes of blindness across Africa. The drug, moxidectin, is being investigated for its potential to kill or sterilize the adult worms of *Onchocerca volvulus*, which cause onchocerciasis. "This is a devastating illness that has plagued 30 African countries for centuries, in particular the populations in the most remote areas 'beyond the end of the road'," says Dr Uche Amazigo, director of the African Programme for Onchocerciasis Control (APOC). Over 100m people are at risk of infection with onchocerciasis in Africa and a few small areas in the Americas and Yemen.

Asia Pacific

India: Ranbaxy gets nod to market Ran-Simvastatin tabs in Canada

Ranbaxy Laboratories Limited (RLL) has received final approval in Canada to manufacture and market Ran-Simvastatin 5 mg, 10 mg, 20 mg, 40 mg and 80 mg tablets (simvastatin) from Health Canada, Therapeutic Products Directorate (TPD). The total generic market size of simvastatin tablets in Canada is US\$153m (\$CAD) [IMS-CDH: October 2008]. Ran-Simvastatin tablets are indicated for use as a lipid metabolism regulator.

India: Dr Reddy's launches halometasone cream in India

Dr Reddy's Laboratories Ltd has launched Execare (halometasone cream 0.05 per cent) in India for the treatment of acute/chronic steroid responsive dermatoses and vitiligo. Execare is a potent steroid and is recommended as an alternative to dexamethasone dipropionate and mometasone furoate. The halometasone monohydrate is known to have very good anti-inflammatory action with significant safety and tolerability profile. Halometasone acts by blocking their production, thus acting as an anti-inflammatory agent. With this launch, Dr Reddy's becomes the first company to introduce this molecule in India. As per ORG IMS, the topical steroid market size is about Rs. 1.20 billion growing at 14%.

Japan: Daiichi Sankyo launches new formulations of antibacterial drug in Japan

Daiichi Sankyo Company has launched new formulations of Cravit, a broad-spectrum oral antibacterial agent. These formulations are 500 mg and 250 mg tablets, and a 10% fine granular preparation in Japan. The company obtained manufacturing and marketing approval on April 22, 2009. Daiichi Sankyo drew on pharmacokinetics-pharmacodynamics theory to develop the once-daily dosage for the 500 mg Cravit tablet. This tablet lifts the maximum blood concentration and is significantly more bactericidal than the 100 mg formulation, taken three times daily, suppressing the development of drug-resistant bacteria.

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India: Cloxacillin drug prices may fall

Leading antibiotic brands based on cloxacillin sodium in sterile form are expected to cost less by Independence Day, following a ruling by the drug price regulator last week that reduced its price by 9.73%. Popular drugs that may become cheaper include Ranbaxy's Suprimox, Cipla's Novaclox, Ipca Laboratories' Imox-clo and Unichem's Ampoxin as they contain this antibiotic bulk drug as a single ingredient or in a combination with other medicines. The price fixation is based on the cost-price study by the National Pharmaceutical Pricing Authority (NPPA) in accordance with the provisions of the Drugs (Prices Control) Order, 1995.

India: Shasun Chemicals launches streptokinase for Indian market

Shasun Chemicals & Drugs Ltd, a leading CRAMS and API exporting pharmaceutical company, has made a foray into biotherapeutics by launching recombinant streptokinase in the Indian market. The technology for this life-saving drug was developed at the Chandigarh-based Institute of Microbial Technology (IMTech), a constituent laboratory of the Council of Scientific and Industrial Research (CSIR). Union minister of science and technology Prithviraj Chavan launched the product in Delhi.

India: Neuro Products India launches InterX 1000 for pain management

Neuro Products India, which is the official distributor for the US-based Neuro Resource Group (NRG), has now made available the new InterX 1000 pain management device. The product, which is a part of the home health technologies can be used by patients or carried by physiotherapists for home visits. It is also an ideal kit for sportsmen to manage pain. NRG specialises in the design, development and manufacture of high end innovative medical products for injury management, rehabilitation and pain management. InterX products carry the European CE mark and are 510(k) cleared by the USFDA as a pain management device.

India: HealthCare Global set for overseas foray; scouting for Rs500m PE fund

The Bangalore-based HealthCare Global (HCG) is gearing up for its overseas debut even while negotiating with a few private equity players to close its fourth round of funding. The oncology major is in advanced talks with PEs including a US-based one, to raise Rs500 million. So far, the Rs. 1.10 billion specialised healthcare operator has raised about Rs500 million from IDFC Private Equity, Evolence India Life Sciences Fund and PremjiInvest. This time around, India Venture Advisors, the Piramal-group healthcare focused private equity fund is also in the fray. Having made considerable headway in its talks with HCG, it is ready to infuse Rs. 600 million. However, further details on the deal are not available.

India: Fortis launches advanced cardiac centre in Hiranandani Hospital, Navi Mumbai

Fortis Healthcare Ltd, one of fast growing chain hospital firms in India, has announced launch of Advanced Cardiac Centre at its Navi-Mumbai-based Hiranandani Hospital. The centre will be the first of its kind in the private sector in the entire Navi Mumbai, the satellite town connected to Mumbai, and Konkan region.

India: Medtronic launches Infuse Bone Graft to treat degenerative disc disease

Medtronic India has launched a novel bone graft called 'Infuse' in the country and it will be available at leading hospitals to treat a spinal condition called degenerative disc disease. The novel graft contains a recombinant human Bone Morphogenetic Protein (rhBMP-2). Infuse Bone Graft provides an alternative to patients by eliminating the pain and complications associated with harvesting bone from their hip.

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INVESTMENTS

UK

Meyer Organics to invest Rs. 1.47bn to set up new unit for export markets

Meyer Organics, a subsidiary of multi-national company Vitabiotics Ltd. UK, is investing Rs. 1.47 billion (US\$30m) to set up a state-of-the-art manufacturing facility in Bangalore. The facility is coming up next to its existing unit in Bangalore at Peenya Industrial Area. It is a modern pharma plant for which the company has purchased land. This unit will cater to its growing export market. Its existing facility in Bangalore manufactures liquids, tablets, capsules and ointments and is being regularly upgraded to increase production capacity.

Asia Pacific

India: Unichem Lab to invest Rs. 1.25bn for expansion

Mumbai based Unichem Laboratories is investing over Rs. 1.25 billion in new manufacturing facilities to expand business in the domestic market and for exports to the regulated drug markets of US and Europe. The company is setting up export oriented Active Pharmaceutical Ingredient (API) multi-purpose manufacturing units at Roha and Pithampur in Maharashtra, each with eight plants at an investment of over Rs. 0.6 billion.

India: Wockhardt divests nutrition businesses to Abbott for Rs. 6.30bn

Wockhardt, a Rs. 35 billion Mumbai based debt ridden pharma major, has divested its Nutritional businesses to Abbott, the global health care company, for a total consideration of Rs. 6.3 billion in cash. These transactions also include nutrition manufacturing facilities located in Lalru and Jagraon, India, Carol Info Services Ltd, and certain Wockhardt subsidiaries and group companies.

India: Elder Pharma sets up division to tap rural markets

Elder Pharmaceuticals has earmarked a Rs. 400 million investment for a rural thrust and set up a dedicated division called 'Elvista' to spread its network to villages, towns, sub-urban/periphery markets and hinterland districts. The initial targets are Class II-IV towns and rural markets with a dedicated sales force of 240. Elvista is targeting therapeutic categories which have greater relevance in rural areas and are preferred by doctors like anti-peptic ulcerants, anti-malarials, anti-infectives, quinolones and cough preparations, among others.

India: Dishman scraps engg SEZ, merges it with pharma project

The Rs. 10 billion Dishman Pharmaceuticals & Chemicals Ltd, a contract research and manufacturing services (CRAMS) major, has scrapped its engineering SEZ project slated to come up near Ahmedabad. The alteration in its Rs. 4 billion SEZ project plans was owing to the fact that the engineering sector is still reeling under the slowdown impact. The company had announced setting up of two SEZs, one for pharma and the other for engineering, near Ahmedabad.

India: MCL to set up medical college

Mahanadi Coalfields Limited (MCL) will set up a 500-bed medical college and super speciality hospital in Talcher. The company also plans to upgrade the existing Nehru Satabdi Hospital on the lines of Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow. The state government has permitted MCL to go ahead with the projects.

India: Investments in health infra to get a booster dose

The spend on healthcare infrastructure in the country is projected to grow at 5.8% annually to reach US\$ 14.2 billion by 2013, a near 50% increase over the 2006 level, according to KPMG. This forecast on the expenditure includes spends both by the government and the private sector on construction and maintenance of buildings that would house medical research, drug production or primary health care services.

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India: PE & VC firms bullish on Healthcare investments

Enchanted by the gradual turnaround of the economy private equity and venture capital investors, who have invested over US\$2 billion into Healthcare & Life Sciences (HLS) companies in India over the last five years, are now keen to increase their investments in this industry, survey of over 60 PE & VC firms conducted by research firm Venture Intelligence shows that the investors are especially keen to tap into sectors like diagnostic services, medical devices / equipment, hospital chains and wellness products and services.

GE to invest US\$ 6bn in healthcare globally

California-based General Electric (GE) said it would invest US\$ 6 billion globally in the next 10 years in healthcare services, including low-cost medical equipment. The company will be investing US\$ 6 billion across the globe on healthcare sector primarily aimed at to reduce cost and improve quality of healthcare services. Of total investment, US\$ 2 billion will be for rural health financing and US\$ 1 billion on awareness of quality healthcare services. Asked about the status of GE Money in the wake of global downturn, the said that the company was now refocusing on other products like aircraft financing, power infrastructure lending, etc.

RESEARCH & DEVELOPMENT

Europe

Study gives impetus to drive for effective malaria vaccine

EU-funded researchers have demonstrated that it is possible to protect healthy volunteers against malaria by infecting them with malaria parasites while treating them with the antimalarial drug chloroquine. The findings, published in the New England Journal of Medicine (NEJM), raise hopes that it will soon be possible to develop an effective vaccine against the deadly disease. Creating a malaria vaccine is proving difficult, partly because immunity to the parasite is difficult to acquire naturally, and partly because we still do not know exactly what constitutes protective antimalarial immunity in humans. However, this technique is only effective if the patient is bitten by irradiated mosquitoes more than 1,000 times over 5 or more immunisation sessions.

GOVERNMENT INITIATIVES

Asia Pacific

India set to sign pharma export deal with Nigeria

The government is set to sign an exhaustive deal with Nigeria to boost pharmaceutical exports to its eighth- largest global consumer, where the reputation of Indian drugs was recently dented by fake drugs from China bearing 'Made-in-India' labels. The department of pharmaceuticals and the ministries of commerce, external affairs and health will start talks with a visiting Nigerian delegation on ways to prevent fake drugs from other countries bearing fabricated 'Made-in-India' labels from reaching the Rs. 10 billion West African market for Indian generic drugs.

India: Dept of pharma asks finance ministry to raise SSI limit from Rs15-50m

The department of pharmaceuticals (DoP) has asked the Union Finance Ministry to raise the pharma SSI exemption limit from Rs. 15m to Rs. 50m and also to increase the abatement rate from the present 35.5% to 60%. According to industry sources, around 95% pharma SSIs are below Rs. 50m turnover. With the Damocles' sword of withdrawal of stimulus package announced by the centre in December last year hanging over their heads, the SSI units are worried that if the government withdraws the package and raises the excise duty from the present 4-8%, they will be in great disadvantage vis-à-vis the manufacturers in tax-free zones like Baddi.

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India needs to allow phase I trials of new drugs developed abroad

Indian regulatory authorities should allow to conduct phase 1 study for compounds developed abroad if India's expertise and skill to invent new drugs is to be recognised internationally according to Dr Ramanand Nadig, president and deputy dean of the Mumbai-based Clinical Research Education and Management Academy (CREMA). He said that so far regulatory authorities have given 38 approvals for phase 1 studies in the country for products developed in India. But what will trigger international interest is when the country accords permission for new drugs developed outside. He added that while the west has accepted Indian Clinical Research data from phase II trials conducted in accordance with ICH GCP norms, they are keenly awaiting India's policy decision on phase I studies.

India: K'taka drugs controller issues order to withdraw Rimonabant from all outlets

Karnataka drugs control department has issued a circular to stop the production and sales of Rimonabant. This order comes well before the drugs controller general of India circular to all the state departments. Going by the reports on the ban of Rimonabant across the world, the company has taken a decision to ensure that this product is not available in the state. The company is giving the pharmacy outlets across the state a month's time to withdraw and return all samples to the manufacturers, drugs controller.. The drug inspectors will start accessing the sales outlets to ensure that the products are off the shelf and dispatched to the companies.

OPERATIONS

Americas

USA: Zydus net rises 39% as formulation exports drive growth in Western markets

The Rs. 30 billion Zydus Cadila Group, registered a 39% jump in net profit even as its total income surged by 27%. The Ahmedabad-based company which ranks among the top five domestic pharma majors claims that its strong all-round performance boosted the group's income growth during the quarter. An overall growth of 66% in formulation exports was driven by growth in US, Europe and the emerging markets. In the US, the group posted Rs. 1.48 billion sales; up by 81% YOY The group had launched Mycophenolate Mofetil Tablets and capsules in May 2009, While in Europe, the group registered growth of 39% and posted sales of Rs. 0.64 billion

Asia Pacific

India: Unichem to set up formulation plant at Sikkim

Unichem Laboratories plans to set up a formulation plant at Sikkim. The company will set up a formulation plant at Sikkim at a cost of Rs. 0.32 billion. The facility will be operational by next year and basically cater to the eastern and north-eastern markets

India: Medicity hospital to commence operations from October 2009

The Medicity Super Specialty Tertiary Care Hospital, Gurgaon, promoted by the noted cardiac surgeon Dr Naresh Trehan under Global Health Pvt Ltd, is at the advanced stage of completion and expected to commence operations from October 2009. The total cost of the project is estimated at Rs. 932 crore and will be funded at a debt-equity ratio of one is ten. Yes Bank, India's new age private sector Bank, has announced the financial closure of an Rs. 500 crore Project Finance for Medicity Hospital.

India: Lilavati Hospital installs IVUS for better prognosis & treatment of cardiac patients

Lilavati Hospital and Research Centre recently acquired and installed a state-of-the-art Intra Vascular Ultrasound Imaging System (IVUS) from USA. This top-of-the-line equipment is only available at Lilavati Hospital & Research Centre, in Mumbai. This system will assist users in performing complex angioplasties in the Cardiology Lab.

India: Fortis Medicity to start phase-1 operations in second half of 2010

The Fortis Healthcare Medicity, the healthcare delivery and learning centre under development in Gurgaon, is all set to start its first phase of operations with three centres of excellence by October 2010. The project, which aims to set up a 1000 beds multi-specialty hospital and learning centre under the fast

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growing hospital chain - Fortis Healthcare Ltd, will have nearly 400 beds for three centres of excellence - Oncology, Trauma Care and Paediatric Care - in the first phase of operations, informed Shivinder Mohan Singh, managing director, Fortis Healthcare Ltd

India: Wockhardt Hospitals performs minimally invasive spine surgery

Wockhardt Hospitals Mumbai has successfully performed the most advanced minimally invasive spine surgery called Transforaminal Lumbar Interbody Fusion (TLIF) surgery which is used for treating unstable spine. TLIF is a very recent, most advanced and highly skilled form of spine surgery for fusion of two or more vertebrae of the lumbar (lower back) spine. The minimally invasive technique is best recommended for appropriately screened patients suffering from degenerative spondylolisthesis, degenerative disc disease, lumbar canal stenosis, black disc, nerve compression with associated low back pain.

CORPORATE

Asia Pacific

India: Orchid gets US FDA nod for amlodipine besylate tabs

The Chennai-based pharma major, Orchid Chemicals & Pharmaceuticals Ltd (Orchid) has received approval from the US FDA for its Abbreviated New Drug Application (ANDA) for amlodipine besylate tablets, 2.5 mg, 5 mg and 10 mg. With this approval, Orchid's cumulative ANDA approval count stands at 32 and the total ANDA filing count stands at 58.

India: Sun Pharma gets US FDA nod for generic Casodex tabs

Sun Pharmaceutical's US subsidiary has received US FDA approval for generic Casodex, bicalutamide tablets. These bicalutamide tablets, USP 50 mg are therapeutically equivalent to Casodex tablets from AstraZeneca. Casodex tablets have annual sales of approximately US\$ 314 million in the US. Bicalutamide tablets are an androgen receptor inhibitor indicated for use in combination therapy with a luteinizing hormone-releasing hormone (LHRH) analog for the treatment of Stage D2 metastatic carcinoma of the prostate.

India: Sun Pharma gets US FDA tentative nod for generic Optivar

Sun Pharmaceutical Industries Ltd announced the receipt of a tentative approval from US FDA for Sun Pharma's Abbreviated New Drug Application (ANDA) for generic Optivar, azelastine ophthalmic solution, 0.05%. This sterile azelastine hydrochloride ophthalmic solution is therapeutically equivalent to Optivar ophthalmic solution, 0.05% from MedPointe Pharmaceuticals which has annual sales of approximately US\$ 48 million in the US. Azelastine is a selective antihistamine for the treatment of the itching of the eyes associated with allergic conjunctivitis

India: Fortis Healthcare net profit at Rs. 208.20m, plans to raise Rs. 10bn through rights issue
Fortis Healthcare, leading chain of private hospitals with a network of 28 hospitals with 3300 bed capacity, has recorded consolidated net profit of Rs. 208.20 million during the year ended March 2009 as against a net loss of Rs. 554.80m in the previous year. Its consolidated income from operations went up by 24.7% to Rs. 6.20 billion from Rs. 4.97 billion. Fortis Escorts Amritsar and Fortis Escorts Heart Institute led the performance during 2008-09. The cardiac sciences, orthopaedics and neuro sciences segments grew by 36%, 45 % and 37 % respectively

Americas

USA: Eli Lilly and company announces new drug discovery initiative

The initiative, called the Lilly Phenotypic Drug Discovery Initiative, or PD2 (pronounced PD-squared), uses Lilly-developed disease-state assays and a secure web portal to evaluate the therapeutic potential of compounds synthesized in university and biotechnology laboratories. Findings from this initiative could ultimately form the basis for collaboration or licensing agreements between Lilly and external institutions.

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Each year, researchers throughout the world design and synthesize compounds in university and biotechnology laboratories that are never fully evaluated as potential drug candidates.

USA: Eli Lilly's cancer drug Alimta receives new indication in Europe

Eli Lilly and Company announced that the European Commission has granted approval for the use of Alimta (pemetrexed for injection) as monotherapy for maintenance treatment of patients with other than predominantly squamous cell histology in locally-advanced or metastatic non-small cell lung cancer (NSCLC), whose disease has not progressed immediately following platinum-based chemotherapy. This approval is based on data that showed pemetrexed improved overall survival in other than predominantly squamous NSCLC patients in the maintenance setting.

USA: KAI Pharma acquires peptide-based therapies patent from Progen Pharma

KAI Pharmaceuticals, Inc, a privately held drug discovery and Development Company, announced the acquisition of an extensive collection of issued and pending patents from Progen Pharmaceuticals Limited, a globally focused biotechnology company. The patents claim compositions and methods related to transporter molecules that can deliver compounds, including peptides such as those being developed in the KAI pipeline, across biological membranes and into cells.

USA: Maxygen establishes joint venture with Astellas to develop protein pharmaceuticals

Maxygen, Inc. announced that Astellas Pharma Inc. and Maxygen have executed an agreement to establish a joint venture focused on the discovery, research and development of multiple protein pharmaceutical programmes, including Maxygen's MAXY-4 programme and other early stage programmes. As part of the arrangement, Maxygen will provide Astellas with an option to acquire all of Maxygen's ownership interest in the joint venture within three years after establishment of the joint venture. The joint venture arrangement represents a significant expansion of the existing collaboration agreement between the parties for the development and commercialisation of MAXY-4 programme candidates for autoimmune diseases and transplant rejection.

UK:France: Sanofi-aventis presents new R&D model project to boost innovation

Sanofi-aventis presented its new research and development model project. The model, which aims to transform R&D and increase innovation, is the first pillar of the Group's new strategy which was presented in February 2009 by Christopher A. Viehbacher, chief executive officer of sanofi-aventis. The objective of this new R&D model is to propose innovative solutions that respond to specific, unmet needs of patients and continue our success in a very competitive international environment. It is centred on the real needs of patients, the development of scientific networks and openness toward outside entities to strengthen creativity, and a flexible and entrepreneurial approach to research.

UK: GE Healthcare, Geron enter global agreement to commercialise stem cell drug discovery tech

GE Healthcare, a unit of General Electric Company and Geron Corporation have entered into a global exclusive license and alliance agreement to develop and commercialize cellular assay products derived from human embryonic stem cells (hESCs) for use in drug discovery, development and toxicity screening. The programme will use stem cells derived from hESC lines listed on the NIH Human Pluripotent Stem Cell Registry. Financial terms are not being disclosed.

London: GSK acquires 13 branded pharma portfolio business from BMS for US\$ 23.2m

GlaxoSmithKline plc (GSK) has acquired the branded generics business of Bristol Myers Squibb (BMS) in Lebanon, Jordan, Syria, Libya and Yemen for a cash consideration of US\$ 23.2 million (£14.2m). The business comprises a portfolio of 13 branded pharmaceuticals with annual sales in 2008 of US\$ 11.8 million. This purchase is another step forward in GSK's strategy to accelerate growth in emerging markets and signals a strong commitment to provide quality medicines to patients in the Middle East and North Africa.

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USFDA APPROVALS

Americas

USA: Sanofi-aventis' Multaq receives US FDA nod to treat patients with Atrial fibrillation
 Sanofi-aventis announced that the US Food and Drug Administration (FDA) has approved Multaq (dronedarone) 400 mg tablets. Patients with atrial fibrillation (AF) or atrial flutter (AFL) soon will have a new treatment option to help improve current management of their disease. Multaq is the first drug approved in the United States that has shown a clinical benefit to reduce cardiovascular hospitalisation in patients with AF/AFL

USA: US FDA approves seasonal influenza vaccine for 2009-10 in US

The US Food and Drug Administration has approved a vaccine for 2009-2010 seasonal influenza in the United States. The seasonal influenza vaccine will not protect against the 2009 H1N1 influenza virus that resulted in the declaration of a pandemic by the World Health Organization (WHO) on June 11, 2009. The FDA continues to work with manufacturers, international partners and other government agencies to facilitate the availability of a safe and effective vaccine against the 2009 H1N1 influenza virus.

USA: Mylan gets US FDA nod for Haloperidol ANDA

Mylan Inc announced that its subsidiary Mylan Pharmaceuticals Inc has received approval from the US Food and Drug Administration (FDA) for its supplemental Abbreviated New Drug Application (ANDA) for Haloperidol tablets USP, 10 mg and 20 mg. These strengths are in addition to Mylan's currently marketed 0.5 mg, 1 mg, 2 mg and 5 mg strengths of the product. Haloperidol tablets are an antipsychotic typically used to reduce the symptoms of schizophrenia and uncontrollable tics and outbursts associated with Tourette syndrome.

Asia Pacific

India: Aurobindo's fosinopril sodium tabs receives US FDA nod for hypertension

Aurobindo Pharma Limited has announced that the company has received US Food and Drug Administration (US FDA) final approval for fosinopril sodium and hydrochlorothiazide tablets USP 10/12.5 mg and 20/12.5 mg. Fosinopril sodium and hydrochlorothiazide tablets USP 10/12.5 mg and 20/12.5 mg is generic equivalent to Monopril HCT tablets 10/12.5 mg and 20/12.5 mg of Bristol Myers Squibb.

REGULATIONS

Americas

USA: FDA approves Onglyza for the treatment of type II diabetes in the US

AstraZeneca and Bristol-Myers Squibb had announced that the US Food and Drug Administration (FDA) has approved Onglyza (saxagliptin) for the treatment of type II diabetes mellitus in adults. Onglyza is a dipeptidyl peptidase-4 (DPP-4) inhibitor. DPP-4 inhibitors affect the action of incretins, hormones that decrease elevated blood sugar levels (glucose) by increasing the body's utilisation of sugar, mainly through increasing insulin production in the pancreas and by reducing the liver's production of glucose. Onglyza is indicated as an adjunct to diet and exercise to improve blood sugar (glycemic) control in adults with type II diabetes mellitus.

Asia Pacific

India: DTAB recommends strict implementation of ICA certificate for medical devices

The Drug Technical Advisory Board (DTAB) has recommended strict implementation of Indian Conformity Assessment Certificate (ICAC) for the medical devices manufactured, imported and marketed in the country to ensure safety and quality of products. The final draft guideline, referred as Schedule M-III, suggests that the medical devices companies should apply for an ICAC mark and should print the ICA mark specifications on the label of the product to ensure quality and safety of the product. The certificate will be issued based on the class of product and will ensure the safety and efficacy of the product as per the standards set out in the rules and regulations of Indian authority.

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India: Neuro Products India launches InterX 1000 for pain management

Neuro Products India, which is the official distributor for the US-based Neuro Resource Group (NRG) has now made available the new InterX 1000 pain management device. The product which is a part of the home health technologies can be used by patients or carried by physiotherapists for home visits. It is also an ideal kit for sportsmen to manage pain. NRG specializes in the design, development and manufacture of high end innovative medical products for injury management, rehabilitation and pain management. InterX products carry the European CE mark and are 510(k) cleared by the USFDA as a pain management device

OTHERS**Asia Pacific****Indian: Pharma mkt valued at Rs. 550bn in FY09**

The total size of Indian pharmaceutical industry, excluding exports and government purchases, stood at Rs. 55.45 billion in the last fiscal. As per the information available with the department through ORG-IMS, April (2009) MAT, value of Indian pharmaceutical market is Rs. 55.45 billion. The total value includes retail pharmaceutical market at Maximum Retail Price (MRP), generic and companies not tracked by ORG, hospitals and institutional sales excluding government procurement, direct doctor purchases, over the counter (OTC) products and diagnostics.

India: Fakes make up 20-25% of Rs. 850bn pharma sales

While the top players of the over Rs. 850 billion pharmaceutical business are up in arms over what they call rampant spread of counterfeit drugs (allegedly 20 to 25% of total pharma sales) in the country, enforcement agencies and some pharma associations say the situation is not that alarming. But, they acknowledged that there are areas, which have slowly gained the dubious distinction of being a major source point for such drugs. Sources in central as well as regional drug enforcement agencies besides industry experts and police said Uttar Pradesh, Bihar, Maharashtra, Haryana and even Himachal Pradesh are some areas of concern when it comes to manufacturing of spurious and adulterated drugs.

India: Hinduja Hospital receives NABH accreditation

P D Hinduja Hospital and Medical Research Center, one of the oldest multi specialty tertiary care hospitals in Mumbai received NABH accreditation (National Accreditation Board for Hospitals & Healthcare Providers) today. The accreditation benefits all stakeholders especially patients. It ensures high quality of care and patient safety with patients receiving medical services from credential medical staff. Patient's rights are safeguarded by regular evaluation of patient satisfaction. The accreditation will help Hinduja Hospital to benchmark with International quality providing world-class quality services to its patients, an official announcement said.

India: Wockhardt Hospital gets NABH accreditation

Wockhardt Hospital, Nagpur has become the first multispecialty hospital in Central India to be accredited by National Accreditation Board for Hospitals and Health Care Providers (NABH), and has joined the list of 34 hospitals, approved for NABH accreditation across India

India: Apollo Children's Hospital successfully performs complicated surgery

The paediatric cardiac team at the new Apollo Children's Hospital successfully performed a complicated surgery to treat a condition called complete a-v canal defect in a four-month-old Nigerian baby.

India: Tata hospital to get Rs. 20m aid for cancer research

The Terry Fox committee, which organises marathon runs to raise funds for cancer patients, will give the Tata Memorial Hospital in Parel a donation of Rs. 20m for cancer research. The panel has been helping the hospital finance treatment of patients who cannot afford it.

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Product Focus – SUPRAX (CEFIXIME)

SUPRAX (CEFIXIME)

Introduction

Cefixime is an antibiotic that belongs to the family of medications known as cephalosporins. It is used to treat certain types of bacterial infections. It is most commonly used to treat gonorrhoea as well as infections of the ear, sinus, bladder, throat, and lung. Lupin Ltd. has launched Suprax tablets (Cefixime USP) in the US. Lupin introduces its first brand in US - Suprax.



Drug Mechanism

Like all beta-lactam antibiotics, cefixime binds to specific penicillin-binding proteins (PBPs) located inside the bacterial cell wall, causing the inhibition of the third and last stage of bacterial cell wall synthesis. Cell lyses is then mediated by bacterial cell wall autolytic enzymes such as autolysins; it is possible that cefixime interferes with an autolysin inhibitor.

Drug Information	
Drug Name	Suprax(Cefixime)
Formula	$C_{16}H_{15}N_5O_7S_2$
ATC Code	J01DD08
CAS No	79350-37-1
Indication	susceptible strains of the designated microorganisms

Dosage

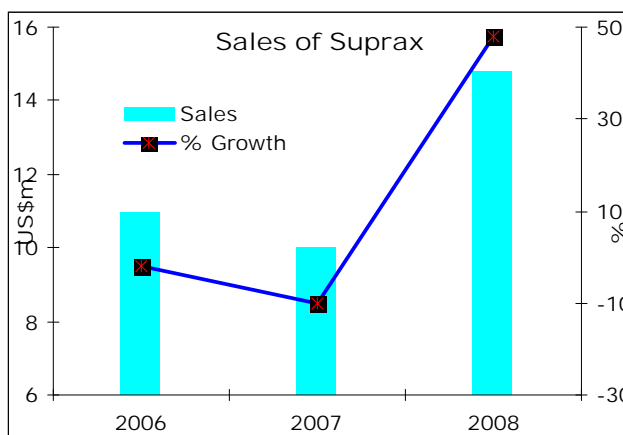
Patient with average weight of 25-35 need to intake 250mg/day, above the weight of 35kg, prescribed dosage is 300mg/day. Children weighing more than 50 kg or older than 12 years should be treated with the recommended adult dose.

Side Effects

- Diarrhea that is watery or bloody;
- Fever, sore throat, and joint pain with a severe blistering, peeling, and red skin rash;
- Numbness or tingly feeling;
- Warmth, redness, or tingling under your skin;
- Swelling in your hands or feet;
- Fast or pounding heartbeats;
- Chest pain, shortness of breath.

Global Scenario

Sales of Suprax - which is used to treat certain bacterial infections such as bronchitis - jumped to about US\$74m from US\$41.2m. Suprax 400mg tablets will help Lupin to further increase its share of the US\$450m antibiotic market for the treatment of urinary tract infections. It will also extend the use of Suprax to the patient population of children of the age of 12 yrs and above. Suprax 400mg tablets will be



Source: Evaluatepharma; Cygnus Research

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promoted by a 60 strong specialty pediatric sales force. During 2008-09, Suprax continued to be on a growth trajectory, with the suprax Double Dose recording an overall prescription growth of 48% over the previous year. In April 2008, Lupin launched Suprax 400mg Tablets in the US. This line extension further extends the Suprax franchise. Suprax 400mg tablet will help the company to increase its share of the US\$450m antibiotic market for the treatment of Urinary Tract Infection.

Evolution

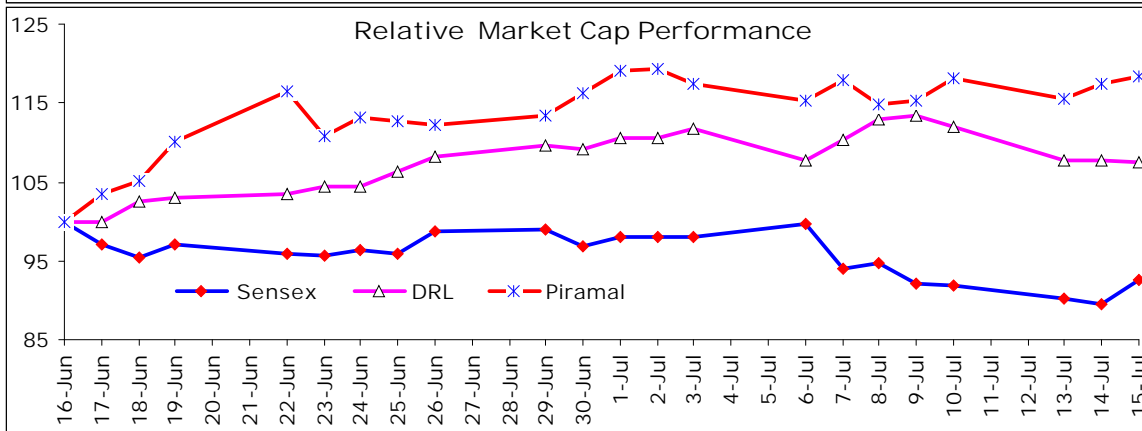
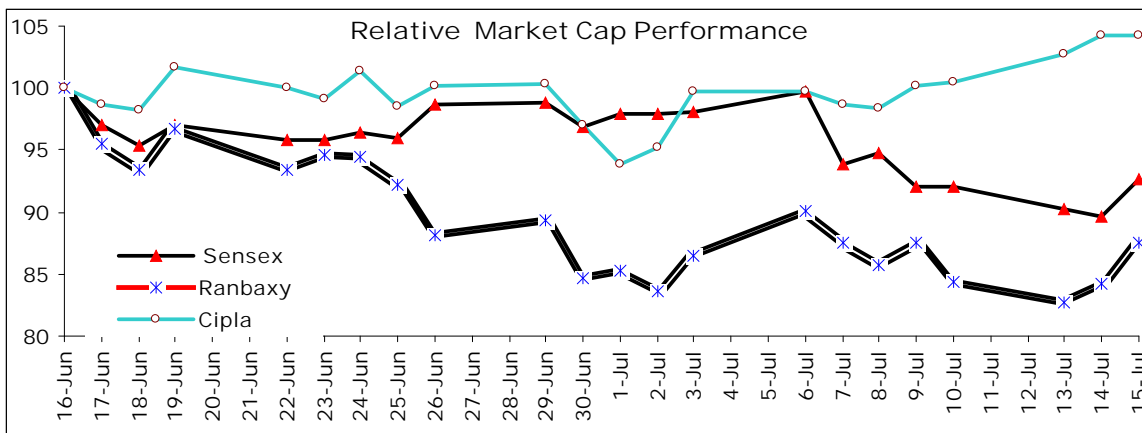
The company's research and development initiatives were focused on Generics research comprising process and formulation research, Advanced Drug Delivery Systems (ADDS), Novel Drug Discovery and Development (NDDD) and biotechnology research. Generic threat to Suprax – Orchid has indicated that it has made an ANDA filing for the 100mg dosage of Suprax recently, which could get an approval in the next 12-18 months, thus adding to competition for Suprax in 2010/2011. However, as 100mg dosage only accounts for close to 1/3 of its total Suprax franchise, Orchid's entry may not impact Lupin to a large extent. We have shown the sensitivity to Lupin's earnings, based on declining sales for Suprax, assuming competition.

Outlook

Recurrent acute otitis media (AOM) is a common illness of childhood occurring during the first year of life in 20 to 30% of the paediatric population. The proportion of children with AOM who were treated with antibiotics declined significantly from 77% to 58%. It is expected trend will be the same in future which may impact the sales of Suprax. With the past trend and innovative skills of the company, it is expected the sales will further increase.

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Stock Scan



Source: BSE India; Cygnus Research

	16 Jun-21 Jun	22 Jun-28 Jun	29 Jun-05 Jul	06 Jul-15 Jul
SENSEX	Weak global cues and selling pressure made Sensex register loss during this period.	Investors remained Bullish during this period and buying seen in the market. Sensex gained during this period.	Sensex ended in positive note during this period on increased capital inflow by funds.	Sensex ended in negative note during this period, as realty, metals, auto, infrastructure stocks had not been performing well.

RANBAXY	Negative sentiments made the share price fall by 3.23%.	Prevailing negative sentiments made its share price to fall by 8.92%.	Lack of demand on shares made the stock price to fall by 1.82%.	The share price gained by 1.24% as the company had been mulling to launch a new growth hormone product to target the emerging global market for new versions of patent-expired biotech drugs; This however attracted the investors during this period.
CIPLA	The share price increased by 1.74% as bullish sentiments prevailed in the market.	Share price declined by 1.56%.	Share price remained flat under consideration.	The share price increased by 4.53% as the company's net jumped over 72%, which led to positive sentiments of the investors during this period.
DRL	The stock price increased by 3.04% as the company had tied up with GSK to develop and market select products across emerging markets outside India; This however attracted the investors during this period.	The share price gained by 5.01% as the company had launched Bispec (Solifencin Succinate) in India; attracted the investors during this period.	The share price witnessed a hike of 3.35% as the company had witnessed a sharp rise of 2.10 times in the net profit for the quarter ended June 30, 2009.	Bearish sentiments prevailed in the market. Stock moved in tandem with BSE sensex.
PIRAMAL	Stock price increased by 10%.	Bullish sentiments prevailed in the market. Stock moved in tandem with BSE sensex.	The share price increased by 4.66% as bullish sentiments prevailed in the market.	Increase in volume of shares traded resulted in the hike in the stock price from Rs. 314.75 to Rs. 317.35.

Regulatory Issues

FDA Issues Final Regulation on Dental Amalgam

The U.S. Food and Drug Administration today issued a final regulation classifying dental amalgam and its component parts – elemental mercury and a powder alloy—used in dental fillings. While elemental mercury has been associated with adverse health effects at high exposures, the levels released by dental amalgam fillings are not high enough to cause harm in patients.

The regulation classifies dental amalgam into Class II (moderate risk). By classifying a device into Class II, the FDA can impose special controls (in addition to general controls such as good manufacturing practices that apply to all medical devices regardless of risk) to provide reasonable assurance of the safety and effectiveness of the device.

FDA Approves Colchicine for Acute Gout, Mediterranean Fever

The U.S. Food and Drug Administration has approved Colcrys to treat acute flairs in patients with gout, a recurrent and painful form of arthritis, and patients with familial Mediterranean fever (FMF), an inherited inflammatory disorder. The medication's active ingredient is colchicine, a complex compound derived from the dried seeds of a plant known as the autumn crocus or meadow saffron (*Colchicum autumnale*).

Colchicine has been used by healthcare practitioners for many years to treat gout but had not been approved by the FDA. The FDA has an initiative underway to bring unapproved, marketed products like colchicine under its regulatory framework. This initiative promotes the goal of assuring that all marketed drugs meet modern standards for safety, effectiveness, quality and labeling.

Asia pacific

NPPA lists 471 cos for overcharging drugs, recovery process moves slow

NPPA has published a list of 471 companies who have violated the norms on yearly price increase so far. And almost all the leading firms appear in the list, indicating that overcharging continued to be so rampant despite all the efforts by the government and criticism by public interest groups.

NPPA has sent notices in around 660 cases so far after its inception, for recovering around Rs 2003 crore. It could recover only about Rs 164 crore so far from the defaulters, leaving the rest of the amount as pending because of litigations. During the last three years, it could collect just about Rs 57 crore from the defaulters, according to the latest statistics. During 2006-07, the agency sent notices in 67 cases for the amount of Rs 38.01 crore, but it could finally recover only Rs 0.96 crore.

Drug units in tax free zones seek clarification of tax holiday schemes after GST implementation

Concerned over the status of tax holiday zones after the implementation of goods and services tax (GST) in the country from April 1 next year, the drug manufacturers in the tax holiday states like Himachal Pradesh and Uttarakhand have asked the government to clarify the status of the tax holiday zones like Baddi in Himachal Pradesh and Uttarakhand after the GST implementation. Federation of Pharmaceutical Entrepreneurs (FOPE), an association of hundreds of pharma units in the tax free zones in Himachal Pradesh and Uttarakhand, has asked the government to clarify the status of tax holiday zones after the GST implementation in the country. In his budget speech, finance minister Pranab Mukherjee has announced the roadmap for the implementation of GST in the country from April 1, 2010. "We have urged the government to clarify how it will take care of the tax holiday zones once GST comes into effect.

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Upcoming Events

1	Event	Health & Fitness Business Expo
	Date	Aug 06-07, 2009
	Venue	Colorado Convention Centre, Denver
	Highlights	Health & Fitness Business Expo is the event where brands are launched, innovations are unveiled and connections are made. Since 1997, manufacturers, suppliers, retailers, buyers, press and industry influencers have converged at Health & Fitness Business in August to shape the future of their business.
	Contact Details	Nielsen Business Media, Sanctuary Parkway Suite 355, Alpharetta, USA. Tel: +(91)-(770)-5691540; Fax: +(91)-(703)-7778821 E-mail: bmcomm@nielsen.com; Web: www.nielsenbusinessmedia.com
2	Event	Asia Pacific Health Safety & Environment Conference & Exhibition
	Date	Aug 04-06, 2009
	Venue	Jakarta International Expo (JIExpo), Jakarta
	Highlights	This conference and exhibition will bring together stakeholders from governments and regulatory agencies, national and public oil and gas companies, academia, service and supply companies, medical and occupational institutions, and others to focus on the HSE needs and requirements both globally and regionally of the upstream industry.
	Contact Details	Society of Petroleum Engineers. 222, Palisades Creek Dr. Richardson, United States Of America. Tel: +(1)-(972)-9529393; Fax: +(1)-(972)-9529435 Email: spedal@spe.org; Web: www.spe.org
3	Event	FIME International Medical Expo
	Date	Aug 12-14, 2009
	Venue	Miami Beach Convention Center, 1901 Convention Center Florida, US
	Highlights	The FIME 2009 is one of the highly renowned event for exhibiting allergy products, biopsy needles, cardiology equipments, blood pressure equipments, blood bags and many others. It is three days event which proves to be successful in attracting large number of buyers and sellers from all over the world.
	Contact Details	FIME International Medical Exposition, Inc 3354, Sarasota, USA. Tel: +(1)-(941)-3662554; Fax: +(1)-(941)-3669861 Web: www.fimeshow.com
4	Event	Saigon MediPharm & BioLab
	Date	Aug 19-22, 2009
	Venue	Saigon Exhibition & Convention Centre, Ho Chi Minh City, Vietnam
	Highlights	Saigon MediPharm & BioLab Exhibition will 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 & services to decision makers from leading pharmaceutical manufacturers.
	Contact details	F. A. S. T. System & Management Services. 18 Richards Avenue, Singapore, Singapore. Tel: +(65)-(9)-7380246; Fax: +(65)-(6)-68584490

5	Event	Saigon MediPharm & BioLab
	Date	Aug 19-22, 2009
	Venue	Saigon Exhibition & Convention Centre, Ho Chi Minh City, Vietnam
	Highlights	Saigon MediPharm & BioLab Exhibition will 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 & services to decision makers from leading pharmaceutical manufacturers.
	Contact details	F. A. S. T. System & Management Services. 18 Richards Avenue, Singapore, Singapore. Tel: +(65)-(9)-7380246; Fax: +(65)-(6)-68584490
6	Event	P-MEC SOUTH AMERICA
	Date	Aug 26-29, 2009
	Venue	Transamerica Expo Centre, Sao Paulo, Brazil
	Highlights	P-MEC South America is an exhibition for pharmaceutical processing and packaging machinery equipment and instruments in South America representing the country's largest industry. The growth in demand for pharmaceutical manufacturing facilities will further stimulate the market for machinery and equipment. It is an exciting environment into which the Pharmaceutical Machinery and Equipment Convention, P-MEC China, will be launched alongside CPhI China and ICSE China.
	Contact details	CMP Information. Industrieweg 54, P.O. Box 200, 3600 AE, Maarsen, The Netherlands. Tel: +(31)-(346)-559444; Fax: +(31)-(346)-573811 Web: www.cmpi.biz
7	Event	Natural Health Conference and Expo - Sydney
	Date	Sep 02-04, 2009
	Venue	AJC Convention Centre, Sydney, New South Wales
	Highlights	The Natural Health Conference and Expo is Australia's only trade event bringing together all areas of Natural Health - natural medicines, supplements, energy medicine, functional foods, massage and yoga supplies, homoeopathic remedies, business and clinic services, magazines and publishers, industry associations and training providers.
	Contact Details	The Intermedia Group Pty Ltd. Unit 39, 100 Harris, Pyrmont, Australia Tel: +(61)-(2)-96602113; Fax: +(61)-(2)-96604419 Email: sales@gpoint.com.au; Web: www.gpoint.com.au
8	Event	Astana Zdorovie
	Date	Sep 04-06, 2009
	Venue	Astana Congress Hall, Astana, Kazakhstan
	Highlights	Astana Zdorovie provides an opportunity to meet thousands of potential clients face to face, learn about new developments in medicine, discuss pressing issues of the sector, build new business contacts, present your products and services, increase your sales and study the market, add to your company's image and position yourself in the market of Kazakhstan.
	Contact Details	Iteca LLP. Timiryazev Street, 2nd, Almaty 42, Kazakhstan. Tel: +(7)-(3272)-583434; Fax: +(7)-(3272)-583444

9	Event	Expo Medical
	Date	Sep 10-12, 2009
	Venue	La Rural Predio Ferial, Buenos Aires, Argentina
	Highlights	Expo Medical is the only show in Argentina where a complete range of new and innovative products and services in medical technology and IT equipment, diagnostics, rehabilitation, nursing and consumer medicine are in display.
	Contact Details	Mercoferias Srl. Corrientes, Olivos, Argentina Tel: +(54)-(11)-47998087; Fax: +(54)-(11)-47906446
10	Event	Info Dental
	Date	Sep 11-12, 2009
	Venue	Dusseldorf Exhibition Centre, Dusseldorf, Nordrhein-Westfalen Germany
	Highlights	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. Product will display stomatological equipment & tools, stomatological expenditures & medicines, modern technologies in dentistry, organisation & equipping of dental rooms & clinics, and service maintenance of dental specialities.
	Contact Details	Messe Dusseldorf GmbH. Stockumer Kirchstrasse, 61, Messeplatz, Germany Tel: +(49)-(211)-4560900; Fax: +(49)-(211)-4560668 E-mail: info@messe-duesseldorf.de; Web: www.messe-duesseldorf.de