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Editorial

Changing Market Dynamics Brew New Order for Chinese Pharma

James J. Shen

Following Pfizer's announcement in late January to acquire Wyeth, the trend of mega deals further intensified in March with Merck's planned US$41 billion acquisition of Schering Plough and Roche finally winning full ownership of Genentech at a price tag of US$47 billion.

As such gigantic deals happen, big pharma companies continue to pick up smaller assets here and there. With healthcare reform looming and anticipated rise of generics in the U.S., R&D-based MNCs are now showing strong interest in acquisition of generic drug businesses, particularly generic product portfolios of Indian companies. Pfizer acquired various generic drug rights from Indian firm Aurobindo in March, as it and its competitor Sanofi Aventis are also eyeing the biotech business of Wockhardt, another Indian drug major.

Impacts of overseas deals on China

While smaller licensing deals of MNCs will help broaden their pipelines in China, the rising trend of generic drug acquisitions are likely to make it easier for these companies to enter the Chinese generic drug business.

Meanwhile, mega mergers between Pfizer and Wyeth as well as between Merck and Schering Plough will make the combined companies much bigger and more influential in China.

Pfizer is already the third largest MNC company in the Chinese hospital market, and its acquisition of Wyeth is likely to make it the biggest, replacing Bayer Healthcare. In addition, Wyeth will open up for Pfizer the potential in China's OTC healthcare market, an area Pfizer is currently not active in. The combination of the two companies will result in a new company with much bigger revenues and diversified business lines. The challenge will lie with successful integration of the two companies and the learning curve of Pfizer executives in OTC healthcare.

Meanwhile, Merck and Schering Plough share a similar business model in China and both concentrate on their ethical drug businesses. Their product lines are quite complimentary to one another with Merck being a leading player in vaccines, cardiovascular, anti-infective, urinary, NSAID, osteoporosis and respiratory areas, and Schering Plough being active in Oncology, Allergy, Hepatitis and Dermatology. Besides, Schering Plough has a small OTC business too. Both Merck and Schering Plough do not have any R&D in China, but the larger revenue base and platform of the combined new company may offer some incentives to Merck in this area. Currently Merck ranks No.7 among MNCs in the Chinese hospital market, and the merger with Schering Plough is likely to bump it to the No. 5 place, overtaking Roche and Novartis.

NPC and CPPCC become a new platform of rising importance for advocating interests of pharma industry

The "*two conferences*", referring to the sessions of the National People's Congress (NPC) and the Chinese People's Political Consultative Conference (CPPCC), are currently ongoing in Beijing as I am writing this editorial. Interestingly, the transformation of NPC and CPPCC offers the world a glimpse of how the Chinese style democracy has been evolving in the past decade.

Instead of turning into the Western-styled legislative bodies, as hoped by many Western groups and bluntly rejected by the Chinese government, NPC and CPPCC have increasingly become a *de facto* consultative forum and a rather liberal platform for airing all kinds of criticisms, suggestions and proposals on Chinese economy, politics and society.

While NPC and CPPCC representatives are not legislators and continue to follow the party line for most of their votes, many of them have become very outspoken and critical to the status quo and government policies. Representatives have the rights by law to submit proposals on subjects of their choice and the executive branches of NPC and CPPCC are required to

resolve such proposals with relevant government departments.

Chinese news media love to chase after those representatives who are active in voicing criticisms and proposals, elevating some of them to popular celebrities in the country. These developments have led to the rising influence and power of the NPC and CPPCC, not to mention the huge publicity and public pressure they can generate.

The platform was already used in the past by local pharmaceutical companies to channel their voices and advocate their interests. For example, local companies successfully asserted intensive pressures on the NDRC over the issue of "innovative category" drug pricing through a number of NPC and CPPCC representatives last year.

R&D-based MNCs are also realizing the risk of neglecting public relations with this platform, so their trade association, RDPAC, submitted a letter recently to NPC and CPPCC representatives and suggested direct communications with them. In the letter, RDPAC calls for renewed attention to drug quality, presents its view of a good quality system and at the same time subtly demonstrates the correlation which exists between quality and price of drugs.

MNCs face new challenges despite continued high growth

Meanwhile, we understand from various sources that MNCs enjoyed another year of high growth in 2008 with many achieving over 20% in revenue growth while a few among them soared at rates higher than 50%. This is obviously good news for MNCs, but the success in the past two years should not be taken for granted as potential threats are abound with the healthcare reform to begin its implementation this year.

We are currently working on an article analyzing the market share fluctuations of local and MNC drug companies in the urban Chinese hospital market between 2002 and 2008 based on audit data from the Chinese Pharmaceutical Association.

We found that the government policy swings bore direct relationship with the rise and fall of MNC market shares. Although MNCs recorded high growth in the past two years, its market share in Chinese urban hospital actually fell to 49% (excluding TCMs) in the first half of 2008 from a peak of 53.5% in 2006. The fall was directly related with the introduction of the "*Provisions for Physician Prescription*" which restricts the use of brand names in physician prescriptions.

Looking forward, there are a number of other policy issues that may lead to significant impacts on MNC's hospital drug sales. Two biggest threats come from the drug pricing reform and the proposed elimination of hospital drug sales margin.

NDRC has already began conducting surveys nationwide on cost structures and market prices of drugs in the reimbursement list, indicating its readiness for another round of drug pricing initiatives. However, it is still unclear if the agency has made up its mind about the much-disputed "innovative category" drug pricing bracket and the proposed uniform drug sales margin policy. Changes in drug pricing policies are expected to produce significant negative impacts on the sales of off-patent "innovative category" drugs by MNCs and subsequently may lead to fast erosion of their hospital market share.

In the meantime, the policy of zero drug sales margins will be implemented in the community healthcare sector this year and tested in selected public hospitals. This policy has similar impacts on MNC hospital drug sales as the NDRC proposed uniform drug sales margin policy, both of which aim to discourage the use of higher priced drug products.

Other healthcare reform measures, such as the promotion for the use of essential drugs and traditional Chinese medicines, will have indirect but long term impacts on the business of MNCs in China. It is therefore high time for MNCs to rethink their existing China business models along with their global restructure plans and come up with strategies that are in steps with the ongoing marketplace transformation.

New regulations on the horizon

In its efforts to keep drug quality and safety under control, SFDA announced plans in march for additional new measures. The agency will introduce an "authorized person" (or qualified person) system for pharmaceutical manufacturing and quality control which aims to hold designated personnel in pharmaceutical companies accountable for GMP compliance and quality control. It was already experimented in Guangdong and will now be implemented in phases in the country.

The agency disclosed later that it is working on the development of a drug master file (DMF) system to regulate APIs, pharmaceutical inactive ingredients and packaging materials. Additionally, SFDA also said at a recent conference that it will begin to raise drug standards and re-register existing drug products this year.

While SFDA is right on target to strengthen control on drug quality, the Chinese government must also look into the roots of recent drug safety incidents, many of which were triggered by deliberate attempts of manufacturers to cut corners for cost savings. It is time that China's industrial and drug pricing policies be reviewed to ensure its manufacturers have sufficient incentives and margins to put into place a good quality system as suggested by RDPAC. Launching more regulations alone will further raise compliance costs and will not address the roots of many existing quality problems.

On the drug registration front, the Center for Drug Evaluation (CDE) under the SFDA issued a number of implementation rules for the special approval process, and a new working procedure for second review of drug registration. These new rules are very useful in making the special approval process and the second review process more transparent and workable.

The CDE also said it is now developing a framework of technical guidelines for drug research on the basis of "*safety and efficacy, science and rationality, encouraging innovativeness, and promoting dialogue and cooperation*".

All of the new developments are pointing to an emerging new Chinese drug regulatory regime that is more stringent, transparent and compliant with international norm.

Healthcare reform to initiate after the "two conferences"

Healthcare is one of the hottest topics at the "*two conferences*" and based on what are disclosed by senior health officials and representatives, the final version of the healthcare reform plan and its implementation policies will be released soon after the "*two conferences*". The reform will officially begin thereafter.

Other information recently leaked on the healthcare reform includes possible adjustments to the essential drug system policy and limited news about the drug pricing reform. On the first subject, the government is likely to retreat from its earlier stance to designate manufacturers and set prices for essential drugs, and may, instead, purchase essential drugs from provincial level tenders with the government setting only guidance prices for such products. On the second subject, it was revealed that the NDRC is presently working on the implementation policy for drug pricing reform and will make

provisions in the document to expand drug price control to more products while keeping both differential and uniform drug sales margin policies.

In the last note …

Finally, I would like to dedicate this editorial to Dr. Ming Pang, a member of Pharma China's editorial board and my long time ally and personal friend. It is very sad to announce that Ming passed away on March 4 in Hong Kong at the young age of 56.

Ming was a pioneer of MNC pharmaceutical business in China. He was the China project manager for Glaxo Wellcome UK from 1982 to 1988, before he founded and managed Beijing JiAi Pharma, Kunming Baker Norton and Baker Norton Asia for IVAX (now a part of TEVA). From 1998 to 2000, he was executive director of Asia Healthcare, Inc. Ming had been a director of the Life Sciences Advisory Group since 2000, and he was instrumental in the IPO of Simcere Pharmaceutical Group on NYSE.

Many of our advisors and readers are friends or acquaintances with Ming, and will remember him as a generous, personable, energetic, humorous and forever light-hearted fellow who always brought joy and laughter to everywhere he went. Ming's departure is a great loss but his contribution to the Chinese pharma industry will be remembered.

News in Focus

MOH releases the results of 4th National Health Service Survey

The Ministry of Health (MOH) conducted China's 4th National Health Service Survey in 2008 with the purpose to review Chinese healthcare developments in the past five years. The previous National Health Service Survey was conducted in 2003.

The survey is composed of questionnaires for family health, medical institutions, medical professionals and specific issues. Nearly 200,000 urban and rural residents of 56,400 households in 31 Chinese provinces, autonomous regions and central municipalities were surveyed.

Findings of the survey are as follows:

Prevalence and disease patterns

The prevalence rate of illnesses among surveyed residents within two week time frame was 18.9% in average. The same rate is 22.2% for urban areas and 17.7% for rural areas. These rates increased 4.6, 6.9 and 3.7 percentage points compared with the same rates in 2003.

The number of people with illnesses in 2008 is therefore estimated to be 6,540 million, an increase of 1,460 million compared with the same in 2003.

The prevalence rate of chronic diseases among surveyed residents was 20.0% with the rate in urban areas to be 28.3% and in rural areas to be 17.1%. The number of chronic disease patients is therefore estimated to be 260 million in 2008, up 60 million compared with the same in 2003.

The survey found the disease pattern of Chinese population to have changed significantly. Among the people with illnesses within two weeks, the share of new illnesses fell to 39% in 2008 from previously 61% in 2003, while that of chronic diseases rose to 61% in 2008 from previously 39% in 2003. Chronic diseases have become the major health problems of the Chinese population.

Among all chronic diseases, the survey found prevalence rates of circulation system (such as heart diseases, cardiovascular diseases and high blood pressure) and endocrine system (such as diabetes) rose sharply in the past five years, while those of respiratory system and digestive system diseases fell.

It is also estimated based on survey findings that the number of circulatory system disease patients in China reached 114 million in 2008 compared with only 37 million in 2003. Among the total, patients of high blood pressure jumped to 73 million from previously 14 million, patients of cerebrovascular diseases surged to 13 million from previously 5 million). The number of diabetes patients also roared to 14 million at present from only 2 million in 2003.

Healthcare service provision

73.7% of the patients visited primary healthcare institutions (urban community and rural healthcare facilities) in 2008 compared with 69.5% in 2003. The same rate is 48.3% in urban areas (up from 36.6%) and 81.7% in rural areas (up from 79.3%).

The rate of failing to seeking medical treatment within a two week time frame by surveyed residents fell to 38.2% in 2008 from previously 46.2% in 2003. The same rate is 47.9% in urban areas and 35.6% in rural areas. 21% of those who were advised to be hospitalized failed to comply.

67.8% of people who did not seek medical treatment say they failed to do so because the symptoms were minor, while 14. 9% say they avoided treatment due to cost concerns. However, 70.3% of the people who avoided hospitalization say they did so due to cost concerns.

Insurance coverage and medical expenditures

71.9% of the surveyed residents possess social medical insurance coverage. 44.2% of surveyed residents are covered by urban employee basic medical insurance while 12.5% are covered by urban resident basic medical insurance. In rural areas, 89.7% of surveyed residents are covered by rural cooperative medical care and 2.9% are covered by other medical insurances.

The average expenditure of outpatient and emergency hospital visits by surveyed residents in 2008 was CNY 169 and the average expenditure per inpatient was CNY 5,058 (up CNY 50 and CNY 1,514 respectively compared with 2003). After adjusting inflation, the average annual growth of these two expenditures in the past five years was 4.4% and 1.5% respectively, which was much lower than the same rates of 12.9% and 10.8% in the five year period of 1998 and 2003.

The average expenditure of outpatient and emergency hospital visits by surveyed urban residents in 2008 was CNY 312 and the average expenditure per inpatient was CNY 8,958, compared with those by surveyed rural residents at CNY 128 and CNY 3,685.

Channels for health information

Major channels for surveyed urban residents to obtain health information include: TV (83.5%), publications (53.8%) and physicians (39.8%).

Major channels for surveyed rural residents to obtain health information include: TV (76.6%), physicians (49.7%) and publications (18.3%). The survey found that, compared with 2003, the share of surveyed residents (both urban and rural) obtaining health information from physicians was much higher in 2008.

Medical service provision

The survey found that the rate of dissatisfaction by surveyed patients over outpatient and hospitalization healthcare services has fallen in the past five years. Among outpatients, the rate of dissatisfaction fell slightly to 41% in 2008, while the same rate for hospitalized patients fell 12 percentage points to 44%.

Among urban outpatients, the main dissatisfactory areas include: high expenditures (15.8%), long waiting time (9.1%) and poor hospital environment (7.5%). Among rural outpatients, the main dissatisfactory areas include: poor hospital environment (18.9%), high expenditures (10.6%) and few choices of drugs (8.6%).

Among urban inpatients, the main dissatisfactory area is high expenditures (26.0%). Among rural inpatients, the main dissatisfactory areas are high expenditures (20.0%) and poor hospital environment (12.0%).

The survey found significantly fewer patients complaining about high medical expenditures compared with five years ago.

Survey of medical professionals

The survey of medical professionals found that 49.7% of medical professionals are highly satisfied with their work, 46.5% are generally satisfied and 3.8% poorly satisfied. 81% of them feel their work is important, but 47.8% of them believe their social status has fallen compared with a few years ago.

40.9% of surveyed medical professionals suggest that the trust of patients in them has decreased, 33.1% say they feel higher pressure from work, 36.9% indicate their medical practice environment is poor, 25.6% experienced verbal or physical abuse by patients, 88.1% believe it is necessary to have measures protecting them from being questioned or held accountable by patients for their medical practices, and 33.3% express that they will use effective but relatively riskier medical technologies in their diagnosis and treatment.

The Market

Data Snaptshot: Chinese OTC healthcare market

The following data was released to Pharma China by Euromonitor. The data was developed by Euromonitor's research team on the basis of various trade sources and statistics.

Chinese OTC healthcare market size

2003 (CNY mln)	2008 (CNY mln)	2003-2008 +/- (%)	2003-2008 CAGR %
49373.1	77284.2 mln	+56.5	+9.4

Source: Euromonitor from trade sources/national statistics

The market size is for OTC drug products sold through retail pharmacies.

Nicholas Hall reports slower growth of OTC GI market in China

Nicholas Hall reported recently that the Chinese OTC gastrointestinal market rose 7% in 2008 to reach US$1,214.4 million. The following table shows top line data on this sector in 2008.

Chinese OTC Gastrointestinal Market Facts 2008

OTC GI sales 2008:	US$1,214.4 mln
Index 08/07 (local currency):	107
Population:	1,324.7 mln
Per capita spend:	US$0.92

Source: Nicholas Hall (www.nicholashall.com)

OTC Gastrointestinal Market Segmentation in China 2008

Category	CNY mln	US$ mln	Index 08/07
Antacids & antiflatulents	4,097.1	598.1 10	106
Laxatives	207.4	30.3	113
Antidiarrheals	2,334.5	340.8	109
Others	1,679.1	245.1	108
TOTAL	8,318.1	1,214.4	107

Source: Nicholas Hall (www.nicholashall.com)

Industry News

Chinese pharma industry performance in 2008 and outlook in 2009

According to an information release by the Ministry of Industry and Information Technology (MIIT), the total output value of the Chinese pharmaceutical industry rose 25.7% last year reaching CNY 866,680 million. The growth rate of the Chinese pharmaceutical industry was 2.6 percentage points higher than the average growth of all Chinese industries.

Among the total, output value of APIs and pharmaceutical chemical formulations were CNY 185,390 million and 233,600 million respectively, up 23.2% and 23.9% respectively.

The following table shows Chinese pharmaceutical industry performance in 2008 by sub-sectors:

Chinese pharmaceutical industry performance in 2008(1) Unit: CNY Million

Sector	Output Value	+/- (%)	Output Value Sold	+/- (%)
APIs	185,390	+23.2	175,600	+22.6
Pharm Chemical Formulations	233,600	+23.9	221,900	+25.8
Formulated TCMs	177,940	+21.2	167,600	+22.1
Herbal Preparations	41,040	+32.8	39,480	+33.6
Biologicals/Biochemicals	76,870	+30.6	73,840	+31.8
Medical Equipment/Devices	75,410	+31.4	73,430	+31.3
Health Materials	39,440	+39.5	38,370	+39.1
Others	36,990	-	35,140	-
Total	866,680	+25.7	825,360	+26.5

Source: MIIT

All sub-sectors experienced sharp growth of over 20% in 2008, but the growth of health materials, medical devices, biologicals/ biochemicals and herbal preparations reached over 30%.

Chinese pharmaceutical industry performance in 2008(2)* Unit: CNY Million

Sector	Net Profit	+/- (%)
APIs	13,590	+49.5
Pharm Chemical Formulations	21,610	+36.0
Formulated TCMs	14,520	+7.7
Herbal Preparations	1,950	+33.7
Biologicals/Biochemicals	7,690	+21.8
Medical Equipment/Devices	6,360	+21.1
Health Materials	2,660	+49.6
Overall	70,890	+28.4

Source: MIIT * First 11 months of 2008

All sub-sectors experienced high profit growth in 2008 with the exception of formulated traditional Chinese medicines. The profit growth of health materials, APIs and pharmaceutical chemical formulation sub-sectors were particularly strong.

Despite high growth for the entire year, the net profit of the Chinese pharmaceutical industry fell quarter by quarter consecutively last year.

In addition, there were 1,445 loss-making companies in the Chinese pharmaceutical industry, accounting for 21.1% of all enterprises. Total losses posted by them in the first 11 months of 2008 rose 10.3% last year reaching CNY 4,180 million.

The Chinese pharmaceutical industry invested a total of CNY 92,810 million into fixed assets in the first 11 months of 2008, up 26% over the previous year. However, the growth of pharmaceutical industry fixed asset investments fell sharply in the fourth quarter and was below 32.2%, the average fixed asset investment growth rate of all Chinese industries last year.

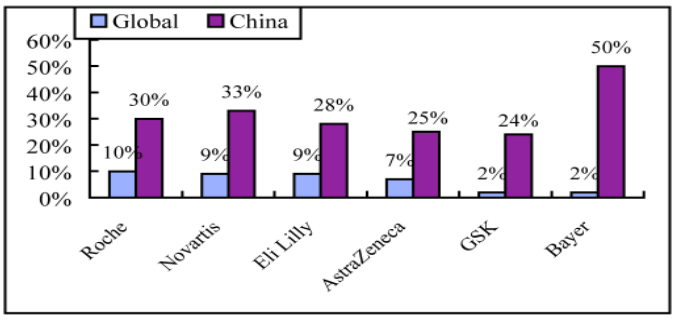
The domestic market environment is generally positive for the pharmaceutical industry this year with the new round of healthcare reform, increased government funding, rising domestic demands for healthcare and expanding coverage basic medical insurance programs and rural cooperative medical care system. On this basis, MIIT predicts the growth of Chinese pharmaceutical output value and revenues to be around 20% in 2009.

Exports of the Chinese pharmaceutical industry was negatively affected by the global economic downturn, but demands for China's pharmaceutical export products, most of which are essential drug products, are not expected to change significantly. Meanwhile, the Chinese government has been introducing measures to support the country's exports, and the pharmaceutical industry structure is being optimized through continuous upgrading and consolidation. It is therefore anticipated by MIIT that Chinese pharmaceutical exports will gradually recover from February 2009 with 15% or higher growth predicted for the entire year.

MNCs report another year of sharp revenue growth in China

Despite slowdown of the global business growth in 2008, multinational pharmaceutical companies saw sharp revenue growth in China last year, according to various press reports.

The following chart shows the global and China revenue growth of six MNC companies in 2008.



Pfizer CEO Jeff Kindler said in late 2008 his company is achieving "enormous growth" in China, Brazil, Turkey, India, Korea and Russia. An industry source suggests that Pfizer China's revenue growth was as high as 70%.

MNCs position for the huge diabetes market potential in China

According to the latest research by the Chinese Diabetes Society (CDS) under the China Medical Association, the prevalence rates of diabetes among males, females and total population aged between 20 and 70 were respectively 12.0%, 9.5% and 10.5% in 2008. These rates were twice and four times of those in 2001 and 1994. CDS estimates the total number of diabetes patients is now approaching 40 million and the figure is likely to reach 80 million by 2030.

With fast rising morbidity rates, diabetes has become a therapeutic field of intensive competition by MNCs and local companies. Major MNC players in this sector are stepping up their efforts and investments in China to position for the huge future market potential.

At a recent diabetes event sponsored by Novo Nordisk, the company announced that it would make an additional CNY 50 million investment in China in the next five years for research and cooperative projects in the diabetes area.

At the same time, the company announced the initiation of two new cooperative projects respectively with the Shanghai Institute for Biological Sciences (SIBS) under the Chinese Academy of Sciences and with the Chinese Diabetes Society under the China Medical Association.

The project with SIBS encompasses the formation of a "pre-diabetes translation research center" which conducts research into prevention, early detection and intervention of diabetes. It is estimated there are around 20 million pre-diabetes population in China who suffer from lowered sugar tolerance.

On the other hand, major players are attempting to expand its diabetes drug business by reaching out to the urban community and even rural primary healthcare facilities.

Bayer has implemented a "Bayer diabetes hut plan" in Shanghai and Guangzhou since mid-2007, while Eli Lilly launched a US$2.5 million "Chinese primary level diabetes education development plan" in June 2008 with the purpose of improving diabetes knowledge of physicians and nurses in community and primary healthcare facilities.

As the competition in China's diabetes sector heats up, MNC companies are likely to seek better segmentation of the market.

Novo Nordisk recently pointed out that its research shows a trend of falling age of diabetes patients in China due to rising obesity and overweight problems among the Chinese children. The company suggests that prevention of the disease must start with children, thus creating a new market segment of pediatric diabetes.

Chinese producers likely to emerge as major global players of recombinant human insulin products

According to WHO estimates, diabetes patient population has exceeded 300 million globally and patients in developing countries account for 71% of the total. The global insulin market will grow to US$14.5 billion in 2010 from US$7.5 billion in 2005.

The international insulin market has been dominated by Novo Nordisk, Eli Lilly and Sanofi Aventis with their recombinant human insulin products.

The Chinese insulin market has been rising sharply with the continuously growing prevalence of diabetes. In the 1980s, animal insulin products were mainly used but they have been increasingly replaced by recombinant human insulin in the past decade.

The Chinese recombinant human insulin market had also been monopolized by Novo Nordisk and Eli Lilly until Dr. Gan Zhongru, an overseas Chinese returnee, developed China's first recombinant human insulin in his laboratory in 1998.

Subsequently Gan transferred his technology to Jilin Tonghua Dongbao Pharmaceutical Co. Ltd. which had a small manufacturing operation with annual capacity of 200 kg of bulk insulin until recently. The company recently expanded its manufacturing facility with CNY 700 million investments and raised its annual production capacity to 3,000 kg bulk and 30 million units of finished products in 2008.

In 2004, Gan and his team built a new recombinant insulin manufacturing facility, Beijing Gan & Lee Pharmaceutical Co. Ltd. in Beijing with the encouragement of Beijing Municipal Government. Jinlin Tonghua Jinbao is the largest shareholder of Gan & Lee Pharma with around 42% stake. The annual output of insulin bulk by Gan & Lee is estimated to be around 1,000 kg at present.

Apart from Gan & Lee and Jinlin Tonghua Dongbao Pharma, two other Chinese companies, Jiangsu Wanbang Bio and Shenzhen Kexing Bio, also possess approvals for production and sales of recombinant human insulin products in China.

Nevertheless, both companies are reported to have failed so far to industrialize their recombinant human insulin products. It is reported that Jiangsu Wanbang Bio has failed to scale up its recombinant human insulin products, while Shenzhen Kexing Bio's R&D team fell apart years ago.

Jilin Tonghua Jinbao Pharma's insulin market share in China has been under 10% and falling below 2007, but it hopes to raise it gradually to 50% following its facility expansion. The company claims that the quality of its products to be comparable with foreign products but with significantly lower costs and prices compared with its MNC competitors. Its new manufacturing process is reported to have only 17 steps as opposed to 31 steps in the conventional manufacturing process, thus offering the company huge raw material, cost and other benefits. In addition, the company believes that the ongoing healthcare reform, which seeks to boost rural and community healthcare, and the Chinese government's policy to contain drug costs will benefit the company's insulin business significantly in the long term.

Gan & Lee Pharma and Jilin Tonghua Jinbao Pharma are also eyeing the international insulin market for long term growth. Both companies are mainly exporting human recombinant insulin bulk at present.

Gan & Lee Pharma has a tiny market share in China but it claims to export to more than 20 European and South American markets. Additionally, the company developed two third generation insulin analogue products, and its export sales of these new products are believed to be around US$10 million annually at present.

Jilin Tonghua Jinbao Pharma is also reported to export to more than ten foreign markets and its bulk human recombinant insulin is registered in over 20 foreign markets including Brazil, Ukraine, Egypt, Pakistan, Bangladesh, Iran, Columbia, Philippines, Chili and Argentina. Last year, more than 400 kg of recombinant human insulin bulk were exported to these markets with an average price of US$60,000/kg.

Seeing great market potential, the two Chinese companies are also hoping to expand sales of their bulk insulin products to Middle Eastern countries in the near future.

The move by the Chinese government to raise export rebates for bulk insulin and its salts to 13% from previously 5% is expected to further elevate the export prospects of the two Chinese insulin producers.

On the front of human recombinant insulin finished products, both Chinese companies are exploring business models under which they will form strategic alliances with foreign companies or governments to build joint insulin formulation manufacturing facilities that cater for local markets.

Chinese press reported that there are already health officials from various developing countries approaching the two Chinese companies for such discussions.

M&A is likely to intensify for retail pharmacy sector in 2009

Under the heavy pressures of narrowing profit margins, intensifying government cost containment measures, upcoming healthcare reform and shortage of working capital, many Chinese pharmaceutical distributors are struggling for survival. Many smaller players are being taken over by larger and healthier companies, while others look to different forms of alliances to band with other distributors in order to improve geographic coverage, reduce costs and secure financing.

Going with this trend, Guangdong-based Dasenlin Pharmacy, the 8th largest retail pharmacy chain in China in 2007, launched late last year an "IPO alliance" scheme under which it would enter into alliance with selected pharmacy chains nationwide. Dasenlin Pharmacy will need to acquire 51% of these chains, but in return will offer them a chance to go IPO together. Dasenlin recently acquired Meikang Pharmacy in Shaoguan city, Guangdong province, which owns 25 retail pharmacy outlets, under this new business model.

By now, the company has over 500 retail pharmacy stores nationwide with over CNY 2 billion in 2008 revenues, up from only CNY 1.4 billion in the previous year. The company plans to expand its chain to 5,000 stores nationwide with over CNY 10 billion in annual revenues within five years.

Meanwhile, Hunan Laobaixing Pharmacy, the largest retail pharmacy chain in China in 2006 and 2007, acquired Xiangtan Haicheng Pharmacy in Hunan province which owned 32 retail stores locally in Xiangtan city, Hunan province.

What Dasenlin and Hunan Laobaixing have in common is that they both have secured venture capital backing. Hunan Laobaixing signed a US$80 million VC deal with EQT Partners Asia, a subsidiary of Sweden's Investor AB, last October.

Dasenlin said it has a different venture capital model without disclosing its venture capital partners. At least for now, Dasenlin is not ready to offer its own stakes to venture capital firms, but instead will let its venture capital partners participate in and partially fund each of its acquisition deals.

Dasenlin said recently that it had postponed its IPO plan due to the poor stock market environment, and it hoped to bring in some well-known venture capital firms or financial institutions in the near future.

With a tough operating environment and increasing venture capital involvements, local analysts believe that M&A activities in the Chinese retail pharmacy sector will intensify this year.

Experts also suggest that Chinese pharmaceutical retailers are often drawn into widespread price wars which drain their profits. This trend provides them with incentives to form alliance with one another to avoid mutual destruction.

Guangzhou introduces online prescription surveillance system

Following experiments in 2008, Guangzhou Municipal Health Department recently announced that it would gradually implement an online drug prescription surveillance system in the city this year to monitor problem prescriptions and to provide leads for commercial bribery investigations.

Seven commercial bribery cases were cited by the health department in Guangzhou involving CNY 578,200. Among the total, six cases involving ten people were prosecuted.

China forms alliance organization for AIDS vaccine research

China AIDS Vaccine Initiative was established at the 1st China AIDS Forum recently, according to local press reports. The Initiative is the country's first collaborative organization for AIDS research and it will serve to foster collaborations among Chinese research groups specializing in AIDS vaccine.

Youchun Wang, an official with the National Institute for the Control of Pharmaceutical and Biological Products, said that the purpose of China AIDS Vaccine Initiative is to make best use of existing resources, avoid wastes from duplicated research, and encourage innovation in AIDS vaccine research.

Local Company News

Harbin Pharmaceutical Group may seek overseas IPO

Jiang Linkui, General Manager of Harbin Pharmaceutical Group, said on March 8 that his company is reconsidering and drafting a plan for overseas IPO. The Group, which controls a 34.76% stake in the SHSE-listed Harbin Pharmaceutical Co. Ltd. and 44.82% of SHSE-listed Sanchine Pharmaceutical Co. Ltd., denied earlier a foreign newspaper report that Harbin Pharmaceutical Group Co. Ltd. was planning a Hong Kong listing this year.

Harbin Pharmaceutical Group planned to launch IPO last year through raising its stake in Harbin Pharmaceutical Co. Ltd. and it failed to implement the plan due to difficulties in its shareholding structure reform.

Jiang did not confirm the time of Harbin Pharmaceutical Group's proposed IPO, but said "everything is still being prepared" and "it is unlikely to be this year".

In preparation for the IPO, Jiang said the group will complete some minor acquisitions in the first half of this year and is working on potential major acquisitions. The group undertook seven acquisitions in the distribution sector and two acquisitions in the manufacturing sector in 2008, he revealed.

The group currently exports more than 20 drug products to 46 overseas markets, but its export sales to Europe and North America fell 64% last year due to impacts of global financial crisis. It is now investing heavily to expand sales to Africa, and is stepping up regulatory compliance for EU and U.S. markets.

Harbin Pharmaceutical Group plans to raise the number of its core products to 25 this year from previously 22, and seeks to boost its revenues and profits by over 20% this year.

Beijing Pharma to form strategic alliance with Immtech

Immtech Pharmaceuticals, Inc. announced in late February that the company had signed a Memorandum of Understanding (MOU) confirming its interest in exploring the development of a strategic alliance with Beijing Pharmaceutical Group Co. Ltd. (BPGC). The MOU confirms the intention of BPGC to consider a range of collaborative global business development opportunities with Immtech.

The strategic alliance would give BPGC rights to develop drugs from Immtech's extensive proprietary library of compounds. Many of these compounds have been designed to target high-prevalence diseases such as hepatitis C and malaria, which are devastating infectious diseases that result in millions of deaths each year around the world.

The strategic alliance would also allow BPGC to leverage Immtech's extensive network of international relationships to gain access to patented technologies as well as advantageous sales and distribution channels in the US, the Middle East, Africa, Europe, and other locations.

Pending BPGC's satisfactory review and valuation of Immtech assets, the companies will continue negotiations related to details of the strategic alliance.

Qingdao Huanghai builds new biopharmaceutical facility

Qingdao Huanghai Biopharmaceutical Co. Ltd., a subsidiary of Qingdao Huanghai Pharmaceutical Co. Ltd., recently began construction of its manufacturing facility in Jiaodong Municipal Development Zone in Shandong province.

The total investment of the new facility is CNY 300 million and its total building area of the facility is 45,000 square meters. The facility includes a marine pharmaceutical plant, a biopharmaceutical plant and a pharmaceutical chemical plant.

Following completion of the facility, Qingdao Huanghai Biopharma is expected to generate a total revenue of CNY 450 million annually. The facility is expected to become operational and initiate trial production in October this year.

Haoyisheng Pharma to build export-oriented cGMP formulation facility

Haoyisheng Pharmaceutical Group announced recently that it would invest a total of CNY 380 million to build the first cGMP formulation manufacturing facility in southwest China.

The new facility is oriented for exports to EU and North American markets, and nine core products including roxithromycin capsule, amoxicillin capsule, ampicillin capsule and penicillin V potassium capsule will be manufactured initially.

SinoPharm's logistics center in Guangzhou became operational

SinoPharm Holdings, the largest pharmaceutical distributor in China, recently announced that its new logistics center in Guangzhou began operation recently. The total investment into the new center by SinoPharm was CNY 142 million.

The center is the largest among all of SinoPharm's logistics facilities in Beijing, Shanghai, Tianjin, Shenyang and Guangzhou, according to Ma Jiancong, general manager of SinoPharm Guangzhou Logistics Center. It possesses capabilities as a third party pharmaceutical logistics facility, he added.

A number of major Chinese cities and provinces including Beijing, Shanghai, Nanjing, Hainan and Shandong are currently experimenting the business model of pharmaceutical third party logistics in drug distribution. SinoPharm's logistics center in Guangzhou is the first to receive authorization for third party pharmaceutical logistics business in Guangdong province, according to Zhu Feng, Deputy Director of the Distribution Department of Guangdong Provincial FDA.

Zhu said Guangdong will also begin introducing large scale third party pharmaceutical logistics centers with the hope to replace a large number of small warehousing facilities currently owned by pharmaceutical manufacturers and small distributors, and to raise efficiency in drug distribution subsequently.

Simcere and Epitomics to co-develop therapeutic monoclonal antibodies

Simcere Pharmaceutical Group and San Francisco-based Epitomics, Inc. will collaborate to develop anti-cancer drugs using RabMAb®, Epitomics' humanized rabbit monoclonal antibodies. Until now, Epitomics has concentrated its efforts on applying RabMAb® to develop diagnostic tools. The Simcere collaboration will be the first attempt to develop humanized antibody therapeutics from the rabbit antibodies.

Chinese pharma public companies report sharp revenue growth last year

Sanjiu Medical & Pharmaceutical Co posted an 87% surge in its net profits in 2008. Business revenue of the Shenzhen-based company increased by 24% to CNY 4.32 billion (US$632 million) in 2008, realizing a profit of CNY 500 million, according to the annual financial report the company filed to the Shenzhen Stock Exchange on March 14. Sanjiu forecasted its business revenue to increase by 6.74% to CNY 4.6 billion in 2009, which would mean a net profit of CNY 650 million. The report said Sanjiu would expand its business scope through mergers and acquisitions, speed its pace in launching new products and enlarge its market share in areas below county level.

Meanwhile, three U.S.-listed Chinese biopharma companies reported their performance in 2008.

3SBio Inc. said 2008 revenues rose 35% to CNY 243 million (US$35.7 million). At the same time, following a trend seen in much of China biopharma, net income failed to keep pace with the increase in revenue. 3SBio said non-GAAP net income was CNY 75 million (US$11 million) for the year, about the same to 2007's results.

Simcere Pharmaceutical Group, which makes both branded generic pharmaceuticals and the anti-angiogenesis cancer drug Endu, reported Q4 revenues climbed 17% to CNY 467 million (US$68.4 million). However, net income fell 34% to CNY 52 million (US$7.6 million). Simcere did not attribute the net income shortfall to any particular cause. The most dramatic increase was in R&D spending, which was up 114% to CNY 34.0 million (US$5.0 million).

American Oriental Bioengineering continued to perform well financially in 2008. The company said 2008 revenues were up 65% to US$264.6 million. Non-GAAP net income rose 45% to US$62.7 million. Both numbers show admirable upside progress.

Foreign Company News

Novartis China sees sharp revenue growth in 2008 and bright prospects

Novartis announced its 2008 performance globally and in China on February 25. While its global sales rose 9% to US$41.5 billion, its Chinese sales grew 29% to reach CNY 3.3 billion (US$483 million). However, its Chinese sales accounts for only 1.16% of the company's global sales.

All divisions of Novartis China experienced similar growth last year, and revenues of Beijing Novartis Pharma surged 32.8%.

According to James Deng, CEO of Beijing Norvartis Pharma, the company ranked No.3 among all MNC pharma companies in China last year. Novartis continues to be the leader in cardiovascular field in China, with its Diovan and Lotensin being the top products respectively in the classes of angiotensin II receptor antagonists and anti-hypertensives. Combined sales of Diovan and Lotensin was over CNY 1 billion in 2008.

Beijing Novartis Pharma plans to launch six new products in China this year including Zometa (anti-osteoporosis), Myfortic (transplant), Lescol XL (anti-cholesterol), Tripaptal OS (anti-epileptic), Exforge (anti-hypertensive) and Cibadrex (anti-hypertensive).

Novartis has been steadily increasing its investments in China, and between 2004 and 2008, the compound annual growth rate of the company's investments in the country was 76% totaling CNY 2.2 billion.

The number of employees of Novartis China has also been rising at the CAGR rate of 22% and it had more than 3,500 employees in China by early 2009.

In 2009, Novartis hopes to achieve a revenue growth of over 30%. The company will continue to increase its investments in China and add 20% more employees. It also plans to form Novartis China University this year.

Novartis China will seek to strengthen its strategic alliance with the Chinese government and the local industry, and it hopes to make breakthroughs in generic drug, vaccine and OTC drug sectors this year.

Pfizer opens new facility in Dalian

Pfizer unveiled its new sterile manufacturing facility for cephalosporin power injection on Feb 27 in Dalian, Liaoning province.

"The new manufacturing facility will almost triple Pfizer's production capacity of cephalosporin vials in the Dalian site, meeting rapidly growing demand in China and other

markets," Ahmet Esen, general manager of Pfizer China said.

The move is part of Pfizer's strategy to continue investments in its Dalian site in a bid to transform the facility into one of the firm's most important global suppliers, said Allan Gabor, regional president of North Asia, Emerging Market Business Unit of Pfizer.

Despite the current global financial crisis, Pfizer invested US$6 million in the expansion. The Dalian site was set up with a total investment of US$60.4 million.

"Even in the middle of this worldwide economic crisis, we see China as a key strategic partner," Gabor said.

Gabor said the Pfizer Dalian site was the first pharma company in China to gain a GMP certificate, and "it has also gained many other certificates. Therefore, it is easier to bring new products to China and to export to other countries," he said.

Pfizer China and Peking University form joint quantitative pharmacology center

Pfizer China and Peking University Medical School announced on March 6 that they had reached an agreement to jointly establish the Peking University - Pfizer Quantitative Pharmacology Education Center.

Under the terms of the agreement, Pfizer China will invest a total of CNY 3 million into the center to help educate and train Chinese students and researchers in quantitative pharmacology.

"The new center will strengthen our capabilities in pharmacometrics. As a field of drug R&D using applied mathematics, it will help scientists better understand their target diseases and new drugs under development," said Dr. Ke Yang, Executive Vice Dean of Beijing University Medical School and Vice President of Beijing University.

"Pharmacometrics has become the center of clinical development nowadays. We believe it is critical for China to develop this field for support of new drug innovation in the country. This project will lead to major and active impacts on the local life science sector, and has demonstrated Pfizer's long term and high standard commitments to China's pharmaceutical industry development," said Feng Guo, Pfizer Asia's Head of Clinical Pharmacology and Pharmacometrics.

Efforts in China in quantitative pharmacology are at an early stage, but it is believed that Chinese scientists embrace the discipline and are keen to promote this methodology in the registration of new drugs in China. While challenges exist, they represent an exciting area of future collaboration.

Tianjin SKF defends safety of its cough & cold medications

Following an announcement by UK's Medicines and Healthcare Products Regulatory Agency (MHRA) in late February that a review of 69 cough and cold remedies for children "found no robust evidence that these medicines work" and that "they can cause side effects, such as allergic reactions, effects on sleep or hallucinations", the news was widely publicized in the Chinese media and caused an uproar among Chinese netizens over the safety and efficacy of cold medicines.

Reports submitted to British regulators show that, in cases involving people of all ages are considered, dozens have died after taking medication containing the ingredients and more than 3,000 people have reported "adverse reactions".

The ingredients involved are: the nasal decongestants pseudoephedrine, ephedrine, phenylephrine, oxymetazoline and xylometazoline; the antihistamines diphenhydramine, chlorphenamine, bromopheniramine, promethazine, triprolidine and doxylamine; the cough suppressants dextromethorphan and pholcodine, and the expectorants guaifenesin and ipecacuanha.

Tianjin SKF Pharma, a leading OTC drug company and a market leader of cough & cold medications in China, became the first Chinese OTC drug company to respond to the latest British claims and speak out about the safety of its products.

Zhang Yun, Tianjin SKF's medical director, told Chinese reporters that his company is "very confident" about the safety of its cough and cold products such as New Contac, a leading OTC cough & cold brand in China which contains pseudo-ephedrine. Zhang said Tianjin SKF would request the Tianjin Municipal Drug Administration to release a "safety" report on its cough & cold OTC drugs.

Zhang stated that Tianjin SKF's New Contac is labeled as "Drug for Adults", and that "all drugs may have adverse reactions, but as long as they are below the maximum rate of adverse drug reactions specified by the government, they can be marketed as safe medicines as it would be impossible to avoid every allergic reaction by each individual to every ingredient of drugs."

Zhang said that Tianjin SKF has a department monitoring adverse drug reactions of its products, and no serious adverse drug reactions were found from patients taking its New Contac or other cough & cold OTC medications in the past 20 plus years. But Zhang did clarify that cold medicines are not antibiotics and they can only relieve cold symptoms rather than killing bacteria.

Meanwhile, a leading Chinese web portal conducted a survey asking Chinese consumers about their trust in leading brand name cough & cold medications such as Black & White and New Contac. More than 10,000 Chinese netizens participated in the survey. 58.7% of participants voted "no trust", while 69. 8% of them indicated they would no longer purchase cold medicines such as Black & White and New Contac.

SciGen to initiate marketing of human insulin in China soon

Singapore-based SciGen has recently secured approvals for the sales and distribution of SciGen's recombinant human Insulin, SciLin, in China.

This long-awaited approval will allow SciGen distributor Shenzhen Meheco and Hefei Life Sciences technology (HLST) to engage in promotional activities through other distribution partners in China to ensure in-depth coverage in all Chinese provinces. The agreement requires Shenzhen Meheco and HSLT to sell SciGen's recombinant human insulin on an exclusive basis during the seven years term. Sales are expected to begin in the second quarter of 2009.

Shenzhen Meheco and HLST are reported to be Chinese companies with expertise in the Diabetic market, including Insulin. Recent estimates put the diabetic population in China at 39.8 million with sales expected to reach US$1 billion by 2010. According to the company, recent clinical trends in China indicate insulin being used more as a first line treatment in Type 2 diabetes.

In China, SciGen expects to generate sales revenues of US$17 million over the next three years with its recombinant human Insulin. Scigen will purchase Insulin from its CMO and major shareholder Bioton of Poland.

Lee's Pharma and Nippon Shinyaku reach licensing deal

Hong Kong Lee's Pharmaceutical Holdings Ltd. announced on March 3 the signing of a license agreement with Nippon Shinyaku Co., Ltd. for the pharmaceutical product containing Nippon Shinyaku's antibacterial agent "Prulifloxacin".

Under the license agreement, Lee's Pharmaceutical is granted an exclusive marketing right of products containing Prulifloxacin in China. The Group pays Nippon Shinyaku an upfront payment, milestone payments based on the sales achievement, and royalty payment based on the sales amount.

Prulifloxacin, which was discovered by Nippon Shinyaku as an oral quinolone antibacterial agent, has been launched in Japan and Europe. In addition, Nippon Shinyaku has already concluded license agreements with other pharmaceutical companies in Korea and U.S., which will develop Prulifloxacin in their territories.

Service Provider News

Frontage Labs to help Beijing Pharma access international generics market

Frontage Laboratories Inc., a provider of bioanalytical, pre-clinical, clinical and drug development services, announced on February 23 it had expanded its R&D agreement with Beijing No.2 Pharmaceuticals under Beijing Pharmaceutical Group (BPG) to accelerate BPG's entrance into the international generic drug market.

The agreement with BPG is a further expansion of Frontage's current relationship with this client and its overall business in China. As part of the agreement, Frontage will obtain a newly constructed, 1,800 sq. meter R&D center and continued access to BPG's GMP manufacturing areas. Frontage will also collaborate with BPG to develop 12 ANDA products over the next 3-5 years, which will be marketed in China, EU and the US.

In 2007, Frontage helped BPG in designing, renovating, and commissioning its manufacturing facilities to meet U.S. FDA and ICH GMP requirements, in building its GMP systems, employee training and in product development efforts. One of the products developed through the relationship was filed with USFDA in 2008, with several more targeted for filing in 2009. EU authorities successfully inspected the facilities in 2008.

Shanghai Drug Clinical Research Center established

Shanghai Drug Clinical Research Center, a non-profit third party clinical research service platform that offers clinical research, clinical testing and professional training services, was established in February at the Xuhui Fenglin Life Science Park of Shanghai. The center is jointly owned and operated by Shanghai Municipal Science Commission and Xuhui District Government of Shanghai.

Its facilities are designed to comply with international regulatory requirements, and construction began recently. Total investment is CNY 1 billion and the premise will occupy a total building area of 65,000 square meters. Core components of the center include its hospital network, central laboratory, data management unit and statistical center.

On the front of its hospital network, the center has signed framework agreements with Zhongshan Hospital Affiliated to Fudan University, Huashan Hospital, Shanghai Oncology Hospital, Shanghai Mental Health Center and Xuhui District Central Hospital to jointly build international GCP centers within these medical institutions.

In addition, it is under discussions for a number of innovative new drug projects, according to the center.

Tigermed forms alliance with MacroStat through asset injection

Tigermed Consulting Co., Ltd, a contract research organization (CRO) in China, and Qiming Venture, a premier venture capital firm based in Shanghai announced on March 3 that they would join hands to inject assets to MacroStat, a CRO specialized in clinical data management and statistical analysis. The union between the two CROs will significantly improve Tigermed's clinical data management serviceability and broaden MacroStat's business line.

MacroStat, an international CRO, founded in 2002 in USA, is one of the few professional CROs dedicated to providing clinical data management and statistical analysis services. MacroStat (China) was established in 2005 in Shanghai.

Regulatory News

New working procedures for drug registration second review issued

The Center for Drug Evaluation (CDE) under the State Food and Drug Administration (SFDA) issued on February 27 a new rule, Working Procedures for Drug Registration Second Review, in accordance with the requirements of Articles 157 and 158 of the Provisions for Drug Registration. The rule became effective on the date of issuance.

Articles 155 through 158 of the Provisions for Drug Registration allow registration applicants to appeal to the SFDA for the second review of the agency's drug application decisions.

The new rule provides that the CDE will establish a second review working group to be responsible for review of all categories of chemical drugs, traditional Chinese medicines and biological products. The group will be under the administration of CDE's Evaluation Management and Coordination Department (EMCD).

The new rule promises transparency and fairness in the second review process with relevant information published on CDE website. All review decisions will be discussed and decided through the second review evaluation meetings to be participated by relevant specialized evaluation personnel. When necessary, external experts will be invited and communications will be conducted with appeal applicants.

CDE will develop, issue and publish, on its website, its plans

for the second review evaluation of new drugs, copy drugs (including dosage form change applications), imported and supplemental applications. In principle, the second review evaluation meetings are held once a week. Such meetings are chaired by the head of EMCD and participated by members of the second review working group and officials who originally evaluated the applications under the second review.

The review task group is responsible for developing the memorandums for the second review evaluation meetings which record the meeting discussions and final conclusions.

The new rule stipulates four final conclusions that can be formed by the second review evaluation meetings as follows:

- Advice to correct current evaluation decision – under the circumstance the applications under review will be returned to the original evaluating departments of CDE for re-evaluation. These applications for re-evaluation should be added to the currently monthly evaluation plan of those departments and be completed in time;
- Advice to maintain current evaluation decision – under the circumstance the conclusions of the second review evaluation meetings will be submitted to the head of EMCD, signed by the head of CDE and returned to the Drug Registration Department of SFDA;
- Supplemental explanations are needed from the applicants – applicants are required to further clarify reasons for the second review or make additional presentations on certain key issues; and
- Conclusion can not yet be reached – this conclusion is issued if major issues or difficulties are encountered by the second review evaluation meetings. Under the circumstance, a three party meeting participated by the applicants, external experts and officials who originally evaluated the applications under review, will be needed. The three-party meetings are chaired by the second review working group and should come up with a conclusion either to advice correction or uphold the current evaluation decision.

NDRC initiates production cost and market price survey of drug products

The National Development and Reform Commission (NDRC) recently issued a notice to its local agencies for a nationwide survey of production costs and market prices of drug products contained in the national drug reimbursement list under the basic medical insurance programs.

The current list contains 1,031 Western medicines and 823 traditional Chinese medicines. All dosage forms and specifications of these products will be covered by this survey, according to the NDRC.

"The survey will cover costs, market prices, tender prices and prices set or filed by the provincial level governments", a senior NDRC official told the local press. He said the purpose of the survey is to better understand the production and distribution costs of drugs as well as their actual market prices, so that the government can adjust drug prices it set accordingly. The survey will help facilitate the implementation of the healthcare reform and the national essential drug system, he added.

According to Beijing Municipal Development and Reform Commission, Beijing Pharmaceutical Co. Ltd., Beijing Yibao Quanxin Pharmacy, the No.3 Hospital and the No. 6 Hospital of Peking University, and Beijing Jinsong Hospital were selected as survey objects in the city.

China to introduce DMF system for APIs and packaging

At a recent SFDA press conference, Zhang Wei, Director of the Drug Registration Department of the SFDA, told the local press that his agency plans to introduce a DMF (drug master file) style system to regulate active pharmaceutical ingredients (APIs), pharmaceutical inactive ingredients, and drug packaging materials.

Compared with the DMF system adopted by many developed countries, which requires filing of relevant information about the products and manufacturers of pharmaceutical APIs, inactive materials and packaging materials for later evaluation by authorities together with registration applications of drug formulations, China currently evaluates and approves APIs and pharmaceutical inactive ingredients separately.

The SFDA has listed the plan for adopting the Chinese DMF system in the 11th Five Year Plan, but the progress has been slow due to various undisclosed factors. Zhang said the SFDA received fiscal funding for the plan in 2008 and will continue to receive fiscal funding support for it in the coming years. Fiscal backing from the central government will accelerate the development of a DMF system meeting Chinese realities and expedite the introduction of it, he indicated.

Considering the risk factors involved, the SFDA is likely to introduce the new Chinese DMF system to cover selected traditional Chinese medicine injections first, Zhang revealed.

China to implement the system of "authorized person" in pharma manufacturing

The SFDA announced at the recent national drug safety supervision conference that it will begin implementing the system of "authorized person (AP)" (or "qualified person" and "QP") in pharmaceutical manufacturing in 2009, starting with manufacturers of high risk products including blood products, vaccines and injections. The system has been experimented in Guangdong province and 12 other provinces or autonomous regions since 2007, and the SFDA has found the trials to be successful.

Guangdong province implemented the system in two phases. Phase I began in July 2007 and covered 30 manufacturers of high risk products including blood products and vaccines, while the system was expanded to 61 manufacturers of biological products, injections and controlled substances in July 2008. By now, 285 authorized persons for pharmaceutical manufacturing are on file with Guangdong Provincial Food and Drug Administration.

According to a survey of manufacturers that introduced the system of "authorized person" in Guangdong province, 98.17% of surveyed senior executives say their law awareness has improved, 94.98% of them say the system has strengthened their sense of accountability, and 98.07% of them say their vigilance of quality control system has been raised.

However, executives and officials suggest that there are still some remaining issues with the "authorized person" system including a lack of relevant laws including legal provisions protecting the interests of authorized persons.

Guangdong Provincial Food and Drug Administration suggests the early full implementation of the system of "authorized person" in pharmaceutical manufacturing nationwide and amendments of the Drug Administration Law and relevant regulations include provisions for this system. It is reported a professional committee for authorized persons was already created under Guangdong Provincial Pharmaceutical Association to promote exchanges between APs.

The system of authorized person or qualified person in pharmaceutical manufacturing has been practiced in Europe and North America for many years under which a representative of a given pharmaceutical company is designated as the AP or QP, and he or she is fully responsible and held accountable for the quality of drug products manufactured by that company.

National drug registration conference to lay out plans for 2009

The national drug registration conference was held between March 4 and 5 in Changsha. SFDA Deputy Commissioner Wu Zhen delivered a speech at the conference calling for improvements of drug evaluation quality and efficiency.

According to Wu, the emphasis of drug registration work in 2009 is to improve the legal framework of drug registration, develop relevant complementary documents for drug registration, and fine-tune the drug registration system.

Specifically, the following tasks will be implemented this year:

- Strengthening control from the root by improving regulation of APIs, pharmaceutical inactive materials, chemical intermediates and pharmaceutical packaging materials;
- Reinforcing registration control of high risk products including traditional Chinese medicine injections;
- Initiating evaluation of drug re-registration on a full scale, and firmly eliminate those high risk drug products without proper manufacturing conditions and quality assurance in order to ensure drug safety and quality;
- Expediting the implementation of action plans for raising drug standards; and
- Continuing the efforts for reform of drug registration and evaluation, and exploring ways to decentralize relevant drug registration and licensing responsibilities.

SFDA News

SFDA revises package insert of piroxicam

The SFDA announced on February 26 the revision of piroxicam's package insert in an effort to control the risks associated with the drug.

The revised package insert explicitly provides that the drug must only be used for osteo-arthritis, rheumatoid arthritis and ankylosing spondylitis. In addition, it spells out that the drug should not be used as frontline medicines when they are used as non-steroidal anti-inflammatory drugs for above indications.

The revised package insert also adds the maximum daily dose of 20 mg under the dosing section, and adds under the notes section that "piroxicam should used when prescribed by physicians with treatment experience for inflammation or retrogression rheumatic diseases" and "the tolerance and benefits of using this product should be re-examined within 14 days and, if it is needed further, more frequent re-examinations are required".

MOH/SFDA suspend sales of pantoprazole sodium for injection from Jilin Yixin Pharma

The Ministry of Health and the SFDA ordered the suspension of sales and clinical application of pantoprazole sodium for injection manufactured by Jilin Yixin Pharmaceutical Co. Ltd. after Jilin Provincial Food and Drug Administration found visible foreign substances in five batches of this product.

In addition, the SFDA ordered Jilin Provincial FDA to conduct inspections of the manufacturing operations of Jilin Yixin Pharma and deal with any violations immediately.

CDE develops framework of technical guidelines drug research

Referencing technical guideline systems of the USFDA, EMEA and ICH, the Center for Drug Evaluation (CDE) under the Chinese SFDA has recently begun planning a framework of technical guidelines for drug research in China. In the meantime, the agency continues its efforts in the development of relevant technical guidelines.

In 2008, the CDE drafted ten technical guidelines for concentrated evaluation of transition products, issued one technical guideline for changes related to post-marketing chemical drugs, completed the development of technical guidelines for six major indications and began drafting ten other technical guidelines.

The SFDA believes that technical guidelines for drug research play an important role in the development of China's pharmaceutical industry and drug innovation.

According to the CDE, the technical guidelines for drug research will be developed based on the principle of "safety and efficacy, science and rationality, encouraging innovativeness, and promoting dialogue and cooperation".

CDE issues various implementation rules for special approval of drug registration

In an effort to implement the "Rules on Special Approval of New Drug Registration", the Center for Drug Evaluation under the SFDA has recently issued a number of implementation rules and guidelines to establish various processes and procedures for relevant technical evaluation, application and approval.

Newly issued implementation rules and guidelines for special approval of new drugs include: 1) Publication of Information on Products under Special Approval; 2) Guidelines for Drawing Up Independent Dossier Information for Products under Special Approval; 3) Implementation Rules on Communication Mechanisms for Products under Special Approval; and 4) Writing Formats for Minutes of Communication Meetings over Products under Special Approval.

SFDA punishes producer of flawed rabies vaccine

The SFDA announced recently that it revoked the production license of Dalian Jingang-Andi Bio-products Co. Ltd. that produced flawed rabies vaccines and banned the firm's principals from any involvement in the industry for 10 years. The SFDA also withdrew the approval certificate for the vaccine.

An SFDA official told Xinhua on March 11 that general manager Wang Quanfeng and deputy general manager Luo Huosheng of Dalian Jingang-Andi Bio-products had been found responsible for the faulty vaccines, according to an investigation by the government of Liaoning Province, where the company is based. However, officials were still investigating how many others could be held accountable.

Police detained Wang and Luo on Feb. 7 after the company was found to have deliberately added nucleic acid in the production of the vaccine to lower production costs.

Nucleic acid acts as an adjuvant, or a substance is used to enhance the effectiveness of anti-viral drugs. However, China has yet to approve it for use in rabies vaccine as it has to undergo clinical trials before it could be used on humans.

Legal / IPR News

SFDA issues drug administrative protection announcements

The SFDA issued the No.133 Drug Administrative Protection Announcement on February 23, 2009, declaring the ending of drug administrative protection for AstraZeneca LP's Toprol XL (metoprolol succinate) extended-release tablets.

The agency also issued, on the same date, the No.134 Drug Administrative Protection Announcement, declaring the ending of protection for Fresenius Kabi's Structolipid (purified structured triglycerides) emulsion for infusion.

Mentholatum sues XiAn Meichen over trademark infringements

Leading eyedrop and healthcare product manufacturer Mentholatum (China) Pharmaceutical Co. Ltd. recently sued XiAn Meichen Pharma, its distributor XiAn Wanbang Biopharma and a retail pharmacy for trademark infringements of its Rohto line of eyedrop products (Chinese trademark of Rohto is Le Dun) at the Fengtai District Court of Beijing. Mentholatum wants the defendants to stop infringements, apologize and pay a compensation of CNY 300,000.

XiAn Meichen is the manufacturer of an eyedrop product under the brand name of "Gold Le Dun" that was launched on the Beijing market recently.

Mentholatum (China) is a subsidiary of Mentholatum of the United States and Japan's Rhoto Pharma. The company was granted the trademark of Le Dun in September 2006. The core business of Mentholatum (China) is composed of Mentholatum and Rhoto (Le Dun) lines of eyedrop products. Rhoto (Le Dun) line of eyedrop products was launched in China in 1996 and has become a market leader in the eye care field.

APIs / Bulk Drugs

Huaxing expands capacity of Amoxicillin and 6-APA

Li Liangcai, Supply Director of Huaxing Pharmaceutical, told the Chinese press recently that his company had recently completed the phase I expansion project, and the new plant would begin production from early March. Huaxing is one of the largest penicillin API producers in China.

Following the phase I expansion, the company's annual capacity of amoxicillin will be over 3,000 tons and that of 6-APA will be above 1,000 tons. It is expected that Huaxing will begin supplying the market with these products in June.

Total investment into Huaxing's new facility, under the name of Henan Lvyuan Pharma, totaled CNY 1 billion, and it is planned to produce more than 30 API products including penicillins, semi-synthetic cephalosporins and vitamins. Anticipated new revenues are CNY 700 million annually with CNY 70 million in profit before taxes.

Li revealed that Huaxing is talking to a few foreign buyers, including a major Indian API player, about its exports.

In addition to amoxicillin and 6-APA, Huaxing is likely to expand its annual vitamin C capacity next year to at least 15,000 tons. If the market situation is good, the company may even expand the capacity to 30,000 or 50,000 tons, according to Li.

Local analysts believe Huaxing is expanding into downstream and less polluting products such as amoxicillin in order to diversify from risks associated with the increasingly stringent environmental standards.

However, the company's entry into semi-synthetic penicillin and vitamin C markets will sharply intensify the competitions in these sectors. The likelihood of price wars among domestic exporters is growing quickly.

The prices of amoxicillin and 6-APA have already been falling for some time and it is believed they have approached cost levels.

NCPG and DSM likely to build a major antibiotic API facility in Changchun

Chang Xing, chairman of North China Pharmaceutical Group (NCPG) recently met with Gao Guangbin, the Mayor of Changchun city during a trip to survey potential manufacturing sites for a proposed joint venture company between NCPG and DSM. The joint venture deal is currently pending government approval.

Changchun's Wukeshu Economic Development Zone is believed to be one of the two potential sites for this major facility. The other choice is Chifeng city, Inner Mongolia.

The proposed new facility will be built in two phases. Phase I investment will be CNY 1 billion for a 6-APA plant with 5,500 tons annual capacity. Phase II of the project will build plants for vitamin C (35,800 tons of annual capacity), vitamin B12 (16 tons), penicillin V potassium (1,500 tons), lactic acid (50, 000 tons), bio-butanol (100,000 tons) and polyglutamic acid (5,000 tons). Total estimated investment for phase II is CNY 5 billion.

Shandong Antibiotics granted Germany GMP certification

Shandong Antibiotics Pharmaceutical Co. Ltd., a leading Chinese antibiotic manufacturer and exporter, recently announced that it had received GMP certifications from German authorities for its spectinomycin hydrochloride and spectinomycin sulfate APIs. This is the first foreign GMP certification received by the company. The company is also seeking cGMP certifications of its facilities and products by the USFDA.

Shandong Antibiotics has implemented a strategy of business expansion to high end markets in Europe and North America in recent years. Receiving EU GMP certifications will accelerate the company's entry into European markets.

Hisun sees profits up sharply in 2008

Leading API producer Zhejiang Hisun Pharmaceutical Co., Ltd. (SHSE: 600267) announced recently that its net profit surged 39.84% to CNY 195 million in 2008, while its operating revenue and total profit jumped 12.09% and 24.21% respectively to CNY 3,182 million and CNY 241 million. In addition, Hisun's export sales rose 27% from a year ago to US$52.77 million.

The Shanghai-listed company is engaged in producing and selling APIs and pharma formulations for cardiovascular diseases, parasitosis, endocrine dyscrasia, oncology and infection.

Hisun has been investing heavily in R&D. Last year, Hisun Pharmaceutical spent CNY 138 million on R&D, accounting for 9.50% of the total sales revenues of its parent, Zhejiang Hisun Group.

Changzhou Yabang-QH builds new cGMP API plant with help from Janssen and J&J

Changzhou Yabang-QH PharmaChem Co. Ltd., a subsidiary of Yabang Group and a specialized API producer of anti-parasitic drugs, announced on March 3 that it began the construction of a new API plant which will be fully compliant with regulatory requirements in the EU and the U.S. The new plant is located in Changzhou, Jiangsu province and was jointly designed by itself, Janssen and Johnson & Johnson, according to the company.

Changzhou Yabang-QH has a long term strategic alliance and OEM partnership with both Janssen and J&J.

Total investments into the new plant will be CNY 57 million including phase I investment of CNY 35 million. Janssen will help Changzho Yabang-QH secure COS and USFDA certifications of the new plant. Phase I of the new plant is expected to be completed in 2009.

Most products of the new plant will be exported to EU, North American and Australian markets and anticipated profit before taxes from the plant is expected to reach 60 million annually.

Currently, Changzhou Yabang-QH Pharma exports 80% of its output to over 100 markets worldwide. It is likely to become China's largest developer and exporter of anti-helmintic drugs following the completion of its new plant.

Shijiazhuang Pharma receives EDQM certification for Vitamin B12

Shijiazhuang Pharmaceutical Group announced recently that it had passed an onsite inspection of EDQM for its vitamin B12 plant. The company already passed COS certification for the product in 2005.

Shijiazhuang Pharma is a leading manufacturer of vitamin B12 API in the world and it currently exports 70% of its annual output. The successful passage of EDQM inspection will help the company expand sales of the product in EU's human pharmaceutical sector.

By the end of 2008, Shijiazhuang Pharma had a total of six COS certifications for its APIs including vitamin C, caffeine, vitamin B12, ranitidine, theophylline and amoxicillin. It also had more than ten DMFs with the USFDA for APIs including amoxicillin and penicillin G. The company has product registrations for more than 80 API and formulation products in nearly 30 countries including various markets in EU, North America, South Korea, Russia and Japan.

India likely to investigate China's 6-APA

According to China Chamber of Commerce for Import and Export of Pharmaceutical and Healthcare Products, Indian authorities plan to launch an investigation into China's 6-aminopenicillanic acid (6-APA) exports to ascertain unfair competition practices. Earlier, India said it would continue the anti-dumping investigation of China's penicillin G.

Chinese analysts say the country is likely to face increasing protectionisms overseas for exports of its pharma and healthcare products with the global economic meltdown in the backdrop.

Chinese producers of 6-APA believe the recent event to be another protectionist measure by India against Chinese pharmaceutical imports.

China exported a total of 3,518 tons of 6-APA to India in 2008, up 68% compared with the previous year and accounting for 59% of the global output for this product. Total export sales of the product by China last year was US$120 million.

The investigation is expected to result in higher custom duties on India's import of Chinese 6-APA. Experts believe the sharp growth in the import of this product by India last year triggered the investigation.

The MOC issues list of authorized exporters of ephedrine drugs

The Ministry of Commerce (MOCrecently issued the 2009-2010 list of authorized exporters of ephedrine category chemical drugs, which can be easily made into narcotics, in accordance with the Interim Rules for Verification of Exporters of Ephedrine Category Chemical Drugs. The list contains 13 authorized exporters and it expires on December 31, 2010.

The 13 authorized exporters are: 1) General Mekang Pharmaceutical Ltd.; 2) Zhejiang Puluokang Pharmaceutical Ltd.; 3) Chifeng Aike Pharmaceutical Science & Technology Ltd.; 4) Inner Mongolia Zhengren Pharmaceutical Ltd.; 5) Erdos Jintuo Pharmaceutical Ltd.; 6) Gansu Meierkang Import and Export Ltd.; 7) Xinjiang International Enterprises Ltd.; 8)

Xinjiang Pharmaceutical Factory; 9) Xinjiang Heshuo Ephedrine Products Ltd.; 10) Jiamusi City Medicines and Health Products Import and Export Co.; 11) Qinghai Lake Pharmaceutical Ltd.; 12) Tianjin Kangxing Medicines and Health Products Import and Export Ltd. under Beifang International Group; and 13) Shenzhen Wolande Pharmaceutical Ltd.

Separately, the SFDA issued a series of measures to raise the licensing requirements for the manufacturing of ephedrine-containing compound formulations. In addition, contract manufacture of such products for foreign companies is banned.

Data Snapshot - COS certifications and DMFs held by Chinese companies

According to SNAPI (*Database-driven Sino-API Intelligence*) co-published by Pharma China and London-based consulting firm Brychem, there were 128 Chinese holders (including seven holders in Taiwan covering 13 products) of COS certifications which covered a total of 146 drug products by the end of January, 2009. Among the total, two holders were trade companies and the rest were pharmaceutical manufacturers. By the end of 2008, 275 Chinese companies filed DMFs with the USFDA covering a total of 466 products. Among the total, 27 were companies from Taiwan and their DMFs covered a total of 122 drug products.

Chinese API in 2008 – Output and Export Volumes Down

API output and export volumes in 1H/2008

According to latest official statistics, the output volume of 24 categories of bulk drugs by China grew only 0.8% in the first half of 2008, while its export volume dropped 17.7% in the same period. Growth rate of China's API output in the period was 10.5 percentage points lower than the same for 1H/2007.

The falling API output and export growth in the past year was related to the temporary production suspensions before Beijing Olympics and elevation of the country's environmental conservation standards. The following table shows the API output volume trends by therapeutic classes:

Output/Export Volume Growth of Major Categories of APIs in 1H/08

Category	Output Volume +/- (%)	Export Volume +/- (%)
Anti-infectives	+7.22	-21.34
Analgesics & antipyretics	+7.33	-16.79
Vitamins & minerals	+7.00	-1.92
Anti-parasitics	-36.10	-11.24
Family planning & hormones	-22.79	-49.99
Anti-cancers	-8.76	-39.52
Cardiovasculars	+6.67	+4.38
Respiratory system	-22.91	-40.49
Central nervous system	-7.87	-5.04
Digestive system	+26.88	-41.31
Urinary system	-89.56	-62.63
Blood system	-2.27	-17.00
Drugs for water, electrolyte and Acid/base balance	-2.65	+33.05
Others	-	
Total 24 categories of APIs	+0.8	-17.70

Source: China National Association of Pharmaceutical Industry

Therapeutic classes including urinary system, respiratory system, family planning/hormonal and anti-parasitic drugs suffered the highest drop in output and export volume in the first half of 2008, while the output volume for digestive system, analgesics & antipyretics, anti-infectives and vitamins & minerals continued to grow in the period despite falling export sales. Both output and export volumes of cardiovascular bulk drugs had modest growth in the period.

The following two tables show the output volume changes of major anti-infective subcategories and products in 1H/2008.

Output volume changes of anti-infective subcategories in 1H/2008

Anti-infective subcategories	Volume +/- (%)
Penicillins	+20.5
Cephalosporins	+6.3
Beta-lactam antibiotics	+41.6
Tetracycline drugs	+17.0
Amide alcohol drugs	+4.9
Aminosides	+8.5
Macrolides	-21.1
Other antibiotics	+38.8
Sulfanilamides and synergists	+19.4
Nitrofurans	-45.2
Quinolones	-41.2
Anti-tuberculosis drugs	-14.9
Anti-fungals	-36.5
Anti-virals	+5.2
Other anti-infectives	-20.9
Overall	+7.2

Source: China National Association of Pharmaceutical Industry

Output volume changes of anti-infective products in 1H/2008

Anti-infective products	Output Volume +/- (%)	Export Volume +/- (%)
Amoxicillin and salts	+37.2	+46.8
Penicillin G	-13.6	-19.1
Ampicillin (for injection)	-18.0	+73.8
Penicillin Procaine	+9.5	+6.1
Penicillin V Potassium	+1.2	+72.0
Penicillin G Potassium	+46.9	+205.0

Source: China National Association of Pharmaceutical Industry

API export sales in 2008

Export sales of APIs by China was US$17,581 million in 2008, up 29.59% compared with the previous year. The share of APIs in China's total export sales Western medicines was 89.72%. But export volume of APIs by the country fell 4.25% in the same period. The drop in export volume was sharp in the first half, but it slowly recovered in the second half. The recovery was then interrupted by the slowing global economy towards the end of 2008.

The fast growth of API export sales in 2008 was triggered by sharp price hikes, and average export price of APIs grew 35.36% in the period.

Export Sales Growth of Major Categories of APIs in 2008

Category	Export sales (US$ mln)	+/- (%)
Central nervous system	1,073	+21.7
Cardiovascular system	3	+218.8
Digestive system	369	+42.5
Vitamins	2,144	+78.3
Cephalosporins	256	+13.4
Tetracyclines	191	+4.6
Penicillins	612	-4.2
Other antibiotics	936	+21.9
Anesthesia drugs	11	-75.67
Chloramphenicol category	49	+40.6
Lincomycin category	91	+15.7
Anti-parasitic drugs	212	+25.8
Analgesics & antipyretics	806	+22.9
Hormonal drugs	334	+16.9
Sulfanilamides	343	+33.7
Respiratory system	15	+6.0
Macrolide antibiotics	162	+45.6
Aminosides	89	+7.9
Amino acids & derivatives	728	+15.5
Other APIs	9,157	+30.0
Total	17,581	+29.6

Source: China National Association of Pharmaceutical Industry

Export Sales of Major API Products in 2008

Product	Export (US$ mln)	+/- (%)	Leading export markets
Vitamin C & derivatives	741	+116.8	USA, Germany, Japan, Netherlands, Belgium
Vitamin E & derivatives	562	+242.2	USA, Germany, Japan, Netherlands, Korea
Penicillin G and derivatives	281	-22.8	India, Iran, Japan, Spain, Italy
6-APA	201	+37.0	India, Spain, Iran, Egypt, UAE
Sodium Glutamate	201	+9.4	Burma, USA, Nigeria, Indonesia, Thailand
Paracetamol	171	+23.8	India, Indonesia, Ireland, Nigeria, USA
Saccharin sodium & salts	163	+102.4	Germany, USA, Japan, Brazil, Korea
Erythromycin & derivatives	149	+51.3	India, Spain, Puerto Rico, Korea, Malaysia

Source: China National Association of Pharmaceutical Industry

Product and R&D News

AOB to initiate clinical trials of TCM drug for UI in the U.S.

American Oriental Bioengineering, Inc. announced on March 9 that the company is initiating a phase one clinical trial of AOBO-001, an oral capsule developed from traditional Chinese herbal medicine for the treatment of urinary incontinence (UI) in the United States. The company currently manufactures and markets the oral capsule in China under the Cease Enuresis Oral Capsule brand, which was approved by China's State Food and Drug Administration ("SFDA") in 2002.

The USFDA accepted the company's Investigational New Drug (IND) for AOBO-001 in late 2008. The U.S. clinical trial phase one will commence shortly in order to evaluate the safety of AOBO- 001 in American populations. During the development of AOBO-001 in the U.S., various preclinical and clinical studies also will be conducted in China or other regions, and all studies will be subject to relevant U.S. FDA regulations.

AOBO-001 oral capsule is developed from traditional Chinese herbal medicine for the treatment of UI. The selection of indication for AOBO-001 was based on previous clinical experiences. Potential effect of AOBO-001 on UI has been evaluated in various in vitro and in vivo models. AOBO has filed several patents in the past 12 months to protect the intellectual property of AOBO-001.

General Health

Health Minister outlines emphasis of medical administration work in 2009

Health Minister Chen Zhu delivered an important policy speech at the recent 2009 National Medical Administration Conference on February 19 outlining the following important tasks of the Ministry of Health's medical administration work in 2009, which he said, will become the foundation of China's successful healthcare reform.

- Healthcare resources must be rationally distributed and allocated regionally, and different types of medical institutions must form comprehensive alliances and collaborative supporting systems to fully utilize existing resources;
- Certain medical specialties, such as pediatrics, mental health, pathology, infectious diseases, rehabilitation and clinical nutrition, are currently underdeveloped. The level of medical technologies and services must be raised further, and hospitals will be guided to develop their own clinical specialties;
- Between 2009 and 2011, all levels of governments will begin supporting the infrastructural development, which should be streamlined and standardized, of 2,022 county level hospitals. Local health departments are requested to guide the related work to ensure the development are planned and implemented in accordance with the mission and objectives of these hospitals. The goal of the infrastructural development is to upgrade these hospitals to the level of grade IIA medical institutions;
- Local health departments are also requested to cooperate with relevant personnel departments in the implementation of the streamlined training scheme of resident physicians, who form the basis for the future physician specialist system;
- Major urban hospitals are leaders in the Chinese medical provision and they should 1) strengthen the development of clinical specialties to deal with difficult and serious diseases in addition to their continuously improving general medical capabilities; and 2) provide training and guidance to and establish collaborative mechanisms with primary and community healthcare institutions in order to establish a convenient mutual referral system;
- Public hospitals must pursue a balanced development path with simultaneous development of its medical services, teaching commitments and research capabilities;
- The abilities of medical administrators should be developed to improve their skills in strategic thinking, development planning and coordination, hospital guidance, law enforcement and scientific decision making;
- The current legal framework for medical administration needs to be improved to cover all elements and processes of

medical service provision to ensure quality of healthcare; licensing of medical institutions, physicians, medical technologies will be strengthened; and the licensing systems for physicians and nurses will be established, while those for other medical technicians and physicists will be studied;

- The development of a system for quality control of medical services will be strengthened; medical quality control centers at the national, regional and provincial levels will be built gradually, and professional rules for the medical service process will be developed; a system of medical service standards, including quality control standards for single diseases and for major hospital departments, will be developed to streamline medical service provision and to form positive interactions with the basic medical insurance programs; and surveillance and early warning systems over medical practices and medical service quality should be strengthened; and
- Clinical paths will be established in phases. Currently the Medical Administration Department of the MOH already drafted clinical paths for certain diseases and conducted experiments at some medical institutions. The MOH will strengthen the development of clinical paths for common, high incidence and expensive-to-treat diseases from now on, and will introduce new clinical paths annually in order to promote the use of appropriate treatments, technologies and essential drugs and to avoid irrational treatments.

Health Minister talks about government healthcare funding

Health Minister Chen Zhu, a member of China People's Political Consultative Conference (CPPCC), spoke to reporters about the allocation of CNY 850 billion government healthcare funding in the next three years at the CPPCC session on March 4.

Chen said the allocation plan of this government funding is still under discussion, but he revealed that the rural cooperative medical system and the urban resident basic medical insurance program will definitely be the highest priorities.

Chen told reporters that the CNY 850 billion funding will be spent in two major areas: 1) investments into the basic medical insurance system in order to ensure basic medical coverage for all people, and 2) investments into medical provision, drugs and especially public health which help promoting prevention and thus reducing diseases.

In response to rising public concerns over possible medical fee hikes after elimination of the current 15% hospital margins on drug sales, Chen indicated that the government will introduce a mix of relevant reform measures, but he suggested that hospitals will need to be compensated for the loss of profit margin elimination and government fiscal investment will be very important in compensating the hospitals and is the determinant in the successful reform of drug sales margins.

He admitted that the elimination of hospital margins on drug sales is not easy and the policy will be implemented gradually.

Rules of essential drug system likely to be adjusted in implementation

According to latest local press reports quoting authoritative sources, the implementation plans for China's healthcare reform plan is likely to be released after the "two conferences" (referring to the upcoming sessions of the National People's Congress and the Chinese People's Political Consultative Conference), rather than before the "two conferences" as previously predicted by many analysts.

According to the same sources, there are likely changes in the implementation plan of the essential drug system including 1) the central government will establish guidance prices for essential drugs, 2) manufacturers will be selected through provincial level tenders, and 3) final prices will be set by provincial level governments after tenders.

Earlier announcements of the essential drug policy called for central government price-setting on all essential drugs and state designation of manufacturers for essential drugs.

The local pharmaceutical industry have responded positively to the possible new policy shift, calling it very good news.

However, sources suggest that even if these changes are adopted eventually in implementation, it does not necessarily mean they will be reflected in the text of the final healthcare reform plan.

Tianjin introduces centralized hospital drug purchase through internet bidding

As of March 1, 2009, Tianjin began implementing centralized drug purchase through internet bidding for all of its public hospitals. The list of drug products subject to this new measure includes 68 Western medicines and 321 TCMs.

In the past, Tianjin's centralized drug purchase was required only for grade II and above public hospitals under the municipal health department. But the new policy requires all public hospitals in Tianjin, including community healthcare service centers and rural township health centers, to participate in the centralized drug purchase through internet bidding.

However, narcotics, psychoactive drugs, medical toxic drugs and radioactive drugs are not subject to centralized hospital drug purchase.

Earlier, Tianjin Municipal Government announced that it would implement the zero drug sales margin policy in the city's community healthcare service centers in 2009, and would gradually expand the measure to other healthcare institutions. The municipal government will centrally purchase drug products for and distribute them to these community healthcare service centers which are required to sell drugs at their original purchase prices.

MOH reports prevalence of infectious diseases in 02/2009

The Ministry of Health released the prevalence information of infectious disease in February 2009.

According to the Ministry, there is no reported incidence of type A infectious diseases and four type B infectious diseases including SARS, poliomyelitis, HpAI (human bird flu) and diphtheria in the period.

A total of 326,145 cases of 21 other type B infectious diseases were reported in the month, and there were also 827 reported deaths for these diseases.

The leading five infectious diseases in the period, ranked by their prevalence rates, were tuberculosis, hepatitis B, syphilis, hepatitis C and dysentery, and together these five leading infectious diseases accounted for 90% of all type C reported cases in February 2009.

In the same period, there were 58,211 reported cases and 11 deaths of type C infectious diseases, and the leading three type C infectious diseases by their prevalence rates were infectious diarrhea, epidemic parotitis and foot & mouth disease. Together they accounted for 87% of all reported cases of type C infectious diseases.

Prevalence of renal disease high in Shanghai

Shanghai Ruijin Hospital recently released a report of epidemiology survey of chronic renal diseases in Shanghai.

The survey found the prevalence rate of renal diseases among Shanghai residents over the age of 18 to be 11.8%, which is much higher than other areas of China and approaches the rate in the U.S. Among the renal disease sufferers, over 90% are not aware of their renal illnesses and most of them are in phase III of the chronic renal diseases.

The survey found that the high morbidity of renal diseases in the city to be related to the rising incidence of high blood pressure, diabetes and other life-style diseases. Among phase III chronic renal disease patient population in the city, 66.4% suffer from high blood pressure, 35.7% from hyperuricacidemia, 26.4% from anemia, 25.7% from fat belly and 22.1% from diabetes.

People in the News

Executive moves

Gao Qiang, former party secretary at the Ministry of Health, was recently appointed the Deputy Head of the Fiscal Finance and Economic Committee and the Head of Budgetary Working Group of the Executive Committee of the 11th National People's Congress. Gao's position at the Ministry of Health was replaced by ***Zhang Mao***, formerly vice minister of NDRC. Prior to his position with the Ministry of Health, Gao was a vice minister of fiscal finance.

aTyr Pharma announced on March 9 the appointment of ***Dr. James Cai*** as Senior Vice President of Clinical Development at aTyr Pharma and President of Pangu BioPharma, a fully owned aTyr Pharma subsidiary in Hong Kong. Most recently, Dr. Cai was Vice President of Research and Development at AstraZeneca China. Prior to joining AstraZeneca, Dr. Cai was External Affairs and HIV Franchise Director at Merck Sharp & Dohme China and Medical Director at Pfizer. Dr. Cai is based in Shanghai, where he has opened an office for aTyr Pharma and Pangu BioPharma.

Frontage Laboratories announced on February 23 the appointment of ***Len Stigliano*** as CFO and ***Derek Zhang*** as VP of Regulatory Affairs and Clinical Pharmacology. Stigliano, a 25 year financial professional in the life sciences business was most recently the CFO of Novavax, a publicly traded novel vaccine development company. Dr. Zhang brings to Frontage over 10 years of combined experience in the areas of drug research, development and regulatory approval, including four years of experience at Pfizer and six years of regulatory experience at the USFDA.

Medicilon/MPI Preclinical Research-Shanghai, a joint venture of Medicilon and MPI, announced on March 2 the appointment of ***Dean E. Rodwell*** as its new President and Chief Operating Officer. Prior to joining Medicilon/MPI, Mr. Rodwell was the Vice President of Toxicology at BioDuro in Beijing, China.

Pharmacyclics, Inc. announced on February 19 the appointment of ***Dr. Glenn Rice*** to its President and COO following its acquisition of Pacific Biopharma Group (PBG) where Dr. Rice is chairman and CEO. Prior to PBG, he was the founder and CEO of leading preclinical CRO in China, Bridge Pharma.

Other News

RDPAC office moves to a new location in Beijing

RDPAC has moved its office to a new location in Beijing with effect from Mar 1, 2009. The new address and contact information are as follows:

Room 506, Office Building 1, Beijing Landmark Towers

8# North Dongsanhuan Road, Chaoyang District, Beijing 100004, P. R. China

中国北京市朝阳区东三环北路 8 号 北京亮马河大厦 1 座 506 室

邮编：100004

Tel: +86 10 6590 7696

Fax: +86 10 6590 7697

Upcoming event

Event: Pharma China Seminar – Building Success in China's Pharma Sector
Date: April 29, 2009
Venue: Boston Hilton Back Bay, Boston, MA
Weblink: www.pharmachinaseminar.com
Contact: Amy Yeh
Tel: +1 212-228-7974/713-398-6888
Email: ayueh@pharmaciconference.com

Event: Pharma CI Conference
Dates: September 15-16, 2009
Venue: Sheraton Parsippany Hotel, Parsippany, NJ
Weblink: www.pharmaciconference.com
Contact: Amy Yeh
Tel: +1 212-228-7974/713-398-6888
Email: ayueh@pharmaciconference.com

Feature Articles

Practical Tips for Pharmaceutical Companies on Patent Litigation in China

Geoffrey Lin, Counsel, Lovells Shanghai

Pharmaceutical companies active in China should be conscious of how the Chinese patent litigation system is developing into an offensive option and how in turn it has created the need to develop defensive strategies. Companies should: 1) understand the system; and 2) prepare to defend their patents.

I. Understanding the System

Pharmaceutical companies active in China should familiarize themselves with the Chinese patent litigation system. China is increasingly becoming a patent battlefield. Patent rights are being used actively by foreign and domestic companies to compete with each other in the market. Western companies are using their rights to take action against their competitor's manufacturing facilities in China. Chinese companies are also suing to keep foreign competitors out of their market.

The author is an attorney acting on numerous patent infringement cases in the PRC involving not just Western companies suing Chinese companies but multinationals suing other multinationals. Local companies are also starting to assert their patent rights against foreign competitors to protect their market share. In 2007, Schneider was ordered to pay US$45 million in damages to a local company, Chint. In 2008, Samsung was ordered to pay US$7 million in damages to another local company, Holley.

The Chinese Patent Litigation System

Using the US patent litigation system as a reference, the key points of difference to bringing a patent infringement case in the PRC are:

- There is no rule of binding precedent;
- There are no jury trials;
- Infringement and validity are tried separately;
- The burden of proof is high;
- PRC Courts principally rely on documentary evidence and require notarization and legalization for overseas evidence;
- Oral evidence is rarely relied upon;
- There is no oral or written discovery;
- There is no "Markman" style hearing. Claims are interpreted based on the wording of the claims when read with the specification and drawings; and
- Every element of a patent claim must be proved by the plaintiff;

The Chinese litigation system is modeled on that of continental Europe and particularly that of Germany. For those familiar with the German system, there are a lot of similarities, for example as noted above there are also no jury trials in the German system.

Bifurcated system for trying infringement and validity

In China infringement and validity are tried separately by different bodies. Infringement cases are heard by the courts with jurisdiction being determined by the location of the Defendant or the place where infringing activity occurs. Obtaining appropriate jurisdiction can be a major issue in patent infringement litigation in China so as to avoid local protectionism. Most cases are heard in intermediate courts. At the time of writing this article, 71 intermediate courts had jurisdiction to handle patent cases in China.

Invalidation actions are filed to the Patent Review and Adjudication Board ("PRAB") an administrative body which is part of the patent office in Beijing. Appeals from decisions of the PRAB are heard by the courts in Beijing. The criteria for invalidating a patent are similar to those in Western countries with the principle reasons being lack of novelty, inventiveness or practical applicability.

Burden of proof on Plaintiff

The courts place a heavy burden on a Plaintiff to prove its case: documentary evidence is the key evidence. Oral evidence is rarely relied upon as it is considered unreliable. Judgments are usually made based on documentary evidence and oral evidence is given low weight. There is an extremely high burden of proof on the plaintiff and every element of a claim must be proved to that high burden. PRC judges rarely shift the burden or make inferences even if those inferences are logical and reasonable.

Generally, original documentary evidence is required. Documents from overseas need to be notarised and legalised. This can be a time consuming process and evidence must be prepared well in advance.

No discovery

There is no oral or written discovery in China. It is possible to obtain from the court an "evidence preservation order" which requires the Defendant to produce certain documents. There are, however, no effective sanctions for non-compliance. Further more, the burden of proof remains on the Plaintiff to prove its case even if an evidence preservation order is not complied with by the Defendant.

Claim interpretation

Claims should be interpreted in China in a way similar to that provided for in Article 69 of European Patent Convention. Article 56 of the Patent Law provides that "the extent of protection of a patent for an invention shall be determined by the terms of the claims. The description and appended drawings may be used to interpret the claims."

The patent law is silent on key issues related to claim interpretation such as the application of doctrine of equivalents and file wrapper estoppel. Despite the patent law not having provisions dealing with these issues, the Chinese courts have issued interpretations and guidance on the handling of such patent cases.

Article 17 of the Supreme Court Patent Guidelines sets forth the framework for China's doctrine of equivalents approach. Article 17 states:

"This provision of Article 56 of the Patent Law means that the extent of protection of patent right should be determined by the necessary technical features expressly stated in the claims, including the extent as determined by the features equivalent to the necessary technical features.

The equivalent features refer to the features which use substantially the same means, perform substantially the same

function and produce substantially the same as the stated technical features and which can be contemplated by an ordinarily skilled artisan in the art without inventive labor."

The Beijing Higher People's Court Patent Opinion also provides for the doctrine of equivalents to be applied for and file wrapper estoppel. The first case on file wrapper estoppel was decided in 2005 where the court held the Plaintiff could not assert a reading of the patent that was specifically disavowed during prosecution.

Proof of infringement

The result of the above is that every element of infringement must be proved by the Plaintiff in the court to a very high standard. This can require collection of evidence, testing and submission of expert evidence that may not be necessary in the US. Without discovery, matters that could easily be proved by discovery (or inferred from lack of proper discovery) must be proved by the Plaintiff. This can be very difficult.

Conclusion

Despite the difficulties described here, many companies are bringing and winning patent infringement cases in China. In some cases, China is the only place where effective action can be taken where infringing products are being produced but then sold to countries where a company does not have patent protection. A good knowledge of PRC patent law is an essential part of a patent litigator's armory in the new world of globalization.

II. Preparing to Defend Your Patents

In addition to understanding China's patent litigation system, pharmaceutical companies active in China should be prepared to defend their patents. In most patent litigations in China, the Defendant will respond by filing an application to invalidate the asserted patent. Plaintiffs should review the validity of patent candidates they wish to assert prior to bringing any actions.

In addition, companies should also be prepared to defend their patents even if they do not have near term plans to assert them. Companies, including local Chinese companies, are becoming more proactive in bringing direct offensive invalidation actions in China. An example of this is the Topfond case below.

Companies should be conscious that validity standards for pharmaceutical patents in China are high and when patents are challenged during invalidation proceedings, their validity is scrutinized very closely. The best way to prepare to defend against such challenges is to prepare one's patent applications rigorously and thoroughly.

For example, companies should be conscious to:

- provide in your patent specification support for how your claimed invention solves a technical problem or achieves a technical effect;
- provide test data in your patent specification to support your claimed invention; and
- be conscious your patent's claim language matches the language in your specification. This is a particular problem in China due to translation errors.

While China does not have a system of binding precedent, the two case summaries below are presented as examples of how the PRAB and Chinese courts have decided and may decide validity issues.

Henan Topfond Pharmaceutical Co., Ltd. ("Topfond") Application to Invalidate Merck & Co Inc. ("Merck") Chinese Patent Number ZL 94194471.

The Topfond case demonstrates how companies are proactively seeking to invalidate pharmaceutical patents in China and that it is important to provide support in the patent specification for how the claimed invention and features (here 0.05-3.0mg of a chemical component) solve a technical problem or achieves a technical effect.

Topfond, founded in 1969, is a publicly listed Chinese pharmaceutical company which has reported that during the period of from 2000 to 2004 it invested CNY 5 million into developing a drug for treatment of hair loss (the "Drug"). Around the time Topfond was preparing to commercialize the Drug, it became concerned with Merck's invention patent number 94194471 ("the '471 Patent").

In 2005, Topfond applied to invalidate the '471 Patent on its own initiative, not in response to an infringement action by Merck. A Merck prior patent, EP0285382A2 was used as the main prior art reference against the '471 Patent.

The PRAB, in comparing the prior art reference with the '471 Patent determined only two differences existed:

The '471 Patent confines the weight of one key chemical component to 0.05-3.0mg, a version of N-tertbutylcarbamoyl, whereas the prior art reference confines the percentage of that chemical component to 0.10%-1.5% of the total weight of the Drug.

The '471 Patent confines that the Drug be for oral administration, whereas the prior art reference does not confine the way in which the Drug should be administered.

However, regarding those two differences, the PRAB found that:

The selection of the amount of effective components of the medicine is a common technological means used by the technicians in that field, and no beneficial effect on the patent could be identified by limiting the amount of effective components of the medicine to 0.05-3.0mg.

Oral administration is a conventional choice that will not bring any unexpected technical effect on this patent.

Thus, the PRAB decision was that the '471 Patent lacked inventiveness and found the '471 Patent invalid. The case was appealed to the Beijing No.1 Intermediate People's Court and to the Beijing Higher People's Court. Both courts upheld the PRAB's decision.

Jiangsu Hansen Pharmaceutical Co., Ltd ("Hansen") Application to Invalidate Eli Lilly and Company ("Lilly") Chinese Patent Number ZL 90110125.7

The Hansen case is another example of the high standard of validity to which pharmaceutical patents in China are held and how pharmaceutical companies should be conscious that a patent's claim language matches the language in the patent specification.

Hansen, established in 1995, is a Chinese pharmaceutical manufacturer in Jiangsu Province, east China. In 1996, Lilly was granted an invention patent number 90110125.7 ("the '125 Patent") which covered methods for producing Premetrexed, a drug for tumour treatment. As Lilly's competitor, Hansen filed an invalidation action against the '125 Patent in 2005.

During the invalidation proceedings before the PRAB, Lilly amended claims 2 and 3 of the '125 Patent to claim that the R2 chemical group covers a range of carbon atoms from 1-6 (the original claims claimed a range of 1-12). The specification disclosed a range of 1-12. The amendment was challenged for going beyond the original scope of the '125 Patent disclosure. Lilly argued that the disclosure of a range of 1-12

covers a range of 1-6 and thus the amendment did not go beyond the original scope. The PRAB held that although the number range 1-6 falls within the number range 1-12, the endpoint number 6 is not contained in the initial description and the claims. Thus, the PRAB held the amendment went beyond the scope of the disclosure contained in the initial description and the claims and claims 2 and 3 were invalid. The PRAB also decided that claims 1-3 were invalid for lack of inventiveness.

In 2008, the Beijing No. 1 Intermediate People's Court reversed the decision and sent it back to the PRAB to re-hear the entire case. However, in regard to claims 2 and 3 of the patent, the Beijing Court stated that the PRAB was correct in finding that Lilly's claim amendments related to these two claims went beyond the original scope of the '125 Patent disclosure. The case is currently on appeal to the Beijing Higher People's Court.

While the view of the PRAB in this case may be considered conservative, pharmaceutical companies should be conscious that their claim language matches the language in the patent specification so as to avoid this potential pitfall.

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Review of Systemic Anti-infective Consumption in Chinese Hospitals 1H/2008

According to the hospital drug purchase audit of the Chinese Pharmaceutical Association which covers representative hospitals in 22 Chinese cities, total hospital drug purchase by these representative hospitals in the first half of 2008 was CNY 25,465 million, and systemic anti-infectives accounted for 24.85% of total at CNY 6,327 million.

The average annual growth rate of anti-infectives was 18.92% between 2005 and 2008, which is lower than the average growth of hospital drug purchase of 20.21% for the same period.

The following table shows drug consumption of various systemic anti-infective drug purchase by representative hospitals between 2005 and 2008, average growth rates and average share of this class in total drug purchase.

Systemic anti-infective purchase by representative hospitals 2005-2008 CNY Mln

Sub-class	2005	2006	2007	1H/08	+/- %	Share %
Other beta-lactams	3,760	4,015	5,529	3,382	+21.61	59.43
Quinolones	1,104	1,106	1,360	750	+10.75	13.18
Beta-lactams	844	921	1,176	672	+16.81	11.82
Other antibiotics	302	390	550	369	+34.73	6.49
Macrolides & Lincosanlides	757	632	679	363	-1.41	6.38
Aminosides	185	179	236	137	+14.00	2.41
Tetracyclines	11	15	20	11	+24.68	0.19
Chloramphenicols	11	11	12	5	-0.94	0.09
Sulfanilades & TMP	1	1	1	1	+18.25	0.01
Total	6,976	7,269	9,562	5,690	+17.72	100.00

Source: CPA

The leading ten hospital suppliers of systemic anti-infectives are (ranked in the order of their hospital sales): Harbin Pharma Group, Pfizer Dalian Pharma, General Sanyang Pharma, Shanghai New Pioneer Pharma, Yangtze River Pharma, North China Pharma, Guangzhou Baiyunshan Pharma, GSK, Bayer and Shanghai Squibb.

Bayer had the highest growth rate in the first half of 2008 at 70%, while North China Pharma and Guangzhou Baiyunshan Pharma also experience sharp growth of around 50%. Yangtze River Pharma and GSK had the lowest growth during the period with rates lower than 10%.

A total of over 200 systemic anti-infectives are supplied to the representative hospitals in the first half of 2008. All of the top ten systemic anti-infectives are anti-bacteria drugs including seven cephalosporins, two quinolones and one penicillin derivative.

Top 10 systemic anti-infectives by representative hospital purchase value

Sub-class	2005	2006	2007	1H/08	+/- %*
Levo-ofloxacin	551	426	478	251	-3.05
Cefotiam	57	229	370	243	+104.81
Cefuroxime	557	484	509	236	-5.30
Sulbactam Sodium / Cefoperazone Sodium	716	473	449	214	-15.80
Cefminox	81	201	325	204	+71.10
Cefmandole	31	82	234	192	+131.22
Cefepime	113	194	272	183	+47.91
Moxifloxacin	48	123	216	162	+88.99
Piperacillin/Tazobactam	160	224	290	152	+23.78
Cefoperazone/Tazobactam	10	54	214	146	+210.02

Source: CPA Unit: CNY Mln

* Average growth rate between 2005 and 1H/2008

The market share of systemic anti-infectives in total hospital drug sales has been shrinking slowly from 25.66% in 2005 to 24.85% in the first half of 2008. Its market share fell the sharpest in 2006 when the government launched regulatory corrections, but anti-infective drug consumption slowly recovered somewhat as of 2007.

As China's healthcare reform moves forward, the market for systemic anti-infectives is likely to see steady growth as a result of expanding rural, suburban and urban community healthcare markets and increased coverage of Chinese population by basic medical insurance programs and rural cooperative medical care system.

Stop Press

Two drug companies expelled from Beijing for advertising violations

Seven municipal departments of Beijing, including Beijing Municipal Food and Drug Administration, recently issued a statement to expel two drug companies, Shenyang Feilong Pharma and Guiyang Dechangxiang Pharma, from drug advertising, participation in the hospital drug purchase tenders and conducting other relevant businesses in the city.

The two companies were expelled due to their repeated drug advertising violations in the city of the Provisions for Drug Advertising Evaluation.

Beijing Municipal FDA also suspended sales of 11 drugs recently for advertising violations, and requested the local FDAs, where the manufacturers of these products are located, to penalize them. Shenyang Feilong Pharma and Guizhou Dechangxiang Pharma continued their advertising violations even during the period of their sales suspension, and were therefore handed the most severe punishment.

Both companies are manufacturers of formulated traditional Chinese medicines. Shenyang Feilong Pharma was well-known previously for using the Chinese name of Viagra (Wei Ge) as the brand name of its own TCM-based sexual enhancement product, and for its lawsuit against the SFDA over the agency's decision to deem that product to be a "fake drug".

SciClone reports sharp revenue growth in 2008

SciClone Pharmaceuticals, Inc. recently reported that for the year ended December 31, 2008, its product revenues increased by 46% to US$54,108,000, compared with product revenues of US$37,038,000 for the same period of 2007. The increase in 2008 product revenues was primarily attributable to an increase in the quantity of ZADAXIN sold, mainly to China.

Sales and marketing expenses for 2008 were US$17,325,000, compared with US$13,928,000 for the same period of 2007. The increase in sales and marketing expenses in 2008 was primarily due to increases in personnel and promotional activities related to SciClone's expanding sales and marketing efforts for its lead product, ZADAXIN, including those activities in both China and Russia.

For the year ended December 31, 2008, net loss was US$8,348,000 compared with net loss of US$9,948,000 for 2007.

SciClone anticipates 2009 revenues as between US$60 and US$62 million, an increase of approximately 15% over 2008. The company expects its revenue growth to be driven by the sales of ZADAXIN and the introduction in 2009 of DC Bead in China for the treatment of patients with liver cancer.

Stop Press

MOH issues "Provisions for Clinical Application of Medical Technologies"

The Ministry of Health recently issued the "Provisions for Clinical Application of Medical Technologies" which will become effective as of May 1, 2009. The new regulation is an effort by the Chinese government to regulate the clinical use of medical technologies in medical institutions. So far, China has only regulated the clinical applications of certain medical technologies, but the new regulation will set up a classified control system for all such technologies, thus closing up the regulatory vacuum in the past.

The new regulation classifies medical technologies into three categories: 1) Category III medical technologies include those involving major ethical issues, high risks, safety and efficacy under further evaluation, and use of scarce resources; 2) Category II medical technologies cover those with confirmed safety and efficacy but certain ethical issues; and 3) Category I medical technologies are those with secured safety and efficacy under routine administration.

According to the new regulation, the Ministry of Health is responsible for regulating and developing a catalog for Category III medical technologies, while provincial level health departments are responsible for regulating and drawing up a catalog of Category II medical technologies, and medical institutions are responsible for regulating the their own use of Category I medical technologies.

The new regulation requires that category III medical technologies must go through safety evaluation and ethics assessment organized by the Ministry of Health before clinical use. Technical evaluations by third parties are also required prior to clinical use of category II and III medical technologies.

Additionally, medical institutions are required to submit reports on the clinical applications of Category II and III medical technologies within two years of approvals, the health authorities will conduct dynamic audits to determine if such technologies can be allowed for further use.

For Category I medical technologies, they should be self-evaluated by medical institutions before clinical applications or follow relevant rules of the provincial level health departments.

The regulation provides that genetic cloning technologies are not allowed for clinical applications for the time being.

NICPBP and US Pharmacopoeia signs second MOU for collaboration

Invited by Roger Williams, CEO of U.S. Pharmacopoeia (USP), a delegation of China Institute for Control of Pharmaceutical and Biological Products (NICPBP) headed by Li Yunlong, Director of the institute, visited the USP in early March.

Following mutual exchanges and discussions, NICPBP and USP reached agreement over further collaborations between the two organizations, and subsequently signed a memorandum of understanding (MOU).

The MOU covers areas including collaborative setting of standard substances, development and verification of analytical methods and technologies, testing methods and technologies for counterfeit drugs, quality control of biological products, and exchanges between personnel of the two organizations.

China becomes engine for Bayer Schering Pharma's growth in Asia Pacific

Bayer Schering Pharma (BSP), the pharmaceutical arm of Bayer AG, said it expects to see revenue growth between 17% and 19% this year in the Asia-Pacific when it outlined its expansion plans for the region on March 17.

BSP, which aims to double its Asia-Pacific revenue over the next five years, revealed that it achieved 23% revenue growth last year in Asia, the fastest growing region of its pharmaceutical business, driven by growth of more than 50% in China.

Bayer Schering's Asia-Pacific's pharmaceutical operation generated 910 million euros (US$1.18 billion) in sales revenue last year out of Bayer AG's total revenue of 32.9 billion euro globally.

"When it comes to healthcare, especially pharmaceutical business, we are not seeing any impact and we do not expect it to happen this year," Lee told Reuters in an interview. "We are comfortable of high teens (growth), in the 17, 18, 19 percent range," Chris Lee, regional head for BSP Asia Pacific, told Reuters.

As the company expected the pharmaceutical markets in the Asia-Pacific to show the highest growth rates in the future, Bayer Schering Pharma would strengthen its investment in the region with China becoming the growth engine, Lee said.

North Asia represented more than 70% of Bayer Schering's business in the region with China alone having a business share of 48%.

Lee said Bayer Schering plans to invest 22 million euros in a new production plant in China, which will increase its capacity by four times and introduce some 20 products over the next five years. It also plans to increase its workforce in China to 4, 000 by next year from about 3,000 currently.

In addition to increasing the capacity of its production plant in Beijing fourfold, Bayer Schering Pharma announced on February 12 it would establish a global research and development center in China, its fourth in the world, with a total investment of US$129 million over the next five years. The new R&D center in China will also improve the company's ability to develop new products which better meet medical needs of Asian patients.

BSP invests about 15% to 17% of its overall sales in research and development (R&D) annually, and said it will spend more on its clinical trials in the Asia-Pacific.

"Our strategy is to move a greater proportion of clinical trials to the Asia-Pacific to speed up clinical development," said Amar Kureishi, the company's head of medical affairs for the region.

Final healthcare reform plan likely to be released in days

According to authoritative sources, the final healthcare reform plan is likely to be released in the week of March 16 and 22 following more than four months of revision and modifications.

The sources disclosed that more than 130 places in the draft healthcare reform plan were modified with most changes being language revisions to ensure accuracy and clarity. At the same time, a number of macro-level statements were deleted, while some specific operating rules were added.

Importantly, the elements of competition and market mechanism were added to a number of reform components such as public hospital reform, essential drug system, medical insurance administrative system and primary & community healthcare.

A number of disputed major reform measures were revised, and they include policies relating to pricing, procurement, distribution and application of essential drugs; principles for separating government from institutions and for separating hospital management from state ownership in public hospital reform; and inclusion of non-public medical investments in the public hospital reform experiments.

The final plan also added a number of definitions, such as "separated administration of hospital revenues and expenditures", "total sum prepayment", "general practitioner", "separation of hospital management from state ownership", "pharmacy service fee" and "drug sales margin policy", in order to enhance clarity and understanding the healthcare reform plan.

Among the revisions to public hospital reform measures, the definition of "*separating medical institutions from drug sales*" was clarified. The final plan removes the notion of "*separated administration of hospital revenues and expenditures*", but added the statement of "*exploring effective channels to convert public hospital outpatient pharmacies into retail pharmacies*".

However, the final healthcare reform plan does not include specific implementation policies for the public hospital reform except general guiding principles. But it establishes that "*the central government healthcare reform coordination group is responsible for developing principles and policy framework of healthcare reform experiments, and planning, coordinating and guiding such experiments nationwide.*"

For the essential drug system, the final plan replaced the previous model of "*designated manufacturing of essential drugs*" with "*essential drugs will be purchased through public tenders*". In addition, the final plans replaces the former proposition of "*governments sets uniform retail prices of essential drugs*" with "*the government sets retail guidance prices for essential drugs, and, within the frame of guidance prices, the provincial level governments determine the uniform purchase prices of essential drugs in their respective jurisdictions in accordance with purchase tender outcomes.*"

The final healthcare reform plan changes the previous language on the use essential drugs by primary medical institutions with "*urban and rural primary medical institutions should all be equipped and use essential drugs*". The new language clarifies that primary medical institutions are also allowed to use non-essential drugs.

Finally, the plan is expected to officially migrate all university students, who are currently under state free medical care system in name, to the new urban resident basic medical insurance program. Although this means university students will have to pay a small premium for basic medical insurance in future, but they will be subsidized by the government in accordance with existing policies for primary and middle school students.

Revenues and profits of Zhejiang Huahai Pharma rise

Zhejiang Huahai Pharmaceutical Co., Ltd. (SHSE: 600521), a leading Chinese pharmaceutical exporter, posted net profit of roughly CNY 150 million for 2008 in its financial report, rising 13.66% from a year earlier. Operating revenue jumped 13.36% year on year to about CNY 801 million, but total assets dropped 11.29% to CNY 168 million.

This year, Huahai Pharmaceutical will strengthen its business expansion, consolidate its R&D resources, and sharpen the core competitive edge of bulk drugs. Meanwhile, the company will accelerate the construction of its new solid preparation production base and push forward the international projects. It aims to gain sales income of CNY 1 billion in 2009.

Guangdong simplifies drug administrative procedures

In an effort to help relieve the impacts of global financial meltdown on the pharmaceutical industry in Guangdong province, the Guangdong Provincial Food and Drug Administration announced 18 measures to simply drug administrative and approval procedures within the province.

Among all the measures, the Guangdong Provincial FDA initiated, within its power, a new special procedure for innovative drugs under which a "green channel" will be established to accelerate drug registration procedures in the province for new drugs and first-to-file copy drugs.

The agency will also simplify and expedite procedures for various drug administrative matters such as supplemental applications involving address change and API supplier change, reduction of sampling batches for drug registration (under the condition of securing quality), issuance of GMP certifications, and exemption of clinical trials for certain medical devices.

Guangdong province has one of the largest provincial pharmaceutical industries in China. Its total pharmaceutical industry output value last year was CNY 75 billion, ranking No. 3 in the country.

China's first novel quinolones to be approved soon

Antofloxacin hydrochloride, the first novel quinolone drug originated by China independently, is likely to be approved soon, according to Kaixian Chen, the lead scientist for the new drug R&D project under the National 973 Program, on March 13.

Chen said that the new drug has similar efficacy as other floxacin drugs and a longer half life of 21.5 hours in vivo. Compared with other quinolones, antofloxacin has lower cardiac toxicity.

Feature Articles

Analytical Review of Gynecological Infection Market in China

The drug market for gynecological infection in China has been rising rapidly in recent years as a result of growing prevalence and improving living standards. The size of this market is estimated by Southern Medicine Economic Institute (SMEI) under the SFDA to be around CNY7.5 billion in 2007, and the average annual growth of the market was 12.72% between 2005 and 2007.

Prevalence and disease patterns

According to a gynecological health survey by the National Center for Disease Prevention and Control in 2001 covering random samples selected from married women in 100 neighborhoods of 50 Chinese cities, reproductive tract infection is the most common gynecological disease in China. The survey found 83.1% of the Chinese women to suffer from at least one type of reproductive tract infection, 15.1% of them suffer from two types of infections and 1.8% of them suffer from three types of infections at the same time.

Among reproductive tract infections, chronic cervicitis has the highest prevalence at 39.30%, followed by vaginitis at 15.90% and chronic pelvic inflammation at 4.10%.

Prevalence of reproductive tract infections in China

Infection	Prevalence rate
Chronic cervicitis	39.3%
Vaginitis caused by:	
Germs	5.3%
Monilia	4.8%
Old-age	3.2%
Infusorian	2.6%
Total chronic pelvic inflammtions	15.9%
Chronic pelvic inflammation	4.1%

Source: National Center for Disease Prevention and Control

The survey found that prevalence among Chinese females under 30 is 53.3%, that among females aged between 31 and 40 is 48.7%, that among females between 41 and 50 to be 41. 0% and that among females over the age of 51 to be 31.0%.

The survey also found that 27.5% of urban females and 26.6% of rural females with reproductive infection sought treatment.

Consumption patterns

According to SMEI, retail pharmacy is the most dominant sales channel of drugs for reproductive tract infections. The share of retail sales of such products in total was 65.31% in 2007, while that of hospital sales was only 34.69%. The following table shows result of a recent SMEI survey on patient buying habits.

Patient buying habits of gynecological infection drugs

Buying habits	Share (%)
Hospital pharmacy at all times	31%
Retail pharmacy at all times	30%
Started with hospital pharmacy but switched to retail pharmacy	20%
Hospital and retail pharmacies with more purchases at hospitals	8%
Hospital and retail pharmacies with more purchases at hospitals	11%

Source: SMEI

Formulated traditional Chinese medicines (TCMs) dominate the market for gynecological infection drugs. In 2007, Formulated TCMs accounted for 67.06% of the market, while Western medicines represented only 32.94%.

Also topical drugs for external use accounted for 59.56% of the Chinese market for gynecological infection drugs, while other dosage form represented 40.44% in 2007.

Leading products

There are more than ten gynecological infection drug products with over CNY 100 million in annual sales on the Chinese market.

The top four and the top eight gynecological drug products accounted 21.26% and 33.62% respectively in 2007. The following table shows the leading ten gynecological infection drug products by sales in China.

Leading ten drug products for gynecological infection by sales in China

Rank	Product	Manufacturer	Type	Route
1	Fuke Qianjin Tablet	Zhuzhou Qianjin	TCM	Oral
2	Fuyanjie solution	Jiangxi Renhe	TCM	External
3	Jie'eryin solution	Chengdu Enwei	TCM	External
4	Daktarin suppository	XiAn Janssen	WM*	External
5	Ornidazole injection	Nanjing Shenghe	WM*	Injection
6	Kangfute suppository	Sunstone Tangshan	TCM	External
7	Huahong tablet	Guangxi Huahong	TCM	Oral
8	Fuyinjie solution	Guangxi Yuanantang	TCM	External
9	Xiaomi Suppository	Jilin Xiuzheng	TCM	External
10	Kangfuyang capsule	Guizhou Yuancheng	TCM	Oral

Source: SMEI * WM = Western Medicine

Future outlook

With rising prevalence of gynecological infections in China, improved living standards, the demands for gynecological infection drugs is expected to surge.

Growing awareness of female health and self-medication by Chinese women is expected to further boost the retail sales of gynecological infection drug products. On the other hand, community healthcare sector is likely to become the primary force for female health maintenance and promotion under the country's future healthcare system, and thus a new sales channel of rapidly growing importance.

Despite good market prospects, local experts believe that the market competition for gynecological infection drugs is likely to intensify in future. Brand building and detailed market segmentation strategies may be the best defense by existing players.

.... continued from page 28

distribution in Beijing, Shenyang, Wuhan, Chongqing, and extension to other provinces planned.

Services cover prescription over numerous categories and therapies, OTC, import logistics and specialty distribution with specially built, state-of-the-art cold chain facilities and management located in Guangzhou. National exclusive, regional cluster and local direct distribution are available to address principals' different needs and product categories, with dedicated account management teams developing customized solutions for both the wide-ranging portfolios and volume requirements of multinationals and niche product suppliers. Clinical trial and drug study logistics are also provided.

Eric Zwisler, CEO of Zuellig Pharma Asia Pacific, said: "With healthcare reform set to open up new opportunities and extend the market beyond major cities, we are seeking to delayer distribution in China. This will enable principals to get closer to end customers, speed the time to market and optimize distribution costs."

Development platform

A distributor plays a different role in the supply chain from a wholesaler, acting as an extended arm of the principal in the market. A distributor's success is therefore tied in to a principal's success, with interests aligned to a principal's sales and marketing plan and motivation to drive channel and price control in line with the principal's strategy.

"China is a push not a pull market," Mr. Quoc Phong Chau, Business Development Director, Zuellig Pharma China, said. "While the principal creates demand, it is the distributor who actively drives supply so that goods flow down to the end customer. As a market partner, the distributor invests time in getting to know and understand a principal's products and positioning to assist this drive." Advantages include greater inventory control, shorter time to collect accounts receivable and a diminished risk of returns.

In line with this, the Zuellig Pharma China platform takes into account the challenges of moving into low-tier cities, rural markets and the community hospital channel in the new healthcare reform era, as well as major city growth. Remote distribution centers offer last-mile logistic services and direct access to community hospitals; and the company is continuing to invest, improving economies of scale through mergers and acquisitions. While seeking to maximize the percentage of products going directly to hospitals and pharmacies, Zuellig Pharma China also works with a group of carefully selected wholesalers, depending on the therapeutic class with which products will be sold and which defined targeted customers will be reached.

Customized solutions

This flexibility allows Zuellig to build customized distribution solutions for principals that boost efficiency by identifying and implementing the shortest channel route. "The platform we have developed is highly adaptable, allowing us to serve the different needs of principals and rapidly respond to any changes in the China healthcare business environment," Mr. Chau said. "Our comprehensive portfolio ranging from pharmaceutical distribution to vaccines and clinical trial logistics means we can match the extensive portfolios of leading MNCs and also provide the services required by smaller, specialized suppliers."

A regional quality management system operating across all Zuellig Pharma sites provides pan-Asia operation consistency, including rigorous quality control, product integrity and business continuity planning. Redressing is in compliance with GMP.

In addition, Zuellig Pharma China's delayered distribution strategy combined with sophisticated IT systems brings greater transparency to the supply chain. In line with Zuellig Pharma Asia Pacific's regional approach, Zuellig Pharma China has information systems specifically focused on serving the distribution needs of the pharma and healthcare product industry. As a result, principals can keep track of which products are going where down to the final customer level. Meanwhile, the availability of timely information on sales, marketing strategy and inventory creates the opportunity for a pro-active response to market conditions.

Empowering hospitals

As hospitals are evolving along with their services to the general population, so have Zuellig Pharma China's distribution models. With this evolution, many healthcare products, particularly medical devices, need a unique distribution model. Hospital surgeries are frequently complex and need specialized tools for a specific sequence in an operation. As operations are not always executed exactly to plan, the need for tools or device comes apparent only in the surgery. Zuellig Pharma China provides flexibility to hospitals by having everything needed for a particular operation at the time. We work closely with hospitals to prepare for their needs and provide what Zuellig Pharma China calls "Last Mile Logistics" to hospitals. This helps hospitals manage their inventory with less overhead and allows them to concentrate on saving lives and patient care.

Zuellig Pharma China has been engaging local hospitals to increase transparency in their forecasting and internal product flows by helping to source, customize and maintain an internal reporting, analytic and business intelligence system. This system has enabled hospitals to look at their raw data in a new way. By drilling by ward, doctor, and even product level, hospitals are able to see their sales on a daily basis with up-to-date information. With enhanced analytics, hospitals have been able to drive efficiency and superior service for their patients while remaining cost friendly. In helping hospitals with consolidating their data, Zuellig Pharma China has been able to understand the customer better and in turn serve their needs.

Other initiatives for hospitals are also underway such as implementing internal ordering systems and looking at consulting with their operational teams.

Strategic outlook

China is on its way to implementing healthcare reform throughout the entire system. While details are not entirely clear for many of its amendments, Zuellig Pharma is poised for this change with its positioning as it seeks closer relationships with its customers (hospitals, retail pharmacies and clinics) and working as a market partner with manufacturers and suppliers. As the fundamental shift in healthcare management begins in China, Zuellig Pharma China's direct relationship with both parties will help move the industry forward.

"Supply chain management in China needs to be viewed as strategic," said Mr. Eric Zwisler, Chief Executive Officer, Zuellig Pharma Asia Pacific. "Given the importance of the China market to the global healthcare market, principals must be able to effectively address a changing business environment to capitalize on the opportunities that are unfolding".

"A distribution partner who can provide flexible, comprehensive solutions that are tailored to the needs of individual principals and cut through supply chain complexity is the kind of solution provider to meet these needs, today and in the future," he said.

Chinese Pharma Distribution Landscape and Zuellig Pharma's Solutions

*By Elsie Lim, Chief Executive, Zuellig Pharma China * elim@zuelligpharma.com*

As the economic meltdown continues and the world shivers at the prospect of icy business conditions in the year ahead, China stands as a ray of warm hope in many eyes. Growth forecasts for the country hover in the range of 6%-8% in 2009. Although such predictions are lower than recent years, they appear relatively robust amid a global recession. In the country's pharma sector, the outlook is one of change, reform and opportunity for manufacturers to improve their top and bottom line.

Market landscape

China is already among the 10 largest pharmaceutical drug sales markets worldwide, and predicted to grow to the largest by 2025, driven in part by large-scale urbanization. An aging population and rising incomes are other important growth factors. However, China's pharmaceutical market offers tough challenges. The current landscape is characterized by:

- Widespread presence of generics
- Low affordability
- Government price controls and cuts
- A complex regulatory environment
- Little medical insurance coverage in rural areas where the majority of the population lives
- Poised for great change

Multinationals have a strong presence but profits have been limited due to competition from thousands of generic producers and non optimized distribution costs. Thus hospital pharmacy sales have dominated the market to date, with multinationals looking to major hospitals in first-tier cities as their main targets. Smaller players providing advanced and niche products have also found room in the market.

In January 2009, the State Council passed the country's long expected medical reform plan. The policy calls for US$123 billion to be spent by 2011 to set up a universal healthcare system. The new system includes the establishment of a national essential drug system and reform of public hospitals, including funding mechanisms.

The evolving social and healthcare landscape is putting pressure on traditional business models. Pharma companies' drive for cost-efficiency amid a challenging global market environment, is adding to the need for change. These factors are opening up fresh opportunities for distribution partnerships that deliver in terms of business results as well as products.

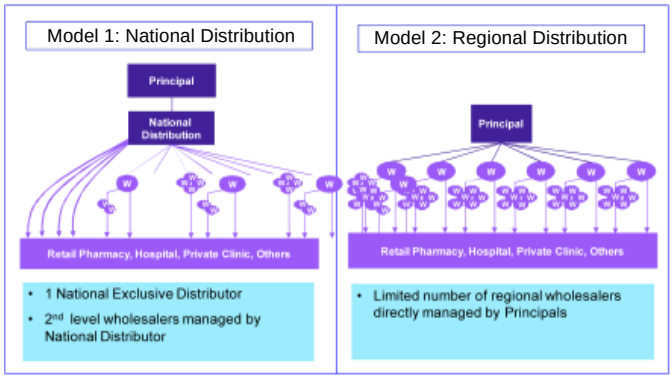
Multi-tiered distribution

Previously in China, suppliers built brands and used direct sales teams to interest major hospitals and pharmacies. Distributors and wholesalers moved products to customers and collected payments. Analysis now suggests this approach needs re-thinking. Economic conditions demand that suppliers receive greater return on sales and marketing costs. At the same time, major hospitals and pharmacies have acquired purchasing power, requiring top service to ensure customer satisfaction. A growing business among smaller customers is adding to the mix.

Such changes can make outsourcing to distributors who provide such services a more efficient option than running an in-house team. However, historically, distribution in China has operated along different lines compared with the international wholesale industry. A trading mindset, high margins, lack of IT and hardware, and no customer service provision are common. Multi-tier distribution structures and a lack of standardization in working practices in different parts of the country further complicate the picture.

In 2000, the country had more than 16,000 wholesalers. Since then consolidation, falling margins and the introduction of a GSP certification requirement have seen figures drop to an estimated 7,000-8,000. Yet the three top wholesalers account for just 15% of distributor channel sales. In the US, the largest wholesalers account for more than 95% of distributor volume.

Figure 1. Dominant distribution models used by MNCs in China



Model in need of a revamp

The predominant distribution model for multinational companies is shown in Figure 01. Such a cumbersome, opaque structure impacts on efficiency and effectiveness. Key issues include credit and liquidity problems which can slow supply to the second level, margin squeeze resulting in the return of basic supply issues to the second level and poor operations at the first level providing little capability to react fast to developing situations. Keeping track of stock and sales data are other major difficulties given the number of distribution layers products need to pass through before reaching the end customer.

As market conditions change, this complex wholesaler model is coming under further pressure. Additional challenges include the capacity to deal with expanding markets and channels; the need to extend coverage to third and fourth tier cities calling for wider geographical operations; the ability to respond to higher regulatory hurdles and a constantly changing environment; how to secure accurate, timely and complete market information; and increasing logistics costs, among others.

Simplifying the chain

Zuellig Pharma China, established in 1993 and the first licensed foreign distributor in the country, is now leading the way forward with a strategic approach that leverages its extensive capabilities in logistics, national and local direct distribution to simplify the distribution channel. The company is the largest pharmaceutical importer in China, with full import and distribution rights. It was the first foreign distributor to join the top 10 distributors and wholesalers in the country.

With more than 15 years' experience in China, Zuellig Pharma has developed extensive coverage across 400 cities though all channels, and through direct distribution and other relationships reaches over 30,000 hospitals, including community hospitals, and 85,000 pharmacies. Zuellig Pharma China has a national hub in Shanghai, with local direct

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