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In This Issue

Chinese Pharma Industry Forecast for 2007 and 2008

SMEI estimated that the total output value of the Chinese pharma industry will reach CNY 630 billion (US$84 billion) in 2007, up by about 18%. *P4*

GSK to Inject $100m on Neuroscience R&D in China

Its new R&D center in Shanghai will be responsible for all GSK's work on neurodegenerative diseases *P9*

Uncertainties Loom over Bayer's Acquisition of Topsun's OTC Business

Despite government approval of the Bayer's acquistion of Topsun's OTC drug business on October 11, the deal has so far not been completed. *P10*

SFDA Publishes Draft of "Rules for the Registration of Technology Transfer of New Drugs"

The revised rule will lift previous restrictions on local sales of contract manufactured foreign drugs. *P12*

SFDA Launches Drug Product Recall System

The new recall rule requires companies to put systems in place to recall problem drugs and to alert the government *P14*

China's Market for Vaccines

Rob Pollard analyzes and comments on the Chinese vaccine market. *P24*

CONTENTS

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Editorial

2007 - A Good Year for R&D-based Multinational Pharmaceutical Companies

James J. Shen

One of the most important features of Pharma China is our monthly editorial under which I summarize and comment on the developments and trends in the recent month. This is done based on my continuous observation of the pharmaceutical industry in China and constant communication with industry insiders, many of whom are also our subscribers.

I just finished another three-week tour of the pharmaceutical industry in China meeting up with senior and operational executives in both domestic and foreign pharma companies as well as industry association officials. A combination of mutual trust, friendship and my strong commitment to confidentiality of information sources allows me unique access to a broad range of insider contacts in the Chinese pharma industry.

A good year for multinationals

My conversation with executives of multinational pharmaceutical companies in China confirmed my own impression from various data sources that most R&D based pharmaceutical companies have made remarkable progress this year with their business in China, both in terms of revenues and profitability.

The excellent performance of multinational pharmaceutical companies in China this year has primarily stemmed from the positive government policies that have been weeding out disorderly competition from many small local companies, thus making room for R&D based companies. Preferential pricing policies of the government for originator drugs and patented products also allow better margin for multinationals.

But an MOH policy that allows only two suppliers for each of the injection and oral dosage forms of a drug under the same generic drug name seems to have won the most applause by MNC executives that I met during this last trip to China. Hospitals tend to choose one MNC and one local company as their suppliers under this policy, thus significantly boosting the chance of hospital entry by MNC products and ensuring fewer competitions.

The latest victory won by multinationals in the area of drug regulation, following years of advocacy, is related to the contract manufacture of foreign drugs. A proposed regulation for technology transfer in the pharmaceutical industry includes provisions that would effectively remove the previous restrictions on sales of contract manufactured foreign drugs in China.

Encouraged by the pro-multinational stance of the Chinese government and against a backdrop of rising restructure pressure on the global R&D based pharmaceutical industry, multinationals are accelerating their R&D relocation to Asia, most notably to China. While Pfizer, BMS and Eli Lilly all stated they will increase R&D activities in China this month, GlaxoSmithKline took a big step forward by relocating all of its research on neurodegenerative diseases, including Alzheimer's, Parkinson's disease and multiple sclerosis, to China. In announcing the news, Moncef Slaoui, chairman of GSK's research and development, said "*We don't want to give them the crumbs… We will link our fate to their fate. Within five to ten years we will be moving from 'made in China' to 'discovered in China'.*" While I am sure the Chinese government will be really pleased to hear this, the remarks somewhat shocked me because just not long ago, the prevalent topic was still about China's poor IPR records.

However, not all are positive. Law firm Sidley Austin said three issues in drug registration, namely the definition of new chemical entity, data exclusivity/ protection and patent linkage, remain unaddressed by the Chinese government. While the first two subjects are relatively easier for the Chinese government to deal with, I believe the SFDA will provoke relentless fire from local companies if it ever dares to cross the line of patent linkage.

As I discussed with many industry leaders, the Chinese government has taken a distinctively different development path for its pharmaceutical sector from

that is taken by India. Just as GSK's Moncef Slaoui suggested earlier, China and multinational pharma companies are increasingly linking their fates together, while India seems to put its local pharmaceutical industry in front of multinationals without any hesitation. In my opinion, China has by now reached a point of no return on its pro-multinational path, and the best strategy would be to pace up on this path without any dithering. By strengthening its support to the R&D based pharmaceutical industry, China will attract more multinational pharmaceutical companies to link their fates with the country, thus benefiting the growth of the local pharmaceutical industry in the long run.

Fair performance expected by local pharma companies

When I met a number of senior executives of leading local pharmaceutical companies, I could see some ease on their faces, but often coupled with sighs. While business performance of many large local companies has improved in 2007 against the great depression last year, few companies have seen any sharp growth as that reported by their multinational counterparts.

Most large local companies have gained considerable revenue growth this year driven by less competition in the urban areas and rising sales in suburban and rural areas, but margins continue to be depressed and profits have grown slower than revenues this year. Although some companies have benefited wildly from the Chinese stock boom this year, I keep asking myself why they had so much spare cash to invest in the stock market in the first place.

IPO star Nanjing Simcere puzzled me with its recent US$4.4 million acquisition of Nanjing Tung Chit, a company I happen to know quite well. The discomfort from sitting on a pile of cold investor money must have driven the company desperate for acquisitions – but good targets are not easy to come by. A temporary relief may sometimes turn out to be a long term pain … *well, I guess I'd better shut up before getting myself in trouble with Simcere again*.

Executives of some mid-size local companies told me that their business remained difficult this year and they felt clueless about future. Export business seems to be the only potential way out, and therefore, more investments are expected to be poured by these companies into upgrading their API and formulation facilities to meet international standards.

API sector face severe challenges

One of the missions of my latest China trip was to launch a chemical process development CRO, a joint venture between a WiCON subsidiary and a UK/USA based process development firm run by two top notch British process chemists. We met dozens of API and fine chemical companies in Jiangsu and Zhejiang provinces, and invariably we found them facing mounting challenges of rising energy prices, growing environmental protection costs and appreciating Chinese currency. Many companies are now forced to double their prices of key products, resulting in great risks and market pressures.

Their continued survival, not to mention growth, seems to side with their ability to innovate their existing inefficient production processes and technologies so as to minimize costs and maximize efficiency.

Contrary to a few years ago, we found Chinese API and fine chemical companies demonstrating strong incentives for acquisition of foreign know-how, production technologies and research services to the point we were quite overwhelmed with potential contracts at the end of the trip.

Regulatory developments this month

Despite failures of its drug pricing policy that led to short supply of many essential drug products, NDRC is displaying a tendency to intensify and broaden its regulatory control on drug prices. Not only the agency hopes to control prices of all prescription drugs, but also it plans to step up its control of drug prices by setting ex-manufacturer prices and regulating profit margins from factory to retail. One other strategy being studied by NDRC is to let patients pay for the price difference between generic drugs and originator drugs – a policy that has been resented by multinationals.

An additional idea currently under scrutiny by NDRC is the so-called "pharmacy affairs fee" (an alternative to prescription fee) which is likely to be assessed on each physician prescription, and current suggested amount is CNY 10. This new idea is designed to reform the existing hospital financing model and is only at its early stage of being assessed. Some experts are concerned that the system can easily be abused by hospitals and physicians. Besides the pharmacy affairs fee, NDRC is also looking at the possibility of raising medical fees of hospitals as another means of hospital financing.

I am becoming increasingly wary of NDRC's tendency to boost government price control, and believe this may lead to another round of meaningless turmoil in the Chinese pharmaceutical and healthcare sector. Hopefully the *Mandarins* will realize the real world is not a laboratory where experiments can be tossed around casually. The final costs of their endless unsuccessful experiments will have to be paid by either the government or the patients.

The Ministry of Health (MOH) also wants to make its mark in 2007 and has introduced a number of new rules and policies affecting the pharmaceutical industry just before the year end. One of them calls for the establishment of a medical ethics evaluation system, but its merits are doubtful because it is entirely based on internal assessments.

However, the Ministry's proposed new pharmacy affairs regulation is nothing trivial and once introduced, it may have broad impacts on the ways medical institutions purchase their drug products and physicians write their prescriptions. It is unclear at this point if the MOH will also include a provision in this regulation for the proposed "pharmacy affairs fee". While this draft regulation is not yet published for comments, it is advisable that industry associations and companies approach the MOH early to communicate over the contents of this regulation.

As usual, there were many activities on the front of SFDA this month. The most significant move by the agency this month is the launch of a national drug product recall system covering both local and imported drugs. The new recall rule requires companies to put systems in place to recall problem drugs and to alert the government of adverse reactions on patients. In addition, foreign companies are required to report their overseas product recalls to the SFDA. The new drug product recall regulation allows the Chinese government to order a compulsory recall of problem drugs when necessary, and violation of the regulation will lead to stiff penalties including fines up to three times of the value of problem drugs and/or suspension and withdrawal of pharmaceutical manufacturing or distribution licenses. Following the introduction of the regulation, Merck became to first company to test the water with its voluntary recall of PEDVAXHIB vaccine in China, and we look forward to hearing some feedback on its experience.

Mixed signals again for healthcare reform plan

We received some mixed signals this month from different government agencies for the timing of the introduction of the draft healthcare reform plan. While a senior CPC policy official and MOH officials declared earlier in December that the draft would be out for public comments before the end of 2007, NDRC stated later that the draft plan will not be published until sometime in 2008.

This indicates how much disagreement is out there among various government agencies involved in the development of the country's healthcare reform plan.

Apart from their differences regarding the timing of this event, what worries me increasingly is the lack of a consensus mechanism among these government agencies. There is a real danger and tendency there that some of these agencies are making pre-emptive moves to experiment and implement their own ideas with the intention to influence the final outcome of the future healthcare reform direction. For example, the MOH is currently experimenting and expanding, in Beijing's community healthcare system, its proposed hospital financing model that seeks to separate revenues and expenditures of medical institutions. Meanwhhile, NDRC is expanding the experiment of a disease-based flat fee medical expenditure system in Henan province. We have also been witnessing expedited development and launch of certain new regulations and policies by individual government agencies as means to reinforce their positions in various policy areas.

Such political standoff and competition are likely to induce more hassles and damages to the pharmaceutical industry and unavoidably lead to higher regulatory compliance costs.

To conclude this month's editorial, on behalf of the editorial team of Pharma China, I wish all our readers and their families a Merry Christmas and Prosperous New Year in 2008.

In our next issue, we will do a thorough review of the Chinese pharmaceutical industry and market in 2007. *Stay tuned ….*

News in Focus

Chinese Pharma Industry Forecast for 2007 and 2008

According to the Southern Medicine Economic Institute (SMEI) under the SFDA, the total output value of the Chinese pharmaceutical industry (including drugs, TCMs, herbal materials, biological products, medical devices, and pharmaceutical packaging & machineries) is expected to reach CNY 630 billion (US$84 billion) in 2007, up by about 18%.

SMEI also forecasted that the total output value of the Chinese pharmaceutical industry in 2008 will grow even faster by 19% to 20% to reach CNY 740 billion to CNY 760 billion (US$99 billion to US$101 billion).

News in Focus

MOH to Introduce Pharmacy Affairs Regulation Soon

A reliable source disclosed at a recent national conference of hospital pharmacy directors, the Ministry of Health (MOH) has recently completed the drafting of "Interim Regulations on Pharmacy Affairs Management of Medical Institutions".

The proposed new regulation will, for the first time, clarify the position and responsibilities of hospital pharmacy and pharmacy management in medical institutions. It will strengthen the role of hospital pharmacy committee within medical institutions whose core positioning, functions and responsibilities are to 1) supervise, inspect and guide the rational use of drug products clinically, and 2) develop pharmacy management related rules and systems for safe, effective and economic drug use. The new regulation aims to build a cooperative and complementing relationship between physicians, pharmacies and nurses. It will require hospitals to establish a "system for clinical drug use supervision and evaluation", an "automatic control system for physician drug prescription advice", and a "computerized control system for physician drug prescription advice time-limit".

In addition, the new regulation will tackle various issues in drug prescription such as the use of generic drug names. The source said that the new regulation will also include provisions for the development of hospital prescription drug list and hospital essential drug list. In principle, for each drug under the same generic name, only two manufacturers will be selected for each of the injectable and oral dosage forms for listing in the essential drug list. For similar compound formulations, only one to two suppliers can be selected for listing in the essential drug list.

The regulation will require physicians to prescribe drugs listed in the prescription drug list and essential drug list of their respective medical institutions. Hospital pharmacies will be required to make purchase plans and execute purchases in accordance with these two lists.

Drug products not listed in the hospital prescription drug and essential drug lists should be approved for one-time purchase by directors of medical affairs and pharmacy affairs departments. Patients will not be allowed to purchase drugs on their own from other sources for use in the hospitals where they are treated, and consent from the treating physician and pharmacist will be needed for special circumstances.

NDRC Reveals New Thoughts for Drug Pricing

In a recent article published on the website of NDRC, Bi Jingqun, Vice Minister of NDRC, revealed that the agency intends to adopt following measures on drug pricing in future:

- Ex-manufacturer prices of drug products will be set in future and retail prices will be required to be printed on the outer packaging of drug products;
- The target profit margin for wholesale/distribution of drug products will be between 5% and 7% on top of the ex-manufacturer price;

- Hospitals and retail pharmacies will not be allowed to add margins to drug product sales, but instead they will be allowed to assess a pharmacy affairs fee on each physician prescription; and
- Basic medical insurance systems will only reimburse drug costs according to the prices of generic drug products, and the difference in prices between generics and originator drugs will be paid by the patients.

It is the first time NDRC publicly announced its intention to introduce the above four measures, according to local experts.

Zhu Changhao, Executive Vice President of China National Association of Pharmaceutical Commerce, expressed to the local press that he doubts the effectiveness and wisdom of publishing retail prices on the outer packaging of drug products and concern that the measure will increase the costs of pharmaceutical manufacturers.

Zhu also suggested that his association advocate a wholesale/ distribution margin of 10%, as according to him that many wholesalers will not survive on a margin between 5% and 7%. The association is not against the measures of zero margin on retail sales and prescription-based pharmacy fees, but Zhu cautioned that the costs for logistic distribution of drug distribution need to be considered.

Zhu is highly supportive of the measure that calls for basic medical insurance reimbursement of drug costs at generic drug prices, and believes the measure to be beneficial in fostering a stronger local generic drug industry.

NDRC likely to raise prices of drug products in short supply

In a separate development, NDRC recently contracted China Price Association to conduct a market research of drug products that are lowly-priced and in short supply.

The market research began in early December, and will cover representative hospitals in ten Chinese cities including Shanghai. In addition, the Association will also visit large pharmaceutical distribution companies for fact finding. Preliminarily, the Association has already chosen more than 250 drug products as the subjects for research.

It is almost certain that this survey report by the China Price Association will become an important reference for NDRC when reviewing and adjusting prices of certain drug products in order to encourage pharmaceutical manufacturers to supply them.

The survey report is likely to be out at the end of December or in early 2008, according to the Association.

The Association said that the short supply of certain low-priced drug products is caused either by the reluctance of manufacturers to produce them without profits, or by the lack of incentives for hospitals and physicians to prescribe them.

The Market

Market Analysis: Hospital Market for Sensory System Drugs 1st Qtr, 2007

According to the hospital drug purchase audit of the Chinese Pharmaceutical Association (CPA), which covers representative hospitals in more than 20 Chinese hospitals and accounts for about 26% of the total Chinese market, hospital purchase volume of sensory system drugs fell in 2006, while the value grew 5.13% (down from 15.2% in 2005).

The purchase of sensory system drugs by representative hospitals in the first quarter of 2007 was CNY 55.9 million, up only 2.9% compared with the same quarter in 2006. The total Chinese hospital market size for sensory system drugs is estimated to be around CNY 215 million in the period.

The therapeutic class of sensory system drugs includes two subclasses, ophthalmology drugs and otology drugs under the CPA's hospital drug purchase audit system. The hospital market share of ophthalmology drugs dominates this therapeutic class, which rose from 88.4% in 2004 to 90.5% in 2006.

The subclass of ophthalmology drugs is again divided into ten sub-categories, and the hospital market share of these sub-classes in the 1st quarter of 2007 is shown in the table below:

Hospital Market Shares of Ophthalmology Drug Subcategories in 1st Qtr., 2007

Rank	Therapeutic Class	Share (%)
1	Anti-infectives	43.63
2	Other ophthalmology drugs	19.95
3	Glaucoma and myotic drugs	10.62
4	Drugs for surgical use	10.04
5	Anti-inflammatory drugs	9.44
6	Mydriatic and cycloplegic drugs	3.34
7	Anti-hyperemia and anti-alergic drugs	1.46
8	Diagnostic agents	0.79
9	Compound preparations of anti-inflammtory and anti-infective drugs	0.37
10	Local anesthesia drugs	0.36
	Total	100.00

Source: CPA

Nicholas Hall Reports Data on Chinese OTC Analgesics Market Mid-2007

Nicholas Hall, a leading global OTC market research company, released to Pharma China its latest market data on Chinese OTC analgesics market in the rolling 12 month period ending June 2007.

The Chinese OTC analgesics market in the period rose 14% to reach CNY 5.4 billion (US$689 million). The following table shows a breakdown of the market data.

OTC analgesics market mid-2007*

Category	CNY (mln)	US$ (mln)	+/- (%)
Systemic analgesics	3,197.4	409.4	+12
Topical analgesics	2,181.3	279.3	+16
Total	5,378.7	688.7	+14

Source: Nicholas Hall * Rolling 12 month period ending June 30, 2007

Export of Pharma Formulations Up Sharply in First Three Quarters

According to Chinese Custom Statistics, China's export sales of pharmaceutical formulation products rose 52.9% in the first three quarters of 2007, reaching US$560 million.

Pharmaceutical formulations were exported to 154 countries and regions during the period, and the leading ten markets accounted for 50% of the total export sales.

While exports by local pharmaceutical companies in the period concentrated on developing countries such as Pakistan and

Nigeria, those by Sino-foreign joint ventures and products contract manufactured in China were mainly destined for Japan, South Korea and Australia.

Most of the leading 20 exporters of pharmaceutical formulations in the period were foreign-invested enterprises.

The export volume of pharmaceutical formulations grew 65.5% in the period, while export sales in value rose 52.9%, showing a trend for export price erosion.

Industry News

Prices of Some Pharmaceutical Formulations Rose Sharply

According to local press reports, pharmaceutical companies are beginning to raise the ex-manufacturer prices of some formulation products, especially antibiotics and formulated traditional Chinese medicines, due to rising costs of APIs. Experts believe the trend will not be eased before the end of this year.

The ex-manufacturer prices for amoxicillin formulation products, for example, rose at least 30% on average, with prices of some products shooting up nearly 100%.

At the same time, ex-manufacturer prices for formulated traditional Chinese medicines are also on the sharp rise due to growing herbal material prices. The trend is widespread for many such products.

Rising ex-manufacturer prices are creating heavy pressure on retail pharmacies, which are reluctant to raise retail prices in fear of losing customers. In addition, government-set maximum retail price caps also prevent retail pharmacies from selling above these price ceilings.

It is unclear if NDRC will raise prices of some pharmaceutical products in response to rising costs, but the central government calls fighting inflation a key contemporary task. Under the situation, NDRC may be even more reluctant to raise prices.

21 Pharma and Medical Distributors Expelled from Beijing Market for Bribing Medical Institutions

Beijing Municipal Department of Health (BJDOH) announced on November 26 that 21 pharmaceutical and medical distributors that have records of bribing medical institutions are banned from selling to medical institutions in Beijing for two years.

The BJDOH said it had cooperated with the law enforcement agencies in the investigation of over 40 pharmaceutical and medical sales related bribery cases since the beginning of 2006.

Local Company News

Xinchang Pharma's Vancomycin Plant Becomes Operational

Xinchang Pharmaceutical Factory under Zhejiang Pharmaceutical Group recently completed the construction of its Vancomycin Hydrochloride bulk drug and formulation plants, and passed relevant state inspections.

China has been depending on import of this product and Xinchang Pharma expects to fill in the gap between domestic supply and demands. The technology for Vancomycin used by Xinchang Pharma was developed by Shanghai Institute of Pharmaceutical Industry, according to the local press.

Shijiazhuang Pharma to Launch Its New Cardiovascular Drug in Korea through Licensing Deal

Shijiazhuang Pharmaceutical Group recently reached a licensing agreement with the reportedly fifth largest Korean pharmaceutical company (Chinese phonetic translation: *Ridong Pharma*) for launch of its patented new cardiovascular drug, Enbipu (Butylpthalide Soft Capsules), in Korea. Clinical trials and registration efforts in Korea are expected to begin soon.

Enbipu is a new drug co-developed by Shijiazhuang Pharma and the Institute of Materia Medica under the Chinese Academy of Medical Sciences with a total investment of CNY 350 million (US$47 million). Despite launching this product in China a few years ago, the company has yet not been able to make any profits on its sales, according to local press reports.

Shijiazhuang Pharma did not disclose financial details of the deal but said the Korean company would pay an upfront payment and royalties on future sales.

IPO Plan of Harbin Pharma Group Shaky

Harbin Pharmaceutical Group (HPG) has been planning an IPO since 2004, but failed to pull it off because its restructure was hindered by Southern Securities, the largest shareholder of its shanghai-listed core subsidiary, Harbin Pharmaceutical Shareholding Ltd. (HPSL), a few years ago.

Following the bankruptcy of Southern Securities in 2005, shares of HPSL held by Southern Securities were frozen so HPG was unable to buy back these shares then. However, shares of HPSL held by Southern Securities are now likely to be released with the liquidation plan for Southern Securities accepted recently by its debtors. This has brought hope to HPG for another round of HPSL restructure and for revival of its overseas IPO plan.

Nevertheless, local analysts suspect that HPG does not have the financial muscle to buy back HPSL shares from individual debtors of Southern Securities as the share price of HPSL nearly tripled in recent years. To buy back the 715 million outstanding shares, HPG will need to spend CNY 12 billion, an amount HPG clearly does not have.

In addition, HPG has been consolidating major assets into its other publicly-listed subsidiary, Sanjing Pharmaceutical Shareholding Ltd., in recent years. As a result, HPG has become almost a shell company with its primary assets being the shares it owns in its two publicly-listed subsidiaries. Local analysts believe this will make the IPO plan of HPG difficult to implement.

NCPG Sets Up Joint Laboratory with Fudan University

North China Pharmaceutical Group (NCPG) recently signed an agreement with Fudan University to establish a joint project,

Fudan-NCPG Medicinal Synthetic Chemistry Joint Laboratory.

The laboratory will specialize in developing cost-reduction synthetic processes of existing drugs, and industrialization of new drugs especially in the field of oncology.

Yunnan Pharmaceutical Group Pushes Forward with Its Restructure

As part of the reorganization plan of Yunnan Pharmaceutical Group (YPG), Yunnan Baiyao Group (a YPG-controlled public company) announced in late November that it will acquire the 95% stake of both Kunming Xingzhong Pharma and Kunming Yunjian Pharma owned by Yunnan Yunyao Corporation, which is a 100% YPG subsidiary and a 46% shareholder of Yunnan Baiyao Group.

Following the acquisitions, Yunnan Yunyao Corporation is a step closer to being terminated. It still owns two other loss-making companies, Yunnan Provincial Institute of Material Medica and Jindian Pharma, which are now under the management of Yunnan Baiyao Group. It is undetermined if the ownership of these two companies will also be transferred to Yunnan Baiyao Group.

The objective of the reorganization is to streamline the structure of YPG whose assets will be increasingly consolidated into Yunnan Baiyao Group and as a result YPG will own a much bigger chunk of the company. What follows that is likely to be fundraising and IPO preparations.

Nanjing Pharma to Launch "Package Deal" Model of Drug Purchase

Li Hailin, Nanjing Pharmaceutical Shareholding Ltd. (NPSL)'s general manager responsible for its hospital pharmacy business, announced on November 27 that the company plans to launch a new "package deal" model of drug purchase in December.

NPSL, one of the largest pharmaceutical distributors in China, manages pharmacies of more than 80 grade II hospitals and nine grade III hospitals in Nanjing city. The pharmacies of nine grade III hospitals were recently added to its hospital pharmacy management business.

The company said its new "package deal" model of drug purchase will be used to buy a mix of 5,000 reimbursable drug products from manufacturers, and 92% of these products will be priced under CNY 10/unit and 60% under CNY 5/unit.

Low retail prices of these drug products can be ensured, according to Li, because NPSL buys directly from manufacturers at the lowest purchase prices and distributes them to retail and hospital pharmacies without any middle layers. No margins will be added to fund hospital sales and marketing expenses, he added.

This new model will be experimented in December, and the full implementation will begin in February 2008, according to a source from the Hospital Pharmacy Business Division of NPSL. The source also confirmed that a number of retail pharmacy chains are now talking to the company about collaboration over the new "package deal" model.

Some local experts expressed that the new model, if implemented, will "bring shock to every stage of the pharmaceutical supply chain in China".

But some experts do not believe that the new move of NPSL will actually bring bottom prices to hospital pharmacies across the board in Nanjing. They pointed out that NPSL has management contracts with hospitals which require NPSL to pay a percentage of its hospital pharmacy drug sales back to these hospitals. NPSL will need a reasonable margin to pay for this and its own expenses and profits.

NPSL announced last week that it plans to raise CNY 650 million (US$87 million) from additional share issuance to fund an expansion of its "third party pharmaceutical logistic capabilities".

Nanjing Pharma Restructures Its Retail Pharmacy Business

Nanjing Pharmaceutical Group (NPG) recently listed 20% equity of its retail pharmacy company, Nanjing Pharmaceutical Baixin Pharmacy Ltd. (NPBPL) for sale at the Nanjing Equity Transaction Center. Local experts believe that NPG is seeking to transfer this asset to its publicly-listed subsidiary, Nanjing Pharmaceutical Shareholding Ltd. (NPSL), in order to restructure its retail pharmacy business.

NPBPL has 100 directly-operated retail pharmacies and 38 franchisee retail pharmacies in Nanjing. NPBPL is currently 20% owned by NPG, 46% owned by NPSL and 36% owned by Nanjing Pharmaceutical Industries Shareholding Ltd. (NPISL).

Local press reports suggest that NPBPL is struggling to survive its poor business. Meanwhile, NPSL raised CNY 139 million (US$18.5 million) in November for restructure of its retail businesses. Following the integration of its seven retail pharmacy subsidiaries, NPSL will control 209 directly-operated retail pharmacy stores in Jiangsu province.

In addition to NPBPL, NPG owns a small number of other retail pharmacy stores, and it is likely these stores will also be transferred to NPSL at some point.

Simcere Acquires Naning Tung Chit Pharma for US$4.4M

Nanjing-based Simcere Pharmaceutical Group announced on November 26 that it purchased Master Luck Corp., majority owner of Nanjing Tung Chit Pharmaceutical Ltd., for CNY 32.6 million (US$4.4 million).

Nanjing Tung Chit, which makes and supplies anticancer drugs in China, is known for Jiebaisu, a chemotherapy drug approved to treat various tumors including head-and-neck cancer and esophageal cancer.

Simcere said the acquisition would enhance its oncology sales position, research and development and production. The company said it plans to use its resources to expand Jiebaisu's hospital usage, market share and sales revenue.

Sihuan and Kambridge to Co-develop Sublingual Interluekin-2

Sihuan Biologicals announced on Novemebr 28 that its subsidiary, Beijing Sihuan Biopharmaceutical Ltd., reached an agreement with Kambridge Life Science Technology Pty. Ltd., an Australian research company specializing in the development of sublingual delivery system for drugs in oncology, to cooperate on the development of the sublingual dosage form of interleukin-2 for the treatment of hepatic cancer.

According to the agreement, both parties will conduct phase II

and III clinical studies of its sublingual CSDS interleukin-2 product in China and register the product as a hepatic cancer treatment in the country. Kambridge already completed the preclinical study of its CSDS interleukin-2 product in China.

Kambridge will contribute clinical related knowhows and fund the clinical trials, while Beijing Sihuan will help register the product in China and be responsible for the manufacturing facilities needed to produce API and formulation products for clinical studies of CSDS interleukin 2 in China and other countries.

Both parties will jointly develop Chinese and international markets through a joint venture in China, according to the agreement. Both parties said they may also seek to extend their cooperation on CSDS interleukin-2 to other products, such as application of Kambridge's CSDS technology on other protein drugs such as interferon, recombinant human EPO, recombinant human GSF and other Sihuan products.

Beijing Med-Pharm and Novartis Reach Deal for Enablex Marketing in China

Beijing Med-Pharm and Shanghai Novartis Trading Limited, a subsidiary of Novartis, inked an exclusive agreement to register, market and distribute Enablex which is used to treat symptoms of urinary incontinence, urgency, and urinary frequency related to an overactive bladder (OAB), in China.

Global annual sales of OAB medication is estimated to be US$2. 25 billion. In China, OAB afflicts an estimated 24-29% of the population over the age of 24, or over 200 million people, and treatment rates are historically low, with less than 15% of OAB sufferers seeking treatment.

"The potential sales opportunity for Enablex is extremely compelling in China. There are currently few medications available to combat OAB and, concurrently, millions of Chinese have not yet accessed treatment. While we are seeking SFDA's approval, we plan to educate doctors and patients on OAB," said David Gao, Chief Executive Officer of Beijing Med-Pharm.

Under the terms of the agreement, Beijing Med-Pharm is responsible for attaining China SFDA's approval of Enablex, a process that is expected to last through 2010. Once approved, Beijing Med-Pharm will have the exclusive rights to sell, market, and distribute Enablex in China for 10 years. Financial details of the deal were not disclosed.

Nepstar Reports Results in the First Three Quarters

China Nepstar Chain Drugstore Ltd. announced on December 10 its unaudited financial results for the third quarter and nine months ended September 30, 2007.

Financial Highlights For the third quarter ended September 30, 2007:

- Revenue rose 6.6% to CNY 484.3 million (US$64.6 million) compared to the same period in 2006
- Gross margin increased to 47.1%, compared with 35.9% for the same period in 2006
- Net income soared 512.6% to CNY 46.3 million (US$6.2 million) compared to same period in 2006

Nepstar Enters Into Strategic Alliance with 16 Local/Multinational Pharma Companies

China Nepstar Chain Drugstore Ltd., one of the largest drugstore chains in China, announced on December 17 that it had signed strategic cooperation agreements with 16 pre-eminent domestic and multinational suppliers of pharmaceutical and healthcare products for 2008.

The cooperation agreements were entered into with each of Tianjin SKF, Bayer Healthcare, Eli Lilly, Boehringer Ingelheim Shanghai, Wyeth Pharmac, Hunan Taier Pharma, Taiji Group, Shandong DONG-E E-JIAO, and Kunming Dihon Medical, as well as seven other suppliers of pharmaceutical and healthcare products. In addition to procuring merchandise from these suppliers, the company will also partner with these suppliers to promote health education among Chinese consumers.

In addition, a number of prominent Chinese and multinational pharmaceutical companies, including Shandong DONG-E E-JIAO., have agreed to establish exclusive manufacturing lines to manufacture certain products based on Nepstar's specifications and packaging requirements and to sell these products solely through Nepstar's network of drugstores.

Mr. Qian Jiannong, Chief Executive Officer of Nepstar, commented, "We believe collaborating closely with key suppliers is one of our primary competitive advantages and such collaboration will enable Nepstar to continue to procure high quality and popular merchandise on favorable terms."

MPI Research and Shanghai Medicilon Form JV for Preclinical Services

MPI Research and Shanghai Medicilon, both CROs specializing in drug discovery research, announced on December 20 a new joint venture, Medicilon-MPI Preclinical Research (Shanghai) LLC. Located initially at the Zhangjiang Hi-Tech Park in Shanghai, China, the company will open a 50,000 ft^2 preclinical testing facility in the Chuansha Economic Park in early 2008. This new facility will meet the regulatory standards set forth by the US FDA and other regulatory agencies worldwide.

With the joint venture, customers of both parent companies will have the advantage of conducting research at the Shanghai site for preclinical development, with potential for worldwide release. Current and future customers of Medicilon and MPI Research will have access to a broader range of both GLP and non-GLP preclinical services. By 2009, the new company will be fully operational, in terms of conducting FDA/IND enabling studies, offering additional preclinical support services, submitting INDs and NDAs, and will have AAALAC accreditation.

Foreign Company News

J&J to Increase Its Stake in XiAn Janssen to 70%

The Ministry of Commerce approved recently the stock transfer agreement between Johnson & Johnson (China) Investment Ltd. and Hangjiang Pharma for transfer of 1.8% of XiAn Janssen to J&J at CNY 78 million. The 1.8% stake represents 37.5% of Hangjiang's total stake in XiAn Janssen.

It is believed that J&J is actively seeking to acquire more stake

from its four Chinese partners in order to raise its equity in XiAn Janssen to 70%.

It is reported that J&J has now reached agreement with three other Chinese partners, Shaanxi Pharmaceutical Corporation, China National Pharmaceutical Industry Corporation and China National Pharmaceutical Foreign Trade Corporation (the two later partners are subsidiaries of SinoPharm Group) to purchase 37.5% of their total stake in XiAn Janssen. As a result, the stake of J&J will increase to 70%.

Local analysts speculate that Hanjiang Pharma was in fact unwilling to reduce its equity in XiAn Janssen, which brings them at least CNY 10 million in profits annually, at a time when the company is making losses itself.

Sanofi-Aventis to Build a Flu Vaccine Plant in Shenzhen with EUR 70 Million

Sanofi-Aventis announced on November 26 that it plans to invest EUR 70 million into the building of a flu vaccine manufacturing plant in Shenzhen, and claims it to be the largest biopharmaceutical investment ever made by a foreign drug maker in China.

The plant in Shenzhen targets an annual capacity of 25 million flu doses after its production begins in 2012, and will employ about 100 people. Last year Sanofi's existing vaccine packaging plant in Shenzhen delivered 5 million doses of flu vaccine, while Sanofi's sales of vaccines in China amounted to EUR 60 million, up 50% from a year earlier.

"China stands at the heart of the area where the next flu pandemic may originate," Sanofi Pasteur International president Jacques Cholat said at a news conference in Beijing. The new plant will be able to rapidly switch production from seasonal flu vaccines to pandemic flu vaccines. Sanofi-Aventis is in advanced talks with China and other governments about building a stockpile of vaccine against bird flu, Cholat added.

The deal between Sanofi-Aventis and Shenzhen local authorities was signed at a ceremony attended by Chinese President Hu Jintao and French President Nicolas Sarkozy, in China on his state visit.

The Chinese vaccine market is worth about EUR 480 million annually, but foreign drug makers have captured only about 22% of the market, Cholat said. That market is growing rapidly however, with the number of doses of flu vaccine expected to grow from 12 million in 2003 to 108 million in 2020.

This growth is being driven by China's rapid urbanization and the higher number of travelers both to and from China, as well as higher incomes and a growing elderly population, Cholat said. Currently only 5.12% of Chinese under the age of 18 is vaccinated for the flu, but this share is targeted to increase to 15% over the next few years.

Sanofi-Aventis has been present in China since 1982. Today it is the number six player in the country's pharmaceutical market, with annual sales of about EUR 200 million.

Pfizer Plans to Expand R&D in China and Asia

Pfizer Inc. announced on November 30 that it intends to expand its research and development activities in Asia, targeting China, India, Japan, and South Korea.

Martin Mackay, the company's president of global research and development, said Asia is key to the company because its pharmaceutical market will grow to US$200 billion by 2017. Pfizer opened a research center in Shanghai in 2005.

"China is going to be really important to us, the Shanghai center is going to be exceptionally important," Mackay told Reuters on the sidelines of an investors' meeting in Hong Kong. "We are looking at Korea, India and other countries."

Mackay gave no further details of the expansion plans, but said he was impressed with the progress made by Pfizer's Shanghai R&D centre since it opened two years ago. The center has about 200 staff.

"We have grown very quickly in Shanghai," Mackay said, adding contributions to revenue from the Chinese market were small but expected to grow fast.

BMS to Step Up R&D Investment in China

According to a recent interview of Kabir Nath, President of Shanghai Squibb Pharmaceutical Ltd. and BMS China Investment Ltd., by China's First Financial Daily, BMS will introduce between nine to ten new drugs to China in the next three to five years.

Kabir Nath told the newspaper that the company will increase its R&D investment and conduct more clinical trials in the country. Elevating the volume of clinical studies in China as parts of BMS's global trials will help the company reduce costs and accelerate patient recruitment, Nath said.

For example, 139 Chinese patients from 12 Chinese clinical centers in eight Chinese cities participated in the global trial of Ixabepilone (total 878 patients) from the beginning, and this has contributed significantly to the global registration of the product and will also facilitate its registration in China.

In 2008, BMS will step up its R&D efforts in China in the following areas: hepatitis B, cardiovascular system, oncology, immunity system and rheumatoid arthritis.

GSK to Inject $100m into Neuroscience R&D in China

GlaxoSmithKline announced on December 13 its plan to channel US$100 million by the end of next year into a neuroscience research center in China which will become pivotal to its global drug development.

GSK is increasing its focus in neurosciences with a significant investment in China, according to Moncef Slaoui, chairman of GSK's research and development.

The new R&D center in Shanghai is responsible for all the company's work on neurodegenerative diseases including Alzheimer's, Parkinson's disease and multiple sclerosis. "For us, China is not about outsourcing and cheap labor," he told the Financial Times.

"We don't want to give them the crumbs. It's about different science. We will link our fate to their fate. Within five to ten years we will be moving from 'made in China' to 'discovered in China'," he added.

The GSK's decision comes after six months of research around the world, co-ordinated by Mr Slaoui and designed to identify "the next seedbed for future discoveries". He said that "qualitatively and numerically, China came out on top", especially in oncology and neurology.

GSK already has an R&D center in the Pudong district of

Shanghai, which will be moved to provide the basis for the new centre. The company is building a fully integrated, end-to-end R&D center that will employ more than 1,000 staff by 2010. China's growing talent pool of scientific expertise is leading to the rapid development of excellence in life sciences in general and neuroscience in particular. GSK's R&D expansion in China will build on ongoing work in neural stem cell research and natural product compound libraries, and will focus on neurodegeneration (Alzheimer's and Parkinson's disease) and neuroinflammation (MS).

The R&D operation in China will become a leading part of the GSK's expanding Center of Excellence for Drug Discovery for neuroscience, one of four therapy areas on which Mr Slaoui plans to concentrate.

China May Become Eli Lilly's Largest Overseas Market in Ten Years

China is set to become the largest overseas market for Eli Lilly in just ten years as demand there rises for drugs to treat diseases such as diabetes and depression, according to Lorenzo Tallarigo, head of Lilly's international business.

Lilly plans to introduce six new drug products by the time when its biggest product, the antipsychotic Zyprexa, faces generic competition in 2011, the company said in a report to investors last week.

"For sales, there's no doubt China is one of the biggest markets, " said Tallarigo. "One of our main areas of development there is in diabetes drugs. It's a disease that's underdiagnosed."

Lilly has almost 1,000 employees in China, said the company spokesman Phil Belt. From 2005 to 2006, the staff there increased by about 50%, he said.

"We also source a lot of chemistry work there," Belt said in a telephone interview. "There's a lot of capability and capacity in China, in ways that are less expensive."

Compounds in development will target diabetes, cancer and nervous-system disorders, Tallarigo said. Sales in China will grow as under-diagnosed diseases receive increasing treatment, he said.

"In terms of a market, China is a long-term opportunity for growth," said analyst Linda Bannister of Edward Jones and Co. "It's possible that in time, given the population, China could be as big a market as the U.S."

Uncertainties Loom over Bayer's Acquisition of Topsun's OTC Business

Despite approval by the Ministry of Commerce of the Bayer-Topsun deal for Topsun's OTC drug business on October 11, the deal has so far not been completed for mysterious reasons.

The deal was approved by the shareholders of Topsun Science and Technology Ltd. on November 16, but three days later the company made an announcement that claimed the agreement between Bayer and itself to be expired, and both sides are under discussion to extend the expiry time of the contract.

No concrete progress on the deal has been made so far. On December 9, Zhang Dong, a responsible Topsun official, told the local press that the deal is now ready for completion.

One of the issues facing both parties is that the Chinese currency has appreciated considerably since the signing of the contract and the acquisition price tags were defined in US dollars.

The total price, including upfront and milestone payments, was US$158 million which totaled CNY 1,264 million using the exchange rate at the time of contract signing and only CNY 1, 169 million using the current exchange rate, thus resulting in a difference of CNY 100 million.

With the contract already expired and a price difference of CNY 100 million, both sides are believed to be negotiating intensively behind doors.

Although Topsun officials were confident that a compromise will eventually be hammered out, Pharma China believes there is real danger that the deal may fall out in the last minute.

Compared with a year ago, the financial situation of Topsun has improved substantially, especially after the sale of one of its core subsidiaries, Hubei Qianjiang Pharma. Topsun Group, the parent of Topsun Science and Technology, has successfully repaid most of its debts in the past year, and it is likely that the company is no as eager to sell its profitable OTC business, which is Topsun's biggest and best asset.

Contract expiry and exchange rate fluctuation do provide Topsun with the best excuses to back out of the deal if this is what the company has in mind.

Bayer Healthcare China refused to comment on the matter.

Bayer to Boost OTC Business in China

Bayer Healthcare will continue to expand its OTC business in China, and 20% of the 20 new drug products Bayer Healthcare plans to launch in China in the next three years will be OTC drug products, Liam Condon, President of Bayer Healthcare China, told the local newspaper First Financial Daily.

Bayer Healthcare ranks No.3 among multinational pharmaceutical companies for its hospital drug sales, but its OTC business has not been as successful.

In 2004, Bayer Healthcare acquired the vitamin business of Roche China, and formed an R&D center for vitamin C products in March 2007 in China. The company entered into an agreement with Topsun Science and Technology in late 2006 to acquire its OTC business, but the contract is yet to be implemented.

Eisai Licenses Rights for Neo-Minophagen C and Glycyron Tablets

Eisai Co., Ltd. signed an in-licensing agreement with Minophagen Pharmaceutical Co., Ltd. for liver disease/allergic disease agents Stronger Neo-Minophagen C and Glycyron Tablets on December 18, 2007.

With this agreement, Eisai will assume exclusive rights for development and marketing of these products in Japan and in the Euro-Asia countries and region where the products are yet to be sold.

For China and the Euro-Asia countries and region where the products are currently sold, Eisai will assume exclusive first negotiation rights, with exclusive marketing rights in China upon termination of the existing agreement between Minophagen Pharmaceutical and its current local marketing partner.

The companies expect to transfer the marketing activities to Eisai in China on April 1, 2009. With this agreement, Eisai said

it can enhance its product lineup for the gastrointestinal disorders area that is available in Asia including Japan and China, and thereby make further contributions to increase the benefits to patients and their families.

AlphaRx Announces Major Product Launch in China

AlphaRx, a Canadian company specializing in Nanotechnology for Drug Delivery Platforms, announced that it will launch Indaflex(TM) in China in 2008 through AlphaRx International Holdings (AIH), its Hong Kong affiliate.

Already a successful topical arthritis relief product in Mexico, AIH is building a plant in China to meet the expected demand. AIH will also produce Dicloflex(TM), an eye-drop formula used to treat ocular inflammation and pain, as well as Vansolin(TM) and Zysolin(TM), used for serious infections such as lung inflammation and nosocomial pneumonia, for the rapidly growing Chinese market.

Genotec to Manufacture Softgels in China

MM2 Group Inc. announced that its wholly owned subsidiary, Genotec Nutritionals Inc., entered into a strategic venture with Anshi Pharmaceutical (Zhongsan) Inc. to manufacture softgel capsules in Zhongsan City, China.

The current capacity of the state-of-the-art plant is 1.5 billion capsules per year, with room to expand capacity to five billion softgels annually. According to the companies, the plant was designed and built according to the current GMP requirements, in compliance with U.S. and China standards.

Organogenesis Signs Partnership Agreement with NTEC

Organogenesis, Inc., a specialized regenerative medicine company in the US, announced on December 10 that it signed a memorandum of understanding with Shanghai-based National Tissue Engineering Center (NTEC), a stem cell and regenerative medicine consortium.

According to the signed agreement between the two firms, the first phase of the partnership will commence immediately, and will include the commercialization and exporting of existing Organogenesis, Inc. technology including its signature product, Apligraf, in the Chinese market, and eventually throughout Asia. Currently, the field of use, according to the memorandum of understanding, covers wound healing and scars. However, performance milestones may expand the scope of the agreement to include broader surgical uses.

Novelos Agrees with Lees Pharma for Development of Cancer and Hepatitis Compounds in Greater China

Novelos Therapeutics, Inc. (OTCBB: NVLT), a biopharmaceutical company focusing on the development of therapeutics to treat cancer and hepatitis, announced on December 17 that it signed an exclusive license agreement with Lee's Pharmaceutical (HK) Ltd to develop and commercialize in greater China, including Hong Kong, Macau and Taiwan, two of Novelos' compounds: NOV-002 for cancer and NOV-205 for hepatitis. NOV-002 is Novelos' lead compound in pivotal Phase 3 trial for non-small cell lung cancer under a Special Protocol Assessment (SPA) and Fast Track.

Lee's Pharmaceutical ("Lee's Pharm") will be responsible for the cost of all clinical development, regulatory submissions and commercialization of NOV-002 and NOV-205 in China. In addition to upfront and milestone payments, Novelos will receive 20-25% royalties from Lee's Pharm on net sales of NOV-002 and 12-15% royalties on net sales of NOV-205.

Ilyang and Livzon Won Chinese Approval for Ilaprozole

Korean pharmaceutical company Ilyang announced on December 17 that Zhuhai Livzon Pharma secured the first marketing approval for its ulcer drug ilaprozole in China.

Zhuhai Livzon Pharma licensed the marketing right to ilaprazole from Ilyang Pharma and rolled out ilaprazole in China immediately after getting approval.

Currently AstraZeneca's Nexium and TAP's Prevacid dominate the China's anti-ulcer drug market, but Livzon said it will take a 30% market share and make other dosage forms of ilaprazole available in the near future.

TAP, Ilyang's U.S. marketing partner, completed phase II trials for ilaprazole in the U.S., earlier than expected, and plans to conduct multinational phase III trials in Southeast Asian countries including India, Thailand, Philippine, Malaysia and Singapore.

Chirachem to Build A CNY 300 Mln New API Facility in Tianjin

US company Chirachem recently signed an agreement with Tianjin's Dagang District to invest CNY 300 million for building a new API manufacturing facility in the district.

The new facility will be completed in two phases on a premise of 100,000 square meters, to includes a research and analytical center, a cGMP plant, a non-cGMP plant and other supporting facilities. Construction is expected to begin in January 2008 and it is planned to become operational in late 2009.

The new facility will be used to develop and produce synthetic APIs and intermediates, APIs by fermentation, and biochemical and enzyme-based APIs.

Chirachem supplies its cGMP standard API products to major pharmaceutical companies in North America and Europe. The company is reported to have invested a total of CNY 800 million to establish four subsidiaries in China since 2006.

Regulatory News

SFDA News

SFDA Extends Campaign to Clean Up the Pharma Sector

The SFDA said on December 4 that it would extend a campaign to clean up its scandal-laden pharmaceuticals industry, calling its task curbing corruption and counterfeiting "arduous."

China's State Council launched the campaign in August in order to improve the safety and supply of drugs after a series of health scares that reverberated in China's export markets around the world. The campaign, originally to last six months, would now continue for 18 months, said Wu Zhen, deputy director general of the SFDA.

"To some extent our personnel and our team are inadequate both in terms of the size of our staff and the resources to fulfill their tasks," Wu told a news conference.

Since the campaign began, Wu said pharmaceutical companies withdrw more than 7,300 drug registration applications, or 24% of the total, indicating the extent of applications that companies may previously have tried to submit, despite their products not meeting standards. In addition, the agency already closed nearly 300 pharmaceutical and medical device companies, and withdrew more than 150 GMP certifications.

"The withdrawals show that pharmaceutical companies are examining themselves and are working hard to improve their products," Wu said.

SFDA Publishes Draft of "Rules for the Registration of the Technology Transfer of New Drugs"

SFDA published its draft of the "Rules for the Registration of the Technology Transfer of New Drugs" on November 22, 2007. The revised regulation will remove previous limitation on the number of times a pharmaceutical technology can be transferred and the restriction on transfers in the surveillance period, thus allowing pharmaceutical technologies to be transferred for unlimited number of times and anytime.

Provisions in this proposed new regulation which address technology transfer of drug products approved for import will have substantial positive impacts on the China business of foreign pharmaceutical companies, especially those with local subsidiaries or joint ventures. Foreign companies will be allowed to transfer the production technology for each of their approved import drugs to one local manufacturer, thus allowing significantly increased options for local production of foreign drugs.

The wording of these provisions is quite simple and offers substantial flexibility. Foreign companies will have the choice of two possible routes of setting up local production of their imported drugs. The first route is a straight forward one with the foreign company transferring the production technologies of an approved import drug directly to a local manufacturer, while the second route offers a much higher degree of control with the foreign company transferring the production technology of an import drug to its own joint venture or subsidiary in China, which may choose to OEM the product with other local manufacturers under the existing regulations for pharmaceutical manufacturing and contract manufacture, that is, after it obtains the local drug approval for production of the product.

In addition, the import registration of the drug under such technology transfer will be allowed to remain effective during and after the technology transfer.

The following is a summary of key contents in the proposed regulation prepared by ***Pharma China***. A full text of the draft in Chinese can be downloaded from SFDA's website.

Chapter One of the regulation deals with essential principles and requirements:

- Article 2 of the regulation defines its scope to cover application and approval of technology transfer of drug products, including application and approval procedures, supporting documentations, and administrative requirements.
- Article 3 provides that technology transfer of drug products is classified into two types, "technology transfer of new drugs" and "transfer of production technologies".
- Technology transfer of new drugs refers to the production technology transfer of a new drug by the holder of its "New Drug Registration Certificate" to a pharmaceutical manufacturer in accordance with its approved production processes and quality standards. As such, the transferee needs to go through the required registration process to apply for approval of the drug.
- Transfer of production technologies refers to the transfer of production technologies of an approved drug product after the expiration of its new drug surveillance period by a pharmaceutical manufacturer with its drug approval to another pharmaceutical manufacturer in accordance with its production processes and quality standards in use.
- Article 5 provides that SFDA can terminate technology transfer of drug products based on the outcomes of its adverse drug reaction surveillance and post-marketing drug reappraisals.

Chapter Two of the regulation governs the application and approval requirements for technology transfer of new drugs.

- Article 6 defines the applicable new drugs covered by this type of technology transfer to include new drugs and drugs with special dosage forms including target-oriented, slow release, controlled release dosage forms (stipulated in the Provisions for Drug Registration) produced in China.
- Article 7 requires that the transferee of new drug technology must possess the pharmaceutical manufacturing license and GMP certification for the transferred products.
- Article 10 stipulates that when a new drug technology is transferred to multiple transferees, separate applications must be filed respectively by each transferee.
- Article 11 provides that applications for technology transfer of new drugs must be submitted during the period of new drug surveillance period.
- Articles 13, 14, 15 and 19 require that applications for technology transfer of new drugs should be filed with provincial level drug administrations which will conduct inspections of the product sites of transferees. The Drug Evaluation Center of the SFDA is responsible for full assessments of such applications and it may require additional clinical studies to be performed in accordance with relevant requirements of the Provisions for Drug Registration. The recommendations of the Drug Evaluation Center are forwarded to SFDA for final decision.
- Article 20 provides that the transferor (pharmaceutical manufacturer) of the new drug technology can continue to keep its original drug approval despite making technology transfers of its new drug to other transferees. The original drug approval can be withdrawn if requested.
- Article 23 defines that, during the course of application and evaluation, applications for technology transfer of new drugs will be returned or rejected under the following occurrences: 1) business registration of the transferor is expired; 2) the pharmaceutical manufacturing license or GMP certification

of the transferor or transferee are withdrawn, 3) the name of transferor is different form the holder of new drug registration certificate or drug approval and satisfactory supporting documentations can not be provided, 4) the surveillance period of the new drug under transfer is expired, 5) drug approval of the new drug held by the transferor is withdrawn, 6) major safety hazards are discovered about the new drug under transfer, 7) the transfers are found by SFDA to seriously affect drug quality and safety, and 8) other circumstances that SFDA deems inappropriate to approve such transfers.

Chapter Three deals with the application and approval of transfer of production technologies.

- Article 24 and 27 require that both transferor and transferee of production technologies must possess valid pharmaceutical manufacturing license, GMP certification with the scope that includes the production technologies under transfer.
- Article 25 provides that an application for transfer of production technology must be submitted after the expiration of its new drug surveillance period, and for a drug without new drug surveillance, such an application should be submitted two years after the original drug approval is issued. The transferee must not be a new pharmaceutical manufacturer and the transferee's production plant for the technology transfer should not be new facilities.
- Article 26 stipulates that the production technology transfer of the following drug products is not subject to this regulation: 1) products under administrative protection, 2) TCM products under protection by the Provisions for Protection of Traditional Chinese medicines, 3) products approved through the registration process for copy drugs (products with national standards), 4) products originally approved according to local drug standards and approved for the first time under the national standards, and 5) other products deemed inappropriate by the SFDA.
- Article 33 and 34 provide that the applications for transfer of production technologies should follow the procedure for supplemental registration applications and should be submitted to local provincial level drug administrations which will conduct inspections and sample examination of the product sites of transferees. The application for withdrawing the original drug approval for the production technology under transfer must be supplied at the same time.
- Article 35 and 39 specify that the Drug Evaluation Center of the SFDA is responsible for full assessments of such applications and it may require additional clinical studies in accordance with relevant requirements of the Provisions for Drug Registration. The recommendations of the Drug Evaluation Center are forwarded to SFDA for final decision.
- Article 40 defines that, during the course of application and evaluation, the applications for technology transfer of new drugs will be returned or rejected under following occurrences: 1) the pharmaceutical manufacturing license or GMP certification of the transferor or transferee are withdrawn, 2) the production technology of the drug under transfer is covered by administrative protection, TCM protection or new drug surveillance period, 3) applicants who have not completed SFDA's post approval requirements, 4) drug approval of the production technology under transfer is expired, withdrawn, canceled or has ambiguity, 5) name of the transferor is different from the names on the drug approval and no satisfactory supporting documents are provided, 6) transferor already applied for registration with final decisions from the SFDA or provincial level drug administrations pending, 7) the quality standards of the drug under transfer are trial standards, 8) major safety hazards are discovered about the new drug under transfer, 9) those transfers found by SFDA to seriously affect drug quality and safety, and 10) other circumstances that SFDA deems inappropriate to approve such transfers.
- Article 41 provides that foreign pharmaceutical manufacturers are allowed to transfer production technologies of their drugs with imported drug registration certificates to local pharmaceutical manufacturers, and in such cases, local transferees should submit their applications for such technology transfers to their local provincial level drug administrations for approvals.
- Article 42 stipulates that only one local manufacturer is allowed to make such an application for each imported drug.
- Article 43 requires that the original or the original copy of the import drug registration certificate and drug approval documentations should be submitted with such a protection technology transfer application. The import drug registration certificate will be returned after the application is accepted.
- Article 44 provides that the import drug registration certificate remains in effect during the period of registration application for such production technology transfer.

Chapter Four includes a number of other related provisions and requirements:

- Article 45 specifies that any disputes on technology transfers should be resolved between the transferor and the transferee, or through court litigations. All approvals or approval withdrawals issued by the SFDA in accordance with drug technology transfer process will remain in force.
- Article 49 provides that the contract manufacture of approved drug products should be carried out in accordance with the Provisions for Control of Drug Manufacturing.
- Article 50 terminates all previous rules on technology transfer of new drugs from the date of the issuance of this regulation.

SFDA Issues Notice to Enforce Batch Inspection and Release of Biological Products

SFDA issued an official notice on November 27 that authorized China National Institute for Control of Drug and Biological Products and provincial level institutes for control of drug and biological products in Beijing, Jilin, Shanghai, Hubei, Guangdong, Sichuan and Gansu to conduct batch inspections of biological products in order to boost safety of such products. The agency also designated 15 representatives in these institutes to sign batch release documents for biological products.

SFDA said that all preventative vaccines, human albumin and human globulin iv injection and its category of blood products are now subject to the new batch inspection and release process. The batch inspection for the four in-vitro diagnostic

reagents for blood screening and ABO blood typing reagents, however, continues, following their original procedures for now. SFDA may decide to subject all blood products to batch inspection and release before the end of the year.

Batch inspections will be carried out through a combination of batch record inspection and lab testing. Onsite inspectors at blood product manufacturing facilities are responsible for sampling and sample storage. All authorized institutes for control of drugs and biological products are required to publish their batch release records every two weeks.

Imported vaccines and human albumin subject to the batch inspection and release process must provide original batch release documentations issued by the drug authorities of the countries or regions where these products were manufactured in order to gain custom clearance.

The notice also includes three attachments: 1) a list of authorized institutes to conduct batch inspections and a list of designated representatives who are authorized to sign batch release documents; 2) a list of biological products subject to batch inspection and release; and 3) procedures of batch inspection onsite sampling. These attachments in Chinese are available on http://www.sda.gov.cn for download.

SFDA Seeks Comments on the Draft of "Certain Interpretations on Criminal Law Applicability of Cases Involving Making/Selling Fake/Substandard Drugs"

The Supreme People's Court and the Supreme People's Procuratorate of China recently drafted an official document "Certain Interpretations on Criminal Law Applicability over Cases Involving Making/Selling Fake/Substandard Drugs", and are seeking public comments through the SFDA.

The document defines criminal law applicability of various situations involving making and/or selling fake and/or substandard drugs. It provides that the term "fake drug" referred to by the Article 142 of the Criminal Law is defined by Article 48 of the Drug Administration Law, while the term "substandard drug" referred to by Article 143 of the Criminal Law is defined by Article 49 of the Drug Administration Law.

The document is set to impose stiff penalties on individuals, manufacturers and health institutions involved in producing, selling and using fake drugs.

Those involved in cases where fake drugs lead to "very serious damage" to human health may face heavy fines, life imprisonment or even the death penalty. The draft defines "very serious damage" as serious deformities, grievous bodily harm to more than three people or slight injury to over 10 people.

Those who produce and sell substandard drugs and that cause death, deformities or injuries may face life imprisonment.

In addition, hospitals that purchase, store or use drugs they know to be fake or substandard will face criminal charges. Those who provide materials, funds, facilities or other help to those who produce, distribute or sell fake or substandard drugs will also face criminal charges.

The SFDA said the draft is aimed at "punishing criminals according to law, safeguarding public health and life safety and maintaining a good order of the drug market."

Full text of the document in Chinese can be found at SFDA website (http://www.sda.gov.cn/WS01/CL0014/26520.html).

SFDA to Raise Quality Standards on 4,000+ Formulated TCMs

Shao Mingli, Director General of SFDA, announced on November 28 that his agency plans to streamline and improve quality standards on more than 4,000 formulated traditional Chinese medicines over a period of three to five years.

Up to now, according to Shao, SFDA has issued more than 9, 100 national quality standards for traditional Chinese medicines, and SFDA has recently been working on improving safety and quality of TCM injectable products.

Shao said that the SFDA will help foster the development of traditional Chinese medicine and other ethic Chinese medicines, encourage innovativeness in TCM R&D, push forward GMP of TCM production, establish a TCM unique registration system and strengthen post marketing surveillance of TCM products.

In a separate development, the agency issued in early December a new technical guideline for registration of traditional Chinese medicine (TCM) injections and natural medicine injections.

SFDA Launches Drug Product Recall System

SFDA launched a nationwide recall system on December 13. The recall plan will place Chinese-made drugs and imported drugs in three classes in accordance with their potential danger to people's health.

The new recall rule puts the onus on companies to have systems in place to recall problem drugs within the set time period and take responsibility to alert the government of any noticeable adverse reactions on patients that are caused by their drugs. Companies are also encouraged to carry out voluntary recalls and may be excused from punishment if they do so.

Unlike in the U.S. where drug recalls by companies are voluntary, the Chinese government can also order a compulsory recall of problem drugs. A fine three times the total value of the recalled drugs will also be levied on a company which do not voluntarily recall a bad drug.

Drug distributors and medical institutes are required to notify authorities of any safety risk from a particular drug. The recall system doesn't deal with counterfeit drugs, which are covered under a different law.

The following is a summary of the important provisions contained in the draft regulation:

- Drug product recall refers to the recall of drugs with potential safety hazards by pharmaceutical manufacturers (including foreign manufacturers of imported drug products) in accordance with legal procedures;
- Potential safety hazards of drug products refer to those unreasonable dangers of drug products that may endanger human health and life safety caused by R&D and manufacturing related reasons.
- Pharmaceutical manufacturers are required, in accordance with the requirements of this regulation, to establish and perfect drug product recall system, to collect relevant drug safety information, and investigate, evaluate and recall drug products with potential safety hazards. Pharmaceutical

distribution companies and clinical institutions should immediately stop sales or use of problem drugs when their safety hazards are discovered, and they should notify pharmaceutical manufacturers or suppliers of the problem drugs and report to drug administrative agencies.

- SFDA is responsible for the administration of national recall of problem drug products. Local provincial level drug administrations where the manufacturers of problem drugs are located are responsible for the supervision and control of these drug recalls, while other local provincial level drug administrations are required to cooperate with and coordinate such efforts.
- Pharmaceutical manufacturing enterprises are required to establish drug quality monitoring and adverse drug reaction monitoring systems to collect and record quality problems of drug products and relevant adverse drug reaction information, and report to drug administrative agencies in accordance with this regulation.
- On the basis of the seriousness of the potential drug safety hazards, product recalls are divided into three classes:

  Class 1: use of the problem drug may lead to serious health hazards or death; and such recalls need to be completed within 24 hours;

  Class 2: use of the problem drug may lead to temporary or reversible health hazards; and such recalls need to be completed within 48 hours; and

  Class 3: use of the problem drug usually does not pose health hazards and it needs to be recalled for other reasons; and such recalls need to be completed within 72 hours.
- Two types of drug product recalls, voluntary recall and ordered recall, are stipulated by the regulation together with their respective procedures for planning and execution. Ordered recalls refers to those drug product recalls enforced by drug regulatory authorities if manufacturers fail to implement voluntary recalls when authorities determine such recalls to be warranted due to potential drug safety hazards. When foreign manufacturers of imported drugs recall their products abroad, they should report to SFDA in time. When imported drugs need to be recalled, the importers are responsible for the implementation of such recalls.
- Pharmaceutical manufacturers would be penalized if they caused potential safety hazards of drug products by not complying with relevant laws and regulations. Those who implement voluntary recalls may have their penalties reduced or removed. Pharmaceutical manufacturers who implement voluntary recalls will not be exempted from their legal liabilities.
- Penalties for violation of this regulation include fines up to three times of the value of problem drugs and/or suspension and withdrawal of pharmaceutical manufacturing or distribution licenses.

SFDA Takes Measures to Boost Production of Blood Coagulation Factor VIII

The SFDA said recently that it is finding ways to address the severe shortage of blood coagulation factor VIII, a medication needed by hemophiliacs across the country.

There is currently an insufficient supply of blood plasma from which factor VIII is made. Official figures show that nationwide supplies of plasma fell by 50% last year. Currently, only three of China's 30 blood product manufacturers can and are making the clotting factor VIII, according to Yan Jiangying, spokeswoman for the SFDA.

"Realizing the severe situation, we have taken a slew of countermeasures," Yan said. These include policies and other forms of support to help manufacturers use plasma more effectively, she said. "We have launched a trial to try and find new ways of maximizing the yield of limited sources," Yan said.

The three firms, which are in Shanghai, Henan and Anhui, are given priority to making factor VIII.

"To ease pressure on production and help redress the shortfall, we have worked with the Ministry of Health to provide the firms with additional supplies of plasma," Yan said.

Chu Yuguang, a hemophiliac from Beijing and director of the Hemophilia Home of China, a volunteer civil society with more than 3,000 members, said: "The current supplies are enough to help just 5% of the country's 100,000 hemophiliacs."

SFDA Withdraws License of Shanghai Hualian Pharma

SFDA revoked the production license of Shanghai Hualian Pharmaceutical Co. after it produced contaminated leukemia drugs, according to Yan Jiangying, the spokeswoman of the State Food and Drug Administration (SFDA) on December 12.

The producer will also be fined to the highest amount allowed by the drug law and its income from the problem drug will be confiscated, she said.

On Sept. 14, the MOH and the SFDA said in a joint notice that investigations revealed that the incidents happened because several batches of the two drugs had been contaminated by vincristine sulphate, an anti-cancer medicine, during production.

Yan said the SFDA and the Ministry of Health (MOH) jointly set up an investigation group after the case was revealed. "However, leaders of Shanghai Hualian Pharmaceutical Company intentionally held back the facts of production violations during the investigation".

"Relevant responsible people of the company have been detained by police," Yan said. The SFDA and the Ministry of Health (MOH) suspended production, sale and usage of methotrexate and cytarabin hydrochloride, two drugs made by the company, on Sept. 5. It is believed that the company executives were detained because they "organized systematical cover up of the truth".

SFDA Suspends Sales and Use of Aprotinin

SFDA announced on December 17 that it suspended the sale and use of aprotinin, which is used to control post-surgical bleeding, after adverse reactions were reported abroad.

"According to statistics from the National Center for ADR Monitoring, aprotinin injections could cause adverse reactions including allergy, allergic shock, palpitation, choking, breathing with difficulty, shivering, fever, sickness and vomiting," SFDA said in a statement posted on its website. No adverse reactions, however, have been reported in China.

Aprotinin is used to reduce blood losses and the need for

transfusions in patients undergoing a cardiopulmonary bypass in the course of coronary artery bypass graft surgery.

Following an overall safety evaluation, the SFDA concluded that the risks of the drug exceeded its benefits and that it should be taken off the market.

The decision followed the suspension last month of aprotinin-containing medicines for systemic use in the United States, Canada, Germany and Spain. Results from a randomized interim trial by the Ottawa Health Institute showed increased mortality for patients receiving aprotinin.

Bayer Healthcare subsequently decided to voluntarily suspend the worldwide marketing of its aprotinin-containing medicinal products, Trasylol and Trasynin.

SFDA and USFDA Sign Agreement on Drug and Medical Device Safety

The Chinese SFDA and the USFDA have reached a consensus to be part of each other's inspection and investigation against counterfeits and substandard drugs, the SFDA said on December 12.

The first-ever Sino-US agreement on drug and medical equipment safety signed on December 11 marks a substantial step forward for the two countries in better supervision on drugs, SFDA spokesperson Yan Jiangying said.

The agreement addresses drugs and medical equipment traded between China and the US such as medicines used to treat impotency, dietary supplements, glucose test strips and condoms from China; and US-made insulin, heart pacemakers and diagnostic kits used for HIV and hepatitis tests, she said.

The US will have to provide China with information on the listed products, recalls, warning letters and adverse side effects. And Chinese drug and medical equipment manufacturers on the US list have to register with the SFDA. The registration will help track and give the number of companies exporting to the US, and help investigators if and when a problem occurs to track them down, Yan said. The current list will be expanded in future. For product safety, the USFDA is entitled to launch a joint probe with the SFDA against a registered firm if its products are found unsafe.

The two countries will set up a working group that will meet within 120 days to devise a plan to implement the agreement, and set performance measurements to evaluate progress in enhancing drug and medical equipment safety, Yan said.

Compilation of Chinese Pharmacopoeia (2010 Edition) Began

The Inaugural Conference of the 9th China Pharmacopoeia Commission and its first General Assembly was held on December 8 and 9, 2007. SFDA Director General and Chairman of the Commission Shao Mingli delivered a speech that called more efforts on development and management of drug standards in order to improve overall drug quality.

The 9th China Pharmacopoeia Commission has 25 subcommittees consisting of 321 experts and scholars from specialized healthcare related fields including clinic, scientific research, teaching, manufacturing, inspection, and management.

According to Shao, the Chinese Pharmacopoeia (2010 Edition) shall further expand the range of inclusion, cover all the varieties indicated in the National Essential Drugs List, adopt new technologies, improve the standards for high-risk varieties, standardize the styles and contents of its Volumes 1, 2, and 3, and speed up compilation and publishing of Supplements to the Pharmacopoeia.

MOH and SATCM to Introduce Medical Ethics Appraisal System

The Ministry of Health (MOH) and the State Administration of Traditional Chinese Medicine (SATCM) issued on December 19 a guidance document on establishment of an appraisal system for medical ethics of healthcare professionals.

The document calls for the establishment of medical ethics files for healthcare professionals including physicians, nurses and other related professionals in all healthcare institutions and annual assessments of their medical assessments. The assessment will include three parts: self assessment, department assessment and institution assessment.

Results of the assessments will be publicized and referenced in the promotion, appointment and performance-based salary review of healthcare professionals.

Parameters for assessments of medical ethics include abilities for life saving, attitudes in serving the people, respect of patient rights, confidentiality of patient information, non-discrimination based on race, sex, occupation, social status and economic situation, civility and courtesy, quality service, harmonization of patient and physician relationship, law-abiding, corruption free, etc.

Guangzhou Launches Drug Classification and Coding Guidelines

Guangzhou Municipal Quality Supervision Bureau issued on December 17 two local regulations, Guidelines for Drug Classification and Coding and Guidelines for Drug Dosage Form Classification and Coding. Both regulations became effective immediately.

The two regulations require medical institutions and retail pharmacies in Guangzhou to adopt a standard coding system for all drug products in the city.

Legal / IPR News

Pharma Company Held Partially Responsible for Choking Death from Large Pill

A Chinese court ordered Yangwenshui Pharmaceutical Co. Ltd. to pay CNY 55,589 (US$7,500) in compensation to a woman who choked to death after taking a large pill produced by the company as part of treatment for a gynecological disorder, the first such case in China.

Relatives claimed that the drug maker failed to provide necessary warning information in the instruction about the risk of taking the medicine. The company blamed the accident on

the woman, named Li, and said she should have been fully aware of how to take the medicine in a safe way.

In defense, the drug maker said that the pill, which is 1.6 cm in diameter, was made in accordance with the state standard and instructions were printed in line with relative laws and regulations and were approved by the SFDA.

After more than ten months of investigation and court hearings, the Wenjiang District People's Court in Chengdu City ordered that the drug maker should share 20% of the responsibility for the accident. Both the plaintiff and the defendant were not satisfied by the verdict and expressed their willingness to appeal to a high court.

Chinese Drug Registration Regulation Remain Weak in Three Areas of Great Concern to Multinationals

Law firm Sidley Austin held a public briefing on recent regulatory trends for drug and medical device products in China on December 11 in its New York Office.

Chen Yang, an attorney in Sidley Austin's Beijing office, was reported by PharmAsia News to have described 2007 as a historic year for the pharmaceutical industry in China, with the SFDA launching a total of 53 regulations related to food, drugs and medical devices.

Among these regulations, she devoted great attention to address concerns of multinational pharmaceutical companies in the area of drug registration. While she praised SFDA for its efforts in improving transparency in drug registration, she commented that the following three areas of concern remain to be unaddressed by the new drug registration regulation that became effective on October 1, 2007.

First of all, the new drug registration regulation does not include a definition of what constitutes a "new chemical entity" and without the definition, she said, there is no way SFDA can identify NCEs among the drug applications it receives and assures non-disclosure of data.

Secondly, Yang said the new regulation fails to improve on its provision for data exclusivity. She believes that the current data confidentiality provision in the new regulation is hard to substantiate, and thus advises R&D-based companies to be cautious with what they submit to the SFDA.

Thirdly, the new regulation also does not address the patent linkage issue that has been of great concern to R&D-based pharmaceutical companies. Currently companies are required to submit a non-patent infringement affidavit with their drug registration application but SFDA will not involve itself in any patent disputes and all such disputes must only be settled in courts. Multinationals have been pushing for the adoption of a patent linkage system similar to USFDA's Orange Book system.

Yang also told PharmAsia News that it remains to be seen if imported drugs will qualify for special drug approval. The regulation on the special drug approval system, which enables fast track drug registration, is being finalized.

APIs/Bulk Drugs

NDRC to Restrict Further Development of Vitamin C and Penicillin API Sector

The National Development and Reform Commission (NDRC) published on December 19 its draft for the 2007 Edition of "Industrial Structural Adjustment Guidance Catalogue".

The document lists vitamin C and penicillin APIs as two areas in the pharmaceutical industry that the country will restrict development in future. Earlier the two areas were also listed as restricted areas for foreign investment by the Ministry of Commerce in its 2007 Edition of the "Foreign Investment Industrial Guidance Catalogue".

China's output of vitamin C and penicillin APIs account for about 70% of the world's total. Local experts attribute the government restriction for the development of the sector to its huge pollution, high energy consumption and low added-value.

Local experts also say that the restriction for development will help ease the current situation of oversupply for these two types of products and thus drive up profit margin.

This restriction policy may also have impacts on foreign investment projects in the sector. For example, the proposed joint venture between DSM and North China Pharmaceutical Group is connected with the production of vitamin C and major antibiotic products, and this may have led to a long delay in the government approval of the project.

Local experts suggest that the collaboration with foreign companies in this sector should emphasize on the development of new production processes, such as the substitution of fermentation processes with enzyme processes, and upstream expansion into the development of inactive ingredients for pharmaceutical formulations.

India Made Preliminary Decision to Impose Anti-dumping Duties on Chinese Ceftriaxone

Indian Ministry of Commerce and Industry recently completed its anti-dumping investigations of Chinese ceftriaxone API and made a preliminary decision to impose between 65% and 89% anti-dumping duties on imports of ceftriaxone API from China during the periods of investigation.

Indian authorities initiated the anti-dumping investigation of Chinese ceftriaxone API in April 2007 following complaints filed by three Indian companies, Aurobindo Pharma, Hyderabad and Andhra Pradesh, who are major producers of the product in India. The period for dumping investigation is between October 1, 2005 and September 30, 2006, and the period of damage investigation is between 2003 and 2005, according to Indian authorities.

India is the second largest export market of ceftriaxone API for Chinese producers. As the current decision is a preliminary one, Chinese producers are actively communicating with India authorities in search for better outcome.

However, if India does make the decision to impose such severe anti-dumping duties and begin enforcing it, Chinese companies are likely to give up the Indian market, according to a

spokesperson of Livzon Group, a major supplier of ceftriaxone API to India.

Experts say that Chinese companies are likely to step up their export sales to South America, Middle East, Italy and Korea to make up the loss of Indian market.

Sales of this product has already been falling since the beginning of the anti-dumping investigation, according to Chinese press reports.

United Pharma's 6-APA Plant Became Operational

According to local press reports, United Pharmaceutical International Holding (UPIH)'s 6-APA plant, under the name of United Pharma (Inner Mongolia) Ltd., became operational recently in Inner Mongolia. The plant has an annual production capacity of 5,000 tons and is the largest 6-APA plant in the world. Total investment is CNY 510 million (US$68 million).

The local government said that it signed another agreement with UPIH that calls for a total investment of CNY 600 million (US$80 million) into five other new plants.

Product and R&D

SFDA Approves Import of Abbott's Kaletra

SFDA announced on November 23 that it approved Abbott's Kaletra (Lopinavir/ritonavir) tablet for import under its special approval procedures designed for qualified AIDS, oncology and orphan new drugs.

The tablet formulation of Kaletra (lopinavir/ritonavir) is a new, more convenient version of the leading protease inhibitor (PI) prescribed worldwide for the treatment of HIV. The Kaletra tablet allows adult patients to take fewer pills with or without food as part of their treatment regimen while maintaining the same safety and efficacy. In addition, the new formulation does not require refrigeration.

China's Second HIV/AIDS Vaccine in Phase I Trial

The first phase of clinical trials on China's second homemade HIV/AIDS vaccine began at Peking Union Medical College Hospital in Beijing on December 1.

The vaccine, jointly developed by the National Center for Disease Control and Prevention and the National Vaccine & Serum Institute, will be tested on 36 volunteers, according to Shao Yiming, lead researcher of the project.

Merck Recalls of Certain Lots of PEDVAXHIB and COMVAX

Merck & Co., Inc. announced on December 13 that the company has initiated a voluntary recall of 11 lots of its Haemophilus influenzae type B vaccine, PEDVAXHIB [Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)], and two lots of its combination Haemophilus influenzae type B/ hepatitis B vaccine, COMVAX [Haemophilus b Conjugate (Meningococcal Protein Conjugate)] which were distributed starting in April 2007.

According to MSD China, one lot of the PEDVAXHIB vaccine (lot #J2438) was exported to China totaling around 100,000 doses. The company said it immediately notified all levels of relevant Chinese government agencies, disease prevention and control centers and distributors. It is working closely with the Chinese side to recall these products in accordance with China's newly issued product recall regulation.

The Chinese SFDA commented that it is monitoring the situation closely and asked all clinical institutions to stop using the affected products. The agency said its national adverse drug reaction monitoring center has so far not received any adverse drug reaction reports on this batch of affected products.

Zhejiang Fuwei Pharma Launches Adefovir Dipivoxil

Zhejiang Fuwei Pharmaceutical Ltd. launched its class one new drug, adefovir dipivoxil, in Guangzhou under the brand name of Jiu Le on December 6.

It is reported the drug was found to have zero drug resistance rate after 48 weeks of treatment, and its hepatitis virogene type tests showed that the product is effective for both hepatitis B and C patients and is particularly effective for Chinese patients. The product is also the only Chinese hepatitis drug under long term efficacy and safety follow-up study.

General Health

Latest Updates on Healthcare Reform

According to Zheng Xinli, Deputy Director of the Policy Research Department of CPC Central Committee, the new healthcare reform plan is now completed drawing from all of the nine healthcare reform proposals from external academic institutions and organizations. Zheng said the draft of the plan is likely to be submitted to the State Council soon, and to be approved for publication before the end of 2007. However, Ma Kai, Minister of National Development and Reform Commission (NDRC), suggested later in December that the healthcare reform plan will be introduced and implemented in 2008, instead of the end of 2007.

Pharma China believes that the delay in the introduction of the healthcare reform plan is a result of continuing disputes among different government agencies and leading healthcare reform experts over a number of key issues such as the hospital financing model. While the Ministry of Health strongly advocates its proposed system of "separating hospital revenues and expenditures", this proposal has been resisted by other government agencies and experts who claim the system's high reliance on government fund allocations is prone for corruption.

Also according to our reliable sources, a restructure of

healthcare related government agencies was proposed and discussed during the development of the healthcare reform plan. Two possibilities were evaluated: 1) a national healthcare commission will be established under the State Council which will coordinate all healthcare related ministries and administrations, and hold overall leadership on healthcare, drug administration and medical insurance sectors; and 2) Either NDRC or the Ministry of Health will be expanded to take over all healthcare reform responsibilities. It is unclear if the expected healthcare reform plan will tackle this issue.

On a separate front, the recent designation of ten pharmaceutical manufacturers by the NDRC and SFDA to supply 18 essential drug products for urban community and rural healthcare system has led to increasing criticisms and questioning from the local pharmaceutical industry over its transparency and fairness of the manufacturer selection and designation process.

Why were these ten manufacturers selected (out of thousands of local pharmaceutical firms) and what was the basis of their selection? NDRC did not answer these questions from the pharmaceutical industry when approached by the local press.

CFHPC Reports High HCV Prevalence in China

About 38 million Chinese are carrying the hepatitis C virus (HCV), but public understanding of the disease is low, said the China Foundation for Hepatitis Prevention and Control (CFHPC) on October 22.

The prevalence of hepatitis C has surged in the past few years, said a CFHPC report. The Ministry of Health said earlier this month that hepatitis C is one of China's top five deadly epidemics.

But the public is not well informed about the disease, the CFHPC said, citing its latest survey that indicated only 1% of the respondents were aware of how HCV spreads and how to prevent it. Only 5% had a test for HCV.

The CFHPC suggested that the government tighten controls on blood products and expand HVC testing.

China Joins WHO's Global Patient Safety Program

China's Ministry of Health signed the Statement of Patient Safety to tackle health care-associated infections on November 27, officially joining in the Global Patient Safety Challenge program initiated by the World Health Organization (WHO).

Huang Jiefu, Vice Minister of health, said the Ministry would establish and implement the technical standards to prevent and control health care-associated infections, intensify control and management of hand hygiene, blood safety, injection and immunization safety, safe clinical procedures, safe water and sanitation in health care.

According to statistics, some 1.4 million patients get infected in hospitals and the rate of health care-infections is about 5% in China. The infections may make the patients' state of illness worse, prolong the time for them in hospital, and even lead to deaths.

HIV Drug Resistance A Growing Concern in China

HIV drug resistance is emerging as a major threat to China's fight against HIV/AIDS, according to the results of a recent study in central China.

Reuters quoted Chen Zhiwei, director of the AIDS Institute at the University of Hong Kong, that a significant number of AIDS patients receiving free antiretroviral treatment had developed resistance to the drugs and their disease had progressed to full-blown AIDS. Chen did not give an exact proportion of patients who had developed drug resistance, saying the statistics were still being checked and evaluated. But he did reveal that the study had identified the specific drug resistant strains being transmitted.

A separate study by the National Center for Disease Control and Prevention in China also revealed drug resistance in HIV/AIDS patients in Henan province, central China. Of patients receiving two-year antiretroviral treatment, 48.2% showed signs of drug resistance against a common combination of drugs Zidovudine, Didanosine and Nevirapine.

China began to offer free antiretroviral treatment to AIDS patients in 2003. By the end of 2005, more than 20,000 patients had received the treatment. China cannot produce most second-line drugs due to patent restrictions.

Chen said drug quality, patients missing doses, and improper use of antiretroviral drugs - using drugs too early in the course of the disease, for example - could all lead to drug resistance. "Many patients in the countryside cannot continue taking doses once there are side-effects. This has contributed to growing resistance," Chen suggested. He believes that it is urgent for China to offer free or cheap second-line drugs that combat viral strains resistant to conventional first-line drugs.

Survey Shows Falling Use of Brand Names in Physician Prescriptions

Following the introduction of "Provisions for Drug Prescription" by the Ministry of Health with effect from May 1, 2007, the Health Department of Anhui Province conducted two surveys of physician prescriptions from doctors of 21 grade III hospitals in the province on July 31 and October 22 respectively.

The first survey covered 1,050 physician prescriptions and 37.4% of them were found to contain drug brand names. While the second survey covered the same number of physician prescriptions, the percentage of physician prescriptions containing drug brand names fell to 22.8%.

The surveys also found that each surveyed physician prescription contains an average of 2.18 drug products, and 38.8% of surveyed prescriptions contain antibiotics, 25.4% contain injectable products and 70.5% contain essential drugs.

Guangzhou to Upgrade Community Healthcare Facilities

According to Guangzhou's municipal health department, the city government will invest CNY 762 million into upgrading of its 64 community healthcare centers, and among which CNY

170 million will be used to raise wages for more than 8,000 community health professionals in order to retain talents for the city's community healthcare system.

The outpatient visits of community healthcare facilities in Guangzhou have been rising in recent years. By now, the city has 120 community healthcare service facilities and 106 community health service stations. The average cost of treatment in community healthcare facilities is estimated to be around 43% of that in hospitals.

In a separate development, Guangzhou City Government recently completed the drafting of "Interim Provisions for Urban Resident Basic Medical Insurance in Guangzhou City" and is now seeking comments from the public. The new urban resident basic medical insurance system is planned to be introduced in 2008 in Guangzhou.

Beijing to Extend Zero-Margin Policy to More Drugs in Community Healthcare Facilities

At a recent government health conference, Beijing Municipal Health Department (BMHD) announced that its zero-margin policy will be extended to more drug products in the city's healthcare facilities.

Following the introduction of zero-margin policy on 312 drug products (923 specifications) that are carried in Beijing's community healthcare facilities, the average drug consumption per capita in the city's community healthcare system fell by nearly 30%, while the number of outpatient visits rose more than three times.

Health Miniter Warns against Lack of Progress in Tuberculosis Prevention

China is not doing enough to fight tuberculosis and should not rest on its laurels with successes achieved to date, the Chinese health minister Chen Zhu warned on December 19.

Tuberculosis is China's deadliest infectious disease, killing more than 200,000 people alone in 2004, according to the World Health Organisation. The country also has a growing problem with cases of drug-resistant forms of the disease.

"Although our tuberculosis prevention campaign has had some initial success, which has been widely recognised by international society, we must clearly recognise that the epidemic has not substantially improved," Chen said.

"At the same time, we face many new challenges and opportunities. We cannot be sluggish in our prevention work, and have to step up efforts. The pressure on prevention work is enormous."

The government had to improve training for health professionals, step up surveillance and ensure there was enough investment in prevention, he said.

Last week, a new World Bank report warned that Asia faced billions of dollars in costs if it did not pay more attention to fighting tuberculosis, with China, India, Pakistan, Vietnam and Indonesia seen as among the worst affected countries.

People in the News

Former CPA Official Stands Trial for Alleged Bribe Taking

Liu Yongjiu, former deputy secretary general of the China Pharmaceutical Association (CPA), will soon stand trial in Beijing for allegedly taking bribes totaling CNY 100,000 (US$13, 333).

Last week, Beijing's Xicheng District Procurators Office filed a document with the Xicheng District Court against Liu, charging him with bribe taking from an advertising company and a pharmaceutical manufacturer, according to local press reports.

Liu, who is in his forties, has been under investigation since last November. He is believed to have strong ties with Zheng Xiaoyu, the corrupt former SFDA boss who was also chairman of CPA.

Executive Moves

Dr. Jubo Liu joined Immtech as Development Liaison for Clinical Trials in China. Dr. Liu will coordinate andmanage Immtech's clinical development program in China, which currently includes the phase III clinical trial for pneumocystis pneumonia (PCP).

Sun Xiaomin recently resigned from his position as the chairman and party secretary of Sanjiu Pharmaceutical, and another board member, ***Zeng Cun***, also quited earlier.

Qiao Shibo was named the general manager and party secretary of Sanjiu Enterprises Group. Qiao is currently deputy general manager of China Resources Group and CEO of China Worldbest Group.

Dr. Ming Pang joined Pharma China's Advisory Board which now is consisted of ten distinguished leaders of the Chinese pharmaceutical industry. Dr. Pang is a pioneer of China business for multinationals as GSK's first China project manager in 1988, and headed IVAX's Asian business as Chairman and CEO of Baker Norton Asia in 1990s. He is now a senior advisor with life sciences group of E2Capital specializing in M&A and IPO projects (such as Nanjing Simcere Pharma's recent IPO in the US) in China and Asia.

Stop Press

Health Minister Chen Zhu Delivers Report on Medical Reform to the NPC

Health Minister Chen Zhu delivered an official report, on behalf of the State Council, on healthcare reform on December 26 to the 31st session of the Standing Committee of the National People's Congress (NPC), China's top legislature.

The minister promised to set up the preliminary framework of basic healthcare by 2010 and a comprehensive basic medical care system for all by 2020.

Chen also pledged to reduce hospital's financial dependence on drug sales, noting that any resulting financial shortfall would be met by government subsidies and a reasonable rise in medical service fees.

Feature Articles

Market Analysis: Oncology Drug Purchase Patterns of Shanghai Hospitals 2004-2006

According to the Science and Technology Information Institute under Shanghai Food and Drug Administration, the total oncology drug purchase by representative hospitals in Shanghai, which are monitored by the institute, was CNY 654 million (US$87.2 million), up 55% from 2005.

The following table shows shares of various oncology sub-classes in the Shanghai hospital market between 2004 and 2006.

Hospital Market Share Changes of Oncology Sub-classes in the Shanghai 2004-2006

Sub-class	2004 (%)	2005 (%)	2006 (%)
Alkylating agents	2.26	1.95	1.22
Antimetabolites	9.98	10.65	17.35
Antineoplastic antibiotics	16.53	14.97	11.09
Antineoplastic Chinese herbal drugs	45.27	41.85	36.45
Other oncology drugs	25.96	30.58	33.89
Total	100.00	100.00	100.00

Source: The Science and Technology Information Institute under Shanghai FDA.

The above data shows that while market shares of anti-metabolics and other oncology drugs were on the sharp rise in the past three years, those of anti-neoplastics fell continuously. Although traditional Chinese anti-cancer drugs still made up a third of the total oncology drug market in Shanghai in 2006, its market share shrank considerably in the past few years.

The top ten oncology drugs are given in the following table along with their growth rates between 2004 and 2006:

Hospital Market Share Changes of Oncology Products in the Shanghai 2004-2006

Rank	2004	2005		2006	
	Product	Product	+/-(%)	Product	+/-(%)
1	Epirubicin	Oxaliplatin	+54	Oxaliplatin	+90
2	Oxaliplatin	Paclitaxel	+54	Paclitaxel	+58
3	Kanglaite	Docetaxel	+63	Docetaxel	+61
4	Paclitaxel	Epirubicin	+11	Capecitabine	+372
5	Vinorelbine	Vinorelbine	+7	Gemcitabine	+92
6	Docetaxel	Compound Banmao	+43	Epirubicin	+5
7	Gemcitabine	Gemcitabine	+33	Vinorelbine	-5
8	Compound Banmao	Lentinan	+61	Compound Banmao	-8
9	Pirarubicin	Pingxiao Capsule	+40	Lentinan	+25
10	Pingxiao Capsule	Pirarubicin	+6	Gefitinid	+127

Source: the Science and Technology Information Institute under Shanghai FDA.

Growth of the top five oncology drugs in Shanghai hospitals was phenomenal in 2006, while AstraZeneca's Gefitinid (Iressa) jumped 127% in the year and climbed to the top 10 status within less than two years after its launch.

Top 20 oncology brand name oncology drugs in Shanghai hospitals in 2006 are listed in the following table with their respective markets shares in 2004, 2005 and 2006 shown.

Top 20 Oncology Drugs by Brand Names in Shanghai Hospitals in 2006

Rank	Product	Manufacturer	Market Share (%)		
			2004	2005	2006
1	Xeloda Tab.	Roche	2.97	3.64	11.25
2	Aiheng Inj.	Jiangsu Hengrui	5.96	7.66	10.25
3	Aisu	Jiangsu Hengrui	4.15	6.35	8.64
4	Gemzar	Eli Lilly	5.67	5.62	6.51
5	Pharmorubicin	Pfizer	9.93	9.09	6.34
6	Eloxatin	Sanofi Aventis	4.14	5.17	6.20
7	Taxotere	Sanofi Aventis	4.13	7.13	5.24
8	Taxol Inj.	BMS	4.71	4.67	4.54
9	Iressa	AstraZeneca	-	-	4.45
10	Zefei Inj.	Jiangsu Haosen	-	3.03	4.37
11	Perarubicin	Shenzhen Wanle	5.68	4.96	3.83
12	Oxaliplatin Inj.	Nanjing Pharma	-	-	3.59
13	Mabthera Inj.	Shanghai Roche	3.29	4.20	3.50
14	Caelyx	Schering Plough	-	3.32	3.50
15	Epirubicin Inj.	Zhejiang Hisun	5.62	5.02	3.38
16	Compound Banmao Capsule	Beijing Yadong	2.93	4.16	3.10
17	Tiandixin	Jiangsu Zhenzhong	4.30	4.77	3.05
18	Gainuo Inj.	Jiangsu Haosen	6.30	5.12	2.84
19	Aidi Inj.	Guizhou Yibai	2.51	-	2.73
20	Lipusu	Jiangsu Sike	-	4.26	2.67

Source: The Science and Technology Information Institute under Shanghai FDA.

In the past three years, the market shares of leading brands of oncology drugs shifted substantially. Roche's Xeloda, Jiangsu Hengrui's Aiheng (Oxaliplatin) Injection and AstraZeneca's Iressa all experienced sharp growth. Iressa, which was only launched in 2005, quickly grabbed 4.45% market share and became the No.9 oncology brand in Shanghai hospitals.

Despite lawsuits initiated by Sanofi Aventis against Jiangsu Hengrui over its patents of Docetaxel, Jiangsu Hengrui Pharma's Aisu (Decetaxol) continued to surge ahead with steadily rising market share and higher ranking in 2006, while Taxotere (Docetaxol) of Sanofi Aventis gained some market share in 2005 but only lost it again in 2006.

Among the top losers was Zhejiang Kanglaite's Kanglaite Injection, which was No.1 in 2004 but disappeared from the 2006 altogehter, and Pfizer's Pharmorubicin whose ranking fell from No.2 in 2004 to No.5 in 2006 while losing more than 3% market share.

Jiangsu Haosen Pharma's Gainuo (Vinorelbine) Injection, Shanghai hospital market's No.3 oncology product in 2004, also suffered a huge loss of 3.5% market share and its ranking fell to No.18 in 2006.

Market Review – Quinolone Drugs

According to the national hospital purchase audit of the Chinese Pharmaceutical Association (CPA), the total purchase of quinolone drugs by representative hospitals in 26 Chinese cities monitored by CPA totaled CNY 945 million (US$126 million) in 2006, up 1.5%. The growth slowed significantly compared with the 12.2% growth in 2005. Based on CPA's projection guidance (representative hospitals accounted for 26% of the total hospital market), the total Chinese hospital market for quinolone drugs was CNY 3,632 million (US$484 million) in 2006.

Quinolone drugs are mostly used as anti-infectives, but are also used as other therapeutics, and the following table provides a breakdown of the hospital market for quinolones.

Chinese Hospital Market for Quinolone Drugs 2004-2006 Unit: CNY mln

Quinolone Drugs by Therapeutic Usage	2004	2005		2006	
	Value	Value	+/- (%)	Value	+/- (%)
Used as anti-infective	787	878	+11.5	887	+1.0
Used as other therapeutics	43	53	+23.3	58	+9.4
Total	830	931	12.2	945	+1.5

Source: CPA

The following table shows the market share of quinolone drugs in anti-infectives:

Shares of Quinolones in Total Hospital Purchase of Anti-infectives 2004-06

	2004	2005		2006	
		Value	+/- (%)	Value	+/- (%)
Anti-infectives (CNY mln)*	5,351	6,064	+13.3	6,460	+6.5
Share of Quinolones (%)	14.7	14.5		13.7	
Share of Levofloxacin (%)	8.5	7.6		5.7	

Source: CPA * Sales of representative hospitals

The hospital sales of quinolone drugs rose considerably in 2005 but the growth rate fell in 2006. The growth of quinolones as anti-infectives rose only 1% in 2006, thus resulting in lower market share of the class in all hospital purchase of anti-infectives. However, the consumption of quinolones as other therapeutics rose sharply in 2005 and again by 9.4% in 2006.

Levofloaxacin is the largest quinolone drug on the Chinese hospital market accounting for nearly 60% of all quinolone hospital sales. The sales of the product fell in recent years with shrinking market share.

11 quinolone drugs are among the top 500 drugs purchased by representative hospitals; they include levofloxacin, gatifloxacin, moxifloxacin, ciprofloxacin, lomefloxacin, ofloxacin, enoxacin, fleroxacin, sparfloxacin, pazufluxacin and pefloxacin.

Among the 11 quinolone drugs, gatifloxacin is a rising new star that was launched in China in 2002. As BMS does not possess Chinese patents or administrative protection in China, local companies swamped the market and it is reported that SFDA issued more than 100 approvals to local companies.

Leading five suppliers of gatifloxacin to the hospital market include Shanghai Haini Pharma, Jiangsu Yangtze River Pharma, Zhejiang Jianfeng Pharma, Shandong Luoxin Pharma and Jiangsu Hengrui Pharma and they control 51% of the market. Sales of the product has been growing steadily since launch with the exception of 2006, but experts expect continuous growth of the market in the years ahead.

Five quinolone drugs have shown a trend of fluctuated sales with minor increases or decreases in recent years, while five other such drugs have demonstrated a persistent declining trend. These trends are shown by the following two tables.

Hospital Sales of Quinolones with Fluctuated or Flat Sales* Unit: CNY mln

Product	2002	2003	2004	2005	2006
Ciprofloxacin	43.8	53.9	52.7	57.5	54.9
Sparfloxacin	20.1	19.7	25.2	27.8	25.2
Rufloxacin	9.1	8.3	7.1	9.5	7.5
Tosufloxacin	1.7	2.6	5.4	7.2	5.8
Norfloxacin	3.9	2.6	1.9	1.8	2.1

Source: CPA * Sales of representative hospitals

Hospital Sales of Quinolones with Falling Sales* Unit: CNY mln

Product	2002	2003	2004	2005	2006
Levofloxacin	277.8	378.5	457.6	458.6	366.8
Ofloxacin	37.7	40.2	45.9	50.5	44.1
Fleroxacin	31.4	44.1	46.3	41.9	32.1
Pefloxacin	9.4	13.7	18.9	18.2	10.7
Pipemidic Acid	0.2	0.2	0.6	0.3	0.2

Source: CPA * Sales of representative hospitals

Market Review – Gastric Drugs and Proton Pump Inhibitors in 2005/2006

Southern Medicine Economic Institute (SMEI) under the SFDA projected that the total Chinese market for gastric drugs was CNY 11.4 billion (US$1.5 million) in 2005, up 7.72% from CNY 10.6 billion (US$1.4 million) in 2004. This market is estimated to have grown another 14% at least in 2006 with a total market size over CNY 13 billion (US$1.7 billion). Among the total, it is believed peptic ulcer and antacid drugs accounted for 80% of the total gastric drug sales.

Proton pump inhibitors (PPIs) are now the dominating category of peptic ulcer drugs in the hospital sector with a market share of 67.44% in 2005. Despite the relatively higher prices of PPIs, five leading PPI products experienced sharp growth in Chinese hospitals in 2006 with an average growth rate of 17.07%, according to the hospital drug purchase audit of the Chinese Pharmaceutical Association (CPA).

Sales and Growth of PPIs in Chinese Hospitals* Unit: CNY mln

Rank (2006)	Product	2005		2006		+/- (%)
		Value	Share (%)	Value	Share (%)	
1	Omeperazole	320	67.24	323	57.94	+0.87
2	Pantoprazole	100	21.00	132	23.62	+31.71
3	Esomeprazole	19	3.89	49	8.76	+163.62
4	Rabeprazole	21	4.36	33	5.92	+58.76
5	Lansoprazole	17	3.51	21	3.76	+25.49
Total		477	100.00	558	100.00	+17.07

Source: CPA * Sales of representative hospitals

The PPI hospital market is dominated by omeperazole, but its growth in 2006 was stagnant with flat sales, while all four other PPIs experienced sharp growth last year. Esomeprazole (Nexim) is the latest generation of PPI launched in China by AstraZeneca in 2003. This product saw phenomenal growth of 164% last year, bumping it to the third position among PPIs. Pantoprazole also grew sharply and narrowed its gap with omeperazole. Rabeprazole had the second highest growth among the five, while Lansoprazole continued to remain in the bottom of the five with the lowest growth other than omeperazole.

Except Esomeprazole (Nexim), the other four PPIs have multiple suppliers in China. The following tables show the leading suppliers of these PPIs to the Chinese hospital market.

Leading Omeperazole Suppliers to the Chinese Hospital Market in 2005 and 2006

Rank	Supplier	Brand	% in 2006	% in 2005
1	AstraZeneca (Wuxi)	Losec	56.82	50.70
2	Jiangsu Aosaikang	Aoxikang	10.63	10.30
3	Changzhou No.4	Aoke	6.18	15.70
4	AstraZeneca (Sweden)	Losec	4.48	6.25
5	Zhuhai Lizhu	Li Ao Jia	3.86	0.16
6	Shandong Lunan	Aomei	3.77	2.58
7	Suzhou No.6	Luokai	3.17	6.06
8	Jiangsu Lianhuan	Aoxikang	2.82	3.96
	Total		91.73	95.71

Source: CPA

AstraZeneca lost some market share to local manufacturers in 2006. Changzhou No.4's Aoke lost more than half of its market share and Suzhou No.6 saw its share shrink of nearly 50% last year, while Zhuhai Lizhu's Li Ao Jia advanced significantly. Together, the leading eight suppliers lost 4% market share to other suppliers in 2006.

Leading Lansoprazole Suppliers to Chinese Hospitals in 2006

Rank	Supplier	Brand	% in 2006
1	Shantou Tuobin Pharma	Lanxiduo	56.82
2	Takeda Pharma	Takepron	10.63
3	Hainan Yier Pharma	Lanyixin	6.18
4	Tianjin Takeda Pharma	Lasuotuo	4.48
5	Taiwan Nankuang	Takepron	3.86
	Total		81.97

Source: CPA

Shantou Tuobin Pharma is the dominant player for this product with Takeda being the second leader. Besides the five leading suppliers, other manufacturers controlled 18% of the market.

Leading Pantoprazole Suppliers to Chinese Hospitals in 2006

Rank	Supplier	Brand	% in 2006
1	Hangzhou Huadong	Banlisu	23.59
2	Byk Gulden	Pantoloc	23.02
3	Jiangsu Yangtze River	Weidi	21.07
4	Shenyang Dongyu	Taimeinike	10.65
5	Shandong Luye	Nuosen	7.73
	Total		86.06

Source: CPA

The market for pantoprazole was led by Hangzhou Huadong Pharma in 2006, followed closely by Byk Gulden and Jiangsu Yangtze River Pharma. Besides the top five, other producers controlled nearly 14% of the market.

Leading Rabeprazole Suppliers to Chinese Hospitals in 2006

Rank	Supplier	Brand	% in 2006
1	Eisai (Suzhou)	Pariet	46.98
2	Sichuan Dikang	Ansifei	20.61
3	Jiangsu Haosen	Ruibote	14.64
4	Jiangsu Jichuan	Jinuo	8.44
5	Zhuhai Mintong	Yutianqing	7.11
6	Shanghai Sine Labs	Xin Wei An	2.09
	Total		99.87

Source: CPA

As shown by the following table, the six leading manufacturers of Rabeprazole almost controlled the entire hospital market for this product. The dominating player in this market is Eisai with other Chinese companies far behind it.

China's Market for Vaccines

Continued from page 24

by Novartis, MSD, Wyeth, Solvay and the Commonwealth Serum Labs (CSL – Australia) are all in the early stages of market entry. The second level companies are those with sales over 100 million RMB which may be private or publicly listed. These include companies such as Beijing Tiantan, Liaoning Chengda and Shenzhen Kangtai. Sitting slightly lower still are those companies with sales less than 100 million RMB such Zhejiang Tianyuan and Zhejiang Pukang.

Development within the various vaccine sub sectors is resulting in added growth. SARS and bird flu which were both centered in Asia have energized the domestic vaccine industry to search for solutions. Polio which was almost eliminated in China has reappeared in the countryside. The prevalence of measles is also increasing with around 130,000 cases reported in 2005. Plans to eradicate measles by 2010 and polio by 2012 have been published. Hib and Pneumococcal disease have been an underlying scourge in China for many years. Finally, as a result of pressure from the WHO, medical experts, NGO's and vaccine manufacturers there is pressure on the government to reclassify the vaccine as Class 1. The flu vaccine rides a roller coaster of use dependent upon government whims. With no recent outbreaks of bird flu or SARS, sales fell in 2005, but in light of the upcoming Olympics there is a drive towards increased inoculation in key cities. Hepatitis B is the #1 burden in China which has been addressed through government infant vaccination programs for several years. Hepatitis A and a combined Hepatitis B + A will soon be available.

Further opportunities exist with new formulations of old vaccines being introduced and classified as Class 2 – paid for vaccines. HBV which is currently beer yeast based will become available in Hansenula Polymorphous Yeast; DTwP will be available as DTaP; Japanese Encephalitis Vaccine will be available in Vero form; Meningococcal A + C will become available in conjugate as well as polysaccharide form; Hepatitis A vaccine will be available in an inactivated form as well as live attenuated.

Increasingly combination vaccines will be introduced – all again initially on the Class 2 paid for vaccine list. In addition to HBV + HAV, we will see the introduction of Men A + C + Hib, DTP + Hib + HBV, plus a string of new Vero vaccines in Japanese Encephalitis, Hepatitis A and Rabies.

Last but by no means the least, there will be an increasing usage of Pre Filled Syringe (PFS) technology, which is well recognized and used in China already but with a massive opportunity to be used in a wider number of vaccines and increasingly by domestic companies.

With the massive population, the growing per capita GDP, the favorable changes in government policy towards vaccine distribution, the stated government investment in the healthcare industry and the growing awareness that prevention is the best cure, the future for the Chinese vaccine industry is looking remarkably healthy.

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China's Market for Vaccines

Rob Pollard, Director - Synovate Healthcare China

The global vaccine market has grown significantly in recent years and is estimated to exceed US $ 10 billion by 2007. Having the world's largest population and with over 17 million new children each year, China's vaccine market is thought to be the world's fourth largest with sales approaching US $ 400 million and historically growing at over 15% per year and likely to increase in the coming years (ref: Yibing Zhou BioPharm April 2007).

With China's continuing economic growth showing no abatement and the rising consumer living standards, the demand for more and better healthcare is very much a topic of discussion in the society. Whilst new and innovative treatments are being introduced almost weekly in the Rx Pharma and OTC sectors, there is also a growing awareness of the need to prevent illness and disease. This has resulted in the vaccine market receiving significant attention both by numerous domestic and multinational vaccine manufacturers as well as by companies providing the needles and other means of taking vaccines to the consumer.

Currently there are more than 30 domestic vaccine manufacturers producing over 41 types of vaccines, targeting 26 viral strains. In total, there are 300 domestic and 103 imported vaccine products of various doses, forms and specifications in the China market. The domestic manufacturers mostly concentrate on Class 1 vaccines whilst the imported vaccines from multinational companies (MNCs) focus on Class 2 vaccines. Class 1 vaccines are government approved vaccines which are ordered and subsidized by the government. In most cases they are supplied to the Chinese people (mostly children) at no charge. Class 2 vaccines are for non-planned immunization and in most cases have to be paid for by consumers themselves.

Class 1 Vaccines	BCG; TOPV; DTwP; measles; Hepatitis B; Japanese Encephalitis: Meningococcal A; Rubella: Mumps
Class 2 Vaccines	Varicella; PPV; Hepatitis A; Flu; Typhoid; Hemorrhagic Fever; Rabies; MMR

China market inherits a number of distinct characteristics which challenge and provide opportunity for domestic companies and MNCs. Vaccine rates vary greatly – currently the class 1 vaccines have claimed immunization rates of 90% whilst the use of class 2 vaccines can be very low.

Data from the USA and Europe suggest that around 25% of the total population and greater than 50% of the elderly receive an annual flu vaccination compared to the figure of less than 1% for flu in China. Further, whilst flu vaccines are not generally covered under the basic medical insurance (BMI) scheme, some cities such as Suzhou and Xian introduced this policy during 2007. In addition, with the Olympics coming to China in 2008, the Beijing government has introduced a pro-active campaign to get more people inoculated against flu this season.

China also has a far more liberal pricing approach to class 2 vaccines allowing market forces to have a greater impact. For class 1 vaccines which are exclusively locally manufactured against quotas, the price has to be competitive to meet government budgets.

The distribution of vaccines has always been the responsibility for the Centre for Disease Control (CDC). Prior to 2005, both manufacturers and importers delivered directly to the Provincial CDC who then passed the vaccines to the next level in the CDC chain - Provincial > City > District > Point of Vaccination (POV) > Customer. Since 2005, the distribution process has become more flexible and today both manufacturers and distributors can distribute vaccines to any level providing they have met the requirements of the SFDA in such matters as GSP, finance, cold storage etc.

Globally MNC vaccine manufacturers are being challenged by governments with respect to the use of mercury based preservatives in the vaccines. This is often referred to as thiomersal and is a preservative which has been in use since the 1930s. In most vaccines, especially for children, this has been removed. However, China has not yet fully implemented the banning of this - as for many local manufacturers, they do not have the capacity to switch to non-thiomersal vaccine production.

Trying to understand the future opportunity for vaccine manufacturers in China is a challenge but one that has occupied considerable research in 2007. Two major government initiatives in recent years have laid the platform for the China vaccine market. Firstly, in 2003 the National Development and Reform Commission (NDRC) published its China Bio Industry Development Strategy stating "to develop new types of vaccines to protect the national public health safety is the number one priority of the China biotech industry." Part of this new policy involved granting tax benefits to vaccine manufacturers as well as subsidizing several major high tech projects in a number of areas. Perhaps most notable is the ongoing research into bird flu, SARS and HIV. Leading this development is the China National Biotech Group which includes the six Institutes of Biological Products located in Beijing, Shanghai, Changchun, Wuhan, Lanzhou and Chengdu. The group employs over 10, 000 workers of whom more than 4,000 are highly educated scientists and technicians. The second major initiative was the 2005 announcement by the State Council which dismantled the long term market monopoly with vaccines controlled by the Provincial CDCs. Sales outlets increased from 54 to almost 6, 000 with licensed pharmaceutical drug distributors entering the scene. This removed many of the bottlenecks in the system and gave a substantial boost to the manufacturers. Further, the 11th Five Year Plan laid out in 2006 stated the government aims to develop and commercialize 10 to 15 innovative drugs and vaccines as well as developing five major domestic pharmaceutical companies with sales over 5 billion RMB and ten Pharma distributors with sales over 3 million RMB.

Currently the major players in the China vaccine market are the members of the China National Biotech Group plus the major MNC players GSK and Sanofi Pasteur. Chiron now owned

... continues on page 23