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In Focus – A tough time for Pharmaceutical SSI units in India

Near about 7 to 9 units of the 70 units in Pondicherry are expected to be closed down by middle of April 2006 due to the stringent action taken by the Food and Drug Administration of Pondicherry against the drug manufacturing companies that have not complied with Schedule M. Meanwhile the pharma SSI units in Karnataka submitted a memorandum to the Union finance minister to look into the issues of excise duty on MRP immediately as it would lead to the closure of many SSI units in the state which are unable to compete in the uneven tax structure. Each day, there is news about the expected closure of pharma SSI units in the different states of the country. This article covers the actual problems pertaining to the pharmaceutical SSI units in the country and their possible future.

Issues that drag down the shutters of pharma SSI units in the country

Compliance to Schedule M

Schedule M represents a set of regulations as per the Indian Drugs and Cosmetics Act, 1940 to ensure safety and efficacy of drug products and biologics that are manufactured in India. The revised Schedule M that came into effect from July 1, 2005, will ensure total cGMP (current Good Manufacturing Practices) where high levels of quality control and quality assurance standards will be maintained in the manufacturing of the drugs. The Union government is insisting on the compliance of drug manufacturing firms to

State	Schedule M non-compliant units	Dated
Gujarat	2000	March 2006
Punjab & Haryana	700	July 2005
Maharashtra	225	July 2005
Andhra Pradesh	100-150	August 2005
Kerala	25	October 2005
Karnataka	13	September 2005
Pondicherry	7-9	March 2006

Source: Cygnus Research

Schedule M and has made the compliance mandatory in order to make the quality of drugs produced in India match world standards. The minimum cost of upgrading one drug manufacturing firm to comply with Schedule M requirements is estimated to be over Rs15 million and most of the SSI units lack the needed financial muscle for this upgradation, hence they have to shut down their operations. Pharmaceutical SSI units in India account for nearly 50 percent of total drug production in the country and they cater to the rural medicine demand by supplying low cost medicines.

A Joint Initiative of **IPA** and **Cygnus** to enable Pharma Professionals to be more successful

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Excise duty on MRP instead of ex-factory price

The next level of problem with pharma SSI units is that, even, if they upgrade their manufacturing facilities to Schedule M standards, the levy of excise duty on MRP with an abatement of 40 percent, that came into effect from January 7, 2005 has made the business of these SSI units still miserable as the tax paid by the small units and large firms is the same irrespective of the selling price and the large firms are starting their manufacturing units in the duty free zones such as Baddi in Himachal Pradesh, Uttaranchal and Jammu & Kashmir. With the migration of manufacturing units into the excise free zones the products manufactured at these locations are far cheaper than those manufactured by the SSI units located in the non-excise free zones. As a result, more than 5000 SSI units, which invested over Rs 75 – 90 billion, are on the brink of closure and the life of more than nine lakh workers and their families dependent on these units are under question.

Union Budget, that neglected SSIs

The pharmaceutical industry, especially, the SSI units, received additional shock as the Union Budget neglected the proposal of reduction in excise duty from 16 percent to 8 percent and rising of exemption limit for SSI units from Rs10 million to Rs 30 million. The approval of the above mentioned proposals could have neutralized the turmoil caused by MRP based excise duty.

Migration of drug manufacturing units to excise free zones

In-order to reap the benefits of 100 percent excise duty exemption for a period of ten years from the date of commencement of commercial production, 100 percent income tax exemption for an initial period of five years and thereafter 30 percent for companies for a further period of five years, capital investment subsidy of 15 percent on plant and machinery subject to a ceiling of Rs3 million in areas such as Baddi in Himachal Pradesh, Uttaranchal and Jammu & Kashmir, the pharmaceutical firms are shifting their manufacturing base to these areas. During early 2005, the pharmaceutical investments in Baddi crossed the Rs.10 billion. This might lead to the structural change in the industry with the concentration of the manufacturing base of drug firms in the excise free zones. In few years, around 200 medium and large-scale drug manufacturing units will be coming up in and around Baddi.

Outlook

Confederation of Indian Pharmaceutical Industry's (CIPI-ssi) plea to save the SSI sector by increasing the turnover limit for SSI's from the present Rs 10 million to Rs 30 million, reducing the excise duty to 8 percent from 16 percent, and exempt small units with a turnover of less than Rs10 million from the purview of the excise duty was not accepted by the Union Government. The number of closures of the pharmaceutical SSI units will increase once the units that are being started in the excise free zones become completely operational. SSI units, which have the financial power to invest around Rs.50 million, will shift their operations to the duty free zones. It is estimated that more than half of India's pharmaceutical production, especially formulations, would originate from Himachal Pradesh in the next few years and it will emerge as the pharmaceutical industry capital of India.



News Briefs

INTERNATIONAL

AMERICAS

US: US pharma companies R&D investments near US\$40bn in 2005

PhRMA's pharmaceutical and biotechnology research member companies have invested US\$39.4 billion in 2005, up from US\$37 billion in 2004, an increase of 6.5%. According to a Burrill & Company analysis for PhRMA, the total R&D investments in biotechnology and pharmaceutical by both PhRMA member companies and non-PhRMA members reached US\$51.3 billion in 2005. In 2005, there were more than 2,000 compounds under development by pharmaceutical companies. In 2005, PhRMA member companies invested around 19.2% of domestic sales on R&D.

US: Lubrizol sells its API and intermediate compounds business

The Lubrizol Corporation (specialty chemical company headquartered at Ohio), as a part of its divestiture plan to sell off the non-core businesses, has finalized to sell its active pharmaceutical ingredient (API) and intermediate compounds business, with facilities in Raubling, Germany and Chennai, India (A&I) to Auctus Management GmbH (Auctus), a

German private equity firm located in Munich, Germany, and the current management of the active pharmaceutical ingredient business.

US: Watson launches generic Pravachol

Under a distribution agreement with Bristol-Myers Squibb, Watson Pharmaceuticals has started shipping a generic version of the former's cholesterol-lowering drug Pravachol in the US. The launch of this authorized generic of Pravachol by Watson comes after Teva's launch of generic pravastatin in the US with 180 days' marketing exclusivity under the country's Hatch-Waxman legislation. The patent of Pravachol expired on April 30, 2006 and Watson has launched 10mg, 20mg and 40mg strengths of pravastatin.

Canada: Tequin to be withdrawn from the Canadian market

Bristol-Myers Squibb stated that it will stop making and selling its antibiotic Tequin (gatifloxacin), which has been linked to serious cases of diabetes and other potentially fatal blood sugar abnormalities. A Canadian study revealed that Tequin users had 17 times greater risk of developing serious diabetes and 4 times greater risk of being hospitalized with low blood sugar complications than patients using other antibiotics. Tequin received FDA approval in 1999 and there have been 388 patients with blood-sugar irregularities linked with Tequin since January 1, 2000.

Canada: Atrium acquires Amisol

Atrium, the leading developer, manufacturer and marketer of science-based products for the cosmetics, pharmaceutical, chemical and nutrition industries acquired Toronto-based Amisol Company Ltd, which is primarily into the personal care for US\$6m. This acquisition marks another step in Atrium's active ingredients and specialty chemicals division's growth strategy aimed at better positioning Atrium's subsidiary MultiChem.

EUROPE

UK: GSK stops enrolment in phase III trial of Tykerb

GSK halted enrolment in its phase III clinical trial evaluating the combination of Tykerb (lapatinib ditosylate) and capecitabine (Xeloda) versus capecitabine alone based on the unanimous recommendation of an Independent Data Monitoring Committee. The study evaluated women with refractory advanced or metastatic breast cancer who have documented ErbB2 (HER2) over expression and whose disease progressed following treatment with trastuzumab (Herceptina) as well as other cancer therapies. The enrolment in the study was stopped as it exceeded its primary endpoint of time to disease progression for women receiving the combination of Tykerb and capecitabine.

France: Sanofi-Aventis to get back Acomplia rights in Japan

Sanofi-Aventis, as a part of its plan to strengthen the presence in Japan, has decided to retrieve all rights of its anti-obesity pill Acomplia in Japan from Astellas Pharma, Japan's second largest drugmaker. The transfer of rights will be implemented by June 2006. Acomplia is Sanofi-Aventis's biggest drug hope and is subject to marketing approval in the US and Europe, in phase IIB clinical trials in Japan. Acomplia is expected to be launched by the second half of 2006 and is estimated to have an annual sales potential of US\$3 billion.

Spain: Forest, Almirall enter into marketing agreement on new therapy for COPD

Almirall, a privately held pharmaceutical company headquartered in Barcelona, Spain, has entered into an agreement with Forest Laboratories Holdings, Ltd., a wholly owned subsidiary of Forest Laboratories, Inc. to develop, market and distribute Almirall's novel inhaled, long-acting muscarinic antagonist, LAS34273, used for the treatment of chronic obstructive pulmonary disease (COPD) in the US. According to the agreement, Forest will make an upfront payment of US\$60m to Almirall and in addition Almirall will receive royalty payments based on LAS34273 sales. Forest will have the sales and marketing rights of LAS34273 in the US and Almirall will co-promote the product in the future and retain commercialization rights for the rest of the world.

ASIA PACIFIC

Japan: Avastin filed for fast track approval in Japan

Chugai Pharmaceuticals, Roche's Japanese subsidiary has filed anti-cancer drug Avastin under fast track approval with the Japanese regulatory authority for use in patients with advanced or recurrent colorectal cancer. Avastin is the first medicine

to be filed under the scheme. Avastin is already approved in the US and Europe for colorectal cancer, and generated a sale of US\$1.3 billion for Roche in 2005.

Japan: Dainippon and Eisai signed licensing agreement for a Gastroprokinetic agent

Dainippon Sumitomo Pharma Co, Ltd. has signed a licensing agreement with Eisai Co, Ltd, whereby Eisai is granted with the rights to develop, manufacture and market Gasmotin, (mosapride citrate), a gastroprokinetic agent, in 10 Asian countries including ASEAN members.

China: AstraZeneca commissions a new packing line at its Wuxi plant in Jiangsu province

UK based pharmaceutical major AstraZeneca, has commissioned its new US\$3.8m packing line at its Wuxi plant in Jiangsu province. The addition of this packing line increases the annual capacity by 40m packages a year. The investments are part of the total outlay of US\$35m proposed to invest by the company in the site over the next five years. The plant is the largest manufacturing base of AstraZeneca in Asia.

China: Chinese pharmaceutical exports register 28% growth in 2005

According to statistics from China's customs, 15,271 domestic companies were involved with medical exports in 2005, and China's export of pharmaceutical products valued US\$13.8 billion in 2005, growing by 28% compared with 2004. The growth rate has surpassed the country's overall export growth. Currently, Chinese pharmaceutical products have reached over 214 countries and regions across the world. The exports were mainly focused on pharmaceutical ingredients and also faced an increasing number of trade conflicts with major trade partners.

China: Guangzhou Pharmaceutical plans to grow big in North China

Guangzhou Pharmaceutical Co Ltd is the leading medicine company in South China. It plans to step up its efforts to get its products better known in North China. It intends to increase its revenue contribution from northern cities to more than 40% this year from 38% in 2005. The company has also planned to invest more on R&D and bring new medicines to the market. Some new products such as diabetes medicine are expected to hit the markets soon and this is expected to contribute near about 10% of the turnover of its manufacturing arm by 2010.

NATIONAL

MUHS to have PG, diploma courses in Pharmaceutical Medicine

Maharashtra University of Health Sciences (MUHS), Nasik will be starting post-graduate and diploma courses in Pharmaceutical Medicine shortly. The University Department of Interpathy Research and Technology (UDIRT) will also be commencing a Training Programme on Good Clinical Practice (GCP) and methodology in conducting clinical trials for the professionals in alternative medicines, including Ayurveda, Homeopathy, Unani, Dentistry among others.

50% of pharmacy colleges in India not recognized by PCI

The Pharmacy Council of India (PCI) has approved only 50% of the total number of pharmacy colleges offering BPharm or DPharm courses in the country while the remaining colleges are functioning on approval from the All India Council for Technical Education and they do not have PCI recognition. Of the 445 institutions that are functioning with AICTE sanction, only 243 have PCI approval. This anomaly is due to the dual system of registration that does not make PCI registration mandatory for all pharmacy institutions.

Indian pharma firms expected to invest US\$3-3.5bn on international acquisitions

In the next 12-18 months, large and medium scale pharma companies in India may invest around US\$3-3.5 billion for acquisitions in Europe, US and Latin America. It is estimated that the Indian pharma may invest about US\$ 2 billion in Europe, US\$1-1.5 billion in the US and around US\$250m in Latin America within the next 18 months. About 70% of the investments will happen in Europe, 20% in the US and the rest in Latin America within the next 18 months. The reason behind the increase in the overseas acquisition is that the mid-size pharma companies in India view inorganic route as the best option for fast growth when compared to a normal growth of 10-15% per annum in the organic route. Most of the deals are in the range of US\$20-700m.

Ranbaxy gets a favorable ruling for Lipitor in Austria

Ranbaxy Laboratories Ltd, India's largest pharmaceutical company, got the boost as a result of a favorable ruling in a patent litigation against Pfizer involving cholesterol-lowering drug Lipitor in Austria. The Supreme Patent and Trademark Board of Austria affirmed an earlier ruling of the Austrian Patent Office that was made in March 2005, which ruled that Pfizer's Austrian Patent AT 207896 as invalid for lack of novelty over Pfizer's International Patent Application PCT/US89/00719, published as WO 89/07598 and lack of inventive step over US Patent No. 4681893.

Torrent launches two anti-diabetic drugs

Azuca, Torrent's recently launched diabetes division launched two new drugs, one Pregeb (Pregabalin) for treatment of neuropathic pain with a global market of US\$2 billion and another drug Piopod (Pioglitazone) that helps in reducing insulin resistance in Type-2 diabetes with a global market of US\$1.5 billion.

Nicholas Piramal to concentrate on diabetes in India

Nicholas Piramal India Ltd (NPIL) has planned to strengthen its range of products for diabetes, including diagnostics. Currently, NPIL markets blood glucose meters and a range of anti-diabetes drugs. It also plans to look for overseas acquisitions that will instantly give it big-contract manufacturing opportunities. NPIL's diagnostic chain, named Wellspring, has over 30 labs in 14 locations and there are plans to expand its chain of diagnostic labs into Kerala and Tamil Nadu.

Ind Swift starts a new formulation manufacturing unit at Baddi

Ind Swift Ltd has started its operations in its new finished dosage manufacturing unit in Baddi, Himachal Pradesh, at an investment of Rs400m, which will manufacture 1,800m tablets/annum, 120m ampoules/annum, 60m vials/annum and 120m Syrups/annum. The unit will be eligible for the Central Excise and Income Tax benefits available to industrial units set up at Baddi and will be built as per the FDA standards.

Product Focus – Citalopram hydrobromide

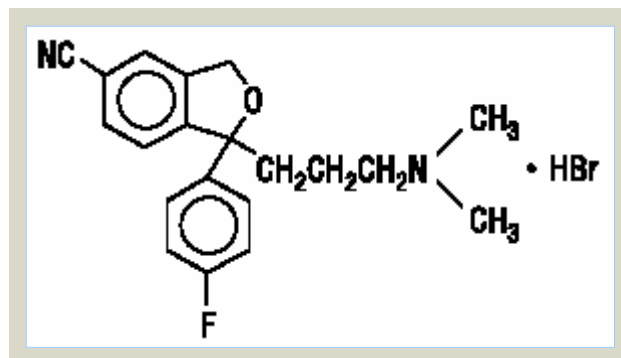
Citalopram, an antidepressant drug used in the treatment of depression is associated with mood disorders and belongs to a class of drugs known as selective serotonin reuptake inhibitors (SSRIs). Citalopram was originally developed by the pharmaceutical company Lundbeck. It is sold under the brand-names Celexa (US) and Cipramil (Europe and Australia) by Forest Laboratories, Inc.

Chemical structure

The chemical formula for Citalopram hydrobromide is $C_{20}H_{22}BrFN_2O$ and the chemical name is (\pm) -1-(3-dimethylaminopropyl)-1-(4-fluorophenyl)-1,3-dihydroisobenzofuran - 5-carbonitrile, hydrobromide. It is a fine white to off-white powder with a molecular weight of 405.35.

Mechanism of Action

Neurotransmitters are chemical substances within the brain that nerves use to send messages to each other. Some of the neurotransmitters are dopamine, serotonin and norepinephrine. These neurotransmitters that are released by nerves are taken up again by them for reuse and this process is referred to as reuptake. Citalopram acts by inhibiting the selective reuptake of serotonin neurotransmitter and hence it falls under the class of SSRIs. As a result of this inhibition, more serotonin neurotransmitters are available to transmit messages to other nerves.



Side effects

Nausea	Somnolence
Dry mouth	Increased sweating
Insomnia	Diarrhea
Dizziness	Ejaculation disorder
Fatigue	Tremor
Anorexia	

Dosage and Indication

Citalopram hydrobromide is indicated for the symptomatic relief of depressive illness. It is available in two different dosage forms 20mg, 40mg tablets and as oral solution. It should be administered at an initial dose of 20mg once daily, generally with an increase to a dose of 40mg/day.

Market

Patent expiry pulls the sales down

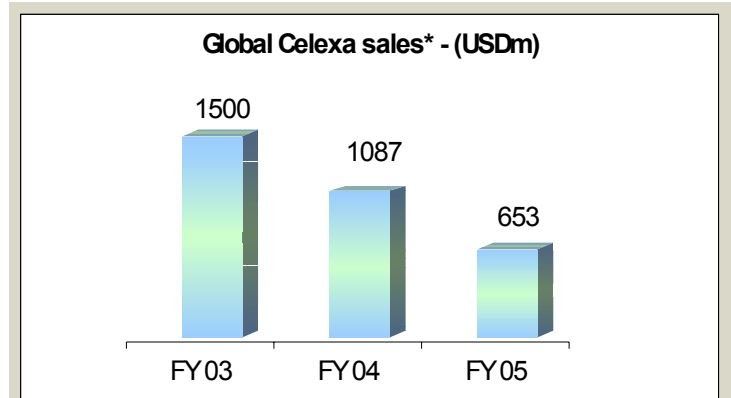
In 2005, Celexa registered a sale of US\$653m, with a sales decline of 40% compared to the previous year due to the patent expiry in the US during FY05. The sales declined by 29% in FY04 due to the patent expiry of Celexa in Europe in the same year. Moreover Forest Laboratories, Inc., themselves has launched a generic version after its patent expiry which recorded a sale of US\$4.56 million in FY05.

Competition

With the loss of patent, Celexa is facing competition from the generic players. In a period of two years, its sale has declined by 56% due to generic competition. It is also facing competition from brands such as GSK’s Wellbutrin, Pfizer’s Zoloft and Eli Lilly’s Prozac.

Outlook

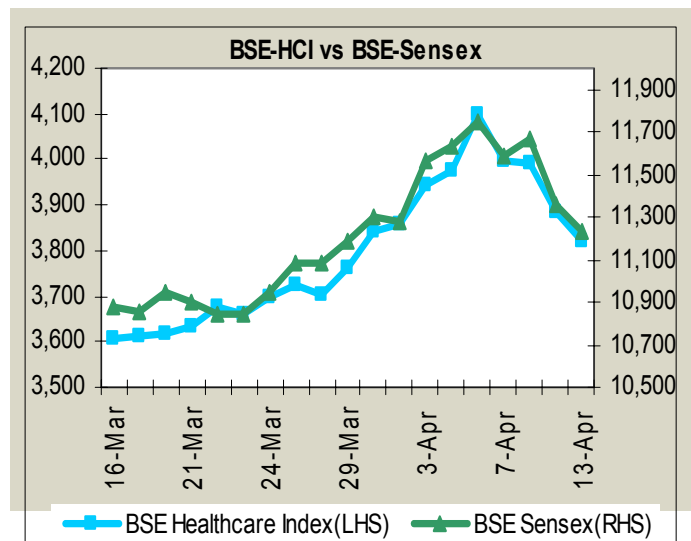
The outlook for the brand Celexa looks bleak as it would face stiffer competition from generics in the future. The sale of Celexa is expected to decline by another 10% in the FY06. Moreover, Forest Laboratories, Inc. is aggressively promoting Lexapro (escitalopram), the racemic form of Citalopram compared to Celexa and the company has succeeded in shifting the prescriptions from Celexa to Lexapro over the years.



Source: Annual Report *Sales is for the financial year April - March

Stock Scan

BSE Sensex touched a new peak of 11,746 during March 16 – April 13, 2006. It has continued the bullish trend after crossing the 10,000 landmark. During the given period, Sensex gained 3.29% from 10,878 to 11,237.23. Positive budget proposals, robust economic growth, expectations of higher than 8% GDP growth and plans for RBI to announce the first roadmap on capital account convertibility by July cleared the decks for the Sensex to cross the 11,000-mark. Sensex saw the biggest two-day decline in about six months on April 12 and 13 as the FII exercised caution and reversed their net-buying trend. BSE Sensex and the healthcare index have shown a very similar trend. The healthcare Index gained 216.20 points in the given period and closed at 3,822.97, showing a growth of 5.99%.



Source: BSE India, Cygnus Research

Regulatory Issues

US: FDA announces new prescription drug guidelines on computer-coded information

FDA insisted pharmaceutical companies to provide information on approved uses and side effects of their products in transferable computer codes. The new guidelines will come into effect from June 30, 2006 and are expected to reduce the estimated 300,000 medical errors made annually. The computer-coded information will be made in a standardized electronic format that can be sent to physicians' computers and hand-held devices. Moreover, in January 2006, FDA instructed pharmaceutical companies to simplify wording and organization of drug package inserts.

India

WHO may encourage preparation of state-level database of branded drugs

In an attempt to reduce the chances of misbranding and wrong dispensation, WHO may assist state-level pharmacy associations or competent NGO to prepare comprehensive database on the drug brand names that have been approved by respective state drug regulatory authorities. This might lead to the development of a national registry of drug brand names, thereby avoiding registration of similar sounding, look-alike drug brands in future.

MRP inclusive of all taxes may be effective for medicines from July 1, 2006

The implementation of uniform maximum retail price (MRP) inclusive of taxes for drugs across the country is going to be a reality by July 1, 2006. The proposed Drugs (Prices Control) Amendment Order, 2006 would make changes in Paragraph 14 of DPCO 1995 to insert terms such as "maximum retail price" and "inclusive of all taxes". The change is proposed to be in force on all batches of production made on July 1, 2006 and thereafter. Any formulation kept for sale prior to the date of commencement of the Drugs (Prices Control) Amendment Order, 2006, shall make necessary arrangements for printing the retail price of that formulation within the words "inclusive of all taxes" within a period of three months from the date of such commencement.

Chemicals Ministry favors an increase in MAPE by 50%

The Union Chemicals Ministry favors an increase in Maximum Allowable Post-manufacturing Expenses (MAPE) for pharmaceutical products from the current 100% to 150%. This 50% increase is aimed at providing an assured minimum profit for price controlled drugs to prevent companies from stopping the production of such essential drugs due to lack of margins. Chemicals Ministry recommends the increase on account of additional expenses occurring to pharmaceutical companies due to Schedule M implementation, burden of fringe benefit tax, service tax, cost of inflation and the extra cost incurred in pollution control programs.

Anti-dumping investigation on Vitamin A import

The Directorate General of Anti-Dumping and Allied Duties (DGAD) initiated anti-dumping investigation concerning imports of Vitamin A Palmitate originating from Singapore and China after it received complaints from Nicholas Piramal India Ltd (NPIL) on alleged dumping of Vitamin A Palmitate from these countries. NPIL, the sole producer of Vitamin A in the country, has pointed out that there is no difference in the products produced and sold by them and the ones imported from these countries.

Dr Reddy's receives FDA approval for fexofenadine hydrochloride

Dr Reddy's Laboratories (DRL) received the final approval from FDA for its Abbreviated New Drug Application for fexofenadine hydrochloride tablets 30mg, 60mg and 180mg. DRL is expected to commercialize the product immediately. Fexofenadine hydrochloride is the AB-rated generic equivalent of Sanofi-Aventis Allegra, a drug indicated for allergic rhinitis and uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children aged 6 years and above. The product had an annual US brand sales of approximately US\$1.4 billion.

Upcoming Events

1.	Event	Interphex Japan
	Date	May 17-19, 2006
	Venue	Tokyo Big Sight, Tokyo, Japan
	Highlights	It showcases the rapidly progressing scenario in the pharmaceutical industry of Japan.
	Contact Details	Reed Exhibitions, 383 Main Avenue, Norwalk, United States of America. Tel: +(1)-(203)-8404800, Fax: +(1)-(203)-8404801
2.	Event	Clinical Trial Methods and Models of Asia 2006
	Date	May 18-19, 2006
	Venue	Grand Hyatt, Singapore
	Highlights	It will highlight the opportunities and winning strategies to enhance, improve and accelerate the execution of clinical trials.
	Contact Details	Pacific Conferences Pte Ltd Email : emily@conferences.com.sg, Website: www.conferences.com.sg
3.	Event	Pharmaceutical R&D Global Summit
	Date	May 21-24, 2006
	Venue	Shangri-La Hotel, Beijing, China
	Highlights	It will highlight the immense opportunity and challenge of the Chinese pharmaceutical market
	Contact Details	Strategic Research Institute, Jon E. Liong, Email: jliong@srinstitute.com
4.	Event	Medtec-China
	Date	Jun 21-23, 2006
	Venue	Shanghai New International Exhibition Centre, Shanghai, China
	Highlights	China's medical device and equipment manufacturers will have access to hundreds of leading medical OEM suppliers from around the globe, providing a vast array of equipment, materials and services.
	Contact Details	Canon Communications 11444 W. Olympic Blvd., Ste. 900, Los Angeles, USA. Tel: +(310)-(4)-454200, Fax: +(310)-(4)-454299
5.	Event	Next Generation Pharmaceutical Sales Strategies
	Date	June 27 - 28, 2006
	Venue	Thistle Marble Arch Hotel, London, UK
	Highlight	It will concentrate on ways of optimizing sales force effectiveness and utilizing alternative routes to market in an evolving healthcare arena.
6.	Event	CPhI China, 2006
	Date	June 27-29, 2006
	Venue	Shanghai New International Expo Centre (SNIEC) in Pudong, Shanghai, China.
	Highlight	It will provide opportunities to global pharmaceutical companies to launch their products and build new ties in the Chinese market
	Contact Details	2345 Longyang Road, Pudong New Area Shanghai 201204 Phone no +86 (21) 2890 6666, Fax +86 (21) 2890 6777 Website cphi@cmpinformation.com
7.	Event	Interphex Asia 2006
	Date	June 27-29, 2006
	Venue	Singapore
	Highlights	Interphex Asia brings together international Pharma suppliers, industry regulators and pharmaceutical professionals from multinational and regional manufacturers
	Contact Details	Reed Exhibitions, 383 Main Avenue, Norwalk, United States of America. Tel: +(1)-(203)-8404800, Fax: +(1)-(203)-8404801

8.	Event	RFID for Pharmaceuticals
	Date	Aug 1-2, 2006
	Venue	Philadelphia, TBA ,USA
	Highlights	One gets an opportunity to meet and interact with market leaders who have already integrated RFID into their supply chain and learning what it takes to succeed.
	Contact Details	Tel 773-695-9400, Fax 773-695-9403 Website: http://www.aliconferences.com
9.	Event	Regulatory Affairs: Part I: The IND Phase Part II: The CTD/NDA Phase
	Date	Aug 7-10, 2006
	Venue	Massachusetts College of Pharmacy, Boston, USA
	Highlights	This course describes the regulatory background of the IND and NDA, and an overview of requirements and recommendations for preparing these applications for submission to the FDA, post-approval and marketing regulatory requirements and processes.
	Contact Details	Tel +(1)-(215)-4426100, Fax +(1)-(215)-4426199, Email dia@diahome.org Website - http://www.diahome.org/product/10178/06446.pdf
10.	Event	Lean Six Sigma for Pharmaceutical and Biotech Manufacturing Excellence
	Date	July 25 - 26, 2006
	Venue	Park Hyatt Philadelphia, Philadelphia, PA, USA
	Highlights	It will highlight the application of Lean Six Sigma techniques to optimize productivity and profitability, best strategies to decrease cycle time and lower inventories and to garner support and understanding within the organization.
11.	Event	Global Partnership Summit
	Date	May 21-23, 2006
	Venue	Goa
	Highlights	It will bring together luminaries from the International and Indian corporate world to identify the immense opportunities that await as a result of this unfolding.
	Contact Details	www.frost.com/cmfgoa-summit2006 . Vishnu Shankar Phone (Chennai): +91-44-42044682, (Mumbai): +91-22-40013440 Mobile : +91 98407 11331, Email : vshankar@frost .