



In Focus – China's Pharmaceuticals R&D scenario

The Chinese pharmaceutical industry has been rapidly growing since the last decade in line with the rapid growth of the economy. China is the eighth largest pharmaceutical market in the world with more than US\$8 bn total sales in 2004. Growing at a rate of more than 12% annually, China's medicine market is set to become the fifth largest in the next five years after USA, Japan, Germany and France. It is difficult to measure precisely the size of China's pharmaceutical market. Most of the estimates place the current size of China's pharmaceutical market at about US\$8 billion, however, the aggregate province-wise pharmaceuticals and drug sales according to pharmaceuticals economic news shows a total of US\$31 bn in 2004. Transparency, especially with Chinese statistics, is a major problem indicated by the above statistics. Interestingly, global pharma sales were US\$550 bn in 2004 so China's contribution is very meager- when compared to North America (US\$248 bn). Despite the fact that it harbours more than one sixth of the world's population!! Exports from the mainland China have witnessed a year-on-year increase of 24.4% amounting to US\$4.3bn and the total product sales income increased by 17.05% to US\$35.5bn.

Basic drugs and bulk drug production dominates the China pharma industry scenario; relatively lesser degree of R&D efforts resulted in little or no invention of new and advanced drugs. China is now the world's second-largest producer of basic medicines, and the largest producer and exporting country of penicillin, beta-lactam and vitamins. Its basic pharmaceuticals output reached 562,000 units in 2002, an annual rise of 11%, and made up 22% of global sales. Exports in this category increased by 28% to \$2.99 billion, and accounted for 70% of China's total pharmaceutical exports.

Status of R&D in Chinese pharma industry

Of late, the Chinese pharma industry is undergoing a favourable change; with its focus on R&D. This is laudable because the Chinese pharma industry is suffering from a low degree of R&D effort in developing new molecules and drugs, and instead concentrating on bulk drugs. However, an increasing number of leading multinational pharma companies have strengthened their R&D facilities either directly or through their subsidiary or in collaboration with local pharma companies. It is understandable that once their initial investment in manufacturing is over, they may turn in to drug research and development. Since 1980s, all the world's top 20 pharmaceutical companies have business operations in China including Pfizer, Novartis, Eli Lilly and Roche.

Why less focus on R&D?

- Prohibitively, higher cost involved in R&D. It costs US\$800m- to develop a new drug and bring into commercial production.
- Wide prevalence of traditional Chinese medicines (TCM) and large proportion of Chinese rural population still depends on it.
- Majority of Chinese commoners are not able to afford costly, branded pharma products developed after incurring heavy R&D expenditure.
- Wide practicing of production and marketing of cheap, often poisonous, imitation/counterfeit drugs. The WHO claims that more than 1,300 illicit pharmaceutical factories have been shut down since China joined the WTO, resulting in the seizure of US\$57m worth of counterfeit drugs.
- An average Chinese spend just \$6 on his prescription drugs annually while Americans spend an average of more than \$500.

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- Poor intellectual property (IP) environment and these IP regulations are often flouted. The recent cases of pharma majors are notable- Pfizer Inc.'s Viagra patent was rejected by Beijing's State Intellectual Property Office while a local generic version of Viagra was freely marketed by Seventeen Chinese companies in a joint venture. The other case is that GSK abandoned efforts to protect one of its patents on Avandia, a top-selling diabetes drug, after Chinese officials ruled that similar products from mainland drugmakers used a different salt compound, a key ingredient in the compound. It means that Chinese generics makers now can legally sell similar compounds. These instances had forced global pharma companies to rethink on making on huge R&D investments in China.

Recent events

- In September, 2005 Switzerland-based Novartis and Shanghai Institute of Materia Medica (SIMM) at the Chinese Academy of Sciences entered into an agreement in extending a joint research to develop natural compounds herbs to 2007.
- Roche Pharma announced the opening of Roche R&D (China) Ltd at the Shanghai Zhangjiang Hi-Tech Park (also called "Drug Valley") to help celebrate the 10th anniversary of Shanghai Roche Pharmaceutical Ltd, which will be operationlised by end of 2005.
- DSM, supplier of performance materials and industrial chemicals especially pharmaceuticals, opened its first R&D Centre in Shanghai, in September, 2005. The DSM R&D Centre, China will be the company's main R&D base in the country that will focus on R&D of DSM Nutritional Products, DSM Food Specialties and DSM NeoResins initially.
- Also research library of Eli Lilly was opened in 2005.
- Pfizer have been evaluating the establishment of an R&D centre in Shanghai.
- AstraZeneca started its East Asia Clinical Trial Centre in Shanghai in April 2003
- Novo Nordisk China relocated its R&D centre to the Beijing Zhongguancun Life Science Park and doubled its size August, 2005.
- Shanghai Shiye Group and Chifeng Pharmacy Group have joined forces to build world-class R&D and manufacturing facilities for the world's largest ephedrine program, a key component of bronchial medications, will be completed by 2005.
- Institutional support from government is also growing. Beijing has committed to build an RMB7 bn "Medical Valley" in Haikou, provincial capital of Hainan Island, to house five bio-med R&D centers to attract domestic players and multinationals.
- Orchid Chemicals and Pharmaceuticals of India signed a 50-50 joint venture on R&D with North China Pharmaceutical Corp (NCPC).
- Shanghai Pharmaceutical Group (SPG), China's biggest drug maker, invested US\$6 million in its Central Research Institute in 2004.
- Though the amount invested in R&D by Chinese firms are paltry compared to US or European pharmas, it reflects the kind of rethinking Chinese players are doing.

Opportunities

- Despite having these many pitfalls, still the bait for the global pharma companies to invest in China is its huge population and growing market. UN predictions say that by 2020, 16% of China's population will be over 65, compared to the 7% now. Therefore, the demand for pharma products will grow multifold during this period. The rising middle class with its improving standard of living is looking for better and affordable health care.
- China's shift to market economy coupled with challenging demographic trends have put conventional health care beyond the reach of more and more Chinese, forcing them increasingly to look for other health care and pharmaceutical options. It offers good opportunities for pharma companies to strengthen their R&D efforts and enhance the quality of production. Also collapsing state companies, which provided fully subsidized medicare and housing to employees, ended free hospital access to millions – forced them to go for paid medical services, which will also a put a great demand for drugs and medicines.
- Only few Chinese have access to many medicines, so it's easier to test drugs without worrying about interactions with other compounds.
- There is low cost, qualified manpower available in China

Outlook

It isn't too late for the China pharma industry, now that they have started focusing on R&D, product innovation and development. Though major efforts by far are by pharma MNC, few Chinese pharma majors are moving in this direction. Lucrative factors such as huge and growing population, growing market, expected increase in the aged population proportion to total population in the coming years, growing affluent middle-class Chinese family, which can afford quality and costly pharma products, new-found opportunity of export of pharma products, availability of trained and yet cheap biomedical manpower are few reasons that could drive the thrust for an improvement in R&D. Other developments like China's entry into WTO, modernization of the regulatory mechanism, restructuring of the industry and trade, etc will play an augmentative role in this regard. Therefore, it is rational to expect that the China pharma industry will continue its efforts in strengthening its R&D in the future despite the odds.

News Items

Perlegen Sciences and Mitsubishi Pharma enter new era of personalized medicines in metabolic disease

Perlegen Sciences, Inc. and Mitsubishi Pharma Corporation today announced a licensing agreement for the late-stage development and commercialization of MCC-555 (a peroxisome proliferator activated receptor (PPAR) agonist) for the treatment of diabetes and other metabolic disorders. An estimated 200 million people worldwide have diabetes. Though different diabetes treatments available, many patients still fail to achieve adequate glycemic control, which can lead to serious complications including retinopathy, neuropathy and nephropathy. Moreover, patients are often not prescribed their optimal treatment regimen immediately, resulting in potentially months of inadequate glycemic control. Thus the availability of a personalized PPAR agonist for diabetes can contribute significantly to the quality care of these patients.

Hepatitis B protein vaccine makes progress in clinical trials

The newly developed hepatitis B protein vaccine has been approved to enter Phase II clinical trials in China. The hepatitis B protein vaccine, which is found to circumvent immunity response to the hepatitis B virus and its antigen, could offer a new treatment for the difficult-to-treat disease. The ineffectiveness of the current leading treatment that uses interferon is due to the immunity tolerance that renders the anti-virus medicine ineffective. The interferon is able to depress the duplication of the virus but is not able to completely wipe out the virus. However, the new hepatitis B protein vaccine works by effectively "teaching" the human immune system to recognize the virus correctly, and alters the tolerance of the immune system so that the immune system can properly produce endogenesis cells to achieve a curative effect. The hepatitis B protein vaccine is a specific immunity treatment. Combined with the non-specific treatment and anti-virus medicine, it can form one prong of a three-part treatment plan for hepatitis B patients.

EU-Chinese co-operation pinpoints potential treatments for SARS

A team of scientists from Europe and China have identified 15 existing drugs of promising anti-SARS (Severe Acute Respiratory Syndrome Coronavirus). compounds. One of the target compounds, cinanserin, was approved in the USA for clinical use in the 1960s to treat psychopathic diseases, such as schizophrenia. The team of scientists in the EU-supported SEPSDA project (Sino-European Project on SARS Diagnostics and Antivirals) have spent the past years screening over 8 000 existing drugs to find prime candidates for combating SARS.

They found that cinanserin can halt the SARS virus from replicating. The team explained that it works against SARS by blocking an enzyme in the virus, called 3Cl^{pro}, which it is now known plays a key part in the viral life cycle. However, the team scientists are cautioned that without animal tests or epidemiological testing on people, it is not sure that these candidate compounds could be developed into effective SARS treatments.

FusoGen Pharma's Anti-AIDS medicine in clinical trial

FusoGen Pharmaceuticals's of Tianjin announced that their new HIV/AIDS medication which acts as HIV fusion inhibitor is undergoing clinical trials. The treatment works by preventing the HIV virus from entering immune cells. Normally, the HIV virus invades the human body by fusing the cell's membrane thus by safeguarding the 'gate' and preventing the occurrence of membrane fusion, the infection is avoided. The new medication is able to target HIV membrane fusion protein and prevent the virus from attacking cells. AIDS patients and those who are HIV positive will need to be injected everyday. The medication has been registered as a new medicine with the State Food and Drug Administration. However, the cost of new medication is significantly lower than comparing the new drug's competitor "T20", which cost US\$20,000 per patient per year. The new medication is likely to be released in the market at the end of next year.

China plans to spend more to fight AIDS/HIV

The Chinese Government is planning to spend 3.9 bn Yuan (US\$474m) by the end of 2007 to help local governments fight AIDS and HIV. In 2004, the central government allocated 3.7 bn Yuan (US\$450m) to help local governments to improve public health, and around 700m Yuan (US\$85m) of it was used to fight HIV/AIDS. Since the second half of 2003, China has earmarked more funds each year to arm local hospitals with HIV testing facilities and offer patients free AIDS drugs. Also, China's central government won the praise of United Nations for its significant efforts in HIV/AIDS prevention of control.

Local scientists invent nanotech-enabled drug delivery device

Scientists from Shanghai Silicate Research Institute of China, a subsidiary of the Chinese Academy of Sciences, have developed a ball-shaped device that can deliver drugs directly to targeted areas of the body using nanotechnology. About one three-hundredth (1/300) of the diameter of human hair, the device is small enough to travel through blood vessels and can carry drugs of the same weight as itself. The device's surface is full of cavities where drugs are stored. Magnetic material within the device helps it to be directed to target areas. When it arrives at its destination, the protective coating will dissolve and start to release the drug. A nanometre is a metric unit of length equal to one billionth of a meter. Generally, these nanometre-sized devices have the potential to treat diseases like cancers in previously inconceivable ways.

China to stop using human flu drug on poultry

China has confirmed reports that its poultry farmers have been using the human anti-flu drug amantadine in poultry, which can cause drug-resistant strains of the virus to develop. But these controls have come in too late, for the "Z" strain of the H5N1 virus has spread through Southeast Asia and killed 54 people. Health officials fear this may develop into a human pandemic, which is already resistant to the drug. China's official newspaper, the *China Daily*, reported in June that the agriculture ministry would send inspectors across the country to halt the practice. However, the ministry of agriculture denied that it had encouraged the use of amantadine. But the worst part of this news is that amantadine has been in use in China since the late 1990's. This cheap, readily available drug is used to treat outbreaks and routine prevention, in the same way that antibiotics are commonly used in livestock.

Mitsubishi Pharma Europe Ltd.,'s first independent product for Europe launched

Mitsubishi Pharma's overseas subsidiary Mitsubishi Pharma., has announced its launch of selective antithrombin agent *Argatroban* under the brand name *Argatra* to be marketed independently in Germany from June 2005. Mitsubishi Pharma Europe plans to carry out successive market release in Sweden, and the Netherlands, where approval has already been obtained and in Austria and Italy, where approval is still pending.

China's Sinopharm sells 50% of subsidiary to Reed Exhibitions

China's Sinopharm, China's largest drug company has agreed to sell half of its subsidiary, China Pharmaceutical Exhibition Corp., to Reed Exhibitions, a subsidiary of international publishing group Reed Elsevier to establish a joint venture targeting the Chinese exhibition industry. The joint venture will be called Reed Sinopharm Exhibitions Co. It is aimed to benefit from the sunrise industry of domestic exhibition which is growing at 20% per annum. The deal marks the largest of such cooperation between a state-owned enterprise and a private company in China's exhibition market, and Reed Exhibitions intends to continue its expansion here through such partnerships. The firm plans to bring three major international shows from the US and Europe to China, Hong Kong or Macau.

China's pharma major pledges to support Africa in its fight against malaria

Holleypharm and its marketing division Holley-Cotec, having 40-years experience in battling malaria in China, have proposed an anti-malaria campaign in Africa that will include distribution of mosquito nets, antimalarial medicine and community education to be sponsored by the Chinese government. The project will be initiated by the end of September aimed at eradicating the deadly disease in the continent. Though Holleypharm had proposed an initial pilot project to be carried out in Tanzania and Cameroon, the Chinese government is pushing at four countries included in the pilot. The company had also put in a bid to supply 1.8 million mosquito nets in a World Health Organisation sponsored project.

The US\$2,716.15 million (2005) worth Mitsubishi Pharma Corporation was formed in October 2001 through the merger of Welfide Corporation and Mitsubishi-Tokyo Pharmaceuticals, Inc. as a response to the challenging business situation in the pharmaceuticals industry, in order to further enhance business base of its parents and to create an optimal scale of operations that would ensure our survival amid intensifying global competition.

Company Scan – Mitsubishi Pharma Corporation Ltd.

In its efforts to transform it as global research-driven pharmaceutical company a New Mid-term Corporate Action Plan is in progress over a three-year period, starting from 2004. In order to achieve the objective, the following four strategic tasks are pursued,

- Maximization of sales and marketing strengths
- Optimization of production and technology divisions
- Total cost reduction
- Increasing the certainty of research and development results and establishment of global marketing basis.

Products

Mitsubishi Pharma is specifically concentrating in four specialist areas of neuropsychiatry, the circulatory system and metabolism, immunology and the respiratory system, and oncology and hepatology. Meeting the challenges of the times head on, Mitsubishi Pharma Corporation will actively participate in the field of genomic drug discovery as a team player in life science, the core business of the Mitsubishi Chemicals Group, by joining forces with the Mitsubishi Kagaku Institute of Life Sciences and others to play a leading role in the post-genomic era.

New drugs under development

The following few drugs are under development but promise to become major new drugs with worldwide applications:

- An immunosuppressive agent FTY720, synthesized using a component of the *Isaria sinclairii* fungus, is currently under clinical trials in Europe and North America.
- MCC-135, a therapeutic agent for myocardial infarction with a novel action mechanism is also under development in Europe and North America.
- Clinical development for AS-013 is under way in U.S., a therapeutic agent for severe chronic arterial occlusion.
- In the biopharmaceuticals field, there has evolved a reliable and efficient production system for recombinant human serum albumin, Albrec, which now awaits approval for domestic manufacture.
- Another promising therapeutic in the pipeline is the immunoliposome MCC-465, which acts like a cancer-seeking missile by taking advantage of antibodies specifically targeting tumors of the digestive tract such as the stomach and the large intestine.

Recent developments

Mitsubishi Pharma together with Mitsubishi Chemical Corporation jointly established a parent company with a 100% holding in the two companies through a stock-for-stock exchange through an agreement in April, 2005. The parent company Mitsubishi Chemical Holdings Corporation will be established on October 3, 2005, following authorization by regulatory entities and other required procedures. The establishment of the joint holding company will broaden its options with regard to the formation of business alliances and other strategies to assist its rapid development as a global research-driven pharmaceutical company, and to further strengthen Mitsubishi Pharma's cooperative relations with other Mitsubishi Chemical Group companies in the healthcare segment.

Business strategies and corporate vision

Mitsubishi Pharma has declared a long-range corporate vision and strategy consisting of three policies

- Business management emphasizing increase of corporate value

Mitsubishi Pharma's main products in market	
Category	Products
Central Nervous System Agents	Depas, Doral, Impromen, Radicut, Rize
Respiratory Agents	Surfacten, Cleanal
Metabolic Agents	Anplag, Heparin Na LOCK
Cardiovascular Agents	Baylotensin, Cholebine, Conan, Kerlong, Liple, Novastan
Gastrointestinal Agents	Omeprazon, Urso
Biological Products	Albumin, Neuart, Venoglobulin-IH
Products on Sales Commission to Nikken Chemicals, Ltd.	Theodur
Other Pharmaceuticals and other products	Pazucross, ZIONE, Biopex

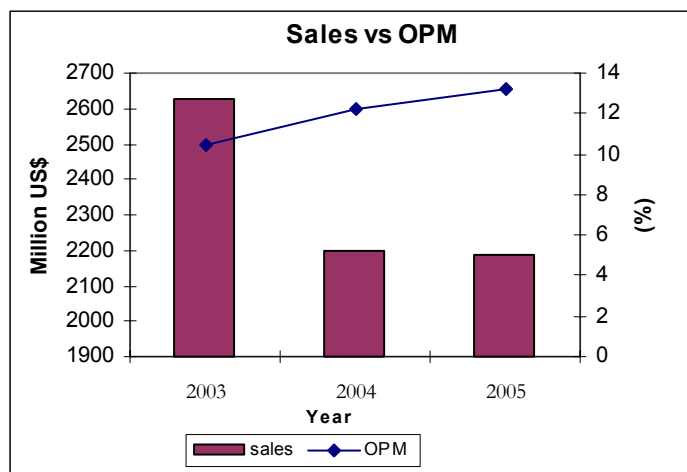
Source: Mitsubishi Pharma

- Highly transparent global-standard management
- Business management taking maximum advantage of the combined strength of the Mitsubishi Chemical Group, of which Mitsubishi Pharma is a member.

The above strategies which help in transforming it to a global research-driven pharmaceutical company that in turn realize its basic philosophy: endeavours to embrace humanity and contribute to the improvement of people’s health and well-being.

Operating performance

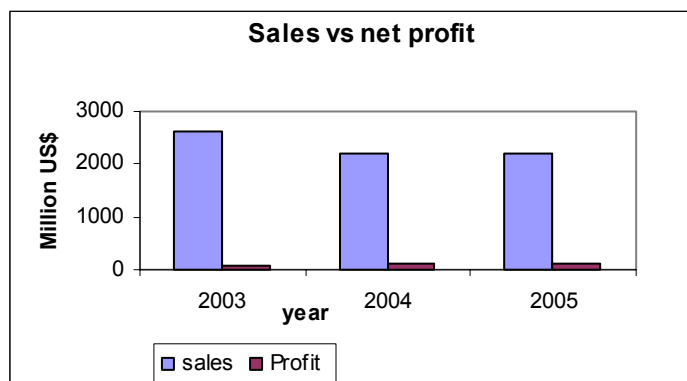
The operating performance of the company is slowly increasing over years as the OPM is improving over the period. Pursue of Mid-term Corporate Action Plan started from 2004, aiming at maximizing sales and profit, cost cutting and optimization of production process, seem to start yielding, indicated by the improving operational performance. The growth in the operating income is mainly brought by improvement in the cost-of-sales ratio and a reduction in selling, general and administrative expenses (excluding research and development expenses). However, it is noteworthy to mention that the sales revenue of the company in the year ended March 31, 2005 is continuously sliding due to negative factors including National Health Insurance Drug Price Revision and the transfer of its over-the-counter business. However, the growth in core products sales and the increase in commercial production following an expansion of facilities at our chemicals plant partly traded off the impact of sales reduction.



Source: Cygnus Research

Financial performance

The financial performance of the company is also improving over years as its net profit is increasing despite the reduction in its sales. Reasons quoted for improvement of operational performance holds good for the improvement of financial performance.



Source: Cygnus Research

Outlook

It is already mentioned that the company is vigorously implementing its Mid-term corporate action plan, hoping to bring in structural changes in the company with its completion by 2007. Therefore, it is convincing that the current year performance is pale, because the company is in its midway in its corporate action plan. Moreover, the company is hopeful of gaining a major market share by means of new drugs introduction, strengthening R&D, focusing on the new-age genomic drug discovery and its development.

Industry Performance

China's pharma industry has been on steady growth path during first half of 2005. However, it was largely a mixed bag of results.

Glimpses of industry performance

- Desirably, the parameters of output value and sales revenue grown by 23% and 24% respectively, when compared with the same 2004 period.
- Though the cumulative performance of pharma industry was plausible, more and more individual pharma enterprises realized revenue losses, totaling to 1.8bn yuan, 19% more than the 2004 period. This is despite the industry's total profit, which increased by 21% year-on-year to reach nearly US\$2.1bn. The chemical drug sector was the biggest loser, which topped US\$61.72 m and 42% of state-owned enterprises suffered losses.
- Major enterprises registered steady drops in profit level. The demand by hospitals and the retail sales market continued its upward trend, due to the expansion of the catalog of medicine covered by medical insurance and a drop in medicine prices.
- Total imports and exports reached US\$6.7 bn in the first half, growing by 19%, with imports growing 13% to US\$3bn and exports growing 24% to nearly US\$3.8bn, leaving a trade surplus of more than US\$800m. Medical apparatus and chemical crude drugs accounted for 75% of the import and export trade.
- The top 100 enterprises generated combined sales revenue of US\$11.54bn in the first six months, 47.4% of the industry's total. The Shanghai Pharmaceutical (Group) Co., Ltd. recorded the biggest sales of US\$1.28 bn, followed by Guangzhou Pharmaceutical Holdings Ltd. with US\$880m.
- The public sector company's performance was also satisfactory. The ten state-owned enterprises achieved US\$1.67 bn in sales revenue and 54 joint stock enterprises generated US\$7.56 bn.

Chinese pharma industry's performance, H1, 2005	
Performance parameter	Value (US\$ bn)
Total output	26.2
Sales revenue	24.34
Total profit	2.10
Cumulative industry revenue losses (total of all loss making enterprises)	0.22
Export	3.8
Import	3.0

Source: Pharmboard

Outlook

The ever growing pharma industry of a country, given its large and growing population of China performed well and is expected to do well in the months to come. With its major policy changes such as scrapping government-backed free medicare facilities to the government employees will increase the domestic demand for pharma products as this large population has to buy from company's retail outlets. However, ground realities such as indifference of Chinese officials to pleas of western pharma companies on violation of intellectual property rights by local pharma manufacturers, large market of counterfeit drugs need to be set right for the pharma industry to augment its growth.

Upcoming Events

1.	Event	China-Pharm 2005- The 10th China International Pharmaceutical Industry Exhibition
	Date	October 25th-28th, 2005
	Venue	Shanghai New international Expo Center
	Highlights	The exhibition will have a large display of following products <ul style="list-style-type: none"> • Medicines and chemical products • Drug testing and analytical instruments • Supplementary equipment for pharmaceutical production and laboratory equipment • Pharmaceutical packaging machinery • Pharmaceutical machinery • Medical devices • Hygienic material • Medical and pharmaceutical books, magazines, information, etc.
	Contact Details	China Center for Pharmaceutical International, Exchange of State Food and Drug Administration, B-5306, No.6 Xizhimen South Road, Beijing, China Phone: +86-10-66155603/66186688-5313/66162161, +86-10-66155632/66186688-5307/66186688-5313, Fax:+86-10 66167891, E-mail: info@mdna.com Web: www.mdna.com
2.	Event	The 54th China International Medical Equipment Fair
	Date	November 1st – 5th, 2005
	Venue	New International Convention & Exposition Centre, Chengd, Province of Sichuan, South West China
	Highlights	CMEF, the largest medical equipment trade fair in Asia, provides all exhibitors and visitors an excellent opportunity with both the Chinese and international medical market. Also a wide variety of seminars, conferences, presentations and symposia greatly enhances the exchange of information will also be presented.
	Contact Details	CMEF Dept., Phone: +86-10-62028899, Fax: +86-10-82022922
3.	Event	Pharma Marketing- Building successful marketing, branding and distributing strategies in China's pharmaceutical industry
	Date	November 10th-11th, 2005
	Venue	Sofitel Jin Jiang Oriental , China
	Highlights	It will be a platform to bring all leading corporate decision-makers and top chief scientific officers to discuss current issues of strategic interest, investment and production opportunities in the pharma & biotech sector, promoting successful strategic alliances and bio-partnering etc., The conference includes experts lectures on <ul style="list-style-type: none"> • Latest regulations and compliance requirements from SFDA • Growing your presence in the marketplace by implementing evolving pharmaceutical marketing techniques • Optimising on the efficiency of your communication and advertising campaigns • Establishing what it takes to be consistently successful in marketing pharmaceutical products • Leveraging new nature branding and the evolving of mega-branding
	Contact Details	Jane Zhou, Unit A&B, 5/F, Phase 2, East Ocean Center, 618 Yan An Road (East) Shanghai China 200001, Tel :+ 8621 5385 5240, Fax :+ 8621 5385 5243 E-mail : janez@marcusevanssh.com

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