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Editorial

Pharma MNCs elevate China business as tension builds between the country and the U.S.

James J. Shen

It seems every time the United States has a new President, there is bound to be a turbulent period for U.S.-China relations. Obama is no exception to this rule. If the spy plane crash incident over the South China Sea in 2001 led to the U.S.-China tension for George W. Bush, the UN Climate Change Conference Copenhagen in late 2009 probably triggered the latest round of confrontations between the two countries.

Less than a month into the New Year, the U.S. and China have already traded a few rounds of punches. The United States set off the battle by initiating trade sanctions and selling advanced arms to Taiwan, as China quickly responded with stiff warnings and a missile defense system test. While these may resemble the Cold War, they are still within the spectrum of predictable practices by superpowers. What has happened thereafter, however, is very unusual and may have undesirable impacts on future China business of MNCs.

Only days after U.S. Secretary of State Hillary Clinton dined with a handful of high-tech's titans to talk about how the Internet and technologies can intersect with the nation's foreign diplomacy needs, Google fired the first shot at the Chinese government by denouncing China's internet content filtering restrictions and threatening to exit the country if China insisted on enforcing these rules. The U.S. government supported Google's move promptly, followed by some congressional leaders and Western media calling for more Western IT companies to take on the Chinese government.

Google's blunt threat of exit is humiliating, as it is the first time a business entity, regardless how big and influential it is, challenges the Chinese government openly. What is worse, the threat carries some real weight. Google owns 35% of the Chinese search engine market and many are dependent on it for business and social activities. Putting aside Google's business and moral obligations for its loyal Chinese users and customers, the company's abrupt departure, with blames laid on the Chinese government, may incite social unrest and economic instability in the country.

Google's action will become an early warning message and classic lesson to the Chinese government about potential threats that large multinationals could exercise on the Chinese political, social and economic security. Blending business with and politics is poisonous for all and will lead to long term repercussions for foreign businesses in China. It is incredibly foolish, selfish and shortsighted of Google and the U.S. government to employ such a tactic at a time when the Chinese market is finally maturing for most foreign companies to begin harvesting (after enduring many years of diligent cultivation and investment).

Even without this incident, there are already growing debates about the effectiveness of Chinese foreign investment policies, rising concerns over the country's economic security and intensifying pressure to move towards at least some degrees of domestic industry and market protectionism. The Google incident will surely lend more firepower to the neo-conservatives in the country.

Chinese government strengthens macro-economic management of pharmaceutical industry

The Chinese pharmaceutical industry has been among the most privatized sectors in China and entirely state-owned companies now account for only less than 5% of the Chinese pharmaceutical formulation sales.

While this offers enormous commercial opportunities, the local pharmaceutical industry has lost much of the government support and political influence along the reform path. Consequently, the industry is left with little representation in government policy-making and legislation, which will eventually undermining its overall competitiveness and long term sustainable development prospects.

Nevertheless, the strategic importance of a strong local pharmaceutical industry is once again receiving attention of the Chinese government, which is taking steps to boost support to state-invested pharmaceutical enterprises and to prop up its macro-economic role in the sector. The muted agenda is in fact being facilitated by the ongoing healthcare reform and the latest central government reorganization initiative.

After years of minimizing industrial administration of the Chinese pharmaceutical industry, the State Council decided in July 2008 to assign this responsibility to the newly established Ministry of Industry and Information Technology (MIIT). In late December last year, it was further announced that the Ministry of Commerce (MOC) will take over industrial administration of the Chinese pharmaceutical distribution sector. "Industrial administration" encompasses formulation and implementation of relevant industry planning and macroeconomic policies, guidance in the formulation of industrial standards, and supporting industry restructure and consolidation. In reality, the local pharmaceutical industry and the local drug distribution sector will now have two powerful government agencies to back them up and represent their interests in future politics affecting the pharmaceutical market environment.

This also means that the local competitors of MNC pharma companies have just become more powerful and influential politically. The Google incident will undoubtedly strengthen existing arguments and conspiracy theories regarding foreign dominance of the Chinese pharmaceutical market.

Movements of local pharmaceutical firms in the past month

Talking about local competitors, leading Chinese pharma companies such as SinoPharm Group and Shanghai Pharmaceutical Group continued their fast expansion recently with more acquisitions and reorganization deals as well as investment plans for new manufacturing or distribution facilities.

But SinoPharm denied any involvement with or interest in acquiring Germany's Ratiopharm. I guess the company has just too many domestic opportunities to consider overseas expansion at this point, not to mention it has no prior international business experience at all.

Meanwhile, Shanghai Pharmaceutical Group, along with a number of other Chinese companies, reported stunning high profit growth last year. In the backdrop of restored market order and rising demand, successful local companies have been rewarded with high profit growth in the past couple of years. I expect to see additional evidences of this trend as more companies release their financial information for 2009.

On the other hand, some faded stars of the Chinese pharmaceutical industry, such as Harbin Pharmaceutical Group (HPG) and North China Pharmaceutical Group (NCPG), have been regrouping for renewed growth. As one of its primary future growth drivers, HPG announced this month that it is ready to launch a multi-level marketing business for OTC healthcare products under the guidance of a former Amway executive. NCPG, which received a financial booster shot after being reorganized by Jizhong Energy, lately boasted a plan that aims to make itself a leading 30 global pharmaceutical company by 2015. The plan seeks to transform the company into an R&D-based biopharmaceutical formulation company, thus moving away from its traditional emphasis on APIs and antibiotics.

In the interim, Chinese companies are resorting to global licensing as a short cut to expand their new product pipelines, in addition to investing heavily into developing independent innovative research capabilities. This month, more international licensing deals have been announced by leading Chinese firms including Hisun and Beijing Double Crane.

We are also likely to see faster growth from Chinese vaccine makers as venture capital firms are now ready to pour some major investments into the sector this year. "The time is ripe for venture capital to take some action in the sector," said a VC executive. "Nobody likes to come in second place when cashing in on a sector that shows promise," he added. The rise of local vaccine companies will also translate into intensified competition on the Chinese vaccine market in the years to come.

MNCs continue to revise China strategy for better positioning

Compared with the previous month, MNC pharma companies have announced few new Chinese projects or deals lately. Instead, they have been active in reorganization and repositioning for the new year.

Most notably, both Roche and Bayer Healthcare announced corporate elevation of their China business divisions. While Bayer Healthcare China became an independent business unit under direct management of the global headquarters, Roche decided to move its Asia-Pacific headquarters to Shanghai. It remains to be seen if this will become a trend for MNCs, but personally I do expect other MNC companies to follow the suit of Roche and Bayer soon in order to stay competitive.

Meanwhile, Michel Vounatosis, President of MSD China, shocked many by announcing a 52% price reduction of MSD's anti-cholesterol drug Zocor (Simvastatin 20 mg x 7) in line with the Chinese national essential drug pricing policy, thus voluntarily giving up the opportunity to apply for differentiated pricing for the product on the ground of high quality. This move will create significant pressure on other multinational players which compete in the same space, in particular Pfizer. It probably also signals the end of an era during which MNCs depend their success on premium pricing of their off-patent drug products.

I am all thumbs up for MSD China's revolutionary strategy (experiment) to lower price for higher market share. With higher quality, better brand and a price rivaling local generic drug companies, MSD is likely to be awarded with a new market horizon in China. What remains to be seen is whether MSD China is capable of making a profit at this price level and if it has the right commercial organization to take advantage of the vast opportunities in lower tier markets.

I am somewhat surprised that MSD, which is a relatively more conservative company, became the first to revolutionize its China strategy. MNCs must transform their China business strategy to meet with local economic and healthcare realities if they wish to achieve sustainable high growth in the country. It is naive to believe that increased government funding or expanded BMI drug reimbursement coverage can facilitate the kind of growth MNCs wish for in these days.

By our estimate, it is likely that China is already the second largest pharmaceutical market in the world by now if we take into account of traditional Chinese medicines and low tier markets. While MNCs may have already possessed a reasonably high market share in the upscale urban hospital market, their shares in the overall Chinese market are still very low. MNCs have been growing fast in recent years, but they should not forget that their local counterparts have been growing at an even faster in the same period. MNC executives are therefore advised to carefully evaluate the growth model and business strategies of successful local companies, and develop

their own winning formula for the entire Chinese market in the new era.

Moving to a different subject, I noticed recently that Japanese companies are becoming increasingly active in the Chinese pharmaceutical distribution sector. Two more Japanese wholesalers, Alfresa and Medipal, established pharmaceutical distribution joint ventures in China in the past month. So far, with the exception of Alliance Boots and Zuellig, Western drug distribution companies are mostly absent from the Chinese pharmaceutical distribution sector. Japanese companies, however, have forged a rising number of low profile deals. Earlier reports suggest that Japanese pharma distributors including Mediceo Paltac, Toho, Miyakoshi, Itochu and Suzuken have established presence in China mostly through joint ventures with Chinese pharmaceutical distribution majors like SinoPharm, Shanghai Pharma and Jointown.

There are also some major developments on the generic drug side lately. Ranbaxy announced suddenly at the end of 2009 the decision to sell its majority stake in Guangzhou Ranbaxy, one of the very few foreign generic drug companies and a flagship of Indian companies in China, to a state-owned Chinese conglomerate which has little pharma presence. Although the company insists it is not exiting China, in reality attempts to sell imported generic drugs to China offer little prospect. Ranbaxy's move is understandable as business has never been easy for foreign generic drug makers in China. Nevertheless, Ranbaxy had held out in China since 1993 and it is a pity to leave at a time when the end of the tunnel is so near, given the ongoing healthcare reform is more likely to benefit generic drug companies substantially.

On the other hand, Alvogen, a US-based generic drug company led by ex-Actavis chief executive Robert Wessman, entered China in high profile late last year. It announced a plan to invest CNY 200 to 350 million and to become one of the strongest pharmaceuticals companies in China within the next five years. "It is our vision to build a leaner and more flexible multinational operation that overcomes the challenges of the traditional generics business model," said the company's CEO. The Chinese generic drug market is a tough nut to crack and I definitely look forward to learning more about the company's new magical approach.

On the drug regulatory front

In recent years, almost not a month has ever passed without a new pharmaceutical regulation issued, and the past month happened to be one of the very few exceptions. Bingo!

But don't sit back and put up your feet just yet - the SFDA indicated lately it is set to issue the new Chinese GMP regulations in the first quarter and the elevated requirements of the new GMP will likely force at least 500 small enterprises out. Additionally, the agency estimated that only the hardware portion of the compliance costs by the pharma industry will reach between CNY 200 billion and CNY 300 billion.

Well, the SFDA will definitely be a step closer to the goal of "lightening" its workload through minimizing the number of companies it has to regulate. While it is quite convenient for Mandarins of the agency to discount the misery of those small potatoes, who the hack is going to pay for the astronomical compliance costs of the new regulation? If the NDRC does not raise drug prices, we are likely to see profitability of the pharma industry heading south again, and in a big way.

Some Mandarins are desperate to contain the prevalent drug safety problems mostly for the sake of their "wusha" hats, but it is brainless to believe that the problems can be resolved through raising standards. It's obvious that the rampant drug safety hazards at present are mostly not caused by the existing GMP standards, but rather the lack of regulatory enforcements by authorities and opportunistic non-compliance of the existing standards. Higher standards can only raise costs and slay small players, but they will not improve compliance.

Most importantly, the massive compliance costs and sharply-increased future production costs will create disturbing financial impacts on the existing healthcare reform and the state basic medical insurance system.

On the brighter side of things, the drug regulatory agencies of China, Japan, and Korea got together recently to discuss clinical data sharing under a joint working group mechanism. If the scheme turns out to be successful, it may lead to more talks on regional harmonization of drug regulations in East Asia.

Additionally, the Center for Drug Evaluation (CDE) under the SFDA recently disclosed that it is building its platform of technical guidelines for drug registration on the basis of translated European, U.S. and WHO technical guidelines.

Healthcare reform moves forward on different fronts

Despite more information leaks from the MoHRSS over the negotiation mechanism under the NDRL in the past month, the Ministry has yet to issue an official rule for the process. According to what's known to us so far, all drugs to be included in the first round of negotiation are truly innovative medicines from MNCs. There is no doubt, however, the mechanism will be extended to local new drugs and even to branded generics at some point in future. What should be noted is that the negotiation will not necessarily emphasize price only, instead the bargaining will involve more diverse aspects covering price, quality & efficacy, sales volume and more. Besides, I am quite impressed that the MoHRSS has pledged to ensure transparency and fairness of the process with relevant safeguarding measures from the beginning.

Meanwhile, Ministry of Health (MOH) has recently been on the hot seat for delays in its reform policy introductions. The Ministry failed again to deliver the Part II of the National Essential Drug List (NEDL) which is to be implemented in public hospitals. There has been no indication from the MOH as to when the document will be introduced, but an official of the Ministry said it is still under research.

A number of impatient Chinese media published reports cited inside sources who claimed that the Ministry's attempts to develop the public hospital reform plan had stalled. Senior health officials rushed to deny these rumors and disclosed that the final draft of the public hospital reform plan was already in the hands of the State Council for final approval.

But sources close to the matter suggest that the reform plan under review is again likely to be a document with many vague principles rather than a clear roadmap. There are still many uncertainties over the reform of financial mechanisms of public hospital, which is the center of the entire public hospital reform. Even MOH party boss Zhang Mao admitted the reform of public hospitals financing is still in the exploratory stage.

Zhang revealed at a recent MOH conference that the real sticky issue of the public hospital reform is money, without which the reform can not move forward. He hinted that the existing low level of premium funding from the basic medical insurance programs and the government's pledge of CNY 850 billion healthcare reform budget for the next three years will not be

sufficient to ensure the success of the public hospital reform.

Basically, I think the MOH is concerned if central and local government funding and additional revenue sources will be enough to financially support its public hospitals after their drug sales profits are cut off. It is an intricate issue for the MOH because it does not have much influence over the central government's wallet and local governments are even less dependable. Despite these challenges and uncertainties, I still believe the public hospital reform will move forward soon even with a set of broad principles and many unknowns. In fact, some of the provinces are already moving on this front ¡- so the public hospital reform may begin even earlier than expected in at least some areas.

Albeit its delays on other fronts, the MOH made progress on some fronts including introduction of the clinical guidelines and drug formulary for national essential drugs (primary healthcare part), which are designed to guide and streamline clinical applications of essential drugs. In addition, the Ministry is pushing forward the clinical pathway management experiment, calling it one of the core components of the public hospital reform and an effective measure to improve medical service quality and management. Indeed, this experiment may eventually lead to major changes in how healthcare expenditures will be reimbursed and become a key cost containment measure.

Finally, local healthcare reform implementations went ahead in the past month with many provinces and autonomous regions launching their respective implementation packages and local essential drug lists. The local implementation plans vary in their emphasis according to local realities, but it is notable that some local governments included the public hospital reform experiment in their plans including phased introduction of zero drug sales margin policy starting from this year.

In close ....

This time last year, we were bewildered about the direction of the Chinese healthcare reform, while businesses were pounded by the raging financial crisis. A year later, the healthcare reform has initiated with better visions forward and the global pharmaceutical industry has promptly restructured to meet challenges and opportunities of our time.

In 2010, however, we will be confronted with the public hospital reform experiment which is likely to be the most virulent reform component of all. Notwithstanding potential risks and poor visibility, we shouldn't be overanxious - afterall, all of the Chinese reforms were achieved through muddled water instead of well-planned roadmaps.

Nevertheless, turbulences will be ahead, especially for pharmaceutical companies - so be ready and be flexible.

The Chinese New Year is approaching again. As in previous years, I strongly caution business leaders of the pharmaceutical industry in China to treasure your corporate images and avoid high profile luxury activities for employees or executives. While profitability in China is improving, let's remember profits are made in the name of better medicines.

To all of our readers: ***Happy Chinese New Year of Tiger and 恭 喜 发 财!***

News in Focus

More details emerge on the negotiation mechanism of the NDRL

More than ten patented innovative medicines will become the first group of products participating in the newly-created negotiation process for inclusion in the latest edition of the National Drug Reimbursement List (NDRL) under the Basic Medical Insurance (BMI), Occupational Injury Insurance and Maternity Insurance Programs, according to Dong Chaohui, Deputy Director of the Medical Insurance Research Office of the Social Security Research Institute under the Ministry of Human Resources and Social Security (MoHRSS), at a recent industry conference. All of these innovative medicines are from MNC pharma companies.

According to Dong, the negotiation mechanism will be open to only a small number of expensive and highly innovative drugs in 2010. The negotiation focuses on prices, volumes and reimbursement ratios, he said.

However, sources suggest that the future outcomes of the negotiation mechanism can be much more diverse than just price cuts. For example, the price reductions or rebates can be linked with sales volume and therapeutic efficacy of the drugs.

In order to create a fair environment for negotiation, relevant supervision and coordination mechanisms will be established for the negotiation process to avoid dominance by either the supply or the demand side, Dong disclosed. These mechanisms will facilitate relevant evidence collections and appraisals as well as pharmaco-economic evaluations, and will also ensure transparency and fairness of the negotiation.

A source close to the MoHRSS said the ministry had already sought comments from pharmaceutical companies at a close-door meeting hosted by the Chinese Pharmaceutical Industry Association (CPIA) and subsequently finalized relevant rules and principles for the negotiation mechanism.

The purposes of the negotiation mechanism are to: 1) reduce excessively high prices of some drugs, and 2) allow drugs with exceptional high therapeutic efficacy but very high prices to enter the NDRL, Dong told member companies of the CPIA at the meeting. The mechanism will allow manufacturers to exchange lower prices with higher sales, while the BMI participants will benefit from improved access to new and innovative drugs.

Dong revealed that a qualified drug for the negotiation mechanism should meet the following four criteria: 1) it should be a patented or original drug which is exclusively supplied; 2) its price is either too high or too low for inclusion in the NDRL; 3) its therapeutic efficacy is certain with obvious clinical value; and 4) it is not yet in the NDRL and the NDRL inclusion (following the price reduction) can assist its supplier improve sales.

MNC pharma companies are reported to have responded actively to the negotiation mechanism and a number of their drugs have been named by the Chinese press to be the possible candidates for negotiation. They include AstraZeneca's Iressa, Roche's Tarceva, Merck Serono's Erbitux and Pfizer's Sutent. But compared with 51 innovative medicines with administrative protection in China and more new drugs with Chinese patents, the current number of drugs participating in the negotiation mechanism seems small. Many foreign companies are still watching the development cautiously and

they are concerned about fairness of the negotiation process, said a MNC pharma executive who does not want to be named.

It is reported by the Chinese press that a few local companies sought for participation in the negotiation mechanism in the first round, but their products failed to meet the criteria set by the MoHRSS. But the door of the negotiation mechanism will not be closed to local companies for long, according to a source close to the matter, and the process is likely to be extended to local new drugs and even generic drugs in future.

Public hospital reform "basically" ready and pending State Council approval

Deng Haihua, spokesman of the Ministry of Health, denied on January 12 that the public hospital reform is stalled as reported by some earlier Chinese press reports. According to Deng, the delayed release of the reform plan is due to the high complexity and wide-ranging impacts of the public hospital reform, which is a core component of the ongoing healthcare reform.

Deng disclosed that the fifth meeting of the State Council's Leaders Group for Deepening Pharmaceutical and Health System Reform, which was held on December 22, 2009 and chaired by Vice Premier Li Keqiang, already reviewed and approved the final draft of the public hospital reform plan and a list of trial cities.

He also said that the final draft of the public hospital reform plan had already been submitted to the State Council for final approval.

Meanwhile, the Ministry of Health hosted a national conference for clinical pathway management experiment on January 8. Vice Minister of Health Ma Xiaowei told the conference that clinical pathway management is one of the core components of the public hospital reform and it is an effective measure to improve medical service quality and management as shown in international practices and domestic trials.

Through clinical pathway management, he said, medical service practices will become better regulated, streamlined and more transparent.

The Work Plan for Clinical Pathway Management Trials was issued at the conference.

TCM hospitals may spearhead public hospital reform

Zhang Mao, Party Secretary of the Ministry of Health (MOH), reinstated on January 14 at the 2010 Work Conference of the State Administration of Traditional Chinese Medicine (SATCM) that "the public hospital reform is not stalled" and the Executive Committee of the State Council will review the public hospital reform plan soon.

Nevertheless, the MOH has so far avoided commenting specifically on its reform plan for the public hospital financing mechanism, which is in the center of the public hospital reform.

"The reform of 'financing public hospitals with drug sales' is still in the exploratory stage", Zhang told the conference.

"Despite coverage of 1.2 billion people by rural cooperative medical scheme and urban basic medical insurance programs, 100 million Chinese are still not covered by any medical insurance. Additionally, the low insurance premium funding has limited the progress of public hospital reform," said Zhang, who predicted that the overall government investment into healthcare reform in the first three years will definitely exceed the planned CNY 850 billion.

Meanwhile, the central government's healthcare reform plan requires the essential drug system to be fully implemented in all primary healthcare institutions before the end of 2011 and gradually implemented in public hospitals. Main components of the essential drug system include 1) central purchase and distribution of essential drugs; and 2) zero margin on essential drug sales.

Hence government subsidy and compensation of medical institutions are quickly becoming the key to implementation of the national essential drug system. Most of the government financing is expected to come from local governments.

In regions where local economies are well-developed, such as Beijing, Shanghai and most coastal provinces, government funding is more readily available and essential drug system implementation is expected to progress as planned. But local government financial support may become a issue to essential drug system implementation in many less-developed regions.

In the meantime, Vice Health Minister Wang Qiang told the Chinese press that the recent experiments of hospital financial mechanism reform in Beijing's traditional Chinese medicine hospitals are progressing well.

In May 2009, the State Council announced a policy to support the development of traditional Chinese medicine (TCM) and committed CNY 4.7 billion to facilitate it.

Chen Xin, a local health official in Beijing, said that it is easier for the Chinese government to support TCM hospitals financially because there are relatively few such hospitals and their expenditures are also lower than other hospitals on average. Thus, the successful reform experiences of TCM hospitals may become good references for the public hospital reform.

The MOH has specifically required SATCM and local TCM authorities to include TCM institutions in the public hospital reform experiment, hence the sector may even turn out to spearhead the trial.

Traditional Chinese medicines represent one third of the national essential drugs for primary healthcare institutions.

The Market

VCs eye potential growth of the Chinese vaccine market

China's vaccine sector will grow 25% annually, according to a report from Zero2IPO, a Chinese venture-capital firm. By 2012, the size of the market will reach CNY 8 billion, the report said.

Attracted by the growing vaccine market, "investors from home and abroad will be piling into China", said Zheng Yufen, senior manager for healthcare at the investment banking division of Zero2IPO.

The local vaccine market has enjoyed strong growth, but vaccine sales accounted for only less than 1% of the nation's healthcare industry, according to figures from CITIC Securities. "That number is comparatively low considering China's large

population base," said Zheng.

Ongoing healthcare reform is giving the vaccine sector a boost because the Chinese government is expected to spend CNY 26 billion on improving public health services before the end of 2011.

During the past year investors were researching the vaccine market, waiting for the opportune time to enter. "The time is ripe for venture capital to take some action in the sector," said a venture capital industry insider surnamed Wang. During the recent three years, Wang's firm has been in contact with five vaccine companies, but no deals have been signed yet.

"There is strong possibility that we will make some investments this year, the vaccine sector is now one of the few key areas that we are eyeing the most," he said.

Several other venture capital companies also have the same idea. Last year, IDG established a healthcare team to study the industry for potential investment targets.

According to Zero2IPO, the gross profit rate for vaccine companies on average is 70%. But challenges do exist. "Compared with their foreign counterparts, Chinese vaccine makers lag behind in innovation and management," Wang said.

Nationwide, China has over 40 vaccine manufacturers. Other than State-owned companies like Shanghai-listed Tiantan Biological Products and US-listed Sinovac Biotech, many of China's vaccine makers are private and still small in size. "Money is their biggest concern when they plan to expand," said Zheng.

In 2009, some multinational pharmaceutical firms entered the vaccine sector through mergers and acquisitions. In late 2009, Novartis International AG, the world's sixth largest pharmaceutical company, agreed to acquire an 85% stake in a Zhejiang-based private vaccine producer.

Last year, GlaxoSmithKline (GSK), the world's leading vaccine producer, wrapped up two joint venture deals in China to establish vaccine manufacturing joint ventures with two local firms committed to researching and developing vaccines in various categories.

TCM for A/H1N1 flu may present challenge to Tamiflu and Relenza

A Chinese herbal medication "*Jin Hua Qing Gan Fang*" was found to be effective in treating A/H1N1 flu patients after seven months of scientific and clinical studies.

"It can shorten patients' fever period and improve their respiratory systems. Doctors have found no negative effects on patients who were treated in this way," said Wang Chen, president of Beijing's Chaoyang Hospital. "It is also very cheap, only about a quarter of the cost of Tamiflu," he said at a press conference held by the Beijing Municipal Government.

The medicine is reported to reduce the fever time of A/H1N1 patients to 16 hours (from 26 hours) and its respiratory system symptom improvement rate is 95.1%. Additionally, the use of antibiotics in such patients can be reduced to 9.7% (from 34.0%).

Over the past seven months, more than 120 medical specialists, led by academicians Wang Yongyan and Li Lianda from the Chinese Academy of Engineering, had participated in the research, Zhao Jing, director of the Beijing Municipal Administration of Traditional Chinese Medicine, said at the press conference. The municipal government earmarked CNY 10 million (US$1.47 million) for the project, she said.

"*Jin Hua Qing Gan Fang*" was picked from among more than 100 classic anti-flu prescriptions based on traditional Chinese herbal medicine. "Scientists proved its effectiveness through medical experiments on more than 4,000 mice and clinical studies on 410 patients with slight A/H1N1 flu syndrome," according to local press reports. 11 hospitals nationwide, including Chaoyang Hospital and Ditan Hospital in Beijing, had conducted clinical studies on "Jin Hua" and gave positive assessments.

Worldwide patents for "*Jin Hua Qing Gan Fang*" are being applied through the Chinese Patent Office.

Dr. Cris Tunon, senior program management officer at the WHO Representative Office in China, said last week that the "WHO welcomes the clinical results," as the TCM offered a low-cost alternative treatment of A/H1N1 flu.

The Chinese A/H1N1 flu market is estimated to be around CNY 10 billion which is presently composed of mostly government purchases of Tamiflu (oseltamivir phosphate) and other antiviral Western medicines.

It is expected that "*Jin Hua Qing Gan Fang*" will be approved as a hospital formulation in January 2010 and thereafter the Beijing Municipal Government plans to spend CNY 70 million to purchase the medicine for 2 million residents.

As "*Jin Hua Qing Gan Fang*" was developed by many Chinese experts from different companies or organization, the manufacturing and marketing rights of the product will be determined by the Chinese government. Leading TCM companies like Beijing Tongrentang Pharma and Guangzhou Baiyunshan Pharma are among the likely contenders.

If proven to be successful on the market, "*Jin Hua Qing Gan Fang*" is likely to challenge the existing global A/H1N1 market landscape and present market threats to Roche's Tamiflu and GSK's Relenza, given its low treatment cost of CNY 80 compared with that of Tamiflu at CNY 200 to 300. In addition, the medicine is reported to be more effective in inhibiting A/H1N1 virus and has better drug tolerance.

However, some experts point out that large scale commercialization of the medicine will be unrealistic given the fact that the product will only be approved as a hospital formulation, rather than a new drug.

A spokesperson of Roche told the Chinese press that it is too early to offer any assessment on the potential market threat of that "Jin Hua Qing Gan Fang" may present to Tamiflu, which is currently licensed to two local pharmaceutical companies in China, Shanghai Pharmaceutical Group and HEC Group. Roche said it is willing to negotiate with other Chinese companies which are interested in licensing Tamiflu.

Industry News

MOC takes over industry administration of Chinese pharma distribution sector

The Ministry of Commerce (MOC) and the SFDA jointly issued a new document, *Notice on Strengthening Industry Administration of Pharmaceutical Distribution*, on December 25, 2009.

The document provides that the commerce authority is responsible for industry administration of the pharmaceutical

distribution sector. The move is supported by the State Council's Leaders Group for Deepening Pharmaceutical and Health System Reform and reinforced by inter-agency agreements.

The Chinese pharmaceutical distribution and manufacturing sectors have been under the administration of a single central government agency since the days of the State Pharmaceutical Administration of China (SPAC). When the SFDA was formed on the basis of SPAC to concentrate on the regulation of the pharmaceutical industry, industry administration of the Chinese pharmaceutical distribution and manufacturing sectors was moved to the State Economic and Trade Commission, which later was restructured into the National Development and Reform Commission (NDRC).

Following the recent administrative shifts, the industry administration of the Chinese pharmaceutical distribution and manufacturing sectors will be separated from the Ministry of Industry and IT assuming industry administration of the pharmaceutical manufacturing sector and the MOC taking over industry administration of the pharmaceutical distribution sector from the NDRC. The move is interpreted by Chinese experts as an attempt by the Chinese government to strengthen administration of the drug distribution sector.

According to the Notice, the SFDA will continue to be responsible for regulation of the Chinese pharmaceutical distribution sector including licensing of pharmaceutical distributors, developing and implementing quality control regulations and punishing distributors for violations.

The MOC, however, will be responsible for formulating industry development plans of the Chinese pharmaceutical distribution sector, introducing relevant industry standards and policies, reforming and modernizing the sector's structure and organization, and assisting the implementation of national essential drug policies.

As the ministry currently does not have a special department for the pharmaceutical distribution sector, its Market Order Department is expected to assume the responsibility for now. In the meantime, the lack of experience and expertise in the pharmaceutical distribution sector is a major concern to both the MOC itself and the industry.

Following release of the Notice, the MOC has hosted a series of symposiums to seek comments on the pharmaceutical distribution sector from drug distribution companies and industry associations. It has also sent out an investigation team to Anhui province for a field survey of the pharma distribution business.

The response of the industry towards this new administrative shift is cautiously positive. Major distributors are generally happy with the hope that their industrial interests are now represented by a powerful ministry. Industrial administration and representation of the sector was almost non-existent in the past five years, a leading executive commented.

Nevertheless, specific impacts of this new development on the sector are yet to be determined as details of the relevant policies are not available so far, another senior executive said.

Meanwhile, the MOC officially initiated an "early warning mechanism for damages to the pharmaceutical industry". Under the mechanism, the MOC will monitor pharmaceutical industry operations, market environmental changes and company moves. The initial batch of products to be monitored includes 32 Western medicine formulations and medical devices.

According to the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCIEMH), one third of the Chinese pharmaceutical companies are foreign-invested to some extent. The import of Western medicines rose 23% and that of medical devices grew 17% in the first 11 months of 2009. In the interim, Chinese exports of medicines and health products were frequently harmed by foreign anti-dumping investigations and trade barriers. CCCIEMH believes that the MOC's early warning mechanism will help improve market intelligence and competitiveness for Chinese pharma enterprises.

The Chinese drug distribution sector currently includes more than 13,000 pharmaceutical wholesalers and over 360,000 drug retailers with millions of employees. Total pharmaceutical distributor sales were CNY 470 billion in 2008.

Local company news

SinoPharm denies bid for Ratiopharm

In early December, Dow Jones Newswires cited people familiar with the situation as saying that China's Sinopharm Group, China's largest pharmaceutical distributor, is among the leading bidders for German generic drug company Ratiopharm.

But Sinopharm Group stated on December 24 that it didn't bid for Ratiopharm Group. A Sinopharm spokeswoman denied the report but declined to give further comment.

Fosun Pharma to raise CNY 635 million for new projects

Fosun Pharmaceutical announced that it would make a private offering to raise no more than CNY 635 million from no more than ten institutional investors including parent company Fosun International.

The funds raised, after deducting expenditures, will be used to fund three new projects including the recombinant human insulin industrialization project, the Artesunate hi-tech industrialization project and the in-vitro diagnosis manufacturing facility. The proposed investments into the three projects are CNY 371 million, CNY 190 million and CNY 74 million respectively.

Direct-sales to become a new growth area for Harbin Pharma

With CNY 300 million as its initial investment, Harbin Pharmaceutical Group, a leading OTC pharmaceutical player in China, announced that it plans to develop its direct sales (or multi-level marketing) of OTC drug & healthcare products into a CNY 10 billion business in the next eight to ten years.

Since Harbin Pharma met its goal of achieving CNY 10 billion sales in 2006, its management had been under pressure to deliver continued high growth. Following thorough research, the company identified biotech, vaccines and direct sales to be the three future growth areas for the company.

Harbin Pharma applied for a "direct sales" license in August 2006 and became the first pharmaceutical company that was issued the license in November 2008. It spent the following year developing business plans for direct sales.

Harbin Pharma also hired former Amway executive and well-known direct sales operative Zheng Fengqiang as its chief advisor for direct sales business.

The company will aim at long term growth in the area and is

prepared not to make any profits in the next three years, according to Zheng.

Jointown lays foundation for its distribution center in Shanghai

Shanghai Jointown Pharmaceutical Ltd., a subsidiary of Jointown Group, recently laid foundation for a modern pharmaceutical logistic and distribution center in Shanghai's Qingpu Industrial Park.

Total investment of the center is CNY 300 million and it is expected to be completed by 2011. The premise occupies a land of 16 acres and the total building area of phase I will be 56,464 square meters. The center can store 600,000 cases of drugs with daily processing capacity of 80,000 cases. Following its completion, the center will be the largest of its kind in Asia and the most advanced in China, according to local press reports.

In the past eight years, Jointown has invested in the building of 14 modern pharmaceutical logistic and distribution centers nationwide.

Jointown Group's sales is expected to have reached CNY 22 billion in 2009, trailing only SinoPharm and Shanghai Pharmaceutical. Although Jointown's core business has been centered on drug distribution to the retail pharmacy, community healthcare and rural healthcare sectors, it has been pushing to expand in the hospital sector recently.

Neptune Group to invest CNY 1 billion for new projects in Henan province

Shenzhen-based Neptune Group recently signed an agreement with the government of Heze city, Henan province to invest in the city a total of CNY 1 billion into four major projects in the areas of pharmaceutical R&D, manufacturing and distribution.

As a part of the deal, Yinhe Neptune Pharmaceutical Logistics, a subsidiary of Neptune Group and a leading regional pharmaceutical distributor covering Shandong, Zhejiang and Henan provinces, will build a large scale pharmaceutical distribution and logistics center in Heze city to strengthen its capabilities in the province and integrate its supplier and manufacturing resources. In addition, the company will also assist sister company Nepstar, one of the largest Chinese retail pharmacy chains, in entering the Henan market.

Tianjin Pharmaceutical Group fails to close merger talk with Dongsheng Yinhua

Tianjin Pharmaceutical Group Ltd. (TPGL), which controls all state-owned pharmaceutical enterprises in Tianjin, is the fourth largest state-owned pharmaceutical conglomerate in China following SinoPharm Group, Shanghai Pharmaceutical Group and Beijing Pharmaceutical Group, all of which have been expanding rapidly through restructures and acquisitions.

The company has been under pressure to expand faster and was in acquisition talks with Dongsheng Yinghua Pharmaceutical Group (DYPG) to acquire 51% of the latter. TPGL already completed relevant due diligence of DYPG's assets and finance in mid-2009.

DYPG is the largest drug distributor in Hebei province and was ranked the 17th largest Chinese pharmaceutical distributor with CNY 3.7 billion sales in 2008. It is a private enterprise and is 100% controlled by Wu Guicun Family.

However, a senior executive of TPGL recently revealed to the Chinese press that the two parties failed to reach an agreement over the price and the deal is now halted.

Earlier, China General Technology Group (Genertec), another major Chinese conglomerate with substantial pharmaceutical business, also approached DYPG for acquisition. Its offer was turned down by DYPG due to price as well.

A source close to DYPG said that the company, despite being a leading pharmaceutical distributor in North China, is now facing significant pressure from extensive business transformations brought by the ongoing healthcare reform. Additionally, it is confronted with rising competitive pressures from SinoPharm and TPGL which are rapidly expanding in Hebei province.

With TPGL failing to close the deal, it remains to be seen if other conglomerates, such as SinoPharm, will move in on the opportunity.

Shanghai Pharmaceutical Group enters into multiple strategic alliances

Shanghai Pharmaceutical Group (SPG), which is now in its final stage of restructure and merger with Shanghai Industrial Investment Corporation (SIIC)'s pharmaceutical business, announced on January 12 that it had signed seven new business deals.

The most notable of all its deals is the alliance agreement with Bailian Group, which owns Shanghai No.1 Pharmaceutical Co. Ltd. (S1PC). Bailian Group is a sister company of SPG under the common ownership of Shanghai Government. S1PC is a leading pharmaceutical distributor in Shanghai with 101 retail pharmacy outlets.

SPG and Bailian Group agreed to share resources in areas including retailing, supply chain & logistics operations and information systems. They also agreed to give each other the priority right to acquire one another's non-core assets.

The alliance has given rise to speculations that Shanghai Government is likely to merge S1PC into SPG soon, as this matches the current government policy for state-owned conglomerates to minimize non-core assets. But Bailian Group came out quickly to deny the speculation.

S1PC is a SHSE-listed public company which generates most of its revenues from pharmaceutical retailing in Shanghai. Its total revenue was CNY 280 million in 2008.

By comparison, SPG's pharmaceutical retailing business, which includes three retail pharmacy chains with 1,130 retail pharmacy outlets nationwide including 578 stores in Shanghai, is much bigger.

SPC's latest deals also include acquisitions of four pharmaceutical distributors outside Shanghai including Guangzhou Zhongshan Pharmaceutical Ltd., Shandong Shanglian Biochemical Pharmaceutical Ltd. and Changzhou Yabang Group. These acquisitions will facilitate SPG's business expansion outside Shanghai.

According to the company, it will obtain a total of CNY 5 billion in loans from a consortium of banks including China Construction Bank, Pudong Development Bank and Minsheng Bank to finance the construction of its central manufacturing site and acquisitions. It expects the new acquisitions to contribute additional revenues of CNY 5 billion in 2010.

Profits rose sharply for three publicly-listed subsidiaries of Shanghai

Shanghai Pharmaceutical Group (SPG) reported on January 15 that its three publicly-listed subsidiaries, Shanghai Pharmaceutical Co. Ltd. (SPCL), Shanghai Zhongxi Pharmaceutical Co. Ltd. and SIIC Pharmaceutical Co. Ltd., achieved sharp profit growth in 2009.

2009 net profits of both Shanghai Pharmaceutical Co. Ltd. and SIIC Pharmaceutical Co. Ltd. are expected to have grown more than 100%, while that of Shanghai Zhongxi Pharmaceutical Co. Ltd. is anticipated to have jumped 660%. The net profit of SPCL is expected to have reached CNY 82 million last year.

SPG anticipates its overall sales revenues to have grown 17%, its operating profits to have risen over 400% and its net profits to have surged more than 250% in 2009, thus completely reversing its business stagnancy in the previous ten years.

SPG hopes to gain approval of the China Securities Exchange Commission and complete the restructure before the Chinese New Year on February 14.

Subsequently, both Shanghai Zhongxi Pharmaceutical Co. Ltd. and SIIC Pharmaceutical Co. Ltd. will be merged into SPCL, which will be the only remaining publicly-listed subsidiary of SPG, according to the company's restructure plan.

After the restructure, SPG will be controlled by SIIC and become the second largest state-owned pharmaceutical conglomerate after SinoPharm.

Hisun licenses tumor imaging technology from RPCI

The Technology Transfer Office of Roswell Park Cancer Institute (RPCI) announced it had signed a licensing agreement with Zhejiang Hisun Pharmaceutical Co. Ltd., for tumor imaging technology developed by RPCI researcher Dr. Ravindra Pandey.

Zhejiang Hisun Pharmaceutical is a leading producer and exporter of oncology bulk drugs and it is working to establish itself also in the pharmaceutical formulation sector.

Hua Bai, President and Chief Executive Officer of Zhejiang Hisun commented, "The license for tumor imaging shows it has potential as an anticancer treatment agent. We believe a drug with these properties would be extremely valuable for patients in China. It may play a significant role in improving treatment options for people with cancer, and will greatly enrich Zhejiang Hisun's growing oncology drug pipeline."

Beijing Double Crane signs LOI for licensing of a DPP-IV inhibitor from LG Life Sciences

Beijing Double Crane Pharmaceutical Co. Ltd. announced on December 27 that it had signed letter of intent with LG Life Sciences for licensing of a DPP-IV inhibitor drug. The two companies agreed to negotiate further details of the licensing agreement.

Dipeptidyl peptidase IV (DPP-IV) inhibitors are a new approach to the treatment of type 2 diabetes. The efficacy of DPP-IV inhibitors is mediated primarily via stabilization of the incretin hormones glucagon-like peptide 1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP). Incretin action is very brief and is terminated by their breakdown by the enzyme dipeptidyl peptidase-IV (DPP-IV).

Chi-Med ties up with Cambridge for research into active ingredients of herbal drugs

Chi-Med recently signed up the University of Cambridge to investigate the potential healing and anti-aging properties of a number of the group's herbal remedies.

Aim-listed Chi-Med sells traditional medicines in China and also has a research and development laboratory in Shanghai where its scientists analyze herbal remedies to establish their active ingredients.

The company already has a proprietary patent medicine for heart disease, the Shexiang Baoxin pill, and sold over 400 million doses of the drug in China over the first half of 2009. It has been shown to have healing properties but the research deal announced on December 22 will focus research on the core ingredients of the pill. The medicine has been shown to control angiogenesis, the growth of new capillary blood vessels in the body. Dysfunctional angiogenesis is associated with more than 80 diseases, from cancer and diabetic eye problems to stroke.

Modulation of angiogenesis in the skin has also been shown to affect skin aging and over the three years of the Cambridge tie-up, which will be run by Dr Tai-ping Fan of the university's department of pharmacology, scientists will try to identify ingredients that could be used in skin care products to be marketed under Chi-Med's Sen consumer products brand.

CNIG to reorganize Hubei Pharma

China North Industries Group (CNIG) and the Municipal Government of Xiangfan city, Hubei province recently reached an agreement for reorganization of Hubei Pharmaceutical Co. Ltd., a major state-owned pharmaceutical enterprise in China.

CNIG also owns Huazhong Pharmaceutical Co. Ltd., a drug company in Xiangfan city with over 50% growth in the past three years. It is also the world's largest producer of vitamin B1.

Xiangfan municipal government seeks to build the city's pharmaceutical sector into a pillar industry and hopes to resolve the current financial difficulties of Hubei Pharmaceutical and facilitate its growth through the reorganization deal.

HTDS agrees to sell its MindUp bioResearch unit to a TCM company

Hard to Treat Diseases (HTDS) recently announced an agreement in principle to sell its MindUp BioResearch division to a large modern traditional Chinese medicines (TCMs) company, Hiru Corporation (HIRU). The buyer, founded in 2004, focuses on production and manufacturing of premium herbs, herbal extracts and herbal preparations.

MindUp BioResearch focuses on research of new therapeutics that would overcome the Cancer Cell Resistance in chemotherapy and also conducts research on identification of genes connected with lung cancer.

According to the company, its Chinese subsidiary Mellow Hope will remain focused solely on vaccine production and distribution, while its other subsidiary Slavica BioChem will continue with their MS research. Slavica will also be in charge of development and launch of its stem cell bank.

Jiangsu Jichuan Pharma acquires Jiangsu Tianji Pharma

Jiangsu Jichuan Pharmaceutical Group recently acquired Jiangsu Tianji Pharmaceutical Co. Ltd., a specialty company of pharmaceutical inhaler and aerosol products.

Jiangsu Jichuan is a major pharmaceutical company in Jiangsu province and it hopes to achieve sales of CNY 1.8 billion in 2010 following the new acquisition and become a top 20 pharma enterprise in the province.

Jiangsu Tianji Pharma has six existing pharmaceutical inhaler/ aerosol products and they will be sold through Jiangsu Jichuan's pharmaceutical distribution network in future. Annual sales of these products in 2010 is planned to be CNY 51 million.

Biostar Pharma to acquire an unnamed medical company

Biostar Pharmaceuticals, Inc. (OTCBB:BSPM) recently announced its intent to acquire a 100% stake in an undisclosed medical equipment and nutrients manufacturer for US$1.1 million. The acquisition will extend Biostar's portfolio of medicines and provide it with a medical equipment distribution opportunity.

Biostar Pharmaceuticals operates through its subsidiary Shaanxi Aoxing Pharmaceutical Co., Ltd. The company is engaged in the business of discovery, R&D, manufacture, and marketing of OTC and prescription pharmaceutical products.

China Medicines receive US$70M in private placement from OEP

China Medicine Corporation (OTCBB: CHME), a leading Chinese distributor and developer of Western pharmaceuticals, TCMs and other nutriceuticals announced on January 6 that it had entered into an equity private placement agreement with One Equity Partners ("OEP"), the global private equity investment arm of JPMorgan Chase & Co. China Medicine is OEP's first investment in Greater China.

OEP has agreed to purchase 4,000,000 of the Company's common shares at US$3.00 per share and 1,920,000 of the Company's redeemable convertible preferred shares at US$30 per share, for an aggregate purchase price of US$69.6 million.

China Medicine expects to use the net proceeds of the financing for capital expenditures relating to its recent acquisition of LifeTech Pharmaceuticals Co. Ltd. for working capital purposes, and for future expansion and/or acquisition.

Under the agreement, China Medicine has set a target of achieving US$25 million in earnings before taxes, interests, depreciation and amortization (EBITDA) assuming that the Company completes certain other acquisitions in fiscal 2010.

Sinovac receives fifth H1N1 vaccine order from the Chinese government

Sinovac Biotech, a leading provider of biopharmaceutical products in China, announced recently that it has received its fifth purchase order for its H1N1 vaccine, PANFLU.1(TM), from China's Ministry of Industry and Information Technology for the national purchase plan. Under this purchase order, Sinovac is required to deliver an additional 8.57 million doses of PANFLU. 1 (15ug/0.5ml) to the Chinese Central Government, of which 2.33 million doses are expected to be delivered before March 15, 2010, and the balance of 6.23 million doses to be stockpiled by the government in Sinovac's warehouse facility.

In aggregate, Sinovac has received orders of PANFLU.1 from the Chinese government for a total 20.05 million doses, and 10.23 million doses of PANFLU.1 have been delivered to date for the Chinese vaccination campaign. In 2009, the Company completed the expansion of its production line used to manufacture the seasonal influenza, H1N1 and H5N1 vaccines, thereby increasing its annual production capacity by approximately 60%.

Beijing Tongrentang Group net profit up 16% in 2009

Beijing Tongrentang Group, a leading traditional Chinese medicine maker, announced on January 14 that its 2009 net profit rose 16% to CNY 800 million (US$117 million) from a year earlier.

The company's sales exceeded CNY 10 billion (US$1.46 billion) for the first time last year, up by 12%. Meanwhile, its overseas sales climbed 10.3% to US$25.44 million.

Beijing Tongrentang plans to open a flagship drugstore with a floor area of 3,000 square meters in Beijing this year. It will also cooperate with 100 hospitals nationwide to open 100 traditional Chinese medicine drugstores in the next five years.

China Yongxin's revenue fell 22% in 2009

China Yongxin Pharmaceuticals announced its projected financial results for the year ending December 31, 2009.

Revenues for the full-year 2009 are projected to have been US$46.1 million, a 22% decrease from US$59.1 million for 2008. The decrease in total revenue was due to the transition of the company's sales strategy, which, because of the uncertain direction of the national healthcare reform, had been refocused from the wholesale sector to the retail and medical facilities sector.

For 2009, net income of the company is projected to have been approximately US$5.4 million, a 35% increase over the US$4.1 million for 2008. The increase primarily was related to higher margin retail and hospital sales.

Foreign company news

Roche moves Asia-Pacific HQ to Shanghai

Roche announced on January 14 that it had decided to move its Asia Pacific headquarters from Australia to Shanghai.

The company's regional headquarters in Shanghai will help maximize the drug firm's performance in Asia Pacific, and "it's an easy decision" because of the city's attractiveness as a hub for high-tech companies, Luke Miels, Roche's head for the Asia Pacific region, told Shanghai Daily in a recent interview.

He told the paper that the firm decided on Shanghai as the base for its regional headquarters due to several factors, including its highly educated workforce, well-built infrastructure, amiable investment environment and the local government's support for foreign firms.

Roche, the world's fifth-largest producer of pharmaceutical and diagnostic products, will regard the Chinese market as one of its six core markets from this year, ranking it with developed markets such as the United States and Germany, Miels said.

Although China's contribution to Roche globally remains relatively small at present, the firm estimates that the country will become the world's third-largest market for Roche in 2013, after the United States and Japan.

"We have a long-term commitment to China, and Shanghai is the most attractive hub for high-tech firms to locate their regional headquarters," Miels said.

"Roche will continue to invest in China and our Chinese team will be deeply involved in global research and development decisions to produce more drugs designed for Chinese clients," he also said.

Since entering China in 1994, Switzerland-based Roche has set up a complete pharmaceutical value chain in Shanghai, from research, development, manufacturing to sales and marketing. Shanghai, San Francisco and Basel are the only three cities which boast a complete value chain.

According to the Shanghai Commission of Commerce, 79 multi-national companies decided to locate their regional headquarters in Shanghai last year, boosting the total number to 755 and making the city the top spot in the Chinese mainland for regional headquarters of MNCs.

MSD cuts price of Zocor for higher market share and growth in China

After Simvastatin was included in China's National Essential Drug List (Primary Healthcare Facilities Volume), MSD announced it would cut price of its Zocor (Simvastatin 20 mg x 7) in line with the Chinese national essential drug pricing policy. It is estimated by the Chinese press that the price cut will be as high as 52% - all the way from previously CNY 52.5 down to CNY 25.0.

The new price of Zocor will be even lower than some of the local generic drug companies, according to an executive of MSD China. Amongst all cholesterol-lowering medicines on the Chinese hospital market, Zocor ranks the second by share.

Most Chinese industry experts interpret the move by MSD China as a means to boost market share through price reduction, and they believe this would create significant competitive pressure on MSD's competitors including both its MNC peers like Pfizer and local generic drug players.

But Michel Vounatosis, President of MSD China, denied any link between its price cut and Zocor's patent or NEDL status. He insisted the move will not affect the overall profitability of MSD in China because of the company's diversified business model.

Vounatosis declined to comment if his company will succeed in boosting the sales volume of Zocor following its price slash.

He said that MSD China has been following China's healthcare reform policies closely and is willing to play on the (essential drug) platform established by the Chinese government.

Meanwhile, MSD expects its China business to grow 20% annually in the near future, Vounatosis told China Daily in a recent interview.

"The signs are positive for pharmaceutical companies in China, " said Vounatsos. "The problem is how to participate in the remarkable reforms."

Bayer Healthcare China elevated on the corporate ladder

According to local newspaper China Business, which quoted an insider source, Bayer Healthcare China became an independent business unit reporting directly to its global headquarters as of January 1, 2010.

Previously, Bayer Healthcare China was part of Bayer Schering Pharma's Asia Pacific Division, which includes markets such as India and Australia.

The upgrade is a result of multiple factors including the rising importance of the Chinese market and new growth opportunities from the country's healthcare reform. Additionally, China is the only country where Bayer Healthcare leads all MNCs by prescription drug sales.

In fact, Bayer Healthcare is not the first MNC company elevating the status of its China business. As early as late 2004, Novartis Pharma China was taken out of the company's Asia Pacific Division and became an independent business region, according to Jeffrey Li, President of Novartis China. This makes things easier when it comes to management and winning headquarter support, he added.

With fast rising importance of the Chinese market, more MNC companies are likely to follow suit of Bayer and Novartis in order to make their China businesses more competitive.

Boehringer Ingelheim launches new ARB/ HCTZ combo drug in China

Boehringer Ingelheim Pharmaceutical (BI) recently launched Micardis Plus (telmisartan and hydrochlorothiazide combination tablets), an antiotensin II receptor blocker (ARB), in China.

Telmisartan was recently approved by the US FDA for "the reduction of the risk of myocardial infarction, stroke, or death from cardiovascular causes in patients 55 years of age or older at high risk of developing major CV events who are unable to take ACE inhibitors."

Fixed combinations with HCTZ are popular product extensions for ARBs - those available in China include irbesartan+ hydrochlorothiazide, losartan+hydrochlorothiazide, and valsartan+hydrochlorothiazide.

Boehronger Ingelheim receives Chinese approval for Circoflex

Circoflex, Boehringer Ingelheim Vetmedica's vaccine to control Porcine Circovirus Disease (PCVD), was recently approved in China. The product contains a combination of purified circo-antigen (a virus-like particle) with a designed adjuvant (Impranflex). It is licensed as a single shot vaccine recommended for convenient vaccination around weaning.

The product has been shown to reduce clinical signs like wasting and mortality in the acute form as well as to improve growth performance in the chronic form of the disease. Since 2006, more than 260 million pigs have been vaccinated with the vaccine.

Porcine circovirus disease (PCVD) is recognised as one of the most economically damaging pig diseases in the world.

Acute infections with the Porcine Circovirus Type 2 (PCV2) compromise the immunity of the pig leading to high mortalities, increased frequency of co-infections with other pathogenes and

reduced growth performance. Almost 100% of pig herds are infected with PCV2.

Baxter sponsors MOH's hemophilia disease management system

Baxter China signed a cooperative agreement with the Ministry of Health (MOH) on January 12 to sponsor the latter's Hemophilia Disease Management System (HDMS).

The HDMS is composed of a national and 31 provincial hemophilia information management centers which are to register hemophilia patients, manage patient information and streamline relevant diagnosis and treatments. It will also compile a "Hemophilia Diagnostic and Therapeutic Guide" and establish a national level R&D, demo therapeutic and training facility for the disease.

As hemophilia diagnosis and treatment requires sophisticated medical expertise and the disease needs lifelong treatment (thus leading to higher costs), experts believe at least 90% of Chinese hemophilia patients have been left untreated so far.

Baxter has 50 years of experience in the field of hemophilia therapeutics and it has donated over 4 million units of genetically recombinant factor VIII (which is worth over CNY 20 million) to Chinese hemophilia patients in recent years.

Ranbaxy sells majority stake in Guangzhou JV to HNG Chembio

Ranbaxy Laboratories said on December 29 that it would divest from one of the highest-profile Indian investments in China as part of its move to consolidate manufacturing operations.

The company announced that the disposal of its entire 83% stake in Ranbaxy (Guangzhou China) Pharmaceutical Co. Ltd., a Chinese joint venture between Ranbaxy, Guangzhou Baiyunshan Pharma and Hong Kong-based New Chemic to HNG Chembio Pharma. Ranbaxy declined to say how much the deal was worth.

But Ranbaxy insisted that "this is not an exit from China. We will continue to supply products from outside [the country] from our other plants. We were manufacturing in 10 countries. Now it is nine."

This transaction is part of Ranbaxy's endeavor to develop a new business model for China which entails the marketing of value added pharmaceutical formulations and the consolidation of manufacturing operations, for cost synergies.

HNG is part of the large state-owned Hunan Nonferrous Metals Holding Group Co., Ltd., located in the Hunan Province in China. HNG has strong operations in the pharmaceutical ingredients business. With this transaction, HNG will gain entry in the field of pharmaceutical dosage forms, in which HNG plans substantial further investments in the near future.

The joint venture, described by Ranbaxy as "a signal development" in trans-Himalayan business, had sales in China of US$13.5 million in 2007. Its range of 40 products focus on anti-infection and cardiovascular treatments.

The divestment is part of a cost-saving consolidation conducted by Daichi Sankyo, Ranbaxy's Japanese parent, since it took control of the company this year.

The Asia Pacific region, including China, had contributed moderate growth of 7% to Ranbaxy's global sales during the third quarter.

Japanese drug wholesalers begin to penetrate the Chinese market

The international business division of Japanese wholesaler Alfresa Holdings will initially focus on business in China and other Asian countries, according to the company's president. In addition, full operations are set to begin soon at Remeje Pharmaceuticals (China) Co. Ltd., a drug distribution joint venture between Alfresa and ITOCHU Corporation.

Separately, Medipal Holdings Corporation, a leading Japanese healthcare service provider and drug wholesaler, announced that it intends to double the sales of its Chinese joint venture with Sinopharm Group from the current US$162 million (Yen 15 billion) to over US$320 billion (Yen 30 billion) by FY 2012.

Invida Group launches branded dermatological drugs in Asia

Invida Group, a major provider of healthcare brands and services to the Asia-Pacific region, announced on January 12 the launches of dermatological brands, Dermatix and Zalain, as well as the successful registration of Kinerase in China. Dermatix and Kinerase are already marketed in several key countries in Asia and Invida is in the process of registration in other markets to ensure complete regional presence.

Invida targets core market segments in ethical and aesthetic dermatology, notably the high growth anti-aging and scar management field with these innovative and effective dermatological brands. While Asian markets comprise only 7-8% of the world's pharmaceutical market; this rapidly expanding region already accounts for 23% of the global skincare market. China, in particular, is on track to exceed the size of the US skincare market in the next few years.

Dermatix, a topical treatment for scar prevention and care, is already widely used throughout the U.S. and Europe. The product is especially suited for the Chinese and Asian markets, where patients have darker skin types that are more prone to scarring. Zalain is a unique topical treatment for fungal skin infections.

"By introducing these leading and proven dermatological brands, we have the opportunity to meet China's growing demand for high quality products and continue to expand upon the Invida brand within the region", said John Graham, CEO of Invida.

Burdica Biomed lands distribution deal with SinoPharm

Burdica Biomed, a Scottish biotech company, has signed a ten-year deal with SinoPharm Group, China's largest distributors of pharmaceuticals and medical devices, to distribute its therapeutic products. Burdica said the tie-up with Sinopharm could be worth "tens of millions of pounds" in trade.

Burdica was set up in 2007 to develop therapeutic applications of hyaluronic acid (HA), found between cells in various body tissue. Last year, Burdica launched its Zestic range, which uses HA to improve the mobility of sperm. Another product in the range is used to alleviate dryness experienced by some women during and after menopause.

Sinopharm will guide Burdica's products through China's regulatory compliance process and then distribute the products, with the Scots firm providing marketing.

Kevin Burd, founder and chief executive of Burdica, said: "We anticipate the regulatory process in China will take 12 to 18 months to complete. Thereafter, the sales projections we have developed jointly with Sinopharm indicate total revenues in the higher reaches of the tens of millions sterling range over our ten-year distribution agreement with them."

Service provider news

Qiagen partners with Wuxi AppTec to support biomarker development in Asia

Qiagen Asia Pacific and WuXi AppTec recently announced a partnership to provide an integrated single solution for molecular biomarker development, validation and personalized healthcare targets to their respective client bases, with Qiagen providing a complete portfolio of instrumentation, training, and consumables and WuXi AppTec providing laboratory facilities and staff to execute the services. The laboratory will be located at WuXi AppTec's campus in Shanghai and will begin operating immediately.

Under the terms of the partnership agreement, WuXi AppTec will also work with Qiagen to help develop biomarkers, assay panels, personalized healthcare diagnostics, and other products that Qiagen intends to bring to market. WuXi AppTec will use Qiagen's technologies for a broad range of applications in support of drug discovery and development on behalf of the company's and Qiagen's customers. Both companies are working closely to identify additional opportunities to expand their relationship.

The alliance creates the first laboratory of its kind in Asia, according to Victor Shi, president, Qiagen Asia Pacific, equipped with a standardized, fully integrated, automated sample and assay technology for drug discovery, development, and molecular diagnostics. "We believe that this partnership is a significant milestone in providing high-quality and complete automated solutions for the molecular biomarker testing industry," he notes.

The partnership with WuXi AppTec follows Qiagen's recent acquisitions of DxS and SABiosciences to pad its offerings in the biomarker and personalized medicine field. Qiagen also recently opened its Asia headquarters in Shanghai's Zhangjiang High-Technology Park.

Qiagen began its expansion into Asia in 2005 and currently maintains 10 offices in China, Korea, Malaysia, Singapore, and India. Including the subsidiary in Japan, these Asian operations currently contribute approximately 13% to the firm's overall net sales, Qiagen notes.

Qiagen also recently opened its new Asia headquarters in Shanghai's Zhangjiang High-Technology Park, a major pharmaceutical R&D hub in China, facilitating industry-leading support for its many pharmaceutical customers.

Pharmaron Holdings acquires Bridge Labs to become an integrated CRO

Pharmaron Holdings Limited, announced on January 11 that it had completed the acquisition of Bridge Laboratories China. With this acquisition, Pharmaron claims to be the first integrated CRO in China supporting clients with drug discovery and development processes in support of IND filings. This strategic acquisition strengthens Pharmaron's leading position in the fast-growing, highly dynamic pharmaceutical CRO industry.

Bridge Laboratories China is the first CRO in China with western GLP-compliant preclinical toxicology service capabilities. It is the only preclinical CRO laboratory in China whose data has been accepted by both the FDA and EMEA as part of successful regulatory filings. The 84,000 square-foot, state-of-the-art facilities in Bridge Laboratories China includes one of the largest and most sophisticated animal vivariums in China that is both AAALAC multi-species accredited and U.S. GLP-compliant.

Founded in 2003, Pharmaron is a pharmaceutical R&D CRO, with operations in China and the United States.

According to Lou, about one third of the Chinese CROs are located in Beijing and their revenues in 2009 are estimated to have reached CNY 5 billion.

Regulatory News

CDE reports on drug registration evaluation performance in 2009

The Center for Drug Evaluation (CDE) under the SFDA announced recently its drug registration evaluation performance in 2009. It undertook a total of 12,267 drug evaluation cases (including new submissions, supplemental applications, meetings/consultations and rejections) last year, among them 9,051 are new submissions and 2,556 are supplemental applications.

The following tables provide a detailed breakdown of the center's work last year:

Table 1 Breakdown of all drug evaluation cases in 2009

	New Drugs	Copy Drugs	Imported Drugs	Import Renewals	Supplemental Applications	Re-exams	Total
Chemical Drugs	1,725	1,979	825	213	3,082	842	8,666
TCMs	570	148	21	52	800	1,335	2,926
IVDs	3	12	11	1	19	0	46
Preventative Biologicals	76	2	14	1	92	0	185
Therapeutic Biologicals	94	0	115	23	162	8	402
Drug Inactive Ingredients	14	7	15	2	1	3	42
Total	2,482	2,148	1,001	292	4,156	2188	12,267

Source: Center for Drug Evaluation, SFDA

Table 2 Breakdown of all new submissions in 2009

	New Drugs	Copy Drugs	Imported Drugs	Import Renewals	Supplemental Applications	Re-exams	Total
Chemical Drugs	951	1,129	506	153	2,687	836	6,262
TCMs	225	87	3	11	660	1,334	2,320
IVDs	0	9	2	1	19	0	31
Preventative Biologicals	54	0	10	1	78	0	143
Therapeutic Biologicals	47	0	87	11	108	8	261
Drug Inactive Ingredients	10	7	12	1	1	3	34
Total	1,287	1,232	620	178	3,553	2,181	9,051

Source: Center for Drug Evaluation, SFDA

Table 3 Breakdown of all supplemental applications in 2009

	New Drugs	Copy Drugs	Imported Drugs	Import Renewals	Supplemental Applications	Re-exams	Total
Chemical Drugs	668	652	310	73	265	6	1,974
TCMs	199	4	15	52	122	1	393
IVDs	3	1	9	0	0	0	13
Preventative Biologicals	19	2	4	1	12	0	38
Therapeutic Biologicals	42	0	28	18	42	0	130
Drug Inactive Ingredients	4	0	3	1	0	0	8
Total	935	659	369	145	441	7	2,556

Source: Center for Drug Evaluation, SFDA

CDE completes drafting of new guideline for drug-induced carcinogenesis test

The Center for Drug Evaluation (CDE) under the SFDA recently disclosed that it is systematically translating foreign technical guidelines for drug registration and localizing them to improve China's drug research guideline system.

On the basis of its past efforts, the CDE has recently completed the drafting of the Technical Guidelines for Necessity of Drug-induced Carcinogenesis Assessment. The document was drafted referencing opinions of Chinese GLP experts, research institutions and pharmaceutical companies, and the Drug Safety Appraisal Committee of the Chinese Pharmaceutical Association. The draft guideline was already submitted to the SFDA for final approval. Full text in Chinese of the draft can be found at www.cde.org.cn/news.do?method=largeInfo&id=311570.

The CDE said it was translating more foreign guidelines relating to drug-induced carcinogenesis assessment including two ICH, three USFDA and three EMEA documents. They will be published on CDE's website.

East Asian drug authorities hold joint working group meeting on clinical trials

On December 17, 2009, China, Japan, and Korea participated in the second Working Group (WG) meeting on drug clinical trials. This meeting included China's SFDA, Korea's Food and Drug Administration (KFDA), and Japan's Ministry of Health Labor and Welfare (MHLW) and Pharmaceuticals and Medical Devices Agency (PMDA).

Mr. Zhang Wei, SFDA's Director-General of the Drug Registration Department, Dr. Sun-Hee Lee, KFDA's Director-General of the Drug Evaluation Department, Mr. Shinobu Uzu, MHLW's International Planning Director, and Dr. Tatsuya Kondo, PMDA's Chief Executive were the main representatives from each country.

The representatives agreed on the Terms of Reference of the WG. The Terms outline WG's objectives, prospective projects, procedures, participants, and other rules. The two projects the WG works on are (1) research on ethnic factors in clinical data from the three countries, and (2) information exchange on drug clinical trials.

Project 1 is primarily focused on pharmacokinetic data from the three countries. The hope is that this analysis will determine the possibility of clinical data sharing within East Asia. MHLW/PMDA will be the coordinator of this project and will propose a detailed work plan to WG.

The second project will involve the three health authorities exchanging information on drug clinical trials both on a regular and ad-hoc basis. KFDA will coordinate this project and will provide a detailed work plan.

KFDA announced it would host the next WG meetings in 2010.

New GMP regulation to be issued soon

Following comment seeking on the second draft of the new edition of the "Quality Control Standards for Drug Manufacturing" (GMP) in late 2009, a senior official of the Drug Safety Supervision Department of the SFDA disclosed recently at an industry conference that the final draft of regulation was completed on the last day of 2009 and is now under government approval process.

The regulation was planned for release before the end of 2009, but it is now expected in the first quarter of this year.

The official estimated that the new regulation is likely to force at least 500 small to medium-sized pharmaceutical enterprises out of business as GMP standards and requirements will be significantly raised. Only the hardware-related compliance costs of the regulation by the pharma industry are likely to reach between CNY 200 billion and CNY 300 billion, he said.

Compared with the previous 1998 edition of the GMP regulation, which emphasizes hardware requirements, the new edition will focus more on "software" aspects of GMP (e.g. process, documentation and personnel management), cGMP dynamic control and post marketing surveillance and regulation.

As a result of the strengthened requirements, pharmaceutical manufacturers may need to double their quality control personnel, the official said. Total personnel are likely to reach 100,000 industrywide.

The pharma industry compliance cost of the previous 1998 edition of Chinese GMP is expected by the Research Group for Competitiveness of the Chinese Pharmaceutical Enterprises to be around CNY 150 billion, 30% of which came from bank loans. The number of Chinese pharmaceutical enterprises fell to around 4,700 from previously 6,000 following the previous round of GMP implementation.

It is reported that many of the leading export-oriented Chinese pharmaceutical companies, such as Zhejiang Hisun Pharma, have already upgraded all or parts of their manufacturing facilities as required by their international business expansion plans. Meeting requirements of the latest edition of GMP will therefore be relatively easier for these companies.

The new edition of GMP will help raise China's pharmaceutical manufacturing standards and harmonize GMP requirements between the country and other developed markets, many industry executives believe.

SFDA said earlier that a two year transition period will be in place for companies with existing manufacturing facilities to meet requirements of the new GMP regulation.

SFDA issues announcement on classified regulation of medical sodium hyaluronate products

In order to strengthen the supervision and management of medical sodium hyaluronate (hyaluronic acid sodium) products, further standardize the application and approval procedure and ensure the safety and effectiveness of drugs and medical devices, the State Food and Drug Administration (SFDA) recently released an announcement on classified regulation of medical sodium hyaluronate on the basis of Drug Administration Law of the People's Republic of China, Regulations for Supervision and Administration of Medical Devices.

With considerations of their different clinical applications (indications), the announcement provides that products with definite pharmacological effects for the treatment of arthritis, xerophthalmia and skin ulcer shall be regulated as pharmaceuticals, while products used in ophthalmic operation aiding, surgical adhesion prevention and tissue augmentation shall be regulated as medical devices.

Legal / IPR News

"*2009 USTR Report on China's WTO Compliance*" highlights concerns in the pharma sector

The U.S. Trade Representative's (USTR) office recently released the *2009 USTR Report to Congress on China's WTO Compliance*, the eighth report required under the U.S.-China Relations Act of 2000. As stated in the foreword, "The focus of the report's analysis continues to be on trade concerns raised by U.S. stakeholders that, in the view of the U.S. Government, merit attention within the WTO context."

In the pharmaceuticals sector, the report cited a range of continuous concerns by the United States as follows.

"The United States has urged China to provide more effective protection against unfair commercial use for undisclosed information, test data and other data generated to obtain marketing approval for pharmaceutical products.

The United States has also encouraged China to more closely coordinate patent grants with pharmaceutical marketing approvals and to consider the adoption of a system of patent term restoration.

In addition, built-in delays in China's marketing approval system for pharmaceuticals continue to create incentives for counterfeiting, as does China's inadequate regulatory oversight of the production and sale of active pharmaceutical ingredients by domestic chemical manufacturers.

In 2009, as in prior years, the United States sought to address all of these issues as part of its broader effort to work with China to improve China's regulatory regime for the pharmaceuticals sector."

In addition, the report complains about the China's continuing restrictions on pharmaceutical distribution as follows:

"China was committed to allow foreign suppliers to distribute pharmaceuticals by December 11, 2004, and it began accepting applications from and issuing wholesale licenses to foreign pharmaceutical companies about 6 months after that deadline. At the same time, despite overall progress in this area, many other restrictions affecting the pharmaceuticals sector make it difficult for foreign pharmaceutical companies to realize the full benefits of China's distribution commitments."

Besides, the U.S. disapproves China's slow progress in reducing the number of products (including pharmaceuticals) and services subject to price control or government guidance pricing.

The report, nevertheless, acknowledges that China is committed to and has strengthened oversight and enforcement of bulk chemicals used as active pharmaceutical ingredients and counterfeit pharmaceuticals, among other results.

APIs / Bulk Drugs

Xinchang Pharma passes USFDA inspection for bulk antimalaria drugs

Zhejiang Pharmaceutical Co. Ltd. announced that its subsidiary, Xinchang Pharmaceutical Factory, had recently passed USFDA inspections for its bulk anti-malaria drugs Lumefantrine and Artemether.

Zhejiang Pharmaceutical expects to supply these bulk drugs to Novartis for it to make compound anti-malaria formulations containing both Artemether and Lumefantrine. Zhejiang Pharmaceutical was already a supplier of Lumefantrine bulk drug to Novartis between 2005 and 2007.

Passing the USFDA inspections by Zhejiang Pharmaceuticals will facilitate its long term Lumefantrine and Artemether supply contracts with Novartis, which is seeking to expand anti-malaria drug sales in South American markets.

NDRC to halt bulk vitamin C expansion wave in China

The National Development and Reform Commission (NDRC) announced recently that it would issue new policies and measures to contain the excessive growth for bulk vitamin C production capacity in China.

The agency said that it would stop approving new bulk vitamin C projects and begin streamline approved projects which are completed, under construction or before construction. Companies that violated regulations will have their production licenses withdrawn and export control of bulk vitamin C will be tightened, according to the NDRC.

As recent as November 26, 2009, Heihe Border Economic Cooperation Zone signed an agreement with China Zenith Chemical Group Limited for a bulk vitamin C project with 25, 000 tons of annual capacity.

Please see our earlier article, Price war for bulk vitamin C looms again, for more information on the current bulk vitamin C production expansion frenzy in China.

Product and R&D News

Chinese and Singaporean scientists identify leprosy genes

In a first-time-ever genome-wide association study (GWAS) of leprosy and the largest GWAS effort on infectious diseases in the world, scientists at the Genome Institute of Singapore (GIS), a biomedical research institute of the Agency for Science, Technology and Research, Singapore and 26 institutes in China found seven genes that can cause people to become susceptible to leprosy. The discovery of these genes - known as CCDC122, C13orf31, NOD2, TNFSF15, HLA-DR, RIPK2 and LRRK2 - highlights the important role of the innate immune response in the development of leprosy.

The discovery of the seven susceptibility genes has not only helped to understand some people's susceptibility to this disease, but also opened the door for further biological and clinical research to reveal the mechanism of leprosy development.

New insights into potential anti-cancer drug derived from Chinese mushroom

A promising cancer drug, first discovered in a mushroom commonly used in Chinese medicine, could be made more effective thanks to researchers who have discovered how the drug works. The research was funded by the Biotechnology and Biological Sciences Research Council and was carried out at The University of Nottingham.

In the research to be published in the Journal of Biological Chemistry, Dr Cornelia de Moor of The University of Nottingham and her team have investigated a drug called cordycepin, which was originally extracted from a rare kind of wild mushroom called cordyceps and is now prepared from a cultivated form.

Dr de Moor said, "Our discovery will open up the possibility of investigating the range of different cancers that could be treated with cordycepin."

Sinovac files application for HFMD vaccine with the SFDA

Sinovac Biotech Ltd., a leading provider of biopharmaceutical products in China, announced on December 28 that it had filed clinical trial application (CTA) with the SFDA to commence a human clinical trial for its vaccine against human enterovirus 71 (EV 71), which causes hand, foot, and mouth disease (HFMD). This is the first CTA for HFMD vaccine submitted in China.

No vaccine or antiviral treatment is currently available for HFMD worldwide, though it has become a very serious problem in Asia in recent years. The disease is highly contagious and a growing number of HFMD cases have been reported in parts of Asia, including Mainland China, Hong Kong, Singapore, Korea, and Taiwan.

According to China's Center for Disease Control (CDC) between January 1 and November 30 of this year, the disease caused more than 400 deaths in China, where health authorities reported over 1.1 million HFMD infections, compared to about 200 reported H1N1 deaths. Due to the severity of the disease epidemic, China authorities recognize the unmet medical need and are expected to support the launch of a HFMD vaccine as soon as possible. Therefore, Sinovac believes that fast track status for the reviewing process and approval may be granted.

As previously announced, the Company began preclinical development in 2008. Sinovac is independently developing the EV 71 vaccine and will retain full commercialization rights of the vaccine upon approval. Created by Sydney University, the animal model showed cross protection and demonstrated that the vaccine is effective in animals. In addition, Sinovac is preparing to file a patent application covering the EV 71 vaccine.

China Aoxing Pharma completes phase II trials of novel PD drug

China Aoxing Pharmaceutical Company, Inc., a pharmaceutical company specializing in R&D, manufacturing and distribution of narcotic and pain-management products, announced on January 5 that it had completed Phase II clinical study for oral TJSL capsules, a novel investigational drug to treat primary dysmenorrhea ("PD"), or menstrual pain in adult women. Top-line results from this study are expected to be announced in the coming weeks.

The Phase II clinical study was a 12-week, multi-center, randomized, double-blind and placebo-controlled study to evaluate the safety and efficacy of TJSL capsules among 240 patients with primary dysmenorrheal. Subjects were between 18 and 35 years old enrolled at four leading university teaching hospitals in metropolitan areas of China.

The prevalence rates of PD among women are from 60% to 90%. It is estimated that 64% of women in China purchase menstrual pain drugs on a regular basis. The annual Chinese market for menstrual pain related healthcare products is estimated at US$3 billion.

3SBio files CTA for Feraheme

3SBio Inc., a leading Chinese biopharmaceutical firm, announced on January 8 that it had submitted a CTA to the SFDA for Feraheme (ferumoxytol) Injection for intravenous use. Feraheme is an intravenous iron therapy that 3SBio licensed from AMAG Pharmaceuticals, Inc. for development in China for the treatment of iron deficiency anemia in adult patients with chronic kidney disease ("CKD").

Feraheme was approved on June 30, 2009 by the USFDA for the same indication for which 3SBio is seeking approval in China and launched commercially in the U.S. by AMAG in July 2009. As previously announced, 3SBio has exclusive rights to develop and commercialize Feraheme in China. Once approved by the SFDA, 3SBio will commence a multi-center randomized efficacy and safety study in China with approximately 200 CKD patients, measuring the mean change in hemoglobin from baseline at Day 35 after first dose.

CAMS announces phase III trials of its novel macrolide antibiotic

The Institute of Medical Biotechnology (IMB) under the Chinese Academy of Medical Science (CAMS) announced recently that

its class one new drug, biotechmycin, had entered phase III clinical trial. Additionally, the institute has secured three Chinese invention patents for the product.

Biotechmycin is a new macrolide antibiotic produced by a stable genetically-engineered bacterial strain constructed via genetic transformation and homologous recombination. Earlier double-blind clinical trials show that biotechmycin has similar therapeutic efficacy and adverse drug reaction profile comparable to those of azithromycin, according to Prof. Wang Yiguang, lead researcher of the project at IMB.

Study shows China a leader in regenerative medicine research

Chinese researchers have become the world's fifth most prolific contributors to peer-reviewed scientific literature on regenerative medicine (RM), according to an international study published recently.

The Canadian-based McLaughlin-Rotman Center for Global Health (MRC) published a research article in the UK journal Regenerative Medicine, saying that China's contributions to scientific journal RM topics leapt from 37 in 2000 to 1,116 in 2008, exceeded only by that of the United States, Germany, Japan and Britain.

"China has been developing very quickly in the area of regenerative medicine", said Dominique McMahon, the leading author of the article, who also told Xinhua that "there is no doubt that China is one of the leaders in the race to develop RM therapies."

The article also said China to date had created at least 25 human embryonic stem cell lines, four of which were of a specialized type that only two other groups worldwide had managed to create then.

The numbers were based on analysis of articles which had been published in international peer-reviewed journals. The creation of some stem cell lines may not be published or only in Chinese journals, and some estimated that China had over 70 cell lines.

"There are three main strengths in China that we believe have helped contribute to this success", said Halla Thorsteinsdottir, co-author of the study. She identified the three as permissive regulations, a skilled labor force, and a focus on applications of RM.

She noted that China's recruitment policy for returned overseas professionals had made an important contribution to RM, and could be a strategy for other developing countries to reverse the brain drain phenomena.

But the authors also pointed out that some of the key elements were "double edged". For example, the focus on application may come at the expense of fundamental research and a better integration between basic and applied research could help move stem cell research forward in China.

Several other challenges for RM in China were mentioned, such as the further improvement of regulations and the safety of stem cell therapies. Regarding the regulation of embryonic stem cell research, which is often controversial in some countries such as the United States but is less contentious to the Chinese culture and religion, the authors said Chinese regulations "are very similar to that which is allowed in the UK". Though it needs improvement, it's not as weak as misinterpreted by some.

Jiangsu hands out US$1.8M grant for stem cell R&D

Jiangsu Government's Science and Technology Department has announced a US$1.8 million grant - the Jiangsu Technological Achievements Transformational Grant - to support the research and development of human umbilical cord mesenchymal stem cell (hUC-MSC) technologies. The grant recipient and administrator, Shenzhen Beike Biotechnology Co., Ltd., is working with Jiangsu University and Nanjing University's Drum Tower Hospital to fulfill the grant's requirements.

This grant marks the start of the second stage of Beike's stem cell engineering industrialization project. The project's first phase began in May 2008, when Beike opened a 1,800 square-meter stem cell bank in Taizhou's China Medical City district. In the second phase, the bank will be used as a library for storing and indexing hUC-MSC samples.

The grant's three-year objectives are to systematically develop hUC-MSC technology and its medical application from "bench-to-bedside" - from harvesting, to laboratory modeling, through clinical trials, and finally clinical applications in treating Systemic Lupus Erythematosus (SLE), Multiple Sclerosis (MS) and other degenerative diseases. In support of this effort, Beike will provide the facilities, equipment, management framework and certain proprietary clinical stem cell technologies for the project.

Nanjing University Medical School's renowned Drum Tower Hospital will be responsible for administering the human trials while Jiangsu University will bring its vast biological research and development resources to the production and animal study phases of the project.

With encouraging outcomes already apparent for MS and SLE, Jiangsu University's next task will be to create animal models for testing hUC-MSCs potential in other disorders such as brain injury, spinal cord injury, liver disease and kidney damage. Jiangsu University has already made advances in hUC-MSC separation, detection, purification, amplification and quality control. As part of this grant, the university will be researching hUC-MSC growth, differentiation characteristics, identification standards and serum-free medium studies.

Suven secures two product patents in China and Russia

Indian biopharmaceutical firm Suven Life Sciences Ltd. announced on January 12 that two product patents had been granted in China (100378108 and 100378109) and Russia (2325392 and 2340619) corresponding to two of their new chemical entities (NCEs) for the treatment of disorders associated with neurodegenerative diseases and these patents are valid until 2023 and 2024 respectively.

The granted claims of the patents include the class of selective 5-HT compounds which were discovered by Suven and are being developed as therapeutic agents and found useful in the treatment of cognitive impairment associated with neurodegenerative disorders such as Alzheimer's disease, Attention deficient hyperactivity disorder (ADHD), Huntington's disease, Parkinson and Schizophrenia.

Products out of these inventions may be out-licensed by Suven at various phases of clinical development such as Phase-I or Phase-II, according to Venkat Jasti, CEO of Suven.

General Health

Essential drug policy objectives delayed

According to Xie Xiaoyu, Director of Essential Drug System Division under the Drug Administration Department, the Ministry of Health, the earlier plan of implementing essential drug system in 30% of urban community healthcare facilities within 2009 has to be postponed now to March 2010, due to delays in introduction of various complementing policies for the essential drug system. Xie made the revelation at a recent industry event, China Pharmaceutical Industry Leaders Summit.

Local experts believe that the postponement is related to the slow progress of and challenges in essential drug policy implementation in local drug purchase tenders. Such challenges include local protectionism and disputes related to tender prices & selection of distributors.

A local pharmaceutical executive pointed out that the current pricing of essential drugs (by generic names) fails to provide incentives for improving quality. In addition, absence of complementing policies and failure of local governments to introduce financial subsidies in time also undermine the essential drug policy implementation at the local level.

Xie said that the central government will strictly control the local product additions to the national essential drug list, and such additions must be selected from category A of the National Drug Reimbursement List in principle and only from category B if necessary. She also stressed that the central government will strictly control quality of essential drugs and will prioritize electronic supervision and administration of such products.

Xie did not respond directly to questions regarding the introduction of Part II of the National Essential Drug List (NEDL), which was planned by the Ministry of Health for release before the end of November, but she said the document is under research. Part II of the NEDL is intended for implementation in public hospitals.

MOH announces priorities for health work and public hospital reform in 2010

The Ministry of Health (MOH) published its "Highlights of Health Work in 2010" on January 7.

Important areas of health work highlighted in the document by the Ministry include: 1) introducing the public hospital reform experiment; 2) strengthening infrastructure building of primary healthcare service network; 3) consolidating the new rural cooperative medical scheme; 4) actively promoting equal access to basic public health services; 5) improving capabilities for prevention and controlling major diseases and for public health emergency response; 6) accelerating implementation of the national essential drug system; and 7) deepening reform of health supervision system and enhancing health supervision abilities.

In the area of public hospital reform experiment, the MOH highlighted the following as its important tasks: to guide the public hospital reform experiment; to encourage local trials of different forms; to formulate and implement plans for public hospital setup and development; to optimize public hospital structure and distribution; to explore and refine the public hospital management system; to improve and strengthen public hospital governance; to push forward compensation mechanism reform of public hospitals; to fulfill relevant government investment policies; to adjust medical service prices; gradually remove drug sales margins; to introduce reforms of operating, personnel and remuneration systems of public hospitals, to strengthen position performance evaluations and explore performance-based remunerations; to conduct trials of the policy allowing physicians to practice at multiple sites and clinical pathway management, and explore single-disease-based quality control; to move forward the implementation of "Basic Guidelines for Electronic Medical Records"; to enhance the research and formulation of public hospital standards; and to strictly control the acquisitions of large scale medical equipment.

In addition, the MOH stated that it encourages and supports participation of "social capital" in opening non-public medical institutions.

MOH: Essential drug system to be implemented in selected grade II and III hospitals in 2010

Health Minister Chen Zhu told the National Health Working Conference on January 5 that the essential drug system will be implemented in grade II and III hospitals of public hospital reform trial areas this year.

The national essential drug system was initiated in August 2009 and thereafter implemented in 30% of the public urban community healthcare facilities and rural primary healthcare institutions nationwide along with the zero drug sales margin policy. These policies have been fully implemented in all primary healthcare facilities of some regions including Beijing and Ningxia.

China will consolidate and expand implementation of the essential drug system to at least 60% of the public primary healthcare institutions and selected grade II and III hospitals this year, according to Chen. Local governments are encouraged to introduce compensation policies to make up for losses of medical institutions from the implementation.

All primary healthcare institutions implementing the essential drug system must fully stock and use essential medicines, and grade II and III hospitals implementing the system must reach the relevant standards for essential drug use, he said. Centralized purchase and distribution of essential drugs at the provincial level is promoted.

In addition, Chen called for rationalization of drug use, especially antibiotics, through the essential drug system.

MOH introduces clinical guidelines and formulary for essential drugs

In accordance with the requirements of China's national essential drug system implementation plan in 2009, the Ministry of Health (MOH) and the State Administration of Traditional Chinese Medicine (SATCM) issued "*Clinical Guidelines of National Essential Drugs (Primary Healthcare Facilities Volume)*"

and "*National Essential Drug Formulary (Primary Healthcare Facilities Volume)*" on December 30, 2009.

Both documents are compiled on the basis of the "*National Essential Drug List (Primary Healthcare Facilities Volume)*" (NEDL) and are designed to guide and streamline rational essential drug use by medical professionals at primary healthcare facilities in the treatment of common diseases.

The "*Clinical Guidelines of National Essential Drugs (Primary Healthcare Facilities Volume)*" shows physicians with drug prescription rights how essential drugs should be used correctly. It covers all common and high-prevalence diseases at present. Its contents are provided in four sections - introduction, diagnostic highlights, drug therapy and notes.

The "*National Essential Drug Formulary (Primary Healthcare Facilities Volume)*" was complied in the order of drugs listed in the NEDL. The contents of the document include: Foreword, General Principles, Individual Volumes, Appendices and Index. All of the dosage forms in the formulary are strictly contained to those listed in the NEDL.

MOH issues clinical pathways for two blood diseases

Following release of clinical pathway guidelines for 17 diseases in four medical specialties on October 16 and a document that calls for trial introduction of clinical pathways for 112 diseases in 50 large hospitals nationwide on December 8, the Ministry of Health issued clinical pathways for two blood diseases, idiopathic thrombocytopenic purpura and acute promyelocytic leukemia, in late December 2009.

The MOH requires local health departments to organize trial implementation of the two clinical pathways in accordance with local medical realities.

Questions and feedbacks should be readdressed to Hu Ruirong and Ma Xudong, Medical Administration Department, the Ministry of Health. Further information in Chinese can be found on the MOH website: *www.moh.gov.cn/publicfiles/business/htmlfiles/mohylfwjgs/s3581/200912/45416.htm*.

Rural cooperative medical scheme covers 94% of rural population

China raised the funding of its rural cooperative medical scheme (RCMS) to a new high of CNY 100 per capita in 2009 and the system compensated 490 million medical claims and 15.6 million health examinations by the end of September last year, according to Mao Qun'an, the Ministry of Health's spokesperson.

According to Mao, more than 833 million rural residents had participated in the RCMS by September 2009, representing 94% of China's total rural population. The central and local governments had injected a total of CNY 63 billion to subsidize the scheme and reimbursement ratios of the scheme had been raised for both outpatient and hospitalization expenditures.

In addition, the central government has invested CNY 20 billion to support the infrastructure building of 986 county level hospitals, 3,549 township central health centers and 1,154 community health service centers.

Jiangsu province and Nanchang city implement essential drug system

In accordance with local economic standards and patient drug consumption patterns, Jiangsu province announced that it had added 292 drugs to the national essential drug list (NEDL) for implementation in the province's primary healthcare institutions. Consequently, the total number of essential drugs in the province is now 599.

According to the Jiangsu Provincial Health Department, the province has selected 37 counties (municipalities) as initial areas for essential drug policy implementation. Primary medical institutions in these areas are required, before the end of this year, to stock and use essential drugs (including both those on the NEDL and drugs added by Jiangsu province) only and sell essential drugs at zero sales margins. 45 days after implementation of the essential drug policy, non-essential drugs should no longer be used by primary medical institutions in these selected areas, and certain non-essential drugs needed by chronic disease patients should be supplied by grade II and III hospitals under referrals from primary medical institutions.

The revenue losses of primary medical facilities from implementation of zero drug sales margin policy will be recuperated by government fiscal subsidies, which are being assessed on the basis of allotted headcounts and average salaries of healthcare professionals of primary medical institutions.

Separately, the municipal government of Nanchang city, capital of Jiangxi province, introduced an implementation rule for essential drug system on December 18. The regulation requires the essential drug system to be implemented in selected township health centers in 2010 and in all public primary healthcare institutions of the city in 2011.

Shenzhen to achieve universal BMI coverage of all residents in 2011

Shenzhen launched on January 12 its healthcare reform implementation plan for the period between 2009 and 2011. The plan calls for universal basic medical insurance (BMI) coverage of the city's full time residents by in 2011.

In order to reach the goal, the city will invest a total of CNY 19. 6 billion in 2010 and 2011 to improve BMI infrastructure, develop primary healthcare system capacity and push forward public hospital reform.

Shenzhen will select three to five urban hospitals this year as its trial sites for public hospital reform, and will inject CNY 100 million annually into the city's urban community healthcare system to facilitate implementation of the zero drug sales margin policy. The city's healthcare reform implementation plan calls for gradual implementation of this policy in all healthcare facilities including public hospitals.

Shenzhen will raise its annual government subsidy of BMI participants to CNY 200 per capita and its annual public health budget to CNY 50 per capita this year, the implementation plan provides. In addition, the city will expand coverage of BMI programs and raise reimbursement ratios for both outpatient and hospitalization expenditures.

The implementation plan requires all retail pharmacies and medical institutions to stock and sell national essential drugs and mandates the setting of essential drug use ratios for

different levels of medical institutions.

According to a healthcare reform survey of city residents undertaken by the Shenzhen government, 70% of the respondents said that drug prices remain to be too high. 80% of respondents were unhappy with the existing healthcare system and the areas of most concern in order of importance are: 1) irrational distribution of medical resources; 2) poor service of healthcare professionals; 3) excessively high medical service prices; and 4) artificially high drug prices. Over 70% of the survey participants believe the new healthcare model should be led by the government with drug price control strengthened in order to materialize the welfare nature of healthcare.

Harbin to experiment zero drug sales margin policy in public hospitals

In line with the central government's healthcare reform plan, Harbin city, capital of Heilongjiang province, announced recently that it will pilot the zero drug sales margin policy in selected public hospitals from next year.

Experimental sites (selected public hospitals) will gradually phase out drug sales margins in the next three years and be banned for receiving drug sales rebates. The losses of these sites from implementation of the new policy will be made up by additional revenues from medical services (including introduction of a pharmacy service fee and price hikes on selected medical services) and increased government subsidies. The proposed pharmacy service fee will be fully reimbursable by the basic medical insurance programs.

Additionally, the city will explore ways to separate drug sales from hospitals and reduce prices of drugs, medical consumables and advanced medical examinations.

The city will also begin to promote a mechanism under which patients are required to pay their initial visits to community healthcare facilities and mutual referrals are facilitated between community healthcare facilities and higher level hospitals.

People in the News

Recent official and executive moves

SFDA announced on November 25 the appointment of ***Zhong Xiuming*** as the Deputy Director of Food Safety Supervision of the agency and the appointment of ***Mao Zhenbin*** as the Deputy Director of the Drug Safety Supervision Department.

At the same time, ***Jin Shaohong*** was removed from the positions of Executive Vice Director of the China National Institute for Control of Drugs and Biological Products and the Director of SFDA's Drug Appraisal Center.

SFDA announced on December 5 the appointment of ***Sun Xianze*** and the removal of ***Bian Zhenjia*** as the Director of the Drug Safety Supervision Department of the agency. Sun was formerly the Director of Food Safety Supervision Department. ***Xu Jinghe***, formerly national food and drug inspector, was appointed the Director of Food Safety Supervision Department.

Juhui Huang, currently Vice President of Government Affairs at RDPAC, will leave the organization before the end of this year to pursue other career goals. Huang was responsible for managing RDPAC's healthcare policy working group in the past two years.

China Medicine Corporation announced recently that ***Richard P. Wu*** has resigned as Chief Financial Officer in order to pursue other professional interests. His resignation was effective December 15, 2009. ***Robert Lu*** was appointed to serve as the Company's Interim Chief Financial Officer until the company selected a permanent Chief Financial Officer.

Shenzhen based China Nepstar Chain Drugstore announced that ***Yongtu Long*** has resigned for personal reasons after serving as an independent director of the company for over two years. The resignation was effective December 31, 2009.

Biostar Pharmaceuticals, Inc. announced on January 4 the resignation of two directors, ***Michael Segal*** and ***Xifeng Nie***. Concurrent with their resignations, the Board appointed two independent directors, ***Zibing Pan*** and ***Zhongyang Shang***, to the Board, effective December 30, 2009.

Zhiqiang Han resigned on January 8, 2010 as president and chief operating officer of BMP Sunstone for personal reasons. Han also resigned as a director of the company and from all of his positions at its subsidiary, Sunstone China Pharmaceutical Co. Ltd. ***Zhijun Tong***, a director of BMP Sunstone and co-founder and former chairman of Sunstone China, will resume his prior role as chairman of Sunstone China and will serve as acting general manager until a successor to Han is identified.

William Pay was recently appointed Senior Outsourcing Manager with Takeda Clinical Research and he is based in Singapore.

Other News

Upcoming events

Event: 2nd DIA China Annual Meeting
Dates: May 16-19, 2010
Venue: TBD, Beijing
Deadline for Abstracts: January 31, 2010
Contact: Tina Peng
Email: dia@diachina.org

Event: Pharma China Forum - *The Dynamic Market Environments in China*
Date: 1 PM to 5:00 PM, March 26, 2010
Venue: ChangAn Club, Beijing, China
Weblink: www.pharmachinaonline.com/services/index.asp
Contact: David Xue, Chief Representative, Pharma China
Tel: +86 13911325130
Email: dxue@pharmaguys.com

Event: Pharma China Seminar 2010 - *Building Success in China's Pharma Sector*
Dates: April 29, 2010 and November 4, 2010
Venue: Sheraton Parsipanny Hotel, New Jersey
Weblink: www.pharmachinaseminar.com
Contact: Amy Yueh
Tel: +1 212-2287974 or 713-3986888
Email: info@pharmachinaseminar.com

Event: The 2nd Annual World Pharmaceutical (China) Summit 2010
Dates: May 19 - 21, 2010
Venue: InterContinental Pudong Hotel, Shanghai China
Weblink: www.innchinc.com
Contact: Jonas Jiang
Tel: +86-21-51920620
Email: wpcs@innchinc.com

Event: Pharmaceutical Regulatory Affairs Conference
Dates: April 27-28, Workshop-April 26, Symposium-April 29, 2010.
Venue: TBD, Singapore
Contact: Weny Thong, Asia Business Forum
Tel: +65 65368676 Ext:114
Fax: +65 65364350
Email: weny.thong@abf.com.sg
Weblink: www.abf-asia.com

Jiangsu FDA busts major counterfeit operation for brand name drugs

Jiangsu Provincial Food and Drug Administration and Jiangsu Provincial Public Security Department jointly busted a major counterfeit operation of leading brand name drugs. A total of 23,000 boxes of counterfeit drugs, including fakes of 14 leading brand name drugs such as Lotensin and Betaloc, were seized and six suspects were apprehended.

The fake drugs were initially discovered by the Food and Drug Administration of Dafeng City, Jiangsu Province in its routine inspections. Subsequent investigations uncovered fake drug production and distribution operations in various parts of the country. A counterfeit drug production site and three distribution operations nationwide were destroyed eventually.

The Chinese government stepped up its crackdown of fake drugs recently. The State Post Bureau and the SFDA recently issued a joint notice which requires postal regulatory departments and drug regulatory departments at all levels to strengthen cooperation and crackdown on counterfeit drug distribution through postal and express delivery.

Stop Press

CAAE and Novartis launch new epilepsy program

China Association Against Epilepsy (CAAE) and Beijing Novartis Pharma launched "*Angel Operation - Epilepsy Community*" lately which seeks to improve diagnostics and treatment of epilepsy in China.

The program will build an internet-based information exchange platform (with patient databank), sponsor training of young doctors in small and mid-size cities and host education events at major urban hospitals for new patients and their families. It will also test a new disease management approach which involves two-way interactions between physicians and patients in order to raise patient compliance and living quality.

China has around 9 million epilepsy patients at present and 400,000 new epilepsy cases each year. More than 50% of Chinese epilepsy patients are children and teenagers.

PKU Shenzhen Innovative Drug Research Center established

Peking University Shenzhen Innovative Drug Research Center was established on January 16 in the Biological and Biotechnology School of Peking University's Shenzhen Graduate Campus.

The new center has three major drug research platforms including the basic biology research platform, chemical genome platform (which conducts research on new drug targets and drug action mechanisms) and translational medical research platform (which conducts biological research utilizing primates).

SinoPharm to build pharma logistics center in Lanzhou and Shijianzhuang

SinoPharm Holdings announced on January 17 its plan to reorganize Gansu Weikang Pharmaceutical Co. Ltd. and invest CNY 150 million to build a modern pharmaceutical logistics center in Lanzhou, capital of Gansu province. The new center will distribute pharmaceuticals to Gansu province and Ningxi, Qinghai & Tibet autonomous regions.

Subsequently, Gansu Weikang Pharma will be renamed SinoPharm Holdings Gansu Co. Ltd. and it will seek to become the leading regional pharmaceutical distributor in Western China with CNY 2 billion sales in the next five years.

In a separate development, SinoPharm Group signed a strategic alliance framework agreement with Shijiazhuang Municipal Government for cooperation in pharmaceutical production, R&D, logistics and conferences.

The agreement calls for strategic alliances in pharmaceutical distribution between SinoPharm and leading pharmaceutical enterprises in Shijiazhuang, capital of Hebei province, including North China Pharma Group and Shijiazhuang Pharma Group.

In addition, the agreement provides that SinoPharm will invest CNY 150 million to build a pharmaceutical distribution and logistics center in Shijiazhuang city before 2015.

Kunming seeks to phase out drug sales margins in public hospitals by 2011

Kunming city, capital of Yunnan province, recently introduced its healthcare reform implementation plan (2009-2011).

The new plan seeks to develop a province-wide basic medical insurance (BMI) electronic settlement system by 2011 and calls for higher reimbursement ratios for outpatient and hospitalization expenditures.

Additionally, the plan requires gradual implementation of the zero drug sales margin policy in all public hospitals. The losses of public hospitals from implementing the policy will be compensated through raised medical fees, introduction of a pharmacy service fee and increased government funding.

Subsequently, all levels of local governments in Kunming municipality will be responsible for funding infrastructure building, large medical equipment purchase and medical specialty development of public hospitals, and subsidizing public health services provided by these institutions, according to the plan.

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dominates the treatment practice for the adjuvant and first-line settings. While China shows no clear standard of care in later lines, combination chemotherapy continues to be frequent, with physicians relying on the same infusional 5-FU-based therapies. In the same setting Japanese physicians may use different TS-1 combinations or offer single-agent paclitaxel or irinotecan in these same patients, whereas in the United States a different oral fluoropyrimidine, Xeloda, is the agent of choice.

TOP THREE CHEMOTHERAPY REGIMENS

	Japan 2008	United States 2008	China 2009
Adjuvant	**TS-1**	ECF	FOLFOX
	TS-1 + cisplatin	Taxotere + carboplatin + 5-FU	5-FU + leucovorin
		5-FU + leucovorin	FOLFIRI
First-line	TS-1 + cisplatin	ECF	**FOLFOX**
	TS-1	Taxotere + carboplatin + 5-FU	5-FU + leucovorin
		FOLFOX	FOLFIRI
Second-line	paclitaxel	Xeloda	FOLFOX
	TS-1 + cisplatin	FOLFOX	FOLFIRI
	TS-1 + Taxotere	cisplatin + irinotecan	cisplatin + Taxotere
Third-line	irinotecan	Xeloda	FOLFIRI
	paclitaxel	Gemzar	cisplatin + Taxotere
	irinotecan + cisplatin	irinotecan	

Top three regimens are listed unless top one or two regimens account for ore than 70% of utilization. Top regimen is bolded as standard if it is at least twice as frequent as the second in rank. Data are based on the surveys mentioned above.

Cost contributes to the preference for infusional 5-FU over competing oral fluoropyrimidines and for oxaliplatin over other platinum agents. TS-1 was approved for gastric cancer in January 2009 in China; while it is the key agent in Japan, its utilization in China has yet to be established. Xeloda, an oral replacement for 5-FU, was approved for gastric cancer in China in August 2008 and is used either in a combination regimen with platinum agents for first-line therapy or as a monotherapy in later lines of therapy. These oral fluoropyrimidines cost substantially more than infusional 5-FU in China. Obstacles such as cost and access may explain their relatively lower use in China than in the United States (Xeloda) or Japan (TS-1). Xeloda (Capecitabine) is on the Category B of the National BMI Drug Reimbursement List, which is partially reimbursed. Price likely limits use of TS-1 to the few patients who can afford to pay out-of-pocket, unless the cost is mitigated by patient assistance programs or other pricing strategies to improve affordability.

Eloxatin (Oxaliplatin) is viewed as a more efficacious version of cisplatin. While it has some advocates in Europe, physicians in China, Japan, and the United Sates prefer to use it with infusional 5-FU as the FOLFOX regimen (5-FU, leucovorin, and oxaliplatin). FOLFOX is the preferred chemotherapy regimen for metastatic gastric cancer in China. Oxaliplatin equivalents are reimbursable under the national basic healthcare insurance plan in China. Therefore, the cost of FOLFOX with domestic oxaliplatin is considerably less than other combination regimens used in China for gastric cancer, such as FOLFIRI or TCF, helping explain FOLFOX's popularity.

In addition to choice of agent, chemotherapy schedules employed in China occasionally differ from those commonly used in the United States, such as a five-day schedule for cisplatin. Differences in drug metabolism or toxicity between Chinese and Caucasian patients sometimes lie behind the altered dosing.

Many drugs in China have generic versions that are produced locally by Chinese companies versus the branded versions that are produced overseas and imported into China. For example, Eloxatin from sanofi-aventis and domestically produced oxaliplatin from many Chinese pharmaceutical companies coexist in the Chinese market. There are distinct differences in the pricing for imported drugs and their domestic counterparts (many of which themselves carry brand names). Chinese physicians can prescribe either the branded or the local generic version of a drug, and reimbursement is dependent on whether the drug is on the National BMI Drug Reimbursement List and the maximum retail price determined by the National Development and Reform Commission. The key decision-marker for which drug ultimately is administered is the patient.

New therapies, especially the emerging targeted therapies, are not covered by health insurance to date, forcing patients to pay out-of-pocket to cover their costs. The high price of these therapies can be a significant barrier to adoption of these agents in the Chinese market. To encourage utilization of higher priced therapies, some companies have introduced different pricing strategies. For example, Roche exports Xeloda as bulk drug into China and repackages it as an SFDA-approved domestic medicine (in another word, "Made in China") at a relatively lower price. This has helped significantly in the uptake of Xeloda in the Chinese market.

Summary

A thorough understanding of the current standards of care in China by tumor type is imperative to the commercial success of your strategy and the validity of your forecasts. MattsonJack DaVinci, now part of KantarHealth, and partner Draco Healthcare Consulting offer similar China reports for other key cancers in China, such as hepatocellular carcinoma, non-small cell lung cancer, colorectal cancer, and esophageal cancer.

Authors

This article was written by Richard Wagner, Ph.D., Senior Director, and Neesha Suvarna, Ph.D., Associate Consultant of KantarHealth, and Linda Zhao, Ph.D., President of Draco Healthcare Consulting. KantarHealth is the market leader in oncology market consulting and has more than 40 offices around the world, including offices in Beijing and Shanghai. Draco Healthcare Consulting is the leader in the China-focused healthcare consulting with offices in the U.S. and China

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[i] Treatment Architecture China: Gastric Cancer. KantarHealth and Draco Healthcare Consulting, LLC. 2009

[ii] Patient Metrics, CancerMPact(R). MattsonJack DaVinci, The Mattson Jack Group, Inc., A KantarHealth Company. 2009.

[iii] Survey of 51 Chinese physicians who treat a total of 695 gastric cancer patients monthly, conducted in April 2009. KantarHealth and Draco Healthcare Consulting, LLC.

[iv] Survey of 66 Japanese physicians who treat a total of 2,890 gastric cancer patients monthly, conducted in December 2008. KantarHealth.

Feature Articles

Gastric Cancer Treatment in China: Significantly Different versus G7 Countries

Dr. Richard Wagner, Dr. Neesha Suvarna and Dr. Linda Zhao

Access to healthcare in China has improved significantly over the last two decades as the country has undergone dramatic economic development. With the Chinese government announcing in April 2009 a new healthcare reform plan totaling CNY 850 billion in the next three years, with the goal of basic medical insurance coverage for all citizens by 2020, the Chinese healthcare market seems set to attain a new level of access.

The rapid growth in the pharmaceuticals market has led many large, multinational pharmaceutical companies to invest heavily in China, which in turn has driven these companies to seek to gain a deeper understanding of China's demographics, lifestyle shift, and current standards of care - which can differ significantly from those in the G7 countries - in order to gain access to this potentially lucrative market. Nowhere is this truer than in China's dynamic and emerging oncology care market.

Gastric cancer is a significant cancer in Asian countries, including China, Japan, and South Korea, with high incidence rates and considerable mortality. In China, gastric cancer is the second most common cancer - nearly one in five of all cancer diagnoses - and represents the third-highest cause of cancer mortality[i]. In contrast, gastric cancer ranks as only the 13th most common cancer in the United States, accounting for only 0.8% of all cancer incidence[ii].

According to a recent study of Chinese physicians who treat approximately 700 gastric patients monthly conducted by MattsonJack DaVinci, now part of KantarHealth, in collaboration with Draco Healthcare Consulting, most gastric cancer patients in China are diagnosed with late-stage disease (Stages III and IV), with only about a quarter of patients diagnosed with early-stage disease[iii]. A very different pattern is observed in Japan, where the majority of patients (two-thirds) are diagnosed with Stage I-II disease. The key reason behind this discrepancy is that patients in Japan, unlike those in China, routinely undergo screening for gastric cancer[iv].

Differences in incidence and stage of diagnosis between China and the other G7 countries also extend to treatment of the disease, which can vary widely.

Surgical Treatment of Gastric Cancer

Surgery is the main modality for gastric cancer. The goal of surgery, the only curative modality, is to accomplish a curative resection (R0) with negative margins, perhaps with lymphadenectomy. Surgery is performed only on locoregional gastric cancer patients.

In most developed countries outside of Asia, an R0 resection is possible in approximately 50% to 80% of patients, whereas in China fewer than 10% of all gastric patients are eligible for curative resection due to the late stages at which they are first diagnosed.

Surgery is the foundation of therapy for Stage I-III gastric cancer in China, with other modalities combined to treat more extensive disease. For example, about one-half of Stage I patients are treated with surgical resection alone, with an additional 30% receiving adjuvant chemotherapy, radiotherapy, or chemoradiotherapy. The frequency of surgery alone declines in Stage II and III patients; the primary approach for these patients is surgery accompanied by adjuvant chemotherapy (approximately 40%). A further 20% of Stage III patients may receive surgery accompanied by adjuvant chemoradiotherapy. In contrast to the use of chemoradiotherapy for Stage III patients in China, Japanese physicians rarely utilize post-operative chemoradiotherapy. Because most Japanese patients undergo an aggressive lymph node dissection as part of surgery, radiation is believed to offer no added benefit.

Traditional Chinese Medicine

In China, traditional Chinese medicine (TCM) is well-accepted by physicians and patients as supportive therapy in combination with surgery, chemotherapy, or radiotherapy. The general notion is that TCM can alleviate toxicity associated with Western treatments, can improve quality of life, and is relatively cheaper compared with other treatment options.

KantarHealth/Draco's survey of Chinese physicians shows that almost two-thirds of Chinese patients receive TCM in combination with Western treatment modalities. About 10% of all patients are treated with TCM alone, with no apparent relationship to stage of disease. Overall, more than three-quarters of physicians incorporate TCM into their overall treatment plan.

Chemotherapy

Chemotherapy is rarely used alone in the treatment of gastric cancer, except in palliative measures or for salvage therapy when surgery is no longer an option or when metastasis has occurred. In early-stage disease, chemotherapy is part of combined-modality approaches such as adjuvant to surgery or in combination with surgery and radiotherapy. Chemotherapy alone becomes a dominant modality as patients advance into metastatic disease.

Chemotherapy is the most common modality used in Stage IV gastric cancer and may provide substantial palliation and occasional durable remission without promise of a cure. The majority of patients with Stage IV disease have tumors that are unresectable for cure at diagnosis. A small number of patients are eligible for palliative surgery; these patients will undoubtedly receive adjuvant chemotherapy with one of the common first-line regimens.

According to KantarHealth/Draco's survey of Chinese physicians as reported in Treatment Architecture China: Gastric Cancer, the top chemotherapy regimens used in China are quite different from those that dominate in G7 countries.

In China, FOLFOX is the preferred choice of chemotherapy regimen as adjuvant to surgery treatment and as initial chemotherapy for metastatic disease treatment.

The preference for FOLFOX is distinct from practices in the United States or Japan (though all regions rely on a platinum/fluoropyrimidine backbone). In the United States, three drug regimens combining epirubicin (ECF) or Taxotere (TCF) with platinum/5-FU regimens are most commonly utilized for the adjuvant and first-line settings. In Japan, the oral fluoropyrimidine TS-1 is the key agent, replacing infusional 5-FU; TS-1 as monotherapy or in combination with cisplatin

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